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# Late acetabular dysplasia after successful treatment for developmental dysplasia of the hip using the Pavlik method: A systematic literature review

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ABSTRACT

The Pavlik method is the most common method used for treatment of developmental dysplasia of the hip (DDH). Late acetabular dysplasia despite successful treatment, however, has had varied reporting. A systematic review was performed, investigating the long-term outcomes of DDH treated with the Pavlik method. Seventeen studies met inclusionary criteria, including 6029 hips treated with an average of 5.29 years follow-up. Radiographic evidence of late dysplasia was present in 280 hips, with 109 hips requiring additional surgery. A specified treatment algorithm had significantly decreased rates of radiographic dysplasia (3.8% vs 17.6%, p = 0.004).
*Level of evidence:* IV.

## 1. Introduction

Developmental dysplasia of the hip (DDH) can have severe long-term consequences if not identified and treated early, including accelerated joint degeneration and chronic pain. After DDH is recognized during newborn examination, treatment is aimed at reducing and maintaining the femoral head in the acetabulum to promote normal growth and development. Fortunately, the use of the Pavlik method has gained ubiquitous appeal in North America as the gold standard for successful primary intervention.

The Pavlik method has been found to have as high as a 98% success rate for successful reduction of subluxed and dislocated hip.[1] However, there continues to be controversy with regard to treatment duration, harness weaning, and length of radiographic followup as it relates to the need for re-intervention and the identification of late acetabular dysplasia. Reports of late dysplasia after successful hip reduction using the Pavlik method have been reported, ranging from 2.4% to 17%.[2–5] Although some risk factors have been proposed for the development of late dysplasia,[2,4,6] a thorough evaluation of the existing literature has not been previously performed.

We sought to perform a systematic review to identify studies investigating the rate of late acetabular dysplasia following successful treatment of DDH with the Pavlik method with the goal of identifying the incidence and to determine potential risk factors for developing late acetabular dysplasia.

## 2. Materials and methods

A systematic search was conducted using MEDLINE, Embase, and Cochrane databases without language restrictions. Maximally expanded search criteria for DDH, Pavlik method, and late dysplasia with Boolean operators were employed (Appendix 1). Publications were identified using a publication period of 1967 to April 2017. Inclusionary criteria consisted of articles reporting on long term radiographic outcomes for children treated for DDH using the Pavlik method.

### 2.1. Study selection

The abstracts of all identified articles were subsequently analyzed to determine relevance to rates of late dysplasia following treatment with the Pavlik method. Articles were excluded if they were non-English publications, reported open and/or closed reduction or skin traction in their treatment protocol, included additional treatment measures following treatment with the Pavlik method (such as abduction bracing), or failed to report long-term radiographic parameters for acetabular development, Fig. 1.

Following abstract review, articles deemed meeting preliminary inclusion criteria were identified for further review. The full manuscripts of the remaining studies were then reviewed for the following inclusion criteria: peer-reviewed clinical studies of level I to IV evidence, involving pediatric patients undergoing primary treatment with the Pavlik method for DDH, reporting on long-term radiographic

