

Advantages of CO₂ laser use in surgical management of otosclerosis

Svjetlana Matković*, Boris Kitanoski*, Živorad Maličević†

Military Medical Academy, *Clinic of Otorinolaryngology, †Institute for Medical Research, Belgrade.

Background. *Otosclerosis is a progressive osteo-destructive disorder of the bony labyrinth in which the fixation of the stapes causes the hearing loss. The aim of this study was the postoperative determination of parameters of the effect of surgical intervention on hearing and the incidence of complications and, on the basis of the differences in the examined parameters of the study, the estimation of the efficacy of the two mentioned surgical techniques in the treatment of otosclerosis.* **Methods.** *In our research 40 patients with conductive hearing loss caused by otosclerosis underwent surgery with CO₂ laser. Functional results were compared postoperatively with the results of 40 patients operated by the classical technique without the use of CO₂ laser. The research was accomplished as a prospective comparative study.* **Results.** *The air-bone interval (gap) as the difference between the rim of air and bone conductivity for separate frequencies did not significantly differ between the control and the experimental group. Both methods were effective in closing the air-bone gap with the rates of closure to within 10 dB in 82.6% and 75.3% for the laser and drill, respectively. The incidence of tinnitus was significantly lower in patients who underwent surgery with CO₂ laser. The frequency of intraoperative and postoperative complications was significantly lower in the laser group. Differences were statistically significant for all parameters ($p < 0.05$).* **Conclusion.** *On the basis of the degree of postoperative hearing improvement, tinnitus and the incidence of complications it can be concluded that the use of CO₂ laser during inverse stapedoplasty represents an effective and safe method, justifying the promotion of its use in the surgical management of otosclerosis.*

Key words: otosclerosis; otologic surgical procedures; stapes, surgery; laser surgery; treatment outcome.

Introduction

Otosclerosis is a progressive osteo-destructive disorder of the bony labyrinth in which the fixation of the stapes causes the hearing loss of the conductive type. As a result of the enhanced pressure of the labyrinth endolymph and the enzymatic activity of otosclerotic lesion in the further course of the disease there occurs the damaging of fragile structures of the internal ear, as well as the sensorineural hearing damage, and the damage of the vestibular function and otosclerotic process might attack the whole capsule of the internal ear and cause deafness (1–3). Hearing damage is almost always bilateral, but the speed of its progression on one and the other ear differs. Otosclerosis is autosomal

dominant familial disease with the different degree of expression, and usually occurs in the second or the third decade of life. Females represent the two third of patients (4–6). According to the previous data microsurgical intervention is presently the only way of successful rehabilitation of hearing in patients with otosclerosis. The aim of microsurgical treatment is to improve the transmission system of the middle ear, which would enable the conditions for the rehabilitation of the ear. However, during microsurgical treatment injuries of the internal ear might occur, which not only compromises the effects which are to be achieved by the intervention, but also might lead to more severe hearing damage, complete deafness and the injury of the vestibular function (7–10). That was the reason for establishing nu-

merous modifications during the development of microsurgical techniques, with the aim of the reduction of such damages. Nowadays most oto-surgeons practice classical stapedoplasty which implies primary disarticulation of incudo-stapedial joint, cleaving the stapedius ligament and parts of the stapes, removal of suprastructure, fenestration of the stapes plate and the implantation of prosthesis (11, 12). Besides this technique, the technique of inverse stapedoplasty with the endaural approach is also used: after the primary stapedotomy is performed, the hole on the stapes plate is made by microinstrument (hand perforator), the prosthesis is placed, adjoined to the long part of the incus, and after that the parts are cut and the suprastructure of the stapes is being removed (14, 15). Although, according to some references, inverse technique proved itself less traumatic than the classical one and gave better results in hearing improvement, it was also followed by possible complications such as undesirable mobilization of the whole stapes plate, its fracture, the fall of the fragments of the footplate into the vestibulum, subluxation of incus and the malposition of the prosthesis (16, 17). This technique, namely, requires longer performance with microinstrument on the stapes footplate, which represents a risk for the occurrence of a possible lesion of the internal ear. In order to avoid instrumental manipulation during the inverse stapedoplasty, a new concept of microsurgical treatment of otosclerosis – the use of laser was established.

Methods

Study Design. This research was performed as a prospective comparative study. The study group consisted of 80 patients in whom otosclerosis was diagnosed according to the standard diagnostic procedures (tonal liminar audiometry, acoustonic impedancometry, including tympanometry, acoustonic reflex and the ventilation function of Eustachian tube, mastoid x-ray according to Schuller), performed two weeks before the surgical intervention. They fulfilled the following criteria: reduction of air-conduction of at least 40 dB, bone-air interval (gap) higher then 20 dB, 20–70 years of age, and patients' consent for surgical treatment.

