FRACTURE FIXATION IN OSTEOPOROTIC BONE

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Abstract

The incidence of osteoporotic fractures will drastically increase in the future as a result of the worldwide demographic change. New challenges for the health care system include not only the rising number of elderly fracture patients requiring surgical treatment, but also the increasing complexity of the single intervention. Post-op mechanical complications occur due to diminished bone mass rendering fracture stabilization considerably difficult. New treatment strategies are needed to encounter these developments.

Within the scope of this thesis, a 3-step approach for osteoporotic fracture management is evaluated from a biomechanical perspective in 20 individual experimental studies. The approach involves:

1. A novel concept for intra-operative assessment of bone strength as potentially important parameter for surgical decision making.
2. A novel design of bone fixation elements, optimized for enhanced anchorage in diminished bone mass: the helical blade.
3. Application of bone cement at the implant-bone interface for additional reinforcement of the implant purchase.

Performance of a bone-strength measuring device was experimentally investigated at the hip, in spine and at the hind-foot. The device involves insertion of a probe into cancellous bone and measurement of the trabeculae's breakaway torque by turning the probe. Measured values correlated significantly with the mechanical fatigue performance of the bone-implant construct. The device output could be used e.g. for decisions on application of bone cement or on a specific implant.

With regard to implant design, the performance of a helical blade for use in osteoporotic bone was experimentally evaluated. At the proximal femur, at the hind-foot and at the proximal humerus, the blade revealed a statistically significant but rather moderate biomechanical advantage over threatened bone screws. It was believed that the improvement may result from cancellous bone compaction while inserting the blade. However, further studies suggested that, contrary to common thinking, compaction does not contribute to enhanced mechanical anchorage of the fixation device.
From these experiences, it was hypothesized that in severely porotic bone, the potential of conventional metallic implants is exploited. The additional strategy of implant augmentation with bone cement was biomechanically investigated in several anatomical key-regions: the proximal femur, the proximal tibia, the hind-foot and the proximal humerus. The experiments revealed a significant potential to enhance fracture fixation in porotic bone, but also suggest that cement augmentation cannot be applied as a routine concept. Potential risk factors associated with cement application, such as generation of heat and pressure, were experimentally judged to draw a comprehensive picture of the concept to increase confidence for clinical use.
2 Introduction

2.1 Osteoporosis

Bone breaks when overloaded. On the one hand, fracturing can occur from high energy impact exceeding the mechanical competence of a healthy bone structure. On the other hand, even low amounts of energy could lead to fracturing if bone mechanics are compromised (Figure 1) [24]. Osteoporosis describes pathological loss of bone mass and thereby gradual weakening of the skeletal structure. It is one of today’s most threatening health issues because of its silent and progressive nature with subliminal dangers such as absence of directly sensible symptoms before devastating events like fracturing of the bone occur. Formerly, osteoporosis was regarded as unpreventable effect of aging. Recently, this perception has changed. A first clinical definition was stated in 1991: "A disease characterized by low bone mass and micro-architectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk." [1]. Since, osteoporosis is recognized as established disease causing annually approx. 9 million fractures worldwide [3]. The likelihood for an individual suffering from a hip, wrist or vertebral fracture during lifetime has been estimated to 30-40% [3]. Women are more affected by osteoporosis particularly after the menopause [2], but generally the fracture risk increases with age with disregard to gender (Figure 1) [24]. In 2006, Court-Brown et al. analysed a cohort of almost 6'000 fracture patients and stated that 30% of all fractures in men and 66% in women could be attributed to osteoporosis [24]. In particular for the elderly a fracture can have life-threatening consequences especially if mobility and independency are significantly compromised. The disability-adjusted life years measure (DALYs) quantifies the burden of a disease by accounting the lost years, be it due to early death or disability during lifetime. For osteoporosis in Europe this number yields to approx. 2 million years, which is below Alzheimer's disease (~3 million years) but higher than Asthma (1.3 million years) or Migraine (1.2 million years). In Europe osteoporotic fractures account to approx. 1.7% of all DALYs attributable to non-communicable diseases [3]. Demographic aging of the planet’s population will lead to considerable upwards adjustment of this number in the near future. Consequently, the WHO "sees the need for
a global strategy for prevention and control of osteoporosis focusing on three major functions; prevention, management and surveillance” [33].

![Figure 1: Incidence of bone fractures with regard to age and gender. An increasing fracture incidence with age becomes obvious. Fractures on the left half of the diagram can be attributed to high-energy impact, whereas fractures on the right are predominantly due to weakened bone structure from osteoporosis. Reprinted from Injury 37, Court-Brown CM, Caesar B, Epidemiology of adult fractures: A review, p. 691-697, Copyright (2006) with permission from Elsevier [24].](image)

### 2.2 Management of osteoporotic fractures

This work focuses on the management of fragility fractures. In 1958 the AO (Association for Osteosynthesis, Davos, Switzerland) defined four principles of fracture care, namely anatomical fracture reduction, stable fixation, preservation of blood supply and early/active mobilization of the patient [49]. These guidelines suggest the employment of the, in those days, revolutionary concept of internal (operative) fracture fixation using stabilizing implants [25,43]. The idea evolved to today's standard of care for complex fractures. However, in the face of osteoporosis fracture fixation with metallic implants often reaches its limits indicated by postoperative complications and revision surgeries. For example, mechanical complications after treating a proximal femur fracture with a dynamic hip screw yield about 12% in the elderly [26]. Complications at the proximal humerus are even more pronounced [21,54,61,62,67]. However, a non-functional shoulder does not necessarily lead to a complete loss of independency. An injured hip does. A mortality rate of 56% within one year is reported after refixation of a revised osteosynthesis (dynamic hip screw as primary treatment) [51]. To prevent complications, physicians sometimes tend to defensive after-care. Fixations may remain intact because of absent weight bearing, but a period of confinement in bed means consequently
immobilization, which is likely to lead to loss of vitality and all too often results in death. Regardless whether a complication after surgical treatment occurred, more than 20% of the geriatric hip fracture patients die within the first year after injury [37]. Therefore, not only severe postoperative complications should be emphasised, but also such cases should be kept in focus, which are not assessed in the failure statistics. Technical advancements could help to improve fixation competence and at the same time accelerate patient mobilization to reduce comorbidities.

Technically speaking, mechanical fixation failures in metaphyseal bone regions such as the proximal femur or proximal humerus occur due to loss of implant purchase within the cancellous bone. Osteoporosis diminishes the anchorage of fixation means by compromising the bony microarchitecture. In cancellous bone the disease is characterized by degradation of the trabecular structure in terms of number and size of trabeculae. Thereby, stress to be borne by the single bone-"pillar" is increased. Recurrent loading by physiological forces promotes crack propagation leading to fatigue of the load-bearing structure. First, implants lose their anchorage on a micro-level by failure of the surrounding trabeculae and then start to migrate through the bone. In consequence, repair constructs collapse on a macro-scale and surgical revision is indicated.

2.3 Objective of the work

A comprehensive strategy for osteoporotic fracture management is needed, aiming at confident fracture fixation and fast mobilization. To improve management of osteoporotic fractures, the AO Foundation has launched the clinical priority program "Fracture Fixation in Osteoporotic Bone" in 2006. Since then, a variety of efforts has been undertaken in the fields of research and development, which represents the framework for this thesis. The distinction of the following five steps within the chain of surgical treatment appeared reasonable to streamline the work [74]:

1. **Surgical decision making.** The degree of osteoporosis remains often undetermined until a fracture occurs. When starting a surgical intervention, a decision for the appropriate treatment is required. Objective intraoperative quantification of, for example, the individual bone strength may be of high value in the future [65].
2. **Implant positioning.** After a decision for a specific implant or technique has been taken, the importance of accurate placement of the fixation hardware within the anatomical surrounding is undisputed, particularly in porotic bone [11,77].

3. **Fracture stabilization.** Besides implant placement, another crucial factor influencing the outcome of the surgery is the actual implant design determining the fixation stability [73].

4. **Fixation reinforcement.** In highly osteoporotic cases, where conventional metal implants run into limits, the concept of bone cement augmentation provides an alternative. After having the implant in place, injectable biomaterials (bone cements) can be added in addition to the implant to reinforce the fixation [58,68].

5. **Healing.** After completing the surgery, uneventful bone healing is important to avoid (late) complications. The faster the load-bearing function of the bone is restored, the earlier the stabilizing function of the implant becomes obsolete [23,28,76].

This thesis covers specific aspects of the mentioned scheme (steps 1, 3 and 4). A new concept to assess local bone strength intra-operatively for surgical decision making is experimentally validated (see chapter 3). A new design for anchoring elements (helical blade) and its aspects with regard to purchase in cancellous bone is evaluated (see chapter 4). Finally, the concept of reinforcement by means of bone cement injection is elaborated and tested within several applications *in vitro*. Risk factors are investigated and objectified (see chapter 5). 20 sub-studies have been published in clinical peer-reviewed journals to provide the results to the medical community. The experiments in their entirety shall draw a comprehensive picture in order to promote and justify the use of the proposed techniques and enhancements for osteoporotic fracture management in clinics.

### 3 Surgical decision making – The DensiProbe concept

Taking decisions in surgery is a key task determining the operational outcome. Typical decisions in osteoporotic fracture management involve the choice for performing joint replacement or in favour of an osteosynthesis to preserve bone and joint. If the latter is the preferred option, the question for the appropriate implant arises (see chapter 4) and,
finally, a decision in favour or against the additional use of bone cement has to be taken (see chapter 5). Surgical decision making involves considering patient history, physical and mental ability of the patient, fracture type, quality of reduction, vascularity of the bone and cartilage, condition of surrounding soft-tissues, implant position [11] and, finally, the mechanical bone competence depending on structural and material properties of bone [5,31].

All too often, decisions are based on subjective opinions related to the experience of the operator. For example, in current clinical practice the bone quality is estimated based on haptic feedback, such as felt resistance when turning a screwdriver or while drilling. These soft facts are critical decision criteria and may lead to wrong conclusions as reflected by persistent high mechanical failure rates [21,26]. A method for quantification of the individual bone competence could be one important aspect to objectify decision making in osteoporotic fracture management.

Today’s only accepted and standardized technology to clinically quantify bone "quality" is Dual-Energy X-ray Absorptiometry (DXA), which measures areal bone mineral density (aBMD) [17,48]. DXA includes reference data for estimating the degree of osteoporosis in comparison to the healthy population. DXA is image based. A summation image is generated from two distinct X-ray beams with different intensities. Since areal BMD represents an integral parameter of both, cortical and cancellous bone, it "only" predicts 66–74% of a bone’s biomechanical competence [44]. Further limitations are poor repeatability and artifacts due to surrounding soft tissues. DXA is not routinely used pre- or intra-operatively and is only available for specific skeletal regions [10]. Another important issue is a discrepancy between drug treatment-induced changes in aBMD and fracture incidence [30]. Watts et al. [72] reported that only 12% of bisphosphonate-induced fracture risk reduction is explained by the associated increase in areal BMD, while the remaining effects occur at the level of the bone’s microarchitecture.

3.1 Local bone strength assessment

To reliably estimate the mechanical competence of an individual bone, it hence seems preferable to directly assess the trabecular mechanics rather than analyzing image representations. Intuitively, it appears important to focus the analysis on the region of interest where the implant is placed and the failure is expected. Moreover, such
measurement should be performed in a fast and efficient way, ideally intra-operatively, without the need for highly frequented imaging devices.

In 2006 a concept was proposed (DensiProbe™), which relates to mechanically measuring the ultimate strength of a confined bone volume within the trabecular structure before an implant is inserted [57]. To avoid additional weakening of the bone (as result of the measurement procedure), the measured volume should be restricted to the volume which will anyway be replaced by the implant. Technically it became apparent that the preferred measurement principle is rotation of a rotation-symmetric probe equipped with radial wings until breakaway of the trabecular bone [27]. It was assumed that surgeons are better used to turning instruments like screwdrivers rather than pushing them. Furthermore, from a security point of view pushing an instrument into weak bone implies the risk of penetrating into sensitive structures like joint spaces.

The device is designed as a handheld surgical instrument comprising 1) a measurement probe, which is temporarily inserted into a target bone and 2) a handle with torque measurement functionality (Figure 2). By turning the instrument about 1/3 of a turn the peak torque is registered. Indicated at the handle, the surgeon directly receives an objective feedback regarding bone quality. The procedure can be embedded into existing clinical workflows as additional step and, hence, requires only minimal additional time.

As part of this thesis, feasibility of the idea was proven in three biomechanical experiments on human cadaveric cancellous bone at anatomical key-regions. Starting at the proximal femur, the prototype device was used to measure cancellous bone strength in the femoral head prior to insertion of a Dynamic Hip Screw (DepuySynthes Inc.). Measurements correlated significantly with the biomechanical performance of the specimens under cyclic physiological loading (Appx. C, p15) [65]. The scope of the concept was extended to application in spine (pedicel screws) (Appx. C, p5) [27], to the hind-foot (arthrodesis) (Appx. C, p9) [41] and to the shoulder (Appx. C, p11) [20,55]. All experiments drew a consistent picture of a clear interdependency of measured breakaway torque and fatigue behaviour at the screw-bone interface. These findings were interpreted as proof of concept and justified the conduction of clinical trials.

The two prototype systems for the proximal femur (Dynamic Hip Screw, DepuySynthes Inc.) and for spine (pedicel screw insertion) were certified for clinical use. A clinical
handling test on 10 hip fracture patients revealed feasible handling without adverse events related to the use of the device (Figure 2). Additional surgery time accounted for 2.2% of the total time of surgery [63]. Subsequently, a multi-center trial was initiated. Data evaluation is still ongoing, but results of a sub-group of 43 hip fracture patients have been recently published [50]. Peak torque and aBMD (DXA) showed a significant correlation ($r = 0.6$, $p < 0.001$). However, within a follow-up period of 12 weeks, no severe mechanical complications were observed. The final proof of the prediction capability of the device is, thus, still pending.

Figure 2: Intraoperative bone strength assessment during Dynamic Hip Screw (DepuySynthes Inc.) insertion in a clinical handling test. Springer and Arch Orthop Trauma Surg, 128, 2008, p. 613-620, Quantification of bone strength by intraoperative torque measurement: a technical note. Suhm N, Haenni M, Schwyn R, Hirschmann M, Muller AM, Fig. 5a, © Springer-Verlag Berlin Heidelberg 2008, with kind permission from Springer Science and Business Media [64].

In spine, 30 patients were examined on 69 vertebral levels undergoing pedicel screw placement. Again, clinical handling appeared feasible with additional surgery time of 1.7min per level. No major intraoperative complications were observed. The recorded peak torque correlated significantly with aBMD (DXA) at the lumbar spine ($r = 0.59$, $p = 0.02$). Again, during a follow-up period of 1 year no mechanical complications were observed, which does not permit a conclusion regarding predication capabilities of the concept [53].
3.2 Conclusion

The work as published on paper (Appx. C, p5, p9, p11, p15) can be summarized as follows:
Surgical decision making is particularly difficult in osteoporotic fracture management. An objective measure of the individual bone quality is believed to be essentially important to take adequate actions for uneventful healing. In the scope of this thesis, a recently introduced concept for intra-operative assessment of bone strength was experimentally tested at the proximal femur, in spine and at the hind-foot. In the laboratory, the device delivered relevant data in terms of fatigue failure prediction of cancellous bone. However, final proof of concept in a clinical setting is still pending.

4 Fracture stabilization – The helical blade concept

After a decision has been made to perform an osteosynthesis with a specific implant, an important factor determining the surgical outcome is the design of the implant itself. Despite the primary function of implants, which is stabilizing bone fragments against physiological loading, the fixation hardware needs to respect a variety of aspects: The implant should minimize additional biological disturbances such as soft tissue damage; must respect the specific anatomical surroundings; should not hinder the blood supply; should promote anatomical reduction of the fracture; should respect morphological size, shape and bone mass variations; must be biologically compatible and should be removable after fracture consolidation. Mechanically, an implant needs to install the appropriate mechanical environment to promote bone healing [76] and, particularly in porotic bone, must provide both, suitable primary stability to prevent overloading, and adequate stability under cyclic loading to avoid fatigue failure of the anchoring material.

These aspects render the implant design process complex. An important technological advancement was the translation of the concept of external fracture fixation with the fixateur externe from outside the human body towards application underneath the skin. Angular stability of screws in internal fixation was introduced, which describes locking of the screw-head in the plate body just like Schanz-screws are rigidly connected to the bars of an external fixator [66]. This concept allows elevation of a bridging plate from the bone surface to prevent compression of the periosteum and, at the same time, improves the accuracy of fracture reduction, because fragments are not pulled against the plate when
tightening the screws [45]. In terms of mechanics, angular stable fixation has been extensively studied, but its performance is discussed controversially [52,56,71]. Considering that most catastrophic failures after fracture fixation happen at the bone-screw interface [26] and both, angular-stable as well as conventional fixation almost exclusively employ screws as fixing elements, the attention should probably be drawn away from the screw-plate connection, towards the point where the failure occurs, the screw-thread.

4.1 Helical blade mechanics

Screw-like fixation elements equipped with threads are still the predominant solution in today's fracture care, even though fixation failures persist particularly in elderly patients. The idea arose to use helically shaped blades instead of screws [18] to improve the interface between bone and fixation device. Helical blades distinguish from screws by a multitude of "wings" advancing spirally along an axis with a significantly larger pitch (Figure 3). Thus, helical blades cannot be screwed into the bone but are inserted dynamically by hammer blows. One major advantage is an increased resistance against rotation, rendering an additional anti-rotation screw obsolete. Blade implants are, hence, promoted as "anti-rotation" devices by the industry (e.g. PFNA, DepuySynthes Inc., Bettlach, Switzerland). On the other hand, care should be taken when implanting a blade into hard bone stock. The dynamic insertion procedure may lead to loss of reduction [73] or could even split the bone. It was hypothesized that blade implants may be beneficial in porotic bone stock due to 1) compaction of cancellous bone during insertion, 2) increased implant surface for reducing bone stress, and 3) reduction of notching effects from sharp edges as present with screw-threads [73].

Figure 3: Tip of a helical blade implant (DHS Blade, DepuySynthes Inc.) with four blades spirally advancing along the implant axis.
Clinically, first application of a blade implant was treatment of proximal femur fractures (PFNA and DHS-Blade). Accordingly, biomechanical studies were performed in the scope of this thesis to investigate the performance of the DHS-Blade (DepuySynthes Inc.) in order to support the design process before market launch. The DHS-Blade is an advancement of the conventional Dynamic Hip Screw (DHS) consisting of a side-plate for angular stable fixation of a single lag screw advancing into the femoral head. The dynamic principle allows the lag screw to slide inside the plate-body generating compression at the femoral neck region. The DHS-Blade replaces the lag screw with a helical blade design. In a paired cadaveric experiment simulating cyclic physiological loading, a moderate but statistically significant improvement of the fixation competence of the blade became obvious when compared to the screw design (Appx. C, p19) [73]. In the meanwhile the implant has entered clinical practise with good results [46]. From the proximal femur the concept has spread to other applications. We further investigated the biomechanical performance of helical blade implants in other anatomical key regions. For example, spiral blade fixation is gaining popularity in hind-food arthrodesis due to varying bone density in the calcaneus and high exposure to physiological loading. A study was performed in cadaveric bone evaluating the use of a spiral blade compared to the exclusive use of screws. Here as well, the blade showed certain improvements and potentials (Appx. C, p8) [40]. At the proximal humerus the Expert Humeral Nail with spiral blade (DepuySynthes Inc.) was biomechanically compared with a design concept supplementing the nail with an additional plate and diverging screws. Both implants were investigated in a cadaveric 3-part fracture model under cyclic loading, again showing good performance of blade implants in porotic bone (Appx. C, p4) [19].

4.2 Role of bone compaction

In these experimental studies certain advantages of helical implants became obvious. However, it was unclear which exact mechanisms contribute to these improvements. A popular argument promoting blade implants is the concept of bone compaction [4]. It appears intuitive, that during insertion into trabecular bone, the implant will radially displace the bony structure leading to a compacted material providing improved anchorage. To investigate this hypothesis, two experimental studies were performed (Appx. C, p17 and p20). On the one hand, the expected increase in bone density in the
surrounding of a blade implant could be confirmed [75]. On the other hand, opposed to current thinking this difference in density did not lead to superior or inferior biomechanical competence [69,75]. Translating this finding into clinics, it can be suggested to predrill a pilot hole and remove bone content even in porotic bone without compromising the implant purchase. This simplifies surgery and significantly reduces risks. However, a major argument in favour of the blade for improved bone anchorage could not be supported.

4.3 Conclusion

The work as published on paper (Appx. C, p4, p8, p17, p19, p20) can be summarized as follows:

Helical blade implants represent an advancement for the treatment of geriatric fractures. Biomechanical advantages became obvious in experimental studies in agreement with clinical experience. However, the benefits may be classified as rather moderate. Bone compaction, believed as a major contributor, does not translate into improved biomechanical competence. The performed test-series revealed potentials but also limitations of design adjustments of conventional metallic implants. In highly osteoporotic cases other approaches, such as bone cement augmentation, may be required to achieve suitable anchorage in compromised bone mass (see chapter 5).

Side note

As a secondary but still important outcome, the mentioned study of Windolf et al. (Appx. C, p20) [75] introduces a novel loading protocol for biomechanical fatigue testing. It is suggested to monotonically increase the loading amplitude during cyclic testing. This approach is opposed to conventional biomechanical testing with step-wise characteristics and obvious disadvantages and enables fatigue testing in a wide range of bone qualities. The protocol builds the methodological basis for the majority of the biomechanical experiments in the scope of this thesis and many more.
5 Reinforcement – Bone cement augmentation

Experience from several years biomechanical research on osteoporotic fracture treatment involving cadaveric testing as well as computer simulations support the following hypotheses:

1. In healthy bone stock available fixation solutions and treatment techniques allow for sufficient fracture treatment.
2. In osteopenic bone optimizing designs of conventional metallic implants carries potential to significantly improve fracture fixation.
3. In severely osteoporotic bone the potential of conventional metallic implants is exploited. Additional treatment concepts are needed.

A potential solution for securing anchoring elements is a mechanical reinforcement of highly compromised bone stock. A mechanical intervention offers the advantage of taking immediate and permanent effect, which cannot be achieved with systemic medication like bisphosphonates. Local application of injectable biomaterials such as bone cements crystalized as a promising approach [9]. Most common are acrylic polymers like Polymethylmethacrylate (PMMA) consisting of a liquid and a solid component to be mixed before use. During exothermic curing of the cement, the material can be delivered ideally towards the implant-bone interface to augment the trabecular structure in contact with the implant [68]. The biomechanical benefits of such a procedure can be explained by reduction of stresses in the bone due to enlarging the load-bearing surface [58,68]. Moreover, peak stresses and notching effects from sharp metal edges and abrupt transitions between rigid implant and bone may be diminished [58]. A bone-cement mantel around an implant enables a smooth "handover" of physiological forces from bony structure to implant. Acrylic cements offer sound mechanical properties in terms of ultimate strength and stiffness and, thus, are suitable for load bearing applications. The flow characteristic during injection represents another crucial parameter to avoid leakage of the cement into critical regions such as fracture gaps or joint spaces [14,16]. Hence, the cement should not be too liquid but still liquid enough to allow manual injection through a cannula and penetration of the trabecular structure. There is a trade-off between cement viscosity and mechanics. Ideally the viscosity should remain constant at a medium to high level for a time-slot of about 20min before hardening of the material [14]. This
behaviour is often on the expense of the material's ultimate strength particularly under tension [15].

Due to its good biological compatibility, use of PMMA bone cement inside the human skeleton has a history of several decades [47]. It was first used for anchoring endoprostheses in the proximal femur as popularised by Charnley in the early 1950's [22]. It is, furthermore, frequently used in Vertebro- / Kyphoplasty procedures in spine with the strong argument of immediate plain relieve [35]. Profiting from the experience, the idea arose to use the concept also in the field of general trauma care, particularly in porotic bone [7,9]. However, injecting PMMA for fracture treatment is still sceptically perceived by the medical community and is not fully embedded in the clinical routine yet. An important reason for this reservation might be the irreversibility of the procedure. Once injected, the cement will remain in the body. The question is raised if this drawback is justified by bridging a fracture-healing period of 2-6 months before function of the cement becomes obsolete. Complication rates and world-wide increase of osteoporosis speak clearly in favour of the idea (see chapter 2). Alternatives are bio-degradable materials such as calcium-phosphate cements [8] or other formulations [36] which are under development. However, current alternatives are still markedly inferior to PMMA in terms of mechanics and should not be used for load-bearing applications (Brodt et al., unpublished data, AO Research Institute Davos). Nonetheless, upcoming cement generations may improve significantly.

5.1 Biomechanical benefits

In 2006 our first experimental efforts were undertaken on cement augmentation of the Dynamic Hip Screw (DepuySynthes Inc.) to prevent screw cut-out in porotic proximal femurs (Appx. C, p16) [68]. A highly beneficial effect became obvious, which encouraged us to further investigate in the field. The logical next step was to augment a blade implant at the proximal femur (PFNA, DepuySynthes Inc.) (see chapter 4). The rationale behind this is a step-wise treatment concept. The use of a blade can by itself improve the anchorage in porotic bone to a certain extent [73]. After placing the implant, the surgeon still has the option for additional cement augmentation based on certain criteria (see chapter 3). As a side note: Cement can physically not be injected into healthy, dens bone.
Cement augmentation can therefore not serve as a salvage procedure to overcome poor surgical execution.

A biomechanical pre-evaluation of PFNA augmentation was performed in a bone substitute material (Appx. C, p13) [59] followed by a mechanical test in cadaveric bone (Appx. C, p12) [58]. These studies, and others [29], revealed a remarkable increase in implant anchorage in porotic bone by adding small amounts of PMMA bone cement. An augmentation set for the PFNA (DepuySynthes Inc.) became commercially available and is nowadays in clinical use (Figure 4). Clinical results confirm the experimental findings [38,39]. However, there is still little knowledge about the optimal procedure for augmenting a hip implant in terms of how much cement is needed and where should it be placed. A systematic experimental analysis of seven different cement configurations was performed and reflected that already 2ml of PMMA placed towards the tip of the implant can be sufficient to achieve confident fixation (Appx. C, p14) [60].

To increase the biomechanical knowledge on the concept and to gain broader acceptance among surgeons, cement augmentation of implants was further tested on other anatomical key regions such as the proximal tibia (Appx. C, p7) [34], the hind-food (Appx. C, p10) [42] and the proximal humerus (Appx. C, p11) [55]. The potential for general use of bone-cement when placing lag-screws to compress bone fragments was also evaluated (Appx. C, p18) [70]. Further studies on distal femur and pelvis (SI screws) are currently ongoing. In all mentioned applications a more or less pronounced improvement of implant anchorage due to cement augmentation became apparent. However, these results also suggest that the benefit of the procedure is highly depending on the distinct application. For example, augmenting three cannulated screws at the tip for femoral neck fracture fixation did not reveal any biomechanical improvement (Nicolino et al., unpublished data, AO Research Institute Davos). Placement of the cement at a biomechanical sound position is crucial to provide the desired effect.

5.2 Associated risks

Permanent and irreversible placement of foreign material inside the human body always carries risks, which need to be carefully weighed against the achievable benefits. These risks include cement leakages, damage of the subchondral bone (Figure 5) or avascular necrosis due to increased intra-osseous pressure (Appx. C, p2) [12]. Particularly with PMMA augmentation there is a concern of thermal damage from the exothermic reaction during PMMA curing, which could lead to heat necrosis of bone and cartilage. In an in-vitro experiment the temperature progression was recorded in cadaveric femora at several distances to a cement cloud surrounding a PFNA blade (Appx. C, p6) [32]. Theoretical curing temperatures of PMMA range around 80°C. Practically, no critical values were found (< 43°C). It has to be noted that medical cements of the newest generation are composed from a variety of components (e.g. X-ray contrast agents) which reduces the actual portion of PMMA and thereby lowers the heat exposure [14]. At least at the proximal femur curing temperatures can therefore be considered uncritical. The experiment was repeated at a different scenario, the proximal humerus (Appx. C, p3) [13]. Results confirmed previous findings.
Finally, within the scope of this work, an idea of mixing a component of autologous bone marrow into PMMA cement during augmentation was developed. It was hypothesized and experimentally proven that such a composition could act as biocompatible cement softener by lowering the material stiffness, which could be biomechanically beneficial (Appx. C, p1) [6]. On the other hand, as undesired side-effect, it became apparent that the ultimate strength of the material is also significantly compromised. Biological effects due to presence of autologous cells inside the cement could not be judged here.

5.3 Conclusion

The work as published on paper (Appx. C, p1, p2, p3, p6, p7, p10, p11, p12, p13, p14, p16, p18) can be summarized as follows:

Within the scope of this work, biomechanical potential and associated risks of cement augmentation in geriatric fracture care were comprehensively investigated to provide experimental base-line data to increase confidence for clinical use. Cement augmentation of implants carries strong potential to improve fracture fixation in porotic bone. However, benefits vary with the distinct application. Cement augmentation can, hence, not be applied as a routine concept. Cement augmentation appears save under the prerequisite of responsible and careful application.
6 Conclusion

The incidence of osteoporotic fractures will drastically increase in the future. Within the scope of this thesis, a 3-step approach for osteoporotic fracture management was biomechanically investigated. The approach involves a method for intra-operative assessment of bone strength for surgical decision making, a novel design of bone fixation elements (the helical blade) and the concept of bone cement augmentation of implants.

Mechanical bone strength measurement was found to carry high potential for predicting fatigue failure of bone-implant constructs and may build an important pillar of osteoporotic fracture care in the future. A proof of concept in clinics is, however, still outstanding. Blade implants show beneficial performance in porotic bone, but may not be suitable for severely osteoporotic cases. Here, cement augmentation provides a unique opportunity to allow early and confident mobilization of the elderly patient. Cement augmentation appears save when applied responsibly, but should not be applied as a routine concept in clinics.
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(55) Roderer G, Scola A, Schmolz W, Gebhard F, Windolf M, Hofmann-Fliri L:
Biomechanical in vitro assessment of screw augmentation in locked plating of

(56) Schutz M, Sudkamp NP: Revolution in plate osteosynthesis: new internal fixator

(57) Schwyn R, Haenni M, Suhm N, inventors; Method and device for measuring the local

(58) Sermon A, Boner V, Boger A, Schwieger K, Boonen S, Broos PL, Richards RG, Windolf
M: Potential of polymethylmethacrylate cement-augmented helical proximal
femoral nail antirotation blades to improve implant stability--a biomechanical
investigation in human cadaveric femoral heads. J Trauma Acute Care Surg 72:E54-
E59 (2012)

M: Biomechanical evaluation of bone-cement augmented Proximal Femoral Nail
Antirotation blades in a polyurethane foam model with low density. Clin Biomech
(Bristol , Avon ) 27:71-76 (2012)

(60) Sermon A, Hofmann-Fliri L, Richards RG, Flamaing J, Windolf M: Cement
augmentation of hip implants in osteoporotic bone: How much cement is needed


Appendix A – Acknowledgment

Since I started my first position at the AO Research Institute Davos (Switzerland) in November 2004, the topic of fracture fixation in osteoporotic bone has dominated by professional career. Over the years, I never lost my enthusiasm and passion for this field, always feeling to make a small contribution to something important. This thesis summarizes the work of the past almost 10 years on the topic. I’m grateful for the opportunity to write this thesis and would like to thank the numerous co-workers, surgeons, medical fellows, students, AOTrauma, AOTK and the industrial partner DepuySynthes who all made a substantial contribution. This is clearly a team effort and would not have been possible without them.

I would like to thank Prof. Dr. Anita Ignatius and my supervisor Prof. Dr. Lutz Dürselen for their support and for providing me the opportunity to submit the thesis to Ulm University. This is very much appreciated.

I thank Prof. Dr. Geoff Richards, Director of the AO Research Institute Davos, for providing me the possibility to take this step and for his constant support along the way.

I would also like to thank the Biomedical Services program and especially the Concept Development group. It is highly inspiring to be part of this team.

Der finale Satz gehört meiner Frau, meinem Sohn, meinem ungeborenen Kind und meinen Eltern. Ihr seid das Wichtigste.
Appendix B – Scientific Curriculum Vitae

**PERSONAL DATA**

Markus Windolf

born in Hamburg, Germany, 1976

**PROFESSIONAL CAREER**

<table>
<thead>
<tr>
<th>Date</th>
<th>Position and Responsibilities</th>
</tr>
</thead>
</table>
| Jan 2011 – present | Leader Concept Development Focus Area, AO Research Institute Davos (ARI), Switzerland  
| Apr 2010 – Dec 2010 | Program Leader (ad interim) Biomedical Services (ARI)  
Restructuring and refocusing of the program. |
| Sep 2009 – Mar 2010 | Senior Project Leader, Concept Development, Biomedical Services (ARI)  
Initiation and management of innovation projects for advancements in fracture care. |
| Nov 2006 – Aug 2009 | Leader Mechanical Testing (ARI)  
Responsible for acquiring, planning and performing commercial and scientific biomechanical studies. Invention and establishment of a novel test method for mechanical testing in bone. |
| Nov 2004 – Oct 2006 | Project Engineer at the Research Services Group (ARI)  
Conducting biomechanical studies. |
| May 2004 – Sep 2004 | Research fellow at the biomechanics section of Technical University Hamburg-Harburg, Germany |
| Jun 2003 – Sep 2003 | Training at DaimlerChrysler Thailand Ltd. in Bangkok, Thailand  
Analysis of business processes. |
EDUCATION

2009 – 2014  Dr. biol. hum., Institute of Orthopaedic Research and Biomechanics, University of Ulm, Germany.


Thesis (Grade 1.0): Windolf et al., 2008: Systematic accuracy and precision analysis of video motion capturing systems. J. Biomech.

2001  Exchange semester at Indian Institute of Technology Madras, India.

1996  Abitur (A-levels) at Sophie-Barat-Schule Hamburg, Germany.

POSITIONS AND AWARDS

Teaching  2010 – present: Faculty of the AO Davos Courses: Masters, Swiss Residents, CPD

Statistics  2010: Statistician of the AO Research Institute

Reviewing  Reviewer for 7 international journals (J. Biomech., J.Orthop.Res., etc)

Awards  8 scientific awards: Best Oral Presentation (1. Price) ECTES 2014, IFFAS Award of Excellence 2010 (as co-author), Wilhelm-Roux-Award 2008 (as co-author) (among others)

PUBLICATIONS

60 Papers published in international peer-reviewed journals

7 International patent applications (PCT)

2 Book chapters

7 Invited lectures

74 Congress-communications
Appendix C – Included papers

All publications forming this cumulative dissertation are listed below. Articles are appended at the end of this section.

<table>
<thead>
<tr>
<th>No. Papers</th>
<th>First authorships</th>
<th>Senior authorships</th>
<th>Co-authorships</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>2</td>
<td>10</td>
<td>8</td>
</tr>
</tbody>
</table>


Research paper

Bone marrow modified acrylic bone cement for augmentation of osteoporotic cancellous bone

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ABSTRACT

The use of polymethylmethacrylate (PMMA) cement to reinforce fragile or broken vertebral bodies (vertebroplasty) leads to extensive bone stiffening. This might be one reason for fractures at the adjacent vertebrae following this procedure. PMMA with a reduced Young's modulus may be more suitable. The goal of this study was to produce and characterize PMMA bone cements with a reduced Young's modulus by adding bone marrow. Bone cements were produced by combining PMMA with various volume fractions of freshly harvested bone marrow from sheep. Porosity, Young's modulus, yield strength, polymerization temperature, setting time and cement viscosity of different cement modifications were investigated. The samples generated comprised pores with diameters in the range of 30–250 μm leading to porosity up to 51%. Compared to the control cement, Young's modulus and yield strength decreased from 1830 to 740 MPa and from 58 to 23 MPa respectively by adding 7.5 ml bone marrow to 23 ml premixed cement. The polymerization temperature decreased from 61 to 38 °C for cement modification with 7.5 ml of bone marrow. Setting times of the modified cements were lower in comparison to the regular cement (28 min). Setting times increased with higher amounts of added bone marrow from around 16–25 min. The initial viscosities of the modified cements were higher in comparison to the control cement leading to a lower risk of extravasation. The hardening times followed the same trend as the setting times. In conclusion, blending bone marrow with acrylic bone cement seems to be a promising method to increase the compliance of PMMA cement for use in cancellous bone augmentation in osteoporotic patients due to its modified mechanical properties, lower polymerization temperature and elevated initial viscosity.

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1. Introduction

Vertebroplasty is regarded as a reasonable alternative to the non-operative treatment of osteoporotic vertebral body compression fractures. Immediate and lasting pain relief is seen in 80%–90% of the cases (Heini et al., 2000; Mathis et al., 2002). Today, the most commonly used bone substitute material in vertebroplasty is polymethylmethacrylate (PMMA) with a Young's modulus (2–3 GPa) 4–40 times higher than that of cancellous bone (50–800 MPa, Banse et al., 2002).

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doi:10.1016/j.jmbbm.2011.07.007
This material has specific disadvantages such as high polymerization temperature (Lewis, 1997), neurotoxicity of the monomer (Dahl et al., 1995), and the lack of sufficient osteointegration (Urrutia et al., 2008). In particular, the long-term stability is questionable due to its bioinert nature (Heini et al., 2001). As a consequence, the addition of bioceramics to enhance its bioactivity has been extensively studied e.g. hydroxyapatite (HA) (Serbetci et al., 2004), bioglass (Mousa et al., 1999), A-W glass (Yamamuro et al., 1998) or strontium-substituted hydroxyapatite (Sr-HA) (Hernandez et al., 2009).

Another undeniable disadvantage of the PMMA is its high temperature during polymerization which may increase to more than 70 °C in the center of the vertebral body during setting (Lewis, 1997). Deramond et al. (1999) and Belkoff and Molloy (2003) found an in vitro temperature of 60 °C in the center and 49 °C at the anterior cortex of a vertebral body augmented with PMMA cement (Simplex P bone cement).

Based on reported threshold levels (Eriksson and Albrektsson, 1983; Li et al., 1999; Lundskog, 1972) there is a high risk of thermal damage occurring inside the vertebral body and a low risk in the structures surrounding it. Another documented complication of vertebral augmentation using PMMA is the elevated fracture rate of adjacent vertebral bodies (Frankel et al., 2007; Grados et al., 2000; Pérez-Higueras et al., 2002; Uppin et al., 2003). Heini et al. (2001) showed an increased stiffness of the augmented vertebral body of 174%, and another study (Boger et al., 2007) using functional spinal units showed an increase of around 180% compared to an intact osteoporotic vertebral body. These figures appear to demonstrate an overly rigid reinforcement of the affected vertebrae in an osteoporotic spine which might contribute to an enhanced fracture risk at adjacent levels (Berlemann et al., 2002; Boger et al., 2007; Frankel et al., 2007; Heini et al., 2001; Polikeit et al., 2003; Rohlim et al., 2005, 2006; Sun and Liebschner, 2003). Adjusting the Young’s modulus of the cement toward that of the surrounding vertebral body is thought to be an efficient way to reduce the material related risk of adjacent vertebral body fractures subsequent to augmentation.

It is therefore desirable to use bone cement with a reduced risk of the above mentioned side effects. An optimal bone cement would show a reduced Young’s modulus, a reduced polymerization temperature and an increased bioactivity leading to sufficient osteointegration without compromising the sound handling characteristics of PMMA cements including cement viscosity over time.

Reduction of the Young’s modulus to around 120 MPa and the polymerization temperature to around 40 °C (Boger et al., 2008a) by the introduction of nonmiscible phases into the PMMA upon polymerization has previously been described (Boger et al., 2008b; De Wijn, 1976; Winteman et al., 1998). Those property variations were made possible by using an aqueous solution of hydroxypropylmethylcellulose (Boger et al., 2008b; De Wijn, 1976), Dextran (Winteman et al., 1998), hyaluronic acid (Boger et al., 2008a), or other plasticizing substances (Boger et al., 2009a). The plasticizers were added to the regular PMMA ingredients during cement preparation. However, these approaches did not address the aspect of increased bioactivity of the augmentation material. Therefore, new concepts have to be evaluated. In a recent study from Ahn et al. (2009) evaluating blood-mixed PMMA, a reduction of the Young’s modulus to around 550 MPa and a corresponding maximal polymerization temperature of around 48 °C was observed.

The approach investigated in the present work used freshly harvested bone marrow for modification. It was mixed into regular PMMA, in order to make it more suitable for osteoporotic cancellous bone augmentation procedures like vertebroplasty. Bone marrow was chosen for the osteogenic potential of its constituent stem cells (Risbud et al., 2006). Other investigations and products have already shown that the perfusion of bone substitute materials with freshly harvested bone marrow leads to enhanced osteoconductive, osteopromotive or osteogenic behavior (Becker et al., 2006; Stoll et al., 2004; http://www.synthes.com/html/chronOS-Perfusion-Concept.7254.0.html?L=0 (Synthes Homepage, 2000)).

Becker et al. (2006) showed that the combination of β-TCP and bone marrow leads to promising osteoinductive properties. They showed that using bone marrow is superior to venous blood or concentrated mononuclear cells (Stoll et al., 2004).

Bone marrow can be aspirated from different sites. The “gold standard” is still the iliac crest but the vertebral body itself can also be used as a reservoir from which the marrow can be harvested. McLain et al. (2005, 2009) showed comparable or greater concentrations of osteoprogenitor cells in bone marrow aspirates from vertebrae compared to the iliac crest. For harvesting the bone marrow from the vertebral body the recently developed jet lavage technique as described by Benneker et al. (2008, 2010) could be used. This method was developed to remove vertebral bone marrow prior to vertebroplasty. This technique has the advantage of preventing the additional surgical morbidity caused by an iliac crest approach. Detailed investigation of other important properties, such as fatigue characteristics, would have to be performed prior to human application of the described method. Furthermore, all necessary regulatory issues would also have to be addressed beforehand.

Since cement extravasation into the circulatory system and into the spinal canal is a major complication in vertebroplasty procedures today, a novel injectable augmentation material must be further investigated with regard to viscosity changes during polymerization.

The purpose of the present study was to confirm that commercially available PMMA cement mixed with freshly harvested bone marrow might lead to a more compliant biomaterial for augmentation procedures of osteoporotic bone. Therefore, experiments were designed and performed to document the influence of the amount of admixed bone marrow taken from sheep on the porosity, mechanical properties, temperature of polymerization and cement viscosity of the biomaterial.

2. Materials and methods

2.1. Materials and mixing procedure

All experiments were carried out using a commercial PMMA cement (Vertecem V+ Cement Kit, Ref.: 07.702.0165, LOT 09CA53010, Synthes GmbH, Oberdorf, Switzerland). Vertecem
V+ is a slow setting, radiopaque acrylic bone cement with a medium to high initial viscosity for use in percutaneous vertebroplasty. The fluid phase is composed of 99.35% methylmethacrylate (MMA), 0.65% N, N-dimethyl-p-toluidine as activator and small quantities (60 ppm) of Hydroquinone as stabilizer. The polymer powder is composed of 44.6% PMMA (polymethylmethacrylate/acylate), 0.4% benzoyl peroxide which initiates the polymerization, 40% Zirconium dioxide as radiopaque agent and 15% hydroxyapatite as biocompatible filler.

Bone marrow for modification of the regular cement was harvested from three skeletally mature female Swiss Alpine sheep. The animals were humanely euthanized as part of another study which was approved by the cantonal office for animal health of Grisons, Switzerland (TVB Nr. 4/2009). At the due date for euthanasia, the sheep were sedated with 0.04 mg/kg Detomidine (Domosedan®, Swissmedic-No: 47542014, LOT 1252594, PfizerAG, Switzerland) administered intramuscularly. Twenty minutes after sedation the animals received 0.2 mg/kg Midazolam (Dormicum®, Swissmedic-No: 44448, LOT B1331, Roche Pharma AG, Switzerland) and 4 mg/kg Ketamine (Ketasol-100, Swissmedic-No: 50375, LOT 6680408, Dr. E. Graeub AG, Switzerland) intravenously for induction. The sheep were intubated using a cuffed endotracheal tube with an inner diameter of 9.5 mm (Rüschelit® Super Safety Clear, Ref.: 112482, LOT 098E09, Rüsch AG, Switzerland) and anesthesia was maintained using 1.5%–1.8% Isoflurane (Isofluran Baxter, Swissmedic-No: 55999, LOT 09120A41, Baxter AG, Switzerland) in oxygen. The animals were placed in right lateral recumbency and the area over the left iliac crest was clipped, prepped and draped for aseptic surgery. Local anesthesia was achieved at the incision site using 5 ml Lidocaine 2% (Lidocain 2% Streuli, Swissmedic-No: 50564, LOT 0870369/2, Streuli Pharma AG, Switzerland) which was injected into the subcutaneous tissue covering the iliac wing. The iliac crest was approached through a 15 mm surgical incision. Using an 11 G biopsy needle (Safe-Cut Biopsy System, Ref. 181130, LOT 86003, Somatex® Medical Technologies GmbH, Teltow, Germany), bone marrow was aspirated in a 60 ml syringe. The bone marrow was always harvested immediately before mixing it with the cement to avoid clotting.

Three compositions of regular acrylic cement modified by different amounts of bone marrow (2.5, 5.0 and 7.5 ml) were compared to the regular cement as control, resulting in four sample groups. Composites of PMMA cement and bone marrow were prepared by manually mixing the bone marrow into the premixed fluid PMMA. First the liquid component of the Vertecem V+ cement was added to the powder component of the Vertecem V+ cement contained already in the Vertecem V+ mixer. A timer was started and the cement components were mixed according to the manufacturer’s instructions for 10 s resulting in around 23 ml premixed cement. Then the appropriate amount of freshly harvested bone marrow (2.5, 5.0 and 7.5 ml) was added followed by additional mixing for 20–30 s resulting in a homogeneous monochrome light red paste. To prepare the samples for rheological investigation and determination of porosity, the paste was filled into cylindrical Teflon molds (30 mm height, 10 mm diameter). Due to the smooth surface of the cast and the shrinkage of the PMMA during two days hardening (around 1%–3% according to Kühn, 2000) the cylindrical samples could easily be removed using a plunger. The samples were turned on a lathe to obtain consistent cylinders with a length of 20 mm and parallel end surfaces. Dimensions of the resulting cylindrical samples were determined using a digital caliper with an accuracy of 0.03 mm.

2.2. Cement viscosity during curing

Rheological investigation was performed to derive the cement viscosity as a function of time after start of cement preparation. During this procedure, qualitatively the polymerization kinetic of the cement and quantitatively the initial viscosity and hardening time were recorded. The hardening time is defined as the time from the start of mixing until a cement reaches a viscosity of 2000 Pa s. For the viscosity measurements, 3 ml of the freshly prepared cement was placed in a rotational rheometer (Viscosafe Viscometer, Anton Paar, Graz, Austria, SN 80215110 REF 03.702.010) according to the method described in a previous study (Boger et al., 2009b). Real viscosity was recorded every 5 s using the corresponding software (RHEOPLUS/32 Multi 128 V2.66, Anton Paar, Graz, Austria). The rheometer was set to operate at an oscillatory frequency of 1 Hz and a maximum torque of 3 mN m. Viscosity measurements were started 3.5 min after mixing commenced. The initial viscosity was determined as minimal viscosity measured during the rheological data acquisition. Three trials were performed for each cement composition (0.0, 2.5, 5.0 and 7.5 ml bone marrow additive). Initial viscosities and time until a cement viscosity of 2000 Pa s was reached, are presented as means and standard deviations (mean ± SD) for the various cement compositions. Cement viscosity as a function of time after the start of mixing is presented with one representative measurement for each cement composition.

