

Intramedullary fixation of forearm fractures with new locked nail

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ABSTRACT

Background: Lack of availability of interlocked nails made plate osteosynthesis the first choice of treatment of forearm fractures inspite of more surgical exposure, periosteal stripping and big skin incision subsequent scar along with higher risk of refracture on implant removal. We hereby report the first 12 cases with 19 forearm bone fractures internally fixed by indegenous interlocked nail. **Materials and Methods:** Existing square nails were modified to have a broad proximal end of 5.5 mm with a hole for locking screw of 2.5 mm. The nail has a distal hole of 1/1.2/1.5 mm in 2.5/3/3.5 mm diameter nail, respectively. A new method of distal locking with a clip made of k wire is designed. The clip after insertion into the bone and hole in nail and opposite cortex snuggly fits the bone providing a secure locking system. Twelve skeletally mature patients, mean age 32 years (range 24-45 years) with 19 diaphyseal fractures of the forearm were treated with this indigenously made new nail. The patient were evaluated for fracture union, functional recovery and complications. The functional outcome was assessed by disabilities of arm, shoulder and hand questionnaire (DASH score).

Results: Time to radiographic union ranged between 12 and 28 weeks, with a 100% union rate. Complications were minimal, with mild infection in open fracture (n=1) and delayed union (n=1) in patient with comminuted fracture of the ulna only. The clinical results were excellent. The DASH score ranged between 0 and 36 points.

Conclusion: This new interlocking nail may be considered as an alternative to plate osteosynthesis for fractures of the forearm in adults. The advantages are benefit of closed reduction, smaller residual scar, reduced cost and early union with allowance of immediate movements.

Key words: Forearm fractures, intramedullary fixation, locked nail, osteosynthesis

INTRODUCTION

Intramedullary fixation is indicated in segmental and compound injuries, fractures with poor skin condition (burns) and osteopenic bones.¹ The chances of infection are significantly decreased due to the possibility of closed procedure and least periosteal stripping. It also has lower refracture rates after implant removal (1–2% vs. 11% to 20 with plate removal).¹⁻⁶

However, the currently available intramedullary nails lack

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torsional stability and require additional immobilization in a cast for achieving better union rates (nonunion up to 7%),^{1,5,7} which leads to worse functional results. The plate osteosynthesis^{1,4,7,8} is termed as the gold standard in surgical treatment of forearm fractures due to excellent outcome.

Torsional stability can be achieved by thru-hole locking the nail. Concern of locking radius was alleviated by the study of Tabor *et al.* in 1995, which suggested that transosseous static locked nailing of the radius is feasible if a proximal locking screw is inserted from a direct lateral entry at least 3 cm from the radial head with the forearm in neutral rotation.⁹

Existing thru-hole interlocking nails described in the literature, namely the Lefevre nail,¹⁰ having a large handle at its proximal end and foresight/Wurn nails¹¹⁻¹⁴ are thick nails with a minimum diameter of 4 mm. Most of the world, especially the Asian population, allows passage of a 3 mm nail by the closed technique, and as also suggested by a morphological study¹⁵ of having a nail system that should have an option of a minimum 3 mm diameter.

To overcome this issue, a clip-type fitting lock is designed that allows thru-hole locking even in 2.5-mm nails.

The purpose of this study was to prospectively evaluate the outcome, the suitability of this nail in radial and/or ulnar fractures.

MATERIALS AND METHODS

This new ulna/radius nail was designed incorporating for biomechanical disadvantages and pitfalls of all former intramedullary devices.

Twelve skeletally mature patients (9 male) with mean age 32 years, range 24–45 years, with isolated or both bones open or closed diaphyseal fractures of the radius and ulna were evaluated. The exclusion criteria were Monteggia or Galeazzi fracture, fractures more than 7 days old, age less than 18 years, concomitant head or other severe injury and associated vascular or neurological injury.

The study was cleared by the local ethics committee of the Anupam and Associated Hospitals, Rudrapur. A biomechanical test in the form of tensile strength test of the nail was conducted by the FDA-approved manufacturer.

