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**Neue morphologische, klinische
und psychometrische Zusammenhänge
der Cochlea-Implantat Versorgung**



Kumulative Habilitationsschrift
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1. Abkürzungsverzeichnis:

AHL-	Asymmetrischer Hörverlust, engl. asymmetric hearing loss
CA-	Cochlear™ (Contour Advance® (CI512/CI24RECA) (Cochlear Limited, NSW, Australien)
CI-	Cochlear-Implant / Cochlea-Implantat
CT-	Computertomographie
DVT-	Digitale Volumetomographie
Flex ²⁴ -	MED-EL Flex ²⁴ Elektrodenträger (MED-EL, Innsbruck, Österreich)
Flex ²⁸ -	MED-EL Flex ²⁸ Elektrodenträger (MED-EL, Innsbruck, Österreich)
Flex ^{Soft} -	MED-EL Flex ^{Soft} Elektrodenträger (MED-EL, Innsbruck, Österreich)
IPIII-	incomplete partition type III
NCIQ-	Nijmegen Cochlear Implantation Questionnaire / Fragebogen zur gesundheitsspezifischen Lebensqualität
OI-	Oldenburger Inventar Fragebogen
PSQ-	Perceived Stress Questionnaire / Fragebogen zur Stresserhebung
SMA-	Cochlear™ Slim Modiolar® (CI532/CI632) (Cochlear Limited, NSW, Australien)
SPL-	Schalldruckpegel, engl. sound pressure level
SSA-	Cochlear™ Slim Straight® (CI422/522/622) (Cochlear Limited, NSW, Australien)
TQ-	Tinnitus Questionnaire / Tinnitus Fragebogen

2. Einleitung:

2.1. Allgemeine Einführung zum Thema:

Das Cochlear-Implant (CI) in seiner modernen Form wurde bis zum Jahre 2019 bei mehr als 736900 Hörgeschädigten implantiert (1). Bei hochgradig schwerhörigen oder sogar tauben Menschen wird durch diese Hörprothese die Teilhabe sicher- oder wiederhergestellt. Die Forschung und die CI-Entwicklung reichen auf erste Versuche von House (2) zurück. Ein Mehrkanalsystem in Form eines in die Cochlea inserierten Elektrodenträgers zur frequenzspezifischen Stimulation wurde erstmals von Clark et al. (3) und von Michelson und Schindler (4) beschrieben und stellt bis heute das Grundprinzip des modernen CIs dar. Dennoch führt die CI-Versorgung nicht bei allen Patient*innen zum Erlangen eines nutzbaren, offenen Sprachverstehens und das Outcome variiert durchaus. Daher ist die Untersuchung von Einflussfaktoren auf das Sprachverstehen von essentieller Bedeutung in der Optimierung der CI-Chirurgie und CI-Versorgung.

2.2. Einflussfaktoren auf das Sprachverstehen:

Veröffentlichungen der letzten 20 Jahre untersuchten viele Faktoren, die signifikanten Einfluss auf das Sprachverstehen mit CI nehmen. Unter anderem haben Blamey et al. (5), Wingfield et al. (6) und Gates et al. (7) unterschiedliche Ergebnisse im Outcome je nach Ätiologie des Hörverlustes, Kognition der Patient*innen und Alter bei Implantation darstellen können. Neben Faktoren, welche bei der Hörrehabilitation nicht veränderbar und somit nicht optimierbar sind, ist die technische Weiterentwicklung der Implantate und Elektrodenträger ein zunehmender Schwerpunkt der CI-Forschung. Hierbei ist insbesondere die Beurteilung der cochleären Anatomie von Bedeutung. Diese ist in der präoperativen Schnittbildgebung gut beurteilbar und gibt dem Chirurgen eine präoperative Information für die Einschätzung der Insertion des Elektrodenträgers in die Cochlea. Die Cochlea kann anatomisch in drei Skalen unterteilt werden: die Scala vestibuli, media und die Scala tympani. Aschendorff et al. (8, 9) und Husstedt et al. (10) veröffentlichten Vergleichsarbeiten postmortaler Felsenbeine, welche die Cone-beam Computertomographie (CT) und die histologische Aufarbeitung der skalären Lage des Elektrodenträgers miteinander verglichen und für gleichwertig erachteten (Abbildung 1).

Aschendorff et al. (11) zeigten erstmalig, dass die Lage des Elektrodenträgers innerhalb der Cochlea einen Einfluss auf das postoperative Sprachverstehen nimmt. Zahlreiche Veröffentlichungen bestätigten, dass das postoperative Sprachverstehen bei Insertion in die Scala tympani, ohne Dislokation in eine andere Scala signifikant besser ist, als bei dislozierten Elektrodenträgern oder einer Insertion in die Scala vestibuli (9, 11 - 14).

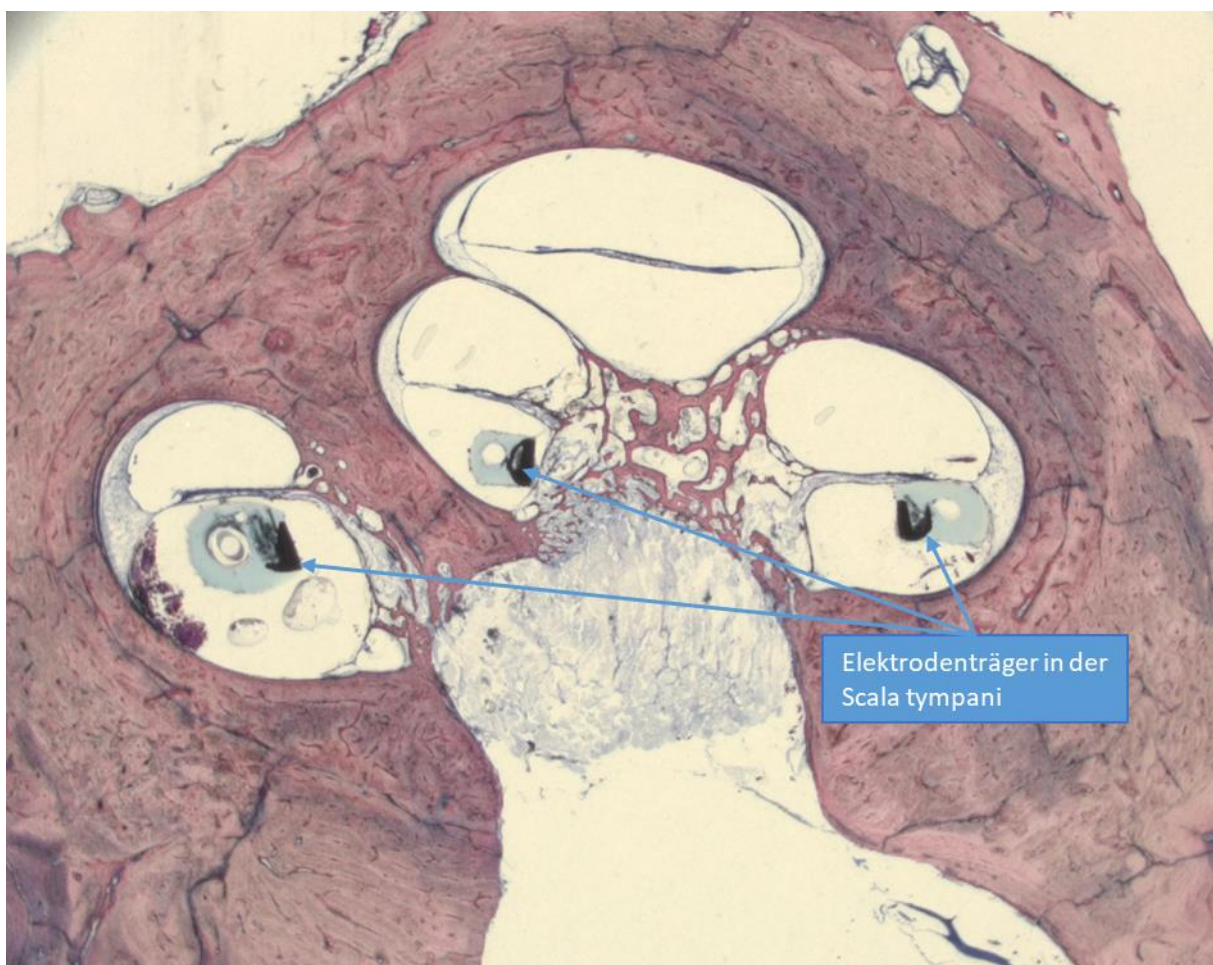


Abbildung 1: Histologische Darstellung der Lage des Elektrodenträgers (Slim Helix Elektrodenträger) in transmodiolärer Schnittführung in einer Hämatoxylin-Eosin Färbung in der Scala tympani der cochleären Basalwindung (Bildquelle: Klinik für Hals-Nasen-Ohrenheilkunde, Universitätsklinikum Freiburg, erstellt und modifiziert durch M.C. Ketterer, 15.01.2022).

Das Ziel bei der Insertion des Elektrodenträgers ist möglichst eine Scala tympani-Insertion zu erreichen. Die Insertion kann prinzipiell über zwei Zugangswege erfolgen: die Insertion über das runde Fenster der Cochlea oder über eine iatrogen erzeugte Öffnung: die Cochleostomie. Die Insertionsmöglichkeit über das runde Fenster der Cochlea ist nur möglich, wenn dieses auch chirurgisch einsehbar ist und erreicht werden kann. Der Rundfensterzugang bringt den Vorteil der direkten Scala tympani Insertion mit sich, da diese anatomisch an das runde Fenster angrenzt (15, 16). Alternativ kann man durch die Cochleostomie die Hörschnecke mit dem Bohrer eröffnen. Die anterior inferiore Lage der Bohrung zum runden Fenster bedingt hierbei die Eröffnung der Scala tympani, was nicht immer sicher zu erreichen ist (17). Die Cochleostomie ist aufgrund der geraden Insertionsmöglichkeit insbesondere bei steiferen Elektrodenträgern von Vorteil (18, 19). Heutzutage werden weiterhin beide Zugangswege verwendet, auch aufgrund der Tatsache, dass das runde Fenster chirurgisch nicht immer einsehbar bzw. zugänglich ist. Bei der Insertion über beide Zugangswege ist das Ziel cochleäre Strukturen nicht zu verletzen, da durch verbesserte Insertionstechniken und atraumatisches Elektrodenträgerdesign die Möglichkeit des Restgehörerhalts (15, 20 - 22) gezeigt wurde.

Die Erfolgsquote an Scala tympani-Insertionen ist von vielen Faktoren abhängig. Insbesondere bei dem Zugangsweg der Cochleostomie ist sie beispielsweise unter anderem von der Erfahrung des Chirurgen abhängig und einer gewissen Lernkurve geschuldet (23). Weiterhin haben Arbeiten über die cochleäre Anatomie und Beschaffenheit weitere Klarheit hierzu geliefert. Escudé et al. (24) schlugen erstmalig vor die Cochlea in der Computertomographie (=CT) in Längs- und Querdurchmesser zu erfassen (Abbildung 2). Sie zeigten an 42 Patient*innen, dass die Größe der cochleären Basalwindung, in welcher der Elektrodenträger überwiegend zu liegen kommt, von Patient*in zu Patient*in variiert. Weiterhin konnten Escudé et al. (24) nachweisen, dass es keine signifikanten Unterschiede zwischen der gemessenen Größe der Basalwindung im Seitenvergleich der untersuchten Patient*innen gibt. Zahlreiche Arbeiten (13, 25, 26) griffen diese Messungen auf und bestätigten die gefundenen definierten Werte (Längsdurchmesser: im Mittel 9.23mm; Querdurchmesser im Mittel: 6.99mm (Werte aus (24))).

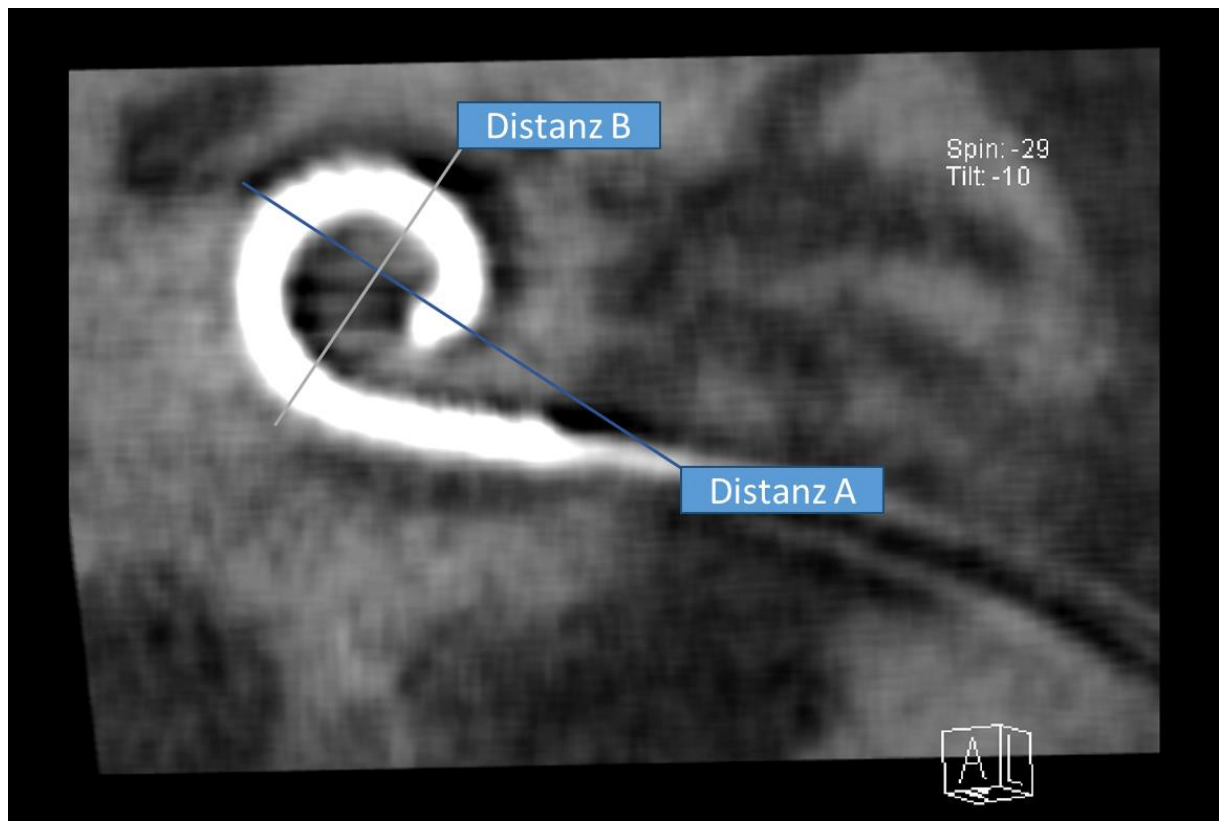


Abbildung 2: Darstellung der durch Escudé et al. (24) etablierten Messung der cochleären Basalwindung in Längs- (Distanz A - blau) und Querdurchmesser (Distanz B - grau) (Bildquelle: Klinik für Hals-Nasen-Ohrenheilkunde, Universitätsklinikum Freiburg, angelehnt an (24); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Unsere Arbeitsgruppe etablierte 2018 (27, 28) durch multiplanare Rekonstruktionen die Messung der cochleären Höhe in zwei Ebenen (Höhe: durchschnittlich 3.85 mm; Darstellung der cochleären Höhe: siehe Abbildung 3) und zeigte, dass bei zunehmender cochleärer Größe der Insertionswinkel des Elektrodenträgers signifikant abnimmt (Abbildung 4).

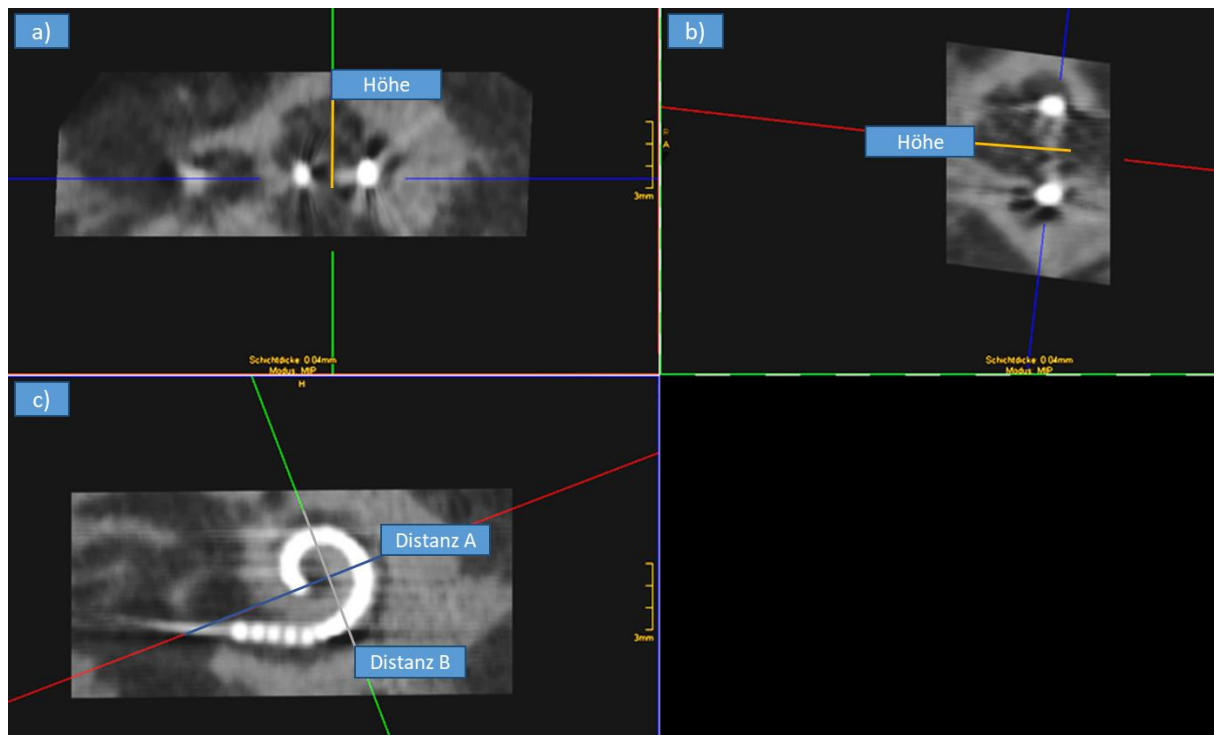


Abbildung 3: Vermessung der cochleären Höhe mittels multiplanarer Rekonstruktion von postoperativen Cone-beam CT. a) und b) multiplanare Rekonstruktion in zwei Ebenen und Darstellung der gemessenen cochleären Höhe. c) Querschnitt zu Vermessung von Distanz A und B nach (24) auf Höhe der cochleären Basalwindung (Bildquelle: Klinik für Hals-Nasen-Ohrenheilkunde, Universitätsklinikum Freiburg, nach (27); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Weiterhin zeigte die Arbeit, dass Scala tympani-Insertionen eher bei kleineren Cochleae im basalen Flächenprodukt dislozieren (Abbildung 5) und somit zu einem cochleären Trauma führen. Scala vestibuli-Insertionen traten häufiger bei kleineren Cochleae nach Cochleostomie auf, insbesondere bei niedriger Höhe (27).

Die cochleäre Höhe wurde somit als neuer präoperativer Faktor etabliert, um die cochleäre Größe zu erfassen und das Risiko einer Dislokation oder einer Scala vestibuli-Insertion präoperativ einzuschätzen (27). Ein hierbei wichtiger Punkt ist, dass diese Arbeit als eine der ersten nur einen einzigen Elektrodenträger (Cochlear™ Contour Advance® (CI512/CI24RECA) (=CA) untersuchte, um Verfälschungen durch mehrere Elektrodenträgerdesigns zu verhindern.

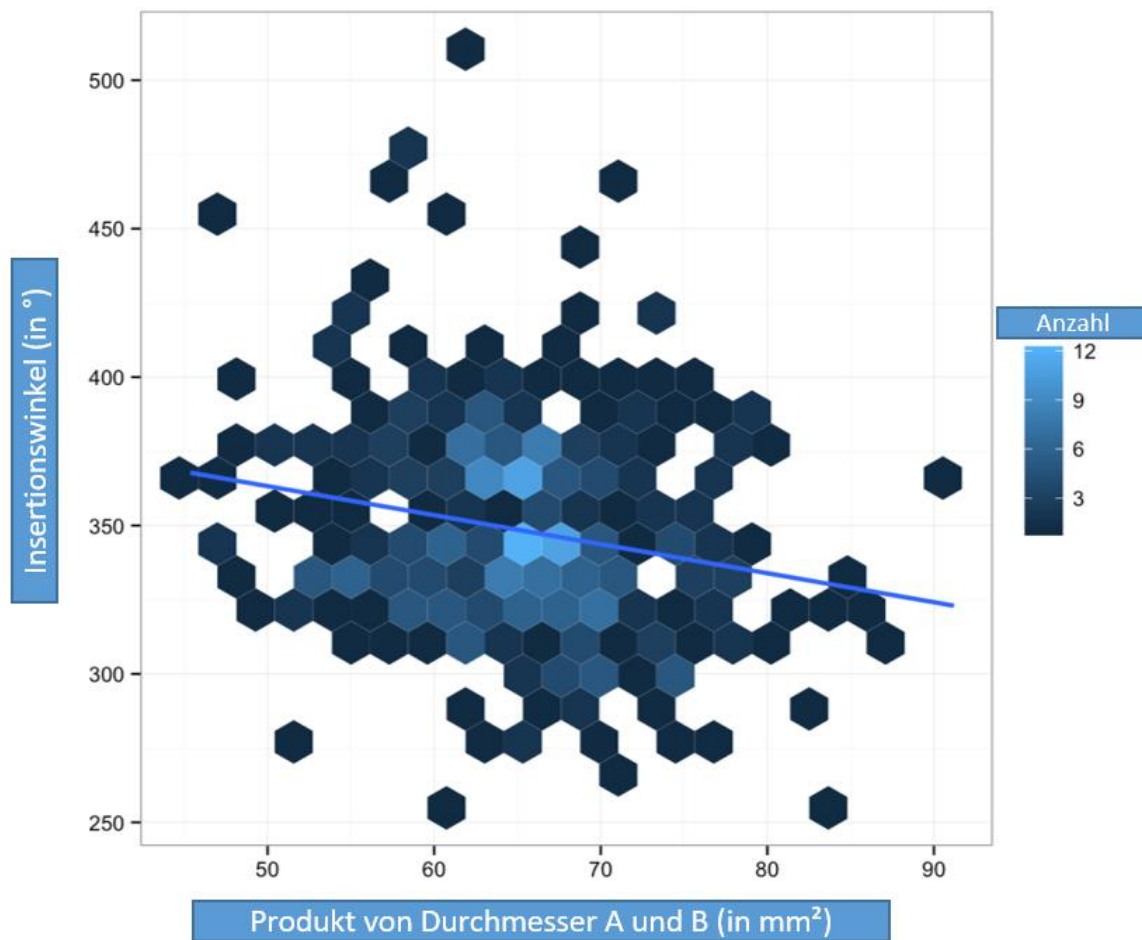


Abbildung 4: Mit zunehmendem cochleären basalen Flächenprodukt (Produkt aus Längs- und Querdurchmesser) nimmt der Insertionswinkel signifikant ab ($p < 0,0001$; $r^2 = -0,20188$) (nach (27); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Die zunehmend detaillierten Erkenntnisse über die cochleäre Anatomie und ihre Beschaffenheit führten zur Entwicklung unterschiedlicher Elektroden­träger­designs. Mittlerweile sind die vier Hersteller Cochlear™ (Cochlear Limited, NSW, Sydney, Australien), MED-EL (MED-EL, Innsbruck, Österreich), Advanced Bionics (Advanced Bionics, Valencia, Vereinigte Staaten von Amerika) und Oticon (Oticon A/S, GmbH, Smørum, Dänemark) mit unterschiedlichen Elektroden­träger­designs auf dem Markt verfügbar. Es können vom Grundprinzip Außenwandelektroden­träger und perimodioläre Elektroden­träger unterschieden werden. Die Außenwandelektroden­träger sind weniger rigide und somit eher flexibel im Vergleich zu den perimodiolären Elektroden­trägern.

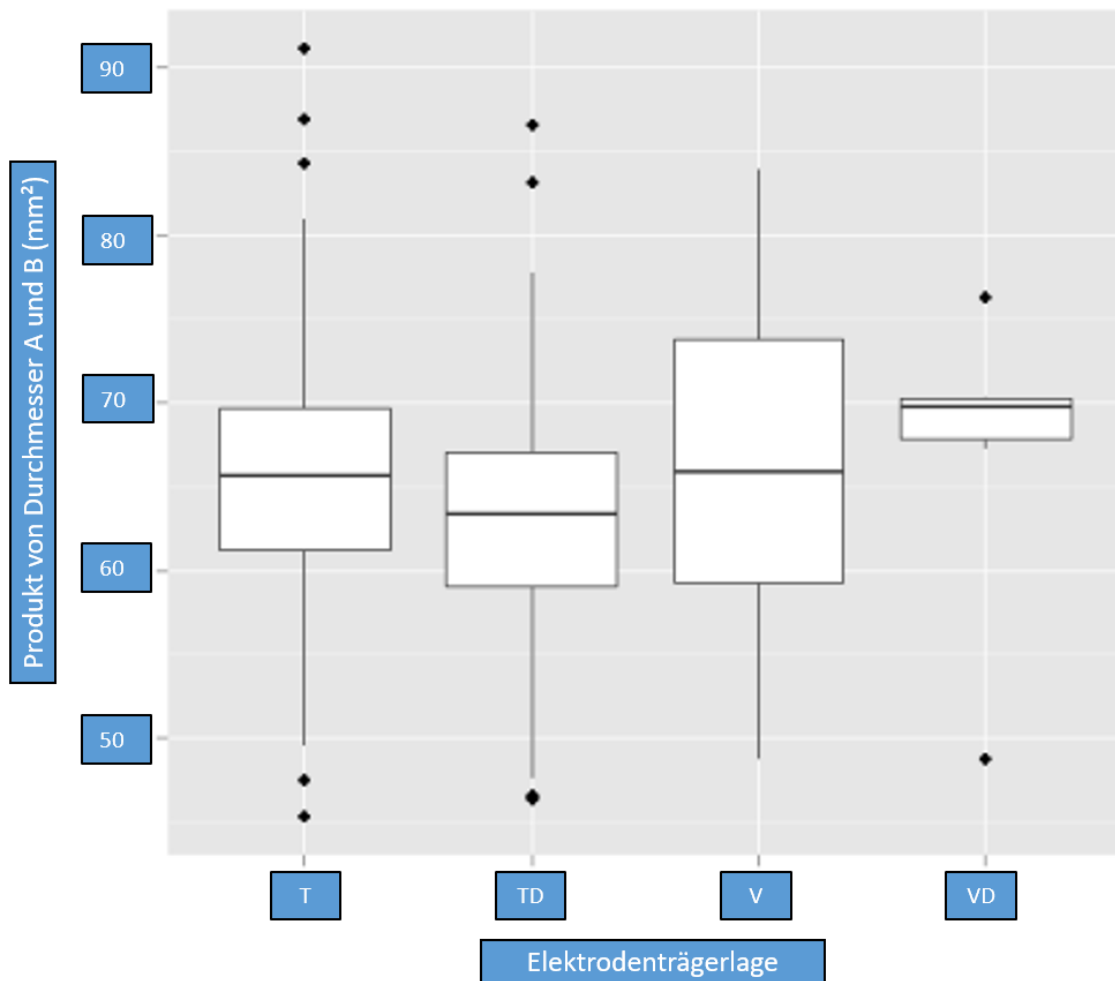


Abbildung 5: Boxplot-Darstellung: Bei kleinerem Flächenprodukt der Cochlea dislozierte der Elektroden­träger häufiger oder wurde in die Scala vestibuli inseriert (T = Scala tympani, TD = disloziert aus der Scala tympani, V = Scala vestibuli und VD = disloziert aus Scala vestibuli) (nach (27); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Außenwandelektroden­träger, welche unter anderem von der Firma MED-EL angeboten werden, sind in den Längen 20 bis 31,5 mm erhältlich. Einige Autoren vertreten den Standpunkt, dass diese aufgrund ihrer Flexibilität weniger traumatisch sind und daher zu weniger cochleärem Trauma durch Dislokationen führen (21, 29 - 31).

Demgegenüber stehen perimodioläre bzw. vorgeformte Elektroden­träger der Firma Cochlear™, welche näher zum Modiolus der Cochlea zu liegen kommen. Autoren vermuten hierdurch eine Reduktion der notwendigen Energie bei der Stimulation des Hörnervs aufgrund der Reduzierung der Überlappungsbereiche der einzelnen Elektrodenkontakte (32 - 35). Die Firma Cochlear™ konzentriert sich zwar hauptsächlich auf perimodioläre Elektroden­träger, hat aber auch einen Außenwandelektroden­träger, die Slim Straight® Elektrode (=SSA) (CI422/522/622), auf den Markt gebracht. Auch wenn der/die Patient*in sich selbst für den Hersteller entscheidet und hier neutral und sachlich beraten wird, ist die Wahl des Elektroden­trägers selbst zumeist Entscheidung des Operateurs. Dies stützt sich unter anderem auf die morphologischen Unterschiede der Cochlea und das Ziel des Restgehörerhalts, aber auch auf persönliche Erfahrung des Chirurgen. Aufgrund der zunehmenden Diversität der Elektroden­träger auf dem Markt gibt es unterschiedliche Hypothesen, welche Lage, Länge oder Flexibilität zu besserem Outcome führt.

Es ist also nicht das Ziel den einen Elektroden­träger für alle, sondern den einen passenden Elektroden­träger für den/die einen individuellen Patienten*in zu finden. Kritikpunkte an den bisher veröffentlichten Arbeiten zu dieser Fragestellung sind, dass Patientenkollektive überwiegend zu klein erhoben worden sind und die Statistiken aufgrund einer nur geringen Patientenzahl nicht Elektroden­träger-spezifisch ausgewertet werden konnten. Somit sind die Ergebnisse perimodiolärer Elektroden­träger und von Außenwandelektroden­trägern nicht separat ermittelt worden. Daher sind die bisherigen Veröffentlichungen in ihren Schlussfolgerungen uneins und fehleranfällig (13, 25, 36). Weiterhin haben die meisten Arbeiten nicht kritisch beachtet, dass perimodioläre Elektroden­träger wie der CA Elektroden­träger für eine Insertion mittels Cochleostomie entwickelt wurden (18, 19). Außenwandelektroden­träger wie die der Firma MED-EL werden jedoch, wenn möglich, bevorzugt über das runde Fenster inseriert. Der Zugangsweg zur Scala tympani ist somit in der Literatur noch umstritten (11, 37, 38) und sollte bei Auswertungen großer Kollektive genau ermittelt und verglichen werden.

2.3. Indikationsbereiche und Veränderung der Lebensqualität:

Objektiv erfassbare Einflussfaktoren auf das Sprachverstehen mit CI wie die cochleäre Morphologie standen lange Zeit im Fokus der CI-Forschung. Die Rehabilitationsergebnisse der Patient*innen zeigten jedoch, dass nicht nur das Sprachverstehen mit CI signifikant verbessert werden kann, sondern auch subjektive Bereiche wie die Lebensqualität. Insbesondere das subjektive, psychometrische Outcome ist von der Verfassung des/der Patienten*in vor CI-Versorgung abhängig, weshalb zunächst die verschiedenen Indikationsgruppen der CI-Versorgung erläutert werden.

Lange Zeit wurden nur beidseits hochgradig schwerhörige oder taube Patient*innen mittels einseitigem CI hörrehabilitiert. Laszig et al. (39) zeigten, dass bei beidseits stark hörgeschädigten Patient*innen durch binaurale, also beidseitige, elektrische Stimulation das Sprachverstehen signifikant verbessert wird. Sie legten damit den Grundstein der beidseitigen CI-Versorgung, welche durch zahlreiche Arbeiten fundiert wurde (40, 41). Weiterhin zeigte sich, dass beidseits taube Patient*innen mit nur einseitiger CI-Hörrehabilitation keine Möglichkeit der Lokalisierung im Alltag haben und psychosozial in sozialer Interaktion und Selbstvertrauen eingeschränkt sind (42, 43). Patient*innen mit einseitiger Taubheit dagegen hatten lange Zeit nur die Möglichkeit der Versorgung mit sogenannten knochenverankerten Hörsystemen wie die BAHA (bone anchored hearing aid), einer CROS-Versorgung (contralateral routing of signal), bei welcher mittels Hörgeräten der Empfänger am gesunden Ohr vom Sender am geschädigten Ohr gespeist wird oder eben gar keiner Therapie (44). Van de Heyning et al. (45) und Vermeire et al. (46) beschrieben erstmalig das Phänomen, dass einseitig taube Patient*innen auf dem tauben Ohr noch oft unter einer Tinnitusbelastung leiden, doch durch CI-Versorgung eine deutliche Reduktion dieser Belastung erfahren. Arndt et al. (44) zeigten daraufhin, dass Patient*innen mit einseitiger Taubheit durch eine CI-Versorgung ein binaurales Hören, ein besseres Sprachverstehen im Störlärm und eine bessere Lokalisierungsfähigkeit erreichen als durch die beiden oben genannten pseudobinauralen Hörsysteme. Weiterhin zeigten sie, dass die CI-Versorgung das Hörvermögen auf dem gesunden Ohr nicht beeinträchtigt (44).

Eine weitere Indikationsgruppe wurde als Gruppe mit asymmetrischem Hörverlust definiert. Boyd et al. (47) und Arndt et al. (48) grenzten diese Gruppe von den einseitig Tauben insofern ab, dass sie weniger als 60 dB bis 4 kHz und über 30 dB SPL (= Schalldruckpegel, engl. sound pressure level) in mindestens einer Frequenz bis 4 kHz auf dem besser hörenden Ohr wahrnehmen.

Somit ist diese Gruppe auf dem schlechter hörenden Ohr meist mit einem CI zu rehabilitieren, auf dem besser hörenden Ohr jedoch von einem Hörgerät abhängig.

Aufgrund der von van de Heyning et al. (45) und Vermeire et al. (46) gezeigten signifikanten Reduktion der Tinnitusbelastung durch CI geriet die Tinnitusforschung und das Erfassen der gesundheitsspezifischen Lebensqualität in den Fokus der CI-Forschung. Olze et al. (49 - 51) etablierten eine psychometrische Testbatterie („Berlin test battery“ siehe (52) bzw. „Charité test battery“ siehe (53); synonyme Begriffe) um zunächst beidseits ertaubte und einseitig CI versorgte Patient*innen auf Lebensqualität, Tinnitusbelastung, Ängstlichkeit und Depressivität zu untersuchen (54). Die einzelnen Fragebögen und Messungen dieser Testbatterie sollen im Folgenden erläutert werden, da sie Grundlage für die kumulativen Arbeiten dieser Habilitationsschrift sind.

Die Testbatterie umfasst die üblichen audiometrischen Testungen durch den Freiburger Einsilbertest bei 65 dB SPL und den Oldenburger Satztest jeweils getrennt für das implantierte und das kontralaterale Ohr vor CI und jeweils 6, 12 und 24 Monate nach CI erfasst (49 - 54). Zum anderen wird durch den in seiner deutschen Form validierten Oldenburger Inventar Fragebogen (= OI) (55) subjektiver Höreindruck und subjektives Sprachverstehen erfasst. Dieser Fragebogen beinhaltet in seiner gekürzten Form drei Unterthemen: das Hören in Ruhe, Hören mit Hintergrundgeräusch und Lokalisierung (56). Je höher der erreichte Punktwert, desto besser das subjektive Hörvermögen des/der Patienten*in (54, 55).

Ein weiterer Teil der Testbatterie ist die Erfassung der gesundheitsspezifischen Lebensqualität. Hierfür wurde 2000 durch Hinderink et al. der „Nijmegen Cochlear Implantation Questionnaire“ (= NCIQ) etabliert (57), welcher validiert auch in deutscher Sprache vorliegt. Eine weitere Möglichkeit die individuelle, nicht- krankheitsspezifische Lebensqualität zu erfassen ist der validierte „Medical Outcome Study Short-form 36 questionnaire“ kurz SF36 (58), welcher ebenfalls validiert auf Deutsch vorliegt (59).

Hörverlust und Tinnitusbelastung sind oft miteinander korrelierend und Tinnitusbelastung betrifft zwischen 67 und 100 % der CI versorgten Patient*innen (60, 61). Der Tinnitus Fragebogen, oder Tinnitus Questionnaire (= TQ) von Göbel und Hiller wird auch wissenschaftlich (54, 62) zur Einschätzung der Tinnitusbelastung verwendet und ist ebenfalls Teil der Testbatterie. Gegliedert in verschiedene Subskalen, kann der Gesamtscore von 0 bis 84 Punkten reichen. Ein dekompensierter Tinnitus ist mit 47 oder mehr Punkten definiert (62 - 64).

Einige bisherig veröffentlichte Arbeiten wiesen darauf hin, dass Hörverlust zu sozialer Isolation, Einsamkeit, Depressivität und Ängstlichkeit führen kann (65 - 68). Um einen Überblick auf das Stresslevel der Patient*innen zu erhalten, stellten Levenstein et al. (69) den „Perceived Stress Questionnaire“ (= PSQ) vor, welcher das subjektive Stresslevel widerspiegeln sollte (70). Weiterhin in der Testbatterie eingesetzt ist das COPE Inventory, um individuelle Coping Mechanismen zu prüfen (54, 71). Der GAD-7 Fragebogen (General Anxiety Disorder-7 Questionnaire) zielt auf eine Einschätzung der Ängstlichkeit der Patient*innen ab (72, 73) und zur Einschätzung der Depressivität wird die „General Depression Scale“ (ADS-L) von Mohiyeddini et al. (74) etabliert eingesetzt.

Die meisten Publikationen zum psychometrischen Outcome fokussierten sich auf beidseits hörgeschädigte und einseitig CI-versorgte Patient*innen (49 - 51, 54, 67). Kleinere Kohortenarbeiten wie die von Rösli et al. (75) konnten an 20 einseitig ertaubten CI Patient*innen zwar zeigen, dass die Lebensqualität evaluiert mit dem NCIQ ebenfalls signifikant gesteigert wird. Louza et al. (76) konnten am Gesamtscore des NCIQ bei zehn eingeschlossenen einseitig Tauben dies jedoch nicht bestätigen. In der 2019 veröffentlichten, prospektiven Arbeit (77) zeigten wir erstmalig, dass auch im Follow-up von 24 Monaten nach CI-Versorgung die Lebensqualität bei 61 beidseits postlingual ertaubten und einseitig CI versorgten Patient*innen signifikant erhöht wird und stabil bleibt. Die Lebensqualität wurde mit dem validierten und CI spezifischen Fragebogen NCIQ erhoben. Weiterhin wurde die subjektive Sprachdiskrimination und subjektive Sprachqualität mit dem OI erhoben. Es zeigte sich eine Korrelation zum einen zwischen dem subjektiven Hören (OI) und den erhobenen audiologischen Ergebnissen. Zum anderen zeigte sich eine positive Korrelation der Lebensqualität (NCIQ) und dem postoperativen Sprachverstehen.

Es zeigte sich in dieser Arbeit, dass erfreulicherweise sowohl Sprachverstehen, subjektives Hören, als auch die Lebensqualität durch CI-Versorgung innerhalb der ersten 6 Monate signifikant verbessert wurden. Weiterhin zeigte sich, dass alle drei Skalen für mindestens 2 Jahre nach CI-Versorgung stabil bleiben. Angesichts der Tatsache, dass die engmaschige Hörrehabilitation mit Training und Angliederung an Rehabilitationszentren nach 12 Monaten für gewöhnlich endet, ist dies sehr erfreulich. Es ist folglich eine intensive Anbindung und ein intensives Training während der ersten Monate zu empfehlen, um Sprachverstehen und Lebensqualität zu maximieren und soziale Isolation durch eingeschränktes subjektives Hören zu reduzieren (77).

Besonders mit zunehmendem Alter nimmt auch die Anzahl der Schwerhörigen zu und bei unzureichender Hörgeräteversorgung droht soziale Isolation, sowie Depressivität und Einsamkeit (65, 68, 78). 12 Monate nach CI-Versorgung zeigte sich bei Patient*innen über 70 Jahren sowohl eine negative Korrelation von Ängstlichkeit als auch von depressiver Symptomatik mit CI-spezifischer Lebensqualität (52). Knopke et al. (52) zeigten, dass auch die über 80-Jährigen hinsichtlich der Lebensqualitätssteigerung erheblich von einem CI profitieren.

Dennoch standen größere, prospektive Studien zur psychometrischen Forschung um Lebensqualität und Tinnitusbelastung, die die einzelnen Indikationsgruppen, insbesondere Patient*innen mit asymmetrischem Hören, getrennt voneinander betrachten, noch aus.

3. Zielsetzung:

Die cochleäre Morphologie und anatomische Beschaffenheit der Cochlea scheint erheblichen Einfluss auf die Lage des Elektrodenträgers zu nehmen und liefert präoperativ wichtige Informationen um ein Trauma der Cochlea bei Insertion durch Dislokation des Elektrodenträgers zu vermeiden. Eine Insertion in die Scala tympani ist zu favorisieren, da diese zum bestmöglichen Sprachverstehen postoperativ führt. Ziel der hier dargestellten morphologischen Arbeiten war es, erstmalig am bisher größten untersuchten Patientenkollektiv Elektrodenträger-spezifisch den Einfluss von cochleärer Anatomie auf die Lage des Elektrodenträgers zu untersuchen und die Dislokationseigenschaften der auf dem Markt gebräuchlichsten Elektrodenträger zu vergleichen.

Hierbei sollte erstmalig das Design und die Beschaffenheit eines jeden Elektrodenträgers individuell berücksichtigt werden, um einen Bias zu vermeiden. Es war Ziel zu untersuchen, ob Dislokation des Elektrodenträgers und anguläre Insertionstiefe auf das postoperative Sprachverstehen Einfluss nehmen. Signifikante Unterschiede unter den Außenwand- und den perimodiolären Elektrodenträgern sollten ausgearbeitet und dargestellt werden. Weiterhin sollte der Einfluss des Zugangsweges, sprich Rundfensterinsertion versus Cochleostomie, auf das Outcome untersucht werden.

Ketterer MC, Aschendorff A, Arndt S, Beck R. Electrode array design determines scalar position, dislocation rate and angle and postoperative speech perception. Eur Arch Otorhinolaryngol. 2021 Nov 15. doi: 10.1007/s00405-021-07160-2. Epub ahead of print.

Im Folgenden wurde ein neu auf dem Markt erhältlicher Außenwandlektrodenträger, der Flex²⁶ Elektrodenträger der Firma MED-EL, mit seinen Vorgängern verglichen und erstmalig morphologisch untersucht. Hierbei wurde zum ersten Mal der Ort der Dislokation von Außenwandlektrodenträgern erfasst und miteinander verglichen.

Ketterer MC, Aschendorff A, Arndt S, Speck I, Rauch AK, Beck R, Hassepas F. Radiological evaluation of a new straight electrode array compared to its precursors. Eur Arch Otorhinolaryngol. 2021 Oct;278(10):3707-3714.

Weiterhin soll auf die CI-Versorgung bei cochleärer Fehlbildung eingegangen werden. So wurde die Insertion des Elektrodenträgers und das Outcome bei der incomplete partition type III (IP III) untersucht.

Alballaa A, Aschendorff A, Arndt S, Hildenbrand T, Becker C, Hassepas F, Laszig R, Beck R, Speck I, Wesarg T, **Ketterer MC**. „Incomplete partition type III“ – Langzeitergebnisse nach Cochleaimplantation [Incomplete partition type III revisited-long-term results following cochlear implant. German version]. HNO. 2019 Oct;67(10):760-768.

Lange Zeit konzentrierte man sich nur auf die Verbesserung im Sprachverstehen. Doch nach und nach wurden weitere signifikante Verbesserungen durch das CI ausgearbeitet. Die CI-Forschung fokussierte neben dem biophysiologischen Aspekt der Anatomie zunehmend auch biopsychosoziale Aspekte des Teilhabemodells. Diese Fragestellung sollte in der Indikationsgruppe der Patient*innen mit asymmetrischem Hörverlust und der beidseits ertaubten und beidseits CI versorgten Patient*innen untersucht werden.

Ein weiteres Ziel dieser Arbeit war es somit indikationsspezifisch nicht nur die Verbesserung im Sprachverstehen, sondern auch Unterschiede im psychometrischen Outcome wie der Lebensqualität, der Tinnitusbelastung, Ängstlichkeit und Depressivität zu untersuchen.

Ketterer MC, Knopke S, Häußler SM, Hildenbrand T, Becker C, Gräbel S, Olze H. (2018b). Asymmetric hearing loss and the benefit of cochlear implantation regarding speech perception, tinnitus burden and psychological comorbidities: a prospective follow-up study. Eur Arch Otorhinolaryngol. 2018 Nov;275(11):2683-2693.

Ketterer MC, Häussler SM, Hildenbrand T, Speck I, Peus D, Rosner B, Knopke S, Graebel S, Olze H. (2020b). Binaural Hearing Rehabilitation Improves Speech Perception, Quality of Life, Tinnitus Distress, and Psychological Comorbidities. Otol Neurotol. 2020 Jun;41(5):e563-e574.

Des Weiteren soll diese Arbeit eine Aussicht auf zukünftige Forschung geben, welche untersuchen soll, ob traumatische Insertion und die Dislokation des Elektrodenträgers zu vermehrter Tinnitusbelastung und zu postoperativem Schwindel führen könnten.

4. Darstellung der eigenen Veröffentlichungen:

4.1. Elektroden­trägerdesign und Einfluss auf postoperatives Sprachverstehen:

Ketterer MC, Aschendorff A, Arndt S, Beck R. Electrode array design determines scalar position, dislocation rate and angle and postoperative speech perception. Eur Arch Otorhinolaryngol. 2021 Nov 15. doi: 10.1007/s00405-021-07160-2. Epub ahead of print.

