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A reconstruction plating system with a new angle-stable locking mechanism for mandibular reconstruction using vascularized fibula bone grafts

Inaugural-Dissertation zur Erlangung der Doktorwürde der Zahnmedizin
der Medizinischen Fakultät der Universität Bern

vorgelegt von

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Beckenried (NW)

Von der Medizinischen Fakultät der Universität Bern auf Antrag der

Dissertationskommission als Dissertation genehmigt.

Promotionsdatum:

……..

Der Dekan der Medizinischen Fakultät:

……..

Meinen Eltern gewidmet.

INHALTSVERZEICHNIS

1. FRAGESTELLUNGEN ZUR STUDIE

Die vorliegende Arbeit soll Aufschluss über folgende Fragestellungen geben:

A Wie häufig treten bei Unterkieferrekonstruktionen mit dem neuen Smartlock®-Plattensystem plattenassoziierte Komplikationen auf?

B Welcher Art sind die aufgetretenen Komplikationen?

C Bei welcher Profilhöhe der neuen Smartlock®-Plattensysteme treten häufiger plattenassoziierte Komplikationen auf?

D Bei welcher Defektart (nach Boyd) treten in Verbindung mit dem Smartlock®-Plattensystem die meisten Komplikationen auf?

E Wie steht das Smartlock®-Plattensystem im Vergleich mit anderen Plattensystemen? Gibt es mehr oder weniger Komplikationen?

F Ist es sinnvoll, alle Unterkieferrekonstruktionen mit dem Smartlock®-Plattensystem durchzuführen?

Um diese Fragen zu beantworten, führten wir anhand von Patienten, welche auf der Klinik für Schädel-Kiefer-Gesichtschirurgie des Inselspitals in Bern Unterkieferrekonstruktionen erhielten, diese retrospektive Studie durch. Insbesondere, Häufigkeit sowie Typ und Charakteristik der jeweiligen Komplikationen wurden dabei detailliert analysiert. Unseres Wissens ist diese Studie die erste dieser Art.

2. ABSTRACT

Purpose: The aim of the study was to investigate the clinical applicability and performance of a new angle-stable reconstruction plate in association with grafting of mandibular defects with osteocutaneous fibular free flaps. In this plating system, threads on the screw head lock into the lip of the plate hole, causing a cold welding of metal (titanium) at the contact surface when screws are tightened.

Materials and Methods: Data were analyzed for 28 patients (20 males and 8 females; mean age 56.8 years) who had undergone mandibular reconstruction with osteocutaneous fibular free flaps and fixation with the angle-stable plating system. The plates used in this series were 1.5 mm (22 cases) and 2.8 mm (6 cases) thick. Postoperative complications were recorded over a mean follow-up time of 30 months (range 7–50 months) and were classified as major (plate exposure, plate fracture, non-union, bone loss) or minor (loosening of solitary screws, superficial infection).

Results: The total plate-related complication rate was 25%, with 66.7% for 2.8 mm plates and 13.6% for 1.5 mm plates. The major complications were predominantly seen in association with 2.8 mm plates. The most significant explanatory factor for complications was extensive angle-to-angle resection.

Conclusion: The locking mechanism described here and the low-profiled plate with a thickness of 1.5mm, are sufficient for primary mandibular reconstruction using fibular free flaps. Despite the gracile dimensions of the plate, bulging of hardware after postoperative radiation therapy and subsequent inconvenience for the patient cannot be totally avoided, however.

3. INTRODUCTION

Fixed-angle (or “angle-stable”) osteosynthetic systems are characterized by mechanical locking of the screw to the plate. The THORP (Titanium Hollow Screw Reconstruction Plate), introduced in 1984, was the first plating system with such a locking mechanism developed for mandibular reconstruction ([1], [2]). Before introduction of the THORP, surgeons using conventional reconstruction plates were frequently confronted with stability problems such as screw and plate loosening, leading to infection. With conventional plates, stability is based on compression pressure between the plate and the underlying bone, caused by tightening of the screws ([3], [4]). In irradiated patients in particular, the pressure from the plate may cause resorption of the underlying bone, leading to a subsequent decrease in stability over time ([1]).

