Early clinical experience with poly-L/DL-lactide 90/10 resorbable plates for mandibular fracture fixation

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In this report, we describe our clinical experiences related to the application of a poly-L/DL-lactide 90/10 bioresorbable fixation system for mandible fractures. Evaluation and comparison of treatment outcomes with those using a metallic system are presented. The plate system was applied for intraosseous fixation after open reduction of a mandible fracture in 4 patients. Clinical data and the surgical procedure were recorded. A questionnaire was used to evaluate the patient’s response to the entire course of treatment. Any significant complaints and evidence indicating any side-effects were well documented and subsequently analyzed. All patients had a satisfactory outcome, and no major material-related side-effects were found. The surgical time and masticatory function were acceptable compared with those using the metal plate system. The results demonstrate the efficacy of this bioresorbable plate/screw system for mandibular fracture fixation.  


Key words: poly-L/DL-lactide, bioresorbable plate, mandibular fracture.

Nonresorbable metal plates have been applied to improve osteosynthesis at mandibular fracture sites for decades. There are some disadvantages of using metal plates due to the material properties, such as osteoporosis12, implant migration14, release of metal ions9, extrusion9, stress shielding9, artifacts on radiographic examinations10,11, restrictions on growth in children12-15, and thermal sensitivity16. In addition to the above drawbacks, the removal of nonresorbable plates and screws may require a second operation17.

The reported removal rates of nonresorbable plates are 12%~18%, and infection is the major cause (in 50%~60% of cases)18,19. In 1966, Kullkarni20 first applied bioresorbable materials for the fixation of maxillofacial bones. Thereafter, several types of bioresorbable plate systems were introduced to refine the treatment modality and replace traditional metal plates. The mechanical strength of bioresorbable plates is weaker than that of metal plates. Through advances in bioengineering and technology, contemporary resorbable plate systems have almost achieved similar strength levels compared to metal plates. In many studies, fixation with bioresorbable plate systems produced no significant impairment of jaw bone function21-25. Several types of bioresorbable plate systems have been investigated in vivo and in vitro, including poly-L-lactic acid (PLLA),
polydioxanone (PDS), polyglycolic acid (PGA), and their derivative copolymers. Among them, suitable copolymers of PLLA and poly-DL-lactic acid (DL-PLA) have been developed for craniofacial surgical applications.

Acceptable outcomes have been reported for bioresorbable plate systems used for pediatric craniofacial surgery, orthognathic surgery, maxillofacial trauma, and reconstruction without significant complications or disadvantages compared with nonresorbable systems. We reviewed those articles and show the data below.

In this study, we present our early experience with applying a novel bioresorbable plate system based on the poly-L/DL-lactide 90/10 copolymer in the treatment of mandible fractures, and evaluate the short-term outcomes and compare the results with a metallic system.

**MATERIALS AND METHODS**

The following criteria were used for subject selection: an untreated mandible fracture, no airway-compromising injury or major infectious disease history, and management by open reduction and internal fixation. The fixation materials used were 1.5-mm-thick bioresorbable plates with 2.5-mm-diameter bicortical screws (BonaPlates, PD series, Bonamates\(^\text{®}\), BioTech One, Taipei, Taiwan). They were composed of the poly-L/DL-lactide 90/10 copolymer (Figure 1)\(^3\).

The gender, age, medical history, and concomitant injury were recorded preoperatively. The fracture sites were precisely classified using Dingman and Natvig definitions\(^3\) by radiography and physical examination. Laboratory data including the complete blood cell count (CBC), white blood cell (WBC) differentiated count, electrolyte, erythrocyte sedimentation rate (ESR) (automated), and C-reactive protein (CRP) were carefully collected through the entire treatment course and the follow-up period.

**Surgical Procedures**

The arch bar was first anchored with intermaxillary fixation using a wire to achieve appropriate occlusion before the operation, and open access to the fracture site was maintained under general anesthesia via nasotracheal intubation. The fracture site was manually reduced to simultaneously achieve proper alignment and check the occlusion. One or 2 Bona-
mates® bioresorbable plates and screws were used for intraosseous fixation. Antibiotic prophylaxis was given preoperatively and was continued for 3 days after surgery. After surgery, the operative time and the numbers of plates and screws used were recorded. In addition, a questionnaire was used to evaluate the response of patients 1 week later. Any symptoms and signs arising or dissolution were checked to identify possible complications. All clinical and laboratory data were collected on a special sheet. The duration of intermaxillary fixation was 4 weeks. Subsequent follow-up included physical and radiographic examinations every week during the fixation period, then 1-month check-ups for the first 3 months in the outpatient department (OPD). A masticatory test was conducted in which the patient masticated things in the regular daily diet (including rice, meat, and fruits). If the masticatory test at postoperative 12th week followed the criteria without difficulties, the outcome of the treatment was determined to be good. The definition of palpability was based on the patient’s ability to palpate the plate. The definition of satisfaction was based on the questionnaire which was completed by patients at the time of discharge.

