OUTCOME OF CONSERVATIVE MANAGEMENT OF DISTAL RADIAL FRACTURES IN ADULTS AS SEEN AT KENYATTA NATIONAL HOSPITAL

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A dissertation submitted in part fulfillment of the requirements of the degree of Master of Medicine in Orthopaedic Surgery, University of Nairobi.

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DECLARATION

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

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LIST OF ABBREVIATIONS

KNH/UON-ERC: Kenyatta National Hospital/University of Nairobi-Ethics and Research Committee.

PRWE: Patient Rated Wrist Evaluation

TFCC: Triangular Fibrocartilage Complex

ORIF: Open Reduction &Internal Fixation

PA: Postero-Anterior (In radiograph view)

RTA: Road Traffic Accident.

K-Wire: Kirschner wire

SPSS: Statistical Package for the Social Sciences

ROM: Range of Motion

DRUJ: Distal Radio-Ulnar Joint

AO: Arbeitsgemeinschaft für Osteosynthesefragen

ABSTRACT

Background: Fractures of the distal radius are quite common accounting for around one sixth of all fractures seen in the emergency department in the USA. Locally, data on the prevalence of these fractures is scarce. Due to the shortage of qualified personnel and inadequate theatre facilities in Kenya, the majority of these fractures are managed conservatively. With closed reduction and casting proper joint alignment may not be achieved in some of intra-articular fractures, or in the case of extra-articular fractures, secondary collapse of the fragments may not restore the distal radial anatomy. Concerns over the morbidity thereof have resulted in a paradigm shift towards restoration of the articular congruency and bony anatomy of the distal radius operatively. The outcome of conservative management in resource limited settings has not been assessed locally.

Objective: To determine the outcome of conservative management of distal radial fractures in adults as seen at Kenyatta National Hospital (KNH).

Study design and setting: A prospective descriptive study on conservative management of adult patients with distal radial fractures presenting at KNH's fracture clinics and the Accident and Emergency (A&E) department, from June 2013 to October 2013.

Patients and methods: Seventy five skeletally mature patients, with unilateral closed distal radial fractures treated by closed reduction and casting, who consented to the study, were recruited. Outcome assessment was done at six weeks after cast removal. Outcome measures were assessed both objectively and subjectively. Objective assessment included wrist deformity based on a radiographic score determined by measuring the dorsal angle, ulnar variance and radial inclination on wrist radiographs; and the wrist function by measuring the range of motion and hand-grip strength. Subjective assessment was done using wrist pain and disability based on the patient rated wrist evaluation (PRWE) score. Data were analyzed using SPSS version 17.0. Chi-square test (χ^2) was used to determine whether the distribution of categorical variables differed from each other. The t-test was used to compare the means and correlation/association between variables.

Results:

The ages of patients ranged from 20 to 80 years with a mean of 42(±14) years, with a male to female ratio of 1:1. Fernandez type I fracture was the most common (48%) regardless of age and gender. Fernandez type III fractures were more common in females and older age-groups. A fall, in 45 patients (60%) was the most likely cause of the fractures more so in older age-groups while assaults and RTA contributed more common in young males. Majority of patients had a good radiographic score (59%), twenty nine percent had fair score, and 12% had an excellent one.

Sixty one patients (81.3%) had a good functional objective score, in 13.4% it was fair and 5.3% had an excellent score.

In the subjective assessment of pain and disability the PRWE score was highest in the 20-39 years age group at 45/100 and least in those at 60 and above years (35/100; p= 0.004). There was a positive correlation (p =0.023) between radiographic assessment and the objective functional assessment; however, there was no correlation between the radiographic score and the subjective assessment (p =0.952).

Conclusion:

At KNH, distal radial fractures occur uniformly across all adults' age-groups and affect males and females equally. The most common fracture is Fernandez type I caused mainly by falls, although there is significant contribution by RTA in younger males. The majority of the patients had a good radiographic score which correlated positively with the objective functional score, especially in the younger patients and simple extra-articular Fernandez type I and IV fractures; however, a good radiographic score does not seem to positively affect the subjective functional outcome. The patient's age is an important factor in the overall patient satisfaction regardless of the radiographic and the objective functional scores, hence to be considered during planning of treatment options.

INTRODUCTION

Fractures of the distal radius are quite common, accounting for around 17% of all fractures seen in the emergency department in the USA. At 300,000 injuries per year, they are the most common fractures of the upper extremity[1, 2.] In Kenya, data on their prevalence is not available.

Fractures of the distal radius are often associated with Abraham Colles, who described the fracture that bears his name as "a displaced fracture of the lower end of the radius within one and a half inches of the wrist joint." [3] Later on Smith described a fracture which is essentially the reverse of Colles' fracture, and then several eponyms followed.

Colles' statement of the wrist's ability to gain "perfect freedom in all of its motions and be completely exempt from pain" after this fracture adopted the concept of dealing with these fractures as a homogeneous group of injuries that could be primarily treated non-operatively with an expected good outcome[4].

Current practice has shown that the understanding of the geometry of the distal radius (figure 1) and biomechanics of the wrist joint are quite important in planning the treatment of these fractures. Fracture configuration including being intra or extra-articular, direction of displacement, dorsal or volar comminution, initial shortening, as well as the age of the patient, are of equal importance in planning the means of treatment and predicting the outcome[5]

The distal radius here refers to the metaphysis or the lower end of the radius within one and half inch from the wrist joint line. Several terminology are used to describe the distal radial geometry, these include:

Radial inclination: The distal radius articular surface inclines radially between 22° and 23° in the frontal plane.

Radial volar tilt: The joint surface slopes with an average palmar inclination of 10° to 12° in the sagittal plane.

Radial length: The distance between the tip of the radial styloid process and the distal articular surface of the ulnar head; this ranges from 11 to 12 mm.

Ulnar variance: This is the relative length between the articular surface of the ulna and the articular surface of the distal radius. While this usually varies between different populations, it ranges from 0 to -1 mm[6].

At normal ulnar variance, 80% of the load goes to the radius while, with negative ulnar variance of -2.5 mm, 95% of load goes through the radius and only 5% goes through the ulna. In positive

ulnar variance of +2.5 mm, 60% of load goes through the radius and 40% goes through the ulna which leads to ulnar sided wrist pain.[7, 8]

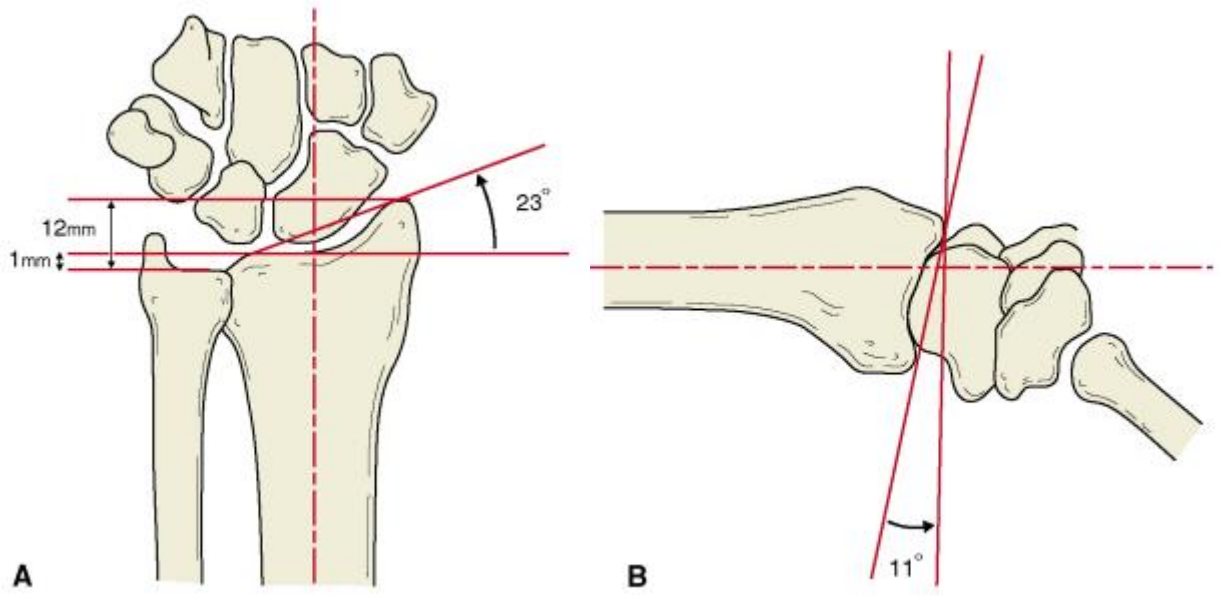


Figure 1: Distal radius geometry

A, Coronal plane showing measurements of the radiographic parameters of the distal radius and ulna. Radial inclination is the angle between the line from the tip of the radial styloid to the ulnar corner of the articular surface of the radius and the line perpendicular to the longitudinal axis of the rdial shaft (averages 23°). Radial length is the distance between the tip of the radial styloid and the articular surface of the ulna (average 12 mm). Ulnar variance is the difference in length between the ulnar and radial articular surfaces (shown as 1 mm ulnar-negative). **B,** Sagittal plane showing radial volar tilt from the perpendicular to the longitudinal axis of the radial shaft, (averages 11°).

