

Use of Biodegradable Plates and Screws in Treatment of Pediatric Facial Bone Fractures

Ahmed A A Ali^{1*}, Mansour M Kabbash², Samia M A Said³, Mohamed A Shoeib⁴, Mohamed H Osman⁵

- 1- Plastic surgery department, Qena faculty of Medicine, South Valley University, Egypt
- 2- General surgery department, Aswan faculty of Medicine, Aswan University, Egypt
- 3- Plastic surgery department, Sohag faculty of Medicine, Sohag University, Egypt
- 4- Maxillofacial surgery unit, General surgery department, Assuit faculty of Medicine, Assuit University, Egypt

* Corresponding author: **Dr. Ahmed Ali Abdelrahim Ali**, Qena faculty of Medicine, South Valley University, Egypt

Email: dr.ahmedali80@yahoo.com

Abstract

Background: Pediatric facial fractures patients present unique challenge in terms of their treatment planning which are different from that of adult patients. Early literature has advocated conservative closed management of pediatric facial fractures to prevent complications. However, recent advances in treatment have enabled us to use biodegradable plates and screws, which overcome the limitations of metallic plates.

Aim: This study was done to evaluate the effectiveness of the Inion CPS biodegradable plates and screws on pediatric facial fractures.

Patients and methods: The study conducted on 30 pediatric patients with maxillofacial fractures requiring open reduction and internal fixation. Fractures with infection, comminuted fractures were excluded. Patients aged from 3 to 12 years, 18 males and 12 females, with different types of trauma: 12 patients with falls, 12 patients with MCA, 4 patients with sports, 2 patients with assault from the others, with different fracture sites: 18 patients with mandibular fractures, 5 patients with zygomatic complex fractures, 4 patients with orbital fractures, 2 patients with maxillary fractures (one isolated and the other with mandibular fracture), one patient with frontal bone and sinus fractures (anterior wall). Fractures were plated with biodegradable system (Inion CPS) using standard plating principles. Post-operative complications were assessed.

Results: Satisfactory reduction was obtained in all patients, as judged with the position of fracture segments in 24 hours postoperative radiographs and compared with all subsequently obtained images. The undisturbed reduction was considered as a marker of the stable fixation provided by the bioresorbable system. The screw holes visible as radiolucencies on the radiograph, were also seen to maintain their position throughout the observed period of follow up.

Conclusion: In our study, we concluded that the use of Inion bio-resorbable plates is effective in treatment of facial fracture in pediatric patient. There was no complication and no growth disturbance in follow up period and this was suggestive of bio-resorbable plate are proven to be stable fixation in children. Our data support the use of bio-resorbable plate fixation in pediatric craniofacial surgery as a means of avoiding the potential and well-documented problems with rigid metal fixation.

Key Words: Biodegradable plate and screw system, Internal fixation, Pediatric facial fractures

Introduction

Treatment of maxillofacial trauma in the pediatric patient presents unique challenges not otherwise encountered in adults. Clinicians must consider distinct anatomic and physiologic differences in the growing facial skeleton when managing these problems. Some fundamental adult facial fracture treatment techniques (e.g. permanent titanium plating) are contraindicated in the pediatric population due to dental development and differential craniofacial growth patterns. Over the last several years, the refinement of rigid internal fixation has revolutionized the surgical management of craniofacial fractures; however, the effects of rigid fixation on craniofacial growth are not completely understood [1].

