Journal of Cranio-Maxillo-Facial Surgery 42 (2014) 417–422

Contents lists available at SciVerse ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Decision-making considerations in application of biodegradable fixation systems in maxillofacial surgery – A retrospective cohort study

N.B. van Bakelen [a,*], G.J. Buijs [a], J. Jansma [a,1], J.G.A.M. de Visscher [b,1], Th.J.M. Hoppenreijs [c,1], J.E. Bergsma [d,1], B. Stegenga [a,e], R.R.M. Bos [a,1]

[a] Department of Oral and Maxillofacial Surgery, University Medical Centre Groningen, University of Groningen, P.O. Box 30.001, 9700 RB Groningen, The Netherlands
[b] Department of Oral and Maxillofacial Surgery, Medical Centre Leeuwarden, P.O. Box 888, 8901 BR Leeuwarden, The Netherlands
[c] Department of Oral and Maxillofacial Surgery, Rijnstate Hospital Arnhem, 6800 TA Arnhem, P.O. Box 9555, The Netherlands
[d] Department of Oral and Maxillofacial Surgery, Amphia Hospital Breda, P.O. Box 90.158, 4800 RK Breda, The Netherlands
[e] UMCG Centre for Dentistry and Oral Hygiene, Department Oral Health Care & Clinical Epidemiology, University Medical Centre Groningen, University of Groningen, P.O. Box 30.001, 9700 RB Groningen, The Netherlands

ARTICLE INFO

Article history:
Paper received 20 August 2012
Accepted 10 May 2013

Keywords:
Intra-operative switches
Predictor variables
Learning curve
Handling characteristics
Surgeons' opinion
Osteosynthesis

ABSTRACT

In a recent RCT comparing biodegradable (Inion CPS) with titanium (KLS Martin) plates and screws for fixation of osteotomies or fractures, we found that in 21% of the cases the surgeon decided intra-operatively to switch from biodegradable to titanium.

The aim of the current retrospective cohort study was to analyse the reasons for these switches in order to find predictor variables that may be helpful in the decision to use biodegradable devices or not. The surgeons' opinion about the biodegradable system, and if there was a learning curve in the application of the biodegradable system were also investigated.

All variables were assessed during the original RCT by using a questionnaire that was completed by the OMF surgeon directly post-operatively. For the outcome variable "surgeons' opinion" a separate questionnaire was used.

Regarding the predictor variables a mandibular fracture had a higher risk of switching compared to a BSSO. However, looking at the reasons for these switches no firm conclusions can be drawn. There was a subjective learning curve to acquire the application-skills for the biodegradable system. There were no changes in isolated Le-Fort-I osteotomies despite the fact that the biodegradable system seems more difficult to apply in the midface. Inadequate stability was the main reason for switching. This can be material-related, or related to inexperience with or lack of confidence in the system, or impatience of the surgeon.

A learning curve and personal preferences probably play an important role in the decision to switch. We think that with more patience and more experience it should be possible to increase both user comfort and confidence in the biodegradable system of Inion CPS, which likely will decrease the number of intra-operative switches.

© 2013 European Association for Cranio-Maxillo-Facial Surgery. Published by Elsevier Ltd. All rights reserved.

1. Introduction

There seems to be a learning curve to acquire the application-skills needed to use biodegradable plates and screws (Singh et al., 2011). When application of biodegradable plates and screws fails, this will result into an intra-operative switch to commonly used titanium plates and screws. Recently, this has also been shown in the study of Buijs et al., 2012. In this study, patients were included who underwent bi-lateral-sagittal-split osteotomies (BSSO), Le Fort-I or bi-maxillary osteotomies and patients with fractures of the mandible, maxilla, or zygoma. In the Intention-To-Treat (ITT)-analysis, there were 117 patients in the biodegradable test-group and 113 patients in the titanium control-group. In the biodegradable-randomized group, there were 25 patients (21%) with an intra-

* Corresponding author. Tel.: +31 503613844.
E-mail address: n.b.van.bakelen@umcg.nl (N.B. van Bakelen).
[1] Participating as a senior OMF surgeon in the current study.

