The Use of Percutaneous Implants for the Prosthetic Rehabilitation of Orbital Defects in Irradiated Cancer Patients: A Report of Clinical Outcomes and Complications

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This retrospective study evaluated the use of percutaneous craniofacial implants for the prosthetic rehabilitation of patients with a history of orbital exenteration and irradiation for oncologic tumors of the head and neck. A total of 24 implants were placed in six patients. All implants were determined to be osseointegrated at the time of uncovering. Three implants were subsequently resubmerged beneath the soft tissue because of positional interferences with prosthesis fabrication. The remaining 21 implants were ultimately used to retain six orbital prostheses. Two implants failed to maintain osseointegration during the follow-up period and were subsequently removed without complications. This represents an overall integration success rate of 90.5% over a mean follow-up period of 32.8 months (range = 11 to 68 months). The significance of these findings and their relationship to comparable reports in the literature are discussed.
(INT J ORAL MAXILLOFAC IMPLANTS 1998;13:121–126)

Key words: craniofacial implants, orbital defect, osseointegration, radiation therapy

Since their introduction in 1977 for use with bone conduction hearing aids, percutaneous craniofacial implants have found more extensive applications in maxillofacial prosthetic rehabilitation.[1] These implants have been shown to effectively retain a wide variety of removable prostheses for individuals with defects of the face resulting from congenital malformation, surgery, or trauma (Fig 1). Craniofacial implants offer significant advantages over traditional means of retaining facial prostheses, including the use of medical-grade adhesives, the engaging of anatomic undercuts within the confines of the defect, and eyeglasses.[2] Implants provide improved retention while avoiding the tissue and prosthesis damage that can be associated with adhesives. In this manner, craniofacial implants can help to provide a convenient, comfortable, and emotionally satisfactory prosthesis with excellent long-term functional and cosmetic results (Figs 2 and 3).

Based on these successes, craniofacial implants are now being placed with increasing frequency in patients who have undergone radiotherapy for oncologic lesions of the head and neck, in spite of the well-documented adverse biologic changes that occur when osseous tissues are exposed to ionizing radiation. These changes include alterations in the cellular components of bone involving a significant reduction in the number of viable osteoblasts and osteocytes, as well as the development of areas of fatty degeneration within the marrow spaces. In addition, the vasculature undergoes progressive endarteritis, hyalin-

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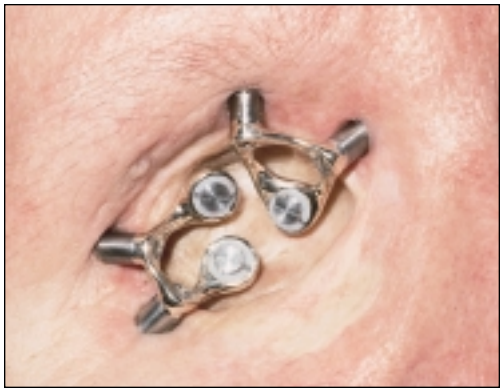

Fig 1 Right orbital defect with four screw-retained transdermal implant abutments in place. Note screw-attached cast-metal alloy framework with three retentive magnets.

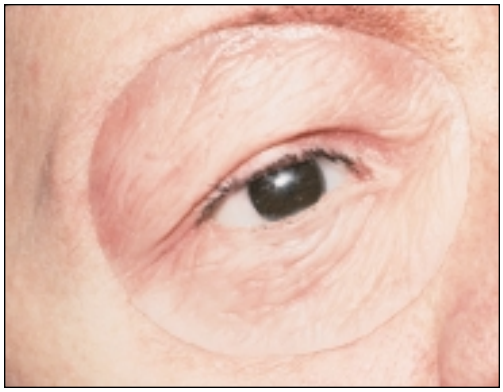

Fig 2 Implant-retained right orbital prosthesis.

