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# Audit on the safety and effectiveness of the use of KTP laser in stapedotomy: One year experience in an Otorhinolaryngology Center at a Tertiary Care Hospital in Sri Lanka

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## Abstract

### Introduction

This retrospective descriptive study was conducted to assess the effectiveness and safety of using KTP laser in surgically diagnosed patients with otosclerosis who underwent Endoscopic Laser Stapedotomy at the Teaching Hospital Anuradhapura from October 2020 to September 2021. Endoscopic Laser Stapedotomy is used as a minimally invasive technique and it is considered superior to conventional stapedectomy.

### Methods

Nine patients who underwent laser stapedotomy were incorporated in the study. Data was collected via a pre-formed paper-based operator filled questionnaire. The results of pre-operative pure tone audiogram (PTA) were compared with a three-month post-operative audiogram in addition to demographic and clinical variables and post-operative complications.

### Results

Mean post-operative air bone gap closure within 10dB was achieved in 55.5% patients. Mean four frequency air bone gap improvement was 25.3dB. Statistically significant post-operative impairment in bone conduction was not demonstrated.

### Conclusion

Use of KTP laser in endoscopic stapedotomy has produced improvement in air bone gap closure resulting in improvement of hearing with less side effects as a minimally invasive surgical modality in patients with otosclerosis.

**Key words:** Stapedotomy, Endoscopic Ear Surgery, KTP laser



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## Introduction

Otosclerosis is a localized disease of bone metabolism of ottic capsule where the stapes footplate is fixed to the oval window manifesting clinically as conductive or mixed hearing impairment. Stapedotomy is a recognized surgical treatment modality for otosclerosis which has progressed from conventional stapedectomy to minimally invasive surgical techniques with laser stapedotomy.

The use of laser for stapedotomy is recognized as a non-touch surgical method for the division of stapedius tendon, stapes crurotomy and foot plate perforation. Due to minimal manipulation with laser, hearing outcomes appears to be better and complications associated with manual perforation of stapes are minimized.

Laser ear surgery was introduced to the Teaching Hospital of Anuradhapura in late 2020 and a retrospective review was conducted on patients with surgically confirmed otosclerosis with the objective of assessing the effectiveness and safety of KTP (Potassium titanyl phosphate) laser in stapedotomy as no data were currently available on laser stapedotomy for Sri Lanka.

## Methods

The study was a retrospective descriptive study conducted at the Otorhinolaryngology unit at the Anuradhapura Teaching Hospital (THA) from October 2020 to September 2021. A total of nine patients who underwent primary stapes surgery with KTP laser for surgically confirmed otosclerosis were included in the study. However, patients who underwent revision surgery, surgeries converted from laser to open surgery and those who defaulted treatment were not included in the study.

Patients who were clinically and audiologically assumed to have otosclerosis were offered therapeutic options such as stapedotomy surgery or usage of hearing aids. Those who preferred stapes surgery as a treatment modality were offered endoscopic laser stapedotomy describing risks and benefits of the procedure. All patients were explained on the possible hearing outcomes as per their preoperative bone conduction thresholds. Informed consent was obtained from all participants for surgery and participation of the study.

All stapedotomies were performed under general anaesthesia by the same consultant, in the same setting conforming to a standard technique of endoscopic stapes surgery after diagnosing otosclerosis surgically with the use of KTP laser for the division of stapedius tendon, division of stapes crura, and perforation of the stapes foot plate with manual crimping. Table 1 describes the KTP laser settings used.

| Surgical step | Power (W) | Average pulse duration(ms) |
|---|---|---|
| Stapes tendon division | 2 – 3 | 50 |
| Posterior crurotomy | 2.5 – 4 | 100 |
| Footplate perforation | 2 – 4 | 50 |

Table 1: KTP laser settings

Stapedotomy was formed by creating a rosette with several pulses (usually 2W, 50ms) with a 0.3 microfiber KTP probe. Subsequently manual perforation was performed using a perforator. 10 W one-shot technique was used only in one case. A fenestration of 0.6 to 0.7 mm was created. Two sizes of fluoroplastic pistons were used (diameter of 0.4mm and 0.6mm) based on the diameter of stapedotomy. Seven patients had 6mm x 4.5 mm prosthesis and two patients had 0.4mm x 4.5 mm prothesis. Fenestration was subsequently secured around the prosthesis with fat, blood or perichondrium.

