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Outcomes of diaphyseal femur fractures managed in children 10 years and younger at Charlotte Maxeke Johannesburg Academic Hospital

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Outcomes of diaphyseal femur fractures managed in children 10 years and younger at Charlotte Maxeke Johannesburg Academic Hospital



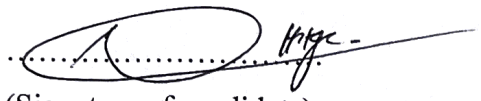
Dr Curran Hitge

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine

Johannesburg, 2023

Declaration

I, Curran Hitge, declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



(Signature of candidate)

23 October 2023

Dedication

This is dedicated to my wife, Kate, daughters Peyton and Brooklyn and son, Laine, as well as my parents, who have always supported me. I will be forever grateful.

Presentations arising from the research project

- Podium Presentation: South African Orthopaedic Congress 01/09/2021
- Podium Presentation: University of the Witwatersrand's Orthopaedic Surgery Research Day 10/11/2021

Abstract

Introduction: Paediatric femur fractures have a bimodal age presentation. Children under the age of six are generally treated with non-operative management, while those older than ten have been shown to do better with surgical fixation. The management of the intermediate age group of six to ten years remains controversial, with recent opinions tending to favour surgical fixation. At Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) a clearly defined stepwise protocol has been established, in which patients that do not meet defined indications for surgery are managed in skin traction until clinical and radiological signs of union are present, at which point, patients are discharged to weight-bear as tolerated.

Methods: This study was a retrospective review with a prospective recall of paediatric orthopaedic patients aged 10 years and younger treated in skin traction for femur fractures at CMJAH from January 2016 to December 2018. X-ray parameters were assessed on the Picture Archiving and Communication System for patients who met the inclusion criteria. Patients were then followed up at a minimum of 24 months to assess outcomes according to Flynn's criteria. Other variables assessed included length of hospital stay and rotational profiles.

Results: One hundred and seventy-nine patients were admitted to the paediatric orthopaedic ward at CMJAH with femur fractures over this period. Sixty-nine patients met the inclusion criteria set out in the study, of which 31 were available for follow-up. Seventy-seven percent of patients were aged 5 years and younger and 52% of injuries occurred due to low velocity falls. In terms of complications, 3 patients were found to have a limb length discrepancy, none of which exceeded 1cm. Three patients were found to have radiological malunion of >5degrees. One patient sustained a pressure sore which healed uneventfully, and no patients had any joint stiffness, pain or refracture. Twenty-four of the patients achieved excellent outcomes, with 6 satisfactory and 1 poor outcome. No patients reported any subjective concerns or complaints with the outcome. Time in traction showed a median of 25 days per patient, with increased length of traction having a significant correlation to advancing age. There was a median time to full weight-bearing of 6 weeks and a median of 8 weeks of school missed per child.

Conclusion: The majority of patients with femur fractures treated non-operatively at CMJAH went on to excellent outcomes with no patient subjective complaints. These findings were comparable to similar studies reviewing surgical management. The findings in this study suggest that there is a role for promoting our protocol of treatment to surrounding regional and peripheral hospitals that do not have access to orthopaedic expertise to offload specialist hospitals.

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Nomenclature

AP	Antero-posterior
AVN	Avascular necrosis
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
CEO	Chief Executive Officer
CT	Computed Tomography
HREC	Human Research Ethics Committee
IMN	Intra-medullary nail
LLD	Leg Length Discrepancy
PACS	Picture Archiving and Communication System
TENS	Titanium Elastic Nailing System

CHAPTER 1

1.1 INTRODUCTION AND LITERATURE REVIEW

1.1.1 Epidemiology of paediatric femur fractures

Paediatric femoral fractures are very common fractures, accounting for 1.6% of all paediatric fractures (1, 2). It has been shown that there is a bimodal age distribution of paediatric femur fractures (2). Femur fractures are most frequently seen in children in the pre-walking or early walking phase of development, and in adolescents over the age of twelve years (2). Up to 80% of children under the age of one year who present with femur fractures may have been exposed to physical abuse, and need to be carefully investigated (2). In the younger age group, femur fractures are commonly a result of low velocity falls, while older children who sustain femur fractures are usually involved in high energy trauma so associated injuries are common (2, 3).

1.1.2 Background

Femoral shaft fractures by definition involve the diaphysis and extend from below the lesser trochanter to the distal femoral metaphysis (2). Treatment of femur shaft fractures in children is controversial (1, 4, 5). In general, it was believed that children under the age of six, would benefit from non-operative management, while those older than ten years old, were better treated and achieved better results with reduction under anaesthesia and surgical fixation (4-6). Children under the age of six have sufficient remaining growth and therefore have very good bone remodelling potential (4). As such, children do not require anatomical or near-anatomical reduction of diaphyseal femur fractures to achieve a satisfactory outcome. Children over the age of ten, however, are more likely to have residual angular deformities because they have reduced remodelling potential (4). As such, this age group may be better treated with surgical reduction and fixation (4). The management of the intermediate age group of six to ten years remains controversial (1, 4, 5, 7). There is also no clear consensus for the most economical choice of treatment because these are very expensive injuries to treat (8). In South Africa, the public health sector serves a large population. The system is overburdened with limited access to surgical expertise, theatre availability and funding. The ideal treatment in this setting is one which results in satisfactory clinical outcomes and is easily and cost-effectively offered in primary and secondary centres with limited specialist support. Attention should also be aimed at minimising family and patient socio-economic fallout.. Patients aged 10 years and younger

treated at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) have been treated according to a fixed protocol bearing these points in mind.

1.1.3 Physiology of bone healing

Bone remodelling at the fracture site occurs according to Wolff's law (2, 9). This process occurs with bone deposition on the compressive side and bone resorption on the tensile side of the bone. This process is more effective, allowing for more remodelling within the plane of motion of the limb (9, 10). This phenomenon occurs in children with growth remaining, with younger children having more remodelling potential, due to longer time to growth cessation (9). It has been shown that 85% of remodelling has occurred within the first two years post-fracture and any significant residual deformity is likely to be permanent (7). After a fracture, the physes also undergo a differential growth response under variable loading, a phenomenon that was initially described by Hueter-Volkmann (2, 9). It has also been shown that most of the remodelling actually occurs at the level of the physis and less so at the fracture itself (4). Wallace and Hoffman found that 75% of remodelling within the femoral shaft occurred at the level of the physes (9). This is significant as it emphasises that mild fracture site malunion can be overcome with progressive physeal bony remodelling, provided there was adequate growth remaining. Wallace and Hoffman also showed that children at different ages underwent similar rates of remodelling, however children under the age of six remodelled marginally better (9). It is believed that due to the high amount of physeal growth at the distal femur, fractures of the femur have a substantial ability to remodel. By comparison it remodels better than distal humerus supra-condylar fractures, where most of the growth happens at the proximal physis (9). Remodelling in the coronal plane or rotational deformity remodelling is less reliable (9, 11). Valgus angulation has been shown to have better remodelling potential than varus angulation, but this is still less reliable than in the sagittal plane (12). Verbeek et al., in their series of 65 patients treated at their institution with various treatment modalities, showed that there is very little remodelling potential for rotational deformities in the growing child (11). Several other studies have shown little to no rotational deformity remodelling potential in children (13-16). Due to the thick periosteum with an abundant blood supply, bony overgrowth at the fracture site is a well described phenomenon in femur fractures in children (3).

1.1.4 Controversies of management of paediatric femur fractures

Traditional techniques of conservative management include inline traction, hip spica casting or a combination of the two. Over the past few decades, treatment of extra-articular, extra-physeal femur fractures has moved away from conservative management (1). Operative fixation is gaining popularity, especially in developed countries (1, 8). In a resource limited economy such as South Africa, where the public health system has a large patient burden and relatively few specialists, surgical intervention would require referral of all these children to specialist tertiary centres. Femur fractures are very expensive to treat, irrespective of treatment modality chosen (8). d'Ollonne et al. showed that prolonged traction is more expensive than other modalities of treatment due to the associated prolonged hospital stay (10). Multiple other studies have however attempted to evaluate the economic burden of femur fractures in children and compare the different treatment options. Economic burden is multi-faceted and should be assessed in terms of healthcare, patient and social costs (17). The exact economic comparison is therefore difficult to assess and have thus yielded conflicting results in terms of overall cost (17). There has been a general consensus, however that early hip spica casting is least costly from a purely financial perspective when compared to all treatment modalities, both surgical and non-surgical (17). It does however require specific expertise to apply and takes time in theatre, it is therefore costly in terms of resources.

1.1.5 Non-operative management of femur fractures

The conservative treatment of femur fractures in children under the age of six would include a period of traction, either skin or skeletal (3). A well-described guide to the period of time to continue in-line traction is one week per year of age up until the age of six years (3). The decision to discontinue traction should be taken once there are clinical and radiological features of healing (2, 5). Traditionally, this would then be followed by a period of three weeks to three months in a hip spica cast (2, 3). This spica cast could be applied in the ward or clinic without the need for anaesthetic, as the acute pain associated with the injury would have subsided (2). Alternatively, the child can be taken to theatre on admission and a closed reduction performed under fluoroscopic guidance and a spica cast fitted in the acute setting (2).

1.1.6 Acceptable reduction parameters

There are multiple reports on what the acceptable limits are for conservative treatment of femur diaphyseal fractures. Malkawi et al. reported that 20 degrees in the coronal plane and 30

degrees in the sagittal plane was acceptable and yielded good outcomes (4, 18). Kasser et al. showed similar acceptable parameters with 15 degrees or less in the coronal plane and 30 degrees in the sagittal plane in children under the age of six years (12). Due to reduced remodelling potential, lesser angulation is preferable for children over the age of six, and children over ten may be best treated with surgical reduction and fixation (5).

Malrotation deformities is a well described complication post fractures of the femur managed both operatively and non-operatively. Of note, clinical evaluation of femoral malrotation has been shown to be unreliably evaluated through general examination alone, leading often to an over-estimation of discrepancy (15). Although, little literature is available in children, improved accuracy can be attained with Computed Tomography (CT) scan evaluation of the femurs. Malrotation of more than 10-15 degrees in adults has been associated with functional difficulties such as climbing of stairs and running, as well as eventual hip and knee osteo-arthritis (15, 19-22). The outcomes following rotational malunions is not well described in children (3, 15, 23). Residual rotational deformities may be associated with excessive anteversion of the hips (11). Verbeek et al. concluded that rotational deformities of more than 20 degrees may be associated with pain and poorer functional outcomes due to biomechanical disturbances (11).

Due to the overgrowth phenomenon associated with femur fractures in children, shortening of between 1cm and 2cm are acceptable and are usually associated with restoration of limb length over time (3).

1.1.7 Skin traction

Skin traction is a method of indirect reduction and immobilisation achieved by applying a longitudinal force in the same axis of the limb. This technique attempts to restore normal length and alignment of a long bone fracture, as well as provide pain relief (2, 24). Many different techniques of traction have been described. Buck's traction, initially described by Gurdon Buck, is still the most commonly applied skin traction technique (25). Buck transformed the idea of skin traction developed by Josiah Crosby and applied it to soldiers who sustained injuries during the American Civil war in 1861 (25). This technique became known as Buck's extension and was used as a technique to reduce pain by controlling muscle contractions thereby preventing movement of the fractured fragments (25). Additional benefits of Buck's

traction are that it is very easy to apply and does not require any orthopaedic expertise. It consists of packaged adhesive tape and malleolar padding on a base plate, which is applied along the entire lower limb, stopping distal to the fracture site (24). The adhesive tape is then secured with a crepe bandage wound around the circumference of the leg and thigh. There is a distal length of string attached to the base plate for attachment to a weight (24). This system is then run through a longitudinal pulley system and a weight attached, which is balanced against the weight of the child's body, allowing for inline traction of the affected limb (24). The counter traction of the child's body weight is enhanced by elevating the foot of the bed to prevent the weight pulling the child down the bed (24). The guideline for weight application is 1kg weight per 10kg body weight up to a maximum of 5kg of skin traction (3, 24).

