

Auricular Reconstruction with Osseointegrated Implant-Retained Prostheses

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Abstract

Background: Auricular defects may be congenital or acquired and can result in functional, aesthetic, and psychological consequences. Their management may involve surgical reconstruction or prosthetic rehabilitation. Osseointegrated implant-retained auricular prostheses provide reliable retention and an aesthetic alternative when surgical reconstruction is unsuitable or declined.

Objective: To review the embryological development and classification of auricular deformities, available surgical and prosthetic reconstruction options, the principles of osseointegration and implant-retention systems, digital planning protocols, and the biomaterials and colour-stability considerations relevant to auricular prosthetic rehabilitation.

Conclusion: Osseointegrated implant-retained auricular prostheses represent an effective reconstructive option for selected patients with auricular defects. Successful rehabilitation depends on careful patient selection and preoperative planning, appropriate implant positioning, adequate osseointegration and soft-tissue management, suitable retention systems, and the long-term stability and biocompatibility of the prosthetic materials.

Keywords: Auricular reconstruction; Microtia; Osseointegration; Implant-retained auricular prosthesis; Craniofacial implants; Prosthetic rehabilitation

Introduction

Microtia is a term used to describe a smaller and usually malformed auricle. Microtia may occur as an isolated condition, or as part of a spectrum of anomalies or a syndrome ⁽¹⁾.

The loss of an auricle, in the presence of an auditory canal, affects hearing, because the auricle gathers sound and directs it into the canal. The auricle acts as a resonator to slightly amplify lower frequency sounds and helps to localize sounds, especially in conjunction with the other ear ^(2,3).

There are no definitive answers to the etiology of microtia, but it is believed to be due to a combination of genetic and environmental factors. Anomalies can be isolated or associated with other syndromes, such as Goldenhar syndrome or Treacher–Collins syndrome. Although studies have identified several genes that could be involved, it is challenging to establish a clear etiological framework due to the complexity of genetic and environmental interactions ⁽⁴⁾.

The deformity occurs with a frequency of one in every 7000 to 8000 live births. The prevalence is significantly higher in Hispanics, Asians, Native Americans and Andeans. Males are affected more than females, and most cases of microtia are unilateral with a higher rate of occurrence on the right side. Environmental and genetic factors are important in the etiology of microtia. Microtia can cause psychological morbidity and surgical repair results in significant relief ⁽⁵⁾.

Microtia occurs more frequently in males, with an estimated 20–40% increased risk compared to females. Microtia can occur bilaterally, although 77–93% of affected individuals have unilateral involvement (Nelson

and Berry, 1984; Castilla and Orioli, 1986; Mastroiacovo et al., 1995; Shaw et al., 2004; Forrester and Merz, 2005; Suutarla et al., 2007; Canfield et al., 2009).

The right ear is affected in approximately 60% of individuals with unilateral microtia (Castilla and Orioli, 1986; Mastroiacovo et al., 1995; Harris et al., 1996; Forrester and Merz, 2005; Suutarla et al., 2007; Gonzalez-Andrade et al., 2010).

Absence of auricle results in an asymmetric, distorted appearance which may not affect function to a great extent, but patient's psychological state and self-esteem are affected deeply. Etiology of auricular defects can be congenital or acquired, and reconstruction of such defects can be surgical or prosthetic ⁽⁶⁾.

Microtia/anotia may be acquired or congenital. Trauma accounts for the most common cause of external ear defects; other causes include dog bites, human bites, burns, and also ablative surgery. Occurring more often unilaterally, with a predilection for the right side ⁽⁷⁾.

Acquired forms of an absent auricle arise from traumatic events, dissatisfying reconstruction or after amputation as a result of surgical treatment of advanced cancer of the auricle and/or external auditory meatus ⁽⁸⁾.

Reconstruction of an auricular defect is a complex modality either surgically or prosthetically, depending on the site, size, etiology, severity, age, and the patient's expectation. Maxillofacial prostheses play a vital role in comprehensive rehabilitation by restoring physical and psychological well-being in patients with missing or disfigured anatomical structures ⁽⁹⁾.

Implant-retained auricular prostheses provide multiple advantages for the patient: convenience, security, consistent retention and positioning, elimination of the need for adhesives, and maintenance of marginal integrity and longevity. It is crucial that each patient is provided with individual reconstruction procedures related to bone and soft tissue handling. In particular, the prosthesis should be tailored to become part of the patient's body ⁽¹⁰⁾.

Surgical reconstruction involves many steps and surgeries, and still, predictability of outcome is not reliable. Further, if cartilage reconstruction has to be planned, it will involve two sites of the surgeries, and it is not generally accepted by the patient due to added difficulty. In these conditions, silicone prosthesis provides a reliable replacement and predictable treatment modality ⁽⁶⁾.

Embryological Development of the Auricle

Little is known about the embryological development of the auricle. Most knowledge is based on early scientific reports, some published more than 100 years ago. The most frequently reproduced developmental theory by His (1885) describes six auricular hillocks: three on the first pharyngeal arch (PA1) and three on the second pharyngeal arch (PA2) ⁽¹¹⁾.

Most patients with microtia have atretic auricle, external auditory canal and tympanic membrane with variable involvement of the ossicles. The middle and external ears are derivatives of the first and second branchial arches. The auricle is made from several bulges in the first and second arches known as auricular hillocks. Each of the hillocks contributes to a specific part of the pinna, and those in the second arch form most of the auricle. Hillock development usually occurs slowly over a period of months, with the overlying ectoderm having a significant role in the final form of the auricle. The inner ear on the other hand have a completely different embryological origin, therefore it is always normal in patients with microtia/anotia ⁽¹²⁾.

Microtia auricular cartilage undergoes varying degrees of hypoplasia during early embryonic stages. It results from altered embryonic development and defective neural crest cell migration in the first and second branchial arches. The external ear begins to form around the sixth week of pregnancy, as six small nodules from the first and second arches merge. By the 12th week, the development of the auricle is completed ⁽⁴⁾.

