Osseointegrated craniofacial implants in the rehabilitation of orbital defects: An update of a retrospective experience in the United States

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Statement of problem. Since their introduction, craniofacial implants have been used in prosthetic rehabilitation of facial defects. The literature, however, indicates marked variability in outcomes using implants for the retention of orbital prostheses.

Purpose. A multicenter report updating the experience in the United States with the use of craniofacial implants for prosthetic rehabilitation of orbital defects is presented.

Material and methods. Surveys were sent to clinicians at 25 centers where maxillofacial prosthetic treatment is provided to obtain retrospective data regarding patients who completed implant-retained orbital prosthetic rehabilitation. Data on implant placement location, radiation treatment history, and use of hyperbaric oxygen therapy were collected and assessed in relationship to implant survival over time. The Kaplan-Meier life table and Wilcoxon analyses (α= .05) were used to assess the significance of the findings.

Results. Ten centers responded, providing data suitable for statistical analysis on 153 implants placed to retain 44 orbital prostheses and followed for a mean period of 52.6 months. Forty-one implant integration failures occurred during this follow-up period, resulting in an overall integration survival rate of 73.2%. No significant relationship was found between radiation treatment history, hyperbaric oxygen therapy history, or implant placement location and implant survival. Individual responses revealed large variability between reporting centers in treatment outcomes.

Conclusion. Craniofacial implants may offer marked benefits in the prosthetic rehabilitation of orbital defects when compared to conventional adhesive retention designs. However, questions remain regarding long-term predictability and the impact specific factors may have on treatment outcomes. Insufficient data is currently available from which to draw statistically meaningful conclusions. The establishment of a national database designed to acquire adequate data to assess treatment outcomes is recommended. (J Prosthet Dent 2005;94:177-82.)

Presented at the 5th meeting of the International Society for Maxillofacial Rehabilitation, Okinawa, Japan, October, 2002.

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While craniofacial implants may offer clinically appreciable benefits in orbital prosthetic rehabilitation, questions remain regarding long-term implant survival outcomes and the impact that factors such as implant placement location and radiation therapy have on treatment results.

Percutaneous craniofacial implants have been used worldwide in facial prosthetic rehabilitation since their introduction in 1984.1 Implants offer several advantages over medical-grade adhesives for retaining facial prostheses. Enhanced retention can be obtained in spite of adverse defect anatomy or size. Retention is not degraded by unfavorable environmental factors such as perspiration. The retentive clips or magnets aid in the proper positioning of the prosthesis, facilitating insertion by the patient. The elimination of the use of adhesives further improves the convenience of wearing and maintaining facial prostheses, while limiting the frequency of dermal irritations arising from long-term skin contact with adhesives. The functional life for implant-retained prostheses is also extended, as marginal degradation due to the daily application and removal of adhesives is eliminated.

In spite of these benefits, questions remain regarding the use of craniofacial implants in facial prosthetic rehabilitation. In an attempt to assess treatment outcomes over time, Parel and Telljstrom2 reported on the use of craniofacial implants as experienced at 13 United States centers and compared the results to those obtained at the Sahlgrens Clinic, Goteborg, Sweden.2 The authors described good overall outcomes, although implant failures were found to be higher in the orbit, particularly in previously irradiated sites. Since then, a number of reports have appeared in the literature describing variable treatment outcomes for implant-retained prosthetic rehabilitation in the orbit.3-8 These reports have suggested that factors such as radiation treatment history, the use of hyperbaric oxygen (HBO) therapy, and implant placement location may have a significant impact on long-term treatment outcomes. The purpose of this study was to update the literature regarding the experience in the United States with craniofacial implants used for the prosthetic rehabilitation of orbital defects in an attempt to further assess clinical effectiveness of treatment at this site. The relationships of radiation therapy, HBO therapy, and the location of implant placement to outcomes were also assessed.

