

Pavlik Harness Disease Revisited: Does Prolonged Treatment of a Dislocated Hip in a Harness Adversely Affect the α Angle?

Alex L. Gornitzky, MD,* Emily K. Schaeffer, PhD,† Charles T. Price, MD,‡
International Hip Dysplasia Institute, and
Wudbhav N. Sankar, MD*

Background: Current dogma contends that prolonged treatment of a dislocated hip in Pavlik harness beyond 3 weeks will cause “Pavlik harness disease.” To our knowledge, however, no previous studies have documented objective morphologic changes to the acetabulum from continued treatment of a persistently dislocated hip.

Methods: We retrospectively reviewed a consecutive series of infants with developmental dysplasia of the hip, below 6 months old, who failed Pavlik treatment from a single, tertiary-care pediatric hospital and a multicenter, international study group. Inclusion criteria were dislocated hips confirmed by ultrasound (both initially and at Pavlik termination) and a minimum of 2 ultrasounds during harness treatment at least 3 weeks apart. As a global measure of acetabular morphology, α angle (AA) was compared between initial and final ultrasound. The final means of obtaining successful hip reduction was recorded from the medical records.

Results: Forty-nine hips in 38 patients were identified. Median age at Pavlik initiation was 4 weeks (range, 0 to 18 wk); median time in harness was 6 weeks (range, 3 to 14 wk). Surprisingly, a mean of 4 degrees improvement in AA (95% CI, 2-6 degrees; $P = 0.001$) was observed between first and final ultrasound. We found no difference in AA change between those in harness 3 to 5 weeks and those with prolonged wear > 5 weeks ($P = 0.817$). There was no significant association between change in AA and time in harness ($P = 0.545$), age at Pavlik initiation ($P = 0.199$),

clinical reducibility of the hip ($P = 0.202$), or initial percent femoral head coverage ($P = 0.956$). Following harness failure, 22/49 hips (45%) were successfully treated with rigid abduction bracing, 16 (33%) by closed reduction/spica casting, and 10 (20%) by open reduction; 1 hip (2%) spontaneously reduced and required no further treatment.

Conclusions: On the basis of the lengths of harness treatment in our series, most hips did not exhibit negative changes in the acetabular AA in response to prolonged treatment of a dislocated hip in harness. Furthermore, 80% of hips failing Pavlik treatment were successfully reduced through closed means, indicating that subsequent treatment was not compromised.

Level of Evidence: Level IV—retrospective case series.

Key Words: DDH, Pavlik harness, Pavlik harness disease, hip dysplasia, developmental dysplasia of the hip, alpha angle

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Developmental dysplasia of the hip (DDH) is one of the most common developmental deformities of the lower extremities, as well as one of the leading causes of early arthritis and total hip replacement.¹ First-line therapy is most often the Pavlik harness,^{2,3} which has a reported rate of successful reduction of 63% to 93% for Ortolani-positive hips.⁴⁻⁶ Although hips typically stabilize within 3 to 4 weeks of initial Pavlik harness application, those that fail to achieve a stable reduction within this timeframe may be at increased risk for “Pavlik harness disease.”⁷ First defined by Jones et al,⁸ Pavlik harness disease is “prolonged positioning of the dislocated hip in flexion and abduction that potentiates dysplasia, particularly of the posterolateral acetabulum, and increases the difficulty of obtaining a stable closed reduction.” As a consequence, prolonged harness use in the setting of a persistent dislocation is thought to result in a greater proportion of patients requiring open reduction.⁹ It has thus become dogma to abandon harness treatment after 2 to 4 weeks if a hip remains unstable.^{5,7,9-12}

To our knowledge, however, no studies have documented objective morphologic changes to the acetabulum over time in response to continued treatment of an irreducible or unstable hip. Instead, the evidence in

From the *Division of Orthopaedics, The Children’s Hospital of Philadelphia, Philadelphia, PA; †Department of Orthopaedic Surgery, British Columbia Children’s Hospital, Vancouver, BC, Canada; and ‡University of Central Florida College of Medicine, Orlando, FL.

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Reprints: Wudbhav N. Sankar, MD, Division of Orthopaedic Surgery, The Children’s Hospital of Philadelphia, 34th and Civic Center Blvd, Wood Building, 2nd Floor, Philadelphia, PA 19104. E-mail: sankarw@email.chop.edu.