Forty ears with conductive hearing loss due to otosclerosis were operated using the laser stapedotomy technique (E group). Audiologic results and incidence of intraoperative and postoperative complications were compared with the results of 40 nonlaser stapedotomies (control group). The postoperative air-bone gap, calculated as the difference between the postoperative air and preoperative bone conduction levels, as recommended by American Academy of Otolaryngology – Head and Neck Surgery. Both groups were studied for the course of the tinnitus after the stapes surgery.

Statistical analysis. Descriptive statistics including means and standard deviations were computed for continuous variables, and frequency of responders were computed for categorical data. Between group differences (laser vs

non laser) were sought using the Mann-Whitney test. For the purposes of this study, $p < 0.05$ was considered significant.

Operations. Under local anesthesia with supplemental intravenous sedation, a 6 mm tympanomeatal flap was elevated and using a drill and diamond burs, a large portion of the scutum (posterior-superior portion of the canal wall) was removed preserving the chorda tympani and providing a good view of the horizontal facial nerve and stapes. The same initial approach and exposure technique were used in each case presented in this study population.

By the experimental group CO₂ laser, Model Sharplan 30 C, was used to vaporise the small fenestra on the footplate using 20W at 0.03 seconds duration. By the control group the instrument was used to create the fenestra. The laser was never fired into open vestibule. After stapedotomy, an appropriate size piston prosthesis was placed and crimped onto the incus. Using either hot (CO₂ laser) or cold instrumentation, the incudostapedial joint was separated, the stapedial tendon lysed, and the stapes superstructure removed. Subsequently, the oval window was sealed with autologous blood and tympanomeatal flap was returned to its normal position.

Results

The study group consisted of 80 patients, 28 male and 52 female, 21–65 years of age (mean, age 39.8 ± 10.1). The average age of the examinees in both groups was 39.8 ± 10.1 (ranging 21–65 years of age). The average age of the control ant the experimental group was similar (40.7 ± 9.8 and 38.8 ± 10.4) and was identical in males and females (39.8 ± 10.7 and 39.8 ± 9.9). In 8 examinees (10 %) otosclerotic process that caused conductive hearing loss was unilateral, while it was bilateral in 72 of them (90%).

There were no significant differences between the control and the experimental group regarding the age, gender and the reciprocity of the process.

In the preoperative period results of tonal liminal audiometry showed that air-bone interval, as the difference between air and bone conductance, was higher in the experimental group in patients operated by CO₂ laser, but the difference was not statistically significant (Figure 1).

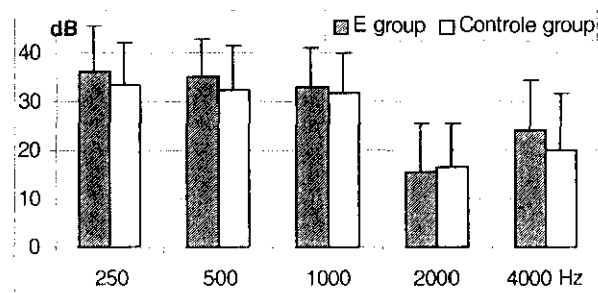


Fig. 1 – Preoperative air-bone interval, as the difference between air and bone conduction

Six months after surgery the level of the closure (deficit) of air conduction in relation to the preoperative level was determined (Figure 2).

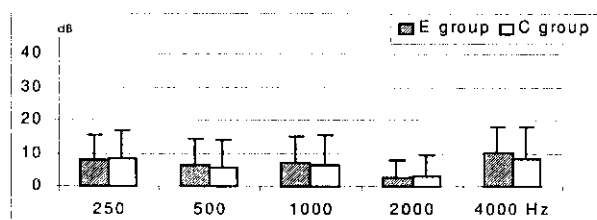


Fig. 2 – Change in air-bone interval six months after surgery

In the estimation of socially adequate hearing the acceptable threshold of air conduction was from 30 dB, and lower. Postoperatively air conduction threshold in the low-frequent area from 250 and 500 Hz was lower from 30 dB in the control and experimental group. In the domain of high frequencies (2 000 and 4 000 Hz) it was above that amount (Figure 3).

