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OSSICULOPLASTY WITH AUTOLOGOUS CARTILAGE VERSUS TEFLON PROSTHESIS: A COMPARISON OF ANATOMICAL AND FUNCTIONAL RESULTS.

ENT

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ABSTRACT

Objective : To determine between autologous cartilage and Teflon, the one which gives the better results of ossiculoplasty, in terms of increase in hearing sensitivity, acceptability and cost effectiveness.

This is a randomized prospective study with 6 months follow up. 40 patients of CSOM were randomly assigned for ossiculoplasty using Teflon and cartilage (20 in each group).Surgical outcome was compared in terms of increase in hearing sensitivity, extrusion rate and cost effectiveness.

Results: Mean hearing gain (closure in A-B gap) was 22.35±6.69 dB in cartilage and 20.35±6.67 dB in Teflon. Extrusion rate was 2 and 1 for Teflon and cartilage respectively.

Conclusion: The study concluded that there is no significant difference in improvement in AB gap and extrusion rate though cartilage is slightly better. The only significant difference between the two groups was the cost effectiveness as the autologous material requires no extra cost so it can be considered as a preferred choice of implant, in comparison to biomaterial in SAARC countries, where the majority is of poor patients.

KEYWORDS

Chronic Suppurative Otitis Media, Ossiculoplasty, Autologous Cartilage, Teflon.

Introduction :

Chronic Suppurative Otitis Media (CSOM) is a very common disease in the developing countries especially in our country affecting mainly the younger population. Various factors like socioeconomic condition, over-crowding, lack of concern about hygiene, poverty, illiteracy etc. contribute much towards the occurrence of this disease.

The audiological impairment is very distressing to the patients even if recurrent otorrhea ceases. To improve upon the hearing and to check the recurrence, tympanoplasty surgery came into existence.

Ossiculoplasty is defined as the reconstruction of the ossicular chain. The ideal prosthesis for ossicular reconstruction should be biocompatible, stable, safe, easily insertable, and capable of yielding optimal sound transmission.

In the present study, we compared Teflon and autologous cartilage, the one which gives the better results of ossiculoplasty, in terms of increase in hearing sensitivity, extrusion rate as well as cost effectiveness.

Aim of the study:

1. To determine amongst Teflon and autologous cartilage, the one which give the best results of ossiculoplasty, in terms of increase in hearing sensitivity and cost effectiveness.

Material and Methods:

Study design and Setting-- This Randomized prospective crossover study was carried in the Department of E.N.T. Hind Institute of Medical Sciences, Barabanki in 40 patients of chronic suppurative otitis media (CSOM) with conductive hearing loss and ossicular chain discontinuity.

Study period-- The duration of the study was around **32** months including observational study of **6** months for each case.

Sample size-- 40 patients from outpatient department of ENT. Hind Institute of Medical Sciences, Barabanki (20 patients for each implant material).

Procedure—All cases of chronic otitis media with conductive hearing loss, with suspected ossicular chain discontinuity, (after diagnosing by Pure tone audiometry and otomicroscopy), were taken up for surgery. In all cases of ossicular discontinuity, ossiculoplasty was done by randomly selected cartilage or Teflon.

1- Cartilage ossiculoplasty: Conchal/Tragal cartilage was used for covering ossicular discontinuity depending upon the necrosis present in various ossicles. The necrosed ossicles were removed and the harvested cartilage was placed in the gap, maintaining the continuity. The perforation was covered with temporalis fascia graft.

2- Teflon implant: The standard sized PORP and TORP were used to gap the defect.

a- PORP—Partial ossicular replacement prosthesis

b- TORP-- Total ossicular replacement prosthesis

In cases where Teflon were used , after placing the implant, a thin strip of conchal cartilage is freshened with the use of cartilage slicer (From Kalelker Surgicals, model no. 27.Q01.3S) **(Fig. 1,2)** of varying thickness ranging from 0.1 to 0.3 mm and is placed over the implant to lower the extrusion rate.

All cases were performed using a post aural approach and standard technique of ossiculoplasty. After the surgery, every patient was followed for next 6 months.

Pre-operatively all patients had a pure tone audiogram calculated for both air conduction and bone conduction. Post-operatively, pure tone audiogram was performed finally at 6th month of follow-up.

Hearing results were assessed by comparing pre-operative and post-operative pure tone averages as well as closure of the air-bone gap. Extrusion rates and complications were also assessed till 6 months of follow up.

Inclusion criteria—

1. Cases of chronic otitis media inactive mucosal disease with pure conductive hearing loss.
2. Both males and females in the age group of 10-55 years were included in the study.