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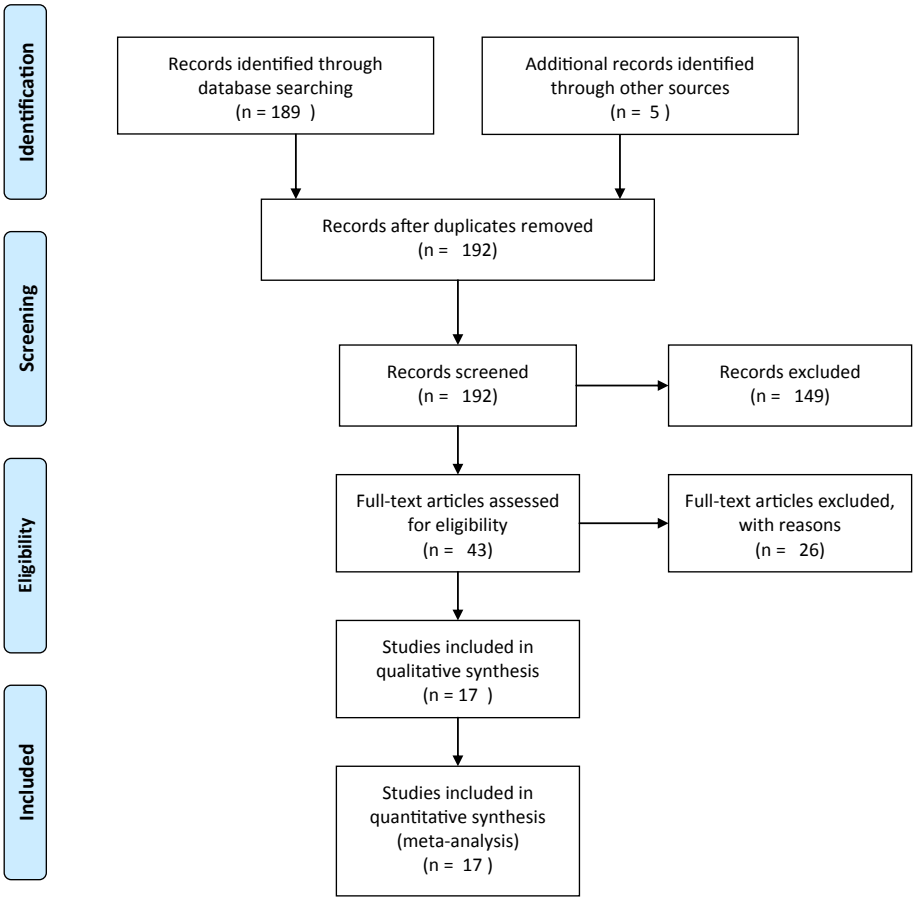


**Fig. 1.** Flow diagram for literature review according to PRISMA protocol.

acetabular development, specifically the rate of late-presenting acetabular dysplasia and the need for further surgery to address dysplasia. Late acetabular dysplasia was defined as a secondary diagnosis of acetabular dysplasia after being successfully treated with the Pavlik method.

The patient cohorts of studies with the same authors and/or institutions were scrutinized to ensure that no redundant data was collected. In the event of multiple publications using the same patient cohort, studies reporting the longest follow-up were included for analysis, with exclusion of other studies. Rates of late dysplasia were restricted to only those patients with an initial successful treatment course with the Pavlik method. These data were further divided into patients with defined radiographic dysplasia, and patients who required further surgical treatment to address late dysplasia.

Data points of interest included patient demographics (age, gender, percentage bilateral involvement), total number of hips treated in the study, average age at treatment initiation, average treatment durations, and average length of follow-up. Treatment protocols were recorded, when stated, and defined according to the presence or absence of a standard treatment protocol for duration of harness wear (recorded as a dichotomous variable). For studies indicating a standard treatment algorithm, the utilization of a harness weaning protocol was also recorded as a dichotomous variable.

Data analysis was performed using SPSS statistical package version 24 (SPSS Inc, Chicago, IL). Significance was set at $P < 0.05$. Descriptive statistics were generated. Univariate analyses were used to assess the implications of a standard treatment protocol, treatment duration, and length of followup on the rate of late dysplasia. Variables identified as statistically significant were entered in a logistic regression analysis to identify predictive factors for late dysplasia and need for additional surgery. Correlation coefficients were applied to identify and variation in the rate of late dysplasia based upon duration of treatment or length of follow-up.

## 3. Results

A total of 192 studies were identified, with 149 of the reviewed abstracts not meeting inclusionary criteria. Of the remaining 43 studies, 23 were excluded for lack of reporting of late acetabular dysplasia with three additional studies were excluded due to the usage of the same patient population in multiple studies, leaving 16 retrospective case series and 1 case-control study reported on the long term radiographic outcomes of hips successfully treated with the Pavlik method, Fig. 1. A total of 6029 hips were included in these studies with gender breakdown provided for 5330 patients consisting of 83.3% female patients and 46.6% with bilateral disease, Table 1. Age at treatment initiation ranged from 1 day to 15 months of age with an average follow-up duration of 5.29 years ( ± 4.94 years, range 1–20 years).

