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ORIGINAL ARTICLE

Functional and Radiological Outcomes of Diaphyseal Fractures of Radius and Ulna in Adults Treated with a Novel Intramedullary Nail: A Prospective Study.

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Abstract

Background: Fractures of the forearm bones are a common occurrence in all the age groups. The management of these fractures in the adult population is usually operative. Various modalities of fixation include compression plates and intramedullary nailing. Both these modalities have their own advantages and disadvantages. The authors present a study to find out whether a novel screw elastic intramedullary nail leads to reproducible, clinically and radiologically successful outcome (i.e. union) in fractures of the forearm bone.

Material and Methods: This prospective study was conducted between December 2017 to December 2018. After obtaining approval from the institutional research and ethical boards and informed consent, a total of 30 adult patients having closed or Gustilo Anderson open Grade I & II fractures which were less than two weeks old were recruited. A novel screw elastic intramedullary nail (SEIN) was used for fixation in all the patients. The SEIN is a solid, round, smooth nail of thickness 2 to 4 mm with pointed tip, a threaded head is blended with the nail, at one end. The threads are self-cutting and are advanced into the metaphysis with the help of a hexagonal screw driver. Operative procedure was done under Brachial or General anesthesia. The ulnar fracture was approached through the olecranon tip and the radial fracture just lateral to the Lister's tubercle. The reduction was achieved indirectly. The procedure was done under the guidance of image intensifier. A posterior slab was applied for 3 weeks. Regular follow up was done at 6 weeks, 3, 6 and 12 months. Radiological assessment was done by X-Rays and functional evaluation was done by the DASH score at each visit.

Results: There were 23 males and 7 females. The mean age was 38.67±13.7 years. DASH score at 6 weeks follow-up was 38.14±8.14. It was 29.71±8.42, 17.0±5.6 & 8.11±2.8 at 3, 6 & 12 months respectively. Two patients were lost to follow up and have not been included in data analysis. The correlation between difference in mean DASH scores at each follow up was found statistically significant (p value <0.05). The DASH score at final follow up was found excellent in 39.28% patients (n=11), good in 50% patients (n=14) and satisfactory in 10.71% patients (n=3). The average union time was 12.3 weeks (range 11.4 weeks to 24 weeks) 5 patients landed into delayed union,1 patient had nonunion.

Conclusion: Use of the novel SEIN has resulted in predictable, good outcomes with minimal complications. All the fractures united except one.

Key words: Fracture Forearm, Screw Elastic Intramedullary Nail, DASH Score.

Introduction

In adults, fractures of the ulna and radius are one of the commonest fractures of upper limb. Rapid industrialization, competitive sports and increased road traffic accidents has led to the rising incidences of forearm bone fracture [1]. The pull of pronators and supinator muscles not only make the reduction difficult but also increase the incidence of malunion or non-union [2].

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The main goal of treating both bone fractures is to maintain the rotational & axial stability with preservation of bone length [3-5]. The gold standard operative management of fracture of both bone forearm is anatomical reduction & ORIF using the DCP [6-9]. However, the disadvantages of plate fixation include a large skin incision, interruption of blood supply because of extensive periosteal dissection, extensive damage to the soft tissue and refracture after the plate removal [9,10].

Nailing of forearm fractures is not new, in fact it dates back even before the advent of tibial and femoral nailing. While Sage, designed and used a triangular nail for fixation of radius and ulna, Talwarkar, used a square nail. Though the Talwarkar nail gained popularity but disadvantage was that it could not provide rotational stability especially in segmental fractures. As a result of which the strong pull of pronators and supinators led to non-union [2] and the implant went into disrepute. The advantages of closed intramedullary nail are a small incision, minimal blood loss, preservation of fracture hematoma, minimal or no chances of infection and low rates of refracture following implant removal.

Interlocking nails have been used for managing fractures of radius and ulna with encouraging results and have the advantage of maintaining length in comminuted or segmental fractures [10,11] but it's limited availability and reported complications like posterior interosseous nerve injury while proximal locking and rupture of the tendon of extensor pollicis longus precluded its widespread use.

In order to overcome these issues, fixation by screw elastic intramedullary nail (SEIN) can be done. This novel design has a threaded head positioned at one end of the nail. This design allows the self-cutting thread to be advanced and screwed into the metaphysis with a screw driver, thus providing rotational stability.

