GHANA COLLEGE OF PHYSICIANS AND SURGEONS

Faculty of Trauma and Orthopaedic Surgery

COMPARATIVE STUDY OF RE-DISPLACEMENT OF DISTAL FOREARM FRACTURES IN CHILDREN IMMOBILIZED IN ABOVE-ELBOW CAST VS BELOW-ELBOW CAST AT KORLE-BU TEACHING HOSPITAL.

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SEPTEMBER, 2024

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Comparative Study of Re-Displacement of Distal Forearm Fractures in Children Immobilized in Above-Elbow Cast Vs Below-Elbow Cast at Korle-Bu Teaching Hospital.

Submitted to the Faculty of Trauma and Orthopaedic Surgery, in partial fulfilment of the requirements for the conferment of a Fellow of the Ghana College of Surgeons (FGCS).

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DECLARATION

I hereby declare that this submission is my own work submitted to the Ghana College of Physicians and Surgeons in partial fulfilment towards the award of the Fellowship of the Ghana College of Physicians and Surgeons.

To the best of my knowledge, it contains no material previously published by another person, except where due acknowledgement has been made in the text. It also does not contain any material which has already been presented or accepted for the award of any degrees or diplomas in the past.

PRINCE GEORGE LARVIE

Signature...

Date: 26th March, 2024

CERTIFICATION BY SUPERVISORS

We confirm that we supervised this research project titled: '**comparative study of re-displacement of distal forearm fractures in children immobilized in above-elbow cast vs below-elbow cast at Korle-Bu Teaching Hospital'** which was undertaken by Dr Prince George Larvie, in partial fulfilment of the requirements for the fellowship of the Ghana College of Physicians and Surgeons.

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ABSTRACT

INTRODUCTION

Distal forearm fractures are among the commonest fractures seen in children. They typically are the result of fall on the outstretched hand during play. The mismatch between the rapid bone growth and mineral accrual, especially in the distal radius, makes the distal forearm susceptible to fractures from simple falls.

These fractures are usually manipulated and stabilized in cast. The choice of cast for immobilizing distal forearm fractures-above elbow versus below elbow still remains controversial. There have been two systematic reviews with meta-analysis till date on the subject. They both recommended further studies on it. There is also paucity of published studies on the subject in West Africa. The literature suggests other factors may be more important in re-displacement of these fractures.

AIM

This study was to ascertain whether re-displacement in a below elbow cast is worse than in an above elbow cast in children with distal forearm fractures, managed at Korle-Bu Teaching Hospital.

METHODS AND MATERIALS

This was a non-blinded, randomized control trial, where 58 children between 4 and 13 years, attended to at Department of Orthopaedics, Korle-Bu Teaching Hospital, with closed displaced distal forearm fracture were assigned to one of 2 treatment groups, one receiving below-elbow cast and the other, above-elbow cast.

Each child underwent manipulation of the fracture under conscious sedation in the Plaster Room. A below-elbow or an above-elbow POP backslab was applied. The pre- and post-manipulation angulation and apposition in the sagittal and frontal planes were assessed and recorded. A week later, the children came for a completion of the cast, before and after which the angulation and apposition, and the cast and three-point indices were recorded. The children were reviewed each week with new radiographs for 3 weeks. The radiographic parameters we measured again and complications noted and managed. Those who met the criteria for re-manipulation were manipulated.

The data was analyzed using Statistical Package for the Social Sciences (SPSS) software, version 20. The categorical data was presented with graphs and tables, and differences assessed with Chi-square analysis. Continuous variables were analyzed with student t-test, using difference of means and multiple regression analysis to ascertain association.

RESULTS

There were no differences between the means for the two-groups with respect to sagittal angulation change (0.76±0.84 vs 0.82±2.02, p=0.88), frontal angulation change (0.49±0.75 vs 0.40±0.69, p=0.64), sagittal apposition change (0.99±1.11 vs 0.83±0.90, p=0.56), and frontal apposition change (0.87±0.82 vs 1.01±1.21, p=0.60).

Multiple regression analysis showed a significant positive association between sagittal angulation change [β (95% Confidence Interval): 6.83(0.45-13.21), p=0.036], and cast index. Stepwise regression modelling also showed a positive association between the cast index and frontal apposition change [β (95% Confidence Interval): 4.69 (0.30-9.08), p= 0.036].

CONCLUSIONS

The study found no difference in re-displacement between the below-elbow and above-elbow cast groups, for the management of distal forearm fractures in children.

It did however find the cast index as a predictor of re-displacement, when the cut-off was set at 0.80.

CHAPTER ONE

INTRODUCTION

Distal forearm fractures are the commonest fractures of the appendicular skeleton in children. They comprise up to 75% of all forearm fractures in the pediatric population, which in turn comprise 40-55% of all fractures in this population[1–4].

Distal forearm fractures are defined as fractures occurring in the distal metaphysis and/or epiphysis of the forearm. The majority are fractures of the distal radius; with or without fractures of the distal ulna[4–6]. Isolated ulna fractures are uncommon. Galeazzi fractures (fracture of the distal radius with radio-ulnar joint dislocation), unlike in adults are uncommon in children. They constitute 3% of all distal forearm fractures[7,8]. The Galeazzi fractures seen in children are usually distal radial fractures with distal ulna physeal injury that results in disruption of the distal radio-ulnar joint; the so-called Galeazzi equivalent fracture in children[9.]

Peak incidence of distal radius fracture occurs during the preadolescent growth spurt period. Males tend to be more affected than females, because of the tendency for boys to be engaged in more risky activities[4,6]. Curiously, the non-dominant hand tends to be more involved[10].

The principles of management of fractures in general require reduction of the fracture, be it by closed or open means. This is followed by holding the fracture reduced for a period long enough for the fracture fragments to be united. This form of stabilization broadly includes cast immobilization, internal or external fixation and others like traction. The cast may be Plaster of Paris (POP) or fiberglass.

Most distal forearm fractures in children are amenable to closed manipulation and casting[11–13]. Cast treatment is a non-invasive, effective way of immobilizing fractures. A slab is applied in the acute traumatic period to account for the oedema of the initial inflammation; which aims to reduce the risk of acute compartment syndrome[14]. After a few days, a circumferential cast is applied to the forearm for three (3) weeks, by which time the fracture is expected to have clinically united[15]. A full cast may also be applied *ab initio* and split on one or both sides (univalved or bivalved, respectively)[16]. The cast may then be reinforced after a few days, when the swelling of the forearm may have improved[12].

When the fracture cannot be held reduced in a cast, stabilization is achieved by means of internal fixation devices, such as k-wires and plates. This is especially important when the child is near skeletal maturity and fracture may not have enough capacity to remodel out any deformity [13–16]

The choice of cast has historically been an above-the-elbow cast[12,13,17] . This is founded on the long-held principle that splinting a fracture requires immobilizing both the joint above and below that fracture[18]. This is because the deforming forces for that fracture may be muscles originating from above the proximal joint, and inserting below the distal joint. The major deforming forces of a distal radius are: the abductor pollicis longus and extensor pollicis brevis, which cause shortening of the distal radius; the pronator quadratus which rotates the fragment, and the brachioradialis which causes shortening and radial deviation[19]. Thus, immobilizing the elbow joint controls, the effect of the brachioradialis muscle which arises from the lateral supracondylar ridge of the humerus, and the lateral intermuscular septum of the arm[20].

Apart from the brachioradialis, the other muscles arise from the forearm, below the elbow. This means that a well molded cast just below the elbow will immobilize the other muscles and significantly reduce the deforming brachioradialis action[21–23]. The advantage of the below elbow cast, would immediately be the reduced risk of associated stiffness of the elbow[24].

Thus far, studies comparing outcomes of below-elbow cast treatment and above-elbow cast treatment for displaced distal forearm fractures have shown no difference in risk of re-displacement between the two treatments[22,25,26].

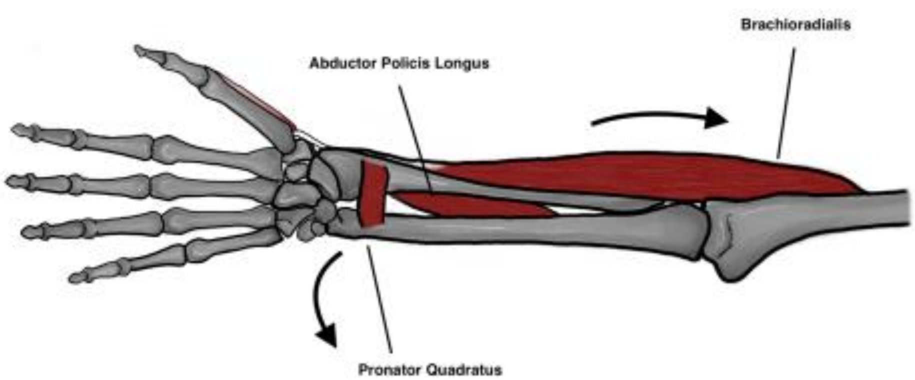


Figure 1.1.1: Deforming forces in distal radius fractures

Source: Alajmi, T (2020)

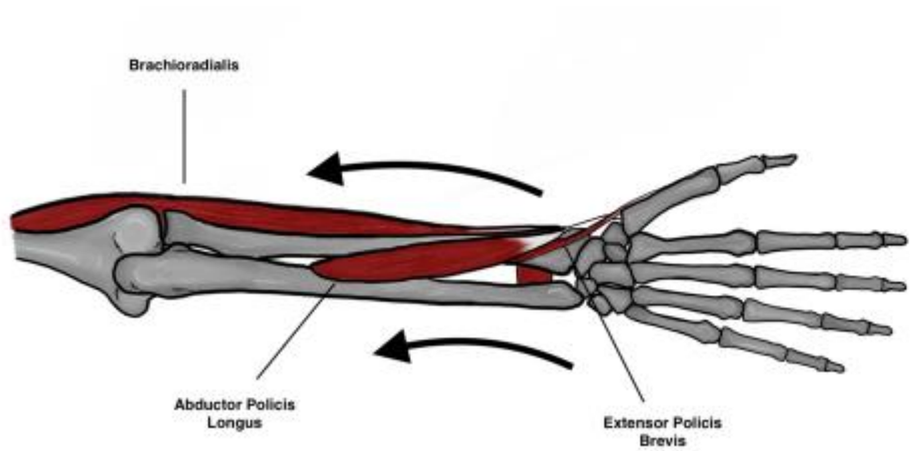


Figure 1.1.2: Deforming forces in distal radius fracture

Source: Alajmi, T (2020)

1.1 PROBLEM STATEMENT

A lot of the work that has been done on this subject, has been done outside West Africa. Indeed, to the best of my knowledge, there is no published study on this subject in West Africa.

Nevertheless, in the Trauma and Orthopaedic Surgery Department of Korle-Bu Teaching Hospital, there is near unanimity in the use of below elbow casts for the management of distal forearm fractures, from a review of patients' records since July, 2020, though this is not backed by rigorous analysis of local data.

Laaksonen et al.[27] in a survey of Orthopaedic surgeons, found that 84% of them still favored the use of the above elbow cast for management of significantly displaced fractures. As well, in some of the published work, fractures in below-elbow casts when re-manipulated, were now immobilized in above elbow cast [19]. This might have been because the reason for the displacement may have been failure to immobilize the brachioradialis fully[28].

A meta-analysis conducted in 2011 by Hendrickx et al. could not draw very strong conclusions, due to the numbers reviewed and the heterogeneity of the data[22,26]. A more recent meta-analysis of 9 studies on the subject, concluded that perhaps even below-elbow casts performed better in the non-operative management of distal forearm fractures[25]. Despite this, they suggest more randomized controlled trials should be done on the subject with well-defined variables. What is more, none of the RCTs pooled had come from any part of Africa. There is clearly an absence of published work on the subject matter in Ghana and the Subregion.

This work seeks to bridge the gap on the dearth of African literature on non-operative management of distal forearm fracture in children.

1.2 JUSTIFICATION

This study is to gather data as to whether below-elbow casts lead to a similar rate of re-displacement, compared to the traditional above-elbow casts, advocated in earlier literature. The ability of a cast type to keep the initial reduction would lead to fewer re-manipulation of the fractures, and a lower risk of a malunited fracture, with its attendant cosmetic and functional outcomes. The outcome of this study will provide the Scientific evidence required to develop protocols in managing distal forearm fractures in children and also document complications associated with these injuries at the Department of Trauma and Orthopaedic Surgery, Korle Bu Teaching Hospital.

1.3 STUDY AIM

This is a non-inferiority study with the aim:

To compare re-displacement of initially displaced distal forearm fractures in children between 4 and 13 years old, immobilized in below elbow cast versus above-elbow cast, in the Department of Trauma and Orthopaedic Surgery, Korle-Bu Teaching Hospital.

1.4 HYPOTHESES

Null Hypothesis

Distal forearm fractures re-displace by more than 5 degrees in below-elbow casts, compared to above-elbow casts.

Alternate Hypothesis

There is no difference in re-displacement between distal forearm fractures managed in below-elbow cast and above-elbow casts.

1.5 OBJECTIVES

1. To compare the degree of loss of reduction in the above elbow versus below elbow cast among children between 4 and 13 years.

2. To assess the factors that predict re-displacement of distal forearm fractures among children between 4 and 13 years old.

3. To ascertain the likely period of fracture displacement, post-manipulation of distal forearm fractures among children between 4 and 13 years.

CHAPTER TWO

LITERATURE REVIEW

2.1 DISTAL FOREARM FRACTURES

Distal forearm fractures result mainly from a fall on the outstretched hand, with the wrist in either extension or flexion[9]. The injury may be to the distal radius, distal ulna or both bones. The distal radius bears about 70-80% of forces transmitted across the distal forearm[9,28]. This means that the distal radius is subjected to significant loads in the case of a fall on the hand. In addition, increased porosity of the distal radius with growth makes the distal radius more vulnerable to fractures[29,30].

2.2 RELEVANT ANATOMY

The distal radial epiphysis appears between six (6) months and 2years 4months in boys and between five (5) months and about 1 year 8 months in girls. This signifies the appearance of the secondary ossification centre. When it appears, it starts out as a transverse epiphysis, before rapidly morphing into the triangular shape seen in adults. There is also progressive elongation of the contour of the radial styloid as the skeleton matures[9,31].

The secondary ossification centre of the ulna however appears much later, at about 5 years in boys and a year earlier in girls. Similar to the radius, the ulnar styloid is seen at around the time of the adolescent growth spurt. The distal ulna rapidly elongates to assume the adult morphology by the time of closure of the physis[9,31,32].

The distal ulna growth plate tends to close by sixteen (16) years in girls and seventeen (17) years in boys. The distal radial growth plate generally closes about 6 months later than the distal ulna[9,28]. The distal ulna and radial growth plate contribute between 75 and 80% of longitudinal forearm growth and 40% overall growth of the upper limb[9,31].

The distal radius articulates with the distal ulna at the distal radioulnar joint (DRUJ). The principal articulation of the distal forearm with the carpus, is through the distal radius[19]. The distal ulna has a minor articulation with the carpus. The radius articulates with the carpus via two concavities- the scaphoid and lunate fossae. It also has the sigmoid fossa for its articulation with the distal ulna head. These joints are stabilized by numerous ligaments both dorsally and volarly, with the volar ligaments being the major stabilizers. These include radiocarpal, ulnocarpal and radioulnar ligaments[9,19,33].

From the radial styloid towards the ulna, there are these volar ligaments- radial collateral, radioscaphocapitate, radiolunotriquetral (long lunate) and radioscapholunate (short lunate). They collectively serve to stabilize the radiocarpal joint volarly. The dorsal radioscaphoid and radial triquetral ligaments are only minor stabilizers. The ligamentous architecture helps to stabilize the distal radius, carpal bones and the ulna through the normal wrist motion of 120⁰ in the sagittal plane, 50⁰ in the frontal plane and 150⁰ of forearm rotation[9,33].

The triangular fibrocartilaginous complex (TFCC) serves as the main stabilizer of the ulnocarpal and distal radioulnar joints. It originates in the sigmoid notch of the radius, travels across the DRUJ, to its insertion at the ulna styloid. Distally it sends fibres as the ulnolunate, ulnotriquetral, and ulnar collateral ligaments. It also inserts on the ulna carpus and the base of the fifth metatarsal. The volar ulnolunate and ulnotriquetral liagments form a V (V ligaments) and are extremely important stabilizers. At the centre of the TFCC is the articular disc. The interaction between the articulation between the distal radius and ulna and the soft tissue of the TFCC accounts for the stable pronation and supination movement of the DRUJ. The DRUJ is most stable at the extremes of rotation. The compressive loads of the DRUJ are aided by the tensile forces produced by the TFCC, and together they help to maintain stability through the full range of rotation[19,33,34].

Proximally, the radius and ulna are held together by the strong fibres of the interosseus membrane or ligament. This allows rotation of the more mobile radius around the static ulna. The interosseus ligament joins the radius and ulna throughout their shaft, being deficient in the distal forearm. The fibres pass obliquely from proximally on the radius to distally on the ulna[9,19,28].

The length relationship between the distal radius and ulna has been termed the ulnar variance. This is determined in adults by comparing the ulnar corner of the radial articular surface to the radial corner of the distal ulnar articular surface[35,36]. (fig.2.1)

However, this method needs to be modified for measuring ulnar variance in youngsters. In order to reduce measurement errors linked to epiphyseal size and form, Hafner[37] proposed measuring from the ulnar metaphysis to the radial metaphysis. Goldfarb[37] has since confirmed this method. Neutral variance exists when the lengths of the radius and ulna are equal.

The variance is positive if the ulna is longer. A shortened ulna results in a negative variance[35]. Typically, variance is measured in millimeters. The measurement of ulnar variance is influenced by radiographic technique and forearm posture, but not by the length of the ulnar styloid. The wrist and hand should be placed on the cassette, the elbow flexed 90 degrees, the forearm in neutral rotation, and the shoulder abducted 90 degrees in order to get standard radiographs of the wrist that are used to measure ulnar variation[35]. When there is axial loading, the force transmission across the wrist depends significantly on the ulnar variance. Normally, 20% of the axial stress across the wrist is borne by the ulnocarpal joint and 80% by the radiocarpal joint[36]. This relative load bearing distribution is altered by variations in the length relationship between the radius and ulna. In adult biomechanical analyses, even a 2.5 mm increase in ulnar positive variance can actually double the pressure applied across the ulnocarpal articulation. This load distribution is significant in fractures, TFCC tears (positive ulnar variance), and Kienbock disease (negative ulnar variance)[34–36]. (Fig 2.2).

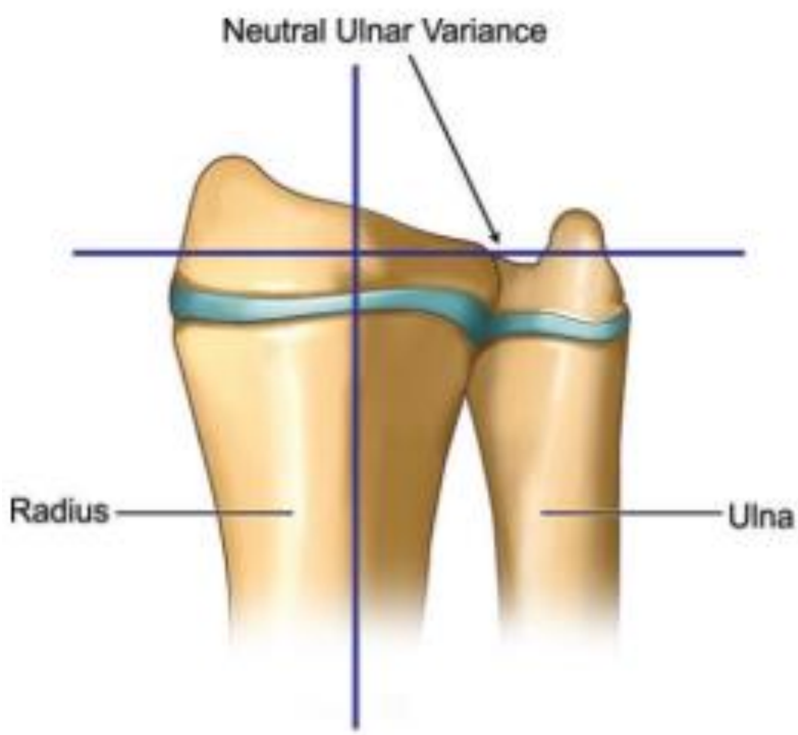


Figure 2.1: Schema of the distal forearm showing neutral ulnar variance

Source: Little et al (2014)

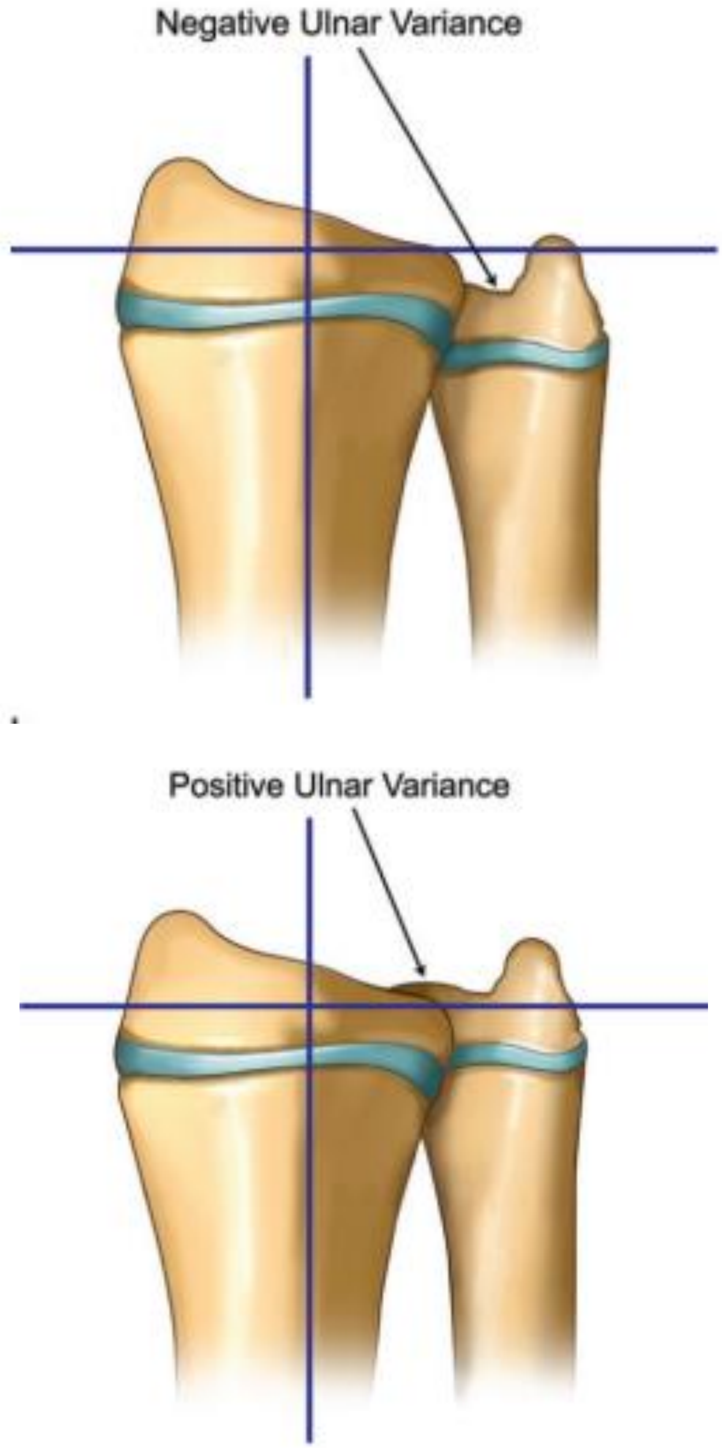


Figure 2.2: Schema of distal forearm showing negative and positive ulnar variance

Source: Liitle et al (2014)

2.3 MECHANISM OF INJURY

Typically, these injuries occur as a result of falls on the outstretched hand. These falls tend to occur at play. The position of the wrist-extended or flexed determines the displacement of the fracture. Loading an extended wrist leads to the volar aspect failing in tension and leading to dorsal angulation; whereas a fall on the flexed wrist, causes tensile failure on the dorsal aspect of the forearm, with the resultant volar angulation seen in these fractures. The rotation of the forearm-pronation or supination, also contributes to the displacement of the fracture[9,20,28].

