

**OUTCOMES OF OPERATIVE MANAGEMENT OF HUMERUS FRACTURE
NONUNION AMONG ADULTS ATTENDING MOI TEACHING AND
REFERRAL HOSPITAL, ELDORET, KENYA**

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**THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE
REQUIREMENT FOR AWARD OF THE DEGREE OF MASTER OF
MEDICINE (ORTHOPEDIC SURGERY) OF MOI UNIVERSITY**

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DECLARATION

Declaration by candidate

I declare that this thesis is my original work, and that it has not been presented elsewhere for academic purposes or otherwise to the best of my knowledge. The research work was carried out while pursuing my Master of Medicine in Orthopedic Surgery course at the Moi University, School of Medicine. No part of this work may be reproduced without permission of the author and/ or Moi University.

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DEDICATION

I dedicate this thesis to my loving wife Eva for her support and encouragement in writing this thesis and to my children Ian, Ryan and Ethan, for their unwavering support and motivation.

ABSTRACT

Background: Humeral fracture account for 5-8% of all fractures in adults. Most of these fractures tend to heal; however, up to 33 % will develop nonunion which is failure of fracture healing in consecutive 9 months without intervention. Humeral fracture nonunion causes major functional disability, chronic pain and reduced quality of life. The incidence of humerus fracture nonunion cases at the Moi Teaching and Referral Hospital (MTRH) has increased by 25% in the last five years. Data on the functional outcomes of operational management of humeral fracture nonunion at MTRH are scanty. This study intends to close the knowledge gap and advance the field.

Objective: To evaluate the outcomes of operative management of humeral fracture nonunion among adult patients attending the Moi Teaching and Referral Hospital, Eldoret Kenya.

Methods: This study was a hospital based descriptive prospective study involving 32 adult patients with humerus fracture nonunion attending the MTRH, Orthopedics unit. Upon meeting ethical considerations, patients who met inclusion criteria and consented were recruited and followed up for a period of 12 months (September, 2021-August, 2022). Data was collected using a structured interviewer administered questionnaire, the Non-Union Scoring System (NUSS) and the American Shoulder and Elbow Surgeons (ASES) Score sheets. The demographic characteristics, the initial injury patterns, operative modalities used and union rate were recorded and analyzed. The functional outcomes were assessed using the ASES score tool at 6, 12, 18 and 24 weeks after the operation.

Results: The mean age was 52.2 years (SD: 11.84) with male predominance. The left hand was more injured than the right (59.4%). Cigarette smoking and alcohol use were recorded in 9 and 17 respondents respectively. The humerus shaft was the most affected site (18, 56.25%). The mechanism of injuries was Road Traffic Accident (26), falls (4) and physical assaults (2). The mean time to diagnosis of nonunion was 10 months (SD: 1.9). The mean NUSS score was 23.34 points (SD: 3.15). Open Reduction Internal Fixation (ORIF) plating and autologous bone grafting were used in all the patients. Union rate of 96.2% was achieved at mean time of 21 weeks (SD: 4.5). The mean ASES score at week 6 and week 24 was 29.89 points (SD: 12.67) and 78.98 points (SD:6.86) respectively. Surgical wound infection and radial nerve palsy was encountered in 3(9.3%) and 2(6.25%) respectively. Bivariate analysis using Fischer's exact test showed no association between smoking, alcohol use, gender and improved ASES ($p >0.05$). Younger age and earlier diagnosis of humerus nonunion were associated excellent union ($p <0.05$).

Conclusion: A union rate of 96.2% and improved functional outcomes with few complications was achieved following the use of ORIF plating with autologous bone graft in the operative management of humerus nonunion at MTRH.

Recommendations: The use of rigid plate fixation with autologous bone grafting is recommended in the operative management of humerus fracture nonunion as it is associated with good functional outcomes. Further studies are needed to evaluate long term functional outcomes

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LIST OF ABBREVIATIONS AND ACRONYMS

ASA	America Society of Anesthesiologist
ASAMI	Association for the Study and Application of Methods of Ilizarov
ASES	American Shoulder and Elbow Surgeons
BMA	Bone Marrow Aspirate
BMPs	Bone Morphogenetic Proteins
DBM	Demineralized Bone Matrix
FDA	Food Drug Administration
MTRH/MU-IREC	Moi Teaching and Referral Hospital/Moi University Institutional Research and Ethics Committee
ISS	Infection Severity Score
MCID	Minimal Clinically Important Differences
MSCs	Multipotent Stem Cell
MTRH	Moi Teaching and Referral Hospital
NUSS	Non-Union Scoring System
OPD	Out-Patient Department
ORIF	Open Reduction and Internal Fixation
PDGF	Platelet Derived Growth Factor
RANK-L	Receptor Activator of Nuclear B ligand

rhBMPs	Recombinant Human Bone Morphogenetic Proteins
RUST	Radiographic Union Scale in Tibial Fractures
TNF-α	Tumor Necrosis Factor
VEGF	Vascular Endothelial Growth Factors

OPERATIONAL DEFINITION OF KEY TERMS

Adult: Any patient aged 18 years and above.

ASES: A functional outcome assessment for the shoulder and elbow, clinician and patient administered.

Fracture: A break in the cortical continuity of a bone.

Functional Outcome: It refers to the measurable goal that helps a patient perform specific activities of daily living after operative management.

Humerus: The humerus is a long bone of the upper limb, which extends from the shoulder joint to the elbow joint.

Nonunion: A fracture that persists for a minimum of 9 months without signs of healing for three months.

NUSS: (Non-Union Scoring Score) A classification of nonunion according to their severity and relates them to four treatment categories.

Operative Management: Surgical procedure performed to correct the humerus fracture nonunion.

ACKNOWLEDGEMENT

I wish to thank the Almighty God for the chance given to undertake this study. I also acknowledge the Moi University and specifically the School of Medicine and the Moi Teaching Referral Hospital, Department of Orthopedics and Rehabilitation for the opportunity to undertake this study. I sincerely wish to thank my supervisors Dr. B. R. Ayumba and Dr. J. Kisorio, for their guidance and support during writing of this thesis. My appreciation also goes to all the Lecturers in the Department of Orthopedics and Rehabilitation, Moi University and the Moi Teaching and Referral Hospital for their invaluable input during this process as well as to all my colleagues and everyone else for their invaluable guidance and support during the development of this thesis.

CHAPTER ONE: INTRODUCTION

1.1 Background information

Fracture nonunion is a serious complication that can occur in any bone healing process following a fracture. The Food and Drug Administration (FDA) defines fracture nonunion as a failure of bone healing lasting more than nine months without any sign of healing for three consecutive months. It occurs when the biological process of bone healing cannot overcome the local biology and mechanics of the bone injury (Thomas & Kehoe, 2023).

Many factors contribute to proper bone healing following a fracture, including host factors, biological factors and mechanical factors. Patient, fracture type, surgeon and clinical factors should be considered and implemented for adequate bone healing to occur. The main patient factor in nonunion is inadequate blood supply. A decrease in the blood supply to the fracture site leads to delayed bone healing and nonunion. Lifestyles activities like chronic smoking and poor nutritional status contribute to poor blood supply (Xu, et al., 2021). The presence of systemic diseases like diabetes mellitus, renal insufficiency and peripheral vascular disease cause poor blood flow and poor bone healing. Prolonged use of some medications like steroids, non-steroidal anti-inflammatory drugs and opioids prolong the fracture healing process. The main determinant in fracture nonunion for patient factors is inadequate blood flow. Bone loss with a gap bigger than 3 mm, heavily comminuted, and butterfly fragments are fracture pattern characteristics that cause nonunion. Early bone healing and function restoration are caused by a balance among all the elements (Mills, et al., 2016).

According to Driesman and others, (2017) the presence of fracture site mobility at six weeks following humerus shaft fractures is a good predictor of nonunion. For such

patients they recommended that there is need for close follow-up and consideration for early surgical options (Driesman, et al., 2017). However, the process of bone healing may result in fracture nonunion, which would put the patient and their caretakers through prolonged discomfort, limb deformity, and a significant financial burden. For the majority of them to restore full functional status, surgery or other forms of intervention are required. It is advised to optimize every element that could result in nonunion. Fracture nonunion presents a multifactorial complex orthopedic problem that requires clinicians to implement various interventional modalities

Clinical and radiological assessment can identify humerus fracture nonunion early enough for appropriate action to be planned. The presence of persistent pain and significant functional limitation are a common feature. Gross mobility at the fracture site with significant deformity is also seen in cases of humerus fracture nonunion. Radiologically, plain radiography shows evidence of fracture healing includes cortical bridging of the fracture line. The most reliable method of identifying humerus fracture nonunion is the use of callus scoring criteria that reduce the subjectivity of the assessor. The use of modified Radiographic Union Scale for the Tibia (RUST) for the humerus diaphyseal fractures at six weeks post injury was well described by Oliver and others (Oliver, et al., 2019). The score ranges from 4 to 16, with a score of four representing no callus on any of the four cortices while a score of sixteen represents a complete remodeling of all the four cortices. The Radiographic Union Score for Humeral fractures (RUSHU) is a reliable and effective in identify patients at risk of Nonunion (Oliver, et al., 2019).

Other investigations that are needed to rule out infectious process include C-reactive proteins (CRP), Erythrocyte Sedimentation Rate (ESR) and Complete Blood Count (CBC).

Operative management of humerus fracture nonunion depends on the nonunion severity as scored using the Nonunion Scoring System (NUSS), presence of complications like infections and presence of other comorbidities. Multiple surgical techniques exist and this should be tailored to the patient's specific needs. Plate fixation, intramedullary nails and external fixation are the commonest surgical treatment methods used to treat humerus fracture nonunion. For cases with bone loss, external fixation, vascularized bone grafts and cortico-cancellous bone grafts are used. Locking plates have been shown to achieve higher union rates when compared with other plate constructs (Zastrow, et al., 2020). Favorable functional outcomes have been documented in the use of fibular allograft in treating distal humerus and mid shaft humerus nonunion (Fink Barnes, Ruig, Freibott, Rajfer, & Rosenwasser, 2020).

The outcomes of operative management include clinical evaluation of the union, the range of motions, functional outcomes and complications. The union of the fracture line is determined using serial post-operative plain radiographs. The presence of cortical callus bridge is a good sign for predicting union in long bones (Nicholson, et al., 2021).

Functional outcome of operative management of humerus nonunion can be assessed using validated scoring systems. The American Shoulder and Elbow Surgeons (ASES) score (**Appendix VII**) has been validated (Michener, et al., 2002). The results of the American Shoulder and Elbow Surgeons (ASES) are in the range of 10 to 100, where 0 indicates worse shoulder condition whereas a score of 100 indicates best shoulder conditions. The score evaluates two dimensions of shoulder function. These are pain and performance of activities of daily living (Wylie, et al., 2014). Improvement of the American Shoulder and Elbow Surgeons (ASES) score following operative management of humerus nonunion is the goal of operative management.

This will enable resumption of activities of daily living and productivity (ASES - Orthopaedic Scores, 2020; Michener, McClure, & Sennett, 2002). The minimal clinically important differences (MCID) for the humerus operative management is the smallest change in the outcome score that is associated with clinically important change to the patient. For rotator cuff injuries and surgeries the value is reported at 6.4 (Dabija & Jain, 2019).

The purpose of this study was to evaluate the operative management and outcomes of humeral fracture non-union among adult patients at the Moi Teaching and Referral Hospital. The functional outcomes were assessed using the ASES standardized forms at various points in time after the operation.

1.2 Problem Statement

Humeral fracture account for 5- 8% of all long bone fractures (Oliver, et al., 2020). Most of these fractures have a tendency to heal with nonoperative treatment using functional braces, however, up to 15 % will develop nonunion (Ekegren, et al., 2018). Functional bracing is best described by Sarmiento and others as being associated with high union rate particularly in closed humerus fractures (Sarmiento, et al., 2000). Furthermore, Sargeant, et al., (2020) advocates for nonoperative treatment of humerus shaft fracture, and plate fixation on those that subsequently develop nonunion in which they documented 17.6% (Sargeant, et al., 2020). In a large cohort study by Harkins and colleague, the rate of nonunion was as high as 33 % following conservative management (Harkin & Large, 2017). However, according to Lode and others, there is reported fewer nonunion rates with operative management of humerus shaft fractures compared to nonoperative management (Lode, et al., 2020). In Africa, the incidence of humerus fracture nonunion ranges from 8-13 % according to Sallemi and others in Tunisia (Sallemi, et al., 2020). In a Nigeria study, eighteen percent of

those who had conservative management of humerus fractures presented with nonunion after an average of 16 weeks (Ayotunde, et al., 2012).

In Kenya the reported nonunion rate is 7.5% among adult patients undergoing intramedullary nail for long bone fractures (Soren, 2010). Readmission due to fracture nonunion in that study was 7%. A study done in Nairobi by Sitati and Kingori documented that despite the successful fracture healing of diaphyseal humerus fracture with non-operative treatment, nonunion was not a rare event (Sitati & Kingori, 2016). In Eldoret, fracture of distal humerus contributed 31.9 % of patients with elbow fractures (Montsho, 2018). In another study in Eldoret, the non-union rate was 8.7% in patients involved in Road Traffic Accident presenting with exposed bone (Ayumba, et al., 2015).

The number of cases admitted at the Moi Teaching Referral Hospital with humerus fracture has increased in the recent past. The hospital registry recorded an annual average of 36 cases in the past five years (2015-2021). Subsequently, the number of operations on humerus nonunion has also increased.

Nonunion occurs when nonsurgical and surgical treatment fails, or when the diagnosis is missed or when the medical care is not accessible. This greatly impacts the patient's life, his/her family and on the health care services especially in the young and physically active patients (Dueñas, et al., 2016). There is significant functional and socioeconomic impact and loss resulting in long absence from work and impairment of the quality of life following humerus fractures and nonunion (O'Hara, et al., 2020).

Humeral fracture nonunion causes major functional, physical and mental impairment. Nonunion of the humerus is a clinical burden associated with high morbidity due to chronic pain, patient functional disability, reduced quality of life and significant treatment cost (Brinker, et al., 2022). These patients also experience social and

psychological repercussions (Ekegren, et al., 2018; Stewart, 2019). Patients with humerus fracture nonunion have a slow return to routine activities. The chronic pain and limited range of motion significantly hinder normal functions of the injured limb.

The orthopedic surgeon is tasked with the achieving union through complex reconstructive procedures based on the underlying pathology. The timing of the operative management of a suspected nonunion differs among surgeons, with some advocating waiting for six to nine months. This gives a window of opportunity to address the factors associated with nonunion earlier. A delay in the diagnosis and ultimate intervention will cause more pain and burden to the patient.

Moreover, the increased rate of hospital readmission and reoperation can result in increased health-care cost to the patient and the health care system. The cost incurred is in the form of direct cost of treatment and also indirect cost, being the loss of income due to the loss of function of the upper limb. The treatment process causes remarkable psychological trauma to the patient due to the limited function and the uncertainty of full recovery (Wang, et al., 2021).

The other challenges faced by orthopedic surgeons in managing humerus nonunion range from unsuccessful previous treatment, critical soft tissue coverage, recurrent infections and poor bone quality. Moreover, they also have to deal with infected hardware, misaligned hardware and inappropriate hardware constructs from previous operations. These factors determine the choice of operative strategies to use and the functional outcome of the procedure.

1.3 Justification

Road traffic accidents are the leading cause of humerus fractures, followed by falls. The rate of road traffic accidents in Kenya is on the rise. This leads to more morbidity

and mortality from injuries sustained (Muguro, et al., 2022). Motor cycle crash injuries account for 22-64% of trauma admission in Kenya (Saidi & Mutisto, 2013). This is an increased burden to the ailing Kenya health system especially in the rural areas (Cholo, et al., 2023). In Africa, similar cases of rising rate of road accidents has been noted in Nigeria (Ezeuko, et al., 2016; Onyemaechi & Ofoma, 2016) and Tanzania (Chalya, et al., 2012).

Majority of these humerus fractures are managed at peripheral health facilities using conservative or non-operative methods with cast immobilization and functional bracing with excellent union rates of around 90% (Ayotunde, et al., 2012; Bounds et al., 2022; Ekegren, et al., 2018; Sarmiento, et al., 2000). However, some will develop complications including nonunion that will require complex surgical interventions

Due to the complexity of presentation of humerus fracture nonunion, there are several surgical approaches and fixation techniques being used to achieve adequate fixation and fracture union. These are often complicated by infections, prior surgical history and significant bone loss. The functional outcomes of the humeral operational varies depending on several factors and settings.

Therefore, there is need to generate information on the operative management and outcomes of humerus fracture nonunion at the Moi Teaching and Referral Hospital. This will help guide the orthopedic surgeons in the operative management of humerus fracture nonunion in similar settings on the best approach and the expected functional outcome.

This will also reduce the subsequent cost of treatment, improve the functional outcome by reducing disability and improve the quality of life of the patients with humerus fracture nonunion.

Currently, there is paucity of published data on the operative management and outcomes of humerus fracture nonunion in the North Rift region of Kenya. The data from this study, when available, will bridge the knowledge gap, contribute to the scanty body of knowledge and form a basis for future research and policy development with regard to the operative management and outcomes of humeral fracture nonunion in the Moi Teaching and Referral Hospital and in Kenya.

The purpose of this descriptive study will be to evaluate the operative management and outcomes of humeral fracture nonunion in adult patients attending the Moi Teaching and Referral Hospital.

1.4 Research question

This study aimed to answer the following research question:

What are the outcomes of operative management of humeral fracture nonunion among adult patients attending the Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya?

1.5 Objectives

1.5.1 Broad objective

To evaluate the outcomes of operative management of humeral fracture nonunion among adult patients attending the Moi Teaching and Referral Hospital (MTRH), Eldoret Kenya.

1.5.2 Specific objectives

1. To describe the demographic characteristics of adult patients presenting with humeral fracture nonunion at the Moi Teaching and Referral Hospital, Eldoret Kenya.
2. To describe the initial humeral fracture characteristics in adult patients attending Moi Teaching and Referral Hospital with humeral fracture nonunion.
3. To assess the operative management modalities utilized in humeral fracture nonunion among adult patients at the Moi Teaching and Referral Hospital.
4. To assess the outcomes of operative management of humeral fracture nonunion among adult patients attending Moi Teaching and Referral Hospital using the American Shoulder and Elbow Surgeon score.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Fracture nonunion is the complete cessation of the bone healing process. The Food Drug Administration (FDA) defines fracture nonunion as the failure of bone healing after nine months and a fracture that shows no visible progressive signs of healing for three consecutive months (Thomas & Kehoe, 2023).

