# Article Stapedoplasty as a Method of Hearing Loss Treatment in Patients with Tympanosclerosis

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Abstract: Objectives: The aim of this study is to evaluate the efficacy of stapedoplasty as a method of hearing loss treatment in patients with stapes tympanosclerotic fixation.

Materials and Methods:The first group included 25 patients with CPOM and TSC who underwent a two-stage surgery (2nd stage – stapedoplasty). The second group included 25 patients with CPOM and TSC who underwent a one-, two-, or three-stage surgery with a typical sta-pedoplasty as a final step, but using a surgical CO2 laser.

Results: Analysis data of ABG mean values (35.3±8.6 dB before surgery) in TSC2 group showed their decrease in 1 month up to 22.1±9.5 dB; in 6 months – up to 17.0±8.0 dB, and in 12 months – up to 14.9±7.4 dB. Stapedoplasty with laser assistance was also effective, but its best results were shown in 6-12 months after surgery. ABG values < 20 dB were reached in 76% pa-tients; from 20 to 30 dB – in 92%, and 30 dB – in 100% patients. Analysis data of BC values (30.3±11.3 dB before surgery) showed their consistency in 1 month after surgery – 31.1±13.2 dB; in 6 months – 28.9±13.1 dB, and in 12 months – 28.3 ± 12.8 dB.

Conclusion: Laser assistance during stapes crus crossing stage and stapedotomy in the early follow-up period results in absence of inner ear reaction for surgery.

Keywords: chronic purulent otitis media, tympanosclerosis, stapedoplasty, CO2 laser.

# 1. Introduction

Surgical procedures in stapes with its tympanosclerotic fixation are not safe due to risk of sensoneural disorders developing. Another complication occurring due to this procedure is prothesis refixation because of undertreated inflammation and lack of blood circulation [1,2,3,4,5,6].

Stapedoplasty in patients with chronic purulent otitis media (CPOM) is performed in 0.3% cases in the event of massive tympanosclerosis (TSC) and stapes tympanosclerotic fixa-tion with its mobilization inefficiency. Usually, stapedoplasty is carrying out in two steps: a tympanal membrane restoration (in 89% patients) and stapedoplasty proper [1,2,7,8].

Some authors recommend performing this method only in cases of severe bilateral con-ductive hearing loss in patients refusing of hearing aid [3]. The hazard of hearing loss and in-stability of stapes surgery results in patients with TSC are the main reasons of surgeons restrain relation to this method. The evidence of this problem are several articles elucidating 12-142 cases of different stapes procedures in patients with TSC; moreover, according to some data, stapedoplasty was performed only in 7-67 cases during last 20 years. Also, this problem is in-sufficiently illustrated in literature due to scarcity of stapedoplasty performing in TSC.

The aim of this study is to evaluate the efficacy of stapedoplasty as a method of hearing loss treatment in patients with stapes tympanosclerotic fixation.

2. Materials and Methods

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Fifty patients with tympanosclerotic stapes fixation were examined and treated. In-formed consent for treatment and participation in clinical study was taken from every patient. Patients were divided into two groups depending on surgery technique. The first group (TSC1) included 25 patients with CPOM and TSC (10 males and 15 females, mean age 43.3±5.4 years) who underwent a two-stage surgery (1st stage – tympanoplasty, 2nd stage – stapedoplasty). All patients were conducted an instrumental stapedoplasty using different types of stapes prosthe-sis, mounted on the venous autograft, covering the vestibule window.

The second group (TSC2) included 25 patients with CPOM and TSC (9 males and 16 females, mean age 44.3±5.2 years) who underwent a one-, two-, or three-stage surgery with a typical stapedoplasty as a final step, but using a surgical CO2 laser.