1010-5182/$ – see front matter © 2013 European Association for Cranio-Maxillo-Facial Surgery. Published by Elsevier Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.jcms.2013.05.032

operative switch to the titanium fixation system. Despite the intraoperative switch, all the patients showed uncomplicated bone healing post-operatively. There were no switches from the titanium to the biodegradable system.

The purposes of this study were: (1) to identify factors associated with surgeons' decisions to switch from one system to the other, and (2) to determine if there was a learning curve in the use of the biodegradable fixation system. The investigators hypothesize that there are factors associated with the decision to switch, and that there is a learning curve. Patient variables, the type of surgical procedure and individual preferences/experience of the Oral and Maxillofacial (OMF) surgeons were investigated.

2. Materials & methods

2.1. Study design

This retrospective cohort study was derived from a previous performed Randomized Controlled Trial (RCT) of Buijs et al., 2012, and has been described according to the STROBE statement (http://www.strobe-statement.org/).

2.2. Patients

To be included in the cohort study sample, patients had to be enrolled in the original RCT and randomized to biodegradable fixation. In the original RCT 117 patients were randomized to the biodegradable system, and 113 patients to the titanium system. Five patients in the biodegradable group and 2 patients in the titanium group were protocol violators and were excluded from further analyses.

The original RCT was conducted from December 2006 to July 2009. The patients were treated at four different departments of OMF Surgery in the Netherlands (University Medical Centre Groningen, Rijnstate Hospital Arnhem, Amphia Hospital Breda, and Medical Centre Leeuwarden). The inclusion and exclusion criteria of the original RCT are summarized in Table 1. All patients were informed regarding the treatment options prior to surgery and had to provide informed consent to participate in the study.

Table 1
In- and exclusion criteria of the original prospective multicentre RCT.

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 form.
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 experienced compromised bone healing in the past;
- patients who were pregnant;
- patients who could/would not participate in a 1-year follow-up (reasons);
- patients who would not agree with an at random assignment to one of the treatment groups, or one of the methods or treatment administered in the study;
- patients who were diagnosed with a psychiatric disorder (diagnosed by a psychiatrist);
- patients who experienced cleft lip and palate surgery in the past;
- patients where fracture reduction and fixation was delayed for more than 7 days (after day of trauma);
- patients of whom the general health and/or medication could affect bone healing, as determined by the oral and maxillofacial surgeon.

Patients meeting the inclusion criteria were randomly assigned to two treatment groups. A computerized program was used for randomization. The sequences were linked to a 24/7-available central telephone. The RCT was approved by the Medical Ethical Committees of the participating hospitals.

2.3. Interventions

In the original RCT 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).

All plates and screws were applied according to the instructions of the manufacturers. For fixation of mandibular osteotomies and fractures 2.5-mm biodegradable or 2.0-mm titanium plates and screws were used, whereas 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. The way mandibles and maxilla's were stabilized can be seen in Fig. 1. Each participating OMF surgeon performed 2 'test-surgeries' using the biodegradable system to acquire the different application-skills, i.e., pre-tapping the screws and pre-heating the plates, and to get used to the different dimensions. These 'test-surgeries' were not included in the study. The patients did not receive rigid maxillomandibular fixation, but soft guiding elastics post-operatively, and they were instructed to use a soft diet.

2.4. Outcome measures

The primary outcome variable in the study was the decision to switch from the biodegradable to the titanium system (yes/no).

Predictor variables that possibly influenced switching:

(1) demographic: female sex, age;
(2) type of surgical procedure: BSSO, Le Fort-I osteotomy, bi-maxillary osteotomy, fracture of the mandible, maxilla, or zygoma;
(3) Number of operations performed by a surgeon with the biodegradable system;

There were three secondary outcome measures:

(1) The "learning curve", i.e., the more operations performed by a surgeon the better the handling characteristics (plate adaptation, drilling/tapping, screw insertion, and wound closure (scale of 1–10));
(2) The differences in handling characteristics (scale 1–10), and reasons for switching (inadequate fixation versus 'other reason') between the types of surgical procedure.

