Original Article

Comparison of Biodegradable And Titanium Screw Plates In Mandible Fracture.

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Abstract

Aims

To compare the postoperative complications of biodegradable and titanium mini plates in mandible fracture and to see that biodegradable plate can replace the titanium plate.

Methods

Patients undergoing open surgical reduction of mandible fractures in between 2009 and 2011 were included in the present study. There were 116 facial fractures in 79 patients who were randomly divided into two groups either to be treated with Bioabsorbable Poly-L-Lactide or with titanium Miniplate and Screw System. 40 patients with 59 fracture sites were treated with biodegradable and 39 with 57 fracture sites were treated with titanium system. The skeletal stability and morbidity at 1, 3, 6 and 12 months after the surgery was recorded.

Results

In the biodegradable plate group; infection occurred in 2 cases (5%), malunion in 4 cases (10%), malocclusion in 1 caseand the plate was removed in 4 cases (10%). Among the complications in biodegradable plate group, 1 case of infection, 3 cases of malunion , 1 case of malocclusion and 3 cases of plate removal found in parasymphyseal region. Whereas, infection occurred in 1 case (2.5%), malunion in 1 cases (2.5 %) and plate removal in 1case (2.5%), in the titanium plate group.

Conclusion

We concluded that complication could occur in both systems of the screw and plate. The complications were more in parasymphyseal region in biodegradable plate. Though the complication rate is slightly higher in case of biodegradable system than in titanium, biodegradable screws and plates can substitute titanium except in the parasymphysis.

Keywords

Biodegradable, mandible fracture, titanium screw plate

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Introduction:

The facial area is one of the most frequently injured areas of the body. Mandibular fracture is the most common facial fracture, with a 4:1 proportion between mandibular and maxillary fractures [1]. The primary goal of fracture management is the restoration of the form and function of the fracture bones with the least postoperative complications .The use of the internal rigid fixation system for the fixation and stabilization of fractured bone segments, has shown the highest success rates with the lowest incidence of nonunion and postoperative infections. At present reconstruction plates, compression plates, miniplates and micro plates are used for the immobilization of bony fragments [2].

The material used for the immobilization of the fracture must be biocompatible and have adequate strength. Plates and screws are generally made of titanium and are currently regarded as the gold standard because of their high biocompatibility and resistance to corrosion. Though titanium screws and plates are widely used in the management of fracture, many disadvantages are mentioned in the literature. The main disadvantage of this system is the removal of titanium plate due to infection, temperature sensitivity, palpation of the plates or the unacceptability of an incorporated foreign body [3,4]. Interference with imaging and radio therapeutic techniques is another reason to look for the alternative materials for titanium. Possible growth disturbance or mutagenic effects [5], plate migration[6] and local macroscopic and microscopic destruction of hard and soft tissue near the plate including the metallic debris accumulation in local lymphatic nodes [7]are some of the shortcomings of this system. A second intervention to remove the implants implies additional surgical discomfort, risks, and associated socio-economic costs [4,8]. To eliminate these problems of the titanium screw and plate system, biodegradable material has been developed. Radiolucency and implying good compatibility with radiotherapy and imaging techniques is the key factor for the preference of biodegradable material.

Bioabsorbable plates and screws are most often made of the polymers polylactide and polyglycolide, as well as copolymers polygly- colide-co-polylactide and poly(L-lactide-co- D,L-lactide) (P[L/DL]LA). They have different mechanical and degradable properties. Depending on the material used, most bioabsorbable materials can be eliminated from the body in 8 months to 5 years [9]. Kulkarni et al. [10] performed the first experimental study about the use of biodegradable devices in surgery. Since then it has been reported to be used for fixation in different caniofacial fractures. Bos et al. [11] first demonstrated zygomatic fractures feasibility of resorbable plate and screw. Initially, the biodegradable materials were used in fewer stress bearing areas in the maxillofacial region such as orbital floor fracture [12], zygoma fractures [11], midface fracture and skull fracture [13,14]. Thereafter in orthognathic surgery [15], pediatric fractures [5].

The presence of polymer make biodegradable plates weaker than plates made of titanium. So due to the less mechanical strength compared to titanium, they were made bulky to use in load bearing areas like mandible that interfere with tensionless wound closing. Enlarged dimensions restrict easy application in small areas that are difficult to access especially in pediatric fracture [16]. Besides; bulkiness other disadvantages of poly-l-lactic acid are foreign body reaction due to degradation product [17] and show a very long degradation period [18]. Some authors claim that despite the many theoretical benefits that biodegradable systems may have, the size of the devices, their adaptability, and other clinical handling properties have been found to be inferior to titanium fixation systems [19].

