Biomechanical assessment of the NCB-PH plate in Proximal Humeral Fractures, and Anatomic Study for its Application Technique

Thesis
For Fulfillment of the Doctorate Degree in Medicine in the Faculty of Medicine

University of Ulm

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2006
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Tag der Promotion: 20-10-2006
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Acknowledgement

Curriculum Vitae
Abbreviations

AO    Association for the study of internal fixation

C     Centigrade

Cm    Centimeter

CT    Computed tomography

Fig   Figure

Hz    Hertz

Mm    Millimeter

MIS   Minimally invasive surgery

N     Newton

NCB-PH Non contact bridging-proximal humerus

P value Probability value

3-D   3-Dimensional
1. Introduction

1.1. Proximal Humeral Fractures

Fractures of the proximal humerus are the third most common type of injury seen in patients over sixty-five years of age. The majority of these fractures are related to osteoporosis (Hessmann et al. 2005). Like fractures of the hip and the distal radius, they are an important source of morbidity in the elderly.

1.1.1. Incidence and Epidemiology

Fractures of the proximal humerus account for 4 to 5% of all fractures. Most occur in elderly individuals and are caused, in part, by osteoporosis (Koval et al. 1996). Eighty-five percent of proximal humerus fractures are minimally displaced. More than 70% of patients with a proximal humeral fracture are > 60 years, ¾ are women (Lind et al. 1989), and from 40 years of age the incidence of fracture begins to rise exponentially. The overall incidence of proximal humeral fractures is rising (Palvanen et al. 2006).

1.1.2. Mechanism of Injury and Risk Factors

The most common mechanism of injury for proximal humeral fractures is a fall onto the outstretched hand from a standing height or less (Lind et al. 1989). In most instances, severe trauma does not play a significant role due to the underlying osteoporosis. In younger patients, high energy trauma is more frequently involved, and the resulting fracture is often more serious. These patients usually have fracture-dislocations with significant soft-tissue disruption and multiple trauma. When multiple trauma is treated, the
proximal humeral fracture is commonly initially ignored, because attention is focused on more life-threatening problems.

Another mechanism of injury, is excessive rotation of the arm especially in the abducted position. The humerus locks against the acromion in a pivotal position and a fracture can occur, especially in older patients with osteoporotic bone. Proximal humerus fractures may also result from a direct blow to the side of the shoulder. This usually occurs in the lateral position and may result in fracture of the greater tuberosity (Flatow 2001).

Factors that increase the risk or severity of falling are likely to increase the risk of proximal humeral fractures (Kelsey 1992). Independent risk factors associated with increased rates of proximal humeral fracture include recent decline in health status, insulin dependent diabetes mellitus, epilepsy, depression, infrequent walking, and neuromuscular weakness. Difficulty walking in dim light, a measure of visual acuity, and use of a hearing aid are other risk factors (Chu et al. 2004).

1.1.3. Clinical Picture of Proximal Humeral Fractures

Most fractures of the proximal humerus present acutely, and, therefore, the most common symptoms are pain, swelling, and tenderness about the shoulder, especially in the area of the greater tuberosity. Ecchymosis generally becomes visible within 24 to 48 hours of the injury and may spread to the chest wall and flank and distally down the extremity. (Flatow 2001).

A detailed neurovascular evaluation is essential in all fractures of the proximal humerus. The brachial plexus and axillary arteries are just medial to the coracoid process, and injury to these structures is not uncommon. It can occur even in undisplaced fractures (Smyth 1989).
Examination of the chest should not be ignored, since complications involving the thoracic cavity have been reported after fractures of the proximal humerus (Patel et al. 1983). Although rare, they do occur, and several authors have reported intrathoracic penetration by the humeral head associated with fractures (Hardcastle and Fisher 1981). Also, a pneumothorax may occur, especially in patients who have multiple trauma.

1.1.4. Radiographic Findings

The trauma series remains the best initial method for diagnosing proximal humeral fractures (Neer 1970). This consists of anteroposterior and lateral radiographs in the scapular plane and an axillary view (Fig.1). This series allows evaluation of the fracture in three separate perpendicular planes, so that accurate assessment of fracture displacement can be achieved.

The axillary view allows for evaluation in the axial plane and is essential for evaluating the degree of tuberosity displacement, the glenoid articular surface, and the relationship of the humeral head to the glenoid (whether or not a dislocation is present). CT clearly visualizes the degree of displacement of tuberosity fragments which is valuable when open reduction and internal fixation is planned (Jurik and Albrechtsen 1994). CT is also extremely helpful in evaluating the amount of articular involvement with head-splitting fractures, impression fractures, chronic fracture–dislocations, and glenoid rim fractures (Haapamaki et al. 2004).

1.1.5. Classification of Proximal Humeral Fractures

A workable classification system for fractures of the proximal humerus is necessary for proper management. Neer’s modification of Codman’s classification has almost universal acceptance for its simplicity despite the growing recognition that it does not produce
interobserver reliability. It relies mainly on the number of “displaced” fragments involved in the fracture. The AO classification is also used (Edelson et al. 2004).

Figure 1: Trauma series in proximal humeral fractures (Flatow 2001, p.1002)

A) Anteroposterior X-ray in the scapular plane.
B) Lateral X-ray in the scapular plane.
C) Velpeau axillary view (preferred after trauma).

Edelson et al (2004) made a new classification for proximal humeral fractures based on Neer’s classification but using 3-D reconstruction CT. This increases the understanding of the fracture pattern, and also increases the interobserver reliability.

Other authors suggested a specially designed questionnaire to be filled with specific questions regarding the fracture fragments as seen in the radiographs. They concluded that this leads to better understanding of the fracture, and decreases the interobserver errors (Shrader et al. 2005).

1.1.6. Treatment Options for Proximal Humeral Fractures

Many methods of treatment of proximal humeral fractures have been proposed through the years. Minimally displaced fractures are generally known to have low morbidity and high patient satisfaction after conservative treatment (Rasmussen et al. 1992). Fortunately,
most proximal humeral fractures are minimally displaced and can, therefore, be treated satisfactorily with a sling and early range-of-motion exercises (Keser et al. 2004).

The controversy exists when the fractures are significantly displaced. Precise x-rays and a reproducible classification system are essential to achieve consistent treatment of displaced fractures. Many options exist for the treatment of displaced fractures of the proximal humerus.

1.1.6.1. Closed Reduction

It is important to differentiate between which fractures are suitable for this technique and which are not. Repeated and forcible attempts at closed reduction may complicate a fracture and even lead to neurovascular injury. Two-part surgical neck fractures are most amenable to this form of treatment, whereas three-part fractures are usually too unstable to be treated by closed reduction alone (Wiedemann and Schweiberer 1992).

1.1.6.2. Percutaneous Pins and External Fixation

Percutaneous pinning may be used after a closed reduction if the reduction is unstable. It is particularly useful in the treatment of unimpacted two-part fractures of the surgical neck, but can be used with limitation in more complex fractures as well. Multiplanar fixation and increasing the number of cortices purchased increases the stability of the fixation (Naidu et al. 1997).

1.1.6.3. Open Reduction and Internal Fixation

Various techniques and devices have been proposed for the treatment of proximal humeral fractures. The choice depends on several factors including the type of the fracture, quality of the bone and soft tissue, and age and reliability of the patient. Open reduction and internal fixation is commonly recommended for displaced three-part fractures (Weinstein et al. 2006). It is also used in some displaced two-part fractures, and can also be used in four-part fractures in young age. The goal of open reduction and
internal fixation is to stabilize the fracture to promote healing while allowing early shoulder mobilization to reduce the risk of stiffness (Weinstein et al. 2006).

1.1.6.4. Prosthetic Replacement

Primary hemiarthroplasty is sometimes used for the treatment of proximal humeral fractures (Robinson et al. 2003). It is usually recommended for four-part fractures especially in the elderly, and in head-splitting fractures (Helmy and Hintermann 2006). Four-part fractures in patients under 40 years of age, and where the head retains its continuity with the glenoid, may be treated by open reduction and internal fixation despite the risk of developing avascular necrosis (Wijgman et al. 2002).

1.1.7. Complications of Proximal Humeral Fractures

Displaced fractures of the proximal humerus are difficult to manage, and numerous complications have been reported after both closed and open treatment. Some of these include avascular necrosis, nonunion, malunion, hardware failure, frozen shoulder, infection, neurovascular injury, and pneumothorax or hemopneumothorax.

1.1.7.1. Avascular Necrosis

Avascular necrosis is not uncommon after three and four-part fractures and has also been reported after some two-part fractures. It is associated with disability (Gerber et al. 1998). Besides the severity of the fracture, extensive dissection of soft tissue has been identified as a major contributing factor (Sturzenegger et al. 1982).

