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Systematic Review

Laser Versus Conventional Fenestration in Stapedotomy for Otosclerosis: A Systematic Review

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Objectives/Hypothesis: To assess hearing results and complications following primary stapedotomy in otosclerosis patients comparing the use of laser and conventional techniques for fenestration.

Study Design: Systematic literature review.

Methods: A systematic bibliographic search was conducted in PubMed, Embase, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, and Scopus. Studies reporting original data on the effect of laser fenestration, compared to conventional techniques, on closure of air-bone gap in patients undergoing primary stapedotomy were included. Directness of evidence and risk of bias of the selected articles were assessed. Studies with low directness of evidence, high risk of bias, or both were not further analyzed. The absolute risks, risk differences, and 95% confidence intervals were extracted only for studies with moderate to high directness of evidence and moderate to low risk of bias.

Results: In total, 383 unique studies were retrieved. Eight of these (including 999 procedures) provided high or moderate directness of evidence and carried a moderate risk of bias, and were considered eligible for data extraction. The included studies show no consistent difference in postoperative air-bone gap closure or immediate postoperative vertigo.

Conclusions: Both footplate fractures and sensorineural hearing loss appear to occur more frequently in the conventional group than in the laser group. Therefore, we prefer laser above conventional methods for footplate fenestration in primary stapedotomy.

Key Words: Laser; microdrill; micropick; otosclerosis; stapedotomy; stapes.
Level of Evidence: NA

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INTRODUCTION

Otosclerosis is characterized by abnormal sponge-like bone growth in the middle ear causing progressive hearing loss.[1] It mainly affects the ossicular chain and can be treated surgically by removing (part of) the stapes and replacing it with a prosthesis—stapedotomy and stapedectomy, respectively. Although stapes surgery has proven to be a safe and effective treatment option for otosclerosis,[2] permanent sensorineural hearing loss (SNHL) does occur in a small percentage of patients. The incidence of this dreaded complication following stapes surgery was <1% in large series.[3,4]

Over the years, stapedotomy fenestration techniques have evolved from the use of microinstruments to microdrills, and more recently laser. The main advantages of the laser include the high precision of its application and the low risk of footplate mobilization as a result of the no-touch principle of this technique. Even though inner ear damage as a result of mechanical trauma is less likely, the potentially harmful effects of laser use should not be underestimated. Thermal effects on the perilymph associated with CO_2 laser use, acoustic trauma in erbium:yttrium-aluminum-garnet laser use, and penetration of the neuroendothelium by the argon and potassium titanyl phosphate laser could all hypothetically result in inner ear dysfunction.[5–8]

The objective of this systematic review was to evaluate whether laser fenestration in primary stapedotomy for otosclerosis is safer than conventional fenestration techniques, measured by air-bone gap closure and adverse effects, including SNHL, vertigo, tinnitus, and footplate fractures.

MATERIALS AND METHODS

Retrieving Studies

A systematic search in PubMed, Embase, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, and Scopus was conducted with the assistance of a clinical librarian. Relevant synonyms for the search terms otosclerosis

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TABLE I.
Search for Studies on the Effect of Laser Fenestration Compared to Conventional Fenestration Techniques in Primary Stapedotomy for Otosclerosis.

Database	Search	Field
PubMed, The Cochrane Library, CINAHL, Scopus	(otosclerosis OR otosclerotics OR otosclerotic OR otospongiosis OR otospongioses OR otospongiotic OR otospongeotic OR stapedotomies OR stapedotomy OR stapedectomies OR stapedectomy OR (stapes AND (surgery OR surgeries OR mobilization OR mobilisation)) OR (ossicular AND (replacement OR replacements))) AND (laser OR lasers OR KTP OR "potassium titanyl phosphate" OR CO2 OR "carbon dioxide" OR "Er-YAG" OR erbium OR "yttrium aluminium garnet" OR diode OR argon OR thulium)	Title/abstract
Embase	(otosclerosis:ab,ti OR otosclerotics:ab,ti OR otosclerotic:ab,ti OR otospongiosis:ab,ti OR otospongioses:ab,ti OR otospongiotic:ab,ti OR otospongeotic:ab,ti OR stapedotomies:ab,ti OR stapedotomy:ab,ti OR stapedectomies:ab,ti OR stapedectomy:ab,ti OR (stapes:ab,ti AND (surgery:ab,ti OR surgeries:ab,ti OR mobilization:ab,ti OR mobilisation:ab,ti)) OR (ossicular:ab,ti AND (replacement:ab,ti OR replacements:ab,ti))) AND (laser:ab,ti OR lasers:ab,ti OR KTP:ab,ti OR "potassium titanyl phosphate":ab,ti OR CO2:ab,ti OR "carbon dioxide":ab,ti OR "Er-YAG":ab,ti OR erbium:ab,ti OR "yttrium aluminium garnet":ab,ti OR diode:ab,ti OR argon:ab,ti OR thulium:ab,ti)	Title/abstract