Rigid internal fixation with metallic materials is a standard technique in use for the last 35 years and performed to align bone segments during healing periods. However, there are inherent drawbacks associated with metallic devices, such as susceptibility to corrosion, need to remove these plates and screws due to infection, stress shielding, plate palpability, temperature sensitivity, interference with advanced imaging technique, possible growth restrictions and implant migration in pediatric population and problem in patients who have to be irradiated as they may cause backscatter.[2]

In an effort to overcome the disadvantages of metallic osteofixation devices, various biodegradable polymers have been developed. [3] The advantages of biodegradable osteosynthesis devices include the gradual transference of physiological forces to the healing bone, the reduced need for a second operation to remove the material, its potential to serve as a vehicle to deliver bone healing proteins

to fracture and osteotomy sites [4] and no growth restrictions or possible migration in growing patients. The implant degrades naturally and totally after fracture has healed thus preventing the stress shielding effect [5] while fibrous tissues or bone fills the space previously occupied by the implant. [6] Ideally, these materials are sufficiently rigid, biocompatible, provide stability without affecting bone healing and bone strength adversely, with no interference with postoperative imaging techniques or radiotherapy. Today most commercially available materials which have optimal characteristics for use as a fixation modality in maxillofacial trauma are co-polymers consisting of polylactide acid (80-82%) and polyglycolic acid (18-20%).

However, firstly these have not been recommended for use in loaded and functional bone such as adult mandible because of the lesser strength and stiffness of the material. The present study was undertaken to evaluate the efficacy of biodegradable plates and screws as a method for internal fixation in pediatric patients with maxillofacial fractures to study the morbidity associated with the use of these devices. [7]

Patients and Methods

This prospective study done from October 2010 to October 2014 (4 years duration) on patients admitted to Upper Egypt university hospitals (Sohag and Assuit University Hospitals), to evaluate the effectiveness of the Inion CPS biodegradable plates and screws on pediatric facial fractures, 30 patients were treated, aged from 3 years up to 12 years, from both sexes (18 males and 12 females). Different mechanisms of trauma were recorded (12 patients with falls, 12 patients with motor car accidents, 4 patients with sports, 2

patients with assault from the others), with different fracture sites: 18 patients with mandibular fractures, 5 patients with zygomatic complex fractures, 4 patients with orbital fractures, 2 patients with maxillary fractures (one isolated and the other with mandibular fracture) and one patient with frontal bone and sinus fractures (anterior wall). All of them had the following inclusion criteria:

1. Onset of trauma: within one week.
2. Non - heavily contaminated fractures.
3. Non- Comminuted fractures
4. No systemic or medical diseases that affect bone healing.
5. Informed consent.

Other patients that did not fit the study criteria were excluded:

1. Onset of trauma: more than one week.
2. Heavily contaminated fractures.
3. Comminuted fractures.
4. Dental and dental-alveolar fractures.
5. Systemic or medical diseases that affect bone healing.

Firstly; after admission to the trauma unit; all patients were underwent to preoperative assessment (primary survey) that concerning the trauma patient according to ATLS (advanced trauma life support), with the assessment of airway, breathing, circulation, disability, presence of associated life threatening injuries and other injuries that require urgent interference. Then; history and physical examination (secondary survey) of these patients according to special trauma data sheet were done. History included: personal data: (name, age, gender, address), history of trauma included: mechanism of trauma, time

from trauma to first seen, any loss of consciousness or vomiting, any interference till arrival to trauma unit, last meal or drink and presence of comorbidities (medical disease and allergies); according to the history taking for the polytrauma patient: (AMPLE history: Allergies, Medications, Previous diseases and surgeries, Last meal, Events /Environment surrounding the injury). Clinical examination begins with assessment of the general condition of the patient, then local examination of the maxillofacial region. Finally; assessment with radiological examination using CT (computed tomography) and panorex (for maxillary and mandibular fractures) were done. All patients after being medically stable were operated, usually not more than one week from the onset of trauma (to avoid callus formation).

Material: Biodegradable Inion CPS plating system (Inion, Tempere, Finland) approved by the Food and Drug Administration, was used as a method of internal fixation, shown in (Fig.1)[8]. The material is copolymer of L-lactide acid (LPLA), poly D-lactide acid (DLPLA), trimethyl carbonate (TMC) and polyglycolic acid (PGA). These plates have been reported to resorb slowly, maintaining 70% of their initial strength at nine to 14 weeks, with 42% bulk resorption by 40 weeks, and are completely resorbed by two to four years. Plates are malleable after activation in the Inion Thermo™ water bath (55°C). After water bath treatment, plates are most malleable for 10-15 seconds for easy adaptation. They can also be re-heated for further contouring or bent once cooled. Plates can be easily cut with scissors.

