Design and Development of an Implant System for Auricular Prosthesis

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Defects of external ear could be corrected using prosthetic reconstructions retained by implants. Bar and clip design is currently followed for retaining the ear prosthesis. Bars are fixed onto osseo-integrated craniofacial implants through a two stage surgery. Clips embedded in an acrylic housing are used to retain the prosthesis on the bars. The major problems in this method are, the bulk of prosthesis that compromises the final cosmetic outcome and the loosening of the clips. A new design for retention mechanism is presented here which consists of a ball-and-socket snap-fit assembly. The implant is designed as a tapered threaded screw with a ball head abutment that needs only a single stage surgery. A matching cylindrical metallic socket with silicone snap ring is used for retaining the prosthesis. Two implants can provide adequate retention and stability to the prosthesis. Any loosening could be managed with the replacement of the snap rings. The socket dimensions are minimal, which are comparable to the natural projection of the ear, thus contributing to good cosmetic appeal of the prosthesis.

Introduction

An auricular defect generally occurs due to congenital abnormalities, trauma (burns, accidents, animal attacks and human bites) or surgical removal of cutaneous malignancies (1). Only two treatment options are available- the surgical reconstruction and prosthetic rehabilitation. Surgical (autogenous) reconstruction of an ear is a laborious process involving multiple plastic surgeries (2). Auricular prosthesis has been suggested as an alternative (1).

The auricular prosthesis can be made with alloplastic materials (like acrylic or silicone), aesthetically matching with intact counterpart. In its history of 400 years, retention has been a challenging problem (3). The simplest method adoptable is attaching to spectacles or hair-bands, but it is prone to inadvertent dis-placement or detachment. Another common retention mechanism is sticking the prosthesis to skin using adhesives. Regular reapplication of adhesive is necessary to secure the prosthesis and the removal needs chemical thinners. Skin reactions and reduced prosthesis life are the problems (1).

A breakthrough in the retention of the auricular prosthesis occurred in 1980's, when Branemark invented osseointegrating implants (4). Implants/fixtures for ear prosthesis are made of biocompatible metal (preferably titanium or its alloys) and placed in the mastoid bone. After osseointegration of the implant (3-4 months period), percuteneous abutments are connected which can hold the prosthesis (1). The prosthesis is mechanically retained either by using embedded clips or magnets (5,6). Implant-retained prostheses offer good aesthetics, close fit to the body and the convenience of easy removal and refitting.

In a typical clip-and-bar design, a system of three clips at different angles is recommended to make the prosthesis stable and improve the fit. This requires a bulky superstructure to hold the clip and enclose the whole bar. When the prosthesis is accommodated over the superstructure, the final outcome will prove aesthetically unappealing(7). Another drawback with the clip system is the loosening over a period of time, which might require a complete replacement (8,9).

Magnetic retention has been tried as an alternative to bar-clip design(5). The mechanism contains a set of small but powerful magnets (typically neodymium-iron-boron magnets of sizes 4mm X 2mm) attached to the abutments and ferromagnetic counterparts embedded in the prosthesis. The magnet is capable of providing a retentive force up to 0.6 N. This system has been commercialised successfully, but with no advantage in size because magnets need protective enclosure to prevent corrosion (5). The magnetic system was found functionally durable, but inferior in retention compared to the bar-and-clip system (10).

A recent innovation is the simplified bar-and-clip design, avoiding multiple arms in the bar. The structure is reduced to a single bar (11), with integrated rings at 45 degrees, to enhance retention and to prevent rotation. A typical case of implant-retained prosthesis using the simplified design (custom-made single Hader-bar and clip system, done by the first author) is shown in figure 1.

The bar, supported on two implants placed 20 mm apart, had a total length 32 mm (including the side rings) and height 5 mm (from the level of the implant). The superstructure was made in 35 mm length with outer cross section having 10mm width and 8mm height.

When prosthesis was mounted, the projection was larger than the natural counterpart, which necessitated additional filling at the rear side to cover visible gap. The outcome was esthetically compromising (as evident from the figure 1b), leading to reduced patient satisfaction. This case shows that the problem of size of the superstructure cannot be avoided completely in the simplified single-bar system.

