Journal of Cranio-Maxillo-Facial Surgery 43 (2015) 515–520

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Application of biodegradable plates for treating pediatric mandibular fractures

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ARTICLE INFO

Article history:
Paper received 3 September 2014
Accepted 2 March 2015
Available online 9 March 2015

Keywords:
Biodegradable plate
Children
Internal fixation
Mandibular fracture
Osteolysis
PLGA

ABSTRACT

Objective: We assessed the clinical results of a biodegradable plate system for the internal fixation of mandibular fractures in children, and observed the imaging features of fracture healing and bone changes around the biodegradable plates and screws during follow-up.

Patients and methods: We enrolled 39 patients (22 male, 17 female, average age 4 years 10 months) with different mandibular fractures. We used 2.0-mm resorbable plates to repair the fractures. Postoperative follow-up ranged from 6 months to 5 years; average follow-up was 1 year 2 months. The outcome measures identified and assessed included facial symmetry, mouth opening, occlusal relationship, infection, nonunion, malunion, and plate dehiscence.

Results: We fixed 42 fractures with 43 resorbable plates; the fracture site of one patient (aged 11 years 3 months) was fixed with two plates. Two patients developed small fistulas at the intraoral incision 2 months after surgery; the fistulas healed after 1 month without special treatment. In the other patients, the incision healed well, there was facial symmetry, mouth opening was >35 mm, and occlusion was good. Follow-up computed tomography examination data were available for 20 cases, and revealed different degrees of radiolucency indicating that osteolysis had occurred. Radiolucency was observed around the resorbable plates 1 month after the surgery. The extent and depth of the radiolucent region were obvious within 1 year of surgery. In the second year, there were obvious repairs, with the bony defect areas becoming shallower. After 2 years, the bony defect areas had almost disappeared.

Conclusion: Biodegradable fixation devices are safe and efficient for treating pediatric mandibular fractures. Osteolysis commonly follows biodegradable fixation of pediatric mandibular fractures, and has no adverse effect on fracture healing.

1. Introduction

Mandibular fracture is one of the most common types of pediatric maxillofacial trauma (Grunwaldt et al., 2011; Iatrou et al., 2010). As the mandible in children is relatively soft and has good elasticity, incomplete fractures are more common; as there are permanent tooth buds in the mandible, the treatment of mandibular fractures in children is often conservative (Rottgers et al., 2011; Zimmermann et al., 2006). Given the progress made in bone-repair materials and the improvement of bone-repair technology, the proportion of children with mandibular fractures treated with open reduction and internal fixation (ORIF) has increased. Currently, titanium plates and screws are the standard for craniomaxillofacial rigid internal fixation, but these are subject to disadvantages such as palpability, visibility, temperature sensitivity, interference with radiographic imaging, and excessive stress shielding. Furthermore, metal fixation may limit mandibular growth in children, and has to be removed in a second operation (Iatrou et al., 2010). Biodegradable fixation does not require removal and will be absorbed gradually – considerable advantages in the management of mandibular fractures in children.

However, there are some disadvantages to biodegradable fixation. First, the duration of the operation is longer as the plate bending requires a heat source, and resorbable screw placement requires screw-thread pretapping before screw insertion (Bell and Kindsfater, 2006). Second, due to insufficient strength of the fixed material, the plates may break and displacement and nonunion might occur after surgery (Vazquez-Morales et al., 2013). Third,

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http://dx.doi.org/10.1016/j.jcms.2015.03.002
1010-5182/

foreign body reaction and complications may occur during the biodegradation and absorption of the plate and screws (Agarwal et al., 2009; Kallela et al., 1999; Landes et al., 2006; Turvey et al., 2011). In this paper, we summarize and analyze the results of biodegradable fixation of pediatric mandibular fractures, and observe the imaging findings for fracture repair and bone changes around the biodegradable plates and screws during follow-up.

