

Diplomarbeit

**The hip loading as prognostic factor in patients with
Perthes disease**

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Abstract

Introduction: Morbus Perthes is one of the most common hip diseases in childhood and the long-term outcome often affects the quality of life in a negative way. The aim of our study was to find out if the hip abductor moment during gait, as surrogate for loading of the hip joint, might be an important prognostic factor for the long-term radiological, functional and subjective outcome in Perthes disease.

Methods: 42 children with Perthes disease, who underwent preoperative gait analysis between 1998 and 2003, were identified as potential candidates for the study. However, only 14 patients (11 males and 3 females) were willing to participate in our study. All patients underwent a clinical and radiological examination as well as kinematic and kinetic 3D gait analysis. The Gait Deviation Index (GDI) as a summary measure of gait pathology was calculated. Additionally, participants were asked to fill in Hip disability and osteoarthritis outcome score (HOOS) and the Harris hip score (HHS) was assessed. The Spearman's rank correlation coefficient was used to test our hypothesis.

Results: There was no correlation between the hip abductor moment at the beginning of the disease and the long-term radiological outcome. The GDI neither correlates with the radiological outcome nor with any clinical parameter. The age at treatment is an important factor for the subjective outcome evaluated by the HHS and the HOOS. However, no correlation between the age and the radiological outcome was found. On the other hand preoperative radiological staging according to Herring classification was proved to be an important factor for the long-term radiological outcome. Patients with worse radiological outcome additionally described more symptoms and problems in sports activities, and limping was also more frequent. When Range of Motion (ROM) was limited, patients showed more limping and reported more symptoms and pain.

Conclusion: As we only had a low number of participants in our study, we unfortunately were not able to confirm our hypothesis that the hip abductor moment during gait influences the radiological long-term outcome in LCPD. However, our study confirmed the important role of Herring classification for the radiologic prognosis as well as the role of age for long-term functional outcome in Perthes

disease. Moreover, simple clinical measurements like hip ROM might be predictors for subjective symptoms, pain and limping. Future studies with larger number of participants and sufficient power are needed to show if loading of the hip might play an important role in long- term outcome of LCPD.

German abstract

Einleitung: Morbus Perthes ist eine häufige im Kindesalter auftretende Erkrankung des Hüftkopfes, die langfristigen Auswirkungen beeinträchtigen die Lebensqualität der PatientInnen. Die Ergebnisse dieser Studie sollen zeigen, ob das Hüftbelastungsmoment bei PatientInnen, die in ihrer Kindheit an Morbus Perthes erkrankt waren und operativ behandelt wurden, einen prognostischer Faktor für die radiologischen, funktionellen und subjektiven Langzeitergebnisse darstellt.

Methoden: 42 Kinder mit Morbus Perthes, die zwischen 1998 und 2003 mit einer präoperativen Ganganalyse untersucht worden waren, wurden ausgewählt. Leider willigten nur 14 der ausgewählten PatientInnen an der Studienteilnahme ein. Alle PatientInnen wurden einer klinischen und radiologischen Untersuchung, sowie einer 3D- Ganganalyse unterzogen. Der Gait Deviation Index (GDI), eine zusammenfassende Messung von Gangabnormalitäten, wurde ebenfalls berechnet. Die TeilnehmerInnen wurden ersucht, einen Fragebogen auszufüllen, der nach dem Hip disability and Osteoarthritis Outcome Score (HOOS) und zusammen mit dem Harris Hip Score (HHS) ausgewertet wurde. Der Spearman Rang Korrelationskoeffizient überprüfte unsere Hypothese.

Ergebnisse: Es konnte kein Zusammenhang zwischen dem Hüftabduktionsmoment und dem radiologischen Langzeitergebnis festgestellt werden. Der GDI korrelierte weder mit dem radiologischen Ergebnis noch mit klinischen Parametern. Das Alter zum Zeitpunkt der Operation spielt eine wichtige Rolle für das subjektive Outcome, es bestand aber keine Korrelation zwischen Alter und radiologischem Ergebnis. Ein wichtiger Faktor für Letzteres scheint die präoperative radiologische Untersuchung nach der Herring Klassifikation zu sein. Außerdem beschrieben PatientInnen mit schlechterem radiologischen Ergebnis sowie einer eingeschränkten Hüftbeweglichkeit mehr Symptome und Schmerzen, und hinkten auch verstärkt.

Zusammenfassung: Da wir nur eine geringe Anzahl von TeilnehmerInnen hatten, war es uns leider nicht möglich, unsere Hypothese zu bestätigen. Wir konnten aber zeigen, dass die präoperative Klassifikation nach Herring wichtig für das radiologische Outcome ist. Außerdem scheint es, dass man mit einfachen klinischen Messungen (z.B. das Ausmaß der Hüftbeweglichkeit, ROM) gute Prognosen über Symptome, Schmerzen und Tendenzen zum Hinken treffen kann. In Zukunft wären aber weitere Studien mit einer größeren Anzahl von TeilnehmerInnen nötig, um unsere eigentliche Fragestellung zu bestätigen.

I. Introduction

1.1. Morbus Perthes

1.1.1. General information

Morbus Perthes is a self-limiting aseptic osteonecrosis of the femoral head (commonly unilateral, in 15% bilateral), affecting the capital femoral epiphysis and the hip joint. The Legg- Calvé- Perthes (Waldenström) disease (LCPD) was named after the three surgeons Arthur Legg (America), Jacques Calvé (France) and Georg Perthes (Germany) who were the first ones to publish their observations of the disease in 1910 (4). The name of Waldenström is sometimes added to the name of the disease as he was the first one to classify the disease into four radiographic stages (see part 1.1.2.). Synonyms like coxa plana or osteochondritis deformans juvenilis might be also sometimes found.

The annual incidence among children under age 15 ranged from 0.2 per 100,000 to 19.1 per 100,000. East Asians are the least affected population and whites the most affected ones (5). Boys are about four times more affected than girls (2). There is significant variability in incidence within racial groups and the number of children suffering from LCPD is frequently higher in lower socioeconomic classes (2). The disease occurs typically in childhood between the ages of 4 to 8 years (average 6.5 years) (6) and might lead to osteoarthritis in adult age. Although the etiology of LCPD remains unclear, the following factors are mainly considered as a cause of the inadequate blood supply in the femoral head (aseptic necrosis), which leads to the LCPD:

- the intraarticular pressure increases caused by an inflammatory process within the hip joint (2);
- an ischemic process caused by anatomically incorrect vascularization of

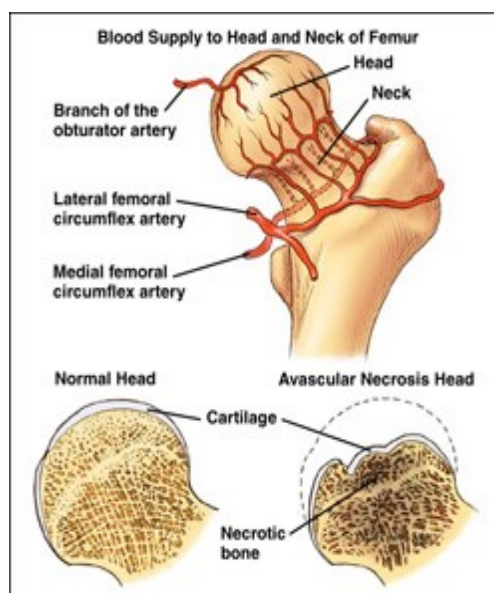


Figure 1 Blood supply of the femoral head(1)

the femoral head (e. g. absence or obliteration of arteria circumflexa femoralis medialis, a. obturatoria or a. epiphysarys lateralis)(6);

- coagulation disorder and a missing factor C or S (in question)(6);
- environmental influences, i.e. passive smoking exposition(6) and genetic factors (multifactorial) (6, 7).

There is also an association with ADHD (attention deficit hyperactivity disorder), and children who are more active than average (running, jumping, regular sports) are also more likely to get LCPD (7).

1.1.2. Pathogenesis and Clinical Characteristics

Children typically present a limp caused by weakness or reflex inhibition of the psoas major muscle (8). During gait the affected leg moves in external rotation, flexion and adduction (8). Most of the time the limp is painless and worse after physical activities and improves after following periods of rest. Some children show a limp accompanied by pain in the leg with projection down to the knee.(9) There is also a limited abduction and internal rotation in both flexion and extension in the early phase of the disease (10).

The pathogenesis of LCPD is divided into four phases related to X- ray abnormalities (3, 11):

Stage 1: Stage of condensation (early/ initial stage): the blood supply to the femoral head is disrupted leading to ischemia. The femoral epiphysis stops growing, the size of the femoral head seems asymmetric and there is a widening of the femoral joint space, smaller on the affected side; the density of the femoral head epiphysis has increased; In addition, X- ray shows a blurring of the physeal plate and radiolucency of the proximal metaphysis. This phase lasts 3 - 6 weeks.

Stage 2: Stage of fragmentation: X- ray shows subchondral lucency (crescent sign), inhomogeneous density and thickened trabeculae. The femoral head seems weak and deformable; this takes 6- 12 months.

Stage 3: Reparative phase: the re-ossification begins; the shape of the femoral head becomes better defined and bone density begins to return. This phase is usually

completed within 6 to 24 months resulting in healing, or a residual deformity in more severe cases.

Stage 4: Healing: the changes depend on how severe the disease harmed the femoral head and may be nearly normal or may demonstrate a flattening of the articular surface or a widening of the head and neck of the femur.

The common phase in which children recognize gait problems and consult a doctor is the above mentioned phase of fragmentation, in which the building of new bone material starts and may cause pain. In some cases the initial radiographic examination already shows the hip in state of condensation.

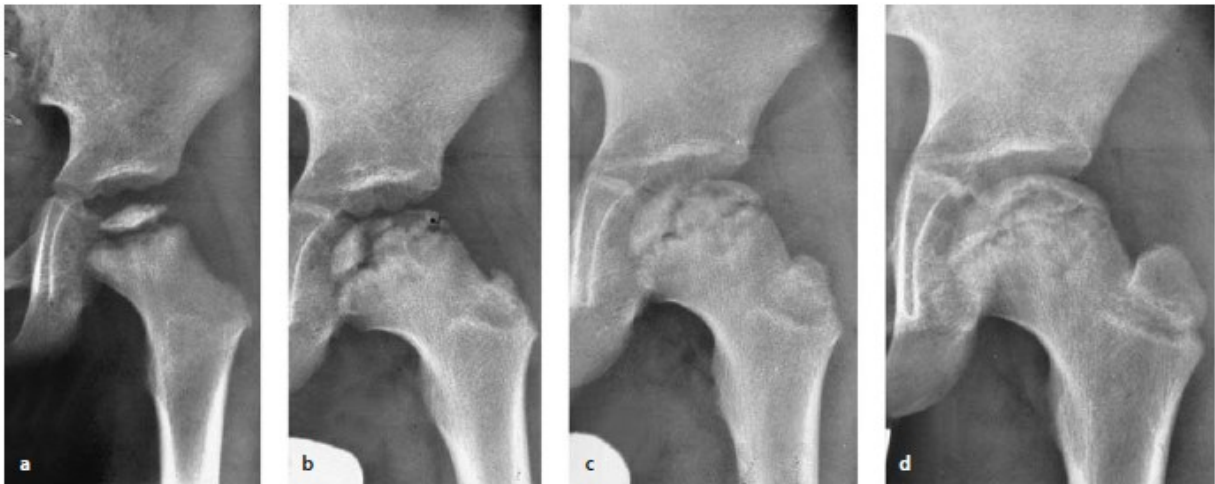


Figure 2 Radiographic progression stages of LCPD: a. boy aged 3 years, femoral head in the condensation stage; b. at the age of 5 years in the fragmentation stage; c. at the age of 7 years in the reparation stage; d. at the age of 9 years in end progress. Hefti et al., 2007 (2)

1.1.3. Diagnostics of LCPD

Diagnosing a Legg- Calvé- Perthes- Disease is simple with clinical and radiographic examination in advanced stage. Only in case of an initial stage of the disease, when neither clinical symptoms are characteristic nor X- ray shows classical signs yet, making a diagnosis may cause difficulties.

In this case of Initial stage, alternative diagnostic methods like MRI, bone scintigraphy or ultrasound could help to differentiate between differential diagnoses as coxitis fugax for example, where the effusion in the hip joint is only visible during the first days after occurrence of symptoms (12). Ultrasound can additionally show changes on the

femoral head as well as accompanied synovitis and effusion of the hip joint. However, the prognostic significance of these alternative methods is controversial. The MRI should replace the X- ray as Gold standard in early diagnosis. I.Schittich et.al.,2001, show that an MRI allows an earlier diagnosis so that at least a physiotherapy can be started earlier. However, several other studies show that there is no possibility to start an adequate therapy as long as there are no radiographic signs, so an early MRI-diagnosis without any X- ray sign does not seem helpful (2).

There are several steps to prove the diagnosis of LCPD:

First, the patients must undergo clinical examination, consisting of evaluating the gait pattern, the muscle status and the joint range of motion. A blood test is also inevitable to define the inflammation parameters (CRP= C- reactive protein, and BSR= blood sedimentation reaction), which would be normal in case of LCPD and lead to inflammatory differential diagnosis of LCPD.

The imaging diagnostic is first choice in proving the diagnosis of a LCPD: X- ray is the first choice method especially for monitoring. The anterior- posterior pelvis overview and the Lauenstein view (or “frog-leg- view”) are the standard methods for radiographic imaging to establish the diagnosis (13).

1.1.3.1. Classifications

Different classifications were developed to simplify the radiological description for the diagnosis and prognosis. The classifications might be divided into those which describe the active phase of LCPD, and classifications describing the disease after healing process which are essential for the prognostic criteria.

Classifications during active phase:

- **Catterall- Classification:** is based on the radiologic appearance of the femoral head necrosis and describes the degree of femoral head involvement in 4 groups. Catterall et al. proposed this classification in 1971, dividing the femoral head into four quadrants on AP and axial X- rays (Table 1 and Figure 3) (2).

