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Soziale, demografische und organisatorische Evaluation von Mensch-Technik-Interaktion in der medizinischen und pflegerischen Versorgung

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Abkürzungsverzeichnis

AT	Assistive Technologien/ Assistive technology
BPMN	Business Process Model and Notation[1]
CC BY 4.0	Creative Commons Attribution License BY 4.0 (BY: Nur Namensnennung)
CFS	Clinical Frailty Scale (Klinische Frailty Skala)
CLEM	Confocal laser endomicroscopy
COPM	Canadian Occupational Performance Measure[1]
DiGA	Digitale Gesundheitsanwendungen
DigiG	Digital-Gesetz (Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens)
ePA	Elektronische Patientenakte
GDNG	Gesundheitsdatennutzungsgesetz (Gesetz zur verbesserten Nutzung von Gesundheitsdaten)
HTI	Human-technology-interaction
IADL	Instrumental activities of daily living (Instrumentelle Aktivitäten des täglichen Lebens)
IKT	Informations- und Kommunikationstechnologie
KI	Künstliche Intelligenz
KLEM	Konfokale Laser-Endomikroskopie
MTI	Mensch-Technik-Interaktion
NA	Not available (nicht vorhanden)
QUEST	Quebec User Evaluation of Satisfaction with Assistive Technology[1]
SD	Standard deviation (Standardabweichung)
TUI	Technology Usage Inventory[1]

[1] Der englische Begriff wird auch im deutschen Sprachraum verwendet

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1. Hinführung zum Thema

1.1 Mensch-Technik-Interaktion in der Gesundheitsversorgung

Veränderungen werden meist durch den Wunsch nach Verbesserung angetrieben, dies gilt auch bei der Einführung und Nutzung neuer Technologien. Ein primäres Ziel von technischer Veränderung ist es, den status-quo zu verbessern, z.B. indem die Nutzenden bei der Erfüllung ihrer Aufgaben unterstützt werden. Um jedoch dem Wunsch nach Verbesserung nachzukommen, sollte Technik nicht nur effektiv und effizient sein, sondern muss auch an die Bedürfnisse und die Situation der Nutzerinnen und Nutzer angepasst sein. Es ist mindestens genauso wichtig, dass eine Software nutzerfreundlich ist und die Arbeit für die Anwenderinnen und Anwender erleichtert, als dass sie dabei hilft, Prozesse zu verschlanken oder Gewinne zu maximieren. Neben Effektivität und Effizienz gibt es eine Reihe von Facetten, die für einen erfolgreichen Einsatz von Technik relevant sind. Hierzu gehören neben individuellen Vorlieben und Hintergründen unter anderem Nutzerfreundlichkeit, Bedienbarkeit, Barrierefreiheit, nahtlose Einbettung in bestehende Abläufe, Kosten und Datenschutz [1]. Je nach Technologie, Personengruppe und Situation können einzelne Aspekte mehr oder weniger relevant sein. In diesem Zusammenhang spricht man von Mensch-Technik-Interaktion (MTI), also der Wechselwirkung zwischen Menschen und Technologie [2].

Die Gesundheitsversorgung ist einer der Bereiche, in dem besonders große Hoffnungen in die Digitalisierung gesteckt werden [3-5]. Die Einsatzfelder sind breit und reichen von der ärztlichen Diagnose und Behandlung in Arztpraxen und Kliniken, über die pflegerische und therapeutische Betreuung (ambulant oder stationär) bis hin zur häuslichen Pflege, die oft auch im privaten Umfeld geleistet wird. Seien es die digitale Dokumentation oder online-Terminbuchung in niedergelassenen Arztpraxen [6], roboter-gestützte Operationen oder Frührehabilitation in Kliniken [7, 8] oder der Einsatz von Sensorik oder künstlicher Intelligenz (KI) zur Warnung vor nächtlichen Stürzen in Pflegeheimen oder im häuslichen Umfeld [9] – es gibt viele Beispiele für die Nutzung von Technik zur Unterstützung der medizinischen und pflegerischen Versorgung.

Die Gesundheitsversorgung ist gekennzeichnet durch eine hohe Multidisziplinarität und Diversität. Beteiligte Personen sind nicht nur Fachkräfte verschiedener Disziplinen, sondern auch die Patientinnen und Patienten sowie deren Angehörige. Daraus resultieren besondere Herausforderungen für die MTI. Welche Aspekte für welche Personen und in welchen Situationen relevant sind kann sehr unterschiedlich sein und muss für jeden Anwendungsfall individuell untersucht und festgelegt werden. Neben der Effektivität der Technologie, die Versorgung zu verbessern, ist daher die Evaluation sozialer, demografischer und organisatorischer Aspekte und die Berücksichtigung der daraus resultierenden Bedürfnisse der Nutzenden essenziell für eine erfolgreiche MTI.

In der vorliegenden Arbeit stehen zwei Beispiele für MTI in der Gesundheitsversorgung im Fokus, die die Autorin während ihrer wissenschaftlichen Arbeit untersucht hat:

1. Einsatz der konfokalen Laser-Endomikroskopie zur Digitalisierung der Schnellschnittdiagnostik in der Neuropathologie
2. Einsatz von assistiven Technologien zur Alltagsunterstützung älterer Menschen

Untersucht wurde also ein Thema aus dem medizinisch-diagnostischen Bereich und eines aus der ambulanten Pflege bzw. Versorgung. Eine Grundannahme der Untersuchung besteht darin, dass in beiden Fällen das Potential besteht, die Gesundheitsversorgung zu verbessern.

Im Kern der Analyse stehen die Nutzenden und die soziale, demografische und organisatorische Evaluation der MTI. Beide Themen werden in den folgenden beiden Unterkapiteln genauer vorgestellt. Die übergeordnete Forschungsfrage lautet:

Welche sozialen, demografischen und organisatorischen Aspekte sind für eine erfolgreiche Mensch-Technik-Interaktion in der medizinischen und pflegerischen Versorgung relevant?

1.2 Einführung Fokusthema 1: Einsatz der konfokalen Laser-Endomikroskopie zur Digitalisierung der Schnellschnittdiagnostik in der Neuropathologie

Bei der operativen Entfernung eines Gehirntumors ist das Ausmaß der Resektion entscheidend für die Prognose und die postoperative Genesung der Patientinnen und Patienten [10-12]. Um die Schädigung des gesunden Gewebes so gering wie möglich zu halten, sollten die zuvor festgelegten Tumorgrenzen intraoperativ überprüft werden [13]. Um den Gewebestatus zuverlässig zu beurteilen, muss in der Regel eine makro- oder (zur Sichtbarmachung der Zellkerne) mikroskopische Gewebeanalyse durchgeführt werden [11, 14]. Die herkömmliche Methode zur intraoperativen Tumorbeurteilung sieht die Entnahme einer Biopsie per Schnellschnitt (Gefrierschnittuntersuchung) vor, die zur histopathologischen Analyse in die Neuropathologie übersandt wird.

Der Zeitaufwand bei diesem Verfahren ist als größter Nachteil zu nennen. Der Transport der Probe in die Neuropathologie, die Untersuchung der Biopsie und die Rückübermittlung der Diagnose in den Operationssaal verursachen eine Verlängerung der Operationsdauer. Nicht selten ist der eigentliche Eingriff dann schon beendet (in diesem Fall dienen die Daten ausschließlich prognostischen Zwecken). Aktuelle Forschungsergebnisse zeigen, dass die Biopsie bis zu 45 Minuten dauern kann, bei Untersuchung mehrerer Proben steigt der Zeitaufwand und damit die Belastung für die Patientinnen und Patienten [11, 13, 15]. Daher erfolgt die primäre Beurteilung des Tumors während der Operation meist visuell durch die Chirurgin/ den Chirurgen.

Die Gewebeuntersuchung mittels konfokaler Laser-Endomikroskopie (KLEM) kann die intraoperative Tumorbeurteilung unterstützen und verbessern. Auf dem Markt sind mehrere KLEM-Geräte verschiedener Hersteller erhältlich, die für unterschiedliche medizinische Bereiche optimiert sind. Die hier vorgestellten Arbeiten basieren auf dem CONVIVO® (Carl Zeiss AG), einem für die Neurochirurgie optimierten KLEM-Gerät der zweiten Generation, das seit 2018 auf dem Markt ist. Der intraoperative neurochirurgische Einsatz dieses Geräts wurde bereits in aktuellen Studien beschrieben [16, 17]. Dennoch befindet sich die Technologie noch in einer experimentellen Phase und ist noch nicht Teil des aktuellen Behandlungsregimes.

Herzstück des CONVIVO® ist ein hochauflösendes Lasermikroskop, das sich in einer Sonde befindet, welche direkt auf das Gewebe gesetzt wird. Die zellulären Strukturen werden auf einem angeschlossenen Bildschirm dargestellt [18] (Abbildung 1). Da es sich um ein nicht-invasives Verfahren handelt und die Ergebnisse innerhalb weniger Minuten verfügbar sind, ist es auch möglich, mehrere Proben hintereinander zu analysieren. Die Tumorränder werden besser identifiziert und eine vollständigere Resektion ohne weitere Gewebeschädigung ist möglich [12, 19]. Im Jahr 2020 wurde eine digitale Plattform für die Neuropathologie veröffentlicht, die es ermöglicht, Bilder aus der Ferne zu diagnostizieren, anstatt im Operationssaal zu sein [20]. Die digitalen Bilder können somit zeitgleich von einer

Neuropathologin/ einem Neuropathologen betrachtet und analysiert werden und mit der Chirurgin/ dem Chirurgen besprochen werden.

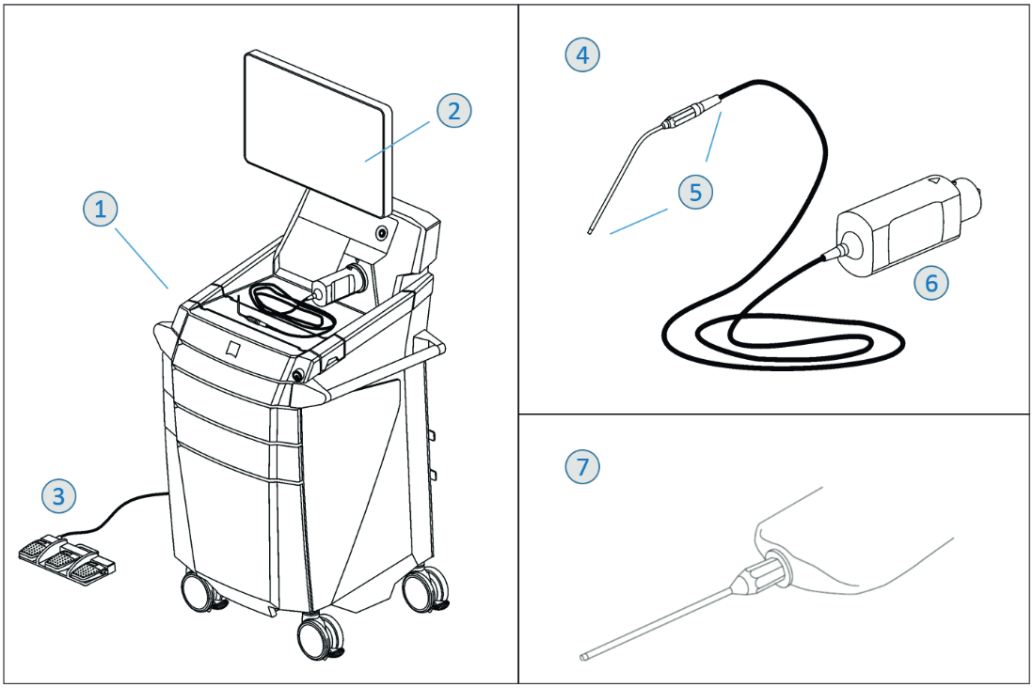

Abbildung 1: Hauptkomponenten des konfokalen Laser-Endomikroskops CONVIVO®. (1) Wagen, (2) Touchscreen-Monitor, (3) Fußschalter, (4) Scannereinheit, (5) Scannersonde, (6) Kupplungseinheit, (7) sterile Hülle [21, p. 3; Abdruck mit Genehmigung der Carl Zeiss Meditec AG]

Das klinische Potential der KLEM für die Resektion von Gehirntumoren wurde bereits in mehreren *ex vivo* und *in vivo* Studien untersucht [16, 19, 22, 23]. Einige Wissenschaftlerinnen und Wissenschaftler erwähnten, dass die Einführung von KLEM unter anderem auch eine Veränderung eingespielter Arbeitsabläufe, einen (Um)Schulungsbedarf und möglicherweise eine Verlagerung von Aufgaben bedeuten kann [13, 16, 18, 24, 25]. Eine detaillierte Analyse dieser sozialen und organisatorischen Aspekte fehlt jedoch bislang. Im Rahmen der MTI ist dies jedoch unerlässlich, um ein umfassendes Verständnis der Auswirkungen von KLEM im klinischen Umfeld zu erlangen. In den in Kapiteln 3.1. und 3.2 vorgestellten Arbeiten wurde zunächst ein Konzeptmodell zu den möglichen Folgen der KLEM entwickelt und mittels der verfügbaren Literatur und Experteninterviews überprüft (Publikation I, Anhang 1). Anschließend wurden eine Prozessanalyse und eine Befragung bei Nutzerinnen und Nutzern durchgeführt, um die sozialen und organisatorischen Auswirkungen des Einsatzes von KLEM zu untersuchen (Publikation II, Anhang 2).

1.3 Einführung Fokusthema 2: Einsatz von assistiven Technologien zur Alltagsunterstützung älterer Menschen

Der medizinische und technische Fortschritt hat im letzten Jahrhundert zu einem Anstieg der Lebenserwartung geführt und ist damit einer der Hauptgründe für die Veränderung der demografischen Struktur in vielen Ländern. Nach den aktuellen Bevölkerungsvorausberechnungen von Eurostat wird der Anteil der Menschen im erwerbsfähigen Alter (20-64 Jahre) in der Europäischen Union bis 2100 um etwa 9% sinken, während die Anzahl der Menschen ab 65 um 11% steigen soll [26] (Abbildung 2).

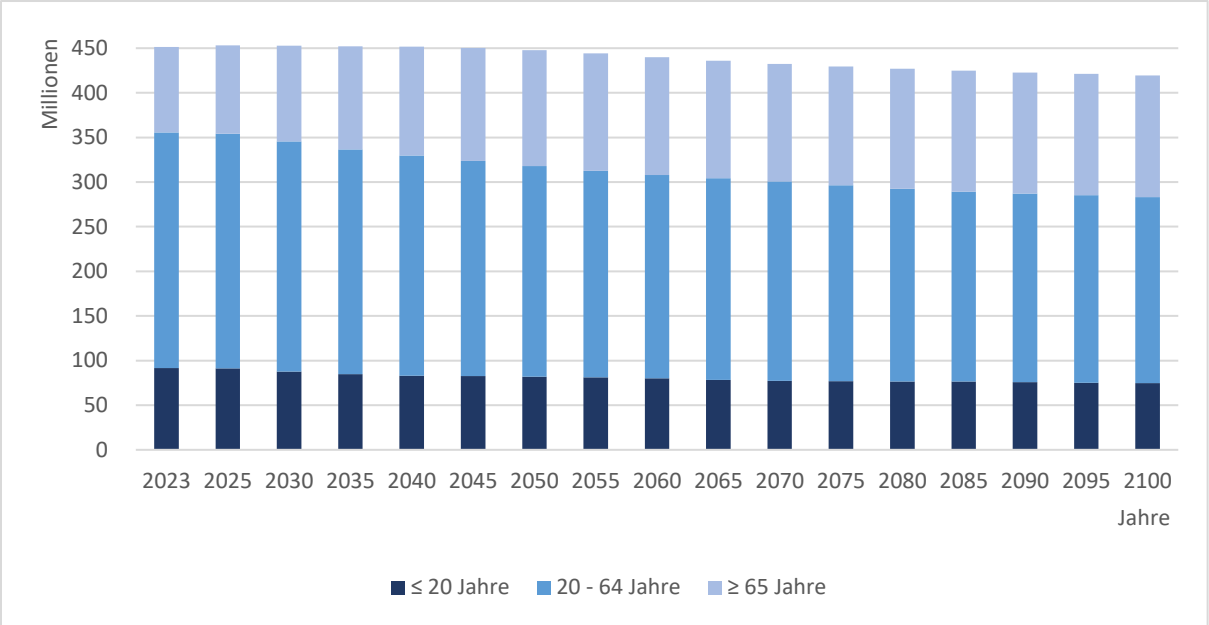

Abbildung 2: Bevölkerungsvorausberechnung in der Europäischen Union nach Altersgruppen von 2023 bis 2100 (eigene Darstellung, Zahlen aus [26])

Durch die wachsende Zahl älterer, oft multimorbider Bürgerinnen und Bürger nimmt auch die Nachfrage nach Gesundheitsdiensten und der Bedarf an Gesundheitsfachkräften zu [27]. In Kombination mit den steigenden Kosten für Diagnose und Behandlung rechnen Politikerinnen und Politiker sowie Interessenvertreterinnen und Interessenvertreter mit Schwierigkeiten bei der Bereitstellung einer angemessenen Versorgung in der nahen Zukunft [28]. Ein wesentlicher Ansatz diesen Herausforderungen zu begegnen, besteht darin, dem Altern an Ort und Stelle und der häuslichen Pflege den Vorzug vor der Heimunterbringung zu geben [27, 29]. Ältere Menschen sollen so lange und so umfassend wie möglich unabhängig bleiben und ein selbstständiges Leben führen können. Technologie bzw. technologische Assistenzsysteme können eine Möglichkeit sein, die Autonomie, Sicherheit und Kommunikation älterer Menschen zu erhalten, ihre Lebensqualität zu verbessern und die Ressourcen des Gesundheitssystems zu schonen [30-34]. Zudem können diese Geräte auch eine Entlastung für Angehörige oder Pflegefachpersonen sein [35]. Die Entwicklung von assistiven Technologien (AT) wurde in den letzten Jahren stark vorangetrieben und es gibt eine Fülle von Anwendungen für ältere Erwachsene mit unterschiedlichen Erkrankungen wie Demenz oder kognitiver Beeinträchtigung [36-38], Morbus Parkinson [39, 40], Diabetes [41, 42], Bluthochdruck [43, 44] oder chronischer obstruktiver Lungenerkrankung [36, 45]. Hierbei können AT unter anderem bei der Krankheitsüberwachung [46, 47], der Verringerung des Sturzrisikos oder der Sturzprävention [48-50], der sicheren und korrekten Einnahme von Medikamenten [44, 51] oder der Förderung sozialer Beziehungen [52, 53] helfen.

Die Weltgesundheitsorganisation definiert AT als „*any item, piece of equipment or product, whether it is acquired commercially, modified or customized, that is used to increase, maintain or improve the functional capabilities of individuals with disability*“ [54, p. 14] (“Alle Geräte, Ausrüstungsgegenstände oder Produkte, unabhängig davon, ob sie kommerziell erworben, modifiziert oder angepasst wurden, die dazu dienen, die funktionellen Fähigkeiten von Menschen mit Behinderungen zu erhöhen, zu erhalten oder zu verbessern” – *Übersetzung der Autorin*). Diese Definition macht deutlich, dass AT ein sehr heterogener Begriff ist. AT umfassen eine breite Produktpalette von einfachen Hörgeräten [55] und Blutdruckmessgeräten über

Gesundheitsapps [43] hin zu technologisch komplexeren Anwendungen wie Systemen zur Hausautomation [34], Tremorlöffeln [40], intelligenten Rollatoren [56] oder KI-gestützte Sehhilfen [57]. Diese Heterogenität erschwert die bedarfsgerechte Verbreitung und Nutzung von AT. In einer sehr umfangreichen Übersicht zu verschiedenen AT veröffentlicht vom Fachbereich Senioren der Stadt Hannover werden die Geräte in die Kategorien „Sicherheit“, „Gesundheit“, „Kommunikation und Unterhaltung“ und „Komfort und Selbstständigkeit“ eingeteilt [58]. Als vereinfachte Form eines Entscheidungsbaumes, kann eine solche Trennung helfen, AT gemäß den individuellen Bedürfnissen auszuwählen.

Beim Einsatz von AT zur Unterstützung älterer Menschen sind in Bezug auf die MTI vor allem Zugänglichkeit und Benutzerfreundlichkeit entscheidend, da ältere Menschen oft unterschiedliche Erfahrungen und Fähigkeiten im Umgang mit Technik haben [59]. Sie benötigen Beratung und Unterstützung bei der Identifikation relevanter AT, was jedoch unter anderem durch fehlendes Wissen auf Seiten der Fachkräfte erschwert wird [60, 61]. Es ist unklar, welche AT tatsächlich von Personen ab 65 genutzt werden. In Bezug auf die Benutzerfreundlichkeit ist wichtig, dass Technologien an körperliche Einschränkungen wie verminderte Sehstärke, Hörverlust oder eingeschränkte Feinmotorik angepasst sind. Zudem müssen sich die Geräte gut in den Alltag der Anwenderinnen und Anwender integrieren lassen. Viele Anwendungen werden jedoch nicht gemeinsam mit der Zielgruppe entwickelt und können daher zu komplex in der Einrichtung und/oder Bedienung sein [62, 63]. Weitere wichtige Aspekte sind Privatsphäre und Datensicherheit. Viele AT zeichnen sich durch kontinuierliches Monitoring bestimmter Parameter aus, was Sorgen eines Missbrauchs sensibler Gesundheitsdaten fördert [64, 65].

In einer Querschnittsstudie wurde die Nutzungsrate und der Nutzen für verschiedene AT in der Bevölkerung ab 65 untersucht (Kapitel 4.1, Publikation III, Anhang 3). In Publikation IV (Kapitel 4.2, Anhang 4) wird eine Anwenderstudie vorgestellt, bei der ältere Menschen eine von zwei AT acht Wochen lang im Alltag getestet haben.

2. Eingebundene Publikationen

Vier Publikationen sind Teil dieser kumulativen Dissertation, jeweils zwei zu einem Fokusthema. Publikationen I und II untersuchen die MTI beim Einsatz der KLEM in der Neuropathologie. Methodisch kommen dabei eine narrative Literaturanalyse, eine qualitative Expertenbefragung, eine Prozessmodellierung sowie eine quantitative Befragung von Nutzenden der KLEM zum Einsatz. Publikationen III und IV beschäftigen sich mit der Untersuchung des Einsatzes von AT bei älteren Menschen. Es wurden eine Querschnittsstudie zur Nutzung von Technologie bei älteren Menschen ab 65 und eine prospektive Anwenderstudie mit zwei verschiedenen AT durchgeführt. Wo erforderlich wurden Ethikvoten eingeholt. Die entsprechenden Aktenzeichen finden sich in den jeweiligen Kapiteln.

Die Publikationen und die Beschreibung des Eigenanteils finden sich in den Anhängen 1, 2, 3 und 4. Tabelle 1 listet die vier eingebundenen Publikationen und die Lizenzrechte aufgeteilt nach den zwei Fokusthemen.

Tabelle 1: Eingebundene Publikationen und Lizenzrechte

Literaturangabe der Publikation	**Lizenz**
Einsatz der konfokalen Laser-Endomikroskopie zur Digitalisierung der Schnellschnittdiagnostik in der Neuropathologie	
I. **Fotteler M**, Heninger L, Holl F, Schlegel J, Swoboda W. Confocal Laser Endomicroscopy for Intraoperative Tumor Assessment: Development of a Conceptual Model for an Evaluation Study. Studies in Health Technology and Informatics. 2019;262:376-379. doi:10.3233/SHTI190097	Lizenzfreigabe von *IOS Press* (Anhang 1.1)
II. **Fotteler ML**, Liesche-Starnecker F, Brielmaier MC, Schobel J, Gempt J, Schlegel J, Swoboda W. Socio-Organizational Impact of Confocal Laser Endomicroscopy in Neurosurgery and Neuropathology: Results from a Process Analysis and Expert Survey. Diagnostics (Basel). 2021;11(11):2128. doi:10.3390/diagnostics11112128	CC BY 4.0[1]
Einsatz von assistiven Technologien zur Alltagsunterstützung älterer Menschen	
III. **Fotteler ML**, Kocar TD, Dallmeier D, Kohn B, Mayer S, Waibel A-K, Swoboda W, Denkinger M. Use and benefit of information, communication, and assistive technology among community-dwelling older adults - a cross-sectional study. BMC Public Health. 2023;23(1):2004. doi:10.1186/s12889-023-16926-8	CC BY 4.0[1]
IV. Wiegel P, **Fotteler ML**, Kohn B, Mayer S, Verri FM, Dallmeier D, Denkinger M. Perceived benefit and satisfaction with a tablet computer and an emergency smartwatch by older adults and their relatives: results from a prospective real-world pilot study. JMIR Human Factors (forthcoming). doi:10.2196/53811 (geteilte Erstautorenschaft)	CC BY 4.0[1]

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Für Publikation I wurde die Lizenzfreigabe vom Verlag *IOS Press* eingeholt (Anhang 1.1). Die drei übrigen Arbeiten sind unter der Creative Commons Attribution License CC BY 4.0 erschienen (https://creativecommons.org/licenses/by/4.0/). Bei Publikation IV handelt es sich um eine geteilte Erstautorenschaft. Die Publikation wurde zur Veröffentlichung angenommen (Anhang 4.2), ist aber zum Zeitpunkt der Abgabe dieser Dissertation noch nicht erschienen.

In den folgenden zwei Kapiteln werden alle vier Publikationen vorgestellt. Es wird jeweils beschrieben, welcher Aspekt der Forschungsfrage untersucht wurde, gefolgt von der Methodik und den Ergebnissen. Abschließend wird eine Teilantwort auf die Forschungsfrage präsentiert.

3. Einsatz der konfokalen Laser-Endomikroskopie zur Digitalisierung der Schnellschnittdiagnostik in der Neuropathologie

3.1 Publikation I: Entwicklung eines Konzeptmodells zu den Auswirkungen der konfokalen Laser-Endomikroskopie

Vollständige Literaturangabe

Fotteler M, Heninger L, Holl F, Schlegel J, Swoboda W. Confocal Laser Endomicroscopy for Intraoperative Tumor Assessment: Development of a Conceptual Model for an Evaluation Study. Studies in Health Technology and Informatics. 2019;262:376-9. doi: 10.3233/shti190097.

3.1.1 Aspekt der Forschungsfrage

Die Einführung von KLEM hat medizinische, aber auch soziale und organisatorische sowie ökonomische Auswirkungen. Zu den möglichen Konsequenzen im medizinischen Bereich zählen eine verbesserte Behandlung für die Patientinnen und Patienten und eine verkürzte Schnitt-Naht-Zeit – beide Aspekte können zu einem besseren medizinischen Ergebnis beitragen. In sozialer und organisatorischer Hinsicht bedeutet die Technologie möglicherweise eine höhere Arbeitsbelastung für das Personal sowie eine Verlängerung des bisherigen Prozesses durch zusätzliche Planungs-, Wartungs- und Pflegeaufgaben. Zudem sind die Kosten für das Gerät sehr hoch. Die fünf Arbeitshypothesen wurden nach Gray and Sockolow [66] in einem Konzeptmodell visualisiert (Abbildung 3). Das Ziel der hier vorgestellten Publikation mit dem Originaltitel *„Confocal Laser Endomicroscopy for Intraoperative Tumor Assessment: Development of a Conceptual Model for an Evaluation Study“* war die Überprüfung des Modells durch eine Analyse der wissenschaftlichen Literatur und der Durchführung von Experteninterviews.