Of 50 patients with TSC, in 41 CPOM cases a tympanoplasty type I (27 patients) and type III (14 patients) using automaterials – ear cartilage and temporal muscle fascia – (Woll-stein classification) were performed. Some patients underwent a one-stage surgery; in 9 cases of adhesive otitis media a stapedoplasty was performed [9]. As a second stage, 40 patients underwent a stapedoplasty after a successful tympanoplasty, and 1 patient underwent a cholestea-toma relapse removal (Table 1).

	lst stage			2nd	stage	3rd stage		
Groups	Tympano- plasty type I	Tympano- plasty type III	Stapedo- plasty	Tympa- num cav- ity revi- sion	Stapedo- plasty	Stapedo- plasty	Overall	
$TSC_1$	18	7	-	-	25	-	50	
$TSC_2$	9	7	9	1	15	1	42	
Overall:	27	14	9	1	40	1	92	

Table 1. Stapedoplasty types and stages in patients with TSC (n=50)

As a third stage, a stapedoplasty was performed in that patient with cholesteatoma re-lapse. As a method of hearing loss treatment in patients with TSC, 92 surgeries were per-formed, 50 of which were stapedoplasties (of these, 27 were vestibuloincudopexies, 19 – ves-tibulomyringopexies, and 4 were vestibulomaleolopexies). Types of prosthetic fastening were determined by the auditory chain elements mobility and integrity (Table 2).

Table 2. Stapedoplasty types and stages in patients with TSC (n=50)
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	lst	stage		2nd stage		3rd stage	
Groups	vestibuloin- cudopexy	ves- tibulomyrin- gopexy	vestibuloin- cudopexy	ves- tibulomaleol- opexy	ves- tibulomy rin-	ves- tibulomyr ingopexy	Overall
					gopexy		
$TSC_1$	-	-	18	4	3	-	25
$TSC_2$	3	6	6	-	9	1	25
Overall:	3	6	24	4	12	1	50

Indications for stapedoplasty performing were hearing loss, low-frequency ear noise, absence of drum membrane defects during a l year after reconstructive surgery, air-bone gap (ABG) > 30 dB in frequencies of conversational range, and TSC first surgery data. Surgery contraindications were elderly age (>75 years) and patients' severe comorbidity.

In TSC1 group, as a first stage tympanoplasty type I was performed in 18 cases, and tympanoplasty type III was conducted in 7 cases. Stapedoplasty was performed in 12-22 months after tympanoplasty. After tympanic cavity intrameatal revision and autografts preparation, an instrumental stapedectomy was performed in 18 cases, and partial stapedectomy (a wide win-dow method) was performed in 7 cases. As a stapes prosthesis, we used patients' auricle carti-lage (length 3.5-5.5 mm) in 22 cases; in other 3 cases we used allocartilage, ceramics, and tef-lon. In all cases, stapes prosthesis was installed on a venous graft from foot dorsum, covering vestibule fenestra (Figure 1).



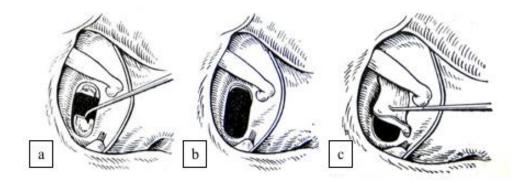
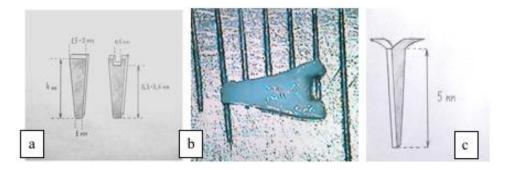


Figure 1. Stapedoplasty stages: a – footplate 2/3 removal (wide opened stapedotomy); b – footplate full removal (stapedectomy); c – oval window closing with autovenous graft.

Vestibuloincudopexy was performed in 18 patients with local sta-pes TSC; vestibulomaleolopexy was conducted in 4 patients, and vestibulomyringopexy was performed in 3 patients with diffuse TSC (Figure 2).



**Figure 2**. Types of autocartilage prosthesis application on the venous graft: a – vestibuloincudopexy with a joint-forming collar; b – vestibuloincudopexy; c – T-shaped vestibulomyringopexy.

