Article

Osteosynthesis Plate Removal: Patient Benefits and Burdens

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Received: 2 January 2020; Accepted: 2 March 2020; Published: 6 March 2020

Abstract: Maxillofacial fractures are lege artis treated via open reduction and internal fixation in cases of dislocation of the fracture. Plate removal is indicated for various reasons. Whereas symptomatic plate removals are justified, elective removals are questionable. This retrospective monocenter study examined the individual benefit of plate removal from the patient’s point of view and involved 233 patients undergoing plate removal. The data of 233 patients undergoing plate removal were first collected, and then, an individual follow-up questionnaire was created that assessed the personal reasons of patients requesting removal and addressed whether the patient gained any benefit from removal surgery. A total of 43 patients agreed to complete the survey. The complication rate was lower after plate removal (13.3%) than after osteosynthesis (31.8%). The most common indication for removal was surgeon recommendation (51.9%), followed by ongoing symptoms (31.3%) and request by the patient (16.7%). Significantly, more patients underwent symptomatic plate removal after mandibular fractures (46.8%, n = 37, \( p = 0.001 \)) than fractures elsewhere. According to the survey, 86% (n = 37) of the patients benefitted from plate removal. Although elective plate removal is nowadays controversial, our data provide evidence for a high level of patient satisfaction after removal surgery.

Keywords: fracture fixation; internal; device removal; maxillofacial injuries; surgery; oral; fracture; quality of life

1. Introduction

Traumatic maxillofacial fractures are treated via osteosynthesis with titanium plates in cases of dislocated fractures, providing that reposition and internal fixation is achievable and gives restitutio ad integrum [1,2]. In the twentieth century, elective surgery to remove all previously inserted plates was common, with the surgeon recommending plate removal after completion of the consolidation of the fractured bone [3]. Nowadays, the rate of routine plate removal varies greatly. Health insurance companies or governmental regulations also play a major role [4]. More than 80% of patients demand plate removal surgery because of their awareness of a foreign object in their body or because of their surgeon’s recommendation [5]. Whereas plate removals after postoperative complications are justified by medical indications, elective removals are questionable [1,6–10]. The most reported complications indicating plate removal are wound dehiscence, infections, thermal- or touch-sensitive skin, pain, hypesthesia, palpability of metal, and titanium intolerance [11–13].

Nevertheless, a second surgical intervention always presents a risk for the patient, especially for elderly patients, because of multimorbidity, and both its risks and costs need to be taken into
consideration [14]. In present-day clinical research, several studies have identified high-risk-factors predisposing patients to an above-average probability of the need for plate removal because of complications.

Moreover, patients wish to know whether the removal surgery will be beneficial. Because a subjective benefit is not only associated with medical issues and outcomes, the patient’s point of view should be therefore evaluated after removal surgery. The null hypothesis to be tested was that patients do not undergo removal due to surgeon recommendation or patient request. Furthermore, we hypothesized that even symptom-free patients benefit individually from their surgeon recommendation or their own request for removal surgery. Furthermore, the alternative hypothesis to be evaluated was that patients undergo removal surgery due to surgeon recommendation or patient request. Depending on the data, the null hypothesis will or will not be rejected.

In the current study, we aimed to evaluate the risk factors predisposing patients to postoperative complications and to assess patient satisfaction after plate removal, because this issue currently lacks evidence within the topic of maxillofacial surgery.

