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Outcome of Ossiculoplasty with Using Autologous Cartilage Graft and Artificial Prosthesis - A Comparative Study

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Abstract **Original Research Article**

Background: The surgical practice of ossiculoplasty rebuilds the ossicular chain for hearing improvement in sufferers with conductive hearing loss caused by ossicular damage. ***Objective:*** The purpose of this prospective comparative study is to study the performance outcomes between autologous cartilage grafts and artificial prostheses within ossiculoplasty surgery. ***Methodology:*** During the period from July 2014 through June 2016 at Sir Salimullah Medical College and Mitford Hospital in Dhaka the study selected 100 patients before dividing them into two equivalent groups. The patients in Group A received ossiculoplasty with autologous cartilage grafts yet Group B recipients received Teflon (PORP, TORP) artificial prostheses. ***Results:*** The assessed air-bone gap decreased substantially following surgery according to both pre- and post-operative audiometric tests among the study groups. The hearing improvement measured 13.8±2.1 dB for Group A and Group B reached 11.4±1.4 dB as their average hearing gain. Research confirmed that Group A achieved 84% success while Group B reached 76% success. These results included minimal discomfort as well as ear discharge in both groups. ***Conclusion:*** This research shows that autologous cartilages produce slightly superior hearing results than cavities made with artificial prostheses. The selection of surgical procedures requires evaluation of endurance patient choice and practitioner skill level. The research team should conduct additional studies involving bigger participant groups and extended observation periods.

Keywords: Keywords: Ossiculoplasty, Autologous Cartilage Graft, Artificial Prosthesis, Teflon PORP, Conductive Hearing Loss, Air-Bone Gap, Middle Ear Reconstruction, Hearing Improvement, Otologic Surgery, Post-Operative Outcomes.

INTRODUCTION

Ossiculoplasty or ossicular chain reconstruction (OSR) is associated with a surgical procedure that repairs the tiny bones in the middle ear, known as ossicles, and improves hearing [1]. The environmental vibrations are transmitted to the inner ear from the tympanic membrane via the ossicular chain. The ossicular flow and chain dynamics interfere with hearing quality [2]. Chronic Otis Media (COM), severe ear infections, Cholesteatoma, Otosclerosis, trauma, aging, and sound pollution can cause damage to the ossicles, and any degree of hearing impairment can occur [3,4]. According to WHO grades of hearing impairment, the Corresponding audiometric

ISO value = 25dB or better is considered as no impairment, 26-40dB is slight impairment, 41-60dB is moderate impairment, 61-80dB is classified as severe impairment and >81dB is graded as profound impairment or deafness [5]. In 2024, WHO reported that 5% of the world's population is suffering from loss of hearing [6]. 13.3% of Bangladeshi patients are suffering from some sort of hearing impairment, and 9.6% among them are experiencing with deafness [7]. Ossiculoplasty using an autologous cartilage graft is a surgical technique where the surgeon reconstructs the ossicular chain by using a piece of cartilage extracted from the patient's own body [8]. In 1971, autologous cartilage was the first material used in this procedure [9]. In Bangladesh, ossiculoplasty uses autologous cartilage grafts and artificial prosthesis; both are potential surgeries for reconstructing the ossicular chain. Unlike the artificial prosthesis, the autologous cartilage ossiculoplasty process needs to extract any cartilage from own body. A synthetic implant, like a titanium or hydroxyapatite piece is used to reconstruct the middle ear in this surgery [10]. This study revolves around finding the outcome of ossiculoplasty using autologous cartilage graft and artificial prosthesis in patients with other related factors.

METHODOLOGY

This is a prospective comparative study that took place in the department of Otolaryngology & Head Neck Surgery, Sir Salimullah Medical College and Mitford Hospital, Dhaka in a timeline of July 2014 to June 2016. A total of 100 patients underwent this study with proper consent. Patients were divided into two study groups where Group A patients were chosen based on ossiculoplasty using autologous cartilage graft (n=50) and Group B contained patients who underwent Ossiculoplasty using artificial prosthesis (n=50). Being a prospective study, no treatments were suggested to the patients from the research team to avoid bias in the study. All patients were enrolled in this study by satisfying some specific inclusion and exclusion criteria.