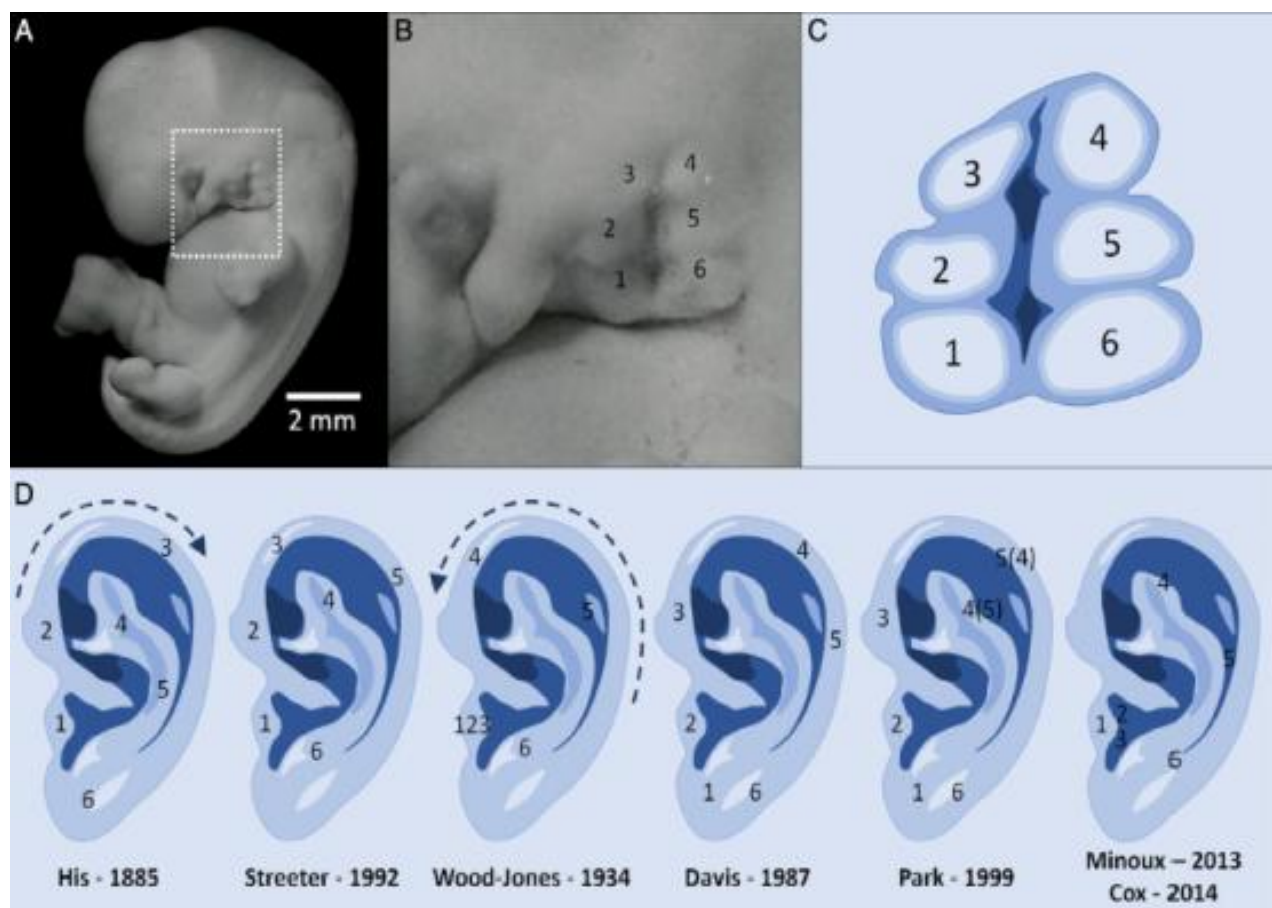


Figure (2. 1): Embryological development of the external ear according to His's six auricular hillocks theory.

Classification Systems for Auricular Deformities

One widely adopted classification system, originally described by Weerda and simplified by Aguilar, assigns a grade from I to III based on the severity of the deformity.

Anotia ("no ear") describes a rare, congenital deformity with a complete absence of the auricle, the external, visible part of the ear. This contrasts with microtia, where there is malformation or hypoplasia (decreased growth) of the auricle. This malformation may range from a small, but otherwise normal, external ear to an external ear with major structural changes⁽¹⁰⁾.



Figure (2. 2): Showing grades of microtia⁽¹³⁾.



Figure (2. 3): Photographs of individuals with different types of microtia. A: typical ear; B–D: first degree dysplasia; E: second degree dysplasia; F–J: third degree dysplasia (classification proposed by Hunter *et al.*, 2009a).

A complex malformation such as microtia requires a standardized classification to facilitate further understanding. A Review of literature revealed several classifications for microtia beginning with Marx classification in 1926 and ending with Hunter *et al.* (2009) classification in 2009. Most relied on the surgical approach, and some on morphology and embryological development for classification.

Table 1. Classification systems for auricular malformations. Source: reproduced and reorganised from Alnujaim *et al.* ⁽¹²⁾.

System / Author (Year).	Category.	Description.
Marx (1926).	Grade I.	A normally structured auricle, but smaller than normal.
Marx (1926).	Grade II.	Abnormal auricle with some identifiable features.
Marx (1926).	Grade III.	Rudimentary ear.
Marx (1926).	Grade IV (added from Rogers, 1977).	Anotia.
Tanzer (1978).	Type 1.	Anotia.
Tanzer (1978).	Type 2.	Completely hypoplastic ear (microtia): (a) with atresia of the EAC; (b) without atresia of the EAC.
Tanzer (1978).	Type 3.	Hypoplasia of the middle third of the auricle.
Tanzer (1978).	Type 4.	Hypoplasia of the superior third of the auricle: (a) constricted (cup and lop) ear; (b) cryptotia; (c) hypoplasia of the entire superior third.
Tanzer (1978).	Type 5.	Prominent ear.

