

Scalar Translocation Comparison Between Lateral Wall and Perimodiolar Cochlear Implant Arrays - A Meta-Analysis

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Objectives/Hypothesis: Two types of electrode arrays for cochlear implants (CIs) are distinguished: lateral wall and perimodiolar. Scalar translocation of the array can lead to intracochlear trauma by penetrating from the scala tympani into the scala vestibuli or scala media, potentially negatively affecting hearing performance of CI users. This systematic review compares the lateral wall and perimodiolar arrays with respect to scalar translocation.

Study Design: Systematic review.

Methods: PubMed, Embase, and Cochrane databases were reviewed for studies published within the last 11 years. No other limitations were set. All studies with original data that evaluated the occurrence of scalar translocation or tip fold-over (TF) with postoperative computed tomography (CT) following primary cochlear implantation in bilateral sensorineuronal hearing loss patients were considered to be eligible. Data were extracted independently by two reviewers.

Results: We included 33 studies, of which none were randomized controlled trials. Meta-analysis of five cohort studies comparing scalar translocation between lateral wall and perimodiolar arrays showed that lateral wall arrays have significantly lower translocation rates (7% vs. 43%; pooled odds ratio = 0.12). Translocation was negatively associated with speech perception scores (weighted mean 41% vs. 55%). Tip fold-over of the array was more frequent with perimodiolar arrays ($X^2 = 6.8, P < .01$).

Conclusions: Scalar translocation and tip fold-overs occurred more frequently with perimodiolar arrays than with lateral wall arrays. In addition, translocation of the array negatively affects hearing with the cochlear implant. Therefore, if one aims to minimize clinically relevant intracochlear trauma, lateral wall arrays would be the preferred option for cochlear implantation.

Key Words: Cochlear implant, scalar translocation, tip fold-over, insertion trauma, hearing preservation.

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INTRODUCTION

The indications for cochlear implantation are continuously expanding. Originally, a cochlear implant (CI) was indicated in patients with profound bilateral sensorineural hearing loss (SNHL). Nowadays, patients with significant residual hearing or with unilateral hearing loss may be considered for a CI, as well as patients with medical indications other than hearing loss (i.e., tinnitus).¹ These developments have led to renewed interest of the

scientific community to investigate insertion trauma of the electrode array and methods to minimize the trauma.²

New electrode arrays have been developed considering both minimization of insertion trauma and optimization of the electrode-nerve interface. Globally, two types of arrays are distinguished: the lateral wall (LW) and perimodiolar (PM) arrays. The PM arrays are precurved arrays, developed to reduce the distance to the centrally located modiolus of the cochlea with the auditory nerve, in theory achieving better frequency resolution by lessening the spread of excitation across electrodes and lower battery consumption as lower currents are needed to activate the nerve.^{3,4} These precurved arrays are straightened before implantation, usually with a stylet. The surgeon removes the stylet during insertion in the cochlea, the so-called Advance Off-Stylet insertion method, which enables the array to curl around the modiolus. Another way of extracting the stylet during insertion is making use of the insertion device (Midscala electrode, Advanced Bionics corporation), or replacing it with a different method using a removable external sheath (Cochlear corporation). The other type of array, the LW, is a 'straight' electrode array. Nowadays, the LW array is introduced in the cochlea without an insertion tool, and achieves its final curled position by following the LW of the cochlear duct. Thus far, both electrode arrays are commonly used in today's clinical

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practice as they each have their specific advantage. The electrode-neuron distance is smaller for the PM array than for the LW array, which is an advantage for neural stimulation as argued above, but on the other hand, the risk of damaging neural structures is larger.

Scalar translocation (STL) of the electrode array, in which the electrode array translocates from the scala tympani to the scala vestibuli or media, can cause intracochlear trauma by piercing the cochlear partition.⁵ In a non-ossified normal-shaped cochlea, the array should completely reside in the scala tympani after insertion. It is unknown, however, whether hearing with the CI is affected by STL.⁶ In addition to trauma, STL leads to an unfavorable position of the array for stimulation of the auditory nerve, which can also negatively affect the hearing outcomes.⁶ Lastly, tip fold-over (TF) of the array can lead to insertion trauma with similar detrimental effects.⁷

The position of the CI in the cochlear duct can be visualized in vivo with improved imaging technology, reduced artifact formation and good spatial resolution, like the cone beam computed tomography (CB-CT).^{8–10} In the past, it was only possible to study STL in cadaveric temporal bone studies.¹¹ The basilar membrane, however, is not visible on the postoperative CT. Recent developments have also led to improved analytic methods, in which micro-CT atlases^{6,12} and computer models⁵ are used to estimate the basilar membrane location. Therefore, it is currently possible to study the scalar location of the electrode array in CI recipients in vivo.

Since STL of the array can lead to intracochlear trauma and potential unfavorable positioning with respect to stimulation of the nerve, it is relevant to know the STL rate for different array types and the impact of STL on speech perception. Several studies over the last decade have employed postoperative CT of STL. Therefore, with a systematic review of those studies we compared the STL rate of LW and PM array types, as well as speech perception outcomes of patients with STL.

MATERIALS AND METHODS

This systematic review was conducted according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines.¹³ There is no review protocol registered.