Several aspects of the THORP system were totally new: 1) use of titanium as the implant material, 2) insertion of screws to achieve direct anchorage to the bone, as with dental implants, and 3) rigid fixation between the screw head and the bridging plate by means of expansion bolts which press the cylinder-shaped screw head to the inner surface of the screw hole. With THORP, screws are directly anchored to the bone and also rigidly attached to the bridging plate, ensuring transmission of loads by the plating system across a defect ([2]). This system combines the benefits of an external fixation device with those of an internal osteosynthesis appliance. Stable fixation is possible even when the plate is not precisely adapted to the underlying bone. For stable fixation, the THORP system requires only two screws on each side of the mandibular defect. Due to these benefits the THORP system found increasing acceptance.

Through the 1990’s, microvascular free flap techniques provided new options for mandibular continuity defect reconstructions. Accordingly, dimensions and designs of reconstruction plates changed, and plate thicknesses and screw diameters were generally reduced. During the last decade, particular attention was paid to the locking mechanism between the screw head and the

plate. Different types of locking systems were developed ([5], [6], [7], [8]). However, all systems allowed screws to be placed in only one fixed position (90-degree fixation) in the plate.

The latest development is a locking system (Smartlock®, Universal Mandibular Reconstruction System, Stryker-Leibinger, Freiburg, Germany) in which the threads on the screw head lock into the lip of the plate hole. In this system, deformation of metal (titanium) occurs at the contact surface when screws are tightened, resulting in a rigid connection between two metallic parts (screw and plate) through so-called cold welding. This system provides the flexibility to insert and lock screws at variable angles in the range of 90°±10°.

The aim of this study was to investigate the clinical applicability and performance of the Smartlock® system in association with mandibular reconstruction with osteocutaneous fibula free flaps. Attention was paid to complication rates, types and reasons.

4. MATERIAL AND METHODS

The material of the present study consisted of files and radiographs of patients who had undergone mandibular reconstruction using the Universal Mandibular Reconstruction System with the Smartlock locking mechanism at the Department of Cranio-Maxillofacial Surgery, University Hospital of Berne, Switzerland, during a 4-year period between January 1, 2002, and December 31, 2005. Additional inclusion criteria with regard to surgery were mandibular segmental resection and reconstruction with osteocutaneous fibula free flap. A total of 30 patients met the inclusion criteria of mandibular segmental resection, fibula osteocutaneous free flap reconstruction and fixation with the Smartlock® system during the defined study period. Two of these patients, however, were excluded from the study because the plating system together with fibula grafts had to be removed due to flap failure at the immediate postoperative stage. Data for analysis were therefore available for 28 patients (93.3%). Of these patients, 20 were males (71%) and 8 were females (29%). Their age ranged from 29 to 80 years, with a mean of 56.8 +/- 8.63 years.

The Universal Mandibular Reconstruction System (Stryker-Leibinger, Freiburg, Germany) used in this study includes different plates and self-tapping screws made of titanium. The mandibular reconstruction plates are available in two thicknesses: 1.5 mm and 2.8 mm (Fig. 1**)**. The low-profile reconstruction plate can be used for mandibular reconstruction with vascularized bone grafts, whereas the 2.8 mm plate can be used with bone grafts or, alternatively, as a bridging plate. There are straight plates for reconstruction of the mandibular body and plates with additional curved shapes to restore the angle.

Locking screws are available with three different diameters: 2.0 mm, 2.3 mm and 2.7 mm (Fig. 2). All of these can be used with either plate, because the heads of the screws are of the same size. Locking screws have fine threads on the underside of the screw head that engage a circular lip in the plate hole during insertion (Smartlock®). This design allows the screw to be inserted at a variety of angles ranging over 10 degrees while still maintaining the locking mechanism (Fig. 3).

For our study, with the aid of the pre-bent template, the proper type of plate was chosen intraoperatively for each case, and bent to the appropriate shape. The plate was placed along the mandibular stumps, and fixed bicortically using 3 locking screws at each residual mandibular segment. The fibular bone was then osteotomized and shaped as required, and finally fixed to the plate monocortically using screws with the locking mechanism.

A database was created for the 28 cases to help characterize the patients and the types of mandibular reconstruction. Medical information on patients' general health and indications for mandibular resection was collected from the patients' charts. With regard to patients' history, specific attention was paid to factors that might be associated with an increased risk of problems with wound healing. Whether radiation or chemotherapy had been administered was also recorded.