2. Material and Methods

This monocenter study is a descriptive and analytical study conducted into two parts. Part I evaluated retrospectively 233 patients undergoing two maxillofacial surgeries, namely the insertion of osteosynthesis plates and their subsequent removal. The osteosynthesis surgeries took place from 2010 to 2016 and the removal surgeries from 2014 to 2016. All osteosynthesis plates were made of titanium. The surgical records of the patients in the current study were identified by a computerized database search. Patient data regarding the surgical procedure were gathered from the operative report, and the data regarding the patient’s history and health status (e.g., nicotine or alcohol abuse, comorbidities, concurrent medication) from the anesthesia screen. Diagnoses of the anesthesiologist were applied without further investigation. The inclusion criteria were traumatic midfacial fractures treated via osteosynthesis and plate removal at the Department of Oral and Maxillofacial Surgery, Klinikum Rechts der Isar der Technischen Universität München, Munich, Germany. Patients with osteosynthesis elsewhere were excluded, as were patients with impaired bone healing. The studied examined as categorial variables age groups, gender, location of the fractures (ICD-Code: International Classification of Diseases), number of inserted plates, time in situ of the plates, surgical approach, concurrent medication, comorbidities, the incidence of alcohol and/or nicotine abuse (applicable/non-applicable from the anesthesiologist’s point of view). As risk factors predisposing patients to postoperative complications and subsequent symptomatic plate removal, we defined female sex, fracture of the mandible, nicotine abuse, intraoral approach, and plate removal within the first postoperative year. The perioperative complications were defined as the outcome. In addition, the evaluation of the reason for plate removal was considered as being important and was indicated by symptoms, patient request, or surgeon recommendation. Part II of the study took place in 2018 after the data collection. A follow-up questionnaire as presented in Appendix A was created in order to assess the personal reasons, grounds, and feelings of patients with regard to removal. Furthermore, the survey evaluated whether the patients benefitted from the removal surgery from their own point of view. Patients included in part I responded to the survey either by phone or face-to-face. In part II of the study, we evaluated as categorial variables the benefit, the burden, and the reason for plate removal in the patient’s point of view. Data from both parts of the study were analyzed by using Microsoft Excel (Version 16.11.1, Microsoft, Redmond, WA, USA, 2017) and IBM SPSS Statistics (Version 25, IBM, Armonk, NY, USA, 2017). We calculated descriptive statistics (mean score, total, abundance distribution) and analyzed contingency tables of the compiled categorial variables by using Pearson’s Chi-Square test. We also calculated the $\chi^2$, degrees of freedom, and Cramer’s V or, if applicable, $\phi$. The significance level was $p = 0.05$. No data were missing. The sample size for the study was calculated with G*Power (Version 3.1.9.5, Heinrich-Heine Universität, Dusseldorf, Germany, 2014). This was calculated for the Chi-square test between the complications and categorial variables of the patients and for the indication of removal and categorial variables of the patients. A total sample size of 220 patients was calculated with an effect size $w$ of 0.3, alpha error probability of 0.05,
power of 0.95, and five degrees of freedom. The study was conducted according to the declaration of Helsinki and approved by the Ethics committee of Technical University of Munich, TUM Faculty of Medicine, Ismaninger Straße 22, 81675 Munich. Written informed consent was obtained from all participants who were given the follow-up survey.

3. Results

3.1. Description of the Study Population

Table 1 provides the descriptive statistics of the study population. Most patients of our study population were male (n = 169, 72.5%). The mean age of the study population was 40.03 years. The most common age groups were 20–29 years and 30–39 years. Most of the patients were healthy and took no concurrent medication. The most common diseases were hypothyroidism at 16.7% (n = 21), hypertension at 14.3% (n = 18), and depression at 10.3% (n = 13).

In all, 396 fractures were registered and categorized via the ICD-Code. They were treated by insertion of 655 titanium plates (Table 2). Most patients had two plates inserted (n = 104, 44.6%). In total, 641 titanium plates were removed from the patients. The median of removed plates per patient was two plates. Consequently, 14 plates remained in situ because of excessive ossification, as this increases postoperative damage when removal is performed, or at the request of the patient. Most of the patients had their removal surgery in the first postoperative year. The earliest removal took place 17 days after the osteosynthesis because of postoperative infection and the latest after a period of over 66 months (2016 days). The data regarding the surgeries are shown in Table 3.

Table 1. Descriptive statistics within the study population: age, gender, fracture type, and health status. Totals of the percentages may not be exactly 100% because of rounding.

| Variable            | Subcategory | Case (n(%) ) |
|---------------------|-------------|--------------|
| Gender              | Males       | 169 (72.5)   |
|                     | Females     | 64 (27.5)    |
| Age (years)         | <19         | 19 (8.2)     |
|                     | 20–29       | 56 (24.0)    |
|                     | 30–39       | 49 (21.0)    |
|                     | 40–49       | 41 (17.6)    |
|                     | 50–59       | 39 (16.7)    |
|                     | 60–69       | 13 (5.6)     |
|                     | >70         | 16 (6.9)     |
| Fracture type       | Upper jaw/Le Fort | 149 (37.6) |
|                     | Infraorbital | 114 (28.8)  |
|                     | Mandibula    | 105 (26.5)  |
|                     | Nasoorbitoethmoid | 18 (4.5)   |
|                     | Supraorbital | 10 (2.5)    |
|                     | Total        | 396 (100)    |
| Nicotine abuse      | Applicable   | 139 (59.7)   |
|                     | Not applicable | 94 (40.3)  |
| Alcohol abuse       | Applicable   | 15 (6.4)     |
|                     | Not applicable | 218 (93.6) |
| Concurrent medication| Applicable     | 79 (33.9)   |
|                     | Not applicable | 154 (66.1)  |
| Comorbidities       | Applicable   | 79 (33.9)    |
|                     | Not applicable | 154 (66.1)  |
Table 2. Location of the inserted plates. The number of patients who had plates inserted at a specific location are indicated. Totals of the percentages may not be exactly 100% because of rounding.

