

Ear Rehabilitation – Is it time for the Osseointegrated Prostheses? Systematic Review

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Abstract

Introduction: Ear deformities are a major problem in aesthetic and social terms for affected patients. Its reconstruction can be basically by autologous grafts or osseointegrated implants, depending on the experience of the surgeon and specific patient's peculiarities. The standard treatment is the autogenous tissue reconstruction, but prosthetic osseointegrating operation may have great results in selected cases.

Objectives: Review the outcomes of osseointegrated implants for ear rehabilitation and discuss the main indications and complications of this technique.

Methods: Systematic review of the literature about complications and patients outcomes after osseointegrated implant for ear rehabilitation from year 2000 to 2015.

Results: 18 articles were selected, a total of 844 ears implanted.

Conclusion: Osseointegrated implants are a good option in selected cases, and with the development of new materials and techniques they may have broader indication and lower rate of unfavorable outcomes.

Keywords: Ear rehabilitation; Ear deformities; Osseointegrated Prostheses

Introduction

Ear deformities resulting from trauma, malformations and tumors represent a major problem in aesthetic, functional and psychological terms, especially in the pediatric population. Increased likelihood of depression, anxiety and lowered self-esteem were identified in affected children, causing irreparable damage in the future [1].

Plastic surgical reconstruction of the defective ear is a great challenge and takes into account the technical capability of the surgeon, viability of the tissues that receive the implants, patient acceptance and collaboration for post-operative follow-up.

There are basically two techniques in ear reconstruction; the use of either autogenous rib cartilage or alloplastic graft material and osseointegrated prosthesis, based on previous experience from retained dental prostheses procedures [1,2].

The best approach is still contradictory as well as the best indications. Surgical reconstruction often requires numerous interventions, may take several years to reach the final result and the resulting structure may not closely resemble the contralateral ear or be positioned to provide facial balance. Despite having a lower initial cost, the osseointegrated prosthesis get more expensive in long term

due to the frequent need for monitoring and eventual replacement of prosthesis [3].

Prosthetic implants may be a good option then, providing excellent support and improving patients' appearance and quality of life, in a less traumatic way [4]. In selected cases it is possible to make high quality prosthesis very similar to a normal ear using modern materials and techniques [5].

Nowadays the accepted standard treatment is the autogenous tissue reconstruction, but certain situations may benefit from prosthetic osseointegrating operation. There have been few large series looking at overall long-term results and complications. These include failed previous autogenous reconstruction, extensive cancer resections, irradiated tissues, medical comorbidities that contraindicate long procedures, severely compromised local tissue due to trauma or thermal injury, and patient preference [5].

The first osseointegrated auricular reconstruction was performed in 1979 to support a bone conduction hearing processor at the Göteborg University, Sweden, and since then, endosseous implants have been used to anchor hearing aids and facial epitheses. The surgery consists in a two-step procedure, initially placing titanium implants directly into bone connecting the prosthesis after 3 to 6 months by magnets or clip-to-bar device [1]. Implants are intended to last a lifetime, and prostheses need to be replaced every 2 to 5 years, depending the way it is used; longevity of the prosthetics decreases with sun and cigarette exposure [2]. The main complication from implants is the

surrounding soft tissue reaction, classified by Holgers, showed in Table 1.

Grade 0	No skin reaction.
Grade 1	Redness with slight swelling.
Grade 2	Redness, moistness and moderate swelling.
Grade 3	Granulation tissue around the abutment.
Grade 4	Evident infection resulting in removal of the implants.

Table 1: Holgers grading system of skin reaction after implants.

Some physicians believe that a prosthesis, differently from the autogenous tissues, don't feel like being part of the individual, once it need to be removed, cleaned and remade periodically. Despite this, many studies showed that the prosthesis get incorporated into the body image of its user [6]. In children, apart from reduced thickness of the bone, inserting implants in the young temporal bone can be problematic because of the continuous growth of the bone and mastoid sinus development, leading the implants deeper with time. So, it is recommended that the use of osseointegrated fixtures in children should be delayed until the mastoid sinus has developed and significant craniofacial growth has occurred [7]. Furthermore, the cost of maintaining long-term implants becomes larger due to the need for frequent maintenance and component replacement.