Study Selection

A systematic search was conducted in PubMed, EMBASE, and the Cochrane Library. See appendix (Supporting information) for the full search. We limited the search to a period of the last 11 years: May 1st, 2009 to June 1st, 2020. Since 2009, when the first CB-CT scan of a CI was described,¹⁴ higher spatial resolution CTs, needed for assessing the scalar location, became available. To avoid introducing a bias, we included all publications in this period, as well as publications, which reported results that were obtained before this period. No other limitations were set. See appendix (Supporting information) for the search strategy, including the complete search used for the PubMed database.

Study Eligibility Criteria

Studies were considered eligible if it provided original postoperative CT data on the occurrence of STL or TF of the array

following cochlear implantation. Only primary insertions as treatment for severe to profound bilateral SNHL were included. Studies comparing LW to PM arrays and one-armed trials evaluating either type were considered to be eligible.

Assessment of Methodological Quality

Two researchers (SJ, AP) independently assessed the relevance and risk of bias for the selected studies using predefined criteria. Risk assessment of bias was based on the Cochrane Collaboration's tool for assessing risk of bias.¹⁵ We included all but one item: we excluded blinding of participants/personnel as blinding of personnel is impossible, and as this item is unlikely to influence scalar location of the array. We added three other items, which considered the standardization of the cochlear implantation procedure and outcome measures: 1) retro auricular approach; 2) insertion approach; and 3) postoperative CT.

If there were disagreements between both researchers, these were resolved by discussion.

Data Extraction and Analyses

The articles selected for analysis were checked for investigation site, investigators, and time period of investigation to avoid including the same patients twice. In case of overlapping study populations, the largest study was selected for this systematic review. Some studies with the same patients were included if they provided unique data. Descriptive data of each study were extracted by two authors (SJ, AP) and included age, angular insertion depth from round window (RW),¹⁶ surgical approach, array, hearing outcome, STL, and TF. Hearing outcome included both postoperative acoustic hearing assessed by tone audiometry, and speech perception scores with a CI. Our primary outcome was STL of the array. We also compared STL rate for LW and PM arrays for round window insertions only, to exclude a possible confounding factor of surgical approach (i.e., leading to a different insertion axis¹⁷). Secondary outcomes were TF of the arrays, and differences in speech perception and preservation of residual hearing between STL group and non-STL group. The Midscale array of Advanced Bionics was defined as PM, because it is a precurved electrode. If a minimum of one electrode contact was likely to be in the scala vestibuli or scala media, we categorized it as translocated. Primary insertions in the scala vestibuli were not seen as STL, unless otherwise indicated. To avoid errors, the two researchers cross-checked the extracted data. For the meta-analysis, odds ratio was used as a summary measure.

RESULTS

Study Selection

A total of 2128 unique articles were retrieved from three databases, see the PRISMA flow-chart in Figure 1. We screened the title and abstract, and excluded articles based on the exclusion criteria. The resulting 78 articles were assessed for eligibility by a whole read, leading to 42 excluded studies. In total, 33 articles were included for analysis.

Assessment of Methodological Quality

The relevance of 33 articles was scored for study population, treatment, outcome measures, and comparison LW versus PM, see Table I. Regarding studied population and treatment, all included studies investigated cochlear

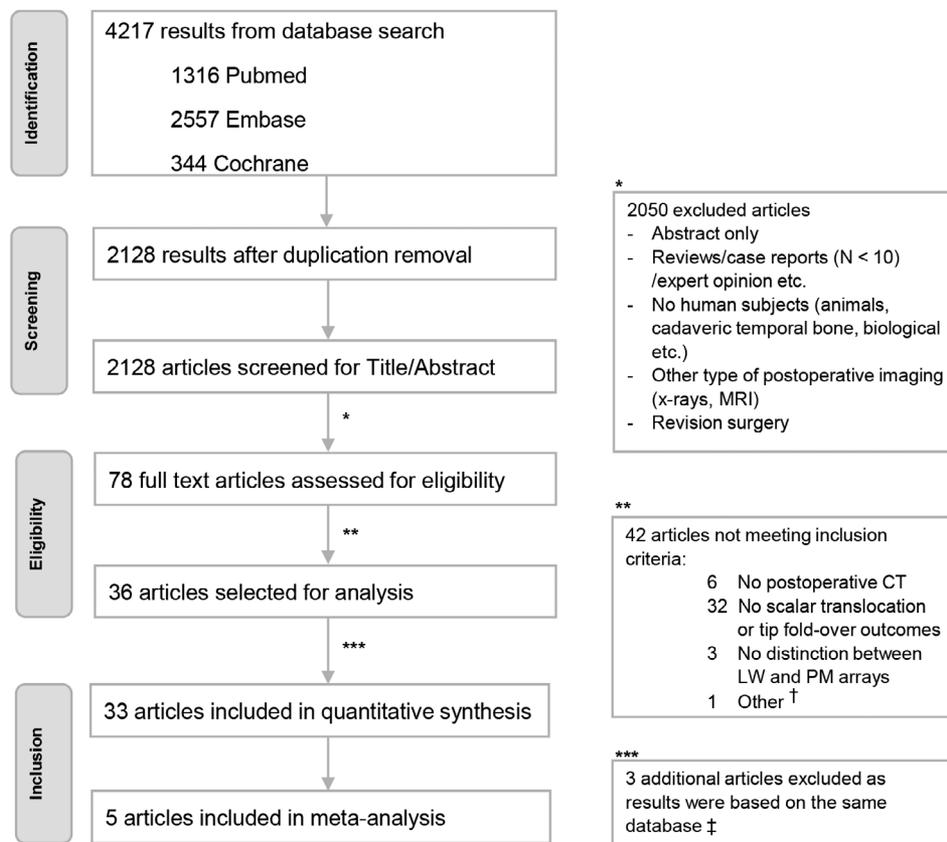


Fig. 1. Study selection process flow diagram. Flow chart of search results and study selection. †Articles excluded as array location was based partly on surgeon's report. ‡Largest study was selected for analysis if studies reported on the same database.

