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Original Research Article

To Evaluate the Effectiveness of LASER Stapedotomy in Improving Hearing Outcome in Otosclerosis Patients at Tertiary Health Center: A Retrospective Study

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Abstract:

Objective: To assess the effectiveness of CO2 LASER stapedotomy in improving subjective and objective hearing loss in patients with clinical otosclerosis and to assess it advantages over the classical "cold" technique.

Materials and Methods: A retrospective study of 40 patients who had undergone LASER stapedotomy following clinical diagnosis of otosclerosis between February 2018 to December 2019.All these patients underwent LASER stapedotomy with prosthesis insertion. Pre and postoperative hearing assessment were done. The audiologic results were assessed in terms of amount of air and bone conduction threshold gains and AB gap closure, intra and postoperative complications if any. Data analysis was done by IBM SPSS Statistics Version 20 and descriptive analysis, Pearson's correlation and paired t tests were applied.

Results: 40 patients underwent LASER stapedotomy from February 2018 to December 2019. There was significant Air Bone Gap closure with more than 10 dB in 77.5%patients and more than 20 dB in 10%. All patients reported subjective improvement in symptoms and quality of life. There were no cases of floating footplate in these cases. In 5 cases of obliterative otosclerosis skeeter drill was used to thin the footplate and LASER was used to make the final stapedotomy hole. In all other cases stapedotomy hole could be made directly without the need to thin the footplate. In 29 patients Teflon piston (Grace Medical Devices) of 0.6 mm diameter was used and in 11 patients Titanium Piston (Kurz Medical Devices) of 0.4 mm diameter was used. The size of stapedotomy hole made by LASER is 0.1mm more than the planned piston diameter size.

None of the patients developed any significant post-operative complication.

Conclusion: Stapedotomy is an effective surgical treatment for improving hearing outcomes in patients with otosclerosis with marked improvement in quality of life. Majority of patients report clinically improved hearing post procedure. LASER stapedotomy is a safe procedure with lower intra and postoperative complications and hence is recommended for patients requiring surgery.

Keywords: Stapes, Otosclerosis, Air Bone Gap (ABG), Stapedotomy, LASER.

Introduction

Hearing loss is a common but physically and emotionally debilitating handicap encountered in human population.Both conductive and sensorineural types of hearing losses are encountered frequently, each with their own set of challenges in diagnosis and adequate management. Otosclerosis is a common cause of progressive conductive hearing loss, with many developing sensorineural component over time. [1] Otosclerosis is primary disorder of otic capsule, leading to stapes ankylosis. [2] Ossicular fixation, especially involving stapes is surgically treatable.Conductive hearing loss is determined by stapes footplate fixation. Sensorineural component of hearing loss is due to invasion of spiral ligament by otosclerosis. [3] There is a definite female preponderance [4] and familial affliction is present in about 60% of cases. [5] Patients present with a range of symptoms including hearing loss, tinnitus, dizziness; most common being slowly progressive conductive hearing loss, most frequently in the age group of 20-45 years. [6]

Diagnosis is based on clinical symptoms and an audiological evaluation comprising pure tone audiogram and impedance audiometry. Audiological evaluation frequently reveals a conductive type of hearing loss, with raised bone conduction thresholds and a characteristic Carhart's notch at 2kHz. [7] Impedance audiometry yields an Astype of tympanogram suggestive of reduced middle ear ossicular mobility. However, a mixed

type or sensorineural hearing loss pattern develops in patients with cochlear involvement. [8] There has been a recent emphasis to obtain CT imaging studies in these patients, both for diagnostic purpose and to evaluate middle and inner ear anatomy preoperatively. CT imaging has been found to be highly specific when correlated with histopathological studies, with sensitivity varying with the disease extent. [9] High resolution CT has been found to be about 90% sensitive with radiological features of thickened footplate, narrowed oval window and round window niche, and double ring sign (hypodense lesion surrounding cochlea). [10-13]