Weerda (1988).	First degree malformation.	Most structures of a normal auricle are recognizable (minor deformities): macrotia; deformities of tragus/antitragus; protruding ears; colobomata; cryptotia; lobule deformities; absence of upper helix; cup ear deformities; Stahl ear.
Weerda (1988).	Second degree malformation.	Some structures of a normal auricle are recognizable, e. g. mini ear.
Weerda (1988).	Third degree malformation.	None of the structures of a normal auricle are recognizable; classified as unilateral or bilateral; anotia is included in this category.
Nagata ⁽¹⁴⁾ .	Lobule-type.	Remnant of the auricle and lobule; without the concha, EAC, and tragus.
Nagata ⁽¹⁴⁾ .	Concha-type.	Variable degree of presence of the lobule, concha, EAC, tragus, incisura tragica.
Nagata ⁽¹⁴⁾ .	Small concha-type.	Remnant of the auricle and lobule with a small indentation representing the concha.
Nagata ⁽¹⁴⁾ .	Anotia.	None, or only minute resemblance of a remnant auricle.
Nagata ⁽¹⁴⁾ .	Atypical.	Cases that do not fall into any of the above classifications.
Hunter et al. (2009).	Microtia, First Degree.	Presence of all normal ear components; median longitudinal length more than 2 SD below the mean.
Hunter et al. (2009).	Microtia, Second Degree.	Median longitudinal length more than 2 SD below the mean, with some but not all normal parts present.
Hunter et al. (2009).	Microtia, Third Degree.	Presence of some auricular structures, but none conforms to recognized ear components.
Hunter et al. (2009).	Anotia.	Complete absence of the ear.

Structural versus Morphological Malformations

Congenital auricular malformations can be categorized into structural and morphological types. Structural malformations involve abnormal development of the skin and cartilage tissues due to impaired auricular growth during the embryonic stage, potentially affecting physiological functions and often necessitating surgical intervention.

Morphological malformations, in contrast, are shape abnormalities resulting from genetic influences or internal and external uterine pressures. These shape abnormalities are often overlooked by the parents of the affected infants due to their less severe nature. This study included 1, 758 newborns (3, 516 ears), of which 562 newborns had auricular malformations, totaling 927 ears ⁽¹⁵⁾.

Management of Auricular Defects

Most microtia reconstructions use autologous costal cartilage to re-create an ear. However, certain disadvantages with this method led to the development of another technique using porous polyethylene implants. First described by Dr Alexander Berghaus in 1982, porous implant ear reconstruction (PIER) has become an accepted alternative to costal cartilage for the treatment of microtia. Both techniques have a steep learning curve and are technically challenging. Fewer surgeons use PIER when compared with rib cartilage in part due to less exposure to this technique during training ⁽¹⁶⁾.

Defects affect many vital functions (that is, respiration, mastication, deglutition, speech, and aesthetics). Ideally, any anatomic defect should be surgically reconstructed. However, when surgical reconstruction is contraindicated, prosthetic reconstruction must be employed to restore anatomy, function, and aesthetics ⁽¹⁷⁾.

Hence, Anaplastology term has been introduced in literature, which is defined as the art and science of restoring a malformed or missing part of the human body through artificial means ⁽¹⁸⁾.

Endosseous craniofacial implants are usually a final treatment option for microtia in the reconstructive process, because potential need for skin thinning and skin grafting that accompanies placement of temporal implants leads to scarring, which precludes other future reconstructive options ⁽¹⁶⁾.

Although, Haug et al. mentioned that soft tissue facial prostheses are artificial appliances used to repair facial deformities as interim or definitive substitutes. Furthermore, these appliances can support patients' social life by improving their self-esteem after restoring aesthetical and functional demands). Nevertheless, Periodic replacement of these prostheses requires exhaustive fabrication schedules, which burden both the patient and anaplastologist.

Randall et al. summarised the various options for the management of microtia (Table 2. 2). Malick et al. reported rehabilitating their patients with osseointegrated implant-supported prostheses, with the choice of attachment guided largely by cost and patient needs ⁽⁷⁾.

Table (2.2): Overview of management modalities for auricular defects.

(Randall et al., 2016)

Approach	Description	Typical indication / source
Accept and wait	No treatment of the absent auricle after counselling	Patient/parent preference ⁽⁸⁾
Adhesive-retained prosthesis	Silicone prosthesis retained by medical adhesive	Short procedure, reversible, but prone to dislodgement ⁽¹⁹⁾
Implant-retained prosthesis	Silicone prosthesis retained on osseointegrated titanium implants	Failed autologous reconstruction; patient preference ⁽²⁰⁾
Autogenous reconstruction	Staged reconstruction using autologous costal cartilage framework	Preferred in suitable candidates ≥ 10 years old ⁽¹⁴⁾
Alloplastic reconstruction	Porous polyethylene (Medpor) framework $\pm$ fascial flap	Alternative to rib cartilage; PIER technique ⁽¹⁶⁾

Surgical Reconstruction of the Auricle

Autogenous Reconstruction

Reconstructive techniques for auricular defects include second intention healing simple linear closures, skin grafts if the perichondrium and soft tissue are intact, local rotation flaps, two-lobed advancement flaps from the post-auricular sulcus, and post-auricular interpolation flaps for larger defects of the ear rim ⁽²¹⁾.

The term autogenous reconstruction, will be used to refer to restoration of normal function and aesthetic using the patient's own tissue alone.

For cartilage reconstruction, the most common complications are exposure due to a local infection, malposition, low-lying hair, resorption, delayed fracture, and disarticulation. Alloplastic reconstruction is reported to have less complications compared to cartilage reconstruction ⁽¹²⁾.

It is extremely important that the surgeon attempting to reconstruct the auricle fully comprehends its three-dimensional [3-D] morphologic features. The best material for fabrication of the 3-D framework is autogenous costal cartilage because of the least number of postoperative complications ⁽¹⁴⁾. The criteria for auricular reconstruction are: the patient is to be over 10 years old; and the chest circumference at the level of the xiphoid

process is to be at least 60 cm. The first stage operation is the fabrication and grafting of the three-dimensional costal cartilage framework [3-D frame] and the second stage operation is the projection of the reconstructed auricle.