### MATERIAL AND METHODS

The protocol for this study was approved by the institutional review boards of all participating institutions in compliance with regulations pertaining to the acquisition and interinstitutional sharing of data. Clinicians at 25 universities and medical centers across the United States were contacted to obtain a nationwide sample of practitioners with experience in craniofacial implant rehabilitation. The practitioners were provided with a survey designed to collect retrospective data regarding the experience of each with craniofacial implants used for orbital prosthesis retention. Data were requested only for implants placed in patients who completed prosthetic treatment. Data regarding implants placed in patients who failed to complete facial prosthetic treatment were not considered for analysis to eliminate this condition as a potential confounding variable. Factors addressed by this survey included the following: (1) the number of implants placed, (2) implant survival over time, (3) implant placement location, (4) radiation treatment history for the site of implant placement, (5) patient history of HBO therapy, and (6) prosthetic rehabilitation outcomes over time. Implant placement location, radiation treatment history, and a history of HBO therapy were specifically selected for evaluation based on previous reports in the literature linking them to implant rehabilitation treatment outcomes.9-12

In the survey, implants were defined as integration survivors if they were present and in function at the last patient follow-up examination. Implant location was characterized as being in either the supra- or infra-orbital rims. The supra-orbital rim was defined as that portion of the bony orbit at, or superior to, the

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<th>Table I. Summary of implant survival rates</th>
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<tr>
<td>Cumulative total</td>
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<tr>
<td>Supra-orbital rim</td>
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<td>Infra-orbital rim</td>
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<tr>
<td>Approximating frontal sinus</td>
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<td>Distant to frontal sinus</td>
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<tr>
<td>Irradiated</td>
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<td>Nonirradiated</td>
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<tr>
<td>Dose ≥50 Gy</td>
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<tr>
<td>Dose ≤50 Gy</td>
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<tr>
<td>HBO exposure</td>
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<tr>
<td>No HBO exposure</td>
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midline transected by the axial plane. The infra-orbital rim was then defined as the remaining portion of the bony orbit inferior to this line. Implant location was further subcharacterized relative to proximity to the frontal sinus using the numbers of a clock face as reference points. For this survey, implants placed in the 1 and 2 o’clock positions in the right supra-orbital rim or in the 10 and 11 o’clock positions in the left supra-orbital rim were defined as approximating the frontal sinus. Implants placed into irradiated sites and the use of HBO therapy prior to implant placement were recorded as “yes” or “no” responses. Approximate radiation doses delivered to each implant site were also requested. Patients who underwent implant placement but did not complete prosthetic treatment were excluded from the survey.

Survey information received from respondents was collated to create cumulative data fields for analyses. The overall pattern of survival during the time period was calculated using the Kaplan-Meier estimate and statistical software (SAS JMP Version 4.01; SAS Institute Inc, Cary, NC). Because the proportional hazard assumption of the log-rank test was not satisfied, Wilcoxon analyses were performed to assess the probability of each factor significantly influencing implant survival outcomes over time ($\alpha=.05$).

RESULTS

Ten of the 25 centers contacted provided usable survey data. Of the remainder, 5 indicated no experience with orbital implant prostheses to date, 2 had insufficient records to provide usable data, and 8 did not respond to the survey. No further attempt was made to obtain information from nonresponders. When information for a specific data field was unavailable from a reporting center, the number of reporting centers providing this data was noted. In this manner, treatment data were collected for 153 implants placed into function in 44 patients (26 men and 18 women; 27 white, 4 black, 1 Asian, and 12 of unknown racial origin) with a mean age of 52 years (range: 4-78 years). Survey data revealed that 128 implants were placed into supra-orbital rim sites, with the remaining 25 implants placed into infra-orbital rim sites. Nineteen implants were placed in sites in proximity to the frontal sinus, and 89 implants were placed at a distance from the sinus. Placement locations in relationship to the frontal sinus were unavailable for 45 implants. Ninety-two implants were placed into previously irradiated sites (mean dose delivered: 56 Gy). The remaining 61 implants were placed into nonirradiated sites. Twenty-two of the irradiated implant sites were exposed to HBO therapy prior to implantation, while no exposure to HBO therapy occurred for the remaining 70 implant sites.

Large between-center variability was noted in the reported dose range of radiation delivered to sites of subsequent implant placement (range: 39.6-80.5 Gy). Due to this variability, the population was subdivided into 2 patient subsets for further analysis, using a radiation dose level of 50 Gy as the point of delineation. When examined in this manner, 60 implants were placed into sites exposed to a dose of 50 Gy or greater (high-dose radiation), while 12 implants were placed in sites exposed to a dose of less than 50 Gy (low-dose radiation). No data were available regarding radiation dose for the remaining 20 implant sites.

