IMPACT OF TREATMENT TIMING ON ELBOW RANGE OF MOTION POST PAEDIATRIC SUPRACONDYLAR HUMERAL FRACTURES

By Dr. Kasereka Masumbuko Claude

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

DECLARATION

Student's declaration

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

Dr. Kasereka Masumbuko Claude, MBChB (UCG)

Registration number H58/72062/2008

Signature

Date _____

Supervisor's declaration

I hereby declare that this research proposal is being submitted with my approval as university supervisor.

Prof Mbindyo Benjamin S., MBChB, University EA, MMed, Nrb, FCS (ECSA)

Professor - Department of Orthopaedic Surgery, University of Nairobi

Signature	 	

Date....

I hereby declare that this research proposal is being submitted with my approval as university supervisor.

DR Gakuya Muthike Edward, MBChB (Nbi), MMed (Surg).

Lecturer - Department of Orthopaedic Surgery, University of Nairobi

Signature.....

Date.....

CERTIFICATE OF AUTHENTIFICITY

This is to certify that this thesis is my original work.

This research was carried out at Kenyatta National Hospital, Department of Orthopaedic Surgery.

Professor J.E.O Ating'a

Professor of Orthopaedic Surgery

Chairman Department of Orthopaedic Surgery

University of Nairobi

Signature

Date

DEDICATION

This thesis is dedicated to my wife Sahika Sivasivugha Eugenie for her understanding and her patience and to our children: Naomi, Deborah and Michael Ndaghane for bearing my absence from home.

ACKNOWLEDGEMENT

I am sincerely indebted to my supervisors Prof Mbindyo Benjamin S., and Dr Gakuya Muthike Edward, who have given constant encouragement and safe advice. They have offered enormous help in bringing this thesis into fruition in a timely manner.

The work could not have crystallized without the help of Chistoffel Blinden Mission (the sponsor), Michael Hawkes, Wobenjo Adili, Sister Karambu, Mayaka Emmanuel and colleague registrars.

Prof Mulimba J.A.O, former Chairman of the Department, has offered insightful counsel.

TABLE OF CONTENTS

DECLARATION	i
CERTIFICATE OF AUTHENTIFICITY	ii
DEDICATION	iii
ACKNOWLEDGEMENT	iv
TABLE OF CONTENTS	v
LIST OF ABBREVIATIONS	vii
LIST OF FIGURES	viii
ABSTRACT	ix
INTRODUCTION	1
LITERATURE REVIEW	
Epidemiology	2
Classification of supracondylar humeral fractures	2
Management	3
Nonoperative	
Closed Reduction and Pin Fixation	4
Open reduction	4
Delayed Treatment	5
Complications	6
Causes of impairment of elbow movement	6
Recovery of elbow motion	8
JUSTIFICATION	10
OBJECTIVES	11
Broad objectives	
Specific objectives	
METHODOLOGY	12
Study design	
Setting	
Sampling	
Main outcome measures	
Procedure	
Sample Size Estimation	15
DATA ANALYSIS AND DATA PRESENTATION	16

Ethical considerations	
Limitations	
RESULTS	
Rate of elbow ROM restoration following SHF	
Loss of ROM with delay in treatment of SHFs	
Effect of supervised versus unsupervised physiotherapy	24
DISCUSSION	26
CONCLUSION	31
RECOMMENDATIONS	
REFERENCES	
APPENDIXES	
APPENDIX I: QUESTIONNAIRE ON ELBOW ROM	
APPENDIX II: CONSENT FORM	
APPENDIX III: ASSENT FORM	
APPENDIX IV : FOMU YA KUSHIRIKI	

LIST OF ABBREVIATIONS

- **CRIF** : Close Reduction and Internal Fixation
- **IQR** : Interquartile range
- KNH : Kenyatta National Hospital
- **ORIF** : Open Reduction and Internal Fixation
- **ROM** : Range of Motion
- SHF : Supracondylar Humerus Fractures

LIST OF FIGURES

Figure 1: Measurement of elbow range of motion	14
Figure 2: Range of motion in 45 pediatric patients with SHFs following management	20
Figure 3: Loss of ROM with delay in treatment of SHFs	23
Figure4: Effect of supervised versus unsupervised physiotherapy	24
Figure 5: Analysis restricted to patients with Gartland III fractures	25

ABSTRACT

Background: Supracondylar humerus fractures (SHFs) are a common pediatric elbow injury contributing 60-80% of all elbow injuries. These fractures are associated with morbidity due to elbow stiffness. Emergent management of the supracondylar fractures is thought to reduce this complication ⁽¹⁾.

Objective: The purpose of the study was to evaluate the effect of timing of supracondylar humeral fractures treatment on the range of motion at the elbow. This aimed at improving the practice of treatment timing. It also evaluated the role of physiotherapy in treatment of residual elbow range of motion (ROM) limitation.

Design and setting: Prospective study from October 2012 to March 2013 at Kenyatta National Hospital.

Methodology: Prospective serial study of 45 pediatric patients managed with varying waiting time to treatment, and to physiotherapy. The measurement of elbow ROM was done at 4 weeks interval, up to 12 weeks after splintage.

Patients/Participants: Forty-five children with isolated supracondylar humerus fractures were followed at 4 weeks interval assessing recovery of elbow ROM.

Results

This study found that:

The ROM (flexion-extension) improved non-linearly from 4 to 12 weeks. The incremental change was greater in the early interval [median (IQR) 32° (24-40)] than in the latter interval [median (IQR) 12° (6-17), p<0.0001]. Similarly, the improvement in the ROM (supination-pronation plane) was greater from 4 to 8 weeks after pins and or back slab removal [median (IQR) 4° (10-20)] than from 8 to 12 weeks pins and or back slab removal [median (IQR) 32° (24-40), p<0.0001].

There was a significant inverse correlation between the time from injury to definitive management and the range of motion (in the flexion-extension axis) at 12 weeks (ρ =-0.42, p=0.005).

In the flexion-extension plane, the range of motion 12 weeks after injury was reduced in all patients relative to published normative data $^{(28)}$. On the other hand, supination and pronation were less severely affected, with 32/45=71% of patients having a normal ROM (supination-pronation arc) after 12 weeks.

Physiotherapy on ROM appears to be deleterious. Patients who underwent physiotherapy had a median (IQR) elbow flexion of 113° (110-128), as opposed to 129° (120-137) for those who did not undergo physiotherapy (p=0.003, MW). No significant difference was found among patients who had mild injuries after stratifying the cohort by injury severity.

Conclusion: In this study, the rate of ROM was less favorable and delay in management was remarkable. Stiffness was as a result of delay and physiotherapy negatively affected its outcome.

INTRODUCTION

Supracondylar fractures of the humerus contribute 13% to 16.6% of all paediatric fractures and account for around 60-80% of all elbow injuries ⁽¹⁾. Approximately 65% of children hospitalized for elbow injury have a supracondylar humeral fracture ⁽²⁾.

Supracondylar humerus fractures (SHFs) in children are associated with morbidity; including malunion, neurovascular complications, compartment syndrome, and elbow stiffness ⁽³⁾. At KNH, among the longstanding complications is elbow stiffness of 52 % magnitude ⁽⁴⁾.

Emergent management of supracondylar fracture in children reduces the risk of elbow stiffness. Every 5 hours delay beyond 15 hours after injury results in a 4-fold increase in the probability of undergoing open reduction and internal fixation (ORIF) rather than a closed reduction. The authors also noted that ORIF was necessary after 32 hours post trauma due to difficulty in closed reduction ⁽⁵⁾.

Several factors may contribute to delay in operative management: late patient presentation to the emergency department, lack of operation theatre space or trained personnel. Delayed management is more common in resource-limited settings because of poorly developed health delivery systems and long distances to reach a health facility ⁽⁶⁾. Closed reduction, in this group of patients, becomes usually unsuccessful and open reduction is required in about 40% of them ⁽⁷⁾.