All children underwent primary treatment with the Pavlik method, with the reported treatment criteria reported in Table 2. A total of 10 studies reported using a standard treatment protocol with the remainder not reporting their treatment algorithm. Reporting of average treatment duration was variable across the studies with 10 studies not reporting any treatment duration. The treatment duration in the remaining 7 studies ranged from 15 days to 7 months of harness wear. Of the 10 studies reporting a standard treatment algorithm, 7 incorporated a weaning protocol.

Overall, 280 children (4.6%, 9.49%/study) were found to have radiographic evidence of late acetabular dysplasia, with 109 children (1.8%, 4.14%/study) requiring additional surgery to address their dysplasia, Table 3. Of the 109 reported subsequent surgeries, 50.4% consisted of either an isolated Salter or Pemberton osteotomy

**Table 1**
Summary of patient variables from identified studies reporting on the long term radiographic assessment for infants treated successfully for DDH using the Pavlik method.

| Lead Author | Location of Study | Year | Total # of Hips | Age at Treatment | % Female | % Bilateral |
|---|---|---|---|---|---|---|
| Cashman[3] | Southamptom General Hospital, UK | 2002 | 546 | NR | 82.8 | 0.64.4 |
| Rachbauer[4] | University of Innsbruck, Austria | 1994 | 200 | NR | 71.0 | NR |
| Grill[14] | 6 European Hospitals | 1988 | 3611 | 4.1 months | 89.0 | NR |
| Alexiev[2] | DuPont Children's, Wilmington, DE | 2006 | 87 | NR | 89.0 | 82.0 |
| Bin[6] | Saint Denis, France | 2014 | 42 | 5 days | 80 | 43.3 |
| David[8] | Royal Orthopaedic Hospital, Birmingham, UK | 2015 | 96 | 2 weeks | NR | 64.5 |
| Nakamura[11] | Chiba City, Japan | 2007 | 130 | 4.8 months | 88.7 | 13.0 |
| Bradley[13] | Oxford, UK | 1987 | 36 | 7 weeks - 6 months | NR | 33.9 |
| Sarkissian[12] | CHOP, Philadelphia, PA | 2015 | 74 | < 8 weeks | 77 | 12 |
| Allington[7] | Belgium | 2015 | 109 | NR | NR | NR |
| Modaressi[26] | University of Zurich, Switzerland | 2011 | 150 | < 6 months | NR | NR |
| Dornacher[9] | University of Ulm, Germany | 2010 | 180 | 7.2 weeks | 80 | 67.8 |
| Fujioka[10] | Shinshu University, Matsumoto, Japan | 1995 | 129 | 4 months | 93.2 | 53.3 |
| Sucato[19] | TSRH, Dallas TX | 1999 | 192 | 12.7 days | 82.1 | NR |
| Walton[17] | Bristol Royal Hospital, UK | 2010 | 123 | 5 weeks | NR | 66.2 |
| Kalamchi[21] | DuPont Children's, Wilmington, DE | 1982 | 139 | 5 months | 83.6 | 13.9 |
| Westacott[18] | West Midlands, UK | 2014 | 185 | A: 5.5; B 8.6 months | NR | 45.2 |

NR – Not Reported.

performed at an unreported patient age. 22.9% of cases were derotational femoral osteotomies, 13.7% having a combined femoral and pelvic osteotomy, and 3.7% undergoing a redirectional osteotomy.

Studies with a specified treatment algorithm had significantly decreased rates of radiographic dysplasia (N = 1861, 3.8% late dysplasia, 95% confidence interval 0.68–6.9%) in comparison to those without a standard protocol (N = 4168, 17.6% late dysplasia, 95% confidence interval 10.4–24.8%) with $P = 0.004$. Seven of the 10 studies reporting a standard treatment protocol, incorporated a weaning protocol, which had no effect on the rate of late dysplasia (N = 1388, 1.94% with weaning vs. N = 473, 3.16% without, P = 0.46). Neither average treatment duration (p = 0.228) or length of follow-up (p = 0.165) had an effect on the rate of late dysplasia. Logistic regression analysis identified the lack of a standard treatment protocol as predictive of late radiographic dysplasia ($p = 0.03$) with an odds ratio of 0.809 (95% confidence intervals (0.691–0.982). There was no difference in the rate of additional surgery according to treatment protocol (3.12% with standard protocol versus 5.97% without, $P = 0.401$).