2.3. Maximum temperature and setting time

Maximum cement temperature and setting time were measured according to the ISO 5833 standard. The temperature was measured using a TC-08 thermocouple data logger (PICO Technology, St Neots, UK) inside the Teflon mold. The temperature sensor was connected to a PC interface (PicoLog data acquisition software; PICO Technology, St Neots, UK) for storing the data (sampling rate: 1 Hz). The accuracy of the measurement was stated by the manufacturer to be 0.5 °C. All four cement compositions (0.0, 2.5, 5.0 and 7.5 ml bone marrow added to one batch Vertecem V+) were investigated. The cement and the test equipment were maintained at 23 ± 1 °C and at a relative humidity of not less than 40% at least 2 h before and during testing. Three samples for each composition were measured. Setting time is defined as the time after start of cement mixing, when the temperature of the cement is exactly halfway between ambient and peak temperature. Maximum temperature (Tmax) and setting time (tset) are presented as mean ± SD. Cement temperature as a function of time after start of mixing is presented with one representative measurement for each cement composition.
2.4. **Porosity and pore size distribution**

Several techniques can be used to determine the pore size distribution and porosity of materials, such as mercury porosimetry, gas adsorption, optical analysis, gravimetric methods and computer tomography ($\mu$CT). Here, the interest was to determine the pore size distributions of pores large enough to be invaded by cells, typically larger than 30–50 $\mu$m (Van Lenthe et al., 2007). As a result, $\mu$CT technique with described settings (Van Lenthe et al., 2007) was selected because it is an easy, non-destructive, reliable method, with an accuracy of around 20 $\mu$m which is considered as sufficient. For the analysis one cylindrical sample of each of the four material compositions was scanned in the transverse plane. From the central cross-section ±2.5 mm were scanned at 8 $\mu$m resolution resulting in a voxel size of $8 \times 8 \times 8 \mu$m$^3$ (desktop $\mu$CT 40°C, SCANCO Medical, Basserdorf, Switzerland). Pore sizes below two to three times the voxel size (reliable accuracy) cannot be detected (Van Lenthe et al., 2007) leading to a detection limit of 20 $\mu$m. The resulting gray-scale images were segmented using a low-pass filter to remove noise, and a fixed threshold to extract the solid phase (Van Lenthe et al., 2007). From the binarized images, structural indices were assessed with three-dimensional techniques (Hildebrand and Ruegsegger, 1997; Laib et al., 2000). Therewith, porosity (i.e. pore volume/total volume) and histograms of pore size distribution were derived from five different randomly chosen locations in each sample. The diameter of spheres filling the structure was defined as pore size. For characterization of the pore size distribution, the histograms were approximated by one or two normal distribution curves. Results on the pore size distributions are presented as the means, standard deviations and the heights of the used normal distribution curves. The height of the normal distribution curve represents the frequency of the pore size at the mean.

2.5. **Mechanical compression testing**

A quasi-static compression test was performed on the cylindrical samples in order to evaluate the mechanical properties of the materials. Testing was carried out on ten samples for each material composition containing 0.0, 2.5, 5.0, and 7.5 ml bone marrow mixed with the PMMA cement. The experiment was conducted according to ISO 5833 using an Instron 4302 material testing machine (Instron Ltd., High Wycombe, England) with a compression speed of 5 mm/min and a 10 kN load cell. Force and displacement were measured with a sampling rate of 10 Hz and post-processed with the Instron Series IX Version 8.06.00 software. All data were evaluated using Matlab software version 6.5 (MathWorks, Stuttgart, Germany). Young’s modulus and yield-strength were determined according to the standard and known methods (Boger et al., 2008a). Intending to compare both mechanical parameters to those of human cancellous bone, published data was added as reference group. Banse et al. (2002) reported a Young’s modulus of 352 ± 145 MPa and an yield strength of 2.5 ± 1.5 MPa (mean ± SD) for cancellous bone based on 62 male and female vertebral bodies. Mean apparent bone density was reported to be 0.17 g/cm$^3$. The statistical comparison of this reference data with the cement groups was performed using independent samples t-tests based on the mean, standard deviation and sample size. To assess differences between the cement groups with regard to Young’s modulus and yield strength, a non-parametric Kruskal–Wallis test was performed. Multiple group comparisons were performed using Mann–Whitney–U tests with a post-hoc Bonferroni correction. Due to this in all cases, a p-value of ≤ 0.005 was used as significance limit.

3. **Results**

3.1. **Materials and mixing procedure**

The preparation procedure of the samples using different amounts of bone marrow appeared easy and reproducible. For the preparation of the modified acrylic bone cement, the two-step mixing was sufficient to obtain a homogeneous monochrome light red paste. Phase separation of the biphasic materials could not be observed. Fig. 1 shows representative samples of each investigated study-group. Cylindrical samples used for mechanical testing and pore size analysis had a diameter of 9.92 ± 0.03 mm and a length of 19.98 ± 0.03 mm (mean ± SD).

3.2. **Cement viscosity**

Fig. 2 shows representative progression of the cement viscosity over time after start of mixing for the four investigated cement compositions. Table 1 shows the differences concerning the initial viscosity and hardening time between study...
Table 1 - Initial viscosity, hardening time, maximum temperature, setting time, Young's modulus and yield strength for the four material compositions presented as mean ± SD.

<table>
<thead>
<tr>
<th>Bone marrow content per Vertecem V+ batch/ml</th>
<th>0.0</th>
<th>2.5</th>
<th>5.0</th>
<th>7.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial viscosity /Pa s</td>
<td>123 ± 15</td>
<td>226 ± 26</td>
<td>194 ± 43</td>
<td>208 ± 73</td>
</tr>
<tr>
<td>Hardening time /min</td>
<td>25 ± 0.5</td>
<td>15 ± 0.9</td>
<td>17 ± 0.8</td>
<td>19 ± 0.8</td>
</tr>
<tr>
<td>T_{max} °C</td>
<td>60.85 ± 2.5</td>
<td>60.7 ± 7.2</td>
<td>42.3 ± 3.2</td>
<td>38.0 ± 4.4</td>
</tr>
<tr>
<td>T_{set} /min</td>
<td>28.3 ± 0.7</td>
<td>16.4 ± 3.3</td>
<td>20 ± 1</td>
<td>24.8 ± 1</td>
</tr>
<tr>
<td>Porosity (%)</td>
<td>23.6 ± 1.3</td>
<td>36.4 ± 0.9</td>
<td>44.1 ± 1.1</td>
<td>50.2 ± 1.1</td>
</tr>
<tr>
<td>Pore size diameter /mm</td>
<td>0.027 ± 0.016</td>
<td>0.037 ± 0.019</td>
<td>0.038 ± 0.02</td>
<td>0.042 ± 0.021</td>
</tr>
<tr>
<td>Height of the pore size distribution /%</td>
<td>17.5 ± 0.4</td>
<td>13.75 ± 0.8</td>
<td>14.5 ± 0.5</td>
<td>12.1 ± 0.6</td>
</tr>
<tr>
<td>Young's modulus /MPa</td>
<td>1833 ± 47</td>
<td>1283 ± 75</td>
<td>896 ± 76</td>
<td>737 ± 82</td>
</tr>
<tr>
<td>Yield strength /MPa</td>
<td>58 ± 4</td>
<td>37 ± 2</td>
<td>26 ± 2</td>
<td>23 ± 1</td>
</tr>
</tbody>
</table>

Fig. 3 – Representative measurements of the cement temperature during curing as a function of time after start of mixing for the four cement compositions investigated.

3.3. Maximum temperature and setting time

Fig. 3 shows representative measurements of the cement temperature during curing as a function of time after start of mixing for all study groups. Table 1 shows the differences concerning the maximum polymerization temperature and setting time of the four investigated materials. The maximum temperature decreased on average from around 61 °C for both, regular cement and 2.5 ml bone marrow composition to 38 °C for the group with 7.5 ml bone marrow added. Setting times did not correlate with the amount of bone marrow. When 2.5 ml bone marrow was added the shortest setting time of 16.4 min was observed. Higher amounts of bone marrow added to the cement batch lead to an increase in setting time up to around 25 min (Table 1), however not reaching the longest setting time (28 min) observed for the regular cement without bone marrow.

3.4. Porosity and pore size distribution

The addition of bone marrow to PMMA cement transformed the unimodal and normal pore size distribution into the sum of two normal distributions (Table 1). Without adding bone marrow the average pore diameter was 0.027 mm. For larger bone marrow fractions, the sum of two normal pore size distributions best approximated the data. The small pore diameters were in the range of 0.037–0.042 mm, whereas the large pores had an average diameter of 142, 163 and 195 µm for 2.5 ml, 5.0 ml and 7.5 ml bone marrow, respectively. Small pore sizes are just above the resolution limit, but the results were consistent for all compositions. As seen in Fig. 4, tomography investigations could not confirm that the porous cement cylinders were open-porous.

3.5. Mechanical analysis

Fig. 5 shows representative stress–strain curves received from the compression testing of the four investigated cement compositions.

The Young’s modulus and yield strength were inversely related to the amount of bone marrow added to the cement batch (Table 1). More specifically, the mean Young’s modulus...
decreased from 1840 MPa for the regular cement (0.0 ml bone marrow) to 740 MPa for the cement composition containing 7.5 ml bone marrow. Similarly, the mean yield strength decreased from 58 to 23 MPa. These differences were significant \((p \leq 0.001)\) between each of the tested groups for both parameters.

Reference values for vertebral cancellous bone, as reported by Banse et al. (2002), were significantly lower compared to the cement groups with 0.0, 2.5, 5.0 and 7.5 ml bone marrow (all \(p < 0.001\)).

### 4. Discussion

Modified PMMA bone cements, showing mechanical properties above human cancellous bone but below regular acrylic cements, were produced and characterized in this study. Characterization included polymerization temperature, cement viscosity, porosity analysis and mechanical properties.

Apart from the preparation procedure, we only used established methods for the material characterization on mechanical, thermal and rheological properties.

#### 4.1. Materials and mixing procedure

For cement preparation several parameters can be investigated. The parameters investigated in this study led to acceptable results. This means that homogeneous mixing with neither phase separation during mixing, nor particle release or partial polymerization of the mixture was achieved.

As reported in the aforementioned blood-mixed PMMA model (Ahn et al., 2009), pre-mixing polymer ingredients by hand for 45 s led to partial phase separation of the blood. The method presented here resulted in a more reproducible cement composition. That might be explained by the different mixing procedures and the higher viscosity of bone marrow in comparison to blood, which is an important parameter when adding an aqueous phase into pre-polymerized PMMA (Boger et al., 2008a).

In this study the iliac crest of sheep was used to harvest the bone marrow. In humans the iliac crest is still regarded as the site of choice for this procedure although other studies have shown that the marrow of vertebrae also contains a comparable amount of osteoprogenitor cells (D’Ippolito et al., 1999; McLain et al., 2005, 2009). It would be advantageous if the marrow from vertebrae could be used in patients undergoing vertebroplasty. Those patients would need only one surgical site because the marrow could be aspirated directly from the affected vertebral body and subsequently mixed with the PMMA. At the same time the risk for cardiovascular side effects (fat embolism, cement embolism) would be minimized. The recently reported jet lavage technique might be an option to flush the bone marrow out of the vertebral body (Benneker et al., 2008, 2010). Further studies have to be conducted to investigate if the harvested bone marrow could be separated in a practical way from the lavage fluid prior to mixing it with the PMMA. Another problem could be that patients treated with vertebroplasty are in most cases osteoporotic or osteopenic, a situation where the bone marrow of vertebrae shows an increased fat content and decreased perfusion in both males and females (Griffith et al., 2005, 2006). This means that those aspirates could have an impaired osteogenic potential. Further studies need to be conducted in order to investigate the cell viability in the mixture of bone marrow and PMMA after polymerization. After those tests, an animal study would be necessary to evaluate if such a mixture facilitates better bony ingrowth than conventional cement.

#### 4.2. Cement viscosity during curing

Determination of the cement viscosity as a function of time revealed a higher initial cement viscosity immediately after mixing and a decreased hardening time in comparison to the regular cement. The higher initial viscosity of the modifications is beneficial for clinical use, because the risk of leakage is decreased (Baroud et al., 2006). The apparent initial viscosity of the regular cement used herein, when injected immediately after preparation, is high enough, leading to a low leakage rate and uniform cement filling as shown in a previous in-vitro study (Boger and Wheeler, 2010). Therefore, the modification of cement composition using bone marrow appears to improve the injection properties. The hardening times of the modified cement were reduced in comparison to the regular cement showing an accelerated polymerization kinetic. The reduction in hardening time of comparable cement mixtures has previously been demonstrated (Boger et al., 2008a), however the group with the lowest amount of bone marrow presented the shortest and the one with the highest amount the longest hardening time. This observation has not been explained and needs further evaluation using for example, calorimetric or dynamic mechanical analysis. However, if the hardening time is too short for the application it could be easily adjusted by reducing the amount of benzoyl peroxide in the polymer powder.

#### 4.3. Maximum temperature and setting time

Results for the maximum temperature and setting time of the regular cement agreed with the manufacturer’s data. The maximum temperatures were significantly lower with 5.0 ml and 7.5 ml bone marrow used for the modification, \((42.3 \pm 3.2) ^\circ C\) and \((38.0 \pm 4.4) ^\circ C\), respectively. This result is promising, because it suggests that the use of such
cement modifications using relative high amounts of bone marrow in human applications would not provoke bone necrosis resulting from high polymerization temperatures. The measured setting times determined by the curing behavior are consistent with the observations on the cement viscosity as a function of time after start of mixing. The maximum temperatures generated from modification with 2.5 ml bone marrow (60.7 ± 7.2 °C) did not differ significantly from regular cement (60.85 ± 2.5 °C). Concerning the maximum temperature it is expected that the maximum polymerization temperature should decrease with increasing amounts of non-reactive bone marrow in the cement mixture. This was verified when comparing the cement compositions containing 2.5, 5.0 and 7.5 ml bone marrow. However, the polymerization kinetic was altered by the addition of bone marrow leading to a reduction in hardening time in comparison to the unmodified cement. The accelerated hardening might explain the unexpected high maximum polymerization temperature measured for the cement composition containing 2.5 ml bone marrow. Due to the reduction in hardening time of around 40% in comparison to the regular cement, the generated heat dissipated in a shorter time frame resulting in an unexpectedly high temperature.

4.4. Porosity

Micro-CT of the cement samples revealed micropores which were distributed evenly but not interconnected, so the PMMA and cancellous bone could not be suspected to be conglomerated in the processing of bone union. However, the porosity obtained might aid in attracting cells and promoting adhesion to the surface resulting in superior osteo-integration of the implanted material. The microstructure of the cement when infiltrated into cancellous bone will be different anyway in comparison to the structure observed in the experimental samples. Therefore the results shown are preliminary and should give a first impression of the structure of the material. The reason why bigger pore sizes were obtained when adding larger amounts of bone marrow to the cement composition is currently not explainable by the authors.

4.5. Mechanical analysis

The cement compositions mixed with bone marrow showed a Young’s modulus (1280–740 MPa) and yield strength (40–20 MPa) above the values of cancellous bone (100–500 MPa and 1–7 MPa, respectively) (Banse et al., 2002), and below those of regular PMMA cement (1830 MPa and 60 MPa, respectively). Therefore the modifications might be more suitable for vertebroplasty in general.

The optimal properties of an augmentation material for vertebroplasty cannot be distinctively defined for the entire patient population. They depend on a variety of parameters such as apparent bone quality, fracture pattern, possible spinal deformities, augmented volume and cement distribution. Our main goal is to compose materials with more compliant mechanical properties, which approach the actual conditions when used for vertebroplasty. Equally important is lifelong pain relief achieved through lasting mechanical stabilization by avoiding micro motion and restoring the vertebral body strength to the pre-injured level. Further complications of augmentation procedures like vertebroplasty could be tissue necrosis, or alterations in spinal loading with subsequent adjacent vertebral body fractures. These issues have to be addressed in the development of innovative products. A study from Polkeit et al. (2003) showed a significantly reduced alteration on vertebral endplate deflection behavior during loading using a modified PMMA material (Boger et al., 2009a) that had a Young’s modulus of around 1000 MPa. Therefore a Young's modulus of 800–1200 MPa, which is well above the bulk modulus of cancellous bone (100–500 MPa), could lead to sufficient fracture stabilization and a significant reduction in the alteration of spinal loading. Hence, bone marrow modified cement with a Young’s modulus of 740–1280 MPa, could be suitable to reinforce cancellous bone. Additionally the material has to provide a sufficient fatigue performance, which generally improves with higher yield strength values. The yield strengths of the cement modifications presented in this study ranging from 40 to 20 MPa were significantly higher than that of cancellous bone (1–7 MPa) (Banse et al., 2002) and therefore such a material might be suitable for cancellous bone augmentation without long-term deterioration. The reduced strength of the cement modifications might be partly compensated due to the altered advantageous failure behavior in comparison to the regular cement. Corresponding to the yield strength, cement with added bone marrow tended to a larger deformation, related to the reduced Young’s modulus, at a given stress and showed no drop in stress after reaching the yield point. Therefore the modified cement showed a more ductile behavior. On the contrary the regular cement showed a more brittle failure behavior with a clear drop in stress after reaching the yield limit (Fig. 5). However, conclusions on fatigue performance could only be made after detailed fatigue testing under physiological conditions. The question of whether or not a fracture of the adjacent vertebral bodies can be avoided with such materials requires further biomechanical and clinical investigation using adapted implant materials such as those in this study. If such investigation shows that the strength is too low for clinical application, a compounding of fillers like glass fibers as demonstrated by Puska et al. (2003, 2004) would be a very promising method for receiving higher strengths.

Due to the industrial relationship of co-authors, we would like to state that the characterization of the cement modification techniques presented herein absolutely does not allow the generation of conclusions on clinical performance and safety e.g. fatigue properties, monomer release, particle release and leachables. Further tests have to be performed to demonstrate the long-term mechanical stability of the investigated material and to evaluate the survival of the osteoprogenitor cells incorporated into the PMMA cement, which is thought to be fundamental for an increased bioactivity of the new cement modification.

5. Conclusion

Blending freshly harvested bone marrow into PMMA cement combines several advantageous effects such as higher initial viscosity, lower polymerization temperature, mechanical
properties closer to physiologic values, and high potential of increased bioactivity, all resulting from an easily applicable method. In conclusion, it can be stated that the presented bone cements could potentially be useful for reinforcement of osteoporotic cancellous bone in general.

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References


Assessment of Intraosseous Femoral Head Pressures During Cement Augmentation of the Perforated Proximal Femur Nail Antirotation Blade

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Objectives: The benefits of cement augmentation with fixation of osteoporotic pertrochanteric fractures have been previously demonstrated. The objective of this study was 3-fold: (1) To quantify the intraosseous pressure produced during cement augmentation of the perforated proximal femoral nail antirotation (PFNA) blade; (2) To assess whether the pressure generated is influenced by the injection rate; and (3) To assess the amount of force applied during the injection.

Methods: Six pairs of human cadaveric femurs were used in the study. A basicervical osteotomy was performed, and the heads were instrumented with the PFNA blade. Each pair was randomly assigned into 1 of 2 groups: slow versus rapid injection with polymethylmethacrylate (PMMA) cement. In the slow group, the augmentation was performed using 6 consecutive 1 mL injections, each over 10 seconds. In the rapid group, each 1 mL injection was performed over 5 seconds. For intraosseous pressure measurements, transmitters were inserted to a depth of 5 mm at both the superior and inferior apices of the head. The reaction forces on the syringe were measured as well.

Results: There were no significant differences between the slow and rapid injection rates with respect to the peak pressures measured at the 6 time points immediately after cement injection. In both groups, elevations in pressure were transient and returned to baseline values within 30 seconds. The highest pressure recorded in the slow group was 37.3 and 30.7 mm Hg in the rapid group. The force required after each sequential injection increased in both groups; however, significantly higher forces were required to inject cement over than 5 seconds ($P = 0.036$).

Conclusions: This in vitro model is the first one to demonstrate that femoral head cement augmentation is associated with a small transient increase in intraosseous pressure with sequential fast and slow 1 mL injections of up to 6 mL PMMA. We conclude that cement augmentation of the perforated PFNA blade carries a low risk of pressure-induced avascular necrosis.

Key Words: cement augmentation, femoral head, intraosseous pressure, osteoporosis, pertrochanteric hip fractures, PFNA

INTRODUCTION

The biomechanical advantage of polymethylmethacrylate (PMMA) cement augmentation for fixation of osteoporotic hip fractures with proximal femoral fixation devices has been demonstrated in both in vitro and clinical studies. Moreover, the safety of PMMA augmentation has been studied. Small amounts of cement ranging from 3 to 6 mL cause an insignificant increase of temperature around the cement cloud. If cement augmentation techniques are going to increase in popularity, the orthopaedic surgeon ought to be aware of the possible consequences linked to injection rates and forces used during the procedure.

Osteonecrosis or avascular necrosis (AVN) of the hip is a progressive devastating disease that leads to femoral head collapse; it often develops within 2–3 years after an insult such as trauma. In early stages of the disease, before head collapse, core decompression of the femoral head is the most widely used procedure that attempts to relieve intraosseous pressure in the femoral head and restore the blood supply. Kiaer et al have previously demonstrated that mean intraosseous pressures of 47 mm Hg are associated with AVN of the femoral head. It is therefore crucial to ensure that femoral head intraosseous pressures do not exceed critical pressures during the augmentation procedure. Intravertebral pressure measurements during vertebroplasty demonstrate no correlation between trabecular bone density and maximum generated pressures in both intact and simulated tumor vertebrae. Reidy et al, however, did find a correlation between the vertebral body size and the maximum generated pressure. Maximum intravertebral pressures were also directly related to the amount of cement injected; thus, minimizing the amount of injected cement during vertebroplasty also reduces pressurization.

There are as yet no published data quantifying the pressure produced within the femoral head during cement augmentation. The objective of this study was 3-fold: (1) To quantify the intraosseous pressure produced during injection of cement through the perforated proximal femoral nail antirotation blade; (2) To assess whether the pressure generated is influenced by the injection rate; and (3) To assess the amount of force applied during the injection.

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antirotation (PFNA) blade into intact femoral heads; (2) To assess whether the pressure generated is influenced by the injection rate; (3) To assess the amount of force required by the surgeon during the injection.

MATERIALS AND METHODS

Six pairs of fresh frozen (−20°C) human cadaveric femoral heads were used in the study. Bone mineral density (BMD) was measured by peripheral quantitative computed tomography using an Xtreme-CT (SCANCO Medical AG, Bassersdorf, Switzerland). A cylindrical area of 2 × 3 cm in the center of the femoral head was evaluated, corresponding to the target location of the helical blade and cement cloud. BMD values were calculated (mg HA/cm³). AP and lateral radiographs were also taken to calculate the femoral head volumes, based on the assumption that the heads’ geometry closely resembles a sphere. Radiographs were also used to exclude the presence of lesions within the femoral heads. One femur of each pair was randomly assigned into 1 of the following 2 groups: slow versus rapid cement injection with Traumacem V+ (Traumacem V+, 07.702.040S; Synthes GmbH, Oberdorf, Switzerland). In the slow group, the augmentation was performed using 6 consecutive 1 mL injections, each over 10 seconds; in the rapid group, each 1 mL injection was performed over 5 seconds.

Proximal femurs were thawed for 24 hours in 4°C, and a basicervical osteotomy was created using a circular saw. A perforated PFNA blade was then placed into the optimal center–center position using a standard technique by an experienced surgeon, with the aid of an image intensifier. Close attention was paid to avoid joint penetration with the guide wire. After insertion of the blade, a guide wire was used to clean the cannulation of the blade and ensure that no bony debris remained within it.

The cartilaginous surface of the superior and inferior apices of each head was then scratched and cleaned with alcohol. Rubber pieces of 8 mm diameter and 2 mm thickness were then glued on and allowed to dry. Samples were then placed in a sealed bag in a 39°C water bath for 30 minutes. A 1.6 mm K-wire was used to drill a hole in the center of each rubber piece. The K-wires were inserted to a depth of 7 mm into the head of each sample. To record the intraosseous pressures, the K-wires were then taken out, and pressure transmitters (Series 33X; Keller AG, Winterthur, Switzerland) were inserted to a depth of 5 mm. The rubber pieces were used to provide a seal around the pressure transmitters, which were 1.6 mm in diameter as well. Each transmitter tubing was flushed with hydraulic oil (Shell Tellus T46; Shell Lubricants Maagtechnic, Dätwyler Schweiz AG, CH-8600, Dübendorf, Switzerland) before and after their insertion into the femoral head.
The samples were then soaked in the 39°C water for 5 seconds to ensure that all air escaped. They were then placed in a custom-made jig on an Instron material testing machine (Instron 5866; Instron, Norwood, MA). A heat lamp was used to prevent the warm samples from cooling down (Fig. 1). The signal of the pressure transmitters was recorded with the READ30/PROG30 software (Keller AG, Winterthur, Switzerland) with a USB converter (K-104; Keller AG). The sampling rate was set at 50 Hz.

The Traumacem V+ bone cement (Synthes GmbH) was stored at room temperature before testing. It was mixed according to the manufacturer’s recommendations. A side-opening disposable commercially available cannula was used for each test and inserted into the blade at full depth (Trauma Needle Kit, 03.702.120S; Synthes GmbH). It was prefilled with 3 mL of cement using the syringe provided in the kit. At that point, the pressure transmitters were reset to zero. The Instron machine was set to inject cement through the 1 mL syringes in a standardized fashion, either over 10 seconds (slow group, constant injection speed $v_i = 5.5 \text{ mm/s}$) or 5 seconds (rapid group, constant injection speed $v_i = 11 \text{ mm/s}$). A 1 kN load cell was used to contact the plunger and measure the reaction forces during the injection procedure. The data recording was performed at a rate of 20 Hz using Merlin software provided by Instron Inc. This procedure was repeated 6 times per sample at 1 minute intervals. After each injection, the cannula was turned 120 degree to achieve an even distribution of cement. After 3 injections, the cannula was withdrawn 5 mm proximally. Last, one control experiment was conducted without the bone and intraosseous pressure measurements to assess the applied injection forces through the cannula and blade alone, independent of the femoral head.

At the end of the procedure, small pins were inserted into the pressure transmitters’ holes to be used as reference...
markers. AP and lateral x-rays were then taken to ensure the transmitters were not touching the cement cloud (Fig. 2).

Statistical analysis was performed using the SPSS (IBM SPSS Statistics 19; IBM Corporation, Armonk NY). $P$ values $<0.05$ were considered significant. After ensuring normal distribution of the data with Shapiro–Wilk test, general linear model repeated measurements were performed to investigate peak pressure and injection force differences between injection rates, and between successive injection volumes. $P$ values were corrected for multiple comparisons according to Bonferroni. Multiple regression model was used and Pearson correlation test was applied to analyze the dependencies and correlations between BMD, femoral head volume, peak pressures, and peak injection forces. Initially, paired $t$ tests were performed to confirm random distribution of the specimens with respect to BMD and head volume.

**RESULTS**

The mean age of the donors (2 females and 4 males) was 72.5 (range, 52–96) years. The mean BMD value in the slow injection group was 176.6 mg HA/cm$^3$ ($\pm 41.2$ SD) and 186.1 mg HA/cm$^3$ ($\pm 43.1$ SD) in the fast group. There was no significant difference in BMD and head volumes between the groups ($P = 0.148$ and $P = 0.580$, respectively). The mean tip–apex distance for the slow injection group was 22.4 mm ($\pm 2.4$ SD) and 21.7 mm ($\pm 2.5$ SD) for the rapid group with no statistical difference between the groups ($P = 0.678$).

Figures 3A and B demonstrate the intraosseous pressures measured from the inferior and superior transmitters, respectively. In both groups, elevations in pressure were transient and returned to baseline values within 30 seconds. The highest pressure recorded in the slow group was 37.3 versus 30.7 mm Hg in the rapid group. There were no significant differences within each group with respect to the intraosseous pressure elevations at the 6 different time points (inferior transmitter: slow group all $P > 0.44$, fast group all $P > 0.35$; superior transmitter: slow group all $P > 0.26$, fast group all $P > 0.12$). There were no significant differences between the slow and fast injection rates with respect to the peak pressures measured at the 6 time points immediately after cement injection ($P = 0.273$ for the inferior transmitter and $P = 0.788$ for the superior).

Figure 4 demonstrates the measured peak force applied during cement injection using the Instron machine. The highest force recorded in the slow group was 145 versus 194 N in the fast group. In the control experiment, the force required remained below 100 N for all injections. In both the slow and rapid groups, the force required after each sequential injection significantly increased as compared with the force of the first injection ($P < 0.026$, power $> 0.995$, $\alpha = 0.05$; $P < 0.019$, power $> 0.995$, $\alpha = 0.05$, respectively). There was a significant difference between the groups, as higher forces were required to inject cement rapidly over 5 seconds ($P = 0.036$, power $= 0.921$, $\alpha = 0.05$).

The multiple regression analysis model showed a strong trend toward significant dependency between the mean values of BMD and head volume on the one hand, and the average of the peak pressures on the other ($P = 0.054$, adjusted $R = 0.6$), with a significant correlation between increasing BMD values and the mean of the peak intraosseous pressures ($P = 0.019$). No significant correlation was detected between the mean of the peak pressures and head volumes ($P = 0.09$). Furthermore, no significant correlation was detected between the mean of the peak pressures applied during the injection and BMD or head volumes ($P = 0.64$, $P = 0.98$, respectively). Last, no significant correlation was detected between the applied force and the intraosseous pressures in either group at any time point (all $P > 0.05$).

**DISCUSSION**

The findings of this study demonstrate that in an in vitro model of femoral head cement augmentation through the
perforated PFNA blade, there is a relatively small transient increase in intraosseous pressure with sequential 1-mL injections of up to 6 mL. The pressures measured through both the superior and inferior transmitters were independent of the injection rate during the augmentation procedure. All mean intraosseous pressures at all time points were below the upper limit of normal (30 mm Hg), except 1 measurement that transiently reached 37 mm Hg. Thirty seconds after augmentation, the measured pressures returned to baseline. We therefore believe that cement augmentation of the PFNA blade carries a low risk of pressure-induced AVN.10,13–15

The applied force required during injection significantly increases with each sequential injection, independent of the pressure generated within the femoral head. Higher forces were required for fast injections. This suggests that the force required by the surgeon during the augmentation procedure is not a result of increasing pressure within the femoral head; rather, the increase in resistance that the surgeon experiences is due to the confined distribution of the cement cloud, which is determined by the bony trabecular morphology around the blade. The cement, unlike the bone marrow fluid did not escape through the osteotomy site. This finding is important because it ascertain that the amount of force that has to be exerted by the surgeon on the syringe should not be falsely interpreted as tactile feedback of the pressures generated within the femoral head. Of note, the cement used in the study was Traumacem V+; this new cement formulation with medium to high viscosity allows the surgeon additional time for augmentation before the cement hardens.

A significant correlation was only detected between the generated intraosseous pressure measurements and BMD values. This finding is reassuring, given the fact that most augmentation procedures are indicated in elderly patients with low BMD; in this patient population, the risk of generating clinically critical intraosseous pressures is therefore low. It is important to emphasize that the authors recommend cement augmentation only in osteoporotic bone, where the surgeon feels minimal resistance during the blade insertion. The experimental design was specifically performed on osteoporotic bone, and we advise against using this technique in young healthy patients.

One limitation of this study is the fact that it is performed in vitro. During the augmentation procedure, the authors observed bone marrow fat extravasation through the osteotomy site. The osteotomy site permitted a path for pressure decompression; this might explain the reason for the intraosseous pressure measurement returning to baseline values so rapidly. In vivo, the osteotomy site would correspond to the unstable osteoporotic pertrochanteric fracture line. The design of this study would not be applicable in instances where the surgeon obtains an anatomic reduction with interfragmentary compression. Furthermore, other factors that could not be controlled for by this study, such as the fracture hematoma or the hydrostatic interstitial or intracapsular pressure, might have an additional effect on the intraosseous pressures. Another limitation of the study is the relatively low intraosseous pressures that were measured, although 6 mL of cement were injected. This is probably a result of the selected position for the pressure transmitters. The authors purposefully decided to place the transmitters more peripherally to avoid contact with the cement. However, peripheral measurements might be slightly lower than central pressures, as noticed in a study of intravertebral pressure measurements during vertebroplasty.16 Last, we did have a small sample size, and there was no randomization between left and right, although the samples were paired.

In conclusion, this in vitro study demonstrates that the intraosseous pressures generated during cement augmentation of the femoral head are small and transient. The authors believe that from a pressure perspective, in a setting of an acute fracture, cement augmentation carries a low risk of generating pressure-induced AVN. The increase in resistance that the surgeon experiences through the syringe and cannula is due to the confined distribution of the cement cloud within the femoral head, which is determined by the bony trabecular morphology; it is not linked to the intraosseous pressures. Future studies should be aimed at measuring the intraosseous pressures in vivo during an augmentation procedure.

REFERENCES


In vitro temperature evaluation during cement augmentation of proximal humerus plate screw tips

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ABSTRACT

Background: The treatment of proximal humerus fractures in patients with poor bone quality remains a challenge in trauma surgery. Augmentation with polymethylmethacrylate (PMMA) cement is a possible method to strengthen the implant anchorage in osteoporotic bone and to avoid loss of reduction and reduce the cut-out risk. The polymerisation of PMMA during cement setting leads, however, to an exothermic reaction and the development of supraphysiological temperatures may harm the bone and cartilage. This study addresses the issue of heat development during augmentation of subchondrally placed proximal humerus plate screws with PMMA and the possible risk of bone and cartilage necrosis and apoptosis.

Methods: Seven fresh frozen humeri from geriatric female donors were instrumented with the proximal humerus interlocking system (PHILOS) plate and placed in a 37 °C water bath. Thereafter, four proximal perforated screws were augmented with 0.5 ml PMMA each. During augmentation, the temperatures in the subchondral bone and on the articular surface were recorded with K-type thermocouples. The measured temperatures were compared to threshold values for necrosis and apoptosis of bone and cartilage reported in the literature.

Results: The heat development was highest around the augmented tips of the perforated screws and diminished with growing distance from the cement cloud. The highest temperature recorded in the subchondral bone reached 43.5 °C and the longest exposure time above 42 °C was 86 s. The highest temperature measured on the articular surface amounted to 38.6 °C and the longest exposure time above 38 °C was 5 min and 32 s.

Conclusion: The study shows that augmentation of the proximal screws of the PHILOS plate with PMMA leads to a locally limited development of supraphysiological temperatures in the cement cloud and closely around it. The critical threshold values for necrosis and apoptosis of cartilage and subchondral bone reported in the literature, however, are not reached. In order to avoid cement extravasation, special care should be taken in detecting perforations or intra-articular cracks in the humeral head.

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Introduction

The introduction of proximal humerus locking plate contributed significantly to the improvement of fracture treatment results in patients with poor bone quality. 1–3 Nevertheless, there is still a high rate of screw cut-out or malunion due to secondary fragment displacement. 1–3 The problem affects primarily the geriatric patients and to a lesser extent younger patients, for instance due to corticosteroid therapy, suffer from osteoporosis. In the case of proximal humerus fractures, various approaches have been investigated in order to improve the operative results. One of the possible methods is implant augmentation with polymethylmethacrylate (PMMA) cement. Especially in very old patients, cement which does not resorb and allows immediate load bearing, early mobilisation and stable fracture healing might be advantageous. One drawback of PMMA, however, is the heat development during cement curing and the possible risk of thermal bone and cartilage necrosis and apoptosis. The question, whether the heat released during cement augmentation of proximal humerus plate screw tips increases the risk of bone and cartilage necrosis and apoptosis, remains unanswered. The goal of this study was to
evaluate the temperature development in the cartilage and in the subchondral bone of the humeral head during cement augmentation of proximal humerus plate screws.

**Materials and methods**

Seven fresh frozen human proximal humeri (four left side and three right side) originating from female donors with a mean age of 74.1 years (range, 69–81) were used in this study. All samples were scanned in an Xtreme-CT (SCANCO Medical AG, Bassersdorf, Switzerland) prior to the experiments in order to obtain the bone mineral density (BMD) values and to exclude the presence of tumorous lesions or other cavities in the humeral head. Prior to instrumentation, the samples were thawed overnight at 4 °C in a refrigerator. Each specimen was instrumented with the proximal humerus interlocking system (PHILOS) plate (Synthes GmbH, Oberdorf, Switzerland) in a standardised manner by the same surgeon. Six proximal screws were inserted according to the manufacturer’s technique guide manual leaving a distance of 5 or 8 mm between the tips of the screws and the articular surface. Four perforated and two conventional locking screws were used for each specimen (Fig. 1a and b). For each sample, two perforated screws were placed in alternating order with a distance of 8 mm to the articular surface and the other two with a distance of 5 mm.

The two conventional screws were always placed with a distance of 5 mm to the joint. To calculate the exact screw length and the corresponding drill depth, a custom-made calliper was used (Fig. 2). A second custom-made measuring device was used to fix stoppers on the drill according to the distance measured at each screw location. This allowed the surgeon to safely drill to the corresponding depth. In the next step, the drilling for the class 2 Ø 1-mm K-type thermocouples (Pico Technologies Ltd., St. Neots, UK) through the articular surface was performed. The custom-made calliper was used also to determine the position of the holes for the thermocouples (Fig. 2). In total, six thermocouples were placed in the humeral head:

- four thermocouples 2.5 mm under the articular surface opposite each perforated screw,
- one thermocouple on the articular surface between the first four thermocouples and
- one thermocouple 2.5 mm under the articular surface, 10 mm distally to the four perforated screws.

The thermocouples were fixed in the bone with help of small rubber slices which were stuck to the articular surface with superglue (Fig. 3). The instrumented proximal humeri with attached thermocouples were placed in a holding device and left in a 37 °C water bath for 1 h prior to augmentation to allow temperature equalisation. Thereafter, each of the perforated screws was augmented with 0.5 ml of PMMA cement (Traumacem V+, Synthes GmbH, Oberdorf, Switzerland) (Fig. 4), which was mixed according to the manufacturer’s recommendation. After cement injection, the augmented humeri were left for 1 h in a water bath. Temperatures were recorded continuously at 1 Hz from start of cement mixing until the initial temperatures were reached again. After the test, the thermocouples were removed and

**Fig. 1.** Humeral head instrumented with the PHILOS plate and augmented with cement, X-rayed in a-p (a) and lateral view (b), the thermocouples were replaced with metal pins.

**Fig. 2.** The custom made calliper was used for the determination of the screw length and the exact positioning of the thermocouples opposite the perforated screws. (a) Humeral head, (b) PHILOS plate with centering sleeve and (c) drill for thermocouples.

**Fig. 3.** Humeral head with attached thermocouples.
the PHILOS plate was explanted. In place of the thermocouples, small aluminium pins were inserted. Thereafter, the bones were scanned again in the Xtreme-CT. Maximum temperatures from each measurement were identified and the Xtreme-CT scans were used to identify the exact location of each thermocouple with respect to the cement cloud. The measurements were divided into four groups according to the thermocouple placement:

- Group 1: measurements from thermocouples placed opposite augmented screws with 5-mm tip-articular surface distance.
- Group 2: measurements from thermocouples placed opposite augmented screws with 8-mm tip-articular surface distance.
- Group 3: measurements from thermocouples placed on the articular surface between the augmented screws.
- Group 4: measurements from thermocouples placed 10 mm distally to the augmented screws.

As the risk of thermal damage to osteocytes and chondrocytes depends on the temperature and exposure time, both factors had been taken into account in calculating the risk of cell necrosis and apoptosis.\(^5\) The temperature/time values measured in the four groups were compared to the critical temperature/time values published in the literature at which bone and cartilage necrosis is likely to occur.\(^6–13\) The relationship between the measured temperature/time values and the published threshold values was quantitatively expressed by the thermal necrosis index, TNI\(^14\):

\[
TNI = \frac{\text{Exposure time of a tissue to temperature } T}{\text{Threshold time for temperature } T}
\]

If TNI is more than 1, then there is a high risk of irreversible tissue damage.

The threshold values in the available literature were estimated on the basis of various analytical methods. The older studies used histochemical and microscopic analysis for evaluation of bone and cartilage damage.\(^7,10\) More recent studies have been based on sophisticated histochemical, immunohistochemical (terminal deoxynucleotidyl transferase deoxyuridinetriphosphate nick end labelling (TUNEL) assay) and microspopical (transmission electron microscopy, TEM) analyses.\(^13\) confocal laser microscopy along with staining with fluorescent markers\(^12\) and fluorescence activated cell sorting (FACS)\(^9,11\) or on analysis of metabolic activity of bone cells.\(^8\) A summary of the relevant threshold values from the literature is given in a condensed form in Table 1.

### Table 1

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th>Time (min)</th>
<th>Effects on cartilage</th>
<th>Effects on bone</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>15</td>
<td>Partial death(^11)</td>
<td>Partial cell necrosis(^3)</td>
</tr>
<tr>
<td>48</td>
<td>10</td>
<td>Apoptosis(^1)</td>
<td>Partial cell necrosis(^7)</td>
</tr>
<tr>
<td>50</td>
<td>5</td>
<td>Over 50% dead(^12)</td>
<td>Total cell necrosis(^7)</td>
</tr>
<tr>
<td>55</td>
<td>1</td>
<td>All chondrocytes are dead(^8)</td>
<td>Partial cell necrosis(^7)</td>
</tr>
<tr>
<td>56</td>
<td>0.13</td>
<td>Almost</td>
<td>Almost all are dead(^12)</td>
</tr>
<tr>
<td>60</td>
<td>0.13</td>
<td>50% apoptotic(^6)</td>
<td></td>
</tr>
<tr>
<td>65</td>
<td>5</td>
<td>100% apoptotic(^6)</td>
<td></td>
</tr>
<tr>
<td>42–45</td>
<td>10</td>
<td></td>
<td>Partial cell necrosis(^3)</td>
</tr>
<tr>
<td>47</td>
<td>5</td>
<td></td>
<td>Partial cell necrosis(^7)</td>
</tr>
<tr>
<td>48</td>
<td>10</td>
<td></td>
<td>Total cell necrosis(^7)</td>
</tr>
<tr>
<td>50</td>
<td>1</td>
<td></td>
<td>Partial cell necrosis(^7)</td>
</tr>
<tr>
<td>50</td>
<td>0.5</td>
<td></td>
<td>Partial cell necrosis(^10)</td>
</tr>
</tbody>
</table>

### Results

The BMD of the seven proximal humeri was 154 mgHA cm\(^{-3}\) on average with a standard deviation (SD) of 33. From a total of 42 temperature measurements (seven samples with six thermocouples each), five were excluded due to detachment of thermocouples or problems with cement injection.

Fig. 5 summarises the maximum temperature values for the four different thermocouple placement groups. The data were analysed by calculating the mean, range and SD. The mean maximum temperature for group 1 (screw tip-articular surface 5 mm) was 40.7 °C (range 38.49–43.54 °C, ±1.7). The other three groups reached significantly lower temperatures (p < 0.001). Group 2 (screw tip-articular surface 8 mm) showed temperatures of 38.6 °C (range 37.31–39.82 °C, ±0.8) and group 3 (articular surface) reached 37.8 °C (range 37.46–38.61 °C, ±0.4). In group 4 (10 mm distally to the perforated screws) no temperature above 38 °C was measured, with a mean temperature of 37.3 °C (range 36.87–37.74 °C, ±0.3). The highest temperature, which was measured in group 1, amounted to 43.5 °C corresponding to a temperature increase by 18% (Fig. 6). The temperature remained above 43 °C for 45 s and above 42 °C for 86 s.

![Fig. 5. Boxplot of temperature measurements relative to the positioning of the thermocouples. Group 1: thermocouples placed opposite augmented screws with 5 mm tip-articular surface distance. Group 2: thermocouples placed opposite augmented screws with 8 mm tip-articular surface distance. Group 3: thermocouples placed on the articular surface between the augmented screws. Group 4: thermocouples placed 10 mm distally to the augmented screws.](image-url)
Later radiograph and Xrteeme-CT analysis showed that the thermocouple tip was surrounded by the cement cloud. The highest temperature measured on the articular surface amounted to 38.6 °C and the longest exposure time above 38 °C was 5 min and 32 s. The measurements carried out in the Xrteeme-CT after the explantation of the PHILOS plates showed that the majority of the thermocouples from groups 1 and 2 were surrounded by the cement clots, two thermocouples remained exactly on the cement–bone border and only few (four) thermocouples stayed in the subchondral bone, beyond the cement clots. The maximal measured temperature at the cement–bone interface amounted to 39.1 °C. The highest temperature measured by the thermocouples, which remained out of the reach of injected cement, amounted to 39.8 °C. The results of these measurements are presented in Fig. 7.

Discussion

Most of the proximal humerus fractures are minimally displaced, low-energy osteoporotic fractures. More than 80% of the proximal humerus fractures can be effectively treated conservatively, especially in elderly patients with low expectations, patients with significant co-morbidities and patients with minimally displaced fractures. However, the non-operative treatment of some fractures has resulted in a poor outcome. This group comprises younger patients, or active older patients, with fractures in which the tuberosities are displaced more than 5 mm, shaft fragment(s) are displaced more than 20 mm and/or the head fragment angulation is >45°. Various studies confirm good operative results in these patients, but they indicate also the unsolved problem of screw cut-out and loss of reduction, particularly in patients with osteoporosis. Some surgeons propose to strengthen the implant anchorage by bone augmentation with an intramedullary fibular graft. Another approach is augmentation of the humeral head with calcium phosphate cement. In a recent in vitro study, Unger et al. augmented the proximal screws of the PHILOS plate with 0.5 ml of PMMA per screw and confirmed a significant improvement of implant anchorage. The augmentation of the proximal screws enlarges the load-bearing surface and diminishes the stress on the trabecular bone. In the varus bending and axial rotation loading test, the number of load cycles until failure increased by more than 50%. A concern is, however, the incidence of thermal bone tissue necrosis and apoptosis due to the exothermic reaction of the PMMA cement. The necrotic or apoptotic bone cells are replaced by connective tissue, which has no mechanical competence and cannot serve as a support for the implant. This can lead again to aseptic implant loosening and loss of reduction.

According to Eriksson et al., bone exposure to temperatures of 50 °C for 1 min and 47 °C for 5 min leads to a partial necrosis, while exposure to 47 °C for 1 min causes no necrosis at all. According to Li et al., thermal necrosis and apoptosis of osteocytes are predicted to occur when bone is exposed to temperatures in excess of 48 °C for at least 10 min. After exposure to temperatures between 42 and 45 °C for 10 min, only partial cell death occurs and this is mainly due to a protective cell mechanism conveyed by heat shock protein 70. The comparison of the temperatures measured in this study with the threshold values observed by Li et al. shows that the highest measured maximal temperature of 43.5 °C would have to last for 10 min to cause at least a partial necrosis and apoptosis of osteocytes and chondrocytes. With 86 s above 42 °C, the highest calculated TNI in this study amounted only to 0.15. The highest temperature measured on the articular surface amounted to 38.6 °C and the longest exposure time above 38 °C was 5 min and 32 s. There are no reports in the literature indicating that an exposure of cartilage to the temperature of 38.6 °C for several minutes can harm the chondrocytes, it can be assumed that the TNI for cartilage after augmentation of perforated screws with 0.5 ml of PMMA cement is close to 0. This confirms that the threshold values for bone and cartilage necrosis and apoptosis have not been exceeded and no tissue damage is to be expected when augmenting the four most proximal screws of the PHILOS plate with PMMA-based cement.