With falls on the extended wrist with forearm pronated, the tensile surface becomes the volar aspect of the bone and so tends to fail first, with propagation to the dorsal surface, giving rise to a transverse fracture or one with some comminution of the dorsal surface on account of the bone failing in compression on the dorsal side. Thus, the fracture is dorsally displaced with volar apex angulation. Conversely, a fall on the flexed wrist produces a volarly displaced fracture which is dorsally angulated[9,28].

The fracture may also be incomplete, such as in a torus fracture of the metaphysis or a greenstick fracture of the diaphysis. This is due to the malleable nature of the pediatric bone due to low calcium content of the bone as compared to adults. Torus or buckle fractures may be the result of compression of the metaphyseal trabecular after axial loading[9,38]. (fig 2.3)

Occasionally, there may be a direct blow to the distal forearm resulting in fracture with displacement[9.] As well, depending on the position of the forearm and the rotational forces impacted to the distal forearm, there may be rotational displacement sustained. The height and velocity of the fall or mechanism of injury also contribute to the degree of displacement and the fracture configuration: the fracture type may be a torus or buckle fracture (if in the metaphysis), greenstick (in the meta-diaphysis), or complete fracture with or without significant displacement[8,9]. For instance, in high velocity injuries, especially in older children, the fracture may be so displaced as to cause foreshortening or “bayonet” apposition[39].

Overweight children, those with ligamentous laxity or poor bone mineralization, as well as those who have suboptimal posture control are particularly vulnerable to sustaining distal radial fractures[4,40]. Also, considering that bone quality measures are higher for boys than girls, it is somewhat surprising that the incidence of distal forearm fractures is so significantly higher for boys than for girls, though other reasons have been cited for this anomaly[29,30,41,42].

Rarely, a significant amount of energy may cause a concomitant proximal forearm or elbow fracture with the distal forearm fracture. Such injuries require thorough assessment to exclude neurovascular injuries or compartment syndrome[43].

Figure 2.3: Torus fracture of distal radius

Source: Little et al (2014)

2.3.1 Distal Forearm Growth Plate Fractures

Physeal injuries are often acute injuries, resulting from failure of the growth plate. They tend to occur in the hypertrophic zone of the bone. They are classified by the Salter-Harris classification (fig 2.4), and are fairly common injuries. The predominant injury type is the type 2 injury which involves the metaphysis as well[9]. They collectively comprise 17% of all distal forearm fractures in children[4].

Physeal stress injuries are almost invariably related to the radius and can result from repetitive axial loading of the wrist. Competitive gymnasts are the most commonly afflicted of these physeal stress injuries. Excessive training, bad form, and attempts to progress too quickly at a competitive level are risk factors for this injury. These traits have also been seen in other sports, such as break dancing and wrestling[44,45].

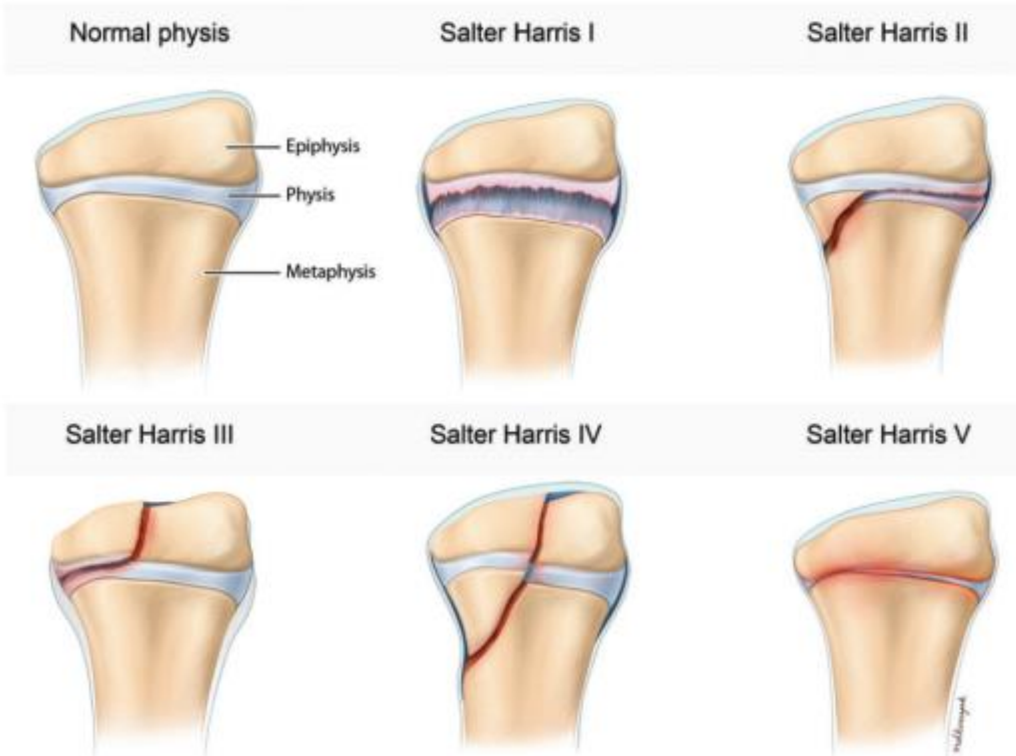


Figure 7. Salter-Harris fracture classifications. Drawings show the normal physis with intact epiphysis and metaphysis; type I fracture, with the physis widened or displaced; type II, with the fracture extending through the physis and metaphysis; type III, with the fracture extending through the physis and epiphysis; type IV, with the fracture extending through the metaphysis, physis, and epiphysis; and type V, a compression injury to the physis.

Figure 2.4: Classification of growth plate injuries by Salter-Harris

Source: Little et al(2014)

a. b.

Figure 8. Salter-Harris type I fracture of the distal radius in a male patient aged 14 years 10 months. **(a)** Slightly oblique radiograph of the wrist shows a widened radial aspect of the distal radial growth plate (arrow). The radial epiphysis is displaced relative to the metaphysis. Marked overlying soft-tissue swelling (*) is seen. There is an associated minimally displaced ulnar styloid fracture (arrowhead). **(b)** Lateral radiograph shows dorsal displacement of the distal radial epiphysis (arrow) relative to the metaphysis. Soft-tissue swelling is seen along the volar aspect of the distal forearm (*).

Figure 2.5: Growth plate fracture of the distal radius

Source: Little et al (2014)

2.3.2 Galeazzi Fractures

Extreme forearm rotation combined with axial loading of the wrist can cause distal radius fractures, also known as "pediatric Galeazzi fractures," which cause disruption of the DRUJ. Adults typically get injuries from falls that load axially while hyperpronating. This causes a dorsal dislocation of the ulna and a distal radial fracture along with disruption of the DRUJ ligament. (fig 2.6).

On the other hand, pronation (apex dorsal) and supination (apex volar) deforming forces in children have both been documented[7,8,20].

When the radial fracture is incomplete, the mechanism of injury is most visible. The distal ulna is displaced dorsally in an apex dorsal (pronation) radial fracture, while it is displaced volarly in an apex volar (supination) radial fracture[8].

On radiographic and clinical examination, this is readily apparent. Furthermore, a complete fracture results in a foreshortened radius, which increases the radial deviation of the hand and wrist. In children, this injury typically results in a distal ulnar physeal fracture, but it can also cause disruption of the DRUJ ligaments[7].

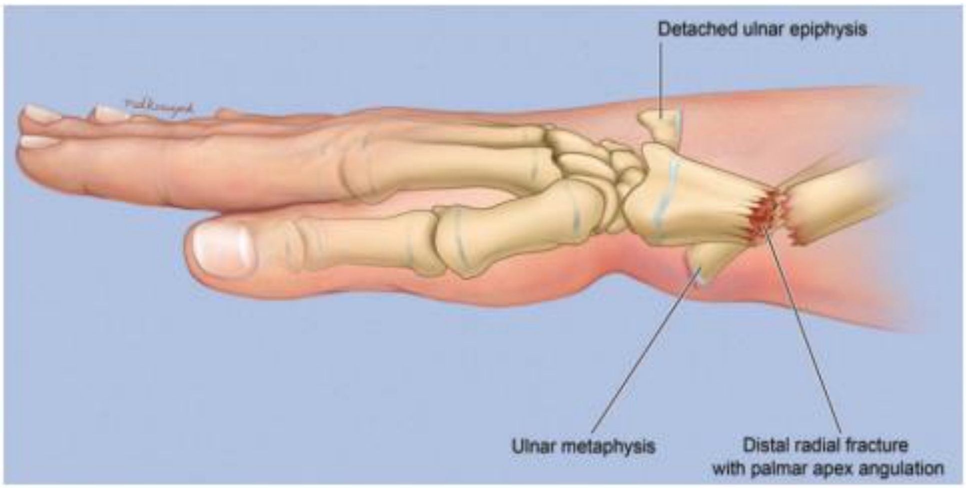


Figure 13. Galeazzi-equivalent wrist fracture. Drawing shows a distal radius fracture with palmar apex angulation at the fracture site. An associated disruption at the distal radioulnar articulation manifests as distal ulnar epiphysiolysis. The detached ulnar epiphysis is dorsally displaced relative to the anteriorly angulated ulnar metaphysis.

Figure 2.6: Galeazzi-equivalent distal forearm fracture in children

Source: Little et al (2014)

2.4 INJURIES ASSOCIATED WITH DISTAL RADIAL AND ULNA FRACTURES

Compared to patients who are skeletally mature, those who are skeletally immature have a much lower risk of related injuries[43]. However, a thorough examination of the entire ipsilateral extremity is still necessary to rule out fractures of the elbow, forearm, or carpus. In fact, ipsilateral extremity fractures have been reported in 3% to 13% of distal radial fractures.

Neurovascular compromise may arise in cases of significant displacement of radial or ulnar fractures. Acute compartment syndrome, prolonged pressure or traction from an unreduced fracture, or a direct nerve contusion received at the time of fracture displacement can all cause median neuropathy in severely displaced distal radius fractures. Similar mechanisms have been reported for ulnar neuropathy, with concomitant entrapment of the ulnar nerve within the fracture site, though rarer than median nerve compression.

In adults, and less frequently so, in children, wrist ligamentous and articular cartilage injuries have been seen with distal radial and ulnar fractures. There have been cases of concurrent scaphoid fractures as well. Multitrauma victims may also present with associated distal radial and ulnar fractures. When treating these distal forearm fractures, concurrent systemic injuries take precedence, but the distal forearm fractures should not be ignored.

An ulnar fracture frequently occurs when the distal radial physis is fractured. It has been reported to coexist in up to 50% of such cases. Although it can also be a distal ulnar plastic deformation such as a torus or buckle fracture, greenstick fracture of the diaphysis, or complete distal ulnar fracture, this is typically an ulnar styloid fracture.

2.5 WHY ARE DISTAL FOREARM FRACTURES COMMON IN CHILDREN?

The incidence of prepubertal distal forearm fractures compares with the incidence in postmenopausal women, although boys are more commonly affected.

Up to 90% of the forearm bone growth in length is from the distal radial and ulna physes[31,46]. During periods of rapid growth in length and diameter of long bones, there should be commensurate cortical and trabecular bone accrual such that there's little change in volumetric bone mineral density (vBMD)[41]. However, in the distal forearm, especially the distal radius, studies suggest that total vBMD, decreases because of a dissociation between bone size and mineral accrual, because the peak growth velocity is in length rather than mineral accrual. In other words, accrual of bone does not "keep up" with the increase in the bone's mineral density[41].

In addition, the difference in diaphyseal and metaphyseal forearm bone formation is in the fact that the shaft is formed predominantly via intramembranous ossification, whereas the metaphysis forms via endochondral ossification[41,42]. Thus, contiguous trabeculae arising from the periphery of the growth plate aggregate to form bone on the metaphyseal surface, which is the metaphyseal cortex. As this metaphyseal corticalization increases the thickness of the endocortex, there is at the same time, resorption of bone on the periosteal surface. The rate of this periosteal resorption outpaces the deposition on the endocortex. This in the end thins out the metaphysis to allow the broader, wider metaphysis to gently narrow to the diaphysis[29,30,42].

Some have suggested that to improve the efficiency of calcium absorption during the rapid growth stage of pre-adolescence, there is a resultant increased porosity of the distal radius[2,47].

It is also noteworthy that the distal radius transmits most of the load across the wrist to the forearm (up to 80%). This means that in falls on the hand, a significant amount of force is taken by the distal radius[36].

The above factors together, explain the preponderance of distal forearm fractures in general, and distal radial fractures over distal ulna fractures in the general population, but more so in children[2,29,30,42].

2.6 RADIOLOGIC EVALUATION OF DISTAL FOREARM FRACTURES

Confirmation of the diagnosis of distal forearm fractures is usually by x-rays (see fig2.7). It involves taking two orthogonal views; an anteroposterior and lateral projections. It allows assessment of angulation, translation in all three planes, and rotation[48]. It also allows evaluation and exclusion of other injuries such as growth plate injuries, Galeazzi-equivalent injuries, and carpal injuries. Radiographs are readily available in most institutions and offer a simple way of assessing fractures. However, they expose the children to ionizing radiation, with the attendant risks[49]. It also may be poorly tolerated when the injured limb has to be positioned for the purpose of adequate exposure[50]. Nonetheless, prudent use of x-rays is invaluable in regular clinical use, even if the diagnostic sensitivity, especially for undisplaced fractures or incomplete fractures, may be lower than other evaluation methods[51,52].

As an alternative, the role of ultrasound has been assessed more in recent times[50,51]. (fig 2.8). The ultrasound has no risk of ionizing radiation. In a recent meta-analysis on the use of diagnostic ultrasonography in distal forearm fractures, Hassankhani et al. concluded that ultrasonography was not inferior to radiographs, in terms of accuracy of diagnosis[51]. The advantages of the ultrasound include improved quality of the images resulting from the proximity of the probe to the bone, and the ability to evaluate soft tissue structures such as tendons and muscle oedema. It thus allows resolution of any interposed soft tissue between the fracture ends[53]. Due to the mobility of the ultrasound machine, it often cuts out having to transport the patient to the radiology suite for the imaging, as it can be done at the bedside readily. This leads to quicker diagnosis with resulting earlier care and shorter hospital stay. It is particularly suited to diagnosing undisplaced fractures and plastic deformations. It also is useful at diagnosing lesions through the cartilaginous ends of the bone, such as injury to the distal radioulnar joint and growth plate injuries[54,55].

The learning curve for pediatricians and emergency staff to become adept at ultrasound use for diagnosis of these fractures is not particularly steep, and so many can be expected to pick up the skill with minimal training. For these reasons, many institutions are tending to use this modality more and more[51]. The study did not consider the use of ultrasound for diagnosis because neither the machines not expertise is readily available in the Department.

Magnetic Resonance Imaging (MRI) is rarely indicated in distal forearm fractures. However, it can be invaluable in the assessment of growth plate injuries, acute or stress fractures and in evaluating bone contusions which may be missed on regular radiographs[32,45].(fig 2.9) Radiographs (x-rays) are the mainstay of diagnosis of distal forearm fractures in our institution now.

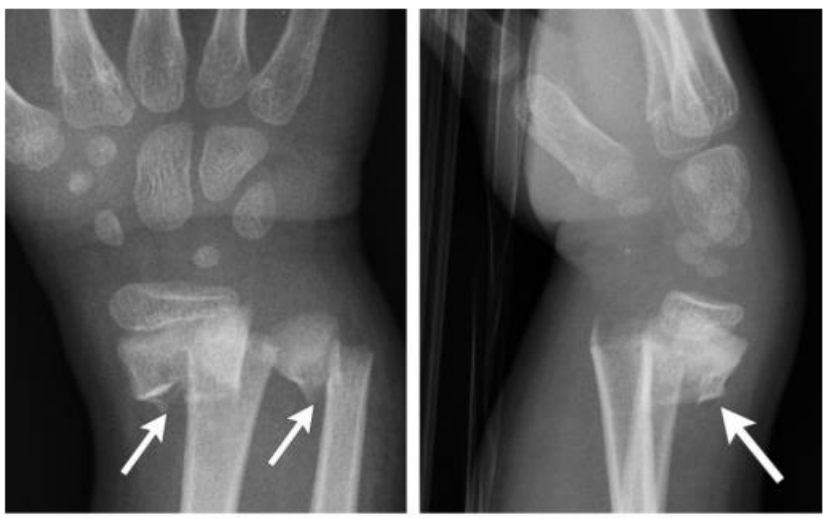


Figure 2.7: Radiographic evaluation of distal forearm fracture-anteroposterior and lateral views are shown

Source: Little et al. (2014)

Figure 2.8: Ultrasound evaluation of distal forearm fracture in a child

Source: Chaar-Alvarez et al. (2011)

Figure 2.9: MRI showing bone bruising in the distal radius-high intensity signal on this fat-suppressed T2-weighted image. Image was not evident on xray

Source: Little et al (2014)

2.7 MANAGEMENT OF DISTAL FOREARM FRACTURES IN CHILDREN

2.7.1 Reduction Techniques

Most distal forearm fractures in children, are managed non-operatively. This involves manipulation of the fracture using the method described by Charnley[18] or the Lower Extremity-aided Fracture Reduction (LEAFR) maneuver[56]. The method described by Charnley, which was used in the study, is narrated in the methodology section of the write-up.

The LEAFR method, was described by Eichinger et al.[56] and subsequently validated in a biomechanical analysis (figs 2.10.1-2.10.4). The surgeon uses his/her lower limb to aid in the fracture reduction. After administration of anaesthesia, the patient is positioned supine with the injured limb abducted off the bed, and supported. The surgeon grasps the hand with the dominant hand, preferably and then places one of his/her legs across the arm, just proximal to the elbow (Fig 2). To ‘anchor’ the patient’s arm for the reduction, the surgeon flexes his/her knee and also flexes the elbow, so that the elbow is secured in the surgeon's popliteal fossa. Thus, the surgeon can use one arm for the axial traction, while the other manipulates the fracture. Axial traction allows restoration of length, and exaggeration of the fracture may be required to enable clearance of the fracture ends, which may be difficult with an intact periosteum. Once the length is obtained, coronal and sagittal plane angulation can be corrected as necessary.

The main advantage of this method is that it is a single-operator method for the fracture reduction and may be useful where there are not enough hands to aid in the fracture manipulation. The authors also argue that it allows a more measured application and efficient use of the reduction force, with the same result. As it had never been used in our institution, we rather chose to use the traditional method of fracture reduction, as described in Charnley's text.

Figure 2.10.1: Forearm held in one hand by the surgeon, preferably the dominant hand.

Source: Eichinger et al (2011)

Figure 2.10.2: Elbow of the patient anchored by the lower limb of surgeon

Source: Eichinger et al. (2011)

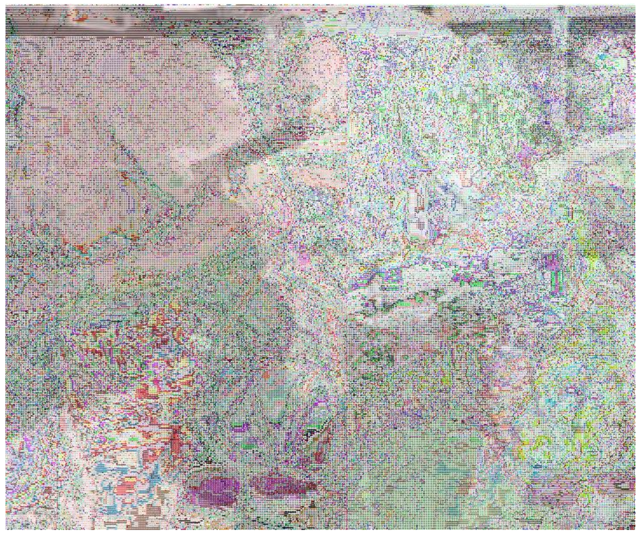


Figure 2.10.3: Fracture manipulation with lower limb as countertraction

Source: Eichinger et al. (2011)

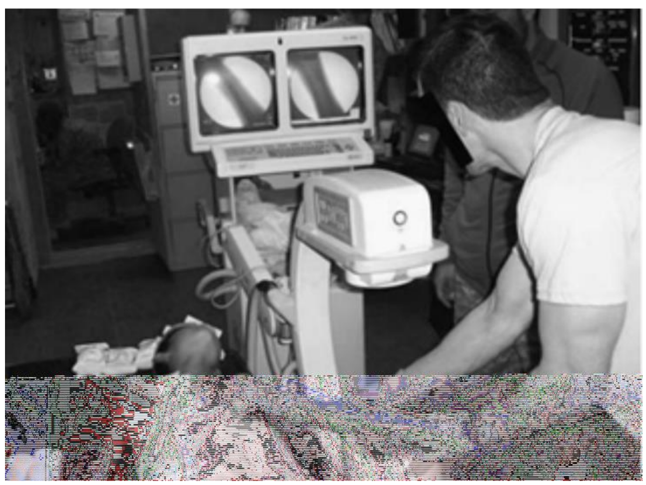


Figure 2.10.4: Verification of Fracture reduction with image intensifier

2.7.2 Choice of Anaesthesia for Reduction

The reduction of forearm fractures in children may be done in theatre under general anesthesia, with conscious sedation in the Emergency Room (ER), or a hematoma block in the ER. General anesthesia provides deep sedation, with the result that the patient is not easily rousable, though they respond purposefully to painful stimulation. This helps to get an uncooperative child sedated enough for fracture reduction. The significant drawbacks include need for assistance with maintenance of airway patency, and possibility of ventilator-assisted respiration. This requires skilled attendants and appropriate equipment to be able to do[57].