1.1.7.2. Brachial Plexus Injury

Brachial plexus injuries also occur after fractures of the proximal humerus. Some authors reported an incidence as high as 6.1% after fractures of the proximal humerus (Stableforth 1984). Any or all components of the brachial plexus may be involved. Isolated injury to the axillary nerve is not uncommon and has been reported.
1.1.7.3. Vascular Injury

Vascular complications occurring after proximal humeral fractures are infrequent, but they do occur and can have profound consequences (Smyth 1989). Injury to the axillary artery occurs secondary to fractures of the proximal humerus and is the most common vascular injury seen in these fractures. If an arterial injury is not recognized, the results can be catastrophic (Hayes and Van Winkel 1983). Angiography should be performed to confirm the diagnosis and to establish the exact location and nature of the injury. Arterial repair should be performed without delay and, if necessary, coordinated with appropriate orthopaedic fracture repair.

1.1.7.4. Frozen Shoulder

A frozen shoulder may result if there is inadequate rehabilitation after a fracture or operative repair. It is essential to have a well-organized and monitored physiotherapy program (Beaufils et al. 1999).

1.1.7.5. Chest Injury

Injury to the thorax can also occur after fractures of the proximal humerus. There have been several reports of intrathoracic dislocation of the humeral head with surgical neck fractures of the humerus (Patel et al. 1983). In addition, a pneumothorax or a hemopneumothorax can occur after fractures of the proximal humerus.

1.1.7.6. Myositis Ossificans

Myositis ossificans, especially after fracture-dislocations, has been reported. It is unusual for this to occur with uncomplicated fractures (Flatow 2001).

1.1.7.7. Malunion

Malunion occurs after an inadequate closed reduction or a failed open reduction and internal fixation. This problem is especially difficult to treat because there is excessive scar tissue with retraction of the tuberosities, displacement of the shaft, or both. In
addition, neurologic and soft-tissue deficits may compromise surgical repair. Greater tuberosity malunions lead to impingement against the acromion if the fragment is superiorly displaced (Platzer et al. 2005), or abutment against the glenoid if there is posterior retraction.

1.1.7.8. Non-union
Non-unions of the proximal humerus are not very common and are usually associated with displaced fractures, but they can also occur after minimally displaced fractures (Bigliani et al. 2000). Unfortunately, treatment may be difficult because they often occur in older, debilitated patients with soft, osteoporotic bone. Also, loss of bone stock can occur.

1.1.8. Rehabilitation After Proximal Humeral Fractures
Rehabilitation of proximal humeral fractures is essential because adequate motion is needed for optimum function. If a fracture or fracture repair is stable, then therapy should be started early. The most useful protocol is the three-phase system. This starts by passive-assistive exercises to proceed to active and active-resistive exercises and finally a maintenance program with stretching exercises is done (Bigliani et al. 2000).

1.2. Anatomy and Biomechanics of the Shoulder
It is important to understand the complex anatomy of the shoulder, since optimum function of the glenohumeral joint is dependent on proper alignment and interaction of its anatomical structures. The shoulder complex has the greatest mobility of all joints of the body. On one hand, this mobility is because of little bony congruity of its articulating surfaces. The joints of the shoulder complex have to rely on adjacent ligaments, and muscles to provide stability. On the other hand, the shoulder complex is composed of the
scapulothoracic articulation, and the glenohumeral joint to share the overall motion, and increase its range (Halder et al. 2000).

The division of motion over these three articulations has two advantages: First, it allows the muscles crossing each of these articulations to operate in the optimal portion of their length–tension curve. Second, the glenohumeral rhythm allows the glenoid to be brought underneath the humerus to bear some of the weight of the upper limb, which decreases the demand on the shoulder muscles to suspend the arm (Morrey and An 2000).

1.2.1. Glenohumeral Joint

The glenohumeral joint is a synovial joint of the ball and socket variety. There is a 4 to 1 disproportion between the large round head of the humerus, and the small shallow glenoid cavity (Jobe 2000).

The articular surface of the humeral head has an ovoid shape facing medially, superiorly, and posteriorly. The humeral head is inclined about 130 degrees relative to the shaft with 30 degrees of retroversion relative to the condyles of the elbow. In contrast to the glenoid, the central portion of its hyaline cartilage is the thickest (Lannotti et al. 1992). The midsuperior and anterosuperior portions of the articular surface of the humeral head are flatter than the central portion (Wataru et al. 2005).

1.2.2. Anatomy of the Proximal Humerus

The proximal humerus consists of the humeral head, lesser tuberosity, greater tuberosity, bicipital groove, and proximal humeral shaft. It is important to differentiate between the anatomical neck, which is at the junction of the head and the tuberosities, and the surgical neck, which is below the greater and lesser tuberosities. The boundaries of the latter are somewhat variable without a distinct line.
Anatomical neck fractures are rare and have a poor prognosis, since the blood supply to the head is completely disrupted. On the other hand, surgical neck fractures are common and the blood supply to the head is preserved. The lesser tuberosity, the area of attachment for the subscapularis muscle, lies on the anterior aspect of the humerus and is smaller than the greater tuberosity. The bicipital groove lies between the greater and lesser tuberosities and is on the anterior aspect of the proximal humerus. There are considerable variations in both the height and depth of the groove (Jobe 2000). The biceps tendon lies in the bicipital groove and is covered by the transverse humeral ligament. The greater tuberosity lies posteriorly and superiorly on the humeral shaft and provides an attachment site for the supraspinatus, infraspinatus, and teres minor muscles. The greater tuberosity does not protrude above the humeral head.

1.2.3. Vascular Supply of the Proximal Humerus

The blood supply to the proximal humerus and its disruption in various injury patterns are keys to predicting continued viability of the humeral head. The anterior humeral circumflex artery is the major arterial contributor to the humeral head. This vessel becomes interosseous as the arcuate artery, perfusing the entire humeral head (Rees et al. 1998). The arcuate artery runs towards the sulcus intertubercularis running laterally along the biceps tendon to the cranial end and penetrating into the major tubercle. The posterior humeral circumflex artery supplies a small portion of the posteroinferior part of the articular surface. On its dorsal course around the surgical neck, distinctive branches were regularly found attached to the bone stretching proximally. Vessels entering the head through the rotator cuff insertions also are significant (Andary and Peterson 2002).
The tubercles receive multiple inflows from both circumflex arteries. The tendons and muscles attached to the tubercles protect this vascular supply so that even in cases of disruption of both tubercles, there is always sufficient fragment perfusion.

The lateral side of the greater tubercle is free of subperiosteal vessels which provides important information as the plates are usually placed there. The vascular group of the humeral head lies out of the range of the fixation bed and can be protected by appropriate operative technique (Meyer et al. 2005).

In a cadaveric perfusion study, the importance of the posteromedial vessels in perfusion of the humeral head after 4 part fractures of the proximal humerus was emphasized (Brooks et al. 1993). These vessels pass beneath the humeral capsular attachment, which at this point extends for 1 cm on to the surgical neck, and run towards the humeral head before entering the bone just below the articular margin. After a four-part fracture when the blood supply from the anterior circumflex humeral artery, the greater tuberosity, the lesser tuberosity and any metaphyseal arterial anastomoses have all been lost, perfusion of the humeral head via the arcuate artery may continue if the head fragment includes part of the medial aspect of the upper part of the neck.

1.2.4. Nerve Supply

Injury to the nerves about the shoulder can occur with fractures. The brachial plexus can be injured with anterior fracture-dislocations and violent trauma to the proximal humerus. Isolated injuries to the major nerves innervating the muscles around the shoulder; the axillary, suprascapular, and musculocutaneous can also occur.

1.2.4.1. The Axillary Nerve

The most commonly injured nerve is the axillary nerve. The axillary nerve is composed of fibers from the fifth and sixth cervical roots, in most cases, and takes its origin from the
posterior cord at the level of the axilla. Then it crosses the anterior surface of the subscapularis muscle and dips back posteriorly under its inferior border. It passes along the inferior border of the capsule of the glenohumeral joint and then through the quadrangular space. It then passes just below the capsule of the shoulder joint, with the posterior circumflex humeral vessels below it, and emerges at the back of the axilla below the teres minor. Having given a branch to the shoulder joint, it divides into anterior, and posterior branches (Sinnatamby 1999).

The posterior branch of the axillary nerve has an intimate relation with the inferior aspect of the glenoid and shoulder joint capsule. It lies medial to the anterior branch of the axillary nerve in the quadrilateral space, at an average of only 1 mm lateral to the glenoid rim. The posterior branch courses medially and posteriorly along the glenoid rim. It has a trunk averaging 10 mm in length. No articular branches arise from it so it is easily elevated from the underlying capsule (Ball et al. 2003).

