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Orange city tapping nail: An innovative implant for humeral diaphyseal fractures

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ABSTRACT

Background: We have conducted this study to evaluate the effectiveness of Orange City tapping nail in humeral diaphyseal fractures in terms of radiological union, shoulder function and complications. It's a pilot study with the new implant "Orange City tapping nail" developed at our institute.
Materials and methods: Thirty patients with humeral diaphyseal fractures were treated with Orange City tapping nail through antegrade nailing procedure. The cases were followed up prospectively for a period of minimum six months. Outcome of the procedure were assessed according to American Shoulder and Elbow Surgeons (ASES) score, radiological union, complications and secondary procedures required.
Results: Twenty eight (93.33%) fractures united with an average consolidation time of 15.75 weeks. Two patients had nonunion. Functional outcome was excellent to good in 24 (80%) patients. One (3.33%) case had infection with Orange City tapping nail.
Conclusion: Results of Orange City tapping nail were excellent to good for humeral diaphyseal fractures in terms of union, shoulder function and complications. It is a safe, easy and reliable method for the treatment of humeral diaphyseal fractures. Postoperative shoulder stiffness and impingement depends on operative technique and postoperative rehabilitation. We need a larger comparative study with conventional antegrade nail to evaluate the effectiveness of the implant.

1. Introduction

Humeral diaphyseal fractures account for three to five percent of all fractures.[1] Causes for humerus fracture range from a simple fall in elderly to high energy trauma like road traffic accident in a young population. The comprehensive AO classification is preferred in studies of humeral fractures.[2]

Fractures of the shaft of humerus have been treated conservatively since ages with good results. Humeral diaphyseal fractures can be treated non operatively, which includes hanging arm cast, velpeau dressing, coaptation splint or U slab, shoulder spica cast, functional brace and rarely skeletal traction.[3–5] Disadvantages of conservative management include joint stiffness, muscle atrophy, osteoporosis and prolonged immobilization

With improved implant design and surgical technique, operative management of humeral diaphyseal fractures increasingly has become accepted. Aim of it was early restoration of joint motion and return to normal physiologic function and minimal morbidity. Rigid plate osteosynthesis is widely used for humeral diaphyseal fractures,[2,6] but in association with large incisions, stripping off of soft tissue and periosteum from the bone that increases the risk of non union or delayed union, infection, radial nerve palsy, less secure fixation in osteoporotic bones.

Intramedullary nail a load sharing device avoids all these problems and is biomechanically stronger. The most common indication for operative management is associated multiple injuries.[7,8] Other indication includes open or segmental fractures, vascular injury and failed conservative management.[9,10] Locked intramedullary nailing usually can be performed using closed techniques, avoiding the extensive periosteal stripping and soft tissue dissection required for plating. Interlocking nail being a load sharing device along with rotational stability allows early mobilization. With improvement in implant design and technique, the complications that were reported earlier have decreased.

In view of the technical difficulties with the use of conventional interlock intramedullary (IMIL) nailing and to simplify the procedure we introduced Orange City tapping nail in which the

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Illustration 1. Orange city tapping nail and Conventional Intramedullary Interlock (IMIL) Humerus Nail.

distal locking component is optional as the distal end of the nail is self tapping and holds the distal medullary canal with the threads in nail design. This design would be possible due to the peculiar anatomy of the humerus in which the medullary canal narrows as we migrate from the proximal to distal end of bone and the distal end is triangular in cross-section. This helps in avoiding the risk of damage to the neurovascular structures related to the distal end of humerus like radial, median, ulnar nerve and the brachial artery which is shown in a cadaveric study and also decreases the operative time.[11] So in this study we will evaluate the results of Orange City tapping nail for humeral diaphyseal fractures.

2. Materials and methods

It's a pilot study carried out between september 2013 and september 2015 after taking necessary approval by the Institutional Ethics Committee at our institute considering it to be a new implant. Thirty patients aged more than 18 years with acute humeral diaphyseal fractures with or without neurological deficits underwent Orange City tapping nailing. Patients with age more than 70 years, pathological fractures, segmental fractures, malunited fractures, Gustilo-Anderson grade IIIa, IIIb and IIIc open fractures, non-unions and chronic smokers were excluded.