The relatively low TNI of 0.15 measured in this study results from certain physical properties of materials and tissues. These are mainly the heat conductivity of bone, cement and implant, the
amount and type of cement used and in an in vivo situation also the bone vasculatisation. Metals are very good heat conductors. The heat conductivity of titanium, of which the PHILOS plate is made, amounts to 22 W m\(^{-2}\) \(\text{C}^{-1}\) and of cancellous and cortical bone to 0.16–0.6 W m\(^{-2}\) \(\text{C}^{-1}\), depending on blood perfusion and water content.\(^{20-22}\) Hence, most of the heat developed during PMMA polymerisation is dissipated by the adjacent titanium. In the in vivo situation, the additional factor reducing the TNI would be cooling of the augmented humeral head by the circulating blood. The humeral head is well vascularised; however, if the vessels have been damaged by the fracture, the perfusion rate of the humeral head diminishes and the osteocytes suffer additionally from hypoxia, which makes them more sensitive to the heat of curing cement.\(^{23}\) On the cellular level, the bone is additionally protected by heat shock protein 70, which is released in situations of thermal stress.\(^{24}\)

In the literature, there are no data on the risk of thermal bone tissue necrosis/apoptosis after augmentation of the PHILOS plate with PMMA, as the technique is quite novel and it requires validation in clinical studies. There are many studies dealing with the use of supraphysiological temperatures in the shoulder joint during thermal capsulorraphy, that is, surgical repair of a tear in the shoulder joint capsule and the possible risk of glenohumeral chondrolysis.\(^{24-25}\) In the capsulorraphy, however, the temperatures in the shoulder joint may reach 65 °C and there is no implant, which leads away the accumulated heat. Therefore, the thermal effects of capsulorraphy cannot be compared to the thermal effects during augmentation of the PHILOS plate with PMMA. Two temperature studies are available for the implant augmentation with PMMA in the proximal femur. Boner et al. augmented in vitro dynamic hip screws (DHs) with Vertecem and reported the average peak temperature of 40.1 ± 1.0 °C at the cement–bone interface after augmentation with 3.0 ml of cement and of 41.7 °C ± 1.2 after augmentation with 6.0 ml of cement.\(^{26}\) Fliri et al. augmented in vitro the proximal femoral nail antitrotation (PFNA) blades with 3 ml of Vertecem V+ and reported the heat development of maximally 41.2 °C at the cement–bone interface and of maximally 38.7 °C in the surrounding bone region.\(^{27}\) These temperature levels were, according to the authors, also much under the critical values reported in the literature. In this proximal humerus study, the highest measured temperature at the cement–bone interface, which is so important for proper implant anchorage, amounted to 39.1 °C and to 39.8 °C in the surrounding bone (Fig. 7).

The results of the experiments from this study correspond to the results obtained by Boner and Fliri. Most of the heat released during polymerisation of PMMA is dissipated by the implant and the rest accumulates mainly in the cement cloud. Therefore, the temperatures measured at the bone–cement interface, in the subchondral bone and on the articular surface are below the critical values.

There is a potential risk of cartilage damage if the augmentation leads to an intra-articular cement extravasation. In the case of a substantial leakage, the cement will cure directly on the articular surface. First, this would mean that the cartilage would be directly exposed to supraphysiological temperatures and to the cytotoxic influence of cement, which could substantially increase the risk of glenohumeral chondrolysis. Second, the presence of cement in the joint can cause direct mechanical damage to the cartilage and a revision surgery can become necessary. Leclair et al. reported about a case of rapid chondrolysis in the hip joint after augmentation with 2.5 ml methylmethacrylate of a benign acetabular subchondral cyst in a 49-year-old patient.\(^{28}\) The cement leaked from the cyst into the joint during augmentation and cured directly on the articular surface. The extravasated cement was removed arthroscopically 5 days after the augmentation with no signs of chondrolysis. However, 8 weeks later three-fourth of the hip joint showed chondrolysis. Leclair suspected that the cartilage damage was caused by the exothermic reaction during cement curing directly on the articular surface and by the toxic influence of the cement monomers. For this reason, no cement augmentation should be performed in patients with an intra-articular fracture and special care should be taken to previously use contrast medium to detect possible leakage pathways.

A practical observation made during the experiments showed that drilling for the perforated screws must be as deep as the screw length. The perforated screws are not self-threaded like the locking screws. If the drilling for the hollow perforated screw is 2 mm shorter than the screw length, it might get congested with the cancellous bone during insertion and it makes the cement injection much more difficult.

There is a limitation to this study. The cement applied in this study (Traumacem V+) contains only 45% of polymerising PMMA. The other parts are ceramic components, which cause no thermal reaction. Many other bone cements are available and they may differ from Traumacem V+ in the content of polymer ingredients, which cause the exothermic reaction. For instance, Simplex (Stryker Corporation, Kalamazoo, MI, USA) contains only 40% of PMMA, Palacos (Heraeus Holding GmbH, Hanau, Germany) 50% of PMMA and Optipac (Biomet Inc., Warsaw, IN, USA) 56% of PMMA. Therefore, this study cannot exclude the logic that the polymerisation of the cements containing more PMMA than Traumacem V+ might lead to higher temperatures than in this study. To our knowledge, there are no reports in the literature on the use of other cements in implant augmentation in proximal humerus fractures. This study is a stepping stone in the process of development of a new fixation technique in osteoporotic fractures of the proximal humerus. Along with the study of Unger et al.\(^{19}\) which confirmed in in vitro biomechanical experiments that the augmented proximal humerus plate screws enhance the implant anchorage in osteoporotic bone, this study confirmed through in vitro experiments that the augmentation of screws with the PMMA cement does not lead to a thermal necrosis of subchondral bone and cartilage. Clinical studies are now needed to evaluate if augmented screws increase the rate of fracture healing and improve clinical outcome.

**Conclusion**

The study shows that the augmentation of the proximal screws of the PHILOS plate with PMMA leads to a locally limited heat development in the cement cloud and the surrounding tissue. The critical threshold values for necrosis and apoptosis of cartilage and subchondral bone are not reached. In order to avoid cement extravasation, special care should be taken in detecting perforations or intra-articular fractures in the humeral head.

**Conflict of interest**

The authors are not compensated and there are no other institutional subsidies, corporate affiliations or funding sources supporting this work, except that some of the implants were donated by Synthes GmbH.

**Acknowledgments**

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**References**

Paper p4

Biomechanical evaluation of a new fixation technique for internal fixation of three-part proximal humerus fractures in a novel cadaveric model

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1. Introduction

Fracture of the proximal humerus is the third most common injury in people over 65 years of age after hip and Colles’ fracture (Baron et al., 1996). Most of these fractures are stable and can be successfully treated conservatively (Court-Brown CM et al., 2002; Court-Brown and McQueen, 2004; Hintermann et al., 2000; Lil and Josten, 2001; Szyszkowitz and Schippering, 1999) but about 20% of the patients need surgical intervention. Nowadays the surgical treatment of two and three-part proximal humeral fractures aims for a stable fixation that preserves the blood supply to the fracture fragments and reduces the risk of shoulder stiffness allowing early joint mobilization (Hintermann et al., 2000; Kwon et al., 2002) but the optimal treatment is still controversial. On one side angular stable plating with locking plates has proven to be an effective treatment option (Brunner et al., 2009; Hirschmann et al., 2007; Plecko and Kraus, 2005; Sudkamp et al., 2009) and minimal invasive technique has become popular (Gallo et al., 2005; Gardner et al., 2004, 2005; Lafi amme et al., 2008). On the other side recent data support the use of intramedullary nailing with new implants as promising alternatives (Gradl et al., 2007, 2009; Mihara et al., 2008). Recently a new implant, the Expert Proximal Humeral Nail with Locking Plate for Humeral Nail (LPHN, Synthes GmbH, Oberdorf, Switzerland), was designed for proximal three or four-part humeral fractures. It combines an additional locking plate with the existing geometry of the Expert Proximal Humeral Nail (Expert PHN, Synthes GmbH, Oberdorf, Switzerland) (Fig. 1). The rationale behind the additional plate is based on the assumption that augmenting the existing humeral nailing system optimizes bone purchase and leads to additional stability of the humeral head.

The purpose of this study is to assess if the new implant provides more interfragmentary stability to a three-part proximal humeral fractures when compared to the standard implant in a novel cadaveric model. The information retrieved aims at providing a biomechanical basis for the use of combined plate-nail implants in the treatment of multi-fragmentary proximal humerus fractures.

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2. Methods

Eight pairs of fresh frozen skeletally mature human cadaveric humeri were obtained and anterior–posterior X-rays were performed to exclude defects affecting the bone structure integrity. The bones were frozen at −20 °C until further processing.

2.1. Bone mineral density measurement

The specimens underwent high-resolution bone densitometry measurement (BMD, mg HA/cm³, 123 μm resolution) using three-dimensional peripheral quantitative computed tomography (pQCT, XtremeCT, Scanco Medical, Brüttisellen, Switzerland). The volume of interest included those areas where the proximal parts of both implants were to be placed during the following instrumentation.

2.2. Prototype features

Similarly to the Expert PHN the LPHN provides a fixed-angle blade in the humeral head and an intramedullary load carrier that controls micro movements at the metaphysis. The LPHN has a 23 mm large square medical stainless steel additional plate restrained to the blade through an angular stable locking system. The plate features at each corner a hole hosting a divergent angular stable locking screw.

2.3. The biomechanical model

2.3.1. Specimen preparation

Prior to instrumentation, the specimens were thawed overnight at 4 °C in a refrigerator. During preparation, each specimen was covered with a towel soaked with saline solution and was periodically sprayed to prevent desiccation. The bone pairs were randomly assigned to treatment with either the Expert PHN or the LPHN. The order in which the fixation was applied (Expert PHN versus LPHN) was similarly randomized, but both specimens in each pair were instrumented on the same day always.

All samples were prepared following the same five steps: 1) marking the reference points and curves on the surface of the bone, 2) performing humeral neck osteotomy creating a lateral fragment (Greater Tuberosity), 3) fixing a custom-made anchor to the lateral–posterior side of this same fragment, 4) anatomical reduction of the fragments and fixation with the Expert PHN or LPHN implant, 5) humeral surgical neck wedge ostectomy creating the humeral head fragment 6) standardization of the shaft length.

Step 1. The following two groups of reference points and curves were drawn on each humerus using a skin marker (Devon® Skin Marker, TYCO Healthcare LANE COVE, NSW 2066 AUSTRALIA): Greater Tuberosity’s reference curves and Surgical Neck’s reference curves (Fig. 2).

Step 2. A microsagittal saw (Synthes Saw Blade 0.4 mm thick, Synthes GmbH 4500 Solothurn, Switzerland) was used to create a lateral fragment, including the Greater Tuberosity, following the reference curves. Step 3. A custom-made anchor consisting of a 2 mm bolt and two 9 mm external diameter washers was connected to the lateral–posterior side of each Greater Tuberosity fragment after pre-drilling with a 2 mm drill tip (Fig. 3). A nut and one washer laid outside of the fragment and the screw’s head and the second washer inside. In order to improve the holding capability, each anchor was augmented using PMMA (Polymethylmethacrylate, Beracryl, W. Troller AG, Switzerland). Once the anchor was in place the bolt was tightened once leading the inner washer to compact the cancellous bone underneath. The bolt was then released and two 7 metric sutures (TI•CRON 5, Syneture, Covidien Norwalk, CT 06856 USA) were independently connected with surgical knots to that part of the bolt protruding out of the bone and located under the external washer. One
milliliter of PMMA at the later hardening stage was applied underneath the internal washer, towards the compacted cancellous bone. The bolt was then retightened and the exceeding PMMA removed. Care was taken not to have any part of the augmented anchor protruding medial to the adjacent fracture plane in order to avoid any additional non-physiological friction between fragments.

**Step 4.** The randomly assigned implant (Expert PHN or LPHN) was fully fixed following the manufacturer’s recommendations including two parallel angular stable locking screws distally.

**Step 5.** The microsagittal oscillating saw was used to perform a surgical neck wedge ostectomy following the most distal and the 15° medially oriented Surgical Neck’s reference curves. Care was taken to remove any contact point between the humeral head’s fragment and the shaft.

**Step 6.** All the samples were reduced to an equal length cutting the shaft perpendicular to its axis 70 mm distal to the center of the most distal angular stable nail screw.

All the procedures, including drawings, osteotomy, augmentation, implant fixation and ostectomy, were performed by the same surgeon (M.P.). Fluoroscopy was used to check the length and position of the implants at each step. Each humeral diaphysis was then embedded in the PMMA perpendicular to the ground in a cylindrical stainless steel base-plate up to 40 mm distal to the center of the most distal angular stable nail screw.

### 2.3.2. Test set up

Biomechanical testing was performed on a biaxial servo-hydraulic machine, MTS Mini Bionix II 858 (MTS Systems Corp., Eden Prairie, MN) using a 4kN/20 Nm load cell (HUPPERT 6, HUPPERT GmbH, Herrenberg, Germany). Each sample was restrained to the machine with a 25° lateral angulation (Fig. 4) according to the measurement range of Bergmann et al. (2007). Distally a cardan joint connected to the stainless steel base-plate restrained all the sample displacements and the rotation around the shaft axis. The load was applied on the samples by means of a custom-made PMMA cup. An even load distribution on the humeral head was provided via a cavity created in the PMMA cup as negative of a plastic humeral head (5010 Humerus, SYNBONE AG, 7208 Malans, Switzerland) simulating the glenoid. Relative rotation of the cup and the humeral head was prevented applying sand paper strips on that part of the cup in contact with the sample. An adequate notch created in the cup, positioned above the nail entry point, always guaranteed free movements to the nail during testing. The PMMA cup was joined to the machine actuator by means of a custom-made flange and transmitted to the samples the axial load only. Rotational bearing associated with the custom-made flange in fact allowed decoupling the effect of the actuator axial and torsional movements. Once the sample was preloaded, rotations of the actuator did not elicit rotations of the PMMA cup. The torsional actuator was then used to independently generate the force pulling on the Greater Tuberosity fragment via a cable. Fitted in a groove, one side of the cable was anchored to the flange by means of a screw. The cable was...
passed through two pulleys during testing and connected to the two sutures attached to the augmented bone anchor. The position of the first pulley was such that the pulling direction of the first end of the cable was always tangent to the flange and perpendicular to its axis of rotation. The position of the second pulley was such that the initial direction of the pulling force acting on the anchor inserted in the Greater Tuberosity fragment was angled 110° to the humeral shaft axis in the medial-lateral plane.

2.3.3. Loading patterns
All specimens were tested according to the following loading patterns:

1. **Axial stiffness test**: axial loading until 200 N in displacement control (0.02 mm/s).
2. **Compound cyclic load till failure**: increasing axial compression load, applied at 1 Hz, in phase with pulling on the bone anchor. The axial compression was a filtered interpolation of the pattern recorded by Bergmann et al. (2007) on an instrumented shoulder prosthesis during flexion movement. Starting from 200 N the maximum (peak) of the curve was cyclically increased (Windolf et al., 2009) (0.05 N/cycle) until failure while its minimum (valley) was kept constant at 50 N during the entire test. The pulling force acting on the anchor was controlled in angular displacement control and torque detectors between 1 and 3 Nm. This torque range produced a pulling force on the anchor ranging from 40 to 100 N. The test was automatically stopped when 8 mm actuator axial displacement was reached. At this stage the wedge ostectomy was almost completely closed and every fixation clearly failed.

2.4. Data collection

2.4.1. Data machine
Displacement and load were recorded from the MTS controllers at 64 Hz.

2.4.2. Fluoroscopy
At the beginning of the test and every 500 cycles until failure the machine observed a two second pause in unloading (valley) condition (50 N axial load, 1 Nm torque) in order to perform a fluoroscopic assessment (43 kV, 10 mAs — Siemens, ARCO SI 100). The assessment was performed with focus on the identification of the failure mechanism and to associate the loading history with the loss of fragments fixation.

2.4.3. Measurement of the interfragmentary motion
During testing an optical 3D motion tracking system consisting of 5 ProReflex MCU digital cameras (Qualisys AB, Gothenburg, Sweden) was used to continuously track the three-dimensional relative motions of the fracture fragments. Reflective marker sets were attached to the humeral shaft, the humeral head and the Greater Tuberosity. Prior to each test the tracking system was calibrated and a reference coordinate system was defined together with the position of the most medial aspect of the surgical neck ostectomy, taken as reference point on the humeral head (Fig. 4).

2.5. Parameters of interest
The construct stiffness was determined between 50 and 100 N on the load-displacement curve via the machine data during the first test. Matching those fluoroscopic images showing the first signs of construct failure with the motion tracking data an arbitrary displacement as failure criterion was defined. The following two datasets of variables were calculated at the failure criterion, at 5000 and at 10,000 cycles from the motion tracking data in the reference coordinate system: Humeral Head dataset and Greater Tuberosity fragment dataset (Fig. 5).

The former were the number of cycles until the failure criterion and the humeral head displacements and rotations at 5000 and 10,000 cycles. The displacements were calculated along the shaft axis (x axis) and the rotations were calculated with respect to an anterior–posterior axis passing through the humeral head and perpendicular to the shaft axis (y axis) in unloading conditions (valley).

The latter were the rotations of the Greater Tuberosity fragment around a medial-lateral axis passing through the humeral head and perpendicular to the shaft axis (z axis) in unloading condition (valley).

2.6. Statistical analysis
Data were evaluated with Matlab (MATLAB 6.5.1®; The MathWorks, Natick, Massachusetts). After testing for normality, non parametric
The BMD was not significantly different between groups (Table 1). In one sample the bone around the custom-made anchor failed immediately not leaving any chance for anchor replacement. For this pair the compound cyclic load till failure ran with just axial compression and only the Humeral Head dataset was included in the statistical analysis.

The axial stiffness of the LPHN was significantly higher than that of the Expert PHN \((P=0.036)\). A qualitative evaluation of the fluoroscopic images taken in unloading (valley) condition shows that the failure mechanism observed in both types of implant was similar and well reproducible throughout tests. Over a critical axial load, the humeral head started sliding along the intramedullary nail due to blade cutting through the cancellous bone. Once in contact with the shaft the humeral head rotated towards medial, partially closing the medial wedge shaped defect. Matching the fluoroscopic images with the machine data we set the arbitrary failure criterion to 3 mm. At this level of statistical tests was set at \(p\leq 0.05\).

### 3. Results

The BMD was not significantly different between groups (Table 1). In one sample the bone around the custom-made anchor failed immediately not leaving any chance for anchor replacement. For this pair the compound cyclic load till failure ran with just axial compression and only the Humeral Head dataset was included in the statistical analysis.

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### 4. Discussion

Three-part fractures of the proximal humerus are still a challenging problem \((\text{Esser, 1994a,b})\) for trauma surgeons in daily practice. Although augmentation with bone cement and bone substitutes, nails, different plating techniques as well as blade plates \((\text{Egol et al., 2008; Kitson et al., 2007; Kwon et al., 2002; Lill et al., 2003; Sanders et al., 2007; Walsh et al., 2006; Weinstein et al., 2006})\) have shown favorable results there is not a shared optimal surgical treatment for proximal humerus poor bone quality multi fragment fractures. This deficiency shows the potential need for an improvement in techniques and instrumentations.

### 4.1. The biomechanical model

Currently there is no clearly defined and generally accepted model for testing different internal fixation techniques and implants designed for proximal humeral fractures. Although clearly oversimplified compared to the clinical situation, in this study we propose an easily reproducible biomechanical model that resembles some in vivo loading and restrain conditions. We standardized the fracture patterns using reproducible reference curves, osteotomies and ostectomy performed with a microsagittal saw. In example, the purpose of the wedge ostectomy was to simulate a comminuted metaphyseal fracture with deficient cortical support on the medial side. Imitating the Glenoid, the PMMA cup introduced no further non-physiological constraint, leaving at the same time room for proximal intramedullary nail migration and free access to the Greater Tuberosity. Previous humeral fracture models and relative fixation methods have been subjected to a wide variety of testing conditions in earlier biomechanical studies. Applied as a single cycle, cyclically or to failure, the loading ranged from standard patterns \((\text{Foruria et al., 2010; Kitson et al., 2007; Koval et al., 1996; Sanders et al., 2007; Seide et al., 2007; Weinstein et al., 2006})\) (torsion, axial or ab-axial load and cantilever bending) to more complex patterns simulating shoulder abduction moving the humerus \((\text{Kwon et al., 2002})\) or acting on the remnant of rotator cuff tendons \((\text{Walsh et al., 2006})\). By effectively decoupling the effect of the actuator we were able to apply axial load and torsional motions in phase and to control two independent loading patterns. With the 25° lateral angulated axial pattern we simulated one of the most severe resultant directions of the glenohumeral compressive forces according to Bergmann's \((\text{Bergmann et al., 2007})\) measurements during different exercises (between 14° and 31° in the frontal plane). To the authors knowledge this is the first proximal humeral fracture model where the actuator was driven progressively increasing a load-time glenohumeral contact force curve recorded in vivo. Restraining the samples with a 25° lateral angulation this model put thus the implants under severe test pointing out their efficacy in stabilizing simulated proximal humeral fractures. With the second loading pattern we simulated the destabilizing effect of a part of a rotator cuff tendon on the Greater Tuberosity. The applied pulling force, set according to the assessment of Favre \((\text{Favre et al., 2005})\), resulted in a maximum torque moment on the humeral head of approximately 3 Nm, comparable to that measured in vivo \((\text{Bergmann et al., 2007})\).
4.2. The axial stiffness and compound cyclic load till failure tests

The data collected demonstrate that combining the Locking Plate for Humeral Nail with the existing geometry of the Expert PHN significantly increased the constructs' stiffness and improved the initial stability of the reconstructed simulated proximal humeral fracture. The failure mode observed in the compound cyclic load test confirmed that one of the main limiting factors in proximal humeral fracture fixation is the implant cut-out through the head's cancellous bone. This is especially true in osteoporotic bones where the weakest point of the whole construct is the implant-bone interaction. Despite our simplified and incomplete simulation of the action of the rotator cuff tendons the final position of the Greater Tuberosity fragments somehow reproduced the clinical situation although no major posterior-superior displacement of the Greater tuberosity was observed. The analysis of interfragmentary motion showed that LPHN offered superior stability both in the Humeral Head and in the Greater tuberosity fragments. The different geometry of the implant assembly and the increased number of fixation points could be the key factor slowing down the plastic deformation process distributing more evenly the stress on the fragments’ cancellous bone.

Despite we did not find any correlation between BMD and the investigated variables better stability can be expected also instrumenting osteoporotic bones with an implant able to share stresses more evenly.

4.3. Study limitations

We built an oversimplified model trying to simulate the physiological conditions of three-part proximal humeral fractures but we are aware that the shoulder is a much more complex joint. We recognize that keeping constant the direction of the resultant axial force acting on the humeral head might not exactly reproduce the physiological loading. Trying to simulate a destabilizing force on the Greater Tuberosity fragment we applied a concentrated force of arbitrary magnitude that scarcely resembles the action of the entire rotator cuff. Collecting bones with a narrow range of BMD we were not able to assess which implant offers the best performances when used to fix osteoporotic fractures. The cadaveric model does not provide information about the effect of soft tissue dissection with possible devascularization of the osseous fragments.

5. Conclusion

In this study we propose a reproducible three-part humeral fracture cadaveric model and we address a compelling question concerning...
internal fixation. We have shown that fixing three-part proximal humeral fractures combining the Expert Proximal Humeral Nail with a new Locking Plate for Humeral Nail improves interfractionary stability in a cadaveric model. The significant decrease of varus displacement of the articular fragment in the LPHN group is a convincing advantage of this new device, mainly when there is a lack of medial column support (Gardner et al., 2007). The results of the present study are promising and provide a good biomechanical basis for the use of combined plate-nail implants in the treatment of multi-fragmentary proximal humeral fractures. However the ultimate advantage of this new implant assembly has to be determined in vivo.

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DensiProbe Spine

A Novel Instrument for Intraoperative Measurement of Bone Density in Transpedicular Screw Fixation

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Study Design. Cadaver study.

Objective. To determine bone strength in vertebrae by measuring peak breakaway torque or indentation force using custom-made pedicle probes.

Summary of Background Data. Screw performance in dorsal spinal instrumentation is dependent on bone quality of the vertebral body. To date no intraoperative measuring device to validate bone strength is available. Destructive testing may predict bone strength in transpedicular instrumentations in osteoporotic vertebrae. Insertional torque measurements showed varying results.

Methods. Ten human cadaveric vertebrae were evaluated for bone mineral density (BMD) measurements by quantitative computed tomography. Peak torque and indentation force of custom-made probes as a measure for mechanical bone strength were assessed via a transpedicular approach. The results were correlated to regional BMD and to biomechanical load testing after pedicle screw implementation.

Results. Both methods generated a positive correlation to failure load of the respective vertebrae. The correlation of peak breakaway torque to failure load was $r = 0.959 \ (P = 0.003)$, therewith distinctly higher than the correlation of indentation force to failure load, which was $r = 0.690 \ (P = 0.040)$. In predicting regional BMD, measurement of peak torque also performed better than that of indentation force ($r = 0.897 \ (P = 0.002)$ vs. $r = 0.777 \ (P = 0.017)$).

Conclusion. Transpedicular measurement of peak breakaway torque is technically feasible and predicts reliable local bone strength and implant failure for dorsal spinal instrumentations in this experimental setting.

Key words: osteoporosis, pedicle screw cut-out, bone strength, breakaway torque, indentation force, regional bone mineral density, spinal fixation, dorsal instrumentation.

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Osteoporosis is a skeletal disease that affects our population in a growing manner. In 2003, in Germany, the prevalence was 7.8 million people out of 80 million inhabitants, of which 6.5 million women.1 Weak bone stock in osteoporosis results in fractures, which mostly occur in the spine, the distal radius, and the proximal femur.2 Transpedicular fixation in spinal fractures, degenerative changes, or deformities is a well-established procedure. In osteoporotic bone, however, this happens to be a major challenge. Rates of failure because of loosening at the insufficient screw-bone interface (“cut-out,” “back-out”) in weak bone stock are reported to be 0.8% to 17%.3–5

While planning pedicle screw instrumentations the spine surgeon is at best provided with preoperative information about the bone quality by radiographs, dual energy radiograph absorptiometry (DXA), or quantitative computed tomography (QCT). The relevant densitometric information, however, only generates indirect evidence of the local bone strength and resulting screw purchase. Bone mineral density (BMD) as evaluated by DXA or QCT only explains about 60% of the variance in strength of trabecular bone.6 Factors such as bone architecture, bone dimension, degree of mineralization, and rate of bone remodelling that also contribute to bone strength7 are so far not routinely evaluated. The judgment of pedicle screw purchase is mostly generated through the subjective tactile feeling the surgeon gets during cavity creation through the pedicle. In case of deficient bone strength with the possibility of screw loosening accessory augmentation with bone cement could be applied.8

From a material science’s view the load-carrying behavior of bone can be described using 4 mechanical terms, which can be determined in a destructive load test: ultimate force (strength), resilience, stiffness, and toughness.9 Bone strength resembles the ultimate force resulting in fracture. Several different destructive testing methods are conceivable like compression of bone cylinders, probe indentation or twisting, or screw pull-out.

Suhm et al reported on the determination of trabecular bone strength of the proximal femur by means of an in situ mechanical test in vitro and in vivo, measured with torque to breakaway of an inserted blade.10,11

Based on these studies, we compared 2 methods of local bone strength evaluation in vertebrae. Using custom-made pedicle probes breakaway torque and indentation force were assessed in their ability to predict pedicle screw failure in a cadaveric bone study.

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An earlier version of this work was presented at the 3rd AO Congress, Davos, Switzerland, June 25–29, 2009.
Materials and Methods

Ten fresh frozen cadaveric lumbar vertebrae (6, L2; 4, L3) were used for testing. The body donors consisted of 7 men and 3 women with an average age of 81.9 years (range, 72–90 years). Mean body size was 163 cm (145–186 cm), mean body weight 63 kg (43–81 kg), and mean body mass index (BMI) 23.7 kg/m² (16.4–30.1 kg/m²). The use of the human specimens for scientific purpose was approved by the local ethical committee.

Preliminary radiograph studies showed no fractures, scoliotic deformations or neoplasms.

Before and in between the different tests the specimens were stored at −20°C. Before testing the specimens were allowed to reach room temperature for 24 hours. While defrosting and during testing the specimens were kept moist with saline solution.

QCT Analysis

Following preparation of the vertebrae, the endplates were embedded in polymethylmethacrylate (PMMA) in such manner that 2 plane-parallel surfaces were created. Thereby a reproducible purchase in the computed tomography (CT)-holder could be established. Also 3 titanium beads of 2 mm size were embedded as CT markers. Before imaging in water in a Plexiglass container (as soft tissue equivalent), the vertebrae were submerged in saline solution and evacuated for 24 hours to eliminate air artifacts in QCT analysis.

Scanning was performed using a high resolution peripheral CT (XtremeCT) scanner (SCANCO Medical AG, Brüttsellen, Switzerland) with a spatial resolution of 82 μm. Attenuation data were converted to equivalent hydroxyapatite (HA) densities. Quality control (based on Shewhart’s rules) was monitored by daily scans of a phantom containing rods of HA (densities of 0, 100, 200, 400, and 800 mg HA/cm³) embedded in a soft tissue equivalent resin (QRM, Mührendorf, Germany).

Global BMD inside the vertebral body was evaluated using the μCT Evaluation Program V6.0 of SCANCO Medical AG, Brüttsellen, Switzerland. The areas of the respective probe and pedicle screw positions within the vertebral bodies were detected from the overlay of subsequent QCT scans by MATLAB Software (The MathWorks, Natick, MA). Therefore the regional BMD of bone cylinders the size of the respective probe (19 × 3.8 mm for Torque Measurement Tool [TMT], 15 × 2.8 mm for Indentation Measurement Tool [IMT]) and cylinders of the pedicle screw tip (25 × 5.2 mm) could be evaluated individually.

Breakaway Torque and Indentation Force Measurement

To determine bone strength 2 methods principally based on local bone destruction were compared. One method measures breakaway torque of a custom-made probe with a blade tip of 3.8-mm diameter and 19-mm blade length (TMT). The other method measures indentation force of a cylindrical probe with 2.8 mm diameter and 15 mm feed (IMT) (Figure 1).

Preparation and measurement were conducted by one of the authors, an experienced spine surgeon (L.M.B.). In both methods the pedicles were prepared using a pedicle awl (Synthes Inc., Solothurn, Switzerland) to open the dorsal cortex and a pedicle probe (Synthes Inc., Solothurn, Switzerland) to create the cavity inside the pedicle. The preparation was halted when reaching the anterior portion of the pedicle as indicated by image intensifier (Siremobil, Siemens Medical Solutions, Zürich, Switzerland). In that manner the bone stock of the vertebra was not compromised. The respective tool was inserted and the method applied thus measuring in the untouched vertebral body where the subsequent pedicle screw tip was to lie.

In case of torque measuring the TMT blade was pushed into the bone with a hammer. When reaching the final position as indicated by image intensifier it was rotated along its longitudinal axis thereby measuring the breakaway torque with a calibrated torque meter (HDM 100, Hios Inc., Akiyama, Japan). In case of indentation force measuring the resistance of the IMT probe was measured with a load sensor (Burster, MTS, Schaffhausen, Switzerland).

In both methods the diameter of the created defects felt clearly under the intended external diameter of subsequently inserted 5.2-mm pedicle screws. After application of the respective method (TMT/IMT) the defect zones were marked by titanium rods and a CT scan with a spatial resolution of 123 μm was performed. In comparison with the initial CT scans this provided an assessment of the probes’ location within the vertebral bodies. The lower resolution was chosen because those CT scans were only required for detecting the defect position, not for BMD evaluation.

Pedicle Screw Instrumentation

After bone strength measurements 5.2-mm USS II titanium pedicle screws (Synthes Inc., Solothurn, Switzerland) with lengths of 40 to 50 mm depending on vertebral size were inserted in the exact positions of previous TMT/IMT-measurements, monitored by image intensifier. After instru-
Another QCT scans with 123-μm resolution were performed to determine the exact locations of the pedicle screws within the vertebral bodies. Also axial radiograph images were obtained by image intensifier to visualize the depth of insertion of the pedicle screws. The point of load transmission in the subsequent biomechanical testing was defined midway between the 2 pedicle screw tips in the axial images.

**Biomechanical Testing**

Load application was carried out in axial direction with the point of force application in the center of the upper vertebral endplate according to previously published test-setups.

The instrumented vertebrae were embedded into blocks of PMMA in the plane of the pedicle screws using custom-made screw extensions that were mounted on the screw heads. The PMMA blocks enabled the fixation in the holder of a dynamic load-testing machine (Mini Bionix 858, MTS Systems, Eden Prairie, MN) (Figure 2). In each vertebra the distance between the point of load transmission and the PMMA block was kept equal thus maintaining an equal lever arm for the load testing. The load plunger of the Mini Bionix was mounted on a cross-table to prevent shear forces in a horizontal plane.

A sinusoidal load with a frequency of 2 Hz was induced. Minimal load was set on 20 N, maximal load was started with 100 N and raised continuous to 800 N with an increment of 0.035 N per cycle.

After each 100 cycles a lateral radiograph image was obtained load-coupled to monitor screw loosening. Screw loosening was determined by the comparison of the position of a pin fixed on the test jig and 1 fixed on the vertebrae as shown by image intensifier. As cut-out criterion an increase of the angle between those pins of more than 1° was defined (Figure 3).

**Statistical Analysis**

Peak breakaway torque (measured by TMT) and peak indentation force (measured by IMT) were correlated with failure load and regional and global BMD by means of a t test. For all groups Pearson correlation coefficient r was calculated to identify correlations. Shapiro-Wilk tests verified the normal distribution of those variables. Data were fed into SPSS software for statistical analysis (SPSS 14.0, SPSS Inc., Chicago, IL).

**Results**

**Global and Regional BMD**

Regional trabecular BMD in the area of pedicle screw purchase was less than global trabecular BMD in the whole vertebral body. Global BMD values of the vertebral body as measured by QCT showed a wide range of densities: 62.96 to 136.30 mg HA/cm³ (mean ± SD: 91.49 ± 25.26 mg HA/cm³). Regarding the torque measuring cylinders (19 × 3.8 mm) the mean BMD was 69.48 ± 34.02 mg HA/cm³, in the cylinders of indentation measuring (15 × 2.8 mm) 42.94 ± 12.82 mg HA/cm³. Considering the areas of the pedicle screw tips (25 × 5.2 mm) in the upper vertebral body the mean regional BMD was 78.00 ± 38.93 mg HA/cm³ for the vertebra examined by TMT and 55.93 ± 15.68 mg HA/cm³ for those processed with IMT.
BMD is higher in the posterior parts of the vertebral body than in the anterior parts where the screw tips will be placed.

**Breakaway Torque and Indentation Force**
Peak torque values ranged from 0.16 to 0.50 Nm (mean 0.32 ± 0.12 Nm). In two cases the value was below detection limit of the torque meter of 0.10 Nm.

Indentation force values ranged from 64.80 to 117.00 N (mean 88.36 ± 21.98 N). Due to technical failure of the electronics of the IMT in one case no measurement could be obtained.

**Failure Loads in Biomechanical Testing**
Cut-out of the pedicle screws was achieved in all specimens. Failure loads ranged from 156 to 418.5 N (mean 256 ± 77.5 N). One vertebra of the TMT group was lost in testing as a result of technical problems with the Mini Bionix testing device.

**Torque Respective to Indentation Force and Failure Load**
Both probes generated a positive correlation to failure load. A higher correlation of TMT’s peak breakaway torque to failure load \( r = 0.959, P = 0.003 \) than IMT’s correlation of indentation force to failure load \( r = 0.690, P = 0.040 \) could be established (Figure 4).

**Torque Respective to Indentation Force and Regional BMD**
The regional BMD of the bone cylinders were also superiorly predicted by the torque measurement compared with indentation force measurement. In the TMT group a highly significant correlation between peak torque and regional BMD of \( r = 0.897, P = 0.002 \) could be shown. Also the IMT group still showed a significant correlation of \( r = 0.777, P = 0.017 \) of indentation force to regional BMD (Figure 5).
Bone Mineral Density and Failure Load

The global BMD of the vertebrae correlated significantly to failure load with \( r = 0.832 \) (\( P = 0.005 \)) thereby reaching a coefficient of determination of \( r^2 = 0.692 \), comparable with the reported value of \( r^2 = 0.6 \) by Goulet et al.\(^6\) However, when taking the regional instead of the global BMD at the area of the tips of the pedicle screws into account, a coefficient of determination of \( r^2 = 0.817 \) (\( P < 0.001 \)) was reached, meaning that 82% of variability in failure load of the pedicle screws is explained by the regional BMD in bone cylinders the size and the position of the first 25 mm of those pedicle screws (Figure 6).

Discussion

Bone strength is the central parameter that influences screw purchase in transpedicular instrumentations. With increases in osteoporosis’ prevalence this factor will gain even more interest. Several researchers were able to find a high linear correlation between insertional torque of pedicle screws\(^12\)–\(^14\) and screw failure \textit{in vitro}, others could not establish such relationship.\(^15\)–\(^17\) The limitation of torque measurement in continuous screw insertion lies in the subjectively defined endpoint of maximum insertional torque.\(^14\) Furthermore maximal insertion torque is not only dependent on local BMD at the screw tip but also on pedicle diameter and orientation relatively to the screw axis. Destructive techniques leading to fracture of bone trabeculae like breakaway torque or indentation force measurements create a distinct endpoint providing objectivity.\(^10\)

In our study, peak breakaway torque was found to be a reliable parameter to quantify trabecular bone strength. There were high correlations between torque measurement via TMT and screw failure load and also to regional BMD. These findings are consistent with studies by Suhm \textit{et al} investigating peak breakaway torque in the proximal femur.\(^10,11\) The respective correlations in measurement of indentation force via IMT were lower.

In our study, regional differences of BMD inside the vertebral body could be shown with higher BMD values in the posterior parts of the vertebral body. These findings of regional differences inside the vertebral body are in accordance with the work of Banse \textit{et al}, which found regional BMD inside the vertebral body to be higher in posterior and inferior regions compared to anterior and superior regions.\(^18\) They reported the least dense area of the vertebral body to be in a transverse zone anterior to the pedicles, the area where pedicle screws typically are positioned.

Another important finding of our study was that major differences of measured torque respective indentation force values exist within some vertebrae considering both pedicle sides. This asymmetry in local BMD underlines the importance of site-specific local bone quality determination, which is missed in a global BMD evaluation by DXA or QCT.

As this study is the first so far to investigate BMD on the exact pedicle screw position it was able to show that 82% of variability of failure load can be predicted by local BMD of the site of the screw tips. This supports the importance of measuring bone strength in that area. Another advantage of measuring in the vertebral body solely is the avoidance of artifacts generated through the pedicle passage. In narrow pedicles, the probes could come into contact with cortical bone yielding falsely evaluated bone strengths.

Although our results are highly significant the sample size was relatively small and has to be reproduced in further studies with more samples. We are also aware that mechanical testing does not fully mimic the clinical conditions where patient dependent factors as body weight and distribution as well as location and length of transpedicular screws are important.
the instrumentation have a great influence for the success of the procedure. A future continuation of peak torque measurement in vertebrae could be a combined instrument for measuring bone strength and pedicle probes for cavity creation (“finder”), thereby enabling the surgeon intraoperatively to determine bone strength without the use of additional instruments. This instrument could then provide an objective value in the decision to augmentation or extension of the pedicle screw instrumentation.

## Key Points

- Pedicle screw cut-out is an increasing problem because of incidence of osteoporosis.
- Bone strength can be determined by breakaway torque or indentation force.
- Of the screw purchase strength variability, 82% arises from regional differences in bone mineral density.

## References

Ex vivo evaluation of the polymerization temperatures during cement augmentation of proximal femoral nail antirotation blades

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BACKGROUND: Previous studies have clearly demonstrated superior biomechanical behavior of augmented proximal femoral nail antirotation (PFNA) blades compared with nonaugmented ones with respect to implant cutout. Nevertheless, there is concern about thermal bone necrosis due to exothermic curing of polymethylmethacrylate (PMMA)-based bone cements. The objective of this study was to quantify the temperatures arising around perforated titanium PFNA blades when augmenting with PMMA.

METHODS: Cylindrical samples from six pairs of fresh frozen human cadaveric femoral heads implanted with a PFNA blade were placed in a 37°C water bath and augmented with 3 mL and 6 mL PMMA. During augmentation, temperatures were measured using six K-type thermocouples that were placed at controlled distances around the implant. With the help of high-resolution quantitative computed tomography images, the locations of all thermocouples with respect to the cement-bone interface were reconstructed. No temperatures higher than 45°C were measured in the interface region and the surrounding cement-free cancellous bone. In the same regions, the longest exposure time above 41°C was 8.5 minutes and was measured in a 6-mL sample. Average maximum temperature was significantly lower for the 3-mL group compared with the 6-mL group (p = 0.017).

RESULTS: The results of this study suggest that augmentation of titanium PFNA blades is not associated with a risk of thermal bone necrosis when using up to 6 mL of PMMA. However, larger amounts of cement lead to higher temperatures. PMMA application should therefore be kept low to minimally alter the biological system.

CONCLUSION: The findings obtained from the previous DHS screw study could not be transferred to the PFNA blade due to different implant designs, materials, cement formulations, and application techniques.

The objective of this study was to quantify the temperatures arising around perforated titanium PFNA blades when augmenting with PMMA.

MATERIALS AND METHODS

Cylindrical samples (40 × 45 mm) from six pairs of fresh frozen human cadaveric femoral heads were prepared using a circular saw. Bone mineral density (BMD) of the femoral head was obtained by high-resolution quantitative computed tomography (Scanco Medical AG, Brüttisellen, Switzerland). The specimens were assigned to two study groups for a randomized left to right comparison: 3 mL cement (n = 6) versus 6 mL cement (n = 6). After centric insertion of the PFNA blade (perforated, TAN, 04.027.035S; Synthes GmbH) using a custom-made jig, six 1-mm holes were drilled radially around the tip of the implant at predefined depths (15, 14, 13, 12, 10, and 8 mm deep). This allowed tight fitting of six class 2 Ø 1 mm K-type (NiCr-Ni) thermocouples at controlled different distances to the centerline of the blade (Fig. 1). To avoid sliding out of the thermocouples, rubber blocks were placed at the right depth on the thermocouples and fixed to the sample with aid of a fixation ring.
To simulate physiologic conditions, the samples were placed in a 37°C water bath with help of a custom-made fixture. The bone cement (Vertecem V+, 07.702.016S; Synthes GmbH) was stored at room temperature before testing. Temperature recording using the six thermocouples was started before cement mixing and maintained for the whole injection procedure until cement curing. Cement was injected with the help of 1-mL syringes in a standardized manner by turning the cannula 120 degrees or 60 degrees, respectively, after each injected milliliter. After cement injection, the cannula was removed. Temperatures were recorded with 1 Hz until they reached the start value again (approximately 3,500 seconds). After testing, thermocouples were removed and the specimens were scanned again with high-resolution quantitative computed tomography. Locations of all thermocouples with respect to the cement cloud were reconstructed, and the distance of each thermocouple tip to the cement-bone interface (x) was calculated as shown in Figure 2. Thermocouples were divided into three groups with different measuring regions: cement region (x < -1 mm), interface region (-1 mm ≤ x ≤ 1 mm), and bone region (x > 1 mm). Data were statistically analyzed using parametric tests. The significance level was set to α = 0.05.

RESULTS

No statistical difference (p = 0.875) was found for BMD between groups (3 mL: 248 mgHA/cm³ [standard deviation (SD), 43]; 6 mL: 252 mgHA/cm³ [SD, 32]). The highest temperature of the experiment was 45.5°C ± 2.6°C (mean ± SD) for the 6-mL group and 44.6°C ± 5.3°C for the 3-mL group and was measured inside the cement cloud. In the interface region, the temperature was 42.3°C ± 1.5°C for the 6-mL group compared with 40.1°C ± 1.1°C for the 3-mL group. In the surrounding bone region, the temperatures were 40.1°C ± 1.1°C and 38.3°C ± 0.4°C for the 6-mL and 3-mL group, respectively. The temperature drop from the cement to the interface region was significant for both groups (p = 0.002). For the 6-mL group, an additional significant temperature drop was detected from the interface to the bone region (p = 0.005). Average peak temperature was significantly lower for the 3-mL group compared with the 6-mL group (p = 0.017). Figure 3 shows the peak temperatures measured with each thermocouple for both groups. No significant relation between BMD and average peak temperature was found, neither for the 3-mL (r = −0.023, p = 0.966) nor for the 6-mL group (r = −0.737, p = 0.095).
heated to 37°C. Furthermore, not only the implant material but also its geometry and volume are crucial factors determining the potential of the implant to absorb generated heat.6 A DHS screw with its numerous thread flanks, for example, offers a bigger surface to absorb the heat generated by the cement than the helically shaped PFNA blade.

No correlation was observed between BMD and average peak temperature in the 3-mL group. For the 6-mL group, however, a nonsignificant trend toward a negative correlation was observed. In osteoporotic bone, for which the procedure of implant augmentation is primarily indicated, slightly higher temperatures might therefore be expected when augmenting with larger amounts of cement (6 mL).

A limitation of the study is the lack of temperature measurements in front of the PFNA blade. Radiographic analysis revealed some samples where a small cement volume was visible in front of the implant toward the articular surface. As the thermocouples were placed radially around the middle of the helical part of the blade, the temperatures in this area remain unknown. Nevertheless, the amount of cement located radially around the blade was generally larger than the amount which penetrated in front of the implant and we therefore believe to have obtained sufficient data to evaluate the risk for thermal damage during augmentation of PFNA blades in the surrounding cancellous bone. The effect of cement application in the subchondral area and its thermal effect on cartilage are not clear and need further investigation.

In summary, the results of this study suggest that augmentation of titanium PFNA blades to reinforce implant purchase is not associated with a risk of thermal bone necrosis when using up to 6 mL of PMMA. However, it could be demonstrated that larger amounts of cement lead to higher polymerization temperatures, especially in low quality bone. PMMA application should therefore be kept at a minimum to alter the biological system to the least possible extent. As nicely shown by several authors, 3 mL of cement is sufficient to significantly enhance the cutout resistance in proximal femur fractures treated with a PFNA.1–3

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DISCLOSURE

The authors declare no conflicts of interest.

REFERENCES


In the interface and bone region, the longest exposure time above 41°C was 8.5 minutes and was measured in a 6-mL sample (Fig. 4).

