# Comparison of Biodegradable and Titanium Fixation Systems in Maxillofacial Surgery: A Two-year Multi-center Randomized Controlled Trial

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# Comparison of Biodegradable and Titanium Fixation Systems in Maxillofacial Surgery: A Two-year Multi-center Randomized Controlled Trial

## ABSTRACT

Biodegradable osteosynthesis could reduce/delete the problems associated with titanium plate removal. The aim of the present study was to compare the clinical performance in the first 2 post-operative years between a biodegradable and a titanium system in oral and maxillofacial surgery. The multicenter randomized controlled trial (RCT) was performed in the Netherlands from December 2006 to July 2009. Included were 230 patients who underwent a bilateral sagittal split osteotomy (BSSO) and/or a Le Fort-I osteotomy and those treated for fractures of the mandible, maxilla, or zygoma. The patients were randomly assigned to a titanium group (KLS Martin) or to a biodegradable group (Inion CPS). Plate removal was necessary in 16 of the 134 patients (11.9%) treated with titanium and in 21 of the 87 patients (24.1%) treated with the biodegradable system within the first 2 post-operative years [$p = .016$, HR biodegradable (95% CI) = 2.2 (1.1-4.2), HR titanium = 1]. Occlusion, VAS, and MFIQ scores showed that both groups had good mandibular function and were (almost) free of pain 1 and 2 years post-operatively (http://controlled-trials.com ISRCTN 44212338).

**KEY WORDS:** surgical fixation devices, oral surgery, oral surgical procedures, maxillofacial injuries, treatment outcome, safety.

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## INTRODUCTION

Titanium is regarded as the "gold standard" for osteosynthesis. Because of sequelae, titanium must be removed following bone healing, in a second operation, in 5% to 40% of the cases (Matthew and Frame, 1999; Kuhlefelt *et al.*, 2010).

Biodegradable plates and screws have been developed to dissolve in the human body, to reduce or even eliminate the problems associated with titanium.

Biodegradable fixation systems may also have their limitations. Adverse tissue reactions to degradation products have been reported (Bergsma *et al.*, 1995; Bostman and Pihlajamaki, 2000). According to the literature, biodegradable osteosynthesis must be removed in a second operation in 0% to 31% of the cases (Landes and Ballon, 2006; Ferretti, 2008)

Most studies reported in the literature comparing biodegradable and titanium osteofixation devices were not randomized controlled trials (RCTs), and the RCTs that are available have a relatively short follow-up (Buijs *et al.*, 2006). We therefore conducted a randomized controlled clinical trial comparing titanium *vs*. a biodegradable fixation system with a long follow-up period. The trial design and short-term outcomes after 8 wks of healing have been previously published (Buijs *et al.*, 2012). Briefly, short-term healing outcomes were similar between biodegradable and titanium fixation, although, in a significant proportion (25/117) of patients randomized to the biodegradable fixation system, the operating surgeons decided intra-operatively to switch to the titanium system, due to either technical complications such as non-grip of the screws or for other reasons. Details regarding these switches have been described elsewhere (van Bakelen *et al.*, in press).

The aim of the present paper was to compare the clinical performance between the biodegradable and the titanium fixation systems after 24 mos of follow-up regarding fixation of mandibular, Le Fort-I, and zygomatic fractures, and bilateral sagittal split osteotomies (BSSO) and/or Le Fort-I osteotomies.

## MATERIALS & METHODS

This RCT has been described according to the CONSORT statement 2010 (http://www.consort-statement.org/).

### Study Population

Recruitment for this RCT was performed from December 2006 to July 2009. Two hundred thirty patients were treated at 4 different departments of Oral and Maxillofacial (OMF) Surgery in the Netherlands (University Medical Centre Groningen, Rijnstate Hospital Arnhem, Amphia Hospital Breda, and Medical Centre Leeuwarden).

The inclusion and exclusion criteria are summarized in Table 1. All patients provided informed consent prior to enrollment. Details regarding the randomization procedure have been described in detail elsewhere (Buijs *et al.*, 2012). The study was approved by the Medical Ethical Committees of the participating hospitals.