Orange City tapping nail is made of 316 L stainless steel alloy by a FDA certified company and is used after thorough evaluation of bending stiffness, tensile strength and other properties. Orange City tapping nail are available in different sizes from 6 m m to 8 m m diameter and different lengths from 20 cm to 30 cm. It's a solid nail with core diameter of 3 mm, 4 m m, 5 m m respectively for 6 mm, 7 mm and 8 mm size nail with pitch of 2.5 mm for all sizes. This nail is having two proximal locking holes in perpendicular planes and one distal locking hole for cases in which the hold in the distal fragment is not stable and needs locking (Illustration 1 and 2). The nail is designed to take hold in the distal unreamed fragment with self-tapping cancellous threads at distal end of the nail (Illustration 1 and 2). Biomechanical studies to evaluate stress risers in supracondylar region were not done to assess risk of iatrogenic fracture. The advantages of this procedure are simple and easy procedure, less operative time, avoidance of distal locking screw which prevents risk of arterial and nerve injury.

3. Surgical technique

A longitudinal skin incision was made from the most lateral point of the acromion, centering over the tip of the greater

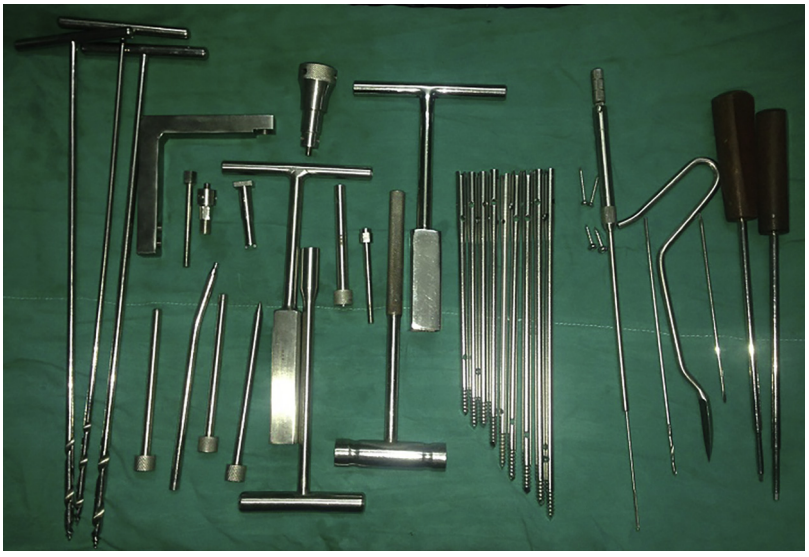

Illustration 2. Instrumentation for Orange city tapping nail.

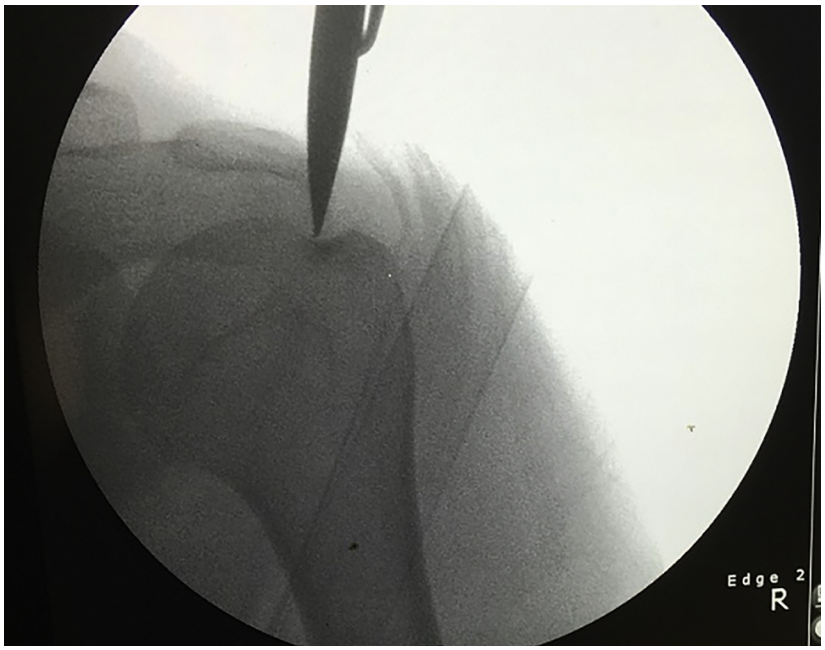

Illustration 3. Intraoperative image showing entry site for Orange city tapping nail.

