Prospective Randomised Study of Outcomes in Patients with Humeral Shaft Fracture Following Two Methods of Fixation: Locked Intramedullary Nailing versus Plate Fixation

By

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Declaration

I, Zainul Aberdeen Abubaker Peer, declare that this Research Report is my own work. It is being submitted for Master of Medicine in the branch of Orthopaedic Surgery to the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University. I further declare that I did not receive any outside funding or grants in support of this research or preparation of this work. Neither I, nor any member of my team or family, nor affiliated university, or department received payments or any other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation division, centre, clinical practice, or other charitable or non profit organization with which I or a member of the research team is affiliated to.

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Zainul Aberdeen Abubaker Peer

20 day of MAY 2010

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In the name of God the most gracious and most merciful, the Lord of the world and what it contains. Ameen.

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ABSTRACT

Fractures of the shaft of the humerus represent between 3 and 5% of all long bone fractures [15, 16, 34]. Most of them heal with adequate conservative treatment. However a small number will require surgical treatment for optimal outcome. The aim of the study was to compare Intramedullary nailing versus plating in humeral shaft fractures, in terms of healing time, outcomes and complication rates.

Fifty nine patients presented to the emergency departments of three tertiary hospitals affiliated to the University of Witwatersrand. They were randomly allocated to either of the two modalities of treatment: 32 of them by intramedullary nailing and 27 by plating. All patients were followed up; the mean time at final review was one year after treatment. At follow up they were assessed clinically by the author and radiologically by an independent radiologist.

RESULTS: Locked Intramedullary nailing had a shorter operation time and less blood loss than did plate fixation. In the nailed group 30 fractures had united (mean time to union 8.64 weeks, [range 6 to 12 weeks]); two x-rays showed no callus at 6 months. In the plated group union was achieved in 24 cases by 9.2 weeks (range 6 to 12 weeks). Three patients did not unite in the plated group. The non-union rate following plating was 3/27 compared to 2/32 in the nailed group. The total non-union rate of nailing and plating was thus 5/59 (ca. 8%), which compares well with international standards. Mean operating time was nearly half an hour less in the nailed group than it was in the plate group (66 minutes vs. 93 minutes - P value = 0.311) and intra-operative blood loss was almost half of that in the plated group (95 ml vs. 180 ml – P Value=0.077). Functional scores (Constant, HSS Elbow score and WOMAC) showed no significant statistical differences. Five patients in the plate group developed radial nerve palsy compared to one in the nail group. In the nail group shoulder pain and decreased range of motion was significant in patients older than 45years. Elbow pain and decreased range of motion were significant findings in the plating group in the early post operative period. All the other complications were similar in both groups.

CONCLUSION: In our setting nailing proved much easier to do than plating, with better outcomes. The shorter operating time and the minimal intra-operative blood loss in nailing are probably related to the widespread exposure of registrars to nailing of long bone fractures compared to plating in the Wits Orthopaedic training circuit. Good functional outcomes can be expected after ante grade nailing of the humerus if attention is given to precise surgical technique, correct size of nail and correct use of transfixing screws.

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Nomenclature

AO - Arbeitsgemeinschaft fur Osteosynthesefragen (Association for the study of Internal Fixation)

BMP- Bone Morphogenic Protein

DCP- Dynamic Compression Plate

FGF- Fibroblast Growth Factor

HSS- Hospital for Special Surgery

IMN - Intramedullary Nail

LCDP- Low-contact Dynamic Compression Plate

ON - Osteonecrosis

TGF-β -Transforming Growth Factor Beta

WOMAC - Western Ontario and McMaster Universities

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INTRODUCTION

Historical Review

General

The history of fracture management has a fascinating background which has evolved over the centuries by trial and error. However it is interesting to know that many of the early problems physicians faced are still unresolved. In the18th centuryNicolas Andry (1658—1724) coined the term "orthopaedics" (from *orthos* straight and *paedos* child) [3, 12]. Aniounins Mathyres (1852) a French military surgeon is acknowledged asthe introducer of plaster of Paris for fracture management [3, 12]. However it was Sir Hugh Thomas(1843-1897) who laid the foundation of modern orthopaedic surgery. He devised splints that carry his name and stressed on the importance of strict immobilization in the treatment of long bone fractures.

The discovery of X-rays in1895 and their introduction to clinical medicine in the first decade of 20th century added a new dimension to fracture diagnosis and treatment. The history of modern internal fixation began in the late 1930's in Europe by Venable and Stuch [3, 12]. In those days internal fixation was in its infancy. It faced enormous challenges such as infection and inappropriate fixation material. Antibioticsand aseptic techniques improved outcomes, while metallurgical experimentation led to the discovery of vanadium and titanium. In 1912 Sherman introducedvanadium steel which showed promising results in the making of orthopaedic implants. The first vitallium implant was used in 1936 in a boy with a femoral shaft fracture [3, 12]. Scientific research into new alloys and better understanding of their properties has brought us closer to the ideal implant.

Humeral fractures

Closed reduction and external support with the elbow in flexion is one of the oldest and most widely used methods of treatment for humeral fractures. Historical records show us that ancient civilizations used external splinting to treat humeral shaft fractures. The Edwin Smith Surgical Papyrus, dating from the seventeenth century BC, is one of the oldest of all known papyri, illustrating the teachings of the Father of Medicine Imhotep. He used external splinting for treatment of humeral shaft fractures for his patients [3, 12]. Celsus(25BC-50AD) distinguished shaft fractures from proximal and distal fractures [3, illustrating the teachings of the Father of Medicine Imhotep. He used external splinting for treatment of humeral shaft fractures for his patients [3, 12]. Celsus(25BC-50AD) distinguished shaft fractures from proximal and distal fractures [3, 12] Paul of Aegina (ca. 625-690 AD) described the complications of excessive traction and tight bandaging. Clearly, ancient doctors used external mobilisation for the treatment of humeral shaft fractures long before the advent of plaster of Paris.

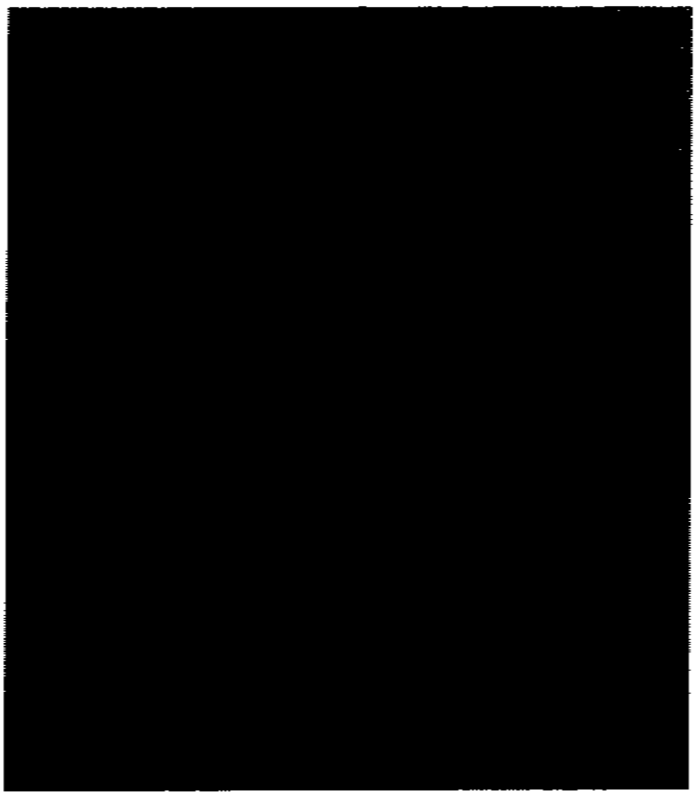

Figure 1. Abstract from the Surgical Papyri. [3, 12]

Abstracts from the Edwin Smith Surgical Papyri [case studies]

Case study from Smith Papyrus [3, 12] – 'a split in his upper arm'

Examination: If thou examinest a man having a split in his upper arm, [and] thou shouldst find the swelling protruding, on the outside of that splint, which is in his upper arm.

Diagnosis: Thou shouldst' say concerning him 'One having a split in his upper arm. An ailment which I will treat.'

Treatment: Thou shouldst bind it with *ymru* [a piece of cloth, similar to a modern bandage]; thou shouldst treat it afterwards with honey, every day until it recovers." [3, 12]

Avicenna (Ibn-Sina) also known as the Galen of Islam was enormously influential through his famous *Canons of Medicine*. [13] He defined a fracture as a "loss in continuity of bone". He subdivided fractures into transverse, longitudinal or comminuted. He defined the symptoms of pain, swelling, deformity and angulations clinically. He introduced bonesetters to prevent complications of deformity and contractures. He advised postponing setting of fractures that are swollen and to wait five days to allow the swelling to settle. Nearly a thousand years later, Professor George Perkins used this delayed splinting principle in 1937 in his management. He described humeral shaft fractures without radiography as "often tilts outside" referring to angulated fractures. He stated that we need to "reduce according to tilting". His method of stabilizing a fracture was to "stabilize by using three bandages: the first one in an ascending direction, the second one descending, the third one ascending and the elbow stabilised in an angular shape with a sling [13]. In 1963 Holstein and Lewis reported a syndrome in which the radial nerve becomes entrapped between the fragments of a closed spiral fracture at the distal third of the humerus. They pointed out that the nerve is least mobile as it passes through the lateral intramuscular septum in the distal third of the arm.

Anatomy

The humerus is a long tubular bone with two extremities and a body, the diaphysis or shaft. In this work the body of the humerus will be referred to as the shaft. The extremities consist of cancerous bone, covered with a thin, compact layer. The shaft is composed of a cylinder of compact bone, thicker at the centre and contains a large medullar canal which extends along its whole length. The shaft is almost cylindrical in the upper half and prismatic and flattened below. It has three borders and three surfaces.

Borders

The *anterior* border runs from the front of the greater tuberosity above to the coronoid fossa below. Its upper part is a prominent ridge. The crest of the greater tuberosity serves for the insertion of the pectoralis major tendon. At its centre it forms the anterior boundary for the deltoid tuberosity. Below it is smooth and rounded affording attachment for the brachialis muscle.

The *lateral* border runs from the back part of the greater tuberosity to lateral epicondyle and it separates the anterolateral from the posterior surface. Its upper half is rounded and indistinctly marked serving for the attachment for the lower part of the teres minor tendon insertion and below this giving origin to the lateral head of the triceps brachii muscle. Its centre is traversed by A broad but shallow oblique depression; the musculospiral groove. Its lower part forms a prominent rough margin which is a little curved forward. The lateral supracondylar ridge presents an anterior lip for the origin of the brachioradialis muscle above and extensor carpi radialis longus muscle below and a posterior lip for the triceps brachii muscle and an intermediate ridge for the attachment of the lateral intramuscular septum.

The *medial* border extends from the lesser tuberosity to the medial epicondyle. Its upper third consists of a prominent ridge, which gives insertion to the tendon of the teres major muscle. At its centre there is a slight impression for the insertion of the coracobrachialis muscle and just below thisis the entrance of the nutrient canal. Sometimes there is a second nutrient canal at the commencement of the radial sulcus. The inferior third of this border is raised into a slight ridge, which becomes very prominent below. It presents an anterior lip for the origins of the brachialis and the pronator teres muscles and a posterior lip for the medial head of the triceps brachii muscle and an intermediate ridge for the attachment of the medial intramuscular septum

Surfaces

The antero-lateral surface is directed laterally above where it is smooth and rounded and covered by the deltoid muscle. At the middle of this surface there is a rough triangular elevation, the deltoid tuberosity, for the insertion of the deltoid muscle. The radial sulcus transmits the radial nerve and brachialis profunda artery.