Date of search: May 22, 2013.
CINAHL = Cumulative Index to Nursing and Allied Health Literature.

and laser were combined (Table I). Two assessors (I.W., D.M.A.K.) independently excluded duplicate titles and screened titles and abstracts of the retrieved records for inclusion. Studies on the efficacy of laser stapedotomy compared to conventional fenestration methods in patients undergoing stapes surgery for otosclerosis were included. Conventional fenestration methods included the use of microinstruments and microdrills, such as the Skeeter drill. Only reports of original study data were included; systematic reviews, opinion papers, animal or laboratory studies, and case reports were excluded (see Fig. 1 for selection criteria). Related publications were searched in PubMed, whereas Scopus and Web of Science were used for cross-reference checking for studies not identified by the initial literature search. Selected articles, related reviews, meta-analyses, and guidelines were hand searched for relevant cross-references.

Assessing Studies

Using predefined criteria, two reviewers (I.W., D.M.A.K.) independently assessed the selected studies for their directness of evidence and risk of bias (Table II). Directness of evidence concerned the applicability of the study findings for answering the clinical question and involved the evaluation of patients and compared treatments and outcomes: 1) patients, notably patients undergoing primary stapedotomy for otosclerosis; 2) treatment comparison, notably comparisons of any type of laser with conventional fenestration techniques; 3) outcomes, notably

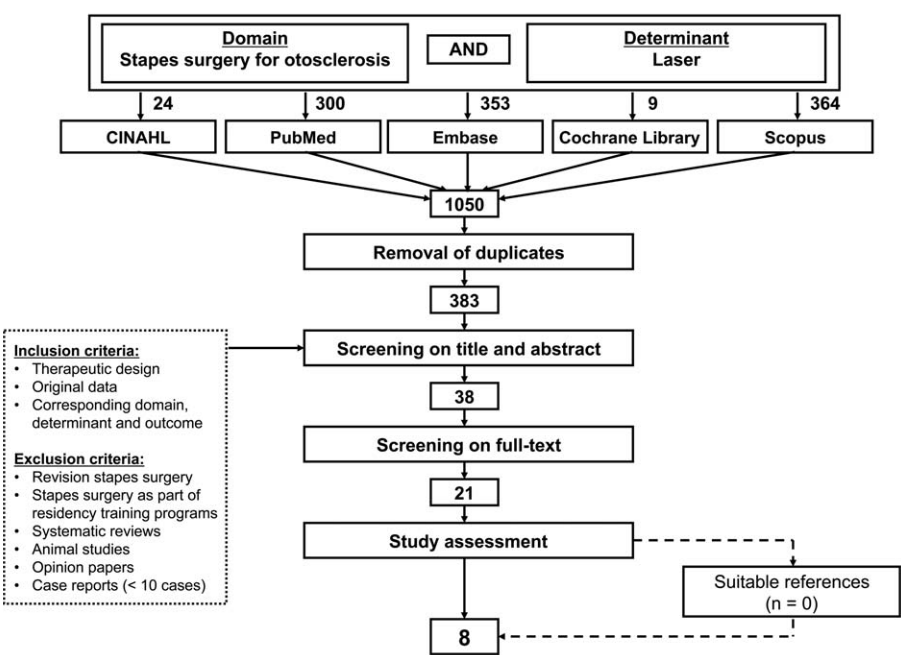

Fig. 1. Flowchart for the selection of studies on the effect of laser fenestration compared to conventional fenestration in primary stapedotomy for otosclerosis. CINAHL = Cumulative Index to Nursing and Allied Health Literature.

