Aus der Klinik für Mund-, Kiefer- und Gesichtschirurgie

der Medizinischen Fakultät Charité – Universitätsmedizin Berlin

DISSERTATION

Survival analysis of orbital implants and potential influence factors: A retrospective long-term study

zur Erlangung des akademischen Grades

Doctor medicinae dentariae (Dr. med. dent.)

vorgelegt der Medizinischen Fakultät

Charité – Universitätsmedizin Berlin

von

Dr. med. Sabine Maria Toso

aus Freyung

Datum der Promotion: 22.09.2017

1. Inhaltsverzeichnis

2. Abstract (deutsch)

Analyse zur Überlebensrate von Orbitaimplantaten und möglichen Einflussfaktoren: Eine retrospektive Langzeitstudie

Entstellungen des Gesichts aufgrund angeborener oder erworbener Defekte führen bei betroffenen Patienten neben der funktionellen Beeinträchtigung auch zu psychologischer Belastung. Vor allem im Orbitabereich zählen diese zu den emotional äußerst stigmatisierenden Deformierungen. Mit Epithesen, welche diese Defekte abdecken, können betroffene Patienten behandelt werden. Durch die Entwicklung enossaler Titanimplantate wird eine zuverlässige, seit vielen Jahren angewandte Verankerung der Epithesen ermöglicht. Allerdings gibt es nur wenige Studien, welche sich mit Langzeitüberlebensraten extraoraler Implantate befassen. Die vorliegende Studie untersuchte extraorale Implantate im Bereich der Orbita und hatte zum Ziel, Langzeitüberlebensraten und mögliche Einflussfaktoren der Implantate zu analysieren. In dieser retrospektiven Untersuchung wurden Patientendaten ausgewertet, bei denen im Zeitraum von 1991 bis 2014 enossale Implantate zur Fixierung von Orbitaepithesen inseriert wurden. Verschiedene Parameter, wie die Überlebensrate der Implantate als auch das Geschlecht, Alter, Nikotineinfluss, Patientenseite, Bestrahlungsstatus, Implantatlokalisation, Implantatsystem, Implantatlänge und der prothetische Retentionstyp wurden ausgewertet. Mit den Daten, welche durch Patientenuntersuchung und Aktenauswertung erhoben wurden, wurde eine SPSS-Tabelle erstellt. Etwaige Zusammenhänge der Überlebenskurven anhand der Kaplan-Meier Methode mit verschiedenen Parametern wurden mittels des Log-Rank Tests geprüft. Insgesamt wurden 78 Patienten mit 282 Orbitaimplantaten über einen Beobachtungszeitraum von 2 bis 268 Monaten (Mittelwert 94.97 Monate) untersucht. Die kumulative Implantatüberlebensrate lag nach 2 Jahren bei 91.3%, nach 5 Jahren bei 80.5%, nach 10 Jahren bei 68.7% und nach 15 Jahren bei 62.2%. Die Überlebensrate war bei Frauen mit 75.3% signifikant höher als bei Männern mit 47.3%. Bei den supraorbital inserierten Implantaten lag sie höher als bei infraorbitalen Implantaten (67.4% vs. 51.5%) und Implantate mit maschinierter Oberfläche (70.2%) zeigten höhere Überlebensraten gegenüber Implantaten mit rauen Oberflächen (54.5%). Die Implantatlänge und Magnetverankerung schienen einen positiven Einfluss

auf das Implantatüberleben zu haben. Kein signifikanter Zusammenhang wurde zwischen Alter, Nikotineinfluss, Patientenseite, Bestrahlungsstatus und Implantatüberleben gefunden. Schlussfolgernd deuten die Ergebnisse der vorliegenden Studie auf gute bis akzeptable Ergebnisse bezüglich der Langzeit-Vorhersagbarkeit von Orbitaimplantaten hin. Faktoren wie das weibliche Geschlecht, die Lokalisation am Supraorbitalrand, die maschinierte Oberfläche des Implantatsystems, die Implantatlänge und Magnetfixierung der Epithese scheinen die Implantatüberlebensrate positiv zu beeinflussen, wohingegen der Bestrahlungsstatus, Alter, Nikotineinfluss und Patientenseite keine Relevanz zeigen. Diese Faktoren sollten bei der zukünftigen Patientenversorgung berücksichtigt werden.

3. Abstract (englisch)

Survival analysis of orbital implants and potential influence factors: A retrospective long-term study.

