Resorbable Plates for the Fixation of Mandibular Fractures: A Prospective Study

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Purpose: The hypothesis for this prospective evaluation is that resorbable plates are equal to the performance of titanium 2-mm plates, regarding healing of the fracture with bone union and restoration of function. To prove this hypothesis, specific end points will be compared with literature norms for titanium 2-mm miniplate rigid fixation. The primary end point variable for this analysis is the union of the fracture and return to normal function. Secondary end point variables included the incidence of complications such as infection, malunion with malocclusion, soft tissue dehiscence, the need for revision surgery, specific technical challenges, operative time, and the learning curve for the surgeon.

Patients and Methods: This prospective study consisted of a sequential enrollment of 50 fractures that met the inclusion criteria of having a fracture of the mandibular body, symphysis, angle, or ramus, and required an open reduction and internal fixation for stabilization and repair. The resorbable plates and screws used consisted of an amorphous injection molded copolymer of L-lactide/D-lactide/trimethylene carbonate (Inion CPS system, Tampere, Finland). Data were collated and compared with literature norms for titanium plates and also compared with nonrigid fixation data from a prospective study performed on a similar population in the same institution.

Results: Clinical and radiographic evaluation indicated union of all fractures at the eighth follow-up visit. Three sites (6%) noted to have clinical signs of infection were treated immediately upon presentation, with fracture union by 8 weeks. There was no need for revision surgery in this series of patients; 12 screw heads fractured during screw placement and were immediately replaced without significant fracture sequelae.

Conclusion: Based on this limited series of patients, the hypothesis formulated for this study was validated.

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Mandibular fractures are among the most common injuries to the facial skeleton, with a 6:2 proportion between mandibular and zygomatic fractures.¹,² The primary goal of fracture management is restoration of healing of the fractured bone resulting in restoration of form and function. Minimizing infection, malunion, soft tissue breakdown, and technical challenges should be included in the overall management of fractures.

Most mandibular fractures have been treated by closed reduction with maxillomandibular fixation, open reduction with nonrigid fixation, and open reduction with rigid internal fixation. Titanium plates have been used for over 2 decades to achieve internal rigid fixation of mandible fractures.

Resorbable materials have been used as fixation materials in craniomaxillofacial surgery and for rigid
fixation in orthognathic surgery. In contrast to titanium plating systems, resorbable plating systems have not been used on a large scale for the fixation of mandibular fractures.

When choosing a plate to achieve rigid fixation of a mandibular fracture, we recommend the following important characteristics.

1. The plate should be simple to place.
2. The plating system should require minimum specialized training for the surgeon to use it proficiently.
3. The plate should have appropriate strength to meet the mechanical demands during fracture healing.
4. A resorbable plate should be biocompatible and degrade in a predictable fashion, maintaining sufficient strength until the bone has healed.
5. A resorbable plate should resorb completely within a reasonable period of time with minimal inflammation.

The hypothesis for this prospective evaluation is that resorbable plates are equal to the performance of titanium 2-mm plates, regarding healing of the fracture with bone union and restoration of function. To prove this hypothesis, specific end points will be compared with literature norms for titanium 2-mm miniplate rigid fixation. The primary end point variable for this analysis is the union of the fracture and return to normal function. Secondary end point variables evaluated included the incidence of complications such as infection, malunion with malocclusion, soft tissue dehiscence, the need for revision surgery, specific technical challenges, operative time, and the learning curve for the surgeon.

**Materials and Methods**

**STUDY DESIGN**

This study is a prospective study consisting of a sequential enrollment of 50 fractures that met the inclusion criteria of having a fracture of the mandibular body, symphysis, angle, or ramus, and required an open reduction and internal fixation for stabilization and repair. All patients who presented for treatment of mandibular fractures were treated regardless of systemic disease, use of tobacco, alcohol abuse, and/or drug abuse. All patients were treated at MCLNO (Charity Hospital New Orleans) by 1 resident surgeon with staffing by 5 different attendings.

