



Conventional approaches versus laser CO₂ surgery in stapes surgery: a multicentre retrospective study

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Abstract

Purpose To analyze and compare surgical and audiological outcomes of conventional approaches versus laser CO₂ surgery in stapes surgery.

Methods 333 patients who underwent stapes surgery were enrolled in the study; the patient population was divided into three groups: group 1: 170 patients treated with conventional stapedotomy with manual microdrill (average age 49.13 years); group 2: 119 patients treated with conventional stapedotomy with electrical microdrill (average age 51.06 years); group 3: 44 patients (average age 50.4 years) who underwent CO₂ laser stapedotomy. Intra-operative, postoperative outcomes and audiological results were investigated.

Results The average surgical time of laser CO₂ surgery was longer than for other surgical procedures. No statistical differences emerged in post-operative abnormal taste sensation. There was also no difference in postoperative dizziness. Air-bone gap (ABG) went down from 29.7 ± 10 dB (group 1) and 27.32 ± 9.20 (group 2) to 10 ± 6.9 dB (group 1) and 10.7 ± 6.03 dB (group 2). In group 3 the preoperative ABG was lowered from 28.3 ± 10.1 to 11.8 ± 10.9 , with a statistical difference in auditory recovery ($p=0.0001$); The group of patients treated with laser CO₂ showed a percentage of patients with an ABG closure of between 0 and 10 dB higher than in the group treated with manual microdrills (77.2% vs. 60%, respectively; $p=0.03$).

Conclusion Overall surgical results of CO₂ laser and conventional stapedotomy are comparable without any significant difference; however, the group treated with CO₂ laser appears to have a percentage of patients with an ABG closure 0–10 dB higher than the group treated using the conventional technique.

Keywords Stapes surgery · Otosclerosis · Stapes · Stapedotomy · Laser stapedotomy · Laser stapes surgery

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Introduction

Stapedoplasty is the first-line surgical technique universally accepted for otosclerosis surgical treatment and consists of the removal of fixed stapes superstructures, stapes footplate perforation and replacement with a prosthetic device. Stapedoplasty is recommended when an air-bone gap (ABG) ≥ 30 dB in frequencies from 250 Hz to 1 kHz is reported and functional discomfort is present. If altered discrimination and/or recent persistent vertigo are reported, further exploration is required before making the surgical decision [1–5].

Shea performed the first stapedectomy operation in 1956; the procedure consisted of complete stapes footplate removal and a subsequent vein graft with prostheses application. The introduction of manual or electric microdrills as well as

different laser devices has since modified the conventional technique of stapedectomy into the stapedotomy technique, which consists of footplate perforation (platinotomy) and the insertion of piston-like prostheses [1–5].

Several tools and technologies have been proposed and developed over the years for footplate perforation, the main aim being to reduce stapes manipulation during surgery. Manual or electric microdrill, laser or piezoelectric devices are applied in main stapedotomy techniques available. The choice of one of these approaches over another depends on the surgeon's experience and the availability of different technologies [1, 2, 6–10].

According to literature data, the manual perforator and microdrill techniques are the most frequently applied stapedotomy techniques, due to the extensive availability of these surgical instruments as well as good audiological and clinical results. Beyond these surgical techniques, many authors have reported the use of CO₂ laser in stapes surgery, for calibrated platinotomy and the sectioning of stapes superstructures. Nevertheless in literature, the number of studies exclusively comparing CO₂ laser with manual footplate perforation is extremely limited [11–15].

The aim of this retrospective multicentre study was to analyze and compare surgical and audiological outcomes of conventional approaches versus laser CO₂ surgery in stapes surgery, in order to evaluate the strengths, advantages and limits of these different surgical techniques.

Material and methods

Patient enrolment

Patients who underwent stapedoplasty for otosclerosis were enrolled in this retrospective multicentre study. Patients included in the study were surgically treated between January 2010 and October 2020 in three tertiary referral centers: the ENT Unit of Santa Maria delle Croci Hospital in Ravenna, the ENT Unit of the Morgagni-Pierantoni Hospital in Forlì, and the ENT clinic of the Santa Maria alle Scotte University Hospital, Siena, Italy.

