# Orbit Rehabilitation with Extraoral Implants: Impact of Radiotherapy

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## ABSTRACT

*Purpose:* The aim of the study was to compare the success rates of osseointegration among irradiated and nonirradiated cases submitted to implant placement for anchorage of orbit prostheses from 2003 to 2011.

*Materials and Methods:* Charts of 45 consecutive patients were analyzed, 31 men and 14 women, and they were divided in two groups, considering previous irradiation therapy. Nonirradiated group had 33 patients, and irradiated group had 12 patients. In total, 138 implants were installed, 42 (30.4%) in previously irradiated bone.

*Results:* The overall implant survival rate was 96.4% with a success rate of 99.0% among the nonirradiated patients and 90.5% among the irradiated patients ($p = 0.03$).

*Conclusions:* Results showed that irradiated sites had a worse prognosis related to success of osseointegration, although the 90.5% survival rate in this group indicates that implant placement is a feasible alternative to anchor orbit prostheses considering the benefits that this technique offers to patients.

KEY WORDS: extraoral implants, irradiation, orbit rehabilitation, survival rate

## INTRODUCTION

Orbital defects can be caused by cancer, trauma, infections, or congenital diseases, resulting in aesthetic, functional, psychological, and social problems.[1]

There are several reconstructive plastic surgery techniques available for the auricular and nasal regions, and these techniques have achieved varying degrees of success.[2] However, when the defects occur in the orbit region, the absence of the ocular globe prevents similar aesthetic surgical repairs and may require silicone or resin prostheses.[2] Orbit prostheses require retainers to hold them in place, such as eyeglasses; however, such devices are poorly tolerated by the patient because of inconveniences as instability, movements, and associated cutaneous inflammatory responses.[3]

Since craniofacial implants for the anchorage of facial prostheses was introduced, its effectiveness as a rehabilitation method has increased.[4,5] Because of the stability gained through the use of osseointegrated implants, the acceptability of and confidence in the use of prostheses have increased in patients; thus, implants have become an essential resource for orbit rehabilitation.[6]

However, the success rates of osseointegration have not been uniformly described and vary from 25 to 75% in the orbital region.[7,8] The main reasons reported for this variation are the small size of implants, low quality and volume of the frontal bone region, and in particular, prior radiotherapy treatment in cancer patients.[7,8]

Previous radiotherapy is considered to be one of the main factors for implant failure and often limits the indications of the procedure.[8,9] Techniques such as hyperbaric oxygen therapy have been described

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as alternatives to increase the survival rate of implants; however, there is no consensus regarding effectiveness.[10,11]

Few studies have focused on the analysis of osseointegration success rates in the orbital region, and even in these studies, the sample size is always small.[12] This fact is probably related to the complexity of these cases, as well as the mortality rates, costs, and relatively small number of professionals involved in this field.[12,13]

In Brazil, craniofacial implants were first used in the mid-1990s; however, the use of these implants was expanded in 2000 when implants started being produced in Brazil.[14]

The aim of the present study is to compare the success rates of implants used for the retention of orbital prostheses, as well as the success rates of prosthetic rehabilitations, between irradiated and nonirradiated patients. The null hypothesis is that previous irradiation would affect success rate of osseointegration.

## MATERIALS AND METHODS

A retrospective study was conducted by examining consecutive files from all patients with orbital defects treated by the same team between 2003 and 2011. The study was approved by the institutional ethics committee (CNEP UNIP: 08359212.7.0000.5512).

### Variables

The independent variables included gender, age, cause of deformity, previous radiotherapy, number and size of implants used, date of surgery, date of the delivery of the prosthesis, date of the last follow-up, successful osseointegration, and prosthesis success. Factors such as smoking habits, diabetes, or systemic disease were evaluated once there was such information in the charts. Considering the study proposal, two groups were formed: group I (irradiated) and group II (nonirradiated). These groups were compared for correlations among the mentioned variables.

Osseointegration success was defined as the presence of functional implants without any mobility or pain, with healthy peri-implant tissue around the abutments and no sign of infection at the final examination. Implant mobility was determined by applying lateral pressure to the implant with two opposing instruments, and recorded as positive or negative. Because it was not possible to obtain standardized radiographs in the orbit region to ascertain bone resorption, it was not used as a criterion for implant success.

The total duration of implant survival was defined as the time between of implant placement and implant removal or to the last assessment of implants that remained in use. Patients with implants but without prosthesis were excluded from the study. Implants lost during the study were regarded as failures.

