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Original Article

Comparing the Quality of Life and Hearing Thresholds Following Stapedectomy Versus Laser Stapedotomy with NiTiBOND Piston

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BACKGROUND: The purpose of this study was to examine the quality of life (QoL) and hearing thresholds of patients who underwent 2 types of stapes surgery.

METHODS: A retrospective cohort study was performed comparing stapedotomy with NiTiBOND prostheses (n = 20) and stapedectomy with autogenous cortical bone columella (n = 20), applying the Glasgow Benefit Inventory (GBI) and the Hearing Handicap Inventory for Adults outcome measures with hearing thresholds. Univariate comparative statistical methods were applied.

RESULTS: The stapedotomy cohort had significantly better values of Social Support Score of the GBI as compared to the stapedectomy cohort ($P = .016$). No statistically significant difference was detected between the groups in the pre- and postoperative audiological results and the further QoL measures.

CONCLUSION: Apart from the excellent postoperative audiological results of the different types of stapes surgeries, stapedotomy with NiTiBOND prostheses seems to be superior as regards QoL over stapedectomy applying autogenous cortical bone columella.

KEYWORDS: Glasgow Benefit Inventory, Hearing Handicap Inventory for Adults, NiTiBOND, stapedectomy, stapes surgery

INTRODUCTION

Stapes fixation is a multicausal disease that may lead to conductive, sensorineural, or mixed type of hearing loss, depending on the localization of the otosclerotic foci. The first line of treatment is stapedotomy, with or without the application of laser; however, laser use on the piston may diminish the intraoperative forces and reduce trauma to the inner ear, allowing for manipulation in a bloodless environment and decreasing the duration of hospitalization.[1] The advantage of the NiTiBOND prosthesis is the heat-memory effect resulting in a hands-free fixation on the incus and the relatively easy maneuverability due to the daisy-shaped piston head. At the same time, the disadvantage is the price of the prosthesis. On the other hand, the advantage of stapedectomy with autogenous cortical bone columella is that the surgeon has immediate access to the prosthesis material, which is harvested from the skull; furthermore, the columella can be shaped in any size and provides good hearing results in the long term.[2] The disadvantage of this technique is the need to form the columella in 1 session instead of using a factory-made prosthesis. Beyond the successful surgery, patient-centered medicine should target the affected patient as a whole along with the treatment outcome of a disease. Therefore, measurements assessing patients' awareness of their health status have gained attention and become a critical indicator of therapeutic success.[3] The Glasgow Benefit Inventory (GBI) is a reliable tool measuring the outcome of surgical interventions in Otorhinolaryngology.[4] It monitors the changes in health status following surgery, including communal, psychological, and physical well-being. In a systematic review, Hendry et al[4] assessed 11 different types of ENT interventions, including stapes surgery, and

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concluded that GBI is a reliable tool for comparing various surgeries with different objectives.[4] On the other hand, the Hearing Handicap Inventory for Adults (HHIA) is a self-assessing questionnaire focusing on the effects of hearing loss.[5] The HHIA is a modified version of the Hearing Handicap Inventory for the Elderly and is suitable for hearing-impaired adults. It is a self-documented handicap measure that focuses on the social and emotional consequences of hearing impairment and can help to estimate the effects of hearing loss on the patients' lives.[5]

This study aimed to evaluate quality of life (QoL) measurements and compare the outcomes with the hearing results of patients who underwent stapedectomy to those who underwent stapedotomy with the application of autogenous bone columella or thermal shape memory NiTiBOND pistons.

