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ORIGINAL ARTICLE

Laser Versus Drill-Assisted Stapedotomy for the Treatment of Otosclerosis: A Randomized-Controlled Trial

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Objective: To assess whether reversal-steps stapedotomy can always be used in otosclerosis surgery and whether use of laser- or microdrill-assisted technique may enable better outcomes in terms of intra- and post-operative complications as well as of hearing gain as compared with classical stapedotomy technique.

Materials and Methods: Eighty-two subjects undergoing primary stapes surgery for otosclerosis were enrolled for this study as having a least pure tone average (PTA) air-bone gap (ABG) of 35 dB. Patients were randomised for four different surgical variants: microdrill-assisted classical stapedotomy; laser-assisted classical stapedotomy; microdrill-assisted reversal-steps stapedotomy; and laser-assisted reversal-steps stapedotomy. Pre- versus post-operative ABG closure has been measured in all the patients, and occurrence of intra- and post-operative complications was rated.

Results: Reversal-steps stapedotomy provided significantly less intra-and post-operative complications than classical stapedotomy. Within the reversal-steps group, the laser-assisted technique gave slightly better hearing outcome than the microdrill-assisted one. In only 7% of the patients, the reversal-steps technique was not practicable due to particular anatomical situations involving position of the stapes into the oval fossa.

Conclusion: Reversal-steps stapedotomy, either microdrill- or laser-assisted, may be considered a reliable procedure for treatment of otosclerosis.

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Introduction

Stapes surgery is nowadays performed via standardized techniques that, in experienced hands, enable recovery from the conductive component of the hearing loss in the majority of the patients affected by otosclerosis. This favorable outcome has widely been reported regardless of the adopted surgical variant, i.e. stapedectomy, partial stapedectomy or stapedotomy.

The latter technique has, however, gained more and more promoters over the last decades by being less likely to jeopardize the inner ear function [1-3] A few technical refinements, including progression of the surgical steps and use of appropriate instrumentation, have also been reported. In this regard, since the 70s, Fisch [4] had proposed the "reversal steps stapedotomy" variant that encompasses perforation of the footplate when the ossicular chain is still intact, followed by immediate placement and stabilization of the prosthesis and, lastly, removal of the stapes superstructure.

The introduction of lasers in otologic surgery has been particularly welcomed in stapes surgery for which hand-held [5] or micromanipulator-mounted systems [6] are available. In fact, lasers can provide a precise, non-traumatic mechanical procedure, the heating effects on the labyrinthine fluids being eventually related to the wavelength of each specific laser system.

Purpose of the present study was to compare classical and reversal-steps stapedotomy in terms of intra- and post-operative complications, as well as functional

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outcome, and to identify eventual advantages achieved by using laser and/or microdrill instrumentation in both surgical variants.

Materials and Methods

Patients undergoing primary stapes surgery from November 2008 to March 2010 have been recruited for this study. Inclusion criteria were represented by uni- or bilateral cases with a least 35 dB air-bone gap (ABG) at 250-2,000 Hertz frequency range (Pure Tone Average, PTA). An informed consent to participate in the trial was signed by all eligible patients and approval by the local University Ethical Committee was also obtained.

Patients were randomized into four arms using a four-faced die, for selection of each surgical procedure: (a) Skeeter® (Medtronic, USA) microdrill and reversal approach stapedotomy; (b) Skeeter® (Medtronic, USA) microdrill and classical stapedotomy; (c) Laser and reversal-steps stapedotomy; and (d) Laser and classical stapedotomy.

Due to possibility of shifting from one surgical variant to another one, owing to anatomical/technical reasons, the four groups were not represented by the same number of patients.

As laser system, the Thulium Revolix junior® (LISA Laser, Katlenburg-Lindau, Germany) fibre-guided laser has been used with a 550 mμ hand-held fibre. When using the Skeeter®, a 0.6 diamond bur was used to perform the calibrated footplate perforation.

