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Laser Stapedotomy Minus Prosthesis: Long-term Follow-up

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Abstract

Objective. To evaluate long-term hearing results following laser stapedotomy minus prosthesis (laser STAMP).

Study Design. Case series with chart review.

Setting. Otologic referral center.

Subjects and Methods. From April 1995 to April 2009, 74 adult patients (77 ears; consecutive cases) underwent primary laser STAMP for otosclerosis limited to the fissula ante fenestram. Pure-tone air, bone conduction thresholds, and word discrimination scores were obtained preoperatively, 1 month postoperatively, and yearly thereafter.

Results. One-year minimum follow-up data were available for 43 patients (44 ears; nonconsecutive cases). The average air-bone gap (ABG) was closed from a mean of 23 dB to 6 dB at 6 weeks postoperatively. At a median of 33 (lower quartile, 20; upper quartile 46; range, 12-140) months postoperatively, the mean ABG was 7 dB, indicating little evidence of refixation. Seven of 77 patients (9%) underwent revision surgery with stapedotomy and placement of prosthesis with good results. Four patients (5%) were revised within 1 year for other problems unrelated to stapes refixation. Refixation was noted in 3 patients (4%) undergoing revision surgery. Two of these patients (3%) were revised within 1 year; and 1 patient (1%) was revised after 12 years.

Conclusions. The laser STAMP is a minimally invasive procedure resulting in stable long-term hearing improvement in those patients available for long-term follow-up. Success depends on proper candidate selection of patients with accessible anatomy and minimal otosclerosis confined to the fissula ante fenestram. Advantages of this procedure include preservation of stapes anatomy and stable long-term, high-frequency hearing improvement.

Keywords

laser stapedotomy minus prosthesis, otosclerosis, STAMP, stapes surgery, stapedotomy

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Improved understanding of anatomy and pathophysiology of the temporal bone as well as developments in technology and microsurgical techniques have led to advances in the treatment of otosclerosis. Rosen’s introduction of the stapes mobilization procedure in 1952 ushered in the modern era of stapes surgery.¹ Initial results were promising, but a low percentage of long-term hearing improvement often resulted from refixation of the stapes footplate.² While Hall and Rytzner³ published their results of stapedectomy and ossicular autotransplantation in 1957, it was not until Shea’s⁴ published description of the stapedectomy procedure in 1958 that consistently successful results were realized. Since that time, Shea’s technique, or its various modifications, has remained the most widespread method of hearing restoration in patients with otosclerosis.

Partial stapedectomy procedures were described by various surgeons during the early development of stapes surgery. Fowler, Altmann, Basek, and Holmgren advocated partial mobilization of the stapes footplate with anterior crurotomy and exclusion of anteriorly located otosclerotic foci.⁵ Results demonstrated higher initial success rates than mobilization procedures with lower rates of refixation.⁵ Hough and Portmann reported further improvements with stapedial repositioning. They described removal of the anterior crus and otosclerotic foci with interposition of the posterior crus and remaining footplate as a strut over a connective tissue graft of the oval window.⁵,⁶

Further refinements in technology and surgical technique continued. Small fenestra stapedotomy techniques and the introduction of the laser by Perkins in 1978 continued the advance toward safer surgical intervention.⁷ The stapes tendon, posterior crus, and stapes footplate could be vaporized without the
need for standard instrumentation. This minimized intraoperative labyrinthine injury due to manipulation of the stapes footplate, even allowing for stapedotomy on a mobilized footplate.

Various authors have advocated stapes preservation techniques in an attempt to maintain normal anatomy and function. Stapes tendon preservation has been advocated by some, who cite decreased hyperacusis, lower complication rates, and improved discrimination in noise.8-10 In 1998, Silverstein described a laser stapedotomy procedure in which the blue footplate was transected after removal of the anterior crus, thus mobilizing the stapes. The stapedial tendon was preserved and no prosthesis was used. Laser stapedotomy minus prosthesis (laser STAMP) was performed for cases of minimal otosclerosis (blue footplate) confined to the fissula ante fenestram.11 In a study published in 2002, up to 4-year follow-up data demonstrated stable long-term hearing results with significantly improved hearing for the high frequencies as compared with the piston prosthesis procedures. Only 1 of 34 patients demonstrated evidence of refixation (3%).12

The purpose of the current study is to provide long-term follow-up data from a group of patients who have undergone the laser STAMP procedure for stapes fixation and minimal otosclerosis limited to the fissula ante fenestram.

