FUNCTIONAL OUTCOME IN CONSERVATIVE MANAGEMENT OF DIAPHYSEAL HUMERUS FRACTURES - A COMPARATIVE ASSESSMENT ON THE USE OF U SLAB VIS-À-VIS FUNCTIONAL BRACE

A Dissertation submitted in partial fulfillment of the requirement for the degree of Master of Medicine (MMED) in Orthopaedic Surgery of the University of Nairobi

DR MUNYUKO EPHANTUS MWANGI

H58/70093/2013

DECLARATION

I hereby declare that this study is my original work and has not been presented for a degree at any other university.

Dr. Munyuko Ephantus Mwangi – Principal Investigator.

Registration number H58/70093/2013

MBCh.B. (UoN)

Sign……Date…….

SUPERVISORS

This dissertation proposal has been submitted for examination with our approval as university supervisors.

DR. VINCENT MUOKI MUTISO

MB.ChB. (Nrb), Mmed (Nrb), FCS (ECSA), AO - International Fellow (Trauma & Orthopaedics)

Consultant ORTHOPAEDIC SURGEON

Senior Lecturer, DEPARTMENT OF ORTHOPAEDIC SURGERY, University of Nairobi

Signed……..Date……..

DR. JOHN KING'ORI

MBChB (UON), MMed ortho (Makerere)

Consultant ORTHOPAEDIC SURGEON and lecturer DEPARTMENT OF ORTHOPAEDIC SURGERY, University of Nairobi

Signed……..Date……..

CERTIFICATE OF AUTHENTICITY

This is to certify that this thesis is the original work of the author.

This research will be carried out at Kenyatta National Hospital Accident and Emergency Department, Orthopaedic clinic and P.C.E.A Kikuyu Hospital.

PROF. JOHN E.O ATING'A

PROFFESOR OF ORTHOPAEDIC SURGERY,

CHAIRMAN,

DEPARTMENT OF ORTHOPAEDIC SURGERY,

UNIVERSITY OF NAIROBI.

Signed……

Date……..

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

OTA – Orthopaedic Trauma Association

ROM – Range of Motion

FCB - Functional Cast Bracing

ASES – American Shoulder and Elbow Surgeons

DASH – Disabilities of Arm Shoulder and Hand

MEPI – Mayo Elbow Performance Score

VAS – Visual Analogue Scale

KNH – Kenyatta National Hospital

POP – Plaster of Paris

ADL – Activities of Daily Living

RUST – Radiographic Union Scale In Tibia

ABSTRACT

Background

Diaphyseal humerus fractures constitute about 3% of the overall fracture incidence with an increasing incidence locally attributed to a rise in road traffic crashes, more so from boda boda related accidents. Overall a majority are conservatively managed with good outcomes. Several methods exist for conservative management of humerus shaft fractures including hanging casts, coaptation splints or u-slabs, velpeau bandages and functional braces. Several authors consider the use of functional brace as the gold standard due to easy applicability and allowance of greater shoulder and elbow motion.

In our local setup, the humerus fractures are conservatively managed by the use of u-slab. This study made a comparative assessment of functional outcomes in terms of u slab vis a vis functional brace, with the aim of establishing whether there was a significant advantage of one method over the other and transferring the same benefits to the overall patient care.

Study objective

To evaluate and compare the early functional outcome in diaphyseal humerus fractures after treatment with either functional brace or u-slab.

Study design

Comparative prospective analytical study

Study setting

The study was conducted at the Kenyatta National Hospital (KNH), Accident and Emergency Department and clinic no 5, and Presbyterian Church of East Africa (P.C.E.A) Kikuyu Hospital, at the Orthopaedic rehabilitation unit.

Materials and Methods

A total of **68** study participants were recruited and followed within a period of 6 months. The participants were divided into two groups, **group A** for u-slab and **group B** for functional bracing. All the participants were initially managed as per the hospital protocol with a u-slab upon being seen

at A & E. Participants in group B were then be converted into a functional brace after one week. All the participants were then followed at 4,8 and 12 weeks. A radiograph was taken after application of u slab or functional brace and during follow-up visits to assess for alignment and bridging callus. At 12 weeks, the u-slab and functional brace were removed and functional assessment done using validated tools.

Data was entered in password protected excel spread sheet tables and then analyzed using SPSS version 21.Descriptive summary statistics included means and standard deviation for continuous data and frequencies and proportions for categorical data. P values and 95% confidence intervals (CIs) were be calculated. A p value <0.05 was considered statistically significant, based on two sided t-tests.

Results

A total of 68 patients were followed for a duration of 12 weeks after which the early functional outcome was assessed. The mean age of patients was 35.7 years .The male to female ratio was approximately 2:1. Majority affected the right humerus. The middle 1/3 of the humerus was the commonly involved segment. Most of the fractures were AO classification 12A.There was a statistically significant difference in functional outcomes as assessed by ASES ($p<0.001$) and MEPI ($p<0.014$) scores between the patients managed on functional braces and those managed on braces with the functional brace showing superior results.

Conclusions and Recommendations

Majority of humerus shaft fractures are managed conservatively. Functional braces have a superior early functional outcome in conservative management of humerus shaft fractures as demonstrated in this study.

It is recommended that where cost allows, patients should be given the benefit of use of functional braces to allow an early return of good shoulder and elbow range of motion.

Further studies with larger sample sizes and longer duration of follow up are required to assess the long term outcomes in terms of union with the use of the two methods.

INTRODUCTION

The Orthopaedic Trauma Association (OTA) fracture classification (1) separates the diaphyseal humerus shaft from the fractures located at proximal and distal ends of the humerus by the rule of squares, similar to the other long bones. The widest portion of the proximal or distal parts of the humerus is take to define the length of the side of the square. Diaphyseal humerus fractures account for roughly 3% of all fractures (6, 7). Their treatment continues to evolve due to the advances in both operative and non-operative management. There are two peaks in the incidences of these fractures, one in the young males in the age bracket between twenty one and thirty years and then a larger peak in the age bracket between sixty one and eighty years (4).

The mechanism of injury in the young is usually due high energy trauma, often with multiple injuries. This change to low impact trauma as age increases (5). Patients tend to present with pain, swelling, deformity and shortened extremity. Diagnosis requires both Antero-posterior and lateral radiographs (5).

Most fractures of the humerus diaphysis can be treated non-surgically and more than 90% will achieve complete union. (8, 9, 10).Surgical indications include; fractures with neurovascular injury, multiply injured patients, patients with bilateral humeral shaft fractures, pathological fractures, severely communited and/or segmental fractures, open fractures and fractures extending into the joint (7).Healing in diaphyseal humerus fractures is anticipated in around 3 months, the average time to union being around eight to twelve weeks.(9, 13, 14).

Gravity plays a significant role in the fracture reduction while the arm is held in the anatomical position. The arm has some significant muscle and soft tissue coverage and as such some degree of deformity can be easily concealed (2). Since the humerus serves no role in weight bearing, it has a large allowance of acceptable deformity which includes; 20 degrees in the sagittal plane, 30 degrees in the coronal plane, 15 degrees in the axial plane and up to 3 cm shortening in children.

Functional bracing has in many places and in the opinion of many authors replaced many other methods applied in conservative management of humerus shaft fractures. This is because of its ease of application and adjustability, minimal limitation in adjacent joint motion, relatively cheap materials used in its design and consistent good outcomes (6).The functional brace has been shown

to be very effective in treatment of closed humerus shaft fractures, with reported union rates of 96-100 % (8,9,10,11,12)

LITERATURE REVIEW

Safe for a few diaphyseal humerus fracture where there are absolute and relative indications for surgical management (28, 36), a majority of them can be treated successfully by conservative methods (27, 28, 36).

The Velpeau bandages, abduction splints, u casts, hanging casts and functional bracing are some of the most common conservative methods in use (28, 36). The hanging arm cast is usually indicated for the midshaft humerus fractures, and especially those displaced oblique or spiral fractures. It relies on gravity traction provided by the weight of the cast and the limb to achieve reduction. As such the patient must remain in an erect or upright position most of the times. The hanging cast may be used definitively or it may be changed into a functional brace after some time. Fracture over distraction may sometimes occur with the use of the hanging cast and this may lead to delayed or non-union. The stockinette Velpeau shoulder dressing is a shoulder girdle immobilizer commonly used in the elderly and young children with minimally displaced humerus shaft fractures who may not be able to tolerate or cooperate with the use of the other forms of treatment. It is cheap comfortable and easily applied. In situations where maintenance of fracture reduction requires the arm to be in abduction and external rotation, then a shoulder spica splint is applied. This is however uncommon as such fractures would ordinarily require surgical management.

The use of functional bracing in many centers across the world is wide to the extent that many authors consider it as the gold standard. The functional brace offers many advantages with regards to preservation of shoulder and elbow range of motion, costs to the patient and general patient comfort compared to the many other conservative methods in use (16, 29, 37, 39, 40, and 41).

The functional brace has no risk for fracture over distraction as it is generally made from light materials. The fact that the patient can remove the brace and reapply it offers an advantage in regards to hygiene.

The functional brace works on principle that Sarmiento described as a pseudo hydraulic environment (19). During concentric muscular contractions, there is an attempted increase in muscular size. This is however contained by the functional brace, translating this into

circumferential and radially directed internal forces, which act to stabilize the fracture (18, 19).It is the inherent size and shape of the cylinder rather than the strength of the material used to make the brace that allows the soft tissue containment so that during the muscular contractions, a consistent pressure is exerted, ultimately generating constant force. (17, 23, 24)

Fracture reduction is also gravity dependent, just like in the u casts and hanging casts. The greatest advantage conferred by the functional brace is lack of adjacent joint immobilization (15, 29, 30, 33, 35, 40, 41), which allows early functional range of motion exercises. These enable some micro motion at the fracture site which is important in improving blood flow and promoting the whole process of bone healing. (15, 29, 30, 33, 35, 40, 41)

The greatest benefit with the use of functional bracing is achieved in those fractures with lesser shortening and angulation initially since the brace stabilizes rather than immobilizes the fracture(17), and these commonly are closed low energy fractures requiring little or no reduction (21).The high rates of fracture union with the use of functional braces are well documented in literature as observed from clinical experience (23,25).Fractures of the lower third of the humerus have however been shown in some studies to have lower healing rates than those of the proximal third. (8, 20)

With the use of functional braces made of plastic materials, frequent removal for purposes of skin care is necessary to prevent any skin reactions and sloughing off. Patients with poor hygiene habits or who are anxious about removal for skin care are likely to develop skin problems (21, 22).Obese patients with a large arm circumference and also females who have a larger breast mass and axillary fat may experience challenges in brace fitting (21).Rarely secondary radial nerve injury as reported by Amr Atef Abdelgawad et al (26) can occur.

Samiento et al in his classic study treated 51 patients with prefabricated braces consisting of plastic sleeves. He noted that it maintained good alignment of the fragments and permitted rapid and uninterrupted osteogenesis. He also noted that early introduction of functional activity to the entire extremity appeared to provide a desirable physiological environment conducive to rapid healing.