Catterall supplemented this classification with five “head- at- risk- signs” as prognostic indicator in LCPD (Table 2) (2).

| Grade | Characteristics |
|-------|---|
| I | Only anterolateral quadrant affected |
| II | Anterior third or half affected |
| III | up to $\frac{3}{4}$ of the femoral head affected- only the dorsal part remains intact |
| IV | Whole femoral head affected |

Table 1 Classification of Catterall(2)

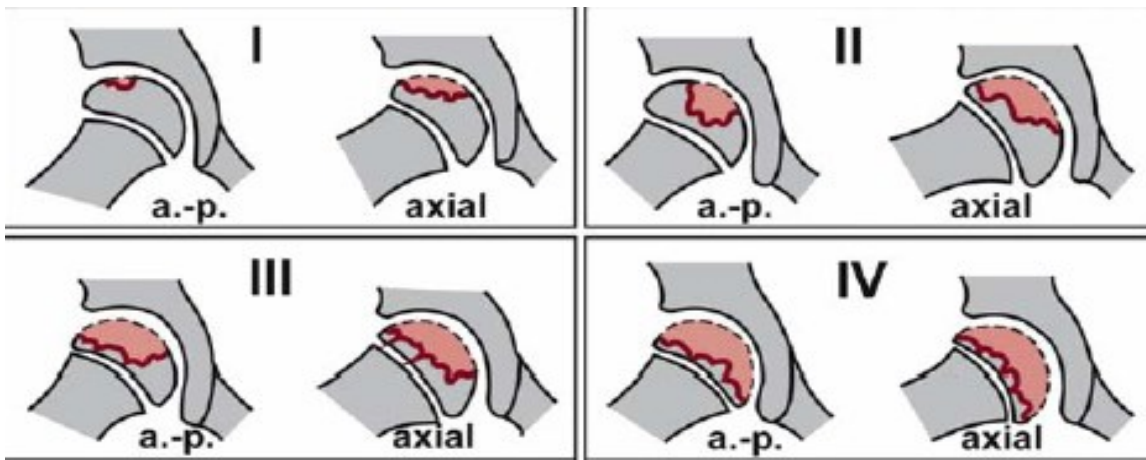


Figure 3 Classification of Catterall: I: only anterolateral section affected; II: anterior third or half of femoral head involved; III: up to $\frac{3}{4}$ of the femoral head affected- only the dorsal part remains intact; IV: whole femoral head affected (2).

| | |
|------------------------------------|---|
| Lateral Calcification | Appearance of a calcification shadow on the x ray lateral to the femoral head |
| Subluxation | Lateral displacement of the head center |
| Metaphyseal involvement | Osteolytic signs in the border of the metaphysis to the epiphyseal plate |
| Gage- sign | Triangular osteolytic area on the lateral femoral head |
| Transverse epiphyseal plate | Realignment of the epiphyseal plate along the horizontal plane. |

Table 2: „ Head at risk- signs“ supplementing the Classification of Catterall(2)

- **Classification of Salter and Thompson:** simplifies the Catterall- Classification by introducing in only 2 groups, whereas Group A is comparable with Catterall I+II and has a better outcome than Group B, comparable with Catterall III+IV (2). This classification includes the subchondral fracture which enables the condition to be classified much sooner than with the Catterall classification (2).
- **The Herring – Classification** (“lateral pillar classification”) describes the integrity of the lateral pillar of the femoral head in an anterior- posterior view during the fragmentation stage of the disease, divided in 3 groups(A, B, C) from no lateral height loss to total lateral height loss [13].

The lateral pillar comprises 15% - 30% of the femoral head, the central pillar 50%, and the medial pillar 20% - 35% (14).

- In Herring Group A, the height of the lateral pillar is radiographically normal as compared with the contralateral hip.
- In group B, the height of the lateral pillar is between 50%- 100% of the original height, and the central medial pillars seem also decreased.
- In group C, the height of the lateral pillar is less than 50% of the original height (14).

This Classification is easier to use than the Classification of Catterall, because it is only based on the height of the lateral pillar during the fragmentation stage and needs less extensive experience in pediatric orthopedics. Besides, the Herring classification is a significantly better predictor of Stulberg outcome than the Catterall classification especially related to the age at onset. Several studies show that the Catterall classification has no significant prognostic correlation with the final outcome (15).

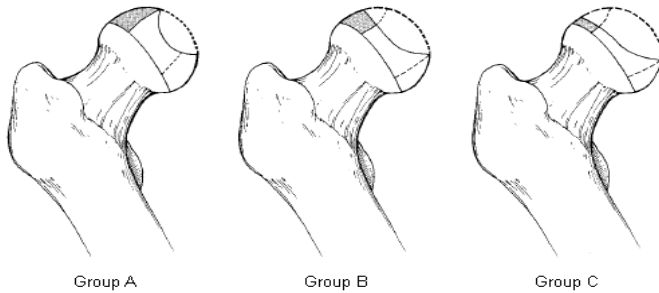


Figure 4 Herring classification: Group A, no involvement of the lateral pillar which retains the original height with no density changes; Group B, lateral pillar shows lucency and a loss of height, not exceeding 50% of the original; Group C, characterizes the lateral pillar with increased lucency and collapse of over 50% of the original height. (16)

Classifications in post-disease- phase:

- **Stulberg- Classification** has been a commonly used classification for researchers and clinicians all over the world for more than 30 years because of its reliability as a predictor of long-term outcome. This made us use the Stulberg System also for our study. The classification of Stulberg et al. (3) predicts the outcome of degenerative joint disease following LCPD disease and has been used to validate the lateral pillar classification (17). This system considers the following radiographic parameters:
 - the sphericity of the femoral head,
 - the length of the femoral neck,
 - the slope of the acetabulum,
 - the presence of coxa magna.

These parameters represent three types of congruency between the femoral head and the acetabulum: spherical congruency (classes I and II-less than 2mm loss of head shape), aspherical congruency (classes III- greater than 2mm loss of head shape, and IV), and aspherical incongruency (class V). The system of Stulberg et al. has been used to determine the long-term prognosis for patients who have Legg-Calvé-Perthes disease and to evaluate the results of a number of alternative treatments.

The system of Mose et al. is based on the evaluation of the spherical shape of the femoral head, using a template of concentric circles and the Lauenstein radiography.

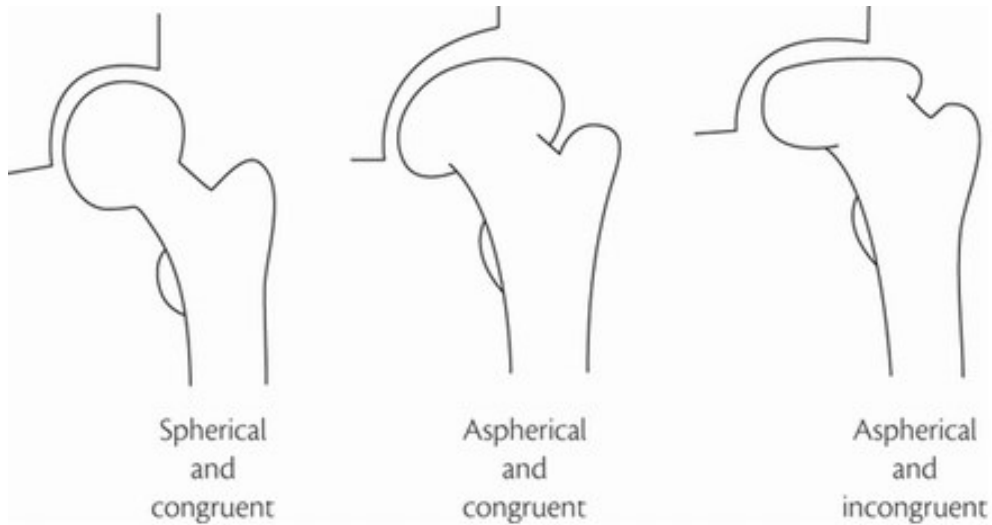


Figure 5 Stulberg et al. (1981) classified hips according to the final shape of the femoral head and acetabulum (3).

| Sphericity of femoral head | Suggestion of Stulberg et. al. | Consensus |
|-----------------------------------|---|---|
| <i>Spherical</i> | Same concentric circle fits contour of head on antero-posterior and frog-leg lateral radiographs with use of method of Mose | Circular template fits contour of femoral head on antero- posterior and lateral radiographs (within 2 mm), although same-size circle does not have to define head on each view; if only 1 radiograph available, sphericity determined on basis of that radiograph |
| <i>Flat</i> | No definition given | At least 1/3 of contour of femoral head resembles a straight line on at least 1 view (1 mm deviation allowed) |
| <i>Nonspherical</i> | Ovoid, mushroom, or umbrella-shaped; not spherical and not flat | Not spherical and not flat |
| <i>Presence of coxa magna</i> | Diameter of involved femoral head (measured from most medial to most lateral point) more than 10 percent greater than that on uninvolved side | Same as in system of Stulberg et al., but if uninvolved hip is not visualized or if patient has bilateral disease, this component is not considered when making overall classification |
| <i>Length of femoral neck</i> | Determined by assessing relationship of height of trochanter to 4 quadrants superimposed on femoral head; no criteria given for normality | Determined by assessing relationship of tip of trochanter to center of femoral head on anteroposterior radiograph; when neck is shorter than normal, tip of trochanter is located proximal to center of head; flat heads associated with short necks |
| <i>Acetabular slope</i> | Determined by measuring acetabular angle of Sharp; no criteria given for steep or normal slope | Determined by measuring slope of most lateral portion of acetabulum on antero- posterior radiograph; in steep acetabula, slope tends to be parallel with the horizontal or is inclined upward |

Table 3: Definitions for the joint structures involved in the classification system of Stulberg et al. (3).

1.1.4. Therapy

Morbus Perthes is always a self-limiting disease; the treatment depends, apart from the age at the onset of disease, on stage and classification of severity of LCPD and can be either conservative or surgical. Primary goal for a successful outcome of therapy is preventing long-term damage to the hip joint and degenerative arthritis by assuring containment of the femoral head and maintaining satisfactory range-of-motion of the hip joint (18).

For children under the age of 6 at onset, the difference in treatment methods does not seem significant (19). They will typically present with mild symptoms and have excellent results even with no treatment intervention (20). However, children under 6 years showing a severe form (Herring-/ lateral pillar classification B/C) and a poor mobility benefit from a surgical intervention.

In patients between the age of 6- 10 years at onset and in the lateral pillar groups B and B/C, or in Catterall stage III and IV, surgical osteotomy was found to produce the best results (19, 20). However, if the containment is preserved and children show a good hip mobility, the conservative treatment seems sufficient for a satisfying long-term outcome.

When a check-up shows a residual hip deformity in children over the age of 10, a surgical intervention is always the best way to treat an LCPD.

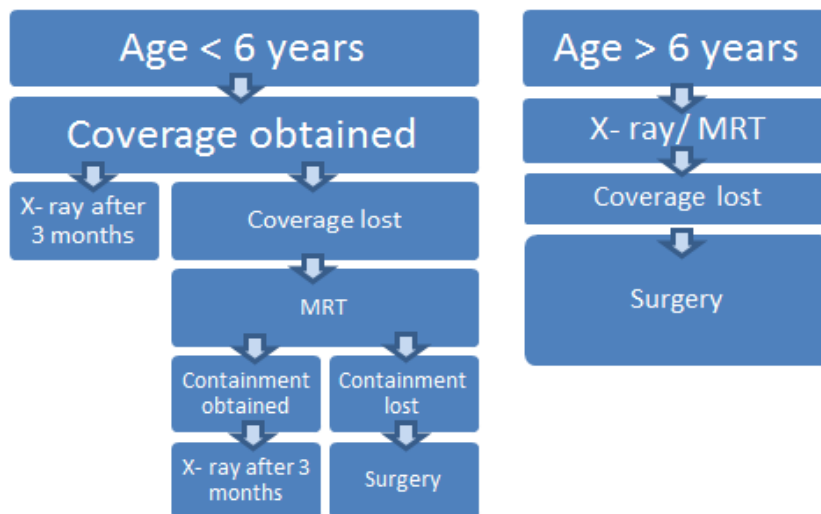


Figure 6 shows the treatment algorithm for Perthes disease, depending on the patient's age and containment(21)

1.1.4.1. Conservative treatment:

Main goal for the conservative way of therapy in children with Morbus Perthes is to preserve the mobility of the hip joint. However, there are many different statements of authors who discussed various results, so it is difficult to define one best way of treatment. Most of the authors recommend the conservative treatment for patients with the radiological stage of Catterall I and II respectively Herring A, and under the age of 8 (16, 22, 23).

Although conservative treatment does not require hospitalization and exclude operation risks, this way of treatment could have a negative psychological effect, because the duration of impairment is much longer (2 years) than after surgical treatment (about 6 weeks) (2).

Following methods of conservative treatment are used to help the patients without surgical intervention:

- Physical therapy – Regular physical therapy helps to reduce stiffness in the hip joint. The affected child may be taught some exercises that can be practiced at home. These can help maintain the range of motion in the hip.
Some studies mention physiotherapy as a pre- and/or postoperative intervention while others consider it a form of conservative treatment associated with other treatments, such as skeletal traction, orthosis, or plaster cast.
- Anti-inflammatory drugs – Medication, such as nonsteroid anti-inflammatory drugs, can help relieve pain and related stiffness as well as inflammation in the hip joint. However, this is just a symptomatic treatment to relief the pain, to support the painless hip mobility and to reduce an eventual joint effusion.
- Supportive equipment such as braces, crutches or nighttime traction devices were often used in the past to help in hip abduction for better joint congruency. However, the present literature does not provide sufficient evidence to support the use of bracing in LCPD. Latest recommendations say that the abduction orthoses should rarely be used in the treatment of LCPD. There used to be two types of orthoses; the ones which only unload the femoral head (i.e. Thomas-splint or Snyder-sling) and abduction orthoses which only improve the congruency (i.e. the Petri cast or the Texas- Scottish- Rite-Orthose) (24).

- Limiting weight bearing – if there is worsening of the limp or too much pain in the hip, it may help to restrict activities such as running or reducing the amount of weight placed on the leg.
- Bed rest – although LCPD patients are not recommended to take several months of bed rest any more, severe pain can be alleviated with a short period of bed rest.

1.1.4.2. Surgical treatment:

Several studies show that children over the age of 6 years with a diagnosis of Catterall group III or IV respectively Herring B or B/C show significantly better outcome after surgical intervention (9, 10, 19, 20). In both grades of classifications, there is a more or less total incongruence between the femoral head and the acetabulum and the containment to the hip joint is lost.

The aim of surgical treatment is to reestablish the lost containment and to redistribute loading patterns applied to the femoral head. To improve the hip joint containment either femoral intertrochanteric varus osteotomy or acetabulum redirection osteotomies might be indicated.

The typical method to improve containment is the intertrochanteric varus osteotomy. The CCD (Centrum- Collum- Diaphysis) angle should be reduced to the extent that is necessary to reposition the femoral head in the center of the acetabulum (not below 105°) (25).

If intertrochanteric varus osteotomy alone does not produce adequate containment, a pelvic osteotomy should be performed in the same sitting. Another way to restore centralization is the Salter pelvic osteotomy, or alternatively, a triple pelvic osteotomy. With these techniques, the leg shortening and high-standing trochanter that often follow varus osteotomy can be avoided (25). The Salter osteotomy is a commonly used method. The main advantage of this osteotomy is its effect on femoral head remodeling during remaining growth (26).

Every patient of our study was treated with Salter pelvic osteotomy. The operative technique is relatively simple but requires considerable experience to be performed

correctly. It is performed to redirect the acetabulum so that the femoral head better fits in the hip joint by providing coverage, the containment re-establishes and the weight-bearing surfaces of the joint get realigned. Under X-ray control, the surgeon cuts the ilium bone in two fragments: The distal fragment is rotated through the pubic symphysis so that a gap generates between the proximal and distal fragment. Additionally, a triangle bone- notch will be cut out and inserted between the two fragments. To fix the bone- notch, two thin wires (“Kirschner- wires”) are drilled into the bone fragments (see figure 7) (27).