The nerve to the teres minor and the superior–lateral brachial cutaneous nerve arise from the posterior branch of the axillary nerve at the lateral edge of the long head of triceps origin. At this site, the nerves lay directly on the joint capsule at the level of the glenoid rim.

The branch to the posterior aspect of the deltoid from the posterior branch of the axillary nerve enters the muscle at an average of 50 mm directly inferior to the posterolateral corner of the acromion (Burkhead et al. 1992). The literature shows a great variance at the level of crossing of the nerve below the acromion ranging from 3.1 cm to 7 cm (Bono et al. 2000). There is always an additional branch from the anterior branch of the axillary nerve to the posterior aspect of the deltoid (Ball et al. 2003). After emerging from the quadrangular space, it gives off a branch to the teres minor and divides into anterior and posterior branches. The posterior branch supplies the posterior deltoid and
1.2.5. Distribution of Bone Density in the Proximal Humerus

Using peripheral qualitative computed tomography, the distribution of bone density in the proximal humerus was carefully analyzed (Tingart et al. 2003). This is important as loosening of implants is a serious complication following surgical treatment of proximal humeral fractures. Trabecular and cortical bone mineral density (BMD) are higher in the proximal half of the humeral head than in the distal half. Trabecular BMD is highest in the proximal and, especially, the proximal-posterior part of the articular surface region.

1.2.6. Rotator Cuff and Muscles

The rotator cuff consists of four muscles: the subscapularis, supraspinatus, infraspinatus, and teres minor. The long head of the biceps tendon is another important component of this complex. Since the rotator cuff muscles are attached to the tuberosities, it is important to understand the direction of pull of their fibers, because this will facilitate an understanding of displacement of the tuberosity fragments (Flatow 2001).

1.2.7. Forces Across the Glenohumeral Joint

Understanding the forces across the glenohumeral joint requires an understanding of the role of the muscles crossing this joint, the calculation of glenohumeral forces, and finally the maximum strength characteristics for each motion function.
1.2.7.1. Muscle Function and Force transmission

The muscle function and force transmission depends on the muscle size, orientation and activity.

Because of the great amount of motion present in the shoulder joint, and because the line of action frequently crosses close to the axis of rotation, some muscles change their function depending on the position of the joint.

Overall, during elevation, anterior deltoid, middle deltoid, and supraspinatus have the largest agonist moment arm. Conversely, teres major, latissimus dorsi, and pectoralis major have the greatest antagonist or depressor moment arms. The infraspinatus, subscapularis, and posterior deltoid have biphasic function; acting as either an elevator or a depressor according to the joint position (Sinnatamby 1999).

1.2.7.2. Gelnohumeral Forces

Forces at the glenohumeral joint during arm elevation have been studied by several investigators (Morrey and An 2000). The forces in abduction can be analyzed considering the deltoid muscle force as a compressive joint force, and a resultant rotator cuff force acting parallel to the lateral border of the scapula. A maximum compressive force of 10 times and a deltoid muscle force of eight times the weight of the extremity at 90 degrees of arm abduction were formed. This is about one-half the body weight. In addition, a maximum resultant rotator cuff force was calculated of nine times the weight of the extremity at 60 degrees of abduction.

1.2.7.3. Maximum Torque

Generally speaking, the greatest strength function is exhibited in adduction, followed by extension, flexion, abduction, internal rotation, and external rotation. Torque in each direction is greatest with the arm by the side, and decreases with the increase of abduction (Morrey and An 2000).
1.3. Aim of the Work: Questions Needing to be Answered

It is known that there is a high complication rate in the management of proximal humeral fractures in elderly osteoporotic patients using conventional osteosynthesis. Loss of fixation is a common problem, and the generous approach needed for implantation of the plate may lead to increased risk of avascular necrosis.

The concept of using locked plates may show superior anchorage of these plates to bones with subsequent less risk of failure of fixation. Using of a new locking concept with adding small locking screws to the screw heads, allows insertion of the locked screws in a polyaxial manner which may lead to a biomechanical advantage in the fixation of such fractures. Furthermore, the advantage of being able to insert such plates in a minimally invasive surgical (MIS) technique will lead to less wound complications and less devascularization of the bony fragments.

In this study, we evaluated the biomechanical characters of the NCB-PH (non contact bridging for proximal humerus) plate, and its minimally invasive technique of application. Our aim was to answer the following questions:

1- Is there a biomechanical advantage of using this new locking technique compared to using non-locked screws?.

2- If there is a biomechanical advantage for this technique, does it offer more stability against translational or rotational motion mainly compared to non-locked screws?.

3- Is the MIS technique described for insertion of this plate a safe approach regarding the risk of injuring the axillary nerve, and what are the guidelines that should be followed when using it?.
2. Material and Methods

This study is designed to test the biomechanical properties of the NCB-PH plate in the fixation of proximal humeral fractures and assess its MIS technique of application. It is divided into two parts. The first part is concerned with the biomechanical testing of the NCB-PH plate on a proximal humerus fracture model using fresh-frozen osteoporotic cadaveric bone. The goal is to compare the biomechanical characters of the plate when used in locked versus non-locked modus and then subjected to cyclic axial loading. The second part of this study is an anatomic study assessing the minimally invasive technique of application of the plate, and its safety regarding injury of the axillary nerve.

2.1. Materials

2.1.1. Plastic Bone Models

Before proceeding with the cadaveric bones, 10 plastic humeral bones were used to plan the osteotomy, and to do the first set of biomechanical testing. The idea was to practice the osteotomy to be uniform in all bones included in our study. The osteotomy was done using an oscillating saw to create a three part fracture (AO-type 11-B1).

2.1.2. Cadaveric Humeri

After completion of the experiment on the plastic bones, the study was conducted in the same steps on the 8 pairs of fresh-frozen osteoporotic cadaveric bones (Southeast Tissue Alliance Inc, Florida). 5 pairs came from women and 3 pairs from men, all of Caucasian
race. The age of the cadaveric bones ranged between 64-84 years with an average age of 77 years.

2.1.3. Fresh-frozen Cadavers
For conducting the anatomic study, 5 fresh-frozen human cadavers were used. The 5 cadavers were for females with a mean age of 85.6 years (range 78-92 years). They all showed no scars indicating any kind of injury or previous operation in the shoulder or upper arm region that may affect the local anatomy or cause fibrosis which might interfere with the dissection of the axillary nerve.

2.1.4. Plates and Screws
For the biomechanical experiments, the 8-holes NCB-PH plate (Zimmer, Switzerland) was used. 8 plates were applied in the locked mode and 8 plates in the non-locked mode. Non cannulated screws were used.

For the anatomic study, the 7-holes NCB-PH plate was used as well as the 8-holes plate. Again, non cannulated screws were used.

2.1.5. Machine Testing and Motion Analysis
All mechanical tests were conducted using a materials testing machine (Model Zwick/Z010). The bone was axially loaded against the loading cell (A.S.T. GmbH Dresden/BTC-LC 2.5K) placed at the base of the machine. A polyethylene socket was added to the loading cell to accommodate the humeral head during loading, and special floor allowing rolling motion was used to abolish any bending moments and to allow only axial loading and shearing forces as designed in our study.
A 3-D motion analysis system (Zebris 3-D motion analyzer) using ultrasound waves was used to analyze the motion of the head in relation to the shaft during the axial loading. It allows analysis of both translation and rotation in 3 planes of motion.

2.2. Methods

The design of the study is to compare the biomechanical characters of the NCB-PH plate when used in the fixation of a 3 part proximal humeral fracture in osteoporotic bone(Fig. 2 a). The biomechanical testing was done in 20 degrees of abduction and axial loading was applied. 20 degrees of abduction were chosen as this simulates the forces acting on the shoulder during early abduction, and to convert the axial loading forces into shearing forces as well (Fig. 2b).

Figure 2 a&b: 3 part fracture and loading in abduction.
2.2.1. Preparation and Testing of Plastic Bone Models

Before proceeding with the cadaveric bones, 10 plastic humeral bones were used to plan the osteotomy, and to do the first set of biomechanical testing. The idea was to practice the osteotomy to be uniform in all bones included in our study. The osteotomy was done using an oscillating saw to create a three part fracture (AO-type 11-B1) (Fig. 3). The first osteotomy line was across the surgical neck, and the second separating the greater tuberosity starting distally at the lateral aspect of the bicipital groove. Impaction of the head fragment was not done in the plastic bones, but was done in all cadaveric specimens. The fragments were anatomically reduced and fixed with the NCB-PH plate. The bones subjected to the early biomechanical testing trials were cut to standard length (19 cm), potted in cement, and then subjected to axial loading in 20° of abduction. The depth of the used pot was 4 cm so that a standard length of bone of 15 cm to the tip of the head was used in every case. A preliminary experiment using the plastic bones while being loaded from 2 till 60 N for 100 cycles was done to properly adjust our motion analyzer system before the start of using of the cadaveric bones.