There is a paucity in the literature regarding the long-term results and patient satisfaction with osseointegrated auricular rehabilitation and the studies series are low-numbered, making it difficult to get to right conclusions about the effectiveness of the auricular prosthesis procedure [7].

The purpose of this article is to review the literature on the outcomes of osseointegrated implants for auricular prosthesis and evaluate its main complications in surgical practice and as an aesthetically and functionally viable therapeutic option.

Materials and Methods

A systematic review of the literature searching for complications and patients outcomes after osseointegrated implant for ear rehabilitation was performed. Databases reviewed were PUBMED / MEDLINE / BIREME.

The search strategy employed in the literature review was guided by the combination of five indexed descriptors in MeSH (Medical Subject Headings), in English – “Ear Deformities”, “Acquired”, “Congenital Microtia”, “Prosthesis Implantation”, “Osseointegration” and “Patient Satisfaction”, starting in January 2015, in articles published before this date. They were examined and references were analyzed for relevant published studies.

Inclusion criteria: Retrospective and prospective studies in humans from 2000 to 2015 on osteointegrated prosthesis of the ear, complications and patients outcomes published in indexed journals. Due to the lack of large population studies on the subject, small case series were included in order to group a larger study population. They were defined by one of the authors, while the others did the analysis of the articles. When 2 articles from the same authors and institution had similar data collection, they were assumed to be from the same retrospective study, the newer one being included and the older excluded.

Exclusion criteria: Articles not written in English, Portuguese or Spanish, lack of information on the outcome of the procedure, case report studies and articles other than osseointegrated prostheses should were excluded.

Results

Using the search terms, 52 articles were found from years 2000 to 2015 on osseointegrated implants. Review studies, case reports, pilot studies, experts' opinion and secondary reviews of previous studies were excluded, totaling 31 items. Other 16 studies were excluded from review because they weren't classified as observational longitudinal studies or when information on the outcome of patients was missing or not clear.

After analysis of the content and method of the studies, 15 articles on osseointegrated prosthesis of the ear and complications and patients satisfaction were selected, a total of 727 implanted ears. Since the fixation of prostheses presents variations from 2 to 3 implants each, complications were analyzed based on the number of implanted ears and not the number of actual bone implants.

Due to the great diversity of outcomes and discussion threads in the articles analyzed, a meta-analysis study could not be conducted, leading this this work as a narrative review.

Outcomes such as skin reaction (ranging from 9.1% to 100%), implant loss, prosthesis damage and durability, prosthesis survival rates, patient's acceptance and comfort and willing to recommend the technique to other candidates were analyzed, summarized in Table 2.

Demographic data such as median age and follow-up period is presented in Table 3. Studies on multiple implantation sites and which didn't grouped data on age of patients with ear implants specifically were not recorded in the Table 2.

Discussion

Rocke et al. consider the osseointegrated implantation a predictable and arguably aesthetically superior treatment compared to the best native tissue reconstruction, with manageable complications which do not affect the final result [8]. Despite its inherent complications, they are easily manageable, rarely affecting the final result.

Botma et al. show a statistically significant increase in the choice for the rib reconstruction ($p < 0.05$), reflecting the recent surgical improving in this technique [9]. The author also reminds the excellent cosmetic results using either technique and the importance of exposing both the options to parents and deciding with them the best treatment for their children. The results of osseointegrated surgery are not influenced by previous reconstruction, but previous osseointegration procedure affects a later reconstruction. So the prosthetic procedure is a good choice in failed reconstructive surgery.