The indications for a Salter osteotomy are basically the same as in any form of containment treatment in LCPD. This includes: age at clinical onset of more than 6 years, more than one-half capital femoral epiphyseal involvement (Catterall groups III or IV, Herring group B), and a good range of hip motion before surgery (26). The osteotomy alone is usually indicated for younger children with recent clinical onset and no femoral head deformity or subluxation. The combined procedure is better suited for older children and those with subluxation or a deformed femoral head (26).

Even after treatment, it is essential to regularly follow-up the healing progress with an orthopedic specialist.

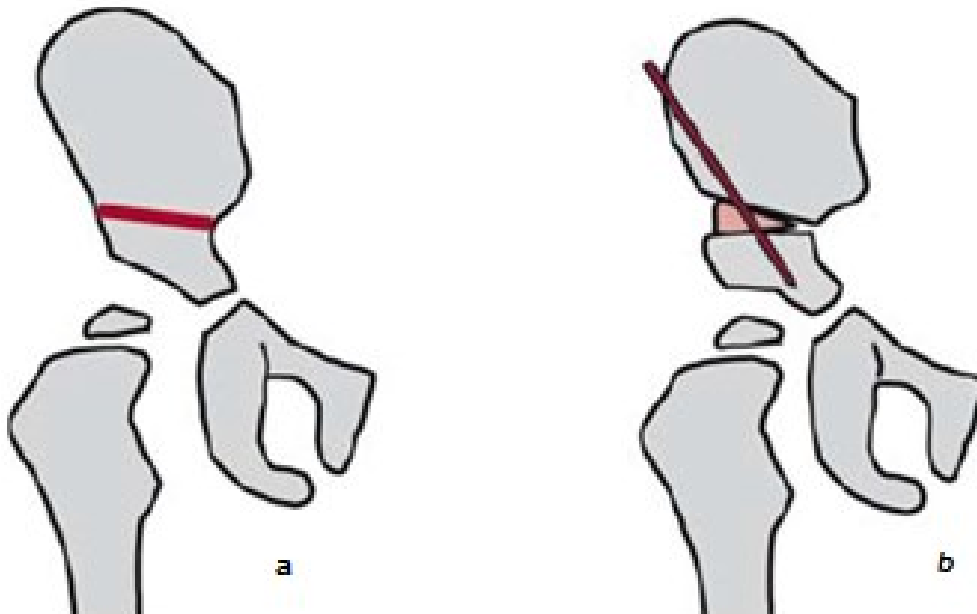


Figure 7 Principle of the Salter pelvic osteotomy: The ilium is divided above the anterior inferior iliac spine (a), the distal fragment is transposed ventrally/laterally, a triangular bone graft with the base facing laterally is wedged between the fragments and fixed with a Kirschner wire (b) (2)

A recent meta-analysis of the medical literature analyzing the effectiveness of surgical and nonsurgical treatment of Legg-Calvé-Perthes disease has found out that there is minimal evidence to determine the most appropriate treatment. Though treatment outcomes recorded are similar, the lack of consistency of methodologies used by different research studies makes it difficult to conclude whether surgical or non-surgical treatment is the most effective in management of this disease (28).

For a good long- term outcome after an osteotomy, the postsurgical treatment is also important. Some authors propose that epidural anesthesia should be left in place after mobilization for several days to improve the postoperative range of motion. Besides, physiotherapy should also be carried out (2).

1.1.5. Prognosis

Studies on long- term results have shown that more than 80 % of affected hips have good outcomes that last until the fourth decade of life. Half of all patients, however, eventually require a hip replacement surgery after a median follow- up interval of 50 years (29).

The incidence of late degenerative osteoarthritis is dependent on several factors.

Factors which may affect the outcome include:

Age The younger the child is at onset of Perthes disease, the better the chance of a good outcome, because the hip has a longer period of time to remodel before the end of growth. Children who develop Perthes disease after the age of 8-9 have the highest risk of permanent hip joint problems, such as stiffness, a restricted ROM and arthritis. If the child is less than 6 years of age, the outcome is good, even without any treatment (2). Between 6-8 years of age, several studies do not show significant differences between conservative or surgical treatment. All authors agree that age is clearly the most important prognostic factor. The older the patient, the worse the prognosis (9, 30-33).

Gender For any age of onset of Perthes disease, boys have a better chance of a good outcome than girls. This may be because girls tend to finish growth earlier than boys (2).

Severity The more severe the condition (according to the X-ray classification of the hip- e. g. Herring group C), the greater the risk of permanent problems with the hip joint and development of hip- subluxation (34).

Mobility is a very significant factor for the prognosis. Patients with considerably restricted range of motion, regardless of age, will show much worse progression and a tendency toward subluxation (2).

1.2. Physiological and pathological gait patterns

The physiological gait pattern

The human gait is a complex cyclic process for forward motion, using several confluent sequences of mechanic motion. It is defined as bipedal, biphasic forward propulsion of the centre of gravity of the human body, in which there is alternate sinuous movements of different segments of the body with least expenditure of energy (35).

J. Perry describes the following fundamental prerequisites for normal gait (36):

- Stability in stance: the person has to be stable when the limb is weight bearing and on the ground.
- Clearance in swing phase: during this, the person lifts the leg so that it leaves the ground.
- Swing phase pre-positioning: in this phase the heel comes down again to the ground. The foot has to be in alignment, getting prepared to accept the force as the person takes a step.
- Adequate step length has to be given, otherwise the gait is inefficient.
- Energy conservation: Minimization of body displacement from the line of progression is accomplished by coordinating pelvic, knee, and ankle motion to keep the relative limb length fairly constant throughout stance and reduce the muscular activity.

The interplay of progression, standing stability, and energy conservation results in a complex and continually changing relationship among the various limb segments as the body advances over the supporting foot and the toe is lifted to clear the ground. Each joint performs a representative pattern of motion (36).

Gait cycle

The gait cycle is described as a single sequence of functions by one limb. It begins when the reference foot connects the ground and ends with the following floor contact of the same foot (Figure 8,9) (37).

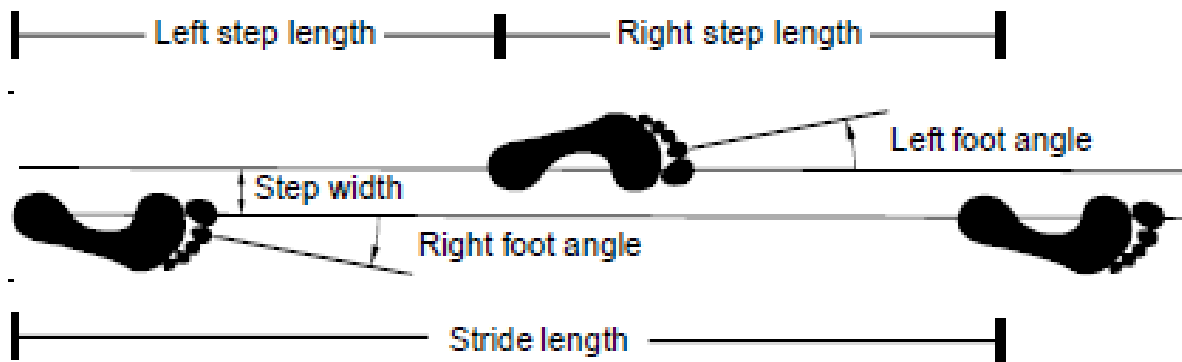


Figure 8 shows a person's footprint within a gait cycle (37).

There are two main phases in the gait cycle (38): During *stance phase*, the foot is on the ground, whereas in *swing phase* that same foot is no longer in contact with the ground and the leg is swinging through in preparation for the next foot strike.

The *stance phase* may be subdivided into three separate phases (38):

1. *First double support*, when both feet are in contact with the ground
2. *Single limb stance*, when the left foot is swinging through and only the right foot is in ground contact
3. *Second double support*, when both feet are again in ground contact (38).

As Figure 9 shows, the gait cycle has additionally been divided into eight phases or periods, five during stance phase and three during swing phase.

In the traditional nomenclature, the *stance* events are as follows:

1. *Heel strike, or initial phase*, initiates the gait cycle and represents the point at which the body's centre of gravity is at its lowest position.
2. *Foot-flat, or loading response (0 – 10%)* is the time when the plantar surface of the foot touches the ground and serves as shock absorption. The M. gluteus maximus and the hamstrings are eccentric to accelerate the leg.
3. *Midstance (10 – 30%)* occurs when the swinging (contralateral) foot passes the stancefoot and the body's centre of gravity is at its highest position. The muscles control the position of the ground reaction force relative to the hip and knee, and contribute to energy conservation. The M. gluteus medius controls the pelvic tilt.

4. *Heel-off or terminal stance (30 - 50%)* occurs as the heel loses contact with the ground and push off is initiated via the triceps surae muscles, which plantar flex the ankle. The hip adductors are eccentric and control the lateral sway. The body rolls forward.

5. *Toe-off, or Pre-swing (50 - 60%)* terminates the stance phase as the foot leaves the ground. The hip flexors are concentric to advance the limb forward, the body weight transferred to the opposite limb (38).

The **swing** events are as follows:

6. *Acceleration, or initial swing (60- 70%)* begins as soon as the foot lifts from the floor and ends when the foot swings to the opposite stance leg. The M. Sartorius and M. gracilis are concentric and control the hip and knee flexion. The knee flexes in response to forward inertia (pendulum).

7. *Midswing (70 – 85%)* occurs when the foot passes directly beneath the body, coincidental with midstance for the other foot.

8. *Deceleration, or terminal swing (85- 100%)* describes the action of the muscles as they slow the leg and stabilize the foot in preparation for the next heel strike.(38)

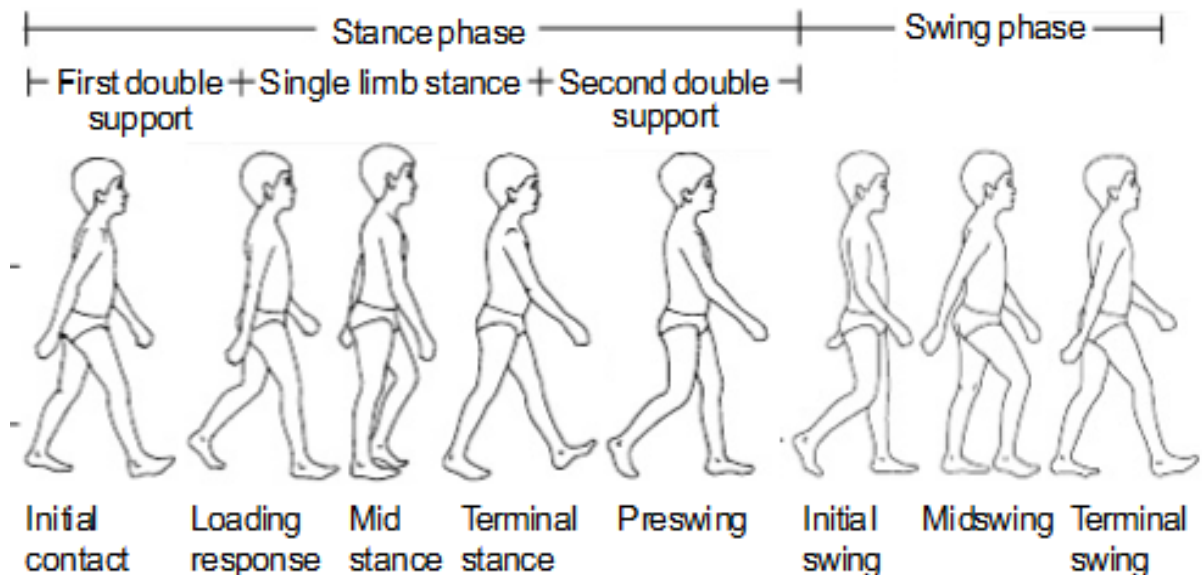


Figure 9 The normal gait cycle of an 8-year-old boy (38).

Distance parameters

Figure 8 illustrates how a set of footprints can provide useful distance parameters.

- *Stride length* is the distance travelled by a person during one stride (or cycle) and can be measured as the length between the heels from one heel strike to the next heel strike on the same side. Two step lengths (left plus right) make one stride length. Stride length is the distance travelled by a person during one stride (or cycle) and can be measured as the length between the heels from one heel strike to the next heel strike on the same side. Two step lengths (left plus right) make one stride length (36).
- Another useful parameter shown in Figure 8 is *step length*, which is defined as the distance between the corresponding successive points of heel contact of the opposite foot. The angle of the foot relative to the line of progression can also give useful information, documenting the degree of external or internal rotation of the lower extremity during the stance phase.
- *Velocity* is defined as the distance covered by the body in unit time, usually measured in meter per second.

- *Cadence* is the number of steps per time, normally between 100 – 120 steps per minute. Cadence: is defined as the number of steps per minute, or strides/gait cycles per second. Natural cadence is between 110 – 120 steps per minute.

Cadence is related to the length of lower- limb- longer legs have a slower cadence ratio (=stride length divided by cadence) (Sekiya & Nagasaki 1998). Since women are on average a little shorter than men, they tend to have a slightly higher cadence. Small children have an even more rapid cadence – up to 180 steps per minute (36), (37).

The walking speed or velocity, cadence and stride length are called the temporal-spatial parameters, or TSP of gait. Their measurement forms are the basis of any gait assessment.

- Walking speed/ velocity is the product of cadence and stride length. Since cadence is usually measured in steps/ minute, it needs to be divided by 120, so that the following equation is very useful, because it enables any one of the three variables to be calculated, given the other two:

$$\text{Speed} = (\text{Cadence} \times \text{Stride Length}) / 120 \quad (38)$$

Speed is easily calculated from the time measured to walk a known distance, and by watching carefully the number of steps taken in that time can be counted. Stride length can be determined by dividing the distance travelled by the number of steps and doubling the results (1 stride = 2 steps).

The dependence of speed on both variables allows a flexible range of combinations of cadence a stride length to be used to maintain speed under a variety of circumstances (38).

Pathological gait patterns

Any alteration affecting one or more motion or timing pattern can create a pathological gait pattern (36). Even minimal changes in gait can increase energy expenditure and progress to pathomechanical involvements. Abnormal gait patterns might be caused by impaired control, deformity, muscle weakness, sensory loss or pain.

1.2.1. *Pathological gait in LCPD*

In patients with LCPD, a physical examination often shows a limitation in ROM mainly of hip internal rotation, abduction and extension as well as an abductor weakness. This is compensated either by a so called “**Trendelenburg**” gait (39), which is characterized by a pelvic drop on the unloaded side during single stance, caused by abductor insufficiency (Mm. glutei medius et minimus). Or by a “**Duchenne**” gait, which is characterized by a trunk lean toward the stance limb with the pelvis level or elevated on the unloaded side.