Conscious sedation is depression of the level of consciousness with drugs, where the patient is easy to rouse, and has a purposeful response to verbal command and/or light touch, with reflex withdrawal from pain, though this response is not purposeful[57]. It has been found in multiple studies to be a safe and cost-effective means of fracture reduction in children, and is associated with excellent orthopaedic outcomes[58,59]. It still requires training of personnel for it, but not to the same level as with general anesthesia. It requires less equipment to carry out, and can be safely done in the ER[58]. The combination of ketamine and midazolam has been found to be very effective for paediatric fracture reduction in the ER[59].

Hematoma block involves transcutaneous injection of a local anesthetic agent into the fracture hematoma to provide anesthesia for fracture reduction. It is time-saving, easy to do and cost-effective[60]. Though it has been widely employed in adult fractures, its use in children has not received wide acclaim. Bear et al. in a prospective study comparing hematoma block to sedation for distal radius fracture in children, found that hematoma block allowed for comparable radiographically-aligned reduction, with good patient satisfaction and analgesia[61]. However, they studied only fifty-two patients, 26 in each arm and 8 of the children in the hematoma block group were given midazolam in addition. Besides, there have been no further follow-up studies on this subject.

This study thus chose to use conscious sedation as anesthesia.

Fracture reduction is often done in a designated place in the Emergency room (such as a cast room) or the theater[17]. Fracture manipulation may be done with the aid of extensions, such as finger traps which allow sustained traction without coming off. In a 2018 systematic analysis of distal forearm fracture reduction in adults, it appeared finger trap traction was associated with better correction of shortening of the radius[62]. The fracture reduced, is then held in a cast[13,63].

2.7.3 Choice of Cast Material

The cast used for immobilizing has traditionally been the Plaster of Paris (POP), a material made of crinoline or muslin cloth bandages impregnated with gypsum (calcium sulphate). Upon exposure to water, the anhydrous salt, becomes hydrated and crystallizes. The compound then matures (the process of hardening) over a period of 24hours to dryness. The crystallization process is an exothermic reaction, and this is felt as heat by the patient. However, POP casts tend to be brittle and erode and weaken upon exposure to water, but they are relatively cheap.

Fiberglass casts are a type of fiber-reinforced plastic which is obtained by using glass fiber. It is impregnated with resin and is activated by immersion in water, to form crystals. They are lightweight, harden quickly and more water resistant. They are porous and so allow for more air circulation beneath the cast, so cause less skin irritation. They are however more expensive than Plaster of Paris casts.

There is limited literature comparing fiberglass cast and Plaster of Paris cast in the management of forearm fractures. Inglis et al. showed that whereas fiberglass casts showed no inferiority with respect to re-manipulation rate of the forearm fractures studied, it was associated with fewer skin complications, such as maceration. Overall patient satisfaction was markedly higher with the fiberglass casts. They upon a further cost-benefit analysis resolved the greater benefit in favour of the fiberglass cast[64].

Even though fiberglass cast is available in the Department, preliminary assessment showed that it would be costlier for patients compared to the plaster of Paris cast, and so the study decided to use POP for all recruited patients.

2.8 REMODELING OF DISTAL FOREARM FRACTURE

Sometimes, stabilizing the reduced fracture in casts might be difficult, with frequent loss of reduction reported. This is especially worrying when the residual deformity may be significant, or the child has minimal skeletal growth left. This has increasingly led to operative treatment of such fractures in some centres[65–67].

The non-operative management protocol is heavily influenced by the remarkable remodeling potential of the distal radius and ulna in growing children[68–71]. As a general rule, remodeling potential is dependent on the amount of remaining skeletal growth, proximity of the injury to the physis, and relationship of the deformity to the plane of adjacent joint motion[68,70,71]. Jeroense et al[72], demonstrated that the rate of remodeling is proportional to the initial angulation although it decreases over time, exponentially. For this reason, distal forearm fractures in very young children can accept significant residual deformity, after manipulation of the fracture[71]. Distal radial physis, with predominantly sagittal plane angulation have the greatest remodeling capacity because flexion and extension are the principal movements of the adjoining wrist. Friberg[69], however, also found significant correction of frontal plane angulation with these fractures. Acceptable sagittal plane angulation of acute distal radial metaphyseal fractures has been reported to be from 10 to 35 degrees, and 10-15 degrees frontal plane angulation, in children under 10 years[71,72].

For children over 10 years of age, acceptable alignment has ranged from 5 to 20 degrees in the sagittal plane, and < 10 degrees frontal plane angulation, depending on the skeletal maturity of the patient[69]. Even in young children (<10 years), complete bayonet apposition often remodels out[68,69]. (Table 2.1)

However, in an excellent review of adolescent distal radius fractures by Greig et al, they found that there is still significant remodeling potential in children older than 12 years, be it for angular deformity or bayonet apposition[73]. Friberg, indeed showed that for children with at least 2years of growth remaining, the most important determinant of remodeling is the degree of angulation, with the remodeling velocity increasing with the degree of angulation and not necessarily age or sex[68]. This has been corroborated by Jeroense et al[72]. Thus, Greig et al argued that angular deformity of up to 15 degrees is tolerable in adolescents at least 2 years removed from skeletal maturity (about 15years in girls and 17 years in boys)[73].

These reasons mean that a certain amount of residual angulation and displacement, is allowable, whether this is after initial manipulation or re-displacement after stabilization. Thus, anatomic reduction and rigid fixation of such fractures are unnecessary[13]. Cast treatment is often sufficient, even if secondary displacement were to occur. This is especially so in younger children.

Table 2.1: Acceptable deformity post-reduction[68,72,73]

AGE	SAGITTAL PLANE	CORONAL PLANE	OTHER
<10yrs	Up to 35 degrees	Up to 25 degrees	Bayonet apposition
10-15years	Up to 15 degrees	Up to 15 degrees	Bayonet apposition up to 1cm

2.9 FACTORS THAT AFFECT SECONDARY DISPLACEMENT (RE-ISPLACEMENT) POST-MANIPULATION.

In spite of the remodeling capacity of children, it is important to be able to maintain fracture reduction, after manipulation. The rate of re-displacement ranges from 20% to 39% after reduction and casting[74,75]. The factors that predict re-displacement in distal forearm fractures in children have been extensively studied[74–87]. They include initial fracture displacement, fracture pattern, whether there is both bone fracture, post-manipulation residual deformity, cast type and cast mold. These factors are examined below.

2.9.1 Initial Fracture Displacement

Initial fracture displacement is a significant risk factor for re-displacement[74,86] . Mani et al[18], in a retrospective study, found that the initial translation of the fracture was the most important factor in predicting outcomes of distal radius fracture in children. They showed that risk of failure in distal radius fractures was 60% when the bone was translated by more than half the diameter, compared to a failure rate of 8% when the fracture had translated by less than half the diameter. Asadollahi et al[47], noted a seven-fold increase in re-displacement with completely displaced distal radial fractures, compared with fractures which were incompletely displaced. Indeed, other authors have advocated percutaneous Kirschner wire fixation of such completely displaced fractures, because they found less re-displacement with such patients[66,81,83].

There may be multiple factors accounting for this. Firstly, such fractures lack a periosteal hinge, by virtue of the complete translation, which would have helped to stabilize the fracture in addition to the cast. This is especially so in children, who tend to have thick periosteum which serves as an aid in maintaining reduction[86]. Thus, these completely off-ended fractures will have little inherent stability. It is also thought that these displaced fractures may have associated severer soft tissue injury, with attendant inflammatory oedema. Once the significant oedema resolves, the casts loosen and so allow for more displacement of the fracture[74].

2.9.2 Fracture Configuration/Geometry

Very few studies have looked at the effect of fracture geometry as a risk factor for re-displacement of distal forearm fracture, even though for fractures of other bones, stability as a function of fracture configuration, is often highlighted. For example, transverse fractures are more length stable than oblique fractures, which in turn are more stable than spiral fractures or comminuted fractures[18]. Perhaps, because most distal forearm fractures tend to be transverse, fracture configuration is overlooked as a risk factor[6].

Alemdaroglu[49], the only known study that makes reference to fracture configuration, found fracture obliquity to be the second most important risk factor for re-displacement, in their seminal paper on three-point index. They found that compared to a transverse fracture, 10° obliquity was associated with a risk of re-displacement of 2.22; 20° obliquity with 4.93 re-displacement risk and 30° obliquity with 10.94 re-displacement risk.

2.9.3 Fractures of Both Bones

The effect of both bone fractures on re-displacement is controversial. Whereas Gibbons[88] and Fenton[75], both found that an associated ulna fracture was not predictive of re-displacement of distal radial fracture, numerous other studies have showed an association[17,77,81]. Gibbons[88] argued that the intact ulna in distal radial fractures, served as a "strut" and made the distal radial fracture more unstable. Other authors however think that the ulna being fractured as well removes the internal splintage it would have offered the distal radius fracture after reduction and so makes the fracture unstable[28,77].

2.9.4 Anatomic reduction

Fractures which have post-manipulation residual deformity, tend to have a higher risk of re-displacement[17,76,77,80]. Thus, the recommendation by most authors is to get as near an anatomic reduction of the fracture as is possible to reduce the risk. Indeed, McQuinn and Jaarsma[80] suggested developing guidelines as above, as to what is acceptable reduction, in order to improve the quality of reduction.

Crawford et al[89], however, also showed that in children between 3 and 10 years, overriding fractures not subjected to manipulation, still yielded excellent results.

2.9.5 Choice of Cast

A short arm (below elbow) cast that is well molded to the normal contours of the arm should control supination and pronation. The traditional teaching had been to immobilize the joint above and below the fracture[11–13]. It ensures the control of supination, performed by the supinator and the more important biceps brachii muscle that arises from above the elbow[19,20]. But this may be more important in diaphyseal fractures than metaphyseal fractures[48]. The brachioradialis, which also arises from the supracondylar ridge of the distal humerus and inserts on the radial styloid, is even a more important deforming force- displacing the fracture radially and to a limited extent dorsally[28]. The above-elbow cast, then, serves to immobilize all these muscles to prevent re-displacement[12].

However, multiple randomized controlled trials have demonstrated that short-arm casts are as effective at maintaining reduction as long-arm (above elbow) casts, provided that acceptable alignment is achieved, and an appropriate cast mold is applied[22,25,26].

The appropriate type of cast immobilization for distal forearm fractures remains unresolved. Both long- and short-arm casts have been proposed following distal radial fracture reduction. A still good number of Orthopaedic surgeons, prefer above elbow casts, especially for severely displaced fractures[27]. However, above elbow immobilization is associated with limitations in activities of daily living, elbow stiffness, as well as more missed days of school[24].

2.9.6 Cast Mold

A cast for immobilizing any fracture should be molded to the bone, such that three-point fixation can be obtained. This gives the strongest buttress to the fracture, thus preventing displacement[18]. However, casts have to be molded not only around the enveloping soft tissue, but around cotton wool padding which serves to reduce the risk of pressure necrosis from an unyielding cast[9,90]. Coupled with poor technique, precise cast molding can be challenging[84,87].

To assess how well a cast is molded around a fracture, especially forearm fractures, various measures have been introduced. These include the cast index, gap index, padding and Canterbury indices, and the three-point index.

The cast index was first described by Chess et al[87] in children immobilized in short arm cast for distal forearm fractures. The principle of the cast index is that the sectional geometry of the cast, ought to be an ellipse, rather than circular; meaning the diameter of the cast in the sagittal plane has to be less than that in the coronal or frontal plane[84]. This index thus particularly was bothered with displacement in the sagittal plane- dorso-ulnar displacement (the usual direction of displacement), and very little to do with displacement in the coronal plane. The cast index is obtained by dividing the inner diameter of the cast on the lateral radiographic projection, by the inner diameter on the anteroposterior projection. They recognized an association between the cast index and the risk of re-displacement. With a cut-off of 0.7, they found that casts with a higher cast index were more likely to re-displace[87]. The cast index is illustrated in the methodology section (fig 3.5).

Malviya et al[91] also devised a measure they termed the gap index. They assessed this by measuring the radiolucent 'gap' between the inner aspect of the cast and the skin, at the level of the fracture. This is taken on both sides of the fracture, volar and dorsal on the lateral projection and radial or ulnar on the anteroposterior projection. The sum on each view is divided by the inner diameter of the cast on that view. The two ratios are summated to get the Gap Index, which should ideally be <0.15. (see fig 2.11). They found higher sensitivity and positive predictive value with the gap index than the cast index.

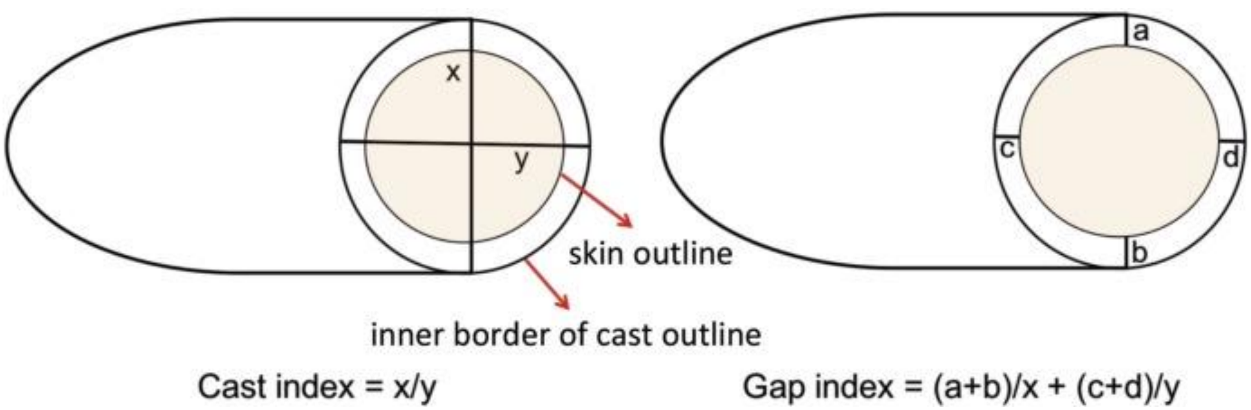
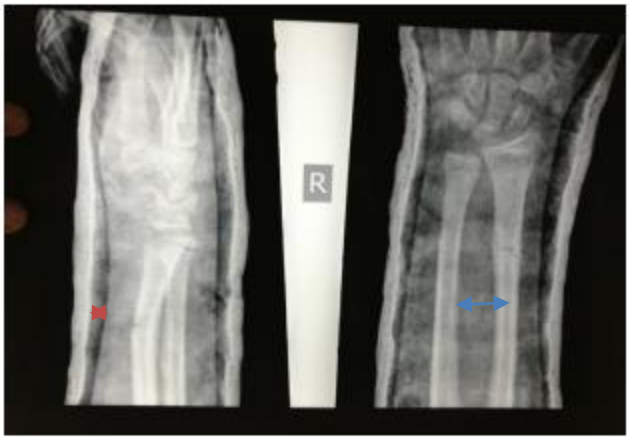


Figure 2.11: Schema showing how Cast index and Gap Index are measured. Pink outline is the bone circumference. Outer circumference is the pad. In the Gap index, the 'gaps' between the bone and inner part of cast on the sagittal and frontal views are each summated and then each divided by the inner width of the cast at the level of the fracture. The two values are added together. Cast index is as outlined in the text.

Source: Shalabh et al. (2018)

The Padding index and the Canterbury index have also been described by Bhatia and Housden[79]. They defined the padding index as "the ratio of the thickness of padding at the fracture site in the plane of deformity correction on the lateral view to the maximum interosseus diameter on the anteroposterior view"[79].(fig 2.12) If the padding index exceeds 0.3, it portends a higher risk of displacement. To obtain the Canterbury index, they added the cast index to the padding index, and advised it should be <1.1, to minimize the risk of displacement[79].



Padding index= x/y

Figure 2: Calculting the padding index.

Figure 2.12: Padding index

Source: Kharbamon et al. (2020)

The three-point index, first described by Alemdaroglu et al in 2009[78], uses indirect measures of the three-point fixation principle. It measures gaps proximally and distally to the fracture and then at the level of the fracture in the plane of the corrected deformity both on the lateral and anteroposterior views. The measured gaps are added for each projection and divided by the width of the fractured bone. The ratios are then added (fig 3.6.1 and 3.6.2). The cut-off was pegged at 0.80[49].

These indices have been subjected to sensitivity assessments[78,84]. The cast index, even though, is the most commonly used in our institution (patient records) because of the simplicity of calculation and good reliability, fails to take the cast mold (three-point fixation) into consideration. It also can be falsely high, despite good cast mold, in children with chubby forearms. Finally, because it focusses less on coronal plane displacement, it fails to identify poorly molded casts on the ulnar or radial side[78].

The gap index changes dramatically when the initial swelling subsides, a problem recognized by the originators of the index[91]. They advised follow-up and re-application of the cast if necessary. The padding index only considers the deformity in one plane, the lateral projection. It does not account for displacement in the coronal plane, radio-ulnar displacement[78]. The Canterbury index suffers from the limitations of the two base indices that are used. Owing to the fact that the padding index, and by extension the Canterbury index, rely on the use of the maximum interosseus width, as the denominator, they might be more suited for assessment of cast mold in forearm shaft fractures instead[78].

The three-point index, though quite cumbersome to assess, has been found to have the highest sensitivity[84].

The study will assess the association between re-displacement of distal forearm fractures with the cast index (which is the simplest and most commonly used in our institution) and the three-point index, which is thought to be the most sensitive.

Re-displacement of fractures is multifactorial and rarely would be caused by one of these factors alone[75–81].

2.10 DURATION OF CAST TREATMENT

Perkins' rule has been traditionally used to guide the period of immobilization of fracture[92]. The teaching has been that for upper limb fractures in children, a period of 3 weeks immobilization is sufficient for bridging callus formation around the fracture. Prosser et al, reviewing signs to date fractures, found that there is usually evidence of hard callus on x-rays by 2 weeks post-injury[15]. In a systematic review, Delft et al found that even for adult distal radius fractures, outcomes are not inferior after immobilization for 3 weeks[93]. Thus, a period of immobilization of 3-4 weeks should be sufficient for managing distal radius fractures in children. In any case, it seems loss of reduction of the fracture typically occurs before 2 weeks and mostly inconsequential[94].

CHAPTER THREE
MATERIALS AND METHODOLOGY

3.1 Study Design

The study is a non-blinded randomized, prospective study to compare re-displacement with below-elbow cast treatment and above-elbow cast treatment for displaced distal forearm fractures.

The patients, children between 4 and 13 years, were randomized in a nearly 1:1 ratio into the treatment arms of the below-the-elbow casting and above-the-elbow casting. The assignment to an arm was done with codes obtained by electronic random number generator (cf. Appendix 4). The electronically generated allocation was sealed in opaque envelopes. Each parent/guardian of the participants randomly selected a sealed opaque envelope and handed it over to the research assistant, who then opening it, mentioned the intervention arm so assigned for the necessary action. Blinding wasn't possible in this case because the patient and the guardian would know from the type of cast given, which intervention arm they had chosen and so assigned. The principal investigator also obviously knew the type of cast applied since he usually was on hand for the cast application. Even for those he was personally absent, it would be obvious from the radiographs, which cast type had been applied. However, the opaque envelopes allowed for allocation concealment[95].

The data was collected between August, 2023 and February, 2024.

3.2 Study Site

The study was conducted at the Department of Trauma and Orthopedic Surgery of Korle Bu Teaching Hospital. Korle Bu Teaching Hospital is in the Greater Accra Region of Ghana, home to over 20 clinical and diagnostic departments, and a stated bed capacity of two thousand (2000). This is the biggest referral hospital in the Southern part of Ghana, to which a sizeable proportion of Orthopaedic trauma patients are referred.

The Trauma and Orthopaedic Surgery Department has a bed capacity of 168, 4 teams with a staff strength of 10 Consultants/Senior Specialists and 11 Senior Residents. It conducts Outpatient Clinics from Monday to Thursday, with an average attendance per day of 70 patients. The Department has three operating rooms for major surgeries, and a minor operating room. It has a room for manipulation and application of casts for fractures. This is staffed by seven (7) trained technicians. It has a standby oxygen cylinder, and a crash cart for resuscitation of both adult and paediatric patients. The Department attends to an average of 185 cases of paediatric distal forearm fracture in a year, most of which are displaced.

3.3 Study Population

The participants for this study were children, 4 to 13 years old, who had presented with displaced distal forearm fracture. A lower age-limit of four years was set, as below-the-elbow casts tend to slip off the arms of the smallest children. An upper age-limit of 13 years was chosen so that all participants, boys and girls, would have at least 2 years of growth left. The closure of the distal forearm growth plate is about 15 years in girls and about 17 years in boys[46,73].

Eligible participants for the study were patients presenting to the Department of Trauma and Orthopaedic Surgery of Korle-Bu Teaching Hospital, who were:

1. Children between 4 and 13 years old,
2. Patients presenting within 5 days of the injury, and
3. Patients with displaced fracture of the distal radius, ulna or both.

