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Osseointegrated Implants and Auricular Defects: A Case Series Study

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Keywords
Craniofacial implants; mastoid implants; implant-retained auricular prosthesis; implant-retained facial prosthesis; facial prosthesis; retrospective study.

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Accepted April 5, 2007

doi: 10.1111/j.1532-849X.2008.00309.x

Abstract

Purpose: The objective of this study was to report on the survival rate of 16 patients treated with extraoral implants in the auricular region, analyze treatment outcomes, and discuss important clinical variables encountered during treatment.
Materials and Methods: Sixteen patients who received extraoral dental implants to retain auricular prostheses between 1987 and 2003 were followed retrospectively. The variables recorded were gender, initial diagnosis, number and size of implants, implant placement date, age at implant placement, history of radiation to the treated field, abutment size, design of initial prosthesis, age of initial prosthesis (when a remake was indicated), date of prosthesis delivery, soft tissue response, grafting procedure, date of last follow-up, and complications. All patients were thoroughly evaluated presurgically by the reconstruction team, which consisted of prosthodontists, a facial prosthetist, and an otolaryngologist. Surgical templates were used for all patients. The criteria for success of the prostheses included marginal accuracy, overall stability and function, symmetry/position, texture, color stability, and patient acceptance.
Results: Thirty-nine implants were placed in 16 patients. All 16 patients were completely satisfied with their reconstructions. No surgical complications, implant failures, or prosthetic failures were encountered. Therefore, the survival rate was 100%. Three patients (18.75%) had grade 0, seven (43.75%) had grade 1, five (31.25%) had grade 2, and one (6.25%) had grade 3 soft tissue inflammation. The inflammation completely resolved in 7 of the 13 patients (54%) with hygiene reinforcement or soft tissue reduction.
Conclusions: The survival rate for bone-anchored titanium implants and prostheses was 100%. Bone-anchored titanium implants provided the 16 patients in this study with a safe, reliable, adhesive-free method to anchor auricular prostheses with recovery of normal appearance. Under the guidance of an appropriate implant team, proper positioning of implants was optimized to allow prosthodontic rehabilitation using implant-retained prostheses.

Traditional means of retaining facial prostheses have involved the use of medical-grade skin adhesives, solvents, eyeglasses, the use of hard and soft tissue undercuts, and other modalities.[1] Unfortunately this treatment was 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.[2,3] Percutaneous craniofacial implants in craniofacial reconstruction have minimized some of these disadvantages and have provided patients with predictable esthetics and durability, improved retention, and stability of the prostheses. Parel et al[4] reported in 1986 that use of implants in maxillofacial prosthetics was the most significant advance in the field of facial prosthetics in the past 25 years.

The concept and evolution of craniofacial implants has developed into a reliable treatment option providing stability and retention to facial prostheses. In 1983, Tjellstrom et al[5] reported a 5-year experience with bone-anchored implants. They

established that with proper surgical technique, it was possible to place implants in the temporal area and percutaneously support facial prostheses with retentive elements. A report by the same lead author in 1985 reported on a 5-year experience with bone-anchored auricular prostheses in 38 patients receiving 159 implants, with a survival rate above 99%.[6] Following these early reports, the use of craniofacial implants to retain and stabilize facial prostheses has become a widely used and proven treatment modality.[7-10]

In 1994, Granström et al[11] reported on implant failure in irradiated mastoid tissues and reported an 86.2% implant survival rate for patients not receiving hyperbaric oxygen (HBO) treatment and 100% implant survival rate for patients receiving HBO. The use of radiation shields in head and neck cancer patients receiving adjuvant radiation therapy is a treatment alternative for protecting anticipated prosthetic implant sites. Shields can be fabricated easily as part of an interdisciplinary treatment protocol. Columbia University, College of Dental Medicine (CCDM), Maxillofacial Prosthetic Center reported on radiation shielding devices for protection of anticipated craniofacial implant sites.[12]

