



Prophylactic removal of titanium osteosynthesis miniplates in patients after midface fractures - A retrospective cohort study

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ARTICLE INFO

Article history:

Paper received 19 July 2022

Received in revised form

11 February 2023

Accepted 25 June 2023

Available online 30 June 2023

Handling Editor: Prof. Emeka Nkenke

Keywords:

Midface fracture

Hardware removal

Complications

Titanium miniplates

ABSTRACT

The aim of the study was to evaluate prophylactic removal of titanium osteosynthesis miniplates in patients after midface fractures.

Complaints after fracture treatment and complications after plate removal were analyzed, retrospectively.

A total of 205 patients were included. Plate removal was performed in 99 cases. Complaints related to the osteosynthesis material resulted in more frequent plate removal ($p < 0.001$). Complications were noted in 22 patients after plate removal. Duration of plate removal did not correlate with postoperative complications. In 69 patients, plates were removed without previous symptoms. Of these patients, postoperative complications were recorded in 15 cases. In patients with complaints after osteosynthesis, complications after plate removal occurred in seven (23.3%) patients. Ectropia developed significantly more often with increasing age ($p < 0.05$).

Conclusion: Within the limitations of the study it seems that prophylactic plate removal is a treatment option that is not associated with an increased complication rate.

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1. Introduction

Miniplate osteosynthesis is an established procedure for the surgical treatment of facial fractures that offers pain relief and early functional recovery (Champy et al., 1978; Jackson et al., 1986; Hernandez Rosa et al., 2016). The majority of authors favor leaving asymptomatic titanium miniplates in situ after fracture treatment due to their excellent biocompatibility, low complication rates and the possible risks of further surgical intervention. Potential risks of surgical intervention for plate removal include wound healing disorders, surgical site infections and nerve damage. Furthermore, additional costs for a second intervention should be taken into account (Rauso et al., 2011; Pan and Patil, 2014; Fani et al., 2020; Aramanadka et al., 2021). Other authors support prophylactic plate removal, especially from those plates that are likely to cause

complaints, that are easy to remove or that are palpable, and that might interfere with later radiological imaging or treatment. Particularly in young patients, delayed plate removal after fracture healing increases the probability of plates being enclosed by bone and predisposes for a complex removal of the osteosynthesis material (Alpert and Seligson, 1996; Rallis et al., 2006).

To date, routine plate removal has been recommended primarily in pediatric patients mainly due to the translation by drift phenomenon and the possibility for growth inhibition (Bos, 2005; O'Connell et al., 2009). The main causes for removal of the osteosynthesis material in adults are wound healing disorders, infections, annoying palpable plates, discomfort, cold sensitivity, and loose or broken hardware (Thorén et al., 2010). Although routine removal of titanium miniplates is still a matter of controversy, there is a lack of current studies showing advantages and disadvantages of postoperative plate removal after midface trauma (Thorén et al., 2008; Hernandez Rosa et al., 2016). Especially in asymptomatic patients, the benefit of routine removal of titanium miniplates remains unclear. Therefore, the aim of this study was to evaluate the

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prophylactic removal of titanium osteosynthesis material after midface fractures in a retrospective cohort study.

2. Material and methods

This retrospective study was performed in accordance with the tenets of the Declaration of Helsinki and the Medical Research Involving Human Subjects Act (WMO) and in compliance with the regulations of the local ethics committee of the Medical Faculty of the University Hospital of Cologne. A total of 205 patients with at least one definite midface fracture and surgically treated with one or more osteosynthesis titanium miniplates at the Department of Oral and Craniomaxillofacial and Plastic Surgery, University Hospital of Cologne between November 2012 and October 2015 were included. All plates used were made of titanium and manufactured by KLS Martin Group (Gebrüder Martin GmbH & Co., Tuttlingen, Germany). After fracture treatment, the patients were not given a specific appointment for plate removal. However, metal removal was recommended for every patient between 3 and 6 months, depending on the fracture pattern. For this purpose, the patients independently arranged an appointment in our clinic after the recommendation of the period for plate removal. Fractures were subdivided into four groups, as follows: zygomatic fractures with latero-orbital surgical treatment; zygomatic fractures without latero-orbital surgical treatment; Le Fort fractures type I to III; and panfacial fractures when the mandible was additionally affected. Exclusion criteria were isolated zygomatic arch fractures, traumatic brain injuries, and fractures of the frontal sinus or the skull base. Data were acquired retrospectively from the clinic's electronic database. Radiologic images included cone-beam computed tomograms, sinus x-rays and orthopantomograms.