The anteromedial surface is less extensive than the anterolateral surface and is directed medially. Its upper part is narrow and forms the floor of the intertubercular groove which gives insertion to the tendon of the latissimus dorsi muscle. Its middle part is slightly rough for the attachment of the insertion of the coracobrachialis muscle. The posterior surface appears somewhat twisted so that its upper part is directed a little medially and its lower part backwards and a little laterally. Nearly the whole of this surface is covered by the lateral and medial heads of the triceps brachii muscle.

Bone circulation and physiology

As an organ bone receives 5 to 10%of cardiac output [4]. The humerus receives blood from three sources (Figure 2, 3):

Nutrient artery system.

Metaphyseal – ephiphyseal system.

c. Periosteal system.

a) The nutrient artery system is a system whereby the nutrient arteries are branches from major

b) systemic arteries. These arteries enter the diaphyseal cortex [outer and inner table], through the nutrient foramen and then enter the medullary canal whereby they branch into ascending and descending branches. These branches into arterioles in the endosteal cortex

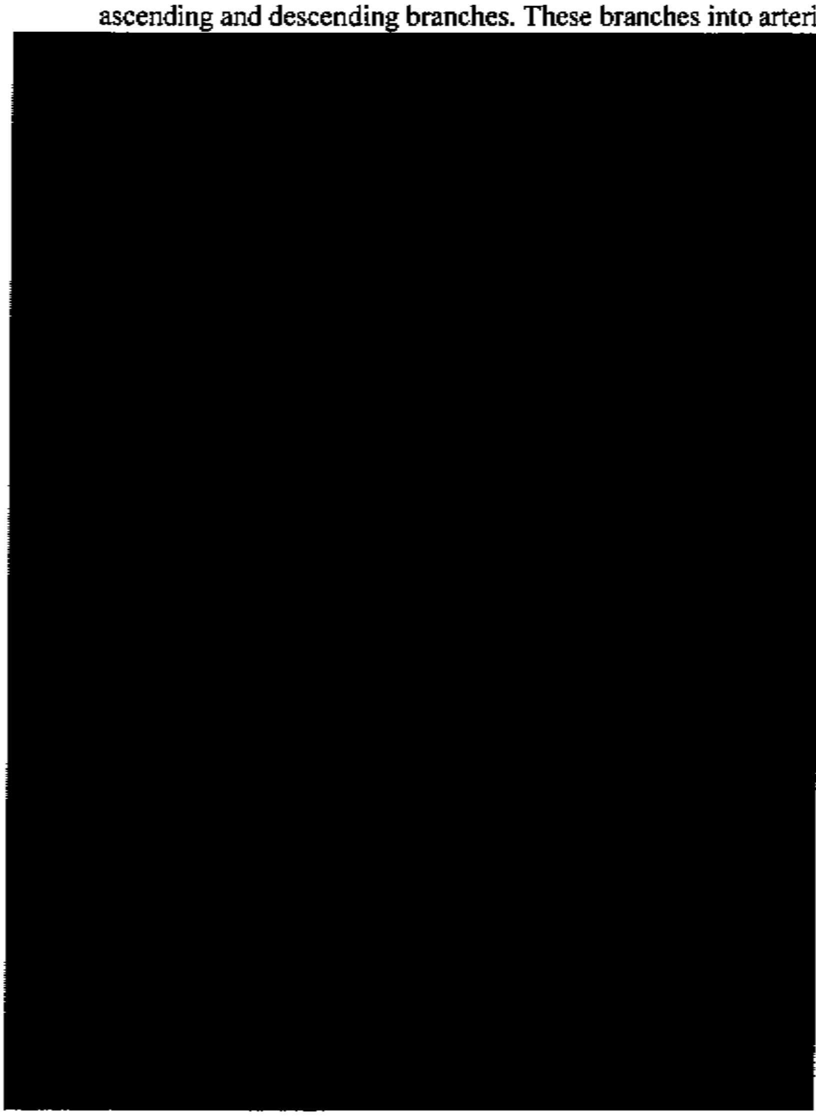

Figure 2 Blood supply of a long bone [4]

Figure 3 Schematic Outlay of Blood Flow in the shaft of humerus[4].

and supply the inner two thirds of the mature diaphyseal cortex via vessels in the haversian system. The nutrient arterial system is a high-pressure system (Figure 2 & 3).

b) The Metaphyseal-epiphyseal system arises from the periarticular vascular plexus (Figure 2).

c) The periosteal system is composed primarily of capillaries that supply at most the outer one.

d) third of the mature diaphyseal cortex. The periosteal system is a low-pressure system. The direction of blood flow in mature bone is centrifugal (inside to outside) as a result of the net effect of the high-pressure nutrient arterial system (endosteal system) and the low-pressure periosteal system (Figure 3). In a completely displaced fracture with disruption of the endosteal system the pressure gradient reverses and the periosteal system pressure predominates and blood flow is centripetal (outside to inside). Venous flow in mature bone is centripetal and cortical capillaries drain to venous sinusoids, which drain in turn to the emissary venous system. Bone blood flow delivers nutrients to the site of bony injury and it is the major determinant of fracture healing. Initial response to a fracture is decreased bone blood flow after vascular disruption. Within hours to days the bone blood flow increases (as part of the regional acceleratory phenomenon) and peaks at approximately two weeks and then returns to normal between three to five months. Bone blood flow is under the control of metabolic, humeral and autonomic inputs. The arterial system of bone has great potential for vasoconstriction from the resting state, but much less potential for vasodilatation. The vessels within a bone have a variety of vasoactive receptors (β-adrenergic, muscarinic, thromboxane/prostaglandin receptors) that may be useful in the future for the treatment of bone diseases related to aberrant circulation e.g. osteonecrosis and fracture nonunion.

Fracture Healing

Bone is the major structural tissue in the human body. It consists of cells and extracellular matrix. One of the functions of bone is to provide support and attachment of other tissues and to allow for movement. Loss of integrity of bone results in decreased function. A fracture is a break in continuity of bone and in order to restore that continuity bone has the ability to heal. For bone to heal the ideal fixation is necessary provided the optimal environment is present.

The sequence of bone fracture healing consists of (Figure 4)

Extravasations of blood at the fracture site and haematoma formation.

Inflammation and cellular proliferation – acute inflammatory cells proliferate and fragment ends are surrounded by cellular tissue. Capillaries grow into the area. This tissue is rich in inductive proteins.

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The sequence of bone fracture healing consists of (Figure 4)

i) Extravasation of blood at the fracture site and haematoma formation.

ii) Inflammation and cellular proliferation – acute inflammatory cells proliferate and fragment ends are surrounded by cellular tissue. Capillaries grow into the area. This tissue is rich in inductive proteins.

[redacted]

Figure 4 Fracture Healing: Five stages of healing. **(a)***Haematoma*: there is tissue damage and bleeding at the fracture site; the bone ends die back for a few millimetres. **(b)***Inflammation*: inflammatory cells appear in the haematoma. **(c)***Callus:* the cells population changes to osteoblasts and osteoclasts; dead bone is moped up and woven bone appears in the fracture callus. **(d)***Consolidation*: woven bone is replaced by lamellar bone and the fracture is solidly united. **(e)***Remodeling*: the new-formed bone is remodeling to resemble the normal structure[33].

iii) Callus formation – the proliferating cells (ii above) are potentially chondrogenic and osteogenic. These form islands of immature bone and cartilage. This mass becomes more densely mineralized and movement at the fracture site decreases. This process is driven by inductive proteins such as fibroblast growth factors (FGF), transforming growth factor beta (TGF-β) and bone morphogenic proteins (BMP). At the end of this stage the fracture is said to have "united".

iv) Consolidation – callus (woven bone) is transformed into lamellar bone. Over the next few months the continued laying down of new matrix by osteoblasts strengthens this bone.

v) Remodeling – The fracture site and surrounding bone are reshaped according to the prevailing stress on the bone.

Biochemical Features

Fractures like any other injuries are followed by the normal metabolic response to trauma with loss of nitrogen, potassium and retention of sodium later. In 1930 Cuthberston first discovered the metabolic response to trauma while studying fractures and osteotomies. The general metabolism of calcium is not disturbed after fractures. The intake and output remains normal. The concentration of organic phosphorous in the plasma may occasionally be increased to about 5mg per dl in the first few days after the fracture. In nearly all cases the loss of phosphorous from the body exceeds the intake. These changes may also occur after injuries of soft tissue, without the fracture.

Biochemical Features of Fracture Healing

Deposition of calcium in the growing tissue constitutes the important difference between repair of fractures and repair of soft tissue injuries. In the first few weeks there is greatly increased concentration of calcium and phosphorous in the fracture haematoma. The general blood calcium level remains unchanged and the local excess is derived from the bone ends.

Histamine and Acetylcholine: In all injured tissue liberation of histamine and acetylcholine causes vasodilatation and hyperaemia. Bone reacts to hyperaemia by resorption and a transfer of calcium from fracture ends to the surrounding space, exudates continues until the hyperaemia subsides [16].Only then does ossification begin.

Phosphate content of fracture haematoma

Within a few days the phosphate content of fracture haematoma increases six to eight times the normal level [16]. Phosphatase, an enzyme secreted by proliferating cartilage cells and osteoblasts, liberates free phosphates by hydrolysis of hexose phosphates, thus causing super saturation with calcium phosphate of the fluid bathing the bone. This persists for about ten weeks, throughout the stage of active growth of cartilage cells and osteoblasts.

Acid Tide of fracture Haematoma

During the first two weeks of the fracture, the haematoma shows a marked acid tide; thereafter the pH swings back to the neutral or alkaline side. The significance of this tide is not clear, although it is due to local biochemical activity. Increasing the blood calcium levels by calcium intake does not accelerate repair.

Type of Bone Healing

There are 2 main types of bone healing:

Primary bone healing

This type of healing occurs in anatomically reduced, stably fixed fractures. Healing occurs by direct osteonal penetration with no external bridging callus (Figure 5b, 6a).

Figure 5 Fracture Healing- Histology: Experimental fracture healing. (a) by bridging callus and (b) by direct penetration of the fracture gap by cutting cone [33].

b) Secondary bone healing

If bone is not rigidly stabilised and there is motion at the fracture site then bone heals by callus formation (Figure 5a, 6b & 6c).