Facial deformities as a result of inborn or acquired facial defects often lead to functional impairment and psychological strain. Especially orbital defects rank among the most emotionally distressing deformations. Affected patients can be rehabilitated by covering the defects with crainofacial prostheses. The development of osseointegrated implants for bone anchorage offers a reliable fixation technique of the prostheses and is applied for many years. But only a little number of studies exists investigating long-term success rates of extraoral implants. This study focused on implants installed for retention of orbital prostheses. The aim was to evaluate long-term survival rates and possible influence factors of implants in the orbital region. Retrospectively, a patient population with a large number of orbital implants was involved in the present study during a reasonable time period (1991 – 2014). The implant survival as well as influence of gender, age, nicotine use, side, irradiation status, location of implant placement, implant system, length and retention type on success rates were investigated. Therefore, patient data were collected by examination of patients and checking patient files. The collected data were transferred into a SPSS-table for calculating Kaplan-Meier curves and performing log-rank test. In total, 282 orbital implants in 78 patients with mean follow-up of 94.97 months (2 to 268 months) were assessed. These implants showed survival rates of 91.3% after 2 years, 80.5% after 5 years, 68.7% after 10 years and 62.2% after 15 years. The results showed that implants in females were more successful than in males (75.3% vs. 47.3%). Furthermore a significant higher survival rate for supraorbital (67.4%) than for infraorbital implants (51.5%) was indicated. The results also revealed that implants with machined surface were more successful than implants with rough surface (70.2% vs. 54.5%). Length and magnetic fixation seemed to have a positive influence on implant survival. However, no significant relationship was found between age, nicotine abuse, side, irradiation status and implant survival. In conclusion, implants in the orbit seem to have a good to passable prognosis over a long period. The study implicates that female gender, localization in the supraorbital rim,

machined surface of the implant system, length and magnetic fixation have a positive effect on the survival of orbital implants, while irradiation status, age, nicotine abuse and location side don’t seem to have any impact. Prospective patient treatment should take these aspects into account.

4. Eidesstattliche Versicherung

„Ich, Dr. Sabine Maria Toso, versichere an Eides statt durch meine eigenhändige Unterschrift, dass ich die vorgelegte Dissertation mit dem Thema:

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Datum Unterschrift

5. Ausführliche Anteilserklärung an der erfolgten Publikation

Publikation: Toso, S., Menzel, K., Raguse, J.D., Nahles, S.

Survival analysis of orbital implants and potential influence factors: A retrospective long-term study. Int J Oral Max Impl. 2017 May/Jun; 32(3): 642-648.

Beitrag im Einzelnen:

1. **Idee, Vorbereitung der Studie: Toso S., Nahles S.**
   Frau Sabine Toso war relevant an der Ideenfindung und Vorbereitung (Designerstellung, Auswahl der zu untersuchenden Parameter, statistische Analysemöglichkeiten) der publizierten Studie beteiligt. Des Weiteren erstellte sie Einwilligungs- und Aufklärungsbögen für die zu untersuchenden Patienten und formulierte den Antrag an die Ethikkommission.
2. **Durchführung der Studie: Toso S., Menzel K.**
   Die Namensliste der für die Studie in Frage kommenden Patienten (Patienten mit Orbitaimplantaten) wurde von Frau Kerstin Menzel zur Verfügung gestellt. Die Untersuchung und Befundung der Patienten, sowie die Aktensichtung- und auswertung der Patientendaten wurde von Frau Toso durchgeführt.
3. **Aufbereitung der Daten zur Vorbereitung der statistischen Analyse: Toso S.**
   Frau Toso bereitete die Daten auf und erstellte die SPSS-Tabelle für die statistische Analyse.
4. **Verfassen der Publikation, Literaturrecherche: Toso S., Nahles S.**
   Frau Toso führte die Literaturrecherche durch. Die Auswahl, Beschreibung und Deutung der Ergebnisse erfolgte in Rücksprache mit Frau Susanne Nahles. Frau Toso verfasste die Publikation.
5. **Korrektur und Revision des Manuskripts: Toso S., Nahles S., Raguse J.D.**
   Korrekturen am Manuskript erfolgten durch Frau Nahles und Herrn Raguse. Frau Toso machte Vorschläge bezüglich der Überarbeitungen und verfasste zusammen mit Frau Nahles die Revisionen des Manuskripts.