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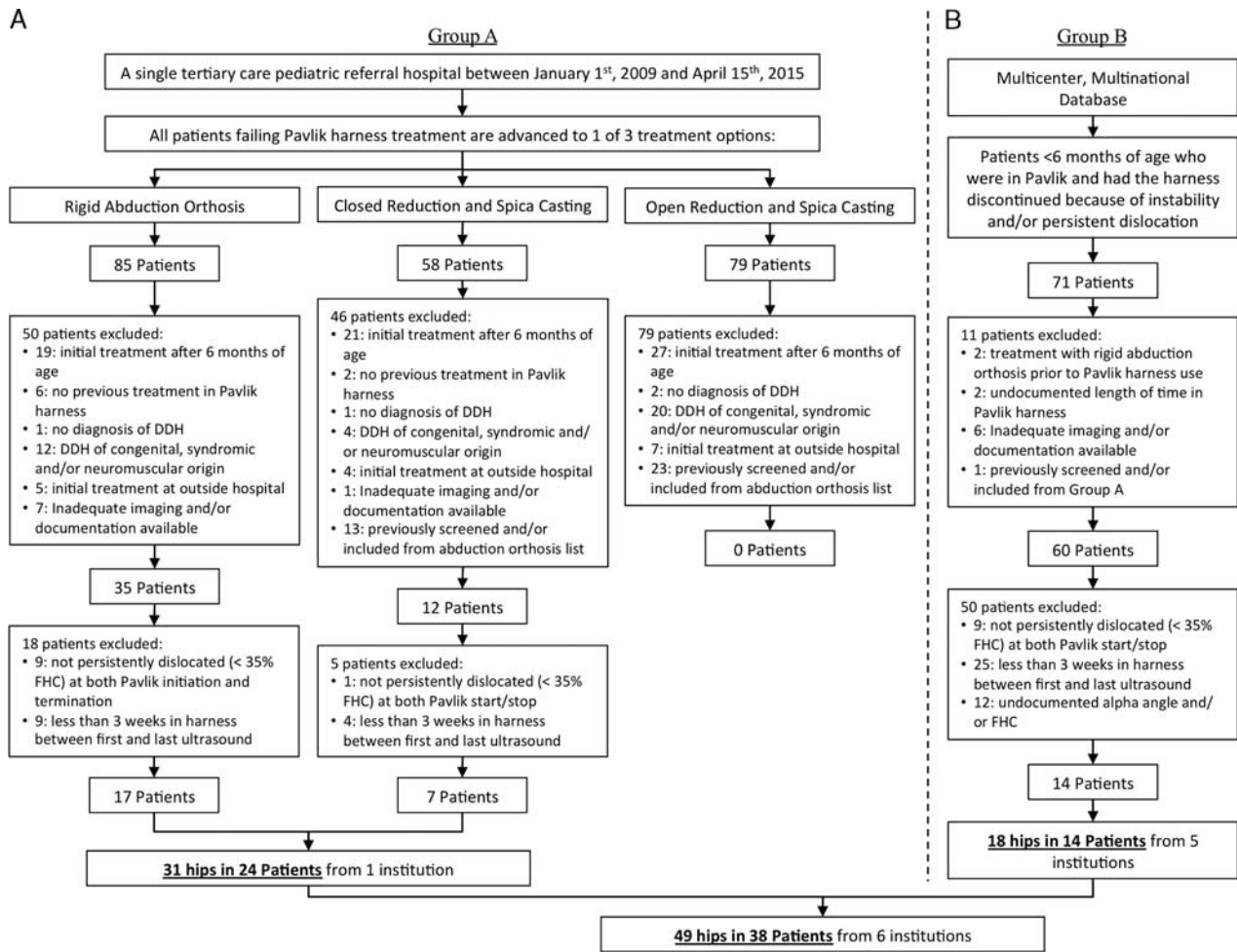


FIGURE 1. CONSORT (Consolidated Standards of Reporting Trials) diagram showing patients evaluated, excluded, and enrolled in (A) group A and (B) group B.

support of Pavlik harness disease originates from several small case series describing observational evidence of posterolateral acetabular insufficiency and surrogate markers such as increased rates of open reduction. Therefore, the purpose of this study was to investigate whether the acetabular α angle (AA) deteriorates with prolonged treatment of a dislocated hip with a Pavlik harness, and to determine the clinical outcome of those hips that fail prolonged harness therapy.