Fracture is a breach in the structural continuity of the bone cortex with some degree of soft tissue injury (Bounds, et al., 2022). Bone healing following fracture can be primary or secondary. The type is governed by the achieved mechanical stability at the fracture site and the strain (Tzioupis & Giannoudis, 2007). In primary bone healing, there is an optimum mechanical condition that allows normal bone remodeling process. This is achieved in constructs that provide absolute stability with a mechanical strain below 2 % (Sheen & Garla, 2022). Intramembranous bone healing occurs through Harversian remodeling. On the other hand secondary bone healing is the most common and is associated with low degree of stability thereby causes formation of periosteal callus (Carrier, et al., 2015). It occurs in nonrigid fixation like braces, external fixation bridging plates and intramedullary nailing. The mechanical strain in these constructs is between 2-10% and therefore endochondral bone healing occurs (Duan & Lu, 2021). For a fracture site with a stain of more than 10% will result in nonunion or delayed union.

Secondary bone healing follows four steps that involve hematoma formation, fibrocartilaginous callus formation, bony callus formation and bone remodeling.

Hematoma formation is the immediate stage following a fracture of the bone and it takes 1-5 days. During this stage, blood vessels supplying the bone and the

periosteum are injured during the fracture. The hematoma clots and forms a temporary frame for subsequent healing. This is followed by secretion of proinflammatory cytokines like tumor necrosis factor (TNF- α), interleukins 1, 6, 11 and 23 and Bone Morphogenetic Proteins (BMPS). All these stimulate macrophages, monocytes and lymphocytes. The role of these cells is to remove debris, necrotic tissues and secrete Vascular Endothelial Growth Factors (VEGF) that stimulates bone healing.

Fibrocartilaginous callus formation occurs between day 5 and day 11 of the injury. During this stage, the VEGF induces angiogenesis at the fracture site. This leads to development of fibrin-rich granulation tissue. Mesenchymal stem cells are induced to differentiate into fibroblast, chondroblast and osteoblast by the action of BMPs. There is chondrogenesis and hyaline cartilage sleeve formation.

Bony callus formation occurs from day 11 to day 28 of the injury. The laid down cartilage begin to undergo endochondral ossification. Receptor Activator of Nuclear factor B (RANK-L) induces differentiation of chondroblast, osteoblast and osteoclast. This leads to resorption of cartilaginous callus and beginning of calcification. The end of this stage is formation of calcified callus of immature bone forms.

Bone remodeling is the last phase and it occurs from day 28 onwards. It may take months to years. The cells involved are osteoblast and osteoclast in a coupled remodeling manner. The osteoclast performs the resorption while the osteoblast continues to form new bone. Compact bone replaces the center of the callus, while lamellar bone replaces the callus edges. Remodeling results in the formation of the normal bone structure. This process follows the Wolff's law and electric charges (piezoelectric charges).

According to Julius Wolff (1836-1902), bone will adapt to repeated loads that is placed on it, and that if the load to the bone increases, remodeling occurs to equip the bone to resist such loads. On the other hand, if the load decreases, homeostatic mechanism will shift toward catabolic state (Elliott, et al., 2016; Frost, 1994). According to piezoelectric charges, compression side is electronegative that stimulates bone formation, while the tension side is electropositive and stimulates osteoclasts. This principle has been used to enhance bone regeneration (Carter, et al., 2021). A successful bone healing after fracture results in regeneration of bone tissue and restoration of mechanical stability.

A non-union of long bone fracture is fracture that will not heal without further intervention. They occur due to failure of the biological process of bone healing. Time aspect is important in determining fracture healing. A nonunion is definite when there is no consolidation nine months after the fracture and there is no radiological progression of healing for three months (Calori, 2017). According to the United States Food and Drug Administration (FDA) the agreed standard definition of a nonunion is a fracture that is at least 9 months old and has not shown any signs of healing for 3 consecutive months (Thomas & Kehoe, 2023).

The time to union varies depending on the local and systemic factors. According to Soni and colleagues the average time to union was 14 weeks(range 12-16 weeks) following locking compression plate fixation (Soni, et al., 2019). Longer time to union was documented by Zalavras and others in which the average time to union was 3.5 months (Zalavras, et al., 2021). Gao and others reported even a longer duration of 6.1 months (range 5-8 months) of the time of surgery to union among patients with surgical neck humerus fracture (Gao, et al., 2012). Four point three months was the

period of time to union in Greece among patients with humerus nonunion after operative management (Koutalos, et al., 2015).

The clinical parameter that defines nonunion is the presence of motion and/or pain at the fracture site. There could be persistent pain and significant functional disability. Several clinical scoring systems have been developed to assist in defining nonunion of bone fractures. They also help to classify and stratify nonunion thereby enabling orthopedic surgeons to choose the correct treatment (Calori, et al., 2014). The resolution of pain with weight bearing and motion at the fracture site is considered clinical markers of healing. Other significant clinical findings include atrophy of the limb and angular deformity.

The radiological parameters that aid in the diagnosis of fracture nonunion includes lack of callus, persistent fracture line and less than 5% bone bridging. Some of the scoring systems developed using radiological parameters include the Radiographic Union Scale in Tibial fractures (RUST) score, that was developed by Whelan and others to assess the healing of tibial fractures after intramedullary nailing (Whelan, et al., 2002). This has helped in the standardization of fractures union among orthopedic surgeons (Leow, et al., 2016). Radiological evidence of cortical bridging of the fracture line is an indicator of healing.

The Non-Union Severity Score (NUSS) was formulated by Calori and others and it helps in the classification and in the stratification of fracture nonunion. It also helps in the choice of treatment and the prognosis of achieving union. A higher NUSS score correlate with difficult achieving union (Calori, et al., 2014). The Non-Union Severity Score (NUSS) summaries several clinical parameters of the particular bone including the bone density, the Weber-Cech classification, the bone alignment, the America

Society of Anesthesiologist (ASA) grade of the patient and clinical characteristics of the fracture. The total score is multiplied by two to get the percentages and the score impact on the complexity and difficulty of treatment of any non-union.

According to the works of Basten and others the Non-Union Severity Score (NUSS) score is both reliable and valid system to classify nonunion (van Basten Batenburg, et al., 2019). The validity was analyzed by comparing the outcomes of the actual treatment groups to the proposed treatment groups following the NUSS scores.

However, some authors have disputed the Non-Union Severity Score in the management of fracture nonunion. Gaddi and others did a comparative outcome study among patients with long bone nonunion and found that the use of the NUSS as described by Caroli and others could underestimate the necessary therapies from a biological point of view (Gaddi, et al., 2023). Karsli and others described the use of NUSS in the treatment of nonunion and found that patients not treated according to the NUSS recommendations had a higher chance of getting nonunion (Karsli, et al., 2021).

2.2 Demographic characteristics of humerus fracture nonunion

In order to adequately address humerus fracture nonunion, all the factors necessary for bone healing including, cellular environment, growth factors, bone matrix and mechanical stability should be addressed. The interaction of these factors is summarized in the form of a diamond. Some authors have come up with the diamond concept of bone healing to outline the interaction (Andrzejowski & Giannoudis, 2019; Giannoudis, et al., 2007). The absence or deficiency of these factors predisposes the fracture to develop nonunion. The biological factors are the local environment of the fracture for example the extent of bone loss, the presence of infections, and the

vascularity of the fracture. The quality of surrounding soft tissue envelop is also important as it assists in the process of bone healing.

Factors that contribute to development of fracture nonunion can also be classified as host factors and local factors (fracture personality, type of fracture, multiple traumas) and surgeons' factors.

The host factors include age, sex, osteoporosis, muscular mass, smoking and drug use. According the Zura and others patient specific factors at presentation greatly contribute to humerus fracture nonunion (Zura, et al., 2017; Zura, et al., 2016). These factors include use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDS), increased body mass index, smoking and alcoholism (Olson, et al., 2020). Other host factors that contribute to humerus fracture nonunion include: hormones, malnutrition, medications and bone quality and vascular status and balance among all elements (Mills, et al., 2016).

With regard to malnutrition, bone fractures increase the rate of catabolism that lead to significant urinary protein loss. This will lead to negative nitrogen balance in the body. Patients with protein malnutrition experiences delay in callus formation and the composition is also not adequate for bone healing. Such patients require protein supplementation (Bernard de Dompure, et al., 2010).

With regard to age, according to Micic and others, the average age of those who develop humerus fracture nonunion is 56 years (Micic, et al., 2019). In a study by Obruba and others, the average age of the patients with humerus fracture nonunion was 62 years (Obruba, Rammelt, Kopp, Edelmann, & Avenarius, 2016). Soni and others analyzed a younger population with humerus fracture nonunion. They documented an average of 32 years in the study population (Soni, et al., 2019).

Several authors have reported that an increased age is associated with increased risk of developing humerus fracture nonunion (Ekegren, et al., 2018; Khan, et al., 2018; Olson, et al., 2020; Zura, et al., 2017). Pollock and others documented that the incidence of humeral shaft nonunion was higher in patients above 55 years as compared with younger patients (Pollock, et al., 2020). Age is a dependent factor causing nonunion but also depends on the type of fracture sustained and the management given.

The gender of the patient determines the risk of injury and developing humerus fracture nonunion. The males are at greater risk given the socioeconomic exposure. They will therefore sustain high energy fractures. In an epidemiological study in Malawi, the males were the majority (60%) of the victims of humerus fractures and subsequent humerus fracture nonunion (Igbigbi & Manda, 2004). Similarly, in a study in Nigeria, the male gender was the predominant group sustaining diaphyseal humerus fractures and nonunion (Ezeuko, et al., 2015).

In a Kenyan study by Muthuuri, the male: female ratio was 4:3 ratio in an analysis of patients undergoing plate osteosynthesis (Muthuuri, 2011). The females are more prone to proximal humerus fractures than the male. This is according to Launonen and others who documented 73 % of the study population with proximal humerus fractures being female (Launonen, et al., 2015). The women have an increased risk of sustaining humerus fracture due to osteoporosis that develops with advancing age. There is also less healing potential as compared to the male counterpart.

The non-dominant hand is prone to more injuries than the dominant hand according to an epidemiological study in Malaysia (Chai, et al., 2000). This is due to the uneven force distribution on the limbs. Gichunge, (2015) expressed similar sentiments.

Papadatou- Pastou and others documented the global rate of right handedness at 89.4%, while the left handedness at 10.6% (Papadatou- Pastou, et al., 2020). Mwangi (2019) however documented a slightly higher rate of right hand dominant at 91%, while Montsho, (2018) found out equal affection by trauma between the dominant and non- dominant.

Smoking increased the risk of delayed union and nonunion of fractures of the long bones. In a systematic review and metanalysis to determine the risk of delayed union and humerus nonunion among smokers, Pearson and others concluded that smokers have a 2.2 times increased risk compared to non-smokers (Pearson, et al., 2016). The same sentiment was expressed by Ji, et al., 2019. The presence of comorbidities in patients with humerus fractures increases the risk of nonunion. In a study by Zalavras, 49% of the study population had comorbidities. Smoking and diabetes was the most prevalent (Zalavras, et al., 2021). Kumar identified smoking as the greatest systemic contributor to nonunion in patients with humerus fracture (Kumar, et al., 2013). Cigarette smoke contains toxic chemicals that affect bone healing. They do so by decreasing the bone mineral density and thereby increasing the risk of pathological fractures due to the osteoporosis. At a cellular level, smoke causes tissue and cell hypoxia and this modifies the cellular metabolic activity. On the other hand, nicotine, which is the main constituent of smoke, causes vasoconstriction of peripheral blood flow. Other component in the smoke is carbon monoxide that reduces the oxygen carrying capacity of blood thereby affecting the vascularity of the fracture site (Xu, et al., 2021).

The local fracture or injury factors include high energy injury, open or closed fracture, bone loss, soft tissue injury and anatomic location. The risk of nonunion is increased with open fractures (Mills, et al., 2017). High energy injuries of the humerus mostly

from road traffic accidents (Ayotunde, et al., 2012; Bhat, et al., 2020; Macharia, et al., 2009; Muguro, et al., 2020; Muthuuri, 2011) cause not only fractures, but also significant soft tissue damage and vascular injury. Displacement of bone fragments in high energy injuries damages the periosteal attachment and nutrient supply to the bone. This cumulatively causes compromised vascularity and eventual development of nonunion (Sarmiento, et al., 2000).

Surgeon factors like soft tissue handling during Open Reduction and Internal Fixation (ORIF) of humerus fracture contribute to nonunion. Similarly, excessive soft tissue stripping and improper or unstable fixation are major contributors to fracture nonunion (Savvidou, et al., 2018). The initial treatment factors contribute to nonunion due to completely appropriate treatment of a fracture or less than appropriate treatment. Such iatrogenic causes of humerus fracture nonunion decreases the vascularity at the fracture site and significantly contribute to nonunion. If device like intramedullary nails are used in distraction, it leads to increased fracture gap and contributes to the nonunion.

Anatomic location of fractures affects the rate of non-union (Fink Barnes, et al., 2020; Leiblein, et al., 2019; Pollock, et al., 2020). Due to the vascular factors involved, the 5th metatarsal, the femoral neck and the carpal scaphoid bones are most likely to develop nonunion in the human body. In the humerus, the proximal humerus has the highest incidence of developing nonunion (Badman, et al., 2009). For humerus shaft, the overall nonunion rate was 32 % in the study by Pollock and others among a population that was 55 years and older (Pollock, et al., 2020). In the same study, the proximal humerus had a 45% chance while the distal had 20 % chance of developing nonunion.

Infections of the fractures are the major cause of humerus fracture non-union. It also contributes to recalcitrant infections, complex deformities, sclerotic bone ends and shortening (Chaudhary, 2017). According to Mills and colleagues all humerus fracture non-union should be considered infected until proven otherwise (Mills, L. Tsang, Hopper, Keenan, & Simpson, 2016). Deep infection was significantly associated with the risk of developing humerus fracture nonunion in the works of Olson and others. The other significant factor was alcohol abuse (Olson, et al., 2020).

The classification of infected nonunion is based on the Association for the Study and Application of Methods of Illizarov (ASAMI) classification or the Infection Severity score (ISS) (Calori et al., 2008). The Infection Severity Score (ISS) grades the severity of infections by the use of six parameters that considers the clinical, history and radiological data of the patient. These parameters include: sinuses, skin, sequestrum, discharge, implant and treatment needed. The six parameters are measured and have maximum score of 25 points. Conversion to percentage enables easy interpretation. It determines the number of surgeries as well as the choice of hardware either internal or external. A higher score points to the need for a second debridement and possibility of incomplete eradication or recurrence of infection. A lower score on the other hand indicates ease of eradication of the infection thereby allowing used of definitive internal fixation (Chaudhary, 2017).

2.3 Initial humerus fracture characteristics

Direct blow to the middle of the arm will result in either transverse or oblique fractures of the humerus shaft. Depending on the location of the fracture and whether open or closed, majority of these fractures are stable and amenable to nonsurgical treatment.

Braces that consist of plastic sleeves can maintain good alignment of the humerus fracture fragment. With the stabilization and immobilization guaranteed, rapid and uninterrupted osteogenesis can occur. Sarmiento and others theorized that, early physical activity does improve the functional outcome and improves bone healing (Mwangi, 2019). In the study by Mwangi, a comparison of the use of U- slab and a functional brace was conducted. The main findings were that of superior functional outcome among those that had functional braces as it was associated with early return of good shoulder and elbow range of motion. The management options for humerus fracture nonunion are based on radiological analysis and complete risk analysis of the patient using the Non-Union Severity Score (NUSS). In order to achieve union, there are three basic requirements: stable fixation, biological stimulation and restored function (Sheen & Garla, 2022).

To achieve stable fixation, the options is either the use of external fixation or internal fixation. This is aimed at increasing the mechanical stability of the fracture. As Tzioupis and Giannoudis noted, mechanical stimulation induces cell proliferation and differentiation and this depends on the strain magnitude and cell phenotype (Tzioupis & Giannoudis, 2007). Initial fracture healing is facilitated by micromotions of the fragment.

Biological stimulation is achieved through bone grafting. The iliac crest is the preferred source of bone graft. Other sources include the proximal tibia and the trochanter. Bone graft provides osteoinductive, osteoconductive and osteogenic material.

The use of NUSS in the treatment planning of fracture nonunion in long bones has been shown to increase the treatment success (Karsli, et al., 2021). In this review in

Turkey, those patients who were not treated according to the NUSS recommendations had a higher rate of nonunion as compared to those that were treated using the system.

During the 4th annual meeting of the Danish Orthopedics Trauma Society, it was recommended that in the management of fracture nonunion and the choice of modalities should depend on the scores on the nonunion (Schmal, et al., 2020).

2.3.1 Classification of fracture nonunion

Several classification systems of fracture non-union exist. Weber and Cech (1973) classification is the most frequently used (van Basten, et al., 2019). It is in this classification that non-unions are divided into four types: hypertrophic, oligotrophic, atrophic (avascular) and pseudarthrosis (Calori, et al., 2008).

Hypertrophic nonunion occurs when there is sufficient vascularization leading to abundant callus formation as seen on plain X-ray radiographs. In this type of nonunion, there is no bone bridging due to excessive motion at the fracture site despite presence of essential biological factors (Bhat, et al., 2020; Carr, et al., 2012; Feng, et al., 2018). The mechanical instability prevents maturation and consolidation of the soft callus (Schmal, et al., 2020). The strain applied should be able to provide the conducive environment for tissue formation between fractured ends thereby aiding in the healing process. The adequate strain promoted fracture healing through appropriate stimulation of angiogenesis and osteogenesis. There is also reported inhibition of osteoclast differentiation which will ultimately lead to reduced bone resorption (Duan & Lu, 2021). This type of nonunion may sometimes mimic an enchondroma as highlighted by Magu and others (Magu, et al., 2014). The principle of treatment of these types of nonunion is application of a stable, rigid fixation using a large fragment plates with 4.5 mm screws with a combination of cancellous autograft.



Figure 1: Radiographs of hypertrophic nonunion of the left humerus (Images courtesy of Matar, et al., 2013)

Oligotrophic nonunion show some minimal or poor callus formation. Radiographically, there is little callus formation in normal biological activity. It is a balance combination of atrophic and hypertrophic. The main cause of oligotrophic nonunion is inadequate reduction and bone ischemia. The other feature of oligotrophic nonunion on plain x ray include variable fracture fragments that point to disturbed local biology (Schmal, et al., 2020). This type of nonunion commonly occurs in the distal humerus and could be subclassified based on the location into supracondylar, transcondylar, intercondylar or osteochondral (Donders, et al., 2017).