**MATERIALS**

The resorbable plates and screws used consisted of an amorphous injection-molded copolymer of L-lactide/D-lactide/trimethylene carbonate (Inion CPS system, Tampere, Finland) (Fig 1). The initial tensile strength was $452.0 \pm 7.8$ N for the Inion CPS 2.5, 6-hole plate, as reported by the manufacturer (data on file with Inion). These plates have been reported to resorb slowly, maintaining 70% of their initial strength at 9 to 14 weeks, with 42% bulk resorption by 40 weeks, and are completely resorbed by 2 to 4 years (in vitro data performed by Inion for the US Food and Drug Administration). The mechanism for resorption is hydrolysis. These plates can be bent to match the curve of the bone, but they cannot be bent to change vertical orientation, for example, to create a c-shaped arc from a straight plate. They can rotate around the central axis.

**SEQUENCE OF PATIENT CARE**

On initial presentation to the emergency department, patients were clinically and radiographically evaluated (Fig 2). Mandible fracture(s) were manually reduced and patients were placed into maxillomandibular fixation with the use of arch bars and 24-gauge circumdental wires with heavy elastics under local anesthesia. All patients received either penicillin or clindamycin for 7 days, pain medication, and chlorhexidine mouth rinse. If the postfixation film indicated that internal fixation was necessary, the patients were scheduled for an interview for inclusion into this study. The criteria used to perform an open re-

![FIGURE 1. A typical resorbable plate and resorbable screws used in this study.](image1)

![FIGURE 2. Postmaxillomandibular fixation panorex. Note the right parasymphysis fracture and left body/angle fracture. This patient had a previous mandibular fracture with 1 lag screw in the angle.](image2)
duction with plate fixation was based on separation of the fracture segments and the need to achieve anatomic reduction.

Either the same day or within 72 hours, the patients were interviewed by a registered nurse and resident surgeon. Patients who met the inclusion criteria and wished to participate in the study signed an institutional review board-approved informed consent form specific for this study, and a case report folder was created. Patient’s folders were assigned a numeric reference specific for each case. Clinical examination was performed by a resident surgeon. Photographs of the mouth were performed and panoramic and posterior-anterior radiographs were taken and duplicated. Preoperative data forms were completed and placed into the patient’s case folder. Subsequently, the patient was scheduled for open reduction internal fixation surgery under general anesthesia.

On postoperative day 1, patients underwent clinical examination by a resident surgeon that included data collection and postoperative panoramic and posterior-anterior radiographs. The patient was given follow-up appointments for postoperative weeks 2, 4, 6, and 8.

On each postoperative follow-up appointment, patients were evaluated and data collected. Panoramic and posterior-anterior radiographs were taken at the final week-8 visit.

At the completion of the 8-week follow-up period, the data were entered into a computer and a spreadsheet formed for evaluation. Data were collated and compared with literature norms for titanium plates and also compared with nonrigid fixation data from a prospective study performed on a similar population in the same institution.

**Surgical Technique**

All fractures were treated with intraoral open reductions under general anesthesia in the operating room. Teeth in the line of fracture were extracted only if they demonstrated mobility, tooth root fracture, apical pathology, were nonrestorable, or interfered with the reduction of the fractures or occlusion. Intraoperative antibiotics were administered intravenously before making incisions.

A 2.5-mm noncompression resorbable plate was selected so that at least 2 screws were in the proximal and distal segments. The plate was placed into a water bath at 55°C for 1 to 2 minutes, allowing the plate to become malleable. The plate was then adapted to the lateral border of the external oblique ridge or the lateral aspect of the ramus in the angle region. The inferior border was used for the parasympyseal and symphysis fractures. At a minimum, 2 screws were placed on each side of the fracture. After adequate plate adaptation, the plates were secured with 2.5-mm resorbable screws with lengths ranging from 6 to 12 mm. Six-mm monocortical screws were used on the superior border plates and in the anterior mandible to avoid the dentition, otherwise bicortical screws were used. The screw sites were hand tapped to avoid stripping threads at screw placement.

A transbuccal trochar was used for percutaneous access for placement of the posterior screws in the angle region of the mandible (Fig 3). All other screws were placed transorally. In the event of screw head fracture during placement of the screw, the head was removed and the previously drilled osteotomy was re-drilled through the remnant of the previous screw shank. The site was re-tapped in standard fashion with placement of a new screw of equal size. No emergency screws were used in this study (Fig 4).

After the screws were placed to secure the plate and the fracture(s) were adequately reduced, the intermaxillary fixation was removed and the occlusion checked for discrepancies and stability. Mucosal incisions were closed with chromic gut sutures in a running horizontal mattress fashion. The patient was placed into maximum intercuspidation and intermaxil-
lary fixation with elastics. No intraoral/extraoral drains were placed. For all patients, intermaxillary fixation was released 2 weeks after open reduction surgery (Fig 5).