MATERIAL AND METHODS

This is a retrospective cohort study, reported by the STROBE statement for cohort studies.[6] We reviewed the electronic medical records for all cases who underwent stapedotomy with the thermal-shape memory NiTiBOND piston or stapedectomy with autogenous cortical bone columella in a tertiary surgical center. Only primary cases were included; patients with chronic ear conditions, with revision surgeries, or cases with incomplete data were eliminated from the study. The daisy-shaped nickel–titanium alloy (nitinol) NiTiBOND prosthesis used measured 4.5 or 4.75 mm × 0.6 mm, following the measurement of the gap between the oval window and the lateral surface of the long process of the incus (Figure 1). The surgical technique was similar in each case.[1] During stapedectomy, autogenous cortical bone columella was harvested from the cortex of the temporal bone with a chisel and shaped to form a truncated triangle between the temporal fascia covering the oval window and the medial surface of the lenticular process. The incudal surface of the columella was grooved to fit the arc of the lenticular process. The cortical bone columella was kept in place by the elastic resistance of the temporal fascia covering the oval window and the lenticular process of the incus. These forces in opposite directions are responsible for fixing the columella[2] (Figure 2). Regarding the complaints, the postoperative period differed between the 2 groups, as on the first postoperative day, significantly fewer patients reported vertigo following stapedotomy, and the intensity of vertigo was markedly lower compared to the patients following stapedectomy.[7] No specific complication was observed in the groups postoperatively. The NiTiBOND prostheses were implanted between January 2012 and August 2014, and the stapedectomies were performed between October 2006 and December 2013. The questionnaires applied to assess the change in the QoL following the stapes surgeries were the GBI and the Hearing Handicap Inventory for Adults. Both questionnaires were validated in Hungarian language (validation code number: 6/2022). The GBI is a nonspecific patient-documented outcome measure that has gained general popularity in otolaryngology. The GBI is designed for postintervention assessment to measure change related to a distinct surgical or medical intervention. It has both positive and negative outcomes with the aim of being able to depict the rate of patients who benefited, did not benefit, or deteriorated following an intervention. Subscores can be used in specifying the fields of benefit and

Figure 1. NiTiBOND stapes prosthesis.

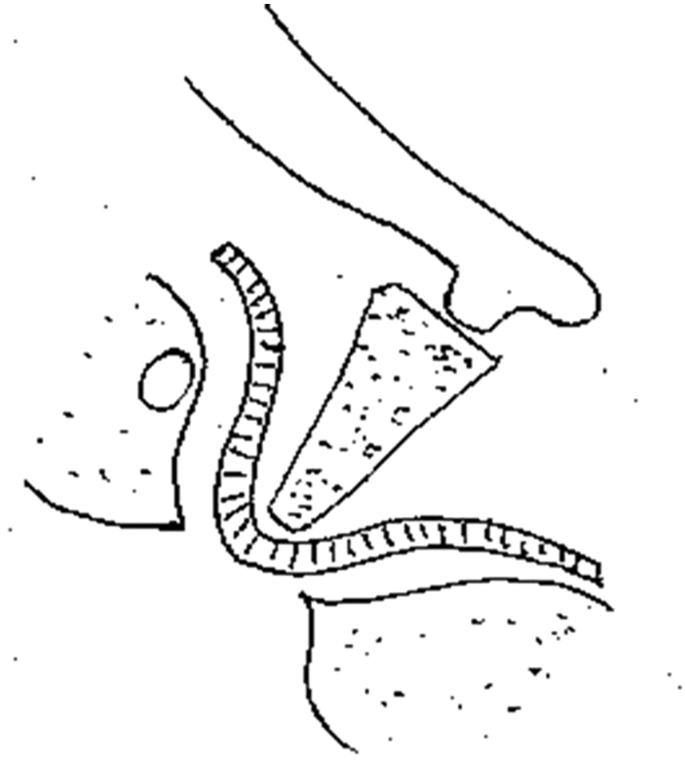

Figure 2. Schematic drawing of the autogenous cortical bone columella inserted between the long process of the incus and the temporal fascia covering the oval window (courtesy of M. Bauer).

MAIN POINTS

- Regardless of the surgical technique, improvement in hearing and QoL was observed following both types of stapes surgeries.
- The Social Support Score was significantly higher in the NiTiBOND group.
- The application of QoL questionnaires is advisable for patients undergoing stapes surgeries.