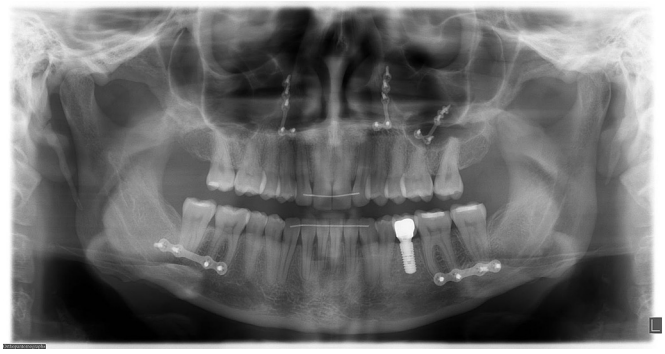

Fig. 1. Orthopantomograph showing the position of the plates and screws in a titanium bimaxillary case. Biodegradable plates and screws in 'biodegradable-cases' were placed in a similar manner, but would not be visible on the X-ray.

(3) Surgeons' opinion

All variables were assessed during the original RCT by using a questionnaire that was completed by the OMF surgeon directly post-operative. For the outcome variable "surgeons' opinion" an extra questionnaire (Table 2) was also used. The questionnaire was sent to all participating OMF surgeons ($n = 11$) who performed more than 5 operations ($n = 5$) with the biodegradable system.

2.5. Statistical analysis

The Statistical Package of Social Sciences (SPSS, version 18.0) was used to analyse the data. Differences between the groups with regard to normally distributed variables were analysed using the Independent-Samples *T*-test. For dichotomous variables Chi-Square/Fisher's Exact Tests were used. To identify predictor variables for switching, potential influencing factors were tested univariately in a logistic regression analysis. To ensure broad inclusion of possible determinants, α was set at .15 for the univariate analyses. All significant variables were then submitted for multiple logistic regression analysis. Regarding the type of surgical procedure, as predictor variable for switching, dummy variables were made. Regarding the number of operations performed by a surgeon with the biodegradable system, as predictor variable for switching, all surgeries received a rank number, i.e., the first operations by each surgeon all received the number '1', the second operations the number '2', etc. The 'learning curve' for the handling characteristics was tested in a linear regression analysis. The outcome variables for the learning curve were the intra-operative handling characteristics. The predictor variable was the rank number of operation performed by each surgeon. The difference in handling characteristics, and reasons for switching between the types of surgical procedure were tested with a One-way ANOVA and Fisher's Exact test respectively. *p*-values less than .05 were considered statistically significant.

3. Results

3.1. Baseline characteristics

The 25 'switch patients' had a mean age of 30 years (s.d. 11 yrs), and 13 (52%) were females (Table 3). The 87 'non-switch patients' had a mean age of 31 years (s.d. 12 yrs), and 44 (50.6%) were females. In 15 of the 70 patients (21.4%) who were treated with a BSSO, in 5 of the 9 (55.6%) mandible fractures, and in 5 of the 21 bi-maxillary osteotomies (23.8%) there was a switch intra-operatively. There were no switches in patients treated with a solitary Le Fort-I osteotomy or in patients treated for a zygomatic fracture. Both age, sex, and types of surgical procedure did not significantly differ between both groups (*p*-values: 0.66; >0.99; and 0.076). There were 11 OMF surgeons who performed between 1 and 5 operations with the biodegradable system (Fig. 2). In 5 of the 11 'first operations' (45%) there was a switch to titanium. There were only 5 surgeons who performed more than 5 'biodegradable-operations'. They decided to switch to titanium in 9–62% of their cases. There was one OMF surgeon who had significantly more switches (8 of his 13 operations (62%); 32% of the total amount of 25 switches) than the other surgeons ($p = 0.025$).

Table 2
Questionnaire used to evaluate the surgeons' opinion.

- Indicate what you think of the user comfort, and confidence in the system for Inion CPS as well as for KLS Martin titanium (scale 1–10);
- Are there important aspects for OMF surgeons who are planning to use Inion CPS? If so, please specify;
- Is there a difference in using Inion CPS between the different surgical procedures?;
- What problems have you encountered when using Inion CPS? And if so, is there a difference between the different types of surgical procedure?

Table 3
Sex/age distribution, and surgical procedures of the biodegradable-randomized group obtained from the original RCT ($n = 112$[a]).