From the operation files, plate profiles (1.5 mm or 2.8 mm) (Fig. 1), plate shapes (straight or pre-shaped), and the size and type of screws that had been used were recorded. The extent of soft tissue and mandibular resection was also identified. Mandibular resections were classified according to Boyd et al., based on postoperative radiographs ([9]). In this classification, H defects are lateral defects of any length, including the condyle but not significantly crossing the midline. L defects are the same but do not include the condyle. C defects consist of the entire central segment, containing the four incisors and the two canines. In addition, combinations of the letters are possible; for instance, an angle-to-angle defect is represented as LCL.

Complications observed up to June 30th, 2006, were registered, with follow-up an average of 30 months (range 7–50 months) after surgery. Postoperative complications were classified as plate-related or non-plate-related. Non-plate-related complications were those that had no relation to hardware or free flap whatsoever. Plate-related complications were further categorized as minor or major. The major complications included plate fracture, plate exposure, and non-union, which can

lead to failure of mandibular reconstruction. Factors explaining plate-related complications were also sought. Clinical data were finally compared with the occurrence of the complications.

5. RESULTS

Twenty-one patients (75%) were smokers, and 12 (42.8%) had a history of alcohol abuse. Twenty-two patients (78.6%) had at least one further medical problem related to their general health. Indications for mandibular resection were neoplasm in 15 patients (53.6%), severe osteoradionecrosis (ORN) in 12 (42.9%) and chronic, suppurative osteomyelitis secondary to trauma in 1 (3.6%). Of the 15 patients with neoplasm, 14 had squamous cell carcinoma (SCC) and 1 had a neuroblastoma infiltrating the mandible. A total of 26 patients (92.9%) had radiation therapy to the mandible at some stage, previous to reconstruction in the 12 patients treated for ORN and postoperatively in the 14 patients treated for SCC.

Resections were performed most commonly in the body and anterior part of the mandible. Table 1 shows the location and size of mandibular resections in the 28 patients. The most common defect was an LCL one (angle-to-angle), reconstructed in 15 patients (53.6%). The size of the bony defect ranged from a minimum of 5 cm to a maximum of 16 cm (mean 10 cm). In total, 23 patients (82.1%) required at least one osteotomy of the fibula, as shown in Table 1. Sixteen patients (57.1%) had combined intraoral and extraoral soft tissue defects. In 11 patients (39.3%), the soft tissue defect was located exclusively in the oral cavity. Only one patient (3.6%) had no soft tissue deficiency at all after resection.

Straight plates were used in 16 cases (57.1%), plates with one pre-shaped angle in 10 (35.7%), and plates with two pre-shaped angles in 2 (7.1%). In 22 patients (78.6%), the low-profile plate (1.5 mm) was chosen, whereas the 2.8 mm plate was used in the rest. The choice of plate profile depended on personal preference. In one case, however, a 2.8 mm plate was chosen because of an additional need for temporomandibular joint reconstruction with prosthesis. In the mandibular residual segments, 2.3 mm screws were used bicortically. Fixation of the plate to the fibula was performed monocortically with 2.0 mm screws.

Postoperatively, non-plate-related complications were observed in two patients (7.1%). Both had prolonged wound healing at the site of the neck incision, but without plate or bone exposure. Both patients healed well under local treatment without further problematic events.

Plate-related complications were observed in 7 patients, with an overall plate-related complication rate of 25%. Major complications were seen in 4 patients (14.3%) and minor in 3 (10.7%), as shown in Table 2. In two of the 4 patients with major plate-related complications, plate exposure occurred during postoperative radiation therapy. In one of these, successful treatment was achieved with the aid of a rotation skin flap. The other patient had partial bone loss and, finally, non-union, which was treated with debridement and re-osteosynthesis. The third patient with a major complication had non-union that was observed radiologically without any related clinical symptoms or signs. This patient was also treated successfully with debridement and re-osteosynthesis. In the fourth patient with a major complication, plate fracture was observed in the late postoperative course, but after bony union. This plate was removed and no further problems occurred.

All 3 patients with minor plate-related complications needed a secondary surgical procedure (Table 2). In one of these, soft tissue swelling with slight signs of infection occurred without any signs of plate or screw loosening or bony non-union. After primary antibiotic therapy, osteosynthesis material was removed. In two patients, loosening of solitary screws was observed radiologically, but without any influence on clinical course or plate stability. The screws were removed but the plate was left in place. In one of the two cases mentioned, the screw had been inserted close (3 mm) to the osteotomy gap.