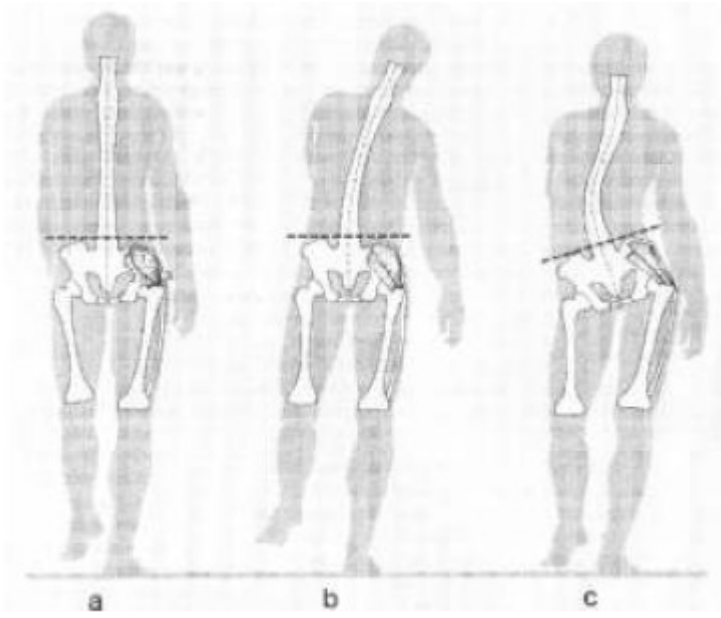


Figure 10 a: normal **b:** Trendelenburg sign **c:** Duchenne sign(40)

1.3. Gait analysis

The individual human gait pattern can be studied either in a qualitative (subjective) or quantitative (objective) way; this can help identify gait abnormalities and treatment recommendations can be developed easier.

The qualitative way is the observational (clinical) gait analysis or video gait recording and analysis. This is the most practiced way of gait analysis that physiotherapists, rehabilitation doctors or orthopedic surgeons practice every day. The equipment is quite simple - required are 4-5 meters of space where the patient can walk unimpeded, and a trained eye of the doctors.

The big advantage of this technique is its lack of expensive equipment and the possibility of practicing it anywhere. On the other hand it is just a subjective method and cannot provide a complete description of an abnormal gait, because only 2 planes (coronal and sagittal) can be observed. Besides it is dependent on the memory of the investigator and the need for many years of training to master the techniques. In addition, the video analysis does not provide any information about the acting forces.

In contrast to the simple clinical examination, video gait recording allows the simultaneous analysis of rapid movements and the position of several joints through slow motion and single frames.

The quantitative gait analysis is the objective, 3 dimensional (3D) method to describe gait. This way uses kinematic analysis (presentation of joint position in 3 dimensional viewing), kinetic analysis (forces acting in the various joints and the physical work performed), EMG (Electromyography) or energy consumption (spiroergometry). All these investigations have to be conducted in a special gait laboratory. Data can usually be recorded simultaneously- the patient gets reflection markers and EMG electrodes on specific bony landmarks and walks at a self-selected speed on force plates along a walkway. Special infrared- cameras positioned around the walkway strobe the bony markers with infrared- or visible light, and the light reflected from the markers back to the cameras is processed by a computer program. The software

provides 3D- animation of the skeleton during walking, synchronized with motion capture and simultaneous display of kinematic and kinetic data (41).

The disadvantages of 3D- gait analysis are the limited access, gait labs are just in special hospitals, and a high level of interpretation skills required. The clinical assessment of the child and the data collection- and interpretation are undertaken by a specialized multidisciplinary team, consisting of clinical and technical staff (41).

It is also essential to use standardized recording orientations and to interpret them with caution. For example, if the joints are not strictly aligned in transversal, frontal and sagittal planes, the angles will be badly distorted.

1.3.1. *Kinematics*

It studies the motion in terms of displacement, angles, velocity, and reproduces the sequences of movements in the joints in 3 dimensions in relation to time (sagittal, coronal, transversal plane). Kinematics gives information on ROM pattern and timing of muscular activity.

A 3D- video gait analysis system visually measures markers that are fixed on the patient's body, calculates the joint angles in 3 dimensions and represents these in relation to time. The results identify relationships between movements in movement sequences in the limbs. The assessment is facilitated by graphics showing normal, standardized curves in the background (38).

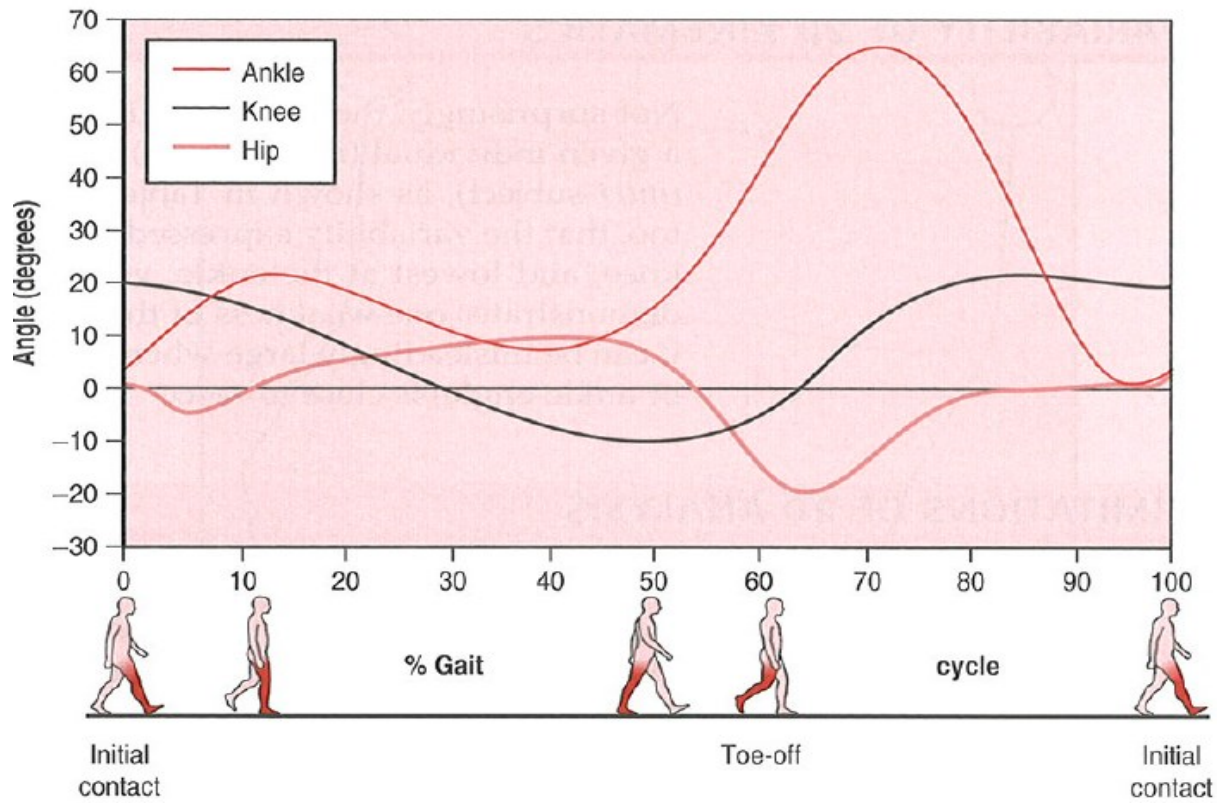


Figure 11 shows the joint kinematics of normal gait (38)

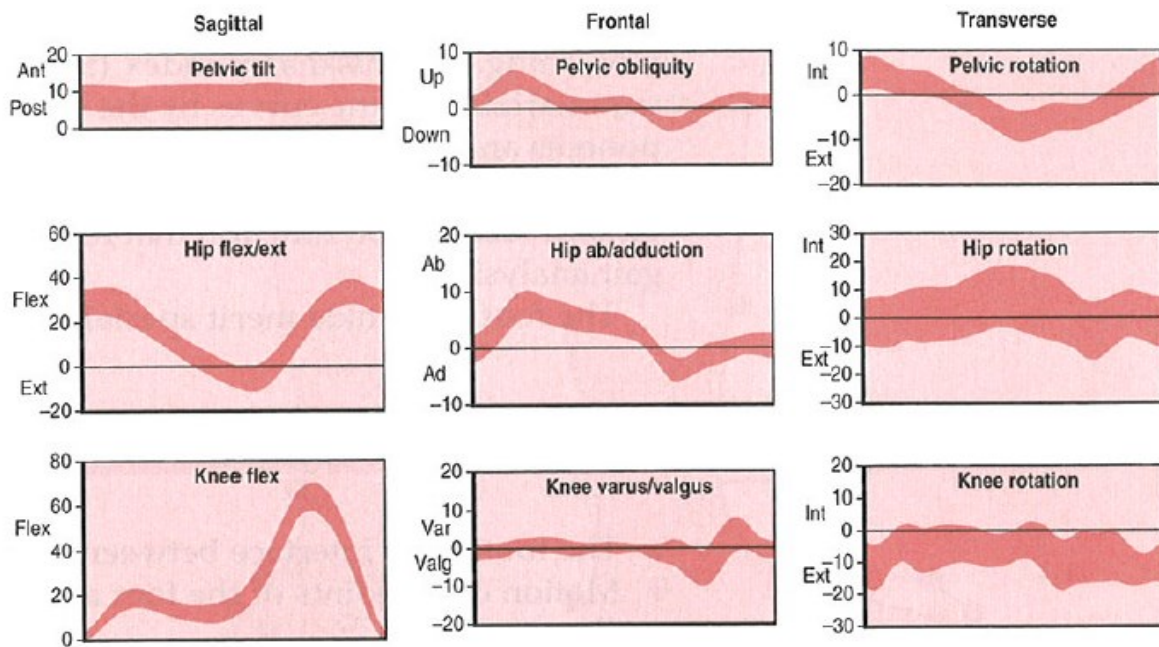


Figure 12 3D Kinematics of pelvis, hip and knee. Normative range is shown as mean +/- SD [27]

1.3.2. Kinetics:

It describes the forces acting in the various joints and the physical work performed. The forces act on segments, which rotate around centers of rotation. They can be calculated if both kinematic data and the ground reaction force are recorded simultaneously. In connection with the physical performance, kinetic analysis can also show the mechanics and efficiency of walking.

1.3.3. GDI (Gait Deviation Index)

Comprehensive measures of gait pathology are widely used in clinical gait analysis research and are an important aid in clinical practice. The computerized 3D- gait analysis renders objective data to describe the gait and generates a complexity and volume of data which is not easy to interpret.

The GDI has been developed as a summary measure of gait pathology. It compares 9 kinematic variables of a child's gait against those of a typically developing comparison group. The kinematics from the pelvis and hip in all 3 planes, the knee and ankle in the sagittal plane, and foot progression are all used for the calculation. A GDI score of 100 and above denotes non- pathological gait, SD bands are scaled to 10- point intervals below 100 (42, 43).

II Aims

Morbus Perthes is one of the most common childhood diseases concerning the femoral head (annual incidence 1:1200) (44). Currently etiology, understanding of natural history and treatment principles in Perthes disease are still controversial and the outcome of the disease might affect the quality of life in a negative way.

There are already several studies and publications about radiological results as well as clinical parameters. However, nearly no studies consider the functional aspects of the disease (e.g. gait). Based on our previous work (45) we hypothesized that hip abduction moment during gait, as surrogate for loading of the hip joint, might be an important prognostic factor for the long-term outcome in Perthes disease. The aim of our study was to show that loading of the hip joint influences the morphological, clinical and functional outcome in Perthes disease in a long- term run.

III Methods

3.1 Subjects

The study aimed to evaluate the long- term outcomes of LCPD. Altogether 42 children who underwent preoperative gait analysis between 1998 and 2003 were identified as potential candidates for the study based on the database of gait laboratory of Pediatric Orthopedic Department, Medical University of Graz. Each of the patients and their parents obtained a personal invitation letter approved by the ethical committee of the University of Medicine of Graz. However, most of the patients were not willing to participate in the study. In total, 14 men and women at the average age of 17, 7 years (SD= 2.76) who were treated between 1998 and 2003 (mean follow-up time 10.8 years, SD= 1.5 years) were willing to participate and met the below listed inclusion criteria- in total, 11 were male and three were female. Before the examination all participants, respectively their legal representatives in case of minors, had been informed in detail by the staff responsible for the study their written consent was obtained.

The left side was affected in 11 children, the right side in three of them. All patients were treated by Salter-Osteotomy in their early childhood (between 1998 and 2003), and radiologically classified after Herring-Classification before surgery. The age at treatment ranged from 4.4 to 12.8 years (mean 8.1 years, SD=2.3). Patients were divided into 3 subgroups, according to hip abductor moments during single stance on the affected side. Six children were identified as unloading their hips (un-loading group), 5 showed abductor moments within normal range (norm-loading group), and only 3 overloaded their hips (over-loading group).

3.2. Inclusion and Exclusion Criteria

Inclusion criteria:

- History of an unilateral LCPD (date of treatment between 1998 – 2003)
- 3D Gait analysis data at the beginning of the disease
- X- ray documentation at the beginning of the disease

Exclusion criteria:

- Bilateral LCPD

3.3. Clinical examination

In all patients we examined, following parameters were measured:

- height
- weight
- leg length
- goniometric measurement of hip joint movement
- Flexion/ Extension
- Internal/ External rotation
- Abduction/ Adduction
- FAI (femoroacetabular impingement)
- Trendelenburg sign

3.3.1. Hip Scores:

- The *Harris Hip Score* (HHS) is the most common clinical- functional follow- up- representation with 91 % of subjective and 9 % of objective points and a total amount of 100 points (46). It is a tool that allows the clinicians to get a rapid objective impression of the functional outcome of a hip surgery and can be compared everywhere in the world.

The HHS consists of 3 sections: the first section asks for the individual pain. The second section reports how the patient does in daily life, and the third section shows the range of hip motion gained during a physical examination. In total, 100 points can be reached. However, the HHS does not give any information about individual differences such as age, health or other personal issues that may affect the total score (47).

- The patients were also asked to fill out a HOOS questionnaire (Hip disability and Osteoarthritis Outcome Score). This patient- oriented questionnaire has been developed as instrument to assess the individual opinion of patients about their hip after total hip replacement. It is intended to be used in an adult population with hip disability and with or without osteoarthritis. The HOOS consists of 5

subscales: pain, function in activities of daily living, other symptoms, functions in sports and recreation and hip related quality of life (48).

We used both questionnaires to evaluate functional parameters as well as patients' symptoms. Both questionnaires have a high reliability; however, the HHS shows more objective results, whereas we additionally gained subjective feelings about hip symptoms and individual handling with the affected hip by using the HOOS.

For the checklist of the clinical examination, the Harris Hip Score table and the HOOS questionnaire see Appendix (49). All in all, the whole examination lasts about one and a half hour for each patient.