METHODS

This was a retrospective case series combining patients from a large tertiary-care children’s hospital (group A) and a multicenter, international study group (group B). Institutional review board approval was obtained before this study (group A) and for participation in the study group (group B).

At the primary institution, infants who fail Pavlik treatment are advanced to either an Ilfeld-style abduction orthosis or operative reduction/spica casting. Therefore, we queried our records to identify a consecutive series of

infants with DDH who were prescribed a rigid abduction orthosis at our center from 2009 to 2015. Current Procedural Terminology codes for closed and open reduction for DDH (27257-9) were also utilized to identify a consecutive series of infants treated with operative hip reduction (Fig. 1A). For both cohorts, records were reviewed to identify all patients who had previously failed Pavlik harness treatment. Per the treating surgeon, Pavlik failure was defined as lack of progressive improvement in ultrasonographic indices and/or clinical examination over a minimum 3-week treatment period leading to discontinuation of the harness. A convenience sample was then established using the following exclusion criteria: no diagnosis of DDH, DDH of congenital, syndromic, and/or neuromuscular origin, above 6 months of age at time of Pavlik initiation, and incomplete availability of ultrasonographic imaging and/or clinical documentation. As details of therapy could not be verified, patients who failed Pavlik treatment at an outside institution were also excluded.

Consistent with agreed-upon standards, hip dislocation was defined as < 35% femoral head coverage (FHC) on the coronal flexion ultrasonographic views.^{13–15}

To isolate a cohort of “persistently” dislocated hips and exclude those that may have been improving with treatment, we included only those hips with $\leq 35\%$ FHC both at Pavlik initiation and termination. At our institution, not all infants receive an ultrasound before Pavlik initiation (eg, < 1 mo old with an Ortolani-positive hip). To provide a sufficient imaging interval to capture morphologic changes to the acetabulum, patients with < 3 weeks between first and final ultrasound were excluded.

For all enrolled infants, outpatient records were reviewed to determine baseline demographic information, birth presentation, family history, and relevant clinical data at the time of Pavlik initiation. Each affected hip was categorized as irreducible or reducible (Ortolani positive) per physical examination and ultrasonographic stress testing.

At the time of Pavlik initiation, parents were instructed to maintain the harness full time with/without the exception of bathing and diaper changes per treating surgeon preference. Infants were subsequently monitored with serial ultrasound and physical examination at 1- to 3-week intervals. At the time of Pavlik discontinuation, total time in harness was noted. Outpatient records were again reviewed to reclassify the clinical stability of each affected hip. Lastly, follow-up records were reviewed to determine the final means of obtaining a stable reduction for each hip (eg, closed reduction, open reduction, etc.).

To identify additional patients, the deidentified database of a multicenter, international study group on hip dysplasia was queried for all patients below 6 months of age who were treated in Pavlik harness for DDH and had the harness discontinued because of instability and/or persistent dislocation (group B) (Fig. 1B). In addition to excluding those with undocumented length of time in Pavlik harness and/or undocumented AA/FHC, patients in group B were screened using identical exclusion criteria as group A. All data points previously described for group A were noted and directly recorded from the database for each patient in group B. The combined cohort (group A + B) was used for all further analyses.

The primary outcomes, AA (Graf angle) and FHC, were measured for each affected hip on the first and final ultrasound in Pavlik harness. For group A, all measurements were made by the first author (A.L.G.) on the coronal flexion view. To determine interrater reliability, a random subset of 20 group A hips was independently measured in a blinded manner by the senior author (W.N.S.). A consensus measurement was then reached for each AA that differed between the raters by > 3 degrees or each FHC that differed by $> 5\%$. Given excellent overall agreement for these 20 hips (interrater intraclass correlation coefficients for AA and FHC measurements, all > 0.920), the primary observer’s measurements were used for the remaining hips ($n = 11$) in group A. For group B, AA and FHC were measured by the individual treating surgeon at each center and directly entered into the database.

Statistical Analysis

Categorical variables were analyzed using the Fisher exact/ χ^2 tests. Continuous variables were assessed using the Shapiro-Wilk test and subsequently analyzed using either paired Student *t* tests, the Wilcoxon signed-rank test, or the Mann-Whitney *U* test. Intraclass correlation coefficient was determined using a 2-way mixed-effects model. Spearman correlations were used to evaluate the association between continuous variables. Linear regression was used to predict total change in AA when holding other patient characteristics and treatment details constant. An α level of 0.05 was used for all tests.