Description	Non-switches[b] ($n = 87$)	Switches[b] ($n = 25$)	*p*-value
Sex/age distribution			
Male (n)	43 (49.4%)	12 (48%)	>0.99
Female (n)	44 (50.6%)	13 (52%)	
Age (mean ± s.d. in yrs) (range in yrs)	31 ± 12 14–59	30 ± 11 18–49	0.66
Surgical procedures			0.076
BSSO (n)	55 (78.6%)	15 (21.4%)	
Le-Fort-1 osteotomy (n)	8 (100%)	0	
Bi-maxillary osteotomy (n)	16 (76.2%)	5 (23.8%)	
Mandibular fracture (n)	4 (44.4%)	5 (55.6%)	
Zygoma fracture (n)	4 (100%)	0	

BSSO = Bi-lateral-Sagittal-Split Osteotomy.
n = number.
s.d. = standard deviation.
[a] The 5 biodegradable-randomized protocol violators are not included. Protocol violation: after randomization it turned out the patient met an exclusion criteria (see Buijs et al. (2012): Fig. 2).
[b] Switches and non-switches are biodegradable-randomized patients where the OMF surgeon decided to switch to the titanium system, and in whom the biodegradable application was successful, respectively.

3.2. Predictor variables

Age ($p = 0.66$; OR 0.99; 95% CI 0.96–1.03), female sex ($p = 0.9$; OR 1.1; 95% CI 0.4–2.6), and the number of 'biodegradable-operations' performed by a surgeon ($p = 0.71$; OR 0.99; 95% CI 0.95–1.04) were not statistically associated with an intra-operative change to titanium in the univariate analyses. A mandibular fracture had a higher risk of switching compared to a BSSO ($p = 0.037$; OR 4.6; 95% CI 1.1–19.2). A multiple logistic analysis was not performed, because this was the only significant variable in the univariate analyses.

3.3. Learning curves

The rank number of the operation performed by the surgeons was not statistically associated with better intra-operative handling characteristics in a linear regression (*p*-values: 0.56; 0.48; 0.27; and 0.56 for plate adaptation, drilling/tapping, screw insertion, and wound closure respectively).

3.4. Differences between the types of surgical procedure

3.4.1. Handling characteristics

As far as the handling characteristics between the surgical procedures are concerned, there was a significant difference between the operation types for screw insertion ($p = 0.023$) and wound closure ($p = 0.022$) (Table 4). The Bonferroni Posthoc Analysis revealed that for screw insertion this difference could be explained by the bi-maxillary osteotomy versus the zygomatic fracture (6.7 versus 9.5; $p = 0.04$), and for wound closure this difference could be explained by the BSSO versus the bi-maxillary osteotomy (8.6 versus 7.8; $p = 0.025$).

3.4.2. Reasons for switches

Inadequate fixation ($n = 17$), especially non-grip of the screws ($n = 6$), was the main overall reason for switching, and for each type of surgical procedure separately (Table 5). There were no significant differences between the types of surgical procedure regarding the reasons for switching ($p = 0.72$).