In Si et al. study, although necessary replacement every 3.5 years in average (specially due to discoloration), prosthesis wearing time was more than 8 hours per day in 95.9%, indicating that the patient felt the auricular prostheses like part of himself [10]. The osseointegrated prosthesis is a good option for ear rehabilitation, especially after autogenous reconstruction failure, defects caused by trauma, tumor or burn with severe scarring and in cases of intolerance to long procedures. The need for special care and revisions may be a complication for some patients.

Country / year	Authors	Type of study	Ear Implants	Outcomes / Conclusions
United States, 2014	Rocke et al. [8]	RL	16	Four patients had complications: granulation tissue, cellulitis, lack of mastoid bone and late nonintegration of implants for osteoradionecrosis.
England, 2001	Botma et al. [9]	RL	23	Increased parental choice for autologous reconstruction versus implants in a multidisciplinary unbiased center, from (69.5%) to (88.6%).
China, 2012	Si et al. [10]	RL	24	All patients presented at some point skin reaction grade 1. Grade 2 (n=9), grade 3 (n=4), grade 4 (n=1).
Canada, 2002	Rotenberg et al. [11]	RL	11	In 33 follow-up visits, 20 of them had no skin reaction, Holgers grade 1 (n=6); grade 2 (n=2); grade 3 (n=3) and grade 4 (n=3). One needed revision surgery.
Sweden, 2001	Granström et al. [12]	RL	43	Of 1140 registrations, 90.9% were Holgers grade 0. Adverse reactions in 94 registrations: grade 1 (5.1%), grade 2 (2.5%); grade 3 (1.5%). Revision surgery made in 22% of patients.
United States, 2008	Wright et al. [13]	RL	16	Holgers grade 0: 18.75% (n=3); grade 1: 43.75% (n=7); grade 2: 31.25% (n=5); grade 3: 6.25% (n=1); grade 4 (n=0).
Netherlands, 2001	Schoen et al. [14]	RL	13	No skin irritation was observed in 42% of the patients, Holgers grade 1 in 46% and grade 2 in 12% of the patients. 1 of 26 implants was lost in na irradiated patient. 69% reported no pain at all and 31% seldom experienced pain.
United Stated, 2002	Roumanas et al. [15]	RL	37	Five implants lost. Skin reaction rates were not exposed.
England, 2010	Hatamleh et al. [16]	RL	294	Prosthesis color change (71%), poor maintenance (40,8%) and tear in silicone body (36,7%) were the most common cause of reduced serviceability of prosthesis.
Turkey, 2010	Karakoca et al. [17]	RL	32	Tear of the prosthesis or substructure failure (43%), discoloration (32.3%), deposits on tissue surface of prosthesis (13.9%), decrease of fit quality (7.7%)
Germany, 2008	Guo et al. [18]	RL	46	Holgers grade 0 in 22 implants (41,5%); grades 1 or 2 in 27 implants (51%) and had no complaints; grade 3 in 4 implants (7,5%).
Canada, 2011	Korus et al. [3]	RL	75	69% had no skin reaction. Holgers grade 1 (15%); grade 2 (3%), including 10% excess tissue; grade 3 (2%) and grade 4 (1%). 97% felt comfortable, 100 percent said the prosthesis felt like part of them, 94% would undergo the procedure again and 97% would recommend it.
Brazil, 2012	Curi et al. [2]	RL	17	Holgers grade 0 (26,7%); grade 1 (53,5%), grade 2 (10,7%), grade 3 (8,9%); grade 4 was not observed. Skin reactions were not grouped complications no way grouped by place of occurrence - nasal, orbital or auricular.
Netherlands, 2008	Visser et al. [19]	RL	60	Holgers grade 0 (35%); grade 1 (21,6%); grade 2 (26,6%); grade 3 (16,6%); grade 4 (0%).
England, 2010	Younis et al. [20]	RL	20	(n=15) had skin problems [(n=6) 'very mild' to 'mild', (n=4) 'moderate' and (n=5) 'severe' to 'very severe']. (n=10) experienced repeated episodes of low grade infection. (n=12) described prosthesis as 'stable' or 'very stable'; (n=4) as 'unstable' or 'very unstable'. (n=17) felt appearance as excellent or very good. (n=1) as 'terrible'. (n=12) were 'very satisfied' or 'satisfied'; (n=5) were neither satisfied nor dissatisfied; (n=3) were 'dissatisfied' or 'very dissatisfied'.