**DISCUSSION**

We could demonstrate that at presence of 6-mL PMMA cement around a perforated PFNA blade, no temperatures above 45°C were reached in the bone region surrounding the cement cloud or in the interface region between bone and cement. However, latter temperatures were on average 2°C higher when using 6-mL compared with 3-mL cement.

Eriksson and Albrektsson7 have shown that heating up to 47°C for 1 minute severely impairs bone formation. Temperatures in the range of 44°C to 47°C were regarded as the threshold for impaired bone regeneration. When heating up to 50°C, necroses have been shown to occur already after 30 seconds.8 Li et al.6 could show that osteoblasts recovered completely after being exposed for 10 minutes at 45°C but showed irreversible necrosis if the temperature was kept at 48°C for 10 minutes. The critical locations where an irreversible damage of bone cells could potentially lead to implant loosening are the interface region between bone and cement and the cement-free cancellous bone. In our study, no temperature remained for longer than 9 minutes above 41°C in the interface and cement-free bone region. Only one thermocouple within each group exceeded the critical value of 47°C. As in both cases the latter measurements happened inside the cement cloud, these temperatures should not be of any concern.

Our results are very similar to the ones found by Boner et al.5 for augmented stainless steel DHS screws. Considering the fact that titanium has a higher thermal conductivity than stainless steel and for the used cement a lower maximal polymerization temperature according to ISO 5833 was reported9 than the one which was used by Boner et al., one would expect lower temperatures. However, because in our case the implant was already inserted when the sample was put in the water bath to reach thermal equilibrium, a worst-case scenario was investigated with the implant already

![Figure 4. Time response for the highest temperatures exceeding 41°C in the interface and bone region for both groups. In the 3-mL group, no temperature exceeded 41°C in the bone region.](image-url)


Metaphyseal Screw Augmentation of the LISS-PLT Plate With Polymethylmethacrylate Improves Angular Stability in Osteoporotic Proximal Third Tibial Fractures: A Biomechanical Study in Human Cadaveric Tibiae

Michael Goetzen, MD,* Tomas Nicolino, MD,* Ladina Hofmann-Fliri, MSc,* Michael Blauth, MD,† and Markus Windolf, Dipl. Ing*  

Objectives: The incidence of osteoporotic proximal tibial fractures has increased during the last 2 decades. A promising approach in osteoporotic fracture fixation is polymethylmethacrylate-based cement augmentation of implants to gain better implant purchase in the bone. This study investigates the biomechanical benefits of screw augmentation in less invasive stabilization system–proximal lateral tibial (LISS-PLT) plates in cadaveric extraarticular comminuted proximal tibial fractures (OTA-41-A3.3).

Methods: Standardized extraarticular proximal tibial fractures were stabilized with the LISS-PLT plate in 6 paired osteoporotic cadaveric tibiae. Bone mineral density was measured with high-resolution, quantitative computed tomography scans to identify bone quality. In the augmented group, the 5 proximal screws of the LISS-PLT plate were augmented with 1 mL of bone cement each, whereas the contralateral tibia was instrumented conventionally as the control. Cyclic axial loading was applied to each specimen with a starting load of 150 N, using a ramp of 0.05 N per cycle to 10-mm axial displacement. Varus displacement was identified from anterior–posterior radiographs.

Results: Bone mineral density showed no significant difference between the 2 groups (P = 0.47). The nonaugmented group reached 9417 load cycles (SD 753) until failure, compared with 14,792 load cycles (SD 2088) in the augmented group (P = 0.002). In the early-onset failure (deformation at 8250 load cycles), varus displacement was significantly smaller in the augmented group (0.46 degrees, SD 0.6) than in the nonaugmented group (3.23 degrees, SD 1.7) (P = 0.01).

Conclusions: This biomechanical study showed that cement augmentation of the LISS-PLT plate screws in osteoporotic proximal extraarticular tibial fractures significantly lowers the propensity toward screw migration and secondary varus displacement.

Key Words: osteoporotic fracture, proximal tibia, augmentation, bone cement, PMMA, LISS-PLT

INTRODUCTION

Age- and gender-specific analysis of tibial fractures demonstrates a bimodal incidence, with 1 peak in young men and another peak in older women.1–3 A relative shift toward more elderly patients seems to be taking place: In an earlier epidemiological study in which data were collected on tibial fractures between 1988 and 1990, 69% of the injuries resulted from high-energy trauma and only 19% from falls of standing height.4 In a 2008 publication, however, 48% of the fractures were caused by high-energy trauma and 33% sustained after a fall from a standing height.5

Many investigations have reported improved fracture fixation of proximal tibial shaft fractures in young patients.4–7 However, in a meta-analysis that included studies of patients with a mean age ranging from 32 to 49 years, a malunion rate of 11% and nonunion rate of 4% for proximal extraarticular tibial shaft and metaphyseal fractures were reported, regardless of the fixation technique.6 The most common failure modes were secondary varus and anterior apex displacements.8,9 To the best of our knowledge, no reports of complications in osteoporotic extraarticular proximal tibial fractures are available. Because of insufficient screw purchase in osteoporotic bone, malunion rates will most likely be even higher.10,11 Elderly patients who have poor tibial bone quality have especially high demands on fracture fixation, with the need for immediate postoperative mobilization to allow weight bearing as tolerated.12,13 Therefore, it is essential to achieve the best possible screw purchase and to prevent screw migration to guarantee axial alignment.

The only recommendation for osteoporotic fractures of the proximal tibia is the use of angular stable implants. Another approach to obtain superior implant purchase in osteoporotic bone is the augmentation of implants with polymethylmethacrylate (PMMA)-based bone cement.14–16 This cadaveric study investigates the augmentation of the metaphyseal screws of the less invasive stabilization system–proximal lateral tibial (LISS-PLT) plate (Synthes GmbH, Oberdorf, Switzerland) with PMMA-based bone cement (Traumacem V+, Synthes GmbH) and its potential to lower varus displacement resulting from screw migration.

MATERIALS AND METHODS

Six pairs of fresh frozen (−20°C) human cadaveric tibiae with the lowest bone quality were chosen from a pool...
of 25 pairs from existing bone mineral density (BMD) and dual-energy x-ray absorptiometry (DXA) data. Of the 6 chosen pairs, the average age was 90 years with an SD of 5 years (range, 76–96 years). The average T score measured in the distal epiphyses by DXA was $-3.6$ (SD 0.8). BMD was calculated for each specimen from high-resolution, quantitative computed tomography scans (XtremeCT; SCANCO Medical AG, Brüttisellen, Switzerland) at the proximal metaphysis to determine local bone quality and to rule out major bone pathologic conditions. In addition, a breakaway torque-measuring device (DensiProbe; AO Research Institute Davos, Davos, Switzerland) was used to analyze bone stock at the location of later screw placement before screw insertion.¹⁷

Pairs were divided so that one tibia of each pair was randomly chosen for conventional instrumentation, whereas additional augmentation of the proximal 5 screws of the LISS-PLT plate was performed in the other tibia. For the augmentation group, cannulated 4.5-mm locking titanium screws (Synthes GmbH) were modified to have 4 perforations, 2 mm in diameter, starting 10 mm distal to the tip of the screw over a distance of 10 mm, alternating by 90-degree angles (Fig. 1). Screw length was determined with a custom-made slide gauge.¹⁸ After instrumentation according to the manufacturer’s technique guide, each of the 5 metaphyseal screws was augmented with 1 mL injectable bone cement by using a custom-made 2.8-mm side-opening cannula (Fig. 1). During the augmentation, the cannula was continuously turned to ensure optimal cement distribution. A comminuted fracture was simulated by a gap osteotomy of 20 mm directly below the most distal metaphyseal screw. An artificial PMMA shaft, with the anatomic 10-degree antecurvature of the proximal tibia, was attached to the distal part of the plate.

The mechanical test setup was designed to apply a physiologic axial load. The proximal tibia was embedded into PMMA (Beracryl; Suter Kunststoffe AG, Fraubrunnen, Switzerland) adjacent to the proximal aspect of the LISS-PLT plate (Fig. 2) and centered vertically on a bidirectional compensator according to the loading center, which was defined as 4 mm medial of the midpoint of the maximal anterior–posterior and mediolateral tibial plateau dimensions.¹⁹,²⁰ The distal end of the construct was fixed to a steel ball, which allowed rotation in all directions (Fig. 2). Force was applied by an MTS 858 Bionix hydraulic test system (MTS Systems Corp, Eden Prairie, MN) and measured with a 25-kN load cell. Cyclic loading was applied at 2 Hz, starting at a peak load of 150 N and increased by 0.05 N per cycle.²¹ The load valley was maintained at 100 N throughout the test. A 10-mm displacement of the machine actuator was defined as failure and used as the test-stop criterion.

After every 250 cycles, anterior–posterior radiographs were taken in the unloaded position during a 2-second pause to record fragment displacement. Varus displacement was plotted by measuring angular changes between the metaphysis and shaft (Fig. 3) with the help of 2 metal pins attached to the bone (Fig. 2). Evaluation was done using MATLAB image processing software (MATLAB; Mathworks Inc, Natick, MA).

For each test, cycles to failure, cycles to 3 degrees varus angulation, and varus angulation at 8250 cycles (early-onset failure) were calculated and statistically evaluated. Early-onset failure was defined as 8250 load cycles, the failure point of the first specimen in the course of testing. Statistical analysis was conducted with SPSS 19.0 (SPSS Inc, Chicago, IL) by using paired samples t tests. Normal distribution of data was confirmed by the Shapiro–Wilk test. Correlations of BMD and DensiProbe values with cycles to failure were measured by the Pearson correlation test. The significance level was set to $\alpha = 0.05$.  

**FIGURE 1.** A and C, cannulated 4.5-mm titanium locking screw with perforations at the tip at 90-degree angle; (B) 2.8-mm custom-made side-opening cannula.
RESULTS

All values given are presented as mean and SD. The average local BMD of all specimens was 88 mg HA/cm^2 (SD 18). There was no significant difference in BMD between the 2 groups (P = 0.47). The average breakaway torque (DensiPorobe) in the nonaugmented group was 0.26 Nm (SD 0.12) and 0.29 Nm (SD 0.15) in the augmented group. The difference between the groups was not significant (P = 0.26).

Failure occurred in the nonaugmented group at 9417 load cycles (SD 753), as compared with 14,792 load cycles (SD 2088) in the augmented group (P = 0.002) (Fig. 4). A 3-degree varus angulation occurred in the nonaugmented group in 5 of the 6 specimens at an average of 6550 load cycles (SD 3114), whereas in the augmented group, only 1 specimen reached a 3-degree varus at 18,000 load cycles. For varus angulation at 8250 load cycles (early-onset failure), the nonaugmented group demonstrated significantly lower stability, with varus angulation of 3.2 degrees (SD 1.7) compared with that of the augmented group, which reached only 0.5 degrees (SD 0.6) (P = 0.01) (Figs. 5, 6).

No significant correlation was found between BMD and cycles to failure for either group. Moreover, torque measurements did not correlate significantly with cycles to failure in either group.

DISCUSSION

In this study, we investigated the potential of screw augmentation with PMMA-based cement in the LISS-PLT plate. We hypothesized that augmentation would increase implant purchase in unstable extraarticular osteoporotic proximal tibial fractures and as a result reduce angular displacement.

The results of this study revealed significantly better implant purchase in the augmented group than in the nonaugmented group, with the augmented samples withstanding 57% more load cycles until failure compared with the nonaugmented samples. Augmentation particularly improved primary stability, as demonstrated by comparing varus angulation of the metaphysis (0.5 degree in the augmented group vs. 3.2 degrees in the nonaugmented group) at 8250 load cycles (Fig. 6). Screw augmentation with PMMA-based bone cement of the LISS-PLT plate provides improved stability immediately after instrumentation.

This biomechanical study had the following limitations: The loads in this study were, however, based on a biomechanical test and cannot be transferred as absolute values for clinical use. Our biomechanical setup was based on the experience of Waehnert et al. A bidirectional compensator allowed medial and lateral tilts, whereas sagittal forces,
mainly applied because of the insertion of the patella tendon, were not simulated. Clinical failure also predominantly occurs in varus; a simplified test setup was thus used that only applied axial load.\textsuperscript{9,23} Furthermore, cement distribution around the screws was uniform in all planes. It can be assumed that not only was axial stability increased but also sagittal stability of the construct was obtained. Testing was performed only to a 10-mm displacement of the machine actuator because closure in the fracture gap occurred when using higher displacements. Within this test range, a significant difference in load cycles and failure load between the 2 groups could be detected. Another limitation of the study was that only a single fracture pattern was tested. The comminuted fracture model was chosen to create a worst-case scenario and hence the most unstable fracture situation to demonstrate the potential of screw augmentation in proximal third tibial fractures. Transverse and oblique fractures most likely resist higher axial load innately, and the advantage of screw augmentation might be less distinct. In this ex vivo model, we could only show the mechanical advantage of PMMA augmentation. The effect of augmentation on fracture healing needs to be further investigated in vivo. In general, higher fracture fixation stability benefits bone healing. However, possible side effects of PMMA are not yet fully known.

Concerns about heat-induced necrosis during PMMA curing have been ruled out for augmentation of the proximal femur nail antrotational (Synthes GmbH),\textsuperscript{23} but the effect of hard PMMA cement replacing the functional subcortical trabeculae has not yet been investigated. New forces might be created at the cement–cortex interface. Clinical long-term results of PMMA implant augmentation are yet to be published.

Earlier studies showed that PMMA blade augmentation of a proximal femoral nail in osteoporotic bone improved clinical results by increasing implant fixation and decreasing implant displacement in pertrochanteric fractures.\textsuperscript{14,15} Sermon et al\textsuperscript{14} could demonstrate a 51% increase in load cycles until failure when augmenting proximal femur nail antrotational blades in simulated proximal femur fractures. In a biomechanical study by Roth et al,\textsuperscript{23} implant augmentation of the proximal tibia was first described by augmentation of the proximal screws of an intramedullary nail. They had similar results to those of our study, as they reported high angular stability with an average reduction of varus/valgus collapse of 5.1 degrees for the augmented samples.\textsuperscript{23} Unger et al\textsuperscript{16} reported a 53% increase in load cycles to varus collapse when augmenting the metaphyseal screws of a proximal humerus plate in a simulated 3-part proximal humerus fracture. With a 57% increase in load cycles to failure, our results
confirmed the high potential of augmentation in the proximal tibia.

The implant augmentation studies of Sermon et al\textsuperscript{14} and Unger et al\textsuperscript{16} demonstrated a negative correlation between cycles to failure and local BMD for the nonaugmented groups. In our study, however, no correlation between local BMD and cycles to failure in either group was shown. This may be related to the fact that the bones selected for this study had the lowest \textit{T} scores of 25 pairs, as measured with DXA at the distal epiphyses (average \textit{T} score $-3.2$, SD 0.8). Therefore, the span of BMD values was low (average 88 mg Ha/cm$^2$, range 65–117). By increasing this range and the number of samples, one could possibly find a better correlation.

Implant augmentation is a viable option in osteoporotic patients for increasing the stability of fracture fixation. However, quantitative preoperative assessment of bone quality, such as DXA or quantitative computed tomography measurements, is not available for most trauma patients. Subjective and inherently biased assessment, such as estimating the resistance during screw insertion or the feeling of insufficient screw purchase, is often used by surgeons for decision making. A mechanical measurement tool, such as the DensiProbe, which can be applied during the surgery, might be a more objective alternative. In our study, however, we could not significantly correlate peak torque values with the cycles until failure in either group. To reveal which screw and location in the proximal tibia benefit most from augmentation, we also correlated torque values separately with cycles to failure in the augmented group. There was no significant correlation for any specific screw. This probably relies on the fact that torque measurements of all 5 metaphyseal screws had a small range (0.25–0.34 Nm) and SD (0.04). No recommendation for screw number or screw position in the metaphysis that benefits most from augmentation can be given by these results. An extensive study comprising a high number of bones with different bone qualities would be necessary to evaluate a possible torque threshold value for augmentation.

In the study of Roth et al\textsuperscript{23}, bone cement was injected into the drill hole before screw insertion. In the present study, modified cannulated screws (Fig. 1) with a perforated tip were used to allow in situ augmentation. The LISS-PLT plate is a well-known standardized implant. Corresponding cannulated screws are readily available. There is no need for complex implant modification to integrate the augmentation option into the LISS-PLT plate set.

Future studies could investigate screw augmentation of the angular stable buttress plate at the proximal tibia in osteoporotic tibial plateau fractures. One pitfall to be aware of is the possible risk of intraarticular cement leakage. Nevertheless, studies that used injectable calcium phosphate cement in tibial plateau depression fractures rarely reported intraarticular leakage.\textsuperscript{25–27} In our study, we observed a uniform cement cloud around the screw tips. Precise prediction of cement distribution during injection for different fracture models needs to be investigated in the future.

**CONCLUSIONS**

In an experimental setting, screw augmentation of the LISS-PLT plate with PMMA-based bone cement in unstable proximal extraarticular tibial fractures has been shown to
reduce varus displacement and early loss of reduction in osteoporotic bone. Injectable bone cement applied through cannulated screws is a promising option in osteoporotic fracture management.

REFERENCES


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Comparison of Calcaneal Fixation of a Retrograde Intramedullary Nail with a Fixed-Angle Spiral Blade Versus a Fixed-Angle Screw

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ABSTRACT

Background: Retrograde intramedullary nailing is an established technique for tibiotalocalcaneal arthrodesis (TTCA). In poor bone stock (osteoporosis, neuroarthropathy), device fixation in the hindfoot remains a problem. Fixed-angle spiral-blade fixation of the nail in the calcaneus could be useful.

Materials and Methods: In seven matched pairs of human below-knee specimens, bone mineral density (BMD) was determined, and TTCA was performed with an intramedullary nail (Synthes Hindfoot Arthrodesis Nail HAN Expert Nailing System), using a conventional screw plus a fixed-angle spiral blade versus a conventional screw plus a fixed-angle screw, in the calcaneus. The constructs were subjected to quasi-static loading (dorsiflexion/plantarflexion, varus/valgus, rotation) and to cyclic loading to failure. Parameters studied were construct neutral zone (NZ) and range of motion (ROM), and number of cycles to failure.

Results: With dorsiflexion/plantarflexion loading, the screw-plus-spiral-blade constructs had a significantly smaller ROM in the quasi-static test \( (p = 0.028) \) and early in the cyclic test \( (p = 0.02) \); differences in the other parameters were not significant. There was a significant correlation between BMD and cycles to failure for the two-screw constructs \( (r = 0.94; p = 0.002) \) and for the screw-plus-spiral-blade constructs \( (r = 0.86; p = 0.014) \). Conclusion: In TTCA with a HAN Expert Nailing System, the use of a calcaneal spiral blade can further reduce motion within the construct. This may be especially useful in poor bone stock. Clinical Relevance: Results obtained in this study could be used to guide the operating surgeon’s TTCA strategy.

Key Words: Retrograde Intramedullary Nail; Spiral Blade; Tibiotalocalcaneal Arthrodesis

INTRODUCTION

Tibiotalocalcaneal arthrodesis (TTCA) is used in the management of arthrosis affecting the ankle and the subtalar joint, and of hindfoot deformities that are refractory to other forms of treatment. Many techniques have been described including screws, blade-plates, external fixators, and intramedullary (IM) nails. Early in the history of intramedullary TTCA, humeral nails or distal femoral nails were used. Current (second-generation) nails feature a more anatomic hindfoot valgus bend, and posterior-to-anterior calcaneal screw orientation for enhanced stability. In a previous study, our group was able to demonstrate the superiority of angle-stable locking in the hindfoot.

Sound fixation in the calcaneus is vital. Millet et al. reported the cut-out of a retrograde nail from the calcaneus. An increased rate of subtalar fusion failure has been reported in most of the clinical studies of nailed TTCA. One of the devices designed to overcome the problems of fixation of the IM nail in the calcaneus is the Hindfoot Arthrodesis Nail (HAN; Synthes AG, Solothurn, Switzerland), which offers the possibility of nail fixation in the calcaneus with two posterior-to-anterior locking screws or with one such screw and a posterior-to-anterior spiral blade. Both the spiral blade and the distal calcaneal locking screw may be locked with an appropriate end cap to create a fixed-angle construct.

A blade-like device provides a larger load-bearing interface between the device and the surrounding bone, which reduces the stress on the cancellous bone during blade impaction and should enhance the stability of the construct. This effect appears to be especially important in poor, osteoporotic bone stock. This study was performed to establish whether, for nail fixation in the calcaneus, the use of a...
screw plus a spiral blade would provide better biomechanical stability than the use of two calcaneal screws.

**MATERIAL AND METHODS**

**Specimens**

Seven matched pairs of human cadaveric below-knee specimens were harvested, with appropriate consent, from six female donors and one male donor (mean age, 77 years; range, 68 to 85 years). The specimens were obtained from voluntary human donors that had agreed to the use of their body or parts of them for education and research after death. The specimens underwent a process of pseudoanonymisation and were stored at −20°C up to its use. Ethical approval was obtained from ethics committee.

The specimens were radiographed to rule out skeletal pathology. Prior to bone mineral density (BMD) determination, the soft tissues were removed; however, as in the technique described by O’Neill et al., the ligaments were left in situ until after the completion of the arthrodesis. The fibula was removed; the forefoot was amputated through the transverse tarsal (Chopart) joint; and the tibia was resected at a site 250 mm proximal to the ankle joint line. The articular surfaces were left intact.

**BMD determination**

Calcaneal bone mineral density was determined using high-resolution peripheral QCT (pQCT) (XtremeCT; Scanco Medical AG, Brütisellen, Switzerland). The specimens were scanned axially with an isotropic resolution of 82 µm. From the sagittal sections, the width of each calcaneus at the calcaneal tuberosity was determined. Scanning medially and laterally from the midline, the BMD of a cancellous cylinder situated 2 mm below the cortex was measured in 30 medial and 30 lateral slices (slice thickness: 82 µm). The average value of these 60 slices was calculated.

**Nail**

The device used for TTCA was a retrograde IM nail (Hindfoot Arthrodesis Nail [HAN]; Synthes, Solothurn, Switzerland). This implant and the associated hardware (HAN Expert Nailing System) are made of titanium alloy (Ti-6Al-7Nb). The nail incorporates a (right or left) valgus bend, and is supplied in a range of lengths and diameters. Talar locking is by means of a screw; calcaneal locking is performed by means of two 6-mm-diameter screw, or with a spiral blade and a screw. The distal calcaneal screw and the spiral blade may be locked with appropriate end caps, to create a fixed-angle construct.

**Calcaneal locking randomization**

On one limb of each pair, TTCA was performed with a 6-mm-diameter conventional screw plus a 12.5-mm-diameter locked spiral blade. On the contralateral limb of each pair one 6-mm-diameter conventional screw and one locked screw of the same diameter were used.

**Nailing**

The nails were inserted by an experienced surgeon (the senior author), following the manufacturer’s instructions. No debridement of any cartilage was performed. Prior to instrumentation, the canal through the calcaneus and the talus was drilled, and the tibial medullary cavity was reamed (SynReam System reaming rod; Synthes AG, Solothurn, Switzerland) to a diameter of 13 mm. In this study, an 180-mm-long, 12-mm-diameter nail was used. Proximal (tibial) fixation was performed, in static mode, with two 5-mm-diameter standard locking screws using the aiming device. Talar locking was performed with a 5-mm-diameter screw. The end caps required for the locking of the devices were tightened with 5 Nm using a torque spanner (M.H.H. Engineering Co LTD, Bramley, Surrey, UK). Implant positioning was checked on an image intensifier.

**Biomechanical testing**

Biomechanical testing was based on a protocol used in previous studies. The calcaneus and 150 mm of the proximal remainder of the tibia were potted in methyl methacrylate (SCS Beracryl; Suter Kunststoff AG, Jegenstorf, Switzerland). Prior to potting, all protruding implant parts as well as the subtalar joint were covered with modeling compound to prevent bridging of the potting medium affecting the biomechanical properties. Testing was commenced once the potting had cured (Figure 1).

Testing was performed on a biaxial test system (MTS Bionix 858; MTS Systems Corporation, Eden Prairie, MN) equipped with a 4 ± 0.005 kN / 100 ± 0.1 Nm load cell.

First, three quasi-static tests were performed, with loading in torsion, varus/valgus, and dorsiflexion/plantarflexion. After five conditioning cycles, the following 15 cycles were analyzed. The specimens were sinusoidally loaded with ± 5 Nm at a rate of 0.1 Hz. For the varus/valgus and the dorsiflexion/plantarflexion tests, an 80-mm-long moment arm was used (Figure 1).

In the torsion test, torque was transmitted directly from the machine’s torsion actuator. Axially, a 5-N compressive preload was applied. Displacements, loads, and torques were acquired by the machine, at a rate of 64 Hz. In the analysis, we used the hysteresis plots to determine the neutral zone (NZ) and the range of motion (ROM) of each construct, as proposed by Wilke et al. for biomechanical studies of the spine. The range of motion was defined as the angulation under the maximum load (of ± 5 Nm); the neutral zone was defined as the range over which the instrumented specimen moved essentially free of applied loading, and reflected the laxity of the entire construct. These load levels were chosen according to the literature and to our pretests to avoid destruction prior to cyclic testing.
Fig. 1: Set-up for the dorsiflexion/plantarflexion test. 1 = X-ray tube; 2 = image intensifier; 3 = joint rod for load transmission; 4 = lever arm (80 mm); 5 = potted calcaneus; 6 = free portion of specimen; 7 = potted tibia, and attachment to the test system.

Fig. 2: Radiographic evaluation of the construct during testing. A, two-screw construct; B, screw-plus-spiral-blade construct. 1 = aluminum section with lever arm for load transmission; 2 = methyl methacrylate potting; 3 = remainder of modeling compound; 4 = radiolucency. The dotted lines were used for the assessment of angular stability. Figure 2A shows failure by loss of angular stability; Figure 2B shows a radiolucency indicative of failure by cut-out.

Next, cyclic testing in dorsiflexion/plantarflexion was performed at a rate of 1 Hz, starting with ± 10 Nm and continuously increasing the load by 0.05 N per cycle until failure of the specimen occurred, using a protocol described in the literature. For evaluation, images were obtained with an image intensifier system (Arcadis Varic; Siemens Medical AG, Erlangen, Germany; resolution: 1024 × 1024 Pixles.) immediately prior to loading, and then every 200 cycles, in dorsiflexion, at the maximum load at the level concerned, as described in the literature. (Figure 2, A and B). Also, the ROM and the NZ of each specimen were determined every 200 cycles. According to our pretest failure by loss of construct angular stability was defined as a change by 7 degrees or more in the dorsiflexion angle between the nail and the calcaneus (Figure 2A). Failure by cut-out was defined as the appearance of a radiolucency along the blade or screw(s) (Figure 2B).

Statistical analysis
The results were analyzed for normal distribution. A nonparametric paired test (Wilcoxon signed rank test) was used to detect differences between the two groups regarding BMD, ROM, NZ, and number of cycles to failure. For the comparison between BMD and the failure modes, the Mann-Whitney test was used. In both groups, Spearman’s correlation coefficient R was determined to study the relationship between BMD and the number of cycles to failure. Significance was set at p = 0.05.
RESULTS

Following randomization, there were seven specimens (three right, four left) in the screw-plus-spiral-blade group, and seven specimens (four right, three left) in the two-screw group. The mean BMD was 103 mg HA/cm³ (range: 22.4 to 185.9 mg HA/cm³; SD: 51.2). The difference between the groups was not significant ($p = 0.61$).

In the quasi-static tests, the constructs incorporating a spiral blade had a significantly ($p = 0.028$) smaller ROM in dorsiflexion/plantarflexion than did the constructs incorporating two calcaneal screws. In regard to the other parameters, the spiral-blade constructs were not significantly superior (Tables 1 and 2).

Early in the cyclic test (out to 400 cycles = 11.6 Nm), the constructs with a spiral blade had a significantly ($p = 0.02$) smaller ROM. By the 600-cycle (12 Nm) stage, the difference had ceased to be significant ($p = 0.06$); and with continued cycling, it decreased further yet (Table 3). There were no significant differences regarding the NZ (Table 4). The mean number of cycles to radiographic failure was 4,657 (SD 2,035) in the two-screw group, compared to 5,314 (SD 2,734) in the screw-plus-spiral-blade group. This difference was not significant ($p = 0.35$).

There was a significant correlation between BMD and the number of cycles to failure, both in the two-screw group ($r = 0.94$; $p = 0.002$) and in the screw-plus-spiral-blade group ($r = 0.86$; $p = 0.014$) (Figure 3).

The failure mode was loss of stability of the distal fixed-angle locking in a total of five cases (two in the two-screw group; three in the screw-plus-spiral-blade group); in the remaining cases, there was cut-out of the distal screw or of the spiral blade in the calcaneus (Figure 2, A and B). The mean BMD of the specimens with loss of angular stability was 142.6 mg HA/cm³ (range 120 to 171.6 mg HA/cm³) than that of the specimens that failed by cut-out (mean

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Table 4: Neutral Zone (NZ) of the Constructs in Degrees, During Cyclic Testing

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<td>Mean ± SD</td>
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<tr>
<td>1</td>
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<td>0.7 ± 0.1</td>
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<tr>
<td>200</td>
<td>0.8 ± 0.3</td>
<td>1.0 ± 0.2</td>
</tr>
<tr>
<td>400</td>
<td>1.0 ± 0.3</td>
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<tr>
<td>600</td>
<td>1.2 ± 0.5</td>
<td>1.3 ± 0.3</td>
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<tr>
<td>800</td>
<td>1.4 ± 0.6</td>
<td>1.5 ± 0.4</td>
</tr>
<tr>
<td>1000</td>
<td>1.7 ± 0.8</td>
<td>1.6 ± 0.5</td>
</tr>
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Fig. 3: This figure shows the correlation between the number of cycles to failure (radiographic evidence of angle between calcaneus and longitudinal axis of nail of 7 degrees or more with dorsiflexion loading) and the BMD. BMD: 80.9 mg HA/cm³; range 22.4 to 165 mg HA/cm³). (p = 0.029).

DISCUSSION

The development of modern devices for TTCA has opened up new possibilities of hindfoot reconstruction. However, the patients requiring TTCA often have multiple comorbidities, Charcot neuroarthropathy, generalized osteoporosis, or local osteopenia from long-term disuse. Under these conditions, stable fixation may be difficult to obtain. The importance of sound fixation in the calcaneus has been shown in a number of studies. Thus, Mann et al. and Means et al. found that a significantly more stable construct could be achieved with posterior-to-anterior orientation of a calcaneal interlocking screw. Mückley et al. showed that angle-stable locking in the calcaneus, and a valgus bend of the IM nail in the hindfoot, were superior to a TTCA IM nailing system with a straight, non-angle-stable device. The use of a spiral blade for IM nail anchoring in the hindfoot was first described by Zwipp et al., after Ito et al., of the same group, had demonstrated the biomechanical superiority of spiral-blade over screw fixation in the distal femur. Ito et al. found that the combination of a spiral blade and a screw provided a bone-device interface that was 38% greater than that obtained with two 6-mm diameter screws, and concluded that this greater surface area accounted for the better performance of the spiral-blade-and-screw constructs under purely axial loading. However, in TTCA the situation is more complex, since (a) greater moments are applied and (b) there are two joints that need to be fused.

To our knowledge, this is the first study designed to establish whether the biomechanical advantages observed in the distal femur can also be obtained in the hindfoot. We were able to show a correlation between BMD and construct failure, which shows that calcaneal bone quality and TTCA construct stability are directly related.

In the quasi-static tests, we were also able to show that initial stability is enhanced by the use of a spiral blade, even though this benefit was significant only in terms of the ROM in dorsiflexion/plantarflexion. In the torsion and the varus/volar tests, there were no significant differences. We think that this pattern may be accounted for by the anatomy of the ankle joint (stabilizing effect of medial malleolus; matching concave/convex joint surfaces). These factors applied equally to the two construct types and would have produced the same effect regardless of whether intracalcaneal fixation was with a screw-and-spiral-blade or with a two-screw arrangement.

With cyclic loading, there were no significant differences in the number of cycles to failure. Over the first 400 cycles, the constructs involving a spiral blade fared significantly better in terms of ROM than did the two-screw constructs; however, this difference became less and less over the subsequent cycles.

The failure modes observed were cut-out in the posterior part of the calcaneal tuberosity, or loss of angular stability between the nail and the distal screw or the spiral blade. Regardless of the mode of intracalcaneal fixation, cut-out
was seen more often at lower BMD, showing that the osteoporotic bone had not been able to cope with the stress at the device/bone interface. In the specimens with higher BMD, the cancellous bone was compressed to the point where angular stability was lost. The only significant differences were seen with dorsiflexion/plantarflexion. This movement is roughly along the axis of the screw or blade, which means that the inherent benefit of the spiral blade’s larger device/bone contact area can be fully brought to bear. We think that this accounts for the initial difference in the constructs’ behavior with cyclic loading and for the difference seen in the quasi-static tests. However, with further cycling, the benefit was lost as a result of loss of device fixation in the hindfoot.

Dorsiflexion stress has been recognized by several authors\textsuperscript{3,11,19,20} as the predominant loading mode of the arthrodesis site during weightbearing in the postoperative period; stresses in other planes can be eliminated with immobilization of the limb in a below-the-knee cast.\textsuperscript{3} We therefore feel that the differences between the two groups’ ROM and NZ observed in this loading mode in the quasi-static tests (Tables 1 and 2) were clinically relevant, even though there was no significant difference between the groups with regard to the number of cycles to failure.

Our quasi-static tests produced ROM and NZ data that were comparable with the results reported by Mückley et al.,\textsuperscript{16} who studied an angle-stable compressed IM nail for TTCA and found this device to be significantly superior to a straight TTCA nail with conventional interlocking. Obviously, a comparison of different biomechanical studies is fraught with difficulties; however, our test set-up and our loading regimes were similar to those used by other investigators, which should afford at least some comparability.

While the test set-up and the loading protocol used were similar to those employed by other investigators,\textsuperscript{1,3,16,22} our study was subject to the limitations common to all biomechanical studies. Thus, the increasing bony union that would be expected to occur in vivo could not be simulated. In common with other authors,\textsuperscript{1,3,16,19,20} we did not prepare the joint surfaces, in order to eliminate one variable. Our previous experience, and the current biomechanical literature,\textsuperscript{1,16,22} suggest that the loads used in our quasi-static tests were not in the destructive range.

Using continuously increasing loading in the cyclic tests ensured that all the specimens could be tested to failure. As may be seen from the studies by Chiodo et al.,\textsuperscript{3} O’Neill et al.,\textsuperscript{19} and Mückley et al.,\textsuperscript{16} cyclic testing at a constant load level would not necessarily have allowed testing to failure, even over 250,000 cycles, and would have made it difficult to compare the groups. The principle of testing with increasing load levels has been found useful in similar studies of bone strength in the femoral head.\textsuperscript{26}

The failure criterion for loss of angular stability chosen in our study was radiographically documented 7-degree or more displacement of the calcaneus from the longitudinal nail axis with dorsiflexion stress. This radiographic parameter allowed assessment especially of device fixation in the hindfoot, as well as a study of the failure pattern. Dorsiflexion was chosen since, according to O’Neill et al.,\textsuperscript{19,20} this represents the predominant loading mode of the arthrodesis site during weightbearing in the postoperative period. The size of the angle was adopted in light of preliminary tests which had shown that displacement by 7 degrees was clear and certain evidence of permanent, rather than of reversible elastic, deformation. Also, a 7-degree deformation in the calcaneus roughly corresponds to the 10-degree deformation of the entire fusion construct that had been used as a failure criterion in other studies.\textsuperscript{3,16,19}

The results obtained cannot be translated directly into clinical practice. Greater initial stability need not go hand in hand with better clinical outcomes. Less initial motion at the fusion site may conceivably promote and speed up bony union. We did not observe any significant differences with regard to the number of cycles to failure. This is why, even with constructs involving the use of a spiral blade, we would still recommend immobilization until definite evidence of bony union at the fusion site has been obtained. Clinical studies will need to be performed before any definitive recommendations can be made.

CONCLUSION

In our study, the screw-plus-spiral-blade construct was significantly more resistant to deformation than the two-screw construct in the quasi-static dorsiflexion/plantarflexion test and in the early stages of the cyclic test. There was no significant difference in the other planes tested. These results suggest that a spiral blade should be considered in patients requiring greater stability or in cases where only the most distal IM nail locking site can be used. We also conclude that, even with a screw-plus-spiral-blade construct, care should be taken to ensure that full weight-bearing is not resumed prematurely.

REFERENCES


Paper p9

The Use of DensiProbe™ in Hindfoot Arthrodesis. Can Fusion Failure be Predicted by Mechanical Bone Strength Determination?

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Key words
tibiotalocalcaneal arthrodesis, biomechanics, hindfoot, bone strength, bone quality

Abstract

Aim: Bone quality is a main factor in implant fixation. After having shown promising results, we have further investigated the use of the Densi-Probe™ as an intraoperative measurement tool for evaluation of calcaneal bone quality and prediction of nailed hindfoot arthrodesis failure.

Method: In this add-on study 19 nail arthrodeses were performed using a conventional screw plus a locked blade (n = 6) or plus a locked screw (n = 13) in the calcaneus. A specially devised tool was inserted at the fixation sites of the screws and the cancellous break-away torque was measured. The constructs were then cyclically loaded to failure.
Results: We saw a wide range of BMD (1.9–185.9mgHA/cm³, mean 102.4mg/cm³, SD 53.5). The peak torque was 0.47–1.78 Nm (mean 0.92 Nm, SD 0.46) at the proximal screw site (PSS) and 0.24 and 1.2 Nm (mean 0.63 Nm, SD 0.37) at the distal screw site (DSS), respectively, and 0.42 and 1.52 Nm (mean 1.00 Nm, SD 0.36) in the screw plus blade group (PSS). The number of cycles correlated with peak torque (two screws group PSS: \( p = 0.002, r^2 = 0.61 \) \( p = 0.001, r^2 = 0.90 \); screw plus blade group PSS: \( p = 0.001, r^2 = 0.99 \)). Peak torque also correlated with BMD in both groups (two screws group PSS: \( p = 0.01, r^2 = 0.71 \); DSS: \( p = 0.001; r^2 = 0.83 \); screw plus blade group PSS: 0.42 and 1.52 Nm, mean 1.00 Nm, SD 0.36).

Conclusion: A mechanical bone measurement tool like the DensiProbe™ seems to be suitable for predicting tibiotalocalcaneal arthrodesis failure in a biomechanical test set-up. As a restriction in clinical practice failure is multifactorial and prediction cannot be based upon these measurements only.

Einleitung

Als wichtigster Parameter zur Beurteilung von Knochenqualität und Implantatverankerung wird derzeit die Bone Mineral Density (BMD) herangezogen. Die BMD kann mittels quantitativer Computertomografie (QCT) oder Dual Energy X-ray Absorptiometry (DEXA) bestimmt werden. Trotz anerkannter Korrelation zur Festigkeit des Knochens bleiben beide Methoden indirekt und intraoperativ nicht durchführbar. CT sowie DEXA liefern globale Messwerte, die in inhomogenen Regionen, wie z.B. dem Kalkaneus, stark variieren können und nur bedingt Rückschlüsse auf die Qualität der Implantatverankerung zulassen. Bei Diabetes mellitus kann die Verwendung von DEXA oder CT sogar zu widersprüchlichen Ergebnissen führen [19,21,24].


In einer vorangegangenen Studie konnte gezeigt werden, dass sich eine derartige Messung auch auf die Verhältnisse bei der Rückfußarthrodese übertragen lässt [26]. Dabei wurde in einem biomechanischen Kadaverversuch an 7 Unterschenkelpräparaten die Stabilität unter zyklischer Belastung und die BMD bestimmt und mit der mechanischen Knochendichtemessung korreliert. Ziel dieser Arbeit ist es, mit einer Erweiterung der oben genannten Studie die beschriebenen Ergebnisse zu validieren und zusätzlich zu überprüfen, ob auch das Versagen eines Nagels mit Klingenverankerung im Kalkaneus vorhergesagt werden kann.

**Material und Methoden**

Die verwendeten Methoden sind identisch zu einer vorangegangenen Studie [26], dabei wurde die Anzahl der Proben um 12 Präparate auf 19 humane Leichenunterschenkel (10 rechte und 9 linke, davon 6 Paare) erweitert. Radiologisch wurden pathologische
Veränderungen ausgeschlossen. Die Spender (9 Frauen, 4 Männer) waren durchschnittlich 76 Jahre alt (Range 64 bis 87). Die Verwendung der Präparate war durch eine Ethikkommission genehmigt worden.


Die Bestimmung der BMD erfolgte im Kalkaneus mittels hochauflösendem pQCT (Xtreme-CT, Scanco Medical AG, Brüttisellen, Schweiz). Die Unterschenkel wurden entlang der axialen Richtung mit einer isotropischen Auflösung von 82 μm gescannt. Aus den Sagittalschnitten wurde die Breite der Kalkanei im Bereich der Tuber calcanei ermittelt. Von der Mitte ausgehend wurde die BMD in einem 2mm subkortikal liegenden Knochenzylinder in der Spongiosa jeweils in 30 Schnitten (Schichtdicke 82 μm) nach medial und nach lateral ermittelt.

Als Implantat wurde der Hindfoot Arthrodesis Nail (Synthes AG, Solothurn, Schweiz) mit einer Länge von 180mm und einem Durchmesser von 12mm verwendet. Das gesamte Implantat ist aus einer Titanlegierung (Titanium-Aluminium-Niobium) gefertigt. Die Verankerung im Kalkaneus erfolgt bei diesem System über 2 Schrauben (Flankendurchmesser 6 mm, Kerndurchmesser von 4,8 mm), von denen die distale Schraube winkelstabil verblockt wird, oder alternativ über eine winkelstabil verblockte Klinge (Durchmesser 12,5 mm) und eine der oben beschriebenen Schrauben.

Die 6 Unterschenkelpaare wurden in 2 Gruppen aufgeteilt, von denen einer Gruppe (Klingengruppe) eine im Kalkaneus winkelstabil verblockte Klinge und eine nicht winkelstabile Schraube und der anderen Gruppe (Schraubengruppe) 2 Schrauben implantiert wurden. Der Schraubengruppe wurden zudem 7 weitere Präparate zugeteilt.

Vor der Instrumentierung wurde der Markraum bei allen Präparaten mit einem SynReam-System (Synthes AG, Solothurn, Schweiz) auf 13mm aufgebohrt. Die zur Erlangung der Winkelstabilität nötige distale Verschlusschraube wurde mit einem Drehmomentschlüssel (M.H.H. Engineering Co LTD., Bramley, England) mit 5Nm angezogen. Proximal wurden 2 5-mm-Schrauben verwendet, wobei statisch
verriegelt wurde. Alle Implantationen erfolgten, entsprechend den Herstellerangaben, unter radiologischer Kontrolle und wurden durch einen erfahrenen Chirurgen durchgeführt (T. M.).


Abb. 1a-d: Konstruktionsplan und Fotografie der Messsonde und Fotografie der Messeinheit mit Klinge und aufgestecktem DensiProbe™ sowie Bildwandlerkontrollen jeweils unmittelbar vor der DensiProbe™-Messung.
Für die Messungen wurde nicht wie üblich über die gesamte Schraubenlänge vorgebohrt, sondern nur die posteriore Kortikalis des Kalkaneus perforiert. Unter Bildwandlerkontrolle und über den Zielbügel wurde nachfolgend die Messklinge bis unmittelbar vor den Nagel eingeschlagen und anschließend die Messung durchgeführt (Abb. 1).

Das Prinzip der Messung ist es, durch Drehung der Klinge die zwischen den Flügeln liegenden Trabekel zu brechen. Dazu wurde die Messklinge mit dem DensiProbe™180° um die Längsachse gedreht und das Spitzendrehmoment gemessen. Der Messbereich des Geräts beträgt 10 Nm mit einer Messgenauigkeit von \( \pm 0,032 \text{Nm} \) im Messbereich von 1Nm.

Abb. 2a und b: Testaufbau mit der Probe (1), der oberen und unteren Einbettung (2, 3) und dem Bildwandler (4). F gibt dabei die Richtung der Krafteinleitung an.

Die biomechanische Testung erfolgte in Anlehnung an vorangegangene Studien [5, 26]. Dazu wurden jeweils der Kalkaneus und 150mm der proximal verbliebenen Tibia in SCS Beracryl (Suter Kunststoff AG, Jenegstorf, Schweiz) eingebettet. Zuvor wurden alle vorstehenden Implantatanteile und das untere Sprunggelenk mit Knetmasse abgedeckt, um die Beeinflussung der biomechanischen Testung durch die Einbettung zu verhindern (Abb. 2 und Abb. 3). Die Testung erfolgte unmittelbar nach Aushärtung der Beracryl-Einbettung.
Die Tests wurden an einer MTS Bionix 858 biaxialen Testmaschine (MTS Systems Corporation, Eden Prairie, MN, USA) mit einer 4 ± 0,005 kN / 100 ± 0,1 Nm Kraftmessdose durchgeführt. Es erfolgte die zyklische Testung in Extension-Flexion, beginnend bei ±10Nm mit einer kontinuierlichen Steigerung von 0,05 N/Zyklus bis zum Versagen [27]. Zur Auswertung wurde unmittelbar vor Belastung und dann alle 200 Zyklen in Dorsalextension unter der jeweils maximalen Belastung eine Röntgenaufnahme erstellt (Arcadis Varic, Siemens Medical AG, Erlangen) [27,28]. Als Versagenskriterium wurde eine Auslenkung des Kalkaneus im Verhältnis zum Nagel von 7° festgelegt (Abb. 3).

**Statistik**

Es wurde eine lineare Regressionsanalyse durchgeführt, um Korrelationen zwischen den DensiProbe™-Messungen an der distalen / proximalen Schraube und der BMD, ROM, NZ bzw. den Zyklen bis zum Versagen zu bestimmen. Weiterhin wurde die Regression für BMD und ROM, NZ bzw. Zyklen bis zum Versagen berechnet. Als Signifikanzniveau wurde p < 0,05 festgelegt.

**Ergebnisse**

Die Proben umfassten in den BMD-Werten eine große Spannweite von 1,9 bis 185,9 g/cm³ (Durchschnitt 102,4 mg/cm³, SD 53,5). Für die Schraubengruppe betrug das
Spitzendrehmoment am Platz der distalen Schraube zwischen 0,24 und 1,2 Nm (Durchschnitt 0,63 Nm, SD 0,37), und im Bereich der proximalen Schraube zwischen 0,47 und 1,78 Nm (Durchschnitt 0,92 Nm, SD 0,46). Dieser Unterschied war nicht signifikant ($p = 0,088$). Das Spitzendrehmoment, gemessen an der distalen Schraube, korrelierte signifikant mit dem BMD ($p = 0,001$; Korrelationskoeffizient $r^2 = 0,83$). Proximal ergab sich eine schwächere Korrelation ($p = 0,01$, $r^2 = 0,71$). Das Spitzendrehmoment korrelierte signifikant mit den Versagenszyklen sowohl am distalen ($p = 0,001$, $r^2 = 0,90$) als auch am proximalen Messort ($p = 0,002$, $r^2 = 0,61$, Abb. 4 und Abb. 5). Die Korrelation zwischen BMD und Versagenszyklen war ebenfalls signifikant ($p = 0,001$, $r^2 = 0,71$).
Bei der mit winkelstabiler Klinge versorgten Gruppe konnte eine Messung aufgrund eines technischen Fehlers nicht aufgezeichnet werden. Bei den übrigen 5 Proben betrug das Spitzendrehmoment am Platz im Bereich der proximalen Schraube zwischen 0,42 und 1,52 Nm (Durchschnitt 1,00 Nm, SD 0,36). Diese Messung korrelierte signifikant mit dem BMD (p = 0,037; r² = 0,75) und den Zyklen bis zum Versagen (p = 0,001, r² = 0,99, Abb. 6). Die Korrelation zwischen BMD und Versagenszyklen war auch hier signifikant (p = 0,037, r² = 0,67).