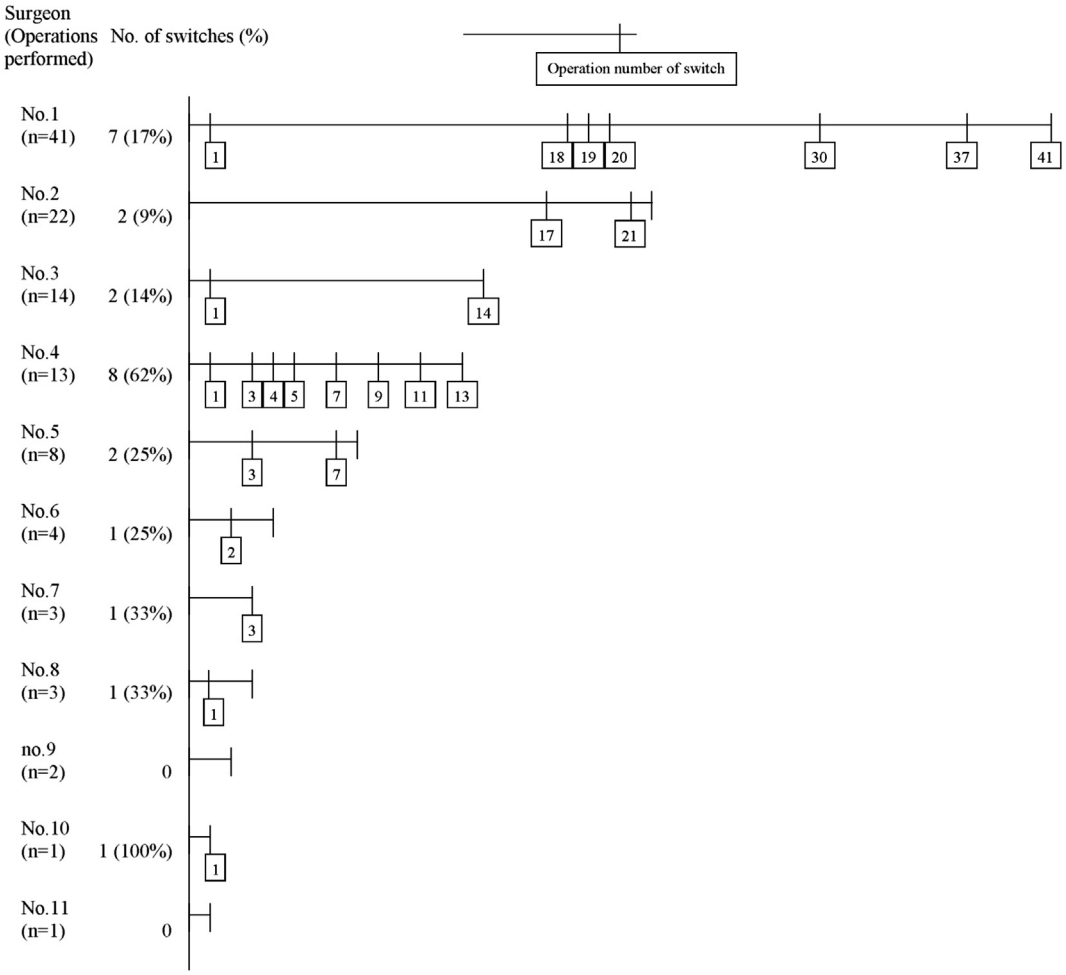

Fig. 2. There were 11 OMF surgeons who performed at least one operation with the biodegradable system. Surgeon no.1 performed a total of 41 operations with the biodegradable system. In 7 of his cases (17%) there was an intra-operative switch to titanium. These switches took place during the 1st, 18th, 19th, 20th, 30th, 37th, and 41st operation that surgeon no.1 performed. Surgeon no.4 had significantly more switches (8 of his 13 operations (62%)) than the other surgeons ($p = 0.025$). In total it seems that there was no less switching as the number of operations performed by a surgeon increased.

Table 4
Handling characteristics listed by the type of surgical procedure.

Description	BSSO ($n = 70$)	Le-Fort-1 osteotomy ($n = 8$)	Bi-maxillary osteotomy ($n = 21$)	Mandibular fracture ($n = 9$)	Zygomatic fracture ($n = 4$)	Total ($n = 112$)[a]
Handling characteristics						
Plate adaptation (Mean ± s.d.)	7.7; 1.4	6.9; 1.6	6.9; 1.9	8.0; 1.4	8.8; 1.0	7.5; 1.6
Drilling/tapping (Mean ± s.d.)	7.3; 1.4	7.1; 1.5	7.0; 2.2	7.9; 2.1	8.8; 1.0	7.3; 1.6
Screw insertion (Mean ± s.d.)[b]	7.2; 1.7	6.5; 0.9	6.7; 2.1	8.0; 1.9	9.5; 1.0	7.2; 1.8
Wound closure (Mean ± s.d.)[c]	8.6; 0.7	8.9; 0.6	7.8; 2.2	8.8; 0.8	9.0; 1.2	8.5; 1.2

BSSO = Bi-lateral-Sagittal-Split Osteotomy.
n = number.
s.d. = standard deviation.
[a] The 5 biodegradable-randomized protocol violators are not included. Protocol violation: after randomization it turned out the patient met an exclusion criteria (see Buijs et al. (2012): Fig. 2).
[b] One-way ANOVA $p = 0.023$ > Bonferroni posthoc: screw insertion bi-maxillary osteotomy versus zygomatic fracture: 6.7 versus 9.5, $p = 0.04$.
[c] One-way ANOVA $p = 0.022$ > Bonferroni posthoc: wound closure BSSO versus bi-maxillary osteotomy: 8.6 versus 7.8, $p = 0.025$.