Reporting of risk factors for late dysplasia varied across the identified studies. One case control study assessed for the effect of harness weaning on radiographic outcomes in 185 hips in 128 patients between 2 institutions. Eighty children underwent a gradual weaning protocol, with the remaining 48 patients undergoing immediate harness cessation following a standard treatment protocol. Average treatment duration varied between institutions with 8.6 weeks of treatment in the weaning cohort and 5.5 weeks in the immediate cessation cohort. Although no significant differences existed between the cohorts at 2 year follow-up, immediate harness cessation trended toward requiring further intervention after successful treatment than those who underwent a gradual harness weaning. Six other studies reported the inclusion of a harness weaning protocol, however due to the varied reporting, a more thorough analysis on the effect of a weaning protocol on the development of late dysplasia was not able to be performed.

**Table 3**
Summary of reported secondary surgical procedures for treatment of late dysplasia.

| Subsequent Surgeries | Number of Cases |
|---|---|
| Closed Reduction | 9 |
| Open Reduction | 1 |
| Femoral Osteotomy | 25 |
| Innominate Osteotomy | 55 |
| Redirectional Innominate Osteotomy | 4 |
| Combined Pelvic and Femoral Osteotomies | 15 |

**Table 2**
Summary of treatment variables and outcomes from identified studies reporting on the long term radiographic assessment for infants treated successfully for DDH using the Pavlik method.

| Lead Author | Standard Algorithm? | Weaning | Average Followup (years) | Average Treatment Duration | Late Dysplasia | % Additional Surgery |
|---|---|---|---|---|---|---|
| Cashman[3] | Yes | Yes | 6.5 | ~ 10 weeks | 2.400% | 0.90% |
| Rachbauer[4] | Yes | No | 1.5 | variable | 6.000% | NR |
| Grill[14] | No | No | 4.46 | min. 4 weeks | 2.680% | 1.30% |
| Alexiev[2] | Yes | Yes | 5.3 | NR | 4.760% | 2.29% |
| Bin[6] | No | No | 6.7 | 34 days (15–75) | 19.000% | 0.00% |
| David[8] | No | No | 1 | NR | 4.000% | 3.10% |
| Nakamura[11] | Yes | Yes | 16 | NR | 16.900% | 16.90% |
| Bradley[13] | No | No | 5 | NR | 16.670% | 16.67% |
| Sarkissian[12] | No | No | 1.04 | NR | 33.780% | NR |
| Allington[7] | Yes | Yes | 10.167 | NR | 0.000% | 0.00% |
| Modaressi[26] | Yes | No | 11.8 | NR | 2.670% | 2.67% |
| Dornacher[9] | No | No | 1.2 | NR | 29.400% | NR |
| Fujioka[10] | No | No | 20 | NR | 17.800% | 8.80% |
| Sucato[19] | Yes | Yes | 1.3 | 6 weeks full time | 0.000% | 0.00% |
| Walton[17] | Yes | No | 2 | 11 weeks | 0.81% | 0.81% |
| Kalamchi[21] | Yes | Yes | 5 | 7 months | 0.700% | 0.700% |
| Westacott[18] | Yes | Yes | 2 | A: 9.2 weeks B: 7.3 weeks | 3.800% | 3.80% |

NR – Not Reported.

