

BASICS

Biomechanical Analysis of stainless Steel In Children with femoral Shaft fractures

Establishing the load to failure in stainless steel elastic nail fixation of a paediatric femur model and correlating this with the maximum patient weight

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Research Protocol

Contents

1. BACKGROUND	1
1.1 Literature review	1
1.2 Problem	6
1.3 Suggestion	6
1.4 Purpose	6
2. OBJECTIVES AND OUTCOMES.....	6
2.1 Research question PICO	6
2.2 Primary outcome.....	7
2.3 Hypotheses.....	7
3.METHODS.....	7
3.1 Definition of terms	7
3.2 Study design	7
3.3 Setting and study population (description).....	7
3.4 Subjects	7
3.5 Sample recruitment and techniques	7
3.6 Sample size and power calculation	8
3.7 Screening, enrolment and study procedures	8
3.8 Measurements	9
4. DATA MANAGEMENT AND ANALYSIS.....	9
4.1 Data collection plan.....	9
4.3 Data entering and storage.....	9
4.4 Data analysis plan.....	9
4.4.1 Descriptive statistics.....	10
4.5 Resources required	10
1. ETHICAL AND LEGAL CONSIDERATIONS	10
2. DATA DISSEMINATION PLAN	10
3. STUDY TIMELINE.....	11
4. LIMITATIONS	11
5. REFERENCES	11

1. BACKGROUND

1.1 Literature review

Paediatric femur fractures are the commonest diaphyseal fractures of childhood after those of the radial and ulnar shaft and the tibial shaft. Common mechanisms include falls, particularly from playground equipment, motor vehicle accidents and sporting injuries.¹ Femur fractures in children are treated by a variety of methods, including traction, immediate spica casting, traction followed by spica casting, internal fixation with plate and screws, external fixation, and intramedullary fixation. The choice of treatment may be influenced by the age of the child, by the location and pattern of the fracture, and to a great extent by regional, institutional, or surgeons' preferences.² Elastic stable intramedullary nailing (ESIN) for paediatric fracture management has gained increasing popularity since its introduction in the late 1970s. This technique, adapted from existing flexible rodding techniques, was developed in Nancy, France and culminated in 1988 with the publication of Métaizeau's book on the technique and Ligier et al published the first major publication on the stabilization of femoral fractures in children in an English language publication.³ Elastic stable intramedullary nailing has become an increasingly popular method of fixation of paediatric femoral fractures across Europe and the United States and during the last ten years titanium elastic nailing have become the most widely-used treatment for fractures of the diaphysis of the femur in children of school age in the United States.⁴

Flexible nailing offers many advantages over traditional nonsurgical management options for the paediatric femoral shaft fracture, including shorter hospital stays, rapid patient mobilization, and alleviation of the psychological impact associated with prolonged immobilization. Moreover, this technique offers distinct advantages over other surgical treatment options because it does not seem to carry the same refracture risk compared with external fixation, requires less exposure than does plate fixation, and avoids the complications of femoral head osteonecrosis and premature greater trochanteric epiphysiodesis associated with rigid intramedullary devices⁵ and most importantly provides a stable fixation and allows rapid functional recovery.⁶

To achieve this balanced nailing when two nails are used, each nail is inserted to achieve a 3-point fixation: the nail entry point, the apex of the curve (which should be at the fracture site), and the tip of the nail, where it is embedded into cancellous bone. This construct produces an "elastic stability" at the fracture site that is an ideal environment for callus formation.⁷ The nails are pre-curved in a "C" configuration to achieve this and in general the pre-curve that should be put on a nail should be approximately three times the diameter of a long bone at its isthmus. By pre-bending the nails the inner contact pressure can be markedly increased, which bring the fragments back into an anatomical position. The curvature of the nails is achieved by bending them beyond their elastic limit. From this new position of stability, they resist the tendency to be straightened (thus creating some tension

within the intramedullary canal) as well as a tendency to be further bent, thus resisting deformation.³ The nails are introduced through a hole made in the distal femoral metaphysis just above the physis. They are carefully pushed up the medullary canal to the already-reduced fracture site. The tip of the nail that entered the lateral distal cortex should come to rest just distal to the trochanteric apophysis. The opposite nail should stop at the same level, but the tip should point toward the calcar region of the femoral neck.⁸ Distally, the nail is cut so that 1–2 cm remains outside the cortex. The extra osseous portion of the nail should be bent slightly away from the bone. Care should be taken to ensure that the pre-bending of both nails is symmetrical over the same length and that both two nails of the same thickness are used to produce an equal “restoring force”.⁹ Each nail should be 40% of the narrowest diameter of the canal.¹⁰