3.5. Surgeons' opinion

The extra questionnaire was answered by all OMF surgeons ($n = 5$) who performed more than 5 'biodegradable-operations'. This showed that the user comfort of and confidence in Inion CPS was significantly less compared to the titanium system (5.6 versus 8.6, $p = 0.001$; and 6.6 versus 9.2, $p = 0.023$ respectively). All our surgeons agree that there was a learning curve to acquire the different application-skills for the biodegradable system. They also agree that in regions with thin overlying skin, i.e., the infra-orbital rim, and in regions with thin bone, i.e., the maxilla/mid-face, the Inion CPS 2.0-mm plate is relatively "bulky", and in the mid-face

Table 5
Reasons switches listed by the type of surgical procedure.

Description	BSSO ($n = 70$)	Le Fort-1 osteotomy ($n = 8$)	Bi-maxillary osteotomy ($n = 21$)	Mandibular fracture ($n = 9$)	Zygomatic fracture ($n = 4$)	Total ($n = 112$)[a]
Number of switches	($n = 15$)	($n = 0$)	($n = 5$)	($n = 5$)	($n = 0$)	($n = 25$)
	21%	–	24%	56%	–	21%
Reasons switching						
Inadequate fixation	**11**	–	**3**	**3**	–	**17**
Non-grip screws (n)	1	–	3[b]	2	–	6
Inadequate stability after first fixation attempt (n)	2	–	0	1	–	3
Inadequate stability after more fixation attempts (n)	4	–	0	0	–	4
Inadequate plate adaptation (n)	2	–	0	0	–	2
Dimension of plate too big (n)	1	–	0	0	–	1
Plate fracture (n)	1	–	0	0	–	1
Other	**4**	–	**2**	**2**		**8**
Logistic problem (n)	1	–	1	1	–	3
'Bad split' (n)	1	–	0	0	–	1
Unknown (n)	2	–	1	1	–	4

BSSO = Bi-lateral-Sagittal-Split Osteotomy.
n = number.
s.d. = standard deviation.
[a] The 5 biodegradable-randomized protocol violators are not included. Protocol violation: after randomization it turned out the patient met an exclusion criteria (see Buijs et al. (2012): Fig. 2).
[b] Two times non-grip screw on the maxilla, 1 time non-grip screw on the mandible.

area the screws are more difficult to apply. They noticed that there is no difference in using Inion CPS in trauma and orthognathic cases, and that screws need to be fixed 'finger tight' only.

4. Discussion

In this study we found that a mandibular fracture had a higher risk of switching from the biodegradable plates and screws of Inion CPS to the titanium plates and screws of KLS Martin compared to a BSSO. However, firm conclusions cannot be drawn, because one switch of the total of 5 switches seen in mandibular fractures was due to logistic problems and for another switch the reason was unknown. There was a subjective learning curve in the use of the biodegradable fixation system, which could not be objectified with statistical analysis.

It is remarkable that there was one surgeon who statistic significantly switched to titanium more often than the other surgeons. Unfortunately there is an inconsistency in the number of operations performed with the biodegradable system by each surgeon. This resulted in a large spread of switching percentages, which makes it hard to extract proper data to support firm conclusions. In retrospect the 2 test-surgeries may have been a too small an amount. Personal preferences probably also play an important role. In total it seems that there was similar switching as the number of operations performed by a surgeon increased (Fig. 2).

In contrast to our expectations switches were mainly seen in the mandible, and only in a small percentage in the maxilla. All switches in the maxilla were during bi-maxillary cases. In solitary Le-Fort-I osteotomies no switches were observed at all.