The relationship between plate-related complications and type of bony defect is shown in Table 2. Complications were observed solely in association with LCL and L defects. The total complication rate was 26.6% (4 of 15 patients) for LCL defects and 42.9% (3 of 7 patients) for L defects. Complications associated with LCL defects were major in most cases (3 of 4

complications; 75%), whereas those associated with L defects were mainly minor (2 of 3 complications; 66.7%).

The relationship between plate-related complications and plate profile is also shown in Table 2. Complications were far more frequent and more serious in patients in whom 2.8 mm plates were inserted compared to those with 1.5 mm plates. Of the 6 patients with 2.8 mm plates, 4 (66.7%) had complications. Of these, 3 (75%) were major complications. The complication rate for patients with 1.5 mm plates was 13.6% (3 of 22 patients). All these complications were minor ones.

In addition to actual complications, 4 patients (14.3% of the total) who had undergone treatment for malignancy experienced the inconvenience of bulging hardware in the chin region because of the atrophying effect of postoperative radiation therapy. All these patients had had reconstruction of LCL defects with 1.5 mm plates (Fig. 4). To avoid possible long-term exposure, all these plates were electively removed after bony union had occurred.

6. DISCUSSION

The aim of the present study was to evaluate clinical applicability of the reconstruction plating system by identifying rates and types of complications, as there has been no comparable clinical report on this particular plating system up to date. Our patients comprised 93.3% of the consecutive cases from a defined 4-year period, and can therefore be considered representative enough for this aim. The total number of patients with 1.5 mm plates inserted—22—can also be considered sufficient for analysis. Moreover, complication parameters were easily and reliably identified from patient records and follow-up radiographs because all postoperative examinations were performed according to standardized clinical and radiological follow-up protocol in our department. Therefore underestimation of complication rates is not likely to have occurred.

There are several options for reconstruction of segmental mandibular defects. Bridging the defect with a reconstruction plate alone or with simultaneous soft tissue coverage (either with local myocutaneous flaps or with soft tissue free flaps) has a high complication rate, particularly with regard to plate exposure ([10], [11], [12]). In addition, prosthetic rehabilitation with implant placement is not possible with these methods. Our analysis focused on a homogenous sample of patients who all had had the treatment of choice for extensive mandibular defects: bony reconstruction with osteo-cutaneous vascularized fibula. The fibular flap is now widely accepted for extensive mandibular reconstruction, presenting a high osseous survival rate of between 85% and 98% ([13], [14], [15]). Our overall flap survival rate (93.3%) lies within this range.

Rigid reconstruction plates have been advocated in association with osseous free flap reconstruction of the mandible, because their use enables rapid resumption of oral function, avoiding intermaxillary fixation and maintaining occlusion. It has also been stated that rigid fixation reduces the occurrence of postoperative infections and other soft tissue complications ([16], [17], [18]). On the other hand, the semi-rigid miniplates have been preferred because of their malleable nature, which allows precise graft contouring and contributes to a “superior aesthetic result” ([19]).

Interestingly, however, overall complication rates for semi-rigid miniplates and 2.4 mm reconstruction plates have not differed significantly, at 22.2%–25% ([19], [20]) and 22.2%–30% ([21], [20]), respectively. Rigid reconstruction plates have become slimmer and more malleable over the years, and so-called low-profiled reconstruction pates have been introduced into clinical use recently. The complication rate for such low-profiled (2.0 mm) locking plates has been reported to be between 4.7% and 14.5% ([22], [21]), which is markedly lower than those of both original rigid plates and semi-rigid miniplates. Our complication rate for the low-profiled 1.5 mm locking plate was 13.6%, similar to those previously reported.

In our study, an attempt was also made to identify factors responsible for success and complications. The retrospective nature of the study posed some limitations. Choice of plate in each case depended on the surgeon's preference, and the 2.8 mm plate had been chosen for only 6 patients. This number is certainly too small to draw any definite conclusions, or even to compare the results of these plates with the results of the 1.5 mm plates. However, it is notable that the only plate fracture we observed occurred in a true lateral defect (L) where no osteotomy of the flap had been performed, and in association with the use of a 2.8 mm plate. This observation showed that the thickness and the rigidity of the plate alone are not decisive factors in the stability of the reconstructed mandible. Other technical factors, such as repeated re-bending of the plate and/or plate bending in the sagittal plane during adaptation, may easily lead to metal fatigue and finally to plate fracture, and full chewing forces caused by the dentition on the intact contralateral side may have contributed to the plate fracture in this particular case. On the other hand, the performance of our 1.5 mm plates and of other low-profile plates ([22], [21]) strongly supports the consideration that low-profile plates are suitable and stable enough for fixation of fibular bone grafts in most cases.

