Aequalis Nail in three and four parts proximal humeral fractures

Key words: Proximal Humerus Fractures, Endomedullary Nail, Aequalis Nail

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Abstract

Introduction. There is not, at present, a unique treatment for 3 and 4 part displaced proximal humeral fractures. The purpose of our study is to evaluate the effectiveness of the use of Aequalis Intramedullary Nail.

Materials and Methods. Between July 2012 to November 2012, 12 patients, 9 females and 3 males, affected by acute AO type A2-A3- B1-B2 fractures, were followed up after surgical treatment with Aequalis intramedullary Nail in our Traumatological Department. The average age of patients was 69,5 (range 62-76), we have excluded from follow up cases of severe glenohumeral arthrosis**,** inveterate or pathological fractures, patients with cognitive decline. We have evaluated the fracture healing time, the functional outcome, the degree of satisfaction and the complications.

Results. In all cases examined a good consolidation of the fracture was obtained in an average time of about 80 days, with excellent functional outcome in patients younger than 65 years, good in patients older than 65 years.

Conclusions. Aequalis Intramedullary Nail permits a quick recovery in young patient and better stabilization of fracture in elderly patients, allowing to adapt the nail to the fracture and not adapting fracture to synthesis device.

Introduction

Proximal humeral fractures are common injuries, about for 4-5% of all fractures; it's third most common fracture in patients over 65 years [1,3]. In older patients this kind of fractures are due to a low-energy trauma, because osteoporosis is a concausa; in younger patients they are higher-energy injuries.

Neer described the displacement of four fragments of Codman (important parts of proximal humeral region) and he noted that the more displacement of these fragments was important for vascularity of the head [4].

(Fig. 1).

Then, about prognosis, these fractures were divided in 2-, 3- or 4-part fractures and fracture-dislocations. A.O. classification describes displacement of a fragment as a separation of more than 1 cm or angle of the head part of more than 45° [5]. To evaluate the best treatment it is important to considerate the age of the patient, comorbidity and functional demands, displacement degree, head splitting and a concomitant dislocation. Displaced 3- and 4-part fractures remain a difficult problem especially in osteoporotic patients.

The aim of any treatment is to achieve a good shoulder functional recovery in the absence of residual pain. Fixation systems described in the literature are manifold: reduction and synthesis with Kirschner wires through distraction technique with epiblock system, plate and screws with angular stability, intramedullary

nail and prosthetic replacement. These systems, however, can present some complications: failure of osteosynthesis with screws pull-out, non-union or pseudoarthrosis, avascular necrosis of the humeral head.
Non-operative management is followed for minimally displaced fractures: these constitute 80% of proximal humeral fractures [6]. This kind of treatment is represented by immobilization for 2-4 weeks with orthosis and rehabilitation as soon as possible. In 20% of fractures of these region there is a non-acceptable displacement: in children displaced fractures are treated with an anatomic reduction and percutaneous fixation with minimal approach techniques (Kirschner wires or cannulated screws) to cause minimal morbidity and reduce the risk of avascular necrosis and post-operative scarring. About internal fixation of proximal humeral fractures is important the develop locked fixed angle screw plates, with the angular stability between the plate and proximal screws to transfers the forces directly from the bone to the plate [7]. This approach needs a deltoid-pectoral or deltoid splitting and requires wide learning curve, difficult surgical technique, extensive and disfiguring scars and large blood loss. The intramedullary nails with proximal locking options to hold any displaced fragments were an important discovery [8]. The potential advantages are limited surgical soft tissue trauma with a percutaneous insertion: this kind of treatment allows the biological principle of osteosynthesis. The damage to the rotator cuff insertion is easily repairable with its rapidly suture. The blood loss is poor and functional outcomes are good.
Hemiarthroplasty is indicated as a salvage procedure in displaced 3- or 4-part fractures with a displaced head fragment or for complications such as Avascular Necrosis of the Humeral Head [9]; reverse polarity shoulder replacement has become an accepted treatment for patients with a severe fracture and cuff arthropathy or an irreparable rotator cuff tear [10].
The aim of this paper is describe the advantages of the intramedullary nail for the treatment of these kind of fractures, especially related to the use of *Aequalis Intramedullary (IM) Nail – Tornier* – based on biomechanics concepts and supported by our preliminary experience.