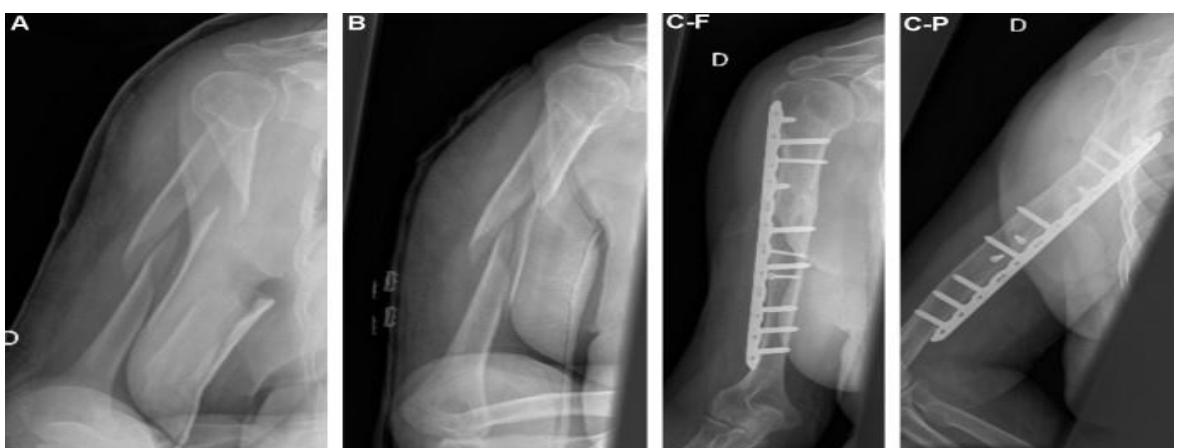


Figure 2: Distal humerus diaphyseal oligotrophic nonunion (Images by courtesy of Bernard de Domsure, et al., 2010)

In atrophic nonunion, there is no evidence of callus formation on X-ray. Bone scan shows ischemic lesions. Such nonunion require bone grafting in order to achieve bone union through biological stimulation(Rollo, et al., 2017). This can be done using piezoelectric stimulation of the bone to facilitate regeneration. This occurs by accumulating electric charge in response to mechanical stress (Carter, et al., 2021).

Atrophic nonunion is the commonest form in most studies (Leiblein, et al., 2019). In Africa, 80 % of humeral fracture nonunion were atrophic type (Ayotunde, et al., 2012). The main pathology underlying atrophic nonunion is insufficient blood supply. Rupp and others discussed this type of nonunion in the diaphyseal long bone fracture. They further recommended that such types of nonunion requires additional bone stimulation and plate augmentation for healing to occur (Rupp, et al., 2017).

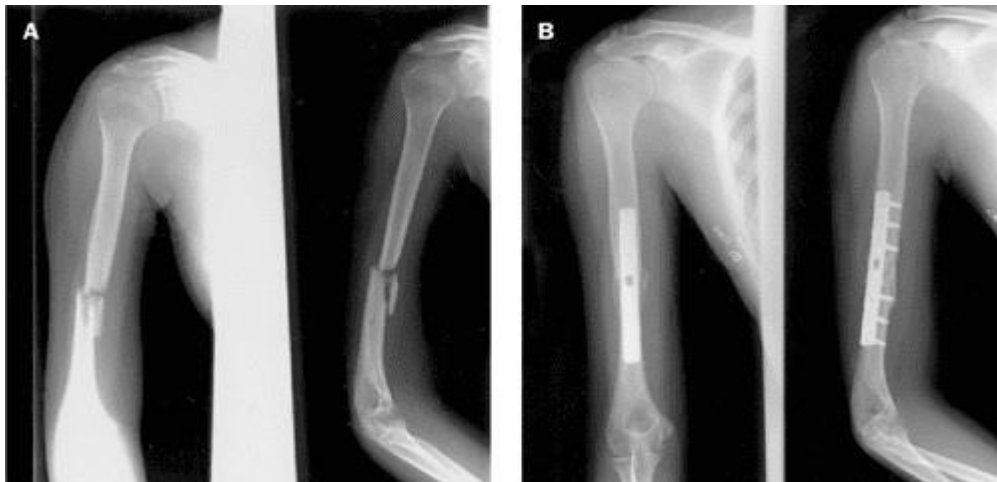


Figure 3: Atrophic right humerus fracture nonunion (Images by courtesy of Kumar, et al., 2013)

Pseudoarthrosis nonunion involves the fracture gap being filled with fluid cavity and presence of synovial-like membrane. There is formation of a false joint over significant time due to excessive motion or instability in the presence of adequate

vascularity. This type of nonunion accounted for 8-13 % of humerus fracture nonunion in a study done in Tunisia (Sallemi, et al., 2020).

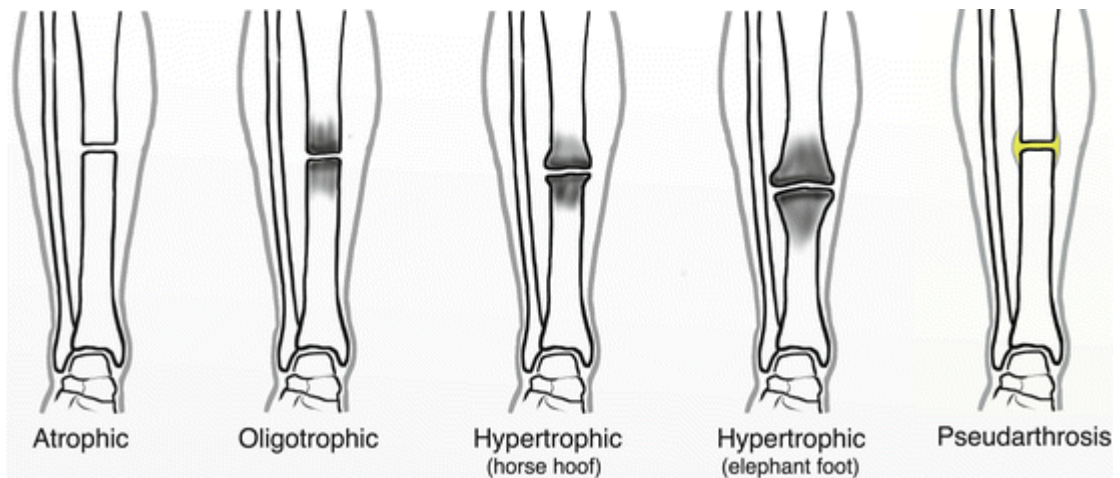


Figure 4: Various types of nonunion (Images by courtesy of Andrzejowski and Giannoudis, 2019)

Various authors (Biglari, et al., 2016; Calori, 2017; Rollo, et al., 2020) have documented the use of NUSS score. This tool provides an algorithm of choice of treatment of humerus fracture nonunion (Calori, 2017). There are four groups of severity that are based on the scores. They are represented in the ladder strategy (**Figure 5 below**). A score of 0-25 is a simple nonunion that requires mechanical stabilization by fixation. According to Karsli and others, adherence to the recommendations of these classification at the preoperative planning leads to more success rates in the treatment of long bone nonunion (Karsli, et al., 2021).

A score of between 26 and 50 involves both mechanical and biological problem and requires more specialized care. Additional biological stimulation using either pulsed electromagnetic fields or biotechnology is needed (Biglari, et al., 2016). They facilitate bone healing through mimicry of the mechanical stress on the bone. Upon

application of mechanical load, a strain gradient develops sending pressure gradient through the canaliculi. This exposes osteocyte membrane to flow-related shear process (Victoria, et al., 2009).

A score of 51 and 75 is caused by both biological and mechanical conditions. It requires resection of the nonunion and bone grafting to correct the defect. Biological agents like cells, scaffold and growth factors are also added. The source of autologous bone grafts includes the iliac crest (Stevens, et al., 2021).

Severe scores of 76 and 100 may require arthrodesis, prosthesis, amputation or mega-prosthesis implantations to correct the defect (Pearson, et al., 2016).

However, several criticisms of this classification system have been proposed. Gaddi and others, questioned the appropriateness of using NUSS in the clinical practice. In their argument, they concluded that the use of NUSS treatment protocol underestimated the necessary therapies (Gaddi, et al., 2023).

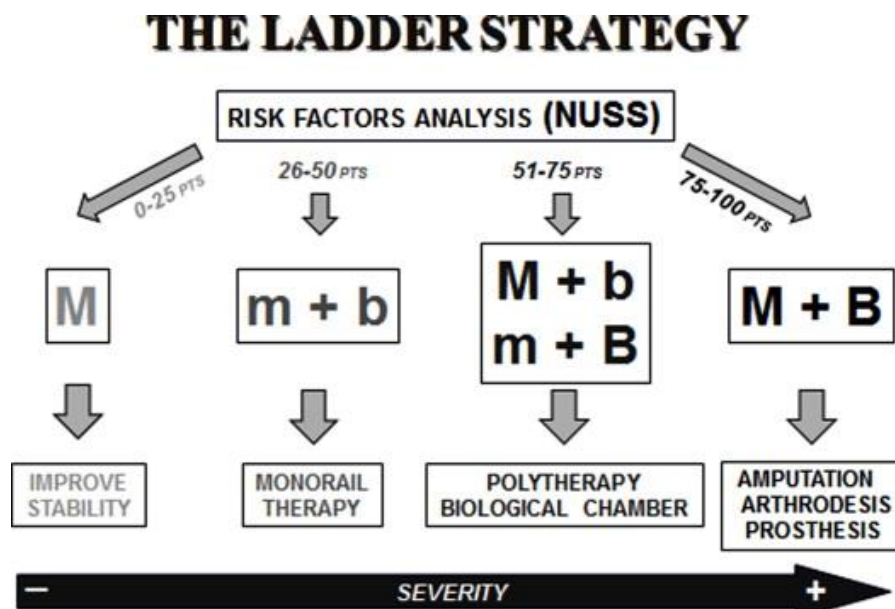


Figure 5: The Ladder Strategy (Images by courtesy of Calori, 2017)

According to the unified theory of bone healing, tissues that form in and around a fracture should be considered as specific functional unit; that produces a physiological response to its biological and mechanical environment. This is essential for normal bone healing (Elliott, et al., 2016).

2.3.2 Non-operative management modalities of humerus fracture nonunion fracture management

The use of biotechnical products to treat nonunion is proving to be the hope in treating this debilitating condition. They augment the biological microenvironment and enhance bone repair.

They include the use of stem cells, osteoinductive growth factors, osteoconductive matrices and anabolic agents. According to the Food Drugs Association (FDA), these biological products include blood and blood products, somatic stem cells, gene therapy and recombinant therapeutic proteins (Bashor, et al., 2022). These cell based therapies are proving to be the emerging modalities that can be used to treat intractable diseases including bone healing in the case of humerus fracture nonunion (Bashor, et al., 2022).

Stem cells from the bone marrow provide a pool of potential cells that can differentiate into a particular phenotype in the presence of appropriate biological stimulus. These include osteoblast, chondrocyte, adipocyte and myoblast. Other sources of stem cells include peripheral blood, vascular pericytes, dermis and periosteum (Squillaro, et al., 2016). Mesenchymal Stem cells (MSCs) have been used in the treatment of humerus fracture nonunion with better outcomes compared to open iliac grafting (Upadhyay, et al., 2016). They are activated in response to the cytokines released by endothelial cells. MSCs differentiate to chondroblast, osteoblast and

fibroblast leading to formation of hard and soft callus. Bone Morphogenetic Proteins (BMPs) play a critical role in inducing osteogenic activity in the mesenchymal stem cells and maturation of lamellar bone.

Bone marrow aspirate (BMA) also contains stem cells, progenitor cells and hematopoietic cells that have the potential of transforming into osteoblast upon receiving osteoinductive stimulation. It has been used in the treatment of delayed unions and nonunion. Bhargava and others documented treatment of 28 patients with delayed and non-union using Bone Marrow Aspirate injections. There was reported 82% union rate after 12 weeks of treatment (Bhargava, et al., 2007). Percutaneous injection of bone marrow aspirate into diaphyseal nonunion site is well elaborated. It has been shown to be an effective and safe method for treatment of diaphyseal nonunion (Sahu, 2018).

Growth factors that have been used in treatment of fracture nonunion include: Bone Morphogenetic Proteins (BMPs), Fibroblast Growth Factor (FGF) and Platelet Derived Growth Factor (PDGF). Aro and others demonstrated the use of human recombinant BMPs in a randomized prospective blinded study involving 277 tibia fractures (Aro, et al., 2011). There was decreased frequency and invasiveness of secondary interventions following the use of rhBMPs in a study involving 169 tibia fractures (Swiontkowski, et al., 2006). Autologous platelet rich plasma is also an option in the management of delayed union of long bone fractures as it is safe and effective (Ranjan, et al., 2023).

Extracellular osteo-conductive matrix promotes migration and adhesion of osteoinductive and osteogenic cells to the fracture site. This is provided by necrotic bone upon excellent apposition of bone. Failure or insufficient scaffold requires

autograft or allograft in the form of Demineralized Bone Matrix (DBM) (Roberts & Rosenbaum, 2012).

Humerus fracture healing and any other long bone fracture is based on the diamond concept theory of bone healing (Andrzejowski & Giannoudis, 2019). According to the Diamond concept, successful bone healing is dependent on the biological environment and the optimum mechanical environment that provide the fracture with adequate stability. A stable mechanical environment leads to evolution of the physiological process leading to adequate bone repair (Toro, et al., 2019).

Cells respond to pressure and mechanical changes through electrochemical signals generated by fluid shift within the canaliculae. Mechanical environment influences cell development through lineage differentiation of the multipotent mesenchymal stem cells. Tension forces encourage fibroblast and osteoblast differentiation. Shear forces encourages chondroblast and osteoblast differentiation. Strain initiates healing (Carter, et al., 2021; Liu, et al., 2022).

These cells include committed osteoprogenitor cells from the periosteum and undifferentiated Multipotent Stem Cell (MSCs) from the bone marrow. They are activated in response to the cytokines released by endothelial cells. Multiple Stem Cells differentiate into chondroblast, osteoblast and fibroblast leading to formation of hard and soft callus. Bone Morphogenetic Proteins (BMPs) play a critical role in inducing osteogenic activity in the mesenchymal stem cells and maturation of lamellar bone (Katagiri & Watabe, 2016).

Extracellular osteo-conductive matrix promotes migration and adhesion of osteoinductive and osteogenic cells to the fracture site. This is provided by necrotic bone upon excellent apposition of bone. Failure or insufficient scaffold requires

autograft or allograft in the form of Demineralized Bone Matrix (DBM) (Lin, et al., 2020).

There are cells and pro-inflammatory cytokines that are released into the hematoma following a fracture. They include interleukins 1, 6, 8, 10 and 12, tumor necrosis factors and activated protein C. Metalloproteinases and angiogenic factors such as vascular endothelial growth factors are involved in bone repair. They also induce differentiation of progenitor cells to form osteoblasts (Khoswanto, 2023). In this regard a compromised vascular supply to the fracture site affects hematoma formation, leading to insufficient osteoinductive and osteogenic cells available for osteogenesis and remodeling.

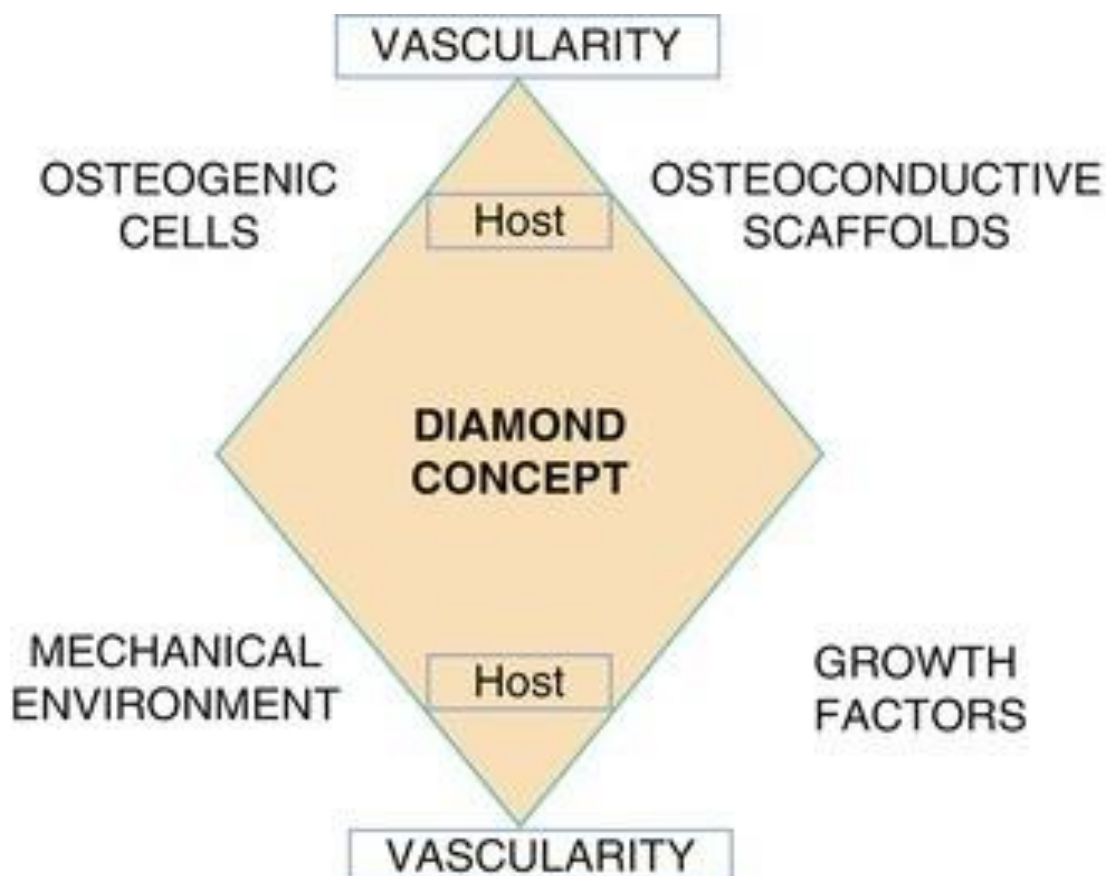


Figure 6: The Diamond concept (Andrzejowski & Giannoudis, 2019)

2.4 Operative Management Modalities for Nonunion Fractures

Successful operative management of humerus fracture nonunion requires review of all the contributing factors identified (Leiblein, et al., 2019). The blood supply to the fracture and the quality of the soft tissue envelop as well as the mechanical stability at the fracture are critical factors to consider. Despite the availability of numerous surgical approaches and techniques (Ayotunde, et al., 2012; Bernard de Dompure, et al., 2010; Naclerio & McKee, 2022; Padha, 2016; Saka, et a., 2021), plate fixation and bone grafting are widely used (Naclerio & McKee, 2022). Plates and screw fixation are the appropriate operative modality for most diaphyseal and end segment humerus fracture nonunion. It has the ability to address angular, rotational and translational deformity associated with the humerus nonunion. It can be used in periprosthetic nonunion following intramedullary nailing. In the works of Ciurlia and others, the use of plates and screws aids in the achievement of union by the provision of biomechanical stability at the fracture site (Ciurlia, et al., 2017). Large fragment plate with 4.5 mm screws combined with autologous autograft is the treatment of choice for hypertrophic humerus nonunion as it provides stable and rigid fixation (Bégué, et al., 2023). Plating with allograft is a better treatment modality in aseptic nonunion as it has shown satisfactory results (Rollo, et al., 2017).