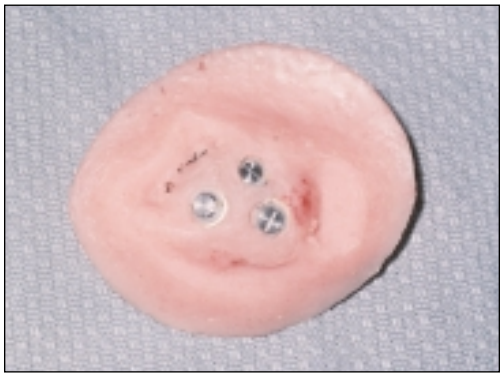

Fig 3 Orbital prosthesis as viewed from tissue surface. Note three magnets incorporated within prosthesis for retention.

Table 1 Reported Integration Success Rates (%) for Orbital Sites in Irradiated and Nonirradiated Populations

	Irradiated	Nonirradiated
Parel and Tjellstrom[3]	45.5	56.8
Roumanas et al[4]	58.3	75.0
Tolman and Taylor[5]	70.0	97.0
Jacobsson et al[10]	62.7	92.1
Mean	59.1	80.2

ization, and fibrosis, resulting in regional ischemia.[3] Following such changes, irradiated sites would presumably be at significant risk for tissue necrosis and integration failure if subjected to implant surgery.

As a result, the appropriateness of using craniofacial implants in the rehabilitation of facial defects in this population subset has been questioned. A number of recent articles have raised such concerns by describing significantly decreased survival rates when implants were placed in irradiated craniofacial bones as compared to nonirradiated sites. Pearl and Tjellstrom[4] described integration success rates as reported from multiple sites within the United States and Sweden. By pooling all data presented, the results indicate overall success rates of 61.3% and 95.9% for irradiated and nonirradiated populations, respectively. Roumanas et al[5] found a similar disparity in results describing integration success rates of 68.4% and 85.3% for irradiated versus nonirradiated patients. Tolman and Taylor[6] described a success rate of 85% and 97% for irradiated and nonirradiated patients, respectively. Most recently, Eckert et al[7] described their experience with endosseous implants placed in multiple irradiated locations, including craniofacial sites. While only two patients were described in this report and the radiation histories were unclear, 7 of the 13 craniofacial implants failed, resulting in an integration success rate of 46%.

The literature also suggests that craniofacial implant integration may be site-dependent. When multiple reports are cumulatively examined for irradiated versus nonirradiated orbital sites alone, the data demonstrate a combined integration success rate of 59.1% and 80.2%, respectively (Table 1).[4–6,8] This appears to indicate that the irradiated orbit presents a poor site for craniofacial implant placement.

The purpose of this study was to review an experience with craniofacial implants used in the retention of facial prostheses for patients with orbital defects and a history of irradiation for oncologic tumors of the head and neck. These findings were then compared to similar reports in the current literature.

Table 2 Demographic Data and Oncologic Treatment Performed

Patient	Age/race/sex	Diagnosis and tumor location	Surgery performed	RT† dose to implant sites (Gy)
1	40/white/m	Adenoid cystic cancer, left antrum	Maxillectomy, orbital exenteration	62.4
2	68/white/f	Scca* left maxillary and ethmoid sinus	Maxillectomy, orbital exenteration	60.0
3	62/white/f	Poorly differentiated cancer, left ethmoid sinus	Orbital exenteration	61.0
4	77/white/f	Scca* left ethmoid and maxillary sinus	Ethmoidectomy, orbital exenteration	66.0
5	74/black/f	Scca* right antrum	Maxillectomy, orbital exenteration	60.0
6	55/white/f	Lymphoma, right orbit	Orbital exenteration	45.0

*Squamous cell carcinoma.
†Radiation therapy

Table 3 Craniofacial Implant Treatment Data

Patient	Surgery/RT time interval (mo)*	No. of implants	Implant location	Healing period (mo)	No. of implants integrated
1	60	3	Superior rim	12	3
2	24	4	Superior rim	9	4
3	15	3	Superior rim	11	3
		2	Inferior rim		2
4	19	4	Superior rim	9	4
5	57	3	Superior rim	11	3
		2	Inferior rim		2
6	149	3	Superior rim	9	3

*Time interval between radiotherapy and implantation.

