Results of CO_2 Laser Stapedotomy with Teflon Piston Prosthesis and Autologous Blood Seal

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Objective: *To study the hearing results and complications in otosclerotic patients who underwent Carbon dioxide (CO_2) laser stapedotomy using Teflon piston prosthesis and autologous blood seal.*
Material and Method: *The charts of all primary CO_2 laser stapedotomy procedures performed at Bangkok Metropolitan Administration Medical College and Vajira Hospital between 1997 and 2005 were reviewed. Patients who used Teflon piston prosthesis and autologous blood seal and had follow-up data of more than one year were selected for inclusion in the study. Any patients who underwent CO_2 laser stapedotomy for diseases other than otosclerosis or those with inadequate postoperative data were excluded. The hearing results from preoperative and postoperative (most recent follow-up) periods were analyzed using closure of air-bone gaps and postoperative sensorineural hearing loss (SNHL) at pure-tone average (PTA) and different frequencies. Major complications were recorded.*
Results: *The present review yielded 73 primary CO_2 laser stapedotomy procedures performed between 1997 and 2005, and 36 patients who underwent 40 CO_2 laser stapedotomies met the criteria for analysis. The hearing outcomes were followed for an average of 22 months. The average preoperative and postoperative PTA air-bone gaps were 32.7 and 7.5 dB, respectively. The rate of patients who had postoperative PTA air-bone gaps within 10 dB was 77.5% and within 15 dB was 95%. There was a significant closure of air-bone gaps at PTA and at all frequencies (the frequencies from 0.5 to 4 kHz) and the closures of air-bone gaps at 0.5, 1, and 2 kHz were statistically better than at 4 kHz. The overall rate of postoperative SNHL was 7.5% at high pure-tone bone conduction average. There were no major postoperative complications.*
Conclusion: *CO_2 laser stapedotomy with Teflon piston prosthesis and autologous blood seal is a safe and effective treatment for otosclerosis. The procedure provides acceptable hearing results and gives the more air-bone gap closure at the low and mid frequency ranges without significant postoperative SNHL and other serious complications.*

Keywords: *Laser, Stapedotomy, Hearing, Otosclerosis, Polytetrafluoroethylene*

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The modern treatment of otosclerosis began with Shea's removal of the stapes and functionally bypassing it by a prosthesis attached to the incus[1]. Further refinements have been in the nature of oval window seal, the design of prostheses, and the development of the small fenestration technique[2-4]. The use of the laser to remove the suprastructure of the stapes and to create the footplate fenestra represents the latest in continuum of such developments. Lasers have been promoted as a safe method because the inner ear is not subjected to the effects of mechanical trauma[5-8]. As the surgery has improved, the prostheses used have evolved as well. There are now many types of stapes prostheses available. They are chosen based on theoretical advantages given by different masses and materials, size, and shape. The prostheses must be able to remain in the oval window without eliciting an inflammatory reaction and must be able to sustain a secure attachment to the incus. Teflon pistons have been one of the commonly used prostheses. The autogenous

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blood seal was also being used successfully by several authors who performed manual small fenestration stapedotomy [4]. Of the prostheses and seals examined in the literature, many of them are well represented, whereas the results of Teflon piston prosthesis and autologous blood seal used in Carbon dioxide(CO_2) laser stapedotomy are less often described.

The purpose of the present study was to evaluate and report the effectiveness of CO_2 laser stapedotomy with Teflon piston prosthesis and autologous blood seal in otosclerotic patients and whether or not any complications are encountered. A series of patients with otosclerosis who underwent CO_2 laser stapedotomy using Teflon piston prosthesis and autologous blood seal were reviewed with regard to hearing improvement and incidence of complications.

Material and Method

The present study was approved by the Ethics Committee for Researches involving Human Subjects, the Bangkok Metropolitan Administration.

A retrospective review of all CO_2 laser stapedotomy cases performed at Bangkok Metropolitan Administration Medical College and Vajira Hospital between 1997 and 2005 were reviewed to find the primary cases that underwent CO_2 laser stapedotomy for otosclerosis. Only patients who using Teflon piston prosthesis and autologous blood seal with follow-up data more than 1 year were selected for inclusion in the present study. Any patients who underwent CO_2 laser stapedotomy for diseases other than otosclerosis and those with inadequate postoperative data were excluded. The hearing results from preoperative and postoperative (most recent follow-up) periods were analyzed using closure of air-bone gaps and postoperative sensorineural hearing loss (SNHL) at pure-tone average (PTA) and different frequencies. Major complications such as facial nerve paralysis, perilymph fistula, granuloma formation, prolonged postoperative vertigo, and severe or profound postoperative sensorineural hearing loss were listed.