Study participants were excluded if they presented with:

1. Open distal forearm fractures or had severe soft tissue injury as to preclude immediate casting, or
2. Distal physeal injury, or
3. If closed reduction was impossible and the child needed open reduction with internal fixation, or
4. If they were multiply injured or polytraumatized

3.4 Sample Size

The sample size was calculated for a noninferiority two-tailed study group design with two independent study groups with a continuous endpoint. It was determined that the mean difference between the two groups will be no more than 5°, for a p value of 0.05 and a power of 80%.

$$n_1 = \frac{(\sigma_1^2+\sigma_2^2/k)(z_{1-\alpha/2}+z_{1-\beta})^2}{\Delta^2}$$ [96]

$\Delta=\mu_2-\mu_1$= difference between the two means

σ_1^2, σ_2^2, being the variance of means 1 and 2 respectively

n_1= sample size for group 1

n_2= sample size for group 2

α= probability of type I error

β= probability of type II error

z= critical Z value for a given α or β

k= ratio of sample size for group 2 to group 1

From previous studies, the difference between the means was set at 5° and a standard deviation of 5° for each group[17,21,23]. The randomization is intended to allocate equal numbers to both arms, so that k=1.

Using the above formula gives a sample size of 64; 32 for each arm. Accounting for a 10% attrition rate, the sample size was set to 35 per arm.

3.5 Randomization

Patients were randomized into the above-elbow cast or below-elbow cast groups. The permuted block randomization technique was used to allocate participants into one of the two groups, aiming for a ratio of 1:1 for randomization. This was done with the aid of a computer program called randomizer.org. A block size of four, six and eight was used to generate a random table using the computer program. The randomization table is attached as appendix 3.

The technique of allocation concealment used in the study was the Sequentially Numbered Opaque Sealed Envelope (SNOSE). The study chose this technique for its simplicity and good cost-benefit. Two 35 sets of standardized paper were labeled 'above-elbow' and 'below-elbow', respectively. These two sets were separated and each paper placed on a carbon paper with the print site. This was wrapped in aluminum foil on both sides to render it opaque. The completed inset was then placed in a standard blank A4 sized brown envelope, with the print size to the front of the envelope. The envelopes were sealed, signed across and numbered sequentially based on the software generated sequence, by the principal investigator solely. Signing across the envelope seal and numbering left a transferred trace from the carbon paper onto the treatment allocation standardized paper for auditing purposes and ensured that there were no violations of the allocation concealment.

3.6 Team Members

In all, four Senior Residents and two Cast Technicians were recruited to help with the study execution. The title, the rationale and objectives of the study were explained to each member of the team. They were to treat every participant with utmost respect, diligence and patience, as the tenets of the study.

3.6.1 Roles of Team Members

The Principal Investigator had ultimate responsibility for the conduct of the study, and had to collaborate with each member of the study. The team members helped with performance of the study and collection of data, in line with the overall objectives and standards outlined for the study.

Their roles are as described below:

1. Each Senior Resident was to discuss recruitment into the study and explain the rights of the participants to their guardians.
2. The Senior Residents collaborated with the Cast Technicians to perform the reduction and application of the cast as per the manual for the study, when the Principal Investigator was not available.
3. The team members helped collect the data upon presentation and after cast application.
4. Follow-up of patients was subsequently done by the Principal Investigator and the Cast Room staff.

The team members were trained in the recruitment of participants, administration of the questionnaires, the study procedure, and data collection. We had a series of face-to-face meetings, with hands-on and video sessions on the technique of reduction and cast application. It was agreed that at least one of the two Cast Technicians be always on hand to assist with the fracture reduction and cast application.

3.7 Study Procedure

3.7.1 Pre-procedure protocol

Consecutive children between 4 and 13 years old, with displaced distal forearm fractures were randomized to one of the treatment arms. The study was explained to the parents/guardians of all the children enrolled. A signed, informed consent was obtained from the parents (Appendix 1). For children between seven (7) and thirteen (13) years, they also provided assent before being enrolled in the study (Appendix 2). The parents/guardians were then asked to fill a questionnaire (Appendix 3), providing some brief demographic data of the child. For those who could not read or write, the questions were asked in a language they understood, and the questionnaire filled on their behalf. Most of the other data sets were taken from the radiographs and so were filled by the investigator. The data taken from the radiographs included the laterality of the injury which was characterized as the dominant or non-dominant arm; which of the forearm bones were fractured-radius, ulna or both; the fracture configuration; and the initial displacement of the fracture in terms of sagittal and frontal plane angulation and translation, respectively.

3.7.2 Anaesthesia

Once enrolled, the child was given an intravenous line and readied for the procedure. All the reduction and casting were done in the Plaster room or the emergency room theatre. The child then was given conscious sedation (after a fast of at least 4 hours) with IV Ketamine 1-2mg/kg and IV midazolam 25-50 micrograms/kg body weight[58] by a second assistant. We waited for the child to be fully sedated while supporting the child with oxygen by facemask at a rate commensurate with the age. The heart rate, blood pressure and oxygen saturation were checked while the child was under sedation by the second assistant. There was always a crash cart available for patient resuscitation if needed. However, there never was an adverse event requiring the use of the crash cart, for the entire duration of the study.

3.7.3 Fracture reduction

Manipulation of the fracture was done by the Investigator and an Assistant. Finger traps were applied to each finger of the affected limb. The Investigator provided axial traction while the first assistant provided counter-traction to dis-impact the fracture. Then coronal plane malalignment was corrected by applying a force counter to the displacement to obtain neutral alignment. Sagittal plane malalignment was corrected by applying a force opposite the initial displacement. Rotational malalignment, if present, was also corrected by de-rotation. In cases of bayonet fracture apposition, the deformity was exaggerated by hyperextension in dorsally displaced fractures and flexion in volarly displaced fractures, while applying traction to cause disengagement of the fragments[18]. Reduction was assessed clinically by the attainment of neutral angulation, alignment and rotation, and loss of any overlap. The reduced fracture was immobilized with Plaster of Paris (POP) backslab.

3.7.4 Plaster of Paris Backslab Application

Natural rayon roll (SoffBan®) was rolled over the forearm starting just distal to the metacarpophalangeal joints, all the way up to the elbow, for those assigned to have below elbow cast. For those in the above-elbow group, it was applied up to the deltoid insertion. The rolls were such that the next overlapped the previous by 50%, so that the result is a uniformly two layered roll of cotton wool. Two sizes of POP were used; 4 inch for children below 6 years or with small forearms and 6 inch for those above 6 years or with large forearms. The width of POP was chosen so a balance could be struck between adequate splintage and avoiding circumferential casting. This was often four or five double layers of the POP. The length of POP was measured from the distal palmar crease to within two fingerbreadths (child's), of the transverse cubital crease for the below elbow cast group. Those randomized to have an above-elbow cast had the POP measured from the distal palmar crease to just distal to the level of the deltoid insertion. The POP was applied by the investigator, while the two assistants maintained the reduction. The four or five laid out double rolls of POP was immersed in lukewarm water from the tap, until all the air bubbles had escaped from the POP to ensure that the POP was fully soaked. The POP was then applied to the dorsum of the forearm for those with dorsally displaced fractures, and volarly for those with volarly-displaced fractures. A 4 or 6-inch crepe bandage, roughly according to the chosen cast, was then rolled over the cast, from distal to proximal forearm or the arm to secure the slab in place. The cast was then molded by the investigator to get 3-point fixation of the fracture, that is close contouring of the cast to the bone proximally, at the level of the fracture and distally. The plaster mould was held in place until it set, which was typically between four and seven minutes (4-7 minutes).

3.7.5 Post-procedure protocol

The patient was then monitored until full recovery from the sedation. The most common difficulty encountered during the sedation was excessive secretions which were suctioned out with bulb syringes. They were then sent to have post-procedure radiographs; antero-posterior and lateral views, to assess for adequacy of reduction. The following parameters were measured and recorded on the questionnaire: degree of sagittal and frontal plane angulation, and percentage of apposition on the frontal and sagittal planes. The measurements were done with a ruler, a pencil and protractor. The children were then monitored for any complications and then sent home the same day with oral paracetamol, dosed according to the weight. One child had a brief period of apnea which responded promptly to intermittent positive pressure ventilation (IPPV) with an ambu-bag. It had been anticipated that 70 patients would be enrolled unto the study. However, by the end of the sixth month, and with deadlines to meet, the study had accrued 58 children, 30 in the below-elbow group and 28 in the above-elbow group. After discussions with the supervisors, we agreed to do the data analysis for the 58 accrued patients, with the understanding that the study would be underpowered and might affect the conclusions.

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Figure 3.1: Patient with finger traps applied after sedation, awaiting manipulation.

Source: Author

Figure 3.2: Fracture reduction, with one of the assistants

Source: Author

Figure 3.3: Above-elbow backslab being applied. Picture with the permission of Assistants.

Source: Author

3.7.6 Follow-up assessment

A week later, the patients would return, with repeat radiographs taken on the day of review. The degree of angulation and amount of apposition were assessed, and if the threshold for re-manipulation was met (Table 3.2), the fracture was re-manipulated and a cylindrical cast given, according to the intervention arm child was randomized to. To apply the full cast, by applying the cotton wool roll as for the initial backslab, followed by application of the cast by rolling it circumferentially from the metacarpophalangeal joint to below or above the elbow. The cast was molded around each bone in the case of both bone fractures, so that a cross-section of the cast would look like a double-barrel.

For those who did not meet the criteria for re-manipulation, the cast was completed by first removing the crepe bandage used to secure the backslab and then applying a few rolls of POP. Molding around each bone was done for both bone fractures. Only one patient met the criteria for re-manipulation after the first week. New radiographs were taken to assess for adequacy of the reduction.

The markers of cast mold; the cast index and three-point index were measured after the application of the full cast, on the repeat radiographs. The measures of reduction- angulation and apposition on the two orthogonal views were also checked on the post-manipulation films. The patients were discharged home if the reduction is acceptable (Table 3.1). If the reduction was unacceptable, according to the set criteria, re-manipulation was done (Table 3.2). These criteria for acceptable reduction, and triggers for re-manipulation of the fracture, were developed according to the literature on the subject[8,19.]

Patients were followed up weekly for up to 3 weeks to assess for loss of reduction in the cast. Each time they came for review, they brought new radiographs (AP and lateral views) and these were again subjected to the criteria for re-manipulation. The sagittal and frontal plane angulation, as well as the sagittal and frontal plane apposition were recorded each week. No one met the threshold for re-manipulation after the first week.

The cast was removed at three weeks post-initial manipulation after assessment of radiological union. Everyone had at least three cortices bridged by callus by the third week. Radiologic union was defined as bridging callus in at least 3 cortices around the fracture. Once the cast was removed, evidence of union was also assessed clinically by:

- absence of pain at the fracture site

- the child being able to move the forearm without ‘buckling’ at the fracture site
- palpable callus at the site
- absence of movement at the fracture site on palpation.

3.7.7 Post-operative instructions and safety measures

The parents were given written instructions for post-op care, after the initial reduction and application of the backslab and then upon application of the full cast, as well as to look out for symptoms of compartment syndrome (Appendix 4). These were also explained to the parent in detail, in a language they understand. They were to return if they developed any complications. However, no such complication was reported in this study.

Table 3.1: Criteria for acceptable reduction [17,23,97]

FRACTURE TYPE	AP/LATERAL ANGULATION	APPOSITION ON AP/LATERAL XRAYS
Isolated distal radius fracture	≤ 5 degrees	≥ 95%
Combined radius and ulna fracture	≤10 degrees	≥50%
Isolated distal ulna fracture	≤ 10 degrees	≥50%

Table 2.2: Criteria to trigger re-manipulation[17,21,78]

FRACTURE TYPE	LATERAL ANGULATION	AP ANGULATION	APPOSITION	OTHER
Isolated distal radius	>15 degrees	>10 degrees	<50% apposition on any view	Angulation of >15 degrees in one week on AP/ lateral radiograph
Combined both bone	>10 degrees	>10 degrees	<25% apposition on any view	
Isolated distal ulna	> 10 degrees	>10 degrees	<25% apposition on any view	

3.8.1 Measurements of Angulation

To measure the degree of angulation on any view, a line was drawn parallel to the long axis of the proximal and distal fragments of the bone. The acute angle formed between these two lines was measured with a protractor to be the degree of angulation. This was done for each bone, in the case of both bone fracture but only the degree of angulation of the radius was subsequently used for the analysis, for simplicity.

Figure 3.4: Measurement of Angulation on initial radiographs. The acute angle subtended by the two lines through the long axes of the fracture fragments, is the angulation. Here, it is shown as α and β in the Sagittal and Frontal planes respectively. NB: in both

Source: Author

3.8.2 Measurement of Apposition

To determine the measure of apposition, on each view, a line from one cortex of the proximal fracture line to the other, was drawn and this width was measured in millimeters(x). Next, the width of the distal fragment that overlapped the proximal fragment was measured in millimeters(y). The percentage apposition was then defined as y/x*100%. This was done for each bone, in the case of both bone fracture. However, only the apposition of the radial bone was used for the analysis, for the same reason cited for the angulation.

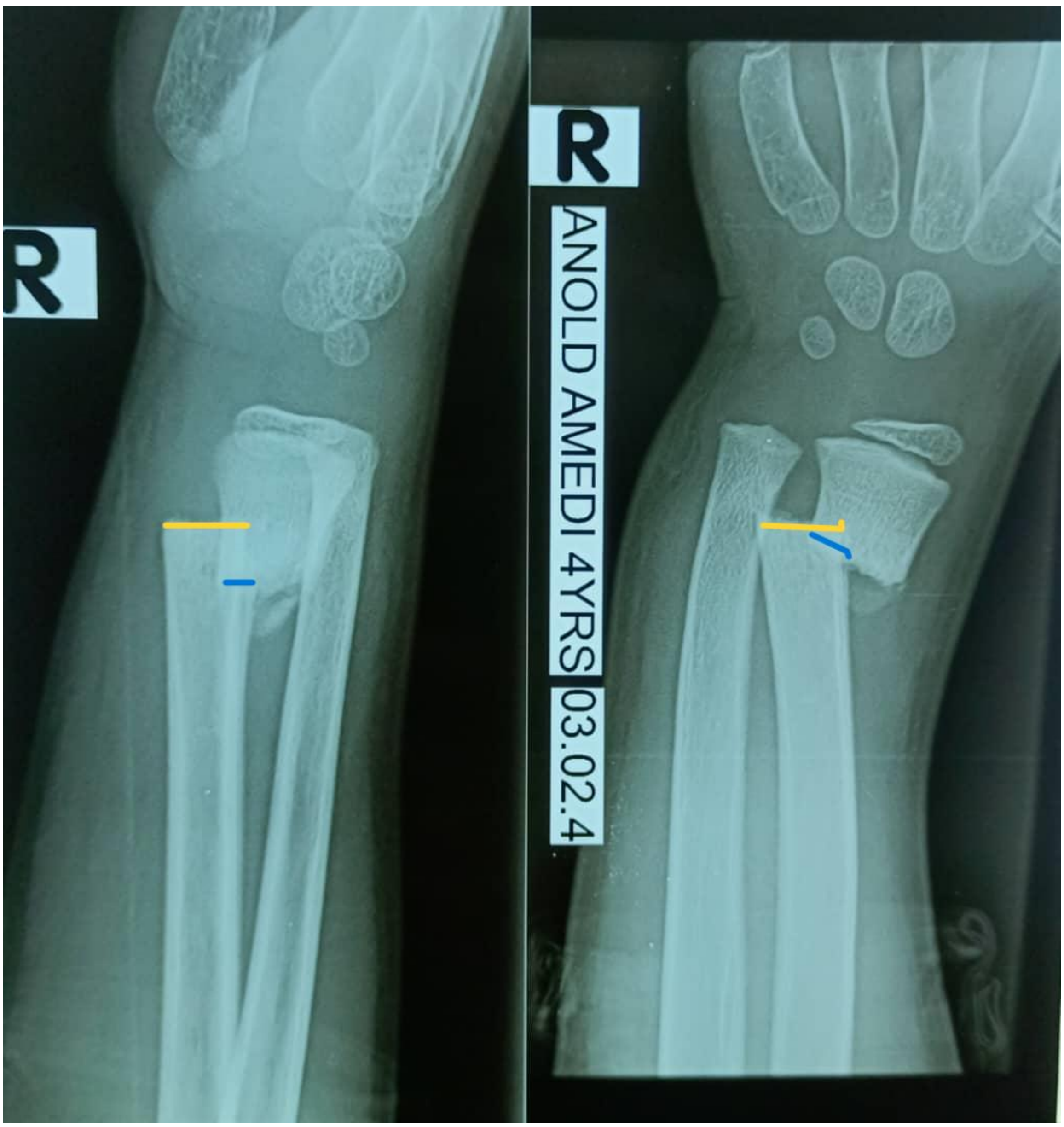

Figure 3.5: The width of distal fragment overlapping proximal fragment is shown in blue, and measured in millimeters in both projections). Width of the proximal fragment is shown in yellow, and measured in millimeters (in both projections. The ratio of length of blue line to length of yellow line as a percentage is determined as apposition.

Source: Author

3.8.3 Cast Index

The inner diameter of the cast on the lateral view, at the level of the fracture, was measured (A) The inner diameter of the cast on the antero-posterior view, also at the level of the fracture, was also taken (B). The cast index was defined as A/B [58].

Figure 3.6: Calculation of Cast Index

Source: Internet photo

3.8.4 Three-point Index

The three-point index [49] was calculated as follows: on an anteroposterior radiograph (Fig.3.6.1), "a" should represent the narrowest radial-side gap between the cast and the skin near the radiocarpal joint or at the level of the scaphoid bone, "b" should represent the narrowest ulnar-side gap within 1 cm of the fracture line, and "c" should represent the narrowest radial-side gap about 3 to 5 cm proximal to the fracture site (Fig. 3.6.1). 'd' should be the narrowest dorsal-side gap between the cast and the skin around the radiocarpal joint or the proximal carpal row on a lateral radiograph of an extension-type fracture (Fig.3.6.2), 'e' should be the narrowest volar-side gap between the cast and the skin within 1 cm of the fracture line, and 'f' should be the narrowest dorsal-side gap about 3 to 5 cm proximal to the fracture. ‘a’, ‘b’, and ‘c’ on a radiograph of a flexion-type fracture should be identical, but ‘d’, ‘e’, and ‘f’ should have the volar and dorsal sides reversed. For the study, we used the gap at the level of the radiocarpal joint for every fracture. We also used the narrowest radial-side gap 3cm from the fracture site.

The index is proportionate when the sums are divided by the contact length of the fracture fragments in each plane, ‘x’ and ‘y’ respectively, preventing measurement mistakes brought on by the plain radiographs' magnification. The sum of these two calculations is the three-point index. For both bone fractures, the three-point index was calculated as described, but the narrowest gap at either the radial side or the ulna side was used, and the radial width at the level of the fracture was used as the denominator.

The study did not predefine an “acceptable” cast index or three-point index and so no cast was re-applied to obtain a certain cast index or three-point index.

Figure 3.7.1: Calculation of the three-point index-component on anteroposterior view

Source: Alemdaroglu et al (2009)

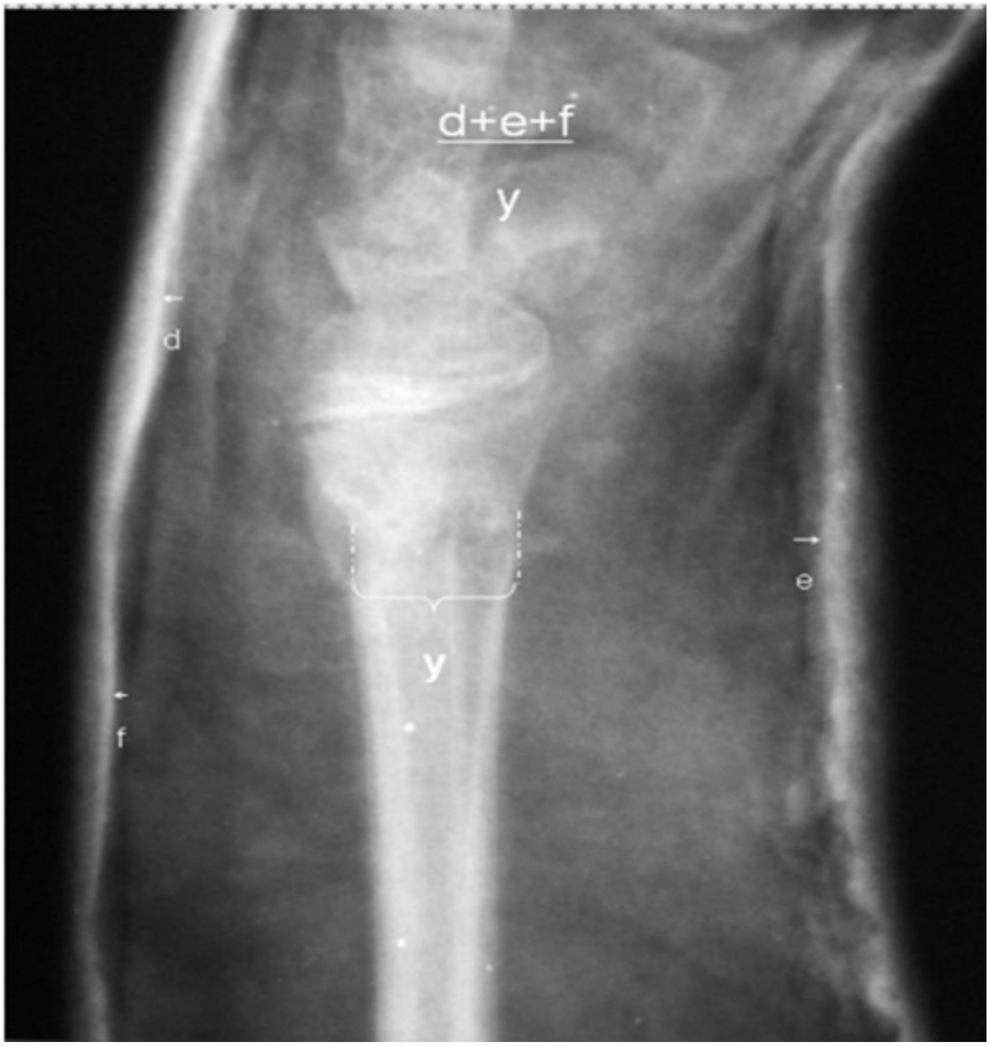

Figure 3.7.2: Calculation of the three-point index on lateral view

Source: Alemdaroglu et al (2009)

***Figure 3.8.1: Initial Fracture pattern on the x-ray of participant assigned to below elbow cast. Had both bones fractured*.**

Source: Author

Figure 3.8.2: Full cast applied after one week, following initial POP backslab application.