2.1. Patient data

Patient data analysis included age, sex, anticoagulation therapy, smoking history, duration of plate removal, American Society of Anesthesiologists physical status (ASA-PS) score, cause of fracture and length of hospital stay. All complaints associated with the osteosynthesis material after primary trauma treatment as well as complications after plate removal were recorded.

2.2. Outcome parameters

Postoperative complaints related to the osteosynthesis material after fracture treatment as well as complications after plate removal were recorded. Complaints related to the osteosynthesis material after fracture treatment included infections, pain, wound and bone healing disorders, wound dehiscence, sinusitis, ectropion, plate palpability in sensitive areas of the face, nerve and tooth damage, hyper- and hyposensitivities, plate fractures and screw loosening. Recorded complications after plate removal involved pain, ectropion, scarring, secondary bleeding, swelling, impaired sensitivity and wound healing disorders.

2.3. Statistical analysis

SPSS software version 25 (IBM Software and Systems, Armonk, NY, USA) was used for data acquisition and statistical analysis. A *t*-test and analysis of variance (ANOVA) were used to compare mean values. A *p* value ≤ 0.05 was considered to be statistically significant. Equality of variance was tested according to Levene. Correlations were determined according to Pearson and Spearman. The level of significance was defined as significant at *p* < 0.05 and highly significant at *p* < 0.01. Correlations with a value of

r = 0.1–0.3 were defined as low, with *r* = 0.3–0.5 as medium and *r* > 0.5 as high correlation (Cohen, 1988).

3. Results

A total of 205 patients with a mean age of 44.6 ± 17.9 years were eligible for inclusion during the observation period. Of these, 153 (74.6%) were male and 52 (25.4%) were female, resulting in a male-to-female range of 2.94–1. Male patients were significantly younger than female patients (*p* < 0.001). Midface fractures were subdivided into four groups as described in the Materials and Methods section. Zygomatic fractures without latero-orbital osteosynthesis accounted for 63.4% of all fractures, followed by central midfacial fractures in 42 (20.5%) patients. Panfacial fractures were detected in 18 (8.8%) cases, while zygomatic fractures with latero-orbital osteosynthesis could be determined in 15 (7.3%) cases. Traffic accidents and falls were the most frequent reasons in 110 patients (53.7%), followed by violence in 76 (37.1%) cases. In 19 (9.3%) patients, the cause of fracture was unknown. Patient characteristics are summarized in Table 1.

After fracture treatment, complaints related to the osteosynthesis material were reported in 41 (20.0%) of all cases, including eight (3.9%) female and 33 (16.1%) male patients. Complaints associated with the osteosynthesis material varied depending on fracture site. Highest rates were documented in panfacial fractures (five cases, 27.8%), and lowest rates in central midface fractures (six cases, 14.3%). Details are provided in Table 2.

During the study period, plate removal was performed in 99 (48.3%) of 205 cases. In five (5.1%) patients, plates were removed within the first 2 months after fracture treatment. In 66 (66.7%) patients, osteosynthesis material was removed between 3 and 6 months, in 25 (25.3%) patients between 7 and 12 months and in three (3.0%) patients after more than 12 months. The mean time between osteosynthesis and plate removal was 5.5 ± 3.0 months. The shortest duration was 2 months and the longest duration within the study period was 21 months. Table 3 shows the distribution of plate removal depending on previous reported complaints or complications with osteosynthesis material. Complaints related to the osteosynthesis material resulted in more frequent plate removal (*p* < 0.001). Complications were documented in 22 (22.2%) patients after plate removal. In detail, with possible multiple answers per case, nine patients had sensitivity disorders, while five patients developed an ectropion. Pain was recorded in five patients, and postoperative complications with secondary bleeding was documented in five patients. A surgical wound infection occurred in four cases, while three patients complained of postoperative swelling. None of the patients had an aesthetically disturbing scar. Duration of fracture treatment and duration of plate removal correlated significantly (*p* = 0.001). A longer operation time for fracture treatment resulted in a longer duration for plate removal. A correlation between the duration of plate removal and postoperative complications was not found. Among the different fracture sites, zygomatic bone fractures with latero-orbital osteosynthesis showed the highest complication rate (37.5%) after plate removal, followed by zygomatic bone fractures without latero-orbital osteosynthesis (35.5%), central/centrolateral midface fractures (25.0%) and panfacial fractures in 11.0% of cases (Table 4).