**Table 1.** Inclusion and Exclusion Criteria

*Inclusion Criteria*:
- patients scheduled for a Le Fort-I fracture, and/or a solitary or multiple (maximum 2) mandibular fracture(s), and/or a zygoma fracture
- patients scheduled for a Le Fort-I osteotomy and/or a bi-lateral sagittal split osteotomy (BSSO)
- patients (also parents or responsible persons, if necessary) who signed the *informed consent* document

*Exclusion Criteria*:
- patients who were younger than 18 years old (trauma), or patients who were younger than 14 years (osteotomies)
- patients presented with heavily comminuted fractures of the facial skeleton
- patients who had experienced compromised bone healing in the past
- patients who were pregnant
- patients who could/would not participate in a one-year follow-up (reasons)
- patients who would not agree with an *at random* assignment to one of the treatment groups, or with one of the methods or treatments administered in the study
- patients who were diagnosed with a psychiatric disorder (diagnosed by a psychiatrist)
- patients who had experienced cleft lip and palate surgery in the past
- patients where fracture reduction and fixation were delayed for more than 7 days (after day of trauma)
- patients whose general health and/or medication could affect bone healing, as determined by the oral and maxillofacial surgeon

### Interventions

The patients were assigned to a titanium control group (KLS Martin, Gebrüder Martin GmbH & Co., Tuttlingen, Germany) or to a biodegradable test group (Inion CPS, Inion Ltd., Tampere, Finland). Neither prior to nor after surgery were the patients informed of the system that had been used.

All plates and screws were applied according to the manufacturers' instructions. For fixation of mandibular osteotomies and fractures, 2.5-mm biodegradable or 2.0-mm titanium plates and screws were used, while 2.0-mm biodegradable or 1.5-mm titanium plates and screws were used for fixation of zygoma fractures, Le Fort-I fractures, and Le Fort-I osteotomies. Each participating OMF surgeon performed 2 'test surgeries' using the biodegradable system to acquire the different application skills, *i.e.*, pre-tapping the screw holes and pre-heating the plates, and getting used to the different dimensions of the material. These 'test surgeries' were not included in the study. Post-operatively, the patients did not receive rigid maxillomandibular fixation, but soft guiding elastics, and were instructed to eat a soft diet for 5 wks. In the design of the RCT, it was agreed that routine removal of asymptomatic plates would not be performed.

### Outcome Measures

The most important outcome variable in the current study was the removal of the plates/screws (yes/no) within the first 2 post-operative yrs after treatment with the biodegradable or the titanium system, with the time of removal, *i.e.*, survival time, taken into account. The 25 intra-operative switches from the biodegradable to the titanium system possibly influenced plate removal.

The following other outcome measures were assessed:

(1) reasons for plate/screw removal;
(2) clinical: correct occlusion (yes/no), palpability of plate/screw (yes/no), wound dehiscence (yes/no), abscess formation (yes/no), and signs of inflammation (rubor, calor, dolor, tumor, or functio leasa: yes/no);
(3) radiographic: correct position of the bone segments (yes/no), position of teeth, path of mandibular canal, and contour of cortical structures;
(4) patient-related (self-evaluation): pain reported on a visual analog scale (VAS; range, 1-100) and mandibular function evaluated by the 17 questions on the Mandibular Function Impairment Questionnaire (MFIQ) (Stegenga *et al.*, 1993); range, 17 to 85: a higher score means worse function; and
(5) interventions within the first and second post-operative yrs: wound irrigation with saline (yes/no), use of antibiotics (yes/no), abscess incision and drainage (yes/no).

The outcome measures were evaluated 1 and 2 yrs post-operatively by a colleague of the surgeon performing OMF surgery and recorded on Case Report Forms. The following radiographs were taken during these outpatient visits: an orthopantomogram (OPT; all indications), a lateral cephalogram (osteotomies), an occipito-mental radiograph (zygomatic fracture), and a fronto-suboccipital radiograph (mandible fracture). Data from unplanned intermediate outpatient visits – such as time-to-event data, *i.e.*, plate removals – were recorded on Case Report Forms.