Source: Author

Figure 3.9.1: Initial radiograph showing anteroposterior and lateral views of a distal forearm fracture. Patient was assigned to above-elbow cast.

Source: Author

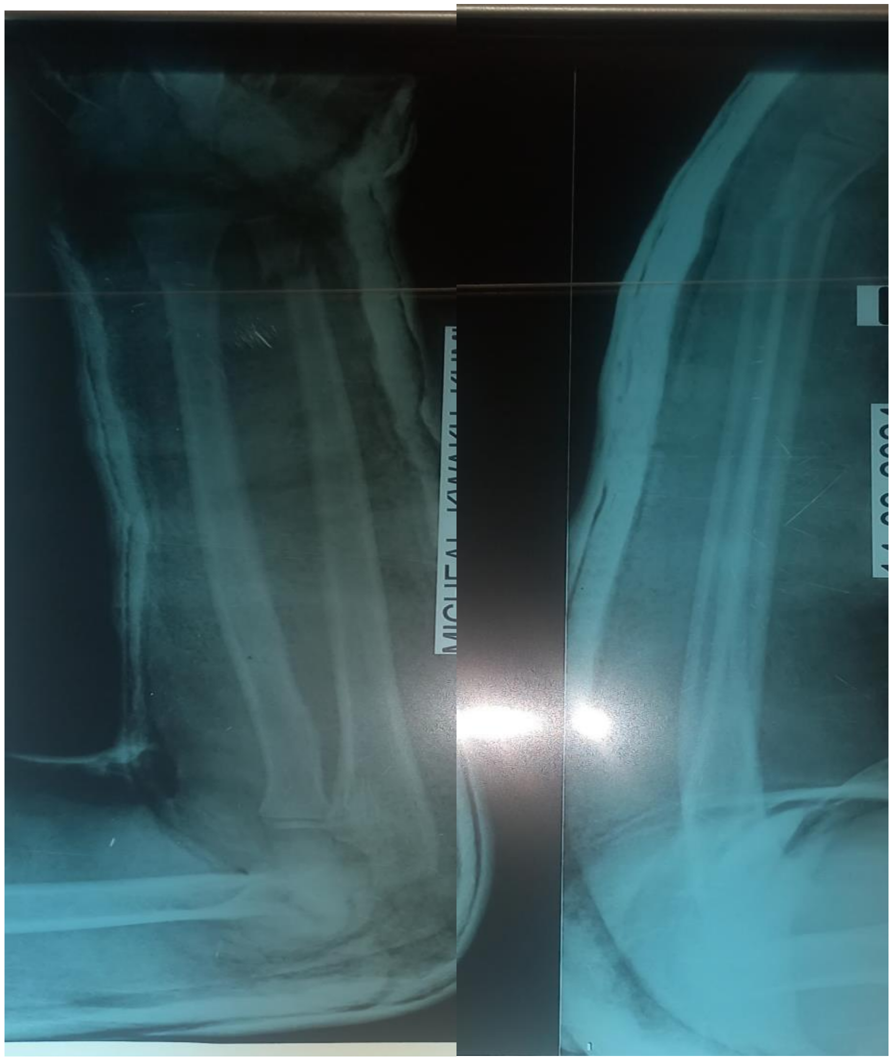

Figure 3.9.2: Post-manipulation of fracture with full above elbow-cast after 1 week.

Source: Author

3.9 DATA MANAGEMENT AND ANALYSIS

For this study, data security, quality assurance and confidentiality of participants' information were regarded as topmost priority. The Principal Investigator was responsible for ensuring that adequate, accurate and relevant data was collected and not excessive for the purposes of the study to uphold quality assurance.

To ensure confidentiality of participants' information, names of participants have been omitted in the write-up. Study participants' data were de-identified and concealed by using codes. The research assigned codes to each questionnaire or participants' information and was treated as confidential. The process for archiving of the collected data has been archived.

All non-electronic research data was stored in locked filing cabinets and electronic data on files with password protection on hard drives, CD, and flash drive. This data has been accessible only to authorized persons. All unwanted documentation or paper which contained confidential data were disposed of appropriately. However, at the end of the study, all documentation or data connected with the study will be kept for five years in a secured cabinet. The Principal Investigator will be the only authorized person to have access to the stored data.

SPSS Statistics software version 20 was used to analyze the data. Continuous numerical data was summarized as mean and Standard deviation (SD) and categorical data as percentages (%). Data was presented using bar charts, histograms, tables, and pie charts as appropriate. Demographic characteristics of study participants such as age, educational status and sex were analyzed and presented as mean and standard deviations, and counts and percentages, as applicable. Chi-square test was used to compare proportions in the demographic and clinical characteristics of study participants. Paired t-test was used to compare the means of re-angulation and loss of apposition between the two arms. Multiple logistic regression was run between demographic variables, viz age, sex, weight and the degree of re-displacement in the two arms. Statistical significance was set at $p \leq 0.05$.

3.9.1 Dissemination of results

The results of the study will be presented to the Ghana College of Physicians and Surgeons in partial fulfillment of the award of Fellow of the Ghana College of Surgeons. Also, the final work will be presented to a peer-reviewed journal for publication.

3.9.2 Outcome

Appropriate recommendations will be made to the Department ocf Trauma and Orthopedics, based on the outcomes of the study. The expectations of the study were largely met.

3.10 ETHICAL AND LEGAL CONSIDERATION

Ethical clearance for this study was obtained from the Institutional Review Board at the Korle Bu Teaching Hospital (Appendix 6). The study was done in keeping with the Declaration of Helsinki for human subjects in medical research. Parents of the participants were provided as much information as necessary on what the study entails. Parents who could not afford the weekly reviews and/or the serial x-rays were assisted financially to do so. Desire to decline participation, or wish to withdraw from the study, did not affect medical care.

It was explained to the parents that exposure to serial radiation came with a low -risk of future development of malignancies and so the total number of x-rays taken were kept to the minimum necessary: immediate post-injury; immediate post-manipulation, and the weekly x-rays for three weeks; the last being immediately before cast removal. If the cast would not be removed at 3 weeks because of delayed healing, there won't be another x-ray before cast removal. The diagnosis of fracture union was made clinically.

The exception would be for those who had fracture displacement. They would have repeat manipulation and so would need another x-ray to confirm the reduction.

The average dose exposure for wrist x ray in children is about 0.6-1 microSievert. This translated to 3.6 to 6 microSievert for the six (6) radiographs to be taken over the period[98]. This was below the safe effective dose for children of 5000 microSievert per year[49]. Discussions were had with the Department of Radiology to limit the amount of radiation to as low as reasonably acceptable. Find the protocol below.

3.10.1 RADIATION PROTECTION DURING X-RAYS FOR PARTICIPANTS IN THE STUDY

The dose used for any x-ray investigation during the study were to follow the ALARA (as low as reasonably achievable) principle. The following were agreed with the Department of Radiology.

1. The tube voltage would not exceed 65kV.
2. The x-ray images would be as well collimated as possible to the affected forearm. This will reduce primary and scattered radiation.
3. The patient had to be in as close contact as possible with the imaging equipment, so that none of the radiation is wasted by escaping from the body.
4. Lead shields would be used to reduce exposure to other parts of the body.
5. Other optimal exposure factors would be maximized in order to reduce the number of attempts at taking an image.

3.11 DATA SAFETY AND MONITORING BOARD (DSMB)

A Data Safety and Monitoring Board was formed. The members were:

1. Dr Amgbo Asare (Chairman)
2. Dr Jasper Kutor (Vice Chairman)
3. Dr Clarence Basogloyele (Secretary)
4. Dr Leslie Adam
5. Mr Dennis Sarpong

Their duties were as defined below:

1. To assist the Principal Investigator to review the final protocol for recommendation to KBTH-IRB for approval.
2. To assist the Principal Investigator in ensuring that all participants are protected and their safety ensured.
3. To help the Principal Investigator assess all the ways to protect the data collected and ensure privacy.
4. To help oversee the progression of the study by assessing data quality and timelines, recruitment and retention of participants and any other ways as may be determined by the membership.

3.11.1 Data Safety and Monitoring Board Meeting

The Board met three times: before patients were enrolled in the study, about halfway through and upon completion of patient recruitment.

3.11.2 Safety Measures

1. The time-tested Departmental protocol for management of fractures with cast, with the safety systems routinely used were strictly applied.
2. Verbal and written instructions were given to the parents and guardians of the recruited patients to enable them report adverse findings promptly. They were provided with the telephone number of the Principal Investigator to call in case of emergency. The instructions are added as Appendix 5.
3. Weekly reviews included thorough assessment for complications such as pressure ulcers, compartment syndrome, and any others
4. Radiation was kept to the minimum dose required to obtain good radiographs. Other radiation safety protocols were implemented as discussed with the Department of Radiology. Appendix 4.

3.11.3 Cessation Rules

The Board could advise termination of the study if:

1. There was reported serious adverse event(s) affecting more than 20% of the study population.
2. There was compromise of the privacy of client or the data, which breach may be irremediable.

3.11.4 Confidentiality and Objectivity

The deliberations of the Board were kept confidential as far as possible. They were expected to be objective in their assessments and to ensure utmost integrity.

CHAPTER FOUR

RESULTS AND ANALYSIS

From August, 2023 to February, 2024, 58 children, aged 4 to 13 years, with distal forearm fractures were randomized into one of two intervention groups-above elbow casting or below elbow casting. These were the children who had met the inclusion criteria. All the children recruited had successful closed reductions. Each of them was followed up for three weeks. There was none lost to follow up. The original study design had planned to recruit sixty-four (64) children with another six (6) to be added, to account for a 10% attrition rate. However, owing to the six months schedule set for data collection, and with fewer than expected numbers presenting with these fracture types, it was decided to terminate the study with 58 recruited patients.

Thirty (30) patients were randomized to the below elbow cast group and twenty-eight (28) were assigned to the above elbow cast group. The background characteristics of the recruited children is as depicted in Table 4.1.

4.1 Background Characteristics

Table 3.1: Background Characteristics of Children at the Start of the Study[1]

Demographic characteristics	Total (n=58)	Group 1 (n=28)	Group 2 (n=30)	P-value[2]
Age, years	7.64 ± 2.39	7.96 ± 2.28	7.33 ± 2.48	0.32
Sex				
Males	36 (62.1)	17 (60.7)	19 (63.3)	0.84
Females	22 (37.9)	11 (39.3)	11 (36.7)	
Educational level/Class				
Nursery	4 (6.9)	1 (3.6)	3 (10.0)	0.43
Kindergarten	12 (20.7)	4 (14.3)	8 (26.7)	
Primary	38 (65.5)	21 (75.0)	17 (56.7)	
Junior High School	4 (6.9)	2 (7.1)	2 (6.7)	
Fracture type				1.0
Transverse	48 (82.8)	23 (82.1)	25 (83.3)	
Oblique	10 (17.2)	5 (17.9)	5 (16.7)	
Fractured bone				
Radius	40 (69.0)	21 (75.0)	19 (63.3)	0.59
Ulna	3 (5.2)	1 (3.6)	2 (6.7)	
Both bones	15 (25.9)	6 (21.4)	9 (30.0)	
Weight, kg	28.10 ± 10.37	29.50 ± 11.15	26.78 ± 9.59	0.32

[1]Values are means ± SDs or n (%)

[2]Based on two-sample t-test or chi-square test (or fisher exact test due to small sample sizes within groups) for continuous and categorical variables, respectively.

Most of the enrolled children were males (62.1%) (Fig. 4.1.1). The mean age of the children was 7.64± 2.39 years. Almost two-thirds (65.5%) of the children were in Primary school (Fig. 4.1.2). They mostly presented with transverse fracture of the distal forearm (82.1%), irrespective of which bone was fractured (Fig.4.1.3), and the fractures were usually distal radius only fractures, accounting for 69.0% of all fracture patterns seen (Fig 4.1.4).

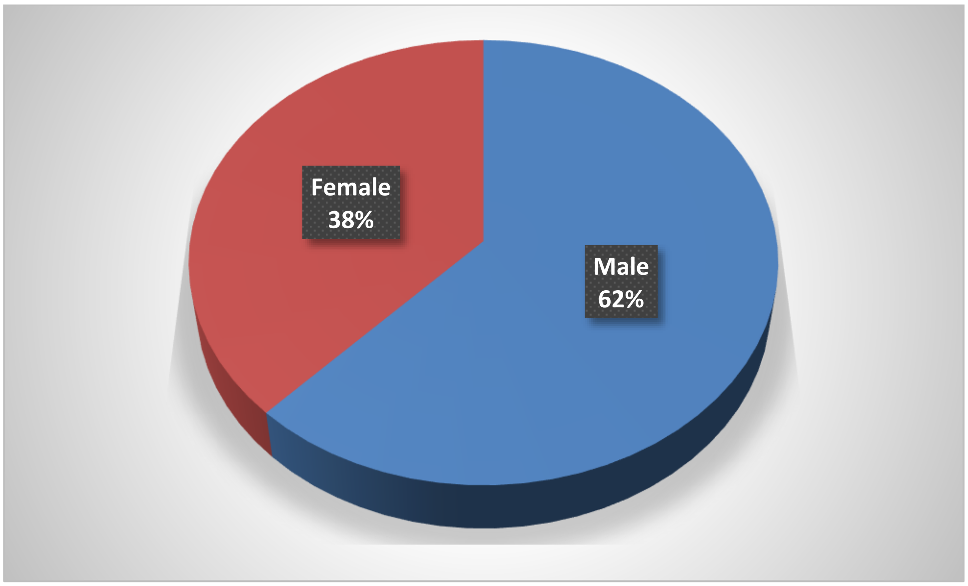

Figure 4.1.1: Distribution by sex of participants

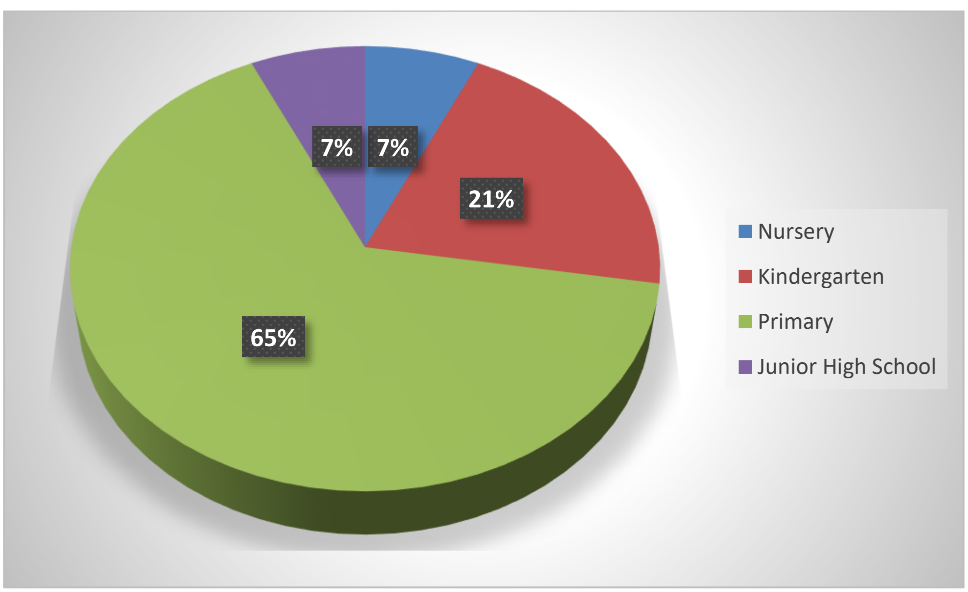

Figure 4.1.2: Distribution by class of participants

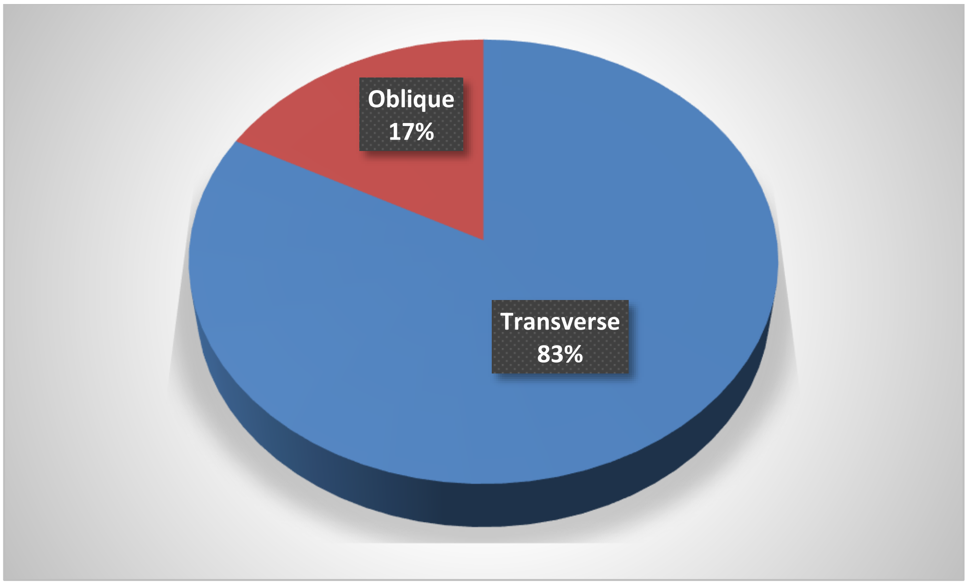

Figure 4.1.3: Distribution by fracture type

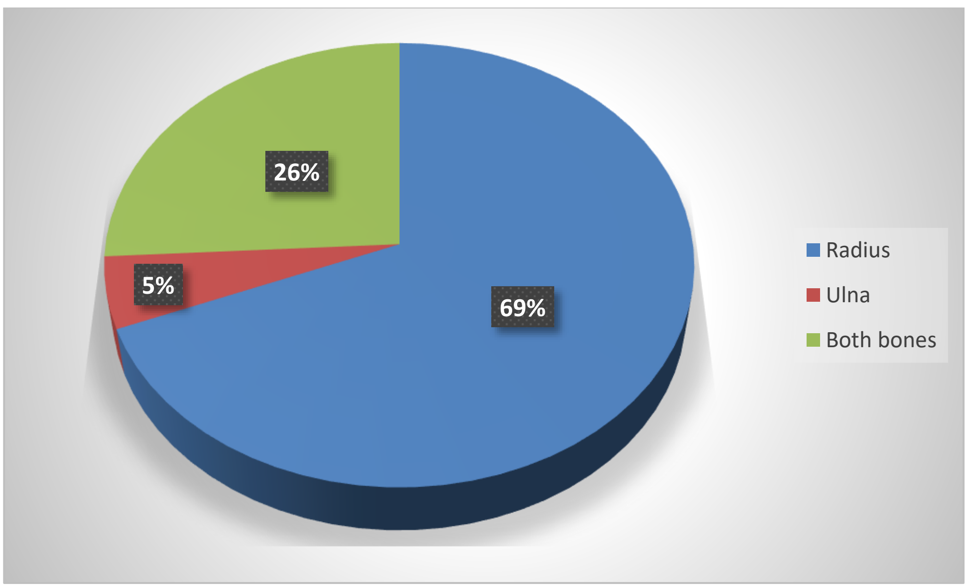

Figure 4.1.4: Distribution by Fractured Bone

There was no difference between the two groups, above and below elbow cast groups, with respect to sex (chi-square test, p-value = 0.84). The groups were also not different in terms of age (two-sample t -test, p=0.32). The assignment to the two groups also did not differ with respect to the educational lev el (Fisher exact test, p= 0.43), or the type of bone fractured- isolated radius, isolated ulna, or both bon e fractures (Fisher exact test, p= 0.59). The weight distribution also did not differ between the two gro ups (two-sample t-test, p= 0.32), neither did the type of fracture of the bone (transverse or oblique), (c hi-square test, p= 1.0).

4.2 Difference between Means

Table 4.2: Post-manipulation and cast characteristics

Variables	Total (n=58)	Below elbow cast (n=28)	Above elbow cast (n=30)	P-value[2]
Cast index	0.80 ± 0.13	0.81 ± 0.15	0.79 ± 0.12	0.54
Three-point index	0.96 ± 0.28	0.94 ± 0.27	0.97 ± 0.30	0.70
Sagittal angulation change	0.79 ± 1.56	0.76 ± 0.84	0.82 ± 2.02	0.88
Frontal angulation change	0.44 ± 0.71	0.49 ± 0.75	0.40 ± 0.69	0.64
Sagittal apposition change	0.91 ± 1.00	0.99 ± 1.11	0.83 ± 0.90	0.56
Frontal apposition change	0.94 ± 1.04	0.87 ± 0.82	1.01 ± 1.21	0.60

[1]Values are means ± SD
[2]Based on two-sample t-test

The post-manipulation fracture and cast characteristics are shown in Table 4.2. There were no signific ant differences in cast index (0.81 ± 0.15 vs. 0.79 ± 0.12, p=0.54) (Fig 4.2.1). The three-point index d id not vary between the two groups (0.94±0.27 vs 0.97±0.30, p=0.70) (Fig 4.2.2). The radiographic m arkers of displacement, being mean sagittal angulation change, mean frontal angulation change, mean sagittal apposition change, and mean frontal apposition change, were not different between the two g roups at the end of the study (p<0.05). They are pictorially depicted in the graphs below.