| Location      | Subcategory          | Case (n(%)) |
|---------------|----------------------|-------------|
| Lower jaw     | Paramedian           | 51 (50.5)   |
|               | Jaw angle            | 23 (22.8)   |
|               | Collum mandibulae    | 20 (19.8)   |
|               | Other                | 7 (7.0)     |
| Upper jaw     | Crista zygomaticoalveolaris | 21 (47.7)   |
|               | Intraoral            | 8 (18.2)    |
|               | Alveolar process     | 6 (13.6)    |
|               | Other                | 9 (20.4)    |
| Orbita        | Infraorbital         | 129 (54.9)  |
|               | Lateroorbital        | 99 (42.1)   |
|               | Supraorbital         | 7 (3)       |
| Nasal         | Paranasal            | 16 (88.9)   |
|               | Nasal                | 2 (11.1)    |
| Other         | Frontal sinus        | 16 (84.2)   |
|               | Glabella             | 2 (10.5)    |
|               | Nasoorbitoethmoid    | 1 (5.3)     |

Table 3. Descriptive statistics of the surgeries within the study population. Totals of the percentages may not be exactly 100% because of rounding.

| Variable                        | Subcategory       | Case (n(%)) |
|---------------------------------|-------------------|-------------|
| Number of inserted plates       | One plate         | 35 (15.0)   |
|                                 | Two plates        | 104 (44.6)  |
|                                 | Three plates      | 38 (16.3)   |
|                                 | Four plates       | 28 (12.0)   |
|                                 | Five plates       | 10 (4.3)    |
|                                 | Six and more plates| 18 (7.7)   |
| Surgical approach of osteosynthesis | Extraoral only | 113 (48.5)  |
|                                  | Intraoral only    | 51 (21.9)   |
|                                  | Combined          | 69 (29.6)   |
| Surgical approach of removal    | Extraoral only    | 116 (49.8)  |
|                                  | Intraoral only    | 59 (25.3)   |
|                                  | Combined          | 58 (24.9)   |
| Time to removal (months)         | <6                | 127 (54.5)  |
|                                  | 6–12              | 92 (39.5)   |
|                                  | >12               | 14 (6.0)    |

3.2. Indication for Removal

The most common indication for plate removal was surgeon recommendation (Table 4). No correlation was found between the indication for removal and gender, age, nicotine abuse, alcohol abuse, and the site of the fracture. Fractures of the mandible were the only exception (Pearson’s Chi-square test, \( p = 0.001 \)), with more patients than expected having their plates removed because of a specific symptom (Table 5).

Whereas within the first postoperative year, surgeon recommendation was the main reason for removal, the rate decreased after the first year. After the second year, patient request and symptoms as an indication increased (Table 6).
Table 4. Distribution of the indication to remove the titanium plates. Totals of the percentages may not be exactly 100% because of rounding.

| Variable                  | Subcategory       | Case (n(%)) |
|---------------------------|-------------------|-------------|
| Indication of removal     | Surgeon recommendation | 121 (51.9) |
|                           | Symptom           | 73 (31.3)   |
|                           | Patient request   | 39 (16.7)   |
|                           | Total             | 233 (100)   |

Table 5. Indication for plate removal in correlation with fractures of the mandible. Significantly more patients underwent symptomatic plate removal after mandibular fractures (46.8%, n = 37, Pearson’s chi-square test, \(p = 0.001\)) than fractures elsewhere.

| Variable                  | Subcategory       | Fracture of the Mandible |
|---------------------------|-------------------|---------------------------|
|                           |                   | No (n(%)) | Yes (n(%)) |
| Indication                | Surgeon recommendation | 88 (57.1) | 33 (41.8)  |
|                           | Symptom           | 36 (23.4) | 37 (46.8)  |
|                           | Patient request   | 30 (19.5) | 9 (11.4)   |
|                           | Total             | 154 (100) | 79 (100)   |

\(p = 0.001\) *

* The result of Pearson’s Chi-square test is \(\chi^2(2) = 13.59, p = 0.001\), Cramer’s V = 0.241. Totals of the percentages may not be exactly 100% because of rounding.