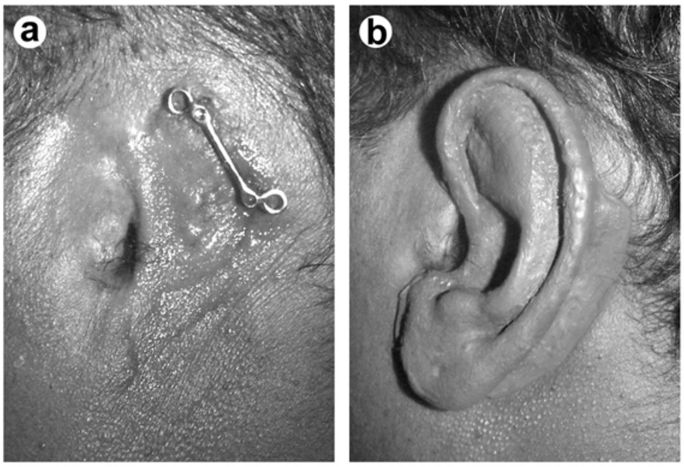

Figure 1: Prosthesis on a single Hader-bar. (a) The single bar mounted on two implants. (b) The finished prosthesis. The clip system is attached behind the upper part and in order to cover the uperstructure, additional fill-up is done at the back side

The present paper demonstrates a new implant design to retain auricular prosthesis with better functional and aesthetic advantages. This system consists of a ball-and-socket snap-fit assembly. The implant is made with an integrated ball head and the retention part is a flanged metallic cylindrical socket. A silicone o-ring placed around the neck of the ball serves as snap ring and ensures proper seating of the socket. The flange in the socket, when embedded in the prosthesis, enables the easy fitting and detachment of the prosthesis. Only the cylinders protrude out of the prosthesis thereby avoiding bulky housing and maintaining natural ear projection. As the ball-socket mechanism holds the prosthesis firmly in position, the number of implants could be reduced to two. Major advantage is that the implant placement could be done in a single stage surgery. The various features of the implant system and the design details are presented here.

Materials and Methods

The implant retained auricular prosthesis system has three parts - The implant, the retention system and the prosthesis. In the present technique, the implant and retention parts are modified, without altering the preparation of the prosthesis.

Rationale for the Design of the Implant

The prime consideration in designing an implant is the loading. In practical situations, an osseointegrated implant experiences forces in compression, tension or shear modes. Bone is known to withstand compression loading better than tensile and shear loading. For the same load, bone is 30% weaker in tension and 65% weaker in shear, as compared to compression (12). The fact that the forces likely to operate on an implant supporting auricular prostheses (0.1 – 1.0 N) are significantly less than those experiences by intra-oral implants (50-200 N) (13), provides certain flexibility in designing.

Size of an implant is determined by the thickness of the bone involved. In mastoid bone, where the intended implant is to be placed, a thickness more than 5 mm will not be available. Since the initial stability of the implant is a function of length and diameter, it should have a comparable diameter.

A tapered body design was chosen in the present case because it imparts lesser shear at the bone interface compared to cylindrical design. Moreover, it ensures easy insertion and improved initial stability. The taper geometry will convert a part of the axial load during fixing to radial direction, the magnitude of which depends on the taper angle (14). However, larger taper compromises screw length and reduce contact surface area, which adversely affect the stability. Hence, it is desirable to keep the cone angle of the taper less than 20 degrees (14).

Threading is preferred in an implant primarily because it offers less shear and more compression to bone in comparison to a smooth cylindrical body. In addition, threading maximizes initial contact, improves initial stability, enlarges surface area and favours the dissipation of the stresses (15). The major thread parameters are the form (the cross sectional shape), the pitch (the distance measured parallel between adjacent thread form features) and the depth, which are to be selected according to the intended function of the implant (16).

Generally, four types of thread forms are suggested for implants – 'V' form, square, buttress and reverse buttress (17). Out of these, V-form is most common in commercially available endosseous implants. Though square thread is able to transmit high compressive and low shear forces to bone, it is unsuitable for small implant lengths. Buttress thread forms are considered more suited for supporting maxillofacial prostheses (18). In an auricular implant, routine removal of the prosthesis for cleaning and reinsertion becomes necessary, which impart compressive and tensile forces. While compressive stresses are effectively resisted by bone, excessive tensile stresses may prove detrimental to the implant survival. Reverse buttress thread form can take care of the pull out force to a great extent because the outward thread face is flat. During the insertion the slant side of the thread helps to change the direction of axial compressive force partially to

