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Research Article

OUTCOME OF FRACTURES FIXED WITH BIODEGRADABLE PINS – A CASE SERIES

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Abstract :

Objectives : To study the outcome of fractures fixed with biodegradablepins and complications asssociated with biodegradable pins.Methods :We included 11 patients in our study involving 13 fractures among which ten were children and one was adult. Fracture fixation was performed either by open reduction or closed reduction with percutaneous fixation using 1.5 or 2mm biodegradable pins.No additional metallic implants were used for fracture fixation. Mean followup period was 10.3 months. Each patient was assessed with regional functional scoring system and radiologically.Results : Intraoperative stability was considered good in 46% off fractures and average in 54% of fractures. Functional outcome was assessed with regional specific scoring system . 91.6% of fractures had excellent results and 8.4% of fractures had good results at six months of follow-up. Implant related complications were closely monitored in all patients . Bony resorption(osteolysis) at fracture site was noticed in all patients starting from two weeks post operatively which persisted till 10.2 weeks on an average. Other implant related complications included pin backing out in 4 patients,loss of reduction and delayed union in one patient each. No patients showed other implant related complication which biodegradable materials are known for like local sinus discharge,local abscess formation or aseptic synovitis.Conclusion:The biodegradable pins used in our study were effective way of fixation for fractures that can be fixed with K-wires with acceptable implant related complications.

KEYWORDS:aseptic synovitis, biodegradable pins,polyglycolic acid,osteolysis,polylevolactic acid

INTRODUCTION

Metallic implants have been mainstay in the fracture fixation in Orthopaedics since ages. However, although excellent results, they are associated with several complications like stress shielding[1], accumulation of metal in tissue[2],hypersensitivity, growth restriction, pain and imaging interference[3]. Because of these problems there is a need for second surgery to remove the implant once bone has healed.

To overcome these complications, biodegradable implants have been evolved significantly over past few decades after lot of research. The biggest advantage of these implants is that since these implants have the potential for complete absorption, the need for second surgery for removal is avoided and long term interference with tendons , nerves and growing skeleton

is avoided. This makes fixation with biodegradable implants particularly appealing in children. They also do not interfere with clinical imaging like MRI and CT[4].Numerous biodegradable polymers have been approved and have been used safely in surgical applications over past four decades initially as suture material like vicryl(polyglycolide / polylactide). Fracture fixation devices have been developed over years and most of the present Orthopaedic devices are polyglycolide (PGA) or polylactide(PLA) polymers. Among these, PLA polymers have better durability in-vivo[5].

Though offer many advantages over metallic implants, biodegradable implants have been associated with some disadvantages like poor mechanical strength, high cost[6], early degradation and foreign body reactions.Current uses of biodegradable implants include stabilisation of fractures[6], osteotomies[7], bone grafts and fusion particularly in cancellous bones as well as reattachment of ligaments[9], tendons, meniscal tears and other soft tissue structures[8].

Though many studies have been performed on their clinical applicability, similar studies from India are few. Hence, this study was conducted to know the outcome of the fractures fixed with biodegradable pins and complications involved in them.

MATERIALS AND METHODS :

This prospective observational cohort study was conducted in department of orthopaedics , JIPMER , Puducherry from June 2009 to April 2010. We included closed fractures,upper limb fractures that can be fixed with K-wires,intraarticular fractures, long bone metaphyseal fractures. Excluded criteria included open fractures, segmental fractures,long bone fractures and communited fractures .

Patients with fractures fitting into inclusion criteria were admitted . Patients were given appropriate plasters according to fracture sites and thorough preoperative work up was done.. Proper consent was taken from patients or patient's guardians in case of minors. In our study, totally 11 patients were included with 13 fractures(four lateral condyle humerus fractures, two medial condyle humerus fractures, two both bone distal end forearm fractures, and three metacarpal fractures). Type of implant used was 1.5 or 2 mm biodegradable pins (INION,Finland). Biodegradable pins are supplied in sterile pack which consists of biodegradable pins,cannula or applicator, K-wires and small tap(Figure.1)