Both CO₂ laser and conventional platinotomy (performed by manual and electric microdrill) were performed in the first two centers, whereas, only conventional electric microdrill platinotomy was performed in the third center.

Main inclusion criteria of the study were: primary stapes surgery for conductive or mixed hearing loss caused by otosclerosis and a postoperative follow-up at least 6-months postoperatively.

Exclusion criteria were: revision cases, patients with other ear pathologies (Eustachian tube dysfunction, tympanic membrane retraction, erosion of long process of incus, malleus fixation, and chronic otitis media).

Patients lost at follow-up and patients lacking audiometric data were excluded from the study.

All procedures were performed by two surgeons, both with surgical experience in laser CO₂ and classical stapedotomy (A.D.V. and F.S.), and one surgeon with experience in conventional techniques (M.M.).

Investigated parameters

Investigated parameters were: the side effects of surgery, preoperative and postoperative hearing levels, intra-operative findings, operating time, post-operative complications.

A titanium /polytetrafluoroethylene prosthesis (PTFE) was fitted in all patients (audio®) according to the diameter of the platinotomy and the measured distance between the incus process and stapes footplate. The length and diameter of prostheses used in both patient groups were recorded and compared.

Hearing was assessed preoperatively, at 1 month, 3 months and 6 months after surgery in both groups. Final hearing recovery at a six-months follow-up was recorded and analyzed according to the draft AAO-HNS hearing classification system [7, 9, 16, 17]. The preoperative air-bone gap (ABG) was calculated as the difference between pre op AC and preop BC, whereas, the postoperative ABG was estimated as the difference between postoperative AC and BC.

Cases of post-operative sensorineural hearing loss were evaluated.

Post-operative complications, such as facial paralysis and chorda tympani injury, were analyzed and compared between both groups. When present, dizziness was reported according to duration.

Statistical analysis

Chi-squared tests were used to compare clinical and surgical data changes in both groups. Differences in average audiometric value were analyzed using the Student's *t* test (SAS, JMP8 version). A *p* value of <0.05 was set as the threshold of statistical significance.

This research study was performed in accordance with the principles of the Declaration of Helsinki and approved by the local Ethics Committee.

Results

A total of 333 patients were enrolled in the study; the patient population was divided into three groups: group 1: 170 patients treated with conventional stapedotomy with manual microdrill (average age 49.13 years); group 2: 119 patients treated with conventional stapedotomy with electrical microdrill (average age 51.06 years); group 3: 44 patients (average

age 50.4 years) who underwent CO₂ laser stapedotomy. All revision surgeries were excluded.

Intra-operative and postoperative outcomes

Intra-operative and post-operative outcomes are summarized in Table 1. Stapes prosthesis with a 0.5 diameter was the most frequently used in all three groups (62.3%, 63% and 61.4% of cases, respectively). Stapes prosthesis with a 0.6 diameter was used the most in the laser CO₂ stapedotomy group compared to the other two groups, with a statistical difference (manual microdrill vs. laser CO₂ $p=0.0004$; electrical microdrill vs. laser CO₂ $p=0.0005$; Table 1).

Average surgical procedure duration was 46.2, 35.5 and 55.3 min in group 1, group 2 and group 3, respectively. The average surgical time of laser CO₂ surgery was longer than other surgical procedures (manual microdrill vs. laser

CO₂ $p=0.04$; electrical microdrill vs. laser CO₂ $p=0.03$, Table 1).

Post-operative abnormal taste sensation emerged in 19.4%, 17.6% and 18.1% of patients in group 1, group 2 and group 3, respectively; no statistical differences emerged (p value >0.05 in each group comparison). There was also no difference in postoperative dizziness (p value >0.05 in each group comparison). No patients in the study experienced postoperative facial palsy.