2.2.2. Preparation of Cadaveric Humeri

After completion of the experiment on the plastic bones, the study was conducted in the same steps on the 8 pairs of fresh-frozen osteoporotic cadaveric bones. The specimens were kept frozen at -21°C until the day before the preparation, at which point they were thawed over night at 4°C before osteotomy and plate application, and were mechanically tested on the same day when possible. In some occasions, they were frozen again to be tested on a different day after being thawed over night at 4°C. A pair was always handled in the same way and under the same circumstances. CT scans were done for the specimens
to measure the bone density and prove the presence of osteoporosis in all our specimens before proceeding to the osteotomy and fixation. All remaining soft tissues were stripped.

Osteotomy of the bones was done after being cut to a fixed length (19 cm from the tip of the humeral head). The osteotomy was done as planned on the plastic bones to simulate an 11-B1 fracture according to the AO/ASIF classification. An oscillating saw (Aesculap) was used to create the osteotomy. In order to simulate the bone loss or comminution often associated with these injuries, the cancellous bone of the head was manually impacted using an impactor in an inferior-to-superior direction. The vertical length of the humeral head was measured, and one-third of that distance marked off on the impaction instrument so as not to over-impact or under-impact the cancellous bone. No cortical bone was removed. Both specimens in each pair were cut in succession to keep the osteotomy lines, and hence the size of the fragments, as similar as possible.

![Figure 3: Osteotomy and fixation of the plastic bones.](image)

As planned, the bones were reduced anatomically and fixed with the 8 holes NCB-PH plate using non-cannulated screws engaging both cortices in the shaft, and reaching to 1 cm of the articular surface in the head. The most proximal part of the greater tuberosity was osteotomized in all bones and removed not to impinge on the polyethylene socket as the bone is loaded in 20 degrees of abduction and to allow the head to rest in the socket and the force to be applied on it (Fig. 4).
One humerus of each pair was reconstructed with the plate in a locked mode, and the other with the plate in the non-locked mode (the locking screws were added in one humerus, and not used in the other). The humerus used for reconstruction with the locked mode was alternated randomly between right and left to control for side to side difference between dominant and non-dominant upper limbs. After reconstruction, radiographs of each humerus were obtained to verify proper screw positioning (Fig. 5). The pair of bone were then tested under cyclic axial loading using the material testing machine consecutively.

Figure 4: Osteotomy and fixation of cadaveric humeri.

2.2.3. Biomechanical Testing of Cadaveric Bones

The bones were fixed to the special metal pot using bone cement. The bones were fixed exactly perpendicular to the floor of the standard pot with 4 cm depth. Before proceeding with the loading, the special sensors and metal beads of the motion analysis system using ultrasound waves (Zebris 3D motion analyzer) were attached to the bone. 3 metal beads have to be fixed to the shaft after drilling to form the coordinate line of measurement and to define the 3 axes of motion. They are implanted using a special applicator to adjust their relative positions. A screw is then adjusted to the shaft with the triplet which emits the
ultrasound waves (Triplet 1) attached to it. Another screw is attached to the head with another triplet attached to it which receives the ultrasound waves (Triplet 2) (Fig. 6). We decided to consider this screw point of the head as our “moving point”. It was a fixed point in the head for all our specimens (2 cm. proximal to the surgical neck osteotomy line, and 1 cm medial to the greater tuberosity osteotomy line). With loading, the system can measure both the translation and the rotation of this moving point in relation to the shaft in 3 planes of motion which are X (sagittal plane), Y (coronal plane) and Z (vertical plane). We decided to have the readings at a frequency of 20 Hz to have numerous readings with a high possibility of getting a reading at the maximum force reached in each loading cycle. Before proceeding with any measurements, our 3 metal beads inserted in the shaft have to be defined to the system using a special probe to which triplet 1 gets attached and then it points to each bead consecutively. Lastly, the probe with the Triplet attached defines the moving point to the system, and then the system is ready for the start of measuring.

Figure 5: X-ray of the specimens before the biomechanical testing.
All mechanical tests were conducted using a materials testing machine (Model Zwick/Z010). The pot with the bone was fixed to its place in the machine which was adjusted to 20 degrees of abduction. Then, the bone was axially loaded against the loading cell placed at the base of the machine. A polyethylene socket was added to the loading cell to accommodate the humeral head during loading, and special floor allowing rolling motion was used (Fig. 12) to abolish any bending moments and to allow only axial loading and shearing forces as designed in our study. Before the start of loading, a “base line” reading by the Zebris system was taken in all planes then loading was started. 100 cycles of loading at a speed of 50mm/min and with a force alternating between 2 and 120 N was used while any translation or rotation of the moving point on the head in relation to the shaft was being recorded using the Zebris 3-D motion analyzer system at a frequency of 20 Hz.

2.2.4. Statistical Analysis

The biomechanical properties of the NCB-PH plate when used in the locked versus the non locked mode was compared within each pair of implants in our series. The mode of locking was randomly assigned within each pair with regard to the side of implantation. For each type of locking mode, the maximum motion measured during the cyclic loading was recorded for each of the 3 planes for translation, and 3 planes of rotation. For each mode of locking, the maximum motion in all tested 8 bones was recorded and then medians and quartiles were calculated. The Wilcoxon signed rank test for non parametric data was used to assess the statistical significance in the differences between the measurements of the plate in the locked versus the non locked modes. p values less than or equal to 0.05 were regarded as indicators of statistical significance.

The JMP statistical software was used for the numerical analysis.
Figure 6: Preparing the bone for measurement by the Zebris system

a) Fixation of the bone into the pot by bone cement.

b) Drilling the holes for implanting the beads needed for the zebras system to define the motion planes.

c) Application of the special metal plates to which the sensors of the Zebris system will be attached.

Figure 7: The Zwick machine with the loading cell (and polyethylene socket), the rolling floor, and the sensors of the Zebris system.
2.2.5. The Anatomical Study

In this study, NCB-PH plates were applied using the minimally invasive technique to the proximal humerus in fresh-frozen human cadavers, and then the axillary nerve was dissected to see its relation to the plate and the possibility of its injury using this technique. Ten plates were applied to the 10 humeri of 5 fresh non-fixed cadavers.

For each of the 10 limbs involved, the 7 holes NCB-PH plate was inserted in a standardized minimally invasive technique. A 4 cm incision was made on the lateral aspect of the shoulder starting 1 cm above the lateral border of the acromion. Sharp knife cutting down to the bone through the deltidoid was done. A blunt periosteal elevator was then used to elevate the deltidoid down along the shaft of the humerus to facilitate the sliding of the plate down strictly on the bone. The plate (attached to its handle) was then tucked down along the shaft of the humerus from the proximal incision. A threaded guide wire was used to secure it to the head so that the upper edge of the plate is approximately 1 cm below the upper edge of the greater tuberosity. The targeting device for the distal screws was then attached. The screws were then inserted using the targeting device; non-cannulated screws were used. For all the distal screws (numbers 4-7) fixed steps were done. The point of incision was marked by the print of the sleeves on the skin, then a 1 cm incision of the skin was done at that point. Scissor dissection in a transverse manner (to be parallel to the axillary nerve) was done till the plate was felt. The sleeve was advanced to the plate, screwed to it, and then a normal drill guide and non-cannulated screws were used. Before proceeding to screw insertion, a second guide wire was used to fix the plate through hole number 5 (after applying the sleeve and trokar) and then the stab incisions of the other screws were done after securing the plate to the bone. For screws 1 to 3, they could always be inserted through the proximal incision (Fig. 8). Screw 3 insertion was sometimes omitted as it is too proximal to jeopardize the axillary nerve.
After insertion of the plate and application of the screws, the cadaver was turned to the lateral side to facilitate dissection of the axillary nerve. A longitudinal incision along the shaft of the humerus combining the proximal incision to all the screw stab incisions was done and extended posteriorly along the spine of the scapula for about 10 cm. Sharp undermining was then done to separate the deltoid muscle from the subcutaneous tissues and skin. The deltoid muscle was then sharply cut from the whole length of its attachment to the spine of the scapula. Dissection continued along the posterior border of the deltoid almost down to its humeral insertion, and the muscle was turned as a flap exposing the quadrangular space below it. The axillary nerve was identified as it crosses the space and followed to determine its exact relation to the plate, and whether or not it has been injured. The nerve was carefully dissected, and it was noticed to bifurcate as it lies directly over the plate, or anterior to this point. The nerve was carefully examined to see if any injury has occurred (Fig. 9).
Figure 9: Dissection of the axillary nerve showing its close proximity to the plate.
3. Results

The results of this study will include both the biomechanical and anatomical studies’ results.