Similarly to our study, Farwell ([21]) and Militsakh ([22]) previously analyzed the occurrence of hardware-related complications after the use of the 2.0 mm locking reconstruction plate (LRP). In the LRP system, locking of a screw to a plate is accomplished by a double-thread mechanism on

the screw. One thread engages the bone; another engages threads in the screw hole of the plate ([8]). These two studies concluded that there was no problem with screw loosening with the use of locking plates in general ([21]) and with low-profile plates in particular ([21], [22]).

The locking mechanism of our plating system differs from that of the LRP. Taking into account the evaluation criteria of the previous studies ([21], [22]), the low frequency of screw loosening in our series indicates that the locking mechanism is also sufficient in the system that we used. However, it is still not known whether 3 screws are necessary for each bone segment for stable fixation, or 2 screws are enough, as in the case of original TORP. Based on our results we can at least conclude that fixation with 3 screws at each segment of the mandible is adequate to avoid long-term plate loosening.

The most significant explanatory factor for complications observed in the present study was the notably high frequency of very extensive removal of the mandibular bone. More than half of our patients (54%) had reconstruction of defects extending from one angle to the other (LCL), and almost one third (26.6%) of these patients had plate-related complications, constituting as much as 57.1% of the total sample of patients with complications. Reconstruction of these defects is particularly challenging, necessitating multiple osteotomies of a long enough graft in order to reconstruct the anterior arch optimally in relation to the maxilla, and for esthetical purposes. As shown by Shaw et al. [20], osteotomy of bone graft is a factor increasing the risk of complications. In our series, the two patients with plate exposure and the four undergoing elective plate removal because of discomfort had LCL defects, highlighting the general problems associated with reconstruction of extensive mandibular defects involving the anterior region and the particular problems associated with postoperative radiotherapy.

We consider our results encouraging, given the high frequency of patients with significant risk factors for surgical complications. Three quarters of our patients were smokers and slightly less

than half had an additional history of alcohol abuse, factors that are well known to have adverse effects on wound healing in general and oral wound healing in particular ([23], [24]). In addition, a high frequency of patients (93%) had radiotherapy at some point: ORN was the reason for treatment in 12 patients, and 14 patients had postoperative radiation therapy because of malignancy.

Controversy persists about the effects of radiotherapy on complication rates after free flap reconstructions ([17], [20]), but in vascularized bone graft mandibular reconstruction in particular, the presence of ORN has been shown to have an independent, statistically significant association with plate complications ([21]). The patients in the present study were undoubtedly at high risk for wound complications from the beginning.

With regard to wound healing complications, plate exposure is an intractable problem, the risk of which increases with postoperative radiation therapy. In association with mandibular reconstruction with vascularized bone, there seems to be a decreasing incidence of plate exposure with decreasing plate thickness. Plate exposure has been associated with THORP in 36.4% of patients ([21]), with 2.7 mm plates in 16.6% ([21]), and with 2.4 mm plates in 8.2%–22.2% ([21], [20]). The corresponding rates for semi-rigid plates are clearly lower: 0%–5.7% ([21], [20]). The figures for 2.0 mm locking plates settle in between, at 4.7%–10.6% ([21], [22]), corresponding to the rate that we observed in association with the 1.5 mm locking plate (4.5%). It must be noted, however, that the single most common reason for plate removal in our series (4 patients) was not a current complication but discomfort of a bulging plate in the chin region because of the adverse effects of postoperative radiation therapy. All these patients had had fixation of the graft with 1.5 mm plates. It seems that low-profiled plates cannot once and for all solve this recurrent problem, a significantly annoying one from the patient's point of view.

7. CONCLUSION

The low-profiled locking plate with a thickness of 1.5 mm is a promising alternative for fixation of osteocutaneous fibula free flaps in mandibular reconstruction, even after extensive resections. The plate, with its gracile dimensions, is rigid enough for bony union to occur, and the mechanical properties are sufficient to hinder plate fracture. The new mechanism locking the screw to the plate seems to function well, preventing subsequent screw and plate loosening. Bulging of hardware in the chin region, after postoperative radiotherapy, with subsequent discomfort for the patient cannot be totally avoided with this plate, however.