implantations as a treatment for patients with severe or profound bilateral SNHL. In these studies, primary cochlear implantations were performed in non-ossified normal-shaped cochleas. Regarding outcome measures, two studies^{18,19} were less relevant as they used a subgroup of their previous studies.^{5,20} However, we still included these studies for the analysis of speech perception as they provided unique data. Lastly, five comparative cohort studies (without studies^{18,19}) were identified, comparing LW arrays versus PM arrays.^{5,9,20–22}

The risk of bias was also assessed (Table I)****. There was no randomized controlled trial comparing LW and PM arrays. Only two studies assessed the outcomes blindly.^{5,9} Most other studies were one-armed trials, investigating either LW or PM arrays. Concerning the retro auricular approach, most studies (n = 21) used the posterior tympanotomy with facial recess approach; a different retro auricular approach, for example, endaural approach, was not mentioned. All other studies (n = 12) did not report the retro auricular approach. The insertion approach of the included studies was mostly unstandardized (n = 16). Eleven studies standardized the insertion approach.^{23–33} Selective reporting bias was low in all included studies; the proposed outcomes in the method sections were met in the result sections. However, there might still be selective reporting bias, as the prospective studies were not registered in a trial database beforehand, and the other studies were retrospective

cohort studies. None of the studies were scored as overall low risk of bias.

Data Extraction

STL. The baseline characteristics of the analyzed studies were extracted (Table II). There were five comparative studies.^{5,9,20–22} The five studies are comparable as they assessed the same outcome for both LW and PM arrays across a large range of arrays. The STL cohort also includes directly inserted SV arrays. We conducted a meta-analysis of these studies comparing STL rate of LW and PM arrays.^{5,9,20–22} The outcome is shown in Figure 2. The heterogeneity was moderate ($I^2 = 28\%$, $P = .23$). The use of LW arrays yielded 7% translocation and PM arrays yielded 43% translocation. The difference is significant: pooled odds ratio is 0.12, 95% confidence interval is [0.06–0.24]; ($P < .001$). In two studies, in which the arrays were inserted through the round window, and which showed virtually no heterogeneity ($I^2 = 0\%$, $P = .85$), the translocation rate with LW array was 2% and with PM array 22% (pooled odds ratio, 0.11; 95% confidence interval: [0.02–0.65], $P = .01$; Fig. 2).^{5,9}

Fourteen one-armed studies evaluating the translocation rates (without direct SV insertions) in PM arrays, showed a translocation rate of 0 to 71%, see Figure 3.^{8, 12,23,26,29–38} The CI-532 of Cochlear corporation had no STL in three^{23, 29,31} of the five studies solely investigating

TABLE I.
Relevance and Risk of Bias Assessment.

Study	Relevance*				Risk of Bias*				Incomplete Outcome Data**	Selective Reporting	
	Study Population†	Treatment‡	Outcome§	Comparison LW vs. PM	Randomization	Blinding of Outcome	Retro Auricular Approach¶	Insertion Approach			Postoperative CT#
Aschendorff 2011							NR				
Anweiler-Harbecker 2012							NR				
Holden 2013								NR			
Wanna 2014					NR						NR
Boyer 2015					NR						NR
Fischer 2015							NR				
Haesepass 2015											
Mittmann 2015											
Wanna 2015					NR	NR	NR				NR
Dalbert 2016					NR	NR	NR				
Nordfalk 2016											
O'Connell 2016a					NR	NR	NR				
O'Connell 2016b					NR	NR	NR				
Aschendorff 2017											
Mittmann 2017											
O'Connell 2017a											NR
O'Connell 2017b							NR				
Zuniga 2017							NR				
Fan 2018											
Gabrielpillai 2018							NR				
Ketterer 2018							NR				
Koka 2018											
Shaul 2018											
Sipari 2018											
An SY 2018							NR				
James 2019					NR	NR	NR				NR
Riggs 2019											
Durakovic 2020											
Iso-Mustajarvi 2020											
Mittmann 2020							NR				
Nassiri 2020											
Shaul 2020											
Zelener 2020											

LW = lateral wall array; NR = not reported; PM = perimodiolar array.

*Light grey = relevant or low bias, red = not relevant or high bias.

†Light grey if study subjects were severe sensorineural hearing loss patients.

‡Light grey if study assessed cochlear implantation as treatment for severe hearing loss.

§Light grey if study assessed scalar translocation and/or tip fold-over with postoperative CT.

¶Light grey if a mastoidectomy with posterior tympanotomy approach was used.

||Light grey if study clearly standardized any of the three insertion approaches; extended round window, round window or cochleostomy.