Open reduction was performed in all fractures except in metacarpal fractures where closed reduction and percutaneous fixation was performed. With proper surgical exposure techniques fracture sites were exposed and anatomical reduction was done under direct vision. Holding fractures in reduced position , K-wires were passed for initial stability under image intensifier. Keeping one K-wire intact,other K-wire was removed. Cannula provided in the biodegradable pin set passed into track formed by K-wire. Bioderadablepin passed into cannula and tapped gently with tap (Figure 2 and 3). Same procedure is repeated after removing other K-wire. 1.5 mm biodegradable pins were used for medial and lateral epicondyle humerus fractures and 2mm biodegradable pins were used in rest of fractures.

Post operative immobilization was given with plaster of paris in all patients for six weeks. Follow up were done on 2nd ,4th , 6th weeks and followed by every monthly followup for 6 months followed by every 2 monthly for another 6 months.Radiological assessment was done at 2,4 and 6 weeks.At 6 weeks , once raodiological features shows satisfactory healing signs and callus, POP were removed and mobilization were started At 6 months, functional score were calculated according to different scoring techniques. For elbow, Mayo elbow

performance score was used (fracture included were lateral condyle humerus fracture, medial epicondyle humerus fracture, supracondylar humerus fracture).For wrist, Modified Mayo Wrist Scoring was used (fracture included was distal end both bone forearm fracture).For hand, Total Active Range of Motion [TAM] score was used (fracture included was metacarpal fracture).

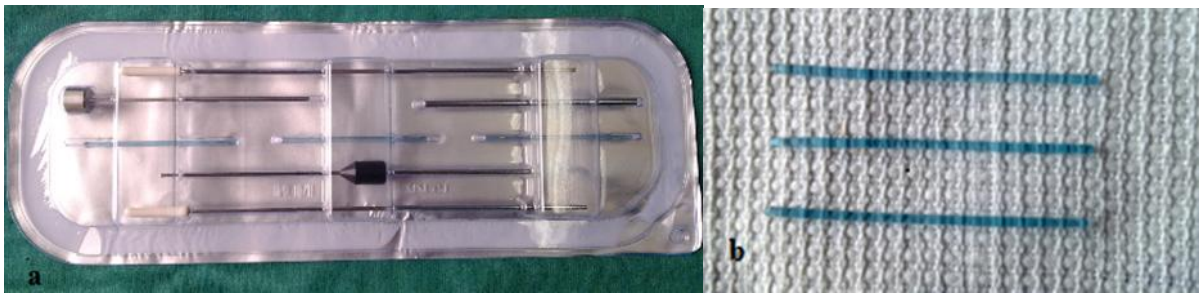

Figure 1. **a**.biodegradable pin set consisting of biodegradable pins,cannula,K-wire and small tap, **b**. biodegradable pins

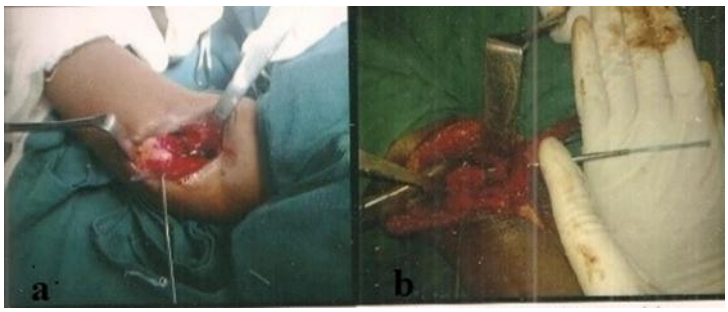

Figure 2. **a**. showing fixation of lateral condyle humerus with 1.5mm biodegradable pins, **b**. supracondylar fracture fixed with 2mm biodegradable pins. Pin is gently tapped into cannula keeping other side K-wire intact

Figure 3. Showing fracture fixation with biodegradable pins in metacarpal fracture. Cannula given in a set used and pin is gently tapped into cannula

RESULTS :

This study included 13 fractures in 11 patients among which eight were males and three were females. Age ranged from 7-19 years with mean being 9.5years.Mode injury was road traffic accidents(n=2) and by fall while playing(n=9).