Classification of distal radial fractures:

Numerous eponyms are applied to fractures in this region, resulting in considerable controversy in the literature regarding the classification, appropriate treatment, and anticipated outcome of these injuries. Fernandez developed a more useful and comprehensive classification based on the mechanism of injury which provides a better understanding of the various fracture patterns for the best method of reduction and fixation [9]

I. *Bending*—metaphysis fails under tensile stress (Colles' dorsal bending, Smith's volar bending)

II. *Shearing*—fractures of the joint surface (Barton's, dorsal and volar)

III. *Compression*—fracture of the joint surface with impaction of sub-chondral and metaphyseal bone (die-punch)

IV. *Avulsion*—fractures of ligament attachments (ulna, radial styloid)

V. Combinations of type I through type IV —high velocity injuries

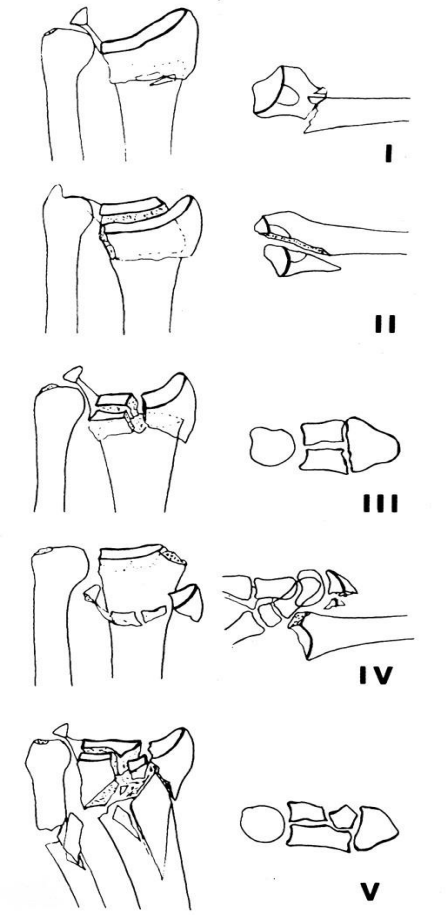


Figure 2: Fernandez classification.

PROBLEM STATEMENT

A better understanding of the geometry of the distal radius and the importance of its restoration in management of distal radial fractures has led to a paradigm shift towards operative management whenever appropriate. At Kenyatta National Hospital, and Kenya at large, several challenges including the trauma burden on theatre space, insufficient competent personnel, the and inaccessibility of implants due to cost has led to widespread use of conservative management of these fractures even in cases where operative treatment would be appropriate.

LITERATURE REVIEW

Distal radial fractures are common and can cause significant morbidity if not managed appropriately[2]. They are associated with complications influenced by several factors including the age and functional demands of the patient, and also injurious force and fracture pattern. These need to be considered while implementing different modalities of treatment.

Complications:

Dorsal angulation

One of the most common complications associated with distal radial fractures is secondary fracture displacement and loss of reduction after cast immobilization, which results in dorsal tilt or angulation. This is common in elderly patients over 60 years old who the lower bone density increases the risk of fracture comminution and intra-articular involvement. In addition, dorsal angulation of more than 20º, reduces fracture stability and can lead to subsequent displacement despite initial satisfactory reduction[10, 11]. In younger patients with higher bone density however, for fracture comminution leading to instability and subsequent collapse after casting to occur, high energy is required.[12]

Axial shortening

Radial shortening occurs as a result of fracture collapse. It should be considered and avoided while treating distal radial fractures because of the risk of poor functional outcome. A number of studies variably state the amount of radial shortening associated with poor functional outcome. In a study by Fuji et al[13] axial radial shortening of more than 6 mm was associated with poor functional outcome. Aro and Koivunen[7] on the other hand found that radial shortening between 3-5mm carried the risk of unsatisfactory functional outcome. The addition of dorsal angulation of more than 15º to radial shortening from as minimal as 2 mm has been shown to significantly worsen the functional outcome.[14, 15]

Ulnar wrist pain

Dorsal angulation of the distal radius may lead to distal radio-ulnar joint (DRUJ) incongruity, which has been found in fractures treated by closed reduction and casting, to be the most influential factor in predicting ulnar wrist pain[16]. Hollevoet *et al*[17] on the other hand found the increase in the ulnar variance as a consequence of radial shortening to be the most significant radiological parameter responsible for an unsatisfactory outcome.

Lindau et al[18], however, could not correlate DRUJ instability with any specific radiographic parameter and considered it as an independent factor affecting outcome.

In another series of 80 patients with distal radial fractures treated by different modalities, the author couldn't correlate an accepted anatomical reduction radiologically to a better outcome[19].

Grip strength weakness

Dorsal angulation of more than 10^0 results in DRUJ instability and dorsal shift of the mechanical axis along the radio-carpal joint, which was found by Gliatis et al[20] to be associated with weakness of the hand grip strength, impairment of daily life activities, work and overall patient satisfaction.

Effect on wrist motion

Maintenance of normal radial length and angulation is crucial in keeping functional wrist range of motion especially supination and pronation. Bronstein *et al* [21] showed that dorsal radial angulation and radial shortening can significantly reduce supination- pronation by up to 29% and 47% respectively. Hove *et al* [22] on the other hand found that radial dorsal angulation and ulnar plus deformity reduced range of motion in all directions.

Amongst the above mentioned complications, there is no consensus on which one affects wrist function most. Some studies show that the amount of residual wrist pain influences patient satisfaction more than motion.[23, 24.] Others like Karnezis *et al* [25] found that grip strength was the most sensitive parameter which affected the patient overall satisfaction after operative treatment of distal radial fractures based on the patient rated wrist evaluation (PRWE) score.

Treatment modalities

Closed reduction and cast immobilization remains the most common and accepted treatment for around 75% - 80% of the distal radial fractures based on the incidence of different types of these fractures[26]. In an epidemiological study in the United States by Fanuele J. *et al* [27], it was found that the older age-groups had the highest rates of distal radial fractures with 83% of them treated non-operatively. This could be probably due to their low functional demands or associated systemic co-morbidities which can make them poor operative candidates. Operative treatment, despite the attendant surgical risks, is recommended for patients with displacement following initial reduction, which is associated with poor functional outcome.[28, 29]

Treatment of Colles or Smith fractures (Fernandez I) non-operatively by closed reduction and casting usually gives good results in most cases; however in some cases reduction can be lost early in the treatment. Several studies have shown that closed reduction and percutaneous pinning reinforced by a below-elbow cast for distal radial fractures gives more superior results.[30, 31, 32, 33.] In a series of 30 patients with different types of distal radial fractures, Mam *et al* [34] found no difference in the functional outcome with closed reduction and K-wires fixation versus closed reduction and cast alone.

Fernandez type II distal radial fractures (Barton's, reverse Barton's) are intra-articular. Because of intra-articular involvement, restoring joint congruency by open reduction and internal fixation is required to prevent late arthritis. While they can also be managed non-operatively, immobilization of the wrist joint in extreme positions to maintain stability is required in such cases, yet displacement is still common. [35, 36] Koeing *et al*, found that internal fixation for these fractures using a volar plate, gives better results in terms of shorter rehabilitation time, union, and faster return to usual activities [37]

Fernandez type III fractures are caused by compression forces, which lead to intra-articular fracture with impaction of the underlying metaphyseal bone. Non operative means using traction to distract impacted metaphyseal bone to maintain radial length, followed by immobilization in a cast, can achieve acceptable reduction[38]. However operative treatment may be required if intra-articular damage or radial shortening is severe, or if fracture collapse after manipulation occurs. Operative options include fixation with multiple K-wires, plate and screws, combination of both open and closed techniques plus or minus using cancellous bone graft to fill impacted areas. [39, 40]

Fernandez type IV is an avulsion fracture of the radial styloid process with its ligamentous attachment, often associated with ulnar styloid fracture. Anatomic reduction of the radial styloid fractures is necessary to restore articular surface congruency and also to preserve the ligamentous architecture. Radial styloid fractures can often be reduced by closed means, but should re-displacement occur, fixation with K-wires and cast may be necessary[38].

Fernandez type V fractures are caused by high energy forces which usually lead to intra-articular comminution and impaction of the metaphyseal bone. The main aim in treating these fractures is to restore the articular surface to get the best possible function and to avoid late arthritis[41, 42]. Because of the nature of these fractures, restoring articular anatomy is not an easy task to achieve especially if comminution is severe. This gives an external fixator advantage over the volar locking plates as it can neutralize the compressive forces which caused comminution and impaction and hence restore radial length and align comminuted fragments by means of distraction. [43, 44, 45]

Observations from different studies have shown that disability does not necessarily result from loss of bony alignment. While surgeons do their best to achieve perfection, it seems that a certain degree of mal-alignment is tolerable. This is due to the fact that many patients are more satisfied with the relief of pain and grip strength, as opposed to anatomical restoration[46, 47, 48]. Graham *et al* [49], recommended restoration of the distal radial anatomy within established guidelines. The patient's functional activity level and general health dictate how closely these guidelines are followed. These are:

1. Radial shortening less than 5 mm at distal radio ulnar joint
2. Radial inclination on postero-anterior (PA) radiographs more than 15 degrees
3. Sagittal tilt on lateral projection between 15 degrees dorsal tilt and 20 degrees volar tilt
4. Intra-articular step-off or gap less than 2 mm of radio carpal joint
5. Articular incongruity less than 2 mm of sigmoid notch of distal radius.

Outcome measures:

There are numerous factors that affect patient satisfaction following a distal radial fracture, including anatomical alignment, age, motion and pain[47]. The overall outcome in the published literature is highly variable. It depends on many factors which differ from one patient to another depending on the difference in functional demands, expectations and pain tolerance. Elderly patients may tolerate greater degrees of residual deformity (up to 30° of dorsal angulation and 5 mm of radial shortening) because of their relatively low functional demands[50]. While in a series of 169 adults below the age of 50 years by Gilatis et al [20], found that only 10° of dorsal tilt was associated with much less patient satisfaction and difficulty in everyday activities.