Table 2: Ears implanted and procedure outcomes (RL=Retrospective Longitudinal).

Rotenberg et al. applied a questionnaire about satisfaction in fit/comfort, aesthetics, maintenance, self-image, mood, interference with leisure activities, interference with classroom activities, and interactions with members of opposite sex [11]. In all domains patients showed high satisfaction in general. The author concludes that the success of his implantation is due to his efficient implant program, patient selection and close follow-up.

Granström et al. concluded that the rate of implant failure is lower in children than in adults, but the same as in adults when considering skin reaction [12]. The revision surgery is more common in young patients because of new bone formation. The data in the article suggest that osseointegrated prosthesis has good functional and aesthetic results in children.

Wright et al. achieved 100% implant survival rate, even among 5 irradiated patients [13]. The results of this study agree with the

importance of thin, immobile soft tissue to promote soft tissue health and systematic hygiene of the implants.

Schoen et al. searching for complications and patient satisfaction, found that prosthesis were psychologically very well accepted with high degree of satisfaction [14]. Dissatisfaction was due to color change and retention. The authors recommend implants insertion immediately after ablative surgery.

Country / year	Authors	Median age (years)	Follow-up period
United States, 2014	Rocke et al. [8]	56.5 years (7 - 66)	7 months (median)
England, 2001	Botma et al. [9]	-	-
China, 2012	Si et al. [10]	28 (9 - 46)	5 years
Canada, 2002	Rotemberg et al. [11]	11.9 (9 - 15)	15 months
Sweden, 2001	Granström et al. [12]	9.6 (5 - 16)	7.8 (1 - 20) years
United States, 2008	Wright et al. [13]	40.6 (6 - 76)	45 months (6 months to 17 years)
Netherlands, 2001	Schoen et al. [14]	60 (23 - 86)	39 months
United States, 2002	Roumanas et al. [15]	-	-
England, 2010	Hatamleh et al. [16]	-	-
Turkey, 2010	Karakoca et al. [17]	31.5 (9-72)	27.7 (12 - 46) months
Germany, 2008	Guo et al. [18]	38 (5-96)	6 months to 11 years
Canada, 2011	Korus et al. [3]	39 (9 - 83)	10 years
Brazil, 2012	Curi et al. [2]	-	48.1 months
Netherlands, 2008	Visser et al. [19]	-	88 months (mean)
England, 2010	Younis et al. [20]	37 (17-56)	31 (7 - 126) months

Table 3: Demographic aspects of the studies.

Roumanas et al. studied 37 not irradiated patients (117 implants) about implants survival rates, which was 95%. Of the five lost implants, two were for early failures (before prosthesis loading) and the other 3 implants were lost after 36 months of loading [15]. Implants allow convenient and secure positioning of the prosthesis with predictable high survival rates for auricular implants, being a good alternative in selected patients.

Hatamleh et al. focused on the prosthesis itself and reviewed the maxillofacial prosthetists' experience in ear prosthesis construction using either bar-and-clip (n=258) or magnet (n=36) fixation system (total n=294). The article does not group patients on age or follow-up time according to the type of facial prosthesis. Low patient dissatisfaction with the prosthesis (6.1%) points that the prosthesis

damage itself is less important than the patient factor in having good results. Better material quality and care of the patient may make this a satisfactory option for reconstruction [16].