Intra-operative stability was considered good if, fracture was not opening-up at fracture site on passive range of movements after fixation and considered average if it was opening-up at fracture site on passive range of movements. On that basis, fixations were considered 'good' in six fractures(46% of fractures) and 'average' in seven fractures(54% of fractures). No additional fixation devices were used.In the initial cases it was observed that the biodegradable pins were loose and did not fit snugly in their bony tunnel. These pins had to be anchored by transfixing the protuberant part of pins into the neighbouring soft tissue using sutures. It was later discovered that the guide wires and the bioabsorbable pins supplied were of the same diameter. The biodegradable pins were deformable and became loose in the similarly sized tunnels. This problem was avoided by drilling the initial tunnel with smaller sized K- wires.

Mean follow up period was 10.3 months . All patients completed minimum of six months follow-up. No wound complications were seen during any stage of follow up. . No patients had symptoms of foreign body like reactions like erythema, swelling, discharging sinus, irritation at any stage of followup. Pin backing out was seen in two cases of lateral condyle humerus fractures and two cases of medial condyle humerus fractures (36.4% of cases) at around 4-5 weeks.

At six months, Mayo Elbow Performance Score was used for patients who had medial epicondyle humerus fracture, lateral condyle humerus fracture and supracondylar humerusfracture.Modified Mayo Wrist Score was used for functional assessment of patients with both bone distal end forearm fractures at six months.For hand, Total Active Range of Motion (TAM) score is used.Acording to Mayo Elbow Performance Score and Modified Mayo Wrist Scoring, Total Active Range of Motion (TAM) score , 91.6% of fractures had excellent results and 8.4% of fractures had good results at six months of follow-up. For one patient(with distal end both bone forearm fractures) functional assessment could not be made as the patient lost follow-up after four weeks.

Radiologically all patients had bony resorption(osteolysis) surrounding fracture site starting on average of two weeks post operatively and persisted upto ten weeks post operatively(Figure 4). In one patient (supracondylar humerus fracture) it persisted upto 14 weeks postoperatively(Figure 5). One patient with both bone distal end bone forearm fracture lost reduction at distal end radius due bone resorption near fracture site at two weeks. However, fracture got remodelled at four months(Figure 6). Bridging callus was seen in all patients at average of four weeks except in one patient (with non union lateral condyle humerus) which appeared at six weeks. Fracture line was visible in all patients at six weeks. But on the basis of clinical union, all the patients were mobilized at six weeks.Complete obliteration of fracture line was seen at average of three months.Delay in union, in terms of appearance of bridging callus was seen in one patient(non-union lateral condyle humerus). In this case, bridging callus appeared at six weeks whereas rest of cases it appeared at an average of four weeks.

Figure 4 a. showing immediate postop x ray of lateral condyle humerus fracture fixed with biodegradable pins, **b**. 2 weeks postop x-ray, showing beginning of bony resorption at fracture site, **c**. at 4 weeks, bony resorption and bridging callus is well seen, **d.** at 16 weeks, fracture is well united and bony resorption is completely disappeared.

Figure 5. Bony resorption persisted till 14 weeks postoperatively in supracondylar humerus fracture (bridging callus is also seen)

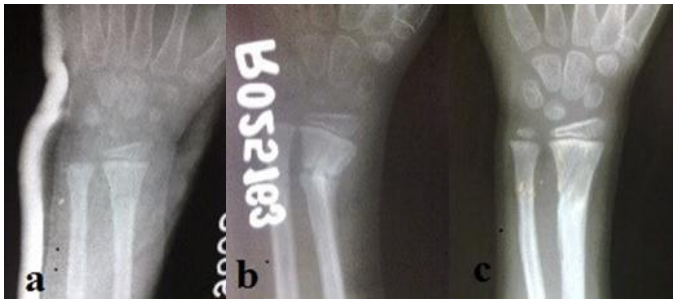

Figure 6. a. showing immediate postop x-rays of distal end both bone fractures fixed with biodegradable pins**, b**. 2 weeks later X-ray showing bony resorption at fracture site and fracture displacement, **c**. fracture remodelled completely at 16 weeks and bony resorption disappeared.