2. Material and methods

Data were collected from 39 patients who underwent ORIF with biodegradable plates at our department from September 2008 to December 2013. There were 22 male patients and 17 female patients. The mean age was 4 years 10 months (range: 7 months to 12 years 9 months). Twelve patients were aged 0–3 years (30.8%), 19 were aged 3–7 years (48.7%), seven were aged 7–12 years (17.9%), and one was >12 years old (12 years 9 months, 2.6%). The causes of fracture were injuries from falls (26 cases), of which 10 were from high falls; and traffic accident injuries (13 cases).

Among the cases, there were 10 cases of 1-site fracture, 15 cases of 2-site fractures, 13 cases of 3-site fractures, one case of a 4-site fracture, and 83 fracture sites in total. There were 19 cases of symphysis fracture (19 sites), 14 cases of parasymphysis fracture (15 sites), six cases of corpus fracture (six sites), three cases of angle fracture (four sites), and 26 cases of condylar fracture (39 sites). Among the condylar fracture cases, there were 13 cases of unilateral fracture, 13 cases of bilateral fracture, 18 cases of intracapsular fracture (27 sites), and nine cases of neck fracture (12 sites).

All fractures were fixed using a biodegradable plate fixation system of 85:15 poly(L-lactide-*co*-glycolide) (PLGA, PolyMax; Synthes, Oberdorf, Switzerland). The plates are available in the form of 4-hole plates (1.0-mm thick). The screws for the system (2.0-mm diameter) are 4–10-mm long. The exclusion criteria were delayed and malunion fracture, bone defect fracture, infected fracture, and comminuted fracture.

2.1. Surgical methods

All fractures were treated through intraoral mucosal incision and the fracture lines were exposed adequately. Steel wires were used to ligate 4–6 teeth on both sides of the fracture line loosely initially. The fracture was reduced, the pre-injury occlusal relationship reestablished, and then the wires were ligated tightly (Fig. 1). An assistant maintained a good occlusal relationship, and intraoperative maxillomandibular fixation (MMF) was not required. A 4-hole resorbable plate was held along the inferior border of the mandible and adapted to the bone surface, with 2 screw holes on each side of the fracture. The screw holes were drilled and the screws inserted after tapping with a hand-held tap to cut the screw threads (Fig. 2).

2.2. Treatment of condylar fractures

All condylar fractures were treated conservatively. Soft occlusal splints were fabricated for patients aged >3 years. The patients wore the splints after surgery throughout the day for 1–3 months (Fig. 3). In the first month after surgery, the patients were required to follow a soft diet and to perform mouth opening exercises 2 weeks after surgery.

Patients were followed at 1, 3, and 6 months, and 1 year after surgery. The ligating wires were removed 1 month after surgery. Clinical examination was performed to assess wound healing, facial symmetry, mouth opening, occlusal stability, infection, nonunion, malunion, and plate dehiscence. Fracture healing was assessed using radiographic examination.

3. Results

We fixed 42 fractures with 43 resorbable plates. We used 19 plates for 19 symphysis fractures; 16 plates for 15 parasymphysis fractures, two plates were used to fix the fracture site in one patient (aged 11 years 3 months); six plates for six body fractures; and two plates for two angle fractures.

3.1. Clinical follow-up

At 1 week after surgery, the wounds of all patients had healed well and there were no postoperative complications. Postoperative follow-up ranged from 6 months to 5 years; average follow-up was 1 year 2 months. In two cases of left parasymphysis fracture combined with right condylar fracture, small fistulas developed at the intraoral incision 2 months after surgery; the fistulas healed after 1 month without special treatment. The incisions of the other patients healed well, there was facial symmetry, a good occlusal relationship, and mouth opening was >35 mm. There was no temporomandibular joint ankylosis, nonunion, or osteomyelitis.