In 69 patients, plates were removed without previous symptoms or complaints. Of these patients, postoperative complications after plate removal were recorded in 15 (21.7%) cases. In the group of patients with postoperative complaints after osteosynthesis, complications were also documented after plate removal in seven (23.3%) patients. There was no statistical difference between the groups (Table 5).

Table 1
Patient characteristics (N = 205).

Characteristics	Mean \pm SD or n (%)
Female sex	52 (25.4)
Male sex	153 (74.6)
Age (y) total	44.6 \pm 17.9
Age (y) female	53.6 \pm 18.0
Age (y) male	41.5 \pm 16.9*
Anticoagulation	
Phenprocoumon	4 (2.0)
Rivaroxaban	1 (0.5)
Acetylsalicylic-acid	14 (6.8)
Clopidogrel	4 (2.0)
Diabetes	4 (2.0)
Coronary heart disease	35 (17.1)
Smoking	55 (26.8)
ASA score	
ASA 1	86 (42.0)
ASA 2	83 (40.5)
ASA 3	25 (12.2)
ASA 4	2 (1.0)
n.a.	9 (4.4)
Fracture site	
Zygomatic fracture <i>without</i> latero-orbital surgical treatment	130 (63.4)
Zygomatic fracture <i>with</i> latero-orbital surgical treatment	15 (7.3)
Le Fort I-III fracture	42 (20.5)
Panfacial fracture (involving the mandible)	18 (8.8)
Cause for fracture	
Traffic accidents and falls	110 (53.7)
Violence	76 (37.1)
n.a.	19 (9.3)
Timing of fracture treatment	
Fracture, osteosynthesis (days)	6.3 \pm 9.7
Osteosynthesis, plate removal (mo)	5.5 \pm 3.0
Duration of Osteosynthesis (min)	105.7 \pm 60.8
Duration of plate removal (min)	65.0 \pm 39.7
Length of hospital stay after osteosynthesis (days)	8.2 \pm 14.5
Length of hospital stay after plate removal (days)	1.6 \pm 1.6

Table shows the parameters sex (female/male), age (y), medication, pre-existing illness, smoking, ASA score, fracture pattern, cause for fracture and different timing of fracture treatment.

*Male patients were significantly younger than female patients ($p < 0.001$).

Table 2
Complaints associated with osteosynthesis material.

	No complaints n (%)	Complaints n (%)	Total n (%)
Zygomatic fracture without latero-orbital surgical treatment	103 (79.2)	27 (20.8)	130 (63.4)
Zygomatic fracture with latero-orbital surgical treatment	12 (80.0)	3 (20.0)	15 (7.3)
Le Fort I-III fracture	36 (85.7)	6 (14.3)	42 (20.5)
Panfacial fracture (involving the mandible)	13 (72.2)	5 (27.8)	18 (8.8)
Total n (%)	164 (80.0)	41 (20.0)	205 (100.0)

Table shows number (n) of complaints associated with osteosynthesis material according to different fracture patterns (zygomatic fracture without latero-orbital surgical treatment; zygomatic fracture with latero-orbital surgical treatment; Le Fort I-III fracture; panfacial fracture (involving the mandible)).

Table 3
Plate removal per fracture site in patients with complaints vs. patients without complaints.

