



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. Hoppenreijns^{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.

operative switch to the titanium fixation system. Despite the intra-operative 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.

Download English Version:

<https://daneshyari.com/en/article/3142559>

Download Persian Version:

<https://daneshyari.com/article/3142559>

[Daneshyari.com](https://daneshyari.com)