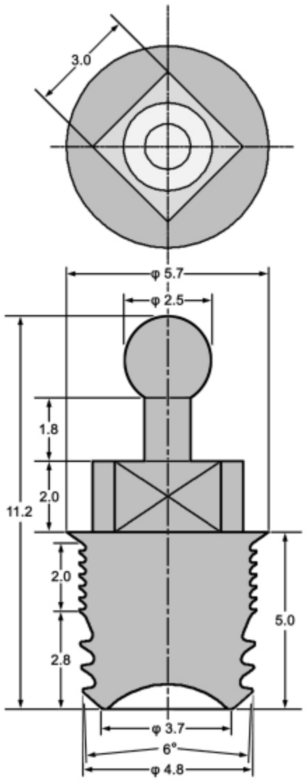

Figure 2: Implant design

transverse force.

A reverse-buttress dual thread design was adopted in the present case, in which the thread pitch and depth vary in the upper and lower parts so as to provide optimum stability in the mastoid bone. Micro-thread was made on the upper part because it can distribute stress effectively and preserve marginal bone support in the cortical

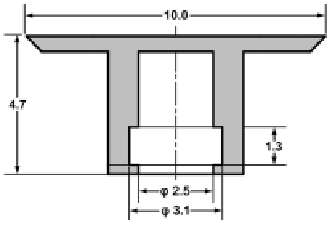

Figure 3: Socket design

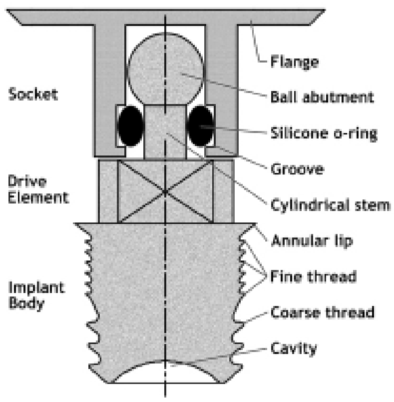

Figure 4: The complete system in assembled form

part of the mastoid bone. The dual thread structure is reported to have low insertion torque and a gentle increase of insertion torque, and hence it will be less harmful to the surrounding bone tissue (19). The design of the thread geometry in this work was based on the International Standard ASTM F 543 – 07.

Design details of the implant

A drawing of the implant is shown in Figure 2. The implant body has an overall length of 5 mm and a diameter 5 mm. Dual reverse buttress thread (ASTM) was made with fine thread at the top 2mm (leaving a space of 0.2 mm for the lip portion) and coarse thread in the remaining 2.8 mm towards the bottom. There are 6 fine threads with a pitch 0.33 mm and depth 0.18 mm. In continuation, 3 coarse threads with a pitch 0.66 mm and depth 0.34 mm were cut.

A taper of 6 degrees was given to the coarse thread part. The rake cut was made at the apical end, as a self tapping lead and an anti-rotation feature. A negative cavity was provided at the apical end to provide more bone contact area.

An annular lip of diameter 5.7mm was provided at the top part of the implant body. A 3 mm 'across-flat' square drive element with 2 mm height of was built on to the implant so that it could be driven with a standard torque wrench. The square section was selected because

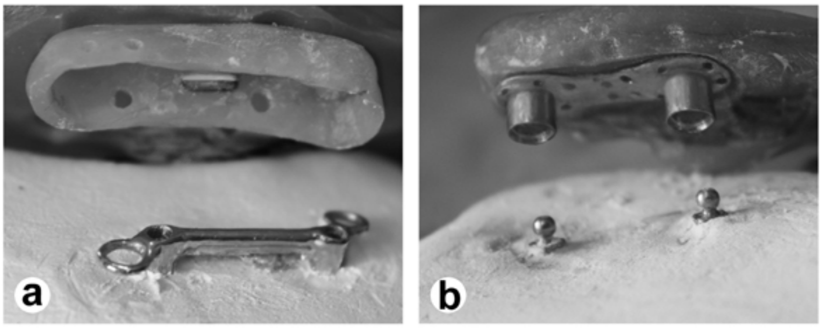

Figure 5: Simulation of the systems in die-stone replicas (a) Single Hader-bar and clip with acrylic housing. (b) The new design with the two sockets welded onto a single flange (not embedded fully into the prosthesis)

ensures a slip-proof drive and is free from space constraints.

