Is Mandibular Reconstruction Using Vascularized Fibula Flaps and Dental Implants a Reasonable Treatment?

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ABSTRACT

Purpose: this study retrospectively analyzed the rate of screwed implant insertion and risk factors in patients undergoing mandibular reconstruction with microsurgical revascularized fibula flaps.

Methods: This study retrospectively analyzed all patients with microvascularized fibula grafts between 1997 and 2005. Collected data included general data and risk factors (e.g., smoking, alcohol use), and irradiation was the main predictor variable. The number of patients rehabilitated with dental implants and the implant success rate were evaluated, possible influencing factors were identified, and the results were compared with previously published data.

Results: The sample included 33 patients (17 men, 16 women; mean age: 52 years); 76% were smokers, 42% drank alcohol regularly, and 73% had undergone mandible irradiation. Twenty-three patients received 140 screw-retained implants for dental rehabilitation. Twenty-three implants were lost. Overall 1- and 5-year implant survival rates were 94% and 83%, respectively. Implant survival rates were 86% in non-irradiated mandibular bone, 86% in non-irradiated grafted fibular bone, 82% in irradiated mandibular bone, and 38% in irradiated grafted fibular bone.

Conclusion: This study showed that the use of dental implants in patients with fibula flaps is an appropriate and successful option for dental rehabilitation, even in those with risk factors such as smoking, alcohol use, and irradiation. Implant placement in irradiated grafted bone seems to be a high-risk procedure.

KEY WORDS: dental implants, dental rehabilitation, fibula graft, patient selection, risk factors, success criteria

INTRODUCTION

Mandibular reconstruction and oral rehabilitation pose many challenges to the surgeon. The face is the body's most important communication feature, and speech and facial expressions convey a person's intentions and character. Orofacial defects also lead to functional loss. For example, impeded breathing and hindered food ingestion reduce chewing and speaking capabilities, thereby significantly decreasing the quality of life.[1–3]

Mandibular resection with the reconstruction and rehabilitation of associated functions was first described in 1810,[4,5] and many orofacial reconstruction strategies have since been developed to provide an ideal bony reconstruction for later dental rehabilitation. Such strategies also aim to restore function and appearance to resemble the normal condition as closely as possible. Today, the use of microsurgical revascularized fibula flaps in combination with dental implants represents the current state of the art of mandibular reconstruction.[6–11] Success rates for dental implants inserted in fibula grafts

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(~93%)[12,13] are similar to those in non-reconstructed jaws.[14–16] However, the reported rate of performed dental rehabilitation, inclusion criteria, and the success rates of dental implants have differed markedly among studies. Factors such as nicotine and alcohol use, irradiation, patients' manual abilities, or compliance may affect the survival and success of inserted bone and implants in this patient group. No standardized criteria have been established to evaluate the success of dental implants or to determine the appropriate inclusion criteria for dental implants in patients who have undergone mandibular reconstruction.[17,18]

Is there a need to exclude patients from current implant-supported dental rehabilitation procedures due to risk factors? How should success be defined in this special group of patients?

The authors hypothesized that all patients undergoing mandibular reconstruction with microsurgical revascularized fibula flaps should receive dental implants to improve dental rehabilitation, but the success criteria must be adapted to this special group of patients.

Therefore, the objectives of this study were to analyze the number and risk factors of patients who had undergone mandibular reconstruction with microsurgical revascularized fibula flaps and who had received dental implants inserted into the grafted bone and the remaining mandible. We also analyzed the number, risk factors, and success rate of dental implants and compared the treatment strategy presented here with previously reported strategies.[8,18–20]