However, due to its relative invasiveness there is great risk of soft tissue loss and associated postoperative complication of edema, wound infections and compartment syndrome following the use of plates and screws. Since it is a load bearing implants, plates and screws require delayed weight bearing. Another disadvantage of plates and screws is the inability to correct limb shortening from bone loss. Failure rates of the plates and screws depend on the size of the plate used. Narrow 3.5 mm plates tend to fail earlier than broad 4.5 mm plats in both axial and torsional stiffness (Padron, et al.,

2017). Moreover, the use of minimally invasive anterior plate osteosynthesis has been shown to have higher union rate and excellent outcome. This makes its cosmetically acceptable and effective technique in treating humerus shaft fractures (Bhimbarwad, et al., 2022).

Dynamic Compression Plate (DCP) is used in the operative management of nonunion of humerus fractures. Several studies have reported high union rates especially when cancellous bone grafting is used (Kumar, et al., 2013). When compared with interlocking nail, there was better outcomes in terms of union time, complications and functional outcomes with the use of DCP (Khan, et al., 2022). DCP with cancellous bone grafting is effective in treatment of humerus shaft nonunion in most set ups. Bhat and others in a study in India, demonstrated reduction in union time (Bhat, Wani, & Nabir, 2020).

Locking Compression Plates (LCP) on the other hand is superior when used in osteoporotic bone (Oboirien, et al., 2017). Locking Compression Plating is the standard operative treatment method for nonunion of the humerus shaft fractures as it provides satisfactory results and the highest union rate. This is in combination with autologous cancellous bone grafting (Saha, et al., 2019).

Khalid and others, in a randomized control trial, compared the use of DCP and LCP in the management of humerus fracture nonunion, and they found out that the use DCP in the operative management of humerus fracture nonunion had better functional outcome (Khalid, et al., 2019). In that randomized controlled trial, 150 patients with humerus nonunion were divided into two treatment groups. In one group, they used locking compression plate with cancellous bone grafting while the other group underwent dynamic compression plate fixation. The modified Constant and Murley score was used to assess the functional outcome between the two groups.

The use of locking compression plate and fibular graft have been shown to be superior when used in treatment of complex diaphyseal humerus atrophic and gap nonunion with significant bone loss (Shetty, et al., 2022). In that review, patients had undergone surgical fixation but failed and presented with atrophic nonunion. Upon the use of locking plates, a follow-up at 24 months showed radiological union and also clinical union with a mean union at 17 (SD 2.2) weeks. The locking plates provided adequate mechanical stability for the bone healing to occur. The biological factors and deficits were corrected by the use of autologous bone grafting.

Intramedullary nailing (IM) of humerus fracture nonunion involves primary nailing, exchange nailing or dynamization. Exchange nailing is used when IM nailing was the initial method of treatment. The main indication of exchange nailing is when the deficiencies of the preexisting nail can be overcome by the newer larger nail. Initial IM nailing can fail due to lack of rotational control and lack of adequate stability due to an undersized nail. Exchange nailing have an additional advantage of depositing small amounts of local bone graft which can stimulate an inflammatory response to promote healing. Correction of malalignment can be done during reaming in addition to debridement and osteotomy (Hierholzer, et al., 2014). Being a load sharing device, the use of IM nailing has lower success rate as it lacks compression necessary for correcting fracture nonunion. The other challenge is the entry site which can be a problem for most orthopedic surgeons.

Dynamization is the removal of interlocking screws at one end of a nail to allow shortening with weight bearing. This technique is applied when there is a small gap at the fracture site due to bone loss, osteoclastic resorption or prior static nailing with distraction at the fracture site. It has the advantage of minimal morbidity and the potential for immediate full weight bearing (Vaughn, et al., 2018). Following a peer

review of 66 articles by Vaughn and others, they found out that union rate was achieved in 66.4 % of the patients who underwent dynamization as compared to 84.7 % among those who underwent exchange nailing. There was also reduced time to union. These secondary surgical techniques are appropriate in patients with delayed union and those with nonunion after IM nailing (Vaughn, et al., 2018).

External fixation for humerus fracture nonunion utilizes a circular ring fixators using thin wire and the Ilizarov concept (Fahad, et al., 2019). It has the advantage of being applicable to any bone in the body, and in settings of failed plate fixation. There is great soft tissue sparing and also it provides opportunity to correct any deformity and length discrepancy. It also conserves the vitality of the remaining bone. This technique is applicable in osteoporotic bones and those with septic nonunion. Circular fixators are appropriately used in the humerus as they correct the identified deformities like angulation, shortening and malunited fragments (Bisaccia, et al., 2017). The disadvantage of the use of external fixators is the bulkiness of the frame and the discomfort arising from the numerous wires. However, they are used temporarily until infection heals and this is followed by definitive treatment.

The need for second plating in the operative management of humerus nonunion depends of the stability of the construct. If there is adequate stability, there is no need for the second plate. Akdemir and others proposed use of either single or dual plating as they provide similar results (Akdemir, et al., 2022). However in recalcitrant humerus shaft nonunion, dual plating should be used (Feng, et al., 2020). Similarly, it can be used in long standing distal humerus nonunion with bone defect. There is reported better outcome when dual plating is augmented with autologous bone graft as documented by Saka and others (Saka, et al., 2021).

According to Fukumoto and others, the choice between IM nail and plating shows that new generation intramedullary nail without bone grafting demonstrated good outcomes in patients with humerus nonunion as it provides the biological activity needed for union (Fukumoto, et al., 2021). Martinez and others compared the use of plating and nailing in the treatment of humerus nonunion of the upper two thirds. They concluded that the functional results and the range of motion in these two groups were similar (Martínez, et al., 2004). In an African study by Madu in Nigeria, plating had better outcomes than IM nailing (Madu, et al., 2018).

In cases of septic nonunion, it will require two stage reconstruction with the use of circular external fixation or Ilizarov frame (Ferreira, et al., 2016). The first stage is infection control while the second is bone stabilization and healing. Extensive debridement of the humerus fracture nonunion site is followed by bone grafting and external fixator application.

New development and advancement in the operative management of humerus fracture nonunion include the use of Proximal Humerus Interlocking System (PHILOS) plate. According to several authors (Haldar, et al., 2021; Martinez, et al., 2009), there is favorable functional outcomes that have been seen with the use of long Proximal Humerus Interlocking System (PHILOS) plate in the management of proximal humerus fracture nonunion..

2.5 Outcomes of operative management of humerus nonunion

2.5.1 Treatment outcome

The aim of operative management of humerus fracture nonunion is achieving a functional upper limb. Other outcome measures include improvement of clinical status, radiological outcomes and complications.

According to Sitati and Kingori, (2016), the outcomes of operative treatment of humeral fracture nonunion are largely influenced by several factors including: cause and type of nonunion, age of patient, surgical approaches and techniques used in treatments. Whether nonunion arises from operative or nonoperative treatment, surgical intervention using various implants and bone grafting in the constructs are mandatory. Prophylactic antibiotics are essential in all the cases (Sitati & Kingori, 2016).

Generally, improved functional score using the American Shoulder and Elbow Surgeons (ASES) score has been documented by several authors (ASES- Orthopedic Scores, 2020; Dabija & Jain, 2019; Fink Barnes, et al., 2020; Khan, et al., 2018; Naclerio &McKee, 2022; Michener, et al., 2002; Werner, et al., 2016; Willis, et al., 2013; Wylie, et al., 2014). This tool is a measure of the good outcomes following operative management of humerus fracture nonunion. A success rate of at least 90% the American Shoulder and Elbow Surgeons (ASES) score at the end of review period was documented by Sitati and Kingori (Sitati & Kingori, 2016). Khan and others reported 81.1% score in patients who underwent operative management for humerus fractures (Khan, et al., 2018). On the other hand Willis and colleagues in an analysis of patients with atrophic nonunion treated with compression plating, had an average ASES score of 76% (Willis, et al., 2013). The final postoperative ASES score after 7.5 years was 65% in a review by Fink Barnes and others in the United States (Fink Barnes, et al., 2020). A score of 46 % was however realized in a study by Soni and others (Soni, et al., 2019). Gichunge, (2005) also documented favorable outcomes of operative management of humeral shaft fractures. On average shoulder functioning following surgery was good with a mean ASES score of 81.1 (SD: 10.6) and range of 46.7- 91.7.

Generally, the complications documented with regard to operative management of humerus fracture nonunion were associated with the severity of injury, presence of co-morbid conditions and poor patient compliance. Failures were attributed to poor bone stock (Vauclair, et al., 2020) and poor patient compliance (Kumar, et al., 2013) inadequate fixation and alcoholism (Olson, et al., 2020).

Radial nerve palsy incidence, superficial and deep infection, and stiffness involving the elbow and shoulder are the most commonly reported complications following operative management of humerus fracture nonunion.

Iatrogenic radial nerve palsy is reported in most of the operative management of humerus nonunion. In as many as eighteen percent (18.5 %) of the patients in a study by Kakazu and others developed radial nerve palsy after operative management of established humerus shaft nonunion (Kakazu, et al., 2016). Sadek and others had 3% of the study population developing transient radial nerve palsy (Sadek, et al., 2021). Other authors have reported varied rate of radial nerve palsy. Oliver and others for instance, documented 6% rate of radial nerve palsy following open reduction and fixation of humerus fracture nonunion (Oliver, et al., 2021). The factors associated with increased risk of iatrogenic radial nerve palsy include the site of the humerus injury and the surgical approach used. Koh and others reported increased risk of radial nerve injury in mid shaft humerus fractures and among those who had operative management (Koh, et al., 2020). One way of preventing this devastating complication is by use of posterior paratricipital approach. This approach enables radial nerve exploration, decompression and protection prior to fracture manipulation and instrumentation (Gibbs, et al., 2022). It involves elevation of the triceps muscle off the posterior humerus but leaving the triceps insertion intact.

2.5.2 Functional Outcome

Functional assessment of operative outcomes of shoulder and elbow pathologies can be assessed using several tools. They can either be those that record general shoulder measures and those that assess conditions specific for the shoulder. Among the general shoulder measures is the ASES score. It was developed by the American Shoulder and Elbow Surgeons to facilitate standardization of outcome measures and to promote multicenter trials in elbow and shoulder surgery as it provides a reliable and consistent method assessment (Michener, et al., 2002).

It is a self-reported outcome measure for assessing disability following hand and upper extremity conditions. It also has a physician rated section. The scale contains one pain item and ten function questions items. The pain scale is assessed using the Visual Analog Scale (VAS). The total score has a 100 maximum of points which is further weighted 50% for pain and 50% for function.

An online version of the ASES score is available. The American Shoulder and Elbow Surgeons (ASES) score has been shown to have a strong correlation with Western Ontario Rotator Cuff Index (WORC). According to Baumgarten and others, they noted that there is comparable responsiveness and less administrative burden when using the American Shoulder and Elbow Surgeons (ASES) (Baumgarten, et al., 2021).

2.5.3 The ASES

The American Shoulder and Elbow Surgeons (ASES) score has well-established psychometric features. Rotator cuff disease, glenohumeral arthritis, shoulder instability, and shoulder arthroplasty have all had their validity, reliability, and responsiveness tested. In addition, the ASES score has been found to be accurate, reliable, and responsive to non-operative therapy (Michener, et al., 2002).

Despite the fact that the American Shoulder and Elbow Surgeons (ASES) score has been thoroughly examined, there are certain inherent limitations to be aware of. The American Shoulder and Elbow Surgeons (ASES) score is weighted in favor of the pain and patient-reported function domains. Physician assessment is not included in the final result, unlike the Constant-Murley score. This is both strength and a weakness of the ASES; however, it should be considered when evaluating findings. In certain versions of the American Shoulder and Elbow Surgeons (ASES) score, the shoulder instability Visual Analogue Scale has been deleted, yet the scale has remained sensitive to instability therapies even without it (Kocher, et al., 2005).

CHAPTER THREE: METHODOLOGY

3.1 Study Site

The research was conducted at the Moi Teaching and Referral Hospital (MTRH), situated in Eldoret town, 320kms Northwest of the Capital city, Nairobi, Kenya. The Moi Teaching and Referral Hospital (MTRH) is the second largest referral facility in Kenya, after Kenyatta National Hospital. It has a bed capacity of over 1,000 and serves as a referral hospital for the western part of Kenya, with a catchment population of about 20 million people (approximately 33% of Kenyan population).

The hospital provides various services ranging from primary to specialized care. It serves the urban, peri-urban and rural populations from near and far counties. The hospital also serves patients from neighboring countries like Uganda, Sudan, South Sudan and Rwanda (MTRH website, 2022).

The study was conducted at the Orthopedic Unit (Outpatient Clinic (OPD)) and Orthopedic Wards (Longonot and Sergoit wards) of the Moi Teaching and Referral Hospital. The department attends to an average of 36 patients with humerus fracture nonunion every year.

3.2 Study Design

The study design was a hospital-based descriptive prospective study. All patients undergoing operative management for humerus fracture nonunion were considered for the study and followed up for a minimum period of 6 months from date of the operative procedure. Patients were recruited and followed up at an interval of every 6 weeks after the surgery during their routine Orthopedic Outpatient Clinic visit. The points of encounter with the patients were at day 0, 6 weeks, 12 weeks, 18 weeks and

24 weeks after the operation. During these visits, the clinical and functional outcome assessment using the ASES score and radiological union were recorded.

3.3 Study Population

The study population was all adult patients who presented to the Moi Teaching and Referral Hospital, Eldoret with humerus fracture nonunion.

3.4 Eligibility criteria

3.4.1 Inclusion criteria

All adult patients attending Moi Teaching and Referral Hospital during the period of the study who were scheduled to undergo operative correction of humerus fracture nonunion (established nonunion as defined in the operational definition of terms) were included in the study.

3.4.2 Exclusion criteria

Adult patients who declined to give informed written consent to participate in the study.

3.5 Sampling Technique

All the adult patients with humerus fracture nonunion seeking treatment at the Moi Teaching and Referral Hospital and those meeting the inclusion criteria were recruited in the study and were sampled consecutively, until the desired sample size was reached. The first patient was conveniently recruited upon approval of the study by the Institutional Research and Ethics Committee (IREC) and the National Commission for Science Technology and Innovation (NACOSTI).

3.6 Sample Size determination

The Fischer's formula was used to calculate the sample size of patients to participate in the study.

$$N = \frac{Z^2 p(1-P)}{I^2}$$

Where: n

N=sample size

Z- normal deviation at the desired confidence interval. In this case it was at 95 %, Z value is 1.96

p- proportion of the population with the desired characteristics.

According to Court-Brown et al 5% of humerus fracture develop non unions (Court-Brown & McQueen, 2008).

I²- degree of precision while 95 % confidence interval is the desired level.

$$N = \frac{1.96^2 * 0.05(1-0.05)}{0.05^2} = 30.1$$

In order to factor in for non-respondents, additional 20% of the sample size was considered.

$$30.1 * 1.2 = 36.12$$

All the patients who meet the inclusion criteria were therefore recruited into the study during the study period. The hospital records at the Moi Teaching and Referral Hospital indicated that for the previous year's 2017, 2018 and 2019, an average of 36 patients per year with humerus fracture nonunion was seen at the hospital. Therefore, the desired sample size was thirty-six (36) as worked out by the Fischer's formula.

3.7 Study Procedure

- i. Preoperative evaluation of the patients- at first encounter, a comprehensive history and physical examinations of the patient was done and details filled into the Questionnaire (**Appendix V**). A Non-Union Severity Score was recorded using the Non-Union Scoring System (NUSS) score sheet (**Appendix VI**).
- ii. First post-operative evaluation- this evaluation involved the collection of information regarding the type of surgical procedure done, the implants used, and any complications associated with the injury. An interviewer administered questionnaire (**Appendix V**) was used.
- iii. The post-operative evaluation and functional assessment. This was done at week 6, week 12, week 18 and week 24 post operation during the routine post-operative orthopedic clinic visit. Plain radiographs with AP and lateral views were taken and serial ASES score was recorded (**Appendix VII**). The X- ray was used to assess the union of the fracture while the ASES was used to assess the functional outcome of the operated limb.

3.8 Study recruitment schema

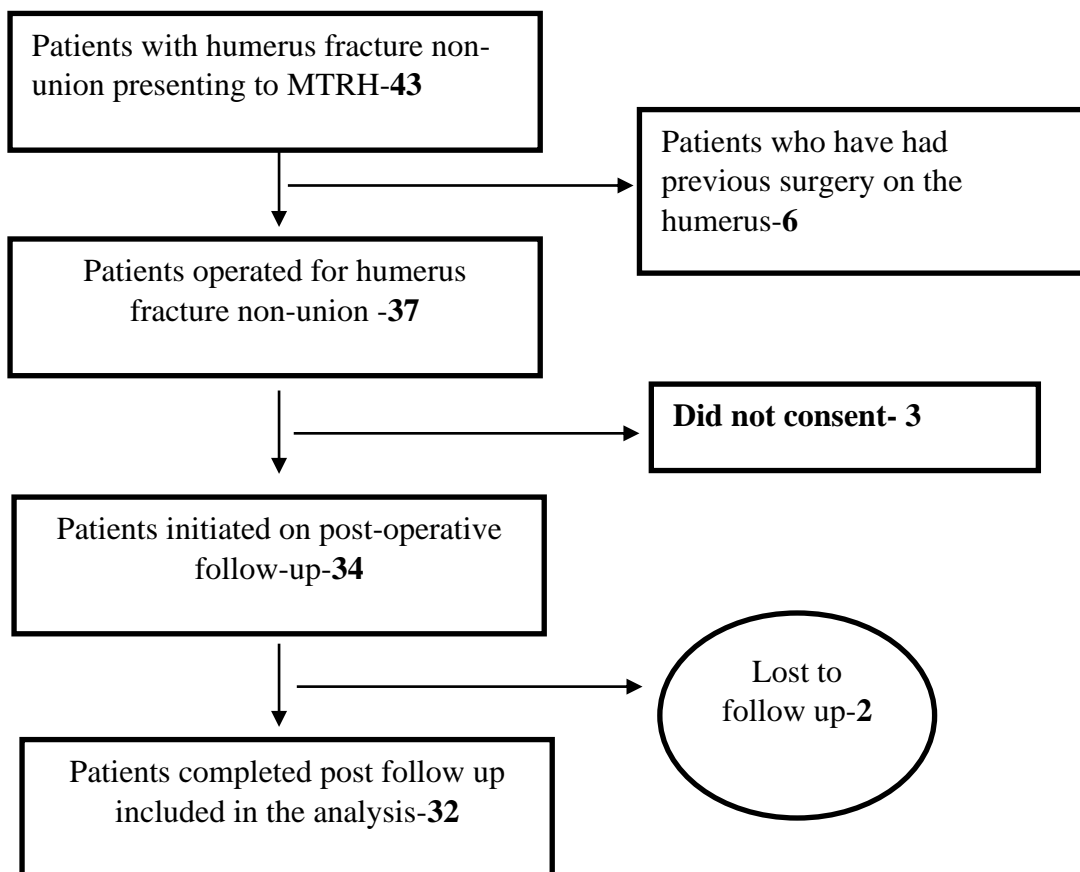


Figure 7: Recruitment Schema (Source: Terer, K.E., 2023)

3.8 Data collection process and analysis

A Research Assistant was trained to assist in data collection. Upon obtaining a written informed consent from the patients, the Principal Investigator with the help of a trained Research Assistant administered the structured questionnaire to collect data on socio-demographic information and the clinical information of the humerus fracture nonunion.

