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Christian Bräuer
Rostock University Medical Center
Michael Dau
Rostock University Medical Center
Bernhard Remschmidt
University Clinic of Dental Medicine and Oral Health, Medical University of Graz
Ralf Wilbrandt
Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology
Jan Matschke
Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology
Adrian Franke
Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology
Henry Leonhardt
Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology
Günter Lauer
Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology
Tom A. Schröder
tom.schroeder@uniklinikum-dresden.de

Faculty of Medicine and University Hospital Carl Gustav Carus, TUD Dresden University of Technology

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Bone Cement-Sheathed Versus Non-Sheathed Reconstruction Plates for Temporary Alloplastic Mandible Reconstruction

Christian Bräuer[1], Michael Dau[1], Bernhard Remschmidt[2], Ralf Wilbrandt[3], Jan Matschke[3], Adrian Franke[3], Henry Leonhardt[3], Günter Lauer[3] and Tom A. Schröder[3, *]

[1]Department of Oral, Maxillofacial and Plastic Surgery, Rostock University Medical Center, Rostock, Germany

[2]Department of Oral and Maxillofacial Surgery, University Clinic of Dental Medicine and Oral Health, Medical University of Graz, Graz, Austria

[3]Department of Oral and Maxillofacial Surgery, Faculty of Medicine and University Hospital Carl Gustav Carus Dresden, Technische Universität Dresden, Fetscherstraße 74, 01307 Dresden, Germany

[*]Corresponding author: tom.schroeder@uniklinikum-dresden.de

Abstract

Background

This study aimed to evaluate and compare implant exposure rates between conventional reconstruction plates and plates sheathed with bone cement in mandibular reconstruction.

Methods

A retrospective study was conducted at a single tertiary care center. All patients who underwent segmental mandibulectomy with either a conventional reconstruction plate or a bone cement-sheathed plate between November 2016 and July 2022 were included. Patients were grouped based on the reconstruction type. Statistical analysis included chi-square or Student's t-tests for categorical and continuous variables, respectively. Fisher's exact test was used for small sample sizes. The Phi coefficient assessed the relationship between myocutaneous flaps and C-segment involvement. A Kaplan-Meier curve and log-rank test compared implant exposure rates between groups.

Results

A total of 62 patients were analyzed, with a mean follow-up of 20.0 months (SD ± 18.3). Implant exposure was significantly less frequent in the bone cement group (P = .047). This effect was particularly pronounced in resections involving the C-segment (P = .036), following tumor surgery (P = .042), and in advanced T3/T4 tumors (P = .039). Myocutaneous flaps were also associated with reduced exposure rates when bone cement was used (P = .019).

Conclusions

Alloplastic mandibular reconstruction carries a notable risk of implant exposure and fracture. A two-stage approach can benefit complex cases by improving soft tissue healing and allowing oncologic reassessment. Bone cement sheathing offers a protective advantage and should be considered in advanced tumors, recurrences, or resections involving the mandibular C-segment to reduce implant exposure risk.

Key Words

salvage therapy, cancer of head and neck, mandibular reconstruction, alloplastic reconstruction, bone cement, osteonecrosis, backscatter effect

Background

Even after successful total surgical removal of oral cavity squamous cell carcinoma (OSCC), local tumor recurrence occurs in about 20% of the cases. Among these cases, 76% of recurrences occur within the first two years after initial treatment, while an additional 11% occur in the third year [1]. Due to its high rate of tumor recurrence and metastatic effect, OSCC is considered one of the most aggressive malignant tumors [2]. OSCC is often diagnosed at an advanced stage, necessitating extensive surgical resections with microvascular reconstruction, often followed by radio- or radiochemotherapy [3], which can significantly impact patients' quality of life [4]. Consequently, in cases of tumor recurrence, patients have typically already experienced radio- or radiochemotherapy, leaving salvage surgery as the only remaining treatment option.

