When to discard Pavlik treatment for dislocated hips?
Assessment of hip reduction and improvement of femoral head position in Pavlik treatment for DDH patients using trans-inguinal ultrasound.

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Abstract
Background
Dislocated DDH hips can often be successfully treated with a Pavlik harness. However, 20-40% of initially dislocated hips are reported to not concentrically reduce with this method. To date it has not been clarified how long Pavlik treatment should be continued, before it should be considered unsuccessful and abandoned for more invasive treatment modalities.

Prolonged Pavlik treatment in not reducing hips might lead to impaired acetabular or femoral development and AVN. Therefore, it would be beneficial to be able to better determine when no improvement in hip position can be expected in the Pavlik harness. For some patients it might be beneficial to discard the harness and not unnecessarily delay initiation of further treatment, whereas for other patients prolonged Pavlik treatment might result in reduction and avoid the need for more invasive treatment.

In most studies reduction is assessed using a combination of physical examination and lateral hip ultrasound (Graf and/or Harcke methods). Both these methods are not optimal to asses hip reduction in the Pavlik harness. For lateral hip ultrasound visualization of the required landmarks, the hip position needs to be changed from the optimal flexed-abducted position in the harness, to an adducted position. This can lead to re-dislocation, and thus the false assumption that a hip does not reduce, when in fact it might well be reduced in the Pavlik harness. This problem is avoided using anterior (trans-inguinal) ultrasound, a method that has proven to be a valid measure of hip reduction.

Study aim / hypothesis
We propose a prospective study, using serial trans-inguinal sonographic measurement of hip reduction to asses when dysplastic hips reduce and when no further improvement in hip position can be expected in the Pavlik harness. This will allow us to come to an optimized treatment protocol, and more accurately time when to discard Pavlik treatment in not reducing hips.

Secondary aim of the proposed study is to asses gradual improvement of the femoral head position in the acetabulum after reduction (the docking effect) in the Pavlik harness. We aim to measure this effect with serial trans-inguinal ultrasound evaluation. This allows for an in-detail analysis on whether the docking effect occurs, the speed of docking and relationship with residual dysplasia later in the course of treatment.

Material and Methods
We aim to include 50 children aged 0 to 6 months with DDH and a completely dislocated hip, Graf type III or IV, indicated for Pavlik treatment. During the Pavlik trial period serial weekly trans-inguinal ultrasounds will be performed to assess the moment of hip reduction. After reduction patients will

be followed for another 6 weeks with weekly trans-inguinal ultrasound to assess the change in medial clear space after reduction. Secondary outcome parameters include physical examination, lateral hip ultrasound according to Graf and follow-up of hip development with pelvic radiographs at least until the age of 5 years.

Primary analysis will be on time to reduction in Pavlik harness, and whether a cutoff point can be identified after which time no reduction can be expected anymore. A second important analysis will be on the docking effect. We will assess whether it can be reliably measured, and whether the occurrence and speed of docking is related to residual dysplasia later in the follow-up period. Other secondary analyses will be on the concurrent validity of inguinal ultrasound versus clinical hip reduction and lateral ultrasound. Furthermore, the relationship between time to reduction and AVN rate and residual dysplasia will be assessed.

Literature review and full research proposal

Background

Abduction brace treatment using a Pavlik harness for dislocated hips

Developmental dysplasia of the hip (DDH) is the most common musculoskeletal disorder in young children.[1] The goal of treatment is to achieve a concentrically reduced and stable hip. Concentric reduction allows for spherical development of the femoral head, remodeling of the acetabulum, and ideally prevention of future osteoarthritis. When diagnosed early it can often be managed with non-surgical measures, and as such surgical treatment with associated morbidity can often be avoided.[1–3] It is therefore widely agreed that the gold standard of DDH management is early detection and initial nonoperative treatment.[1]

The Pavlik harness is the most popular dynamic splint used for initial non-operative treatment of DDH.[3] The Pavlik harness can be used to correct stable dysplasia, unstable dysplasia, or completely dislocated hips, with success rates up to 98%.[1–3] Nevertheless, success percentages are reported to be lower in completely dislocated hips with a failure rate of 20-40%.[2,4–7] Other predictors of Pavlik treatment failure are age at initiation of treatment, male gender, bilaterality and degree of head coverage at initiation of treatment.[7,8]

To date there is no consensus on how long to continue Pavlik treatment, before it should be discarded in favor of other treatment modalities for hips that do not reduce in the Pavlik harness. A commonly cited period is to abandon Pavlik treatment if reduction is not achieved at 3-4 weeks.[1,5,9] The Dutch guideline on DDH advises to discard hip abduction treatment after 6-8 weeks if the hip does not center in the acetabulum center by then.[10] Others advocate even more prolonged periods of Pavlik treatment before switching to closed reduction.[11]