Abb. 6: Die Zyklenzahl bis zum Versagen in Abhängigkeit vom Spitzendrehmoment am proximalen Messort in der Klingengruppe.

Discussion


Mit der vorliegenden Arbeit konnten wir starke Korrelationen zwischen den DensiProbe™-Messungen an den verschiedenen Messorten und den Versagenszyklen aufzeigen. Damit


Bei den Präparaten, die mit einer Klinge versorgt wurden, konnten wir ebenfalls eine sehr hohe Korrelation zwischen DensiProbe™-Messung, die hier nur am proximalen Messort durchgeführt wurde, und Versagenszeitpunkt feststellen ($p = 0,001; r^2 = 0,99$). Dies ist insofern überraschend, als dass bei der Schraubengruppe die Messung am proximalen Messort nicht annähernd so stark korrelierte ($p = 0,02; r^2 = 0,61$). Einschränkend ist zu sagen, dass nur 5 Präparate der Klingengruppe ausgewertet werden konnten, sodass dieses Ergebnis allenfalls als Machbarkeitsstudie gewertet werden kann.

Durch das neue Messprinzip konnten wir Unterschiede in der lokalen Knochenqualität im Kalkaneus zwischen proximalem und distalem Schraubensitz nachweisen, wobei wir eine höhere Knochenfestigkeit am proximalen Messort ermittelt haben. In unserer Vorarbeit mit 7 Proben war dieser Unterschied signifikant [26]. Dieses Ergebnis hat sich in der vorliegenden Arbeit relativiert. Zwar zeigt sich immer noch ein tendenziell höheres
Drehmoment im proximalen Messort, dieser Unterschied ist allerdings nicht mehr statistisch signifikant.

Bei der in dieser Arbeit gezeigten Korrelation der BMD-Werte mit dem Versagenszeitpunkt sei darauf hingewiesen, dass wir ein hochauflösendes pQCT (82 μm Auflösung) verwendet haben. Das klinisch eingesetzte QCT erreicht diese Auflösung derzeit nicht und liefert damit ungenauere Werte. Vorteil der DensiProbe™-Messung ist, dass hier die Knochenfestigkeit genau am Ort der Implantatverankerung gemessen wird. Zudem ist unsere Messmethode so entwickelt, dass sie intraoperativ ohne großen Mehraufwand einsetzbar ist und dabei keinen Einfluss auf die Arthrodese hat.


Der Testaufbau und die Höhe der Belastung gelten als gängiges Verfahren zur biomechanischen Testung von tibiotalokalkanearen Arthrodosen, auch wenn damit die tatsächliche In-vivo-Situation nur sehr eingeschränkt wiedergegeben wird [5,31-33]. Mit der kontinuierlichen Kraftsteigerung während der zyklischen Tests konnten wir ein Versagen innerhalb der Testung sicherstellen. Dies wäre, wie die Arbeiten von Chiodo et al. [32], O’Neill et al. [34] und Mückley et al. [5] zeigen, bei einer zyklischen Testung mit gleichbleibender Belastung selbst über 250000 Zyklen nicht sichergestellt gewesen. Diese Art der ansteigenden Belastung hat sich bereits bei Untersuchungen am Femurkopf bewährt [27].
Als Versagenskriterium haben wir das Abwinkeln des Kalkaneus im Röntgenbild von 7° zur Nagelachse in Dorsalflexion festgelegt. Mit diesem radiologischen Parameter konnte vor allem die Rückfußverankerung beurteilt werden. Weiterhin konnten Aussagen über das Versagensmuster gemacht werden. Als Auslenkungsrichtung wurde die Dorsalflexion gewählt, da diese nach O’Neill et al. unmittelbar postoperativ der größten Belastung ausgesetzt ist [6,34]. Ein Winkel von 7° wurde nach Evaluierung der Vorversuche gewählt, da sich hier radiologisch eindeutige Zeichen einer destruktiven Verformung zeigten und so die Grenze zwischen reversibler elastischer Deformation und permanenter Deformation sicher überschritten war. Weiterhin entsprachen die 7° Verformung im Kalkaneus in etwa einer Deformation der gesamten Arthrodese um 10°, was in vorangegangenen Arbeiten als Versagenskriterium gewählt wurde [5,32,34].


Zusammenfassung


Interessenkonflikt: Nein


(23) Sterner W, Messow C, Schultz A: [Osteoporotic bone changes as the result of immobilization and their control by drugs]. Med Welt :1149-1153 (1975)


Paper p10

Development of a technique for cement augmentation of nailed tibiotalocalcaneal arthrodesis constructs

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A B S T R A C T

Background: Tibiotalocalcaneal arthrodesis with a retrograde nail is an established procedure. Many patients considered for this arthrodesis have poor bone stock, which may make it difficult to obtain construct stability. This study was undertaken to determine whether stability could be enhanced by the cement augmentation of the calcaneal locking screws.

Methods: A cannulated and perforated screw, and a technique for cement augmentation via this screw, were developed. Eight pairs of human cadaver bones were instrumented with a retrograde intramedullary device (Expert Hindfoot Arthrodesis Nail, Synthes AG, Solothurn, Switzerland). Within each pair, one specimen was randomized to have the nail interlocked in the calcaneus with two conventional screws; while the other specimen was similarly instrumented with the use of two cement-augmented screws. The bone mineral density was determined. In quasi-static tests, the neutral zone and the range of motion of the constructs were determined. Subsequently the specimens were tested in dorsiflexion/plantar flexion until failure occurred. The neutral zone and the range of motion of the constructs were determined every 200 cycles.

Findings: Augmentation resulted in significantly greater stiffness and a significantly smaller range of motion in the quasi-static dorsiflexion/plantar flexion test, and in a significantly smaller neutral zone in all quasi-static tests. With cyclic loading, the number of cycles to failure was significantly larger in the augmented group. In both groups, bone mineral density was significantly correlated with the number of cycles to failure. Two augmented screws broke.

Interpretation: Cement augmentation confers significant mechanical benefit in hindfoot arthrodesis and therefore can be used as a salvage procedure. Further development should be performed to validate the concept.

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1. Introduction

Tibiotalocalcaneal arthrodesis is used in the management of arthrosis affecting the ankle and the subtalar joint, and of hindfoot deformities that are refractory to other forms of treatment (Amirfeyz et al., 2008; Anderson et al., 2005; Boer et al., 2007; Chou et al., 2000; De Smet et al., 2003; Goebel et al., 2003; Hamnett et al., 2005; Klos et al., 2009a; Millett et al., 2002; Moore et al., 1995; Nagashima et al., 2005; Niinimäki et al., 2007). Most of the patients concerned have poor bone stock quality from a variety of causes. The literature

(De Smet et al., 2003; Goebel et al., 2003; Hamnett et al., 2005; Millett et al., 2002; Moore et al., 1995; Nagashima et al., 2005; Niinimäki et al., 2007) shows the average age of arthrodesis candidates to be 57 years, which is the time of life associated with an increased prevalence of generalized osteoporosis. Among the indications for arthrodesis are rheumatoid arthritis and Charcot arthropathy, which may cause local deterioration of bone quality (Frank and Gottwald, 2008; Herbst et al., 2004; Jirkovska et al., 2001). There is a comparatively high rate of such comorbid conditions as diabetes mellitus and renal impairment, which also adversely affect skeletal health (Raska and Broulik, 2005; Schwartz and Sellmeyer, 2007; Strotmeyer and Cauley, 2007). In addition, disuse (Sterner et al., 1975) and vascular problems (Laroche et al., 1994), which are not uncommon in this patient population, may cause local impairment of bone density.

Bone strength is crucial to sound implant fixation. In tibiotalocalcaneal arthrodesis, device fixation in the calcaneus is of prime

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importance: Most of the studies of tibiotalocalcaneal arthrodesis using a nail have reported an increased rate of subtalar fusion failure (De Smet et al., 2003; Nagashima et al., 2005; Elder et al., 2000; Frank and Gottwalt, 2008), distal screw breakage (Kile et al 1994) and cut-out in the calcaneus (Millett et al., 2002).

Latest-generation implants provide features such as posterior-to-anterior screw routing in the calcaneus (Nagashima et al., 2005; Niinimäki et al., 2007), angle-stable locking in the hindfoot (Mückley et al., 2008), or a spiral blade (Klos et al., 2009b), designed to enhance construct stability. With increasing device rigidity, bone stock quality is increasingly proving to be the limiting factor (Klos et al., 2009b).

The problem of how to achieve stability in poor host bone is also encountered in the management of proximal femur fractures. Research into cement augmentation techniques, with a view to enhancing the stability of the implant-bone interface, is ongoing in several countries and yielding promising results (Augat et al., 2002; Elder et al., 2000; Frihagen et al., 2007; Moore et al., 1997; von der Linden et al., 2006).

This biomechanical study was performed to establish whether cement augmentation of the calcaneal locking screws of a tibiotalocalcaneal arthrodesis nail could produce significantly better stability. For this study, a specially cannulated and perforated screw was developed, and a cement augmentation technique via these screws was devised.

2. Methods

Eight fresh frozen pairs of human cadaveric below-the-knee specimens were obtained. All donors agreed to the use of their body or parts of them for education and research. The specimens were radiographed to exclude prior bone pathology. The mean age at death of the donors (five females, three males) was 77.6 (range, 64 to 89) years. The specimens were stored at −20 °C. The bone mineral density was determined with a three-dimensional peripheral quantitative computerized tomography (Xtreme CT, Scanco Medical AG, Brützwil, Switzerland). As in the technique used by O’Neill et al. (2007), the soft tissues were removed, but the supporting ligamentous structures were left in place until the arthrodesis had been completed. The fibula was removed; the foot was amputated through the transverse tarsal (Chopart) joint; and the tibia was resected at a site 250 mm proximal to the ankle joint line. The articular surfaces were left intact.

2.1. Implants

The nail used was a 180 mm-long, 12 mm-diameter Titanium Cannulated Hindfoot Arthrodesis Nail (HAN, Synthes AG, Solothurn, Switzerland). Proximal interlocking, in the nail-tip region, was done with two 5 mm locking screws inserted in static mode. Distally, the nail was locked with a 5 mm-diameter talar screw. Locking in the calcaneus was done with one proximal non-angle-stable and one distal angle-stable screw (angle-stability is provided by the end cap), routed posterior to anterior. The external (major) diameter of all the calcaneal locking screws used was 6 mm.

The calcaneal screws intended for augmentation had been specifically developed for this study, in light of a prior finite-element study. The geometry and thread design of these titanium screws was based on the standard self-taping screws from the nail system with a diameter of 6 mm and a core diameter of 4.8 mm. The screws were cannulated over 62.5% of their length, and featured 1.4 mm-diameter holes at 8.5 mm centers, arranged in two orthogonal planes along the longitudinal screw axis (Fig. 1). The screw length was determined during implantation following the manufacturer’s instructions for conventional screws.

2.2. Implantation

The medullary canal was reamed to a diameter of 13 mm with use of a SynReam system (Synthes AG, Solothurn, Switzerland), and the intramedullary nail was retrogradely inserted. Within each pair of specimens, one specimen was randomized to interlocking of the nail in the calcaneus with a standard implantation (one angle-stable and one non-angle-stable conventional locking screw), while the other specimen received intracalcaneal nail locking with two cement-augmented screws, of which one was angle-stably locked in the calcaneus while the other one was non-angle-stable. The end caps required for angular stability were tightened with 5Nm, with the use of a torque wrench (MHH Engineering Co Ltd, Bramley, UK).

Following insertion, 3.5 ml of polymethylmethacrylate cement (Vertecem plus; Synthes AG, Solothurn, Switzerland) was injected in each of the screws to be augmented. The augmentation system used was a Vertecem Vertebroplasty System (Synthes AG, Solothurn, Switzerland), with a cannula custom-made for this study (Fig. 1). Cement mixing and delivery via the 1 ml syringe of the system were performed in strict conformity with the manufacturer’s instructions.

All the instrumentations were performed with radiographic monitoring, and were done by an experienced surgeon (the senior author).

2.3. Biomechanical testing

Biomechanical testing was based upon a protocol used in previous studies (Klos et al., 2009b; Mückley et al., 2007, 2008). The calcaneus and the proximal 150 mm of the remaining tibia were each potted with the use of a methylmethacrylate resin (SCS Beracyl; Suter Kunststoff AG, Jegenstorf, Switzerland) in an aluminum casing, after all protruding implant portions and the gap of the subtalar joint had been covered with a modeling compound to prevent bridging of the potting medium affecting the biomechanical properties. Testing was commenced as soon as the resin had cured (Figs. 2 and 3).

Measurements were performed on a biaxial test machine (MTS Bionix 858; MTS Systems Corporation, Eden Prairie, MN) equipped with a ±0.005 kN/100 ± 0.1 Nm load cell.

First, three quasi-static tests were performed, first in torsion, than in varus/valgus, and last in dorsiﬂexion/plantar ﬂexion, respectively. The specimens were loaded sinusoidally, within the elastic range, with ±5 Nm, at a rate of 0.1 Hz. After five conditioning cycles, the
following fifteen consecutive cycles were analyzed. In the varus/valgus and the dorsiflexion/plantar flexion tests, the moment was applied via an 80 mm-long lever (Fig. 2). In the torsion test, torque was applied directly from the torsion actuator of the test machine; in this test, an axial compressive preload of 5 N was applied. All tests were performed in load-control. Displacements, forces, and torques were acquired by the sensors of the machine at a rate of 64 Hz. The quasi-static tests were analyzed with use of criteria described by Wilke et al. (Wilke et al., 1998) for spinal implants: From the hysteresis loop, the range of motion and the neutral zone were determined. The range of motion describes the total range over which the specimen moves with maximal loading (in this case, ±5 Nm); the neutral zone describes the range over which the specimen moves essentially free of applied loading, and provides a measurement of the laxity of the construct.

Next, cyclic testing in dorsiflexion/plantar flexion was performed, starting at ±10 Nm and continuing at 0.05 N/cycle (a moment of 0.004 Nm) increments with a rate of 1 Hz until specimen failure occurred. Failure was defined as a change by ≥7° in the dorsiflexion angle between the nail and the calcaneus, or device breakage/bone fracture (Fig. 3). For analysis of angulation and device/bone brakage, radiographs in dorsiflexion were obtained with a mobile C-arm system (Arcadis Varic; Siemens, Erlangen, Germany), immediately prior to loading and thereafter at 200-cycle intervals at the maximum load of the cycle concerned. Also, the range of motion and the neutral zone were determined over the first 1000 cycles, at 200-cycle intervals.

Our null hypothesis was that cement augmentation of the calcaneal locking screws of a tibiotalocalcaneal arthrodesis nail can produce significantly better stability.

2.4. Statistical analysis

The data were analyzed with use of SPSS software (SPSS 14.0.2; SPSS Inc., Chicago, IL). The results were analyzed for normal distribution with the Shapiro–Wilk test. For the detection of significant differences between the groups in terms of the bone mineral density and the number of cycles to failure, a paired-samples t-test was used, while the Wilcoxon signed-rank test was used to detect significant differences in terms of the range of motion and the 

Fig. 2. Schematic showing the biomechanical test set-up for the dorsiflexion/plantar flexion tests A = aluminum casing holding the potted calcaneus; B = calcaneus; C = talus; D = tibia (free portion); E = potted proximal extremity of tibia; F = load transmission system with lever arm; G = image intensifier.

Fig. 3. Radiographs illustrating the assessment of the non-augmented (left) and the augmented (right) constructs during testing. A = aluminum casing, and lever arm for load transmission; B = methylmethacrylate resin; C = remainder of modeling compound; D = radiolucent line indicative of cut-out; E = injected cement. The dotted lines were used for the assessment of angular stability.
neutral zone. Where the data were found to be normally distributed, Pearson's correlation coefficient $R$ was determined for the correlation between the bone mineral density and the number of cycles to failure. Analysis of the range of motion and the neutral zone in the cyclic tests was performed with use of GLM repeated measures analysis of variance with a Greenhouse–Geisser epsilon adjustment. The bone mineral density was used as a covariate in the analysis. Significance was defined as $P<0.05$.

3. Results

3.1. Bone mineral density

The mean bone mineral density (in mg hydroxyapatite/cm$^3$) in the two groups was 105.2 (range, 2.0 to 172.9). In the non-augmented group, the mean bone mineral density (in mg hydroxyapatite/cm$^3$) was 107.4 (range, 2.0 to 160.6); in the augmented group, the mean value was 105.2 (range, 9.8 to 172.9). This difference was not significant ($P=0.69$, power: 0.065).

In both groups, the bone mineral density was significantly correlated with the number of cycles to failure (non-augmented group: $R=0.76$; $P=0.028$; augmented group: $R=0.77$; $P=0.026$).

3.2. Quasi-static tests

The augmented specimens were significantly stiffer in plantar flexion (non-augmented group: mean, 3.42 Nm/°; SEM, 0.59 Nm/°; SD, 1.66 Nm/°; augmented group: mean, 4.63 Nm/°; SEM, 0.79 Nm/°; SD, 2.23 Nm/°; $P=0.017$) and in dorsiflexion (non-augmented group: mean, 4.16 Nm/°; SEM, 0.60 Nm/°; SD, 1.69 Nm/°; augmented group: mean, 5.59 Nm/°; SEM, 0.69 Nm/°; SD, 1.95 Nm/°; $P=0.036$).

In the augmented group, the neutral zone was significantly smaller, in all loading modes, than in the non-augmented constructs (Table 1), whereas a significantly smaller range of motion was seen only with dorsiflexion/plantar flexion loading (Table 2).

3.3. Cyclic tests

The mean number of cycles to radiographically demonstrated failure was 6100 (SEM, 1118; SD, 3162) cycles in the non-augmented group, as compared with 7825 (SEM, 1256; SD, 3552) cycles in the augmented group. This difference (1725 cycles, 86.25 N, 6.9 Nm) was significantly smaller than in the non-augmented group ($P=0.036$). The average within pair difference for the number of cycles to failure was 38.5%.

The evaluation of the neutral zone and the range of motion at the start of the cyclic-testing part of the protocol showed the following results (Fig. 4):

In the augmented group, the neutral zone was significantly smaller than in the non-augmented group ($P=0.036$). The bone mineral density was seen to be a significant covariate ($P=0.001$) affecting the neutral zone.

In the augmented group, the range of motion was significantly smaller than in the non-augmented group ($P=0.024$). As with the neutral zone, the bone mineral density was a significant covariate ($P=0.002$).

During cyclic testing, there were two cases of augmented-screw breakage resulting in an immediate failure of the implantations. Breakage occurred at a mean of 8450 cycles (43.8 Nm). In one case, both screws broke at a distance of about 5 mm from the nail; in the other case, the angle-stable distal screw broke at a similar distance. In both cases, the fracture line went through the perforations in the screw. In the other cases the failure mode was a cut-out.

3.4. Cement distribution patterns

Cement distribution along the screw tracks was found to be non-uniform, but showed the same general pattern. Cement was extruded mainly at a distance from the nail, in the first one-third of the screw track. Closer to the nail, cement around the non-angle-stable screws was in some cases seen to flow retrogradely into the calcaneus, through the lumen of the nail.

4. Discussion

State-of-the-art intramedullary devices for tibiotalocalcaneal arthrodesis have enhanced the surgeon’s armamentarium for hindfoot reconstruction. However, many of the patients considered for tibiotalocalcaneal arthrodesis will have multiple comorbidities, Charcot arthropathy, generalized osteoporosis or local osteopenia (for instance from prolonged disuse), and achieving construct stability can be a major challenge (Anderson et al., 2005; Chou et al., 2000; Hammett et al., 2005; Herbst et al., 2004; Laroche et al., 1994). In a number of studies, intracalcaneal fixation has been shown to be an important factor affecting stability (Mann et al., 2001; Means et al., 2006; Mückley et al., 2008). Thus, Mann et al. (2001) and Means et al. (2006) concluded that the posterior-to-anterior routing of a calcaneal locking screw significantly enhances stability. Mückley et al. (2008) demonstrated the superiority of angle-stable over non-angle-stable intracalcaneal locking.

The present study was designed to develop and test an augmentation technique that would provide an additional option for the stabilization of a hindfoot arthrodesis, the principle being the reinforcement of the implant-bone interface to prevent device cut-out. Our study provided proof of the mechanical concept.

During the augmentation procedure, markedly more cement was extruded close to, as compared with further away from, the tip of the injection cannula. This observation tallied with the findings of prior studies (Gisep et al., 2006). We therefore think that the length of the screw cannulation (which, in this study, amounted to 62.5% of the total screw length) could be markedly reduced. This would ensure that screw strength would not be unduly compromised, and might prevent a potential devastating complication like screw breakage of the kind seen in two cases in the present study. Similarly, a shorter cannulated length could prevent cement run-off into the nail lumen, and reduce the volume of cement required for the procedure. We

### Table 1

Neutral zone (in degrees) of the non-augmented and the augmented constructs, in the quasi-static tests.

<table>
<thead>
<tr>
<th>Loading mode</th>
<th>Non-augmented* Mean</th>
<th>Non-augmented* SEM</th>
<th>Augmented* Mean</th>
<th>Augmented* SEM</th>
<th>$P$ value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>DF/FF</td>
<td>0.376</td>
<td>0.120</td>
<td>0.124</td>
<td>0.034</td>
<td>0.012</td>
</tr>
<tr>
<td>Var/Valg</td>
<td>1.324</td>
<td>0.545</td>
<td>0.466</td>
<td>0.189</td>
<td>0.025</td>
</tr>
<tr>
<td>Torsion</td>
<td>2.498</td>
<td>0.776</td>
<td>1.346</td>
<td>0.419</td>
<td>0.036</td>
</tr>
</tbody>
</table>

*The values are given as the mean and the standard error of the mean (SEM); a $P$ value of <0.05 indicates significance. DF/FF = dorsiflexion/plantar flexion; Var/Valg = varus/valgus.

### Table 2

Range of motion (in degrees) of the non-augmented and the augmented constructs, in the quasi-static tests.

<table>
<thead>
<tr>
<th>Loading mode</th>
<th>Non-augmented* Mean</th>
<th>Non-augmented* SEM</th>
<th>Augmented* Mean</th>
<th>Augmented* SEM</th>
<th>$P$ value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>DF/FF</td>
<td>1.493</td>
<td>0.304</td>
<td>1.102</td>
<td>0.198</td>
<td>0.036</td>
</tr>
<tr>
<td>Var/Valg</td>
<td>3.305</td>
<td>0.909</td>
<td>2.336</td>
<td>0.678</td>
<td>0.093</td>
</tr>
<tr>
<td>Torsion</td>
<td>7.033</td>
<td>1.013</td>
<td>5.938</td>
<td>0.905</td>
<td>0.093</td>
</tr>
</tbody>
</table>

*The values are given as the mean and the standard error of the mean (SEM); a $P$ value of <0.05 indicates significance. DF/FF = dorsiflexion/plantar flexion; Var/Valg = varus/valgus.
think that this study could provide the basis for screw-design optimization.

The volume of cement injected into the calcaneus was two lots of 3.5 ml each. Prior studies (Boner et al., 2009) suggest that this should not be associated with an undue risk of thermal bone necrosis, although larger volumes are likely to be unsafe. However, the cement has to be injected into a confined space; cement removal might be less than straightforward; and there may be an increased risk of infection as a result of a markedly enlarged foreign-body interface in a poorly vascularized space. The infection risk could conceivably be controlled by the use of antibiotic-containing cement. The actual cement volume required for reinforcement will need to be determined in further studies. In general, we feel that, for the reasons outlined above, our technique should be a salvage, rather than a standard, procedure. Clinical studies will need to be performed in order to establish whether the benefits seen in this biomechanical study can be translated into the clinical setting.

In common with other authors (Mückley et al., 2008; O’Neill et al., 2007; Alfahd et al., 2005; Chiodo et al., 2003; O’Neill et al., 2008), we left the joint surfaces intact. This was done in order to eliminate an additional variable, and to create a worst-case scenario of minimal intraarticular friction. The test set-up and the load levels used were similar to those employed in other biomechanical studies of tibiotalocalcaneal arthrodesis (Alfahd et al., 2005; Chiodo et al., 2003; Mückley et al., 2008; Santangelo et al., 2008).

The load magnitudes in the quasi-static tests were chosen in light of our experience and of the current literature (Alfahd et al., 2005; Mückley et al., 2008; Santangelo et al., 2008). The failure criterion chosen was radiographically detected and documented ≥ seven-degree displacement of the calcaneus from the longitudinal nail axis with dorsi flexion. This radiographic parameter allowed assessment especially of device fixation in the hindfoot, as well as a study of the failure pattern (Klos et al., 2009b; Windolf, et al., 2009a; Windolf et al., 2009b). Dorsiflexion was chosen since, according to O’Neill et al. (2008); (2007), this represents the predominant loading mode of the arthrodesis site during weight-bearing in the postoperative period. The size of the angle was adopted in light of prior studies (Klos et al., 2009b) which had shown displacement by seven degrees to provide clear and certain evidence of permanent, rather than of reversible elastic, deformation. Also, a seven-degree deformation in the calcaneus roughly corresponds to the ten-degree deformation of the entire arthrodesis construct that had been used as a failure criterion in other studies (Mückley et al., 2008; Chiodo et al., 2003; O’Neill et al., 2008).

Our investigation was subject to the limitations common to all biomechanical studies, which can reflect the actual in-vivo conditions only to a very limited extent. As well as the increasing bony union and the stabilizing action of the surrounding soft tissues that would be expected to occur in vivo and could not be taken into account. Another restriction of our study is the mean donor age of the tested specimens that was higher (77.6 years) than described in the literature (Frank and Gottwald, 2008; Herbst et al., 2004; Jirkovska et al., 2001). On the other hand we think that this kind of geriatric patients is the group that profits most from bone augmentation techniques. Furthermore a wide range of SD was seen that might be caused in part by the wide range of BMD within the specimens and the complexity of the investigated anatomical structures. This is why the results obtained cannot be translated directly into the clinical setting. Also, greater initial stability does not necessarily signify a better clinical outcome. However, less movement at the tibiotalocalcaneal arthrodesis site could conceivably result in faster and sounder bony union, and the greater load tolerance of the construct could allow earlier resumption of weight-bearing.

**Contributors**

The first author performed the implantation of the nails and the potting of the specimens, implemented the concept of this study, and wrote the paper.

The second and third authors helped with the implantations and the potting and performed the measurements.

Authors one, two and seven selected and provided the cadaveric specimens, performed the CT investigation of the bones, and dissected the bones.

Authors 3 and 6 programmed the testing machine and performed the statistical analysis.
Author 6 helped with the dissection, performed the BMD measurements, and made a major contribution to the writing of this paper. Author 5 supervised the implantations and the performance of this study, and also provided valuable advice. The last author conceived the idea for this study, monitored the implementation of the concept, supervised the implantations, and headed the team.

Authors 1, 4, 5 and 7 took care of the financing and cooperation with other Institutes.

All the authors took an active part in writing the paper, and agree with the statements made in this paper.

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Biomechanical in vitro assessment of screw augmentation in locked plating of proximal humerus fractures

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A B S T R A C T

Introduction: Proximal humerus fracture fixation can be difficult because of osteoporosis making it difficult to achieve stable implant anchorage in the weak bone stock even when using locking plates. This may cause implant failure requiring revision surgery. Cement augmentation has, in principle, been shown to improve stability. The aim of this study was to investigate whether augmentation of particular screws of a locking plate aimed at a region of low bone quality is effective in improving stability in a proximal humerus fracture model.

Materials and methods: Twelve paired human humerus specimens were included. Quantitative computed tomography was performed to determine bone mineral density (BMD). Local bone quality in the direction of the six proximal screws of a standard locking plate (PHILOS, Synthes) was assessed using mechanical means (DensiProbeSM). A three-part fracture model with a metaphyseal defect was simulated and fixed with the plate. Within each pair of humeri the two screws aimed at the region of the lowest bone quality according to the DensiProbeSM were augmented in a randomised manner. For augmentation, 0.5 ml of bone cement was injected in a screw with multiple outlets at its tip under fluoroscopic control. A cyclic varus-bending test with increasing upper load magnitude was performed until failure of the screw–bone fixation.

Results: The augmented group withstood significantly more load cycles. The correlation of BMD with load cycles until failure and BMD with paired difference in load cycles to failure showed that augmentation could compensate for a low BMD.

Discussion and conclusion: The results demonstrate that augmentation of screws in locked plating in a proximal humerus fracture model is effective in improving primary stability in a cyclic varus-bending test. The augmentation of two particular screws aimed at a region of low bone quality within the humeral head was almost as effective as four screws with twice the amount of bone cement. Screw augmentation combined with a knowledge of the local bone quality could be more effective in enhancing the primary stability of a proximal humerus locking plate because the effect of augmentation can be exploited more effectively limiting it to the degree required.

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Introduction

Fractures of the proximal humerus are a common injury and account for 5% of all fractures and 45% of humeral fractures. 1 The injury typically occurs in elderly patients and is associated with osteoporosis. 2,3 Options for surgical treatment are numerous, including anatomical reconstruction using extra- or intramedullary fixation techniques or hemiarthroplasty. 3–5 A major goal of head-preserving procedures is to achieve high primary stability, allowing early postoperative functional treatment. This is difficult to achieve in osteoporotic bone, which makes surgical treatment of the most complex fractures of the proximal humerus a challenge. 6 As in other anatomical regions, locking plates have successfully been introduced for the proximal humerus and clinical experience is rapidly growing. 7–10 Despite improved results, secondary fragment dislocation still occurs in up to 13% of
the patients. Though different reasons may apply, it is unlikely that all the problems associated with the treatment of osteoporotic proximal humerus fractures have been fully solved, such that sufficient primary stability cannot be obtained in some of these cases. In vitro augmentation of implants using bone cement was shown to enhance primary stability in the proximal femur. The in vitro insertion of 10 ml of calcium phosphate in the metaphyseal region in a proximal humerus fracture model using different fixation techniques was shown to significantly improve mechanical performance. The in vivo treatment of metaphyseal comminution in proximal humerus fractures again using calcium phosphate led to significantly less humeral head settling and screw penetration. However, these studies more or less injected the bone cement in an untargeted manner ignoring local bone quality within the humeral head. On the other hand, it is well known that there are local differences in the distribution of bone mineral density (BMD) within the humeral head. Accordingly, screws of a standard proximal humerus locking plate have been identified which aim at regions of low BMD. The aim of the present biomechanical in vitro study was to investigate whether the stability of locked plating in a proximal humerus fracture model could be effectively improved by targeted augmentation of these particular screws.

Materials and methods

Specimens

Six pairs (n = 12) of fresh frozen human cadaveric humeri free of all soft tissues were included (three females; three males; mean age 78.2 ± 8.5 years). A quantitative computed tomography (qCT) scan was performed (GE Lightspeed VCT 16, Milwaukee, WI, USA) to rule out relevant bony pathologies and to determine local BMD of the humeral heads. BMD was assessed using the method described by Krapfinger including a European Forearm Phantom (EFP) calibration (EFP Phantom, QRM GmbH, Mührendorf, Germany). Subsequently, the specimens were stored in double vacuum-sealed plastic bags at −20°C. Prior to testing, the specimens were thawed overnight at −4°C. Within each pair of specimens one sample was randomised for screw augmentation.

Fracture model and instrumentation

A three-part fracture model of the proximal humerus was simulated by a 10-mm horizontal gap just below the anatomical neck and a greater tuberosity osteotomy using an oscillating saw with a blade thickness of 0.4 mm (Synthes, Oberdorf, Switzerland; Fig. 1). Fragment fixation was performed using a standard locking plate (PHILOS, Synthes) by means of the standard instrumentation tools and following the manufacturer’s manual. In all the specimens the plate was attached to the humeral shaft using three bicortical locking screws. For fixation of the head fragment, locking screws were placed in the six most proximal plate holes following the direction as provided by the aiming block of the PHILOS plate. The length of the head screws was determined with a modified calliper, which allowed precise measurement of the distance between the plate holes and the curved proximal humerus joint surface along the direction defined by the drill sleeve. For the conventional (non-augmented) group, 6 mm was subtracted from the maximum measured length as recommended by the manufacturer. For the augmented screws, the length chosen was −10 mm of the maximum measured length.

The design of the screws to be augmented shows both an axial and three radial outlets at its tip, allowing injection of 0.5 ml of Traumacem V+ bone cement (Synthes) under fluoroscopic control (Fig. 1). The rationale for choosing the two screws to be augmented was based on the results of a previous study in which local bone quality along the course of the six head screws of the PHILOS plate as determined by the aiming block, was assessed. According to these data, screws in positions 4 and 5 for a right and the corresponding positions 3 and 6 for a left proximal humerus specimen representing the anteromedial or −inferior region of the humeral head were identified as aimed at the region of the lowest BMD (Fig. 2). The remaining screws in the augmented group were regular locking screws as in the conventional group.

Local determination of bone quality using mechanical torque

Prior to screw insertion, local bone quality in the area of the tip of six proximal screws of the PHILOS plate was assessed using mechanical torque as described previously. In this study the method correlated very well with the determination of BMD in the exact same volume of interest using high-resolution CT scans. The torque measurement tool (DensiProbe™, ARL, Davos, Switzerland) is shown in Fig. 3. The solid cylinder runs through a polyacetal copolymer (POM) holder that allows rotation of the solid cylinder with negligible friction. A calliper was introduced in the standard sleeves of the aiming block for the proximal screws of the PHILOS plate, and the distance between the flat surface of the sleeve and the humeral head surface (a) was recorded. A second custom-made measuring device was used to fix stoppers at predetermined distances both on the drill...
Thus, the gauging tip was fully in contact with undrilled cancellous bone at a 3-mm subchondral distance. After gently hammering the probe into the bone, the sensor (MECMESIN Torque Handsensor, UK; 10-N m range, accuracy 178 ± 0.032 N m at 1 N m) was attached to the DensiProbe via the bush connection. Next, the probe was rotated 120° clockwise and the peak torque recorded on the sensor display was documented as an indicator for local bone resistance.

**Biomechanical testing**

All the specimens of both groups (n = 6 augmented, n = 6 non-augmented) underwent a varus-bending test. For specimen fixation in the material testing machine, the specimens were shortened to a total length of 250 mm. Both the humeral head and the distal end were embedded in polymethylmethacrylate (PMMA) cement (Technovit 3040, Heraeus Kulzer, Wehrheim, Germany). Tests were conducted using a biaxial servo-hydraulic material testing machine (MTS, 858 MiniBionixII, Shakopee, MN, USA). An ultrasound-based three-dimensional (3D) motion analysis system (Winbiomechanics, Zebris, Isny, Germany) was used to directly measure the relative motion between the PHILOS plate and the humeral head without superimposed plate bending or torsion. Thus, the markers of the motion analysis system were mounted to the proximal part of the PHILOS plate and the lesser tuberosity of the specimens (Fig. 4).

For the bending test, the humeral shaft was fixed to the actuator of the servo-hydraulic testing machine. The humeral head was fixed in a device allowing rotation in the anterior–posterior plane and was mounted on a ball-bearing cushion to minimise shear forces (Fig. 4). Specimens were cyclically loaded with a constantly increasing upper load magnitude. The sinusoidal load started ranging from 15 N to 50 N and was applied at 0.25 Hz. The upper load magnitude was increased by 0.035 N after every load cycle; for example, after 1000 cycles loading ranged from 15 N to 85 N. Motion data after every 100 load cycles were captured, and elastic...
and plastic deformation in the varus angular tilting was recorded. Specimens were cyclically loaded until failure of the screw–bone fixation. Failure was defined as an increase of angular tilting in the varus of >0.5° within 100 load cycles at the lower load magnitude (constant 15 N).

Statistical analysis

The software package Statistical Package for the Social Sciences (SPSS) 18.0 (SPSS Inc., Chicago, IL, USA) was used to perform statistical analysis. Data were checked for normal distribution using the Shapiro–Wilks test. Comparison of the number of load cycles to failure between the two groups was obtained using a paired Student’s t-test. The correlation between the BMD values and the number of cycles to failure was analysed using the bivariate Pearson correlation. The level of significance was $p < 0.05$.

Results

All the results are presented as the mean value ± standard deviation (SD). Mean BMD was 68.29 mg cm$^{-3}$ which represents osteoporotic bone quality. The two groups did not significantly differ in BMD. All specimens failed, with loosening of the head, screws and subsequent varus collapse of the humeral head relative to the plate. On average, the augmented group withstood significantly more load cycles until failure (6900 ± 690 load cycles) compared to the non-augmented group (4600 ± 810 load cycles; $p = 0.01$). This corresponds to a total loading of 291.5 ± 24.2 and 211 ± 28.7 N for the augmented and non-augmented group, respectively. The correlation of BMD with load cycles until failure determined by the Pearson coefficient $R^2$ was 0.292 and 0.5755 for the augmented and non-augmented group, respectively (Fig. 5). The correlation of the paired difference in load cycles to failure and the mean BMD of the humeral head is shown in Fig. 6.

Determination of the local bone quality in the area of the tip of the six proximal screws using the DensiProbe confirmed previous results, with the anteromedial or -inferior region representing the area of the lowest BMD (data not shown). The correlation of the DensiProbe (mean of all the screws) with BMD determined by the Pearson coefficient $R^2$ was 0.481 for the whole sample. The correlation of the DensiProbe (mean of all the screws) with cycles until failure according to $R^2$ was 0.0803 for the augmented group and 0.0474 for the non-augmented group. When correlating the DensiProbe results for only the two augmented screws with cycles until failure, $R^2$ was 0.0624 for the augmented group and 0.0902 for the non-augmented group.

Evaluation of the DensiProbe for the different screws (mean of all the samples) with cycles until failure showed $R^2 = 0.4724$ for screw no. 6 (anteromedial region). For all the other screws, $R^2$ was <0.14.

Discussion

Locking plates have successfully been introduced for the surgical treatment of proximal humerus fractures, a typical injury of the elderly patient associated with osteoporosis. Though results have clearly improved, the literature still reports considerable rates of postoperative secondary displacement. Among other mechanisms of failure, the problem of achieving adequate primary stability in an osteoporotic bone stock frequently remains unsolved in these cases. One reason could be the local distribution of bone quality within the humeral head, that is, it remains unclear in what quality of bone screws of standard implants purchase. An approach to enhance the primary stability of implants in vitro is to augment them using bone cement. For the proximal humerus this was demonstrated in principle by inserting 10 ml of calcium phosphate cement in the metaphyseal and diaphyseal regions of a three-part proximal humerus fracture model. However, the local distribution of bone quality is not addressed with this technique. The purpose of the present study was to investigate the efficacy of cement augmentation of locked plating in consideration of the local distribution of bone quality within the humeral head.

Considering the effect of augmentation in general, the results are in accordance with the literature. As demonstrated previously, the augmented group withstood significantly more load cycles. In addition, the correlation between BMD and load cycles until failure for the two groups demonstrated that augmentation to a certain degree compensated for a low BMD. The recent study by Unger et al. showed a statistically significant improvement of the primary stability in a proximal humerus fracture model when augmenting the four most proximal screws of a PHILOS plate with 0.5 ml of PMMA each. By contrast, there are some fundamental differences in the design of the present study which could improve the efficacy of the method: Only two screws were augmented, using 0.5 ml of PMMA per screw, which led to a 50% improvement in the number of load cycles withstood. Using twice as many screws with the same amount of PMMA per screw in the study by Unger et al. led to an approximately 54% improvement in the load cycles withstood and thus marginally more. In our opinion, the main reason for this is the rationale which was used for choosing the screws to be augmented. They, like other authors, randomly chose the
anatomical location or number of screws to be augmented.\textsuperscript{6,18} By contrast, we determined the local bone quality along the course of the six proximal screws of the PHILOS plate as determined by the aiming block of the device.\textsuperscript{16} Using both high-resolution CT scans and mechanical torque, two screws aimed at the anteromedial or -inferior region of the humeral head were identified as aimed at the region of the lowest BMD.\textsuperscript{16} Augmenting these two screws was almost as effective as augmenting twice as many screws using twice as much PMMA.\textsuperscript{18}

Therefore, the major strength of the present study is the combination of the local determination of bone quality with targeted cement augmentation of particular screws which the previous identified as aiming at regions of low bone quality. Weak points of the study are, besides a small sample size, the typical ones of any proximal humerus fracture model, that is, realistic simulation of comminution and fragment displacement. Another critical aspect of the study are the potential negative biological side effects of cement augmentation close to the joint cartilage, which were not a subject of the present study and therefore no conclusions can be drawn.\textsuperscript{29–31} In addition to the interaction of bone cement being injected close to cartilage, the optimum amount should be an aspect of future research. Considering the DensiProbe\textsuperscript{16} clinical use from a technical point of view is possible since the system is adapted to a standard locking plate. Therefore, as a next step an in vivo study should be performed to clarify if the system provides reliable and reproducible results.

With respect to the clinical application the results of the present study emphasise the beneficial mechanical aspects of \textit{in vitro} cement augmentation. In addition, the authors consider a knowledge of local bone quality as provided by the DensiProbe\textsuperscript{16} of great potential because it can help to be more effective in augmenting, which could mean a reduction of valuable OR time and potential negative side effects of inserting bone cement (extravasation, heat necrosis and disturbance of subchondral blood supply) due to a reduced amount without fundamentally limiting the stability. The DensiProbe\textsuperscript{16} together with cement augmentation could therefore be effective to perform more ‘customised’ procedures helping to improve the outcome of surgical treatment of osteoporotic proximal humerus fractures in the future.

Conclusion

In the present study, cement augmentation in a proximal humerus fracture model led to a significant improvement in the primary stability. Two screws aimed at a region of low bone quality were augmented, which was almost as effective as augmenting twice as many screws in a previous study. The intra-operative knowledge of local bone quality could therefore be helpful in being more effective in exploiting the positive mechanical effects of cement augmentation.

Conflict of interest

The authors are not compensated and there are no other institutional subsidies, corporate affiliations, or funding sources supporting this work unless clearly documented and disclosed.

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References


Potential of polymethylmethacrylate cement-augmented helical proximal femoral nail antirotation blades to improve implant stability—A biomechanical investigation in human cadaveric femoral heads

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BACKGROUND: Cement augmentation may improve fixation stability and reduce cut-out rate in the treatment of intertrochanteric hip fractures. The aim of this study was to compare the number of cycles to failure of polymethylmethacrylate (PMMA)-augmented helical blades with nonaugmented ones in human cadaveric femoral heads.

METHODS: Six pairs of cadaveric femoral heads were instrumented with a perforated proximal femoral nail antirotation blade. Within each pair, one blade was augmented using 3 mL of PMMA. All specimens underwent cyclic axial loading under physiologic conditions. Starting at 1,000 N, the load was monotonically increased by 0.1 N/cycle until construct failure occurred. To monitor the migration of the blade, anteroposterior radiographs were taken at 250 cycle increments. Nonparametric test statistics were done to calculate correlations and identify differences between study groups.

RESULTS: Inducing failure required a significantly higher number of cycles in the augmented group \( (p = 0.028) \). Bone mineral density was significantly related with the number of cycles to failure in nonaugmented specimens \( (p < 0.001, R^2 = 0.97) \), but not in the augmented group \( (p = 0.91, R^2 = 0.34) \).

CONCLUSION: Implant augmentation with small amounts of PMMA enhances the cut-out resistance in proximal femoral fractures. Especially in osteoporotic bone, the procedure may improve patient care. (J Trauma. 2012;72: E54–E59. Copyright © 2012 by Lippincott Williams & Wilkins)

KEY WORDS: Intertrochanteric hip fracture; cut out; helical blade; cement augmentation; cadaveric study.

Recently developed intramedullary implants with new features are increasingly used in the treatment of intertrochanteric hip fractures.\(^1,2\) With the introduction of helical blade designs for improved anchorage in the femoral head, the incidence of cephalic implant cut out has dropped from \(~12\%)\(^3\) to \(3.6\%).\(^4\) However, in the light of the known demographic pressure and the aging of the population, optimizing fracture fixation remains a priority. Particularly in osteoporotic bone, providing confident and reliable fracture treatment could lead to earlier load bearing and functional recovery with the potential to reduce morbidity and even mortality. The mechanical competence of osteosynthesis depends on a number of factors. In addition to surgery-related issues, such as insufficient reduction or suboptimal implant positioning,\(^5,6\) bone quality would also seem to be critically important.\(^8\) In older individuals, bone quality tends to be compromised by osteoporosis, a systemic skeletal disease that continues to become more prevalent but also continues to be underestimated and undertreated.\(^9\) Cement augmentation of cephalic hip implants may enhance the implant anchorage, as shown in biomechanical studies.\(^10,11\) The proximal femoral nail antitrotation (PFNA; Synthes GmbH, Bettlach, Switzerland) was adapted for additional bone cement application to improve mechanical competence. The PFNA blade is laterally perforated along its axis to enable controlled cement injection through the cannulation of the implant into the cancellous bone structure. Augmentation is performed using a new acrylic cement formulation with medium to high viscosity. The technique allows the surgeon to decide for or against cement augmentation after the implant has been inserted. Until now, we are not able to perform an intraoperative quantitative assessment of the bone quality, but systems that will enable us to perform an intraoperative mechanical assessment of local bone strength are under development (Den- siProbe AO Research Institute, Davos, Switzerland). The purpose of this in vitro study was to analyze the biomechanical potential of a newly proposed PFNA cement augmentation concept in osteoporotic human specimens.
MATERIALS AND METHODS

Six pairs of fresh frozen (-20°C) human cadaveric proximal femurs with low bone density were used in this study, selected out of 15 pairs of femurs from female donors above the age of 80 years according to bone mineral density (BMD). BMD was measured by peripheral quantitative computed tomography (pQCT) using an Xtreme-CT (SCANCO Medical AG, Bassersdorf, Switzerland). A cylindrical area of 20 mm diameter and 30 mm length in the center of the femoral head was evaluated, corresponding to the target location of the helical blade and cement cloud. The six paired samples with the lowest BMD values were included in the study. One femur of each pair was randomly assigned to conventional helical blade fixation, whereas the contralateral one was treated with a cement-augmented helical blade.