Table 1. Collected Glasgow Benefit Inventory Scores of the 2 Groups

	TS		GSS		SSS		PHS	
Group	**I**	**II**	**I**	**II**	**I**	**II**	**I**	**II**
Minimum	−27.78	−13.89	−45.83	−20.83	−16.67	−50	−66.67	−33.33
Maximum	72.22	25	95.83	79.17	66.67	50	50	33
Median	30.56	2.08	52.08	37.5	25	16.67	0	0
Average	32.36	22.22	46.04	32.92	25.83	10	5	0
SD	22.72	24.78	31.08	36.52	16.64	22.56	24.24	17.1

I = NiTiBOND group, II = Stapedectomy group.
GSS, General Subscale Score; PHS, Physical Health Score; SSS, Social Support Score; TS, Total Score.

comparing various interventions where the objective surgical results might seem similar.

Patients were contacted to fill in the questionnaires via email, via post, or personally. Besides the baseline values, results from the actual hearing assessments were also collected. The hearing results and the questionnaire scores were treated as continuous variables; the Mann–Whitney *U*-test and the Wilcoxon signed-rank test were applied for univariate analysis, and $P < .05$ was considered to be statistically significant software used: Statistical Package for the Social Sciences Statistics (SPSS) version 11.0, (SPSS Inc., Chicago, IL, USA). The study was approved by the Scientific and Research Ethics Committee of the Medical Research Council, the University of Pécs Medical School (Approval number: 9127-PTE 2022). All patients provided informed consent to the study.

Table 2. Distribution of Patients Following Surgery According to Hearing Handicap Inventory for Adults Severity Groups

HHIA groups		Total Score	Social Handicap	Emotional Handicap
No handicap (0%-16%) (No.)	I group	10	9	10
	II group	5	7	3
	Total	15	16	13
Mild-to-moderate handicap (18%-42%) (No.)	I group	6	8	5
	II group	8	8	9
	Total	14	16	14
Significant handicap (>44%) (No.)	I group	4	3	5
	II group	7	5	8
	Total	11	8	13

I = NiTiBOND group, II = Stapedectomy group
HHIA, Hearing Handicap Inventory for Adults.

RESULTS

Twenty-seven patients were with NiTiBOND (17 via email, 7 via post, and 3 appeared in person), and another 33 patients following stapedectomies (28 via email and 5 via post) were contacted to fill in the questionnaires. The response rates were 74% and 60.6% in the NiTiBOND and stapedectomy groups, respectively; so, 20 patients were included in each group. Female predominance was observed (14/20 and 13/20 patients, respectively), with a mean age of 45.1 years (range 22-62) and 42.1 years (range 20-54) in the groups, respectively. The elapsed time between the surgeries and the filling-in of the questionnaires was a median of 1.5 years (range 0.75-3.1 years) and 3.1 years (range 1.3-8.4 years, $P < .01$) in the NiTiBOND and in the stapedectomy groups, respectively. The median audiological follow-up was 4 months (range 0.5-31) and 13.7 months (range 0.5-81, $P = .012$) in the NiTiBOND and stapedectomy groups, respectively.

Table 1 summarizes the results of the comparison between the 2 groups by GBI results. A statistically significant difference, favoring the NiTiBOND group, was measured between the average values of the Social Support Score (SSS) of the 2 groups ($P = .016$), while the difference between the General Subscale Score (GSS) values ($P = .432$) and the Physical Health Score (PHS) values ($P = .312$) were not statistically significant. Table 2 demonstrates the distribution of patients following surgery by HHIA severity groups. Table 3 presents hearing values and intragroup statistical analysis. Table 4 presents the intergroup statistical analysis. No statistically significant difference was realized in the pre- and postoperative audiological results between