Our aim was to compare the postoperative complications of biodegradable and titanium miniplate in mandible and to show the efficacy of biodegradable plate in the fracture management and to show that biodegradable plate can replace the titanium plate. The hypothesis set for the study is that there is no difference in stability and morbidity regarding the fixation of bone segments with biodegradable fixation device (poly-l-lactide (PLLA) miniplate system) and titanium screw and plate in mandible fractures.

Patients and methods

Patients undergoing open surgical reduction of

mandible fractures in the Department of Oral and Maxillofacial Surgery, Wuhan Union Hospital between 2009 and 2011 were included in the present study. There were a total number of 79 patients with 55 males and 24 females and age ranged between 17 to 66 years. The patients were classified into 3 groups according to the site of the fracture. (Table 1 and table 2) The mandibular fracture was divided into parasymphysis, angle and ramus. Patients with condylar, infected or comminuted fractures were not included in the study.

The patients were randomly divided into two groups based on the type of screw and plate system for the reduction of the fracture. They were either treated with biodegradable Poly-L-Lactic Acid (PLLA) screw and plate or titanium screw and plate. Written consents were taken from every patient undergoing operation. The biodegradable system was Poly-L-Lactic Acid (PLLA) (GRANDFIX (Gunze) Kyoto, Japan) screw and plate and the metal plate were titanium (KLS Martin Tuttlingen, Germany). The basic properties of the materials provided by the company were summarized in Table 3, Figure 1 and Figure 2.According to the information provided by the manufacturer the material loosed 50% of its strengths in 4-6 months and all its strengths in 8 to 10 months. The material will be completely degraded in 3-5 years. 15% of the material will be lost in 25 months and 25% in 30 months.

A team of four surgeons performed the surgery. The surgical approach was intraoral and extraoral depending on the ease of approach to the fracture site and less scar formation after the surgery. The plates were placed on the Champy's ideal line of osteosynthesis. Maxillomandibular fixation was given in patients before fixation of the screw. Fixation of the screw and plates were done according to the instruction from the manufacturer. The patients were advised to take soft diet for 6 weeks postoperatively. Maxillomandibular fixation was continued in biodegradable patients for 3 weeks after surgery. While arch bars, Ivy loops were removed after 6 weeks from both groups of patients. Figure 3 (preoperative and follow-up CT scan in different patients in different follow up visits). All the clinical and radiological findings of the patients were recorded preoperatively and 1, 3, 6 and 12 months after the surgery. The complications were recorded. The Outcome Assessment Indices for Mandibular Injuries were according to Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParCare 2012)[20]. The indices were evaluated at each follow up visit. Both clinical and radiographic analysis was done by more than 1 of the surgeons.

All the data were analyzed using the statistical software package SPSS for windows. Descriptive statistics and test of significance were used, and the significance level was set at $p<0.05$.

Results

The result of the present study was summarized in Table 4. A total number of 116 plates (59 PPLA and 57 titanium) were applied in 79 patients. The mean age of the patient was 41.5 years (17 to 66 years). There were 3 cases (3.79%) with infections. The infection was generally seen within 1 month postoperatively, 2 (5%) patients with biodegradable plate had an infection and 1 (2.5%) patient with titanium plates and screw had infection in angle. Malunion was more prevalent in biodegradable screw and plate in 4 (10%) patients, compared to 1 (2.5%) in the titanium system. A total of 3 patients with biodegradable system in the parasymphysis of the mandible presented with malunion, while only 1 in the angle region. Malunion in the case of titanium was observed in 1 case in parasymphysis. Plate removal was done in 6(7.5%) patients, 4 (10%) biodegradable plates were removed in which malunion was observed and 2(5.12%) titanium plates were removed in which 1 had malunion of the reduced bone and 1 had infection in the angle of the mandible.The 5 cases of malunion underwent re-surgery and fixation with titanium screw and plate. A single patient refusing resurgical intervention developed malocclusion, which was corrected after grinding. Apart from the complications our study did not met with nerve damage or soft tissue infections.

The data were tested statistically, fishers test was done but no significance was found at $p<0.05$.