Postoperative care included cefazolin 1 g intravenously every 8 hours or clindamycin 900 mg intravenously every 8 hours, and pain medication as necessary. The patient was advanced as tolerated to a full liquid diet that was continued after discharge for 8 weeks. On discharge patients were given oral antibiotics for 7 days and chlorhexidine mouth rinse for 7 days. They were seen every 2 weeks until week 8, at which time their arch bars were removed.

Data Collection

For mandibular fracture treatment, 5 indices of outcomes as per the AAOMS Parameters of Care were evaluated at 2-week intervals from the time of fracture treatment to 8 weeks. The indices evaluated were occlusion, soft tissue dehiscence/exposure of plates, mobility of segments, sign/symptoms of infection, and pain. Mobility of segments was noted as absent, minor, or grossly mobile. Signs or symptoms of infection included the presence of erythema, edema, or purulent drainage over the fracture site. Soft tissue dehiscence with exposure of plates was noted as present or absent. Stability of the plates and screws was also recorded if infection or wound breakdown was present. Pain was evaluated by using a scale noting no pain, mild, moderate, or severe pain in the area of the plate. The radiographs were evaluated for alignment of the fracture segments. The presence of malalignment of the segments was recorded if present. All of the patients’ radiographs were reviewed by more than 1 resident surgeon and at least 1 of the coauthors of this article (Fig 6).

2-mm Titanium Miniplate Literature Review

We established literature norms for the use of titanium plates for mandibular fracture repair by reviewing 6 articles that included a similar sample compared with the patient pool for this prospective study. The data found for the end point variables of non- or fibrous-union, infection, and hardware removal are presented in Table 1.

The incidence of soft tissue dehiscence, learning curve, and operating room time were not reported in these articles.

Results

Thirty-five patients (92% male; 8% female) with 50 fractures of the mandible were enrolled into the study and all reached the week-8 final data collection visit. The patients’ ages ranged from 15 to 50 years, with a mean of 29 years of age. Interpersonal violence was the leading mechanism of injury (90%), followed by motor vehicular trauma (7%), and falling from unknown cause

| Table 1. COLLATION OF FRACTURE DATA FOR TITANIUM PLATES USED FOR RIGID FIXATION OF MANDIBULAR FRACTURES WITH INTRAORAL PLACEMENT |
|-----------------|---------------|---------------|---------------|---------------|-----------------|---------------|---------------|
| Fracture sample size (n =) | Kuriakose et al⁴ | Gabriella et al⁵ | Ellis & Walker⁶ | Ellis & Walker⁷ | Lamphier et al⁸ | Cawood⁹ | Total |
| Nonunion/fibrous union | 116 | 168 | 69 | 81 | 97 | 86 | 617 |
| Infection | 9 | 4 | 6 | 1 | 4 | 0 | 24 (3.9%) |
| Hardware removal | 15 | 22 | 17 | 11 | 10 | 5 | 80 (13.0%) |

⁴Of the 56 plates removed, 17 (29.7%) were removed electively without clinical indication, with 39 removed secondary to pathology.

Of the 50 fractures enrolled in the study, 26 were treated with monocortical screws and 24 with bicortical screw fixation of the plates.

Fractures included 46.5% angle fractures, 31.0% parasymphysis fractures, 17.2% body fractures, and 5.3% symphysis fractures; 91% of the fractures were associated with a single tooth or multiple teeth in the line of fracture, and 9% of these teeth were extracted at the time of open reduction. The time from injury to initial exam and treatment ranged from 0 to 30 days, with an average of 4.3 days. Time from initial exam to open reduction averaged 9.3 days.

The outcome data from this study is compared with literature norms in Table 2.

### PRIMARY END POINT VARIABLE

**Union of the Fracture**

No mobility was noted in any fracture site at the 8-week follow-up examination. Clinical and radiographic evaluation indicated clinical union of all fractures at the 8-week follow-up visit.

### SECONDARY END POINT VARIABLES

**Infection and Soft Tissue Dehiscence**

Three of the 50 fracture sites (6.0%) were noted to have clinical signs of infection. These 3 infections were noted at weeks 2 and 3 postoperatively and were treated immediately upon presentation.