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A paper-based operator filled questionnaire was used as the study tool**.** Pre-operative pure tone audiometry and tympanogram were performed. Intraoperative details were obtained from bed head tickets. Post operatively patients were reviewed in the ENT clinic to assess complications. Post-operative pure tone audiograms were performed after three months following surgery. All audiograms were performed by a senior audiologist.

Intraoperative and post-operative clinical variables were analysed. The intra operative clinical variables were intra operative complications such as chorda tympani nerve injury, facial nerve injury, dislocation of the incus, dislocation of the stapes footplate and perilymphatic fistula. Post-operative clinical variables analysed were post-operative complications such as vertigo, facial nerve palsy, chronic ear infection, transient dizziness, tinnitus.

Pre-operative and post-operative air conduction (AC) and bone conduction (BC) thresholds were obtained for four pure tone frequencies of 500 kHz, 1 kHz, 2 kHz and 4kHz. Pre-operative and post-operative air bone gap (ABG) were calculated by the air conduction and bone conduction threshold difference. Air bone gap improvement was calculated from the difference of pre-operative and post-operative air bone gap. All calculations were performed with statistical software (SPSS). The paired t-test were used to compare means. A $p$ value of $<0.05$ was considered significant.

**Results**

The total number of patients analysed were nine. The age distribution was from age 30 to 72 years. Six patients were female and three patients were male. Seven patients underwent surgery in the left ear and two patients underwent surgery in the right ear. The demographic data are summarized in Table 2.

| Parameter | Demographic data |
|---|---|
| Age (Range) | 30 to 72 years |
| Sex | |
| Male | 66.7% |
| Female | 33.3% |
| Laterality | |
| Left | 77.8% |
| Right | 22.2% |

Table 2: Baseline characteristics of study population

The pre-operative and post-operative AC, BC and ABG were analyzed at frequencies 500Hz, 1kHz, 2kHz, and 4kHz. The pre-operative and post-operative audiological results are compared in Table 3.

| **Audiological outcomes** | **Pre-Operative** | **Post Operative** ( 3 months) |
|---|---|---|
| Mean Air Conduction threshold (AC) | 64.1dB | 38.3dB |
| Mean Bone Conduction threshold (BC) | 25.4dB | 23.6dB |
| Mean Air Bone Gap | 39 dB | 13.7dB |

Table 3: Pre-operative and post-operative audiological outcomes

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The mean four frequency pre-operative air bone gap was 39.0 dB and the mean four frequency post-operative air bone gap was 13.7dB. A statistically significant improvement was demonstrated from mean four frequency pre-operative air bone gap to mean four frequency post-operative air bone gap. ($p < 0.05\%$).

Post-operative ABG closure within 10dB is identified as the benchmark for successful stapedotomy surgery. However, post-operative ABG closure within 15dB and 20dB are also used as parameters in determining success in stapes surgery. Table 4 demonstrates the post-operative ABG closure within 10dB, 15dB and 20dB. Post-operative ABG within 10dB, 15dB and 20dB at frequencies of 500Hz, 1kHz, 2kHz and 4kHz are illustrated in Figure 1.

| Post-operative ABG Closure | Percentage of patients |
|---|---|
| <10dB | 55.5% |
| <15dB | 66.5% |
| <20dB | 88.9% |