All operations were carried out by the senior surgeon (MB) and, according to patient's compliance, either local or general anaesthesia was utilized.

Pure tone average (PTA) thresholds were pre-operatively assessed as mean from 0.25 and 2 kHz, in order to measure the ABG, and were also post-operatively measured in terms of closure of the pre-operative ABG. CS was carried out according to the standardized technique. The following details encompass the reversal-steps stapedotomy variant. Once exposed the oval fossa area, with full visualization of the horizontal fallopian canal and the pyramidal eminence with the stapedial tendon, position and orientation of the stapes in the oval fossa was documented [7] and matched with the operated side. A 0.6 mm hole in the footplate was then produced and eventually regularized, by using the chosen randomized arm, i.e. laser- or microdrill-assisted stapedotomy technique. At this step, patients under local anaesthesia were asked to refer on any experienced disturbance, such as noise, vertigo, etc. A 5.25/5.50 mm long, 0.4/0.5 mm wide platinum piston prosthesis (AudioTechnologies, Piacenza, Italy) was then placed in the calibrated hole without interposition and immediately crimped on the long process of the incus. This length is justified by the fact that the abovementioned Company gives measures from the lateral instead of the medial incudal aspect. So, no more penetration of the prosthesis tip is likely to occur. For the "Skeeter" group, surgery continued with disarticulation of the incudo-stapedial joint, severance of the stapedial tendon with microscissors and luxation of the stapedial arch, allowing the removal of the entire superstructure. In the "Revolix jr" group, surgery continued with the disarticulation of the incudo-stapedial joint, vaporization of both stapedial tendon and posterior crus, and removal of the superstructure remnant.

Audiometric assessment was carried out one month after surgery. At the same time, patients were asked to report about the eventual presence and duration of post-operative vertigo/imbalance, fullness or tinnitus.

For the statistical analysis, three outcomes have been taken into account: (a) intra-operative complications; (b) post-operative complications; and (c) hearing outcome.

Intra-operative complications included those related to damage to the stapes footplate (cracking, flotation or involuntary total removal) or to the instrumentation used (laser heating, drill noise) that could be in relation to the occurrence of nausea and/or vomiting with vertigo spells, during or soon after surgery; post-operative complications included balance disorders, fullness or tinnitus during the first month after surgery; hearing outcome was calculated as PTA ABG closure < 10 dB or between 10-20 dB PTA ABG closure.

Multiple multilevel (three patients had bilateral interventions) logistic regression models were used to assess the effect of the exposure variables versus the outcomes. The Likelihood Ratio test was used to evaluate the interaction between the two main exposure variables – i.e. method of intervention (reversal-steps or classical stapedotomy) and technology used (laser or drill) – to see if, for example, the hypothesized effect difference between laser and drill can be modified by the type of approach.

Results

The sample consisted in 79 patients, 40.5% represented by males (n=32), with a median age of 51 years, and an average age of 50.9 years (sd=11.9). Three patients had bilateral surgery and therefore the total sample consisted in 82 observations. Stapes position was classified as Type I (toward the promontory) in 75% of the cases; Type II (intermediate) in 20%; and Type III (towards the fallopian canal) in 5%. General anaesthesia was used in 31.7% (n=26) of the interventions (Table 1).

Table 1. Sample description and variables for each randomized technique under study.

	Microdrill-assisted classical stapedotomy	Laser-assisted classical stapedotomy	Microdrill-assisted reversal-steps stapedotomy	Laser-assisted reversal-steps stapedotomy	TOTAL
Variable	**Mean (sd or %)**	**Mean (sd or %)**	**Mean (sd or %)**	**Mean (sd or %)**	**Mean (sd or %)**
Male	34.5%	40.0%	47.8%	40.0%	40.2%
Age	50.8% (11.1)	54.5% (9.1)	49.6% (14.3)	50.2% (11.5)	50.8% (11.9)
Right Ear	44.8%	50.0%	39.1%	40.0%	42.7%
Gen. Anaesth.	41.4%	50.0%	8.7%	35.0%	31.7%
Intra-op compl.	20.7%	50.0%	4.3%	5.0%	15.9%
Post-op compl.	6.9%	40.0%	8.7%	5.0%	11.0%
<10 dB post-op ABG	86.2%	90.0%	86.9%	90.9%	88.5%
10-20 dB post-op ABG	13.8%	10.0%	13.1%	9.1%	11.5%
Tot pts n.	29	10	23	20	82

