Journal of Cranio-Maxillo-Facial Surgery 45 (2017) 704–709

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Comparison of functional outcomes and patient-reported satisfaction between titanium and absorbable plates and screws for fixation of mandibular fractures: A one-year prospective study

Maria Belén Leno [a, 1], Stanley Yung Liu [a, 1], Chien-Tzung Chen [d], Han-Tsung Liao [a, b, c, *]

[a] Craniofacial Research Center, Department of Plastic and Reconstructive Surgery, Chang Gung Memorial Hospital, Taoyuan, Taiwan
[b] Division of Trauma Plastic Surgery, Department of Plastic and Reconstructive Surgery, Chang Gung Memorial Hospital, 5, Fu-Shing Street, Kuei-Shan, Taoyuan, 333, Taiwan
[c] College of Medicine, Chang Gung University, Kuei-shan, Taoyuan, Taiwan
[d] Department of Plastic and Reconstructive Surgery, Chang Gung Memorial Hospital at Keelung, College of Medicine, Chang Gung University, Craniofacial Research Center, 222, Maijin Road, Keelung, Taiwan

ARTICLE INFO

Article history:
Paper received 29 July 2016
Accepted 31 January 2017
Available online 13 February 2017

Keywords:
Resorbable fixation
Mandibular fractures
Biting forces
Poly-L/DL-lactide

ABSTRACT

Purpose: The aim of this study is to compare the 1-year functional outcomes and patient-reported satisfaction in treating mandibular fractures between resorbable and titanium fixation devices.
Materials and methods: A 1-year prospective study was conducted; 41 consecutive patients presenting with mandibular fractures were included. A resorbable system was used in 21 patients, while in 20 patients a titanium fixation device was used. Functional outcome was evaluated objectively at several time points (2, 4 and 6 weeks, 3 and 6 months, and 1 year after surgery). Bite forces over molars and incisors, mouth opening distance, occlusal status, operation time, fee for implants, bone healing and plate-associated complications were evaluated. Functional and overall satisfaction was measured by patients themselves subjectively.
Results: A statistical difference was found only in maximal mouth opening and molar bite force, both greater for the titanium group in the 2-week time point, achieving comparable measurements in subsequent ones. This coincides with the patient-reported statistically lower satisfaction rates. The cost of the resorbable device was nearly 3 times more expensive than the titanium devices.
Conclusion: Resorbable fixation can achieve stability of bone healing at 1 year postoperatively, with functional and satisfaction outcomes comparable to those associated with titanium hardware from the fourth week postoperatively, while yielding unique advantages.

1. Introduction

Internal fixation using titanium plates and screws in cranio-maxillo-facial surgery remains the gold standard. It has been demonstrated to provide primary bone healing without callus formation and to allow rapid return to premorbid jaw function (Ellis and Miles, 2007). Fixation requirements and outcomes for single and multiple mandibular fractures have been well reported for titanium osteosynthesis (Ellis, 2013). However, titanium hardware has reported disadvantages, including stress shielding, implant migration, bothersome palpability, allergic hypersensitivity, chemical carcinogenesis, growth disturbance, cold intolerance and hardware-related infection (Cheung et al., 2004; Gosain et al., 1998). For a variety of reasons, 5%–40% of all patients with facial fractures stabilized with titanium fixation will undergo a second surgical procedure to remove implants, according to different studies (Prein, 1998; Van Bakelen et al., 2013).

Resorbable osteosynthesis addresses a number of these disadvantages, most notably with no need for implant removal, and no growth disturbance in pediatric populations (Yerit et al., 2005), and allows a gradual transfer of stress to healing bony segments

* Corresponding author. Division of Traumatic Plastic Surgery, Department of Plastic and Reconstructive Surgery, Craniofacial Center, Chang Gung Memorial Hospitals, Chang Gung University, College of Medicine, 5, Fu-Shing Street, Taoyuan 333, Taiwan. Fax: +886 3 328 9582.
E-mail address: lia01211@gmail.com (H.-T. Liao).
[1] These authors contributed equally to this work.

http://dx.doi.org/10.1016/j.jcms.2017.01.034
1010-5182/

without stress shielding. The use of resorbable osteosynthesis has been demonstrated to be reliable in low-load situations such as midface osteotomies and pediatric fractures (Bhatt et al., 2009). Currently, the most compelling reports of the suitability of biodegradable plates and screws for adults in cranio-maxillo-facial surgery are from the orthognathic surgery literature, with multiple well-designed, prospective, randomized controlled trials (Cheung et al., 2004; Bell and Kindsfather, 2006; Van Bakelen et al., 2013) comparing this system to the traditional titanium one. The cleanly cut bone ends and the optimized bone-to-bone contact make these elective osteotomies amenable to being fixed with resorbable systems. Of note, the undesired outcomes reported in most studies are discrete events such as wound dehiscence, purulent discharge, sinus formation, and plate exposure (Cheung et al., 2004). Nevertheless, the patient's return to function and overall satisfaction with mandibular resorbable fixation as compared to that with titanium plates have not been quantitatively assessed in a prospective fashion.