Of the 153 implants placed into function, 112 survived during the cumulative mean follow-up interval of 52.6 months. This represents an overall cumulative implant survival rate of 73.2%. Of the 44 prostheses, 35 remained in function retained by craniofacial implants as of the last follow-up examination. This represents an overall prosthesis survival rate of 79.5% over the time interval reviewed. Endpoint proportions of cumulative implant survival and implant survival as a factor of location, radiation treatment history, and history of HBO therapy are listed in Table I.
A Kaplan-Meier life table plot of cumulative implant survival demonstrated a steady decline of implant survival over the first 2.5 years, followed by a marked, step-wise pattern of survival over the remaining review period (Fig. 1). Comparative plots of implant survival for irradiated and nonirradiated sites, high-dose and low-dose irradiated sites, HBO use, and implant location demonstrated overlapping curves, indicating no significant impact for any of these factors on implant survival (Figs. 2 through 4). Wilcoxon analysis demonstrated no statistically significant relationship between any of the above factors and implant survival over time (Table II).

**DISCUSSION**

The results of this survey revealed a cumulative survival rate of 73.2% for craniofacial implants used in the retention of orbital prostheses over a mean follow-up period of 52.6 months. This survival rate falls within the range of reported percentages, as described by others.\(^2\)\(^-\)\(^8\) Presenting outcomes as a percentage of implant survival is of limited usefulness, however, as it describes implant survival only at a single point in time—typically at the end of the follow-up period.

Such proportional values fail to consider changing patterns of implant survival across the entire period under review. Without more detailed data analyses, it becomes difficult to draw meaningful conclusions regarding outcomes and compare the results to those reported by others.

In the present study, life-table plots combined with other statistical analyses were used in an attempt to more accurately assess implant survival and the impact that specific factors exerted on survival over time. The life table plot of cumulative survival demonstrated a steady loss of implants over the period reviewed. These findings are consistent with those reported by Roumanas et al.,\(^8\) in which a continuous trend of implant failures in orbital sites resulted in a much lower rate of implant survival when compared to implants placed in auricular and nasal sites. Results from the present study and that of Roumanas et al.\(^8\) suggest that a clinically significant time-dependency effect exists for implant survival in orbital sites.

Several specific factors have been implicated as impacting craniofacial implant survival outcomes. A direct relationship between exposure of osseous tissues to therapeutic doses of radiation and implant integration failures in the orbit has been suggested, based on decreased survival percentages reported for these irradiated populations when compared to nonirradiated subsets.\(^9\)\(^,\)\(^10\) A review of the literature, however, reveals wide variations in reported outcomes, with implant survival rates ranging from 33.3% to 96.4% in irradiated sites and from 37.5% to 100% in nonirradiated sites.\(^2\)\(^-\)\(^8\) While the proportional survival rates found in this study for irritated and nonirradiated populations fell within these reported ranges, no statistically significant relationship was found between radiation treatment history and implant survival over time (\(P=0.90\), Fig. 2, A). Reports in the literature suggest that there is an increased incidence of orofacial complications and risk for osteoradionecrosis following extractions when radiation doses range beyond 50 Gy.\(^9\)\(^,\)\(^10\) However, in this

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**Table II.** Probability values for expressing relationship between implant survival and specific factors assessed

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<thead>
<tr>
<th>Factors</th>
<th>(P) values</th>
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<tr>
<td>Radiation vs No radiation</td>
<td>0.90</td>
</tr>
<tr>
<td>High-dose vs Low-dose radiation</td>
<td>0.33</td>
</tr>
<tr>
<td>HBO vs No HBO</td>
<td>0.89</td>
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<tr>
<td>HBO + radiation vs Radiation only</td>
<td>0.89</td>
</tr>
<tr>
<td>Supra-orbital vs Intra-orbital rim</td>
<td>0.62</td>
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<tr>
<td>Approximating frontal sinus vs Distant to front sinus</td>
<td>0.65</td>
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study no significant relationship was found between the subcategories of high-dose ($\geq 50\text{Gy}$) or low-dose ($<50\text{Gy}$) irradiation and implant survival ($P=0.33$) (Fig. 2, B).

