

Application of Bioabsorbable Plates in Orthognathic Surgery

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Abstract

Backgrounds: Though they are considered as reliable devices, titanium plates and screws have limitations due to some potential problems. To overcome these problems, researches on bioabsorbable materials for internal fixation have been continuing. Recently, there are many clinical trials to apply biodegradable internal fixation devices in oral and maxillofacial surgery. The purpose of this study was to evaluate the clinical results of application of bioabsorbable plates and screws in orthognathic surgery.

Methods: Fifty-four patients with dentofacial deformity (17 male patients and 37 female patients) were selected in this study. The patients were treated by internal fixation using bioabsorbable plates and 2.4-mm, 2.0-mm pretapped screws (Biosorb FX, Bionix Implants, Inc., Finland). The patients were evaluated for complications during the follow-up period.

Results: Five patients (9.3%) experienced complications. All complications in these cases were infection. No other complications related with physical or mechanical properties of bioabsorbable plates were found such as malunion or nonunion, fractures of plates and loosening of screws. All complications were minor and adequately managed with drainage and supportive care with antibiotics coverage.

Conclusions: From the results, the use of these fixation systems in orthognathic surgery will provide a promising alternative titanium fixation in appropriate cases.

Key words

Bioabsorbable, Internal fixation, Biodegradable, Orthognathic surgery

INTRODUCTION

For stabilizing craniofacial skeleton, various internal fixation devices have been developed and titanium plates and screws are regarded as the standard treatment in oral and maxillofacial surgery until now. Also, for the fixation of osteotomized segments in orthognathic surgery, titanium plates and screws have been generally used.

Though they are considered as reliable devices, titanium plates and screws have limitations in application due to some potential problems. In the literature, many clinical studies showed that titanium devices had to be removed in considerable portion of cases due to several reasons^{1,2}. These included infection, unacceptable palpability, thermal conductivity, allergenicity, carcinogenicity and so forth. The removal of titanium plates and screws should be considered in the case of infection and plate exposure. Some patients, in the follow-up period, complained unacceptable palpability resulted from physiologic bony remodeling or response against toxic materials³. Thermal conductivity is one of the common post-operative complaints of the patients especially in the aspect of cold hypersensitivity. Also, it is hard to get

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accurate image from computed tomography (CT) scanning or magnetic resonance imaging (MRI) due to artifact, though it may be negligible in comparison with other metallic devices, caused by titanium internal fixation devices^{4,5}. Furthermore, passive translocation of titanium devices according to the growth, it is problematic, especially, in infant or child patients. A second operation may be planned to remove the internal fixation devices, whether it was clinically important or not, on the bases of some animal and human studies that showed the presence of titanium particles in the scar tissue, in the lungs and in locomotional lymph nodes^{6,7}.

To overcome these problems, research into the development of bioabsorbable materials for internal fixation has been continuing as an alternative. Biodegradable properties of these bioabsorbable devices can solve the aforementioned problems. In contrast to metallic devices, bioabsorbable devices have no scattering or ferromagnetic effect. Bioabsorbable fixation has already been used successfully in children patients without showing any adverse effect on normal bony growth^{8,9}.

Especially in the elective procedures for esthetics such as orthognathic surgery, more safe and predictable treatment is required. The necessities of additional surgery to remove foreign materials from their bodies may be burden to the patients. In this aspect, the application of bioabsorbable plates is very advantageous.

Recently, with the technical development, there are many clinical trials to apply biodegradable internal fixation devices in oral and maxillofacial surgery. The purpose of this study was to evaluate the clinical results of application of bioabsorbable plates and screws in orthognathic surgery. For this, we reviewed our early experience using Biosorb FX plates and screws (Bionix Implants, Inc., Finland) for internal fixation in 54 patients undergoing orthognathic surgery.

MATERIALS AND METHODS

The research protocol was approved by the Institutional Review Board on Human Subjects of the Seoul National University Bundang Hospital. From the patients with problems of dentofacial deformity requiring orthognathic surgery, the patients who had been operated at Seoul National University Bundang Hospital from May 2003 to Dec 2004 were included in this study. All patients agreed to the use of bioabsorbable plates and screws in the operation after the detailed information.

All the operations in this study were performed by the same surgeon with the same surgical protocol. The patients were treated by internal fixation using bioabsorbable plates and 2.4-mm, 2.0-mm pretapped screws (Biosorb FX, Bionix Implants, Inc., Finland). A single 2.4-mm plate was used for the fixation of split segments of mandible during bilateral sagittal split ramus osteotomy (BSSRO) procedure (Fig. 1). Four 2.0-mm plates were applied for stabilizing the maxillary segment in Le Fort I osteotomy (Fig. 2). Two 2.0-mm plates were bended and adapted to the chin segment in genioplasty (Fig. 3). All the patients had full fixed orthodontic treatment before and after operation. The patients were evaluated for complications during the follow-up period.