With about 0.3-0.4% prevalence of clinically symptomatic otosclerotic patients in Indian and Caucasian population with autosomal dominant mutation, [14-15] otosclerosis is one of the leading causes of hearing loss induced quality of life deterioration. It progresses steadily from unilateral to bilateral ears and also in severity, with about 70–85% of cases reporting bilateral hearing losses. [16] Treatment modalities range from a wait and watch approach, hearing aid trials, and stapedotomy with prosthesis insertion which is now the gold standard of treatment. Surgery has produced excellent stable hearing, tinnitus and dizziness improvement. [17-20]

Since the introduction of stapedotomy with prosthesis insertion by Shea, [21] surgery has become the mainstay of management of otosclerosis. With first LASER stapedotomy being performed by Rodney C. Perkins, [22] numerous advances have been made in the area, aiming at improving surgical techniques to yield better hearing outcomes and fewer intraoperative complications. Currently LASER technique has been accepted as a safe and precise modality, with fewer incidences of footplate mobilization and mechanical trauma to inner ear, better hearing outcomes and rarer incidences of sensorineural hearing loss; thus becoming the choice of surgeons worldwide for both primary and revision stapedotomies. [23-26]

Surgical outcomes of stapedotomy, though a very precise and safe procedure, vary across operating centers in view of varied patient demographics, symptomatology and extent of the disease. Quality of life expectations too vary across regions, which is an often-overlooked aspect, but can significantly influence outcomes. And not the least, but surgeon's experience does count towards a favorable outcome in a particular centre. [27] Hence we conducted this study to evaluate our surgical parameters in patients undergoing LASER stapedotomies at our hospital.

Material and Methods

We conducted a retrospective study of 40 patients who had a clinical and audiometric diagnosis ofotosclerosis. All of our patients underwent LASER stapedotomy with prosthesis insertion between February 2018 to December 2019. All patients were operated by the same set of surgeons. Patients were evaluated with Pure Tone Audiometry (PTA) and impedance audiometry. On audiometric evidence of otosclerosis, all these patients were evaluated radiologically with a high-resolution CT imaging. Patients were counselled about the disease etiopathology, progression and various available treatment modalities. Once these patients were planned for surgery, all underwent routine blood investigations preoperatively to ascertain surgical fitness. Both titanium and Teflon pistons were used as prosthesis. The selection of prosthesis type was non-randomized and choice given to the patients regarding the prosthesis after adequate relevant counselling. A well-informed consent was taken for the surgery and its probable outcomes and complications if any.

Pure Tone and Impedance Audiometry were performed both preoperatively and at 1 month and 3 months postoperative intervals to measure audiological gain. Pure tone thresholds for air conduction (AC) at frequencies of 0.25, 0.5, 1, 2, 4 and 8 kHz and bone conduction (BC) at 0.5, 1, 2 and 4 kHz were assessed and Air Bone Gap (ABG) was calculated. Hearing improvement was determined by ABG closures as per recommended guidelines.[28]

All patients underwent LASER stapedotomy under general anaesthesia. Middle ear was accessed via trans canal route. After elevation of tympanomeatal flap, middle ear ossicles were inspected and stapes footplate fixity ascertained. Absolute hemostasis is ascertained before we introduce the LASER in the operative field. In all the cases free beam CO2 LASER was used using the micromanipulator. Small pieces of gelfoam are used to shield the footplate region and adjoining areas when LASER is used on the stapes superstructure.

Step 1- Using the CO2 LASER straight beam 0.5-1mm size, average wattage of 15w and depth 1 to cut the stapedius tendon. Small pieces of gelfoam are used to shield the footplate region

Step 2- Cutting the posteriorcrura using straight beam 0.5-1mm length, average wattage between 18-20 W and depth of 1. LASER beam weakens the crura which then easily breaks.