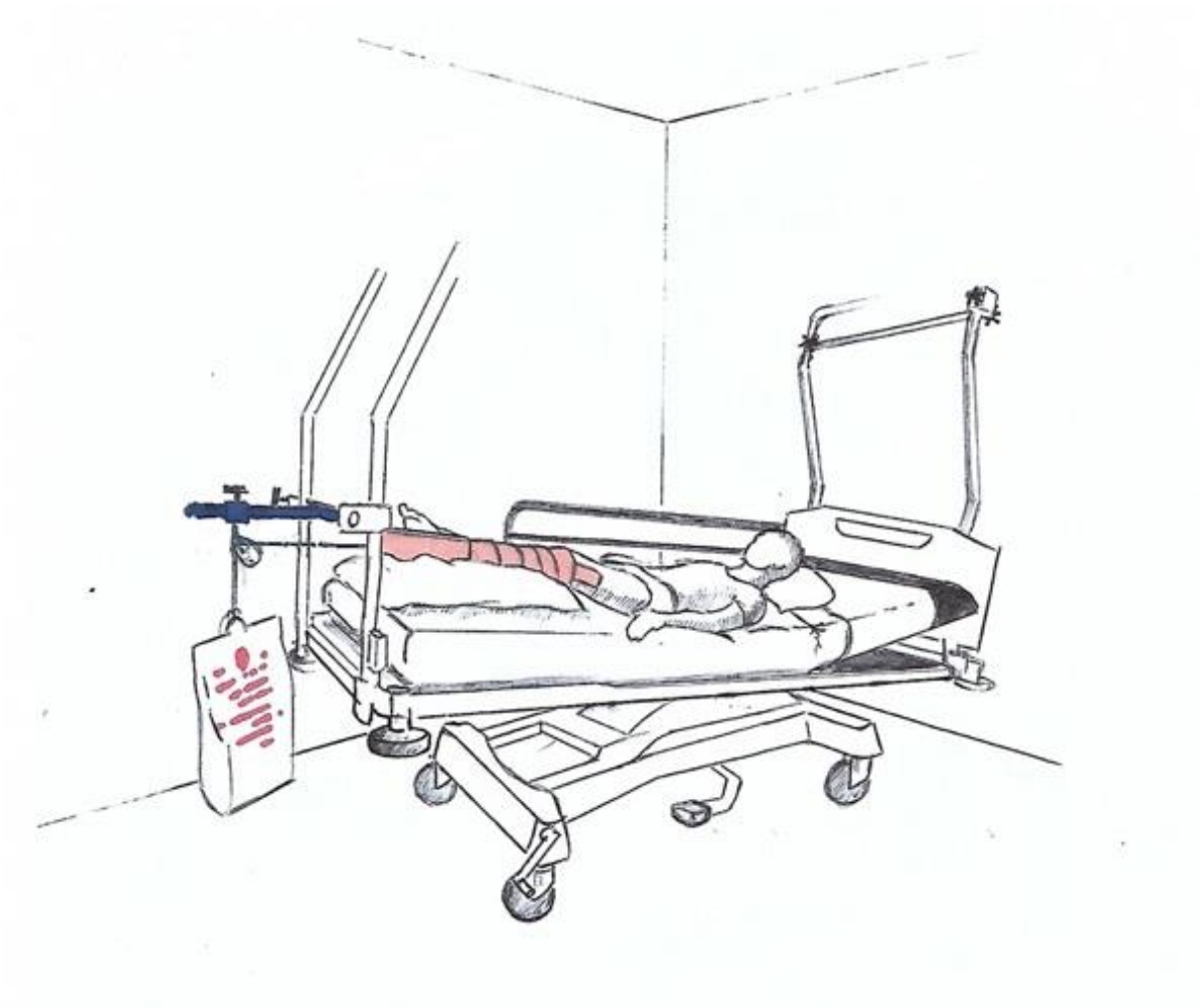


Figure 1.1: Illustration depicting the set-up of Buck's traction.

Complications of skin traction are usually minor. Although not common, the most prevalent clinical complication of skin traction is the development of pressure sores, especially around bony prominences (3). The prolonged hospital stay experienced with management of these fractures is however also associated with prolonged school absence and associated emotional distress (4, 5). There has also been shown to be a longer delay until return to full weight-bearing in children treated with skin traction (2, 5, 10).

1.1.8 Other types of traction

Skeletal traction may be indicated for children weighing more than 50kg, or those who cannot tolerate skin traction due to an allergy to the zinc oxide in the adhesive tape (8). Extensive abrasions or wounds to the soft tissue of the affected limb can also prevent the use of skin traction. Skeletal traction can be applied via a trans-femoral or trans-tibial Steinmann pin, which is attached to a string through a metal stirrup on the pin (2, 24, 26). This also allows one to increase the weight of pull up to 10kg (2). This method should however be avoided if possible in paediatrics due to the risk of physeal injury (2). Other techniques of traction include Gallows' traction for children under 12kg in weight; Thomas splinting in older children as well as balanced traction, such as Hamilton-Russell traction (2, 24). The use of balanced traction techniques is limited by its demand for specialist equipment such as bulkan frames, which are not readily available in our environment. They also require expertise to apply.

1.1.9 Hip spica casting

To reduce the length of hospital stay, some authors have recommended application of a hip spica immediately upon admission (17, 27). This is typically followed by immediate discharge if there is less than two centimetres of shortening at the fracture site on the control X-ray (17, 27). This strategy was popularised by Cassinelli et al., who showed high rates of satisfactory clinical and radiological outcomes with this method (27). Alternatively, the patient could be admitted for acute analgesic control for a few days and then have hip spica placement in theatre with the patient under general anaesthesia using fluoroscopic guidance to monitor reduction (10). These options allow for rapid discharge of patients from hospital and have been associated with decreased overall pain and shorter time to full weight-bearing (10). It has also been shown to be up to four times less expensive overall than the prolonged traction treatment regimen (10). The American Academy of Orthopaedic Surgeons, have now in fact, recommended this

as the treatment of choice for diaphyseal femur fractures in children aged six months to five years (26).

The application of a hip spica cast is complex and requires expertise to apply correctly to avoid the potential complications. (2, 5, 26). It involves the use of a spica table with a torso support and perineal pole to balance the child while applying the cast (2). A stockinet followed by cotton wool padding is applied to the lower limbs and torso of the patient. Plaster of Paris casting is then applied over the padding (2). An assistant is required to ensure that the hips are immobilised in 45 degrees of flexion, 50 degrees of abduction and 15 degrees of external rotation; the knees at 45 degrees of flexion and the ankles should be positioned at 90 degrees of dorsiflexion (10, 28). Previously 90 degrees of flexion at the hips and knees was recommended, but this was found to have an increased risk of lower limb compartment syndrome (28). Care must be taken not to apply the Plaster of Paris wrapping too tightly. The cast can then be re-enforced at the end with fiberglass casting to enhance its durability and limit its weight. An adequate perineal space needs to be left to allow for good hygiene and perineal care (2, 26).

Spica casting is a labour-intensive treatment modality for both the treating specialist and the caregiver. Although the materials are inexpensive, the time taken on limited theatre lists makes it a less attractive option in a constrained system. Close follow-up and assessment for shortening or loss of reduction at the fracture site is required (2, 3). Daily disadvantages of spica casting include difficulty with transportation, schooling and cast intolerance by the child, and difficulty with soiling and hygiene (17). The prolonged immobilisation and bedrest have also been shown to be poorly tolerated by the patients (2, 10).

There are several well described complications that have been associated with spica casting in the literature. These range from fairly minor complications such as skin maceration, pressure ulcers, loss of reduction, malunion and refracture (2). Major and potentially life or limb threatening complications described with spica casting include superior mesenteric artery syndrome and compartment syndrome of the lower limbs (2, 26).

1.1.10 General complications associated with non-operative management

Other concerns with conservative management depend on the method of treatment chosen.

It has been shown that one of the most distressing complications of non-surgically managed femoral shaft fractures is overgrowth of the fractured bone resulting in an ultimately longer limb on the affected side (2, 3, 5, 10, 29). Limb length discrepancy with shortening, malunion and refracture are also associated with all non-surgical treatment options. (2, 5, 10).

1.1.11 The role of surgical management

To negate the drawbacks associated with conservative management, in particular the perceived increased cost of long hospital stays and the prolonged school absence, the management in many well-resourced institutions has moved towards early surgical management (5). Described surgical fixation techniques includes Titanium Elastic Nailing System (TENS), Locked Intra-medullary nails, submuscular plating and external fixation (4). All these surgical treatment modalities offer effective means to reduce and definitively treat femur fractures in appropriately selected patients. These techniques are especially useful in cases of polytrauma, soft tissue compromise or older children not suitable for conservative management (30). To provide these services, orthopaedic specialist care must be available. Each modality is associated with its own set of benefits and risks.

The choice of treatment in paediatric femur fractures requires careful assessment of multiple factors (17). These may include age, size and weight of the patient, fracture pattern and location, associated injuries, condition of the soft tissue and aetiology of the fracture (17). Further important considerations include social circumstances of the patient and family, as well as resources available at the treatment facility (8, 17). Surgical treatment of femur fractures are reportedly associated with decreased complications, shorter hospital stays and possibly decreased overall cost (4). Improved emotional wellbeing of the child and earlier return to function and school have also been cited (3, 4).

1.1.12 External fixation

External fixation offers a minimally invasive reduction and provides relative stability at the fracture site (7, 31). It can provide rapid stabilisation and is useful in cases of polytrauma and soft tissue compromise (2, 17). It has also been shown to reduce malunion rates compared to non-operative treatment (7, 31). However, this method is perceived to be unacceptable to families due to their extrusive nature. This, however, was not reflected in the study performed by Wright et al. (7). External fixation has also been associated with high rates of delayed union

and refracture due to the rigidity of fixation and the poor quality of callus that forms (4). There are also areas of weakness at the site of pins once the ex-fix is removed, that may predispose to fracture (4). Pin track sepsis, the most common complication, has been shown to occur in up to 72% of patients (3, 7, 32). External fixation also carries a very high cost.

1.1.13 Intra-medullary Nail fixation

Rigid intra-medullary nailing (IMN) is the treatment of choice for older children, usually over the age of 12 years (32). IMNs have in the past, prior to implant design alterations and improvements, been associated with avascular necrosis (AVN) of the femoral head, which is a particularly disastrous complication in children (2, 32). Further cited complications include post-operative coxa valga deformity development and per-trochanteric growth arrest in children with ongoing active physeal growth due to injury to the trochanteric physis (30).

1.1.14 Open reduction internal fixation with submuscular plating

Submuscular plating offers superior stability and a more anatomical reduction to other modalities, but this comes with the expense of violation of the fracture site, soft tissue stripping and increased blood loss (32). It also has a steeper learning curve compared to other surgical options (32). Minimally invasive plate osteosynthesis with bridge plating technique can be performed to limit soft tissue stripping (3). This treatment modality also requires a second procedure to remove the plates once the fracture has healed, which may create a risk for refracture through the screw holes left in the healed bone (3).

1.1.15 Titanium Elastic Nails

The Titanium Elastic Nailing System (TENS) has gained a lot of popularity amongst surgeons over the last two decades. The system is appealing in younger children to get them mobilising and back to school sooner. TENS is best suited to midshaft transverse or short oblique type fracture patterns, without significant comminution (2). TENS does however require the patient to undergo an additional surgery and anaesthetic to remove the implants once the fracture has healed between six and 12 months (3). Elastic nails are also associated with complications. These include skin irritation, nail breakage or migration, and physeal injury (1, 5, 7). Deep infection, albeit uncommon, can be a distressing complication seen post TENS. The most common side-effect of elastic nails is knee pain at the nail insertion site, which occurs in up to 49% of patients (7). Elastic nails, in similarity to conservative modalities have been associated

with malunion, bone overgrowth and shortening (5). Moroz et al. showed much higher complication rates associated with TENS in children over the age of 11 and/or weighing more than 50kg (33).

Flynn et al. performed a multicentre trial that assessed early clinical and functional outcomes as well as complications in a series of 234 consecutively managed femur fractures with TENS in otherwise healthy children (30). They formulated a measure to assess outcomes of femur fractures treated with TENS (30). The chosen parameters include limb length discrepancy, radiological fracture site malalignment, complications that may have occurred and any pain experienced by the patient (30). No reason for the choice of the above parameters was provided in the paper by Flynn et al. and the significance of its findings may need review. These parameters are however easily reproducible and provide insight into the functional and radiological outcomes of patients undergoing treatment of femur fractures. It is a valuable tool as it allows for the comparison of outcomes of femur fractures treated with different modalities.