RESULTS

Fifty-four patients with dentofacial deformity (17 male patients and 37 female patients) were selected in this study. The patients ranged from 15 to 52 years in age (mean 22.6) and follow-up period was between 8 to 24 months (mean of 15). Thirteen patients had bimaxillary osteotomies and 41 patients had mandibular repositioning only. Genioplasties were performed for 20 patients in combination with other procedures except 2 cases.

The duration of intermaxillary fixation ranged from 7 to 14 days, with a mean of 8.3 days. Five patients (9.3%) experienced complications. All complications in these cases were infection. No other complications related with physical or mechanical properties of bioabsorbable plates were found such as malunion or nonunion, fractures of plates and loosening of screws. All complications were minor and adequately managed with drainage and supportive care with antibiotics coverage. (Table 1, 2)

DISCUSSION

Clinical tests have already proved the excellent biocompatibility and corrosion resistance of titanium material. And there is little evidence regarding the long term local and systemic effect when in the maxillofacial skeleton. However, it is foreign substance that remains permanently in the body. Additional operation may be necessary to remove fixation devices. More over, in the cases of elective procedure such as orthognathic surgery, it is important to guarantee optimal results. Though the

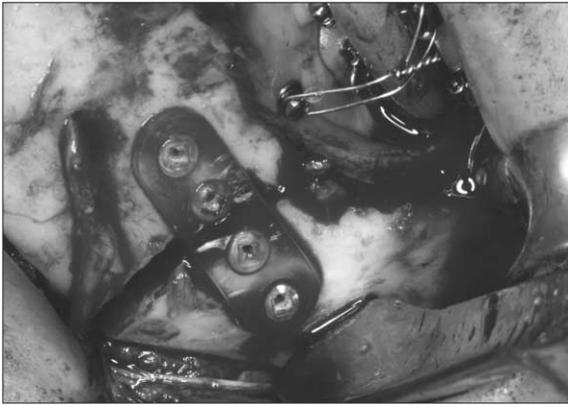


Fig. 1. Application of bioabsorbable plate and screws in BSSRO. A single 2.4-mm plate was used for the fixation of split segments of mandible during BSSRO procedure.

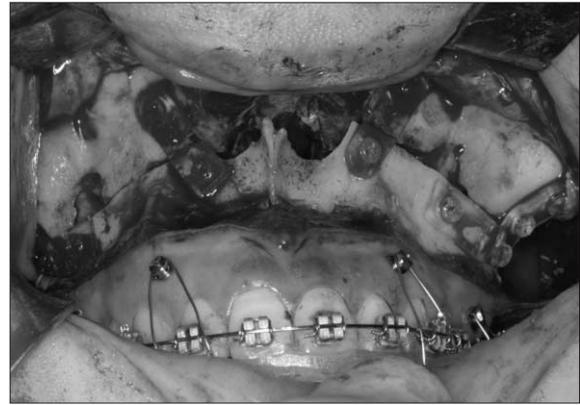


Fig. 2. Application of bioabsorbable plates and screws in Le Fort I osteotomy. Four 2.0-mm plates were applied for stabilizing the maxillary segment in Le Fort I osteotomy procedure.



Fig. 3. Application of bioabsorbable plates and screws in genioplasty. Two 2.0-mm plates were bended and adapted to the chin segment in genioplasty procedure.

Table 1. Patients' characteristics

Diagnosis	Number of patients (male/female)
Facial asymmetry	13 (7/6)
Mandibular prognathism	39 (10/29)
Mandibular retrognathism	2 (0/2)
Total	54 (17/37)

Table 2. Clinical data of application of bioabsorbable plates in orthognathic surgery

Type of Surgery	Number of Patients	Number of Plates	Complication
Maxillary osteotomy	13	52	0
LeFort I osteotomy	13	52	0
Advancement	5	20	0
Impaction	8	32	0
Mandibular osteotomy	72	144	0
Bilateral Sagittal Split Ramus Osteotomy	52	104	5
Advancement	1	2	1
Set-back	51	102	4
Genioplasty	20	40	0
Advancement	4	8	0
Set-back	6	12	0
Reduction	10	20	0
Total	85	196	5

removal of metallic plate is not mandatory procedure, there were some cases to remove plates and screws for various reasons. Furthermore, some patients just want to remove the metallic plates from their body without any complications.