Inclusion Criteria

i. Patient aged 18 years or above.
ii. A history of conductive hearing loss due to ossicular chain defect.
iii. Patient with no prior middle ear surgery.
iv. Patients with written informed consent.

Exclusion Criteria

i. Child or adolescent patient (Age<18 years).
ii. A history of sensorineural hearing loss.
iii. Active ear infections or severe perforation in the tympanic membrane.
iv. Lack of informed consent.

A study-specific case report form (CRF) was developed for data collection, and all study subjects were followed up on 6 months of post-operation. MS Excel and the Statistical Package for Social Sciences (SPSS) version 20.0 were the prime data analysis tools for this study. A P-value>0.05 is considered significant in a 95% confidence interval.

RESULTS

This is a male-dominant study. A sum of 100 patients participated in this study with 57 male participants and 43 female. The mean age of the patients was 38.5±4.8 with an age ranging from 21 to 51 years.

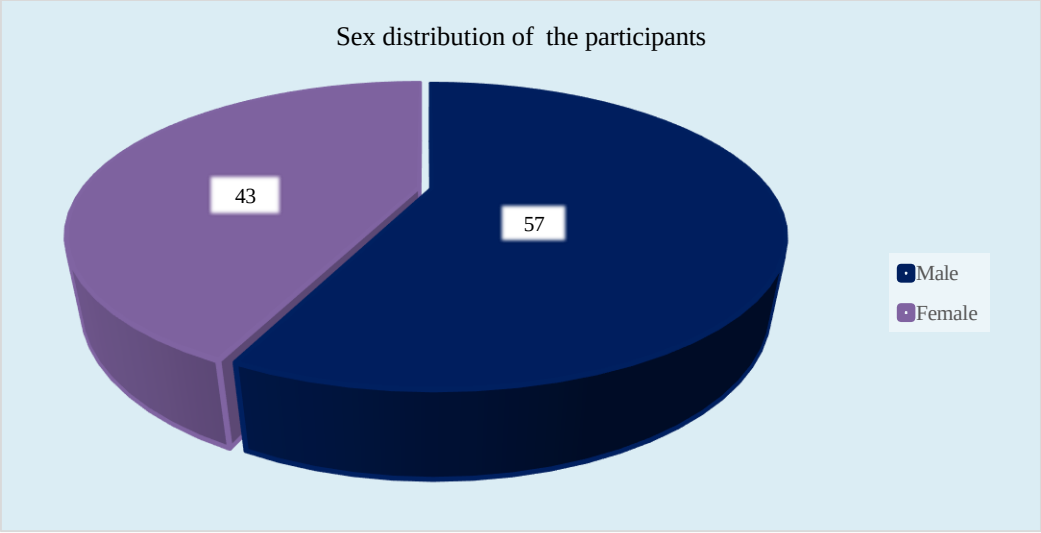

Figure I: Pie chart showed sex wise patients' distribution (N=100)

Table 01: Distribution of Patients; Age

Age (in years)	Number	Percentage
10-20 Yrs.	0	0.0

Age (in years)	Number	Percentage
21-30 Yrs.	60	60.0
31-40 Yrs.	36	36.0
41-50 Yrs.	2	2.0
50-60 Yrs.	2	2.0
Mean±SD	38.5±4.8	
Range (min, max)	21, 51	

The occupational status of respondents shows that the majority 24.0% of patients were students followed by 23.0% daily labor, 23.0% were housewives, 10.0% were service holders, 12.0% were businessmen and 8.0% were farmers.