Unterschrift, Datum und Stempel des betreuenden Hochschullehrers/der betreuenden Hochschullehrerin

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7. Druckexemplar der Publikation

Survival Analysis of Orbital Implants and Potential Influencing Factors: A Retrospective Long-Term Study

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Purpose: *Application of endosseous implants in prosthetic orbital reconstruction seems to be very successful, but few reports have evaluated cumulative survival rates of orbital implants over a long period. The aim of this study was to analyze long-term survival rates and potential influencing factors of orbital implants.* **Materials and Methods:** *A retrospective evaluation of patients treated with extraoral screw implants for retaining orbital prostheses from 1991 to 2014 was performed. Patient records were assessed for implant survival, demographic data, defect etiology, irradiation status, location of implant placement, implant systems, length, and retention type. Data were analyzed using the Kaplan-Meier method and log-rank test to compare survival curves.* **Results:** *A total of 282 orbital implants placed in 78 patients were evaluated during an observation period ranging from 2 to 268 months (mean: 94.97 months). The cumulative implant survival rate was 91.3% at 2 years, 80.5% at 5 years, 68.7% at 10 years, and 62.2% after 15 years. The survival rate was significantly higher in females (75.3%) vs males (47.3%), in supraorbital vs infraorbital implants (67.4% vs 51.5%), and in Brånemark implants (70.2%) vs Straumann implants (54.5%).* **Conclusion:** *The presented data suggest that the long-term predictability of orbital implants revealed good to acceptable results. Factors such as female gender, localization in the supraorbital rim, a machined surface of the implant system, length, and magnetic retention seem to affect the implant survival rate positively, whereas irradiation status does not show any influence. These factors should be considered in planning future patient rehabilitation.* Int J Oral Maxillofac Implants 2017;32:642–648. doi: 10.11607/jomi.5273

Keywords: *exenteration, facial prosthesis, orbital implant, reconstruction*

The expanding progress of microsurgery and reconstructive transplantation offers various treatment options for patients suffering from facial defects. Yet, reconstructing individual specialized units of the face remains challenging.[1] Especially, orbital exenteration, which involves the removal of the orbital contents and all parts of the eyelids, still poses a major reconstruction problem, though the procedure, first described already in 1583, has a long history.[2] Nevertheless, surgical reconstruction of the orbit is still limited and provides only poor esthetic results.[3] The possibility of rehabilitating orbital defects with craniofacial prostheses, however, offers an approved therapeutic method.[4] Using external cranial titanium implants for fixation represents a viable technique, which has been known for more than 30 years.[5] Osseointegrated implants have become a substantial instrument for orbit rehabilitation, providing benefits and convenience over conventional retention methods such as adhesives, and thus, improving the quality of life for patients wearing facial prostheses.[6,7]

The use of osseointegrated implants in the treatment of orbital defects has been frequently documented in the literature.[6–15] However, a number of studies provide results of increased variability with implant survival success rates ranging from 30% to 100%. Most of the studies have focused on success rates in the nonirradiated compared with the irradiated orbit. The less favorable results were obtained particularly in irradiated sites.[6,8,12–14] According to the literature, the quality and volume of the bone in different anatomical

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sites as well as radiation therapy are main factors influencing the outcome of craniofacial implants.[13,16,17] However, controversial issues exist, since in most of these studies, the number of implants placed and the follow-up time are limited. To the best of the authors' knowledge, only one study provides follow-up times over more than 20 years,[18] and only a few studies address a multitude of potential influencing factors.[11,17,19]

The aim of this study was to evaluate long-term survival rates and potential influencing factors of extraoral orbital implants.

MATERIALS AND METHODS

Study Design

A retrospective evaluation of patients treated with extraoral solitary screw implants for retaining orbital prostheses between the years 1991 and 2014 was conducted in the Department of Oral and Maxillofacial Surgery, Campus Virchow-Clinic, Charité University Hospital. Patient records were assessed for implant survival, demographic data, defect etiology, nicotine use, irradiation status, location of implant placement, implant systems, length, and retention type. The total survival time for each implant was defined as the time from implant placement to the date of implant removal or the last follow-up visit at which the implant was present without any mobility or pain. Implants placed in patients who failed to complete prosthetic treatment were excluded from the study. The study was approved by the Ethics Committee of the Charité University of Medicine (Berlin, Germany) (EA2/023/14).