RESULTS

Our combined series consisted of 49 hips in 38 patients from 6 institutions (Fig. 1). Except for a higher proportion of patients with bilateral DDH in group A, there were no differences in baseline characteristics between the 2 groups (Table 1). Median age at Pavlik initiation was 4 weeks (range, 0 to 18 wk), with details of Pavlik harness treatment presented in Table 2. There were 20 patients

TABLE 1. Demographics and Baseline Variables

| | n (%) | | | P† |
|--------------------------------------------------------------------|----------|----------|-----------|-------|
| | Group A | Group B | Combined* | |
| No. patients | 24 | 14 | 38 | |
| No. hips | 31 | 18 | 49 | |
| Patients with bilateral DDH of any severity‡ | 21 (88) | 7 (50) | 28 (74) | 0.021 |
| Sex (female) | 26 (84) | 12 (67) | 38 (78) | 0.286 |
| Laterality (no. left hips) | 18 (58) | 11 (61) | 29 (59) | 0.834 |
| History of breech position | 14 (45) | 6 (33) | 20 (41) | 0.417 |
| Positive family history of DDH | 5 (16) | 3 (17) | 8 (16) | 1.000 |
| History of clubfoot, torticollis, or other congenital foot disease | 5 (16) | 2 (11) | 7 (14) | 1.000 |
| Age at Pavlik initiation [median (range)] (wk) | 3 (0-18) | 5 (0-12) | 4 (0-18) | 0.138 |

Data are presented as frequency (%) or median (range).

*The combined cohort was used in all future analyses.

†P-values correspond to intergroup differences based on the Fisher exact/ χ^2 test for categorical variables and the Mann-Whitney *U* test for continuous variables.

‡Affected hips from bilateral patients were only included in final analyses if they were dislocated ($< 35\%$ femoral head coverage on coronal flexion ultrasound) at both Pavlik initiation and termination. Thirteen patients in group A and 3 patients in group B had bilateral dislocations at Pavlik initiation but only unilateral dislocation at Pavlik discontinuation, whereas 1 patient in group A had unilateral dislocation at Pavlik initiation and bilateral dislocations at Pavlik discontinuation.

DDH indicates developmental dysplasia of the hip.

TABLE 2. Details of Pavlik Harness Treatment

| Details | Number |
|-------------------------------------------------------------------------------------------|----------|
| Length of time in Pavlik harness [median (range)] (wk) | 6 (3-14) |
| Length of time in Pavlik harness between first and last ultrasound [median (range)] (wk)* | 4 (3-14) |
| Total no. ultrasounds received while in harness [median (range)] (n) | 3 (2-4) |

Data are presented as median (range).

*12 out of 49 (24%; all in group A) patients did not have an ultrasound at the time of Pavlik harness initiation, instead receiving it a median of 2 weeks (range, 1-3 wk) following harness initiation.

(40%) treated for > 5 weeks in harness between first and final ultrasound, of which 4 (8%) were treated for > 10 weeks.

Surprisingly, we found an overall mean improvement of 4 degrees in AA and a mean increase in FHC of 1% between first and final ultrasound in harness (Table 3 and Fig. 2) Patients in groups A and B did not differ in terms of total change in AA ($P = 0.942$). There was no significant difference in mean change in AA between those in harness < 5 weeks (4 ± 7 degrees) and those with prolonged harness wear ≥ 5 weeks (4 ± 9 degrees) ($P = 0.521$). Over the study period, 30/49 hips (61%) exhibited an increase in AA, 15 hips (31%) a decrease in AA, and 4 hips (8%) no change. There was no difference in any baseline characteristics or markers of disease severity, including femoral head reducibility and FHC, between hips with either no change or increases in AA versus those with decreases in AA (Table 4).

Looking further at potential moderating factors, Spearman correlations revealed no statistically significant linear association between change in AA and time in harness between ultrasounds ($P = 0.545$; Fig. 3), age at Pavlik harness initiation ($P = 0.105$), FHC at first ultrasound ($P = 0.956$), or FHC at final ultrasound ($P = 0.651$). Independent regressions indicated that bilateral disease, family history of DDH, history of breech presentation, femoral head reducibility, and FHC at initial/final ultrasound did not significantly predict change in AA when controlling for length of time in harness (all P 's > 0.05). Furthermore, length of time in harness did not by itself significantly predict total change in AA when separately controlling for each of these above variables (all P 's > 0.05).