TABLE II.
Assessment of Studies on the Effect of Laser Fenestration Compared to Conventional Fenestration in Primary Stapedotomy for Otosclerosis.

			Directness of Evidence				Risk of Bias					
Study	Sample Size of Study (N)	Study Design	Patients	Treatment	Outcome	Directness of Evidence	Treatment Allocation	Blinding	Standardization Treatment (T)	Standardization Outcome (O)	Complete Data	Risk of Bias
Häusler (1996)[6]	83	RCS	●	●	●	H	?	?	●	●	●	M
Badran (2006)[15]	85	RCS	●	●	●	H	?	?	●	○	●	M
Barbara (2011)[16]	39	RCT	●	●	●	H	?	?	?	●	●	M
Moscillo (2006)[23]	110	RCS	●	●	●	H	?	?	?	●	●	M
Matkovic (2003)[22]	80	PCS	●	●	●	H	?	?	?	●	●	M
Motta (2002)[24]	451	RCS	●	●	●	H	?	?	○	●	●	M
Just (2012)[20]	48	PCS	●	●	○	M	○	○	?	●	●	M
Cuda (2009)[18]	60	PCS	●	●	○	M	○	○	●	●	●	M
Singh (2012)[31]	20	RCS	●	●	●	H	?	?	●	●	?	H
Malafronte (2011)[21]	83	PCS	●	●	●	H	○	?	?	?	●	H
Nguyen (2008)[25]	253	RCS	●	●	●	H	?	?	●	●	○	H
Galli (2005)[19]	70	PCS	●	●	●	H	?	?	●	?	?	H
Parrilla (2008)[26]	152	RCS	?	●	●	M	?	?	●	●	?	H
Rauch (1992)[27]	100	RCS	●	●	●	H	?	?	?	○	○	H
Brase (2013)[17]	302	RCS	●	●	○	M	?	?	?	●	○	H
Szymanski (2007)[33]	420	RCS	●	●	○	M	?	?	●	?	?	H
Arnoldner (2006)[14]	151	RCS	●	●	●	M	?	?	?	●	○	H
Shabana (1999)[29]	350	RCS	?	●	●	M	○	?	?	○	?	H
Silverstein (1989)[30]	47	RCS	●	○	●	M	?	?	○	○	○	H
Ryan (2009)[28]	19	RCS	●	?	○	L	?	?	?	?	?	H
Somers (2006)[32]	336	PCS	?	●	○	L	?	?	?	●	?	H

Directness of evidence

Patients: ● = primary stapedotomy for otosclerosis; ○ = primary stapedectomy, revision surgery for otosclerosis, stapes surgery as part of residency training programs, other. Treatment: ● = any type of laser compared with conventional techniques (e.g., micropick or microdrill); ○ = other. Outcome: ● = recovery of conductive hearing loss measured by closure of the air-bone gap; ○ = other.

Risk of bias

Treatment allocation: ● = adequate concealment (e.g., sealed envelopes) and randomization (e.g., random number table or coin toss); ○ = no adequate concealment and/or randomization; ? = unclear, no information provided. Blinding of fenestration method during postoperative pure-tone audiometry and interpretation of audiometry: ● = patients and clinicians blinded; ○ = only patients blinded or no blinding; ? = unclear, no information provided. Standardization (T) of surgical procedure and laser settings: ● = yes; ○ = no; ? = unclear, no information provided. Standardization (O) of postoperative pure-tone audiometry with regard to frequencies used and follow-up duration: ● = yes; ○ = no; ? = unclear, no information provided. Completeness of outcome data for primary outcome: ● = below 10% missing data; ○ = 10% or more missing data; ? = unclear, no information provided.

H = high; L = low; M = moderate; PCS = prospective cohort study; RCS = retrospective cohort study; RCT = randomized controlled trial.

TABLE III.
Descriptives of Studies on the Effect of Laser Fenestration Compared to Conventional Fenestration in Primary Stapedotomy for Otosclerosis.