Treatment Protocol

Treatment planning and surgery were performed by two long-term experienced oral and maxillofacial surgeons in accordance with the Anaplastology team of the department (H. M. and M. K.). For assessing sufficient bone volume at the defect site, bone availability was measured with computed tomography preoperatively. Implants were placed in the supraorbital rim and/or into the infraorbital rim. The superior orbital rim was defined as the part of the bony orbit transected by the midline of the axial plane. The inferior orbital rim was defined as the remaining orbital part inferior to this line as described by Toljanic et al.[11] All patients were treated according to a two-stage procedure under general anesthesia.[20] The implant healing time was at least 3 months in nonirradiated and at least 6 months in irradiated patients. Before loading of an orbital prosthesis, implants were exposed in local anesthesia. The procedure of implant exposure und handling of peri-implant tissue was performed using a standard protocol and was previously described by Klein and Menneking.[21]

Most implants were provided with magnetic abutments (Steco-System-Technik). After a healing time of 2 to 4 weeks with a strict use of healing disks, the orbital prostheses were fabricated by the Anaplastology team using conventional laboratory procedures.

All patients were advised of hygiene measures, including daily mechanical and chemical home care of the abutments. The patients were routinely seen for clinical examination at 4 weeks after prosthetic restoration and every 3 months thereafter within the first year. Beginning with the second year, the evaluation was performed annually. During clinical follow-up visits, the facial prosthesis was removed to check the peri-implant soft tissue and the implant integration with a torque control device. Instructions for hygiene measures were refreshed when patient compliance seemed to decline.

Statistical Analysis

Statistical analyses were performed using SPSS 23 (SPSS). Descriptive analysis was assessed for all available data. Implant survival using the Kaplan-Meier curve and the confidence intervals by Peto with logit-transformation were analyzed. Applying Cox regression analysis, the impact of age on the implants' survival rates was evaluated. Additionally, the influence of gender, side, radiotherapy, localization (supra-/infraorbital rim), and implant system on the survival rates were analyzed by using the log-rank test. A P value of $< .05$ was considered to be statistically significant.

RESULTS

The study population consisted of 78 patients (42 females and 36 males) with a mean age of 56.5 years (range: 9.1 to 86.9 years) at the time of implant placement. Twenty-six patients (15 females and 11 males) died during the study period (Table 1). Orbital exenteration due to tumor was the most common indication for orbital prostheses (71 patients). Other indications included deficit because of trauma (6 patients) and Wegener's disease (1 patient). The right orbit was affected in 40 patients, the left orbit in 37 patients. In one patient, exenteration was performed on both sides due to bilateral retinoblastoma.

In 35 patients who had undergone tumor surgery, additional radiotherapy was necessary. The radiation therapy was delivered up to a dose of 75 Gy and was performed before implant placement or after implant placement. In two patients, radiotherapy was applied before and after implant placement due to recurrence of malignancy. Patient data are summarized in Table 1.

Table 1 Summary of Patient Data

Study population	No.
Total	78
Male	36
Female	42
Age (y)	
Mean	56.5
Range	9.1–86.9
Smoker	11
Deceased	26
Defect etiology	
Tumor	71
Trauma	6
Wegener's disease	1
Side	
Right	40
Left	37
Both	1
Radiation status	
Nonirradiated	43
Irradiated	35

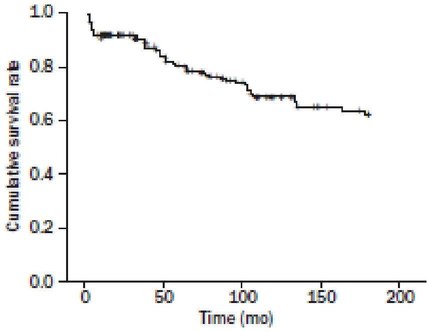


Fig 1 Overall Kaplan-Meier survival analysis.

Within this study, 334 implants were inserted for prosthetic retention: two implants were placed in one patient, three implants in 25 patients, four implants in 20 patients, five implants in 17 patients, six implants in 13 patients, and 7 implants in two patients, including reinsertions and sleeping implants. Fifty-two implants were sleeping implants and were not involved in the statistical analysis; therefore, 282 implants were considered for the study. The sleeping implants were left unexposed and serving for future use in case of implant loss.

The observation period of the implants ranged from 2 to 268 months (mean: 94.97 months; Fig 1). A total of 79 implants were lost, 21 without functional loading. Of these 21 implants, 16 implants were loosened at exposure, 4 implants were lost before exposure, and 1 implant after exposure without functional loading, so 29.1% of the implant failures were found in the first 12 months (Fig 2). Twenty-six patients with a total of 90 implants died during the observation period.