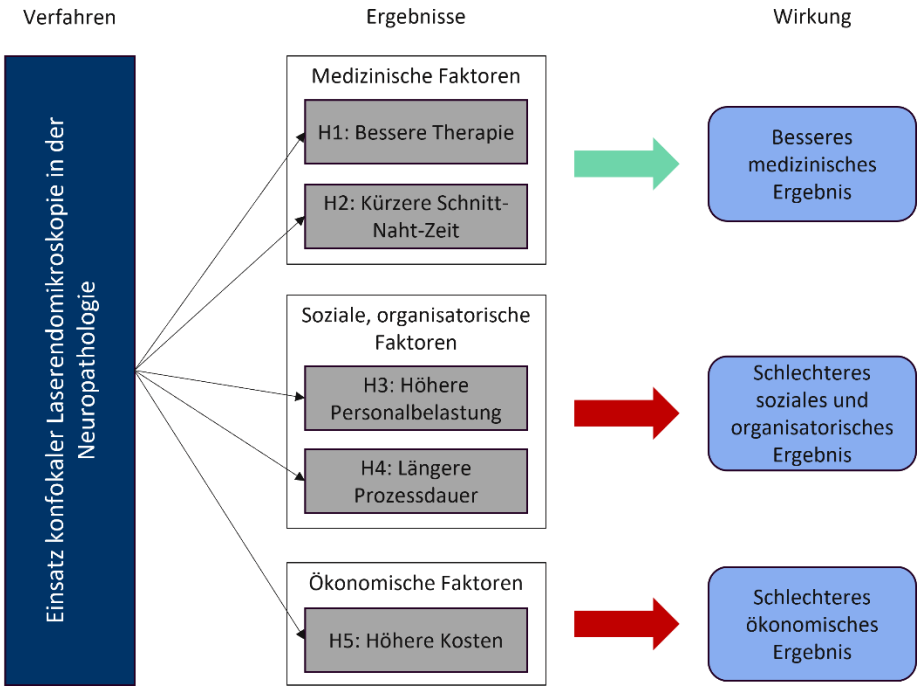

Abbildung 3: Konzeptmodell mit fünf Arbeitshypothesen zu den möglichen Auswirkungen der konfokalen Laser-Endomikroskopie in der Neuropathologie (nach [25]; Abdruck mit Genehmigung des Verlags (siehe Anhang 1))

3.1.2 Methoden

Im Rahmen einer narrativen Literaturanalyse wurden wissenschaftliche Studien untersucht, die sich mit dem Einsatz von KLEM in der Neuropathologie beschäftigen und seit 2010 veröffentlicht wurden. Da es sich um eine neue Technologie handelt, wurde diese zeitliche Einschränkung vorgenommen. Für die Suche wurden die Datenbanken PubMed, GoogleScholar und Scopus mit einer Kombination aus den Begriffen *confocal laser endomicroscopy*, *neurosurgery*, *neuropathology* und *brain tumor* durchsucht.

Zusätzlich wurden sieben semi-strukturierte Interviews mit Expertinnen und Experten geführt, um eine tiefere Einsicht in die Chancen und Risiken der Digitalisierung in der Pathologie zu gewinnen (Tabelle 2). Um das Thema aus verschiedenen Perspektiven beleuchten zu können, wurden Personen aus verschiedenen, von der digitalen Biopsie betroffenen, Fachbereichen gewählt. Die Expertinnen und Experten wurden telefonisch oder per E-Mail angefragt und um ein Interview gebeten.

Tabelle 2: Übersicht über die in den Interviews befragten Expertinnen und Experten und deren Fachgebiet

Expertin/Experte	Fachbereich
A	Medizintechnik
B	Neuropathologie
C	Neurochirurgie
D	Pflege
E	Klinisches Qualitätsmanagement
F	Wissenschaft/Lehre
G	Kostenträger

3.1.3 Zusammenfassung der Ergebnisse

Medizinische Auswirkungen der KLEM

In Bezug auf die medizinischen Ergebnisse berichteten mehrere Studien, dass KLEM in Kombination mit einem Fluoreszenzmittel für eine bessere Auflösung und Bestimmung der Tumorränder sorgt. Dadurch kann die Gewebeanalyse schneller erfolgen und eine umfassendere Tumorresektion durchgeführt werden. Zudem wurde betont, dass das Verfahren nicht-invasiv ist, weshalb die Anzahl der Proben nicht limitiert sei. Die kürzere Operationsdauer wurde als weiterer Vorteil des Verfahrens in der Literatur genannt [11, 12, 19, 21, 67].

Die befragten Expertinnen und Experten bestätigten die Hypothese eines verbesserten medizinischen Outcomes. Expertin/ Experte C sagte beispielsweise: *„Wenn es zuverlässig funktioniert, dann ist es eine sehr gute Sache, die es effizienter macht und vor allem für den Patienten sehr viel sicherer und auch Re-Operationen vermeidet.“*. Die Chance, eine kürzere Schnitt-Naht-Zeit zu erreichen, wurde von Expertin/ Experte D betont: *„Durch digitale Biopsie werden Prozesse beschleunigt. Man hat deutlich kürzere OP-Zeiten, man muss nicht so viel Zeit im OP überbrücken, bis der Befund da ist.“*

Soziale und organisatorische Auswirkungen der KLEM

Nur wenige Studien gingen auf mögliche soziale und organisatorische Auswirkungen der KLEM ein. Es wurde erwähnt, dass ein erhöhter Schulungsaufwand benötigt wird, sowohl in Bezug auf die Pflege und Wartung des Gerätes als auch die Bedienung und vor allem die Interpretation der Bilder [10, 11]. Einige Studien bestätigten, dass die KLEM die Arbeitsabläufe

in den Abteilungen für Neurochirurgie und Neuropathologie verändern werden [11, 19, 67]. Es wurden jedoch keine empirischen Untersuchungen zu diesen Themen durchgeführt.

Expertin/ Experte B erwähnte, eine potenziell höhere Arbeitsbelastung für einzelne Berufsgruppen: *„Für die Pflegekräfte denke ich, ist es vermutlich aufwändiger, weil es ein weiteres Tool ist, was sie letztlich pflegen müssen. Es ist ein weiterer Gegenstand im OP, der hergeholt werden muss und gepflegt werden muss.“*. Auch der Schulungsaufwand kam in den Interviews zur Sprache: *„Wichtig ist eine intensive Ausbildung, um die Bilder sicher interpretieren zu können.“* (Expertin/ Experte A).

Ökonomische Auswirkungen der KLEM

Keine der untersuchten Studien hat mögliche ökonomische Auswirkungen der KLEM evaluiert. Expertin/ Experte B bestätigte die hohen Investitionskosten: *„Wenn ich ein Verfahren, dass normalerweise ca. 16 Euro kostet durch ein Gerät ersetze, was eine halbe Million kostet, ist die Frage, was das bringt.“*. Auch Expertin/ Experte D äußerte sich zu der Frage nach den Kosten: *„Ich denke, dass es schon sinnvolle Verfahren gibt, die auch helfen Geld zu sparen, aber Innovation ist immer erstmal teuer.“*.

3.1.4 Antwort auf die Forschungsfrage

Diese Untersuchung hat gezeigt, dass in der aktuellen Literatur nur wenig auf die sozialen, demografischen und organisatorischen Aspekte der KLEM eingegangen wird. In einzelnen Studien finden sich relevante Anmerkungen, empirische Erhebungen zu diesen Facetten der MTI konnten jedoch nicht gefunden werden.

Die Expertinnen und Experten betonten das Potential des Verfahrens für die Patientenversorgung, brachten jedoch auch mehrere Themen zur Sprache, die eine erfolgreiche MTI beeinträchtigen könnten. Dazu gehören eine erhöhte Arbeitsbelastung beispielsweise durch die Pflege und Wartung des Gerätes (inkl. der Klärung der Verantwortlichkeiten hierfür), die Ausbildung und damit verbundene Änderung der Arbeitsabläufe und auch die Kosten einer solchen Anschaffung.

3.2 Publikation II: Untersuchung der sozio-organisatorischen Auswirkungen der konfokalen Laser-Endomikroskopie in der Neurochirurgie und Neuropathologie

Vollständige Literaturangabe

Fotteler ML, Liesche-Starnecker F, Brielmaier MC, Schobel J, Gempt J, Schlegel J, Swoboda W. Socio-Organizational Impact of Confocal Laser Endomicroscopy in Neurosurgery and Neuropathology: Results from a Process Analysis and Expert Survey. Diagnostics. 2021;11(11):2128. doi: 10.3390/diagnostics11112128.

3.2.1 Aspekt der Forschungsfrage

Wie in Kapitel 3.1 beschrieben wurde, gibt es bislang kaum empirische Evidenz zu den sozialen und organisatorischen Auswirkungen der KLEM in der Neuropathologie bzw. -chirurgie. Wie Ammenwerth und Hackl [68] jedoch feststellten, ist es für die erfolgreiche Einführung einer solchen Technologie wichtig, die Auswirkungen auf die sozio-organisatorischen Strukturen innerhalb einer Einrichtung zu verstehen. Hierzu muss der Zusammenhang zwischen dem beteiligten Personal, den notwendigen Aktivitäten sowie der erforderlichen Infrastruktur geklärt werden. Die Prozessmodellierung ist eine etablierte Methode, die eine (grafische) Sprache zur Verfügung stellt, die von Angehörigen verschiedener Berufsgruppen verstanden wird [69, 70].

Die hier vorgestellte Studie mit dem Originaltitel *„Socio-Organizational Impact of Confocal Laser Endomicroscopy in Neurosurgery and Neuropathology: Results from a Process Analysis and Expert Survey“* untersucht die sozialen und organisatorischen Auswirkungen der KLEM, insbesondere im Kontext der Gehirntumorresektion im Vergleich zur aktuellen Praxis der Gefrierschnittanalyse. Das Ziel war die Beantwortung von zwei Forschungsfragen:

1. Wie könnte ein Arbeitsablauf aussehen, bei dem KLEM in der Neurochirurgie eingesetzt wird, verglichen mit dem derzeitigen klinischen Prozess der Analyse von Schnellschnitten?
2. Was sind die Meinungen des klinischen Personals, das mit KLEM arbeitet bzw. arbeiten wird, hinsichtlich der sozioorganisatorischen Auswirkungen einer Einführung der KLEM?

3.2.2 Methoden

Um das Potenzial der KLEM für die Neurochirurgie und Neuropathologie zu untersuchen und die Forschungsfragen zu beantworten, wurden sowohl der aktuelle Prozess der Gefrierschnittanalyse als auch das zukünftige KLEM-Verfahren modelliert und verglichen. Zudem wurde eine Umfrage unter klinischen Fachkräften, die mit der neuen Technologie arbeiten, durchgeführt. Für die Studie liegt ein positives Votum der Gemeinsamen Ethikkommission der Hochschulen Bayerns vor (GEHBa-202008-V-008 vom 07.10.2020).

Prozessanalyse

Beide Prozessmodelle wurden mit Business Process Model and Notation (BPMN) modelliert, einem Standard zur Dokumentation von Arbeitsabläufen [71]. BPMN ist besonders nützlich für die Visualisierung und das Verständnis komplexer Prozesse [68].

Der Prozess der Gefrierschnittanalyse wurde in einer Klinik der Maximalversorgung in Süddeutschland erhoben, wo bereits eine Interventionsstudie mit CONVIVO® durchgeführt wird. Für die Modellierung der Arbeitsschritte, wurden unstrukturierte Experteninterviews mit

Neuropathologinnen und Neuropathologen geführt. Zudem wurden Zeitmessungen der Biopsieresektion, des Transports und der Schnellschnittanalyse genommen. Für den KLEM-Prozess wurden Mitarbeitende des Herstellers befragt und Präsentationsmaterial, Handbücher und andere Dokumente herangezogen.

Nachdem die Expertinnen und Experten in die BPMN-Syntax eingeführt worden waren, wurden beide Modelle in mehreren Zyklen verfeinert, um Genauigkeit und Vollständigkeit zu gewährleisten.

Expertenumfrage

Ein Online-Fragebogen mit 16 Fragen in vier Abschnitten (allgemeine Informationen, Arbeit mit dem KLEM-Gerät, Meinung über das KLEM-Gerät und Vorteile/Nachteile) wurde entwickelt. Der Fragebogen wurde in deutscher Sprache verfasst und mit individuellen Zugangscodes an Neuropathologinnen und Neuropathologen, Neurochirurginnen und Neurochirurgen und Medizinstudierende verteilt. Alle Personen habenZi bereits *in vivo* oder *ex vivo* mit dem konfokalen Mikroskop gearbeitet. Die Umfrage war anonym. Alle Teilnehmenden gaben ihre informierte Zustimmung. Der Versand der Umfrage erfolgte zwischen April und September 2021. Es wurden bis zu drei Erinnerungsschreiben verschickt.

3.2.3 Zusammenfassung der Ergebnisse

Prozessanalyse

Für beide Prozesse wurden je ein detailliertes und ein vereinfachtes Prozessmodell entwickelt. Die Analyse basiert auf den detaillierten Prozessmodellen (Anhang 5 und Anhang 6 (auf Englisch)), die vereinfachten Modelle sind in Abbildung 3 dargestellt.

Die Anzahl der Aufgaben ging von insgesamt 42 im Schnellschnittprozess auf 26 im KLEM-Prozess zurück (-38,1%). Während jedoch die Aufgaben in der Neuropathologie aufgrund des Wegfalls von Verwaltungs- und Laboraufgaben von 30 auf 9 (-70%) zurückgingen, sind das Personal in der Neurochirurgie bzw. im Operationssaal mit einer leichten Zunahme der Aufgaben aufgrund der Wartung und Bedienung des Geräts von 12 auf 17 (+41,7%) konfrontiert. Wenn mehrere Bilder aufgenommen werden, was einer der Hauptvorteile der KLEM ist, steigt die Arbeitsbelastung für die Neurochirurgie weiter an. Im Schnellschnittprozess wurde die Zeit bis zur Verfügbarkeit der Ergebnisse mit ca. 18 Minuten gemessen.

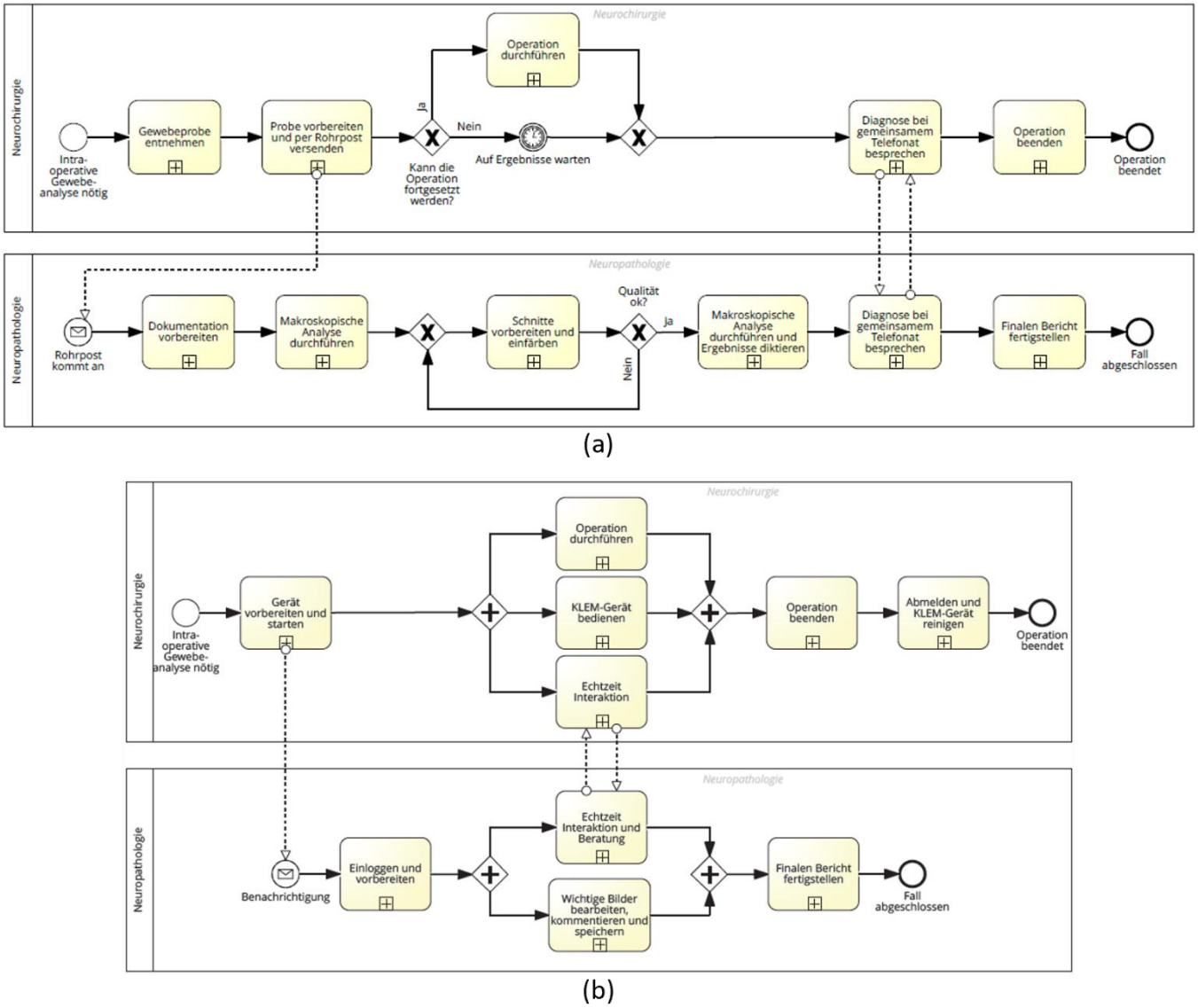

Abbildung 4: Vereinfachte Prozessmodelle: (a) Aktueller Prozess der Gefrierschnittanalyse; (b) Digitalisierter Prozess mit konfokaler Laser-Endomikroskopie (KLEM) (übersetzt aus [72]; Lizenz: CC-BY 4.0: https://creativecommons.org/licenses/by/4.0/). *Kreise markieren den Beginn und das Ende des Prozesses, Pfeile zeigen den Prozessfluss, Rechtecke stellen Aufgaben dar, Aufgaben mit dem "+" weisen auf zusammengeklappte Teilprozesse hin, die Raute mit dem "x" steht für ein exklusives Gateway (XOR), was bedeutet, dass nur ein Pfad weitergeht. Die Raute mit dem "+" bezeichnet ein paralleles Gateway (AND), was bedeutet, dass alle Pfade weitergehen*

Expertenumfrage

12 von 15 angesprochenen Expertinnen und Experten nahmen an der Befragung teil (Antwortrate: 80%). Niemand gab an, mit dem Gerät unzufrieden zu sein, zehn Teilnehmende (83,3 %) waren mit dem Gerät zufrieden und zwei (16,7 %) hatten eine neutrale Einstellung. Am besten wurden die Benutzerfreundlichkeit, die Integration in die tägliche Routine und die Patientensicherheit des KLEM-Gerätes bewertet. Fünf Teilnehmende (41,6 %; drei Personen aus der Neurochirurgie, zwei Personen aus der Neuropathologie) gaben an, dass sich ihre Arbeitsbelastung durch die Verwendung der KLEM erhöht hat. Sie begründeten dies mit der Tatsache, dass die Methode derzeit als Ergänzung zur Schnellschnittanalyse und nicht als Ersatz verwendet wird. Neun Personen (75 %) sind der Meinung, dass die Operationszeit reduziert werden kann, sobald das Gerät als Standard in der klinischen Routine eingesetzt wird. Als die größten Vorteile der KLEM wurden die schnellere Diagnose und die verkürzte

Operationsdauer sowie verbesserte Diagnose und Resektion genannt. Herausforderungen umfassen die Notwendigkeit von Training und Erfahrung für eine effektive Anwendung, sowie die Gefahr von Fehldiagnosen.

3.2.4 Antwort auf die Forschungsfrage

Soweit bekannt, ist dies die erste Studie, die den Einfluss der KLEM auf das klinische Personal in Neuropathologie und Neurochirurgie und deren Arbeitsabläufe untersucht hat. Die meisten Teilnehmenden zeigten eine positive Einstellung zu der Technologie. Nichtsdestotrotz deuten die Ergebnisse der Prozessanalyse und Befragung darauf hin, dass die Implementierung der KLEM signifikante soziale und organisatorische Veränderungen für das Fachpersonal mit sich bringt. Veränderungen zeigen sich insbesondere in der Neugestaltung und Verlagerung von Aufgaben sowie der Notwendigkeit von spezieller Aus- bzw. Weiterbildung. Vor allem in einer Übergangsphase zwischen zwei Verfahren kann auch die Arbeitsbelastung steigen, da Prozesse parallel laufen. Für eine erfolgreiche MTI ist es entscheidend, dass Entscheidungsträgerinnen und Entscheidungsträger diese Veränderungen sorgfältig begleiten und neue Prozesse unter Einbezug der betroffenen Mitarbeitenden gestalten.

4. Fokusthema 2: Einsatz von assistiven Technologien zur Alltagsunterstützung älterer Menschen

4.1 Publikation III: Querschnittstudie zur Erhebung der Nutzung und des Nutzens von assistiven Technologien bei selbstständig lebenden älteren Menschen

Vollständige Literaturangabe

Fotteler ML, Kocar TD, Dallmeier D, Kohn B, Mayer S, Waibel A-K, Swoboda W, Denkinger M. Use and benefit of information, communication, and assistive technology among community-dwelling older adults – a cross-sectional study. BMC Public Health. 2023;23(1):2004. doi: 10.1186/s12889-023-16926-8.

4.1.1 Aspekt der Forschungsfrage

Obwohl es eindeutig eine Fülle von AT für ältere Erwachsene mit unterschiedlichen Gebrechlichkeitsgraden und Krankheiten gibt, ist ungewiss, welche dieser Geräte von der Zielgruppe in ihrem täglichen Leben genutzt werden. Nur wenige Studien berichten aktuelle Nutzungsraten für einzelne AT, wie beispielsweise Wearables [32, 34, 73]. Zudem bestehen Unstimmigkeiten hinsichtlich der mit einer Nutzung bzw. Nicht-Nutzung assoziierten soziodemografischen Charakteristika [74].

Laptops/Computer, Smartphones und Tablets gehören zur Gruppe der Informations- und Kommunikationstechnologien (IKT). Diese sind häufig eine Voraussetzung für die Nutzung vieler AT (z. B. wenn eine Smartphone- oder Tablet-Anwendung für die Nutzung von Hilfsmitteln erforderlich ist) und könnten daher als Indikator für die Nutzung von AT angesehen werden [75]. Die Ziele der hier vorgestellten Querschnittsstudie waren, 1) die Nutzung von IKT und damit assoziierter soziodemografischer Merkmale zu untersuchen und 2) zu ermitteln, welche Hilfsmittel von Erwachsenen im Alter von ≥ 65 Jahren genutzt werden.

4.1.2 Methoden

Ein papierbasierter Fragebogen wurde im April 2021 postalisch an 2.500 Erwachsene ≥65 Jahren geschickt, die in einem süddeutschen Landkreis registriert waren. Die Adressen für den Postversand wurden von den regionalen Einwohnermeldeämtern bezogen. Neben dem Fragebogen erhielten die Personen ein Informationsschreiben, in dem die Studie vorgestellt wurde, sowie einen frankierten Rücksendeumschlag. Es wurde kein Erinnerungsschreiben verschickt.

Der Fragebogen wurde in deutscher Sprache entwickelt und enthielt Fragen aus drei Hauptbereichen: soziodemografische Aspekte, Gesundheitszustand und Technologienutzung. Er enthielt unter anderen Fragen zu Alter, Geschlecht, Bildungsniveau, Wohnsituation, Größe des Heimatortes, Technologieinteresse und Internetanschluss zu Hause. Mithilfe einer Software wurde der Fragebogen in ein maschinell lesbares Format umgewandelt. Dadurch konnten die zurückgesandten Fragebögen automatisch eingescannt und die Daten ausgelesen werden.

Für die Studie liegt ein positives Votum der Gemeinsamen Ethikkommission der Hochschulen Bayerns vor (GEHBa-202,101-V-014 vom 05.02.2021).

4.1.3 Zusammenfassung der Ergebnisse

Der Fragebogen wurde von 619 Personen (Antwortrate: 24,76%) zurückgeschickt. Für die Studie wurden 616 Fragebögen berücksichtigt, in denen über die Nutzung von IKT berichtet wurde. Von diesen waren 497 (80,68%) IKT-Nutzende und 119 (19,32%) IKT-Nicht-Nutzende. Die Charakteristika der Studienpopulation sind in Tabelle 3 dargestellt. Nutzende von IKT waren jünger, hatten ein höheres Bildungsniveau, lebten eher mit anderen Personen zusammen, verfügten über einen Internetanschluss, zeigten ein größeres Interesse an Technologie und hatten weniger Komorbiditäten (alle p<.05).

Tabelle 3: Charakteristika der Studienpopulation nach IKT[1]-Nutzenden und IKT[1]-Nicht-Nutzenden (übersetzt aus [76]; Lizenz: CC-BY 4.0: https://creativecommons.org/licenses/by/4.0/)

	Gesamt (n=616; 100%)		**IKT[1]-Nutzende (n=497; 80,68%)**		**IKT[1]-Nicht-Nutzende (n=119; 19,32%)**		***p***
	n(%)	**na[2]**	**n(%)**	**na[2]**	**n(%)**	**na[2]**	
Alter (in Jahren)		1		1		0	<0,001[4]*
Mittelwert (SD[3])	74,22 (7,03)		72,74 (5,97)		80,35 (7,8)		
65-70	237(38,54)		220(44,35)		17(14,29)		
71-80	252(40,98)		210(42,34)		42(35,29)		
80+	126(20,49)		66(13,31)		60(50,42)		
Geschlecht		15		12		3	0,185[4]
Weiblich	301(50,08)		236(48,66)		65(56,03)		
Männlich	300(49,92)		249(51,34)		51(43,97)		
Bildung		20		15		5	<0,001[4]*
≤10 Jahre	448(75,17)		344(71,37)		104(91,23)		
>10 Jahre	148(24,83)		138(28,63)		10(8,77)		
Wohnsituation		1		1		0	0,008[4]*
Alleine	161(26,18)		118(23,79)		43(36,13)		
Mit anderen	454(73,82)		378(76,21)		76(63,87)		
Größe des Heimatortes		22		17		5	0,45[4]
< 1000	51(8,59)		38(7,92)		13(11,4)		
1000-9999	259(43,6)		209(43,54)		50(43,86)		
≥10000	284(47,81)		233(48,54)		51(44,74)		
Internetanschluss		7		5		2	<0,001[4]*
Ja	524(86,04)		474(96,34)		50(42,74)		
Nein	85(13,96)		18(3,66)		67(57,26)		
Technologieinteresse		2		2		0	<0,001[5]*
Hoch	121(19,71)		118(23,84)		3(2,52)		
Mittel	327(53,26)		304(61,41)		23(19,33)		
Gering	119(19,38)		67(13,54)		52(43,7)		
Nicht vorhanden	47(7,65)		6(1,21)		41(34,45)		
Gesundheitsstatus		0		0		0	0,008[5]*
Keine Komorbiditäten	46(7,47)		43(8,65)		3(2,52)		
1-2 Komorbiditäten	247(40,1)		206(41,45)		41(34,45)		
≥3 Komorbiditäten	323(52,44)		248(49,9)		75(63,03)		

[1]IKT: Informations- und Kommunikationstechnologie (hier: Computer/Laptop, Smartphone, Tablet)
[2]na: not available (Anzahl fehlender Werte)
[3]SD: Standard deviation (Standardabweichung)
[4]Berechnet mit Pearson's Chi-square test
[5]Berechnet mit Fisher's Exact Test
*p<.05

Die Nutzung von AT wurde für 31 verschiedene Geräte bzw. Gerätekategorien erfasst (Abbildung 5). Die am häufigsten genutzten AT waren herkömmliche Festnetztelefone, Körperwaagen und Blutdruckmessgeräte. Einige AT wurden ausschließlich von IKT-Nutzenden verwendet (z. B. Videotelefonieanwendungen und digitale Terminkalender). Andere AT wiederrum, wurden häufiger von IKT-Nicht-Nutzenden verwendet (z.B. Seniorenhandys und Hausnotrufe). Die Anzahl der im Besitz befindlichen ATs reichte von null bis zwölf, wobei es keinen signifikanten Unterschied zwischen IKT-Nutzenden und IKT-Nicht-Nutzenden gab.