3.1. Age and Sex of Cadaveric Bones

The age of the 8 pairs of cadaveric humeri involved in the biomechanical study ranged between 64-84 years with an average of 77 years. 5 pairs came from women while 3 pairs came from men (Table 1).

Table 1: Age, sex, and race of the cadaveric humeri involved in the biomechanical study

<table>
<thead>
<tr>
<th>Sample</th>
<th>Age</th>
<th>Sex</th>
<th>Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>84</td>
<td>F</td>
<td>Caucasian</td>
</tr>
<tr>
<td>2</td>
<td>80</td>
<td>F</td>
<td>Caucasian</td>
</tr>
<tr>
<td>3</td>
<td>69</td>
<td>M</td>
<td>Caucasian</td>
</tr>
<tr>
<td>4</td>
<td>75</td>
<td>F</td>
<td>Caucasian</td>
</tr>
<tr>
<td>5</td>
<td>84</td>
<td>M</td>
<td>Caucasian</td>
</tr>
<tr>
<td>6</td>
<td>80</td>
<td>M</td>
<td>Caucasian</td>
</tr>
<tr>
<td>7</td>
<td>64</td>
<td>F</td>
<td>Caucasian</td>
</tr>
<tr>
<td>8</td>
<td>80</td>
<td>F</td>
<td>Caucasian</td>
</tr>
</tbody>
</table>

Female=female, M= male.

3.2. Results of Translational Motion Analysis During the Cyclic Axial Loading

Interfragmentary translation was measured using the Zebris 3-D motion analyzer in 3 planes of motion along the X (sagittal plane), Y (coronal plane) and Z (vertical plane) axes. The Zebris system has an accuracy of 0.1 mm in measurement and the measurements given are in mm. Interfragmentary motion was measured between the shaft (reference point) and the head (moving point) (table 2).
### 3.2.1. Translational Motion Analysis in the Non-Locked Group

Interfragmentary translational motion was limited with the bone being loaded cyclically to 120 N for 100 cycles. The median for the maximum movement measured during the loading of each of the 8 bones tested in this mode was 0.400 mm along the X axis, 0.65 mm along the Y axis, and 0.45 mm along the Z axis.

### 3.2.2. Translational Motion Analysis in the Locked Group

Interfragmentary translational motion with the bones fixed by the plate in the non locked mode showed a median of 0.30 mm for the maximum motions measured during the testing of each of the 8 bones along the X axis, 0.50 mm along the Y axis, and 0.30 mm along the Z axis.

#### Table 2: Interfragmentary translational motion under axial cyclic loading with the plate used in the locked versus the non locked modes

<table>
<thead>
<tr>
<th></th>
<th>Translation along X axis</th>
<th>Translation along Y axis</th>
<th>Translation along Z axis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>75th quartile</td>
<td>Median</td>
<td>25th quartile</td>
</tr>
<tr>
<td>Locked plate</td>
<td>0.375</td>
<td>0.300</td>
<td>0.300</td>
</tr>
<tr>
<td>Non locked plate</td>
<td>0.750</td>
<td>0.400</td>
<td>0.250</td>
</tr>
</tbody>
</table>

Interfragmentary motion is measured in mm. and for each locking mode, the median, 75th quartile, and 25th quartile of the interfragmentary translational motion for the 8 tested bones is calculated.
3.3. Results of Rotational Motion Analysis During the Cyclic Axial Loading

The Zebris 3-D motion analyzer was also used to assess the rotation of the head in relation to the shaft in 3 planes of motion; X axis (sagittal plane), Y axis (coronal plane) and Z axis (vertical plane). Rotation is measured in degrees and the system has an accuracy of 0.1 degree in measurement (Table 3).

Table 3: Interfragmentary rotational motion under axial cyclic loading with the plate used in the locked versus the non locked modes

<table>
<thead>
<tr>
<th></th>
<th>Rotation along X axis</th>
<th>Rotation along Y axis</th>
<th>Rotation along Z axis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>75th quartile</td>
<td>Median</td>
<td>25th quartile</td>
</tr>
<tr>
<td>Locked plate</td>
<td>0.675</td>
<td>0.350</td>
<td>0.150</td>
</tr>
<tr>
<td>Non locked plate</td>
<td>1.075</td>
<td>0.500</td>
<td>0.325</td>
</tr>
</tbody>
</table>

Interfragmentary motion is measured in degrees and for each locking mode, the median, 75th quartile, and 25th quartile of the interfragmentary rotational motion for the 8 tested bones is calculated.

3.3.1. Rotational Motion Analysis in the Non-Locked Group

The median for the maximum interfragmentary rotation between the head and the shaft detected during the loading of each bone in the 8 tested bones with the plate in the non locked mode was 0.50° along the X axis, 0.45° along the Y axis, and 0.45° along the Z axis.
3.3.2 Rotational Motion Analysis in the Locked Group

The median for the maximum interfragmentary rotation between the head and the shaft detected during the loading of each bone in the 8 tested bones with the plate in the locked mode was 0.35° along the X axis, 0.15° along the Y axis, and 0.20° along the Z axis.

3.4. Comparison Between Biomechanical Properties of the Plate in the Locked Versus the Non-Locked Modes

Interfragmentary motion was less with the plate in the locked mode compared to the non locked mode. This difference was statistically significant along the 3 planes of rotation motion (Table 4).

Table 4: Medians for the interfragmentary motion along the 3 planes of translation and rotation with the plate in the locked versus the non locked modes, and the $p$ value of the difference.

<table>
<thead>
<tr>
<th>Plane of interfragmentary motion</th>
<th>Plate in locked mode</th>
<th>Plate in non locked mode</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median of translation along X axis</td>
<td>0.30</td>
<td>0.40</td>
<td>0.031</td>
</tr>
<tr>
<td>Median of translation along Y axis</td>
<td>0.50</td>
<td>0.65</td>
<td>0.219</td>
</tr>
<tr>
<td>Median of translation along Z axis</td>
<td>0.30</td>
<td>0.45</td>
<td>0.438</td>
</tr>
<tr>
<td>Median of rotation along X axis</td>
<td>0.35</td>
<td>0.50</td>
<td>0.031</td>
</tr>
<tr>
<td>Median of rotation along Y axis</td>
<td>0.15</td>
<td>0.45</td>
<td>0.016</td>
</tr>
<tr>
<td>Median of rotation along Z axis</td>
<td>0.20</td>
<td>0.45</td>
<td>0.031</td>
</tr>
</tbody>
</table>

3.4.1. Comparison Regarding Translational Motion

Although the medians of the interfragmentary motion in the 3 planes of translational motion were less for the plate in the locked mode compared to the non locked mode (Fig.
10), however this difference was statistically significant only along the X (sagittal) axis where it showed a p value < 0.05 ($p$ value = 0.031). The difference was not statistically significant along the Y (coronal) and Z (vertical) axes.

![Figure 10: The medians (in mm.) of interfragmentary translation motion with the plate applied in the locked and non-locked modes along the X (sagittal) axis, Y (coronal) axis, and Z (vertical) axis.](image)

**3.4.2. Comparison Regarding Rotational Motion**

The bones fixed by the plate in the locked mode showed statistically significant less interfragmentary rotational motion ($p$ value < 0.05) along the 3 planes of motion compared to the bones fixed with the plate in the non-locked mode (Fig. 11).

**3.5. Age and Sex of Cadavers included in the Anatomic Study**

This study was conducted on 10 upper extremities of 5 fresh-frozen female cadavers with a mean age of 85.6 years (range 78 to 92 years).

The axillary nerve was carefully dissected in all limbs after the minimally invasive application of the NCB-PH plate.
3.6. Position of the Axillary Nerve in Relation to the Plate

In all cases the nerve was crossing directly over the plate. In 2 limbs the nerve was almost directly lying on hole number 4 (lower edge), in 2 limbs it was between holes 4 and 5, in 4 limbs it was directly on hole number 5, and in 2 limbs it was between holes 5 and 6. (Table 5, and Fig.12). It is worth mentioning that the turning of the deltoid flap might affect the position of the nerve pulling it to a slightly more distal position than it normally is.

3.7. Bifurcation of the Nerve in Relation to the Plate

The nerve was seen to bifurcate into 2 branches quite anterior to the plate in 8 limbs. It divided into a proximal and a distal branch and each was followed as it goes into the anterior deltoid.