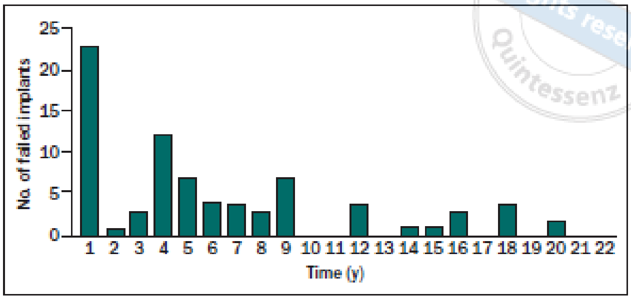
Due to dropout from follow-up as well as the death of patients, of all implants, 134 implants had a follow-up period of 5 years (75 implants were followed up to 10 years, and 48 implants were followed up to 15 years after insertion). The cumulative probability of implant survival was 91.3% at 2 years (0.92; 95% CI [0.866–0.941]), 80.5% at 5 years (0.80; 95% CI [0.732–0.854]), 68.7% at 10 years (0.68; 95% CI [0.572–0.771]), and 62.2% after 15 years (0.62; 95% CI [0.480–0.743]) (Fig 1). For the statistical analysis testing influencing factors, an observation period of 15 years was chosen to work with a sufficient data level. The loss of follow-up and death before the end of the study were labeled as censored observations.

Considering gender, 153 implants were placed in 42 female patients and 129 implants in 36 male patients; 34 implants in females and 45 implants in males were lost. A log-rank test revealed that the cumulative survival rate of orbital implants was significantly higher in females with 75.3% than in males with 47.3% after 15 years ($P = .001$). Comparative Kaplan-Meier curves are presented in Fig 3.

Cox regression analysis revealed that patient age had no significant influence on implant survival rate ($P = .496$).

Implant failures in relation to irradiation status were also investigated. As Table 2 shows, 131 implants were placed in 35 oncology patients who underwent radiotherapy; 44 implants (33.6%) were lost. Comparative Kaplan-Meier curves of implant survival in irradiated and nonirradiated sites are seen in Fig 4, indicating no significant impact for radiation therapy on implant survival (no radiation therapy: 64.9%; radiation therapy: 59.9%) ($P = .163$). In addition, implant survival in relationship to irradiation date was analyzed. One hundred seven of the 131 implants were placed in patients with previous radiotherapy; 30.8% of these implants failed (nine of the 131 implants in oncology patients were placed in sites with irradiation prior to and after implant placement; however, they were counted as implants in previously irradiated sites). Twenty-four of 131 implants were placed in patients with irradiation therapy afterward; of these 24 implants, 45.8% failed. When comparing survival rates, $P = .399$ showed no significant impact on the survival of implants placed prior to or after irradiation therapy.

Fig 2 Time from implant insertion to failure of the 79 implants.



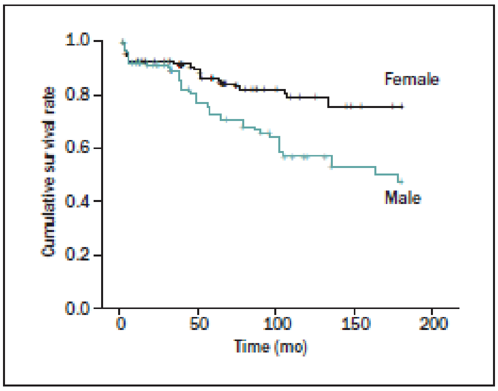


Fig 3 Kaplan-Meier survival analysis for implants placed in male and female patients.

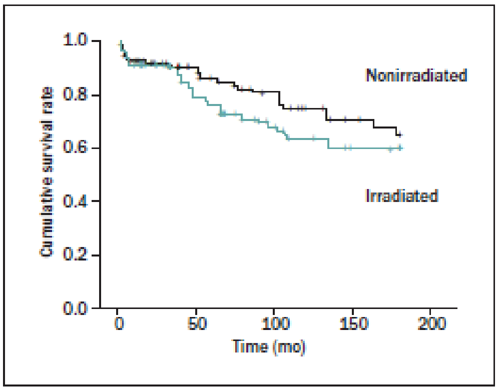


Fig 4 Kaplan-Meier survival analysis for implants placed in irradiated and nonirradiated sites.