In a follow up study, Samiento et al followed 620 patients of the original 922 recruited until clinical and radiological union of diaphyseal humerus fractures managed conservatively with a prefabricated brace.75% of the fractures were closed and the rest were open. 15% were in the proximal 1/3, 49% middle 1/3 and the rest in the distal 1/3.In these fractures, a coaptation splint was applied initially with the elbow flexed to ninety degrees for about nine days. None of the fractures were manipulated.

The brace was made up of two plastic sleeves, anterior and posterior, joined up with velco straps. An assessment of radiological and clinical union was made and when deemed satisfactory, the brace was removed, averagely after eleven weeks.

In this study, the rate of non-union was less than 2% in the 465 patients with closed fractures and 6% in 155 patients with open fractures. 87% of the fractures healed with acceptable angular deformities with an average angulation of about sixteen degrees and only permanent varus deformity exceeding twenty five degrees in only two percent. This high rate of union and satisfactory functional results has given credence to this method of treatment.

Many authors followed the same principle to get uniformly good results. (43, 44, 45, 46, 47, 48, 49) Some literature has questioned the efficacy of the conservative methods of diaphyseal humerus fractures despite the opinion of the majority of the authors. Although most of the authors support that vast majority of the diaphyseal fractures can be treated successfully by conservative methods, efficacy of conservative management of these fractures has been questioned. There has not been a universal reproducibility of the excellent results, with some authors observing union rates between 6% and 23 %(31, 34).

In a review by Efthimios papasioulis et al involving sixteen case series and two comparative studies that fulfilled the criteria set, it was noted that the average time to union was 10.7 weeks, with the rates of non-union standing at 7%.In the same review, they also noted that in 85% of patients, there was an angulation of less than 10 degrees. Toiren et al were forced to abandon the use of functional bracing after failing to demonstrate any radiological or clinical signs of union in 22.6% of patients at 6 weeks.

Several studies have been done comparing the effectiveness of Functional cast bracing (FCB) and u-slab in the management of diaphyseal humerus fractures.

Camden et al (16) in a series of 8 patients with humerus shaft fractures treated with u-slab matched them for type and level of fracture with another group treated with FCB. They compared them with regard to fracture healing and functional outcome. There was no difference between groups for healing time and final alignment of the fracture. However, there was a greater range of elbow motion at the time of union in the FCB group (11-126 degrees) compared with the u-slab group (50-119 degrees), p value <0.05. These results confirmed that fracture bracing permits greater functional use of limb without affecting fracture healing and alignment.

In another study Sharma VK et al (62) demonstrated the superiority of FCB over U –slab, 40 cases of diaphyseal fracture of humerus were treated with FCB, results were compared with 25 patients treated by u cast. Average union time was 7.5 weeks by FCB and 10 weeks by U- cast. Stiffness at the shoulder and elbow was uniformly found in patients treated with U-cast. More than 50 % patients had varus angulation less than 5 degrees after treatment with FCB. Only 16 % had varus angulation less than 5 degrees by U-cast method while 32% had varus angulation more than 15 degrees.

In another study by Kakade et al (32) in Mulago hospital,Kampala, 88 patients were sampled and grouped into those treated by the use of functional brace and those treated on coaptation splint.58 patients were treated on coaptation splint while the rest were treated on a brace. In their findings there were no statistically significant differences in healing rates between the two patient groups, however, they noted a statistically significant difference in healing rates between open and closed factures. Of significance, there was a shorter time to full recovery in extension and flexion in patients treated on a brace than those treated on a coaptation splint. This translated to a statistically significance difference (P <0.001) in the time to extend and flex elbow in the two patient groups. Based on those findings they recommended the use of the brace in those patients who could afford.

The study closest to the study in question was done by Munir et al in Benazir Bhutto hospital. They selected 280 patients aged between 20 – 60 years with closed diaphyseal humerus fractures and divided them in two groups, using a Lottery method of random sampling. One group was then

managed with a functional brace and another with conventional u-cast. Functional assessment was the then carried out using the Hunter's criteria at 6 weeks. After analysis of the Hunter scores in both groups, they concluded that humerus brace had a better functional outcome than the conventional u-cast.

Several functional assessment criteria have been used in literature while specifically dealing with conservative management of humerus fractures. Stewart and Hundley did a comparative study in methods of treatment of fractures of the humerus. They examined more than one thousand cases of entire humerus fractures treated with rigid plaster fixation and hanging cast for a period of 15 yrs. They adequately followed 546 cases which included 251 neck of humerus fractures, 223 diaphyseal and 52 humerus head fractures. The results were classified as follows:

Excellent: Painless, normal function and no deformity

Good: Painless and normal function ordinarily, less than 20 % limitation in motion of adjacent joints, less than 10 degrees of angular deformity.

Fair: Mild pain occasionally, more than 20% motion limitation in adjacent joints and more than 10 degrees of angular deformity but satisfactory function.

Poor: Continuous pain with adjacent joint motion limitation of more than 40% angular deformity with significant motion impairment

Hunter SG (63) managed 60 angulated humerus shaft fractures using a u slab which acted as a dynamic splint. He noted functional recovery was relatively rapid in patients younger than 35 yrs. He assessed the functional outcome by comparing the affected side with the normal side and came up with Hunters Criteria which has 5 grades as follows: -

G1: Total absence of motion in adjacent joints, total impairment in ADL

G2: Significant loss of adjacent joint motion and impairment in ADL

G3: Lesser loss of adjacent joint motion and impairment in ADL

G4: Mild adjacent joint motion loss and impairment in ADL

G5: Complete adjacent joint motion with no impairment in ADL

The above described assessment tools although not validated are objective physician based evaluation schemes relying on range of motion and radiological evaluation.

Current research has shifted more from objective to subjective evaluation criteria. (50) Several scoring systems are used in current orthopaedic practice to assess outcomes in various diseases processes and interventions. (57) The Questionnaires utilized are mainly of two types; physician-based and patient-based questionnaires, in terms of rating. The Physician-based questionnaires uses both clinical and/or functional measurements. Patient based questionnaires however subjectively assesses the various components of a patient's condition.(58,59) Patient reported outcome measures can be general health related quality of life measures, health utility measures, region specific health related quality of life measures or condition specific measures.(50,51,52) Questionnaires must be properly validated in terms of consistency, sensitivity and reliability.(60)

A study by James D Wyle and James T Beckmann on functional outcome after upper limb surgery validated 18 scoring systems for shoulder dysfunction. They found that the DASH (disabilities of arm, shoulder and the hand) and the ASES (American Shoulder and Elbow surgeons) scores to be the most sensitive and specific. In the same study, they favoured ASES over DASH score because of the shorter questionnaire than DASH (eleven vis a vis thirty) (53). According to Umile Ciuseppe Longo and Franceschi, the ASES and MEPI (Mayo Elbow Performance Score) are amongst the most sensitive and specific physician and patient based functional outcome scores. (54)

The ASES score is a tool that was developed by the American Shoulder and Elbow surgeons to help in standardization of outcome measures and to promote the undertaking of multicentre trials in shoulder and elbow surgery (55).It contains a physician-rated and a patient rated section, however, only the pain visual analogue scale (VAS) and ten functional questions are typically used to tabulate the reported ASES score. The total score – 100 maximum points – is weighted 50 % for pain and 50% for function. The final pain score (maximum 50 points) is calculated by subtracting VAS from 10 and multiplying by five. For the functional portion, each of the ten separate questions is scored on an ordinal scale from 0 to 3 for a maximal raw functional score of 30 points. The raw score is multiplied 5/3 to make the maximal functional score out of 50 possible points. The pain and functional portions are the summed to obtain the final ASES score.

Among the many elbow score in current use today, the mayo elbow performance index (MEPI), (56) is one of the most commonly used physician-based elbow rating systems. The index consists of four parts: Pain, with a maximum score of 45 points, ulnohumeral motion (20 points), stability (10 points) and ability to perform five functional tasks (25 points). Pain is rated as none (45 points), mild (30points) if there is no limitation of activity and occasional use of analgesics, moderate (15 points) if there is limitation of activity and regular use of analgesics. The joint's stability is classified as stable, mildly unstable or unstable. The functional score is determined on the basis of the patient's ability to perform activities of daily living. The total score ranges from 5 to 100 points, with higher scores indicating better performance. A total score between 90 -100 points is excellent, between 75 – 89 points is good, between 60 – 74 points fair and less than 60 points poor.

STUDY JUSTIFICATION

The majority of the diaphyseal humerus fractures can be managed uneventfully through conservative methods save for a few where relative and absolute indications for surgery exist (27, 28, 36).The global prevalence of diaphyseal humerus fractures is 3% .Locally, it's likely to be slightly higher than the global prevalence due to an increase in orthopaedic trauma in the region attributed to motor vehicle accidents and especially those involving boda boda riders and passengers.

The current protocol for conservative management of humerus fractures in KNH entails exclusive use of the u-slab for 8 to 12 weeks. Many centers across the globe have adopted functional brace as the standard of care in conservative management of disphyseal humerus fractures.

This study aimed to make a comparative assessment of functional outcome of both u - cast and functional brace in our local setting with an aim of encouraging the adoption of use of the functional brace if the results seemed favorable.

NULL HYPOTHESIS

There is no difference in the functional outcome between patients with diaphyseal humerus fractures treated on U-slab and those treated on Functional brace by 12 weeks.

STUDY OBJECTIVES

Main Objective

To evaluate and compare functional outcome of diaphysis humerus fractures after treatment with either functional brace or u-slab by 12 weeks.

Specific objectives

1. Determine functional outcome in patients conservatively managed on a u-slab by 12 weeks
2. Determine functional outcome in patients conservatively managed on a functional brace by 12 weeks
3. Compare the treatment outcome in the two patient groups

MATERIALS AND METHODS

STUDY DESIGN

A comparative prospective analytical study

STUDY SETTING

The study was conducted from the patients received at KNH accident and emergency department and clinic 5 and P.C.E.A Kikuyu hospital orthopaedic rehabilitation unit.

INCLUSION CRITERA

Patients with acute closed diaphyseal fractures of humerus, acute being defined as two weeks from the time of injury, who were above 18 yrs.

EXCLUSION CRITERIA

- Patients with neurovascular injuries
- Pathological fractures
- Open fractures and those secondary to gunshot
- Bilateral humeral shaft fractures
- Segmental humerus shaft fractures
- Humerus shaft fractures with an intra-articular extension
- Patients with head Injury

SAMPLE SIZE CALCULATION

In the series by Camden et al, it was noted by the time of union, that the patients treated with the facture brace had a greater elbow range of motion compared to those treated with the u slab (11degrees -126 degrees vs 50 degrees -119 degrees respectively), p value less than 0.05.Taking elbow flexion to be 145 degrees, then it was deduced that the functional brace group had an overall functional outcome at 79.3% while the u-slab group was at 47.6 %.