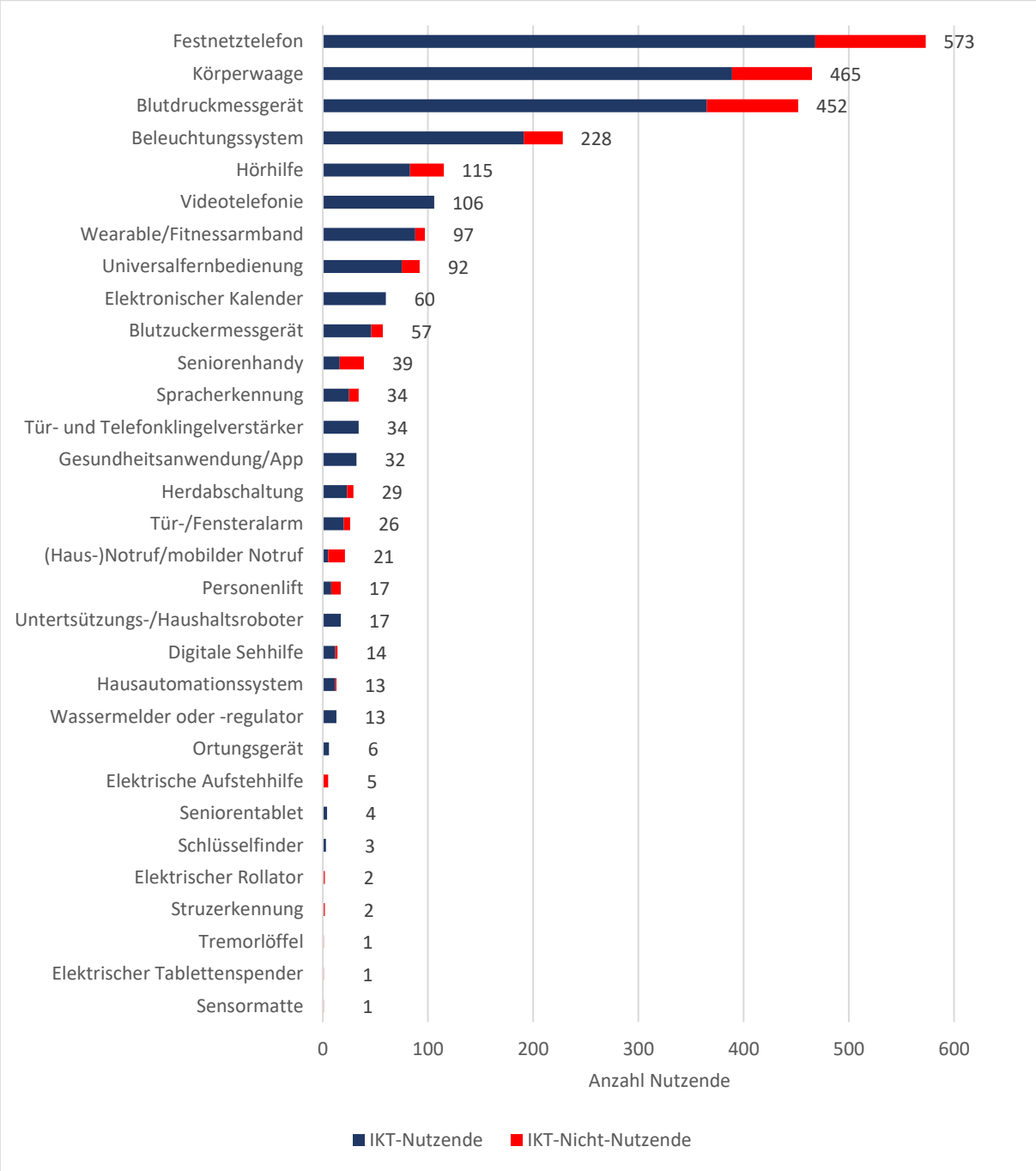

Abbildung 5: Anzahl der Nutzenden ≥65 Jahre von verschiedenen assistiven Technologien getrennt nach Personen, die Informations- und Kommunikationstechnologien (IKT, hier: Laptop/Computer, Smartphone, Tablet) nutzen (= IKT-Nutzende) und Personen, die keine IKT nutzen (= IKT-Nicht-Nutzende) (übersetzt und angepasst aus [76]; Lizenz: CC-BY 4.0: https://creativecommons.org/licenses/by/4.0/)

Zum Nutzen der verwendeten Technologien äußerten sich 476 (77,27%) Personen. Es gab einen signifikanten Unterschied zwischen IKT-Nutzenden und IKT-Nicht-Nutzenden (p<0,001). Nur etwa 4,15% der IKT-Nutzenden berichteten über einen geringen oder keinen Nutzen. Im Gegensatz dazu lag diese Einschätzung bei den IKT-Nicht-Nutzenden bei 27,27%. Eine Bernoulli-Naive-Bayes-Analyse zeigte, dass ein geringer Nutzen der Technologie in umgekehrtem Verhältnis zur Nutzung bestimmter fortschrittlicher Hilfsmittel (z.B. Videotelefonie, Spracherkennung) stand, während ein hoher Nutzen in umgekehrtem Verhältnis zur Nutzung einfacher Hilfsmittel (z.B. Seniorenhandy, Hausnotrufknopf) stand. In anderen Worten, nutzten verhältnismäßig wenig Menschen, die einen geringen oder keinen Nutzen durch die Technik berichteten, moderne Hilfsmittel.

4.1.4 Antwort auf die Forschungsfrage

Die Studie hat gezeigt, dass jüngeres Alter, ein höheres Bildungsniveau, das Zusammenleben mit anderen, die Verfügbarkeit eines Internetanschlusses, ein höheres Technologieinteresse und bessere Gesundheit mit einer Nutzung von IKT assoziiert und damit für eine erfolgreiche MTI relevant sind. Moderne und innovative AT wurden mehrheitlich von IKT-Nutzenden verwendet (z.B. Videotelefonie, Gesundheitsanwendung), während IKT-Nicht-Nutzende zu einem größeren Anteil traditionellere Geräte (z.B. Hausnotruf, Seniorenhandy) nutzten. Die Ergebnisse der hier vorgestellten Studie können dazu beitragen, dass beispielsweise Informationsmaterialien zu AT zielgerichteter verbreitet und spezifische Programme besser auf die Zielgruppe zugeschnitten werden können.

Die vorgestellte Studie hat auch gezeigt, dass vor allem neue und innovative AT nach wie vor wenig genutzt werden und deren Potential nicht voll ausgeschöpft wird. Generell stößt die Nutzung von AT jedoch auf eine hohe Akzeptanz in der älteren Bevölkerung [29]. Der Prozess, als älterer Erwachsener eine regelmäßige Nutzerin/ ein regelmäßiger Nutzer von Hilfsmitteln zu werden, ist komplex [30, 59, 77]. Eine wissenschaftliche Evaluation von 14 Good-Practice Beispielen von Wohnungsunternehmen zeigt, dass viele Technologien zwar positiv bewertet, aber nicht genutzt werden. Laut den Autorinnen und Autoren könnten die Gründe dafür u.a. die mangelnde Information über die Technologien, die mangelnde Anpassung an die individuellen Anforderungen und den eigenen Lebensstil sowie die mangelnde Gebrauchstauglichkeit der Technologien sein [78].

4.2 Publikation IV: Nutzen und Zufriedenheit mit einem Tablet-Computer und einer intelligenten Notfalluhr bei älteren Erwachsenen und ihren Angehörigen

Vollständige Literaturangabe

Wiegel P, Fotteler ML*, Kohn B, Mayer S, Verri FM, Dallmeier D, Denkinger M. Perceived benefit and satisfaction with a tablet computer and an emergency smartwatch by older adults and their relatives: results from a prospective real-world pilot study. JMIR Human Factors (forthcoming). 2024. doi: 10.2196/53811.*

*gleichermaßen beigetragen

4.2.1 Aspekt der Forschungsfrage

Da die Gegebenheiten im Alltag in der Regel unvorhersehbarer und variabler sind als in einer künstlichen Testumgebung, ist es wichtig, die Wirksamkeit von AT für ältere Menschen unter Alltagsbedingungen zu testen [79]. Bei solchen Studien kann auch untersucht werden, ob sich eine Technologie in die Routine der Nutzenden integrieren lässt. Zudem kann bewertet werden, ob die Technologie von älteren Menschen leicht bedient werden kann und welche Funktionen wirklich nützlich sind.

Im Rahmen der hier vorgestellten prospektiven, explorativen Anwenderstudie wurden ein Tablet-Computer mit einer vereinfachten Oberfläche oder eine Smartwatch mit programmierbaren Notfallkontakten von älteren Menschen im Alltag getestet, um den wahrgenommenen Nutzen von und die Zufriedenheit mit den Geräten zu untersuchen. Häufig werden ältere Menschen von Angehörigen bei der Nutzung von Hilfsmitteln unterstützt, weshalb in dieser Studie mit dem Originaltitel *„Perceived benefit and satisfaction with a tablet computer and an emergency smartwatch by older adults and their relatives: results from a prospective real-world pilot study“* zwei Probandengruppen betrachtet wurden: ältere Erwachsene und ihre Angehörigen oder eine nahestehende Person (im Folgenden als Angehörige bezeichnet).

4.2.2 Methoden

Studienpopulation

Die Einschlusskriterien für ältere Erwachsene waren ein Alter ≥65 Jahre, ein Wohnsitz ≤50 km um den Studienort, eine unabhängige oder unterstützte Wohnsituation, Deutschkenntnisse und Einwilligungsfähigkeit. Angehörige mussten verwandt oder nahestehend sein, Deutsch sprechen und ein internetfähiges Gerät (z.B. Smartphone, Laptop) besitzen.

Studienablauf

Basierend auf den individuellen Bedürfnissen der Teilnehmenden wurde das passende Produkt ausgewählt und bei einem Erstbesuch eingeführt. Die Teilnehmenden testeten das gewählte Produkt acht Wochen lang in ihrem täglichen Leben. Probleme sollten wenn möglich mithilfe des Handbuches oder durch Kontakt mit der Firma gelöst werden. Das Studienteam kontaktierte die Teilnehmenden regelmäßig, um sich nach dem Verlauf zu erkundigen, bei der Lösung möglicher Probleme zu helfen und an die Dokumentation von Fehlern, Problemen und der Nutzungshäufigkeit zu erinnern. Vor und nach der Intervention erfolgte eine Befragung. Für die Studie liegt ein positives Votum der Ethikkommission der Universität Ulm vor (Nr. 230/21 vom 05.07.2021).

Datenerhebung

Sowohl die älteren Erwachsenen als auch die Angehörigen bewerteten die Technologie auf der Grundlage ihrer Erfahrungen. Die Angaben der Angehörigen stellen die eigenen Wahrnehmungen dar und nicht die Einschätzung der Nützlichkeit des Geräts für die älteren Erwachsenen. Neben soziodemografischen Daten wurden die Nutzung und Akzeptanz der Technologie (Technology Usage Inventory – TUI [80]), die Zufriedenheit mit der Anwendung (Quebec User Evaluation of Satisfaction with Assistive Technology – QUEST 2.0 [81, 82]), sowie die Zufriedenheit bezogen auf vorab definierte Problembereiche (Canadian Occupational Performance Measure – COPM [83]) erhoben.

Datenauswertung

Für alle Endpunkte wurden der Mittelwert ± die Standardabweichung berechnet. Darüber hinaus wurden explorative statistische Inferenztests durchgeführt, um die Auswirkungen der AT auf die mit dem COPM identifizierten Alltagsprobleme der älteren Erwachsenen und ihrer Angehörigen zu bewerten. Um die Daten vor und nach der Intervention zu vergleichen, wurden t-tests durchgeführt. Die statistische Signifikanz wurde für alle Tests auf $p<.05$ festgelegt.

4.2.3 Zusammenfassung der Ergebnisse

17 ältere Erwachsene (Tablet n=8, Smartwatch n=9) und 16 Angehörige (Tablet n=7, Smartwatch n=9) nahmen an der Studie Teil. Die teilnehmenden älteren Erwachsenen waren im Schnitt > 80 Jahre alt. Ältere Erwachsene in der Smartwatch-Gruppe waren abhängiger und gebrechlicher als die der Tablet-Gruppe. Weitere Charakteristika sind in Tabelle 4 zusammengefasst.

Tabelle 4: Soziodemografische Charakteristika der älteren Erwachsenen ≥65 Jahre vor der achtwöchigen Testphase getrennt nach der zu testenden Technologie (Tablet vs. Smartwatch) (übersetzt aus [84]; Lizenz: CC-BY 4.0: https://creativecommons.org/licenses/by/4.0/)

		Tablet (n=8)	**Smartwatch (n=9)**
Geschlecht (w/m)		5/3	5/4
Alter (in Jahren) (Mittelwert (SD[1]))		80,1 ± 8,2	82,7 ± 7,9
Gefühltes Alter (in Jahren) (Mittelwert (SD[1]))		76,9 ± 12,4	72,6 ± 15,4
Wohnsituation	Alleine	3	6
	Mit Partner/in	5	3
Ausbildung	< 10 Jahre	4	4
	≥ 10 Jahre	4	5
Selbst eingeschätzter	Exzellent/ sehr gut	2	1
Gesundheitszustand	Gut	6	4
	Mittelmäßig/ Schlecht	0	4
Pflegegrad	Ja	2	5
	Nein	6	4
IADL[2] (Mittelwert (SD))		7,4 ± 1,4	5,3 ± 2,6
CFS[3] (Mittelwert (SD))		3,4 ± 1,2	3,7 ± 2,1
Gebrechliche Personen (CFS[3] >4)		0	4
Technologieinteresse	Hoch	4	4
	Mittel	3	2
	Gering	1	3

[1]SD: Standard deviation (Standardabweichung)

[2]IADL: Instrumentelle Aktivitäten des täglichen Lebens (Lawton-Scale)

[3]CFS: Klinische Frailty Skala (clinical frailty scale)

Technologieakzeptanz

Die TUI-Werte für Nützlichkeit waren in der Smartwatch-Gruppe (ältere Erwachsene (Mittelwert ± Standardabweichung (SD)) 5,0 ± 1,0; Angehörige 5,4 ± 1,4) höher als in der

Tablet-Gruppe (ältere Erwachsene 3,8 ± 1,5; Angehörige 4,2 ± 1,6), jedoch nicht signifikant (ältere Erwachsene t(12,3)=1,9, *p*=0,07, d=0,98; Angehörige t(12,1)=1,6, *p*=0,14, d=0,83). Die TUI-Werte für die Nutzungsabsicht waren bei älteren Erwachsenen in der Smartwatch-Gruppe (6,1 ± 3,4) signifikant höher als in der Tablet-Gruppe (2,7 ± 2,2) (t(13,6)=2,4, *p*=,03, d=1,14). Die Bewertungen der Nutzungsabsicht durch die Angehörigen in der Smartwatch-Gruppe waren ebenfalls höher (7,8 ± 2,7) als in der Tablet-Gruppe (5,9 ± 1,5), jedoch nicht signifikant (t(11,0)=1,7, *p*=0,11, d=0,86).

Zufriedenheit mit der Technologie

Die Gesamtzufriedenheit (QUEST 2.0) über alle Items hinweg war bei älteren Erwachsenen und Angehörigen beider Gruppen ähnlich. Der mittlere Zufriedenheitswert (Skala von 1 bis 5) der älteren Erwachsenen lag bei 3,2 ± 0,6 in der Tablet-Gruppe und bei 3,6 ± 0,4 in der Smartwatch-Gruppe (t(11,4)=1,5, *p*=0,16, d=0,75). In ähnlicher Weise betrug die mittlere Zufriedenheit über alle von den Angehörigen bewerteten Items 3,6 ± 0,7 in der Tablet-Gruppe und 3,5 ± 0,4 in der Smartwatch-Gruppe (t(8,6)=0,3, *p*=0,77, d=0,16).

Wahrgenommene Leistung und Zufriedenheit

Die am häufigsten mit dem COPM identifizierten Alltagsprobleme waren der Kontakt/ die Kommunikation mit Verwandten (Tablet-Gruppe), Unterhaltung/ Informationen über Nachrichten (Tablet-Gruppe), Sicherheitsempfinden (Smartwatch-Gruppe), Hilfe in Notsituationen zu bekommen (Smartwatch-Gruppe) und Benutzerfreundlichkeit der AT (beide Gruppen). Die Anzahl der angegebenen Themen lag zwischen einem und vier.

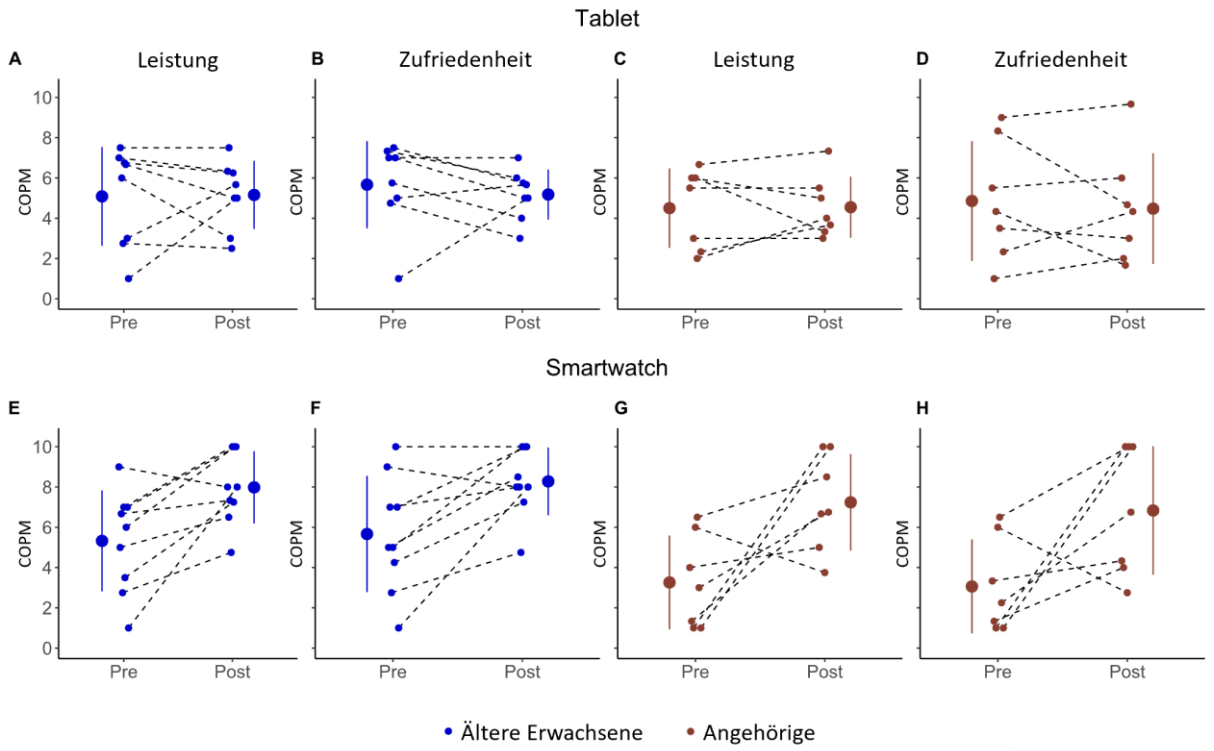

Abbildung 6: Ergebnisse des Canadian Occupational Performance Measure (COPM, Skala von 0 bis 10) von älteren Erwachsenen ≥65 Jahre und deren Angehörigen vor und nach einer achtwöchigen Testung eines Tablet-Computers oder einer Smartwatch (übersetzt und angepasst aus [84]; Lizenz: CC-BY 4.0: https://creativecommons.org/licenses/by/4.0/). *Höhere Werte stehen für eine höhere wahrgenommene Leistung und Zufriedenheit. Kleine Punkte stellen Daten von einzelnen Teilnehmenden dar. Größere Punkte und Balken stellen Mittelwert ± Standardabweichung dar.*

In der Tablet-Gruppe haben sich die selbst wahrgenommene Leistung (ältere Erwachsene: t(7)=0,09, *p*=.93, d=0,03; Angehörige: t(6)=0,08, *p*=.94, d=0,03) und die Zufriedenheit (ältere Erwachsene: t(7)=0,6, *p*=.54, d=0,23; Angehörige: t(6)=0,5, *p*=.64, d=0,18) während der Intervention nicht signifikant verändert (Abbildung 6, Felder A - D). In der Smartwatch-Gruppe berichteten mit einer Ausnahme alle älteren Erwachsenen über eine signifikant verbesserte wahrgenommene Leistung (t(8)=3,5, *p*=.008, d=1,17) und Zufriedenheit (t(8)=3,2, *p*=.01, d=1,06) (Abbildung 2, Felder E - F). Bei den Angehörigen der Smartwatch-Gruppe stiegen die selbst wahrgenommene Leistung (t(6)=2,5, *p*=.04, d=0,96) und die Zufriedenheit (t(6)=2,3, *p*=.06, d=0,87), jedoch nicht statistisch signifikant (Abbildung 2, Felder G - H).

4.2.4 Antwort auf die Forschungsfrage

Die Ergebnisse dieser Studie verdeutlichen die Heterogenität von AT und wie groß die Unterschiede für Nutzende und Angehörige sein können. Während die Studie für den Bereich Sicherheit (Smartwatch) positive Effekte in den Bereichen Akzeptanz, Leistung und Zufriedenheit zeigten, konnte dies für den Bereich Kommunikation (Tablet) nicht bestätigt werden. Die teilnehmenden älteren Personen in der Smartwatch-Gruppe waren älter, fühlten sich jedoch jünger, waren gebrechlicher, schätzen ihren eigenen Gesundheitszustand schlechter ein und hatten vermehrt einen Pflegegrad im Vergleich zu den älteren Personen in der Tablet-Gruppe. Möglicherweise konnte die Smartwatch besser in den Alltag integriert werden und die Wünsche der Nutzenden besser erfüllen. Mehrere Teilnehmende betonten beispielsweise, dass sie sich sicherer fühlten, wenn sie mit dem Gerät draußen unterwegs waren.

Aufgrund der Heterogenität von AT und den ganz unterschiedlichen Erwartungen an technische Unterstützung, ist ein individualisierter Ansatz essenziell für eine erfolgreiche MTI bei älteren Menschen. Zukünftige Studien und technische Entwicklungen sollten die Präferenzen, Probleme und Ziele älterer Menschen, aber auch ihrer Angehörigen bzw. des Pflegepersonals berücksichtigen, um die Akzeptanz und Effektivität von AT zu erhöhen. Der COPM als Messinstrument, mit dem die individuellen Probleme der Teilnehmenden identifiziert und untersucht werden konnten, erwies sich als geeignet, um die wahrgenommene Leistung der Technologie sowie die Zufriedenheit mit der Anwendung zu erfassen.

5. Diskussion und Ausblick

5.1 Beantwortung der Forschungsfrage

Die Digitalisierung hält in der medizinischen und pflegerischen Gesundheitsversorgung Einzug und betrifft unter anderem Patientinnen und Patienten, deren Angehörige und das medizinische Fachpersonal. Anhand zweier Beispiele und unter Nutzung verschiedener Methoden wurde in dieser kumulativen Dissertation untersucht, welche sozialen, demografischen und organisatorischen Aspekte für eine erfolgreiche MTI relevant sind. Die Prozesse sind komplex, da eine Vielzahl von Faktoren berücksichtigt werden müssen, die sowohl den Menschen als auch die Technologie betreffen. Eine erfolgreiche MTI umfasst nicht nur technische Herausforderungen, sondern erfordert auch ein tiefes Verständnis für menschliches Verhalten und soziale Kontexte [2, 85]. Menschen haben unterschiedliche Fähigkeiten, Erfahrungen, Vorlieben und Bedürfnisse. Eine Technologie, die für eine Person intuitiv ist, kann für eine andere verwirrend sein. Im Gesundheitswesen ist dies besonders relevant, da multidisziplinäre Teams und Menschen ohne explizite technische Ausbildung oder technischen Hintergrund mit oft komplexen neuen Anwendungen umgehen müssen. Hinzu kommt, dass sich technologische Innovationen rasant entwickeln und verändern, wodurch ein regelmäßiger Schulungs- und Lernbedarf entsteht. Die vorliegende Arbeit zeigt auch, dass eine erfolgreiche MTI stark kontextabhängig sein kann. In einem zwar technisch gut ausgestatteten, aber hektischen Arbeitsumfeld gibt es andere Herausforderungen als im ruhigen aber möglicherweise abgelegenen privaten Umfeld.

In den Interviews mit Expertinnen und Experten und der Befragung des betroffenen Fachpersonals zur KLEM waren vor allem soziale und organisatorische Auswirkungen relevant. Hier wurde angemerkt, welche Berufsgruppen betroffen sein werden, wie gut sich die neue Technologie in den Arbeitsalltag integrieren lässt, wie sich die Aufgabenbereiche verändern werden und ob sich die Arbeitsbelastung erhöhen wird. Zu relevanten demografischen Parametern können mit den Studienergebnissen nur bedingt Schlussfolgerungen gezogen werden. Auch die derzeitige Evidenzlage weist hier Lücken auf. Es ist möglich, dass Charakteristika wie Alter, Geschlecht, Berufsgruppe und Berufserfahrung eine Rolle spielen [86, 87].

Eine Prozessmodellierung und -analyse mittels BPMN kann bei der Vorbereitung auf die Einführung neuer Technologien in den klinischen Alltag wertvolle Unterstützung bieten. BPMN ist ein Modellierungsstandard, mit dem auch komplexe Prozesse visualisiert werden können. Entscheidungsträgerinnen und Entscheidungsträger können so die organisatorischen Konsequenzen besser abschätzen und die betroffenen Fachkräfte können sich auf die ihre Arbeit betreffenden Änderungen einstellen. Da bei der Digitalisierung im Arbeitsumfeld viele Personen betroffen sind, kann eine solche Prozessanalyse helfen, eine gemeinsame Basis für alle zu schaffen.

Die Ergebnisse der Studien zu Fokusthema 2 zeigten primär soziale und demografische Aspekte der MTI. Bei einem Technikeinsatz im privaten Umfeld sind die eigene technische Ausstattung und die Verfügbarkeit von Unterstützung durch Angehörige oder Freunde relevant für eine erfolgreiche MTI. Das Alter, das Bildungsniveau, die Wohnsituation und vor allem der Gesundheitszustand beeinflussen die Nutzung bzw. nicht-Nutzung sowie die Wirksamkeit von AT bei älteren Menschen. Bei dieser Zielgruppe ist ein individualisierter Ansatz, der diese Faktoren und die Ziele und Probleme der Nutzerin/ des Nutzers berücksichtigt essenziell für eine erfolgreiche MTI. Der COPM ist ein Instrument, das dabei hilft, alltägliche Probleme in

den Bereichen Selbstversorgung, Produktivität und Freizeit zu identifizieren, um somit etwaige Erfolge einer Technologie ganz konkret messbar zu machen. Das Instrument wurde für die Nutzung durch Ergotherapeutinnen und Ergotherapeuten entwickelt, ist jedoch ein Ansatz dafür, wie die individuelle Bewertung der Bedürfnisse zukünftiger Nutzerinnen und Nutzer von AT die Basis für eine erfolgreiche MTI legen kann. Beratungsangebote, die ältere Menschen mit einer solchen Analyse unterstützen, können die Nutzung und Verbreitung von AT positiv beeinflussen. Tabelle 5 fasst die Erkenntnisse aus den vier vorgestellten Studien zusammen.