Of the remaining studies, age at time of treatment initiation was found to have no effect on rate of late dysplasia. Abnormal echogenicity of the cartilaginous roof was predictive of late dysplasia in 2 separate studies.[2,4] Additionally, abnormal radiographic parameters at final followup were predictive of need for further surgical intervention. However, normal radiographic center edge angle and acetabular index at age 2 years were protective against the development of late dysplasia in a single study.[7]

## 4. Discussion

Previous studies investigating the incidence of late acetabular dysplasia after successful treatment with the Pavlik method have been reported with a wide clinical range,[1–12] with few identified risk factors. Of the identified 6029 hips treated with the Pavlik method in this review, 9.49% of hips were found to have radiographic evidence of late acetabular dysplasia, with 4.14% undergoing additional surgery to address their dysplasia.[5,6,8,10–19] We identified that in studies presenting a standardized treatment protocol, the incidence of radiographic acetabular dysplasia dropped significantly to 3.8% as compared with 17.6% in studies that did not report a standard treatment protocol.

### 4.1. Age at treatment initiation

The age of time of treatment initiation has been shown to influence the ability to obtain a successful treatment outcome with the Pavlik method. Eidelman et al.[1] reviewed the results of their patients treated with the Pavlik method over a 5 year period, treating 127 hips for DDH. In all cases, harness application occurred prior to the age of 14 weeks, resulting in a 98% success rate. In comparison, Pollet et al.[20] reported on the in the success rate in their series of 26 hips in children aged 6–24 months treated with the Pavlik method, resulting in a 46% success rate.

The age at treatment initiation varied considerable across the identified studies, beginning as early as the first day post-natal up to 15 months of age. Given the considerable variation in the clinical series, we were unable to comment definitively on the effect of age at time of treatment initiation on the rate of late acetabular dysplasia. Fujioka et al.[10] reported on the outcomes of 129 hips treated at their institution with the Pavlik method with an average of 20 years followup. They identified 17.8% of their patients with radiographic evidence of later acetabular dysplasia with 8.8% of the overall patients requiring additional surgery to address their dysplasia. Patients were subdivided into those who that harness use implemented before and after the age of 4 months, and found no significant difference between the age at treatment initiation and the final center edge angle measurement.

### 4.2. Treatment duration

We were unable to assess the effect of brace duration on the incidence of late acetabular dysplasia given the low rate of reporting. Ten studies failed to report any data regarding to average treatment duration. Of the remaining 7 studies, significant variation existed for average treatment durations, ranging from 34 days to 7 months.[5,6,8,10–18] Taylor et al.[16] reported an average of 7 months treatment duration with their standard protocol, which included a weaning protocol that occurred over 8–11 weeks. In their series, only 0.7% of patients were found to have last acetabular dysplasia requiring acetabuloplasty. In comparison, Ramsey et al.[15] reported an average treatment duration of 5.8 months using a non-standardize protocol of patient treatment, with 14.8% having late radiographic acetabular dysplasia.

### 4.3. Harness cessation

There has not been a well-accepted protocol for handling of the harness cessation after obtaining a stable reduction of the femoral head in the acetabulum. Of the ten identified studies that provided a standard treatment algorithm, seven included a weaning protocol in their case series, whereas the remaining studies did not comment on the method by which they addressed harness cessation. Weaning protocols varied across the seven studies ranging from Taylor et al.[16] and Allington et al.[7] who did not provide specific details, to Nakamura et al.[11] who performed part time harness wear for 5 months following full-time harness wear for 4 weeks. Sucato et al.[19] weaned over a 6 weeks period and Kalamachi et al.[21] weaning away from day time wear over 3 weeks and continuing night bracing for 6–8 weeks afterwards. Rates of late radiographic acetabular dysplasia did vary in these series with Nakamura et al.[11] reporting the highest incidence of dysplasia at 16.9%, whereas the other 4 studies have an average incidence of 0.97%.

Only one study performed a direct comparison of cohorts with differing strategies for addressing harness cessation. Westacott et al.[18] reported on the clinical outcomes of patients with DDH treated with either immediate harness cessation following successful hip reduction or staged harness weaning. Although the authors found no statistical differences between the patients groups, a trend was noted for higher rate of re-intervention in children treated with immediate harness cessation (8.3% versus 3.8%).