Following harness failure, 38 hips were treated with a trial of rigid abduction bracing, of whom 22 (58% of

those treated in-brace; 45% overall) stabilized and required no further treatment (Table 5). Sixteen hips (33%) were treated successfully with closed reduction/spica casting and 10 (20%) required open reduction; 1 hip (2%) spontaneously reduced and required no further treatment. Only 1 patient (2%) required a revision open reduction following the initial attempt. In total, 39/49 hips (80%) were successfully reduced through closed means, with no significant differences between those with a decrease in AA versus those that improved or remained stable ($P = 0.702$), and no differences between those in harness < 5 weeks versus those ≥ 5 weeks (83% vs. 75%; $P = 0.720$).

DISCUSSION

The Pavlik harness is the treatment of choice for most infants with a developmental dislocation of the hip under 6 months of age. For those that do not respond to Pavlik treatment, concerns exist that prolonged use of the harness in the setting of a persistent dislocation can result in "Pavlik harness disease," or erosion of the posterior acetabulum, making subsequent hip reduction more challenging.⁷⁻¹⁰ Accordingly, current recommendations are to carefully monitor progress for 2 to 4 weeks before abandoning harness treatment of a persistently dislocated hip.^{5,7,9-12} Given the deep-rooted nature of this dogma, no recent studies have evaluated Pavlik harness disease, and very few patients, if any, are ever maintained in harness for prolonged periods of time.

The actual evidence to support Pavlik harness disease, however, is surprisingly limited. Early case series guiding current recommendations described findings from hips treated for significantly longer than 2 to 4 weeks. The mean duration of harness use in Jones et al⁸ study was 16 weeks (range, 8 wk to 15 mo), with 7/19 (37%) treated for 15 weeks or longer. In addition, their descriptions of posterolateral acetabular deficiency were purely observational, and in those infants treated in harness for < 10 weeks, only 1 (20%) required an open reduction. Similarly, Viere et al⁹ reported on 30 hips that were treated for a mean of 8 weeks (range, 3 to 23 wk), with only 4 hips requiring an additional procedure; there was no difference in mean length of preceding harness use between those treated successfully with closed reduction and those requiring an open reduction. Reviewing this evidence, Harding et al¹² concluded that the 2- to 4-week guideline is more so associated with a lack of adverse

TABLE 3. Change in Ultrasonographic Measurements Between First and Final US in Harness

| | First US in Harness* | Final US in Harness* | Mean Change (95% CI) | Mean Change per Week in Harness (95% CI) | P † |
|---------------------------------------|----------------------|----------------------|----------------------|------------------------------------------|-------|
| α angle (mean \pm SD) (deg.) | 42 \pm 9 | 46 \pm 7 | 4 (2-6) | 0.8 (0.3-1.3) | 0.001 |
| FHC [median (range)] (%) | 11 (0-30) | 11 (0-34) | 1 (-3 to 4) | 0.3 (-0.6 to 1.1) | 0.853 |

*Data are presented as mean \pm SD or median (range). All measurements recorded from coronal flexion view.

† P -value corresponds to intrasubject differences for total change in the given measurement based on a paired Student t test or Wilcoxon signed-rank test. CI indicates confidence interval; FHC, femoral head coverage; US, ultrasound.