	Zygomatic fracture without latero-orbital surgical treatment n (%)	Zygomatic fracture with latero-orbital surgical treatment n (%)	Le Fort I-III fracture n (%)	Panfacial fracture (involving mandible) n (%)
Complaints with osteosynthesis material	27	3	6	5
Plate removal in patients with complaints	18 (66.7)	3 (100.0)	5 (83.3)	4 (80.0)
No complaints with osteosynthesis material	103	12	36	13
Plate removal in patients without complaints	44 (42.7)	5 (41.7)	15 (41.7)	5 (38.5)

Table shows number and percentage [n (%)] of plate removal in patients with complaints vs. patients without complaints associated with different fracture patterns (zygomatic fracture without latero-orbital surgical treatment; zygomatic fracture with latero-orbital surgical treatment; Le Fort I-III fracture; panfacial fracture (involving the mandible)).

Table 4

Type of complication after plate removal per fracture pattern.

	Zygomatic fracture without latero-orbital surgical treatment n (%)	Zygomatic fracture with latero-orbital surgical treatment n (%)	Le Fort I-III fracture n (%)	Panfacial fracture (involving mandible) n (%)	Different complications in total n (%)
Pain	4 (6.5)	0 (0.0)	1 (5.0)	0 (0.0)	5 (5.0)
Sensitivity disorder	6 (9.7)	2 (25.0)	0 (0.0)	1 (11.1)	9 (9.0)
Swelling	2 (3.2)	1 (12.5)	0 (0.0)	0 (0.0)	3 (3.0)
Infection	4 (6.5)	0 (0)	0 (0.0)	0 (0.0)	4 (4.0)
Bleeding	2 (3.2)	0 (0)	3 (15.0)	0 (0.0)	5 (5.0)
Ectropion	4 (6.5)	0 (0)	1 (5.0)	0 (0.0)	5 (5.0)
Scarring	0 (0.0)	0 (0)	0 (0)	0 (0.0)	0 (0)
Complications per fracture pattern in total	22 (35.5)	3 (37.5)	5 (25.0)	1 (11.1)	
Plate removal in total	62	8	20	9	99

Table shows number (n) of different complications (pain; sensitivity disorder; swelling; infection; bleeding; ectropion; scarring) after plate removal associated with different fracture patterns (zygomatic fracture without latero-orbital surgical treatment; zygomatic fracture with latero-orbital surgical treatment; Le Fort I-III fracture; panfacial fracture (involving the mandible)).

Table 5

Correlation of complaints regarding osteosynthesis material compared to complications after plate removal.

Osteosynthesis material	Plate removal		Total n
	No complications n (%)	Complications n (%)	
No complaints n (%)	54 (78.3)	15 (21.7)	69
Complaints n (%)	23 (76.7)	7 (23.3)	30
Total	77	22	99

Table shows correlation of complaints after fracture treatment compared to complications after plate removal. There were no significant differences between the groups ($p = 0.58$).

Table 6

Complications after plate removal in relation to plate removal per fracture pattern and the duration from fracture treatment to plate removal.

	Complications MR/MR zygomatic fracture without latero-orbital surgical treatment n (%)	Complications MR/MR zygomatic fracture with latero-orbital surgical treatment n (%)	Complications MR/MR Le Fort I-III fracture n (%)	Complications MR/MR panfacial fracture (involving the mandible) n (%)	Complications MR/MR Total n (%)
1–2 mo	1/3 (33.3)	0/0 (0.0)	1/2 (50.0)	0/0 (0.0)	2/5 (40.0)
3 ≤ 6 mo	11/40 (27.5)	2/8 (25.0)	3/12 (25.0)	0/6 (0.0)	16/66 (24.2)
7 ≤ 12 mo	3/18 (16.7)	0/0 (0.0)	0/4 (0.0)	1/3 (33.3)	4/25 (16.0)
> 12 mo	0/1 (0.0)	0/0 (0.0)	0/2 (0.0)	0/0 (0.0)	0/3 (0.0)
Total	15/62 (24.2)	2/8 (25.0)	4/20 (20.0)	1/9 (11.1)	22/99 (22.2)

Table shows number (n) of complications after plate removal (MR) associated with different fracture patterns (zygomatic fracture without latero-orbital surgical treatment; zygomatic fracture with latero-orbital surgical treatment; Le Fort I-III fracture; panfacial fracture (involving the mandible) and the duration from fracture treatment to MR in months.

