Post Stapedotomy Vestibular Deficit: Is CO₂ Laser Better than Conventional Technique? A Non-randomized Controlled Trial

Anubhav Singh¹ · Rakesh Datta¹ · B. K. Prasad² · Ajith Nilakantan³ ·
Renu Rajguru¹ · Manoj Kumar Kanzhuly¹ · Salil Kumar Gupta¹ ·
Inderdeep Singh⁴

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Abstract The current standard of care for surgical management of Otosclerosis is small fenestra stapedotomy, which can be done by CO₂ Laser assisted as well as conventional techniques. Vertigo is the commonest complication after stapes surgery. The use of CO₂ Laser has been rising recently owing to its no touch principle, high precision and possibly lower risk of vertigo post operatively. To compare the post-operative vestibular deficit in patients of Otosclerosis having undergone small fenestra stapedotomy by conventional versus CO₂ Laser assisted technique. 80 clinically diagnosed Otosclerosis patients fulfilling the inclusion criteria were enrolled. They underwent small fenestra stapedotomy by either conventional or CO₂ Laser assisted technique. Vestibular function was assessed objectively by measuring sway velocity using modified clinical test of sensory interaction on balance by static posturography. Subjective measurement of balance was done using Vestibular balance subscore of Vertigo Symptom Score (VSS-sf-V). The outcome measures were compared pre-operatively and at first and fourth week post-operatively. All patients had vestibular deficit 1 week post-operatively in the form of increased sway velocity and symptom scores, which reduced by 4 weeks after Stapedotomy. The vestibular deficit in the two groups was

similar at 1 week after surgery. 4 weeks after surgery, the sway velocity in conventional group was significantly greater than Laser group though there was no significant difference in the symptom scores. The use of CO₂ Laser for Stapedotomy results in lesser post-operative vestibular deficit as compared to conventional method.

Keywords Stapes surgery · CO₂ laser · Posturography · Otosclerosis · Vertigo · Postural balance

Introduction

The current standard of care for surgical management of Otosclerosis is Stapedotomy [1]. Stapedotomy can be done by conventional technique with hand held instruments and by Laser assisted technique. The main advantages of Laser include the precision of its application and the low risk of footplate dislodgement as a result of the no-touch principle of this technique [2].

The commonest post-operative complication of Stapedotomy is vertigo [3]. The prevalence of postoperative vertigo has been reported to be 3.4–55% after conventional stapedotomy and 0–26% after Laser assisted Stapedotomy [2]. The assessment of post-operative vestibular deficit has traditionally been difficult. Computerized Posturography is a tool which provides a functional measure of the patient's ability to use proprioceptive, vestibular and visual system for the maintenance of balance. The test protocols are designed to assess how well a person is using sensory inputs when one or more of the sensory inputs are compromised. It is one of the most sensitive technologies available for the evaluation of balance [4].

Matkovic et al. [5] in a comparison of outcomes of CO₂ Laser versus conventional stapedotomy, found post-

✉ Rakesh Datta
rakeshdatta@gmail.com

¹ Department of ORL-HNS, Armed Forces Medical College, Wanowrie, Pune 411040, India

² Department of ORL-HNS, Command Hospital (CC), Lucknow 226002, India

³ 167 Military Hospital, c/o 56 APO, Pathankot, India

⁴ Department of ORL-HNS, INHS Asvini, Mumbai 400005, India

operative vertigo in 26% of Laser group and in 55% of conventional group. They attributed this difference to the lesser risk of mechanical trauma to inner ear with the use of Laser.

Badran et al. [5] compared CO₂ Laser versus mechanical techniques (skeeter and microperforator) for Stapedotomy. They observed the occurrence of vertigo in post-operative period. They found that 2.8% of the patients in Laser group had post-operative vertigo as compared to 12.2% of patients in the mechanical group, which they attributed to lesser footplate manipulation and greater precision of piston placement in the Laser group.

On the contrary, Cuda et al. [7] compared the results in use of CO₂ Laser versus skeeter drill for Stapedotomy in 60 patients. They analysed the medical records of the patients to record the incidence of Vertigo in the study groups. 10% of the patients treated with Laser Stapedotomy versus 6.7% of those treated with conventional Stapedotomy had reported post-operative vertigo 1 month after surgery.

There is therefore contrary data available to suggest the better of the two techniques of small fenestra stapedotomy in terms of post-operative vestibular deficit. Moreover, the limited data available relies primarily on patient's symptoms or records and lacks objectivity. The aim of this study is to observe and compare the post-operative vestibular deficit in patients of Otosclerosis undergoing small fenestra Stapedotomy by conventional versus CO₂ Laser assisted technique. The present study is a novel attempt to quantify the difference in post-operative vestibular deficit in terms of objective and subjective measures.