In 2 limbs (one cadaver), this bifurcation was found to occur directly over the plate.
Table 5: Level of crossing of the axillary nerve in relation to the plate.

<table>
<thead>
<tr>
<th>Level of crossing of the axillary nerve</th>
<th>At hole 4</th>
<th>Between holes 4 and 5</th>
<th>At hole 5</th>
<th>Between holes 5 and 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of upper extremities</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

Figure 12: Different positions of the axillary nerve in relation to the plate.

3.8. Integrity of the Axillary Nerve

The axillary nerve was carefully examined for any injury in all 10 limbs. In the 8 limbs where a main trunk crossed the plate (Fig. 13a), and the bifurcation occurred anterior to the plate, no injury was found despite the position of the nerve being directly on the plate.

In the 2 limbs where the bifurcation occurred opposite the plate (Fig. 13b), the nerve divided into a larger proximal division, and a smaller distal division. An injury of the lower (distal) division was noted in one of the limbs. Both divisions were intact in the
other limb. This injury was recorded as a partial injury of the nerve as it affected only the distal division.

![Figure 13 a&b: Division of the axillary nerve in relation to the plate.](image)

Therefore, our results showed 90% intact nerve, 10% partial injury, and 0% complete injury of the axillary nerve using the minimally invasive technique of application of the NCB-PH plate (Fig. 14).

![Figure 14: Incidence of injury to the axillary nerve using the MIS technique for application of the NCB-PH plate.](image)
4. Discussion

Complex fractures of the proximal part of the humerus are an extremely challenging problem because of the need to achieve sufficient stability to allow postoperative range of motion in the presence of fracture comminution and poor bone quality (Kwon et al. 2002). Failure of fixation is a frequent problem especially in osteoporotic bone (Esser 1994). Patients with good bone quality tend to have a favorable outcome when treated with the conventional plate osteosynthesis (Wijgman et al. 2002). However, this method has been associated with a high complication rate particularly in the elderly patients with comminuted fractures (Cofield 1988).

4.1. Evaluation of Different Fixation Techniques for Proximal Humeral Fractures

The goal of treatment for proximal humerus fractures is restoration of a painless shoulder with satisfactory function. This requires an understanding of the injury including the patient’s age, expectations, medical condition, bone quality, and knowledge of the available fixation techniques and their limitations (Koukakis et al. 2006).

For the past decade there has been a trend toward techniques requiring limited exposure and minimal internal fixation. Although these techniques may minimize the risk of osteonecrosis, the low postoperative stability may compromise the rehabilitation (Helmy and Hintermann 2006).

Metaphyseal bone plays no significant role in the holding power of cancellous screws (Harnroongroj and Techataweewan 1999), and only a well-inserted cancellous screw into bone cortices can achieve good screw holding power at metaphysis of a long bone. This knowledge should always be kept in mind while deciding on the management of proximal humerus fractures.
4.1.1. Different Techniques for Fixation of the Proximal Humerus

Many techniques have been described for the fixation of proximal humerus fractures and they include bone sutures, tension band, cerclage wires, K-wires, Schanz screws, intramedullary devices, double tubular plates, semitubular plate, AO T-plate, and prosthetic replacements (Koukakis et al. 2006).

Percutaneous wires allow the surgeon to maintain fracture alignment without resorting to ORIF (Kocialkowski and Wallace 1990). Various pin configurations have been advocated (Jaberg et al. 1992). Multiplanar fixation increases the torsional stability. However, early motion can’t usually be initiated (Naidu et al. 1997).

In a biomechanical cadaveric study, tension band wiring was shown to provide the least effective fixation compared to Schanz screws, Ender nails, and AO T-plate (Koval et al. 1996).

The AO T-plate shows effective and strong fixation in non-osteopenic bone, however their effectiveness diminishes in osteoporotic bone. T-plate fixation for complex fractures currently is widely used for the treatment of complex proximal humeral fractures. Apart from osteonecrosis and impingement, the T-plate is associated with a high rate of screw loosening in the humeral head (Instrum et al. 1998). Four Schanz screws with one pin through the greater tuberosity were shown to provide stronger fixation in osteoporotic bone than the T-plate (Koval et al. 1996).

Use of semitubular plates bent to 90 degrees and used as a blade-plate was shown to offer proper stability (Sehr and Szabo 1988). It was shown to be significantly better fixation than the AO T-plate in another biomechanical study (Instrum et al. 1998). Use of a modified cloverleaf plate has also been recommended (Esser 1994).
Combining the use of Ender nails with a tension band wiring seems to have biomechanical advantages. The nail rests within the intramedullary canal with less dependence on the bone quality of the humeral head, and the proximal tension band is secured to the eyelet of the nail rather than to the bone. However, it has inferior biomechanical properties compared to the AO T-plate (Koval et al. 1996).

As osteoporosis in the elderly negatively influences the rigidity of any type of fixation, the addition of calcium phosphate cement has been proposed by some authors to improve the rigidity of fixation (Kwon 2002).

Conventional locked humeral nails, although preserving the periosteal blood supply and retaining surrounding soft tissue attachments, do not provide reliable stability in the treatment of metaphysial fractures (Bernard et al. 2000). Use of specific nails as the Polarus nail for the treatment of proximal humeral fractures led to improved results (Rajasekhar et al. 2001).

Adapting the implant design according to the specific anatomic and biomechanical needs of proximal humeral fractures, led to the development of shorter nails with alternative and more stable interlocking options. The proximal humeral nail (PHN) is one example of such nails (Hessmann et al. 2005).

4.2. New Trends in the Treatment of Proximal Humeral Fractures

New techniques have been introduced in the treatment of proximal humerus fractures such as the Plan Tan Humerus Fixator Plate, the PHILOS plate and other locked plates. These implants were designed to allow more stable fixation especially in osteoporotic bone and allow early rehabilitation (Koukakis et al. 2006). Also, some of them allow a minimally invasive technique of insertion which avoids the extensive soft tissue dissection needed to place the conventional plate and screw with the associated risks of
delayed union, nonunion, and avascular necrosis of the humeral head. Moreover, limited contact of these new plate designs to the periosteal blood vessels, allows preservation of the blood supply to the humeral head (Ruch et al. 2000).

4.2.1. Plan Tan Humerus Fixator Plate

This device is characterized by the placement of two cancellous screws in the humeral head together with a plate on the humeral shaft (Sadowski et al. 2003). It represents a hybrid fixation combining an internal fixator with a neutralization plate; hence the name fracture fixator-plate (Machani et al. 2006).

The insertion of such plate needs an extensive surgical exposure, and the results are not superior to any other type of fixation used to treat similar injuries. The plate does not provide stable fixation in osteoporotic bone, and the goal of early active rehabilitation is not realistic using it (Machani et al. 2006).

4.3. Locked Plates in Proximal Humeral Fractures

Recently, new implants providing greater angular stability (resistance to bending) have been proposed for operative fracture treatment. Their theoretical advantage is better anchorage of screws in osteoporotic bone as well as their function as a locked internal fixator. Additionally, some can be inserted using a minimally invasive technique without trauma to the soft tissues (Helmy and Hintermann 2006).

4.3.1. Advantage of Locked Plates

A major goal of surgical therapy in proximal humeral fractures is to obtain fracture reduction and stable fixation to allow immediate functional rehabilitation without the need for postoperative immobilization (Hessman et al. 2005). The key to optimal functional recovery in the management of proximal humeral fractures is early range of motion (Ruch et al. 2000).
When addressing implant selection, the morbidity of the procedure, maintenance of integrity of the soft tissues, and preservation of the blood supply to the bony fragments must be taken into consideration (Ruch et al. 2000).

Various authors have published results of internal fixation of proximal humeral fractures with conventional osteosynthesis, using a combination of objective and subjective outcomes. Almost uniformly, they report poor results in older patients (Machani et al. 2005).

To prevent screw loosening and possible secondary displacement, new implants with locked head screws have been developed. The plate-screw construct acts mechanically as an internal fixator or a splint and shows superior anchorage, particularly in osteoporotic bone, compared with conventional plates (Helmy and Hintermann 2006). Although the concept of fixed-angel internal fixation of shoulder fractures had already been described since 1949, a growing interest in these implants did not develop until recently (Hessmann et al. 2005).

In fixed-angle plates with locking head screws, all forces are transmitted from the bone to the screws, from the screws to the plate, and vice versa from the fracture back to the screws. This principle enables a good purchase of the plate-screw construct, especially in osteoporotic bone and reduces the chance of angulation of the construct. In conventional plate-screw constructs, stability depends on the friction between the plate and the bone. Good screw anchorage is important for stable fixation. However, it is often impossible to achieve in osteoporotic bone (Helmy and Hintermann 2006).