3.2. Imaging findings

Twenty cases underwent one or more computed tomography (CT) examinations during the entire follow-up period, which showed that the fracture lines healed normally. We observed radiolucency around the resorbable plates on the CT scans of all these 20 patients as early as 1 month after surgery, indicating that osteolysis had occurred. The extent and depth of the region was obvious within 1 year after surgery, and the bone underlying the

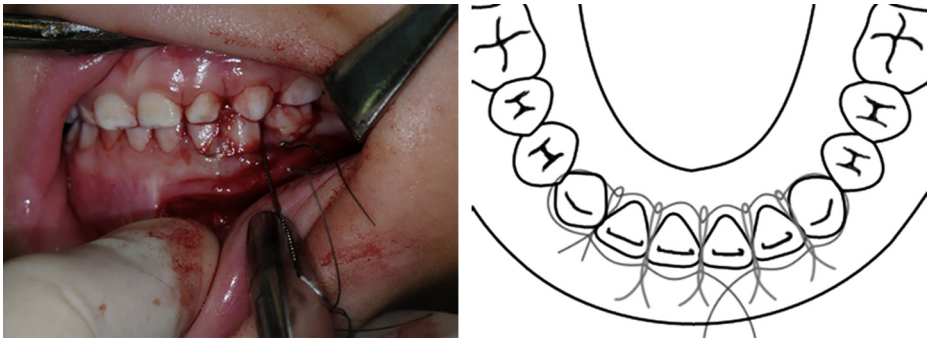

Fig. 1. Steel wires were used to ligate 4–6 teeth on both sides of the fracture line loosely initially. The fracture was first mobilized and the pre-injury occlusal relationship reestablished, then the fracture was reduced and the wires ligated tightly.

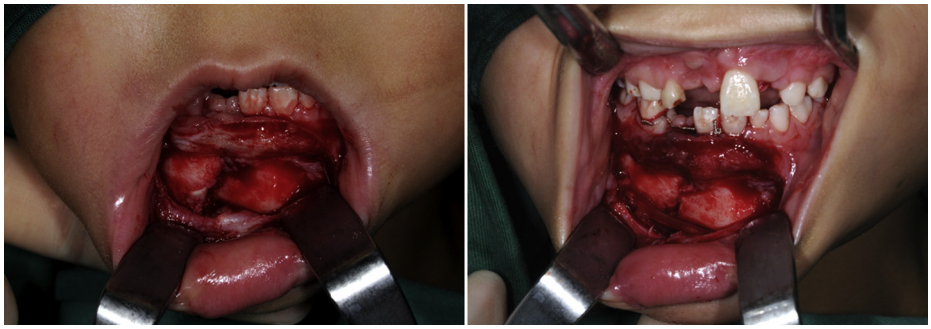

Fig. 2. An assistant maintaining a good occlusal relationship during surgery; the mandibular fracture was fixed with one resorbable plate along the lower margin of the mandible.

Fig. 3. Children aged >3 years with condylar fractures wore soft occlusal splints for 1–3 months after surgery.

plates was clearly irregular and depressed when compared with the adjacent bone (Fig. 4). In the second year, there were obvious repairs to the radiolucent region and the bony defect area had become shallower. After 2 years, the bony defect areas had almost disappeared (Fig. 5). In the patient aged 12 years 9 months, we did not observe osteolysis on CT at 3 months after surgery, but there was slight bone resorption at 10 months after surgery; this persisted even after 1.5 years (Fig. 6). The other patients were aged 7 months to 10 years.

Condyle shape in the condylar fractures was gradually restored after remodeling. The bilateral condylar fractures were symmetrical; the unilateral condylar fractures were asymmetrical (Fig. 5).

4. Discussion

When treating pediatric maxillofacial fractures, factors such as age and anatomical site and complexity of the fracture should be considered (Haug and Foss, 2000). In general, treatment of patients with undisplaced or incomplete mandibular fracture should include liquid diet, close observation, and regular follow-up. For displaced and mobile mandibular fractures, monomandibular fixation can be performed using an arch bar or acrylic splint; an alternative method is intermaxillary fixation. As the contour of the primary dentition is lower, ligating the arch bar to the dentition is difficult; the situation is the same situation in mixed dentition, and circummandibular wires and some form of skeletal suspension are often required (Eppley, 2005). In children, especially younger children, monomandibular fixation (MMF) cannot reduce fractures anatomically, and does not facilitate early recovery of mandibular function. Furthermore, as children generally find it difficult to cooperate with the treatment conditions, conservative treatment is relatively difficult.