In TSC2 group, as a first stage tympanoplasty type I was performed in 9 cases, and tym-panoplasty type III was conducted in 7 cases. In one case as a second stage a tympanic cavity revision was performed. As a final stage, in all 25 patients stapedoplasty with laser assistance technique was performed. Laser was used during stapedotomy and stapes crus crossing proce-dures. Stapedoplasty was the only surgery stage in 9 patients, the second surgery stage in 15 pa-tients, and the third stage surgery method in 1 case. Stapedoplasty was performed in 12-20 after tympanoplasty was conducted. Partial stapedotomy was performed in 14 cases; total stapedot-omy with autocartilage stapes prosthesis (prosthesis length 3.5-5.0 mm; for stapedotomy a su-perimpulse mode with flash scanner was performed; focus distance 250 mm, perforation diam-eter 0.7-1.0 mm, laser radiation power 16-24 W [mean value 21.9±2.1 W]) usage was per-formed in 11 cases. Partial stapedotomy was carried out by one impulse, whereas total stape-dectomy was carried out by several impulses. In case of necessity, posterior stapes pole was removed instrumentally (Figure 3).

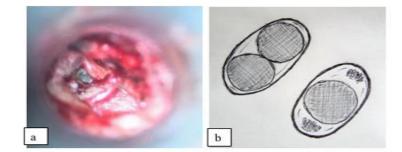


Figure 3. Footplate hole laser formation: a – micropicture of footplate formed hole (1 mm diam.); b –hole laser formation scheme.



A one-impulse hole in footplate was generated in 7 cases; in 18 cases due to thick and dense footplate, 2-20 impulses (mean value 4.3±1.2) needed. Vestibulomyringopexy was performed in 16 patients – as a first stage in 6 patients, as a second stage in 9 patients, and as a third stage in 1 case. Vestibuloincudopexy was performed in 9 patients – as a first stage in 3 patients and as second stage in 6 patients.

A choice of total or partial stapedectomy with installed on autovenous graft autocarti-lage prosthesis usage is determined by its high efficacy (ABG < 10 dB in 96% cases) and long-lived results in patients with otosclerosis during 45 years [10,11,12].

To provide safe stapedectomy, a CO2 laser system (Lumenis, USA) with mirror hinge manipulator attached to the microscope was used; wave length (I) 10.6 Im. A CO2 laser system had an adopted to stapes surgery software that depending on focus distance and superimpulse diameter automatically provides effective and safe laser radiation duration and power. Howev-er, this software did not neglect thickness of laser impulse application area, but it provided for software parameters, influencing on laser impulse duration and power, change. Thus, we set up laser impulse individually, depending on stapes crus and footplate thickness and diameter of perforation; CO2 laser impulse duration in footplate by one or two impulses.

A surgery was performed intrameatally (intraauricularly) with local applying of 8.0 ml 2% solution of lidocaine and addition of 0.1% adrenaline hydrochloride solution (1:100000), using a stereomicroscope (Moller-Wedel GmbH, Germany). A tympanic cavity was opened widely due to usual autocartilage semiplate presence in tympanic membrane thickness deter-mining its rigidity. Absence of annulus fibrous during re-operations complicated this surgery stage. During tympanum cavity revision, a state of mucosa, some auditory chain elements mo-bility and presence, TSC areas character and localization and cicatrization processes, oval win-dow niche anatomical features, and additus and auditory tube isthmus state were evaluated.

To cross stapes crus a flash scan with superimpulse mode and focus distance 250 mm was used. Afterwards, stapes crus was crossed, and arch removed without footplate mobiliza-tion. In cases of instrumental stapes mobilization during its crus crossing, a footplate laser per-foration with individual matching of impulse diameter and power after grafts and oval window niche preparation, stapes was fully removed.

After removal of oval window frame mucosa and plastic materials preparation, a flash scan with superimpulse regimen and focus distance 250 mm were used for stapedotomy per-forming.

A footplate perforation was performed in its central part or closer to its posterior pole. A choice of perforation diameter depended on state of footplate and canal of n. facialis tympa-nal part.

After the footplate posterior pole instrumental removal, an autograft was applied on oval window frame; to predict occasional contamination of inner ear liquids and adhesive pro-cess development, an intimal part of autograft was turned to oval window side. These surgery stages were performed quickly to avoid blood penetration into oval window liquids that can re-sult in vestibulocochlear disorders development.

Beyong autovenous graft application, under lenticular process of incus long crus, or un-der a tympanic membrane, on autograft an autocartilage prosthesis was applied. At the end of surgery, for stapedial reflex restoration, a stapedius muscle tendon was placed at stapes pros-thesis.

