

Clinical and radiographic evaluation of biodegradable bone plates in the treatment of mandibular body fractures

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ABSTRACT

Background: Many different systems are available for the treatment of fractures ranging from the heavy compression plates for mandibular reconstruction to low profile plates for mid-facial fixation, and are made either from stainless steel, titanium or vitallium. Recently, biodegradable, self-reinforced polylactide plates and screws have been used for the internal fixation of fractures of the mandible with good results. **Aim of this study:** This study evaluated clinically the biodegradable bone plates for treatment of mandibular body fracture and to evaluate bone healing during the follow-up period using digital radiography. **Materials and Methods:** Eight patients had been suffered from mandibular body fractures were treated using Inion CPS™ bioresorbable fixation system and the healing process were followed up using digitised panoramic radiography at first week and after 1, 3 and 6 months. **Results:** Clinical examination of fractured segments revealed stable fixation across the fracture sites while visual and quantitative assessment of radiograph showed healing process was comparable with results previously reported by titanium bone plates. **Conclusion:** Open reduction and internal fixation of mandibular fractures using bioresorbable fixation system with a brief period of inter-maxillary fixation have evolved to the point where the physical properties are sufficient to withstand the post-operative loads required for fracture repair of mandibular body fractures. The foreign body reaction is a major material-related problem which requires further studies.

Key words: Biodegradable bone plates, mandibular body, fractures

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INTRODUCTION

Many different systems are available for the treatment of fractures ranging from the heavy compression plates for mandibular reconstruction to low profile plates for mid-facial fixation. The thickness of plates range from 0.5-3.0 mm and are made either from stainless steel, titanium or vitallium. Recently, biodegradable, self-reinforced polylactide plates and screws have been used for the internal fixation of fractures of the mandible with good results.¹

There have been many suggested disadvantages of the use of metallic miniplates systems, including the necessity

for a second procedure of removal of plates routinely at 3-6 months. That is for the avoidance of stress shielding of the healed fracture, the theoretical toxicity of corroding metal and possible carcinogenic potential of titanium has also recorded.²

Synthetic polymers have in general had a large impact on human life. The most commonly used polymers are homopolymers of polylactides (PLLA), polyglycolides (PGA) and copolymers of polyglycolide polylactide (PLGA).³

The degradation of these polymers proceeds by diffusion of water, which starts hydrolytic scission of the polymer chains leading to loss of strength and eventually of implant mass. The hydrolytic degradation of these polymers (PLA and PGA) or their copolymers *in vivo* yield glycolic acid (GA) and lactic acid (LA) monomers, which are metabolised to carbon dioxide and water.⁴

Biodegradable fixation system could reduce or delete the problems associated with metallic system, since removal is not necessary.⁵

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The aim of this study is to evaluate clinically the biodegradable bone plates for treatment of mandibular body fracture and to evaluate bone healing during the follow-up period using digital radiography.

MATERIALS AND METHODS

Medical history and the history of trauma, clinical extra-oral, intra-oral examination and preoperative radiograph were taken for eight patients. All patients were given standard dose of Unasyn. The surgical procedures were performed under general anaesthesia, local anaesthetic solution with a vasoconstrictor was infiltrated along the operative area for homeostasis, and the operative field was scrubbed and draped according to the standard oral and maxillofacial procedures.

Intra-operative inter-maxillary fixation was secured to assure proper occlusion.

The mandibular body fractures were approached through an intra-oral or extra-oral incision according to accessibility in each case.

The fractured segments were reduced and fixed temporarily into perfect anatomical position using a compression clamps secured to cortical bone holes drilled on both sides of the fracture line.

Inion CPS™ bioresorbable fixation system consists of fixation plates, meshes and screws of degradable copolymers composed of L-lactic, D-lactic and trimethyl carbonate. These polymers have a long history of safe medical use and they degrade in vivo by hydrolysis into alcohols and acids that are metabolised by the body. The implant gradually loses their strength within 18-36 weeks. Bioresorption takes place within 2-4 years. The implants have been sterilised with ionising radiation. 2.5 mm Inion CPS™ system is intended for use in mandibular fixation.