Table 3. Collected Hearing Values and Intragroup Statistical Analysis

Variables	NiTiBOND		*P*	Stapedectomy		*P*
	Preoperative	Postoperative		Preoperative	Postoperative	
Mean ABG, dB ± SD	23.5 ± 5.9	7.6 ± 5.3	<.001*	27.0 ± 9.5	11.3 ± 12.1	<.001*
Mean BC, dB ± SD	26.5 ± 7.8	22.4 ± 10.6	.035*	23.3 ± 8.4	23 ± 9.3	.856
Mean AC, dB ± SD	50 ± 8.6	30 ± 14.3	<.001*	50.3 ± 13.8	34.5 ± 16.8	.002*
Mean BC (1,2, and 4 kHz), dB ± SD	27.4 ± 9.8	23.8 ± 11.4	.067	23.8 ± 9.2	21.9 ± 11	.203
AC at 4 kHz, dB ± SD	50.2 ± 18.3	40.7 ± 18.2	.018*	52.7 ± 19.6	45 ± 21	.07

ABG, air–bone gap; AC, air conduction; BC, bone conduction; dB, decibels; kHz, kilohertz; SD, standard deviation.
*Significant difference.

Table 4. Collected Hearing Values and Intergroup Statistical Analysis

Variables	Preoperative		*P*	Postoperative		*P*
	NiTiBOND	Stapedectomy		NiTiBOND	Stapedectomy	
Mean ABG, dB ± SD	23.5 ± 5.9	27.0 ± 9.5	.290	7.6 ± 5.3	11.3 ± 12.1	.225
Mean BC, dB ± SD	26.5 ± 7.8	23.3 ± 8.4	.228	22.4 ± 10.6	23 ± 9.3	.424
Mean AC, dB ± SD	50 ± 8.6	50.3 ± 13.8	.871	30 ± 14.3	34.5 ± 16.8	.285
Mean BC (1,2, and 4 kHz), dB ± SD	27.4 ± 9.8	23.8 ± 9.2	.233	23.8 ± 11.4	21.9 ± 11	.725
AC at 4 kHz, dB ± SD	50.2 ± 18.3	52.7 ± 19.6	.785	40.7 ± 18.2	45 ± 21	.587

ABG, air–bone gap; AC, air conduction; BC, bone conduction; dB, decibels; kHz, kilohertz; SD, standard deviation.

the 2 cohorts. Figure 3 presents the values of the GBI subscales. Figure 4 displays the values of the HHIA subscales of the 2 groups.

DISCUSSION

Our paper is the first to compare stapedectomy with laser-assisted stapedotomy applying NiTiBOND piston in terms of QoL and audiological results. However, regardless of the surgical technique, improvement is observed following both types of stapes surgeries.

In our study, every subscale of the GBI demonstrates better improvement in QoL in the NiTiBOND group, and the HHIA indicates that the NiTiBOND cohort is least affected by the disadvantages of hearing loss. The presumable cause may be better postoperative pure-tone threshold results, the less invasive surgical approach, milder postoperative vertigo, and decreased period of hospitalization.[1] The GBI subscale values demonstrate unequivocal improvement regarding the GSS and SSS categories in both groups, while the PHS was the least affected by the 2 types of stapes surgeries. Comparing the results of the 2 groups, the SSS demonstrated significantly better results in the NiTiBOND group compared to the stapedectomy group. We assume that the slightly better hearing thresholds measured in the stapedotomy cohort might be responsible for the significantly better SSS results, as patients' social QoL relies on their ability to communicate effectively. Significant improvement in QoL was reported by Lailach et al[8] in a group of 23 patients following stapes surgery by applying a disease-specific questionnaire, SPOT-25, along the GBI and the HHIA. Deterioration in QoL (TS <0) was detectable in only 6 cases (15%) out of 40 patients included in this study, and 34 patients (85%) reported improvement in their QoL.