Salvage surgery after previous radiation is connected with a decreased 5-year survival rate of just about 43.4% [5]. Postoperative complications and resulting functional limitations occur in 39–53% of cases, while mortality rates are between 3.2% and 5.2% [5,6]. Despite these challenges, salvage surgery remains a crucial last-line treatment for tumor recurrence. Achieving an R0 resection is similarly challenging in extensive T4 tumors infiltrating adjacent structures or organs. However, the R0 resection is a fundamental prerequisite and the key prognostic factor for successful tumor therapy [7].

Osteoradionecrosis (ORN) of the mandible is another major challenge for reconstructive surgery. In these cases, chronic infection, impaired vascularization, and progressive bone resorption often lead to extensive defects that make immediate reconstruction difficult [8]. A two-stage approach may be advantageous as it allows initial infection control and soft tissue healing before final bone reconstruction. Reducing the risk of postoperative complications

leads to optimized conditions for the subsequent microvascular grafting [9,10]. Furthermore, multimorbid patients in a palliative setting could additionally benefit from this approach, as the operation time is significantly shorter than microvascular bone reconstructions.

Single-stage bone reconstruction with microvascular grafts is considered the gold standard [11,12]. Regarding the aforementioned, the indication for immediate bone reconstruction should be critically assessed in advanced tumor stages, salvage surgery, or ORN. Alloplastic reconstruction of the mandible with reconstruction plates and extensive soft tissue flaps is a suitable option as the first step of a two-stage reconstruction or, in some cases, as a definitive solution [13]. However, progressive tissue shrinkage frequently leads to intraoral or extraoral exposure of the implant over time, leading to consecutive infection of the plate [13]. Moreover, plate fractures may occur, further complicating the clinical course [14]. These factors create an unfavorable foundation for secondary bone reconstruction. We have developed an alternative reconstruction approach to reduce tissue shrinkage and avoid implant exposure. After tumor or necrosis resection with segmental bone defect of the mandible, temporary alloplastic reconstruction using a reconstruction plate sheathed with bone cement (BCP) was performed. The soft tissue defect was covered either by free microvascular or pedicled flap grafts. Definitive reconstruction with a microvascular osseous flap graft was conducted secondarily, following a confirmed R0 resection and a recurrence-free follow-up period of at least 6 months.

This treatment option is also suitable for subtotal mandibulectomies due to medication-related osteonecrosis (MRONJ) of the jaw [15,16]. It should be considered for segmental mandibulectomy due to MRONJ, particularly in elderly, multimorbid patients in a palliative setting. The operation time is significantly shorter compared to microvascular bone reconstructions.

Methods

Study Design

A retrospective analysis of 62 mandibular reconstructions was performed with the approval of the local ethics committee (EK 439102016). The study included all segmental resection of the mandible with a conventional reconstruction plate (CP) or BCP at the Department of Oral

and Maxillofacial Surgery at Dresden University Hospital between November 2016 and July 2022. Two groups were defined based on the type of reconstruction (CP and BCP). No exclusion criteria were applied. All interventions and follow-ups were conducted within the university's facilities, ensuring a standardized setting and comprehensive documentation for the study.

Sample Size

Based on the known complication rates for patients with segmental resection of the mandible and subsequent alloplastic reconstruction – described by Kämmerer et al. [14] – the number of patients needed per group was calculated. Assuming a targeted complication rate of about 1%, an a priori power calculation (type-I error = 0.05 and type-II error = 0.2) suggested a required sample of 25 patients per group.

Intervention Technique

All alloplastic reconstructions were planned preoperatively using a CT scan dataset. The extent of the bony resection was determined, and a custom-made 3.0 mm laser sintered reconstruction plate was ordered utilizing the KLS-Martin IPS-Gate® protocol (Gebrüder Martin GmbH & Co. KG, KLS Martin Group®, Tuttlingen, Germany).

In some cases, a conventional 3.0 mm reconstruction plate (Universal Mandible System, Stryker Leibinger®, Tuttlingen, Germany) was used to shorten the preoperative lead time. In these instances, a customized mandibular model (Phacon GmbH, Leipzig, Germany) was fabricated, and the plate was pre-bent accordingly.



Figure 1: After tumor resection, the reconstruction plate was attached to the mandibular stumps; middle: Then the plate was coated with bone cement in the area of the bony resection; right: Postoperative orthopantomogram.