An integral ball abutment with 2.5 mm diameter was provided on top of the drive element. The cylindrical stem connecting the ball to the drive element has a diameter of 1.3 mm and length 1.8 mm. A silicone o-ring of 1 mm thickness and 1.2mm inner diameter was slipped onto the stem.

The retention part was made as a cylindrical metallic socket exactly matching with the ball head, as per the drawing given in Figure 3. An inner groove is provided so as to lock-in into the o-ring which can impart sufficient friction grip force to retain the prosthesis in position. The outer diameter is 4.2 mm and the height is 4.7 mm. The socket has an integral circular flange of diameter 10 mm and thickness 0.5 mm. Small holes were provided on the flange so that silicone can flow across and bind together, while casting the prosthesis.

The complete assembly of the system is shown in Figure 4. The implant body will go into bone and the flange of the socket will get embedded in the prosthesis. This system enables easy fitting and detachment of the prosthesis. Only the cylinder part of the socket will be protruding out of the prosthesis, thereby avoiding the need for a bulk housing in the bar and clip system.

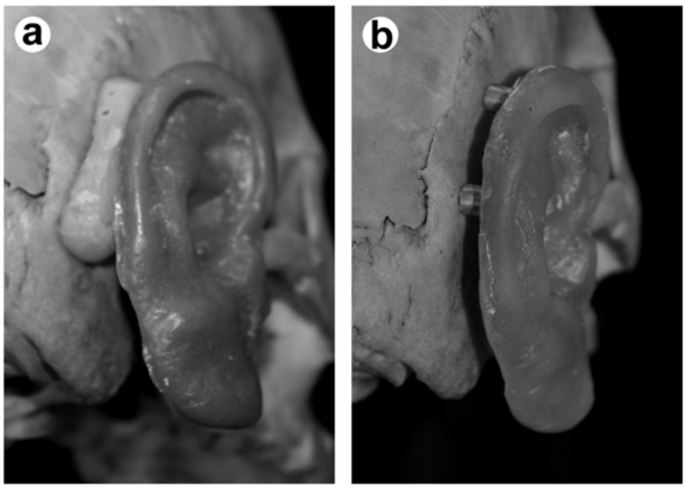

Figure 6: Comparison of prosthesis retention on a skull model. (a) Bar and clip system of fig 5a (b) The new system of fig 5b

Experiment

In vitro experiments were carried out to compare the aesthetic advantage of the new retention system with the currently accepted bar-and-clip system. First, the size comparison of the superstructure alone was simulated on replicas and then they were attached to prosthesis and fitted onto a skull model to measure the projection.

The experiment for the size comparison of the new system with the bar-and-clip system (single Hader-bar) was done on die-stone replicas of the mastoid portion of the skull. The implant spacing was kept at 20mm (Figure 5).

In the first case, the implants were placed onto the cast, upon which the bar was fixed (Figure 5a). The top of the bar was measured to be at 4.8mm from the surface of the cast. An acrylic superstructure was made to enclose the clip as per the description of Srithavaj et al (11). The superstructure base had 12 mm width and 35 mm length, with a height 7.8 mm.

In the second case, the newly designed implants with ball heads were placed in the cast. The two sockets were prepared with a single flange to provide stability to the prosthesis (Figure 5b). The flange was 0.5 mm thick, with a length of 30 mm (dumb-bell shaped) and maximum width of 10 mm. When inserted into the balls of the implants, the top of the flange resided at 4.7 mm from the base of the cast.

It could be seen that there is an advantage of 3.1 mm in the height of the retention system. This difference has a notable bearing on the projection of the prosthesis.

After the size measurements, the clip housing and the twin-socket system were embedded in respective prostheses made from the same mould. These were then fitted on to skull model (Figure 6) and the ear projections in the ear-eye horizon were measured using a vernier caliper (20). For the bar-and-clip system, the value was 12.07mm (Figure 6a) and for the new system it was 8.85 mm (Figure 6b). An advantage of 3.22 mm could be obtained which is significant in the perspective of cosmetic appearance. The projection achieved with the new system is close to natural ear projection. The sockets could be easily concealed with a small additional covering, which will not be prominent.

