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Is one of these two techniques: CO_2 laser versus microdrill assisted stapedotomy results in better post-operative hearing outcome?

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Abstract

Objective To evaluate hearing results and outcome using two different surgical techniques (microdrill and CO_2 Laser fenestration) in the treatment of conductive hearing loss in patients with otosclerosis.

Study design Retrospective audiometric database and chart review from January 2005 until December 2016.

Setting Two tertiary referral hospitals

Materials and methods Seven-hundred forty-two primary stapedotomy have been reviewed retrospectively in two referral hospitals. This multicenter study compared 424 patients operated for otosclerosis with microdrill technique and 318 patients operated with CO_2 laser assisted stapedotomy. Preoperative and postoperative audiological assessment (following the recommendations of the Committee on Hearing and Equilibrium) were compared between the two groups at least 6 weeks and at 1 year or more. Measure of overclosure and hearing damage have been analyzed and compared between the groups.

Results There were no statistically significant differences in demographic data between the two groups and no statistically significant difference in hearing outcome between the two groups. CO_2 Laser with 0.4 piston showed slightly better results to close the air–bone gap postoperatively to ≤ 10 dB (84% as compared with the 80% of patients operated with microdrill technique). Patients operated with microdrill technique and 0.6 piston have less damage to hearing at 4 kHz.

Conclusion The use of CO_2 laser seems associated with better postoperative air–bone gap closure. However, it carries more risk of hearing damage at 4 kHz at it is the case for the microdrill at 1 kHz. In general, postoperative hearing outcome using these two surgical techniques is comparable.

Keywords Bone conduction threshold change · Otosclerosis-pure-tone average · Sensorineural hearing loss · CO_2 laser-microdrill

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Introduction

Otosclerosis, also known as otospongiosis as described by Siebenmann in 1912 [1], is a pathology that affects the otic capsule leading to disturbances in the activity of the osteoblasts and osteoclasts. This disturbance is accompanied by vascular proliferation and bone remodeling resulting in ankyloses and stapes fixation [1–4]. Surgical treatment of otosclerosis is nowadays highly demanded by patients to improve their hearing level, and thus avoid wearing hearing aids. Stapes mobilization surgery was first introduced by Johannes Kessel in 1876 which has been abandoned later on [2]. Jenkins, Holmgren [5] and Sourdille [6] have developed the fenestration surgery to improve hearing level caused by otosclerosis, which was modified later on by Lempert in 1938 [2, 7]. In 1958, Shea introduced the stapes prosthesis which has since been developed and many types of prosthesis are currently used to replace the stapes [2, 8]. Following this, small fenestration stapedotomy became the preferred technique that can be performed by many surgical methods, such as a perforator, microdrill, laser or piezoelectric devise. The surgical method depends on the surgeon's experience and the availability of the material. The perforator and microdrill techniques are used widely because of their availability and good results. However, laser technology is a safe alternative; argon laser was the first type of laser used to perform successful stapedotomy and showed interesting results [9, 10], and later other types of laser were introduced among which CO_2 lasers are reported to be safe for stapedotomy [11]. There are many advantages of CO_2 laser like high precision, and low risk of stapedectomy or floating footplate as there is no contact between the instrument and the foot plate. However, the limitations for using laser technique are: heating effect on the labyrinthine fluids [12], and dehiscence of the facial nerve canal which makes it at risk of injury. The microdrill technique is preferred to laser-based techniques by many surgeons due to its availability, contact appreciation, and is also safer in difficult cases such as narrow footplate or facial nerve dehiscence. Although inner ear damage as a result of mechanical trauma and floating foot plate remain always the risks of microdrill technique. However, the choice of the surgical technique should depend tightly on the hearing outcome and complications. Closure of air–bone gap (ABG) has been demonstrated to be better with laser fenestration than conventional techniques in some studies and the opposed in the others [12, 13]. Damage to the bone conduction has been shown to be one of the risks of thermal effect of CO_2 laser with multiple shots [14]. However, in other opinion less inner ear damage is in favor of laser technique [14, 15].

Many questions have been raised in comparison between the two techniques. Each technique has it is own difficulties and characteristics. The present study was conducted to compare postoperative hearing level between two surgical techniques of stapedotomy: CO_2 Laser versus microdrill assisted stapedotomy.