Tabelle 5: Faktoren, die für eine erfolgreiche Mensch-Technik-Interaktion von Gesundheitsfachkräften und älteren Patientinnen/ Patienten in sozialer, demografischer und organisatorischer Hinsicht relevant sind (basierend auf den Ergebnissen aus den vorgestellten Publikationen I – IV; Tabelle nicht abschließend)

Domäne	Fachkräfte	Ältere Patientinnen/Patienten
Sozial	- Berücksichtigung einer möglichen Veränderung der Abläufe - Berücksichtigung einer möglichen Verlagerung von Aufgaben und Verantwortlichkeiten - Vermeidung eines Anstiegs der Arbeitsbelastung	- Verfügbarkeit von IKT-Technologien - Verfügbarkeit eines Internetanschlusses - Technologieinteresse - Soziales Umfeld/ Angehörige zur Unterstützung
Demografisch		- Alter - Bildungsniveau - Wohnsituation - Gesundheitszustand - Selbstständigkeit/ Autonomie - Gebrechlichkeit
Organisatorisch	- Nahtlose Integration in bestehende Abläufe - Einbezug aller betroffenen Personen bei der Neugestaltung von Abläufen - Aus- und Weiterbildung bzw. regelmäßige Schulungen	- Nahtlose und unkomplizierte Integration in den Alltag - Verfügbarkeit von Beratungs- und Informationsangeboten - Verfügbarkeit von Schulungsmöglichkeiten

Die vorliegende Arbeit bietet Einblicke in die für eine erfolgreiche MTI relevanten sozialen, demografischen und organisatorischen Aspekte, vermittelt jedoch kein vollständiges Bild dieser Thematik. Die Generalisierbarkeit der Ergebnisse wird unter anderem durch die untersuchten Technologien und die berücksichtigten Personengruppen eingeschränkt. Nichtsdestotrotz zeigt sich, wie komplex es sein kann, die Rahmenbedingungen für eine erfolgreiche Nutzung von Technologie zu schaffen. Die vorliegende Arbeit profitiert von der Anwendung und Kombination einer breiten Palette qualitativer und quantitativer wissenschaftlicher Methoden. Diese helfen, das Thema aus vielfältigen Perspektiven zu beleuchten und können als Anregung für andere Forschende dienen. Auch Entscheidungsträgerinnen und Entscheidungsträger im Gesundheitswesen oder Gesundheitsfachpersonen, die Digitalisierungsprojekte planen, können von den Ergebnissen dieser Arbeit profitieren.

5.2 Bestehende Herausforderungen

Hinsichtlich der KLEM hat sich gezeigt, dass sich die aktuelle Literatur primär auf die medizinischen Auswirkungen der Technologie bezieht. Soziale, demografische und organisatorische Aspekte einer Einführung der KLEM wurden bislang nur selten angesprochen. Da hier aber wie berichtet große Veränderungen zu erwarten sind, sind weitere Untersuchungen, die über den medizinischen Vorteil hinausgehen elementar, um die

Technologie langfristig und erfolgreich in der Regelversorgung etablieren zu können. Das betroffene Personal eng in den Implementierungsprozess einzubinden kann helfen, Ablehnung, Unverständnis und Frustration zu vermeiden.

Auch die Berücksichtigung ökonomischer Aspekte ist für ein effizientes Gesundheitssystem essenziell. Für die KLEM wurde dies in der Literatur bislang kaum untersucht. Es ist möglich, dass sich dies in den kommenden Jahren wandeln wird, wenn die Technologie in größerem Stil in die Routineversorgung integriert wird. Einige der befragten Expertinnen und Experten und das medizinische Fachpersonal nannten die Kosten als einen relevanten Faktor.

Bei Studien zur Bewertung von AT für ältere Menschen werden vor allem soziale und ethische Endpunkte häufig vernachlässigt [88]. Bei einer eigenen systematischen Literaturanalyse von randomisiert kontrollierten Studien, zeigte sich, dass die Auswertung häufig eindimensional ist und sich primär auf die Wirksamkeit von AT konzentriert. Dies ist analog zum Fokus auf die medizinischen Auswirkungen der KLEM. Von den 19 Studien, die in der Literaturarbeit berücksichtigt wurden, haben nur zwei Studien die Auswirkungen von AT auf Pflegefachpersonen oder Angehörige untersucht [79]. Die sozialethische Perspektive fehlte bei den berücksichtigten Studien. Hier wären Fragen des Datenmanagements und -schutzes sensibler Gesundheitsdaten beispielsweise im Zusammenhang mit intelligenter Haustechnik wichtig [88, 89]. Nutzende müssen darauf vertrauen können, dass ihre Daten sicher sind und die Technologie keinen Schaden anrichtet.

Weiterhin zeigen die vorgestellten Ergebnisse zu Fokusthema 2 die Relevanz von gesundheitlichen Einschränkungen [76, 79, 84]. Um wirksam im Alltag genutzt zu werden, müssen AT die besonderen Anforderungen von älteren, gebrechlichen Menschen mit physischen oder psychischen Einschränkungen berücksichtigen. Es besteht auch dringender Bedarf, diese Zielgruppe in wissenschaftlichen Studien stärker einzubinden. Gebrechliche und/oder stark beeinträchtige ältere Menschen können in hohem Maße von AT profitieren, haben jedoch auch spezielle Anforderungen wie beispielsweise Unterstützung bei der Beschaffung/ Verschreibung, Schulung und Nachbetreuung [59]. Aktuelle Angebote und AT werden diesen Anforderungen möglicherweise noch nicht gerecht, wodurch die Nutzbarkeit für diese Zielgruppe eingeschränkt wird. Studien, die sich stärker auf diese gefährdete Gruppe konzentrieren und dabei auch die Gebrechlichkeit der Studienpopulationen messen sind nötig.

Eine der größten Herausforderungen bei der Evaluation von AT besteht in der Heterogenität der Produkte [79, 90]. Es gibt Produkte, die darauf abzielen, die Unabhängigkeit und Autonomie von Menschen mit alters- oder krankheitsbedingten Einschränkungen nachhaltig zu verbessern. Andere Produkte wiederrum haben das übergreifende Ziel, die Sicherheit und/oder den Komfort zu verbessern, ohne Fokus auf bestimmte Defizite. Basierend auf dieser Annahme, zeigt Abbildung 7 einen Vorschlag für eine Aufteilung von AT in drei Kategorien mit unterschiedlichen Zielen und Folgen für Autonomie und Unabhängigkeit der Nutzenden. Diese Einteilung kann helfen, gesellschaftliche und wissenschaftliche Bewertungen zu fokussieren und den erfolgreichen Einsatz von AT zu unterstützen

Kategorie	Hauptsächlich bezogen auf einzelne Defizite/Krankheiten	Hauptsächlich bezogen auf (I)ADL[1] oder persönliche Sicherheit*	Hauptsächlich bezogen auf Haushalt, Komfort oder Sicherheit im Außenbereich*
Beispiele	- Blutdruckmessgerät - Blutzuckermessgerät - Tremorlöffel - KI-unterstützte Lesehilfe/Kamera, die an der Brille angebracht wird - Gesundheitsanwendung/ App - Elektronische Sehhilfe - GPS-Ortungsgerät - Körperwaage - Ergänzung von Haushaltsgeräten (Waschmaschinen, Backofen usw.) für blinde Menschen - Hörhilfe - Tür- oder Telefonklingelverstärker	- Elektronisches Schloss - Hausnotruf - Elektronischer Kalender - Eketrischer Tablettenspender - Personenlift - Elektrische Aufstehhilfe - Wearable/Smartwatch - Geräte zur Sturzerkennung wie Sensormatten/Raumüberwachun - Spracherkennung - Kommunikationstablets für Senioren inkl. Videoanruf - Seniorenhandy - Elektrischer Rollator	- Elektrischer Rolladen - Beleuchtungssystem - Außenkamera - Herdabschaltung - Wassermelder oder -regulator - Normale Haushaltsgeräte (z. B. Waschmaschine, Festnetztelefon) - Universalfernbedienung - Unterstützungs-/Haushaltsroboter - Hausautomationssystem - Schlüsselfinder - Tür-/Fensteralarm
Kommentar	Verbesserung sehr ausgeprägter, oft krankheitsbedingter und nutzungsspezifischer Defizite, auch bei seh- und hörbehinderten Menschen.	Verbesserung der Selbsthilfe, Selbständigkeit und Autonomie. Nutzer:innen könnten auch eine Triage in Bezug auf die äußere Sicherheit benötigen (elektronische Schlösser könnten weniger sicher sein).	Optimierung und Erleichterung regelmäßiger Aufgaben (die auch externalisiert werden können, wie z. B. das Waschen von Wäsche) und das Gefühl, vor externen/umweltbedingten Stressfaktoren sicher zu sein.
	Hohe Auswirkungen auf die Autonomie/ unabhängige Lebensführung		**Geringe Auswirkungen auf die Autonomie**

Abbildung 7: Vorschlag zur Einteilung von assistiven Technologien in drei Kategorien mit unterschiedlichen Zielen und Auswirkungen auf Autonomie und unabhängige Lebensführung (übersetzt aus [76]; Lizenz: CC-BY 4.0: https://creativecommons.org/licenses/by/4.0/). ([1](I)ADL: (Instrumentelle) Aktivitäten des täglichen Lebens; *: Äußere Sicherheit: sichere Häuser, Alarmsysteme, Außenüberwachung vs. persönliche Sicherheit: Sturzerkennung, andere ADL-bezogenen Maßnahmen)

5.3 Ausblick

An einer fortschreitenden Digitalisierung des Gesundheitswesens führt kein Weg vorbei. Technologien, die aktuell noch wenig eingesetzt werden, wie KI, Robotik und Wearables, werden die Diagnose, Behandlung und Überwachung von Patientinnen und Patienten und das Arbeitsumfeld von Gesundheitsfachkräften in Zukunft stark verändern. Um Unsicherheit oder sogar Ablehnung zu vermeiden, ist es essenziell, die Rahmenbedingungen für eine erfolgreiche MTI zu schaffen.

Im europäischen und weltweiten Vergleich erzielt Deutschland in verschiedenen Digitalisierungsindizes derzeit nur mittlere bis schlechte Ergebnisse [91, 92]. Andere westliche Länder wie Dänemark, Kanada, Estland und Österreich sind deutlich voraus was beispielsweise die Vernetzung zwischen den Leistungserbringern sowie die Nutzung einer elektronischen Patientenakte (ePA) betrifft. Aber auch in Deutschland wird die Digitalisierungsstrategie weiter vorangetrieben. Die Einführung der digitalen Gesundheitsanwendungen (DiGA) in den Leistungskatalog der gesetzlichen Krankenkassen im Dezember 2019 war weltweit ein Novum. DiGA sind Apps, die umfangreich geprüft wurden und auf Rezept verschrieben werden können [93]. Am 14.12.2023 beschloss der Deutsche Bundestag zwei zentrale Gesetzesvorhaben. Das „Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens“ (Digital-Gesetz – DigiG) sieht die Bereitstellung einer ePA für alle gesetzlich Versicherten ab dem 01.01.2025 vor. Zudem wurde bereits zum 01.01.2024 das E-Rezept eingeführt, das unter dem DigiG noch weiterentwickelt wird. Ein weiterer Bestandteil des DigiG ist die bessere Integration der DiGA in die Versorgung. Eine bessere Nutzung von Gesundheitsdaten für Forschungszwecke soll mit dem „Gesetz zur

verbesserten Nutzung von Gesundheitsdaten“ (Gesundheitsdatennutzungsgesetz – GDNG) ermöglicht werden [94].

Sowohl für den Einsatz von Technologie im klinischen Alltag als auch im privaten Umfeld bestehen mit diesen beiden Vorhaben große Chancen. Daten aus der klinischen Versorgung können unter dem GDNG für die Forschung genutzt und miteinander verknüpft werden. Dadurch können größere und detailliertere Datensätze entstehen und die Ergebnisse beispielsweise eine Integration von neuen Technologien in die Regelversorgung vorantreiben. Gesundheitsdaten, die mit digitalen Gesundheitsanwendungen oder auch AT erhoben wurden können in die ePA gespeichert werden und zu Vorsorgezwecken genutzt werden oder von Ärztinnen und Ärzten bei der Behandlung berücksichtigt werden [95]. Welchen Einfluss diese verstärkte politische Initiative in Zukunft tatsächlich auf den Digitalisierungsfortschritt und die Versorgung im deutschen Gesundheitswesen haben wird, bleibt abzuwarten.

6. Zusammenfassung/ Abstract

Einleitung

Die Mensch-Technik-Interaktion (MTI) ist komplex, nicht zuletzt aufgrund der Vielfalt der Nutzenden und deren Erfahrungen, Wünschen und Fähigkeiten. Neben der Effektivität der Technologie, müssen soziale, demografische und organisatorische Facetten der MTI zwingend berücksichtigt werden. Dies ist besonders relevant im Gesundheitswesen, wo neben Gesundheitsfachkräften auch Patientinnen und Patienten und deren Angehörige Teil der MTI sind. Anhand zweier Fokusthemen zur Digitalisierung im Gesundheitswesen – (1) dem Einsatz konfokaler Laser-Endomikroskopie (KLEM) in der Neuropathologie und (2) der Nutzung von assistiven Technologien (AT) zur Unterstützung älterer Menschen – wurde untersucht, welche sozialen, demografischen und organisatorischen Aspekte für eine erfolgreiche MTI in der medizinischen und pflegerischen Versorgung relevant sind.

Methoden

Zu Fokusthema 1 wurde die vorhandene Literatur im Rahmen einer narrativen Recherche nach der Evaluation sozialer, demografischer und organisatorischer Endpunkte untersucht. Um den Einfluss der KLEM auf die MTI zu untersuchen, wurden Expertinnen und Experten verschiedener Fachrichtungen (u.a. Medizintechnik, Neuropathologie, Wissenschaft) im semi-strukturierten Interviews zum Potential der KLEM befragt. In einer weiteren Studie wurde das klinische Gesundheitsfachpersonal einer Klinik, die die KLEM derzeit im Rahmen einer Interventionsstudie erprobt, mit einem Fragebogen befragt. Zudem wurde eine Prozessanalyse mittels des Notationsstandards Business Process Model and Notation durchgeführt. Hierbei wurde der aktuelle Prozess mit dem Einsatz der KLEM verglichen. Zu Fokusthema 2 wurde im Rahmen einer Querschnittsstudie 2.500 Menschen ab 65 mit einem Fragebogen zur Nutzung von Informations- und Kommunikationstechnologie (IKT) sowie AT kontaktiert. Der Fragebogen wurde postalisch mit einem Informationsbrief zur Studie und einem frankierten Rücksendeumschlag versandt. In einer prospektiven, explorativen Anwenderstudie wurden ein Tablet-Computer mit einer vereinfachten Oberfläche oder eine Smartwatch mit programmierbaren Notfallkontakten von älteren Menschen im Alltag getestet, um die wahrgenommene Leistung von und die Zufriedenheit mit den Geräten zu untersuchen.

Ergebnisse

Für beide Fokusthemen liegt der Schwerpunkt der bisherigen Evidenzbasis auf medizinischen und/oder klinischen Endpunkten. Soziale und organisatorische Facetten (wie beispielsweise der Unterstützungs-/ Schulungsbedarf oder die Integration in bestehende Routinen) werden seltener untersucht, sind aber sowohl für Patientinnen und Patienten als auch für Gesundheitsfachkräfte relevant. So zeigte die Analyse des KLEM-Prozesses zwar eine Reduktion der Gesamtzahl an Aufgaben (-38.1%) aber auch eine Zunahme der Aufgaben in der Neurochirurgie (+41.7%). Diese Zunahme entsteht vor allem durch eine Verlagerung der Aufgaben und zusätzliche Wartungs- und Reinigungstätigkeiten. Die Bedeutung demografischer Aspekte zeigte sich vor allem bei Fokusthema 2, also einer MTI im privaten Umfeld. Alter, Wohnsituation und Gesundheitsstatus sind einige Beispiele für Charakteristika, die die Nutzung von IKT oder AT bei älteren Menschen signifikant beeinflussen (p<.05). Zudem scheint eine IKT-Nutzung einen Einfluss auf die Nutzung von modernen und innovativen AT zu haben. In der Anwenderstudie erreichte nur die Smartwatch signifikante Verbesserungen in den Bereichen Leistung und Zufriedenheit (p<.05). Seitens der Fachkräfte lassen sich aufgrund der geringen Studienpopulation keine Angaben für demografisch relevante Charakteristika machen.

Schlussfolgerung

Das Potential neuer Technologien für Verbesserungen im Gesundheitswesen ist groß. Der Erfolg hängt jedoch maßgeblich von den Nutzerinnen und Nutzern (also beispielsweise Gesundheitsfachkräften und Patientinnen und Patienten) und deren Einstellung zu der neuen Anwendung ab. Während es selbstverständlich wichtig ist, dass Technologie effektiv und effizient ist, müssen auch soziale, demografische und organisatorische Facetten der MTI berücksichtigt werden. Eine zu eingeschränkte Sichtweise und eine Vernachlässigung dieser holistischen Perspektive auf die MTI, kann zu einer Ablehnung seitens der Nutzenden führen.

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Anhang 1: Publikation I: Confocal Laser Endomicroscopy for Intraoperative Tumor Assessment: Development of a Conceptual Model for an Evaluation Study

Anhang 1.1: Eigenanteil und Lizenzfreigabe für Publikation I

Literaturangabe	**Fotteler M**, Heninger L, Holl F, Schlegel J, Swoboda W. Confocal Laser Endomicroscopy for Intraoperative Tumor Assessment: Development of a Conceptual Model for an Evaluation Study. Studies in Health Technology and Informatics. 2019;262:376-379. doi:10.3233/SHTI190097
Eigenanteil	Die einzelnen Anteile an der Studie habe ich erarbeitet und mit WS konkretisiert. Der Interviewfragebogen wurde von LH erstellt und im fachlichen Diskurs mit mir finalisiert. LH führte die Interviews durch und erstellte die Transkripte. Die Datenanalyse wurde von LH und mir durchgeführt. Ich habe das Manuskript geschrieben und die Abbildungen erstellt. Alle Autorinnen und Autoren haben das Manuskript gelesen und überarbeitet und nach meiner Finalisierung bewilligt. Ich habe das Manuskript bei der International Conference on Informatics, Managment and Technology in Healthcare eingereicht, die Kommunikation während des peer-review Prozesses geleitet und die Anmerkungen der Gutachter eingearbeitet. Zusammenfassung des prozentualen Eigenanteils: – Planung der Studie: 80% – Erhebung, Aufbereitung und Auswertung der Daten: 50% – Verfassen des Manuskriptes und editorielles Handling: 90%
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Confocal Laser Endomicroscopy for Intraoperative Tumor Assessment: Development of a Conceptual Model for an Evaluation Study

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Abstract. Brain tumor surgery is a complex medical procedure. The extent of tumor resection is essential for postoperative recovery and survival. The neurosurgeon needs to regularly check the borderline between healthy and cancerous tissue. Currently, tissue samples are extracted via instantaneous sections and sent to a neuropathologist for examination. This process takes time and requires extensive human resources. Confocal laser endomicroscopy (CLE) allows visualization of cellular structures in vivo without the need for sample extraction. This paper presents a conceptual model which serves as the hypothetical basis for a planned intervention study to evaluate CLE with the case example of brain tumor surgery. Using current literature and expert interviews, the model has been tested. The expected improvement of the medical outcome could be confirmed. Regarding the socioeconomic impact of CLE, the literature is scarce. Expert interviews confirmed the hypotheses that costs and the workload for clinical staff might increase.

Keywords. Confocal endomicroscopy, digital biopsy, neuropathology

1. Introduction

Brain tumor surgery is a complex procedure. The extent of tumor resection is essential for postoperative recovery and survival [1-3]. The neurosurgeon needs to regularly check the borderline between healthy and cancerous tissue. Depending on tumor type and penetration, it can be difficult to impossible to determine the border intraoperatively [4; 5]. Currently, tissue samples are extracted via instantaneous sections and sent to a neuropathologist for micro- and macroscopic assessment. Transport, examination and redelivery of results prolong the surgery. According to scientists it is not uncommon for the surgeon to wait up to 45 minutes before continuing with the operation [3].

Digital technologies are considered to be an essential stimulus for improved processes in medicine. Telemedicine, remote diagnosis or therapy with information and

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communication technologies, is especially promising [6]. Confocal laser endomicroscopy (CLE) digitalizes the biopsy process and has the potential to accelerate intraoperative decision-making and improve patient outcome. This article describes a project aiming to evaluate CLE using the tool CONVIVO (Carl Zeiss AG, Figure 1). CONVIVO is equipped with a confocal microscope located in a handheld scanner probe which can be placed on the tissue surface. Cellular tissue structures can be visualized in vivo during surgery and are shown on a monitor. There is no need for sample resection.

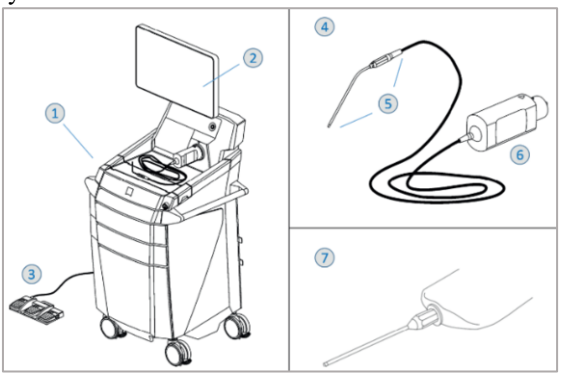

Figure 1: Main components of CONVIVO including sterile sheath. (1) Cart, (2) touchscreen monitor, (3) foot control panel, (4) scanner unit, (5) scanner probe, (6) coupler unit, (7) sterile sheath [7]

2. Methods

The increasing availability of digital devices in health care, rises the need for assessment studies. The planned pilot study (funded by the Bavarian Ministry for Science and Arts) aims to test CONVIVO at the Technical University of Munich Hospital using the case example of brain tumor surgery. The device will be connected to the Department of Neuropathology for remote image analysis. We intent to evaluate both socioeconomic and medical indicators to measure the tool's impact. Examples for evaluation criteria are economic feasibility, usability, data reliability and medical outcome. The study started in January 2019 with a duration of 36 months.

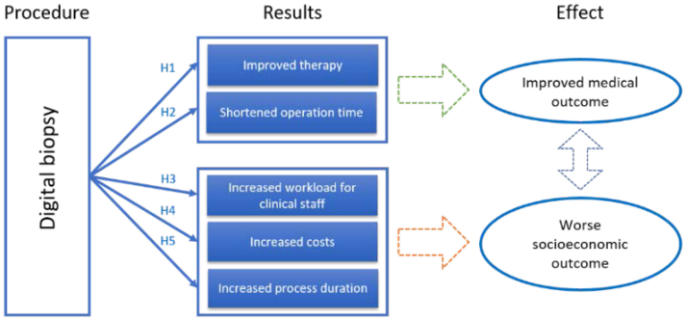

Figure 2: Conceptual model visualizing the hypothetical basis for the project

To establish a common theoretical basis and guide future project activities, the authors began by developing a conceptual model (Figure 2) to determine and visualize the working hypotheses following the framework suggested by Gray and Sockolow [8]. The model was tested analyzing current literature and conducting seven interviews with

experts from various relevant backgrounds including neuropathology, neurosurgery, nursing, quality management and medical engineering.

3. Results

Several studies have shown that CLE combined with a fluorescent agent allows for better resolution and determination of tumor edges. Faster histopathologic examination and more extensive resection are possible. The procedure is non-invasive and the number of samples is not restricted [2-4; 7; 9]. An additional benefit is the shorter time needed for surgery which is also advantageous for patient recovery [2; 9]. All seven interviewed experts confirmed the assumptions of an improved medical outcome and the chance to avoid reoperations using CLE (quotes translated from German by MF): *"If it is reliable, it is great and can increase efficiency and in particular patient safety and avoid reoperations.", "Using digital biopsy processes will be sped up. We will have markedly shorter surgery duration; we do not have to bridge the time gap until the results arrive."*.

Few studies report on socioeconomic outcomes of CLE. We assume that the procedure harbors technical and operative challenges. The device must be scheduled, prepared and maintained for surgery, which was also mentioned by the experts: *„For the nurse, I think, it probably means an increased effort. […] It is another piece of equipment that has to be prepared for surgery and maintained."*. All clinical staff has to be trained and in particular surgeons and pathologists need to get accustomed to CLE-images [1; 3]. The neuropathologist must be available on call, ready to assist with the diagnosis. An increased workload for all clinical staff is expected.

Initial investment costs for CLE are high, which was mentioned by experts: *„Replacing a procedure that normally costs approximately 16€ with a device that costs half a million - the question is, if this helps."*, *"I think there are systems that make sense and help to save money but innovation is always expensive in the beginning."*. The literature did not mention the cost aspect. Work flows in neurosurgery and -pathology will change as confirmed by both literature and experts [3; 4; 9]: *"To have neuropathologists in centers that diagnose via telepathology at some point, will be reality, I think."*. However, no evidence could be found confirming an increased process duration overall. Table 1 summarizes these preliminary results.

Table 1. Overview of results

Hypotheses	Literature	Expert Interviews
H1	confirmed	confirmed
H2	confirmed	confirmed
H3	partly confirmed	confirmed
H4	not confirmed	confirmed
H5	not confirmed	not confirmed

4. Discussion

Available literature primarily focuses on the medical outcome of CLE. H1-H3 (improved therapy, shorter operation time, increased workload) could all be confirmed, at least partially. The literature does not include evidence on an increase of costs. Consequently, H4 could only be confirmed by expert interviews. Peyre et al. [5] recommend to combine CLE with fluorescence-guided surgery to increase cost-efficiency, suggesting high costs

of CLE. Certainly, investment costs for the device are high. Streamlining the process and reducing operating costs might counterbalance initial spending. The economic feasibility of the procedure requires further investigation.

CLE promises medical improvements by reducing errors, shortening operation time and decreasing the number of reoperations [2]. The technique is not yet equivalent to instantaneous sections and scientists currently do not agree whether it should replace [2; 3] or only complement the current procedure [1; 5]. CLE is more expensive, including not only investment costs but also potentially process costs, and increases the workload for clinical staff. Neurosurgeons and –pathologists are not familiar enough with CLE-images to replace instantaneous sections [3]. Process duration might increase through use and maintenance of the device (H5). It is however possible that time saved during surgery and gained efficiency compensate for the increased process complexity.

Study limitations include a lack of generalizability of interview data. The data represent opinions and the analysis is person-dependent. CLE in neuropathology is a very specific topic and results might not be transferrable to other areas. The seven interviews are not sufficient to confirm the hypotheses. The literature review was not exhaustive and existing studies might have been missed. Nevertheless, the results strengthen the hypothetical basis and provide support and justification for the planned study.

Neuropathology is a highly specialized field and CLE provides a chance to more efficient use of this expertise. The development of telemedical centers where one neuropathologist assists several clinics could reduce the personnel demand and contribute to overcome socioeconomic challenges mentioned here [2; 3; 10]. Further research and evaluation of the method is necessary to advance the establishment of CLE.

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Anhang II: Publikation 2: Socio-Organizational Impact of Confocal Laser Endomicroscopy in Neurosurgery and Neuropathology: Results from a Process Analysis and Expert Survey

Anhang 2.1: Eigenanteil und Lizenzfreigabe für Publikation II

Literaturangabe	**Fotteler ML**, Liesche-Starnecker F, Brielmaier MC, Schobel J, Gempt J, Schlegel J, Swoboda W. Socio-Organizational Impact of Confocal Laser Endomicroscopy in Neurosurgery and Neuropathology: Results from a Process Analysis and Expert Survey. Diagnostics (Basel). 2021;11(11):2128. doi:10.3390/diagnostics11112128
Eigenanteil	Das Design der Studie wurde von mir erarbeitet und zusammen mit WS und JS (Jürgen Schlegel) finalisiert. Das methodische Vorgehen wurde von mir und WS festgelegt. Die Erhebung der Prozesse wurde von mir und FL-S durchgeführt. Die Prozessmodelle wurden von mir erstellt und im Diskurs mit WS, JS (Jürgen Schlegel) und FL-S finalisiert. Der Fragebogen wurde von mir entwickelt und mit MCB finalisiert. Die Umfrage und Datenauswertung wurden von mir durchgeführt. Ich habe das Manuskript geschrieben. Alle Autorinnen und Autoren haben das Manuskript gelesen und überarbeitet und nach meiner Finalisierung bewilligt. Ich habe das Manuskript bei Diagnostics eingereicht, die Kommunikation mit dem Journal während des peer-review Prozesses geleitet und die Anmerkungen der Gutachter eingearbeitet. Zusammenfassung des prozentualen Eigenanteils: – Planung der Studie: 80% – Erhebung, Aufbereitung und Auswertung der Daten: 90% – Verfassen des Manuskriptes und editorielles Handling: 90%
Lizenz	Dieser Artikel ist ein frei zugänglicher Artikel (Open Access), der unter den Bedingungen der Creative Commons Attribution Lizenz (CC BY 4.0) veröffentlicht ist (https://creativecommons.org/licenses/by/4.0/).