Table 6. Indication for plate removal in correlation with the date of plate removal.

| Variable                  | Subcategory       | Time of Plate Removal |
|---------------------------|-------------------|-----------------------|
|                           |                   | First Postoperative Year | Second Postoperative Year or Later |
| Indication                | Surgeon recommendation | 118 (53.9) | 3 (21.4)   |
|                           | Symptom           | 67 (30.6) | 6 (42.9)   |
|                           | Patient request   | 34 (15.5) | 5 (35.7)   |
|                           | Total             | 219 (100) | 14 (100)   |

\(p = 0.039\) *

* The result of Pearson’s Chi-square test is \(\chi^2(2) = 6.505, p = 0.039\), Cramer’s V = 0.167.

3.3. Complications

A total of 94 complications occurred after osteosynthesis insertion (Table 7). The rate of complication after osteosynthesis was 31.8% (n = 74). No significant statistical connection was determined by Pearson’s Chi-square test between the complications and characteristics of the patient (Table 8). The only exception was that more smokers than statistically expected suffered from wound dehiscence (Table 9). The location of the fracture was related to some complications. We calculated that patients with fractures of the mandible (Pearson’s Chi-square test, \(p = 0.001\)) suffered significantly more from wound dehiscence, and patients with fractures of the maxilla (\(p = 0.048\)) suffered significantly less from this problem. The complication rate of plate removal was 13.3% (n = 31, see also Table 7). Hypesthesia occurred as a new complication only in two patients after plate removal (0.86%). In one case in which the patient suffered a blowout fracture, the facial nerve was affected, whereas in the other case, the ophthalmic nerve was affected because of multiple midfacial fractures. In 5.9% (n = 2) of all cases within the study population, paresthesia, unintended remaining plates, unintended remaining screws, or double vision occurred as a complication after plate removal. No postoperative infection was found after plate removal.

No statistical correlation was determined by Pearson’s Chi-square test between the complications and the patient’s characteristics (Table 10). Evaluating each complication separately, we found a correlation between postoperative hemorrhage and the number of plates (Table 11). In contrast, postoperative hemorrhage occurred less often in fractures of the maxilla (Pearson’s Chi-
square test, \( p = 0.013 \) and the orbital cavity (Pearson’s Chi-square test, \( p = 0.001 \)) than in fractures of other areas. Total complications after orbital fractures were statistically significantly lower (Table 12).

The recommendation of the surgeons in this study was to remove the osteosynthesis plates after six months. This suggestion was based on the clinical experience of the surgeons, who considered that a proper consolidation without the overgrowth of bone could be expected after six months. Following the advice of the surgeons, 30% (\( n = 70 \)) of the patients had their plates removed exactly after six months, with even more (66.9%, \( n = 156 \)) having plate removal after five to seven months. Remarkably, fewer complications occurred than statistically expected when the plates were removed during the advised timeframe. This correlation was statistically significant as shown by Pearson’s Chi-square test (\( \chi^2(50) = 86.837, p = 0.009, \text{Cramer’s-V= 0.171} \)) but should be taken with caution as \( \chi^2 \) and the degree of freedom are elevated. An increased sample size is required for significance.

Table 7. Complications after osteosynthesis. Complications not listed in this table occurred less frequently at osteosynthesis (<4%) or plate removal (<3%) and were not included in the statistical tests of this study. Totals of the percentages may not be exactly 100% because of rounding.

| Variable          | Subcategory          | Case (n%) |
|-------------------|----------------------|-----------|
| Complications after osteosynthesis | Hypethesia | 34 (42.0) |
|                   | Wound dehiscence    | 19 (23.5) |
|                   | Postoperative hemorrhage | 11 (13.6) |
|                   | Double vision       | 10 (12.3) |
|                   | Infection           | 7 (8.6)   |
|                   | Total               | 81 (100)  |
| Complications after plate removal | Postoperative hemorrhage | 13 (56.5) |
|                   | Hypethesia          | 5 (21.7)  |
|                   | Intraoperative hemorrhage | 5 (21.7)  |
|                   | Total               | 23 (100)  |

Table 8. Complications after osteosynthesis in correlation to gender, age group, and nicotine and alcohol abuse. All results were calculated by the Pearson’s Chi-square test. The calculation of the correlation of the age group had more degrees of freedom. The result of this Chi-square test might not be as powerful as the other results. Totals of the percentages may not be exactly 100% because of rounding.