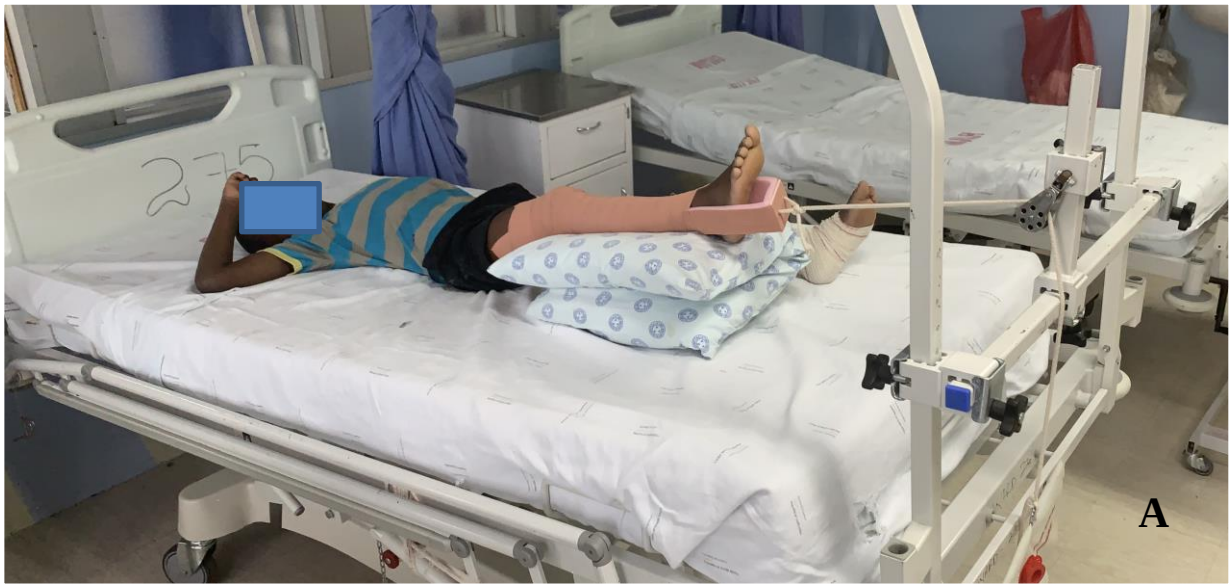
1.1.16 Charlotte Maxeke Johannesburg Academic Hospital protocol for the management of diaphyseal femur fractures in children aged 10 and younger

There is a standard treatment protocol for isolated closed paediatric diaphyseal femur fractures at CMJAH. All children aged 10 years and younger presenting with a femur fracture are initially given analgesia and then they are placed in skin traction to immobilise the fracture. Indications for surgical management in these patients are where an adequate reduction cannot be achieved by closed means with skin traction. Open fractures, severe soft tissue injury, subtrochanteric femur fractures, fractures in pathological bone and patients with multiple fractures or injuries are likely to also be treated with surgical fixation.

Those children who do not meet immediate indications for surgery, are planned for definitive management in skin traction. A pillow is placed under the knee, flexing it to about 20 degrees, to prevent external rotation of the limb. This technique also aids in relaxing the gastrocnemius muscle, preventing the distal fragment being displaced into extension. A control X-ray is ordered within 24 hours to assess the position of the fracture. Generally accepted criteria are adhered to, with an aim of achieving less than two centimetres of shortening, less than 15 degrees angulation in the coronal plane and less than 30 degrees angulation in the sagittal plane. Rotation is also monitored clinically and corrected appropriately with the pillow. The weight

of traction is adjusted according to patient size and control X-ray, but a well-known guide is one kilogram of weight per 10kg body weight, with a maximum of five kilograms. Anecdotally, less than three kilograms of weight is found to provide very little reduction and as such less weight than this is seldom applied. If the parameters on initial radiography are acceptable, skin traction will be continued, and the patient will undergo weekly X-rays in traction until the fracture unites.

Patients are assessed daily for signs of systemic or psychological stress. The fractured limb is assessed clinically for signs of healing such as tenderness, mobility, and callus formation at the fracture site. Traction is also reviewed daily and appropriately adjusted to ensure optimal position of the patient and the limb. Patients are monitored for skin blisters, pressure areas, perfusion, and neurological changes. Parents are counselled on admission that they can expect the child to be admitted for roughly one week per year of age up to six weeks, but ultimately the decision for discharge is based on clinical and radiological healing. Radiological evidence of union is evidenced by the presence of callus bridging on three out of four cortices. Conversion to surgical treatment at any stage during this process is reserved for patients that have had a loss of reduction or those that have developed skin compromise or other complications preventing the continuation of traction.



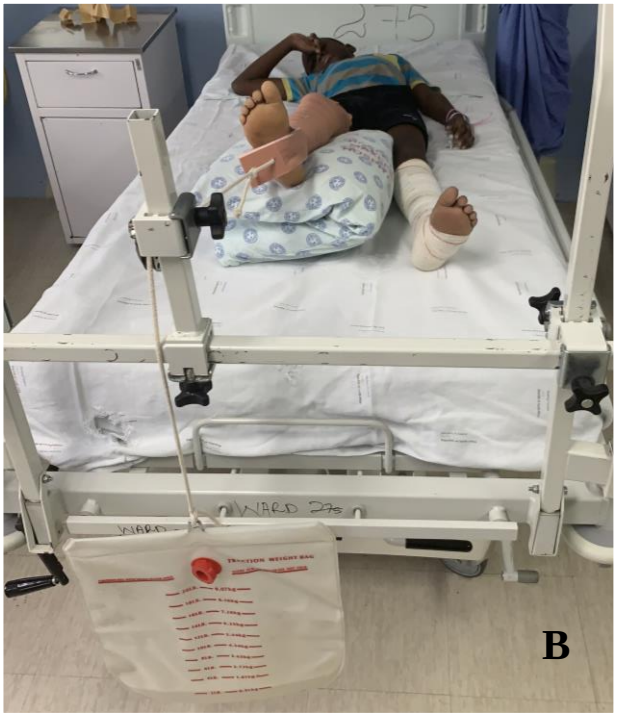


Figure 1.2: Clinical images of a patient with a femur fracture placed in Buck's skin traction (A, B). Note the adhesive tape with circumferential bandage around the leg and thigh to a level below the fracture site and attached to a weight via a string through a pulley system. The head of the bed is also lowered to provide a counter force to the pull of the weight. A pillow is placed under the knee to control rotation of the limb.

Once the patient has clinical and radiological evidence of union, the traction is removed, and the child is observed for 24 hours to assess comfort. Children over the age of five years, are taught to mobilise non-weight-bearing with crutches and are discharged home without a cast to continue rehabilitation. The parents of younger children under the age of five are counselled that they will start weight-bearing on their own accord and are sent home to 'bum-shuffle' and mobilise as they are able. The protocol facilitates discharge without immobilisation to weight-bear as tolerated rather than what is traditionally sited in most of the literature, where conversion to spica casting at this stage is the norm. Patients at CMJAH are followed up four-weekly until they are fully weight-bearing and then six-monthly thereafter until cessation of growth.

1.2 PROBLEM STATEMENT

In a resource-constrained health system, there is a need to identify patients that can be safely treated at peripheral hospitals to offload tertiary centres. Femoral shaft fractures could potentially be safely treated in these settings if appropriate treatment guidelines can be developed and are readily accessible.

1.3 STUDY AIM

The aim of the study was to assess the outcomes of isolated closed paediatric femoral shaft fractures managed by our current protocol at CMJAH.

1.4 OBJECTIVES

The objectives of this study are:

- To review the clinical and radiological outcomes of these fractures at a minimum of 2-year follow-up utilising Flynn's criteria as an outcome measure.
- To determine any complications of treatment during and after initial management.
- To determine the median time in traction and hospital stay.
- To determine the median time to return to weight-bearing.
- To determine the basic costs associated with this treatment modality.

CHAPTER 2

METHODOLOGY

2.1 Research question

Does the protocol implemented at CMJAH for the management of femur fractures result in acceptable clinical outcomes?

2.2 Research design

The research design is a retrospective review with prospective recall of patients treated at CMJAH.

2.3 Materials and methods

The paediatric orthopaedic ward admission record book was utilised to identify children admitted with femur fractures admitted from 01/01/2016 to 31/12/2018. Discharge summaries for all patients with femur fractures were then obtained from the CMJAH electronic discharge system. These records were examined for inclusion and exclusion criteria. If specific details regarding the choice of treatment provided were not clear on the discharge summary, full patient admission records were sought from hospital records.

2.4 Selection criteria

Inclusion criteria:

- All diaphyseal femur fractures in children aged 10 years and under treated at CMJAH.

Exclusion criteria:

- Polytrauma patients.
- Open fractures.
- Subtrochanteric femur fractures.
- Pathological fractures.
- Smaller children treated in Gallows traction.

2.5 Data collection

A minimum of a two year follow-up was chosen, which allowed adequate time for the majority of remodelling to have occurred.

All patients meeting the inclusion criteria had their initial X-rays, as well as X-rays at discharge, reviewed. These X-rays were traced on the CMJAH Picture Archiving and Communication System (PACS). X-ray assessment included review of the antero-posterior (AP) and lateral full length femur films with measurement and recording of:

- fracture shortening
- femur length
- axial fracture malalignment

The built-in software available in the program was utilised to measure the above parameters.

These patients were contacted telephonically and given an appointment to be seen at the clinic for their routine follow-up. At the appointment, the study was discussed with the family and if they were willing to participate, complete anonymity was insured with the use of an anonymous study number allocated to each patient. A participant information leaflet and assent form were given to the patients and their assent was attained. A more detailed information sheet and informed consent form was signed with the accompanying parent/s. The patient was then assessed both clinically and radiologically according to Flynn's criteria and a research questionnaire was completed (see Table A.1 in Appendix A). This data collection sheet was allocated to all patients and completed during the follow-up consultation. A study number was also allocated to each patient to maintain anonymity.

In terms of clinical assessment:

- Children were examined bare-foot and in their under garments.
- The gait cycle was assessed for evidence of an antalgic or short-limb gait. A foot progression angle was also observed, noting an internal or external rotational discrepancy between the limbs.
- Limb length discrepancy was analysed making use of a true limb length measurement. This was done with the patient supine and lower limbs fully extended. A tape measure was used to record the length from the anterior superior iliac spine of the pelvis to the tip of the medial malleolus.

- Range of motion at the hip and knee was documented. Hip flexion, abduction, adduction, internal and external rotation was assessed and compared to the contralateral side. Knee flexion and extension was be assessed bilaterally.
- Rotational profiles of the lower limbs, specifically comparing to the contralateral limb, was conducted. This was done utilising two techniques with the child in a prone position, the thighs parallel and the knees flexed to 90 degrees. The pelvis was stabilised to avoid tilting and internal and external rotation of the hip was assessed with a goniometer and compared to the normal side (11).
    - The first technique, comparison of discrepancy between right and left hip internal and external rotation was assessed to assess femoral versional disparity. Increased internal rotation on the affected side was reflective of increased femoral anteversion and increased external rotation was reflective of femoral retroversion (11).
    - Craig's test was used to improve the accuracy of assessment of femoral version. In the same prone position as highlighted above, the greater trochanter of the individually examined limb was palpated while passively rotating the hip until the trochanter became most prominent in the most lateral position. The angle between the shaft of the tibia with the greater trochanter most prominent and a vertical line indicates the femoral anteversion (34).
- A discrepancy of more than 10 degrees between the limbs was considered significant for femoral malrotation.

Flynn's criteria (see Table A.2) was applied to all patients so that their outcome was scored as excellent, satisfactory or poor. This was achieved by applying the least favourable parameter. To get an excellent result, all parameters needed to score optimally (30). This score was then later used in comparison to the available literature (30). Any abnormality or limitation detected in this assessment was recorded and further interrogated.

Radiological assessment included bilateral full length femur X-rays, in the AP and lateral plane to review femur length discrepancy, malunion and overgrowth. The fracture site diaphyseal angle was measured as the angle between where two lines drawn parallel to the shaft of the proximal and distal femur fragment, as illustrated below in Figure 2.1. Femur length was measured from the tip of greater trochanter to the distal most aspect of intercondylar fossa on

the AP plane. The same parameters used to assess the initial and discharge X-rays were utilised to assess the degree of remodelling that has occurred at final follow-up.

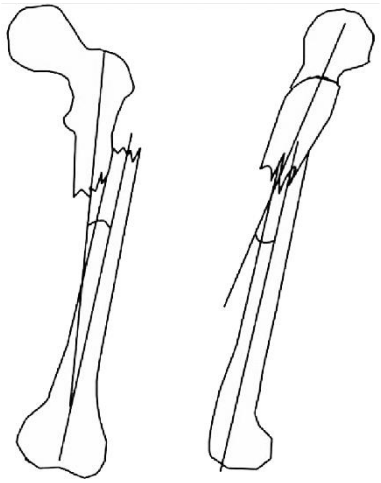


Figure 2.1: Measurement of fracture-site diaphyseal angle (9).

The parents were asked specifically for any complications that the child may have experienced both during the hospital admission and since discharge. Common complications, including pressure sores, refracture and malunion were sought. The amount of time the child spent out of school was also assessed as well as the need to repeat a school year as a result.