Step 3- Using a curved pick to dislocate the incudo-stapedial joint and then placing the pick on the neck of stapes and outfracturing the stapes suprastructure. Since the posterior crura has already been weakened using LASER, it is easily outfractured. We never had to use LASER for the anterior crura.

Step 4- In majority of our cases a "blue footplate" could be visualized where circular LASER beam was used to perform stapedotomy. The size of stapedotomy hole was 0.1mm more than the piston diameter to be used. In five cases footplate was thick and skeeter drill (Medtrionic) was used to thin the footplate. Once the footplate was "blue lined", LASER beam was used to make the final stapedotomy hole. The settings of LASER for stapedotomy are as follows

Shape – Circular, Size- 0.7mm for 0.6mm piston and 0.5mm for a 0.4mm piston, Wattage- 20-22 W, Depth 1-2 depending on the thickness of footplate.

Step 5- Measuring and cutting the piston.

Step 6- Placing the piston in the stapedotomy hole and crimping it to the incus long process.

Step 7- Replacing back the tympanomeatal flap.

Laser stapedotomy is essentially a "no touch technique" where instrumentation is used only during removal of suprastructure of stapes and occasionally during drilling of the footplate region. With LASER there is minimal manipulation of the footplate and minimal risk to inner ear. We did not encounter a single case of floating or subluxated footplate in our series.

Patients were followed up on outpatient basis and relevant otoendoscopic inspection and audiological investigations performed at regular intervals.

The results were compared in terms of amount of AB gap closure and postoperative complications.Statistical analysis was done using IBM SPSS Statistics Version 20 software and relevant tests were applied (descriptive, paired-samples T tests, Pearson correlation). P value was calculated at 95% confidence levels and a value of <0.05 was taken as statistically significant.

Results and observations

We performed 40 LASER stapedotomies during the time interval of February 2018 to December 2019. Preoperative data analyzed were age, sex, laterality of ear and type of hearing loss. Of the 40 patients evaluated in the study, 14(35%) were male and 26(65%) were females (M:F::2:3).The mean age of patients at intervention was 29.87±9.57 years and range of 37 years, with most patients being affected in their 3rd decade (40%).23 (57.5%) patients underwent right sided and 17 (42.5%) patients left sided stapedotomy (Table 1).

Table 1: Patient demographic data

Patient demographics	Frequency	Percentage (%)
Age group (years)		
10-20	07	17.5
21-30	13	32.5
31-40	16	40.0
41-50	02	05.0
51-60	02	05.0
Total	40	100
Mean age (years)	29.87	
Gender		
Male	14	35
Female	26	65
Laterality		
Right	23	57.5
Left	17	42.5

Table 2, figure 1 describes the overall hearing improvements experienced by our patients.There was a significant improvement in mean Air Conduction Threshold (ACT, at 0.25, 0.5, 1, 2, 4 and 8 kHz) 19.36 dB (SD 4.84, t=25.30, df=39, correlation 0.936, p<0.001, 95% confidence level). We calculated BCT at 2kHz, and found that there was a significant gain in BCT of 29.50 dB (SD 7.58, t=24.84, df=39, correlation 0.677, p<0.001, 95% confidence level). This gain was pronounced only at 2kHz and was attributed to cahart's notch closure.

The mean ABG closure was significant at 12.05dB (SD 5.81, t=13.12, df=39, correlation 0.447, p<0.001, 95% confidence level).37 patients (92.5%) showed a postoperative Air Bone Gap of 10dB or less, which correlated with clinically improved hearing outcome in these.Overall 31 patients (77.5%) had a significant ABG closure of 10 dB or more, and 4 patients (10%) had more than 20 dB closure values. Mean hearing threshold improvements across different age groups of patients is described in Table 3, figure 2.