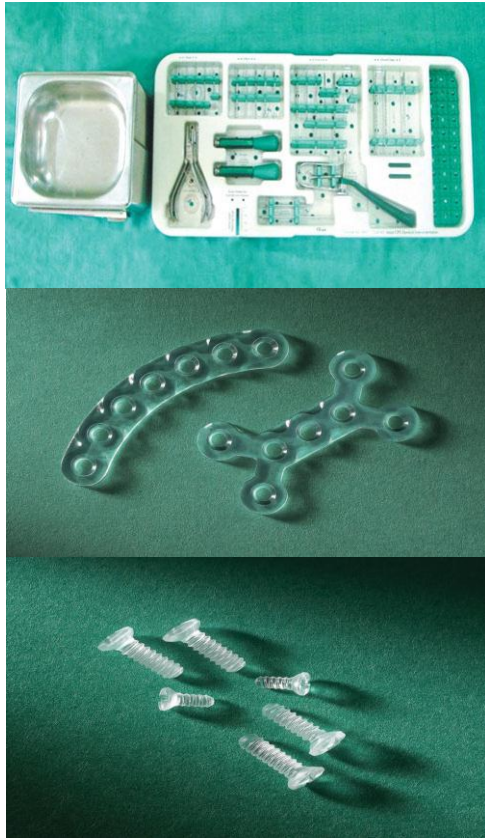


Fig. (1) Shows Inion biodegradable system(8)

Surgical procedures

Surgical access was gained either through an existing skin laceration or a

standardized surgical approach, reduction of fracture segments was achieved and segments were stabilized for plate fixation under general anesthesia. Intravenous antibiotics were injected during operations such as penicillins and cephalosporins.

There were 18 patients with mandibular fractures with a totally of 30 fractures: (6 condyles, 6 angle, 7 body, 7 parasymphiseal, 4 symphyseal fractures) were operated, 12 patients with multiple fractures and 6 patients with single fractures, as shown in table one. Fig. (2) Shows patient (no. 10) with intraoperative fracture exposure and fixation and fig. (3) shows preoperative CT. Maxillomandibular fixation (MMF) with arch bar was done for cases with condylar fractures and multiple fractures to achieve proper fracture reduction and proper occlusion. MMF was left postoperatively for 7 to 10 days, in cases with condylar fractures to maintain occlusion. In patients with isolated mandibular fractures, interdental wires were done for fracture reduction and removed after two weeks. Only one patient had no MMF or interdental wiring.

