Soft Tissue Response and Survival of Extraoral Implants: A Long-Term Follow-up

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Maxillofacial defects may be reconstructed by plastic surgery or treated by prosthetic mean rehabilitation. In case of large defects, prosthetic rehabilitation rather than surgical reconstruction is preferred due to the insufficient esthetic results of surgical interventions. However, retention of the craniofacial prosthesis is a great problem despite the satisfactory esthetic results. With the presentation of extraoral implants, the retention of maxillofacial prostheses was improved, and osseointegrated craniofacial implants have become indispensable for retention and stability. However, there are conflicting results regarding the success rates of osseointegrated implants used at the craniofacial region. A total of 24 patients with 64 implants (30 in auricular region of 13 patients, 24 in nasal region of 8 patients, and 10 in orbital region of 3 patients) ranging in age from 16 to 83 years (mean age = 45.45 years) were evaluated. One patient among 13 patients (1/13) has lost his implants in the auricular area, 1 patient among 8 patients (1/8) lost his implants, and 1 patient among 3 patients (1/3) has lost all of her implants. Peri-implant soft tissue response was evaluated for a 60-month period and a total of 654 visits/sites recorded. Grade 0 (no irritation) was present in 72.8% (476/654) of the visits/sites. Grade 1 (slight redness) was observed for 18.8% (123/654). Grade 2 (red and slightly moist tissue) was scored in 6.9% (45/654). Grade 3 (red and slightly moist tissue with granulation) was noted in 1.5% (10/654) and grade 4 (infection) could not be found. Ossseointegrated implants provide reasonable support and show successful results when used with maxillofacial prostheses.

Key Words: extraoral implant, tissue response, survival

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INTRODUCTION

Maxillofacial defects may occur as a result of trauma, congenital disorders, and or ablative surgery, and be reconstructed by plastic surgery or treated by prosthetic mean rehabilitation. In case of large defects, prosthetic rehabilitation rather than surgical reconstruction is preferred due to the insufficient esthetic results of surgical interventions. However, retention of the craniofacial prosthesis is a great problem despite the satisfactory esthetic results.[1–3]

Skin adhesives, eyeglasses, and anatomic undercuts in the defect area are commonly used aids for the retention of the prosthesis, yet the results are not satisfactory both for the clinician and the patient. Each aid has a disadvantage of its own: skin adhesives usually cause adverse skin reactions and deformation at the edges of the prosthesis, while eyeglasses and undercuts provide insufficient retention accompanied with discomfort to the patient.[2] Attempts were made to overcome these disadvantages through the use of extraoral implants. With the presentation of extraoral implants, the retention of maxillofacial prostheses was improved and osseointegrated craniofacial implants have become indispensable for retention and stability. A prosthesis retained with implants has a longer functional lifetime and better esthetics due to fine margins. Furthermore, the patient is less subjected to skin irritation.[1–5]

However, there are conflicting results regarding the success rates of osseointegrated implants used at the craniofacial region. In Figure 1, extraoral implants in the auricular region, nasal region, and orbital region are shown. Several studies have focused on the use of craniofacial implants and described satisfactory outcomes, but success rates vary according to the anatomical region in which they were used. Implant failures were found to be higher in the orbital region and in irradiated sites. Studies have reported the highest survival rates in the auricular area. It was suggested that the quality and volume of the bone, hygiene, soft tissue thickness, surgery conditions, and radiation therapy may affect the outcomes of the craniofacial implants.[2,4–8]

Bar or magnetic abutments can be used for the retention of implant supported craniofacial prostheses. Bar attachments provides enhanced support and stability when compared to magnetic attachments, but cleaning under the bars is hard to achieve. Therefore, granulation tissue formation around the abutments is a common complication following the use of bar attachments, and this may lead to severe skin reactions

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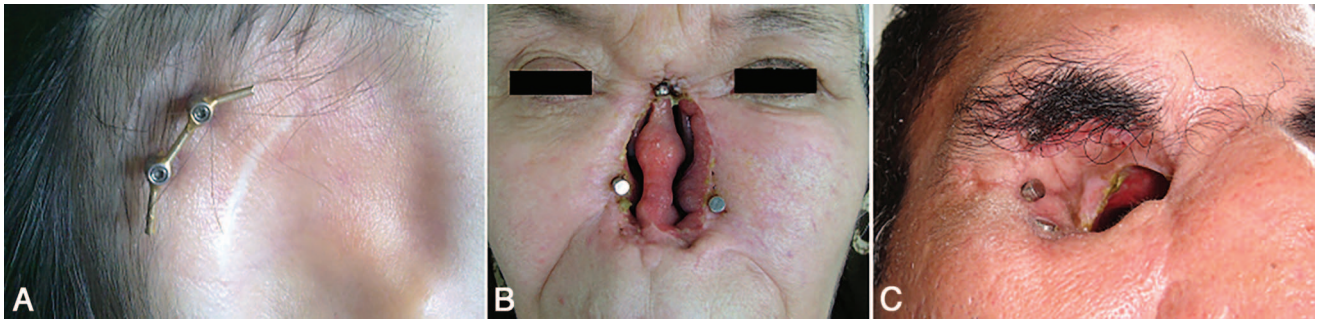