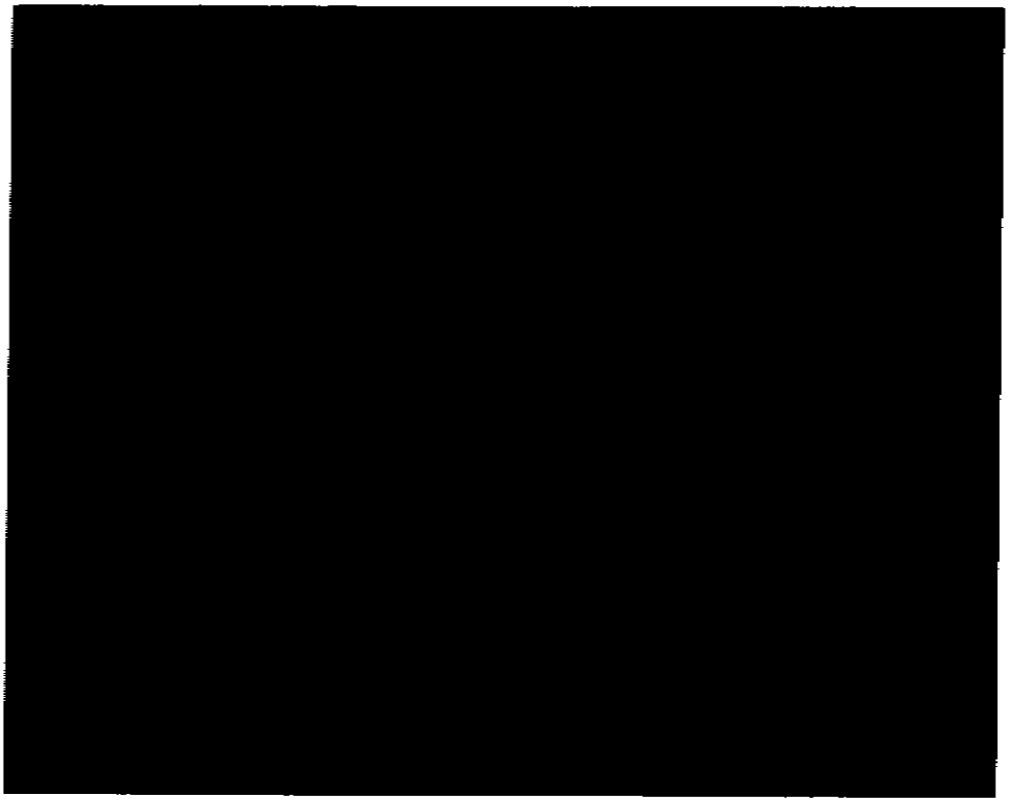


Figure 6 Callus and Movement: Three patients with femoral shaft fractures **(a)** and **(b)** are both six weeks after fixation. In **(a)** the Küntscher nail fitted tightly preventing any movement, and there is no callus; in **(b)** the nail fitted loosely permitting some movement, so there is a callus. **(c)** This patient had cerebral irritation and thrashed around wildly; at three weeks callus is excessive [33].

Problems with bone healing

Repair by Fibrous Union: The mescenchyal cells or osteoblastscan form bone but if immobilisation is inadequate cartilage may develop. With excessive motion of bone ends this may result in bone ends healing by fibrous union. This could be replaced by osteoid formation but it is a very slow process. Fibrous union is always unsatisfactory. Occasionally due to excessive movements the cells differentiate into synovial cells and a false joint orpseudoarthrosis results (Figure 7).

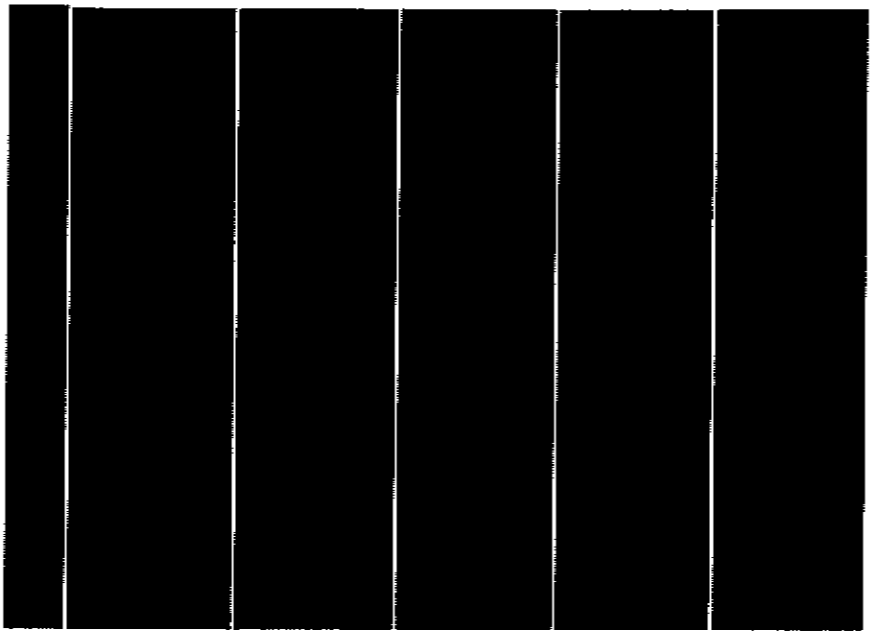


Figure 7 Non-union [19].

Delayed union

Delayed union is defined as a prolonged time for a fracture to unite. This term is usually reserved for fractures that have not achieved union by the expected time but eventually go on to unite. The expected time for union in a humeral fracture is 6-10 weeks in an adult.

Non union

Non union is defined as failure to show any progressive change in radiographic appearance for at least three months after this period of time during which normal fracture union was expected to take place. This is generally accepted as six months from time of injury. Non- union is due to failure of biology (high energy injury with devascularisation) or host factors (smoking, vascular disease, other commodities), failure of mechanics(improper stabilisation) or treatment failure. Sepsis should always be considered in any non- union.

Malunion

Union of the fractured bone in a position other than anatomically correct is defined as malunion. This may occur in any of the three planes sagittal, coronal or axial. Depending on the bone involved the amount of deviation from normal will have variable effects. This could lead to shortening of the limb or a cosmetically unacceptable limb.

Humeral shaft fractures

Humeral shaft fractures are defined as fractures in which the major fracture line occurs distal to the insertion of the pectoralis major and proximal to the supracondylar ridge. It is estimated that these fractures comprise about 3 to 5 %of all long bone fractures in adults [15, 16, 34]. The humerus has a relatively small cortical mass. This together with specific biomechanics of the humeral bone to torsional loading commonly results in fractures of the middle third of the humerus [Katzner et al].

Fracture of the humeral shaft in young adults is usually due to high energy trauma. In the elderly the fracture is most often due to a fall on an osteoporotic arm. The mechanism of injury dictates the clinical features and thepatternof fracture. Briefly, a direct injury to the humerus from a missile or motor vehicle accident results in a comminuted fracture. An indirect fall on an outstretched arm results in a spiral or oblique fracture in the elderly; rarely a throwing injury can cause a humeral fracture. All fractures follow a similar pattern and the events are governed byNewton's second law, which states that the force acting on a body is proportional to the product of the mass of the body and its acceleration or deceleration. The kinetic energy can either cause a temporary, elastic deformation or a permanent, plastic deformation or cause a complete disruption.

In many cases the character of displacement of the fragments in fracture of the shaft of the humerus is due to the mode of injury and not to muscular action. This accounts for less uniformity in diaphyseal fractures. The fracture lineis usually more or less oblique and in rare cases nearly transverse. Notwithstanding this latter fact non-union of fractures of the shaft of the humerus is one of the most frequent of any bone in the body. Muscular action shows its influence most markedly in producing displacements in three directions viz. towards the body, away from the body or directly anterior.

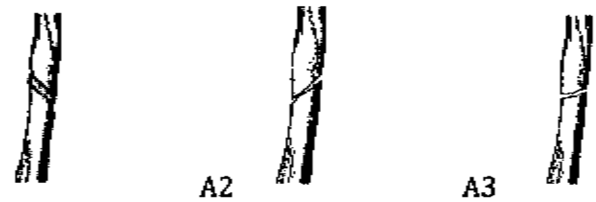
The bone may be fractured immediately above the deltoid insertion. In this case the axillary fold muscles (pectoralismajor, teres major, and latissimus dorsi) are attached to the upper fragment and tend to draw it towards the body, while the deltoid tends to draw it away from the body. The influence of other muscles like biceps, coracobrachialis and triceps increase the overlapping of the fractures. The line of fracture is most apt to be from above downwards and outwards. The upper fragment is displaced anteriorly by the coracobrachialis and anterior portion of the deltoid and is drawn outward by the deltoid aided by the action of the supraspinatus.

Classification of Humeral Shaft Fractures

Classifications are instrumental in defining the characteristics of a fracture and for defining results for similar fractures. They play a pivotal role in the treatment and prognostication of various injuries. Clinicians need them for research and clinical audit and to measure the outcomes of their work. It is essential that they be based on agreed terminology, precise nomenclature, methods of coding, information storage and retrieval systems.

The AO (Arbeitsgemeinschaft fur Osteosynthesefragen) classification [31] uses pattern recognition similar to that applied in a real clinical setting. Fractures are coded in an alphanumeric pattern with each letter and number contributing to define the fracture at a level. It is commonly used at our institutions. The possible types of humeral shaft fractures are shown below:

AO Type A fractures are simple fractures, with A1 being spiral, A2 oblique and A3 transverse (figure 8).

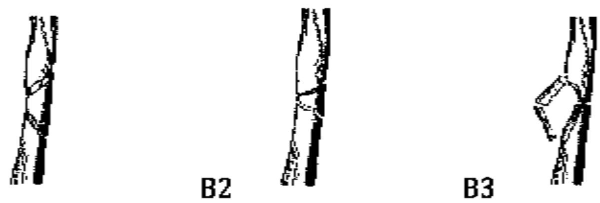


A1 A2 A3

Spiral Oblique Transverse

Figure 8 AO Type A Fractures

AO Type B fracture is a fracture with an extra butterfly fragment, with B1 being a spiral wedge, B2 bending wedge, and B3 fragmented wedge (figure 9).

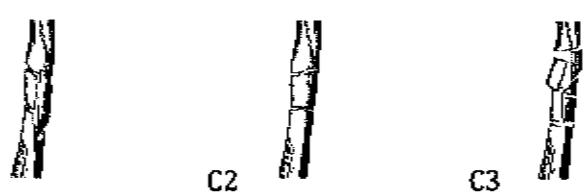


B1 B2 B3

Spiral wedge Bending wedge Fragmented wedge

Figure 9 AO Type B Fractures

AO Type C fractures are more complex fractures, with C1 being complex spiral, C2 complex segmental and C3 complex irregular (figure 10).



C1 C2 C3

Complex Spiral Complex Segmental Complex Irregular

Figure 10 AO Type C Fractures

Plate fixation

Many surgical approaches have been described for open reduction and internal fixation of the humeral shaft. These include the extended lateral approach, the anterolateral approach, posterior approach and the medial approach. The extended lateral approach to the humeral shaft takes advantage of the lateral approach to the elbow. This approach is advantageous in that the patient can be positioned supine and the distal two thirds of the humerus can be exposed easily at the intramuscular plane between the triceps and the anterior arm musculature. This allows exposure of the radial nerve throughout its distal course. If necessary the incision can be extended proximally in a posterior triceps splitting exposure or an anterolateral extension taking advantage of the deltopectoral interval.

The anterolateral approach (Figure 11) is used most widely in proximal and middle third fractures. Proximally it takes advantage of the deltopectoral interval and its distal extension is performed just on the lateral border of the biceps muscle and anterior musculature. Distally this approach requires dissection in the intramuscular plane between the brachialis and brachioradialis where the brachialis is retracted medially with the brachioradialis taken laterally. At this level the radial nerve is between the brachialis and brachioradialis and it must be protected throughout the procedure.