A basic economic cost analysis was performed, which included:

- an assessment of the cost per day as an inpatient at CMJAH (ward cost and treating specialist *versus* general practitioner cost);
- The length of hospital stay per patient as well as the overall cost of the hospital stay
- The cost per day at CMJAH in comparison to a level 2 hospital to assess if there is a difference in price for inpatient stay at a tertiary and a district or regional hospital.

A more thorough cost analysis is not possible in a state setting as the miscellaneous costs of medication, radiography and consumables, such as skin traction and gloves is not readily available. As such a basic cost analysis will be performed and used for comparison.

All the information attained in the data sheet was transcribed into an excel spread sheet and saved for each patient under their name and study number. Only the principal researcher (Dr Hitge) had access to these records to ensure anonymity was maintained.

2.6 Data Analysis

The data were analysed using a Statistical Package for Social Sciences, version 27 with the assistance of a statistician.

Due to the small sample size, descriptive analysis was performed to get an overview of the data. For categorical variables, the count and percentages of each category were reported. For continuous variables the mean, median, standard deviation, inter-quartile ranges, minimum and maximum values were calculated.

Spearman Rho correlation tests were applied to test for relationships between variable, in particular the patients' age and time in traction and in hospital as well as time to full weight-bearing. A finding was considered significant if a *p*-value of less than 0.05 was obtained.

The distribution of the variables were tested using the Kolmogorov-Smirnov test if the sample was greater or equal to 50, or the Shapiro-Wilk test if the sample was less than 50. If the resulting distribution was normally distributed, then parametric tests were used for inferential analysis. If the distribution was non-normal, then non-parametric tests were used.

The difference between measurements on the left and right were tested using the Wilcoxon Signed Rank test (non-parametric) for the Femur length.

The differences over time of the measurements were tested using the Friedman test (non-parametric). These tests were done on three-time periods for Femur length (each side), Fracture-site and diaphyseal angle (AP and Lateral).

2.7 Ethics

Ethical approval was obtained from the Human Research Ethics Committee (HREC)(Medical) of the University of the Witwatersrand, ethics number: M191196. Subsequently, permission was granted by the CEO of CMJAH and Orthopaedic Head of Department.

The follow-up visits required performance of a radiograph of the lower limbs. This meant that the child was exposed to additional radiation. This would however occur at their routine follow-up anyway to assess the clinical progression. The appointment was treated as a follow-up consult that the child would have attended anyway as part of their routine follow-up and any other concerns or requests were attended to even if not required for the study.

CHAPTER 3

RESULTS

3.1 Descriptive overview

During the study period, 179 patients were admitted to the paediatric orthopaedic ward at CMJAH with a femur fracture. Ninety-six patients were initially excluded from the study. Of these, 54 patients were children under the age of two years, or under 12kg in weight, and as a result, were managed in Gallows traction. Seventeen patients required surgical fixation from the outset for various reasons, which included subtrochanteric or intertrochanteric femur fractures, open fractures, polytrauma, or not otherwise specified. Thirteen patients were excluded due to associated neuromuscular disorders causing pathological fractures such as osteogenesis imperfecta (ten patients), cerebral palsy (two patients) and Bruck's syndrome (one patient). Ten patients sustained distal femur fractures that were managed conservatively in a Plaster of Paris cast. Two patients with subtrochanteric femur fractures were treated with 90/90 traction. The remaining 83 patients qualified for inclusion in the study. Of these, 14 patients subsequently failed to maintain adequate reduction at repeat Xray and required surgical fixation. This represented a 16.8% rate of conversion to surgical fixation. The age range of the patients that failed to maintain reduction was five years and nine months and 10 years and four months. This left 69 patients who were ultimately included in the study.

Of the 69 patients who met final inclusion criteria, the contact details of 32 of the patients were either incorrect or no longer in use. Six of the patients were no longer residing in Johannesburg and were unable to follow-up. This meant that 38 (55%) patients meeting the inclusion criteria were lost to follow-up. Thirty-one of the 69 patients (45%) were contacted and asked to follow-up, all of whom attended a follow-up as scheduled telephonically (see Figure 3.1).

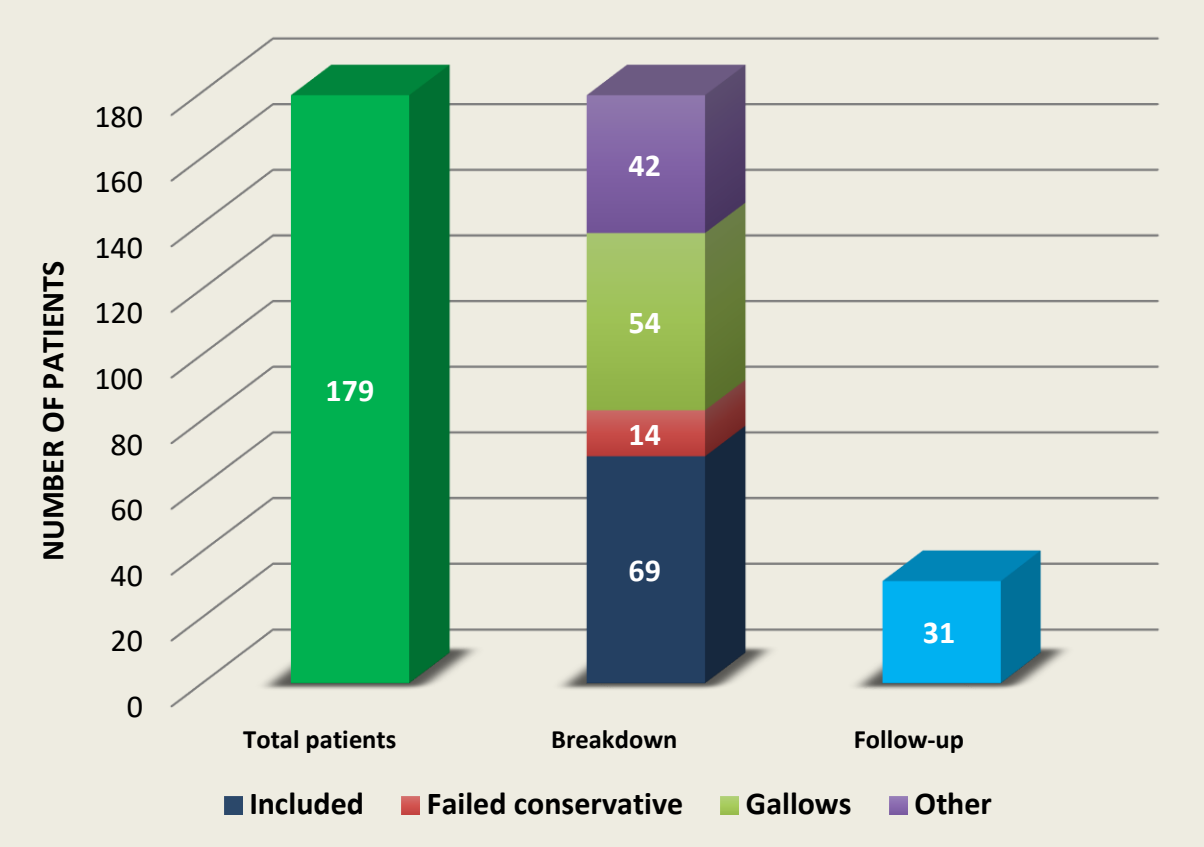


Figure 3.1: Breakdown of patients treated for femur fractures at CMJAH between the beginning of 2016 and the end of 2018. Other: primary surgical management, pathological fractures, subtrochanteric femur fractures managed in skeletal traction, distal femur fractures.

3.2 Epidemiology of sampled patients

The raw data for all the patients can be sourced in Appendix B.

From the 31 patients followed up in this study, the age ranged from one year and eight months to ten years and six months, with a mean age of four years and four months. Twenty-six (83.9%) were male and five (16.1%) were female. Nine patients (29%) were not South African citizens.

The time frame established for the data collection allowed for a minimum of two-year follow-up, with follow-ups ranging from 24 months to 51 months post injury, with a mean of 36.9 months. Sixteen of the 31 patients (51.6%) were aged two or three years at the time of injury with 24 (77.4%) being aged five years and younger (see Figure 3.2).

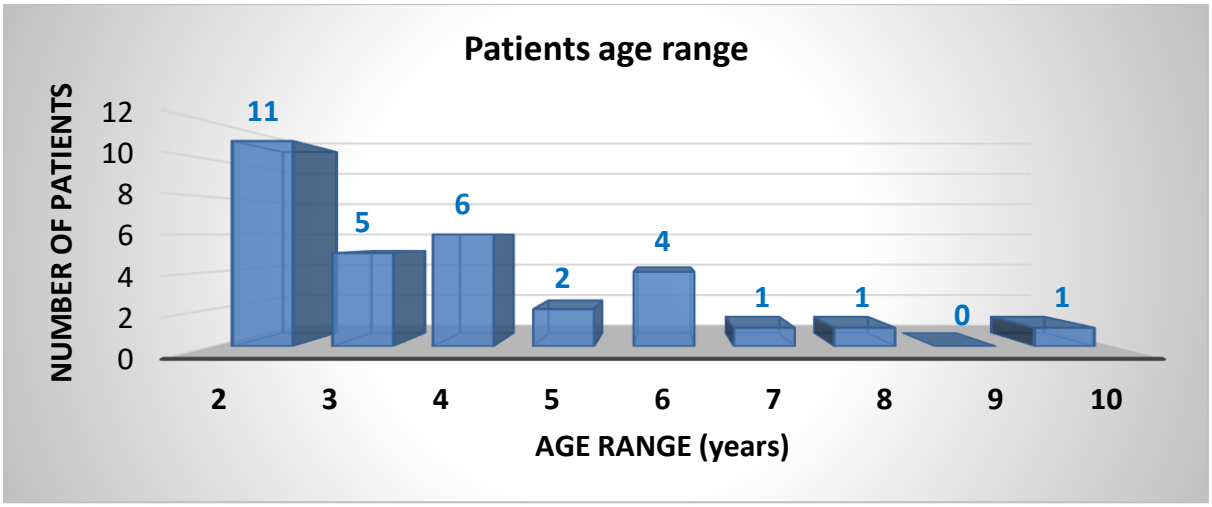


Figure 3.2: Study patient age range and distribution (N = 31).

3.3 Mechanism of injury

Low velocity falls made up the majority of injuries, with 16 (51.6%) occurring as a result of falling from a couch, bed, or jungle gym while playing. Eight children sustained femur fractures after being involved in a pedestrian vehicle accident, three sustained falls from significant height and two were injured playing sport (see Figure 3.3). The two other injuries were isolated events of falling off a motorbike, and a wall collapsing on the child (see Figure 3.3). Nineteen (61.3%) patients sustained fractures of the left femur with 12 (38.7%) sustaining right femur fractures. Twenty-six (83.9%) fractures involved the mid-diaphyseal region of the femur, while two involved the distal one-third of the femur and three involved the proximal one-third. Sixteen of the fracture patterns were spiral in nature, while 11 were transverse. There were two oblique and two comminuted fracture patterns.

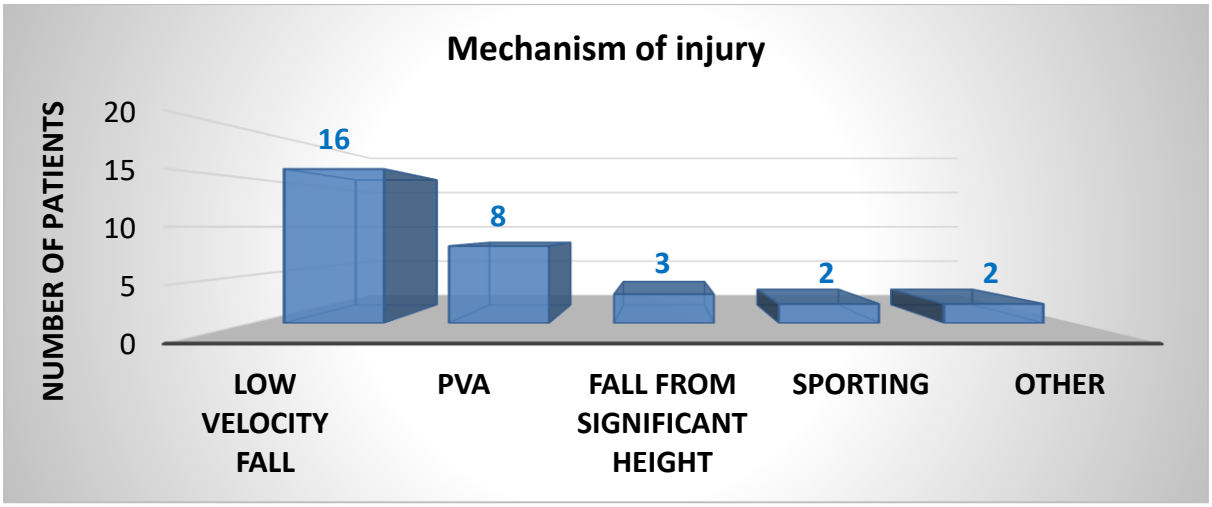


Figure 3.3: Mechanism of injury (N = 31).