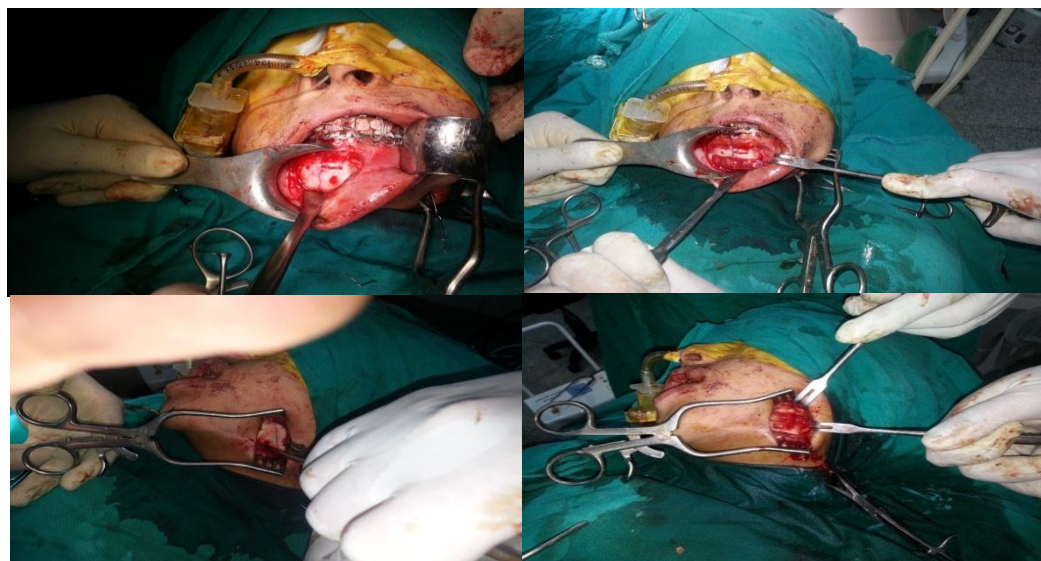


Fig (2) Intraoperative view shows the site of fracture and fixation

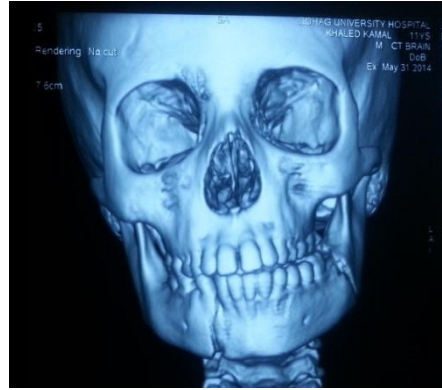


Figure (3) Preoperative CT scan shows site of fracture

No	Age yrs.	Sex	Etiology	Fracture Site	MMF (arch bar)		Interdental wiring
					Intraop.	Postop.	
1	7	M	Fall	RT parasymphiseal + LT condyle	+	+	-
2	3	M	Fall	LT body + RT condyle	+	+	-
3	4	M	MCA	LT body + RT angle	+	-	-
4	9	F	Fall	RT body + LT angle	+	-	-
7	12	M	Assault	RT parasymphiseal + LT condyle	+	+	-
9	3	F	Fall	Symphiseal + RT condyle	+	+	-
10	11	M	MCA	RT parasymphiseal + LT angle	+	-	-
12	4	F	Fall	Symphiseal + RT condyle	+	+	-
16	10	F	Fall	RT parasymphiseal	-	-	+
17	11	M	Sport	RT body	-	-	+
18	12	F	MCA	LT angle + RT parasymphiseal	+	-	-
20	10	M	Sport	LT parasymphiseal	-	-	+
22	9	F	MCA	LT body	-	-	+
23	12	M	Fall	Symphiseal	-	-	+
25	11	F	Sport	RT body + LT parasymphiseal	+	-	-
28	4	F	MCA	RT body + LT condyle	+	+	-
29	10	M	MCA	LT angle	-	-	-
30	5	M	Fall	LT angle + symphiseal	+	-	-

Table (1) patients with mandibular fractures

Totally 5 patients were presented with zygomatic complex fractures, from both sexes (3 males and 2 females), presented with different etiologies (2 fall and 3 MCA). There were 3 patients with right zygomatic complex fracture and 2 with left zygomatic complex fractures. Different points of fixation at zygomaticofrontal suture, infraorbital rim zygomaticomaxillary buttress, were done. Fig (4) shows patient no. 27 with rt zygomatic complex fracture,

fixation was done at one point fixation (at zygomatico maxillary buttress) ,fig (5) show preoperative CT.