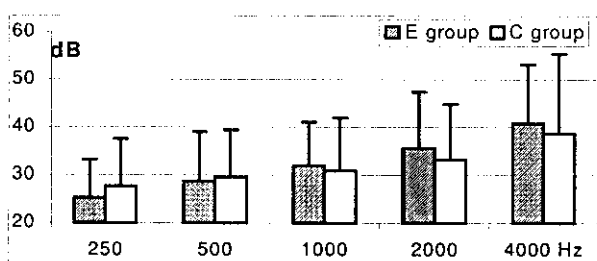


Fig. 3 – Postoperative air conduction threshold

The value of its change regarding the level of the initial threshold manifested more successful treatment in relation to the threshold of air conduction (Figure 4).

Both groups were compared in regard to the postoperative air-bone gap closure. There were no significant differences between the groups, comparing the pure tone average (PTA) at frequencies of 250, 500, 1 000, 4 000 Hz. Both methods were effective in closing the air-bone gap, with the rates of closure to within 10 dB of 82,6% and 75,3% for the laser and drill, respectively. The improvement in PTA for air conduction was 28.6 dB on average at frequencies of 250 Hz, 27.4 dB at frequencies of 500 Hz, 23.8 dB at frequencies of 1000 Hz, 12 dB at frequencies of 2 000 Hz, 13 dB at frequencies of 4 000 Hz for the experimental group and 23.7 dB, 26.6 dB, 23.5 dB, 13 dB, 11. dB for the control group, respectively (Figure 4).

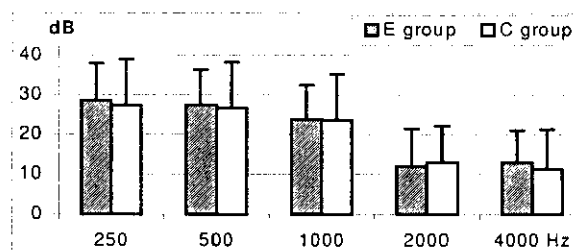


Fig. 4 – Postoperative improvement in pure tone average for air conduction

Tinnitus was recorded by each patient using a self-rating system that included subjective pitch (high or low), and loudness (low, moderate, or high). The postoperative course of the tinnitus was classified into four categories: complete disappearance, improvement, unchanged, and worse.

Changes in tinnitus according to the performed surgical technique are presented in Figure 5. The incidence of tinnitus was significantly lower in patients who underwent surgery with CO₂ laser. The incidence of intraoperative complications like stapes mobilisation or footplate fracture, bleeding and problems with adaptations of prosthesis in the fenestra ovalis was significantly lower in the laser group (Table 1). The incidence of postoperative complications like sensorineural hearing loss and vestibular symptoms was significantly lower in the laser group (Table 2). No patient in this series developed a postoperative perilymph fistula.

Table 1

The frequency of intraoperative complications

	CO ₂ laser	Without CO ₂ laser
Mobilization of the footplate	0	2 (5 %)
Fracture of the footplate	0	5 (12.5%)
Bleeding	6 (15%)	18 (45 %)
Problems with adaptation of prosthesis	4 (10%)	16 (40 %)

Table 2

The frequency of postoperative complications

	CO ₂ laser	Without CO ₂ laser
Vertigo	11 (26%)	22 (55%)
Nistagmus	7 (16%)	15 (37.5%)
Transient fall of bone conductivity	1 (2.5%)	6 (15%)
Continuous fall of bone conductivity	0	3 (7.5%)

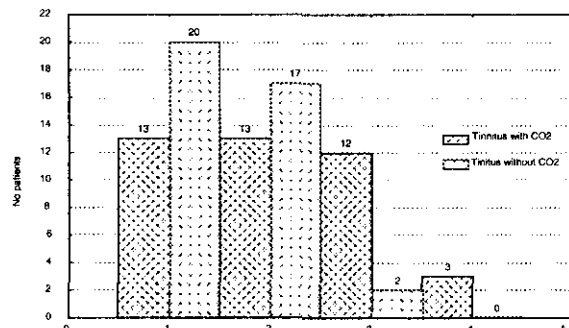


Fig. 5 – Pre- and postoperative incidence of tinnitus. (1=complete disappearance; 2=improved; 3=unchanged; 4=exacerbated).

Discussion

The first significant use of laser in ear surgery was in stapedovestibular surgery. Most published reports pointed to the advantages of laser stapedotomy in relation to the classical technique in which fenestra was opened with an instrument (20, 21).