Materials and Methods

A non-randomised controlled trial was carried out in the Otorhinolaryngology department of a tertiary care centre from November 2015 to October 2017. Patients were followed for a period of 1 month following surgery. The study was approved by the institutional ethical committee (reference number IEC/Nov 2015 dated 10 Nov 2015).

The study population comprised of clinically diagnosed Otosclerosis patients fulfilling the eligibility criteria and undergoing surgery. A presumptive diagnosis of Otosclerosis was made in patients with normal tympanic membrane having conductive hearing loss of at least 20 dB, with type 'A' or 'As' tympanogram. All patients of Otosclerosis undergoing Stapedotomy for first time and aged between 15 and 60 years were included in the study. Patients with a prior history of Stapedotomy done in one ear, head trauma, peripheral or central vestibular deficit due to other known causes and patients with systemic diseases affecting balance were excluded. Written informed consent

was obtained from all individual participants included in the study.

The sample size was calculated to test the null hypothesis that there is no difference in the proportion of patients developing post-op vertigo by either conventional or Laser assisted technique with 5% level of significance and 80% power. Based on the data from previous studies, a sample size of 40 patients in each group (i.e. total 80 number of patients) was calculated.

All the patients underwent the standard pre-operative workup including pure tone audiometry and tympanometry. Objective evaluation of balance was done by performing modified clinical test of sensory interaction on balance (mCTSIB) protocol of static posturography with NeuroCom® Basic Balance Master® (Natus Medical Inc, USA). Subjective evaluation was done using the Vestibular balance subscale of Vertigo Symptom Score (VSS-sf-V) [8]. The tests were administered pre-operatively and post-operatively at 1 and 4 weeks after surgery.

Static posturography was done under 4 test conditions:

1. Eyes open on firm surface.
2. Eyes closed on firm surface.
3. Eyes open on unstable surface.
4. Eyes closed on unstable surface.

All the patients were counselled about the procedure of Posturography prior to the test. Standard safety precautions were taken to prevent fall and injury. The patients were instructed to stand on the balance platform under the aforementioned test conditions (Fig. 1). The balance platform has pressure sensitive gauges which determine the centre of pressure of the individual standing on it. Three measurements were taken in each of the four test conditions. The sway of centre of pressure (in °/s) under the four test conditions was measured. The data was recorded and composite sway velocity was calculated by the software provided with Posturography machine.

The patients underwent small fenestra Stapedotomy by either CO₂ Laser assisted or conventional technique as per the decision taken by surgical team in weekly pre-op clinic. The surgeries were performed by experienced surgeons with minimum 5 years practice in operative otology in a tertiary care centre. The surgeries were carried out under local anaesthesia. Per meatal approach was used in all cases. Standard steps of Stapedotomy were followed. For conventional technique, the stapedius tendon and posterior crus was cut, anterior crus was fractured, the stapes suprastructure was removed and a 0.7 mm perforator was used to create a fenestra in the Stapes footplate. In Laser technique, CO₂ Laser (Lumenis® AcuPulse™) was used for vaporization of stapedius tendon, posterior crus and for creation of fenestra in stapes footplate. CO₂ Laser was used at 2 W for

Fig. 1 **a** Static posturography setup, **b** performing static posturography with a patient

vaporization of stapedius tendon, 6 W for vaporizing posterior crus and at 20 W, scan, continuous wave, single shot, round shape, 0.7 mm spot size for creating fenestra in stapes footplate. The distance from the medial side of long process of Incus to the stapes footplate was measured. 0.25 mm was added to this measure to get the length of piston required. In both the techniques, a Teflon piston of 0.6 mm diameter and appropriate length was inserted and crimped to the long process of Incus. Ear lobe fat was used to seal the fenestra in all cases. No steroids were administered intra-operatively. The patients were discharged from hospital on 4th post-op day.

Post-operatively, the patient's balance was evaluated 1 and 4 weeks after the surgery with mCTSIB protocol of static posturography and VSS-sf-V. All the data was stored in a Microsoft Excel[®] spreadsheet. The data was analysed using IBM SPSS Statistics[®] version 20 (IBM Corp. Armonk, NY). The study variables were tested for normality of distribution using One Sample Kolmogorov–Smirnov test. The pre and post-operative study variables of the patients were compared using Wilcoxon signed-rank test. The study variables of patients in the two groups were compared by using Mann–Whitney *U* test. For all the statistical tests, a *p* value of < 0.05 was considered as significant.