Design feature

This nail is square in shape and is made from stainless steel of grade 316L, with a diameter of 3, 3.5 or 4 mm and a length of 18, 20, 22, 24 or 26 cm. The base of the nail is widened to 5.5 mm over a distance of 3 cm and is round in shape. The base has one proximal locking hole of 2.7 mm for a 2.5-mm self-tapping screw [Figure 1]. Only one locking hole each at base and at tip. In some nails to be used for radius there is one extra hole 6 cmm away from tip. The base of the nail is also the driving end of the nail and is mounted on a drill guide.

The tip of the nail is reduced conically over a distance of 1 cm. A single hole of either 1.2, 1.5 or 1.8 mm diameter is located at 1 cm from the tip. This hole is locked with a specially designed clip lock [Figure 2a and b] or a specialized threaded snap-off pin [Figure 3].

The shape and design for the nails for the radius and ulna are the same. Some nails have an additional hole 6 cm away from the tip. Locking thru this hole gives absolute assurance of being away from the danger area of the posterior interosseous nerve.

Broad base of nail lies at lower end of radius as radius is approached retrogradely. Tip of nail will lie around radial head. Distal locking is performed by a special clip made of 1.2/1.5/1.8/2 mm k wire. It has two arms that look like the letters L and U. The U arm gets joint with the short arm of L. The long arm of L traverses the hole of the nail and bone, and its size depends on the length measured. After drilling, the short arm of L is 5 mm. U snugly fits into the curvature of bone [Figure 2b]. Size of the U arm is made in few millimeter increments to fit into different thickness of bones.



Figure 1: Clinical photograph of the nail

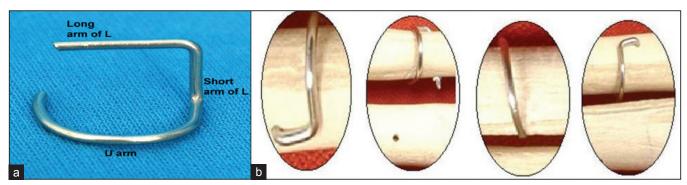


Figure 2: (a) Clinical photograph of the clip lock for distal hole. (b) Views of clip lock after insertion in bone model



Figure 3: Clinical photograph of the snap of threaded pin for locking distal hole as an alternate

Square shape makes the construct rotationally more stable. It also allows better visualization of the hole and easy distal targeting as the drilling wire does not skid along the circumference.

Clip locking makes the construct rotationally stable and additional encircling on curvature of bone gives threepoint fixations; therefore, one clip is enough. It also gives the possibility of drilling the near cortex slightly bigger as fixation is also secured along the circumference of the bone. Because of clip, thru-hole distal locking has become possible in small-diameter nails.

Instrumentation is basically for insertion and extraction and consists of a nail drill guide bolt, forearm nail driver and hammer. Nail bender is needed for prebending to provide an anatomical shape in thick nails. In addition, an aiming device called Jig is also designed to put proximal and distal screws in their respective holes with precision [Figure 4].

Preoperative planning

The length of nail to be inserted is assessed with an X-ray in the usual way, with extra care to make sure of placement of hole at the nondriving end, approximately 1-2 cm above the head in ulna and within 3 cm or 6 cm away from the head in radius.

Strict prebending is needed to ease insertion and maintenance of the radial bow if thicker nail (4 mm) is being used. 3.5-mm diameter nails need only general prebending and nails up to 3 mm are flexible enough to conform to the bows without needing this step.

For strict prebending, malleable templates are bent to match contours of the radius and ulna using an X-ray of the uninjured forearm. Insert the selected nail in the nail bender and make several small bends along the length of the nail in order to create a smooth curve according to the contoured template.

For general prebending, it is advisable to make a 3 degree bend in the proximal portion of the nail. The nail is inserted with this 3 degree bend facing laterally in the radius and posteriorly in the ulna. In the frontal plane, the nail for radius should have a bow to match the radial convexity and the ulnar nail should have a lazy S shape to maintain proximal lateral bow.