Materials and methods

The design of our study is retrospective multicenter study. The patients included were operated on for primary otosclerosis in two referral otology centers, between January 2005 and December 2016. In one center CO_2 laser was exclusively used to perform stapedotomy and in the second center only microdrill was used. The inclusion criterion was primary otosclerosis surgery for conductive or mixed hearing loss caused by otosclerosis and followed up at least for 6 weeks postoperatively. Exclusion criteria were: revision cases, patients with other ear pathology (Eustachian tube dysfunction, tympanic membrane retraction, erosion of long process of incus, malleus fixation, chronic otitis), cases with facial nerve dehiscence, narrow footplate, and patients operated by the senior residents and fellows. All patients underwent high-resolution computed tomography of the temporal bone, and the diagnosis was confirmed by testing per-operatively the mobility of the ossicular chain and footplate. Furthermore, all patients underwent pure tone audiogram (PTA) at a university center and inside a standard soundproof room including air conduction (AC), bone conduction (BC) before and after the stapes surgery; all the patients with their audiograms done in other private centers were also excluded. The study was approved by the institutional ethics committee (Ethics committee of Lyon; August 8, 2018) and all patients gave their verbal informed consent for the use of their personal clinical data.

Surgery

All the patients were operated on by a total of four senior otology surgeons under general anesthesia with no perioperative complications. The operation was done through a transcanal standard otosclerosis surgical approach. In one otology center, footplate fenestration was done using a microdrill 0.7 mm burr followed by introduction of the prosthesis into the stapedotomy opening and manual crimping of the prosthesis loop around the long process of the incus. A 0.6 mm-diameter Teflon piston) (Causse Fluoroplastic Large Loop Piston; Medtronic Xomed., Jacksonville, FL, USA) was used for these patients. In the other otology center, CO_2 laser fenestration technique was performed with a Sharplan 30C system Acuspot, and a 0.4 mm-diameter Teflon piston (Causse Fluoroplastic Large Loop Piston; Medtronic Xomed., Jacksonville, FL, USA) was inserted. All patients in the first center were operated on by a senior surgeon whereas in the second center the patients were operated on by one of three senior surgeons. Postoperatively, and for all patients, a simple dressing (Pope OTO Wick Merocel, Medtronic Xomed, Jacksonville, FL, USA) was placed in the external auditory canal with the installation of local antibiotic drops twice daily. The dressing was removed at postoperative day 7 or 8.

Data collection, reporting and analysis

For all patients we gathered the preoperative PTA (Pure Tone Audiometry) and postoperative PTA (at 6–8 weeks, and at 1 year or more after surgery) from archived paper-based files and electronic records. All audiometric examinations were performed by certified university clinical audiologists at the two departments. Not all of the data on speech discrimination were available, thus we did not include speech discrimination analysis. The data were collected and analyzed according to the recommendations of committee on Hearing and Equilibrium of the America Academy of Otolaryngology-Head and Neck Surgery [16]. The mean of the thresholds for bone and air conduction, at frequencies 0.5, 1, 2, and 3 kHz was used to form a four-tone pure-tone average. Among those operated on by CO_2 laser, the audiometric data and postoperative results of patients treated by the three surgeons were compared to verify the homogeneity between the sub-groups. The audiometric pure tone thresholds by the air conduction were recorded at octave intervals from 0.5 to 8 kHz and by bone conduction at octave intervals 0.5 to 4 kHz and at 3 kHz. As recommended by Hearing and Equilibrium committee, we compared the mean and standard deviation (SD) of the postoperative air–bone gap and the number of decibels of closure of air–bone gap for only the patients with audiometric test 1 year or more postoperatively. The audiometric results at 6 weeks or more after the operation were considered for analysis of the change in high-tone bone-conduction level [16, 17]. The mean preoperative pure-tone bone-conduction, mean pure-tone air-conduction, and mean preoperative air–bone gap were compared between the two groups using Mann–Whitney *U* test, to verify that the two groups are homogeneous. Preoperative and postoperative air-bone gaps (mean air conduction minus mean bone conduction) were calculated for all patients. The air–bone gap closure defined as the preoperative minus postoperative air–bone gap. Thus, a positive value indicates less gap after the treatment, and negative value indicates a worse gap.

The hearing damage was measured by comparing the mean pre-operative and post-operative pure-tone bone-conduction thresholds at the frequencies 1, 2, 3 and 4 kHz separately. Overclosure was defined as the mean preoperative minus postoperative high pure-tone bone-conduction thresholds. Thus, a positive value indicates overclosure and a negative value indicates damage to the hearing. All of the audiometric data, sex, and age at surgery were recorded in an Excel spreadsheet (Microsoft 2010, Redmond, WA, USA). The patients were grouped according to type of surgery (microdrill assisted stapedotomy, and CO_2 Laser assisted stapedotomy) and the postoperative air–bone gap for each group was classified in bins as follows: 0–10 dB, 11–20 dB, 21–30 dB, and > 30 dB. In our study, in addition the classic air–bone gap we have calculated the air–bone gap considering mean preoperative pure-tone bone-conduction thresholds instead of mean postoperative pure-tone bone-conduction thresholds. The success rate of stapedotomy was defined by a postoperative air–bone gap ≤ 10 dB.