The purpose of the study was to evaluate the effect of timing of paediatric supracondylar humeral fractures definitive treatment on the elbow ROM at KNH. The justification of this study is to improve the practice of treating paediatric humeral supracondylar fractures.

LITERATURE REVIEW

Epidemiology

Supracondylar humoral fractures occur most commonly in children under 10 years of age, with a peak incidence between 5 to 7 years of age ⁽¹⁾. In Kenya, the peak occurs between the ages of 4 and 8 ⁽⁴⁾. A significant drop is noted after the age of 12 ⁽²⁾. Girls are less affected (27.5%) than boys and the nondominant arm is more often injured (68.2%) ⁽⁴⁾. SHF occur year-round, with a characteristic seasonal distribution in northern climates: most cases occur in the summer months when children are more likely to be playing outdoors; and fewer than a quarter of fractures are sustained during winter months ⁽⁸⁾.

The mechanism of injury often involves a fall on the outstretched hand while the elbow is in extension. In 65%, this produces a bending force at the distal humerus by the tip of the olecranon, leading to fracture, and hence the name of extension injuries. The injury occurs with the elbow in extension, and displacements are varied. The distal humeral fragment angulation, rotation, postero-lateral displacement is common. Less commonly, direct force to the flexed elbow results in anterior displacement of the distal fragment; referred to flexion injuries. The author also found that fall on level ground, motor vehicle accident and assault were also cause of the injury in 33%, 1.7% and 0.5% respectively ⁽⁹⁾.

Classification of supracondylar humeral fractures

Classification of supracondylar humerus fractures is based mainly on the degree of displacement. Supracondylar fractures fall into two broad categories: extension-type and flexion-type. The extension type predominates (98% of injuries) ⁽¹⁰⁾. Wilkins ⁽¹¹⁾ modified the Gartland classification of extension injuries. It's based on plain radiograph of the elbow and describes the anatomical severity (simple or complex depending on the degree of displacement) of the fracture and, hence guides the fracture management.

Gartland I fractures are described as undisplaced or minimally displaced (by <2 mm) with the anterior humeral line (Rogers line) still passing through the mid-third of the ossified capitellum. The olecranon fossa is intact, there is no medial or lateral displacement, no collapse of the medial column, and the Baumann angle is normal. Radiographic evidence of bony injury may or may not be present. The only evidence of the fracture may be the posterior fat-pad sign ^(2, 11).

Gartland II fractures show posterior angulation of the distal humeral fragment but with the posterior humeral cortex remaining in contact, although hinged ⁽¹¹⁾. The anterior humeral line does not pass through the middle third of the capitellum on a true lateral roentgenogram. In order to determine the real size of the capetellum in young children, a circle of diameter equal to humerus shaft if drawn and placed over the visible bone nucleus in the lateral radiograph ⁽¹²⁾. On an anteroposterior roentgenogram, rotational displacement is not observed because of the intact posterior hinge ⁽²⁾.

Gartland III fractures have complete displacement of the distal humeral fragment with no significant cortical contact. There is usually extension in the sagittal plane and rotation in the frontal and/or transverse planes. The periosteum is significantly stripped. Soft-tissue and neurovascular injuries usually accompany this fracture ⁽²⁾. The radiographic appearance of the distal fragment depends on the extent of ossification of the distal humeral epiphysis, the metaphyseal fragment size, and the position of the distal humeral fragment ⁽¹¹⁾.

Management

The goals to achieve when treating a paediatric SHFs are anatomical reduction and uneventful healing. The treatment of paediatric SHFs is influenced by the direction and amount of displacement of the fragment, stability and the presence of neurovascular compromise⁽¹⁾.

Nonoperative

Non-displaced fractures (Gartland type I) which are very rare and are managed nonoperatively using a posterior backslab. A number of Type II fractures with minimal swelling, no medial comminution or with a Rogers line intersecting the capitellum can be also treated with a posterior backslab for 3 weeks.

Closed Reduction and Pin Fixation

These fractures are optimally managed using closed reduction and percutaneous fixation with Kirschner wires. The therapeutic goals are: (1) restoration of Baumann angle (>10 degree) on the AP x-ray; (2) restoration of medial and lateral columns based on an oblique view; and (3) positioning the anterior humeral line through the middle third of the capitellum on the lateral view. The fracture reduction is immobilized with two or three Kirschner wires ⁽²⁾. However, a satisfactory reduction will depend on surgeon skill, presence or absence of edema with a trend towards an increased operating time in case of delayed manipulation ⁽¹³⁾.

Ozkoc G et al comparing ORIF and CRIF in children with displaced extension-type SHFs found that closed reduction and pinning was superior to open reduction and pinning for the treatment of pediatric SHFs ⁽¹⁴⁾. However, during closed reduction, more than two unsuccessful attempts to reduce fracture segments lead to iatrogenic soft tissue damage and high risk of elbow stiffness ⁽¹⁵⁾.

Open reduction

Open reduction is indicated in cases of unstable or comminuted fractures, unsatisfatory closed reduction, vascular injury, and open fractures. Open reduction has more potential morbidity than

percutaneous pinning method such as higher rates of infection, myositis ossificans, unsightly scarring, iatrogenic neurovascular injury, longer hospital stay and worse functional results ^(2, 15).

Closed reduction and percutaneous pinning provide the best cosmetic and functional results. However, some fractures are irreducible by closed means ⁽¹⁶⁾. Patients presenting late after their injury (> 36 hours), are often treated by continuous traction, resulting in prolonged hospitalization. Another management option is to allow healing in non-alignment and later corrective osteotomy ⁽¹⁶⁾.

Good selection of patients for either method of treatment is recommended ⁽¹⁵⁾. Kaewpornsawan et al suggested that closed reduction should be performed first and, open reduction to be done in case of failure of closed method ⁽¹⁸⁾. Oh and Kaewpornsawan comparing results of open reduction versus closed reduction found no difference ^(17,18).

Delayed Treatment

One persistent controversy in the treatment of SHFs in children is the timing and urgency of treatment of Gartland II and III injuries without vascular compromise. Several retrospective studies have shown that 8 to 12 hour does not increase complication rate, prolong hospital stay, or affect long-term outcome ⁽¹⁹⁾. These reports suggest that it may be safe to postpone surgical intervention in order to allow for adequate fasting, wait for daylight hours and experienced theatre staff to be available.

On the other hand, other authors have challenged the safety of this approach. Complications may arise if the surgery is delayed, including a need for open reduction, and increasing swelling with an increased risk of compartment syndrome ⁽¹³⁾.

Complications

Paediatric SHFs pose special management challenges, in particular displaced fractures. The complications of these injuries include neurovascular compromise, ischemic contractures, angular deformities and elbow stiffness that statistically increase on treatment delay.

Malunion, which is largely due to rotation, results in cubitus varus deformity. Inadequate correction of medial collapse can also lead to cubitus varus, hence, lead to a decrease of elbow range of movement ⁽²⁰⁾.

At KNH, stiffness was the commonest complication, ranging from 5.6% to 51.6% ^(4,9). Temporary elbow stiffness that is noted after the treatment of a supracondylar humeral fracture is often a parental concern ⁽²¹⁾. Therefore, inform parents on the likely timeframe and course in recovery of elbow ROM to enhance compliance in treatment protocol.

Causes of impairment of elbow movement

Several conditions may lead to reduced elbow range of motion; these are extrinsic and intrinsic causes. Intrinsic contractures are produced by adhesions within the joint, joint misalignment, loss of articular cartilage. Extrinsic causes are contractures of the joint capsule, muscles spanning or surrounding the joint, and collateral ligaments ⁽²²⁾.