Table 2: Pre and post operative mean hearing threshold improvement

Parameter	Preoperative	Postoperative	Gain
Air conduction threshold (ACT)	59.85 dB(±12.13)	40.49dB (±13.59)	19.36 dB* (±4.84)
Bone conduction threshold(BCT, 2kHz)	49.75 dB (±10.06)	20.13 dB (±5.37)	29.50 dB**(±7.58)
Air bone gap (ABG)	20.50dB (± 6.485)	8.45dB (±3.23)	12.05 dB^ (±5.81)

* t=25.30, df=39, correlation 0.936, p<0.001, 95% confidence level
** t=24.84, df=39, correlation 0.677, p<0.001, 95% confidence level
^t=13.12, df=39, correlation 0.447, p<0.001, 95% confidence level

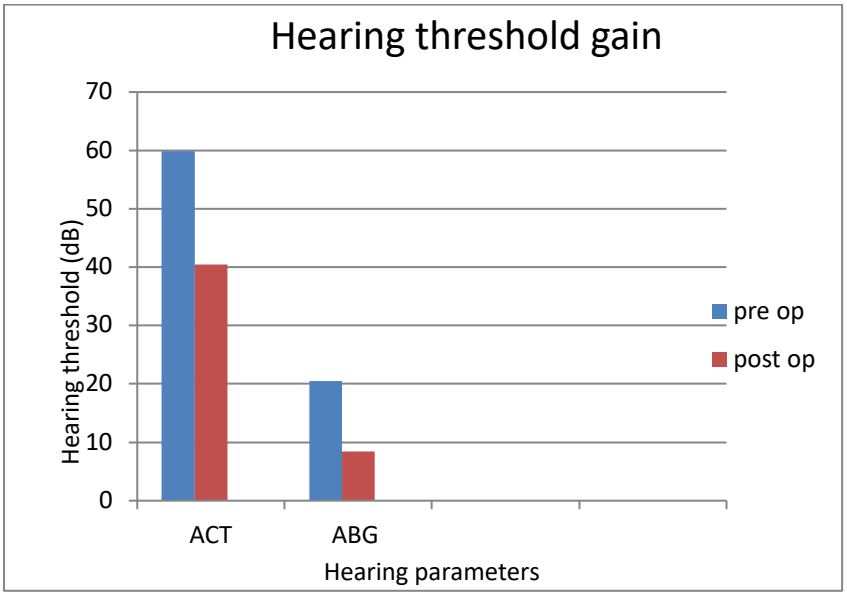

Figure 1:Meanimprovements in hearing thresholds (dB)

Table 3: Age related mean hearing threshold improvements

Mean hearing thresholds (dB)	10-20 years	21-30 years	31-40 years	41-50 years	51-60 years
Preop ACT	47.29 ± 07.41	56.16 ± 10.15	64.97 ± 09.17	81.65 ± 02.33	65.00 ± 14.14
Postop ACT	28.02 ± 06.34	34.71 ± 12.11	47.44 ± 10.36	60.80 ± 02.54	45.80 ± 20.08
ACT Gain	19.27 ± 06.90	21.45 ± 04.78	17.53 ± 03.45	20.85 ± 01.20	19.20 ± 05.94
Preop ABG	17.15 ± 04.88	18.86 ± 03.63	21.25 ± 06.19	32.50 ± 10.61	25.00 ± 14.14
Postop ABG	07.86 ± 02.67	06.92 ± 02.53	09.56 ± 03.43	12.50 ± 03.54	07.50 ± 03.54
ABG Closure	09.29 ± 03.45	11.92 ± 03.84	11.69 ± 06.65	20.00 ± 07.07	17.50 ± 10.61