3.4. Radiological examination

The radiological examination consists of a pelvic and hip overview in anterior-posterior as well as Lauenstein view. The X- rays were evaluated according to the Stulberg classification.

| Grade | Characteristics |
|--------------|---|
| I | Round head, normal hip |
| II | Round head, Coxa magna |
| III | Oval or mushroom- shaped head, Coxa magna |
| IV | Flat head, congruent with acetabulum |
| V | Flat head, incongruent |

Table 4: Classification of Legg-Calvé-Perthes disease according to Stulberg et al.(2)

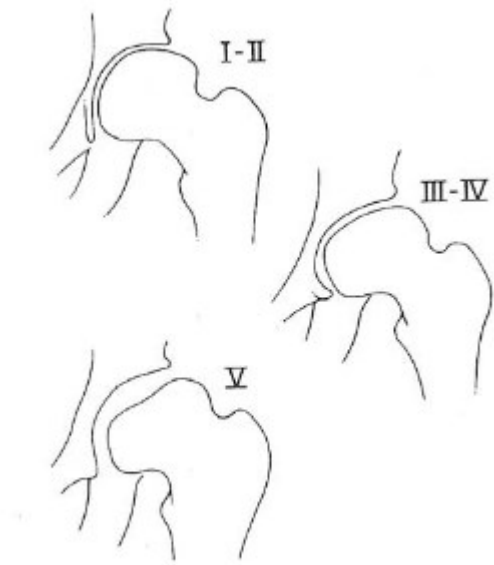


Figure 13 shows a schematic representation of Stulberg classification. I and II show a spheric congruency, III and IV an aspheric congruency, and V shows a aspheric incongruence (3)

3.5. 3D - Video gait analysis

Computerized gait analysis was performed using a video- based motion capturing system (Vicon Oxford Metrics, Oxford, UK). Vicon Clinical Manager software (Oxford Metrics) was used for data processing.

Small retro reflective markers were affixed on specific bony landmarks on the patient's body, and all patients were asked to walk barefoot at a self-selected speed along a 10- meter walkway. For each child, a minimum of five trials providing a clear foot force plate contact were captured and averaged. The Gait Deviation Index was calculated (38, 41). This index has been proposed as a summary measure of gait pathology. It compares nine kinematic variables of a child's gait against those of a typically developing comparison group. The kinematics from the pelvis and hip in all three planes, the knee and ankle in the sagittal plane, and foot progression are all used for the calculation. A GDI score of 100 and above denotes non-pathological gait, SD bands are scaled to 10- point intervals below 100.

3.6. Outcome measures

- Primary outcome measures: Radiologic classification of long-term outcomes of LCPD according to Stulberg.
- Secondary outcome measures: Hip Scores (HHS, HOOS), age at the treatment, clinical examination of the hip (ROM – Range of Motion), Gait Deviation Index.

3.7. Statistics

The Spearman's rank correlation coefficient was used to prove our hypothesis that hip abduction moment might be an important prognostic factor for the long-term outcome in Perthes disease. Our aim was to show how the loading of the hip joint influences the morphological, functional and subjective outcome of Perthes disease after surgical intervention in long-term run. The significance level was set at 5% for all statistical tests. For a basic data analysis descriptive statistics was used. All the data analyses were performed using statistical software package Statistica 8.0 (StatSoft, Tulsa, OK, USA).

IV Results

Morbus Perthes is a common childhood disease concerning the femoral head and often limits the quality of life. Patients with Morbus Perthes commonly show abnormal gait pattern due to the weak abductors and limitation of range of movement (ROM) (2). The loading of the hip joint might be an important factor to influence the long-term results of Morbus Perthes. The aim of our study was to show the influence of the hip joint loading during gait on the prognosis and long-term radiological outcome using 3D gait analysis.

Hip abductor moment

Based on our previous work we hypothesized that the hip abduction moment in the frontal plane during gait, as a surrogate for loading of the hip joint, might be a prognostic factor for long-term results of the LCPD.

We found a significant correlation of the hip abduction moment in the frontal plane with the age at the surgery ($r=0,539$), showing that older children tend to overload their hips during gait. We also tried to find out if the gait pattern represented by Gait Deviation Index might play any role in long-term results of LCPD. However, we did not find any proof to support such a hypothesis.

| | Unloading group | | | Normal loading group | | | Overloading group | | | | | |
|--------------------------------|-----------------|------|-------|----------------------|------|------|-------------------|------|-------|------|------|------|
| | mean | min | max | SD | mean | min | max | SD | mean | min | max | SD |
| Age | 7.5 | 5.5 | 10.2 | 2.3 | 6.2 | 4.4 | 8.3 | 1.5 | 10.6 | 7.2 | 12.8 | 2.9 |
| Stulberg Classification | 2.5 | 1 | 4 | 1 | 2.2 | 1 | 3 | 0.8 | 2.6 | 1 | 4 | 1.5 |
| Herring Classification | 2.5 | 2 | 3 | 0.5 | 2 | 1 | 3 | 0.8 | 2.6 | 2 | 3 | 0.8 |
| HHS total | 95.5 | 89 | 99 | 4.1 | 95.8 | 92 | 99 | 2.6 | 91 | 89 | 94 | 2.6 |
| Pain | 42 | 40 | 44 | 2.2 | 43.2 | 40 | 44 | 1.8 | 40 | 40 | 40 | 0 |
| Sitting | 4.6 | 3 | 5 | 0.82 | 5 | 5 | 5 | 0 | 5 | 5 | 5 | 0 |
| Limping | 10.5 | 8 | 11 | 1.2 | 10.4 | 8 | 11 | 1.3 | 9 | 5 | 11 | 3.5 |
| HOOS Symptoms | 91.8 | 66 | 100 | 13.3 | 95 | 90 | 100 | 5 | 86.7 | 70 | 95 | 14.4 |
| HOOS pain | 95.3 | 75 | 100 | 10 | 98 | 90 | 100 | 4.5 | 97.3 | 95 | 100 | 2.5 |
| HOOS function daily | 97 | 91 | 100 | 3.8 | 99 | 97 | 100 | 1.4 | 96.6 | 95 | 100 | 2.8 |
| HOOS Sports | 95 | 81 | 100 | 7.4 | 90 | 87 | 100 | 19.2 | 93.6 | 81 | 100 | 10.9 |
| HOOS Quality | 89 | 56 | 100 | 17.8 | 90 | 56 | 100 | 19.2 | 91.7 | 81 | 100 | 9.7 |
| HOOS Total | 95 | 80 | 100 | 7.8 | 97 | 90 | 100 | 4.25 | 94.7 | 89 | 99 | 5.1 |
| GDI | 91.4 | 74.6 | 113.5 | 13.4 | 96.1 | 85.7 | 108.2 | 8.2 | 85.4 | 56.7 | 105 | 25.3 |
| ROM Flexion/Extension | 152.8 | 130 | 167 | 13.5 | 143 | 130 | 148 | 7.4 | 131.3 | 100 | 161 | 30.5 |
| ROM Abduction/Adduction | 42.5 | 33 | 58 | 11.7 | 51.6 | 40 | 64 | 9.5 | 37.6 | 34 | 42 | 4 |
| ROM External/Internal Rotation | 57 | 20 | 74 | 18.7 | 49.2 | 20 | 86 | 26 | 48.6 | 30 | 72 | 21.4 |

Table 5: the descriptive statistics of our study, including average and standard deviation as well as maximum

Radiological results

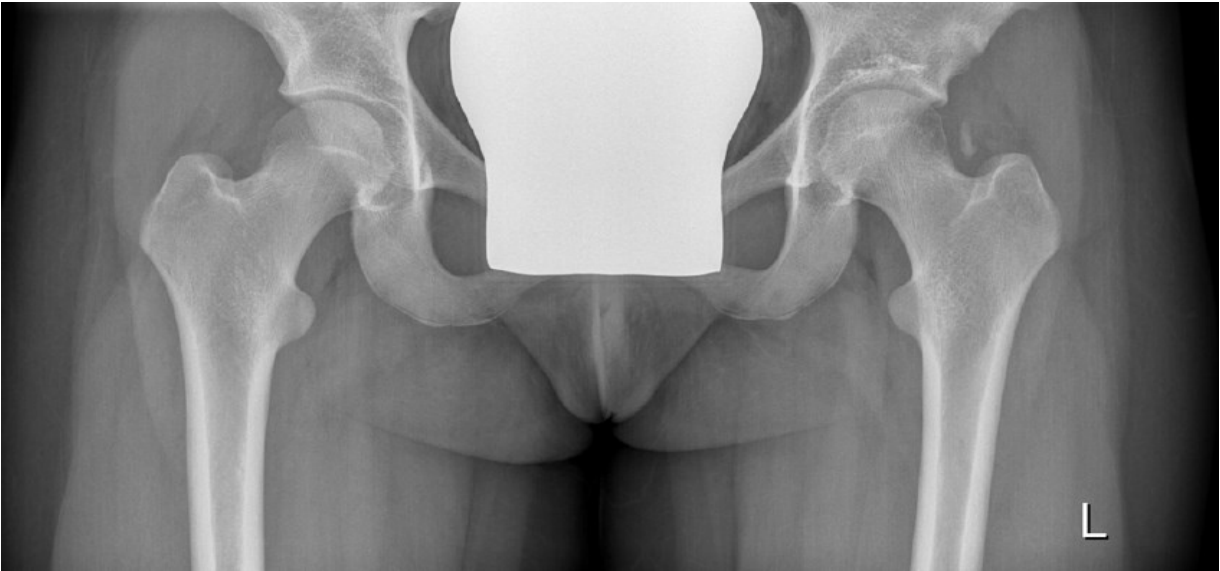
The radiological examination showed that age is not a relevant factor for the morphological outcome. We compared the preoperative classification of LCPD according to Herring and the postoperative Stulberg- Classification and found a significant correlation between these classifications ($r=0.685$). The better the preoperative Herring classification, the better the outcome in our long-term follow-up. Moreover, patients with a lower Stulberg- classification showed more limping ($r= -0.514$) and also had more symptoms ($r=-0.535$) and problems in sports activities ($r=-0.589$).

In our study there was no correlation between the hip abductor moment and the radiological long- term outcome.

Pictures



Picture 1 shows a radiological outcome of Stulberg IV, the worst result of our study. The left femoral head is aspherical flat, but shows a congruency to the acetabulum.



Picture 2 shows a Stulberg I –classification on the left side. The left head is spherical round and is congruent to the hip acetabulum.



Picture 3 shows the hip of the same patient as in picture 2, in Lauenstein view.

Hip Scores

The statistical evaluation with the Spearman rank correlation coefficient showed that the subjective symptoms evaluated by the Harris Hip Score and the HOOS, mainly depend on the *age* at the treatment. The older the patient at the time of surgical intervention, the lower the total score of the HHS ($r=-0.851$) and the HOOS($r=-0.776$). We have found that the age correlates especially with the category “limping” of the HHS ($r=-0.558$) and the categories “quality” ($r=-0.784$) and “daily function” ($r=0.732$) of the HOOS.

Clinical examination

The parameters of clinical examination are easily measurable and clinically valuable signs of the hip impairment. Therefore the correlation between range of hip motion and hip scores or radiologic evaluation might be of clinical interest. Our results show that patients with limited range of movement in hip flexion/ extension and hip rotation achieve worse functional results and reached lower hip scores. Especially the category “limping” significantly correlated with the decreased ROM in hip rotation ($r= 0.700$). Moreover, patients with limited rotation ROM showed lower total HOOS scoring, and more symptoms ($r= 0.603$) and pain ($r= 0.569$) as well as limitation in quality ($r= 0.548$).

V DISCUSSION

Based on our previous work (45), where we hypothesized that hip abduction moment might be an important prognostic factor for the long-term outcome, our aim was to show how the loading of the hip joint influences the morphological and clinical outcome several years after surgical intervention.

There is a generally accepted view that age is an important factor for the prognosis: If the patient is younger than 6 years at onset of disease, the prognosis of better morphologic as well as clinical and subjective long-term outcome is more likely.

A comprehensive study on LCPD by Terjesen, Wiig, and Svenningsen (34) was conducted in Norway in 2008 with a follow-up of 5 years. The study included 212 children (mean age 5.1 years) who were affected unilaterally, but had been treated conservatively with physiotherapy and not operatively as the patients in our study. 5 years after treatment, they were followed with X-ray. The radiographic outcome was good (i.e. spherical femoral head) in 54% of patients, fair (ovoid femoral head) in 28%, and poor (flat femoral head) in 18% (34). The average age of patients with a poor result after the 5-year radiographic outcome was 6.1 years and those with a good result had a mean age of 4.8 years.

Authors conclude that “There was a clear association between the radiographic outcome and the age of the patients at the time of diagnosis. Younger children had better results than older children, no matter whether the age was 5, 6, or 7 years”(34). Another study in 2008 conducted by Dimeglio and Canavese, included 166 hips of children before their 6th birthday. Patients with mild forms (Catterall I and II) were treated conservatively (by restricting weight-bearing), severe forms (Catterall III and IV) either conservatively or operatively (by innominate osteotomy). All patients were followed to skeletal maturity with a mean follow-up of 11 years. The radiographic results evaluated by the classifications of Stulberg and Mose showed that all hips with mild disease had a good result at skeletal maturity. Of the hips with severe disease, 67.3% had good (Stulberg I and II), 22.4% fair (Stulberg III) and 10.3% poor results

(Stulberg IV and V) (31). The conclusion of this study was that the prognosis in Perthes disease is generally good when the age at onset is less than 6 years.

As we could not find any significant correlation between the age and the radiographic outcome after Stulberg classification, our results are not in agreement with these studies. However, the explanation for this negative result might be an insufficient power of our study and based on our clinical experience age at the onset of the LCPD is an important prognostic factor for the long-term results.

The main statement of most studies concerning this topic was that it is more important to differentiate between mild and severe cases and the degree of involvement of the femoral head as prognostic factor than the age at beginning of the disease (50).

The original study of Herring showed that 46% of 78 patients under the age of 9 years of onset and 33% of 15 patients older than 9 years were classified in Lateral pillar classification group C. Further 12 of 36 patients reached a radiological outcome of Stulberg II, 19 Stulberg III and 5 patients reached Stulberg IV (17).

In agreement with the original paper of Herring in 1992 (17), we can confirm that the lateral pillar classification is an important factor for the postoperative radiological outcome according to Stulberg classification. The results of our study showed that the better the preoperative Herring classification, the better the long-term radiological outcome according to Stulberg Classification.

Dennis Wenger et al. (51) analyzed 40 hips of children between the ages of 5 to 13 years treated with triple pelvic osteotomy. All of them had preoperative lateral pillar assessment, which Wenger et al. compared in their follow-up study using a modified Stulberg classification. Additionally they evaluated limp, limb-length discrepancy, ROM and activity level. The results showed that 53% of hips were graded as lateral pillar/ Herring B and 48% were Herring C. At final follow up after 3 – 9 years, 42% had a good outcome after Stulberg I or II, 47% had a fair outcome after Stulberg III and 11% had a poor outcome. Thus, hips with Herring B outcome preoperatively were more likely to have a good outcome (65%) compared to hips with Herring C (12.5%).