Soft tissue injury triggers inflammation, pain, and alters stress patterns within tissues, leading to loss of joint function. The formation of fibrous scar tissue may impair muscle healing and lead to incomplete regeneration of the injured muscle tissue ⁽²¹⁾.

The condition of the soft tissues is as important as the condition of the bone in determining the eventual functional outcome. In elbow fractures, long term disability is believed not to be a

result of damage to the bone but a result of damage to the soft tissues with resultant stiffness of neighboring joints ⁽²³⁾.

Operative treatment of SHFs in children may result in limitation of active movement of the elbow joint ⁽²⁴⁾. The posterior approach is associated with a high incidence of restricted range of motion. Furthermore, this procedure can disrupt the posterior end arterial supply to the trochlea of the humerus and lead to osteonecrosis ⁽²⁾. Moreover, the posterior approach might lead to weakening of muscle strength and joint motion loss due to splitting triceps muscle ⁽²⁵⁾. Spencer et al noted that patients with more severe fractures requiring surgical treatment demonstrated a 4% to 8% lower relative arc of motion for up to twenty-four weeks after the original injury, as compared to those non-surgically treated ⁽²¹⁾.

The duration of immobilization after open reduction and Kirschner wire stabilization of SHFs is an important variable that affects joint mobility. In one report, restricted active range of motion was common at the time of K-wire removal, and the author recommended that immobilization period should not exceed 3 to 4 weeks ⁽²⁴⁾. However, this study included only open reduction cases and half of them underwent physical therapy.

The failure to gain full ROM may be caused by inadequate fracture reduction or severe soft tissue injury ⁽²⁶⁾. Parmaksizoglu et al noted that unsatisfactory reduction or loss of primary reduction during fixation required repeated attempts of fracture reduction leading to iatrogenic soft tissue injury ⁽¹⁵⁾.

Post-operative joint stiffness is a function of the magnitude of the initial trauma and the extent of surfaces involvement. The intensity of the trauma correlates with the fracture displacement, which in turn affects bone healing and remodeling. In Gartland I and II fractures, the periosteum is usually intact on the compression side of the fracture. This may be helpful in clinical practice, since the periosteal hinge can be helpful in fracture reduction, and promotes rapid bone healing. Age also affects outcome, less to five years old patients achieve 3 to 9% greater arc of motion in follow up relative to older patients ⁽¹⁵⁾.

Recovery of elbow motion

Recovery of elbow motion has been shown to be progressive with good functional outcome. Zionts et al did a retrospective study on the time of return of elbow motion after percutaneous pinning of paediatric SHFs. At 12 weeks post removal of pins, the elbow range of motion returned to 86% of contralateral elbow motion. The study does not verify the effect of delay in starting appropriate definitive treatment on the range of elbow motion ⁽²⁵⁾.

Wang et al ⁽²⁷⁾ reviewed 45 children with distal humerus supracondylar and 16 other children with lateral condylar fractures and assessed recovery of ROM. Authors included in their study 27 other children, as control group, with distal forearm fractures. The control group was managed with a long cast for 4 weeks, to determine the extent of the elbow flexion-extension recovery after joint immobilization but without elbow fracture. With a goniometer, the patients were followed-up after cast removal until 90% ROM of uninjured limb was achieved. The authors found that 90% ROM in extension, flexion, supination, and pronation were achieved within six weeks in children with SHFs. In the distal forearm fracture group, the total flexion-extension angle (135 degrees) was recovered in less than two weeks. However, apart from wide variability in time required to recover flexion motion, the effect of delay in treatment was not investigated in the study.

Spencer et al conducted a prospective longitudinal evaluation of elbow motion following SHFs. Surgery was done 3.4 ± 3.1 days post injury with a minimum of follow-up of 7 weeks. The authors noted that there was greatest restoration of elbow ROM within the first month after cast removal. Spencer et al also noted that there was a progressive improvement of the elbow ROM up to around 1 year post injury ⁽²¹⁾. This is good information to relative and guardian to allay anxiety.

JUSTIFICATION

Demonstrating an association between delayed treatment and elbow impairment of ROM will provide avenue to emphasize early intervention for improved quality of management in children with supracondylar humeral fractures.

This study has generated an objective answer on restoration of ROM to parent/guardian. It will also influence, with judicious use of resources, the practice of physician in managing SHFs in children. The results of this study will be used as a springboard for further research in functional outcome of the elbow post a paediatric SHF.

OBJECTIVES

Broad objectives

To evaluate the effect of timing of treatment on elbow stiffness after supracondylar humerus fractures in children.

Specific objectives

- 1. To evaluate the rate of elbow ROM restoration following SHF.
- 2. To correlate elbow ROM at 12 weeks post-treatment with delay in treatment of SHFs.
- 3. To determine the effect of physiotherapy on elbow ROM at 12 weeks post-treatment.

METHODOLOGY

Study design

This was a prospective conveniently sampled study, starting after cases recruitment

Setting

The study was conducted at the KNH Orthopaedic outpatients' clinic, Casualty and paediatric Orthopaedic Ward.

Sampling

Non-random convenience sample of patients who met inclusion criteria were recruited from KNH casualty until sample size was obtained.

Main outcome measures

Elbow ROM was measured longitudinally with a goniometer at four-week interval after back slab and or pin removal up to 12 weeks with reference to published normative data.

Procedure

In Casualty department, the identification of all fresh cases was done. Parents or guardians of eligible patients gave consent. Consenting parents or guardians were interviewed for demographic and clinical information and entered into a structured questionnaire (Appendix I). A lateral view of an x-ray centered at distal humerus, and a true anteroposterior view of the involved elbow were used to categorize patients according to Gartland classification.

Nondisplaced fractures were managed on a back slab and followed as outpatients. The second group of patients with more severe injuries was admitted, pending surgical intervention. After surgery (CRIF or ORIF), patients were discharged and managed as outpatients.

For both groups, patients were reviewed, at the orthopaedic outpatients' clinic by the researcher, three weeks later for removal of pins and or back slab. Elbow angle of immobilization was then measured. This angle in which the elbow was first immobilized was correlated with the rate of elbow ROM restoration.

Patients were recruited until the desired sample size was attained and each patient was followed, from his date of back slab and or pins removal, up to 12 weeks. The ROM was measured, on the day of back slab removal, and thereafter, every 4 weeks up to 12 weeks for each patient.

The measurements of elbow ROM were performed using standardized methods ⁽²⁷⁾. With the forearm in neutral position, the elbow was placed in the angle at which the joint was immobilized. Using gentle active elbow ROM (by encouraging the patient on motion as far as he could) the limit of flexion, extension, forearm supination, and pronation were measured using plastic goniometer.

To measure flexion and extension, the goniometer was centered at the distal humerus, which represents the approximate axis of elbow flexion–extension. The arms of the goniometer were aligned parallel to the humerus and the forearm, respectively (Fig. 1A).

To determine the extent of maximal forearm rotation, the arm was immobilized against the chest wall, and the elbow was placed in the position of immobilization. The neutral position was defined as the position at which the extended thumb (pointer) had aligned with the humerus. One arm of the goniometer was made parallel to the radially abducted thumb (pointer), and the other arm remained exactly vertical (Fig. 1B). Active ROM was recorded as the maximum number of degrees the joint moves in each direction. All the measurements were performed by the researcher. The mean and standard deviation of elbow ROM in each direction at the day of back slab removal and at 4 week-interval were calculated.

During this study, the researcher encouraged all patients to attend physiotherapy session after back slab and or pin removal. At the end of the proposed follow-up period, patients were divided into two groups of attending or not attending physiotherapy. The researcher or trained assistant also encouraged each patient to do daily elbow active ROM at home as pain allows.