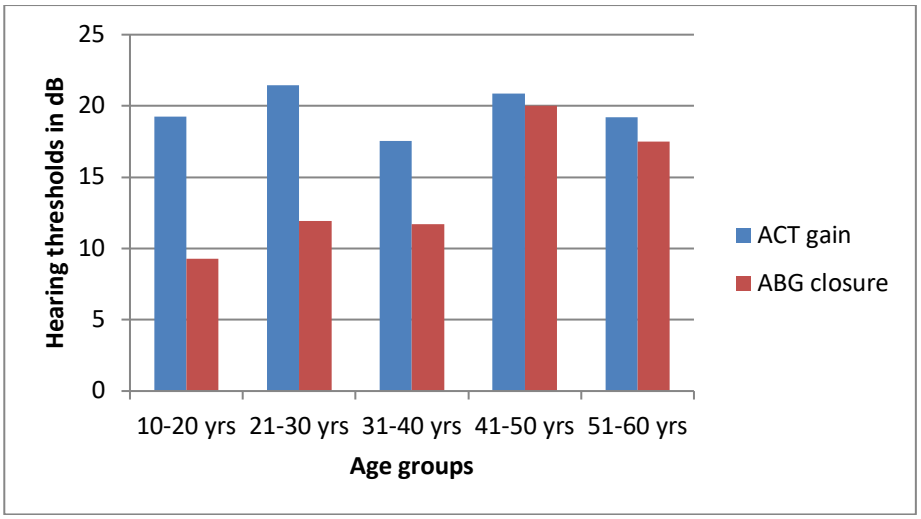

Figure 2: Mean hearing gain across age groups

Discussion

Surgical management of stapedial otosclerosis has become a standard and safe modality across otologic centres around the world. Both stapedectomy and stapedotomy have been employed, with stapedotomy finding widespread favourover time due to lesser incidence of inner ear complications. [27,29-30]

Various studies have proven that stapedotomy with prosthesis insertion results in improved hearing in patients with conductive hearing losses, with even mixed hearing loss patients being benefitted in many cases. There is a generalized improvement in air conduction thresholds, with bone conduction gain at 2kHz, and clinically significant air bone gap closure. [27,31-32]

Our study sample included 40 patients, which though less, is comparable to some other studies being conducted worldwide. [33] We had 65% female and 35% male patients, with a ratio of M:F::2:3. This corresponds to the available data depicting female preponderance of the disease. [34] Mean age of our study population was 29.87±9.57 years, with most patients being affected in the age group of 31-40 years(40%), which is in accordance to the observation that the disease peaks at 3rd decade of life. [6]

We observed a mean air conduction (ACT) gain of 19.36±4.84 dB, which was similar to other studies by Alzhrani et al. [27] 37 patients (92.5%) had a postoperative ABG of 10dB or less, which was considered a successful outcome. [27,28] The audiologic results of stapedotomy vary across centres, with most of them reporting ABG closure rates from 33.3% to 94.4%. [35] The variation in results has been attributed to various patient and surgery related factors.We also observed that about 77.5% of our patients had an ABG closure of 10dB or more.These were significant improvements in hearing outcome measures which also correlated to a well perceived symptomatic hearing improvement in patients.

It has also been shown that BCT improvement is significant only at 2KhZ and leads to the closure of the characteristic cahart's notch. Specific BCT improvement at 2kHz depends on effective stapes footplate function restoration, which remedies the Cahart effect and resolves the impedance mismatch between middle and inner ear due to otosclerosis. We also experienced a significant BCT gain at 2kHz, which is in accordance with other studies. [27,36,37]

LASER stapedotomy has been considered a safe surgical procedure in terms of minimal perioperative complications as documented in numerous studies. [23-26] Being highly precise in its application, LASER avoids manipulation of the footplate. This results in reduced risk of any resultant floating footplate. [38] LASER reduces mechanical trauma of the stapes footplate and suprastructure by their direct instrumental manipulation, thus avoiding membranous labyrinth irritation and damage. LASER use has negligible incidence of fracture dislocation of the plate fragments into fenestra ovalis and subsequent inner ear damage. [39]

We also experienced good results in terms of no major perioperative complication of facial nerve palsy or perilymph fistula.