No patients with Herring B showed a poor result. Wenger et al. confirmed that surgical treatment is an effective method for patients over the age of 8 with Herring B, and younger patients with Herring C (51).

As our study showed a correlation between the preoperative radiological classification after Herring and the postoperative outcome after Stulberg, we can confirm the statement of Wenger et al.

Ismail and Macnicol (52) investigated 81 hips and compared several classifications such as Herring, Catterall and Salter- Thompson as well as the arthrographic shape of the femoral head with the post-disease outcome of Stulberg classification after varus- osteotomy (41 hips) or conservative treatment (40 hips). They came to the result that the Herring classification and sphericity of the femoral head proved to be the best predictors for a good outcome. The age of onset of their patients ranged from 2.5 to 9.5 years. They advised surgical treatment for children over the age of six years in Herring group C and for those in Herring group B when arthrography shows loss of sphericity (52).

As mentioned above, our study showed that there is a significant correlation between the preoperative Herring classification and the postoperative Stulberg classification, so we can confirm the statement of Ismail and Macnicol that the Herring classification is one of the best predictors for a good long- term result.

Moreover, several studies show a significant correlation between the radiological long-term outcome according to Stulberg classification and the results of the hip scores (HHS, HOOS).

A study of Ippolito et al.(33) in 1987 included 61 patients affected unilaterally to identify the most important long-term prognostic factors in Perthes disease. The average age was 7.5 years and the average follow- up interval was 25 years, which was much longer than the follow-up interval of our study. Statistically significant correlations were found between Stulberg class and Iowa hip score, a hip score easily comparable with the HHS (33).

Another study of Zilkens et al. in 2009 (53) investigated a cohort of 25 patients between 18 and 35 years who were treated because of LCPD in their childhood. In the follow-up study (mean follow-up was 18.7 years +/- 6.2 years), hip function and clinical symptoms were evaluated by the HHS, additionally ROM, extension, flexion, abduction, adduction, internal and external rotation were measured. The activity level of each patient was evaluated according to the Tegner-Lysholm classification. For radiological evaluation, a standard AP radiograph of the pelvis and a lateral Lauenstein radiograph were obtained and evaluated by Stulberg classification and Tönnis osteoarthritis evaluation system. The results showed a total of 10 hip joints classified as Stulberg class I and II, 16 as Stulberg class III and IV, and 7 as Stulberg V. Zilkens et al. noted a correlation of decreasing ROM and the morphological grade of joint deformity.

Our study showed no correlation between the ROM and the Stulberg classification, so we can not confirm the statement of this study.

For the HHS, Zilkens et al. only used the categories “pain” and “function” and noted significant differences for these two categories in all grades of deformity. They conclude that the clinical outcome significantly depends on the degree of morphological deformity (53).

As we could not find any correlation between the clinical and the radiological outcome, we can not confirm what Zilkens et al found out.

However, an older investigation of Snyder (1975) (54) studied 31 hips in patients younger than 5 years at onset and found that 32 % had poor results and that there was no correlation between radiographic classification and functional results. (54).

We can confirm that children with worse morphological results showed more limping. They also tend to have more symptoms and problems with sports activities. However, there was no significant correlation between other functional parameters (ROM) and the morphological outcome. There was no correlation between the total score of neither the HHS nor the HOOS.

Limitations of the study

Our study shows long-term outcome of treatment of patients with Perthes disease based on clinical, radiological as well as functional data including gait analysis. The main drawback of the study is the small number of participants. Based on our database, 42 children were invited to take part in the study. However, only 14 of those adolescents and young adults were willing to participate. Our primary aim was to compare the groups of patients based on the hip loading, to be able to give more detailed information about how hip loading influences the outcomes in Perthes disease. However, this was not possible with the limited number of participants.

VI Conclusion

Unfortunately, we were not able to confirm our hypothesis that the hip abductor moment during gait influences the radiological long-term outcome in Perthes disease. The reason for that might be the low number of participants willing to take part in the study. Moreover, the Gait Deviation index, as a summary measure of gait pathology, does not seem to influence the outcome either. Therefore we might conclude that gait and hip loading during gait cannot be used as a prognostic factor in Perthes disease. On the other hand, our study confirms the important role of Herring classification for the radiologic prognosis as well as the role of the age for long-term functional outcome in Perthes disease. Moreover, simple clinical measurements (e.g. hip rotational range of motion) might be predictive for subjective symptoms, pain and limping. Future studies with larger number of participants and sufficient power are needed to show if loading of the hip might play an important role in long-term outcome of Perthes disease.

VII Appendix

7.1 Abbreviations and acronyms

| | |
|-------------|---|
| LCPD..... | Legg- Calvé- Perthes Disease |
| HHS..... | Harris Hip Score |
| HOOS..... | Hip disability and Osteoarthritis Outcome Score |
| FAI..... | Femoroacetabular Impingement |
| ROM..... | Range of Movement |
| TSP..... | Temporal Spatial Parameter |
| A..... | Arteria |
| M./ Mm..... | Musculus/ Musculi |
| EMG..... | Electromyography |
| ADHD..... | Attention Deficient Hyperactivity Disorder |
| MRI..... | Magnetic Resonance Imaging |
| CRP..... | C- reactive Protein |
| AP..... | anterior- posterior |
| CCD..... | centrum- collum- diaphysis- angle |
| SD..... | standard deviation |
| PRS..... | Physician Rating System |

7.2. Invitation letter and consent sheets

7.2.1. Invitation letter

Einladung zur Nachuntersuchung für ehemalige PatientInnen mit Morbus Perthes für die Studie:

„Das Hüft- Belastungsmoment als prognostischer Faktor bei PatientInnen mit Morbus Perthes

Sehr geehrte Patientin, sehr geehrter Patient!

Wir möchten Sie/ Dich hiermit herzlich einladen, an der oben genannten klinischen Studie teilzunehmen. Es handelt sich hierbei um eine Studie, in welcher die Langzeitergebnisse nach der Behandlung eines Morbus Perthes (Hüftkopfnekrose im Kindesalter) erhoben werden sollen.

Die Untersuchungen planen wir so kurz wie möglich zu halten, sodass jeder/e PatientIn nur einmalig für insgesamt ungefähr drei Stunden in unser Ganglabor kommen muss.

Wir werden uns bemühen, die Termine so flexibel wie Ihnen/ Dir möglich zu vereinbaren.

Anbei finden Sie/ findest Du Informationsblätter über die Studie sowie die dafür benötigten Einverständniserklärungen. Für Kinder unter 18 Jahren wird eine Unterschrift des Erziehungsberechtigten benötigt. Lesen Sie/ lies bitte den beiliegenden Text als Ergänzung zum Informationsgespräch mit Ihrem/ Deinem Arzt sorgfältig durch und zögern Sie nicht Fragen zu stellen.

Wir würden uns sehr freuen, wenn wir gemeinsam mit Ihnen/ Dir weitere Schritte in der erfolgreichen Behandlung von Morbus Perthes gehen können!

Mit freundlichen Grüßen

Das Team des Ganglabors der Universitätsklinik für Kinderchirurgie am LKH Graz, sowie Diplomandin cand. med. Isabella Maresch

7.2.2. Consent sheet for legal guardians

Nachuntersuchung für ehemalige PatientInnen mit Morbus Perthes für die Studie:

„Das Hüft- Belastungsmoment als prognostischer Faktor bei PatientInnen mit Morbus Perthes“

Einwilligungserklärung der Eltern zur Teilnahme an einer klinischen Studie ihres Kindes

Sehr geehrte Eltern!

Wir möchten Sie und Ihr Kind hiermit einladen, an der oben genannten klinischen Studie teilzunehmen. Es handelt sich hierbei um eine klinische Studie, in welcher die Langzeitergebnisse nach Behandlung von Morbus Perthes, einer Erkrankung des Hüftkopfs, erhoben werden sollen. Die Aufklärung wird in einem ausführlichen ärztlichen Gespräch stattfinden.

Die Teilnahme an einer klinischen Studie ist freiwillig und kann jederzeit ohne Angabe von Gründen durch Sie beendet werden, ohne dass Ihrem Kind hierdurch Nachteile in der medizinischen Betreuung entstehen. Klinische Studien sind notwendig, um verlässliche neue medizinische Forschungsergebnisse zu gewinnen. Unverzichtbare Voraussetzung für die Durchführung einer klinischen Studie ist jedoch, dass Sie Ihr Einverständnis zur Teilnahme an dieser klinischen Studie schriftlich erklären. Bitte lesen Sie den folgenden Text als Ergänzung zum Informationsgespräch mit Ihrem Arzt sorgfältig durch und zögern Sie nicht Fragen zu stellen.

Bitte unterschreiben Sie die Einwilligungserklärung nur

- wenn Sie und Ihr Kind Art und Ablauf der klinischen Studie vollständig verstanden haben,
- wenn Sie und Ihr Kind bereit sind, der Teilnahme zuzustimmen und
- wenn Sie sich über Ihre Rechte als Teilnehmer an dieser klinischen Studie im Klaren sind.

Zu dieser klinischen Studie, sowie zur Patienteninformation und Einwilligungserklärung wurde von der zuständigen Ethikkommission eine befürwortende Stellungnahme abgegeben.

1. Was ist der Zweck der klinischen Studie?

Ihr Kind war vor einigen Jahren aufgrund von Morbus Perthes, einer degenerativen Erkrankung des Hüftkopfs, an unserer Klinik in Behandlung.

Die Therapie dieser Erkrankung im Kindes- und Jugendalter erfolgt nach Ausschöpfung der konservativen Maßnahmen so spät als möglich und erst dann operativ, wenn Schmerzen und/oder eine zu starke Bewegungseinschränkung besteht sowie radiologische Befunde ein fortgeschrittenes Stadium zeigen.

Die Patientinnen und Patienten weisen auch unterschiedliche Gangmuster auf, und wir möchten anhand dieser Studie nun feststellen, auf welche Art sich ein Morbus Perthes unter Anwendung verschiedener Gangvarianten bestmöglich therapieren lässt, sodass Kinder möglichst hüftkopfschonend wieder gesund werden können.

Nach Auswertung der gewonnenen Ergebnisse können eventuell neue Therapierichtlinien erstellt werden.

2. Wie läuft die klinische Studie ab?

Diese klinische Studie wird an der klinischen Abteilung für Kinderorthopädie in Graz durchgeführt. Es werden ungefähr 40 Personen daran teilnehmen. Bei Aufnahme in die klinische Studie wird die Vorgeschichte Ihres Kindes anhand der bisher vorliegenden Dokumente erfasst und durch zusätzliche Fragen ergänzt. Weiters wird eine klinische und ganganalytische, sowie eine radiologische Untersuchung an unserer Klinik stattfinden.

Folgende Maßnahmen werden durchgeführt:

- neuerliches Röntgen
- Ausfüllen von Erhebungsbögen
- Beurteilung von Gangbild, Beweglichkeit, Beschwerden, knöchernen Veränderungen und des Zurechtkommens im Alltag mittels verschiedener Erhebungsbögen (Harris Hip Score)

3. Worin liegt der Nutzen einer Teilnahme an der Klinischen Studie?

Der Morbus Perthes ist eine der häufigsten im Kindesalter auftretenden orthopädischen Erkrankungen. Dabei wird der Hüftkopf aus weitgehend unbekanntem Ursachen nicht ausreichend versorgt, sodass es frühzeitig zur Degeneration und weiters zu arthrotischen Veränderungen kommen kann.

Mit den neuerlichen Untersuchungsergebnissen von ehemaligen Patientinnen und Patienten, die in ihrer Kindheit aufgrund von Morbus Perthes am LKH Graz in Behandlung waren, sollen ehestmögliche Prognosen auf die späteren Auswirkungen gemacht werden können und außerdem mögliche Therapieoptionen für die bestmögliche Prognose geschaffen werden.

Für Ihr Kind persönlich besteht der Vorteil, dass Beschwerden, die im Zusammenhang mit dieser Erkrankung stehen, direkt auf unserer Klinik behandelt werden können, bzw. im Rahmen der Nachuntersuchung erkannte, latent bestehende Probleme bereits früher erkannt werden können.

4. Gibt es Risiken, Beschwerden und Begleiterscheinungen?

Um das Ausmaß der Abnützung des Hüftkopfs beurteilen zu können, ist ein Röntgenbild notwendig. Röntgenbilder sind mit einer Strahlenbelastung verbunden und können potentiell Schaden anrichten. In der aktuellen Studie handelt es sich allerdings um extrem niedrige Strahlenwerte (insg.ca. 1mSievert). Frauen/Mädchen die gebärfähig sind, werden nach einer möglichen Schwangerschaft befragt. Sollte eine Schwangerschaft vorliegen oder auch nur angenommen werden, wird die Patientin von der radiologischen Untersuchung ausgeschlossen werden und lediglich an der klinischen Untersuchung und Befragung teilnehmen.

Im Rahmen der klinischen und ganganalytischen Untersuchung sind keine Risiken zu erwarten.

5. Hat die Teilnahme an der klinischen Studie sonstige Auswirkungen auf die Lebensführung und welche Verpflichtungen ergeben sich daraus?

Es ergeben sich daraus keinerlei Auswirkungen und/oder Verpflichtungen.

6. Wann wird die klinische Studie vorzeitig beendet?

Sie und Ihr Kind können jederzeit auch ohne Angabe von Gründen, die Teilnahme widerrufen und aus der klinischen Studie ausscheiden ohne dass für Sie dadurch irgendwelche Nachteile für die weitere medizinische Betreuung entstehen.

Ihr Prüfarzt wird Sie über alle neuen Erkenntnisse, die in Bezug auf diese klinische Studie bekannt werden, und für Sie wesentlich werden könnten, umgehend informieren. Auf dieser Basis können Sie dann die Entscheidung zur weiteren Teilnahme an der klinischen Studie neu überdenken.

Es ist aber auch möglich, dass Ihr Prüfarzt (oder gegebenenfalls der Auftraggeber dieser klinischen Studie) entscheidet, die Teilnahme an der klinischen Studie vorzeitig zu beenden, ohne vorher Ihr Einverständnis einzuholen. Die Gründe hierfür können sein:

- Ihr Kind kann den Erfordernissen der Klinischen Studie nicht entsprechen
- Ihr behandelnder Arzt hat den Eindruck, dass eine weitere Teilnahme an der klinischen Studie nicht in Ihrem Interesse oder dem Interesse Ihres Kindes ist.

7. In welcher Weise werden die im Rahmen dieser klinischen Studie gesammelten Daten verwendet?

Sofern gesetzlich nicht etwas anderes vorgesehen ist, haben nur die Prüfer und deren Mitarbeiter, sowie in- und ausländische Gesundheitsbehörden Zugang zu den vertraulichen Daten, in denen Ihr Kind namentlich genannt wird. Diese Personen unterliegen der Schweigepflicht.