Die individuelle Wahl des Elektroden­trägers passend zu präoperativ erfasster cochleärer Morphologie ist zunehmend im Fokus der CI-Forschung. Wie in der Einleitung dieser Arbeit beschrieben, wurden verschiedene Arten der cochleären Größenvermessung publiziert und vorgeschlagen. Durch zunehmend bessere Qualität der postoperativen Schnittbildgebung mittels Cone-beam CT oder digitaler Volumentomographie (= DVT) ist heute eine zuverlässige Bestimmung der skalären Lage des Elektroden­trägers möglich. Ziel der Arbeit (79, 80) war es, die am häufigsten implantierten Elektroden­träger hinsichtlich ihrer skalären Lage und ihres Dislokationsverhaltens zu untersuchen. Hierfür wurden Außenwand- und perimodioläre Elektroden­träger hinsichtlich ihrer intracochleären Lage in der postoperativen Schnittbildgebung verglichen. Weiterhin wurde erstmalig an einer so großen Kohorte die Position der Dislokation perimodiolärer und Außenwandelektroden­träger innerhalb der Cochlea bestimmt und nachgewiesen, dass diese vom Elektroden­trägerdesign abhängig ist. Hierzu wurden 495 Patient*innen, die zwischen 2013 und 2017 entweder mit einem Elektroden­träger von Cochlear™ (Contour Advance® (=CA) (CI512/CI24RECA), Cochlear™ Slim Straight® (=SSA) (CI422/522/622) oder Cochlear™ Slim Modiolar® (=SMA) (CI532/CI632) (Cochlear Limited, NSW, Australien)) oder einem Elektroden­träger der Firma MED-EL (MED-EL Flex²⁴, MED-EL Flex²⁸ oder MED-EL Flex^{Soft}) implantiert wurden, in diese Arbeit eingeschlossen. Anhand der durchgeführten Cone-beam CT (DynaCT-equipped Axiom Artis dTA angiography unit; Siemens Co., Erlangen, Germany), beschrieben von (9, 11), wurden die cochleäre Größe, die skaläre Lage des Elektroden­trägers, der Insertionswinkel und die Position der Dislokation durch dreidimensionale Rekonstruktion bestimmt. Tabelle 1 gibt eine Übersicht über die bisher größte internationale Studienkohorte, die diese Fragestellung untersuchte.

Hersteller (n)	Cochlear™: 327	
	MED-EL: 168	
Elektrodenträger (n)	Contour Advance (Cochlear™) (=CA):	143
	CI 422/522/622 (Cochlear™) (=SSA):	162
	CI 532/632 (Cochlear™) (=SMA):	22
	Flex ²⁴ (MED-EL):	24
	Flex ²⁸ (MED-EL):	129
	Flex ^{Soft} (MED-EL):	15
Seite (n)	Links: 259	
	Rechts: 236	
Alter	52,7 Jahre (Min: 18,0; Max: 86,2)	

Tabelle 1: Verteilung der Studienkohorte nach untersuchten Herstellern, Elektrodenträgern und Alter der Patient*innen (im Mittel, Minimum und Maximum) (nach (79, 80); erstellt und modifiziert durch M.C. Ketterer; 17.12.2021).

Abbildung 6 zeigt, dass die untersuchten Elektrodenträger unterschiedliche Dislokationsverhalten aufwiesen und der Flex^{Soft} Elektrodenträger am häufigsten dislozierte, während der CA Elektrodenträger die häufigsten Scala vestibuli-Insertionen aufwies, was sicherlich seiner häufigen Insertion via Cochleostomie geschuldet ist.

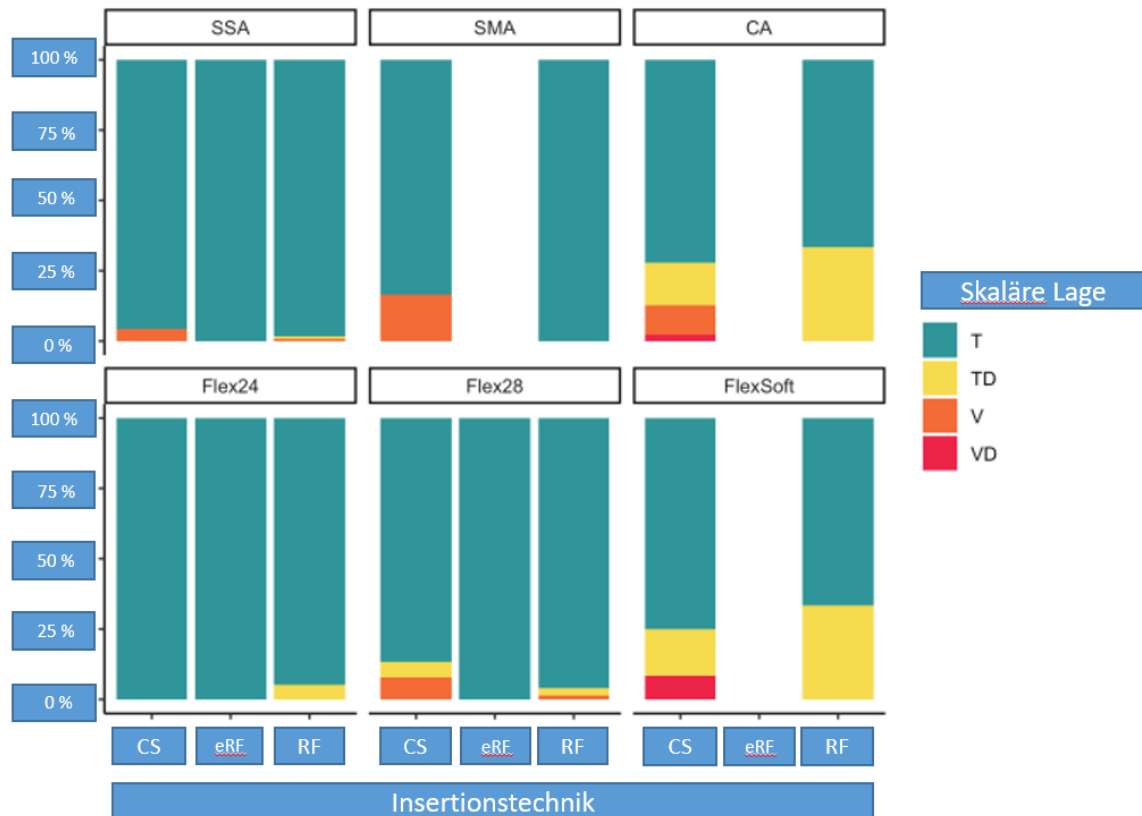


Abbildung 6: Anzahl der skalären Insertionslagen und Dislokationen Elektroden-Träger-spezifisch und in Abhängigkeit von der Insertionstechnik (CS = Cochleostomie; RF = Rundfensterinsertion; eRF = erweiterte Rundfensterinsertion) ausgewertet.

Legende: skaläre Lage: T = Scala tympani Insertion ohne Dislokation; TD = Dislokation aus der Scala tympani; V = Scala vestibuli Insertion ohne Dislokation; VD = Dislokation aus der Scala vestibuli (nach (79); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Weiterhin sollte diese Arbeit untersuchen, ob der Ort der Dislokation innerhalb der Cochlea spezifisch ist, von der cochleären Anatomie abhängig ist oder beispielsweise unspezifisch verteilt auftritt. Diesbezüglich verglich diese Arbeit (79) erstmalig den Ort der Dislokation von perimodiolären und Außenwandelektroden-Trägern. Es zeigt sich, dass der Ort der Dislokation Elektroden-Träger-spezifisch und somit vom Design und nicht der cochleären Anatomie abhängig ist. Perimodioläre Elektroden-Träger dislozierten zwischen 170 und 180°, während Außenwandelektroden-Träger erst bei 360 bis 390° dislozierten (siehe Abbildung 7).

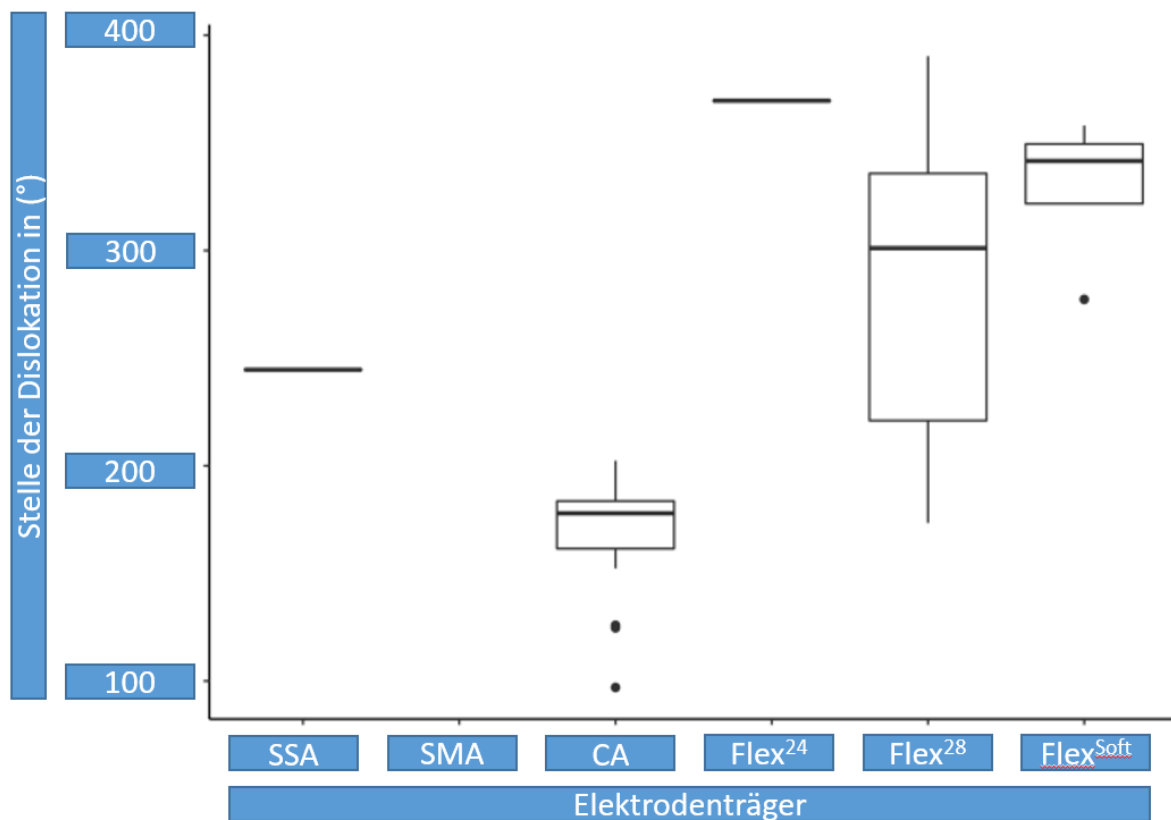


Abbildung 7: Der Ort der Dislokation ist Elektroden-träger-spezifisch und liegt bei der CA bei circa 180°; bei den Außenwandelektroden-trägern von MED-EL zwischen 360 und 390° (nach (79), erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Wie Abbildung 8 zeigt, erreichten die perimodiolären Elektroden-träger (SMA und CA) von Cochlear™ deutlich weniger Insertionswinkel als die langen Außenwandelektroden-träger (Flex²⁸ und Flex^{Soft}) der Firma MED-EL. Eine multivariate nonparametrische Analyse zeigte jedoch (siehe Abbildung 9), dass das postoperative Sprachverstehen mit zunehmendem Insertionswinkel negativ beeinflusst wird ($p < 0,0001$), die Dislokation des Elektroden-trägers jedoch keine signifikante Rolle zu spielen scheint.

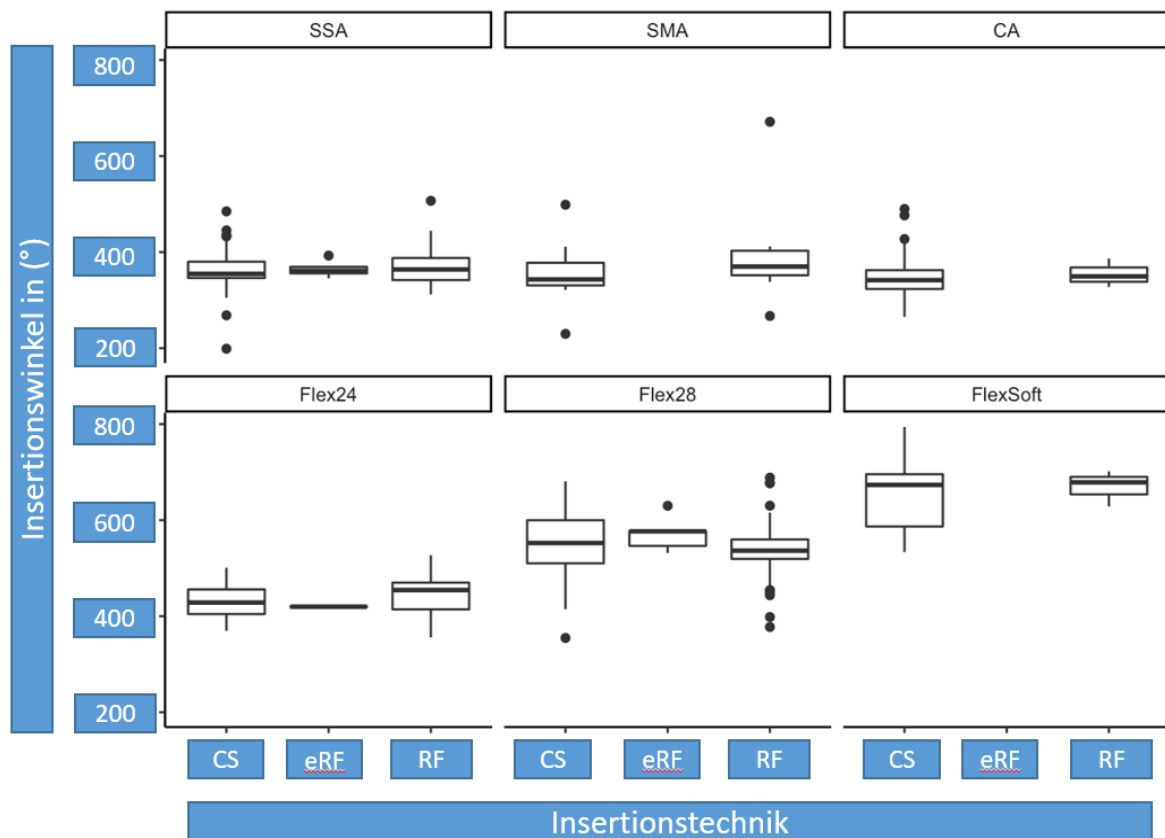


Abbildung 8: Der Insertionswinkel (in °) hängt signifikant vom Elektroden­trägerdesign ab und korreliert wie zu erwarten zu dessen Länge. Die Insertionstechnik (Erläuterungen siehe Abbildung 6) zeigte hierbei keinen signifikanten Einfluss (nach (79); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

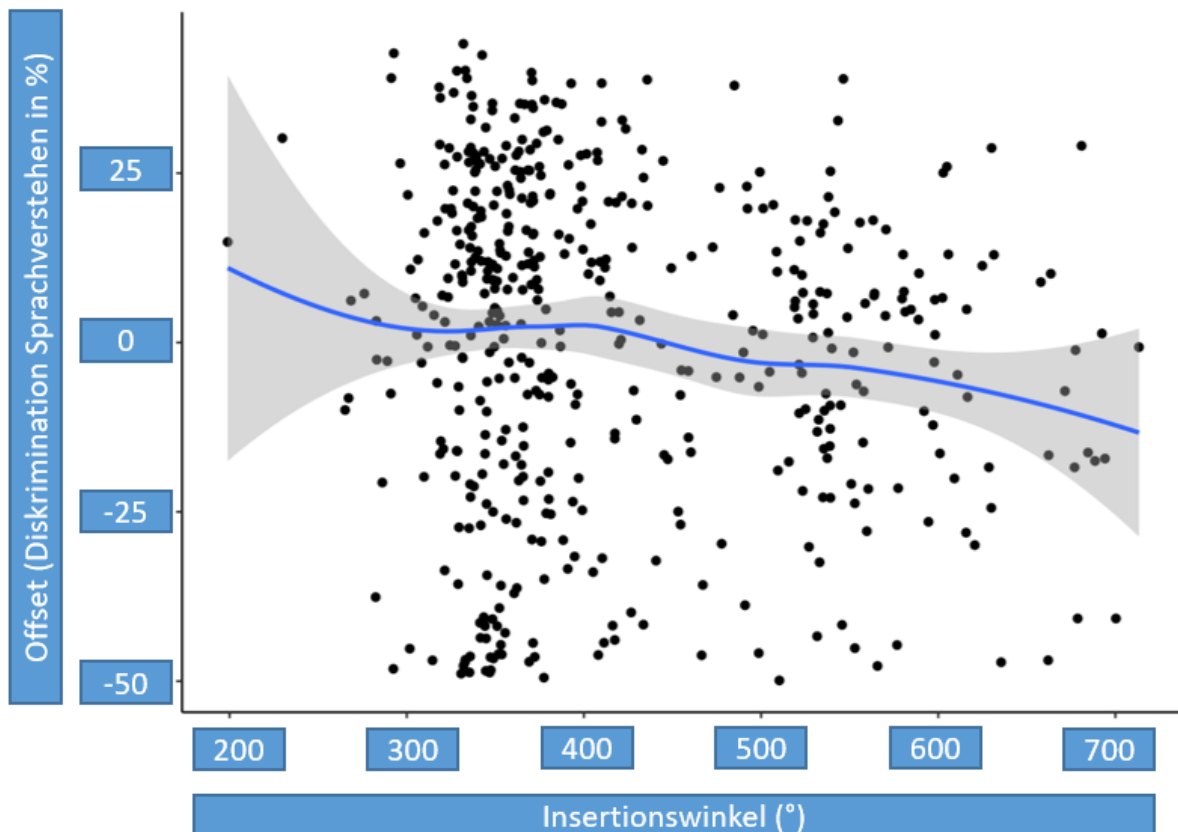


Abbildung 9: Mit zunehmendem Insertionswinkel (in ° - x-Achse) zeigten die Patient*innen signifikant abnehmende Sprachverstehens- Ergebnisse (in % - y-Achse) (nach (79); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Ketterer MC, Aschendorff A, Arndt S, Speck I, Rauch AK, Beck R, Hassepas F. Radiological evaluation of a new straight electrode array compared to its precursors. Eur Arch Otorhinolaryngol. 2021 Oct;278(10):3707-3714.

Atraumatische Insertion und die Position des Elektrodenträgers innerhalb der Cochlea sind zunehmend in den Fokus der einzelnen Hersteller gerückt. Da dies nicht nur von den Fähigkeiten des Chirurgen, sondern auch von der cochleären Anatomie und Größe und dem Design des Elektrodenträgers abhängt (13, 81), erweitern besonders die Firmen MED-EL und Cochlear™ ihr Portfolio der Elektrodenträger. Ketterer et al. (82) war die erste morphologische Arbeit zur Evaluation des Außenwandelektrodenträgers Flex²⁶ der Firma MED-EL mit 26mm Insertionslänge.

Bis dato waren keine anderen morphologischen Arbeiten weder in vivo noch an Felsenbeinpräparaten veröffentlicht worden. Es wurden 15 Patient*innen, die mit dem neuen Flex²⁶ Elektrodenträger inseriert wurden, in diese Studie eingeschlossen. MED-EL produziert Außenwandeletrodenträger unterschiedlicher Länge von 20 bis zu 31,5 mm. Insgesamt wurden 201 Ohren, welche zwischen 2013 und 2019 implantiert wurden, miteinander verglichen (Tabelle 2). Ziel der Arbeit war den neuen Flex²⁶ Elektrodenträger mit seinen Vorgängern (Flex²⁴, Flex²⁸ und dem Flex^{Soft} Elektrodenträger; MED-EL) bezüglich Elektrodenträgerlage, Dislokationshäufigkeit und Scala vestibuli-Insertionshäufigkeit zu vergleichen. Während der Flex^{Soft} Elektrodenträger wie auch in Ketterer et al. (79) die häufigsten Dislokationen aufwies, zeigte der neue Flex²⁶ Elektrodenträger keinerlei Dislokationen und auch einen geringeren Insertionswinkel.

	T	TD	V	VD	Anzahl (gesamt)
Flex ²⁴	27 (96,43%)	1 (3,57%)	0	0	28 (100%)
Flex ²⁶	15 (100%)	0	0	0	15 (100%)
Flex ²⁸	125 (89,93%)	6 (4,32%)	8 (5,75%)	0	139 (100%)
Flex ^{Soft}	13 (68,42%)	5 (26,32%)	0	1 (5,26%)	19 (100%)

Tabelle 2: Verteilung und Dislokationshäufigkeit der untersuchten Außenwandeletrodenträger (jeweils dargestellt Anzahl und in Klammern der prozentuale Anteil) (T = Scala tympani Insertion ohne Dislokation; TD = Dislokation aus der Scala tympani; V = Scala vestibuli Insertion ohne Dislokation; VD = Dislokation aus der Scala vestibuli) (nach (82); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Um morphologisch überhaupt vergleichbare Gruppen zu erhalten und hier keinen Bias durch die cochleäre Größe im Elektrodenträgervergleich zu haben, wurden Gruppen von vergleichbarer cochleärer Größe gebildet (Abbildung 10). Dies erfolgte, wie in der Einführung dargestellt, durch die von Escudé et al. (24) und Ketterer et al. (27) etablieren Messverfahren.

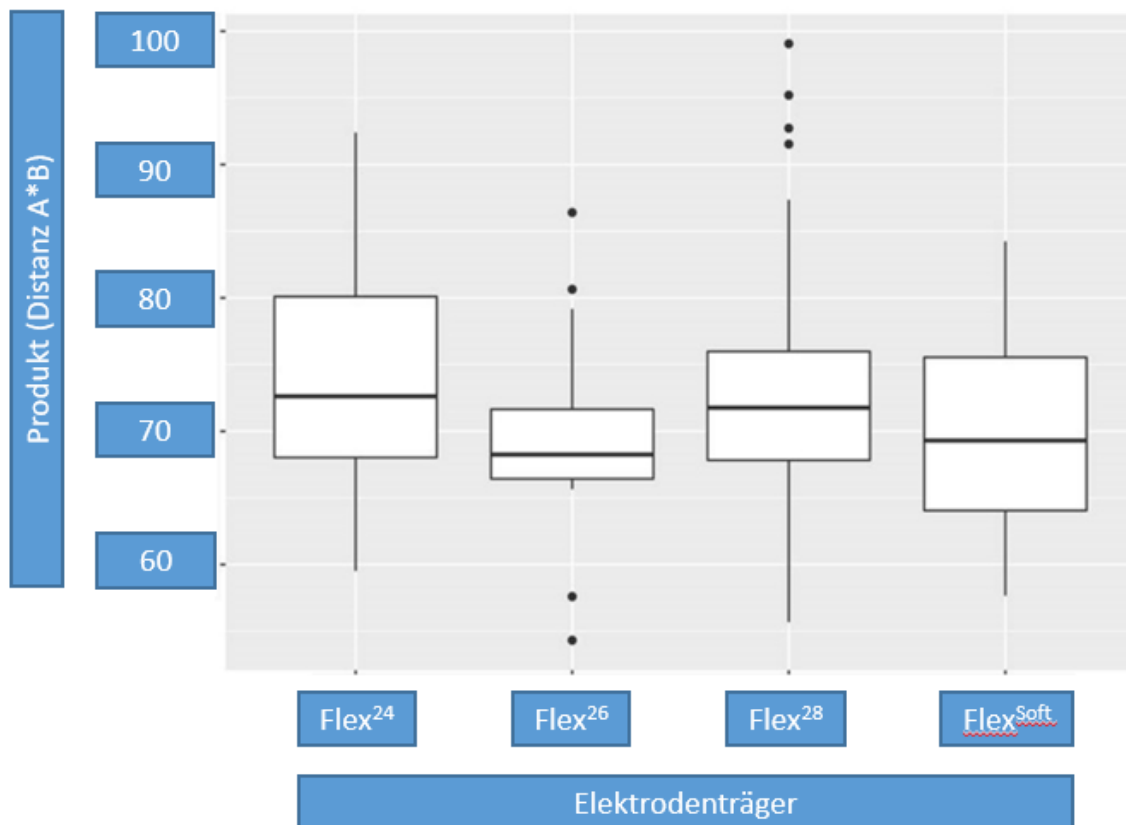


Abbildung 10: Die untersuchten Elektrodenträger wurden in Gruppen vergleichbarer cochleärer Größe (Produkt A * B) untersucht (nach (82); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Die bisherig dargestellten Arbeiten (27, 79, 82) bezogen sich auf sogenannte normcochleäre Patient*innen. Es wurden also vor Studieneinschluss präoperative Einschätzungen des CTs vorgenommen und malformierte Cochleae ausgeschlossen. Die folgende Arbeit dagegen beschäftigte sich mit einer besonderen Malformation der Cochlea: der IP III.

Alballaa A, Aschendorff A, Arndt S, Hildenbrand T, Becker C, Hassepas F, Laszig R, Beck R, Speck I, Wesarg T, **Ketterer MC**. „Incomplete partition type III“ – Langzeitergebnisse nach Cochleaimplantation [Incomplete partition type III revisited-long-term results following cochlear implant. German version]. HNO. 2019 Oct;67(10):760-768.

Die IP III ist radiologisch durch zum einen eine kürzere Ausbildung der Cochlea, zum anderen durch die nicht ausgebildete knöcherne Begrenzung zwischen der cochleären Basalwindung und dem inneren Gehörgang definiert (83, 84), was zu einem andauernden, erhöhten perilymphatischen Druck (84) führt und circa einen von 50.000 neugeborenen Knaben betrifft (85). Es wird X-chromosomal vererbt, sodass Frauen meist nur weitertragende Erbträger sind (86, 87) sind. Viele männliche Erbträger dagegen zeigen einen progredienten und beide Ohren betreffenden kombinierten Hörverlust bis hin zur Indikation zur CI-Versorgung (88, 89).

Die CI-Versorgung ist bei diesen Patient*innen chirurgisch äußerst anspruchsvoll (85, 89, 90). Die Verletzung der Cochlea durch Cochleostomie oder Eröffnen des runden Fensters führt nämlich aufgrund des erhöhten perilymphatischen Drucks zu einem massiven Gusher (87, 89). Dies entspricht einem starken Austritt von zunächst Perilymphe und dann aufgrund der Ruptur der Membran zwischen cochleärer Basalwindung und innerem Gehörgang einem Liquoraustritt mit der Folge der Ertaubung (91) und erhöhtem Risiko einer Meningitisentwicklung (84, 92).

Weiterhin kann das syndromal bedingte Fehlen der knöchernen Begrenzung wie in Abbildung 11 a) dargestellt dazu führen, dass der Elektrodenträger bei CI-Operation versehentlich in den inneren Gehörgang inseriert wird, was das Risiko der Verletzung von Nervus facialis oder Fazialisstimulation birgt (83, 91) (siehe Abbildung 11c).

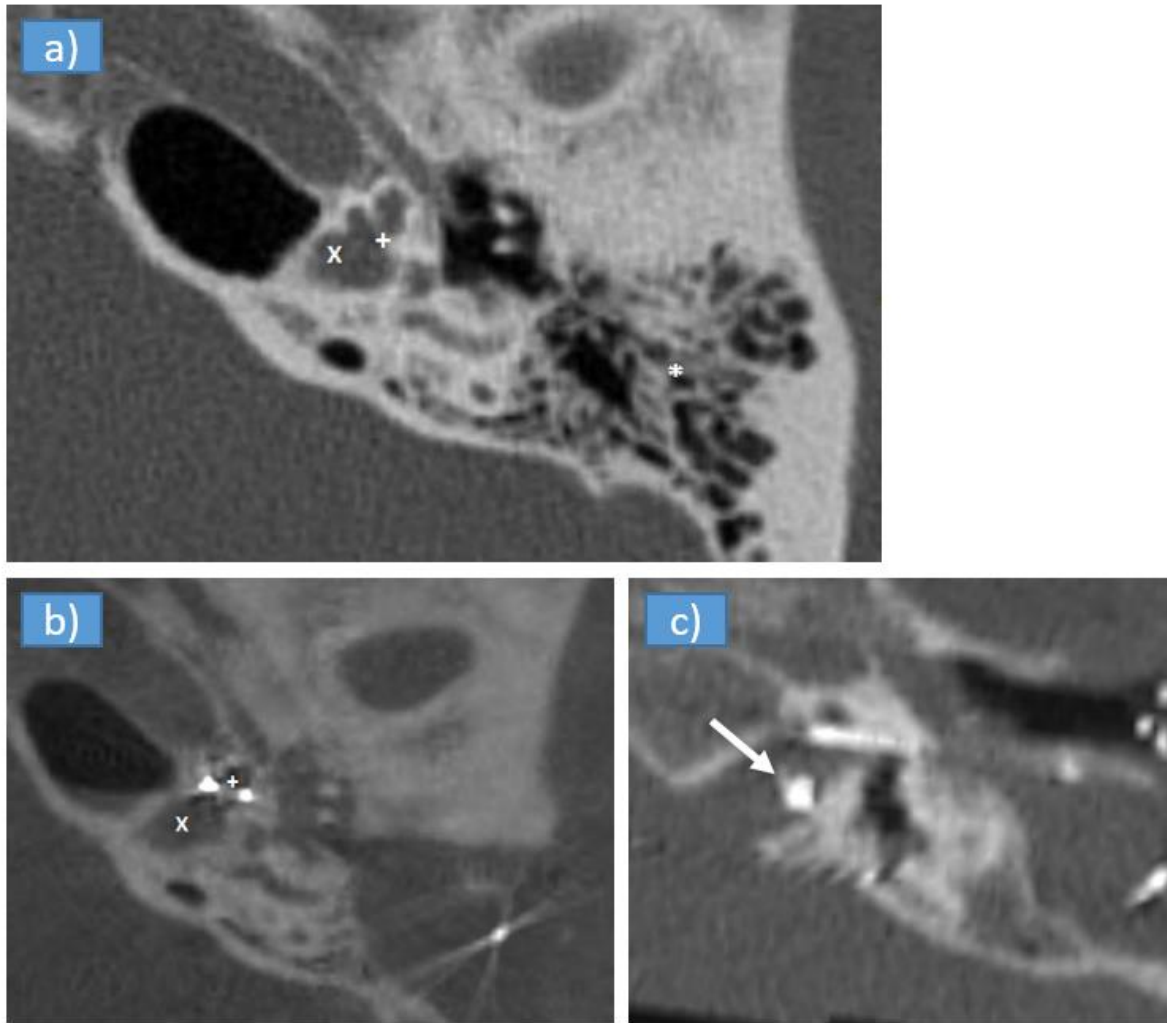


Abbildung 11: a) präoperative CT, die die fehlende knöcherne Begrenzung zwischen cochleärer Basalwindung und dem inneren Gehörgang (X) zeigt. (+ = cochleäre Basalwindung; * = Mastoid). b) postoperative Cone-beam CT, die den Elektrodenträger korrekt in der cochleären Basalwindung zeigt (+). c) postoperative Cone-beam CT, welche den inserierten Elektrodenträger fehlerhaft inseriert im inneren Gehörgang statt in der Cochlea zeigt (Pfeil). (nach (93); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Aufgrund der Seltenheit des Syndroms und der umstrittenen Möglichkeit der CI-Versorgung sind bisher nur wenige Fallberichte oder Fallserien veröffentlicht worden (84, 85, 91, 92, 94, 95).

Die hier dargestellte Arbeit (93) ist die erste Langzeitstudie, welche das audiologische Langzeitoutcome dieser Patient*innen darstellt. Es wurden Anpassungsdaten, Stapediusreflexe, Impedanzen und ECAP-Schwellen erhoben und mit je drei normcochleären Patient*innen hinsichtlich Geschlecht, Alter, Seite, Typ des Elektrodenträgers und OP-Datum gematched. Das Sprachverstehen wurde mittels Freiburger Einsilbertest bei Erwachsenen und bei Kindern mit dem Göttinger Sprachtest ermittelt (93).

Weiterhin war dies die erste Arbeit, die die individuelle CI-Anpassung (T- und C-Level und benötigten Pulsbreite) dieser Patient*innen untersuchte und zeigte, dass die neun mit einem perimodiolären Elektrodenträger implantierten Patient*innen keinen signifikanten Unterschied im postoperativen Sprachverstehen aufwiesen.

Dennoch zeigten die IP III Patient*innen auffällige Anstiege in Anpassungsdaten wie der Pulsbreite (Abbildung 12) und den basalen Impedanzen, was für eine basocochleäre Fibrosierung sprechen könnte. Das Sprachverstehen blieb dennoch im Langzeitvergleich stabil.

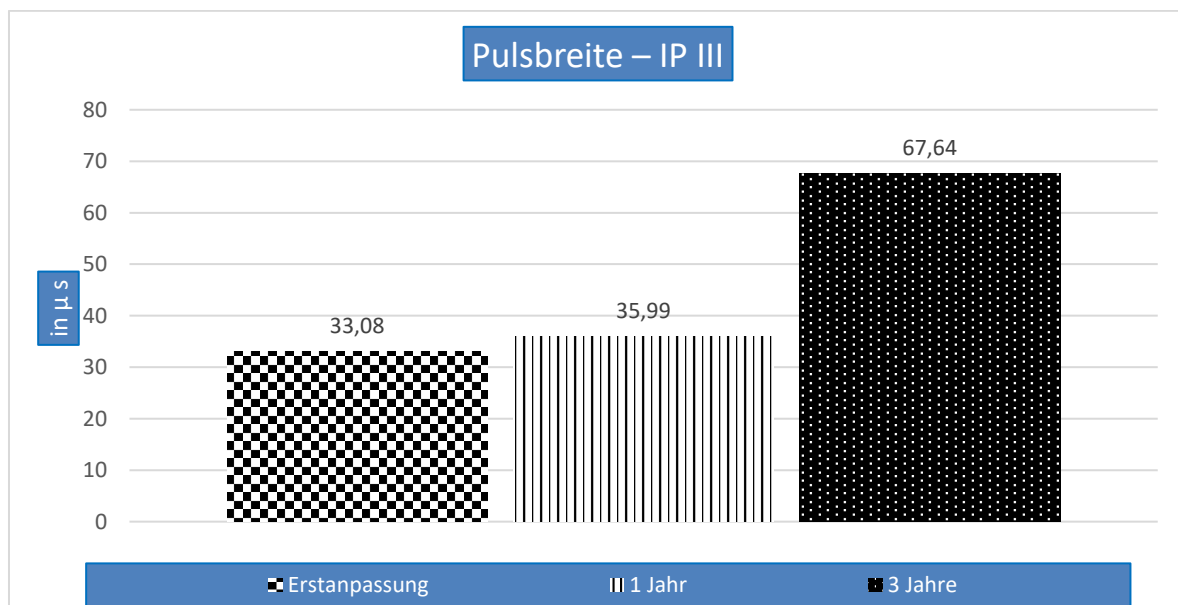


Abbildung 13: Darstellung der Pulsbreite von IP III Patient*innen über einen Beobachtungszeitraum von der Erstanpassung zu einem und drei Jahren nach Implantation. Es zeigt sich ein signifikanter Anstieg der benötigten Pulsbreite (nach (93); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

4.2. Indikationsbereiche und Veränderung der Lebensqualität:

Vorangegangene Arbeiten (49 - 51, 54) zeigten, dass am Kollektiv der beidseitig Hörgeschädigten und einseitig CI versorgten Patient*innen, auch die gesundheitsbezogene Lebensqualität signifikant verbessert werden kann und die Tinnitusbelastung signifikant reduziert wird. Folgearbeiten untersuchten, ob auch andere psychometrische Verbesserungen wie das subjektive Hörvermögen, Ängstlichkeit oder Depressivität verbessert werden (52, 56, 77, 96, 97). Die hier dargestellten Arbeiten (53, 98) weiteten die psychometrischen Testungen anhand der oben in Kapitel 2.3. aufgeführten „Berlin test battery“ auf die erweiterten CI-Indikationsgruppen der Patient*innen mit asymmetrischem Hören und der beidseitig CI Implantierten aus.

Ketterer MC, Knopke S, Häußler SM, Hildenbrand T, Becker C, Gräbel S, Olze H. (2018b). Asymmetric hearing loss and the benefit of cochlear implantation regarding speech perception, tinnitus burden and psychological comorbidities: a prospective follow-up study. Eur Arch Otorhinolaryngol. 2018 Nov;275(11):2683-2693.

In dieser prospektiven Follow-Up Studie wurden 44 Patient*innen mit asymmetrischem Hörverlust (= asymmetric hearing loss = AHL), die zwischen 2011 und 2016 mit einem CI versorgt wurden, hinsichtlich ihres Sprachverstehens und psychometrischer Begleitfaktoren der „Berlin test battery“ oder synonym „Charité test battery“ entsprechend untersucht. Bei ihnen wurden vor CI, sowie 6 und 12 Monate danach Sprachverstehenstestungen in Form des Freiburger Einsilbertest und des Oldenburger Satztest durchgeführt. Weiterhin wurde wie in Kapitel 2.3. beschrieben die Lebensqualität anhand des NCIQ, das subjektive Hörvermögen durch das CI, die Tinnitusbelastung, Coping Mechanismen und Ängstlichkeit sowie Stresslevel und Depressivität erhoben. AHL Patient*innen waren bis dato in wenigen Arbeiten differenziert von einseitig tauben Patient*innen betrachtet worden und wie Arndt et al. (48) darstellen ist die Trennung der beiden Subgruppen aus verschiedenen Gründen sinnvoll. Während einseitig Taube mit ihrem gesunden Ohr im sozialen Alltag gut kommunizieren können, wenn auch besonders ihre Lokalisierungsfähigkeit stark eingeschränkt ist (44), sind AHL Patient*innen auf ihr Hörgerät im besseren Ohr angewiesen.

Aus diesem Grund sind die Differenzierung der beiden Gruppen und die getrennte wissenschaftliche Untersuchung von Bedeutung. Die hier dargestellte Studie (53) war die erste prospektive Arbeit, die die psychometrische Entwicklung vor und nach CI bei AHL Patient*innen getrennt von einseitig Tauben untersuchte und abbildete. Die AHL Patient*innen aus Ketterer et al. (53) zeigten, dass deren Sprachverstehen im Freiburger Einsilbertest nach CI-Versorgung signifikant stieg, während das Hörvermögen auf dem besseren Ohr mit Hörgerät stabil blieb (siehe Abbildung 13).

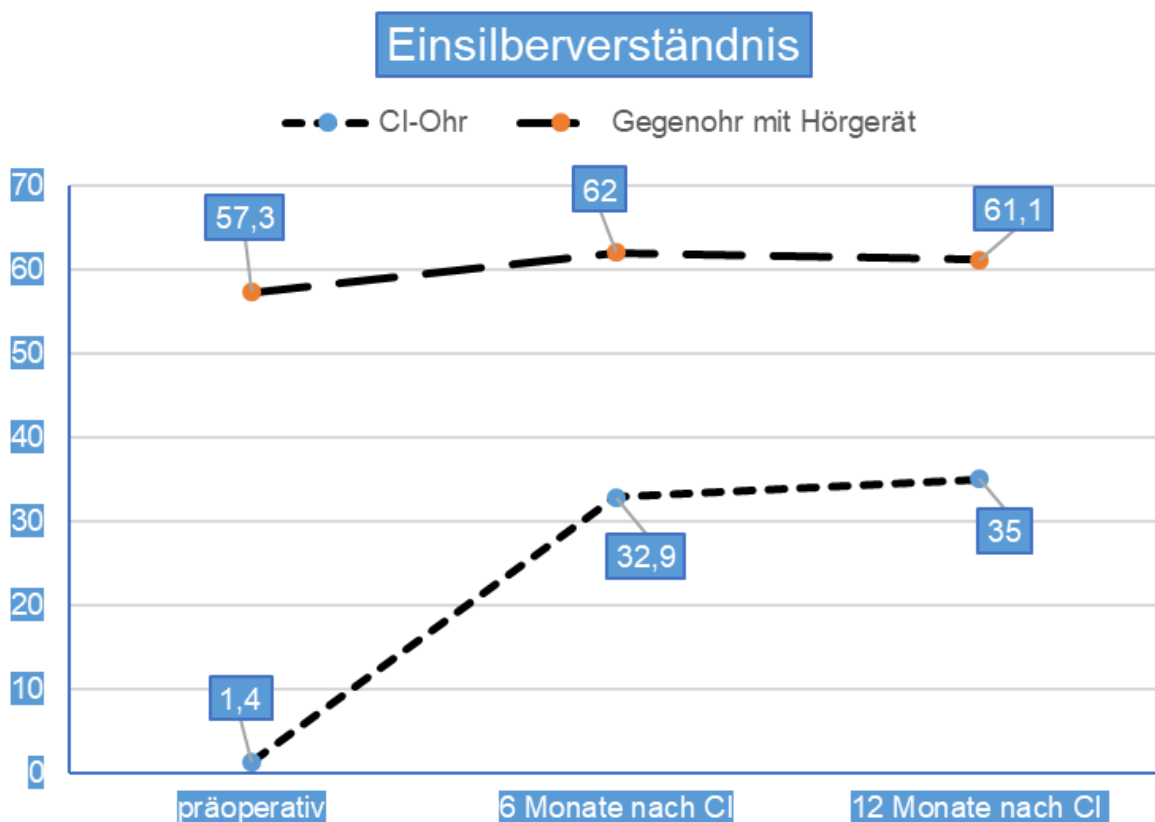


Abbildung 13: Darstellung des Sprachverstehens (Einsilberversständnis) im Freiburger Einsilbertest auf dem implantierten CI-Ohr (blau) und dem Hörgeräte-versorgten, besseren Ohr (orange) präoperativ, nach 6 und nach 12 Monaten bei 65 dB SPL (nach (53); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

Weiterhin zeigte sich sowohl 6 als auch 12 Monate nach CI eine signifikante Verbesserung der Lebensqualität, des subjektiven Hörvermögens und eine signifikante Reduktion der Tinnitusbelastung (siehe Abbildung 14).