There have been controversial opinions on the removal of fixation devices. Removal of titanium plates and screws after completion of bony healing process is advocated in some surgeons without any evidence of complications. Other clinicians reported successful clinical results of titanium devices and claimed that routine removal of titanium fixation devices was not recommended¹⁰. Kim et al suggested that the titanium plates should be removed routinely after completion of bone healing on the base of destructive findings of hard and soft tissue surrounding titanium plates in microscopic examination¹¹.

The use of bioabsorbable materials to stabilize the facial skeleton was firstly reported by Cutright et al.¹² The development of self-reinforcing manufacturing technique marked a new era in bioabsorbable materials. Reinforcement by parallel polylactide fibers and polymer blending increases the mechanical strength of this material considerably, and therefore suggested the possibility of its use for internal fixation. With this sintering technique, it could be possible to avoid the use of bulky plates which have been associated with some shortcomings. Self-reinforcing technique also produce strong and malleable devices which are bent at room temperature by a set of mini-bending pliers. A variety of synthetic high-molecular weight polymers have been investigated including polylactides (PLA) and polyglycolides (PGA)^{13,14}. In the past, poly-L-lactide (PLLA), a derivate of polyhydroxy acids, was used for internal fixation in oral and maxillofacial surgery. Initial results of PLLA plates and screws were promising. However, some of the disadvantages of PLLA have become clear, including foreign body reactions, osteolysis around the screws and a long degradation period. To overcome these problems, various polymer combinations have been tried to improve the mechanical properties and degradation kinetics of the bioabsorbable fixation devices. By adding D-lactide it was possible to reduce crystallinity and so increase biodegradability.

In this study, the Biosorb FX bioabsorbable fixation system (Bionix Implants Inc., Tampere, Finland) was used. The Biosorb FX system is composed of screws of diameter 2.0- and 2.4-mm, and fixation plates of various

designs, which are made of self-reinforced poly-L/D lactide (PLDLA) copolymer in a ratio of 70% L-lactide and 30% D-lactide. The hydrolytic degradation of these copolymers yields lactic acid monomers, which are further metabolized by the citric acid cycle, yielding energy, carbon dioxide and water. Carbon dioxide is excreted by the lungs.

In recent years, there have been a number of studies reporting successful clinical application of bioabsorbable internal fixation devices in orthognathic surgery^{15,16}. Many researchers were able to demonstrate promising results in terms of clinical morbidities and skeletal stability^{17,18}.

In this study, successful results were obtained. Only minor complications were detected in 5 cases. The infection subsided rapidly with drainage and supportive care with antibiotics coverage and there was no clinical evidence of chronic inflammation in the infected site. It was interesting that there were no infection in maxillary procedures. It was known that the fixation devices applied in maxillary procedure can be the source of maxillary sinusitis and there were several reports on the removal of fixation devices due to maxillary sinus infection⁹. The bioabsorbable fixation device was ruled out from the direct source of infection or foreign body.

The successful application of bioabsorbable plates and screws may be associated with technique during the drilling procedure. Careful attention to the preparation of the holes is requested to get the adequate angulation and to avoid oversized holes that preclude effective tapping. Also, there is accidental grinding of the plates during drilling procedure. For the correct angulation of drilling procedure, vertical osteotomy was performed more anterior in BSSRO. It is suspected that the denatured polymer particles heated and grinded during the drilling procedure is the source of infection.

Close adaptation of plates to the bony segment is important for the stability of fixation. Easy manipulation of plates at room temperature in the same way of titanium plates is possible in Biosorb FX system. Biodegradable property is associated with several subsequent advantages. Most of all, it is consequently more economic because there is no need to consider the cost of additional operation for device removal. Radiolucency is beneficial to patients unwilling to disclose the history of their surgical interventions. Many patients are psychologically satisfied with the undetectable property in the radiographic examination.

However, in contrast to the titanium internal fixation devices, biodegradable devices have not been used on a large scale in orthognathic surgery. Hesitation to choose bioabsorbable devices is partly due to the deficiency of confidence on the strength of materials and additional time-consuming procedure including tapping or heating. Also bioabsorbable devices have several technical problem to be improved such as weakness of screw head.

Nevertheless, it is still attractive to use bioabsorbable materials as fixation devices. Making up for these weak points in the current systems, the use of these fixation systems in orthognathic surgery will provide a promising alternative of titanium internal fixation devices in appropriate cases.

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