Die Weitergabe der Daten im In- und Ausland erfolgt ausschließlich zu statistischen Zwecken und Ihr Kind wird darin ausnahmslos nicht namentlich genannt. Auch in etwaigen Veröffentlichungen der Daten dieser klinischen Studie wird Ihr Kind nicht namentlich genannt.

8. Entstehen für die Teilnehmer Kosten ? Gibt es einen Kostenersatz oder eine Vergütung?

Durch die Teilnahme an dieser klinischen Studie entstehen für Sie – abgesehen von den Fahrtkosten - keine zusätzlichen Kosten. Für die anfallenden Fahrtkosten kann kein Kostenersatz geleistet werden. Darüber hinaus ist keine Vergütung vorgesehen.

9. Möglichkeit zur Diskussion weiterer Fragen

Für weitere Fragen im Zusammenhang mit dieser klinischen Studie stehen Ihnen Ihr Prüfarzt und seine Mitarbeiter gern zur Verfügung. Auch Fragen, die Ihre Rechte als Erziehungsberechtigter des Patienten und Teilnehmer an dieser klinischen Studie betreffen, werden Ihnen gerne beantwortet.

Name der 1. Kontaktperson: Isabella Maresch

Erreichbar unter: 0664 43 44 64 3

Name der 2. Kontaktperson: PhD Dr. Martin Svehlik

Erreichbar unter: 0316 385 14 12 9 (Ganglabor)

Name der 3. Kontaktperson: Univ. Prof. Dr. Wolfgang Linhart

Erreichbar unter: 0316 385 3772

10. Einwilligungserklärung

Name des Patienten:

Ich erkläre mich bereit, mein Kind an der Nachuntersuchung für die klinische Studie: „Das Hüft – Belastungsmoment als prognostischer Faktor bei PatientInnen mit Morbus Perthes“ teilzunehmen zu lassen.

Wir sind von Herrn/Frau ausführlich und verständlich über mögliche Belastungen und Risiken, sowie über Wesen, Bedeutung und Tragweite der klinischen Studie, sowie die sich für uns daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text dieser Patientenaufklärung und Einwilligungserklärung, die insgesamt 6 Seiten umfasst gelesen. Aufgetretene Fragen wurden mir vom Prüfarzt verständlich und genügend beantwortet. Wir hatten ausreichend Zeit, uns zu entscheiden. Wir haben zurzeit keine weiteren Fragen mehr.

Wir werden den ärztlichen Anordnungen, die für die Durchführung der klinischen Studie erforderlich sind, Folge leisten, behalten uns jedoch das Recht vor, die freiwillige Mitwirkung jederzeit zu beenden, ohne dass meinem Kind daraus Nachteile für die weitere medizinische Betreuung entstehen.

Ich bin zugleich damit einverstanden, dass die im Rahmen dieser klinischen Studie ermittelten Daten meines Kindes aufgezeichnet werden. Um die Richtigkeit der Datenaufzeichnung zu überprüfen, dürfen Beauftragte der zuständigen Behörden beim Prüfarzt Einblick in die personenbezogenen Krankheitsdaten meines Kindes nehmen.

Beim Umgang mit den Daten werden die Bestimmungen des Datenschutzgesetzes beachtet. Eine Kopie dieser Patienteninformation und Einwilligungserklärung habe ich erhalten. Das Original verbleibt beim Prüfarzt.

.....
(Datum und Unterschrift des Erziehungsberechtigten)

.....
(Datum, Name und Unterschrift des verantwortlichen Arztes)

(Der Patient erhält eine unterschriebene Kopie der Patienteninformation und Einwilligungserklärung, das Original verbleibt im Studienordner des Prüfarztes.)

7.2.3. Consent sheet for adults

PatientInneninformation, und Einwilligungserklärung zur Teilnahme an der klinischen Studie

„Das Hüft- Belastungsmoment als prognostischer Faktor bei PatientInnen mit Morbus Perthes“

Sehr geehrte Teilnehmerin, sehr geehrter Teilnehmer!

Wir laden Sie ein an der oben genannten klinischen Studie teilzunehmen. Die Aufklärung darüber erfolgt in einem ausführlichen ärztlichen Gespräch.

Ihre Teilnahme an dieser klinischen Studie erfolgt freiwillig. Sie können jederzeit ohne Angabe von Gründen aus der Studie ausscheiden. Die Ablehnung der Teilnahme oder ein vorzeitiges Ausscheiden aus dieser Studie hat keine nachteiligen Folgen für Ihre medizinische Betreuung.

Klinische Studien sind notwendig, um verlässliche neue medizinische Forschungsergebnisse zu gewinnen. Unverzichtbare Voraussetzung für die Durchführung einer klinischen Studie ist jedoch, dass Sie Ihr Einverständnis zur Teilnahme an dieser klinischen Studie schriftlich erklären. Bitte lesen Sie den folgenden Text als Ergänzung zum Informationsgespräch mit Ihrem Arzt sorgfältig durch und zögern Sie nicht Fragen zu stellen.

Bitte unterschreiben Sie die Einwilligungserklärung nur

- wenn Sie Art und Ablauf der klinischen Studie vollständig verstanden haben,
- wenn Sie bereit sind, der Teilnahme zuzustimmen und
- wenn Sie sich über Ihre Rechte als Teilnehmer an dieser klinischen Studie im klaren sind.

Zu dieser klinischen Studie, sowie zur Patienteninformation und Einwilligungserklärung wurde von der zuständigen Ethikkommission eine befürwortende Stellungnahme abgegeben.

1. Was ist der Zweck der klinischen Studie?

Sie waren in Ihrer Kindheit aufgrund von Morbus Perthes, einer degenerativen Erkrankung des Hüftkopfs, an unserer Klinik in Behandlung. Die Therapie dieser Erkrankung im Kindes- und Jugendalter erfolgt nach Ausschöpfung der konservativen Maßnahmen so spät als möglich und erst dann operativ, wenn Schmerzen und/ oder eine zu starke Bewegungseinschränkung besteht sowie radiologische Befunde ein fortgeschrittenes Stadium zeigen. Die Patientinnen und Patienten weisen auch unterschiedliche Gangmuster auf, und wir möchten anhand dieser Studie nun feststellen, auf welche Art sich ein Morbus Perthes unter Anwendung verschiedener Gangvarianten bestmöglich therapieren lässt, sodass Kinder möglichst hüftkopfschonend wieder gesund werden können. Nach Auswertung der gewonnenen Ergebnisse können eventuell neue Therapierichtlinien erstellt werden

2. Wie läuft die klinische Studie ab?

Diese klinische Studie wird an der klinischen Abteilung für Kinderorthopädie in Graz durchgeführt. Es werden ungefähr 40 Personen daran teilnehmen. Bei Aufnahme in die klinische Studie wird Ihre Vorgeschichte anhand der bisher vorliegenden Dokumente erfasst und durch zusätzliche Fragen ergänzt. Weiters wird eine klinische und ganganalytische, sowie eine radiologische Untersuchung an unserer Klinik stattfinden.

Folgende Maßnahmen werden durchgeführt:

- neuerliches Röntgen (mit geringer Strahlenbelastung von etwa 2x 0,6 mSievert, entspricht etwa der kosmischen Strahlenbelastung in 2000m Höhe)
- Ausfüllen von Erhebungsbögen
- Beurteilung von Gangbild, Beweglichkeit, Beschwerden, knöchernen Veränderungen und des Zurechtkommens im Alltag mittels verschiedener Erhebungsbögen (Harris Hip Score)

3. Worin liegt der Nutzen einer Teilnahme an der Klinischen Studie?

Der Morbus Perthes ist eine der häufigsten im Kindesalter auftretenden orthopädischen Erkrankungen. Dabei wird der Hüftkopf aus weitgehend unbekanntem Ursachen nicht ausreichend versorgt, sodass es frühzeitig zur Degeneration und weiters zu arthrotischen Veränderungen kommen kann. Mit den neuerlichen Untersuchungsergebnissen von ehemaligen Patientinnen und Patienten, die in ihrer Kindheit aufgrund von Morbus Perthes am LKH Graz in Behandlung waren, sollen ehestmögliche Prognosen auf die späteren Auswirkungen gemacht werden können und außerdem mögliche Therapieoptionen für die bestmögliche Prognose geschaffen werden. Für Sie persönlich besteht der Vorteil, dass Sie Beschwerden, die im Zusammenhang mit dieser Erkrankung stehen, direkt auf unserer Klinik behandeln lassen können, bzw. im Rahmen der Nachuntersuchung erkannte, latent bestehende Probleme bereits früher erkannt werden können

.4. Gibt es Risiken, Beschwerden und Begleiterscheinungen?

Um das Ausmaß der Abnutzung des Hüftkopfs beurteilen zu können, ist ein Röntgenbild notwendig. Röntgenbilder sind mit einer Strahlenbelastung verbunden und können potentiell Schaden anrichten. Die Strahlendosis für die Hüftaufnahmen beträgt insgesamt ungefähr $2 \times 0,5$ mSievert (entspricht ungefähr der kosmischen Strahlung in 2000m Höhe). Frauen/Mädchen die gebärfähig sind, werden nach einer möglichen Schwangerschaft befragt. Sollte eine Schwangerschaft vorliegen oder auch nur angenommen werden, wird die Patientin von der radiologischen Untersuchung ausgeschlossen werden und lediglich an der klinischen Untersuchung und Befragung teilnehmen.

Im Rahmen der klinischen und ganganalytischen Untersuchung sind keine Risiken zu erwarten.

5. Hat die Teilnahme an der klinischen Studie sonstige Auswirkungen auf die Lebensführung und welche Verpflichtungen ergeben sich daraus? Es ergeben sich daraus keinerlei Auswirkungen und/oder Verpflichtungen

6. Wann wird die klinische Studie vorzeitig beendet?

Sie können jederzeit auch ohne Angabe von Gründen, die Teilnahme widerrufen und aus der klinischen Prüfung ausscheiden ohne dass für Sie dadurch irgendwelche Nachteile für die weitere medizinische Betreuung entstehen. Ihr Prüfarzt wird Sie über alle neuen Erkenntnisse, die in Bezug auf diese klinische Prüfung bekannt werden, und für Sie wesentlich werden könnten, umgehend informieren. Auf dieser Basis können Sie dann die Entscheidung zur weiteren Teilnahme an der klinischen Prüfung neu überdenken. Es ist aber auch möglich, dass Ihr Prüfarzt (oder gegebenenfalls der Auftraggeber dieser klinischen Prüfung) entscheidet, die Teilnahme an der klinischen Prüfung vorzeitig zu beenden, ohne vorher Ihr Einverständnis einzuholen. Die Gründe hierfür können sein:

- Sie können den Erfordernissen der Klinischen Prüfung nicht entsprechen
- Ihr behandelnder Arzt hat den Eindruck, dass eine weitere Teilnahme an der
- klinischen Prüfung nicht in Ihrem Interesse ist

7. In welcher Weise werden die im Rahmen dieser klinischen Studie gesammelten Daten verwendet?

Sofern gesetzlich nicht etwas anderes vorgesehen ist, haben nur die Prüfer und deren Mitarbeiter, sowie in- und ausländische Gesundheitsbehörden Zugang zu den vertraulichen Daten, in denen Sie namentlich genannt werden. Diese Personen unterliegen der Schweigepflicht. Die Weitergabe der Daten im In- und Ausland erfolgt ausschließlich zu statistischen Zwecken und Sie werden darin ausnahmslos nicht namentlich genannt. Auch in etwaigen Veröffentlichungen der Daten dieser klinischen Prüfung werden Sie nicht namentlich genannt.

8. Entstehen für die Teilnehmer Kosten? Gibt es einen Kostenersatz oder eine Vergütung?

Durch die Teilnahme an dieser klinischen Prüfung entstehen für Sie – abgesehen von den Fahrtkosten - keine zusätzlichen Kosten. Für die anfallenden Fahrtkosten kann kein Kostenersatz geleistet werden. Darüber hinaus ist keine Vergütung vorgesehen.

9. Möglichkeit zur Diskussion weiterer Fragen

Für weitere Fragen im Zusammenhang mit dieser klinischen Studie stehen Ihnen Ihr Studienarzt und seine Mitarbeiter gern zur Verfügung. Auch Fragen, die Ihre Rechte als Patient und Teilnehmer an dieser klinischen Studie betreffen, werden Ihnen gerne beantwortet.

Name der 1. Kontaktperson: cand.med. Isabella Maresch
Erreichbar unter: 066 43 44 64 3

Name der 2. Kontaktperson: PhD Dr. Martin Svehlik
Erreichbar unter: 0316 385 14 12 9 (Ganglabor)

Name der 3. Kontaktperson: Univ. Prof. Dr. Wolfgang Linhart
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10. Einwilligungserklärung

Name des Patienten:

Ich erkläre mich bereit, an der Nachuntersuchung für die klinische Studie: „Das Hüft – Belastungsmoment als prognostischer Faktor bei PatientInnen mit Morbus Perthes“

Ich bin von Herrn/Frau ausführlich und verständlich über mögliche Belastungen und Risiken, sowie über Wesen, Bedeutung und Tragweite der klinischen Studie, sowie die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text dieser Patientenaufklärung und Einwilligungserklärung, die insgesamt 5 Seiten umfasst gelesen. Aufgetretene Fragen wurden mir vom Prüfarzt verständlich und genügend beantwortet. Ich hatte ausreichend Zeit, mich zu entscheiden. Ich habe zurzeit keine weiteren Fragen mehr.

Ich werde den ärztlichen Anordnungen, die für die Durchführung der klinischen Studie erforderlich sind, Folge leisten, behalte mir jedoch das Recht vor, meine freiwillige Mitwirkung jederzeit zu beenden, ohne dass mir daraus Nachteile für meine weitere medizinische Betreuung entstehen.

Ich bin zugleich damit einverstanden, dass meine im Rahmen dieser klinischen Studie ermittelten Daten aufgezeichnet werden. Um die Richtigkeit der Datenaufzeichnung zu überprüfen, dürfen Beauftragte des Auftraggebers und der zuständigen Behörden beim Prüfarzt Einblick in meine personenbezogenen Krankheitsdaten nehmen.

Beim Umgang mit den Daten werden die Bestimmungen des Datenschutzgesetzes beachtet. Eine Kopie dieser Patienteninformation und Einwilligungserklärung habe ich erhalten. Das Original verbleibt beim Prüfarzt.

.....
(Datum und Unterschrift des Patienten)

.....
(Datum, Name und Unterschrift des verantwortlichen Arztes)

7.2.4. Consent sheet for children over 14 years

Nachuntersuchung für ehemalige PatientInnen mit Morbus Perthes für die Studie:

"Das Hüft- Belastungsmoment als prognostischer Faktor bei PatientInnen mit Morbus Perthes"

Informationsblatt für Kinder und Jugendliche ab 14 Jahren

Liebe Patientin, lieber Patient!