MATERIAL AND METHODS

Study Design and Patients

We performed a retrospective analysis of patients who had undergone mandibular reconstruction with a fibula flap due to facial trauma, osteomyelitis, malignancy, or severe mandibular atrophy in the Department of Craniomaxillofacial Surgery at the University Hospital of Zürich between 1997 and 2005. Data collected included general information such as gender, age, indication for reconstruction, flap success rate, risk factors such as smoking and alcohol use, local risk factors such as irradiation, and the success rate, number, and reason for failure of subsequently placed dental implants. Smoking was defined by the authors in this study as consumption of at least 20 cigarettes a day for a minimum of 5 years until the time of mandibular reconstruction. Alcohol "yes" was defined as chronic abuse of alcohol. All those patients defined themselves as alcohol-dependent. Irradiation was performed with an average of 63 Gy in the area of reconstructed mandible (with a range of 50–73 Gy). All patients signed an informed consent form prior to the data analysis. The study design fulfilled the Ethical Principles for Medical Research Involving Human Subjects presented in the Declaration of Helsinki. The study design also fulfilled the criteria of paragraphs 4a and b in the guidelines of the cantonal ethics committee of Zürich (version 21.5.2010.2010) and was therefore exempted from institutional review board approval.

Study Variables

The predictor variables were grouped into general variables (age, indication, gender), risk factors (tobacco, alcohol use), and irradiation. The irradiation predictor variable was then specified according the timing of the reconstruction procedure (before or after mandibular reconstruction). Therefore, in this study, four different types of bone were used as an implant bed: irradiated mandible, non-irradiated mandible, irradiated fibula, and non-irradiated fibula. The actual (primary) outcome variable was defined as the success of inserted dental implants subsequent to mandibular reconstruction. Exclusion criteria for the placement of dental implants were tumor recurrence or demographic reasons, such as the patient's residence in a remote location that prevented regular follow-up in the outpatient clinic. Risk factors such as smoking, alcohol use, or radiotherapy were not exclusion criteria.

The following three criteria were used to evaluate implant success in this study: absence of pain and clinical signs of severe infection, such as pus and loosening of implants; secondary implant stability (evaluated manually) at the time of implant loading as described by Sennerby et al.,[21] characterized by the absence of implant rotation and/or vertical movement; and functional loading capability and feasibility of integration in a suprastructure. Each implant that failed to meet one of these three criteria was removed to avoid infection and/or future graft loss; thus, implant success and survival rates were the same.

Data Analysis

All patients' charts were analyzed, and a database was created. Descriptive statistics were performed with the

Statistical Package for the Social Sciences (ver. 19; SPSS, IBM Corporation, Armonk, NY, USA). The survival of all implants was examined using the Kaplan–Meier survival analysis method. Implant survival was defined as the interval (in months) between implant insertion and implant failure, death of the patient, or end of the observation period.

Cox regression analysis with shared frailty was performed to analyze implant loss over time for the four different groups of bone (irradiated grafted fibula, non-irradiated grafted fibula, irradiated mandible, non-irradiated mandible). The patient was used as a shared frailty identification variable to address implant clustering (December 31, 2009). Statistical analyses were performed with the Stata software (ver. 11.2; StataCorp, College Station, TX, USA).

Surgical Methods

Before surgical treatment for mandibular reconstruction, a detailed medical history was collected and co-morbidities and potential risk factors, such as smoking, alcohol use, and irradiation, were evaluated. The donor sites were assessed by clinical examination and lower-leg angiography. The surgery was performed using a two-team approach. Depending on the individual situation, titanium reconstruction plates, miniplates, or lag screws were used for intraoral fixation. Immediately after the operation, clinical and flap monitoring was performed in an intensive care unit for 24 hours. All patients received intravenous anticoagulation therapy (Liquemin®; 10,000 IE/24 hours for 5 days; Pfizer AG, Zürich, Switzerland), followed by the subcutaneous application of low-molecular-weight Fragmin® (Pharmacia GmbH, Erlangen, Germany; Pfizer AG) for 5 days. Prophylactic antibiotic treatment [cefuroxime (Zinat®); GlaxoSmithKline AG, Munich, Germany] was administered for 5 days postoperatively. Three days after the operation, all patients were mobilized and the donor leg was loaded to the pain threshold.