After tumor or necrosis resection, the reconstruction plate was fixed to the mandibular stumps with 2.7 mm bicortical locking screws with at least three screws on each side (**Error! Reference source not found.**). For sheathing the reconstruction plates, bone cement (Palacos® RV + G bone cement, Heraeus Medical GmbH, Wertheim, Germany) was used in the area of the bony defect. For this purpose, the bone cement was mixed to a kneadable consistency and molded around the reconstruction plate, approximating the dimensions of a fibula graft (**Error! Reference source not found.**). Once the bone cement had fully hardened, the surface was smoothed using a diamond bur, including the transitions to the mandibular stumps. The soft tissue defect resulting from the resection and the alloplastic reconstruction was then adequately covered using a microvascular flap graft. The choice of flap was primarily based on defect size and the available reconstructive options. Due to the diversity of flap grafts, they were grouped into myocutaneous and non-myocutaneous grafts in the analysis. The flaps used in the study included the radial forearm flap, free vertical rectus abdominis muscle (VRAM) flap, latissimus-dorsi flap, pectoralis-major flap, and a few other flaps (Table 1).

Table 1: Baseline characteristics.

	Total (n = 62)	CP (n = 26)	BCP (n = 36)	p-value
sex				
male	52	23	29	
female	10	3	7	0.499
mean age (SD) (years)	61 (10.2)	60 (10.5)	62 (10.0)	0.515
primary disease				
tumor	57	24	33	
ORN	5	2	3	1.000
Radiation				
None	11	4	7	
Pre-OP	21	7	14	
Post-OP	30	15	15	0.459
tumor size				
T1	1	0	1	
T2	0	0	0	
T3	7	5	2	
T4	48	19	29	0.193

ASA				
I	0	0	0	
II	9	5	4	
III	45	20	25	
IV	1	0	1	0.543
Time of surgery (SD) (minutes)	457.1 (152.7)	444.7 (170.1)	466.0 (140.6)	0.591
Length of defect (SD) (cm)	7.7 (1.9)	7.5 (1.7)	7.8 (2.1)	0.519
HCL				
+ C	46	19	27	
- C	16	7	9	0.864
Flap (total number)				
myocutananeous	40	17	23	
non-myocutaneous	18	8	10	0.890
Implant (total number)				
exposure	31			
non-exposure	31	17	14	
		9	22	0.039

RP = reconstruction plate; ORN = osteoradionecrosis; ASA = American Society of Anesthesiologists; HCL = Jewer classification [18]: "C" = defect between the canines.

Outcome Measures

The study's primary aim was to evaluate the incidence of implant exposure between CP and BCP. All cases of oral and extraoral dehiscence were documented and assessed. Follow-up was conducted until the last outpatient presentation or, in case of death, until the date of death.

Additionally, various variables, such as sex, age, primary disease, and so on (see complete list in Table 1), were recorded for further in deep analyses.

All bony defects of the mandible were classified using the Jewer classification HCL system, distinguishing between "H" defects (area between the symphysis and the condyle), "C" defects (central segment between teeth 33 and 43), and "L" defects (area between canine tooth to the base of articular process excluding the condyle) [17,18]. Furthermore, a distinction was made regarding the involvement of the C segment. The length of the bone defect at anterior-posterior alignment was measured after resection.

Statistical Analysis

The retrospective data were acquired from the hospital information system ORBIS® (DH Healthcare GmbH, Version 03.15.02.00, 53227 Bonn, Germany) and the dental database DENTWARE® (DENTWARE Computer GmbH, Version 1.3n, Maisach, Germany). The statistical analysis was performed using SPSS® (IBM SPSS Statistics for Windows, Version 28.0. IBM Corp, Armonk, NY, USA). The significance level was set at $p < 0.05$. The chi-square or Student's t-test was used to analyze categorical or continuous variables. Fisher's exact test was used for samples of less than five variables. Two-sided tests were used in each case. The Phi coefficient was determined to investigate the association between myocutaneous flaps and the involvement of the C segment according to Jewer classification [17,18]. A Kaplan-Meier curve and a log rank-test were performed to investigate the difference in exposed implant material between the cohorts.