#Light grey if the same protocol and type of CT was used for all subjects.

**Light grey if <10% of outcome data were missing.

TABLE II.
Characteristics of Studies Reporting Scalar Translocation.*

Studies	Year	Age (Mean)	Cochlear Implantations (n)	Mean Angular Insertion Depth Degrees (SD)		Surgical Approach	Electrode-array
				LW	PM		
LW vs. PM							
Wanna	2014	61	116	NR	NR	RW, ERW, CO	Cochlear, AB, MED-EL
Boyer	2015	50	61	559 (83)	370 (39)	RW	Cochlear, MED-EL
O'Connell	2016a	60	221	469 (117)	385 (56)	RW, ERW, CO	Cochlear, AB, MED-EL
Dalbert	2016	51	14	NR	NR	RW, CO	Cochlear
James	2019	58	96	median 513	median 410	RW, ERW, CO	Cochlear, AB, MED-EL
PM							
Aschendorff	2011	NR	21 [†]	NA	NR	CO	Contour
Mittmann	2015	NR	23	NA	NR	RW, ERW	Contour Advance
O'Connell	2017a	67	18	NA	NR	RW, ERW	Midscala
Aschendorff	2017	61	44	NA	403 (32)	RW, ERW, CO	CI-532
Shaul	2018	>60	79	NA	NR	ERW, CO	CI-512
Ketterer	2018	NR	368 [†]	NA	348 (36)	CO	Contour Advance
Koka	2018	NR	32	NA	378 (37)	RW, ERW	Midscala
Sipari	2018	60	28	NA	376 (39)	RW, ERW	Midscala
Riggs	2019	NR	21	NA	NR	RW, ERW	Midscala
Durakovic	2020	median 69	76	NA	NR	RW, ERW	CI-532
Iso-Mustajarvi	2020	42	18	NA	395 (26)	RW	CI-532
Shaul	2020	NR	125 [†]	NA	NR	ERW	CI-532
Nassiri	2020	median 67	24	NA	388 (43)	RW, ERW, CO	CI-532
Zelener	2020	55	30	NA	17 (2) [§]	RW	Midscala
Zelener	2020	42	30	NA	17 (2) [§]	RW	Helix
LW							
Fischer	2015	51	63	451–495	NA	RW, CO	Flex 24,28, soft, and standard
Hassepass	2015	49	39	388 (35)	NA	RW, CO	CI-422
Nordfalk	2016	58	29	576	NA	RW	Flex 24,28, soft, and standard
O'Connell	2017b	median 69	48	514 (110)	NA	NR	Flex 24,28, and standard
Mittmann	2017	55	50	NR	NA	RW	CI-422/522
Fan	2018	2	26	NR	NA	RW, CO	MED-EL standard
An	2018	58	22	562 (45)	NA	RW, CO	Flex 28
An	2018	58	5	451 (78)	NA	RW, CO	CI-422

AB = advanced bionics; CO = cochleostomy; ERW = extended round window; LW = lateral wall array; n = total number; NA = not applicable; NR = not reported; PM = perimodiolar array; RW = round window; SD = standard deviation.

*If possible, study characteristics were separately indicated for a specific electrode-array.

[†]Including primary scala vestibuli insertions.

[‡]Children were left out as they did not receive postoperative CT scans.

[§]Insertion depth in millimeters.

this array. Seven one-armed studies, which evaluated translocation rates (without direct SV insertions) in LW arrays, showed a translocation rate of 0% to 20% (Fig. 3).^{10,21,24,25,28,39,40}

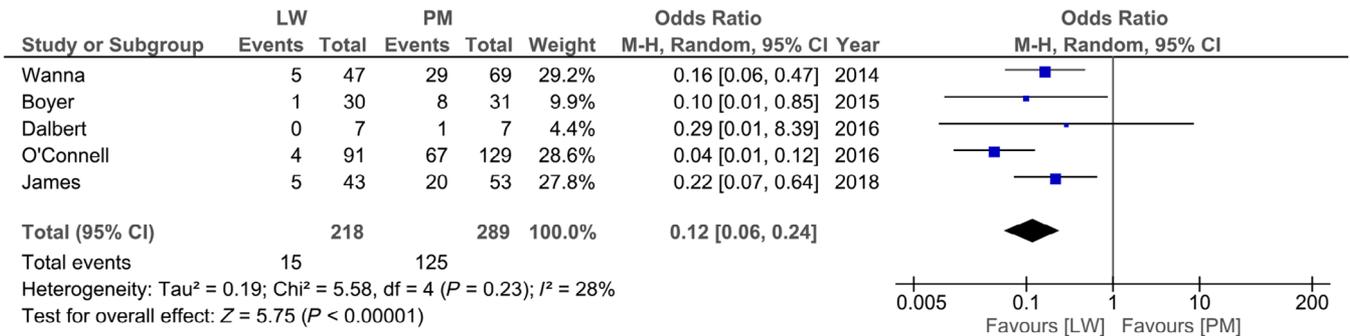
STL site. Eight studies described the site of translocation in the cochlea.^{9,10,12,27,30,35,38,39} For the LW group the majority of STL (n = 7/9) were found below the first 90° of which three were inadvertently primarily inserted in the scala vestibuli through a cochleostomy (CO) approach.³⁹ Two translocations were above 180°. In contrast, for the PM group, most arrays translocated between 90° and 180° (20/22), predominantly near 180°.