Methods

Patient Selection

Following approval of the Institutional Review Board at Sarasota Memorial Hospital, a retrospective chart review was performed on a consecutive series of patients who had undergone primary laser STAMP. The decision whether to perform this procedure was made by the principal investigator at the time of surgery. Primary laser STAMP was attempted in patients with favorable anatomy and a blue footplate with minimal otosclerotic disease limited to the fissula ante fenestram.

From April 1995 to April 2009, 74 adult patients (77 ears) evaluated and treated by the senior author underwent primary laser STAMP (77 consecutive cases). At least 1 year minimum of follow-up data were available for 43 patients (44 ears). Patients with less than 1 year of postoperative follow-up data were excluded from evaluation of long-term (1 year or greater) hearing results.

All patients underwent preoperative evaluation and testing including pure-tone audiometry, speech discrimination testing, tympanometry, and acoustic reflex testing. Postoperative testing was performed at approximately 6 weeks postoperatively and yearly thereafter. Results were reported according to the recommendations of the American Academy of Otolaryngology—Head and Neck Surgery Committee on Hearing and Equilibrium guidelines.13 Four-frequency pure-tone averages for air and bone conduction were calculated from thresholds measured at 0.5, 1, 2, and 3 kHz. Overclosure was evaluated by comparing the preoperative high-frequency bone conduction minus the postoperative high-frequency bone conduction average (1, 2, and 4 kHz).

Surgical Technique

The surgical technique has been described in detail in previous publications.11,12 Following induction with general anesthesia, infiltrative anesthesia (1% lidocaine with 1:100 000 epinephrine) is injected into the external auditory canal. Standard tympanomeatal flap elevation is accomplished. A portion of the bony scutum is removed to allow visualization of the horizontal portion of the facial nerve, oval window, stapes superstructure, and pyramidal process. The malleus and incus are palpated and inspected followed by the stapes to confirm otosclerosis limited to the fissula ante fenestram.

In the confirmed laser STAMP candidate, a handheld fiber-optic probe 200 µm in diameter attached to the Argon laser is bent to a 30° angle using a small hemostat. The laser is then used to vaporize the anterior crus of the stapes using 2.5 W at 0.2 seconds’ duration. Complete transection of the crus is confirmed by passing a 1.5-mm right-angle pick or the fiber-optic laser tip through the area of vaporization.

A linear stapedotomy approximately 0.5 mm in width is then created across the anterior one-third of the thin blue footplate with the laser set to 0.8 to 1.0 W at 0.2 seconds’ duration. Perilymph overheating is prevented by allowing 3 seconds between laser bursts. Small picks are used to ensure complete transection of the footplate and to confirm complete mobility of the posterior two-thirds of the footplate. The stapes should become completely mobile if fixation has occurred because of limited fissula ante fenestram otosclerosis. A 2- × 3-mm piece of earlobe adipose tissue is placed over the footplate to seal the perilymph space.

If the stapes cannot be mobilized, the STAMP is converted to a conventional stapedotomy with piston prosthesis. There is an attempt to preserve the stapedius tendon. The tympanomeatal flap is replaced, and small packing strips and a sponge are used to hold the flap in place for 1 week.

Statistical Analysis

The mean, standard deviation, 95% confidence interval, and minimum/maximum values were calculated for each data point using statistical formulas available in Microsoft Excel 2000. The median, upper quartile (75th percentile), and lower quartile (25th percentile) for follow-up duration values were also calculated using statistical formulas available in Microsoft Excel 2000. A 2-tailed Student t test for paired values was used for comparison of mean values using the built-in functions of Microsoft Excel 2000. A level of significance was set with P less than .05.

Results

Primary laser STAMP was performed on 74 adult patients (77 ears) from 1995 to 2009 (77 consecutive cases). One patient who had undergone laser STAMP developed Ménière’s disease following treatment and was treated with intratympanic gentamicin. As a result, this patient was excluded from evaluation in the current group of patients.

One-year minimum of follow-up data were available for 43 patients (44 nonconsecutive cases). The longest follow-up was 140 months (median, 33 months; lower quartile, 20 months; upper quartile, 46 months). The median 33-month results were used as the most recent data points. This group was composed of 11 male and 32 female patients with a mean
patient age of 57 years (range, 27-83 years). Laser STAMP was performed on 27 right ears and 17 left ears.

There were 31 patients (33 ears) with less than 1 year of follow-up data who were excluded from long-term evaluation. Five of these patients (5 ears) recently underwent surgery and did not have long enough postoperative follow-up for inclusion. Another 6 patients (6 ears) underwent revision surgery with placement of piston prosthesis prior to 1 year after the initial laser STAMP procedure and were not included in evaluation of long-term (greater than 1 year) laser STAMP results. The remaining 22 ears (28%) were lost to follow-up.