Results

The study was conducted in the Otorhinolaryngology department of a tertiary care centre from November 2015 to October 2017. 80 patients meeting the inclusion criteria were enrolled for study (40 patients in each study group). No patients were lost to follow-up.

The mean age of patients in Conventional group was 34.52 ± 10.59 years and in the Laser group was 36.00 ± 09.88 years. The gender distribution in Conventional group was Males: Females = 3:2 while it was almost equal in the Laser group. As seen from Table 1, both the study groups were comparable with respect to age, gender, pre-op composite sway velocity and VSS-sf-V ($p > 0.05$) (Fig. 2). None of the patients had abnormal sway measurement on Computerized Posturography pre-operatively.

The study variables (pre-op composite sway velocity and VSS-sf-V) were tested for normality of distribution using One Sample Kolmogorov–Smirnov test (Fig. 2). Since the study variables were not normally distributed ($p < 0.05$) in study population, non-parametric tests (Wilcoxon signed-rank test and Mann–Whitney *U* test) were used for all statistical calculations.

The pre and post-operative composite sway velocities and VSS-sf-V were compared within the groups using Wilcoxon signed-rank test. In the conventional group, it was seen (Table 2) that the 1st week composite sway velocity and VSS-sf-V were significantly greater than the

Table 1 Baseline characteristics between the two study groups

	Conventional (<i>N</i> = 40)	Laser (<i>N</i> = 40)	<i>p</i> value
Mean age (years)	34.52 ± 10.59	36.00 ± 09.88	0.52
Males (<i>N</i>)	24	21	0.498 ^a
Females (<i>N</i>)	16	19	
Mean pre-op composite sway velocity (°/s)	0.712	0.702	0.905 ^b
Mean pre-op VSS-sf-V (0–32)	0.250	0.225	0.642 ^b

^aChi square test^bMann–Whitney *U* test **Fig. 2** **a** Comparing mean age of study groups, **b** comparing gender distribution of study groups, **c**, **d** frequency distribution of composite sway velocity and VSS-sf-V

pre-op values ($p < 0.05$). The 4th week post-op composite sway velocity was also significantly greater than the pre-op values ($p < 0.05$). However, the 4th week post-op VSS-sf-V was similar to the pre-op scores ($p > 0.05$).

In the CO₂ Laser group, it was seen (Table 3) that the 1st week composite sway velocity and VSS-sf-V was significantly greater than the pre-op values ($p < 0.05$). The

4th week composite sway velocity and VSS-sf-V were similar to the pre-op values ($p > 0.05$).

The post-operative vestibular deficit in terms of composite sway velocity and VSS-sf-V was compared between the two study groups (Table 4) using Mann–Whitney *U* test. It was seen that at 1 week after surgery, the composite sway velocity and VSS-sf-V scores among the two groups were similar ($p > 0.05$). At 4 weeks after surgery,

Table 2 Comparison of pre-op with post-op 1st and 4th week composite sway velocity and VSS-sf-V in conventional group

Variable	Pre-op	1st week	<i>p</i> value [#]
Composite sway velocity (°/s)	0.7125	0.9375	0.000 ^a
VSS-sf-V (0–32)	0.2500	1.5250	0.000 ^a
	Pre-op	4th week	<i>p</i> value ^b
Composite sway velocity (°/s)	0.7125	0.7625	0.003 ^a
VSS-sf-V (0–32)	0.2500	0.3500	0.102

All figures are means

^aSignificant at $p < 0.05$

^bWilcoxon signed-rank test

the composite sway velocity in conventional group was greater than that in the Laser group ($p < 0.05$) (Fig. 3). However, the 4th week VSS-sf-V scores in the two groups were similar ($p > 0.05$) (Fig. 3).

Discussion

Posturography is a quantitative method for isolating and assessing the sensory and motor components of balance in a standing person. AAO-HNS, in a position statement, has recognized that Posturography is medically indicated and appropriate in evaluation and therapy of persons with suspected balance or dizziness disorders [9].

Black et al. [4] identified the applications of Computerised Dynamic Posturography as an excellent tool for monitoring recovery of vestibular function in peripheral and central vestibular dysfunction, for study of balance isolating the somatosensory, visual and vestibular elements of postural control, identification of non-physiological balance tests and for novel applications in study of balance problems in elderly and following exposure to microgravity environments.