Relatively few modifications have been made to the original technique in the last forty years, which illustrates the sound biomechanical principles and simplicity of the technique. Jean-Paul Metaizeau, the originator of the technique, pointed out that poor results after ESIN were typically due to incorrect constructs, incorrect indications, and insufficient surgeon training.¹⁰ With widespread acceptance of the ESIN technique for paediatric patients with diaphyseal fractures of longbones, the indications have been further expanded to metaphyseal fractures, comminuted fractures, pathologic fractures, and fractures of smaller bones (including clavicular, supracondylar humeral, and metacarpal fractures).¹⁰

The literature is replete with reports of the clinical success of ESIN, but initial reports related to its complications were scarce.

The most commonly reported complication related to ESIN involves pain and irritation at the nail entry site. The prevalence of nail irritation has been reported up to 52%, with the femur being the most commonly affected site.² Nail prominence can lead to more serious complications such as skin breakdown, superficial or deep infection, effusion at the adjacent joint and stiffness due to soft-tissue irritation, bursitis, reoperation to perform nail trimming or nail advancement, and early implant removal with the subsequent risk of refracture. The worst complication is osteomyelitis, which can extend to the diaphysis. For femoral ESIN, Shital et al.¹⁰ recommend that approximately 1 to 2 cm of the nail should be left outside of the medullary canal, with the nail ends flush with and parallel to the metaphysis.

The various factors implicated in malunion are nail size, fracture pattern, material, age and body weight. Angular malunion and limb-length discrepancy are relatively common.

The correct nail thickness (40%) is required for adequate stability and optimum biomechanics. Both nails must have identical thickness and curvature. Any mistake is particularly detrimental for the

femur, since a second anaesthesia is required either to replace the nails, perform further reduction or apply a spica cast.⁹

Malunion and loss of reduction requiring reoperation were significantly associated with the use of mismatched nails. Unni et al.² reported that loss of reduction or radiographic malunion was 19 times more likely when mismatched nails were used. The use of nails of two different diameters produces asymmetric forces resulting in angulation in the direction determined by the larger nail.

Femoral fractures in the paediatric population can be classified as either “length stable” or “length unstable” with the length-unstable fractures comprising of either comminuted or long oblique fracture configurations. Ideally, ESIN should be used for length-stable (transverse or short oblique) fractures.^{11,12} Up to 16% angular malunion after femoral ESIN have been reported in literature.¹³ Sink et al.¹² and Narayanan et al.² reported an increased incidence of complications, including malunion, resulting in unplanned surgery when elastic nails were used in the unstable fracture group.

Ho et al.¹⁴ reported a 12% rate of unplanned revision surgery after treatment of unstable fracture patterns compared with 5% for stable fractures. However, other studies have shown no association between fracture pattern and malunion^{11,15}

The material properties of titanium and stainless steel are very different. Titanium nails are quite flexible in bending yet must be substantially overbent to maintain a curvature. This “elastic” nature of titanium is a feature that has been purported to be important in achieving success with this technique of femoral fixation. Stainless steel, on the other hand, is much stiffer, requiring more force to bend the nails.¹⁶ In vitro mechanical studies have demonstrated equal or superior fixation of paediatric femoral fractures with use of titanium elastic nails as compared with stainless steel elastic nails. The biomechanical properties of titanium are often considered to be superior to those of stainless steel for intramedullary fracture fixation with regard to biocompatibility, modulus of elasticity, osseointegration, corrosion resistance, and magnetic resonance imaging compatibility whereas titanium is more notch-sensitive and has a fatigue strength less than that of stainless steel.¹¹

However, comparing the clinical complications associated with stainless steel elastic nails and titanium elastic nails when used for the treatment of paediatric femoral shaft fractures, Wall et al.¹¹ reported the unexpected finding that the rate of malunion was nearly four times higher in association with titanium nails as compared with stainless steel nails. They reported that their results indicate that the less expensive stainless steel elastic nails are clinically superior to titanium nails for paediatric femoral fixation primarily because of a much lower rate of malunion. They concluded that the increased flexibility of titanium as compared with stainless steel nails may be responsible for this outcome.