Prosthetic success or survival was defined as patients with prostheses that remained functional and were retained by the implants at the time of the last assessment. The total duration of prosthetic survival was defined as the time between prosthetic delivery and prosthetic removal or the last assessment of the prostheses that remained in use. Patients who required prosthetic replacement or repair but which remained functional were considered to be prosthetic successes. Patients who declined to use their prosthesis or were unable to use it because of implant failures were regarded as prosthetic failures. The detailed information of follow-up of prostheses will be subject of another study.

### Surgical Techniques

The surgical procedures were performed by the same surgeon and in accordance with the same principles. All patients were evaluated clinically and subjected to the proposed rehabilitation with implant-retained prostheses. After their approval of the procedure, preoperative clinical examinations were conducted, and patients who were deemed fit and able were scheduled for surgery. The imaging examinations were not uniform for all patients because of their socioeconomic conditions. When possible, tomographic images were taken to evaluate the thickness of the orbital rim; however, in most cases, only frontal and lateral radiographs of the orbit were available, making the definition of the anatomic site and the depth of the implant a perioperative decision. All procedures were performed in a hospital setting under local anesthesia (xylocaine with epinephrine 1:200,000) and intravenous sedation, which was supervised by an anesthesiologist.

The regions chosen for the fixation of the implants were the superior or inferior orbital rim and were selected in consideration of the quantity of bone, cavity depth, and prosthetic plan. All of the implants used were extraoral, external hexagons with flanges

(ConexãoSistema de Próteses, Arujá, Brazil). Each implant was 3.75 mm in diameter and ranged from 3 to 8 mm in length.

A semilunar incision on the inner side of the orbital rim was performed, and a dissection up to the periosteum exposed the entire bone rim for the selection of anchoring areas. Once an installation site was selected, drilling began under abundant irrigation with a saline solution using a 2-mm-diameter spherical drill and continued at a speed of 2,000 r.p.m. to a depth of 3 to 8 mm based on the availability of bone. After the depth was defined, a countersink drill was utilized (under irrigation with saline solution) to broaden the bone niche and elaborate the countersink for the placement of the implant flange. The self-tapping implants were placed at a speed of 20 r.p.m., with 40 to 70 N of torque. The number of implants fixed per patient ranged from one to five according to the extent of the defect and surgical possibilities.

The mounts were removed after installing the implant, and implant orifice was covered with a cover screw. Then, the cutaneous-periosteal flap was reattached into position and sutured with 4.0 nylon sutures removed after 1 week.

After at least 4 months of healing, the site was reopened by lifting the cutaneous-periosteal flap, and subcutaneous tissue was dissected and excised, and the flap thinned as much as possible without perforating the skin. This subcutaneous tissue reduction was performed to reduce the risk of inflammatory reactions around the transcutaneous abutments.

The cutaneous flap then was sutured into position, and the skin was punctured with 4-mm perforations to fit the abutments. All abutments were standard type, 4 mm in length, and connected using torque wrench with 20 N force. Abutments were protected with a silicon disc on top of a gauze soaked in antibiotic and anti-inflammatory ointment (oxytetracycline).

Dressing and stitches were removed after 1 week, and the patients were instructed to periodically wash the area with 0.2% chlorhexidine and cover it with gauze. The patient was evaluated weekly until the region had healed and had reached the conditions needed for the initiation molding procedures for the fabrication of the prosthesis.

### Making of the Prostheses

A minimum of 4 months after the implant was placed and after the skin around the abutments had healed, the patients were referred to the prosthetic specialist who performed the molding, wax sculpting, testing, and characterization of the prosthesis in silicon according to the protocols that were previously defined by the anaplastologist. After the delivery of the prostheses, the patients were instructed to clean around the magnetic abutments daily with a toothbrush and to not use the prosthesis while sleeping. Clinical follow-up visits were scheduled at 1 week, 1 month, 6 months later, and once per year thereafter.

### Data Collection

All patient data were reported in medical charts during the clinical and surgical procedures. A retrospective, observational study was performed based on the patients' charts. The data were collected on spreadsheets by one researcher who separated the patients into two groups according to previous irradiation (irradiated and nonirradiated).

### Statistical Analysis

The independent variables were the success of osseointegration and success of rehabilitation based on prior radiotherapy. The following variables were considered to be predictive (dependent): gender, age range, cause of the defect, and number of implants.

The survival rates of implants were estimated as a function of the two groups under study (groups I and II), and the confidence intervals were assessed using a Kaplan–Meier analysis.

The statistics software used to perform the statistical calculations was SPSS 2.1 (SPSS, Inc., Chicago, IL, USA).

## RESULTS

Table 1 summarises the data from patient's clinical records. One hundred and thirty-eight implants were fixed, 96 in nonirradiated and 42 in irradiated with an average of three implants per patient. The observation period ranged from 6 to 96 months, with 133 implants surviving this period for an overall survival rate of 96.4%.