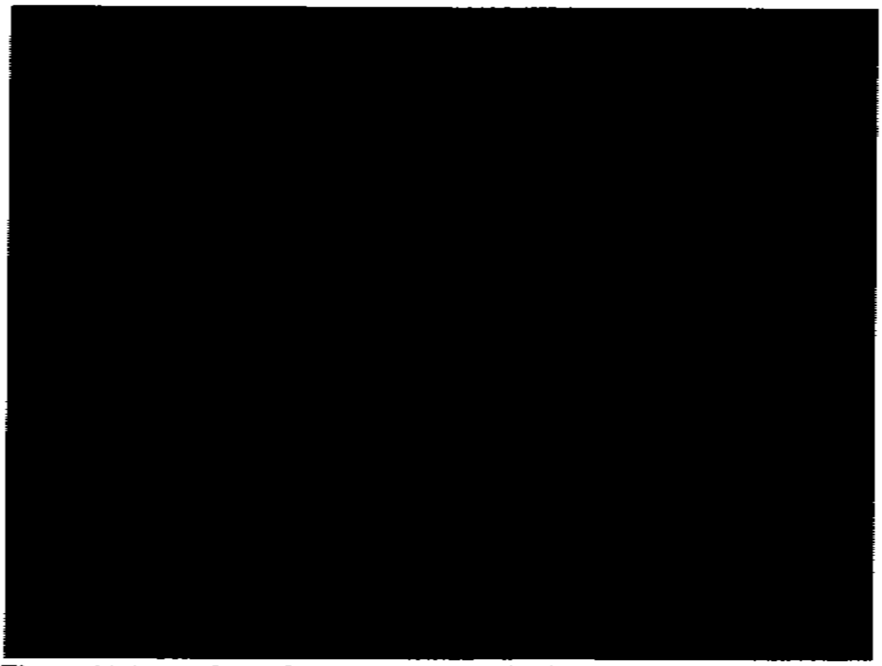


Figure 11 Anterolateral approach to shaft of humerus. [21]

The anterior approach is used less commonly because it is less useful and less extensile than the anterolateral approach. The distal limit of the incision is approximately 5 cm proximal to the elbow flexion crease. The intramuscular interval between the biceps and brachialis muscle is exposed and the fibres of the brachialis muscle are split longitudinally exposing the anterior surface of the humeral shaft. Proximally the anterior approach is identical to the anterolateral approach taking advantage of the deltopectoral interval with the cephalic vein as an important landmark.

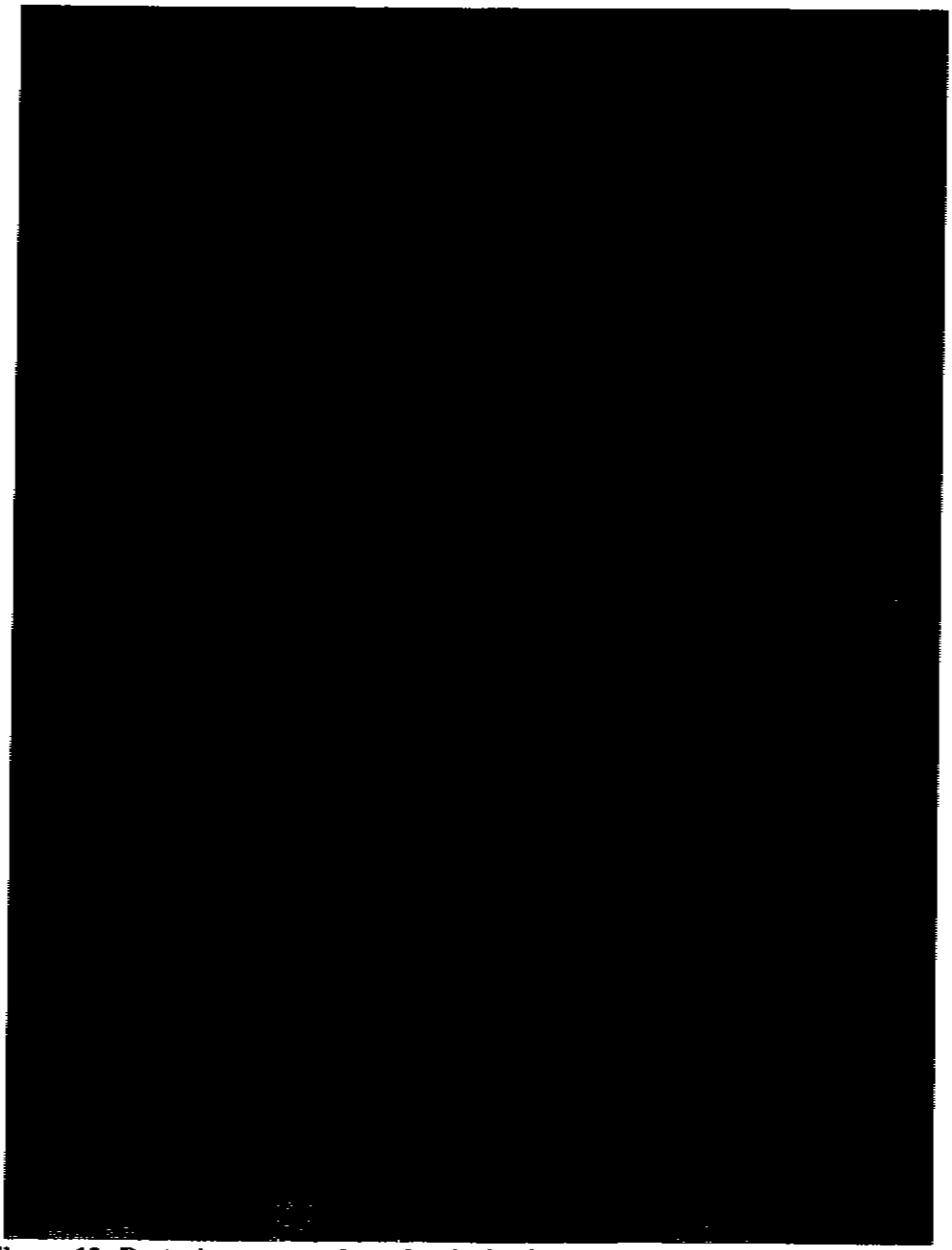


Figure 12: Posterior approach to the shaft of humerus [19]

The posterior approach provides exposure to the majority of the humerus through the interval between the lateral and long ends of the triceps muscle (figure 12). The proximal extent of the dissection is limited by the posterior circumflex vessels and the axillary nerve. Once the interval between the lateral and long heads of the triceps muscle is identified the exposure of the medial head is necessary. The radial nerve should be located along lateral border of the medial head of the triceps and traced throughout its entire course before longitudinally incising the medial head of the triceps that exposes the posterior aspect of the humerus.

Although the fracture pattern and location may dictate which surgical exposure is most advantageous, the general principles of open reduction and internal fixation remain constant. These include extensive exposure, identification and protection of the radial nerve, limiting soft tissue dissection of the fragments as much as possible, avoiding devascularisation of small or butterfly fragments and application of a plate of sufficient size and length to provide mechanical support to the entire humerus. With newer plate designs such as a limited contact dynamic compression plating [LCDCP, AO Research Institute, Davos, Switzerland] reduction is better achieved. The authors have found narrow 4.5 mm plates of at least eight holes in length to be preferable. The LCDCP Plate is preferred because of its design features such as scalloping of the under surface of the plate that minimises vascular damage beneath the plate, and screw holes that allows greater angulations to accommodate more fracture patterns and allow compression in multiple directions.

Intramedullary nailing

Intramedullary nails have been proposed as a means of preserving blood supply [find references]. There are several types that can be inserted through various surgical approaches. Load sharing biomechanical properties and closed insertion techniques with preservation of extramedullary blood supply makes Intramedullary nailing advantageous in many instances especially when early mobility and return to function is necessary. The nails can be divided into rigid and flexible types. The rigid nails are further subdivided into interlocking and expanding types. Both flexible and rigid nails can be inserted by antegrade or retrograde techniques. Although flexible nails are easier to insert the rotational strength is less than with rigid nails. Rigid nails provide excellent biomechanical stability and are comparable with the stability seen in compression plating techniques. However, the larger Intramedullary nail devices may require reaming which carries the risk to damage to nearby neurological and vascular structures and temporarily disrupting the endosteal blood supply of the bone or causing iatrogenic comminution of the bone. Since the humerus is not a typical weight bearing bone, the principles that have led to great success in lower extremity fractures may not be applicable, specifically those of a load sharing implant. For these reasons the humeral shaft is best left unreamed when inserting the nail. Most Intramedullary nails available for the humerus are designed for antegrade placement. The rotator cuff is identified, and a minimal amount of soft tissue trauma is critical when inserting the nail to minimize post-operative shoulder dysfunction which has been described to as a cause of shoulder pain in many studies. The insertion site for the nail is just medial to the greater tuberosity. Extreme care must be taken to bury the humeral nail well below the rotator cuff to prevent sub-acromial impingement postoperatively. In addition the proximal interlocking screws when placed must be placed from the superolateral position as it may also lead to subacromial impingement if the screws are not beneath the equator of the humeral head. When placing distal interlocking screws an anteroposterior direction is used. Open insertion technique with direct visualization of the cortex will minimize the likelihood of nerve injury.

An anterior acromial approach has been described for antegrade Intramedullary nailing. This approach has been used as a result of anatomic dissections, which have showed that the previously described anterolateral approach through the sulcus medial to the greater tuberosity did not allow linear access to the Intramedullary canal. Thus, the nail had to be pushed medially to facilitate entry thereby tearing the medial fibres of the rotator cuff and lateral fibres of the coracoacromial ligament. Residual irritation of either of these structures was cited as a potential cause of impingement and stiffness postoperatively.

Therefore it is recommended that an incision anterior to the acromion should be undertaken with the shoulder extended approximately 30 degrees. The rotator cuff incision at this point transects the coracoacromial ligament and there is linear access to the medullary canal. The development of this approach was done to offset the risk of shoulder dysfunction associated with antegrade nail placement.

The other proposed advantage of a more linear entry portal is decreasing the potential risk of iatrogenic fracture on nail insertion. Retrograde insertion of nails also can be performed. There is an absence of shoulder dysfunction with retrograde insertion.

There are many ways of "skinning a cat" and the surgeon should plan his surgery and the indications should be accurate.

The advantage of intramedullary fixation that is applicable to the lower extremity may not be directly applied to fractures of the humeral shaft. The knowledge of other forms of fixation is necessary for appropriate treatment. The surgeon must always be vigilant and know his technique. Browner et al and Rockwood and Green recommendfixation of diaphyseal fractures of the humerus by IMN because there is less tissue violation and improved biomechanics[29].

Research questions

The question asked in this research: How does nailing and plating of humeral shaft fractures compare in terms of rate of union, functional outcome and complications?

MATERIALS AND METHODS.

Ethics

This study was approved by the Human Research Ethics Committee of the University of the Witwatersrand. Clearance number R14/49 PEER

Study design

This is a prospective randomized study of patients who presented to Charlotte Maxeke Johannesburg Hospital, Chris Hani Baragwanath Hospital, and Helen Joseph Hospital. Most of the surgery was done at Chris Hani Baragwaneth Hospital where the author was employed.

Inclusion criteria

The inclusion criteria were outlined as follows: -

- Skeletally mature patients
- Unstable fractures
- Transverse fracture with fracture gap >0.5 cm
- Fractures angulated >20 degrees in any plane
- Fractures 3 cm distal to surgical neck and 5 cm proximal to olecranon fossa

Exclusion criteria

Patients were excluded from the study if they met any of the following criteria: -

- Skeletally immature patients
- Fractures with radial nerve palsy
- Pathological fractures
- Revision procedures

- Previous fracture of humerus
- Grade IIIB or C compound fractures
- Fractures >21 days old
- Psychosis

Recruitment

All the members of the division of Orthopaedic Surgery at University of the Witwatersrand were briefed on the purpose of the study as well as the inclusion and exclusion criteria.

On admitting a new patient the surgeon on call notified the author and patient's eligibility was assessed. All patients deemed eligible to the study were given a full explanation of the study and informed consent was obtained prior to inclusion (Appendix A). When a patient consented to the study, he/she was randomized to one of the two systems.

At recruitment a data sheet was completed (Appendix B) and the fracture was classified according to the AO classification system as shown on the same sheet.

Surgery

All operations were performed under regional or general anaesthesia in Charlotte Maxeke Johannesburg Hospital, Chris Hani Baragwanath Hospital or Helen Joseph Hospital. The timing of surgery depended on the admitting doctor, the availability of theatre time and the general health status of the patient. Registrars and consultants in the department performed all operations.