Material and Methods

Between July 2012 to November 2012, 12 patients, 9 females and 3 males, mean age of 69,5 (range 62-76, standard deviation of 3,84), affected by acute AO type A2-A3- B1-B2 fractures, were followed up after surgical treatment with Aequalis IM Nail in our Traumatological Department.
We chose to use the intramedullary nail as synthesis device for biological and biomechanical disadvantages associated with the use of plates.
In these cases we evaluated the fracture healing time, the functional outcome, the degree of satisfaction and the complications at follow up medical visits. The functional outcome were established by Constant Scoring System (CSS) effectuated by a physiotherapist. We have excluded from follow up cases of severe glenohumeral arthrosis**,** inveterate or pathological fractures, patients with cognitive decline.
The surgical technique that we used was the positioning of the patient in beach-chair; we made closed reduction of fracture, a mini-longitudinal peri-acromial approach of the deltoid muscle and rotator cuff split,

insertion of the nail after preparation of the humeral canal with appropriate instruments and final fixing with proximal and distal screws in most suitable configurations.

(Fig. 2).

The average surgical time was 45 minutes. Elbow and wrist mobilization was started immediately in our Department after surgery. The rehabilitation protocol was passive mobilization of shoulder by the second week after surgery and an active mobilization after four weeks. Rotations of the arm were forbidden until one month.
Follow-up included controls to one, two, three and six months after surgery.

Results

In all cases examined was obtained a good consolidation of the fracture in an average time of about 80 days (between of the 2nd and the 3rd month) and an excellent functional outcome. Table 1 shows the results of CSS tests: the average of CSS value at 1 month follow up was 40,16 (S.D. of 4,85), at 2 month follow up was 51,83 (S.D. of 2,88), at 3 month follow up was 64,83 (S.D. of 5,70) and at 6 month follow up was 72,58 (S.D. of 5,36).

Table 1.

There were no complications such as infections, tromboembolism, functional disability, skin rupture or problems due to entrapment. Figures 3 and 4 show the clinical and radiographic control of a 67 year's old female patient at 3 months after surgery.

(Figure 3 and 4)

Discussion

We discuss the appropriate assessment and treatment options available for proximal humeral fractures. Important factors to consider are fracture pattern, bone quality and any co-morbidities. These are common injuries and are increasing in incidence due to an ageing population. The management of displaced 3- and 4-part fractures remains controversial. The goal is anatomic reduction and stable internal fixation of the fractures, especially the tuberosities, to allow early mobilization. The recent introduction of fixed angle locking plates allows stable fixation even in markedly osteoporotic bone. The early results are encouraging however there are presently no randomized trials comparing these devices to conservative treatment, conventional plating or hemiarthroplasty.

Plates increase the risk of humeral head avascular necrosis because of a more invasive approach to the fracture instead of a limited trauma to soft tissues needed for nail insertion, permit poor tuberosities fixation that needs additional sutures and, biomechanically, screws are parallel to the fracture plane instead of perpendicular [11].

(Fig. 5)

Nailing can be a solution but not all the nails have the right features to allow a proper bone healing. Also in some nails screws are parallel to the main vertical fracture and they don't have the possibility to fix the greater tuberosity resulting in a tuberosity migration and sometimes in glenoid erosion. No locking mechanism is responsible for screws back out and loss of reduction. Malunion, nonunion or pseudoarthrosis are more common in too big and too long nails due to distal jamming. Another problem linked to some nail design is cuff tear related to bending.

So, which could be new concepts in nail design? First of all fixation of the tuberosities instead of humeral head fixation.

In this way screws are perpendicular to fracture line and resist to pulling forces of rotator cuff muscles. The Aequalis IM Nail was created from extensive proximal humerus dimension and geometry studies. Additionally, the basic pathophysiology of displaced unstable 2, 3 and 4-part fractures was revisited, resulting in the 5 design principles:

1. Humeral Head support: the nail must act as a mechanical strut to support humeral head fragments under compressive forces thereby resisting valgus/varus subsidence;
2. Tuberosity Based Screw Pattern: proximal screw orientation must be tuberosity based (Posterior-Anterior) and not humeral head based (Latero-Medial) to be perpendicular to the main fracture line splitting the tuberosities and to resist the horizontal pull forces of the rotator cuff muscles;
3. Nail Based vs. Bone Based Screw Fixation: proximal holes must capture screws to provide improved tuberosity fixation regardless of bone quality to prevent loss of tuberosity reduction, screw loosening and/or screw backout;
4. Nail Centering and Stabilization: nail must be centered inside the medullary canal to support head fragments and avoid toggling through diverging distal screws;
5. Anatomic Stabilization: instrumentation must position the humeral head toward the glenoid when the forearm is placed in neutral rotation.