Inadvertently direct scala vestibuli insertion.

Very rarely, arrays are intentionally inserted in scala vestibuli, and still rare but more frequently, the scala

vestibuli insertion occurs unintentionally. Two studies examined arrays that were inadvertently directly inserted in the scala vestibuli.^{8,37} These studies investigated implantations performed with a CO approach, which included for one study also extended round window (ERW) approaches.³⁷ Only PM arrays were evaluated. One study solely evaluated the CI-512 array³⁷ and the other study⁸ evaluated the Contour Advance array (older version of the CI-512 array). In one study,⁸ from a total of 368 implantations, 49 arrays were directly inserted in the scala vestibuli (13%). The other study³⁷ noted 7 out of 79 arrays that were directly inserted in the scala vestibuli (9%). That study³⁷ also looked at insertions primarily intended for the scala vestibuli (in cases with otosclerosis and post-meningitis), which resulted in 4 out of 13 arrays being translocated to the scala tympani.

Analysis of all insertions:



Analysis of round window insertions:

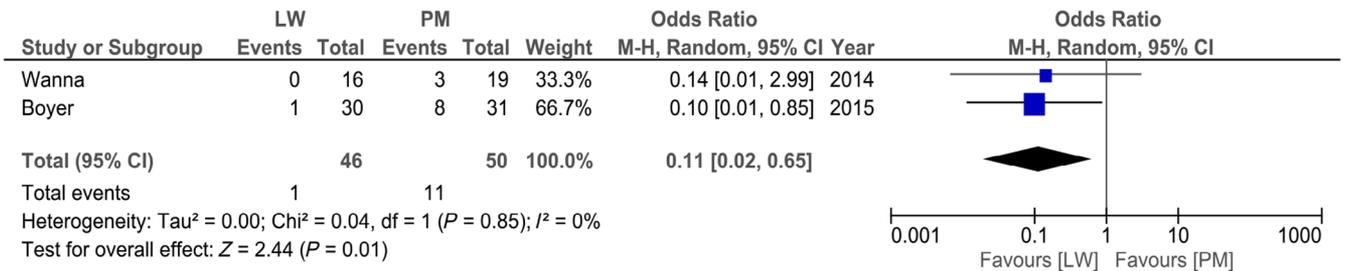


Fig. 2. Forest plots presenting odds ratio for scalar translocation of lateral wall (LW) versus perimodiolar (PM) arrays. The scalar translocation rate is significantly lower when using a LW array compared to a PM array, also if only round window insertions are analyzed. Results are based on a random effects Mantel-Haenszel model. An event is scalar translocation. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

Speech perception. Six studies compared postoperative speech perception scores between postlingually deafened adult CI recipients with and without translocated array (see Table III).^{5,6,20,22,32,37} One study⁶ showed that patients in the two groups with the lowest

performers with STLs had a worse outcome with the consonant-nucleus-consonant (CNC) words test than patients in the highest performers group without STLs (41% and 18% vs. 87%; $P < .001$). Another study⁵ showed that the STL group scored significantly less with the

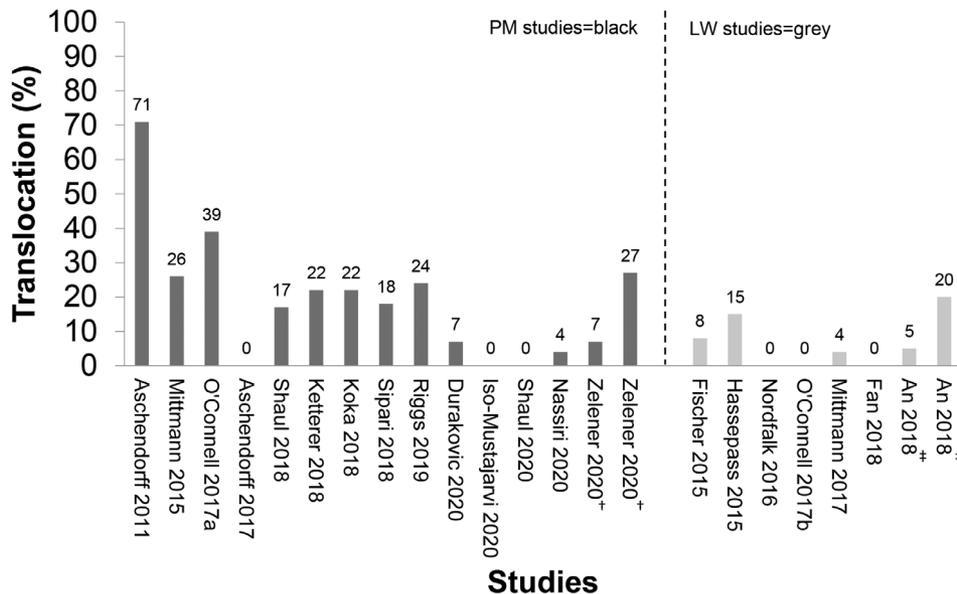


Fig. 3. Scalar translocation of one-armed studies. The scalar translocation rate presented for both the perimodiolar (PM) and lateral wall (LW) one-armed studies. Three studies of both groups had no translocation. ⁺same study, different array (first Midscale, second Helix), ⁺same study, different array (first Flex28, second CI422).