tuberosity. The entry point was exposed by splitting the deltoid muscle and longitudinal incision along the rotator cuff and tagged for repair later. The entry portal was made at a point just medial to the routine entry portal used for conventional interlocking nailing as the nail is straight, in line with the medullary canal and 0.5 cm posterior to the bicipital groove using a bone awl (Illustration 3). Its position in the center of the canal was confirmed using an image intensifier. Reaming of the proximal fragment is done and the size of the canal is assessed to decide diameter of the nail to be used (Illustration 4). Nail length is assessed intraoperatively using image intensifier by measuring distance from entry point to just proximal to olecranon fossa using ruler. Reduction is done directly with the nail using counterforce from the elbow to avoid distraction at the fracture site and the nail is inserted gradually using screwing movements just like reaming (Illustration 5). Nail insertion should be careful to avoid nail prominence, iatrogenic comminution and distraction as these can change the outcome significantly. The nail was then fixed with proximal locking and rotational stability is assessed intra-operatively by the feel of insertion and looking at the movement of jig on doing passive rotations. Proximal locking is done with zig which is attached after nail insertion in most of the cases and can be done through free hand technique. We didn't face any problem with proximal locking due to nail insertion as it can be done with jig or through image intensifier by adjusting nail rotation to get screw hole for insertion using free hand technique. In case of lack of rotational stability, we can opt for distal locking option rather than changing to conventional IMIL nail (Illustration 1). We had one case of elderly patient with osteoporosis in which intraoperatively we could not attain rotational stability and distal locking was done to achieve it, this case was then excluded from the study. The design of nail and procedure does not allow for back slapping as proximal locking is done first and distal stability is accessed later. The rotator cuff is repaired carefully under vision followed by routine closure and sterile dressing.

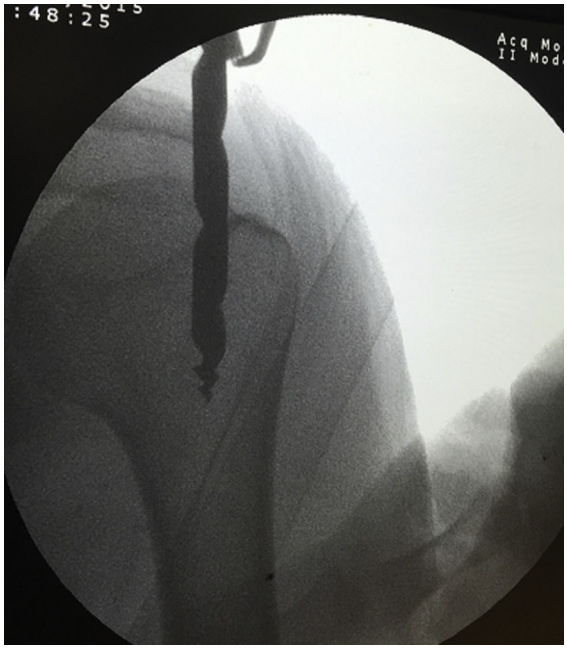

Illustration 4. Intraoperative image showing proximal fragment reaming and sizing of nail.

Active and active-assisted range of motion exercises of the elbow and pendulum exercises of the shoulder were started as early as possible. Patients were followed up at six, ten, sixteen weeks and monthly thereafter. Lifting of weights and heavy work was not allowed before fracture healing. Functional outcome of the upper limb was assessed using the American Shoulder and Elbow Surgeons (ASES) score.[12]

4. Results

Of the 20 men and 10 women in the group, the causes of injury were road traffic accidents (n = 15), falls (n = 12), and assault (n = 3). According to the AO classification,1 the most common fracture type was A3 (n = 15), followed by A2 (n = 10) [Table 1]. The fractures were closed in 27 patients and open in 3 patients (2 patients had

Illustration 5. Intraoperative image showing technique for insertion of Orange city tapping nail.