The group of patients with less than 1 year of postoperative follow-up was composed of 8 male and 25 female patients, with a mean patient age of 54 years (range, 30-77 years). Laser STAMP was performed on 21 right and 12 left ears. Comparison of clinical characteristics between patients with greater than and patients with less than 1 year follow-up were similar and are represented in Table 1.

For patients with greater than 1 year of follow-up, the mean preoperative air-bone gap (ABG) of 23 dB hearing loss (HL; SD, 11; range, 8-53 dB) was closed to a mean ABG of 6 dB HL (SD, 9; range, 0-25 dB) at 6 weeks postoperatively (P < .0001). The most recent tests at a median of 33 months (lower quartile, 20 months; upper quartile, 46 months) postoperatively demonstrated a mean ABG of 7 dB (SD, 9; range, 0-29 dB; Figure 1). There was no statistically significant difference between 6-week postoperative and most recent mean ABG values (P = .4).

Mean pure-tone bone conduction levels were 29 dB (SD, 13; range, 11-59 dB) preoperatively, 25 dB (SD, 14; range, 4-63) 6 weeks postoperatively, and 27 dB (SD, 15; range, 6-70) upon most recent evaluation (Figure 2). There was no statistically significant difference between 6-week and recent mean bone conduction levels (P = .59).

| Table 1. Comparison of Patient Clinical Baseline Characteristics |
|------------------|------------------|------------------|
|                  | <1 y Follow-up   | >1 y Follow-up   |
| Number of ears   | 33               | 44               |
| Age, mean (range), y | 54 (30-77)      | 57 (27-53)      |
| Gender           |                  |                  |
| Male             | 8                | 12               |
| Female           | 25               | 32               |
| Surgical ear     |                  |                  |
| Right            | 21               | 27               |
| Left             | 12               | 17               |
| Mean (SD) preop ABG, dB | 21 (9)       | 23 (11)         |
| Mean (SD) postop ABG (most recent postop), dB | 8 (9)       | 7 (7)         |
| Mean (SD) preop discrimination, % | 93 (9)       | 93 (9)         |
| Mean (SD) postop discrimination, % | 90 (11)      | 93 (12)        |
| Revision surgery, no. of ears | 6           | 1               |

Abbreviation: ABG, air-bone gap.

Mean pure-tone air conduction levels were 52 dB (SD, 18; range, 26-95) preoperatively, 32 dB (SD, 18; range, 8-75) 6 weeks postoperatively, and 34 dB (SD, 20; range, 6-99) upon most recent evaluation (Figure 3). There was no statistically significant difference between 6-week and most recent mean air conduction levels (P = .37). These levels remained stable at 4, 6, and 8 kHz postoperatively and were significantly different from preoperative values (P < .0001).

Average overclosure (preoperative high-frequency pure-tone average bone levels minus postoperative high-frequency pure-tone average bone levels) was +3 dB (SD, 9; range, -23 to 23; Table 2). The preoperative average word recognition
score remained stable at 93% (SD, 9; range, 63%-100%; 6 weeks postop eratively, \( P = .90 \), and most recent, \( P = .46 \)).

Revision surgery with stapedotomy and placement of prosthesis was performed on 7 of 77 patients (9%). Four patients (5%) were revised within 1 year for other problems unrelated to stapes refixation. These patients never had sufficient improvement following initial operation and in retrospect were not appropriately selected laser STAMP candidates. Refixation was noted in 3 patients (4%) undergoing revision surgery. Two of these patients (3%) were revised within 1 year and found to have refixation involving the remainder of the footplate. One of these 2 patients never experienced a significant improvement in hearing following initial laser STAMP. These patients may have had undiagnosed otosclerosis involving the posterior stapediovestibular joint. One patient (1%) revised after 12 years had an initial favorable hearing result that slowly declined.

Discussion

A review of the development of stapes surgery reveals an early shift away from mobilization procedures because of variable footplate pathology and concerns over refixation.\(^2\,^5\)

Despite these concerns, clinical evidence suggests that fractures of the stapes footplate may heal by fibrous union rather than osseous fixation, particularly in cases in which the fracture is posterior to the otosclerotic focus. In 1969, Rosen reported long-term results of his stapes mobilization procedure in 340 cases, citing a 42% complete ABG closure and 32% ABG closure to within 10 dB at 4 years following mobilization.\(^14\) Cases with good long-term hearing outcomes were assumed to be the result of mobilization posterior to the otosclerotic focus.\(^14\)

