CO2 Laser-Assisted Stapedotomy Combined With Wengen Titanium Clip Stapes Prosthesis: Superior Short-Term Results


Objective: To report on the short-term results of CO2-laser assisted stapedotomy combined with the Wengen titanium clip stapes prosthesis. A comparison with published series using other prostheses and/or different stapedotomy techniques is made.

Study Design: Retrospective case series.

Patients: Patients with a history and audiologic data matching stapes fixation and computed tomographic imaging excluding other anomalies such as malleus fixation, dehiscent superior semicircular canal, and large vestibular aqueduct that may mimic stapes fixation—like hearing loss.

Intervention: All patients underwent CO2 laser–assisted stapedotomy (Lumenis Co. Israel CO2 laser, Acuspot 712, Surgi-Touch 870 scanner) and subsequent reconstruction by means of the Wengen titanium clip stapes prosthesis by Heinz Kurz Medizintechnik GmbH (Germany).

Outcome Measures: Comparison and statistical analysis of preoperative and postoperative audiologic data.

Results: Sixty-two stapedotomies were performed (61 patients) using the CO2 laser and Wengen titanium clip stapes prosthesis. The mean postoperative air-bone gap 3 months postoperatively was 5.1 ± 0.5 dB (standard deviation [SD], 4.1 dB; 0.5, 1, 2, 4 kHz). Air-bone gap closure less than or equal to 10 dB was achieved in 54 cases (87%). Air-bone gap closure less than 20 dB was achieved in all cases. The average gain was 27.8 ± 1.5 dB (SD, 12 dB; 0.5, 1, 2, 4 kHz). The average bone-conduction threshold shift or “overclosure” on 2,000 Hz was 13.6 ± 1.3 dB (SD, 10 dB). There was no postoperative perceptive hearing loss exceeding 15 dB on any measured frequency. The Amsterdam Hearing Evaluation Plots have also been used to evaluate our data. These data were statistically analyzed and compare favorably to other published series.

Conclusion: The authors conclude that the combination of CO2 laser–assisted stapedotomy and the Wengen titanium clip stapes prosthesis is a combination likely to yield superior results in experienced hands. Key Words: Wengen stapes clip prosthesis—CO2 laser—Otosclerosis—Stapedotomy.

optical fibers, which is an advantage. Carbon dioxide laser radiation has a strong absorption in bone and perilymph but cannot be transmitted through optical fibers. A micromanipulator such as the Lumenis Acuspot 712 mounted on the operation microscope has to be used in conjunction with a scanning system such as the Lumenis SurgiTouch 870 scanner to direct the laser beam. Jovanovic et al. (8) has studied the so-called “one-shot CO₂ laser stapedotomy” and concludes that it is a safe procedure with a lower incidence and severity of intraoperative and postoperative complications than conventional stapes surgery. Garin et al. concur (9). Somers et al. (10), however, have found that there is no statistically significant difference between the “skeeter” microdrill technique and laser stapedotomy as far as transient postoperative cochlear dysfunction or bone threshold shift are concerned.

Since Shea fabricated his first Teflon prosthesis, resembling a real human stapes, in 1956, a multitude of stapes prostheses have been designed. After an episode during which he used a polyethylene tube, Shea designed a prosthesis entirely made of Teflon, and so did Marquet (11). In 1960, Schuknecht (12) developed his steel wire–adipose tissue prosthesis, which led to the well-known steel wire–Teflon prosthesis (13). In the 1990s a soft-band piston made of pure gold was introduced by Pusalkar and Steinbach (14). Although the functional results were encouraging (15), the gold prosthesis has been reported to cause inner ear damage due to material intolerance, which resulted in granulomatous reactions, progressive postoperative sensorineural hearing loss, and extrusion of the prosthesis (16–18). In 1999, titanium was introduced as well. Titanium prostheses are highly biocompatible (19), very light, and easy to handle. The extrusion rate is extremely low, and the audiometric results are reported to be very good (20–22). However, as Ugo Fisch once so eloquently pointed out, “these new technologies will not make good surgeons out of bad ones,” but they might help good surgeons to obtain even better results.

To the best of our knowledge, this is the first report on the short-term results of the combination of CO₂ laser stapedotomy and reconstruction by means of the âWengen titanium clip stapes prosthesis (Heinz Kurz Medizintechnik).