Singh et al. (2011) in a study that included 14 patients with zygomatic fractures treated with Inion reported no intra-operative switches (Singh et al., 2011). This is in conjunction with our results since we also found no switches in patients treated for zygomatic fractures. They noticed no plate fracture during manipulation, but 2 cases of screw head fracture occurred while tightening. To prevent this they stated that screws need to be fixed 'finger tight' only, and care must be taken while placing them, especially in thin bones. The surgeons in our study agree on these items. Furthermore, Singh et al. stated that the angulation and the pressure at the time of drilling and tapping are important factors in this technique-sensitive system, and that inadequate drilling or tapping length could be a reason for screw head fracture. When screw fractures occur, a new hole can be drilled through the broken screw, and after re-tapping, a new (emergency) screw may be inserted (Haerle et al., 2009; Bayat et al., 2010). We found that plate fracture was a reason to switch to titanium, screw fractures were not. In the current study inadequate fixation, especially non-grip of the screws, was the main overall reason for switching. For sufficient screw grip there has to be sufficient cortical bone. Removing too much bone, i.e., drilling too broadly, or tapping too roughly, or when screw insertion is performed too roughly (with subsequent breaking of the thread), results in non-grip of screws. The reasons for inadequate fixation can be material-related, but can also be related to inexperience or impatience of surgeons. Less confidence in the system could be another reason for switching. In our study the confidence in the biodegradable system was significantly less when compared to the titanium system. Singh et al. (2011) agree that there was a learning curve to acquire the different application-skills for the Inion biodegradable system.

Choi et al. (2011) evaluated the post-surgical relapse in maxillary surgery in 20 patients. They also used the resorbable plates of Inion CPS. In contrast to our study they did not report any intra-operative switches (Choi et al., 2011).

Paeng et al. (2012) reported on a comparative study of skeletal stability after mandibular setback between Inion CPS and a titanium system with 25 patients in both groups. They did not report any intra-operative switches, but they used bicortical screw fixation instead of the monocortical plate/screw-fixation that was used in our study (Paeng et al., 2012).

Bayat et al. (2010) in a study that included 19 patients with mandibular angle fractures treated with Inion CPS also did not report any intra-operative switches (Bayat et al., 2010).

Many authors that use different other kinds of biodegradable systems also did not report any intra-operative switches (Norholt et al., 2004; Ueki et al., 2005; Stockmann et al., 2010; Moure et al., 2012).

Wittwer et al. (2005) evaluated the clinical application of three different biodegradable fixation systems for treatment of zygomatic fractures (Wittwer et al., 2005). In this study in 23 (24.5%) of

the 94 fracture sites there was a switch to titanium plates and screws. Non-stable fixation ($n = 7$) and fixation of small fragments ($n = 16$) were the reasons for switching. They stated that biodegradable materials were frequently unfeasible for use at the infra-orbital rim and in the zygomaticomaxillary/anterior sinus wall area, probably because the biodegradable plates are too bulky in these areas. Although the surgeons in our study agree on this item in the questionnaires, the number of zygomatic fractures in our series is too small ($n = 4$) to substantiate these findings.

Unlike the study of Buijs et al., (2012), Jain et al. (2006) stated that contouring resorbable plates is easier than metallic plates (Jain et al., 2006). It has been stated that with few extra tools (i.e., heating bath, bending templates) biodegradable plates can be easily handled and adapted (Landes et al., 2003). In our study the user comfort of the biodegradable system was significantly less when compared to the titanium system. Contouring of the plates was not always easy and in a few cases inadequate plate adaptation was a reason to switch to titanium. Bos (2005) mentioned that biodegradable plate bending, pre-tapping and screw insertion are very time consuming and far more complicated than titanium (Bos, 2005). In our original RCT it is described that an operation with the biodegradable system takes 7 min longer on average than an operation with the titanium system (Buijs et al., 2012).

The extra questionnaire for the OMF surgeons who performed more than 5 'biodegradable-operations' is non-validated and limited by potential recall bias, i.e., a surgeon who decided to switch systems more often may be more apt to recall technical difficulties with instrumentation.

We could not objectify the subjective learning curve, probably because the numbers are too small. Several OMF residents performed (parts of the) surgeries for their training program. This may have resulted in lower scores and failure to identify a learning curve.

There probably would have been fewer switches when all the surgeries were performed by a smaller number of skilled and experienced surgeons, but this was practically unfeasible in OMF Training Clinics. In daily practice without residents the usage of Inion CPS may therefore be easier and may result in fewer switches.