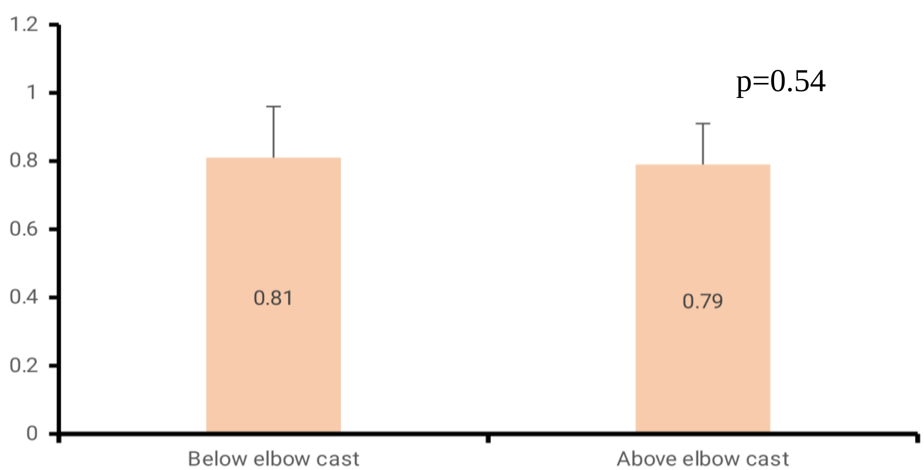

Figure 4.2.1: Cast Index by Cast group

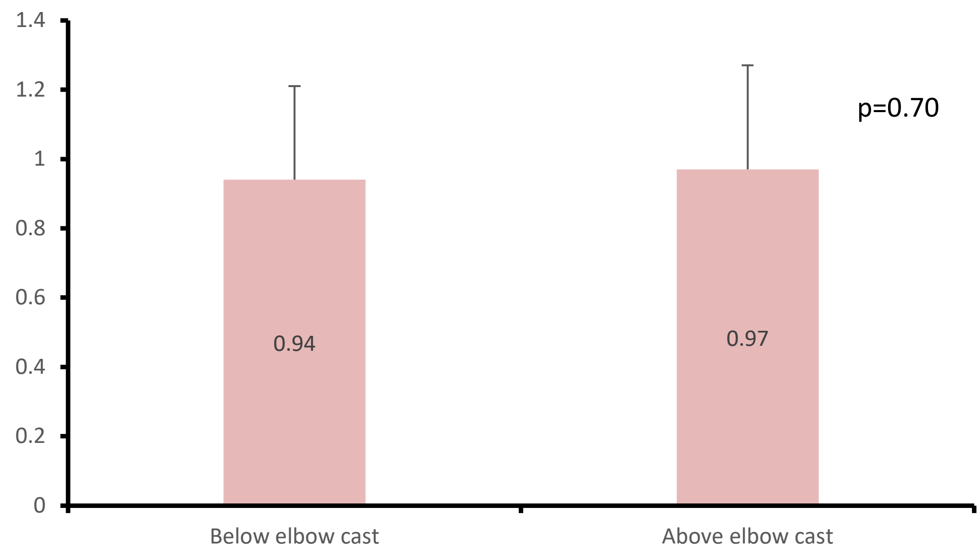

Figure 4.2.2: Three-point Index between Groups

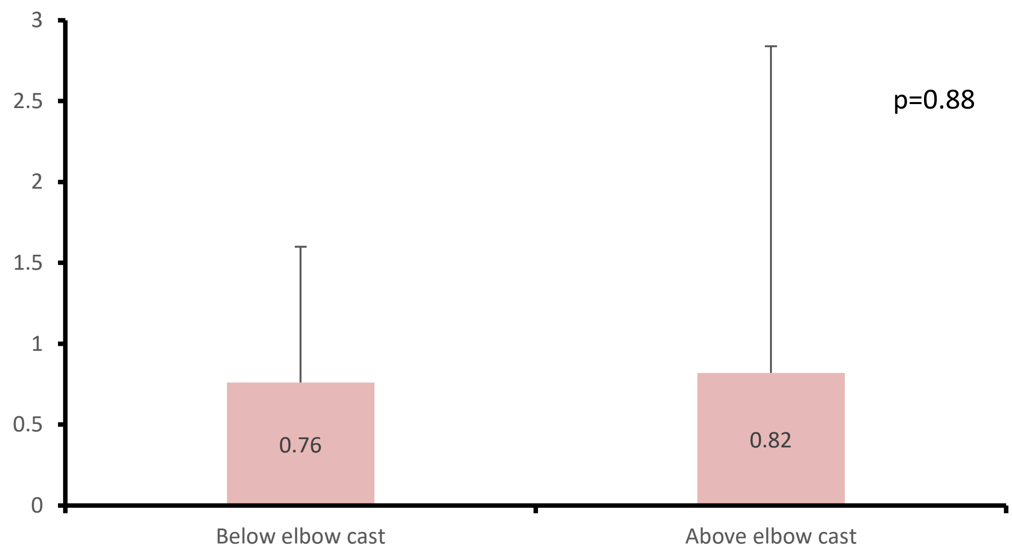

Figure 4.2.3: Change in Sagittal Angulation per cast group

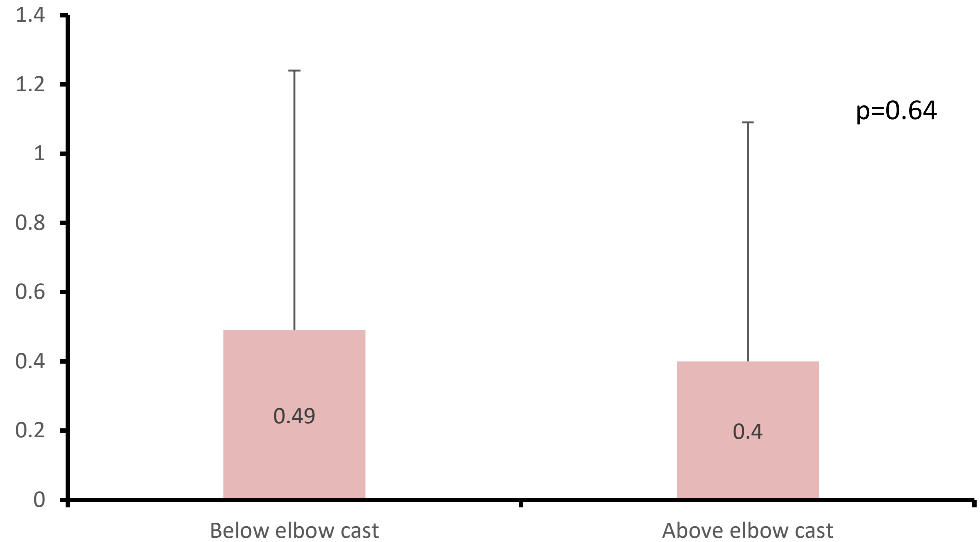

Figure 4.2.4: Change in Frontal plane angulation per cast group

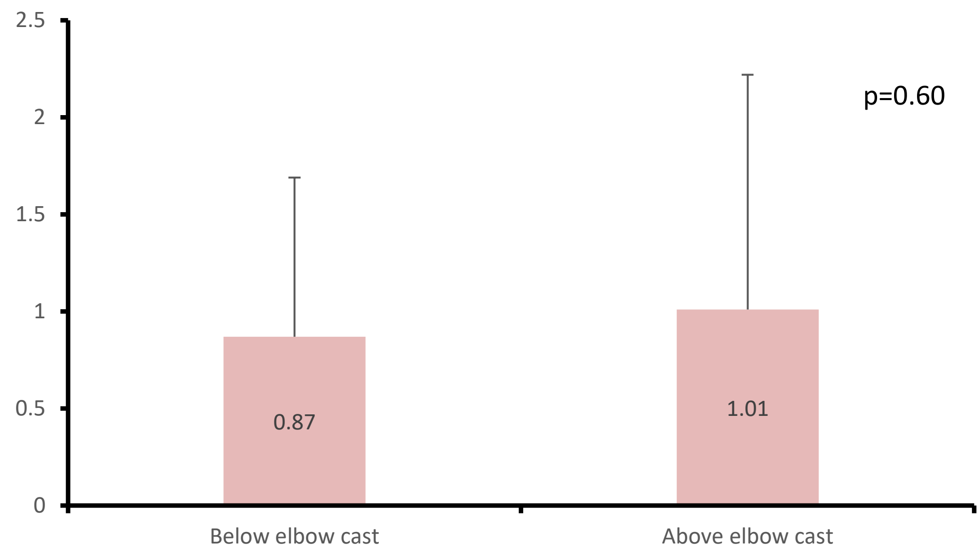

Figure 4.2.5: Change in Frontal plane apposition per cast group

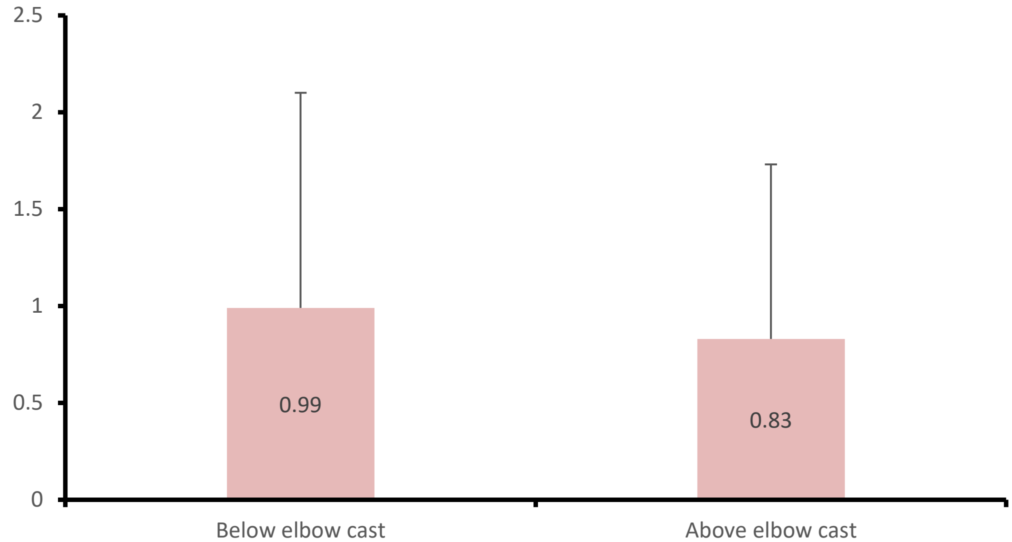

Figure 4.2.6: Change in Frontal plane angulation per cast group

Only one child met the criteria for re-manipulation, and went on to have re-manipulation. The assign ed group was the below elbow cast group. Post-manipulation, he was immobilized in a below-elbow c ast. As the only such event, analyzing it for any level of significance would not have been helpful.

4.3 Tests of Association of Predictors of Re-displacement and Re-displacement Outcomes

Stepwise logistic regression analysis was used to assess the association between the cast index, three-point index, sex, fracture type, the type of fractured bone, and the weight of the patients, with re-displacement of the fracture, viz. frontal and sagittal plane angulation and frontal and sagittal plane apposition, as the outcome measures.

At the first step of the backward regression (Table 4.3), there was an association found between any of the measures of re-displacement and the cast type, the cast index and the timepoint- week 1 and week 2.

Table 4.3.1: Association between Angulation and Apposition and Body Weight, Fracture Type, Fractured Bone, Cast Index, and Three-point Index[1].

	Sagittal angulation change, (n=58)			Frontal angulation change, (n=58)			Sagittal apposition change, (n=58)			Frontal apposition change, (n=58)		
Predictors	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*
(Intercept)	-5.92	-9.86 – -1.99	**0.003**	1.17	-0.71 – 3.04	0.222	0.67	-2.01 – 3.36	0.622	-3.37	-6.04 – -0.70	**0.014**
Group												
Below elbow cast	RG			RG			RG			RG		
Above elbow cast	1.24	-0.10 – 2.58	0.069	-0.42	-1.03 – 0.19	0.173	-0.08	-0.96 – 0.80	0.855	1.44	0.53 – 2.35	**0.002**
Timepoint												
Timepoint [T1]	RG			RG			RG			RG		
Timepoint [T2]	1.36	-1.60 – 4.32	0.367	-0.90	-2.17 – 0.38	0.168	-0.94	-2.82 – 0.93	0.322	2.04	0.03 – 4.05	**0.047**
Timepoint [T3]	-0.37	-3.33 – 2.59	0.807	-1.36	-2.64 – -0.08	**0.037**	-2.13	-4.00 – -0.25	**0.026**	0.04	-1.97 – 2.05	0.966

Fracture type												
Transverse	RG			RG			RG			RG		
Oblique	-0.03	-1.12 – 1.05	0.951	-0.00	-0.53 – 0.53	0.993	0.27	-0.49 – 1.02	0.487	0.06	-0.68 – 0.80	0.870
Fractured bone												
Radius	RG			RG			RG			RG		
Ulna	-0.78	-2.73 – 1.17	0.431	0.82	-0.13 – 1.77	0.092	-0.29	-1.64 – 1.07	0.677	-0.44	-1.77 – 0.89	0.513
Both bones	-0.79	-1.76 – 0.18	0.109	0.42	-0.05 – 0.89	0.082	0.42	-0.26 – 1.09	0.223	-0.24	-0.89 – 0.42	0.481
Cast index	6.83	0.45 – 13.21	**0.036**	0.27	-2.84 – 3.38	0.863	1.98	-2.45 – 6.41	0.379	4.25	-0.08 – 8.58	0.055
Three-point index	-0.27	-3.07 – 2.53	0.849	-0.08	-1.45 – 1.29	0.907	-0.83	-2.77 – 1.12	0.403	-0.98	-2.89 – 0.92	0.309
Weight, kg	0.03	-0.01 – 0.07	0.150	-0.00	-0.02 – 0.02	0.880	0.02	-0.01 – 0.04	0.281	0.02	-0.00 – 0.05	0.084

Group × Timepoint [T2]	-1.68	-3.53 – 0.17	0.076	0.43	-0.37 – 1.23	0.289	-0.13	-1.30 – 1.04	0.829	-2.00	-3.26 – -0.74	**0.002**
Group × Timepoint [T3]	-0.88	-2.74 – 0.97	0.348	0.40	-0.40 – 1.20	0.327	0.16	-1.01 – 1.34	0.782	-1.22	-2.48 – 0.04	0.057
Random Effects												
σ^2	6.38			1.19			2.55			2.94		
τ_{00}	0.00 $_{ID}$			0.11 $_{ID}$			0.17 $_{ID}$			0.00 $_{ID}$		
ICC				0.08			0.06			0.00		
N	58 $_{ID}$			58 $_{ID}$			58 $_{ID}$			58 $_{ID}$		
Observations	174			174			174			174		
Marginal R^2 / Conditional R^2	0.191 / NA			0.118 / 0.193			0.206 / 0.257			0.241 / 0.241		

[1]P-values are based on mixed effects model. Possible convergence or overestimation of model due to sample size or number of predictors

RG: reference group

There was an association between the above-elbow group and translation in the frontal plane (frontal apposition change) at the first regression modeling [β (95% confidence interval, CI): 1.44(0.53-2.35), $p=0.002$]. This association was still evident at the third regression analysis (Table 5), when the weight, fracture type and three-point index were excluded. [β (95% CI): 1.27(0.38-2.16) $p=0.005$]. This means that the above-elbow cast performed worse statistically than a below-elbow cast with respect to frontal plane translation. The sagittal plane angulation and translation and frontal plane angulation showed no such association.

There was also found a significant positive association between sagittal angulation change [β (95% Confidence Interval): 6.83(0.45-13.21), $p=0.036$], and cast index after adjustment for three-point index, fracture type, fractured bone, body weight, and variability across intervention groups and measurement time points (Table 3). After accounting for the weight in the second regression step, a positive association was also found between the cast index and frontal apposition change [β (95% Confidence Interval): 4.69 (0.30-9.08), $p= 0.036$] (Table 4). (Refer to Figures 11 and 12). However, there were no significant associations between frontal angulation change or sagittal apposition change and cast index. There was no association found between re-displacement and the three-point index ($p>0.05$).

There was no recorded displacement of the fractures in the third week of immobilization. The displac ement of the fracture was likeliest between the first and second weeks. This was noted with the front al angulation [β(95% Confidence Interval): -1.36(-2.62- -0.08), $p=0.037$] and the sagittal appo sition [β(95% Confidence Interval): -2.13(-4.00－-0.25), $p=0.026$]. It was also noted that the frontal p lane translation in the above elbow group had a strong association with the first week timeline (p= 0.0 02). This is shown in Tables 4.3.1-4.3.3.

Table 4.3.2: Association between Angulation and Apposition and Fracture Type, Fractured Bone, Cast Index, and Three-point Index[1].

	Sagittal angulation change, (n=58)			**Frontal angulation change, (n=58)**			**Sagittal apposition change, (n=58)**			**Frontal apposition change, (n=58)**		
Predictors	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*
(Intercept)	-5.59	-9.51 – -1.67	**0.005**	1.15	-0.70 – 3.00	0.222	0.85	-1.83 – 3.52	0.533	-3.10	-5.80 – -0.41	**0.024**
Group												
Below elbow cast	RG			RG			RG			RG		
Above elbow cast	1.19	-0.16 – 2.53	0.083	-0.42	-1.02 – 0.19	0.173	-0.11	-0.99 – 0.77	0.805	1.39	0.48 – 2.31	**0.003**
Timepoint												
Timepoint [T1]	RG			RG			RG			RG		
Timepoint [T2]	1.36	-1.61 – 4.33	0.368	-0.90	-2.17 – 0.38	0.168	-0.94	-2.82 – 0.93	0.322	2.04	0.03 – 4.05	**0.047**
Timepoint [T3]	-0.37	-3.34 – 2.60	0.808	-1.36	-2.64 – -0.08	**0.037**	-2.13	-4.00 – -0.25	**0.026**	0.04	-1.97 – 2.05	0.966
Fracture type												
Transverse	RG			RG			RG			RG		
Oblique	0.10	-0.98 – 1.17	0.860	-0.01	-0.53 – 0.51	0.973	0.33	-0.41 – 1.08	0.378	0.17	-0.57 – 0.91	0.657
Fractured bone												
Radius	RG			RG			RG			RG		
Ulna	-1.08	-3.00 – 0.83	0.266	0.83	-0.09 – 1.76	0.076	-0.44	-1.77 – 0.88	0.510	-0.69	-2.01 – 0.64	0.306
Both bones	-0.90	-1.86 – 0.06	0.067	0.42	-0.04 – 0.89	0.072	0.36	-0.30 – 1.03	0.285	-0.32	-0.99 – 0.34	0.339
Cast index	7.37	1.01 – 13.72	**0.023**	0.25	-2.81 – 3.31	0.874	2.26	-2.15 – 6.66	0.314	4.69	0.30 – 9.08	**0.036**
Three-point index	-0.09	-2.89 – 2.72	0.952	-0.09	-1.44 – 1.26	0.895	-0.73	-2.67 – 1.21	0.458	-0.83	-2.77 – 1.10	0.395

Group × Timepoint [T2]	-1.68	-3.54 – 0.18	0.076	0.43	-0.37 – 1.23	0.289	-0.13	-1.30 – 1.04	0.829	-2.00	-3.26 – -0.74	**0.002**
Group × Timepoint [T3]	-0.88	-2.74 – 0.98	0.350	0.40	-0.40 – 1.20	0.327	0.16	-1.01 – 1.34	0.782	-1.22	-2.48 – 0.04	0.057
Random Effects												
σ^2	6.42			1.19			2.55			2.94		
τ_{00}	0.00 $_{ID}$			0.10 $_{ID}$			0.18 $_{ID}$			0.04 $_{ID}$		
ICC				0.08			0.06			0.01		
N	58 $_{ID}$			58 $_{ID}$			58 $_{ID}$			58 $_{ID}$		
Observations	174			174			174			174		
Marginal R^2 / Conditional R^2	0.182 / NA			0.119 / 0.188			0.201 / 0.253			0.228 / 0.239		

[1]P-values are based on mixed effects model. Possible convergence or overestimation of model due to sample size or number of predictors
RG: reference group

After the third backward regression analysis, we found an association between both bone fracture and isolated ulna fracture with frontal angulation displacement (refer to table 5). This was after adjusting for three-point index, fracture type, fractured bone, body weight, and variability across intervention gr oups and measured time points.

Table 4.3.3: Association between Angulation and Apposition and Fractured Bone and Cast Index[1].

	Sagittal angulation change, (n=58)			**Frontal angulation change, (n=58)**			**Sagittal apposition change, (n=58)**			**Frontal apposition change, (n=58)**		
Predictors	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*
(Intercept)	-5.48	-8.75 – -2.21	**0.001**	1.27	0.34 – 2.20	**0.008**	2.10	0.74 – 3.47	**0.003**	-2.16	-4.32 – -0.00	**0.050**
Group												
Below elbow cast	RG			RG			RG			RG		
Above elbow cast	1.18	-0.14 – 2.49	0.079	-0.43	-1.01 – 0.16	0.150	-0.21	-1.06 – 0.65	0.634	1.27	0.38 – 2.16	**0.005**
Timepoint												
Timepoint [T1]	RG			RG			RG			RG		
Timepoint [T2]	1.36	-1.59 – 4.31	0.365	-0.90	-2.17 – 0.38	0.168	-0.94	-2.82 – 0.93	0.322	2.04	0.03 – 4.05	**0.047**
Timepoint [T3]	-0.37	-3.32 – 2.59	0.807	-1.36	-2.64 – -0.09	**0.037**	-2.13	-4.00 – -0.26	**0.026**	0.04	-1.97 – 2.05	0.966
Fractured bone												
Radius	RG			RG			RG			RG		
Ulna	-1.02	-2.77 – 0.73	0.253	0.85	0.04 – 1.66	**0.041**	-0.09	-1.27 – 1.10	0.884			
Both bones	-0.89	-1.81 – 0.04	0.061	0.44	0.03 – 0.85	**0.037**	0.50	-0.10 – 1.10	0.103			
Cast index	7.16	4.10 – 10.22	**<0.001**							2.63	0.68 – 4.59	**0.009**
Group × Timepoint [T2]	-1.68	-3.53 – 0.17	0.075	0.43	-0.37 – 1.23	0.289	-0.13	-1.30 – 1.04	0.829	-2.00	-3.26 – -0.74	**0.002**
Group × Timepoint [T3]	-0.88	-2.73 – 0.96	0.347	0.40	-0.40 – 1.20	0.327	0.16	-1.01 – 1.34	0.782	-1.22	-2.48 – 0.04	0.057
Random Effects												
σ^2	6.34			1.19			2.55			2.94		

τ_{00}	0.00_{ID}	0.07_{ID}	0.15_{ID}	0.00_{ID}
ICC		0.06	0.06	0.00
N	58_{ID}	58_{ID}	58_{ID}	58_{ID}
Observations	174	174	174	174
Marginal R^2 / Conditional R^2	0.183 / NA	0.121 / 0.172	0.196 / 0.241	0.224 / 0.224

RG: reference group

[1]P-values are based on mixed effects model. Possible convergence or overestimation of model due to sample size or number of predictors

The study defined an oblique fracture as one whose fracture line made an angle of 10° with a line perpendicular to the long axis of the broken bone. For both bone fractures, we used only the radial fracture inclination. The limit of 10° was chosen because it had been found in a prior study to predict re-displacement[21]. We subjected all oblique fractures to both multivariate analysis and found no association with fracture re-displacement. Thus, no further subgroup analysis was done according to degree of obliquity. This was also because the numbers with defined oblique fracture was too small for further meaningful analysis.