The degree of the closure of air-bone interval was for a long time the only parameter for the determination of the efficiency of reconstruction in surgery in the conductive hearing loss. The closure of air-bone interval indicated the improvement of the threshold of air conduction in relation to the threshold of bone conduction. In the evaluation of good postoperative surgical outcome the air-bone interval was determined as the difference between postoperative threshold of air conduction and preoperative threshold of bone conduction. In this research successful management from the aspect of the evaluation of air-bone interval was obtained in 75 (93.75%) of patients. It was concluded that six months after the operation air bone interval was completely closed in 32 patients, reduced to 10 dB in 27 patients, and reduced to 20 dB in 16 patients, which was regarded as a successful result (22, 23). The failure of the success (the same air - bone interval in relation to the initial values) was registered in five patients from which in only one of them the technique of the inverse stapedoplasty with the laser was used (Table 1). The results of some authors showed the decrease of the air - bone interval to 10 dB in more than 85% of the patients operated with the use of laser, which corresponded to the results of this research. Although the technique of inverse stapedoplasty might be successfully performed both with and without the use of laser, Cremers (24) suggested that the use of laser reduced mechanical trauma of the stapes and the irritation of membranous labyrinth which is more vulnerable in the ear with otosclerotic process. Other authors suggested that standard technique with the use of instruments is equally safe and effective as the treatment with the use of laser, and that in some cases the instrument represented a better choice, particularly when the plate was thick (25). Although there were no significant differences between the results completed in both groups

of patients, the authors of this study supported the opinion of the authors who gave priority to the inverse technique with the use of laser because this technique ensured the opening of fenestra with minimal instrumental manipulation in oval niche, and surgical treatment was significantly simplified and lasted shorter.

The Committee for Hearing and Balance of the American Academy for Otorhinolaryngology and Surgery of Head and Neck recommended the standards for the evaluation of the results of the middle ear surgical treatment. According to these standards, the golden standard in the evaluation is the estimation of the threshold of verbal discrimination, and the closest to this parameter in significance is the threshold of air conductivity. The percentage of the function with socially adequate hearing is determined more by the threshold of the air conduction of 30 dB and less than the closure of air-bone interval. The threshold of air conduction for both groups was estimated in relation to the recommended standards, and it was found that in the low-frequent area from 250 and 500 Hz the threshold was lower from 30 dB, whilst in the domain of high frequencies it was above that value without statistically significant difference between groups.

Controversies in choosing the surgical technique in the treatment of otosclerosis have also been noted in current surgery. The estimation of total efficacy of surgical technique is made on the basis of hearing improvement and the incidence of complications. During microsurgical intervention on the stapedovestibular joint, injuries of the internal ear might occur, which not only compromises the effects to be achieved by the operation, but could also lead to more severe hearing injury, complete deafness and the injury of the vestibular function (26). During the development of microsurgery numerous modifications have been established with the aim of reduction of such injuries (27). According to the opinion of numerous authors, establishing the use of laser represents highly acceptable concept in microsurgical treatment of otosclerosis, because its energy can precisely evaporate the tissue without the mechanical trauma (28).

Minimal trauma of the surrounding tissue and bloodless management with simultaneous cauterization of blood vessels in the operative field increases safety in the creation of fenestra which becomes of desirable shape and dimension, while the clearance of oval niche becomes better because with laser use there is no use of surgical instruments in the operative field. As the fenestra is created by laser, it has precise dimensions and the desirable position, the implanted prosthesis is positioned perpendicularly in relation to the stapes, which prevents the excessive abrasion and consequent postoperative complications (malposition of the prosthesis, necrosis of the long limb of the incus).

During the operation following complications such as bleeding, undesirable mobilization of the plate, fracture dislocation of the plate and problems with the adaptation of prosthesis in fenestra ovalis, might occur. In this research the results showed statistically significant lesser incidence

of all intraoperative complications in the group who underwent surgery with CO₂ laser.

All the operations were performed under local anesthesia, and none of the patients complained of dizziness or ear-buzzing during the laser evaporation of the stapes plate. Although all the operations were performed by the inverse treatment, in two cases mobilization and fracture of the stapes occurred when we tried to open the fenestra by the hand perforator. In both cases the use of laser in the further course of the operation was valuable. During the opening of the plate with the instrument fracture, dislocation occurred in five cases, and in the aim of prevention of the deterioration of fragment into the vestibulum the operation was continued by laser. Bleeding was the complicating factor in some parts of surgical treatment. The usual cause of bleeding is the trauma of mucosis of medial wall of cavum, or the active otosclerotic process. In both cases the use of laser with its ability of evaporation of the tissue without the mechanical trauma and bleeding was significant, confirmed by our results. The problem with the adaptation of the prosthesis in the oval window was present in 20 patients who underwent surgery, out of whom the standard technique was used in 16. Although the use of laser did not eliminate the risk of intraoperative trauma, the results of this study showed that such risk was significantly lower for intraoperative trauma with the use of laser than in the classical treatment without its use.