Discussion

Today, extra-oral endosseous maxillofacial implants have revolutionized the prosthetic management of maxillofacial defects. This technology took off with the discovery of biocompatible materials such as titanium and the development of osseointegrating implants by Branemark and his associates in 1980's (21). Studies have shown that there is a considerable improvement in the degree of retention and longevity of the prostheses with the use of maxillofacial implants (22).

The implant retained prostheses are a boon to patients, mainly because they offer better aesthetics and the convenience of removal and refitting. The chances for dislodgement of the prosthesis in routine activities and the consequent embarrassment are reduced, which enhance the self esteem and confidence of the patient.

In contrast to intra-oral implants, which are available in a wide range of shapes and with different surface preparations, extra oral endosseous craniofacial implants are far less diverse. These implants are comparatively shorter and have a dual structure with an endosseous part and a thread-in abutment. Generally a perforated flange is provided to increases the implant surface area in contact with bone, to facilitate initial immobilization and to prevent undue intra-cranial penetration.

A two-stage surgery is suggested for the osseo-integrating implants. As per the accepted protocol, the implants are to be placed in the mastoid area 15 mm apart keeping a distance of 20mm from auditory canal opening. After confirming the osseointegration radiographically (in a period of 3 – 4 months) the second surgery is done to place the abutment.

The implant designs currently available are identified to have problems which may lead to the failure (23). One is prosthesis misfit, which is considered to be the consistent cause of failure of mechanical components.

Misfits play an important role in complications such as abutment screw fracture. It must be recognized that all metallic objects implanted in the body is likely to undergo flexural fatigue and embrittlement. Neck of the abutments, if thin, can fracture. Screw loosening is another complication which causes inconvenience to the patient and practitioner. If the case occurs frequently, it may prove financially burdensome (24).

The new implant and retention system presented here, offer significant improvement from the existing designs. which reduces the surgical requirements. The retention mechanism is sleek and provides an ear separation close to the natural case.

The main feature is that the implant and abutment are integrated to a single structure. The implant body contains a dual reverse-buttress thread. Coarse thread provided in the apical portion enables the growth of the cancellous bone and the fine thread provided in the crestal region of the screw ensure good apposition with denser cortical bone. The fine pitch thread provides larger surface area for bone bonding.

Conventional designs incorporate a flange at the crest of the body, in order to avoid intra-cranial penetration. Though the flange is capable of enhancing the load bearing area, it may lead to the accumulation of debris and microbial colonization followed by infection (25).

In the present design, crestal flange is replaced with an annular lip having an extra diameter of 0.7mm. The drive element and the abutment (in the form of a ball head) are integrated to the implant body. The single piece construction of the new implant provides good strength.

The most notable advantage of the present implant is that the implantation could be done through a single stage surgery.

Instead of a skin flap as in normal procedure, a tissue punch could be used at the marked sites. This reduces the trauma to soft tissue. Immediate placement of a temporary prosthesis could be done which takes care of the cosmetic concern of the patient. In addition, a single stage surgery has advantages in reducing both the rehabilitation period and the cost of the procedure.

Generally three implants are placed in the conventional protocol, so as to place the bars at an angle to avoid lateral displacement of the snap mechanism. In the modified design, only two implants are required. As the ball and socket retention mechanism provides localized support, the two implants can hold the prosthesis in position. This reduces the trauma of putting more implants.

As evident from the results of the experiment, the new retention system reduces the bulk of the superstructure. The bar system is observed to affect the local hygiene by limiting access to the defect area (26). The new system exposes only two ball heads, which allows easy cleaning of the surrounding area. With the ball-socket arrangement, it is easy to maintain the prosthesis to natural projection, which has cosmetic advantage and improved patient satisfaction.

Conclusion

This work presents a design of an improved system for the retention of auricular prosthesis. The implant is a single structure incorporating the ball-head abutment. The retention part is a snap-on socket, the flange of which could be embedded in the prosthesis. This reduces the bulk of the superstructure while providing good retention. In vitro studies show that the new system leaves out a prosthesis projection close to the natural ear.

The integrated structure of the implant reduces the surgical steps to single stage. This system is more hygienic, easy to repair and affordable, compared to the existing bar-and-clip system.

Further studies are necessary regarding the tissue reactions, osseointegration, functional performance and longevity. The related in vitro evaluation and animal experiments on this new system are in progress.

This design concept could be extended to other maxillofacial prostheses (nose and orbital) also. That may lead to a more aesthetically appealing, convenient and affordable rehabilitation for the needy.

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