MATERIALS AND METHODS

Subjects

Sixty-one patients (35 women; 26 men) ranging in age from 29 to 79 years underwent a CO₂ laser–assisted stapedotomy and subsequent reconstruction by means of the âWengen titanium clip stapes prosthesis (Heinz Kurz Medizintechnik) between

![Box-and-whisker plot depicting total functional gain (dB) on 125, 250, 500, 1,000, 2,000, 4,000, and 8,000 Hz obtained 3 mo postoperatively.](attachment://fig1.png)
March 2005 and September 2007. They all had a medical history and audiologic data matching stapes fixation. High-resolution computed tomographic imaging was performed in all cases to exclude other anomalies (such as malleus fixation, dehiscent superior semicircular canal, and large vestibular aqueduct) that might mimic stapes fixation—like hearing loss, thus preventing unnecessary surgery and complications. One patient had bilateral surgery during this period, so this study comprises 62 ears with confirmed stapes fixation. There were 38 left ears and 24 right ears.

**Surgical Technique**

All patients were operated by the same surgeon (G.F.) at the ear, nose, and throat Department of the Heilig Hart General Hospital (Roeselare, Belgium). In all cases, the CO₂ laser (Lumenis Co. Yokneam, Israel) was used in conjunction with the Lumenis Acuspot 712 micromanipulator and the Lumenis SurgiTouch 870 scanner. The device and the microscope (Zeiss Opmi Sensera S7) focus length were both set to 300 mm. The approach to the middle ear cleft was invariably endaural using a slightly modified Rosen incision. Before even starting with the actual stapedotomy, the mobility of the ossicular chain was assessed by gently moving the malleus handle and the lenticular process with a microhook. During the latter maneuver, the incudostapedial joint was closely observed to evaluate synchronous movement of the stapes. Finally, after having convinced ourselves that malleus and incus were mobile, the stapes was gently palpated and fixation was ascertained. Only then was the stapedius tendon cut with a few single laser pulses. The incudostapedial joint was conventionally severed in all cases. The posterior crus was vaporized with several pulses, again using the cutting function (4.5 W, 0.05 s). Extreme care was taken to not accidentally damage the chorda tympani or—worse—the facial nerve. Whenever necessary, nontarget middle ear structures were protected with saline-soaked swabs or gelatin sponges (e.g., Spongostan). Subsequently, the anterior crus was fractured using a microhook. We have always attempted to create a 0.8-mm circular perforation of the footplate using a single shot (24 W, 0.05 s). Whenever there was no perforation of the footplate after the first shot, a second or even third pulse was delivered. However, we have never administered additional laser shots as soon as the vestibulum was opened. Therefore, whenever there was an opening in the footplate after the first shot, but the desired diameter was not yet achieved, the opening was manually enlarged using microhooks. In cases where the oval window was too narrow to accommodate a 0.6-mm piston, the laser spot settings were changed to a 0.6-mm diameter, and a 0.4-mm prosthesis was used. After creating the calibrated hole, we inserted either the 0.6-mm or the 0.4-mm aWengen titanium clip stapes prosthesis (Heinz Kurz Medizintechnik) as described by aWengen (20). The desired length was established immediately after removing the superstructure. We use no vein interposition or additional sealing, following Marquet’s example (11).

**Audiometry and Statistics**

All patients had at least 2 preoperative hearing tests, determining pure-tone thresholds in the frequency range from 125 to 8,000 Hz by air and bone conduction (Madsen Orbiter II; Madsen, Denmark). All patients were tested again preferably 2 weeks, 6 weeks, and 3 months postoperatively, again by air and bone conduction. These tests were performed by qualified audiologists at our department. The data were stored in an Excel...
spreadsheet (Microsoft Corp., Redmond, Wash, USA). The audiologic data used for our calculations and reported in this article were all collected 3 months postoperatively. We have calculated the preoperative and postoperative air-bone gap on 250, 500, 1,000, 2,000, and 4,000 Hz. A mean preoperative and postoperative air-bone gap using the calculated values for 500, 1,000, 2,000, and 4,000 Hz was also defined (23). According to continental habit, 3,000 Hz was not used in our calculations. Furthermore, the bone-conduction threshold shift was also calculated for these frequencies to evaluate the overclosure phenomenon or to assess postoperative perceptive hearing loss. Finally, total air-conduction gain was calculated for all the frequencies. Statistical analysis was performed using SPSS Statistics software. All values are presented using a box-and-whisker plot (featuring maximum, minimum, average, median, first-, and third-quartile values) as proposed by Govaerts et al. (24), and we have also used the Amsterdam Hearing Evaluation Plots as defined by De Bruijn et al. (25). This way, we have endeavored to facilitate interpretation and comparison with other reports.