In this study, we compared titanium and resorbable osteosynthesis for mandibular trauma patients. Patient-centered objective and subjective functional outcomes were prospectively evaluated, in addition to classically reported outcomes. Our study aims to characterize how, in mandibular fracture patients, resorbable osteosynthesis compares to titanium osteosynthesis, using subjective, objective and quantifiable functional outcomes.

2. Materials and methods

2.1. Study design and population

The study was conducted over a 1-year period at the department of plastic and reconstructive surgery, Chang Gung Memorial Hospital. Patients who presented with simple mandible fractures at one or two sites and who had enough dentition to achieve stable occlusion were included in the study. Patients were excluded if they presented with comminuted fractures, concomitant condylar fractures, pre-injury dentofacial deformity with malocclusion, and edentulism. A total of 41 patients met the inclusion criteria. As all patients were eligible for the use of resorbable plates, each patient chose voluntarily the fixation materials before surgery, once the surgeons explained to them the advantages and disadvantages of each fixation system. Therefore, the assignment of this medical intervention was not at the discretion of the investigators. Both patient-related and surgery-related information were collected, including age, gender, fracture site, time to operation, operative time, number of plates and cost of fixation system.

Outcome measurements were performed at 2 weeks, 4 weeks, 6 weeks, 3 months, 6 months and 1 year postoperatively. An age- and gender-matched control group of healthy subjects were enrolled for comparison of bite force and maximal incisal opening with both the titanium and resorbable groups. Occlusion and satisfaction was also evaluated in the resorbable group. The principles outlined in the Declaration of Helsinki were followed in the study.

2.2. Materials

The resorbable material used in this study was made of Poly-L/DL-lactide 90/10 copolymer (Bonaplates©, PD series, Bonamets, BioTech One, Taipei, Taiwan). Its use is preceded by its immersion in a 70-degree Celsius water bath for 10 s, which provides approximately 15 s of working time to bend the plate and match the shape of the bone. The mechanical strength of this implant remains greater than 100 Mpa 6 months after implantation, which allows undisturbed bone healing. Implants are absorbed by hydrolysis in approximately 36–60 months, depending on the thickness. All of the titanium plates used were manufactured by Stryker Liebinger.

2.3. Interventions

Operative methods were standardized. Erich arch bars were applied, and premorbid occlusion was achieved with intermaxillary wiring. After exposure of the fracture sites, reduction clamps were used for anatomic reduction. Fracture sites were fixated with either titanium or resorbable plates and screws, depending on patient choice. Antibiotic prophylaxis was given intraoperatively and continued for 3 days after surgery.

For the symphysis, parasymphysis, and body fractures, two 4-hole resorbable plates of 1.5-mm thickness were used with eight screws measuring 2.5 mm in diameter and 12–14 mm in length. Corresponding titanium fixation used were standard 4-hole bone plates measuring 2.3 mm in thickness, with screws measuring 2.3 mm in diameter and 12–14 mm in length.

For the angle, one or two 4-hole absorbable plates of 1.5-mm thickness were used with four or eight screws measuring 2.5 mm in thickness and 6 mm in length, and the screws were applied percutaneously. Corresponding titanium fixation used were one or two 4-hole mini-plates measuring 2.0 mm in thickness, with screws measuring 2.0 mm in thickness and 5 mm in length.

Postoperatively, patients remained on a liquid diet for 2 weeks. During this time, elastic intermaxillary fixation was maintained in the patients in the resorbable group. Patients were then gradually advanced to a soft diet for the following 2 weeks. Then the patient's arch bar was removed at 4 weeks post-operatively and a tolerated diet was recommended at this time.

2.4. Outcome measures

For the comparison of the functional and aesthetic outcomes between two groups, both objective and subjective evaluations were analyzed.

2.4.1. Objective evaluation

Objective outcomes were measured including tolerated bite force, maximal mouth opening, post-operative occlusion status and radiographic evidence of bony union.

The bite force test consisted of an apparatus with a pressure sensor to measure force at 3 bite points: right molars, left molars and central incisors. All measurement were made with the patient seated with the head in an unsupported natural head position and looking forward. Patients were asked to bite onto the pressure sensor three times at their maximal tolerated force without pain, and an average force was obtained at 2, 4 and 6 weeks, and 3, 6 and 12 months postoperatively at each three bite points.

The maximal mouth opening (MMO) was defined as the distance between the incisal edge of the upper and lower incisors while the patients opened their mouth extremely. This was measured with a Vernier caliper. The post-treatment MMO were recorded and compared between the two groups at 2, 4 and 6 weeks and at 3, 6 and 12 months postoperatively. The MMO <35 mm was recognized as trismus which represented limited range of TMJ motion.

For occlusion status, a scale from 0 to 2 was used to grade postoperative condition, where 2 was stable occlusion with no premature contacts or crossbite, 1 was mild malocclusion in which premature contact or crossbite could be corrected by an orthodontist, and 0 was severe malocclusion needing a repeat operation. The occlusion status was evaluated by both the operative surgeon and an orthodontist.