In addition, CCDM previously reported in 1999 on their first six craniofacial implant patients.[13] This initial report included a protocol using a 3D surgical template to enhance the prosthetic result.[14] There were no failures or rejections noted for the extraoral dental implants, and the patients used their bone-anchored prostheses with high levels of satisfaction. Four patients were treated with a bar and clip design and two with magnets to retain the prostheses.[13] Initially used by the Swedish implant team, the bar and clip design provides excellent retention in the region of the bar but may have less ability to maintain satisfactory peripheral margins.[15] More space is generally required under the antihelix for the acrylic resin base, the clip, and the bar. In contrast, magnets have a lower profile and can improve marginal adaptation of large facial prostheses. [4]

The present study expanded the original CCDM study to 16 patients. The goals of this study were to report on the survival rate with extraoral osseointegrated implants, analyze treatment outcomes, discuss important clinical variables encountered during treatment, and determine criteria for success for the implants and prostheses.

Materials and methods

A review of patients' charts was conducted with the institution's investigational review board approval. All patients treated for auricular defects with implant-retained auricular prostheses at Columbia's Maxillofacial Center were included in the report. The variables recorded were gender, initial diagnosis, number and size of implants (1987-1999: 3.75 × 3.0 or 4.0 mm, Nobel Biocare, Göteborg, Sweden; 1999-present: Vistafix™, 3.75 × 3.0 or 4.0 mm, Entific Medical Systems, Göteborg, Sweden), implant placement date, age at implant placement, history of radiation to the treated field, abutment size, design of initial prosthesis, age of initial prosthesis, date of prosthesis delivery, soft tissue response, grafting procedure, date of last follow-up, and complications.

Surgical protocol

Following the completion of the surgical template, patients were scheduled for implant surgery. All procedures were performed under general anesthesia. The application of the surgical templates was performed under the guidance of the maxillofacial prosthetic team in the operating room (Fig 1). The templates were prepared in a way that allowed skin markings through openings in the template where the implants would be ideally placed. In the event mastoid air cells were encountered or bone depth was inadequate, a wider area was marked for alternative placements. In addition, planning for alternative placements was used due to the possibility of encountering poor bone quality where primary implant stability could not be achieved. Insertion torque (15 Ncm minimum) was used to evaluate primary stability. After a full thickness skin flap was reflected, the periosteum was marked with methylene blue using a needle injection. The first stage included excision of auricular remnants, skin tags, or scar tissue. Every effort was taken to preserve and use as much of the local skin as possible. Care was taken to thin the skin and subcutaneous tissue to a thickness not exceeding 2 mm (Fig 2).

A drilling unit (DEC 500, Nobel Biocare) and guide drill were used to create the osteotomies. A drill depth of 4 mm was preferred. In children with thin cortices, a 3-mm drill was used. Titanium implants were placed with slow rotation (1200-1500 rpm) and high irrigation for appropriate cooling of the implant sites. Two or three implants were used for prosthesis retention. Percutaneous abutments (4.0 or 5.5 mm, Entific Medical Systems) were attached in a single stage protocol in nine patients. For these patients (n = 9), the skin was redraped over the abutments and penetrated with an 11 Bard–Parker blade (Becton Dickenson AcuteCare, Franklin Lakes, NJ) or punch biopsy tool (4-mm dermal punch biopsy, Ace Surgical Supply Co., Brockton, MA). Healing caps were attached to the abutments and a pressure dressing was applied. The skin was packed against the periosteum using xeroform gauze (Kendall, Inc., Mansfield, MA) impregnated with an antibiotic ointment (Bacitracin, Invacare, Holliston, MA). Three patients who lacked healthy skin in the area were grafted with split thickness skin grafts obtained from an arm or thigh.

The implants were not loaded for 3 to 6 months, during which postsurgical visits were scheduled. The scheduled visit periodicity was 1 week postoperatively and monthly thereafter to ensure proper skin healing. After 3 to 6 months, the patients were referred back to the maxillofacial prosthetic team for fabrication of the prostheses. Pediatric patients (n = 1) with poor bone quality and patients with a history of radiation therapy (n = 2) to the implant area were treated using a two-stage surgical protocol and were loaded after 6 months.