In 91.5% of the cases (75 patients), the planned randomized technique has been completed, as laser-assisted reversal-steps stapedotomy (20 patients), microdrill-assisted reversal-steps stapedotomy (23 patients), laser-assisted classical stapedotomy (10 cases) and microdrill-assisted classical stapedotomy (22 cases). In 8.5% of the cases (7 patients), instead, poor visualization or limited access to the footplate during the reversal-steps procedure was experienced so that shifting to classical stapedotomy was necessary. The shifted operations regarded 5 microdrill-assisted reversal steps stapedotomies with type III stapes in left ears, and 2 microdrill-assisted reversal steps stapedotomies with type II stapes in the right ear: a microdrill-assisted classical stapedotomy procedure was therefore selected in all of them.

Tables 2 to 5 describe the results of logistic regression analysis. There is strong evidence that reversal-steps stapedotomy decreases the chances of intra-operative complications (OR=0.08; P=0.006; 95% CI=0.01-0.47). There is some evidence that reversal-steps stapedotomy decreases the chances of post-operative complications (OR=0.18; P=0.058; 95% CI=0.03-1.06). There is some evidence that use of laser instead of drill increases the chances of post-operative complications (OR=5.41; P=0.058; 95% CI= 0.97-30.21). There is some evidence that the use of general anaesthesia increases the chances of < 10 dB PTA ABG closure (OR= 2.80; P= 0.061; 95% CI= 0.95-8.22). The Likelihood Ratio test gave no significant results.

Table 2. Multiple multilevel logistic regression output modeling the occurrence of intra-operative complications.

	OR	P	95%CI	
Laser	3.42	0.102	0.78	14.97
Reverse	0.08	0.006	0.01	0.47
One year increase of age	0.97	0.380	0.90	1.04
General anaesthesia	0.99	0.991	0.25	3.98
Right ear	1.96	0.352	0.47	8.12

Table 3. Multiple multilevel logistic regression output modeling the occurrence of post-operative complications.

	OR	P	95%CI	
Laser	5.41	0.054	0.97	30.21
Reverse	0.18	0.058	0.03	1.06
One year increase of age	0.96	0.284	0.88	1.04
General anaesthesia	0.21	0.116	0.03	1.46
Right ear	3.16	0.168	0.61	16.26

Table 4. Multiple multilevel logistic regression output modeling the chances of post-operative PTA ABG closure of <10 dB.

	OR	P	95%CI	
Laser	0.85	0.736	0.32	2.25
Reverse	0.92	0.869	0.35	2.41
One year increase of age	1.00	0.821	0.97	1.05
General anaesthesia	2.80	0.061	0.95	8.22
Right ear	0.87	0.783	0.33	2.28

Table 5. Multiple multilevel logistic regression output modeling the chances of post-operative PTA ABG within 10 and 20 dB.

	OR	P	95%CI	
Laser	0.62	0.452	0.18	2.17
Reverse	0.78	0.706	0.22	2.83
One year increase of age	0.99	0.834	0.94	1.05
General anaesthesia	1.66	0.494	0.39	7.16
Right ear	1.10	0.888	0.30	3.95

Discussion

Stapedotomy is considered a standardized technical variant for the recovery of the conductive hearing loss due to otosclerosis. Nevertheless, also in experienced hands, hearing threatening situations may occur, eventually leading to irreversible inner ear damage. In this regards, in the classical technique, specific steps at risk can be individuated, such as perforation of the footplate with appropriate calibration, sectioning of the posterior crus, removal of the superstructure, and positioning and crimping of the prosthesis, that may lead to fracture or floatation of the footplate, as well as mobilization/luxation of the incus. It would seem likely that less risk is in play when the aforementioned maneuvers are carried out when the ossicular chain is still intact and even less mobile than normal due to otosclerosis fixation. This principle has inspired the Fisch's reversal step procedure that was originally performed by manual instrumentation, such as gradually-increasing perforators and crura microscissors, and insertion of a self-closing piston Teflon prosthesis.