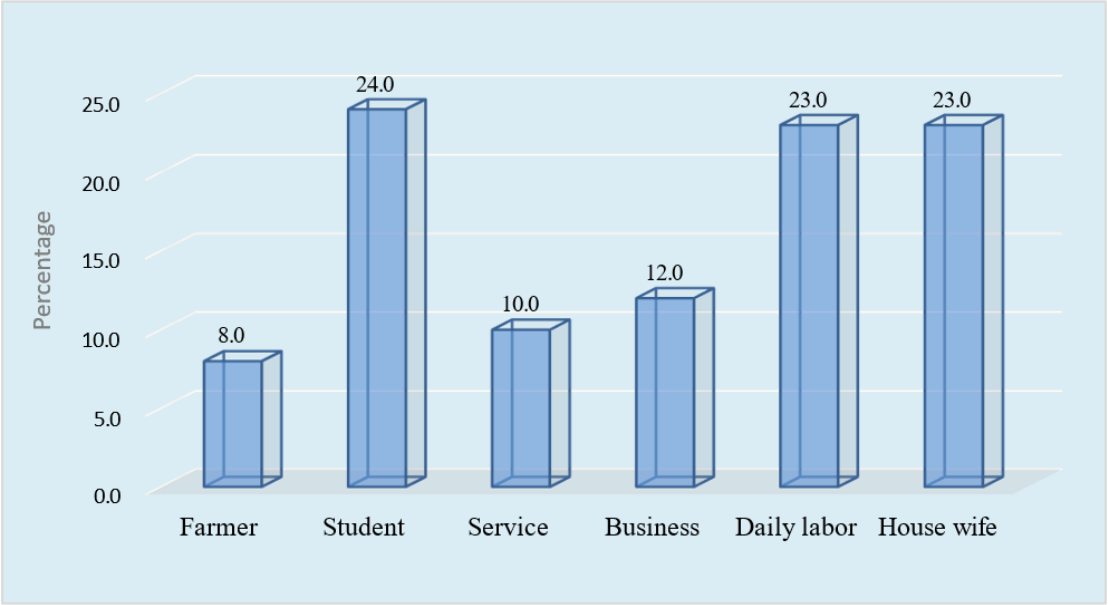

Figure II: Column chart showed occupational status wise patients' distribution (N=100)

Patient socio-economic background data revealed that half (50.0%) of the patients came from lower-middle-class families, 34.0% from middle-class families, and 16.0% from upper-middle-class families.

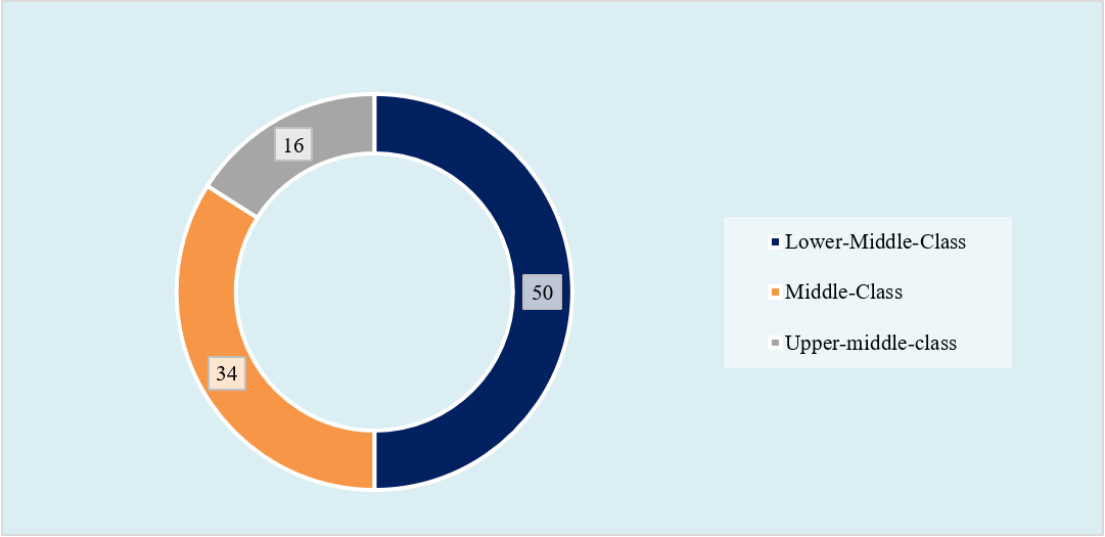

Figure III: Ring chart showed distribution of patients; Socio-economic background (N=100)