Anhang 2.2: Publikation II im Vertragslayout

diagnostics

MDPI

Article

Socio-Organizational Impact of Confocal Laser Endomicroscopy in Neurosurgery and Neuropathology: Results from a Process Analysis and Expert Survey

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Abstract: During brain tumor resection surgery, it is essential to determine the tumor borders as the extent of resection is important for post-operative patient survival. The current process of removing a tissue sample for frozen section analysis has several shortcomings that might be overcome by confocal laser endomicroscopy (CLE). CLE is a promising new technology enabling the digital in vivo visualization of tissue structures in near real-time. Research on the socio-organizational impact of introducing this new methodology to routine care in neurosurgery and neuropathology is scarce. We analyzed a potential clinical workflow employing CLE by comparing it to the current process. Additionally, a small expert survey was conducted to collect data on the opinion of clinical staff working with CLE. While CLE can contribute to a workload reduction for neuropathologists and enable a shorter process and a more efficient use of resources, the effort for neurosurgeons and surgery assistants might increase. Experts agree that CLE offers huge potential for better diagnosis and therapy but also see challenges, especially due to the current state of experimental use, including a risk for misinterpretations and the need for special training. Future studies will show whether CLE can become part of routine care.

Keywords: confocal laser endomicroscopy; neurosurgery; neuropathology; frozen sections; healthcare processes; clinical workflow analysis

1. Introduction

In brain tumor surgery, the extent of resection is essential for post-operative patient recovery and survival [1–3]. To keep the damage of healthy tissue to a minimum, tumor borders need to be determined intraoperatively [4]. Usually, macro- or microscopic tissue analysis is needed to reliably assess the tissue status [2,5]. Currently, frozen sections are the state-of-the-art procedure to determine tumor borders and type. A biopsy is removed by the neurosurgeon and sent to the neuropathologist for histopathological frozen section analysis.

However, the described process has several disadvantages. As it is an invasive method, usually only one sample is removed and analyzed. Additionally, damage to the brain tissue is possible. Preparing and freezing the tissue sample in the lab can change or destroy structures which are important for diagnosis. Additionally, it can take up to 45 min until the results are ready and can be communicated to the neurosurgeon [2,4,6].

The last couple of years have seen the emergence of a new technology that has the potential to digitize and improve intraoperative tissue analysis and decision making. Confocal laser endomicroscopy (CLE) is a promising digital biopsy approach using a high-resolution microscope located in a handheld probe. By placing the probe directly on the surgical site, tissue structures can be visualized in vivo in near real-time [7]. The procedure is non-destructive, allowing the investigation of several tumor areas. Combined with a fluorescent agent administered prior to using the device, CLE enables tissue differentiation, tumor type diagnosis, and the identification of tumor borders comparable to frozen sections. This has been shown in several studies, both for in vivo and ex vivo analyses of animal and human brain tumor tissue [1,8–11]. The authors of a recent systematic literature review, however, found the evidence-base to be insufficient to formulate a definite conclusion on the usefulness of CLE for intraoperative decision support [12]. Yet, several other medical fields such as gastroenterology [13,14], urology [15], and others [5,16,17] report promising results for the effective and safe use of CLE.

Several CLE devices from different manufacturers and optimized for different medical fields are available on the market. In neurosurgery, the technology is still in an experimental phase and not yet part of the current treatment regime. In order to introduce this promising technology into daily routine, it is essential to properly understand the underlying clinical processes [18]. As stated by Ammenwerth and Hackl [18], the impact on socio-organizational structures within the institution is especially important. Therefore, the connection between involved personnel, necessary activities, as well as the required infrastructure must be clarified. To that extent, process modelling is a well-established methodology providing a (graphical) language that can be understood by both computer scientists and physicians [19,20]. To our knowledge, no study explicitly addressed socio-organizational aspects of the introduction of CLE into routine neurosurgical diagnostic and therapy so far. A recently published conceptual model on the impact of CLE included three hypotheses focusing on socio-economic aspects, specifically, the increase in the workload for clinical staff, the high cost, and the potentially longer process duration overall due to the maintenance of the device [21]. The aim of this study was to answer the following two research questions (RQ) using the case example of brain tumor resection surgery:

RQ1: What could a workflow employing CLE in neurosurgery look like compared to the current clinical process analyzing frozen sections?

RQ2: What are the opinions of clinical staff working with CLE regarding its socio-organizational aspects?

2. Methods

To investigate the potential of CLE for neurosurgery and neuropathology and answer the research questions, we (1) modelled and analyzed the current process of frozen sections, (2) modelled a digital process visualizing the possible procedure with CLE, (3) compared both process models, and (4) conducted a survey among medical experts working with the new technology. Our study was conducted based on the ZEISS CONVIVO®, a second-generation CLE device optimized for neurosurgery that has been on the market since 2018. The intraoperative use of this device has been described in recent studies [11,22]. In 2020, a digital platform for neuropathologists has been released allowing the expert to remotely diagnose images instead of being available in the operating theatre. The CLE model presented in this study includes this new In Vivo Pathology Suite [23].

2.1. Process Analysis

The case of surgical brain tumor resection has been used as the basis for the process analysis. Both processes (current and CLE) were modelled using Business Process Model and Notation (BPMN 2.0), a high-level standard used to graphically document the steps in a workflow [24]. BPMN is mathematically complete and particularly useful to visualize and understand complex processes [18]. A web-based tool, Signavio Explorer Version 15.6.0 by the BPMN Academic Initiative, was used for modelling.

Data collection for the current process of tissue diagnosis using frozen sections took place in a large clinic for maximum care located in Southern Germany. To model the process, non-structured expert interviews were conducted with two neuropathologists who guided the interviewer through the clinical and laboratory process. Additionally, observations and time measurements for the biopsy resection, the transport, and the frozen section analysis were conducted on site. To collect data and model the digitized process with CLE, engineers and project managers from the manufacturer of the microscope were interviewed. Additionally, presentation material, manuals, and other documents such as visual boards depicting the envisioned workflow were consulted. The resulting CLE model shows what the process could look like once CLE has been established. After introducing the experts to the BPMN syntax, both models were refined in several cycles to ensure accuracy and completeness.

2.2. Expert Survey

An online questionnaire was developed consisting of 16 questions in four sections: general information, work with the CLE device, opinion of the microscope, and biggest advantages/disadvantages. The questionnaire was written in German, and a translated version can be found in Table 1. The community edition for the web-based Open-Source software LimeSurvey (version 3.x, LimeSurvey GmbH, Hamburg, Germany) was used for the online survey. The questionnaire was distributed with individual access codes to neuropathologists, neurosurgeons and medicine students working with the confocal microscope in vivo and ex vivo at three German hospitals. The survey was anonymous. All participants gave their informed consent. The survey was sent out between April and September 2021. Up to three reminders were sent. An ethics vote was obtained for the survey from the Joint Ethics Committee of the Bavarian Universities of Applied Sciences (approval code GEHBa-202008-V-008, approval date 7 October 2020).

Table 1. List of all survey questions.

Section	Questions
1. General information	How old are you?
	What is your gender?
	What is your position?
	How long have you been working in this position?
2. Your work with the device	Conditional question depending on position: How many operations have you conducted/assisted with using the device?/What is the number of operations using the device you analyzed images of? [1]
	What tasks do you conduct with the device? (multiple choice)
	How does your workload change when using the device?
	Conditional question: Please explain how your workload increased/decreased. [1]
3. Your opinion of the device	How do you rate the following indicators on a scale from 1–3: usability, integration, reliability, data/image quality, medicinal use, patient safety, data protection?
	Do you think it makes sense to use the device for standard diagnostics?
	Conditional question: Please comment why you do not think that this makes sense. [1]
	Do you think, surgery duration could be shortened using the device?
	What is your opinion on telepathology?
	How satisfied are you overall with the device?
4. Final questions	What do you think are the biggest advantages/chances of the device?
	What do you think are the biggest disadvantages/risks of the device?

[1] Previous answer determined phrasing or appearance of this question.

3. Results

3.1. Process Analysis (Results for RQ1)

Two process models were created using the BPMN 2.0 notation, one depicting the current process of frozen section analysis and the other one visualizing a process using CLE. In the following section we present and describe collapsed and simplified versions of the

process models. The process comparison is based on the detailed models, which can be found in the supplementary material (Figure S1: current process, Figure S2: digitized process).

3.1.1. Current Process

The process starts with the need for an intraoperative histology. Once the surgical site is prepared, the neurosurgeon takes a tissue sample, which is then sent to the neuropathology laboratory together with the request form including all necessary information via a tube system. At the reception, the request form is processed, and relevant information is added. A laboratory technician and the Jr. neuropathologist are informed, and the sample is transported to the laboratory. Macroscopic analysis is performed, and the first impressions are dictated by the Jr. neuropathologist, possibly supervised by a Sr. neuropathologist. After embedding and freezing, a laboratory technician prepares the frozen sections (slicing and staining with hematoxylin and eosin (HE)). After having checked the quality and potentially requested a new section, the microscopic analysis is performed by a Jr. neuropathologist alone or together with the Sr. neuropathologist. They record the results and report them back to the surgery room using a regular phone call. The final report is typed by the secretary (Figure 1a).

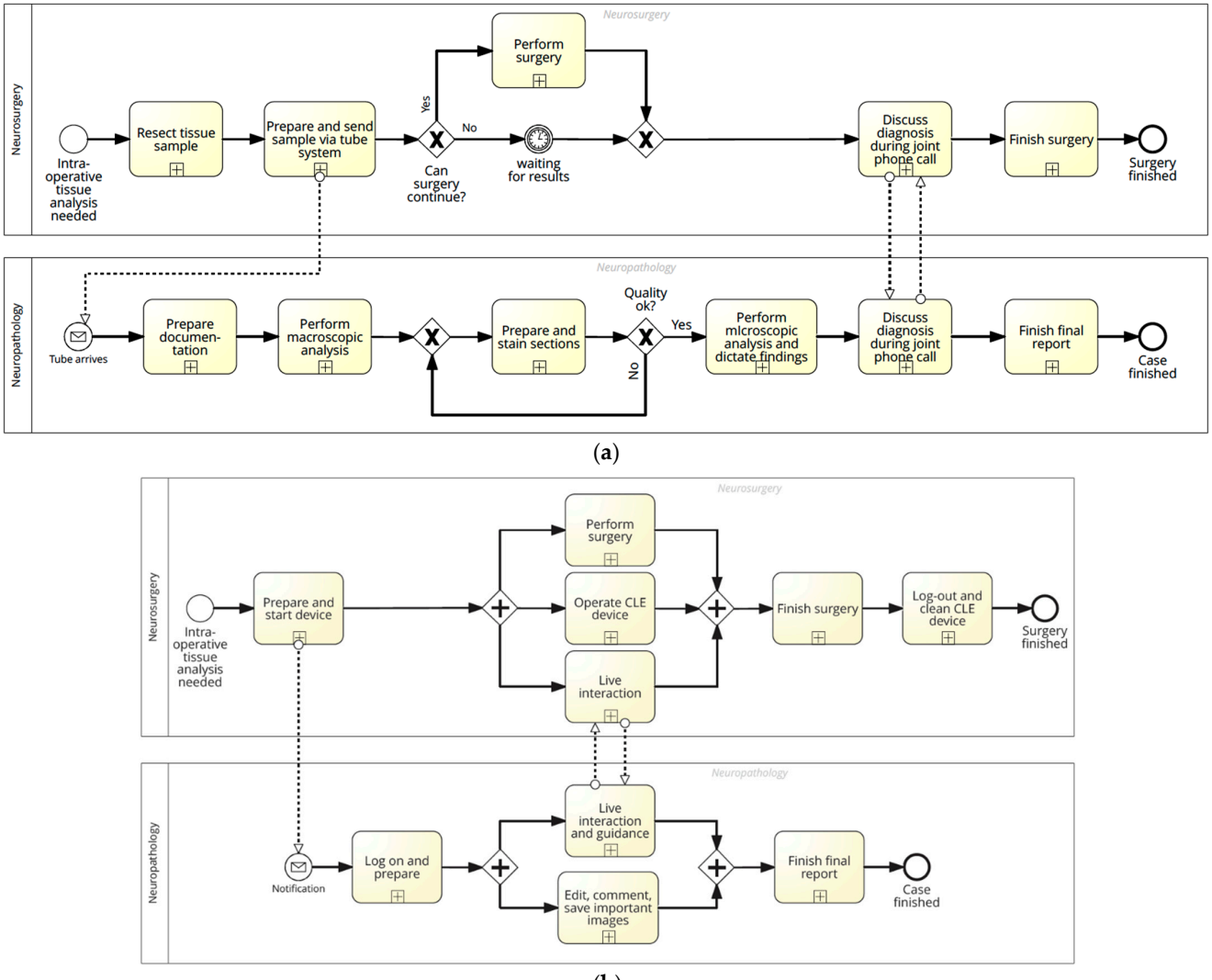

Figure 1. Simplified versions of the two processes: (**a**) Current process of frozen section analysis; (**b**) Digitized process using CLE. Circles mark the start and end of the process, arrows show the process flow, rectangles represent tasks, tasks with the "+" indicate collapsed subprocesses, the diamond with the "×" represents an exclusive gateway (XOR), meaning only one path continues, and the diamond with the "+" denotes a parallel gateway (AND), meaning all paths continue.

In addition to modelling the process, the time needed for the analysis of frozen sections was measured. Three sections were timed separately: (1) the resection and packing of the biopsy, (2) the transport to the laboratory, and (3) the preparation of sections, analysis, and report of results. On average, 4:25 min were needed to extract and pack the biopsy (four measurements ranging from 2:28 to 6:52 min). For the tube transport, three measurements were taken, resulting in an average duration of 1:40 min. Four measurements were taken for the tasks conducted in the laboratory. The average duration was 11:57 min, with a range from 08:53 to 15:04 min. On average, 18:02 min passed from biopsy resection to the reception of results in this clinic.

3.1.2. CLE Process

When working with the CLE device, the surgery assistant logs into the device and establishes a connection. Then, the case is created by importing data from a radiology system (here, the DICOM Modality Worklist) or by entering the information manually. The neuropathologist or a team of neuropathologists receive a consultation request and the neuropathologist scheduled to participate in the surgery can log in to review the available patient information in an anonymized format. Once the live stream is established by the surgery assistant, different image capturing modi are available. A continuous audio communication can be made available via the traditional channels (phone, intercom). Thus, the neurosurgeon and neuropathologist are able to cooperate and jointly assess the tumor region. Images that are considered important by the neuropathologist can be edited, annotated, and saved for the final report. While the surgery continues, the neuropathologist finishes entering the diagnostic information and selecting images. The final report is created automatically and can also be accessed by the neurosurgeon. After logging off, the device is cleaned by the surgery personnel (Figure 1b).

3.1.3. Process Comparison

In both processes, two parties are involved, the clinic for neurosurgery and the department of neuropathology. However, while the current process requires up to seven people (neurosurgeon, surgery assistant, neuropathology receptionist, neuropathology secretary, lab technician, Jr. neuropathologist, and Sr. neuropathologist), the digital process using the CLE device only requires three people (neurosurgeon, surgery assistant, neuropathologist). Different indicators comparing the two workflows are listed in Table 2. The number of tasks overall decreased from 42 to 26 (−38.1%). However, while tasks in the neuropathology department decreased due to the elimination of administrative and laboratory tasks from 30 to 9 (−70%), the neurosurgeon and the surgery personnel are faced with a slight increase in tasks due to the maintenance and operation of the device from 12 to 17 tasks (+41.7%). If several images are taken, which is one of the main advantages of CLE, the workload for the neurosurgery increases even further. The digitized process relies solely on digital and phone communication compared to the paper documentation in the current process.

Table 2. Comparison of the current process and the CLE process.

	Current Process	CLE Process
Parties	2	2
Staff members	6–7	3
Tasks total	42	26
Tasks neurosurgery	12	17
Tasks neuropathology	30	9
Transfers between parties	2	2
Medium of transfer	tube (paper, sample), phone	digital, phone
Time until results are ready	~18:02 min	immediately (continuous communication)

3.2. Expert Survey (Results for RQ2)

Fifteen experts were contacted for the online survey of which twelve responded (80% response rate). Table 3 characterizes the study participants. The majority of participants (66.7%) were between 30–59 years of age. Seven (58.3%) were male, half worked as a neurosurgeon while a quarter each were neuropathologists and medical students. With the exception of one person, all had experience with CLE from more than five surgeries. Interestingly, no participants stated that they were dissatisfied with the device, while 10 participants (83.3%) were overall satisfied with the device and 2 (16.7%) had a neutral position.

Table 3. Characteristics of the survey participants.

	Total	Satisfaction with CLE Device (N) [1]	
	N (%)	Satisfied	Neutral
Age			
Below 30 years	3 (25.0)	3	0
30–59 years	8 (66.7)	6	2
60 years or older	1 (8.3)	1	0
Gender			
Female	5 (41.7)	4	1
Male	7 (58.3)	6	1
Position			
Neurosurgeon	6 (50.0)	5	1
Neuropathologist	3 (25.0)	2	1
Medical student	3 (25.0)	3	0
Experience			
<5 years	3 (25.0)	3	0
5–10 years	5 (41.7)	4	1
>10 years	4 (33.3)	3	1
Number of operations with CLE			
<5	1 (8.3)	0	1
5–20	4 (33.3)	4	0
>20	7 (58.3)	6	1

[1] The option 'dissatisfied' was not selected by the participants. For brevity purposes, the table only shows the distribution between the options 'satisfied' and 'neutral'.

The characteristics receiving the highest number of positive votes were usability, integration into daily routine, and patient safety (N = 10 each). The images provided by the CLE device were voted to be of medium quality by six people versus five who found them to be good. The tasks conducted with the device include patient education (N = 4), appointment planning (N = 4), preparation in the operating theatre room (N = 6), login (N = 6), preparation of the sterile scanner probe (N = 6), selection/alternation of the modus (N = 7), placement of the probe on the tissue (N = 6), interpretation of images (N = 4), editing the images (N = 4), logoff (N = 5), and cleaning (N = 2).

Five participants (41.6%; three neurosurgeons, two neuropathologists) expressed an increase in their workload due to the use of the CLE device. They explained this with the fact that the methodology is currently used as an addition to the frozen section analysis, not as a replacement. Preparation, operation, and cleaning were mentioned as other reasons. However, nine experts (75%) think that the surgery time can be reduced once the device is used in standardized clinical routine.

In general, the faster diagnosis and shortened surgery duration is the biggest advantage of CLE, mentioned by seven experts (58.3%), four of them neurosurgeons. This is followed by an improved diagnosis and resection when using the device. The training and experience needed to effectively use CLE are current disadvantages mentioned six times by neurosurgeons, neuropathologists, and medical students in even measure. The issue of user dependency was only mentioned by neurosurgeons. All advantages and

disadvantages mentioned by the experts are listed in Table 4 (answers to part 4 of the questionnaire: final questions).

Table 4. Advantages and disadvantages of CLE according to the survey participants (frequency).

Advantages	Disadvantages
- Faster diagnosis (real-time) and surgery (N = 7) - Better diagnosis and resection (N = 6) - Potential for future progress (e.g., visualization of live tissue, use of artificial intelligence) (N = 5) - Unlimited biopsies (non-destructive) (N = 3) - Remote analysis (N = 1)	Training and experience needed (N = 6) Imprecise diagnosis, risk of misinterpretation (N = 4) User dependent (N = 2) Additional effort for neurosurgery (N = 2) Price (N = 1)

4. Discussion

To our knowledge, this is the first study investigating the impact of CLE on the clinical workflow and staff in neuropathology and neurosurgery. Other studies have cursorily discussed potential implications of CLE for workflows and staff but have not explicitly analyzed these issues [1,2,22,25].

BPMN proved to be feasible to model and compare clinical processes. A clinical workflow relying on CLE in neurosurgery and neuropathology could be successfully represented. Several advantages have been shown. Particularly, administrative and laboratory staff in the neuropathology can be relieved. Neuropathologists benefit from a streamlined workflow without interruptions and the fact that they can conduct diagnoses remotely from their desk. Additionally, a continuous communication, directly involving both experts in the diagnosis and treatment process, is possible. The neuropathologist can provide guidance while images can be analyzed in real-time (i.e., no transport via tube) [7]. The team of the neurosurgery, i.e., the neurosurgeon and any surgery assistant, face a potential increase in workload due to the preparation, operation, and cleaning procedures of the CLE device, confirming previously published hypotheses [21]. Especially when investigating multiple tumor areas, which is one of the main advantages of CLE, clinical staff are burdened with additional work.

More than 80% of the interviewed experts were satisfied with the device, and no survey participant voiced general dissatisfaction. The potential to shorten surgery time from incision to closure and improvement of resection were confirmed. Our measurements resulted in an average time of approximately 18 min for the frozen sections (including biopsy resection and transport), other authors report average durations of 30 to 45 min [2,5]. Longer distances or a lack of neuropathologists are possible aspects that can lead to longer duration. However, much of this time can be saved in a process employing CLE. A potentially shortened surgery duration is highly advantageous for the patient [3,8] and can also be economically beneficial [26]. Other advantages from a medical point of view are mainly the elimination of the need for tissue removal for the biopsy and the opportunity to analyze several tumor regions [27].

Ten experts highlighted the need for training and experience for both the neurosurgeon and the neuropathologist before reliable diagnoses can be performed [2,28]. Images produced by CLE differ from those known to neuropathologists. In this context, the lack of a reference catalogue has been mentioned. Particularly in the beginning, the interpretation of images can be challenging or imprecise, including the risk for misdiagnosis [12]. However, this is most likely only a temporary challenge. Once the technology is better established, an atlas with images will be available, and the use of CLE becomes part of medical training, this will become less and less of an issue. Other researchers mention the small field of view, motion artifacts, and image obscuring through blood cells that can inhibit the data quality. However, existing studies showed that this can be solved by cleaning the probe or irrigating the surgical field [2,3]. With the option to analyze several samples, these problems can be further mitigated. Further potential shortcomings of CLE

revealed in the expert comments are the added workload caused by an additional device in the operating theatre confirming the results from the process analysis. Finally, CLE is linked to considerable costs with prices of USD 200,000 and above for the device, not including operation and maintenance [17]. The sterile sheaths, for which currently only one manufacturer exists, and the fluorescent agent cause additional costs. The sheaths cost up to EUR 40 per piece. The current contrasting agent Natriumfluorescein (NaF) costs between EUR 8–10 per vial of 500 mg. Per patient, a minimum of one vial is needed.

The use of CLE in clinical settings is still in a preliminary phase leaving many blank spots to be investigated further. Potentially groundbreaking for future clinical research and diagnostic is the chance to visualize live tumor cells with CLE. The realization of telepathology, or teleneuropathology, is another promising aspect associated with the implementation of CLE. As CLE produces digital images of tissue structures, remote analysis by neuropathologists from other clinics or laboratories is possible [10,29]. A small, highly proficient team can assist smaller institutions for the diagnosis of difficult cases. Considering the shortage of expert neuropathologists, this can improve clinical care in hospitals without a neuropathology department. All survey participants confirmed the future-oriented character of teleneuropathology. Pioneering studies also show the potential to automatically analyze CLE images using deep learning methods [30–32].

This study has limitations. The experimental nature of CLE implementation limits the applicability of the results from this study. The current process for the analysis of frozen sections modelled here is based on the workflow in a German clinic. Even though the analysis of frozen sections is a standardized routine, the results might not be generalizable to other countries. The CLE device is stored in another room and needs to be transported to the operating theatre before performing the surgery and back again after surgery. These tasks are not represented in the model as both processes start with the intraoperative histopathological analysis to limit complexity. Additionally, an anesthetist administers NaF directly after the first incision. Albeit important for the tissue analysis, this task is negligible regarding the overall process complexity as the anesthetist is present during the entire surgery to monitor vital signs and narcosis. CLE is not yet integrated into standardized care, therefore the number of experts with experience using the methodology is limited. The results of the small sample included in this survey lack reliability. In light of other positive research results regarding the use of CLE in neuropathology and neurosurgery, this study provides additional confirmation for the potential of this methodology and presents a first insight into the socio-organizational consequences of CLE. Additionally, it can serve as the basis for future research, e.g., a thorough economic evaluation of CLE in the form of a dynamic investment calculation for the setting of neuropathology and neurosurgery.

5. Conclusions

This study confirms the potential of CLE for the improvement of intraoperative tissue analysis and decision making in neurosurgery, specifically during brain tumor resection. The streamlining of processes, faster and better diagnosis and tumor resection, and workload relief for neuropathologists are some of the main advantages. Training experts to interpret CLE images will be of the utmost importance for an establishment of CLE. The results of future studies, in particular economic evaluation and larger clinical trials, will determine whether the technology can become part of standardized care. Many possible applications of CLE in clinical care have yet to be studied. The visualization and analysis of live cancer cells, telepathology, and the combination with deep learning methods hold large promise for the safe, effective, and efficient delivery of care in the future.

Supplementary Materials: The following are available online at https://www.mdpi.com/article/10.3390/diagnostics11112128/s1, Figure S1: Full BPMN model for the current process of frozen section analysis in a large German clinic for maximum care, Figure S2: Full BPMN model for the digitized process with the CLE device ZEISS CONVIVO® by the Carl Zeiss Meditech AG.

Author Contributions: The study was conceptualized by W.S., J.S. (Jürgen Schlegel), and M.L.F. The methodology was selected by W.S. and M.L.F. Data collection was prepared and performed by M.L.F., F.L.-S., J.S. (Jürgen Schlegel), M.C.B., and W.S. The data was analyzed by M.L.F. The first draft of the manuscript was written by M.L.F. All authors reviewed and edited the draft. W.S. acquired the funding and formally supervised the project. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Joint Ethics Committee of Bavarian Universities of Applied Sciences (protocol code GEHBa-202008-V-008, 7 October 2020 and revision protocol code GEHBa-202008-V-008-P, 29 March 2021). The statements of the ethics committee are in German and can be provided upon request.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: All data collected for the process models have been incorporated into the respective BPMN models, which can be found in the supplementary material. The data from the survey were collected in German and translated for this manuscript. The data can be made available upon request.

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Anhang 3: Publikation III: Use and benefit of information, communication, and assistive technology among community-dwelling older adults – a cross-sectional study.

Anhang 3.1: Eigenanteil und Lizenzfreigabe für Publikation III

Literaturangabe	**Fotteler ML**, Kocar TD, Dallmeier D, Kohn B, Mayer S, Waibel A-K, Swoboda W, Denkinger M. Use and benefit of information, communication, and assistive technology among community-dwelling older adults - a cross-sectional study. BMC Public Health. 2023;23(1):2004. doi:10.1186/s12889-023-16926-8
Eigenanteil	Die Idee für die Studie wurde von mir erarbeitet. Das Studiendesign wurde von mir und MD entwickelt. Der Fragebogen wurde von mir entwickelt und im Diskurs mit MD finalisiert. Der postalische Versand der Fragebögen wurde von mir und AW durchgeführt. Ich habe die Daten aufbereitet und zusammen mit TK, MD und DD analysiert. Ich habe das Manuskript geschrieben und die Abbildungen erstellt. Alle Autor:innen haben das Manuskript gelesen und überarbeitet und nach meiner Finalisierung bewilligt. Ich habe das Manuskript bei BMC Public Health eingereicht, die Kommunikation mit dem Journal während des peer-review Prozesses geleitet und die Anmerkungen der Gutachter eingearbeitet. Zusammenfassung des prozentualen Eigenanteils – Planung der Studie: 80% – Erhebung, Aufbereitung und Auswertung der Daten: 70% – Verfassen des Manuskriptes und editorielles Handling: 80%
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Anhang 3.2: Publikation III im Vertragslayout

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RESEARCH

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Use and benefit of information, communication, and assistive technology among community-dwelling older adults – a cross-sectional study

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Abstract

Background Technology can support healthy aging and empower older adults to live independently. However, technology adoption by older adults, particularly assistive technology (AT), is limited and little is known about the types of AT used among older adults. This study explored the use of key information and communication technologies (ICT) and AT among community-dwelling adults aged ≥ 65.