Performing stapes surgery with less risk and less harmful maneuvers may also become an important issue in the forthcoming years when the predicted reduced incidence of surgical cases will surely affect quality and skillfulness of young otosurgeons. In this regard, some sophisticated tools have implemented the otologic surgery. Dedicated microdrills, for instance, are nowadays widely used for generating a regular hole of desired size in the footplate in order to accommodate snugly fitted piston prostheses. For the same purpose, it would be logical to assume that laser systems, available with different wavelength and modality of beam transmission (hand-held or micromanipulator), would also play an important role. In fact, their use is not involving mechanical contact or pressure on the treated areas (footplate, posterior crus), their only limitation being the heating effect on the labyrinthine fluids that might jeopardize the inner ear function.

On the light of these premises the present study has aimed at evaluating whether reversal-steps stapedotomy, once planned, could always be carried out; if it would be beneficial in comparison with classical stapedotomy; and if the routine use of non-manual instrumentation, such as laser or microdrill, might enable better results in term of intra- or post-operative complications as well of functional outcome.

Therefore, a consecutive group of otosclerotic patients, primarily scheduled for stapes surgery, have been randomized and selected for either reversal-steps or classical stapedotomy, microdrill- or laser-assisted. In this latter case, a new laser system, i.e. Revolix junior ®, has been used. This laser, first proposed during urologic surgical procedures [8], is based on Thulium and, similarly to CO_2 systems [9], should provide a neat cutting power with minimal carbonization.

One of the aims of the present study was the comparison between laser- and drill-assisted stapedotomy. An important limitation has, however, consisted in the reduced and uneven sample size. In fact, due to technical reasons, some of the procedures did not work effectively and statistical evidence was not always strong. On the other hand, the number of operations was not purposely increased in order to outline the procedure that needed to be shifted towards unplanned surgical variants, as it occurred in a limited group of patients.

It is interesting to consider that during the reversal-steps stapedotomy, the adverse anatomical situation, i.e. stapes position combined with the operated side, has been the major obstacle to proceed with the procedure selected by randomization. The most critical situation has included stapes bent toward the fallopian canal (type III). In this regard, from the present study it is possible to assume that the possibilities to perform a reversal-steps procedure are high but still, in a few cases, around 7% of our group, the surgeon needed to be ready to change his plans.

Similarly to recent reports [10], our analysis confirmed that reversal-steps stapedotomy allows better overall results than classical stapedotomy. In fact, less intra-operative complications have been encountered when the surgical maneuvers were carried out with the ossicular chain still intact. This finding has been also recently pointed out by other investigators who advised to perform it either with a slight surgical modification [11] or only with specific otosclerotic findings at the footplate level [12].

General anaesthesia also showed to provide better, although not significant clinical outcomes. Clear explanations are difficult to find and could be related to the even smaller sample under study, i.e. 31.7% of the whole group.

Conclusion

- Reversal steps stapedotomy may be considered a reliable technique to be used in almost all cases of otosclerotic surgery, being able to reduce – in experienced hands – the likelihood of intra- and post-operative complications.
- Use of laser during reversal-steps stapedotomy may further decrease the incidence of intra-operative complications, such as floating or fractured footplate.
- The use of laser-assisted reversal-steps stapedotomy can be proposed for standardizing stapes surgery as useful tool for speeding up the learning curve of less-experienced otosurgeons against the overall decrease of new surgical cases.

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