All comparisons were made using the Mann–Whitney *U* test and the Chi-square test, significance level (*p* value) was considered to be 0.05 and all analyses were performed using IBM SPSS Statistics for Windows, Version 19.0 (IBM Corp. Armonk, NY, USA).

Results

Population

Between January 2005 to December 2016, a total of 1540 patient were operated on for otosclerosis and among these 742 were included in the study. There were 424 patients operated on using the microdrill fenestration technique, and 318 patients were operated on by the CO_2 fenestration technique (Table 1).

Comparison groups

The mean age at surgery was significantly greater in the microdrill group than in the CO_2 laser group ($p < 0.001$).

Table 1 Patient characteristics of the two groups

	Microdrill	CO_2 laser	*p* value
Total population			
Number of patients	424	318	
Sex, females (%)	271 (63.9%)	201 (63.2%)	0.843
Mean age at surgery (years)	51.3 (12.4)	45.9 (12.1)	< 0.001*
Age range (years)	18–84	18–80	
Right ear involved (%)	226 (53.3%)	167 (52.5%)	0.832
Population with audiometric results ≥ 1 year			
Number of patients	153	216	
Sex, females (%)	101 (66.0%)	146 (67.6%)	0.751
Mean age at surgery (years)	51.7 (11.7)	45.5 (11.8)	< 0.001*
Age range (years)	18–75	18–80	
Right ear involved (%)	86 (56.2%)	111 (51.4%)	0.360

CO_2 carbon dioxide

**p* value significance level < 0.05

There was no significant difference between groups in terms of sex ($p = 0.843$), and operated side ($p = 0.832$) (Table 1).

In the microdrill group, 153 patients were followed up post operatively for 1 year or longer. On the other hand, we noted 216 patients in the second group were followed up for 1 year or longer. Among these, the mean age at surgery was significantly higher in the microdrill group than in the CO_2 laser group ($p < 0.001$). There was no statistically significant difference in terms of gender ($p = 0.751$) or operated side ($p = 0.360$, Table 1). In the CO_2 group, there was no significant difference in either preoperative and postoperative data between the three surgeons.

Table 2 Postoperative air–bone gap (ABG) classified in to three bins based on the recommendation of the committee of Hearing and Equilibrium of American Academy of otolaryngology, Head and Neck Surgery

	Microdrill	CO_2 laser	*P* value
ABG after 45 days			
Patients	424	318	
0–10 dB	342 (80.7%)	269 (84.6%)	0.199
> 10–20 dB	55 (12.9%)	36 (11.3%)	
> 20–30 dB	14 (3.3%)	9 (2.8%)	
> 30 dB	9 (2.1%)	2 (0.6%)	
SNHL	4 (0.9%)	2 (0.6%)	
Facial paralysis	0	0	
ABG after 1 year			
Patients	153	216	
0–10 dB	128 (84%)	188 (87%)	0.362
> 10–20 dB	17 (11%)	20 (9%)	
> 20–30 dB	4 (2.5%)	6 (3%)	
> 30 dB	4 (2.5%)	2 (1%)	

ABG air–bone gap, *CO_2* carbon dioxide, *dB* decibels, *SNHL* sensorineural hearing loss

Hearing results and outcome

In the total population we found slightly better results for postoperative air–bone gap (ABG) in the CO_2 laser assisted stapedotomy (Table 2). 84% of patients in the CO_2 group achieved an ABG between 0–10 dBs postoperatively, compared with 80.4% achieved the same level in the microdrill group. Postoperative sensorineural hearing loss was observed in four patients (0.9%) operated with microdrill technique and two patients (0.6%) in the CO_2 group. There was no postoperative facial paralysis in either group (Table 2).