| Variable | Subcategory | Complication after Osteosynthesis |
|----------|-------------|-----------------------------------|
|          |             | No (n%)                           | Yes (n%)                           |
| Gender   | Male        | 111 (69.8)                        | 58 (78.4)                          |
|          | Female      | 44 (30.2)                         | 16 (21.6)                          |
|          |             | \( \chi^2(1) = 1.860, p = 0.173, \phi = -0.89 \) |
| Age group| <19         | 12 (7.5)                          | 7 (9.5)                            |
|          | 20–29       | 34 (21.4)                         | 22 (29.7)                          |
|          | 30–39       | 30 (18.9)                         | 19 (25.7)                          |
|          | 40–49       | 28 (17.6)                         | 13 (17.6)                          |
|          | 50–59       | 32 (20.1)                         | 7 (9.5)                            |
|          | 60–69       | 10 (6.3)                          | 3 (4.1)                            |
|          | >70         | 13 (8.2)                          | 3 (4.1)                            |
|          |             | \( \chi^2(6) = 7.937, p = 0.243, \text{Cramer’s V = 0.185} \) |
| Nicotine abuse | Applicable | 61 (38.4)                        | 33 (44.6)                          |
|          | Not applicable | 98 (61.6)                       | 41 (55.4)                          |
|          |             | \( \chi^2(1) = 0.814, p = 0.367, \phi = 0.059 \) |
| Alcohol abuse | Applicable | 10 (6.3)                         | 5 (6.8)                            |
|          | Not applicable | 149 (93.7)                      | 69 (93.2)                          |
|          |             | \( \chi^2(1) = 0.018, p = 0.892, \phi = 0.009 \) |
Table 9. Statistical correlation between nicotine abuse and rate of wound dehiscence after osteosynthesis.

| Variable          | Subcategory | Wound Dehiscence |
|-------------------|-------------|------------------|
|                   |             | No (n(%)) | Yes (n(%) |
| Nicotine abuse    | No          | 133 (62.1) | 6 (31.6) |
|                   | Yes         | 81 (37.9)  | 13 (68.4) |
|                   | Total       | 214 (100)  | 19 (100)  |

\[ p = 0.009 \]

* The result of Pearson’s Chi-square test is \[ \chi^2(1) = 6.776, p = 0.009, \phi = 0.171. \]

Table 10. Complications after plate removal in correlation to patient’s characteristics. All results were calculated by Pearson’s Chi-square test. The calculation of the correlation of the age group had more degrees of freedom. The result of this Chi-square test might not be as powerful as the other results. Totals of the percentages may not be exactly 100% because of rounding.

| Variable          | Subcategory | Complication after Plate Removal |
|-------------------|-------------|----------------------------------|
|                   |             | No (n(%)) | Yes (n(%)) |
| Gender            | Male        | 146 (72.3) | 23 (74.2) |
|                   | Female      | 56 (27.7)  | 8 (25.8)  |

\[ \chi^2(1) = 0.050, p = 0.824, \phi = -0.015 \]

| Age group         |              | No (n(%)) | Yes (n(%)) |
|-------------------|--------------|------------|------------|
|                   | <19          | 17 (8.4)   | 2 (6.5)    |
|                   | 20–29        | 50 (24.8)  | 6 (19.4)   |
|                   | 30–39        | 38 (18.8)  | 11 (35.5)  |
|                   | 40–49        | 35 (17.3)  | 6 (19.4)   |
|                   | 50–59        | 36 (17.8)  | 3 (9.7)    |
|                   | 60–69        | 11 (5.4)   | 2 (6.5)    |
|                   | >70          | 15 (7.4)   | 1 (3.2)    |

\[ \chi^2(6) = 5.872, p = 0.438, Cramer’s V = 0.159 \]

| Nicotine abuse    | Applicable   | 82 (40.6)  | 12 (38.7)  |
|                   | Not applicable | 120 (59.4) | 19 (61.3)  |

\[ \chi^2(1) = 0.040, p = 0.842, \phi = -0.013 \]

| Alcohol abuse     | Applicable   | 13 (6.4)   | 2 (6.5)    |
|                   | Not applicable | 189 (93.6) | 29 (93.5)  |

\[ \chi^2(1) < 0.001, p = 0.997, \phi < 0.001 \]

| Surgical approach| Extraoral only | 102 (50.5) | 14 (45.2)  |
|                   | Intraoral only | 50 (24.8)  | 9 (29.0)   |
|                   | Combined       | 50 (24.8)  | 8 (25.8)   |

\[ \chi^2(2) = 0.360, p = 0.835, Cramer’s V = 0.039 \]