At conclusion of the operation the operating surgeon completed the surgery section of the data sheet in Appendix B documenting the fixation system and the sizes of components used, operating time, blood loss estimate (on the advice of the anaesthesiologists, one swab was considered to carry about 25mls of blood), any unusual intra- operative findings and any intra-operative complications. This data was collected by the operating team.

Follow up.

The initial protocol called for follow up of patients at 6 weeks, 10 weeks, 14 weeks, 18 weeks, 6 months 8 months and 1 year. In most cases, follow up was carried out by the investigator; however in some instances, when this was not possible, the assessment was done by the local registrar. The follow up forms (appendix D) and radiographic assessment forms (Appendix E) were delivered by the author to the orthopaedic outpatient department of each hospital. Registrars and consultants were requested to complete the forms when following up any study patients. Posters were placed in consulting rooms reminding doctors to look out for these patients and complete the forms. The investigator then collected these forms and X-rays. The data was entered into a spreadsheet. If forms were not available then information was taken from the doctors' notes where applicable.

Final Assessment

At mean follow-up time of 11.8 months from the operation (3 months to 3 years) all patients were assessed. The primary outcomes measured were non-union and functional outcome. To assess function we used the Modified Constant Score HSS, Elbow Score and WOMAC Score. Union was considered to be achieved when bridging callus was seen on the radiograph in at least two cortices and the patients could use their arms without discomfort. The modified Constant Score is a shoulder specific score used to measure shoulder function.

It is composed of individual scores of pain, activities of daily living and range of movement of the shoulder. the shoulder. Possible scores range from 0 to 75 with higher scores corresponding to full function. The HSS Elbow Score is an elbow-specific score used to measure elbow function. It is composed of individual scores of pain, function, muscle strength, range of movement and deformity. Possible scores range from 0 to 100 with higher scores corresponding to higher elbow function. WOMAC score is a general patient-based score that assesses difficulties that a person may have to perform activities of daily living. It is composed of individual scores of pain, stiffness and function. Possible scores range from 0 to 96 with lower scores corresponding with higher function. Secondary outcomes of the study were the incidence of complications and the need for further operations.

RESULTS

Demographics

This series contains 59 patients with traumatic fractures. There were 23 females and 36 males. Thirty two of them were treated with IMN and 27 with plating (Table 1). The overall age distribution was bimodal with a major peak in the third decade and a minor peak in the fifth decade. Average age was of 29 years (range 19 - 66 years). Fifty six fractures were closed and 3 were grade 1 open fractures. The right humerus was involved in 32 patients while the left was involved in 27. Traffic related accidents caused these fractures in 45 patients and most of these were in young patients, 7 were assaulted and 7 were due to a fall (Table 2). AO type A & B fractures formed almost 95% of the cases. The breakdown of fractures is shown in Table 4. The midshaft was fractured in about 80% of the cases, the proximal and distal thirds in 20% of the cases. The TYPE A1 (simple spiral fracture) of the midshaft was the most common, and type C fractures were the least common. The breakdown of the fracture in the 2 groups is shown in Table 3

Gender	NAIL	PLATE	Total
FEMALE	10	13	23
MALE	22	14	36
Total	32	27	59

Table 1 Gender breakdown in the two groups

Pearson $chi_2(1) = 1.7580$ $Pr = 0.185$

Mechanism	Freq.	Percent
ASSAULT	7	12%
FALL	7	12%
MVA	38	64%
PVA	7	12%
Total	59	

Table 2 Mechanism of injury

Fracture Type	NAIL	PLATE	Total
A	16	12	28
B	14	14	28
C	2	1	3
Total	32	27	59

Table 3 Fracture type breakdown in the 2 groups

Pearson $chi_2(2) = 0.4845$ $Pr = 0.78$. Fisher's exact =0.913.

The mean operation time for patients with a solitary humeral shaft fracture was 66 minutes [35 to 120] for the nail group and 93 minutes [60 to 139 minutes] for the plate group (P=0.456) (figure 13). the more complex Type C fractures took longer to fix in both groups (figure 14). No blood transfusion was required for either group. For postoperative bracing a simple collar and cuff support was used in all patients for post-operative pain relief.

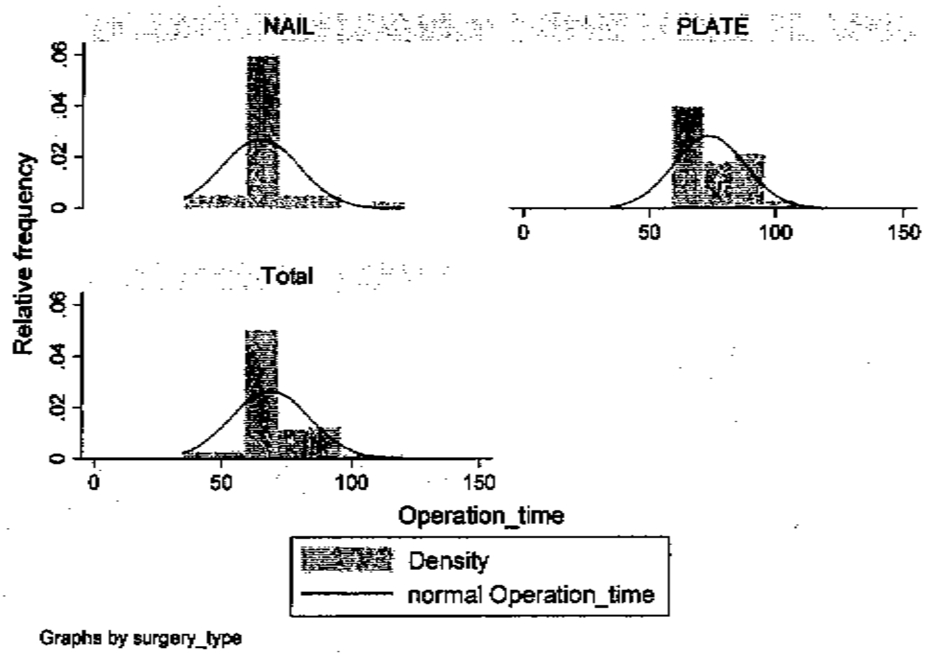


Figure 13 Operating time of the 2 groups

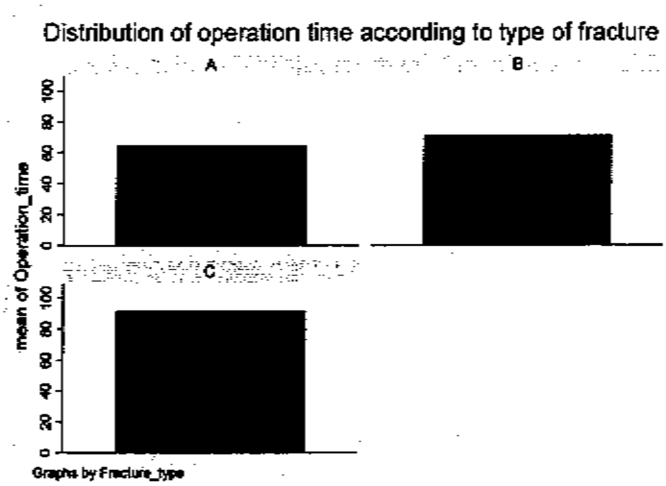


Figure 14 Operating time in different types of fractures.

Blood loss was estimated by adding the volume of blood in the suction bottle to the number of gauze swabs; a volume of 25ml/swab was proposed by the anesthesiologists. Patients in the nail group had much lower blood loss during surgery as compared to the plate group (95ml vs. 180ml). In the nail group the smallest amount of blood loss was about 50 ml. This is important because patients can lose about 500 ml of blood at the time of injury and blood replacement is very costly. Type C fractures that were plated had a greater blood loss than the other types of fractures. Type A fracture pattern showed a significantly lower blood loss.

Fracture Healing

In the nail group, all except two fractures had united at an average follow-up of 11.8 months, with a mean time to union of 8.64 weeks[range 6 to 12 weeks]. Two fractures showed no callus by six months. One of these patients underwent an exchange nail with reaming and subsequently united in two months. The other patient declined further surgery, and was lost to follow-up. Among the plate group, union was achieved in all but three of the cases by 9.2 weeks [range 6 to 12 weeks]. Three patients went on to nonunion. One had a Rush pin inserted, one united uneventfully after redo plating and third refused any further treatment.

Differences in *time* to union were statistically significant between the two groups (figure 15) but the *rate* of union did not differ.In the plate group 23/27 fractures healed in good position. The four less than ideal results had fractures that united in 10°of varus and a slight rotatory deformity; this was radiologically significant but not functionally so.

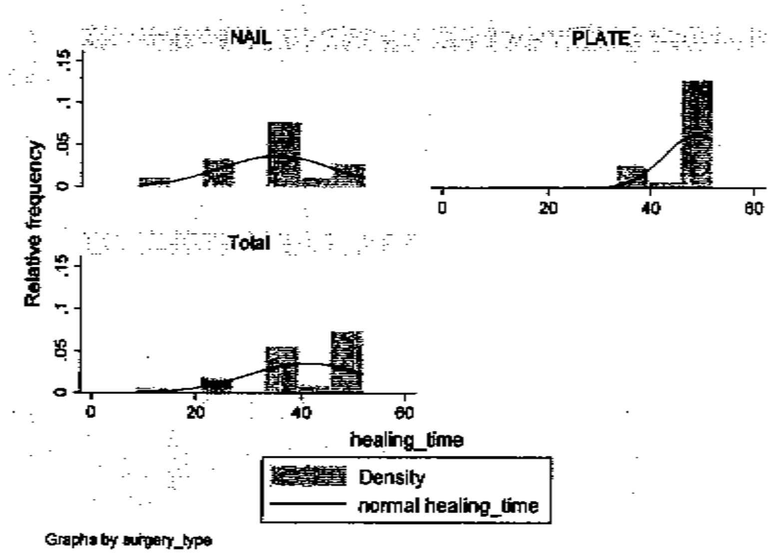


Figure 15 Average time to healing

Functional Outcome.

Modified Constant Score

In all of thepatients, the fractured side was compared to the healthy side. At final assessment, the average modified Constant score for the nail group was 57, and the average score for the plate group was 63 (figure 16). This was not statistically significant.

Most patients in the IMN group presented with some degree of shoulder impairment in the early postoperative period. This is not unexpected because of the surgical interference with rotator cuff tendons. In both groups most patients younger than 45 years recovered fully.Lower Constant scores were noted in patients with previous history of rotator cuff pathologyand in patients in the older age group.

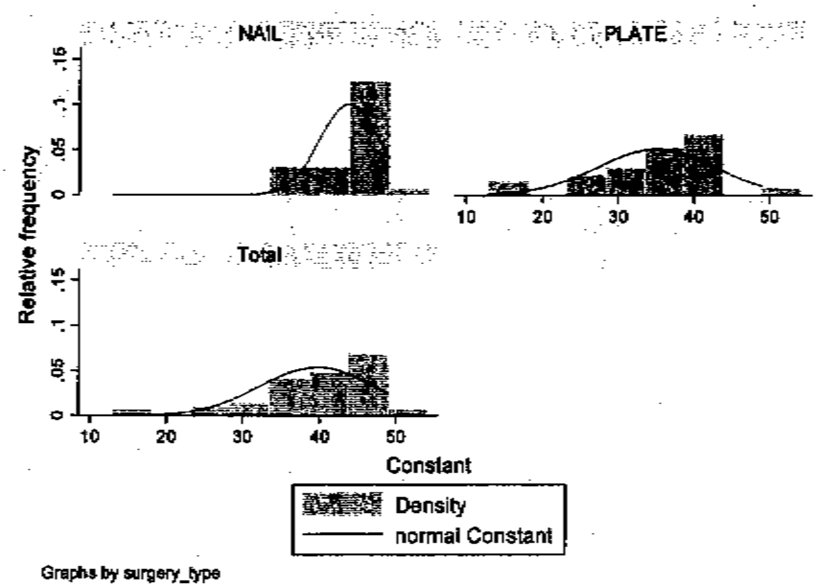


Figure 16 Constant score in the 2 groups

HSS Elbow Assessment Score

At final follow-up patients in the nail group had statistically betterHSS Elbow Scores than the plate group in the first 3 months. The average HSS Elbow Score in the plate group was 78.5, compared to 88.78 in the nail group (P=0.814) (figure 17).