Both Primary and Secondary data were collected. Primary data was obtained from the patients using the Non-Union Scoring System (NUSS) sheet (**Appendix VI**), a structured questionnaire (**Appendix V**) and the American Shoulder and Elbow Surgeons (ASES) score (**Appendix VII**). An interviewer administered questionnaire

was used to obtain other demographic data. Secondary data was obtained from the patients' record and plain radiographs of the humerus. The Principal Investigator examined the patients and reviewed the radiographs of the arm. Patients' records were reviewed and data on the surgical procedure and immediate post-operative outcome were collected.

The American Shoulder and Elbow Surgeons (ASES) score was used to assess the functional outcomes at week 6th, 12th, 18th and 24th week after the procedure during the post operation Orthopedic Out-patient Clinic visits.

The clinical data that was collected included: the socio-demographic characteristics, the initial fracture characteristics and the Non-Union Scoring System (NUSS) score, the operative management modality used and functional outcome using the American Shoulder and Elbow Surgeons (ASES) score.

Correlation and associations between variables were done using 2 by 2 tables, and the measure of association determined using the Fischer's Exact test.

3.9 Study variables

The study variables were the social-demographic data, the initial fracture characteristics and the Non-Union Scoring System (NUSS) score, the operative management modalities and the functional outcome using the American Shoulder and Elbow Surgeons (ASES) scores. The independent variables were the socio-demographic characteristics, the initial fracture characteristics and the operational modalities used. The dependent variables were the union and improved functional outcome.

3.10 Data management and analysis

Data entry and cleaning: Data on the study variables was entered into MS Excel. Data cleaning was done on a daily basis.

Data protection: Access to study data was limited to the relevant personnel. This was done through use of passwords and antivirus/firewall software.

Data analysis: Descriptive analysis was performed to answer the study objectives. Where categorical data such as gender, age, operative management, fracture type, etiology and occupation were summarized as frequencies and corresponding percentages. Numerical data such age, Non-Union Scoring System (NUSS) score and the American Shoulder and Elbow Surgeons (ASES) score were summarized as means and corresponding standard deviations.

Quality control: Data was collected using validated tools like the Non-Union Scoring System (NUSS) and the American Shoulder and Elbow Surgeons (ASES) score sheets. Data was reviewed to check for missing data to ensure completeness and were counter checked and verified before analysis.

3.11 Ethical Considerations

Ethical approval for the study was obtained from the Moi Teaching Referral Hospital-Moi University Institutional Research and Ethics Committee (IREC) (Reference: IREC/2021/130, dated 12th August, 2021, approval number FAN: 0003952 (**Appendix I**)) and Research License (Ref. No. 903125 dated 08/September/ 2021) from the National Commission for Science, Technology and Innovation NACOSTI/P/21/12868 (**Appendix III**). The Institutional approval was obtained from the Chief Executive Officer of the Moi Teaching and Referral Hospital REF: ELD/MTRH/R&P/10/2/V.2/2010, dated 13th August, 2021 (**Appendix II**).

Informed consent was sorted from the patients before recruiting them to the study (**Appendix IV**). The right to access treatment was granted and the patients were at liberty to exit the study at any point without prejudice.

Confidentiality of study data and information was ensured by use of appropriate data protection mechanism that included use of passwords and removal of personal identifiers. The study information was not made available to anyone not involved in the study.

The results were presented in the Moi University School of Medicine oral thesis defense and the final findings will be made available for referencing at the College of Science Resource Centre and the Moi University Repository. The findings and recommendations of this study will be available for access and referencing in reputable scientific journals and general population for the use in the improvement of patient care. The findings are scheduled for dissemination in scientific conferences both locally and internationally.

3.12 Study Limitations

The limitations in this study were the fact that it was a single hospital-based study and the other challenge was loss to follow up of some study participants.

Loss to follow up was mitigated by regular telephone contact with the patients recruited during the study.

The study was conducted during the COVID-19 pandemic period. It was anticipated that the restrictions on hospital outpatient visits would affect the post-operative review of patients. However, this was mitigated by advising the patients to visit the hospital as soon as the guidelines were reviewed and outpatient visits allowed.

CHAPTER FOUR: RESULTS

4.1 The demography characteristics of study participants

The findings of this study were based on 32 patients aged 18 years and above with the diagnosis of humerus fracture nonunion who underwent operative management at the Orthopedic Department of the Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya, between August 2021 and July 2022.

The demographic characteristic of adult patients presenting with humerus fracture nonunion at the Moi Teaching and Referral Hospital is summarized below, and included: the age of the respondents, the gender, the side of the injury and nonunion, and the hand dominance data. The lifestyle demographic characteristics of interest were the history of smoking and alcohol use.

The study had 32 participants. The response rate was 80.5%. The mean age of the respondents was 52.21 (SD: 11.84) years with a range of 32-73 years. Majority of the respondents were between the ages of 44 and 58 years. Majority of patients resided in Uasin Gishu County N=18(56.25%).

Table 1: The demographic characteristics of adult patients with humerus fracture nonunion at the Moi Teaching and Referral Hospital

Variables	Parameter	Value
Number of respondents		32
Age	Mean age (years)	52.21 (SD: 11.84)
	Range of age (years)	32-73
Gender	(M: F)	18:14 (or 1.29:1)
Side of non-union	Right	13 (41.0%)
	Left	19 (59.0%)
Upper limb dominance	Right	26 (81.25%)
	Left	6 (18.75%)
Smoking	Yes	9(28.13%)
	No	23(71.87%)
Alcohol use	Yes	17 (53.12%)
	No	15(46.87%)

There were 18 male participants and 14 female participants, with a male/female ratio of 1.29: 1. The males made up n=18(56.25%) of the study participants while the female was n=14(43.75 %).

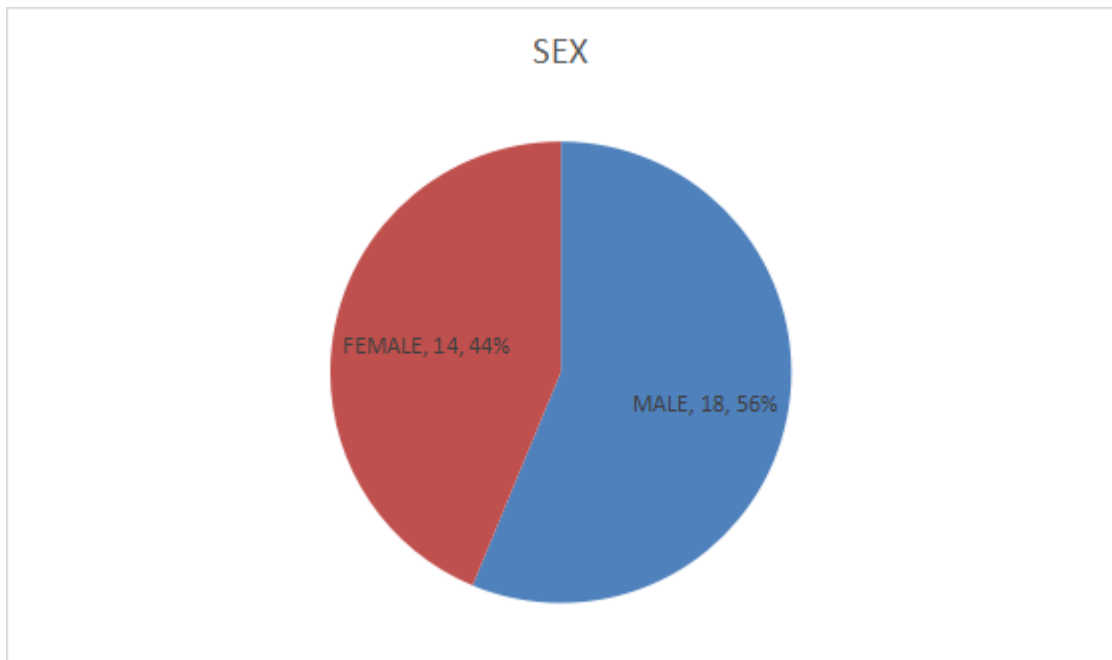


Figure 8: Sex of the respondents

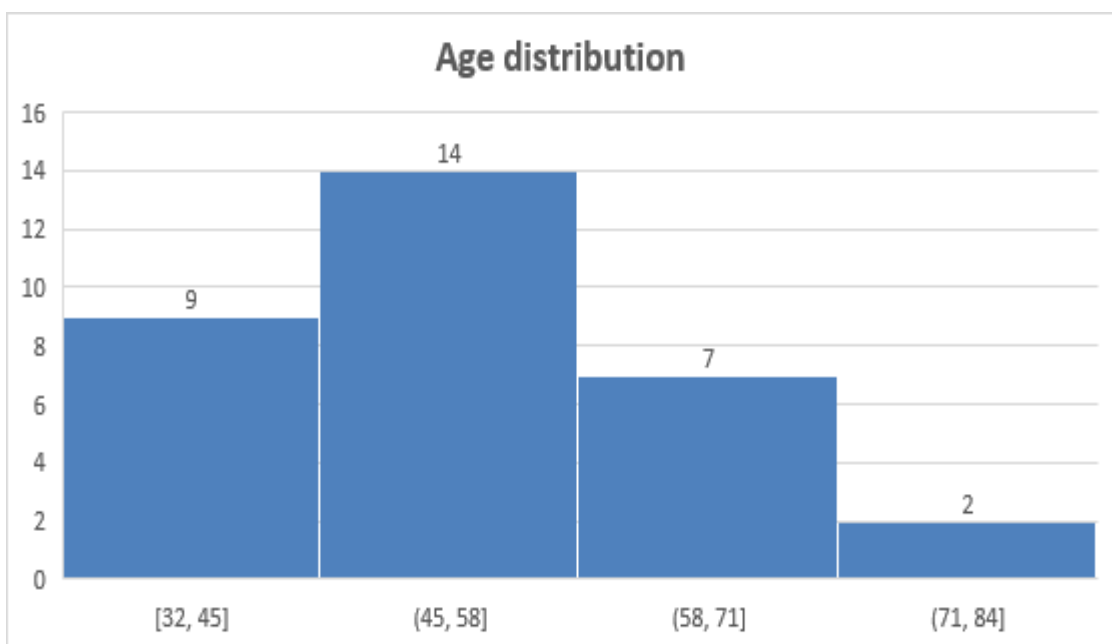


Figure 9: Age distribution of study participants

On admission, participants with the left upper limb injury were more than those with the right upper limb injury **19(59%)**, however, the right side was the dominant hand in **26(81.25%)**. On performing Fischer's exact test, this was statistically significant ($p < 0.05$).

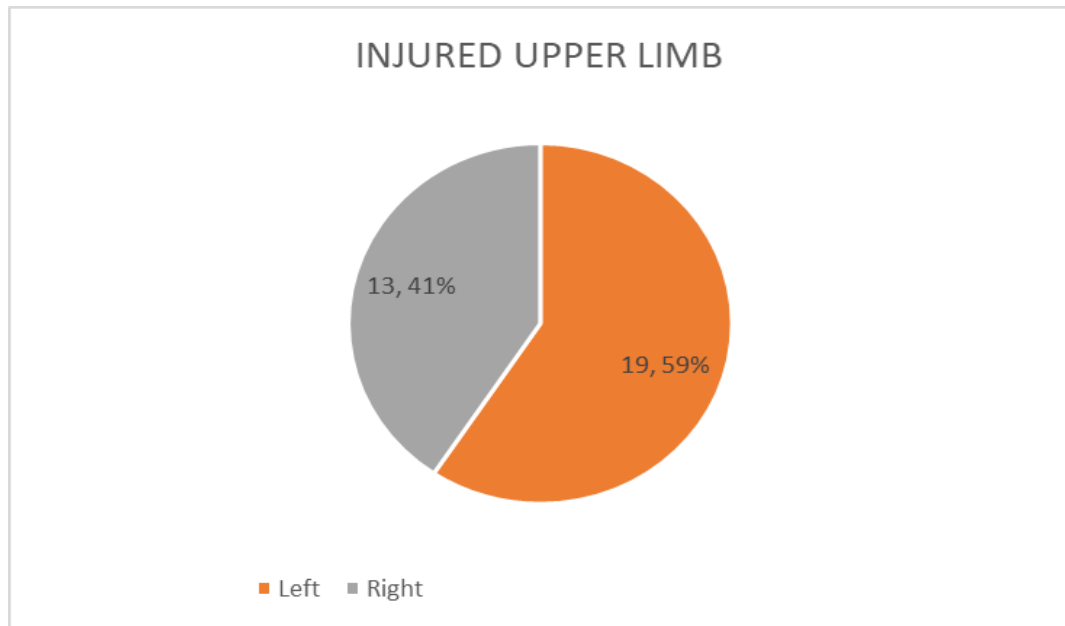


Figure 10: Side of the injured upper limb

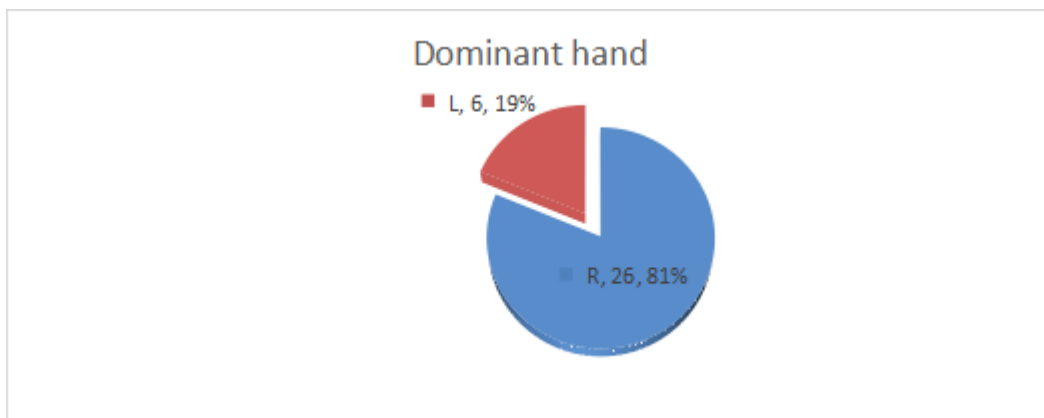


Figure 11: Proportion of the injured upper limb in terms of limb dominance in the respondents

Table 2: The association between the injured upper limb side and the upper limb dominance

Limb affected	Frequency n (%)		Total n (%)	p- Value
	Dominant	Nondominant		
Right	10(31.25%)	3(9.37%)	13(40.625%)	0.00013
Left	2(6.25%)	17(53.12%)	19(59.375%)	

The association in terms of handedness (dominant and nondominant) was statistically significant (p - value= 0.00013).

Nine (28.12%) respondents had a positive history of smoking. This was in the form of tobacco use and cigarette smoking.

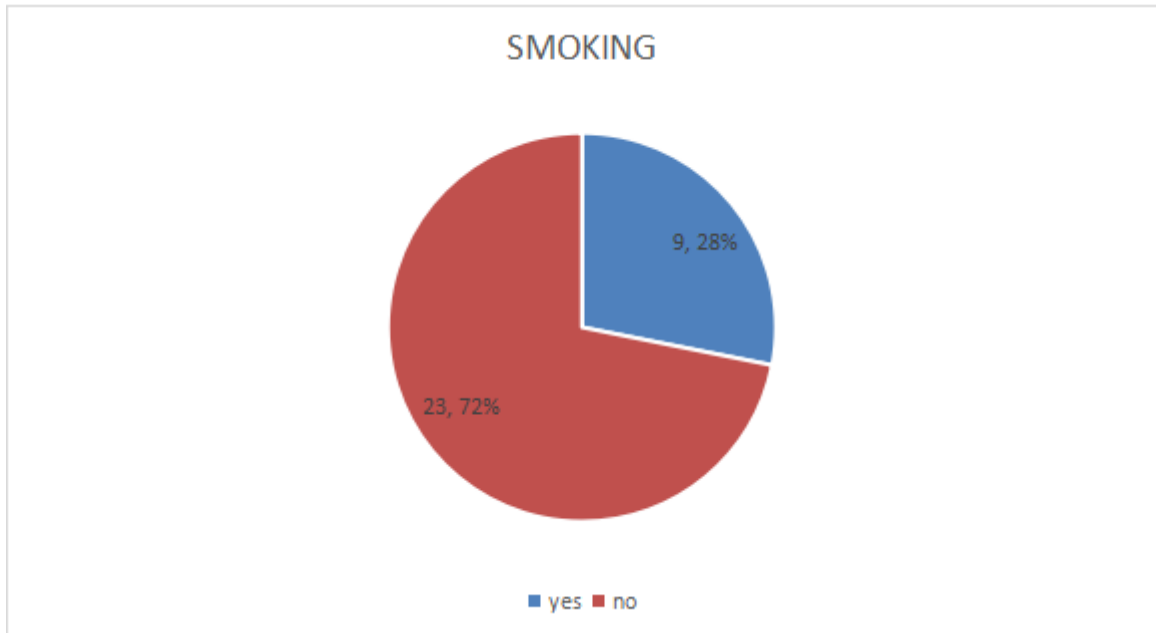


Figure 12: History of smoking among the respondents

Seventeen (53.12%) of the respondents had history of alcohol use by the time of presentation.

4.2 The Initial humerus fracture Characteristics

Table 3: The initial humerus fracture characteristics of adult patients attending the Moi Teaching and Referral Hospital

Variable	Parameter	Values
Site of injury/nonunion in the humerus	Proximal	7(21.871%)
	Shaft	18(56.25%)
	Distal	7(21.8%)
Mechanism of injury	High energy- RTA	26(81.25%)
	Low energy-Falls	4(12.5 %)
	Assault	2(6.25 %)
Time from initial injury to nonunion	Average	10 months
	Range	7-13 months
Type of nonunion (Weber-Cech classification)	Atrophic	24(75%)
	Hypertrophic	5(15.63%)
	Pseudoarthrosis	2(6.25%)
	Oligotrophic	1(3.13%)
The non-union scoring system (NUSS)	Average points (%)	23.34(46.68 %)
	Range of NUSS	15-35

The humerus shaft was the most affected site in 18(56.27%) while the distal and proximal end were equally affected in 7(21.8 %) of the respondents studied. Road traffic accident was the leading cause of injury to the humerus 26(81.25 %), followed by low energy such as falls 4(12.5%) and last by assaults 2(6.25%). The average time from injury to nonunion was 10 months (Range: 7- 13 months). The type of union was categorized according to the Weber and Cech group (van Basten Batenburg, et al., 2019). Majority of the non-union was atrophic in 24(75%), followed by hypertrophic in 5(15.62%), pseudo arthrosis in 2(6.25%) and the least was oligotrophic in 1(3.12 %) of the respondents studied. The degree of bone healing was assessed on the radiographs and the severity of the nonunion was scored using the Non-Union Scoring System (NUSS). The average Non-Union Scoring System (NUSS) score was 23.34 (46.68%) with a range of 15-35%.