Figure 1. Extraoral implants: (a) in auricular region, (b) in nasal region, (c) in orbital region.

endangering the osseointegration.[4] Considering the hygiene that is necessary in this area, the residues should be removed as described in literature, because the junction between the skin and the abutment is weak or nonexistent.[9–11]

From a clinical point of view, strong data exists indicating that an implant-retained craniofacial prosthesis has a positive impact on the patient's perceptions of the prosthesis. In contrast with a conventional craniofacial prosthesis, an implant-retained prosthesis often is not experienced as a prominent foreign object in the head and neck region, thereby improving the quality of life.[12–15]

The aim of this study was to evaluate the clinical performance of craniofacial implants in the orbital, auricular, and nasal region in terms of survival rates, soft tissue reactions, and prosthetic complications.

Materials and Methods

A total of 24 patients with 64 implants (30 in auricular region of 13 patients, 24 in nasal region of 8 patients, and 10 in orbital region of 3 patients) ranging in age from 16 to 83 (mean age = 45.45 years) were evaluated. Nine conical extraoral implants (Straumann AG, Basel, Switzerland; Ø 3.3 mm/3.5–5 mm) with bar attachments (Straumann) in 4 patients and 11 conical extraoral implants (Straumann; Ø 3.3 mm/3.5–5 mm) with bar attachments (Straumann) in 5 patients, 8 conical extraoral implants (Straumann; Ø 3.3 mm/3.5–5 mm) with magnetic attachments (Straumann) in 3 patients in the auricular area; 24 shoulder extraoral implants (Straumann; Ø 3.3 mm/5.5–4 mm) with magnetic attachments (Straumann) in 8 patients in the nasal area; and 10 shoulder extraoral implants (Straumann; Ø 3.3 mm/5.5–4 mm) with magnetic attachments (Straumann) in 3 patients in the orbital area are inserted. One patient with 2 conical extraoral implants (Straumann; Ø 3.3 mm/3.5–5 mm) in the auricular area lost the implants because of early trauma, so no attachments were inserted. All extraoral implants were the same brand (Straumann) and titanium grade 4, sandblasted with large grit and acid etched surface. The exclusion criteria for the study were as follows: irradiated patients who had received greater than 6000 cGy dose, alcohol or drug abuse, present or latent psychotic conditions, and pregnancy. Thirteen of the patients had a cancer history, and 10 of them had been treated with radiotherapy; 5 of the patients had trauma history, 4 patients had congenital deficiency, and 2 had burn history. A summary of the patients is shown in Table 1. Implant surgery was applied in at least a 1-year period after radiotherapy to all 10 patients.

Surgical procedure

Patients were treated with 2-stage implant surgery procedure under general anesthesia.[16,17] The first stage consisted of the implant insertion to the proper bone region and covering for osseointegration. In all cases, surgical templates were used for the right place and proper angulations for the implant placement. In the second stage, implants were exposed by an elevation of a full-thickness flap and the peri-implant soft

Table 1

Summary of the patient data

Defect Site	Defect Etiology	Gender	Mean Age	Number of Patients	Number of Implants	Retention Type
Auricular	Trauma 5 Congenital 4 Cancer 2 Burn 2	Male 11 Female 2	16–70/39.69	13	30	Bar 9* Magnet 3*
Nasal	Cancer 8	Male 3 Female 5	57–83/71,75	8	24	Magnet 8
Orbital	Cancer 3	Male 2 Female 1	44–56/50	3	10	Magnet 3
Total	Trauma 5 Congenital 4 Cancer 13 Burn 2	Male 16 Female 8	16–83/45.45	24	64	Bar 9 Magnet 14

*One of the patients with 2 implants in the auricular area had lost the implants before the second surgery because of trauma.