Statistical analysis also focused on the location of the implants in the orbit. Two hundred five implants were placed in the supraorbital rim with a loss of 48 implants (23.4%). Seventy-seven implants were inserted into the infraorbital rim with a loss of 31 implants (40.3%). The Kaplan-Meier curves are illustrated in Fig 5 and show early implant failures in the infraorbital rim and late implant failures in the supraorbital rim. Up to 180 months, a significantly higher survival rate for supraorbital implants (67.4%) than for infraorbital implants (51.5%) was indicated ($P = .008$).

As implants of the Brånemark-titanium and the Straumann EO system were applied, statistical analysis was used to compare both systems; 118 Brånemark-titanium implants and 164 Straumann EO implants were placed. Within the Brånemark system, 37 implants (31.4%) were lost, and within the Straumann system, 42 implants (25.6%) were lost. The Brånemark implants showed later implant failures than the Straumann implants (Fig 6). The survival rate was significantly higher for the Brånemark system (70.2%) than for Straumann (54.5%) ($P = .003$).

According to the available bone volume, implants of different lengths were used: two implants with 2.5 mm, 16 implants with 3.5 mm, 130 implants with 4 mm, and 134 implants with 5 mm. Long survival times were shown by 4-mm implants (mean survival time: 198.95 months), followed by the 5-mm length (156.28 months); 2.5-mm and 3.5-mm implants showed early failures (mean survival times: 106 months for 2.5-mm implants and 24.58 months for 3.5-mm implants).

Table 2 Implants Placed in Patients with Radiotherapy

	No. of implants	No. of implants lost	% lost
Placed in oncology patients	131	44	33.6%
Placed in patients with previous radiotherapy[a]	107	33	30.8%
Placed in patients with radiotherapy afterward	24	11	45.8%

[a]Includes nine patients with irradiation prior to and after implant placement.

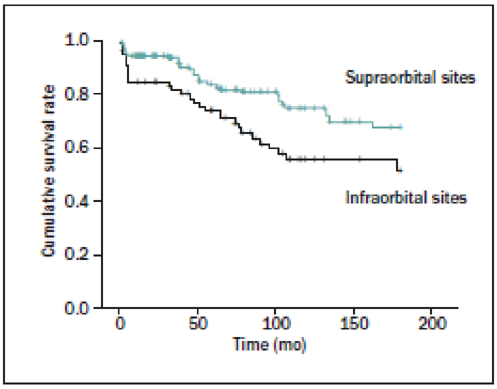


Fig 5 Kaplan-Meier survival analysis for implants placed in supraorbital and infraorbital rim sites.

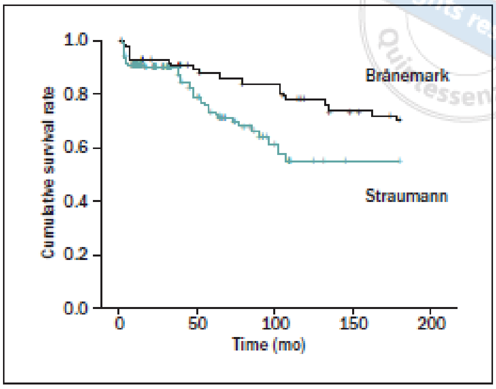


Fig 6 Kaplan-Meier survival analysis for implants of the Brånemark and the Straumann EO system.

Implants were provided with different abutment types. The most-selected retention method was the magnetic supraconstruction: X-line magnetic abutments were used in 239 implants (85.1%); of those, 51 implants (21.3%) failed. Ten implants (3.5%) were provided with Z-line magnetic abutments; none of these implants failed. Eleven implants (3.9%) were linked with bar-and-clip supraconstructions; of those, six implants (54.5%) failed. Twenty-two implants (7.8%) were lost before a supraconstruction was attached.

DISCUSSION

The aim of this study was to assess long-term survival rates and potential influencing factors of a large sample size of orbital implants in exenterated patients rehabilitated with craniofacial prostheses. The results reveal an overall survival rate of orbital implants of 80.5% at 5 years and 68.7% at 10 years. These results are consistent with those reported in previous studies.[13,15,22] Besides that, this study's survival curve shows a continuous loss of implants over the observed time period with approximately 30% of the implant failures found in the first year. This high rate of failures shortly after implant insertion might primarily be associated with nonosseointegration. During the observation period, 90 implants were lost due to patients' death. As most of the patients provided with implants suffered from malignancies, recurrences may be a reason for the high patient death rate. In light of these statistics, orbital implants may not seem to be a viable economic treatment immediately after surgical tumor resection. Nevertheless, an implant-retained craniofacial prosthesis has a positive impact on the quality of life for oncologic patients.[23] Therefore, it should be offered to patients as soon as possible after surgical resection.