Bearing in mind the encouraging results achieved with internal fixators in the management of metaphyseal fractures of the tibia and femur, it was suggested that these implants would be superior to non-locked plates in maintaining the reduction in shoulder fractures (Hessmann et al. 2005). The special design of these plates with threaded screw
holes that are designed to lock the screws to the plate, eliminates motion of the screw heads with respect to the plate (Weinstein et al. 2006).

The locking plate provides improved torsional stability compared to conventional plates which allows for earlier motion after reconstruction and improves the outcome in elderly and osteoporotic patients (Weinstein et al. 2006).

4.3.2. The PHILOS Plate

This is an internal locked plate system developed by the AO/ASIF group. It provides excellent fixation to the humeral head even in osteoporotic bone. The main challenge, however, is achieving an anatomical reduction of the fracture. The plate is applied via a standard open approach (Koukakis et al. 2005). It is biological in the sense that the blood supply to the humeral head is not compromised, and the plate does not need to be contoured (Bjoerkenheim et al. 2004).

4.3.3. Other Locked Plate Systems

In order to minimize the dissection with the subsequent increased rates of avascular necrosis associated with standard open plate application, new designs of locked plates that allow percutaneous minimally invasive application are being developed (Chudik et al. 2003).

4.3.4. NCB-PH Plate

A new angular stable device for MIS treatment of proximal humeral fractures is the NCB-PH plate (Zimmer Company, Winterthur, Switzerland). The plate is inserted via high antero-lateral deltid splinting approach with the help of an aiming device. It also allows the advantage of using the plate itself to achieve indirect fracture reduction.

NCB-PH (Non-Contact Bridging for the Proximal Humerus) plate is a recent solution for the treatment of complex fractures at the proximal humerus. The system allows for polyaxial screw placement (30 degrees) with subsequent screw locking for improved
stability especially within osteopenic bone. Before locking, the screws can act as lag
screws and can also be used for fracture reduction, a benefit which is not offered with
standard locking systems.

The targeting device ensures divergent screw alignment for increased pull-out resistance
in the metaphysial and disphysial regions. In the locked modus, the NCB-PH acts as
internal fixator without contact of the plate to the bone surface reducing the risk of
periosteal blood supply impairment.

The NCB-PH can be applied through an open deltopectoral approach or using minimally
invasive (MIS) techniques using a fully radiolucent targeting device, cannulated and
cortical screws with cannulated instruments. Two cannulated screw types are offered.
Cancellous NCB screws are used preferably for the epiphysis and metaphysis, whereas
cortical NCB screws are used for the diaphysis. Both self-drilling, and self-tapping types
are available.

4.4. MIS Technique for Proximal Humeral Fractures

The deltopectoral approach exposing the anterior and lateral shoulder region has been
most commonly used for open reduction and internal fixation of proximal humeral
fractures. However, using this approach for accessing the lateral aspect of the shoulder
requires extensive soft tissue dissection and retraction as it is an indirect approach for this
region. The resulting disruption of the local blood supply including the periosteum leads to
higher rates of avascular necrosis. Minimally-invasive surgical (MIS) techniques have
been developed to solve the problem of compromising soft tissues (Lill et al. 2004).

Because extensive exposure and insertion of large metal implants increases the risk of
osteonecrosis (Szyszkowitz et al. 1993), limited exposure and dissection of the soft tissues
with a minimal amount of hardware has been recommended. However, greater stability is
required with surgical intervention because of the disruption of the soft tissues and the blood supply crucial for fracture healing (Hintermann et al. 2000).

Unlike other open procedures, percutaneous pinning avoids the extensive soft tissue stripping associated with the insertion of conventional osteosynthesis therefore avoiding much of its complications. However, the lack of primary stability is always a problem (Naidu et al. 1997).

Several authors describe the anatomical course of the axillary nerve as far as 5cm distal to the tip of the acromion. However, literature shows a great variance with a range from 3.1 to 7cm. These data led to the recommendation to perform limited incisions in the lateral deltid splitting approach not extending 5cm distal to the tip of the acromion (Bono et al. 2000).

A well recognized risk in surgical exposure and fixation of proximal humeral fractures is injury of the axillary nerve. According to literature, iatrogenic nerve palsies after plate fixation range from 0% to 5% (Riemer and D’Ambrosia 1992).

The risk of injuring the axillary nerve is also present in MIS techniques. In a cadaver study, 10 9.5mm Synthes® Short Proximal Humeral Nails (Synthes, Paoli, PA, USA) were inserted, in 6 cases the oblique locking screw came into contact with the ascending branch of the axillary nerve (Prince et al. 2004).

4.5. Study Design

There is no clearly defined model for testing the internal fixation of the proximal humerus (Ruch et al. 2000). We chose to use the three-part fracture model as an example of unstable proximal humeral fractures following other authors (Ruch et al. 2000). We impacted the head to one third of its height to simulate a comminution. We did not choose the simple subcapital fracture model as these injuries clinically are often treated
conservatively. Also, we did not choose the gap osteotomy model as we believe that it
does not reflect surgical reality as the surgeon usually restores the contact between the
head and shaft fragments to increase the stability of fixation. We chose to use stripped
cadaveric specimens in an effort to eliminate variables such as the quality, and integrity of
the rotator cuff. This has also been the choice of many other investigators (Ruch et al.
2000).

Many muscle forces act upon the shoulder, which is the most mobile joint in the body,
and we are not aware of any model that reproduces them all (Kwon et al. 2002). However,
cyclic loading is a condition that occurs in daily life, and therefore we chose cyclic axial
loading for our biomechanical testing. Loading with the humeral shaft oriented at 20
degrees produces approximately twice the amount of shear than compression. We chose to
use a “rolling” floor for our loading cell to make sure that we are applying only axial loads
and that no bending loads result.

We believe that 120 N is reasonable for testing upper limb fractures following other
authors (Hessman et al. 2005). For measuring even very small interfragmentary motions,
we decided to use the Zebris 3-D motion analyzer based on the use of ultrasound waves.
The system detects interfragmentary motion as small as 0.1 mm, and interfragmentary
rotation as small as 0.1°. We were careful to mount our sensors in the same position in the
2 bones of each pair to optimize the accuracy of the system.

The strengths of this biomechanical study are its simple design, the consistency of the
“fracture”, and the precise way of measuring the interfragmentary motion using the Zebris
3-D motion analyzer system. Also, the aim was clear and the design of the study helped to
access the aim directly. We also were keen to prove the presence of osteoporosis in all the
bones by doing CT examination before the starting of any preparation.
Regarding the anatomical study, we believe that the use of fresh-frozen cadavers largely simulates the in vivo conditions and is a reliable way to assess the relation of the axillary nerve to the plate.

However, there are many limitations to this study as we realize. Starting with the Osteotomy, the saw-induced osteotomy that was used is an oversimplification of the injury, but we felt that this method was the only way to create fragments that would be equivalent enough to allow for comparison. We did not create any cortical bone loss which contributed to the small amount of interfragmentary motion observed during testing. Also, some bones were quite weak, and the amount of impaction of the head could not be equally made sometimes in the two bones of the same pair.

In addition, the specimens were devoid of the surrounding musculature, which presumably would affect the results because of the additional factors of soft tissue support or potential deforming or destabilizing forces, or both, under normal in vivo conditions. Also, like all in vitro studies, the biological aspects were not addressed.

Lastly, although cyclic loading is a condition that occurs in daily living, the actual loading is far more complex than that used in the testing. The exact mechanism by which proximal humerus fracture fixation fails is not known (Koval et al. 1996). Fixation failure may be secondary to fatigue which can’t be adequately tested in cadaver bone because biologic repair processes can’t be simulated.

In this anatomic study we analyzed the high antero-lateral deltoid split and its application for the MIS technique in using NCB®-PH. The second aspect was the detection of possible injuries to the axillary nerve and its relation to the plate.
4.6. Biomechanical Advantages of Locking in Our Study

Unlike other studies which compared the new implant to a reference conventional implant, we chose to compare the biomechanical properties of the new implant when used in the locked mode versus when used in the non locked mode. We believe that this clearly emphasizes the biomechanical advantages of the locking concept. Also, the figures obtained during the cyclic axial loading can be compared to other literature to compare the implant to others.

We believe that the polyaxial divergent screw distribution in the humeral head offers significant stability so that even in the non locked mode, the amount of interfragmentary translational motion under the axial loading was limited and the plate was shown to offer good stability in osteoporotic bones.