Dental implants were placed after the fibula had healed completely with no complication. In patients who underwent reconstruction after tumor surgery, implants were placed after a postoperative period of about 1 year without tumor recurrence. All dental implants were placed under general anesthesia with complete exposition of the bone to ensure precise placement. Different implant systems were used in this study: titanium implants without surface modification of the Brånemark Implant system®, TiUnite implants® (Nobel Biocare, Management AG, Kloten, Switzerland) and NEOSS implants (NEOSS, Cologne, Germany) with bimodal surface. Because the focus of this manuscript lies on patient specific risk factors, this variable was specifically not included in the statistical analysis and will be focus of a separate analysis. After a 6-month submerged period of osseointegration, the implants were loaded and prosthetic rehabilitation was performed. All patients received a fixed implant-supported prosthesis as a superstructure.

In patients with osteomyocutaneous flaps or additional soft tissue flaps, different minimal invasive surgical interventions for soft-tissue management have been performed simultaneously to implant insertion and abutment connection, as for example laser-debridement or surgical reduction of volume of those flaps.

RESULTS

The study sample consisted of 33 patients (17 men, 16 women; mean age at surgery: 52.4 years, range: 20–69 years) who received a total of 35 fibula flaps. One female patient and one male patient received two fibula flaps. Eleven patients died before the end of the observation period due to recurrence and concomitant systemic diseases. The median follow-up time was 67 months. The descriptive data of all patients are shown in Table 1.

Fibula Flap

The right leg was the donor site for 80% (n28) of the 35 fibula flaps, and the left leg was the donor site in 20% (n7) of the procedures. With respect to the defect, the ipsilateral fibula was used in 18 cases and the contralateral fibula in 12. The anterior mandible was reconstructed in three patients and no resection was performed in two patients with atrophic mandibles.

Implants

In total, 140 implants were placed in 23 of 33 (70%) patients. On average, the dental implants were inserted 17 months (range: 4–48 months) after reconstruction. Ten of the 33 patients received no implant. Of these, five died before implant insertion took place, and five lived in remote locations or foreign countries and attended the hospital only to receive mandibular reconstruction. Further dental rehabilitation was administered in their places of residence.

In total, 27 (19%) implants in eight patients were lost. Analyses of implant loss showed that five implants failed because of osteoradionecrosis of the fibula flap

TABLE 1 Descriptive Statistics for All Patients ($n = 33$) Who Underwent Mandibular Reconstruction with Microsurgical Revascularized Fibula Flaps ($n = 35$)

Patients ($n = 33$)	
General variables	
Gender (male; n, %)	17 (52)
Mean age (years)	52
Range (years)	19–68
Indication for reconstruction (n, %)	
Squamous cell carcinoma	10 (30)
Osteosarcoma	1 (3)
Malignant peripheral neural tumor	1 (3)
Osteoradionecrosis	14 (42)
Ameloblastoma	1 (3)
Osteomyelitis	2 (6)
Facial trauma	2 (6)
Mandibular atrophy	2 (6)
Risk factors (n, %)	
Smoking	25 (76)
Alcohol use	16 (42)
HIV	1 (3)
Drug abuse	1 (3)
Irradiation	24 (73)
Irradiation of the grafted fibula	3 (9)
Implant insertion performed ($n = 1$; n, %)	23 (70)
Fibula flaps ($n = 35$; n, %)	
Primary procedure	18 (51)
Secondary after titanium plate	9 (26)
Second choice*	8 (23)
Osteomyocutaneous flap	14 (40)
Additional soft-tissue flaps	7 (20)
Pectoralis	3
Radial forearm	2
Temporalis	1
Deltopectoral flap	1

*"Second choice" is defined as a second flap after failure of a free bone graft.

after irradiation, and 17 failed due to the lack of primary stability at the time of planned implant loading, about 6 months after insertion. One implant screw fractured in one patient, and four implants were lost in another patient due to pathological fracture of the remaining mandible. (Table 3) Five patients with additional 13 implants died during the observation period due to underlying progressive squamous cell carcinoma. At the end of the observation period, 100 of 140 implants in 18 living patients had been successfully inserted and used for integration into the superstructure (Figure 1). The results of an overall Kaplan–Meier survival analysis are shown in Figure 2; the overall survival rate was 93.6% after 1 year (128 remaining cases) and 83.3% after 5 years (80 remaining cases). Table 2 shows descriptive data of all placed implants.