### 4.4. Risk factors

Identifying risk factors to predict late dysplasia is a difficult endeavor given the delayed ossification of the femoral head and acetabulum. Several articles remarked on early risk factors for the development of late dysplasia. Alexiev et al.[2] reported on pre-intervention criteria predicting late acetabular dysplasia in their series of 87 dysplastic hips in 55 children with 6% going on have late dysplasia at an average of 5.3 years followup. Using a contingency table analysis, they identified 3 ultrasonographic parameters on the screening ultrasound that were predictive of late dysplasia: dynamic coverage index $\leq 22\%$, alpha angle $< 43^{\circ}$, and abnormal echogenicity of the cartilaginous roof. Of these factors, abnormal echogenicity was the most specific, single predictor with 100% sensitivity and 88% specificity.

However, ultrasonographic abnormalities are not an uncommon occurrence in the screening infant hip ultrasound. Sucato et al.[19] reported on the outcome of children with ultrasonographic abnormalities but a clinical exam indicating a stable hip. In 149 infants with ultrasonographic abnormalities that did not receive treatment, 1.3% had late radiographic dysplasia. There was no correlation in their series between the severity of ultrasonographic abnormalities and the development of later dysplasia. They concluded that ultrasound may be too sensitive and not warranted in the setting of a clinically stable hip.

Abnormality of the cartilaginous roof is a factor that was reported by Bin et al.[6] and Rachbauer et al.[4] Rachbauer et al.[4] reported that the radiographic appearance of the acetabulum at conclusion of harness wear, obtained at a minimum of 3 months of age. In their series of 200 DDH treated with the Pavlik method, 6% were found to have radiographic late dysplasia. 14 of the treated hips were found to have delayed ossification of the acetabular roof at treatment conclusion with 43% of these cases going on to have late dysplasia by acetabular index measurement at an average of 18.5 months followup.

### 4.5. Secondary Surgery

The overall rate of secondary surgery to address late dysplasia after successful treatment with the Pavlik method was 4.14%. Of the 109 reported surgery, an isolated Salter or Pemberton osteotomy was the most frequent (50.4%), followed by a derotational femoral osteotomy (22.9%), combined femoral and pelvic osteotomies (13.7%), and redirectional acetabular osteotomies (3.7%). Abduction bracing is another treatment modality that has been recommended by authors to address residual or early presenting late acetabular dysplasia.[5,12,22] Gans et al.[22] reported on the use of abduction bracing for patient with

DDH treated with the Pavlik method who were found to have acetabular dysplasia, defined as acetabular index ≥30° on radiographs obtained at age 6 months. In their cohort of 31/76 identified hips treated with abduction bracing, they had significant improvements in the acetabular index (average 5.3°) versus an unbraced cohort (1.1° improvement) treated over a 6 month period. None of the identified patients were found to require surgical intervention in either patient cohort by the age of 1 year.

### 4.6. Radiographic follow-up

The duration of radiographic followup following successful treatment with the Pavlik method has not been well elucidated. The ossific nucleus begins to ossify around the age of 6 months, allowing for the use of plain radiographic examination of continued acetabular development. Several parameters are used for the clinical assessment of the acetabular maturation, with the acetabular index used most commonly for children less than 8 years old and the center edge angle for children older than 5 years.[23]

Li et al.[24] performed a cross sectional analysis investigating the osseous and cartilaginous development of hip in patient without DDH compared with control patient as assessed by magnetic resonance imaging. Two cohorts of 81 children with DDH and 241 normal control subjects underwent MRI of the hips to assess the evolution of maturation and development. The found that the normal cartilaginous acetabular index (CAI) decreased rapidly within the first 2 years of life, then remaining constant until adolescence. Additionally, the CAI was found to significantly higher in children with unilateral DDH when compared to the contralateral unaffected hip. The osseous acetabular index (OAI), however, had a distinctly difference maturation pattern, progressively decreasing from an average of 26.7° at 12 months of age to 18.2° at the age of 4 years before reaching a steady state until the age of 8 years.