Table 1
Distribution of patients according to the AO classification of fractures.

Fracture Type	No. (%) of patients with orange city nailing
A1 (simple wedge)	0 (0)
A2 (simple oblique)	11 (36.67)
A3 (simple transverse)	15 (50)
B1 (spiral wedge)	0 (0)
B2 (bending wedge)	3 (10)
B3 (fragmented wedge)	1 (3.33)
C1 (complex spiral)	0 (0)
C2 (complex segmental)	0 (0)
C3 (complex irregular)	0 (0)

Table 2
Distribution of patients by age.

Age (years)	No. of patients with orange city nailing
21–30	7
31–40	7
41–50	6
51–60	7
61–70	3

grade 1 open fractures, and one patient had grade 2 open fracture according to Gustilo-Anderson classification). One patient had radial nerve palsy. The most common fracture was transverse (n = 15), followed by oblique (n = 11) and comminuted (n = 4).

In the study mean patient ages were 42 (range, 20–70) years (Table 2), mean operating time was 26 min, mean times to union was 15.75 weeks (Illustration 6 and 7), ASES scores were excellent (47–52) in 18 patients (Table 3), non-union rates were 6.67% (2/30), and delayed union rates were 6.67% (2/30). With this procedure, two patients had non-union which may be due to multiple factors like old age, osteoporosis and fracture site distraction. We didn't have postoperative radial nerve palsy with Orange city tapping nailing which may be due to reduced manipulation as the distal fragment is not reamed but still it can happen during fracture reduction and nail insertion.

5. Discussion

Intramedullary nailing involves a simpler technique with minimal exposure and shorter operating time and less blood loss. The preservation of fracture hematoma, soft tissues, and periosteum around the fracture enables higher rates of union and good results,[13,14] without any iatrogenic risk of radial nerve palsy.[15] Intramedullary interlocked nailing is rotationally stable and prevents backing out of nails as seen with earlier nails.[16] However, the anatomic configuration of the humeral shaft may lead to fracture site distraction if the procedure is not done correctly,[14,17,18] especially when the sagittal diameter of the distal humerus is small, and eventually delayed union and non-union may ensue. Antegrade nailing may injure the rotator cuff which may lead to residual disability and poor functional results.[19] A medial starting point may avoid the avascular area of the cuff and give straight access to the medullary canal, without compromising rotator cuff healing. Adhesive capsulitis of the shoulder has also been reported after antegrade nailing.[14,20]

The results of the use of interlocking nailing for humeral shaft fractures are varied. RTA was the main mode of injury in most of the studies. Rommens et al[21] reported union in 95% cases with mean time of 13.7 weeks, Crates et al[22] reported union in 97% of fractures with mean time of 3.2 months. In our study with Orange City tapping nail union was achieved in 93% of cases with an average time of 15.75 weeks which is comparable to the present available modalities. Fernandez et al[23] reported 2 cases and Jinn lin et al[24] reported 1 case of iatrogenic fracture comminution, case of iatrogenic fracture comminution, we also had two such cases which healed uneventfully. Rommens et al.,[21] Ikpeme et al.,[25] Crates et al[22] reported no infections in their series but in our series, one of the fractures got infected and implant removal was done and the patient was managed conservatively. The operative time for this procedure is quiet less as compared to all other studies, decreasing the morbidity to the patient and enhances recovery.

