**Femoral Diaphyseal Fractures in Children and Young Adults;**

**Stability, Residual Deformity and Recovery of Physical Function**

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BACKGROUND

Femoral diaphyseal fractures represent approximately 1.6% of all paediatric fractures. In adults the incidence is approximately 10 per 100,000 person-years [1] and in children 20 per 100,000 person-years [2, 3]. Common mechanisms are falls, sporting injuries and motor vehicle accidents. The aetiology differs depending on the patients age, where for example a child of 2 years of age can easily by a simple fall or when running sustain a diaphyseal femoral fracture whereas more energy is needed to cause a fracture in adolescents and adults. There are different options for treatment depending on age, type of fracture and associated injuries [4-6]. From 6-7 years of age up into skeletal maturity and adulthood intramedullary nail (IMN) fixation is by far the most common treatment. Flexible IMN are now widely used in children, whom previously were treated by skeletal traction and bedridden in hospital 4-6 weeks. The goal is a stable fixation and pain free fracture that allows discharge from the hospital after 3-5 days. The socio-economic advantages are obvious.

The importance of stability for fracture healing has been reported in adults. In children, however, the open growth plates and the vulnerable blood supply to the femoral head makes the surgical technique a challenge and stability after nail fixation varies. The technique has proven difficult and does not lack complications, where loss of reduction is one [7-9]. The stability achieved with different applications of flexible nails in comparison with newly introduced semi-rigid nails in children has been limitedly reported. Delayed healing and loss of reduction may lead to unnecessary suffering with pain because of insufficient stability and prolonged hospital stay. The stability after fracture fixation, when considering the physiological loading when weight-bearing and walking with assessment of different loads and moments of torque in three dimensions is not well investigated.

In children overgrowth after femoral diaphyseal fractures is commonly reported [10]. A fracture overlap and/or other deformities in the combination with unstable fixation generate what is described as indirect bone healing with extensive callus (new bone) formation. The opposite is direct healing without excessive new bone formation following a near anatomical reduction and stable fixation. The excessive bone formation with indirect healing, will decrease with time but may contribute to a prolonged healing and remodelling process and hence potentially to overgrowth with leg length discrepancy (LLD) as a consequence. The mechanism of overgrowth is increased blood flow at the fracture site during healing and remodelling which stimulates the growth plates on the fractured side. LLD up to 2 cm is considered to possibly cause asymmetrical gait, with an individual variation of ability to adapt the movement pattern [11]. Some patients can not adapt, and
it is therefore believed that a leg length discrepancy of more than 2 cm at skeletal maturity should be treated, as to avoid future low back pain and arthritis of the knee and hip [12, 13].

In both children and adults the question of time to recovery after fractures in general is of importance, and in particular in fractures involving the lower extremity and walking ability. Many children and their parents as well as physically active adults inquire already in the emergency room concerning the prognosis, time to recovery and return to sports and other activities [14]. As physicians we are reluctant to answer questions about full recovery and time to recovery in the emergency situation. Even after the initial operative treatment, the focus is on mobilization and on avoiding complications. The speed of mobilization depends on fracture stability, patient cooperation and motivation, beside advice and instructions from the physician and physiotherapist. In children it is often presumed that more rapid healing leads to full recovery early. There is a balance between optimizing rehabilitation and limit the time of recovery with the risk of failure with mal- or non-union as a consequence. It is difficult to provide a realistic prognosis and timetable for recovery due to the lack of previous studies [14].

There are limited studies in adolescents and among young adults regarding quality of life and self esteem in relation to ambulatory capacity [11, 15, 16]. Even though the physical function improves after sustaining a femoral diaphyseal fracture, some patients decrease their activity, and we do not know if there is any impact on their quality of life. In addition, we know from other conditions, e.g. unilateral CP, that there is a correlation between deviations in gait and quality of life [17]. However we do not know if residual gait deviations with asymmetrical movement pattern could influence quality of life and well-being in the otherwise healthy patients group with femoral fractures. During the last decade interest has been directed towards psychological aspects on movement and rehabilitation [18, 19]. Fear of movement (or kinesiophobia) has been suggested to cause disability, disuse and depression in patients with various orthopaedic conditions [20].

PURPOSE

The overall purpose is to study stability of fixation of femoral diaphyseal fractures, to investigate the influence on movement pattern and assess time to normalization of gait and to assess the final outcome regarding remaining deformity with developed leg length discrepancy and quality of life.
PRIMARY HYPOTHESIS
The primary hypothesis is that an unstable fixation of femoral shaft fractures causes overgrowth and leg length discrepancy.