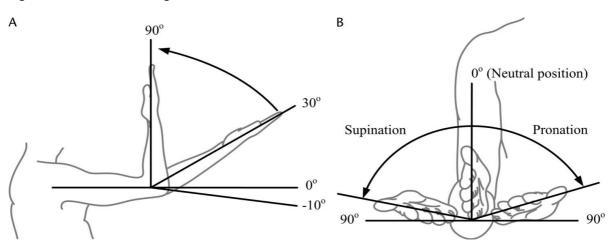


Fig1: Measurement of range of motion

Figure 1: Measurement of elbow range of motion



Fig 1B: Supination- pronation

 Figure 1: Measurement of elbow range of motion, A flexion-extension, B supination-pronation [Wang, et al. The recovery of elbow range of motion after treatment of supracondylar and lateral condylar fractures of the distal humerus in children. J Orthopaed Trauma. 2009. 23(2), pp 120-125]²⁷.

Sample Size Estimation

The following formulae was used to get the study sample size.

$$Z^2_{\alpha/2} * PQ$$

n = _____

$$\delta^2$$

Where:

n = required sample size

 δ = the desired precision level set at 10% (0.1)

P = is the expected SHFs prevalence = 13%

Q=1-P.

 $Z_{\alpha/2}(1.96).$

n = $43.4 \approx 44$ patients

Inclusion criteria

- Age 0 -15 years
- Radiologically confirmed isolated supracondylar fracture of the humerus.

Exclusion criteria

- Open fracture or burns
- Bilateral supracondylar humerus fracture
- Patients above 15 year old
- Patients treated (definitive management) outside KNH
- Patients with neurovascular injuries before treatment
- Multiple fractures
- Ipsilateral forearm fractures

DATA ANALYSIS AND DATA PRESENTATION

To answer the primary objective, we examined the rank correlation between the time interval from injury to intervention and the recovery time of elbow range of motion at 3 months. For secondary objective, descriptive and comparative statistics were used as appropriate.

Data processing was done by the statistical software SPSS 20.0. Descriptive statistics including mean, standard deviations, and proportions were calculated. T-test and χ^2 tests were used to calculate the significance of determined results, 95% confidence interval and P value <0.05. Results were presented in form of tables and bar graphs.

Ethical considerations

Approval to carry out the study was sought from the Orthopaedic Surgery Department University of Nairobi and the Kenyatta National Hospital Ethics and Research Committee.

Parents of patients recruited into the study gave a signed informed consent after a clear explanation of the nature and purpose of the study and their right to withdraw from the study if they wish so. Parents who declined to consent were assured of standard treatment of their children.

Limitations

- Guardian/ parent memory bias: time of injury, period of discarding arm sling, education of parents and number of physiotherapy sessions attendance.
- Situation: patient anxiety at goniometry and degree of active arc
- Instrument: protractor and quality of X ray.
- Extraneous variable: duration of each physiotherapy session, inter-surgeon differences

RESULTS

Forty-five children with SHFs were followed monthly for 12 weeks after treatment in a prospective cohort study. Demographic details are given in Table 1. The median age was 7 years (range 2-15). Sixty-two per cent (62%) were male and thirty-eighty per cent (38%) were female. Most injuries (71%) occurred in the non-dominant limb. The median time to treatment was 24 hours for Gartland type I and II fractures managed non-operatively and a week for Gartland type III fractures managed by ORIF.

Table 1: Demographic data

Variables	n = 45 (%)	
$C_{\rm ext}$ for μ (0(1)		
Gender, n (%)		
Female	17 (38%)	
Male	28 (62%)	
Side of injury, n (%)		
Dominant limb	13 (29%)	
Non-dominant limb	32 (71%)	
Age [years], median (range)	7 (2-15)	
Time to treatment [days], median (range)		
Non-operative management	1 (1-5)	
CRIF	1*	
ORIF	7 (3-13)	

* A single case was managed by CRIF (no range given)

Patients were grouped according to severity based on Gartland's classification and treated accordingly (Table 2). Gartland I and II fractures were treated non-operatively, and within the first 24 hours in most cases. Gartland III fractures were managed using open reduction and internal fixation in 97% of cases, with a median interval between injury and surgery of 7 days (range 5-14).

		Nonoperative	CRIF	ORIF	Total
Gartland's	type 1	10 (100%)	0	0	10
classification	type II	6 (100%)	0	0	6
	type III	0	1 (3%)	28 (97%)	29
Total		16	1	28	45

Table 2: Severity and Management

Rate of elbow ROM restoration following SHF.

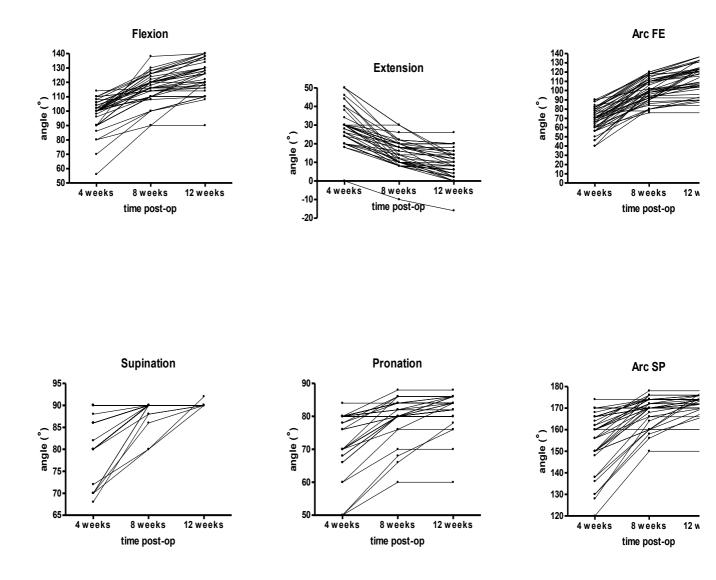


Figure 2: Range of motion in 45 pediatric patients with SHFs following management

Serial measurements of elbow flexion, extension, supination and pronation were taken at 4, 8, and 12 weeks after pins and or backslab removal. The flexion-extension arc (Arc FE) represents the sum of the flexion and extension ranges, and the supination-pronation arc (Arc SP) represents the sum of the supination and pronation ranges.

Table 3 shows the elbow ROM in multiple dimensions as a fraction of the expected normal range of motion based on published normative data ⁽²⁸⁾. Flexion angle was most markedly reduced, with a median recovery of only 57% of the expected normal angle by 12 weeks post-treatment. In the flexion-extension plane, the range of motion at 12 weeks after cast and pins removal was reduced in all patients relative to published normative data ⁽²⁸⁾. The ROM reached >90% of normal ranges in extension, supination and pronation. Seventy-one per cent (32/45) of patients achieved a normal ROM (supination-pronation arc) after 12 weeks.

	4 weeks	8 weeks	12 weeks	
	1(0/ (0.00)	4007 (00 51)		
Flexion	16% (0-22)	42% (33-51)	57% (41-67)	
Extension	72% (68-79)	87% (83-93)	93% (87-100)	
Arc FE	46% (38-51)	65% (59-72)	73% (66-81)	
Supination	102% (100-111)	113% (106-113)	113% (106-113)	
Pronation	85% (80-93)	91% (85-95)	92% (88-97)	
Arc SP	92% (87-96)	98% (95-100)	99% (97-101)	

Table 3: Percent recovery in range of motion [median (IQR)]*

*relative to age and sex-specific norms for elbow range of motion in a healthy population ⁽²⁸⁾.