With the present study the authors wanted to find out whether the use of this novel implant would lead to reproducible, clinically and radiologically successful outcome (i.e. union) in fractures of the forearm bone.

Material and Methods

This prospective study was performed in Department of Orthopedics at our institute between December 2017 to December 2018. After obtaining approval from the institutional research and ethical boards and informed consent, a total of 30 adult patients having closed or Gustilo Anderson open Grade I & II fractures and fractures less than two weeks old were recruited. Patients having Monteggia or Galeazzi fracture, multiple injuries of same limb, history of previous fractures with angular deformities of the affected forearm, concomitant head or other severe injury, history of systemic steroid intake were excluded.

The Implant Design

The SEIN (316L steel nail manufactured by UMA SURGICALS, Mumbai, India) is a solid, round & smooth nail of thickness 2 to 4 mm with pointed tip. In place of rounded running notch placed at the end of nail shaft, a threaded head is blended with the nail, to hold the nail in place. The threads are self-cutting and are advanced into the metaphysis with the help of a hexagonal screw driver. By adequately burying the nail into the metaphyseal region the soft tissue irritation is prevented. It also imparts rotational stability. (Figure 1)

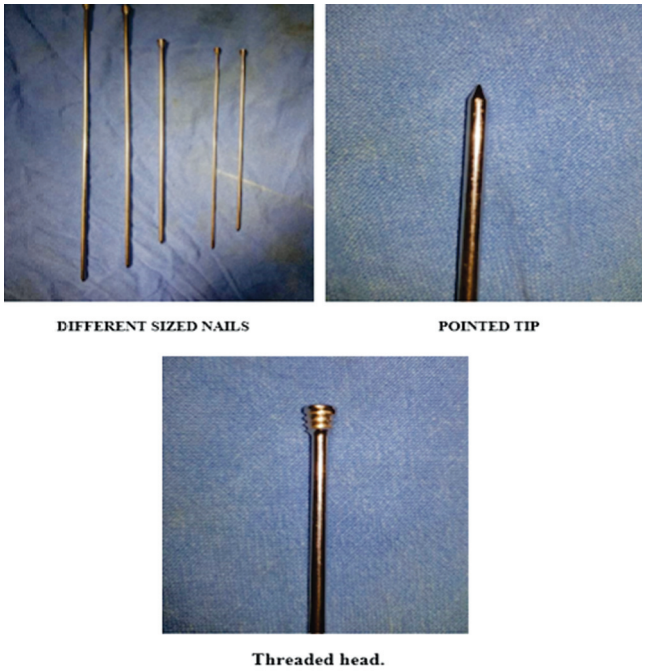

Figure 1: Screw Elastic Intramedullary Nail

Operative Procedure

Patient was positioned supine on a radiolucent operating table with hand rested over arm board. Operative procedure was done under Brachial or General anesthesia. We addressed the ulnar fracture first due to its subcutaneous position. This helped in restoring length and alignment of the forearm. A 2 or 4mm SEIN was introduced through the tip of the olecranon and negotiated across the fracture till it reached subchondral bone in distal ulna. A 2 or 4mm screw elastic intramedullary nail was introduced just lateral to Lister's tubercle of the radius and negotiated across the fracture till it reached the subchondral bone of radial head. All this while reduction was being checked by image intensifier. One dose of third generation cephalosporin

was given preoperatively & two doses after surgery. Post operatively the limb was kept immobilized by an above elbow POP slab. The post-operative check x-ray was done the next day. Suture removal was done on the tenth day. The slab was removed after three weeks and physiotherapy for wrist and elbow was initiated. Further x-rays were taken at 6 weeks, 3, 6 and 12 months respectively. Radiological assessment was done by checking signs of union (callus), angulation and backing out of nail. Functional outcomes were assessed by DASH score at each follow up. The DASH score is a 30-item questionnaire which is a self-reported tool. There are 21 items in the questionnaire that enquires about the level of difficulty in executing physical activities of upper-limb. Five items are used to assess about the symptoms and activities related to pain along with tingling, weakness and stiffness. While four items are designated to assess the problem impact on work, sleep, self-image and social functioning. All the items are scored on Likert scale. DASH score ranges from 0-100. DASH score less than 10 means excellent, 11-20 good, 21-30 average & a score more than 30 shows poor outcome. The DASH has two parts, the first one consists of 11 items related to symptom/disability areas and the second part has 4 items which are concerned with high performance activities like sports or work [12].