Implant Success and Risk Factors

Of the 23 patients who received dental implants, 78% were smokers, 52% drank alcohol regularly, and 83% underwent irradiation therapy. According to irradiation, four different groups of bone were present as an implant bed: group 1, irradiated grafted bone (fibula); group 2, irradiated mandibular bone; group 3, non-irradiated grafted bone (fibula); and group 4, non-irradiated mandibular bone. The 5-year success rate of dental implants in irradiated mandibular bone was 82%, and that of implants in irradiated grafted bone was 38%. The 5-year implant success rates in non-irradiated mandibular bone and non-irradiated grafted bone were both 86%.

TABLE 2 Descriptive Statistics and Information of All Implants ($n = 140$) Placed in 23 (70%) of Patients

Implants ($n = 140$; n, %)	
Number of Patients with Implants ($n = 23$, 70)	
Implant location (n; %)	
Irradiated grafted fibula	13 (9)
Irradiated mandibula	34 (25)
Non-irradiated fibula	86 (61)
Non-irradiated mandibular bone	7 (5)
Indication (n; %)	
Malignant tumor	47 (34)
Osteoradionecrosis	61 (44)
Ameloblastoma	11 (8)
Osteomyelitis	0
Facial trauma	17 (12)
Mandibular atrophy	4 (3)
Risk factors (n; %)	
Smoking	104 (74)
Alcohol	85 (61)
HIV	11 (8)
Drug abuse	10 (7)
Implant loss (n; %)	27 (19)
Osteoradionecrosis grafted bone	5 (4)
Lack of primary stability	17 (12)
Mandibular fracture	4 (3)
Implant screw fracture	1 (1)

TABLE 3 Number of Failed Implants in Context to the Reason of Failure and Localization of Implants

	Irradiated Grafted Bone	Irradiated Mandible	Non-Irradiated Grafted Bone	Non-Irradiated Grafted Mandible
N of placed implants	13	34	86	7
Lack of primary stability	3	4	9	1
Osteoradionecrosis grafted bone	5			
Mandibular fracture		1	3	
Implant screw fracture		1		
N failure (%)	**62**	**18**	**14**	**14**

The Cox regression model with shared frailty for these four groups is shown in Figure 3.

Irradiation of the inserted fibula flap was significantly associated with implant failure ($p = .004$). The hazard ratio and 95% confidence interval for localization in correlation with irradiation were 6.5 and 1.8–2.3, respectively. Irradiation after reconstruction was performed within 6 months in all cases. One male patient and one female patient had radiotherapy 2 months after reconstruction of the mandible and one male patient had radiotherapy 4 months after reconstruction of the mandible.

All other evaluated predictor variables showed no significant association with implant failure.

DISCUSSION

Several treatment strategies for mandibular reconstruction with excellent survival rates and impressive functional and aesthetic outcomes have been reported.[19,22] In a 10-year follow-up study, Hidalgo and Pusic[23] concluded that mandibular reconstruction with microsurgical revascularized fibula flaps was a functional and aesthetically durable method. Factors relevant for success of free flaps are well studied.[24,25] However,

Figure 1 Example of dental rehabilitation with a fixed superstructure in a patient with a previously inserted fibula flap for reconstruction after resection of a squamous cell carcinoma and adjuvant irradiation therapy. (A) After insertion of the microvascularized osseomyocutaneous fibula graft. (B) After osseointegration of screw-retained dental implants. (C) After insertion of the fixed superstructure.

