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Article *in* Journal of Maxillofacial and Oral Surgery · December 2011 DOI: 10.1007/512663-011-0330-x

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**RESEARCH PAPER** 

# **Bio-Resorbable Plates as Effective Implant in Paediatric Mandibular Fracture**

Geeta Singh · Shadab Mohammad · R. K. Chak · Norden Lepcha · Nimisha Singh · Laxman R. Malkunje

Received: 8 October 2011/Accepted: 5 December 2011/Published online: 28 December 2011 © Association of Oral and Maxillofacial Surgeons of India 2011

#### Abstract

*Aim* To evaluate the efficacy of bio-resorbable plates in paediatric mandibular fracture.

*Materials and Methods* In the present study, 40 cases of mandibular fractures were treated by *Inion Cps plating system* using, 2 and 2.5 mm (LPLA/DLPLA/TMC/PGA) bio-resorbable bone plates and screws of 6 and 8 mm screws. The assessment of the patients was done at 2 week, 1, 3, and 6 months using the clinical parameters and bite force recording.

*Results* There was significant reduction in pain at different follow-ups. Paraesthesia was found in two patients with body fracture which remained for 2 week and 1 month follow-up. No paraesthesia was found after 3rd follow-up. Significant stability of fracture fragments were found on different follow ups. Implant exposure was present only in two patients (5%) at 1 month follow up. There was significant increase in incisor, right molar and

G. Singh  $(\boxtimes) \cdot S.$  Mohammad  $\cdot$  N. Lepcha  $\cdot$  N. Singh  $\cdot$  L. R. Malkunje

Department of Oral & Maxillofacial Surgery, CSM Medical University, Lucknow 226003, India e-mail: drgeetasinghkgmc@gmail.com

S. Mohammad e-mail: shadab31aug@yahoo.com

N. Lepcha e-mail: drnordenlepcha@gmail.com

N. Singh e-mail: dr.nimisha24@gmail.com

L. R. Malkunje e-mail: laxmanmalkunje@gmail.com

R. K. Chak Department of Pedodontics, CSM Medical University, Lucknow 226003, India left molar bite force at 1, 3 and 6 months, from 2nd week onwards.

*Conclusion* These findings show that the use of bio-resorbable plates in paediatric mandibular fracture was efficacious enough to bear the masticatory loads during osteosynthesis of the fracture. The recent and significant achievement is the advent of bio-resorbable osteosynthesis devices that has almost solved the problems of stress shielding, secondary surgery and corrosion when metal implants are left-in situ.

**Keywords** Paediatric · Mandibular fracture · Bio-resorbable · Bite force

#### Introduction

The incidence of facial fractures in children has been well documented in the oral and maxillofacial surgery literature since World War II. Perhaps one of the most dramatic changes in this field has been a new interest in etiology, incidence, and prevention, shifting away from the traditional emphasis only on the technical aspects of surgical management.

Facial fractures are less common in children than in adults. In children younger than 12 years, the incidence ranges from 1.5 to 8% of all facial fractures (adults and children) treated in trauma centers [1-3]. In children younger than 5 years, the reported incidence is approximately 1% of all facial fractures seen in trauma centers [4, 5]. In a series limited to pediatric patients who sustained facial fractures, Kaban et al. [4] found only 26.8% of these children were younger than age 5. Posnick et al. [6] also reviewed a group of pediatric facial fracture victims and found that the 6–12 year age range was the most common

and that boys were approximately twice as frequently affected as girls.

Mandibular fractures are the most frequent facial skeletal injuries reported in hospitalized pediatric trauma patients [6]. Both nasal and dentoalveolar injuries are common, but often do not appear in statistics for facial trauma. The force of the trauma required to produce these injuries is less than that required for the mandible. Hence, these children may be treated in the outpatient surgical center or by the oral and maxillofacial surgeon in an office setting. Therefore, they are usually not included in large series of hospitalized patients. The midface is the most protected area in children because of its retrusive position relative to the prominent calvaria.

The conservative approach in the treatment of maxillofacial trauma in children was common for many reasons. The presence of tooth buds and the elasticity of the paediatric bone were factors for splinting and/or intermaxillary fixation as a standard treatment of mandibular fractures in children during deciduous dentition. Open reduction and internal fixation were avoided in most cases so as not to harm the teeth. The development of micro-plates and miniplates made it possible to apply these fixation materials in paediatric traumatology as well. This technology offers improved initial stability but its application in children is limited in the mandible not only due to the abovementioned reasons but also due to concerns over growth restrictions, stress shielding, corrosion, and palpability. Resorbable osteofixation materials promise to overcome these problems.