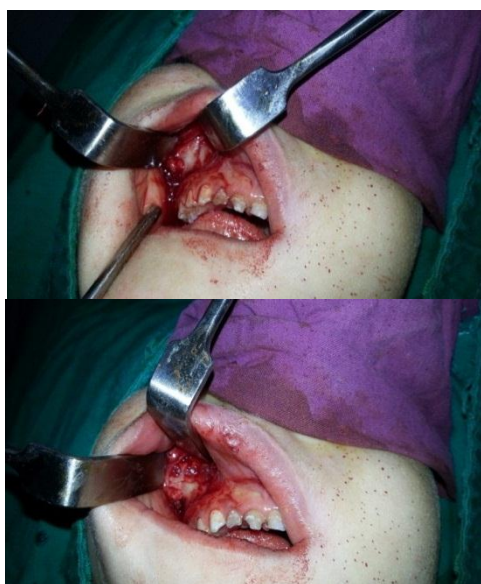


Fig. (4) Intra operative view shows rt zygomatic fracture with resorbable plate fixation at zygomatic buttress

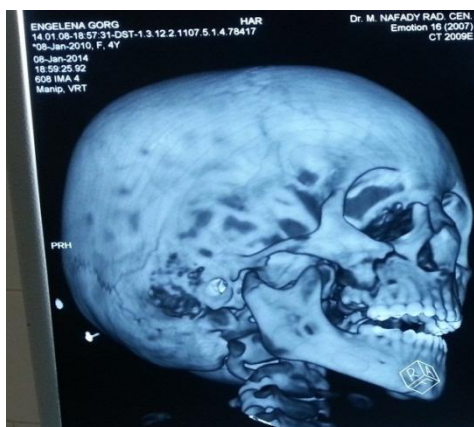


Figure (5) CT imaging shows the site of the fracture

Patients with orbital fractures were all males, with different types of trauma: (2 MCA, 1 sport injury, and 1 assault from the other). There were 3 with right orbital floor fractures and 1 left orbital roof fractures. Reconstruction of orbital floor was done with Inion CPS resorbable mesh and calverial bone grafts.

There were two patients with maxillary fractures one patient had right maxillary (le fort 1) oblique

fracture and was associated with mandibular fracture (right mandibular body fracture) and one patient had only right maxillary (le fort 1) oblique fracture.

There was only one male patient that had left anterior wall frontal sinus fracture displacement associated with supraorbital rim and orbital roof fracture due to motor car accident.

Follow up of the patients were assessed clinically and radiologically with frequent visits in outpatients clinic (one week, one month, 3 months, 6 months and one year): clinically to reveal wound healing complications, fracture segment stability and radiologically by CT for osseous healing, screw-hole ossification and fracture union complications.

Results

This prospective study included 30 patients with age ranges from 3-12 years (mean age: 7.5 years), patients under the age of 5 years were 5 (16.7%); but patients 5 years and up to 12 years were 25 (83.3%), shown in fig. (6). This is due to the children are protected from injury in home environment by the parents during this age, but the incidence of trauma from the age of 5 years and thereafter increases due to increasing activity, sports and outdoors.

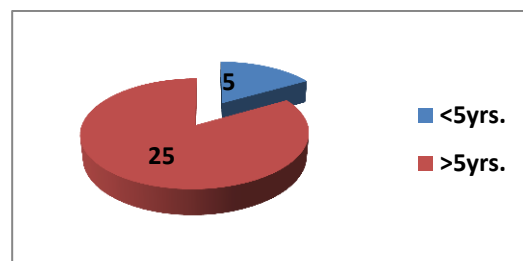


Figure (6): Age group related incidence of trauma

In this study, both sexes were affected by trauma with ratio male: female = 3:2, male: 18 patients (60%),

female: 12 patients (40%) and this indicates the increasing rate of trauma among males than females due to higher activity and including in sport related activities in boys than girls.

There are different etiologies of trauma were recorded with common insult by fall from height (12 patients), motor car accidents (12 patients) and less in sport related injuries (4 patients) and rare in assaults from the others (2 patients), as shown on fig. (7).

