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Author manuscript

*Laryngoscope*. Author manuscript; available in PMC 2019 September 01.

Published in final edited form as:

*Laryngoscope*. 2018 September ; 128(9): 2153–2156. doi:10.1002/lary.27128.

## Osseointegrated Implants for Auricular Prostheses: An Alternative to Autologous Repair

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### Abstract

**Objectives**—This study compares the hospital cost of osseointegrated implants for retention of an auricular prosthesis to autologous ear reconstruction.

**Methods**—This retrospective review includes patients who underwent reconstruction for either congenital or acquired ear defects at Duke University Medical Center during 2009–2015.

**Results**—A total of 9 patients had autologous repair representing 9 operative ears and 16 patients had an osseointegrated implant representing 18 operative ears (2 bilateral). The average age for the autologous repair was 11.6 years with 56% male vs 40.7 years with 56% male for the osseointegrated implant patients. For autologous patients, indications for surgery were anotia/microtia in 8/9 (89%) and trauma in 1/9 (11%) vs 6/16 (387.5%) anotia/microtia, 8/16 (50%) cancer, and 2/16 (132.5%) trauma in the osseointegrated implant group. The mean number of surgeries was 3.1 for autologous repairs and 1.0 for osseointegrated repairs (mean difference CI –2.4 to –1.8 P <0.001). The average cost to the hospital for an osseointegrated repair was \$6491.39 vs \$10047.93 for autologous repairs (CI –\$6496.38 to \$–616.68, P = 0.02)

**Conclusions**—Osseointegrated implants for retaining an auricular prosthesis has a similar cost to autologous repair of ear defects, but patients underwent an average of 2 more surgeries with autologous repair. Patients should be able to choose the reconstruction option that best suits their condition and preferences.

### Keywords

osseointegration; auricular prosthesis; anotia; microtia

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**Financial Disclosures:** There are no relevant financial disclosures to report.

**Conflicts of Interest:** There are no relevant conflicts of interest to report.

## Introduction

As many as 1 in 2,000 children are born with external ear defects including anotia and microtia.<sup>1</sup> Hispanics, Native Americans and Asians have a 2 to 3-fold increased risk of being born with these defects.<sup>2</sup> Children with microtia and their parents have significantly more social and mental health problems,<sup>3</sup> but these problems can improve after ear reconstruction.<sup>4</sup> In addition to the significant aesthetic and psychosocial challenge of a congenital external ear defects, 90% of are associated with hearing loss that also requires treatment.<sup>5</sup> Auricular defects can also be acquired through trauma or cancer resection. Regardless of the cause of the defect, these individuals benefit from surgical repair, as well as hearing rehabilitation to improve aesthetics and function.

Traditionally these defects have been treated with complex reconstructions that require 3–4 separate surgeries using autologous tissue, such as skin and rib cartilage, and in some cases synthetic scaffolding. First described in 1959 by Tanzer<sup>6</sup>, modifications of the autologous rib cartilage technique were meant to decrease complications and improve aesthetics. In a study of nearly 600 patients, Brent<sup>7</sup> noted major complications in only 1.6% of cases. A separate method described by Nagata<sup>8</sup> in 1993 was performed in two stages, and eliminated many of the major problems of the conventional method. The use of Medpor (Stryker, USA) was pioneered by Reinisch<sup>9</sup> as an alternative to conventional autologous rib cartilage. The material is made of porous polyethylene which has been used in many parts of the body for decades, but since Medpor ear reconstruction began in 1991, the outcome of the implant over a lifetime is not known<sup>10</sup>. In comparing these two techniques, Firmin<sup>11</sup> argued that refinements of the cartilage framework made reconstruction with autologous rib cartilage superior to that with synthetic materials.

An additional procedure can be performed to place an osseointegrated or bone anchored hearing aid (BAHA), for hearing loss that cannot be primarily corrected or adequately rehabilitated with a traditional hearing aid. Osseointegrated implants to retain an auricular prosthesis are an alternative method of repair to autologous reconstruction, and they are placed in a similar fashion to the BAHA implant. This procedure can be done in a single surgical stage and seamlessly completed in conjunction with BAHA placement. Anaplastologists create life-like auricular prostheses out of silicone that are then attached to the osseointegrated titanium implants via magnets or a bar-clip mechanism. The cost of the osseointegrated implant and prosthesis are not uniformly covered by all the United States' healthcare payers who cover the cost of autologous auricular reconstruction. The purpose of this project is to compare the costs and relative benefits of these two methods of ear reconstruction at a tertiary academic medical center.