The instrumentation was performed pairwise by an experienced surgeon. Each femur was sawed 50 mm distal to the articular surface, in a plane orthogonal to the planned implant axis. To place a guidewire in the center of the femoral head, a custom-made jig was used (Fig. 1). The guidewire was inserted to a depth of 40 mm to avoid perforation of the femoral head. Perforated PFNA blades (PFNA Blade, perforated, length 100 mm, 04.027.035S; Synthes GmbH, Oberdorf, Switzerland; Fig. 2) were inserted over this K-wire without predrilling to a depth of 38 mm. Hence, a 12 mm distance was left between the tip of the implant and the apex of the femur corresponding to a tip-apex distance of 24 mm according to the definition of Baumgartner et al. Subsequently, the guidewire was removed. In the augmented group, a side opening disposable cannula (Traumacem Needle Kit, Ø 3.3 mm cannula with side opening, 03.702.120S; Synthes GmbH; Fig. 2) was filled with polymethylmethacrylate (PMMA) bone cement (Vertecem V+, LOT 09CA53010; Synthes GmbH) with 3 mL syringes (Viscosafe Injection Kit, 07.702.210; Synthes GmbH) and inserted into the cannulation of the blade to the full depth. Augmentation of the implant with 3 mL of bone cement was performed in a standardized manner with the plunger provided with the cannula system (Traumacem Needle Kit, Ø 3.3 mm Cannula with side opening, 03.702.120S; Synthes GmbH); 1 mL and 0.5 mL etched markings on the plunger provided information on the amount of injected cement. After injection of 1 mL of PMMA through the perforations of the blade into the cranial side of the femoral head, the cannula was turned 180°, allowing caudally directed injection of another 1 mL. Subsequently, the cannula was withdrawn over 10 mm, and the same procedure was repeated by injecting 0.5 mL of PMMA twice.

Mechanical testing was conducted according to the model described by Sommers et al. (Fig. 3), simulating an unstable intertrochanteric fracture with a lack of posteromedial support and load sharing at the fracture gap. Implant...
blade shafts were rigidly mounted to a base fixture at 149° to the vertical plane. This setting reflects a 130° femoral neck angle, a 16° resultant joint load vector to the vertical, and 3° offset of the femoral shaft axis from the sagittal plane. The femoral heads were mounted on a polymer back plate that rested on two cylindrical rollers, allowing for varus collapse of the head and simulating the characteristics of a reduced unstable intertrochanteric fracture. The blade was free to slide, mimicking full implant dynamic. Testing was performed on a MTS Mini Bionix II 858 hydraulic test system (MTS Systems Corp., Eden Prairie, MN) equipped with a 4 kN load cell. To simulate an alternating load during walking, a loading trajectory resulting from in vivo measurements in the human hip was transferred to the femoral head.14 Starting at 1,000 N, the peak load was monotonically increased by 0.1 N/cycle, whereas the load valley of the trajectory was maintained at 100 N.15 Cyclic testing was performed at 2 Hz and was stopped when the displacement of the machine actuator exceeded 10 mm. This value provoked a distinct damage at the bone-implant interface in all cases allowing meaningful retrospective data evaluation.

Data acquisition was performed by radiographic imaging using an image intensifier (Siemens Arcadic Varic, Siemens Medical Solutions AG, Munich, Germany). Anteroposterior radiographs were taken every 250 cycles at the minimum load to monitor the movement of the head with respect to the blade. The position of the image intensifier was maintained constant throughout the experiment. The varus rotation of the femoral head with respect to the initial X-ray was determined from the radiographs by means of image processing algorithms (Matlab, Mathworks Inc., Natick, MA). A varus collapse of 2°, indicative for loosening of the helical blade, was defined as the point of failure. The number of test cycles to failure was identified for all specimens. After assessing data distribution (Shapiro-Wilk test), paired nonparametric test statistics (Wilcoxon signed-rank test) were done to identify differences between groups regarding cycles to failure and BMD. Spearman’s correlation coefficient $R^2$ was calculated for cycles to failure and BMD for both groups. The significance level was set $\alpha = 0.05$.

**RESULTS**

BMD of the six bone pairs was 142 mgHA/cm$^3$ on average with a standard deviation (SD) of 35. No statistical difference ($p = 0.35$) was found for BMD between groups (nonaugmented: 145 mgHA/cm$^3$ [SD, 42]; augmented: 138 mgHA/cm$^3$ [SD, 30]).

The augmented specimens had to be subjected to a significantly higher number of cycles to induce failure ($p = 0.028$). The mean number of cycles to failure was 22,708 (SD, 4,411) for the augmented and 15,042 (SD, 7,226) for the nonaugmented group, respectively (Fig. 4). All constructs failed by implant cut out, resulting in a varus-type collapse of the femoral head (Fig. 5). No implant failures were observed during the tests.

The relation between BMD and number of cycles to failure is shown in Figure 6 for both groups. A significant correlation was observed between BMD and the number of cycles to failure for nonaugmented specimens ($p < 0.001$, $R^2 = 0.97$). No correlation was found in the augmented group ($p = 0.91$, $R^2 = 0.34$). A significant correlation was observed between BMD and the percentage increase in cycles to failure because of augmentation ($p < 0.001$, $R^2 = 0.99$, nonparametric test). The impact of cement augmentation was inversely related with BMD (Fig. 7).
DISCUSSION

The aim of this study was to compare PMMA-augmented helical blades with nonaugmented controls in human cadaveric femoral heads. A new augmentation-based implant-set and the corresponding procedure for PFNA were evaluated in a laboratory environment. The results confirmed that even with small amounts of bone cement (in every augmented specimen 3 mL of PMMA was injected), augmentation significantly improves the implant anchorage in bone of low quality. In the context of the loading protocol, the constructs, on average, sustained 51% more load cycles when cement augmentation had been performed. In augmented specimens, no correlation was observed between BMD and cycles to failure, supporting the concept that augmentation rules out the impact of low bone quality and hence reduces the impact of osteoporosis on the implant purchase. However, the effect of augmentation is reduced with increasing bone quality, suggesting that PMMA augmentation is primarily useful in osteoporotic bone.

Translating the high-resolution peripheral quantitative CT measurements to a clinical context needs to be performed with caution, because dual energy X-ray absorptiometry is the predominant method to diagnose osteoporosis. The fact that we used samples from women over the age of 80 years—the segment of the population most at risk of osteoporotic fractures—further adds to the clinical relevance of our findings. Other authors measured a representative population of 174 cadaveric femora (median donor age, 87 years) with CT and reported bone mineral densities corresponding to 90 mgHA/cm^3 to 290 mgHA/cm^3. Hence, our data ranging between 98 mgHA/cm^3 and 220 mgHA/cm^3 suggest that our samples were representative of the overall elderly population.

Support for potential clinical benefits of implant augmentation comes from both biomechanical and clinical studies. A significant increase in the initial fixation stability of a modified and augmented hip screw compared with a conventional one has been demonstrated in an intertrochantric fracture model. In agreement with our findings, the most improvement in the context of the lowest bone quality was reported. Another biomechanical study provided evidence for the benefit of hip screw augmentation under cyclic loading, with significantly smaller head displacements and lower failure rates in augmented specimens. In a clinical study, a significantly lower complication rate in intertrochantric fracture patients treated with cement augmentation was reported.

Despite supportive evidence, implant augmentation has not achieved a clinical breakthrough yet. Reasons for the rather restrained acceptance of the concept in the medical community may be manifold. One explanation is that, up to now, a standardized technique and a dedicated implant set were missing. In this article, we present a procedure for PFNA, which allows controlled injection of bone cement. Standard instrumentation can be performed with the known biomechanical advantages of blade implants. The lateral perforations of the modified blade implant represent a potential weak point of the implant. Standardized material testing of the implants, as performed by the manufacturer in beforehand, revealed no increased risk for implant failure because of the perforations. Furthermore, our tests did not reflect any failure of the implant itself. If required, the anchorage may be further enhanced by additional cement augmentation. In our study, this was done according to a defined protocol. Compared with previously reported augmentation techniques, possible devastating complications can be avoided by including careful adaptations to this protocol, of which avoidance of femoral head perforation, the use of a limited amount of PMMA, and localization of the PMMA around the implant are the most important.

In the current clinical workflow, feedback during surgery is essentially based on subjective judgment by the surgeon. Most hip fracture patients do not undergo dual energy X-ray absorptiometry or CT measurement. However, to prevent unnecessary cement injection, a quantitative assessment of the bone quality might be useful, because cement augmentation seems to be most effective in osteoporotic bone. Mechanical assessment of local bone strength might be
an alternative. In fact, in a number of biomechanical experiments, measuring the breakaway torque of the local trabecular structure (DensiProbe AO Research Institute) during surgery has been proven to reliably predict implant cut out at different anatomic regions. Application of this concept to the hip is currently investigated in a clinical multicenter trial and may ultimately be included in the PFNA implantation set as a next step.

When using cement injection, extravasation of nonbiodegradable bone cement into the hip joint might have devastating consequences. A perforation of the K-wire through the femoral head should therefore be avoided. In cadaver experiments and in in vivo trials, preserved cortical and cartilage layers were verified by injection of Iopamid contrast agent (Ultravist 300; Schering AG, Zürich, Switzerland) before cement application. When leakage of the contrast agent is identified by radiography, augmentation should be strictly avoided. One strategy to reduce the risk of cement leakage is to use a new type of PMMA cement with a medium to high viscosity. In our cadaver experiments, it seemed that the required injection pressure increased with increasing BMD. In fact, in some of our pilot specimens with higher bone density values, it was not even possible to manually inject cement into the bone structure. In some experiments, we recognized a scattered, uneven distribution of the PMMA along the blade axis despite a standardized augmentation technique (Fig. 5), with PMMA accumulating at the tip or at the base of the helical blade or at the cranial or caudal site, respectively. In addition to inhomogeneities of the bone structure, cancellous bone compaction as a result of implant insertion might impede or redirect the cement flow toward a certain region. However, the relevance of these issues from a clinical perspective remains to be clarified. Nevertheless, from a biomechanical perspective, it would seem that the cement should be concentrated at the implant tip and that radiographic monitoring of cement distribution is recommended. Baumgaertner et al. already expressed the importance of the tip-apex distance as key factor for a successful component outcome. Mechanically, reducing the distance between implant tip and apex reduces the lever arm of the hip joint contact force and hence diminishes the stresses in the bone structure. Accentuated presence of bone cement at the tip might therefore be beneficial from a biomechanical perspective. The individual roles of several key factors, such as cement location, amount of cement, tip-apex distance, with regard to the implant anchorage is still unclear and will be the subject of future experiments.

Potential drawbacks of PMMA augmentation such as cement leakage, fat emboli, toxicity, thermal effects, and devascularization are directly related to cement volume and distribution. Contrary to studies performed by pioneers in PMMA application for the treatment of unstable intertrochanteric hip fractures, we used comparatively small amounts of bone cement (3 mL) to minimize impact on the biological environment. The risks of cement leakage and fat emboli have been evaluated in vertebroplasty related studies, where in an extreme case of multiple level augmentation total cement volumes of up to 25 mL have been advocated as safe, but this should also be evaluated in the hip joint. In addition to cement volume, heat generation may have safety implications as well. One of the concerns with heat generation because of exothermic polymerization is osteocyte necrosis. According to a previously performed ex vivo study, cement volume may not affect bone sensitivity to thermal destruction. Finally, it should be noted that chondrocytes might be more sensitive to the deleterious effects of PMMA than osteocytes. Therefore, any subchondral localization of bone cement should be avoided. The absence of temperature monitoring at the surface of the femoral head during the application of PMMA, can be considered as a first limitation of this study. Besides this, some other limitations need to be mentioned. First of all, only one mode of failure (varus collapse and cut out of the helical blade) was tested, whereas other modes of failure like backing out of the helical blade and nonsliding of the system have been mentioned in clinics. Second, only uniaxial loading was tested, whereas multiaxial loading, more suggestive to normal gait, was not tested. In our experiments, a suboptimal implant position was chosen as represented by a rather large tip-apex distance (24 mm according to Baumgaertner et al.). This configuration created a worst case scenario and provoked clinical failure even in specimens with healthy bone stock. However, clinically a reduced tip-apex distance is recommended.

With regard to implant removal, our tests in the laboratory did not reveal any difficulties to withdraw the blade from the cement volume. A layer of fat and bone marrow between implant and cement might prevent bonding of the materials. In the unlikely event of a revision osteosynthesis, where arthroplasty would normally be the operation of choice, it was already suggested to power drill and tap PMMA cement.

Some of the above-mentioned risks and dangers are related to the nature of acrylic-based biomaterials. Biodegradable bone cements, e.g., those based on calcium phosphates, are upcoming. Possible advantages are disintegration of leaked cement, the absence of an exothermic reaction, and the feasibility of revision operations. Nevertheless, inferior biomechanical properties disqualify currently available biodegradable alternatives for the indented use. Moreover, their disappearance over time because of resorption questions the application in old and frail patients in whom avoidance of fixation failure and refracturing are of utmost importance.

CONCLUSION

This ex vivo study shows that implant augmentation with small amounts of bone cement significantly enhances the cut-out resistance in proximal femur fractures treated with a modified PFNA. The procedure is primarily indicated for osteoporotic bone and seems to be a valuable treatment option with clinical benefits in the elderly that seem to outweigh any possible risks associated with implant augmentation.

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DISCLOSURE

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REFERENCES

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Biomechanical evaluation of bone-cement augmented Proximal Femoral Nail Antirotation blades in a polyurethane foam model with low density

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ABSTRACT

Background: Helically shaped cephalic implants have proven their benefit to provide an improved stabilization of unstable hip fractures. However, cut out ratios up to 3.6% still occur. This in vitro study evaluated the biomechanical performance of a novel cement augmentation technique of the Proximal Femoral Nail Antirotation in surrogate femora.

Methods: Four study groups were formed out of 24 polyurethane foam specimens with low density. Proximal Femoral Nail Antirotation blades were implanted, either non-augmented, or augmented using 3 ml of injectable Polyethylmethacrylate bone-cement. The influence of implant mal-positioning was investigated by placing the blade either centered in the femoral head or off-centric in an anteroposterior direction. All specimens underwent cyclic loading under physiological conditions. Starting at 1000 N, the load was monotonically increased by 0.1 N/cycle until construct failure. Movement of the head was identified by means of optical motion tracking. Non-parametric test statistics were carried out on the cycles to failure, to compare between study groups.

Findings: Compared to control samples; augmented samples showed a significantly increased number of cycles to failure (P = 0.012). In the groups with centric position of the Proximal Femoral Nail Antirotation blade, cement augmentation led to an increase in loading cycles of 225%. In the groups with off-centric positioning of the blade, this difference was even more accentuated (933%).

Interpretation: Cement augmentation of the Proximal Femoral Nail Antirotation blade with small amounts of bone-cement for treatment of osteoporotic hip fractures clearly enhances fixation stability and carries high potential for clinical application.

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1. Introduction

Among fragility fractures, hip fractures constitute the most dramatic complication of osteoporosis and a major public health concern. From a clinical perspective, the major concern is the associated morbidity and mortality. Up to 25% of fragility-related hip fracture patients die in the year following their fracture and of those who do survive, again some 20% will have to be institutionalized because of the fracture and its clinical consequences (Block and Stubbs, 1997; Boonen et al., 2004; Cauley et al., 2000; Ioannidis et al., 2009; Shi et al., 2009). Because of the aging of the population, the incidence and costs related to hip fractures will continue to increase exponentially. By 2025, there will be an estimated more than three million annual incident fractures in the United States, creating direct medical costs of $25 billion (Burge et al., 2007). Despite new developments in the management of age-related osteoporosis, a lack of awareness continues to contribute to underdiagnosis and undertreatment of the disease (Boonen et al., 2008). In addition to surgeon-dependent factors like quality of reduction and correct positioning of the implant, bone quality plays a major role in the occurrence of fixation failure (Barrios et al., 1993; Baumgaertner and Solberg, 1997; Baumgaertner et al., 1995). Especially cut out, a failure mechanism characterized by migration of the implant through the cancellous bone of the femoral head, is significantly related to the bone mineral density of the proximal femur (Leichter et al., 1982; Swiontkowski et al., 1987). Cut out ratios up to 12.6% are reported in literature when using screw-based fixation types like the Dynamic Hip Screw (DHS), Gammanail or Proximal Femoral Nail (PFN) for the treatment of unstable intertrochanteric fractures (Al Yassari et al., 2002; Boldin et al., 2003; Davis
et al., 1990; Gadgone and Salphale, 2007; Schipper et al., 2004; Simmermacher et al., 1999). Helical and spiral blade concepts have been proven to biomechanically improve resistance to cut out (Windolf et al., 2009a, 2009b). However, cut out ratios of the Proximal Femoral Nail Antitrotation (PFNA) of up to 3.6% are still seen in clinics (Mereddy et al., 2009; Simmermacher et al., 1999; Takigami et al., 2008). The application of bone-cement based on for example, polymethylmethacrylate (PMMA) could potentially further reduce the risk of cut out in severe osteoporotic cases. Biomechanically, a clear benefit of cement augmentation has already been demonstrated as exemplified by dynamic hip screw instrumentations placing the implant into an afose-injected cement volume (Kramer et al., 2000; von der Linden et al., 2006). Improved resistance to cut out is believed to relate mainly to an increase in implant surface with reduced stress on the trabecular structure. Clinically, the first attempts of implant augmentation with promising outcome were reported back in 1985 (Bartucci et al., 1985). Surprisingly however, the technique never became clinical routine. This is most probably because of the concerns in the medical community regarding interference with fracture healing due to excessive cement application and the presence of cement at the fracture site, the possible damage to periostal blood supply leading to femoral head necrosis, leakage of PMMA into the hip joint and the difficulties regarding implant removal (Augat et al., 2002; Bartucci et al., 1985; Eriksson et al., 2002; Heini et al., 2004; von der Linden et al., 2006). Some of these objections however have already been dispensed: nonunion can be avoided by keeping the cement to the proximal fragment and out of the fracture site (Bartucci et al., 1985). Furthermore newly designed implants which allow for augmentation through the implant, will prevent cement leakage into the hip joint or into the fracture area (Augat et al., 2002; von der Linden et al., 2006). Finally, thermal necrosis can be avoided by the use of limited amounts of PMMA (not more than 3 ml) (Boner et al., 2009). By changing the properties of the PMMA and making it more viscous, the risk of cement leakage can even be further mini-
mized (Rüger and Schmoelz, 2009).

In the current study, perforated PFNA-blades were augmented with 3 ml of an injectable medium to high viscosity PMMA cement. The cannulation of the implant and additional perforations allow for injection of the cement into the surrounding bone tissue subsequent to implant insertion. Hence, a decision in favor or against cement augmentation can be taken intra-operatively after the implant has been placed. The aim of our study was to biomechanically compare cut out resistance and rotational stability under cyclic loading of PMMA augmented PFNA-blades with non-augmented instrumenta-
tion in surrogate femoral heads. In order to be able to provoke failures, a suboptimal implant positioning was chosen in two ways. First of all, in all study groups, a tip–apex distance of 24 mm was chosen. According to the literature, this rather large tip–apex distance would make the specimen more prone to cut-out (Baumgaertner et al., 1995). Secondly, an off center position of the helical blade would create a moment arm, making the construct rotationally unstable.

2. Methods

2.1. Specimens and instrumentation

A total of 24 surrogate specimens with defined geometry were manufactured of cellular polyurethane foam (10 pcf, 1522–10, Pacific Research Inc., Malmö, Sweden). This closed cell foam represents a standardized and uniform material with properties in the range of human cancellous bone. A density of 10 pcf (pounds per cubic foot, 160.2 kg/m³) was chosen to mimic an osteopenic bone structure (ASTM International, 2001). Four study-groups (augmented/non-augmented with centered or off-centered implant position) were formed, each comprising 6 samples (Table 1).

The foam specimens (length 50 mm, width 38 mm, height 50 mm, Fig. 1a) were confined to a custom-made polymer shell (diameter 56 mm) mimicking the cortex of the femoral head for subsequent load introduction. With the aid of a special jig, a 3.5-mm guide-wire was inserted into the foam either centered (groups 1 and 2) or with a 7 mm anter-posterior offset (groups 3 and 4) generating a moment toward negative pitch of the blade under physiological loading conditions (Fig. 1b). Standard PFNA-blades (length 100 mm, Synthes GmbH, Bettlach, Switzerland) were inserted over the guide-wire without predrilling to a depth of 38 mm, yielding a 12 mm distance between the implant tip and the apex of the foam (Fig. 1c). For the augmented groups 2 and 4 modified PFNA-blades (length 100 mm, Synthes GmbH, Bettlach, Switzerland) with 12 lateral perforations were used (Fig. 2). To inject the bone-cement, the guide-wire was removed and a side opening cannula (Vertebroplasty Needle Kit, 8 Ga, Articlenumber: 03.702.216S, Synthes GmbH, Oberdorf, Switzerland, Fig. 2) was inserted into the cannulation of the implant to the full depth. The side opening at the tip of the cannula was enlarged to a dimension of 3×12 mm. Injection of 3 ml PMMA bone-cement (Vertecem V+, Synthes GmbH, Oberdorf, Switzerland) was done in a standardized manner: after mixing of the components, the cement was filled into 3.0 and 1.0 ml syringes (Viscosafe Injection Kit, Articlenumber: 07.702.210, Synthes GmbH, Oberdorf, Switzerland) (Boger and Wheeler, submitted for publication). First of all, the cannula was prefilled with 3.0 ml of PMMA. Subsequently, 1.0 ml of PMMA was injected through the perforations of the blade into the foam toward cranial. After turning the cannula by 180°, another 1.0 ml was injected. Finally, the cannula was withdrawn by 10 mm and the procedure was repeated injecting 0.5 ml cement toward cranial and 0.5 ml toward caudal.

2.2. Mechanical testing

Mechanical testing was conducted according to the model described by Sommers et al. simulating an unstable intertrochanteric fracture with lack of postero-medial support and load sharing at the fracture gap (Sommers et al., 2004). Implant shafts were rigidly mounted to a base fixture at 149° to the horizontal plane. This setting reflected a 130° femoral neck angle, a 16° resultant joint load vector to the vertical plus 3° offset of the femoral shaft axis from the sagittal plane (Fig. 3a and b). The femoral surrogates were confined in a

![Fig. 1](image-url)
plastic shell to simulate the characteristics of a reduced unstable intertrochanteric fracture. A polymer back plate rested on two cylindrical rollers allowing the head to collapse into varus. The implant was free to slide mimicking full implant dynamic. Testing was performed on an MTS Mini Bionix II 858 hydraulic test system (MTS Systems Corp., Eden Prairie, USA) equipped with a 4 kN load cell. In order to simulate an alternating load during walking, a loading trajectory measured in vivo in the human hip was transferred to the femoral head. The curve was provided by Bergmann et al. (2001). Starting at 1000 N the load was monotonically increased by 0.1 N/cycle until failure of the construct according to the protocol of Windolf et al. (2009a, 2009b). The load-valley was maintained at 100 N throughout the test. Cyclic testing was performed at 2 Hz. Testing was stopped when the crosshead displacement exceeded 7 mm.

2.3. Data acquisition and evaluation

Using an optical 3D motion tracking system with five ProReflex MCU digital cameras (Qualisys AB, Gothenburg, Sweden) the motion of the surrogate femoral head in terms of varus rotation and rotation around the implant axis was evaluated throughout the experiment. A reflective marker set was attached to the plastic shell (Fig. 3b).
Additionally, a set of markers was attached to the shaft of the PFNA-blade in order to measure implant migration. For statistical analysis, failure criteria were set to 5° varus collapse and 10° rotation about the blade axis (Fig. 3c and d). Blade migration was defined as displacement of the implant tip greater than 1 mm. Number of cycles until failure at unloading condition (plastic deformation) was determined for each failure criterion. After checking the data for normal distribution (Shapiro–Wilk test), non-parametric test statistics were carried out. Multiple Mann–Whitney-U tests were performed on the cycles until failure for pairwise comparisons between study-groups. P-values were corrected according to Bonferroni. Significance level was set to \( \alpha = 0.05 \).

3. Results

Compared to control samples, augmented samples showed an increased number of cycles to failure. The samples of the non-augmented groups 1 and 3 failed by cut out of the implant, resulting in a varus collapse of the femoral head. In the presence of augmentation, the cement was split into a cranial and a caudal segment (Fig. 4). No severe damage of the implants was observed during the tests. For centric position of the PFNA-blade, the number of cycles to 5° varus rotation of the head was mean 8317 (SD 1205) for the non-augmented group (1) compared to mean 27,025 (SD 3077) for the augmented group (2). This reflects a 225% increase in load cycles due to augmentation. This difference was even more pronounced in the study-groups with eccentric implant position (933% increase). Cycles to 5° varus collapse of the head were mean 20,575 (SD 1771) for the non-augmented specimens (group 3) compared to mean 27,025 (SD 3077) for the augmented group (1) compared to mean 20,575 (SD 1771) for the non-augmented group (3) compared to mean 8317 (SD 1205) for the augmented group (2). All pairwise comparisons between study-groups regarding varus rotation revealed statistically significant differences (all \( P = 0.012 \)). Fig. 5 shows the varus rotation of all groups in the course of testing. In contrast to the specimens with centric blade position, all specimens of the groups with off-centric blade placement (groups 3 and 4) revealed additional head rotation around the blade axis. Number of cycles to 10° head rotation was mean 1200 (SD 1376) for the non-augmented off-center group (3) and mean 20,575 (SD 1548) for the augmented off-centric specimens (group 4). This difference was significant between groups (\( P = 0.002 \)) (Fig. 6). In the off-center group without augmentation (3), 3 out of 6 samples showed early failure due to backing out of the blade (migration > 1 mm). As soon as the test started, the blade tended to wander out of the surrogate toward distal with simultaneous rotation of the femoral head.

4. Discussion

The problem of fixation failure of cephalic hip implants for the treatment of intertrochanteric fractures is well known. Causes can be divided into two major groups. First of all, there are a number of surgeon and surgical technique related issues, like insufficient reduction or suboptimal positioning of the implant (Baumgaertner et al., 1995; Pervez et al., 2004). Secondly, fixation failures are more likely to occur in osteoporotic bone (Barrios et al., 1993). New implant designs have improved failure rates but cut outs remain an issue (Mereddy et al., 2009; Takigami et al., 2008). Because osteoporosis continues to be underdiagnosed and undertreated, surgical options are mandatory (Cummings et al., 2002; Swiontkowski et al., 1987). Both in biomechanical and clinical studies, the technique of cement augmentation of cephalic implants to increase the anchorage in osteoporotic femoral heads has been successfully introduced (Augat et al., 2002; Bartucci et al., 1985; Eriksson et al., 2002; Moore et al., 1997; Szpalski et al., 2004; von der Linden et al., 2006).

This in-vitro study evaluated a novel PMMA augmentation concept of the helical blade of the Proximal Femoral Nail Antirotation (PFNA) in terms of cut out resistance and rotational stability using surrogate femoral heads. The augmented implants with centered position showed an increase in the number of cycles to fatigue failure by 225% when compared to non-augmented controls. In cases of eccentric implant placement, this difference was even more pronounced. In agreement with other studies, these results strongly suggest that augmentation enhances implant anchorage and carries potential to prevent fixation failure, even in cases with mal-positioned hardware (Bartucci et al., 1985; von der Linden et al., 2006). However, in the first instance, augmentation is meant to compensate for
reduced bone quality. Our study showed that off-centered positioning affects implant purchase even when associated with augmentation. Misinterpretation of the method as “all-purpose tool” against cut out should be avoided in any case. Proper fracture reduction and accurate implant positioning remain key factors to achieve a satisfying surgical outcome.

Before augmentation can be embedded into the existing surgical technique, some additional steps are needed. One strategy could be to use perforated implants. The same implant could then be used solely or combined with augmentation. The decision to augment can be taken during the surgical intervention on the basis of distinct criteria. The opportunity to inject bone-cement after placing the implant represents a clear advantage in terms of safety. Major complications, like missing the implant insertion during the curing period of the cement, can be excluded. No implant failures were observed during the course of testing. A relatively viscous type of PMMA cement was used. It was technically feasible to inject the PMMA but a comparatively high injection pressure was required. 1 ml syringes provided a feasible transmission of the injection forces and allowed for controlled cement application. By using injectable medium-to-high viscosity PMMA, undesired cement leakage may be avoided (Boger and Wheeler, submitted for publication). Cement portions could block the sliding capability of the implant or could squeeze into the fracture site. This might lead to healing complications like non-unions, persistence of non-reducible fracture gaps and interference with periosteal healing (Augat et al., 2002; Cheng et al., 1989). To minimize the risk for avascular- and heat-necrosis during PMMA polymerization, and, in more general terms, to follow the principle of minimal alteration of an existing biology, a limited amount of PMMA (3 ml) was used (Boner et al., 2009; Heini et al., 2004). Excessive application of PMMA could destruct cartilage because of subchondral cement localization, or could generate fat emboli. In addition, excessive amounts of PMMA alter the risk of infection (Bartucci et al., 1985) due to the potential space for bacteria adhesion and the possible tissue necrosis associated to heat generation. With respect to implant removal, no problems were encountered when withdrawing the blade from the cement volume. Removal of the blades was performed on each test specimen with the dedicated instrument and following the surgical technique as provided by the manufacturer. The extraction screw driver was attached to the blade by turning it counterclockwise and gentle blows were applied with the hammer. As mentioned by other authors, the cement sheared completely off the implant (Paré et al., 2011). The relicts of bone-cement could complicate revision surgeries but drillable PMMA, as used in this study, allows for anchoring implants in a hardened state. The use of alternative biomaterials like degradable Calcium-Phosphate cements might be an option for the future. However, the mechanics of current formulations, especially concerning shear (Eriksson et al., 2002), are still not comparable to PMMA based solutions in load bearing applications.

A polyurethane foam model with comparatively low density was used to imitate severely osteoporotic bone. The foam type was chosen from pilot experiments to achieve an acceptable compromise between loading regime, number of test-cycles until fatigue failure, and failure patterns. All parameters were in line with those in previous test trials using human cadaver bones in the same setting. However, the question to what extent our results can be extrapolated to clinical practice remains open. The use of synthetic bone structures for biomechanical testing is still subject to ongoing debate (Papini et al., 2007; Szivet et al., 1995). The foam we used showed closed porosity, which might alter cement distribution compared to an open trabecular structure. However, the derived cement volumes surrounding the implants appeared homogenous and were comparable to the infiltration observed in cadaver samples. In human bones, trabecular structure and bone density might vary along the blade axis, which could lead to a more scattered cement distribution. However, as shown in another study, our cement was optimized to enhance uniform filling (Boger and Wheeler, submitted for publication).

Our test setup simulated the dynamic situation of a reduced, unstable intertrochanteric hip fracture after completion of implant sliding (Sommers et al., 2004). A controlled load sharing between implant and fracture site was established. Since our focus was on the implant–bone interface, an isolated head model was deemed as most practical despite general limitations. To avoid secondary failures, PFNA-nail and femoral shaft fragment were not considered, limiting the modeling of the actual biomechanical situation to an acceptable extent. The center of varus-rotation was statically located at the center of the roller, whereas the actual rotational center might dynamically migrate. The polymer shell confining the head samples does only marginally compared to the anatomical dimension of a femoral head which alters the acting lever arm between joint force vector and implant. However, the observed failure patterns like a varus collapse of the femoral head were comparable to the ones seen in clinic, supporting clinical relevance of our model. Cyclic testing was performed using an in-vivo measured loading curve simulating the main forces acting in the hip joint during gait (Bergmann et al., 2001). A 3D motion analysis system was used for data acquisition because spatial movement of the head fragment had to be assessed. Assuming test fixture and implant as rigid, a reference marker-set was not installed. Compliance of the system was therefore neglected.

To interpret our findings with more confidence, follow-up investigations on fresh frozen cadaveric femoral heads should include assessment of bone mineral density. Ultimately, the full operational procedure should be evaluated in a clinical setting. Potential issues associated with cement injectability, cement leakage, implant removal and revision surgeries will require further assessment before bringing this promising technique into clinical practice.

5. Conclusion

Osteoporosis and osteoporotic fractures remain undertreated. The technique of implant augmentation using bone-cement appears to significantly enhance the implant anchorage in a context of poor bone quality. Our promising in vitro results suggest that augmentation of the PFNA-blade with small amounts of PMMA cement in the treatment of osteoporotic hip fractures clearly enhances fixation stability and carries high potential for clinical application.

Conflict of interest statement

The authors are not compensated and there are no other institutional subsidies, corporate affiliations, or funding sources supporting this work unless clearly documented and disclosed: partial funding was received from Synthes GmbH who also kindly provided the implants and bone cement.

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Cement Augmentation of Hip Implants in Osteoporotic Bone: How Much Cement Is Needed and Where Should it Go?

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ABSTRACT: Several studies proved the beneficial effect of cement augmentation of proximal femoral nail antirotation (PFNA) blades on implant purchase in osteoporotic bone. We investigated the effect of different localizations and amounts of bone cement. Polyurethane foam specimens were instrumented with a PFNA blade and subsequently augmented with PMMA bone cement. Eight study groups were formed based on localization and amount of cement volume related to the blade. All specimens underwent cyclic loading with physiological orientation of the force vector until construct failure. Foam groups were compared between each other and to a cadaveric control group. The experiments revealed a significant dependency of implant purchase on localization and amount of cement. Biomechanically favorable cement positions were found at the implant tip and at the cranial side. However, none of the tested augmentation patterns performed significantly inferior to the cadaveric benchmark. These findings will allow surgeons to further reduce the amount of injected PMMA, decreasing the risk of cement leakage or cartilage damage. © 2013 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. J Orthop Res

Keywords: implant augmentation; hip fracture; cement; osteoporosis; helical blade

With the use of fixation devices like helical blades for treating proximal femoral fractures, the incidence of cut-out of cephalic implants has decreased.1–5 Nevertheless failures occur. Besides surgeon-related factors such as quality of the reduction and implant positioning, bone quality plays an important role in the occurrence of mechanical complications.6,7 Due to the aging population and relatively poor compliance to drugs that prevent osteoporotic fractures, the incidence of osteoporosis related fractures will increase.8

The technique of implant augmentation is based on an increasing congruence between the implant and the bone, reducing the stresses developed at the interface.9,10 A biomechanical study on augmentation of conventional hip screws showed beneficial results in osteoporotic cadaveric bones.11 Subsequently, augmentation was performed through a cannulated and perforated implant. In several in vitro studies, cement augmentation of Proximal Femoral Nail Antirotational blades (PFNA, Synthes GmbH, Bettlach, Switzerland) proved beneficial in biomechanical performance in osteoporotic bone.12–14 Recently, the first clinical results of PFNA helical blade augmentation were published.15

However, both in vitro and in vivo studies revealed considerable variation of cement distribution around the implant when using at least 3 ml PMMA. Accurate cement positioning seems difficult to achieve. The role of localization and cement volume on implant purchase is unclear. Determination of optimal cement localization and volume could reduce the risk of hazards such as cement leakage or adverse effects on the cartilage.16

We systematically investigated the effect of cement localization and amount on the mechanical competence of PFNA proximal femur constructs under cyclic loading. We wanted to determine the position and amount of cement needed to achieve sufficient implant purchase in the osteoporotic femoral head with minimal alteration of the biological system.

METHODS

Study-Groups

Thirty six surrogate foam specimens with defined geometry were used to model human cancellous bone (Fig. 1). The specimens consisted of cellular polyurethane foam (1522-10, Pacific Research, Inc., Malmö, Sweden) with a density of 10 lbs/ft3 (160.2 kg/m3) to simulate an osteopenic structure.13,17 Samples were divided into six groups (n = 6) with different cement amounts and localization with respect to the blade (Fig. 2 and Table 1). From a previous study, the mechanical test raw data from a group with concentric distribution of 3 ml PMMA at the tip of the blade (n = 6) and a non-augmented control group (n = 6) were re-evaluated to fit the failure criterion of the present study (groups 7–8).13 Two other reference groups were established from 12 fresh-frozen human femoral heads by adding the re-evaluated mechanical test raw data of the six non-augmented heads of a former study14 to the mechanical test raw data of six heads instrumented with a helical blade without augmentation for the present study. The heads consisted of four right and eight left, eight females, and four unknown at a mean age of 87.2 ± 5.2 years (mean ± SD, range = 81–96 years). Specimens were obtained from the Department of Pathology, Kantonspital Basel, Switzerland, with appropriate consent of the relatives.

Prior to testing, all specimens underwent BMD measurements in the cancellous bone with peripheral quantitative computed tomography (pQCT) using an Xtreme-CT (SCANCO Medical AG, Bassersdorf, Switzerland). According to the mechanical testing results, specimens were retrospectively divided into “weak” and “strong” groups (groups 9–10, n = 6).
Figure 1. Polyurethane foam block to simulate porous cancellous bone in the femoral head machined to fit into a custom-made polymer shell for mechanical testing. Height (H) = 50 mm, length (L) = 50 mm, width (W) = 38 mm.

Instrumentation
The foam specimens were placed in a custom-made polymer shell to mimic the cortex of the femoral head for subsequent load introduction. A special jig was used to introduce a 3.5-mm guide-wire in the center of the foam. Perforated PFNA-blades (length 100 mm, Synthes GmbH, Fig. 3a) were inserted over the guide-wire without predrilling to a depth of 38 mm, resulting in a 12 mm distance between the implant tip and the apex of the foam. This led to a suboptimal tip-apex distance of 24 mm to provoke failure as seen clinically.18

Subsequently, cement augmentation was performed through the cannulation of the blades following a standardized technique. In all augmented groups, the guide-wire was removed and a side opening cannula (Vertebroplasty Needle Kit, 8 Ga, Articlenumber: 03.702.216S, Synthes GmbH; Fig. 3b) was prefilled with PMMA cement (Vertecem V+; Synthes GmbH). Thereafter, 2 ml (groups 1–5) or 1 ml (group 6) of PMMA was injected through the perforations into the foam by using 1 ml syringes (Traumacem V+ Syringe Kit, Articlenumber: 03.702.130S, Synthes GmbH). In groups 1–3, 2 ml of PMMA was concentrically distributed around the blade’s base (group 1), center (group 2), or tip (group 3) by injecting 1 ml of PMMA to the cranial side, turning the cannula by 180°, and injecting another 1 ml to the caudal side. The cannula was completely inserted (group 3) and subsequently withdrawn by 7 (group 2) or 12 mm (group 1) to position the cement at the respective localization along the blade axis. In group 4, 2 ml PMMA was placed at the caudal side by inserting the cannula completely, injecting 1 ml of PMMA to the caudal side, withdrawing the cannula by 7 mm without turning it, and injecting another 1 ml to the caudal side. In group 5, 2 ml of PMMA was placed at the cranial side by inserting the cannula completely, injecting 1 ml of PMMA to the cranial side, withdrawing the cannula by 7 mm without turning it, and injecting another 1 ml to the cranial side. In group 6, 1 ml of PMMA was injected to the cranial side after inserting the cannula completely (Fig. 2).

By prefilling the cannula with cement and by inserting it deep enough to enable the side opening to directly reach the perforations of the blade in all study groups, the exact amount of injected PMMA was known. Because the foam allows for well-controlled cement distribution,13 a consistent cement configuration was obtained for each study group (Fig. 4).

Human specimens were instrumented according to a published protocol14 according to the procedure described above without augmentation and without using the polymer shell.

Mechanical Testing
A previously described model13,14,19 simulating an unstable intertrochanteric fracture was used. The setup allows the head component to rotate into varus, while the blade migrates through the foam. The foam samples were placed in a plastic shell for load introduction. Testing was performed on a servo-hydraulic testing machine (model 858, Mini Bionix; MTS, Eden Prairie, MN) equipped with a 25 kN load cell. The force progression in the human hip during gait20 was cyclically transferred to the specimen in physiological orientation of the load vector.13 To achieve a 16˚ resultant load vector, a 130˚ neck angle, and a 3˚ offset of the femoral shaft axis from the sagittal plane, the implant shaft was mounted to a base fixture at 149˚ to the horizontal free to slide along its axis (Fig. 5). A cross-table was used to eliminate shear forces during testing. Starting at 1,000 N the load was monotonically increased by 0.1 N/cycle until failure of the construct according to the protocol of Windolf et al.3,21,22 The minimum load was maintained at 100 N. Cyclic testing was performed at 2 Hz.

Testing was stopped when crosshead displacement exceeded 8 mm. Failure occurred at the implant to bone or cement to bone interface depending on PMMA localization and was determined by radiographic analyses performed throughout the test.

Human specimens were cyclically tested in a similar manner. Load was not introduced via the polymer shell but directly transferred to the head using a molded cup.

Data Acquisition and Evaluation
A K-wire was connected to the polymer shell/human femoral head in the mediolateral plane to monitor progression of varus rotation of the specimens from radiologic images. A C-arm (Arcadis Varic, Siemens Medical Solutions AG, Munich, Germany) was positioned in an AP direction. Radiographs were taken every 250 cycles at minimum load (100 N) to monitor the varus deformation of the specimen in relation to the blade. The change in angulation of the K-wire with respect to the initial X-ray was determined by image process-
ing algorithms (Matlab, Mathworks, Inc., Natick, MA). Retrospectively, a varus collapse of 2˚ was defined as failure; this criterion is a pure varus rotation as all other movements were eliminated by the test fixture. Implant bending was not observed in any specimen. The number of test-cycles to failure was identified for all specimens. The radiographs were further analyzed to identify the distance of the center of the PMMA volume to the apex of the foam sample for groups 1 (blade base), 2 (blade center), and 3 (blade tip). The centroid of the projected volume was estimated by fitting an ellipse to the cement contour. The six human specimens that survived the most cycles until 2˚ varus collapse formed the “strong” cadaveric reference group; the remaining 6 specimens formed the “weak” group.

Statistics

Shapiro–Wilk tests served as decision criterion for the appropriate test statistics. All study groups were compared with respect to number of cycles to 2˚ varus rotation employing a univariate ANOVA with Bonferroni post hoc correction for multiple comparisons. Pearson’s correlation coefficient $R$ was calculated for cycles to failure and PMMA localization along the implant axis by pooling groups 1, 2, and 3. BMD of the “weak” and “strong” cadaveric specimens were compared using a $t$-test. The significance level was set to $\alpha = 0.05$.

RESULTS

Regardless of the augmentation pattern, all augmented foam samples survived significantly longer than the non-augmented group (group 8, Fig. 6, all $P < 0.001$). However, a clear influence was found of augmentation pattern on the mechanical competence of the construct. The best performance was in the 3 ml group (group 7) with 253% increase in cycles to failure compared to the non-augmented control. However, the performance of this group was not significantly different to 2 ml cranial cement placement at the implant tip (group 5, $P > 0.99$). The least competent augmentation pattern was 2 ml cement at the implant base (group 1) leading to 99% increase in cycles to failure compared to the non-augmented control. However, no statistical differences were found between the latter group and 2 ml caudal placement at the implant tip (group 4, $P > 0.99$) or 1 ml cranial placement at the tip (group 6, $P > 0.99$). Two milliliters cranial cement placement (group 5) was significantly superior to 2 ml cement at the caudal side (group 4, $P < 0.001$). Two milliliters cranial cement (group 5) was also superior to 1 ml cranial cement (group 6, $P = 0.001$). The distance of the center of the PMMA volume to the apex of the foam correlated inversely with cycles to failure ($R = 0.77$, $P < 0.001$).

BMD of the “weak” and “strong” cadaveric groups (9 and 10) was $143 \pm 35$ and $195 \pm 33 \text{mg HA/cm}^3$, respectively ($P = 0.023$). Cycles to failure of the “weak” group were not different to the non-augmented foam (group 8, $P > 0.99$). Cycles to failure of the “strong” group were not significantly different to the augmented foam groups (all $P > 0.99$). Exceptions were 2 ml cranial cement placement at the tip (group 5) and 3 ml cement at the tip (group 7); both performed superior to the “strong” group (both $P < 0.009$).

DISCUSSION

Cement augmentation of PFNA blades for enhanced fixation in porous bone showed promise in several biomechanical studies. A study performed on foam models mimicking osteoporotic bones showed a beneficial effect on implant stability by an increased cut-out resistance. Two other studies performed on osteoporotic cadaveric bones showed increased rotational stability and pull-out and cut-out resistance with augmentation.

A first clinical study of PFNA augmentation also showed promising radiological and functional results.

Table 1. Study Groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Specimens</th>
<th>Cement Volume</th>
<th>Cement Location Axial</th>
<th>Cement Location Transverse</th>
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<td>1</td>
<td>Foam</td>
<td>2 ml</td>
<td>Implant base</td>
<td>Concentric</td>
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<td>Foam</td>
<td>2 ml</td>
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<td>Caudal</td>
</tr>
<tr>
<td>5</td>
<td>Foam</td>
<td>2 ml</td>
<td>Implant tip</td>
<td>Cranial</td>
</tr>
<tr>
<td>6</td>
<td>Foam</td>
<td>1 ml</td>
<td>Implant tip</td>
<td>Cranial</td>
</tr>
<tr>
<td>7</td>
<td>Foam</td>
<td>3 ml</td>
<td>Implant tip</td>
<td>Concentric</td>
</tr>
<tr>
<td>8</td>
<td>Foam a</td>
<td>——</td>
<td>——</td>
<td>——</td>
</tr>
<tr>
<td>9</td>
<td>Human bone “weak”</td>
<td>——</td>
<td>——</td>
<td>——</td>
</tr>
<tr>
<td>10</td>
<td>Human bone “strong”</td>
<td>——</td>
<td>——</td>
<td>——</td>
</tr>
</tbody>
</table>

Groups 1–7 consist of foam samples for testing different amounts and localizations of cement. Group 8 represents a non-augmented control. aIndicates groups from a different study. Groups 9 and 10: human cadaveric references. Group-size $n = 6$. 

Figure 3. Instrumentation of foam specimens. (a) Perforated PFNA blade. (b) Side-opening cannula to inject bone-cement through the perforated blades.
without major intra-operative complications. Augmentation of the femoral head through a cannulated, perforated PFNA blade is gaining acceptance. A side-opening cannula is used to selectively position cement at the blade tip. The risk of leakage into the fracture site or at the level of the sliding mechanism of the nail is reduced. Leakage into the hip by perforating the head, frequently created during guide-wire placement, can be excluded by performing a leakage test prior to augmentation. However, clinical and experimental experience shows that controlled positioning of the cement volume is not always possible. Cement cannot always be sufficiently directed by the injection procedure. The question arises to which extent unfavorable localization can compromise the desired biomechanical benefits. Moreover, to what extent the amount of cement can be reduced to exclude potential complications such as leakage or thermal necrosis is unclear.

We compared selected cement amounts and patterns along and transverse to the PFNA blade axis in a foam model (Fig. 4). Cement distributions in foam are clearly not fully comparable to those in human bone. The questions how and why certain cement distributions in human bone occur are beyond the scope of this study. Foam was used for sake of reproducibility of cement patterns. A clear effect on implant purchase of both cement localization and amount was obvious. The biomechanical competence of the construct increased with placing cement towards the implant tip. A longer lever to the hip joint contact force generates higher moments acting on the anchoring point of the implant. Reducing the lever creates a mechanically superior situation. This principle was already stated by Baumgaertner and Solberg stressing the importance of the tip-apex distance for fracture fixation. Conversely, care should be taken not to inject PMMA too close to the subchondral area to avoid cartilage damage.
the blade was biomechanically inferior compared to cranial and concentric positions, since physiological loading is dominated by compression and cements provide superior performance under compression. From a handling perspective it might be easier to create a concentric cement volume; however, cement placed cranial to the implant tip seems most promising mechanically.

A cranial localization of two milliliters of PMMA was comparable to a concentric localization of 3 ml around the blade tip. Furthermore, a 1 ml cranial cement placement revealed comparable resistance against cut-out as a 2 ml caudal cement position. Provided that reliable augmentation of biomechanical superior bone regions becomes possible, the cement volume could be reduced to 1 ml.