After infusion of 0.2 ml dexamethasone solution into tympanum cavity, a meatotympa-nal graft was straightened on its previous place. A compulsory moment of this stage was hear-ing assessment with a "live" speech. At the end of surgery, silicone protectors were applied along the section line, and external auditory meatus was doughly tamponaded with microporous swabs with oxycellulose (Merocel) and antiseptic.

Patients' examination on surgery treatment and follow-up stages included endoscopy, otomicroscopy, and audiological tests. To evaluate efficacy of stapedoplasty techniques, tonal threshold audiometry (TTA) in the frequency range of 0.125 to 8 kHz as a method of air con-duction (AC) and bone conduction (BC) by clinical audiometer MA-31 (Germany) in sound-isolated camera was performed. TTA was carried out before surgery, then – before discharge, and three more times – in 1, 6, and 12 months after surgery. Pathomorphological assessment of removed TSC complexes were performed in 16 cases during two stages of reconstructive sur-geries. A study data statistical evaluation was carried out by applying an analysis of variance and Student test evaluation by computer programs Microsoft Excel and SPSS 17.0. The follow-up period lasted from 1 to 5 years. Ethics committee approved all stages of this study. Written informed consent was obtained from patient who participate in this study.



3. Results

After the first reconstructive stage, all patients had thin tympanic membrane with TSC complexes in its thickness or with autocartilage semiplate in membrane's center or posterior quadrants, when otomicroscopy (Figure 4).



Figure 4. Endopicture of tympanic membranes in patients with TSC before stapedoplasty.

Histological evaluations during reconstructive surgery stages had shown that tympanic membrane integrity restoration provided decrease in inflammatory processes and TSC areas character changes due to tympanum cavity isolation; auditory tube functions and middle ear aeration improvement. This is responsible for necessity of stapedoplasty performing and appli-cation of stapes prosthesis on closing oval window autovein, to predict cochlear complications, not less than in a 12 months after the first reconstructive stage carrying out.

Analysis data of ABG mean values (35.8±6.4 dB before surgery) in TSC1 group showed their decrease in 1 month up to 27.1±7.3 dB; in 6 months – up to 18.3±8.3 dB, and in 12 months – up to 13.3±9.2 dB (Figure 5).

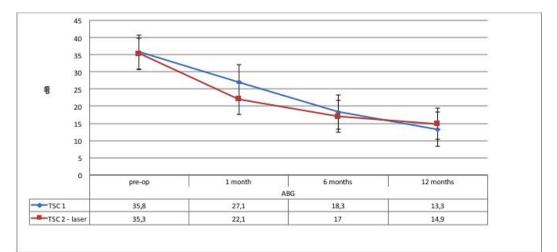


Figure 5. ABG mean values dynamics graph in both TSC groups.

Hence, instrumental stapedoplasty was effective during whole follow-up period, but its best efficacy was determined in 12 months after surgery. ABG values < 20 dB were reached in 71.4% patients; from 20 to 30 dB – in 85.7%, and [] 30 dB – in 100% patients. Analysis data of auditory threshold by BC values (36.8±5.4 dB before surgery) showed their decrease in 1 month after surgery up to 44.1±5.5 dB; in 6 months – up to 17.0±8.0 dB, and in 12 months – up to 28.2±2.1 dB determined by inner ear reaction on surgery treat-ment.

Analysis data of ABG mean values (35.3±8.6 dB before surgery) in TSC2 group showed their decrease in 1 month up to 22.1±9.5 dB; in 6 months – up to 17.0±8.0 dB, and in 12 months – up to 14.9±7.4 dB. Stapedoplasty with laser assistance was effective during whole follow-up period, but its best results were shown in 6-12 months after surgery. ABG values < 20 dB were reached in 76% patients; from 20 to 30 dB – in 92%, and [] 30 dB – in 100% patients. Analysis data of auditory threshold by BC values (30.3±11.3 dB before surgery) showed their consisten-cy in 1 month after surgery – 31.1±13.2 dB; in 6 months – 28.9±13.1 dB, and in 12 months – 28.3 ± 12.8 dB.