While the ROM (flexion-extension) improved from 4 weeks to 8 weeks, and from 8 weeks to 12 weeks, the incremental change was greater in the early interval [median (IQR) 32° (24-40)] than in the later interval [median (IQR) 12° (6-17), p<0.0001]. Similarly, the improvement in the ROM (supination-pronation plane) was greater from 4 to 8 weeks pins and or cast removal [median (IQR) 10° (4-20)] than from 8 to 12 weeks post-treatment [median (IQR) 0° (0-4), p<0.0001]. In summary, a median (IQR) of 75% (67-83) of gains in flexion-extension and 100% (76-100) of gains in supination-pronation were achieved within the first 4 weeks after removal of backslab. Thus, the rate of improvement in ROM restoration tends to decrease over time, a non-linear decelerating time course of improvement.

Loss of ROM with delay in treatment of SHFs

Delayed surgical management was associated with reduced range of motion at 12 weeks postcast and pins removal. There was a significant inverse correlation between the time from injury to definitive management and the range of motion (in the flexion-extension axis) at 12 weeks (ρ =-0.42, p=0.005). Assuming a linear relationship between the variables, for each additional day of delayed surgery, there was a reduction in ROM (flexion-extension) at 12 weeks of 1.8° (95%CI 0.6 to 3.0; p=0.005). The relationship between delay in management and reduced ROM was primarily among patients undergoing ORIF (ρ =-0.40, p=0.041). No significant relationship was observed between timing of non-operative management and outcome among patients with milder injuries (Fig. 3).

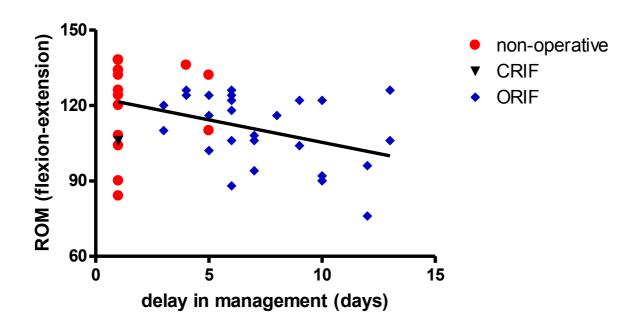


Figure 3: Loss of ROM with delay in treatment of SHFs

Effect of supervised versus unsupervised physiotherapy

Among patients who underwent physiotherapy, the median (IQR) elbow flexion was 113° (110-128), compared to 129° (120-137) among patients who did not undergo physiotherapy (p=0.003, MW). However, patients who underwent physiotherapy had more severe injury at baseline, according to Gartland classification (p=0.032) [Fig 4].

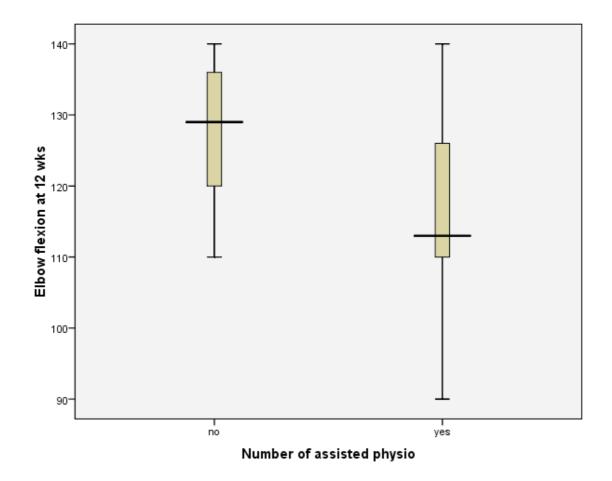


Figure4: Effect of supervised versus unsupervised physiotherapy

Patients undergoing physiotherapy had lower flexion ROM at 12 weeks post pins and or cast removal.

After stratifying the cohort by injury severity, we found no significant differences among patients with less severe injuries (p=0.53). Patients with severe injuries (Gartland type III) had lower ROM at 12 weeks if they underwent physiotherapy (101° versus 117°, p=0.001). It appears that physiotherapy is not associated with improved ROM (Fig 5).

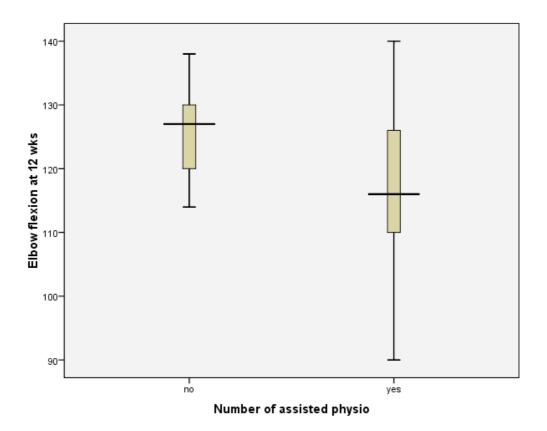


Figure 5: Analysis restricted to patients with Gartland III fractures

Guarded use of limb was noted in supervised physiotherapy group who worn arm sling for a prolonged period. Thirty-nine per cent of patients who underwent physiotherapy wore an arm sling for more than 4 weeks compared to 11% of patients who did not undergo physiotherapy (p=0.028). Moreover, use of an arm sling was associated with a lower range of motion in the flexion-extension plane at 12 weeks pins and or cast removal (p=0.008). Thus, prolonged joint immobilization is an important confounder that may explain why physiotherapy was associated with restricted elbow range of motion at 12 weeks.

DISCUSSION

This prospective study of children with supracondylar fractures is distinct among other reports in the literature for its setting in a developing country, with severe human resource and infrastructure limitations. While other series from Africa have described the epidemiology of supracondylar fractures ^(9,29-30) and challenges in their management at resource-constrained settings ⁽³¹⁾, none have reported on outcomes and determinants of poor recovery in such contexts. Characteristics of this cohort differ markedly from others reported in the medical literature, notably in surgical management delay; and incidence of adverse outcomes. This study was evaluating the effect of timing of treatment on the elbow stiffness after supracondylar humerus fractures in children.

Evaluating restoration of injured elbow range of motion, this study revealed that elbow range of motion in flexion-extension plane improved to a median of 57% of the expected flexion angle by 12 weeks in ORIF cases. In other axes, the range of motion was >90% of normal for extension, supination and pronation by 12 weeks after pins and or cast removal. The elbow arc of flexion-extension (Table 3) returned to 46%, 65%, and 73% compared to norms for elbow range of motion in a healthy population at 4 weeks, 8 weeks and 12 weeks respectively after pins removal. However, a median (IQR) of 75% (67-83) of gains in flexion-extension and 100% (76-100) of gains in supination-pronation were achieved within the first 8 weeks after removal of backslab. Other authors have examined the time of recovery following SHFs, and found similar trend in ROM improvement. This might be due to the fact that whereas the humero-ulna joint is spanned by strong capsulo-ligaments structures, the proximal radio-ulna joint is not crossed by strong anatomical structures.

In a 3 year retrospective series, Zionts et al. ⁽²⁶⁾ followed children with closed and displaced flexion type SHFs managed by CRIF to stabilize the fractures with either two or three lateral entry pins. Zionts et al found that elbow ROM returned to 72% of contralateral elbow motion by 6 weeks after removal of pins and progressively increased to 86% by 12 weeks. This optimal improvement in elbow ROM at 12 weeks has been demonstrated in this study, and hence expected further gains in flexion ROM if followed up to 1 year. Unlike this study, this report concentrated only on the surgical cases, non-operative cases were not included ⁽²⁶⁾. Reorganization of new collagen fibers in line with direction of forces and tension-stress induced growth and development of connective tissue may explain the progressive improvement of ROM.

Another study done by Wang et al. showed a 90% recovery of ROM in 29.5 days for children with SHFs. However, patients were treated either with a long arm cast or by CRIF and followed up to when 90% ROM of noninjured limb was achieved ⁽²⁷⁾. The recovery time in this study was faster than in this cohort; however, direct comparisons are difficult because the study does not give timing of treatment versus injury. It is possible that the more rapid improvement noted in this study may be related to short delay in management of injured patients compared to this study in a more resource-limited setting. Severity of soft tissue injury and genetic variation in healing process may be a contributing factor.