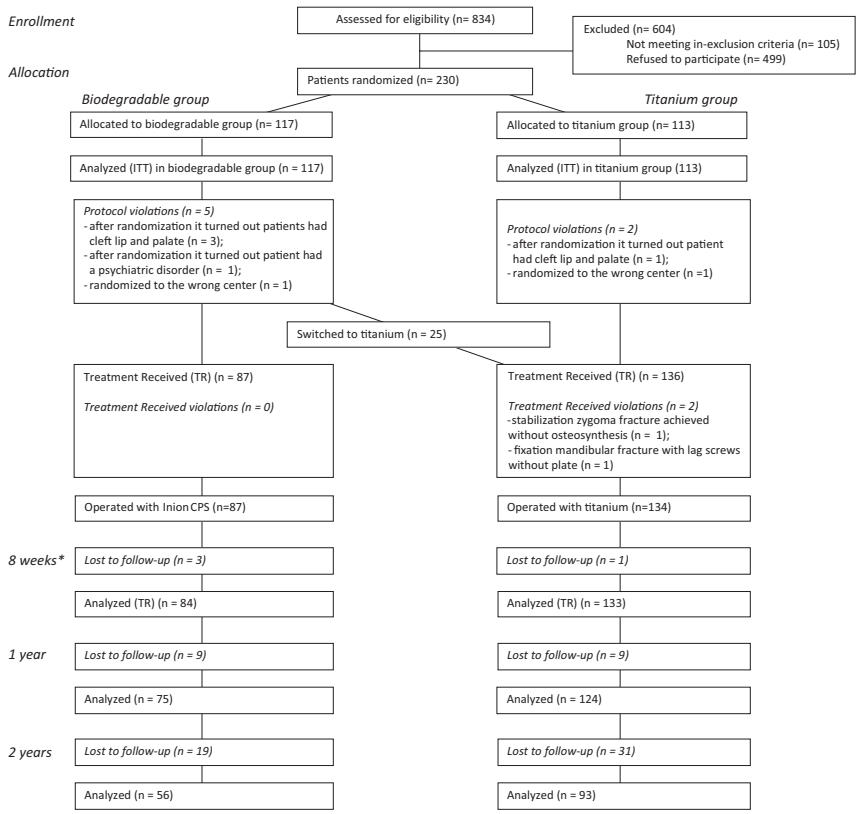


**Figure 1.** Flow diagram of patients' progress though the phases of RCT. *The analyses 8 wks post-operatively have been described in detail elsewhere (Buijs *et al.* 2012).

(1) the exposure time up to removal of plates that were removed during the observation time;
(2) the exposure time of plates that were not removed and could be followed for the entire observation period; these patients were censored at 2 yrs in the survival analysis;
(3) the exposure time up to the end of the observation of plates that were not removed and where patients did not complete the entire observation period as a result of reasons such as missed appointments or refusal to participate in follow-up visits (lost to follow-up). Patients in this category were contacted by telephone, and were asked if their plates had been removed during the lost-to-follow-up period. We also viewed their (digital) records. If their records showed no plate removal, no matter if they could be reached by telephone, these patients were also censored at 2 yrs.

The other post-operative interventions were analyzed in the same way. Any $p$ values less than .05 were considered statistically significant.

## Statistical Analysis

Inclusion of the 230 patients was based on power analysis with the outcome measure 'bone healing after 8 weeks' and has been described in detail elsewhere (Buijs *et al.*, 2012). The Statistical Package for the Social Sciences (SPSS, version 20.0) was used for data analysis. The means and standard deviations of normally distributed variables were calculated and analyzed by the independent-samples $t$ test. Skewed variables were either transformed to obtain normally distributed variables or (if this could not be achieved) analyzed by non-parametric tests. Dichotomous variables were analyzed by the Chi-squared or the Fisher's exact test. The survival of plate removal between the biodegradable and the titanium groups was analyzed by the Logrank test (or Cox regression when the 'intra-operative switches' appeared to contribute significantly to plate removal according to a separate Logrank test, for which $\alpha$ was set at $< 0.10$). The Hazard ratio was calculated by Cox regression. The Hazard ratio and a Kaplan-Meier curve were described only when the Logrank/Cox regression for plate removal revealed a significant difference. The estimated plate removal rate was calculated by dividing the number of events (plate removal) by the total plate exposure time. The total exposure time was calculated by taking the sum of:

## RESULTS

Fig. 1 represents the flow of the 230 randomized patients during the phases of the research project. Eight wks post-operatively, there were 133 patients in the titanium group and 84 patients in the biodegradable group (Buijs *et al.*, 2012). This is the starting point of the present study. There were 18 'lost-to-follow-up' patients from 8 wks to 1 yr post-operatively. This resulted in an analysis of 124 patients in the titanium group and 75 patients in the biodegradable group after 1 yr. Another 50 patients did not complete the follow-up after 2 yrs. This resulted in 93 patients in the titanium group and 56 patients in the biodegradable group. There were significantly more men lost to follow-up and more plate removals in the lost-to-follow-up patients (Appendix Table).

All baseline characteristics did not differ significantly between the biodegradable and titanium groups after 1 and 2 yrs (Table 2).

Regarding the removal of the plates/screws within the first 2 post-operative yrs, there were 16 of the 134 patients (11.9%) who received titanium and 21 of the 87 patients (24.1%) who received the biodegradable system who needed a second operation to remove the plates/screws (Table 2; Fig. 2). Thirteen of these removals were seen in the 72 patients who did not complete the entire observation period of 2 yrs. Viewing the records of the other 59 lost-to-follow-up patients revealed 3 extra plate

**Table 2.** Baseline Characteristics and Outcome Measures after 1 Year and 2 Years

| | 1 Year | | | 2 Years | | |
|---|---|---|---|---|---|---|
| Description | Titanium (n) | Biodegradable (n) | *p* value* | Titanium (n) | Biodegradable (n) | *p* value* |
| **Baseline characteristics†** | | | | | | |
| Surgical procedures | 124 | 75 | | 93 | 56 | |
| BSSO | 83 (66.9%) | 46 (61.3%) | .62 | 61 (65.6%) | 37 (66.1%) | .21 |
| Le Fort-I osteotomy | 7 (5.6%) | 7 (9.3%) | | 5 (5.4%) | 6 (10.7%) | |
| Bi-maxillary osteotomy | 26 (21.0%) | 14 (18.7%) | | 24 (25.8%) | 10 (17.9%) | |
| Mandibular fracture | 4 (3.2%) | 4 (5.3%) | | 3 (3.2%) | 1 (1.8%) | |
| Le Fort-I fracture | 1 (0.8%) | 0 | | 0 | 0 | |
| Zygoma fracture | 3 (2.4%) | 4 (5.3%) | | 0 | 2 (3.6%) | |
| Gender/age distribution | | | | | | |
| Male | 51 (41.1%) | 36 (48%) | .38 | 35 (37.6%) | 23 (41.1%) | .73 |
| Female | 73 (58.9%) | 39 (52%) | | 58 (62.4%) | 33 (58.9%) | |
| Age (mean ± SD in yrs) | 31 ± 11 | 31 ± 12 | .92 | 31 ± 11 | 33 ± 12 | .37 |
| (range in yrs) | 16-60 | 15-59 | | 16-59 | 15-59 | |
| **Outcome measures** | | | | | | |
| Post-operative interventions‡ | | | | | | |
| Removal of plates/screws [n (%)] | 13/134 (9.7%) | 19/87 (21.8%) | | 16/134 (11.9%) | 21/87 (24.1%) | .016 |
| Removals, surgical procedures | | | | | | .62 |
| Removals, osteotomies | 10/124 (8.1%) | 19/79 (24.1%) | | 13/124 (10.5%) | 21/79 (26.6%) | |
| BSSO | 7/87 (8.0%) | 15/55 (27.3%) | | 9/87 (10.3%) | 17/55 (30.1%) | |
| Le Fort-I osteotomy | 0/8 | 0/8 | | 0/8 | 0/8 | |
| Bi-maxillary osteotomy | 3/29 (10.3%) | 4/16 (25%) | | 4/29 (13.8%)¶ | 4/16 (25%)# | |
| Removals, fractures | 3/10 (30%) | 0/8 | | 3/10 (30%) | 0/8 | |
| Mandibular fracture | 2/6 (33.3%)‖ | 0/4 | | 2/6 (33.3%)‖ | 0/4 | |
| Le Fort-I fracture | 0/1 | 0/0 | | 0/1 | 0/0 | |
| Zygoma fracture | 1/3 (33.3%) | 0/4 | | 1/3 (33.3%) | 0/4 | |
| Irrigation with saline [n (%)] | 0 | 2 (2.3%) | | 1 (0.7%) | 2 (2.3%) | .33 |
| Antibiotics [n (%)] | 10 (7.5%) | 7 (8.0%) | | 11 (8.2%) | 8 (9.1%) | .78 |
| Abscess incision and drainage [n (%)] | 1 (0.7%) | 0 | | 2 (1.5%) | 2 (2.3%) | .66 |
| Clinical assessments† | | | | | | |
| Non-correct occlusion | 15 (12.1%) | 5 (6.7%) | .33 | 11 (11.8%) | 6 (10.7%) | > .99 |
| Palpability of plate/screw• | 44 (38.9%) | 39 (69.6%) | < .001 | 44 (51.2%) | 28 (68.3%) | .085 |
| Dehiscence | 1 (0.8%) | 1 (1.3%) | > .99 | 0 | 0 | – |
| Abscess formation | 3 (2.4%) | 2 (2.7%) | > .99 | 0 | 1 (1.8%) | .37 |
| Inflammatory reactions | 4 (3.2%) | 6 (8.0%) | .18 | 0 | 5 (8.9%) | .006 |
| Radiographic assessment† | | | | | | |
| Changed position bone segments | 1 (0.8%) | 0 | > .99 | 0 | 0 | – |
| Self-evaluation of patient† | | | | | | |
| Pain VAS (mean ± SD) | 1 ± 7 | 2 ± 9 | .45 | 2 ± 9 | 2 ± 6 | .93 |
| MFIQ ( median)** | 21 | 17 | .006 | 19 | 17 | .001 |
| (range) | 17-39 | 17-44 | | 17-42 | 17-44 | |