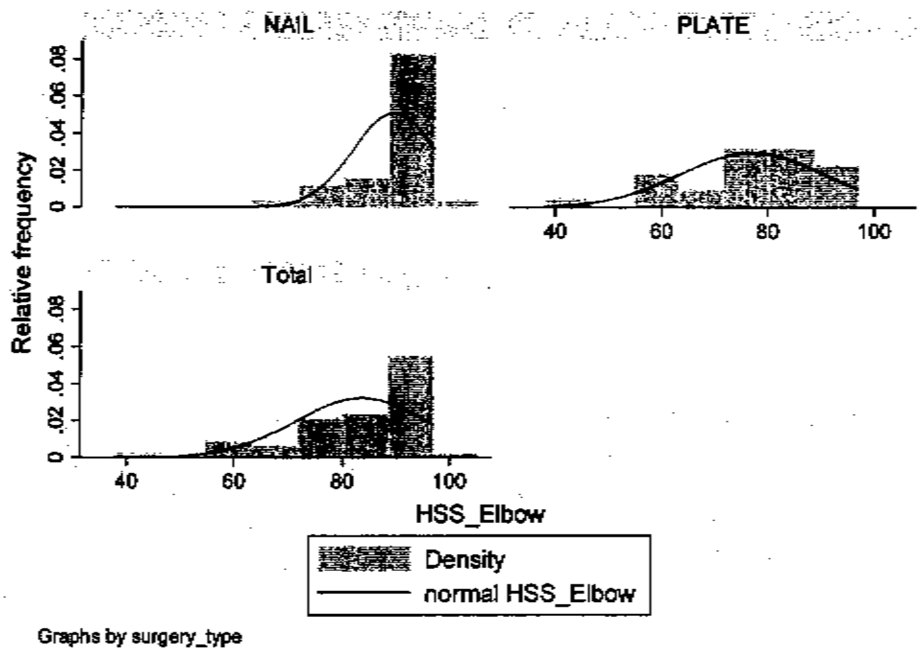


Figure 17 HSS Elbow Assessment Score of both groups

WOMAC

At final follow-up, in the whole series a score of 0 was recorded in 49 patients out of 59(83%). The score was 0 in 84% of the nailed cases and 81% of the plated cases (N.S.). In each group five patients had a score between 24 and 40(Table 4). The WOMAC scores were better in patients who were younger. This suggests that some degree of shoulder and/or elbow impairment does occur in older patients regardless of the technique used.

WOMAC	NAIL		PLATE		Total
	Number	Score	Number	Score	
NONE	27	84%	22	81%	49
MILD	2	6%	3	11%	5
MODERATE	3	9%	2	7%	5
Total	32	100%	27	100%	59

Table 4 WOMAC score in the 2 groups

Pearson chi^2 (3) = 2.3030 Pr = 0.512. Fischer s exact = 0.0607

Complications and Secondary Procedures

Overall, there were fewer postoperative complications in the nail group as compared to the plate group (Table 5). Postoperative nerve palsy developed in five patients in the plate group and one patient in the nail group. All were treated conservatively with a wrist extension splint, and no patient was offered surgery because nerve conduction studies only showed neuropraxia or axonotmesis.All except one of these patients recovered within three months, however in one patient it took six months for the nerve to recover. In the plate group, two patients developed superficial infection and there was one with deep infection. The latter one was a 43-year-old lady with grade 1 compound fracture who subsequently developed MRSA in the wound. After further surgery to remove the plate she went on to union, but the infection persisted. The patients with superficial infections settled uneventfully after wound debridement and antibiotics. In the nail group only one patient had superficial infection that settled with antibiotics.

Complication	**PLATE**	**NAIL**
Iatrogenic Palsy of the radial nerve	5	1
Non Union	3	2
Intraoperative Comminution	2	5
Infection	3	1
Severe Impingement	0	1
Minimal loss of fixation	3	0
Total	17	10

Table 5 Complications

Overdistraction at the fracture site occurred in two patients treated with nailing. This distraction was in the range of 5mm and had no adverse effect on the healing of the fracture. Among the fractures treated by nailing five patients had furthercomminution at the fracture site; two cases had further comminution in the plate group.

Implant removal was done in two patients in the nail group:one had subacromial impingement due to a proud nail andanother had too long a screw. Table 6 summarizes secondary procedures done to rectify these complications.

	PLATE	NAIL
Rev of fixation	2	2
Debridement	3	1
Implant Removal	0	2
Total	5	5

Table 6 Secondary Surgical Procedures

DISCUSSION

This prospective study found important advantages with locked nailing compared to plate fixation in the surgical treatment of humeral shaft fractures. Thirty three to ninety percent of humeral shaft fractures are reported to be treated conservatively with functional bracing being the most common nonoperative treatment option for the majority of fractures [32]. With improved implant technology and surgical technique, operative treatment of humeral shaft fractures has yielded a success rate equal to that of closed treatment. Operative intervention may include compression plating, intramedullary nails or external fixators depending on the fracture pattern [17]. The unique anatomy of the humerus allows the surgeon many options to treat the patient operatively. The author has chosen two modes of fixation, namely by plate or nail. In plate fixation there is extensive soft-tissue trauma and high risk of intraoperative radial nerve injury.

As for nailing, the author has chosen antegrade nailing as choice of fixation for this study. Antegrade nailing done by following correct technique has an excellent functional outcome [22, 27, 30].In this study reaming was not done. The complication of distraction of the fracture ends does not contribute to fracture non-union provided the gap is less than 3mm[21]. The one concern related to the use of locked nailing is interference of shoulder motion associated with the antegrade approach. A key to preventing impairment of shoulder motion is correct operative technique.No significant differences between shoulder function in the plate or nail group were found in this study. Patients who were plated experienced a similar decreased elbow range of movement as compared to those patients who received a nail [6]. McKee et al [24] and Reimer [27] have shown that antegrade nailing itself is not the factor most likely to jeopardize shoulder function. Most patients recovered shoulder function slower than patients who had plating done but they went on to full shoulder function, which is evident from the modified constant scores in our study. Shoulder joint ROM and strength recover to normal after humeral shaft fractures [23]. In the plate group, the occurrence of complications, including non-union and infection and intraoperative radial nerve injury was similar to other reported studies. Plate fixation was associated with more instances of iatrogenic radial nerve palsy [16%] and infection [5%][17]. Closed nailing is associated with fewer complications, because there is less periosteal stripping as compared to tight plate contact, which may jeopardize bone blood circulation, which could be, detrimental to fracture healing. The closeness of the radial nerve to the humeral shaft and the necessity to dissect the radial nerve in plating has a potential risk of nerve injury but with improved surgical techniques and more experience, permanent damage is generally rare, but transient neuropraxia still occurs.

Nonunion is the pressing problem on every orthopedic surgeons mind. Caution should be taken in interpreting time to union and other outcomes [37]. In reports of dynamic compression plate (DCP) fixation, the incidence of non-union has ranged from 2 to 10%[37]. My study has shown a nonunion rate of 11% in the plate group (3/27). This compares well with international studies. The problem is how to quantify non-union. In this study evaluation of the radiographs was used to confirm various stages of fracture healing. It was also presumed that patients without pain at six months were fully recovered and their fractures were completely healed. Operating time and blood loss was not the same for both the nail group and plate group. Blood loss was greater in the plating group compared to nailing group (180 cf. 95ml)[And see ref. 7]. Mean hospital stay, blood loss and operation time was cited in two randomized controlled studies [6, 8].

In summary the treatment of fractures of the shaft of the humerus remains controversial[31]. The rationale of nonoperative treatment largely stems from work done by Sarmiento et al [32].They had a rate of union in closed injuries of 98%with all patients achieving a satisfactory return to function[32]. It should be noted that most authors have had difficulty replicating these results with non-operative methods.
Internal fixation is indicated following failure to maintain satisfactory alignment, incomplete reduction, bilateral humeral fractures, multiple fractures, open fractures, segmental fractures, floating elbow and associated neurovascular injuries [38]. The advantage of fixation is that once the limb is stabilised it can be mobilized early without

external support and allows the patient the comfort of sleeping in the supine position. Additionally the angular deformity so often seen with conservative treatment is effectively prevented.

McCormack et al[38] found no difference in shoulder and elbow scores, shoulder pain, or range of motion between nailing and plating in a prospectivecontrolled randomisedstudy [23]. Lin and Hou reported good functional outcomes in a retrospective study of a group of 48 patients treated with antegrade nailing [20]. If nailing is performed properly shoulder scores and isometric measurements showed no difference between groups [37].

It has been suggested that injury to the rotator cuff during insertion of the nail is not the main reason for residual problems in the shoulder joint. Changulani et al compared the use of IMN with dynamic compression plating in a series of 47 patients and found thatfunction of the shoulder was similar in both groups [8].

Most authors have considered impingement of the rotator cuff as the most important factor contributing to the problems in the shoulder joint. Other technical factors which are thought to cause poor recovery include massive tears of the rotator cuff with inadequate repair, prominence of the nail or the locking screws, axillary nerve injury and further comminution, and gaps at fracture site greater than 3mm. Incision into the supraspinatus tendon is made to gain access for insertion of the humeral nail. This is near the so-called *critical zone* in the tendon, which is believed to have a poor blood supply, leading to problems with healing. Studies have shown this area to be hypovascular, and that even degenerative tears of this zone heal poorly following surgical treatment.Many reports support the idea that antegrade nailing, when carried out correctly is not the cause of impairment of shoulder function. Insertion of the nail through an already compromised rotator cuff maybe the cause or aggravated by the introduction of the nail. Shoulder impairment is a multi-factorial problem and IMN is not the sole cause of shoulder dysfunction. Therefore further investigationsare required to evaluate the preoperative status of the rotator cuff in patients with humeral fracturesby high resolution ultrasound or magnetic resonance for later comparison.

We used three scoring systems to assess shoulder and elbow function postoperatively. Using the WOMAC score to assess pain due to osteoarthritis, it was shown that patients who were older than forty five years had more pain during the rehabilitation period. The HSS elbow score had a higher average score for the nails [91.5 points] as compared against the plate group [79.5 points]. The modified Constant score did not show significant differences when compared after six months in both groups.

The complications were much higher in the plating group as compared to the nailed group. The most common of the complications was noted in the plate group post-operatively and involved the radial nerve [10%] and second was nonunion [5%] of the fracture. In our study there were five cases of iatrogenic nerve injury and three cases of nonunion. In pooled studies percentages of patients with non-union [0.4 to3.1%] and iatrogenic nerve injury [0.7 to 16.0%] [6, 8]. These figures correlate with our study. In our study the time to union was 8.64 weeks for the nail group as compared to the plate group with 9.2 weeks. This was compared to different pooled studies which correlated with our findings and it was noted that in the nail group it was 6.3 to 9.8 weeks and in the plate group it was 8.9 to 10.4 weeks [6, 8]. Infection was more common in the plated group at 11%(3/27) but it was mostly superficial with only one case developing deep seated infection.