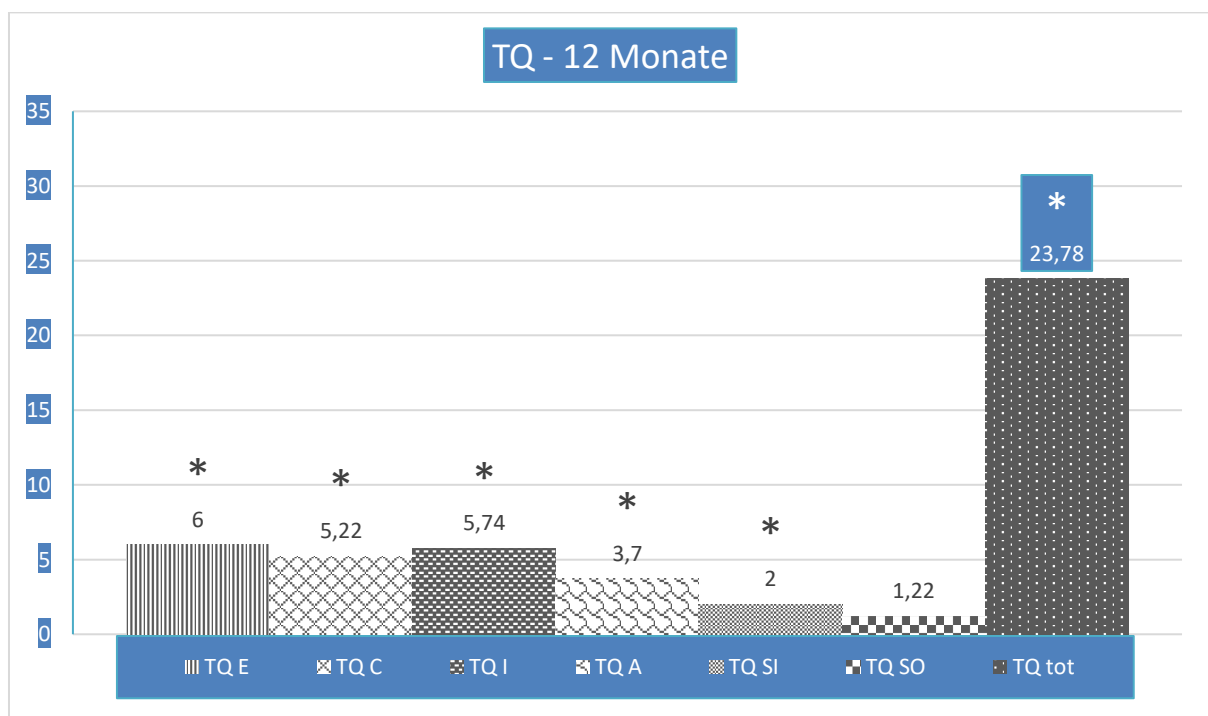
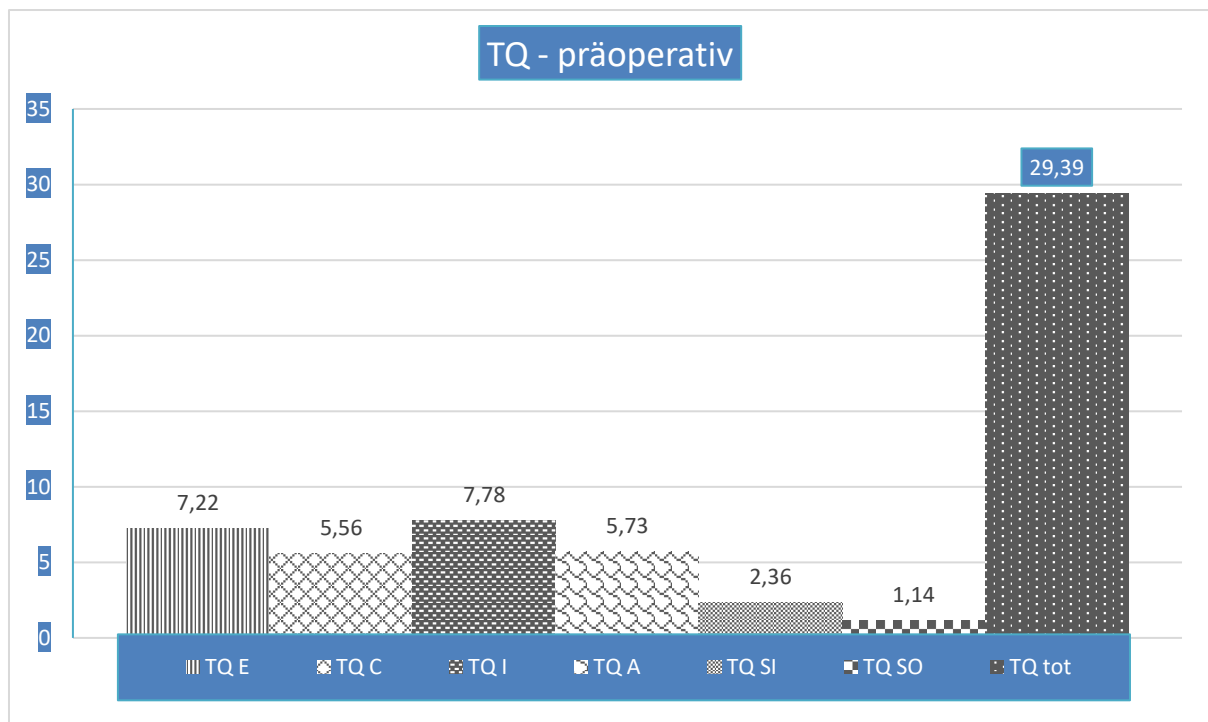


Abbildung 14: Die Tinnitusbelastung im Totalscore (TQ tot) sinkt signifikant nach 12 Monaten (b) nach CI im Vergleich zum präoperativen Wert (a). Auch die Tinnitussubskalen TQ E (emotionale Belastung), TQ C (kognitive Belastung), TQ I (Penetranz des Tinnitus), TQ A (Hörprobleme) und TQ SI (Schlafstörung) werden signifikant verbessert. Die Subskala TQ SO (somatische Belastung) dagegen bleibt unbeeinflusst (nach (53); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

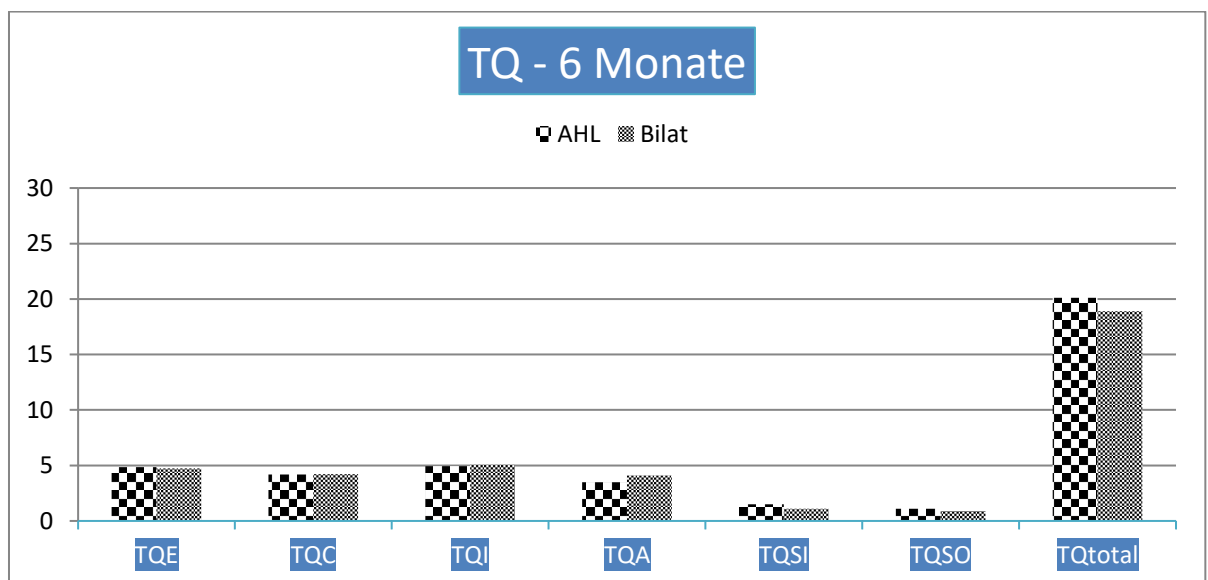
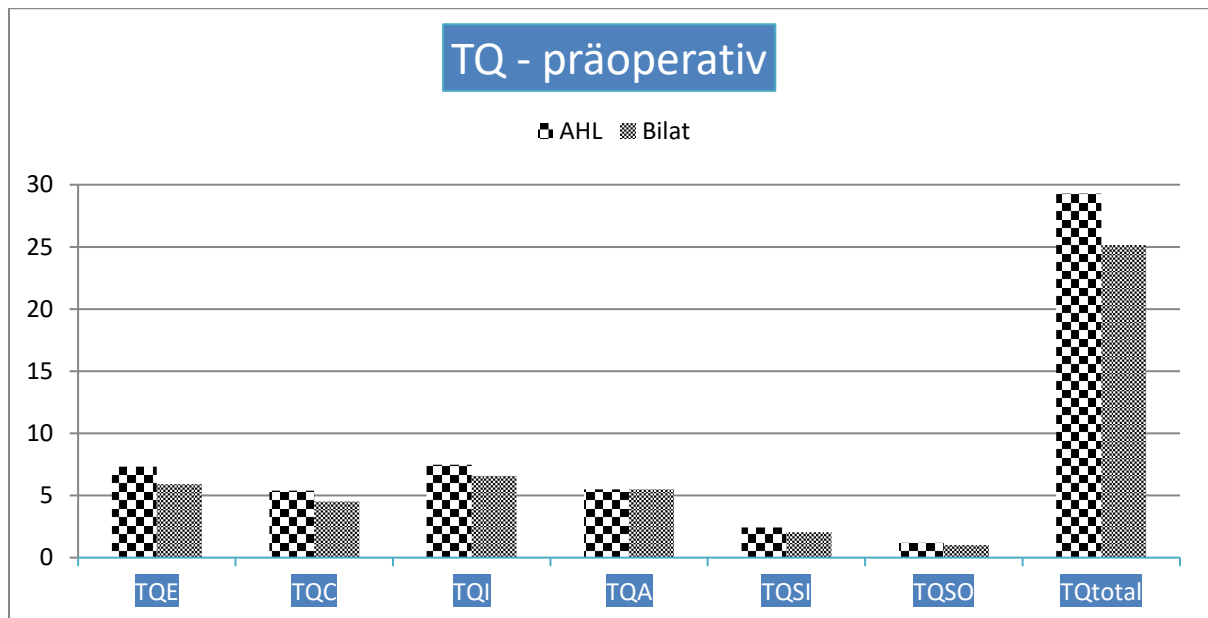
Die erhobenen Daten zur Ängstlichkeit, Depressivität, zu Coping Mechanismen und dem Stresslevel von AHL Patient*innen vor und nach CI waren durch die Implantation jedoch nicht beeinträchtigt. Somit ist eine Hörgeräteversorgung von AHL Patient*innen auch aus psychometrischer Sicht dringend notwendig, da die CI-Versorgung die Patient*innen zwar hinsichtlich Tinnitusbelastung und Lebensqualität deutlich verbessert, andere psychometrische Skalen wie die Ängstlichkeit der Patient*innen dagegen nicht beeinflusst werden.

Ketterer MC, Häussler SM, Hildenbrand T, Speck I, Peus D, Rosner B, Knopke S, Graebel S, Olze H. (2020b). Binaural Hearing Rehabilitation Improves Speech Perception, Quality of Life, Tinnitus Distress, and Psychological Comorbidities. *Otol Neurotol*. 2020 Jun;41(5):e563-e574.

Die Arbeit zu AHL Patient*innen (53) wurde durch die prospektive Follow-Up Vergleichsarbeit von Ketterer et al. (98) erweitert. Hier wurde die binaurale Hörrehabilitation von zwei erweiterten CI-Indikationsgruppen miteinander verglichen: 24 AHL Patient*innen und 29 beidseits Implantierte. Das interessante an diesen beiden Gruppen ist, dass beide Patientenkollektive an beiden Ohren jeweils von einem technischen Gerät abhängig sind. Die AHL Gruppe trägt ein CI und ein Hörgerät, die beidseits Implantierten zwei CIs. Diese prospektive 24-Monatsstudie ist die erste Arbeit, die die Hörrehabilitation und vor allem die psychometrische Situation dieser beiden Gruppen miteinander vergleicht (98).

Das Spannende und Neue an dieser Arbeit ist der Vergleich zweier Indikationsgruppen und derer psychometrischer Belastung. Es zeigte sich, dass die gesundheitsbezogene Lebensqualität (NCIQ), die Tinnitusbelastung (TQ) und auch das subjektive Hörvermögen (OI) in der unversorgten Situation signifikant unterschiedlich ist (siehe Abbildung 15 und 16). Die Tinnitusbelastung zeigte sich präoperativ bei AHL Patient*innen stärker, dies jedoch ohne statistische Signifikanz (siehe Abbildung 15: Darstellung der Tinnitusbelastung im TQ präoperativ, 6 und 24 Monate nach CI bei AHL und beidseits Implantierten im Vergleich). Beidseits schwerhörige bis taube Patient*innen zeigten signifikant schlechtere Ergebnisse der Lebensqualität und der subjektiven Hörleistung verglichen zu AHL Patient*innen (siehe Abbildung 16).

24 Monate nach CI-Versorgung näherten sich die Totalscores der jeweilig psychometrisch erhobenen Daten an und unterschieden sich nicht mehr signifikant voneinander (siehe Abbildung 15 und 16).



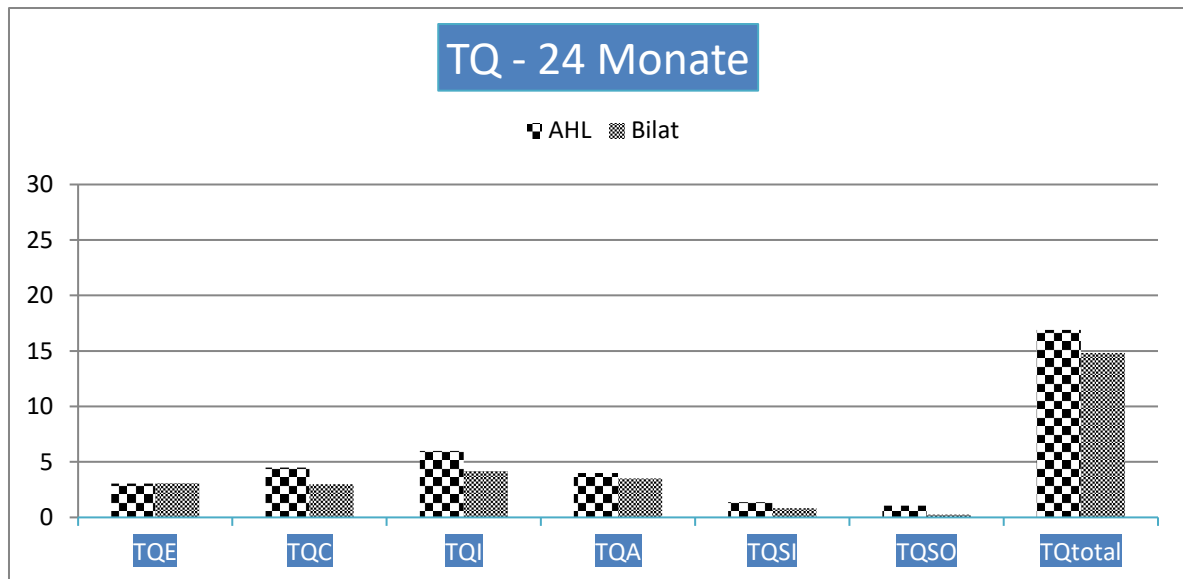
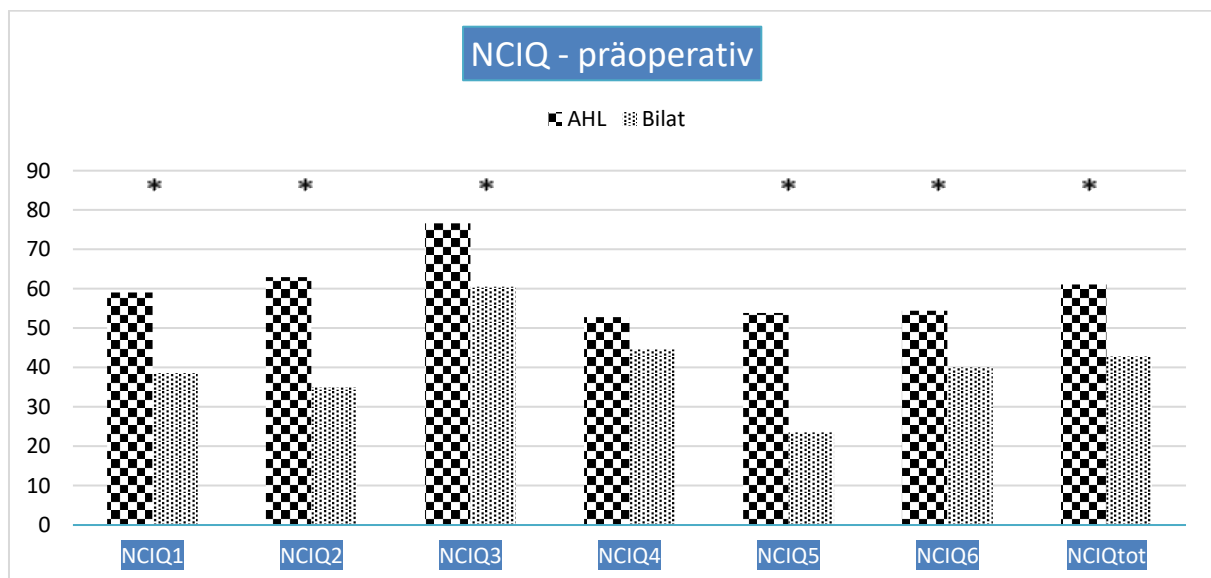


Abbildung 15: Darstellung der Tinnitus-Gesamtbelastung (TQ total) und der Subskalen (ausführlich erläutert siehe Abbildung 15) der AHL Patient*innen und der bilateral implantierten Patient*innen (Bilat) jeweils präoperativ, 6 und 24 Monate nach CI-Versorgung. Eine binaurale Hörrehabilitation führt in beiden Indikationsgruppen zu einer signifikanten Verbesserung im Gesamtscore der Tinnitusbelastung (nach (98); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).



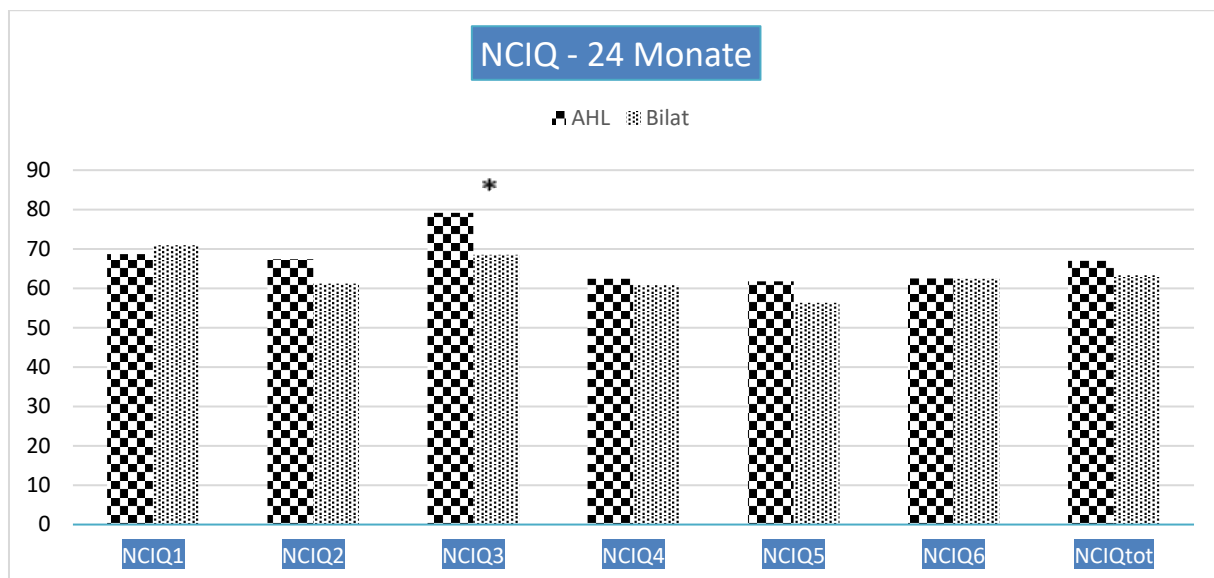
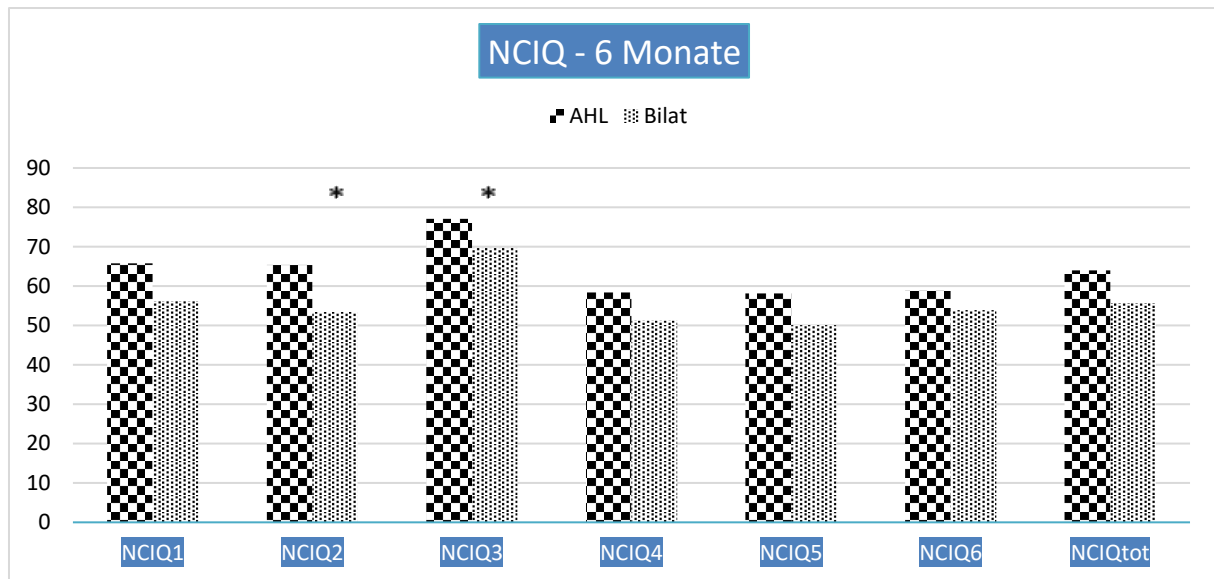


Abbildung 16: Darstellung der gesundheitsbezogenen Lebensqualität mittels NCIQ im Gesamtscore (NCIQtot) und den Subskalen (NCIQ 1: elementare Schallwahrnehmung. NCIQ 2: erweiterte Schallwahrnehmung. NCIQ 3: Sprachproduktion. NCIQ 4: Selbstachtung. NCIQ 5: Beeinträchtigung der Aktivität. NCIQ 6: soziale Interaktion) jeweils für AHL Patient*innen und bilateral implantierte Patient*innen (Bilat) präoperativ, 6 und 24 Monate nach CI-Versorgung (* = $p < 0,05$ = signifikant) (nach (98); erstellt und modifiziert durch M.C. Ketterer, 17.12.2021).

5. Diskussion:

5.1. Elektrodenträgerdesign und Einfluss auf postoperatives Sprachverstehen:

Die Arbeiten von Aschendorff et al. (9) und Escudé et al. (24) lieferten erstmalig Aussagen über radiologisch erfasste cochleäre Morphologie, die Möglichkeit der cochleären Vermessung und die skaläre Lage des CI-Elektrodenträgers. Dass die Fehlinsertion des Elektrodenträgers auch zu signifikant schlechterem Sprachergebnis führt, zeigten zahlreiche Folgearbeiten (11, 12). Holden et al. (13) und James et al. (36) wiesen an größeren Kollektiven nach, dass die skaläre Lage auch bei den aktuell auf dem Markt verfügbaren Elektrodenträgern einen Einfluss auf das Outcome nach Implantation nimmt. James et al. (36) beschrieben, dass das Sprachverstehen mit zunehmendem Insertionswinkel des Elektrodenträgers abnimmt. Boyer et al. (30) zeigten erstmalig Dislokations-spezifische Punkte von perimodiolären Elektrodenträgern auf und behaupteten zwar an einer kleinen Fallzahl, doch mit Signifikanz, dass perimodioläre Elektrodenträger überwiegend, wenn dann bei 180° innerhalb der cochleären Basalwindung dislozieren. Die Arbeit von Ketterer et al. (27) vervollständigte die Messungen von Escudé et al. (24) und etablierte erstmalig die dreidimensionale Rekonstruktion und Vermessung der Cochlea durch die cochleäre Höhe. Alle bisher veröffentlichten Arbeiten zur cochleären Größenvermessung (24, 25, 26) untersuchten ihre Bilder nicht Elektrodenträger-bereinigt und schlossen Patient*innen mit perimodiolären und Außenwandelektrodenträgern ein. Ein mögliches Bias durch die Artefakte der Elektroden wurde hierbei nie berücksichtigt. Ketterer et al. (27) war die erste Arbeit mit der bisher größten Kohorte, welche cochleäre Größenvermessungen und skaläre Lage bereinigt auf nur einen Elektrodenträger untersuchte (CA Elektrodenträger; Cochlear™).

Dass die Artefakte von Außenwandelektrodenträgern zu keinem Bias der cochlären Messung in postoperativen Cone-beam CT führen, verglichen zum präoperativen CT, zeigte die Arbeit von Ketterer et al. (79), womit die vorherigen Arbeiten durchaus ihre Berechtigung haben. Dennoch sind die bisher großen Arbeiten von Holden et al. (13) und James et al. (36) in ihrer Aussagekraft eingeschränkt zu betrachten. Beide Arbeiten schlossen sowohl perimodioläre als auch Außenwandelektrodenträger in ihre Analysen ein.

Aufgrund einer deutlich kleineren Fallzahl verglichen mit Ketterer et al. (79, 82) hatten sie jedoch nicht die statistische Kraft ihre Auswertungen Elektroden­träger-spezifisch vorzunehmen.

Ketterer et al. (79) ist somit die Arbeit mit der größten Fallzahl, welche den Einfluss von skalärer Lage und Dislokation und Insertionswinkel des Elektroden­trägers auf postoperatives Sprachverstehen untersucht. Diese Arbeit bestätigt beispielsweise die ersten Ergebnisse von Aschendorff et al. (99) zum SMA Elektroden­träger der Firma Cochlear™. Dieser relativ neue, sehr schlanke, perimodioläre Elektroden­träger zeigt kaum Dislokationstendenz auf und scheint nahezu immer in der Scala tympani zu liegen zu kommen. Weiterhin bestätigte Ketterer et al. (79) die Vermutung von James et al. (36), dass die Zunahme des Insertionswinkels und folglich die sehr tiefe Insertion des Elektroden­trägers zu schlechterem Sprachverstehen führt. Somit kann Ketterer et al. (79) vorherige Studien mit deutlich geringerer Fallzahl und ohne Elektroden­träger-spezifische Analysen (100 - 102) durchaus korrigieren, welche Außenwandelektroden­träger aufgrund höherer Insertionswinkel und angeblich besserem Sprachverstehen favorisierten. Die Arbeit von Ketterer et al. (82) konnte innerhalb der Außenwandelektroden­träger erstmalig den neue Flex²⁶ Elektroden­träger der Firma MED-EL untersuchen. Dieser zeigte keinerlei Dislokationen und führte somit bei Insertion ähnlich zum von Aschendorff et al. (99) untersuchten perimodiolären SMA Elektroden­träger der Firma Cochlear™ zu keinem cochleären Trauma. Der Insertionswinkel der Flex²⁶ zeigte sich vergleichbar mit der Flex²⁴, welche in Ketterer et al. (79) ähnliche Insertionswinkel wie die perimodiolären Elektroden­träger erreichte und somit außerhalb des Risikobereichs von Überinsertion und vermindertem Sprachverstehen lag. Die Arbeiten Ketterer et al. (79, 82) sind somit wegweisend, dass schlanke Elektroden­träger, welche nicht überinsertiert werden und ein flexibleres Design aufweisen, deutlich von Vorteil sind, um traumatische Insertionen oder Fehlinsertionen und somit schlechteres Outcome zu vermeiden.

Die meisten größeren Arbeiten zu cochleärer Morphologie und Elektroden­trägerdesign wie Ketterer et al. (27, 79, 82) oder James et al. (36) sind an normcochleären Patient*innen erfolgt und Patient*innen mit cochleären Malformationen wurden exkludiert. Daher untersuchten Alballaa et al. (93) eine spezielle Gruppe der cochleären Malformation, die IP III. Entgegen der Meinung von Sennaroglu et al. (94), welcher flexible Außenwandelektroden­träger in der CI-Versorgung dieser

Patient*innen favorisierte, konnte diese Arbeit (93) die problemlose Insertion von perimodiolären Elektroenträgern in diesem Patientenkollektiv bestätigen. Die stabilen audiologischen Langzeitdaten der hier untersuchten Patient*innen bestätigten den Eindruck, dass perimodioläre Elektroenträger gewisser Rigidität wie der CA Elektroenträger hier Vorteile in der Stabilisierung innerhalb der Cochlea und dem Langzeit-Outcome haben (93).

5.2. Indikationsbereiche und Veränderung der Lebensqualität:

Neben der Optimierung der Hörrehabilitation und des Sprachverstehens mit CI nach Implantation sind in den letzten Jahren zunehmend Teilbereiche der psychologischen Verbesserung in Lebensqualität, der subjektiven Hörleistung und der Tinnitusbelastung in den Fokus der CI-Forschung gerückt (49 - 51, 54, 67).

Die Erfassung von psychologischen Teilaspekten wie Ängstlichkeit und Depressivität mittels validierten Fragebögen sind bei hörgeschädigten Patient*innen enorm wichtig, da diese in ihrem sozialen Alltag oft eingeschränkt sind und ein erhöhtes Risiko der Depressivität und der sozialen Isolation aufweisen (65, 66, 68, 78). In der Literatur ist sogar der Verdacht beschrieben, dass starke Tinnitusbelastung zu erhöhter Suizidalität führen kann, wobei dies sehr umstritten ist (103 - 105). Gerade in sozial oder politisch schwierigen Zeiten, wie der Corona-Pandemie kann die Rehabilitation von hörgeschädigten Patient*innen auch nach CI-Versorgung stark vom Umfeld und der rehabilitativen Eingliederung abhängen (106).

Daher ist die ausführliche, psychometrische Erfassung und Untersuchung von hörgeschädigten Patient*innen äußerst wichtig und die in dieser Habilitationsschrift beschriebenen Arbeiten, welche die „Berlin test battery“ auf die erweiterten CI-Indikationsgruppen ausweiteten von großer Bedeutung (53, 77, 96, 97, 98). Besonders hervorzuheben ist, dass die Arbeit von Ketterer et al. (98) erstmalig darauf hinweist, dass die initial psychologische Situation der Patient*innen je nach Schweregrad der Hörschädigung unterschiedlich ist und Lebensqualität, subjektives Hörvermögen und auch die Tinnitusbelastung initial schlechter sind, je schlechter die binaurale Hörsituation des/der Patienten*in ist. Dass die Patient*innen sich bei effektiver binauraler Rehabilitation durch beidseits CI oder einseitig CI und kontralateral Hörgerät bereits nach 24 Monaten angleichen ist spannend und bedarf weiterer prospektiver Untersuchungen.

6. Ausblick in zukünftige Forschung:

Zahlreiche, wie die in dieser Schrift dargestellten Arbeiten untersuchten den Einfluss von skalärer Lage des Elektrodenträgers auf die Ergebnisse der Hörrehabilitation und zeigten die Zusammenhänge von morphologischen Eigenschaften der Cochlea zur Dislokationswahrscheinlichkeit des Elektrodenträgers. Weiterhin zeigten die im zweiten Teil dieser Schrift dargestellten Arbeiten (Kapitel 4.2.), dass die CI-Versorgung zu signifikanter Verbesserung in vielen Bereichen neben dem Sprachverstehen wie der Tinnitusbelastung und der Lebensqualität führt.

Die CI-Versorgung ist eine anerkannte Möglichkeit der Hörrehabilitation sowohl bei beidseits tauben (13, 36), als auch mittlerweile bei einseitig tauben Patient*innen (44). Weiterhin führt sie bei vielen Patient*innen zu einer signifikanten Reduktion der Tinnitusbelastung (49 - 51, 54). Dennoch ist bisher völlig unklar, warum nicht wenige Patient*innen trotz Implantation und gutem Sprachverstehen unter Tinnituspersistenz oder gar Tinnitusexzitation leiden. Weiterhin berichten Patient*innen häufig von akut aufgetretenem Schwindel nach Implantation. Hier variieren Studien stark und sprechen von 17.4% (107) bis zu 60% (108, 109). Einige, laut Literatur bis zu ein Drittel der Patient*innen, klagen jedoch über dauerhaft anhaltenden Schwindel (108, 110). Basta et al. (108) beschrieben, dass CI-Patient*innen, welche postoperativ über Schwindel klagten, Ausfälle in cVEMPs (cervikal evozierte myogene Potentiale) zeigen und somit einen sacculären Funktionsverlust aufweisen. Sie führten dies zum einen auf Fibrosierung zum anderen auf sacculäre Membranschädigung durch Insertion des Elektrodenträgers zurück (108, 111, 112).

Einige Arbeiten evaluierten den chirurgischen Insertionszugang retrospektiv (37, 107, 113). Die Ergebnisse dieser Arbeiten weisen darauf hin, dass ein Rundfensterzugang weniger postoperativen Schwindel provoziert als eine Cochleostomie; sie sind jedoch nicht eindeutig und an kleinen Patientenkollektiven erhoben.

Arbeiten, wie Häußler et al. (96) zeigten, dass die Tinnitusbelastung und die Lebensqualität der Patient*innen signifikant negativ korrelieren. Postoperativer Schwindel und vermehrte Tinnitusbelastung nach CI-Operation sind von vielen Patient*innen berichtet und in zahlreichen Studien beschrieben worden. Es gibt bisher jedoch keine Arbeit, welche den Einfluss der skalären Lage und Dislokation des Elektrodenträgers auf postoperative Tinnitusbelastung oder Schwindel untersucht.

Weiterhin gibt es noch keine systematische Arbeit, welche den Einfluss des Elektrodenrägerdesigns auf postoperativen Schwindel und Funktionsausfälle des peripheren Vestibularorgans untersucht. Das Design des Elektrodenrägers ist abhängig vom Hersteller, doch auch vom individuellen Elektrodenräger-Portfolio.

Aktuell laufende prospektive Arbeiten unserer Arbeitsgruppe untersuchen, ob die Scala tympani-Insertion des Elektrodenrägers ohne Dislokation und somit ohne cochleäres Trauma zu einer Reduktion von postoperativ berichtetem Vertigo und vestibulären Funktionsstörungen führt. Vor allem soll erstmalig untersucht werden, ob bei Dislokation des Elektrodenrägers und folglich traumatischer Insertion des Elektrodenrägers peripher-vestibuläre Störungen nachweisbar sind und eine höhere Tinnitusbelastung berichtet wird. Weiterhin soll der Einfluss der Insertionstechnik (Rundfensterinsertion versus Cochleostomie) auf Schwindel und Tinnitusbelastung untersucht werden.

7. Zusammenfassung:

Der Zusammenhang von cochleärer Morphologie und skalärer Lage des Elektrodenträgers ist seit längerem im Fokus der CI-Forschung (11, 12, 27). Diese vorliegende Arbeit präsentiert neue Zusammenhänge von skalärer Lage, Dislokationsverhalten und Sprachverstehen (79) und untersuchte auch die neuesten Elektrodenträger der marktführenden Hersteller (79, 82). Die Tatsache, dass das Elektrodenträgerdesign in seiner Länge, Flexibilität und dem Durchmesser entscheidend für die skaläre Lage und somit auch für die Wahrscheinlichkeit eines cochleären Traumas ist, ist zielführend für die Weiterentwicklung der Elektrodenträger und der Insertionstechniken. Weiterhin zeigte sich, dass bei cochleärer Dysmorphie perimodioläre Elektrodenträger mit gewisser Rigidität zu stabilem Sprachverstehen im Langzeit-Vergleich führen (93).

Prospektive Studien, die in dieser Arbeit zusammengefasst sind, zeigen, dass bei CI-Patient*innen nicht nur die Hörrehabilitation, sondern auch psychologische Komorbiditäten eine besondere Beachtung erfahren müssen (53, 98) und dass die erweiterten CI-Indikationen des asymmetrischen Hörverlusts und die beidseits implantierten Patient*innen durch binaurale Hörrehabilitation in psychologischen Aspekten wie der subjektiven Hörleistung, Tinnitusbelastung und Lebensqualität eine signifikante Verbesserung durch CI erfahren (53, 98).

Inwiefern ein cochleäres Trauma oder eine sehr tiefe Insertion des Elektrodenträgers in Abhängigkeit zu cochleärer Morphologie und Elektrodenträgerdesign bei Insertion nicht nur zu schlechterem Sprachverstehen, sondern auch zu erhöhter Tinnitusbelastung oder postoperativer Schwindelentwicklung führen, sollen aktuell laufende prospektive Arbeiten zeigen.

8. Danksagung:

Zunächst möchte ich meinem ärztlichen Direktor, Herrn Universitätsprofessor Dr. med. Andreas Knopf, danken. Er nahm mich nach seinem Wechsel an das Universitätsklinikum in Freiburg operativ, klinisch und wissenschaftlich an die Hand und ich durfte bereits sehr viel von ihm lernen und bin ihm hierfür äußerst dankbar.

Mein ganz besonderer Dank gilt meiner einstigen Doktormutter und nun wissenschaftlichen Unterstützerin Frau Universitätsprofessorin Dr. med. Antje Aschendorff. Liebe Antje, viele Manuskripte haben wir gemeinsam geschrieben, Ideen ausgetüftelt und Vorträge vorbereitet. Ich danke dir zum einen für deine Unterstützung und Schulter beruflich wie privat, konstruktive Kritik und den roten Faden in meiner wissenschaftlichen Arbeit.

Ein riesiges Dankeschön gilt Herrn Dr. med. Rainer Linus Beck. Unzählige Cochleae haben wir vermessen, Statistiken gerechnet und Arbeiten geschrieben. Lieber Rainer, einen Kliniker mit dem man klinische Tätigkeit, wissenschaftliche Arbeit, didaktische Seminare und Freundschaft verbinden darf, ist selten zu finden. Vielen Dank hierfür!

Weiterhin danke ich Frau Prof. Dr. med. Susan Arndt. Liebe Susan, du hast mir in der Sprechstunde, wie im OP viel beigebracht und meine Arbeiten immer mit besonnener, konstruktiver Kritik und Geduld korrigiert. Danke für alles!

Ganz besonders gilt mein herzlicher Dank meiner Familie und meinen Freunden, welche mich immer unterstützt haben und mir mit Tat und Wort in den anstrengenden doch lohnenswerten letzten 5 Jahren zur Seite standen.

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10. Schriftenverzeichnis:

10.1. Originalarbeiten, die in die kumulative Habilitationsschrift einfließen:

1. Ketterer MC, Knopke S, Häußler SM, Hildenbrand T, Becker C, Gräbel S, Olze H. Asymmetric hearing loss and the benefit of cochlear implantation regarding speech perception, tinnitus burden and psychological comorbidities: a prospective follow-up study. Eur Arch Otorhinolaryngol. 2018 Nov;275(11):2683-2693.

Studienkonzeption (MCK, HO), Methodik (MCK, SMH, HO), Studienleitung (HO, SG, SK), Datenerhebung (MCK, SMH), Analyse (MCK), Entwurf und Korrektur der Publikation (MCK, HO, TH, CB).

2. Ketterer MC, Häussler SM, Hildenbrand T, Speck I, Peus D, Rosner B, Knopke S, Graebel S, Olze H. Binaural Hearing Rehabilitation Improves Speech Perception, Quality of Life, Tinnitus Distress, and Psychological Comorbidities. Otol Neurotol. 2020 Jun;41(5):e563-e574.

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3. Ketterer MC, Aschendorff A, Arndt S, Speck I, Rauch AK, Beck R, Hassepas F. Radiological evaluation of a new straight electrode array compared to its precursors. Eur Arch Otorhinolaryngol. 2021 Oct;278(10):3707-3714.

Studienkonzeption (MCK, RB, AA), Methodik (MCK, FH, AA), Studienleitung (SA, AA), Datenerhebung (MCK, AKR, RB), Analyse (MCK, RB), Entwurf und Korrektur der Publikation (MCK, AA, FH, IS).

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11. Sonderdrucke der Schlüsselpublikationen:



Electrode array design determines scalar position, dislocation rate and angle and postoperative speech perception

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Abstract

Purpose The aim of this study is to examine the scalar dislocation rate in straight and perimodiolar electrode arrays in relation to cochlear morphology. Furthermore, we aim to analyze the specific dislocation point of electrode arrays depending on their design and shape and to correlate these results to postoperative speech perception.

Methods We conducted a comparative analysis of patients (ears: $n = 495$) implanted between 2013 and 2018 with inserted perimodiolar or straight electrode arrays from CochlearTM or MED-EL. CBCT (cone beam computed tomography) was used to determine electrode array position (scalar insertion, intra-cochlear dislocation, point of dislocation and angular insertion depth). Furthermore, cochlear morphology was measured. The postoperative speech discrimination was compared regarding electrode array dislocation, primary scalar insertion and angular insertion depth.

Results The electrode array with the highest rate of primary SV insertions was the CA; the electrode array with the highest rate of dislocations out of ST was the Flex^{Soft}. We did not find significantly higher dislocation rates in cochleostomy-inserted arrays. The angle of dislocation was electrode array design-specific. A multivariate nonparametric analysis revealed that the dislocation of the electrode array has no significant influence on postoperative speech perception. Nevertheless, increasing angular insertion depth significantly reduced postoperative speech perception for monosyllables.

Conclusion This study demonstrates the significant influence of electrode array design on scalar location, dislocation and the angle of dislocation itself. Straight and perimodiolar electrode arrays differ from each other regarding both the rate and place of dislocation. Insertion via cochleostomy does not lead to increased dislocation rates in any of the included electrode arrays. Furthermore, speech perception is significantly negatively influenced by angular insertion depth.

Keywords Cochlear morphology · Electrode array design · Scalar position · Coverage · Speech perception

Abbreviations

ST	Insertion in scala tympani
SV	Insertion in scala vestibuli
TD	Tympani dislocation = dislocation out of ST
VD	Vestibuli dislocation = dislocation out of SV
CBCT	Cone beam computed tomography
HRCT	High-resolution computed tomography
CI	Cochlear implant/cochlear implantation
CA	Cochlear TM Contour Advance [®] electrode array
SMA	Cochlear TM slim modiolar [®] electrode array
SSA	Cochlear TM slim straight [®] electrode array

Flex ²⁴	MED-EL Flex ²⁴ electrode array
Flex ²⁸	MED-EL Flex ²⁸ electrode array
Flex ^{Soft}	MED-EL Flex ^{Soft} electrode array
RW	Round window
ERW	Extended round window
CS	Cochleostomy

Introduction

Cochlear implant (CI) surgery focusses more and more on the impact of cochlear morphology and consequently on intra-cochlear electrode array position and postoperative speech perception. Previous studies described different ways of estimating cochlear morphology preoperatively. Escudé et al. [1] established distance A as the distance from the round window (= RW) to the lateral wall and a perpendicular distance B, both intersecting the modiolus. Ketterer et al. [2]

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described a third measure, the cochlear height and the fact that the electrode array was more likely to dislocate within a cochlea of smaller height and smaller diameter. Aschendorff et al. [3] first examined scalar position via rotational tomography for patients inserted with a Contour ($n = 21$) versus a Contour Advance ($n = 22$) (=CA) electrode array and described significantly higher speech discrimination results for scala tympani (ST) compared to scala vestibuli (SV) insertion. In a linear regression analysis for 14 of the 15 patients described by Skinner et al. [4], Finley et al. [5] calculated that scalar position, age at implantation and total number of electrode contacts within the SV accounted for 83% of the variance in monosyllabic word scores. Holden et al. [6] described that the position of electrode arrays closer to the modiolus was positively correlated with the outcome. As a result, scalar position detection of the electrode array via CBCT (cone beam computed tomography) or HRCT (high resolution computed tomography) should be a consideration in postoperative quality control to provide important feedback to the surgeon [3]. The goal of this study is to examine the scalar dislocation rate in both straight and perimodiolar electrode arrays. To the best of our knowledge, this is the first large cohort study analyzing the specific position of dislocation of electrode arrays depending on their design and shape. Furthermore, we aimed to evaluate the impact of scalar dislocation, electrode array design and angular insertion depth on postoperative speech perception.

Methods

Study and subject

We performed a retrospective analysis of adult patients implanted between 2013 and 2018. HRCT and magnetic resonance imaging had been conducted preoperatively and patients with cochlear anomalies and signs of sclerosis or obliteration were excluded from this study. We only included patients inserted with a Cochlear™ Contour Advance® (CI24RECA, CI412/512/612) (=CA), Cochlear™ slim straight® (422/522/622) (=SSA) or Cochlear™ slim modiolar® (532/632) electrode array (=SMA) (Cochlear Limited, NSW, Sydney, Australia) and MED-EL Flex²⁴, MED-EL Flex²⁸ and MED-EL Flex^{Soft} (MED-EL, Innsbruck, Austria). Electrode arrays were inserted via cochleostomy (=CS), round window (=RW) and extended round window (=ERW) insertion. The patient chose the manufacturer following individual consulting. If the patient chose MED EL and showed residual hearing, the FLEX²⁴ was used in most cases. In patients implanted with a device from Cochlear™, the SSA or the SMA was used in patients with residual hearing, otherwise the CA was also used quite often due to the later availability of the SSA and the SMA.

Radiological evaluation

Postoperative imaging was performed using a DynaCT-equipped Axium Artis dTA angiography unit (Siemens Co., Erlangen, Germany) with a digital flat-panel detector [3, 7]. Two experienced head and neck surgeons and two head and neck radiologists independently analyzed the scans regarding scalar electrode position (ST versus SV insertion, intracochlear dislocation, angular insertion depth) and cochlear size (diameters in length and width) and used Impax 6 from Agfa Healthcare for reconstruction. The scans were not evaluated by the surgeons who performed the CI surgery but by independent and experienced head and neck surgeons to reduce bias. All included electrode arrays were fully inserted. Cochlear size was evaluated in distance A from the round window to the lateral wall through the modiolus and perpendicular distance B [1, 2, 8]. The angular insertion depth was evaluated between the vectors of distance A and the distance through the bloom artefact of the apical electrode and the modiolus as described before [2, 8, 9]. Dislocation analysis and analysis of scalar position were performed on three-dimensionally reconstructed cross-sectional images as previously described [2, 8], i.e. the 3D-reconstruction could be rotated and browsed in whichever direction the specialists needed to come to their respective conclusion. Every image with discrepancy was reviewed and discussed interdisciplinary until a final agreement and measurement was achieved.

We compared preoperative HRCT scans to postoperative CBCT scans to examine the hypothesis that straight electrode arrays could lead to a mismatch of cochlear morphology measurements due to their more lateral electrode artifacts.

Audiological evaluation

Open set speech perception is evaluated regularly in a soundproof chamber in a standard clinical setting using the Freiburg numbers and the Freiburg monosyllables test both with presentation at a volume of 65 dB SPL in quiet. Speech discrimination is scored as percentage correct. The audiologists conducting speech perception were blinded and did not know scalar position or dislocation analysis.

Statistics

Statistical analysis was performed using Gnu R statistical computation and graphics system (GNU R, Version 3.6.2, Core Team, Vienna, Austria, <http://www.R-project.org>), extended with the packages NLME (Linear and Nonlinear Mixed Effects Models, Version 3.1, Pinheiro et al., <https://CRAN.R-project.org/package=nlme>) and ggplot2 (Version

3.3.1, Hadley Wickham, <https://ggplot2.tidyverse.org>). Where applicable, ANOVA and Tukey's Honest were used. Nonlinear mixed effect models were applied for the analysis of speech discrimination and compared directly by ANOVA and AIC. For array comparisons, the residuals were analyzed using pairwise Mann–Whitney *U* tests with adjustment by Holm. Results were calculated descriptively and are shown in the text and in tables as mean, standard deviation, maximum and minimum. The level of significance was set at 5.0%.

Ethics committee

This retrospective study took place in the Department of Otorhinolaryngology, Head and Neck Surgery at the Implant Center of the University Hospital Freiburg. The study was approved by the hospital's Ethics Committee according to the Declaration of Helsinki (Washington, 2002) (Number of Ethics Committee approval: 406/19) and registered in

the German Clinical Trials Register (<http://www.drks.de/DRKS00019807>).

Results

Study, subject and cochlear morphology

We included 495 ears implanted between 2013 and 2018. We included 40 bilaterally implanted and 415 unilaterally implanted patients. 259 left and 236 right cochleae; 327 ears, implanted with a device from Cochlear™ and 168 ears implanted with a device from MED-EL were included. The mean age was 52.7 years and the most-often inserted electrode array was the SSA with 32.7% (see Table 1: distribution of analyzed electrode arrays). The measurements of the diameters of the cochlear basal turn confirm previous studies [1, 2], calculating mean distance A with 9.92 mm and distance B with 6.74 mm (see Table 2). Regarding the electrode array portfolio of Cochlear™, the cochlear basal turn size (product of distance A and B) shows significant impact on the surgeon's electrode array choice (see Fig. 1). Differences between the two manufacturers regarding the cochlear basal turn product were not analyzed due to patient's pre-operative choice of the manufacturer. The use of the CA is significantly more frequent in cochleae with a smaller cochlear basal turn product of distance A and B compared to the SMA and the straight electrode (SSA) array of Cochlear™ (CA versus SSA: $p < 0.0001$; SMA versus SSA: $p = 0.0025$). Nevertheless, we did not find significance for the cochlear basal turn product between the different electrode arrays of MED-EL.