*Two-tailed test.
†Analyses performed without the Protocol violations, the Treatment Received violations, and lost-to-follow-up patients (see Fig. 1).
‡Percentages (%) on total Treatment-received group of 221 patients: 134 patients in the titanium group, and 87 patients in the biodegradable group. The numbers (and percentages) given at '2 Years' include the numbers after '1 Year'. There were five biodegradable-randomized patients with an intra-operative switch to the titanium fixation system, who needed plate removal within the first post-operative year. For analysis, these 'switches' were added to the titanium group. There were no titanium-randomized patients with an intra-operative switch to the biodegradable system. The 'intra-operative switches' did not significantly contribute to plate removal ($p = .59$), or to any of the other post-operative interventions (data not shown). Therefore, the treatment variable, *i.e.*, biodegradable or titanium, was tested (univariately) in the analyses of the post-operative interventions using the Logrank. A separate Logrank test showed no significant difference in plate removal percentages between the surgical procedures ($p = .62$).
¶Removal of plates/screws in the mandible as well as the maxilla.
#Removal of plates/screws only in the mandible.
‖These 2 removals of plates/screws were at patients' requests for asymptomatic plates/screws. All the other removals in Table 2 were due to clinical problems, *i.e.*, swelling, dehiscence, infection, abscess formation, screw loosening, irritation/pain.
•The patients in whom the plates/screws were removed were not included in the analysis.
**The mandibular function was evaluated by the 17 questions of the MFIQ (Stegenga *et al.*, 1993); range, 17-85; a higher score means worse function.
Abbreviations: BSSO = bilateral-sagittal-split osteotomy, MFIQ = Mandibular Function Impairment Questionnaire, n = number, SD = standard deviation, VAS = visual analog scale (range, 1-100).