Patients who did not have ear canals or middle ear pathology (n = 5) received an extra implant for the attachment of a bone anchored hearing device [Bone Anchored Hearing Aid (BAHA) system, Entific Medical Systems]. The system allowed transmission of sound percutaneously to the cochlea, thereby reestablishing hearing in addition to the esthetic and psychosocial benefits of auricular prostheses.

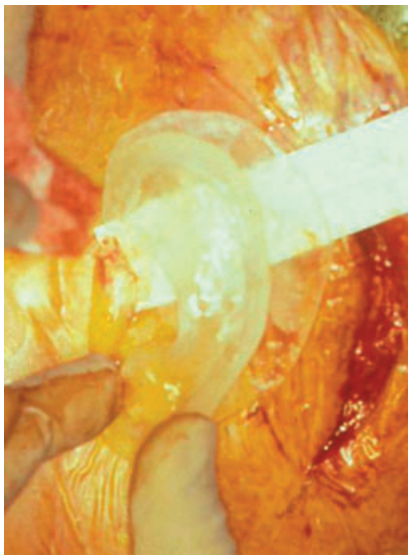

Figure 1 Surgical template fabricated from diagnostic wax pattern in place to assist with proper implant placement during surgery.

Prosthetic protocol

The prosthetic procedures began with the fabrication of the surgical templates.[17] Presurgical impressions were made and used to fabricate earwax patterns. When the positions, contours, and form were confirmed, the wax patterns for the surgical templates were converted to acrylic resin surgical templates while preserving the wax patterns to be used as the patterns for the final prostheses. The maxillofacial prosthetic team ensured proper use and placement of the surgical template at implant placement surgery to ensure prosthetic success.[13,14]

After healing, abutments were either in place or were connected, and abutment level impressions were made using square impression copings with long guide pins (Entific Medical Systems). Retention was provided by magnets or magnet keepers (Technovent, Leeds, England) (Figs 3 and 4), or a cast bar and substructure with clips (CM Gold Riders, Cendres & Metaux, Bern, Switzerland) (Figs 5 and 6). Round, plastic burnout patterns were used to fabricate the bars (1.8 mm, 13 gauge, Attachments International, San Mateo, CA). The patterns were waxed directly to the gold cylinders (Gold cylinders, Entific Medical Systems). A type III gold alloy was used for the castings (Rajah, Jelenko, San Diego, CA). After the prosthetic substructures containing the retention elements were made, the prosthetic substructures were incorporated into the wax patterns to allow for wax pattern try-in.

The majority of the silicone prostheses (n = 15) were cast in a silicone material after the contours and position of the wax pattern had been verified (2186-F, Factor II, Lakeside, AZ). One prosthesis, made in 1987, was made with a different silicone (polydimenthylsiloxane, Dow Corning, Wilmington,

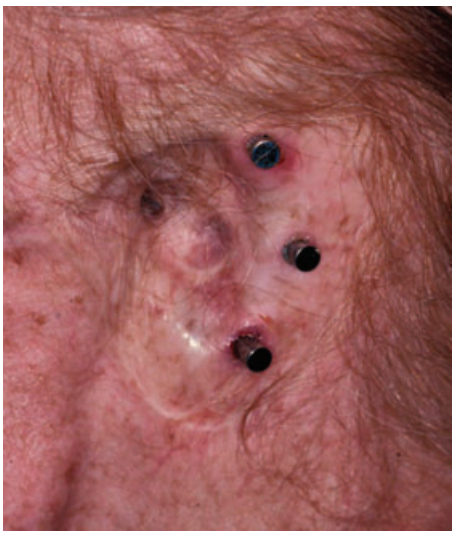

Figure 3 Magnetic retention on three implants.

