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Comparison of Pavlik Harness treatment regimens for reduced but dislocatable (Barlow positive) hips in infantile DDH

David Neal[a], Terri Beckwith[b], Adam Hines[d], Wei Chun Lee[e], Bekir Eray Kilinc[f], ChanHee Jo[b], Harry Kim[b,c,*]

[a] John Peter Smith Hospital, Fort Worth, TX, USA
[b] Texas Scottish Rite Hospital for Children, Dallas, TX, USA
[c] Orthopedic Surgery Department at UT Southwestern Medical Center, Dallas, TX, USA
[d] Irwin Army Community Hospital, Fort Riley, KS, USA
[e] Bone and Joint Research Center, Chang Gung Memorial Hospital, Linkou, Taiwan
[f] Health Science University, Fatih Sultan Mehmet Training and Research Hospital, Orthopaedics, Istanbul, Turkey

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ABSTRACT

Objective: Although the Pavlik Harness (PH) is the most utilized treatment for developmental dysplasia of the hip (DDH), the ideal treatment protocol (frequency of clinic visits in the first month and daily wear duration) for Barlow + hips (reduced but dislocatable) has yet to be defined.
Methods: This study compared DDH patients with Barlow hips who were treated with 23 vs 24 h per day PH wear and weekly vs every other week visits. Clinical success was defined as a stable hip that did not require closed or open reduction, or the use of an abduction orthosis prior to achieving clinical stability. Radiographic success was based on the acetabular index at 2-year follow up.
Results: Sixty-five patients (75 hips/58 females) with Barlow hips had a mean age of presentation of 15 ± 12 days (range 4–70) and mean follow-up of 33 ± 17 months (range 6–90). There was no difference in clinical or radiographic success rate between 23 h vs 24 h wear groups ($p > 0.99$ both) or the Frequently vs Infrequent visit groups ($p = 0.49$ both). Overall clinical success rate was 97% (73/75 hips) and radiographic success rate at 2 years was 97% (58/60 hips).
Conclusion: A strict, weekly clinic visit and 24-h PH regimen may not be necessary to obtain good clinical and radiographic outcomes in infants presenting < 6 months of age with Barlow positive hips.
Level of evidence: Therapeutic, Level III.

1. Introduction

Developmental dysplasia of the hip (DDH) encompasses a wide spectrum of hip pathology ranging from hip ligamentous laxity, to dislocatable hip (Barlow+), to dislocated but reducible hip (Ortolani +), to a hip with fixed dislocation (Ortolani-). The diagnosis of DDH in infants is based primarily on physical examination and the findings of Barlow or Ortolani sign.[1] In conjunction with family history and breech presentation, these physical findings allow primary care physicians to suspect or diagnose infantile DDH and refer the patient to a pediatric orthopedist for definitive treatment.[1]

The Pavlik Harness (PH) is the treatment of choice for DDH due to a high success rate, long track record, and low incidence of complications.[2,3] The PH is used to treat infants across the spectrum of hip instability with success rates in the literature up to 99%.[4–6] Despite its widespread acceptance, variation exists in the literature as to the specific PH treatment protocol, specifically the frequency of clinic visits and the daily wear duration in the first month of treatment.[2,7,8] These protocols vary by institution, and to our knowledge, there is no study demonstrating the superiority of one PH treatment regimen to another. A recent clinical practice guideline from the American Academy of Orthopedic Surgeons on infantile DDH reflects this knowledge gap listing specific areas where further research is needed including "what constitutes standardized bracing treatment of DDH."[9] This lack of consensus is evident at our institution where PH protocol for daily wear duration (23 vs 24 h) and number of clinic visits in the first month is highly dependent on surgeon preference.

It has been suggested that PH treatment regimen and outcomes

* Corresponding author. Center for Excellence in Hip Disorders, Texas Scottish Rite Hospital for Children, 2222 Welborn Street, Dallas, TX, 75219, USA.
E-mail address: harry.kim@tsrh.org (H. Kim).

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should be stratified to reflect the important differences in hip pathology of subcategories of DDH.[3] While there is considerable evidence to support the conclusion that the PH is an effective and reliable treatment method, the specifics of the treatment regimen for the subcategories of DDH (Barlow + vs. Ortolani + hips) have yet to be defined. Although our group previously looked into this question for Ortolani + hips,[10] it is unclear whether a weekly clinic visit during the 1st 4 weeks of treatment is necessary for Barlow + hips or whether 24 h per day PH wear is required to obtain a stable hip. Thus, the purpose of this study was to determine if frequency of follow-up visits in the first 4 weeks of PH treatment or the daily PH wear duration (23-h vs. 24-hour) affected the outcome of obtaining stable, reduced hips in infants with dislocatable (Barlow+) hips.