The aim of augmentation is to rule out the influence of osteoporosis by enhancing the purchase of implants to a level similar to healthy bone. Rather than clustering the cadaveric samples according to BMD, grouping into “weak” and “strong” was performed according to cycles to failure because the target parameter of the study was mechanical bone strength and not mineral density. Comparing the BMD of the “strong” or “healthy” group (~200 mg HA/cm³) to the literature (BMD range ~90–290 mg HA/cm³, n = 174), this appears to be a reasonable assumption. All augmented study groups performed as well or better than the non-augmented cadaveric benchmark, suggesting that even unfavorable augmentation patterns can provide sufficient benefit. This implicates that clinical difficulties with cement positioning might be of minor importance.

There are limitations associated with the study. The foam can only resemble human cancellous bone in a restricted way. However, the homogeneity of a synthetic material offers reproducibility over that of biological bone samples. The foam was successfully used previously and compared to a group of human bone samples with low BMD. No statistical difference was found between non-augmented foam and human bone under cyclic loading, supporting their similarity. In the actual study, a group of 12 cadaveric human femoral heads was used to create a benchmark of 6 “healthy” bones. On a mechanical base, the 6 weaker specimens were discarded to come closer to a “healthy benchmark” than when using all 12. Considering the mean age of the donors (87 years), it is likely that not
all were healthy; however, defining the benchmarks of human cadaveric bones is beyond the scope of this work.

Furthermore, care should be taken when applying our results to the clinical situation. It remains difficult to control PMMA localization around implants in human bones. Thus, radiographic monitoring of the cement distribution during augmentation is crucial. Subchondral localization or leakage must be avoided, and the procedure should be stopped if cement flows into undesired directions. New methods or instruments for controlling/predicting cement flow during injection are needed to increase security. PMMA formulations have evolved in terms of viscosity and curing window, but they can be further optimized. These findings stress the promising and challenging aspects of implant augmentation in osteoporotic bone.

In conclusion, we showed that the mechanical competencies of all groups of augmented specimens were comparable to those of non-osteoporotic cadaveric bones, independent of the augmentation pattern or the amount of PMMA used. Our findings suggest even in an unfavorable localization, augmentation is still better than no augmentation. When cement flows to a superior position from a biomechanical point of view, the amount of injected PMMA can even be further reduced. Conversely, an augmentation procedure can be halted after injection of 2 ml of PMMA in an undesired direction, making multiple attempts to direct more PMMA to other localizations avoidable. In both situations, the amount of injected PMMA can be reduced to a minimum that will decrease the risk of cement leakage or cartilage damage.

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REFERENCES

Paper p15

Mechanical torque measurement predicts load to implant cut-out: a biomechanical study investigating DHS® anchorage in femoral heads

Norbert Suhm · Clemens Hengg · Ronald Schwyn · Markus Windolf · Volker Quarz · Markus Hänni

Abstract

Introduction Bone strength plays an important role in implant anchorage. Bone mineral density (BMD) is used as surrogate parameter to quantify bone strength and to predict implant anchorage. BMD can be measured by means of quantitative computer tomography (QCT) or dual energy X-ray absorptiometry (DXA). These noninvasive methods for BMD measurement are not available pre- or intra-operatively. Instead, the surgeon could determine bone strength by direct mechanical measurement. We have evaluated mechanical torque measurement for (A) its capability to quantify local bone strength and (B) its predictive value towards load at implant cut-out.

Materials and methods Our experimental study was performed using sixteen paired human cadaver proximal femurs. BMD was determined for all specimens by QCT. The torque to breakaway of the cancellous bone structure (peak torque) was measured by means of a mechanical probe at the exact position of subsequent DHS® placement. The fixation strength of the DHS® achieved was assessed by cyclic loading in a stepwise protocol beginning with 1,500 N increasing 500 N every 5,000 cycles until 4,000 N.

Results A highly significant correlation of peak torque with BMD (QCT) was found \((r = 0.902, r^2 = 0.814, P < 0.001)\). Peak torque correlated highly significant with the load at implant cut-out \((r = 0.795, P < 0.001)\). All specimens with a measured peak torque below 6.79 Nm failed at the first load level of 1,500 N. The specimens with a peak torque above 8.63 Nm survived until the last load level of 4,000 N.

Conclusion Mechanical peak torque measurement is able to quantify bone strength. In an experimental setup, peak torque identifies those specimens that are likely to fail at low load. In clinical routine, implant migration and cut-out depend on several parameters, which are difficult to control, such as fracture type, fracture reduction achieved, and implant position. The predictive value of peak torque towards cut-out in a clinical set-up therefore has to be carefully validated.

Keywords Bone mineral density · Mechanical torque measurement · Osteoporosis · Hip fracture · Implant cut-out
osteoosynthesis' failure, when such implants are used for fracture fixation in osteoporotic bone. If the surgeon could get pre- or intra-operative information on bone strength indicating that implant loosening might develop, then supplementary augmentation could be used [2].

There is a clinical demand for a direct or surrogate measure of bone strength. Parameters that have been applied to quantify bone strength and to predict implant fixation strength include bone mineral density measured by dual energy X-ray absorptiometry [BMD (DXA)] or by quantitative computer tomography [BMD (QCT)]. These methods are non-invasive, but also not available pre- or intra-operatively on a routine basis. Instead, the surgeon could determine bone strength by direct mechanical measurement. Intra-operative measurement of insertion torque was evaluated for the determination of pedicle screw anchorage with uneven results [8, 12].

We have developed a method for standardized mechanical measurement of peak torque to breakaway of the femoral head's trabecular bone (peak torque). It was the goal of this study to evaluate this measurement method for its ability to measure bone strength by correlating peak torque with BMD (QCT) and to verify the predictive value of peak torque towards load at implant cut-out in the proximal femur biomechanically.

**Material and methods**

**Bone specimens**

Sixteen paired fresh frozen cadaveric femurs were used for testing. The medians and ranges of age, weight and height of the donors were 73.5 years (range 63.8–94.0 years), 63.5 kg (range 47.0–84.0 kg) and 164 cm (range 148–174 cm), respectively. The use of the human specimens for scientific purpose was approved by the local ethical committee. The bones and adjacent joints did not show any macroscopic pathology, such as lower limb fracture, generalized bone disease or severe arthrosis, which might have interfered with the mechanical properties of the bone. Prior to and in between the different tests, the specimens were stored at-20°C. All specimens were allowed to reach room temperature before testing for 24 h. While defrosting and during testing, the specimens were kept moist.

**Mechanical torque measurement**

Torque to breakaway of trabecular bone was measured by means of a custom made mechanical probe. It was designed as a wing blade with 7.0 mm outer diameter and 24.0 mm blade length (Fig. 1). Cannulation allowed the insertion over a pre-positioned guide wire. The guide wire was placed in the posterior-inferior quadrant of the femoral head according to the DHS® operation technique using the 135° aiming device. The position of the guide wire was controlled by means of an image intensifier (Arco si 100®, Applicazione Tecnologie Speciali SRL, Pedrengo, Italy) in two planes. The lateral cortex of the femur was opened with the 8.0 mm cannulated spiral drill. Subsequently, the cannulated torque measurement probe was inserted along the guide wire into the femoral head to reach a tip apex distance of 10.0 mm (Fig. 2). The final position of the measurement probe was documented by X-ray in two planes. The guide wire was removed prior to torque measurement in order to exclude any interference with the following measurement process. The peak torque until complete breakaway of the cancellous bone between the wings of the measurement probe (peak torque) was assessed by rotating the probe around its longitudinal axis. The peak torque was recorded by means of a calibrated digital torque meter (HD-100®, HIOS Inc., Akiyama, Japan). The data were processed with MATLAB® Software (The MathWorks, MA, USA).

**Measurement of bone mineral density by quantitative computer tomography [BMD (QCT)]**

Bone mineral density (QCT) was measured in the femoral head using a routine given by the scanner’s manufacturer (DensiScan 1000®, Scanco Medical, Bas-sersdorf, Switzerland; basis data: acceleration voltage 50 kV at 0.5 mA). Seven CT slices were considered for measurement. The central slice was placed at the largest...

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**Fig. 1** Custom made probe for mechanical measurement of peak torque to breakaway. Central cannulation of the probe (left) allows insertion over a guide wire. The measurement probe itself comprises three blades that are placed at an angular distance of 120° each. A scale for length measurement (right) enables adaptation of the probe to varying length of the femoral neck.
diameter of the femoral head and three additional slices were placed in both medial and in lateral direction with 1.0 mm interslice distance. BMD (QCT) was determined from a cancellous bone cylinder of 50% core volume of the resulting femoral head section. CT-data were processed directly into BMD in the unit gram per cubic centimeter (g/cm$^3$) by the manufacturer’s software. The CT scanner was calibrated to the European Forearm Phantom (EFP-060, QRM GmbH, Mührendorf, Germany) representing hydroxyapatite (HA) densities of 50, 100 and 200 mg HA/cm$^3$. No soft tissue equivalent was approved for application with this scanner.

Biomechanical testing

For biomechanical testing, the femoral necks were cut perpendicular to the femoral neck axis and 50 mm underneath the joint surface. A DHS$^\circledR$ (length 105 mm) was implanted in the exact point of previous torque measurement. Implant position within the femoral head was documented radiographically (Mobilett XP$^\circledR$, Siemens Medical Solutions, Zürich, Switzerland). Each specimen was mounted on a custom made testing jig with the screw axis at a 20° angle to the unidirectional force transmission axis, thus simulating the main force direction acting on the human proximal femur [4]. The specimens were exposed to cyclic loading, which was transmitted by an artificial articulation component in order to decrease the surface pressure on the femoral head. The test jig was placed on an x-y-table to allow for small compensational movements in a horizontal plane. The loading curve introduced into the femoral head was set similar to the forces in human hip joints for the main force axis during normal gait [3]. Six load steps were applied, each one running for 5,000 cycles at 2 Hz. Starting at peak loads of 1,500 N (250% body-weight for a person of 60 kg), the force was increased by 500 N every 5,000 cycles. Testing was stopped either when cut-out of the implant occurred, or when a total number of 30,000 cycles was reached, applying 4,000 N as the maximum load. Base load was kept at 200 N for all 30,000 cycles. Cut-out of the DHS$^\circledR$ was defined as 5.0 mm displacement of the femoral head when compared to the starting position. The amount of displacement was derived from the traverse path of the force application piston. The tests were performed on an MTS 858 Bionix$^\circledR$ servo-hydraulic testing machine (MTS Systems Cooperation, Eden Prairie, MN, USA).

Statistical analysis

The peak torque was correlated with BMD (QCT) using the Pearson test for correlation. The relationships were evaluated by linear regression analysis and by analysis of variance (ANOVA). Normal distribution was confirmed for these variables (Shapiro-Wilk test). Peak torque and BMD (QCT) were correlated with the load at cut-out using nonparametric Spearman correlation. For paired comparison of peak torque and BMD (QCT) data of right/left specimens the Paired-samples $t$ test was applied. Statistical tests were considered significant at levels of $P$ values $\leq 0.05$, $\leq 0.01$ and $\leq 0.001$.

Data were collected in Microsoft$^\circledR$ Office Excel tables (Microsoft Corporation, Redmond, USA) and transferred into SPSS$^\circledR$ Software for the statistical analysis (Version 14.01, SPSS Inc., Chicago, USA).

Results

Measurement of peak torque and BMD

The specimens examined in this study covered a wide range of BMD (QCT): 0.2–0.51 g/cm$^3$. The peak torque
was found in a range from 3.72 to 12.54 Nm. Comparison of peak torque and BMD (QCT) values in paired specimens did not reveal a significant difference (peak torque: $P = 0.576$, BMD (QCT): $P = 0.542$). Complete data of peak torque and BMD (QCT) is given in Table 1.

Relationship of peak torque and BMD

A high correlation of peak torque with BMD (QCT) was found ($r = 0.902$, $P < 0.001$). Accordingly, there was a high linear relationship between peak torque and BMD (QCT) with $r^2 = 0.814$, $P < 0.001$ (Fig. 3).

Implant cut-out under biomechanical testing

The DHS® cut-out in all specimens under the cyclic loading.

The peak torque measured correlated significantly with the load at cut-out ($r = 0.795$, $P < 0.001$). Considering the relationship in detail, all specimens with a measured peak torque below 6.79 Nm cut-out at a load of 1,500 N (first load step). All specimens with a peak torque above 8.63 Nm survived until 4,000 N (last load step) (Fig. 4). BMD (QCT) also correlated significantly with the load at cut-out ($r = 0.845$, $P < 0.001$).

<table>
<thead>
<tr>
<th>Sample</th>
<th>Peak torque (Nm)</th>
<th>BMD (QCT) (g/cm³)</th>
<th>Load (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Right</td>
<td>7.14</td>
<td>0.30</td>
<td>2,000</td>
</tr>
<tr>
<td>1 Left</td>
<td>7.55</td>
<td>0.34</td>
<td>2,000</td>
</tr>
<tr>
<td>2 Right</td>
<td>8.63</td>
<td>0.44</td>
<td>2,000</td>
</tr>
<tr>
<td>2 Left</td>
<td>12.54</td>
<td>0.42</td>
<td>3,000</td>
</tr>
<tr>
<td>3 Right</td>
<td>7.32</td>
<td>0.31</td>
<td>1,500</td>
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<td>7.37</td>
<td>0.30</td>
<td>3,000</td>
</tr>
<tr>
<td>4 Right</td>
<td>5.43</td>
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</tr>
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</tr>
<tr>
<td>6 Right</td>
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<td>0.51</td>
<td>4,000</td>
</tr>
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<td>12.41</td>
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<td>4,000</td>
</tr>
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<td>5.90</td>
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<tr>
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<td>7.49</td>
<td>0.30</td>
<td>2,500</td>
</tr>
<tr>
<td>8 Right</td>
<td>3.90</td>
<td>0.20</td>
<td>1,500</td>
</tr>
<tr>
<td>8 Left</td>
<td>4.23</td>
<td>0.27</td>
<td>1,500</td>
</tr>
<tr>
<td>Mean</td>
<td>7.58</td>
<td>0.34</td>
<td>–</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>2.83</td>
<td>0.09</td>
<td>–</td>
</tr>
</tbody>
</table>

| Range | 8.82 | 0.31 | 2,500 |
| Minimum | 3.72 | 0.20 | 1,500 |
| Maximum | 12.54 | 0.51 | 4,000 |
| Median | 7.35 | 0.30 | 2,000 |

*Peak torque* peak torque to breakaway of the trabecular bone during in situ testing. *BMD (QCT)* bone mineral density measured by quantitative computer tomography. *Load* load at cut-out under biomechanical testing.

**Table 1** Peak torque, BMD (QCT) and load at cut-out found for the specimens ($n = 16$)

Discussion

The insertional torque has been used to predict pedicle screw fixation strength in vitro [14, 15, 18] and in vivo [10, 11, 13]. This method has limitations as the measurement of screw insertion torque is based on the subjectively defined end point of maximum insertional torque [12]. Measurement of peak torque to breakaway of trabecular bone with our dedicated probe has...
to be looked upon as a superior method, as it objectively measures the resistance of the trabecular bone against complete destruction.

Peak torque is a reliable parameter to quantify trabecular bone strength

This can be concluded from a high correlation we found between peak torque and BMD (QCT) over a wide range of BMD values. Our finding compares well with a biomechanical study that found a correlation between insertional torque of pedicle screws and BMD (QCT) [12].

Bone mineral density (QCT) is unique in describing bone strength, because it provides a 3-dimensional distribution of bone mineral [5]. Accurate measurements of bone mass and 3D orientation have been demonstrated to explain 80 to 90% of the variance in the mechanical behaviour of trabecular bone volumes (Goldstein S. Bone Quality: A Biomechanical Perspective. In: Bone Quality: What Is It And Can We Measure It? A Scientific Meeting. The American Society for Bone and Mineral Research, Bethesda, MD, USA, May 2–3, 2005).

In clinical routine—however, peak torque would be superior to BMD (QCT) as a parameter to quantify bone strength. Like QCT, the proposed peak torque measurement provides information on the exact site of implant anchorage within the femoral head. As our measurement method was especially designed for intra-operative application it would be available to the surgeon, whereas QCT is not available pre- or intra-operatively on a routine basis.

Peak torque was able to predict load to cut-out in our experimental setting

Specimens, which failed at low loads could be identified as well as such specimens which bore high loads. The use of isolated femoral heads in a biomechanical test set-up allowed us to investigate the sole relationship between the strength of cancellous bone and the risk of implant cut-out.

In spinal surgery, the predictive value of pedicle screw insertional torque towards pedicle screw fixation strength was examined. A correlation was found between insertional torque and pullout force [15], between insertional torque and number of cycles to ultimate pedicles screw pullout [18], and the maximum insertional torque and screw pullout force [12]. However, the correlation between peak insertional torque to pullout strength was found to be low by Reitman [14]. Furthermore, a sole validity of pedicle screw insertion torque for prediction of mechanical failure could not be shown in a clinical set-up [10, 11, 13].

To our knowledge, no study was published describing the use of a mechanical parameter for the assessment of implant anchorage within the femoral head. The relevance of bone strength described by BMD for hip screw fixation was shown by push-out and pullout tests in vitro [7, 16]. Considering osteosynthesis of femoral fractures in vivo, it is the type of fracture, quality of fracture reduction achieved and implant position that influences the risk for implant failure aside from bone strength [1, 6, 7, 9, 17]. Intra-operative measurement of peak torque to breakaway is therefore not meant to predict failed osteosynthesis on its own. Instead, the hypothesis that intra-operative measurement of peak torque at the proximal femur is beneficial to the surgeon to judge the stability of his construct needs careful clinical validation.

References

Biomechanical Evaluation of a New Augmentation Method for Enhanced Screw Fixation in Osteoporotic Proximal Femoral Fractures

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ABSTRACT: A biomechanical investigation on eight pairs of human cadaver proximal femurs was performed to evaluate the impact of a new augmentation method on the internal fixation of osteoporotic proximal femur fractures. The study focused on enhancing implant purchase to reduce the incidence of implant cut-out in osteoporotic bone. In a left–right comparison, a conventional hip screw fixation (control) was compared to the new cement augmentation method. After bone bed preparation through high pressure irrigation to remove fat, blood, and bone debris, the bones were augmented with low viscosity polymethylmethacrylate (PMMA) cement. Step-wise fatigue testing was performed by cyclically loading the femoral heads in a physiological manner, beginning at 1,500 N and increasing 500 N every 5,000 cycles to 4,000 N, and continuously monitoring head displacement. Failure was defined as >5.0 mm head displacement. The head displacement at 2,000 N was significantly smaller (p = 0.018) for the augmented group as compared to the conventionally treated bones (0.09 ± 0.01 mm vs. 0.90 ± 0.32 mm; mean ± SEM). The displacement rate at the second load step was significantly higher (p = 0.018) for the conventionally treated bones as compared to the augmented ones. All of the nonaugmented specimens failed during testing, whereas 50% of the augmented specimens did not fail. The promising results of these experiments suggest that this new standardized irrigation/augmentation method enhances the implant anchorage and offers a potential solution to the problem of implant cut-out in osteoporotic metaphyseal bone.

INTRODUCTION

Implant cut-out after osteosynthesis of proximal femoral fractures is a major complication with severe and sometimes lethal complications.1–7 The rate of implant cut-out was significantly reduced in the past by changing from mostly rigid fixation principles to dynamically acting devices such as the dynamic hip screw. The failure rates remain high, however, for comminuted fractures in osteoporotic proximal femurs.8 Depending on the specific type of implant, cut-out rates vary between 1.1% and 6.3%.9,10 Given that the absolute number of osteoporosis-related proximal femur fractures will increase with future demographic changes,11 further improvement of implant fixation is urgently needed.

A correct surgical technique must first be applied to obtain anatomical reduction; the tip apex distance is an important parameter contributing to the cut-out risk.12–14 The application of different bone cements, mostly based on polymethylmethacrylate (PMMA) or calcium phosphates (CaP), is a promising approach for further reducing implant cut-out.15–27 However, no standardized technique has so far been developed that achieves safe and reproducible augmentation. Furthermore, infiltration of the trabecular network with viscous bone cements is difficult.28,29

This study used a new standardized technique to augment hip screws in human proximal femurs,
including pulsed lavage for fat and marrow removal prior to cement application—a technique taken from endoprosthetics.\(^3\) To determine the benefit of this technique, it was compared to conventional fixation by means of a standard hip screw in a controlled experimental study, simulating the clinical postoperative situation as realistically as possible. Specimens were tested under loading conditions corresponding to the physiological situation\(^4\) to investigate their biomechanical behavior in terms of implant anchorage.

**METHODS**

Eight pairs of human cadaver femurs were used. Conventional hip screw fixation of a proximal femoral head fragment (group 2) was compared with the new modified fixation method using additional PMMA augmentation of the previously irrigated trabecular bone structure in the contralateral femoral head (group 1). Bone mineral density (BMD) was measured by \(\mu\)CT (DensiScan 1000, Scanco Medical, Bassersdorf, Switzerland; group 1: 0.382 ± 0.058 g/cm\(^3\); group 2: 0.376 ± 0.060 g/cm\(^3\); average ± standard deviation). BMD was measured at the center of the femoral head at the location of the later screw position.

Each femur was sawed orthogonally to the eventual implant axis at 45° to the lateral cortex of the intact femoral shaft and 50 mm distal to the articular surface to simulate an unstable neck fracture. The isolated head with a length of 105 mm was inserted after central drilling of an 8.0-mm diameter and 30-mm deep hole into the head fragment, leading to a 20-mm tip-apex distance. After tapping, the bones of the augmentation group (group 1) underwent pulsatile irrigation (ScandiMed Lavage System; Biomet Merck GmbH, Ried, Switzerland) of the drill hole with 500 mL of isotonic saline solution at an operating pressure of 7 bars. After placement and withdrawal of the hip screw for seven turns, 3.0 mL of low viscosity PMMA bone cement (Vertecem biomimetic bone cement; Synthes Inc.) were injected through the screw cannulation. The screw was then reinserted, displacing the cement.\(^2\) The bones and cement were kept at room temperature during the whole procedure.

After the cement had cured for 12 h, each specimen was mounted on a specially designed test jig with the screw axis at a 20° angle to the force transmission axis, according to the main force direction stated by Bergmann and colleagues.\(^4\) The femoral head was cyclically loaded by an artificial articulation component to decrease the surface pressure on the head. Tests were conducted on a Bionix servo-hydraulic testing machine (MTS Systems Corp., Eden Prairie, MN). The jig was mounted on an \(x-y\) table to allow movements in a horizontal plane only (Fig. 1).

The applied load simulated the main forces occurring on the human proximal femur during normal walking\(^4\) (Fig. 2). A total of six load steps were performed, each running for 5,000 cycles at 2 Hz. Starting at peak loads of 1,500 N (~two times body weight), the force was increased by 500 N every 5,000 cycles either until failure or cut-out of the implant occurred, or until 30,000 cycles was reached, applying 4,000 N as the largest load. The minimum load in each cycle was maintained at 200 N for all 30,000 cycles. Cut-out failure was defined when 5.0 mm of total migration of the tip of the DHS occurred inside the femoral head (arrow (c) in Fig. 1).

The relative displacement of the screw inside the femoral head was measured using repetitive (after every 5,000 cycles) \(\mu\)CT imaging (Mobiliett XP, Siemens Medical, Germany) and a three-dimensional (3D) optical motion capture analysis system (Qualisys motion capture systems, Gothenburg, Sweden). Retroreflective markers were attached to the screw and the femoral cortex to calculate the position of the screw within the bone. Every 1,000 cycles, a data sequence of 100 s sampled at 50 Hz was recorded by the motion capture system.

A Wilcoxon signed rank test (nonparametric test for non-normally distributed data) was performed to compare the load displacement at the end of load step 2 of each bone to investigate stability differences between the two groups. The test was done on data from seven pairs of bones only; one bone in the conventionally treated group suffered early failure. The same analysis was done on data from the same seven pairs to compare the displacement rate during the second load step (2,000 N, 5,000–10,000 cycles).

**RESULTS**

Bones treated with the additional bone bed preparation and cement augmentation either failed after a greater number of cycles compared to the corresponding bone of the control group or did not fail during the 30,000 cycle test (Table 1). Representative migration curves are shown in Figure 3. The curves illustrate the measured migrations of the hip screw inside the bone with the augmented bone (gray curve) surviving all 30,000 cycles and the screw within the native bone (black curve) reaching the defined failure criterion after about 22,000 cycles. Four bones in the augmented group did not fail; all other specimens failed by screw cut-out similar to that which occurs clinically leading to varus collapse (Fig. 4).
Displacement after 10,000 cycles was $0.09 \pm 0.01$ mm for the cement augmented group versus $0.90 \pm 0.32$ mm in the conventionally treated group (mean $\pm$ SEM), a significant difference ($p = 0.018$) for displacement at the end of this second load step (2,000 N). The displacement rates during the second load step (2,000 N) were also significantly different ($p = 0.018$) with the rate in the augmented group being smaller than in the conventionally treated group (Fig. 5).

DISCUSSION

The bones treated with the new augmentation method, including bone bed preparation by jet lavage, showed significantly better results under biomechanical loading conditions than the nonaugmented implants. Therefore, implant anchorage in metaphyseal bone could be enhanced through application of bone cement after high pressure irrigation, thus providing an easy-to-apply, inexpensive, and clinically feasible solution to the problem of implant cut-out.

Previous studies produced similar results, but each had limitations. Despite problems of toxic monomer release and the heat generation during polymerization, some of these studies used excessive amounts of PMMA, leading to potential thermal and chemical necrosis of large areas of bone.\textsuperscript{16,20} The small amount of 3.0 mL of low viscosity PMMA cement used in the present study provided superior biomechanical properties, while presumably reducing the risk of extensive bone necrosis. Some investigators used injectable calcium phosphate cements.\textsuperscript{18,21–25} These materials, however, have inferior mechanical properties, especially in shear and tension, which occur in the human proximal femur.\textsuperscript{19}

Another drawback in earlier studies was the cement distribution pattern. Almost every study

![Figure 1. (Left) Schema of the test setup showing the femoral head force at $20^\circ$ to the screw axis via the artificial articulation component (1), the hip screw being fixed with axial (2) and rotational restriction (3). The setup was mounted on an x-y table (4). Markers were attached to the screw (a) and the femoral head (b1). Migration of the head relative to the stiff screw was calculated from the spatial locations of markers a, b1, and b2. (Right) Magnification of the femoral head, with the displacement vector for cut-out (c) displayed and calculated in three dimensions.](image-url)
used large amounts of bone cement to ensure distribution around the whole implant, but did not account for potential nonunion due to cement leakage into the fracture gap or to blocking of the sliding mechanism of the dynamic screw. In the present study, this complication could be avoided by placing cement only around the screw thread by injecting it through the implanted and

Table 1. Sample Details, Including BMD and Test Results. The Shaded Groups are Left-right Paired Femoral Heads

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Treatment</th>
<th>BMD (qCT) [g/cm³]</th>
<th>Failure load [N]</th>
<th># of cycles</th>
<th>Screw migration magnitude [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>914 L</td>
<td>Cemented</td>
<td>0.412</td>
<td>4,000</td>
<td>30,000*</td>
<td>0.75 mm</td>
</tr>
<tr>
<td>913 R</td>
<td>Conventional</td>
<td>0.420</td>
<td>3,500</td>
<td>21,930</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>002 R</td>
<td>Cemented</td>
<td>0.393</td>
<td>3,500</td>
<td>21,508</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>002 L</td>
<td>Conventional</td>
<td>0.324</td>
<td>2,500</td>
<td>11,810</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>003 L</td>
<td>Cemented</td>
<td>0.258</td>
<td>3,000</td>
<td>16,985</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>003 R</td>
<td>Conventional</td>
<td>0.262</td>
<td>1,500</td>
<td>37</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>970 R</td>
<td>Cemented</td>
<td>0.404</td>
<td>4,000</td>
<td>30,000*</td>
<td>0.16 mm</td>
</tr>
<tr>
<td>971 L</td>
<td>Conventional</td>
<td>0.389</td>
<td>3,000</td>
<td>19,620</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>968 R</td>
<td>Cemented</td>
<td>0.344</td>
<td>4,000</td>
<td>26,518</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>969 L</td>
<td>Conventional</td>
<td>0.364</td>
<td>2,500</td>
<td>11,675</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>973 L</td>
<td>Cemented</td>
<td>0.448</td>
<td>4,000</td>
<td>30,000*</td>
<td>0.23 mm</td>
</tr>
<tr>
<td>972 R</td>
<td>Conventional</td>
<td>0.439</td>
<td>3,000</td>
<td>15,955</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>974 R</td>
<td>Cemented</td>
<td>0.401</td>
<td>4,000</td>
<td>30,000*</td>
<td>0.27 mm</td>
</tr>
<tr>
<td>975 L</td>
<td>Conventional</td>
<td>0.436</td>
<td>3,500</td>
<td>22,850</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>983 L</td>
<td>Cemented</td>
<td>0.400</td>
<td>4,000</td>
<td>25,184</td>
<td>5.0 mm</td>
</tr>
<tr>
<td>982 R</td>
<td>Conventional</td>
<td>0.372</td>
<td>2,500</td>
<td>10,162</td>
<td>5.0 mm</td>
</tr>
</tbody>
</table>

*run-out bones.
subsequently loosened screw. Thus, only the thread was surrounded by cement, reducing or avoiding cut-out.

This study used an isolated head model to eliminate parameters such as sintering of the fracture, screw sliding, or proximal femur bending, and to obtain a precise view of the cut-out phenomenon. Perfusion and blood flow were omitted. However, neither parameter is detrimental to cement setting and mechanical properties. Cements are often used in joint replacements or vertebroplasty, where blood flow does not inhibit the ability of the cement to penetrate the cancellous bone structure.

Supplementary high pressure irrigation also contributed to the described reproducible and homogeneous cement distribution pattern by means of better penetration depth and cement–bone interdigitation. Additional jet lavage removes fat, blood, and bone debris, allowing better penetration, a major factor for enhanced implant anchorage. Possible biological disadvantages of high pressure irrigation such as fat embolism or destruction of the trabecular structure need further experimentation. These potentially negative effects might be avoided by low pressure syringe irrigation, but at the price of inferior cement penetration and interdigitation.

Several investigators used modified implants to deliver bone cement. The use of the standard hip screw, as it was done in this study, is advantageous, because the application of the described augmentation method can be done without additional implants or instruments.

Earlier studies investigated the performance of augmented bones in a static mechanical test.

Figure 3. Migration of the implant inside the bone (black, native DHS; gray, augmented DHS).
We used cyclic loading simulating the main forces acting on the human femoral head during gait. Failure patterns of the DHS fixation were similar to those observed clinically in terms of the required loads, the low number of cycles (early stage of fixation), and the radiographic appearance of the failure. In the left–right comparison of the conventional and the new standardized fixation method, the biomechanical advantages of the new bone cement application method were shown under quasi-physiological in vitro testing conditions. Our study did not account for the changing force introduction angle observed in vivo, but the neglected variations are small (24° in the x-z plane, 14° in the y-z plane).

Because all the bones had low to average BMDs and the loading conditions were for normal gait (no strenuous activities), our results suggest that the new augmentation method could be applied to osteoporotic metaphyseal fractures to reduce the incidence of implant cut-out. Because augmentation is the last step of the operation, the implant can be perfectly positioned before addition of the cement. In the case of postoperative fixation failure, the salvage procedure is most likely total joint replacement, so for very osteoporotic bones where augmentation was used, further complications would not be expected.

The need for augmentation has to be addressed. The surgeon should be provided with a technique to pre- or intraoperatively decide on quality of the bone that will surround the implanted screw. Investigations should provide more information than in the actual situation with two-dimensional radiographs, CT, or BMD values.

This biomechanical in vitro study suggests that the use of a new standardized augmentation technique, comprising a bone bed preparation through high pressure irrigation followed by injection of low viscosity PMMA bone cement, leads to improved implant purchase. The new fixation method could therefore be a potential solution to the clinical problem of implant cut-out in osteoporotic metaphyseal bone. The described easy-to-apply and inexpensive cement application method showed promising results under laboratory quasi-physiological loading conditions. Clinical verification is now required.

Figure 4. Two femoral heads after testing. (Left) There is a clear cut-out of the DHS screw, resulting from the dynamic loading. (Right) The augmented femoral head was stable throughout 30,000 cycles; no migration of the screw inside the head was observed.
ACKNOWLEDGMENTS

Synthes Inc. is acknowledged for providing the bone cement.

REFERENCES


Figure 5. Boxplots of the displacement rates during the second load step of the two groups of bones. Note the logarithmic scale. The augmented bones had a significantly lower displacement rate over the 5,000 cycles as compared to the conventionally fixed bones ($p = 0.018$).


Brief report

Does cancellous bone compaction due to insertion of a blade implant influence the cut-out resistance? A biomechanical study

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1. Introduction

The most devastating complication of osteoporosis is the fracture of the hip with an incidence of 14% of all osteoporotic fractures (Majumdar, 2008). In 2025, there will be more than three million fractures in the United States per year, creating direct medical costs of $25 billion (Burge et al., 2007).

Surgical treatment of proximal femur fractures relied traditionally on a screw-based fixation of the femoral head (e.g. Dynamic Hip Screw — DHS). Particularly in diminished bone quality, the screw frequently migrates through the cancellous bone, resulting in a severe post-operative complication (cut-out). Cut-out ratios up to 6% are reported in the literature when treating unstable intertrochanteric fractures (Gardner et al., 2004). Lately, helical blade concepts have been introduced as advancement of the screw. Even though recent studies still report cut-out ratios of up to 3.6% (Mereddy et al., 2009; Simmermacher et al., 2008; Takigami et al., 2008), the use of blade implants seems to decrease the incidence of cut-out significantly. Besides other reasons, the compaction of cancellous bone, which occurs when inserting a blade, is believed to enhance the implant anchorage (Channer et al., 1996; Chareancholvanich et al., 2002; Green et al., 1999). To our knowledge no evidence is reported yet to support this thesis. In a recent investigation our group quantified the compaction after DHS Blade (Synthes GmbH, Bettlach, Switzerland) insertion with and without predrilling (Windolf et al., 2009a,b). Even though significant higher compaction was found when predrilling was omitted, no differences were observed between bone groups and regarding to cut-out resistance. However, some methodological issues became obvious suggesting follow-up investigations to draw a confident conclusion. These points include implants insertion in a quasi-static manner, a potential effect of implant removal and re-insertion on the implant purchase and the use of a test method simulating only the specific scenario of blocked implant sliding.

Therefore, the aim of this in vitro study was to analyze the potential of cancellous bone compaction with respect to cut-out resistance in human cadaveric femoral heads. DHS Blades were instrumented with and without predrilling to generate different degrees of bone compaction. The samples were cyclically loaded until cut-out in a physiological setting.

2. Methods

The methodology was based on published work (Windolf et al., 2009b) with certain modifications. Six pairs of fresh frozen (−20 °C) human cadaveric proximal femora were instrumented with DHS Blades. Prior instrumentation, bone mineral density was determined in the center of the femoral head by Xtreme-CT measurement. After instrumentation biomechanical testing was performed under cyclic loading. The bone-implant interface was monitored by means of fluoroscopic imaging throughout the experiment. Paired t-tests were performed to identify differences regarding bone mineral density, stiffness and cycles to failure. Findings: No significant differences were found between study groups with regard to axial stiffness (P = 0.626) and number of cycles to failure (P = 0.961).

Interpretation: This in vitro study did not show differences in biomechanical stability of proximal femora instrumented with a helical blade implant with or without predrilling. Clinically, the findings suggest that predrilling may be performed to ease the surgical procedure without compromising the implant anchorage.

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human cadaveric proximal femora were used. Bones within a pair were randomly assigned to two groups: 1) predrilled; 2) non-predrilled. Equal number of left and right bones was ensured for both groups. Prior instrumentation, bone mineral density (BMD) was determined in the center of the femoral head by Xtreme-CT measurements (Scanco Medical AG, Bassersdorf, Switzerland). CT data from the former study (Windolf et al., 2009b) was re-evaluated using the present evaluation protocol to enable a comparison between the bone populations of both investigations. By showing similar bone qualities, a comparable degree of bone compaction could be assumed between both investigations.

All femoral necks were cut 50 mm lateral to the femoral apex at 45° to the lateral cortex of the femoral shaft. For instrumentation 100 mm stainless steel DHS Blades (Synthes GmbH, Bettlach, Switzerland) were used (Fig. 1). According to the operative guideline of the manufacturer, a 2.5-mm Kirschner-wire was placed in the center of the femoral head, perpendicular to the sawing plane for guiding of drill bit and implant. A custom-made jig was utilized for reproducible placement of the Kirschner-wire and fixation of the specimen. The jig was designed to distribute the implantation forces evenly over the surface of the femoral head. Pre-drilling was performed for the specimens in group 1 using the standard DHS Blade drill bit (diameter 6 mm). For all samples the blade insertion was performed manually by hammer strokes until a tip–apex distance of 15 mm was reached.

In contrast to the earlier study (Windolf et al., 2009b) mechanical testing was conducted according to the model described by Sommers et al. simulating an unstable intertrochanteric fracture with lack of postero-medial support. The implant was free to slide along its axis simulating a load sharing situation between the implant and bone (Sommers et al., 2004). The DHS Blade was inserted into a barrel of the original DHS side-plate to reproduce the sliding conditions of the implant. The free implant length was 25 mm. The femoral heads were mounted on a polymer back plate equipped with spikes to prevent rotation of the head. The polymer plate rested on two cylindrical rollers allowing for varus collapse of the head (Fig. 2). Testing was performed using a servo-hydraulic testing machine (MTS 858 Mini Bionix II, MTS, Eden Prairie, USA) equipped with a 4 kN load cell. In order to simulate an alternating load during walking, a loading trajectory measured in vivo in the human hip was transferred to the femoral head at a physiological orientation of 20° with respect to the implant axis (Bergmann et al., 2001). For load introduction into the femoral head a polymer shell was used. A cross-table was placed between machine actuator and shell to ensure a free center of rotation of the femoral head. Cyclic loading was performed at 2 Hz until failure of the construct. Starting at 1500 N

Fig. 1. DHS Blade used in this study with a length of 100 m shown in views on the tip (top) and from lateral (bottom).

Fig. 2. Test setup with specimen mounted on the testing machine (right); schematic drawing of the setup used with the angles and load directions indicated (left).
(Windolf et al., 2009a) compression force, the load was monotonically increased at 0.1 N/cycle according to the loading protocol first introduced by Windolf et al. (2009b). The load-valley was maintained at 200 N throughout the test.

2.1. Data acquisition and statistics

A Kirschner-wire was attached to the femoral head in the anteroposterior plane to serve as landmark for X-ray data evaluation (Figs. 2 and 4). At increments of 250 cycles, fluoroscopic imaging was performed in anteroposterior direction at load-valley to assess the migration of the head with respect to the implant (Siemens Arcadis Varic, Siemens Medical Solutions AG, Munich, Germany). The angle of the Kirschner-wire projection was identified for all repeated radiographs by means of a custom-made software routine (Matlab, Image processing Toolbox, The MathWorks GmbH, Ismaning, Germany) to track the specimen’s varus rotation over time. Number of cycles to 5° varus collapse with respect to the initial X-ray was identified for all specimens. Construct stiffness was calculated from the testing machine’s load and displacement signals after 50 cycles of preconditioning. After assuring normal distribution of the test data (Shapiro–Wilk test), paired t-tests were carried out to identify differences between study groups with regard to BMD, stiffness and cycles to failure. Pearson’s correlation coefficient R was calculated for BMD and cycles to failure. The software package SPSS 18.0 (SPSS Inc., Chicago, USA) was used for all statistical evaluations. Level of significance was \( \alpha = 0.05 \).

3. Results

The mean BMD was 152.5 mgHA/cm³ (SD 30) for predrilled and 148.7 mgHA/cm³ (SD 31) for non-predrilled group. This difference was not significant between groups (\( P = 0.65 \), power 0.07). The values were comparable to the study of Windolf et al. (2009b): Predrilled: 165.6 mgHA/cm³ (SD 30); Non-predrilled: 166.6 mgHA/cm³ (SD 28) with no significant difference between the two studies (\( P = 0.46 \), power 0.056).

The mean axial stiffness of the bone-implant construct was 1519 N/mm (SD 153) for predrilled and 1560 N/mm (SD 301) for non-predrilled group (Fig. 3). This difference was also not statistically significant (\( P = 0.63 \), power 0.07).

During the cyclic tests all specimens failed at the bone-implant interface by varus collapse of the femoral head (Fig. 4). The mean

![Fig. 3. Axial stiffness [N/mm] as box plots for predrilled and non-predrilled group at cycle 50.](image)

![Fig. 4. Mode of failure for predrilled (top) and non-predrilled (bottom) specimen with first x-ray (left) and x-ray at failure (right) showing the varus collapse.](image)
number of load cycles to 5° varus rotation was 9167 (SD 5205) for the predrilled and 9250 (SD 4254) for the non-predrilled samples (Fig. 5). Again, this difference was not significant ($P=0.96$, power 0.05). The corresponding mean failure loads were 2417 N (SD 521) for the predrilled and 2425 N (SD 425) for non-predrilled specimens. The increase in cycles to failure within each bone pair of the non-predrilled specimens in relation to the contralateral predrilled bones was in average 22% (SD 54%).

Due to no statistical significant differences all samples were pooled for correlation analysis. We found a significant positive correlation between BMD and number of cycles to failure ($P=0.045$, $R=0.587$, power 0.68; Fig. 6).

4. Discussion

We found no differences in anchorage of a blade implant for fixation of osteoporotic hip fractures when implantation was performed either with removal of bone content (predrilling) or without. In a recent study with comparable setup (Windolf et al., 2009b) cancellous bone compaction in the surrounding of a DHS Blade had been quantified to approx. 30% increase in BMD as a result of implant insertion without predrilling. When bone had been removed by drilling a pilot hole, the compaction dropped significantly to about 20% BMD change. Based on this 10% difference in bone density, we concluded that predrilling/non-predrilling is a valid model for simulating different degrees of bone compaction. Since the bone quality of the specimens was found comparable between both studies, the outcomes of the mentioned paper appear also valid here. Although compaction was significantly higher for the non-predrilled group, Windolf et al. reported no differences in cut-out resistance in agreement with the results of the present experiment. Three main methodological issues of the previous paper were addressed here. First, we inserted the implants in a clinically relevant manner by manual hammer blows instead of quasi-static insertion using a material test machine. The difference in mechanical impetus may have an impact on the compression of the trabecular structure. Second, implants were not removed and reinserted. Windolf et al. used polymer implants for CT scanning to avoid metallic artifacts and replaced them afterwards with commercial DHS Blades for mechanical testing. The impact of removal and re-insertion on the implant purchase is unclear. Third, the test-setup was adapted to a more physiological and clinically relevant model allowing full implant sliding and varus collapse of the femoral head. Even though physiological loading is complex, the resulting force vector in the hip joint can generally be split into two components. The component in direction of the implant axis is borne by the test fixture simulating load sharing at the fracture gap. The component perpendicular to the implant axis acts on the bone-implant interface and causes typical varus collapse when the trabecular scaffold collapses (Fig. 2). This failure mechanism is predominant in clinics (Gardner et al., 2004; Nordin et al., 2001; Thomas, 1991). Our experiment revealed a significant correlation between BMD and cycles to construct failure, which again proofs the known relation between bone density and implant fixation.

However, a benefit of helical or spiral blade designs is repeatedly reported in literature (Simmermacher et al., 2008; Strauss et al., 2006; Windolf et al., 2009a). If bone compaction is not a major contributor, the increased implant surface in comparison to a screw equivalent as well as the reduced exposure of the bone to sharp implant edges like thread flanks are believed to play an important role (Windolf et al., 2009a). With regard to the clinical practice, the results of the study suggest that difficulties related to implant insertion when aiming to preserve bone content, may be avoided by predrilling the bone without compromising construct stability. However, to which extent these experimental findings can be transferred to a clinical and biological environment and how they apply to comparable fixation hardware besides the DHS Blade cannot be fully answered here. Furthermore, it has to be noted that a low statistical power (as observed here) reflects the mathematical impossibility to confidently prove similarity in hypothesis testing. Hence, it may be decided individually whether a potential difference should be regarded as clinically relevant by studying the presented raw data.

5. Conclusions

This in vitro study revealed no differences in primary stability of proximal femora instrumented with a helical blade implant with two different degrees of cancellous bone compaction (predrilled/non-predrilled). The importance of compaction with regard to implant anchorage under cyclic loading seems therefore diminished. Clinically, the findings suggest that predrilling may be performed to ease the surgical procedure without compromising the implant anchorage.

References


Cement augmentation of lag screws: an investigation on biomechanical advantages

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Abstract

Background In trauma surgery, lag screws are commonly used. However, in osteoporotic bone, anchorage can be considerably compromised. This study investigates the biomechanical potential of cement augmentation in terms of improved fixation.

Methods 36 Surrogate osteoporotic bone specimens were utilised in three biomechanical experiments, each comparing 6 augmented with 6 non-augmented samples. Standard partially-threaded lag screws (Synthes) were placed following surgical standard. For the augmented groups, 0.4 ml of polymethylmethacrylate was injected into the pre-drilled hole prior to screw placement. Interfragmentary compression was determined using a cannulated ring compression sensor. Maximum torque was recorded with a torque wrench. Compressive relaxation after 24 h, relaxation after loosening and re-tightening the screw as well as maximum compression and torque at failure were measured.

Findings Mean relaxation was significantly lower for the augmented group ($p < 0.01$). After 24 h, a remaining fragmental compression of 62 % for the augmented and 52 % for the non-augmented specimens was found. Loosening and re-tightening of the screw did not affect the compressive relaxation when augmentation was applied ($p = 0.529$), compared to an increased relaxation after re-tightening in the non-augmented group ($p = 0.04$). The mean maximum compression and torque until failure were significantly higher for the augmented group ($p < 0.001$).

Interpretation Cement augmentation of lag screws can improve fixation stability in terms of installing and maintaining interfragmentary compression. Effects of relaxation can be reduced and re-tightening of screws is possible without compromising the fixation. Particularly in reduced bone mass, augmentation of lag screws can markedly increase the security of the technique.

Keywords Biomechanics · Lag screw · Compression screw · Interfragmentary compression · Augmentation · PMMA

Introduction

In trauma surgery, lag or compression screws are commonly used. They can be applied in combination with a plate or as a single osteosynthesis. Lag screws are not only used to achieve and secure reduction but also to generate interfragmentary compression [1–4], a major determinant for primary fracture healing [5]. The increasing number of fragility fractures and fractures associated with osteoporosis are becoming a major problem in orthopaedic and trauma surgery, resulting in reduced effectiveness also for the lag screw technique in an increasing number of patients [1, 6]. Due to the altered density and properties of the cancellous bone, stable anchorage of the lag screw is compromised, resulting in considerably reduced interfragmentary compression and diminished reduction reliability.

Today there is no final solution regarding the problem of effective and uneventful treatment of fragility fractures.
With the existing techniques, e.g. angle stable plates and angle stable locked intramedullary nails, an improved stability can be reached [7, 8]. However, for fixation of metaphyseal fractures, lag screws are often used to maintain anatomical reduction of the joint surface. In this region, failures occur at the bone–implant interface, sometimes even during operation if the screw is over tightened.