Spencer et al. performed a prospective observational study of 375 fractures in 373 children in a longitudinal evaluation study of elbow motion following SHFs managed either nonoperatively or operatively (CRIF or ORIF). Surgery was done around 3 days post injury, which is significantly shorter delay than in this cohort ⁽²¹⁾. Like the study done by Zionts et al, they found that there is a progressive improvement for up to around 1 year post injury ^(21,26).

Delays in the management of patients in this study are several-fold longer than other published series. The median delay in this study, 168 hours (7 days), was more than 5 times longer than the average reported in most other series. Even compared to the United States of America (USA) series with longest delays, Gartland type 3 fractures were managed within 19 hours (range 0 to 48 hours)^[4] versus a median of 168 hours (range 7 to 312) in this study. Another USA series with delays on the order of days to weeks (similar to our study) involved only type 2 fractures that were managed with closed reduction ⁽³³⁾. Pediatric SHFs are generally regarded as surgical urgencies requiring expedited reduction and pinning, yet patients at KNH often waited more than a week for definitive management. Some debate in the literature surrounds whether the treatment of closed, displaced SHFs may be safely delayed until the next day. This is to allow the patient to fast before anesthesia and the surgeon to operate in daylight hours, saving time, hospital resources, and surgeon fatigue ⁽³⁴⁻ ³⁶⁾. However, the magnitude of delay debated in the literature is on the order of half a day, in contrast to delays of a week or more in this study. This finding highlights an important gap in the management of supracondylar fractures in an urban tertiary care centre in sub-Saharan Africa. Delayed surgical intervention may be common phenomenon at similar centres across the continent and in other resource-limited hospitals globally. This study further demonstrated that delayed surgery is associated with significant residual elbow stiffness at 12 weeks post pins and/or cast removal. The study provides evidence that surgical delay is harmful. Increased attention to patient triage, effective use of operating room resources and manpower are potential solutions to alleviate the burden of morbidity identified in this study.

Outcomes were generally less favorable in this cohort, with only one patient (2%) achieving a ROM within 15° of population norms in the flexion-extension plane by 12 weeks of pins and or cast removal. In contrast, 79% to 97% of patients had ROM within 15° of the contralateral

uninjured elbow in other series ^(19,32,37). These pronounced differences may be due to several factors. First, different measurement methods were used: comparison to published norms versus to the contralateral limb. Second, duration of follow-up was up to 12 weeks in this study, yet longer in others. Third, surgical technique differed: a posterior approach with triceps splitting used in this study whereas other authors used lateral or medial approaches. Finally, observed differences may be due to prolonged delays in management in this study compared to others. Nonetheless, these differences highlight major gaps in the outcomes of children in Africa versus North America and Europe.

Several case series from North America, Europe and China have evaluated whether delayed management of pediatric SHFs results in increased risk of complications ^(19,32,34-38,40). Elbow ROM, the primary outcome in this study, was examined in several of these series, and did not differ among children managed with early versus late intervention^(19,32,36). In contrast, this study identified delay in surgical management as a significant determinant of restricted elbow ROM (flexion-extension plane) at 12 weeks after pins and or cast removal. Major differences in the time interval from injury to treatment between this study and series from higher income settings likely explain this discrepancy. Such extreme delays are outside the range of clinical practice in higher income settings, have not been reported previously, and may plausibly lead to the adverse outcomes observed in this study.

In this study, it was also noted that elbow ROM was reduced in patients who underwent physiotherapy compared to those who did not. This finding is subject to several limitations, including the observational design which introduces the possibility of bias due to measured and unmeasured confounders. Furthermore, the physiotherapy regimen was variable and nonstandardized at Kenyatta National Hospital and in this study. The timing spent during each physiotherapy session differed between practitioners, due in part to long waiting-times and high patient volumes. The frequency of the intervention (one physiotherapy session per week) was less than that recommended by other authors (2-3 sessions per week) ^[24]. Finally, prolonged elbow joint immobilization is another important factor to be considered. The role of physiotherapy after operative treatment of SHFs in children has been studied in a prospective randomized study which included 51 children with isolated SHFs type II or III ^[24]. All the participants underwent ORIF and K wiring. Keppler P et al found no significant difference in terms of recovery of elbow ROM between patients who underwent physiotherapy and the ones who did not receive it. They concluded that children receiving physiotherapy achieved a more rapid return of a normal or near normal elbow ROM. The end result, however, was not changed by physiotherapy; making its long-term effectiveness questionable ⁽²⁴⁾.

These results contrast with the ones reported in this study, which suggested that patients undergoing physiotherapy have a restricted elbow ROM. However, bias cannot be excluded in this study design, and a prospective, randomized design in this setting would be necessary to determine conclusively if physiotherapy is useful in the sub-Saharan African tertiary hospital setting.

CONCLUSION

Supracondylar humeral fractures are common and are associated with a high rate of complications. By the time of plaster and or pins removal, all the children treated for SHFs have a significantly reduced elbow range of motion, and becoming a major concern of parents.

This study dealing with the impact of treatment timing on elbow ROM after SHFs in children found that the injured elbow returned to 46%, 65%, and 73% of arc of flexion-extension compared to norms for elbow range of motion in a healthy population at 4, 8 and 12 weeks respectively after pins removal. Other studies, in contrast suggested that improvements in elbow ROM may occur up to 1 year postoperatively, and patients in this study may have demonstrated further gains in flexion ROM if followed up to 1 year

The most striking finding in this study was seven day delay before operative management. This study showed that delayed operative management of Gartland type III injuries leads to significant reduction of elbow ROM in the flexion-extension plane. This finding suggests that greater attention to prompt patient management through efficient triage of the most severe injuries is warranted and could reduce post-operative elbow stiffness in pediatric patients at Kenyatta National Hospital.

This study further demonstrated that delayed surgery is associated with elbow stiffness at 12 weeks post pins and or cast removal. Increased attention to patient triage, effective use of operating room resources and surgeon time, efficient scheduling, improved surgical capacity and manpower are potential solutions to alleviate the burden of morbidity identified here.

This study noted also that physiotherapy had deleterious effect on elbow ROM.

RECOMMENDATIONS

Considering the results demonstrated by this study, SHFs should be managed as emergency to reduce the rate of restricted elbow ROM;

Multicentre, prospective, and randomized study with large sample size should be done to assess the role of physiotherapy post SHFs.