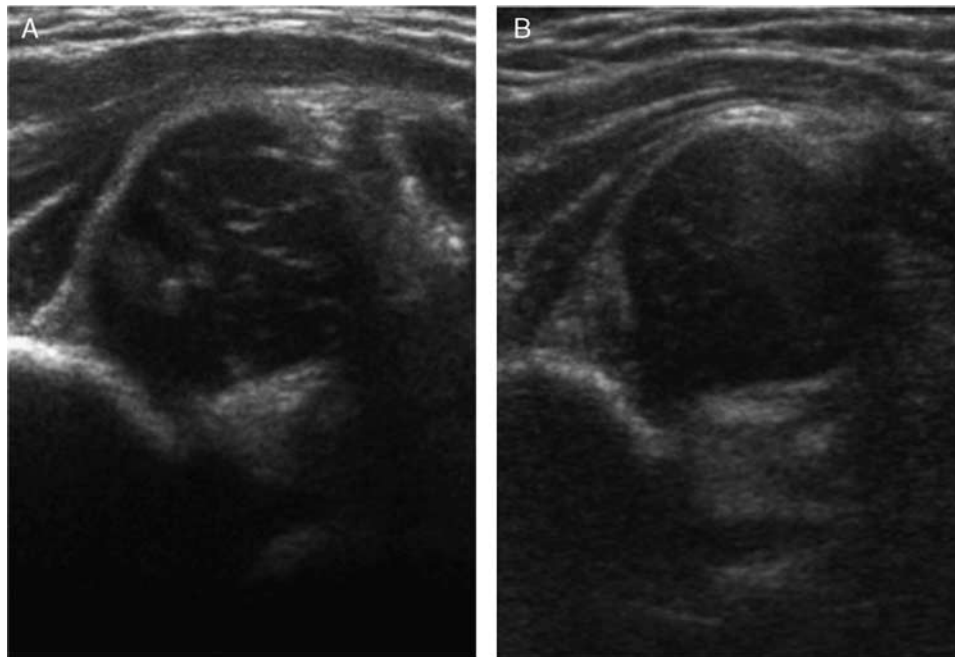


FIGURE 2. Case example of a 6-week-old female with developmental dysplasia of the left hip. A, Initial ultrasound before Pavlik harness initiation demonstrates a left hip dislocation. B, Follow-up ultrasound after 12 weeks in harness demonstrates persistent dislocation but similar acetabular morphology. Of note, the hip was Ortolani positive on clinical exam at both Pavlik initiation and termination. Following Pavlik harness failure, the patient was treated successfully with closed reduction and spica casting.

outcomes and a fear of causing iatrogenic damage than direct evidence of negative morphologic changes. To our knowledge, no previous studies have attempted to evaluate objective morphologic changes to the acetabulum in response to continued Pavlik treatment of a persistently dislocated hip.

In fact, recent evidence suggests that prolonged harness treatment may be beneficial in certain cases. In a

prospective study, van der Sluijs et al¹⁶ reported that 77% of their Graf type-III hips that went on to achieve reduction with harness treatment did so after 6 weeks, suggesting that treatment may be continued in those patients with improving hip abduction and ultrasonographic indices. In a qualitative study, Senaran et al¹⁷ noted that 32/35 hips that failed Pavlik harness treatment had a stable and/or improved sonographic grade at

TABLE 4. Comparison of Disease Characteristics Between Hips With Either an Increase in AA or No Change Over Treatment Period Versus Hips With a Decrease in AA

| Variables | n (%) | | | P† |
|------------------------------------------------------------------------|---------------------------|-----------------|----------|-------|
| | Increase/No Change in AA* | Decrease in AA* | Overall | |
| No. hips | 34 | 15 | 49 | |
| Change in AA (mean ± SD) (deg.) | +8 ± 7 | -4 ± 3 | +4 ± 8 | |
| Age at Pavlik initiation [median (range)] (mo) | 5 (0-18) | 3 (0-9) | 4 (0-18) | 0.172 |
| Age ≤4 wk at Pavlik initiation | 14 (41) | 9 (60) | 23 (47) | 0.224 |
| Treatment in harness ≥5 wk | 13 (38) | 7 (47) | 20 (41) | 0.580 |
| Sex (female) | 28 (82) | 10 (67) | 38 (78) | 0.275 |
| Laterality (no. left hips) | 19 (56) | 10 (67) | 29 (59) | 0.479 |
| History of breech position | 15 (44) | 5 (33) | 20 (41) | 0.479 |
| Positive family history of DDH | 6 (18) | 2 (13) | 8 (16) | 1.000 |
| History of clubfoot, torticollis, or other congenital foot disease | 5 (15) | 2 (13) | 7 (14) | 1.000 |
| Reducibility of femoral head at any point throughout treatment course‡ | 20 (59) | 6 (40) | 26 (53) | 0.224 |
| FHC ≤0% at Pavlik termination | 10 (29) | 5 (33) | 15 (31) | 0.784 |
| Decrease in FHC between Pavlik initiation and Pavlik termination | 12 (35) | 6 (40) | 18 (37) | 0.753 |

Data are presented as frequency (percentage) or mean ± SD for each characteristic.

*Increase/decrease in AA defined as absolute change in measured AA from first to final ultrasound in Pavlik harness, with change of 0 degree included in the “increase” group.

†P-values correspond to intergroup differences based on the Fisher exact/ χ^2 test for categorical variables and the Student *t* test for continuous variables.

‡Reducibility defined as Ortolani positive on physical exam.