Surgical technique

All surgical procedures were performed under intra-aural local anesthesia supplemented by parenteral sedation. The external auditory canal was infiltrated with 2% lidocaine with 1:80,000 units of epinephrine. A tympanomeatal flap was elevated, exposing the middle ear structures. When necessary, bone was curetted until the oval window could be visualized to the pyramidal eminence. The stapes was palpated to confirm fixation. The distance from the long process of the incus to the oval window was measured, and the incudostapedial joint divided. Mobility of the remaining ossicular chain was confirmed. The CO_2 laser was used to divide the stapedial tendon and the posterior crus. A Sharplan 30C laser was used with a 0.6 mm spot size, 2-4 watts and superpulse mode with 0.1 second duration. The suprastructure was fractured inferiorly at the anterior crus. A stapedotomy was created with the laser at the power of 1-2 watts by creating a standard rosette pattern. Char was removed with a pick, and the stapedotomy enlarged to at least 0.6 mm diameter. Ossicular continuity was reestablished with a Teflon piston prosthesis (Causse piston, fluoroplastic type, 5 mm length, 0.6 mm diameter; Smith & Nephew Richards, Memphis, TN) positioned between the long process of the incus and the oval window. An autogenous blood clot obtained by venous puncture was placed around the piston at the stapedotomy. The tympanomeatal flap was returned to its anatomic position, and the patient's hearing was tested by the operator by asking the patient to repeat a softly whispered statement.

Audiometric evaluation

Audiometric testing was performed in double-walled sound rooms using standard procedures. Preoperative audiometric data consisting of air conduction at 0.25, 0.5, 1, 2, 4, and 8 kHz and bone conduction at 0.5, 1, 2, and 4 kHz were recorded. Postoperative air and bone conductions were recorded at the same frequencies as preoperative air and bone conductions. Preoperative and postoperative speech reception thresholds (SRT) and speech discrimination scores (SDS) were also recorded. Pure-tone average (PTA) thresholds were calculated from 0.5, 1, and 2 kHz. Air-bone gaps for the PTA and for individual frequencies were computed from air and bone conduction thresholds obtained at the same test interval. A high pure-tone bone conduction average (HPTBCA) of 1, 2, and 4 kHz was also computed for evaluation of operative damage to hearing (postoperative sensorineural hearing loss). Hearing results from preoperative period and postoperative period (most recent follow-up) were analyzed.

The data were statistics calculated using SPSS for windows (version 11.5). The descriptive statistics: range, mean, standard deviation (SD), frequency, and percent were used to describe the results. The paired t-tests were used to evaluate postoperative changes of air-bone gaps and postoperative sensorineural hearing loss. One-way ANOVA was used for comparisons

Table 1. Patient's characteristics

Characteristics	No. of ears (n = 40)	Percent
Gender		
Female	28	70.0
Male	12	30.0
Ear		
Right	24	60.0
Left	16	40.0
Case type		
Unilateral	32	80.0
Bilateral	8	20.0
Age in years (mean (SD))	43.6 (9.8)	
Fallow-up time in months (mean (SD))	22.0 (15.5)	

Table 2. Mean hearing thresholds and air-bone gaps (difference between air and bone conduction thresholds) at pure-tone average (PTA) (0.5,1,2 kHz) (dB)

Time	Mean (SD) PTA hearing thresholds (dB) (n = 40)		Mean (SD) PTA air-bone gaps
	Air conduction	Bone conduction	
Preoperative	62.7 (10.8)	30.0 (9.4)	32.7 (8.5)
Postoperative	35.2 (13.4)	27.7 (11.0)	7.5 (6.6)

involving more than two groups. Criterion for statistical significance was at p-value within 0.5, two-tailed.

Results

The present review yielded 73 primary CO_2 laser stapedotomy procedures performed between 1997 and 2005, and 36 patients who underwent 40 CO_2 laser stapedotomies met the criteria for analysis. Patient's characteristics are summarized in Table 1.

Closure of air-bone gaps

Table 2 shows mean hearing thresholds and air-bone gaps (difference between air and bone conduction thresholds) at pure-tone average. The mean air conduction hearing threshold at PTA was 62.7 dB preoperatively and 35.2 dB postoperatively. The average preoperative PTA air-bone gaps was 32.7 dB and postoperative PTA air-bone gaps was 7.5 dB.

The rate of patients who had postoperative PTA air-bone gaps (difference between postoperative air and bone conductions) within 10 dB was 77.5% and within 15 dB was 95% (Table 3).