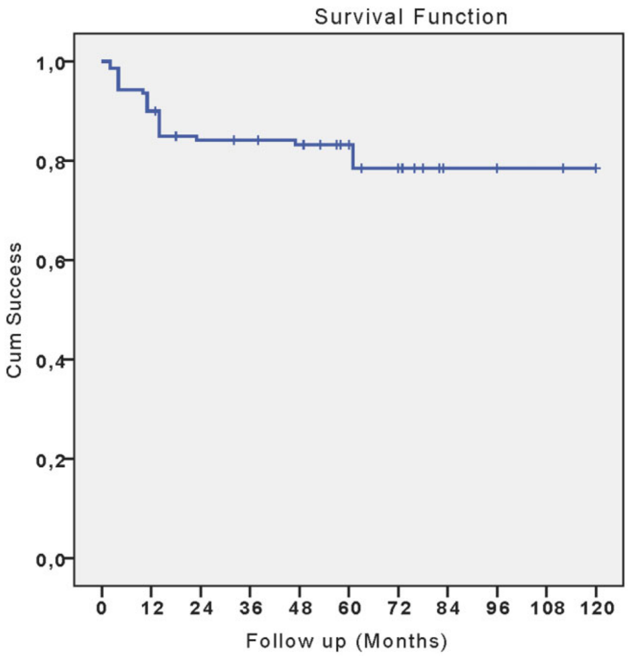

Figure 2 Kaplan–Meier analysis of overall implant survival after 1 year (93.6%) and 5 years (83.3%).

prosthetic reconstruction in patients with fibula grafts remains challenging, although several studies have reported good functional and aesthetic results with the use of implants for dental rehabilitation. In the present study, 70% of all patients who underwent mandibular reconstruction with a fibula flap subsequently received dental implants for dental rehabilitation, regardless of anamnestic or local risk factors such as smoking, alcohol use, or irradiation. Ten patients received no implant because they did not live near the hospital or they died before implant placement took place. Thus, all patients except those with logistical issues or tumor progression received screw-retained implants for dental rehabilitation. The overall survival rate of the inserted implants after 5 years was 83%.

Insufficient bone height, poor overlying and often concomitantly irradiated soft tissue with xerostomia, and the lack of a vacuum effect for prosthesis fixation are only some of the many challenges faced by specialists in maxillofacial prosthetics when treating this patient group.[7,26] Hence, the local situation differs markedly from that of healthy patients who have undergone mandibular reconstruction. Irradiation further

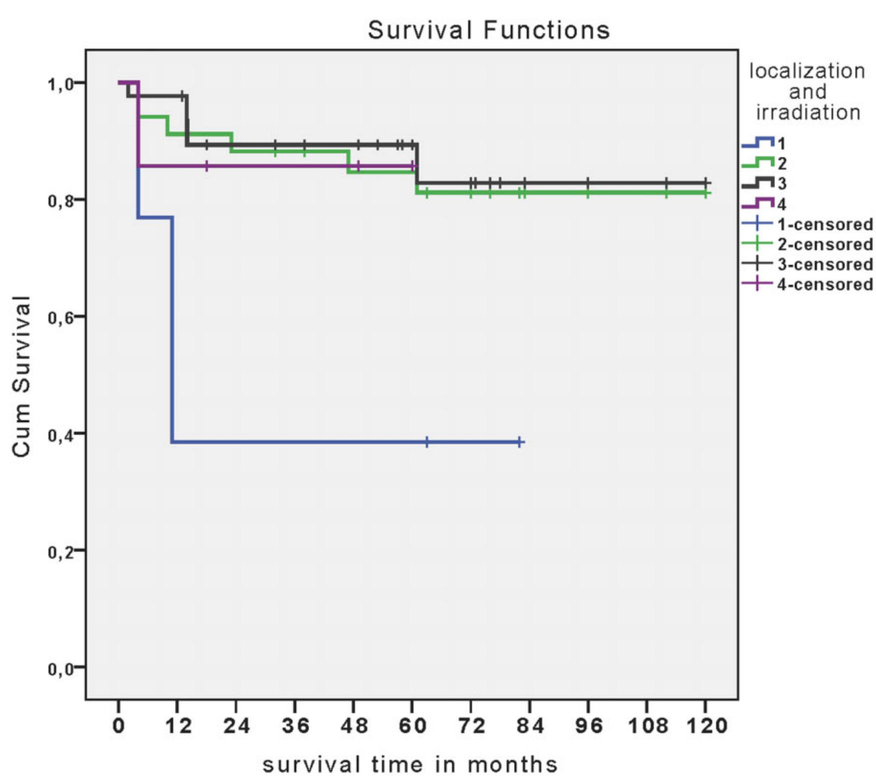

Figure 3 Survival analysis according to four different groups of bone used as an implant bed: group 1, irradiated grafted bone (fibula); group 2, irradiated mandibular bone; group 3, non-irradiated grafted bone (fibula); and group 4, non-irradiated mandibular bone.