We excluded the hypothesis that the SSA could lead to larger cochlear measurements due to the lateral electrode array artifacts. Therefore, we compared preoperative HRCT

Table 1 Synopsis of study group (in total: $n = 495$)

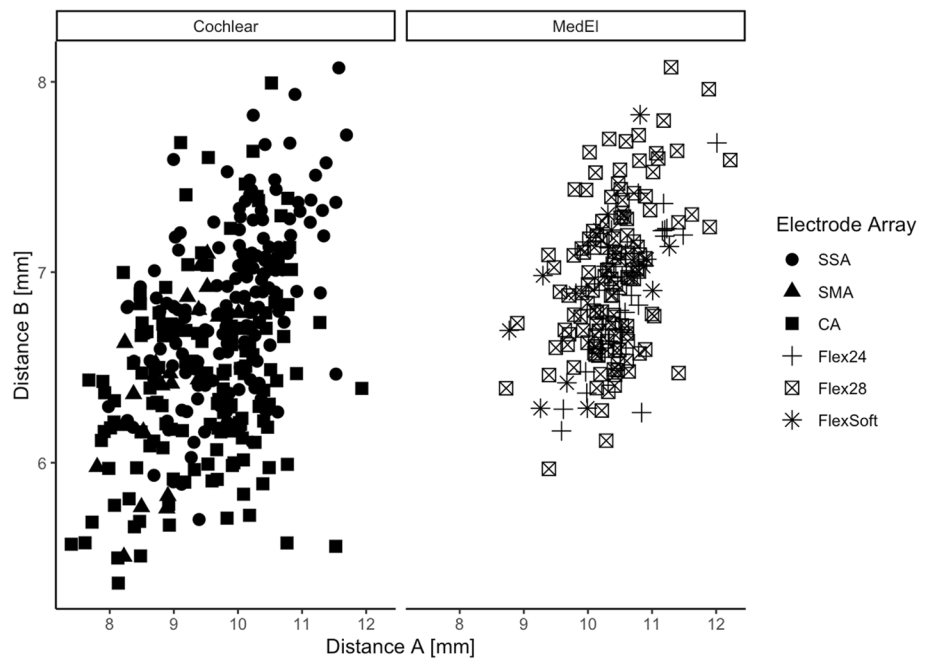
Manufacturer (n)	Cochlear™: 327 MED-EL: 168
Electrode array (n)	Contour Advance (Cochlear™) (=CA): 143 CI 422/522/622 (Cochlear™) (=SSA): 162 CI 532/632 (Cochlear™) (=SMA): 22 Flex ²⁴ (MED-EL): 129 Flex ²⁸ (MED-EL): 24 Flex ^{Soft} (MED-EL): 15
Side (n)	Left: 259 Right: 236
Age	52.7 years (min 18.0; max 86.2)

Table 2 Cochlear measurements (distance A and B), insertion angle, scalar position in total (SD = standard deviation) and distribution of the insertion technique

	Mean	SD	Minimum	Maximum
Distance A (mm)	9.92	0.86	7.4	12.2
Distance B (mm)	6.74	0.49	5.4	8.1
Insertion angle (°)	418.8	103.7	199	794
Scalar position in total (n)	ST: 434 (87.7%) TD: 32 (6.5%) SV: 25 (5%) VD: 4 (0.8%)			
Insertion technique in total (n) and percentage (%)	Electrode array	CS	RW	ERW
	CA (Cochlear™)	140/98%	3/2%	/
	SSA (Cochlear™)	47/29%	110/68%	5/3%
	SMA (Cochlear™)	12/54.5%	10/45.5%	/
	Flex ²⁴ (MED-EL)	21/16.3%	102/79.2%	6/4.2%
	Flex ²⁸ (MED-EL)	10/41.6%	13/54.2%	1/4.2%
	Flex ^{Soft} (MED-EL)	12/80%	3/20%	/

CS cochleostomy, RW round window, ERW extended round window

Fig. 1 Left: Regarding electrode arrays from Cochlear™ (CA = Contour Advance; SMA = CI 532/632 = slim modiolar array; SSA = CI 422/522/622 = slim straight array) the use of the CA is significantly more frequent in cochleae with a smaller size of the cochlear basal turn (product of distance A and B). Right: We could not find significance for the cochlear basal turn product between the different electrode arrays of MED-EL



scans to postoperative CBCT scans. We evaluated both scans blinded and independently and did not find different measurements for either distance A or B.

Furthermore, we compared cochlear size to dislocation behavior and could not detect significant differences for cochlear distance A or B compared dislocated or non-dislocated electrode arrays.

Angular insertion depth and dislocation manner

Figure 2 shows the mean angular insertion depth for each included electrode array. Regarding the included Cochlear™ electrode arrays, we measured a significantly higher angular insertion depth for the SSA compared to the CA ($p=0.0004$). The angular insertion depth was comparable between the CA and the SMA ($p=0.15$) or between the SSA and the SMA ($p=0.9996$). Regarding the electrode arrays from MED-EL, the Flex²⁴ showed significantly lower angular insertion depth compared to the longer electrode arrays Flex²⁸ and Flex^{Soft} ($p<0.00001$) as expected. All included electrode arrays from Cochlear™ showed significantly shorter angular insertion depth than the electrode arrays from MED-EL (p in all comparisons <0.0065) (see Fig. 2).

In regard to insertion types, the electrode arrays behaved distinctively in this cohort: CA exhibited the highest rate of SV insertions [SV: 16.1%; TD (dislocation out of ST): 15.4%]; the electrode array with the highest rate of ST dislocations was the Flex^{Soft} (SV 6.7%; TD 20.0%). The SMA showed no dislocations; the SSA only one dislocation out of ST and 3 SV insertions via CS (SV 1.9%; TD 0.6%) (see Fig. 3). An SV insertion was defined as a direct insertion

into SV. SV insertions mostly occurred in CS approaches and most frequently for the CA electrode array (see Fig. 3). As SV insertions mostly depend on the position of the CS, they are only partially influenced by array design.

Table 2 and Fig. 3 show that electrode arrays included in this study were inserted via CS and RW and in some cases via ERW. Comparing angular insertion depth in all approaches (ANOVA Tukey post-hoc), we could not find any significant impact.

Measuring the specific position of dislocation for each electrode array, we found that the position of dislocation depends on the electrode array itself (see Fig. 4). We measured a significant lower point of dislocation for the CA compared to both the Flex²⁸ ($p<0.00001$) and the Flex^{Soft} ($p<0.00001$). The point of dislocation is electrode-design specific. Perimodiolar electrode arrays dislocate between 160 and 180° (CA: mean \pm SD: 170 \pm 25°), whereas straight electrode arrays dislocate between 280° and 330° (Flex²⁸: mean \pm SD: 284 \pm 87°; Flex^{Soft}: mean \pm SD: 330 \pm 36°).

Impact on speech perception

Data could not be acquired for 11 ears for the evaluation of speech discrimination, therefore 484 ears were included. The Freiburg Number discrimination test showed a considerable ceiling effect over all measurements in all patients (1st quartile 80%, mean 82.25%, 3rd quartile 100%) and was therefore discarded in regard to further analysis. The Freiburg Monosyllable test showed a more homogeneous distribution (1st quartile 20%, mean 43.9%, 3rd quartile 70%). After constructing an asymptotic growth model for every individual ear, the

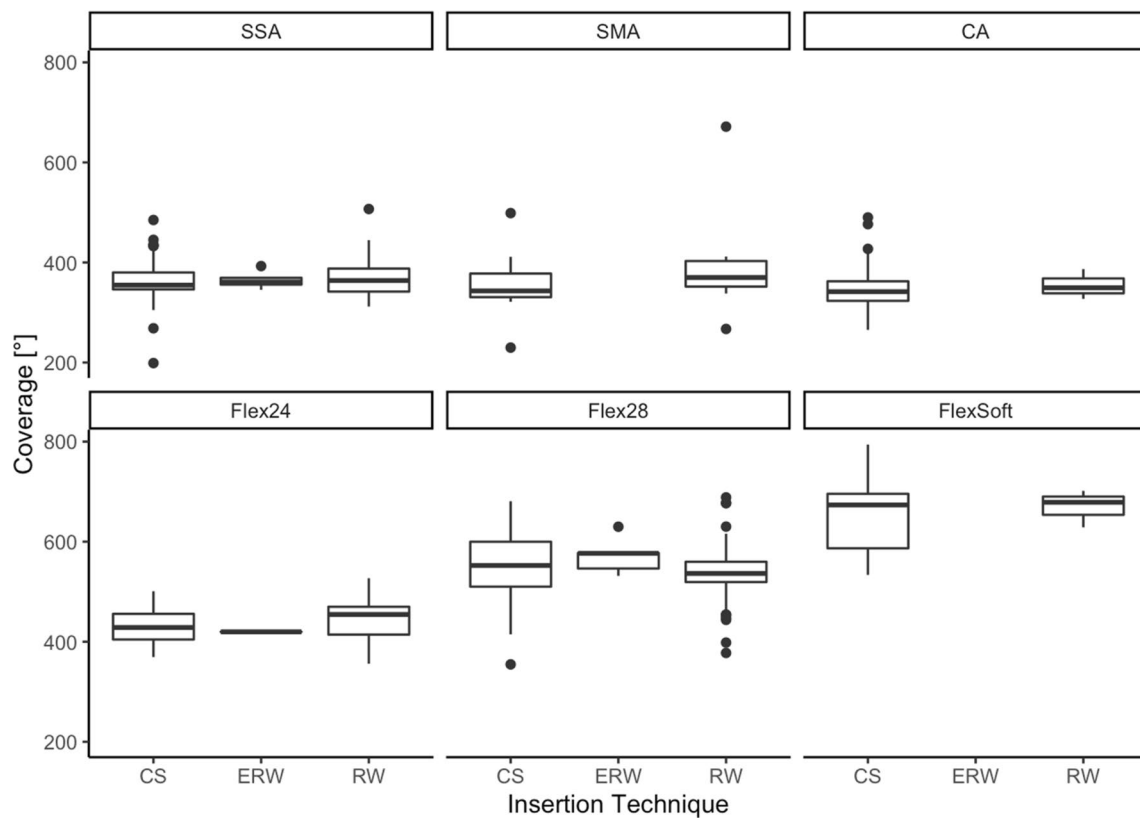


Fig. 2 Angular insertion depth depends on electrode array design and correlates to electrode array length. Insertion technique has no significant influence on electrode array-specific angular insertion depth (CS=cochleostomy; RW=round window; ERW=extended round window)

fitness of different models could be compared using ANOVA. Including angular insertion depth could improve the fitness of the model significantly when including all electrode arrays ($p < 0.0001$), but not when comparing electrode arrays from Cochlear™ and MED-EL separately. Pooling all electrode arrays, there was a significant ($p < 0.0001$) but very small effect favoring shorter electrode arrays (see Fig. 5). In regard to primary insertion into SV or ST and in regard to dislocated or non-dislocated electrode arrays, the models showed no higher or lower speech perception results (pooled and manufacturers separately).

Comparing the residual hearing of the different electrode arrays, expressed as PTA 2 (250 and 500 Hz), the tendency towards shorter electrode arrays in patients with better residual hearing can be seen (see Fig. 6). How the surgeon chooses the respective length of the electrode array should be examined further.

Discussion

Study, subject and cochlear morphology

This is the largest study ($n = 495$ ears) so far evaluating the influence of cochlear morphology and electrode array design on electrode array position. We measured the cochlear basal turn with a mean distance A of 9.92 mm and distance B of 6.74 mm (see Table 2). Once more, we can now confirm the data published so far [1, 2, 10]. Furthermore, this is the first study describing that the CA was more frequently implanted in smaller cochlea with less basal turn size (product of distance A and B) (see Fig. 1). The surgeon usually chooses the CA electrode array in patients without residual hearing to be as close to the modiolus as possible. Furthermore, the CA is usually not the first

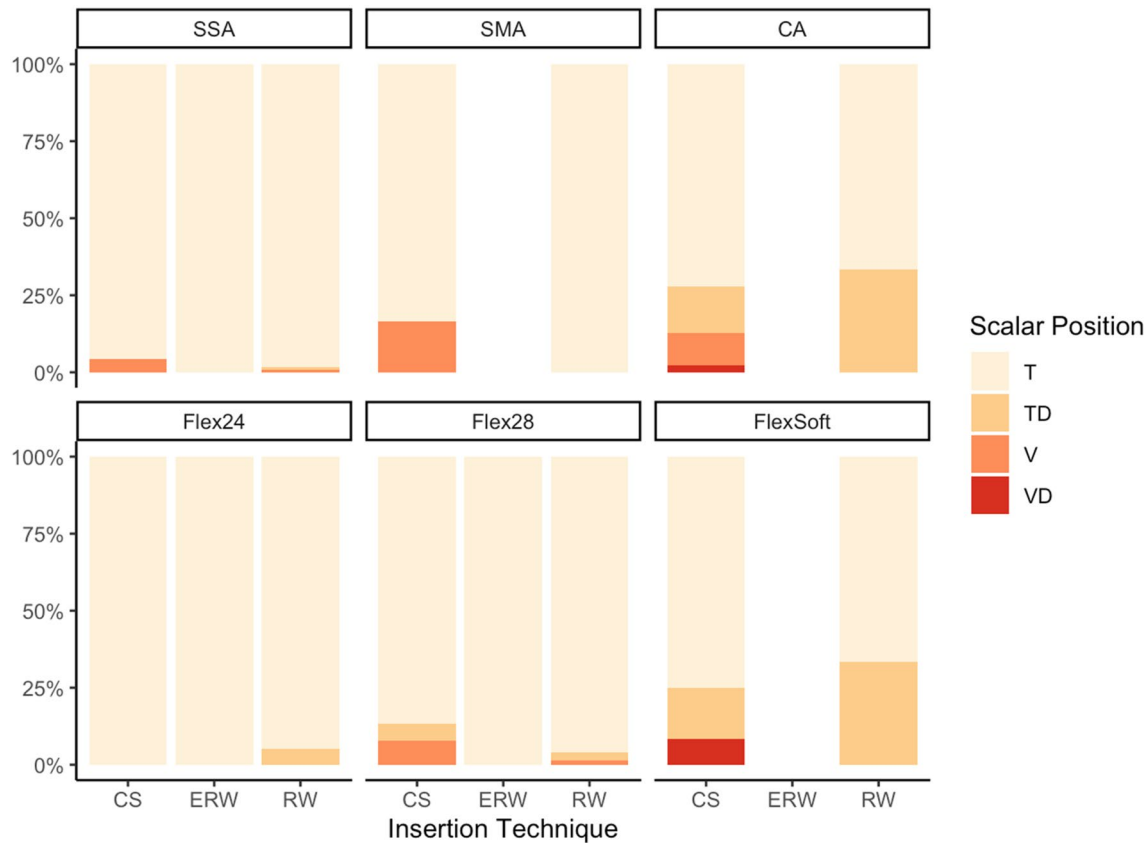


Fig. 3 Count of primary scala tympani insertions (T), dislocations out of ST (TD), scala vestibuli insertions (V) and dislocations out of scala vestibuli (VD) for each examined electrode array

electrode array choice to preserve residual hearing due to its rigidity and larger diameter.

Angular insertion depth and dislocation manner

We could measure specific angular insertion depth for each included electrode array (see Fig. 2). Previous studies [1, 2] showed that the angular insertion depth is dependent on the cochlear size. This work extends the earlier studies by defining electrode array-specific angular insertion depth, depending on both electrode array design and cochlear morphology.

This study demonstrates specific dislocation behavior of each examined electrode array (see Fig. 3). The electrode array with the highest rate of ST dislocations was the Flex^{Soft} array. The electrode array with the highest rate of SV insertions was the CA due to insertion via CS. Ketterer et al. [2] showed that dislocation depends on cochlear morphology and that a smaller cochlear height is a risk factor for SV insertion and dislocation for CS-inserted CA electrode arrays. Nevertheless, Aschendorff et al. [11] described individual learning curves of the surgeon and dislocation rates also depend on the surgeon's experience not only on electrode array design and cochlear morphology.

The SMA did not dislocate in any of the included patients in this study. Aschendorff et al. [12] described in a multi-center study that all patients ($n = 44$) implanted with the SMA from CochlearTM exhibited a complete ST insertion without dislocation in round window and cochleostomy approaches. We can now confirm that the SMA is the electrode array without any dislocation and seems to be very well designed for staying within the initial inserted cochlear scala.

We could show that the position of dislocation is electrode-design specific (see Fig. 4) and depends on electrode array design itself. The SSA has a stiff internal stylet and is a lateral wall array. Therefore, the dislocation point is more apical than the dislocation point of the perimodiolar CA. The CA is inserted via an Advance Off-StyletTM insertion technique and due to its preformed perimodiolar design the point when dislocation might happen is earlier and at approximately 180°. Further studies described the ascending cochlear basal turn at around 180° as sensitive for scalar dislocation [13–15]. Aschendorff et al. [7] speculated that perimodiolar electrode arrays may touch the outer cochlear wall at 180° while rotating with an upward

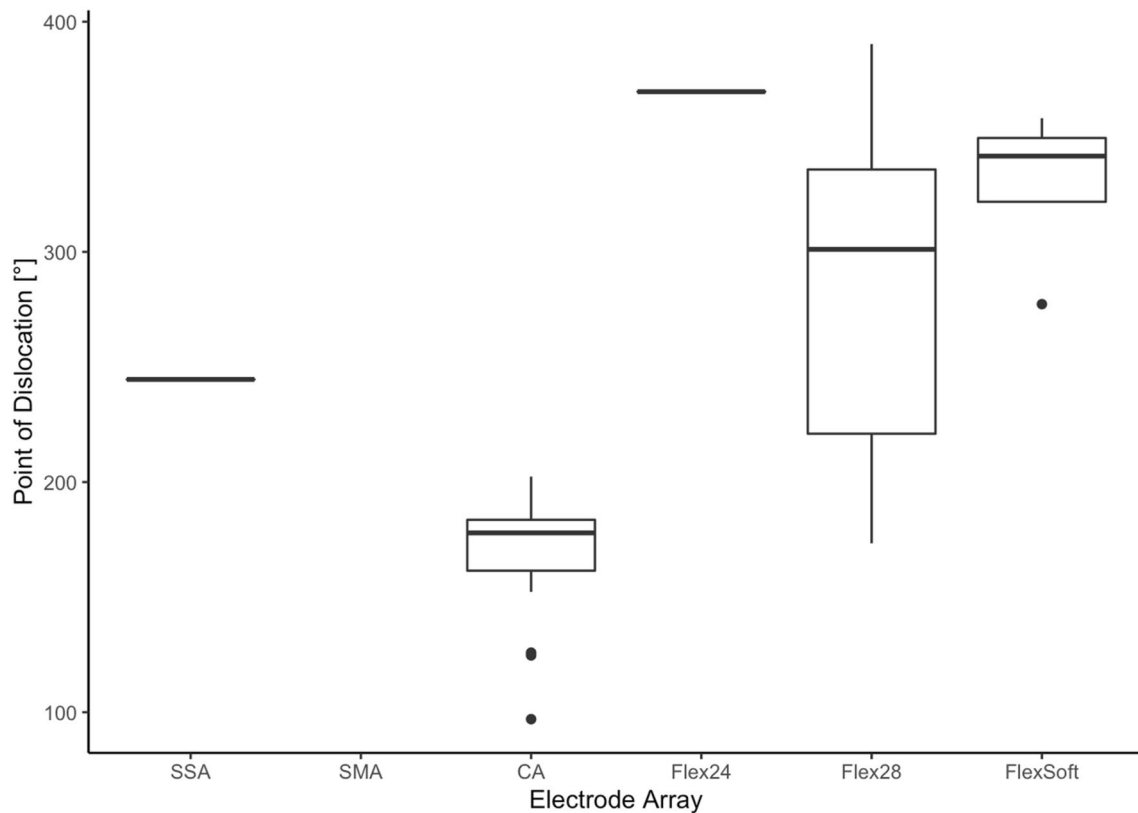


Fig. 4 The angle of dislocation is electrode-array-specific

direction and being pushed forward, resulting in perforation of the basilar membrane.

With a maximal active length of 25 mm (source: CochlearTM), the SSA is shorter than the straight Flex²⁸ and Flex^{Soft} and shows less insertion depth. MED EL electrode arrays do not have such a rigid internal stylet as the SSA. Therefore, the point of dislocation is higher in longer and more flexible MED EL Flex²⁸ and Flex^{Soft} due to their flexibility and trajectory. Furthermore, the height of the ST decreases within the ascending part of the basal turn towards the apical cochlear part [16]. Therefore, long electrode arrays like the Flex²⁸ and Flex^{Soft} showed increasing risk of dislocation in the apical cochlear part. The fact that the Flex²⁴ showed the highest dislocation point is interesting but since there was only one dislocated Flex²⁴ array further studies are required.

Boyer et al. [13] analyzed 61 CBCT scans of 54 patients. Eight perimodiolar electrode arrays and one straight electrode array were described as dislocated. The authors speculated that straight electrode arrays dislocate at approximately 370°, whereas perimodiolar electrode arrays dislocate at around 170°–190°. We can now confirm that the CA dislocates at approximately 170°, corresponding to the ascending part of the cochlear basal turn. Boyer et al. [13] compared only two groups: perimodiolar (CI 512 and CI24RECA)

versus straight (Flex^{Soft}, Flex²⁴, Flex²⁸ and Flex^{Standard}) electrode arrays. Whereas their defined perimodiolar group seems to be a homogeneous electrode array cohort ($n = 31$), the straight electrode array group ($n = 30$) is not only too small to define angular insertion depth and manner of dislocation but also inhomogeneous, comparing electrode arrays from MED-EL of different lengths and diameters. Furthermore, they neither excluded the CS-inserted electrode arrays nor calculated if there is a statistically relevant effect of RW versus CS or not. We examined the influence of the insertion location and can show that CS does not lead to higher dislocation rates or SV insertions in any of the included arrays. Boyer et al. and Wanna et al. [13, 17] described that straight electrode arrays are more often completely inserted within the ST and hypothesized that straight electrode arrays are more flexible due to the silicon density of the electrode array. Nevertheless, they did not exclude CS-inserted electrode arrays. Additionally, the CA electrode array, which was originally designed for CS approach, was inserted via RW. Rebscher et al. and Souter et al. [18, 19] described that the CA is only designed for CS due to the higher incidence of cochlear trauma in RW approach. They argued that the electrode array may be too close to the lateral wall, which might result in traumatic deflection. Therefore, the insertion of the CA via CS is recommended, even though RW insertions are

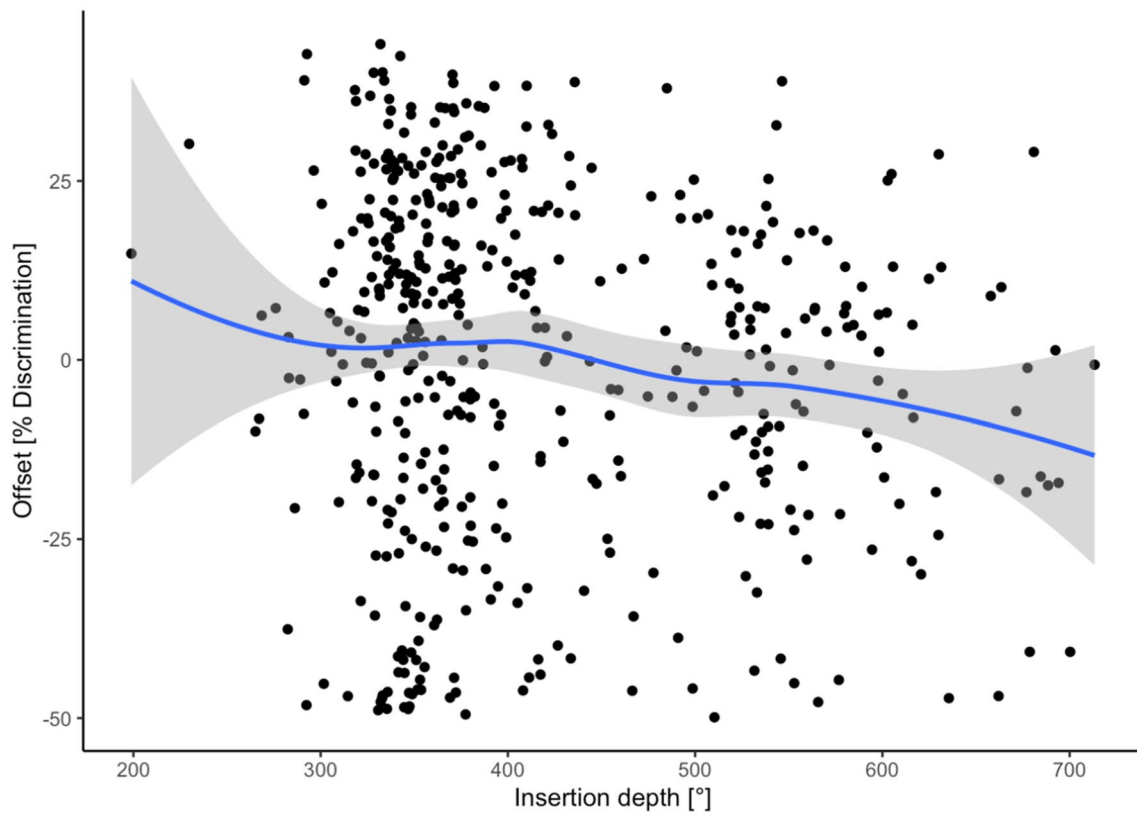


Fig. 5 Plotting individual speech discrimination versus the insertion depth shows a significant negative effect of deeper angular insertion with regard to speech discrimination. The y axis depicts the influence

of angular insertion depth as offset in speech discrimination compared to the model that does not comprise angular insertion depth as a factor

also possible in exceptions. Table 2 shows that with only a few exceptions, the included CA arrays of our study were not inserted via RW, but in 98% via CS. In conclusion, this study extends the previous knowledge of angular insertion depth, dislocation behavior and the influence of cochlear morphology. Furthermore, we could measure defined angular insertion depth and dislocation data of each included electrode array and could show that each electrode array has a specific position of dislocation.

Impact on speech perception

Electrode array design and its influence on speech perception is still a disputed topic. This study demonstrates that speech perception may be negatively influenced by the electrode array's angular insertion depth. Scalar dislocation has no significant impact on postoperative speech perception. Perimodiolar electrode arrays have been described as closer to the spiral ganglion cells with reduced spread of excitation [12, 20] and situated closer to the target spiral ganglion cells, therefore requiring lower stimulation levels than the lateral wall straight electrode arrays. That might provide better speech perception results [12]. Holden et al.

[6] reported that the position of electrode arrays closer to the modiolus was positively correlated with the outcome. Nevertheless, other studies reported lower speech discrimination levels for perimodiolar electrode arrays compared to straight electrode arrays [21, 22]. We did not observe different speech discrimination between the groups of perimodiolar and straight electrode arrays. But we could show that the number of dislocations and of SV insertions depends on the electrode array itself. Furthermore, this study demonstrates that the angular insertion depth negatively impacts on speech perception results. Previous studies showed different results examining the influence of angular insertion depth on postoperative outcome [23–26]. Finley et al. [5] examined 14 patients, implanted with a device from Advanced Bionics™, and reported that lower outcome scores are associated with greater angular insertion depth and greater number of contacts located in SV. They speculated that the scalar dislocation compromises neural pathways by damaging the basilar membrane and spiral ganglion. Holden et al. [6] ($n = 114$) described that the CNC final score was higher in patients with more electrodes located in ST compared to SV. Finley et al. and Holden et al. [5, 6] speculated that SV inserted electrode arrays can lead to pitch confusion and

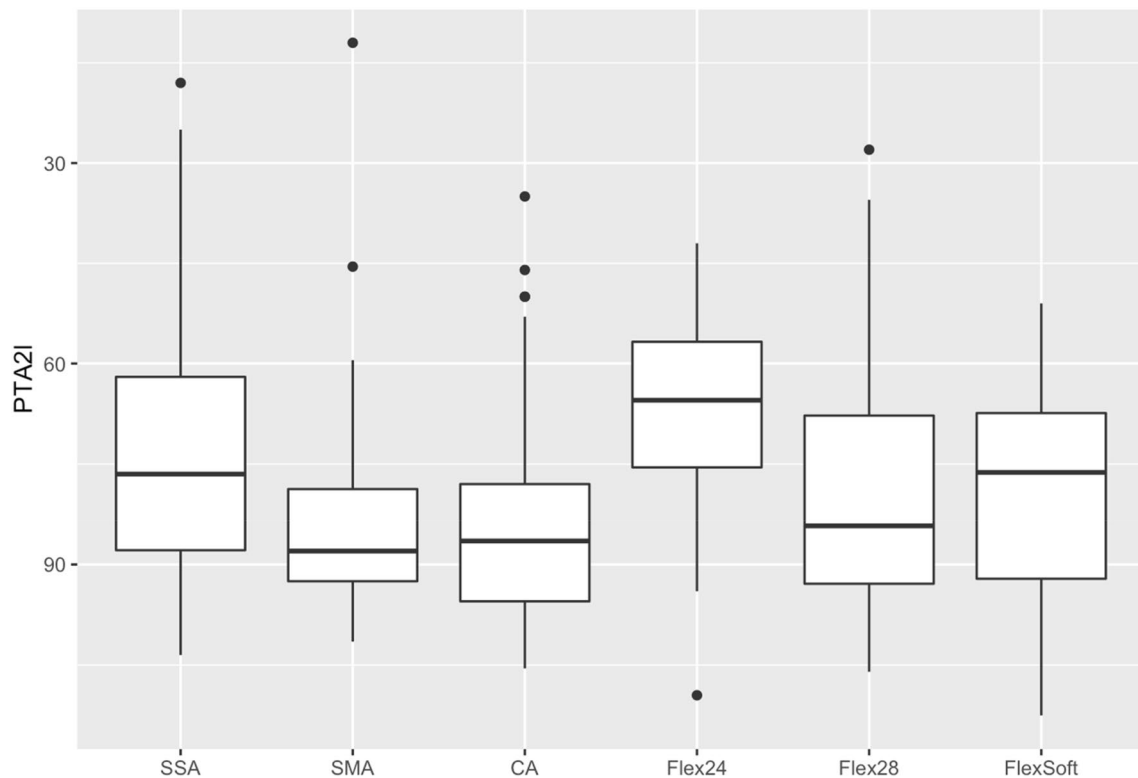


Fig. 6 Preoperative residual hearing levels expressed as PTA 2 (250 and 500 Hz) for each included electrode array

diminished speech recognition due to cross-turn stimulation, but included different types of electrode arrays and did not calculate their results electrode array-specific. Baskent and Shannon [27] examined MED-EL recipients and manipulated electrical stimulation via deactivation of apical electrodes. They described no further benefit for active electrodes over an angular insertion depth of 360° . James et al. [28] collected radiological data via computed tomography and described a negative correlation of angular insertion depth and speech recognition with statistical significance ($p < 0.001$) but detected a very weak correlation ($r^2 = 0.09$). However, they included only 96 patients with 9 different electrode arrays. We can now confirm their results regarding the negative impact of increasing angular insertion depth on speech perception in one of the largest cohort studies examining the influence of electrode array design on scalar location, dislocation and the position of dislocation. James et al. [28] described that less insertion depth is associated with better residual hearing preservation [29, 30]. We speculate that the negative correlation of speech perception with increasing angular insertion depth is due to cross-talk of the electric fields in the apical scalae. Nevertheless, there are also other factors to mention, such as the cochlear morphology. As the suspicious lack of publications shows, there is still a lot for speculation and discussion.

The included number of SMA and Flex^{Soft} arrays in this study was lower compared to the other included electrode arrays and therefore statistical analysis was more difficult. The dislocation rates and SV insertion rates via CS of the included CA group are lower in this study compared to previous studies [28]. Therefore, there might be a sampling bias regarding the influence analysis of scalar dislocation and SV insertion on speech perception results. Further research should be multi-centric to examine more of these electrode arrays. Nevertheless, in conclusion, this is the only study with statistical power and analysis of each electrode array separately, without the bias of electrode arrays differing with respect to length, diameter and rigidity.

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Author contributions MCK, M.D. and RB, M.D. analyzed data, provided statistical analysis and wrote the paper; the other co-authors provided critical revision.

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Declarations

Conflict of interest Manuel Christoph Ketterer and Rainer Beck declare no conflict of interest. Antje Aschendorff received travelling expenses and financial support for research from Cochlear Ltd, Australia; financial support for research and travelling expenses from Med-El, Innsbruck, Austria; financial support for research and travelling expenses from Oticon Inc., Somerset, NJ; financial support for research and travelling expenses from Advanced Bionics, Valencia, CA, USA. Susan Arndt received financial support for research and travelling expenses from Cochlear Ltd, Australia; financial support for research and travelling expenses from Med-El, Innsbruck, Austria travelling expenses from Advanced Bionics, Valencia, CA, USA. This study is not sponsored by industry.

Compliance with ethical standards Yes.

Research involving human participants No.

Ethics approval Approved by the Hospital's Ethics Committee according to the Declaration of Helsinki (Washington, 2002) (Number of Ethics Committee approval: 406/19).

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Correction to: Electrode array design determines scalar position, dislocation rate and angle and postoperative speech perception

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**Correction to: European Archives of
Oto-Rhino-Laryngology**
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In the original publication of the article, some values for the electrode arrays Flex²⁴ and Flex²⁸ (MED EL) have been interchanged in Tables 1 and 2 in the original manuscript. The authors apologize for that mistake. The correct Tables 1 and 2 are depicted below. The numbers used in the article itself were correct.

Table 1 Synopsis of study group (in total: $n = 495$)

Manufacturer (n)	Cochlear™: 327 MED-EL: 168
Electrode array (n)	Contour Advance (Cochlear™) (= CA): 143 CI 422/522/622 (Cochlear™) (= SSA): 162 CI 532/632 (Cochlear™) (= SMA): 22 Flex ²⁴ (MED- EL): 24 Flex ²⁸ (MED- EL): 129 Flex ^{Soft} (MED- EL): 15
Side (n)	Left: 259 Right: 236
Age	52.7 years (min: 18.0; max: 86.2)

The original article can be found online at <https://doi.org/10.1007/s00405-021-07160-2>.

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Table 2 Cochlear measurements (distance A and B), angular insertion depth, scalar position in total (SD = standard deviation) and distribution of the insertion technique

	Mean	SD	Minimum	Maximum
Distance A (mm)	9.92	0.86	7.4	12.2
Distance B (mm)	6.74	0.49	5.4	8.1
Insertion angle (°)	418.8	103.7	199	794
Scalar position in total (<i>n</i>)	ST: 434 (87.7%) TD: 32 (6.5%) SV: 25 (5%) VD: 4 (0.8%)			
Insertion technique in total (<i>n</i>) and percentage (%)	Electrode array CA (Cochlear™) SSA (Cochlear™) SMA (Cochlear™) Flex ²⁴ (MED-EL) Flex ²⁸ (MED-EL) Flex ^{Soft} (MED-EL)	CS 140/98% 47/29% 12/54.5% 4/16.6% 52/40.3% 12/80%	RW 3/2% 110/68% 10/45.5% 19/79.2% 72/55.8% 3/20%	ERW / 5/3% / 1/4.2% 5/3.9% /

CS cochleostomy, RW round window, ERW extended round window

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Radiological evaluation of a new straight electrode array compared to its precursors

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Abstract

Objective The aim of this study is to examine electrode array coverage, scalar position and dislocation rate in straight electrode arrays with special focus on a new electrode array with 26 mm in lengths.

Study design Retrospective study.

Setting Tertiary academic center.

Patients 201 ears implanted between 2013 and 2019.

Main outcome measures We conducted a comparative analysis of patients implanted with lateral wall electrode arrays of different lengths (F24 = MED-EL Flex²⁴, F26 = MED-EL Flex²⁶, F28 = MED-EL Flex²⁸ and F31.5 = MED-EL Flex^{Soft}). Cone beam computed tomography was used to determine electrode array position (scala tympani (ST) versus scala vestibuli (SV), intracochlear dislocation, position of dislocation and insertion angle).

Results Study groups show no significant differences regarding cochlear size which excludes influences by cochlear morphology. As expected, the F24 showed significant shorter insertion angles compared to the longer electrode arrays. The F26 electrode array showed no signs of dislocation or SV insertion. The electrode array with the highest rate of ST dislocations was the F31.5 (26.3%). The electrode array with the highest rates of SV insertions was the F28 (5.75%). Most of the included electrode arrays dislocate between 320° and 360° (mean: 346.4°; range from 166° to 502°).

Conclusion The shorter F24 and the new straight electrode array F26 show less or no signs of scalar dislocation, neither for round window nor for cochleostomy insertion than the longer F28 and the F31.5 array. As expected, the cochlear coverage is increasing with length of the electrode array itself but with growing risk for scalar dislocation and with the highest rates of dislocation for the longest electrode array F31.5. Position of intracochlear dislocation is in the apical cochlear part in the included lateral wall electrode arrays.

Keywords Cochlear implant · Electrode array · Dislocation · Scalar position · Cone beam computed tomography

Introduction

All manufacturers diversify their electrode array portfolio more and more regarding shape, size, diameter and flexibility to enable the personalized choice of the implant. The relationship between cochlear morphology, electrode array position and postoperative speech discrimination is of increasing interest. Aschendorff et al. [2] first

examined scalar position via rotational tomography for patients inserted with a Cochlear[®] Contour ($n = 21$) versus a Cochlear[®] Contour Advance[®] ($n = 22$) electrode array (Cochlear Ltd., Lane Cove, Australia) and reported significantly higher speech discrimination results for scala tympani (ST) compared to scala vestibuli (SV) position. Further studies confirmed the beneficial initial ST position [13, 39]. Rotational tomography, cone beam computed tomography (CB-CT) and high resolution computed tomography (HR-CT) are widely accepted tools for the evaluation of the electrode array position detecting tip-fold over, scalar deviation or electrode misplacement (e.g. [1, 2, 9, 14, 24, 42]). The methods have been validated by histomorphological studies that included imaging and sectioning (e.g. [1, 6, 17, 23, 27]). Ketterer et al. [24]

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analyzed 403 ears in CB-CT inserted with a Cochlear® Contour Advance® electrode array (Cochlear Ltd., Lane Cove, Australia) and described that the electrode array was more likely to dislocate within cochleae with smaller height and smaller diameter. There is some evidence of less frequent dislocation rates in lateral wall (LW) arrays than in precurved arrays (e.g. [5, 6, 9, 36, 45]). Although, a newly developed slim precurved electrode array demonstrated 0% dislocation in both temporal bone studies and human implantation [1]. As already known for precurved electrode arrays, Wanna et al. [45] also stated that for LW electrode arrays an electrode position entirely within the ST leads to superior audiological outcomes.

Some studies described shorter electrode arrays (e.g. the Nucleus Hybrid L24 electrode array with 16 mm length) as being sufficient for hearing preservation, but as being insufficient for optimal speech perception production via electrical stimulation due to a less focused stimulation and increasing channel interaction [15, 22, 26, 38]. Atraumatic insertion does not only depend on surgical skills and electrode array design, but also on individual cochlear duct lengths, anatomical abnormalities, the angle of insertion determined by anatomical trajectory to the round window, as well as cochlear heights that determines the spiraling of the lumen [9]. Therefore, manufacturers produce electrode arrays with different designs and length to best suit individual anatomy. MED-EL (MED-EL GmbH Innsbruck, Austria) designed and produces LW electrode arrays of different lengths (20–31.5 mm).

Cochlear coverage of the electrode array and its influence on postoperative outcome have been discussed in many previous studies. Long arrays with 28 mm length or more can be inserted deeply and have therefore higher coverage rates. They might have the ability to stimulate not even the cochlear basal turn but also the cochlear apex. Previous and recent studies have reported that greater depth of insertion is associated with better audiological results [1, 7, 20, 21, 32, 34].

The aim of this study is to evaluate retrospectively the new LW electrode array (Flex²⁶, MED-EL = F26) regarding scalar dislocation rate and electrode coverage compared to other LW electrode arrays with different electrode array lengths of the same manufacturer in correlation to cochlear size (Flex²⁴ = F24, Flex²⁸ = F28 and the Flex^{Soft} = F31.5; MED-EL G.m.b.H. Innsbruck, Austria). To the best of our knowledge, until now neither temporal bone nor human studies have been published to evaluate the new 26-mm long LW electrode array F26. This is the first study assessing the F26 electrode array regarding scalar position and dislocation behavior. Furthermore, to the best of our knowledge this is the first study evaluating the position of the dislocation in this type of LW electrode arrays.

Material and methods

Study and subject

We performed a retrospective analysis of adult patients implanted between 2013 and 2019 at the department of Otorhinolaryngology, Head and Neck surgery at the Implant Center of the University hospital Freiburg. HR-CT and magnetic resonance imaging (MRI) including contrast agent to exclude intrameatal or intralabyrinthine schwannoma have been conducted preoperatively. Patients with cochlear anomalies and signs of sclerosis were excluded of this study. Only patients inserted with a MED-EL Flex²⁴ (F24), MED-EL Flex²⁶ (F26), MED-EL Flex²⁸ (F28) and MED-EL Flex^{Soft} (F31.5) electrode array were included in this investigation. Electrode arrays have been chosen by different criteria as cochlear morphology, surgical preference and in cases of residual hearing shorter arrays have been inserted. Patient's sex, age, implanted side and cochlear size (distance *A* and *B* referring to Escudé et al. [11]) and product of the cochlear basal turn referring to Ketterer et al. [24] were analyzed. Partial inserted electrode arrays due to residual hearing have been excluded from this study resulting in a total of 6 patients (two patients with F28 and four with F31.5 electrode arrays) that have been excluded from further analysis.

Radiological and morphological evaluation

We evaluated the scalar location of the electrode array postoperatively in all patients by CB-CT (DynaCT-equipped Axiom Artis dTA angiography unit; Siemens Co., Erlangen, Germany) [2, 3]. All included electrode arrays were fully inserted. Two physicians analyzed the scans regarding scalar electrode position (ST versus SV insertion, intracochlear dislocation, insertion angle) and cochlear size (diameters in length and width referring to Escudé et al. [11] see Fig. 1) independently, and used Impax 6 by Agfa Healthcare for reconstruction. The insertion angle has been evaluated between distance *A* and the bloom artefact of the apical electrode as described before by Ketterer et al. [24] (see Fig. 1).

Statistics and ethics committee

We performed statistical analysis using Gnu R statistical computation and graphics system (ANOVA, Tukey's Honest Significant Difference; GNU R, Version 3.0.3, Core Team, Vienna, Austria, <https://www.R-project.org>). We calculated our results descriptively and the level of significance was set at 5.0%.

This study was conducted in agreement with the University of Freiburg Ethics Committee according to the

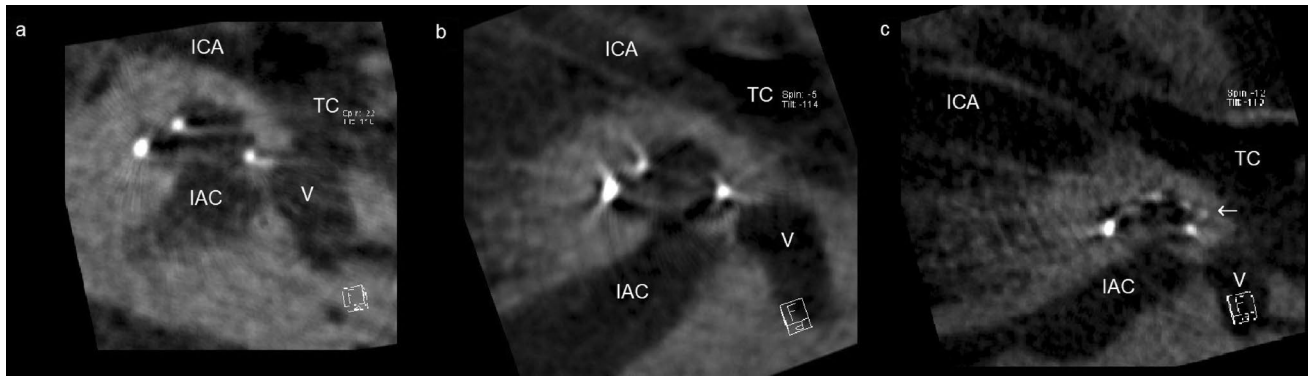


Fig. 1 **a** CB-CT image of the Flex26 inserted in scala tympani without any signs of dislocation. **b** Flex28 inserted in scala vestibuli via cochleostomy. **c** FlexSoft inserted in scala tympani with a dislocation

(arrow) to scala vestibuli. *ICA* internal carotid artery, *IAC* internal acoustic canal, *TC* tympanic cavity, *V* vestibulum)

Table 1 Distribution table of the study cohort and cochlear size measurements

	Mean	Standard deviation	Minimum	Maximum
Age (years)	55.0	16.4	18	83.4
Distance <i>A</i> (mm)	10.4	0.6	8.7	12.7
Distance <i>B</i> (mm)	6.9	0.4	5.6	8.1
Product <i>A</i> × <i>B</i> (mm ²)	72.2	7.3	54.3	99.1

declaration of Helsinki (Washington, 2002) (Number of ethic committee approval: 406/19) and registered on German Clinical Trials Register (<https://www.drks.de/DRKS00019807>).

Results

Study cohort

Altogether we included 201 ears implanted between 2013 and 2019. We identified 99 left and 102 right cochleae. The mean age was 55 years. Tables 1, 2 and 3 shows the distribution of the study cohort. For analyzing electrode array design and position cochlear size must be included into the assessment to assemble the final insertion of the electrode arrays independently of cochlear size. No significant difference in cochlear size (distance *A* and *B* established by Escudé et al. [11] and cochlear basal turn product of distance *A* and distance *B* established by Ketterer et al. [24] see Fig. 2) was detected between our four defined electrode array groups, so that eventually there is no influence of the cochlear morphology on the described cochlear coverage.

Table 2 Distribution of the included electrode arrays in total and percentage and their surgical management (cochleostomy versus round window insertion)

Distribution total	F24	<i>n</i> = 28 (13.8%)
<i>n</i> = 201	F26	<i>n</i> = 15 (7.5%)
	F28	<i>n</i> = 139 (69.2%)
	F31.5	<i>n</i> = 19 (9.5%)
Side	Left: 99	Right: 102
Inserted via	Round window: 110 in total (54.7%)	Cochleostomy: 91 in total (45.3%)
	F24: 8 (28.5%)	F24: 20 (71.5%)
	F26: 4 (25%)	F26: 11 (75%)
	F28: 64 (46%)	F28: 75 (54%)
	F31.5: 15 (78.9%)	F31.5: 4 (21.1%)

Table 3 Included electrode arrays (F24 = MED-EL Flex²⁴, F26 = MED-EL Flex²⁶, F28 = MED-EL Flex²⁸ and F31.5 = MED-EL Flex^{Soft}) and their dislocation behavior (T = scala tympani; TD = dislocation out of the scala tympani; V = scala vestibuli; VD = dislocation out of the scala vestibuli)

	T	TD	V	VD	Total
F24	27 (96.43%)	1 (3.57%)	0	0	28 (100%)
F26	15 (100%)	0	0	0	15 (100%)
F28	125 (89.93%)	6 (4.32%)	8 (5.75%)	0	139 (100%)
F31.5	13 (68.42%)	5 (26.32%)	0	1 (5.26%)	19 (100%)

Cochlear coverage

Figure 3 shows the mean insertion angle for each included electrode array. As expected, within the study cohort the F24 showed significant different coverage compared to the longer electrode arrays F28 and F31.5 ($p < 0.0001$). Surprisingly we could not find significant different coverage

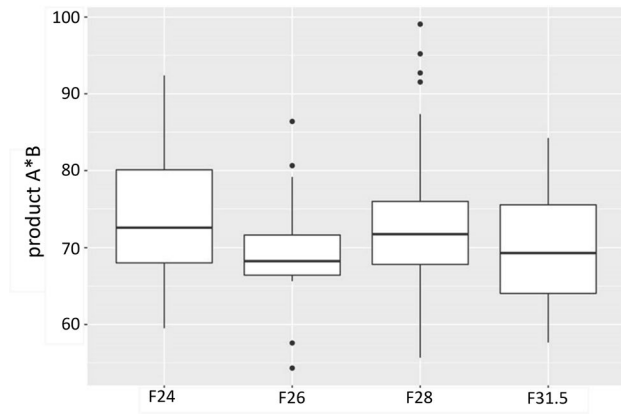


Fig. 2 Distribution of the expanse of the cochlear basal turn (product of distance *A* and *B* [11] for each electrode array separately ($p > 0.05$). There is no significant difference regarding cochlear size between the included electrode array groups

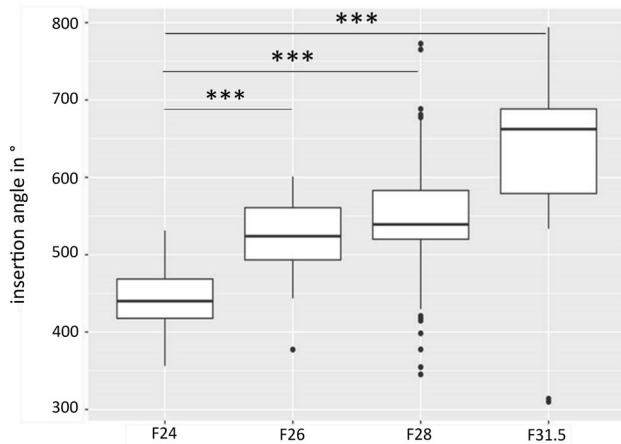


Fig. 3 Insertion angle for each included electrode array. Statistical difference could have been found between all electrode arrays (all $p < 0.008$), except F26 versus F28 ($p = 0.422$)

Table 4 Electrode array coverage (in °)

	Mean	Standard deviation	Minimum	Maximum
F24	443.3	43.9	356.1	531.2
F26	517.0	60.36	377.4	601.0
F28	546.8	68.0	354.3	772.8
F31.5	616.7	124.4	309.9	794.1

between the F26 and F28 group ($p = 0.42$) (see Table 4: electrode array coverage). As mentioned before, the cochlear size comparing the F26 and F28 group was not significantly different.