The authors note that hearing thresholds were not correlated with physical or mental health outcomes; furthermore, hearing loss is associated with depression, anxiety, and social restrictions.[9,10] Although QoL questionnaires are subjective, they are essential indicators of therapeutic success by providing data about the patient's self-documented health status. From the patient's point of view, surgery is successful when it improves QoL in their everyday activities. Therefore, it is necessary to acquire the patient's subjective impression of the surgical intervention in addition to the audiometric data. Healthcare providers can benefit from the results of self-reports by identifying issues in their patients' lives that are not revealed in postoperative audiometric data.

Limitations of our study are the small number of retrospective cases, the application of univariate analysis, and the differences between the elapsed time among the surgeries and the filling in of the questionnaires and between the audiological follow-up periods. Strengths include the use of both specific and generic validated quality-of-life questionnaires supported by audiological results of well-documented consecutive cases with thorough statistics.

Regardless of the surgical technique, improvement in hearing and QoL was observed following both stapedectomies with autogenous

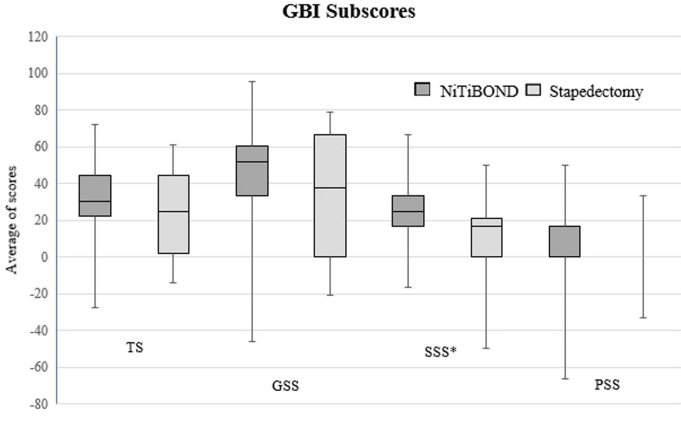

Figure 3. Box plot demonstrating the values of the 2 groups by Glasgow Benefit Inventory results. *Indicates a statistically significant difference. GSS, General Subscale Score; PHS, Physical Health Score; SSS, Social Support Score; TS, Total Score.

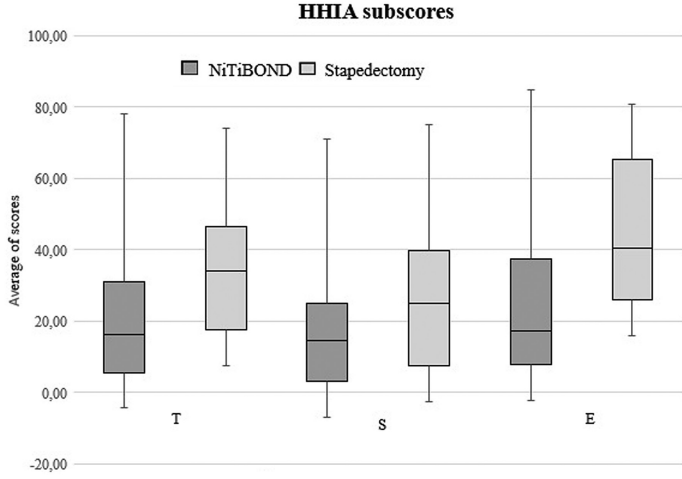

Figure 4. Box plot demonstrating the values of the 2 groups by Hearing Handicap Inventory for Adults results. E, Emotional HHIA, Hearing Handicap Inventory for Adults; S, Social; T, Total.

cortical bone columella and stapedotomies with NiTiBOND heat-memory prostheses. Concerning the QoL measures, stapedotomy with NiTiBOND piston resulted in a significantly better SSS compared to the stapedectomy with bone columella. Based on our findings, we encourage the use of self-assessing questionnaires to improve the validity of audiological outcomes.

Ethics Committee Approval: This study was approved by the Scientific and Research Ethics Committee of the Medical Research Council, University of Pécs, Hungary (Approval Number: 9127 - PTE 2022).

Informed Consent: Informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

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