3.4 Outcome findings

When applying Flynn's criteria, 25 patients had an excellent result, five patients had a satisfactory result, and one patient had a poor result. One patient had a satisfactory result because of a skin complication whilst on traction. Two patients had isolated residual limb length discrepancies of 1cm, while two patients had residual angular deformities of five to ten degrees, one of which also had an additional residual limb length discrepancy of 1cm shortening. The single poor result had a residual angular deformity of more than ten degrees (see Figure 3.4). The details of satisfactory and poor results are described in Table 3.1 and Appendix B.

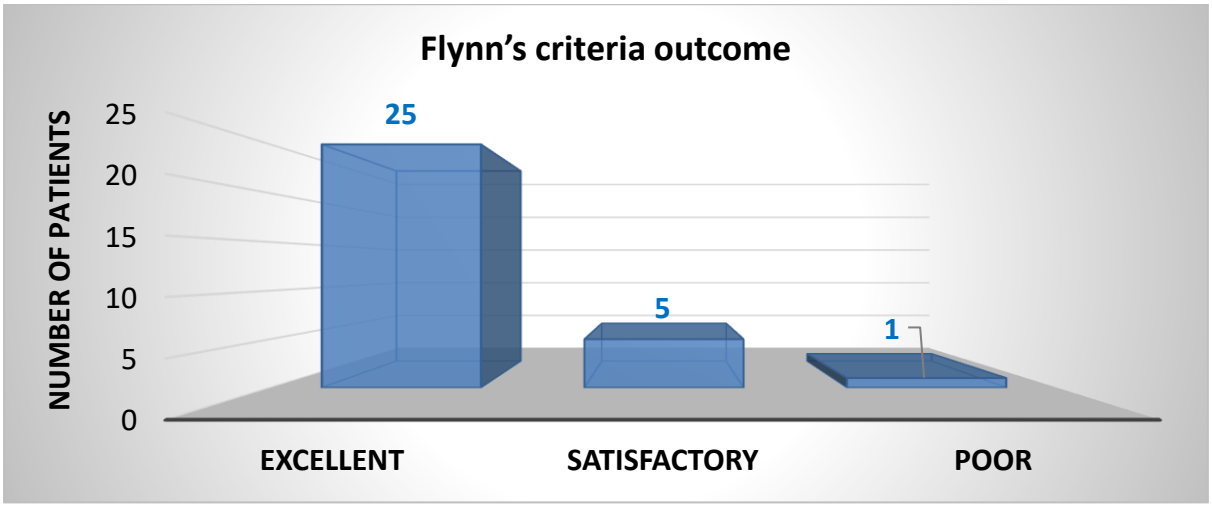


Figure 3.4: Outcomes according to Flynn's criteria (N = 31).

Table 3.1: Breakdown of patients scoring satisfactory (N = 5) or poor (N = 1) results.

Patient number	Outcome	Reason
2	Satisfactory	Developed complication: pressure sore
8	Satisfactory	Limb length discrepancy: 1cm
18	Satisfactory	Angulation deformity: 7 degrees varus
21	Satisfactory	Limb length discrepancy: 1cm Angulation deformity: 5 degrees varus
25	Satisfactory	Limb length discrepancy: 1cm
10	Poor	Angulation deformity: 14 degrees varus

Fifteen out of 16 (94%) patients who sustained spiral fractures went onto an excellent result. Of note, the single satisfactory result in this group was due to the development of a pressure sore, which healed uneventfully. Nine out of the 11 patients with transverse fractures had an excellent result, with the other two achieving satisfactory results. Of the two patients who sustained an oblique fracture, one went onto an excellent result, while the other had a poor outcome, due to an angulation deformity at final follow-up of >10 degrees. Finally, the two patients with comminuted fractures had satisfactory outcomes. Incidentally, these were older children, aged eight years and 10 years (see Table 3.2). A larger sample size is required to allow for inferential testing.

Table 3.2: Breakdown of fracture patterns sustained, and the outcome achieved.

Fracture Pattern	**Total number of patients**	**Outcome**	**Number of patients per outcome score**
Transverse	11	Excellent	9
		Satisfactory	2
		Poor	0
Oblique	2	Excellent	1
		Satisfactory	0
		Poor	1
Spiral	16	Excellent	15
		Satisfactory	1
		Poor	0
Comminuted	2	Excellent	0
		Satisfactory	2
		Poor	0
Total	31		

When reviewing initial displacement, two fractures were undisplaced, 15 were mildly displaced, with some apposition on either an AP or lateral radiograph, and 14 were completely displaced (see Table 3.3). In the undisplaced group (N = 2), the outcome was compromised by a traction-associated pressure sore. Due to the small sample size, there was no reliable relationship between initial fracture displacement, length of time in traction, length of time to weight-bearing and overgrowth in our study (see Appendix B).

Table 3.3: Breakdown of initial fracture displacement and the outcome achieved.

Fracture displacement		**Excellent**	**Satisfactory**	**Poor**
Undisplaced (N = 2)	Number	1	1	0
	Percentage	50%	50%	0
Mildly displaced (N = 15)	Number	13	2	0
	Percentage	86.7%	13.3%	0
Completely displaced (N = 14)	Number	11	2	1
	Percentage	78.6%	14.3%	7.1%

3.5 Complications

Thirty of 31 patients were found to have a fracture shortening of two centimetres or less on the initial traction X-ray. At final follow-up, three patients were found to have a clinically relevant limb length discrepancy, two of which were 1cm longer on the affected side. The other patient was found to be 1cm shorter on the affected side. This was the only patient that had a shorter affected limb at follow-up. Fourteen (45.2%) patients were found to have no limb length discrepancy at all, while 16 (51.6%) were found to have a half to one-centimetre longer leg on the fractured side (see Appendix B)

Eight of the 31 patients (25.8%) were found to have rotational discrepancies of 10 degrees or more between their limbs. The discrepancies detected ranged from 10-30 degrees of malrotation on of the affected limb, all in retroversion or external rotation compared to the normal limb (see Figure 3.5).

None of the 31 patients sited long-term residual pain in the thigh and there was no reported hindrance to activity. One patient sustained a pressure sore from the traction whilst in hospital, which healed uneventfully. There were no reports of refracture in our group of patients post discharge and no patients had any residual hip or knee stiffness (see Figure 3.5).

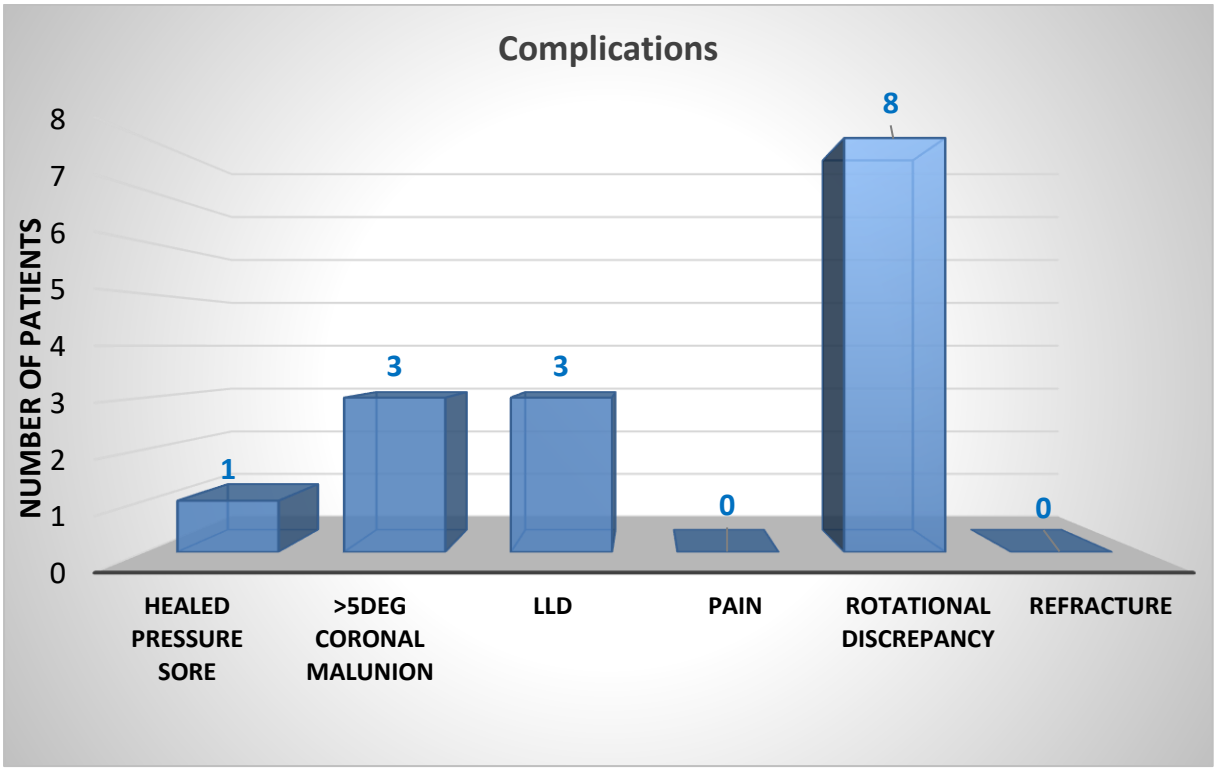


Figure 3.5: Complications.

3.6 Hospital stay, time to full weight-bearing and school missed

Time spent in skin traction ranged from 12 days to 51 days, with a median of 25 days. The Spearman's rho correlation coefficient was used to test for the relationship between age and time in traction. The results show that there was a strong positive relationship with rho = 0.866 and $p < 0.01$. The 95% confidence interval was [0.763;1.068]. This indicates that with increasing age of the child, time in traction also increases (see Figure 3.6). Inpatient admission lengths ranged from 14-53 days.

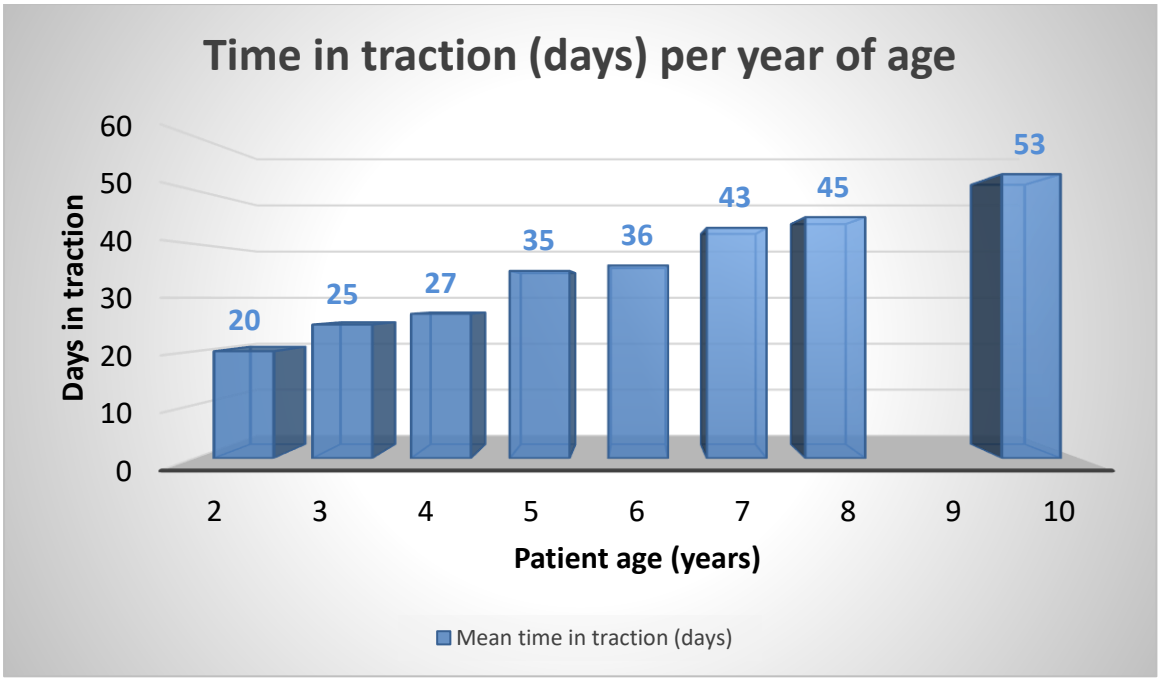


Figure 3.6: Time in traction per year of age.

