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ORIGINAL ARTICLE

Functional results in ossiculoplasty with different titanium prostheses

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KEYWORDS

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Abstract *Background:* Titanium prostheses provide functionally promising results after reconstruction. Additional designs are created to improve and facilitate the surgical technique.

Objectives: To compare the functional results in patients receiving classic and Vario® titanium prostheses for ossicular reconstruction and to document the amount of time required to prepare both prostheses.

Study design: Prospective randomized comparative study.

Patients and methods: 16 Patients underwent ossiculoplasty. The first group received the classical titanium prosthesis ($n = 8$), and the second group received the Vario® titanium prosthesis ($n = 8$). Three patients underwent primary ossicular reconstruction after trauma and 13 underwent second stage reconstruction after tympanoplasty.

Results: Audiological assessment at 12 months revealed a significant improvement ($p < 0.0001$) in air-bone gap (ABG), in each group separately, with an average improvement by 21 dB in the classical, and 25 dB in the Vario® titanium groups. However, there was no significant difference in improvement of the ABG between both groups. Closure of the average postoperative air bone gap within 20 dB or less was considered a successful hearing result and this was achieved in 83% (10/12) of cases in the classical group, 75% (6/8) of cases in the Vario® group and in 80% (16/20) in both groups.

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Conclusion: Ossiculoplasty using either the classic or Vario titanium prosthesis showed a significant improvement in hearing. The classical titanium prothesis is preferred over the adjustable Vario® type as the latter proves to be time consuming for intraoperative shaping and trimming rendering it to be not cost effective.

1. Introduction

Reconstruction of a disrupted ossicular chain and restoration of sound transmission are one of the most delicate tasks to achieve in otologic surgery.[1] Over 60% of cases with chronic otitis media are reported to have ossicular involvement; therefore the need for ossiculoplasty is compulsory.[2]

Many types of prostheses are available, including alloplastic, auto graft, and homograft prostheses, which have been used with variable success. The ideal ossicular prosthesis should be manageable, versatile, biocompatible and stable over time.[3,4]

Titanium (Ti) is an excellent biocompatible material. It proved to be a suitable material for ossicular reconstruction because of its biostability and low ferromagneticity.[5–8] Titanium is light and strong, allowing versatility in the prosthetic design; thus the prosthesis can be thin and yet rigid making it a good sound conductor.[9] All the current designs have an open head plate rather than a solid plate, to allow observation of the stem of the prosthesis with an accurate placement.

The aim of the present study was to compare the functional hearing results of two different types of titanium implants: the classic fixed length Kurz (Kurz GmbH, DuBlingen, Germany) titanium prosthesis, available as partial ossicular replacement prosthesis (Bell, PORP), or total ossicular replacement prosthesis (Aerial, TORP); second, a Tuebingen titanium prosthesis Vario® (TTP-Vario®) whether partial or total with an adjustable length. The Vario® model can be modified intraoperatively to the required length in steps down to 0.25 mm using the TTP-Vario® instrument. Secondary outcomes included the documentation of the surgical-handling attributes of both prostheses, regarding timing of preparation, ease of handling, adjustment and placement.

2. Materials and methods

In the period from June 2007 till March 2008, 16 patients undergoing ossiculoplasty in the Otolaryngology department, Ain Shams University, Cairo, Egypt, were included. The study was approved by the institutional review board of the University.

All patients had titanium prostheses placed during surgery. The patients were randomly assigned into two groups according to the type of prosthesis used (Fig. 1). In the first group (A), the Kurz (Kurz GmbH, Dublingen, Germany) with classical fixed length, titanium prosthesis, available in different lengths was used. In the second group (B) the Tuebingen titanium prosthesis Vario® (TTP-Vario®) with adjustable length was used (Tables 1–3). We only included patients with traumatic ossicular disruption and second stage ossiculoplasty after tympanomastoidectomy.

Patients' data, operative details and audiological evaluation were collected. For the fixed length prostheses, the most approximate prosthesis length was used (total ossicular replacement prosthesis = TORP or partial ossicular replacement prosthesis = PORP according to the ossicular status). For the Vario® group, the prosthesis was accurately fashioned after measurement. A piece of tragal cartilage was routinely placed between the tympanic membrane and the head of the prosthesis. The tympanomeatal flap was slightly tented by the cartilage and prosthesis to ensure a firm columella effect.

2.1. Data analysis

Endpoint analysis was evaluated for audiological results, extrusion rate, average operative time and ease of surgical procedure. The success rate in relation to the surgical technique and the type of prosthesis whether partial or total were also documented. Preoperative and postoperative audiograms, done one year after surgery, were obtained and compared in all patients. Results are reported according to the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) committee on hearing and equilibrium guidelines for the evaluation of conductive hearing loss treatment results.[10] Threshold frequencies of 0.5, 1, 2, and 3 kHz were used. Mean differences in threshold were calculated for air and bone conduction and air-bone gap (ABG). A successful functional result was defined as a postoperative ABG of 20 dB or less. The data were therefore analyzed with regard to the type of the material (classic Kurz and Vario®), type of prosthesis

Table 1 Audiological data preoperative and postoperative of all patients.

			Percentage						
Air bone gap (dB) 0.5, 1, 2, and 3 kHz	Mean	SD	< 0	1–10	11–20	21–30	31–40	41–50	50 +
Pre-operative AC	38.7	4.8265	0	0	0	7	68	25	0
Post-operative AC	15.9	7.219	0	25	56	13	6	0	0
			Percentage change						
			dB better				dB worse		
Change (negative values indicate better hearing)			< −30	−29 to −20	−19 −10				
Air conduction (dB) 0.5, 1, 2, and 3 kHz	22.4375	6.772186	4	7	5				