Two of the 3 sites received incision and drainage, hardware removal, tooth extraction in the line of fracture, and replating of the fracture site (1 titanium; 1 resorbable) at postoperative week 2. Intraoral plate dehiscence was noted in 1 of these fracture sites. In both cases, upon exposure of the site, at least 1 screw was mobile. On removal of the screws the plate was noted to remain stable and adherent to the bony surface. A periosteal elevator was needed to remove the plate from the bony surface.

The third infected site was treated by intraoral incision and drainage with drain placement and a 7-day course of oral antibiotics. The plate was not removed in this patient because it was stable. No screws were clinically noted to have mobility, and the plate was tightly adherent to the cortex.

All infected sites responded well to therapy and fully resolved by postoperative week 6. At the week-8 evaluation the fracture sites had healed without the need for a bone graft.

**Malunion**

Three patients were noted to have minor occlusal discrepancies at the 2-week evaluation. The occlusal discrepancies were corrected by postoperative week 4 with the placement of light guiding elastics or occlusal equilibration.

**The Need for Revision Surgery**

Two fracture sites were noted to have radiographic signs of segment malalignment at 8 weeks’ follow-up; however, the patient’s occlusion was stable and there were no functional impairments, thus there was no need for revision surgery in this series of patients.

**Specific Technical Challenges**

A total of 12 screw heads fractured during screw placement, representing a 6% incidence of specific technical problems. All of these fractured screws were removed and replaced as described in the Methods section. These screw head fractures occurred in the early phase of the study. As the surgeon developed more experience, the incidence of screw head fractures decreased.

**Pain**

The majority of patients reported mild pain at the first postoperative visit with resolution by week 2. Two patients reported moderate pain at 4 weeks. All patients were pain-free at the 8-week postoperative visit.

**Operative Time and the Learning Curve for the Surgeon**

Operative/anesthesia time ranged from 35 to 140 minutes with a mean time of 80 minutes. “Start time” was noted on injection of local anesthesia and “end
time” was after placement to pressure dressing. Because of the complex nature of several of the fractures and concomitant other injuries, operating time could not be used as a variable to objectively evaluate the learning curve.

Discussion

Titanium plates for rigid fixation of mandibular fractures allow the patient to have mandibular function and to achieve a normal diet earlier than those patients treated with closed reduction and a period of intermaxillary fixation. This avoids hypomobility secondary to prolonged intermaxillary fixation.5-9 Also, rigid fixation is believed to result in faster bone repair caused by compression of the fracture segments and lack of mobility between the fracture segments.5-9

Open reduction with the use of wires for nonrigid fixation of mandibular fractures was reported by James et al.10 Their prospective study of 442 mandibular fractures included 265 treated by closed reduction and 177 treated with open reduction techniques including reduction with intraosseous wires (148/177), bone plates (11/177), and Steinmann pins (18/177). Of these 177 fractures, delayed or nonunions were found in 12 patients. Malunion was seen in 3 patients, and the incidence of postoperative infection was 6.78%.

The disadvantages of titanium plates include the possibilities of hardware removal. Resorbable plates do not have to be removed. The plates used in this study will resorb over a period ranging from 2 to 4 years.

Titanium plates do not allow full visualization of the fractures on postoperative radiographs. Resorbable plates are radiolucent, thus full visibility of the fracture site is available to the clinician. When resorbable plates are used to stabilize bone graft reconstruction of larger defects, the radiolucent property may enable the surgeon to see the progress of the bone graft easily.

A number of biodegradable polymers have been approved for safe internal use and have been used as suture material in surgical applications for the past 35 years. The following polymers have been used: polyglycolide, polyglycolic (PGA)/polylactide (PLA), polydioxanone, and PGA/tri-methylene carbonate. The use of resorbable plates in the fixation of maxillofacial bone was initially reported in the literature by Kulkarni et al in 1971.11 Pilot studies in the early 1970s concluded that the use of resorbable plates and screws were not mechanically adequate without intermaxillary fixation and were excessive in thickness for use in the craniofacial skeleton.12-14 Vert et al15 was the first to report on poly-L-lactide (PLLA) plates for orthopedic use in 1984. The first clinical reports in

a maxillofacial series were in reference to the fixation of zygomatic fractures with melt-molded PLA plates and screws.16 In 1997, Bessho et al17 introduced a PLLA miniplate fixation system for fixation of facial fractures and osteotomies. Haers et al18 showed the use of self-reinforced PLA miniplates that allowed the use of bending pliers to adapt the plates without the need of a warm water bath. In a sheep model, Kallel et al19 showed that PLA lag screws compared favorably with metal lag screws for the fixation of mandibular body osteotomies.