Recent otologic papers contain reports of the authors who ensued the frequency of postoperative disorders of the vestibular and cochlear function related with the use of laser (29). In this research, the signs and symptoms that occurred in first two weeks after the operation and were not present before the operation were registered as postoperative complications. They were: the occurrence of vertiginous symptoms, nystagmus, continuous fall of bone conductivity for more than 20 dB in relation to preoperative values, and transitive fall of bone conductivity in high frequencies. Significantly larger number of these compli-

cations was present in the control group patients (Table 2). For all the parameters differences were statistically significant ($p < 0.05$). Vertiginous disturbances and nystagmus completely dispersed six months after the operation. In the postoperative period reparative granuloma occurred in only one patient who underwent surgery without laser, and re-operative intervention was successfully performed by laser. In this research no perilymphatic fistula was recorded as a complication.

Conclusion

On the basis of the results of this research it was concluded that:

– The evaluation of the effects of surgical treatment on hearing on the basis of tonal liminal audiometry showed that inverse technique with the use of CO₂ laser was as efficient as the standard technique.

– The use of CO₂ laser did not completely eliminate the risk of intraoperative complications, but with the use of laser that risk was significantly lower, as well as the frequency of probable intraoperative complications, such as mobilization or the fracture of the plate, bleeding and problems with the adaptation of prosthesis in the fenestra.

– In the operations on the stapes of the plate the use of CO₂ laser had significant priority because the possibility of mechanical trauma of internal ear, which might lead to undesirable postoperative complications such as vertigo, nystagmus, transitory or sensoryneural injury of the ears, was significantly smaller.

The incidence of tinnitus was significantly lower in patients who underwent surgery with CO₂ laser.

– On the basis of the degree of postoperative hearing improvement, tinnitus and the frequency of complications, the use of CO₂ laser during inverse stapedoplasty in our study was efficient and safe method, justifying the pleading for its use in surgical treatment of otosclerosis.

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Apstrakt

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PREDNOSTI PRIMENE CO₂ LASERA U HIRURŠKOM LEČENJU OTOSKLEROZE

Cilj. Otoskleroza je progresivno osteodistrofijsko oboljenje koštane kapsule labirinta koje dovodi do fiksacije pločice stapesa i uzrokuje oštećenje sluha. Cilj rada bio je postoperativno određivanje parametara efekta hirurške intervencije na sluh i učestalost komplikacija i, na osnovu razlike u praćenim obeležjima posmatranja, određivanje ukupne efikasnosti dve hirurške tehnike u lečenju otoskleroze. **Metode.** U istraživanju je 40 bolesnika sa oštećenjem sluha uzrokovanim otosklerozom hirurški lečeno uz primenu CO₂ lasera. Funkcionalni rezultati upoređivani su sa rezultatima 40 bolesnika koji su operisani klasičnom tehnikom bez primene CO₂ lasera. Istraživanje je izvedeno kao prospektivna komparativna studija. **Rezultati.** Vazdušno - koštani interval (razmak) kao razlika između praga vazdušne i praga koštane provodljivosti za pojedinačne frekvencije nije bio signifikantno različit između kontrolne i eksperimentne grupe. Obe metode bile su efektivne uz zatvaranje vazdušno- koštanog razmaka do 10 dB u 82,6% u eksperimentnoj odnosno 75,3% u kontrolnoj grupi. Incidencija tinitusa bila je značajno niža kod bolesnika kod kojih je u hirurškom postupku primenjen CO₂ laser. Učestalost intraoperativnih i postoperativnih komplikacija bila je signifikantno niža u laserskoj grupi. Razlike su bile statistički signifikantne za sve parametre ($p < 0,05$). **Zaključak.** Na osnovu stepena postoperativnog poboljšanja sluha, tinitusa i učestalosti komplikacija, primena CO₂ lasera tokom inverzne stapedoplastike predstavlja efikasnu i bezbednu metodu, čime se u potpunosti opravdava zalaganje za njenu primenu u hirurškom lečenju otoskleroze.

Ključne reči: otoskleroza; hirurgija, otološka, procedure; stapes, hirurgija; hirurgija laserom; lečenje, ishod.