Table 4 : Mean four frequency post-operative ABG closure

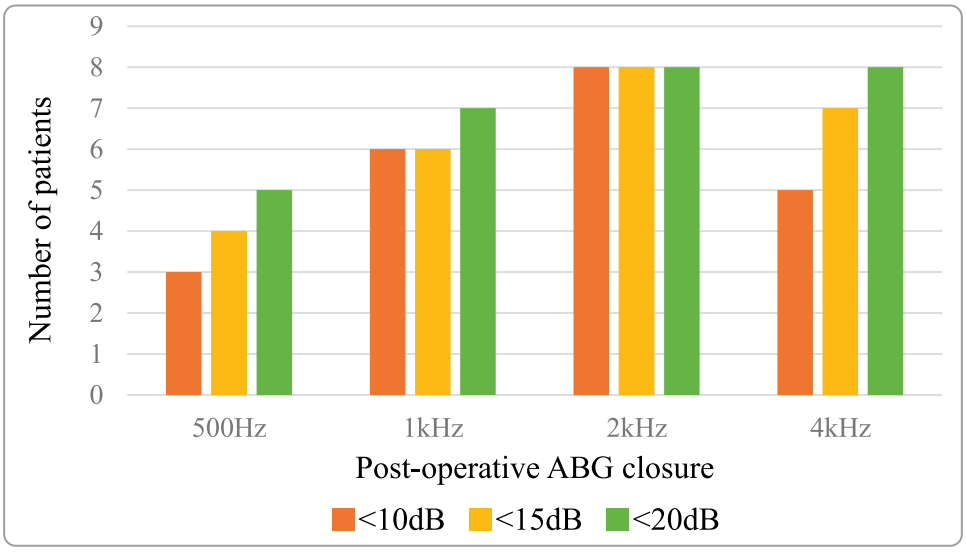


Figure 1 : Patients with Post- operative Air Bone Gap ( ABG) Closure within < 10dB, <15dB and <20dB

The mean four frequency pre-operative AC was 64.15dB and the mean four frequency post-operative AC was 38.33dB. A statistically significant improvement was demonstrated in the post-operative AC compared to pre-operative AC ( $p < 0.05\%$). The mean pre-operative and post-operative AC at 500Hz, 1kHz, 2kHz and 4kHz is demonstrated in Figure 2.

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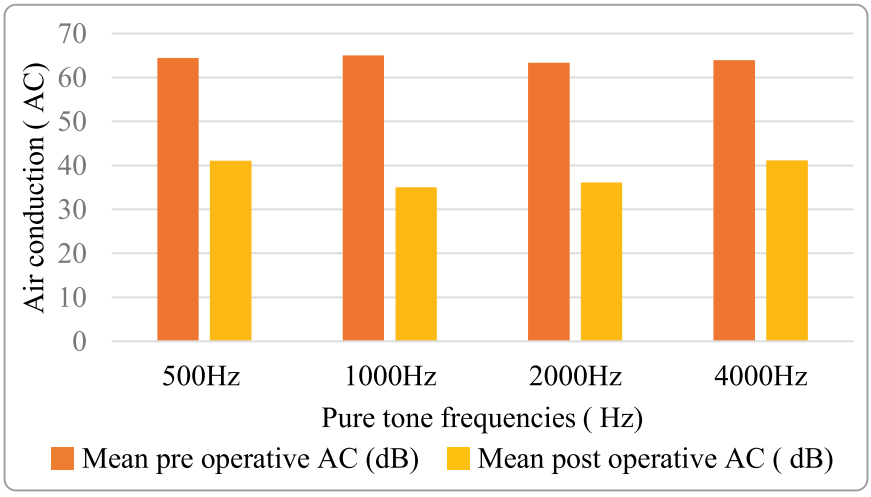


Figure 2 : Mean pre-operative and post-operative Air Conduction ( AC)

All nine patients demonstrated an ABG improvement for the frequencies 500Hz, 1000Hz, 2000Hz, and 4000Hz within the range of 0-40dB. The mean four frequency ABG gain was 25.3dB. The mean ABG improvement was 27.22dB, 26.14dB, 21.7dB and 26.13dB for 500Hz, 1kHz, 2kHz, and 4kHz. The mean air bone gap improvement for 500Hz, 1kHz, 2kHz, and 4kHz is demonstrated in Figure 3.