Initial pilot resorbable plates and screws were created from a single polymer. These degraded quickly causing tissue reactions, or took too long to degrade offering no real advantages over metal.20

PLA and PGA and their copolymers are typically produced by ring opening polymerization of corresponding cyclic monomers. PLA is a slow-degrading hydrophobic polymer, whereas PGA is more hydrophilic and degrades faster. It is possible to copolymerize the 2 monomers to extend the range of each polymer’s properties.

Copolymers of lactate with glycolide or L-lactide with D,L-lactide are especially interesting for use in craniomaxillofacial implants because they possess attractive combinations of strength and resorption profiles. The properties can be tailored by further incorporation of trimethylene carbonate (TMC) into the polymer backbone. The proportions of these constituents have a strong impact on the strength and malleability of the final product and on its resorption profile.

The main attraction of a biodegradable device, to both surgeons and patients, is that it provides the proper strength when necessary and then harmlessly degrades over time, until the load can be safely transferred to the healed bone. Subsequently, there is no need for an additional removal operation, as there could be if a metallic device were used. Therefore, biodegradable devices reduce the total treatment and rehabilitation time of the patient. This may also reduce costs related to this type of trauma.

A nonresorbable plate may affect growth in a growing individual.21 Theoretically, placing metal plates across a growing suture is believed to inhibit growth. The effect of nonresorbable plates on the growth of the mandible is not clear. Resorbable plates would not be present across the suture line over a long period of time, hence their effect on growth may be less than nonresorbable plates.

Local macroscopic and microscopic tissue changes in hard and soft tissue near titanium plates have been described by Kim et al.22 but the long-term effects of these findings have not been determined. In our literature review of titanium 2.0 miniplates, hardware was removed in 3.6% of patients complaining of pain.
in the area of hardware placement, potentially as the result of tissue inflammation. In contrast to the titanium plate review, in this and other studies using resorbable materials, the site of the plate has not been associated with pain. No hardware was removed secondary to pain in the area of plate placement in this study; however, 2 plates were removed because of infection.

The results of this study show the combination of noncompression resorbable plates and short-term maxillomandibular fixation for the treatment of mandibular fractures provided adequate healing with complication rates comparable to nonresorbable plate fixation. Based on the descriptive statistics here, the incidence of infection and complications was similar (Table 2).

There are specific technical aspects unique to the resorbable plates used in this study. For screw placement, a tapping step is needed for placement of the resorbable screw. While this may appear to be a disadvantage because of an additional step and a small (1 to 3 minutes) increase in operative time, the formation of threads allows placement of the fixation screw with minimal pressure and stable alignment of the bone segments.

The amount of dissection necessary to place these resorbable plates is similar to titanium plates. The use of the warming bath to allow for softening of the plate is not a disadvantage because once malleable, the resorbable plate is easily adapted by pressure to the bony surface. No bending pliers are necessary, although they are available for final bending. In our experience, once the surgeon learns this technique, the adaptation of these resorbable plates seemed less cumbersome than titanium plates.

Resorbable plates have evolved to the point where their physical properties are sufficient to withstand the postoperative loads required for fracture repair and a brief period of intermaxillary fixation. In this study, because no data were available on the use of resorptive plates and immediate function with the patient eating a normal textured diet, it was decided to be conservative and place the patient through a limited time of intermaxillary fixation. This treatment protocol resulted in a low overall failure rate in an indigent patient population. These results are similar to other reports using resorbable plates in other fracture sites.

The results of this study are excellent and most likely result from several factors. One surgeon was primarily responsible for all of the surgical procedures. Therefore, the learning curve usually associated with resident surgeons was not found in this study. All fracture sites were included in this study, and the analysis was not performed according to site because of sample size. The controls were literature based and were not included in the protocol, which is not ideal. However, all patients were included regardless of their medical problems, social status, condition of their teeth, or associated substance abuse. The plates used in this study did result in excellent stability and healing of the fractures treated in this study.

Based on this limited series of patients, the hypothesis formulated for this study was validated.

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