Table 02: Pre-operative and post-operative hearing status of patients (Group-A)

Pure tone audiometry (PTA)	Pre-operative	Post-Operative	ABG difference Hearing Gain	P-value
Air-bone gap (dB)	32.1±8.0	18.3±5.9	13.8±2.1	0.001

We can see a significant reduction in the ABG of the patients of group-A after surgery (P=0.001).

Table 03: Pre-operative & post-operative hearing status of patients (Group-B)

Pure tone audiometry (PTA)	Pre-operative	Post-Operative	ABG difference Hearing Gain	P-value
Air-bone gap (dB)	30.7±11.2	19.3±9.8	11.4±1.4	0.019

Pre-operative audiometry data shows that all study patients of the autologous cartilage group have a positive significant reduction in their air-bone gap reduction (P<0.05).

Table 04: Comparison of Success and failure rates between groups (After 6 months of operation)

Pure Tone Audiometry (PTA)	Group A N=50	Group B N=50	P value
Success (PTA dB)	N=42; 84%	N=38; 76%	0.039
Failure (PTA dB)	N=8; 16%	N=12; 24%	

Table 04 compares the success and failure rates of both procedures and the success rate is significantly visible with ossiculoplasty using an autologous cartilage graft (P<0.05).

Post-operative complications were assessed carefully for both groups of patients. No major complication was recorded in this study. Majorities of the patients suffer from discharge and pain.

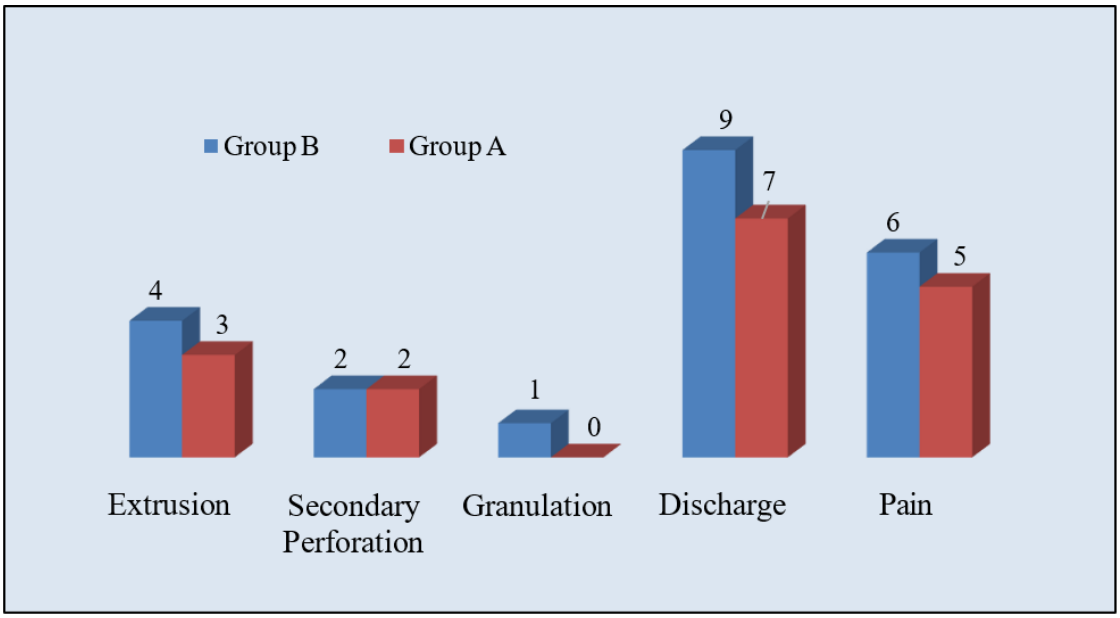

Figure III: Ring chart showed comparison of postoperative complications among groups (N=100)