In the past, open reduction was generally avoided so that damage to the tooth buds would not occur. However, with the current availability of mini-plates and micro-plates, it is possible to perform open reduction and internal fixation without damaging the tooth buds in specific instances. For example, fractures of the symphysis or the parasymphysis in mixed dentition patients, after the incisors and/or canines have erupted beyond the inferior border may be amenable to plate fixation. Open reduction and direct fixation also may be used in the body, angle, and ramus in pediatric patients.

In contemporary maxillofacial surgery, biodegradable bone fixation is becoming an alternative treatment in trauma, orthognathic, and craniofacial surgery [7-14]. The fast development of new biodegradable materials expands the application to areas where a few years ago only the rigid fixation by metallic plates and screws was possible.

In our study we proved that the uses of bio-resorbable plates effective in treatment of mandibular fracture in paediatric patient. In our study there was no complication and no growth disturbance in mandible and also the bite force recorded in follow up period was suggestive of bioresorbable plate are proven to be stable fixation in children. Our data support the use of bio-resorbable plate fixation in paediatric craniofacial surgery as a means of avoiding the potential and well-documented problems with rigid metal fixation.

#### **Materials and Methods**

Subjects for the present study were amongst the patients who reported to the emergency and Out Patient Department of Oral and Maxillofacial Surgery, Faculty of Dental Science, Chatrapati Sahauji Maharaj Medical University, Lucknow, from February 2009 to July 2010.

Preoperatively, detailed histories of the patients were recorded. Preoperative evaluation included careful examination of the soft tissues and underlying skeleton of the facial region, where a thorough physical examination was carried out to exclude any other injuries.

All selected patients were informed about the experimental nature of the study and the possible complications were explained. Their co-operation was solicited, and a written consent was obtained from their parents. The patient received prophylactic antibiotic coverage and analgesics at the time of initial presentation. The diagnosis was made on the basis of the clinical examination findings and radiographic interpretation.

All patients were admitted to the hospital prior to surgery. In case of children from 10 to 15 years, Erichs arch bar or eyelet wires were placed on upper and lower standing teeth to stabilize the fracture segment and to achieve occlusion before plating. In case of children, less than 10 years of age, either a splint was made after impression or inter-dental eyelet wiring was done prior to surgery. Though inter-dental wiring is difficult, but it is possible if the adjacent teeth are firm.

In the present study, 40 cases of mandibular fractures were treated by Inion Cps plating system (Fig. 1), using 2 and 2.5 mm (LPLA/DLPLA/TMC/PGA), bio-resorbable



Fig. 1 Armamentarium

bone plates (Fig. 2) and screws of 6, and 8 mm screws (Figs. 3, 4, 5, 6, 7, 8 9).

The cause of trauma, interval from injury to surgery, average age, gender, and site distribution were all reviewed. Follow-up was done at 2 week, 1, 3 and 6 months. The following clinical parameters were assessed for each patient at each follow-up visit: pain (visual analogue scale 1-10), swelling, infection, paraesthesia,



Fig. 2 Resorbable plate



Fig. 3 Intraoral picture showing fracture at right parasymphysis region



Fig. 5 Exposure of fracture site and fixation of resorbable plate



Fig. 6 Immediate post operative OPG showing reduced fracture with resorbable plate in place



Fig. 7 OPG after 1 month



Fig. 4 OPG showing fracture at right parasymphysis region



Fig. 8 OPG after 6 months



Fig. 9 Occlusion after 6 months



Fig. 10 Bite force recording machine

hardware failure (implant exposure), mobility between fracture fragments, and bite force recording at the incisor, right molar, and left molar regions (Fig. 10).

All bite force measurements were made using the indigenous bite force recorder which consists of four strain gauges mounted on steel bars, forming a wheatstone bridge. Load changes in the steel bar produced a measurable voltage change across the four strain gauges, which were converted into the kilogram force (kp). All measurements were made with the subject seated with the head upright, looking forward, and in an unsupported natural head position. The subjects were asked to remain in this position throughout the trial and to refrain from extraneous movements. The subjects were instructed to bite on the pads of bite force gauge to the maximal level.

#### Results

In the present study, road traffic accident (50%) and fall from height (50%) was the most common cause of etiology. The most common age group that underwent surgery was between 6 and 10 years comprised of 60% of patients. The mean age was 9.2 years.

In the present study 80% of the fracture was of parasymphysis which was most common fracture site, followed by body fracture consist of 20% of cases. Preoperatively deranged occlusion was present in 36 patients (90%) while 4 patients (10%) had normal occlusion.

80% of patients received 2.0 mm and 20% patients received 2.5 mm monocortical plate fixation, of which 80% of patients received 6 mm and 20% patients received 8 mm monocortical screws. The healing of fracture was assessed clinically and biomechanically.