However, there was no difference found between functional results in speech frequencies range after cartilage prosthesis application under incus long process or under tympanic membrane (Figure 6).

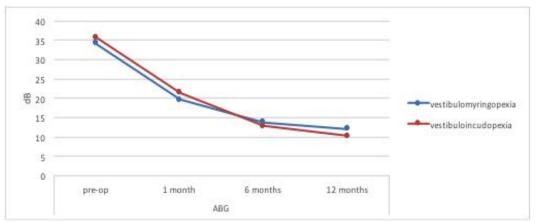


Figure 6. ABG mean values dynamics graph in TSC2 group after surgery regarding on stapedoplasty type.

## 4. Discussion

Stapes surgery (mobilization, stapedotomy, and stapedectomy) efficacy in TSC with decrease in ABG < 20 dB can be reached in 25-87.5% cases (Table 3).

As well, best results are observed after stapedotomy (37.5-78%) and stapedectomy (25-87.5%) vs. stapes mobilization (30.8-72%) [1-3,5,13-18].

Last decade, a BC thresholds increase after stapes surgery in patients with TSC occurs in 4-10.6% cases; more frequently in stapedoplasty than in stapes mobilization (14.3% vs 8%) [1,2,5,18]. However, many authors do not mention inner ear negative reaction after stapedoplasty in patients with TSC when staging, carefulness, and patients' rigorous selection [2,4,9,14,17,19,20]. This is why stapedoplasty in TSC should be performed not less than in a year after successful tympanoplasty when enclosed tympanum cavity and normal mucosa form, and auditory tube functions recover [1,3,5,21,22].

Piston stapedoplasty (stapedotomy) is a preferable surgery technique in tympanosclerot-ic stapes fixation, due to inner ear minimal traumatization and performance facility. In cases of intact ossicular system, stapedoplasty can be performed in a classic or in a "backspace" manner with stapes prosthesis fixation on incus. In other cases, piston prosthesis fixation is realized by a handle of malleus or by a prepared foot (neomalleus) situated in the tympanic membrane thickness. In the after-surgery period, there is an evidence of ABG decrease < 10 dB in 20-39% patients and < 20 dB in 37.5-78% patients [1,2,3,5,7,13,16,18,20,23].

In cases of TSC, stapedectomy is not a preferable technique for hearing loss treatment [15,24]. However, due to technical difficulties, about 20% of planned stapedotomies are result in stapedectomies [7]. In stapes TSC fixation, stapedectomy with different prosthesis (under incus, malleus handle, or neomalleus) usage allows to reduce ABG up to 10 dB in 25-45% patients and up to 20 dB – in 25-87.5% patients [1,3,14,16,17,19,25,26]. In this case, a prosthesis applies on the autovenous graft (vein, fascia, adipose tissue, or perichondrium) that closes the oval window.

Comparing different stapedoplasty techniques results in patients with tympanosclerotic stapes fixation, some authors refer to stapedectomy and prosthesis application on a graft ad-vantages versus piston technique performing in the long-term follow-up period [3,14,,19,]. Con-trary, another data show stapedoplasty less efficacy when stapes prosthesis fixation on malleus handle versus fixation on an incus long crus [8,13,16]. Several studies data did not find any sig-nificant differences in surgery efficacy, depending on its technique, materials, and stapes pros-thesis fixation type [1,5,17,27].

Some investigators testify for better functional results in stapedotomy with laser assis-tance and microdrill usage versus instrumental technique [1,5,18,28]. Comparing CO2 laser and microdrill imply for calibrated stapedotomy on inner ear function, in the early follow-up peri-od, its transient depression is evaluated [29].