DISCUSSION

A prospective comparative two-year study on ossiculoplasty replicates the advantages and disadvantages of both autologous cartilage and artificial prosthesis reconstruction of the ossicular chain. This study portrays that most of the study subjects requiring ossiculoplasty for middle ear problems in Bangladesh are male. Another related Bangladeshi study also replicates a similar result with 60% of male participants with similar age group data to our research [11]. A 2021 study on Iran also ended 53.7% of male subjects [12] which implies that male subjects are more susceptible to getting affected by middle ear disease. The patient age range was 21 to 51 with a mean age of 38.5±4.8 for this study. The Iran-based study here shares different results with the 18-58 years of age range; the mean age is 44.21±10.57 [12]. The demographic profile of patients states that the majority of the patients are students (24%) and the second most dominating groups are daily laborers (23%)

and housewives (23%). A recent meta-analysis result shows that 19% of college students are suffering from hearing loss at the age of 17–35 years. Among them, 85% of students are musicians and are exposed to loud sounds in daily life [13]. The daily labor group includes construction workers, garment workers, factory workers, etc. who have to work in a noisy environment in daily life. 76.7% of Bangladeshi workers from Tangail reported self-assessed hearing issues in a 2018 study [14]. Connecting the statistics with socio-economic data, we can see half of the study subjects belong to lower-middle class backgrounds or labor class. Only 16% of our study subjects belong to the upper class which can draw a statement that due to the daily life hustle, most of the study subjects here are troubled with ossicular chain errors. Clinically significant Air Bone Gap (ABG) is observed among patients in both groups. In group A, patients recovered their ABG to 13.8±2.1 dB whereas in group B, the Air Bone gap was minimized to 11.4±1.4 dB. Both reductions are clinically significant according to the study standard ($P<0.05$). A similar study shows the pre-operative ABG reduction to 23.3±10 dB from 37.9±8.9 dB in cartilage ossiculoplasty [15]. Some other studies also resemble our results in their study with ABG reduction to 21± 4.66 from in cartilage ossiculoplasty and 43.0±4.48 dB to 36.3±5.56 dB with artificial prosthesis (Teflon) ossiculoplasty [14]. A 2018 study about bone versus cartilage ossiculoplasty shared an interesting fact that clinically, bone ossiculoplasty is superior to cartilage in terms of hearing improvement [16]. The overall success rate in Group A is 84% and in Group B is 76%. Both groups share a notable failure rate, at 16% and 24%, respectively. Sharma T. *et al.*, 2017 share a similar result to our study; they observed 60% success in the cartilage group and 55% in the Teflon prosthesis group [17]. The basic analogy in both studies is that the failure rate is also significant here. Some unavoidable complications were also recorded. 7 patients from Group A and 9 patients from Group B suffered from post-operative ear discharge. Pain is observed in 6 patients from Group A and 5 patients from Group B. Other complications were extrusion, secondary perforation, and granulation. Previous studies also shared similar complications to their studies with ossiculoplasty using autologous cartilage graft and Prosthesis [18].

LIMITATION

This study was conducted with limited randomization options. Only 6 monthly follow-ups after surgery cannot completely manifest the outcome. Long-term follow-up could add extra value to this study. Moreover, it is a single-center study. The multi-centered study has the benefit of replicating better outcomes with patients from multiple regions.

CONCLUSION

Ossiculoplasty is an effective operating technique to restore hearing to patients with ossicular chain damage. This comparative study shows that both of the study groups; ossiculoplasty with using autologous cartilage graft and artificial prosthesis have a potential improvement capability to improve hearing outcomes. The success rates for air-bone gap reduction proved slightly better in patients who received autologous cartilage than those who received artificial prostheses. Post-operative complications included ear discharge and pain despite the implementation of these surgical procedures. The selection process for surgical procedures should be patient-centric because it requires considering individual treatment needs combined with access to grafts and the medical staff's experience. Additional long-term investigations must examine the durability and performance stability of these surgical operations throughout the entire treatment period.

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