Preoperative and postoperative audiometric hearing thresholds and results for the patients followed up at least for 1 year are shown in Table 3. There was no significant difference between groups in terms of mean preoperative pure-tone air-conduction ($p = 0.951$), mean preoperative pure-tone bone-conduction ($p = 0.650$), and preoperative air–bone gap ($p = 0.692$). The mean of pure-tone bone-conduction and pure-tone air conduction for both groups improved post operatively. By one year-post operatively the air–bone gap has improved dramatically for both groups. The difference in mean postoperative air–bone gap was not statistically significant ($p = 0.112$) between the groups. When comparing air–bone gap (taking in consideration the preoperative pure-tone bone-conduction averages instead of postoperative bone-conductions averages), we found no significant difference between microdrill group (4.3 ± 15.3) and CO_2 group (4.5 ± 12.4, $p = 0.213$, Table 3).

The mean air–bone gap (ABG) closure in the microdrill group was 17.5 ± 11.3, whereas in the CO_2 group it

Table 3 Pre- and post-operative audiological data

	Microdrill (SD)	CO_2 laser (SD)	*p* value
Mean preop BC (SD)	24.5 (± 11.3)	24.4 (± 10.2)	0.650
Mean preop AC (SD)	47.4 (± 16.1)	46.5 (± 13.1)	0.951
Mean preop ABG (SD)	22.9 (± 9.9)	22 (± 9.5)	0.692
Results ≥ 1 year			
Mean postop ABG (SD)	5.4 (± 8.7)	5.2 (± 6.7)	0.112
Mean ABG closure	17.5 (± 11.3)	16.8 (± 10.9)	0.492
Mean postop AC − mean preop BC	4.3 (± 15.3)	4.5 (± 12.4)	0.213
Results ≥ 6 weeks			
Change in bone-conduction level (1 kHz)	− 1.87 (± 14.3)	0.38 (± 12.5)	0.017*
Change in bone-conduction level (2 kHz)	4.01 (± 14.9)	3.13 (± 12.7)	0.140
Change in bone-conduction level (3 kHz)	2.15 (± 14.1)	0.39 (± 12.2)	0.009*
Change in bone-conduction level (4 kHz)	0.34 (± 15)	− 2.88 (± 13.6)	< 0.001*

BC pure-tone bone conduction averages, *AC* pure-tone air-conduction averages, *ABG* air–bone gap, *SD* standard deviation, *preop* preoperative, *postop* postoperative, *kHz* kilohertz

*p value significance level < 0.05

was 16.8 ± 10.9. The difference in regard to ABG closure between the two groups was not statistically significant (Table 3). Among the patients operated by CO_2 laser stapedotomy technique, 87% had postoperative ABG between 0 and 10 dB, which is slightly better result in comparison with patients in microdrill group 84%, but the difference was not statistically significant ($p = 0.362$, Table 2).

The change between preoperative and postoperative (at least 6 weeks) bone conduction threshold is shown in Table 3. At 1 kHz we observed better results in CO_2 group with level of mean bone-conduction threshold remained almost stable 0.38 dB. On the other hand, the mean of bone-conduction threshold in the microdrill group has dropped by 1.87 dB. The difference in change of bone conduction threshold between the groups at 1 kHz is statistically significant in favor of CO_2 laser ($p = 0.017$). At 2 kHz we observed approximately comparable results and the difference is not significant. At 3 and 4 kHz we noted statistically significant difference in favor of microdrill assisted stapedotomy. At 3 kHz the bone-conduction threshold in CO_2 group remained approximately unchanged which is a good result, but it showed a loss of 2.88 dB at 4 kHz. In the microdrill group, the bone-conduction threshold level showed an improvement by 2.18 dB at 3 kHz and remained unchanged at 4 kHz (Table 3).

Discussion

Stapedotomy is the current standard intervention for the treatment of conductive hearing loss caused by otosclerosis. The aim of the stapes surgery is to improve the hearing and minimize the risk of hearing damage or any other complications in relation to footplate fenestration which opens an access to the inner ear. Thermal effects of CO_2 laser [18] and mechanical contact injury in case of microdrill stapedotomy are factors that may affect the hearing outcome.

In our study, we included high number of patients operated in two referral otology university centers. Our study is a multicenter retrospective study, thus the patients were operated on by different senior surgeons. All patients included were operated on under general anesthesia. Although Maureen et al. concluded their study by better postoperative results under general anesthesia; their analysis showed that the differences were not statistically significant [19].

In the present study, the sex ratio in the population of both groups shows more affected women than men which is similar to that reported elsewhere due to endocrine factors that have been involved in the etiopathogenesis of the otosclerosis [20]. Kishimoto et al. concluded in their study that male sex could be one of the significant prognostic factors [21]. In our study, the results were not affected by that factor as there was a similar proportion of males and females in both groups (Table 1).