Table 3 Comparison of pre-op and post op 1st and 4th week composite sway velocity and VSS-sf-V in CO₂ laser group

Variable	Pre-op	1st week	<i>p</i> value ^b
Composite sway velocity (°/s)	0.7025	0.9400	0.000 ^a
VSS-sf-V (0–32)	0.2250	1.7500	0.000 ^a
	Pre-op	4th week	<i>p</i> value ^b
Composite sway velocity (°/s)	0.7025	0.7030	0.798
VSS-sf-V (0–32)	0.2250	0.4000	0.106

All figures are means

^aSignificant at $p < 0.05$

^bWilcoxon signed-rank test

Di Fabio et al. [10] in a meta-analysis identified that the specificity of Sensory Organisation Test and Motor Control Test of Computerised Dynamic Posturography was over 90% in identifying patients with balance disorders. However these tests have a low sensitivity of 61% which can be increased to 89% by using the results of Posturography in conjunction with clinical tests of balance.

The commonest post-operative side effect of Stapedotomy is vertigo. In the immediate post-operative period, vertigo can be due to serous and chemical labyrinthitis, an overlong prosthesis, mechanical trauma due to manipulation of Stapes footplate or the use of suction over the fenestra [11]. Delayed vertigo following Stapedotomy is attributed to development of perilymph fistula or BPPV secondary to dislodged bony fragments from the fenestra floating into the vestibule and semicircular canals [12]. The vertigo resolves post-operatively by the resolution of labyrinthitis and vestibular compensation. It has been postulated that Laser assisted Stapedotomy might result in lesser incidence of post-operative vertigo than conventional technique due to less chances of mechanical trauma as a result of the no touch technique of Laser. However, Lasers are also associated with thermal effects on perilymph and injury to neuroepithelium due to the penetration of Laser energy [13].

Our study demonstrates a significant vestibular deficit in post-operative patients of Otosclerosis. This was seen in patients who have undergone small fenestra stapedotomy by conventional as well as CO₂ Laser assisted technique. It was observed that the composite sway velocity and VSS-sf-V scores increase in the early post-operative period but reduce by the end of 1 month after surgery.

Panda et al. [14] had used Caloric test with Electronystagmography for objective measurement of vestibular function. They found vestibular hypofunction on caloric stimulation pre-operatively in patients of Otosclerosis, which became worse following Stapedotomy. Ozmen et al. [3] measured the postural sway with Computerized

Table 4 Comparison of the pre-op and post-op composite sway velocities and VSS-sf-V scores between the two study groups

Time	Study parameter	Conventional	Laser	<i>p</i> value ^b
1st week	Composite sway velocity (°/s)	0.9375	0.9400	0.883
	VSS-sf-V (0–32)	1.5250	1.7500	0.704
4th week	Composite sway velocity (°/s)	0.7625	0.7030	0.045 ^a
	VSS-sf-V (0–32)	0.3500	0.4000	0.871

All values are means

^aSignificant at $p < 0.05$

^bMann–Whitney *U* test

Fig. 3 **a** Variation of mean composite sway velocity with time, **b** variation of mean VSS-sf-V with time

Dynamic Posturography pre-operatively and at 1 week and 1 month post-operatively in patients of Otosclerosis undergoing small fenestra Stapedotomy. They found greater sway at 1 week after surgery, which reverted to the pre-operative values by 1 month after surgery. Our results are similar to the above studies as the study subjects have a significant increase in vestibular deficit as measured by subjective and objective methods 1 week after surgery which reduces by the end of 4 weeks post-operatively.

A comparison of the post-operative vestibular deficit between the two study groups shows that 1 week after Stapedotomy, the composite sway velocity and the VSS-sf-V scores in both the study groups were similar. 4 weeks after Stapedotomy, the composite sway velocity in the conventional group was significantly greater than that in

the Laser group while the VSS-sf-V scores were found to be similar in both groups.

This shows that subclinical vestibular deficit persists 4 weeks post-operatively in patients of Otosclerosis who undergo surgery by conventional technique. This vestibular deficit can be demonstrated objectively even when not reported by subjective methods 1 month after Stapedotomy.

Motta et al. [15] compared the results in patients of Otosclerosis undergoing surgery by CO₂ Laser vs micro-drill. None of their patients in the Laser group had post-operative vertigo, as compared to 9.5% of patients in control group who had post-operative vertigo. They concluded that the absence of post-operative vertigo in the Laser group rules out any damage to the inner ear due to CO₂ Laser. Badran et al. [6] used CO₂ Laser and skeeter/

microperforator for Stapedotomy. They found that 2.8% of the patients in Laser group had post-operative vertigo as compared to 12.2% of the control group. Similar results were reported by Matkovic et al. [5], who found post-operative vertigo in 26% of Laser group and 55% of the control group. They concluded that the use of CO₂ Laser had a significant priority in Stapes surgery because of its precision and reduced possibility of mechanical trauma to inner ear due to lack of physical contact with stapes which reduces the chances of undesirable post-operative complications such as vertigo.