Then Aequalis IM Nail allows, through different locking options, proximal screws placed in the most favorable way to achieve stability of the fracture. The reduced diameter allows the insertion through a small access in the rotator cuff, without any damage to it; a polyethylene insert inside the nail, which locks the proximal screws, completes implant stability and allows early mobilization.

Despite the limited number of patients treated, we observed positive preliminary results, especially with regard to the technical characteristics of the nail, the high patient compliance and excellent functional results.

Conclusion

In our experience the intramedullary nailing is the most versatile synthesis for the treatment of proximal humeral fractures due to the less invasive surgical aggression both against the bone, soft tissues and skin. Aequalis IM Nail allows to adapt the nail to the fracture and not the fracture to the nail.

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Table 1: functional outcome based on Costant Scoring System								
N°	sex	age	Hospital dimission	1 month after surgery	2 months after surgery	3 months after surgery	6 months after surgery	Fracture healing time on X-Ray view
1	M	69	31	45	51	73	73	3rd month
2	F	62	30	43	55	63	70	2nd month
3	F	68	32	36	54	68	74	3rd month
4	M	64	34	48	57	66	73	3rd month
5	F	72	35	43	48	65	75	2nd month
6	F	71	37	42	49	58	86	2nd month
7	F	69	38	32	52	57	70	2nd month
8	M	72	35	34	51	56	68	3rd month
9	F	73	30	36	52	74	75	3rd month
10	F	71	30	38	47	65	74	2nd month
11	F	76	31	42	53	66	69	2nd month
12	F	68	34	43	53	67	64	3rd month
average		69,5	33,08	40,16	51,83	64,83	72,58	
max		76	38	48	57	74	86	
min		62	30	32	47	63	64	
S.D.		3,84	2,81	4,85	2,88	5,70	5,36	

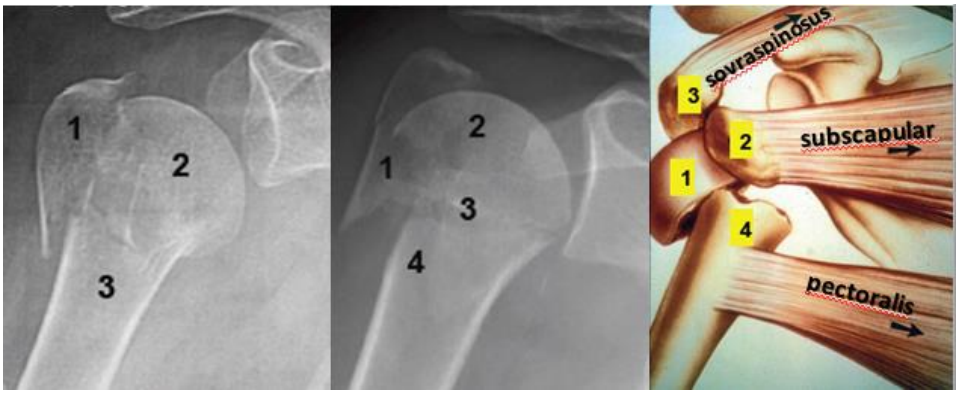

Figure 1: Image A and B show x-ray images of proximal humerus three and four parts fractures; Image C shows the breakdown of fracture

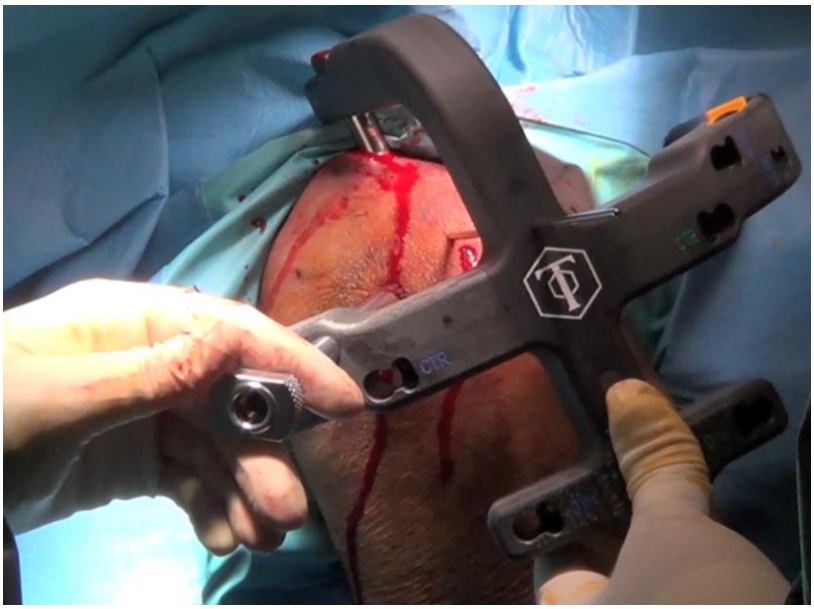

Figure 2. Surgical time of Aequalis IM Nail proximal screw fixation

Figure 3: Clinical follow up 3 months after surgery of a female 67 year's old patient