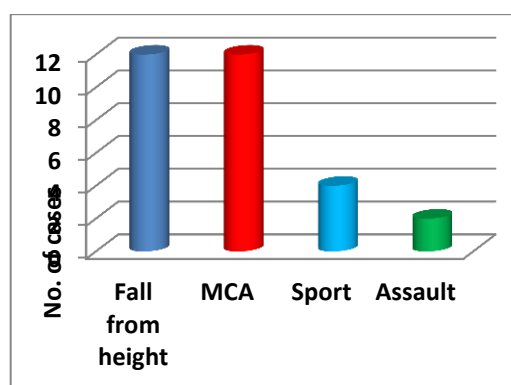


Figure (7): Frequency of mechanisms of trauma

There were different fracture sites were recorded with highest incidence in mandibular fractures (18 patients) due to its prominent feature, then with zygomatic complex fractures (5 patients), 4 patients with orbital fractures, and least with maxillary fractures (2 patients), one isolated and the other with mandibular fracture, and lastly, frontal bone and sinus fractures (one patient).

Patients with Mandibular Fractures:

All mandibular fractures were treated with Inion CPS resorbable plates (2.5 mm) and screws with total number of plates and screws (28 plates and 112 screws) except fracture condyles (intracapsular) that underwent closed reduction only with short period of maxillomandibular fixation and intermittent elastics for 7

to 10 days postoperatively. Follow up shows mild to moderate facial edema, mild intra oral ecchymosis, and mild infections healed with antibiotics; no extrusion of plates. In patients with condylar fractures, no airway compromise and normal occlusion was achieved after removal of arch bars (7 to 10 days) with good healing. In CT follow up, shows good bony union without any signs of instability, non-union, malunion but the drill holes for insertion of the screws wires. Fig (9) shows postoperative CT for patient no. 10 and fig. no.(10) shows normal mouth opening and occlusion.

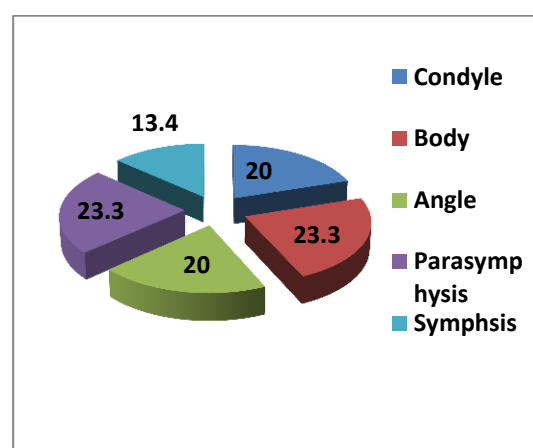


Figure (8) Percentages of types of mandibular fractures



Fig. (9) Shows postoperative CT for patient

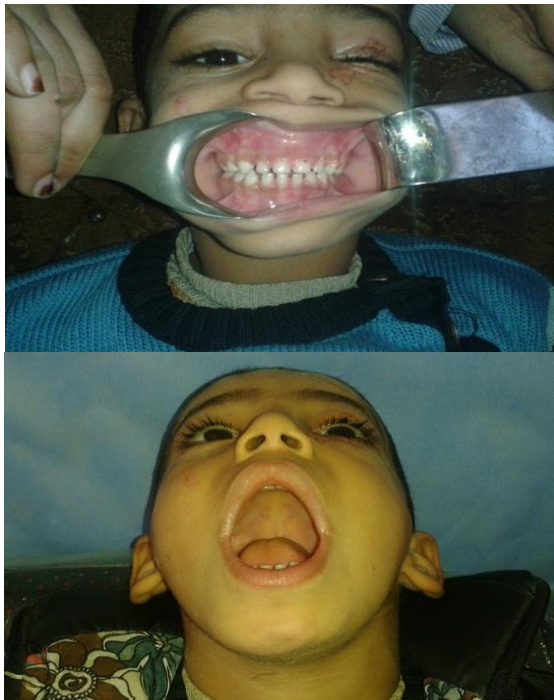


Fig. (10) Shows normal mouth opening and occlusion

Patients with Zygomatic Complex Fractures:

Follow up shows persistent periorbital edema, periorbital ecchymosis, that persist for 7 days, persistent infraorbital nerve hypoesthesia for 10 days, no diplopia, no enophthalmos, no anti-mongoloid slant, no flattening of malar eminence, mild limitation of mouth opening. Fortunately, no infection or plate extrusion had occurred. CT shows no bony healing complications (malunion, displacement), there were no need for orbital floor reconstruction.

Patients with Orbital Fractures:

Follow up shows persistent periorbital edema and ecchymosis, no diplopia, no enophthalmos, no limitation of eye movements, no ocular dystopia, and radiologically shows fracture healing, reduction of herniated orbital contents from maxillary sinus

(no opacification of maxillary sinus, no tear drop sign).

Patients with Maxillary Fractures:

Follow up shows clinically mild intra oral ecchymosis, presence of mild infection that healed with antibiotics after 7 days, no extrusion of plates, normal occlusion, no mouth deviation, and presence of abnormal bite. CT shows good bony healing (no malunion or non-union).

Patient with Frontal Sinus Fracture:

Follow up shows clinically no CSF leak or signs of meningitis, mucocoele or frontal sinusitis. Radiologically by CT shows good bony healing, no pneumocephalus, or dural tears.

Discussion

Trauma is a healthcare problem for humans. Maxillofacial trauma in particular is a major component of the whole trauma and causes severe mortality and morbidity. [8] Dento-alveolar and soft tissue injuries account for the majority of the pediatric maxillofacial injuries but the frequency of facial fractures are considerably low.[9] Trauma to the facial region is especially significant because of the conspicuous location of the human face, its esthetic importance and psychological image adversely affecting important functions like speech, mastication, respiration and deglutition. [10]

In modern maxillofacial surgery, rigid Osteosynthesis has become one of the major breakthroughs. For 25 years now, titanium has shown its excellent qualities [11] and is currently regarded as the golden standard. When using metallic materials; sometimes it is necessary to perform a second

operation for the removal of these metallic materials such as palpation, sensitivity, migration, obstruction in the X-ray, possible bone resorption, allergies, and growth delays in children that leads to the development of resorbable materials.[12] Since the introduction of biodegradable devices in 1966, the development of their mechanical properties and degradation characteristics has been extensive.

Bioresorbable materials mostly used in maxillofacial surgery are a mixture of rigid and elastic polymers selected for their strength, malleability, and degradation properties. The degradation profiles have been tailored to provide initial stability and then progressively load bone to stimulate regeneration. The results of various studies suggested that the use of biodegradable fixation in selected patients with facial fractures is acceptable.[7]

In the present study, 30 cases of maxillofacial fractures were treated with internal fixation using Inion CPS biodegradable plates and screws. There were 18 patients with mandibular fractures, 5 patients with zygomatic complex fractures, 4 patients with orbital fractures, 2 patients with maxillary fractures (one isolated and the other with mandibular fracture), one patient with frontal bone and sinus fractures (anterior wall). Although the tensile strength of a biodegradable plate is less as compared to the titanium it provides enough stability to the fracture segments so that healing can take place.

In the present study, none of the patient had wound dehiscence and plate exposure in the post-operative period. This is somewhat contradictory to incidence of wound dehiscence reported in literature which varies from

screws. All the disadvantages inherent 2% to as high as 6%. [13]. These results can be attributed to the tight closure of the incision obtained with meticulous suturing, adequate soft tissue cover over the implant site and the newer thinner implants. No local tissue reaction and foreign body type of reaction was noticed in the evaluation of surgical site during the follow up period which is contrary to study by Wittwer *et al.*[13]. Although, implant material could not be seen on radiographs, yet these were obtained in all patients, post-operatively, at predecided follow-up intervals.