The length of radiographic and clinical followup is a point of contention that has not been definitively determined.[4] Sarkissian et al.[12] utilized follow up radiographs at 6 months of age and at 12 months, or when ambulatory, for all patients with DDH identified at infancy and treated with closed reduction and harness. This is viewed in contrast to Dornacher et al.[9] who delayed radiographic examination until 2 years of age to avoid radiation exposure in undeveloped acetabula.

Allington et al.[7] reported on the10-year follow-up of children with DDH treated by a standardized protocol using the Pavlik method that had a normal AP radiograph at age of 2 years. All children had annual clinical and radiographic examinations between 2 and 4 years of age, and every 2 years until maturity. In their series, 109 hips met inclusionary criteria, of whom, none went on to develop late acetabular dysplasia. Their recommendation was that for children with normal radiographic parameters at 2 years of age, long-term follow-up is not necessary.

### 4.7. Limitations

This review has a number of limitations. First, the identified studies were nearly all case series, without any control groups, historic or otherwise, to compare the data amongst. Secondly, the followup is significantly limited, with an average of 5.29 years, leaving up to additional 6 years of continued skeletal development that is not accounted for. The study quality was unable to be qualitatively assessed, such as with the Newcastle-Ottawa Scale, given the lack of cohort study groups. There are several sources of heterogeneity. The specific protocol for treatment was inconsistently reported, as such, data was recorded as dichotomous for either the presence or absence of a treatment algorithm. Additionally, the age at treatment initiation, duration of brace utilization, degree of alpha angle correction, the specific criteria used to determine a successful treatment course, and age at final followup varied significantly across the studies. Several studies failed to state any method relevant to their treatment protocol and several more failed to state their method of brace cessation.

The method for defining radiographic dysplasia was inconsistent reported in the articles. The most commonly reported definition was the Tonnis and Brunken system[25] based upon age-specific ranges for acetabular index, being used in 5 of the selected studies.[4,9,16,17,19] Of the remaining studies, 2 used arbitrary cut off values for acetabular index,[11,12] a third used the center edge angle,[15] with the remaining consisting of author derived definitions,[8,14] if mentioned at all. When possible, the Tonnis and Brunken system was extrapolated to studies that failed to specifically define last dysplasia. Additionally, the additionally surgeries performed for patients with late dysplasia where incompletely described and varied greatly across the various studies.

In addition, the identified studies included a diverse patient population including hips treated in the United States, United Kingdom, Japan, Austria, Belgium, Germany, Switzerland, and the majority treated in various European Hospitals as part of a multicenter investigation. The patient characteristics varied across these populations regarding gender prevalence as well as the percent of bilateral cases. Due to varied reporting of variables, we were unable to quantitatively characterize the various geographic differences, however, there could be an underlying difference in the etiology of the underling dysplasia that could have an impact on the clinical success and long-term acetabular development.

In conclusion, the present study identified that late acetabular dysplasia is not an uncommon clinical entity following successful treatment of DDH, with radiographic evidence occurring in 9.49% of hips and 4.14% requiring additional surgery to address their dysplasia. Additionally, children treated by institutions with a standard treatment protocol had significantly lower incidences of radiographic late dysplasia, although there was no statistical difference in the rate of subsequent surgery. This data emphasizes the necessity of standard treatment protocols when using the Pavlik method to treat DDH.

## Conflicts of interest

The authors have no conflicts relative to this study.

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The opinions or assertions contained herein are the privartifies that he or she has no commercial associations that might pose a conflict of interest in connection with the submitted article.

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or reflecting the views of the Department of Defense or US Government. The authors are employees of the US government. This work was prepared as part of their official duties and, as such there is no copyright to be transferred.

## Appendix

| Search Strategy |
|---|
| 1. Hip dislocation or congenital or CHD or DDH or congenital hip dysplasia or developmental dysplasia of the hip or ((Developmental or congenital) and (dysplasia or dislocation or subluxation) and (hip* or acetabulum*)) |
| 2. Pavlik method or Pavlik harness or dynamic splintage or splintage |
| 3. Late dysplasia or dysplasia or surgery |

Search Strategy

4. Hip or hips or acetabular or acetabulum
5. 1 and 2 and 3 and 4

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