Conclusion

The results of our study conclude that LASER stapedotomy is a safe surgical treatment modality for stapedial otosclerosis with significant clinical and audiologic hearing improvement. It has so far resulted in no major perioperative complication and hence can be offered as a standard surgical management for these patients.

References

1. Ishai R, Halpin CF, Shin JJ, et al. Long-term incidence and degree of sensorineural hearing loss in otosclerosis. OtolNeurotol2016; 37:148 9–96.
2. Wang PC, Merchant SN, McKenna MJ, et al. Does otosclerosis occur only in the temporal bone? Am J Otol1999; 20:162–5.
3. Antoli-Candela F Jr, McGill T, Peron D. Histopathological observations on the cochlear changes in otosclerosis. Ann OtolRhinol Laryngol.1977 Nov-Dec;86(6 Pt 1):813-20.
4. Schrauwen I, Khalfallah A, Ealy M, Fransen E, Claes C, et al. COL1A1 association and otosclerosis: a metaanalysis. American journal of medical genetics. Part A 2012;158A: 1066-70.
5. Niedermeyer HP, Arnold W. Etiopathogenesis of otosclerosis. ORL. 2002; 64:114-9
6. Gristwood RE, Venables WN. 2003. Otosclerosis and chronic tinnitus. The Annals of otology, rhinology, and laryngology 112:398-403.
7. Probst R. Audiological evaluation of patients with otosclerosis. In: Arnold W, Hausler R, editors. Otosclerosis and stapes surgery. Adv Otorhinolaryngol. Vol. 65. Basel: Karger; 20 0 7. pp. 119–126.
8. Uppal S, Bajaj Y, Rustom I, Coatesworth AP. Otosclerosis: the aetiopathogenesis of otosclerosis. Int J ClinPract. 2009; 63:1526–30.
9. Quesnel AM, Moonis G, Appel J, et al. Correlation of computed tomography with histopathology in otosclerosis. OtolNeurotol. 2013; 34(1):22-28.
10. Mafee MF, Valvassori GE, Deitch RL, Norouzi P, Henrikson GC, Capek V, et al. Use of CT in the evaluation of cochlear