Results

The study included 62 patients. The reconstruction method applied (CP or BCP) divided them into two groups. The CP cohort consisted of 26 patients, while the BCP group contained 36 patients. The basic characteristics of both groups (**Error! Reference source not found.**) revealed no differences between the groups and suggested the matching of the analyzed patient cohorts. A significant difference was observed between CP and the BCP (P = .039) regarding implant exposure. Soft tissue reconstruction was achieved by using myocutaneous flaps (VRAM flap (n=21), latissimus-dorsi flap (n=13), pectoralis-major flap (n=6)), non-myocutaneous flaps (radial forearm flap (n=15)) and other flaps (rotation and transposition flaps (2) and a supraclavicular pedicle flap (1)). The implant exposure rates between CP and BCP are shown in **Error! Reference source not found.**.

Table 2: Exposure rate of both operation methods depending on different variables.

	Total			CP		BCP		p value
	non-exposure	exposure	p value	non-exposure	exposure	non-exposure	exposure	
sex								
male	26	26		8	15	18	11	0.051
female	5	5	1.000	1	2	4	3	1.000
mean age (SD) (years)	60.4 (11.1)	61.6 (9.3)	0.657	60.7 (12.3)	69.7 (9.9)	60.3 (10.8)	63.9 (8.3)	ne 0.938

								e
								0.208
primary disease								
tumor	28	29		8	16	20	13	0.042
ORN	3	2	1.000	1	1	2	1	1.000
Radiation								
None	3	8		0	4	3	4	0.236
Pre-OP	11	10		2	5	9	5	0.183
Post-OP	17	13	0.240	7	8	10	5	0.269
tumor size								
T1	0	1		0	0	0	1	
T2	0	0		0	0	0	0	
T3	3	4		2	3	1	1	
T4	24	24	0.585	6	13	18	11	0.039
ASA								
I	0	0		0	0	0	0	
II	6	3		3	2	3	1	
III	22	23		6	14	16	9	
IV	0	1	0.367	0	0	0	1	0.023
Time of surgery (SD) (minutes)	117 (164.4)	454.6 (142.7)	0.897	452.2 (238.4)	440.7 (129.4)	462.2 (130.1)	471.4 (160.7)	ne 0.876
								e 0.561
Length of defect (SD) (cm)	7.4 (1.8)	8.0 (2.0)	0.221	7.0 (1.5)	7.8 (1.9)	7.5 (1.9)	8.3 (2.3)	ne 0.461
								e 0.544
HCL								
+ C	23	23		6	13	17	10	0.036
- C	8	8	1.000	3	4	5	4	1.000
Flap (total number)								
myocutananeous	18	22		4	13	14	9	0.019
non-myocutaneous	12	6	0.127	5	3	7	3	1.000

RP = reconstruction plate; ORN = osteoradionecrosis; ne = non-exposure; e = exposure; ASA = American Society of Anesthesiologists; HCL = Jewer classification [18]: "C" = defect between the canines.

In tumor cases, a lower exposure rate of the reconstruction plates was observed in BCP (P = .042), particularly in the T4 stage (P = .039). Cases with the resections, including the "C" segment (area between the canines according to the Jewer-classification [17,18]), showed significant (P = .036) higher exposure rates when only using a CP. The bone defect classification regarding the mandibular bone segments revealed an unbalanced distribution (L=14, LC=16, LCL=26, H=2, HC=3, and HCL=1) with a higher number of bone defects in the area between the canine teeth to the base of the articular process excluding the condyle. Despite using

myocutaneous flaps, higher exposure rates were observed when CP was used (P = .019). Higher ASA stages (ASA III) were connected with a significantly higher risk of implant exposure (P = .023) if the reconstruction plate was not sheathed with bone cement. Myocutanous flaps showed a higher risk for implant exposure (P = .019) if CP was used. The C segment was involved in 34 of 40 cases (85%) treated with a myocutaneus flap. In non-myocutaneus flaps, the C segment was involved in 50% of cases. Regarding implant exposure using CP and BCP, no associations were found between using a myocutaneous flap and C-segment involvement (**Error! Reference source not found.**).

Table 3: Exposure rate after myocutaneous flaps depending on the C-Segment involvement.