Table 4 shows mean closures of air-bone gaps (difference between preoperative and postoperative air-bone gaps) for PTA and individual frequencies. There was a significant closure of air-bone gaps at PTA and at all frequencies (the frequencies from 0.5 to 4 kHz). Further test by one-way ANOVA (Scheffe's post-hoc test), closures of air-bone gaps at 0.5, 1, and 2 kHz were statistically better than at 4 kHz.

Postoperative sensorineural hearing loss

In the present study, postoperative sensorineural hearing loss (SNHL) was defined as a postoperative bone conduction threshold that was more than 10

Table 3. Hearing results shown as a function of postoperative pure-tone average (PTA) (0.5,1,2 kHz) air-bone gaps (difference between postoperative air and bone conduction thresholds) (dB)

Postoperative PTA air-bone gaps (dB) (n = 40)	No. (%)	Accumulative %
0-5	17 (42.5)	42.5
6-10	14 (35.0)	77.5
11-15	7 (17.5)	95
16-20	0 (0.0)	95
21-25	0 (0.0)	95
26-30	2 (5.0)	100
> 30	0 (0.0)	100

Table 4. Closure of air-bone gaps (difference between preoperative and postoperative air-bone gaps) at pure-tone average (PTA) (0.5,1,2 kHz) and individual frequencies (dB)

Frequency (kHz)	Mean (SD) air-bone gaps (dB) (n = 40)			
	Preoperative	Postoperative	Closure of air-bone gaps	p-value
PTA	32.7 (8.5)	7.5 (6.6)	25.2 (10.8)	0.000
0.5	41.7 (14.3)	11.0 (10.3)	30.7 (16.7)	0.000
1	37.5 (11.2)	8.2 (7.3)	29.3 (14.9)	0.000
2	26.0 (14.3)	3.3 (5.9)	22.7 (15.6)	0.000
4	20.5 (13.5)	11.2 (11.7)	9.3 (15.7)	0.001

Table 5. Rates of postoperative sensorineural hearing loss (SNHL) at high pure-tone bone conduction average (HPTBCA) (1, 2, and 4 kHz) and individual frequencies (dB) (SNHL indicates more than 10 dB increase in bone conduction threshold)

Frequency (kHz) (n = 40)	No. (%)
HPTBCA	3 (7.5)
0.5	7 (17.5)
1.0	1 (2.5)
2	3 (7.5)
4	7 (17.5)

dB worse than preoperatively and HPTBCA indicated high pure-tone bone conduction average at 1, 2, and 4 kHz.

The overall rate of SNHL was 7.5% at HPTBCA (Table 5). There were no cases of SNHL more than 20 dB at HPTBCA.

Table 6 shows postoperative changes in mean bone conduction thresholds and SDS. There was no significant difference between preoperative and postoperative bone conduction thresholds at HPTBCA and at 0.5 kHz, but at 1 and 2 kHz, there was significant improvement of mean postoperative bone conduction thresholds. In contrast, mean postoperative bone conduction thresholds at 4 kHz worsen significantly. Postoperative SDS was significantly improved.

Other postoperative complications

There were no cases of major postoperative complications such as facial nerve paralysis, perilymph fistula, granuloma formation, prolonged postoperative vertigo, and profound postoperative sensorineural hearing loss.

Discussion

CO_2 laser stapedotomy is one of the modern stapes surgery for otosclerosis. There are a number of prostheses of differing design and tissue seals have been used in laser stapedotomy. Currently available prostheses are most commonly composed of three materials: a Teflon-type polymer (tetrafluoroethylene), stainless steel, or platinum. Teflon remains the most common material placed into the oval window as stapes prosthesis. An all Teflon piston is one of the commonly

Table 6. Changes in postoperative bone conduction thresholds at high pure-tone bone conduction average (HPTBCA) (1, 2, and 4 kHz) and individual frequencies (dB), and speech discrimination scores(SDS) (%)

Frequency (kHz)	Mean (SD) bone conduction thresholds (dB) (n = 40)			
	Preoperative	Postoperative	Differences between preoperative and postoperative	p-value
HPTBCA	33.2 (11.1)	31.7 (13.0)	1.5 (7.7)	NS
0.5	20.2 (9.9)	23.0 (12.8)	-2.8 (9.8)	NS
1	29.2 (10.7)	25.8 (10.7)	3.4 (8.1)	0.012
2	40.7 (12.6)	34.2 (15.1)	6.5 (10.1)	0.000
4	29.7 (14.2)	35.1 (17.4)	-5.4 (10.8)	0.003
SDS (%)	93.8 (6.6)	98.5 (2.9)	4.7 (6.2)	0.000