Using **Kesley's Formula**(64),

$$\boldsymbol{x = \frac{p1(1-p1) + p2(1-p2)}{(p1-p2)^2}\, x\, f(\alpha, \beta)}$$

Where,

x = sample size in each group

P1 = assumed proportion to be detected in group 1

P2 = assumed proportion to be detected in group 2

Assuming 80 % power and 5 % significance, then

$$\boldsymbol{f(\alpha, \beta) = 7.85}$$

Substituting,

$$\boldsymbol{x = \frac{0.79(1-0.79) + 0.48(1-0.48)}{(0.79-0.48)^2}\, x\, 7.85 = 33.94}$$

34 patients in each group, total **68 patients**, 10 % was to be added for drop out cases.

METHODODLOGY

All patients with humerus shaft fractures who met the inclusion criteria and consent to participate in the study were enrolled. Those who did not consent to participate in the study were managed as per existing hospital protocol. The Principal investigator had included one research assistant, who was a final year undergraduate medical student. The principal investigator and his research assistant assessed all the patients with humerus shaft fractures who were intended for conservative management. A patient was diagnosed to have a diaphyseal humerus fracture based on both clinical and radiological findings. The clinical findings included a history with elaborated mechanism of injury, pain, swelling and deformity of the affected arm. A radiograph was then taken to confirm the diagnosis. The radiograph included two views, an anteroposterior and a lateral view, which exposed the full length of the humerus, including both the shoulder and elbow joints. These were done by the radiographers at the accident and emergency departments of the study locations. If the patient presented with radiographs from another facility and the principal investigator deemed them adequate, they were used for evaluation. The principal investigator interpreted the radiographs and classified the fracture as per the AO classification. The patient file was reviewed and patient data and information relating to the fracture collected. This included:-

Patient Bio-data

- Age
- Sex
- Occupation
- Telephone contacts

Injury characteristics

- Date and Time of Injury
- Limb affected
- Mechanism of injury

Site of fracture (proximal, mid or distal third)

AO classification

The patients were divided into two groups, A and B based on a random sampling technique. This entailed use of a lottery method where participants picked an envelope with the treatment modality, ensuring both the participants and the investigator were blinded. All patients were initially treated as per hospital protocol with a u – slab. Patients in group A were managed up to the end with a u-slab; patients in group B were changed to a functional brace after a week, in order to allow for any significant soft tissue swelling to settle down. The duration on u slab for patients in group B was standardized to one week, such that any patient randomized to group B who had a u-slab applied elsewhere and was more than one week was considered a dropout and continued with care on u-slab per protocol. The application of u-slab was done as described in **appendix 2.**

Follow up protocol

The two groups of patient were followed for up to 12 weeks from the time of injury, by which time fracture union was anticipated to have occurred. Union was assessed based on clinical and radiological parameters. The clinical parameters which were relied on, indicative of union were absence of pain and inter-fragmentary motion at the fracture site. The RUST (radiographic union scale in tibia) criteria (**appendix 4**), was used for assessment of radiological union (65). A score of 7 or greater i.e. presence of callous in three cortices was taken as evidence of union.

Group A patients were followed up in 2, 4, 8 and 12 weeks. Assessment visits included checking the position of the u- slab and the neurovascular status of the limb. A check x-ray was also done at each visit to check for limb alignment and angulation, and presence of bridging callous at 8 and 12 weeks.

Group B patients were reviewed after one 1, 4, 8 and 12 weeks. At one week, the u slab was removed and exchanged for a functional brace. The brace consisted of one circumferential thermoplastic sleeve with overlapping edges, fitted with adjustable velco straps to hold the edges together. The brace was designed to extend up to the tip of the acromion laterally; two finger breaths distal to the axilla on the medial side and a finger breadth proximal to the medial and

lateral epicondyles. This design was in line with the original Sarmiento brace, the only modification being use of a single circumferential sleeve, instead of two separate medial and lateral sleeves, since the material used was flexible enough to allow for that. The patients were guided on how to adjust the brace by tightening the velco straps to accommodate any changes in the arm circumference that would arise from reduced swelling. The patients were then followed at week 4, 8 and 12, with a check radiograph being done at week eight to assess the alignment and bridging callous at 8 and 12 weeks

The patients in both groups had a collar and cuff for comfort which could be removed to allow for active range of motion exercises in group B patients. After 12 weeks, both groups of patients had either the u-slab or functional brace removed, after qualifying for union using both the clinical and radiological criteria. A functional assessment of the shoulder and elbow was carried out using validated assessment tools i.e. ASES score for the shoulder and MEPI score for the elbow. Thereafter patients continued with physiotherapy as and when was necessary.

Whenever there was to be doubt as to the state of fracture union as specified, the patients were to be dropped from the study but would have continued with further follow-up up to 16 weeks, after which if there was no union, surgical options were to be considered.

The patients were provided with a self-evaluation form that included components that were used for computing both the ASES and MEPI scores. The principal investigator, assisted by his research assistant evaluated all the patients soon after the removal of u slab or the functional brace and took them through the self-evaluation using the predesigned form. The research assistant was also trained on administering the patient self-evaluation forms so that he could guide the patients appropriately.

The patient's self-evaluation form had two parts, with an annex that was filled by the principal investigator or his assistant during patient evaluation. Part A for Shoulder assessment had the Visual Analog Scale (VAS), a 10 cm scale grading for severity of pain the patient experiences at the shoulder, which ranged from zero for complete absence of pain to ten, the greatest level of pain. The next segment in part A had the Activities of Daily living (ADL) section. Ten activities of daily living were assessed on a four point scale. The patients were asked to circle zero, if they were completely unable to do the activity, 1, if it was very difficult for them to do the activity, 2, if it was

somewhat difficult for them to do the activity, and 3, if they had no difficulty at all in doing the activity. The maximum score arising from the 10 questions asked was to be 30.The 10 questions included activities that were highly dependent on painless, adequate shoulder range of motion. The patients were also asked to grade the ease of doing normal duties and a sporting activity of interest. The scores for each individual activity were then totaled to obtain the cumulative score of the activities of daily living.

The expected Shoulder Score was arrived at using the formula;

{(10 – Visual analog pain score)x5} +{ (5/3) x Cumulative ADL score}

Part B of patient evaluation was used for the elbow assessment. The first segment was for assessment of elbow pain. The patient was asked whether there was presence of elbow pain. If yes, then it was graded on a three point scale; 1 being mild, 2 being moderate and 3 being severe. The next segment assessed elbow function based on patient's ability to perform 5 functions including combing hair, feeding oneself, personal hygiene tasks, putting on a shirt and putting on shoes. Overall scoring was done as per the Mayo Performance Index Scoring in **appendix 5**.The radiographs at 8 weeks were also be assessed for the presence of callus and alignment.

Data was entered in password protected excel spread sheet tables and then analyzed using SPSS version 21.Continuous data was analyzed and summarized to include, amongst others, means and standard deviation. Categorical data was analyzed and displayed by use of frequencies and proportions. P values and 95% confidence intervals (CIs) and Pearson correlation coefficient were calculated. A p value <0.05 was considered statistically significant, based on two sided t-tests.

The final outcome measures were the shoulder score index and the mayo elbow performance index scores. Functional outcomes were graded as excellent, good, fair or poor. Excellent healing meant complete functional recovery was achieved. Good outcome meant there was suboptimal recovery without any impact on work and everyday activity. Fair outcome was when patients experienced functional impairment in daily activities and work. Poor outcome meant that daily activities or work had to be abandoned because of the functional impairment.

ETHICAL CONSIDERATIONS

Approval for the study was obtained from the department of Orthopaedic Surgery, University of Nairobi and KNH Ethics and Research Committee before commencement.

Informed consent (**see Appendix 1**) was obtained from the patients or parents/guardians who accepted to participate in the study. For those who declined to consent for the study, they were managed as per the existing hospital protocol and their treatment was not affected by refusal to participate in the study.

STUDY LIMITATIONS

During the assessment of shoulder and elbow functions using the ADL scoring criteria in the ASES score, one of the parameters, The ease of *undertaking a patient's usual sport*, was difficult to evaluate in most of the patients as most of them did not participate in any form of sporting activity. The patient score for the *throwing a ball overhead*, was taken as a representation of the former.

DISSEMINATION OF FINDINGS

The study findings will be disseminated as follows:

- A copy will be forwarded to the department
- A second copy will be forwarded to college of health sciences library
- Study findings will be published in at least one peer reviewed journal
- Study findings will be presented at the KNH Research and Programs journal club

RESULTS

A total of 68 patients were recruited into the study from the A&E department of Kenyatta National Hospital (KNH), and the orthopedic clinics at both KNH and P.C.E.A Kikuyu and followed up for 12 weeks.

This chapter presents the study findings which show an analysis of the patient's demographics, fracture characteristics and functional outcomes as assessed by MEPI and ASES scores.

PATIENT DEMOGRAPHICS

Sex Distribution

The distribution of gender of the patients was as shown in the figure below.

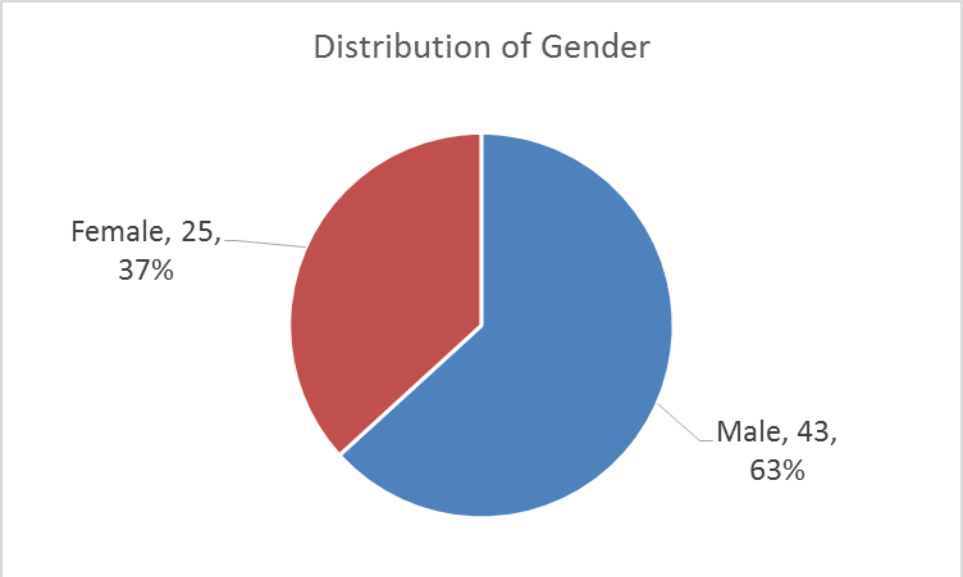


Figure 1: Gender distribution

Forty-three (63.2%) of the patients were male, and 25 (36.8%) were female, with a male to female ratio of approximately 2:1

Age Distribution

The distribution of age of the patients was as shown in the chart below.