TABLE III.
Speech Perception, Normal Position Versus Scalar Translocation.

Study	Year	Array Type	Speech Audiometry	Incl. Prelingually Deaf	STL (n/Total)	Timing of Test	Non-STL Mean Score	STL Mean Score	P Value
Holden	2013	PM/LW	CNC	No	NR/114 ^a	2 wk. – 2 y	MVA: translocation related to worse outcome		$P < .01^{\dagger}$
Wanna	2014	PM/LW	CNC	No	34/116 [‡]	NR	49%	36%	$P < .05^{\dagger}$
			AzBio	No	NR	NR	NR	NR	$P > .05$
			HINT	no	NR	NR	NR	NR	$P > .05$
O'Connell	2016a	PM/LW	CNC	no	46/137	mo. 6–18	51%	39%	$P < .05^{\dagger}$
			AzBio	no	33/107	mo. 6–18	61%	50%	$P < .05^{\dagger}$
Shaul	2018	PM (CI-512)	CNC	yes	14/72	mo. 3	53%	45%	$P > .05$
			CNC	yes	14/72	mo. 12	58%	46%	$P > .05$
			CNC	no	10/51	mo. 3	64%	47%	$P > .05$
			CNC	no	10/51	mo. 12	69%	50%	$P < .05^{\dagger}$
James	2018	PM	MBAA2 list in quiet, and +10 dB SNR	no	25/96	mo. 1–12	MVA: electrode contacts in SV associated with lower speech perception scores		$P < .01^{\dagger}$
Zelener	2020	PM (Helix)	FMS	NR	7/19	mo. 12	50%	22%	Not possible
			HSM quiet		7/19		65%	35%	
			HSM +10 dB SNR		7/19		17%	17%	
Zelener	2020	PM (Midscala)	FMS		2/26		56%	30%	
			HSM quiet		2/26		~ 50%	50%	
			HSM +10 dB SNR		2/26		38%	36%	

AzBio = Arizona biomedical sentences; CNC = consonant-nucleus-consonant words; dB HL = decibels hearing level; FMS = Freiburger monosyllables; HINT = hearing in noise test; HSM = Hochmail-Schuls-Moser sentence test; LW = lateral wall array; MVA = multivariate analysis; MBAA2 = French sentence test; MS = midscala electrode array; n = number; NR = not reported; PM = perimodiolar array; ScTr = scalar translocation; SNR = signal noise ratio; SV = scala vestibuli.

^a23% of all electrode contacts in scala vestibuli.

[†]Statistically significant.

[‡]This represents all patients, unknown how many were included for the speech perception scores.

CNC test (49% vs. 36%; $P < .05$), but similarly as the non-STL group for the Arizona Biomedical sentences test (AzBio) and hearing in noise test (HINT). The third study²⁰ showed that the STL group scored significantly less with both the CNC test and AzBio test (51% vs. 39% CNC, 61% vs. 50% AzBio; $P < .05$). The fourth study³⁷ showed no difference between STL and non-STL group with the CNC word test, however, analyses of only postlingually deafened patients at 12 months postoperatively revealed worse CNC scores for the STL group (69% vs. 50%; $P < .005$). Another study showed that STL was associated with worse results with the French sentence test (MBAA2) both with and without background noise (increasing proportion of electrodes in SV was associated with lower scores; $P < 0.01$). Finally, the last study³² had small groups leading to inconclusive results. They observed non-significant worse scores for the Freiburger monosyllables test for the STL group with both, PM arrays, the Midscala, and Helix electrode array.

We used the weighted mean to summarize the speech perception results for the postoperative word list score in quiet between the STL and non-STL group. Four out of the six studies comparing speech perception scores between STL and non-STL reported postoperative means (see Table III), and were, therefore, included.^{5,20,32,37} These studies evaluated mainly PM arrays, with time of testing ranging between 3 and 18 months. In addition,

three types of lists were used; the CNC words, AzBio sentences, or the Freiburger monosyllables (FMS). The STL group had a weighted mean of 41% correct and the non-STL group 55%, resulting in a difference of 14%. Apart from one study,³⁷ no standard deviations were reported. That study reported a standard deviation of 17% for the STL group and 21% for the non-STL group for postlingually deaf patients at 12 months postoperatively. If we assume the same standard deviations for the groups of the other studies, the difference in speech scores between STL and non-STL would be significant ($Z = 5.82$, $P < .001$), favoring non-STL.

Finally, only one study¹⁹ compared LW and PM speech perception scores between patients with confirmed non-translocated arrays. Specifically, they compared the CI422 array (LW) with the CI512 (PM), and reported higher AzBio scores (70% vs. 46%, $P = .02$) for the CI422 array.

Residual hearing. Four other studies compared residual hearing around 4 weeks postoperatively in CI recipients with and without translocated array (Table IV).^{18,26,33,36} Residual hearing was assessed in two of these studies by measuring the difference between postoperative and preoperative outcomes of pure tone audiometry at low frequencies (LF-PTA).^{26,33} The other two studies assessed postoperative loss of functional residual hearing (<80 dB HL).^{18,36} Three of the four

TABLE IV.
Residual Hearing, Normal Position Versus Scalar Translocation.