The initial angulation was tested for any association with loss of reduction. The results of the multivariate analysis showed no association between the initial frontal or sagittal plane angulation and the loss of reduction, be it angular or translation in any of the planes (Tables 4.3.4 and 4.3.5). We however ignored the association between the initial and post-manipulation sagittal and frontal plane angulation. This is because the post-manipulation angulation in particular is a derivative of the initial angulation in that plane, and so looking for any association is meaningless. Instead, we chose to test if there being angulation in any plane was a predictor of angulation in the other plane.

Figures 4.3.1 and 4.3.2 are scatter plots showing a positive association between the cast index and the change in sagittal plane angulation and the cast index and the change in frontal plane apposition. Figures 4.3.3 and 4.3.4 depict a lack of association between initial fracture angulation and post-manipulation angulation.

Table 4.3.4: Association between Angulation and Apposition Change and Frontal Angulation[1].

	Frontal apposition change, (n=58)			Sagittal apposition change, (n=58)			Frontal angulation change, (n=58)			Sagittal Angulation change, (n=58)		
Predictors	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*
(Intercept)	0.39	-1.52 – 2.30	0.688	2.10	0.28 – 3.92	**0.024**	1.57	0.11 – 3.03	**0.035**	1.60	0.41 – 2.79	**0.009**
Group												
Below elbow cast	RG			RG			RG			RG		
Above elbow cast	1.21	0.10 – 2.32	**0.033**	-0.17	-1.22 – 0.89	0.757	-0.37	-1.10 – 0.36	0.315	-0.16	-0.86 – 0.53	0.646
Timepoint												
Timepoint [T1]	RG			RG			RG			RG		
Timepoint [T2]	1.75	-0.71 – 4.21	0.161	-0.90	-3.22 – 1.41	0.441	-0.79	-2.31 – 0.74	0.311	0.17	-1.23 – 1.56	0.813
Frontal Angulation	-0.03	-0.08 – 0.03	0.316	0.01	-0.05 – 0.06	0.839	-0.00	-0.02 – 0.01	0.584	-0.01	-0.05 – 0.02	0.485
Group × Timepoint [T2]	-2.00	-3.50 – -0.50	**0.010**	-0.11	-1.53 – 1.31	0.875	0.44	-0.49 – 1.36	0.349	-0.61	-1.46 – 0.24	0.159
Random Effects												
σ^2	4.13			3.67			1.58			1.32		
τ_{00}	0.43_{ID}			0.46_{ID}			0.39_{ID}			0.46_{ID}		
ICC	0.09			0.11			0.20			0.26		
N	58_{ID}			58_{ID}			58_{ID}			58_{ID}		
Observations	115			115			116			115		
Marginal R^2 / Conditional R^2	0.108 / 0.192			0.075 / 0.178			0.019 / 0.213			0.093 / 0.328		

RG: reference group

[1]P-values are based on mixed effects model. Possible convergence or overestimation of model due to sample size or number of predictors

Table 4.3.5: Association between Angulation and Apposition Change and Sagittal Angulation[1].

	Frontal apposition change, (n=58)			Sagittal apposition change, (n=58)			Frontal angulation change, (n=58)			Sagittal Angulation change, (n=58)		
Predictors	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*	*Estimates*	*CI*	*p*
(Intercept)	-0.77	-2.79 – 1.25	0.452	1.39	-0.52 – 3.31	0.151	1.74	0.41 – 3.07	**0.011**	0.77	-0.47 – 2.02	0.221
Group												
Below elbow cast	RG			RG			RG			RG		
Above elbow cast	1.25	0.15 – 2.36	**0.027**	-0.13	-1.18 – 0.91	0.804	-0.38	-1.11 – 0.35	0.301	-0.13	-0.81 – 0.56	0.710
Timepoint												
Timepoint [T1]	RG			RG			RG			RG		
Timepoint [T2]	2.75	0.21 – 5.28	**0.034**	-0.27	-2.66 – 2.13	0.826	-1.28	-2.85 – 0.29	0.110	0.89	-0.53 – 2.31	0.217
Sagittal Angulation	0.05	-0.01 – 0.12	0.109	0.05	-0.01 – 0.11	0.103	-0.03	-0.07 – 0.02	0.209	0.05	0.00 – 0.09	**0.029**
Group × Timepoint [T2]	-2.09	-3.58 – -0.59	**0.007**	-0.20	-1.62 – 1.21	0.775	0.50	-0.43 – 1.42	0.289	-0.69	-1.52 – 0.14	0.102
Random Effects												
σ^2	4.06			3.63			1.54			1.25		
τ_{00}	0.43 $_{ID}$			0.40 $_{ID}$			0.43 $_{ID}$			0.48 $_{ID}$		
ICC	0.10			0.10			0.22			0.28		
N	58 $_{ID}$			58 $_{ID}$			58 $_{ID}$			58 $_{ID}$		
Observations	115			115			115			115		
Marginal R^2 / Conditional R^2	0.120 / 0.204			0.097 / 0.187			0.029 / 0.240			0.127 / 0.369		

RG: reference group

[1]P-values are based on mixed effects model. Possible convergence or overestimation of model due to sample size or number of predictors

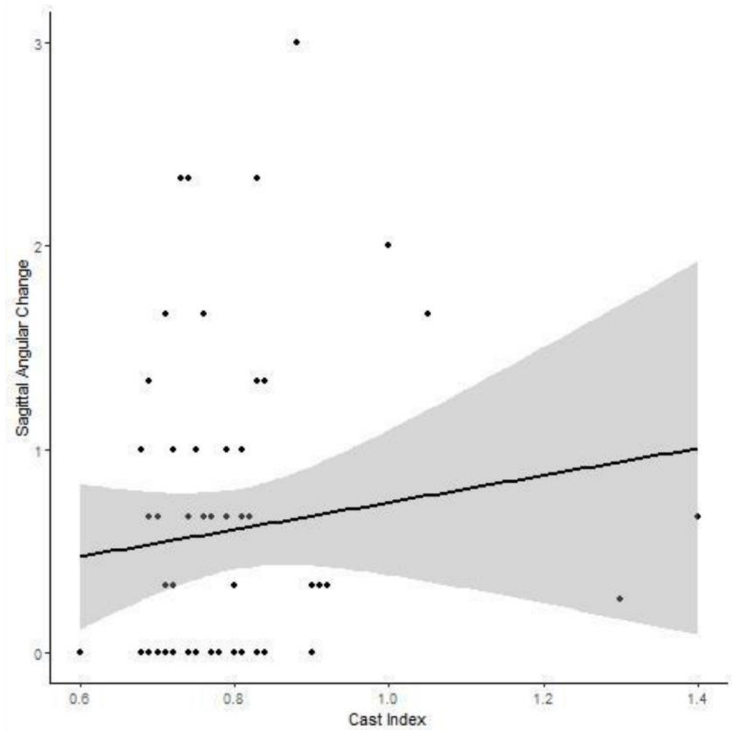

Figure 4.3.1: Association between Cast index and Sagittal Plane Angulation Change

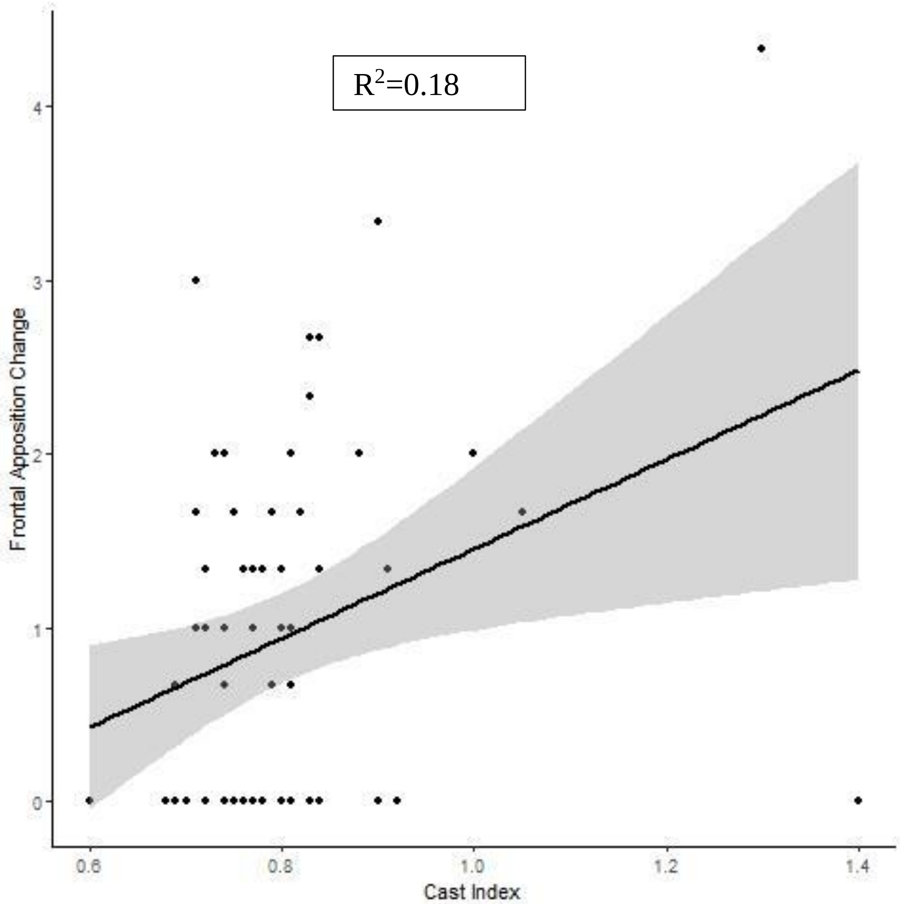

Figure 4.3.2: Association between Cast Index and Frontal Apposition Change

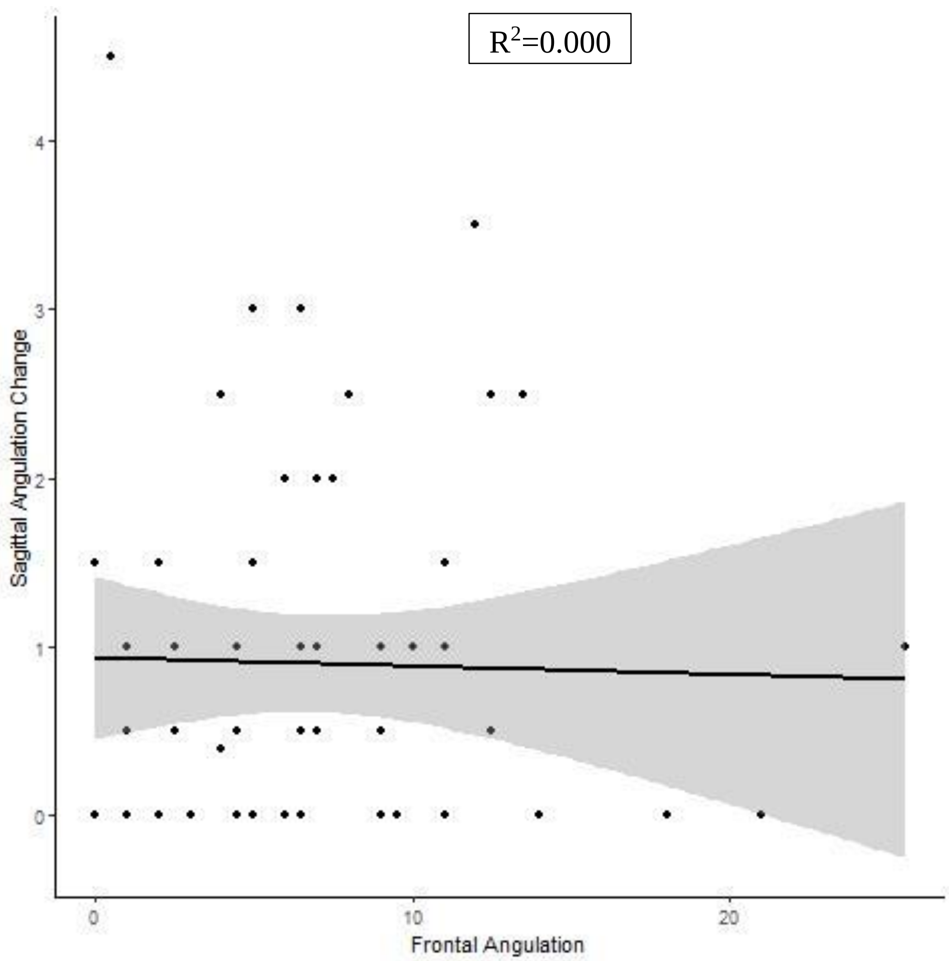

Figure 4.3.3: Association between frontal angulation and Sagittal Angulation Change

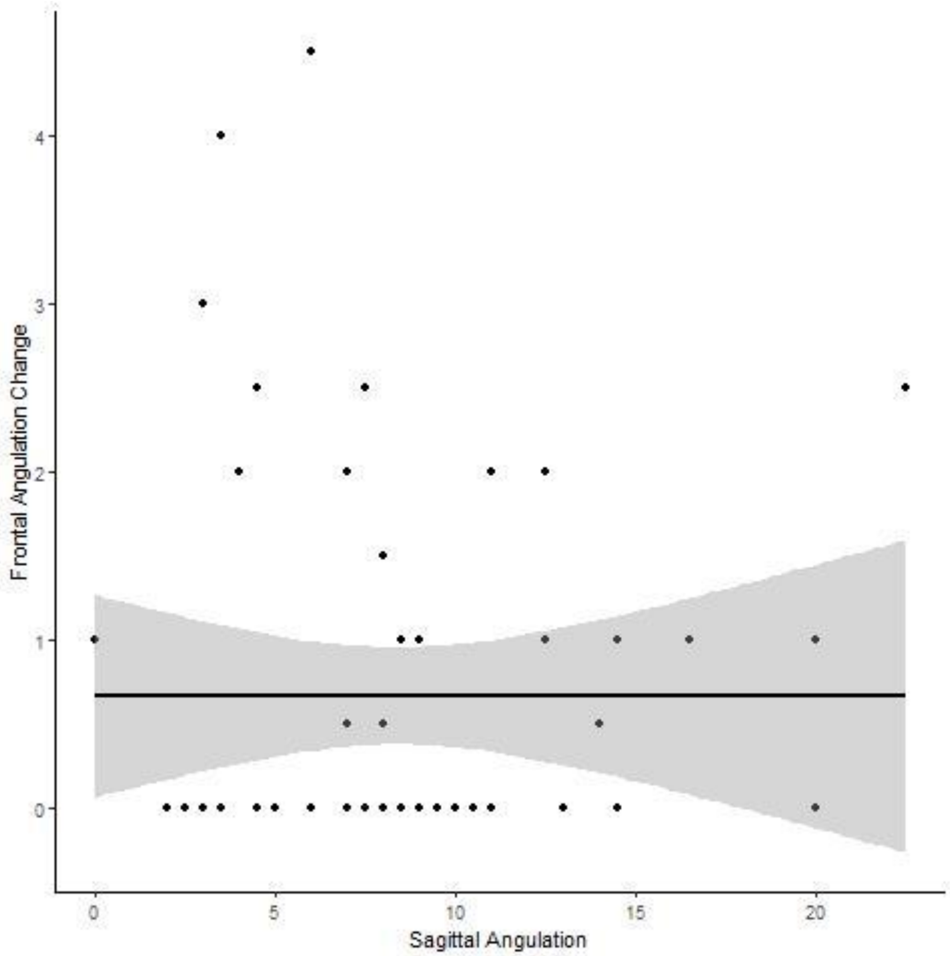

Figure 4.3.4: Association between sagittal angulation and frontal angulation change

CHAPTER FIVE

DISCUSSION

What are the factors that predict re-displacement of displaced distal forearm fractures in children in our institution? The study was designed to collect data on as many of the known variables as possible, and these will be discussed. The focus, though, will be to answer the objectives of the study. These objectives are again highlighted below:

1. To measure and compare the degree of loss of reduction in the above elbow versus below elbow cast among children between 4 and 13 years.
2. To assess the factors that predict re-displacement of distal forearm fractures among children between 4 and 13 years old.
3. To ascertain the likely period of fracture displacement, post-manipulation of distal forearm fractures among children between 4 and 13 years

The study design and analysis were novel, in that it assessed each parameter of predictors of displacement against the mean displacement in both sagittal and frontal planes, i.e. angulation and apposition. Any displacement in either plane- translation or angulation, was recorded as a significant event. The absolute value of the translation or angulation was used in the calculation of the averages because whether the displacement worsened or fortuitously ‘improved’ post-reduction, it was considered as an inability of the cast to maintain the index reduction and so a re-displacement event. Then each parameter was taken and the sum of the absolute figures over the three-week period was done, with the first backslab as the baseline. Thus, for example, the frontal apposition change was calculated as the sum of the change per week over the three-week period. The average was then taken and used as the outcome measure.

BASELINE CHARACTERISTICS OF PARTICIPANTS

5.1.1 Sex

The study had almost twice the number of males as females. Agbley et al[6] found about thrice as many boys as affected as girls. Baidoo et al[1] found twice as many boys as girls. Most other studies in other climes have also found more boys to be affected than girls[3,38,40]. This has been explained by the fact that boys are likely to be engaged in higher-risk activities than girls, even though with the participation of more girls in sporting activities, the epidemiology might be changing[2].

5.1.2 Weight (Body Mass Index) vs Re-displacement

The study was to also assess the body mass index as a predictor of re-displacement. In previous studies, obesity has been found to be a significant predictor of loss of reduction or re-displacement[99,100]. Indeed, Liu et al[100] found that obese children were twice as likely as non-obese children to re-displace. This study, however, could not assess the association between obesity and the risk of re-displacement because there was loss of some data with respect to the height, which made it difficult to obtain the body mass index for all the children. There was an attempt at looking at any association between weight (generic) and fracture re-displacement. Even though none was found, this analysis suffers from the inability to standardize the weight with respect to the height. This was a significant limitation of the study.

5.1.3 Age

The prepubertal age group in most epidemiologic studies have been found to have the highest incidence and the highest likelihood of distal forearm fractures for reasons explained in the literature review[2,3,38,40]. However, in studies done in the country, the average age of children sustaining distal forearm fractures was less than 9 years[1,6].

In this study, the average age of participants was 7.64±2.39 years, which agrees with the previous studies. Most of these children were of primary school age (65.5%).

It can be inferred then that children in this part of the world tend to have these fractures earlier than in the temperate areas, about three years earlier on average. It might be due to differences in climate and nutrition, which might influence vitamin D levels and the strength of bone at different ages[38]. This might need to be studied in detail going forward.

5.1.4 Type of Bone Fractured and Fracture Pattern

There are few reported incidences of the type of bone fractured, in displaced fractures[17,78]. The commonest distal forearm fracture type is a greenstick fracture[4]. Bohm et al[17] reported two-thirds of their fractures were fractures of both radius and ulna; 32% were isolated distal radius fractures, with none being ulna fractures.

Another review found half of all children presenting with distal forearm fractures being of both radius and ulna[78]. We found in this study, about 70% of participants had distal radius fracture, whereas just about a quarter had both radius and ulna fracture. We cannot find a reasonable explanation for the variation, except perhaps there may have been overcounting of the isolated radius fractures, if a concomitant undisplaced or greenstick distal ulna fracture was missed. It has been reported that there may be interobserver discordance in reading and reporting in classification of distal forearm fractures in children, especially when those reviewing the radiographs are not the most experienced[52].

Agbley et al[6], found in their study, more than 90% of the fractures being transverse, with only about 8% being oblique. This study made a similar finding of 83% being transverse fractures and 17% being oblique fractures.

5.2 PREDICTORS OF FRACTURE RE-DISPLACEMENT

5.2.1 Below elbow cast vs above elbow cast

Comparing the two cast types with respect to re-displacement of fractures, the below elbow casts performed as well as the above elbow casts. There was only one case of significant loss of reduction requiring re-manipulation, and he had had a below elbow cast. An analysis of this event was not possible because it was the sole event. However, we also found that there was a statistically significant translation in the frontal plane, with the above elbow group. It's important to stress that the analysis focused on all displacement, as opposed to displacement beyond a certain threshold, because it was felt that the role of the cast would be to keep the reduction. Thus, the displacement noted here might not necessarily be clinically significant, but it was statistically significant displacement.

Hafeez et al[101], found the rate of re-displacement with the below-elbow casts was lower than the above-elbow cast (70.4% vs 52.2%). Most other authors have found them to be at par, in terms of risk of displacement[17,21,23,24,101].

When Bohm[17] and Webb[24] conducted the first trial comparing below- and above-elbow casts, the accepted teaching was above-elbow casts for immobilization of distal forearm fractures, though many surgeons used below-elbow casts in the management of these fractures. Those studies in 2006 clearly should the below-elbow cast to be non-inferior to the above-elbow casts, with lower risk of fracture disease[13]. Since then, others such as Paneru et al.[21] and Rahman et al.[101], among others have also demonstrated the non-inferiority of the below-elbow cast compared to the above-elbow cast. Colaris et al.[23] assessed the two methods of immobilization, with respect to both bone fractures, and found no difference in outcomes. The three systematic reviews which have pooled the data on the subject have all concluded there is non-inferiority of the below-elbow cast[22,25,26]. This study, even with the limitation of the number of participants, also shows that below-elbow cast are not inferior to above-elbow cast when re-displacement is the outcome measure. However, if anything, there was statistically significant re-displacement in one of the planes of displacement with the above-elbow cast.