When reviewing the time from injury to full weight-bearing, most children were weight-bearing without crutches within one month of discharge. This ranged from immediate weight-bearing upon discharge up to six weeks post discharge, with a mean of two and a half weeks. There was a median time to full weight-bearing from the date of injury of six weeks (range: three-14 weeks) (see Appendix B). Again, the Spearman's rho correlation coefficient was used to test for the relationship between age and time to full weight-bearing. The results show that there was a moderate positive relationship with rho = 0.376 and p-value of 0.037. The 95% confidence interval was [0.109;0.788]. This indicates the as the age of the children increases, time to full weight-bearing also increases.

Seventeen (55%) patients were not of school-going age at the time of injury. Of those of school going age, a median of 8 weeks of school were missed per child with a range of 5 to 24 weeks. Two children had to repeat a year of school as their parents felt they had missed too much school.

3.6 Cost analysis

According to the schedule of fees published by the South African Department of health, the cost per day of admission at CMJAH, which is a level 3 facility, in a regular ward is R2202 (price quote - April 2022) (35). There is also an additional R331 daily specialist fee. This means

that in our study the basic in-patient cost per patient ranged from R35 462 to R134 249 (for range of 14 to 53 in-patient days spent in traction).

CHAPTER 4

4.1 DISCUSSION

4.1.1 Epidemiological comparison

The findings of this study reinforce what is known regarding the epidemiology of femur fractures in children. Fifty-two percent of fractures in this study were due to low velocity falls. This is similar to data available from the United Kingdom showing 49% of paediatric femur fractures occurring due to falls and 35% reported in the United States of America (36). Paediatric femur fractures occur most commonly in children under the age of 5 years and the most common mechanism of injury sustained is a low velocity fall (2). Seventy seven percent of our patients were aged five years and under and 67% of injuries in this age group were due to low velocity falls. None of the patients in our group were suspected of having sustained a femur fracture secondary to a non-accidental injury. Twenty-nine percent of patients were foreign patients. This is in keeping with the reported national figures of percentage of foreign patients treated in South African government hospitals, where on roughly 25% of patients seen in South African State hospitals are foreign (37). These patients add to an already overwhelming patient load in a constrained system.

4.1.2 Alignment assessment

Acceptable alignment to allow for continued traction in the protocol was 15 degrees or less of varus or valgus angulation in the coronal plane and 30 degrees or less of sagittal plane angulation. The accepted fracture alignment parameters for continued traction in this study ranged from 13 degrees valgus to 23 degrees varus angulation. This reflects a lenience on the application of fracture position in traction, where more than 15 degrees of coronal angulation was accepted on several occasions. No reasons were given in the clinical notes as to why these values were accepted. This however did not seem to affect outcomes with only three patients having final angular deformities of five degrees or more. Of note, initial angulation seemed to have little correlation to fracture position at discharge. Two of the three patients (see Appendix B - patient 17 and patient 20) who scored a satisfactory result because of residual angular deformities of five degrees and seven degrees respectively, were over the age of eight years at the time of injury. The only poor outcome in the study belonged to a 2 year 11-month-old child (Appendix B - patient 9) who sustained a midshaft oblique fracture after a fall from a significant height. His initial angulation on X-ray was 13 degrees of varus angulation. Upon discharge, his

angulation was 11 degrees of varus angulation and at follow-up after 40 months, his final angulation was 14 degrees of varus. The patient had no limb length discrepancy and had no complaints. These findings may highlight that more than the recommended limit of coronal angulation of 15 degrees used in this study may be acceptable with good remodelling potential, especially in younger patients.

When comparing the findings of our study to a study of femur fractures in 207 children managed in traction initially and then converting to spica casting, Essenyel et al. found that four percent healed with greater than 15 degrees coronal malunion at final follow-up (23). Casas et al., in a similar study reviewing outcomes of femur fractures managed initially in traction with ultimate conversion to spica casting, in 41 children aged four to 10 years, found that no patients had angular deformities exceeding 15 degrees at final follow-up (4). Malkawi et al., in their review of 141 patients with femoral shaft fractures of similar age treated exclusively on skin traction reported good outcomes with fractures that had united with angulations of up to 20 degrees in the coronal plane (18). These findings are similar to our study where only three patients (9.6%) had residual malalignment of more than 5 degrees in the coronal plane, and none were more than 15 degrees. The low incidence of complications seen in our study, was despite the fact that patients were discharged early to mobilise as tolerated. This avoided the need to subject children to the potential complications, difficulty of care and emotional distress associated with spica casting.

4.1.3 General complications

Complications of skin traction are generally minor, unlike the potential major complications associated with spica casting (3-5). One patient in our study developed a pressure sore, which healed uneventfully, and no patients reported any long-term pain or any hip or knee stiffness. Refracture is also a well-documented complication of the management of femur fractures regardless of the technique used (2). None of our patients experienced any refractures. Most review articles and meta-analyses comparing surgical management to immediate or delayed spica casting, conclude that surgical management and in particular TENS reduces the risk of major complications over non-operative management (5, 36, 38). These major complications that are referred to, however, stem from the use of spica casting, and not skin traction, so interpretation of these findings should be made with caution (2, 26).

The absence of refracture, stiffness and malunion or non-union in our series highlighted the low risk of long-term physical complications associated with skin traction alone. Casas et al., in their review of outcomes of femur fractures managed initially in traction with ultimate conversion to spica casting, in 41 children aged four to 10 years found that no patients sustained refracture and only 2 patients had a limb length discrepancy of more than 10mm (4). They also found shortening to be more common than overgrowth, whereas in our study, all patients except for one reconstituted their initial lost length or were up to 10mm longer on the affected side (4). Patients in this group also complained of short-term stiffness, after spica removal all of which had resolved after 3 months (4). Essenyel et al. found that 12% had >1cm shortening of the fractured limb at final follow-up and 2 children sustained refracture (23).

There is a high incidence of bony overgrowth with conservative management of femur fractures. Hariga et al. found that the degree of overgrowth is especially associated with the degree of initial fracture shortening, and it occurs most prevalently within 18 months of injury (39). In a comparative analysis, our results compared favourably to Edvarson et al., who found in their study of non-operatively managed femur fractures, that 60% had post-fracture femur overgrowth of >1cm (40). Overgrowth was also exaggerated with comminuted and long oblique fractures (40). Comparing this finding with our study, we found that no patients had overgrowth >1cm and 97% reconstituted their initial lost length. In our study, there was also no identifiable association between increased initial shortening and increased limb overgrowth, but all patients managed within the parameters of 2cm of initial shortening went onto limb overgrowth, with 16 patients (51.6%) actually developing a longer leg. The one patient who had a 1cm shortening on the affected side was treated in traction despite an initial shortening of 3.2cm. This child was aged 10 at the time of injury with reduced growth and remodelling potential than a younger patient. The decision to treat on traction despite more than 2cm short ending was made based on the complex comminuted fracture pattern, which was deemed not a suitable fracture pattern for TENS surgery. He subsequently scored a satisfactory result. Our sample size was also too small to comment on any relationship between fracture patterns and limb overgrowth.

4.1.4 Rotational assessment

Rotational malunion is a common complication that occurs after femur fractures managed both operatively and non-operatively. Rotational deformities may lead to more than just cosmetic derangement, such as altered knee joint alignment, posterior shift of the weight-bearing axis in

the sagittal plane and even risk of later hip and knee degeneration (41, 42). However, these studies were not specific to the paediatric population, where there is potential for remodelling, and as such the true long-term effects of malrotation of the femur in children remain unclear. Malrotation was identified in 25% of our patients, all of which united in relative external rotation. Interestingly, none of the patients had noticed the deformity, nor reported any clinical sequelae. Malrotation is not considered in Flynn's criteria and therefore had no influence on our patient population outcome scores. Zeckey et al., in their study of 24 patients aged less than 15 years managed by various operative means, however found femoral malrotation of greater than 15 degrees in 41.6% of their patient population (15). Other similar studies have found femoral malrotation post-operatively ranging from 30-46% of their patient populations (21, 43). Of note, the accuracy of the clinical evaluation of femoral rotation has been shown to be unreliable, with a propensity to over-estimate malrotation (15). For this reason, especially given our absence of subjective patient complaints, the identified rotational discrepancy in our patient population may not be clinically relevant. CT evaluation may provide a more accurate representation of the true rotational profile in these patients and longer-term follow-up may yield clinical complaints that may manifest over time.

4.1.5 Considerations with prolonged skin traction in comparison with spica casting

Definitive management in traction requires in-patient monitoring and care. This requires prolonged admission and time away from family and school (3, 36). A draw-back of our treatment protocol is the time spent away from school, as was seen with a median of 8 weeks missed per school-going child. This loss of academic and social stimulation can be minimised by hospital facilities providing inpatient schooling. This however is not always possible. For these reasons, if this treatment modality is to be recommended over spica casting, Burton & Fordyce state that there should be proof of superior outcomes (44).

Gross et al. reviewed 72 femur fractures treated with immediate spica casting, 22 were found to have significant residual shortening and angulation (45). Lee et al. reviewed 63 closed femoral diaphyseal fractures treated with traction and delayed spica casting (6). They found no complications of malunion, non-union, LLD >1.5cm or rotational deformities (6). Unacceptable shortening of the femur has been seen in as many as 40% of patients with the use of early spica casting (23).

Delayed spica casting after an initial period of traction has been shown to yield better results with fewer complications compared to early or immediate casting, particularly with regards to malunion and shortening (6). This technique does however require a prolonged period of hospital admission until a period where there is radiological evidence of callus formation. When reviewing the literature for this treatment modality, the mean time in traction and hospital stay prior to conversion to spica casting ranged from 9 days to 31 days, with most studies recommending at least three weeks in traction prior to conversion to spica (6, 23, 38, 46-48). Casas et al. in their study had a mean age of 6.5 years and their mean hospital stay was 21 days with a mean time at spica removal was 10 weeks post injury (4). Our results with traction alone until clinical and radiological evidence of union averaged 26 days per child and is comparable to those of traction followed by spica casting. While we did have a young mean age (4.4 years), which would generally warrant less time spent in traction, our treatment protocol avoids the need for spica treatment and therefore, even in an older cohort, treatment time is reduced.

Akinyoola et al., in their retrospective review of 134 patients with a mean age of just over 6 years with isolated femoral shaft fractures, managed definitively in skin traction found a mean hospitalisation time of between six and seven weeks and a time to return to full independent weight-bearing of roughly ten weeks (8). Our study found a median time to full weight-bearing of 6 weeks. Younger children reliably showed a more rapid return to full weight-bearing than older children. This may explain the shorter time noted in our study compared to the older mean age of the patient cohort in Akinyoola's study.

4.1.6 Comparison of non-operative and operative modes of treatment

Gupta et al. described the ideal treatment of paediatric diaphyseal femur fractures as one that controls length and alignment, is convenient for the family, tolerable for the patient and causes little social or psychological distress (38). Chen et al. defines the optimal treatment as the one that results in faster fracture healing and fewer related complications (49). In their meta-analysis comparing conservative management using spica casting with surgical management with TENS, external fixation, and plate fixation, they showed that TENS was associated with the least risk of malunion and joint stiffness (49). It was also associated with reduced time to union, and reduced infection risk compared to other surgical techniques, although the infection risk is still higher than with non-invasive conservative management (49). Ghosh et al. showed that a lower cost of implants as well as decreased blood loss and operative time meant that

TENS is the preferable surgical treatment modality (50). As such, TENS has become the most widely used treatment modality in paediatric femoral fractures in the United States of America. According to the American Academy of Orthopaedic surgeons, there is level III evidence to recommend its use in length-stable, diaphyseal femur fractures in children aged five years to 11 years to reduce traction associated complications such as prolonged admission and school absence (3, 5, 50). There is also an overall reduction in cost and perceived emotional distress to the child (3, 5, 38, 50).

Song et al. in their retrospective series compared their outcomes according to Flynn's criteria of 51 patients that underwent treatment with either skin traction followed by spica casting or surgery with elastic nails (5). They showed in the non-operative group that 38% had excellent, 46% satisfactory and 16% poor outcomes, compared to 70% excellent, 26% satisfactory and 4% poor outcomes with TENS (5). They also showed smaller initial deformities and less shortening, overgrowth or overall limb length discrepancy with elastic nails compared to traction (5). They went on to recommend that due to the poorer remodelling potential, children over the age of six should preferentially undergo surgical fixation to avoid angular deformity that requires significant remodelling (5).