RESULTS

All raw preoperative and postoperative audiometric data are available to the reader on request but have not been included in this article. Postoperative gain per frequency, bone-conduction threshold shift (i.e., overclosure or inner ear damage), and postoperative air-bone gap have all been calculated and are likewise available on demand. The postoperative air-bone gap is defined as the postoperative air-conduction threshold minus the postoperative bone-conduction threshold, as recommended by the Committee on Hearing and Equilibrium in 1994 (23).

Obviously, the goal of stapes surgery is improvement of functional hearing. Consequently, the total gain in the frequency domain between 500 and 4,000 Hz has the greatest impact on speech discrimination. Figure 1 illustrates the total functional gain we have obtained at 3 months postoperatively. In our series, the mean total functional gain ± standard error (SE; 500, 1,000, 2,000, and 4,000 Hz) amounts to $27.8 \pm 1.5$ dB. The mean preoperative hearing loss (air conduction) was $64.3 \pm 2.1$ dB (standard deviation [SD], 16 dB).

Figure 2 illustrates the postoperative air-bone gap. Our mean postoperative air-bone gap (500, 1,000, 2,000, and 4,000 Hz) is $5.1 \pm 0.5$ dB (SD, 4.1 dB). The mean air-bone gap of all our patients is smaller than 20 dB. Of our 62 ears, 54 (87%) have a mean postoperative air-bone gap of 10 dB or less. The mean preoperative air-bone gap was $27.3 \pm 1.3$ dB (SD, 10 dB).

Finally, we have evaluated postoperative bone-conduction threshold changes. Figure 3 illustrates the so-called overclosure phenomenon, which occurs most prominently at 2,000 Hz due to the elimination of...
Carhart notch. At 2,000 Hz, the improvement of the bone-conduction threshold was $13.6 \pm 1.3$ dB (SD, 10 dB) with a median of 15 dB. None of our patients has a loss exceeding 15 dB on either of the measured frequencies. In Figures 4 and 5, we have depicted our results using the Amsterdam Hearing Evaluation plots, as suggested by De Bruijn et al. (25). The first graph shows preoperative bone-conduction values plotted against postoperative bone-conduction values for each operated ear. The

![Pre-op versus post-op BC](image)

**FIG. 4.** Amsterdam Hearing Evaluation Plot 1. Preoperative bone-conduction values are plotted against postoperative bone-conduction values for each operated ear. The 2 diagonal lines enclose the area where the postoperative bone-conduction threshold has not changed more than 10 dB with respect to the preoperative bone-conduction threshold. Iatrogenic cochlear damage is indicated by every point above the uppermost diagonal line. Significant overclosure is indicated by every point below the lower diagonal line.

![Post-op gain AC versus pre-op AB gap](image)

**FIG. 5.** Amsterdam Hearing Evaluation Plot 2. The horizontal axis represents the postoperative change in air-conduction threshold, and the vertical axis represents the preoperative air-bone gap. The lower diagonal line indicates total closure of the air-bone gap. Consequently, every point below this diagonal line indicates a gain in air-conduction threshold that is larger than one might expect from total air-bone gap closure. Such a result can be regarded as a very successful result with overclosure. An unsuccessful result is considered to be a negative change in air-conduction threshold or a positive change that fails to reduce the air-bone gap to less than 20 dB. A point above the uppermost diagonal line indicates such an unsuccessful result.
2 diagonal lines enclose the area where the postoperative bone-conduction threshold has not changed more than 10 dB with respect to the preoperative bone-conduction threshold. Iatrogenic cochlear damage is indicated by every point above the uppermost diagonal line. Conversely, significant overclosure is indicated by every point below the lower diagonal line. In the second graph, the horizontal axis represents the postoperative change in air-conduction threshold, and the vertical axis represents the preoperative air-bone gap. The lower diagonal line indicates total closure of the air-bone gap. Consequently, every point below this diagonal line indicates a gain in air-conduction threshold that is larger than one might expect from total air-bone gap closure. Such a result can be regarded as a very successful result with overclosure. An unsuccessful result is considered to be a negative change in air-conduction threshold or a positive change that fails to reduce the air-bone gap to less than 20 dB. A point above the uppermost diagonal line indicates a gain in air-conduction threshold that is larger than one might expect from total air-bone gap closure. Such a result can be regarded as a very successful result with overclosure. An unsuccessful result is considered to be a negative change in air-conduction threshold or a positive change that fails to reduce the air-bone gap to less than 20 dB. A point above the uppermost diagonal line indicates such an unsuccessful result.