REFERENCES

- 1. Allen SR, Jacqueline RH, Raphael CH. Paediatric supracondylar humeral fractures: emergency assessment and management. Em. Med Australia. 2010. 22, 418–426.
- Omid R, Choi PD, Skaggs DL. Supracondylar humeral fractures in children. J. Bone Joint Surg. Am. 2008; 90: 1121–32.
- Battaglia TC, Armstrong DG, Schwend RM. Factors affecting forearm compartment pressures in children with supracondylar fractures of the humerus. J Pediatr Orthop. 2002; Jul-Aug; 22(4):431-9.
- Kiraitu WM. Complications and outcome of supracondylar fractures of the humerus in children at the Kenyatta National Hospital (dissertation MMED Surgery): Nairobi University; 2003.
- 5. Ozgur AY, Sema VU, Fuad OO, et al. Timing of surgical treatment for type III supracondylar humerus fractures in pediatric patients. J Child Orthop. 2009. 3(4): 265–269.
- 6. Abdullah E, Melih G, Bulent E, et al. Delayed surgical treatment of supracondylar humerus fractures in children using a medial approach. J Child Orthop. 2008 February; 2(1): 21–27.
- 7. Chenq JC, Lam TP, Maffulli N. Epidemiological features of supracondylar fractures of the humerus in Chinese children. J Pediatr Orthop B. 2001 Jan;10(1):63-7.
- Young S, Fevanq JM, Guillaksen G, et al. Deformity and functional outcome after treatment for supracondylar humerus fractures in children: a five to 10 year follow-up of 139 supracondylar humerus fractures treated by plaster cast, skeletal traction or crossed wire fixation. J Child Orthop. 2010 Oct; 4(5):445-53.
- 9. Odongo C. supracondylar fractures of the humerus at Kenyatta National Hospital (dissertation MMED Surgery): Nairobi University; 1987.
- 10. Mercer Rang. Elbow Fractures in Children: "Pity the young surgeon whose first case is a fracture about the child's elbow." Surgery in Africa. Nov 2011.
- 11. Wilkins KE. Supracondylar fractures. In: Rockwood ChA, Wilkins KE, King RE. Fractures in children. 3rd ed. Philadelphia: J B Lippincott Company; 1991. p. 526-617.
- Nicholas L, Audige L, Schmittenbecher P, et al. diagnostic algorithm for a validated displacement grading of paediatric supracondylar fractures. J Pediatr Ortho. 2011. 31 (2):117-23.
- 13. Walmsley PJ, et al. Delay increases the need for open reduction of type-III supracondylar fractures of the humerus. J Bone Joint Surg Br 2006;88(4):528–30.
- Ozkoc G, Gonc U, Kayaalp A, et al. Displaced supracondylar humeral fractures in children: open reduction vs. closed reduction and pinning. Arch Orthop Trauma Surg. 2004; 124(8) : 547–55.

- Parmaksizoglu AS, Fuat Bilgili UOF, SayÂn E, et al. Closed reduction of the pediatric supracondylar humerus fractures: the "joystick" method. Arch Orthop Trauma Surg. 2009. 129:1225–1231.
- 16. Tiwari A, Kanojia RK, Kapoo SK. Surgical management for late presentation of supracondylar humeral fracture in children. J Orthop Surgery 2007;15(2):177-8.
- Oh CW, Park BC, Kim PT, et al. Completely displaced supracondylar humerus fractures in children: results of open reduction versus closed reduction. J Orthop Sci. 2003;8(2):137-41.
- 18. Kaewpornsawan K. Comparison between closed reduction with percutaneous pinning and open reduction with pinning in children with closed totally displaced supracondylar humeral fractures: a randomized controlled trial. J Pediatr Orthop B.2001;10:131-7.
- 19. Sibinski M, Sharma H, Bennet GC. Early versus delayed treatment of extension type-3 supracondylar fractures of the humerus in children. J Bone Joint Surg Br 2006;88(3): 380–1.
- 20. Bulent E. the management of elbow fractures in children. Marmara Medical Journal. 2004; 17(2):93-98.
- Spencer HT, Wong M, Fongo YJ, et al. Prospective longitudinal evaluation of elbow motion following pediatric supracondylar humeral fractures. J Bone Joint Surg Am. 2010. 92(4):904-10. (11).
- 22. Park, MJ; Kim, HG; Lee JY. Surgical treatment of post-traumatic stiffness of the elbow. J Bone Joint Surg [Br] 2004;86-B:1158-62.
- 23. Pike JM, Athwal GS, Faber KJ, et al. Radial head fractures--an update. *J Hand Surg* [Am]. Mar 2009;34(3):557-65).
- 24. Keppler P; Salem K; Schwarting B; et al. The effectiveness of physiotherapy after operative treatment of supracondylar humeral fractures in children. J Pediatr Orthop. 2005;25:314-6.
- 25. Gurkan V; Orhun H, Akca O, et al. Treatment of pediatric displaced supracondylar humerus fractures by fixation with two cross K-wires following reduction achieved after cutting the triceps muscle in a reverse V-shape Acta Orthop Traumatol Turc 2008;42(3):154-160).
- Zionts LE, Woodson CJ, Marira N, et al. Time of return of elbow motion after percutaneous pinning of pediatric supracondylar humerus fractures. Clin Orthop Relat Res. 2009 Aug;467(8):2007-10.
- 27. Wang, Yu-Ling, Chang, Wei-Ning, et al. The recovery of elbow range of motion after treatment of supracondylar and lateral condylar fractures of the distal humerus in children. J Orthopaed Trauma. 2009. 23(2), pp 120-125.

- 28. JM, Wang C, Forsyth A, Funk S, Denney M, Roach KE, Boone D, and the Hemophilia Treatment Center Network. Range of motion measurements: reference values and a database for comparison studies. Haemophilia 2010; e-pub November 11, 2010.
- 29. Omololu AB, Alonge TO, Adebisi A. A review of 100 cases of supracondylar fractures in children seen in Ibadan. *Afr J Med Med Sci* 2000, 29:167-169.
- 30. Igbigbi PS, Manda K: Epidemiology of humeral fractures in Malawi. *Int Orthop* 2004, 28:338-341.
- Gaudeuille A, Douzima PM, Sanze BM, et al. Difficulties in the management of supracondylar fractures of the humerus in children living in Central African Republic. *Med Trop (Mars)* 1998, 58:273-276.
- 32. Bales JG, Spencer HT, Wong MA, et al. The effects of surgical delay on the outcome of pediatric supracondylar humeral fractures. *J Pediatr Orthop*, 30:785-791.
- 33. Silva M, Wong TC, Bernthal NM. Outcomes of reduction more than 7 days after injury in supracondylar humeral fractures in children. J Pediatr Orthop 2011;31:751–756.
- 34. Iyengar SR, Hoffinger SA, Townsend DR. Early versus delayed reduction and pinning of type III displaced supracondylar fractures of the humerus in children: a comparative study. J Orthop Trauma 1999, 13:51-55.
- 35. Ramachandran M, Skaggs DL, Crawford HA, et al. Delaying treatment of supracondylar fractures in children: has the pendulum swung too far? *J Bone Joint Surg Br* 2008, 90:1228-1233.
- 36. Walmsley PJ, Kelly MB, Robb JE, et al. Delay increases the need for open reduction of type-III supracondylar fractures of the humerus. *J Bone Joint Surg Br* 2006, 88:528-530.
- 37. Leet AI, Frisancho J, Ebramzadeh E. Delayed treatment of type 3 supracondylar humerus fractures in children. *J Pediatr Orthop* 2002, 22:203-207.
- 38. Gupta N, Kay RM, Leitch K, et al. Effect of surgical delay on perioperative complications and need for open reduction in supracondylar humerus fractures in children. *J Pediatr Orthop* 2004, 24:245-248.
- 39. Mehlman CT, Strub WM, Roy DR, et al. The effect of surgical timing on the perioperative complications of treatment of supracondylar humeral fractures in children. *J Bone Joint Surg Am* 2001, 83-A:323-327.
- 40. Han QL, Wang YH, Liu F. Comparison of complications and results of early versus delayed surgery for Gartland type III supracondylar humeral fractures in pediatric patients. *Orthop Surg*, 3:242-246.

APPENDIXES

APPENDIX I: QUESTIONNAIRE ON ELBOW ROM

STUDY No	IPNo/CAS No	PHONE	2 No
Gender: Female	Male	AGE	
Side of injury: Domin	nant No	on-dominant	
Time of injury		Time to t	reatment DOA
Treatment			
Nonoperative t	reatment		
Conversion YES	NO		
Operative treatment : CRIF ORIF + approach			
Gartland's Classifica	tion (severity)	I II	III
Physiotherapy	No Ye	es (supervised)	Duration/sessions

Duration of Immobilization/Pins

Time of discarding arm sling

Restoration of ROM in degrees	Cast and/or Pins removal	4 wks	8 wks	12 wks
Flexion				
Extension				
Supination				
-				
Pronation				

APPENDIX II: CONSENT FORM

Impact of treatment timing on elbow range of motion post paediatric supracondylar humeral fractures

Study N <u>o</u>		
Hospital N <u>o</u>		

Research study

You are invited to participate in a research study on the impact of treatment timing on elbow range of motion post paediatric supracondylar humeral fractures at Kenyatta National Hospital being conducted by Dr Claude Kasereka Masumbuko, a postgraduate student in the Department of Orthopaedic Surgery; University of Nairobi.