To evaluate the outcome of a treatment method, appropriate, reliable and validated outcome measures that take into account all aspects of patient life that may be affected, are required.

Gartland and Werley[51] demerit point scoring system, which relies on the concept that a minimum range of motion is considered functional, is one of the very few outcome measures which provide an objective evaluation of the wrist function. That's why most investigators as well as in this study have relied on it despite the lack of validity studies.[52] However, this score doesn't consider other parameters which my influence the overall outcome such as the patient's ability to perform activities of daily living, the ability to return to previous occupations and pain[52]. The patient rated wrist evaluation (PRWE) scoring system which was developed by Macdermid et al[53] in 1998 and provide the patient with a tool to quantify wrist pain and disability, has been proven to be a reasonably reliable, valid and sensitive tool for assessing outcome in patients with distal radial fractures[54].

JUSTIFICATION

Distal radial fractures are quite common both in younger and old patients. At KNH, most of these fractures are managed conservatively regardless of the fracture type or age of the patient. This is occasioned by the never-ending trauma burden on the already overstretched theatre facilities. Determining the functional outcomes of this treatment modality in a resource-limited setting will help rationalize the current practice and give clinicians involved in the management of these fractures appropriate information in improving patient care including designing relevant treatment protocols.

OBJECTIVES

MAIN OBJECTIVE

To determine the outcome of conservative treatment of distal radial fractures in adults at KNH.

SPECIFIC OBJECTIVES

1. To determine the age and gender distribution of distal radial fractures and their relation to fracture type and mechanism of injury.
2. To determine the prevalence of pain, disability, deformity and stiffness in relation to fracture type.
3. To determine the association between radiological and functional outcomes at 6 weeks after cast removal.

PATIENTS AND METHODS

DESIGN

Prospective descriptive study.

SETTING

KNH fracture clinic, A&E department,

STUDY POPULATION

All skeletally mature patients above the age of 18 years old, with unilateral closed fractures of the distal radial coming for follow up at the fracture clinic at any stage of conservative fracture treatment were recruited after signing informed consent.

SAMPLE SIZE

The following formula was used to get the study sample size.[55]

$$n = \frac{4(Z^2)P(1-P)}{d^2}$$

n : Sample size

z: 1.96 for a confidence interval of 95%

p: Pre study estimate of the proportion to be measured (0.83)

d: Total width of the expected confidence interval (0.17)

Substituting the above in the formula **n** becomes = 75 patients.

SELECTION CRITERIA

Inclusion criteria

- Skeletally mature patients above 18 years old, with unilateral closed fractures of the distal radius.

Exclusion criteria

- Patients with compound, bilateral, highly comminuted intra-articular distal radial fractures (Fernandez V), which are considered absolute indication for ORIF, those with other injuries to the same upper limb which could have affected the functional outcome; presence of local or systemic neuromuscular condition that could affect the assessment of the functional outcome. Finally those patients who refused to give informed consent were also excluded.

METHODS

Patients who presented for review soon after cast application in the A&E department and those who were referred to the fracture clinics at KNH with casts applied in peripheral hospitals were recruited after fulfilling the selection criteria and giving a written informed consent.

Using a predesigned data sheet, relevant information was recorded. Demographic data included patient's age and sex while clinical information included the handedness, cause of the fracture, date of injury and cast application; fracture type based on Fernandez classification. Patients with fractures which after review by a consultant orthopaedic surgeon were scheduled for internal fixation were excluded from the study. Telephone contacts of the patients were then taken to ensure communication to assess progress and establishment of the time of cast removal and for booking an appointment to collect further data at or just after six weeks post cast removal. Reviews of patients was done at contact based on scheduled hospital appointments and only when such appointments were missed was the patient called to schedule assessment review for the study; those who were lost to follow-up were subsequently excluded. Due to the anticipated inconsistencies in the administration of physical therapy to the patients because of the variable access they had to such services, all patients were encouraged to perform active home-based wrist ROM exercises [56] (appendix III) after full explanation of the nature and frequency of these exercises.

At or just after 6 weeks post cast removal, the fracture sites were evaluated for range of motion at the wrist and distal radio-ulna joint and grip strength; these formed the basis for the objective functional outcome as per Gartland and Werley's demerit points scoring system. The functional outcome was further assessed but this time subjectively based on two parameters of pain and function consolidated in the Patient Rated Wrist Evaluation (PRWE) score. Radiographs of the healing fractured wrist taken at the time of cast removal were used to determine the radiographic score. On these films, the dorsal angle, the radial length and the radial inclination were determined. These were entered into Samiento's modification of Lidstrom's scoring system that formed the basis of the radiographic outcome.

RADIOGRAPHIC ASSESSMENT

The radiographic assessment was based on PA and lateral views radiographs of the involved wrist obtained after the fracture had united. Communication with hospital's radiology department and radiographers was made on a standardized technique of getting standard PA views[57] in which the wrist of the patient was flat on the radiographic table, elbow flexed at 90^0 and shoulder abducted at 90^0. For the lateral view, the patient's shoulder was abducted 90^0 with the upper limb fully extended and resting on its ulnar side on the radiographic table with the fingers slightly flexed in resting position.[57] Where digital films were taken, a magnification of 100% was used for standardization.

Scores which were assigned for each of the 3 measurements were added together and a final grade of excellent (0), good (1–3), fair (4 –6), or poor (7–12) was assigned.

Table 1: Radiographic scoring system modification of Lidstrom's scoring system by Sarmiento et al[58].

Final Dorsal Angle (°)	Loss of Radial Length (mm)	Loss of Radial Inclination(^{0})	Score for Each Measurement
Neutral	<3	0–4	0
1–10	3–6	5–9	1
11–14	7–11	10–14	2
≥15	≥12	≥15	4

FUNCTIONAL ASSESSMENT

Objective criteria

All measurement were performed by the principal investigator and a score was given according to Gartland[51] and Werley's demerit points scoring system (Table 2)

1. **Grip strength:**

This was done using a BASELINE® hydraulic hand dynamometer 200 lb**.** The non involved hand grip strength was measured as a reference (right-handed subjects are 10% stronger in grip strength on the dominant side while in left-handed subjects, the mean grip strength is the same for both hands) [59]. The patient was standing or sitting comfortably, the shoulder was adducted and neutrally rotated, elbows at 90^{o} flexion, forearm in a neutral position and wrist in a neutral position. The patient was asked to arrange the instrument so that it fits in his/her hand comfortably, and then was asked to squeeze with his maximum strength. Measurements taken were recorded in the corresponding part of the data collection sheet.

2. **Range of motion[60]:**

Measurement of involved wrist range of motion using a plastic goniometer was done as follows:

Flexion/extension (Figure 3)

Patient was sitting with the elbow flexed 90^{o} with the forearm pronated resting on a table; hand was in 0^{o} ulnar- radial deviation. The stationary arm of the goniometer was parallel to the longitudinal axis of the ulna (marked from olecranon to ulnar styloid processes)the moving arm was aligned to the lateral border of the 5th metacarpal and the fulcrum was just over the ulnar styloid process.

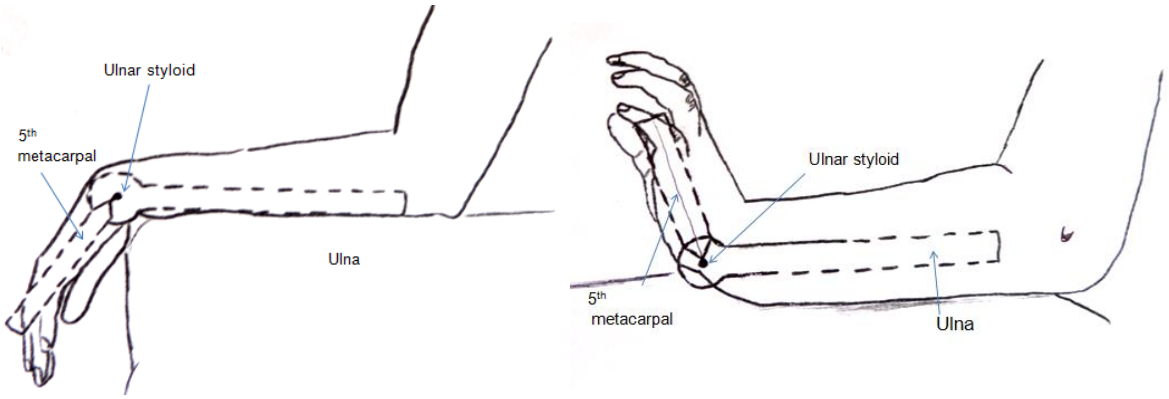


Figure 3: Flexion/extension

Radial/Ulnar deviation (Figure 4)

Patient was sitting with the elbow flexed 90^{o} with the forearm pronated resting on a table; hand was in 0^{o} ulnar/radial deviation and 0^{o} flexion/ extension. The stationary arm of the goniometer was over dorsal midline of forearm (reference lateral epicondyle of humerus), fulcrum was over the centre of dorsal aspect of the wrist over the capitates (dimple just proximal to the 3rd metacarpal bone) and the moving arm was parallel to the dorsum of the 3rd metacarpal bone

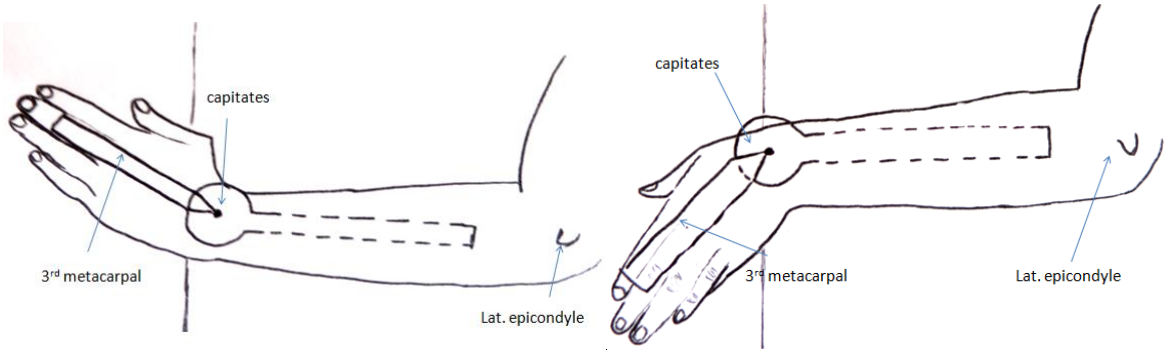


Figure 4: Radial/Ulnar deviation

Supination/pronation (Figure 5)

Patient was Sitting, shoulder in 0^{0} of flexion, extension, abduction, adduction, & rotation, Elbow flexed 90^{0}, Forearm supported by examiner, initially in 0^{0} pronation-supination, stationary arm of the goniometer parallel to the anterior midline of the humerus. When measuring supination the fulcrum was just lateral to the ulnar styloid process and the moving arm will be across the dorsal aspect of the wrist. When measuring pronation the fulcrum was just medial to the ulnar styloid process and the moving arm will be across the volar aspect of the wrist.