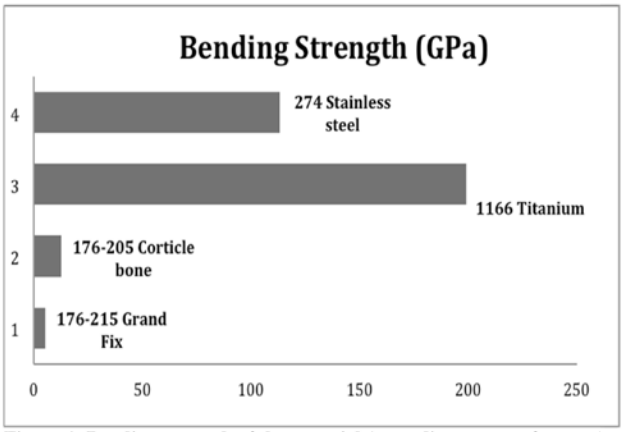

Figure 1- Bending strength of the material (according to manufacturer)

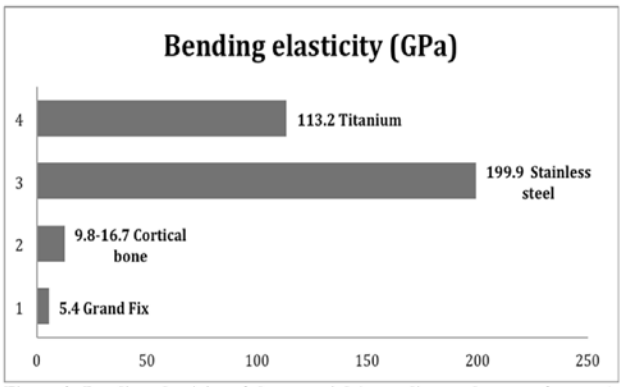

Figure 2- Bending elasticity of the material (according to the manufacturer)

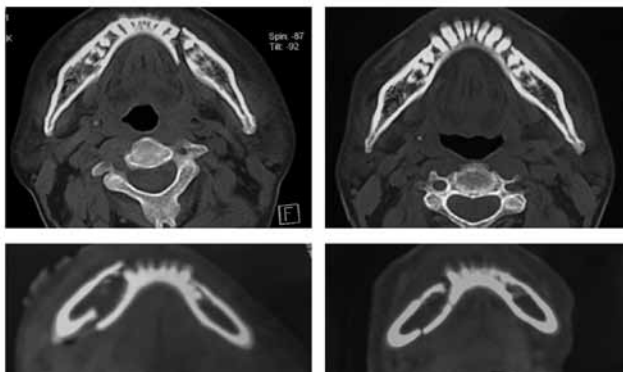

Table 1 TOTAL NO OF FRACTURE SITES

Fracture site	System for fracture treatment		Total
	Biodegradable plate	Titanium plate	
Parasymphysis	31	28	59
Angle	19	21	40
Ramus	9	8	17
Total	59	57	116

Table 2 TOTAL NO OF PATIENTS

	Biodegradable plate	Titanium plate	Total
Angle + Parasymphysis	12	12	24
Ramus only	9	8	17
Parasymphysis only	12	10	22
Angle only	7	9	16
Total	40	39	79

Table 3 Materials for fixation

	KLS Martin Tuttlingen,Germany		GRANDFIX, (Gunze) Kyoto, Japan
Material	Titanium		Poly-L-Lactic Acid (PLLA)
Screw diameter (mm)*	1.5	2.0	Internal-1.7; external-2.2
Screw length (mm)*	6.0	6.0	5.0, 7.0 or 10.0
Plate length (mm)*	18.5	25.5	22.0, 25.0, 28.0 or 34.0
Plate width (mm)*	3.5	5.0	5.0
Plate thickness (mm)*	0.6	1.0	1.5
Tensile strength (MPa)*	251.21	369.84	-
Side bending (MPa)*	248.23	370.20	-
Torsion (MPa)*	248.53	367.96	-
Bending strength (MPa)*	-	-	176-215
Bending elasticity (GPa)*	-	-	5.4
Compressive strength (MPa)*	-	-	5390

*As per the manufacturer.

Table 4: Summary of the complications

Fracture site	Infection		Malunion		Malocclusion	Plate removal	
	Bio	Ti	Bio	Ti	Bio	Bio	Ti
Parasymphysis	1		3	1	1	3	1
Angle	1	1	1			1	1
Total (n)	2(5%)	1(2.5%)	4 (10%)	1(2.5%)	1(2.5%)	4(10%)	2(5.12%)
Total (n)	3(3.79%)		5(6.32%)		1 (1.2%)	6(7.5%)	

n -Percentage; Bio- Biodegradable, Ti- Titanium

Discussion

Mandibular fracture is the most common fracture in the facial skeleton. Screws and plates in the fracture were applied along the Champy's line. Champy et al. determined the ideal line of osteosynthesis in the mandible. The miniplates placed in that line was thought to be more stable [21].