We also selected another 6 patients with mandibular fractures using the same criteria in whom the titanium plate/screw system was used for open reduction, and the operative time was recorded. The results were compared with those of poly-L/DL-lactide 90/10 copolymer implants.

Table 1. Essential data, including the patients’ basic data, fracture site, operation date and time, number of plates and screws used, and results

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Gender</th>
<th>Age (yr)</th>
<th>Fracture location</th>
<th>Operation date</th>
<th>Operative time</th>
<th>Plates and screws</th>
<th>Outcome</th>
<th>Complications</th>
<th>Satisfaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>30</td>
<td>Symphysis</td>
<td>18 May 2006</td>
<td>1 h 15 min</td>
<td>one 4-hole plate 3 screws*</td>
<td>Good</td>
<td>None</td>
<td>Good</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>50</td>
<td>Right parasymphysis</td>
<td>24 June 2006</td>
<td>1 h 15 min</td>
<td>two 6-hole plates* 11 screws</td>
<td>Good</td>
<td>None</td>
<td>Good</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>23</td>
<td>Left body</td>
<td>8 July 2006</td>
<td>1 h 30 min</td>
<td>1 of 4-hole plate 4 screws</td>
<td>Good</td>
<td>None</td>
<td>Good</td>
</tr>
<tr>
<td>4</td>
<td>Male</td>
<td>19</td>
<td>Left subcondyle</td>
<td>31 July 2006</td>
<td>1 h 55 min</td>
<td>one of 4-hole plate 4 screws</td>
<td>Good</td>
<td>Facial nerve weakness</td>
<td>Good</td>
</tr>
</tbody>
</table>

*: One screw broke. #: One 6-hole plate was cut to 5 holes.

RESULTS

Four male patients met the criteria and were recruited for this study from May to July 2006 at the Chi-Mei Medical Center. The age of patients ranged from 19 to 50 (mean, 30.6) years. The time period between injury occurrence and surgery was 1 to 4 (mean, 2.25) days. The fracture sites included 1 in the symphysis, 1 in the parasymphysis, 1 in the body, and 1 in the subcondyle. The follow-up period ranged from 3 to 5 months postoperatively. All patients had satisfactory outcomes including occlusion. No broken plates, extruded screws, mucosal dehiscence, infection, plate exposure, mal-union, or non-union were noted in any cases in the follow-up clinical physical and radiographic examinations. So the bone union condition and masticatory function regained were reliable. No soft tissue inflammatory response or palpability of implants by patients was noted at the last follow-up. Only 1 weakness of the facial nerve occurred after open reduction in the patient with the subcondylar fracture (Table 1).

These plates and screws can easily be cut with scissors after immersion in the BonaBath™ (Figure 2) containing 70°C sterile water for 5–10 seconds. After that, nearly 15 seconds is available when the plate is malleable so the operator can shape it, place it in the actual site, and check the position for drilling. Further immersion in the BonaBath™ can then be limited to specific areas of the plates which require further contouring. Heating and bending can be repeated many times without affecting the strength or degradation properties.

Holes were drilled bicortically using 2.0-mm-diameter drills with normal saline irrigation for cooling. Then the hole was tapered with a 2.5-mm hole taper requiring no extra effort. After measuring the length of the drill hole by a gauge, the chosen screws were cut into a proper length and inserted. All surgical steps proceeded smoothly, except that 1 screw...
fractured while nearly inserted into the final position for patient 1 for whom one 4-hole plate was used for a mandibular symphyseal fracture. We decided to drill along the fractured screw again and immediately inserted another emergent screw. The entire operative time was similar to those surgeries using metal miniplate or another kind of bioresorbable plate.

Postoperatively intermaxillary fixation was kept in position for 4 weeks. Preoperative and postoperative Panorex images are shown in Figure 3. Mild pain was reported in the first 3 days after surgery, and palpation tenderness occurred in 2 patients, but none of symptoms or signs lasted over 5 days. The masticatory test in the 12th week indicated the no patients had trouble masticating their regular daily diet (include rice, meat, and fruits).

The average operative time for mandibular fractures fixed by the titanium plate/screw system was around 1~2 hours depending on the different fracture sites and the approaches used. Palpability after surgery was noted by all patients with titanium plates and screws. The outcome of using the titanium plates and screws achieved the criteria. There was no difference in satisfaction of patients after surgery, except the possible need to remove the titanium plates and screws and the palpability. Wound healing proceeded with no complications such as infection, screw extrusion, plate exposure, nonunion, or malunion after 12 weeks of follow-up; the same results were seen with the bioresorbable plates.