In this prospective study of acute humeral fractures, humeral locked nails with their less invasive surgical technique gave more favourable results than did plate fixation. Correct nailing direction, meticulous technique, good quality hardware, and stable transfixing screws are the prerequisites for a successful outcome

Comparison of results with published data:

The results of this study are comparable with other studies, but the difference in mode of fixation points towards the use of an intramedullary nail by far having better outcomes. The complications are similar to other studies. This study is equal to studies published from the Far East [20].

Limitations of study:

In some cases, follow-up was difficult because some of our patients were unemployed or lived far from the hospital. The number of patients in the study is not great but many published studies have similar number of patients and have been able to draw statistically sound conclusions.

CONCLUSION AND RECOMMENDATIONS

Most humeral shaft fractures heal uneventfully, whether an invasive or non-invasive protocol is followed. Complications cannot be prevented entirely but are reduced significantly by proper technique and patient selection. A common error is failure to provide adequate stability for the fracture, which is subjected to large angular and torsional loads. In our setting our registrars are confident in nailing of long bone fractures; as far as plating of the humerus is concerned, surgeons are always concerned because of the proximity of radial nerve. I have shown in my study that if doctors follow principles and use the correct implant, namely an intramedullary nail, the results are excellent and the radial nerve is always out of harm's way. The data presented indicates that even though the plate is regarded as the standard of care in most of Europe and in America, in countries like the Far East (Taiwan)[23, 20] the nail has had far better results. In our setting of the nail inserted in antegrade fashion is a good fixation device that is safe and gives results that are reproducible with good healing times compared to the plate. However, it would be interesting to persue further study to visualise preoperatively the rotator cuff by ultrasound or magnetic resonance to confirm that it is not injured during insertion of the nail.

REFERENCES:

1. **Balfour, G.W., Mooney, V. & Ashby, M.E. Diaphy**seal fractures of the humerus with **a ready-made fracture brace.** *J Bone joint surgery Am,* vol. 64-A, 1982, pp.11.
2. **Bell, M.J., Beaucamp, C.G. & Kellman, J.K., et al.** The results of plating humeral shaft fractures in patients with multiple injuries. The Sunnybrook experience. *J BoneJoint Surg Br*, vol. 67- B, 1985, pp. 293-296.
3. **Breasted,** J.H. The Edwin Smith Surgical Papyrus. vol. 2. Chicago: The University of Chicago Press, 1930.
4. **Brinker, M.R. & O'Connor, D.P.***Review of Orthopaedics.*[4th] ed Miller.Charlottesville, Virginia: Saunders, 2004. 1-38 p.
5. **Brumback, R.J., Bosse, M.J. & Poka., et al.** Intramedullary stabilisation of the humerus shaft fractures in patients with multiple trauma. J Bone Joint Surg. Am, vol. 68-A, 1986, pp. 960-70.
6. **Chapman, J., Weber, T.G., & Henley, M.B., et al.** Randomized Prospective Study of humerus fixation: nails versus plate. Annual meeting of the Orthopaedics Trauma Association, 1995, pp. 104-105.
7. **Castella, F.B., Garcia, F.B., & Berry, E.M., et al.** Nonunion of the humeral shaft. *Clinical Orthop Relat Res*, vol. 424, 2004, pp. 227-230.
8. **Changulani, M., Jain, U.K. & Keswani,** T.Comparison of the use of plate and nail. A randomised controlled study. International Orthop.
9. **Crolla. R.M.P.H., de Vries, L.S. & Clevers, G.J.** Locked Intramedullary nailing of humerus fractures. *Injury*, vol. 24, 1993, pp. 403-405.

10. **Debezies, E.J., Banta, C.J. & Murphy, C.P., et al.** Plate fixation of the humeral shaft for acute fractures with and without radial nerve injuries. *J Orthop Trauma,* vol. 6, pp.10-13.

11. **Foulk, D.A. & Szabo, R.M.** Diaphyseal humerus fractures. Natural history and occurrence of non-union. *Orthopedics,*vol.18,1995, pp 333-335.

12. **Google** <http://www.aldokkan.com/science/edwin_surgical_papyrus.htm/ >New York Academy of Medicine, 2008.

13. **Google** <**http://www.muslimheritage.com/topics/taxonomy.htm/**>New York Academy of Medicine, 2008.

14. **Habernek, H. & Orthner,** E. A locking nail for fracture of the humerus. *J Bone J Joint Surg,* vol. 73-B, 1991, pp. 651-653.

15. **Heim, D., Herkert, F. & Hess, P.** Surgical treatment of the humeral shaft fractures. *J of Trauma,* vol. 35, pp. 226-232.

16. **Hems, T.E., & Bhullar, T.P.** Interlocking nailing of the humeral shaft fractures.*Injury*, vol. 27, 1996, pp 28.

17. **Houwelingen, A.V. & McKee, M.D.** Management and Complications of Humeral shaft fracture. *University of Toronto Medical Journal,* vol. 81, 2004, pp. 96-102.

18. **Igbigbi,** P.S. & Manda, K. Epidemiology of humeral fractures in Malawi. *Int Orthop,* vol. 28, 2004, pp. 338-341.

19. **La Velle, D.G. Campbell's Operative Orthopedics. 9th ed. St Louis, Missouri: Mosby, 1998. vol 3, 2579-2629 p.**

20. **Lin, J., Hou, S.M. & Shen, P.W. Treatment of humeral shaft fractures with humeral locked nails and comparison with plate fixation.** *Journal of Trauma,* vol .44, 1998, pp. 859-864.

21. **Loomer, R. & Kokan, P.** Nonunion of shaft of the humerus. *Injury*, vol. 7, 1976, pp. 274-278. 1

22. **Mast, J.W., Spiegal, P.J. & Harvey, J.P., et al.** Fractures of the humeral shaft. *Clin Orthop*, vol. 12, 1975, pp. 254-262.

23. **McCormack, R.G., Brien, D., & Buckley, R.E., et al.** Fixation of fractures of the shaft of the humerus by dynamic compression plate and Intramedullary nailing. A prospective randomised trial. *J Bone Joint Surg* Br, vol. 82- B, 2000, pp 336-9.

24. **McKee, M.D., Pedlow, F.X. & Cheney, P.J., et al**. Fractures below the end of locking the humeral nails. *J Orth Trauma*, vol. 10, pp. 500-513.

25. **Muller, M.E., Nazarian, S. & Koch, P., et al.** Comprehensive classification of fractures. AO/ASIF Documentation Center, Davos, Switzerland.

26. **Netter, F.H. Netters Concise Atlas of Orthopaedic Anatomy.** 1st ed. Teteboro, NJ: ICON Learning Systems, 2002. 77-86 p.

27. **Riemer, B.L., Foglesong, M.E. & Burke, C.J., et al.** Complications of Seidal Intramedullary nailing of narrow diameter humeral diaphyseal fractures. *Orthopaedics,* vol. 17, 1994, pp19-29

28. **Robinson, C.M., Bell, K.M.& Court- Brown, C.M., et al.** Locked nailing of humeral shaft fractures. *J Bone Joint Surg* Am, vol. 74- A, 1992, pp 558-62.

29. **Rockwood, C. A. & Green, D.P. Rockwood and Green"s fracture in adults. 4th** ed. Philadelphia: Lippincott - Raven, 1996, 1025-1037 p.

30. **Rommers, P.M., Verbruggen, J. & Broos, P.L.** Retrograde locked nailing of the humeral shaft fractures. *J Bone Joint Surg*, Br, vol 77- B, 1995, pp. 84-9.

31. **Rudi, T.&** Murphy, W.M. AO Principles of Fracture Management. Stuttgart-New York: Thieme, vol. 1, 2000.

32. **Sarmiento, A., Kinman, P. & Galvin, E.** Functional bracing of fractures of the shaft of the humerus. *J Bone Joint Surg* Am, vol 59- A, 2008, pp. 596-601.

33. Solomon, L., **Warwick, D. & Nayagam, S.** ***Apleys System of Orthopaedics and Fractures.*** **8th ed. London: Arnold, 2001.** 541-543 p.

34. **Tytherleigh-Strong, G., Walls, N. & McQueen, M.M.** The epidemiology of humeral shaft fractures. Journal of Bone and Joint Surgery Br, 1998, pp.249-253.

35. **Wagner, M.S., Patterson, M.B.& Wilber, J.H., et al.** Comparison of outcomes for humeral diaphysis fracture treated with either closed Intramedullary nailing or open reduction internal fixation using a dynamic compression plate in the multiple trauma patient. *Procs annual meeting of the Orthopaedic Trauma Association, 1995*, pp. 102-103

36. **Ward, E.F., Savoie, F.H. & Hughes, J.L.** Fractures of the diaphyseal humerus. Skeletal trauma. Philadelphia: *W.B. Saunders*, Vol. 2, 1992, 1177-1193 p.

37. **Zuckerman, J.D. & Koval, K.J.** Factures of the shaft of the humerus. *Rockwood and Green fracture in adults*. 4th ed. Philedalphia: Lippincott-Raven, 1996, vol.1, 1025-1029 p.

38. **Zuckerman,** J.D., & Kenneth, J.K. Hand Book of Fractures. 2ed. Philadelphiae:Lippincott Williams & Wilkins, 2002. 86-90 p.

Glossary

Fracture

Humerus

Shaft

Intramedullary

Nail

Nailing

Plate

Plating

The protocol and study forms are included for reference.

Appendix A

Introduction Sheet and Consent Form

Good day. My name is Zain Peer; I am an orthopaedic registrar here at Helen Joseph Hospital. We are conducting a study on the results after two different types of fixation for fractures of the arm (nail and plate), and we would like to ask you to consider participating.

Under normal circumstances (i.e. if we were not doing the research) you would be given one of these two types of fixation, depending purely on the preference of the surgeon who would do your operation. As far as we know, these two means of fixation are entirely equivalent.

What we are proposing is that you would still receive exactly the same care and operation as if you were not in the study, with the only difference that you would be allocated randomly (by chance, or flipping a coin) to receive one or the other method of fixation. In addition we would like to record what happens to you after the operation, to measure the outcome.

Why are we doing this? Research on different fixation methods for fractures is continually being done to find the optimal implant that will produce the best outcome. We want to compare the results of two known successful implants for the fracture of humerus. Both systems are used routinely in our unit and have gained acceptance worldwide.

What do we expect from the participants in the study? Patients who need a surgical fixation of fractured humerus, and agree to participate in the study will be randomly assigned to receive one of the implants mentioned above. After you have been discharged, we would ask you to come back for a checkup and X-rays at 3 weeks, 6 weeks, 3 months, 6 months, and 1 year. This data will be documented and recorded for later analysis. Please note that these follow-up visits are just the same as for any patients undergoing surgical fixation of humerus in this unit. In other words, the only "experimental" aspect of the study is that we will record how you do after the operation. Everything else will be standard.

Are there benefits to the participants? There are no direct financial benefits to you. However you will undoubtedly benefit from the closer follow-up involved in the study.

How will the data collected be used? Only the researchers and a few other authorized people have access to your records. These data will be used for presentation in orthopaedic meetings and congresses and for publication in the future. At no time will any personal information be revealed; all information will be handled with complete confidentiality and anonymity.

May participants withdraw from the study? Certainly, you may do so at anytime without giving a reason. Remember that the study is voluntary and not taking part in it, or withdrawing from it, carries no penalty of any sort.

If you have any queries, more information may be obtained from Isabella at telephone number (011) 489 0636.

If you agree to participate in this study, please sign the consent form below.