It is important to comprehend the relationship between the angle of projection, distance from the temporal surface to the highest plane of the auricle and the height of the cartilage construct for a successful and symmetrical projection of the reconstructed auricle ⁽²²⁾.

Surgical reconstruction using autologous tissue is the most natural method of restoration of any missing tissue (Vergilis et al., 2010; Johnson et al., 1997). However, especially in pediatric patients, the impact of surgical invasion and donor-site morbidity can be severe, and the collectable volume of autologous graft is limited ⁽²²⁾.

The major disadvantages of autogenous reconstruction of large defects are the technical difficulties and the consequent need for multiple surgical procedures, multiple donor sites and long hospital stay, which expose the patient to a higher morbidity and reduce motivation and the capacity to tolerate this lengthy surgical reconstruction (Sugar & Beumer, 1994). The final reconstructed defect is not exactly similar to the normal unaffected side. In addition, a number of immediate and delayed complications have been reported (Wilkes et al., 1994; Firmin, 1998).

To achieve a satisfying cosmetic result in surgical reconstructions with autogenous rib cartilage or porous polyethylene, three criteria should be met: presence of the skin envelope, anatomically precise framework, and proper anatomical location of the auricle (Al Kadah et al., 2018).

Alloplastic Reconstruction

Repair of microtia by alloplastic reconstruction uses a synthetic implant, typically porous polyethylene like Medpor, to create the ear's framework instead of the patient's rib cartilage.

A 2-piece porous polyethylene implant consisting of a helical rim and an antihelical base are soldered together using a handheld high-temperature cautery to create the adult-sized ear (MEDPOR [Stryker] or Su-Por [Poriferous LLC, Newnan, GA]). The tragus and intertragal incisura are removed because they are preferably reconstructed with cartilage from the microtia remnant (Fig. 4A). The 2-piece implant is the most prevalent option ⁽¹⁶⁾.

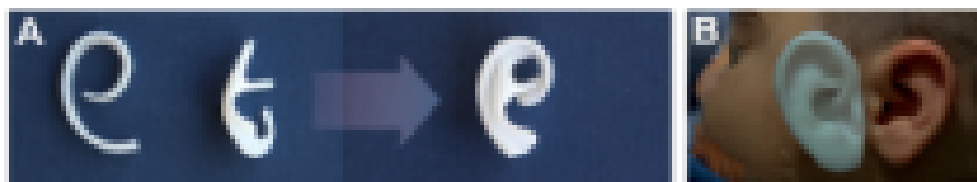


Figure (2. 4): Auricular reconstruction by the alloplastic technique ⁽¹⁶⁾.

Porous polyethylene has been successfully used for reconstructive operations in the head and neck region (Rubin et al., 1994; Romo et al., 2000). Ear implants made of porous polyethylene (Medpor®) have been used for more than two decades as a suitable framework material due to many advantages of this material, e. g. , good biocompatibility, short hospitalization time and the possibility of a one-step reconstruction of total or subtotal ear defects. Polyethylene implants can also promote revascularization due to their porous structure, resulting in a good incorporation at the implantation site (Naumann et al., 2011). Furthermore, their implantation is less invasive compared with rib cartilage reconstruction (Romo et al., 2009; Al Kadah et al., 2018).

Reinisch and Lewin described a method using a porous polyethylene (PPE) framework covered by a large temporoparietal fascia (TFP) flap raised with the underlying subgaleal fascia (SGF) ⁽¹⁶⁾. They concluded that the PPE/TFP method allows ear reconstruction in children with minimal scarring and discomfort, while the

reconstructed ear can closely mimic the shape and projection of the natural contralateral ear in fewer stages and with a shorter learning curve (Al Kadah et al., 2018).

Prosthetic Reconstruction of the Auricle

Rationale and History

Prosthetics have become available and have been developed into functional and esthetic alternatives to plastic and reconstructive surgery ^(25,26). Since the introduction of percutaneous endosseous implants for use with bone conduction hearing aids in 1977, implants also have acquired an important role in the prosthetic rehabilitation of patients with craniofacial defects.

An ear prosthesis can be retained to the skull by either adhesives or an implant, adhesives were an impractical method. Osseointegrated titanium implants made prosthetic replacements more practical by placing a titanium anchored to the temporal bone ⁽¹²⁾.

Auricular prosthesis represents an artificial substitution for the auricle ⁽²⁷⁾.

Modern silicone, used for prosthetic implant rehabilitation, is a flexible material, which is able to adapt to the body temperature (Alvi et al., 2002).

An advantage of modern silicone is the possibility of integrating hairs and pigments into the material and, additionally, that its edges can be shaped thin enough to become transparent, in such a way that the prosthesis blends into the face, thereby enhancing camouflage even more. At the same time, the prosthesis can be designed according to the patient's individual preferences in order to fit his/her lifestyle (Federspil, 2010; Al Kadah et al., 2018).

An auricular prosthesis is an alternative to the autologous and alloplastic reconstruction of the auricle. Advantages such as the short procedure, possible under local anesthesia and usability in compromised tissues make this an excellent option in patients with medical comorbidities and oncological patients ⁽²⁴⁾.

Also, a prosthesis is indicated after failed autologous reconstruction and can be indicated primarily in microtia, depending on the patient's preference ⁽²⁰⁾.

Probably the absolute indications for prosthesis are a failed autologous reconstruction for a child or a traumatic anotia in an adult ⁽¹²⁾.

Adhesive versus Implant Retention

Historically, the use of medical-grade skin adhesives, solvents, eyeglasses, the use of hard and soft tissue undercuts, and other modalities became traditional means of retaining facial prostheses ⁽¹⁹⁾.

However, skin adhesives and solvents may lead to adverse tissue reactions, discoloration and deformation at edges of the epithesis, loss of adhesion because of perspiration, and difficulties in maintaining the position of the epithesis ^(28,3,29,30).