used prostheses that design as a loop for an attachment to the incus. It has an advantage of well tolerance in the middle ear. The disadvantages include a chance of postoperative displacement of the prosthesis because of the lack of tissue ingrowths with this material and a chance of postoperative incus necrosis can still occur if the blood supply is interrupted with a loop of the prosthesis[4]. The seal of the oval window in stapedotomy is another important topic to prevent postoperative complications. Gelfoam once recommended for oval window reconstruction, has been abandoned because of postoperative fistula formation, balance disturbance, and granuloma formation[9]. Vein or fascia may be used to form a seal around the shaft of the prosthesis. Autologous blood is also used to create a seal around the prosthesis with the small fenestra technique[10]. Autogenous blood has an advantage of the time saved, but the disadvantage includes it does not provide resistance for the prosthesis initially, but with healing, an endosteal membrane forms under the prosthesis later, creating a watertight seal[4].

The present study evaluated the hearing results and complications of CO_2 laser stapedotomy with Teflon piston prosthesis and autologous blood seal. The authors observed that surgical success (postoperative PTA air-bone gaps within 10 dB) was 77.5% and 95% of the patients were maintained postoperative PTA air-bone gaps within 15 dB. This success rate is comparable to that of several reports for the laser stapedotomy with other prostheses and seals[11-15]. The mean preoperative PTA air-bone gap was 32.7 dB and the average postoperative PTA air-bone gap close to 7.5 dB, demonstrating significantly improvement. When comparing at individual frequencies, the air-bone gaps at all frequencies (the frequencies from 0.5 to 4 kHz) were significantly improved, and the closures of air-bone gaps at 0.5, 1, and 2 kHz were better than 4 kHz. These results support that the procedure gives better postoperative hearing gain at lower frequencies than higher frequencies as proposed by the earlier report[16].

The serious side effect of SNHL was also assessed. Three patients (7.5%) have more than 10 dB increase in bone conduction at HPTBCA postoperatively. There were no cases of SNHL more than 20 dB at HPTBCA. These reflect the safety of the procedure. When comparing at individual frequencies, the authors observed slight, but statistically significant, improvement in bone conduction thresholds at 1 and 2 kHz but worsening at 4 kHz. The improvement seen at 1 and 2 kHz is due to the disappearance of the Carhart's notch after stapes surgery as described by many reports[17-19]. The higher frequency(4kHz) sensorineural hearing loss is consistent with those reported previously for larger fenestra, conventional technique and small fenestra stapedotomies either microdrill or laser[6,12,20,21] which may have resulted from the mechanical trauma to the inner ear or may have reflected disease-specific injury resulting from cochlear otosclerosis as suggested by Meyer[22].

There were no cases of perilymph fistula, granuloma formation, prolonged postoperative vertigo, or profound postoperative sensorineural hearing loss. These reflect the effectiveness of using CO_2 laser and the use of blood as a seal. Thus, CO_2 laser stapedotomy with Teflon piston prosthesis and autologous blood seal can be a good alternative choice for stapes surgery in otosclerosis.

Conclusion

In the present study, CO_2 laser stapedotomy with Teflon piston prosthesis and autologous blood seal provides acceptable results in performing operation in otosclerotic patients. It is a safe and effective surgery for otosclerosis. The procedure appears to give more air-bone gap closure at the low and mid frequency ranges with an acceptable rate of postoperative SNHL and no serious complications.

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ผลการผ่าตัดเจาะฐานกระดูกโกลนด้วยคาร์บอนไดออกไซด์เลเซอร์ร่วมกับการใช้กระดูกโกลนเทียมชนิดเทฟลอนและปิดรอยรั่วด้วยเลือด

รณยุทธ บุญชู, พิชัย พัวเพิ่มพูลศิริ

วัตถุประสงค์: *เพื่อศึกษาผลการได้ยินและโรคแทรกซ้อนในผู้ป่วยโรคโอโตสเคอโรซีส (ฐานกระดูกโกลนยึดติด) ภายหลังการผ่าตัดเจาะฐานกระดูกโกลนด้วยคาร์บอนไดออกไซด์เลเซอร์ร่วมกับการใช้กระดูกโกลนเทียมชนิดเทฟลอนและปิดรอยรั่วด้วยเลือด*