	CP			BCP		
Flap ± C segment	non-exposure	exposure	p value	non-exposure	exposure	p value
myocutaneous +C	4	10	0.290	12	8	0.825
myocutaneous –C	0	3		2	1	

RP = reconstruction plate; "C" = defect between the canines (Jewer classification [18]).

Overall, the cumulative incidence of implant exposure (Figure 2) was significantly lower in BCP group (**Error! Reference source not found.**). The mean follow-up time was about 20.0 (±18.3) months.

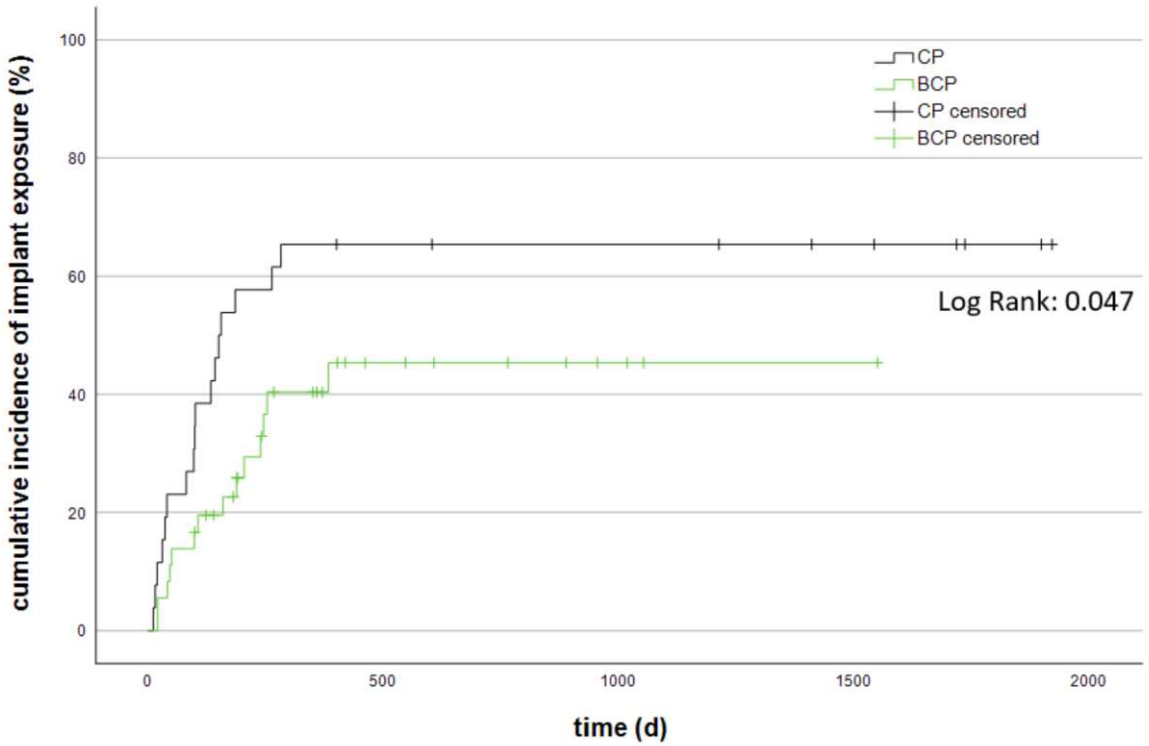


Figure 2: Kaplan-Meier curve showing the cumulative Incidence of implant exposure for conventional reconstruction plate (CP) and reconstruction plate sheathed with bone cement (BCP).

Table 4: Implantat exposure.