To attach the auricular prosthesis, an adhesive substance or osseointegrated implants can be used. An adhesive-retained prosthesis has a few disadvantages compared to an implant-retained prosthesis: it is easily dislocated and has a chance of adverse tissue reactions. The use of osseointegrated percutaneous implants has minimized these disadvantages, although the implants themselves require daily maintenance and skin infections do occur. The concept of osseointegration with titanium implants was first implemented in dental medicine in 1965 by Brånemark. In 1977 osseointegrated implants were introduced for the first time outside the oral cavity by Tjellström, i. e. in the temporal bone for application of bone conduction hearing and eventually for auricular prostheses in 1983 ⁽⁸⁾.

A variety of adhesive systems have been employed to retain the facial prosthesis in position. They are classified as (a) Pastes, (b) Liquids, (c) Emulsions, (d) Spray-on, and (e) double sided tapes with last one most commonly used (41%) among patients with facial prosthesis because of its easy manipulation ⁽³¹⁾.

Hence, thickness and mobility of the tissues near the defect edges are especially important for achieving aesthetic results and since muscle movements on the face, appearances of facial prostheses around areas where tissues move create aesthetic problems. It was found that adhesives, anatomic undercuts and frames (holding devices) were found to be least mechanism of retention if they are to be used solitary.

Therefore, the use of osseointegrated implants in craniofacial reconstruction has minimized some of these disadvantages and has provided patients with predictable cosmetics, improved retention, and stability of the epithesis. For that Nowadays, methods of retention varied within each prosthesis type. Retention methods for auricular prostheses are bars, magnets, and mechanical devices ⁽³²⁾.

Outcomes and Survival Rates

Predictable esthetic results coupled with a survival rate of more than 95% have made implant-supported auricular prostheses one of the most accepted modalities to treat auricular defects. Osseointegrated implants have demonstrated an excellent level of predictability when placed in bone in the auricular area ⁽¹⁰⁾.

The use of osseo-integrated percutaneous implants has minimized these disadvantages, although the implants themselves require daily maintenance and skin infections do occur ⁽²⁷⁾.

A failed autogenous reconstruction is one of the major indications for prosthetic rehabilitation, as fibrosis from previous surgeries makes it difficult to reconstruct the external ear surgically. Prosthetic rehabilitation for auricular defects has been carried out for decades for cosmetic reasons; however, the development of the craniofacial implant (CI) was the milestone that provided optimum retention, support, and stability to the auricular prosthesis. The bone thickness in the mastoid region varies between 2.5 mm and 6.5 mm; therefore, the length of craniofacial implants is usually selected between 3 mm and 6 mm to retain the auricular prostheses. Upon osseointegration, CI can be used in combination with various types of retentive attachments (clip bar attachment, magnet attachment, locator attachment, or combination of these types of attachments, i. e., bar with locator attachments or bar with ERA attachment) to retain the auricular prostheses ⁽³³⁾.

Prosthetic rehabilitation using endo-osseous implants offers an effective alternate treatment modality for older patients or patients who are not good surgical candidates and for patients who are not willing for other forms of reconstructive surgery. The use of craniofacial implants for the retention of a prosthesis, such as an ear, offers excellent support and retentive abilities when proper selection of cases and meticulous planning and execution of surgical and prosthetic techniques are followed ⁽⁷⁾.

Surgical Protocol for Craniofacial Implants

Preoperative Planning

In preparation for treatment, one must consider a balanced location for the epithesis as part of the craniofacial organ, especially considering the symmetry of location and shape in relation to the unaffected ear when seen from the front. The basic materials that need to be gathered for this process are the facial photos (frontal, oblique, and lateral views) and a simple craniofacial CT scan, which are both mandatory. Furthermore, we recommend that one keep in mind simulation surgeries and model surgeries that may take place at a later time and either make sure to back up and store the CT data or, if the model fabrication occurs at an external facility, to have the data transferred to that location ahead of time ⁽³⁴⁾.

In surgery planning, clinical anatomy-based selection of the location for implant placement is critical. First, during the facial observations, verify the distance between the outer canthus and the tragus, as well as whether the angle of the naso-auditory meatus line is symmetrical in relation to the bipupillar line ⁽³⁴⁾.

In other words, this is a method that considers a safe implant site to be the site where the following is taken into consideration: the reference axis is set based on the straight line that connects the outer canthus and the tragus in the 3:00 to 9:00 direction of a clock, and a straight line that perpendicularly crosses the previous line centering the external auditory canal in the 0:00 to 6:00 direction also: if the right side is the affected side, the 7:30 to 8:30 and the 10:00 to 11:00 directions along with the location would form an antihelix. As the antihelix is located approximately 20 mm from the external auditory canal, during the operation, there will be a total of two

implants: one implant in the 7: 30 to 8: 30 direction and the other in the 10: 00 to 11: 00 direction at a distance of approximately 20 mm away from the external auditory canal ⁽³⁴⁾.

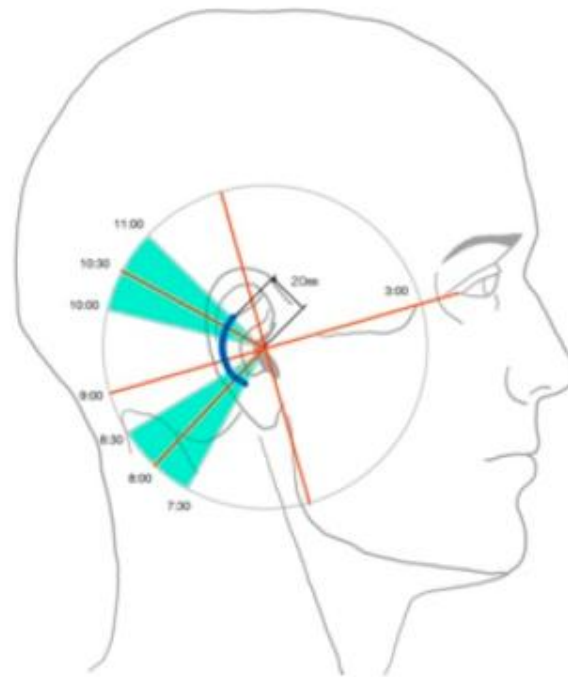


Figure (2. 5): Safety area for implant placement described by Tjellström.

(34).