Age is an important factor related to postoperative results of stapes surgery; Fisch et al. found that the best results were in patients aged less than 50 years [22]. This could be due to better capability of resistance or recovery from surgery-related damage and is substantiated by Wengen et al. who conclude to significantly better functional results of total stapedectomy in younger patients [22]. Herein, the mean age of the CO_2 group was significantly lower. However, the groups had comparable preoperative hearing loss which reduces the bias caused by the difference in age. Furthermore, it is of note that, although high-resolution computed tomography of temporal bone was performed for all patients, we did not include the radiological grades of otosclerosis, but this was not necessary as the two groups were homogenous with regards to preoperative hearing level.

Audiometric hearing results were documented for all of the patients at least 6 weeks postoperatively. All surgical procedures compared in our study showed surgical success of > 80%). The comparison of postoperative ABG for these patients, we observed slightly better results with CO_2 laser fenestration technique (84.6%) as compared with microdrill fenestration technique (80.7%). Four patients in the microdrill groups suffered from the complication of complete sensorineural hearing loss (0.9%) as compared with two cases documented with sensorineural hearing loss in CO_2 group (0.6%). In both groups, the percentage of post op deafness is within the levels previously reported for primary stapes surgery (0.2–1%) [23]. In one of the cases herein (operated on by the CO_2 laser technique), the cause was identified as inflammatory granuloma that has been reported to be one of the cause of postoperative sensorineural hearing loss after stapes surgery [24].

The results show slightly better postoperative air bone gap closure for the microdrill group 17.5 ± 11.3 versus 16.8 ± 10.9 in CO_2 group. That could also be attributed to the piston diameter 0.6 mm used for the patients in the first group and is supported by Bernardeschi et al. who demonstrated that 0.6 mm piston allowed a statistically significant higher AC gain compared with the 0.4-mm diameter piston [25]. Mechanically when the dead space between the diameter of the inserted piston and the periphery of the footplate opening is large there will be even more loss of transmitted energy. We think that a 0.6 mm piston inserted in an opening of approximately 0.7 mm in diameter can at the same time prevent loss of energy and thus vibrating a larger volume of fluid and transmitting more acoustic energy. This is supported by Wegner et al. who measured and compared the round window velocity in response to acoustic stimuli at different frequencies and through different piston diameter. They found that at mid-range frequencies (between 500 and 4000 Hz) round window velocity increased by 2–3 dB when using 0.6 mm diameter compared with a 0.4 mm diameter piston [26].

The recommendation of committee on Hearing and Equilibrium of American Academy of otolaryngology, Head and Neck Surgery [16]: the only results at 1 year or more should be taken in consideration when reporting results. As shown in Table 3, the mean of preoperative pure-tone bone-conduction, pure-tone air-conduction and ABG were comparable between the compared groups (p value > 0.05). This can reduce the bias caused by the difference in the mean age. In our study, there is no statistically significant difference between the two surgical techniques in terms of postoperative ABG, and ABG closure. Postoperatively in both groups (84% in MD group, 87% in CO_2 group) high percentage of patients achieved the level of ABG 10 dB, which is a successful result (Table 2). High percentages of our patients achieve closure of ABG up to 20 dB, 95% for MD group patients and 96% for CO_2 patients. This result is comparable with the result demonstrated by Dhooge et al. [27].

In addition, it is important to measure the overclosure to observe the postoperative hearing improvement or damage. Overclosure in the stapes surgery is an apparent improvement in bone conduction hearing due to Carhart phenomenon. In the present study, there was greater hearing damage around the frequency of 1 kHz postoperatively when using microdrill fenestration technique Whereas, more damage is observed in CO_2 Laser fenestration technique at 4 kHz. Both techniques resulted in good hearing improvement at 2 kHz due to Carhart phenomenon. Somers et al. demonstrate in their study that there is no statistically significant difference was detected between the two techniques with regard to the measure of overclosure [28]. Brase et al. demonstrated that CO_2 laser stapedotomy showed a trend toward better bone conduction thresholds than classic perforation [14]. Hearing damage could be explained by thermal effects of CO_2 laser or mechanical damage in case of microdrill fenestration technique. Other explanation for that is the degree of footplate and stapes fixation that sometimes lead to aggressive utilization of the fenestration's materials. The degree of fixation is difficult to be measured radiologically.

Conclusion

Even though the surgical techniques, the diameter of the piston and the surgeons are different, the overall surgical results of stapedotomy are comparable without significant difference. Surgeon's preference and experience, availability of the material and anatomic condition should determine the surgical technique.

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Compliance with ethical standards

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