Therefore, one method to improve stability between bone and implant is augmentation with bone cement [9]. Augmentation has shown to increase anchorage between bone and implant and to rule out the influence of osteoporosis. Many biomechanical studies could demonstrate the benefit of augmentation techniques in osteoporotic fracture fixation [10–15].

The aim of this biomechanical study was to compare conventional lag screws with cement augmented ones. The remaining interfragmentary compression after 24 h relaxation, torque and fracture gap compression at failure and the effect of augmentation on the re-tightening of lag screws were investigated.

Materials and methods

Specimens and instrumentation

Surrogate bone blocks (40 × 40 × 40 mm) prepared from cellular polyurethane foam (density 0.16 g/cc, Nr. 1522-10, Pacific Research Inc., Malmö, Sweden) were used in this study to simulate osteoporotic cancellous bone samples. A total of 36 samples were used in three biomechanical test series (relaxation, re-tightening and stripping experiments), each test comparing 6 augmented with 6 non-augmented lag screw fixations. To ensure comparable mechanical behaviour not only for static but also for time-dependent characteristics, we performed a pre-test and compared the results with the work of Zilch et al. [16]. Depending on the location of the cancellous bone, they found a stress relaxation of 14–20 % after 10 min of loading. We found a relaxation of 18 versus 14 % for the non-augmented and the augmented specimens, respectively. So we conclude that this artificial material is appropriate to investigate the potential of cement augmentation in lag screws.

Standard partially threaded lag screws (Synthes GmbH, Solothurn, Switzerland) with a core diameter of 4.5 mm were used. The screws had a length of 35 mm with a thread length of 16 mm. The outer diameter of the thread was 6.5 mm.

Instrumentation of the lag screws followed surgical standard. The foam blocks were centrically pre-drilled with a 4.5-mm drill to a depth of 20 mm. For the augmented group, 0.4 ml of polymethylmethacrylate (PMMA) cement (Beracryl, Suter Kunststoffe AG, Fraubrunnen, Switzerland) was injected into the drill hole (Fig. 1) before the screw was inserted to a depth of 16 mm. Hardening time was set to 6 h. For the non-augmented group, the screw was inserted in an equal manner without the application of cement. Figure 2 shows a cross section of an augmented sample displaying the cement distribution around the threaded part of the lag screw.

Test setup

The interfragmentary compression was determined with a 2-kN cannulated ring compression force sensor with a diameter of 40 mm and a central 12 mm hole (Lorenz Messtechnik GmbH, Alfdorf, Germany). A 1.5-mm washer under the screw head allowed placement of the sensor between screw head and specimen (Fig. 3). Torque at screw insertion was recorded with a 10-Nm torque wrench (Mecmesin, Brütsch/Rüegger AG, Zürich, Switzerland). The test setup was fixed horizontally by clamping the foam blocks in a vice.

Mechanical testing

In a relaxation test, the screw was tightened until a compression force of 160 N was achieved. Relaxation, defined as percentage drop of compression force, was then measured over 24 h.

For a re-tightening test, the screw was tightened to 160 N compression force, followed by a 40-min relaxation period. After loosening the screw completely, it was...
re-tightened to 160 N. Relaxation was measured for another 40 min.

In a third test series, the maximum compression force and the maximum torque until failure were recorded to investigate the resistance against screw stripping.

Data acquisition and statistics

Compression force was recorded with the sensor software GM80 (Version 1.03, Lorenz Messtechnik GmbH, Alfdorf, Germany). Sampling rate was 0.16 Hz for the 24 h relaxation test and 20 Hz for the other two tests. Insertion torque was recorded with the Mecmesin internal software at 10 Hz.

Statistical evaluation was performed using SPSS software (Version 18, SPSS Inc., Chicago, USA). After assessing data distribution using the Shapiro–Wilk test, independent sample t tests were carried out to identify significant differences between the groups regarding initial compression, failure load and torque. For the evaluation of the 24 h relaxation and the re-tightening tests, compression force at 0, 1, 12 and 24 h or at 0, 10 and 40 min, respectively, was identified and analysed using repeated measures ANOVA statistics. Significance level was set to $\alpha = 0.05$.

Results

24 h Relaxation test

The mean initial interfragmentary compression was 159 N (SD 1.7) for the augmented compared to 158 N (SD 1.5) for the non-augmented group. There was no significant difference in compression force at the starting point ($p = 0.74$, power 0.12).

The progression of the 24 h relaxation test (mean compression ± SD) of the augmented and non-augmented specimens is shown in Fig. 4. The evaluation at hours 0, 1, 12 and 24 showed a significant difference in interfragmentary compression between the two groups ($p < 0.01$, power 0.91). After 1 h, the augmented specimens had an interfragmentary compression of 122 N (SD 2.4), while for the non-augmented samples, compression dropped to 98 N (SD 13.2). The remaining interfragmentary compression after 12 and 24 h was 104 N (SD 2.7) and 99 N (SD 2.5) for the augmented specimens compared to 84 N (SD 13.2) and 81 N (SD 12.4) for the non-augmented specimens. The augmented specimens showed a significant smaller relaxation compared to the non-augmented ones ($p < 0.01$, power 0.92). After 1 h, the relaxation was 23 % for the augmented compared to 37 % for the non-augmented group, and at the end of the test, the relaxation was 38 % and 48 % for the augmented and non-augmented group, respectively.
Re-tightening test

The augmented screws showed no significant difference between the first relaxation and the relaxation after re-tightening of the screws ($p = 0.72$, power 0.06). On the contrary, the non-augmented screws showed a significantly higher relaxation after re-tightening ($p = 0.01$, power 0.80). After 40 min of the first tightening, relaxation for the augmented group was 22% while for the non-augmented, it was 27%. After 40 min of the re-tightening, the relaxation was 21% for the augmented samples while the non-augmented ones showed 37% (Fig. 5).

Stripping test

Maximum compression force before failure occurred was on average 338 N (SD 21.8) for the augmented compared to 174 N (SD 28.6) for the non-augmented samples. The augmented group showed a 94% higher maximum compression compared to the non-augmented group ($p < 0.001$, power >0.99). The maximum torque was significantly higher ($p < 0.001$, power >0.99) for the augmented specimens as well. With 1.5 Nm (SD 0.25) versus 0.4 Nm (SD 0.09), the augmented group reached four times higher maximum torque compared to the non-augmented one (Fig. 6).

Discussion

In osteoporotic patients, lag screws cannot be used in their full effectiveness. The goal of this study was to investigate the potential of cement augmented lag screws with respect to biomechanical parameters. We could show significant biomechanical advantages associated with the use of cement augmentation for lag screws. The mean relaxation in the first 24 h was significantly reduced for the augmented group. Furthermore, the interfragmentary compression after

![Fig. 4 Mean relaxation within 24 h for the augmented and non-augmented group with standard deviation](image1)

![Fig. 5 Mean interfragmentary compression force (%) compared to the measurement of the first tightening at the same time for the augmented and non-augmented group](image2)
re-tightening of the screws as well as compression force and torque until failure was significantly higher for the augmented specimens. A lag screw can provide good interfragmentary compression, but is at a risk to fail directly if over tightened. Therefore, augmentation not only increases interfragmentary compression and reduces the loss of compression over time by the undesired effect of material relaxation, but also increases the security of the technique because of a higher torque to screw stripping.

Some studies investigated the effect of augmentation techniques on screw fixation [11, 17], others dealt with the compression force of different screw types [2, 18], but no work has been published combining both aspects. The mechanical advantages of screw augmentation have been shown in several studies for different body regions. Chen et al. tested cannulated and perforated pedicle screws in artificial femoral shafts [11]. The pull out forces for screws placed in doughy cement, when the influence of the cement viscosity and found the highest pull out force for augmented 4.5 mm AO screws in synthetic femur sawbones. Additionally, they investigated the cement distribution, which differs significantly in human cancellous bone materials [4]. Another concern is the cement distribution, which differs significantly in human and artificial bone. In artificial material (even closed cell polyurethane foam), a standardised homogeneous cement cloud can be created around the implant, in contrast to human bone in which cement distribution cannot be controlled [22, 23].

The static properties and especially the behaviour over time are highly important concerning lag screw fixations. Interfragmentary compression is one major aspect of bone healing and is not only used in fracture treatment, but also for ankle joint fusions. One technique is arthrodesis using compression screws. Gosch et al. could show the correlation between bone mineral density (BMD) and compression force in a subtalar joint fusion. In specimens with low BMD (0.1–0.4 g/cm²) less than 200 N compression force was achieved [1]. These results are comparable to our findings where we found an average compression force of 174 N before failure occurred in an osteoporotic bone model. With augmentation, we could nearly double the compression force before failure.

Artificial materials are often used for biomechanical investigations, especially for augmentation studies [6, 10, 11]. Advantages are the minimal variance, the uniform shape and the possibility to simulate bone with varying mechanical properties. Several in vitro studies using artificial cancellous bone as a substitute for human cadaveric material have shown that synthetic cancellous bone is a good model for the mechanical characteristics seen in real patients [19–21]. The density of human cancellous bone is generally between 0.09 and 1.25 g/cm³. The artificial bone material chosen for this study had a density of 0.16 g/cm³, and thus may be considered as representative for osteoporotic cancellous bone [6]. Wheeler et al. compared different types of compression screws using human vertebrae and cancellous bone models (density 0.16 g/cm³). For the AO screw, no significant differences in interfragmentary compression and push out force were found between human and artificial cancellous bone materials [4]. Another concern is the cement distribution, which differs significantly in human and artificial bone. In artificial material (even closed cell polyurethane foam), a standardised homogeneous cement cloud can be created around the implant, in contrast to human bone in which cement distribution cannot be controlled [22, 23].

In conjunction with augmentation techniques, concerns regarding different risks and complications arise. One fear concerning the use of nonresorbable cements is implant removal. The augmentation technique used in this study does not cause a problem regarding screw removal. When using standard screws, the maximum torque for removal was not affected by cement augmentation. Our experience is confirmed by Waits et al., who showed no differences in maximum torque during screw removal for cemented and un-cemented standard screws. In contrast, the torque for removal of augmented cannulated and perforated screws was 12 times higher [24]. The polymerisation temperature generated during the exothermic curing of the cement is another concern regarding PMMA augmentation. As shown before, the temperature increase caused by 0.4 ml of cement is very unlikely to lead to thermal damage or necrosis in the bone structure [25, 26].

This study has some limitations like the use of artificial bone material that allows only a limited transferability to human bone. But the authors think that, in the treatment of osteoporotic fractures, every effort must be made to achieve an uneventful healing.
This study was performed to investigate the potential of lag screw cement augmentation. With the currently commercially available cements, this technique is hardly applicable in clinics due to the relative long hardening time. Although, the hardening time of modern bone cements is fast enough for implant augmentation techniques. Further investigations, mainly focusing on cement properties, application systems, but also studies using human cancellous bone are necessary.

Conclusion

This study shows that augmentation of lag screws with small amounts of bone cement can improve the interfragmentary compression in terms of compressive force and timely relaxation. Re-tightening of the screw is possible without compromising the achieved compression. Lag screw augmentation might help particularly in severe osteoporotic fracture fixation of larger fragments at meta-/epiphyseal regions. It carries potential to improve the osteoporotic fracture fixation of larger fragments at met-/screw augmentation might help particularly in severe without compromising the achieved compression. Lag screw cement augmentation. With the currently commercially available cements, this technique is hardly applicable in clinics due to the relative long hardening time. Although, the hardening time of modern bone cements is fast enough for implant augmentation techniques. Further investigations, mainly focusing on cement properties, application systems, but also studies using human cancellous bone are necessary.

References

Paper p19

Is a helical shaped implant a superior alternative to the Dynamic Hip Screw for unstable femoral neck fractures? A biomechanical investigation

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**Abstract**

**Background:** The Dynamic Hip Screw is well established for the treatment of femoral neck fractures. However, cut-out occurs in 1–6% of all cases. This study compared the biomechanical performance of a helical shaped implant (DHS-Blade) to the Dynamic Hip Screw in an unstable femoral neck fracture model.

**Methods:** Ten pairs of human cadaveric femora were either instrumented with a DHS-Blade or a Dynamic Hip Screw. Osteotomies were created using a custom-made saw-guide. Cyclic loading was performed by introducing in vivo measured load-trajectories to the femoral head. Starting at 1500 N, the load was step-wise increased until failure of the construct. Radiographs were taken in 5000 cycles increments to identify onset of femoral head migration with respect to the implant. A survival analysis was performed on the cycles to onset of migration. A paired \( t \)-test was carried out on the displacements of the femoral head relative to the shaft as determined by optical motion tracking.

**Findings:** One hundred percent migrations occurred for the Dynamic Hip Screw compared to 50% for the DHS-Blade. The survival probability in terms of implant anchorage was found higher for the blade (\( P = 0.023 \)). However, significant higher deformation of the repair construct was observed for the DHS-Blade (\( P = 0.004 \)).

**Interpretation:** The study showed superior implant anchorage of the DHS-Blade compared to the DHS, which might reduce the cut-out risk. Nevertheless, the blade allowed higher deformation of the femur mainly resulting in shortening of the neck, which might be due to a systematic loss of fracture reduction.

**1. Introduction**

Femoral neck fractures are one of the most common traumatic injuries seen in the elderly, and the numbers are on the up rise among our aging population (Alfram, 1964; Melton et al., 1982; Boyce and Vessey, 1985). In 2005 14% of 2 million fractures in the United States were related to the hip and caused 72% of total costs for fracture treatment (Burge et al., 2007). Despite continuous improvement in the sectors of geriatric care and orthopaedic surgery, the failure rate that accompanies fractures of the proximal femur after treatment is still significant (Lowell, 1980; American Academy of Orthopedic Surgeons, 1993; Bonnaire et al., 2005).

Besides intramedullary nail constructs, today’s preferred methods of internal fixation are either three cannulated bone screws, the Angled Blade Plate or the Dynamic Hip Screw (DHS) with side-plate (Swiontkowski et al., 1987; Sommers et al., 2004). Intramedullary nails and DHS can yield success rates of over 95% (Mad-
Implant head. The shaft is compatible with the standard DHS side-plate. Unlike the DHS-Screw, the DHS-Blade is driven into the cancellous bone by hammer strikes. Free rotation of the head can be blocked after instrumentation.

The aim of the study was to analyse the implant anchorage in the femoral head of the DHS-Blade compared to the conventional DHS-Screw under cyclic loading in an unstable femoral neck fracture model. Moreover the biomechanical stability of the proximal femur repair construct was investigated in terms of displacement of the femoral head with respect to the shaft. We hypothesized the DHS-Blade performing equal or superior to the DHS-Screw with respect to implant anchorage.

2. Methods

Ten pairs of fresh frozen (−20 °C) human cadaveric femora were obtained from the Department of Pathology of the Kantonsspital Basel, Switzerland. BMD was measured in the femoral head by peripheral quantitative computed-tomography (pQCT) using a Densiscan 1000 (SCANCO Medical AG, Bassersdorf, Switzerland). The femora were assigned to two homogeneous groups: (1) DHS-Screw group and (2) DHS-Blade group. To account for variations in BMD between left and right bones of a pair, an iterative routine (Matlab, Mathworks Inc., Natick, USA) was established to obtain the optimal permutation based on the criteria: (a) pairwise assignment of the bones; (b) BMD mean and variance equal for both groups; (c) number of left and right bones equal for both groups.

Before instrumentation, all specimens were thawed at room temperature and stripped of soft tissue. All operations were performed by a single experienced surgeon under fluoroscopic guidance to ensure centered implant positioning in anteroposterior and mediolateral direction. Bones of a pair were treated simultaneously to ensure comparable implant placement. Standard tool-sets were used and the implantation manuals were followed including guide wire placement (2.5 mm Kirschner wire) and predrilling. In case of DHS-Screw samples the bore was tapped prior screw insertion. Implant length was determined individually. The tip-apex distance was set to 10 mm under fluoroscopic guidance in anteroposterior direction. A 135° 4-hole DHS side-plate was secured to the bone with four 4.5 mm cortex-screws. All DHS-Blades were arrested against rotation of the head with a 1.5 Nm torque screwdriver engaging the interlocking mechanism of the implant. Material was stainless steel for all implants and screws.

After instrumentation standardized osteotomies were created by using a custom-made saw-guide (Fig. 1). The device was fastened to the side-plate and enabled simulation of an unstable 31-B2 fracture. Besides setting of the cutting position along the femoral neck axis, the saw-guide could be adjusted in anteroposterior direction to account for left and right bones. The blade of an oscillating saw (0.9 mm thickness) was guided in circular slots around the bone. Initially, the specimens were cut in the center of the femoral neck at an angle of 20° with respect to the shaft axis. Thereafter, a 30° distal wedge and a 15° posterior wedge were removed to eliminate posteriori medial support (Fig. 1). All femurs were shortened distally to a total length of 40 cm. Six centimeter of the distal end were embedded in Polymethylmethacrylate (PMMA, Beracryl, W. Troller AG, Fulenbach, Switzerland).

For mechanical testing the specimens were placed in a servohydraulic testing machine (MTS Bionix 858, MTS, Eden Prairie, USA) equipped with a 10 kN loadcell. The femora were physiologically oriented at 25° lateral tilt with respect to the vertical line. A 9° varus angulation and an angle of 16° of the resulting hip contact force \( F_H \) with respect to the craniocaudal direction was simulated (Bergmann et al., 2001). The function of the iliotibial band and of an abductor muscle group (musculus gluteus medius and minimus) were simulated by a bracing attached to the greater trochanter, resulting in a passive trochanter force \( F_T \) at 25° to the craniocaudal direction (Fig. 2). The head of the femur was loaded via a spherical shaped greased metal shell. Gliding of the shell perpendicular to the direction of the force was allowed to ensure a free center of rotation. The distal embedding of the femur was attached to a cardanic joint. In order to simulate an alternating load during walking a loading trajectory measured in vivo in the human hip was transferred to the femoral head. The curve was provided by Bergmann et al. (2001) representing the average hip joint contact force of five patients during fast walking. Cyclic compression testing was carried out at 2 Hz in load control. Starting at 1500 N...
the peak load was increased by 500 N every 5000 cycles (von der Linden et al., 2006). The load valley was kept constant at 200 N throughout the experiment. The test was stopped when the machine’s actuator exceeded a displacement of 20 mm.

Digital radiographic images (Siemens Mobilett XP, Siemens Medical Solutions AG, Dietikon, Switzerland) were taken with the specimen placed in the testing apparatus prior testing (initial image), in 5000 cycle increments and in case of failure of the construct (20 mm actuator displacement). All radiographs showed anteroposterior orientation and were captured at minimum load (200 N). Radiographic settings and placement of the X-ray device were kept constant during the tests. In order to determine migration of the femoral head with respect to the implant, all radiographic images of a test were reoriented regarding to the initial image by adapting the implant silhouettes by means of image processing software (Photoshop, Adobe Systems Inc., San Jose, USA). The displacement of the tip of a reference screw, inserted at the medial aspect of the femoral head (Fig. 4), was identified for all radiographs with respect to the initial image using a software caliper. A displacement of \( P > 0.5 \text{ mm} \) was considered as onset of head migration. The corresponding number of test-cycles was identified for statistical evaluation.

The overall performance of the repair construct in terms of displacement of the femoral head with respect to the shaft was investigated by means of optical 3D motion tracking. Five Qualisys ProReflex MCU digital cameras (Qualisys AB, Gothenburg, Sweden) were used for the measurements. Computation of the relative motion was based on the coordinates of retro-reflective marker-sets attached to the femoral head (A) and the femoral shaft (B) (Fig. 2). Two collinear markers attached to the implant (C) were used to determine the orientation of the implant-axis defining the x-axis of the global coordinate system (COS) rigidly linked to the shaft marker-set B. The y-axis of the global COS was located in the plane spanned by the femoral neck and shaft axes. The fragment COS rigidly bonded to the femoral head fragment was established from marker-set A. The origin of both coordinate systems was defined to be at the tip of the implant in untested condition (Fig. 5). Displacement of the femoral head with respect to the shaft was determined throughout the test at 50 Hz. Plastic deformation (at minimum load) at the beginning of the test (after 200 cycles) and after 10,000 test-cycles was computed for all specimens.

2.1. Statistical analysis

To assess differences between groups a survival analysis (Cox-regression) was performed on the number of cycles to onset of head migration considering BMD as covariate. Additionally, we carried out a Fisher’s Exact Test in order to analyze the head migration rate. The tests were performed one-tailed according to the study hypothesis. A paired \( t \)-test was carried out on the plastic deformation of the repair construct after 200 and 10,000 cycles. Furthermore, we determined Pearson’s correlation coefficient \( R \) with respect to plastic deformation after 10,000 cycles and BMD. Level of significance was \( \alpha = 0.05 \). The software package SPSS (SPSS Inc., Chicago, IL, USA) was used for statistical evaluations.

3. Results

During the test period, all 10 DHS-Screw samples showed femoral head migration (100%) compared to five observed migrations in the DHS-Blade group (50%). This difference in migration rate was significant \( (P = 0.016) \). When dividing the DHS-Blade group into two subgroups of five samples with lower and five with higher bone density, two of five DHS-Blade migrations occurred at lower BMD, three of five happened at higher BMD. A survival analysis on the cycles to onset of head migration including all specimens revealed a significant advantage of the DHS-Blade \( (P = 0.023, \text{power} = 0.74) \); Fig. 3). Fig. 4 shows X-rays of an instrumented bone pair before testing (A1, B1) and after 10,000 cycles (A2, B2). The DHS-Blade specimen did not reflect any sign of migration (B2) whereas a varus-tipping of the femoral head is clearly visible in the contra-lateral DHS-Screw specimen (A2).

For all specimens 20 mm actuator displacement was exceeded between 10,100 and 23,900 cycles. The measured displacement...
of the femoral head relative to the shaft mainly represented a shortening of the femoral neck. This deformation was observed for all specimens. At the beginning of the test (200 cycles) the DHS-Blade samples showed significant larger displacement magnitudes yielding a mean of 8.65 mm (SD 2.14) compared to 6.20 mm (SD 1.68) for the DHS-Screw samples ($P = 0.004$; Fig. 5). Furthermore, the direction of the displacements with respect to the implant-axis, projected into the anteroposterior plane, was significantly different between groups [DHS-Blade: mean 31.6° (SD 8.6); DHS-Screw: mean 43.5° (SD 11.2); $P = 0.001$]. After
10,000 cycles, average displacements of 10.96 mm (SD 2.49) were found for the DHS-Blade specimens compared to 8.96 mm (SD 3.24) for the DHS-Screw specimens. This difference was still significant between groups (P = 0.026).

Singh et al. (2005) measured a population of human femora from highly osteoporotic to healthy bones with pQCT and reported a BMD span of 0.2–0.6 g/cm³ in the femoral head. Here, BMD varied between 0.29 and 0.45 g/cm³. The mean BMD was 0.38 g/cm³ (SD 0.057) for the DHS-Blade group and 0.38 g/cm³ (SD 0.06) for the DHS-Screw group, respectively. A significant, negative correlation was observed between BMD and the displacements of the femoral head after 10,000 test-cycles for the DHS-Blade group (R = 0.809, P = 0.005). The correlation obtained for the DHS-Screw group was not significant (R = 0.538, P = 0.109).

4. Discussion

Since cut-out still remains one of the major clinical challenges in the field of osteoporotic proximal femur fractures (Al-yassari et al., 2002; Audige et al., 2003; Bonnaire et al., 2007), remarkable efforts are made in developing superior treatment concepts. Besides upcoming cement augmentation (Heini et al., 2004; Szpalski et al., 2004; Mattsson et al., 2005; von der Linden et al., 2006) and investigations on mechanically sensitive parameters like the tip-apex distance (Baumgaertner and Solberg, 1997), implant development and design remains a major approach (Giannoudis and Schneider, 2006). The DHS-Blade was introduced as advancement of the established but still optimizable DHS concept. By driving the blade into the femoral head, the surrounding trabecular structure might undergo a volumetric compaction. This consolidation of the material in combination with the visco-elastic behaviour of cancellous bone (Green et al., 1999; Kold et al., 2005) might enhances the implant anchorage. A controversial theory describes a potential loss of implant fixation due to trabecular micro fracturing (Stulberg et al., 1991). The role of bone compaction is therefore not entirely clarified. Another design advantage of the DHS-Blade could be the increased implant surface projected orthogonally to the direction of the force, resulting in superior load distribution and stress reduction at the bone-implant interface. Moreover, in contrast to the DHS-Screw, the DHS-Blade does not exhibit sharp edges that can cut through the bone structure in the direction of the applied force. In agreement with these assumptions, our in vitro experiment shows superior implant anchorage of the DHS-Blade under cyclic loading. Further clinical investigation is, however, necessary to evaluate the performance of the fixation in an in vivo context. The provided bone stock was considered as population of poor to good bone quality with regard to Singh et al. (2005). Surprisingly, the observed femoral head migrations in the DHS-Blade group were evenly distributed over the full range of available bone densities. Emphasis on the osteoporotic samples could have been expected. The mechanisms of bone compaction might play a role here, but follow-up investigations are required. However, this finding supports the use of the blade in osteoporotic bone. Onset of femoral head migration with respect to the implant, considered as preliminary stage of cut-out (Sommers et al., 2004; Stoffel et al., 2007), was determined by radiographic evaluation in 5000 cycle increments. This comparatively low temporal resolution was found sufficient to assess differences between implant groups as proved by a statistical power-analysis. However, shorten the detection intervals for future investigations could improve monitoring of the migration process. The method for quantifying the femoral head migration based on X-rays was preferred over e.g. an optical motion tracking approach since the bone-implant interface is directly assessable. Nevertheless, image processing is still based on visual judgement to a certain extend. A fully automated procedure is thinkable and might be implemented in the future. A comparatively low failure criterion (0.5 mm) was chosen to identify the onset of head migration. We provoked 100% migrations for the DHS-Screw and 50% migrations for the DHS-Blade caused by the extreme conditions of the utilized model. The created osteotomy was highly unstable due to removal of posterior and distal support leading to increased load transfer via the implant. Furthermore, the loading regime was raised stepwise from initially 1.8 times body weight to a maximum of approx. 4 times body weight according to the protocol of von der Linden et al. (2006) simulating full weight bearing in the direct postoperative phase. The observed varus-tipping of the femoral head is frequently seen in clinics. Therefore, the model, including simulated abductor muscle group and in vivo measured joint reaction force, is deemed appropriate, even though, the muscle-force remains passive and the directions of the forces were kept constant during the simulated gait cycle. In this study we investigated the performance of DHS-Screw and Blade implanted according to the surgical guidelines. Numerous complications, however, occur due to poor implant placement (Baumgaertner and Solberg, 1997). Follow-up studies are required to investigate the cut-out resistance of the DHS-Blade with regard to misplacement in mediolateral, antero-posterior and cranio-caudal direction.

Besides investigating the bone-implant interface, the study evaluated the overall performance of the proximal femur repair constructs. Displacement of the head relative to the shaft was measured by means of optical motion tracking. As the DHS concept allows dynamic compression of the fracture site, the major portion of the found displacements represented sintering of the fracture resulting in significant shortening of the femoral neck. This effect correlated with the BMD of the specimens. The impact of neck shortening is discussed controversially. Anatomically, the truncated moment arm leads to higher forces the abductors have to generate (Zlowodzki et al., 2007). Clinical relevance of an intact lever arm for the abductor musculature is unquestioned (McGrory et al., 1995; Sakalkale et al., 2001; Charles et al., 2005). On the other hand, increased neck shortening might indicate an improved load sharing situation, in favour of the highly stressed bone-implant interface. Here, implant-shafts and side-plates as well as the orientation of the implants with respect to the direction of the force were identical for both study-groups. Hence, an improved sliding capacity for one of the investigated implants seems unlikely. However, neck shortening was found higher for the DHS-Blade samples as indicated by a significant higher displacement magnitude as well as by the displacement vectors approaching the direction of the neck axis. A considerable portion of the observed deformation did already occur after 200 test-cycles. The achieved fracture reduction might be an attempt to explain this phenomenon. Stresses in the bone structure, induced during insertion of the blade, were relieved when creating the osteotomy. Inhomogeneity of the trabecular structure in the femoral head might cause deflection of the implant due to high insertion momenta, in contrast to quasi-static screwing of the conventional DHS. The resulting malalignment of the fragments may lead to early incision of the cortices (Fig. 6). Furthermore, the healing process could be altered by the reduced cortical contact area at the fracture site. However, this theory, based on our findings in a laboratory environment, requires further investigation.

4.1. Conclusion

One of the most challenging problems in the treatment of femoral neck fractures is the occurrence of implant cut-out. The DHS-Blade was designed to overcome this exact problem in poor bone quality. The study compared the biomechanical performance of
the DHS-Blade and the DHS-Screw under cyclic loading in an unstable neck fracture model. Even though the DHS-Blade revealed increased neck shortening, probably due to a systematic loss of fracture reduction, a significantly enhanced cut-out resistance became obvious. Since the conventional DHS-Screw seems established in good bone stock, the DHS-Blade appears to be a promising alternative in osteoporotic fracture treatment in order to prevent cut-out.

References


Paper p20

Quantification of cancellous bone-compaction due to DHS® Blade insertion and influence upon cut-out resistance

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Abstract
Background: Compaction of cancellous bone is believed to prevent cut-out. This in vitro study quantified the compaction in the femoral head due to insertion of a dynamic hip screw-blade with and without predrilling and investigated the resulting implant anchorage under cyclic loading.

Methods: Eight pairs of human cadaveric femoral heads were instrumented with a dynamic hip screw-blade made of Polyetheretherketon. Pairwise instrumentation was performed either with or without predrilling the specimens. CT scanning was performed before and after implantation, to measure bone-compaction. Subsequently the implant was removed and a third scan was performed to analyze the relaxation of the bone structure. Commercial implants were reinserted and the specimens were cyclically loaded until onset of cut-out occurred. The bone-implant interface was monitored by means of fluoroscopic imaging throughout the experiment. Paired t-tests were performed to identify differences regarding compaction, relaxation and cycles to failure.

Findings: Bone density in the surrounding of the implant increased about 30% for the non-predrilled and 20% for the predrilled group when inserting the implant. After implant removal the predrilled specimens fully relaxed; the non-predrilled group showed about 10% plastic deformation. No differences were found regarding cycles to failure (P = 0.32).

Interpretation: Significant bone-compaction due to blade insertion was verified. Even though compaction was lower when predrilling the specimens, mainly elastic deformation was present, which is believed to primarily enhance the implant anchorage. Cyclic loading tests confirmed this thesis. The importance of the implantation technique with regard to predrilling is therefore decreased.

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1. Introduction

Due to aging of the population, osteoporosis is an increasingly frequent pathology (Tarantino et al., 2007). More than two million incident fractures resulted in costs of $17 billion for 2005 in the United States. The most devastating complication of osteoporosis is hip fracture (Majumdar, 2008). With a total incidence of 14% of all osteoporotic fractures, hip fractures caused 72% of the total costs (Burge et al., 2007).

Post-operative complications accompanying osteosynthetic treatment of proximal femur fractures become more and more significant in the face of decreasing bone quality (American Academy of Orthopedic Surgeons, 1993; Lowell, 1980; Bonnaire et al., 2005). Implant cut-out, which describes a loss of implant anchorage in the cancellous bone, occurs in 1–6% of the cases when using screw-based fixation like the dynamic hip screw (DHS) or the proximal femur nail (PFN) (Gardner et al., 2004). Helical or spiral blade concepts have been shown to biomechanically improve the cut-out resistance (Strauss et al., 2006; Windolf et al., 2008). The process behind, is not entirely described and is controversially discussed in the literature. The compaction of cancellous bone, which occurs when inserting a blade implant, is believed to play a major role (Channer et al., 1996; Chareancholvanich et al., 2002; Green et al., 1999) due to visco-elastic behaviour of compacted bone (Kold et al., 2005b). On the other hand, compression of cancellous bone could lead to micro-fracturing and brakeage of trabeculae. This may result in non-vital bone in the surrounding of the implant and hence, to loss of fixation (Kold et al., 2005a). To the knowledge of the authors, bone-compaction as caused by blade implant application has not been quantified yet. The DHS Blade (Synthes Inc., Bettlach, Switzerland) was introduced recently as advancement of the conventional DHS for treatment of osteoporotic fractures. The implant comprises a helical shaped head, designed to

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maximize bone-compaction. According to the surgical guidelines of the DHS Blade, it is recommended to predrill prior implantation in order to prevent complications. On the other hand, the removal of bone due to predrilling might reduce the compaction effect and hence, could influence the implant anchorage. In poor bone stock, omitting predrilling might be an option to improve the fixation.

The aim of this study was: (1) to quantify the compaction of cancellous bone in human femoral heads when inserting a DHS Blade; (2) to analyze the morphological effect on the trabecular structure (destructive plastic deformation vs. non-destructive elastic deformation) by investigating the regeneration of the structure after implant removal; (3) to analyze the potential of bone-compaction for enhancement of implant fixation under cyclic loading by comparing predrilled and non-predrilled instrumentation.

2. Methods

Eight pairs of fresh frozen (−20 °C) human cadaveric proximal femora were used in this study. All femoral heads were cut 50 mm lateral to the femoral apex at 45° to the lateral cortex of the femoral shaft. Bone pairs were randomly assigned to two study groups: (1) predrilled; (2) non-predrilled. Equal number of left and right bones was ensured for both groups.

2.1. Computed-tomography (CT) measurements

A sequence of three CT scans (peripheral quantitative computed-tomography) was performed for each specimen: (1) prior implant insertion; (2) after implant insertion; (3) after implant removal. An Xtreme-CT (Scanco Medical AG, Bassersdorf, Switzerland) with a spatial resolution of 82 μm was used. Prior scanning, each specimen was instrumented with a Kirschner-wire in anteroposterior direction close to the femoral apex. A PEEK-cone (Polyetheretherketon) was inserted into the Adams’ arc close to the sawing surface. Kirschner-wire and PEEK-cone established a three-point support to enable reproducible placement of the specimen with respect to the scanner (Fig. 1). Starting at 10 mm distance from the femoral apex, a total length of 27.1 mm was scanned for each specimen setting the slice-increment to 1.23 mm (23 slices total). After the first scan was performed, a 2.5 mm guide-wire was inserted perpendicular to the sawing surface at the geometric center of the femoral head. The specimens of the first group were predrilled using a conventional DHS Blade drill bit until a distance of the drill tip to the femoral apex of 12 mm was reached (Fig. 2). To avoid peri-implant radiographic artifacts, the helical shaped head of the DHS Blade was machined from PEEK following the exact dimensions of the implant. The PEEK-blade was then pressed into the cancellous bone in a quasi static manner at 10 mm/min using an electro-mechanical testing apparatus (Instron 5866, Instron Inc., Norwood, USA) until a tip-apex distance of 12 mm was reached. Free rotation of the blade was ensured during insertion. After removing the guide-wire, scan-series 2 was performed in identical orientation of the specimens. The PEEK-blades were removed by means of the testing machine and the specimens were stored at room temperature for 10 h to ensure complete relaxation of the trabecular structure. All specimens were again scanned in identical orientation. Using a custom-made software routine (Matlab, Mathworks Inc., Natick, USA), bone mineral densities (BMD) were computed from the CT raw data for each specimen and scan within an area confined by a cylinder (diameter 14 mm) aligned to the implant axis and by the outer contour of the implant. Identical masking was applied to the corresponding CT slices of scans 1, 2 and 3 (Fig. 3).

2.2. Mechanical testing

For investigating the purchase of the implant, stainless steel DHS Blades (length 100 mm) were reinserted into the bones under defined, displacement controlled conditions using the Instron testing apparatus. The tip-apex distance was decreased to 10 mm to provide additional anchorage to the implant. The specimens were then placed in a servo-hydraulic testing machine (MTS Bionix 858, MTS, Eden Prairie, USA) equipped with a 4 kN load cell. The implant shaft was constrained at 20° to the machine axis according to the main direction of the hip contact force as measured by Bergmann et al. (2001). For transferring the load to the femoral head a polymer shell was used. A cross-table was placed between machine actuator and shell to ensure a free center of rotation of the femoral head (Fig. 4). In order to simulate an alternating load during walking an in vivo measured loading trajectory (Bergmann et al., 2001) was used instead of a sinusoidal curve. Cyclic loading was performed at 2 Hz. Starting at 700 N compression force, the load was monotonically increased at 0.08 N/cycle until an actuator displacement of 8 mm was reached. The load-valley was maintained at 100 N throughout the test. At increments of 250 cycles, fluoroscopic imaging was performed in anteroposterior direction using an image intensifier (Siemens Arcadis Varic, Siemens Medical Solutions AG, Munich, Germany). Radiographs were taken at minimum load with the specimen placed in the testing apparatus to monitor the implant anchorage throughout the experiment. The position of the image intensifier was maintained constant with respect to the implant. The migration of the implant relative to the femoral head in direction of the implant axis was determined from the radiographs by means of image processing algorithms (Matlab, Image Processing Toolbox). The projection of the cutting edge of the head and a parallel edge of the fixture were identified using an edge detection method. Reference lines were fitted to the edges by linear regression of all identified pixels. The distance d between these lines at a point parallel to the implant axis was computed for all X-rays of a test (Fig. 5). Radiographs were calibrated using the implant diameter as reference dimension d₀. A displacement of 0.5 mm with respect to the initial X-ray was suggested as onset of implant migration (Windolf et al., 2008). The number of cycles until onset of migration was identified.

![Fig. 1. Fixture for repetitive CT scanning. A three-point support of the femoral head was established by a Kirschner-wire and a PEEK-cone. The position of the cone could be adjusted to align scan-axis and implant shaft axis. A total length of 27.1 mm was scanned starting at 10 mm from the apex of the femoral head.](image-url)
2.3. Statistical evaluation

Differences between CT scans 1 and 2 (bone-compaction), between scans 2 and 3 (bone relaxation) and between scans 1 and 3 (plastic deformation) were investigated separately for the predrilled and non-predrilled group by means of an ANOVA (analysis of variance) for repeated measures. P-values were adjusted according to Bonferroni for multiple comparisons. For both groups Pearson’s correlation coefficient $R$ was calculated to identify correlations between compaction and initial BMD of the specimen (scan 1). Furthermore, paired $t$-tests were carried out to identify differences between predrilled and non-predrilled groups regarding bone-compaction and plastic deformation. To investigate the BMD distribution along the implant axis, the area around the implant was divided into three zones: (1) implant tip area; (2) implant body; and (3) run-out area (Fig. 6). Differences in bone-compaction between zones were investigated using a one-way ANOVA with Bonferroni post-hoc correction. A paired t-test was used to compare predrilled and non-predrilled groups regarding cycles to onset of implant migration. The software package SPSS 14.0 (SPSS Inc., Chicago, IL, USA) was used for all statistical evaluations. Level of significance was $\alpha = 0.05$.

3. Results

As determined from CT scans 1, BMD ranged between 0.29 and 0.72 g/cm$^3$ for the predrilled group and between 0.28 and 0.70 g/cm$^3$ for the non-predrilled group. After implanting the PEEK-blade, the mean BMD increased from 0.42 g/cm$^3$ (SD 0.13) to 0.50 g/cm$^3$ (SD 0.14) for the predrilled group and from 0.43 g/cm$^3$ (SD 0.14) to 0.54 g/cm$^3$ (SD 0.14) for the non-predrilled group (Fig. 3). This compaction of the cancellous bone was significant for both groups (both $P < 0.001$). The non-predrilled group
revealed significantly higher compaction compared to the predrilled group \((P < 0.001)\). After removal of the implant, the BMD decreased to 0.43 g/cm\(^3\) (SD 0.15) for the predrilled group and to 0.47 g/cm\(^3\) (SD 0.15) for the non-predrilled group. This relaxation effect (scan 3 compared to scan 2) was significant for both groups (both \(P < 0.001\)). The BMD after implant removal (scan 3) compared to the intact bone (scan 1) was significantly higher for the non-predrilled group \((P = 0.004)\). No difference was found for the predrilled specimens \((P = 0.79)\). For both groups the amount of compaction due to implant insertion did not correlate with the initial BMD of the specimen (scan 1; predrilled: \(R = 0.075, P = 0.86\); non-predrilled: \(R = 0.236, P = 0.57\)). For the non-predrilled group, the compaction due to implant insertion was significantly higher at the implant tip compared to implant body and run-out area (both \(P < 0.005\)). For the predrilled specimens no differences were found between zones (all \(P > 0.05\)) (Fig. 6). When cyclically loading the constructs, all specimens failed due to migration of the head in direction of the implant axis (Fig. 5). Cycles to onset of implant migration did not reveal any differences between groups (predrilled: mean 10906 cycles (SD 9701); non-predrilled: mean 12781 cycles (SD 10538); and \(P = 0.32\)).

4. Discussion

The use of blade implants in clinics is gaining acceptance since potentials for osteoporotic fracture fixation became obvious. Clinical (Simmermacher et al., 2008) as well as biomechanical studies (Strauss et al., 2006) have shown promising performance of blade concepts. A biomechanical comparison of conventional DHS and DHS Blade reflected 100% cut-outs of the tested DHS specimens due to extreme conditions of the utilized model. In contrast, only half of the DHS Blade samples failed due to cut-out (Windolf et al., 2008). The underlying mechanism for improved purchase of the blade implant is unclear but bone-compaction is deemed to play a major role (Windolf et al., 2008). In contrast to the thread of the conventional DHS, the blade is likely to involve a certain densification of bone due to its helical design. To our knowledge neither screw- nor blade-compaction has been measured yet. In a first step, this in vitro study quantified the compaction of cancellous bone surrounding a DHS Blade after predrilled and non-predrilled instrumentation by means of repetitive CT measurements. We observed significant increase of bone mineral density due to...

Fig. 4. Setup for mechanical testing. The isolated head was cyclically loaded at 20° to the vertical line. The load was monotonically increased starting at 700 N until onset of cut-out occurred. The load-valley was kept constant at 100 N.

Fig. 5. Monitoring of the bone-implant interface during mechanical testing. Radiographic imaging was performed in 250 cycle increments. X-rays of a specimen at the beginning of the test (A) and after failure (B). All specimens of the experiment cut through the cancellous bone and migrated along the implant axis. The distance between cutting edge of the head and fixture was measured for each X-ray. \(d_B - d_A > 0.5 \text{ mm}\) was considered as onset of migration. All X-rays were calibrated using the known reference dimension \(d_R\).

Fig. 6. Distribution of bone-compaction along the implant axis for predrilled and non-predrilled groups. Curves represent mean BMD of a group. For the non-predrilled group compaction was significantly higher at the implant tip compared to other zones. For the predrilled specimens the compaction was evenly distributed.
DHS Blade insertion of about 30%. When predrilling, the bone-compaction was significantly lower (about 20%) due to removal of bone content. The degree of compaction was found independent from the specimens’ bone quality since no correlation between compaction and BMD was observed. After implant removal the bone structure tended to relax but in case of non-predrilled instrumentation the state before implantation could not be recovered (about 10% remaining deformation). This indicates that fracturing of the trabeculae and therefore destruction of the meshwork might have occurred to a certain extent. On the other hand, the observed relaxation of the bone structure indicates that at least a portion of the loaded trabeculae underwent deformation in the elastic range. The “spring back effect” of cancellous bone, already observed by Kold et al. (2003), is believed to enhance the implant purchase due to elastic restoring forces. Since the actual relaxation velocity of trabeculae following compaction is unknown, a comparatively long relaxation period (10 h) was chosen to ensure full expansion of the structure. In the predrilled group, showing lower bone-compaction, beneficial elastic deformation seems to be predominant. For the non-predrilled group, a significant higher compaction was observed at the tip of the implant compared to other regions. This indicates a material transport towards the implant tip during blade insertion. In the direct post operative phase, considered as most critical for cut-out, these loose fragments are unlikely to contribute to a superior implant purchase. Later on, bone healing and remodeling might integrate the bone chips into a solid union for enhancement of the implant fixation. Nevertheless, the blood supply, considered as driving force for healing, may be disturbed by bone-compaction to a certain extent. Hence, not only from the mechanical but also from a biological perspective, an extensive compaction of bone may not necessarily lead to a superior load bearing of the structure. However, further investigations with respect to latter thoughts are strongly required. To the knowledge of the authors, no evidence regarding biological impact of bone-compaction has been reported in the literature.

In agreement with latter hypothesis, cyclic loading until failure of the bone-implant interface did not reflect differences between predrilled and non-predrilled specimens. Even though, the used setup for mechanical testing represents only a rough approximation to reality, an isolated head model was deemed to be most practical (Suhm et al., 2007; von der Linden et al., 2006). The setup mimicked a highly unstable femoral neck fracture and at the same time simulated a blocked sliding mechanism of the implant. This scenario is considered as worst case for the bone-implant interface. The setup allowed direct access to the interface by radiographic monitoring. Parameters such as screw-sluiding, femur bending or stress shielding at the fracture gap could be excluded. Loading of the hip was modeled using an in vivo measured load pattern with physiological orientation of the force. To account for the unstable situation of the head and variations in bone density, the loading trajectory of Bergmann et al. was downscaled from 230–30% body weight (average loading–unloading of the hip during gait) to approximately 100–15% body weight (700–100 N) at the beginning of the test. As determined from pilot experiments, a monotonic increase of the load of 0.08 N/cycle appeared appropriate to achieve adequate test duration for the available population of specimens until failure occurred. In all cases, the implant migrated along its axis towards the apex. This mode of failure is frequently seen in clinics accompanying various types of fixations of the proximal femur. Here, it might be due to sharp edges of the blade on its face side in combination with the absent load sharing at the fracture site.

Compaction was quantified by means of CT scanning. BMD was evaluated at three time points in a cylinder confining the implant with exclusion of the implant volume. To assure reproducible orientation of the specimen with respect to the scanner coordinate system, a special holder with three-point support of the femoral head was used. Repeated measurements of an intact control specimen revealed an accuracy of 0.5% for determining the BMD. This was suggested to be sufficient for the measuring task. In order to avoid radiographic artifacts, making a quantitative evaluation of BMD based on CT data impossible, a PEEK-blade was used, showing the identical design of the commercial implant. However, surface properties, grading of the edges, elastic modulus of the material, etc. differ from the conventional implant. Moreover, in contrast to the clinical procedure the implant was inserted in a quasi static manner by using a mechanical test apparatus. This method was preferred in order to standardize the insertion. However, influence of the mentioned factors on the compaction process cannot be entirely excluded. The PEEK implant was removed after measuring the compaction, in order to investigate the relaxation of the bone structure. A commercial implant was reinserted and anchored by reducing the tip-apex distance from 12 to 10 mm. Nevertheless, it is not clarified to what extent implant removal and reinsertion alters the fixation. With respect to the mentioned limitations of the study, the presented results have to be viewed on a critical note.

5. Conclusion

This in vitro study revealed significant amount of bone-compaction in the femoral head as result of DHS Blade application. The compaction was considerably lower when predrilling the specimens, but the bone structure fully regenerated after implant removal. In contrast, the non-predrilled specimens revealed partly plastic deformation due to compaction. No difference in cut-out resistance was found under cyclic loading. We conclude that maximizing the bone content around the implant forgoing predrilling does not necessarily enhance the cut-out resistance, since mainly elastic deformation seems to contribute to the implant anchorage. Importance of the implantation technique with or without predrilling is therefore decreased.

References