With regard to gender, the survival curves indicate that in female patients, significantly more orbital implants survived compared with male patients. This implies that gender represents an influencing factor for orbital implant survival. It is known that inflammation of peri-implant soft tissue can cause implant failure, due to thick soft tissue and epithelial debris surrounding the implants.[17,24,25] Maybe there is a difference in peri-implant soft tissue response and maintenance habits in female and male patients. However, to date, nothing is known about the reason for the difference between the implant survival in female and male patients.

Many patients with orbital defects due to ablative cancer surgery have undergone prior irradiation or are subjected to postoperative radiotherapy. As a consequence, implants are frequently placed in irradiated bone. Although it is well-defined that adverse biologic effects of ionizing radiation compromise regular bone and soft tissue healing,[16,26] the prognosis of endosseous implant therapy is still ambiguous. In the literature, various investigations focus on comparing extraoral implant osseointegration in irradiated sites with non-irradiated sites.[6,8,12–14] The majority of these studies describe decreased survival rates for implants in irradiated bone. However, controversial reports exist. For example, a histologic evaluation by Pack et al showed that bone healing around orbital implants seemed not to be reduced by radiotherapy, even though radiation damage in bone tissue was observed.[27] A couple of newer studies show no significant relationship between radiation treatment history and implant survival.[11,17,19,28] In line with these studies, the results of the present study present no statistically significant impact of radiation therapy on orbital implant survival over time. Furthermore, no significant difference in the success rate of implants placed prior to or after radiation therapy was found. Yet, the irradiation date is a controversial issue in the literature. Some authors recommend implant placement before irradiation. This may allow an uncomplicated osseointegration in a noncompromised area, limit surgical intervention in irradiated tissue to stage-two surgery, and enable earlier prosthetic rehabilitation. However, to the best of the authors' knowledge, only a few studies with low sample sizes or animal experiments are available.[23,29] The results of the present study may be a consequence of permanent education and further development, concerning the management of irradiated patients with respect to precautionary measures for the surgical procedure, postsurgical treatment, and hygiene maintenance. Nevertheless, many parameters such as radiation dose, time between radiation therapy and implant placement, and adjunctive therapies may influence the osseointegration and should be evaluated in further statistical analyses.

Implant placement location has also been considered as a factor that may influence long-term implant survival. The implants are placed radially within the orbital rim due to the osseous anatomy of the orbit. The preferred site is the lateral supraorbital rim, providing increased bone thickness for retention.[30] However, for adequate support of the orbital prosthesis, additional implants are often placed into the infraorbital rim. To the best of the authors' knowledge, only one study with a limited mean follow-up time and sample size focused on the success rate comparing implants placed in the supraorbital and infraorbital rim.[11] No significant relationship was found. In the present study, a significantly higher survival rate for supraorbital implants was found, with a failure rate of 23.4% for supraorbital and 40.3% for infraorbital implants. This indicates that a correlation between implant location and survival exists. One possible explanation is that soft tissue could affect the success rate in these different anatomical sites. Immobilization of the epithelial tissue around the implant is a critical factor, as movements between the implant and the skin result in chronic inflammation.[5,8] However, skin mobility in the infraorbital rim due to patients' cheek movements is frequently observed. This may lead to increased soft tissue reactions and subsequent infections, resulting in bone loss and implant failure. A secondary possible explanation for early failures of the infraorbital implants may be that extrusions and sulcus fluid facilitate chronic inflammation of the peri-implant soft tissue due to gravity. Further studies should evaluate the role of the soft tissue in supraorbital and infraorbital implants.

In the present study population, two systems, the Brånemark-titanium implants and Straumann EO implants, were applied for orbital prosthesis retention. Both systems provide threaded and self-tapping screws and are designed for extraoral use. The statistical analysis revealed a significantly higher success rate for Brånemark-titanium implants with later implant failures compared with Straumann EO implants. This could be due to different surfaces. Straumann EO implants are provided with a sand-blasted, large-grit, acid-etched (SLA) surface, whereas Brånemark implants have a machined titanium surface. Histologic studies verify osseointegration of the craniofacial Brånemark implants and show high bone-to-implant contact.[27,31,32] No histologic study measuring osseointegration was found for Straumann EO implants. Studies referring to dental implants revealed that implant surface affects plaque accumulation.[33] This indicates that the surface of extraoral implants has an impact on debris accumulation and subsequent soft tissue reaction. In future studies, the influence of different extraoral implant systems on the soft tissue should be investigated.