ORIF reduces fractures anatomically, and children can resume a normal diet as soon as possible, which ensures the nutrition

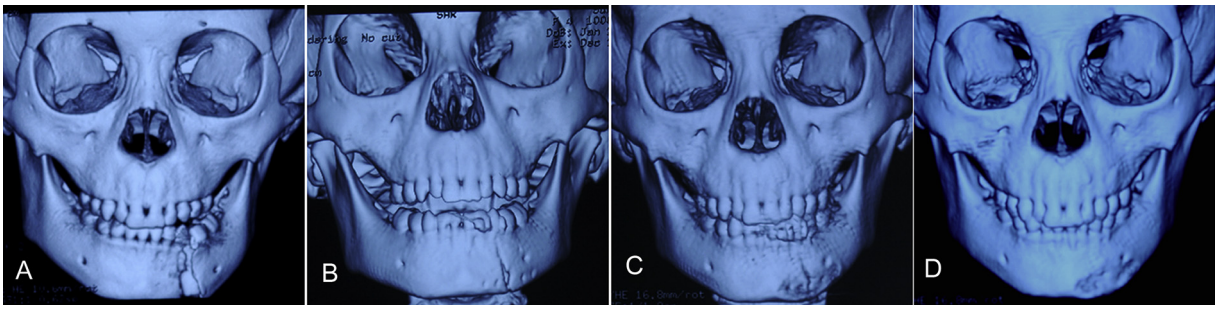

Fig. 4. A 5-year-old girl sustained a left parasymphysis fracture from a traffic accident. (A) Preoperative 3-dimensional CT scan of the fracture. (B) A 3-dimensional CT scan 1 week after the operation; the left parasymphysis fracture was fixed with a resorbable plate. (C) A 3-dimensional CT scan 1 month after the operation; there is bone resorption around the plate and the fracture line still exists. (D) A 3-dimensional CT scan 6 months after the operation; there is no obvious change to the bone depression area, but the fracture healing is good.