A sterile Inion thermo drape placed into Inion thermo water path containing sterile water or saline to minimum 0.4 liters and switched on. Waiting until water was heated up to the setting temperature 55°C, this takes about 20 min. A plate was immersed in the water bath at least for a minute. The plate becomes malleable after 15-20 seconds and can be shaped as desired using the plate bending pliers.

A suitable hole was drilled using the appropriate self tapping drill bit corresponding to the screw diameter attached to a low speed drill (maximum speed of 2,000 rotation per minute, rpm) with irrigation to the bone.

Tapping the screw hole was done using appropriate tap manually with gentle pressure. The tap was held parallel to the long axis of the drill hole both during insertion and retrieving of the bone tap. Screw was picked up using screw

driver and held parallel to the long axis of the drill hole while keeping the plate in position, inserting the screw fully into the drill hole.

The steps of drilling, tapping and screwing of all panel holes were repeated for all screw holes.

Suturing the incision is done as usual manner.

For all patients, intra-operative maxillomandibular fixation was removed and the jaw was manipulated to insure reproducible occlusion without fracture displacement and the stability of the fracture sites checked. A transental wiring was made around the teeth on each side of the fracture line as a tension band.

MMF was applied for one week post-operatively.

Post-operatively, pressure bandage was applied for all patients covering the submental region and the chin to eliminate dead space and hematoma formation in this area and removed after 2-3 days.

Cold application in the form of ice packs ten minutes every half an hour for the next 8-12 hour post-operatively was applied.

Intramuscular injection of Unasyn 1,500 mg every 12 hours was performed 2-3 days then the route of administration changed into oral route (375 mg tablet every 8 hours) for another 2 days post-operatively.

Intramuscular injection of one single dose of Depomedrol 80 mg was injected immediately post-operatively. A single dose of Voltarine 75 mg was injected inter-muscularly immediately post-operative and then replaced by Brufen 400 mg tablets every 8 hours for control of pain.

Hixitol mouth rinses three times daily were used for 2 weeks post-operatively.

All patients were discharged second day post-operatively and instructed to have liquid/soft diet for 2 weeks post-operatively.

The sample in this study was limited in number because of the expense of the material.

This research has got an ethical approval (Ref/0132/).

RESULTS

Minimal oedema was observed immediately post-operatively, which started to resolve by the third day and was completely resolved by the fifth day.

During first post-operative week, all intra-oral and extra-oral wounds healed uneventfully, no abnormal pain, swelling or discharge. All patients showed some degree

of deranged occlusion on admission; however, post-operatively good occlusion was achieved in all patients.

Bimanual examination of fractured segments revealed stable fixation across the fracture site. No movements were noticed in any of the patients. During the post-operative follow-up, no patient was complained from plate palpability or discomfort. Foreign body reaction was reported in three cases which cause transient mild swelling that subsided 2-3 months after fixation of the fracture. Hypertrophic scar of the extra oral incision was observed in two patients who were gradually subsided by application of Contractubex® gel three times daily for 1 month.

Visual assessment of fracture healing using digitised panoramic radiography at the first week post-operatively revealed properly reduced fracture segments with no inter-fragmentary gap and correctly aligned inferior border. One month post-operative radiographic examination revealed no change in the position of the fracture segments. Bone formation and fading of the fracture lines were seen. Three months post-operative radiographic examination showed no change in the position of the fractured segments, bone formation and fading of the fracture lines were seen.

At 6 months post-operatively, the position of the fracture segments were maintained and the fracture lines could not be detected in most of cases. The sites of the screws could still be seen as radiolucent areas with no signs of adverse reaction around the screw holes in all cases except one case which show widening of the holes. This patient had periapical radiolucency related to the apex of lower left second premolar which was in the line of the fracture in the first month post-operatively, endodontic treatment was established the sequence of healing was not compromised.

Statistical analysis of the data with mean \pm standard deviation (SD) and paired t test of radiographic bone densities during the follow-up period.

Quantitative measurement of radiographic density for assessment of fracture healing showed that all cases in the first week had decreased radiographic bone densities followed by increase in bone densities during the follow-up period (1, 3, 6 months) compared to the preoperative values showed that the decrease in the mean values of bone density after 1 week was statistically significant, (P -value = 0.007)*. After 1 month post-operatively, there was insignificant increase in the mean values of bone density, (P -value = 0.150). After 3 months post-operatively, there was statistically insignificant increase in the mean value of bone density (P -value = 0.449), After 6 months post-operatively, there was statistically significant increase in the mean value of bone (P -value = 0.029*).

