ORIGINAL ARTICLE

Bioresorbable Versus Titanium Plates for Mandibular Fractures

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ABSTRACT

Objective: To compare bioresorbable plates with titanium plates for treatment of mandibular fractures.

Study Design: Randomized controlled trial.

Place and Duration of Study: Oral and Maxillofacial Surgery Department, Armed Forces Institute of Dentistry, Rawalpindi, from January to December 2010.

Methodology: Patients with mandibular fracture were randomly divided in to two groups. The control group received titanium plates while the experimental group received the bioresorbable plates. All the procedures were carried out under general anaesthesia using standard surgical techniques. Frequency of plate/screw breakage or loosening, development of infection, malocclusion, malunion, wound dehiscence, the need for hardware removal and any other technical difficulties were compared between the two groups using chi-square test with significance at $p < 0.05$.

Results: A total of 34 patients were included in the experimental group where 53 resorbable plates were applied. The control group consisted of 35 patients and received 52 titanium plates. The mean age in the experimental group and the control group were 31.35 $\pm$ 11.16 years and 34.31 $\pm$ 10.69 years respectively. Breakage of 16 screws and 03 plates was seen in the experimental group while no screw or plate broke in the control group. The results showed significant association of screw breakage with resorbable plates and plate removal with titanium plates.

Conclusion: Bioresorbable plates can be used as an alternative to titanium plates in mandibular fractures but with caution. They are a good means to stabilize fractures in patients where growth retardation and hardware removal may be a consideration.

Key words: *Mandibular fracture. Titanium plates. Bioresorbable plates.*

INTRODUCTION

Mandibular fractures are among the most common injuries to the facial skeleton.[1,2] The primary goal of management in such cases is the realignment of fracture segments and restoration of which aids healing of fractured segments.[3] Multiple surgical modalities have been devised over time. These include treatment by closed reduction with maxillomandibular fixation, open reduction with non-rigid fixation, and open reduction with rigid internal fixation.[4,5] All of these modalities carry certain advantages and disadvantages. Titanium plates have been used for over two decades to achieve internal rigid fixation of mandible fractures because of their bio-inert behaviour, unmatchable strength, ease of application and less frequency of reported complications.[6] Titanium plates may, however, require removal in circumstances like growing patients associated infection or on patient preference etc.[7]

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With the introduction of biodegradable materials in the field of medicine, a new treatment modality was introduced as a substitute for titanium plates.[8,9] These plates are available in different materials like poly-glycolic acid or poly-lactic acid, with varying properties.[10,11] They have less strength as comparable to metallic plates but provide a major advantage; they get resorbed approximately in a year.[12] This gives an advantage over conventional metal plate; they do not require subsequent removal and thus a second surgery is avoided.[13]

Although resorbable plates for rigid craniomaxillofacial fixations were introduced couple of decades ago, they are still not used on a large scale. They can be ideal for young patients in which growth is occurring at a fast pace as metallic plates are thought to restrict the growth.[14]

The aim of the current study was to compare the bioresorbable plating system with the standard titanium plating system for treatment of mandibular fractures in terms of fracture union, restoration of function, frequency of complications and any specific technical challenges that may be encountered.

METHODOLOGY

This experimental study was conducted at Oral and Maxillofacial Surgery Department, Armed Forces Institute of Dentistry, Rawalpindi, from January to December 2010.

Prior permission was obtained from the ethical committee of the hospital to carry out the study. Patients with mandibular fractures reporting to Oral and Maxillofacial Surgery Department were inducted in the study and patients with contraindication to general anaesthesia, comminuted fractures, metabolic bone disorders and those with pathologic fractures were excluded from the study and evaluated for rigid osteosynthesis. A detailed history of patients was recorded, noting down etiology of fracture and any significant medical/ general/ systemic or dental history that may have its bearing on the outcome of treatment. It was followed by a thorough clinical examination to determine the nature of injury, any immediate emergency, exact type of fracture, site, associated soft and hard tissue damage, nerve derangements etc. Patients requiring any immediate medical/surgical assistance for underlying threats to life were referred to respective specialists for appropriate management. Specific investigations pertinent to the fracture like orthopantomogram were carried out along with the baseline investigations for general anaesthesia fitness. After careful review of the case, a treatment plan was devised. Patients were briefed about the nature of the study and only the patients willing to take part in the study were included and informed written consent was obtained from them.