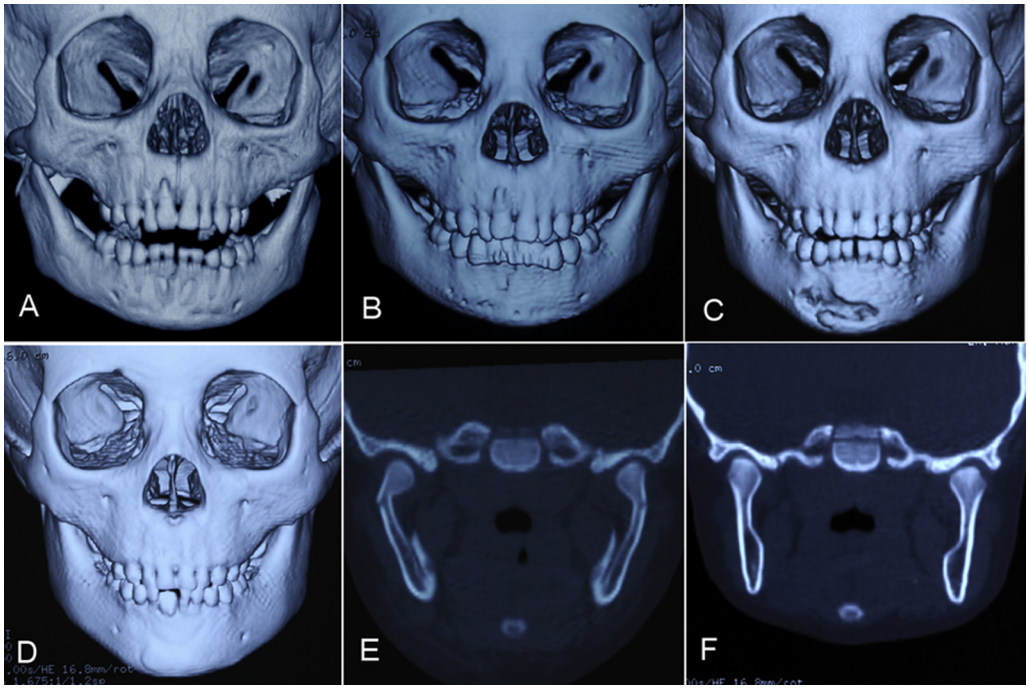

Fig. 5. A 2-year-old boy sustained symphysis and bilateral condylar fractures from a high fall. (A) Preoperative 3-dimensional CT of the fractures. (B) A 3-dimensional CT scan 1 week after the operation showing good reduction of the symphysis fracture and screw hole images on both sides of the fracture line at the lower margin. (C) A 3-dimensional CT scan 6 months after the operation revealing severe osteolysis at the biodegradable fixation site. (D) A 3-dimensional CT scan 2.5 years after the operation showing good reossification at the osteolytic region. (E) Preoperative coronal CT of the bilateral condylar neck fractures. (F) Coronal CT at 2.5 years later showing good remodeling of the bilateral condylar processes.

required for fracture repair and bone growth (Haug and Foss, 2000). It can also reduce the duration of mandibular immobilization, which is conducive to the recovery of joint function (Eppley, 2005; Yerit et al., 2005a). ORIF is the standard treatment for displaced mandibular fractures in children (Iatrou et al., 2010; Zimmermann et al., 2006), but issues regarding the application of titanium fixation may arise, such as allergies, stress shielding, corrosion, limitation of bone growth, and plate migration, necessitating a second operation to remove the titanium plates.

After 30 years of development, an increasing number of clinicians have gradually accepted the use of biodegradable fixation for maxillofacial fractures. In the field of craniomaxillofacial surgery, biodegradable fixation is mainly used for oral and maxillofacial trauma, orthognathic surgery, and cranial vault modeling. In addition to the titanium plating system, biodegradable fixation is another option for maxillofacial skeletal fixation. The biodegradable plating systems commonly used are mainly composed of polyglycolic acid (PGA), poly(L-lactic acid) (PLLA), and their copolymers (Poore and Penna, 2008). Generally, plate bending requires a heating device to cause the polymer chains to bend and not break, and placement of the resorbable screws requires pretapping of the screw threads before screw insertion; consequently, the operation is more complicated and more time-consuming compared with that for similar metal fixation systems (Bell and Kindsfater, 2006). In addition, it has been reported that mandibular fractures have been treated with ultrasonic-aided fixation of biodegradable implants (Aldana et al., 2011; Reichwein et al., 2009). As the fractures heal, the absorbable materials are absorbed after a