The period from 1 week to 1 month showed statistically significant increase in the mean values of bone density

(P -value = 0.001*), the period from 1 month to 3 months showed statistically significant increase of the mean values of bone density (0.000*), the period from 3 months to 6 months also showed a significant increase in the mean value of bone density (P -value = 0.0005*).*[significant at P -value < 0.05]

As a result, there was decrease in the mean value and change of percentages of bone densities in the first week followed by gradual increase during the 6 months follow-up period. The period from 1 month to 3 months showed the highest change rate while the period from 3 months to 6 months showed the least change rate [Figure 1].

DISCUSSION

Titanium plates have been used for over five decades to achieve internal rigid fixation for mandibular fractures, resorbable materials have been used as fixation materials in cranio-maxillofacial surgery and for rigid fixation in orthognathic surgery. Biodegradable plates and screws is an ideal system for pediatric fractures with favorable outcome.⁶ In contrast to titanium plating system, resorbable plating systems have not been used on a large scale for the fixation of mandibular fractures.

The results of this study showed that the combination of resorbable plates and short-term maxillomandibular fixation for the treatment of mandibular body fracture provided adequate healing with complication rate comparable to non-resorbable bone plate fixation system. This is in agreement with Laughlin,⁷ Leonhardt *et al.*,⁸ Bayat⁹ who used Inion system in fixation of mandibular fractures.

Quershy *et al.*¹⁰ found that biodegradable bone plates fulfill the treatment goal of immobilisation, fixation and stabilisation in the repair of mandibular fractures. Wood¹¹ used Inion biodegradable system and found that the fractures have been sufficiently stable to allow bony healing clinically indistinguishable from those treated with titanium miniplates.

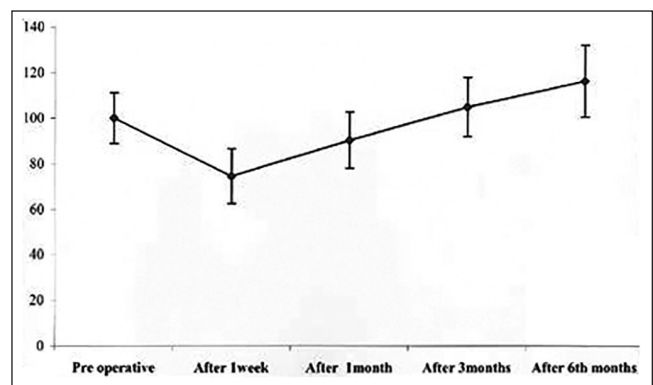


Figure 1: Histogram showing means \pm standard deviation (SD) of radiographic densities in the follow-up periods (1, 3 and 6 months) in relation to preoperative values

Self re-inforced technique provided sufficient mechanical stability of the implants for primary healing of high-load mandibular bone areas. Biodegradable self-reinforced implant show efficient stability during initial bone healing and promise a high potential for successful use in osteofixation of mandibular fractures.¹²

In contrast, there were several studies that described the low mechanical properties; Shetty¹³ showed inferior modulus of elasticity and unfavorable resistance to permanent deformation (yield strength) in comparison with titanium or stainless steel osteosynthesis plates and screws.

Also Yoshaioka *et al.*¹⁴ recommended the use of biodegradable bone plates for minimally loaded situations. And inter-maxillary fixation should be considered to reinforce initial stability in stress-bearing areas.¹⁵

The amount of dissection necessary to place these resorbable plates is similar to titanium plates.

There were specific technical aspects unique to the resorbable plates used in this study.

For screw placement, a tapping step is needed for placement of the resorbable screws. While this may appear to be a disadvantage because of an additional step and a little (1-3 minutes) increase in operative time. The formation of threads allows placement of fixation screws with minimal pressure and stable alignment of bone segments. The use of warming bath is not a disadvantage because once malleable, the resorbable plate is easily adapted by pressure to the bony surface.