**DISCUSSION**

Several articles confirming the safety and usefulness of CO₂ laser-assisted stapedotomy and skeeter microdrill have been published in contemporary literature (3–10, 26–28). We have also found several studies reporting on metallic stapes prostheses in general and the âWengen titanium clip stapes prostheses combined have, to the best of our knowledge, not yet been published. Because all data were collected 3 months postoperatively, the authors wish to emphasize that theirs are short-term results, whereas some of the published series we refer to are long-term results. Comparison of functional results over time is difficult because perceptive hearing loss might increase due to presbyacusis or cochlear otospongiosis on the one hand and the air-bone gap tends to enlarge again with 0.9 dB per year, as demonstrated by Aarsmisalo et al. (29), on the other hand.

In Table 1, our results pertaining to air-bone gap closure 3 months postoperatively are compared with other published results. The methods used by the respective surgeons are also given. Comparison between published series is often difficult because all required parameters (e.g., SE or SD) are rarely reported, and methodology varies greatly. In addition, as mentioned earlier, some studies discuss long-term results. To facilitate comparison, we have also included the follow-up time in our tables. To make a sensible comparison, we have included only the short-term (3–11 months’ follow-up) section of the collection of Vincent et al. (30). Among the articles we have quoted, only Vincent et al. (30) and Shea (34) report a percentage of patients with a postoperative air-bone gap less than or equal to 10 dB that is statistically significantly higher than ours. Considering the number of patients, our results are statistically significantly better than those reported by Grolman and Tange (22) and Fisch (31). Table 2 shows the average functional gain...
of our data compared with other series. In addition, the average air-conduction gain in our series proves to be superior to the gain mentioned by Vincent et al. (30), Grolman and Tange (22), and Rondini-Gilli et al. (32). However, they are inferior to the results obtained by Marquet, as reported by Somers et al. (35) and those of Lundman et al. (33). These comparisons could only be made by taking the standard deviation (SE) of the respective data into account, thus allowing us to apply the appropriate t test. However, the SD values are lacking in the series of Vincent et al. (30), Grolman and Tange (22), Somers et al. (35), and Rondini-Gilli et al. (32). To solve this problem, we have assumed a safe standard deviation of 15 dB for these series. Our analysis shows that our gain is statistically significantly better (p < 0.05) than the gain reported by Vincent et al., Grolman & Tange and Rondini-Gilli et al. The difference with Lundman et al. (33) was not statistically significant, while the gain obtained by Somers et al. (35) was statistically significantly better than ours (p < 0.05). Even when we changed the assumed SD to 12.7 or 11.6 dB, these conclusions did not change. Therefore, we can safely assume that our conclusions are valid from a statistical point of view.

Additionally, while contemplating gain, one should take into account that the average preoperative air-bone gap in the older reports is significantly larger than the average air-bone gap in contemporary series. Consequently, the maximum gain that could possibly be obtained at that time is much larger than at the present time.

We have also taken a closer look at the results of the Colombiers group (30) because their mean postoperative air-bone gap is statistically significantly smaller than ours (p < 0.05), whereas our total gain is statistically significantly larger than theirs (p < 0.05). The only possible explanation for this phenomenon is that we have consistently obtained more important “overclosure.”