Karakoca et al. evaluated prosthesis failure and concluded that higher rate of tearing of the prosthesis or substructure failure (43%) may be attributed to patient inexperience in manipulating it [17]. Discoloration was the most frequent reason for fabricating a second prosthesis and third for patients (51.4% and 66.7%), which indicates a limitation on its material. Prostheses can remain esthetically satisfactory and serviceable for a relatively short time, from 1 to 2 years (mean time of 14.1 months), greater than previous studies. This durability information should be pointed to guide patients' choice for this technique.

Guo et al. evaluated non-irradiated patients, with 100% implant survival rate from 6 months to 11 years of follow-up [18]. Besides skin reactions, two clinical parameters - skin probing depth and Sulcus Fluid Flow - an objective peri-implantitis marker - were examined. The authors felt that implant-retained auricular prosthesis has a high success rate, but it requires constant monitoring for late complications.

In Korus et al. series all patients were able to wear the prosthesis for lifespan as long as 21 years [3]. The authors stated that osseointegrated prosthesis is a good option for reconstruction, but should be discouraged in primary approaches for microtia or younger children and in patients who present difficulty in keeping a follow-up program due to a high rate of skin reaction. At 10 years, the cost of osseointegrated auricular reconstruction becomes quite comparable to that of autogenous reconstruction due to follow-up and the assumption of replacement of the prosthesis at least twice.

Curi et al. had a high implant and prosthesis survival rates, respectively 94.1% and 100%, after 2 years [2]. High grades of soft tissue response around the abutments had a statistically significant impact on determining implant success (P<0.001). Graft reconstructive surgery should be limited in some cases because of unpredictable and unsatisfactory cosmetic results.

Visser et al. showed the need for new silicone facial prosthesis every 22.2 months on average, because of discoloration of the prosthesis (31.5%), attachment problems (30.0%), rupture of the silicone (15.4%), bad fit (9.2%), others (13.9%) [19]. Despite this, making replacement prostheses isn't as time-consuming as making a first prosthesis because the original mold can be reused. Some prosthesis have lasted more than 5 years. The authors felt that osseointegrated ear implants showed to be a reliable treatment on ear deformities, with a high success rate and minor need for surgical after-care, both in irradiated (80%) and non-irradiated (95%) areas.

Younis et al. pointed that despite high rate of dissatisfaction, 14 out of 20 patients found the prosthesis good or very good aesthetically and would undergo the procedure again and 15 would recommend to others [20]. When a stable implant is achieved from the start or early treatment of skin problems is done, a long-term trouble-free is expected. The author proposes a modification of the implant design that may reduce the prevalence of chronic skin complications.

Conclusion

This systematic review of the literature demonstrated that institutions that have experience in using osseointegrated implants for ear rehabilitation showed them as a good, safe and predictable option

especially when there is previous failure in the reconstruction by autologous grafts or when the latter is contraindicated due to inoperability or to patient's choice.

Due to the need for special care and high rate of skin complications in osseointegrated prosthesis rehabilitation (most of them low graded but persistent), a stablished indication for osseointegration is the cancer resected patient, while autologous cartilage auricular reconstruction should always be the first choice in children, both for the lowest cost in the long term as for the reduced need for revisions and replacements.

With the systematic cleaning of protheses and the development of more durable and inert materials, the auricular prosthesis will have better acceptance by patients and less adverse effects, maintaining its role as a feasible option to recover both the aesthetics and functionality of patients. Careful patient selection is also essential for this type of rehabilitation to be successful. They must have the motivation and knowledge necessary to maintain the health and hygiene of the device for better results [20].

As the evaluated studies are retrospective, not comparative and describe specific services experience in patients already selected for the use of osseointegrated implants, there is an obvious optimism about the choice and advantages of this rehabilitation technique. Although the results in the medium and long term prove good cheer in an initial analysis, comparative studies should be conducted in order to circumvent possible bias in the completion of the works presented.

The development of protocols is necessary to guide the best indication of reconstructive procedure of ear deformities. For this, comparative studies of the techniques of osseointegrated implants versus reconstruction by autologous grafts using meta-analysis are needed, considering the lower rates of complication, high satisfaction and costs in public health.

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