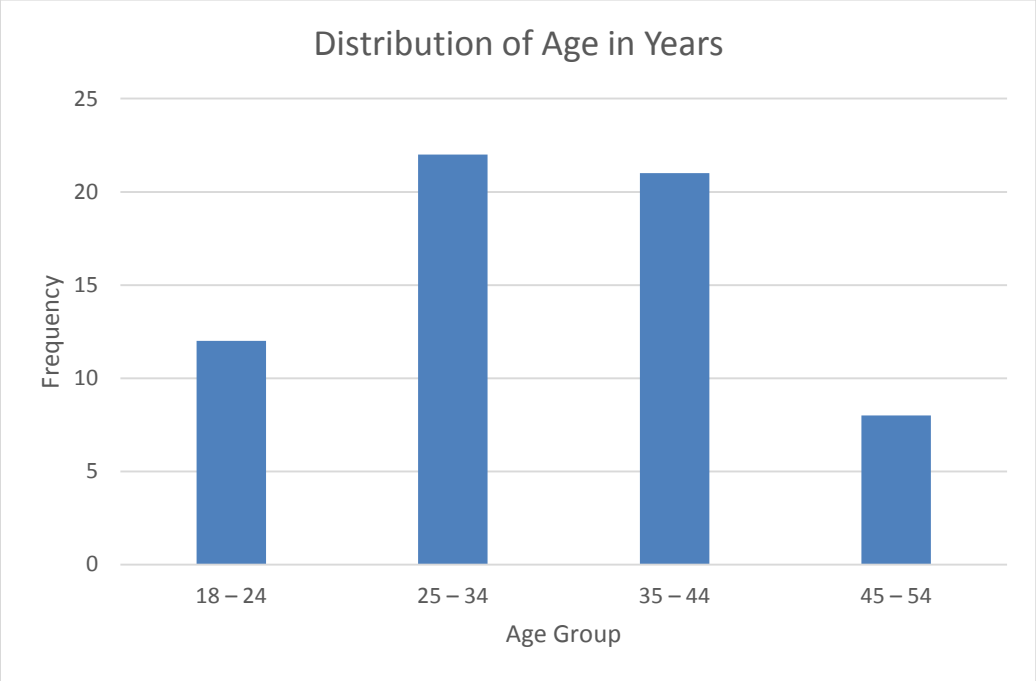


Figure 2: Age distribution

The mean age of patients presenting with diaphyseal humerus fractures in the two recruitment centres was 35.7 (SD 10.7), with a range between 18 and 62 yrs. The modal age group was 25 – 34 with 22 patients (32.4%).

FRACTURE CHARACTERISTICS

The data collected entailed characterizing the fracture in terms of limb affected, location of the fracture, the AO classification and the injury mechanism. The results were as explained below.

Limb affected

The table below shows the distribution of the patients fracture according to the side involved and the dominance.

Table 1: Limb affected and dominance

	Frequency n (%)		Total n (%)	P value
	Dominant	**Non dominant**		
Limb affected				
Right	44 (91.7)	2 (10.0)	46 (67.6)	<0.001
Left	4 (8.3)	18 (90.0)	22 (32.4)	

Forty-six (67.6%) patients had the right hand involved, where 44 were right hand dominant, 2 were left hand dominant. Twenty-two (32.9%) patients had their left hand involved, where 4 were left had dominant, while the rest 18 were right hand dominant.

There was noted an association between the side of the limb involved and the hand dominance, ($p < 0.001$)

Location of the fracture

The figure below presents the distribution of the fractures in the study population.

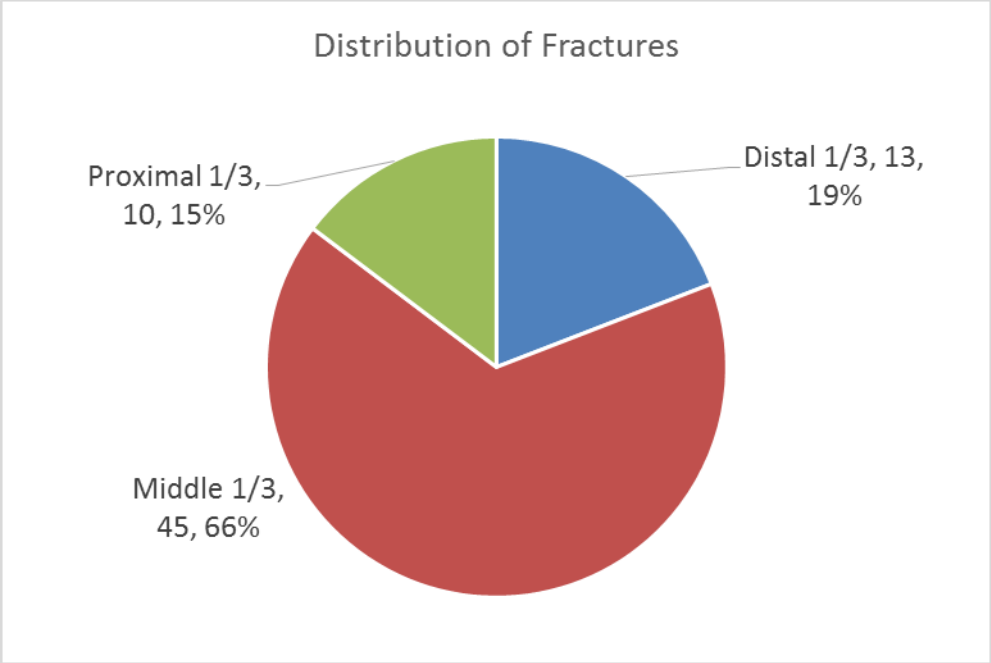


Figure 3: Distribution of Fractures according to diaphyseal segments

Ten patients (14.7%) had fractures involving proximal 1/3 of the humerus, forty five patients (66.2%) involved middle 1/3 of the humerus, and 13 patients (19.1%) involved the distal 1/3 of the humerus (figure below). The pattern of involvement was similar in the two study groups as tabulated.

Table 2: Location of fracture in each study group

	Frequency n (%)		Total n (%)
	Brace	**U-Slab**	
Distal 1/3	6 (17.6)	7 (20.6)	13 (19.1)
Middle 1/3	22 (64.7)	23 (67.6)	45 (66.2)
Proximal 1/3	6 (17.6)	4 (11.8)	10 (14.7)

AO fracture classification

The Table 3 and Figure 4 below illustrate the distribution of patient's fracture as per the AO classification.

Table 3: AO Classification as per treatment group

	Frequency n (%)		Total n (%)	P value
	Brace	**U-Slab**		
12A	20 (55.6)	16 (44.4)	36 (52.9)	0.422
12B	8 (38.1)	13 (61.9)	21 (30.9)	
12C	6 (54.5)	5 (45.5)	11 (16.2)	

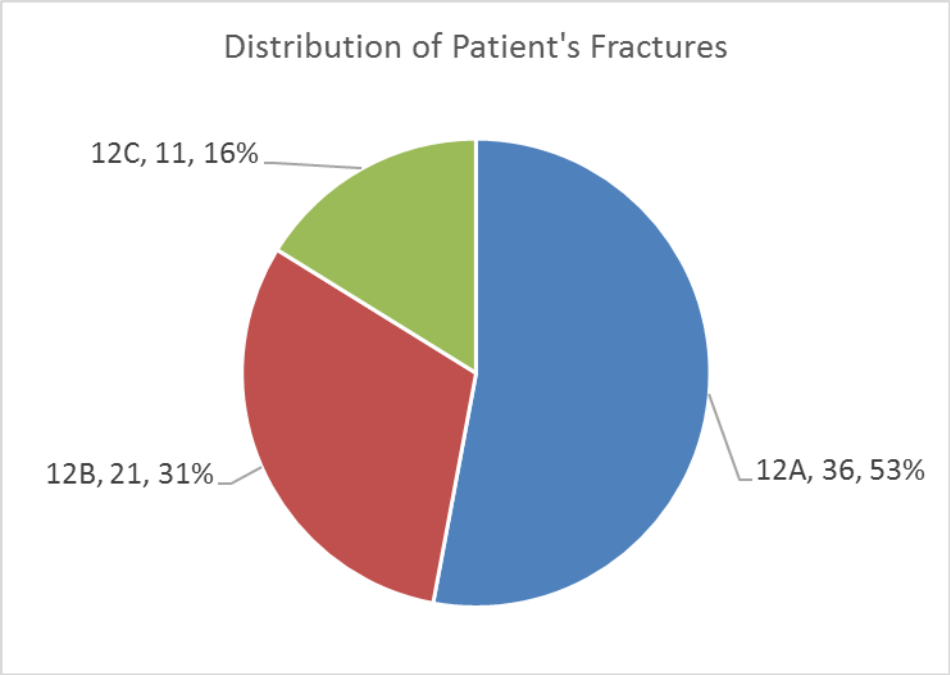


Figure 4: AO classification of the fractures within the study population

The commonest fracture pattern in both the study groups and overall was 12A, followed by 12B and 12C respectively.

Mechanism of injury

The mechanism of injury was as illustrated in the figure below.

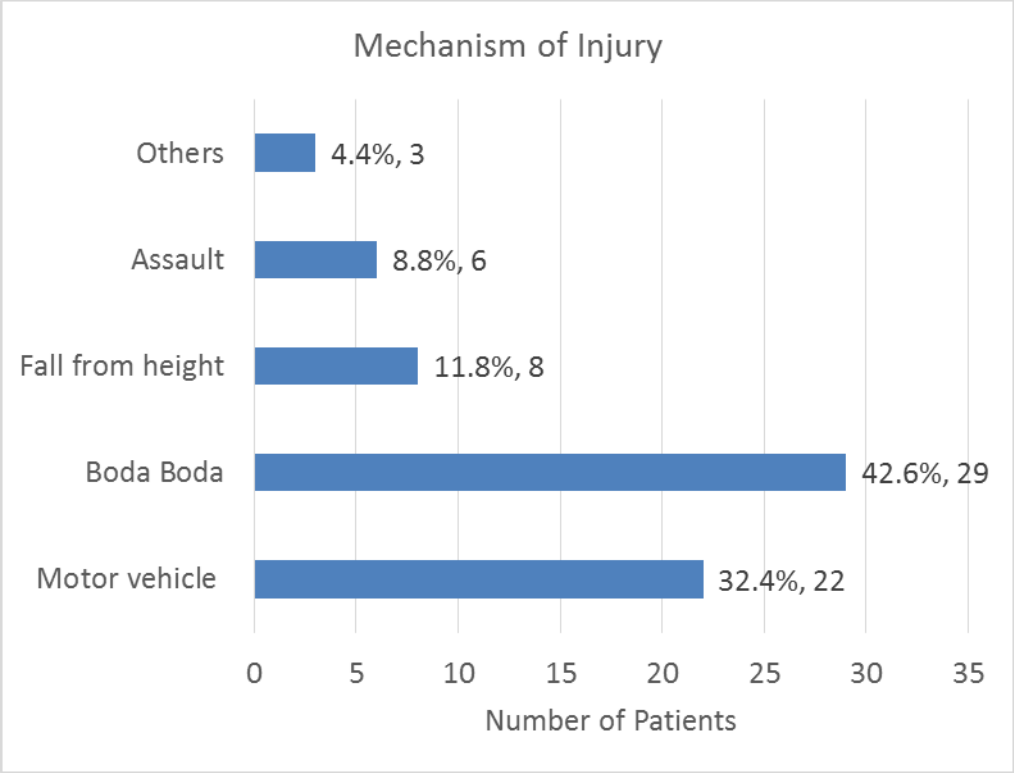


Figure 5: Patterns of Mechanism of Injury

Majority (42.6 %) got injured through involvement in bodaboda accidents, followed by motor vehicle accidents (32.4%).