Table 11. Statistical correlation of postoperative hemorrhage with patient’s characteristics after plate removal. Patients with more than three plates suffered statistically significantly more from postoperative hemorrhage.

| Variable          | Subcategory | Postoperative Hemorrhage |
|-------------------|-------------|--------------------------|
|                   |             | No (n(%)) | Yes (n(%)) |
| Amount of plates  | One plates  | 35 (15.9) | 0 (0.0)    |
|                   | Two to three plates | 136 (61.8) | 6 (46.2)  |
|                   | More than three plates | 49 (22.3) | 7 (53.8)  |

\[ \chi^2(2) = 7.654, p = 0.022, Cramer’s V = 0.181 \]

* The results were significant as shown by Pearson’s Chi-square test.
Table 12. Statistical correlation between amount of complications after plate removal and orbital fractures.

| Variable          | Subcategory        | Orbital Fracture |
|-------------------|--------------------|------------------|
|                   |                    | No (n(%))        | Yes (n(%)) |
| Amount of complications | No complication | 94 (81.7)        | 108 (91.5) |
|                   | One complication   | 17 (14.8)        | 10 (8.5)   |
|                   | Two complications  | 4 (3.5)          | 0 (0.0)    |
| $p = 0.034$ *     |                    |                  |            |

* The result of Pearson’s Chi-square test is $\chi^2(2) = 6.748$, $p = 0.034$, Cramer’s $V = 0.170$.

3.4. Survey Analysis

In part II of the study, 43 patients of all patients included within the study population of part I completed the follow-up survey. As many patients were contacted years after their removal surgery, we experienced major difficulties contacting them (e.g., invalid phone numbers, incorrect addresses in the patient data). Furthermore, not all of the successfully contacted patients were willing to participate in part II of the study. Most of the patients completing the survey stated that they did not consider the removal surgery as a severe burden. A minority stated that the surgery was a burden, with two patients experiencing postoperative complications (Table 13). In one case, the complication was hypesthesia and, in the other, double vision. Both complications began after the osteosynthesis. An even larger number of patients indicated that the burden of surgery was no more severe than leaving the plates in situ. The majority of the patients undergoing removal surgery stated that they benefitted from plate removal, and even patients suffering from postoperative complications after plate removal considered the surgery as beneficial. The reasons for the beneficial feeling are presented in Table 14.

Table 13. Evaluation of the survey.

| Variable                      | Subcategory         | Case (n(%)) |
|-------------------------------|---------------------|-------------|
| Plate removal as severe burden | Yes                 | 7 (16.3)    |
|                               | No                  | 36 (83.7)   |
| Burden more severe than leaving plates in situ | Yes | 2 (4.7) |
|                               | No                  | 41 (95.3)   |
| Plate removal as benefit      | Yes                 | 37 (86.0)   |
|                               | Neutral             | 6 (14.0)    |
|                               | No                  | 0 (0.0)     |
| Plate removal as benefit despite complications | Yes | 5 (71.4) |
|                               | No                  | 2 (28.6)    |

Table 14. Reasons for individual benefit of plate removal from the patient’s point of view. The removal of a foreign body in situ was the most common reason. Totals of the percentages may not be exactly 100% because of rounding.

| Variable                             | Subcategory                                      | Case (n(%)) |
|--------------------------------------|--------------------------------------------------|-------------|
| Reason for benefit                   | Removal of foreign body                          | 14 (37.8)   |
|                                      | Less pain                                       | 8 (21.6)    |
|                                      | Scared of more severe fractures attributable to plates | 4 (10.8)   |
|                                      | Less palpability                                | 4 (10.8)    |
|                                      | No difference felt but benefitted                | 3 (8.1)     |
|                                      | Less weather sensitivity                         | 2 (5.4)     |
|                                      | Loose plate                                      | 1 (2.7)     |
|                                      | Simultaneous tooth extraction                    | 1 (2.7)     |
|                                      | Total                                            | 37 (100)    |
4. Discussion

Some authors have stated that the lack of evidence indicating plate removal is attributable to the removal rate being low (3%) and the clinical indication for plate removal being unclear. Furthermore, they describe the removal surgery as the most expensive complication in maxillofacial traumatology [1,9,10,15]. Although the practice of elective removal has become controversial nowadays, the present study has revealed that the complication rate after plate removal is low (13.3%, n = 31). In this regard, we should mention that the surgeons of this study recommend plate removal after six months, as this leads to a lower rate of complications. Surgery is more difficult following an overgrowth of bone and is considered, among researchers, a complication of belated plate removal, especially in young patients [1,5,16].