Single-Stage versus Two-Stage Surgery

The 2-stage process involves a sequential approach where the implant is initially placed in the mastoid, followed by a period of healing and osseointegration. After 3–6 months, the patient is taken back to the operating room for debulking of the subcutaneous tissue and abutment placement. Conversely, in the 1-stage process, the implant and abutment are placed simultaneously during a single surgical procedure, reducing overall treatment time. Nonetheless, the 1-stage procedure still requires a period of 3–4 months postoperative for osseointegration before loading of the prosthesis ⁽³⁵⁾.

Most of the studies reported using the 2-stage surgical procedure for placing craniofacial implants, to allow for undisturbed healing. However, **Khamis et al.** ⁽³⁶⁾ described a new technique with modified abutments in implant-retained auricular prostheses, using a single-stage surgical procedure. They screwed the modified O-ring abutments directly onto the implants at the time of surgery. Plastic washers were attached to the O-ring heads of the exposed abutments to avoid skin overgrowth to allow a single-stage surgical procedure. After an osseointegration period of 4 months, a silicone prosthetic ear was fabricated and retained using clips over the O-ring abutments ⁽⁵⁾.

However, the use of implant retained epithesis has been the protocol of choice, a debate has been found between using single stage versus two stage surgery. The concept of loading of extraoral implants were found to be close to intraoral implant loading concepts.

Multiple studies Lundgren et al. (1993) and **Parel et al.** ⁽³⁷⁾ have supported the single stage as well as two stage surgery. In which limited thickness of facial bones, variation in peri-implant soft tissue thickness, difference in bone quality between various facial sites and the attachment mechanism were found to be the criteria upon which maxillofacial surgeon and anaplastologist depend on.

Khamis et al. ⁽³⁶⁾ were found to favor one stage over two stage surgery. Implant-retained prosthesis using single stage was found to be successful and more tolerable by the patient, in which difficulty in locating implants at

stage-2 surgery, the need for 2 surgeries and time required before loading, was no longer found. On the other hand, most of the studies reported using the 2-stage surgical procedure for placing craniofacial implants, to allow for undisturbed healing ^(28,32,37,38,39,40,41).

Advantages, Disadvantages, and Complications

Some of the advantages of implant-supported auricular epithesis treatment are as follows: surgical invasion is minimal and it is possible to operate under local anesthesia depending on the case; the danger and probability of facial nerve damage are extremely low; it is unnecessary to collect autologous tissue; the number of operations can be clearly limited to two with just one implant placement and one implant fenestration; and the epithesis can be morphologically corrected, its color adjusted, and it can be refabricated non-invasively.

In addition, patients are much more accepting of implant-supported auricular epithesis than of epithesis of the midface or the eye sections, as the ears are on the side of the face and are unimpacted by dynamic facial movements; furthermore, they do not play a role in facial expression creation ⁽³⁴⁾.

Some of the disadvantages of implant-supported auricular epithesis are as follows: the auricular epithesis is not part of the body, which necessitates the attachment and detachment of the epithesis; one needs to be meticulous in cleaning around the implant; there are risks of ambient inflammation around the implant and the epithesis may inadvertently fall off; and it is not suitable for pediatric patients as children are poor at cleaning and tend to dislike wearing artificial material ⁽³⁴⁾.

Complications associated with silicone prostheses include the following:

- Rapid degradation of elastomers and color dexterity. Deterioration due to environmental exposure to UV light, air pollution, and changes in humidity and temperature. Tearing of margins.
- Delamination of silicone rubber from the resin plate, fracture of the resin plate, and loosening of the retentive components.
- Microbial growth due to the porous nature of silicones. Short durability (1–2 years).
- Necessity for meticulous hygiene at skin/implant interface.
- Preclusion of future autogenous reconstruction. ⁽¹⁰⁾.

Osseointegration

The history of Osseo integrated implants, with carefully documented animal experiments and corresponding clinical studies has documented favorable results using commercially pure titanium implants. The achievements of osseointegrated implantology are based on an atraumatic surgical procedure, a specific metallurgic response, an initial implant healing period without loading, and a passive stress-distributed prosthetic technique. Together these factors contribute to a predictably high degree of implant longevity and long-term prosthesis use (Denissen et al., 1989).

Using osseointegrated implants to retain an auricular prosthesis is an alternative method to autologous reconstruction. It was initially described as the “clinically asymptomatic rigid fixation of alloplastic materials” in the bone to eventually achieve functional loading. Derived from dental implantology, where they revolutionized tooth replacement, osseointegration techniques have been adapted to craniofacial reconstruction. The breakthrough in ear prostheses was made with the introduction of modern silicones and then evolved tremendously with advances in the movie industry ⁽³⁵⁾.

Since the introduction of craniofacial implant-retained prostheses in 1977 ⁽³⁷⁾, few implants specifically designed for extra-oral use have been introduced. The most popular was the Branemark craniofacial implant (Nobel Biocare AB, Goteborg, Sweden), which has been evaluated in many studies ^(32,38,42,26).

Other implant designs, such as the 3.5-mm endosseous screw-type implant (Bud System, East Aurora, NY), have also been used, and high levels of survival were reported ^(42,43,44).

According to Al Kadah et al., the optimal age to reconstruct the ear using a silicone prosthesis or porous polyethylene is before the child begins school, at approximately 5–6 years of age, as recommended in the available literature (Al Kadah et al., 2016).

Retention Systems for the Prosthesis

For the retention of the prostheses to implant abutment, different attachment mechanisms and devices has been used like magnets, bars, studs and ball /socket. Each mechanism showed advantages and disadvantages as been stated in literature. Different attachment mechanisms have also been proposed and evaluated in various studies (19,38).

Splinting with a bar-type attachment has been popular, in spite of its limitations, which include technical difficulty and time required for bar fabrication, difficulty in cleaning under the bar, and increased cost.

A bar/clip mechanism or magnets are used as the interface for attaching the prosthesis (Figure 6). One contraindication to osseointegrated implants is radiation therapy treatment. After radiation therapy, the bone suffers from demineralization, hard tissue vasculitis, fibrosis, long-lasting infections, poor blood supply, and oxygen deficiency (7).