Within 2 months after fracture treatment, 40.0% of the patients experienced symptoms after plate removal. Between 3 and 6 months, 16 (24.2%) of 66 patients had complaints after plate removal. In the period from the month 7 to the month 12, complaints occurred in four (16.0%) of 25 cases. There was no significant difference between these two groups (Table 6).

4. Discussion

Routine plate removal of asymptomatic titanium miniplates in adults is controversial due to the excellent biocompatibility, the low complications of plates remaining in situ, and the risks associated with further surgery, e.g. infections, nerve damage, wound healing disorders, as well as the costs for the secondary operation (Rallis et al., 2006; Pan and Patil, 2014; Aramanadka et al., 2021). On the other hand, the osteosynthesis material becomes a non-functional foreign body and might possibly cause local or systemic side effects (Bhatt et al., 2005; Rallis et al., 2006; O'Connell et al., 2009). Therefore, the present study aims to analyze the feasibility and complications of prophylactic plate removal after midface fractures.

This study included 205 patients with a mean age of 44.5 ± 17.8 years. As expected and as previously demonstrated in other studies, male patients showed a higher frequency of midface fractures and were significantly younger than female patients (Pan and Patil, 2014; Ghosh and Gopalkrishnan, 2018; Bonitz et al., 2021). This might be explained by the fact that men between 20 and 30 years of age are more likely to be involved in interpersonal violence and accidents than women in a comparable age group. Traffic accidents and falls were the most common cause for midface fractures. These two main causes have also been confirmed by other working groups (Septa et al., 2014; Schneider et al., 2015; Bonitz et al., 2021). Patients with diabetes mellitus, coronary heart disease or anti-coagulation therapy did not show increased complication rates in our study cohort. Due to the small number of patients, however, a statement is only possible to a limited extent.

Duration of fracture treatment correlated with the duration of plate removal and suggests that a more complex fracture treatment requires a longer duration of plate removal. In turn, no significant correlation could be identified between the duration of the plate removal and the occurrence of complications.

Of the 632 plates, 367 (58.1%) were placed via an intraoral and 265 (41.9%) via an extraoral approach. The mean number of intraoral compared to extraoral plates was also increased. This indicates a preference for fracture treatment via an intraoral approach, as this does not result in any visible scarring. The access for the plate removal was extraoral and intraoral via the existing scar of the fracture operation. Since all plates (extraoral and intraoral) in an individual were generally removed during plate removal, it is difficult to evaluate the surgical approaches separately from each other.

Complications from zygomaticomaxillary fractures can originate from initial trauma, surgical intervention, or inaccurate surgical treatments (Birgfeld et al., 2017). In our study cohort, complaints associated with the osteosynthesis material were reported in 41 (20.0%) patients after fracture treatment. Due to the routine plate removal, no conclusions can be drawn regarding complaints that might have been occurred in a treatment concept which supports leaving the osteosynthesis material in situ. Moreover, a review by Hernandez Rosa et al. found that approximately 50% of patients with complaints after osteosynthesis were treated with plate removal (Hernandez Rosa et al., 2016). Complaints related to the osteosynthesis material resulted in more frequent plate removal. During the study period, plate removal was performed in 99 (48.3%) cases. A correlation between postoperative complaints after fracture treatment and complications after plate removal cannot be clearly identified. Considering complications after plate removal, of 30 patients with complaints after osteosynthesis, complications after plate removal were documented in seven (23.3%) cases.

Sensitivity disorders accounted for the majority of complications after plate removal in nine patients, and symptoms were already present in three patients before plate removal. The incidence of dysesthesia of the infraorbital nerve is a common side effect after zygomatico-orbital fractures and varies between 30% and 84%, depending on the results in different studies (Jungell and Lindqvist, 1987; Taicher et al., 1993; Fogaça et al., 2005; Olate et al., 2011). Since no standardized and targeted neurological examination was performed, it can be assumed that the actual number of sensory disorders might be higher than stated here.