	Total (n = 62)	CP (n = 26)	BCP (n = 36)
Implantat exposure	31 (50.0 %)	17 (65.4 %)	14 (38.9 %)
Time to exposure (SD) (days)	125.5 (96.2)	108.1 (82.5)	146.6 (110.0)

Discussion

OSCC is one of the most aggressive malignancies due to its high recurrence rate and metastatic potential. Despite multimodal therapy, including surgical resection and subsequent radio- or radiochemotherapy, local recurrence occurs in around 20% of patients, with most cases recurring within the first two years after treatment [1]. In such cases, salvage surgery is often the only remaining curative option, although it presents significant challenges. The 5-year survival rate following salvage surgery is only 43.4%, and postoperative complications occur in up to 53% of cases, with mortality rates ranging from 3.2% to 5.2% [5,6]. Extensive ORN of the mandible also complicates patient management. ORN is characterized by impaired healing, chronic infection, and progressive bone loss, often resulting in extensive defects and severe functional impairment. Many of the affected patients are elderly or have multiple comorbidities, making them poor candidates for extensive microvascular reconstruction [9,10].

Although the current gold standard for subtotal mandibular resection is a single-stage bone reconstruction using microvascular grafts [11,19], this should be carefully evaluated in advanced tumor stages, salvage surgeries, or patients suffering from ORN. In severe ORN cases, a two-stage approach can be beneficial for initial infection control and optimize soft tissue conditions before definitive bone reconstruction. In cases of extensive tumors and tumor recurrence, it is essential to have a complete histological examination before bone

reconstruction. Thus, a two-stage procedure with primary alloplastic and secondary microvascular osseous reconstruction is becoming increasingly common in clinical practice. After safe R0 resection and recurrence-free follow-up, secondary reconstruction can be planned if the patient is in good general health. However, a major disadvantage of a two-stage procedure using CP remains the intraoral or extraoral plate exposure, which varies from 8 to 92% [13,20–22].

The study aimed to compare two cohorts undergoing mandibular reconstruction using either CP or BCP. The primary objective was to assess the reliability of this method concerning material exposure. Both groups were homogeneous and showed no significant differences in baseline characteristics, allowing proper comparative analysis (Table 1). We observed a reconstruction plate exposure of 31 out of 62 patients over a follow-up time of 20.0 (±18.3) months. These findings demonstrate that sheathing the reconstruction plate with bone cement significantly reduces reconstruction plate exposure from 65.4% to 38.9% (P = .047). The mean time to implant exposure was 125.5 (±96.2) days (**Error! Reference source not found.**), aligning with previous findings that report the highest exposure rates during the first postoperative year [20,23,24]. No plate fractures were observed during the entire study. The soft tissue surrounding the defect area typically contracts around the alloplastic reconstruction, replacing the space previously occupied by bone. The bone cement sheathing of the reconstruction plate intends to counteract this shrinkage procedure and preserve the soft tissue surrounding the bone defect. Regarding facial aesthetics, the external appearance of the patient remains largely unchanged [15,25]. In addition, a larger soft tissue pocket is created, which allows for easier integration of the microvascular bone graft during secondary reconstruction, as the necessary space for the graft has already been obtained [25,26].Once the spacer has healed completely, secondary reconstruction is possible solely via an extraoral approach. If soft tissue is preserved in the defect area, it may be possible to entirely dispense with soft tissue grafting in addition to bone grafting [27].

Remodelling the resected jaw area with bone cement preserves the original three-dimensional shape of the jaw, counteracts tissue shrinkage, and helps maintain facial aesthetics. The bone cement used in the presented study is a biologically inert alloplastic material based on polymethyl methacrylate (PMMA), which has been used for over 40 years

with outstanding long-term results in orthopedic endoprosthetics and neurosurgical cranioplasties, among others [28,29]. PMMA bone cement is well tolerated by bone and soft tissue, allowing the overlying intraoral mucosa, soft tissue, and skin to heal undisturbed. Additionally, a fibrous capsule forms around the inserted BCP, contributing to its biocompatibility [25,30,31]. Another advantage of the proposed two-stage reconstruction approach is its potential to reduce the backscatter effect on the soft tissue coverage of the plate during radiation. Sakamoto et al. showed that the maximum backscattered radiation dose occurs right on the surface of titanium plates [32]. The bone cement sheathing will protect the surrounding soft tissue, creating a gap and keeping the soft tissue out of the high-dose radiation zone, potentially reducing radiation-induced complications. This protective effect should be considered, particularly in patients requiring adjuvant radiotherapy. Even though we could not observe any influence of adjuvant radiotherapy on the exposure rates, we saw a tendency whereby only 5 of 15 patients with BCP showed a plate exposure (**Error! Reference source not found.**).