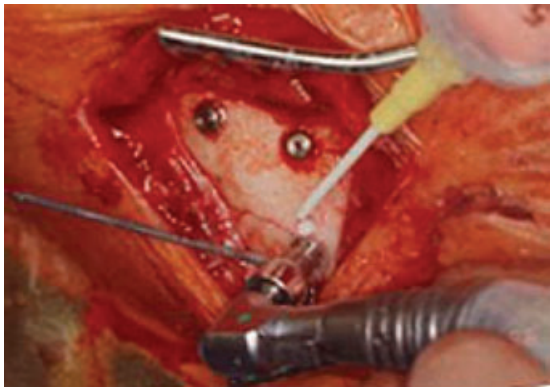

Figure 2 After thinning the skin and subcutaneous tissue, the third implant was placed in the left mastoid process using slow rotation and copious irrigation.

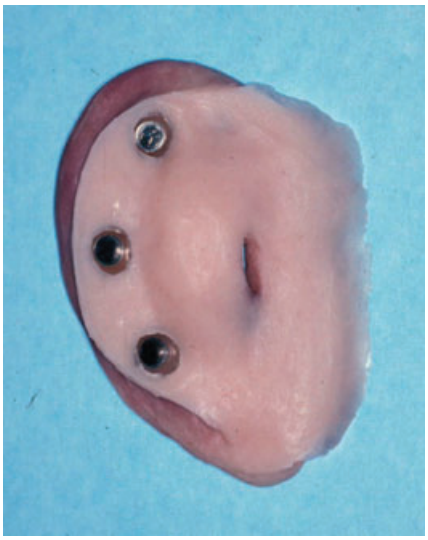

Figure 4 Intaglio surface of an auricular prosthesis. Magnet keepers were processed and incorporated into the silicone prosthesis.

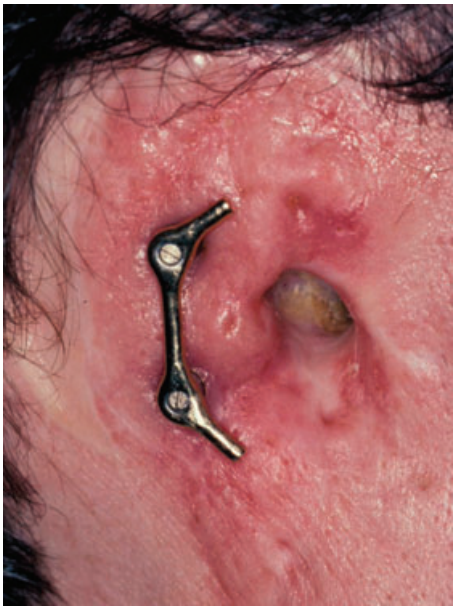

Figure 5 Retentive bar in place on two implants.

DE). Intrinsic and extrinsic coloring and flocking (Factor II) were performed and the prostheses were delivered (Fig 7).[18]

Magnets were used when there was less than 9 mm of vertical space under the antihelix for prosthetic components. Better access for hygiene for patients with limited dexterity was an additional indication for magnets. Bar and clip designs were used to provide retention, especially in physically active patients (Figs 5-7).

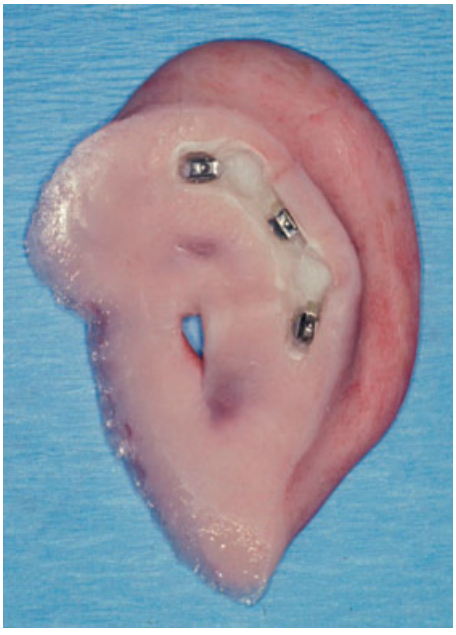

Figure 6 Intaglio surface of an auricular prosthesis demonstrates the three retentive clips.