Removal within a year or less after osteosynthesis is frequently reported [3,5,14,17,18]. The most common complication after osteosynthesis was hypesthesia in this study. Hypesthesia may not be the main problem of the osteosynthesis, because it can be caused by the trauma itself. On exclusion of hypesthesia as a complication, the complication rate was lower in our study (17.2%, n = 40). We did not differentiate between hypesthesia before and after the osteosynthesis more precisely, as plate removal was the central issue of the study. The high complication rate including hypesthesia in our study is different from that of other studies in which infection has been reported as the most common complication [2,13,15,19]. In the investigation of Rausos et al. who studied a population of 164 patients undergoing osteosynthesis from 2004 to 2007, smoking was suggested as the main reason for the high infection rate that they observed. The patients were administered with perioperative antibiotics [10]. Palpability is also reported as a highly common complication [3,12]. Kubota et al. state that frontozygomatic fractures are a risk factor for the palpability of plates because of the anatomical properties of this region. Nevertheless, the number of patients with plates at the frontozygomatic suture was high in their study. Nagase et al. noted a high rate of palpability for supraorbital and infraorbital fractures and proposed that the discomfort was related to the thin soft tissue in this area. Wound dehiscence was the second most common complication (20.2%) in the present study, and palpability occurred in less than 5% of the patients. A probable explanation for the high rate of wound dehiscence is the large number of mandibular fractures in our study. Peisker et al. reported moreover that patients with mandibular fractures suffer more pain than patients with midface fractures [20]. However, surprisingly, the number of supraorbital and infraorbital fractures was also high, although the rate of palpability was low compared with other studies. In the current investigation, we identified mandibular, nasal, and orbital fractures and smoking habits to be statistically significantly associated with more complications (e.g., wound dehiscence, postoperative hemorrhage). We noted that the complication rate of plate removal was lower than the rate after osteosynthesis, but the literature is lacking with regard to postoperative complications after removal. Only Kubota et al. have reported that plate-associated complications are reduced after removal surgery [3]. Surgeon recommendation as the main indication for removal in our investigation is contrasts with data from other studies [10,15,18,21] but can be deduced from the policy of our department whereby we advise patients to undergo elective removal. Most surgeons no longer recommend elective removal. The indication for removal is consequently more often a symptom in other studies, especially with respect to infection. In contrast, Park et al. have reported patient demand as the main reason for removal; in their study, the surgeon did not recommend elective plate removal, and surgery was only performed because of patient request or symptoms [5]. The frequency of patient request averaged 16.7% in the present study increasing in the second postoperative year.

Furthermore, our patient survey revealed a high rate of patient satisfaction after removal. Benefit from removal surgery was claimed by 86% of all patients and 71.4% of the patients suffering from postoperative complications after removal as viewed from their own standpoint. Remarkably, most of the patients considered the burden of plate removal to be no more severe than leaving the plates in situ. This topic is not easy to evaluate, because a single person cannot experience both scenarios, namely, the removal and the permanence of the plates. In the literature, no evidence can be found for the subjective benefit to patients after plate removal in maxillofacial surgery. Reith et al. performed a similar survey regarding all bones with the highest removal rate at the ankle joint and the wrist.
Surgeon recommendation was also the most common indication for removal. Patient satisfaction was based on the improvement of symptoms [22]. Considering the high patient satisfaction after elective removal, the policy of leaving asymptomatic plates in situ as the most beneficial option for the patient becomes questionable. Leaving the plates in situ is, for example, the routine practice in the United Kingdom, in Oman, and at the Department of Maxillofacial Surgery in Zurich [4,23,24]. Another study mentions geographical reasons as being a positive influence on the policy of removal [13]. Thoren et al. have observed that patients experiencing the chilly climate in Finland remark on their discomfort attributable to the cold sensitivity of the inserted plates [17]. However, a second surgery is always a risk for the patient, especially for elderly or multimorbid patients, and this risk needs to be taken into consideration. Removal surgery can be a difficult surgical procedure, for example, when the plates are overgrown by bone or because of systemic diseases of a patient. Moreover, the additional costs of routine removal surgery are considerable for the health system.