FUNCTIONAL OUTCOMES

The patients were followed up for a total duration of 12 weeks after which the functional outcomes of the affected limbs were assessed using the ASES and MEPI scores. A score of 90 – 100 was graded as excellent, 75-89 as good, 60 -74 as fair and below 60 as poor for both ASES and MEPI scores.

Relationship between the Functionality Scores and Intervention

A comparison of the two groups was done with the grouped scores for both ASES and MEPI as shown in the figure below.

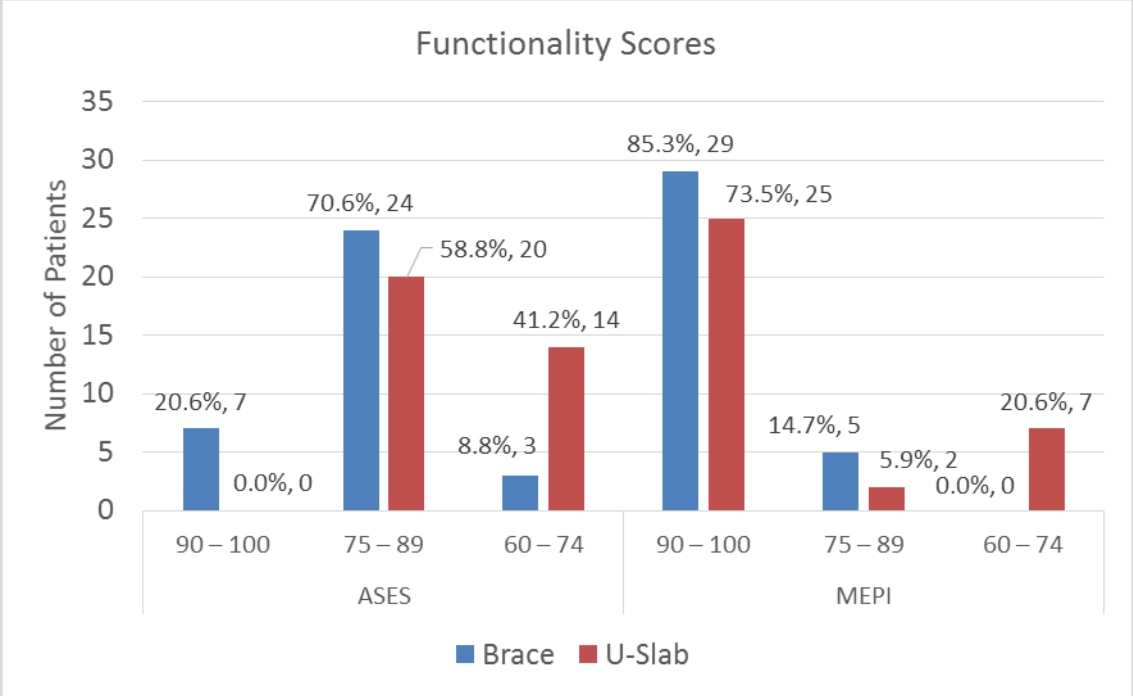


Figure 6: Comparison of Functionality Scores for the Two Groups

Seven (20.6%) patients of those on brace had an excellent ASES score while none on u-slab had such a score. Patients on brace also had a higher score for a good outcome than patients on u-slab, 70.6% vs 58.8 %. A similar pattern was observed for the MEPI score with 29 (85.3%) patients on brace having an excellent score as opposed to 25 (73.5%) patient on u-slab.

A chi-square test indicated that there was a statistically significant difference between the ASES scores for the patients managed on the brace and those managed of u-slab (p=0.001). Equally, there was also a statistically significant difference in MEPI scores between the patients managed on the brace and those on u-slab (p =0.014).

Relationship between Functionality Scores and Gender

The Table 4 below shows the breakdown of the outcomes for each gender in both groups of the intervention.

Table 4: Distribution of Functionality Scores against Gender for both Groups

	Frequency n (%)		Total n (%)	P value
	Male	**Female**		
ASES				0.823
90 – 100	4 (9.3)	3 (12.0)	7 (10.3)	
75 – 89	29 (67.4)	15 (60.0)	44 (64.7)	
60 – 74	10 (23.3)	7 (28.0)	17 (25.0)	
MEPI				
90 – 100	34 (79.1)	20 (80.0)	54 (79.4)	0.854
75 – 89	4 (9.3)	3 (12.0)	7 (10.3)	
60 – 74	5 (11.6)	2 (8.0)	7 (10.3)	

There were no statistically significant differences between the ASES and MEPI scores for males and females in both interventions as assessed by chi-square test.

Relationship between Functionality Scores and Age

The ASES and MEPI scores were compared with the different age groups in both interventions. The distribution of those functionality scores in each age category was as shown in the tables below.

Table 5: The distribution of combined MEPI scores in different age groups

	MEPI Score n (%)			Total n (%)
	90-100	**75-89**	**60-74**	
18 – 24	12 (22.2)	0 (0.0)	0 (0.0)	12 (17.6)
25 – 34	18 (33.3)	2 (28.6)	2 (28.6)	22 (32.4)
35 – 44	15 (27.8)	4 (57.1)	2 (28.6)	21 (30.9)
45 – 54	6 (11.1)	1 (14.3)	1 (14.3)	8 (11.8)
≥55	3 (5.6)	0 (0.0)	2 (28.6)	5 (7.4)
Total	54 (100.0)	7 (100.0)	7 (100.0)	68 (100.0)

Table 6: The distribution of combined ASES scores in different age groups

	ASES Score n (%)			Total n (%)
	90-100	**75-89**	**60-74**	
18 – 24	2 (28.9)	9 (20.5)	1 (5.9)	12 (17.6)
25 – 34	1 (14.3)	17 (38.6)	4 (23.5)	22 (32.4)
35 – 44	3 (42.9)	11 (25.0)	7 (41.2)	21 (30.9)
45 – 54	1 (14.3)	4 (9.1)	3 (17.6)	8 (11.8)
≥55	0 (0.0)	3 (6.8)	2 (11.8)	5 (7.4)
Total	**7 (100.0)**	**44 (100.0)**	**17 (100.0)**	**68 (100.0)**

No significant correlation was noted between the age and MEPI scores for the brace and u-slab groups (r =0.086, 0.284 respectively) and age and ASES score for brace and u-slab groups (r =0.179, 0.239 respectively) as determined by Pearson Correlation coefficient test.

DISCUSSION

Humerus shaft fractures can be managed conservatively via a variety of techniques, including hanging cast, velpeu bandages, u- slab and functional braces, for a duration ranging from 8 to 12 weeks(8,9,10).In this study, a total of 68 patients were recruited at PCEA kikuyu and KNH hospitals and followed up for 12weeks, after being conservatively managed on either functional brace or u-slab

Majority of the patients (63.2%) were male, the rest female, with a male to female ratio of approximately 2:1.Many other studies in literature show a higher prevalence of humerus shaft fractures in males than females(28,38).This however varies depending on the population studied. Carl Bergdahl et al (66), published a review of 2011 fractures from Swedish fracture register which showed a higher prevalence of the same in female patients with a female to male ration of 2.4:1

The mean age of patients presenting with humerus shaft fractures was 35.7 yeas, with a range between 18 and 62 years. The modal age was 25-34years with 22 patients in this category. Tytherleigh-Strong G et al (38) found that there was a bimodal age distribution with a peak in the third decade as a result of moderate to severe injury in men and a larger peak in the seventh decade after a simple fall in women. Spiguel AR (4) also noted a bimodal distribution of humerus shaft fractures, one in the young males 21-30 years and a larger peak in women 60 – 80 years of age.

Forty six patients had their right humerus involved while 22 had the left involved. Of those who had right humerus injury, 44 (92%) had a right had dominance while the rest had left hand dominance. For the left side injured patients, 18 (90 %) had a right had dominance and the rest had left hand dominance. There was a noted association between the limb involved and the hand dominance ($P<0.001$).There however lacks a clear explanation for this association from the various mechanisms of injury and this perhaps was a chance finding.

Most of the fractures involved the middle third of the shaft of humerus, with 45 patients (66.2%), followed by distal third with 13 patients (19.1%) and proximal third with 10 patients (14.7%). Ruturi (67) in his prospective study of patients seen with diaphyseal humerus fractures at KNH also

demonstrated that middle 1/3 of the humerus shaft was the commonly involved with 67.9% of patients.

The commonest fracture pattern as per the AO classification was 12A, with 36 patients (52.9%), followed by 12B with 21 patients (30.9) and 12 with 11 patients (16.2%).A similar pattern was noted by Tytherleigh-Strong G et al(38) when he analyzed 249 consecutive fractures of the humeral shaft treated over a three-year period. In that study, the fractures were classified as AO type A in 63.3%, type B in 26.2% and type C in 10.4%.

Injuries from boda boda accidents topped the mechanism of injury with 29 patients (42.6%), followed by Motor vehicle accidents with 22 patients (34.2%).The rest were from falls from height and assault. These findings underscore the role of Boda Bodas as major cause or agent of road traffic injuries and a significant economic burden as was observed by Naddumba (68) in his retrospective study on bodaboda related injuries at Mulago hospital, Kampala.

This study sought to compare functional outcomes after use of either u-slab or functional brace for a period of 12weeks.At both KHN and PCEA kikuyu hospitals, the commonly adopted treatment method for diaphyseal humerus fractures is the u-slab. Functional brace as popularized by Sarmiento (32) in 1977 has been widely accepted as a gold standard for management of these fractures in most centers around the world due to its ease of application and preservation of elbow and/or shoulder ROM (6).

The functional outcome was assessed by use of the ASES and MEPI scores, both of which depend on painless shoulder and elbow range of motion. The maximum scores for both MEPI and ASES are 100.They were graded as excellent (90-100), good (75-89), fair (60 -74) and poor < 60.

Seven (20.6%) of the patients on brace treatment had an excellent ASES score, while non on u-slab had a similar score. The patients on brace also had a higher good ASES score, than those on u-slab, 24 patients(70.6%) vis a vis 20 patients(58.8%).However, more patients on the brace scored fairly for ASES, 14(41.2%) as opposed to u slab, 3(8.8%).A similar pattern was observed in regards to MEPI scores with 29(85.3%) of patients on brace having an excellent score compared to 25(73.5%) of patients on u-slab; and 5(14.7%) of patients on brace having a good score compared to 2 (5.9%)

of patients on u –slab. Seven (20.6%) of the patients on u slab were categorized in the fair score group, with none of the patients on brace in that group.

These results showed a statistically significant difference between the ASES scores for the patients managed on the brace and those managed of u-slab (p=0.001).Similarly, the MEPI scores showed an equally statistically significant difference between the two groups (p=0.014).These findings are similar to those of a study by Kakande et al(32) at Mulago hospital in Kampala, which compared 58 of the patients conservatively with a coaptation u-splint of plaster of paris and 30 patients treated with humeral brace. In that study, he found a statistically significant difference (P <0.001) between the time taken to flex and extend elbow in the brace and u-slab groups.