Exclusion criteria–

1. Patient with sensorineural hearing loss.
2. Chronic suppurative otitis media squamosal disease with or without complications.
3. Patients below 10 years and above 55 years were excluded from the study.
4. Discharging ear, previous history of ear surgery, otitis externa.
5. Comorbid systemic diseases like hypertension, diabetes, or any chronic infection were excluded from study.

Statistical Tools Employed—

The following Statistical formulas were used to analyze the data: *Mean*
Standard Deviation
Chi square test
Student 't' test

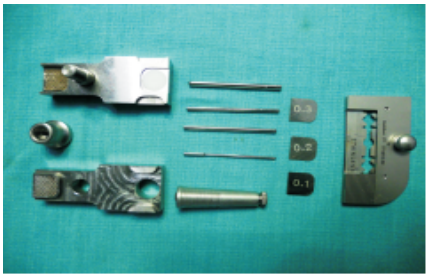

Fig.1 Cartilage Slicer(Used for reshaping cartilage)

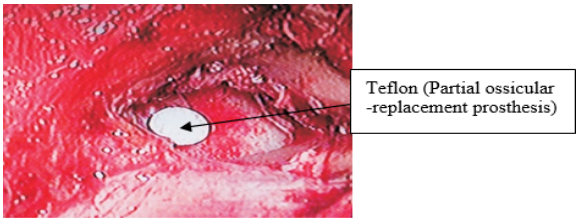

Fig.2 Teflon Partial ossicular replacement prosthesis. {X 10}

Results:

A) Mean hearing gain (closure in A-B gap)–
1-Cartilage implant- 22.35±6.69 dB.
2-Teflon implant-20.35±6.67 dB.

B) Hearing Success Rate –
It indicates, total no. of patients, whose postoperative AB Gap calculated by an audiogram at 6 months of follow-up , is equal to or less than 20 dB.

In the present study the overall hearing success rate at follow up period of 6 months is **78.8%.(** For cartilage implant it is 80% and for teflon it is 75%.)

C) Extrusion Rate -- Extrusion rate was 2 and 1 for Teflon and cartilage respectively.

D) Comparison of Cost of Implant – The cost of Teflon implant was 600 INR.

In Autologous Group- Cartilage, no cost was incurred on implant
Statistically, there was no significant difference between two groups in terms of hearing gain, hearing success rate and extrusion rate, but the difference of cost between two groups was significant.

Discussion:

Chronic suppurative otitis media often ends up in the breach in conductive chain of the middle ear leading to conductive deafness. The breach in conductive chain calls for rehabilitation of patient through prosthesis. Ossiculoplasty is the surgical treatment. It has been over 50 years since the use of implants has been started in the ossiculoplasty[1].

Although, autologous and biomaterial implants, both are in practice, yet it is always of interest to find out innovative use of materials other than those being conventionally used. Silicon implants have been successfully used in rhinoplasty[2,3]. The prospects of silicon implants in jaw surgery and innovative areas has been proposed as long back as 1963[4].Although autologous implants such as Bone and Cartilage are used extensively for ossiculoplasty, the use of biomaterials such as Teflon is also in practice since long. Use of Teflon has been reported in literature for as long back as 1962 when Austin for the first time reported their use. However, use of silicon implants in ossiculoplasty is rarely reported because of high extrusion rate.[5].

A host of biomaterials have been used including vinyl-acryl, polyethylene[6],PTFE/Teflon[7], Stainless steel[8], Proplast,Plastipore[9] ,Aluminium oxide ceramic, Ceravital[10] , Hydroxyapatite[11,12],Bioglass[13], Carbon[14] and have shown to be comparable results in terms of change in hearing status. The acceptability and extrusion rates in these materials were ranged from as low as 1.3% to 30%[15,16]. In the present study, both autograft and biomaterial behave equally well in ossiculoplasty[17,18]. Biomaterials need to be reserved for cases in which autologous implants are in short supply.

As compared to autografts which cost nothing, the minimum cost of Teflon prosthesis is around Rs 600/. Considering the relatively comparable success rates of biomaterials it was an option to be tried in order to provide an affordable option to the patients. It is pertinent to mention here that despite the economic and technological growth, India still has a large section of population who find it difficult to make their ends meet. For them affording a prosthesis that costs Rs 600/- is unacceptable when they find that they can get the autologous implant free of cost.

Conclusion:

In our study, there is no statistically significant difference in terms of improvement in Air bone gap, extrusion rate of implants and overall success rate between teflon and autologous cartilage. The only significant difference between the two groups was the cost effectiveness. The autologous material requires no extra cost so it can be considered as a preferred choice of implant, in comparison to biomaterial in our setup, where the majority is of poor patients. The role of biomaterial is only recommended for use, in places where the autologous implant could not be harvested for some reason (revision surgery).

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