AA indicates α (Graf) angle; DDH, developmental dysplasia of the hip; FHC, femoral head coverage.

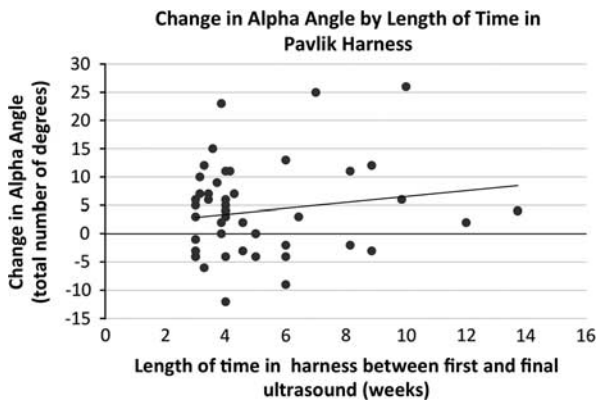


FIGURE 3. Scatterplot depicting change in α angle over length of time in Pavlik harness (Spearman $\rho=0.089$). Given these findings, there is no evidence of a statistically significant association between change in α angle and length of time in Pavlik harness ($P=0.545$).

treatment termination as measured by femoral head position and stability. Taylor and Clarke¹⁸ agreed, noting that it is important to utilize ultrasound to fully distinguish the gradually improving subluxed hip from the irreducible one. Conversely, operative hip reduction introduces a number of significant concerns, including exposure to general anesthesia, challenges from spica cast care, and an increased risk for iatrogenic avascular necrosis and its accompanying impact on long-term outcomes and function.^{19,20}

Anecdotal experience from our institution suggests that subsequent treatment has not been compromised by continued use of the harness beyond the 2- to 4-week recommendation. Therefore, we sought to begin to question the concept of Pavlik harness disease by investigating potential changes to the AA that may result from continued treatment of a persistently dislocated hip. Surprisingly, our

results demonstrated a slight mean improvement in both AA and FHC for hips that remained dislocated through a minimum 3-week treatment period. In terms of clinical significance, we do not interpret our results to mean that continued Pavlik harness use for a persistently dislocated hip is beneficial for the acetabulum. It is possible that the observed “improvement” in AA was due to some positive development of the acetabulum even in the absence of a concentric reduction.²¹ Regardless, our data do suggest that in a properly monitored hip, continued Pavlik use beyond current recommendations may be reasonable, and at the very least, it may not always be deleterious. It should be noted, however, that some hips in our series did demonstrate deteriorations in AA, implying that blind use of a harness for prolonged periods of time may indeed be harmful for certain hips. Although we did not ascertain any significant predictors for this behavior, proper monitoring (using serial ultrasound) would identify these select hips, and allow continued safe use of the harness in others, especially for those showing progressive improvement in clinical exam and/or ultrasonographic indices. Perhaps most importantly, unsuccessful harness treatment did not seem to adversely affect treatment outcomes, as 80% of hips in our cohort were reduced successfully using closed means, and only 1 hip failed open reduction and required revision surgery.

Previous studies have reported rates of open reduction for infants aged 1 month and below at Pavlik initiation who went on to fail harness treatment. Tiruveedhula et al²² noted in a prospective study of 37 hips that 46% required an open reduction. Novais et al²³ reported on 215 hips treated in Pavlik harness, including 30 that failed treatment. Of these, 8 (27%) required open treatment, all of which were initially Ortolani positive. Ibrahim et al²⁴ reported an open reduction rate of 43% for their 7 hips that were braced after failed Pavlik, although the mean age at harness initiation was slightly older at 2.1

TABLE 5. Final Means of Obtaining a Concentric Reduction Following Failure of Pavlik Harness Therapy

| | n (%) | | |
|------------------------------------------------|---------------------------|-----------------|---------|
| | Increase/No Change in AA* | Decrease in AA* | Overall |
| No. hips | 34 | 15 | 49 |
| Nonoperative management | | | |
| Spontaneous reduction† | 1 (3) | 0 | 1 (2) |
| Rigid abduction bracing‡ | 12 (35) | 10 (67) | 22 (45) |
| Operative management | | | |
| Closed reduction | 13 (38) | 3 (20) | 16 (33) |
| Open reduction§ | 8 (24) | 2 (13) | 10 (20) |
| Treated successfully through closed management | 26 (76) | 13 (87) | 39 (80) |