DISCUSSION

The biodegradable implants have been relatively newer concept in management of fracture fixation. The history of bioabsorbable implants in the repair of bone tissue began in the late 1960's . Schmitt and Polistina [10] first suggested the use of polyglycolide(PGA) as reinforcing pins, screws, and plates for fixation of fractures. Since then there has been lot of development in manufacturing and usage of these implants in different types of fractures. Some of the earlier biodegradable implants were made up of materials like PGA which

degraded too early within six months and were found to be not suitable for clinical use. Biodegradable implants used nowadays are made up of Poly-levolacticacids(PLLA) which have longer life which persist in tissues as long as five years[5]. For Orthopaedic usage, the main hindrance to development of bioabsorbable implants has been the question of obtaining sufficient initial strength and retaining this strength in the bone. With the use of self reinforcing (SR) technique the material was sintered together at high temperature and pressure, resulting in initial strengths 5 to 10 times higher than those implants manufactured with melt moulding technique[23]. Though initial strengths of SR-PLLA screws are lower than SR-PGA, strength retention in the former is longer than the latter.[24,25] Now a- days, biodegradable implants show no difference in the stiffness, linear load & failure mode when compared with metallic devices[26].

Many studies have been done regarding use of biodegradable implants in various fractures like fractures around elbow and ankle[6,15,16,17], patella fractures[18], injuries around knee[19,20].But very few studies shows their applicability in metacarpal fractures and distal end both bone forearm fractures. Equal literatures have been available regarding their use in adults as well as children. Our study mainly includes fractures in children(n=10).

Biodegradable implants are more flexible when compared to metallic implants therefore, their on-table stability is a concern. Some studies were satisfied with their stability while other studies have used additional fixation with metallic implants to improve their stability. Lowell H Gill et al [21], used fixation with biodegradable pins in distal Chevron bunionectomy(57 patients). He compared fixation with K-wire used in some patients of distal Chevron bunionectomy(57 patients). The comparisons between two studies were done and it was found that there was no difference in the stability of fixation between two groups. Dhillon et al[6] did a study on 15 patients with fractures around elbow and ankle which were fixed with biodegradable implants. All fractures were fixed only with biodegradable implants except in three cases (one lateral condyle humerus fracture and two capitulum fractures) which were supplemented with additional K-wires to increase the stability. Intraoperative stability was considered excellent in 66.7% of cases and good in 33.3% of cases.

In our study of 13 fractures, were assessed regarding intraoperative stability on table. Fixation of smaller bones like lateral humeral condyle, medial epicondyle humerus were considered as ‘good stability’ as fracture sites were not opening-up on passive range of movements after fixation(46% of fractures) while fixation in metaphyseal bones like supracondylar fracture humerus, distal end both bone forearm fractures and metacarpal fractures(54% of fractures) were considered as ‘average stability’ as fracture sites were opening-up on passive range of movements. No supplementary fixation with metallic implants were used in any of the cases.

Wound complications have been reported with use of biodegradable implants[13]. O.Bostman et al[16], showed wound infection in 3.5% of cases in their study. Wound infection consisted of delayed manifestation at three to four months with uneventful wound healing. It consisted of sterile wound sinus formation with no bacterial growth. Hope PG et al[15] in thier study of 13 children with elbow fractures(medial epicondyle humerus and lateral condyle humerus fractures), found no wound complications in any of the cases after fixation with biodegradable implants. On the other hand, they compared fixation of these fractures with metallic K-wires in a group of 12 patients, where three cases (8.3% of cases) were proved to have superficial wound infections.

Biodegradable implants have several complications generated during their degradation. These complications are classically called 'foreign-body reactions'[11] manifests in the form of aseptic inflammatory reactions, sterile sinus formation[12], osteolysis[13], synovitis[14], hypertrophic fibrous encapsulation and sometimes fixation failure[6]. However, though these complications are quite common in usage of biodegradable implants, they are rarely severe enough to cause disturbances in the fracture healing process[15].