5.2.2 Does Cast Mold Have an Association with Fracture Re-Displacement?

The cast index, three-point index, gap index, padding index and Canterbury index have all been used as markers of cast mold. The most commonly used is the cast index, first described by Chess et al.[87]. He reported a strong association between the cast index and fracture re-displacement. The three-point index, however, has been a recent introduction, built on the concept of three-point fixation of fractures[78]. The study tested the association between the cast index or the three-point index on one hand, and fracture re-displacement on the other. There was an association between sagittal plane angulation and frontal plane apposition re-displacement and the cast index. Bohm et al.[17], also reported a relationship between the cast index and the risk of re-displacement. They found that cast index greater than 0.8 was an important risk factor for re-displacement, in their study. The average cast index in this study was 0.80±0.13, and those who had a higher cast index had more significant re-displacement. Chess[87] had suggested a cut off cast index of 0.7. Considering the fact that other authors[6,17] had not found the 0.7 to be clinically significant, it may be that a slightly higher threshold of 0.80 may be acceptable[78]. This is good middle ground between clinically significant cast mold and adequate padding to prevent pressure ulcers and reduce the risk of compartment syndrome.

The study found no association between the three-point index and fracture re-displacement, both on stepwise multivariate analysis and univariate analysis. This was quite surprising as multiple studies had found a strong association between the three-point index and fracture re-displacement[78,84]. The unusual result may be due to the fact that the average three-point index in our study was 0.96 ± 0.28, which was far higher than the recommended 0.80 by Alemdaroglu et al.[78], and so it may not have been a good discriminant.

5.2.3 Fracture obliquity and fracture re-displacement

There was no relationship found between the fracture obliquity and the risk of re-displacement. Alemdaroglu[78] found the fracture obliquity to be the second most important predictor of the risk of displacement. Our study only had nine participants who met the criterion for obliquity. This may have been too small a number to see any effect for.

5.2.4 Initial fracture displacement

We used the initial angulation- frontal and sagittal, as surrogate markers of initial displacement, and looked for any association between that and frontal and sagittal plane angulation or apposition. We found no such association, even with univariate analysis. Others[74,86] have found this to be the most important factor in loss of reduction. This, as has been explained, may be due to the instability wrought by the disrupted periosteal hinge in severely displaced fractures.

5.2.5 Fractured bone

We found after stepwise regression an association between frontal angulation and both bones being fractured, or with isolated ulna fracture. The finding of fracture of both bones being a risk factor for re-displacement has been noted in other studies[17,76,80]. The explanation, as has been given previously, has to do with the loss of splintage from an intact radius or ulna in the case of isolated ulna or radius fracture. What has not been reported on is an isolated ulna fracture being a risk factor for displacement. It may be due to the very low numbers of isolated ulna fractures seen in other studies[17,74].

5.3 TIME OF RE-DISPLACEMENT AND NEED FOR RADIOGRAPHS

The study did not find statistically significant displacement after two weeks of fracture immobilization. Most of the displacement happened between the first and second weeks, perhaps attributable to the conversion from backslab to full or cylindrical cast. During the process, some of the fractures were re-manipulated even though they didn't meet the threshold for re-manipulation, and so there were not reported as adverse events. Some other fractures may have lost reduction as the initial oedema continued to improve, with the result that the cast may have become loose around the smaller limb. The cast mold, as discussed above, may also be a factor. From other studies, fracture displacement after 14 days is unusual[94,102]. The explanation for that is the formation of bridging soft callus, which keeps the fracture from further displacement[15].

Another important inference to make from the result is that if fractures tend to not displace after week two, then radiographs after week two to assess fracture displacement may be unnecessary. Also, because children in the study population still had some growth left, even if there is residual deformity after re-displacement, they tend to remodel[69] and so radiographs may only be needed for follow-up in the first two weeks, when most displacement might occur. This will serve to avert the repeated exposure of the children to unnecessary radiation and will also cut down on cost[32,49,98].

5.4 DOES REDUCTION OF DISTAL FOREARM FRACTURES REALLY MATTER?

The question as to whether fractures need to be reduced and maintained has spawned a fair amount of literature recently. This is especially important for children with many years of growth left (<10 years) with metaphyseal fractures of the distal forearm[103,104]. Fractures of the distal forearm have remarkable remodeling potential. It has been shown that these fractures irrespective of the amount of displacement remodel. Considering that the amount of remodeling and how quickly it takes place is proportional to the initial degree of displacement (remodeling speed/ velocity), significantly displaced fractures will remodel at a quicker rate to eventually remodel out deformities completely, over about the same length of time as those with less displacement[70–72]. This means that the role of the cast might be purely for splinting with the resultant pain relief it gives[104]. Thus, it might be worthwhile questioning the utility of subjecting children to anaesthesia and manipulation for the treatment of these fractures[103].

5.5 LIMITATIONS OF THE STUDY

- The study was unable to recruit the expected number because of constraints of time. This reduced the power of the study and the ability to draw strong conclusions.
- Even though the study was able to prove statistically significant levels of re-displacement per some of the predictors of displacement, it is unclear whether such displacement may be clinically significant.
- The study was done in a Teaching Hospital, which may have a different patient profile and expertise to other facilities which also may see such cases, and so the ability to generalize the result may be limited.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The study found, like other studies, that there was no difference between using an above-elbow cast or a below-elbow cast in the management of distal forearm fracture, when the outcome measure is risk of re-displacement.

It was also determined that the cast index is an important predictor of re-displacement, if the threshold is set at 0.80.

Last but not least, distal forearm fractures in children are unlikely to re-displace after two weeks, and so radiographic follow-up for displacement after the second week is unnecessary.

RECOMMENDATIONS

1. Distal forearm fractures may be immobilized in either an above-elbow or below-elbow cast after manipulation, with identical outcomes. Thus, in clinical practice, the choice of which cast a treating surgeon should apply will depend on such factors as cost, safety and early return to school or play. The study may thus form the basis, with other studies, to develop a protocol for the management of distal forearm fractures in children.
2. There must be further training of all practitioners to help improve on the application of forearm casts, especially with respect to cast mold. This study had average cast and three-point indices higher than had been seen in other published work.
3. A larger, multicenter study may help to clarify the importance of some of the other predictors of re-displacement, such as three-point index, obliquity of fracture and quality of reduction, better.
4. A large study may be done to assess the importance of fracture reduction in distal forearm fractures in children, especially those with still large remodeling capacity, with the cost-benefit analysis.

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APPENDICES

APPENDIX 1

PATIENT INFORMATION SHEET

TITLE OF RESEARCH: Comparative Study of Re-Displacement of Distal Forearm Fractures in Children Immobilized in Above-Elbow Cast Vs Below-Elbow Cast at Korle-Bu Teaching Hospital.

RESEARCH SITE: Department of Trauma and Orthopaedic surgery, Korle-Bu Teaching Hospital.

PRINCIPAL INVESTIGATOR: Dr Prince George Larvie

Telephone Number: (+233) 0502402863

This information sheet is to provide as much information about this research, as will enable you make a decision as to participation. You will be giving consent as to participation on behalf of your child, who is legally considered to be a minor. It explains the selection criteria, the aim and objectives of the study, and what will be required of you, a prospective participant. This will be explained to you in detail, in a language you understand. Kindly ask any questions you have. You will be able to keep a copy of the signed consent form. Also note that you are at liberty to opt out of the study at any point, and that decision will not affect the quality of treatment provided to you.

INTRODUCTION

This study is to compare the risk of distal forearm fracture displacement in an above elbow cast and below elbow cast. Traditionally, distal forearm fractures were reduced in held in above-elbow casts. Recently, some researchers have found that below elbow casts are as effective.

PURPOSE OF THE STUDY

The study is to compare the likelihood of the fracture re-displacing in the cast types. It will also assess whether other factors may contribute to the fracture displacement in the cast, such as the mold of the cast and the type of fracture suffered. It will also be used to follow-up on the minimum period after which displacement is unlikely.

PROCEDURE

You will be asked or assisted to fill out an evaluation form, which will capture:

- Demographic data of your child
- The fracture types

The researcher will take some pieces of information from the x-rays your child will make both before the cast is applied and after its application and then weekly for 3 weeks.

Once you give consent for your child to participate, he/she will be randomly assigned to either have an above elbow cast or a below elbow cast. This will be done with computer generated random numbers. The Principal Investigator or a collaborator will not know beforehand which arm of the study your child will be recruited to.

The child will then be given mild sedation, under the highest levels of safety, the fracture will be reduced and the chosen backslab cast type applied. The backslab cast allows for swelling.

The angulation, apposition and the cast mold indices will be taken by the investigator, from the pre-procedure and post-procedure x-rays.

The weekly reviews will involve taking x-rays each time you come. The cost of the x-rays is 80 cedis per film which you will pay for. All the parameters will be measured again. If there's displacement which meets the threshold for re-manipulation, it will be done, again under light sedation.

If for any reason, you can't have the child take the x-ray, kindly call Dr Prince Larvie, the Principal Investigator on the number provided, and any necessary assistance will be provided.

Any complications associated with the management, will be noted and treated accordingly.

BENEFITS

Cast treatment for distal forearm fractures is the mainstay of treatment. A deeper understanding as to which type of cast is better, how to apply it to reduce the chances of it displacing, will help doctors to offer the best treatment available.

RISKS

The study offers treatment types which have been used in our and other jurisdictions, and been shown to be really effective. The multiple x-ray exposures may be associated with a really low risk of overdosing of radiation as per the Ghana Atomic Energy Commission. The x-rays will be taken with the minimum amount of radiation needed to take the radiographs.

There is also a low risk of aspiration and respiratory problems with the sedation, but steps have been taken to forestall and in the extremely unlikely event, deal with such complications.

You will also be required to bring the child for follow up each week for the first three weeks, after which if fracture has healed, the cast will be taken off. The cast removal will not require anaesthesia, and is a painless procedure.

CONFIDENTIALITY

Your child's actual name will not be used at any point during the information collection, or in the report-writing; instead, your child and any other person and place names involved in the study will be given an identification number. Only the investigator and supervisors will have access to information that can identify your child. Any publication or dissemination of the findings will not have your child's name in it. Your information that will be collected will be safeguarded and your privacy and anonymity will be ensured throughout the study and publication of the research material.

PARTICIPANTS' RIGHTS

Your participation in this research is voluntary; you have the right to withdraw at any point of the study, for any reason, and without prejudice, and the information collected, and reports written will be turned over to you.

Kindly ask any questions that may come up. I am also very open to constructive suggestions.

If you decide to take part, you will be asked to sign the consent form below. Signing the consent form indicates that you:

• Understand what you have read

• Consent to take part in this study

CONSENT

Declaration by Participant

I …………………………………………., the Guardian/ Parent of …………………………… have read the Participant Information Sheet or it has been read to me in a language I understand. I understand the purpose, procedures and the risks of the study being conducted. I am satisfied with the answers given to my questions and concerns. I willfully agree for my child to participate in this study as described and understand that I can withdraw from this study as described and at any point without my healthcare being compromised.

Signature: ………………………………. **Date**: ……………………………….

(Parent/Guardian)

Signature: ……………………………… Date: ………………………………….

(Witness)

APPENDIX 2

ASSENT FORM FOR CHILDREN BETWEEN 7 AND 13 YEARS

TITLE OF STUDY: **COMPARATIVE STUDY OF RE-DISPLACEMENT OF DISTAL FOREARM FRACTURES IN CHILDREN IMMOBILIZED IN ABOVE-ELBOW CAST VS BELOW-ELBOW CAST AT KORLE-BU TEACHING HOSPITAL.**

I have been informed that my parent(s)/ guardian(s) have given permission for me to participate, if I want to, in a study concerning ***'Treatment of Broken Wrist in Children with Plaster of Paris Cast'.*** My participation in this project is voluntary and I have been told that I may stop my participation in this study at any time. If I choose not to participate, it will not affect my treatment or care in any way.

Name...

Date...

....

Name of Investigator or Assistant who explained the procedure to the child

....

Signature

APPENDIX 3

DATA COLLECTION SHEET

PATIENT ID NUMBER

…………………………………………………………………………………………………….

CONTACT NUMBER(S)……………………………………………………………………………

A. DEMOGRAPHICS

i. Gender: Male……….... Female……………………

ii. Age…………

iii. Weight(kg)………………...

iv. Class: Nursery………. KG…………. Primary school……… Junior High School ……………….

v. Address…………………………………...

vi. Co-morbidities (Asthma, Diabetes mellitus, etc.) ………………………………….

B. INITIAL FRACTURE CHARACTERISTICS

Type of bone fractured: distal radius……….. distal ulna………….. both bones……………….

Fracture type: transverse……………… oblique……………….. spiral…………

comminuted…………..

Displacement of fracture in sagittal plane: dorsal…… volar……………. none……………..

Displacement of fracture in frontal plane: radial……….. ulnar……….. none……………..

Apposition (%) sagittal plane……………….. frontal plane……………………

Angulation (in degrees)……………….sagittal plane …………..frontal plane………….

Shortening (in mm)……………………

Fractured arm dominant………… non-dominant…………………….

C. POST-REDUCTION CHARACETERISTICS

Type of cast……… above-the-elbow……………….. below-the-elbow…………………….

Apposition (%) in sagittal plane………….. frontal plane……………….

Angulation (in degrees) …sagittal plane……………….. frontal plane……………….

Cast index……………..

Three point index………………..

A. FIRST WEEK REVIEW CHARACTERISTICS

Apposition (%) in sagittal plane………….. frontal plane……………….

Angulation (in degrees) …sagittal plane……………….. frontal plane……………….

Change in angulation…………..sagittal……………….. frontal………………..

Change in apposition……………….sagittal……………..frontal………………..

Need for re-manipulation? …………. yes…………… no…………….

Post-manipulation angulation…………..

Post-manipulation apposition……………

B. SECOND WEEK REVIEW CHARACTERISTICS

Apposition (%) in sagittal plane………….. frontal plane……………….

Angulation (in degrees) …sagittal plane……………….. frontal plane……………….

Change in angulation…………..sagittal……………….. frontal………………..

Change in apposition……………….sagittal……………..frontal………………..

Need for re-manipulation? …………. yes…………… no…………….

Post-manipulation angulation…………..

Post-manipulation apposition……………

C. THIRD WEEK REVIEW CHARACTERISTICS

Apposition (%) in sagittal plane………….. frontal plane……………….

Angulation (in degrees) …sagittal plane……………….. frontal plane……………….

Change in angulation…………..sagittal……………….. frontal………………..

Change in apposition……………….sagittal……………..frontal………………..

Need for re-manipulation? …………. yes…………… no…………….

Post-manipulation angulation…………..

Post-manipulation apposition……………

Duration of immobilization in cast (days)…………..

Complications during treatment…………………………

Intervention following complication………………………….

APPENDIX 4

ELECTRONICALLY GENERATED RANDOMIZATION SEQUENCE LIST

block identifier	block size	sequence within block	treatment
1	4	1	Group B
1	4	2	Group A
1	4	3	Group A
1	4	4	Group B
2	4	1	Group B
2	4	2	Group A
2	4	3	Group A
2	4	4	Group B
3	4	1	Group B
3	4	2	Group B
3	4	3	Group A
3	4	4	Group A
4	8	1	Group B
4	8	2	Group A
4	8	3	Group A
4	8	4	Group A
4	8	5	Group B
4	8	6	Group B
4	8	7	Group A
4	8	8	Group B
5	6	1	Group B
5	6	2	Group A
5	6	3	Group A
5	6	4	Group B
5	6	5	Group A
5	6	6	Group B
6	8	1	Group A
6	8	2	Group A
6	8	3	Group A
6	8	4	Group A
6	8	5	Group B
6	8	6	Group B
6	8	7	Group B
6	8	8	Group B
7	8	1	Group B
7	8	2	Group A
7	8	3	Group B

7	8	4	Group A
7	8	5	Group A
7	8	6	Group B
7	8	7	Group B
7	8	8	Group A
8	6	1	Group B
8	6	2	Group B
8	6	3	Group B
8	6	4	Group A
8	6	5	Group A
8	6	6	Group A
9	4	1	Group A
9	4	2	Group B
9	4	3	Group B
9	4	4	Group A
10	4	1	Group B
10	4	2	Group B
10	4	3	Group A
10	4	4	Group A
11	8	1	Group A
11	8	2	Group A
11	8	3	Group B
11	8	4	Group A
11	8	5	Group B
11	8	6	Group B
11	8	7	Group A
11	8	8	Group B
12	8	1	Group A
12	8	2	Group A
12	8	3	Group B
12	8	4	Group B
12	8	5	Group B
12	8	6	Group A
12	8	7	Group A
12	8	8	Group B

APPENDIX 5

SAFETY PROTOCOL FOR PARENTS

Cast treatment of fractures is generally very safe. However, a few complications may follow its application.

If you notice any of the following with your child, kindly call the Investigator on 0502402863

1. If the child complains of tingling in the fingers after the cast application.
2. If the child reports pain, which doesn't improve even after taking the pain-killers.
3. If you notice the child's finger nails to be darker than usual or with a bluish tinge.
4. If ulcers(sores) develop around the points of application of the cast.
5. Any other unusual change with the child since the cast application.

APPENDIX 6

KORLE BU STC AND IRB APPROVAL

In case of reply the number
And the date of this
Letter should be quoted

My Ref. No. KBTH/MD/G3/23
Your Ref. No.......................

Excellence in Healthcare
KORLE BU TEACHING HOSPITAL
KBTH
1923

KORLE BU TEACHING HOS
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-
Fax: +233 302 667759
Email: Info@kbth.gov.gh
pr@kbth.gov.gh
Website: www.kbth.gov.gh

6th July, 2023

DR PRINCE GEORGE LARVIE
DEPARTMENT OF TRAUMA AND ORTHOPAEDICS
KORLE BU TEACHING HOSPITAL
KORLE BU

SCIENTIFIC AND TECHNICAL COMMITTEE APPROVAL
PROTOCOL IDENTIFICATION NUMBER: KBTH-STC 00060/2023

The Korle Bu Teaching Hospital Scientific and Technical Committee (KBTH-STC), on 6th July, 2023, approved your submitted study protocol.

TITLE OF PROTOCOL: "Comparative Study of Re-Displacement of Distal Forearm Fractures in Children Immobilized in Above-Elbow Cast Vs Below-Elbow Cast at Korle-Bu Teaching Hospital"

This approval requires that you **forward your approved document to Korle Bu Teaching Hospital –Institutional Review Board (KBTH-IRB) for the ethical aspect of the proposal to be assessed before the project can be initiated.**

PRINCIPAL INVESTIGATOR: PRINCE GEORGE LARVIE

This STC approval is valid till 30th June, 2024

You may, however, request extension of the approval period, or renewal as the case may be, should the study extend beyond the stated period.

Upon completion, you are required to submit a final report on the study to the STC. This is to enable the STC ensure among others that, the project has been implemented as per the approved protocol. You are also required to inform the KBTH-STC and Research Directorate of any publications that may emanate from the research findings.

Kindly note that, should the need arise, the KBTH-STC or IRB may institute appropriate measures to satisfy itself that study is being conducted according to the highest scientific and ethical standards.

Please note that any modification to the study protocol without Scientific Technical Committee (STC) approval renders this approval invalid.

Prof. G. Obeng Adjei
Chairman, KBTH-STC

Cc: The Chairman, KBTH-IRB

In case of reply the number
And the date of this
Letter should be quoted

My Ref. No. KBTH/MD/G3/23
Your Ref. No.............................

KORLE BU TEACHING HOSPITAL
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3rd October, 2023

DR PRINCE GEORGE LARVIE
DEPARTMENT OF TRAUMA AND ORTHOPAEDICS
KORIE-BU TEACHING HOSPITAL
KORLE BU

COMPARATIVE STUDY OF RE-DISPLACEMENT OF DISTAL FOREARM FRACTURES IN CHILDREN IMMOBILIZED IN ABOVE-ELBOW CAST VS BELOW-ELBOW CAST AT KORLE-BU TEACHING HOSPITAL

KBTH-IRB 00060/2023

Investigator: DR PRINCE GEORGE LARVIE

The Korle Bu Teaching Hospital Institutional Review Board (KBTH IRB) reviewed and granted approval to the study entitled: "Comparative Study of Re-Displacement of Distal Forearm Fractures in Children Immobilized in Above-Elbow Cast vs Below-Elbow Cast at Korle-Bu Teaching Hospital"

Please note that the Board requires you to submit a final review report on completion of this study to the KBTH-IRB.

Kindly, note that, any modification/amendment to the approved study protocol without approval from KBTH-IRB renders this certify invalid.

Please report all serious adverse events related to this study to KBTH-IRB within seven days verbally and fourteen days in writing.

This IRB approval is valid till 31st August, 2024. You are to submit annual report for continuing review.

Sincere regards,

DR. DANIEL ANKRAH
VICE CHAIR (KBTH-IRB)
FOR: CHAIR (KBTH-IRB)

Cc: The Chief Executive Officer, KBTH
The Director of Medical Affairs, KBTH

In case of reply the number
And the date of this
Letter should be quoted

My Ref. No. KBTH/MD/G8/23

Your Ref. No.........................

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4th October, 2023

DR PRINCE GEORGE LARVIE
TRAUMA AND ORTHOPEDIC
DEPARTMENT OF SURGERY
KORLE BU TEACHING HOSPITAL

INSTITUTIONAL APPROVAL: KORLE BU TEACHING HOSPITAL-SCIENTIFIC AND TECHNICAL COMMITTEE/INSTITUTIONAL REVIEW BOARD (KBTH-STC/IRB/00060/2023

Following approval of your study entitled "Comparative Study of Re-Displacement of Distal Forearm Fractures in Children Immobilized in Above-Elbow Cast Vs Below-Elbow Cast at Korle-Bu Teaching Hospital" by the Korle Bu Teaching Hospital-Scientific and Technical Committee/Institutional Review Board.

I am pleased to inform you that institutional approval has been granted for the conduct of your study in Korle Bu Teaching Hospital.

Please contact the Heads of Departments to discuss the commencement date of the study.

Please note that, this institutional approval is rendered invalid if the terms of the Institutional Reviewed Board/Scientific and Technical Committee approval are violated.

Sincere regards,

Dr. Frank Owusu-Sekyere
Director of Medical Affairs

Cc: The Chief Executive, Korle Bu