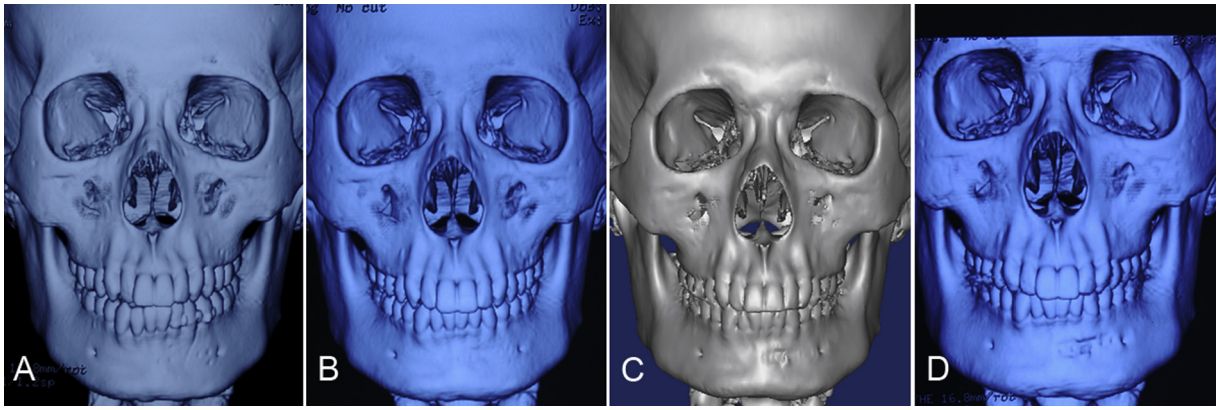

Fig. 6. A boy aged 12 years 9 months sustained symphysis and right condylar fractures. (A) A 3-dimensional CT scan 1 week after the operation; the screw holes in the symphysis region are visible. (B) Three months after the operation, the symphysis fracture line has disappeared and the local bone surface is smooth. (C) Ten months after the operation, slight bone absorption was observed at the symphysis region just around the biodegradable fixation site. (D) No obvious change to local bone absorption at 1.5 years after surgery.

certain period without necessitating additional surgery for removal, which is a clear advantage when treating displaced and mobile pediatric mandibular fractures (Senel et al., 2006).

Most of the patients in this study were aged 0–7 years old (79.5%) and had primary and mixed dentition and permanent tooth germs in the mandible. We placed a biodegradable plate along the lower margin of the mandible, which would effectively avoid injuring the permanent tooth germs. In deciduous and mixed dentition, the crowns of the teeth are short, and fixing them with an arch bar is difficult, therefore we ligated the teeth on both sides of the fracture line, which was equivalent to tension band compensation fixation. This fixation method provides reliable stability for pediatric mandibular fractures, and plate dehiscence and nonunion does not occur postoperatively. Where temporary intermaxillary fixation could not be performed during the operation, an assistant held and pushed up the mandible to maintain normal occlusion prior to plate fixation. Eppley (2005) believed that this free-hand technique is fairly effective for maintaining good centric occlusion before fixation of isolated pediatric mandibular fractures.

Several clinical studies reported that MMF was required after surgery for pediatric or adult mandibular fractures involving biodegradable fixation (Eppley, 2005; Ferretti, 2008; Iatrou et al., 2010; Kallela et al., 1999; Lee et al., 2010; Vazquez-Morales et al., 2013; Yerit et al., 2005b). In particular, MMF ranged from 1 to 4 weeks for combined mandibular and condylar fractures (Eppley, 2005; Iatrou et al., 2010; Kallela et al., 1999; Yerit et al., 2005b). Of the 39 cases of mandibular fracture in this study, 26 were combined with unilateral or bilateral condylar fracture. This group did not undergo intermaxillary fixation or traction during and after surgery. Children aged >3 years who had condylar fractures wore fabricated soft occlusal splints. The splints guided and maintained normal occlusion, which was conducive to condylar remodeling and did not affect the mouth opening exercises. Radiographic imaging at follow-up showed that despite intracapsular or neck fractures, the shape of the condyle was good and joint function was normal. This confirmed that conservative treatment of pediatric condylar fractures (age <12 years) is stable and reliable, and surgical treatment is not required (Iatrou et al., 2010; Zimmermann et al., 2006). Biodegradable fixation is conducive to early recovery of mandibular function. In children with combined mandibular and condylar fractures, joint ankylosis can be prevented with reliable biodegradable fixation and early postoperative joint function training.

The biodegradable fixation system is used for mandibular fractures and even condylar fractures in adults, and is stable and reliable. However, some researchers question its mechanical strength, even arguing that when the role played by resorbable plates is helping to maintain fracture reduction and alignment they should be accompanied by additional approaches (e.g., wires, splints, and intermaxillary fixation) (Bos, 2005; Smartt et al., 2005). We believe that the retention force of biodegradable fixation may be insufficient for mandibular fractures in older children and adults. Mechanical strength remains a key problem limiting the wider use of biodegradable fixation.