4.3 Operative management modalities

All patients underwent preoperative assessment that included history taking, physical examination and investigations the included laboratory tests for Erythrocyte Sedimentation Rate (ESR), C- Reactive Protein (CRP) And Complete Blood Count (CBC).

Surgery was performed on the humerus fracture nonunion using the Anterolateral approach in 23 (71.9%) of the patients. Posterior approached was used in 5(15.6%) of the humerus fracture nonunion. Deltopectoral approach was used in 4 (12.5%) of the patients with humerus fracture nonunion. This is summarized in the table below.

Open reduction and plate fixation were done in all the cases during the study period.

Table 4: The operative modalities used in the management of humerus fracture nonunion among adult patient attending the Moi Teaching and Referral Hospital

Variable	Parameter	Value
Plating	Locking compression plate and bone graft	32 (100 %)
Surgical approach	Anterolateral	23(71.9%)
	Posterior	5 (15.6%)
	Deltopectoral	4 (12.5%)

The operated upper limb was immobilized in arm sling for one week. Thereafter, physiotherapy rehabilitation protocol was started. Active assisted shoulder and elbow exercises were started after one week.

The initial post-operative review was after 6 weeks. It involved both clinical and radiological assessments. Clinical assessment included scoring and documentation of the level of pain, shoulder and elbow function, wound healing status and peripheral nerve function. The radial, ulnar and median nerves were examined.

Radiological assessment for union was done in each of the post-operative visits. Plain radiographs with at least two views were taken on the injured humerus that had been operated upon. Presence of bridging callus in at least three cortices was considered adequate union for bone healing. This was recorded as the time to union of the fracture nonunion.

4.4 Outcomes of operative management of humerus fracture nonunion

4.4.1 Functional assessment

Functional assessment was done using the American Shoulder and Elbow Surgeons Score (ASES). Scoring was done on each post-operative visit. The final score was done at 24 weeks after the operation. The average American Shoulder and Elbow Surgeons score at each visit was summarized in the table below. The mean change in the American Shoulder and Elbow Surgeons score was documented for each visit.

The mean American Shoulder and Elbow Surgeons (ASES) score was 48.90 (SD: 12.2) at week 12 and the final American Shoulder and Elbow Surgeons (ASES) score was 78.98 (SD: 6.7) at the end of the study period of 24 weeks.

The mean American Shoulder and Elbow Surgeons (ASES) score change was 49.65 (SD: 5.7) points from the first post-operative review to the last post-operative review. The range was 29.89- 78.98 points. The table below summarizes the American Shoulder and Elbow Surgeons (ASES) scores measurements.

In this study the mean time to union was 19.04 (SD: 2.9) weeks. The range was 18-24 weeks. Thirty-one (31) of the cases had union at the end of the study period N=31(96.8%).

Table 5: The functional outcome using the American Shoulder and Elbow Surgeons score

Variable	Parameter	Value
Time to union	Mean	19.06 (SD: 2.9) weeks
	Range	(18-24 weeks)
Mean ASES score at post-operative review visit (%)	ASES 6-	29.89 (SD: 6.1)
	ASES 12-	48.90 (SD: 12.2)
	ASES 18-	67.254 (SD: 5.2)
	ASES 24-	78.98 (SD: 6.7)
Mean ASES change	Mean change	49.65 (SD: 4.1)
	Range	(29.89-78.98)

The complications that were noted during this study included iatrogenic transient radial nerve palsy and wound infections. This was summarized in the table below.

Table 6: Complications record during the study

Variable	Parameter	Value (n (%))
Complication	Radial nerve palsy	2(6.25%)
	Wound infection	3(9.37 %)
	Recalcitrant Nonunion	0
	Implant failure	0

4.4.2 Association between time to union and other variables

Fisher's exact test was done to show the association between the mean time to union and the independent variables. The age of the respondents was stratified into two categories: those below 45 years and those above 45 years.

The mean time to union was also stratified to those that achieved union in less than 20 weeks and those that achieved union after 20 weeks.

A 2 by 2 contingency table was developed and analysis done.

This was summarized as shown in the table below.

Table 7: The association between the mean time to union and other variables

Variable	Parameter	Mean time to union		p-Value
		<20 weeks	>20 weeks	
Age	<45 years	10(31.2%)	2(6.2%)	0.00013
	>45 years	3(9.37%)	17(53.12%)	
Time to diagnosis of nonunion	<10 months	5(15.6%)	14(43.75%)	0.04317
	>10 months	8(25%)	5(15.6%)	

There was significant statistical association between age ($p=0.00013$) and the time to nonunion diagnosis ($p=0.0417$) and the mean time to Union after operative management of humerus nonunion ($p<0.05$).

The younger the age of the respondents, the earlier the time to achieve union. Those who were identified as having humerus fracture nonunion earlier and managed promptly achieved fracture union faster than those with delayed diagnosis.

4.4.3 The factors affecting change in the American Shoulder and Elbow

Surgeons (ASES) score and the union rate

The Fischer's Exact test was used to assess the measure of association between improved American Shoulder and Elbow Surgeons (ASES) score and the independent variables. The independent variable included age, sex, handedness, smoking, alcohol use, injured hand, the mean time to diagnosis of nonunion and the average ASES score change between Week 6 and Week 24.

The table below summarizes the findings.

Table 8: The association between the average American Shoulder and Elbow Surgeons (ASES) score change and other variables

Variable	Parameter	Average ASES Score Change		<i>p</i> - Value
		34-50	51-65	
Gender	Male	10(31.2%)	8(25%)	0.9284
	Female	8(25%)	6(18.75%)	
Smoking	Yes	5(15.6%)	4(12.5%)	0.9604
	No	13(40.62%)	10(32.25%)	
Alcohol Use	Yes	9(28.12%)	8(25%)	0.6879
	No	9(28.12%)	6(18.75%)	

The association between the average ASES score change and other variables were statistically not significant ($p > 0.05$).

CHAPTER FIVE: DISCUSSION

5.1 The Demographic characteristics of patients with Humerus fracture nonunion attending the Moi Teaching and Referral Hospital

5.1.1 Introduction

The purpose of this study was to assess the functional outcomes of operative management of humerus fracture nonunion at the Moi Teaching and Referral Hospital. There were 43 participants initially in this study being a census of all adult patients with humerus fracture nonunion visiting the hospital during the study period. Out of these 32 participants completed the study follow-up period of 6 months. Majority of patients resided in Uasin Gishu County.

A similar study with 33 patients was that of Sadek and others in Minia, Egypt. The Egyptian study was a retrospective case series of resistant humerus diaphyseal nonunion managed using a combination of locked compression plating and non-vascularized fibular graft (Sadek, et al., 2021). Similarly, a prospective study in India by Bhimbarwad and others involved 22 patients with mid- shaft humerus fracture treated with minimally invasive anterior plate osteosynthesis (Bhimbarwad, et al., 2022).

5.1.2 Age of patients with humerus nonunion

The mean age of the patients with Humerus nonunion in this study was 52.21 (SD: 11.84) years. This is the economically productive age group in the study area and is therefore most likely to be involved in the motorcycle transport business. This findings were in agreement with those of a study in Serbia by Micic and others in which they had an average age of respondents at 53.25 years (Range: 21-79 years) (Micic, et al., 2019). The Serbian study was a retrospective comparative study of 52

patients with humerus nonunion managed either with conservative management and those managed surgically with plate or Intramedullary nail fixation.

These findings contrast those of a study in Czech Republic by Oubruba and others in which they had an average age of respondents at 62 years (Oubruba, Rammelt, Kopp, Edelmann, & Avenarius, 2016). The difference could be attributed to the larger sample size of 156 patients and the longer duration of study of ten years in the Czech study. Another study with contrast findings was that of Soni and others in India that had an average age of 31.2 years in an analysis of fifteen (15) cases of the humerus shaft nonunion managed operatively with locking compression plates with autogenous bone grafting (Soni, et al., 2019).

Older patients have a worse union rate following fracture of long bones and therefore develop nonunion as compared to younger age. According to Pollock and others, the overall nonunion rate can be as low as 32% in patients over 55 years with significant decrease in union rate as age of the patients increases (Pollock, et al., 2020). With increasing age, the bone quality reduces as well as the bone biology. This will require additional interventions to improve the biological environment for bone healing. For instance, Toro and others in Italy, detailed the use of stem cell in addition to cortical allograft in the management of humerus fracture nonunion in the elderly (Toro, et al., 2019). With regard to the humerus injury, older patients have a higher risk of severe proximal humerus fractures.

5.1.3 Gender of patients with humerus nonunion

In this study, the males were the majority of the respondents (N=18(56.25%)) while the remainder were females (N=14(44%)). The male: female ratio was 1.29:1. The male tend to engage more in motorcycle economy and other risky socioeconomic activities than the female gender.

These findings concur with those of a study in Switzerland by Vauclair and others in which they had 41% of the reported cases being female while the male formed 59% of the respondents (Vauclair, et al., 2020). The study focused on distal humerus nonunion. Similarly, in a Nigerian study by Madu and others, there was a male: female ratio of 1.9:1 among the study population (Madu, et al., 2018). The Nigerian study was a retrospective review of patients with long bone nonunion.

Contrast findings in terms of gender were noted in Serbia by Micic and others. They had had more females with a female to male ratio of 11:9 (Micic, et al., 2019). In that study, the surgical intervention was both plate and intramedullary nail of humerus fracture nonunion. Other contrast findings are documented by Fink Barnes and others in the United States of America in which there were more females than males with ratio at 11:2 (Fink Barnes, et al., 2020). The reason for the contrasting results could be that the United States of America study involved patients who underwent revision surgery in a single surgeon's clinical practice.

5.1.4 The handedness and injuries status of patients with humerus nonunion

The right hand was the dominant hand in majority of the respondents (N=26, 81.25%), however, the left were more affected. This was in agreement with the findings in a study conducted in Nairobi by Gichunge who found that the right hand was dominant in 84.4% of the reported cases (Gichunge, 2015). The similarity could be attributed to the fact that the study population in both studies were from almost similar geographic location of Kenya where most of the population is right handed. In a meta-analysis by Papadatou and others in 2020, the rate of right handedness

worldwide is estimated to be around 89.4%, while the left handedness is 10.6% (Papadatou-Pastou, et al., 2020).

However, contrary findings were documented by Munyuko Mwangi in Nairobi who had 91% of the patients being right hand dominant (Mwangi, 2019). He was analyzing the functional outcome in conservative management of diaphyseal humerus fractures and comparing the use of a U- slab vis-à-vis functional brace. In a study done in Eldoret by Montsho, he found out that both the dominant hand and the non-dominant hand were affected by trauma in equal measure (Montsho, 2018).

5.1.5 Injury laterality and dominant arm among patients with humerus nonunion

In this study, more upper limbs with humerus injuries occurred in the left-hand non-dominant participants N=19(59%) as compared to the right-hand dominant N=13(41%). The nondominant hand in the study population and during injury tends to be affected more than the dominant hand.

These findings concur with those of an epidemiological study in Malaysian by Chai and others in which the non-dominant hand was most affected in humerus injuries (Chai, et al., 2000). This was also appreciated in a prospective Indian study involving twenty two patients by Bhimbarwad and others that had 59.1% of the patients having left side humerus fractures (Bhimbarwad, et al., 2022).

An Africa study with contrary findings was that in Malawi by Igbigbi and colleague that indicated most humerus injuries affected the right hand dominance more than the left at 62 % versus 38% (Igbigbi & Manda, 2004). The Malawian study was an epidemiological analysis of humerus fractures over a 5-year period.

Another study with contrast findings was that of Khan and others in India that documented that the left humerus was injured in 42.2 % of the study population compared to the right (Khan, et al., 2018). This was a prospective cohort study of humerus diaphyseal fracture nonunion.

5.1.6 Smoking history among patients with humerus nonunion

Nine (28.12%) of the respondents had a positive history of smoking. These findings were in agreement with those of Zalavras and others in the United States of America (USA) which had 27% of the study participants having a positive history of smoking (Zalavras, et al., 2021). It was a retrospective study focusing on 41 adult patients with aseptic humerus shaft nonunion undergoing plate osteosynthesis over a 17-year study period. The implication of the smoking as a risk factor to healing following plate osteosynthesis was not statistically significant even in the long term.

Contrast findings to this study were documented by Kumar and others in India in which 16.7 % of the respondents had smoking as a risk factor (Kumar, et al., 2013). Another contrast findings was noted by Fink and others in which 46% of the study participants had a positive history of smoking (Fink Barnes, et al., 2020). The study was a retrospective review of patients with humerus shaft nonunion who were undergoing revision surgery for persistent nonunion.

Smoking is a modifiable risk factor that increases the risk of nonunion after long bone fracture. The toxins in cigarette affect the bone physiology that ultimately leads to reduced bone mineral density. With regard to fracture healing, cigarette causes vasoconstriction leading to hypoxia and modification of cellular metabolic activity. In a metanalysis by Pearson and others, the risk of getting nonunion is as high as 2.2 times among smokers as compared to non-smokers (Pearson, et al., 2016). Among men, smoking is an independent factor that increases the risk of nonunion of initial

humerus shaft fractures (Ji, et al., 2019). There is also increased risk of deep surgical site infections among smokers as compared to non-smokers (Xu, et al., 2021).

5.1.7 Alcohol use among patients with humerus nonunion

Seventeen (53.12%) of the respondents reported that they had been taking alcohol during the period prior to the humerus fracture injury. In the works of Olson and others, they reported 45 % of the study participants having a positive history of alcohol use. This was in a retrospective cohort study in the United States looking at the risk factors for nonunion after traumatic humerus shaft fractures in adults. Alcohol use was associated with three times the risk of developing nonunion (Olson, et al., 2020). There was significant association between alcohol use and increased risk of nonunion as emphasized by Zura and others in a prospective cohort study (Zura, et al., 2017).

5.2 The Initial humerus fracture characteristics of patients with humerus fracture nonunion at Moi Teaching and Referral Hospital

5.2.1 The site of humerus injury

Majority of the humerus injuries and nonunion in this study involved the shaft of the humerus N=18(56.25%). This is the most exposed part of the bone and vulnerable to direct blows during road traffic accidents, especially motorcycle injuries.

These findings were in agreement with those of Leiblein and others in Frankfurt, Germany who had most of the nonunion involving the shaft at 48.4 % compared to the proximal and distal third that were 16.7 % and 11.9% respectively (Leiblein, et al., 2019). It was retrospective study involving chart review of twenty-six patients treated for humerus nonunion. Another study findings in United States of America being in agreement with this one at MTRH were documented by Barnes and colleagues, whereby the humeral shaft injuries were 54% compared to the proximal third at 23 %

(Fink Barnes, et al., 2020). It was a retrospective study of thirteen patients who underwent revision surgery for a humerus shaft nonunion.

In an African study in Sfax, Tunisia by Sallemi and others, the humerus shaft had 53.4% of the humerus nonunion involved (Sallemi, et al., 2020). That study focused on fifty-eight humerus pseudarthroses cases treated with dynamic monoplane axial fixation and followed up for a period of 12 months.

The findings on the site of humerus that was injured contrasted those of Pollock and colleagues who found that 45 % of the humerus nonunion involved the proximal third as compared to 20 % that involved the distal third (Pollock, et al., 2020). The middle third of the humerus was involved in 26%. It was a retrospective study involving older patients treated at a Level I Trauma Center. The specific age group in that study could explain the difference. Older patients are prone to pathological fractures of the proximal third of the humerus while the young get involved in high energy injuries to the humerus shaft.

Another contrast finding documented in studies that showed distal humerus having majority of the injuries includes a Malawian study by Igbigbi and Manda. In that study 48.8% of the humerus injuries were type C(distal humerus) and compared to 41.1% involving the shaft (Igbigbi & Manda, 2004). The study in Malawi was a retrospective 5-year study period involving 258 humeri of patients aged 3-81 years.

5.2.2 The Mechanism of injury of the humerus

Road traffic accidents accounted for the majority N=26(81.25%) of the initial humerus fracture injuries in this MTRH study. This was followed by falls N=4(12.5%) and assault N=2(6.25%).

These findings were in agreement with those in a study in Lagos state, Nigeria, by Ezeuko and others in which road traffic accidents was the leading cause of humerus

injuries at 61.4 % (Ezeuko, Esechie, Oigbochie, & Ighalo, 2016). The similar findings could be due to the rising trend of road traffic accidents in Kenya (Macharia, et al., 2009; Muguro, Sasaki, Matsushita & Njeri,2020) and in Nigeria (Onyemaechi & Ofoma, 2016). In both countries, road traffic accident is among the leading causes of injury, disability and death. There is also improvement in the road infrastructure and increased motorization rate in both these countries.

Similarly, trauma was the leading cause of long bone injury and fractures at 86.4 % in a retrospective study done by Ayotunde and others in Ondo State, Nigeria (Ayotunde, et al., 2012). The two studies in Nigeria were both retrospective with similar mechanism of injury being trauma.

Contrast findings were reported by Muthuuri in a study in Mombasa that had majority (43%) of the injuries being caused by RTA involving motor vehicle accidents, bicycle accidents and pedestrian injuries (Muthuuri, 2011). In the Mombasa study, simple falls contributed to 36% of the humerus injury documented. The difference could be due to the fact that the Mombasa study was a retrospective analytical study of proximal humerus fractures.

Another contrast findings were in a study in India by Bhat and others in which road traffic accident was the leading cause of humerus injuries at 60 % (Bhat, Wani, & Nabir, 2020). It was a prospective study on twenty patients with humerus shaft nonunion treated with dynamic compression plating in Srinagar, India. The other causes of injury were falls from heights.

5.2.3 The type of nonunion of the humerus

The type of non-union was assessed based on the clinical and radiological findings and classified according to fracture nonunion classification as described by Weber and Cech in 1973 (van Basten Batenburg, et al., 2019).

In this MTRH study, atrophic nonunion formed the majority type of humerus fracture nonunion seen N=24(75%). This was followed by hypertrophic nonunion at N=5(15.63%) and pseudarthrosis nonunion at N=2(6.25%) and oligotrophic nonunion at N=1(3.2 %).