## Materials and Methods

Duke University Institutional Review Board approval was obtained prior to review of the patient's records (Pro00074470). All patients who had either osseointegrated or autologous ear reconstruction from 2009–2015 at a single tertiary academic medical center were identified. Only patients who had completed all surgical stages of their reconstruction were included. The cost to the hospital for each ear reconstruction was provided by the Duke

University Hospital Finance Department. All statistical analyses were conducted using SAS v9.1 (SAS Institute Inc. Cary, NC, USA). Differences in numeric variables were compared using a two-tailed independent T-test. Significance level for assessing the statistical tests was set to  $\alpha = 0.05$ .

## Results

### Patient characteristics

There were 16 osseointegrated repairs and 9 autologous repairs identified and reviewed (Table 1). Two of the osseointegrated repairs were bilateral and all of the autologous repairs were unilateral. All patients who underwent osseointegrated implant and one patient who had autologous repair had simultaneous BAHA placement. Patients were older in the osseointegrated group. Other characteristics of the two patient groups are described in Table 1.

### Procedure characteristics

Osseointegrated repair required one surgery per patient, even in the two patients in whom both ears were repaired. Autologous repair required a mean of 3.1 surgeries and therefore on average 2 more surgeries under general anesthesia. One patient who underwent autologous repair had a complicated course and required a prolonged ICU stay making the cost of his surgery greater than three standard deviations away from the mean cost for the autologous groups. The osseointegrated procedure was performed as an outpatient procedure in all instances. The length of stay for autologous repair varied secondary to the patients' medical conditions. The median length of stay for autologous repair was two days.

### Cost analysis

When including patients undergoing bilateral surgery, osseointegrated implantation was significantly less expensive than autologous repair in our cohort (Table 2). When the bilateral cases were excluded from the analysis, there was no significant difference in cost between the two surgical approaches (Table 3).

The costs specific to concurrent BAHA placement were excluded in this analysis. However, being able to place the implant for the BAHA at the same surgery as the auricular prosthesis implant could contribute to relative cost and time savings compared to placing a BAHA with autologous repair, since different equipment and possibly a different surgical procedure may be utilized. The technique and equipment used for the osseointegrated implants for both the auricular prosthesis and the BAHA are similar and therefore the duration of surgery and use of different surgical instruments are minimized when both procedures are performed together.

For the osseointegrated implant repairs, 70% of the cost were for the prostheses, 23% were operating room costs, and 7% were miscellaneous. There were no costs associated with an inpatient hospital stay for the osseointegrated group, as these were performed as outpatient procedures. For the autologous repairs 64% of costs were operating room expenses, 18% were related to the inpatient hospital stay, and 18% were miscellaneous costs.

## Discussion

Autologous repair and osseointegrated implants are both good options for external ear reconstruction. Tjellstrom et al first described placement of osseointegrated implants to retain auricular prostheses in 1981<sup>12</sup>. They applied the concept of osseointegration that was initially described by Branemark in 1969 for fixation dental prostheses.<sup>13</sup> Since these early descriptions of osseointegration, there have been several advances in the design and type of implants used and techniques to place them. Image guided systems can be used if needed to facilitate proper implant placement within areas of adequate bone stock.<sup>14</sup> Osseointegrated implant placement is a safe procedure with a low incidence of complications.<sup>15</sup> This analysis shows that osseointegrated implants may save costs and also requires fewer surgeries than autologous repair. The lower cost of osseointegrated repair is driven by the fewer surgical stages, short case duration and low risk of costly complications.

Adhesive retained prostheses can avoid operative intervention entirely, except in cases where the remnant auricle needs to be removed to allow placement of the prosthesis. However adhesive retained prostheses have downsides including skin damage from adhesive, inconsistent bonding, difficult positioning, need for removal for water or contact sports and decreased lifetime of the prosthesis. An osseointegrated implant to retain the prosthesis resolves all of these challenges leading to a more aesthetically pleasing result

There are certain types of patient characteristics and clinical scenarios that are better suited to one or another of the methods of repair (Table 4). Autologous repair is technically easier when the lower half of the ear is intact and anchors the reconstruction. Individuals who have poor manual dexterity secondary to injury or arthritis may have difficulty placing and removing the ear prosthesis that is placed onto the osseointegrated implant. Infrequent, but long-term follow-up is needed with the anaplastologist to maintain the prosthesis and with the surgeon to evaluate any issues with the implant. Therefore, an autologous repair is better suited for those unable or unwilling to maintain follow-up.