The osseointegration success rate in nonirradiated group was 99.0%, with one implant lost because of trauma related to a fall from standing height. The osseointegration survival rate in irradiated group was 90.5%, with loss of four implants (Table 2, Figure 1). This difference was statistically significant ($p = 0.03$).

**TABLE 1 Summary of Data Collected**

| | Irradiated | Nonirradiated | Total |
|---|---|---|---|
| Number of patients | 12 | 33 | 45 |
| Gender | Male 7 | Male 24 | 31 |
| | Female 5 | Female 09 | 14 |
| Age range/mean age (years) | 20–81/50.5 | 25–85/55 | 52 |
| Cause of defect | tu 11 | tu 31 | tu 42 |
| | in 0 | in 1 | in 1 |
| | tr 0 | tr 2 | tr 2 |
| Number of implants installed | 42 | 96 | 138 |
| Number of implants installed per patient (average) | 3–5 (3) | 1–5 (3) | |
| Number of implants installed per patient/frequency of patients (pts) | 3 imp/8 | 1 imp/1 | — |
| | 4 imp/1 | 2 imp/8 | |
| | 5 imp/2 | 3 imp/19 | |
| | | 4 imp/5 | |
| | | 5 imp/1 | |
| Number of implant failure/cause | 4/radiation | 1/trauma | 5 |
| Follow-up period in months (median time) | 12–60 (43) | 6–96 (28) | — |

imp = implant; in = infection; pts = patients; tr = trauma; tu = tumor.

Means and standard deviations of the implant survival time according to previous irradiation are shown in Table 3. There were no correlations among number or size of implants and failures in irradiated group.

The prosthetic success rate was 95.5%; out of 45 prostheses, 43 remained functional at the last examination. There was no statistically significant difference between the groups under study (Table 4). One patient in irradiated group refused to wear the prosthesis for lack of aesthetic adaptation, whereas the other patient in the nonirradiated group did not use the prosthesis because of social difficulties in reaching the treatment unit after he lost the first one made. Both withdrawals occurred early, after less than 1 year of use, whereas the remaining cases continued using the prostheses until the last follow-up.

**TABLE 2 Success and Failure of Osseointegration Related to Previous Irradiation**

| Medical Condition | | | |
|---|---|---|---|
| | Irradiated Number of Implants (%) | Nonirradiated Number of Implants (%) | Total Number of Implants (%) |
| Osseointegration success | 38 (90, 5%) | 95 (99, 0%) | 133 (96, 4%) |
| Osseointegration failure | 4 (9, 5%) | 1 (1, 0%) | 5 (3, 6%) |

Fisher's exact test: $p$ value = 0.37.

**TABLE 3 Means and Standard Deviations of the Implant Survival Time (Years) and the Confidence Intervals according to Previous Irradiation**

| Groups | Survival Time (Years) | Confidence Intervals of 95% |
|---|---|---|
| Irradiated | 7.5 a | 7.1–7.9 |
| Nonirradiated | 6.1 b | 6.1–6.2 |
| Total | 7.7 | — |

$p$ = 0.45. Different letters indicate statistical difference by Kaplan–Meier survival analysis.

**TABLE 4 Success and Failure of Prostheses Related to Previous Irradiation**

| | Irradiated Number of Patients (%) | Nonirradiated Number of Patients (%) | Total Number of Patients (%) |
|---|---|---|---|
| Prosthetic success | 11 (91, 7%) | 32 (96, 9%) | 43 (95.5%) |
| Prosthetic failure | 1 (8, 3%) | 1 (3, 1%) | 2 (4.5%) |

Fisher's exact test: $p$ value = 1.0.