Audiological results

Groups 1 and 2 showed an average value of pre-operative AC of 57.9 ± 13.1 and 55.2 ± 15 that was lowered to 36.1 ± 13.4 dB and 35.5 ± 12.9 , respectively, after stapedotomy surgery (Table 2). In these groups, ABG went down from 29.7 ± 10 dB (group 1) and 27.32 ± 9.20 (group 2) to 10 ± 6.9 dB (group 1) and 10.7 ± 6.03 dB (group 2). A

Table 1 Patient characteristics, intraoperative and postoperative results

	Manual perforation 170 pts	Microdrill (skeeter) 119 pts	Laser CO ₂ 44 pts	p value
Sex				0.1
Female	113 (66.4%)	83(69%)	35 (79.5%)	
Male	57 (33.6%)	37 (31%)	9 (20.5%)	
Average age (years)	49.3	51,06 \pm 11,90	50.4	1
Side				0.5
Left	79 (46.4%)	72 (60.5%)	21 (47.7%)	
Right	91 (53.6%)	47 (39.5%)	23 (52.2%)	
Diameter of prosthesis used				$>0.05^*$
0.4 mm	48 (28.3%)	31 (26%)	3 (6.8%)	$>0.05^*$
0.5 mm	106 (62.3%)	75(63%)	27 (61.4%)	Perforator vs. laser CO ₂ $p=0.0004$ Microdrill vs. laser CO ₂ $p=0.0005$
0.6 mm	16 (9.4%)	13(10.9%)	14 (31.8%)	
Diameter of prosthesis used				$p>0.05$ for each group comparison
5.25 mm	38 (22.3%)	25 (15.9%)	8 (18.1%)	
5.50 mm	81 (47.6%)	62 (52.1%)	24 (54.4%)	
5.75 mm	51 (30%)	32 (26.8%)	12 (27.2%)	
Average surgical time (mins)	46.2	35.5	55.3	Perforator vs. microdrill $p>0.05$ Perforator vs. laser CO ₂ $p=0.04$ Microdrill vs. laser CO ₂ $p=0.03$ (Student's t test)
Postoperative complications				
Postoperative facial palsy	–	–	–	
Abnormal taste sensation	35 (19.4%)	21 (17.6%)	9(18.1%)	$>0.05^*$
Postoperative dizziness				
No dizziness	139 (81.7%)	98 (82.3%)	37 (84%)	$>0.05^*$
Two days	22 (12.2%)	14 (11.7%)	5 (11.5%)	$>0.05^*$
More than 2 days	9 (5.2%)	7 (5.8%)	2 (4.5%)	$>0.05^*$

Bold has been reported the statistical test used

* p value >0.05 in each group comparison (manual perforator vs. microdrill; microdrill vs. laser CO₂ and manual perforator vs. laser CO₂)

statistical difference between pre-operative and post-operative average values emerged in both groups ($p = 0.0001$, Table 2).

Group 3 had a preoperative AC of 54.4 ± 12.5 dB and a postoperative AC of 37.5 ± 13.9 . ABG was lowered in this group from 28.3 ± 10.1 to 11.8 ± 10.9 , with a statistical difference in auditory recovery ($p = 0.0001$).

The average values of pre-operative and post-operative air-conduction and air-bone-gap of all three patient groups are reported in Table 2; hearing gain in all groups according to ABG classes is shown in Table 3.

A comparison of group 1, group 2 and group 3 showed no differences in postoperative air-bone gap values (Table 4).

Table 2 Hearing results, average values of preoperative and postoperative air-conduction and air-bone gap

	Preop BC	Preop AC	Postop AC	<i>p</i>	Preop ABG	Postop ABG	<i>p</i>
Manual perforation 170 pts	28,21 ± 9,89	57,98 ± 13,41	36,15 ± 13,42	0.0001	29,77 ± 10,35	10,09 ± 6,94	0.0001
Microdrill (skeeter) 119 pts	24,4 ± 10,16	55,24 ± 15,09	35,51 ± 12,90	0.0001	27,32 ± 9,20	10,74 ± 6,03	0.0001
Laser CO2 44 pts	26,11 ± 9,02	54,40 ± 12,59	37,54 ± 13,94	0.0001	28,30 ± 10,16	11,89 ± 10,82	0.0001