Table 3. Efficacy of different stapes surgery	techniques in patients with TSC
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A	V	C		Follow-up	Efficacy (ABG	BC increase >
Authors	Year	Surgery techniques	n	period duration	<20 dB)	10-20 dB
		F.2				

Sheehy J., Crabtree	1973	Stapedectomy	32	6 yrs	60%	deafness in
J.	1975	stapedectomy	32	0 yrs	00%	6.3%
Kinney S.	1978	Mobilization Stapedectomy	60			8%
Killiey 5.	1970		00	-	-	26%
Gormley P.	10.97	Piston method	6	5	720/	deafness ir
Gornney P.	1987	Stapedectomy	61	5 yrs	72%	4.5%
T ) (	1000	Mobilization Stapedectomy	72	1 15	60%	
Tos M. et al.	1990		73	1-15 yrs	25%	-
Gidding N., House		Mobilization	102	~	<10 dB 45%	
J.	1992	Stapedectomy	40	5 yrs	< 20 dB 72%	-
Teufert K., De La		Mobilization Stapedectomy	53		60-1	
Cruz A.	2002		20	0.5-1 yrs	60%	-
		Piston method	19		<10 dB 39%	
Vincent R. et al.	2002	Stapedectomy+TORP	45	0.5-7 yrs	< 20 dB 70%	8%
Berenholz L., Lippy		Piston method			<10 dB 20%	
W.	2004		10	1.5 yrs	< 20 dB 60%	-
		Mobilization Stapedotomy			30.8%	
Yang S. et al.	2005	Stapedectomy	119	0.5-5 yrs	62.5%	
0		- ,		-	43.1%	
	2007	Mobilization + PORP	5	4.3 yrs		
Yetiser S. et al.		Stapedectomy+TORP	7		33%	NA
		Mobilization	23		47.8%	
Kizilkaya Z. et al.	2008	Piston method	8	2 yrs	37.5%	NA
				,		
Al-Qahtani M.,	2008	Stapedectomy	8	0.5 yrs	87.5%	NA
Hagr A.	2000	Stupedectomy	0	0.5 yrs	0, 2, 10	1411
Çelik H. et al.	2008	Stapedotomy	8	0.5-10 yrs	65-71%	8%
çelik 11. et al.	2000	Stapedectomy+TORP	17	0.5 10 913	05 /1/0	0,0
Stankovic M.	2009	Stapedectomy	12	-	50%	NA
Chernushevich I.I.	2012	Piston method	26	3 mo-2 yrs	78%	
Cheffiushevieli I.I.	2012	Stapedectomy+TORP	9	3 III0~2 yIS	_	2
Querat C. et al.	2012	Piston method	20	0.5-3 yrs	50-67%	NA
		Stapedectomy+TORP	28		43-68%	INA
Querat O. et al.		Mobilization	38		50.9%	7.9%
-			•	3 yrs	71.4%	14.3%
Khorsandi-Ashtiani	2014	Stapedectomy+TORP	28	J y13	71.1/0	11.3 /0
-	2014	Stapedectomy+TORP	28 (66)	J y13	(63.6%)	(10.6%)

Yrs – years; mo – months; NA – data are not available.

Hearing loss treatment results insecurity in this pathology is common and occurs due to undertreated inflammatory processes and lack of blood supply. Most surgeons tell about de-crease in stapedoplasty functional results in TSC (from 50.3% in 6 months after surgery to 34.5% in 5 years) while increase in follow-up period duration [1,16,27]. Contrary, another data show good results even in long-term follow-up period, evidencing hearing improvement up to 10 years [2,15].



Our results are similar to these of stapedoplasty efficacy studies in patients with TSC. This type of technique is more safe when laser assistance and vestibular liquids isolation. How-ever, partial stapedectomy, with stapes autocartilage prosthesis application on venous graft in patients with TSC, results are significantly worse than these in otosclerosis patients; these data are evidenced by another study results, as well [23]. Our stapedoplasty with laser assistance re-sults in TSC patients do not show BC thresholds increase in 10-15 dB that is found in 81-83% otosclerosis patients [30,31].

### 5. Conclusions

In sum, to predict after-surgery cochlear complications after stapedoplasty in TSC pa-tients, it is necessary to notice undertreated inflammation conditions and to isolate vestibule by autotissue. Stapedoplasty with stapes autocartilage prosthesis application is effective with ABG decrease < 20 dB in 73.7% TSC patients. Laser assistance during stapes crus crossing stage and stapedotomy in the early follow-up period results in absence of inner ear reaction for surgery; moreover, ABG mean values decrease more rapidly than these during instrumental surgery technique.

#### Application of artificial intelligence:

The article is written without the use of artificial intelligence technologies.

Conflicts of Interest: The authors declare no conflict of interest.

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