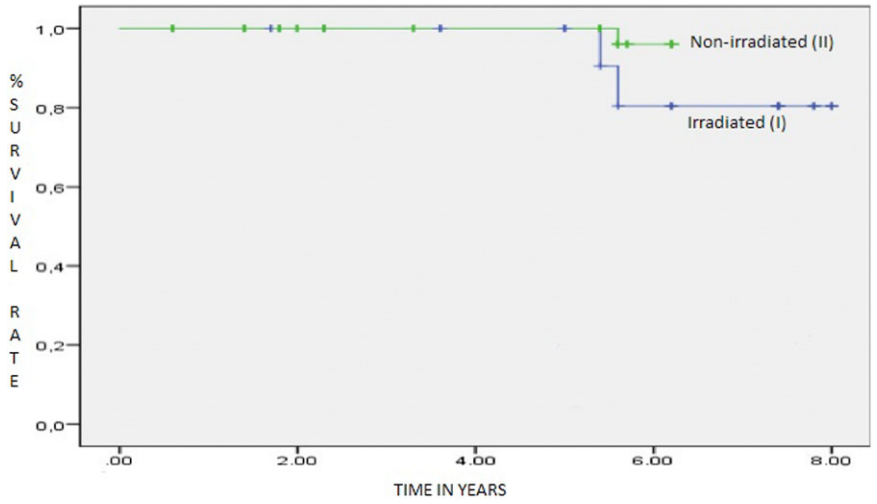


**Figure 1** Comparison of survival rates for implants placed in groups I and II (Kaplan–Meier method, time in years).

## DISCUSSION

The results of the present study confirmed the null hypothesis. Prior irradiation has always been considered the main risk factor for implant loss. The decrease in peripheral circulation and the cellular changes caused by radiotherapy directly interfere in the success of osseointegration by modifying the permanent skin microbiota around implants. This issue may result in the appearance of opportunistic infections that ultimately lead to implant loss.[8,15]

In the present study, the overall implant success rate was 96.4%, which represents the efficacy of the method. The statistical difference found in irradiated group represents the impact of previous irradiation in relation to osseointegration success. These results shows that implant placement could be a good option for prosthetic anchorage even in irradiated areas; however, the planning in such cases should consider placing a larger number of implants because of the higher risk of implant loss found.

Some authors have reported a success rate of 100% for implants in the orbital region; however, these studies used intraoral implants with lengths ranging from 7 to 10 mm.[7,12] The use of intraoral implants in the craniofacial region is controversial because without the flange around the neck of the implant, patients may suffer an intrusion into the cranial cavity after a trauma or in the case of osseointegration failure.[15]

In the present study, all implants used were extraoral shape (acid etch and ti-blasted surface), and there was no statistical difference in overall implant survival rate related to the length of the implants. When discussing craniofacial implants, it is quite natural to emphasize on the success of osseointegration, but to the patient, the desirable outcome is a safe and reliable facial prosthesis. While planning the implant placement, the possibility of partial failure should be taken into account, and regardless of its occurrence, a consistent plan for the rest of the prosthesis should be retained in the remaining implants. In addition to the factors affecting the success of osseointegration, another critical consideration is a situation in which there is a need for further resections because of tumor recurrence that may affect the previously rehabilitated area. Thus, whenever possible, more implants should be placed to anchor the prosthesis. This is not always feasible (e.g., when lack of bone structure is the result of previous major resections or infections and would deny adequate implant fixation). In addition, economic issues may also interfere with this plan as greater numbers of implants induce a higher cost, which may make this procedure inaccessible to underprivileged populations living under poor government health structures.

In the present study, the number of implants per patient ranged from one to five, with 62.2% of patients receiving three implants. There was only one patient who received one implant, and it was because of surgical impossibility to fixate more because of lack of bone structure. The ideal number of implants per patient has not yet been established in the literature; thus, we believe that further cost-benefit analyses and studies on the prosthetic factors related to the optimal conditions for long-term stability and predictability are necessary, especially in irradiated patients.

Nevertheless, the ultimate success of a rehabilitation treatment is measured by the rate of prosthesis use

among the patients. This factor may be affected not only by implant loss but also by the patient's prosthetic and psychological factors. Important prosthetic factors are characteristics such as prosthesis durability, cutaneous inflammatory reactions under the prosthesis or around the implants, prosthetic settlement, stability, and aesthetic results. The patient-related aspects of the outcome are the most variable because the acceptability of using a foreign device is not uniform across all patients.[12] Several studies have highlighted the importance of selecting appropriate patients for rehabilitation treatment with implants as it is not uncommon to encounter situations where patients simply decide not to use their prosthesis for reasons difficult to explain.[16]

Regarding the prosthetic use, a success rate of 95.5% was obtained, with 43 patients still using their prostheses at the time of their last examinations. In the present study, planning a number of implants greater than the minimum requirement allowed the prosthesis to be retained by the remaining implants, even in the three patients who had implant loss. Because each of these patients had received three implants, the prosthesis remained in place because of one implant in two patients and because of two implants in the third patient.

Within the limitations of the study, more related to limited data and short-term follow-up, it was possible to conclude that the results of the present study showed a high success rate of extraoral implants in the orbital region for the retention of orbit prostheses. The success rate of 96.5% is among the highest in the literature, reaffirming that the technique is safe and can be widely used as a resource for anchoring orbit prostheses.[17] Although a success rate of 90.5% among irradiated patients also constitutes a good result, the statistical difference founded in the success rate of osseointegration in the irradiated group should be taken as a warning for the correct selection of patients to minimize implant loss and risk of complications in these conditions. Further studies should be performed considering strategies to increase the success rate of osseointegration in irradiated sites.

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