Operative procedure

Under general or regional anesthesia, the patient is positioned supine on a table having a radiolucent arm board. The shoulder is abducted and the elbow is flexed 90 degree for the nailing of the ulna whereas for the nailing

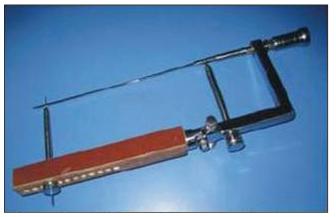


Figure 4: Clinical photograph of nail assembly in target device

of the radius, the arm is extended. Traction is needed for reducing the fragments, which is better with a forearm traction device with a modified finger trap set then pull by assistant. Tourniquet cuff is applied but inflated only if open reduction is needed.

We nailed the ulna antegrade first, providing a more stable forearm for retrograde nailing of the radius. The ulna is approached from the radial side of the olecranon tip and the radius is entered preferably through the Lister tubercle approach.

Entry portal up to the first 2.5 cm is enlarged gradually up to 6.0 mm to accept a larger diameter base of the nail. Canal proximal to fracture is gradually reamed starting with 2.5 mm reamer to maximum possible size. Reaming of the canal distal to the fracture site is attempted by reducing the fracture. If closed reduction does not succeed, limited open or percutaneous reduction may be needed. If repeated reductions are difficult, one can perform unreamed insertion of a correspondingly small diameter nail.

Assemble the nail drill guide and drive the nail from the entry portal, achieve closed reduction under fluoroscopic control and then gently negotiate the nail past the fracture site. The wrist should be flexed and extensor tendons retracted and elbow bent during insertion in the radius and ulna, respectively. Drive the nail until fully seated under hand pressure or by lightly tapping with a hammer. The base of the nail should flush with the floor of the extensor compartment or with the cortex of the olecranon.

Proximal locking (locking at the driving end of the nail) is through a target device, which is 100% accurate. Screws are directed medial to lateral in the ulna and lateral to medial in the radius.

Locking at the nondriving end of the nail can be done

through a specially designed distal aiming jig. Its accuracy is higher for the ulna, and this further increases if the nail is properly prebent.

The free hand technique with image magnification as employed for locking in other long bones [Figure 5] is employed if the Jig fails. Alternatively, a slightly bigger hole in the near cortex can be drilled to aid in localization of the hole in the nail [Figure 6a].

The ulna is locked from posterior to anterior in maximal pronated position as this helps in placing the C-arm and visualizing the hole better. The radius is reached from the lateral side with the forearm in neutral rotation, and this is done either within 3 cm or 6 cm away from the radial head (avoided over biciptal tuberosity) to avoid injury to the posterior interosseous nerve (PIN). For locking within 3 cm from the radial head, instead of clip a special threaded pin [Figure 6b] is inserted and snapped from the base after being fully inserted.

For inserting a clip, a stab incision is carried down sharply through the skin and subcutaneous tissues. The fascia is split and blunt separation of the tissues is performed to develop a plane between the muscles to expose bone. Use of a self-retaining retractor is advantageous. An image intensifier with magnification is used to determine a perfect circle view of the screw hole. The hole is drilled with a k wire, the position is verified and correct length and sized clip lock is placed and rotated so that it fits snuggly over the bone [Figure 5]. In radial fractures, the clip is rotated toward the wrist.

The end-cap (optional) may be inserted with the 2.5 mm screwdriver into the proximal end of the nail. The wound is closed in the usual manner. Ideally, the nail should not be removed before 1 year. Unlike the precaution necessary

after plate removal, the risk of refracture is minimal and there is no need for protection.

The risk of ulnar and posterior interosseous nerve injury during locking and soft tissue irritation by screw head or clip is added to the list of possible complications of standard intramedullary nailing of the forearm bones; however, appropriate preoperative planning and careful attention to detail and strict adherence to operative technique can avoid these complications.

It appears that big incision and soft tissue dissection will be needed to accommodate the clip; but, practically, it is just 1.5–2-times the size of the standard incision used for locking with screws in any interlocking system. Very limited gentle soft tissue dissection and soft issue separation to a length of <5 mm along the two cortices of the bone is needed to accommodate the clip.

The main limitation of this technique is in locating the small distal hole initially, which improves gradually with the learning curve.