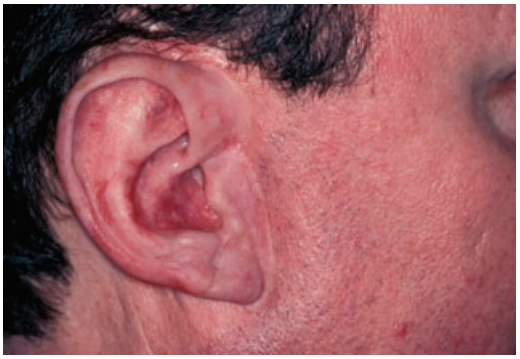

Figure 7 Bar and clip retained auricular prosthesis in place.

At delivery, patients were given both verbal and written homecare instructions. Patients were instructed to clean the prosthesis daily with a soft bristled or child's toothbrush and dish detergent. Peri-abutment instructions included using diluted 3% hydrogen peroxide solution and a child's toothbrush to remove skin accretions daily. Patients were told not to sleep with their prostheses.

Follow-up visits were scheduled at 1 week, 6 months, and 1 year. Following the first year, patients were scheduled semiannually both by the prosthodontic team and the otolaryngologist. Data was recorded during recalls at 6-month intervals by one maxillofacial prosthodontic attending (RW) and the anaplastologist (EA). Implant failure was defined as clinically detectable implant mobility. Criteria used to classify health of peri-implant soft tissue were based on that used by Holgers et al[16] (0 = no irritation, epithelium debris removed if present; 1 = slight redness, local treatment; 2 = red and slightly moist tissue, no granuloma formation noted, local treatment, extra controls; 3 = status as in 1 and 2 but local revision became necessary; 4 = removal of skin-penetrating implant necessary due to infection).

To systematically evaluate the success of the implant prosthesis, criteria were developed to assess reversible and irreversible factors with regard to both the integration of implants and qualities of the prostheses (Table 1). Implant factors examined included position, integration, and skin reactions. Prosthetic considerations included marginal accuracy, overall stability and function, symmetry/position, texture, color stability, and patient acceptance. Irreversible factors were defined as those that could not be corrected, and therefore any one problem would signify a failure. Reversible factors required reassessment and correction (Table 2).

Results

A total of 39 implants were placed in sixteen patients between 1987 and 2003. The majority (15/16) of the patients in this study were treated after the United States Food and Drug Administration approved the use of craniofacial implants in 1997. One patient was treated as part of a BAHA study in 1987. Ten of these defects were diagnosed as congenital anomalies, two were related to trauma, and four were secondary to tumor resection. Of the patient population, 87.5% (14/16) were males

Table 1 Criteria for success

	Implant	Prosthesis
Reversible factors	Position (corrections: angulated abutments, use of magnets instead of clips and bars)	Margins/marginal accuracy
	Peri-abutment skin Rxn: Grades 0, 1, 2, and 3	Color stability (extrinsic)
		Stability/functionality
		Prosthesis mobility
		Symmetry/position
		Pt acceptance/QOL
Irreversible factors	Integration vs. mobility/pathology	Color stability (intrinsic)
	Position (cannot be corrected without compromising esthetics or functionality of prosthesis)	Contour/form
	Peri-abutment skin Rxn: grade IV	Pt acceptance/QOL

Pt = patient; QoL = quality of life; Rxn = reaction.

and 12.5% (2/16) were females. Age distribution was as follows: 12.5% (2/16) younger than 18 years; 50% (8/16) between the ages of 19 and 40 years; 12.5% (2/16) between the ages of 41 and 69 years; and 25% (4/16) 70 years or older. The average age of the 16 patients at the time of stage I surgery was 40.6 years (range: 6 to 76 years).

The observation period ranged from 6 months to 17 years. Six patients were followed for 6 to 19 months, three patients were followed for 20 to 39 months, and seven patients were followed for 40 or more months. The average follow-up for the 16 patients was 45 months.