Potential complications of prolonged Pavlik treatment in not reducing hips

A potential risk of prolonged Pavlik treatment in not reducing hips is the development of avascular necrosis (AVN) of the femoral head. AVN, caused by the disruption of blood flow to the femoral head, is an irreversible complications with potentially severe long-term influence on clinical outcomes.[12] In completely dislocated hips an incidence of 1-8% AVN after successful Pavlik treatment is observed, whereas after failed Pavlik treatment an AVN rate of 27% is reported.[5,8,9] Overall, unsuccessful hip reduction, presentation beyond 3 months of age, fixed dislocation and bilateral hip involvement have been related to higher AVN rates in Pavlik treatment.[2,5,9] Nevertheless, the duration of Pavlik treatment has not been shown to correlate to AVN risk.[11] Both Pavlik treatment failure and AVN rate seem to be related to severity of the initial dislocation.[9,13] It remains uncertain whether the Pavlik treatment itself initiates the AVN, or that the severity of initial dislocation is the main contributing factor.

Another suggested risk of prolonged Pavlik continuation in not reducing hips is so-called 'Pavlik disease'. This refers to erosion of the posterior acetabulum, making subsequent hip reduction and maintaining this reduction more challenging.[14,15] The risk of Pavlik disease is the most commonly suggested rationale behind the dogma to not prolong treatment beyond 3 to 4 weeks in not reducing hips.[15] Nevertheless, the occurrence of this effect has been challenged.[11,15] Gornitzki et al. describe that most hips did not exhibit negative changes in acetabular development in response to prolonged treatment of a dislocated hip in Pavlik harness. Furthermore, the success of subsequent treatment was not compromised by extended use of the harness. It is therefore likely that prolonged trial of the Pavlik harness beyond 3 weeks of treatment is safe in this regard.

Besides AVN and Pavlik disease, femoral head shape changes are observed as well after failed Pavlik treatment. 3-dimensional MRI analysis of femoral head shape after failed Pavlik treatment has shown asphericity, size changes and signs of focal growth failure.[16] It is uncertain whether these changes are caused by the DDH/dislocation itself or exaggerated by the Pavlik treatment,[16,17] but pressure on a dislocated, largely cartilaginous femoral head, might well add this growth disturbance. In the series of Tsukagoshi et al, Pavlik treatment was discarded after 2 weeks if reduction did not occur, and in these patients after closed reduction the shape changes to the femoral head did seem to normalize.[17] It is however unclear if these changes are still completely reversible after a longer period of treatment (up to 8 weeks as some suggest) before Pavlik treatment is discarded in not reducing hips.

How to measure reduction – inguinal ultrasound

In most studies to date reduction is assessed using a combination of physical examination and ultrasound using the Graf method and/or Harcke method. Both these ultrasound methods are not optimal to asses hip reduction in the Pavlik harness. This is mainly because for visualization of the required landmarks, the hip position needs to be changed from the optimal flexed-abducted position in the harness.[18] Especially the abduction needs to be decreased, potentially leading to re-dislocation. This in turn could lead to the false assumption that a hip does not reduce, when in fact it might well be reduced in the Pavlik harness.[19,20]

Therefore, it has been proposed to assess concentric hip reduction with an anterior (inguinal) ultrasound.[21,22] With this method the hip position in the Pavlik harness can be maintained, and a real-time visualization of the hip position during treatment can be obtained.[19,20] In retrospective series this methods has been shown to be effective in assessing hip reduction in Pavlik treatment for unstable hips, and a reduction in treatment time has been suggested.[19,20] Nevertheless, the Pavlik harness failure rate remained relatively high and Pavlik treatment was discarded relatively early when reduction was not achieved in 2 weeks.[19] Therefore, trans-inguinal ultrasound does seem beneficial in monitoring Pavlik treatment, but it's exact position does warrant further research.

Hip development after reduction - docking effect

It has been previously observed that after reduction of the hip a 'docking' effect occurs; over time the femoral head position gradually improves to a deeper-seated position in the acetabulum.[23] The proposed mechanism is a gradual decrease in soft tissue interposition (joint capsule, hypertrophic fat pad, inverted limbus), and improvement of the congruency of the femoral head and acetabulum. This effect has been quantified using MRI scan in patients that had closed reduction and spica casting.[23] It is likely that a docking effect also occurs after hip reduction during Pavlik treatment, but this has to date not been studied.

Furthermore, persistence of soft-tissue interposition has been related to higher risk of residual dysplasia.[24,25] In this regard, the absence of a docking effect might be related slower sonographic acetabular development (Graf ultrasound) and impaired long-term outcome. Therefore, delayed or a not occuring docking effect might be an early predictor of residual dysplasia, or even an indication that other treatment modalities should be considered. These relationships have not been studied in detail before.

Quantification of the docking effect has thus far only been described in the paper by Talathi et al, using serial MRI scans after closed reduction.[23] To assess the effect the distance between the femoral head and the acetabulum on a coronal section of a pelvic MRI was measured. This view is comparable to visualization obtained using inguinal ultrasound measures, using landmarks that can also be obtained with this less burdensome imaging modality.

Research question / hypotheses

In the proposed project several we aim to construct an optimized treatment protocol for dislocated hips due to DDH treated with a Pavlik harness.