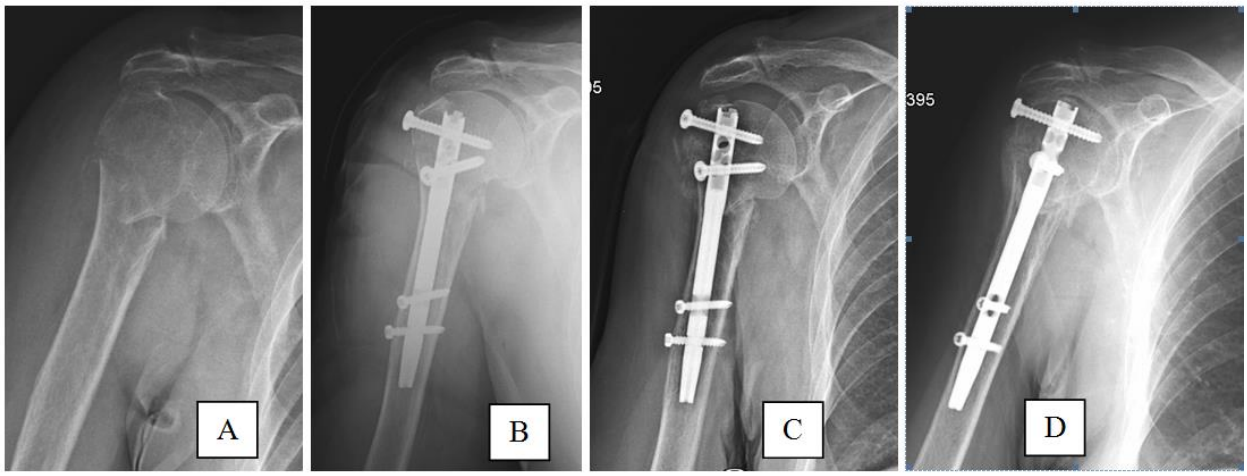

Figure 4: Preoperative X-Ray image (A), After surgery X-Ray image (B), One month after surgery X-Ray image (C), Follow up 3 months after surgery X-Ray image (D).

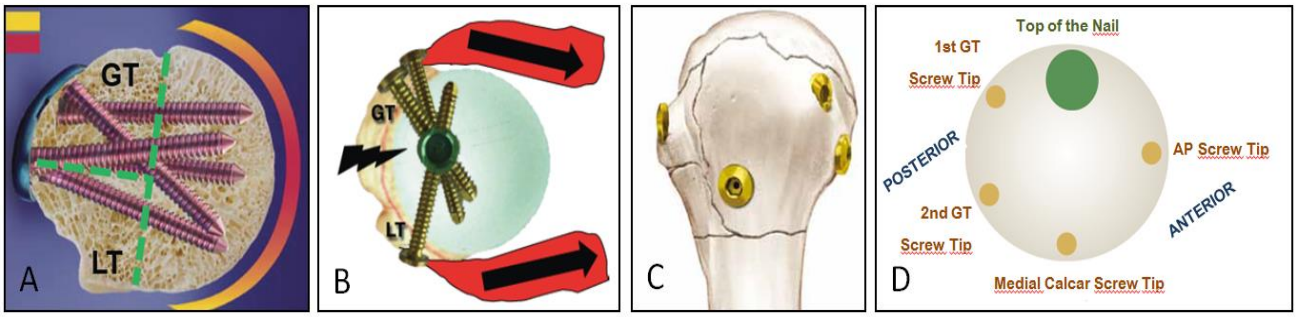

Figure 5: advantages of the use of intramedullary nail. Plate and screws system allow an exclusive stiffness only in the central zone - red zone - instead the peripheral zone of greater tuberosity (GT) and lesser tuberosity (LT) - yellow zone (Image A); the images B, C, D summarize the biomechanical concept of tuberosity-based screw orientation of Aequalis Intramedullary Nail.