No bending pliers are necessary although they are available for final bending. This agrees with Laughlin and wood.^{7,11} Screw failure was low and in this study, in contrast to metal plates relocation could be avoided because extra holes can be drilled through the plate *in situ*, this is in agreement with Haers *et al.*¹⁶ Clinical evaluation indicated clinical union of all fractures at 8-weeks follow-up, this is in agreement with Queresby *et al.*¹⁰

In this study, foreign body reaction was noted in three patients. A transient sterile mild swelling was seen about 3 months post-operatively, which is encountered as a major post-operative complication of the biodegradable materials. Clinically manifested, occasionally foreign body reaction to PLLA has been recorded even 4 years after initial operation.^{17,18}

The degradation of PLLAs involves hydrolytic enzymes, macrophages and cells are responsible for ultimate digestion of the polymeric debris. Microscopically, this is associated with transient foreign body reaction that is not necessary clinically evident. Bostman *et al.*¹⁸ suggested that local tissue tolerance and transport potential in relation to

possibly high amount of polymeric debris formation can cause this foreign body reaction, Turvey *et al.*,¹⁹ Kallela *et al.*,²⁰ Bergesma *et al.*,²¹ Bryan bell²² were observed fibrous tissue, some giant cells, and a mild inflammatory infiltrate in the site of the plate.

In contrast to our study, Haers *et al.*,¹⁶ Eduard *et al.*²³ didn't found any clinically manifested foreign body reactions during the follow-up period. And the plates and screws examined maintain adequate strength for the healing period of bone fracture or osteotomy, producing no harmful foreign body reactions.²⁴

The price of the implant is expensive and in the study by Bouwman,²⁵ he described that the price of the biodegradable screw is roughly ten times more than titanium screw.

The preliminary radiographic evaluation of the fractures treated with biodegradable plates through the visual assessment of digitised panoramic radiography revealed that the sequence of healing is comparable to that treated with titanium plates. The radiographic findings of the present study are comparable with the histological phases of healing after tubular bone fracture²⁶ and similar to those reported previously.²⁷ The increased incidence of osteogenic changes 1-2 months after mandibular fracture can be explained by the histological phase in this period when the stage of hard callus starts. However, at the beginning of this stage, the amount of newly formed bone is minimal, in addition, this stage generally continues from 1-3 or 4 months with a vigorous increase in the formation of new bone.

Quantitative assessment of digitised panoramic radiographs through density measurement showed that 1 week after surgery, there is marked decrease in bone density of fracture site which is attributable to the normal necrotic bone resorption and soft callus seen in the early period of normal bone healing process after fracture or bone grafting. This finding proved that digital radiography could detect minimal changes in radiographic density during early stage of fracture healing.

One month post-operatively measured from digitised panoramic radiography showed increase in bone density compared with 1 week, reliable with that observed in bone grafting²⁶ and reimplantation of frozen autogenous mandibular bone.²⁸

Three months post-operative measurement of digitised panoramic radiography showed a noticeable increase in bone density that denotes the osteogenic changes with the highest rate of bone density changes compared with other periods (1 week and 1 month) and (3 months and 6 months), those results are in agreement with previous study²⁹ which observed vigorous increase in the formation

of new bone in the stage of 1-3 and 4 months that represent complete healing and union of the fracture site. This may be the remodeling of the bone in order to be compatible with the same density and contour of the bone. All screw holes were visible at 6 months. Radiographic changes around screw holes were observed in one case during the follow-up period. Osteolytic changes around resorbable implants have been seen by Böstman,¹⁸ Kallela *et al.*³⁰ The explanation of such reaction is considered to be that the capacity of surrounding tissues to absorb polymer remnants has been exceeded; increased amount of polymer debris could increase osmotic pressure and cause osteolysis.²¹ Clinically, the patient was asymptomatic and it was self-limiting.

CONCLUSION

From the results of this study, it could be concluded that:

Open reduction and internal fixation of mandibular fractures using bioresorbable fixation system with a brief period of inter-maxillary fixation have evolved to the point where the physical properties are sufficient to withstand the post-operative loads required for fracture repair of mandibular body fractures. The foreign body reaction is a major material related problem which requires further studies. Digitised panoramic radiographs allowed evaluation of fracture healing through both visual and quantitative measurements of density changes and help in early detection of these changes which cannot be measured from conventional radiographs. Changes of radiographic densities in the follow-up periods reported in this study were parallel to the sequence of histological phases during fracture healing.

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