Experience shows that excellent results have been achieved in children less than 10 years old, whatever the implant material used. However a completely different situation is encountered in older children and adolescents, especially if overweight or obese. Adolescents have less potential to fully remodel residual angulation, malunion and shortening.

Moroz et al.⁴ reported an age of more than eleven years to be a predictor of poor outcome, whereas Ho et al.¹³ reported an increased complication rate in children over ten years of age. Moroz et al.⁴ and Weiss et al. suggested an upper weight limit of 49 or 50kg respectively. Others have found no direct correlation between excessive body weight and malunion.¹¹ Luhmann et al.¹⁵, however, concluded that a combination of increased body weight and smaller nail diameter would lead to increased sagittal angulation postoperatively. All of these studies used titanium nails exclusively. Shital et al.¹⁰ recommended the use of stainless steel elastic nails for lower-extremity longbone fractures, especially in older, heavier patients or patients with a length-unstable fracture. Hunter³ suggested the use of stainless steel nails for adolescent and obese children. He reported that the Arbeitsgemeinschaft für Osteosynthesefragen (AO) paediatric group has shown that a stainless steel nail is more rigid and has the same strength and resistance to recall forces compared to a titanium nail one size larger (e.g., a 3.5-mm stainless steel nail has the strength of a 4.0-mm titanium nail). Therefore, if titanium nails are used, their diameter must be larger than the corresponding stainless steel nail. This suggests that 3.5-mm titanium implants should be used cautiously in large patients with a relatively wide intramedullary canal.¹⁷

Titanium is currently the most popular material used for elastic stable intramedullary nail fixation of paediatric femoral fractures¹¹. By establishing the load at which failure of titanium elastic nails in the sagittal and coronal planes occurs, one can determine the maximum patient weight at which titanium elastic nails can prevent malalignment in the sagittal and coronal planes when used to treat a midshaft femur fracture in a child. Ying et al.¹⁸ determined the load at which permanent sagittal and coronal deformation of titanium elastic nails occurs and provided biomechanical evidence that patients weighing more than 40 to 45 kg who undergo stabilization of a transverse midshaft femur fracture with titanium elastic nails are at risk for loss of reduction in the sagittal and coronal planes.

This weight cut-off correlates well with findings from clinical studies. Children weighing more than 49kg were five times more likely to have a poor outcome than those weighing less than this when using titanium elastic nails.⁴

Multiple authors have recommended the use of stainless steel elastic nails in adolescent and overweight children to prevent loss of reduction and malunion however there are currently no

biomechanical or clinical evidence that we can use to guide decision making in these patients.^{10,11,17} With the prevalence of childhood obesity on the rise and the tendency for sagittal and coronal angulation of femur fractures treated with titanium elastic nails, it is necessary to determine the load at which permanent sagittal and coronal deformation of stainless steel elastic nails occurs. This will determine the maximum patient weight at which stainless steel elastic nails can prevent malalignment in the sagittal and coronal planes when used to treat a midshaft femur fracture in an adolescent or overweight child. If the treating surgeon doesn't know the weight cut off, when opting to treat a patient with stainless steel elastic nails, this may result in an unfavourable outcome because this will lead to loss of reduction of the fracture and malunion.

1.2 Problem

The biomechanical literature has not established the load at which failure of stainless steel elastic nails in the sagittal and coronal planes occurs.

1.3 Suggestion

If we could determine the load at which permanent sagittal and coronal deformation of stainless steel elastic nails occur in a paediatric femur fracture model, then the resulting bending moments could be correlated with in vivo gait data to find a patient weight cut-off.

1.4 Purpose

The purpose of this study is to determine the load at which failure of stainless steel elastic nails in the sagittal and coronal planes of a transverse midshaft femur fracture occurs and to correlate this with the maximum patient weight.

2. OBJECTIVES AND OUTCOMES

2.1 Research question PICO

Population and Context: Synthetic paediatric-sized femur models will be used for mechanical testing.

Issue: The load at which permanent sagittal and coronal deformation of stainless steel elastic nails occurs in the paediatric femur fracture model is unknown.