These findings were in agreement with to those of other studies notably one in Ondo State, Nigeria by Ayotunde and colleagues (Ayotunde, et al., 2012) and another one in Srinagar, India by Bhat and colleagues (Bhat, et al., 2020) which had atrophic nonunion forming a proportion of 81.8% and 80%, respectively. The Indian study by Bhat and others was a prospective analysis of twenty patients with humerus nonunion fractures who underwent operative management with dynamic compression plating and cancellous bone grafting. Similarly, the Nigerian study by Ayotunde and others was a retrospective review of twenty-two patients with humerus non-union in a tertiary healthcare institution. Both these studies and this MTRH study were undertaken in tertiary health institutions hence the similar findings. In such settings it is expected that the severe forms of nonunion that cannot be managed effectively at lower levels of health care are referred.

Contrast findings were documented by Leiblein and others in Frankfurt, Germany that had a 63% of the humerus nonunion being atrophic (Leiblein, et al., 2019). The proportion was slightly less than that found in this MTRH study. The difference could be the longer duration of the study, with the Germany study being a five-year review.

In a study in Sfax, Tunisia by Sallemi and others, there were contrast findings with hypertrophic nonunion being 34.5% and atrophic nonunion being 43.1% of the humerus fracture nonunion analyzed (Sallemi, et al., 2020). The differences could be

due to the fact that the Tunisia study focused on the humerus diaphyseal pseudoarthrosis nonunion.

Hypertrophic nonunion was found in N=5 (15.63%) of the participants in this MTRH study. This was in agreement with a study in China by Feng and others that had 16% of the humerus nonunion being hypertrophic (Feng, et al., 2018). This was a retrospective study analysis of six patients with long standing humerus nonunion.

Contrast findings were documented in a study by Bhat and others in Srinagar, India that had 20% of the nonunion analyzed being hypertrophic (Bhat, et al., 2020) and in another study in Gujarat, by Soni and colleagues that had 27 % of the humerus nonunion being hypertrophic (Soni, et al., 2019). The study by Soni analyzed humerus fracture nonunion following internal fixation with intramedullary elastic nails alone while this MTRH study focused on those who developed nonunion following nonoperative management

5.2.4 The Non-Union Scoring System (NUSS) score of patients with humerus nonunion

The Non-Union Scoring System (NUSS) score average points was 23.34 (46.68%), with a range of 15-35. This translated to about 47%.

The use of Non-Union Scoring system (NUSS) in nonunion management helps guide in the planning and anticipated difficulty in achieving union. A higher score indicates more challenging nonunion that requires aggressive interventions like amputations (Calori, et al., 2014).

Notable studies with contrast findings were those of Biglari and others in German that had an average Non-Union Scoring System (NUSS) score of 38.9% (Biglari, et al., 2016). The possible explanation to this difference could be the fact that the

German study involved all the long bones, not the humerus alone as was this MTRH study.

Another contrast finding was that of Rollo and others in Italy that had an average Non-Union Scoring System (NUSS) score of 61.7 (Range: 35-74). That study was a prospective study of cases with aseptic humerus fracture nonunion and the follow up was up to 12 months post-surgery (Rollo, et al., 2020).

5.3 Operative management modality used

5.3.1 Surgical approaches and techniques used

The operative management for all the cases of humerus fracture nonunion in this MTRH study was done with the patient supine position and under general anesthesia. Additional regional anesthetic blocks were given to selected patients for post-operative pain control. Prophylactic antibiotics were administered within one hour prior to making the first skin incision.

The surgical approaches varied depending on the site of the injury on the arm and the location of the nonunion.

Anterolateral approach to the humerus was used in N=23 (71.87%) of the cases. Posterior approach was used in N=5 (15.62 %) of the cases while deltopectoral approach was used in N=4 (12.5%) of the cases reported.

The findings of this study concur with those documented by Padha in which 73.3 % of the humerus nonunion were managed operatively using the anterolateral approach with compression plating (Padha, 2016). This approach to the humerus shaft allows for easy extension of the incision distally. This was the most commonly used approach in this MTRH study at N=23 (71.9%).

Similarly, the anterolateral approach was used in 60.7% of the cases in the works of Bernard and others in Switzerland (Bernard de Dompsure, et al., 2010). The study had majority of the patients having humerus shaft fractures.

Ayotunde and colleagues in Nigeria had a similar proportion of patients undergoing posterior approach at 18.2%. (Ayotunde, et al., 2012). Similarly, in a case report in Tokyo, Japan by Saka and others, a posterior approach was used to perform dual plating of a long standing nonunion of the humeral shaft (Saka, et al., 2021).

In this MTRH study, a dorsal 3.5 mm or 4.5 mm Dynamic Compression Plate or Locking Compression Plate was utilized. A minimum of three or four cortices of fixations proximal and distal to the humerus fracture nonunion site was used. Autogenous cancellous bone graft was harvested from either the iliac crest or the tibial tuberosity and placed at the nonunion site.

Post operatively, radiographs were done in the anteroposterior view and lateral views. This was done to assess the alignment of the bone and the implants. Radiographs taken much later were used to assess presence of bridging callus across the nonunion site.

The post-operative rehabilitation involved use of an arm sling for comfort for two weeks. Stable fixation using plate and screws is the most reliable treatment for humeral nonunion. Autograft is preferred for its osteogenic, osteoinductive and osteoconductive properties. According to Fink and others, the use of fibula allograft is an effective and straight forward option for treating humeral midshaft and distal shaft fracture nonunion (Fink Barnes, et al., 2020). However, it carries the risk of transmitting infections and thereby lowering the osteogenic and osteoconductive potential of the graft. It also cannot restore compromised vascularization of the humerus. Some authors do not recommend the use of bone graft as a routine in the

management of humerus shaft nonunion as it avoids the risk of donor site morbidity (Oliver, et al., 2021).

5.3.2 The Follow up period for patients with humerus nonunion managed at Moi Teaching and Referral Hospital

The follow up period for this study was 24 weeks (6 months). This was the period after the operative management of humerus fracture nonunion.

The period was similar to other studies that did follow up for six months. For instance, Khan and others in Rawalpindi, Pakistan had a six months follow of forty five patients with humerus shaft fractures (Khan, et al., 2018).

Contrast findings have been noted in studies that had longer follow up period, for example, those of Soni and others in Gujarat, India, that had 12 months follow up (Soni, et al., 2019). This was a retrospective study of patients with diaphyseal humerus fracture nonunion treated with different flexible nails.

Another study with longer follow up period of Fifty (50) months was that of Bernard de Dompure and others in France. It was a study involving 21 patients with uninfected nonunion fracture of the humeral diaphysis who were surgically treated with compression plates at Geneva university hospital (Bernard de Dompure, et al., 2010). The review was a ten-year period and hence the longer follow up duration.

Furthermore, longer follow up duration have been documented in other studies. For instance, there was a mean follow up period of 7.5 years (Range: 0.5-15.6 year) in a study in the USA by Fink and others. This study involved thirteen(13) patients who underwent open reduction and internal fixation of humerus shaft fracture nonunion with supplementary non vascularized fibular strut allograft (Fink Barnes, et al., 2020).

It was a retrospective study review of a single surgeons practice over sixteen years. This long duration of enrolment would require longer follow up period.

5.4 Outcomes

5.4.1 Union rate of humerus fracture nonunion managed at Moi Teaching and Referral Hospital

In this MTRH study, N=13 (41%) of the cases had radiological and clinical union at the 19.06-week post-operative visit, while N=31(96.88%) of the cases in this study had clinical and radiological union by the time of the final follow up visit at 24 weeks. Union was assessed radiographically and confirmed when there was evidence of cortical bone bridging at the nonunion site. The clinical parameters were absence of pain with manual palpation of the nonunion site. The radiographic union was confirmed by the appreciation of bridging callus in more than three cortices on the posteroanterior and lateral views of the humerus. Clinically, union was confirmed by absence of pain at the fracture site and ability to perform activities of daily living and function using the affected limb

These findings compare very well and agreeing with those of Kumar and others in India who reported a union rate of 95.8% following plate osteosynthesis of humerus shaft fracture nonunion following failed internal fixation. They used locking compression plates and autologous bone grafting in managing diaphyseal humerus fracture nonunion among the twenty-four patients. The cause of the failure in the initial fracture fixation included breakage of plates and loose screws (Kumar, et al., 2013).

Another study with a relatively higher union rate was that of Oliver and others in the United Kingdom. It was a retrospective study and the overall union rate was 78 %.

They were documenting union rate after open reduction and internal fixation of humerus shaft fracture nonunion without bone grafting (Oliver, et al., 2021).

Other studies with contrast findings were those reported by Fink and others in the United States of America in which the union rate in their study was 76.9%. This was after revision surgery of humerus fracture nonunion using non-vascularized fibular strut allograft (Fink Barnes, et al., 2020). This was a retrospective review of 13 patients who underwent revision surgery for humerus nonunion in a single surgeon's clinical practice.

5.4.2 The average time to union

The average time to union in this study was 19.01 weeks (Range: 18-24 weeks). This was greatly influenced by the surgeon's factors, the fixation methods and the host factors. Earlier union rate was achieved among the younger population, and this was statistically significant ($p < 0.05$). The use of plate fixation provided adequate compression on the fracture nonunion thereby facilitating union

Similar findings were documented in studies and have shown that there was union at an average of 14 weeks (Range: 12-16 weeks), for example, in an analysis of 15 cases of humerus fracture nonunion in India by Soni and others. All the cases had undergone open reduction and internal fixation by Locking Compression Plating with cancellous bone graft (Soni, et al., 2019).

Another study with similar finding was that of Koutalos and others in Greece in which they found an average time to union of 4.3 months (Koutalos, et al., 2015). The study was looking at outcome of surgically treated humerus nonunion among forty-two patients. Presence of infections was associated with prolonged union time.

Contrasting findings were recorded in studies elsewhere with a shorter humerus fracture nonunion healing time at 3.5 months being in a retrospective analysis by Zalavras and others in the USA. All the patients had union by three and half months after surgical treatment with plate osteosynthesis (Zalavras, et al., 2021). The study had forty-one adult patients with aseptic nonunion of the humeral shaft fractures. The shorter period to union was attributed to prompt identification and treatment of comorbidities

Another study with contrasting findings was the one by Gao and others, in which the average time to union was 6.1 months with a range of 5-8 months (Gao, et al., 2012). The patients included in the study were those with surgical neck humerus fracture nonunion that were managed operatively using locking plate fixation and autologous fibular strut bone graft.

5.4.3 The American Shoulder and Elbow Surgeons (ASES) score

5.4.3.1 The mean postoperative ASES score

The functional outcome of operative management of humerus fracture nonunion was assessed using the American Shoulder and Elbow Surgeons (ASES) score. It entails evaluation of 10 activities of daily living that require full shoulder and elbow movements. The total score for this is 50 points and additional pain scale worth 50. The maximum possible score is 100 points. Successful treatment of humerus fracture nonunion is expected to record improved function and improve the quality of life for the patients (Naclerio & McKee, 2022). This is after achieving union at the fracture site.

In this MTRH study the mean American Shoulder and Elbow Surgeons (ASES) score at 24 weeks (6 months) after the operative management of humerus fracture nonunion

was 78.98 (SD: 6.86) points. The average American Shoulder and Elbow Surgeons (ASES) score increased from 29.89 (Range: 20-42) at 6 weeks to 78.98 (SD: 6.86) points (Range: 66-91) at 24 weeks. The change on the mean ASES score in this study was 49.09 points.

The clinically significant change in the American Shoulder and Elbow Surgeons (ASES) score was quoted as at least nine (9) points by Werner and others (Werner, et al., 2016). This was in trying to quantify the least change in the American Shoulder and Elbow Surgeons (ASES) score that relates to a clinical significance.

The findings of this study compares very well and hence in agreement with the findings of a study in Rawalpindi, Islamabad, Pakistan by Khan and others in which they assessed 45 patients using the American Shoulder and Elbow Surgeons score following the use of Dynamic Compression Plate for humerus shaft fracture (Khan, et al., 2018). The mean American Shoulder and Elbow Surgeons (ASES) score was 81.1 (SD: 10.6) based on the shoulder function and patient reported Visual Analog Score (VAS) for pain. The range was 46.7- 91.7. The similarity could be the small number of study participants and both being prospective studies.

Similarly, Willis and others assessed patients with humerus atrophic fracture nonunion who underwent compressive locked plating with augmented strut allograft using the American Shoulder and Elbow Surgeons (ASES) score. The average American Shoulder and Elbow Surgeons (ASES) score was 76 at six months (Willis, et al., 2013). The functional outcome also had a higher patient satisfaction of 9.3/10 score. The greatest improvement was on the increase in the average forward elevation, abductions and external rotation of the shoulders. The study was also in a University

Hospital setup involving twenty patients with painful humerus atrophic fracture nonunion.

Another study with almost similar findings was that of Fink Barnes and others in the United States of America. The mean postoperative score was 65.4 points (SD: 28.5). This was in an analysis of 13 patients who underwent open reduction and non-vascularized fibular strut allograft in the operative treatment of humerus shaft fracture nonunion (Fink Barnes, et al., 2020). This was a review of a single surgeon's clinical practice.

However, on the contrary an average American Shoulder and Elbow Surgeons (ASES) score of 46 points was recorded by Soni and others, during the final 12 months follow up of humerus shaft fracture nonunion managed operatively with Locking Compression Plating and bone grafting (Soni, et al., 2019). In that study involving fifteen cases of humerus shaft fracture nonunion that had previously been managed using elastic nails, the functional score was lower due to the numerous surgeries on the affected limb. The other difference could be the longer duration of follow up of fourteen (14) months.

The factors or variables associated with an improved American Shoulder and Elbow Surgeons (ASES) score from the initial follow up to the final score was analyzed. The attributes that highly contributed to an increase in change in the American Shoulder and Elbow Surgeons (ASES) score was the age of the patient and the initial American Shoulder and Elbow Surgeons (ASES) score are 6 weeks ($p < 0.05$). Younger individuals had a greater improvement in the functional score as compared to the older individuals.

5.4.3.2 Complications rate

The transient radial nerve palsy rate in this study was N=2(6.25%). This was in agreement with an analysis by Koh and others in the United States of America in which they had radial nerve palsy rate of 6.9% (Koh, et al., 2020). This was a multicenter sample analysis involving eighteen (18) Academic Trauma Centers. There were three hundred and seventy-nine (379) adults with humerus shaft fracture nonunion that were being repaired. In that study, the midshaft fracture was the predisposing factor to the nerve palsy rather than the surgical approach. Other similar findings were recorded by Oliver and others in which they had 6% of the patients in Edinburgh, United Kingdom(UK) having radial nerve palsy (Oliver, et al., 2021). The study in the United Kingdom was a retrospective, involving 86 patients reviewed over a period of ten years.

The findings in this MTRH study were in contrast with those of Kakazu and others in Cincinnati, Ohio, that had radial nerve palsy of 18.5% (Kakazu, et al., 2016). This study was done in a Level 1 Trauma Center that provides the highest level of surgical care to trauma patients. This was exceptionally higher rate compared to other open procedures. Another study in Egypt by Sadek and others had a lower radial nerve palsy rate of 3.4% (Sadek, et al., 2021). It was a study of patients with resistant humerus fracture nonunion that underwent non-vascularized bone grafting in combination with locked compression plate and screws.

Iatrogenic injury to the radial nerve and its branches can occur at any level during operative management of the humerus. The nerve is most vulnerable at the midshaft where it is in contact with the periosteum and also where it pierces the intramuscular septum. Symptoms of radial nerve injury include sensory loss; wrist drop and deficit in finger extension in the metacarpophalangeal joints. Conservative treatment is the

main treatment of choice for neuropraxia of the radial nerve. Surgical treatment is indicated in cases of obvious nerve transection.

5.5 Sample images

Sample images: case 1



Figure 13: Case of humerus shaft nonunion in this study

CASE: Right humerus shaft fracture nonunion that **was** initially managed nonoperatively using a dynamic cast. He presented eleven (11) months after injury.



Figure 14: Intraoperative images showing dynamic compressive plating with autologous bone grafting of left humerus shaft fracture nonunion

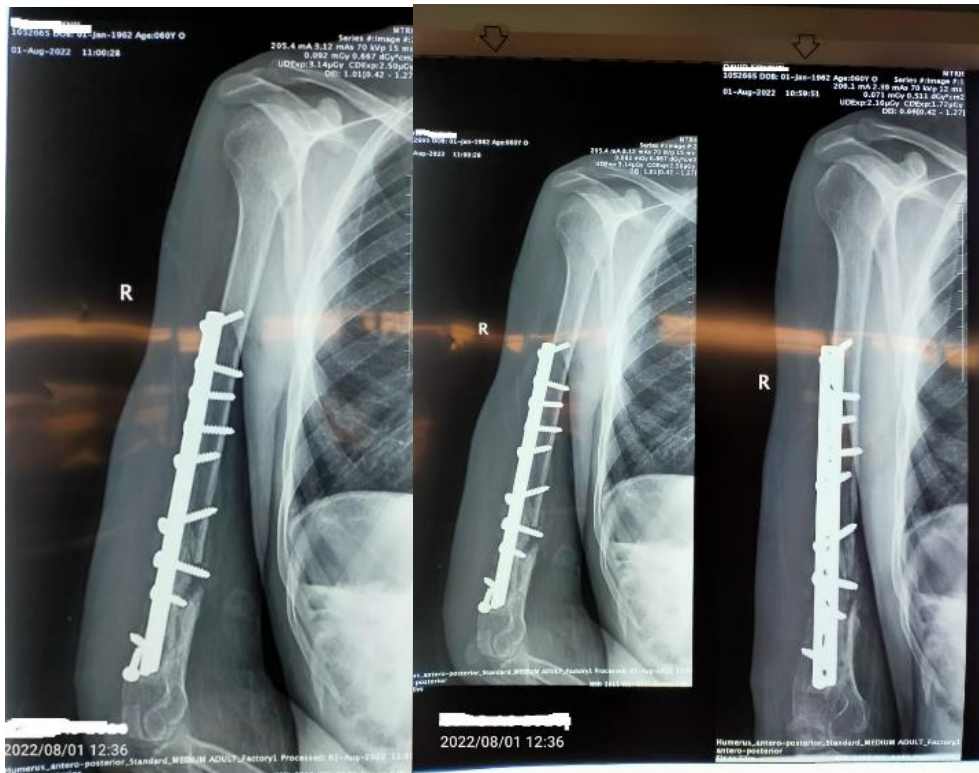


Figure 16: Post-operative images of plain radiographs of a case in the study with right Humerus shaft nonunion managed operatively using Plates and screws with autologous bone grafting at the end of the study period showing union at the fracture site

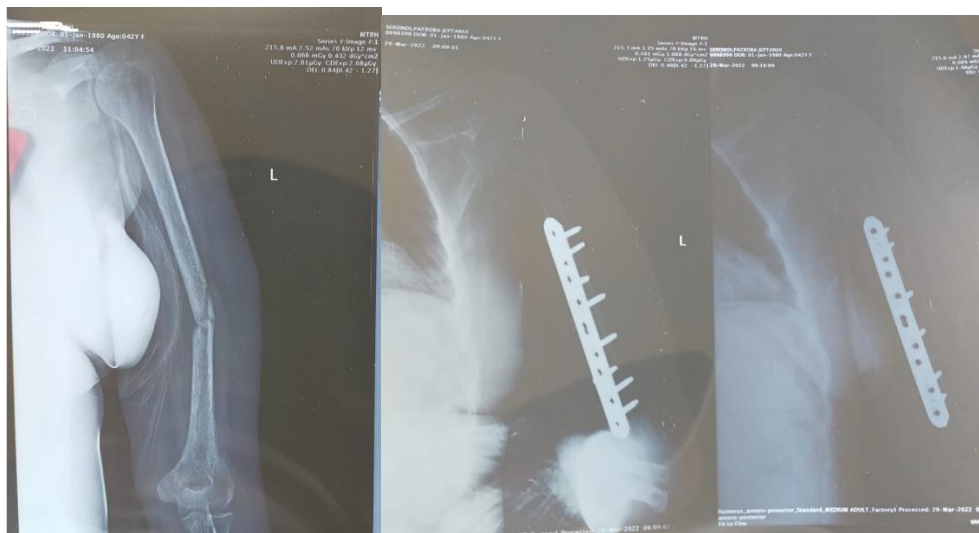


Figure 17: Plain radiographs of a second case of a female patient with left humerus atrophic nonunion that was operatively managed using plate and screws with autologous bone grafting

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

The average age was 52.21 (SD: 11.84) years (Range: 32-73 years) with a more male predominance.