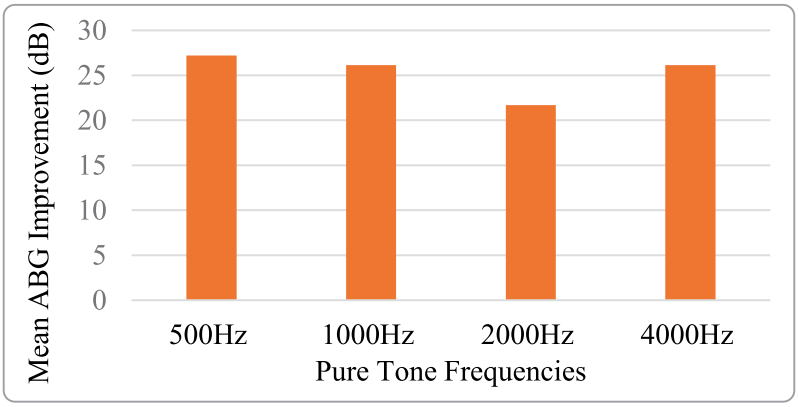


Figure 3 : Mean air bone gap (ABG) improvement

Bone conduction worsening may reflect an iatrogenic sensorineural hearing impairment. Mean four frequency pre-operative BC is 25.4dB and mean four frequency post- operative BC is 23.6dB. There is no statistical significance between the pre-operative and post-operative bone conduction values. Table 5 demonstrates pre-operative and post-operative BC. A post-operative bone conduction improvement is demonstrated at 2kHz.

| Frequency | Pre-operative BC (dB) | Post-operative BC (dB) |
|---|---|---|
| 500Hz | 16.1 | 20.0 |
| 1 kHz | 26.7 | 20.6 |
| 2 kHz | 32.2 | 25.2 |
| 4 kHz | 26.7 | 28.9 |

Table 5: Four frequency Pre-operative and Post-operative Bone Conduction (BC)

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The following complications were documented over the course of three month post operative follow-up. A dehiscent facial nerve canal was found in one patient with a stiff incus. Transient dizziness was observed in three cases (33%). Injury to chorda tympani or tympanic membrane perforation was not observed. Postoperative ear infection occurred in one patient. (11%) Vertigo was complained by one patient (11%) and tinnitus was complained by one patient (11%).

**Discussion**

Stapedotomy is a recognized and proven surgical treatment method for otosclerosis. It offers a reduction in the air bone gap on pure tone audiometry improving conductive or mixed hearing impairment.

Stapedotomy is described in literature as a surgery requiring a greater degree of precision performed by the most experienced otologist in an ENT unit. The first stapes surgery, a stapedectomy was performed by John Shea in 1956 with microscopic approach. Over the course of years stapes surgery has witnessed a great degree of advancement from cold steel techniques to minimally invasive endoscopic approaches. The first laser stapes surgery was performed in 1980 by Perkins with argon laser and KTP and carbon dioxide laser were introduced to stapes surgery in the same decade[1].

Laser in stapes surgery is used for the dissection stapedius muscle tendon & crura of stapes superstructure and perforation of stapes foot plate. However, some surgeons combine the use of laser, low speed microdrill or cold steel method with micro instruments such as perforators.

Laser surgery is considered a safe and precise non touch dissection technique in ear surgery[2]. Therefore, laser stapes surgery is known to provide higher audiological outcomes and less sensorineural hearing impairment. Due to a more precise non touch dissection, laser holds an exceptional advantage in stapes surgery in various instances and can be used as an indication in instances such as a floating foot plate whilst dissecting the incudostapedial joint or manipulation of crura to allow a gentle perforation of the foot plate.

KTP laser has a wavelength of 532nm and owing to its low wavelength, it has a higher selective absorption by haemoglobin causing haemostatic dissection and minimal absorption by water leading to deeper penetration into tissue with high percentage of water. Hence, perilymph can transmit laser thermal energy threatening inner structures of thermal damage[3].