Five patients had implants to retain individual BAHA units. There were 44 mastoid implants in the 16 patients. The remaining 39 implants were used for prosthesis retention or anchorage. Of the 39 implants used to retain auricular prostheses, 5 implants were 3 mm in length, and 34 implants were 4 mm in length. Nine patients had only two implants placed because of limited bone quality and quantity at the surgical sites. One patient received 4500 cGy and the other received 6500 cGy of radiation therapy to their defect sites before implant placement. These two patients had five implants placed into irradiated bone. A radiation shield was constructed for one of these patients to reduce the radiation dosage to the mastoid region and anticipated implant sites.[12] The tissue bed for six patients was a full thickness skin graft. Three patients had split thickness skin grafts to improve the tissue bed, and seven patients had no grafting.

After a 3 to 6 month healing period all implants (n = 39) had achieved osseointegration as defined by immobility of the implant and absence of pathology. On 22 of the implants, 4-mm abutments were attached, and 5.5-mm abutments were attached to 17 implants to anchor auricular prostheses. A retentive bar and clip design was used initially in six patients (Figs 5-7), while ten patients initially had prostheses retained by magnetic elements. One patient with the magnet design was converted to the bar and clip design in an attempt to improve retention. One patient with a bar and clip design was converted to the magnet design to lower the profile of the prosthetic components to improve esthetics.

Thirteen patients demonstrated varying degrees of soft tissue inflammation for brief periods during the study. The response of the peri-implant soft tissues was followed from 6 to 204 months with an average of 45 months. The soft tissue grades for the patients in the study are listed in Figure 8. All patients with a recorded soft tissue response greater than grade 1 returned to a soft tissue response of grade 0 or grade 1 once hygiene and homecare instructions were reinforced.

Discussion

In the present study, the implant cumulative survival rate (CSR) for implants in the auricular region was 100% (39/39). The results of this study demonstrate that extraoral implants provide a valuable alternative to conventional, adhesive-retained facial prostheses. The extraoral application of the Branemark titanium implant system for craniofacial rehabilitation and bone-anchored hearing aids provided a safe, retentive, reproducible, and adhesive-free attachment for extraoral prostheses. The highest survival rates occurred in mastoid bone. This finding is similar to the findings of other studies in densely corticated temporal bone where implants have provided excellent stabilization for dental implants as well as satisfactory vascularity conducive to maintaining the interfaces between the bone and implants.[9,10] The mastoid region in nonirradiated patients has provided a high degree of predictable individual implant survival. The present study demonstrated similar outcomes, and the CSR was consistent with other reports on mastoid implants.[5-10]

A prior history of radiation therapy has been associated with a higher implant failure rate.[11] In the present study, all five implants placed in irradiated tissue were successful. A radiation shield for the mastoid area was used during radiotherapy for one patient. The use of radiation shields in head and neck cancer patients receiving adjuvant radiation therapy has been described as a treatment alternative for protecting anticipated prosthetic implant sites.[12]

Premature loading of implants has been shown to increase the risk of failure.[19] To minimize implant failures, no loading or instrumentation of the abutments were performed prior to 3-month unloaded healing periods for osseointegration. Another method used in this study to minimize failure was the use of the original two-stage protocol for patients unable to care for the implants during the healing phase of osseointegration. Patients undergoing single-stage procedures were instructed to be well aware of the importance of avoiding any pressure or premature loading and were advised to wear protective mastoid dressings or gauze at bedtime to improve the survival rate.