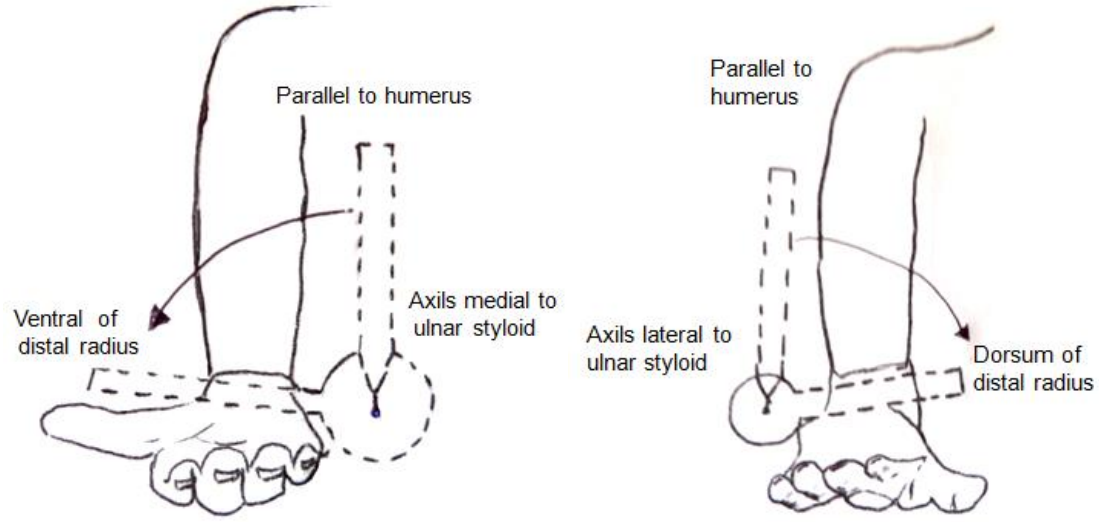


Figure 5: Supination/pronation

Table 2: Functional objective scoring according to Gartland and Werley's demerit points scoring system.

Movement	**Range**	**Score**
Extension	< 45º	5
Flexion	< 30º	1
Radial deviation	< 15º	1
Ulnar deviation	< 25º	3
Supination	< 50º	2
Pronation	< 50º	2
Grip strength	< 60%	1

Subjective criteria: (appendix I)

Subjective assessment of pain and disability was done using patient rated wrist evaluation (PRWE) score.

This is a 15-item questionnaire designed to measure wrist pain and disability in activities of daily living. The PRWE allows patients to rate their levels of wrist pain and disability from 0 to 10 and consists of 2 sub-scales of pain and function.

Computation of the sub-scales was done as:

Pain Score = Sum of the 5 pain items (out of 50) → Best Score = 0, Worst Score = 50

Function Score = Sum of the 10 function items,

Divided by 2 (out of 50) → Best Score = 0, Worst Score = 50

Patients answered the questionnaire after adequate explanation of all parts of the questionnaire in attendance of the investigator and language interpreter whenever was necessary. If the patient rarely perform the task he/she was encouraged to estimate the amount of pain or disability, and if still couldn't give an answer the question was left blank, and missing data were replaced by the mean score of the subscale.

Computing the Total Subjective Score:

Total Score = Sum of pain score + function score → Best Score = 0, Worst Score = 100.

DATA MANAGEMENT

Data were coded, entered and managed in a Microsoft Excel® 2007 database and later exported to the data editor of SPSS version 17.0 for analysis.

Continuous variables and are presented as means with standard deviation. Associations of continuous variables with the final outcome were demonstrated using Students t-test. Categorical variables were summarized using proportions. Associations of categorical variables with the final outcome were demonstrated using the Chi-square test.

All statistical tests were performed at 5% level of significance (95% confidence interval). The results of the study were presented in forms of tables, pie charts bar graphs.

ETHICAL CONSIDERATIONS

Approval for the study was sought from the University of Nairobi and the KNH ethics and research committee (KNH/UON- ERC) approval number A/162. All patients prior to enrolment into the study gave a signed informed consent either in English or Kiswahili depending on the language of their choice.

LIMITATIONS

- Inability to include wrist osteoarthritis as part of the outcome measures due to the short follow-up time.
- Difficulty to detect and/or assess other associated injuries like of carpal ligaments or the triangular fibrocartilage complex (TFCC) from plain radiographs, which could have affected the outcome.
- Reduction and plaster application was performed by different plaster technicians; this may have influenced the radiographic score in the patients.
- Despite attempts to unifying the physical therapy regime by offering a self-administered home-based protocol, it was not possible to verify its use in individual patients. This influenced the objective functional score.

RESULTS:

Seventy five patients fulfilled the selection criteria and were followed to up to the final assessment. To answer the secondary objectives, patients were divided into 3 age-groups (20-39years), (40-59years) and (>60 years).The characteristics of the patients were as shown in table 3.

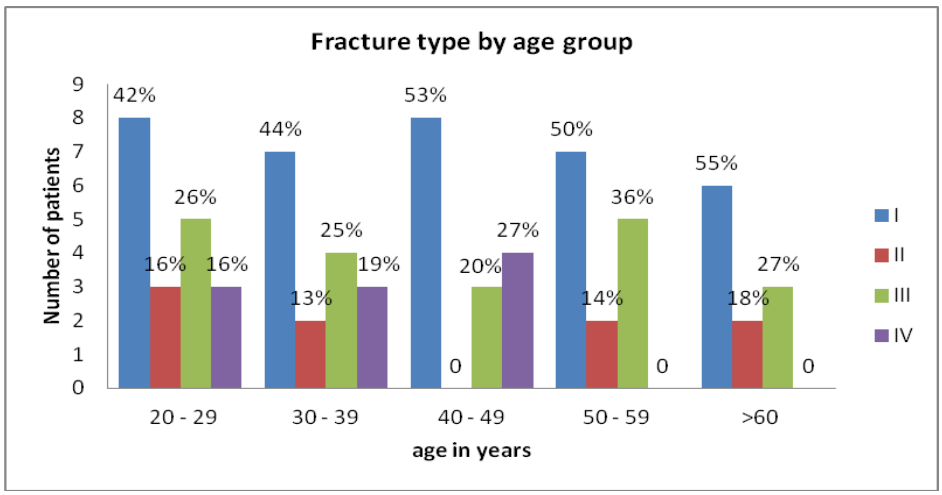
Table 3: Patients' demographics

	Overall (all patients in the study)
	n=75 (%)
Age	
20 – 39 years	35 (46.7%)
40 – 59 years	29 (38.7%)
>=60 years	11 (14.7%)
Gender	
Female:	38 (50.7%)
Male:	37 (49.3%)
Hand dominance	
Right	70 (93%)
Left	5 (7%)
Fracture type (Fernandez)	
I	36 (48%)
II	9 (12%)
III	20 (27%)
IV	10 (13%)
Mechanism of Injury:	
Fall	45 (60%)
Assault	8 (11%)
RTA	22 (29%)

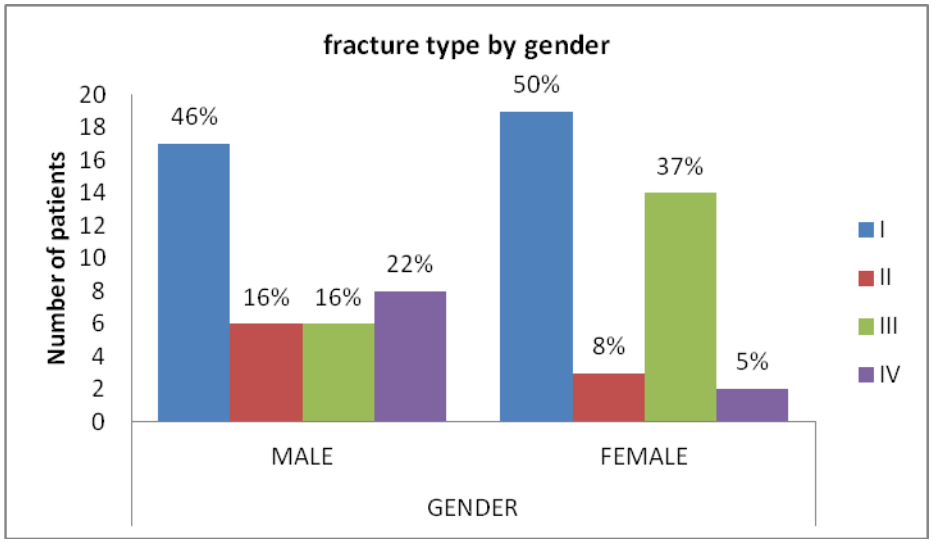
The mean age was 42 years (SD ± 14) years, with a range of 20-80 years. Most of the injuries were due to falls (60%) with majority of the fractures being Fernandez I at 48% regardless of age and gender. Fernandez type III fractures were more common in females and older age groups while Fernandez type IV was more common in males (p=0.04) and especially in the younger patients (**Figure 6A and 6B**)

Figure 6: Fracture type's distribution in age groups (A) and age (B).