วัสดุและวิธีการ: *ทบทวนเวชระเบียนของผู้ป่วยโรคโอโตสเคอโรซีสทั้งหมด ที่ได้รับการผ่าตัดเจาะฐานกระดูกโกลนด้วยคาร์บอนไดออกไซด์เลเซอร์เป็นครั้งแรก ณ วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาลตั้งแต่ พ.ศ. 2540 ถึง พ.ศ. 2548 คัดเลือกเฉพาะผู้ป่วยที่ใช้กระดูกโกลนเทียมชนิดเทฟลอนและปิดรอยรั่วด้วยเลือดและมีข้อมูลการติดตามผลภายหลังการผ่าตัดมากกว่า 1 ปี โดยไม่รวมผู้ป่วยที่ทำผ่าตัดจากสาเหตุอื่นหรือมีข้อมูลไม่ครบถ้วนสมบูรณ์ วิเคราะห์ผลการตรวจการได้ยินก่อนผ่าตัดและภายหลังผ่าตัด (การติดตามผลครั้งล่าสุด) โดยเปรียบเทียบประสิทธิผลในการปิดช่องความต่างของระดับการได้ยินโดยการนำเสียงทางอากาศกับการนำเสียงทางกระดูก และการสูญเสียการได้ยินเสียงแบบประสาทรับฟังเสียงบกพร่องจากผลของการผ่าตัด ที่ค่าเฉลี่ยของเสียงบริสุทธิ์ที่ความถี่ 500, 1000 และ 2000 รอบต่อวินาที และที่เสียงความถี่ต่าง ๆ กัน รวมทั้งบันทึกโรคแทรกซ้อนที่สำคัญ*

ผลการศึกษา: *ตั้งแต่ พ.ศ.2540 ถึง พ.ศ.2548 มีการผ่าตัดเจาะฐานกระดูกโกลนด้วยคาร์บอนไดออกไซด์เลเซอร์เป็นครั้งแรกทั้งหมดจำนวน 73 หู และได้ผู้ป่วยตามเกณฑ์คัดเข้าจำนวน 36 ราย 40 หู นำมาศึกษา ระยะเวลาติดตามผลเฉลี่ยภายหลังการผ่าตัด 22 เดือน พบว่าค่าเฉลี่ยของช่องความต่างของระดับการได้ยินโดยการนำเสียงทางอากาศกับการนำเสียงทางกระดูกที่ค่าเฉลี่ยของเสียงบริสุทธิ์ก่อนผ่าตัดและภายหลังผ่าตัดเท่ากับ 32.7 และ 7.5 เดซิเบล ตามลำดับและภายหลังการผ่าตัดผู้ป่วยมีช่องความต่างของระดับการได้ยินโดยการนำเสียงทางอากาศกับการนำเสียงทางกระดูก ที่ค่าเฉลี่ยของเสียงบริสุทธิ์ภายใน 10 และ 15 เดซิเบล เท่ากับร้อยละ 77.5 และ 95 ตามลำดับ ประสิทธิผลในการปิดช่องความต่างของระดับการได้ยินโดยการนำเสียงทางอากาศกับการนำเสียงทางกระดูกที่ค่าเฉลี่ยของเสียงบริสุทธิ์ และที่เสียงความถี่ 500,1000,2000 และ 4000 รอบต่อวินาทีก็พบว่าดีกว่าก่อนการผ่าตัดอย่างมีนัยสำคัญทุกความถี่ และพบว่าประสิทธิผลในการปิดช่องความต่างของระดับการได้ยินโดยการนำเสียงทางอากาศกับการนำเสียงทางกระดูก ที่เสียงความถี่ 500,1000 และ 2000 รอบต่อวินาที ดีกว่าที่เสียงความถี่ 4000 รอบต่อวินาทีอย่างมีนัยสำคัญ อัตราการสูญเสียการได้ยินเสียงแบบประสาทรับฟังเสียงบกพร่องจากผลของการผ่าตัดเท่ากับร้อยละ7.5 และไม่พบว่ามีโรค แทรกซ้อนที่สำคัญ*

สรุป: *การผ่าตัดเจาะฐานกระดูกโกลนด้วยคาร์บอนไดออกไซด์เลเซอร์ร่วมกับการใช้กระดูกโกลนเทียมชนิดเทฟลอนและปิดรอยรั่วด้วยเลือด เป็นเทคนิคการผ่าตัดที่ปลอดภัยและได้ผลดีในการรักษาโรคโอโตสเคอโรซีส วิธีการผ่าตัดชนิดนี้ให้ผลการได้ยินที่ดีภายหลังการผ่าตัดและให้ประสิทธิผลในการปิดช่องความต่างของระดับการได้ยินโดยการนำเสียงทางอากาศกับการนำเสียงทางกระดูกดีที่เสียงความถี่ต่ำและกลาง โดยไม่มีการสูญเสียการได้ยินเสียงแบบประสาทรับฟังเสียงบกพร่องจากผลของการผ่าตัดและโรคแทรกซ้อนอื่นที่สำคัญ*