Wie du sicher noch weißt, wurdest du vor einiger Zeit in unserem Krankenhaus behandelt, weil du an Morbus Perthes erkrankt warst, der Krankheit, bei der dein Hüftgelenk bzw. der Femurkopf zu wenig versorgt wurde und dadurch Gangprobleme gemacht hat.

Die genaueren Ursachen sind uns leider immer noch nicht bekannt, jedoch wollen wir jetzt herausfinden, wie man Behandlungsmöglichkeiten verbessern und auf alle Perthes- PatientInnen anwenden kann.

Uns interessiert für diese Studie, wie es dir nun nach deiner Erkrankung geht- ob du noch Folgebeschwerden vom Morbus Perthes hast oder ob du dein Bein problemlos und ohne Beeinträchtigungen im Alltag oder beim Sport bewegen kannst.

Die Untersuchungen und Studien, um eine bessere und gezieltere Therapie zu entwickeln, laufen weltweit auf Hochtouren. Auch die Ärztinnen und Ärzte des LKH Graz und der MedUni Graz wollen sich daran beteiligen.

Dazu müssen ein paar Nachuntersuchungen gemacht werden, für die wir deine Hilfe benötigen würden:

Um zu sehen, wie du damals mit deiner Krankheit umgegangen bist und ob dir unsere Therapie geholfen hat, möchten wir dich zu so einer Nachuntersuchung einladen.

Was soll ich tun?

Damit wir anderen Kindern, die gerade an Morbus Perthes leiden, so gut und schnell wie möglich helfen können, ist es sehr wichtig zu wissen, wie dir die Therapie damals geholfen hat und was man noch machen könnte, damit sich die Beine der PatientInnen ohne Beeinträchtigung normal entwickeln und so spätere Probleme verhindert werden können.

Wir würden uns also sehr freuen, wenn du bei dieser kleinen Untersuchung mitmachst und uns und anderen Kindern damit hilfst.

Wir laden dich also herzlich ein uns einmal zu besuchen damit wir dir ein paar Fragen stellen und dich klinisch untersuchen können.

Was wird mit mir geschehen?

Bei deinem Besuch würden wir gerne wissen, wie es dir jetzt geht, und ob du jetzt noch etwas von

deiner damaligen Krankheit spürst. Dazu möchten wir dir einige Fragen stellen. Wir wollen beispielsweise wissen, ob du dich ohne Einschränkungen bewegen kannst oder ob du dein Bein und deine Hüfte nicht so belasten kannst, wie du möchtest, weil du Schmerzen oder andere Probleme mit deinen Beinen hast. Wir möchten dein Bein gerne untersuchen und ansehen, ob du alle Bewegungen machen kannst. Mittels eines Computers im Ganganalyselabor werden deine Beine während des Gehens genau analysiert.

Zum Schluss wollen wir auch noch ein Röntgenbild von deiner Hüfte machen.

Sollte dir etwas unangenehm oder unklar sein, musst du uns das nur sagen. Deine Eltern können während der Befragung und Untersuchung natürlich die ganze Zeit über bei dir bleiben.

Kann ich meine Meinung ändern?

Wenn du dich dazu entschließt, dass du bei dieser Nachuntersuchung nicht mitmachen möchtest, teile uns oder deinen Eltern dies einfach früh genug mit.

Wenn du uns jetzt helfen möchtest, deine Meinung aber später änderst, macht das auch nichts. Du kannst jederzeit, wann immer du willst, mit der Studie aufhören, die Ärzte werden dich auch dann jederzeit betreuen, wenn dies nötig ist. Wenn du Fragen zu den jeweiligen Untersuchungen oder zur Studie hast, kannst du dich gerne an uns Ärzte wenden. Wir werden versuchen, alle deine Fragen beantworten.

Anbei findest du eine Einwilligungserklärung, die du bitte selbst ausfüllst! Deine Eltern bekommen ein eigenes Formular dafür.

Einwilligungserklärung des Patienten

Der/Die Patientin sollte das gesamte Blatt selbst ausfüllen

| | | |
|--|-----------------------------|-------------------------------|
| Hast du das Informationsblatt gelesen? | <input type="checkbox"/> Ja | <input type="checkbox"/> Nein |
| Hast du alle Fragen gestellt, die du stellen wolltest? | <input type="checkbox"/> Ja | <input type="checkbox"/> Nein |
| Hat der Arzt alle deine Fragen beantwortet? | <input type="checkbox"/> Ja | <input type="checkbox"/> Nein |
| Ist dir bekannt, dass du mit der Nachuntersuchung aufhören kannst, wenn du das möchtest? | <input type="checkbox"/> Ja | <input type="checkbox"/> Nein |
| Möchtest du teilnehmen? | <input type="checkbox"/> Ja | <input type="checkbox"/> Nein |

| | | |
|-------------------|----------------------|-------|
| Patient/in | Name (Blockschrift): | _____ |
| | Unterschrift: | _____ |
| | Datum: | _____ |
| Aufklärender Arzt | Name (Blockschrift): | _____ |
| | Unterschrift: | _____ |

7.2.5. Consent sheet for children under 14 years

As there were no participants under 14 years, there was no need for this sheet.

7.3. Questionnaires

7.3.1. Harris Hip Score(55)

| Schmerzen | | Punkte |
|-----------------------------|--|---------------|
| kein Schmerz | | 44 |
| leichter Schmerz | gelegentliche Beschwerden oder geringgradige Schmerzwahrnehmung, die Aktivität ist nicht behindert. | 40 |
| geringe Schmerzen | keine Auswirkung auf die durchschnittliche Aktivität, selten mäßige Schmerzen nach ungewohnten Tätigkeiten, gelegentlich z.B. Aspirin. | 30 |
| mäßige Schmerzen | Schmerz erträglich, regelmäßige Arbeit möglich, jedoch Behinderung bei gewöhnlicher Aktivität, gelegentlich stärkere Analgetika erforderlich | 20 |
| deutliche Schmerzen | starke gelegentlich auftretende und wieder vergehende Schmerzen, ernsthafte Einschränkung des Aktivitätsniveaus, stärkere Schmerzmittel | 10 |
| schwere Schmerzen | starker Schmerz auch im Bett, der Schmerz zwingt den Patienten überwiegend im Bett zu bleiben, schwerste Beeinträchtigung | 0 |
| Tägliche Tätigkeiten | | |
| Treppen | eine Stufe nach der anderen ohne Nachziehen des Beines und ohne den Gebrauch eines Geländers | 4 |
| | Stufe nach Stufe ohne Nachziehen eines Beines, aber mit Geländer | 2 |
| | Treppengehen ist noch möglich mit beliebigen Hilfsmitteln | 1 |
| | Patient ist nicht in der Lage Treppen zu steigen | 0 |
| Öffentliche Verkehrsmittel | Patient ist in der Lage, öffentliche Verkehrsmittel zu benutzen | 1 |
| Sitzen | Patient kann bequem auf jedem Stuhl für 1 Stunde sitzen | 5 |
| | Patient kann bequem auf einem hohen Stuhl für eine halbe Stunde sitzen | 3 |
| | Patient ist nicht in der Lage, auf irgend einem Stuhl bequem zu sitzen | 0 |
| Schuhe und Strümpfe | Patient kann ohne weiteres Strümpfe anziehen und Schuhe binden | 4 |
| | Patient kann unter Schwierigkeiten Strümpfe anziehen und Schuhe binden | 2 |
| | Patient ist nicht in der Lage, Schuhe oder Strümpfe anzuziehen | 0 |
| Gefähigkeit | | |
| Hinken | kein Hinken | 11 |
| | leichtes Hinken | 8 |
| | mäßiges Hinken | 5 |
| | schweres Hinken | 0 |
| Gehhilfen | keine | 11 |
| | einzelner Stock für längere Strecken | 7 |
| | einzelner Stock für die meiste Zeit | 5 |
| | eine Unterarm-Gehstütze | 3 |
| | zwei Stöcke | 2 |
| | zwei Unterarm-Gehstützen oder Gehunfähigkeit | 0 |
| Entfernungen | unbegrenzt | 11 |
| | zwei Kilometer | 8 |
| | 200 bis 500 Meter | 5 |
| | nur in der Wohnung | 2 |
| | Bett oder Stuhl | 0 |

| Fehlhaltungen und Deformitäten | | |
|---|----------------------|---|
| Adduktions- kontraktur | weniger als 10 Grad | 1 |
| | 10 Grad oder mehr | 0 |
| Innenrotations- kontraktur | weniger als 10 Grad | 1 |
| | 10 Grad oder mehr | 0 |
| Beugekontraktur | weniger als 15 Grad | 1 |
| | 15 Grad oder mehr | 0 |
| Beinlängen- differenz | weniger als 3 cm | 1 |
| | 3 cm oder mehr | 0 |
| Beugung | 90 Grad oder mehr | 1 |
| | weniger als 90 Grad | 0 |
| Abduktion | mehr als 15 Grad | 1 |
| | 15 Grad oder weniger | 0 |
| Adduktion | mehr als 15 Grad | 1 |
| | 15 Grad oder weniger | 0 |
| Außenrotation | 30 Grad oder mehr | 1 |
| | weniger als 30 Grad | 0 |
| Innenrotation | mehr als 15 Grad | 1 |
| | 15 Grad oder weniger | 0 |

Interpretation:

| | |
|------------------|-------------------------|
| 90-100 Punkte: | Hervorragendes Ergebnis |
| 80-90 Punkte: | Gutes Ergebnis |
| 70-80 Punkte: | Mäßiges Ergebnis |
| Unter 70 Punkte: | Schlechtes Ergebnis |

7.3.2. HOOS (Hip Disability and Osteoarthritis Outcome)(49)

Symptoms - These questions should be answered thinking of your hip symptoms during the **last week**.

S1. Do you feel grinding, hear clicking or any other type of noise from you hip?

Never Rarely Sometimes Often Always

S2. Difficulties spreading legs wide apart

None Mild Moderate Severe Extreme

S3. Difficulties to stride out when walking

None Mild Moderate Severe Extreme

Stiffness - The following questions concern the amount of joint stiffness you have experienced during the **last week** in your hip. Stiffness is a sensation of restriction or slowness in the ease with which you move your hip joint.

S4. How severe is your hip joint stiffness after first wakening in the morning?

None Mild Moderate Severe Extreme

S5. How severe is your hip stiffness after sitting, lying or resting **later in the day**?

None Mild Moderate Severe Extreme

Subtotal:

Pain

P1. How often is your hip painful?

Never Monthly Weekly Daily Always

What amount of hip pain have you experienced the **last week** during the following activities?

P2. Straightening your hip fully

None Mild Moderate Severe Extreme

P3. Bending your hip fully

None Mild Moderate Severe Extreme

P4. Walking on flat surface

None Mild Moderate Severe Extreme

P5. Going up or down stairs

None Mild Moderate Severe Extreme

P6. At night while in bed

None Mild Moderate Severe Extreme

P7. Sitting or lying

None Mild Moderate Severe Extreme

P8. Standing upright

None Mild Moderate Severe Extreme

P9. Walking on a hard surface (asphalt, concrete, etc)

None Mild Moderate Severe Extreme

P10. Walking on an uneven surface

None Mild Moderate Severe Extreme

Subtotal:

Function, daily living - The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your hip.

A1. Descending stairs

None Mild Moderate Severe Extreme

A2. Ascending stairs

None Mild Moderate Severe Extreme

A3. Rising from sitting

None Mild Moderate Severe Extreme

A4. Standing

None Mild Moderate Severe Extreme

A5. Bending to floor/pick up an object

None Mild Moderate Severe Extreme

A6. Walking on flat surface

None Mild Moderate Severe Extreme

A7. Getting in/out of car

None Mild Moderate Severe Extreme

A8. Going shopping

None Mild Moderate Severe Extreme

A9. Putting on socks/stockings

None Mild Moderate Severe Extreme

A10. Rising from bed

None Mild Moderate Severe Extreme

A11. Taking off socks/stockings

None Mild Moderate Severe Extreme

A12. Lying in bed (turning over, maintaining hip position)

None Mild Moderate Severe Extreme

A13. Getting in/out of bath

None Mild Moderate Severe Extreme

A14. Sitting

None Mild Moderate Severe Extreme

A15. Getting on/off toilet

None Mild Moderate Severe Extreme

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)

None Mild Moderate Severe Extreme

A17. Light domestic duties (cooking, dusting, etc)

None Mild Moderate Severe Extreme

Subtotal:

Function, sports and recreational activities - The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the **last week** due to your hip.

SP1. Squatting

None Mild Moderate Severe Extreme

SP2. Running

None Mild Moderate Severe Extreme

SP3. Twisting/pivoting on your injured knee

None Mild Moderate Severe Extreme

SP4. Walking on uneven surface

None Mild Moderate Severe Extreme

Subtotal:

Quality of Life

Q1. How often are you aware of your hip problem?

Never Monthly Weekly Daily Constantly

Q2. Have you modified your life style to avoid potentially damaging activities to your hip?

Not at all Mildly Moderately Severely Totally

Q3. How much are you troubled with lack of confidence in your hip?

Not at all Mildly Moderately Severely Extremely

Q4. In general, how much difficulty do you have with your hip?

None Mild Moderate Severe Extreme

Subtotal:

7.3.3. Checklist for clinical examination

H
a
r
r
i
s

H
i
p

S
c
o
r
e

ROM

| | | | Anmerkung | | Gesundes Bein | |
|------------------------------------|----------------------------------|-----------|-----------|--|---------------|--|
| Adduktionskontraktur | < 10° | 1 | | | | |
| | > 10° | 0 | | | | |
| Innenrotationskontraktur | < 10° | 1 | | | | |
| Beugekontraktur | < 15° | 1 | | | | |
| | >15° | 0 | | | | |
| Beinlängendifferenz | < 3 cm | 1 | | | | |
| | > 3 cm | 0 | | | | |
| | | | Aktiv | | Passiv | |
| ROM | Flexion HG | 90°- 110° | 1 | | | |
| | | < 90° | 0 | | | |
| | Abduktion | > 15° | 1 | | | |
| | | < 15° | 0 | | | |
| | Adduktion | > 15° | 1 | | | |
| | | < 15° | 0 | | | |
| | Außenrotation | >30° | 1 | | | |
| | | < 30° | 0 | | | |
| | Innenrotation | >15° | 1 | | | |
| | | < 15° | 0 | | | |
| Hüft- Extension | | | | | | |
| Gesamtpunkte | | | | | | |
| | | | | | | |
| KRAFT | Normal | 5 | | | | |
| | Gegen leichten Widerstand | 4 | | | | |
| | Gegen Schwerkraft | 3 | | | | |
| | Ausschaltung der Schwerkraft | 2 | | | | |
| | Kontraktion ohne Bewegungseffekt | 1 | | | | |
| | Lähmung | 0 | | | | |
| Trendelenburg | - | | | | | |
| | + | | | | | |
| FAI = femoroacetabular Impingement | IR + ADD + Flex | | | | | |

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