Outcome: To determine a patient weight cut-off for adolescents and overweight children, who undergo stabilization of a transverse midshaft femur fracture with stainless steel elastic nails, who are at risk for loss of reduction in the sagittal and coronal planes.

2.2 Primary outcome

To determine the load at which failure of stainless steel elastic nails in the sagittal and coronal planes of a transverse midshaft femur fractures occurs and to correlate this with the maximum patient weight.

2.3 Hypotheses

Stainless steel elastic nails have a higher load to failure than titanium elastic nails in a paediatric femur fracture model and could therefore be used in adolescent and overweight children.

3. METHODS

3.1 Definition of terms

TENS: Titanium elastic nailing system.

ESIN: Elastic stable intramedullary nailing.

Malunion: Defined as healing of a fracture in a nonanatomic position.

Overweight child: Overweight is defined as a BMI at or above the 85th percentile and below the 95th percentile for children and teens of the same age and sex.

3.2 Study design

Biomechanical analysis of stainless steel elastic nailing in a paediatric femur fracture model.

3.3 Setting and study population (description)

Biomechanical analysis will be conducted in the Mechanical engineering department of the University of Cape Town.

3.4 Subjects

Paediatric sized femur models (Sawbones, Europe AB, Sweden). Each 4th generation model is made of a rigid foam cortical shell with cancellous material in the distal and proximal ends. This specific femur model allows for biomechanical testing. The femurs measures 37.5cm in length and has an intramedullary canal diameter of 9.5mm. Synthetic femurs will be used because of the low availability and expense of obtaining cadaveric paediatric femurs. Synthetic models also minimize the variability between specimens and provide a consistent specimen size.

3.5 Sample recruitment and techniques

10 Synthetic paediatric-sized femur models will be used for biomechanical testing.

3.6 Sample size and power calculation

Paediatric sized femur models are manufactured identical to minimize the variability between specimens. The elastic femur nails will be inserted in an identical fashion for each specimen to further limit any differences between the specimens. Therefore a fixed number of fracture models needed to test cannot be calculated and we decided on 10 fracture models which is in line with multiple previous biomechanical studies similar to this one.¹⁶¹⁷¹⁸

3.7 Screening, enrolment and study procedures

Synthetic pediatric-sized femur models will be used for mechanical testing. A synthetic model will be used to minimize the variability between specimens and because pediatric cadaveric bones are expensive and difficult to obtain. The specific 4th generation Sawbone used is corresponding to an adolescent sized femur and the approached question is most relevant for children weighing more than 40 kg and adolescents. Modern synthetic bone models have been shown to simulate physical behaviour of cadaveric bone and also reproduce anatomical landmarks with cortical walls and cancellous canals.¹⁷

Transverse midshaft fracture patterns will be created with a handheld saw. The fracture will be created 12.5 cm distal to the lesser trochanter in all of the models. Two 4.0-mm stainless steel elastic nails will then be contoured with a long, gentle 3-point bend and placed intramedullary in a retrograde fashion through medial and lateral insertion sites in the metaphysis of the distal femur to stabilize the simulated fractures. The lateral nail will be advanced until the tip laid just distal to the greater trochanteric apophysis. The tip of the medial nail will be advanced to the same level, with the tip pointing toward the calcar region of the femoral neck. The final nail configuration will be a divergent C, with the apex of the convexity at the level of the fracture. Fluoroscopic imaging will be used to place the nails in a divergent configuration and to assess nail position and fracture reduction.

All specimens will be biomechanically tested using a Zwick universal material testing machine (UTM, Zwick Company, Ulm, Germany). Five specimens will be subjected to anterior-posterior (sagittal plane) bending, and 5 specimens to lateral (coronal plane) bending. For the sagittal plane bending test, each femur will be placed horizontally between 2 sets of rollers. For the coronal plane bending test, each femur will be rotated 90 degrees so that the rollers rested on the lateral and medial surfaces of the femur. The fracture site will be centred between the rollers. Each model was supported on its surface by rollers spaced 12.5 cm apart. The distance between the rollers will be identical for all the specimens to ensure uniform distribution of load. A preloading force of 10N was applied with accommodation time of 30 seconds. This is to ensure complete and reproducible contact between the specimen and loading fixture. A vertical load was applied at 0.1 mm/s until failure of the instrumented femur. Sagittal angulation of the instrumented femur will be measured after failure.