Materials and Methods

Six consecutive patients treated at the University of Chicago, Zoller Dental Clinics for postoncologic orbital defects, were included in this review. All data were obtained from patient medical and dental charts. Table 2 presents selected demographic data and oncologic treatment performed. Each patient history was significant for surgical exenteration of an orbit and postoperative adjuvant radiotherapy. Two patients underwent hyperbaric oxygen (HBO) therapy as an adjunctive means to address unanticipated postoperative wound healing complications unrelated to subsequent implant rehabilitation. Patient 1 developed necrosis and bleeding in the area of the left cavernous sinus. He received HBO therapy prior to and after base of skull reconstruction. Patient 2 was given adjunctive HBO for treatment of osteomyelitis of the medial wall of the orbital defect. A variable time interval was allowed to elapse after irradiation before implant placement because of individual patient desires for rehabilitation (Table 3).

After a thorough clinical and radiographic evaluation, each patient underwent craniofacial implant placement in the operating room under general anesthesia employing surgical techniques as described by Tjellstrom et al.[9] The superior orbital rim was typically the implantation site of choice because of the availability of adequate bony volume. However, for two patients, four implants were placed in the inferior orbital rim (Table 3). Postoperative healing progressed uneventfully for all patients. Stage-two implant uncovering proceeded 9 to 12 months following implantation. At that time, the subcutaneous tissues were thinned and transdermal healing abutments were screwed into place. Following adequate healing, orbital prosthesis fabrication was initiated following standard clinical and laboratory procedures.[10] Retention was obtained in all patients through the use of magnets incorporated into retentive frameworks (Shiner Magnets, Preat Corp, San Mateo, CA). All patients were instructed in appropriate home care, which included daily use of soap and water at the implant sites as well as mechanical debridement of the abutments and retentive bar with the use of floss.

Patients typically presented for follow-up at 1- and 3-month intervals after prosthesis placement. Subsequently, 6-month follow-up appointments were routinely scheduled. At each examination, the retentive frameworks were removed and cleaned and soft tissue health at the implant sites was evaluated. The

Table 4 Implant Treatment Complications

Patient	Prostheses in place (mo)	Implants removed	Implants submerged	Soft tissue complications
1	14		1	
2	11			
3	55	2	1	
4	18			
5	68		1	Soft tissue infection treated with antibiotics
6	31			Soft tissue infection treated with antibiotics

status of implant integration was determined by digitally torquing the abutment using the appropriate hand-held driver. The prostheses were also evaluated for adequacy of fit and function.

Results

A total of 24 implants were placed in six patients. All implants were clinically determined to be integrated at the time of stage-two uncovering. Three of the integrated, asymptomatic implants were subsequently resubmerged beneath the soft tissues prior to concluding prosthetic treatment because of anticipated prosthetic treatment interferences secondary to implant location as determined by a maxillofacial prosthodontist (Table 4). Each submerged implant has remained in place without complication as of the time of this report.

Of the 21 implants available for prosthetic restoration, two were subsequently removed because of loss of integration and concomitant complaints of pain and tenderness (Table 4). Both implants were located in the inferior orbital rim of Patient 3. The first implant was removed during prosthesis fabrication. The second implant required removal 16 months after uncovering while the prosthesis was in function. Each implant was removed without complication, and healing proceeded uneventfully. Retention of the prosthesis was effectively maintained using the remaining implants in the superior orbital rim. As of the time of this report, the remaining 19 implants continue in function, and all six patients have successfully worn their orbital prostheses without interruption throughout the period under review. This represents an integration rate of 90.5% over a mean postprosthesis placement follow-up interval of 32.8 months (range = 11 to 68 months).

In addition, two episodes of soft tissue infection were encountered during the evaluation period. Patients 5 and 6 each developed one episode of periimplant soft tissue erythema and swelling. Purulent exudate was noted upon probing. Each situation was treated successfully with antibiotics and reinforcement of home care without the need for surgical intervention. The implants at these sites remain integrated and in function as of the writing of this report.