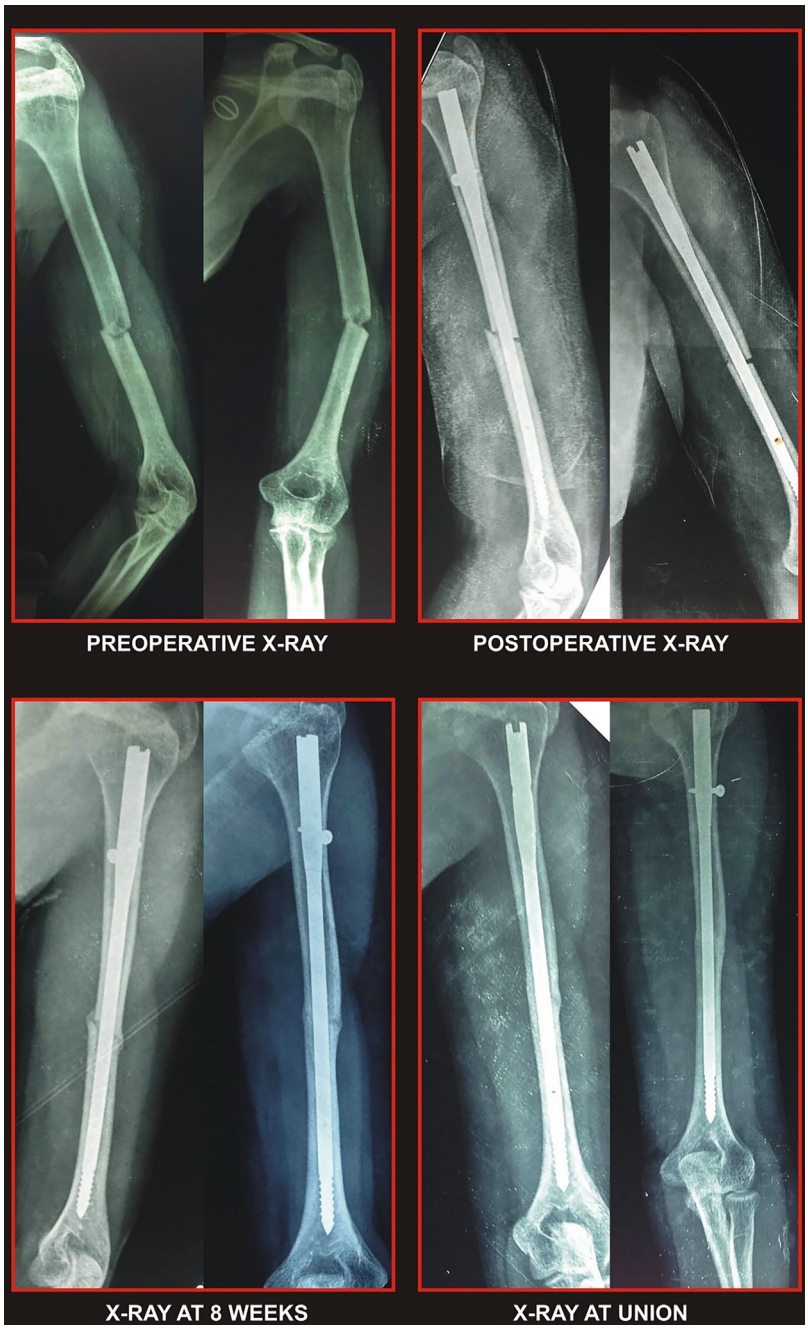

Illustration 6. Humeral shaft fractures treated with Orange City nail showing preop, postop, 8 weeks and union X-rays (Case 1).

This may be attributed to closed method of nailing and avoidance of distal locking. Robinson et al[26] reported 3.3%, Crates et al[22] reported 2.7% & Jinn lin et al[24] reported 0% iatrogenic radial nerve palsy similar to us. The most frequent critisim of antegrade humeral nailing has been its potentially deleterious effect on shoulder function. Crates et al[22] reported 90%, Petsatodes et al[27] reported 87.2% patients regaining full shoulder function. Kropfl et al[28] reported limited shoulder motion in 19 out of 111 patients. In our study shoulder function was excellent in 60%, good in 30% & satisfactory in 10%. Post operatively early mobilization of the shoulder & elbow was very critical in attaining full range of movements. It was observed that the movements & the functional ability of the shoulder depend upon the operative technique and rehabilitation program. Most of our findings, including period of fracture consolidation, union rates, complications & functional results are comparable with studies where Conventional IMIL nailing was used to treat humeral diaphyseal fractures. The limitation of this study is small sample size and absence of comparison with conventional antegrade humerus nail at the same center.

6. Conclusion

Orange City tapping nailing is a valuable option for the treatment of humeral diaphyseal fractures with relatively less morbidity and complications. However, functional outcome and rate of union is similar to conventional antegrade humerus nailing. A larger randomized trial or may be a multicenter trial can further improve the interpretation of the results.