Methods A cross-sectional study was conducted among community-dwelling adults aged ≥ 65 in southern Germany using a paper-based questionnaire. The questionnaire included questions on the three domains sociodemographic aspects, health status, and technology use. Technology use was considered separately for key ICT (smartphone, computer/laptop, and tablet) and a range of 31 different AT. Data were analyzed using descriptive statistics, univariate analyses, and Bernoulli Naïve Bayes modelling.

Results The questionnaire was answered by 616 participants (response rate: 24.64%). ICT were used by 497 (80.68%) participants and were associated with lower age, higher level of education, living together with someone, availability of internet connection, higher interest in technology, and better health status ($p < .05$). No association was found with sex and size of the hometown. The most frequently owned AT were a landline phone, a body scale, and a blood pressure monitor. Several AT related to functionality, (instrumental) activities of daily living- (IADL), and morbidity were used more frequently among non-ICT users compared to ICT-users: senior mobile phone (19.33% vs. 3.22%), in-house emergency call (13.45% vs. 1.01%), hearing aid (26.89% vs. 16.7%), personal lift (7.56% vs. 1.61%), electronic stand-up aid (4.2% vs. 0%). Those with higher interest in technology reported higher levels of benefit from technology use.

Conclusions Despite the benefits older adults can gain from technology, its use remains low, especially among those with multimorbidity. Particularly newer, more innovative and (I)ADL-related AT appear underutilized. Considering the potential challenges in providing adequate care in the future, it may be crucial to support the use of these specific AT

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among older and frailer populations. To focus scientific and societal work, AT with a high impact on autonomy ((I)ADL/disease-related) should be distinguished from devices with a low impact on autonomy (household-/ comfort-related).

Keywords Information and communication technology, Assistive technology, Benefit, Sociodemographic, Older adults, Cross-sectional

Background

The demographic landscape is undergoing a significant shift towards an aging population, increasing the need for care in the future. Additional challenges arise from a shortage of skilled healthcare professionals and growing healthcare expenses [1]. Thus, reducing morbidity and the demand for care is essential for the continued stability of healthcare systems. Policy makers are trying to prioritize aging in place and home care over institutionalization whenever possible [2, 3]. Technology can be one way to enable independent living, improve quality of life, and promote healthy, active aging [4–8].

Especially those living with multimorbidity or frailty might benefit from technological assistance in their daily life. Information and communication technologies (ICT) and assistive technologies (AT) aim to compensate impairments related to diseases, disabilities, or old age and support independence of older adults. A rapidly increasing body of literature reports the effectiveness of a wide variety of ICT and AT for older adults with different impairments and diseases such as dementia and mild cognitive impairment [9, 10], Parkinson's Disease [11–13], or chronic obstructive pulmonary disease [14, 15].

Smartphones, computers, and tablets are considered key ICT that are omnipresent in todays connected world and an essential part of active participation in the community [16]. AT are manifold and heterogenous with different levels of complexity and price ranges [17]. Prominent examples are wearable devices [5], robotic systems [18], smart in-home technology [7], or mobile health applications [19]. Devices range from more traditional ones such as hearing aids [20] to new and innovative devices such as tremor spoons [13], smart electric walkers [21, 22], or artificial intelligence enhanced vision aids [23]. Other examples include systems that manage fall risk [24, 25], ensure safe and timely medication [26, 27], enable personal disease management [28, 29], or promote social connections [30, 31].

While there clearly is an abundance of available AT for older adults with different frailty levels and diseases, it is uncertain which of those devices, especially the more innovative ones, are being used by the target group in their daily lives. ICT are a prerequisite for the use of many AT (e.g., when a smartphone or tablet application is required for AT operation) and could thus be considered an indicator for AT use [32]. Smartphone use among those aged 65+has increased from 13% in 2012 to 61% in 2021 but remains below the rates for adults aged 18–49 (95%–96%) [33]. For older adults with increased levels of frailty or multimorbidity, lower numbers have been reported in the past [34]. At the same time, AT uptake among the older community has been low [7]. A study from 2021 reported a prevalence of around 30% for AT supporting hearing, vision, or mobility among healthy Canadians aged 65–85 [20]. However, only more traditional devices have been included and the frequency has not been reported for specific devices. In another study, a low level of wearable use of 17.49% was reported for US Americans aged 65 or older [5]. Taken together, few studies report usage rates for AT among the age group above 65 and there are inconsistencies regarding associated sociodemographic and health-related variables [35]. Thus, the goal of this study was (1) to explore the use of key ICT and associated sociodemographic characteristics and (2) to determine and describe which AT are used among community-dwelling adults aged≥65.

Methods

A cross-sectional study was conducted in a county in southern Germany among older community-dwelling adults aged≥65. The survey instrument was a paper-based questionnaire sent out via the postal service. An ethics approval was obtained from the Joint Ethics Committee of the Bavarian Universities of Applied Sciences (GEHBa-202,101-V-014, 5 Feb 2021). This article is written in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement (supplementary file 1: STROBE Checklist) [36].

Study population

Community-dwelling adults aged≥65 and registered at a private residence or a care facility in the selected county were eligible to participate. Based on an estimated frequency of AT in the target population of 20–30% [5, 20] and an expected response rate of 10-15%, we aimed to achieve a sample size of at least 250 for an estimated 95% confidence in the analysis (calculated using the web-based, open source software OpenEpi [37]). Considering we did not send out any reminders or offered compensation, the expected response rate was set lower than has been reported by other cross-sectional studies [38, 39]. Addresses were obtained through regional registration offices covering towns ranging in size from <1,000 to >10,000 inhabitants. A randomly selected sample, sized in relation to the ratio of persons aged≥65 registered at

each registration office, was requested from all 15 registration offices in the selected county. In total, the individual samples added up to the targeted 2,500 persons (supplementary file 2: Overview of sample compilation). Only names, sex, and addresses were requested and deleted immediately after the questionnaires had been sent out. One registration office denied to release the requested address data.

Questionnaire and measures

To enable participation of older adults with different ranges of digital literacy, a paper-based questionnaire was developed in German. No personal data was recorded on the questionnaire. The questionnaire included questions on the following three domains: (1) sociodemographic aspects, (2) health status, and (3) technology use.

Sociodemographic variables studied included age, sex, education (highest degree), living situation (alone, with others), size of hometown (<1,000; 1,000–9,999; ≥10,000), technology interest (no, little, medium, strong interest), and home broadband internet connection (yes, no). Age was categorized into three groups, 65–70, 71–80, and 80+. Education status was categorized as having≤10 years or >10 of education. Having>10 years of education is the threshold needed to qualify for university in Germany. Comorbidities were captured using the list from the Cumulative Illness Rating Scale for a geriatric population (CIRS-G) [40]. A new variable was computed categorizing health status in three levels: no comorbidities, 1–2 comorbidities, and ≥3 comorbidities [41]. Technology use was reported for two domains: (1) Key ICTs including smartphone, computer/laptop, and tablet (based on the definition in [42]), and (2) different AT covering devices related to single deficits/diseases, (instrumental) activities of daily living ((I)ADL), and comfort or household tasks (Table 1). For ICTs frequency of use (daily, weekly, rarer, never) was also collected. ICT-Users are defined as persons using at least one of the three key technologies (smartphone, laptop/computer, tablet). The AT were selected based on a compilation of the most promising devices for older adults developed by the senior community service of the German city of Hannover [43] and also included devices related to functional deficits, disability and/or frailty, respectively the domains of a comprehensive geriatric assessment (CGA) such as mobility, cognition, and the ability to self-aid [44, 45] (Table 1). Perceived benefit from technology use was captures using three levels: High, medium, little/no use.

The primary outcome was ICT use, defined as using at least one key ICT, i.e., smartphone, tablet, or computer/laptop, or non-use. Secondary outcomes were the frequency of ICT use, the use of different AT, and the benefit gained from the technology used.

Study procedure

Questionnaires were sent out via the German postal service in the beginning of April 2021. Envelopes included a cover letter explaining the study goals and potential risks and a stamped return envelope with the return address printed on. Informed consent was obtained from all participants. Returned questionnaires were accepted until June 15th, 2021. No reminders were sent out.

Data analysis

Using the QuestorPro software (Blubbsoft GmbH) the questionnaire was transferred to a machine-readable format prior to distribution. All returned questionnaires were checked for inconsistencies or error-prone markings. Nine of the returned questionnaires were recorded manually and checked by a second researcher as they contained handwritten information in the margins and/or difficult to determine checkmarks. All other questionnaires were automatically recorded by scanning the documents and using the software for data verification

Table 1 Overview of assistive technologies included in the questionnaire (based on [43])

Single deficit-/ disease-related	(I)ADL[1]- and personal-safety-related	Household-, comfort- and exterior-safety-related
- Blood pressure monitor	- Mobile/ in-house emergency call	- Lighting system (e.g., motion detectors, light sensors)
- Blood sugar monitor	- Digital calendar	- Stove switch-off
- Tremor spoon	- Electronic medication dispenser	- Water alarm/ regulator
- Health application	- Personal lift (e.g., for stairs, bathtub)	- Landline phone
- Digital viewing aid	- Electronic stand-up aid	- Universal remote
- GPS-locating device	- Wearable device (e.g., smartwatch, fitness tracker, smart clothing)	- Support/ household robot
- Body scale	- Sensor mat	- Home automation/ smart home system
- Hearing aid	- Fall detection device	- Key finder
- Doorbell/ringtone intensifier	- Speech recognition assistant	- Door/ window alarm
	- Senior tablet	
	- Senior mobile phone	
	- Video call application	
	- Electric walker	

[1] (I)ADL: (Instrumental) activities of daily living

and extraction. Free text was recognized but had to be entered manually into the database. The entered data was verified by a second person using random samples.

Descriptive statistics were calculated as mean and standard deviation for numerical variables and as frequencies and percentages for categorical variables. Pearson's chi-square test and Fisher's exact test were used to analyze categorical variables. The statistical significance was set at $p<.05$ for all tests. Data analysis and visualization was done using R Version 4.1.2 on R Studio Version 2023.03.1 and Microsoft Excel Version 2304 for Windows. In addition, we calculated a Bernoulli Naive Bayes Model with Laplace smoothing [46] to see if there is a general trend between the AT and the benefit rating of the technology. All subjects that gave a technology benefit rating were included in the analysis, irrespective of ICT-use. Only AT with >5 reported users in our sample were analyzed. For the calculation, we used the scikit-learn 1.2.2 library for python [47], with the default hyperparamters (alpha=1.0, force_alpha=False, binarize=0.0, fit_prior=True, class_prior=None=). Model performance was evaluated by calculating the accuracy score and the receiver operator characteristics (ROC) area under the curve (AUC), the latter using the one-vs-rest method calculating the micro average. The 95% confidence intervals (CI) were determined by bootstrapping with 1000 iterations [48]. To examine whether specific devices are associated with the overall benefit rating of the technology, we extracted the conditional probability of the AT (given the benefit rating) from the model using the 'feature_log_prob_' attribute. For better comparability, we applied a softmax function to these probabilities.

Results

Six hundred and nineteen participants returned the questionnaire (response rate: 24.76%). Data are presented for 616 participants who reported on ICT use. Table 2 shows the participant characteristics overall and stratified by ICT use. The mean age was 74.22 (±7.03) with a range from 65 to 101. Sex was distributed equally with 301 (50.08%) female participants. Approximately one fourth (n=148, 24.83%) of the participants had>10 years of education. More than half of the participants (n=310, 52.19%) lived in cities/villages below 10.000 inhabitants. Strong interest in technology was recorded by 121 (19.71%) participants.

ICT use

In this study, 497 (80.68%) users and 119 (19.32%) non-users of ICT were observed. ICT-users were noted to be younger, have higher levels of education, live more often together with others, have internet connection, to have a higher interest for technology, and to have on average less comorbidities than non-ICT-users.

There were 425 (85.51%) smartphone users, 421 (84.71%) computer users, and 220 (44.27%) tablet users. Of all ICT-users, 101 (20.32%) reported using one device, 223 (44.87%) reported using two devices, and 173 (34.81%) reported using three devices. For those using only one device, a computer was the most frequent one overall. Frequency of use, however, was highest for smartphones. Daily smartphone use was at 66.67% for single device users but rose above 80% for multiusers compared to 46%–63.64% for computer users.

There was a discrepancy between ICT ownership and ICT use. Among the participants, 13 (3.06%) smartphone owners, 28 (6.65%) computer owners, and 24 (10.91%) tablet owners did not use their devices ("use never"). While participants who only owned a smartphone always used it at least sometimes, participants who owned only a computer did not use it in 14% (n=7) of the cases. Ownership was reported by 95 (19.11%) participants for one device, by 221 (44.47%) participants for two devices, and by 198 (39.84%) participants for three devices. Figure 1 presents frequency of device use (incl. "use never") by number of ICT devices owned.

AT use

AT use has been recorded for 31 different devices or device categories (Table 1). The most frequently used device was a traditional landline phone (n=573, 93.02%), followed by a body scale (n=465, 75.49%), and a blood pressure monitor (n=452, 73.38%) (Fig. 2). A sensor mat, a digital pill dispenser, and a tremor spoon were only named once respectively, all three by non-ICT-users.

Several devices were exclusively used by ICT-users, namely a video call application, a digital calendar, a speech recognition assistant, a health application, a support/household robot, a GPS locating device, a smart-home system, a senior tablet, and a key finder. The following AT were used with a higher ratio among non-ICT-users compared to ICT-users: a senior mobile phone (19.33% vs. 3.22%), an in-house emergency call (13.45% vs. 1.01%), a hearing aid (26.89% vs. 16.7%), a personal lift (7.56% vs. 1.61%), and an electronic stand-up aid (4.2% vs. 0%).

Participants owned between zero and 12 different AT. The amount of owned AT within our study population showed a right skewed distribution with a mode of 3 and a median of 4 devices. Seven (1.14%) participants owned no AT and nine (1.5%) participants owned≥10 devices. While all participants owning≥10 AT were exclusively ICT-users, overall, no significant difference was found regarding ICT-use and the number of AT devices owned (Fig. 3).

Table 2 Characteristics of the study population by ICT-users and non-ICT-users

	Total (n = 616; 100%)		ICT-users (n = 497; 80.68%)		Non-ICT-users (n = 119; 19.32%)		*P*
	n(%)	na	n(%)	na	n(%)	na	
Age (years)		1		1		0	< .001[1]*
mean (SD)	74.22 (7.03)		72.74 (5.97)		80.35 (7.8)		
65–70	237(38.54)		220(44.35)		17(14.29)		
71–80	252(40.98)		210(42.34)		42(35.29)		
80+	126(20.49)		66(13.31)		60(50.42)		
Sex		15		12		3	.185[1]
Female	301(50.08)		236(48.66)		65(56.03)		
Male	300(49.92)		249(51.34)		51(43.97)		
Education		20		15		5	< .001[1]*
≤ 10years	448(75.17)		344(71.37)		104(91.23)		
> 10 years	148(24.83)		138(28.63)		10(8.77)		
Living situation		1		1		0	.008[1]*
Alone	161(26.18)		118(23.79)		43(36.13)		
With others	454(73.82)		378(76.21)		76(63.87)		
Size of hometown		22		17		5	.45[1]
< 1,000	51(8.59)		38(7.92)		13(11.4)		
1,000–9,999	259(43.6)		209(43.54)		50(43.86)		
≥ 10,000	284(47.81)		233(48.54)		51(44.74)		
Internet connection		7		5		2	< .001[1]*
Yes	524(86.04)		474(96.34)		50(42.74)		
No	85(13.96)		18(3.66)		67(57.26)		
Technology interest		2		2		0	< .001[2]*
Strong	121(19.71)		118(23.84)		3(2.52)		
Medium	327(53.26)		304(61.41)		23(19.33)		
Little	119(19.38)		67(13.54)		52(43.7)		
Not at all	47(7.65)		6(1.21)		41(34.45)		
Health status		0		0		0	.008[2]*
No comorbidities	46(7.47)		43(8.65)		3(2.52)		
1–2 comorbidities	247(40.1)		206(41.45)		41(34.45)		
≥ 3 comorbidities	323(52.44)		248(49.9)		75(63.03)		

[1]Calculated using Pearson's Chi-square test

[2]Calculated using Fisher's Exact Test

*$p < .05$

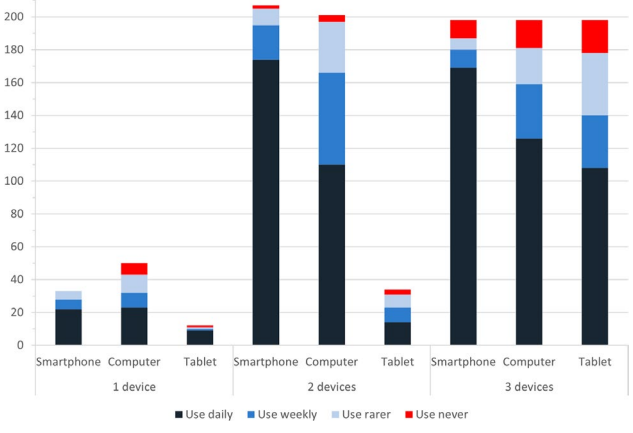

Fig. 1 Frequency of device use by number of ICT devices owned with the number of participants on the y-axis

Technology benefit

There were 476 (77.27%) participants who reported their perceived overall benefit from the used technology (ICT and AT combined). Most people indicated a high benefit (n = 287, 60.29%), followed by medium (n = 154, 32.35%), and little or no benefit (n = 35, 7.35%). There was a significant difference between ICT-users and non-ICT-users ($p < .001$). Only about 4.15% of ICT-users reported low or no benefit gained from the used technology. In contrast, among non-ICT-users this rating was more frequent, with 27.27% reporting low or no benefit. High benefit was reported by users of more innovative AT such as smart home systems, support/household robots or health applications.

The Bernoulli Naïve Bayes analysis could estimate the technology benefit rating from the presence or absence of owned AT with an accuracy of 0.62 (95% CI 0.58–0.67)

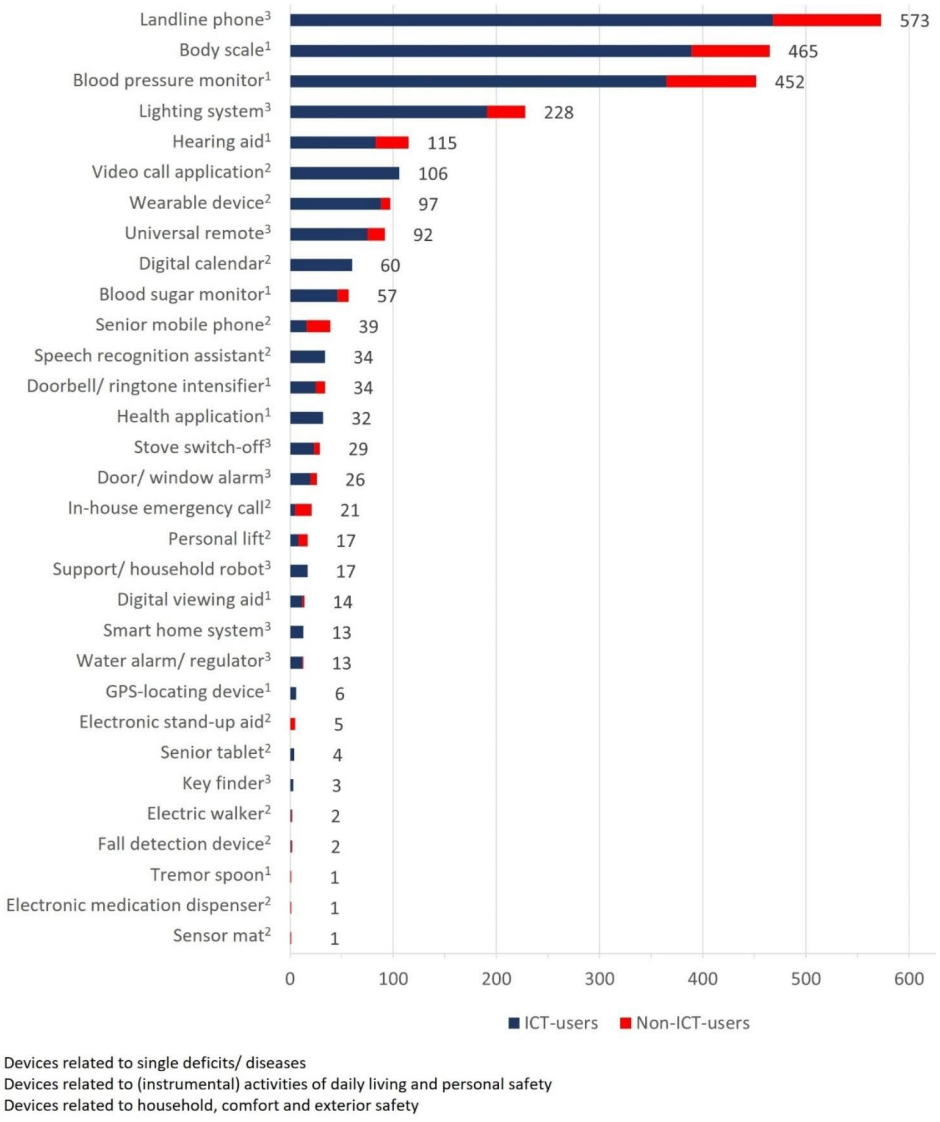

Fig. 2 Total use of AT by ICT-users and non-ICT-users

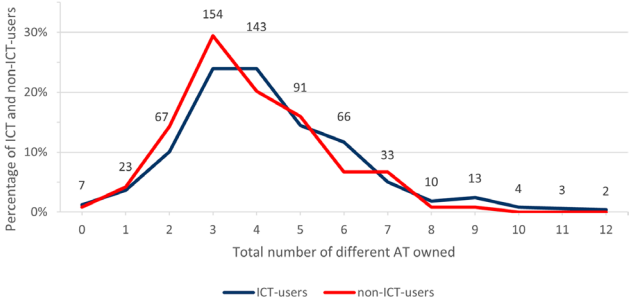

Fig. 3 Distribution of the total number of different AT owned by ratio of ICT-user vs. non-ICT-users. Numbers above the lines indicate the sum of ICT-users and non-ICT-users using the respective amount of different AT depicted on the x-axis

and an ROC AUC of 0.82 (95% CI 0.8–0.84). The empirical probabilities for presence or absence of an AT (given the technology benefit rating) after applying a softmax function are presented in Fig. 4, which can be understood as displaying the predictive power of the technology benefit rating for the relative use of different AT. Little or no technology benefit was inversely related to the use of a video call application, a digital calendar, a health application, and a speech recognition assistant. In other words, comparatively few people who reported little or no benefit from technology used these devices. In turn, a high technology benefit was inversely related to the use of a senior mobile phone and an emergency call button.

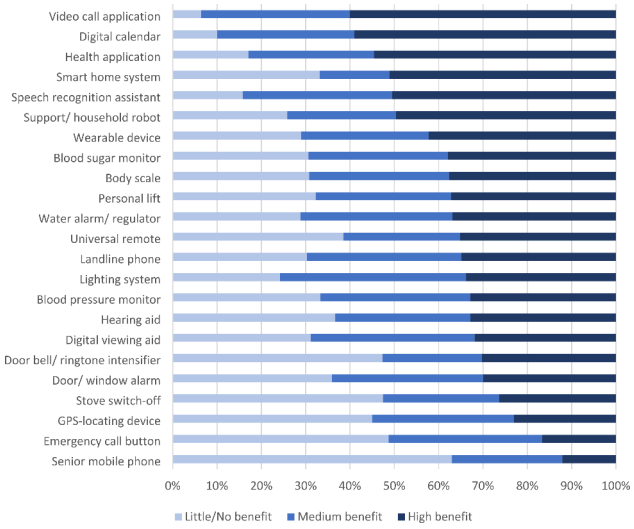

Fig. 4 Association of the technology benefit rating with the relative use of different AT. All subjects that gave a technology benefit rating were included, irrespective of ICT-use. Only AT with n > 5 reported users in our sample were included in the analysis. Displayed are the empirical probabilities for an AT given the technology benefit rating after applying a softmax function

Discussion

ICT and AT have the potential to improve independence, increase safety, and help users stay socially connected [49, 50]. These aspects are especially important for older adults and high hopes are being put in the use of technology to assist healthcare providers [17]. This study presents a comprehensive overview of technology use among older, community-dwelling adults for both key ICT (smartphone, computer/laptop, and tablet) and a range of different AT, including those specifically for frailer older adults.

Regarding ICT-use, it could be shown that younger age, higher level of education, living together with others, the availability of an internet connection, higher interest in technology, and a better health status are associated characteristics. Other studies with older adults had similar results and identified higher education, higher income level, and better overall health status to be associated with an increased likelihood of technology use among older adults [5, 34]. No association could be found for the size of the hometown. This is in contrast to a recent study from the United States that found that older adults who live in rural areas tend to use less technology [30]. One explanation could be that the population density is much higher in Germany and even rural areas are usually well accessible. Other studies showed that female gender and living alone increased the likelihood for technology uptake, contradicting the results presented here [5, 51]. A recent review confirms these apparent inconsistencies within the current research, stating that the influence of sociodemographic variables and health condition on technology uptake remains unclear [35].

Overall, ICT-use or non-use was not significantly associated with the number of different AT owned. However, similarly to other research, the association was significant when looking at individual devices or device groups [32]. The present study confirmed that non-ICT-users are exempt from many potentially beneficial AT that rely on a smartphone or other mobile device. Examples are video call systems, health applications (used to e.g., monitor chronic diseases), digital calendars, smart home systems, GPS locating devices, or speech recognition assistance systems. Perceiving the overall technology benefit as high was associated with the ownership of many of these devices. Likewise, estimating the overall technology benefit rating from AT use in a Bayesian Model yielded good results (ROC AUC 0.82). There were some AT for which the usage rate was higher among non-ICT-users such as an in-house emergency call, a hearing aid, or a personal lift. These devices are related to functional deficits and multimorbidity which is consistent with the results that non-ICT-users are older and have more comorbidities. Interestingly, a senior mobile phone was used about six times as frequently among non-ICT-users compared to ICT-users. This suggests that non-ICT users have a desire to remain connected and engaged but might not feel comfortable with using a smartphone.

About 96% of ICT-users reported high or medium perceived benefit gained from using technology, confirming the potential and advantages of technology use. However, across the entire study population, including ICT-users, AT remained largely underused. Classic devices such as a landline phone, a body scale, and a blood pressure monitor remain the most used and newer, more innovative technologies lack behind [7]. While existing studies show, that older adults are generally willing to use technology [2], several aspects can explain the current trend. First, AT, particularly modern and innovative ones, can arouse distrust regarding functionality and privacy. Also, many devices are not developed with the target group in mind, reducing usability [52, 53]. Second, technological devices can be expensive, and many older adults may not be able to afford them [54]. Most AT are not (yet) covered by insurance or other forms of financial assistance, keeping them out of reach for many individuals. Third, while the market offers an abundance of AT solutions, many devices are only available online and service providers or healthcare professionals lack the knowledge to give appropriate recommendations [55]. This gap in availability and knowledge limits access to AT for many older adults. Last, the use of AT can raise concerns about social isolation and dependency. Some older adults may feel that using modern AT makes them more reliant on others for technological assistance, which can be detrimental

to their self-esteem and overall well-being [54, 56]. For many AT, the numbers reported in this study were too small and larger sample sizes are needed to conduct conclusive analyses. However, it has been found that factors that affect adoption of technology might be the same across different types of devices [35].

Around 3% of participants (n=18) also added household items, standard entertainment devices, or sports equipment as AT they use in their daily life, highlighting the issue that the term assistive technology is a very broad umbrella term that makes homogeneous research difficult [17]. A 2015 definition by the World Health Organization states that AT include "any item, piece of equipment or product, whether it is acquired commercially, modified or customized, that is used to increase, maintain or improve the functional capabilities of individuals with disability" [57, p.14] and thus confirms this heterogeneity. We believe that there is a relevant difference between AT that are developed to improve autonomy and independence versus those that are well established and primarily related to exterior safety or comfort. For a more focused scientific and societal appraisal of these devices, we propose to highlight items that are associated with use-cases related to (I)ADL or clear deficits/ diseases (high impact on autonomy) and to separate them from devices that are closer linked to household tasks, comfort, and exterior safety (low impact on autonomy) (Fig. 5).