A



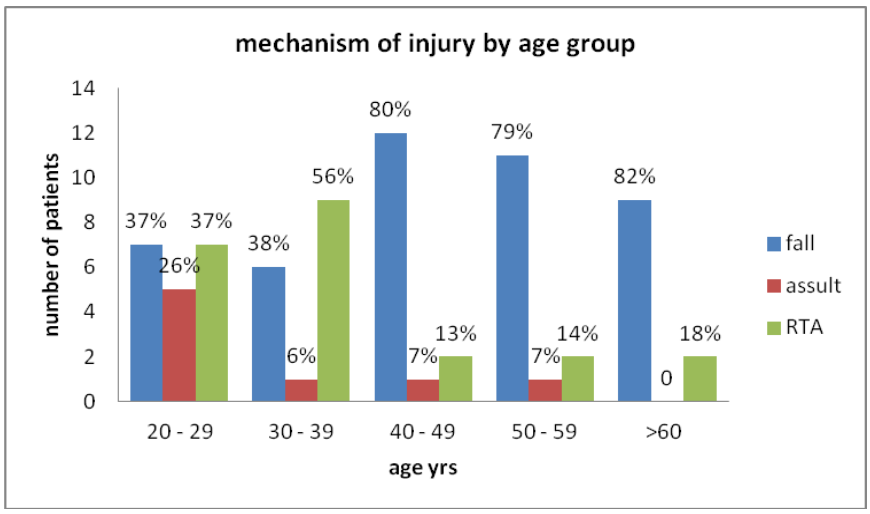
B



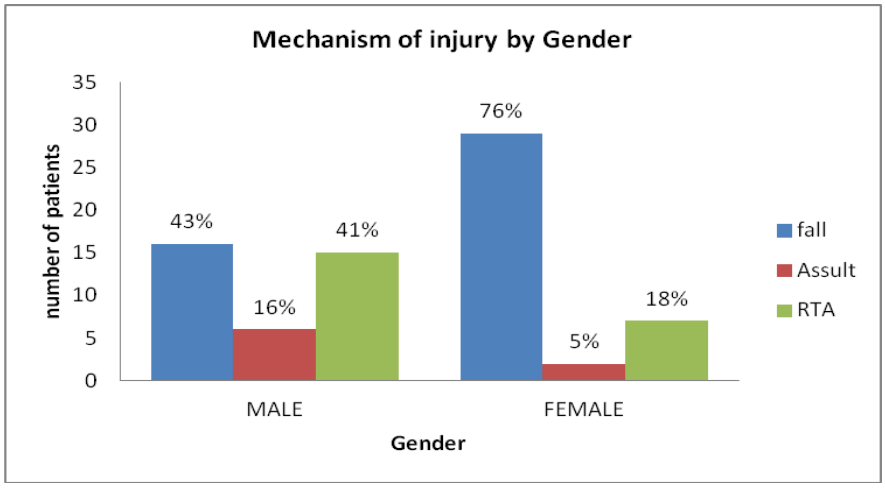
The most common overall mechanism of injury was falls, in (60%) of the patients; their proportional contribution increased with age in females. Assaults and RTA were more common in young males. **(Figure 7A and 7B).**

Figure 7: Distribution of mechanism of injury in relation to age (A) and gender (B).

A



B



On radiographic assessment, 44 patients (59%) had good radiographic score, 22 patients (29%) had fair, while 9 patients (12%) had an excellent radiographic score. None of the patients had a poor score. **(Figure: 8)**

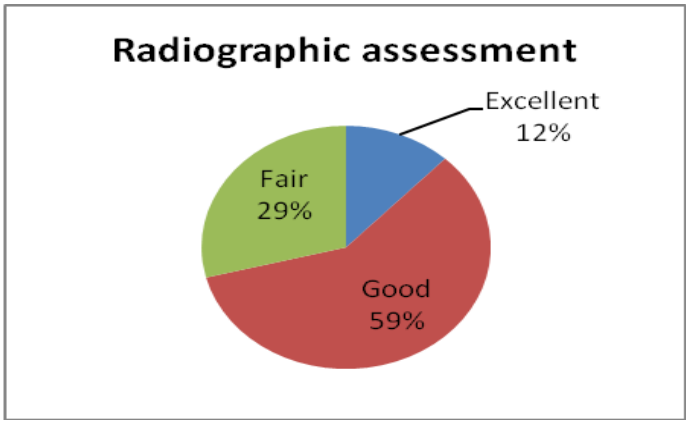
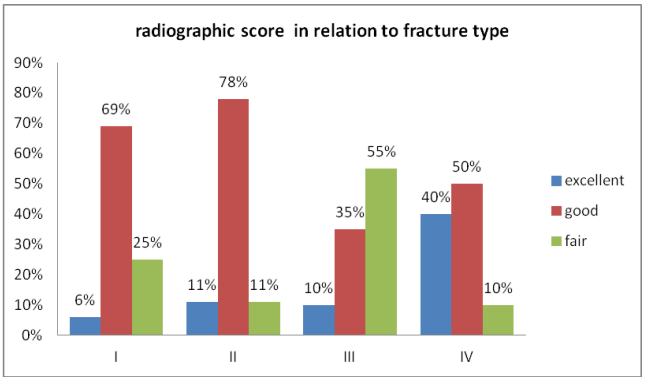
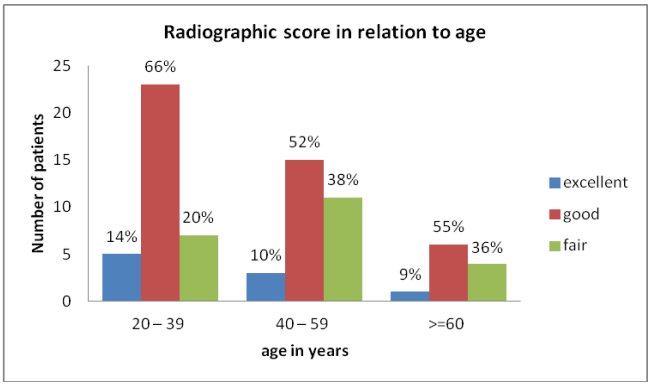


Figure 8: Overall radiographic scores.

Fractures type (IV) had the highest radiographic score followed by type (II) then type (I) , while fractures type (III) had the lowest radiographic score, (p =0.06). **(Figure: 9A).**

Figure 9: Radiographic score in relation to fracture types (A) and age (B).





A **B**

Younger age groups (20-39 years) had a higher radiographic score compared to older population especially those older than 60 years, (p= 0.589), **(Figure 9B).**

TABLE 4: Characteristics and the radiographic outcome

	Radiographic outcome			
	Excellent n=9 (%)	**Good n=44 (%)**	**Fair n=22 (%)**	**P value**
Age				
20 – 39 years	5 (14)	23 (66)	7 (20)	0.589
40 – 59 years	3 (10)	15 (52)	11 (38)	
>=60 years	1 (9)	6 (55)	4 (36)	
Injury mechanism:				
Fall	7 (16)	20 (44)	18 (40)	**0.041**
Assault	0 (0)	7 (88)	1 (12)	
RTA	2 (9)	17 (77)	3 (14)	
Fracture type				
I	2 (6)	25 (69)	9 (25)	0.06
II	1 (11)	7 (78)	1 (11)	
III	2 (10)	7 (35)	11 (55)	
IV	4 (40)	5 (50)	1 (10)	

In relating patient's characteristics to radiographic outcome, the most significant difference was in respect to the mechanism of injury ($p = 0.041$), where falls had less favorable radiographic score **(Table 4).**

On objective assessment of the wrist function, 61 patients (81.3%) had a good objective functional score, 10 patients (13.4%) had fair, while 4 (5.3%) had excellent functional objective score and none of the patients had a poor score**.(Figure 10).**

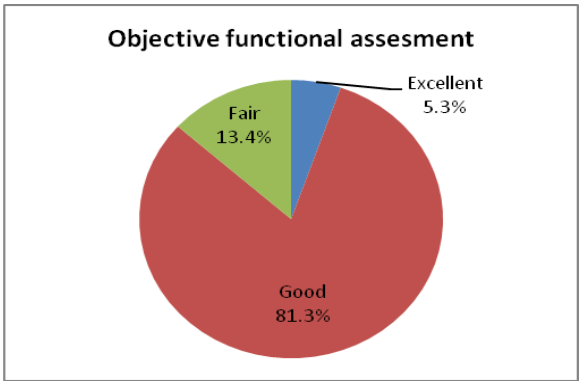
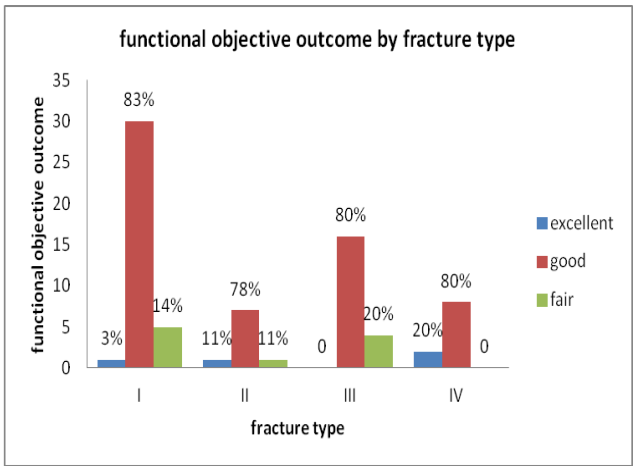