Ectropion of the lower eyelid is one of the most common complications after subciliary approach in the treatment of fractures of the zygomatico-orbital complex (Raschke et al., 2013). In a meta-analysis, Ridgway et al. found an average ectropion rate of 4.7% after lower eyelid incisions (Ridgway et al., 2009). In the present study, ectropion occurred in five cases. Of these five cases, two were previously present and one patient suffered from visual impairment. Consequently, two ectropies may have occurred after plate removal. Ectropia developed significantly more often with increasing age. Subciliary plate removal in elderly, asymptomatic patients should therefore be carefully considered.

In our study, the plate removal rate is significantly higher than the international plate removal rate, which fluctuates between 1.0% and 33.3%. However it has to be mentioned that most of the international treatment concepts are based on leaving the plates in (Nagase et al., 2005; Bakathir et al., 2008; O'Connell et al., 2009; Pan and Patil, 2014; Aramanadka et al., 2021). According to the German Scale of Medical Fees for Physicians (GOÄ), removal of osteosynthesis material is chargeable, and it is conceivable that this might, together with potential risks of leaving plates in situ, have an impact on the decision-making process of removing or not removing plates. Nonetheless, it is unknown how plate removal rates would develop if the healthcare system in other countries would pay for the procedure and doctors and patients could freely

decide on plate removal. By now, indications for leaving or removing plates after midface fractures are not well defined (Hernandez Rosa et al., 2016). Prospective studies comparing how complication rates and symptoms differ between prophylactic and complaint-oriented plate removal would be helpful in comparisons of the two therapy concepts.

To the best of our knowledge, there are currently no studies examining postoperative complications after plate removal in the midface in more detail. The optimal time for plate removal cannot be determined and must be decided individually. Early removal within the first two months was associated with a higher complication rate. Between 3 and 12 months after fracture treatment, there were no differences concerning complications after plate removal. Hernandez Rosa et al. reported that most of the symptomatic plates were removed between 6 and 12 months.

With 5.5 ± 3 months, there was a large scattering of the timepoints of plate removal. One simple explanation for this could be that patients, as already mentioned, do not receive a specific appointment for plate removal and independently arranged an appointment after recommendation of the period for plate removal. The assumption that complications probably increase with time because plates are overgrown by bone might be another aspect contributing to varying timepoints of plate removal.

In this study, the ratio between the duration of the fracture treatment and the duration of the plate removal was 1.9:1. The ratio dropped to 1.3:1 only if there was a period of more than 12 months between the fracture treatment and the plate removal, which suggests that plate removal took relatively longer in this case. Rallis et al. confirmed a more difficult plate removal with increasing time between fracture treatment and plate removal operation. On the other hand, the statement that late plate removal represents an increased risk of complications for the patient could not be significantly confirmed by our data (Rallis et al., 2006). Based on the results of Hernandez Rosa et al. prophylactic plate removal between 6 and 12 months seems reasonable, since the complication rate after plate removal is lower than that between 3 and 6 months, but a prolonged plate removal operation is not yet to be expected (Hernandez Rosa et al., 2016). Further investigations to determine the optimal time for prophylactic plate removals are necessary.

This retrospective study has several limitations and a risk of bias. First, the small number of patients allows merely restricted recommendations regarding prophylactic plate removal. Second, due to the method of retrospective data collection, this examination is not based on a standardized patient anamnesis, findings and documentation, which partially limits its informative value. Third, the patients were not included in a specific recall system for planned plate removal. Removal of the plates after an average of 3–6 months, depending on the fracture pattern, was recommended for every patient after fracture treatment. Therefore it should be mentioned that patients who presented within the determined 3-year time frame could not be included consecutively, since not all patients appeared at a planned appointment for plate removal. This might be due to the fact that patients with complaints or complications after osteosynthetic treatment were more likely to present for plate removal than patients who were free of symptoms. Ultimately, this study is limited by the fact that the surgical approach at the time of plate placement (extraoral versus intraoral) or at the time of plate removal (extraoral approach versus intraoral) was not analyzed in detail.

This is worth mentioning, because it is known that there is a higher tendency for wound infection during plate removal with intraoral approaches than with extraoral approaches (Thorén et al., 2010).

5. Conclusion

Within the limitations of the study it seems that prophylactic plate removal is a treatment option that is not associated with an increased complication rate.

Funding

No funding was received.

Declaration of competing interest

The authors declare no conflict of interest.

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