Paraesthesia was found in two patients with body fracture which remained for 2 week and 1 month follow-up. No paraesthesia was found after 3rd follow-up.

Stability of fracture fragment was noticed in 8 patients (20%) at 2nd week. 80% patients had mobility at 2nd week. Mobility was seen in 8 patients at 2nd follow-up and no mobility was seen from 3rd and last follow-up. Implant exposure was present only in two patients (5%) at 1 month follow up. It was not observed in any other patient at any follow-up assessment.

There was significant reduction in pain at different follow-ups (2 weeks, 1, 3 and 6 months) from initial pain. No pain was observed after 1 month in any of the patient.

There was significant increase in bite force at 1, 3 and 6 months, from 2nd week onwards.

#### Discussion

The use of resorbable plates in the treatment of mandibular fractures appears very exciting because the subsequent hydrolysis of the plates and screws would mean no extra hardware, a better evaluation of fracture healing because the resorbable plates are radiolucent, and would obviate the need for repeat surgery for hardware removal. In the recent past, resorbable plates have been successfully used in low-load situations of mid-face osteotomies and paediatric fractures.

As an alternative to metal plate fixation in children, clinicians have recently taken a greater interest in biodegradable fixation techniques. Resorbable sutures have long been used to secure bone fragments; however, they have the same mechanical disadvantages as interosseous wires and cannot provide the necessary rigidity required in many situations. Early animal experiments in the development of resorbable fixation of the facial skeleton date back to the 1970s [15, 16]. The features of an ideal bio-resorbable fixation system include the following: (1) it facilitates internal fixation with the sufficient initial strength to stabilize bone segments and allow uneventful bone healing, (2) it degrades predictably and completely after osteosynthesis has restored adequate intrinsic bone strength, (3) it is biocompatible so as not to induce a significant inflammatory foreign body response or immunologic reaction, (4) it is technically easy to use, and (5) it is cost-effective.

The rationale of using monocortical plate in mandibular fracture is that synthesis by plate screwed on the outer cortical plate is solid enough to support the strain developed by masticatory muscle. The principle of osteosynthesis is to re-establish the mechanical qualities of the mandible, taking into account the anatomical conditions. Bell (2006) used bio-resorbable plates for the patient with mandibular and midface fracture and found uneventful healing [17]. The same finding was reported in our study, where we found uneventful healing in majority of cases.

A minimum of two screws on each side of segment were used to prevent rotational movement of fracture fragment. Intermaxillary fixation were done in above 12 years of patient and in younger patient with mixed dentition where IMF was not feasible the occlusal splint is made, this allow the use of free hand technique during fracture repair. All patients have the stable occlusion, thus showing the post operative stability of bio-resorbable osteosynthesis.

In our study we did not encounter any persistent swelling other than post operative oedema, post operative infection, wound dehiscence, only one patient developed plate exposure at 1 month follow up, by 3rd follow up, the plate was fully covered without traces of any exposure. These finding in our studies are in accordance with Suronen et al. (1993) who treated more than 200 patients with bio-resorbable plates successfully and stated that use of bio-resorbable fixation can be considered routine and it will be definitely state of art at the beginning of millennium [18]. Suuronen et al. (2000) stated that, today, most maxillofacial fractures and osteotomies may be adequately fixed with bio-resorbable materials as we did in our study [19].

As a result of clinical experience, it can be inferred that the use of tripolymer (PLLA/PDLA/PGA/TMC), osteosynthesis system in the management of fractures involving the mandible and middle third of facial skeleton gives excellent results in terms of function, esthetics and acceptability.

In the present study, mobility of fracture was seen in all patient preoperatively, at 2 week follow up mobility was present in 32 patient and in 1 month follow up mobility was present in eight patients, no mobility was found after third and fourth follow up, assessment of stability of fracture segment revealed that the mobility of fragment gradually decreased as the time progressed, and was significant. The forces that must be countered in mandibular fracture have been derived from maximum voluntary bite force measurement, which in healthy adult ranges in the order of (0–20 kPa) average (15.3 kPa) in the incisor, and (0–60 kPa), average (48.3 kPa) and (0–70 kPa), average (49.3 kPa) in left and right molar regions respectively [20, 21].

In our study a statistically significant reduction in incisor bite force was found at first follow up after surgery when compared with second follow up. At first follow up incisor bite force was only 1.05 kPa compared with 3.61 kPa in the second follow up after surgery there is significant increase in incisor bite force of 1.05 kPa in 2 week through 3.61 kPa after 1 month, 5.05 in 3 months. There were no significant difference between the incisor bite force at third follow up (5.05 kPa) and fourth follow up (6.30 kPa) (Table 1). These finding correlate with the finding of Ellis and Throckmorton (1994) as the subject in the study was children [20].