Our study suggested that, even in the presence of subtle limb length discrepancies and angular deformities, these children were clinically unaware of their deformity. These outcome findings are similar to findings of Stans et al., who looked at 85 fractures in 81 patients between the ages of six and sixteen comparing spica casting to the various surgical modalities (51). In their series it was noted that the deformities recorded in the conservative group remodelled sufficiently so as not to cause outcome concerns and were still found to yield excellent results (51).

4.1.7 Cost analysis of different modes of treatment for paediatric femur fractures

It has been suggested that irrespective of the treatment modality chosen, the overall cost is high, with conservative management in the form of skin traction in particular causing prolonged hospital stay and therefore high associated costs (8). Our study highlighted that the basic cost per patient ranged from R35 462 to R134 249 (for range of 14 to 53 in-patient days spent in traction in our sample) at CMJAH. Of interest, the daily cost for an inpatient is significantly cheaper at a regional or level 2 hospital compared to a level 3 hospital. The cost per day in a general ward in a level 2 facility is R1164 with an additional daily general medical

practitioner rate of R190 (35). Our patient sample treated at a level 2 facility would have cost R18 956 to R71 762, nearly half the price of that incurred at a level 3 facility. This is however a basic daily cost assessment that does not include other in-patient costs such as medication, X-rays and other miscellaneous costs that are not included in the quoted price. A more detailed assessment of the cost to both the hospital and to the patient and family would have required an in-depth analysis of the activity based-costing and social circumstances surrounding each patient, which is not easily accessible in our setting and therefore it fell outside the scope of this report. Despite the general consensus that early hip spica is the most cost-effective modality to treat femur fractures in children, the drawbacks and limitations have been cited (17). Hedin et al. did a cost analysis of traction in hospital until union, traction in hospital for 2 weeks and then completed at home, and immediate treatment with external fixation managed at 3 different hospitals (52). Both traction options were more expensive overall than external fixation, with the main determinant of cost being the amount of days spent in hospital (52). Costs of traction can be cut by 40% by introducing a home program after 2 weeks, but this requires appropriate home care and facilities, which may not be present in resource-constrained environments (52). When comparing definitive management in traction to surgical treatment with TENS, Gaid et al. showed a reduction of hospital stay by 75% with operative treatment and an overall cost reduction of 60% with TENS (including readmission for removal) compared to traction alone (53).

4.1.8 Application of findings to a resource-constrained environment.

While the current recommendations are supporting the use of TENS in younger patients for the reasons highlighted, in resource poor or overburdened health systems, the expertise or resources may not always be available (50). Providing evidence that conservative management with skin traction provides at least similar results, despite longer admission times, supports the use of this treatment modality, which may assist in easing the surgical burden faced by many of these resource constrained environments. In an attempt to draw these conclusions, our results were compared to those of Flynn et al. (30). In their study, they looked at the outcomes of femur fractures managed by TENS in 234 femur fractures. Of note, their mean age was markedly older than in our study, with an mean age of 10 years compared to that of 4 years and 5 months in our study (30). However, looking at the outcomes of patients in their study aged 10 and younger, 72% had excellent outcomes, 22% satisfactory and 6% poor (30). This is in comparison to 81% of patients in our study obtaining an excellent outcome, 16% satisfactory and 3% poor according to the same outcome measure. In further comparison to Flynn et al., we

had no refractures compared to their 1.7% refracture rate and Coronal malunion rates were similar (30).

Ghosh et al. compared 40 children with diaphyseal femur fractures between the age of 6 and 14 years allocated randomly to treatment with TENS to conservative management with traction (Skeletal and Thomas splint traction) (50). Outcomes were reviewed at one year post injury, where according to Flynn's criteria, 20% of conservatively managed patients had excellent results and 70% had satisfactory results with 10% poor results (50). This compared to 80% excellent and 20% satisfactory results with no poor results for patients managed with TENS (50).

4.1.9 Implications of findings

A particular advantage of our treatment algorithm is the potential for its use in small regional level 2 hospitals without access to orthopaedic expertise with confidence to yield equivalent long-term outcomes to those managed with surgery in tertiary specialist hospitals. In these cases, all that is required is appropriate patient selection, traction set up, nursing and radiographs to ensure appropriate reduction, as well as closely monitored progress. If at any stage parameters for continuation of traction are not met, the patient can be referred to a specialist center for further management and consideration for surgical fixation. According to our study, 83.2% of patients initiated on traction completed time in traction, with 16.8% losing reduction and requiring surgical intervention. The children that lost reduction had an age range from five years and nine months to 10 years and four months, suggesting that older children may be at risk of losing reduction while on traction. Despite this, there is a high success rate, potentially allowing more than four out of five patients aged 10 years and under with isolated closed diaphyseal non-pathological femur fractures to be successfully treated in non-orthopaedic centres at nearly half the cost to state than if they were treated at a level 3 facility. It would just mean that with older children, there is a higher risk loss of reduction. This protocol allows a reduction in patient burden of tertiary level hospitals and reduces surgical load on theatres that are beyond capacity. An algorithm of this treatment protocol is provided below.

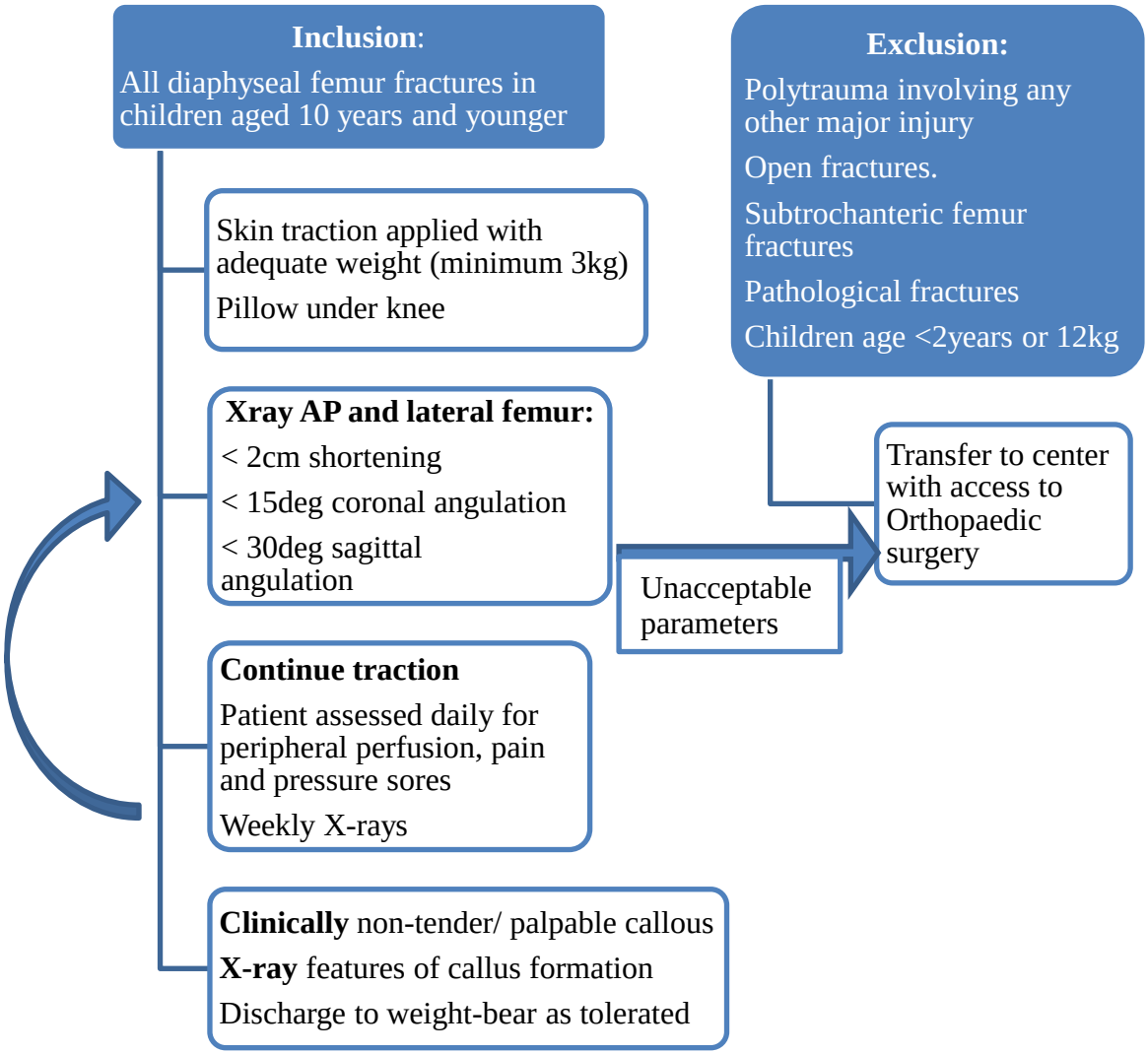


Figure 4.1: CMJAH treatment algorithm for femur fractures in children aged 10 years and younger.

4.2 LIMITATIONS

The retrospective nature of the study meant that at the time of data collection many contact details for patients recorded had changed and as a result many patients that met the inclusion criteria were not reachable for follow-up. The low follow-up rate affected the sample size of included patients in the study, which limited the conclusions that could be drawn from the study and meant that results obtained did not reach statistical significance.

There is a lack of understanding of anticipated outcomes, especially in paediatric patients sustaining femur fractures, which makes evaluating outcomes very difficult (54). There is a lack of validated outcome measure tools in paediatric patients who have sustained fractures in general. A validated and fracture-specific patient-reported outcome measure may more

accurately identify subtle subjective complaints associated with residual limb deformities as a result of femur fractures. The utilisation of Flynn's criteria may be a limitation of measured outcomes of the study. Flynn's criteria is the most common instrument used to evaluate lower limb outcomes (54). It is a physician-reported outcome measure that has been used in nine trials previously to assess functional outcomes post femur fractures, despite it being designed in the evaluation of outcomes post TENS in femur fractures (54). The accuracy of Flynn's criteria in determining a true reflection of patient outcomes post non-operative management of femur fractures in children has not been validated.

A detailed cost analysis reviewing additional costs not included in the pricing schedule, such as X-rays, medication and consumables; as well as the cost to patients and families was not performed. Future studies may help to shed more light in this area and potentially highlight that the cost of in-patient traction may not be an affordable means of treating children with femur fractures definitively.

There was also no control group to compare the findings of the treatment protocol to, which meant that the findings need to be compared to outcomes of other modalities of treatment reported in the literature. Our sample reviewed outcomes of a range of patients aged 10 and under.

A further possible limitation is the possibility of inaccuracy of the built-in measurement tool in the PACS software system, that may influence radiological outcome measurements.

4.3 RECOMMENDATIONS

Future research in this area would require a larger sample size to establish whether there is significance to the outcomes highlighted in this study, possibly to implement the protocol highlighted in this study in peripheral hospitals and re-evaluate the outcomes in a prospective and more high-powered study.

An improved, updated and more specific patient reported outcome measure tool should also be used to more directly ascertain if there are truly no adverse clinical effects experienced by paediatric patients having sustained femur fractures that were managed conservatively in skin traction until union.

CHAPTER 5

CONCLUSION

This study shows that clinical and radiological outcomes of isolated closed femoral shaft fractures, treated with the use of skin traction alone, in children aged 10 years and under yield clinically acceptable results with few complications. The protocol used is shown to be safe and reliable with 83.2% of patients successfully completing traction without the need for surgical intervention.

Time spent in skin traction had a mean of 26 days per patient in this study with older children spending more time in traction as expected. Most children had returned to full weight-bearing without assistance within one month of discharge. In addition, this study also shows that the described conversion of traction to spica casting once radiological features of callus formation are present, may not be necessary. Patients in our study were discharged to weight-bear as tolerated after evidence of union with no cases of refracture or further complications.

The cost of definitive treatment of femoral fractures in traction is the most expensive modality of treatment for paediatric femur fractures, where we showed that the cost per patient ranged from R35 462 to R134 249 for the period they were admitted. This is however the cost of treatment at a level 3 hospital. It would be significantly less costly if patients were treated definitively in primary and secondary hospitals. These patients may be safely and reliably treated using our treatment algorithm without the need for an Orthopaedic specialist in most cases.

Despite surgical treatment, in particular TENS, becoming the favoured treatment modality in the majority of paediatric femur fractures with ever expanding indications, femur fractures in children are very forgiving. Outcomes of our study are comparable to those reported for TENS in the literature. Due to the powerful remodelling capacity of growing femurs there is still a significant role for non-operative management and in particular skin traction, especially due to its low risk profile and ease of application and follow-up.