Patients were randomly divided into two groups using lottery method. Control group received titanium plates (Treu-dynamic, Germany), a total of 52 plates. The experimental group received the bioresorbable plates (Bonamates® series Bio-Resorbable Osteofixation System, Germany). Resorbable plates were manufactured from medical grade 90:10 Poly (L-lactide-co-D, L-lactide). The surgery was carried out by the same surgical team and in the conventional manner using standard incisions. Resorbable plates were adapted using a hot water bath at 65°C. Bone tap was used to cut threads in the bone for resorbable screws as they were not self-tapping. Intermaxillary fixation using eyelets and tie wires was carried out in both groups for one week only. After the surgery, patients were admitted to the ward facilities for two or three days on an average. Follow-up visits were carried out at 1 week, 2 weeks, 1 month, 2 months and 3 months interval. Postoperative orthopantomograms were taken as a record. Intermaxillary fixation was removed after one week in both groups. The per-operative parameters to be compared included breakage or loosening of plates/screws and any other technical difficulties that may be met. Postoperative parameters included development of infection, mobility at fracture segments, malunion, malocclusion, soft tissue dehiscence, necessity for hardware removal and the requirement of revision surgery. In case where malocclusion was seen, it was treated with occlusal equilibration. Wound dehiscence was managed with re-suturing and maintenance of oral hygiene using chlorhexidine mouth rinses.

The data was analyzed using statistical software Statistical Package for Social Sciences (SPSS) version 17.0. Frequency and percentages were calculated for categorical data such as gender while mean, range and standard deviation were calculated for numerical data like age. Variables in both the groups were compared using chi-square test, Fisher's exact test and student t-test. P-value of < 0.05 was taken as significant.

RESULTS

A total of 34 patients were in the experimental group where 53 plates were utilized, out of these 53 plates three plates were broken during fixation, hence, in actuality 34 patients received 50 plates. The control group consisted of 35 patients and received 52 titanium plates. The overall mean age was 32 years in this study. The mean age in the experimental group and the control group were 31.35 ± 11.16 years and 34.31 ± 10.69 years respectively. Breakage of 16 screws was observed in the experimental group while no screw broke in the control group. Five patients in experimental group and 3 patients in the control group did not present for the last follow-up visit. Mean follow-up for the control group was 88.97 ± 5.5 days while for study group it was 89.65 ± 4.3 days (Table I). Mobility at fracture site was dealt with performing IMF and maintaining it for 2 – 3 weeks. In 4 patients, titanium plates had to be removed. The reasons for removal included chronic infection in 2 cases, patient preference in one and hindrance with prosthesis in the fourth case. The consolidated results are shown in Table II. There was a significant

Table I: Baseline comparison of both groups.

Variable	Resorbable plates (experimental group)	Titanium plates (control group)	p-value
Age (mean and SD)	31.35 ± 11.16	34.31 ± 10.69	0.253
Subjects (n)	34	35	-
Plates used	53	52	-
Screws used	216	208	
Mean follow-up	89.65 ± 4.3	88.97 ± 5.5	0.193
Male:Female ratio	31:3	31:4	-

Table II: Comparison of outcome and complications in both groups.

Variable	Resorbable plates (experimental group)	Titanium plates (control group)	p-value
Plate breakage	3 (8.8%)	0 (0%)	0.114
Plate loosening	0 (0%)	0 (0%)	-
Screw breakage	16 (8%)	0 (0%)	0.004
Screw loosening	10 (5%)	4 (2%)	0.063
Infection	0 (0%)	2 (5.7%)	0.15
Mobility at fracture site	2 (5.9%)	1 (2.8%)	0.53
Malunion	0 (0%)	0 (0%)	-
Malocclusion	1 (2.9%)	0 (0%)	0.30
Wound dehiscence	2 (5.9%)	2 (5.7%)	0.98
Plate removal	0 (0%)	4 (11.4%)	0.04

Figure 1 (a): Mandibular fracture (L) parasymphysis.

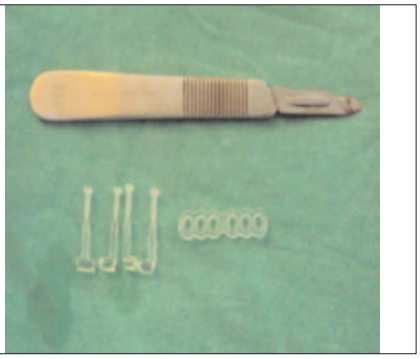

Figure 1 (b): Bioresorbable plate and screws.