PRIMARY RESEARCH QUESTION
1. Does the intramedullary semi-rigid nail provide better stability compared to the different flexible nail combinations and is it sufficient to allow full weight bearing?
2. Does more precise reduction and high stability decrease the risk of overgrowth and the development of leg length discrepancy?
3. How soon after femoral diaphyseal fracture can one expect recovery regarding gait and more demanding physical tasks, i.e., jumping, and return to physical activities?
4. Does kinesiophobia occur after femoral diaphyseal fractures, and is it associated to time of recovery?

SPECIFIC HYPOTHESIS
1. Increased stability can be expected with larger or with increasing numbers of flexible nails. The semi-rigid interlocking nail provides better stability than any combination of flexible nails.
2. Overgrowth is more common in insufficient fracture reduction and fixation.
3. Time to recovery depend on fracture fixation and age. Gait pattern normalization can be expected long before recovery of more complex physical functions, such as muscle work performance during walking and in jumping.
4. Kinesiophobia is related to persistent movement deviations and age after femoral diaphyseal fractures and might influence rehabilitation.

SPECIFIC GOALS
1. To study stability after different types and combinations of intramedullary nail fixation in a synthetic pediatric femur bone model.
2. To study overgrowth in skeletally mature patients, and possible correlation with initial reduction and stability after femoral diaphyseal fractures treated with intramedullary nail fixation in childhood before skeletal maturity.
3. To study the recovery of normal gait pattern and return to physical performance in children and young adults.
4. To study kinesiophobia and possible correlation to physical function and age after femoral diaphyseal fractures in children and young adults.
ETHICS COMMITTEE
The research plan has been approved by the regional ethics committee in Göteborg (Regionala etikprövningsnämnden i Göteborg).

MATERIAL
Power analysis will be performed.

Paper 1. Twenty-four synthetic femur (6 bones in 4 series to compare differences) (Sawbones).

Paper 2. Patients treated in childhood with IMN nails due to femoral diaphyseal fractures and a complete set of remaining radiographs pre- and postoperatively will be invited to the follow up. Patients were treated at the Queen Silvia Children’s Hospital, Astrid Lindgren Children’s Hospital, Stockholm and Skaraborg Hospital. All patients now should have reached skeletal maturity. Exclusion criteria are: pathological fracture type, other skeletal injuries or diseases of the lower extremities that the patient sustained and could influence growth prior to or after the actual fracture, any secondary bony surgical procedure on the lower extremities after the fracture except removal of the IMN.

Paper 3. Patients between 6 and 16 years of age who sustain a femoral diaphyseal fracture will be recruited from the Orthopaedic Departments in Skaraborg and from the Queen Silvia Children’s Hospital in Göteborg, in Sweden. Exclusion criteria are: pathological fractures, inability to perform three-dimensional gait analysis (3D GA), other physical impairment or injuries that might influence gait, rehabilitation or previous skeletal injury of the lower extremities. Patients need to live in the region and be able to fully understand the outcome questionnaires in the Swedish language.

Paper 4. Patients between 17 and 30 years of age who sustain a femoral diaphyseal fracture will be recruited from the Orthopaedic Departments in Skaraborg, in Sweden. Exclusion criteria are: pathological fractures, inability to perform three-dimensional gait analysis (3D GA), other physical impairment or injuries that might influence gait, rehabilitation or previous skeletal injury of the lower extremities. Patients need to live in the region and be able to fully understand the outcome questionnaires in the Swedish language.

Paper 5. Those included in paper 3 and 4.

METHODS
A. Biomechanical tests
The application and fixation of the nails in the synthetic bones (Sawbones) were performed at Skaraborg Hospital. One experienced paediatric orthopaedic surgeon applied the nails in the
synthetic femurs that were mounted on a working table in a stable fashion, making sure not to
damage the plastic bone. All bones were prepared with a transverse fracture made with a saw at the
exact same location. Five to six bones of each combination were prepared. Imaging was used to
confirm adequate positioning of the nails. From three-dimensional gait analysis (Motion Analysis
Corp., Santa Rosa, CA) the maximal torque/moment over the knee was calculated in an age and
weight correlated group of children (10 years and 40 kg body weight). The synthetic bone model
was then exposed to/tested with 50 and 100% of the maximal torque. The biomechanical testing of
the prepared femurs was performed at the Kungliga Tekniska Högskolan in Stockholm. A fixed
material test machine (MTS with Instron) applied the exact moments to the bones after they had
been mounted in the machine. The machine applied moments to the bone distally to the fracture in
rotation, angulation, bending and compression.

B. Imaging

Standing radiographs: The validated and standardized method of standing radiographs will be
used to assess femur and tibia length in skeletal mature patients [21]. An assessment of angular
deformity as well as other skeletal changes and deformity will be performed.

Assessment of childhood postoperative images regarding reduction and stability:

Postoperative radiographs of the femur will be assessed in two planes (frontal and sagittal)
regarding shortening/lengthening, ad latus dislocation of 0, 25, 50, 75 or 100% and degrees of
angulation [22].