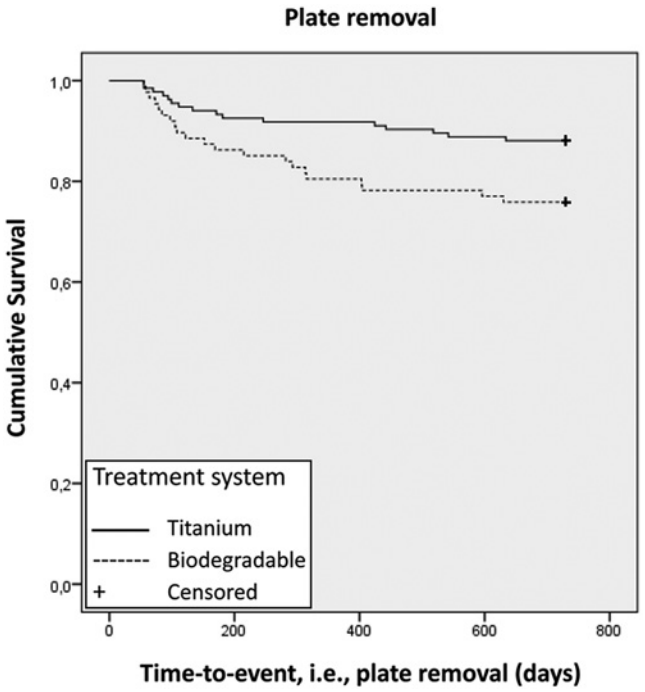


**Figure 2.** Kaplan-Meier curve of plate removal for the first 2 post-operative yrs on total Treatment-received group (n = 221: titanium n = 134, biodegradable n = 87). Hazard Ratio (HR) biodegradable = 2.2 (95% CI: 1.1-4.2), HR titanium = 1; $p$ = .016.

removals, and no other post-operative interventions. Forty of the other 56 patients could be contacted by telephone. This revealed no extra interventions. The 'intra-operative switches' did not contribute significantly to plate removal ($p$ = .59), nor did they contribute to any of the other post-operative interventions (data not shown). Therefore, the treatment variable, *i.e.*, biodegradable or titanium, was tested (univariately) in the plate removal analysis by the Logrank: $p$ = .016 [hazard ratio (HR) biodegradable (95% CI) = 2.2 (1.1-4.2), HR titanium = 1].

In the biodegradable group, all 21 removals were due to clinical problems located in the mandible and were seen in the 79 patients (26.6%) treated with an osteotomy. In the titanium group, 2 of the 16 removals (12.5%) were at the request of mandibular fracture patients with clinically asymptomatic plates/screws. All the other removals (87.5%) were due to clinical problems and, with one exception, were seen only in patients who had undergone an osteotomy.

Abscess formation was the main reason for plate/screw removal in both groups: 12 of the 21 removals (57.1%) in the biodegradable group, and 10 of the 16 removals (62.5%) in the titanium group.

The analysis after 1 yr showed significant differences regarding palpability (titanium 38.9% *vs*. biodegradable 69.6%; $p <$ .001) and MFIQ [titanium: median 21 (17-39) *vs*. biodegradable: median 17 (17-44); $p$ = .006]. There were no significant differences regarding occlusion, dehiscence, inflammatory reactions, and position of the bone fragments 52 wks post-operatively. Self-evaluation of pain revealed VAS scores near zero for both groups. The post-operative interventions 'wound irrigation with saline', 'use of antibiotics', and 'abscess-incision-and-drainage' within the first post-operative year did not differ significantly between groups. Analysis after 2 yrs revealed significant differences regarding inflammatory reactions [titanium 0/93 *vs*. biodegradable 5/56 (8.9%); $p$ = .006] and MFIQ [titanium: median 19 (17-42) *vs*. biodegradable: median 17 (17-44); $p$ = .001].

## DISCUSSION

Analysis revealed that the biodegradable system (Inion CPS) performed inferiorly to the titanium system (KLS Martin) in terms of plate/screw removal. The risk for removal when biodegradable plates and screws were used was 2.2 times higher than that when titanium was used, within the first 2 post-operative yrs.

In the biodegradable group all plate/screw removals and in the titanium group nearly all removals were due to clinical problems located in the mandible, due mainly to abscess formation. This is possibly related to the morphology of the bone and the lesser vascularization of the mandible as compared with other parts of the facial skeleton. In the biodegradable group, there were no removals in patients who were treated for a fracture, probably because of the relatively low number of fractures included in this study.