Similarly, no significant relationship was found between the use of HBO and survival outcomes for craniofacial implants placed into irradiated orbital sites ($P=0.89$) (Fig. 3). The use of HBO, as described by Marx and Ames,11 is well recognized as one means of enhancing the healing capabilities of osseous tissues with limited vascular perfusion as a result of trauma or disease.11 The findings of this study do not support the use of HBO to improve implant survival outcomes. Further, the use of HBO appears to vary widely between institutions. In the current survey, only 22 of the 92 irradiated sites evaluated were exposed to HBO prior to implant surgery. This suggests that HBO has not gained widespread acceptance for inclusion in the treatment regimen for irradiated orbital sites, in spite of the reported benefits.

Implant placement location has also been implicated as a factor that may impact long-term implant survival. Lack of stabilizing bony volume in proximity to the frontal sinus or a decrease in vascular perfusion at this site may compromise implant survival.9,12 The results of this survey do not support a correlation between implant location and survival. No significant difference in survival was found for implants placed in either infraorbital or supra-orbital sites ($P=0.62$, Fig. 4, A) or for implants placed in proximity to the frontal sinus as opposed to those placed distant to the sinus ($P=0.65$, Fig. 4, B).

While the results of the survey data analyses used in this study would appear to provide predictive information with regard to implant survival over time, closer examination reveals marked between-center variations in implant survival outcomes. Clinical experience with craniofacial implants could be one explanation for these outcome variations. It is well accepted that improved integration survival rates result from increased clinical experience treating partially dentate and edentulous patients undergoing dental implant rehabilitation.15 Parel and Tjellstrom2 allude to the importance of experience when comparing relative differences in reported survival between participating centers in the United States and Sweden.

In the current survey, the cumulative data obtained from all centers revealed a mean treatment experience of 4.4 patients per center (range: 1-12 patients). Such small patient treatment numbers with large ranges in outcomes suggest that extensive clinical experience in providing orbital implant prosthetic rehabilitation may be limited in the United States. The total number of 44 patients treated by all reporting centers over a period extending over 14 years further suggests that this overall experience may not be growing rapidly.

The method of data collection and the impact on the analysis of results must also be recognized. All data were gathered retrospectively by reviewing charts, some of which may have been incomplete and written many years ago. Such reviews require greater interpretation of available raw data, with potentially significant gaps in data acquisition when compared to data captured through more controlled settings. In addition, a between-subject comparison of results across reporting centers assumes a level of homogeneity between patients and implant sites that likely does not exist within the population reviewed. The population may not easily lend itself to prospectively controlling for this site heterogeneity. Moreover, multicenter data surveys are dependent on the level of participation from the respondents questioned. In this study, only 10 of 25 centers contacted responded to this survey and provided usable data for analyses.

All of these factors increase the risk of not recognizing true clinical trends or of making inappropriate inferences when assessing data obtained on craniofacial implant orbital rehabilitation. This makes it difficult to provide statistically meaningful statements regarding a specific factor or combination of factors that may significantly impact long-term integration survival. In spite of these challenges, cumulative data surveys may serve as a useful means of observing larger patient population trends in an attempt to obtain a better sense of clinical outcomes. The deficiencies that exist with the methodology should serve as a stimulus to improve research efforts in this area. Given the relatively low numbers of patients with orbital defects treated at any one center, future studies will benefit from ever widening contributions from clinicians to generate larger patient numbers over a reasonable period of time to further increase the validity of these assessments. This may be best achieved through a coordinated effort at data acquisition, perhaps through the establishment of a national database permitting the controlled accumulation of greater volumes of data, with sufficient statistical power to more accurately assess efficacy of the use of craniofacial implants in orbital prosthetic rehabilitation.

CONCLUSIONS

While craniofacial implants may offer clinically appreciable benefits for patients in need of prosthetic rehabilitation of orbital defects, the results of this survey indicate that questions remain regarding long-term survival for implants used in this area. No statistically significant relationships were found between radiation treatment history, the use of HBO, or implant placement location on implant survival. However, difficulties in survey methodology and limited data availability make it difficult to draw strong, statistically meaningful conclusions.
REFERENCES


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