8. ANTWORTEN

A Gesamthaft sind in dieser retrospektiven Studie bei den neuen Smartlock®-Plattensystemen rund 28% plattenassoziierte Komplikationen aufgetreten.

B Es sind dies, lokale Infektionen, Schraubenlockerungen, Plattenexposition mit und ohne Fistelbildung, Nichtverknöcherungen, Plattenbruch und partieller Knochenverlust.

C Bei der Rekonstruktionsplatte mit 2,7mm Profilhöhe traten gesamthaft drei Komplikationen (50%) auf (zwei schwerwiegende, eine geringfügige). Bei der Rekonstruktionsplatte mit 1,7mm Profilhöhe waren es deren vier (18%; alles geringfügige Komplikationen).

D Bei den LCL-Defekten traten am häufigsten Komplikationen auf.

E Obwohl die Komplikationsraten nach Rekonstruktion der Mandibula aufgrund der verschiedenen Defektgrössen, allfälligen Radiotherapie, verwendeten Knochentransplantaten und postoperativem Beobachtungszeitraum nur zum Teil vergleichbar sind, zeigen unsere Resultate, dass vaskularisierte Knochentransplantate für Mandibularekonstruktionen mit dem neuen Rekonstruktionsplattensystem erfolgreich fixiert werden können.
Das Smartlockplattensystem schneidet im Vergleich mit anderen Plattensystemen gut ab und weisst in den meisten Kategorien weniger Komplikationen auf (Daten aus Studien mit vergleichbaren Untersuchungen).

F Ja, denn die Verknöcherung des Transplantates ist auch mit der low-profile Platte möglich, welche weniger rigide ist als die konventionellen Rekonstruktionsplatten. Die verminderte Profilhöhe der Platte erlaubt ein einfacheres Formen und vereinfacht so den klinischen Gebrauch. Der Gebrauch der 2,7mm Profilhöhe messenden Platte sollte auf bestimmte klinische Situationen beschränkt werden. Bei nicht vaskularisierten Knochentransplantaten empfehlen wir aufgrund unterschiedlicher Biologie der Knochenheilung die Verwendung von 2,7mm Platten.

10. FIGURE LEGENDS

Figure 1

Reconstruction plates are available with 1.5 mm (left) and 2.8mm (right) profile height.

Figure 2

Locking screws are available with three different diameters: 2.0 mm, 2.3 mm and 2.7 mm (from left to right).

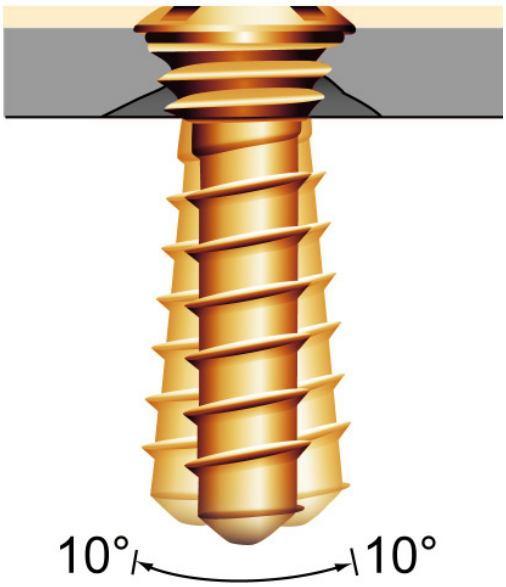

Figure 3

Smartlock® allows insertion and locking of screws at variable angles in the range of 90°±10°