The chi square test between the scores for the two groups and gender did not establish any significant differences. A Pearson Correlation test did not detect any association between the Age and the Functionality scores in the two treatment groups. It should however be noted that the ASES and MEPI scores may be affected by age since poorer scores are expected as age increases. Only fourteen (20.5%) of patients enrolled in the study were above 45 years and the small sample size may reflect the outcome of lack of any association between the functional outcome scores and age.

CONCLUSION

Functional braces when used for conservative management have a better early functional outcome than U-slab in terms of shoulder and elbow range of motion.

Majority of the humerus fractures still largely involve the middle third of the humerus and are mainly simple fracture types. This is well in keeping with findings of previous studies done locally and globally.

Motorcycle accidents seem to play major role as a causative factor in most of the humerus fractures, followed closely by vehicular accidents.

RECOMMENDATIONS

This study clearly shows there is a difference in functional outcomes between the use of u-slab and functional brace. The practice in our local setup favours the use of u-slab, majorly due to the lower costs of treatment involved.

It is recommended that we encourage the use of functional braces routinely for management of diaphyseal humerus fractures which fall within the indications for conservative management, especially for those patients who can meet the costs.

Further comparative studies with larger sample size are required to assess other longer outcome measures such as time to union and any associated complications with use of either method, so as to further gather evidence to influence a change of protocol in management of diaphyseal humerus fractures in our setup.

REFERENCES

1. Marsh JL, Slongo TF, Agel J, Broderick JS, Creevey W, DeCoster TA, Prokuski L, Sirkin MS, Ziran B, Henley B, Audig´e L. Fracture and dislocation classification compendium - 2007: Orthopaedic Trauma Association classification, database and outcomes committee. J Orthop Trauma. 2007 Nov-Dec; 21(10)(Suppl):S1-133.

2. MastJW, SpiegelPG, HarveyJPJr,HarrisonC. Fractures of the humeral shaft: a retrospective study of 240 adult fractures. Clin Orthop Relat Res. 1975 Oct ;(112):254-62.

3. Klenerman L. Fractures of the shaft of the humerus. J Bone Joint Surg Br. 1966 Feb; 48(1): 105-11.

4. Spiguel AR, Steffner RJ. Humeral shaft fractures. Curr Rev Musculoskeletal Med. 2012; 5: 177-83.

5. Conor Regan, Brandon, D. Bushnell, Timothy N Taft. Humeral shaft fracture. Miller M, Hart J, Macknight J (eds). Essential Orthopedics. 1st ed. Philadelphia: Saunders. 2010; 204-07

6. Crenshaw AH Jr, Perez EA (2007) Fractures of the shoulder, arm and forearm. In: Canale ST, Beaty JH (eds) Campbell's operative orthopaedics, 11th edn. Mosby, Philadelphia, pp 3389–3398 2. Rutgers

7. M, Ring D (2006) Treatment of diaphyseal fracture of humerus using functional brace. J Ortho Trauma 20:597–601

8. Sarmiento A, Kinman PB, Galvin EG et al (1977) Functional brac ing of fractures of the shaft of the humerus. J Bone Joint Surg 59A:596–601

9. Blafour GW, Mooney V, Ashby ME (1982) Diaphyseal fractures of the humerus treated with a ready-made fracture brace. J Bone Joint Surg 64A:11–13

10. Zagorski JB, Latta LL, Zych GA et al (1988) Diaphyseal fractures of the humerus treated with prefabricated braces. J Bone Joint Surg Am 70:607–610

11. Bell MJ, Beauchamp CG, Kellam JK et al (1985) The results of plating humeral shaft fractures in patients with multiple injuries. J Bone Joint Surg 67B:293–296

12. Zagorski JB, Aych GA, Latta LL et al (1987) Modern concepts in functional fracture bracing: the upper limb. In: Paul GriYn (ed) Instructional course lectures, vol 36. American Academy of Orthopaedic Surgeons, Park Ridge, pp 377–401

13. Klenerman L (1966) Fractures of the shaft of the humerus. J Bone Joint Surg 48B:105–111

14. Christensen S (1967) Humeral shaft fractures. Operative and conservative treatment. Acta Chir Scand 133:455–460

15. Balfour GW, Mooney V, Ashby ME. Diaphyseal fractures of the humerus treated with a ready-made fracture brace. J Bone Joint Surg [Am] 1982; 64:11–3.

16. Camden P, Nade S. Fracture bracing the humerus. Injury 1992;23(4):245–8.

17. Latta LL, Sarmiento A,Tarr RR:The rationale of functional bracing of fractures.Clin Orthop Relat Res 1980;146:28-36

18. Latta LL, Sarmiento A: Biomechanics. In: Cooms R, Green S, Sarmiento A, ed. External fixation and Functional Bracing, London: Orthotext; 1989:25-28.

19. Sarmiento A: Functional fracture bracing: an update.Instr Course Lect 1987;36:371-376

20. Sarmento A, Latta LL, Zych G, et al: Isolated ulnar shaft fractures treated with functional braces. J Ortho Trauma 1998;12(6):420-423.

21. Sarmento A, Latta LL:Functional bracing and external fixation:rival techniques in fracture management. In Coombs R, Green S, Sarmiento A, ed. External Fixation and Functional Bracing, London: Orthotext; 1989:47-56.

22. Sarmiento A, Zargorski JB, Sincalir WF: Fuctional bracing of colles' fractures: a prospective stydy of immobilizationin supination vs. pronation. Clin Orthop Relat Res 1980; 146: 175-183.

23. Modern concepts in functional fracture bracing: the upper limb. In: Zargorski JB, Zych GA, Latta LL, McCollough NC, ed. Instru Course Lect, 1987:377-401. Vol. 36

24. McKibbin B: Callus formation. In: Coombs R, Green S, Sarmiento A, ed. External fixation and Functional Bracing, London: Orthotext;1989:3-7

25. Zargorski JB, Latta LL, Zych GA, Finnieston AR: Diaphyseal fractures of the humerus, J Bone and Joint Surg 1988; 70A (4):607-610

26. Amr Atef Abdelgawad, Andrew Wassef, Nabil A. Ibrahim. Late onset radial nerve palsy with conservatively managed humeral fracture.

27. Charnley J. The closed treatment of common fractures, 3rd ed., Edinburgh and London: E. and S. Livingstone; 1968.

28. McKee MD. Fractures of the shaft of the humerus., In: Rockwood CA, Green DP, Bucholz RW, editors. Sixth edition, Rockwood and Green's fractures in adults, vol. 1, Sixth edition Philadelphia: Lippincott Williams & Wilkins; 2006. p. 1118.

29. Pehlivan O. Functional treatment of the distal third humeral shaft fractures. Arch Orthop Trauma Surg 2002; 122:390–5.

30. Rosenberg N, Soudry M. Shoulder impairment following treatment of diaphy- sial fractures of humerus by functional brace. Arch Orthop Trauma Surg 2006;126:437–40.

31. Rutgers M, Ring D. Treatment of diaphyseal fractures of the humerus using a functional brace. J Orthop Trauma 2006;20: 597–601.

32. I Kakande, A P Kidza, E K Naddumba A com,parison of the use of coaptation U-splintage and a polypropylene brace for humeral shaft fractures, East and Central African Journal of Surgery (ISSN: 1024-297X) Vol 5 Num 2

33. Sarmiento A, Horowitch A, Aboulafia A, Vangsness Jr CT. Functional bracing for comminuted extra-articular fractures of the distal third of the humerus. J Bone Joint Surg [Br] 1990;72(2):283–7.

34. Sarmiento A, Zagorski JB, Zych GA, et al. Functional bracing for the treatment of fractures of the humeral diaphysis. J Bone Joint Surg [Am] 2000;82:478–86.

35. Sarmiento A, Latta L. The evolution of functional bracing of fractures. J Bone Joint Surg [Br] 2006;88(2):141–8.

36. Schemitsch EH, Bhandari M. Fractures of the diaphyseal humerus. In: Browner BD, Jupiter JB, Levine AM, Trafton PG, editors. Skeletal trauma. 3rd ed., Toronto: WB Saunders; 2001. p. 1481–511.

37. Toivanen JA, Nieminen J, Laine HJ, et al. Functional treatment of closed humeral shaft fractures. Int Orthop 2005;29:10–3.

38. Tytherleigh-Strong G, Walls N, McQueen MM. The epidemiology of humeral shaft fractures. J Bone Joint Surg [Br] 1998;80:249–53.

39. Wallny T, Sagebiel C, Westerman K, et al. Comparative results of bracing and interlocking nailing in the treatment of humeral shaft fractures. Int Orthop 1997;21:374–9.

40. Wallny T, Westermann K, Sagebiel C, et al. Functional treatment of humeral shaft fractures: indications and results. J Orthop Trauma 1997;11:283–7.

41. Zagorski JB, Latta LL, Zych GA, Finnieston AR. Diaphyseal fractures of the humerus. Treatment with prefabricated braces. J Bone Joint Surg [Am] 1988; 70:607–10.

42. Muller ME, Nazarian S, Coch P, Schatzker JA. Berlin: Springer Verlag; 1990. Comprehensive Classification of Fracture of Long Bones.

43. Papasoulis E, Drosos GI, Ververidis AN, Verettas DA. Functional bracing of humeral shaft fractures. A review of clinical studies. Injury. 2010;41:e21–27.[PubMed: 19523625]

44. Sarmiento A, Horowitch A, Aboulafia A, Vangsness CT., Jr Functional bracing for comminuted extra- articular fractures of the distal third of the humerus. J Bone Joint Surg Br. 1990;72:283–7. [PubMed: 2312570]

45. Koch PP, Gross DF, Gerber C. The results of functional (Sarmiento) bracing of humeral shaft fractures. J Shoulder Elbow Surg. 2002;11:143–50.[PubMed: 11988725]

46. Pehlivan O. Functional treatment of the distal third humeral shaft fractures. Arch Orthop Trauma Surg. 2002;122:390–5.[PubMed: 12228799]

47. Bhalla R, Narang TS, Lobo LH. Functional brace treatment of the fractures of the shaft of the humerus. Indian J Orthop. 1982;16:9–13.

48. Mavani DP, Johari AN, Thakkar AP, Vengsarkar SS, Shah SV. Functional brace for the fractures of the humeral shaft. Indian J Ortho. 1986;20:192–96.