Bold has been reported statistical difference

BC bone-conduction, AC air-conduction, ABG air-bone gap

Table 3 Hearing results, reported as classes of air-bone gap

	Manual perforation 170 pts		Microdrill (skeeter) 19 pts		Laser CO2 44 pts	
	Preoperative air-bone gap n.pts/percentage	Postoperative air-bone gap n.pts/percentage	Preoperative air-bone gap n.pts/percentage	Postoperative air-bone gap n.pts/percentage	Preoperative air-bone gap n.pts/percentage	Postoperative air-bone gap n.pts/percentage
10	–	102 (60%)	–	65 (54.6%)	–	34 (77.2%)
11–20	25 (14.7%)	54 (29.4%)	29 (24.3%)	46 (38.6)	2 (4.5%)	5 (11.3%)
21–30	83 (48.8%)	7 (4.1%)	55(46.2%)	4 (3.3%)	20 (45.5%)	2 (4.5%)
31	62(36.4.3%)	4 (2.5%)	35(29.4%)	1 (0.8%)	22 (50%)	2 (4.5%)
Sensorineural hearing loss	–	3 (1.7%)	–	3 (2.5%)	-	1 (2.2%)

Table 4 Hearing results, differences in classes of air-bone gap between manual perforation, microdrill and laser CO2

	Manual perforation 170 pts	Microdrill (skeeter) 119 pts	Laser CO2 44 pts	<i>p</i> value
Postoperative bone gap average value	10,09 ± 6,94	10,09 ± 6,94	12 ± 10.9	> 0.05* (<i>t</i> student test)
10	102 (60%)	65 (54.6%)	34 (77.2%)	Perforator vs. microdrill $p > 0.05$ Perforator vs. laser CO2 $p = 0.03$ Microdrill vs. laser CO2 $p = 0.02$
11–20	54 (29.4%)	46 (38.6)	5 (11.3%)	Perforator vs. microdrill $p > 0.05$ Perforator vs. laser CO2 $p = 0.007$ Microdrill vs. laser CO $p = 0.006$
21–30	7 (4.1%)	4 (3.3%)	2 (4.5%)	> 0.05*
31	4 (2.5%)	1 (0.8%)	2 (4.5%)	> 0.05*
Sensorineural hearing loss	3 (1.7%)	3 (2.5%)	1 (2.2%)	> 0.05*

**p* value > 0.05 in each group comparison (manual perforator vs. microdrill; microdrill vs. laser CO2 and manual perforator vs. laser CO2)

However, some aspects on laser CO₂ technique emerged from an analysis of hearing recovery classes. The group of patients treated with laser CO₂ showed a percentage of patients with an ABG closure of between 0 and 10 dB higher than the group treated with manual microdrills (77.2% vs. 60%, respectively; $p=0.03$); the same was observed for the electrical microdrill group (77.2% vs. 54.6%, respectively; $p=0.02$). Contrary to these results, a lower percentage of ABG closure between 11 and 20 dB emerged in the laser CO₂ group. Post-operative sensorineural hearing loss was present in 1.7% and 2.5% of group 1–2 subjects and 2.2% of group three subjects, respectively, (p value > 0.05 in each group comparison).

Discussion

The aim of stapes surgery is to improve the hearing level of patients suffering from otosclerosis. To improve surgical and audiological outcomes and reduce the risk of hearing damage or other complications during footplate fenestration, different techniques, implant materials and technologies have been proposed over time.

CO₂ laser is used in head and neck surgery and this technology has since been applied in stapes surgery too. Different authors consider CO₂ laser stapedotomy a safe procedure that yields excellent results in terms of postoperative clinical and audiological outcomes [6, 11–24].

CO₂ laser technology is used as an alternative to classical footplate fenestration, which is performed with manual or electrical microdrills. According to the literature data, CO₂ laser is considered superior to other techniques due to reduced inner ear trauma and the incidence of post-operative hearing loss or dizziness. Some studies in the literature have shown that laser fenestration is more effective for air-bone gap (ABG) closure than conventional techniques, while other studies reported similar results in both surgical techniques [6, 14, 15, 21, 22].