Implementing this protocol within our cluster hospitals would possibly allow for alleviation of the burden of referral to tertiary hospitals in our resource poor environment.

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Appendices

Appendix A: Research Questionnaire

Table A.1: Patient follow-up record

Patient Study number	
Contact details	
Patient age (years)	
Gender	
Demographic	
Mechanism of injury	
Associated injuries	
Limb injured	
Pattern of fracture	
Location of fracture	
Length of hospital stay (days)	
Requirement to repeat school year	
Time taken to return to school	
Time to return to full weight-bearing	
Time from injury to current follow-up	
Antalgic gait	
Short limb gait	
True limb length discrepancy	
Hip Flexion	Right Left
Fixed Flexion Deformity	Right Left
Hip Abduction	Right Left
Hip Adduction	Right Left
Hip Internal rotation	Right Left
Hip External rotation	Right Left
Knee ROM	Right Left
Femur length (mm)	Right

Initial	Left
Femur length (mm) Discharge	Right Left
Femur length (mm) Follow-up	Right Left
Fracture-site diaphyseal angle (degrees) Initial	AP Lateral
Fracture-site diaphyseal angle (degrees) Discharge	AP Lateral
Fracture-site diaphyseal angle (degrees) Follow-up	AP Lateral
Interphyseal angle (degrees)-Initial	AP
Interphyseal angle (degrees)-discharge	AP
Interphyseal angle (degrees)- follow-up	AP
Flynn's criteria result	

Table A.2: Flynn's criteria (30)

Parameter	Excellent	Satisfactory	Poor
Limb length discrepancy (Clinical)	<1cm	1-2cm	>2cm
Malalignment (Radiological)	<5deg	5-10deg	>10deg
Pain	None	None	Present
Complication	None	Minor	Major or lasting morbidity

Appendix B: Overview of patient raw data including age, outcome, fracture pattern, displacement, length of traction, presence of limb length discrepancy and rotational discrepancy.

Patient number	Age at injury (years-months)	Time to follow-up (mon)	Outcome (reason for less than excellent outcome if applicable)	Fracture pattern	Initial displacement	Length of traction / length of hospital stay (days)	Limb length discrepancy	Rotational discrepancy	Time to full weight-bearing from date of injury (weeks)
1	2-9	48	Satisfactory (pressure sore)	Spiral	Undisplaced	14/ 14	Nil	Nil	4
2	3-6	47	Excellent	Spiral	Incomplete	25/ 26	0.5cm long	Nil	8
3	4-4	44	Excellent	Transverse	Complete	18/ 22	Nil	Nil	6
4	5-9	46	Excellent	Transverse	Complete	31/ 35	Nil	Nil	11
5	2-10	46	Excellent	Spiral	Complete	19/ 19	0.5cm long	Nil	5
6	2-4	43	Excellent	Spiral	Incomplete	21/ 22	0.5cm long	Yes (15deg external)	4
7	6-0	43	Satisfactory (LLD)	Transverse	Incomplete	35/ 37	1cm long	Yes (10deg external)	6
8	4-5	40	Excellent	Transverse	Complete	30/ 31	0.5cm long	Nil	7
9	2-11	40	Poor (residual angulation - 14deg varus)	Oblique	Complete	25/ 29	Nil	Nil	6
10	4-2	39	Excellent	Spiral	Incomplete	28/ 31	Nil	Nil	5
11	6-10	39	Excellent	Transverse	Complete	32/ 35	Nil	Nil	9
12	2-5	37	Excellent	Spiral	Incomplete	19/ 22	Nil	Nil	5

13	2-2	43	Excellent	Spiral	Incomplete	16/ 19	Nil	Nil	6
14	4-3	36	Excellent	Spiral	Incomplete	22/ 25	0.5cm long	Nil	8
15	2-7	34	Excellent	Transverse	Incomplete	19/ 23	0.5cm long	Yes (10deg external)	5
16	1-8	34	Excellent	Spiral	Incomplete	13/ 14	Nil	Nil	6
17	8-4	34	Satisfactory (angulation 7deg varus)	Comminuted	Incomplete	44/ 45	0.5cm long	Yes (10deg external)	9
18	4-7	24	Excellent	Transverse	Complete	30/ 30	Nil	Yes (15deg external)	6
19	6-7	30	Excellent	Transverse	Complete	37/ 41	Nil	Nil	8
20	10-6	29	Satisfactory (angulation 5deg varus & LLD)	Comminuted	Complete	51/ 53	1cm short	Yes (30deg external)	14
21	2-8	28	Excellent	Spiral	Incomplete	19/ 19	0.5cm long	Nil	4
22	4-2	25	Excellent	Spiral	Complete	25/ 25	0.5cm long	Nil	6
23	3-7	24	Excellent	Spiral	Complete	20/ 22	Nil	Nil	5
24	6-5	24	Satisfactory (LLD)	Transverse	Complete	26/ 31	1cm long	Nil	6
25	2-4	32	Excellent	Oblique	Incomplete	12/ 14	0.5cm long	Nil	3
26	7-3	49	Excellent	Transverse	Incomplete	42/ 43	0.5cm long	Yes (20deg external)	11
27	2-4	26	Excellent	Spiral	Undisplaced	22/ 22	Nil	Nil	3
28	3-1	51	Excellent	Spiral	Complete	25/ 26	0.5cm long	Nil	5
29	3-9	24	Excellent	Spiral	Complete	22/ 23	Nil	Nil	5

30	3-5	44	Excellent	Spiral	Incomplete	26/ 28	0.5cm long	Yes (10deg external)	6
31	5-4	40	Excellent	Transverse	Incomplete	34/ 35	0.5cm long	Nil	7

Appendix C: University of Witwatersrand Human Research Ethics Committee ethics clearance certificate

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Dr C Hitge

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M191196

NAME: (Principal Investigator)	Dr C Hitge
DEPARTMENT:	School of Clinical Medicine Department of Surgery Division of Orthopaedic Surgery Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Outcomes of diaphyseal femur fractures managed in children 10 years and younger at Charlotte Maxeke Johannesburg Academic Hospital
DATE CONSIDERED:	2019/11/29
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Professor A Robertson and Dr D Simmons
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2020/03/26

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. I agree to submit a yearly progress report. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **November** and will therefore reports and re-certification will be due early in the month of **November** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

30/3/2023
Date

PLEASE QUOTE THE CLEARANCE CERTIFICATE NUMBER IN ALL ENQUIRIES

Appendix D: CMJAH CEO permission letter

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. N. Mzila
Office of the Clinical Director
Email: Nolwazi.Mzila@gauteng.gov.za
Tell: (011): 488-4812
17 September 2019

Dear Dr. C. Hitge

STUDY TITLE: Structural and Functional Outcomes of Peadiatric Femur Fractures Managed Non-Operatively In Traction at Charlotte Maxeke Johannesburg Academic Hospital

Permission to review patient file for conduction of the above mentioned study is provisional approved. Your study can only commence once Ethics approval is obtained. Please forward a copy of your Ethics Clearance Certificate as soon as the study is approved by the Ethics Committee for the CEO's office to give you the final approval to conduct the study.

Supported /~~not supported~~

Dr. M.I. Mofokeng
Clinical Director
DATE:

Approved /not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 20.09.2019

Appendix E: Participant information leaflet and assent form

PARTICIPANT INFORMATION LEAFLET AND ASSENT FORM

Study title: Outcomes of diaphyseal femur fractures managed in children 10 years and younger at Charlotte Maxeke Johannesburg Academic Hospital

RESEARCHERS NAME(S):
DR C Hitge, Prof. A Robertson, Dr D Simmons

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What is research?

Research is something we do to find new knowledge that helps us treat people to the best of our ability. This is done by looking at all the people we treat after we have treated them to see how they are doing.

What is this research project all about?
Our research project is based on children who have broken their leg like you did. Because you hurt your leg and were with us in hospital for so long, we want to see how your leg is doing now.
I will need to ask you some questions, examine your leg and send you for an X-ray so that I can see how well the bone has healed. At no stage will you feel any pain or discomfort, and if you feel uncomfortable at all, you can tell me to stop.

Will anyone know I am in the study?
If you and your parent have agreed to be in the study. All of the information we get from you will be kept confidential. This means we will not share it with anyone without getting permission from you and your parents. We will also give you a study number which will be your secret identity to keep your information.
Do you understand this research study and are you willing to take part in it?

YES	NO

Has the researcher answered all your questions?

YES NO

Signature of child	Date	Time	Printed Name
Signature of person who explained this research	Date	Time	Printed Name

Appendix F: Participant Information Document and Consent Form given to parents

WITS UNIVERSITY

STUDY INFORMATION DOCUMENT

Study title: Outcomes of diaphyseal femur fractures managed in children 10 years and younger at Charlotte Maxeke Johannesburg Academic Hospital

Thank you very much for taking your time to consider involvement in this research study.
Introduction:

I, Curran Hitge, am a post-graduate student of the University of the Witwatersrand. I am doing research on the outcome of femur fractures managed in skin traction in children at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). Research is a process used in seeking new knowledge to improve care for future similar patients. In this study we want to learn if the method used for treating these femur fractures at CMJAH has similar functional and radiological outcomes to those treated with surgery in other institutions. We hope to show equivocal outcomes between the treatment options and therefore provide an argument for these fractures to be treated at peripheral hospitals without orthopaedic surgeons in an attempt to lessen the patient burden on academic or tertiary hospitals.

Invitation to Participate: We are asking for your permission to include your child in a research study.

What is involved in the study:

1. The reason for requested participation in the study is because the patient suffered a femur fracture that was treated at CMJAH and met the criteria for inclusion.
2. The study will retrospectively assess the X-rays of the patient from admission as well as upon discharge. The patient will then be called back for a routine follow-up visit, where the study will be discussed with the family and if they are willing to participate an informed consent will be signed.
3. Each appointment will take roughly 20 minutes of the patient's time, with a further 30 minutes for performing an X-ray.
4. X-rays will be attained of the patient's normal and injured thigh.
5. A hardcopy questionnaire will be completed by the examiner for all patients. Questions will attempt to seek information around the injury itself, the rehabilitation process, as well as any problems or complications experienced by the patient.
6. A physical examination of the lower limbs will be performed.
7. Information attained will be converted into an excel spreadsheet and viewed relevant results added to the collective and compared to available literature.

There are no risks associated with being included in the study.

Benefits of being in the study: There is no direct benefit for the patient of being involved in the study. The longer-term objective is the possibility of helping to lessen the patient burden

on tertiary hospitals by enabling non-orthopaedic healthcare professionals to manage these fractures in a regional or peripheral hospital.

Any pertinent information on the study while involved in the project and after the results are available will be made available to the participant if requested.

Participation is voluntary, refusal to participate will involve no penalty and the participant may discontinue participation at any loss of benefits to which the Participant is otherwise entitled. There is no requirement to provide a reason for withdrawing and any data collected on such a person will in default be destroyed, unless the Participant specifically consents to its retention.

Confidentiality: Personal information will be treated in the strictest confidence and will only be available to the Principal Investigator (PI) and his/her Supervisor. The only exceptions - and all of them are rare - would normally be:

1. personal information may be disclosed if required by law
2. the Human Research Ethics Committees of the University may exceptionally require personal data to respond to a formal complaint, or for a compliance audit
3. the South African Health Products Regulatory Authority (SAHPRA), which is the successor body to the South African Medicines Control Council (SAMCC), might conceivably require access to personal data, if conducting an investigation into a drug trial

If results are published, this may, exceptionally, lead to cohort, or more rarely, individual identification. All data collected in the course of the study will be securely retained for two (2) years, if a scientific publication arises from the study and six (6) years, if there is no publication. Thereafter it will be destroyed accordingly.

Contact details of researcher/s:

Dr C. Hitge:
Cell: 0714006969
Email: cuz.hitge@gmail.com

Outputs
Tell the reader what the outputs of the study will be and offer to share them with him/her after the study is completed

Contact details of HREC administrator and chair – for reporting of complaints / problems. This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za
Thank you for reading this Study Information Sheet.

Signature and Consent/Permission To Be in the Research Section

Before making the decision regarding enrollment in this research, you should have:

- Discussed this study with an investigator
- Reviewed the information in this form
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research, and have received answers to those questions. You will receive a copy of the signed and dated form to keep for future reference.
Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

Signature of Caregiver of Participant	Date	Time	Printed Name

Person Explaining the Research: Your signature below means that you have explained the research to the participant or participant representative and have answered any questions about the research.

Signature of person who explained this research	Date	Time	Printed Name

Only approved investigators for this research may explain the research and obtain informed consent.
A witness or witness/translator is required when the participant cannot read the consent document, and it was read or translated.