49. Denard A, Jr, Richards JE, Obremskey WT, Tucker MC, Floyd M, Herzog GA. Outcome of nonoperative vs operative treatment of humeral shaft fractures: A retrospective study of 213 patients. Orthopedics. 2010;33 doi: 103928/01477447-20100625-16

50. Bayley KB, London MR, Grunkemeier GL, Lansky DJ. Measuring the success of treatment in patient terms. Med Care 1995; 33: AS226-AS235 [PMID: 7723451]

51. Noble PC, Fuller-Lafreniere S, Meftah M, Dwyer MK. Challenges in outcome measurement: discrepancies between patient and provider definitions of success. ClinOrthopRelat Res 2013; 471: 3437-3445 [PMID: 23955192 DOI: 10.1007/ s11999-013- 3198-x]

52. Gartland JJ. Orthopaedic clinical research.Deficiencies in experimental design and determinations of outcome. J Bone Joint Surg Am 1988; 70: 1357-1364 [PMID: 3182887]

53. World J Orthop 2014 November 18; 5(5): 623-633 ISSN 2218-5836 (online)

54. British Medical Bulletin 2008; 87: 131–161 DOI:10.1093/bmb/ldn023

55. Richards RR, An KN, Bigliani LU, Friedman RJ, Gartsman GM, Gristina AG, Iannotti JP, Mow VC, Sidles JA, Zuckerman JD. A standardized method for the assessment of shoulder function. J Shoulder Elbow Surg 1994; 3: 347-352 [PMID: 22958838 DOI: 10.1016/S1058-2746(09)80019-0]

56. Morrey BF, An KN, Chao EYS (1993) Functional evaluation of the elbow. In Morrey BF (ed.) The Elbow and Its Disorders, 2nd ed. Philadelphia: WB Saunders, 86–89

57. King GJW, Richards RR, Zuckerman JD et al. (1999) A standardized method for assessment of elbow function. J Shoulder Elbow Surg, 8, 351–354.

58. Streiner DL, Norman GR (1995) Health Measurement Scales: A Pratical Guide to Their Development and Use. New York, NY: Oxford University Press.

59. Kirshner B, Guyatt G (1985) A methodological framework for assessing health indices. J Chron Dis, 38, 27–36.

60. Sathyamoorthy P, Kemp GJ, Rawal A, Rayner V, Frostick SP (2004) Development and vali- dation of an elbow score. Rheumatology (Oxford), 43, 1434–1440.

61. Cochran WG. The distribution of quadratic forms in a normal system, with applications to the analysis of covariance. Math Proc Cambridge Philos Soc. 1934178–91.

62. Sharma VK, Jain AK, Gupta RK, et al. Non operative treatment of fractures of the humeral sfaft: a comparative study. Journal of the Indian Medical Association 1991;89:157–160.

63. Hunter SG. The closed treatment of fractures of the humeral shaft. Clin Orthop Relat Res 1982;(164):192-8.

64. Kesley et al,Methods in Observational Epidemiology, 2nd Edition,table 12-15

65. Kooistra BW,Dijkman BG,Busse JW, et al.The radiographic union scale in tibial fractures: reliability and validity. J Orthop Trauma 2010;24:S81 – S86.

66. Carl Bergdahl, Carl Ekholm, David Wennergren, Filip Nilsson, Michael Möller,Epidemiology and patho-anatomical pattern of 2,011 humeral fractures: data from the Swedish Fracture Register, BMC Musculoskelet Disord. 2016; 17: 159.

67. Ruturi Albert J.M, Seven month prospective study of patients enn at Kenyatta National Hospital with diaphyseal fracture of the humerus, Mmed Dissertation,Dept of Surgery UON, 2004.

68. Naddumba, E. A cross-sectional retrospective study of boda boda injuries at Mulago hospital in Kampala-Uganda.East Cent. Afr. J. Surg.2004,9,44–47

APPENDIX 1

Consent FORM

English version

This is an informed consent form for persons in the study whose title is **'Functional outcome in conservative management of diaphyseal humerus fractures – A comparative assessment on the use of a U-slab vis-a -vis functional brace'**.

Principal investigator: **Dr Munyuko Ephantus Mwangi**

Institution: School of Medicine, Department of orthopaedic surgery, University of Nairobi

Supervisors: **Dr Vincent Mutiso** and **Dr John King'ori**

This informed consent is in three parts

i. The Information sheet that seeks to give you details about the study
ii. The certificate of consent to append your signature if you agree to take part
iii. Statement by the principal researcher

PART 1: Information sheet

Study Background

My name is Dr Munyuko Ephantus Mwangi, a Postgraduate student at the School of medicine, University of Nairobi. I am conducting a research study titled **'Functional outcome in conservative management of diaphyseal humerus fractures – A comparative assessment on the use of a U-slab vis-a -vis functional brace'**

Diaphyseal Humerus shaft fractures are commonly encountered at Kenyatta National hospital and a majority of them are successfully managed conservatively commonly through the use of U-slab for about 8 - 12 weeks. In other parts of the world there is widespread of functional brace, which applied on first presentation or about a week after initial use of a u-slab.

Broad Objective

This study aims to explore the functional outcome after use of the two methods by assessing the shoulder and elbow functions and thereafter make a comparison to assess if there are benefits of use of functional brace over the u-slab with the aim of improving treatment of the said fractures at KNH.

Voluntariness of Participation

I would like to invite you to take part in this study. Participation is purely voluntary and you are allowed to consent either immediately after getting this information or after a period of consultation. You are free to ask any questions at any time regarding this study, or to seek any clarification from either myself or my research assistant. If you consent to participate in the study, some personal details as well as information concerning your condition will be sought. Withdrawal from this study can be done at any stage and will not affect your treatment at this hospital.

Confidentiality

You are guaranteed that all the information taken from you will be kept strictly confidential and will not be accessed by anyone other than the researchers and any other person authorized by the University of Nairobi/ Kenyatta National Hospital Ethics and research committee. This information will be coded with numbers such that only the researchers can identify you.

Risks

Participation in this study will be through a clinical interview and a clinical examination. You will not be exposed to any risks as you participate in this study.

Benefits

The Principal investigator and/or his research assistant will follow you up to completion of your treatment. Your participation in the study will help generate important information to the body of knowledge on the conservative management of humerus fractures.

There are no financial benefits attached to participation in the study

Part 2: Consent certificate:

I…….. freely give consent of myself /my proxy…….. to take part in the research study carried out by Dr Munyuko Ephantus Mwangi, the nature of which he/ his research assistant has explained to me. I understand that my participation in the study is purely voluntary and that I am free to withdraw this consent at any time. I also understand that withdrawing my consent will not affect the quality of care given to myself/my proxy at the Kenyatta National Hospital.

Signature of participant/Guardian/Next of kin…….

Date……..

I certify that the above consent has been freely given in my presence

Witness Name……..

Witness Signature…….....

Date……..

This study has been approved by the UON/KNH-ERC which is a body that ensures the protection of persons like you that take part in research studies.

This approval has been granted after submission of the study proposal to the committee by the Chairman of the Department of Orthopaedic Surgery, School of Medicine, University of Nairobi with the approval of a University supervisor.

In the event that you require any additional information or for any other purpose regarding this study, relevant contact details are listed below:

1. The Secretary, UON/KNH-ERC P.O.BOX 20723-00202

   KNH, NAIROBI.

   Tel: +254207263009

   Email:KNHplan@Ken.Healthnet.org

2. Dr. Munyuko Ephantus Mwangi

The Principal Investigator,

Department of Orthopaedic Surgery,

University of Nairobi

Tel 0720859179

Email: emunyuko@gmail.com

3. Dr. Vincent Mutiso,

The Lead Supervisor,

Department of Orthopaedic Surgery,

University of Nairobi

Tel 0723289922

Email: vmmutiso@gmail.com

Part 3: Statement by the researcher

I confirm that the information relating to this study as contained in the information sheet has been accurately read to the participant. I confirm that I have ensured the understanding of its contents by the participant who understands that:

- Declining to give consent or otherwise participate in this study will not affect the quality of care given at this institution
- All information provided by the participant will be kept strictly confidential
- The conclusions from this study may be used to influence local clinical and surgical practice

I further confirm that the participant has been allowed to seek clarification of all aspects of this study and that he/she has freely and willingly given consent. The participant has also been provided with a copy of the Informed consent form.

Name of researcher/ Research assistant……..

Signature…….

Date…….

Swahili Version

STAKABADHI YA IDHINI

Sehemu ya kwanza: Maelezo

Msingi wa Utafiti

Jina langu ni Daktari Ephantus Mwangi Munyuko, mwanafunzi katika Kitivo cha masomo ya Udaktari, Chuo kikuu cha Nairobi. Ninafanya utafiti kuhusu: - '**Matokeo baada ya matibabu kufuatia kuvunjika mfupa wa juu wa mkono kwa kulinganisha aina mbili ya tiba isiyohushisha upasuaji – Matumizi ya 'U-slab' au njia badala ya 'Functional brace'.**

Wagonjwa waliovunjika mfupa wa juu wa mkono huhuduiwa kwa wingi katika hospitali ya KNH.Wengi wao hawahitaji upasuaji ila wao hutibiwa kwa njia ya kutumia 'U-slab' kwa muda wa wiki nane hadi wiki kumi na mbili hivi hivi. Katika sehemu nyingine za ulimwengu, njia badala ya 'Functional brace' hutumika kutoka mwanzo, ama baada ya wiki moja, ikibadilishwa kutoka kwa 'u-slab'.

Lengo Kuu

Utafifti huu unalenga kuangalia matokea baada ya matibabu ya kutumia jinsi hizi mbili, kwa kukagua utendakazi wa viungo vya bega na kiniko.Matokea hayo yatalinganishwa ili kuibua kama kuna njia bora zaidi ya nyingine, kwa nia ya kubadili mfumo wa matibabu ya kuvunjika mfupa wa juu wa mkono hapa hosptali ya KNH.

Hiari ya kujumuishwa

Ningependa kukualika kujumuishwa kwenye utafiti huu. Kujumuishwa kwako ni kwa hiari na unayo haki kujiondoa kwenye utafiti huu wakati wowote. Idhini yako ya kujumuika unaweza kuipa maramoja baada ya kusoma nakala hii ama baada ya muda wa kufikiria. Unao uhuru wa kuuliza maswali yoyote kuhusu utafiti huu kutoka kwangu ama msaidizi wangu

Usiri

Ukikubali kujumuishwa kwenye utafiti,maelezo yako binafsi pamoja na maelezo ya ugonjwa wako yatachukuliwa. Utapatiwa hakikisho ya kwamba maelezo yote utakayotoa yatawekwa siri wala hakuna atakayeoona maelezo haya isipokuwa watafiti na watu waliokubaliwa na kamati ya uadilifu ya Hospitai kuu ya Kenyatta ikishirikiana na Chuo kikuu cha Nairobi. Nambari zitatumiwa badala ya majina ili kukinga maelezo yako.

Hatari

Maelezo yatachukuliwa kwa njia ya maswali pamoja na uchunguzi wa kimatibabu. Utafiti huu hautakuweka katika hatari yoyote.

Faida

Mtafititi mkuu na masaidizi wake watakufuatilia hadi umalize matibabu yako.Kushiriki kwa utafiti huu kutawezesha kuongezea ujuzi katika matibabu ya kuvunjika mfupa wa juiu wa mkono kwa njia badala na upasuaji.

Hakuna faida yoyote ya kifedha utakayopata kwa kushirirki kwa utafiti huu.