compromises the load-bearing capacity of native and reconstructed tissue, and tongue control is often limited in such patients due to the previous resection.[27] Therefore, many centers have established strict inclusion criteria for the placement of intraosseous dental implants in these patients (e.g., Chiapasco et al.[19]). Proposed inclusion criteria include good prognosis after tumor resection, good oral hygiene, absence of periodontal disease, and patient request, whereas alcohol abuse, smoking, and noncompliance have been proposed as exclusion criteria.[4,20,23] After reconstruction with a vascularized bone graft, sometimes in combination with additional soft-tissue flaps, the maintenance of oral hygiene is difficult for most patients. Additionally, the majority of such patients are older than 50 years of age and have reduced manual ability. Chiapasco et al.[19] found that only 27% of 59 patients who underwent reconstruction with a free fibula flap received dental implants (93% success rate) due to the application of inclusion criteria, and 40 of the 59 patients received no dental rehabilitation. Similarly, Raoul et al.[20] reported that only 15% ($n = 30$) of 198 patients received dental implants (96% success rate) due to strict inclusion criteria.

Kramer et al.[8] compared the implant success rate in patients ($n = 16$) with a previously inserted fibula free graft with that in a control group of 16 healthy patients. The application of their inclusion criteria for dental implant placement (no tumor relapse, favorable maxillomandibular relationship) resulted in the placement of 51 dental implants into fibular bone and an implant success rate of 96%, similar to that in healthy patients. However, maintaining strict inclusion criteria is difficult, and their application often means that only a minority of reconstructed patients will receive adequate contemporary dental rehabilitation. In the present study, the majority of patients were smokers, and about half of them consumed alcohol regularly. Furthermore, most patients also underwent irradiation therapy. Only two (6%) of the patients in our sample would have received implant rehabilitation if we applied the previously mentioned criteria. Using a single inclusion criterion (absence of tumor recurrence), we achieved an overall success rate of 83% of dental implants placed in 70% of patients who were alive after a mean follow-up period of 3 years. This favorable outcome contributed to a high psychosocial and functional quality of life for these patients.[3] We achieved success rates of 83% in smokers and 81% in patients who consumed alcohol. The surgeon should consider the selection of criteria that facilitate decision-making about whether to insert a dental implant, use an alternative prosthetic, or avoid prosthetic treatment. In the authors' experience, trying to achieve the goals of full functionality, perfect aesthetics, and absence of peri-implantitis is simply unrealistic in this group of patients, although these objectives can be achieved in healthy patients. Instead, quality of life and psychosocial comfort must be prioritized. Similarly, improved oral hygiene is impossible to obtain in this patient group, due to the use of intraoral soft-tissue flaps and the reduction of mouth-opening ability.