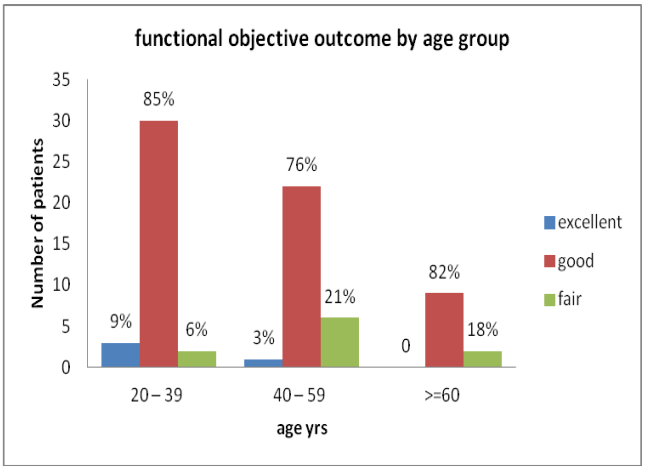
Figure 10: Objective functional score

Patients with Fernandez type IV fracture had a better objective functional score where 100% of the patients scored good to excellent, while those with type III had the least functional objective score however there was no significant difference (p=0.225), **(Figure 11A).**

Figure 11: Objective functional score in relation to fracture types (A) and age (B).



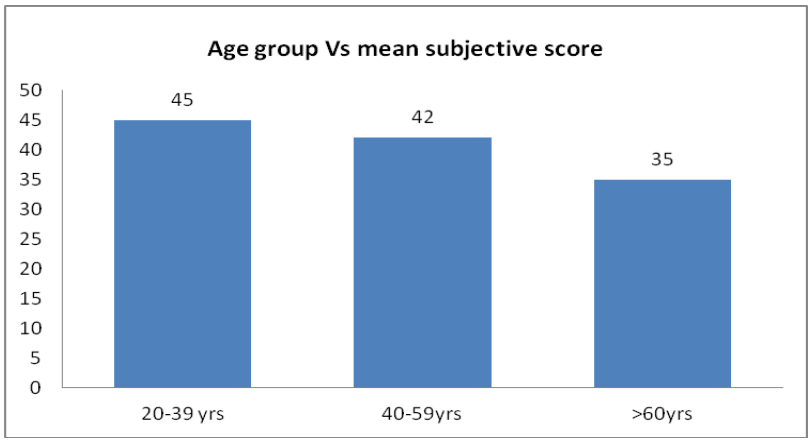
A



B

Patients in the age group of (20-39 years) had a higher functional objective score compared to older age groups however the difference was not significant (p= 0.336), **(Figure 11B).**

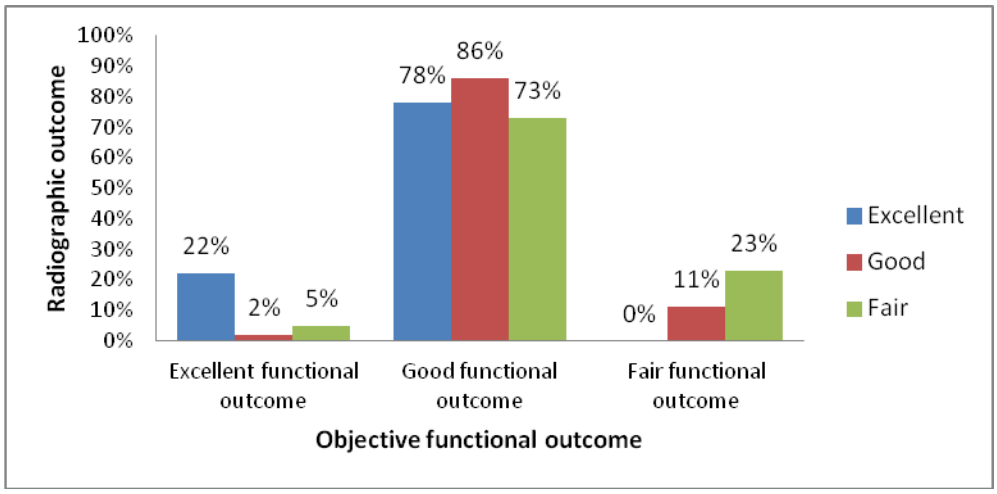
Figure 12: Association between age and subjective score



The mean subjective PRWE score in this age group (20 – 39 years) was the highest 45/100 which indicates less satisfaction, while in those above 60 years was the lowest 35/100 i.e. more satisfaction . There was a significant negative correlation between age and the mean PRWE subjective score (p= 0.004). **(Figure 12)**

This implies that older age groups had a lower (PRWE) score i.e. better subjective score despite lower radiographic and or functional objective score.

Figure 13: Association between radiographic and objective functional scores



There was a positive correlation between radiographic outcome and functional objective outcome. This shows that, the better the radiographic outcome the better the functional objective outcome. (p =0.023) **(Figure 13)**

However the correlation between the radiographic score and the subjective assessment was not statistically significant (p =0.952), which indicate that patient satisfaction was not necessarily related to good radiographs after treatment. **(Fig: 14)**

Figure 14: Association between radiographic and subjective scores.

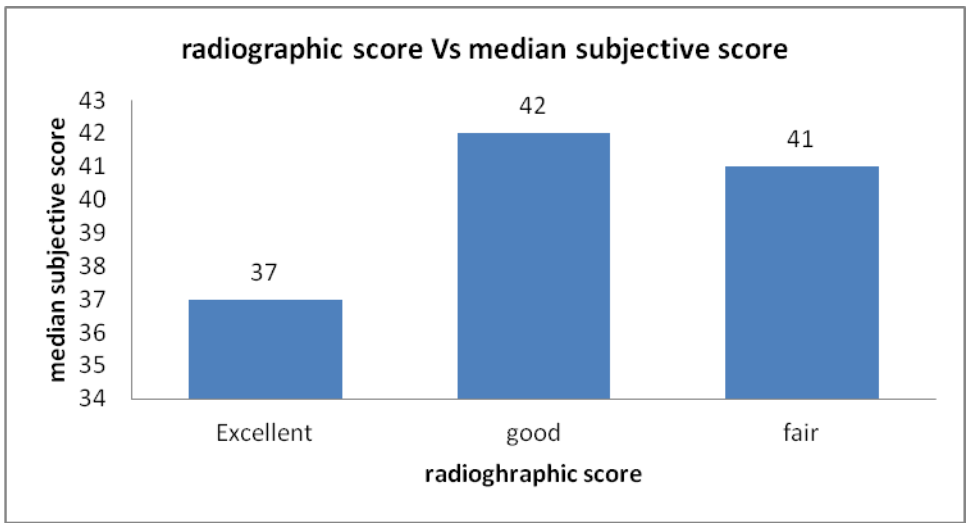
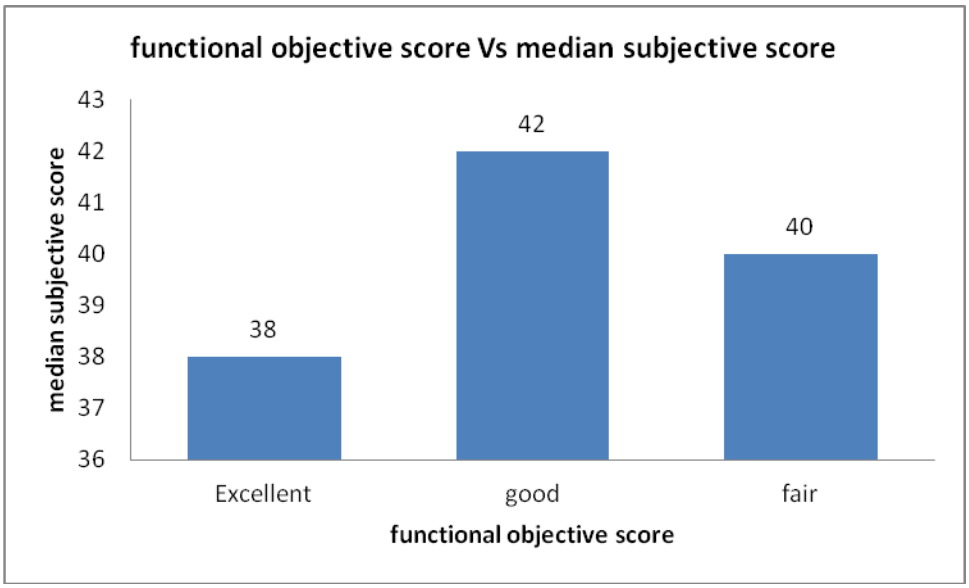


Figure 15: Association between functional objective and subjective assessment.



There was no correlation between the mean subjective PRWE score and the objective functional score (p=0.498), **(Figur15)**. This indicates that, better objective functional assessment is not always associated with higher patient satisfaction.