According to Jewer [17,18], the affection of the C-segment is associated with higher implant exposure rates and is primarily attributed to torsional forces resulting from concentrated muscular tension and the creation of a dead space [14,20,33]. The findings of the presented study demonstrate, that in cases with bone defects within the C-segment, the use of bone cement sheathing significantly reduced implant exposure ($P = .023$).

Significantly lower numbers of exposed BCP implants ($P = .019$) were observed using myocutaneous flap grafts. This effect was not found in non-myocutaneous flaps, which may be associated with the smaller sample size, as a trend toward reduced implant exposure was seen in only 3 out of 10 cases. In the context of C-segment involvement and the type of flap grafts used, it is important to note that analyses revealed no correlation and, therefore, be seen as individual predictive parameters (**Error! Reference source not found.**). The soft tissue wear caused by reconstruction plates may play an important role, which was already addressed in a preliminary study [34]. Further investigations should focus on the biomechanical properties of a suitable test bench [35].

Looking at the cases with bone resection based on tumor – particularly advanced tumor stages (T3 vs T4) – a lower rate of implant exposure was found in the BCP group. As soft tissue in advanced tumor stages is known to be more vulnerable, soft tissue covering of the BCP might benefit from the gentamycin contained in Palacos®. The number of plate exposures was lower for higher ASA stages (ASA III vs ASA II) (P = .023) using BCP. These results are expected, as relevant considerable comorbidities, such as poorly managed diabetes, coronary heart disease, and COPD, are included in ASA III [36]. These comorbidities will presumably have a primary negative impact on wound healing in general, and the use of bone cement sheathing may help based on the considerations mentioned above.

The single-center retrospective design of the conducted study limits the generalizability of the presented results, as surgical protocols and patient care may differ in various clinics. In addition, variations in reconstructive techniques, particularly flap choice, might influence implant exposure rates regardless of reconstruction method and, therefore, require a separate research focus on this topic. While the follow-up period is adequate to assess early complications, it is not enough to evaluate long-term outcomes. Further research is needed to validate the observed benefits of bone cement resurfacing, especially in larger, multicentre studies with a more extended follow-up period.

Conclusions

A temporary alloplastic reconstruction after subtotal mandibulectomy with alloplastic material still leads to exposed implant material in most cases. We showed that using bone cement sheathing as a novel approach leads to an overall reduction in implant exposure rates. Furthermore, an extended complication-free period was observed even in cases where reconstruction plate exposure was observed, providing a larger complication-free time window for planning and performing the secondary bony reconstruction and, thus, more convalescence for the patient and a longer tumor-free interval before the definitive reconstruction. The surgical approach presented here could offer a definitive solution while preserving facial aesthetics in patients with extensive ORN and multiple comorbidities. Notably, implant exposure was also observed less frequently in cases involving the C-segment, which is typically associated with a high risk of implant exposure. With additional supportive effects on myocutaneous flaps, we assume a reduced soft tissue stress due to the increased

surface area. Furthermore, bone cement sheathing facilitates secondary reconstruction by preserving the anatomical dimensions.

Declarations

Ethics approval and consent to participate: This study was approved by the local Ethics Committee (Reference No. EK-439102016), Department of Oral Maxillofacial Surgery, University Hospital Carl Gustav Carus, Technische Universität Dresden, Germany. Consent to Participate declarations: not applicable. This study is in accordance with the Declaration of Helsinki.

Consent for publication: All participants agreed to publication

Availability of data and materials: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to ethical restrictions.

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Author contributions:

C.B. Conceptualization, Data curation, Investigation, Methodology, Validation, Writing – original draft

M.D. Data curation, Formal analysis, Validation, Writing – review & editing

B.R. Conceptualization, Methodology, Validation, Writing – original draft

R.W. Data curation, Validation, Writing – review & editing

J.M. Data curation, Validation, Writing – review & editing

A.F. Data curation, Validation, Writing – review & editing

H.L. Validation, Writing – review & editing

G.L. Conceptualization, Project administration, Writing – review & editing

T.A.S. Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Validation, Writing – original draft

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