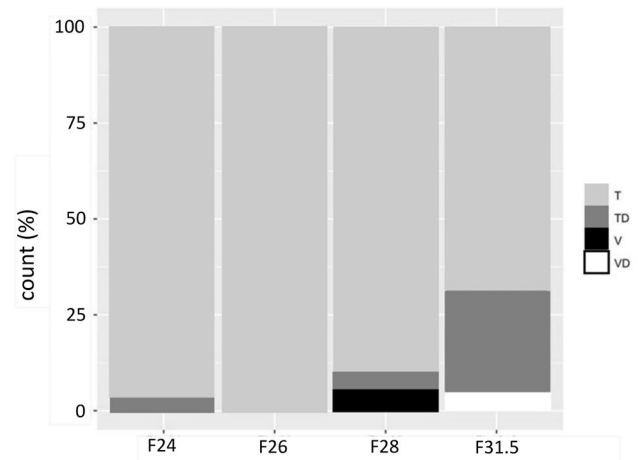


Fig. 4 Electrode array position for each included electrode array (T=scala tympani; TD=tympani dislocation; V=scala vestibuli; VD=vestibuli dislocation) (see also Table 3/counts, total and percentages)

Dislocation rates and the position of dislocation

No scalar dislocation or SV insertion was present for the new LW electrode array F26 (Table 3). The electrode array with the highest rate of scalar dislocations (27.78%) was the F31.5. The F28 showed 4.58% dislocated electrode arrays and the F24 showed only one dislocation (3.57%) (see Fig. 4). Both, round window and cochleostomy insertions have been performed in all electrode array specific subgroups (see Table 2). Comparing the study cohorts of cochleostomy versus round window inserted electrode arrays we could find 10 dislocations (F24; F28; F31.5) and 8 SV insertions (F28) for cochleostomy inserted electrode arrays (Table 3). For round window insertions a dislocation from ST to SV was detected in two cases (F28 and F31.5). In all cases of round window insertions, we detected a primary ST insertion. Most of the LW electrode arrays in the present study dislocated between 320° and 360° (see Fig. 5).

Discussion

Study cohort and cochlear coverage

Cochlear implantation focuses on reducing trauma during insertion to preserve residual hearing and prevent scarring. Appropriate cochlear electrode array design including electrode array length resulting in less traumatic surgical techniques is particularly important in this respect [10]. To the best of our knowledge, this is the first study evaluating the scalar position of the new LW F26 electrode array by MED-EL. Furthermore, we detected the specific position of dislocation in LW electrode arrays in the largest study

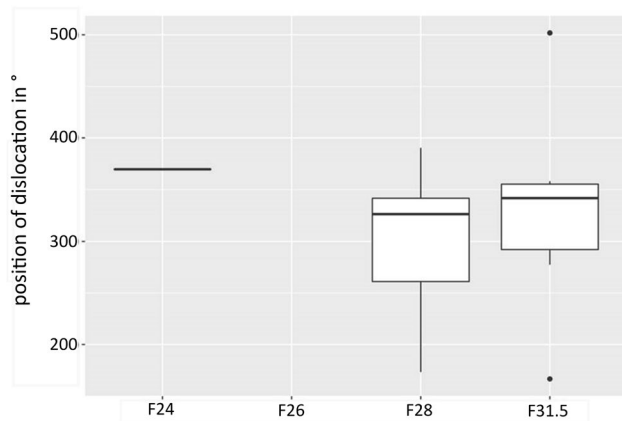


Fig. 5 Position of intracochlear electrode array dislocation in ° for each included electrode array. The F26 showed no dislocations (mean total: 346.4°; mean F24: 360°; mean F28: 335°; mean F31.5: 344°)

cohort evaluated so far with 201 implanted ears. In the present study, cochlear sizes of all four electrode array design groups did not show significant differences so that a direct comparison of the four groups is ensured. Previous literature described cochlear coverage in average-sized models [8] and reported that angular insertion depth depends on both electrode array length and cochlear size. Ketterer et al. [24] demonstrated significant differences in human cochlear morphology. Though, electrode array comparisons are valid, because the examined electrode array groups included in this study do not differ regarding cochlear size.

Dislocation rates

This study demonstrates significant different dislocation behavior of the included LW electrode array designs. The shorter F24 and the new straight electrode array F26 show less (F24: $n=1$) or no signs (F26) of scalar dislocation or SV insertion, neither for round window inserted nor via cochleostomy inserted electrode arrays. Nordfalk et al. [30] and O'Connell et al. [33] also found no scalar dislocation of the F24. Nevertheless, the cohorts of the aforementioned studies [30, 33] were considerably smaller.

The electrode array with the highest rate of dislocations in our study was the F31.5 electrode array (26.3%), which is the longest array in the present study. Most of the studies that examined the F31.5, did not find and describe dislocations for this certain array ([5], F31.5 $n=9$) or did not analyze their data for dislocations at all ([4], F31.5 $n=8$). Comparing the published CB-CT images and the used flat panel detector of Boyer et al., the CB-CT used in this study provides higher resolution and we also included 19 instead of 9 F31.5 inserted patients [5].

Recent reviews [8, 9] of 26 articles, described the incidence rate of scalar dislocations for 21 different electrode

arrays of five different manufacturers (Advanced Bionics, Valencia, CA, USA, Cochlear Ltd., Lane Cove, Australia; MED-EL GmbH Innsbruck, Austria; Advanced; Oticon Inc., Somerset, NJ and Nurotron Biotechnology Co. Ltd. Hangzhou, China). While a total of 424 ears implanted with precurved electrode arrays showed scalar dislocation (incidence rate: 32%), LW electrode arrays accounted to a total number of scalar dislocation rate of only 6.7% (34/507) [9]. This data is in line with the results for LW electrode arrays of our study (this study: 5.97% of ST dislocations in the total study cohort/see Table 3).

Regarding the reported 21.6% dislocation rates of the Cochlear® Contour Advance® electrode array by Ketterer et al. [24], the straight F31.5 (dislocation rate: 26.3%) in the present study and the precurved Contour Advance® electrode array are the electrode arrays used and analyzed nowadays with the highest rate of dislocations. Both have wider basal diameter and are more rigid than shorter electrode arrays designed within the last years. Aschendorff et al. [1] described that all patients ($n=44$) implanted with the new slim precurved electrode array (CI 532) of Cochlear™ exhibited a complete ST insertion without dislocation in round window and cochleostomy approaches. Nevertheless, surgeons shall be careful with over insertion and tip-fold overs [1]. Therefore, we hypothesize that in LW as well as in precurved electrode arrays slim and more flexible electrode array design significantly reduces cochlear trauma and scalar dislocation.

The design of the electrode array and the influence of scalar position and dislocation on preserving residual hearing are still disputed. Nordfalk et al. [31] found a loss of residual hearing in patients with traumatic intracochlear dislocation using the PTA method of Helbig et al. [18]. Nevertheless, they did not have the statistical power to show significances and included only 13 patients with five different electrode arrays. Previous studies showed that the success of preserving residual hearing depends on intracochlear damage [25]. Soda-Merhy et al. [40] compared straight and perimodiolar electrode arrays at residual hearing rates across frequencies and described no significant difference. Nonetheless, some studies reported a higher loss of residual hearing in straight electrode arrays with increasing angular insertion depth [33]. Furthermore, the influence of the insertion technique comparing round window versus cochleostomy on residual hearing is still part of CI research discussion. Even though, Hassepass et al. [16] described no significant difference for the insertion technique evaluating the straight electrode array of a different brand (Cochlear™).

This study is the first study showing that straight electrode arrays dislocate at approximately 360° within the second cochlear turn, whereas studies published before [5] described the position of dislocation in perimodiolar arrays at 180° within the cochlear basal turn. Therefore, further

prospective studies are necessary to evaluate the influence of cochlear dislocation within the second turn in straight arrays inserted via round window versus cochleostomy on the preservation of residual hearing.

The position of dislocation

Most of the included LW electrode arrays in the present study dislocated between 320° and 360°. Boyer et al. [5] analyzed 61 CB-CT scans of 54 patients (31 ears with a perimodiolar versus 30 ears with a LW electrode array) and reported of eight perimodiolar electrode arrays with a dislocation from ST to SV. The different LW electrode array designs evaluated in their study (MED-EL F24, F28, F31.5 (=Flex^{Soft}) and Flex^{Standard}), showed only one dislocation from ST to SV, which was one from the longest LW electrode array design cohort (Flex^{Standard} length: 31.5 mm) [5]. The Flex^{Standard} and F31.5 both have the same length of 31.5 mm but differ in design and flexibility. Boyer et al. [5] speculated that with precurved arrays, dislocation usually occurs in the ascending part of the basal turn of the cochlea [5]. The LW electrode array dislocated at approximately 370° in their study, whereas perimodiolar electrode arrays dislocated at around 170°–190° [5]. Our investigation confirms their assumption (see Fig. 4) and extends the previous knowledge of LW electrode array coverage and dislocation behavior with a higher number of implanted arrays. Since the cochlear sizes of the presented electrode array groups are comparable, we assume that the position of dislocation is design specific in LW electrode arrays of the included manufacturer. In this respect, the surgeon should keep this in mind during insertion to prevent dislocations. For future surgeries, we recommend measuring cochlear size in diameter preoperatively to choose the best fitting electrode array primarily in terms of cochlear size even if residual hearing, preference of the patient, anatomy and underlying medical (ear) conditions influence the decision. Instruments like the Otoplan® planning software by MED-EL have been established in the last years to assist the surgeon in measuring the cochlear and to find the best fitting array. These measurements and demonstration of the results to the patient can also help to bring the issue to the attention of the patient prior to CI surgery.

Limitations of the study

A limitation of this study is that the F26 inserted patients recently got implanted and therefore reliable and comparable postoperative speech discrimination results are pending. Further studies should evaluate the influence on long-term postoperative speech perception and hearing preservation. A follow-up comparison will extend the knowledge about the F26 and its dislocation behavior by outcome results.

Conclusion

This is one of the first studies evaluating the new straight electrode array F26 which shows no signs of scalar dislocation and intracochlear trauma, neither for round window nor for cochleostomy inserted electrode arrays compared to its precursors. The most frequent scalar dislocations occur in the longest electrode array designs. Scalar dislocations in LW electrode arrays occur at a predetermined angle at approximately 320°–360°.

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Author contributions MCK and FH analyzed data, provided statistical analysis and wrote the paper; the other coauthors provided critical revision. AA and SA performed the surgeries and provided surgical expertise.

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Compliance with ethical standards

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Incomplete partition type III revisited—long-term results following cochlear implant

Introduction

Incomplete partition type III (IP III) is a rare syndrome that causes deafness, and patients often present with symmetrical progressive mixed hearing loss or deafness [9, 11, 20] as a result of increased perilymphatic pressure [2, 13]. The syndrome is characterized by a shortened cochlea, a dilatation of the internal auditory canal (IAC) and a missing bony separation between the basal turn of the cochlea and the IAC [1, 10, 13]. Stapes fixation and a conductive component have been reported in most cases due to the absence of partitioning bone between the lateral IAC and the cochlea and therefore the communication between perilymphatic and cerebrospinal fluid (CSF) [11, 13, 18]. Violating the otic capsule via stapedectomy or cochleostomy results in a profuse CSF gusher [12, 14] and worsening of the sensorineural hearing loss [4].

As a consequence of the missing bony separation, a cochlear implant (CI) may result in an incorrect insertion of the electrode array into the IAC [1] without auditory stimulation but the risk of facial nerve injury or facial nerve stimulation [4]. Furthermore, CI may result in continuous and persistent CSF leak and an increased risk of CSF rhinorrhea, meningitis and intracranial infections [13, 17].

For these reasons, CI has been controversially discussed in IP III patients [11, 12, 18]. Aschendorff et al. [1] reported the benefit of controlling the insertion via intraoperative three-dimensional volume tomography (DVT) to avoid incorrect placement of electrode arrays. Some case reports and series have been published over the last 10 years and reported successful surgical procedures and hearing rehabilitation after CI [4, 8, 13, 14, 17, 18]. Studies analyzing implanted IP III patients are rare. No data are available as yet with regards to audiological long-term outcome, mapping parameters (T- and C-level, pulse width) and electrophysiological data (electric compound action potentials [ECAPs], impedances) in implanted patients with this particular cochlear malformation.

Methods

Study design and subjects

A retrospective chart analysis was performed to identify IP III patients implanted between 1999 and 2014 at the University Medical Centre Freiburg, Department of Otorhinolaryngology—Head and Neck Surgery, Freiburg, Germany. Each IP III patient was matched with three implanted patients, each with normal cochlear morphology regarding sex, age, side, implant type and surgical date. Matched CI candidates were selected out of an anonymized pool to reduce selection bias. Audiological

speech discrimination results (Freiburger monosyllabic word test = FBMS, Oldenburger sentence test for adults = OLSA and Göttingen audiometric speech test for children) and mapping results (C-/T-level and pulse width [PW]) at first fitting (4–6 weeks after CI), after 1 and 3 years, thresholds of intraoperative electrically evoked stapedius reflexes, intra- and postoperative ECAP thresholds (electrically evoked compound action potentials) and electrode impedances between IP III patients and the control group with normal cochlear morphology were compared. The electric load was calculated based on the formula published by Cohen [3] with the T-level and pulse width. Only patients implanted with a CI24RECA or a CI512 were included in this calculation, since the formula according to Cohen [3] is not validated for electrode arrays older than the CI24M [3].

Statistical analysis

Statistical analysis was performed with SPSS (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 24.0, Armonk, NY: IBM Corp.). Results were calculated descriptively and are shown in the text and in tables as mean, standard deviation, maximum and minimum. All comparisons between pre- and postoperative measures were computed using the Wilcoxon test for paired observations. The comparison between IP III patients and patients with normal

The German version of this article can be found under <https://doi.org/10.1007/s00106-019-00733-y>.

Table 1 Synopsis for the study group

	IP III	Match	Total
Patients	9 (one excluded from further analysis)	27	36
Sex	Male: 8 Female: 0	Male: 27 Female: 0	Male: 36 Female: 0
Side	Left: 6 Right: 2	Left: 21 Right: 6	Left: 28 Right: 8
Implant type (all Cochlear™)	CI24RECA: 5 CI24M (custom made): 2 CI 512: 1	CI24RECA: 15 CI24M: 9 CI 512: 3	CI24RECA: 20 CI24M (custom made) and CI24M: 12 CI 512: 4
Number of surgeons	4	4	4
Revisions	1 (IAC insertion)	0	1

IAC internal auditory canal, CI cochlear implant

Table 2 Results for IP III patients vs. patients without cochlear malformation (matching group)

	IP III	Match	Total
<i>a)</i>			
OLSA (1 year) for adults	33 ± 26.2 min: 5 max: 57	48.3 ± 33.7 min: 12 max: 100	43 ± 30.7 min: 5 max: 100
OLSA (3 years) for adults	39.3 ± 21.6 min: 22 max: 70	63.7 ± 29.3 min: 19 max: 100	54.8 ± 28.25 min: 19 max: 100
Göttingen audiometric speech test for children (3 years)	56 ± 18.2 min: 40 max: 80	68 ± 23.9 min: 10 max: 90	65 ± 22.82 min: 10 max: 90
<i>b)</i>			
T-level in CL (first fitting)	122.8 ± 40.1	101.6 ± 39.6	104.9 ± 40.5
C-level in CL (first fitting)	159.6 ± 45.4	146.7 ± 41	148.5 ± 41.9
PW in µs (first fitting)	33.1 ± 10.7	25 ± 0	27 ± 6.3
T-level in CL (1 year)	146.1 ± 26.62	129.8 ± 31.9	132.4 ± 31.3
C-level in CL (1 year)	194.4 ± 19.4	183.7 ± 24.9	184.1 ± 24.2
PW in µs (1 year)	35.9 ± 12.1	25.5 ± 2.3	28.8 ± 8.5
T-level in CL (3 years)	138.3 ± 19.9	129.3 ± 24.5	128.6 ± 23.9
C-level in CL (3 years)	187.5 ± 17.2	181.4 ± 22.9	182.9 ± 21.6
PW in µs (3 years)	67.6 ± 37.6	26 ± 3.2	36.3 ± 25.8

a) Means ± SD for Oldenburger sentence test (OLSA) for adults comparing IP III patients and the matching group 1 and 3 years after implantation and for the Göttingen audiometric speech test for children 3 years postoperatively

b) Means and standard deviation (SD) (mean ± SD) for T-/C-levels in clinical units (CL) and pulse width (PW) in µs for IP III patients versus patients with normal cochlear morphology and in total for the first fitting, after 1 year and after 3 years

IP III incomplete partition type III, *min* minimum, *max* maximum

cochlear morphology was calculated with the Levene test to define homo- versus heterogeneous variance and the T-test to define statistically significant differences. Bivariate correlations were assessed using the Pearson test. The level of significance was set at 5.0% for all tests.

Ethics committee

This retrospective study took place in the department of Otorhinolaryngology, Head and Neck surgery of the University Hospital Freiburg, Germany. The study was approved by the Hospital's Ethics Committee (number: 319/18) according to the declaration of Helsinki (Washington, 2002) and is registered in the German Clinical Trials Register (www.drks.de/DRKS00016355).

Results

Study and subject

A total of 9 male IP III patients were implanted between 1999 and 2014 at the department of Otorhinolaryngology, Head and Neck surgery of the University hospital Freiburg. One patient did not want to sign the declaration of consent, while the other eight patients were included in this study (■ **Table 1**). Their mean age was 25.7 years (7–56 years). Two children and six adult patients were included. Both IP III children showed signs of mental retardation.

All patients were identified radiologically. The typical anatomy of IP III was observed independently on computed tomography (CT) and magnetic resonance imaging (MRI) in all patients by two radiologists and the ear, nose and throat (ENT) surgeon (see ■ **Fig. 1a**). Patients were followed for a mean of 9.1 years (range: 5–19 years). The hearing loss in IP III patients was identified in early childhood and was progressive in all cases. All patients used hearing aids bilaterally until CI.

All patients were implanted with a Nucleus Cochlear™ Implant (Cochlear™ Limited, Australia) via cochleostomy. Three different types of perimodiolar electrode arrays were implanted (perimodiolar cus-

tom made CI 24M, CI 24 RE CA, CI 512) (see [Table 1](#)). Three IP III patients underwent sequential bilateral implantation. For adequate results, data for the first implanted side were considered in this study. All unilaterally implanted patients continued to use a contralateral hearing aid for bimodal stimulation.

Surgical procedure

In all, 11 surgical procedures were analyzed. Three IP III patients underwent sequential bilateral implantation. Surgeries were performed by four different surgeons under general anesthesia including facial nerve monitoring. After performing the mastoidectomy and posterior tympanotomy through the facial recess, the promontory and the round window could be identified. Stapes fixation was found in all cases during surgery. An anterior and somewhat superior cochleostomy was performed to improve the implant trajectory angle and to avoid insertion into the IAC. A profuse CSF gusher was observed in all cases. The electrode array was inserted following suctioning of CSF and optimization of patient position to control the insertion. Muscle and fascia harvested from the temporalis muscle were used to seal the cochleostomy after insertion. No lumbar drainage was used intra- or postoperatively in any of the cases. Mild CSF rhinorrhea, which stopped following conservative measures, was observed in two patients. Intraoperative measurements of stapedius reflexes and electrode impedances were performed. Two patients were implanted with a CI 24M, so that auditory response telemetry was only applicable in six cases. Patients received either X-ray imaging, CT ([Fig. 1b, c](#)) or DVT intraoperatively to confirm the correct electrode positioning within the cochlea. One IP III patient exhibited IAC insertion of the electrode array postoperatively and underwent revision ([Fig. 1b](#)).

Audiological outcome

Patients followed the usual postoperative rehabilitation schedule (>3 years in adults and >5 years in children), with

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Incomplete partition type III revisited—long-term results following cochlear implant

Abstract

Background. Incomplete partition type III (IP III) is defined by a missing lamina cribrosa between the cochlea and the internal auditory canal (IAC). Cochlear implantation (CI) may result in an insertion of the electrode array into the IAC. The aim of this study is to evaluate CI surgery protocols, long-term audiological outcome, mapping and electrophysiological data after CI in IP III patients.

Materials and methods. Nine IP III patients were implanted with perimodiolar electrode arrays between 1999 and 2014; eight of them were included in this study. We evaluated mapping data, stapedius reflexes, electrode impedances and ECAP thresholds. We matched them with 3 CI patients each with normal cochlear morphology regarding sex, age, side, implant type and surgical date. Speech discrimination was evaluated with the Oldenburger sentence test for adults, Göttingen audiometric speech test for children and the Freiburger monosyllabic word test.

Results. 3 years after CI IP III patients showed a significant increase in pulse width, calculated electric load and electrode impedances in basal electrodes. Intraoperative electrically-evoked stapedius reflexes could be measured in all patients. Speech recognition scores were lower than average scores for matched patients, but without statistical significance.

Conclusions. The significant increase of pulse width, electric load and electrode impedances of basal electrodes over time seem to be characteristic for IP III patients probably occurring due to fibrosis and neurodegeneration of the cochlear nerve. The long term audiological results are stable. Intraoperative imaging and stapedius reflexes are highly recommended to control the right position of the electrode array.

Keywords

Mapping · Cochlear implant · Mapping data · Incomplete partition type III · Longterm results

continuous follow-up once a year at the Implant Center Freiburg. To distinguish speech perception results in children and adults, the FBMS and OLSA were performed in adults 1 and 3 years after implantation and the Göttingen audiometric speech test for children 3 years after implantation. Adult IP III patients showed lower OLSA scores 1 and 3 years postoperatively (see [Table 2](#)). No statistically-significant difference ($p = 0.15$) was found for implanted IP III adults compared to their matching group regarding the OLSA scores 1 and 3 years after implantation. Furthermore, there was no significant difference ($p = 0.486$) for speech perception 3 years postoperatively for implanted IP III children compared to their matching group (see [Table 2](#)). Significantly increased results were detected for the FBMS for IP III and matched patients 1 and 3 years after implantation compared to preoperative results. Nonetheless, a significant difference for monosyllabic word test results

was detected neither 1 nor 3 years after CI between those two groups ($p > 0.05$).

Mapping data, electrode impedances, ECAP thresholds and intraoperative stapedius reflexes

Mapping data for the first fitting showed no significant difference between the implanted IP III patients and their matching cohort (T-levels $p = 0.146$) (C-levels $p = 0.401$) (see [Fig. 2](#)). Pulse width was higher in IP III patients (see [Table 2](#)), but without statistical significance ($p = 0.054$). The calculated electric load based on the formula of Cohen [3] was different between IP III and matched patients, but without statistical significance ($p = 0.054$). At 1 year postoperatively, pulse width was significantly higher ($p = 0.011$) in IP III patients compared to data at first fitting ([Fig. 3](#)). Furthermore, the calculated electric load was significantly higher in IP III patients 1 year after CI ($p = 0.049$). At 3 years

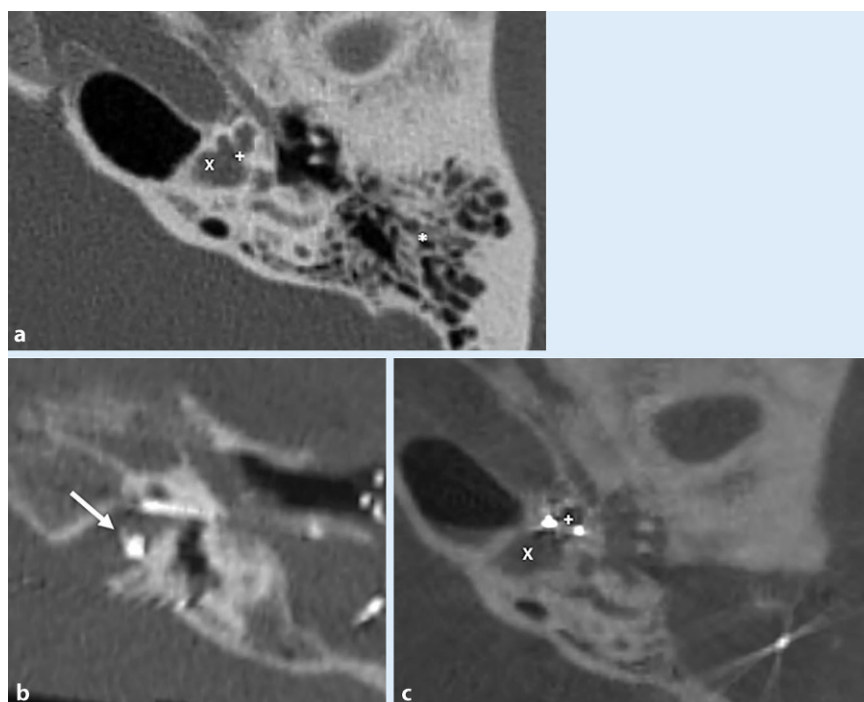


Fig. 1 ▲ Pre- and postoperative computed tomography (CT) and digital volume tomography (DVT) scans in incomplete partition type III patients. **a** Preoperative CT scan showing the cochlear basal turn (+) and the missing bony separation between cochlear basal turn and dilated internal auditory canal (IAC) (X). Asterisk = Mastoid. **b** Postoperative DVT scan with the electrode array dislocated in the IAC (arrow). **c** Postoperative DVT scan with the electrode array within the cochlear basal turn (+), missing lamina cribrosa and the IAC (X)

following CI, pulse width ($p = 0.01$) and electric load ($p = 0.002$) (■ Fig. 4) were significantly greater in IP III patients.

Electrode impedances were measured in mode MP1 + 2. No significant difference could be found for the averaged electrode impedances between IP III and matched patients 4 weeks after implantation (mean: $11.5 \text{ k}\Omega \pm 4 \text{ k}\Omega$ for IP III versus mean: $9.9 \text{ k}\Omega \pm 3.7 \text{ k}\Omega$ for matched patients). However, IP III patients showed significantly larger electrode impedances 1 year ($p = 0.018$) and 3 years ($p = 0.013$) after implantation compared to their matched patients (see ■ Fig. 5).

Neural response telemetry was applied in six IP III patients intra- and postoperatively. In three IP III patients, ECAP thresholds could not be obtained for each of the 22 electrodes. The other three subjects showed ECAPS in only 2–4 out of 22 electrodes. AutoNRT in matched patients yielded typical ECAPS for all assessed electrodes. Intraoperative stapedius reflexes could be obtained in seven out of eight IP III patients.

Stapedius reflexes were detected in those seven IP III patients for the most apical electrode 22. One patient underwent revision and then exhibited stapedius reflexes in the electrode 16.

Discussion

Surgical approach, gushers and CSF leakage management

The middle ear was reached via a conventional postauricular transmastoid approach and posterior tympanotomy. After opening the facial recess, the round window niche and the promontory were detected. The course of the facial nerve and the chorda tympani were unremarkable and no anatomical abnormalities of the middle ear could be detected in seven out of eight patients. One patient showed an aberrant route of the facial nerve as described by Aschendorff et al. [1]. While Smeds et al. [17] could not identify abnormalities of the facial nerve and chorda tympani, other authors reported middle ear, ossicular and facial nerve abnormal-

ities [9, 13, 15]. In conclusion, a standard transmastoid approach is feasible to identify the round window niche and the promontory in patients with IP III.

A profuse gusher was encountered following cochleostomy as expected and reported before [5, 6, 16–18]. Due to the reported massive gusher, preventive lumbar drainage is discussed. Lumbar drains were not used in any of the patients, similarly to Smeds et al. [17], Wootten et al. [21] and Saeed et al. [13]. Other surgeons reported using lumbar drains to control the profuse gusher [4, 16, 18, 19]. In the authors' opinion, lumbar drainage is not necessarily required. Given the risks of lumbar drains as an added cause of infection and pneumocephalus [7], the authors do not recommend the use of lumbar drains to prevent continuous CSF leak, especially not in childhood.

The two cases of mild CSF rhinorrhea were treated conservatively with head elevation and intravenous antibiotics for 5 days to prevent meningitis, which was sufficient. Smeds et al. [17] proceeded similarly. Other authors reported surgical techniques such as the surgical obliteration of the Eustachian tube, the middle ear cleft and the blind end closure of the external ear canal to prevent CSF leakage [13, 15, 21]. In the authors' opinion, conservative treatment of rhinoliquorrhea is sufficient in most cases and standard vaccination against pneumococci should be performed. If not, surgical obliteration techniques can be used.

Implantation and control of the electrode array position

All IP III patients were implanted with devices from Cochlear™ and the perimodiolar electrode arrays (18 mm length) were inserted via an anterior and somewhat superior cochleostomy. A large cochleostomy was also recommended in a number of previous studies [5, 16, 17]. Smeds et al. [17] inserted the electrode arrays in three cases via cochleostomy and in seven cases via a round window. Furthermore, they recommended using a straight electrode array (24–25 mm, devices from MED EL™). They reported that it was not possible to insert the full length of

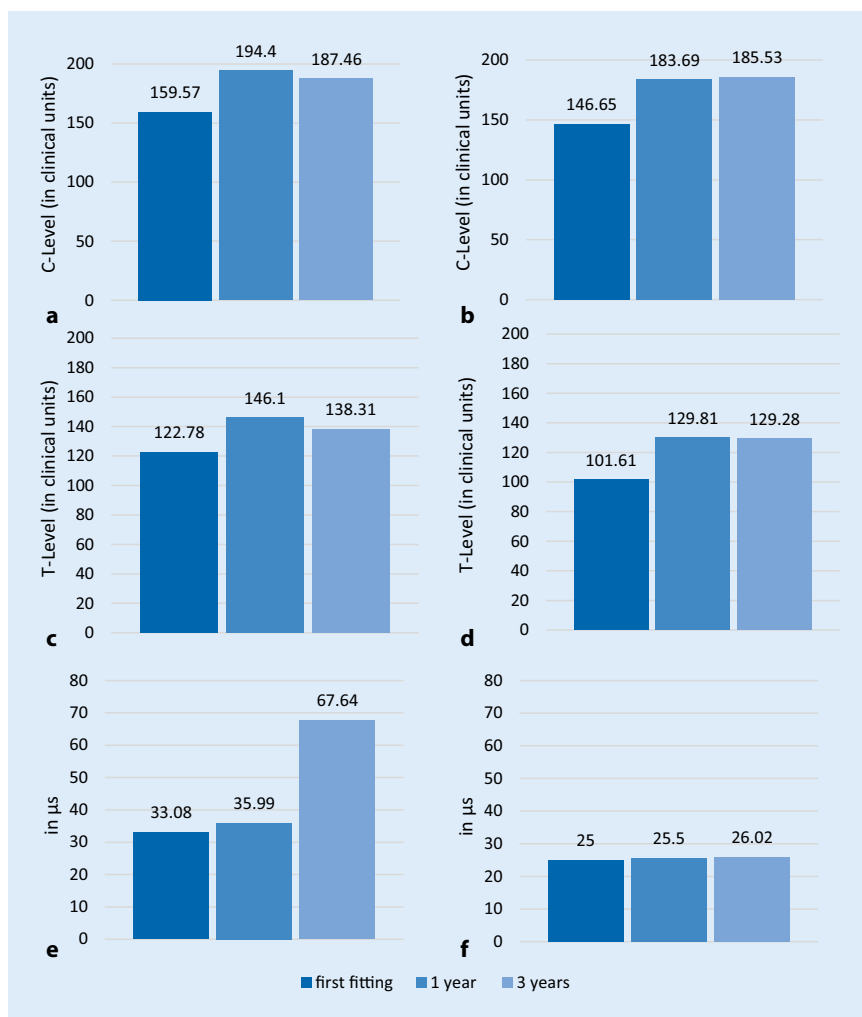


Fig. 2 ▲ Means of C-/T-levels and pulse width in incomplete partition type III versus patients with normal cochlear morphology. **a** C-Levels IP III, **b** C-Levels normal, **c** T-Levels IP III, **d** T-Levels normal, **e** pulse width IP III, **f** pulse width normal

the electrode array in four cases [17], while the authors achieved full insertions with a shorter array without any cases of electrode array kinking. Due to reported shortened cochlear length, the use shorter electrode arrays is recommended to achieve full insertion and full stimulation. Furthermore, Smeds et al. [17] reported 20% non-favorable IAC insertions, whereas the authors had to revise only one out of twelve (11%) electrode arrays due to IAC insertion. Saeed et al. [13] performed an anterior inferior cochleostomy in both included IP III patients due to inadequate access to the round window. They used a perimodiolar Contour Advance array (Cochlear™) in the first and the CI 422 slim straight array (Cochlear™) in the

second patient. They used the Contour Advance electrode array (Cochlear™) for the sequential contralateral implantation of the second patient, as the CI 422 straight array (Cochlear™) was pushed out of the Cochlea by CSF leakage in the previous surgery.

Sennaroglu et al. [15] described a straight electrode array including a “cork”-stopper (device: 25-mm electrode by MED EL™ with a “cork”-type stopper) instead of the last silicon ring especially designed for cochlear malformation to seal the cochleostomy after insertion. In the authors’ opinion, perimodiolar electrodes that are straight for insertion due to the stylet and not flexible are favorable for the surgeon. The insertion of a relatively stiff elec-

trode array can be controlled, at least to some extent, with the tip positioned upwards to prevent insertion into the IAC. It seems advisable to leave the stylet in situ if using the Contour electrode array; at least until intraoperative imaging has been performed and the correct electrode array position demonstrated.

To exclude IAC insertion, intraoperative X-ray imaging was performed in all patients. Whereas intraoperative X-ray imaging showed no signs of IAC insertion in one patient, postoperative DVT clearly showed a dislocation of the electrode array into the IAC (■ Fig. 1b). This patient underwent revision surgery. In summary, IAC insertion is one of the major risks of CI in IP III patients. Intraoperative imaging is highly recommended to recognize IAC position of the electrode array

Audiological outcome

The audiological results (FBMS, OLSA and Göttingen audiometric speech test for children) of IP III patients included in this study were lower than the average scores for the implanted matched patients, but without statistical significance. An important factor that influences audiological outcome and speech perception is that two IP III patients included in this study, as well as patients included in studies published before [17, 18], showed signs of cognitive and developmental retardation. While most studies reported sufficient and good speech perception results [4, 6], Stankovic et al. [18] reported poor audiological outcome and did not recommend CI in IP III patients. In conclusion, all patients included in this study are using their CI daily, even 19 years after implantation. Furthermore, all patients showed increased speech perception scores 1 year and 3 years after implantation. The major limitations of this study are the relatively small number of IP III patients and the lack of homogeneity. Due to the rareness of IP III, this study is one of the studies with the largest patient cohort. Another limitation is the inclusion of adults and children, which complicated the comparability of speech perception score results.

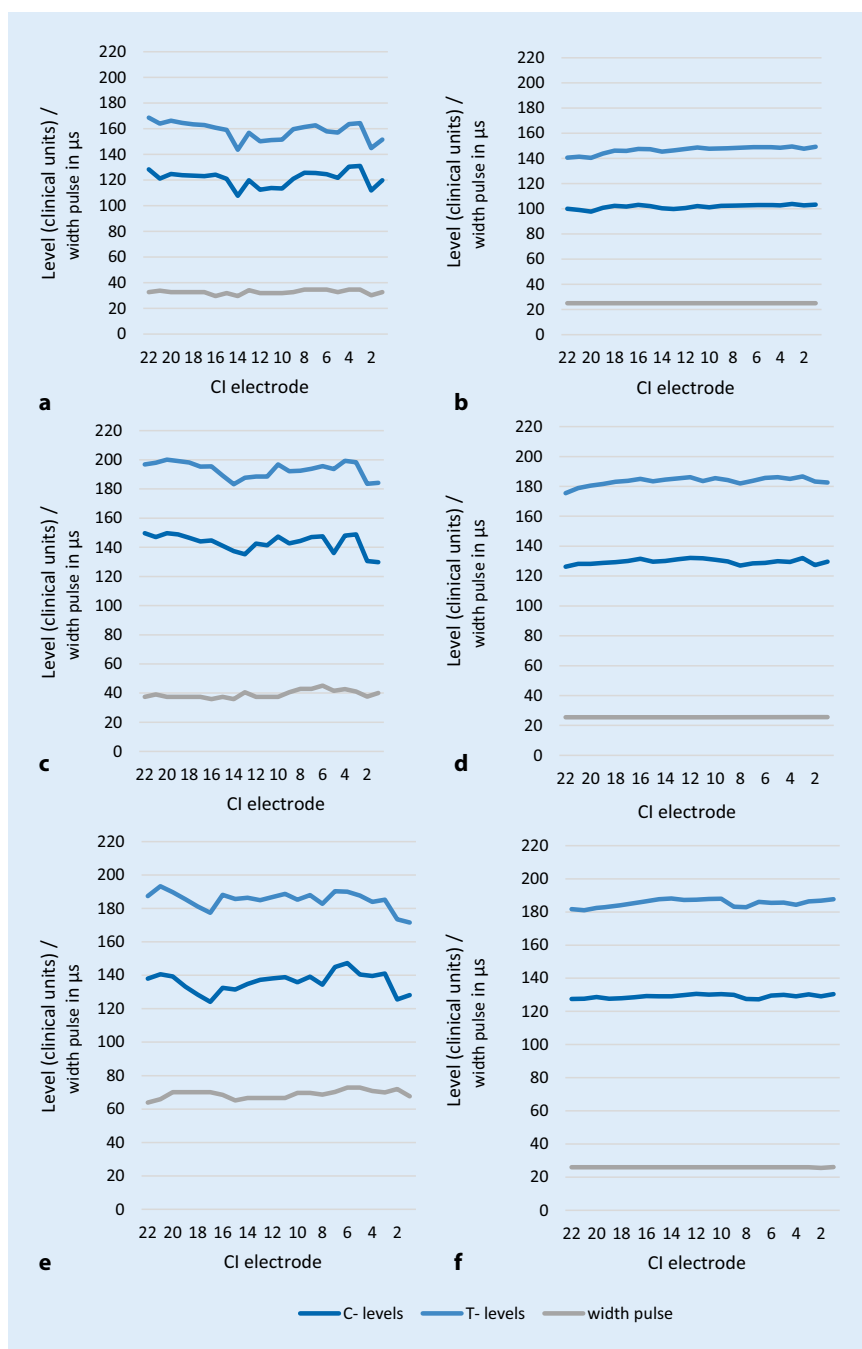


Fig. 3 ▲ Trends in the means of C-/T-levels (in clinical units) and pulse width (in μs) per electrode over time (first fitting, 1 year, 3 years) for incomplete partition type III versus patients with normal cochlear morphology. **a** Mapping (first fitting IP III), **b** Mapping (first fitting) normal, **c** Mapping (1 year) IP III, **d** Mapping (1 year) normal, **e** Mapping (3 years) IP III, **f** Mapping (3 years) normal

Mapping data, electrode impedances, ECAP thresholds (T-ECAP) and intraoperative stapedius reflexes

Some electrodes needed to be deactivated in seven implanted IP III patients due to of facial nerve stimulation. The authors assume that basal electrodes (mostly electrodes 1–10) near the missing lamina cribrosa are without bony separation to the cochlear and facial nerve. For that reason, electrode stimulation via CI results in a higher risk of stimulating the facial nerve. Kang et al. [6] reported that none of the four patients they implanted showed signs of facial stimulation post-operatively. While Kang et al. [6] reported on only four patients observed over a period of 12 months, the authors observed their patients for a mean of 9.1 years. Furthermore, facial nerve stimulation has also been reported in other studies [5].

Whereas intraoperative stapedius reflexes could be obtained in seven out of eight IP III patients in this study, the authors could only measure ECAP thresholds in 2–4 electrodes in three of them. The use of intraoperative stapedius reflex telemetry is recommended to confirm the correct electrode array position, especially since stapedius reflexes were obtained in the most apical electrode 22 in seven out of eight patients.

A significant increase in pulse width in IP III patients was observed over 3 years ($p = 0.01$) after CI. Saeed et al. [13] assumed that the increase in pulse width may be needed to achieve auditory stimulation, but long-term audiological results were awaited. The authors can confirm this hypothesis with long-term results over a mean of 9.1 years. Furthermore, a significant increase in the electric load was calculated 1 and 3 years after CI in IP III patients. To date, there is no study reporting long-term mapping results in IP III patients after CI. It can be speculated that due to missing bony separation between cochlear duct and IAC, posttraumatic fibrosis leads to neurodegeneration of the cochlear nerve. However, to the best of the authors' knowledge, no post-mortem study has been published as yet. The patients in the present study reached

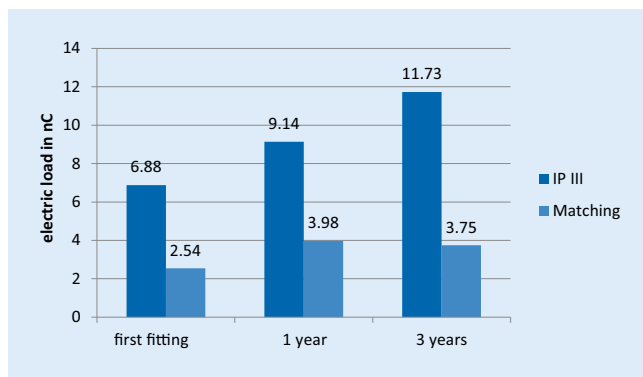


Fig. 4 Trends in the calculated electric load in nC based on the T-levels at first fitting, after 1 and 3 years comparing incomplete partition type III and patients with normal cochlear morphology calculated with the formula of Cohen [3]

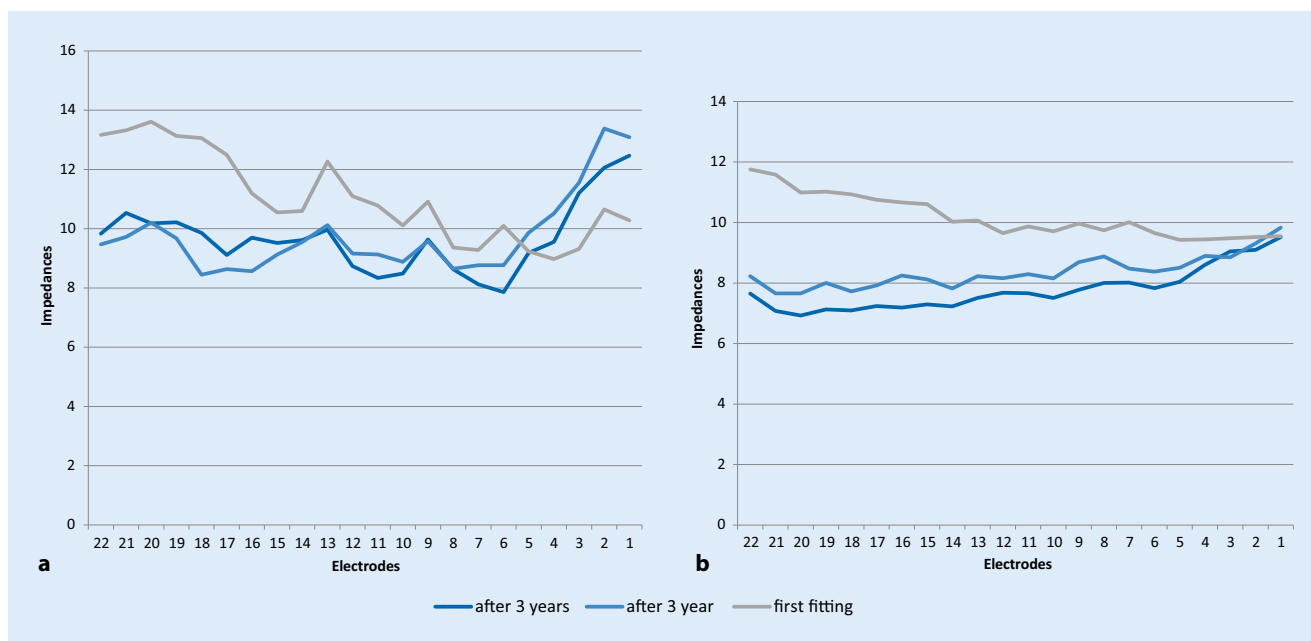


Fig. 5 Impedance profiles of incomplete partition type III (a) and matched patients (b) over 3 years

a needed pulse width of up to 200 μ s and a calculated electric load of up to 22.6 nC. Nevertheless, all patients included in this study with a mean observation time of 9 years (maximum up to 19 years) are using their CI daily.

The IP III patients included in this study showed significantly higher electrode impedances 1 and 3 years after CI compared to their matched group. The assumed fibrosing process after violating the otic capsule could induce higher impedances over time. Smeds et al. [17] described almost normal impedances in all of their cases, but they did not specify the impedances for each electrode individually. The authors observed a significant increase in impedances 1 and 3 years after implantation starting with electrode 1–6 (see Fig. 5 above); thus,

they assume that the fibrosing process affects the basal cochlea in particular.

Conclusion

In conclusion, no study has confirmed the long-term audiological benefit of CI in IP III patients as yet. The surgical procedure is challenging and intraoperative imaging and intraoperative electrically-evoked stapedius reflex telemetry are highly recommendable to prevent IAC insertion of the electrode array. Mapping after implantation is more difficult than in implanted patients with normal cochlear morphology and should be performed in experienced implant centers, particularly in view of the increasing pulse width required.

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M.D. Wesarg, T, PhD., contributed to data analysis and provided critical revision; Aschendorff, A., M.D., PhD, provided critical revision and surgical analysis. The other coauthors provided critical revision.