In the study the time between fixations of fracture from the time of injury is 3.3 days. There are controversies that early treatment may decrease the rate of complications. Champy et al. [21] recommended fixation within 12 h, whereas Cawood [22] extended this period to 24 h after injury. However it is also reported that the complication rates with delayed miniplate osteosynthesis were comparable with miniplate osteosynthesis performed within 24 h [23].

Various complications can be seen after miniplates and screw fixation, such as infection, malunion, palpability, plate removal and nerve paralysis [24]. The infection rate was 5% in biodegradable plate and 2.5% in titanium plate. The overall result was 3.79 %. The data agrees with the rate of infection 1%-3.6% as mentioned in other literatures [24,25]. The infection present can be grouped as early and delayed infection. The early infection occurred within 1 month after the surgery. The patients were given antibiotics. Incision and drainage were performed in the cases that did not respond to antibiotic. The plates were kept intact. The infection subsided within 5 to 7 days. The dead space between the fractured pieces was responsible for the early infection. The infection could be due to the dead space created after the extraction of the tooth in the fracture line or between multiple fracture pieces. The infection in titanium palate was in angle due to multiple fracture fragments. The plates were removed when the condition was not improved after the antibiotic therapy [26]. Like in other cases most of the infection were seen in the parasymphysis region [24].

Fracture stability is considered a key factor for prevention of infection. So it is advised for the application of intermaxillary fixation and non-chew diet postoperatively is necessary to stabilize the bony fragments postoperatively [14]. In the present study 3 weeks of maxillomandibular fixation and 6 weeks of placement of arch bar and Ivy loops were done in PPLA screws and plate system. Only arch bar and Ivy Loops were placed for 6 weeks in titanium. In the literature some has been mentioned 0 to 4 weeks MMF only in case of condylar fracture [27] and Laughlin et al. [28], Vázquez-Morales et al. [29] and C. Ferretti [30] for 2, 3 and 4 weeks respectively. One of the principle factors responsible for the malunion is the mobility of the fracture segments during the healing phase. The malunion in 5(6.32%) cases developed due to the poor patient compliance that is chewing solid food voluntarily postoperatively [14]. So it is advised for the application of intermaxillary fixation and non-chew diet postoperatively is necessary to stabilize the bony fragments postoperatively [14]. As described in other literatures, nonunion is predominant in the mandibular parasymphyseal region in case of mandibular fractures [31,32], 4 cases of malunion were observed in the mandibular parasymphyseal region. Literatures had mentioned 2.5% of the cases of malunion in case of mandibular fracture [31,33,34].

The crystalline nature of PLLA is responsible for producing complications like foreign body reaction and incomplete resorption of the plate [16]. Foreign body reaction has been mentioned as 14.28% by Bell and Kindsfater [14] and 6.1% by Kim and Kim [35]. In some literatures, it is mentioned that the inflammatory responses are seen 4-20 months postoperatively. Our study did not show such types of reaction. A long-term follow-up is needed to conclude the foreign body reaction [26].

A total number of 6(7.5%) plates were removed in our study and 4 (10%) plates were removed in patients who received biodegradable screws and plate and 2 (5.12%) in titanium screw and plates.

The rate of plate removal mentioned in the literature ranged from 1.51%-10% [26,28,35-37] . In our case the main cause was malunion due to voluntary chewing of food after surgery only a case of titanium plate was removed from the angle due to persistent infection even after incision and drainage and antibiotic treatment while many literature stated infection to be the main cause of plate removal [38,39]. The majority

of the plates were removed from the mental or the symphyseal region followed by the angle as mentioned in other studies [40,41]. The time interval between plate placement and removal was 3 months in our scenario. The period mentioned in other literatures is 1 year [38]. Besides these complications we did not met soft tissue infection and nerve injury.

Conclusion

Both the systems for fracture reduction are not free of complications. There is no statistically significance difference in postoperative complications and fracture healing between biodegradable and titanium groups in our study. Though Ferretti and Reyneke [30] and Wittwer et al.[42] reported that biodegradable materials and titanium fixation are not significantly different regarding long-term stability and postoperative complications, a great frequency of material-related complications is observed in the biodegradable fixation plate group. Many of the complications we come across are in parasymphyseal region as occlusal force is more concentrated in this region. So stronger material is desired in this region. As titanium screw and plate had greater resistance to occlusal loads than biodegradable screw and plate [17,43], titanium screw and plates are suitable to use in parasymphyseal region.Except for the parasymphyseal region biodegradable plates can substitute titanium in most of the situations.

Competing interests: None

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