Thank You

Dr. Zain Peer

Consent Form

I ________________________________ agree to participate in the study "prospective randomized study of outcomes in patients with humeral shaft fractures following two methods of fixation: locked intramedullary nailing versus plate fixation"

Signature ___________________

Witness: ___________________

Date: ___________________

Appendix B

DEMOGRAPHICS &SURGERY (1/2)

Last Name: ____________________ **First Name:** ______________________

Patient No.: ____________________ **Study ID:** ________________________

Date of Birth (dd/mm/yy) : ____ / ____ / _______**Gender: 0 Male0 Female**

Date of Admission(dd/mm/yy) : ____ / ____ / _______

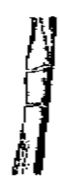
Mechanism of injury: O MVA   O PVAO Fall   0 Assault

O Other: ________________________

Fracture Type: OClosedOOpen: **O I O II O IIIA O IIIB O IIIC**

O12A1  O12A2  O12A3 

O12B1  O12B2  O 12B3 

O 12C1  O12C2  O12C3 

OTHER INJURIES:___________________________________

Surgery date (dd/mm/yy) :____ _/ ____ _/ _______

Operated arm: ORight   OLeft

SURGEON:_______________ **AASSISTANT 1:** _____________

ASSISTANT 2: _______________________

Operating time: _________   min   **Blood loss estimate:** _______ml

SYSTEM: OAO UHN ODCP

NAIL: ____mm X ____mm **DCP:** ____hole + ____Screws

ARCHIVING: O A: On file O B1: Lost to FU O B2: Dead

O B3: revised (infection) O B4: exchange (traumatic) O B5: Out of study

O C1: Failure (implant) O C2: Failure (nonunion)

Complication?* O No O Further comminution O Wound breakdown

O infection OCompartment syn . ORadial Nerve OAxillary N.

OMedian N. O Ulnar N. OVascular OOther:____________

Revision?** O No O Yes Date: ______________________

Implant Failure?*** O No O Yes Date: ______________________

Exchange implant?**** O No O Yes Date: __________________

Data Entry on: ____ / ____ / __________ ***by:*** __________________

**Complication refers to any adverse effect, with or without reoperation*
***Revision refers to any local surgical procedure, with or without retrieval of the implants*
****Implant failure refers to a mechanical failure e.g. screws pullout, bent plate, broken plate or other implant-related problem with or without exchange of implant with or without bone graft.*
***** Exchange implant refers to an implant removal and exchange with another implant with or without bone graft.*

PATIENT NOTES:

____

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Appendix C

CONSTANT SCORE (1/2)

Last Name: ________________________ **First Name** ________________

Patient No.: _____________________ **Study ID:** ________________________

Date of Surgery (dd/mm/yy) : ____ / ____ / ________

Reviewer: ____

Reviewed by: O Operator **O** Other MD **O** Physio **O** Phone **O** Questionnaire

Date of reviewdd/mm/yy) : ______ / ______ / ________

Reviewed at: O 3/52 O 6/52 O 10/52 O 14/52 O 18/52

O 6/12 O 8/12 O 1 yr O Other:________ weeks

Fracture Type: O 12A1 O12A2 O12A3 O 12B1 O12B2

O 12B3 O 12C1 O12C2 O12C3

Side O Right O Left

Pain

None	15
Mild	10
Moderate	5
Severe	0

Activities of Daily Living

Activity Level

Full work	4
Full recreation / sport	4
Unaffected sleep	2

Positioning

Up to waist	2
Up to xiphoid	4
Up to neck	6

Up to top of head	8
Above head	10

Forward and Lateral Elevation

Elevation

0-30	0
31-60	2
61-90	4
91-120	6
121-150	8
151-180	10

External Rotation

Hand behind head with elbow held forward	2
Hand behind head with elbow held back	2
Hand on top of head with elbow held forward	2
Hand on top of head with elbow held back	2
Full elevation from on top of head	2

Internal Rotation

Dorsum of hand to lateral thigh	0
Dorsum of hand to buttock	2
Dorsum of hand to lumbosacral junction	4
Dorsum of hand to waist (3rd lumbar vertebra)	6
Dorsum of hand to 12th dorsal vertebra	8
Dorsum of hand to interscapular region (DV 7)	10

TOTAL	

Appendix D

HSS Elbow Assessment Scale (1/2)

Last Name: ________________________ **First Name** __________________

Patient No.: ____________________**Study ID:**________________________

Date of Surgery (dd/mm/yy) : ______ / ______ / __________

Reviewer: ____

Reviewed by: O Operator **O** Other MD **O** Physio **O** Phone **O** Questionnaire

Date of Review (dd/mm/yy) : ______ / ______ / __________

Reviewed at: O 3/52 **O** 6/52 **O** 10/52 **O** 14/52 **O** 18/52

O 6/12 **O** 8/12 **O** 1 yr **O** Other:________ weeks

Fracture Type: O 12A1 **O**12A2 **O**12A3 **O** 12B1 **O**12B2

O 12B3 **O** 12C1 **O**12C2 **O**12C3

Side **O** Right **O** Left **O** Bilateral

Parameters

(1) pain: 2 measures (pain when bending, pain at rest)
(2) function and activities: 2 measures (bending activities, elbow use)
(3) muscle strength: 1 measure
(4) range of motion: 3 measures (sagittal arc, pronation, supination)
(5) deformity: 2 measures (flexion contracture, extension contracture)

Parameter	Finding	Points
pain when bending	none	15
	mild	10
	moderate	5
	severe	0
pain at rest	none	15
	mild	10
	moderate	5
	severe	0
bending activities	can do bending activities for 30 minutes	8
	can do bending activities for 15 minutes	6
	can do bending activities for 5 minutes	4
	cannot do bending activities	0
use of elbow	unlimited use	12
	limited only during recreation	10
	household and employment use	8
	limited to independent self-care	6

	cannot use elbow (invalid)	0
sagittal arc	degrees of motion	1 point for each 7°
muscle strength	can lift 2.3 kg to 90°	10
	can lift 0.9 kg to 90°	8
	moves through arc of motion against gravity	5
	cannot move through arc of motion	0
flexion contracture	< 15°	6
	between 15 and 45°	4
	between 45° and 90°	2
	> 90°	0
extension contracture	> 125° (within 15° of 135°)	6
	100 - 124° (< 125°)	4
	80 - 99° (< 100°)	2
	< 80°	0
pronation	> 60°	4
	> 30 to 60°	3
	> 15 to 30°	2
	0 to 15°	0
supination	> 60°	4
	> 30 to 60°	3
	> 15 to 30°	2
	0 to 15°	0

TOTAL		

Interpretation:
- minimum score: 0
- maximum score: 100
- The higher the score, the better the elbow function.

Notes

Appendix E

Evaluation WOMAC (1/3)

Last Name: ____________________**First Name**: ____________________

Patient No: ____________________ **Study ID**:____________________

Date of Surgery (dd/mm/yy) : ______ / ______ / ________

Reviewer: ____

Reviewed by: O Operator O Other MD O Physio O Phone O Questionnaire

Date of Review (dd/mm/yy) : ______ / ______/ ________

Reviewed at: O 3/52 O 6/52 O 10/52 O 14/52 O 18/52

O 6/12 O 8/12 O 1 yr O Other:________ weeks

Fracture Type: O 12A1 O12A2 O12A3 O 12B1 O12B2

O 12B3 O 12C1 O12C2 O12C3

Side O Right O Left

*The 12 questions **in BOLD** are used for both Original Womac and Reduced Womac Score RWS*

P :*These questions concern the amount of **pain** you are currently experiencing due to arthritis in your hips and your knees. For each situation, please enter the amount of pain you have recently experienced.*
How much pain do you have…

1. (1) Walking on a flat surface
O None O Mild O Moderate O Severe O Extreme O Unknown

2. (2) Going up or down stairs
O None O Mild O Moderate O Severe O Extreme O Unknown

3. (3) At night while in bed
O None O Mild O Moderate O Severe O Extreme O Unknown

4. (4) Sitting or lying
O None O Mild O Moderate O Severe O Extreme O Unknown

5. (5) Standing upright
O None O Mild O Moderate O Severe O Extreme O Unknown

M :*These questions concern the amount of **joint stiffness** (not pain) you are currently experiencing due to arthritis in your hips and or knees. Stiffness is a sensation of restriction or slowness in the area around which you move your joints.*

6.How severe is your stiffness after first waking in the morning
O None O Mild O Moderate O Severe O Extreme O Unknown

7.How severe is your stiffness after sitting, lying or resting later in the day.
O None O Mild O Moderate O Severe O Extreme O Unknown

F :*These questions concern your* ***physical function****. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you are experiencing due to arthritis.*
What degree of difficulty do you have with…

8.Descending stairs:
O None O Mild O Moderate O Severe O Extreme O Unknown

9. (6) Ascending stairs:
O None O Mild O Moderate O Severe O Extreme O Unknown

10. (7)Rising from sitting:
O None O Mild O Moderate O Severe O Extreme O Unknown

11.Standing:
O None O Mild O Moderate O Severe O Extreme O Unknown

12.Bending to floor:
O None O Mild O Moderate O Severe O Extreme O Unknown

13. (8) Walking on flat:
O None O Mild O Moderate O Severe O Extreme O Unknown

14. (9)Getting out of / into car:
O None O Mild O Moderate O Severe O Extreme O Unknown

15.Going shopping:
O None O Mild O Moderate O Severe O Extreme O Unknown

16. (10) Putting on socks / stockings:
O None O Mild O Moderate O Severe O Extreme O Unknown

17. (11)Rising from bed:
O None O Mild O Moderate O Severe O Extreme O Unknown

18.Taking off socks / stockings:
O None O Mild O Moderate O Severe O Extreme O Unknown

19.Lying in a bed:
O None O Mild O Moderate O Severe O Extreme O Unknown

20.Getting into / out of bath:
O None O Mild O Moderate O Severe O Extreme O Unknown

21. (12) Sitting:
O None O Mild O Moderate O Severe O Extreme O Unknown

22.Getting on / off toilet:
O None O Mild O Moderate O Severe O Extreme O Unknown

23.Heavy domestic duties:
O None O Mild O Moderate O Severe O Extreme O Unknown

24.Light domestic duties:
O None O Mild O Moderate O Severe O Extreme O Unknown

NOTES

Appendix F

Radiographic Evaluation (1/1)

Radiographic Patterns

Last Name: ____________________ **First Name:** ____________________

Patient No.: __________________ **Study ID:** __________________________

Date of Surgery (dd/mm/yy) : ______ / ______ / ________

Reviewer: ______________________________________

Reviewed by : O Operator O Other MD

Date of Review (dd/mm/yy) : ______ /______/ ________

Reviewed at: O 3/52 O 6/52 O 10/52 O 14/52 O 18/52

O 6/12 O 8/12 O 1 yr O Other:________ weeks

Fracture Type: O 12A1 O12A2 O12A3 O 12B1 O12B2
O 12B3 O 12C1 O12C2 O12C3

Side O Right O Left O bilateral

Alignment In AP: O Well O Valgus ____ deg. O Varus ____ deg.

Alignment in Lateral: O Well O Procurv ______ deg. O Recurv_____ deg.

Apposition: O________%

Distraction: O None O ____________ mm

Screws: O in place O lucency around O pulled out: How many? ______
O Broken: How many? _______

Plate: O N/A Oin plate Obent O pulled off O broken

Nail: ON/A Oin place O broken O migrated up
O migrated down

Fracture line: Ovisible O Hazy O Partially obliterated in one plane
O Partially obliterated in two planes O Totally obliterated in one plane
O Totally obliterated in two planes

Callus:O Absent O Hazy around fracture O Bridging callus - one cortex
O Bridging callus – 2 cortices O Bridging callus – 3 cortices
O Bridging callus all around O Solid union

NOTES

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