The postoperative care depends on fracture configuration and quality of fixation achieved. In uncomplicated circumstances, additional immobilization is not needed and immediate active and passive motion, including pronation and supination (but not against resistance), can be commenced. Lifting restrictions are 2–3 kg for up to the first 8 weeks. Once bridging callus is observed, activity is unrestricted.

Patients were evaluated clinically weekly and radiographically at 4-weekly intervals till union and then at 3-monthly intervals. The results were assessed on the basis of the time to union, functional recovery and complications. The patient-rated outcome was assessed

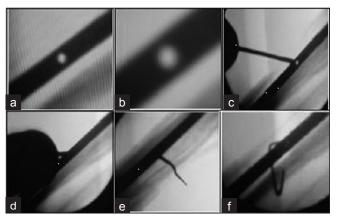


Figure 5: Peroperative image intensifier images (a) showing distal hole. (b) Showing distal hole after zoom. (c) Showing localization of distal hole. (d) Showing drilling of hole. (e) Verify the position of hole by Kwire. (f) Image showing inserted clip lock

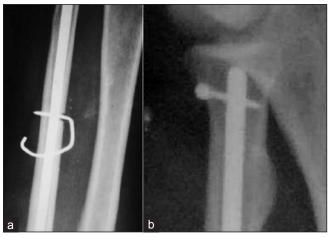


Figure 6: (a) Clinical X-ray showing near cortex of ulna drilled bigger to ease clip lock insertion. (b) Clinical X-ray showing snap off pin inserted in neck radius

1 year postoperatively, with use of the Disabilities of the Arm, Shoulder and Hand Questionnaire (DASH). This questionnaire, which is recommended by the Upper Extremity Collaborative Group, allocates scores as percentages. A score of 0 points indicates a perfectly functioning upper extremity whereas a score of 100 points indicates complete impairment.

RESULTS

The results of this pilot study are summarized in Table 1. Open fractures were treated with debridement, irrigation and primary closure with intramedullary nail fixation on the day of admission. All the other fractures were stabilized within 7 days after the injury.

Only one patient needed limited open reduction. The nail gets adapted to intramedullary width. Distal locking is tricky and more difficult in the radius, but gradually eases with learning curve. Limited dissection in the area of 1.5–2 cm at the nondriving end was needed to accommodate the clip. The stability of the system is complete as assessed by intraoperative fluoroscopy.

Table 1: Summarized results of study

No. of fractures	19 Single bone radius – 2	Age of patient	Mean age 32 years
	Single bone ulna – 3 BB – 7	patient	Range 24–45 years
Type of fracture	4 type A (%) 6 type B (%) 2 type C (%) Open fracture – 3 2 grade I 1 grade II 0 grade III injuries	Time to surgery	Within 24 h – 2 24–72 h – 6 72 h to 7days – 4
Time needed per operation	For closed reduction per individual bone 35 min (range 20–50 min)	Size of nail	2.5 mm – 3 bones 3.0 mm – 9 bones 3.5 mm – 7 bones
Time for fluoroscopy	3.5 min (range 2–10 min)		
Average hospital stay	2 days		
Union	100%		
Time to union	12–28 weeks (16 weeks)		
Pop immobilization	No pop immobilization		
Follow-up Functions	28 months average		
Free ROM Evans/Grace DASH	Patients $- 11$ Excellent $- 11$ pts Good pts $- 01$ Acceptable $- 00$ 11 pts $- 8-16$ points 1 pt $- 36$ points		
Complications	1 superficial infection No refracture in 3 implant removals after 12 months		

No intraoperative complication required a change in the operative procedure. All fractures had healed uneventfully with a marked callus formation between 12 and 28 weeks. Delayed union was observed in one isolated midshaft ulna fracture, which, however, consolidated itself by 28 weeks.

The other complication noticed was mild superficial infection in one patient with open fractures, which subsided in 3 weeks with oral antibiotics. There were no cases of deep infection, radioulnar synostosis between the forearm bones, mechanical irritation by nails or interlocking screws at the distal part of the radius or at the olecranon and failure of fixation or breakage of a device (a nail or a locking screw or clip).

Eleven patients attained full range of flexion/extension pronation/supination compared with the normal arm. In one patient – pronation was 72 (96 degrees in the contralateral arm) and the mean supination was 80 (105 degrees in the contralateral arm).