Study	Year	Array Type	PTA (Hz)	STL (n/Total)	Timing of Test	Non-STL [*]	STL [*]	P Value
Wanna	2015	PM/LW	250	7/45	wk. 4	22/38 functional residual hearing (<80 dB HL)	0/7 functional residual hearing (<80 dB HL)	$P < .01^\dagger$
O'Connell	2017a	PM (Midscala)	125, 250, 500	6/15	wk. 2/3	Threshold shift 16	Threshold shift 38	$P < .05^\dagger$
Koka	2018	PM (Midscala)	125, 250, 500	7/32	wk. 4	Threshold shift 28	Threshold shift 36	$P > .05$
Riggs	2019	PM (Midscala)	250, 500, 1000	7/21	wk. 4	Mean 53% loss 1/14: 100% loss	Mean 94% loss 6/7: 100% loss 1/7: 55% loss	$P < .01^\dagger$

dB HL = decibels hearing level; LW = lateral wall array; PM = perimodiolar array; PTA = pure tone audiometry; STL = scalar translocation.

*Threshold shifts values are in decibel.

†Statistically significant.

studies^{18,33,36} showed significantly more loss of residual hearing for patients with a STL compared to patients with normal positioned array; in contrast, one study²⁶ showed no effect of STL on residual hearing.

TF. Eleven studies reported TF results.^{12,23,29-31,38,39,41-44} Just two studies compared LW and PM arrays.^{42,43} One study⁴² described 15 TFs from a total of 1722 implantations (0.9%). TFs occurred mostly with PM arrays (13/15), with a rate of 1.67% PM versus 0.23% for the LW insertions. The second study⁴³ described six TFs in a cohort of 303 (2%) implantations, in which a PM and LW array was used in, respectively, 51% and 48% of the cases with four TFs with PM arrays (three Contour Advance and one Midscala), and two with LW arrays (CI-422 and 1 J). In total, these two studies evaluated 2025 implantations for TF, with significantly more TFs with PM arrays ($X^2 = 6.8, P < .01$).

Six studies described the TF rate of the CI-532 electrode array.^{12,23,29-31,44} From a total of 622 implantations, 37 TFs were identified, resulting in a TF rate of 5.9% for the CI-532. Finally, for the remaining three studies, two studies reported one TF,^{38,39} and one study⁴¹ reported no TF.

DISCUSSION

STL

Our study shows with a comprehensive overview of the literature that STL of the array is frequently seen after cochlear implantation and negatively affects speech perception scores. The meta-analysis, which includes five studies, shows that the STL rate is significantly lower for the LW than the PM arrays (7% vs. 43%). In addition, the STL rate for LW arrays is still significantly lower (2% vs. 22%) when only considering RW approaches. The CI-532 electrode array was not included in the meta-analysis. The one-armed studies show similar large differences in STL rate between LW and PM arrays. However, there was a substantial risk of bias in the included studies, mainly caused by lack of randomization or standardization of the insertion approaches (i.e., ERW, RW, and CO) and inclusion of different arrays of both groups. In addition, since this review study focused on large insertion trauma (i.e., STL or TF), other more subtle insertion traumas might have been

missed.⁴⁵ In current medical practice, postoperative CTs are not able to detect minute insertion traumas. Lastly, other factors like cochlear morphology, although not evidently shown by a previous study, might affect STLs (i.e., smaller cochleas leading to increased STLs).⁸

The possible explanation for the higher STL rate encountered with PM arrays is as follows. Nowadays, most surgeons prefer the RW approach for insertion of the array, as shown by this and previous studies.^{46,47} The combination of RW and PM arrays introduces possible difficulties for the surgeon, because the PM array is larger than in LW arrays. This aspect might lead to increased friction forces, for example, by obstruction at the round window entry,^{48,49} although in theory the RW and scala tympani dimensions should be sufficient for PM arrays.^{50,51} In addition, insertion with PM arrays requires more experience than with LW arrays. Probably, surgeons with ample experience with the PM arrays encounter fewer STLs.³⁴ This can be explained by the surgeon needing to accurately position the stylet in the basal turn of the cochlea, and subsequently perform the insertion off-stylet technique. The off-stylet technique can be done with or without an insertion tool.⁴⁶ Lastly, the stylet itself is a semi-rigid structure that can penetrate intra-cochlear structures like the osseous spiral lamina, thus causing STLs.^{52,53}

The latest PM arrays of both Advanced Bionics and Cochlear - namely the Midscala and the CI-512/CI-532 arrays - were included in our analysis. Notably, the CI-532 had no STL in three^{23,29,31} out of five studies.^{12,23,29-31} A possible explanation for the much lower STL rate is the different method of insertion: the stylet is replaced by an external sheath tube used for guiding the array during insertion, leading to less friction forces. Furthermore, the CI-532 array is smaller.

Location of Translocation

Eight studies described the translocation site for 32 translocations.^{9,10,12,27,30,35,38,39} Most translocations occurred at around 180° depth, predominantly with PM arrays. Cadaveric studies have shown that translocation occurs mainly at the base of the cochlea leading to the first ascending turn of the cochlea, around 180° depth, which is possibly caused by a steep decrease in the dimensions of the scala tympani.⁵⁴⁻⁵⁶ Increased

intracochlear friction can also be caused by the complex and heterogeneously shaped cochlear hook region at the very most basal part of the cochlea.⁵⁵⁻⁵⁷ The included studies support the notion that STL occurs mainly at the base of the cochlea, especially around 180° depth.