Figure (2. 6): Diagrammatic representation of a prosthesis retained on a bar placed on osseointegrated implants (7).

Bar and clip systems were advantageous biomechanically in that they effectively splinted the implant sites together, offering stronger immediate retention. Despite this, their use has been limited to patients with adequate, controlled hygiene, and when the prosthesis was mounted, the projection was often larger than the natural counterpart, necessitating additional filling at the rear to cover a visible gap-an esthetically compromising outcome (26).

When the temporal bone is intact, implants can be positioned ideally, directly beneath the antihelix. As such, they are centered beneath the bulk of the prosthesis and thereby minimize pivoting movements and dislodgement of the prosthesis during wear. When an implant connecting bar is used to retain the prosthesis, retention is optimal when the attachments are tripodized (45).

Despite the advantages of both magnet and bars in retention, Quatela *et al.* (46) confirmed that both magnets and bar type techniques were often wrought with difficulties associated with retention, stability, adverse tissue reactions, discoloration and prosthesis deterioration, inconvenience of use or application, poor hygiene, discomfort, and lack of acceptance.

Even though the implants improve the retention of the prosthesis, young patients still report disappointing retention of the prosthesis during bathing, swimming, or other sport activities ⁽¹⁹⁾.

Since ear prostheses slack more frequently than do orbit and partial face prostheses as they are unprotected by adjacent tissue and more prone to shearing forces. For that, the more implants are inserted, the better retention can be achieved ⁽⁴⁷⁾.

Finally, the use of osseointegrated implants to retain facial prostheses has become an integral part of treatment planning for facial reconstruction. Implant retention is currently considered the standard of care in many situations because of the numerous advantages it provides over adhesive retention.

Imaging and Digital Planning Protocols

Computed tomography (CT) scan measured the thickness of available bone in the mastoid region. Adequate thinning of the flap is an important factor for better adaptation over the bony surface ⁽⁷⁾.

The preprosthetic planning of guided surgeries using CBCT were found to be easier for both maxillofacial surgeon and prosthodontist, Moreover superior esthetic satisfactory results were to be obtained on both clinical and patient level. As well as, CBCT has been used as an objective method of evaluation of implant osseointegration.

The computed tomography (CT) scan (ossa petrosa) is used to determine the optimal location of the implants to retain the prosthesis. To define this exact location, it is important to assess if sufficient temporal bone is present at the preferred location of the implant guaranteeing a symmetric position of the prosthesis. When the ideal position of the implant is determined by the ENT-surgeon, anaplastologist and Radboudumc 3D laboratory, the virtual implant planning is transferred to a skin template which is manufactured using 3D printing. All to assure the most accurate placement of the implant during surgery ⁽⁸⁾.

The use of implant guided surgery has been recently used. Those type of surgeries were used to guide the placement of implant in the mastoid region with the proper direction and proper distribution. CBCT scans are readily available. The use of CT scans allows parts of the body to be serially recorded slice by slice. The three-dimensional computed data obtained can be used to construct an anatomic model or prosthesis of exactly the same dimensions and geometry of the deformed side of the face ^(48,49).

Watson *et al.* ⁽⁵⁰⁾ used CT data in planning and positioning implants to support an artificial prosthetic ear for patients with hemifacial microsomia. This technique required a large number of contiguous slices (30- 40 slices 2-mm apart) for bone depth to be assessed with reasonable accuracy. However, the use of CT scans to obtain 3-D anatomic data cannot be ethically justified because of the high dose of radiation administered.

CBCT was found to be valuable in detecting the amount and type of bone present in the defect side. The 3D-printed surgical guides and CBCT guidance enabled osteotomy and implant placement in sound bone, avoiding intraoperative complications such as bleeding, inner cortical perforations of the pneumatized mastoid portion into underlying tissues, angulation discrepancies, or compromised osseointegration, thus optimizing a prosthetically driven approach to the surgical phase, and in turn, also optimizing the final prosthetic result.

Implant-retained auricular prostheses have a considerable track record of success in the literature, beginning with a 38-patient retrospective series by **Tjellstrom *et al.*** ⁽³⁸⁾ and including others dating to 2002 (Domingue *et al.*, 2020).

Biomaterials for Craniofacial Implants and Prostheses

Implant Biomaterials and Reported Survival

As described by Lemons (1990), there are presently three types of synthetic biomaterials suitable for endosseous implants: metals and alloys, mainly titanium and titanium-6-aluminium-4-vanadium (Ti6Al4V); ceramics and carbons, including aluminium oxide and calcium phosphate hydroxy apatite; and polymers, such as polymethyl methacrylate. However, titanium, titanium alloy and hydroxyapatite (HA) coated endosseous implants are the most commonly used in the craniofacial region.

Implant-retained auricular prostheses have a considerable track record of success in the literature, beginning with a 38-patient retrospective series by **Tjellstrom *et al.*** ⁽³⁸⁾ and including others dating to 2002. Of note, a 25-year retrospective analysis of 341 craniofacial implants in 110 patients by Subramaniam *et al.*, temporal implants overall showed the highest comparative success rate (97%) and statistically significant) prosthetic ($P < .0001$) and implant survival rates ($P < .0001$). Brandao *et al.* also reported an auricular implant success rate of over 98%; two-implant retention showed the lowest failure rate. While adhesive- and bar-retained prostheses have shown clinical success a 2012 review by Sharma *et al.* (Domingue *et al.*, 2020).

Silicone and Acrylic Prosthetic Materials

A successful facial prosthesis depends on several factors; durability, biocompatibility, flexibility, weight, color, hygiene, thermal conductivity, ease of use, texture and availability. No facial material has all of these ideal properties although several materials are available that possess most of these properties with increased tear strength, tensile strength and significant durability.