To ascertain this assumption, we have sought to compare our preoperative and postoperative bone-conduction thresholds to those of other studies. However, there are disappointingly few reports that mention detailed preoperative and postoperative bone-conduction thresholds. Nevertheless, we seem to have obtained more significant overclosure: Table 3 compares our overclosure data to those of Grolman and Tange (22) and those of Zuur et al. (21), both short-term result series. The difference between our results and both aforementioned series are statistically significant (p < 0.05). Vincent et al. (30) define overclosure as “an improvement of the four frequency average bone conduction threshold greater than 10 dB”. They report a thus defined overclosure rate of 4%. Conversely, they report 0.5% of their cases to have a postoperative sensorineural loss of 15 dB or worse. Rondini-Gilli et al. (32) wrote that 90% of their patients had no postoperative perceptive loss, 4% had experienced an improvement of at least 10 dB, and 3% had a perceptive loss exceeding 30 dB (but no deafness). Lundman et al. (33) report an improvement of more than 10 dB in 24% of their cases and only 1% of worsening greater than 20 dB. In our series, 8 out of 62 had an improvement of their average bone-conduction threshold (500, 1,000, 2,000, and 4,000 Hz) greater than 10 dB, which amounts to no less than 13%. Again, the difference with the quoted series is statistically significant (p < 0.05).

Our results therefore confirm that single-shot CO₂ laser–assisted stapedotomy is a safe and atraumatic procedure if the required safety measures are observed. The âWangen titanium clip prosthesis, is in our opinion, an excellent prosthesis that allows optimal air-bone gap closure. The combination of both surgical devices seems to yield superior results, as illustrated by our data.

Finally, it has been frequently put forward that one should use as large a prosthesis diameter as possible. Our data corroborate this maxim. In our series, the 0.6-mm-diameter prosthesis yields statistically significant better results than the 0.4-mm-diameter titanium prosthesis (as systematically used by Grolman et al. [22]). Our average gain (500, 1, 2, and 4 kHz) is 31.3 ± 2.1 dB (SD, 11; n = 28) with the 0.6-mm prosthesis and 24.9 ± 2.0 dB (SD, 12; n = 34) with the 0.4-mm prosthesis. The difference once again is statistically significant (p = 0.038). The observations of Marchese et al. (36) agree with these findings. We therefore conclude that, whenever possible, one should endeavor to create a 0.8-mm stapedotomy and use a 0.6-mm-diameter prosthesis.

### Table 3. Comparison of postoperative bone-conduction threshold shift

<table>
<thead>
<tr>
<th>Stapedotomy Prosthesis</th>
<th>CO₂ laser Kurz</th>
<th>aWangen</th>
<th>Micropick K-Piston</th>
<th>Micropick Kurz</th>
<th>aWangen</th>
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<tbody>
<tr>
<td>n</td>
<td>62</td>
<td>58</td>
<td>23</td>
<td>23</td>
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<td>−2</td>
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<td>−2</td>
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<tr>
<td>500 Hz</td>
<td>4</td>
<td>2</td>
<td>−3</td>
<td>−3</td>
<td>−3</td>
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<tr>
<td>1,000 Hz</td>
<td>6</td>
<td>2</td>
<td>−2</td>
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<tr>
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</table>

**Conclusion**

The small-hole stapedotomy, followed by reconstruction by means of a stapes prosthesis, is a well-established and standardized procedure. In experienced hands, the results are usually very good. However, further improvement of our results seems to be possible thanks to modern technology such as laser-assisted stapedotomy and more refined prostheses, such as the âWangen titanium clip stapes prosthesis (Heinz Kurz Medizintechnik).

With this article, we present the first report on the short-term results of the combination of CO₂ laser stapedotomy and reconstruction by means of the âWangen titanium clip stapes prosthesis (Heinz Kurz Medizintechnik).

Our short-term results seem to be superior to other short-term results obtained with laser-assisted stapedotomy, followed by reconstruction with another prosthesis.
and those obtained by manual or skeeter drill stapedotomy, followed by reconstruction with either a conventional or the aWegen titanium clip stapes prosthesis (Heinz Kurz Medizintechnik). However, it remains to be seen whether this will also be the case in the long run.

Based on these short-term results, we advocate the combination of CO₂ laser-assisted stapedotomy and reconstruction with the aWegen titanium clip stapes prosthesis (Heinz Kurz Medizintechnik).

Finally, our data also confirm that a 0.6-mm-diameter prosthesis is to be preferred to a 0.4-mm-diameter prosthesis whenever feasible.

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REFERENCES