Endoscopic stapedotomy was introduced to teaching Hospital Anuradhapura in 2018. Early experience was promising according to an audit carried out in 2020. Endoscopic approach is known to give better visibility of the operative field and it is especially useful when the middle ear anatomy is abnormal[4]. KTP laser was introduced to the Teaching Hospital Anuradhapura in 2020 to improve outcomes further by reducing complications with manual technique. The objective of our study was to assess the effectiveness and safety of using KTP laser in endoscopic stapedotomy. Multiple studies are available in literature demonstrating the efficacy of different lasers in stapes surgery. However, no data currently exists for the Sri Lankan population on the effectiveness and safety of laser in stapes surgery. Hence this audit will be helpful in providing data on safety and efficacy for patients awaiting stapes surgery in the future.

Amongst the patients who were clinically and audiologically assumed to have otosclerosis at the ENT clinic at Teaching Hospital Anuradhapura, patients who opted for stapedotomy were informed of the availability of endoscopic stapedotomy with the possibility of dissection with micro instruments or KTP laser. However, patients who were awaiting revision surgery were not offered laser stapedotomy.

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Certain laser stapedotomy surgeries were converted to cold steel dissection with micro instruments due to anatomical challenges. As this study was conducted as a retrospective analysis performed three months post operatively, the study exclusively included patients where the KTP laser was used for the division of stapedius tendon, stapes crura, and perforation of the stapes foot plate. The patients who underwent revision surgery, surgeries converted from laser to open surgery and those who defaulted treatment were considered as exclusion criteria. No randomization was used for selecting patients for the study.

The study included nine patients whose age ranged from 30 to 72 years. Six patients were female and three were male. Seven patients underwent surgery in the left ear and two patients underwent surgery in the right ear.

Several audiological variables are used in literature to determine the success in stapes surgery. Mean post-operative ABG less than 10dB is considered as the benchmark in determining the success in stapes surgery. However, mean post-operative ABG less than 15dB and 20dB are also considered as determining factors. Literature describes that ABG gain (improvement), restoration of interaural symmetry and mean post-operative AC gain can also be used for determining surgical success[5].

The study demonstrated a mean four frequency post-operative ABG closure within 10dB in 55.5% patients at 3 months. No post- operative audiograms were performed at 1 month, 6 month and 12-month intervals. However, other similar studies conducted with KTP laser has performed audiograms at 1 month, 6 month and 12 months post-operative intervals which have showed a steady increase in the ABG closure within 10dB. Our study demonstrated a mean four frequency post-operative ABG <20dB in 88.9 % patients at 3 months. Most studies with KTP laser show 100% post-operative ABG closure within 20dB in one year[6].

Our study achieved a mean four frequency ABG improvement of 25.3dB with a mean four frequency post-operative ABG of 13.7dB at 3 months. Mean four frequency post-operative AC gain at 3 months was statistically significant to mean four frequency pre-operative AC. Our study did not use restoration of interaural symmetry as a success criterion since our study had a limited number of patients of whom the ones with suboptimal hearing in the other ear[(5)].

Post-operative bone conduction impairment will reflect sensorineural hearing impairment occurred during surgery. However, no statistical significance was demonstrated between mean four frequency pre-operative BC of 25.4dB to mean four frequency post- operative BC of 23.6dB. However, mean four frequency pre-operative BC improvement was demonstrated at the Carhart Notch - 2kHz. Only one case demonstrated a post-operative sensorineural hearing impairment > 15dB at 2kHz and 4kHz.

Minimal post-operative complications were noted. Three patients developed transient dizziness, one patient each developed vertigo, tinnitus and ear infection. Considering the low incidence of post-operative sensorineural hearing impairment and other aforementioned post-operative complications, laser stapedotomy can be considered a safe surgical procedure.

Early experience in stapedotomy with KTP laser appears to be promising. However, the outcome can be improved by refining the technique and by performing regular surgical procedures. There were certain limitations such as lack of certain instruments (7mm skeeter burr), long learning curve, infrequent operations (especially due to COVID pandemic) and small sample size of the study population. Moreover, the sample size is limited as laser is avoided in anatomically challenging stapes surgery where the access for laser is hindered.

## Conclusion

A retrospective study performed at a tertiary referral centre in Sri Lanka demonstrated that KTP laser achieves post-operative air bone gap closure and air conduction gain significantly and does not significantly reduce post-operative bone conduction, indicating that KTP laser is an effective and a safe method for stapes surgery.

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