DISCUSSION

Fractures of the distal radius are common injuries in all age groups[61] with higher incidence in the elderly especially osteoporotic women[27]. Concerns arise about loss of reduction and the need to maintain joint congruency when such fractures are managed conservatively. Studies [62, 63, 64] which have looked at the effectiveness of conservative management of these fractures by casting alone are relatively scarce compared to those which discussed operative treatment. In Kenyan settings, where open reduction and internal fixation (ORIF) is not widely performed for such fractures because of resource limitations, the purpose of this study was to provide information about the outcome of conservative management of distal radial fractures locally.

In the current study, all adults' age groups were affected basically equally with a gender ratio of almost 1:1. This is similar to the findings of a study by Koo et al[61] and another study by Zoltan et al[62] in terms of different age groups representations however in these studies there was a peak incidence of distal radial fractures at the age group of 50-60 years, unlike the current study where there was no predominant age group with higher incidence of these fractures. This could be attributed to the relatively lower mean age of the current study (42 years) compared to the higher mean age of these studies (55 years) where osteoporosis is more common rendering the wrist vulnerable to fracture from minor trauma. In the current study, falls were the most common mechanism of injury which is similar to the findings of other studies[47, 61, 62]; however assaults and RTA significantly affected other patients especially younger males which explains the relatively equal distribution of fractures among age groups and both gender.

One of the challenges of comparing outcomes of the distal radial fractures is the variability of fracture classifications used in different studies. Fernandez classification was used in this study as it correlates the mechanism of injury to fracture pattern, outcome and options of treatment[9]. Young and Rayan[47] in their study in the USA used Frykman classification, while koo et al[61] in their study in Singapore and Zoltan et al[62] in their study in Sweden used the AO classification where AO class A (corresponding to Fernandez type I) was the commonest fracture type followed by AO class C (corresponding to Fernandez type III). These findings are similar to those of the present study possibly because of the similarity of the common mechanisms of injury.

Majority of patients in this study (71%) had good (59%) to excellent (12%) radiographic score while (29%) of the patients had fair radiographic score. These results are in keeping with what Young and Rayan[47] found in a series of 25 patients older than 60 years with distal radial fracture treated conservatively where (68%) of the patients had good (44%) to excellent (24%) radiographic score, while (8%) had fair, except that 24% of patients in that study had poor score while none of the patients in the current study had a poor radiographic score. This could be explained by the relatively low mean age (42 years) of the cohort of this study where there was a negative correlation between age and radiographic score. Anzarut et al[63], also found similar results in their study where Seventy-four patients who were at least 50 years of age with conservatively managed distal radial fractures were assessed radiographically. It was found that (64%) of patients were considered to have an acceptable radiographic reduction.

It was noticed in this study that there was a negative correlation between age and radiographic assessment where younger age groups especially (20-39 years) tend to have higher radiographic score compared to those above > 60 years probably due to lower bone density and higher risk of fracture displacement. This finding was also illustrated by Makhni et al,[64] in a study which assessed the radiographic outcomes of conservatively treated distal radial fractures of patients who were 18 to 44 years old (group 1), 45 to 64 years old (group 2), and older than65 years old (group 3). There was a positive correlation between the displacement rate and the increase in patients' age. (58% in group 1, 81% in group 2, and 89% in group 3); ($p = 0.03$).

In determining the correlation between fracture types and radiographic outcome it was found in this study that intra-articular comminuted fractures like Fernandez type III tend to have less overall radiographic score compared to extra-articular Fernandez type I fractures ($p = 0.06$). This is in keeping with the findings of Zoltan et al, [62] where patients who had an unsatisfactory radiographic outcome had sustained more displaced, higher AO class fractures that also healed with greater displacement. However this was different from the results of Beumer and McQueen[65] who found no correlation between fracture classification, initial displacement and the radiographic outcome.

This present study evaluated the functional outcome using Gartland and Werly score and the patient reported satisfaction using the PRWE score and correlated it to the radiographic outcome. It was found that, there was a positive correlation ($p = 0.023$) between radiographic outcome and the objective functional outcome. This shows that, the better the radiographic outcome the better

the functional objective outcome. Given the relatively low mean age of 42 years in this cohort, this finding is similar to what Gilatis et al[20], found in their study about outcome of distal radial fractures in young adults where minor dorsal tilt as low as 10^0 was associated with reduced wrist mobility and increased difficulty performing daily life activities. On the other hand, findings from other studies[19, 48,50,63,66] agreed that there was no correlation between acceptable reduction or better radiographic outcome and better objective functional assessment; however the mean age of the cohort in these studies was relatively high ranging from 60 – 65 years, compared to the mean age of this study. In other words, in younger age groups better radiographic outcome is associated with better functionality, unlike in elderly patients where this association is abscent. On assessing residual pain and disability using PRWE score, the findings in the current study were similar to several other studies[19, 48,50,63,66], where there was no correlation between the radiographic assessment and the patient reported satisfaction, meaning, that patient satisfaction was not necessarily related to good radiographs after treatment. Also similar to those studies there was no correlation between the functional objective score and the patient reported satisfaction.

Age was an important factor particularly on subjective assessment of the outcome and overall patient satisfaction. Comparing the mean subjective score per each age group, there was a negative correlation between age and the mean (PRWE) subjective score ($p= 0.004$). This implies that older patients tend to have lower (PRWE) score i.e. better subjective score despite lower radiographic and or functional objective scores, probably, due to lower functional demands. These findings are in keeping with the findings of some other studies[19, 47, 48, 50, 63, 66]. On the other hand younger age groups were less satisfied with their outcome regardless of the radiographic and or functional objective score, which is similar to Gilatis'[20] findings assessing the outcome of distal radial fractures in young adults.

CONCLUSIONS

- At KNH, distal radial fractures occur uniformly across all adults' age-groups and affect males and females equally.
- The most common fracture is Fernandez type I caused mainly by falls, although there is significant contribution by RTA in younger males.
- The majority of the patients had a good to excellent radiographic score which correlated positively with the objective functional score, especially in the younger patients; however, a good radiographic score does not seem to positively affect the subjective functional outcome.
- The patient's age is an important factor in the overall patient satisfaction regardless of the radiographic and the objective functional scores, hence to be considered during planning of treatment options.

RECOMMENDATIONS

- Where resources are limited, in younger patients with good bone quality, the simple uncomplicated Fernandez type fractures can be managed conservatively with expected good outcome. However in more complicated fractures factors like age and functional demands should be considered in planning the treatment.
- The positive correlation between radiological and objective functional outcome in younger patients suggests that regular follow-up radiographs are required to assess that reduction of the fragments is maintained till fracture union is achieved.
- Further prospective randomized studies with longer follow up periods should be done aiming to compare outcomes of different treatment modalities in different fracture types to be able to come up with a local standard protocol for managing these fractures locally.

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APPENDICES

APPENDIX I: <u>PATIENT RATED WRIST EVALUATION(PRWE)form</u>

*The questions below will help us understand how much difficulty you have had with your wrist in the past week. You will be describing your **average** wrist symptoms **over the past week** on a scale of 0-10.* Please provide an answer for **ALL** questions. If you did not perform an activity, please **ESTIMATE** the pain or difficulty you would expect**.** If you have **never** performed the activity, you may leave it blank

<u>1-PAIN</u>

Rate the average amount of pain in your wrist over the past week by circling the number that best describes your pain on a scale from 0-10. A zero (0) means that you did not have any pain and a ten (10) means that you had the worst pain you have ever experienced or that you could not do the activity because of pain.

Sample scale 0 1 2 3 4 5 6 7 8 9 10

No Pain Worst Ever

At rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with repeated wrist movement	0	1	2	3	4	5	6	7	8	9	10
When lifting a heavy object	0	1	2	3	4	5	6	7	8	9	10
When it is at its worst	0	1	2	3	4	5	6	7	8	9	10
How often do you have pain?	0 Never	1	2	3	4	5	6	7	8	9	10 Always

Pain score = the sum of patient's answer out of 50

2- FUNCTION:

A-SPECIFIC ACTIVITIES

*Rate the **amount of difficulty** you experienced performing each of the items listed below - over the past week, by circling the number that describes your difficulty on a scale of0-10. A **zero** (0) means you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do it at all.*

Sample scale 0 1 2 3 4 5 6 7 8 9 10

No Difficulty Unable To Do

Turn a door knob using my affected hand	0	1	2	3	4	5	6	7	8	9	10
Cut meat/vegetables using a knife in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Fasten buttons on my shirt	0	1	2	3	4	5	6	7	8	9	10
Use my affected hand to push up from a chair	0	1	2	3	4	5	6	7	8	9	10
Carry a 10 b object in my affected hand	0	1	2	3	4	5	6	7	8	9	10
Use bathroom tissue with my affected hand	0	1	2	3	4	5	6	7	8	9	10

B- USUAL ACTIVITIES

*Rate the **amount of difficulty** you experienced performing your **usual** activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities you performed **before** you started having a problem with your wrist. A **zero** (0) means that you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do any of your usual activities.*

Personal care activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

Function Score= (patient score in specific activities + patient score in usual activities)/2 out of 50

Total Score = patient pain score + patient function score out of 100

APPENDIX II : DATA COLLECTION SHEET.

Study number**……..**

PATIENT DATA:

1. Patient number……. Phone number:
2. Age in years …….
3. Sex : M ☐ F ☐
4. Dominant hand: R ☐ L ☐

FRACTURE DATA:

1. Injured hand: R ☐ L ☐
2. Mechanism of injury

   Fall ☐ Assault ☐ RTA ☐ Others ☐
3. Fracture classification according to Fernandez

   I ☐ II ☐ III ☐ IV ☐ V ☐
4. Radiographic assessment

parameter	measurement	score
Final Dorsal Angle (°)		
Loss of Radial Length (mm)		
Loss of Radial Inclination(°)		

Excellent (0), good (1–3), fair (4 –6), or poor (7–12).