The strengths of this study lie in the use of both subjective and objective tools for the assessment of balance before and after stapedotomy. There are some limitations in this present study. Methodical randomization of exposure was not done. A Randomised control trial with allotment of study groups and intervention by randomization would have increased the validity of the study. Similarly, there is no blinding in the study which can admittedly add bias. The use of Computerized Dynamic Posturography instead of static posturography will allow balance testing to be done in wider clinical scenarios and dynamic environments which will better estimate the functional status of patient's balance. However, the present study uses static posturography as it was available in the department.

Conclusion

By the results of this study we can conclude that small fenestra Stapedotomy by both conventional and CO₂ Laser assisted technique results in vestibular deficit in 1st week post-surgery. The vestibular function recovers to pre-operative levels by the end of first post-operative month in patients undergoing surgery by CO₂ Laser assisted technique whereas vestibular deficit remains in patients undergoing surgery by conventional technique. The use of CO₂ Laser in Stapedotomy thus results in earlier recovery of vestibular function. The use of CO₂ laser can be hence recommended in Stapedotomy.

Compliance with Ethical Standards

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

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964

Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Written informed consent was obtained from all individual participants included in the study.

References

1. Aarnisalo AA, Vasama JP, Hopsu E, Ramsay H (2003) Long-term hearing results after stapes surgery: a 20-year follow-up. *Otol Neurotol* 24:567–571
2. Wegner I, Kamalski DMA, Tange RA et al (2014) Laser versus conventional fenestration in stapedotomy for otosclerosis: a systematic review. *Laryngoscope* 124:1687–1693. <https://doi.org/10.1002/lary.24514>
3. Ozmen AO, Aksoy S, Ozmen S et al (2009) Balance after stapedotomy: analysis of balance with computerized dynamic posturography. *Clin Otolaryngol* 34:212–217. <https://doi.org/10.1111/j.1749-4486.2009.01915.x>
4. Black FO (2001) Clinical status of computerized dynamic posturography in neurotology. *Curr Opin Otolaryngol Head Neck Surg* 9:314–318. <https://doi.org/10.1097/00020840-200110000-00011>
5. Matković S, Kitanoski B, Malicević Z (2003) Advantages of CO₂ laser use in surgical management of otosclerosis. *Vojnosanit Pregl* 60:273–278
6. Badran K, Gosh S, Farag A, Timms MS (2006) How we do it: switching from mechanical perforation to the CO₂ laser; audit results of primary small-fenestra stapedotomy in a district general hospital. *Clin Otolaryngol* 31:546–549
7. Cuda D, Murri A, Mochi P et al (2009) Microdrill, CO₂-laser, and piezoelectric stapedotomy: a comparative study. *Otol Neurotol* 30:1111–1115
8. Kondo M, Kiyomizu K, Goto F et al (2015) Analysis of vestibular-balance symptoms according to symptom duration: dimensionality of the vertigo symptom scale-short form. *Heal Qual Life Outcomes* 13:4. <https://doi.org/10.1186/s12955-015-0207-7>
9. Position Statement: Posturography American academy of otolaryngology-head and neck surgery. <http://www.entnet.org/?q=node/913>. Accessed 24 Jan 2018
10. Di Fabio RP (1995) Sensitivity and specificity of platform posturography for identifying patients with vestibular dysfunction. *Phys Ther* 75:290–305
11. Causse JB, Causse JR, Cezard R et al (1988) Vertigo in post-operative follow-up of otosclerosis. *Am J Otol* 9:246–255
12. Atacan E, Sennaroglu L, Genc A, Kaya S (2001) Benign paroxysmal positional vertigo after stapedectomy. *Laryngoscope* 111:1257–1259
13. Jovanovic S (2006) Laser stapedotomy. In: Hildmann H, Sudhoff H (eds) *Middle ear surgery*. Springer, Heidelberg, pp 120–130
14. Panda NK, Saha AK, Gupta AK, Mann SBS (2001) Evaluation of vestibular functions in otosclerosis before and after small fenestra stapedotomy. *Indian J Otolaryngol Head Neck Surg* 53:23–27. <https://doi.org/10.1007/BF02910974>
15. Motta G, Mosillo L (2002) Functional results in stapedotomy with and without CO₂ laser. *ORL* 64:307–310. <https://doi.org/10.1159/000066079>