Compliance with ethical guidelines

Conflict of interest A. Aschendorff received travelling expenses and financial support for research from Advanced Bionics, Stäfa, Switzerland; financial support for research and travelling expenses from Cochlear Ltd, Australia; financial support for research and travelling expenses from Med-El, Innsbruck, Austria; travelling expenses and financial support for research from Oticon, Copenhagen, Denmark. S. Arndt received travelling expenses from Advanced Bionics, Stäfa, Switzerland; financial support for research and travelling expenses from Cochlear Ltd, Australia; financial support for research and travelling expenses from Med-El, Innsbruck, Austria and travelling expenses from Oticon, Copenhagen, Denmark. R. Laszig received financial support for research and travelling expenses from Advanced Bionics, Stäfa, Switzerland; financial support for research, travelling expenses and consultancy fees from Cochlear Ltd, Australia; travelling expenses from Oticon, Copenhagen, Denmark; financial support for research from Med-El, Innsbruck, Austria; financial support for research and travelling expenses from ARRIAG Munich, Germany; travelling expenses from Otologics Boulder, USA; travelling expenses from SonovaHolding, Stäfa, Switzerland; travelling expenses from the General Secretary of the German ENT Society; contract fees, consultancy fees and travelling costs from Medupdate and fees from Springer Medicine EiC. R. Beck received travelling expenses from Cochlear Ltd, Australia. This study was not sponsored by industry. M.C. Ketterer, C. Becker, T. Hildenbrand, F. Hassepass, T. Wesarg, A. Alballaa and I. Speck declare that they have no competing interests.

Retrospective study; compliance with ethical standards is given and the authors have no funding, financial relationships or conflicts of interest to declare.

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„Incomplete partition type III“ – Langzeitergebnisse nach Cochleaimplantation

Hintergrund und Fragestellung

„Incomplete partition type III“ (IP III) ist ein seltenes, zu Taubheit führendes Syndrom, und betroffene Patienten zeigen einen symmetrischen, progredienten, kombinierten Hörverlust bis hin zur Taubheit [9, 11, 20] als Folge des dauerhaft erhöhten perilymphatischen Drucks [2, 13].

Das Syndrom ist charakterisiert durch eine anatomisch kürzere Cochlea mit dilatiertem innerem Gehörgang („internal auditory canal“, IAC) und einer fehlenden knöchernen Begrenzung zwischen der basalen Windung der Cochlea und dem IAC [1, 10, 13]. Eine Stapesfixierung und Schallleitungskomponente wurden als Folge der fehlenden Begrenzung zum IAC und folglich aufgrund der Kommunikation von Perilymphe und Liquorraum in den meisten bisher veröffentlichten Arbeiten beschrieben [11, 13, 18]. Bei Verletzung des Labyrinths durch Stapedektomie oder Cochleostomie führt dies zu einem massiven Gusher [12, 14] mit der Folge der Ertaubung [4].

Bei Implantation kann es unbeabsichtigt zu einer Insertion des Elektroden-trägers in den IAC kommen [1]. Dies kann zu fehlender auditorischer Stimulation, Verletzung von N. facialis oder Fazialisstimulation führen [4]. Darüber hinaus kann ein CI zu einem kontinu-

ierlichen Liquorausstritt mit dem Risiko der Rhinoliquorrhö und Meningitis [13, 17] führen.

Aus diesen Gründen ist die CI-Versorgung bei IP-III-Patienten noch immer umstritten [11, 12, 18]. Aschendorff et al. [1] berichteten über den Vorteil der Insertionskontrolle durch intraoperative 3-dimensionale digitale Volumentomographie (DVT), um inkorrekte Insertionen des Elektroden-trägers zu vermeiden. Einige Fallberichte und Fallserien wurden in den letzten 10 Jahren veröffentlicht und zeigten, dass erfolgreiche Operationsprotokolle und Hörrehabilitation durch CI möglich sind [4, 8, 13, 14, 17, 18]. Bisher gibt es jedoch wenige Publikationen zu IP III. Dies ist die erste Arbeit, welche audilogische Langzeitergebnisse, die individuelle Anpassung (T- und C-Level und Pulsbreite) und elektrophysiologische Parameter (ECAP, „electrically evoked compound action potential“; Impedanzen) untersuchte.

Untersuchungsmethoden

Studiendesign und Teilnehmer

Die Autoren führten eine retrospektive Aktenanalyse aller am Universitätsklinikum Freiburg in den Jahren 1999–2014 mit einem CI versorgten Patienten durch, um IP-III-Patienten zu identifizieren. Pro Patient wurden je 3 Patienten ohne cochleäre Fehlbildung hinsichtlich Geschlecht, Alter, Seite, Typ des Elektroden-trägers und Operations-

datum entsprechend zugeordnet. Die Vergleichskohorte wurde aus einem anonymisierten Pool per Zufall ausgelost, um einen Selektionsfehler zu vermeiden. Anschließend verglichen die Autoren IP-III-Patienten mit der Kohorte ohne cochleäre Fehlbildung hinsichtlich ihres audilogischen Sprachverstehens (Freiburger Einsilbertest; Oldenburger Satztest bei Erwachsenen, OLSa; und Göttinger Sprachtest für Kinder), Anpassungsdaten (C-/T-Level und Pulsbreite) bei Erstanpassung (4–6 Wochen nach Implantation), nach ein und 3 Jahren, intra- und postoperativen ECAP-Schwellen (AutoNRT, „neural response telemetry“), Schwellen der intraoperativen Stapediusreflexe und intra- und postoperativen Elektrodenimpedanzen. Die benötigte Ladung wurde nach der Annäherungsformel, veröffentlicht von Cohen et al. [3], aus T-Level und Pulsbreite berechnet. In diese Berechnung wurden nur Elektroden-träger CI24RECA und CI512 eingeschlossen, da sie nur hierfür ausgelegt ist [3].

Statistische Analyse

Die statistische Auswertung erfolgte mittels SPSS (IBM SPSS Statistics for Windows, Version 24.0, IBM Corp., Armonk/NY, USA). Die Ergebnisse wurden deskriptiv berechnet und sind in den entsprechenden Tabellen mit Mittelwert, Standardabweichung, Maximum und Minimum angegeben. Alle Vergleiche prä- und postoperativer Messungen

Die englische Version dieses Beitrags ist unter <https://doi.org/10.1007/s00106-019-00732-z> zu finden.

Tab. 1 Übersicht über die Studienpopulation

	IP III	Matching	Gesamt
Patienten	9 (einer nicht in weitere Analyse eingeschlossen)	27	36
Geschlecht	m: 8 w: 0	m: 27 w: 0	m: 36 w: 0
Seite	Links: 6 Rechts: 1	Links: 21 Rechts: 6	Links: 28 Rechts: 8
Implantattyp (alle von Fa. Cochlear™, Sydney, Australien)	CI24RECA: 5 CI24M (individuell angefertigt): 2 CI 512: 1	CI24RECA: 15 CI24M: 9 CI 512: 3	CI24RECA: 20 CI24M (individuell angefertigt) und CI24M: 12 CI 512: 4
Anzahl der Chirurgen	4	4	4
Revisionen	1 (IAC-Insertion)	0	1

CI Cochleaimplantat, IAC „internal auditory canal“, innerer Gehörgang, IP III „incomplete partition type III“, m männlich, w weiblich

Tab. 2 Ergebnisse bei IP-III-Patienten vs. Patienten ohne cochleäre Fehlbildung (Matching). a) OISa für Erwachsene ein Jahr und 3 Jahre nach CI-Versorgung sowie Göttinger Sprachtest für Kinder 3 Jahre nach CI-Versorgung. b) T-/C-Level und Pulsbreite für Erstanpassung, ein Jahr und 3 Jahre nach CI-Versorgung

	IP III	Matching	Gesamt
a)			
OISa (ein Jahr) für Erwachsene	33 ± 26,2 Min.: 5 Max.: 57	48,3 ± 33,7 Min.: 12 Max.: 100	43 ± 30,7 Min.: 5 Max.: 100
OISa (3 Jahre) für Erwachsene	39,3 ± 21,6 Min.: 22 Max.: 70	63,7 ± 29,3 Min.: 19 Max.: 100	54,8 ± 28,25 Min.: 19 Max.: 100
Göttinger Sprachtest für Kinder (3 Jahre)	56 ± 18,2 Min.: 40 Max.: 80	68 ± 23,9 Min.: 10 Max.: 90	65 ± 22,82 Min.: 10 Max.: 90
b)			
T-Level in CL (Erstanpassung)	122,8 ± 40,1	101,6 ± 39,6	104,9 ± 40,5
C-Level in CL (Erstanpassung)	159,6 ± 45,4	146,7 ± 41	148,5 ± 41,9
Pulsbreite in µs (Erstanpassung)	33,1 ± 10,7	25 ± 0	27 ± 6,3
T-Level in CL (ein Jahr)	146,1 ± 26,62	129,8 ± 31,9	132,4 ± 31,3
C-Level in CL (ein Jahr)	194,4 ± 19,4	183,7 ± 24,9	184,1 ± 24,2
Pulsbreite in µs (ein Jahr)	35,9 ± 12,1	25,5 ± 2,3	28,8 ± 8,5
T-Level in CL (3 Jahre)	138,3 ± 19,9	129,3 ± 24,5	128,6 ± 23,9
C-Level in CL (3 Jahre)	187,5 ± 17,2	181,4 ± 22,9	182,9 ± 21,6
Pulsbreite in µs (3 Jahre)	67,6 ± 37,6	26 ± 3,2	36,3 ± 25,8

Angegeben sind jeweils Mittelwerte ± Standardabweichung (SD)

CL „clinical units“, IP III „incomplete partition type III“, Min. Minimum, Max. Maximum, OISa Oldenburger Satztest

wurden mithilfe des Wilcoxon-Tests für gepaarte Beobachtungen berechnet. Der Vergleich von IP-III-Patienten mit Patienten ohne cochleäre Fehlbildung wurde mit dem Levene-Test zur Festlegung von Homo- oder Heterogenität und anschließend mit dem T-Test berechnet, um statistisch signifikante Unterschiede zu berechnen. Bivariate Korrelationen wurden mit dem Pearson-Test berechnet. Für alle Berechnungen wurde das Signifikanzniveau bei 5,0 % festgelegt.

Ergebnisse

Patienten

Neun IP-III-Patienten wurden in den Jahren 1999–2014 in der Hals-, Nasen-, Ohrenklinik des Universitätsklinikums Freiburg mit einem CI versorgt. Ein Patient wünschte nicht an dieser Studie teilzunehmen, die anderen 8 willigten schriftlich ein und wurden in diese Studie eingeschlossen (■ Tab. 1). Ihr durchschnittliches Alter lag bei 25,7 Jahren (7–56 Jahre). Alle waren männlich. Unter ihnen waren 2 Kinder und 6 Erwachsene. Bei 2 Patienten zeigten sich Zeichen mentaler Retardierung.

Alle Patienten wurden mittels radiologischer Bildgebung identifiziert und wiesen die typische Anatomie sowohl in der Computertomographie (CT) als auch in der Magnetresonanztomographie (MRT) auf, welche von 2 Radiologen und dem Operateur unabhängig voneinander befundet wurden (■ Abb. 1a). Der durchschnittliche Beobachtungszeitraum lag bei 9,1 Jahren (Spanne: 5–19 Jahre). Ein kombinierter Hörverlust mit Progredienz wurde bei allen Patienten in der frühen Kindheit festgestellt, und alle wurden vor Implantation mit Hörgeräten versorgt.

Alle Patienten wurden mit einem Implantat des Typs Nucleus Cochlear™ (Cochlear™ Limited, Sydney, Australien) via Cochleostomie versorgt. Es wurden 3 verschiedene perimodiolare Elektroden-träger verwendet (■ Tab. 1). Bei 3 der Patienten erfolgte die Implantation sequenziell bilateral. Es wurden die Daten der Erstimplantation betrachtet, um vergleichbare Ergebnisse zu erhalten. Alle einseitig implantatversorgten Patienten verwenden

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„Incomplete partition type III“ – Langzeitergebnisse nach Cochleaimplantation

Zusammenfassung

Hintergrund. Das Incomplete-Partition-Type-III(IP-III)-Syndrom wird durch die fehlende knöcherne Begrenzung zwischen Basalwindung der Cochlea und dem inneren Gehörgang („internal auditory canal“, IAC) definiert. Die Cochleaimplantation kann darin resultieren, dass der Elektrodenträger unbeabsichtigt in den IAC inseriert wird. Das Ziel dieser Arbeit ist es, das Langzeitergebnis im Sprachverstehen, Anpassungs- und elektrophysiologische Daten in diesem Patientenkollektiv zu evaluieren.

Material und Methoden. Bei 9 Patienten wurde im Zeitraum 1999–2014 ein perimodiolarer Elektrodenträger implantiert, 8 davon wurden in diese Studie eingeschlossen. Es wurden Anpassungsdaten, Stapediusreflexe, Impedanzen und ECAP-Schwellen („electrically

evoked compound action potential“) erhoben. Die Autoren verglichen diese Ergebnisse mit je 3 Patienten ohne cochleäre Fehlbildung, entsprechend hinsichtlich Geschlecht, Alter, Seite, Elektrodenträgertyp und Op.-Datum zugeordnet. Die Einsilberdiskrimination wurde mittels Freiburger Einsilber-, das Satzverstehen bei Erwachsenen mit dem Oldenburger Satz-, bei Kindern mit dem Göttinger Sprachtest ermittelt.

Ergebnisse. IP-III-Patienten zeigten einen signifikanten Anstieg der Pulsbreite, der errechneten Ladung und der Impedanzen in basalen Elektroden 3 Jahre nach Versorgung mit einem Cochleaimplantat (CI). Stapediusreflexe waren intraoperativ bei allen messbar. Das Sprachverstehen lag unter dem der

Patienten ohne cochleäre Fehlbildung, jedoch ohne statistische Signifikanz.

Schlussfolgerung. Der signifikante Anstieg der Pulsbreite, der benötigten Ladung und der basalen Impedanzen scheint charakteristisch und ist vermutlich durch eine basocochleäre Fibrosierung verursacht. Das Sprachverstehen blieb dennoch im Langzeitvergleich stabil. Die intraoperative Bildgebung und Messung der Stapediusreflexe ist zu empfehlen, um die korrekte Lage des Elektrodenträgers sicherzustellen.

Schlüsselwörter

Mapping · Cochleaimplantat · Anpassungsdaten · Incomplete-Partition-Type-III-Syndrom · Langzeitergebnisse

Incomplete partition type III revisited—long-term results following cochlear implant. German version

Abstract

Background. Incomplete partition type III (IP III) is defined by a missing lamina cribrosa between the cochlea and the internal auditory canal (IAC). Cochlear implantation (CI) may result in an insertion of the electrode array into the IAC. The aim of this study is to evaluate CI surgery protocols, long-term audiological outcome, mapping and electrophysiological data after CI in IP III patients.

Materials and methods. Nine IP III patients were implanted with perimodiolar electrode arrays between 1999 and 2014; eight of them were included in this study. We evaluated mapping data, stapedius reflexes, electrode impedances and ECAP thresholds. We matched them with 3 CI patients each with

normal cochlear morphology regarding sex, age, side, implant type and surgical date. Speech discrimination was evaluated with the Oldenburger sentence test for adults, Göttingen audiometric speech test for children and the Freiburger monosyllabic word test.

Results. 3 years after CI IP III patients showed a significant increase in pulse width, calculated electric load and electrode impedances in basal electrodes. Intraoperative electrically-evoked stapedius reflexes could be measured in all patients. Speech recognition scores were lower than average scores for matched patients, but without statistical significance.

Conclusions. The significant increase of pulse width, electric load and electrode impedances of basal electrodes over time seem to be characteristic for IP III patients probably occurring due to fibrosis and neurodegeneration of the cochlear nerve. The long term audiological results are stable. Intraoperative imaging and stapedius reflexes are highly recommended to control the right position of the electrode array.

Keywords

Mapping · Cochlear implant · Mapping data · Incomplete partition type III · Longterm results

kontralateral weiterhin ein Hörgerät zur bimodalen Stimulation.

Chirurgisches Vorgehen

Die Autoren analysierten 11 Operationsprotokolle, da bei 3 der 9 Patienten die Implantation sequenziell bilateral erfolgte. Die Implantationen wurden von 4 unterschiedlichen Chirurgen in Intubationsnarkose und unter Fazialismonitoring durchgeführt. Nach Durchführen der Mastoidektomie und der postero-

ren Tympanotomie konnten sowohl Promontorium als auch rundes Fenster identifiziert werden. Eine Stapesfixation wurde in allen Fällen nachgewiesen. Anschließend wurde eine anteriore und eher superiore Cochleostomie durchgeführt, um den Insertionswinkel zu vereinfachen und eine IAC-Insertion zu vermeiden. Ein massiver Gusher wurde in allen Fällen beobachtet. Der Elektrodenträger wurde nach Abklingen des Gushers, Absaugen des Liquors und Optimierung der Patientenlagerung inseriert. Die Cochleosto-

mie wurde anschließend mittels Temporalisfaszie und -muskel abgedichtet, um einem späteren Liquoraustritt vorzubeugen.

Bei keinem der hier beschriebenen Patienten war intra- oder postoperativ eine Lumbaldrainage notwendig. Bei 2 Patienten beobachteten die Autoren eine leichtgradige postoperative Rhinoliquorrhö, die konservativ therapiert wurde.

Intraoperativ wurden die Stapediusreflexe und Elektrodenimpedanzen gemessen. Von den Patienten wurden 2 mit

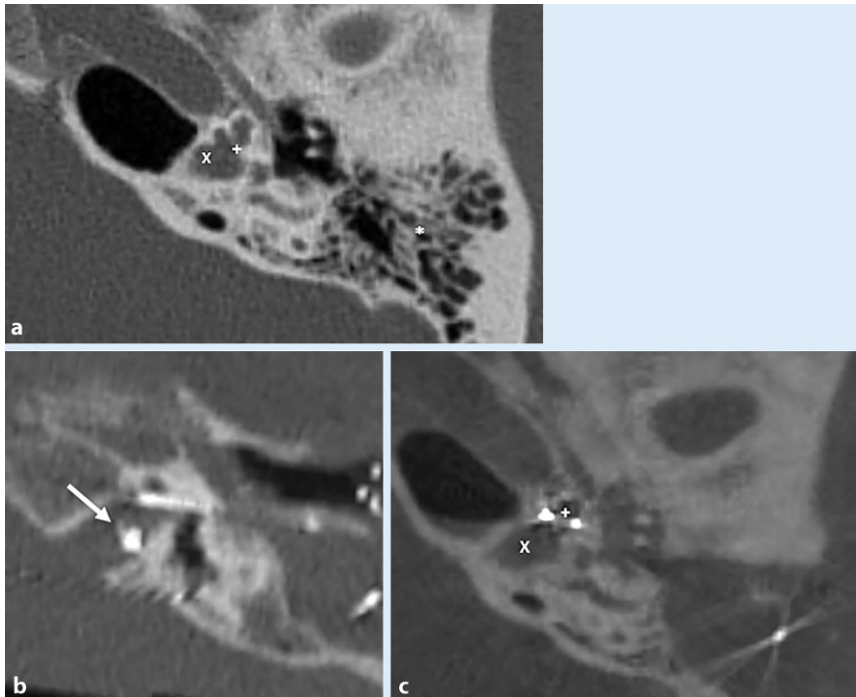


Abb. 1 ▲ Prä- und postoperative Computertomographie (CT) und digitale Volumentomographie (DVT) von Patienten mit IP III („incomplete partition type III“). **a** Präoperative CT, Darstellung der cochleären Basalwindung (+) und der fehlenden knöchernen Begrenzung (X) zwischen Basalwindung und erweitertem innerem Gehörgang (IAC). * Mastoid. **b** Postoperative DVT-Aufnahme mit einem dislozierten Elektrodenträger im IAC (Pfeil). **c** Postoperative DVT-Aufnahme mit dem Elektrodenträger innerhalb der cochleären Basalwindung (+), fehlende Lamina cribrosa und IAC (X)

einem individuell angefertigten CI24M-Elektrodenträger versorgt, bei welchen ECAP-Messungen noch nicht möglich waren. Bei den anderen Patienten wurden ECAP-Schwellen intraoperativ bestimmt. Die Lage des Elektrodenträgers wurde entweder mittels DVT, CT (Abb. 1b,c) oder konventioneller Röntgenuntersuchung geprüft. Ein Patient wies in der postoperativ durchgeführten CT eine Fehlinsertion des Elektrodenträgers in den IAC auf (Abb. 1b). Es erfolgte daher die Revision.

Ergebnisse im Sprachverstehen

Alle Patienten erhielten jährliche Follow-up-Untersuchungen und Anpassungen im Rahmen der Hörrehabilitation im Cochlear Implant Centrum Freiburg (Erwachsene: >3 Jahre, Kinder: >5 Jahre). Das Sprachverstehen wurde bei Erwachsenen mittels Freiburger Einsilbertest und OLSa sowohl ein Jahr als auch 3 Jahre nach Implantation überprüft, bei Kindern mittels Freiburger Einsilbertest und Göttinger Sprachtest für Kinder

3 Jahre postoperativ. Erwachsene IP-III-Patienten wiesen sowohl ein Jahr als auch 3 Jahre nach CI-Versorgung ein geringeres Sprachverständnis im OLSa verglichen mit der Kohorte ohne cochleäre Fehlbildung (Tab. 2) auf. Dennoch konnten die Autoren weder ein Jahr noch 3 Jahre nach CI-Versorgung einen statistisch signifikanten Unterschied ($p = 0,15$) bezüglich des OLSa zwischen den IP-III- und den ihnen entsprechend zugeordneten Patienten nachweisen. Außerdem zeigte sich kein signifikanter Unterschied im Sprachverstehen bei den in die Studie eingeschlossenen Kindern 3 Jahre nach CI-Versorgung ($p = 0,486$; Tab. 2). Beide Gruppen verbesserten sich signifikant im Einsilberverstehen sowohl ein Jahr als auch 3 Jahre nach CI-Versorgung im Vergleich zur Ausgangssituation. Einen signifikanten Unterschied zwischen den Gruppen konnten die Autoren jedoch weder ein Jahr noch 3 Jahre nach CI-Versorgung nachweisen ($p > 0,05$).

Stimulationsparameter

Die Stimulationsparameter zeigten bei Erstanpassung keine signifikanten Unterschiede zwischen IP III und gematchten Patienten (T-Level $p = 0,146$; C-Level $p = 0,401$; Abb. 2). IP-III-Patienten wiesen bei Erstanpassung zwar eine höhere Pulsbreite auf (Tab. 2), jedoch ohne statistische Signifikanz ($p = 0,054$). Die nach Cohen et al. [3] errechnete Ladung auf T-Level bezogen unterschied sich zwar; jedoch nicht signifikant ($p = 0,104$). Die Pulsbreite der IP-III-Patienten stieg ein Jahr nach CI signifikant an, verglichen mit den Erstanpassungsdaten ($p = 0,011$) (Abb. 3). Weiterhin zeigte sich ein signifikanter Unterschied der errechneten Ladung ($p = 0,049$). IP-III-Patienten wiesen 3 Jahre nach CI-Versorgung eine signifikant höhere Pulsbreite ($p = 0,01$) und benötigte Ladung auf ($p = 0,002$; Abb. 4).

Die Elektrodenimpedanzen wurden im Modus MP 1+2 gemessen und verglichen. Die Impedanzen bei Erstanpassung wiesen keinen signifikanten Unterschied auf (IP III: $115 \text{ k}\Omega \pm 4 \text{ k}\Omega$ vs. Matching: $9,9 \text{ k}\Omega \pm 3,7 \text{ k}\Omega$). Jedoch zeigten IP-III-Patienten sowohl ein als auch 3 Jahre nach Implantation einen signifikanten Anstieg der Impedanzen (ein Jahr postoperativ: $p = 0,018$; 3 Jahre: $p = 0,013$) verglichen zur Matching-Kohorte (Abb. 5). Bei 6 IP-III-Patienten waren ECAP-Schwellenmessungen technisch möglich. Jedoch wiesen 3 dieser Patienten keine messbaren ECAP-Schwellen in allen 22 Elektroden auf. Die verbliebenen 3 wiesen nur in 2–4 der 22 Elektroden bestimmbare ECAP-Schwellen auf. ECAP-Schwellen bei den Patienten ohne cochleäre Fehlbildung waren dagegen in allen Elektroden möglich. Die Stapediusreflexmessung war bei 7 von 8 IP-III-Patienten intraoperativ beobachtbar. Bei diesen 7 IP-III-Patienten konnte der Stapediusreflex sogar in der apikalen Elektrode 22 gemessen werden. Ein IP III musste aufgrund einer Elektrodenträgerfehlage revidiert werden. Hier waren die Stapediusreflexe folglich erst nach erfolgter Revision in der Elektrode 16 messbar.

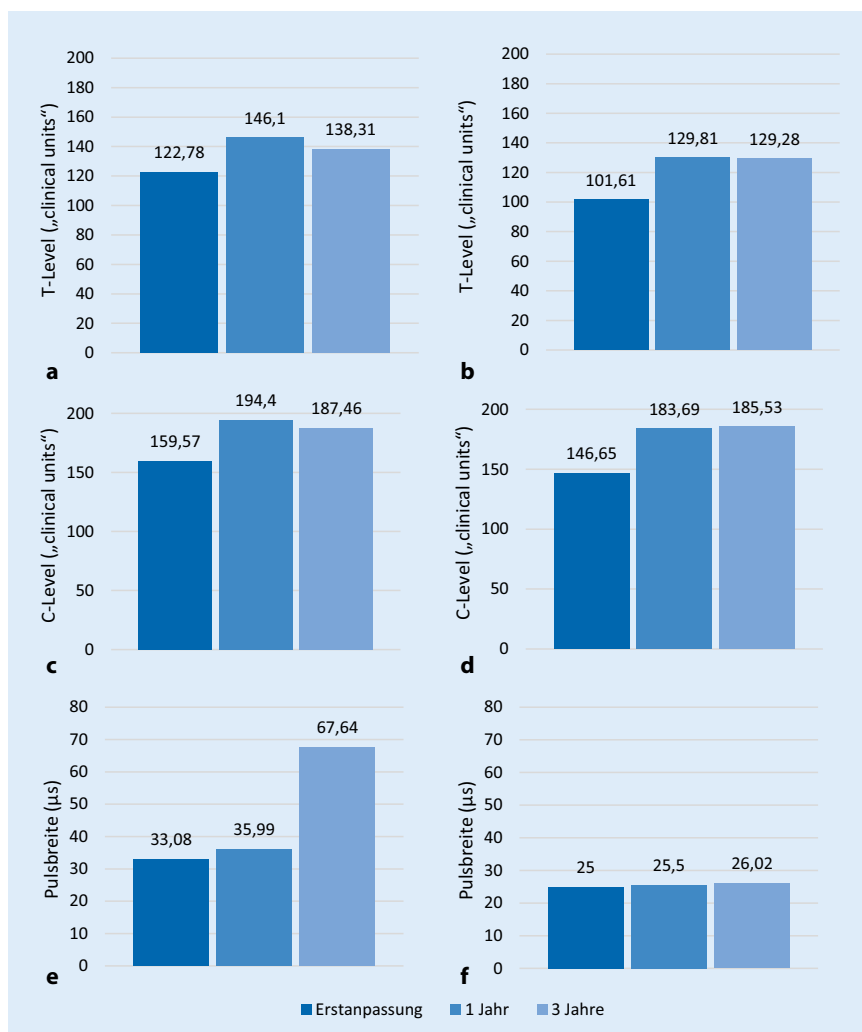


Abb. 2 ▲ Durchschnittliche C-/T-Level und Pulsbreite von Patienten mit IP III („incomplete partition type III“) vs. Patienten ohne cochleäre Fehlbildung bei Erstanpassung, ein Jahr und 3 Jahre nach Versorgung mit einem Cochleaimplantat (CI). **a** T-Level IP III, **b** T-Level normal, **c** C-Level IP III, **d** C-Level normal, **e** Pulsbreite IP III, **f** Pulsbreite normal

Diskussion

Chirurgischer Zugang

Nach konventioneller Mastoidektomie und posteriorer Tympanotomie war bei allen IP-III-Patienten das runde Fenster und das Promontorium zu identifizieren. Es zeigten sich bei 7 der 8 Patienten keine anatomischen Abnormitäten des Mittelohrs, und der Verlauf von N. facialis und Chorda tympani waren regelhaft. Ein Patient zeigte einen nichtregelhaften Verlauf des N. facialis, wie von Aschendorff et al. [1] bereits beschrieben. Während Smeds et al. [17] keinerlei abnorme Fazialis- und Chorda-tympani-Verläufe beschrieb, wurde von anderen Autoren

über Dysplasien des Mittelohrs, der Gehörknöchelchen und abnorme Verläufe des N. facialis berichtet [9, 13, 15]. Zusammenfassend ist ein retroaurikulärer transmastoidaler Zugang ausreichend, um Promontorium und rundes Fenster zu identifizieren, und Dysplasien des Mittelohrs sowie abnorme Fazialisverläufe sind zwar vorbeschrieben, jedoch nicht die Regel.

Gusher

Wie von zahlreichen Autoren berichtet [5, 6, 16–18], beobachteten die Autoren einen massiven Gusher nach Cochleostomie. Aufgrund des Gushers wird die präventive Lumbaldrainage in der Lite-

ratur diskutiert, worauf die Autoren des vorliegenden Beitrags wie andere Autoren auch [13, 17, 21] verzichteten. Andere Autoren berichteten davon, durch die Lumbaldrainagen den Gusher besser kontrollieren zu können [4, 16, 18, 19]. Nach Meinung der Autoren des vorliegenden Beitrags sind präventive Lumbaldrainagen nicht notwendig und angesichts der Risiken von zusätzlicher Infektionsgefahr bis zum Pneumocephalus v. a. im Kindesalter nicht zu empfehlen [7].

Verhinderung des Liquoraustritts

Bei 2 der hier beschriebenen Patienten bestand postoperativ eine leichtgradige Rhinoliquorrhö, die mittels erhobener Kopflege und antibiotischer Therapie i.v. ausreichend therapiert wurde. Smeds et al. [17] bestätigt diese Vorgehensweise. Andere Autoren schlagen ein chirurgisches Vorgehen mittels Mittelohrobliteration, Verschluss des äußeren Gehörgangs und Abdichten der Eustachi-Röhre in Fällen von Rhinoliquorrhö vor [13, 15, 21]. Nach Meinung der Autoren des vorliegenden Beitrags ist in den meisten Fällen ein konservatives Vorgehen ausreichend.

Implantate und Elektrodenträger

Alle IP-III-Patienten wurden mit Implantaten von Cochlear™, Sydney, Australien, versorgt, dabei wurde ein perimodiolärer Elektrodenträger (Länge: 18 mm) über eine anteriore und eher superiore erweiterte Cochleostomie inseriert. Die erweiterte Cochleostomie wurde ebenfalls von vorherigen Studien propagiert [5, 16, 17].

Smeds et al. [17] dagegen berichteten, in 3 Fällen via Cochleostomie und in 7 Fällen über einen erweiterten Rundfensterzugang inseriert zu haben. Außerdem empfahlen sie, einen geraden Elektrodenträger zu verwenden (24–25 mm, Implantate von MED-EL™, Innsbruck, Österreich). Sie berichten jedoch, dass in 4 Fällen keine vollständige Insertion erreicht werden konnte [17]. Dagegen erzielten die Autoren des vorliegenden Beitrags mit einem kürzeren, perimodiolären Elektrodenträger

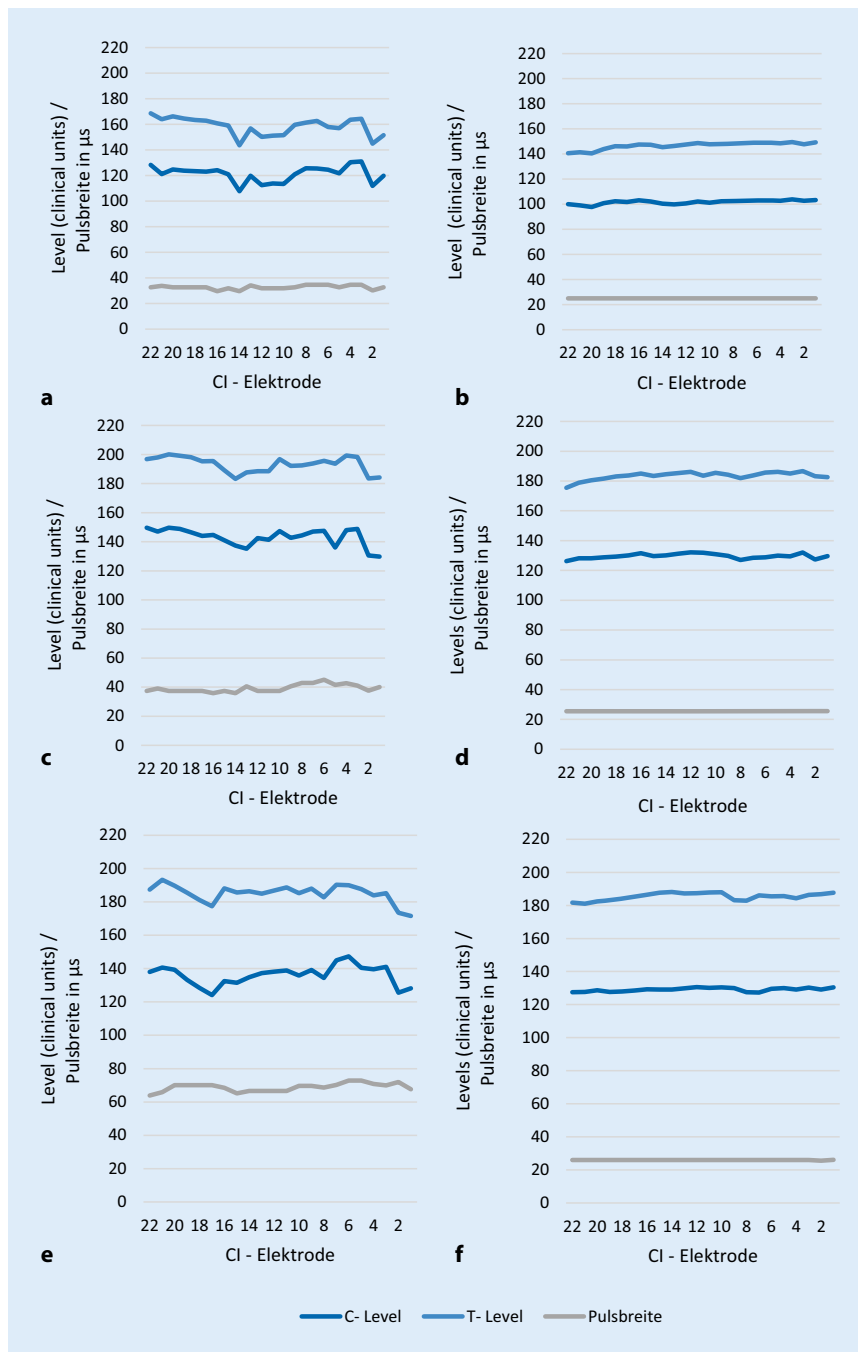


Abb. 3 ▲ Entwicklung der durchschnittlichen C-/T-Level (in „clinical units“) und der Pulsbreite (in μs) bei jeder Elektrode einzeln betrachtet (bei Erstanpassung, ein Jahr und 3 Jahre nach Versorgung mit einem Cochlea-Implantat, CI) von Patienten mit IP III („incomplete partition type III“) vs. Patienten ohne cochleäre Fehlbildung (Mapping); **a** Erstanpassung IP III, **b** Erstanpassung normal, **c** Mapping (ein Jahr) IP III, **d** Mapping (ein Jahr) normal, **e** Mapping (3 Jahre) IP III, **f** Mapping (3 Jahre) normal

eine vollständige Insertion ohne Anhalt für Elektrodenkinking in allen Fällen. Aufgrund der berichteten kürzeren anatomischen cochleären Länge ist es nach Meinung der Autoren des vorliegenden Beitrags empfehlenswert, auch kürzere Elektrodenträger zu implantieren, um eine vollständige Insertion zu erreichen. Es musste nur bei einem Patienten aufgrund einer IAC-Insertion eine Revision erfolgen (11 %), während Smeds et al. [17] von einer IAC-Insertion bei 20 % berichteten. Saeed et al. [13] implantierten über eine anteriore, inferiore Cochleostomie in den 2 veröffentlichten Fällen aufgrund eines fehlenden Zugangs zum runden Fenster. Hierbei inserierten sie den perimodiolaren Elektrodenträger Contour Advance (Cochlear™) beim ersten und den CI422-Slim-Straight-Elektrodenträger (Cochlear™) beim zweiten Patienten. Aufgrund der Tatsache, dass der CI422-Slim-Straight-Elektrodenträger vom Liquorfluss wieder aus der Cochlea gedrängt wurde, verwendeten sie beim zweiten Patienten jedoch erneut den Contour-Advance-Elektrodenträger für das kontralaterale Ohr.

Sennaroglu et al. [15] empfahlen einen geraden Elektrodenträger, welcher einen „cork stopper“ beinhaltet (Implantat: 25-mm-Elektrodenträger von MED EL™ mit einem „cork type stopper“), der statt des letzten Silikonrings speziell für cochleäre Malformationen entwickelt wurde, um die Cochleostomie nach Insertion abzu-dichten.

Nach Meinung der Autoren sind perimodioläre Elektrodenträger mit Stylet zu bevorzugen, da diese bei Insertion aufgrund ihrer Steifigkeit besser zu kontrollieren sind. Außerdem ist es empfehlenswert, bei Verwendung des Contour-Elektrodenträgers das Stylet in situ zu belassen, bis eine intraoperative Bildgebung die korrekte Lage des Elektrodenträgers bestätigt.

Um eine IAC-Insertion auszuschließen, führten die Autoren bei allen Patienten eine intraoperative Röntgenuntersuchung durch. Bei einem Patienten wies die intraoperative konventionelle Röntgenuntersuchung keinen Anhalt für Dislokation auf, die postoperative DVT zeigte dies jedoch klar (Abb. 1b). Daher musste ein Patient aufgrund einer

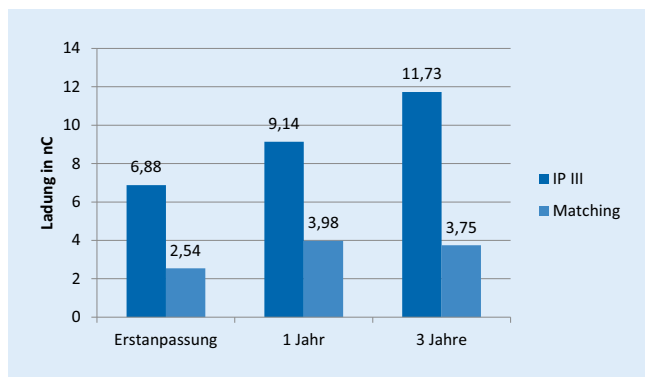


Abb. 4 ▲ Entwicklung der errechneten Ladung auf T-Level bezogen in nC (bei Erstanpassung, ein Jahr und 3 Jahre nach Versorgung mit einem Cochleaimplantat, CI) von Patienten mit IP-III („incomplete partition type III“) vs. Patienten ohne cochleäre Fehlbildung (Matching) nach der Annäherungsformel von Cohen [3]

IAC-Insertion revidiert werden. Zusammenfassend ist die IAC-Insertion eine der Hauptkomplikationen der CI-Versorgung bei IP-III-Patienten. Eine intraoperative Bildgebung zur Lagekontrolle ist daher sehr empfehlenswert.

Sprachverstehen

Die Ergebnisse im Sprachverstehen (Freiburger Einsilbertest, OLSa und Göttinger Sprachtest für Kinder) der in diese Studie eingeschlossenen IP-III-Patienten lagen unter den durchschnittlichen Ergebnissen der Patienten ohne cochleäre Fehlbildung, waren jedoch ohne statistische Signifikanz. Ein wichtiger Punkt, welcher das Sprachverstehen beeinflusst, besteht darin, dass 2 der in dieser Studie untersuchten Patienten Zeichen kognitiver Einschränkung und Entwicklungsverzögerung aufwiesen. Auch bisher veröffentlichte Arbeiten berichteten hiervon [17, 18]. Während die meisten Arbeiten insgesamt zufriedenstellende Ergebnisse schildern [4, 6], beschrieb Stankovic et al. (2010) sehr geringes Sprachverstehen und empfahl die CI-Versorgung in diesen Fällen daher eher nicht.

Zusammenfassend nutzten alle in diese Studie eingeschlossenen IP-III-Patienten ihr CI täglich, einer seit mehr als 19 Jahren. Darüber hinaus wiesen alle einen Anstieg im Sprachverstehen ein und 3 Jahre nach Implantation auf. Dennoch gibt es Schwächen dieser Arbeit: die geringe Patientenanzahl, das Durchführen 2 verschiedener Sprachverständnistestungen bei Erwachsenen und Kindern

und die große Heterogenität des Patientenkollektivs in Bezug auf das Alter bei Aufnahme in diese Studie, präoperative Kognition und Alter bei Implantation. Angesichts der Seltenheit von IP-III-Patienten ist diese Studie dennoch eine der größten und die bisher einzige, welche auch Langzeitergebnisse vergleicht.

Anpassungsdaten

Es mussten bei 7 Patienten Elektroden aufgrund einer Fazialisstimulation deaktiviert werden. Die Autoren vermuten, dass aufgrund der fehlenden knöchernen Lamina cribrosa die Stimulation basaler Elektroden (v. a. Elektrode 1–10) ein erhöhtes Risiko der Fazialisstimulation darstellt. Kang et al. [6] berichteten von keinerlei Fazialisstimulation bei den von ihnen mit einem CI versorgten 4 Patienten. Doch ist zu beachten, dass der Beobachtungszeitraum bei Kang et al. [6] lediglich 12 Monate betrug. Die Autoren der vorliegenden Studie hingegen beobachteten die Patienten über eine durchschnittliche Zeit von 9,1 Jahren. Außerdem wurde über Fazialisstimulation auch von anderen Autoren berichtet [5].

Bei 7 von 8 Patienten waren Stapediusreflexe sogar in der apikalen Elektrode 22 ableitbar. Bei einem Patient waren Stapediusreflexe erst nach einer Revision messbar, die wegen Fehlinserterion notwendig wurde, dort in der Elektrode 16. Daher empfehlen die Autoren neben der intraoperativen Bildgebung auch die intraoperative Stapediusreflexmessung, um die

korrekte Lage des Elektrodenträgers zu bestätigen.

Die Autoren beobachteten einen signifikanten Anstieg der Pulsbreite über 3 Jahre nach CI-Versorgung ($p=0,01$). Bereits Saeed et al. [13] vermuteten, dass IP-III-Patienten zur auditorischen Stimulation eine zunehmende Pulsbreite benötigen, lieferten jedoch noch keine Langzeitergebnisse. Diese Hypothese können die Autoren des vorliegenden Beitrags nun mit Langzeitergebnissen von durchschnittlich 9,1 Jahren bestätigen. Darüber hinaus zeigten sie einen signifikanten Anstieg der errechneten Ladung über 3 Jahre. Nach Meinung der Autoren könnte der beobachtete Anstieg der benötigten Pulsbreite auf die fehlende knöchernen Separation von cochleärer Windung und IAC zurückzuführen sein. Die Autoren vermuten, dass aufgrund der Implantation posttraumatische Fibrosierungsprozesse zu einer Neurodegeneration des N. cochlearis führen. Postmortale Felsenbeinstudien liegen bisher nicht vor. Die in dieser Studie untersuchten Patienten erreichten benötigte Pulsbreiten von bis zu 200 μ s und errechnete Ladungen von bis zu 22,6 nC. Dennoch nutzen alle von den Autoren CI-versorgten Patienten mit einem Beobachtungszeitraum von 9 Jahren ihr CI täglich (Maximum: über 19 Jahre).

Die in diese Studie eingeschlossenen IP-III-Patienten zeigten nach 3 Jahren signifikant höhere Elektrodenimpedanzen im Vergleich zu Patienten ohne cochleäre Fehlbildung. Der vermutete Fibrosierungsprozess nach cochleärem Trauma bei CI könnte jedoch der Grund für die höheren Impedanzen sein. Smeds et al. [17] beschrieben zwar nahezu normale Impedanzen in den von ihnen betrachteten IP-III-Patienten, bestimmten sie jedoch nicht für jede Elektrode einzeln. Dahingegen beobachteten die Autoren der vorliegenden Arbeit einen signifikanten Anstieg der Impedanzen nach einem und 3 Jahre nach CI von Elektrode 1 bis 6 (Abb. 5). Folglich vermuten sie, dass der Fibrosierungsprozess v. a. basale cochleäre Abschnitte betrifft.

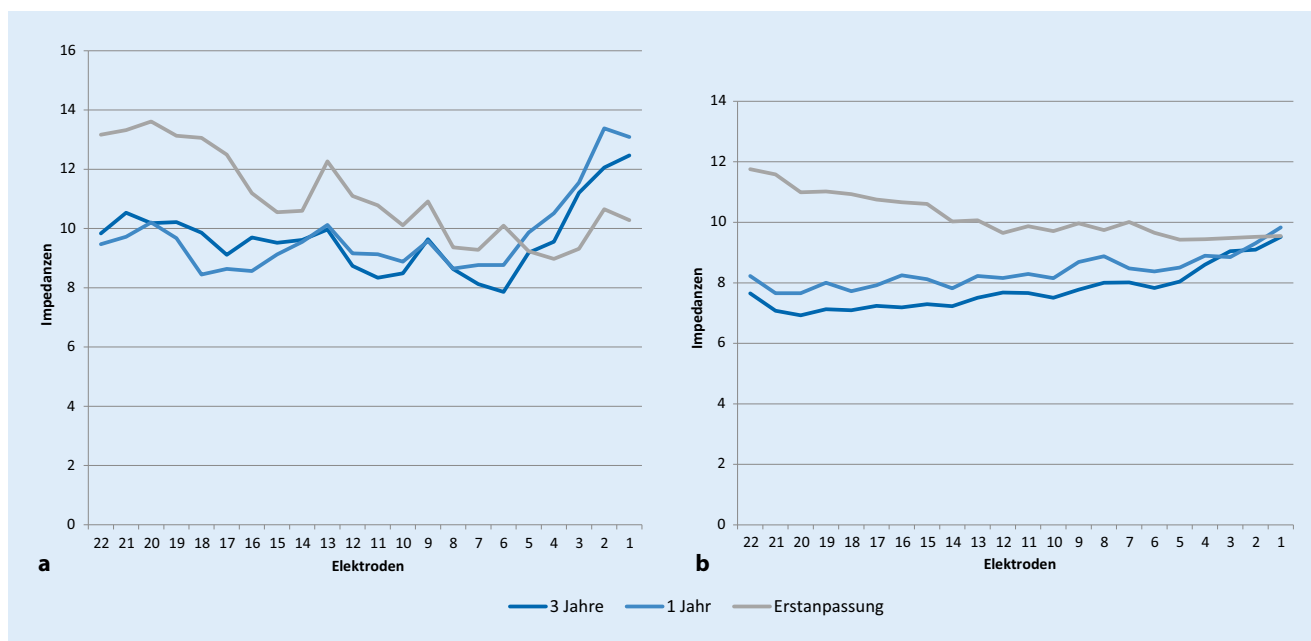


Abb. 5 ▲ Profil der Impedanzen von IP III (a) und Patienten ohne cochleäre Fehlbildung (b), verglichen über 3 Jahre

Fazit für die Praxis

- Dies ist die erste Studie, in der sowohl audiologische als auch technische Langzeitdaten bei implantatversorgten IP-III-Patienten untersucht wurden.
- Das chirurgische Vorgehen ist herausfordernd und sowohl eine intraoperative Kontrollbildgebung als auch die intraoperative Stapediusreflexmessung sind zwingend notwendig, um eine Insertion des Elektrodensträgers in den inneren Gehörgang zu verhindern.
- Die Anpassung der Patienten nach Cochleaimplantat (CI) ist aufgrund der sich steigernden Pulsbreite und der drohenden Fazialisstimulation eine Herausforderung.
- Sie sollte an erfahrenen Implantatzentren stattfinden, gerade in Anbetracht der signifikant zunehmenden benötigten Pulsbreite.