In 1980, Perkins et al. published the first study on laser stapes surgery, reporting the results of 11 subjects treated using argon laser stapedotomy; 100% of the 11 patients had an air-bone gap closure of between 0 and 10 dB with 86% closing to 0–5 db [23]. Forton et al. reported their experience of sixty-two CO₂ laser stapedotomies: mean 3 postoperative months ABG was 5.1 ± 0.5 . An ABG closure of less than or equal to 10 dB was achieved in 87% of cases [13].

We performed a retrospective study to evaluate and compare clinical and audiological outcomes of three different stapedotomy surgery techniques: manual or electrical microdrill perforation or CO₂ laser platinotomy. In reviewing literature, we observed that few studies have compared CO₂ laser and manual microdrill use exclusively for platinotomy

and the effectiveness of one surgical technique over the other is still debated [14, 15, 21–25].

Fang et al. [24] compared CO₂ laser vs. electrical microdrill stapedotomies and found that the laser group had significantly better ABG closure, with a combined relative risk of 107, although no significant differences in procedure safety emerged from the study. In contrast, Wegner et al. [25] compared CO₂ laser technique with different stapes surgical techniques and were unable to demonstrate the superiority of any method over another regarding hearing outcomes.

In a clinical study, Cuda et al. [26] compared 30 patients who underwent laser CO₂ surgery with 30 patients who underwent electrical microdrill stapedotomy. CO₂ laser appears to have resulted in less residual ABG and more functional gain at low frequencies. Significant differences in AC thresholds gain and residual ABG were found between groups, in favor of the laser-treated group. Similarly, in the study by Pauli et al. the CO₂ + drill laser group had the best hearing outcome, based on the following criteria: ABG closure ≤ 10 dB, air-conduction improvement > 20 dB, and bone conduction not worsened > 5 dB. In contrast, Altamami et al. [15] compared CO₂ laser versus electrical microdrill assisted stapedotomy and among patients who underwent CO₂ laser stapedotomy, reported 87% with a postoperative ABG of between 0 and 10 dB, which is a slightly better result compared to patients in the electrical microdrill group, 84%, although the difference is not statistically significant ($p=0.362$). The difference in mean post-operative air-bone gap was not statistically significant ($p=0.112$) in either group.

Ryan et al. [21] compared both approaches and found that laser use does not show improved air-bone gap closure compared to the traditional approach (pre- and post-op air-bone gaps of 34 ± 3 and 9 ± 2 for laser stapedectomy compared to 35 ± 4 and 13 ± 2 for traditional stapedectomy). Wegner et al. [25] also compared laser CO₂ with different stapes surgical techniques and were unable to demonstrate the superiority of any method over another regarding hearing outcomes.

In our study, no difference emerged in the value of postoperative ABG between patients treated with CO₂ Laser and those treated with conventional stapedotomy. However, from the analysis of hearing recovery classes, it emerged that the group treated with CO₂ laser and electrical microdrill conventional stapedotomy contained a percentage of patients with an ABG closure of between 0 and 10 dB.

The group of patients treated with laser CO₂ contained a percentage of patients with an ABG closure between 0 and 10 dB higher than the group treated with manual microdrill (77.2% vs. 60%, respectively; $p=0.03$); the same was found in the electrical microdrill group (77.2% vs. 54.6%, respectively; $p=0.02$).

These data could confirm the findings of authors who reported that CO₂ laser and electrical microdrill could be superior to the manual techniques, regarding ABG closure.

CO₂ laser offers multiple advantages: it is an instrument that can precisely apply energy to vaporize the posterior crus of the stapes, transect the stapedius tendon and create a stapedotomy. With CO₂ laser there is no contact between instruments and the stapes footplate, with a low risk of primary traumatic fracture or secondary fracture to a floating footplate [4, 6, 11, 12].

Some authors also claim that laser surgery avoids trauma to the inner ear and reduces the incidence of post-operative hearing loss or dizziness [11–14].