Data analysis will be performed to determine the yield load, bending stiffness, and bending moments for both testing configurations.

3.8 Measurements

The following variables will be recorded:

- I. Sagittal bending
 - a. Yield load (N)
 - b. The sagittal angulation of the instrumented femurs after failure.
 - c. The sagittal angulation of the instrumented femurs after removal of the load.
 - d. Bending stiffness (N/mm).
 - e. Bending moment calculated from the average yield load (Nm).
- II. Coronal bending
 - a. Yield load (N)
 - b. The coronal angulation of the instrumented femurs after failure.
 - c. The coronal angulation of the instrumented femurs after removal of the load.
 - d. Bending stiffness (N/mm).
 - e. Bending moment calculated from the average yield load (Nm).

4. DATA MANAGEMENT AND ANALYSIS

4.1 Data collection plan

Measurements as listed above will be entered into a password protected Excel spreadsheet available only to the authors. A unique identifying study number will be sequentially allocated to each specimen as it is included in the study.

4.3 Data entering and storage

Data will be recorded via an electronic collection sheet as above (Appendix 1) and then transferred directly to our statistical storage and calculation program STATA 13. All data will be kept secure via electronic password only accessible to the study authors.

4.4 Data analysis plan

The femoral fracture models will be loaded at a rate of 1mm/s until failure. Each model will be loaded in an identical way. The universal testing machine will provide a graph with the ramped load(N) and displacement(mm). This graph will be printed and used for statistical purposes. From this data we can determine the yield point, bending stiffness(N/mm) and the bending moment(Nm) using various standardised formulae. These variables will be analysed to determine the variation between the specimens. We hypothesised that there will be minimal variation between the specimens. If the variable is normally distributed, the mean, standard deviation and coefficient of variation will be measured.

4.4.1 Descriptive statistics

Basic descriptive statistics will be used to describe the data obtained. As the sample sizes are small, distributions will be checked for normality before statistical analyses will be performed. The data will be analysed to evaluate for normal distribution, as indicated by a normal P-P plot of the standardized residuals and the Kolmogorov-Smirnov test. All data will be described using means and standard deviations.

4.5 Resources required

Various institutions with research funding available will be approached for possible funding. The main expenses will be the femoral models and the stainless steel nails (see appendix). No extra costs will apply for using the laboratory facilities of the Mechanical engineering department of the University of Cape Town.

The authors will use personal time as well as designated academic research time provided for in their schedules to collect and analyse data; therefore no extra costs apply to hire data collectors or statisticians. Personal computers will be used to store and analyse data. Cost of a printed protocol to distribute to the protocol review board and Ethics application should not be excessive and will be covered by the authors.

1. ETHICAL AND LEGAL CONSIDERATIONS

Composite femoral models will be used in this study. No patients will be directly or indirectly affected by the study.

Conflict of interest:

The researchers do not expect financial benefit from conducting this study. The researchers aim to be objective in data collection and analysis. This study forms the basis of a Masters in Orthopaedics submission.

2. DATA DISSEMINATION PLAN

The researchers aim to publish results in peer-reviewed journals such as the South African Orthopaedic Journal or the Journal of Bone and Joint Surgery. Protocols and/or results may also be presented at conferences or meetings of societies such as the South African Orthopaedic Association.

Research results may provide information for future clinicians to aid in the management of femur fractures in adolescent and overweight children when treated with elastic stable intramedullary nailing.

3. STUDY TIMELINE

Calendar Year	2016											
Month	1	2	3	4	5	6	7	8	9	10	11	12
Protocol development, submission to ethics and obtaining funding, hospital approval				x	x	x	x	x				
Data collection									x	X		
Data clean up and analysis											x	
Write up of results, data presentation and dissemination												x

4. LIMITATIONS

As applies to all biomechanical tests on bone models, the results of our study can only be extrapolated to the in vivo situation to a limited extent. One reason is that the tests were performed on synthetic bones, another is that none of the effects of the adjacent muscles, soft tissues, and periosteum can be taken into account.

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6. APPENDICES

1. Data capture sheet
2. Budget
3. Ethics approval certificate (not attached; pending ethics approval)