P.G.Hope et al [5] in a study of 13 children with elbow fractures fixed with biodegradable pins reported as no evidence of foreign body reactions. One child developed ectopic bone formation along the K- wire track which produced painless subcutaeneous swelling. One child with avulsion fracture of medial epicondyle had avascular necrosis. Hirvensalo.E and Bostman et al[11,16], used biodegradable pins in the fixation of radial head fractures in 24 patients. They found transient inflammatory reactions around implants in 8% of cases at around 8-12 weeks postoperatively. Casteleyn et al[12] on their study in wrist fractures fixation with biodegradable pins showed sterile sinus formation in 40% of cases. Lee.S.K et al [21] conducted a study on 12 patients with Freiberg disease where they used biodegradable pins in the fixation after intraarticular dorsal wedge osteotomy. There was no report of foreign body reactions in any of the cases conducted.

In our study, there were no complications of foreign body reactions in the form of sinus formation, synovitis, or abcsess formation. But we encountered mechanical problems like pin-backing out in four patients (30.7% of fractures)(Fig 7). This might be due to use of same sized K- wire for getting primary fixation before putting biodegradable pins. Due to larger hole created by K-wires, pins backed out gradually. This was overcame in subsequent cases by using smaller K-wires for primary fixation and suturing free end of the pins to surrounding periosteum with help of absorbable suture.

Fixation of fractures with biodegradable implants is known to cause bone resorption(osteolysis). These osteolytic changes first described by Bostman et al[16] should be reviewed as expected reactions to the biodegradable implant and not as complications. This is seen as cystic changes around the degrading pin and around fracture site and radiographically as radiolucent areas. This complication generally requires only observation because radiographic changes are transient which would heal in time subsequently. It is not associated with any clinical symptoms. However, if these changes exceed certain level, they are likely to interfere with fracture healing especially in apical fractures, particularly since their first occurrence after surgery is within the period of fracture healing(four to eight weeks). Pelto-Vasenius K et al[13] performed 94 Chevron osteotomies in 70 patients in which, osteolytic changes around degrading pins occurred in 21 of 94(22%) metatarsal heads. At follow-up,16 of 21osteolytic changes resolved spontaeneously and four resolved partially. In the remaining one, osteolytic lesion remained for six years post operatively.

In our study, all patients showed bony resorption(osteolysis) starting on average of two weeks and persisted upto an average of ten weeks. It was seen around fracture site and around implant site. All these changes were asymptomatic and needed only observation. Because of these changes, we decided to continue plaster immobilization for six weeks post operatively so as to prevent fracture displacement.

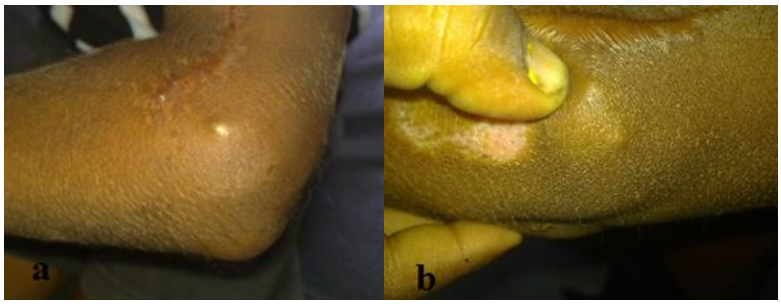

Figure 7(a and b) showing pin backing out in two cases of lateral condyle humerus fractures

CONCLUSION

The biodegradable pins used in our study were effective way of fixation for fractures that can be fixed with K-wires. Results of our study have shown excellent and good functional results with acceptable implant related complications. However it was noted that compared to metallic implants (K-wires), intraopertive stability was average in majority cases and fracture healing was delayed for a few weeks. They were associated with mechanical problems like pin backing out and radiological findings like bone resorption(osteolysis). Hence, in carefully selected cases biodegradable pins can be effective alternative for K-wires for fracture fixation.

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