Statistical Analysis

Microsoft Excel was used in creating the database and producing graphs, while the data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 23 for Windows.

Mean and standard deviation (±SD) were used to describe quantitative data meeting normal distribution. Survival analysis of patients of nailing procedure was assessed with Kaplan-Meier Graphs. The level of significance was taken as $p < 0.05$.

Results

There were 30 patients, 23 (76.7%) males and 7 (23.3%) females. The mean age was 38.67±13.7 years. Fracture both bones was present in 18 (60%) patients, isolated fracture shaft of ulna in 7 (23.3%) patients and isolated fracture shaft of radius in 5 (16.7%) patients. 17 (56.7%) patients had fracture on left side and 13 (43.3%) on right side. Two patients were lost to follow-up and have not been included in analysis; the mean DASH score at 6 weeks follow-up was 38.14±8.14. It was 29.71±8.42, 17.0±5.6 & 8.11±2.8 at 3, 6 & 12 months respectively. The correlation between difference in mean DASH scores at each follow up was found statistically significant (p value<0.05) (figure 2). The DASH score at final follow up was found excellent in 39.28% patients (n=11), good in 50% patients (n=14) and satisfactory in 10.71% patients (n=3). The average union time was 12.3 weeks (range 11.4 weeks to 24 weeks) (Table 1). 5 patients landed into delayed union, 1 patient had nonunion. There was no case of post-operative infection. The fractures of patients who had delayed union ultimately united in an average union time of 20 weeks (range 17 weeks-26 weeks) without any intervention. The case of non-union was managed by ORIF with locking compression plate & bone grafting.

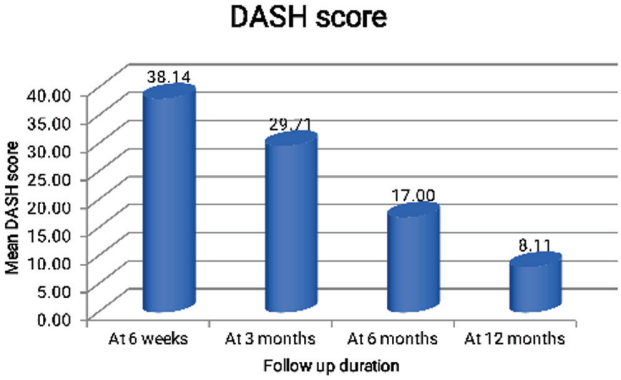

Figure 2: Distribution of mean DASH scores at different follow up duration

Table 1: Distribution of radiological outcome with their respective follow up duration

Radiological outcome		At 6 weeks (%)	At 3 months (%)	At 6 months (%)	At 12 months (%)
Callus	Present	24 (80.0)	3 (10.0)	0 (0.0)	0 (0.0)
	Absent	4 (13.3)	0 (0.0)	1 (3.3)	1 (3.3)
Union in progress		0 (0.0)	25 (83.3)	3 (10.0)	0 (0.0)
Union found		0 (0.0)	0 (0.0)	24 (80.0)	27 (90.0)