To assess the reliability of the measurements, the reproducibility and the degree of agreement
between the observers, both intra-, and inter-observer comparisons will be performed. Two or three
experienced radiologists will independently measure the images to minimize inconsistencies. To
standardize the method the observers will agree on common reference points for the measurements.
After a few weeks the images will be re-measured independently by the observers, blinded to the
previous results.

C. Physical variables

Physical examination

Physiotherapists will perform a physical examination regarding passive range of motion in the hip,
knee, ankle and subtalar joint, using a goniometer of the lower extremity in standardized positions
[23]. Measurements of weight and height will be obtained.

Three-dimensional gait analysis

Gait will be recorded with a, 12 camera 3D motion analysis system. Retroflective markers are
placed on bony landmarks or specific anatomical position (Helen Heys model). Multiple gait cycles
will be collected and a mean cycle with standard deviation will be calculated. The patient will walk
at a self-selected speed on a 10-meter walkway. The kinetic data will be collected using four force plates. Generally three trials from each foot will be collected. The kinetic and kinematic data will be collected from the same trials. The ground reaction force vectors will be collected together with the kinematic data. Parameters of time and distance will be registered. Work from concentric muscle contraction, will be calculated from the ankle, knee and hip joint. In addition from the kinematic data the degree of deviation for the lower extremity (Gait Profile Score) and upper extremity (Arm Posture Score) will be collected. Patients will be scheduled for the three-dimensional gait analysis at 3, 6, 12 18 and 24 months.

Jump test with motion analysis

*Drop vertical jump:* From a 30 cm high box the patient drops down with each foot on a force plates and immediately jumps as high as possible in a vertical direction, which is a validated test used most commonly in knee assessments [24]. From the force plates’ data together with the movement measurement, the absorption and the power generation will be calculated from both the fractured and non-fractured side. The amount of absorption provides measurement of the eccentric muscle work performed when landing. The amount of power generation is a measurement of the concentric muscle work performed when jumping and taking off from the force plates [25].

*One-legged jump for distance.* To evaluate physical function the validated one-legged jump for distance was chosen. The participants were instructed to jump on one leg from a 30 cm high box as far as possible and were instructed to perform a controlled landing on the jump-off foot. The longest distance of three trials of an approved jump was analyzed. The test was demonstrated by a physiotherapist and the non-fractured side was tested first [25, 26].

Free-living activity

ActivPAL™ (PAL Technologies Ltd) will be used for measuring physical activity. The device is mounted on the thigh and registers free-living activities and sedentary behavior (i.e. standing or lying) [27, 28].

D. Questionnaires

Validated self reporting questionnaires:

Disease/hip specific assessment:
-Harris Hip score. The hip specific Harris hip score is a disease specific score most widely physician-assessed measure of hip function after total hip replacement. It has also been used in many other conditions (acetabular and femur specific conditions). It consists of a range of motion assessment and an activity of daily life assessment [29].

Activity assessment:
-Activity scale for kids performance version (ASK): ASK will be used to measure rehabilitation time [30].

Kinesiophobia assessment:
-Tampa Scale for Kinesiophobia (TSK-SV). Kinesiophobia, or the irrational fear of movement, will be measured by the Swedish version of the Tampa Scale on Kinesiophobia (TSK-SV) [31]. TSK-SV contains 17 items told to measure the patients experience on kinesiophobia. Each item is rated from 1 (Do not agree) to 4 (Do agree) on a Likert Scale [32, 33].

PAPERS; an overview

Paper 1
Biomechanical Comparison of Flexible Titanium Nails with Semi-rigid Paediatric Locking Nail Using a Femur Fracture Model

A: Method: Twenty-four synthetic bones have undergone biomechanical tests comparing four types of combinations of intramedullary nail fixation.

B: Hypothesis: Increased stability can be expected with larger or with increasing numbers of flexible nails. The semi-rigid interlocking nail provides better stability than any combination of flexible nails.

C: A detailed and standardized protocol was developed and followed. The manuscript is submitted to the Journal of Pediatric Orthopaedics.

D: Importance: This study can guide in the selection of IMN to use for optimal stability.

Paper 2
Leg length discrepancy at skeletal maturity: a retrospective study of femoral diaphyseal fractures in children treated with flexible intramedullary nails.

A: Method: Children previously treated with flexible intramedullary nails after femoral diaphyseal fractures at the Queen Silvia Children’s Hospital in Göteborg, and at Astrid Lindgren Children’s Hospital, Stockholm will be recruited. They will be scheduled for a radiological examination with standing radiographs for leg length assessment.
**B: Hypothesis:** Overgrowth is more common and related to insufficient fracture reduction and fixation.