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Author Contribution. Dr. med. Manuel Christoph Ketterer analysierte die Daten und schrieb die Veröffentlichung. Alballa, A. analysierte die Daten und führte die statistische Analyse gemeinsam mit Dr. med. C. Becker durch. Dr. T. Wesarg unterstützte bei der statistischen Analyse und der kritischen Überarbeitung der Veröffentlichung. Prof. Dr. med. A. Aschendorff lieferte die chirurgische Analyse der Daten und überarbeitete die Veröffentlichung kritisch. Alle anderen Koautoren lieferten eine kritische Analyse von Statistik, Daten und Veröffentlichung.

Einhaltung ethischer Richtlinien

Interessenkonflikt. A. Aschendorff erhielt Reisekostenerstattung und finanzielle Unterstützung für Forschung von Advanced Bionics, Stäfa, Schweiz; Reisekostenerstattung und finanzielle Unterstützung für Forschung von Cochlear Ltd, Sydney, Australien; Reisekostenerstattung und finanzielle Unterstützung für Forschung von MED-EL, Innsbruck, Österreich; Reisekostenerstattung und finanzielle Unterstützung

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Diese retrospektive Studie wurde bewilligt durch die Ethikkommission der Albert-Ludwig-Universität Freiburg (Antrag-Nummer: 319/18) und stand in Einklang mit den Deklarationskriterien von Helsinki (aktuell und überarbeitet; 2013). Außerdem wurde die Studie im Register für deutsche klinische Studien (www.drks.de/DRKS00016355) registriert. Von allen beteiligten Patienten liegt eine Einverständniserklärung vor.

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Peter Sickert

Gehörschutz für Beruf und Freizeit

Erich Schmidt Verlag 2019, 288 S., (ISBN: 978-3-503-18216-9), 59,90 EUR

Das im Erich Schmidt Verlag erschiene Buch „Gehörschutz für Beruf und Freizeit“, herausgegeben von Peter Sickert, verspricht als erste Gesamtdarstellung im deutschsprachigen Raum einen umfassenden Überblick über das Thema Gehörschutz.

Thematisch teilt sich das 283 Seiten umfassende Buch in zwei Teile. Im ersten Teil werden die Eigenschaften und die Anwendung von Gehörschutz ausführlich dargestellt. Dazu werden die relevanten Rechtsgrundlagen und DIN Normen besprochen, sowie Kriterien zur Auswahl des Gehörschutzes vorgestellt. In einem zweiten Teil werden einzelne, für die Praxis relevante Themen besprochen. Hier finden sich Kapitel über die Kommunikation am Lärmarbeitsplatz, Gehörschutz für Personen mit Hörminderung und für Gehörschutz für spezielle Nutzergruppen wie Musiker. Darüber hinaus wird die praktische Anwendung von Gehörschutz an Arbeitsplätzen und im privaten Bereich beschrieben.

Dem Autor, einem studierter Physiker, der lange Zeit in leitender Tätigkeit im Sachgebiet Gehörschutz im Fachbereich „Persönliche Schutzausrüstungen“ der DGUV arbeitete, ist das profunde Wissen und der Wunsch anzumerken, das Thema Gehörschutz umfassend und kompetent darzustellen. Dabei setzt er beim Leser grundsätzliche Kenntnisse zur Schallphysik und Hörphysiologie voraus und behandelt das Thema mit einer Tiefe und Ausführlichkeit, die dem augenblicklichen Wissensstand entspricht.

Insgesamt ist das Buch für Personen zu empfehlen, die in ihrer täglichen Arbeit mit Gehörschutz im allgemeinen und speziellen Fragestellungen konfrontiert sind. Der Nutzen dieses Nachschlagewerks für Laien erscheint mir aufgrund der behandelten Fülle der Themen und der Tiefe, mit der diese behandelt werden, eher begrenzt.

Prof. Dr. D.A. Groneberg, Frankfurt

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Asymmetric hearing loss and the benefit of cochlear implantation regarding speech perception, tinnitus burden and psychological comorbidities: a prospective follow-up study

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Abstract

Objectives We determined the audiological outcome, the subjective and objective hearing quality in patients suffering from asymmetric hearing loss (AHL). Furthermore, we evaluated psychological comorbidities and tinnitus burden before and after cochlear implantation.

Study design Prospective cohort study.

Methods 44 AHL patients were unilaterally implanted with a multichannel cochlear implant between 2011 and 2016. Speech discrimination (Freiburg Monosyllable Word Test, Oldenburg Sentence Test) was measured before, 6 and 12 months after implantation. Subjective hearing quality, health-related quality of life (HRQoL), tinnitus burden, anxiety, depressiveness, perceived stress level and coping abilities were evaluated before implantation, 6 and 12 months postoperative using specific validated questionnaires (Oldenburg Inventory, Nijmegen Cochlear Implantation Questionnaire, Tinnitus Questionnaire, General Anxiety Disorder-7, Depression Scale, Perceived Stress Questionnaire and Cope Inventory).

Results Subjective and objective hearing quality, speech discrimination and health-related quality of life were significantly increased in AHL patients. Tinnitus burden significantly decreased over the 12 postoperative months. No significant alteration was observed for anxiety, depressiveness, coping abilities and stress level.

Conclusions This study demonstrates that cochlear implantation achieves hearing rehabilitation, increases HRQoL and decreases tinnitus burden in patients suffering from AHL. Subjective hearing quality increased, while tinnitus burden significantly decreased 6 and 12 months after implantation. HRQoL in AHL patients is an important factor to focus on and is significantly increased postoperatively. In contrast, general anxiety, depressiveness, coping abilities and perceived stress level remained unaffected.

Keywords Asymmetric hearing loss · Cochlear implantation · Health-related quality of life · Audiological outcome · Tinnitus burden

Introduction

Cochlear implantation (CI) is a reliable and established way to achieve hearing rehabilitation in bilaterally deafened patients. In recent years, indications for CI have been extended regarding single-sided deafness (SSD), asymmetric hearing loss (AHL), residual hearing, elderly patients and bilateral implantation in bilaterally deaf patients. To evaluate the impact and benefit of CI in these diverse subgroups, it is highly necessary to define homogeneous groups separately from one another.

Until lately, patients suffering from single-sided deafness (SSD) had three therapeutic options: no treatment, BAHA

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(bone-anchored hearing aid) or CROS (contralateral routing of signal) [2]. Arndt et al. showed that CI is superior to conventional treatment options and does not interfere with speech perception in the normal-hearing ear. SSD is defined as the condition with one near-normal-hearing ear and one ear fulfilling CI criteria [2].

AHL patients suffering from ipsilateral deafness and contralateral progressive hearing loss had to rely on their one-sided hearing aid device to avoid isolation in their social environment. While SSD patients are still able to communicate and to interact in their social life with the one near-normal-hearing ear, AHL patients become increasingly dependent on their hearing aid. Therefore, it is important to distinguish AHL from SSD regarding the clinical definition published by Boyd et al. 2015 [3, 6, 46]. AHL was defined as audiometric hearing loss of ≤ 60 dB SPL (sound pressure level) up to 4 kHz and > 30 dB SPL in at least one frequency up to 4 kHz in the better ear [3, 46]. While many studies focus on CI and its impact in SSD patients, this is not well examined in AHL patients. Furthermore, to the best of our knowledge, authors have not strictly distinguished AHL from SSD in most published studies. Studies examining a homogeneous AHL cohort are underrepresented compared to the other extended CI indications such as bilateral implantation, SSD and elderly patients.

HRQoL (health-related quality of life) and psychological burden such as anxiety and depressiveness are important topics of discussion in AHL patients, beside the audiological outcome and subjective hearing quality. Hearing loss is

positively correlated with a more frequent and intense tinnitus. Tinnitus affects between 67 and 100% of CI candidates [29, 30, 36]. Various studies reported the positive effect of CI on patient's quality of life and tinnitus burden [32–36, 39]. Furthermore, unilateral tinnitus treatment was the starting point for CI in SSD patients [43, 45].

Hearing loss is positively associated with depression, anxiety and loneliness [26, 35, 37]. HRQoL captured with disease-specific questionnaires such as the NCIQ (Nijmegen Cochlear Implantation Questionnaire) [16] has an increasing focus in CI research. To the best of our knowledge, no prospective follow-up study has yet examined audiological outcome, subjective and objective hearing quality, tinnitus and psychological burden in AHL patients strictly distinguished from the other extended CI indications, especially SSD.

Methods

Study population

44 patients suffering from postlingual AHL, implanted between 2011 and 2016 at the department of Otorhinolaryngology, Head and Neck surgery of the Charité University Hospital Berlin, were examined prospectively. They had been using their implant for a minimum of 12 months (see Table 1). All 44 patients participating in this study were assigned to the AHL group with respect to pure tone audiometry measured in the better hearing ear. We distinguished

Table 1 Demographic characteristics of the study population

Ears implanted	44		
	Mean	Standard deviation (SD)	Min/max
Age (years)	62.7	12.84	26/80
Duration of deafness (years)	17.54	20.5	0.5/68
CI wearing (in h/day) after 6 months	13.1	3.1	6/24
CI wearing (in h/day) after 12 months	13.0	2.8	7/18
CI wearing (in h/day) (6 versus 12 months) (<i>p</i>)	6 months versus 12 months (<i>p</i> =0.587)		
Gender	Male: 24		Female: 20
Side	Left: 21		Right: 23
Implant type	CI24RE cochlear: 9		
	CI512 cochlear: 11		
	MedEl Flex 28: 24		
Cause	Sudden sensorineural hearing loss: 20		
	Progressive sensorineural hearing loss: 14		
	Otosclerosis: 3		
	Ménière's disease: 2		
	Cholesteatoma: 2		
	Mumps infection in childhood: 1		
	Meningitis: 1		
	Temporal bone fracture: 1		

the AHL patients from patients with single-sided deafness or bilateral indication for CI regarding the suggested criteria and clinical definition published by Boyd [3, 6, 46]. Criteria for the asymmetric hearing loss group were audiometric hearing loss of ≤ 60 dB SPL (sound pressure level) up to 4 kHz and > 30 dB SPL in at least one frequency up to 4 kHz in the better-hearing ear [3, 46]. AHL patients were differentiated from bilaterally deaf patients by speech discrimination of $> 50\%$ in the Freiburg Monosyllabic Word Test (FMBS) at 65 dB SPL in the better-hearing ear. Audiological and psychometric testing (see below) was performed preoperatively, 6 and 12 months after implantation (see Fig. 1: study design).

Audiometric testing and speech discrimination by Freiburg Monosyllabic Word Test (FB MS) and the Oldenburg Sentence Test (OLSA)

The FB MS [14] in quiet was used to determine speech perception preoperatively without and with optimized hearing aid at 65 dB SPL in both ears. It was conducted in the left and right ears separately as described by Brüggemann et al., characterized as “ear to be implanted” and “opposite ear”. The FB MS (65 dB SPL) as well as the OLSA (65 dB SPL) were performed 6 and 12 months after implantation for the “implanted ear” and “opposite ear”.

“The Charité test battery”

The Oldenburg Inventory Questionnaire (OI) [23] aims to describe subjective auditory changes. The shortened version used in this study includes 3 categories (hearing in quiet, hearing with background noise and localization) and 12 questions [22]. The higher the score, the better the subjective hearing [7].

The Nijmegen Cochlear Implantation Questionnaire (NCIQ) established by Hinderink et al. is a validated questionnaire to evaluate cochlear implant-related quality of life pre- and postoperatively.

The Medical Outcome Study Short-Form 36 questionnaire SF36 [38] focuses on the individual’s non-disease-specific

perception of general health and health-related quality of life (HRQoL) in general [7, 18].

The Tinnitus Questionnaire (TQ) by Goebel and Hiller [13] is used to score the individual burden of a patient’s tinnitus and to assess the tinnitus-related distress [35]. The mean value determines the individual severity from 0 to 84 and can be graduated into compensated (0–46 points) and decompensated (47–84 points) tinnitus burden [15, 48].

Designed by Levenstein et al., the Perceived Stress Questionnaire (PSQ) aims to exhibit the subjective stress level and its individual emotional correspondence [11, 22, 24].

A patient’s individual resource and mode of coping with stress are represented by the COPE Inventory [7, 8, 20].

The General Anxiety Disorder-7 Questionnaire (GAD-7) [42] is used to identify the level of anxiety. Established by Mohiyeddini et al. [31], the General Depression Scale (ADS-L) is a self-rating tool to evaluate the duration, intensity and presence of depressiveness.

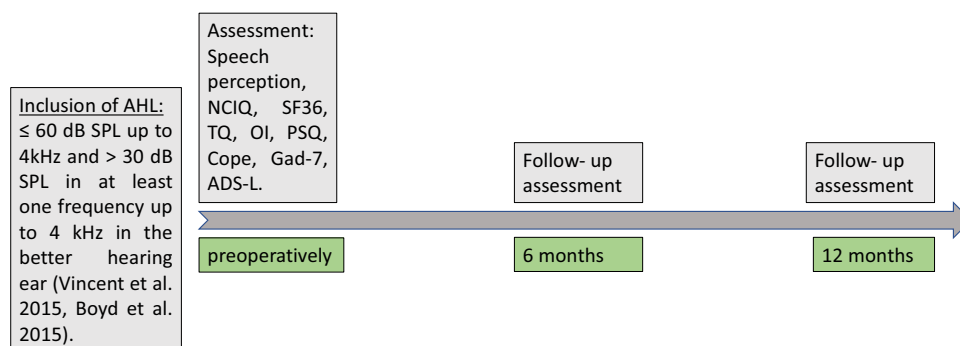
Additional questions

Two questions were added to the questionnaires. First: For how many hours do you use your CI daily? Second: For how long had you been deaf when you received your CI?

Statistical procedure

Statistical analysis was performed with SPSS (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0, Armonk, NY: IBM Corp.). Results are shown in the text and in tables as mean, standard deviation, maximum and minimum and were calculated descriptively. Comparison between pre- and postoperative data was computed using the nonparametric Wilcoxon test for paired observations. We compared the scores of patients with and without tinnitus using the Mann–Whitney *U* test. We used Bonferroni’s post hoc test to compare individual scores. The different subgroups showed variance homogeneity analyzed by the Levene test and were normally distributed (Kolmogorov–Smirnov test). Correlations between different scores were computed using the Spearman’s rank correlation

Fig. 1 Study design



coefficient. The level of significance was set at 5.0%. We used Microsoft Excel® to create the graphs.

Ethics committee

This prospective study took place in the Department of Otorhinolaryngology, Head and Neck Surgery at the Charité University Hospital Berlin. The study was approved by the Charité University Hospital Ethics Committee according to the Declaration of Helsinki (Washington, 2002). All patients gave their written consent.

Results

Demographic characteristics

44 patients (24 males and 20 females) implanted between 2011 and 2016 were included (Table 1). 21 patients were implanted in the left ear and 23 in the right ear. The mean age of the study group was 62.7 years (min: 26 years, max: 80 years, SD: 12.84). The mean duration of deafness before implantation was 17.54 years (min: 6 months, max: 68 years, SD: 20.5). Causes leading to deafness are depicted in Table 1. All 44 patients were implanted with a multichannel cochlear implant device: 9 received the CI24RE from Cochlear, 11 the CI512 from Cochlear and 24 Med El's Flex28.

Audiometric testing and speech perception by FB MS and OLSA

Speech perception significantly improved in the implanted ear. Data obtained before and after CI showed significantly increased results in the Freiburg Monosyllabic Word Test ($p < 0.0001$). The mean score increased from $1.4\% \pm 4.9\%$ preoperatively to $35\% \pm 23.2\%$ 12 months after implantation. The level of speech discrimination, measured by the OLSA, significantly increased within 12 months postoperatively to 9.9 ± 2 dB S/N (signal/noise ratio). We determined no significant alteration of audiometric testing and speech discrimination between 6 versus 12 months postoperatively (Fig. 2).

Assessment of auditory abilities by the OI

The subjective quality of hearing (OI) significantly improved after both 6 and 12 months versus preoperative (OI total $p < 0.002$ preoperative versus 12 months postoperative) (Fig. 3). All three subscales (hearing in quiet, hearing with background noise and localization) showed significantly improved results (see Table 2). Comparing the total value of the OI and the three subscales preoperative versus 12 months after implantation revealed a significant

improvement (OI total: before: mean: 2.97 ± 0.823 , after: 3.49 ± 0.69 ; OI hearing in quiet: before: 3.5 ± 0.94 , after: 4.01 ± 0.68 ; OI hearing with background noise: before: 2.6 ± 0.94 , after: 3.07 ± 0.75 ; OI localization: before: 2.5 ± 1.1 , after: 3.25 ± 0.87). Comparing the subjective audiological assessment 6 months versus 12 months after implantation, there is significant improvement in neither the subscales nor in the OI total score.

HRQoL by the NCIQ and the SF36

Data show a significant increase in NCIQ total from 61.4 ± 16.0 preoperative to 64.5 ± 14.6 after 6 months and to 66.6 ± 14.1 after 12 months (preoperative versus after 6 months: $p = 0.049$; preoperative versus after 12 months: $p = 0.025$) (see Fig. 4). NCIQ subscales 1, 4, 5 and 6 (NCIQ1 = basic sound perception, NCIQ4 = self-esteem, NCIQ5 = activity, NCIQ6 = social interactions) significantly improved after 12 months. The mean scores for NCIQ 6 (social interactions) significantly increased the most (before: 53.43 ± 20.2 ; after 6 months: 58.7 ± 21.1 ; after 12 months: 63.3 ± 16.8). NCIQ subscales 2 and 3 showed significant changes neither after 6 months nor after 12 months (NCIQ2 = advanced sound perception; NCIQ3 = speech production). NCIQ3 (speech production) showed less alteration and remained approximately stable (before: 77.7 ± 16.6 ; after 6 months: 79.0 ± 15.9) (see Fig. 4). The SF36 score evaluating psychological and physical health demonstrated a significant change only for psychological health after 6 months (SF36 psychological: preoperative: 47.3 ± 9.0 versus after 6 months: 50.9 ± 7.5).

Comorbidities

Tinnitus distress by the TQ

35 of the 44 AHL patients (79.5%) reported tinnitus preoperatively. 9 patients not suffering from tinnitus were excluded from further TQ calculation. 12 months after CI, 30 patients still suffered from chronic tinnitus (68.2%). The mean value of TQ before CI was 28.7 ± 17.9 and significantly decreased 6 and 12 months after implantation (after 6 months: 24.7 ± 19.1 ; after 12 months: 22 ± 16.1) (see Fig. 5). A worsening of tinnitus burden was not reported by the AHL patients. Tinnitus-related distress significantly decreased after CI in this study population (TQ total: preoperatively versus after 12 months: $p < 0.001$). Even though there was no significant change in the subscale 'somatic complaints', all other tinnitus-specific subscale scores significantly improved after 12 months

Table 2 Results using Wilcoxon test (*p*) for all subjective measurements: preoperative versus 6 months, 6 months versus 12 months and preoperative versus 12 months (**p* < 0.05 = statistically significant)

	Preoperative versus after 6 months (<i>p</i>)	After 6 months versus after 12 months (<i>p</i>)	Preoperative versus after 12 months (<i>p</i>)
NCIQ1	0.103	0.135	0.031*
NCIQ2	0.254	0.531	0.475
NCIQ3	0.669	0.325	0.918
NCIQ4	0.048*	0.399	0.049*
NCIQ5	0.026*	0.044*	0.002*
NCIQ6	0.006*	0.123	0.001*
NCIQ total	0.049*	0.159	0.025*
TQ emotional distress	0.038*	0.188	0.002*
TQ cognitive distress	0.171	0.647	0.075*
TQ intrusiveness	0.006*	0.357	< 0.001*
TQ auditory perceptual difficulties	0.003*	0.304	0.010*
TQ sleep disturbance	0.205	0.145	0.006*
TQ somatic complaints	0.834	0.798	0.389
TQ total	0.010*	0.196	< 0.001*
OI quiet setting	0.002*	0.113	0.007*
OI noise interference	< 0.001*	0.156	0.012*
OI directional listening	< 0.001*	0.123	< 0.001*
OI total	< 0.001*	0.310	0.002*
SF36 physical health	0.125	0.337	0.603
SF36 psychological health	0.001*	0.407	0.174
PSQ worries	0.814	0.265	0.338
PSQ tension	0.392	0.901	0.202
PSQ joy	0.473	0.265	0.540
PSQ demands	0.868	0.614	0.016*
PSQ total	0.161	0.684	0.133
COPE avoidance	0.535	0.376	0.007*
COPE seeking support	0.611	0.256	0.173
COPE-positive thinking	0.038*	0.237	0.414
COPE active problem-solving	0.321	0.037*	0.081
Depression (ADS-L)	0.576	0.352	0.092
GAD7	0.247	0.586	0.209

(emotional distress, cognitive distress, intrusiveness, auditory perceptual difficulties and sleep disturbance).

Stress level by the PSQ

Data obtained to evaluate the stress level of CI patients before and after implantation by the PSQ showed no significant alteration (see Table 2). Only the subscale PSQdemands improved significantly after 12 months (*p* = 0.016). PSQtotal before implantation (0.3 ± 0.18) after 6 months (0.31 ± 0.22) and after 12 months (0.23 ± 0.154) showed no significant score reduction or improvement.

Coping with stress by the COPE inventory

We found a significant increase for COPE active problem-solving, positive thinking and avoidance (*p* < 0.05)

comparing preoperative data to data after implantation. No significant improvement was found for COPE seeking support.

Anxiety by the GAD-7

Patient's anxiety score preoperative, with a total score of 3.9 ± 3.3 , showed no significant reduction after 6 (Gad-7: 3.1 ± 2.9) or 12 months (Gad-7: 2.73 ± 2.9). Standard values for the GAD-7 are gender specific and indicated by Lowe et al. Scores for GAD-7 in AHL patients (preoperative: 3.9 ± 3.3) were slightly but not significantly higher than in the general public ((males: 2.7 ± 3.2 , females: 3.2 ± 3.5) [28, 42].

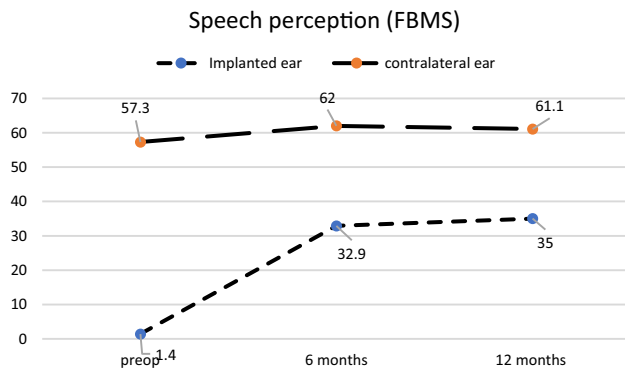


Fig. 2 Speech perception results regarding the Freiburger Monosyllabic Word Test (FBMS) for AHL patients included. Below: CI ear, preoperative, 6 and 12 months after implantation measured separately from the contralateral ear (above) measured with hearing aid at 65 dB SPL

Depressiveness by the ADS-L

The ADS-L scored a total value of 11.9 ± 7.8 preoperatively, 11.5 ± 9.2 6 months and 9.2 ± 6.6 12 months postoperatively. The score, evaluating the depressiveness, demonstrated no significant change after implantation and remained stable ($p > 0.05$). A score over 23 points stands for a serious depression [7]. The average score of the general public is 14.30 ± 9.7 [31]. The score of depressiveness in AHL patients did not change significantly 6 and 12 months after implantation and average scores remained below the average conjugated to members of the general public.

Additional questions

The mean duration of CI-wearing per day was 13.1 h after 6 months and 13.0 h after 12 months. There was no significant longer duration of CI-wearing within this episode ($p > 0.05$). Furthermore, there was no significant correlation between duration of daily CI-use and results in subjective or objective hearing quality.

Discussion

Audiometric testing and speech perception by FBMS and OLSA

Regarding the extended indications for CI as AHL, SSD, residual hearing, elderly patients and bilateral implantation, it is highly important to analyze the impact of CI on these heterogeneous subgroups. Therefore, follow-up studies strictly distinguishing different extended indications from

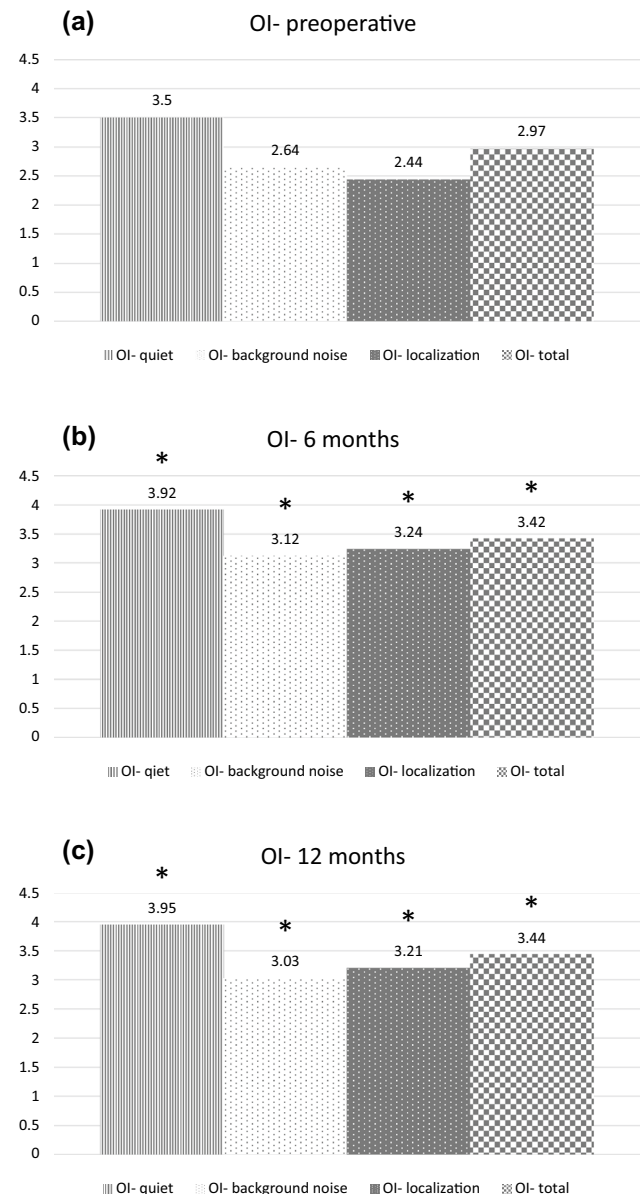


Fig. 3 Subjective hearing quality: OI total score and OI subscores preoperative (a) and 6 months (b) and 12 months (c) after implantation. *Significant improvement ($p < 0.05$) 6 months after implantation versus preoperative and 12 months after implantation versus preoperative

one another are expedient. To the best of our knowledge, this is the first study examining the influence of CI on hearing rehabilitation, HRQoL, tinnitus burden, assessment of auditory abilities and psychological comorbidities in a homogeneous cohort of AHL patients in a prospective follow-up study.

CI is a reliable way to achieve hearing rehabilitation in AHL patients. Patients suffering from AHL show significant improvement in speech discrimination 6 months and

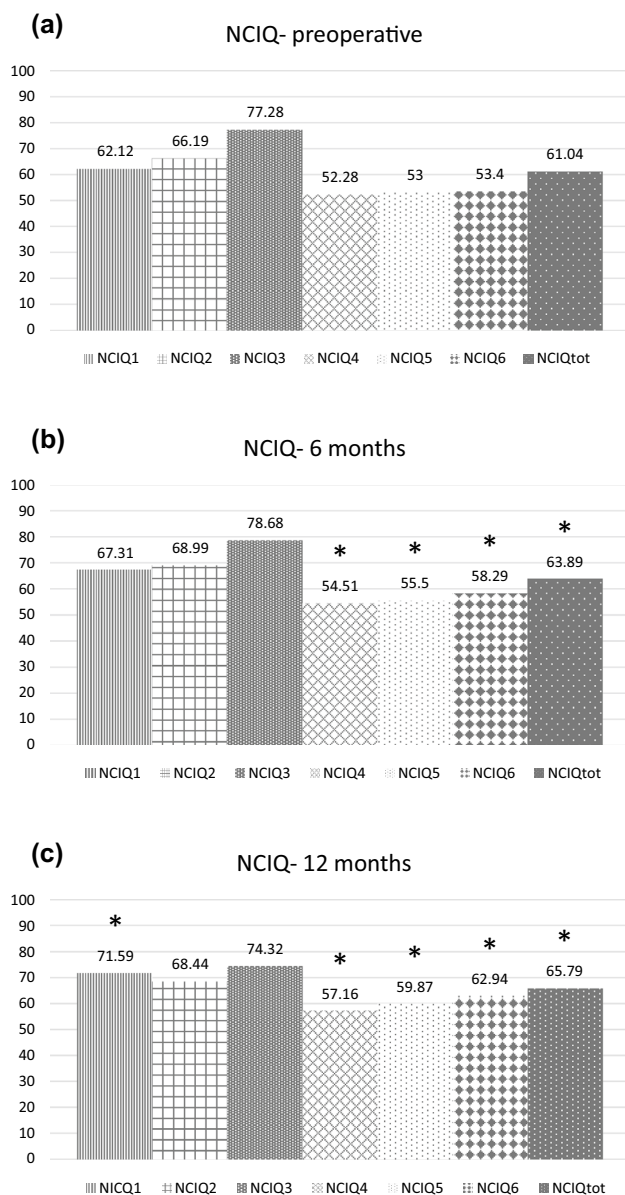


Fig. 4 Health-related quality of life: NCIQ total score and NCIQ subscores preoperative (a) and 6 months (b) and 12 months (c) after implantation. *NCIQ 1* basic sound perception, *NCIQ 2* advanced sound perception, *NCIQ 3* speech production, *NCIQ 4* self-esteem, *NCIQ 5* activity, *NCIQ 6* social interactions. *NCIQ tot* NCIQ total score. *Significant improvement ($p < 0.05$) 6 months after implantation versus preoperative and 12 months after implantation versus preoperative

12 months after implantation compared to the preoperative monaural condition. The present study confirmed findings of prior analysis of AHL patients. Van Loon et al. examined seven adults with AHL prior to and after CI. They described improved speech recognition after CI through bimodal stimulation [44]. In contrast to the study of van Loon et al., one of the major limitations of this study is that both ears were

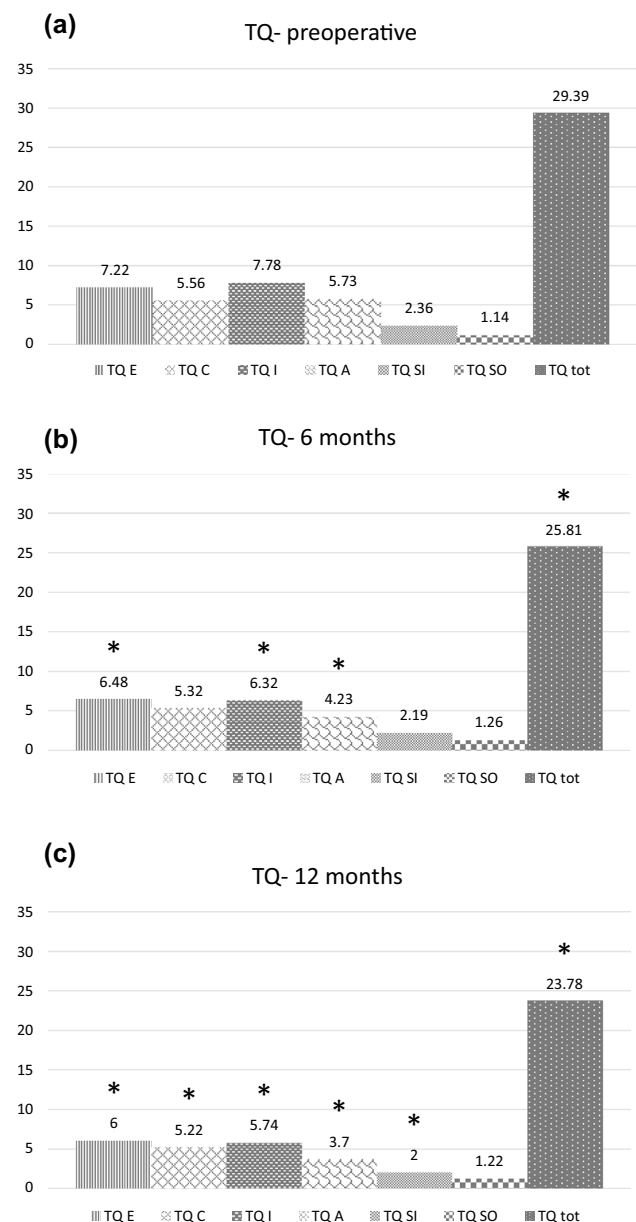


Fig. 5 Tinnitus burden: TQ total score and TQ subscores preoperative (a) and 6 months (b) and 12 months (c) after implantation. *TQE* emotional distress, *TQC* cognitive distress, *TQE + C* summation of emotional and cognitive distress, *TQI* intrusiveness, *TQA* auditory perceptual difficulties, *TQSI* sleep disturbances, *TQSO* somatic complaints, *TQtot* TQ total score. *Significant improvement ($p < 0.05$) 6 months after implantation versus preoperative and 12 months after implantation versus preoperative

tested with FB MS and OLSA, separately but not simultaneously. Thus, no binaural hearing rehabilitation results are included in this study. Nevertheless, all AHL patients use their CI daily and the evaluated daily CI-wearing time of 13.1 ± 3.1 h after 6 months does not differ from daily CI-wearing time of bilaterally deaf and unilaterally implanted

patients reported by Brüggemann et al. (CI-wearing time after 6 months: 13.1 ± 3.7).

Assessment of auditory abilities by the OI

In the present work, we demonstrated significant benefit for CI on subjective hearing quality (OI) in AHL patients. While many studies evaluated the effect of CI on hearing quality and speech discrimination [3, 27] in SSD patients, AHL is still not well explored. A strict division between and clinical definition of SSD and AHL patients is necessary to cope with these two specific relatively new implanted cohorts. Arndt et al. described the positive influence of CI in SSD and AHL patients on subjective hearing quality. They used the standardized Speech, Spatial and Quality of Hearing Scale (SSQ) to define subjective assessment of therapy with CI [3]. The SSQ consists of three sections: speech comprehension, spatial hearing and quality of hearing. The study included 13 AHL patients and assessed them preoperatively, representing the monaural condition and 12 months after implantation, representing the binaural condition. A significant improvement for speech comprehension and spatial hearing in AHL patients was found 12 months postoperatively, but no difference was found for sound quality. Due to the evaluation of different validated questionnaires (OI in this study versus SSQ [3]), the results cannot be compared directly. However, using the OI we could find a significant improvement in all three scales: listening in a quiet setting, listening with noise interference and directional listening, as well as in OI total. In contrast to the OI, the SSQ does not summarize results of different sections in a total score. Furthermore, Arndt et al. only included 13, while we evaluated 44 AHL patients. In our opinion, the OI yields one decisive answer, the SSQ does not. Two of the main problems for AHL patients are speech perception and social interaction with noise interference. Preoperatively they depend on their contralateral hearing aid and report social isolation due to missing speech comprehension in everyday situations such as crowded rooms. The SSQ does not appropriately evaluate subjective hearing and listening with noise interference. For these reasons, we recommend using the OI for the assessment of auditory abilities in further studies on AHL patients.

HRQoL by the NCIQ and the SF36

In this study, the NCIQ total, NCIQ 4 (self-esteem), 5 (activity) and 6 (social interactions) significantly increased 6 and 12 months after CI. Whereas NCIQ 2 (advanced sound perception) and 3 (speech production) did not change significantly, NCIQ 1 (basic sound perception) improved 12 months postoperation. This study shows a significant improvement with CI in NCIQ6 (social interactions) 6 and 12 months after implantation. Progressive loss of social

interaction is one of the most interfering handicaps of AHL patients. But AHL patients still perceive basic and advanced sound (NCIQs 1 and 2) and usually are not restricted in their speech production (NCIQ 3) with the help of their contralateral hearing aid. In contrast, bilaterally deaf patients are restricted in sound perception (NCIQs 1 and 2), speech production (NCIQ 3) and social interactions (NCIQs 4, 5 and 6). Different studies examining bilaterally deaf patients after CI described significant improvement in NCIQ total and in all NCIQ subscales [12, 17, 36]. This leads to the assumption that, on the one hand, bilaterally deaf patients significantly benefit from CI in sound perception (NCIQs 1 and 2), in speech production (NCIQ 3) and in social interactions (NCIQs 4, 5 and 6) [17, 36]. On the other hand, AHL patients benefit from CI initially (after 6 months) not only regarding social interactions (NCIQs 4, 5 and 6), but subsequently (after 12 months) also regarding basic sound perception (NCIQ 1).

CI in SSD patients significantly increases not only bilateral hearing, but also HRQoL [4, 40]. Louza et al. [27] described the significant influence of CI in SSD patients regarding the NCIQ subscale 1 (basic sound perception), but found no significant improvement for the NCIQ total or the other subscales. Regarding the CI indication in SSD compared to AHL, localization, social interaction in quiet, in crowds and telephoning are important factors. Comparing the preoperative NCIQ results of SSD patients [27] and AHL patients (this study), we could only find a significant difference for advanced sound perception (NCIQ 2). SSD patients scored higher than 80 [27], while AHL patients only scored 66.19 points for preoperative NCIQ2. The items of NCIQ 2 described by Hinderink et al. are conversation in quiet, in crowds, telephoning, hearing rhythm and melody and enjoying music. While AHL patients depend preoperatively on their hearing aid for social interactions (NCIQs 4, 5 and 6) and for advanced sound perception (NCIQ 2), SSD patients still have one almost normal-hearing ear. Thus, SSD patients have more benefit for social interactions in quiet and in crowds, and telephoning, hearing rhythm and enjoying music are still possible for them with their near-normal-hearing ear, without having the side effects known from hearing aids.

We could find a significant improvement for the psychological section of the SF36 after 6 months compared to preoperative, but detected no significant change after 12 months.

Implanted AHL patients benefit rapidly during their rehabilitation process, not only regarding their auditory abilities, but also regarding their psychological condition. The psychological domain of SF 36 includes role functioning due to emotional problems, vitality and mental health. Compared to bilaterally deaf patients, AHL patients can still benefit from their contralateral ear fitted with a hearing aid

and might, therefore, show a more rapid improvement after implantation. Another factor might be a better training effect due to six weekly appointments in our rehabilitation centre, including CI fitting and hearing exercises, during the first 6 months. However, many studies described the lack of sensitivity of the SF36 evaluating HRQoL in CI patients [17, 32]. In conclusion, CI in AHL patients significantly improves their HRQoL, but AHL patients differ from bilaterally deaf patients and SSD and further studies should use the NCIQ rather than the SF36 to evaluate HRQoL in CI patients.

Comorbidities

Tinnitus distress by the TQ

The tinnitus total score and five of six specific subscales significantly improved after 12 months in AHL patients evaluated in this study. Tinnitus-related distress significantly decreased after CI (TQ total: preoperative versus after 12 months, $p < 0.001$). None of the patients exhibited worsening tinnitus burden after CI. Studies described the association of tinnitus-related distress with stress, depression and anxiety [1, 36, 41, 49]. Knopke et al. described the significant benefit of CI on tinnitus burden in bilaterally deaf patients. High tinnitus distress correlated significantly with low quality of life [21]. Unilateral tinnitus treatment was the starting point for CI in SSD patients [43, 45] and evaluated as a reliable way of both hearing rehabilitation and tinnitus treatment. This study confirmed the statistically significant relationship between CI and decreasing tinnitus burden. The impact of CI on tinnitus burden certainly depends on a variety of different factors. It is well known, for example, that increasing cochlear morphology influences atraumatic insertion of the electrode array and scalar tympani positioning and, therefore, has a positive influence on hearing rehabilitation [4, 19]. But insertion and scalar position are still unexplored for tinnitus burden after CI. The aim of CI is to achieve successful hearing rehabilitation. However, the attenuation of tinnitus burden and enhancement of HRQoL are important side effects of CI in bilaterally deaf, SSD and AHL patients.

Stress level by the PSQ, coping with stress by the COPE inventory, anxiety by the GAD-7 and depressiveness by the ADS-L

We found a statistically significant decrease for PSQ demands 12 months after CI in AHL patients, but could not find significant changes of stress level in total (PSQ total). We assume that AHL patients used to interact with their contralateral hearing aid-fitted ear and present lower stress levels than bilaterally deaf patients for that reason. Therefore,

further investigations comparing AHL and bilaterally deaf patients are necessary.

We could not find a statistically significant change for depressiveness (ADS-L) or general anxiety (GAD-7) ($p > 0.05$). Furthermore, there was no significant improvement for two out of four coping abilities (COPE seeking support and COPE active problem-solving). However, we identified significant improvement for COPE avoidance after 12 months and COPE-positive thinking 6 months postoperative. Brüggemann et al. evaluated 47 postlingual bilaterally deaf and unilaterally implanted patients. They reported that the level of stress (PSQ) and coping mechanisms (COPE) changed marginally but not significantly after CI in bilaterally deaf patients. The significant increase in PSQ demands, COPE-positive thinking and COPE avoidance after CI in this study leads to the assumption that CI in AHL patients reduces mental overload and avoidance behavior and that AHL patients also differ from bilaterally deaf patients regarding psychological comorbidities.

Whereas we could not find statistical significance for GAD7 or ADS-L in AHL patients, Brüggemann et al. described significant improvement in anxiety (GAD7) and depressiveness (ADS-L) after CI. The mean values for depressiveness evaluated in this study (11.9 ± 7.8) preoperatively were relatively low compared to members of the general public evaluated by other authors (mean: 14.3 ± 9.7) [31]. Brüggemann et al. evaluated ADS-L scores at two time points and found higher scores than those for the general population in bilaterally deaf patients. Whereas we found a mean ADS-L score of 11.9 preoperatively, they reported a mean value of 17.93. Both studies observed lower scores than the cut-off of 23 representing manifest depression [31]. However, ADS-L scores evaluated pre- and postoperatively are lower for AHL patients than Brüggemann et al. reported for bilaterally deaf patients. Knopke et al. evaluated 17 elderly patients aged 80 years or more. All patients suffered from progressive bilateral deafness and were unilaterally implanted [21, 22]. While they found a significant increase in HRQoL and subjective hearing, the perceived stress, general anxiety and depressiveness scores were low prior to and after implantation [21, 22].

Current research focused on psychological comorbidities in SSD and bilateral deafness before and after CI. Wie et al. described the significant disability and affected communication skills and social interaction in unilaterally deaf patients (SSD). Furthermore, they reported feelings of exclusion and reduced well-being in SSD before CI [47]. Other studies [5] focused on HRQoL in unilaterally deaf children. Borton et al. described a larger variance in social functioning for children suffering from unilateral hearing loss. While more and more studies focus on psychological comorbidities in SSD, to the best of our knowledge, AHL patients are still not well explored.

Fellinger et al. showed that deaf patients have more social contact and communication with hearing-impaired than with unimpaired patients. AHL patients suffer from bilateral hearing loss and often feel socially isolated. Usually AHL patients have two hearing aids, at least one without sufficient benefit. They feel sidelined and have a higher risk for dementia or depressiveness. Lin et al. demonstrated the aggravation of cognitive deficits by severe hearing loss [9, 10, 22, 25]. Therefore, besides conventional therapeutic options, such as Bi-CROS or BAHA, CI can help to achieve bilateral hearing rehabilitation and reintegrate AHL patients into social life. Validated questionnaires for subjective hearing, tinnitus burden and psychological comorbidities are necessary to improve the rehabilitation process in AHL patients. In our opinion, a consistent use of internationally accepted and validated questionnaires is recommendable in AHL research to achieve better comparability and scientific discussion. Subjective testing and psychological comorbidities need special focus in both AHL clinical evaluation and research to improve not only the audiological outcome but also to prevent social isolation, feelings of exclusion and depressiveness or dementia. Thus, we recommend the standard use of OI for the assessment of subjective auditory abilities, the NCIQ with special focus on NCIQ subscales 4, 5 and 6 for HRQoL-evaluation, the TQ for measuring tinnitus burden and the COPE inventory with special focus on COPE avoidance and positive thinking before and after CI in AHL patients. Further studies are running to examine the different extended CI indications regarding both audiological outcome and psychological comorbidities.

Conclusions

AHL is one of the extended indications for CI and the implanted patients need special focus. Their subjective hearing quality increases, while tinnitus burden decreases significantly 6 and 12 months after implantation. HRQoL in AHL patients is an important factor of focus and significantly increased postoperatively. This prospective follow-up study evaluated HRQoL, tinnitus and psychological burden in AHL patients after CI for the first time. Outcome after CI in AHL and SSD patients will be a relevant question for future research and until now, to the best of our knowledge, no study has examined quality of life and mental comorbidity after CI in AHL patients strictly distinguished from other extended CI indications.

Compliance with ethical standards

Conflict of interest The authors have no funding, financial relationships or conflicts of interest to declare.

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Binaural Hearing Rehabilitation Improves Speech Perception, Quality of Life, Tinnitus Distress, and Psychological Comorbidities

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Objectives: To determine and compare the benefit of binaural hearing rehabilitation via cochlear implantation (CI) on speech perception, assessment of auditory abilities, tinnitus distress, health-related quality of life (HRQoL) and psychological comorbidities in patients suffering from asymmetric hearing loss (AHL) as well as bilaterally-deafened and sequentially bilaterally-implanted patients.