Based on the data collected from our biomechanical testing, we believe that the NCB-PH plate is a reliable implant for fixation of unstable proximal humeral fractures. The distribution of 3 polyaxial screws in the humeral head offers a good strength of fixation. Even in the non-locked mode, the interfragmentary motion under cyclic axial motion was limited and the construct was stable. We believe that the placement of 3 screws in the head in very important in this stability and that placement of the third screw should not be omitted.

Comparing the results of interfragmentary motion with the plate used in the locked mode versus the non locked mode, relevant data were found. There was a significant difference in the translation motion in only the X (sagittal) plane of motion. In the other 2 planes of motion, although the locked mode also showed less interfragmentary motion, yet the difference was not statistically significant. Both modes showed limited interfragmentary motion and satisfactory results. It is our belief that 100 cycles of loading will not show the advantages of the locked plates in this aspect and that a loading to failure test may
demonstrate this advantage. However, there were statistically significant differences in the interfragmentary rotation between both modes. The locked mode showed less interfragmentary motion in all the 3 planes of rotation. This leads us to the conclusion that, in the clinical situation, the locked mode will show less movement of the head into the varus position which is a common complication in these fractures. Showing more rotational stability leads us to the conclusion that the plates in the locked mode will show more fracture stability when torsional loading is applied which will be a matter of further study as rotational failure is another mode of failure of fixation of these fractures in the clinical situation.

Varus collapse is a major cause of failure of fixation of proximal humeral fractures specially in osteoporotic bones. It has been reported to occur in 3.2 to 21% of fractures (Hessman et al. 2005). Furthermore, retroversion was observed to occur in up to 8% of cases. Implants that offer increased stability positively affect the clinical outcome (Hessman et al. 2005). Interfragmentary rotational motion was less in our testing in the group where the plate was used in the locked mode compared to the group where the plate was used in the non locked mode. This difference was statistically significant ($p$ value<0.05) in all the 3 planes of motion. This confirmed superior rotational stability offered by the plate when used in the locked mode supports the conclusion that the use of this locking mode can lead to better clinical outcomes when used in fixation of proximal humeral fractures especially in osteoporotic patients.

4.7. Safety of the MIS Technique

We performed ten MIS procedures in a standardized fashion in 5 fresh-frozen human cadavers. In 90% (n=9) we did not see any injury to the axillary nerve, partial injury was seen in 10% (n=1). In all cases, the nerve crossed directly over the plate between the
fourth and the sixth holes. This leads to the conclusion that the initial insertion of the plate must achieve strict bone contact to avoid covering the nerve with the plate. The latter could lead to structural damage of the nerve when placing the screws.

Most authors recommend not extending the incision more than 5 cm distal to the tip of the acromion in the high antero-lateral deltoid split. Based on our gained experience during the cadaveric application of the plate, in the particular situation of NCB®-PH, we found that it is not necessary to extend it more than 3 cm during application of the plate using the MIS technique. To further minimize the risk of axillary nerve injury, scissor dissection after stab incisions for screw placement should be performed in a transverse manner which is parallel to the axillary nerve’s course.

In our view, the high antero-lateral deltoid split is well suitable for the MIS technique using NCB®-PH. The relationship of the plate to the axillary nerve is quite close. Strictly sticking to the principles for the MIS technique of plate application, we only saw one partial injury in our study. Nevertheless, the limitations of an anatomic cadaver model and individual variances of the anatomic course of the axillary nerve in vivo have to be considered when interpreting these data.

The MIS deltoid-split approach is an effective and relatively safe approach for fixation of proximal humeral fractures using the NCB-PH plate if closed reduction can be achieved. One of the advantages of the NCB-PH plate is that it can be used to achieve closed reduction starting by fixing it distally to the bone and using the plate as a “buttress”. This is very helpful especially in the situation when the shaft is medially displaced in relation to the head. To minimize the risk of injuring the axillary nerve, certain principles have to be followed. The plate has to be inserted in direct contact with the bone, and the deltoid split should not be extended more than 4 cm distal to the tip of the acromion. Using a periosteal elevator to create the path of the plate and allow it to slide directly on
the bone is very helpful. We found a lateral deltid split of 3 cm to be enough for the application of the plate in our cadaveric study. The percutaneous application of the screws has to follow strict guidelines including stab incision of only the skin, and then transverse dissection of the muscle down to the plate before the trokar is screwed to the plate and drilling started. These guidelines must be strictly followed especially when drilling for screw holes number 4, 5, and 6 where the axillary nerve usually crosses in direct contact with the plate.

4.8. Answers and information gained from this work

The use of the NCB-PH plate in the fixation of proximal humeral fractures in the locked mode shows a biomechanical advantage over its use in the non-locked mode. The interfragmentary motion was less when the the proximal humeral fracture was fixed with the plate in the locked mode.

Interfragmentary rotational motion was less in the bones where the fracture was fixed with the plate in the locked mode. This difference was noted in all the 3 planes on rotation and was statistically significant in all of them. On the other hand, although the interfragmentary translational motion was also less in the bones where the fracture was fixed with the plate in the locked mode and along all the 3 planes of translation, yet this difference was statistically significant only along the sagittal plane. This shows the superior biomechanical advantage of locking in offering rotational stability.

The MIS approach recommended for insertion of this plate is a safe approach regarding the risk of injuring the axillary nerve provided that it is done meticulously. The incision should not extend more than 4 cm. distal to the tip of the acromion, and blunt dissection in a horizontal direction should be done for each screw hole till the plate is reached.
5. Summary

Proximal humeral fractures are a common problem especially in the elderly population. Due to the osteoporosis associated with old age, loss of fixation is a problem encountered with the use of conventional plate osteosynthesis. Also, the generous approach needed for implantation of conventional plate osteosynthesis compromises the blood supply of the bony fragments and may lead to avascular necrosis of the humeral head.

The non contact bridging plate for the proximal humerus (NCB-PH plate) has the advantage of being a locked plate when the locking screws are added to its screws after insertion. This new technique of locking allows a polyaxial insertion of the screws which improves the purchase within the humeral head. It can be applied using a minimally invasive (MIS) surgical technique using the handle and targeting device for the screws through a lateral deltoid splitting approach. This helps to minimize the surgical insult and preserve the blood supply to the bony fragments. Furthermore, the buttressing effect of the plate can be used to achieve reduction of the fracture using the MIS technique.

The biomechanical advantage of the locking mode of the NCB-PH was tested by comparing the interfragmentary motion between the head and the shaft in 8 pairs of fresh-frozen human humeri. One bone in each pair was fixed with the plate in the locked mode and the other bone with the plate in the non locked mode after creating a 3-part fracture of the proximal humerus with head comminution which is classified as 11-B1 fracture according to the classification system of the association for the study of internal fixation (A0/ASIF), and then reducing it anatomically and fixing it with the plate.

Biomechanical testing of the NCB-PH under cyclic axial loading showed superior biomechanical characters for the plate when used in the locked versus the non locked modes. The interfragmentary rotational motion between the head and the shaft was less
with the plate in the locked mode in all the 3 planes of motion and the difference was statistically significant. The advantage of locking in providing rotational stability was emphasized by this work. Regarding translational motion, the locked plate still showed less interfragmentary motion in all 3 planes of motion but this difference was statistically significant only along the sagittal plane. We believe that the NCB-PH plate is a suitable implant for fixation of proximal humeral fractures in osteoporotic bones.

To assess the safety of the MIS deltoid-split approach of plate application regarding the axillary nerve, the technique was applied on 10 upper limbs of 5 fresh-frozen human cadavers and then the axillary nerve was dissected to assess its integrity. Rigid rules of application of the plate including not extending the incision more than 4 cm. distal to the tip of the acromion, strict subperiosteal sliding of the plate, and careful blunt dissection in a horizontal direction at the stab wounds opposite the screw holes till reaching the plate to insert the screws were adhered to. In our 10 cases, there was only one case of partial injury to the axillary nerve, and no complete injuries were found. This shows the relative safety of this technique of application of the plate provided that the guidelines of the technique are adhered to.

The NCB-PH plate is a locked plate with polyaxial screws that can be applied in a minimally invasive technique for the fixation of proximal humeral fractures. It shows superior biomechanical characters and the MIS technique of its application is safe regarding the risk of injuring the axillary nerve provided that it is meticulously done.
6. References


Acknowledgement

I would like to express my deepest gratitude and utmost thanks to Prof. Dr. med. L. Kinzl and all the members of the department of Trauma surgery, hand and reconstructive surgery in the university of Ulm for their help and support during the accomplishment of this work.

I would also wish to express my deep thanks to Prof. Dr. L.Claes and the members of the trauma surgery biomechanics research institute of the university of Ulm for their guidance and help.

Last, but not least, I want to thank the members of my family for their support and help.

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