Chronic inflammation of peri-implant soft tissues can cause implant failure.[10] In this study, patients exhibited varying grades of soft tissue problems, which were most commonly associated with poor hygiene, physical irritants, and excessive thickness and mobility of the peri-implant soft tissues. All except one patient had either grade 0, 1, or 2 tissue responses. Thin, immobile soft tissue beds led to fewer peri-implant tissue complications.[5] Results of this study agree with the importance of thin,

Table 2 Categories I-V

		CATEGORY				
Reversible	**Implant**	**I**	**II**	**III**	**IV**	**V**
	Position *(corrects: via angulated abutments, use of magnets instead of clips and bars)*				■	■
	Peri-abutment skin Rxn: grade 0		■	■	■	■
	Peri-abutment skin Rxn: grade 1	■		■	■	■
	Peri-abutment skin Rxn: grade 2	■	■		■	■
	Peri-abutment skin Rxn: grade 3	■	■	■		■
	Prosthesis					
	Margins/marginal accuracy					■
	Color stability (extrinsic)					■
	Stability/functionality					■
	Prosthesis mobility					■
	Symmetry/position					■
	Pt acceptance/quality of life					■
Irreversible	**Implant**					
	Position *(cannot be corrected without compromising esthetics or functionality of prosthesis)*	■	■	■		
	Integration vs. mobility/pathology	■	■	■	■	
	Peri-abutment skin Rxn: grade 4	■	■	■	■	
	Prosthesis					
	Color stability (intrinsic)	■	■	■	■	
	Contour/form	■	■	■	■	
	Pt acceptance/quality of life	■	■	■	■	

Category I: Ideal outcome. Soft tissue and hard tissue condition healthy. Implants integrated, and prosthesis is esthetic and accepted by patient. Grade 0 Holgers possible.

Category II: Minimal to no bone resorption and/or reversible soft-tissue reaction up to grade 1 Holgers. Prosthesis esthetically acceptable or may require minimal modification. Positioning or angulation of implants is not ideal but can be corrected.

Category III: Soft tissue reaction requires prosthesis design or fabrication changes, and/or minor surgical intervention. Prosthesis requires moderate esthetic modification. Peri-abutment skin reaction up to grade 2 Holgers. Requires correction that is difficult, but possible to achieve.

Category IV: Prosthesis with reservation can be used, but retention or esthetics is compromised. Result is substandard. Prosthesis should be refabricated. Peri-abutment skin reaction up to grade 3 Holgers.

Category V: Prosthesis cannot be retained by implants due to lack of osseointegration or positioning that cannot be corrected. Peri-abutment skin reaction up to grade 4 Holgers. All irreversible factors qualify. Patient refuses to wear prosthesis.

Note: The most complex factor determines the overall classification for the case.

Pt = patient; Rxn = reaction.

immobile soft tissue to promote soft tissue health. Soft tissue reduction causes formation of an epithelial collar around the abutments that facilitates hygiene maintenance and promotes healthy peri-implant soft tissues.[1] Minor soft tissue complications (slight redness or redness without granulation tissue formation) were most commonly associated with occasional lapses in daily hygiene. In all patients, soft tissue inflammation resolved rapidly with resumption of appropriate daily hygiene measures, removal of physical irritants, or with soft tissue revision. Patients received written hygiene instructions covering daily homecare on delivery of the implant-retained prostheses. Only six patients were not able to maintain the levels of hygiene required to prevent soft tissue problems during the entire study period. Regular follow-up examinations, repeated hygiene evaluation, education, instruction, and reinforcement optimized the outcomes. Even though the examiners were familiar with the grading scale for soft tissue inflammation, the examiners in this study were not calibrated. Future studies should include

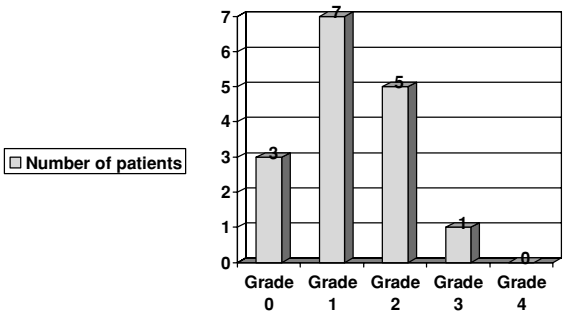

Figure 8 Soft tissue grade: grade 0: 18.75% (n = 3); grade 1: 43.75% (n = 7); grade 2: 31.25% (n = 5); grade 3: 6.25% (n = 1); grade 0 (n = 0).

calibration of examiners for not only the soft tissue examination, but also for other variables evaluated, including the esthetic evaluation of the prostheses.