Discussion

In the current study, the percentage of successful implant integration in irradiated orbital sites for six patients was found to be 90.5% over a mean follow-up period of 32.8 months (range = 11 to 68 months). The results are consistent with those reported by Wolfaardt et al,[11] who described an integration success rate of 96.4% for this population subset over a follow-up period that ranged from 12 to 48 months. These findings lend support to the placement of craniofacial implants in irradiated sites. However, the results are at significant variance with a number of other reports (Table 1). These variations in described integration outcomes pose serious difficulties when attempting to interpret the data or draw appropriate conclusions for selecting patient treatment. While differences between centers with regard to treatment techniques and duration of patient follow-up may play a role in reported integration success, perhaps an interaction between patient-specific factors heretofore undetermined, compounded with biologic changes associated with irradiation, may prove to be the principal factors for integration success. The ability to identify and assess these factors with sufficient accuracy so as to make meaningful predictions of outcome then appears to be the major challenge to be addressed in the future.

One such factor under investigation is the relationship of the time interval between irradiation and surgical manipulation of the bone. The importance of long time intervals between irradiation and surgery has been suggested by some authors. An improvement in the bone-healing capacity by a factor of almost 2.5 during a 12-month period following irradi-

ation was found using animal models.[12] Conversely, Marx and Johnson[13] recommend that reconstructive surgery should be performed within a shorter time interval ranging from 1 to 6 months postirradiation. This was based on findings of late progressive loss of vascular perfusion and healing capacity over time following radiation therapy. In the current study, issues unrelated to implant treatment planning resulted in a postirradiation implantation time frame that ranged from 15 to 149 months. This variation in timing for implant placement typically was dictated by overall patient health factors, as well as delays in ultimately accepting and proceeding with treatment. The uncontrolled manner in which the time frame evolved, as well as the small population size, limits the ability to draw conclusions from this study regarding when to place implants in irradiated craniofacial sites. The ideal time period for proceeding with implantation following radiation therapy awaits further elucidation.

Hyperbaric oxygen therapy has also been recommended as a means to improve regional vascularity and to heighten implant integration success.[12,14] HBO therapy is known to stimulate angiogenesis, resulting in neovascularization and an increase in cellular oxygen tension to support new osteoblast and fibroblast proliferation.[15] In the current study, no patient underwent preplanned HBO in preparation for craniofacial implant placement. Two patients received HBO therapy to address postoncologic treatment-healing complications. Therapy was initiated in each patient prior to implant surgery without the direct intention of improving the implant integration potential. These results do not permit the drawing of conclusions, as the data were obtained from a relatively small population. However, the results suggest that the application of HBO may not be a universal requirement for successful craniofacial implantation in an irradiated population. Further, the data as found in this review and described by others demonstrate little postoperative morbidity associated either with implantation or integration failure and implant removal. This would indicate that an irradiated craniofacial population may be at minimal risk for serious treatment complications such as osteoradionecrosis. Perhaps larger trials will be required to adequately assess these risks.

In addition to the two implant integration failures in Patient 3, peri-implant soft tissue complications were noted for two patients in this study. Each patient experienced one episode of pain and tenderness along with soft tissue erythema and purulent drainage. Each was successfully treated empirically with antibiotics and by encouraging proper home maintenance without further complications. While each episode of infection was effectively treated using conservative measures, these findings demonstrate the potential for other complications that may be encountered in this population. Such complications, if left untreated, may pose serious risks that need to be addressed aggressively. The presence of enteric and hemolytic streptococcal organisms apparently existing as part of the normal microflora in the peri-implant crevicular space has been documented.[16] These opportunistic pathogens are commonly associated with significant infection that could lead to implant failure. Regular follow-up examinations and closely supervised home care appear to be warranted.

Conclusion

A retrospective review was undertaken to evaluate the use of percutaneous craniofacial implants placed in irradiated osseous tissues for the retention of orbital prostheses. Over a mean follow-up period of 32.8 months, 19 of a total of 21 integrated implants placed into function remained integrated, representing an overall success rate of 90.5%. While this result supports the use of implants in irradiated craniofacial sites, it is at variance with data reported by others in the literature, suggesting that the factors that determine integration success in this patient population are not clearly understood. Further study is needed to determine the appropriate time interval between the conclusion of radiotherapy and implant placement. In addition, both the role of HBO in maximizing osseointegration and the effects of the resident crevicular microflora in long-term maintenance need to be further assessed.

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