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TABLE 2

The relationship among implant site, having radiotherapy, and implant success

Implant Site	Radiotherapy	Implant Failed n (%)	Implant Succeeded n (%)	*P* value
Auricular	No	2 (100)	26 (92.9)	0.869
	Yes	0 (0)	2 (7.1)	
Nasal	Yes	3 (100)	21 (100)	No analysis could be performed
Orbital	No	0 (0)	7 (100)	0.008
	Yes	3 (100)	0 (0)	
Overall	No	2 (25)	33 (58.9)	0.077
	Yes	6 (75)	23 (41.1)	

tissues were thinned to a thickness of 2 to 4 mm. The osseointegration period was 3 months for the auricular region and 6 months for the nasal and orbital region.[6]

Prosthetic procedure

Impression was obtained with impression cylinders for conical abutments or magnetic impression caps for magnetic abutments 1 week after the abutment attachment with silicone impression paste (Express XT Putty Quick and Express XT Light Body Quick, 3M ESPE, Seefeld, Germany). A wax model was prepared on the master model formed from the impression. The prosthesis was fabricated from this wax model after the trial session on the patient by maxillofacial silicone (Cosmesil Platinum Silicone M511, South Wales, UK).

Patients received hygiene instruction to clean the soft tissue around the implants with soap and water by a soft toothbrush and or Superfloss (Oral B, Germany) on the delivery of the implant-retained prostheses.

Assessment of patients

Follow-up visits were scheduled after 3 and 6 months, and then every 6 months and recorded by a trained examiner. Implant success was clinically assessed as the absence of the clinically detectable mobility of the implant. Soft tissue reaction around the implants was evaluated and recorded as grade 0 (no irritation), grade 1 (slight redness), grade 2 (red and slightly moist tissue), grade 3 (red and slightly moist tissue with granulation), and grade 4 (infection).[18]

Statistical analyses

We classified all implants according to the success (succeeded/failed), retention type (bar/magnetic), having history of radiotherapy (no/yes), and implant sites (auricular/nasal/orbital). Comparisons between categorical variables were analyzed using Fisher's exact test. Statistical analyses were performed with SPSS Statistics version 19.0.0 (IBM Corporation, Somers, NY).

RESULTS

A total of 24 patients with implant-retained extraoral prostheses were evaluated. The youngest patient was 16 years old and the oldest patient was 83 years old with a mean age of 45.45 years. A total of 64 implants were inserted. Thirty implants were placed in the auricular area of 13 patients (2 with cancer, 4 with congenital, 5 with trauma, and 2 with burn history), 24 implants were placed in the nasal area of 8 patients (all with cancer history), and 10 implants were placed in the orbital area of 3 patients (all with cancer history). Retention of the auricular prostheses of 13 patients was provided with bar-clips (9 patients) and magnets (4 patients); retention of the nasal prostheses of 8 patients was provided with magnets; and retention of the orbital prostheses of 3 patients was provided with magnets. Patient data is summarized in Table 1.

Early failures were considered as prior to functional loading or within the first 6 months of loading. Late failures were considered as on or after 6 months after the functional loading. One of the patients lost his implants in the auricular area in the early stage as a result of trauma caused by the hit of his dog, 1 of the patients lost all 3 of his implants in the late stage because of trauma when renewing his prosthesis by a dentist, and 1 of the patient's 3 implants in the orbital area were removed surgically in the late stage because of the tumor recurrence. Ten of the 13 cancer patients had received 45 to 60 Gy of radiation therapy to their defect sites before implant surgery. Thus, 29 implants were placed into the irradiated bone and 10 implants into the nonirradiated bone area, however, none of these patients lost their implants because of radiotherapy.

Seven patients had 2 implants attached with a bar under their auricular prostheses, 2 patients had 3 implants attached with a bar under their auricular prostheses, 1 patient had 4 implants with magnetic attachments under his auricular prosthesis, 1 patient had 3 implants with magnetic attachments under his auricular prosthesis and 1 patient had 1 magnetic attachment under his auricular prosthesis. All 8 patients with nasal defect had 3 magnetic attachments under their prostheses. Two patients with orbital defects had 3 magnetic attachments under their prostheses and 1 patient had 4 magnetic attachments under his orbital prosthesis.

We performed statistical analysis to evaluate implant success. As seen in Table 2, we found no significant relationships between the retention types and implant success in both total number of implants and the implants placed in the auricular, nasal, and orbital sites. There was not enough data to perform extra analysis to show relationship among implant sites, retention type, and implant success. A total of 20 implants with bar attachments have shown 100% success, and 36 of 42 implants with magnetic abutments have survived with a success rate of 85.7% ($P = 0.164$). Additionally, extra analysis

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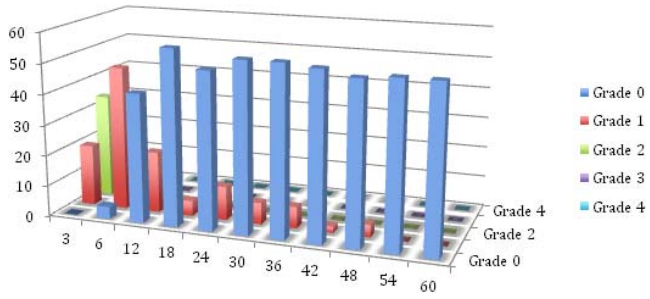


Figure 2. Soft tissue response in overall regions (implant sites/months).

was performed to access the relationship between radiotherapy and implant success according to the implant type, and we found no statistically significant differences between them (data not shown).