Speech Perception

Postoperative speech perception was poorer for the CI patients with STL compared to those without a STL (a weighted mean difference of 14%). Due to the low STL rate for the LW group in general (7%), these results are primarily based on the PM arrays. The non-STL group was patients with an array fully inserted in the ST and the STL group were patients with at least one electrode contact in the SV. Previous studies have shown that speech perception improves up to 1-year post implantation.^{58,59} The results show that STL negatively impacts speech perception irrespective of the timing of the test (i.e., between 1 and 24 months), indicating a probable irreversible effect of STL during insertion. Note that speech perception results at 3 months and earlier after surgery are not ideal to assess speech perception outcomes. Several factors may contribute to the detrimental effect of translocation on hearing with a CI. Translocation of the array to the scala vestibuli increases the distance to the auditory nerve compared to the normal position in the scala tympani, leading to inferior stimulation of the auditory nerve. In addition, the array in the scala vestibuli might possibly lead to increased overlap of stimulated neural regions between electrodes.⁶ In addition, the STL itself can damage the structures in the cochlear partition, therefore, interacting with and destroying the fine microstructures (e.g., stria vascularis, organ of Corti, and spiral ganglion cells).⁵⁴ For instance, it may accelerate degeneration of the spiral ganglion cells (SGCs), by damaging these cells or indirectly by damaging residual hair cells and/or supporting cells, which promote survival of the SGCs.⁶⁰⁻⁶² These factors also apply to patients with an array directly inserted in the SV. Two studies described these patients in more detail.^{8,37} While full SV insertion is disadvantageous, one should note that arrays directly inserted in the SV can translocate to the ST.

We identified only one study¹⁹ comparing LW and PM speech perception scores between patients with confirmed non-translocated arrays. They reported higher speech perception scores for the LW group. In contrast, another study reports better outcomes if the array is closer to the modiolus, even though STL was not excluded.⁶ The majority of the studies, however, show no difference between the two groups.⁶³⁻⁶⁷ We have to note that STL was not assessed in those studies. In future studies, STL of the array should be considered in the analysis of speech perception outcomes.

Residual Hearing

Preserving residual hearing is important assuming it leads to better speech understanding with CI.⁶² Studies with electric and acoustic stimulation (EAS) CIs have shown that residual hearing can improve speech understanding.⁶⁸⁻⁷⁰

The underlying mechanisms are not clear. Two hypotheses have been put forth: that the survival of the hair cells at the lower frequencies leads to better auditory nerve survival, or that the acoustic stimulation of these hair cells directly contributes to speech understanding.^{62,71} There is no definitive proof supporting either of these hypotheses. All in all, preferably both hair cells and SGCs (i.e., the residual hearing of patients) are preserved.

Preservation of residual hearing was assessed between the STL group and non-STL group, again primarily based on the PM arrays; especially the Midscale array of Advanced Bionics corporation (Table III).^{18,26,33,36} These studies pointed to a negative effect of STL on hearing preservation. The results of these studies were based on audiometric testing 1 month after cochlear implantation. However, previous studies have shown that residual hearing of CI recipients deteriorates over time.^{70,72,73} Therefore, it is not clear whether the difference in postoperative residual hearing between STL and non-STL persists over time.

To our knowledge, there are no studies that evaluated preservation of residual hearing for non-translocated arrays between PM and LW arrays. One study showed - without analysis of array position - that patients with LW arrays had smaller differences between post- and preoperative low frequency tone audiometry than patients with PM arrays.⁷³ These results are in line with our finding that STL negatively affects residual hearing of CI recipients, and occurs mainly with PM arrays. Therefore, LW arrays are probably better suited to preserve the residual hearing of CI recipients.

TF

TF rate of the array is very low; specifically, in two large studies investigating several arrays, it was less than 2%.^{42,43} The TF rate was almost three times larger for the CI-532 (5.9%), which might be related to a different method of insertion, using an external sheath for insertion. The TF rate of around 2% corresponds to an older study with intra- and postoperative plain x-rays.⁷⁴ This can be explained in two ways: either the TF rate is not different from the latest generation of arrays (except for the CI-532), or the TF rate has decreased while improved imaging techniques unmask otherwise undetected TFs.

Overall, our study shows most TFs were observed for PM arrays. This is not surprising, considering the method of implantation of PM arrays. The stylet can be too shallow or too deeply inserted before release of the array, resulting in a misalignment with the modiolus wall causing a TF.^{75,76} Surprisingly, a new method of insertion for the PM arrays, the external sheath of the CI-532, has an increased chance of TF.

CONCLUSION

STL of the array is quite common during cochlear implantation surgery, especially when using a PM array, occurring predominantly at 180° intracochlearly. In addition, STL seems to negatively affect speech perception outcomes, especially word perception scores in quiet and residual hearing of CI recipients. However, speech

perception outcomes are not only determined by type of array. Lastly, TF of the array is an infrequent and persisting phenomenon, seemingly associated with both stylet and external sheath based PM arrays. If one aims to minimize clinically relevant intracochlear trauma, LW arrays would be the preferred option for cochlear implantation for the current medical practice.

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