Purpose of the study: The purpose of this study is to evaluate impact of treatment timing on elbow range of motion post supracondylar humeral fractures in Children at Kenyatta National Hospital. The information gathered will be useful both in your patient's treatment and for other patients in future who will present similarly and require same management of humerus supracondylar fractures.

Risks and benefits: There is no harm or risk to your child by participating in this study. Apart from taking a detailed history from you, a series of x-rays of the injured elbow of your child will be taken as follows: (1) at the time of arrival at the hospital (to confirm the diagnosis), (2) the second one to check for fracture reduction; and (3) a last one at 12 weeks to assess healing. These are all commonly done investigations for humeral supracondylar fractures that carry minimal risk but which will be of benefit in your child's follow-up. From 3 weeks post treatment, as your child is coming for his (her) first follow up, elbow flexion, extension, supination, and pronation will be measured at each visit at 4-week interval to assess the recovery of range of motion.

Other risks including anesthesia and surgery are part of routine care for supracondylar fractures and are not a study-specific risk. Your child would undergo the same treatment whether or not you choose to participate in this research study.

Close monitoring of restoration of elbow motion is the benefit from this study and participation in the study is out of your own free will. Your child will not be denied medical care in case you refuse to participate in the study.

Confidentiality: Information related to your child will be treated in strict confidence to the extent provided by law. Your child's identity will be coded and will not be associated with any published results. The records of this study will be kept private in a locked file and any written results will discuss group findings and will not include information that will identify your child. Research records will be stored securely and only researchers and individuals responsible for research oversight will have access to the records.

Contacts: You should feel free to ask questions now or at any time of the study. If you have any questions about this study, you can contact Dr Claude Kasereka Masumbuko, phone no. 0720-071145, email: claudemasumbuko@gmail.com. If you have any questions concerning the rights of human research participants, contact the Chairperson, the KNH Ethics and Research Committee at 020-2726300.

I have read and fully understand the consent form. I sign it freely and voluntarily.

Signature/Thumb print:

Date _____

(Parent/Next of Kin)

Telephone No (Parent/Next of Kin)

APPENDIX III: ASSENT FORM

Impact of treatment timing on elbow ROM post paediatric supracondylar humeral fractures

Study N <u>o</u>		
Hospital N <u>o</u>]

Research study

You are invited to participate in a research study on the impact of treatment timing on elbow ROM post paediatric supracondylar humeral fractures at Kenyatta National Hospital being conducted by Dr Claude Kasereka Masumbuko, a postgraduate student in the Department of Orthopaedic Surgery; University of Nairobi.

Purpose of the study: The purpose of this study is to evaluate impact of treatment timing on elbow range of motion post supracondylar humeral fractures in Children at Kenyatta National Hospital. The information gathered will be useful both for your treatment and for other patients in future who will present similarly and require same management of humerus supracondylar fractures.

Risks and benefits: There is no harm or risk to you by participating in this study. Apart from taking a detailed history from you, a series of x-rays of the injured elbow will be taken as follows: (1) at the time of arrival at the hospital (to confirm the diagnosis), (2) the second one to check for fracture reduction; and (3) a last one at 12 weeks to assess healing. These are all commonly done investigations for humeral supracondylar fractures that carry minimal risk but which will be of benefit in your follow-up. From 3 weeks post treatment, as you are coming for the first follow up, elbow flexion, extension, supination, and pronation will be measured at each visit at 4-week interval to assess the recovery of range of motion.

Other risks including anesthesia and surgery (for the patient going to theatre), are part of routine care for supracondylar fractures and are not a study-specific risk. You would undergo the same treatment whether or not you choose to participate in this research study.

Participation in this study is out of your own free will. You will not be denied medical care in case you refuse to participate in the study.

Confidentiality: Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. The records of this study will be kept private in a locked file and any written results will discuss group findings and will not include information that will identify you. Research records will be stored securely and only researchers and individuals responsible for research oversight will have access to the records.

Contacts: You should feel free to ask questions now or at any time of the study. If you have any questions about this study, you can contact Dr Claude Kasereka Masumbuko, phone no. 0720-071145, email: claudemasumbuko@gmail.com. If you have any questions concerning the rights of human research participants, contact the Chairperson, the KNH Ethics and Research Committee at 020-2726300.

Minor's age:

The undersigned hereby give consent/assent for, to be recruited into the study entitled impact of treatment timing on elbow range of motion post paediatric supracondylar humeral fractures at Kenyatta National Hospital.

Signature/Thumb print:

Date

(Parent/Next of Kin)

Telephone No (Parent/Next of Kin

APPENDIX IV: FOMU YA KUSHIRIKI

Athari ya wakati wa matibabu na vile unavyo athiri matokeo kati ya watoto walio na jeraha la kuumia na kuvunjika mkono.

Jina	 Nambari	
Nambari ya hospitali		

Unakaribishwa kujiunga katika utafiti kuhusu matokeo ya matibabu ya jeraha la mkono yanavyo athiriwa na wakati wa matibabu. Utafiti huu utafanywa na Daktari Claude Kasereka Masumbuko mwanafunzi katika kitengo cha utabibu wa mifupa chuo kikuu cha Nairobi.

Matokeo ya utafiti huu yatawezesha kuboresha matibabu kwa wagonjwa hao na wale wengine ambao watapata jeraha kama hili la kuvunjika mkono.

Hakutakuwa na athari yeyote kwa siha na mwili ambayo itatokana na kushiriki kwenywe uchunguzi huu.Picha tatu za mfupa zitafanya, moja wakati wa kwanza mgonjwa kuonekana hospitali mara ya kwanza, pili baada ya matibabu kuhakikisha matibu ya mkono yamefanyika vile inayvo takikana, na mwisho baada ya wiki 12 kuangalia kama mkono umepona. Na huu ni uchunguzi unaofanya kwa kila mgonjwa ambaye ana jeraha kama hili wakati wowote mwengine. Na madhara yake ni kidogo kuliko faida zake.

Kushiriki katika uchunguzi huu ni hiari wala si lazima, na kutoshiriki kwako hakutaathiri matibabu utakayo pata kwa namna yeyote ile.

Habari kuhusu mtoto wako itahifadhiwa kulingana na sharia. Matokeo ya utafiti huu yatahifadhiwa na mjadala wowote kuhusu matokeo ya utafiti utafanywa kwa ujumla bila kutowa habari kumhusu mtoto wako. Kumbukumbu za utafiti nazo zitahifadhiwa ipasavyo.

Kwa ufafanuzi zaidi au suala lolote kuhusiana na uchunguzi huu piga simu kwa, Daktariasereka Masumbuko Claude – mchunguzi mkuu, simu 0720071145 Ama barua pepe kwa anwani: <u>claudemasumbuko@gmail.com</u>

Pia unaweza kuwasiliana na mwenywe kiti wa kitengo cha uchunguzi, chuo kikuuK cha nairobi /hospitali kuu ya kenyatta simu 020-2726300 ext 44355

Mimi niloweka sahihi hapo chini ninahakika nime mueleza mshiriki mambo yalio hapo juu, na amekubali kushiriki kwa hiari baada ya kuelewa maelezo.

<u>Sahihi ama kidole</u>

Tarehe

(Mzazi/ mwakilishi)

Nambari ya simu(Mzazi/ mwakilishi)