The humerus shaft atrophic fracture nonunion type was the most common of all the nonunion encountered among adult patients at the Moi Teaching and Referral Hospital.

The use of locking compression plate with autologous bone graft achieved 96.2 % union rate at the end of study period among adult patients with humerus fracture nonunion managed operatively at the Moi Teaching and Referral Hospital.

There was improved function as assessed using the American Shoulder and Elbow Surgeons score, reduced disability and improved quality of life for patients following operative management of humerus fracture nonunion among adult patients attending the Moi Teaching and Referral Hospital.

6.2 Recommendations

Humerus fractures and nonunion occur in males at their economically productive age-group. Prompt operative management will enable resumption of economic activities, improve the quality of life and reduce disability.

Road traffic accident is the leading preventable cause of humerus injuries, and these can be reduced through creating public awareness and enforcement of traffic safety rules.

A surgical protocol should be developed to address the challenges Orthopedic Surgeons face in the operative management of humerus fracture nonunion among adult patients.

And

The use of rigid plate fixation with autologous bone grafting is recommended in the operative management of humerus fracture nonunion as it is associated with good functional outcomes.

Use of the America Shoulder and Elbow Surgeons score should be encouraged by Orthopedic Surgeons in order to monitor the outcomes of operative management more effectively

Further studies are needed to evaluate long term functional outcomes.

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APPENDICES

APPENDIX I: MTRH/MU-INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE(IREC) APPROVAL

 <p style="text-align: center;">MOI TEACHING AND REFERRAL HOSPITAL P.O. BOX 3 ELDORET Tel: 334711/2/3</p>	<p style="text-align: center;">INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)</p>	 <p style="text-align: center;">MOI UNIVERSITY COLLEGE OF HEALTH SCIENCES P.O. BOX 4606 ELDORET Tel: 334711/2/3 12th August, 2021</p>												
<p>Reference: IREC/2021/130 Approval Number: 0003952</p> <p>Dr. Terer Kiprotich Erick, Moi University, School of Medicine, P.O. Box 4606-30100, <u>ELDORET-KENYA.</u></p> <p>Dear Dr. Kiprotich,</p> <p><u>OUTCOMES OF OPERATIVE MANAGEMENT OF NONUNION HUMERAL FRACTURE AMONG ADULT PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA</u></p> <p>This is to inform you that MTRH/MU-IREC has reviewed and approved your above research proposal. Your application approval number is FAN: 0003952. The approval period is 12th August, 2021- 11th August, 2022.</p> <p>This approval is subject to compliance with the following requirements;</p> <ol style="list-style-type: none"> i. Only approved documents including (informed consents, study instruments, Material Transfer Agreements (MTA) will be used. ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by MTRH/MU-IREC. iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to MTRH/MU-IREC within 72 hours of notification. iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to MTRH/MU-IREC within 72 hours. v. Clearance for export of biological specimens must be obtained from MOH at the recommendation of NACOSTI for each batch of shipment. vi. 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. vii. Submission of an executive summary report within 90 days upon completion of the study to MTRH/MU-IREC. <p>Prior to commencing your study; you will be required to obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and other relevant clearances from study sites including a written approval from the CEO-MTRH which is mandatory for studies to be undertaken within the jurisdiction of Moi Teaching & Referral Hospital (MTRH) and its satellites sites.</p>														
<p>Sincerely,</p>  <p>PROF. E. WERE CHAIRMAN</p>	<div style="border: 2px solid purple; padding: 5px; width: fit-content; margin: 0 auto;"> <p style="text-align: center; margin: 0;">INSTITUTIONAL RESEARCH & ETHICS COMMITTEE</p> <p style="text-align: center; color: red; font-weight: bold; font-size: 1.2em;">12 AUG 2021</p> <p style="text-align: center; color: blue; font-weight: bold; font-size: 1.2em;">APPROVED</p> <p style="text-align: center; font-size: 0.8em;">P. O. Box 4606-30100 ELDORET</p> </div>													
<p>INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE</p> <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">cc</td> <td style="width: 33%;">CEO - MTRH</td> <td style="width: 33%;">Dean - SOP</td> </tr> <tr> <td></td> <td>Principal - CHS</td> <td>Dean - SON</td> </tr> <tr> <td></td> <td></td> <td>Dean - SOM</td> </tr> <tr> <td></td> <td></td> <td>Dean - SOD</td> </tr> </table>			cc	CEO - MTRH	Dean - SOP		Principal - CHS	Dean - SON			Dean - SOM			Dean - SOD
cc	CEO - MTRH	Dean - SOP												
	Principal - CHS	Dean - SON												
		Dean - SOM												
		Dean - SOD												

APPENDIX II: MOI TEACHING AND REFERRAL HOSPITAL CEO'S APPROVAL



An ISO 9001:2015 Certified Hospital



MOI TEACHING AND REFERRAL HOSPITAL

Telephone : (+254)053-2033471/2/3/4
 Mobile: 722-201277/0722-209795/0734-600461/0734-683361
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 Email: ceo@mtrh.go.ke/directorsofficemtrh@gmail.com

Nandi Road
 P.O. Box 3 – 30100
 ELDORET, KENYA

Ref: ELD/MTRH/R&P/10/2/V.2/2010

13th August, 2021

Dr. Erick Kiprotich Terer
 Moi University
 School of Medicine
 P.O. Box 4606-30100
ELDORET-KENYA

OUTCOMES OF OPERATIVE MANAGEMENT OF NONUNION HUMERAL FRACTURE AMONG ADULT PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

You have been authorised to conduct research within the jurisdiction of Moi Teaching and Referral Hospital (MTRH) and its satellites sites. You are required to strictly adhere to the regulations stated below in order to safeguard the safety and well-being of staff, patients and study participants seen at MTRH.

- 1 The study shall be under Moi Teaching and Referral Hospital regulation.
- 2 A copy of MTRH/MU-IREC approval shall be a prerequisite to conducting the study.
- 3 Studies intending to export human bio-specimens must provide a permit from MOH at the recommendation of NACOSTI for each shipment.
- 4 No data collection will be allowed without an approved consent form(s) to participants unless waiver of written consent has been granted by MTRH/MU-IREC.
- 5 Take note that **data** collected must be treated with due confidentiality and anonymity.

The continued permission to conduct research shall only be sustained subject to fulfilling all the requirements stated above.

13/08/2021
 DR. WILSON K. ARUASA, EBS
 CHIEF EXECUTIVE OFFICER
 MOI TEACHING AND REFERRAL HOSPITAL



cc - Senior Director, Clinical Services
 - Director, Nursing Services
 - HOD, HRISM

All correspondence should be addressed to the Chief Executive Officer

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APPENDIX IV: INFORMED CONSENT

Principal Investigator's profile

My name is Dr. ERICK TERER, a student pursuing masters of Medicine in Orthopedic Surgery at the Moi University. I am a qualified Medical Officer, registered by Kenya Medical Practitioners and Dentist Council. I would like to recruit you into this study entitled *Outcomes of Operative Management of Humeral Fracture Nonunion Among Adult Patients Attending Moi Teaching and Referral Hospital, Eldoret Kenya.*

The purpose of this study is to seek understanding of your demographic and initial clinical characteristics as a patient, operative approaches and outcomes of the humeral fracture nonunion at 6, 12, 24 and 30 weeks after the operation and help improve patient care.

Procedure: All the patients at the Moi Teaching and Referral Hospital who are scheduled to undergo surgical correction of humeral fracture nonunion will be guided by the researcher to fill the informed consent and their details entered into a questionnaire. The nonunion severity scores will be assessed.

Benefits: There will be no direct benefit to the participant in this study. You will be awarded same level of quality care like other patients.

Risks: There are no anticipated risks associated with participating in this study.

Confidentiality: All information obtained in this study will be treated with utmost confidentiality and shall not be divulged to any unauthorized person.

Rights to Refuse: Participation in this study is voluntary, there is freedom to decline to take part or withdraw at any time. This study has been approved by the Institutional Research and Ethics Committee (IREC) of Moi University/Moi Teaching and Referral Hospital. The administration of the hospital has also approved this study in this hospital.

Patient informed consent

I

Mr./Mrs./Miss.....

hereby give written informed consent to Dr. Terer Erick to include me in the proposed study entitled:

Outcomes of Operative Management of Humeral Fracture Nonunion Among Adult Patients Attending Moi Teaching and Referral Hospital, Eldoret Kenya.

I have read the information concerning this study, and I fully understand the purpose and my requirement. I also understand that my withdrawal from the study will not affect the care that I require for my condition.

Signature.....

Date.....

KISWAHILI VERSION

Mpelelezi: Jina langu ni Dr. TERER ERICK. Mimi ni daktari aliyefuzu nakusajiliwa na bodi ya madaktari ya Kenya (Kenya Medical Practitioners and Dentist Council). Mimi ni msomi wa shahada ya uzamili katika Orthopedics and Rehabilitation Department katita chuo kikuu cha Moi. Ningependa kukusajili ujiunge na uchunguzi ninaofanya kujua matokeo ya upasuaji wa mfupa uliochelewa kupona.

Kusudi: Utafiti huu utatafuta kuelezea matoke ya upasuaji wa mfupa wa mkono.

Utaratibu: Watu wenye umri wa miaka kumi na nane na juu wataelekezwa na mtafiti kujaza fomu za utafiti baada ya kukubali kufanyiwa utafiti. Matokeo ya upasuaji wa mfupa wa mkono utachunguzwa wiki sita baada ya upasuaji.

Faida: Hakutakuwa na manufaa ya moja kwa moja ya kushiriki katika utafiti huu. Masomo ya kujifunza yatapewa ubora wa usimamizi kama masomo yasiyo ya kujifunza

Hatari: Hakuna hatari inayotarajiwa kwa washiriki inayotokana na utafiti huu.

Usiri: Taarifa zote zilizopatikana katika somo hili zitatambuliwa kwa usiri mkubwa na hazitafunuliwa kwa mtu yeyote asiyeidhinishwa

Haki za Kuepuka: Kushiriki katika utafiti huu ni kwa hiari, kuna uhuru wa kupungua kushiriki au kuondoka kwa wakati wowote. Utafiti huu umekubalika na Kamati ya Utafiti na Maadili ya Taasisi (IREC) ya Chuo Kikuu cha Moi / Chuo cha Mafunzo na Hospitali ya Moi na Kwenye hospitali za kibinafsi.

Kusaini au kufanya alama unakubalikushiriki katika utafiti

Mgonjwa.....

Mpelelezi.....

Tarehe.....

APPENDIX V: QUESTIONNAIRE

OUTCOMES OF OPERATIVE MANAGEMENT OF HUMERAL FRACTURE NONUNION AMONG ADULTS ATTENDING THE MOI TEACHING AND REFERRAL HOSPITAL, ELDORET.

Patient study number.....Date.....

Section A: Demographic Factors

- a. Age.....
- b. Sex
 MALE FEMALE
- c. Telephone number (1)
- d. Telephone number (2)
- e. What is the Highest Level of education attained?
 None
 Primary
 Secondary
 Tertiary/college
 University
- f. What is your County of Residence?.....
- g. What is your current Occupation?
- h. Which is your dominant hand (Handedness)?
 Right Left
- i. Do you take Alcohol?
 YES NO
- j. DO you use tobacco and smoke Cigar or Cigarette?
 YES NO

Section B: Initial Fracture Characteristics

- a. What was the cause of the primary humerus injury?
- HIGH Energy LOW energy
- (Low energy: falls, assault) (High energy: Road traffic accident, Motorcycle's accidents)
- Others

- b. What is the Site of injury?
- Proximal humerus
- Shaft
- Distal humerus

c. What was the Type of Fracture according to the AO/OTA classification?

What nonoperative management was initiated initially?

- a. Cast immobilization and casting
- b. ARM Sling
- c. Back slab
- d. Others.....
- d. What is the NUSS score.....

Section C: Operative Management

- a. Compression plate fixation
- a. With autologous bone grafting
- b. Without autologous bone grafting
- b. Intramedullary nailing
- a. With autologous bone grafting
- b. Without autologous bone grafting
- c. External fixation
- d. Bone strut fixation
- e. Others (specify)
- f. Immediate post-operative outcomes;
- a. Intra-operative blood loss
- b. Duration of surgery
- c. Length of hospitalization

Section D: Functional Outcomes using ASES score assessed at week 6, 12, AND 24 Weeks post operation.

	ASES score	Comments / Union as seen on plain X ray.
Week 6		
Week 12		
Week 24		

Complications

- a. Transient radial nerve palsy
- b. Fracture of the distal humeral segment
- c. Infection
- d. Joint stiffness/ contractures

APPENDIX VI: NONUNION SCORING SYSTEM SCORE (NUSS)

The bone			
Quality of the bone	Good		0
	Moderate (e.g. mildly osteoporotic)		1
	Poor (e.g. severe porosis or bone loss)		2
	Very poor (Necrotic, appears avascular or septic)		3
Primary injury - open or closed fracture	Closed		0
	Open 1° grade		1
	Open 2-3° A grade		3
	Open 3° B-C grade		5
Number of previous interventions on this bone to procure healing	None		1
	<2		2
	<4		3
	>4		4
Invasiveness of previous interventions	Minimally-invasive: Closed surgery (screws, k wires, . . .)		0
	Internal intra-medullary (nailing)		1
	Internal extra-medullary		2
	Any osteosynthesis which includes bone grafting		3
Adequacy of primary surgery	Inadequate stability		0
	Adequate stability		1
Weber & Cech group	Hypertrophic		1
	Oligotrophic		3
	Atrophic		5
Bone alignment	Non-anatomic alignment		0
	Anatomic alignment		1
Bone defect - Gap	0.5-1 cm		2
	1-3 cm		3
	>3 cm		5
Soft tissues			
Status	Intact		0
	Previous uneventful surgery, minor scarring		2
	Previous treatment of soft tissue defect (e.g. skin loss, local flap cover, multiple incisions, compartment syndrome, old sinuses)		3
	Previous complex treatment of soft tissue defect (e.g. free flap)		4
	Poor vascularity: absence of distal pulses, poor capillary refill, venous insufficiency		5
	Presence of actual skin lesion/defect (e.g. ulcer, sinus, exposed bone or plate)		6
			6
The patient			
ASA Grade	1 or 2		0
	3 or 4		1
Diabetes	No		0
	Yes - well controlled (HbA1c < 10)		1
	Yes - poorly controlled (HbA1c >10)		2
Blood tests: FBC, ESR, CRP	FBC: WCC >12		1
	ESR >20		1
	CRP >20		1
Clinical infection status	Clean		0
	Previously infected or suspicion of infection		1
	Septic		4
Drugs	Steroids		1
	NSAIDs		1
Smoking status	No		0
	Yes		5

^a Higher score implies more difficult to procure union.

APPENDIX VII: AMERICAN SHOULDER AND ELBOW SURGEONS (ASES)

5/31/2021

ASES - Orthopaedic Scores

 www.orthopaedicscores.com

ASES Shoulder Score

Name _____

Age _____

Date _____

1. Usual Work

2. Usual Sport/Leisure activity?

3. Do you have shoulder pain at night?

- Yes
 No

4. Do you take pain killers such as paracetamol (acetaminophen), diclofenac, or ibuprofen?

- Yes
 No

5. Do you take strong pain killers such as codeine, tramadol, or morphine?

- Yes
 No

6. How many pills do you take on an average day?

7) Intensity of pain?

- 10 9 8 7 6 5 4 3 2 1

Pain as bad as it can be

8) Is it difficult for you to put on a coat?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

9) Is it difficult for you to sleep on the affected side?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

10) Is it difficult for you to wash your back/do up bra?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

11) Is it difficult for you manage toileting?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

12) Is it difficult for you to comb your hair?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

13) Is it difficult for you to reach a high shelf?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

14) Is it difficult for you to lift 10lbs. (4.5kg) above your shoulder?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

15) Is it difficult for you to throw a ball overhand?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

16) Is it difficult for you to do your usual work?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

17) Is it difficult for you to do your usual sport/leisure activity?

- Unable to do
 Very difficult to do
 Somewhat difficult
 Not difficult

To save this data please print or
Nb: This page cannot be saved due to patient data protection so please print the filled in form before closing the window.
The Total ASES score is:

Page design : Aaron Rooney

Reference : American Shoulder and Elbow Surgeons Standardized Shoulder Assessment I report section; reliability, validity, and responsiveness. Michener LA, McClure PW, Senr Elbow Surg. 2002 Nov-I

APPENDIX VIII: BUDGET

ITEM	QUANTITY	UNIT COST	TOTAL
Laptop	1	70,000	70,000
Printer & Photocopier	1	10,000	10,000
Stationery	-	15,000	15,000
Biostatistician	1	20,000	20,000
Internet & Communication	-	10,000	10,000
Transport	960	50	50,000
Publication	-	30,000	30,000
Research Assistant	-	20,000	20,000
Investigation	160	400	64,000
Miscellaneous	-	-	20,000
GRAND TOTAL	-	-	309,000

APPENDIX IX: WORK PLAN

TIME	2020	2021				2022				2023	
ACTIVITY	OCT - DEC	JAN - MAR	APR - JUN	JUL - SEP	OCT - DEC	JAN - MAR	APR - JUN	JUL - SEP	OCT - DEC	JAN - MAR	OCT - DEC
Proposal/concept Development											
Department Presentation											
Proposal Writing											
IREC Approval											
Data Collection											
Data Analysis											
Thesis Writing											
Mock Defense											
School Defense											