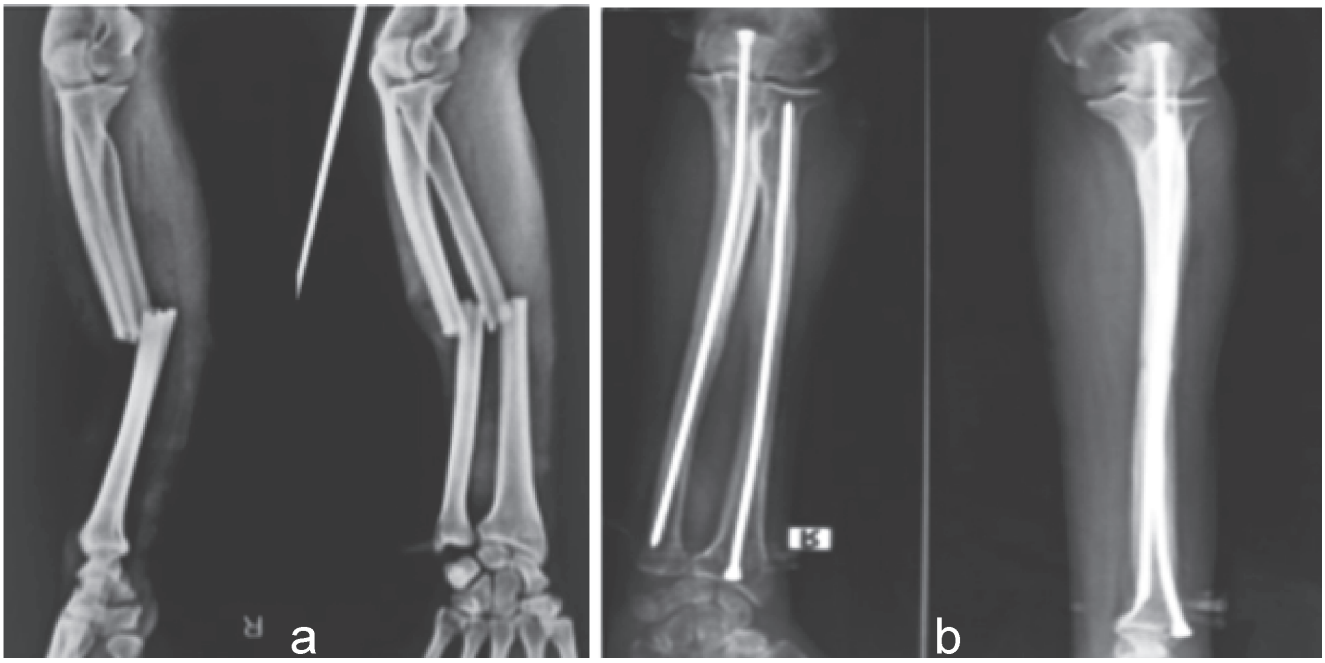

Fig. 3: a: Preoperative and X rays b: Post operativeX rays at 9 months.

Fig. 4: Functional evaluation after 9 months

Discussion

In adults, fractures of radius and ulna are one of the commonest fractures of upper limb. To achieve a good functional outcome apposition, axial alignment, restoration of length and neutral rotational alignment are very important [1]. In our study 60% (n=18) patients had fracture of both bone, 23.3% (n=7) patients had an isolated fracture shaft of ulna and 16.7% (n=5) had fracture shaft of radius. Azboy I et al [14] reported 68.7% patients had fracture both bones, 21.9% had fracture of the radius & 9.4% had ulnar fracture. In our study, 80% of patients had visible callus formation at 6 weeks. 80% patients (n=24) showed radiological union within 24 weeks. The DASH score at final follow up was found excellent/good in 89.28% patients (n=25) and satisfactory in 10.71% cases (n=3). Khanna G et al [15] reported that 21 cases (70%) showed radiological union within 16 weeks and final outcome was excellent / good in 90% cases (n=18) & acceptable in 2 cases (10%). In a study by Azboy I et al [14], functional assessment was done on the basis of DASH score. Excellent score was reported in 21 (65.6%) patients, good in 7 (21.9%), acceptable in 3 (9.4%) and poor in 1 (3.1%) patient. Garampalli A et al [16] reported excellent outcome in 14 (70.0%), good in 2 (10.0%), acceptable in 2 (10.0%) and unacceptable in 2 (10.0%) patients.

In our study, 22 (66.7%) patients reported no complications, 5 (16.66%) reported delayed union and 1 (3.3%) patient reported non-union. In study by Khanna G et al [15] delayed union was seen in 3 and non-union in

only 1 patient. Azboy I et al [14] reported complications in 4 patients, 2 patients had superficial infection, 1 patient had radioulnar synostosis and 1 had delayed union.

Conclusion

Use of the novel SEIN has resulted in predictable, excellent to good outcomes with minimal complications. All the fractures united except one. The SEIN nailing incorporates the merits of a closed nailing, preserves the biology and thus carries a promising future in treatment of fracture both bone forearm considering minimal complications & acceptable outcomes.

Conflict of interest:	All authors declare no COI
Ethics:	There is no ethical violation as it is based on voluntary anonymous interviews
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Guarantor:	Dr. Najmul Huda will act as guarantor of this article on behalf of all co-authors.

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