Methods: 53 patients were implanted between 2011 and 2016. 24 AHL patients were implanted unilaterally, using a hearing aid on the other side. 29 bilaterally-deafened patients were sequentially implanted bilaterally. Speech perception, subjective hearing quality, HRQoL, tinnitus distress, anxiety, depressiveness, perceived stress level and coping abilities were evaluated before implantation, as well as 6 and 24 months postoperatively.

Results: Before CI, AHL and bilaterally-deaf patients showed significant differences regarding assessment of auditory abilities, speech discrimination, tinnitus distress and HRQoL. 24 months after CI both groups significantly

improved in those scales. We could not find a significant difference between the groups after 2 years. Tinnitus distress significantly decreased 6 and 24 months postoperatively in both groups.

Conclusions: This study demonstrates the long-term benefit of binaural hearing rehabilitation in AHL and bilaterally-deaf patients not only regarding speech perception but also HRQoL, tinnitus distress and subjective hearing quality. Bilaterally-deafened patients present lower scores preoperatively, but they did not differ from AHL patients 2 years after CI. Up to now, this is the first study evaluating the outcome of CI in AHL patients compared to bilaterally-implanted patients and demonstrating the benefit of binaural hearing rehabilitation in these specific groups. **Key Words:** Asymmetric hearing loss—Audiological outcome—Bilateral deafness—Bilateral implantation—Cochlear implantation—Health-related quality of life—Tinnitus distress.

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Due to the extended global cochlear implantation (CI) indications, binaural hearing rehabilitation can be achieved in patients suffering from asymmetric hearing loss (AHL) and bilateral deafness. Boyd (1) published a clinical definition separating AHL from single-sided deafness (SSD) and bilateral CI indication (2,3). It has been demonstrated that CI in AHL patients significantly improves speech perception, subjective hearing quality, and health-related quality of life (HRQoL) (4,5). Furthermore, our research group described significantly

decreased tinnitus distress and increased coping abilities in AHL patients after implantation (4).

Previous studies demonstrated the improved speech discrimination and localization abilities in bilateral CI recipients compared with unilateral CI recipients in patients with bilateral CI indication (6,7). Laske et al. (8) reported the subjective and objective benefits in bilaterally-implanted patients. The positive effect of CI on HRQoL in unilaterally-implanted patients has been described in multiple studies (9–13). Furthermore, studies published earlier reported positive effects of CI on tinnitus distress (9–16). Psychological comorbidities such as anxiety and depressiveness are important issues to discuss in CI candidates, as hearing loss is positively associated with depression, anxiety, and loneliness (12,17–19). The comparison of bilaterally-implanted patients and AHL is very interesting. Both are extended CI indications and in both groups, patients rely on hearing devices in both ears (AHL: CI and hearing aid. Bilateral: CI and CI). Up to now, no

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Level of evidence: 2b

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prospective follow-up study has examined the influence of binaural hearing rehabilitation on speech perception, HRQoL, assessment of auditory abilities, tinnitus distress, and psychological comorbidities in AHL compared with bilaterally-implanted patients.

MATERIALS AND METHODS

Study Design and Subject

Fifty three post-lingual deafened patients were implanted with a multichannel cochlear implant between 2011 and 2016 at the Department of Otorhinolaryngology, Head and Neck Surgery of the Charité University Hospital Berlin. Twenty four AHL patients were implanted unilaterally. Twenty nine bilaterally-deafened patients were implanted bilaterally. They were implanted sequentially with a minimum 6-month interval (mean time interval: 23 mo). We included 22 female and 31 male patients (see Table 1). The mean age of the study group was 60.0 years (min: 26 yrs, max: 80 yrs, standard deviation: 12.65). The mean duration of deafness before implantation was 16.71 years in AHL patients and 18.92 years in bilaterally-implanted patients. There was no significant difference regarding mean age or duration of deafness between bilaterally-implanted and AHL patients ($p > 0.05$). All other CI indications, apart from AHL and bilaterally-implanted patients, such as SSD, unilaterally-implanted bilaterally-deafened patients, and patients with residual hearing were excluded from this study. All patients had used their implant for a minimum of 24 months.

AHL was defined with respect to pure tone audiometry measured in the better-hearing ear and all AHL patients used hearing aids bilaterally for more than 5 years up to implantation. We distinguished AHL from SSD or bilateral CI indication by the clinical definition published by Boyd (1). Criteria for the AHL group were audiometric hearing loss of less than or equal to 60 dB SPL (sound pressure level) up to 4 kHz and more than 30 dB SPL in at least one frequency up to 4 kHz in the better-hearing ear (1,3). AHL and bilaterally-deafened patients were defined by more than/less than 50% speech discrimination in the Freiburg monosyllabic word test (FMBS) at 65 dB SPL in

the better-hearing ear. We performed audiological and psychometric testing preoperatively, 6 months and 24 months after implantation. Figure 1 shows the preoperative thresholds for both ears for both groups.

Audiological outcome was measured with the FMBS and the Oldenburg Sentence test (OLSA). Speech comprehension was tested in three presentation set-ups $S0^\circ N0^\circ/S-45^\circ N+45^\circ/S+45^\circ N-45^\circ$ in background noise. We described these different conditions as S0N0 (speech and noise from the front), SBNP (speech from the better-hearing/noise from the poorer-hearing side), and SPNB (speech from the poorer-hearing/noise from the better-hearing side). The summation effect, squelch effect, and head shadow effect were calculated as previously described (6,8).

Furthermore, we performed

- 1) the Oldenburg Inventory (OI) (20) to describe subjective auditory assessment
- 2) the Nijmegen Cochlea Implant Questionnaire (NCIQ) (21) to establish CI-related quality of life before and after CI
- 3) the Tinnitus Questionnaire (TQ) (22) to score the individual tinnitus-related distress (11)
- 4) the Perceived Stress Questionnaire (PSQ) to exhibit the subjective stress level (23)
- 5) the COPE Inventory to represent the individual coping abilities (24)
- 6) the General Anxiety Disorder-7 questionnaire (GAD-7) to evaluate the level of anxiety (25)
- 7) the General Depression Scale (ADS-L) (26) to score intensity and presence of depressiveness.

We added two questions to the questionnaires. First: for how many hours do you use your CI daily? Second: How long had you been deaf when you received your CI?

Statistical Analysis

The statistical analysis was performed with SPSS (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0, Armonk, NY: IBM Corp.). The level of significance was set at 5.0%. Results were calculated descriptively and are shown in the text and in tables as mean, standard deviation, maximum, and minimum. The Kolmogorov–Smirnov test was used to verify normal distribution within the groups. The comparison between pre- and postoperative data was computed using the Wilcoxon-test. The comparison between AHL and bilaterally-implanted patients was calculated with the Levene-test to define homo- versus heterogeneous variance and the t test to define statistically-significant differences. Bivariate correlations were computed using the Pearson test.

Ethics Approval

This prospective study was approved by the Charité University Hospital Ethics Committee (appl. no.: EA2/030/13) according to the Declaration of Helsinki (Washington, 2002). We only included patients who gave their written consent and the study was registered in German Clinical Trials Register (www.drks.de/DRKS00016542).

RESULTS

Speech Discrimination and Assessment of Auditory Abilities

Speech discrimination improved significantly in AHL and bilaterally-implanted patients. Data are available for both extended CI indication groups regarding

TABLE 1. Study population

Ears Implanted	All: n = 53		
	AHL: n = 24		
	Bilateral: n = 29		
	Mean	Standard Deviation (SD)	Min/Max
Age (yr)			
Total	60.0	12.65	26/80
AHL	62.85	12.77	26/80
Bilateral	57.63	12.27	28/80
Duration of deafness (yr)			
Total	17.66	19.36	0.2/67
AHL	16.71	19.23	0.4/67
Bilateral	18.92	19.93	0.2/63
Gender			
Total	Male: 31	Female: 22	
AHL	Male: 13	Female: 11	
Bilateral	Male: 18	Female: 11	

AHL indicates asymmetric hearing loss.

1 a)

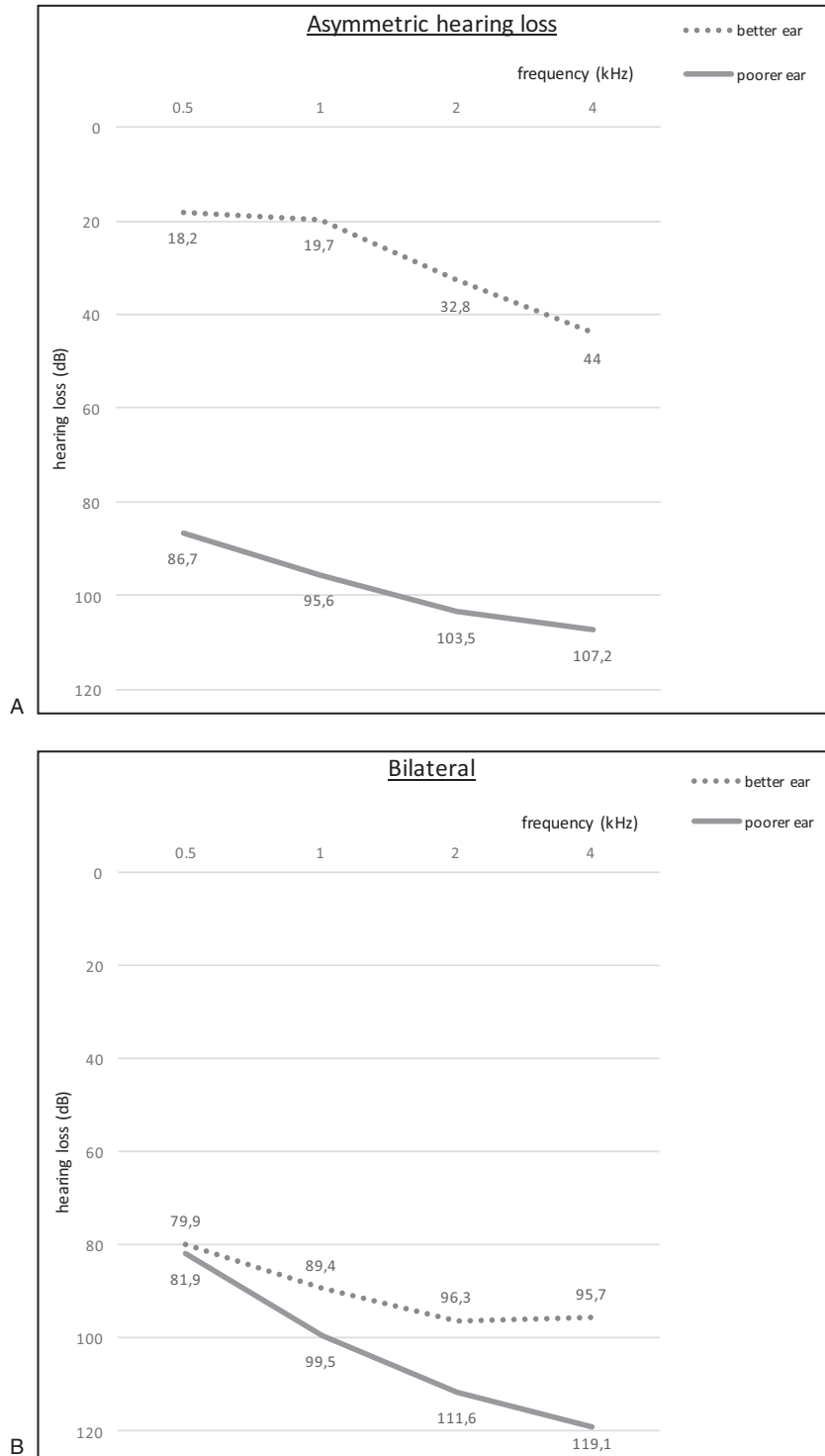


FIG. 1. Preoperative mean pure tone thresholds via air conduction for AHL (A) and bilaterally-implemented patients (B) for better and poorer hearing ear. AHL indicates asymmetric hearing loss.

monosyllabic word discrimination (FMBS) (see Fig. 2: (A) AHL, (B) bilateral) and speech discrimination (OLSA) (see Fig. 3: (A) AHL, (B) bilateral) 24 months

after CI for bilateral listening as well as poorer and better ear, separately. AHL patients showed significant improvement in the bilateral hearing situation and in

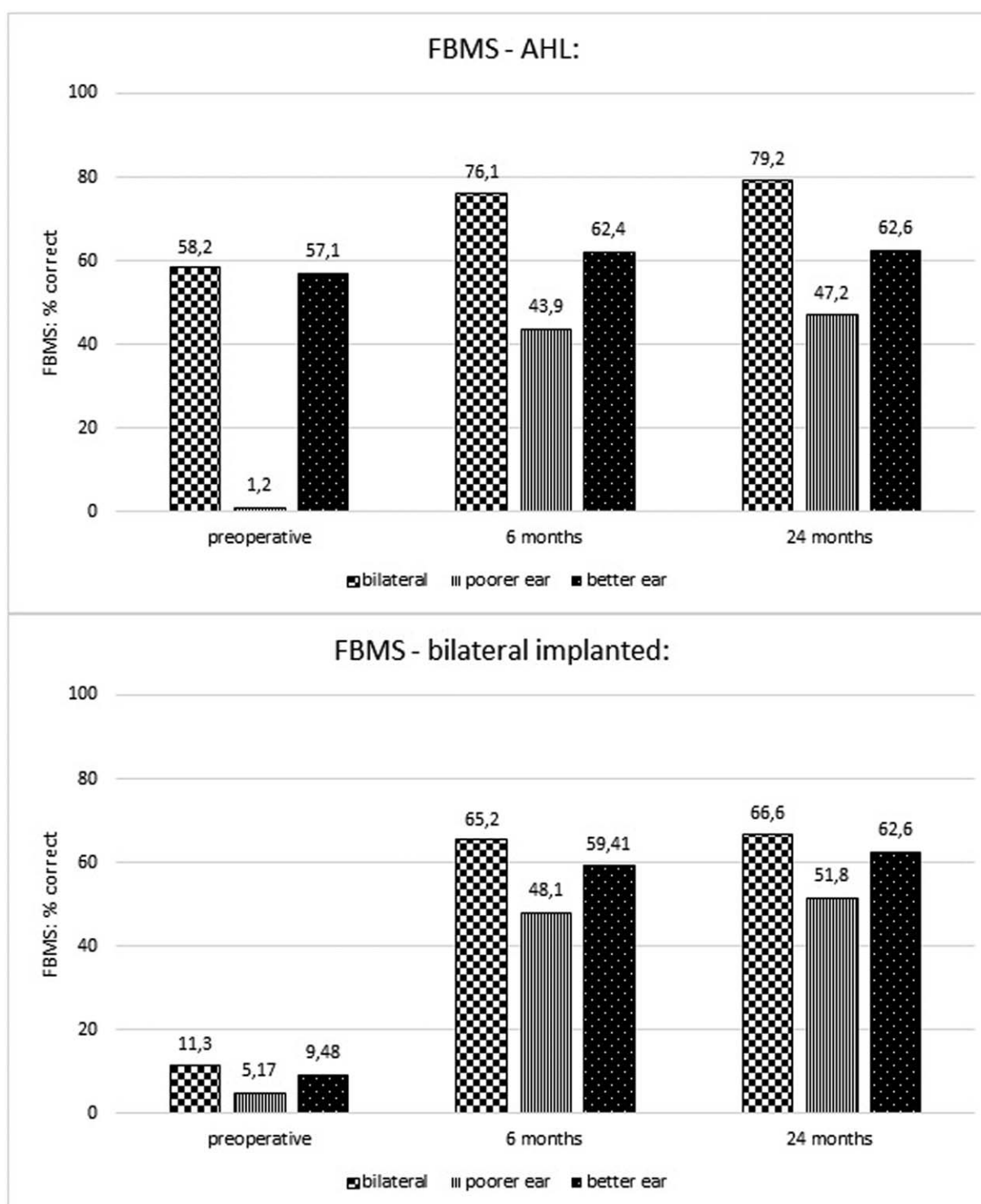


FIG. 2. Monosyllabic speech perception, evaluated with the Freiburger monosyllabic word test in AHL (A) and bilaterally-implanted (B) patients, preoperatively, after 6 and after 24 months. AHL indicates asymmetric hearing loss.

the implanted (poorer) ear (see Figs. 2A and 3A, $p < 0.05$) in both Freiburger monosyllabic word test and OLSA. The better ear, sufficiently fitted with a hearing aid, remained stable and did not change significantly ($p > 0.05$). Bilateral monosyllabic word discrimination was significantly

better than monaural results for the implanted (CI) ear and the hearing aid-fitted better ear ($p < 0.05$). AHL patients benefitted significantly from CI in speech comprehension in the condition S0N0 in the implanted ear and in bilateral condition compared with preoperative results (Fig. 3A).

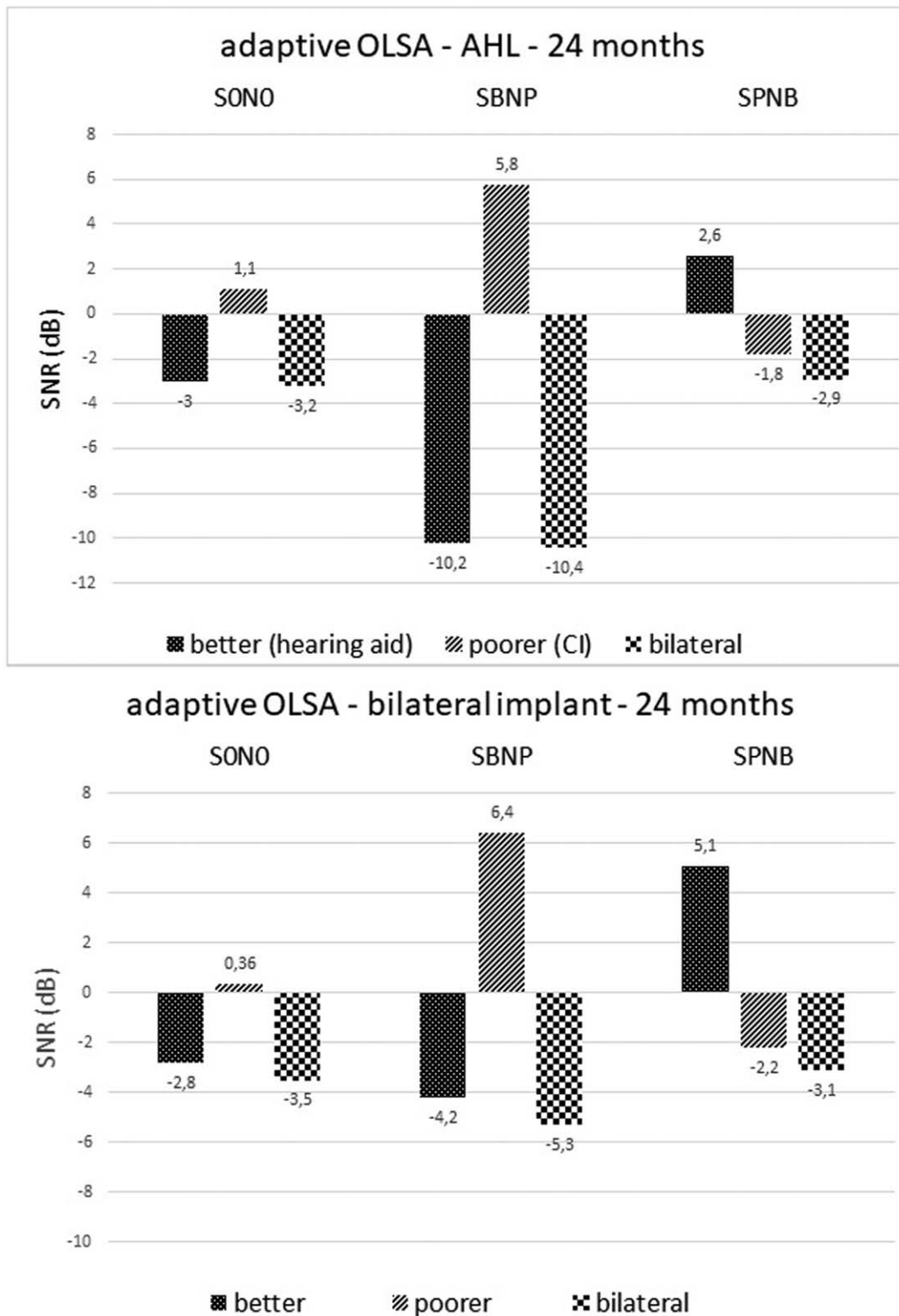


FIG. 3. OLSA in AHL (A) and bilaterally-implanted (B) patients 24 months after CI for condition SONO (speech and noise from the front), SBNP (speech at better, noise at poorer ear), and SPNB (speech at poorer, noise at better ear). AHL indicates asymmetric hearing loss; CI, cochlear implantation; OLSA, Oldenburg Sentence test.

TABLE 2. Total values and *p*-values for NCIQ and Oldenburger Inventory in AHL and bilaterally-implanted patients preoperatively and 2 years after CI

	AHL	Bilateral	<i>p</i> -Value
OI quiet (preop.)	3.3 ± 1.0	2.05 ± 0.7	<0.0001
OI background noise (preop.)	2.6 ± 1.0	1.47 ± 0.5	<0.0001
OI localization (preop.)	2.55 ± 1.2	2.0 ± 0.78	0.076
OI total (preop.)	2.89 ± 0.98	1.8 ± 0.55	<0.0001
OI quiet (2 yr)	3.86 ± 0.69	4.0 ± 0.8	0.53
OI background noise (2 yr)	3.1 ± 0.88	2.95 ± 0.9	0.56
OI localization (2 yr)	3.19 ± 0.89	3.37 ± 0.8	0.5
OI total (2 yr)	3.46 ± 0.70	3.46 ± 0.78	0.98
NCIQ 1 (preop.)	59.05 ± 21.05	38.57 ± 18.45	0.0001
NCIQ 2 (preop.)	62.95 ± 23.1	35.03 ± 15.89	<0.0001
NCIQ 3 (preop.)	76.66 ± 16.99	60.49 ± 17.59	0.002
NCIQ 4 (preop.)	52.78 ± 17.86	44.6 ± 16.37	0.106
NCIQ 5 (preop.)	53.54 ± 23.53	38.69 ± 15.1	0.014
NCIQ 6 (preop.)	54.42 ± 20.33	40.05 ± 17.84	0.013
NCIQ total (preop.)	61.07 ± 17.56	42.8 ± 11.34	<0.0001
NCIQ 1 (2 yr)	68.74 ± 15.31	70.94 ± 22.84	0.7
NCIQ 2 (2 yr)	67.35 ± 16.82	61.18 ± 24.49	0.33
NCIQ 3 (2 yr)	79.13 ± 12.68	68.48 ± 18.1	0.025
NCIQ 4 (2 yr)	62.42 ± 14.44	60.82 ± 18.0	0.741
NCIQ 5 (2 yr)	61.74 ± 17.21	56.32 ± 23.9	0.38
NCIQ 6 (2 yr)	62.47 ± 17.91	62.39 ± 20.40	0.98
NCIQ total (2 yr)	66.98 ± 11.43	63.28 ± 18.53	0.42

AHL indicates asymmetric hearing loss; NCIQ, nijmegen cochlea implant questionnaire; OI, Oldenburg Inventory.

Bilateral speech discrimination was better in all three conditions (S0N0, SBNP, and SPNB) than monaural hearing. The speech discrimination for the condition SPNB with the CI (mean score: −1.8 dB) significantly improved compared with preoperative values (mean score before CI: 0.9 dB; $p < 0.005$). We could not determine significance for the squelch effect (SBNP better: −10.2 dB SNR; bilateral: −10.4 dB SNR, not significant [$p > 0.05$]. Difference: 0.2 dB). Furthermore, AHL patients exhibited a significant difference for the summation effect between poorer ear and bilateral condition, but not between better ear and bilateral condition (S0N0 better: −3 dB SNR; poorer: 1.1 dB SNR; bilateral: −3.2 dB SNR). We found a significant head shadow effect for AHL patients 24 months after CI for the better (better ear: SBNP: −10.2 dB SNR; SPNB: 2.6 dB SNR. Difference: 12.8 dB), and the poorer ear (poorer ear: SBNP: 5.8 dB SNR; SPNB: −1.8 dB SNR. Difference: 7.6 dB). Bilaterally-implanted patients also showed significant improvement regarding monaural and binaural speech and monosyllabic word discrimination (see Figs. 2B and 3B). We could not find significance for either the squelch effect (SBNP better: −4.2 dB SNR; bilateral: −5.3 dB SNR, not significant [$p > 0.05$]. Difference: 1.1 dB) or the summation effect (S0N0 better: −2.8 dB SNR; poorer: 0.36 dB SNR; bilateral: −3.5 dB SNR) between better ear and bilateral condition. Nevertheless, we found a significant summation effect between poorer ear and bilateral hearing. Furthermore, we calculated a significant head shadow effect for the better (Better ear: SBNP: −4.2 dB SNR; SPNB: 5.1 dB SNR. Difference: 9.3 dB) and the poorer ear (poorer ear:

SBNP: 6.4 dB SNR; SPNB: −2.2 dB SNR. Difference: 8.6 dB) 2 years following the second CI in bilaterally-implanted patients.

The assessment of subjective auditory abilities, evaluated with the OI, significantly improved after 6 and 24 months in AHL and in bilaterally-implanted patients. All three subscales showed significantly improved results in both groups. AHL patients showed a significantly increased value for OI total, OI in quiet and background noise compared with bilaterally-implanted patients preoperatively (see Table 2), but we did not find a significant difference for OI localization before CI. Comparing the OI total and the OI subscales in AHL and in bilaterally-implanted patients we could not detect a significant difference, either 6 months or 2 years after CI (see Table 2 and Fig. 4).

Health Related Quality of Life

Both AHL and bilaterally-implanted patients showed a significant increase in NCIQ total 6 months and 2 years after CI compared with preoperatively. We found significantly lower scores for NCIQ 1, 2, 3, 5, 6 and NCIQ total for bilaterally-deafened patients compared with AHL patients before CI (see Table 2 and Fig. 5). Six months after CI, bilaterally-implanted patients exhibited significantly lower NCIQ 2 and 3 scores compared with AHL patients. Furthermore, bilaterally-implanted patients remained at a significantly lower speech production score (NCIQ3) 2 years postoperatively compared with AHL. Nevertheless, we could not detect a significant increase for NCIQ subscales and NCIQ total in AHL patients and

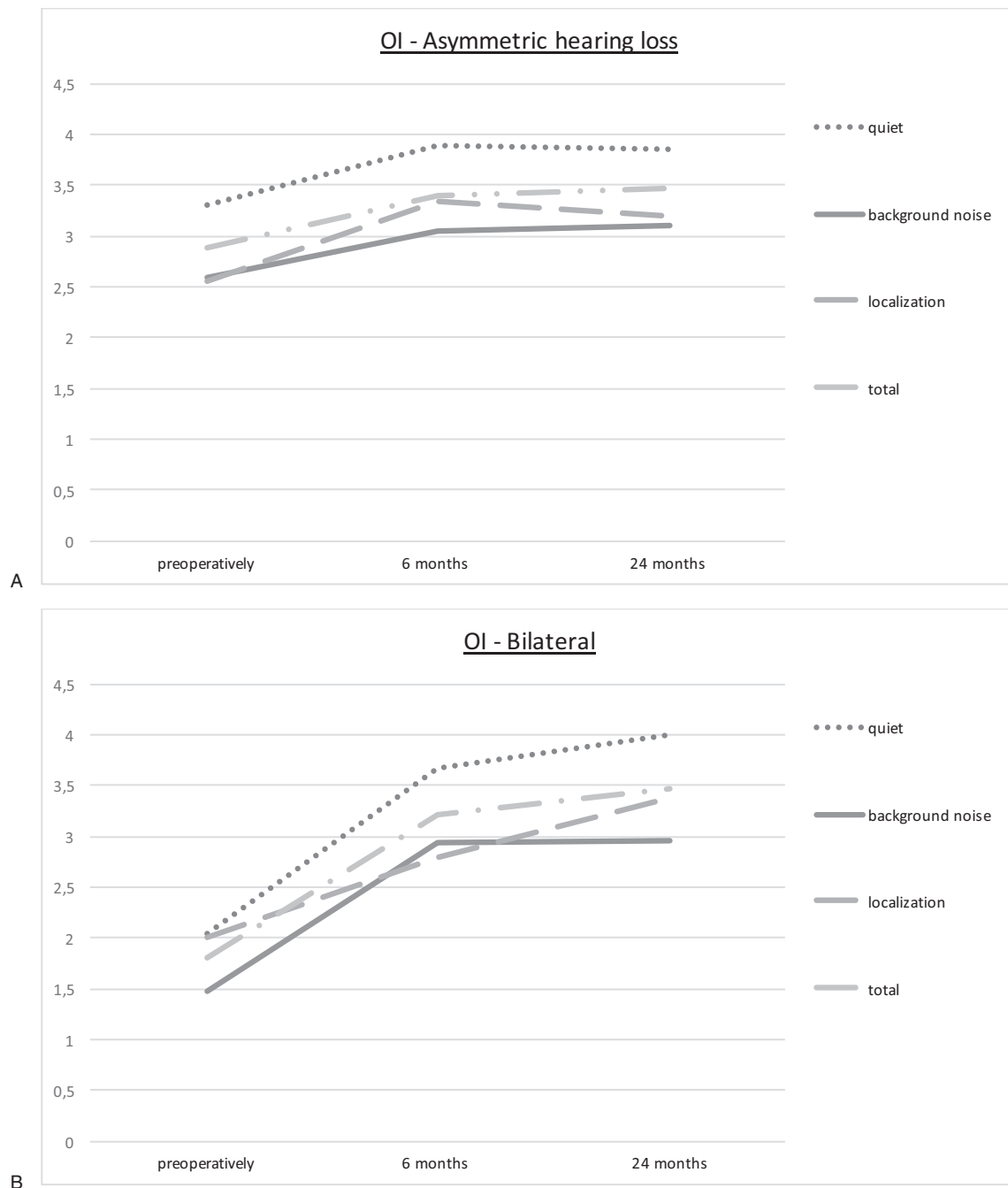


FIG. 4. Assessment of auditory abilities: OI total score and OI subscores preoperatively, 6 months and 24 months after implantation in AHL patients (A) and bilaterally-implanted patients (B). AHL indicates asymmetric hearing loss; OI, Oldenburg Inventory.

bilaterally-implanted patients comparing results 6 months and 2 years after CI.

Tinnitus Distress

The TQtotal decreased significantly in both AHL and bilaterally-implanted patients 2 years after CI (AHL: $p = 0.002$; bilateral: $p = 0.024$), demonstrating a significant improvement of tinnitus distress. But, whereas the tinnitus distress in AHL patients decreased significantly

6 months after CI ($p = 0.005$), a significant reduction in bilaterally-implanted patients could only be demonstrated after 24 months (bilateral: preoperative vs 6 mo: $p = 0.091$) (see Fig. 6). Furthermore, almost all tinnitus-specific subscales showed significant improvement 2 years after CI in the AHL cohort. There was no significant change in the subscale “somatic complaints” ($p = 0.206$) in AHL patients, or improvement of “emotional distress” in bilaterally-implanted patients

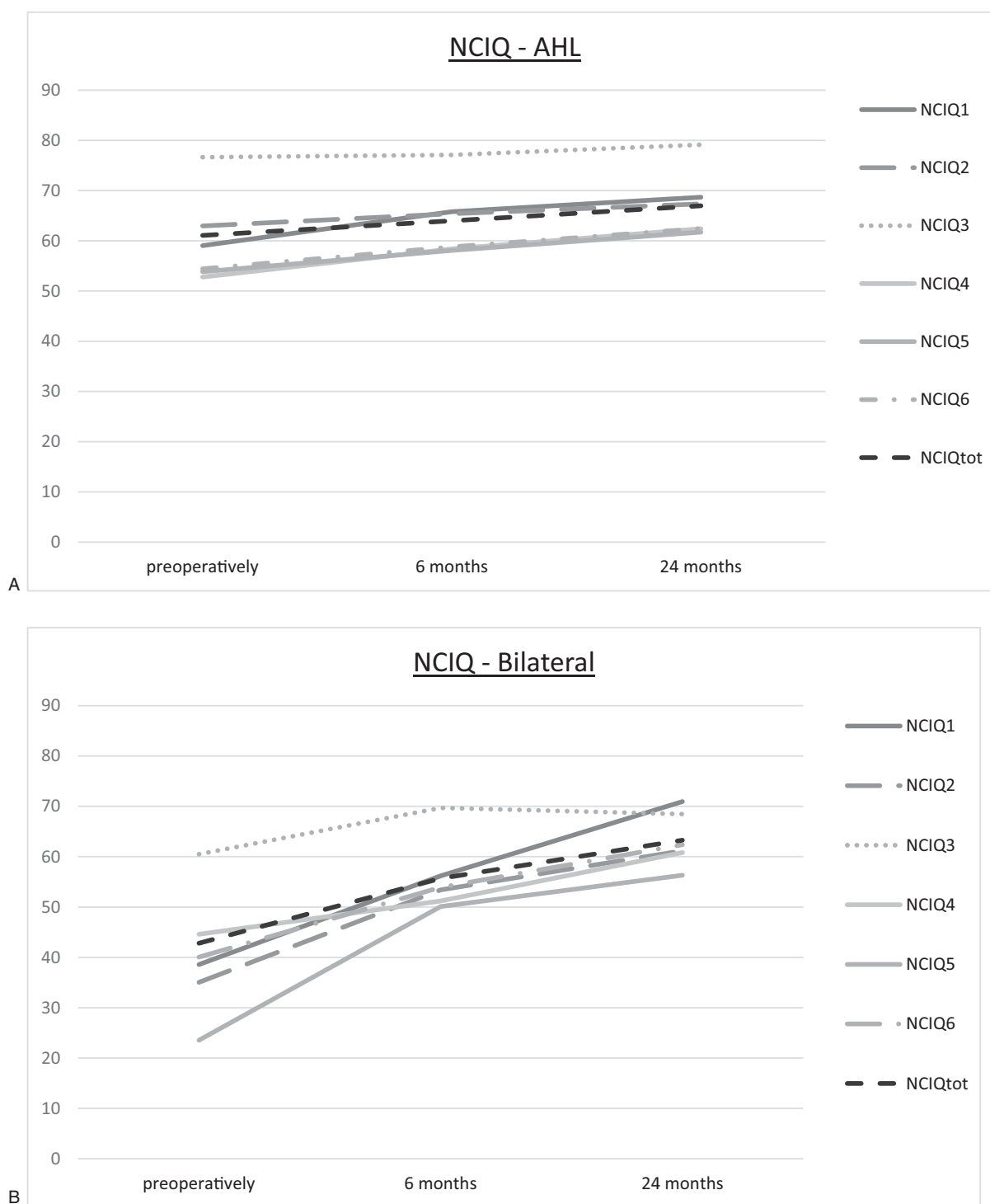


FIG. 5. Health-related quality of life: NCIQ total score and NCIQ sub scores preoperatively and 6 months and 24 months after implantation for AHL patients (A) and bilaterally-implanted patients (B). (NCIQ 1: basic sound perception. NCIQ 2: advanced sound perception. NCIQ 3: speech production. NCIQ 4: self-esteem. NCIQ 5: activity. NCIQ 6: social interactions. NCIQ tot: NCIQ total score). AHL indicates asymmetric hearing loss.

24 months after CI compared with preoperative results. All other subscales significantly improved in both AHL and bilaterally-implanted patients (cognitive distress, intrusiveness, auditory perceptual difficulties, and sleep

disturbance [$p < 0.05$]). Nevertheless, we could not find a significant difference between the TQ subscales of AHL and bilaterally-implanted patients preoperatively, 6 or 24 months after CI.

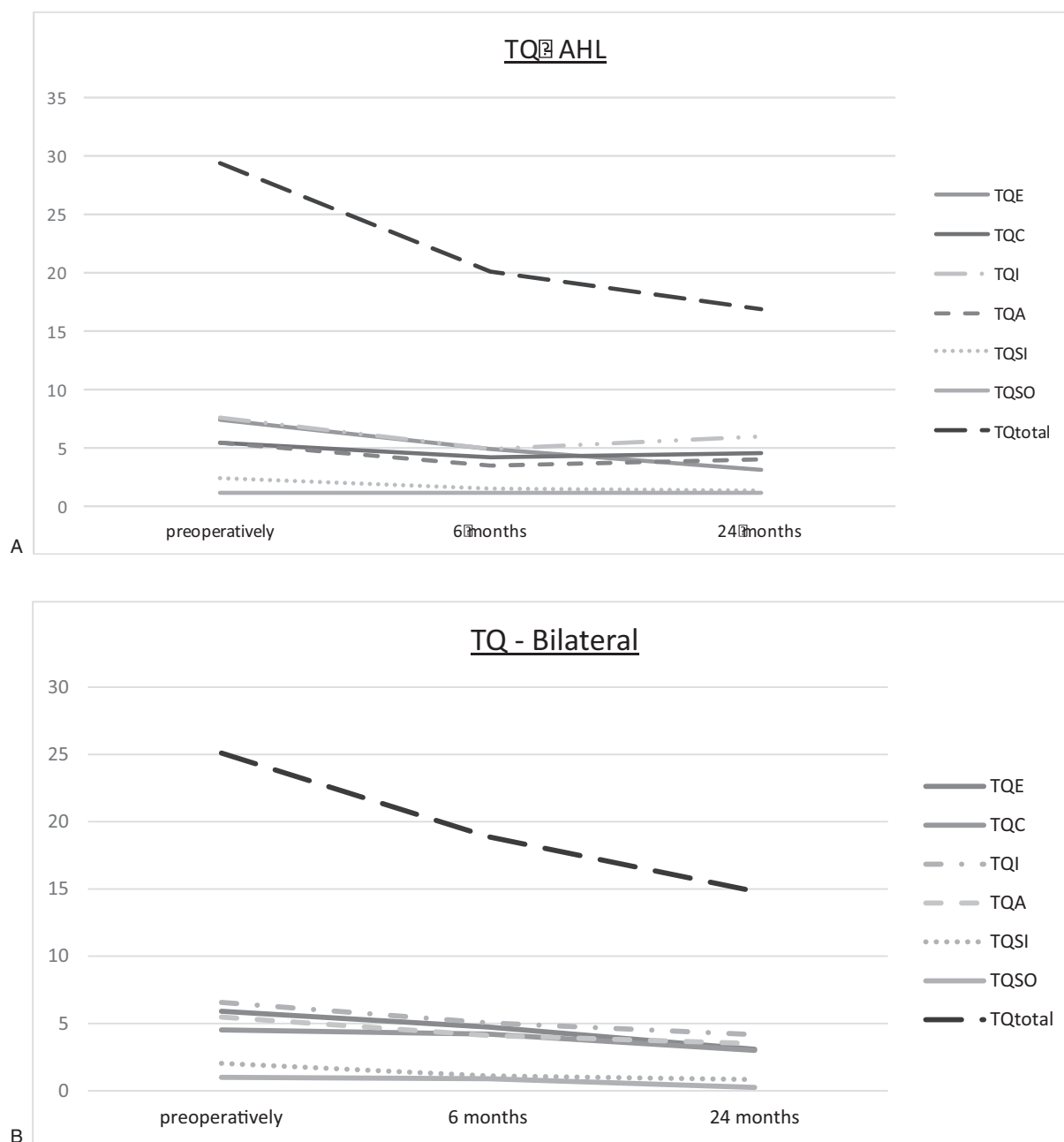


FIG. 6. Tinnitus distress: TQ total score and TQ subscores preoperatively, 6 months and 24 months after implantation in AHL patients (A) and bilaterally-implemented patients (B). (TQE: emotional distress. TQC: cognitive distress. TQE+C: summation of emotional and cognitive distress. TQI: intrusiveness. TQA: auditory perceptual difficulties. TQSI: sleep disturbances. TQSO: somatic complaints. TQtot: TQ total score) (* $p < 0.05$ = significant). AHL indicates asymmetric hearing loss.

Psychological Comorbidities

The PSQ, evaluating the stress level showed no significant alteration in AHL or in bilaterally-implemented patients. Furthermore, all PSQ subscales did not change or differ significantly 6 and 24 months after CI. We could not find a statistically-significant alteration of the COPE Inventory, representing the individual coping abilities, the GAD-7 evaluating the level of anxiety

and the ADS-L, scoring the intensity and presence of depressiveness in either AHL or bilateral patients 6 and 24 months after CI compared with preoperative results. There was no significant difference in time wearing the CI in AHL patients (mean after 24 months: 13.4 ± 3.1 h) compared with bilaterally-implemented patients (mean after 24 months: 14.45 ± 3.3 h) after 6 and 24 months ($p > 0.05$).

DISCUSSION

To the best of our knowledge, this is the first study comparing binaural hearing rehabilitation in AHL and bilaterally-implanted patients regarding speech discrimination, bimodal hearing performance, subjective assessment of auditory abilities, HRQoL, and psychological comorbidities, such as tinnitus distress and depressiveness.

Speech Perception and the Assessment of Auditory Abilities

The present study demonstrates that both groups can achieve better performance in noise via bimodal stimulation. We could calculate a significant head-shadow effect in both groups. But neither AHL nor bilaterally-implanted patients exhibited significantly-improved results for the squelch or the summation effect comparing better ear and bilateral condition. Laske et al. (8) also described no significant difference for the squelch effect in 29 bilaterally-implanted patients. These findings are in contrast to the improvements of summation and squelch effect described by different authors (27–31).

We found a significant summation effect for AHL patients for the poorer, implanted ear, but not for the better, hearing-aid adjusted ear. Van Loon et al. (32) described comparable 1-year postoperative results for AHL patients, but included only seven patients. We can now confirm his results with a longer postoperative observation period of 24 months and a larger study group of 24 AHL patients. Nevertheless, whereas we could not find a significant squelch effect for AHL patients, van Loon et al. (32) described significance for squelch and better-ear effect. The different result in our study regarding squelch effect of the better ear could be due to the included AHL CI recipients. van Loon et al. (32) included post- and prelingually-deaf patients and described that one of their patients had never worn a hearing-aid before CI. In our study, all included patients were postlingually deaf and all were stimulated and fitted with a hearing-aid before implantation.

The present study confirms findings of prior analysis of AHL patients from our research group (4). Arndt et al. (33) described the positive influence of CI in AHL patients on subjective hearing quality. They described a significant improvement for speech comprehension and spatial hearing in AHL patients 12 months postoperatively, but no difference was found for sound quality. Laske et al. (8) described that subjective results of included bilaterally-implanted patients were better than those of unilaterally-implanted patients, but the difference did not reach statistical significance. They also evaluated subjective hearing quality and described a significant positive correlation between objective and subjective results. While different authors described the benefit of CI regarding localization in AHL (32,33) and bilaterally-implanted patients (6), we did not perform a localization test. This is one of the limitations of this study. In conclusion, AHL and bilaterally-implanted patients show the same benefit regarding

bimodal stimulation and bilateral hearing effects. Binaural hearing rehabilitation leads to significant improvement in head-shadow effect and subjective hearing quality.

Health-Related Quality of Life

The results of this study demonstrate that HRQoL significantly improves after CI in AHL and bilaterally-implanted patients. The bilaterally-deaf patients included in this study showed significantly lower scores before CI compared with AHL patients. This leads to the assumption that bilaterally-deaf patients are much more restricted regarding their HRQoL compared with patients with AHL before CI. While AHL patients benefit from their one hearing-aid adjusted ear and can still interact with their social environment, bilaterally-deaf patients often feel isolated from their environment. In an earlier study, our research group described that AHL patients still perceive basic and advanced sound with the help of their contralateral hearing aid (NCIQ 1 and 2) and are usually not restricted in their speech production (NCIQ 3) (4). The present study can confirm these results with 24-month results. Different studies examining bilaterally-deaf and unilaterally-implanted patients described significant improvement in NICQ total and in all NCIQ subscales (13,33,34). Van Loon et al. (32) described significant improvement for all subscales except NCIQ 3 (speech production) in AHL patients 12 months after CI. In conclusion, CI improves HRQoL in both AHL and bilaterally-implanted patients. As early as 6 months after CI, bilaterally-implanted patients do not differ significantly regarding their psychosocial level (NCIQ 5 + 6) compared with AHL patients.

Tinnitus Distress

Tinnitus distress significantly improved in both AHL and bilaterally-implanted patients 2 years after CI. But although AHL patients already demonstrated significant results 6 months postoperatively, significance in bilaterally-implanted patients was only reached after 24 months. TQ subscales showed no significant difference between AHL and bilaterally-implanted patients either preoperatively or postoperatively. None of our patients exhibited worsening in tinnitus distress after CI. Many studies described the association of tinnitus-related distress with stress, depression and anxiety (19,35,36). Knopke et al. (16) described the significant benefit of CI on tinnitus distress in bilaterally-deafened and unilaterally-implanted patients. High tinnitus distress correlated significantly with low quality of life. A limitation of the present study is that we only evaluated tinnitus distress with the TQ and not combined with a visual analog scale. This study confirmed the statistically-significant relationship between CI and decreased tinnitus distress in both AHL and bilateral implantation patients. It can be assumed that binaural hearing rehabilitation and binaural central stimulation leads to a significant reduction in tinnitus distress independent of the etiology of hearing handicap.

Psychological Comorbidities

We found no significant difference or improvement in the stress level (PSQ total) and PSQ subscales in AHL and bilaterally-implanted patients. Our previous results in AHL patients showed a significant improvement in PSQ demands 12 months after CI, but no significant changes in total stress level (4). Unfortunately, we cannot confirm these results with this follow-up study. We could not find a significant improvement 6 and 24 months after CI compared with preoperative results for the COPE Inventory and the GAD-7 evaluating the level of anxiety in both AHL and bilaterally-implanted patients. Brüggemann et al. (37) reported that the level of stress (PSQ) and coping mechanisms (COPE) changed only marginally but not significantly after CI in bilaterally-deafened and unilaterally-implanted patients. Whereas we could not find statistical significance for GAD7 or ADS-L in AHL and bilaterally-implanted patients, Brüggemann et al. (37) described significant improvement in anxiety (GAD7) and depressiveness (ADS-L) after CI. Preoperatively, the mean values for depressiveness in both groups were relatively low compared with members of the general public evaluated by other authors (26). AHL patients and bilaterally-deaf patients depend on acoustic instruments on both sides and usually have two hearing-aids, at least one without sufficient benefit. They feel sidelined and have a higher risk for dementia or depressiveness (17,18,38–40).

CONCLUSION

This study demonstrates that binaural hearing rehabilitation improves speech discrimination in AHL and bilaterally-implanted patients. Tinnitus distress decreases and the assessment of auditory abilities improves significantly 6 and 24 months after CI. Furthermore, HRQoL significantly improves in both extended CI indication groups. Up to now, to the best of our knowledge, this is the first study evaluating long-term outcome and demonstrating the benefit of CI in AHL patients compared with bilaterally-implanted patients.

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