The procedure time, donor site morbidity and challenge of matching two autologous reconstructions makes the benefits of an osseointegrated implant over an autologous repair more substantial for bilateral ear defects. Placing an osseointegrated implant for a prosthesis in conjunction with an implant for BAHA is a seamless procedure. Additionally, if someone plans on long-term follow-up and maintenance for a BAHA then having an additional implant and prosthesis that requires concurrent long-term follow-up is more easily tolerated. If someone has had a failed autologous reconstruction due to infection, scarring or tissue loss they may not have the donor tissue available to undergo another autologous reconstruction. An osseointegrated prosthesis can usually still be placed in those situations. Osseointegrated implants can also be placed in previously irradiated areas that have less robust local tissues and higher proclivity for impaired wound healing<sup>14,15</sup>. These tissue factors make autologous repair relatively more risky. As for any operative intervention, people who are at higher risk of complications from repeated general anesthetics, including the chronically ill and elderly, are better suited to a one surgery implant placement rather than a multi-stage autologous repair. For children with congenital ear defects, reconstruction is often ideally timed prior to entering elementary school, since this is the time when

psychosocial pressures from peers increase. The neurobehavioral effects of repeated general anesthetics on the developing brain are not fully understood and this area requires further study, although current literature supports limiting the duration and frequency of anesthetics when possible.<sup>16</sup> Although the period of highest risk for anesthetics is currently considered to be less than 3 years, a lack of risk in older children has not been confirmed, and efforts to minimize length and frequency of general anesthetics are important.<sup>16</sup> Ultimately, every person and their preferences vary and patients should be able to choose the option that is best for them. The surgical and anaplastology teams should guide patients to understand the relative benefits of each option in order to make the most well-informed decision for themselves

## Conclusion

Osseointegrated implants for retaining an auricular prosthesis has a similar overall cost to autologous repair of ear defects, but patients underwent an average of 2 more surgeries with autologous repair. Patients should be able to make a well-informed choice with their medical team for the reconstruction option that best suits their condition and preferences. Weakness in this study included the difficulty obtaining and interpreting financial information and evaluating cases over a several year period leading to differences in the value of currency over time. Future studies can compare patient perception of cosmetic and quality outcomes of life between these two types of procedures and therefore elucidate their cost-effectiveness.

## Acknowledgments

**Funding:** This work was supported by a NIDCD training grant to the Division of Head and Neck Surgery & Communication Sciences at Duke University (T32 DC013018-03).

We thank the Duke University Hospital Finance Department for providing the cost data for this analysis.

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**Table 1**

Characteristics of patients who had ear reconstruction in 2009–2015

	Osseointegrated Implant		Autologous	
	N=	Mean(SD)	N=	Mean(SD)
<b>Sex</b>				
Female	7/16	44%	4/9	44%
Male	9/16	56%	5/9	56%
<b>Age at time of first surgery (Years)</b>		11.6 (7.5)		40.7 (24.8)
<b>Race/ethnicity</b>				
White, non-Hispanic	12/16	75%	5/9	56%
Hispanic	0/16	0%	3/9	33%
Black	0/16	0%	0/9	0%
Other	4/16	25%	1/9	11%
<b>Indication for surgery*</b>				
Microtia/anotia	6/16	38.5%	8/9	89%
Cancer resection	8/16	50%	0/9	0%
Trauma	2/16	12.5%	1/9	11%
<b>Location of surgery</b>				
Inpatient at hospital	1/16	6%	9/9	100%
Outpatient at hospital	11/16	69%	0/9	0%
Outpatient at ambulatory surgery center	4/16	25%	0/9	0%

**Table 2**

Comparison per Ear Including Bilateral Implants

	<b>Osseointegrated Implant</b>	<b>Autologous</b>
Average	\$6,491.39	\$10,047.93
CI	-6496.38 to -616.68	
p	0.02	

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**Table 3**

Comparison Per ear Excluding Bilateral Patients

	<b>Osseointegrated Implant</b>	<b>Autologous</b>
Average	\$7,304	\$10,047.93
CI	-\$13166.08 to \$7679.10	
p	0.59	

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**Table 4**

Patient characteristics making osseointegrated vs. autologous reconstruction more favorable

Osseointegrated auricular prosthesis	Autologous reconstruction
<ul style="list-style-type: none"><li>• Bilateral defect</li><li>• Need for osseointegrated hearing aid</li><li>• Failed autologous reconstruction</li><li>• History of radiation to the area</li><li>• High operative risk</li></ul>	<ul style="list-style-type: none"><li>• Unilateral defect</li><li>• Lower half of ear intact</li><li>• Poor manual dexterity</li><li>• Inability to follow-up long-term</li></ul>

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