The complications of biodegradable fixation are mucosal dehiscence, plate dehiscence, nonunion, malunion (Aldana et al., 2011; Ferretti, 2008; Landes and Ballon, 2006; Lee et al., 2010; Vazquez-Morales et al., 2013; Yerit et al., 2002, 2005b), and foreign body reaction (Agarwal et al., 2009; Kallela et al., 1999; Landes et al., 2006; Turvey et al., 2011). Foreign body reactions include local swelling, fistula formation, sterile abscess, and osteolysis (Agarwal et al., 2009; Kallela et al., 1999; Landes et al., 2006; Turvey et al., 2011). The most common foreign body reaction is aseptic abscess (Agarwal et al., 2009). Mackool et al. (2006) described four patients who underwent cranial vault modeling using a standard resorbable plating system (PLLA) for fixation. They reported that the plates were not absorbed after more than 2 years, necessitating a second procedure for removal. At a 6-month follow-up, Landes et al. (2006) reported radiographically apparent local osteolysis 2 months after curettage subsided. Kallela et al. (1999) reported on 11 cases of anterior mandibular fracture in adult patients fixed with self-reinforced PLLA lag screws; one patient had osteolysis 6 weeks after surgery, which disappeared 6 months later.

In the literature, osteolysis is rare when resorbable plates and screws were used in the oral and maxillofacial regions. This might be because osteolysis is extremely rare in itself. Another reason might be that the radiographic examinations at follow-up often involved plain films, such as panoramic radiographs, and CT scans were relatively rare (Eppley, 2005; Li et al., 2014; Vazquez-Morales et al., 2013). Panoramic radiographs only disclose the change in screw hole density, but cannot reveal changes in the bone around the resorbable plates. In this study, no osteolysis occurred 3 months after surgery in the patient aged 12 years 9 months with mandibular body fracture; however, there was slight local osteolysis 10 months after surgery, which persisted 1.5 years after surgery. In the younger children, osteolysis appeared earlier and was more severe. Is osteolysis more common in children after using the resorbable plate system? Is osteolysis not obvious or relatively rare after biodegradable fixation of mandibular fracture in older children and adults? Due to the lack of clinical and imaging data from adult mandibular fractures fixed with resorbable plates, the answers to these questions are not forthcoming.

In many patients, the drill holes for screw insertion are visible on radiographs as persistent radiolucent areas (Bell and Kindsfater, 2006; Ferretti, 2008; Landes et al., 2006; Lee et al., 2010; Yerit et al., 2002, 2005a). Some researchers believe that the screw holes may serve as a measure of degradation time in that once the screw hole is no longer visible, it can be assumed that the material has been resorbed (Bell and Kindsfater, 2006; Lee et al., 2010). Landes et al. (2006) observed that the screw holes of 85:15 PLGA reossified 24 months later, and those of 70:30 P (L/DL) LA reossified 36 months later. Ferretti (2008) believed that screw hole reossification was subject to site-dependent variability, generally being more rapid at the mandibular angle and body as compared with the symphysis.

Weiler et al. (1996) studied the effect of PGA rods in 12 sheep with standardized osteochondral fractures of the medial femoral condyle fixed with PGA rods, and observed moderate to severe osteolysis at 4–6 weeks, with maximum changes at 12 weeks in 10 animals. The dissolved areas began to repair 6 months after surgery, and were not fully repaired 2 years after surgery. We believe that biodegradable fixation absorption and osteolytic region repair are not synchronous, and the time from plate implantation to complete bone defect repair should include the time taken for absorption and for osteolytic region repair. From the observation data, osteolysis could have occurred 1 month after surgery, reaching the maximum range 1 year after surgery in most of the cases, and repair began thereafter. In the second year, the extent of osteolysis was reduced, and the defects were distinctly repaired 2 years after surgery in most of the cases. This result was consistent with the data from the manufacturer, which stated that absorption would span approximately 1 year, but that bone defect repair would span approximately 2 or more years after surgery. In this study, all fractures healed normally regardless of the extent of osteolysis; in other words, osteolysis did not affect fracture healing.

5. Conclusion

Biodegradable fixation devices repair pediatric mandibular fractures safely and effectively. Osteolysis commonly follows biodegradable fixation of pediatric mandibular fractures, and is

typically more severe in children aged less than 12 years. Initial osteolysis appears 1 month after surgery, but does not affect fracture healing.

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