In a study by **Bali et al**, [2] ten patients with maxillofacial fractures treated by Inion CPS biodegradable plates, two patients with angle (10%) and parasymphysis (10%) fracture and eight patients with midface fractures, out of which 5 (50%) were zygomatico-maxillary complex fractures, two (20%) were Le Fort II and one (10%) patient was of Le Fort III fracture, were included in this study. Reduction of the fracture segments was satisfactory and occlusion relationships were judged as normal in all the cases at every follow up. Adequate stability was maintained throughout the post-operative period in all the patients (100%). There was no incidence of (0%) post-operative paraesthesia, diplopia, enophthalmos/ exophthalmos, wound dehiscence and plate exposure. In one patient (10%), signs of post-operative infection were noticed including swelling and pain, which was managed conservatively with administration of oral antibiotics and analgesics.

Satisfactory reduction was seen in all patients, as judged with the position of fracture segments in postoperative radiographs and compared with all

subsequently obtained images. The undisturbed reduction was considered as a marker of the stable fixation provided by the bioresorbable system. The screw holes visible as radiolucencies on the radiograph, were also seen to maintain their position throughout the observed period of follow up. This again was considered as a marker for maintenance of reduction which is in accordance with Ferretti[14] and Bell *et al.*[7] Rozema *et al.*,[15] studied the effect of these plates and screws when radiation is applied. They stated that these can be regarded as tissue equivalents that do not interfere with the dose distribution of radiotherapy and can safely be used for fracture fixation of bone segments when postoperative radiotherapy is needed.

Postoperative complications after facial fracture or repair are uncommon in children. Because of the child's greater osteogenic potential, faster healing response, and less frequent need for open reduction and rigid fixation, postoperative infections, malunions, and nonunions are all less frequent than that seen in the adult population[12]

Several clinical trials have shown the safety of absorbable fixation system in maxillofacial surgery. Observational studies in maxillofacial surgery have demonstrated that the bioresorbable plate leaves a stable bridge of healed bone or soft tissue after complete degradation with foreign-body reactions. On the contrary, Randomized, prospective controlled

trials have shown no statistically significant differences in the incidence of material-related complications between the biodegradable and titanium groups. [18]

However, *Buijs et al.*, [16] reported that biodegradable plates and screws performed inferiorly to titanium plates and screws in malocclusion (11.1% vs. 8.8%), palpability plate/screw (50.4% vs. 38.1%), dehiscence (4.3% vs. 0%), abscess formation (9.4% vs. 3.5%) and inflammatory reactions (17.1% vs. 7.1%), respectively. In addition, absorbable fixation systems cost more in clinical use. Therefore, absorbable fixation systems should not be considered as the first selective treatment materials for the management of bone fixation in maxillofacial surgery as concluded by.

Bioresorbable fracture fixation has been in clinical use in humans for twenty five years. Still, there are apprehensions to the use of these materials and they have not been able to find place in the armamentarium of the common practicing surgeon. Their exorbitant cost and questionable ability to be used in load bearing areas remains a major hurdle. Its effects on growth may need longer periods of follow up. Another significant factor of the limited use is the resistance by surgeons to modify their conventional, well experienced, treatment techniques. However, if these problems could be completely overcome and these implants could offer the same benefits as metallic implants, they would be able to find a greater place in craniofacial fracture fixation.[18]

Conclusion

- Inion CPS biodegradable fixation system provided satisfactory stabilization when used as internal fixation for pediatric maxillofacial fractures.
- The Inion CPS biodegradable implant material did not evoke any significant immune response and is non - toxic.
- The fixation system did not alter the healing process.
- The fixation technique was not difficult to handle.
- A second surgical procedure was not carried out in all of the patients

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- The encouraging results as obtained in this study seem to reinforce the use of biodegradable plates and screws in fixation of maxillofacial fractures.

Conflict of interest: no.

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