Despite the RCT protocol prescribing non-removal of asymptomatic plates, in the titanium group there were 2 removals of clinically asymptomatic plates/screws at the patients' request.

The reasons for inflammatory reactions/abscess formations are unclear. Bacterial cultures were taken in only a few (three) patients with biodegradable plate removal. These cultures showed sterile inflammatory reactions. We speculate that these inflammatory reactions are due to the degradation phase. As long as the biodegradable material is solid (in the early stages), only a fibrous capsule is formed. At the moment that small particles, which can undergo phagocytosis, have developed (at later stages), a foreign body reaction develops (Bergsma *et al.*, 1995). A low pH, caused by lactic acid (degradation product), may contribute (Grizzi *et al.*, 1995; Vert *et al.*, 1998).

Occlusion, VAS, and MFIQ scores showed that the patients in both groups had good mandibular function and were (almost) free of pain 1 and 2 yrs post-operatively. We believe that the small difference in MFIQ is not clinically relevant.

One yr post-operatively, there were more patients in the biodegradable group in whom the plates/screws were palpable. After 2 yrs, there were no significant differences in palpability. According to the manufacturer, this can be expected, since full resorption of Inion CPS should take place within 2 to 4 yrs (Nieminen *et al.*, 2008).

Many other studies have reported plate removal in OMF surgery. Titanium plate removal in trauma surgery (5-40%) (Matthew and Frame, 1999; Bakathir *et al.*, 2008) and in orthognathic surgery (7-19%) has been described (Manor *et al.*, 1999; Kuhlefelt *et al.*, 2010). For biodegradable systems, these percentages are 0% to 31% (Ferretti, 2008; Lee *et al.*, 2010) and 0% to 3% (Laine *et al.*, 2004; Mazzonetto *et al.*, 2004; Landes and Ballon, 2006), respectively. None of these studies was a RCT, so no firm conclusion can be drawn.

There are few RCTs that compared Inion with titanium plate removal. Bhatt *et al.* (2010) reported 0% biodegradable *vs*. 31% titanium (Synthes) plate removal in 40 patients treated for

mandibular fractures (Bhatt *et al.*, 2010). These percentages are similar to the removal percentages for mandibular fractures in our study. Their follow-up period was only 8 post-operative wks, while in our study most removals occurred beyond that period. Leonhardt *et al.* (2008) also compared Inion with the KLS Martin titanium system in the treatment of mandibular fractures (Leonhardt *et al.*, 2008). They reported removal of clinically symptomatic plates in five of the 30 patients (16.6%) in the biodegradable group, and in four of the 30 patients (13.3%) in the titanium group in the first 6 post-operative mos. In this study, on occasion, unavailability of the required plating system obscured randomization. In our study, there were no removals of clinically symptomatic plates/screws in patients treated for a mandibular fracture.

The titanium plate removal percentages do not outweigh the (disturbing) intra-operative switching from the biodegradable to the titanium system. In fact, there were even more plate removals in the biodegradable group.

It is unclear why significantly more men were lost to follow-up. We believe that this did not influence the outcome of the post-operative interventions, *i.e.*, plate removal, because we viewed the patients' records and contacted them by telephone. Theoretically, for the patients who could not be contacted by telephone, it could be possible that a plate was removed in a hospital other than that in which the patient's surgery was performed, but this is highly unlikely.

The study was performed in 4 different hospitals, and no center effect for plate removal could be identified (data not shown). It can therefore be expected that the results of the use of the Inion CPS biodegradable system in other hospitals will be similar to those from our study.

In conclusion, in terms of plate/screw removal within the first 2 post-operative years, the performance of the Inion CPS biodegradable system is inferior compared with that of the titanium KLS Martin system for fixation of mandibular, Le Fort-I, and zygomatic fractures, and BSSOs and/or Le Fort-I osteotomies. Given the rates of plate removal and the intra-operative switches from the biodegradable system to the titanium system, there seems to be no place for the clinical usage of Inion CPS in treatment of these surgical situations. To put the usage into a broader perspective, it is also necessary to take relapse and cost-effectiveness into account.

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