Excellent ☐ good ☐ Fair ☐ Poor ☐

5. Functional assessment:

A- SUBJECTIVE:

PATIENT RATED WRIST EVALUATION (PRWE) form

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How often do you have pain?	0 Never	1	2	3	4	5	6	7	8	9	10 Always

Pain score =

2- FUNCTION:

A-SPECIFIC ACTIVITIES

*Rate the **amount of difficulty** you experienced performing each of the items listed below - over the past week, by circling the number that describes your difficulty on a scale of0-10. A **zero** (0) means you did not experience any difficulty and a **ten** (10) means it was so difficult you were unable to do it at all.*

Sample scale 0 1 2 3 4 5 6 7 8 9 10

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Work (your job or usual everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational activities	0	1	2	3	4	5	6	7	8	9	10

Function Score= /2 out of 50

Total subjective Score = …….+ …… out of 100

B- OBJECTIVE:

movement	**range**	**score**
Extension		
Flexion		
Radial deviation		
Ulnar deviation		
Supination		
Pronation		
Grip strength		

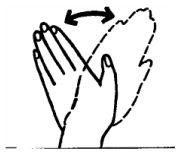
Total objective score:

Excellent (0 - 2) ☐ good(3 – 8) ☐ fair(9 – 13) ☐

poor (≥14) ☐

APPENDIX III: HOME SELF EXERCISE INSTRUCTIONS

Side to side movement (Queen wave) :



Rest your elbow on a table with the hand held up at face height. Support your forearm by holding with your other hand. Keep your forearm still whilst moving your hand from side to side to perform the 'Queen's wave'. Repeat 10 times

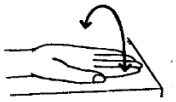
Prayer position :

With your forearms resting on a table, push palms together to perform the 'prayer' position. Hold for 10 seconds. Repeat 10 times

Flexion/extension:

Place your hand on a table with your hand relaxed over the edge of the table. Move your wrist up and down as far as you can. You can also use your other hand to give a little stretch. Repeat 10 times

Supination/ pronation:



Keep your elbow bent and tucked into your side. Turn your hand over so the palm faces the ceiling (ensure elbow is kept still) and then twist wrist so palm faces the floor. Repeat 10 times

Grip exercise:

Curl fingers round to make a fist and then fully straighten. Repeat 10 times

The previous exercises are very important part of your rehabilitation. They should be performed regularly at least twice a day. The discomfort in your wrist will reduce with exercise but your wrist is likely to ache until your wrist is fully mobile. Perform exercises slowly and gently to begin with. Should your symptoms worsen significantly please contact Dr. Alfons 0735698402

APPENDIX IV: CONSENT FORM

Study No……….

Hospital No……..

I'm Dr. Michael Alfons Shafek, a post graduate student at the University of Nairobi currently pursuing masters degree in. As part of my course work, I shall be carrying out a research entitled "Outcome of adults' distal radius fractures conservative management at Kenyatta National Hospital."

I wish to request you to participate in this study which has been approved by the department of orthopaedic surgery and University of Nairobi and Kenyatta National Hospital Ethics and Research Committee

The purpose of the study is to determine the outcome of treating distal radius fractures non operatively using closed reduction and plaster immobilization

In this study you will be asked to provide personal information after consenting to the study. During the treatment you will undergo plain x-ray for your wrist to check stability and healing of your fracture, and if the need arises, your fracture might need to be re-manipulated and plaster re-applied. This information will be treated with utmost confidentiality. There is no harm or risk anticipated for participating in this study. However, if a complication does arise appropriate treatment will be given. No additional tests outside the usual ones for treatment will be carried out and no extra cost to you will be incurred for participating in the study. Participation in this study is out of your own free will. Medical care will not be denied in case you decline to participate in the study. You may terminate participation at any time with no consequences whatsoever.

I …….. do hereby consent to participate in this study as explained to me by Dr. …… I have been informed of the nature of the study being undertaken and there are no risks or harm involved. I also understand that my participation in the study is voluntary and the decision to participate or not, will not affect my treatment in any way whatsoever. I may also choose to discontinue my involvement in the study at any stage without any explanation or consequences. I have also been assured that my personal details and the information I will relay will be kept confidential. I confirm that all my concerns about my participation in the study have been adequately addressed by the investigator.

Participant's signature (or thumb print) ……..

Date……

I confirm that I have clearly explained to the participant the nature of the study and the contents of this consent in details and the participant has decided to participate voluntarily without any coercion or undue pressure.

Investigator's signature……date……

Witness's signature…… ( )

For any enquiries, please contact:

1. DR.Michael Alfons
   Principal investigator
   Tel: 0735698402

2. Gitau Alice Wangari
   Research assistant
   Tel: 0726548558

3. CHAIRMAN,
   KENYATTA NATIONAL HOSPITAL ETHICS & RESEARCH COMMITTEE
   Tel: 020-2726300. Ext: 44355

CHETI CHA KUKUBALI

Nambari ya utafiti .....

Nambari ya Hospitali .....

Mimi Dr Michael Alfons Shafek, mwanafunzi Uzamili katika Chuo Kikuu cha Nairobi na sasa natafuta shahada ya mabwana katika ..... Kama sehemu ya kozi yangu, mimi natakiwa kufanya utafiti uitwao ‘Matokeo ya radius ya watu wazima distal fractures usimamizi kihafidhina katika Hospitali ya Taifa ya Kenyatta. "

Napenda kuomba wewe kushiriki katika utafiti huu ambao umepitishwa na idara ya upasuaji wa mifupa na kuidhinishwa na Utafiti wa Maadili na Kamati ya Chuo Kikuu cha Nairobi na Hospitali ya Taifa ya Kenyatta.

Madhumuni ya utafiti ni ya kupanga matokeo ya kutibu distal Radius fractures bila upasuaji mbali kutumia kupunguza funge na utohamasishaji wa plasta.

Katika utafiti huu unatakiwa kuulizwa kutoa taarifa binafsi baada ya kukubali kujihusisha na utafiti.

Wakati wa matibabu, wewe utapigwa picha ya x-ray kwa mkono wako ili kuangalia utulivu na uponyaji wa fracture yako, na kama kuna mahitaji, fracture yako itahitaji kughilibiwa tena na plasta kutumiwa tena. Habari hii itatibiwa na usiri mkubwa. Hakuna madhara au hatari kutarajia kwa ajili ya kushiriki katika utafiti huu. Hata hivyo, ikiwa matatizo yatatokea, matibabu sahihi yatapeanwa. Hakuna vipimo za ziada nje ya zile za kawaida kwa ajili ya matibabu utakayofanyiwa na hakuna gharama za ziada kwa ajili ya kushiriki katika utafiti. Kushiriki katika utafiti huu ni nje ya mapenzi yako mwenyewe. Huduma ya matibabu haitakanwa katika kesi ya kukataa kushiriki katika utafiti. Unaweza kuondoa ushiriki wako wakati wowote bila madhara yoyote.

Mimi ..... nimekubali ridhaa ya kushiriki katika utafiti huu kama nilivyoelezewa na Dr ..... Nimefahamishwa asili ya utafiti unaofanywa na hakuna hatari au madhara kushiriki. Mimi pia naelewa kwamba ushiriki wangu katika utafiti ni wa hiari na uamuzi wa kushiriki au la, hauwezi kuathiri matibabu yangu katika njia yoyote. Naeza kuchagua kuacha kujihusisha katika utafiti wakati wowote bila maelezo yoyote au madhara. Mimi pia nimekuwa na uhakika kwamba maelezo yangu binafsi na taarifa mimi

itakuwa siri. Nathibitisha wasiwasi kwamba kuhusu ushiriki wangu katika utafiti wangu wote umekuwa wakutosha kushughulikiwa na mpelelezi.

Sahihi ya mshiriki (au chapa ya kidole gumba) .....

Tarehe .....

Mimi nathibitisha wazi kwamba nilielezea mshiriki asili ya utafiti na yaliyomo ya idhini hii katika maelezo na mshiriki ameamua kushiriki kwa hiari bila kulazimishwa au shinikizo visivyofaa.

Sahihi ya Mpelelezi ..... Tarehe .....

Sahihi ya Shahidi .....

Kwa maswali yoyote, tafadhali wasiliana na:

1. DR. Michael Alfons

   Mpelelezi Mkuu

   Simu; 0735698402
2. Gitau alice wangari

   Research assistant

   Simu; 0726548558
3. Mwenyekiti,

   Kamati ya Maadili na Utafiti, Hospitali Taifa Ya Kenyatta,

   Simu: 020-2726300 Ama: 44355

APPENDIX V: APPROVAL FROM KNH/UON-ERC

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

Link:www.uonbi.ac.ke/activities/KNHUoN

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/162

19th June 2013

Dr. Michael Alfons Shafek
Dept. of Orthopaedic Surgery
School of Medicine
University of Nairobi.

Dear Dr. Alfons

RESEARCH PROPOSAL: OUTCOME OF CONSERVATIVE MANAGEMENT OF DISTAL RADIUS FRACTURES IN ADULTS AT KENYATTA NATIONAL HOSPITAL (P485/08/2012)

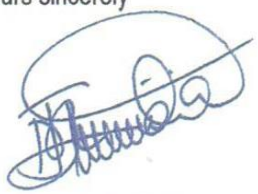
This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 19th June 2013 to 18th June 2014.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN:**

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

c.c. Prof. A.N. Guantai, Chairperson, KNH/UoN-ERC
The Deputy Director CS, KNH
The HOD, Records, KNH
Principal, College of Health Sciences, UoN
The Dean, School of Medicine, UoN
The Chairman, Dept. of Orthopaedic Surgery, UoN