As an example, a patient suffering from diabetes but without further restrictions does not have the same needs as a person suffering from diabetes who also has polyneuropathy and mobility, visual, and hearing impairments. Both use-cases could however, benefit from AT in terms of autonomy and independent living. An external webcam, a landline-phone, or automatic lighting are much less relevant for independent living and more comfort related [58]. A CGA provides a multidisciplinary view of the patient and could help to identify the most promising AT for an individual by separately evaluating ADL and IADL, mobility, emotion including loneliness, nutrition, social network, and others [58]. There are different examples that can be mentioned: lonely people could be offered easy to use senior phones or tablets, people with IADL difficulties could be further evaluated for electronic medication dispensers, prefilled by caregivers, or people with frequent falls could use wearables with fall detection. Thus, we suggest considering the domains of a CGA when categorizing different AT to identify all deficits and resources of an individual and enhance understanding, and ultimately use of AT among the target population. In case it is not possible to perform a full CGA, other screening tools focusing for example on

Category	Primarily single deficit-/ disease-related	Primarily (I)ADL[1]- or personal-safety-related*	Primarily household-, comfort- or exterior-safety-related*
Examples	- Blood pressure monitor - Blood sugar monitor - Tremor spoon - AI-powered reader/ camera attached to glasses - Health application - Digital viewing aid - GPS-locating device - Body scale - Enhancement of household items (washing machines, oven etc.) for blind individuals - Hearing aid - Doorbell/ringtone intensifier	- Electronic lock - Home emergency call - Digital calendar - Electronic medication dispenser - Personal lift - Electronic stand-up aid - Wearable device/ smartwatch - Other fall detection devices such as sensor mats/ room surveillance - Speech recognition assistant - Communication tablets for seniors incl. video call - Senior mobile phones - Electric walker	- Electric roller shutter - Lighting system - Outdoor webcam - Stove switch-off - Water alarm/ regulator - Regular household items (e.g., washing machine, landline phone) - Universal remote - Support/ household robot - Smart home system - Key finder - Door/window alarm
Comment	To improve very distinct, often disease-related and use-case-specific deficits, also including vision-/ hearing-impaired individuals.	To improve self-help, independency and autonomy. User could also need a triage with respect to exterior safety (electronic locks could be less safe).	To optimize and ease regular tasks (that could also be externalized, such as washing clothes) and to feel/ stay safe from external/ environmental stressors.
	High impact on autonomy/ independent living		**Low impact on autonomy**

[1]: (I)ADL: (Instrumental) activities of daily living
*: Exterior safety: safe houses, alarm systems, exterior surveillance vs. personal safety: fall detection and other ADL-related measures

Fig. 5 Proposal for separation of AT into three categories with different goals and different levels of impact on autonomy and independent living

frailty (such as the Clinical Frailty Scale [59]), ADL (such as the Barthel Index [60]), or increased risk (such as the Identifying Seniors at Risk (ISAR) score [61, 62]) could be used.

With almost 25%, the response rate for this study was higher than expected considering that no reminders or incentives were given. This might have been due to a general interest in the topic. Another explanation might be the restrictions due to the Covid-19 pandemic that caused more people to be at home with spare time on their hands. Other cross-sectional studies with older participants reported response rates between 40 and 60%, but made use of interventions to boost responses (such as sending out reminders [38, 63, 64] or cooperating with doctor's offices [65]).

Limitations

For this study, addresses were only obtained from one county in Southern Germany. A regional bias in the data is possible and generalizability might be limited to predominantly rural areas in countries with similar economic status and level of digitalization as Germany. Additionally, the second largest registration office denied our request for address data. Older adults with severe physical or cognitive impairments are less likely to participate, resulting in a potential sample bias. Additionally, no pre-selection was made regarding sex. As there are more female citizens in the age group ≥65, a potential oversampling of female participants is likely. The questionnaire used was developed by the research team and did not undergo a validation process. The questionnaire was not tested in a rigorous manner. Possible misunderstandings with respect to the definition of an AT may explained the heterogeneity in the answers. Furthermore, there is no information available on how participants answered the questionnaire (e.g., with the help from a relative). As the questionnaires were returned anonymously, it can also not be determined if the person, the questionnaire was addressed to, was the one answering the questions or if the document was handed to the partner or someone else. Last, as this is a cross-sectional study, no causal relationships can be determined from the analysis.

Conclusion

This study presented insights into the use of key ICT as well as standard and technologically advanced AT among older, community-dwelling adults. While most older adults aged ≥65 use some type of technology, newer, more innovative AT appear underutilized. Additionally, the use of AT related to functional deficits (IADL) and to certain diseases (morbidity), remains low, while more ordinary household devices and ICT are highly utilized. However, for those who do use technology, the perceived benefits are high. To find a common language and to categorize these tools for research purposes among frail older people we propose a categorization to separating disease-, IADL- and personal safety-related devices with higher potential impact for autonomy from exterior safety-/ comfort-related AT and established household-related items with a lower impact.

Research and development that focuses especially on the first two categories could leverage independent living in challenging situations. By providing insight into the characteristics associated with the use or non-use of ICT and AT, this study can assist community workers and policy makers with targeting relevant information and specific programs.

Abbreviations

AT	Assistive technology
AUC	Area under the curve
CGA	Comprehensive geriatric assessment
CI	Confidence Interval
(I)ADL	(Instrumental) activities of daily living
ICT	Information and communication technology
ROC	Receiver operator characteristics
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology

Supplementary Information

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Supplementary file 1: STROBE Checklist

Supplementary file 2: Overview of sample compilation

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Authors' contributions

M.F. and M.D. designed the study and developed the questionnaire. All authors contributed to the development of the questionnaire. M.F. and A.W. organized the postage of the questionnaires. M.F., T.K., M.D., and D.D. worked on the data analysis. M.F. prepared the first draft of the manuscript and the figures. All authors reviewed, edited, and approved the manuscript.

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Data Availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

All the methods included in this study are in accordance with the declaration of Helsinki. Informed consent was obtained from all participants. An ethics approval was obtained from the Joint Ethics Committee of the Bavarian Universities of Applied Sciences (GEHBa-202101-V-014, 5 Feb 2021).

Consent for publication

Not applicable.

Competing interests
The authors declare no competing interests.

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Anhang 4: Publikation IV: Perceived benefit and satisfaction with a tablet computer and an emergency smartwatch by older adults and their relatives: results from a prospective real-world pilot study

Anhang 4.1: Eigenanteil und Lizenzfreigabe für Publikation IV

Literaturangabe	Wiegel P, **Fotteler ML**, Kohn B, Mayer S, Verri FM, Dallmeier D, Denkinger M. Perceived benefit and satisfaction with a tablet computer and an emergency smartwatch by older adults and their relatives: results from a prospective real-world pilot study. JMIR Human Factors (forthcoming). doi:10.2196/53811
Eigenanteil	Zusammen mit BK, SM, DD und MD habe ich die Studie geplant und alle Unterlagen (inkl. Ethikantrag) vorbereitet. Die Studie wurde von BK und SM durchgeführt, ich stand zur Unterstützung und als Ansprechpartnerin zur Verfügung. Zusammen mit PW, BK, SM und FV habe ich die Daten analysiert. Das Manuskript haben PW und ich geschrieben. Alle Autorinnen und Autoren haben das Manuskript gelesen und zur Finalisierung beigetragen. Ich habe das Manuskript bei JMIR Human Factors eingereicht und die Kommunikation mit dem Journal während des peer-review Prozesses geleitet. Die Anmerkungen der Gutachterinnen/ Gutachter haben PW und ich eingearbeitet. Es handelt sich um eine geteilte Erstautorenschaft. Zusammenfassung des prozentualen Eigenanteils – Planung der Studie: 30% – Erhebung, Aufbereitung und Auswertung der Daten: 20% – Verfassen des Manuskriptes und editorielles Handling: 60%
Lizenz	Dieser Artikel ist ein frei zugänglicher Artikel (Open Access), der unter den Bedingungen der Creative Commons Attribution Lizenz (CC BY 4.0) veröffentlicht ist (https://creativecommons.org/licenses/by/4.0/).

Anhang 4.2: Publikation IV im Vertragslayout

Original Paper

Perceived Benefit and Satisfaction With a Tablet Computer and an Emergency Smartwatch by Older Adults and Their Relatives: Prospective Real-World Pilot Study

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Abstract

Background: Assistive technologies (ATs) have the potential to promote the quality of life and independent living of older adults and, further, to relieve the burden of formal and informal caregivers and relatives. Technological developments over the last decades have led to a boost of available ATs. However, evidence on the benefits and satisfaction with ATs in real-world applications remains scarce.

Objective: This prospective, real-world, pilot study tested the perceived benefit and satisfaction with different ATs in the real-world environment.

Methods: Community-dwelling adults aged ≥65 and their relatives tested a tablet computer with a simplified interface or a smartwatch with programmable emergency contacts for 8 weeks in their everyday life. Perceived benefits and satisfaction with ATs were assessed by all older adults and their relatives using different assessment tools before and after the intervention. Outcome measures included the Technology Usage Inventory, Quebec User Evaluation of Satisfaction with Assistive Technology 2.0, and Canadian Occupational Performance Measure.

Results: A total of 17 older adults (tablet computer: n=8, 47% and smartwatch: n=9, 53%) and 16 relatives (tablet computer: n=7, 44% and smartwatch: n=9, 56%) were included in the study. The number of participants that were frail (according to the Clinical Frailty Scale) and received care was higher in the smartwatch group than in the tablet computer group. Older adults of the smartwatch group reported higher technology acceptance (Technology Usage Inventory) and satisfaction (Quebec User Evaluation of Satisfaction with Assistive Technology 2.0) scores than those of the tablet computer group, although the differences were not significant (all $P>.05$). In the tablet computer group, relatives had significantly higher ratings on the item *intention to use* than older adults ($t_{12.3}=3.3$, $P=.006$). Identified everyday issues with the Canadian Occupational Performance Measure included contact/communication and entertainment/information for the tablet computer, safety and getting help in emergency situations for the smartwatch, and the usability of the AT for both devices. While the performance ($t_8=3.5$, $P=.008$) and satisfaction ($t_8=3.2$, $P=.01$) in these domains significantly improved in the smartwatch group, changes in the tablet computer group were inconsistent (all $P>.05$).

Conclusions: This study highlights the remaining obstacles for the widespread and effective application of ATs in the everyday life of older adults and their relatives. While the results do not provide evidence for a positive effect regarding communication deficits, perceived benefits could be shown for the area of safety. Future research and technical developments

need to consider not only the preferences, problems, and goals of older adults but also their relatives and caregivers to improve the acceptability and effectiveness of ATs.

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Keywords: assistive technology; older adults; caregiver; benefits; usability; gerontechnology

Introduction

In their global disability action plan from 2015, the World Health Organization (WHO) defined assistive technologies (ATs) as "any item, piece of equipment or product, whether it is acquired commercially, modified or customized, that is used to increase, maintain or improve the functional capabilities of individuals with disability" [1]. For older adults, ATs can positively impact not only functionality but also autonomy, safety, and communication. In particular, ATs might support older adults who wish to remain in their own homes instead of depending on institutional care. In addition, the application of ATs has become a valid option in relieving the formal and informal caregivers of older adults [2].

In recent years, the field of ATs has evolved to include a wide range of devices for different audiences, varying in complexity and price. Examples include mobile health applications [3], wearable devices [4,5], robotic systems [6], virtual reality applications [7], or sensory aids [8]. ATs are used for various purposes such as personal disease management [3], managing fall risks [9], ensuring correct medication [10,11], and preventing social isolation [12,13]. Clearly, there is an abundance of available ATs assisting with age-related challenges. Yet, the effectiveness of ATs for older adults remains inconclusive [3,9,12,14]. Nevertheless, studies investigating the benefits and usability of ATs for older adults in the real-world environment are still lacking [15-17]. A focus on multimorbid and frail populations is of special interest, as one would expect that this cohort might especially benefit from the use of ATs. In addition, the use of ATs by older frail and nonfrail adults often depends on and includes relatives and caregivers who significantly contribute to the (successful) application of ATs. Additionally, this group itself might benefit from the application of ATs through a reduction of care burden [18]. Thus, studies testing the effectiveness of ATs should also consider the effects on caregivers and relatives.

Older adults are less likely than younger adults to use technology, and this depends on a number of factors including sociodemographic factors, attitudinal variables, and cognitive abilities [19]. However, despite the assumption that older adults are afraid and reluctant to use ATs, recent evidence indicates that they are relatively open to the idea of using technologies in their everyday life, independent of their age and subjective health status [20,21]. The factors that influence the intention of older adults to use digital technologies are complex and include environmental, psychological, and social determinants [22]. Among the most important ranked criteria for the selection and use of ATs by older adults are the promotion of independence, affordability, ease of use, and ethical company policies [23]. Thus, the use and effectiveness of ATs ultimately depend on the alignment of the technological developments and user needs.

Recently, emergency buttons or watches and wearable devices with GPS tracking or fall detection for older adults have gained special interest. However, few studies exist investigating the benefit of these devices for older adults. Most existing research focuses on wearables worn for disease monitoring or activity tracking [24]. A recent study with an emergency button (worn as a wristband or necklace) that was connected to the landline did not show any improvement for health-related quality of life and other outcome measures [5]. Focusing on the issues of loneliness and lack of social interaction, software systems for (tablet) computers designed specifically for older adults are entering the market. The systems feature large icons and simple menus. Functionalities include video calls, access to the news, photo albums, or games. However, the benefit of such ATs remains unclear. While 1 study reported a significant improvement of loneliness, social support, and well-being among community-dwelling older adults living alone using a special computer system [13], a large systematic review and meta-analysis of similar interventions found no benefits on psychological outcomes in people with cognitive impairment and dementia [7].

This prospective, real-world, pilot study aims to assess the individual benefits and satisfaction gained from an emergency smartwatch and a senior tablet computer by community-dwelling older adults and their relatives in the real-world environment. The products were selected based on the results of a product competition for companies.

Methods

Study Population

Since the use of ATs often requires or supports the contact and interaction with relatives, this study considered 2 participant groups: older adults and their relatives or a close friend (hereinafter referred to as relatives). The inclusion criteria for older adults were (1) aged ≥65 years; (2) residence in the area of Ulm (distance ≤50 km); (3) an independent or assistive living situation; (4) the ability to speak and read German; and (5) the ability to consent to the study participation (adults with dementia were excluded). In addition, older adults had to have intact vision and hearing (normal or corrected). The relatives had to (1) be a family member or someone close to the adult; (2) speak and read German; (3) give consent to study participation; and (4) have a smartphone, tablet computer, or PC with internet connection. Participants were recruited in Southern Germany using convenience (via analogous and digital recruitment methods such as flyers, social media, and clinic staff) and snowball

sampling (asking participants for other potential participants). As this was an exploratory study, no sample size calculation was conducted. The aim was to recruit between 6 to 10 participants per selected device. This number was defined based on feasibility. For 4 different ATs with 5 available devices each, 2 rounds of the study with 40 participants can be performed within 4 months.

Ethical Considerations

Ethical approval was obtained from Ulm University Ethical Committee (Nr. 230/21, 05.07.2021). Before entering the study, individuals received detailed information about the study and provided written informed consent to participate. Data analyses were performed on pseudonymized data. No financial remuneration was provided for participation.

Selection of the ATs

Initially, 4 different AT were chosen for this interventional study. The ATs were selected from the 2020 product competition "Daheim Dank Digital" (at home thanks to digitalization) [25] aimed at startups and established companies in German-speaking countries (Germany, Austria, and Switzerland). Companies were asked to apply with ATs that could compensate age-related deficits and impairments described in 5 predefined use cases. The use cases were designed together with experts from different areas of expertise and focused on (1) nocturnal restlessness and fall risk; (2) loneliness, hearing and vision impairment, and forgetfulness; (3) inactivity and listlessness in daily routine; (4) urinary incontinence and reduced fluid and food intake; and (5) limited mobility, weakness, and loneliness.

A total of 9 companies presented their products, and a scientific jury evaluated the devices based on availability; readiness for use; and impact in at least 1 of the categories of communication, security, or autonomy. These categories were specified as target areas in the overall project. A total of 4 products were selected for this user study based on their availability. The identified devices focused on safety (an intelligent bed exit alarm from the company NevisQ and a smartwatch with an emergency button from the company CareIOT GmbH) and communication (the Media4Care tablet computer from Media4Care GmbH and the Eldertech app, which supports communication and coordination of care within a family, from Eldertech GmbH). At the time of the study, all products were commercially available and had a CE certificate.

Study Design

We performed a prospective, real-world, pilot study of 4 different ATs with community-dwelling adults aged ≥65 years and their relatives. Together with the participants, the investigators decided which product was the most suitable for the older adult. Based on their individual needs, a decision was made for 1 of the targeted areas: communication or safety. Unfortunately, no candidates were identified for the evaluation of the bed exit alarm and the app; therefore, the selection was limited to the tablet computer and the emergency smartwatch. Both devices were used in their versions that were current as of August 2021. Details on the main functionalities of these 2 devices are listed in Table 1. Further technical information on the 2 products can be found in Multimedia Appendix 1.

In an introductory assessment session, all participants and their relatives were informed of the study procedure, goals, and possible risks and consented to participate. Baseline data were captured in a subsequent meeting at the participant's home or in the study center (SM and BK). Participants were given the selected AT and a short introduction to the device. Participants then tested the AT in their daily life over a period of 8 weeks. In case problems with the use of the AT arose, participants were asked to first seek help in the manual, on the web, or via the company hotline before contacting the study center. This was done to reproduce a real-life setting as accurately as possible.

During the study period, the study team called the participants after 1, 2, 4, and 6 weeks to inquire about the use of the product; help solve possible issues; and remind participants to document errors, problems, and the frequency of use. After the test period of 8 weeks, the participants and their relatives were assessed a second time. This meeting took place at the participant's home or in the study center. The relatives performed an independent assessment of the AT based on their user experience gathered during the testing period (assisting or interacting with older adults). Thus, the relatives' ratings represent their own perception of the AT rather than the perception of the usefulness of the AT for the older adult.

Table 1. Main functionalities of the 2 assistive technologies tested in the study.

Device	Main functionalities and features
Smartwatch	• Emergency button, including the notification of contacts via phone and mail • GPS tracking • Analysis of movement profile and automatic notification of contact persons in case of deviations from the norm
Tablet computer	• Video calls • Messenger service • Entertainment (games, news, podcasts, radio, and music) • Photo album • Touchscreen

The questionnaires were paper based and filled out by 1 of the investigators (SM or BK) during the interview sessions before and after the intervention. Older adults and their relative were interviewed in separate sessions to reduce the interview duration and to avoid interaction, except when older adults required support from the relative. Interviews were performed face-to-face with all older adults. Interviews with relatives were also performed by phone.

Data Collection

At baseline, sociodemographic data were collected including sex, age, living situation (alone, together with partner, or with someone else), education (<10 y or ≥10 y), level of care (administratively assigned level of care measuring a person's care need and determining their claim for additional support), self-perceived health status (excellent, very good, good, fair, or poor), and self-perceived age. Additionally, information on interest in technology was collected (high, medium, or low).

To assess older adults' ability to perform instrumental activities of daily living (IADL), the Lawton scale was used [26]. The corrected IADL score was calculated taking into account the possibility that the activities have never been performed [27]. To capture additional information about the participants' social situation, the Lubben Social Network Scale-6 was used [28]. With the Clinical Frailty Scale (CFS), frailty and fitness of the older adults (scale from 1="very fit" to 9="terminally ill") were assessed [29]. In addition, both older adults and relatives had to rate their life satisfaction (scale from 0 to 10, with higher values indicating higher life satisfaction).

Frequency of Use

Older adults were asked to document their use frequency of the technology in each of the 8 intervention weeks. The frequency of use was reported on a 5-point scale, that is, it captured whether the technology was used on 7, 5-6, 3-4, 1-2, or 0 days per week.

Technology Usage Inventory

The Technology Usage Inventory (TUI) was administered to the older adults and their relatives to assess the influence of psychological factors on the use and acceptance of technology [30]. The items *curiosity* and *technology anxiety* were asked before the intervention, whereas the items *interest*, *usability*, *usefulness*, *skepticism*, and *accessibility* were asked after the intervention. Answers were given on a 7-point Likert scale (1="strongly disagree" and 7="strongly agree"). In addition, the *intention to use* the AT was asked on a visual analog scale (0="agree" and 10="disagree") after the intervention. For orientation purposes, the item *intention to use* has been reversed in the *Results* section of this paper.

Quebec User Evaluation of Satisfaction With Assistive Technology 2.0

Satisfaction with the technology was evaluated after the intervention using the German version of the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) 2.0 [31]. Of the original 12 items of the QUEST 2.0, only the 8 items relating to an AT device (domain device) were considered. Each question was scored on a 5-point scale (1="not satisfied at all" and 5="very satisfied"). The questionnaire was completed by both the older adults and their relative. Additionally, they were asked to choose the 3 items with the highest relevance for them. Overall satisfaction was calculated as the mean score across all answered items. The QUEST 2.0 has been shown to be a valid and reliable assessment for a population of assistive device users [32].

Canadian Occupational Performance Measure

The Canadian Occupational Performance Measure (COPM) is a semiquantitative, client-centered instrument that was used to investigate the perceived satisfaction with the performance of the AT in the specified problem areas of the older adults and their relatives [33]. For this purpose, everyday issues of personal importance related to the use of the AT were determined together with an occupational therapist during the interview before the intervention. For each participant, up to 5 everyday issues were identified, and for each of these issues, the older adults and their relatives had to rate their perceived level of performance and satisfaction on a scale from 1 to 10, with higher scores indicating higher performance or satisfaction. Ratings for the defined issues were then summed and divided by the number of issues to obtain a performance score and a satisfaction score. After testing the AT, the older adults and their relatives repeated the rating on the previously defined everyday issues of personal importance.

Data Analysis and Statistics

For all outcome measures, descriptive statistics were calculated and included the mean (SD). The focus of the analysis was on the outcomes that assessed the usability aspects of the ATs, that is, the TUI and QUEST 2.0. In addition, exploratory statistical inference testing was performed to assess the effects of the ATs on the specified everyday issues of the older adults and their relatives (COPM). The assumption of a normal distribution was tested by the Kolmogorov-Smirnov test of normality. Subsequently, 2-tailed t tests were used to compare intervention groups using the Welch t tests (life satisfaction, TUI, and QUEST 2.0) and preintervention and postintervention data using paired t tests (COPM). Uncorrected P values are presented in the *Results* section. However, to control the false discovery rate, we used the correction of the P values via the Benjamini-Hochberg procedure [34]. If this correction changed the outcome of the statistical test, this is reported in the *Results* section. In addition, effect sizes were calculated using Cohen d. The statistical significance was set at $P<.05$ for all tests. Statistical analyses were performed using RStudio (RStudio Team).

Results

Participants

The study was performed from August 2021 to April 2022. A total of 44 older adults were screened for inclusion in the study. From this sample, 18 older adults and their relatives

met the inclusion criteria and were enrolled in this study. There was 1 dropout who stopped study participation due to dissatisfaction with the technology. A total of 17 older adults (tablet computer: n=8, 47% and smartwatch: n=9, 53%) and 16 relatives (tablet computer: n=7, 44% and smartwatch: n=9, 56%) completed the study and were included in the final data analysis. In the tablet computer group, there were 2 cases where the same relative belonged to 2 older adults, and there was 1 case where 2 relatives belonged to the same older adult.

The sociodemographic characteristics of the older adults and their relatives are shown in Tables 2 and 3, respectively. Older adults in both groups were aged >80 years on average but reported a younger self-perceived age. Even though participants in the smartwatch group were older on average, they felt younger than those in the tablet computer group. Data on self-perceived health status, level of care, corrected IADL, and frailty indicated that older adults in the smartwatch group were more dependent and slightly frailer than those in the tablet computer group. A total of 4 participants, all in the smartwatch group, perceived their own health to be poor or fair. However, older adults of the smartwatch group were socially more engaged than those of the tablet computer group. While most older adults (tablet computer: 7/8, 88% and smartwatch: 6/9, 67%) and all relatives indicated at least a medium level of technology interest, one-third (3/9, 33%) of participants in the smartwatch group reported a low level of technology interest. Relatives in the smartwatch group had a higher mean age and included more male persons than the relatives in the tablet computer group.

Table 2. Sociodemographic characteristics of older adults. Data are presented as frequency and percentage or as mean (SD).

Characteristics	Tablet computer (n=8)	Smartwatch (n=9)
Sex, n (%)		
Female	5 (62)	5 (56)
Male	3 (38)	4 (44)
Age (years), mean (SD)	80.1 (8.2)	82.7 (7.9)
Self-perceived age (years), mean (SD)	76.9 (12.4)	72.6 (15.4)
Living situation, n (%)		
Alone	3 (38)	6 (67)
With partner	5 (62)	3 (33)
Education (years), n (%)		
<10	4 (50)	4 (44)
≥10	4 (50)	5 (56)
Self-perceived health status, n (%)		
Excellent or very good	2 (25)	1 (11)
Good	6 (75)	4 (44)
Fair or poor	0 (0)	4 (44)
Level of care[a], n (%)		
Yes	2 (25)	5 (56)
No	6 (75)	4 (44)
Corrected IADL[b], mean (SD)	7.4 (1.4)	5.3 (2.6)
CFS[c] score, mean (SD)	3.4 (1.2)	3.7 (2.1)
Frailty (CFS score>4), n (%)	0 (0)	4 (44)
LSNS-6[d] score, mean (SD)	15.4 (3.5)	21.8 (2.0)
Socially isolated (LSNS-6 score<12), n (%)	1 (12)	0 (0)
Technology interest, n (%)		
High	4 (50)	4 (44)
Medium	3 (38)	2 (22)
Low	1 (12)	3 (33)

[a]Level of care: administratively assigned level of care measuring a person's care need and determining their claim for additional support.
[b]IADL: instrumental activities of daily living (Lawton scale).
[c]CFS: Clinical Frailty Scale.
[d]LSNS-6: Lubben Social Network Scale-6.

Table 3. Sociodemographic characteristics of relatives. Data are presented as frequency and percentage or as mean (SD).

Characteristics	Tablet computer (n=7)	Smartwatch (n=9)
Sex, n (%)		
Female	6 (86)	5 (56)
Male	1 (14)	4 (44)
Age (years), mean (SD)	50.3 (18.2)	64.3 (11.3)
Education (years), n (%)		
<10	1 (14)	1 (11)
≥10	6 (86)	8 (89)
Technology interest, n (%)		
High	3 (43)	5 (56)
Medium	4 (57)	4 (44)
Low		0 (0)

Frequency of Use

The frequency of use of the tablet computer and smartwatch in everyday life was heterogeneous across the study period. In the tablet computer group, 5 older adults reported varying use frequencies, which ranged between not using the technology at all (0× per week) and regularly using the technology (7× per week). Two participants of the tablet computer group stopped using the technology after the first week of the intervention. In the smartwatch group, 6 older adults used the technology consistently across all 8 intervention weeks (mostly 7× per week). In the smartwatch group, 2 participants stopped using the technology after the first 1 to 3 weeks. A total of 2 older adults (1 in each group) did not document their frequency of use.

Life Satisfaction

The mean life satisfaction of older adults changed nonsignificantly from 7.9 (SD 3.3) to 7.3 (SD 3.1) in the tablet computer group (t_7=1.1, P=.31, d=0.29) and from 7.2 (SD 2.1) to 8.1 (SD 1.9) in the smartwatch group (t_8=1.1, P=.29, d=0.44). Similarly, the mean life satisfaction of relatives changed nonsignificantly from 8.9 (SD 0.9) to 8.0 (SD 2.1) in the tablet computer group (t_6=1.5, P=.17, d=0.53) and from 7.7 (SD 1.4) to 8.1 (SD 0.7) in the smartwatch group (t_6=0.9, P=.41, d=0.39). In the smartwatch group, 2 participants only provided the preintervention (n=1) or postintervention (n=1) value and were not considered in the statistical analysis.