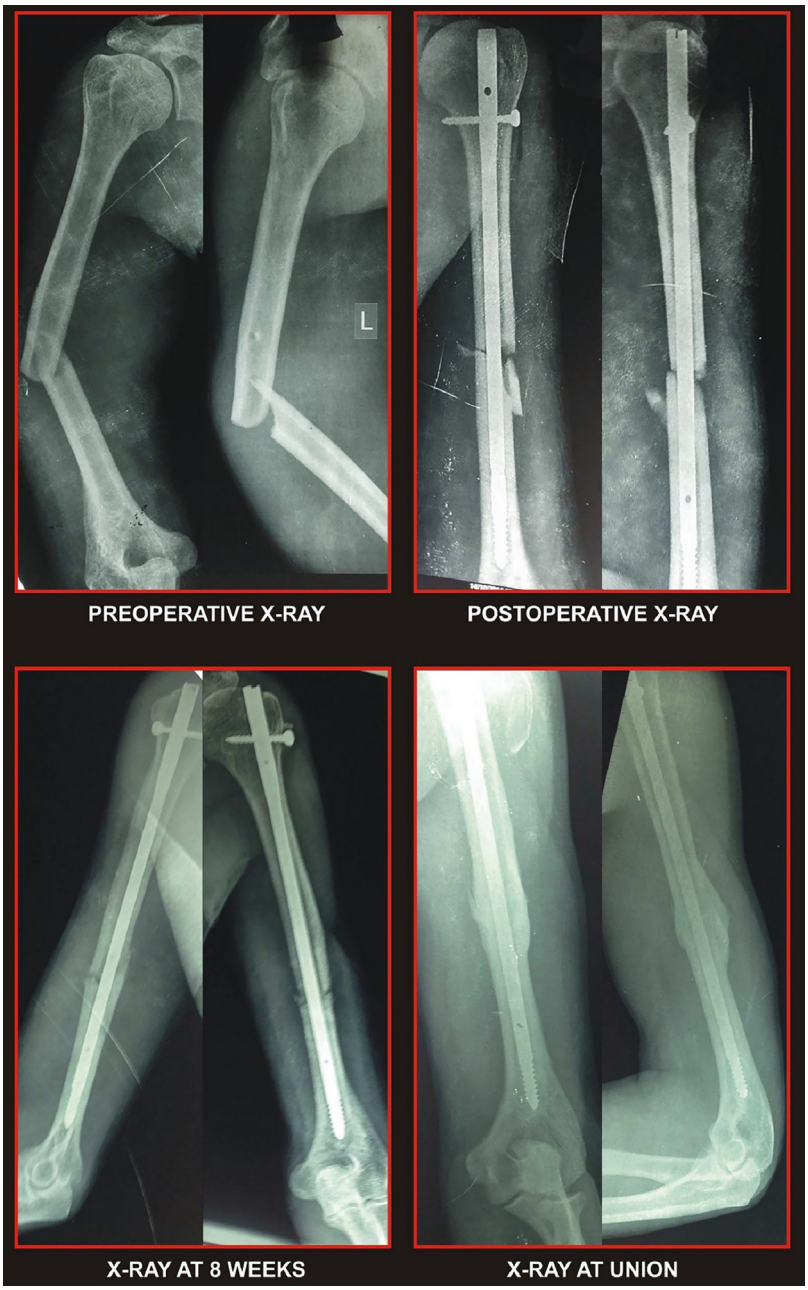

Illustration 7. H Humeral shaft fractures treated with Orange City nail showing preop, postop, 8 weeks and union X-rays (Case 2).

Table 3
The American Shoulder and Elbow Surgeons (ASES) scores of the patients.

ASES SCORE	No. (%) of patients with orange city nailing
47-52 (Excellent)	18 (60)
42-46(Good)	9 (30)
36-41(Satisfactory)	3 (10)
31-35(Poor)	0
<30(Very poor)	0

Contribution details

Abhishek P Bhalotia: Definition of intellectual content, Clinical studies, Data acquisition, Statistical analysis, Manuscript preparation, Manuscript editing, Manuscript review, Guarantor.

Conflict of interest

None.

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