For the retention of the orbital prostheses, magnetic fixation was the most-selected method represented in this study; 88.6% of the implants were provided with magnetic abutments, and only 3.9% were linked with bar-and-clip supraconstructions. There is no significance determinable in the success rate of implant survival, related to the small number of implants with a bar-and-clip system. However, an implant failure rate of 21.7% for magnetic and 54.5% for bar-and-clip abutments confirms a clear trend toward a reliable application of the magnetic system. This well-established treatment concept provides several approved advantages, such as simple hygiene control of the peri-implant soft tissue, eased insertion of the prosthesis, and low moment forces on the supporting abutment, minimizing the stress delivered to the implants.[34,35]

Comparing the implants' length, the study shows a tendency toward a more successful implant survival for 4-mm and 5-mm implants. However, statistical evaluation does not define any significance, which may be due to the low case number of the 2.5-mm and 3.5-mm implants.

CONCLUSIONS

Only long-term observations are able to measure efficacy and prognosis of implants. The presented data suggest that the predictability of orbital implants over a long time period revealed good to acceptable results. The most important findings show that—besides well-known factors such as sufficient peri-implant tissue handling—gender, localization of the implant, implant and abutment system, and implant length affect the implant survival rate. On the other hand, irradiation status does not play a decisive role in the success of extraoral implants.

ACKNOWLEDGMENTS

Special thanks to Martin Klein, Horst Menneking, and Yvonne Motzkus. The authors also thank Gerda Siebert for her statistical assistance. The authors reported no conflicts of interest related to this study.

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8. Lebenslauf

„Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht.“

9. Publikationsliste

Publikation 1: Toso S., Menzel K., Raguse J.D., Nahles S.

Survival analysis of orbital implants and potential influence factors: A retrospective long-term study. Int J Oral Max Impl. 2017 May/Jun; 32(3): 642-648. (IF 1.859)

Publikation 2: Toso S.M., Menzel K, Motzkus Y., Adolphs N., Hoffmeister B., Raguse J.D.

Patient-specific implant in prosthetic craniofacial reconstruction: First report of a novel technique with far-reaching perspective. J Craniofac Surg. 2015 Oct; 26(7): 2133-5. (IF 0.700)

Publikation 3: Toso S.M., Menzel K., Motzkus Y., Klein M., Raguse J.D., Nahles S., Hoffmeister B., Adolphs N.

Anaplastology in times of facial transplantation: Still a reasonable treatment option? J Craniomaxillofac Surg. 2015 Sep; 43(7): 1049-53. (IF 1.592)

Publikation 4: Hoffmeister B., Toso S.

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Publikation 5: Appel B., Baumer J., Eyrich D., Sarhan H., Toso S., Englert C., Skodacek D., Ratzinger S., Grässel S., Goepferich A., Blunk T.

Synergistic effects of growth and differentiation factor-5 (GDF-5) and insulin on expanded chondrocytes in a 3-D environment. Osteoarthritis Cartilage 2009 Nov; 17(11): 1503-12. (IF 4.535)

10. Danksagung

An erster Stelle gilt mein großer Dank Frau PD Dr. Susanne Nahles für die Unterstützung und stetige Motivation bei der Erstellung dieser Dissertation.

Ganz herzlich bedanke ich mich bei meinem Epithetik-Team Herrn Dr. Dr. Horst Menneking, Herrn PD Dr. Dr. Jan-Dirk Raguse, Frau Kerstin Menzel und Frau Yvonne Motzkus für ihre tatkräftige Unterstützung sowie für die schöne gemeinsame Zeit.

Des Weiteren bedanke ich mich bei Frau Gerda Siebert für ihre Hilfe bei der statistischen Auswertung der Daten.

Mein besonderer Dank geht an meine geliebte Familie - meinen Ehemann Dr. Ramin Gamerschlag, meine Tochter Greta Lucia sowie meine Eltern und Schwiegereltern. Für Eure Geduld und kontinuierliche Unterstützung während des gesamten Entstehungsprozesses dieser Arbeit bin ich Euch sehr dankbar.