Despite the advantages of CO₂ laser surgery, it should be noted that during the application of laser energy to the footplate, changes in inner ear temperature may occur, which could be the cause of a traumatic event to the inner ear and delayed sensorineural hearing loss [6, 11, 16, 18]. Although lasers have ideal optical properties for microsurgery, thermal energy may pass through the perilymph, causing it to be absorbed by pigmented tissue of the inner ear, with consequent temperature elevation in the vestibule. Multiple laser applications increase the risk of guiding laser beam misalignment and of receiving too many laser shots to an already open vestibule. Therefore, as suggested by different authors, the footplate should be perforated with a single shot and the laser combined with a laser scanner [6, 11, 15, 21]. However, sensorineural acoustic damage is also possible due to improper electrical microdrill use or acoustic trauma caused by drill vibrations [12, 26, 27]. In our study, no differences between groups emerged in the incidence of post-operative sensorineural hearing loss: 1.7% (group 1), 2.5% (group 2) and 2.2% (group 3) with a *p* value > 0.05 in each group comparison.

A more detailed description of surgical advantages and disadvantages of the three techniques considered in this

study, according to literature findings and authors' experience, has been reported in Table 5.

The percentage of post-operative deafness is within the levels reported in literature for post-operative sensorineural hearing loss after primary stapes surgery (0.2–2.5%) [1–6, 11–15, 18–20, 27]. Similar data has been reported by Altamami et al. [15], who observed postoperative sensorineural hearing loss in four patients who were operated on using the microdrill technique and two patients in the CO₂ group. In one of the patients with sensorineural hearing loss (operated on using the CO₂ laser technique), an inflammatory granuloma was identified. This has been reported to be one of the causes of postoperative sensorineural hearing loss after stapes surgery [18–25]. In our experience, an inflammatory reaction after laser CO₂ surgery occurred in two cases. These patients showed prosthesis extrusion, inflammatory granuloma tissue over the footplate and developed a postoperative air-bone gap > 30 dB.

Finally, CO₂ laser stapedoplasty preparation is lengthier and the learning curve of laser stapes surgery requires a longer period of time compared to conventional stapes surgery [12, 13, 29]. In our study, the average surgical time of laser CO₂ surgery was longer compared to other surgeries (manual microdrill vs. laser CO₂ *p* = 0.04; electrical microdrill vs. laser CO₂ *p* = 0.03, Table 1).

The major limitation of this study is the smaller number of patients enrolled in group 3 (treated with CO₂ laser) compared to patients in group 1 (manual platinotomy) and group 2 (electrical microdrill platinotomy).

Moreover, it should be considered that audiological outcomes in stapes surgery are multifactorial (otosclerotic foci extension, associated diseases of the inner ear, surgeon's experience, type of prosthesis employed, size of platinotomy, etc.) and some of these factors could be bias factors in obtained results. Further studies are underway to extend our case-series study and to analyze all these factors in CO₂ and conventional stapes surgery.

Table 5 Advantages and disadvantages of the different stapes surgery techniques

	Advantages	Disadvantages
Manual perforator stapes surgery	Tactile sensation during footplate hole realization Feasible to perform even in cases of complex anatomy, such as procident facial nerve	Floating footplate Ossificate footplate
Microdrill stapes surgery	Simple platinotomy to perform in ossificate footplate	Risk of traumatic fracture or creating floating footplate Acoustic trauma caused by drill vibrations
Laser CO ₂ stapes surgery	Precision in platinotomy More precision in posterior crus of the stapes and stapedius tendon section	changes in inner ear temperature and delayed sensorineural hearing loss More difficult to perform in abnormal anatomical conditions as procident facial nerve inflammatory granuloma tissue on the platine footplate longer learning curve longer preoperative setup time

Conclusion

Overall surgical results of CO₂ laser and conventional stapedotomy are comparable without any significant difference.

No difference in the average value of postoperative ABG between classical stapes surgery and CO₂ laser stapes surgery emerged. The group treated with CO₂ laser appears to have a percentage of patients with an ABG closure between 0 and 10 dB higher than the group treated using the conventional technique.

The surgeon's preference, experience, surgical skills, availability of material and anatomical condition should determine the choice of surgical technique.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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