Histologic studies of the temporal bone suggest that fibrous union of the footplate may occur following stapes mobilization. As early as 1958, Altmann and Basek\(^\) published the results of histologic evaluation of a patient who had undergone successful stapes mobilization 15 months prior to death. The stapes footplate demonstrated a posteriorly located fracture that had healed by fibrous union despite otosclerosis involving the fissula ante fenestram.\(^15\) Similarly, Lindsay et al\(^16\) examined the temporal bone of a patient with stapes subluxation into the vestibule following mobilization. One year following mobilization, the anterior footplate had refixed; however, the posterior footplate remained free of disease.\(^16\)

Meyers et al\(^17\) presented a temporal bone study of a patient who had undergone stapes mobilization 7 years prior to his death. Fibrous union of the stapes footplate was noted without evidence of refixation or involvement of the posterior footplate despite extensive otosclerosis involving the cochlea and fissula ante fenestram.\(^17\)

In a more recent histologic evaluation, Merchant et al\(^18\) noted that 53 of 140 (38%) otosclerotic temporal bones demonstrated otosclerosis limited to the fissula ante fenestram. These bones demonstrated no ankylosis or otosclerosis involving the posterior stapediovestibular joint with disease limited to the fissula ante fenestram. Based on histologic evaluation, they concluded that the laser STAMP procedure would likely be successful for cases of otosclerosis limited to the fissula ante fenestram. No correlation was noted between otosclerosis or ankylosis at the posterior stapediovestibular joint and preoperative measures including duration or degree of hearing loss.\(^18\)

The long-term results of the laser STAMP procedure compare favorably to previously published reports.\(^12\) Silverstein et al\(^12\) noted a postoperative ABG closure from 22 dB to 6 dB at 6 weeks and an average ABG of 5 dB at greater than 4 months following surgery. The current study confirms those findings. In patients available for long-term follow-up, the mean preoperative ABG of 23 dB HL (SD, 11; range, 8-53 dB) was closed to a mean ABG of 6 dB HL (SD, 6; range, 0-25 dB) at 6 weeks postoperatively (\( P < .0001 \)). At a median of 33 months postoperatively, the mean ABG was 7 dB (SD, 7; range, 0-29 dB).

The results of the current study, at a median of 33 months postoperatively (12-140 months), demonstrate a stable long-term hearing improvement following laser STAMP with little evidence of refixation (4%) in patients available for greater than 1 year of follow-up. Significant improvement in the high-frequency (6, 8 kHz) air conduction thresholds remained stable postoperatively, confirming the findings of a previously published study demonstrating better long-term high-frequency improvement following initial laser STAMP.

![Figure 3. Average air conduction thresholds for preoperative, 6-week postoperative, and most recent audiograms in patients with laser stapedotomy minus prosthesis and long-term follow-up. Vertical bars represent 95% confidence intervals.](image-url)
air conduction thresholds for laser STAMP patients as compared with stapedotomy with piston.\textsuperscript{19} The results of the current study are consistent with previously published data demonstrating a refixation rate of 3\% for patients undergoing laser STAMP for limited otosclerosis.\textsuperscript{12,19}

Various authors have advocated preservation of the normal stapes architecture.\textsuperscript{2,6,8-12} Laser STAMP takes advantage of a greater amount of the normal stapes anatomy. Elimination of the stapes prosthesis may decrease complications while allowing for the restoration of the ossicular chain to normal mobility.\textsuperscript{10-12,19} Preservation of the stapedius tendon and annular ring may also provide the added benefit of better long-term high-frequency hearing results, hearing in noise, and decreased hyperacusis.\textsuperscript{8,12,15}

The authors acknowledge there are some limitations applicable to the findings of the current study. Thirty-three of 77 (43\%) laser STAMP procedures had less than 1 year of follow-up, and 22 of 77 (28\%) laser STAMP procedures were lost to follow-up. While results were good for patients available for long-term follow-up (1 year or greater), this study’s findings may not be generalizable to all patients. There may also be some inherent bias in patient follow-up; there may be a tendency for patients not to return for follow-up visits when they are hearing well and having no problems or complications. Table 1 compares patients included and excluded from long-term postoperative hearing evaluation based on duration of follow-up.

Conclusions
The laser STAMP procedure is a minimally invasive technique resulting in stable long-term hearing improvement in those patients available for long-term follow up. Success depends on appropriate candidate selection of patients with accessible anatomy and minimal otosclerosis confined to the fissula ante fenestram. Advantages of this procedure include preservation of stapes anatomy and stable long-term high-frequency hearing improvement with little evidence of refixation.

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Author Contributions
Herbert Silverstein, corresponding author, conception, design and interpretation of data, drafting article/revision, final approval; Mark J. Van Ess, data acquisition/interpretation, drafting article/revision, final approval of article; Yadiel A. Alameda, data acquisition, drafting/revision article, final approval.

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