A statistically significant reduction in left molar bite force was found at second week (follow up I) after surgery when compared to the left molar bite force 1 month (follow up II) after surgery. At second week (follow up I) left molar bite force was only 6.03 kPa compared with 10.01 kPa at 1 month (follow up II) after surgery. These findings correlate with the findings of Ellis and Throckmorton (1994) who reported average left molar bite force of 6.03 kPa in 2 weeks and 10.01 in 1 month and 11.10 kPa after 3 months there was no significant difference between the left molar bite force at third month i.e. follow up III (11.59 kPa) and sixth month follow up (12.59 kPa) (Table 2) [20].

**Table 1** Bite force in incisor (n = 40)

	Bite force Mn ± SD	Change in bite force from Mn ± SD	t value	P value
2 weeks	$1.05\pm0.31$	_	-	_
1 month	$3.61\pm0.74$	$2.56\pm0.62$	13.05	< 0.001
3 months	$5.05\pm0.54$	$4.00\pm0.52$	24.19	< 0.001
6 months	$6.30\pm0.56$	$5.25\pm0.50$	33.09	< 0.001

**Table 2** Bite force in left molar (n = 40)

	Bite force LT molar Mn $\pm$ SD	Change in bite force LT molar from Mn $\pm$ SD	t value	P value
2 weeks	$6.03\pm0.52$	_	-	-
1 month	$10.01 \pm 0.99$	$3.98\pm0.85$	14.72	< 0.001
3 months	$11.59\pm1.06$	$5.02\pm0.83$	19.22	< 0.001
6 months	$12.59\pm1.12$	$6.13 \pm 0.96$	20.06	< 0.001

**Table 3** Bite force in right molar (n = 40)

	Bite force RT molar Mn $\pm$ SD	Change in bite force RT molar from Mn $\pm$ SD	<i>t</i> value	P value
2 weeks	$6.88 \pm 1.04$	-	_	_
1 month	$9.41 \pm 1.01$	$2.53 \pm 1.46$	5.47	< 0.001
3 months	$11.51\pm0.59$	$4.71 \pm 1.02$	14.60	< 0.001
6 months	$12.50\pm0.84$	$5.62 \pm 1.28$	14.75	< 0.001

In our study statistically significant reduction in right molar bite force was found at second week (follow up I) (6.88) after surgery when compared to the right molar bite force at 1 month follow up (9.41). Follow up I: right molar force was only 6.88 kPa compared with 9.41 kPa at second follow-up after surgery. These findings correlate with the finding of Ellis and Throckmorton (1994) who reported average right molar bite force of 6.88 (KPa) in 2 week through 9.41 kPa after 1 month. There was no significant difference between the right molar bite force at third month (i.e. follow up III: 11.51 kPa) and sixth month (i.e. follow up IV: 12.50 kPa) (Table 3) [20].

From the forgoing discussion we can conclude that the use of bio-resorbable plate in mandibular fracture was efficacious enough to bear masticatory loads during the osteosynthesis of fracture. The fractures have been sufficiently stable to allow bony healing clinically indistinguishable from those treated with metal mini-plates.

The problem with this system in the high degree of skill required to appropriately fix the plate firmly with screw while taking care not to damage the screw by applying too much force.

#### Conclusion

The recent and significant achievement is the advent of bioresorbable osteosynthesis devices that has almost solved the problems of stress shielding, secondary surgery and corrosion when metal implants are left-in situ. Based on the study following conclusion were derived.

- All the patients in this study were in the age group of 1–15 years, mean (9.2 years). Road traffic accidents and fall were found to be equally responsible for majority of fractures, male–female ratio was 1:1.
- 2. No plates were broken during manipulation and only one screw heads fractured in one patient, this result shows good handling properties.
- 3. No patients reported for any kind of persistent swelling other than post-operative edema which substantially subsided with time.

- 4. High cost of the material is the greatest deterrent to its wider use.
- 5. Bio-resorbable plate have enough strength to bear masticatory force and can be used safely in mandibular fractures as Bite force recordings showed increasing values at subsequent follow up, corresponding to healing of fracture.
- 6. Easily contourable and mouldable intraoperative quality to achieve a closely match-targeted anatomy.

Biomaterials research is an exciting and rapidly growing field and the research has advanced in leaps and bounds over the last two decades. Although the current concepts, knowledge and experience in this field is satisfactory, the ever increasing demand and applications of bio-resorbable plates and screws demands further research and advancements in this field of maxillofacial surgery.

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