Extra-oral prostheses are usually made of silicone elastomers, acrylic resin, or of both of these. According to the literature survey of **Karakoca *et al.*** ⁽⁴⁸⁾, the use of silicones have been used for over 50 years in the field of craniofacial prosthetics, with desirable material properties including flexibility, biocompatibility, ability to accept intrinsic and extrinsic colorants, translucency, chemical and physical inertness, moldability, and ease of cleaning (Karakoca *et al.*, 2010; Karayazgan *et al.*, 2010; Gumieiro *et al.*, 2009).

However, silicone elastomers **Goiato *et al.*** ⁽³¹⁾ and **Dootz *et al.*** ⁽⁵²⁾ have been widely used because of their chemical inertness, strength, durability, ease of manipulation and biocompatibility to surrounding tissues. Silicone rubber is one of the most important synthetic rubbers, used for various applications due to its excellent properties, such as flexibility, chemical resistance, and thermal stability ⁽⁵³⁾. As a result silicone was found to be the most common material used to fabricate maxillofacial prosthesis. However, silicone suffers from a rapid deterioration of physical properties and color instability and is difficult to repair, limiting its use in maxillofacial prostheses. After a few months of insertion, the prosthesis becomes unpleasant ^(31,54,55).

Silicone elastomers were introduced in 1946 but have been used in the fabrication of maxillofacial prosthesis only for the past few years. Silicones consist of alternate chains of silicon and oxygen which can be modified by attaching various organic side groups to the silicon atoms or by cross-linking the molecular chains ⁽⁵⁶⁾.

Silicones have a range of properties from rigid plastics through elastomers to fluids. They exhibit good physical properties over a range of temperatures. Silicon can be cured at room temperature or heat ⁽⁵⁴⁾. Since, they were introduced around 1946, Silicone elastomers were first used for external prosthesis by Barnhart in 1960 (Barnhart *et al.*, 1960), but only in the past few years have they been used in fabricating maxillofacial prostheses ⁽⁵⁷⁾. Silicones exhibit weathering properties and maintain good physical properties over a wide temperature range ⁽⁵⁶⁾.

Regards to silicon material, **Ariani *et al.*** ⁽⁵⁸⁾ stated that silicon facial prostheses are susceptible to bacterial and fungal colonization; this is attributed to surface irregularities and microscopic porosities in which micro-organisms easily colonize ⁽⁵⁸⁾.

Poly methyl methacrylate is a transparent resin of remarkable clarity. It is extremely stable, it will not be discolored in ultraviolet (UV) light, and it exhibits remarkable aging properties. Like all acrylic resins, poly (methyl methacrylate) tends to take up water by a process of imbibition.

Materials have been innovated starting from acrylic resin, this is used in fabricating both intra- and extra-oral prostheses. In powder form, these resins can be injection and compression molded; or in dough form, they can be molded in gypsum molds.

These acrylic resins are derivations of ethylene. The degree of polymerization varies with the conditions of polymerization, such as temperature, method of activation, type of initiator used, and purity of chemicals ⁽⁵⁹⁾.

The prosthesis is usually attached either to the framework of spectacles or to a clip attachment. It is used particularly in those cases in which little movement of the tissue bed takes place during the function ⁽⁶⁰⁾. The

material consist of acrylic powder: Polymethyl methacrylate and liquid: Methyl methacrylate and colors that can be used: Acrylic base paint used in monomer or chloroform solvent. Heat polymerized is preferred when compared to auto polymerized because of no residual monomer is more color stable and is free of tertiary amine activator.

Acrylic resin have shown advantages such as being durable, color stable, cosmetic and can be relined or repaired. Disadvantages of acrylic resin: Rigidity, the duplicate prosthesis is not possible, because of the destruction of the mold during processing and Water sorption that cause increased weight 0. 5% after 1 week ⁽⁶⁰⁾.

Aziz *et al.* ⁽⁵⁴⁾ stated that Silicone elastomers are the material of choice to replace missing facial parts which have been lost through disease or trauma. The ideal material for external facial prosthesis has been well defined ⁽⁶⁰⁾. Some of the desirable properties are (1) Resistance to tear at the thin margins (2) Tensile strength and the resulting elongation gives an indication of flexibility of the prosthesis (3) Ease of moulding (4) Colour stability (5) Water absorption (6) Non toxicity and non-sensitivity to the host tissues.

Colour Matching and Stability of the Prosthesis

Color matching substantially affects the acceptance of the prosthesis by the patient. External light conditions are important for visual color assessment because the spectral composition of standard light sources differs from that of daylight, leading to metamerism ⁽¹⁰⁾.

Collecting accurate skin color information is an important issue during color matching. Many approaches and techniques have been utilized to attempt to achieve an accurate skin appearance match. A chair-side visual trial-and- error method of mixing different pigments and dyes with a base maxillofacial prosthetic material is still widely used in current clinical practice ⁽⁶¹⁾.

Since **Haug *et al.*** ⁽⁶²⁾ stated that the Physical properties of maxillofacial elastomers were changed by the incorporation of coloring agents. They recommended the use of dry earth pigments, kaolin, and rayon flocking acted as a solid filler without bonding to the Silicone, and artists' oils and liquid cosmetics acted as a liquid phase without bonding to the silicone matrix.

The mechanical and physical properties of facial prosthetic materials have improved over recent years, but the color instability of the facial prostheses still limits the serviceability and is often the reason for remaking the prosthesis ^(18,62,63,64,65,66).

Environmental factors, such as weathering, normal aging and cleaning agents cause degradation of the optical and mechanical properties of the silicone elastomer ^(62,67,68), Polymeric materials usually have a low thermal stability and little resistance to solar radiation ⁽⁶⁵⁾.

Some factors that affect the color stability are UVA-UVB irradiation (sunlight), temperature, moisture, wind, dust and pollutants ⁽⁶⁹⁾.

The color change of the conventional pigments that are used in maxillofacial elastomers, has been studied by **Beatty *et al.*** ⁽⁷⁰⁾. They studied how UV irradiation caused color changes in a silicone elastomer that was colored with 5 oil pigments, which were applied either as base colorants (intrinsic) or surface tints (extrinsic). The authors postulated that either a chemical reaction or a chemical incompatibility between the pigments and the elastomer was responsible for the observed color changes ⁽⁷⁰⁾.

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