It should be taken into consideration that an effective postoperative management is essential for the patient’s well-being. Modern research is debating on pain caused by dental procedures. Isola et al. report favorable effects of lornoxicam compared to flurbiprofen or placebo. A reduction of swelling by lornoxicam was not registered. Another study of Isola et al. favors etoricoxib compared to diclofenac and placebo. However, both studies evaluated postoperative pain after third molar surgery [25,26]. Ibuprofen was rated as equally effective for pain treatment compared to lornoxicam in another study. Moreover, non-steroidal anti-inflammatory drugs (NSAIDs) optimally dosed commonly provide a high patient satisfaction [27,28].

The evaluation of postoperative discomfort after plate removal should be accomplished by further studies, since studies focusing this important aspect are lacking. A procedure-specific treatment is desirable [29]. The studies can profit by using internationally well-established pain scales, e.g., Numeric Rating Scale or Visual Analogue Scale [29].

Controversial opinions with regard to plate removal have also been expressed in orthognathic surgery. A meta-analysis of Gómez-Barrachina et al. revealed that plate removal was indicated in 13.4% patients. The main cause for removal was infection (6.6%) followed by plate exposure and thermal sensitivity. Similar to our study, the study of Gómez-Barrachina et al. evaluated risk factors predisposing patients to plate removal in orthognathic surgery. Significant risk factors were female sex, nicotine abuse, and plates in the lower jaw. Except for the category of female sex, this observation is mostly congruent with our results [30]. Other studies in the field of orthognathic surgery agree with ours, especially with regard to smoking and plates in the mandible as risk factors [31–33].

The limitation of the present study is its lack in the follow-up of patients without removal surgery. The satisfaction of patients with and without removal surgery has to be assessed in further studies, at best in a randomized trial. Another limitation of the study is the small number of patients who completed the survey of part II of the study. Consequently, the results need to be viewed with caution and require further investigation to provide stronger evidence. A combination of the survey with an internationally validated and accredited score would be reasonable. Nevertheless, our study has registered that the individual benefit of plate removal is high.

5. Conclusions

Based on the initially defined risk factors, this study has confirmed that mandibular fractures and nicotine abuse can predispose to plate removal because of complications after osteosynthesis. The most common indication for plate removal was surgeon recommendation. Moreover, the results of the survey suggest that patients can benefit from removal surgery because of the subsequent relief of ongoing symptoms or personal fears.

Author Contributions: Conceptualization, O.B., C.G., K.-D.W., A.K.; methodology, O.B., C.G.; software, O.B., C.G., L.B.; validation, O.B., C.G., L.B.; formal analysis, O.B., C.G., L.B.; investigation, O.B., C.G., L.B.; resources, O.B., C.G., L.B.; data curation, O.B., C.G., L.B.; writing—original draft preparation, O.B., C.G., L.B., A.K., K.-D.W.; writing—review and editing, O.B., C.G., L.B., A.K., K.-D.W.; visualization, O.B., C.G., L.B., A.K., K.-D.W.; supervision, O.B., C.G.; project administration, O.B., C.G.; funding acquisition, no funding. All authors have read and agreed to the published version of the manuscript.
Funding: This research received no external funding.

Acknowledgments: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Conflicts of Interest: The authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers’ bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements) or non-financial interest (such as personal or professional relationships, affiliations, knowledge, or beliefs) in the subject matter or materials discussed in this manuscript.

Appendix A

Patient survey
1. Questions regarding the first surgical intervention (insertion of the plates)
   Did you experience complications?
   Yes  No
   Please specify your complications:
   - Foreign body sensation
   - Infection
   - Exposed plate
   - Paralysis
   - Bleeding
   - Swelling
   - Changed appearance
   - Weather sensitivity

2. Questions regarding the second surgical intervention (removal of the plates)
   Did you experience complications?
   Yes  No
   Please specify the complications:
   - Foreign body sensation
   - Infection
   - Exposed plate
   - Paralysis
   - Bleeding
   - Swelling
   - Changed appearance
   - Weather sensitivity

Did you benefit from the plate removal?
   Yes  No
   Please describe the reason for the benefit:_____________________

Did you consider plate removal as an immense burden?
   Yes  No
   Was the burden of plate removal retrospectively more severe than the possibility of leaving the plates in situ?
   Yes  No
   What was the reason for your decision to undergo plate removal?
   - Surgeon recommendation
   - My own request without any complaints
   - Complaints What sort of complaints? _________________________
   Other reasons:_________________________
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