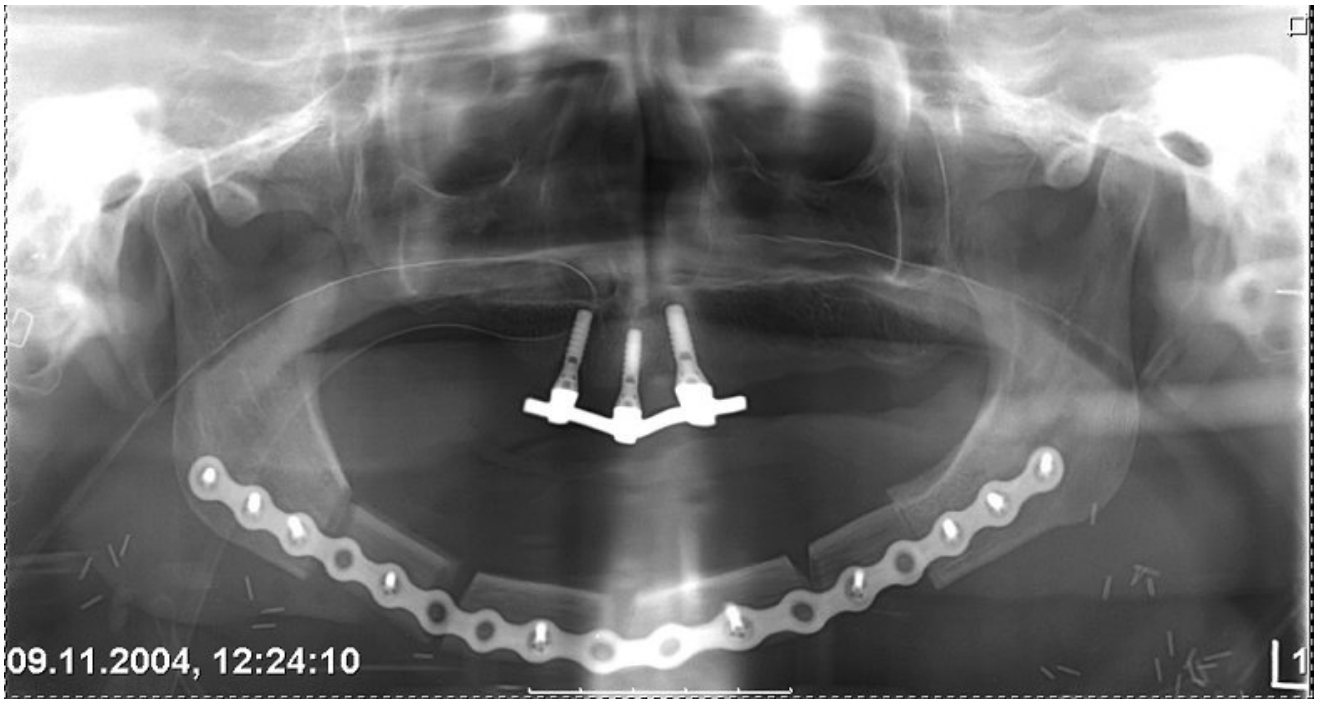

Figure 4

Postoperative X-ray after reconstruction of an LCL defect with a 1.5 mm low-profile plate and fibula free flap graft

Table 1. Defect size, bone defect classification and number of bone segments for reconstruction (28 patients)

Defect size	No (%)	HCL Classification of bone defects	No (%)	Number of bone segments for reconstructions	No (%)
5-8 cm	7 (25)	L	7 (25)	1	5 (18)
>8-12 cm	12 (43)	LC	5 (18)	2	9 (32)
>12-16 cm	9 (32)	H	1 (3)	3	10 (36)
Mean	10.44 cm	LCL	15 (54)	4	4 (14)
		HC	-	Mean	2.46
		C	-	Total number	69

Table 2. Major and minor complications observed in 28 patients

	Plate size	Defect Classification
Minor complications (3 patients)		
Superficial infection	1.5 mm	L
Solitary screw loosening	1.5 mm	L
Solitary screw loosening	2.8 mm	LCL
Major complications (4 patients)		
Plate exposure + partial bone loss + non-union	2.8 mm	LCL
Plate exposure	1.5 mm	LCL
Non-union	2.8 mm	LCL
Plate fracture	2.8 mm	L

10. ACKNOWLEDGEMENTS (DANKSAGUNGEN)

An dieser Stelle bedanke ich mich ganz herzlich bei Dr. med. Dr. med .dent. Wock Hallermann, der mich seit Beginn der Arbeit unterstützt und begleitet hat. Mein besonderer Dank gilt Herrn Professor Dr. med. Dr. med. dent. Tateyuki Iizuka, der mir die Arbeit ermöglicht hat. Ein grosses Dankeschön gebührt auch med. dent. Philip Jost, der mich zu jeder Zeit unterstützte, sowie dem ganzen Team der Klinik und Poliklinik der Schädel-, Kiefer- Gesichtschirurgie des Inselspitals in Bern, welche zum Gelingen dieser Arbeit beigetragen haben.

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