5. Conclusion

In summary, it is concluded that analysis of the intra-operative switches showed that a mandibular fracture had a higher risk of switching compared to a BSSO. However, looking at the reasons for these switches no firm conclusions can be drawn. We found no other statistically significant predictor variables that could aid in deciding to use Inion CPS or not.

There is a subjective learning curve to acquire the application-skills for the biodegradable system of Inion CPS. A learning curve and personal preferences probably play a crucial role in the decision making process of switching. The results presented are part of a longer running follow-up study. The potential incentive to use this biodegradable fixation system, i.e., less plate removals, should be determined after at least 5 years of follow-up. This will be described elsewhere.

Sources of support

No sources of support.

Acknowledgements

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors. The authors declare that they have no conflict of interest.

References

Bayat M, Garajei A, Ghorbani K, Motamedi MH: Treatment of mandibular angle fractures using a single bioresorbable miniplate. J Oral Maxillofac Surg 68: 1573–1577, 2010

Bos RR: Treatment of pediatric facial fractures: the case for metallic fixation. J Oral Maxillofac Surg 63: 382–384, 2005

Buijs GJ, van Bakelen NB, Jansma J, de Visscher JG, Hoppenreijs TJ, Bergsma JE, et al: A randomized clinical trial of biodegradable and titanium fixation systems in maxillofacial surgery. J Dent Res 91: 299–304, 2012

Choi JY, Kim JW, Yoo CK, Yun PY, Baek SH, Kim YK: Evaluation of post-surgical relapse in maxillary surgery using resorbable plate. J Craniomaxillofac Surg 39: 578–582, 2011

Haerle F, Champy M, Terry B: Atlas of craniomaxillofacial osteosynthesis, microplates, miniplates, and screws, 2nd ed. New York: Thieme Stutgart; 137–138, 2009

Jain SA, Simmons OP, Hanemann MS, Baratta RV, Guerra AB, Metzinger SE: Comparison of tensile strength of resorbable plating systems used in monocortical mandible angle osteotomy repair. Arch Facial Plast Surg 8: 390–395, 2006

Landes CA, Kriener S, Menzer M, Kovacs AF: Resorbable plate osteosynthesis of dislocated or pathological mandibular fractures: a prospective clinical trial of two amorphous L-/DL-lactide copolymer 2-mm miniplate systems. Plast Reconstr Surg 111: 601–610, 2003

Moure C, Qassemyar Q, Dunaud O, Neiva C, Testelin S, Devauchelle B: Skeletal stability and morbidity with self-reinforced P (L/DL) LA resorbable osteosynthesis in bimaxillary orthognathic surgery. J Craniomaxillofac Surg 40: 55–60, 2012

Norholt SE, Pedersen TK, Jensen J: Le Fort I miniplate osteosynthesis: a randomized, prospective study comparing resorbable PLLA/PGA with titanium. Int J Oral Maxillofac Surg 33: 245–252, 2004

Paeng JY, Hong J, Kim CS, Kim MJ: Comparative study of skeletal stability between bicortical resorbable and titanium screw fixation after sagittal split ramus osteotomy for mandibular prognathism. J Craniomaxillofac Surg 40(8): 660–664, 2012

Singh V, Sharma B, Bhagol A: Evaluating the applicability of a biodegradable osteosynthesis plating system in the management of zygomatico-maxillary complex fractures. Otolaryngol Head Neck Surg 145: 924–929, 2011

Stockmann P, Bohm H, Driemel O, Muhling J, Pistner H: Resorbable versus titanium osteosynthesis devices in bilateral sagittal split ramus osteotomy of the mandible – the results of a two centre randomised clinical study with an eight-year follow-up. J Craniomaxillofac Surg 38: 522–528, 2010

Ueki K, Nakagawa K, Marukawa K, Takazakura D, Shimada M, Takatsuka S, et al: Changes in condylar long axis and skeletal stability after bilateral sagittal split ramus osteotomy with poly-L-lactic acid or titanium plate fixation. Int J Oral Maxillofac Surg 34: 627–634, 2005

Wittwer G, Adeyemo WL, Voracek M, Turhani D, Ewers R, Watzinger F, et al: An evaluation of the clinical application of three different biodegradable osteosynthesis materials for the fixation of zygomatic fractures. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 100: 656–660, 2005