**DISCUSSION**

According to the manufacturer’s in vitro study, poly-L/DL-lactide 90/10 implants (Bonamates®) still had more than 100 MPa of strength 6 months after implantation. They are completely absorbed in approximately 36–60 months depending on the plate thickness. There are 2 phases to the absorption mechanism of the Bonamates® plate system, namely,
hydrolysis and fragmental metabolism. Initially hydrolytic deesterification begins when body fluids (including H$_2$O) attach onto the implant surface, then PLA oligomers are formed after the polymer chains are broken during degradation. Subsequently, fragmental metabolism occurs when lactic acid molecules are finally metabolized by lactate dehydrogenase through the pyruvatic cycle in the liver into CO$_2$ and H$_2$O.

Tissue regeneration is affected by the above process for the 2-phase degradation of the biodegradable plates and screws. In the first inflammatory response phase, the hydrolytic degradation of the plate causes an overall reduction in the molecular weight, and finally loss of implant strength. Subsequently, macrophages and giant cells digest the fragmental polymeric debris. Such an immune response associated with a transient microscopic foreign body reaction is not necessarily clinically evident. In our study, no such signs of adverse inflammatory reactions specific to the bioresorbable devices were observed. This adverse inflammation is probably due to an imbalance between the rapid rate of degradation and the slower rate of absorption. In contrast to PGA or PLLA homopolymers, amorphous copolymeric P (L/DL) LA implants had a lower risk of foreign body reactions owing to their specific degradation characteristics.

One of the disadvantages of nonresorbable plates systems is that some patients may need a second operation to remove the plates and screws. Kim et al. revealed local and macroscopic destruction in both the hard and soft tissues surrounding the removed titanium miniplates by an biopsy study. The plates can introduce further tissue damage, for example, titanium particles can cause degenerative changes in the bone matrix and pigmentation of soft tissues. Some scholars have recommended removing the plates after bone healing if they have stayed in place an extraordinary length of time. The safety and efficacy of bioresorbable plate systems have positively been proven by many animal studies.

The metal plate can interfere with bone growth in children. In the same situation, the self-degradation character of bioresorbable plates is particularly attractive and useful in children who have bone growth potential. In terms of allergies to metal, less metal ion release can save such patients from compromising the treatment modality by allowing onlyextraosseous fixation. The translucent character means that the bioresorbable plate system generates no significant artifact shadow on computed tomographic or magnetic resonance images, which is beneficial for evaluating trauma postoperatively. The bioresorbable plate can also safely be used in orthognathic surgery, maxillofacial trauma surgery, and mandibular swing osteotomies. However, the ability to bridge severely comminuted mandibular fractures is still poor. The bioresorbable plates also have advantages in cancer surgery for repositioning access osteotomies and attaching microvascular bone grafts because they do not interfere with the postoperative computed tomographic or magnetic resonance images.

In our study, no infection was observed in any patients. The major complaints were mild wound pain, and all of these resolved within 5 days. Facial nerve paralysis occurred in 1 case (with a condylar fracture) that did not correspond to the material itself, but to the surgical procedure. From such results, it can be concluded that this system is very comparable with other systems. Clinically manifested inflammatory reactions to biomaterials are rare, occurring in less than 1% of cases using self-reinforced bioresorbable poly-L/DL-lactide [SR-P(L/DL)LA] 70/30 miniplates and miniscrews for fixation of anterior mandibular fractures. Cheung et al. reported only a 1.82% (3 of 165) infection rate and a 1.21% (2 of 165) exposure rate with the poly-L/DL-lactide 70/30 copolymer BiosorbFX™ bioresorbable fixation system (Bionx™ Implants Inc, Tampere, Finland) in orthognathic surgery.

Additional operative accessories are required when using the bioresorbable plate system; for instance, a water bath is used for shaping the plate, and the drill holes must be tapered before inserting the screws. In our series, all the additional procedures consumed no more than 3 minutes, so they take little time and do not impair the entire operation compared with the time used to bend the metal plates. There were no obvious differences in the total time consumed between these 2 types of plates according to our results.

Lower mechanical strength increases the risk of plate breakage if insufficient immobilization is used before the jaw bones are exercised. But the flexibility of synthetic bioresorbable polymers can transfer the loading stress to the damaged area. Several studies had proven that such light loading forces improve the healing of traumatized tissues and induce os-
teogenesis\(^*\),\(^{46,47}\). One screw broke in 4 patients, a complication rarely seen with metallic screws. There is a learning curve in utilizing this material.

Previous studies showed no significant differences in either histological or biomechanical aspects of bone healing between segments fixed with titanium and bioresorbable systems\(^*\),\(^{48,49}\). Support.

However, long-term follow-up and more cases are needed to confirm these results.

**CONCLUSIONS**

Based on this early experience, the poly-L/DL-lactide 90/10 bioresorbable plate system provided reliable stability for osteosynthesis of mandibular fractures without major complications. However, long-term follow-up and more cases are needed to confirm these results.

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