Study	Laser	Laser Settings				
		Power (W)	Duration (s)	Spot Size Diameter (cm)	Pulse Mode	Fluence (J/cm^2)
Häusler (1996)[6]	Argon	1.5	0.1	0.06	NA	53
Badran (2006)[15]	CO_2	20	0.05	0.07–0.08	Continuous	199–260
Barbara (2011)[16]	Thulium	NA	NA	0.05	NA	NA
Moscillo (2006)[23]	CO_2	NA	NA	NA	NA	NA
Matkovic (2003)[22]	CO_2	20	0.03	NA	NA	NA
Motta (2002)[24]	CO_2 (Zeiss, Sharplan, or Flashscan)	5–18	0.05	0.06–0.07	Single defocused impulse (Zeiss), superpulse (Sharplan), continuous (Flashscan)	65–318
Just (2012)[20]	CO_2	20	0.04	0.06	Continuous	283
Cuda (2009)[18]	CO_2	20	0.05	0.07	Continuous	260

NA = not available.

our outcome of interest was air-bone gap closure. Studies were classified as having high, moderate, or low directness of evidence if they complied with all three, two, or one of these criteria, respectively. With the risk of bias assessment, the extent of selection and information bias was established. Assessment of risk of bias involved evaluation of selection bias, notably 1) concealed treatment assignment with random allocation and 2) completeness of reported data; and information bias, notably 1) blinding of treatment nature and outcome assessment, 2) standardization of treatment, and 3) standardization of outcome assessment. Studies were classified as having a low risk of bias if they satisfied all of these criteria, moderate risk of bias if they satisfied at least one of the criteria for selection bias plus one of the criteria for information bias, and the remainder were classified as high risk of bias. When an item of the study assessment was not reported, it was rated “unclear.” When an item was reported, it was classified as either “satisfactory” or “unsatisfactory.” Initial discrepancies between independent reviewers were resolved by discussion, and reported results are based on full consensus. Studies with low directness of evidence, high risk of bias, or both were excluded from further review.

Data Extraction

For the included studies, two authors (I.W., D.M.A.K.) independently extracted descriptive data of patients and interventions. For the outcomes of interest, the absolute risks and their risk differences with the corresponding 95% confidence intervals (CIs) were extracted. The primary outcome measure was closure of the air-bone gap to within 10 dB or less, preferably for the frequencies 500, 1,000, 2,000, and 3,000 or 4,000 kHz, which is generally considered a successful outcome of stapes surgery in the literature in regard to the surgeon’s surgical performance.[4,9–11] According to the Committee on Hearing and Equilibrium, follow-up should be at least 1 year for this outcome measure, because results change over time, and long-term results provide a more realistic prognosis.[12] Secondary outcome measures were SNHL, vertigo, tinnitus, and fractured footplate. Preferably, absolute risks were extracted. If these were not given or could not be recalculated, the findings as reported in the article were presented.

RESULTS

Retrieving Studies

A total of 1,050 titles were retrieved, of which 383 were unique studies (see Fig. 1; date of the last search was May 22, 2013). Articles published in Chinese were excluded.[13] After selection based on title and abstract, and subsequent full-text screening, 21 articles[6,14–33] were initially considered eligible for answering our question. Cross-reference checking revealed no additional articles.

Assessing Studies

The directness of evidence was found low or moderate for 10 studies and high for 11 studies (Table II). Assessing all 21 studies, it was unclear whether all patients had undergone primary stapes surgery in three studies,[26,29,32] more than one type of laser was used without performing subgroup analyses in one study,[30] and air-bone gap closure was not reported in six studies.[17,18,20,28,32,33] In eight studies,[6,15,16,18,20,22–24] the risk of bias was moderate, whereas it was high in the other 13. Adequate randomization, treatment allocation, and blinding were either not achieved or no information was provided regarding these criteria in any of the 21 included studies. Standardization of treatment was achieved in eight of the included studies[6,15,18,19,25,26,31,33] and standardization of postoperative pure-tone audiometry in 13 studies.[6,14,16–18,20,22–26,31,32] In the studies that did not meet these criteria, laser settings were not adequately described or standardization of follow-up duration was lacking. For five studies,[14,17,25,27,30] a large amount of outcome data was missing, and in another seven studies[19,26,28,29,31–33] it was unclear whether outcome data were complete. Selective reporting cannot be ruled out in the retrospective cohort studies. Two retrospective studies explicitly reported that patients lacking

TABLE IV.
Results of Studies on the Effect of Laser Fenestration Compared to Conventional Fenestration in Primary Stapedotomy for Otosclerosis.