**C:** A detailed and standardized protocol will be developed and followed.

**D: Importance:** More knowledge will help us identify those that are at risk to develop leg length discrepancy in the future and therefore should be closely monitored. The indication for treatment in the individual child can be established early. Treatment for leg length discrepancy in the still growing child can be performed in a minimal invasive way, as opposed to after skeletal maturity when extensive surgical procedures with long rehabilitation times are warranted.

**Paper 3**

**Time to return to normal gait and physical function after femoral diaphyseal fracture: a longitudinal prospective study in children.**

**A: Method:** Children with femoral diaphyseal fractures treated at Skaraborg Hospital and Queen Silvia Children’s Hospital in Göteborg will be recruited and treated according to general practice. Patients included in the study will be followed and they will undergo physical examinations as well as three-dimensional gait and jump test analysis. Questionnaires regarding health and kinesiophobia will be obtained at the same occasion.

**B: Hypothesis:** Time to recovery depend with conventional treatment mainly on age. Walking normalization can be expected long before recovery of more complex physical functions such as jumping.

**C:** A detailed and standardized protocol will be developed and followed.

**D: Importance:** Patients will be better informed on expected time to recovery and be able to follow their own progress which will also help the rehabilitation physiotherapist as to monitor improvement and identify possible slow or altered recovery.

**Paper 4**

**Time to return to normal gait and physical function after femoral diaphyseal fracture: a longitudinal prospective study in young adults.**

**A: Method:** Young adults with femoral diaphyseal fractures treated at Skaraborg Hospital and Queen Silvia Children’s Hospital in Göteborg will be recruited and treated according to general practice. Patients included in the study will be followed and they will undergo physical examinations as well as three-dimensional gait and jump test analysis. Questionnaires regarding health and kinesiophobia will be obtained at the same occasion.
**B: Hypothesis:** Time and pattern of recovery is different in different age groups. Walking normalization can be expected long before recovery of more complex physical functions such as jumping.

**C:** A detailed and standardized protocol will be developed and followed.

**D: Importance:** Patients will be better informed on expected time to recovery and be able to follow their own progress which will also help the rehabilitation physiotherapist as to monitor improvement and identify possible slow or altered recovery.

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**Paper 5**

**Quality of life and kinesiophobia after femoral diaphyseal fracture.**

**A: Method:** The patients in study 3 and 4 will be followed and their general health related quality of life and kinesiophobia will be evaluated using questionnaires.

**B: Hypothesis:** Quality of life and degree of kinesiophobia, is related to persistent movement deviations and age after femoral diaphyseal fractures and might influence rehabilitation.

**C:** A detailed and standardized protocol will be developed and followed.

**D: Importance:** The impact on quality of life and kinesiophobia on recovery can be monitored and expected goals obtained.

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**STATISTICS**

The data will be length/tension data and degrees of deformity, kinematic and kinetic from the gait analysis together with temporal-spatial data. The radiographs will be used for the leg length of femur and tibia. The quality of life assessment scores and the kinesiophobia scale from the questionnaires will be used.

Depending on the distribution of the different variables of data parametric or non-parametric statistics will be used as well as correlation coefficient Spearman or Pearson. A multi regression analysis will also be performed to assess influence from various variables such as age, gender, length, weight, leg length discrepancy, time from fracture etc.

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**PROCEDURE**

Individuals with the diagnosis of femoral diaphyseal fracture treated with intramedullary nail fixation will be identified through the medical records and the National register (Socialstyrelsen). A letter with information of the study and a question of participation will be sent to each former patient. From the medical records, gender, age, side of involvement, and confirmation of the
diagnosis will be recorded. Oral and written information will be provided and a written consent obtained. The patients who indicated willingness to participate will be contacted after a few weeks by telephone and their eligibility reconfirmed against the inclusion and exclusion criteria. Patients will receive oral and written information and a written consent will be obtained and the questionnaires will be obtained at the same occasion. The osteosynthesis (intramedullary nails) will be removed after 13-14 months if there are medical indications.

TIMING OF STUDIES
Paper 1 started in 2011 and was finalized 2013.
Paper 2 was started 2013 and is ongoing with collection of data. Paper 2 is planned to be finalized 2014.
Paper 3-4 will start late 2013 or start of 2014 and will continue until 2016-2017.

IMPORTANCE / EXPECTED RESULTS / SIGNIFICANCE
To be able to develop rational treatment plans for femoral diaphyseal fractures in children and adults comprehensive knowledge is of great importance. Much of the earlier studies on skeletal remodelling and on remaining deformities are based on conventional radiographs and are quite old. The assessments on gait are not well investigated and hardly any information on self reported quality of life exists. The long term result is not well investigated either. The studies planned in this research project, using modern harmless techniques, will provide an extended knowledge that can be of importance for future treatments of these relatively common and resource demanding fractures.

REFERENCES