Figure 1 (c): Plates and screws in place.

association between plate/screw breakage and type of plate used ($p < 0.05$).

DISCUSSION

In this study, standard titanium plates were compared with bioresorbable plates for treatment of mandibular fractures in isolated fracture mandible cases in adult patients. The bioresorbable plates which we used were Bonamates® series manufactured from medical grade 90:10 Poly (L-lactide-co-D, L-lactide) which is produced from a mixture of 90% L-lactide and 10% DL-lactide. This product retains more than 100 MPa of its strength after 6 months and converts into carbon dioxide and water by the process of bulk hydrolysis and absorbs completely in approximately 36 – 60 months.[15] The absorption happens in two phases; hydrolysis and fragmental metabolization.[16] Hydrolysis occurs when body fluids enter the implant and chemically reacts with the polymer and break the polymer chains. Fragmental metabolization occurs as the polymer continues to fragment until single lactic acid molecules are finally metabolized in the liver into carbon dioxide and water.[10] Poly-lactide polymers degrade slowly as compared to poly-glycolide and hence are more suitable for use in adult patients.[11] Six-hole straight plates were used with screws of 2 mm diameter and 6 mm or 8 mm length. Six mm screws were used in the fractures of the angle and body region while 8 mm screws were preferred in fractures of the symphysis and parasymphysis region. In the control group, standard miniplates with mono-cortical screws of either 6 mm or 8 mm length was used.

This is almost similar to studies by Menon *et al*.[8] and Turvey *et al*.[17] Out of all the above mentioned parameters, screw breakage was significantly more common in the experimental group (8%) compared to 0% in control group. On the contrary, hardware removal was required in 11.4% cases in the control group while none was needed in the experimental group. These results are in accordance with those reported by Menon *et al*.,[8] Turvey *et al*.,[17] Leonhardt *et al*.[12] and Bayat *et al*.[18] Wound dehiscence was observed in 2 cases of the experimental group and both of them were in the symphysis region. The reason could be inflammatory response or delicate soft tissues in the area. Three resorbable plates broke during placement. The cause in one case was improper adaptation, and when screws were tightened, they lead to fracture of the plates. In the other case, the plate fractured due to heating and bending multiple times and in the third patient, the breakage occurred due to improper patient selection in a patient with markedly displaced fracture pull of the segments.

We observed some technical difficulties regarding the experience with the resorbable plates. The plates and screws were transparent and most of the times it was difficult to distinguish between the plates and screws especially when inserting at the mandibular angle area with trans-buccal instruments. Care had to be taken while drilling or tapping in order to prevent the grinding of screw holes in the plates. There were significantly more screw breakages in bioresorbable plates mostly in the form of shearing of the head of the screw. There were two important reasons for that; under-tapping of the screw holes and use of excessive pressure while tightening. This can be avoided by thorough tapping upto the full length of the hole according to the length of the screw being used and using thumb and index finger while tightening the screws instead of using the palm. Use of thumb and fingers generates more controlled force and can help to reduce the frequency of screw breakage. A good thing in case of screw breakage is that the same holes can be re-drilled and reused with new screws and plates need not to be relocated. This point has been highlighted by Menon *et al*. too.[8] There was an increase in operation time for resorbable plate patients as the plates had to be heated and then bent according to the mandible's anatomy. Tapping before insertion of screw is technically difficult especially at mandibular angle area which requires extra time. The plates lack considerable strength and tend to break under excessive loading and hence we would recommend their use in undisplaced or minimally displaced fractures only. There was a learning curve and with experience the incidence of screw and plate breakage reduced and also

with patient selection and this point has also been highlighted by Turvey *et al*.[17] Another problem which we anticipate in the use of the resorbable systems, is the cost of the implant. They are almost 4 – 6 times more costly than the titanium ones. Keeping in view the economic status of most of the trauma patients, extensive use of resorbable implants may not become possible in the near future.

CONCLUSION

Bioresorbable plates can be used as an alternative to titanium plates but with caution in severely displaced fractures. They are a good means to stabilize fractures in patients where growth retardation and hardware removal may be a consideration.

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