Peri-implant soft tissue response was evaluated for a 60-month period and a total of 654 visits/sites recorded. Grade 0 (no irritation) was present in 72.8% (476/654) of the visits/sites. Grade 1 (slight redness) was observed for 18.8% (123/654). Grade 2 (red and slightly moist tissue) was scored in 6.9% (45/654). Grade 3 (red and slightly moist tissue with granulation) was noted in 1.5% (10/654) and grade 4 (infection) could not be found. Peri-implant soft tissue response was given in Figure 2.

Discussion

Comparisons of survival rates of implants in different areas such as auricular, orbital, and nasal with different variables such as sex, age, implant size, radiation status, and prosthetic type are difficult to establish because of the insufficient number of patients enrolled, which is a limitation of the present study. Therefore, the characteristics of the patients are given according to the soft tissue evaluation. Assessment of the implant survival is determined as the number of exposed implants.[18,19]

Extraoral implants present a preferable choice for extraoral prostheses and increase the acceptability by the patient with improved retention and stability and ease of using the prosthesis. Osseointegrated implants have many advantages compared to conventional retention methods in maxillofacial prostheses. However, implants are not uniformly successful in the auricular, orbital, and nasal region. In this study, 1 patient among 13 patients (1/13) lost his implants in the auricular area because of early trauma to that region, 1 patient among 8 patients (1/8) lost his implants because of late trauma to his implants and 1 patient among 3 patients (1/3) lost her implants because of recurrence of the cancer. The rate of the implant success in the auricular area showed the highest values similar to the recent studies.[5–8,20–22]

Three factors may affect the outcome of the extraoral implants, especially the quality and volume of the bone, hygiene condition, and radiation therapy.[2,4–8] Implant failure is related to weak or no primary stability of the implant at the time of insertion. Previous studies reported that the mastoid process has the best bone quality in the facial skeleton to achieve primary stability. [18,29–31] Existence of inflammation in the soft tissue around implants can cause implant failure,[15] and several studies have shown that hygiene is an important factor for peri-implant tissue health.[4,6,12] Therefore, hygiene control is taught to the patients and daily hygiene is provided by the patients. Bar and magnetic abutments are used for the retention of implant-supported craniofacial prostheses in this study. Cleaning under the bars when used bar attachments is hard to achieve when compared to magnetic abutments.[4] In this study, magnetic retention is used in 14 patients whereas bar-clip retention is used in 9 patients. According to this study, the type of retention system had no significant impact on implant success.

Most of the patients after cancer surgery are subjected to postoperative radiotherapy. Studies indicate that radiotherapy affects the bone regeneration capacity, which leads to reduction of osseointegration success, so many authors suggest that insertion of implants should be at least 1 year after irradiation.[25] In this study insertion of implants was postponed to 1 year after radiotherapy. Several studies show lower survival rates for osseointegrated implants placed in the irradiated craniofacial region.[26,27] In contrast with the implant failures due to the poorly vascularized bone reported in cancer patients with radiotherapy history, no patient lost their implants in the irradiated bone in the present study. Of the 3 patients who lost their implants, 1 was from the recurrence of cancer and 2 were from early and late trauma. However, our patients had received 45 to 60 Gy of radiation doses. Long-term predictability of implants placed in the higher doses of irradiated bone remains unclear.[28] Our patients had 1 or more implants in auricular region, and 7 of them had bar with 2 implants, whereas 2 of them had bar with 3 implants, 1 of them had 1 magnetic attachment, 1 of them had 3 magnetic attachments and one of them had 4 magnetic attachments. In the auricular region, a minimum of 2 or more implants are suggested for bar attachments to reduce cantilevering and to obtain a tripod effect for the mechanical advantage. However, bar attachments have a laboratory cost for the patient and require experienced technicians. For these reasons, we preferred magnetic attachments instead for 3 patients.

Conclusion

Ossseointegrated implants provide reasonable support and show successful results when used with maxillofacial prostheses. In this study, low failure rates were found: 2 patients lost their implants because of early and late trauma, and 1 patient because of the recurrence of the cancer. Extraoral implants should be an option under appropriate conditions, and the general health condition of the patient and the received dose for radiotherapy should be evaluated carefully before proceeding with maxillofacial prostheses.

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