				Air-Bone Gap Closure (<10 dB)*			Adverse Events			
Study	Laser (n)	Control (n)	Follow-up	Laser (%)	Control (%)	Risk Difference (% [95% CI])	Outcome	Laser (%)	Control (%)	Risk Difference (% [95% CI])
Häusler (1996)[6]	Argon (54)	Skeeter drill (29)	8 weeks	98	86	12 [9.5, 14.5]	Vertigo	1.9	3.4	1.5 [1.3, 1.7]
							SNHL	1.9	3.4	1.5 [1.3, 1.7]
Badran (2006)[15]	CO_2 (36)	Skeeter drill or microperforator (49)	<1 year	53	66	−13 [−10.1, −15.9]	Vertigo	2.8	12.2	9.4 [7.5, 11.3]
							Tinnitus	2.8	2	−0.8 [−0.5, −1.1]
							Footplate fracture	0	8.2	8.2 [6.6, 9.8]
							SNHL	0	2	2 [1.7, 2.3]
Barbara (2011)[16]	Thulium (10)	Skeeter drill (29)	1 month	90	86.2	3.8 [3.1, 4.5]	—	—	—	—
Moscillo (2006)[23]	CO_2 (65)	Microdrill (45)	3 years	90.6	86.2	4.4 [3.7, 5.1]	SNHL	1.6	4.4	2.8 [2.4, 3.2]
Matkovic (2003)[22]	CO_2 (40)	NA (40)	6 months	82.6	75.3	7.3 [5.8, 8.8]	Vertigo	26	55	29 [22.8, 35.2]
							Tinnitus	7.5	0	−7.5 [−5.7, −9.2]
							Footplate fracture	0	12.5	12.5 [9.9, 15.1]
Motta (2002)[24]	CO_2 (282)	Shea microdrill (169)	>1 year	87.4	73.7	13.7 [12.5, 14.9]	Vertigo	0	9.5	9.5 [8.7, 10.3]
							SNHL	1.8	3	1.2 [1.2, 1.2]
Just (2012)[20]	CO_2 (35)	Microperforator (13)	14–21 days and 6 weeks	—	—	—	—	—	—	—
Cuda (2009)[18]	CO_2 (30)	Skeeter drill (30)	1 month	—	—	—	Vertigo	10	6.7	−3.3 [−2.5, −4.1]
							Footplate fracture	0	0	0

When risk difference is positive it favors laser.
*Frequencies 0.5, 1, 2, and 3 or 4 kHz used in all studies for calculation of air-bone gap closure, except for the studies performed by Häusler et al. (0.5, 1, and 2 kHz used instead) and Barbara et al. (0.25, 0.5, 1, and 2 kHz used instead).
CI = confidence interval; n = number of procedures; NA = not available; SNHL = sensorineural hearing loss.

adequate audiological follow-up were excluded.[15,27] Thirteen studies with either or both low directness of evidence and high risk of bias were excluded from further review.[14,17,19,21,25–33]

Eight studies that carried moderate risk of bias were included for further review, of which six provided evidence of high directness[6,15,16,22–24] and the other two of moderate directness.[18,20] Air-bone gap closure was not reported in the studies with moderate directness.[18,20] Conclusions were based on these eight studies. The study reported by Häusler et al.[6] failed the least risk of bias criteria. Therefore, we put most trust in the data presented in this study.

Data Extraction

The eight selected studies included in total 999 procedures. There are major dissimilarities between studies regarding type of laser, type of conventional fenestration technique, and follow-up duration. In most studies, the CO_2 laser was used.[15,18,20,22–24] However, different laser settings were used in these studies or it was not clear which settings were used (see Table III for reported laser settings). A difference in laser settings most likely influences outcome (e.g., as a result of more heat generation on and through the footplate).[34] Argon[6] and thulium[16] were used in the remaining two studies.