Sehemu ya pili: Idhini

Mimi……..nimekubali kwa hiari yangu/hiari ya mgonjwa niliyemsimamia…….kujumuishwa kwenye utafiti unaoendeshwa na Dr Munyuko Ephantus Mwangi, baada ya kupewa maelezo kamili na yeye/ msaidizi wake. Ninaelewa kuwa kujumuika kwangu ni kwa hiari na nina uhuru wa kujiondoa wakati wowote. Naelewa kwamba kujiondoa kwangu hakutaathiri kwa vyovyote kiwango cha huduma nitakayopokea katika Hospitali Kuu ya Kenyatta.

Jina la mgonjwa/Msimamizi wa mgonjwa……

Sahihi……

Tarehe……

Nimeshuhudia ya kwamba idhini ya mhusika imetolewa kwa hiari yake mwenyewe

Jina la shahidi……

Sahihi ya shahidi…….

Tarehe……

Ruhusa ya kufanya utafiti huu umepatiwa kutoka Kamati ya Uadilifu wa Utafiti ya Hospitali kuu ya Kenyatta ikishirikiana na Chuo Kikuu cha Nairobi, kupitia Mwenyekiti wa Idara ya Upasuaji, Kitivo cha Masomo ya Udaktari, Chuo Kikuu cha Nairobi.

Ikiwa unahitaji maelezo zaidi kuhusu utafiti huu, tafadhali wasiliana na wafuatao:

1. Katibu Kamati ya Maadili na Utafiti ya Hospitali kuu ya Kenyatta na Chuo kikuu cha Nairobi,

   SLP 20723-00202 KNH Nairobi

   Simu: +254202726300

2. Dr. Munyuko Ephantus Mwangi,

   Mtafitit Mkuu,

   Idara ya Upasuaji wa Mifupa, Shule ya utabibu, Chuo kikuu cha Nairobi,

   Simu: 0720859179

   Barua pepe: emunyuko@gmail.com

3. Dr. Vincent Mutiso,

   Msimamizi mkuu wa utafiti huu,

   Idara ya Upasuaji wa Mifupa, Shule ya utabibu, Chuo kikuu cha Nairobi,

   Simu:0723289922

   Barua pepe: vmmutiso@gmail.com

Sehemu ya tatu: Idhibati ya Mtafiti mkuu

Ninatoa idhibati ya kwamba maelezo kuhusu utafiti huu yametolewa kikamilifu kwa mhusika, na kwamba nimemsaidia kuelewa kwamba: Kutotoa idhini ama kujiondoa kwenye utafiti huu hautaathiri kwa vyovyote kiwango cha matibabu atakayopata katika hospitali hii, Maelezo yote yatakayotolewa yatawekwa siri, Matokeo ya utafiti huu yanaweza kutumiwa katika kuchangia ujuzi wa kubaini ugonjwa unaochunguzwa.

Ninatoa idhibati pia ya kuwa mhusika amekubaliwa kuuliza maswali yoyote kuhusu utafiti huu na kwamba ametoa idhini kwa hiari bila kulazimishwa. Mhusika pia amepewa nakala ya stakabadhi ya idhini.

Jina la mtafiti/ mtafiti msaidizi……

Sahihi……

Tarehe…….

APPENDIX 2

Procedure for u – slab application

The patient sits on a chair, supports the wrist with the uninjured hand so that the elbow is flexed at 90 degrees. Soft wool (orthoband) padding will be applied applied around the arm, two thicknesses in depth, except over the prominences of the elbow, where two extra turns are needed. The padding will extend from the top of the shoulder, over the lateral clavicle, to a point one third of the way down the forearm.

Using the uninjured contralateral extremity, the length of the POP used will be measured starting a hands breath from the base of axilla, around the inferior aspect of the elbow, over the top of the shoulder to the base of the neck. Eight thicknesses of 6 inch POP will then be cut according to the measured size and after immersing in tepid water for about 4 seconds; the excess water will be squeezed out and then applied as per the way it was measured. The slab will then be secured with a crepe bandage firmly enough to prevent it from falling off but avoiding constriction. Depending on the level of fracture, gentle molding will be used to resist dominant deforming forces. A collar and cuff arm sling will then be applied. An assessment of distal radial pulse, capillary refill and sensation will then be done after u slab application. A check x-ray will then be taken and if the alignment is not acceptable, the u-slab will be reapplied once again followed by another check x-ray. Patients who fail to have acceptable reduction on second attempt will be advised to undergo surgery.

APPENDIX 3

Initial Data Collection Form

A. BIODATA

i. Serial No ……

ii. D.O.B(Age) …….

iii. Gender M/F

iv. Occupation…….

v. Telephone No……..

B. INJURY CHARACTERISTICS

i. Date of injury……..

ii. Time of injury……..

iii. Date of initial hospital/point of care presentation…….

iv. Date of presentation at KNH/P.C.E.A kikuyu……..

v. Limb affected

a. Dominant

b. Non dominant

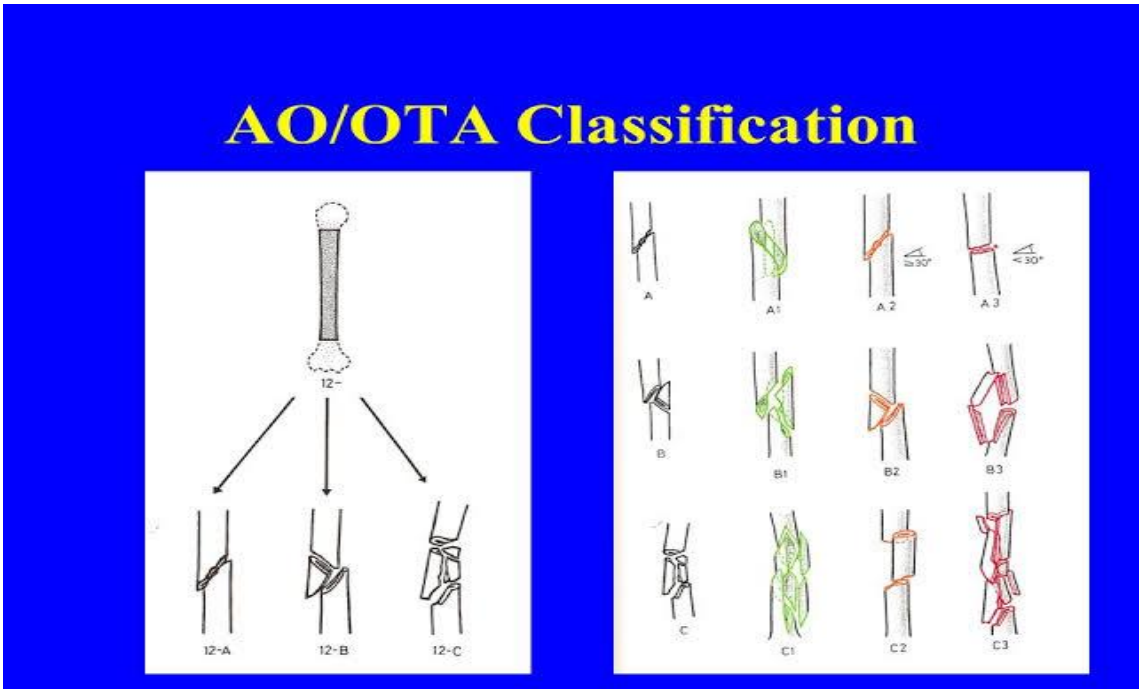
vi. Location of fracture at diaphysis

a. Upper 1/3

b. Middle 1/3

c. Lower 1/3

vii. AO Classification……..



viii. Injury mechanism

a. Motor vehicle accident
    i. Driver
    ii. Passenger
    iii. Pedestrian

b. Bodaboda accident
    i. Rider
    ii. Passenger
    iii. Pedestrian

c. Fall from height
    i. Standing height
    ii. Greater than standing height ……specify……

d. Assault

e. Others

specify…….

APPENDIX 4

RUST (Radiographic Union Score for Tibia)

SCORE PER CORTEX	CALLUS	FRACTURE LINE
1	Absent	Visible
2	Present	Visible
3	Present	Invisible

APPENDIX 5

Shoulder and Elbow functional assessment form at 12 weeks

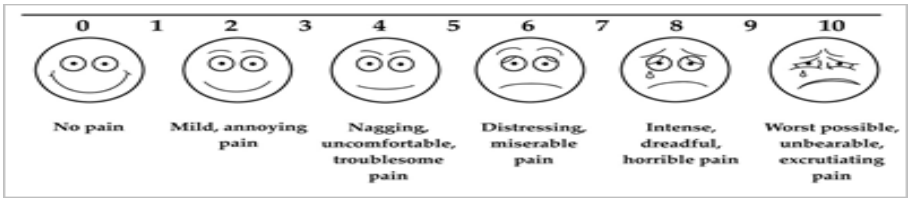
PART A

I. VISUAL ANALOG SCALE

a. Are you having pain in your shoulder?

YES……. NO……

b. How bad is your pain today (mark a number in the chart)



II. ACTIVITIES OF DAILY LIVING

Circle the number in the box that indicates your ability to do the following activities, using the affected limb:

0 = Unable to do; 1 = Very difficult to do; 2 = Somewhat difficult; 3 = Not difficult

Activity	**Ability**
1. Put on a coat	0 1 2 3
2. Sleep on your painful or affected side	0 1 2 3
3. Wash back/do up a bra in the back	0 1 2 3
4. Manage toileting	0 1 2 3
5. Comb hair	0 1 2 3
6. Reach a high shelf	0 1 2 3
7. Lift 10lbs(4.5 kg) above shoulder	0 1 2 3
8. Throw a ball overhand	0 1 2 3
9. Do usual work – List:	0 1 2 3
10. Do usual sport – List:	0 1 2 3

PART B

i. Do you have pain at the elbow?

YES……. NO……

ii. In your own assessment, what is the degree of pain you are experiencing, tick appropriately

MILD…… MODERATE……. SEVERE…….

iii. Tick whether you are able to perform the following activities, using affected limb

Activity	YES	NO
Comb hair		
Feed oneself		
Perform personal hygiene tasks eg tooth brushing		
Put on a shirt		
Put on shoes		

iv. Assessment of the elbow range of motion (circle appropriately)

a. Arc > 100 degrees
b. Arc 50 – 100 degrees
c. Arc < 50 degrees

v. Assessment of elbow stability – presence of varus/valgus elbow laxity (circle appropriately)

a. Stable
b. Moderately unstable
c. Grossly unstable

APPENDIX 6

The Mayo Elbow Performance Index Score

Variable	Definition	No. of points
PAIN (max., 45 points)	None	45
	Mild	30
	Moderate	15
	Severe	0
RANGE OF MOTION (max.,20 points)	Arc > 100 degrees	20
	Arc 50 to 100 degrees	15
	Arc < 100 degrees	5
STABILITY (max., 10 points)	Stable	10
	Moderately unstable	5
	Grossly unstable	0
FUNCTION – using affected limb (max., 25 points)	Able to comb hair	5
	Able to feed oneself	5
	Able to perform personal hygiene tasks	5
	Able to put on a shirt	5
	Able to put on shoes	5