Success was affected by the position of the implant. The use of surgical templates and the presence of the prosthodontic team to ensure proper positioning and angulations of the implants at the time of surgery enhanced prosthetic results.[13,14] Furthermore, presurgical planning guidelines were contained in the parameters of care document for intraoral and extraoral implant prostheses as a method to provide prosthodontic-driven implant placement.[20]

Several factors affected the choice of bars and clips versus magnets. In the early portion of this study, the initial goal of treatment included three implants in a nonlinear alignment in each defect. This was intended to distribute functional loads and reduce bending moments by avoiding the use of cantilevers or to distribute the loads if magnets were used. When magnets were used for retention, three implants placed in a tripod fashion provided the best stabilization. When bar and clip systems were planned, two implants often sufficed. Magnets offered the advantages of easier fabrication, shortened appointments, and access for peri-abutment hygiene procedures. Magnets also maintained a longer, more predictable level of retention than clips, which tended to loosen in a shorter period of time; however, bar and clip systems were advantageous biomechanically in that they effectively splinted the implant sites together, and these systems offered stronger immediate retention. Few problems were encountered in this study during fabrication of the bar and clip system (n = 6) and ear prostheses. In ten patients treated with magnets for retention, corrosion was not seen.

The success of bone-anchored auricular prostheses was based upon the patients' acceptance, contribution to quality of life, and use of the prostheses as a replacement prosthesis for either a developmental defect or acquired defect. Ten patients had congenital or developmental defects, two lost the auricles due to trauma, and four defects were associated with tumor ablation. Patient acceptance was evaluated during prosthesis delivery and at follow-up examinations and noted in the charts. The acceptance of the prostheses for all 16 patients was excellent.

Another measure of prosthesis success was based on the criteria of marginal accuracy, color stability, stability and function, and symmetry/position and form or contour. Marginal accuracy was one measure of success, and the use of implants as retentive anchorage allowed thinner margins to blend better with the adjacent skin because there were no adhesives that could cause margin deterioration. Color and color stability were also important, and the prostheses matched the adjacent tissues and contra-lateral ears through intrinsic and extrinsic coloring and surface texturing.

The retentive elements provided stability and function; this was evaluated by inspection and through assessments to ensure that patients reported stability during normal activity. Stability of the prostheses was also assessed during mandibular movements. Symmetry and positions of the prostheses were evaluated from four different views for symmetry and position. The prostheses were viewed from the front, side of the defect, rear, and top to assess symmetry with the contra-lateral ears. The form and contour was also a measure of success and the prostheses were contoured similar to the contra-lateral ears. Form and contour were appropriate if the implants were placed in the planned positions. After evaluation by the prosthodontic team, the 16 patients in this study all had successful prostheses based on the above criteria.

Conclusions

This retrospective clinical study revealed 100% cumulative implant (n = 39) and prosthesis (n = 16) survival rate in 16 patients. The efficacy of skin-penetrating osseointegrated implants used to restore the auricular defects in this study was excellent. Complications were seen where the surrounding soft tissues were not thin and exhibited mobility or when hygiene compliance was inconsistent. Generally, hygiene compliance required constant monitoring to maintain soft tissue health at the implant sites. Tissue complications were resolved when hygiene compliance was improved. Criteria for success were defined for extraoral osseointegration by specific reversible or irreversible factors for the implants and the prostheses. These criteria should take into account the uniqueness of extraoral osseointegration and its distinctiveness from intraoral dental implants.

Due to the small sample size, this study should be viewed as identifying trends only and not as proof of predictable survival rates. The survival rates are considered likely to change with time as the number of patients treated with extraoral implants increases, and the duration of follow-up is extended. Additional multicenter studies with longer follow-up periods are necessary, because the number of patients treated in this study was relatively small. There is also a need for more research and clinical trials regarding craniofacial implants in irradiated tissue.

Acknowledgment

This research received IRB approval: CU-IRB #15132.

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