The extracted outcome data of the included studies are described in Table IV. Risk differences are positive when results favor laser fenestration and negative when results favor conventional fenestration. In the study performed by Häusler et al.[6], the difference in postoperative air-bone gap closure is in favor of laser fenestration, with a risk difference of 12% (95% CI: 9.5, 14.5). Another five studies report risk differences for postoperative air-bone gap closure between −13% (95% CI: −10.1, −15.9) and 13.7% (95% CI: 12.5, 14.9),[15,16,22–24] some of which are in favor of laser fenestration[16,22–24] and some of which are in favor of conventional fenestration.[15]

SNHL occurs less frequently in the laser group in the study performed by Häusler et al., with a risk difference of 1.5% (95% CI: 1.3, 1.7). Another three studies report risk differences for sensorineural hearing loss between 1.2% (95% CI: 1.2, 1.2) and 2.8% (95% CI: 2.4, 3.2).[15,23,24]

Häusler et al. report a risk difference for postoperative vertigo of 1.5% (95% CI: 1.3, 1.7). Another three studies evaluating immediate postoperative vertigo report risk differences between −3.3% (95% CI: −2.5, −4.1) and 29% (95% CI: 22.8, 35.2).[15,18,22] In one of these three studies, postoperative vertigo occurs less frequently in the conventional group,[18] whereas in the other two risk differences are in favor of laser fenestration.[15,22]

Immediate postoperative tinnitus was evaluated in two studies[15,22] and seems to occur more frequently in patients treated with the use of the laser. Risk differences for postoperative tinnitus in these two studies are −0.8% (95% CI: −0.5, −1.1) and −7.5% (95% CI: −5.7, −9.2).

A decreased incidence of footplate fracture was witnessed in the laser group in two studies, with risk differences of 8.2% (95% CI: 6.6, 9.8) and 12.5% (95% CI: 9.9, 15.1).[15,22]

DISCUSSION

The number of available studies on the effect of laser fenestration compared to conventional fenestration techniques on postoperative air-bone gap closure is substantial. The eight included studies all carry a moderate risk of bias, whereas the directness of evidence is high for six of the included studies. Some of the included studies show a difference in postoperative air-bone gap closure and immediate postoperative vertigo that favors the conventional approach. However, footplate fractures and sensorineural hearing loss also occur more frequently in the conventional group than in the laser group, whereas tinnitus appears to occur more frequently in the laser group. Taken into consideration the potential risks of the conventional methods, we would prefer to use the laser for fenestration instead of conventional techniques.

In interpreting the findings, the following considerations need to be taken into account. First, the designs of the included studies differ in their approach to the type and settings of the laser, the conventional fenestration technique, the choice of pure-tone audiometric frequencies, and follow-up duration. In most studies, the duration of follow-up was short and never reached 1 year. Furthermore, different piston types and sizes were used. Several studies showed that choice of piston diameter and type of prosthesis affect hearing outcome.[35,36] These heterogeneities in the comparisons and follow-up durations prohibited us from pooling the data, and therefore a descriptive analysis was used instead. Second, all of the included studies carry moderate to high risk of bias due to lack of randomization, treatment allocation, blinding of observations, and poorly standardized treatment and test procedures. Furthermore, selective reporting, as a result of excluding cases lacking adequate follow-up, cannot be ruled out in the retrospective cohort studies. Moderate to high risk of bias can lead to overestimation or underestimation of true intervention effects. Therefore, caution in trusting the results from studies with high risk of bias is warranted. Third, the sample sizes, varying from 48 to 451 ears, are rather small, and in the majority of studies, sample sizes were uneven. Given that sensorineural hearing loss occurs in less than 1% of stapedotomies, very large series are needed to make reliable statements about this outcome measure. Small sample sizes can lead to overestimation or underestimation of intervention effects as well. Last, adverse events were not systematically evaluated in all of the included studies. It seems likely that postoperative vertigo and tinnitus occur less often in laser-assisted stapedotomy as a result of the noncontact principle, in particular because footplate fracture and sensorineural hearing loss do occur less frequently following laser-assisted stapedotomy.

CONCLUSION

To date, there is no evidence that either the laser fenestration or conventional fenestration technique is superior to the other technique with regard to hearing outcome or immediate postoperative vertigo. Therefore, becoming comfortable with one technique and using what works best seems most appropriate for surgeons. There does, however, seem to be an increased risk of footplate fracture and SNHL following the use of micro-instruments or microdrills. Taken into account this risk of harm, the authors prefer laser over conventional methods for footplate fenestration in primary stapedotomy. However, future randomized trials and prospective follow-up of well-defined cohorts are needed to provide low risk of bias and high directness of evidence for firm practice statements.

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