Knowledge gaps regarding Pavlik treatment for DDH can be filled. The primary focus will be to determine how long Pavlik treatment should be trialed, before more invasive treatment modalities should be considered. This is one of the key knowledge gaps identified in the Dutch guideline for treatment of children with DDH under the age of 1 year.[10] Other questions that can be answered from the collected data concern the concurrent validity of anterior ultrasound and physical examination

Primary research question

- How long should Pavlik treatment be continued in dislocated hips in children aged < 6 months, before it is discarded and other treatment modalities should be considered.

Secondary research questions

- Reliability of medial clearspace on inguinal ultrasound reduced hips; can the docking effect be quantified?
- Is the occurance and speed of docking related to residual dysplasia?
- Assessment of reduction on inguinal ultrasound versus clinical examination
- Assessment of reduction on inguinal ultrasound versus lateral ultrasound
- Analysis of AVN rate in relation to time-to-reduction in Pavlik harness
- Analysis of residual dysplasia in relation to time-to-reduction in Pavlik harness

Methods

Patients

Inclusion/exclusion criteria

Inclusion

- Children aged 0 to 6 months with DDH and a completely dislocated hip, Graf type III or IV.
- Indicated for Pavlik treatment

Exclusion criteria:

- No diagnosis of DDH
- DDH of congenital, syndromic, and/or neuromuscular origin
- Aged > 6 months of age at time of Pavlik initiation
- Treated with flexion-abduction device other than Pavlik

Sample Size

We aim to include 50 patients during a study period of 2 years.

Erasmus MC is the largest pediatric orthopedic center in the Netherlands and has an important supra-regional referral function for DDH patients. Approximately 150 new DDH patients are referred yearly, and of these between 25 and 50 would fit the inclusion/exclusion criteria. Therefore, it is feasible to include the necessary number of patients within a timeframe of 2 years.

Measurements

Primary outcome measure

Time to hip reduction during Pavlik treatment. Reduction will be assessed using inguinal ultrasound.[21] On serial inguinal ultrasound measurements hip reduction (femoral metaphysis in line with the symphysis pubis) and medial clear space (in mm's) will be assessed.[21]

Secondary outcome measures

At baseline the following patient characteristics will be recorded: sex, age at diagnosis, age at treatment initiation, breech position, delivery type, gestational age, birthweight, side affected, bilaterality, DDH family history. Age

At baseline the following factor will be assessed with physical examination: Galeazzi's test, Barlow test, Ortolani test, Abduction in flexion. During each follow-up clinic visit hip abduction in flexion will be measured.

Details on treatment will be monitored: duration of Pavlik treatment, Pavlik treatment succesfull?, other treatment modalities initiated after failed Pavlik?, impression of treatment adherence.

Results of Graf ultrasound hip assessment will be recorded including alfa angle, beta angle and Graf classification.[18]

On standardized AP pelvic x-rays the following factors will be assessed: acetabular index, Shentons' line, International Hip Dysplasia Institute (IHDI) classification[26], AVN (Kalamchi and MacEwen)[27]

Table 1. Timing of measurements for study purposes.

	Baseline	Week 1-6 weekly	Week 3	Week 6	Every 6 weeks until hip normalization	Age 1 year	Age 3 years	Age 5 years
Patient characteristics	O							
Physical examination	O	**X**	O	O	O	O	O	O
Graf ultrasound	O		O	O	O			
Inguinal ultrasound	**X**	**X**	O	**X**				
Pelvic x-ray						O	O	O

O; measurement part of standard care. **X**; additional measurement for study purposes.

Workflow

The study protocol is integrated in the current standard of care. In table 1 the timing of measurement is described. Most assessments (especially radiographic evaluation) are standard care and not additional for research purposes. Additional measurements for study purposes only concern 4 additional inguinal ultrasound measurement in week 1,2,4 and 5 after initiation of Pavlik treatment. All other clinic visits and imaging are current standard of care as described in the nation guideline on treatment of DDH.[10] Measurements marked with **X** in table **1** are added to regular care for research purposes.

We aim to perform the inguinal ultrasound measurements using a point of care ultrasound device in the outpatient clinic. As such we will be able to minimize patient burden as well as prevent

interference with regular care because additional to the radiology department visits will not be necessary.

Analysis

Primary analysis will be on time to reduction in Pavlik harness, and whether a cutoff point can be identified after which time no reduction can be expected anymore. This will allow for optimization of the Pavlik harness trial period, and as such prevent as much further interventions such as closed an open reduction and on the other hand minimize negative influence of prolonged Pavlik harness treatment in not reducing hips.

A second important analysis will be on the docking effect. We will assess whether it can be reliably measured, and whether the occurrence and speed of docking is related to residual dysplasia later in the follow-up period.

Other secondary analyses will be on the concurrent validity of inguinal ultrasound versus clinical hip reduction and lateral ultrasound. Furthermore, the relationship between time to reduction and AVN rate and residual dysplasia will be assessed.

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