otosclerosis. Radiology. 1985 Sep;156(3):703–8.
11. Sakai O, Curtin HD, Fujita A, Kakoi H, Kitamura K. Otosclerosis: computed tomography and magnetic resonance findings. Am J Otolaryngol. 2000 Mar-Apr;21(2):116–8.
12. Lagleyre S, Sorrentino T, Calmels MN, Shin YJ, Escude B, Deguine O, et al. Reliability of high-resolution CT scan in diagnosis of otosclerosis. OtolNeurotol. 2009 Dec;30(8):1152–9.
13. Shin YJ, Fraysse B, Deguine O, Cognard C, Charlet JP, Sevely A. Sensorineural hearing loss and otosclerosis: a clinical and radiologic survey of 437 cases. Acta Otolaryngol. 2001 Jan;121(2):200–4.
14. Ealy M., Smith R.J.H. Otosclerosis. Adv. Otorhinolaryngol., 2011;70, 122–129.
15. Ealy M., Smith R.J.H. (2010) The Genetics of otosclerosis. Hear. Res., 266, 70–74.
16. Emmett J.R. (1993) Physical examination and clinical evaluation of the patient with otosclerosis. Otolaryngol. Clin. North Am., 26, 353–3 57.
17. Kisilevsky VE, et al. Hearing results of 1145 stapedotomies evaluated with Amsterdam hearing evaluation plots. J Laryngol Otol. 200 9; 123:730–6.
18. Marchese MR, Paludetti G, De Corso E, Cianfrone F. 2007. Role of stapes surgery in improving hearing loss caused by otosclerosis. The Journal of laryngology and otology 121:438-43.
19. Hornung JA, Brase C, Zenk J, Iro H. Results obtained with new superelastic nitinol stapes prosthesis in stapes surgery. OtolNeurotol. 2011 Dec; 32(9):1415-21.
20. Sparano A, Leonetti JP, Marzo S, Kim H. 2004. Effects of stapedectomy on tinnitus in patients with otosclerosis. The international tinnitus journal 10:73-7.
21. Shea JJ. A personal history of stapedectomy. Am J Otol1998; 19:2–12.
22. Perkins RC. Laser stapedotomy for otosclerosis. Laryngoscope 1980; 90:228–41.
23. Jovanovic S, Scho¨ nfeld U, Scherer H. CO2 laser stapedotomy with the ‘‘oneshot’’ technique – clinical results. Otolaryngol Head Neck Surg2004; 131:750–7.
24. Cuda D, Murri A, Mochi P, Solenghi T, Tinelli N. Microdrill, CO2-laser, and piezoelectric stapedotomy: a comparative study. Otol Neurotol 2009; 30:1111–5.
25. Lesinski SG, Stein JA. Stapedectomy revision with the CO2 laser. Laryngoscope 1989;99: 1 3–9.
26. Häusler R, Messerli A, Romano V, Burkhalter R, Weber HP, Altermatt HJ. Experimental and clinical results of fiberoptic argon laser stapedotomy. Eur Arch Otorhinolaryngol. 1996;2 53:193–200.
27. Alzhrani F, Mokhatrish MM, Al-Momani MO, Alshehri H, Hagr A, Garadat SN. Effectiveness of stapedotomy in improving hearing sensitivity for 53 otosclerotic patients: retrospective review. Ann Saudi Med. 2017;37(1):49-55.
28. Committee on Hearing and Equilibrium. Committee on Hearing and Equilibrium guidelines for the evaluation of results of treatment of conductive hearing loss. Otolaryngol Head Neck Surg. 1995; 113:186–7.
29. Tange RA, Grolman W. Late postoperative hearing results after stapedotomy. Int Adv Otol. 2009; 5:323–6.
30. Thamjarayakul T, Supiyaphun P, Snidvongs K. Stapes Fixation surgery: Stapedectomy versus stapedotomy. Asian Biomedicine. 2010; 4: 42 9-434.
31. Vincent R, Sperling N, Oates J, Jindal M. Surgical findings and long-term hearing results in 3,050 stapedotomies for primary otosclerosis: A prospective study with the otology-neurotology database. Otology & Neurotology. 2006; 27: S25-S47.
32. Dall’igna C, Texeira V, Dall’gna D, Rosito L. Results of stapes surgery for otosclerosis with two kinds of prosthesis in residency training. Braz J Otorhinolaryngol. 2008; 74: 826-32.
33. Fang L, et al. Laser versus non-laser stapedotomy in otosclerosis: a systematic review and meta-analysis. Auris Nasus Larynx. 2014; 41 (4):337–342.
34. Crompton M, Cadge BA, Ziff JL, et al. The Epidemiology of Otosclerosis in a British Cohort. OtolNeurotol. 2019;40(1):22-30.
35. Adedeji TO, Indorewala S, Indorewala A, Nemade G. Stapedotomy and its effect on hearing - our experience with 54 cases. Afr Health Sci. 2016;16(1):276-281.
36. Moscillo L, Imperiali M, Carra P, Catapano F, Motta G. Bone conduction variation poststapedotomy. American Journal of Otolaryngology. 2006 Sep-Oct;27(5):330-333.
37. Carhart R. Clinical application of bone conduction audiometry. Arch Otolaryngol. 1950; 51:798–808.
38. Arnoldner C, Schwab B, Lenarz T. Clinical results after stapedotomy: a comparison between the erbium: yttrium–aluminum–garnet laser and the conventional technique. Otol Neurotol2006; 27:458–65.
39. Matkovic S, Kitanoski B, Malicevic Z. Advantages of CO2 laser use in surgical management of otosclerosis. Vojnosanit Pregl 2003; 60:273–8.