Data are presented as frequency (percentage).
 *Increase/decrease in AA defined as absolute change in measured AA from first to final ultrasound in Pavlik harness, with change of 0 degree included in the “increase” group.
 †Patient was found to spontaneously reduce on routine follow-up radiographs preceding a scheduled surgical reduction.
 ‡All rigid abduction brace trials preceded any attempt at surgical reduction. In total, 38 patients were treated with a trial of rigid abduction bracing for a median of 12 weeks (range, 1 to 27 wk), of whom 22 (58%) went on to not require further treatment. This included 12/25 (48%) infants with an improvement in AA and 10/13 (77%, $P=0.255$) infants with a decrease in AA.
 §Of those undergoing open reduction, 6 (12%) were treated with open reduction on the first attempt, whereas 4 (8%) were treated with open reduction following a closed reduction that was initially perceived as successful. One patient (“Increase in AA” group) required a second open reduction following the initial procedure, resulting in a revision rate for those undergoing open reduction of 10%.
 AA indicates α angle.

months. In contrast, Hedequist et al²⁵ reported that all 15 of their hips that were treated with a rigid abduction orthosis following failed Pavlik were eventually reduced through closed means, and Senaran et al¹⁷ noted that only 2 of their 35 hips (6%) that failed Pavlik required an open reduction. However, it should be noted that only 46% of the hips in Senaran's series were dislocated by ultrasound at Pavlik termination. In summary, our observed open reduction rate of 20% compares favorably to the published literature, further suggesting that prolonged harness treatment in this cohort did not seem to compromise subsequent treatment.

This study has a number of limitations. First, we used AA as a global measure of acetabular morphology, but did not specifically measure the anatomic changes in the posterior wall. Unfortunately, no previous studies have described objective measures to evaluate posterior wall anatomy, and although we explored several possible measurement techniques, including transverse views, these were abandoned for poor reproducibility and lack of normative data. Consequently, using the AA as a global measure of acetabular morphology and tracking the clinical outcomes of those hips that fail harness therapy may be the best available method to indirectly account for the posterior wall changes purported to occur with Pavlik harness disease. In addition, we did not have data regarding the specific location of the femoral head for each dislocated hip (eg, perched, posterolateral, superior to transverse ligament, etc.), which may have influenced the risk of developing of Pavlik harness disease. Nevertheless, in this study, neither femoral head reducibility nor FHC affected change in AA, indicating that within the confines of our data, femoral head position seemed not to affect the risk of developing negative changes to the acetabulum.

In this study, the median length of time in harness between ultrasounds was only 4 weeks, although 40% were treated for >5 weeks. As a result, our data may not be generalizable to longer-term Pavlik use. Given the extreme dogma of Pavlik harness disease, however, it is nearly impossible either retrospectively or prospectively to identify a cohort of infants with persistent dislocations treated in a harness for longer periods than this study. Although the number of hips in this series was somewhat modest, a larger series would be challenging to isolate given the high success rate of Pavlik harness treatment. By pooling patients from a large, tertiary-care children's hospital and a multicenter, international study group, we feel that the study cohort was as robust as feasibly allowed, and also more broadly representative of the general population. As a retrospective sample, our study was subject to inherent selection bias, as a predetermined criterion for Pavlik harness failure was not utilized. In addition, it is possible that the hips in this study were developing "better" than other hips failing harness treatment, which is why the treating surgeon felt comfortable continuing use of the Pavlik beyond the typical guidelines. To minimize this possibility, we used a consistent definition of a dislocation based on objective ultrasonographic criteria to ensure that hips were "similarly" dislocated both at Pavlik initiation and termination, thereby implying that no

significant improvement occurred over the treatment period. Finally, a decision was made a priori only to follow patients until the point at which stable reduction was achieved, as this study's primary objective was to investigate changes to the acetabulum during failed harness use and their potential effect on the ultimate means of reduction. We therefore cannot comment on the incidence of osteonecrosis or residual dysplasia following failed Pavlik treatment. Despite these limitations, we believe this study is an important first step toward objectively questioning a widely believed concept that has little supportive evidence.

In conclusion, based on the lengths of harness treatment in our series, most hips did not exhibit negative changes in the acetabular AA 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. With appropriate monitoring, therefore, prolonged management of a dislocated hip with Pavlik harness may have fewer adverse consequences than previously thought. Further investigation is required to definitively confirm or refute the presence of Pavlik harness disease.

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