According to the Grace and Eversmann rating system, 11 patients had an excellent result and only one patient had results falling in the good category, with no acceptable or failures. DASH score in all 12 patients at 1 year postoperatively varied between 8 and 36 points (mean 14). Eleven forearms reached between 8 and 16 (mean 12) points and, thus, an excellent result. The outcome of 36 points was seen in only one patient.

Three nails were removed after bony consolidation at 12 and 14 months postoperatively, with no refractures reported even after an average of 8 months post removal.

DISCUSSION

Restoration of radial bow, reconstruction of radioulunar joints and early commencement of movements are vital to gain excellent forearm function. Holding a good fracture reduction during the reaming of the intramedullary canal, prebending thicker nails before inserting and static locking helped restore and maintain the anatomy to an acceptable limit of 10 degrees in any plane¹⁶ [Figures 7 and 8].

Static locking is important for the commencement or early exercises and, therefore, we attempted and achieved distal locking with clip or pin in all the cases. However, locking the small hole at the nondriving end by the free hand technique using the image is tedious and tricky. It is also responsible for most of the operating and intraoperative flouoroscopy time.¹⁴ The time taken in this step gets reduced by gradual learning, and a time of 4 min of



Figure 7: Clinical X-ray showing (a) segmental fracture ulna (b) well aligned fracture fragments after insertion and locking of nail (c) good union achieved after 6 months (d) well remodeled fracture after implant removal



Figure 8: Clinical X-ray showing (a) fracture both bones forearm (b) well aligned fracture fragments after insertion and locking of nail (c) good union achieved after 24 weeks

fuoroscopy needed per operation is a realistic goal.^{13,14} A distal aiming device has been developed but it still needs further improvisation. Its accuracy is quite high for the ulna and reasonably fair for the radius. The precision further improves if this Jig is meticulously preadjusted with a prebent nail.

Time to bony consolidation experienced in our patients did not differ from that after plate osteosynthesis^{2,4} or other locked nailing.^{10,12,13,14} Compared with plate osteosynthesis, time to radiological union may seem long but restoration of extremity functions with the exception of heavy lifting and twisting was achieved in all patients by less then 12 weeks before radiographic consolidation.

Our results in terms of 100% of fracture union are also comparable to other studies with locked nails. De Pedro *et al.* in 1992 reported 100% union with the use of straight ulnar locking Lefevere nails in 20 ulnar fractures.¹⁰ Various studies using foresight nail^{12,13,14} have reported a complete

consolidation rate despite having many a segmental forearm fracture. However, the rates of nonunion for both plate osteosynthesis and bundle nailing have been reported to be around 3%.¹⁴

Functional outcome in our series was excellent, with the mean DASH score of 14-points, indicating only mild disability. Movements in one patient were poor, less because it was an open injury and the patient could not comply well for early commencement of exercises.

The complication rate were low compared with other series with locked nailing probably because of strict exclusion of patients with vascular damage, refractures, pathologic fractures, less number of C-type fracture and less time delay between injury and surgery. Good results are also attributable to achievement of closed reduction in a majority of the cases along with static locking and allowance of immediate movements. Meticulous preparation at the olecranon and at the site of Lister's tubercle avoids tendon injuries and damage of the superficial branch of the radial and ulnar nerves.

The study clearly weaned off the concern of damage to the posterior interosseous nerve in locking the radius at the nondriving end of the nail remaining within 3 cm or 6 cm away from the radial head.⁹

Despite a lesser number of patients in this study, it can however be said that this implant could reduce the rates of nonunion following use of unlocked nails. The results and complications are equivalent to that associated with plate osteosynthesis, and it can be considered as an alternative to plate fixation in fractures of the radius and ulna.

Locked intramedullary nailing can maintain stable anatomic reduction along with preservance of radial bow in diaphyseal fractures of the radius and ulna. It allows immediate movements and reduces surgical exposure; hence, risk of infection. It may be considered as an equivalent alternative to plate fixation of forearm fractures with an added advantage, especially in segmental, communited, open and osteoporotic fractures. Prolonged duration in locating distal hole initially and exposure to radiation are the main limitations, which however decrease with learning.

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