Irradiation is another controversial local risk factor for implant failure in these patients. Some studies have excluded patients who have undergone irradiation therapy prior to dental implant placement, citing previous studies that have reported decreased implant success rates in such patients.[28,29] Note that the implant failure rate was higher in implants placed after a longer period of time following irradiation.[29] Other studies, however, have found no significant difference in the survival rates of dental implants in irradiated and non-irradiated bone. Gbara et al.[30] recently reported a 96% 10-year survival rate for dental implants in a sample of 30 patients, the majority of whom had undergone irradiation before implant placement. Bolind et al.[28] examined cadavers with a total of 16 intraoral (dental) and six extraoral implants in previously irradiated bone and found no correlation between a high irradiation dose and reduced bone–metal contact or bone in threads. However, they found a correlation between the time since irradiation and the amount of visible bone in threads. Although they were unable to draw a definite conclusion due to the study design and limited sample size, irradiated bone seemed to show a regeneration tendency after surgery. The present study found significantly different success rates for dental implants placed in bone before and after irradiation. The implant survival rate in irradiated mandibular bone was 83%, and those in non-irradiated mandibular bone and non-irradiated grafted bone were both 86%. Implants placed in irradiated grafted bone showed the worst implant survival rate (38%). Thus, dental implant placement in non-irradiated fibular bone in previously irradiated patients appears to be safe, whereas implant insertion in a fibula graft before subsequent irradiation appears to have an unacceptably high failure risk. Similar findings have been described by other authors.[31–33] Yerit et al.[33] presented the outcomes of 316 dental implants placed in 71 patients who had previously undergone irradiation therapy. After an 8-year observation period, the implant survival rate was 72% in irradiated bone, 95% in non-irradiated bone, and 54% in grafted bone. Previous irradiation therapy, even in patients with vascularized grafts, is thus not a contraindication for dental implants. However, as the results of this study show, the irradiation of microvascular reanastomized fibula flaps after dental implant insertion seems to be associated with a high risk of losing previously inserted dental implants and even the bone graft. Therefore, if possible, dental implant insertion should be performed after irradiation therapy has been completed.

No standardized definition of implant success has been established for this group of patients and local situation. Buch et al.[34] discussed the difficulty of standardizing the definition of implant success, even in non-reconstructed, healthy patients. They evaluated 508 inserted implants using five different internationally accepted classifications and obtained different success rates for the same sample: 88% (Albrektsson criteria), 89% (Naert), 88% (Buser), 85% (NIH conference), and 75% (Jahn-d'Hoedt).[35–39] Iizuka et al.[18,40] published a treatment concept for mandibular reconstruction and dental rehabilitation according to different classes of mandibular defects and the number of osteotomies of the inserted fibula graft. Depending on the classification, patients received different types of prosthetic suprastructures. Only 5 of 28 patients received efficient implant-supported, fixed or removable dentures, and 18 patients received no dental rehabilitation. No implant was lost, but only 23 of 37 implants were used to anchor the prostheses. Whereas the implant survival rate was 100%, the effective loading rate was only 85%. In the present study, the overall survival rate of 83% after 5 years was consistent with the overall dental implant success rate because each unloaded implant was considered an implant failure and explanted. Only three basic clinical criteria were used to define the dental implant success rate: the absence of pain, primary stability, and functional loading ability (and thus integration into a prosthetic suprastructure). Primary stability was evaluated manually. Any mobility of the inserted implant was considered to indicate failure, and the implant was removed. The present study was limited by several factors, including the retrospective design and the small sample size, which may explain the lower dental implant success rates we obtained compared with those described in previous studies.[19,20,40] Different implant types might be an additional factor influencing implant success. This variable would have been beyond the scope of this manuscript and should be considered for an additional analysis. However, the limited application of typical inclusion criteria significantly improved the dental rehabilitation outcomes of these patients, demonstrating the feasibility of achieving a better quality of life after dental implant placement, even in high-risk patients after mandibular reconstruction.[3]

CONCLUSION

In conclusion, the placement of implants in patients who have undergone mandibular reconstruction with a microsurgical revascularized fibula flap is associated with acceptable implant success rates. This patient group presents with many restrictions, such as soft-tissue thickness, altered anatomy, reduced oral hygiene, alcohol and tobacco consumption, and often, previous or subsequent irradiation. We achieved reasonable dental implant success rates, even in patients with anamnestic risk factors such as smoking and alcohol use; these factors should not be considered exclusion criteria for rehabilitation with implants. Irradiation, especially the irradiation of grafted bone, seems to be a high-risk factor for implant failure. As in our study, implant success criteria must be adapted situationally to make them more realistic and simpler. Further prospective evaluation of these patients with regard to possible changes in irradiation therapy, surgical reconstruction, implant systems, and implant insertion with computer-guided insertion techniques should be performed to monitor criteria and risk factors for the success and failure of dental rehabilitation in these patients.

CONFLICT OF INTEREST

The authors hereby state that there is no conflict of interest.

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