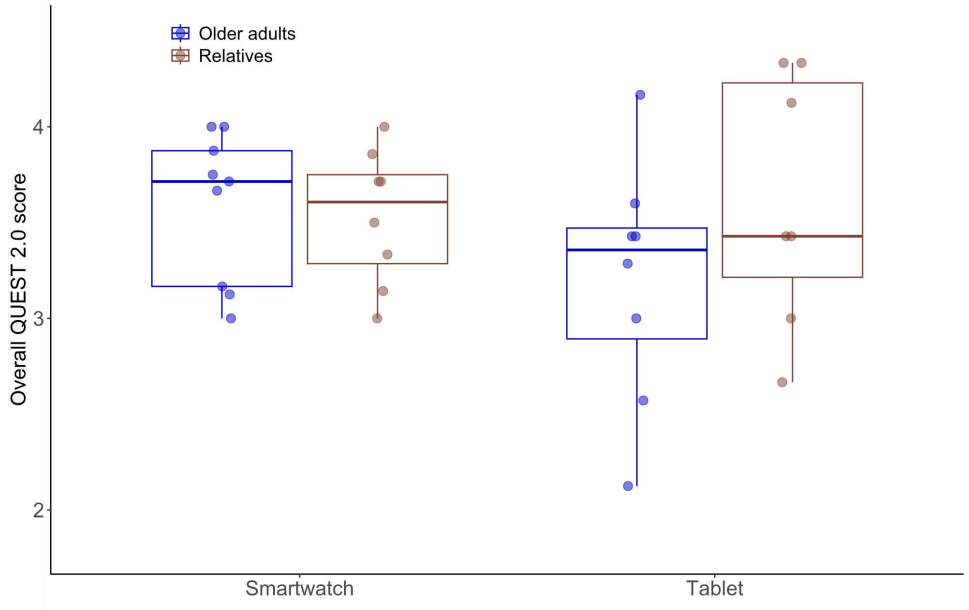
Technology Acceptance

Prior to the intervention, mean ratings for technology acceptance of older adults and their relatives ranged between 5.8 and 6.5 points for *fearfulness* and between 4.4 and 5.1 points for *curiosity* in the tablet computer and smartwatch group, respectively. For both items, the differences between the tablet computer and smartwatch groups were not significant (older adults: *fearfulness* P=.11 and *curiosity* P=.77; relatives: *fearfulness* P=.43 and *curiosity* P=.36). After the intervention, ratings from the older adults and their relatives of the tablet computer and smartwatch groups were similar for the items *interest*, *accessibility*, *usability*, and *skepticism* (older adults: *interest* P=.90, *accessibility* P=.64, *usability* P=.26, and *skepticism* P=.67; relatives: *interest* P=.65, *accessibility* P=.78, *usability* P=.64, and *skepticism* P=.39). This was different for the items *usefulness* and *intention to use*. TUI scores on the item *usefulness* were higher in the smartwatch group (older adults: mean 5.0, SD 1.0; relatives: mean 5.4, SD 1.4) than in the tablet computer group (older adults: mean 3.8, SD 1.5; relatives: mean 4.2, SD 1.6), although this did not reach statistical significance (older adults: $t_{12.3}$=1.9, P=.07, d=0.98; relatives: $t_{12.1}$=1.6, P=.14, d=0.83). TUI scores on the item *intention to use* were significantly higher in the smartwatch group (mean 6.1, SD 3.4) than in the tablet computer group (mean 2.7, SD 2.2; $t_{13.6}$=2.4, P=.03, d=1.14) in older adults (note that after correction for multiple comparisons, the P value exceeded .05). Although ratings on *intention to use* from the relatives were also higher in the smartwatch group (mean 7.8, SD 2.7) than in the tablet computer group (mean 5.9, SD 1.5), the differences were not significant ($t_{11.0}$=1.7, P=.11, d=0.86). Interestingly, in the tablet computer group, relatives' ratings on the item *intention to use* (mean 5.9, SD 1.5) were on average twice as high as those of older adults (mean 2.6, SD 2.2; $t_{12.3}$=3.3, P=.006, d=1.66). In contrast, the relatives' and older adults' ratings on the item *intention to use* were similar in the smartwatch group (older adults: mean 6.1, SD 3.4; relatives: mean 7.8, SD 2.7; $t_{14.8}$=1.1, P=.28, d=0.54). Descriptive data on all items of the TUI can be found in Multimedia Appendix 2.

Satisfaction With the Technology

The overall satisfaction score of the QUEST 2.0 across all items was similar for the older adults and relatives of both groups (Figure 1). The mean satisfaction score of older adults was 3.2 (SD 0.6) in the tablet computer group and 3.6 (SD 0.4) in the smartwatch group ($t_{11.4}$=1.5, P=.16, d=0.75). Similarly, the mean satisfaction across all items rated by the relatives was 3.6 (SD 0.7) in the tablet computer group and 3.5 (SD 0.4) in the smartwatch group ($t_{8.6}$=0.3, P=.77, d=0.16).

Figure 1. QUEST 2.0 score (scale from 1 to 5) of older adults and their relatives for the tablet computer and smartwatch groups. Higher values represent higher satisfaction. Dots represent data from individual participants. QUEST: Quebec User Evaluation of Satisfaction with Assistive Technology.



The 3 most relevant rated items for both AT groups were *safety and reliability* (n=4), *ease of use* (n=7), and *effectiveness* (n=7). Thus, these items were analyzed separately (Table 4). This analysis suggested that older adults of the smartwatch groups rated all 3 items better than older adults of the tablet computer group. Likewise, the relatives of the smartwatch group rated the items *safety and reliability* and *effectiveness* better than those of the tablet computer group. This was different for the item *ease of use*. This item was rated better by the relatives of the tablet computer group than those of the smartwatch group. In addition, item ratings of relatives were better than those of older adults in the tablet computer group. However, none of the abovementioned comparisons yielded significant test results (older adults: *safety and reliability* P=.06, *ease of use* P=.57, and *effectiveness* P=.40; relatives: *safety and reliability* P=.21, *ease of use* P=.40, and *effectiveness* P=.21).

Table 4. Results (mean and SD) of selected QUEST[a] 2.0 items (scale from 1 to 5) for the tablet computer and smartwatch groups. Higher values represent higher satisfaction.

QUEST 2.0 items	Tablet computer		Smartwatch	
	Older adults (n=8)	Relatives (n=7)	Older adults (n=9)	Relatives (n=9)
Safety and reliability, mean (SD)	2.8 (1.0)	3.2 (1.5)	3.7 (0.7)	3.5 (1.2)
Ease of use, mean (SD)	3.1 (1.4)	3.9 (1.2)	3.9 (0.8)	3.5 (1.2)
Effectiveness, mean (SD)	3.1 (1.4)	3.2 (1.5)	3.6 (1.5)	3.9 (1.6)

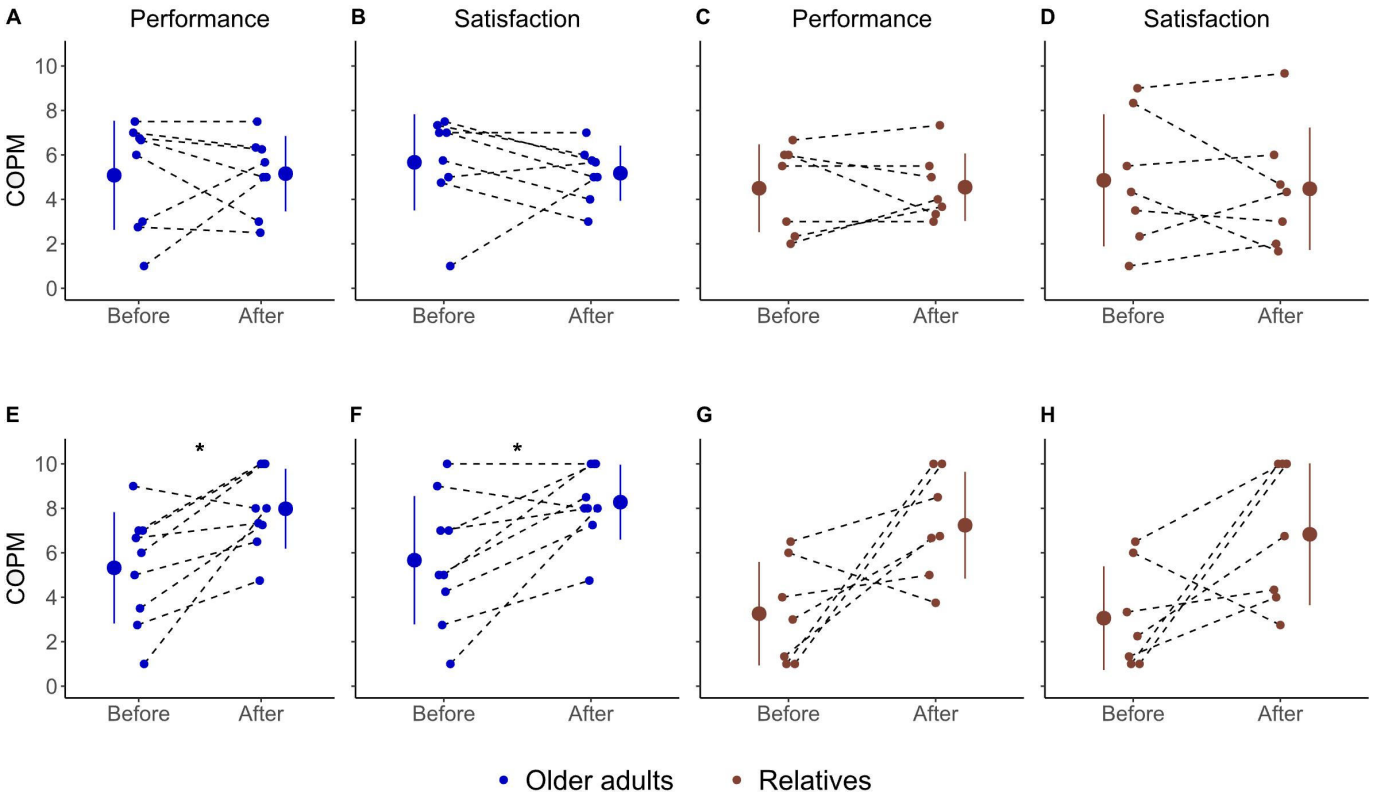
[a]QUEST: Quebec User Evaluation of Satisfaction with Assistive Technology.

Self-Perceived Performance and Satisfaction

The most frequently reported everyday issues identified in the COPM were contact/communication with relatives (tablet computer group), entertainment/information on news (tablet computer group), perception of safety (smartwatch group), getting help in emergency situations (smartwatch group), and usability of the AT (both groups). The number of specified issues ranged between 1 and 4.

In the tablet computer group, the older adults and their relatives reported diverse scores for self-perceived performance and satisfaction, with both improved and reduced scores. Statistical analysis showed that self-perceived performance (older adults: t_7=0.09, P=.93, d=0.03; relatives: t_6=0.08, P=.94, d=0.03) and satisfaction (older adults: t_7=0.6, P=.54, d=0.23; relatives: t_6=0.5, P=.64, d=0.18) did not significantly change in the tablet computer group during the intervention (Figure 2A-D). This was different in the smartwatch group. All but 1 older adult and 1 relative reported improved performance and satisfaction in the defined issues. Statistical analysis showed that self-perceived performance (t_8=3.5, P=.008, d=1.17) and satisfaction (t_8=3.2, P=.01, d=1.06) significantly increased in the older adults of the smartwatch group (Figure 2E-F). In the relatives of the smartwatch group, self-perceived performance (t_6=2.5, P=.04, d=0.96) and satisfaction (t_6=2.3, P=.06, d=0.87) increased, although this result was not statistically significant (after multiple comparison correction; Figure 2G-H).

Figure 2. COPM score (scale from 0 to 10) of older adults and their relatives for the (A-D) tablet computer and (E-H) smartwatch groups. Higher values represent higher self-perceived performance and satisfaction. Small dots represent data from individual participants. Bigger dots and error bars represent mean and SD. Asterisks (*) indicate significant differences after correction for multiple comparisons. COPM: Canadian Occupational Performance Measure.



Discussion

Principal Findings

This prospective, real-world, pilot study analyzed the perceived benefit and satisfaction with 2 types of AT for older adults and their relatives addressing different user needs (communication related vs safety related). The devices were (1) a tablet computer with a video call function and entertainment content for older adults and (2) a smartwatch with an emergency button and GPS tracking. Both older adults and their relatives in the smartwatch group consistently reported improved outcomes in the domains of life satisfaction and self-perceived performance and positive ratings for technology acceptance and satisfaction. Several participants emphasized feeling more secure when going out while wearing the device. In contrast, experiences with the tablet computer were more diverse, with several participants reporting poorer technology acceptance, satisfaction, and self-perceived performance.

Wearables with sensor-based risk assessment or fall detection and GPS locating can contribute to reducing older adults' fear of going outside and thus preserve participation in the community, autonomy, and mobility [35-37]. However, issues with device aesthetics, reliability, and ease of use can negatively impact device acceptance [35,38,39]. Most available studies that focus on the accuracy of device measurements are conducted within a laboratory setting. Contrary to our study, the main sensor location in existing studies is the waist or lower back [36,37]. However, it has been shown that a sensor location at the wrist (eg, watch or wristband) is an important feature for better acceptance of the device [40]. Another study found the highest satisfaction for a pendant worn on a key chain or around the neck [35]. Both forms have the advantage of being familiar or comfortable—aspects that are essential for technology adoption as stated by Fischer et al [41]. Although many emergency smartwatches for older adults have entered the market in recent years, only a few intervention studies with devices similar to the smartwatch tested here exist. Thus, the benefit and results for older adults and their caregivers remain inconclusive [38,42]. Future interventional studies in a real-world setting that take into account the wearers' wishes and focus on reliability, familiarity, and ease of use are needed.

Tablet computers for older adults are designed to improve participation, provide social support, and reduce loneliness or anxiety. Based on the existing research, the effectiveness of these systems remains inconclusive [5,13,43]. In our study, older adults in the tablet computer group reported on average reduced life satisfaction after the 8-week test period and worse scores for safety and reliability when compared to the smartwatch group. Several participants reported technical failures. Some of the issues mentioned included video calls that did not work, difficulties in receiving pictures from relatives, and defective charging. Considering the high value put on device reliability, these problems are part of the explanation for the negative results of the tablet computer. Additionally, the device is operated via a touchscreen, a

technology older adults are mostly unfamiliar with. Consistently, the item ease of use was rated higher by the relatives in the tablet computer group, who belong to a generation already familiar with the use of a touchscreen [43].

Participants received no training prior to using the ATs in their daily lives. This procedure was chosen to create a situation that is as realistic as possible. In most cases, older adults purchasing ATs need to rely on the assistance of their relatives or the company support hotline [35]. In both groups, there were 2 participants who stopped using the ATs after the first few weeks of the intervention period, potentially due to a lack of adequate preparation or lack of support. Indeed, previous research indicates that older adults wish to receive additional training of the technology items they use in the home [44]. Thus, it might be necessary to incorporate training, particularly for more innovative ATs with reduced familiarity and potentially challenging features [38].

This study included 3 older adults characterized as vulnerable or prefrail (CFS score=4) and 4 with some level of frailty (CFS score>4). Physical frailty is a "medical syndrome with multiple causes and contributors that is characterized by diminished strength, endurance, and reduced physiologic function that increases an individual's vulnerability for developing increased dependency and/or death." (p. 4) [45]. Frail older adults face specific challenges when it comes to using and deriving benefits from ATs [46]. However, this subgroup is frequently underrepresented in intervention studies, thereby impeding a comprehensive understanding of their requirements [47]. In this study, all vulnerable or frail older adults reported a high likelihood for intention to use the ATs, indicating that this population is overall open to using ATs in their daily lives. Additionally, vulnerable or frail older adults had an average technology satisfaction score of 3.5 (SD 0.5), that is, their satisfaction was between "more or less satisfied" and "quite satisfied."

As clearly deduced from the introductory WHO definition [1], the term AT is a very broad umbrella term, and it covers an extremely heterogeneous group of products. Each product targets users with specific needs and specific goals. Measuring such diversity is challenging within scientific research. The COPM is unique in the sense that it allows the analysis and quantification of individual user needs and specific AT aims. Thus, it can be adapted to different settings, targets, domains, and participants—irrespective of their age, sex, or other attributes. The tool has been used in other studies investigating the effectiveness of ATs [48,49]. The TUI and QUEST 2.0, however, include predefined items or questions that are not developed specifically for older adults. A recent study suggests that independence, affordability, ease of use, and ethics are the most important AT evaluation criteria for older adults [23]. It is possible that these domains are not adequately represented by the TUI and QUEST 2.0. Assessments focusing on older adults or specifically adapted to the needs and wishes of this group might be better suited in future studies.

Limitations

The 2 ATs studied target different domains (communication vs safety). Thus, the comparability and generalizability of results are limited. However, the used of the COPM allowed an item-specific evaluation according to its properties to help resolve the identified issues. Although the overall interest in the study was high, only 17 older adults and 16 relatives were included in this study. Thus, the statistical power of the study was relatively low, and further studies with larger samples are required to draw robust conclusions. Having the participation of a relative as a prerequisite for enrollment was one of the biggest obstacles for recruitment as they often declined to participate due to time restrictions. However, as many ATs require or support the interaction with relatives, we consider it important to investigate both perspectives, that of the older adults and that of the relatives. A large systematic review on ATs for older adults with dementia analyzed 571 studies and found that most investigations of clinical effectiveness were conducted with small sample sizes of <20 participants [50]. Conducting real-life intervention studies on the effectiveness of ATs requires a significant amount of effort and time. Combined with difficult recruitment among the population aged ≥65 years, this explains the low sample sizes. Unfortunately, we did not find any older adults–caregiver dyads who were willing to test the smart bed rail or the care planning app and able to participate in the study assessments. Both products are possibly of interest for frail older adults with a higher risk for fall or need for care. These individuals might be too sick to participate in a study such as this, live in some form of assisted living facilities or nursing homes, and be more difficult to reach. Older adults with no interest in technology did not participate in the study, causing a certain sample bias. The study was conducted with the device versions (including the software) that were current as of August 2021. The reproduction of the study using newer device versions could potentially change the results.

Conclusion

This prospective, real-world, pilot study confirmed the potential of ATs to support older adults and their relatives, especially for safety-related issues, but also highlighted the remaining obstacles for widespread use. Frail older adults and their relatives, who would potentially benefit the most from ATs, are especially difficult to reach. Thus, future research and technical developments of ATs should take into account the preferences, problems, and goals of older adults. In addition, this study highlights that individualized measures such as the COPM are necessary to identify the needs and assess the user benefits of the ATs in real-world applications.

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Authors' Contributions

MD, DD, SM, BK, and MLF conceived and designed the research. BK and SM were responsible for recruitment and data collection. BK, PW, MLF, and FMV analyzed the data. PW and MLF drafted the paper. All authors edited and revised the manuscript. All authors approved the final version of manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Technical Information on tablet and smartwatch.
[PDF File (Adobe File), 108 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Results (mean and SD) of the Technology Usage Inventory (TUI, scale from 1 to 7 for all items except for intention to use (scale from 1 to 10)) for the tablet and smartwatch group. Higher values represent better evaluations.
[PDF File (Adobe File), 99 KB-Multimedia Appendix 2]

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Abbreviations

AT: assistive technology
CFS: Clinical Frailty Scale
COPM: Canadian Occupational Performance Measure
IADL: instrumental activities of daily living
QUEST: Quebec User Evaluation of Satisfaction with Assistive Technology
TUI: Technology Usage Inventory
WHO: World Health Organization

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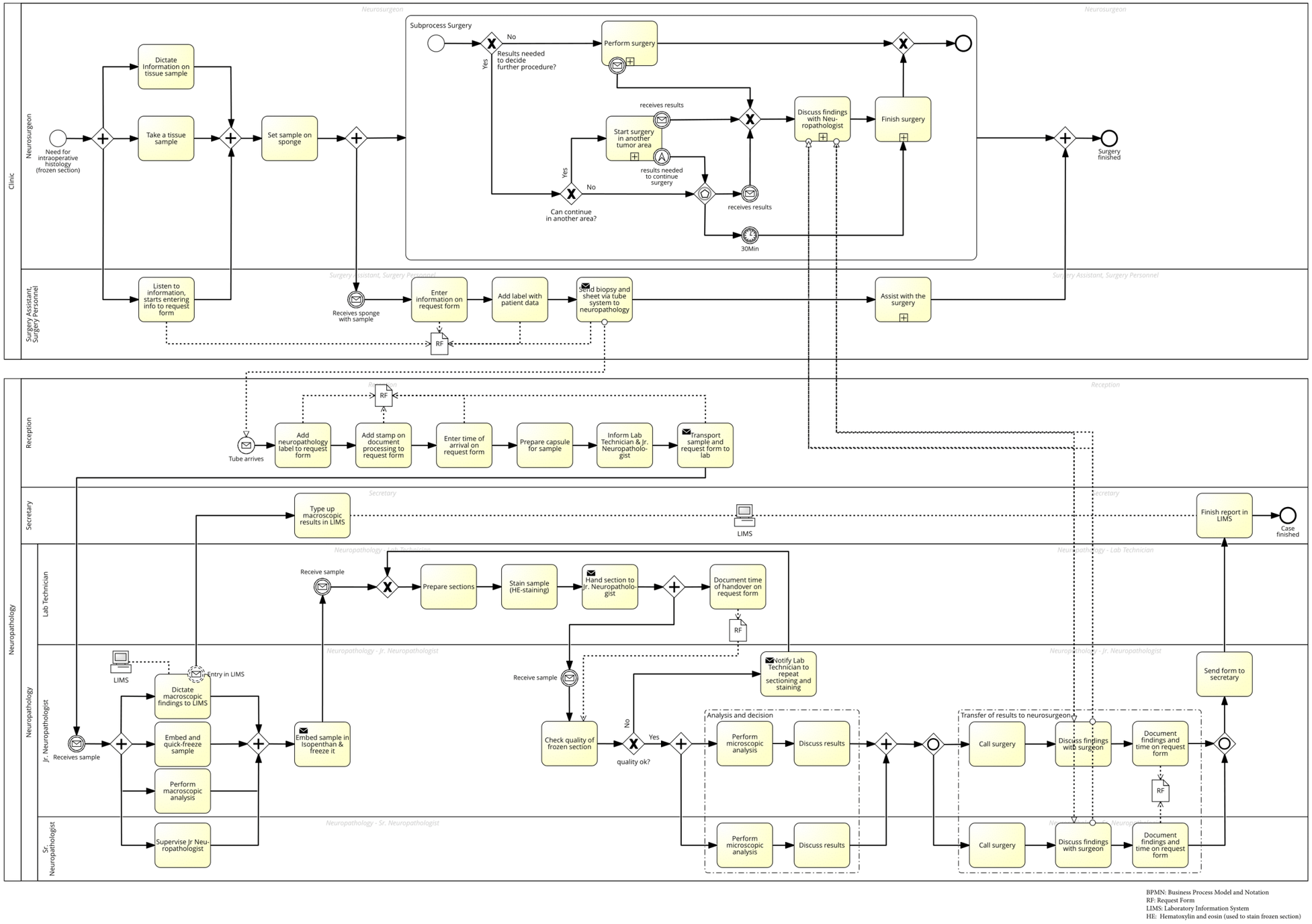
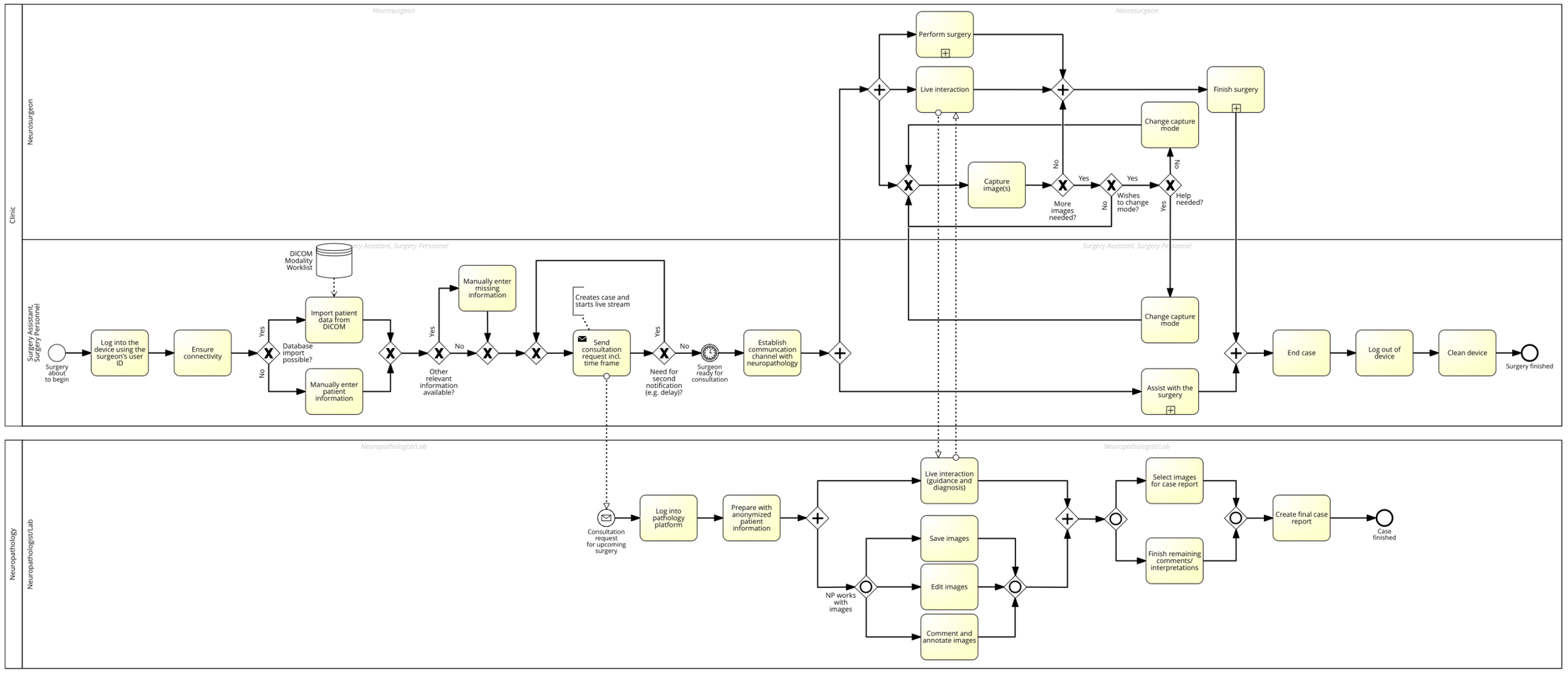
Anhang 5: BPMN-Prozessmodell der Schnellschnittanalyse



Quelle: Fotteler ML, Liesche-Starnecker F, Brielmaier MC, Schobel J, Gempt J, Schlegel J, Swoboda W. Socio-Organizational Impact of Confocal Laser Endomicroscopy in Neurosurgery and Neuropathology: Results from a Process Analysis and Expert Survey. Diagnostics. 2021;11:2128. doi: 10.3390/diagnostics11112128.

Anhang 6: BPMN-Prozessmodell der digitalen Biopsie mittels konfokaler Laser-Endomikroskopie



Quelle: Fotteler ML, Liesche-Starnecker F, Brielmaier MC, Schobel J, Gempt J, Schlegel J, Swoboda W. Socio-Organizational Impact of Confocal Laser Endomicroscopy in Neurosurgery and Neuropathology: Results from a Process Analysis and Expert Survey. Diagnostics. 2021;11:2128. doi: 10.3390/diagnostics11112128.

Anhang 7: Lebenslauf

Der Inhalt dieser Seite wurde aus Gründen des Datenschutzes entfernt.