2. Materials and methods

This study was approved by our institutional review board. Data from patients evaluated for DDH at a tertiary referral center from January 2008 to June 2014 was prospectively gathered and retrospectively reviewed. All patients were evaluated clinically by one of ten fellowship-trained pediatric orthopedic surgeons at the time of the initial presentation. Patients less than 6 months of age diagnosed with a reduced but dislocatable (Barlow+) hip were eligible for inclusion in this study. Exclusion criteria were infants greater than 6 months of age at the time of diagnosis, those with less than 6 months of follow-up to assess outcome, presence of a fixed or teratologic dislocation, or those with stable ultrasonic hip dysplasia. Infants unable to wear the PH due to femoral nerve palsy within the first 2 weeks of initiating treatment and those not compliant (1 patient) were also excluded. Three patients (two patients from 23-h PH wear group and one from the 24-h group) were excluded for femoral nerve palsy.

Demographic data, physical exam findings (type of instability), and 2-year x-ray results were entered into a prospective DDH database. Additional data not captured in the database was gathered through a chart review: PH wear schedule (23-h vs. 24-hour), frequency of clinic visits and ultrasounds, need for rigid abduction orthosis to obtain hip reduction, and need for closed or open reduction. We defined 24-h wear as not taking any breaks from the PH treatment even for bathing for at least the first week.

Clinical success was defined as obtaining a stable hip on physical examination and hip ultrasound without a need to perform a closed or open reduction or to use a rigid abduction orthosis prior to achieving clinical stability on exam. Radiographic success was defined as a hip without residual acetabular dysplasia on a standardized standing AP pelvis radiograph obtained at two years of age. Residual dysplasia was defined as acetabular index greater than two standard deviations above the value expected for the age, as defined by Tonnis.[11] Acetabular indices were measured by two independent observers.[12] If both of the observers had acetabular measurements above the normal range for age, it was deemed dysplastic and a radiographic failure.

3. Statistical analysis

A chi-square test was used to compare categorical variables between two groups and continuous variables with the Mann-Whitney *U* test. X-ray comparisons utilized two-sample t-tests when comparing all hips. Intraclass correlation coefficient (ICC) analysis was used to assess the inter-observer agreement of acetabular index measurements. Statistical significance was set at $p < 0.05$ and SAS version 9.4 (SAS Institute INC, Cary, NC) was used for the statistical analysis.

4. Results

From January 2008 to June 2014, 65 patients (75 hips, 58 females) with Barlow + hips treated with PH met the inclusion criteria. The left side was affected in 40 patients, the right side in 15 patients, and bilateral in 10 patients. Twenty-three patients had breech presentation, thirty-eight were 1st born and 14 patients had a family history of DDH. The mean age at presentation was 15 ± 12 days (range 4–70) and mean follow-up of 33 ± 17 months (range 6–90). While pre-treatment ultrasound is not a standard of care at our institution, it was performed in 33 patients (51% of patients, 38 hips- Table 3). The mean pre-treatment femoral head coverage was 11% ± 13% (range 0–45).

Thirty-five patients (54%) had greater than 2 visits in the first 4 weeks and 30 patients (46%) had less than or equal to 2 visits in the first 4 weeks. A comparison of clinical hip outcome based on the frequency of follow-up showed no statistically significant difference with 100% success for the ≤2 Infrequent group and 95% success for the > 2 Frequent group (Table 1, $p = 0.49$). Forty-eight patients (74%) were prescribed 23 h per day wear of the PH and 17 (26%) were prescribed 24 h per day wear. A comparison of clinical success rate by hip based on daily wear duration prescribed showed no statistically significant difference with 97% success for the 23-h group and 100% for the 24-h wear group (Table 2, $p > 0.99$).

Two patients in the frequent group demonstrated a clinical failure with harness treatment. The first patient (Frequent group, 23-h harness wear) presented as a bilateral case of Barlow positive hips. The right hip responded successfully to harness treatment. The left hip required an open reduction when the patient was 7 months of age due to persistent hip dislocation on a follow-up X-ray. This hip was also classified as radiographically unsuccessful at 2-year follow up. The second patient (Frequent group, 23-h harness wear) presented with a Barlow positive left hip and required a closed reduction at 3 months of age due to persistent hip subluxation on ultrasound (5% head coverage). This hip was a radiographic success at 2-year follow up.

There were 6 patients (2 Infrequent group, both 23-h wear and 4 Frequent Group, 1 in 24-h wear and 3 in 23-h wear) who had clinically stable hip exam after the PH treatment, but were put in an abduction brace for residual ultrasonic dysplasia. These 6 patients were deemed

Table 1
Comparison of Frequent vs. Infrequent Follow-Up by Hip.

	# of Visits > 2		# of Visits ≤2		
Variable	n	Mean ± SD (Range)	n	Mean ± SD (Range)	p Value
Age at PH treatment (Days)	35	14 ± 10 (4–69)	30	17 ± 17 (4–44)	0.98
# Visits in 1st 4 weeks	35	3 ± 0.4 (3–4)	30	2 ± 0.4 (1–2)	0.00
# Ultrasounds in 1st 4weeks	35	1.9 ± 1.4 (0–4)	30	1.6 ± 0.5 (1–2)	0.16
Clinical Success Rate (By Hip)	37	Yes (95%)	36	Yes (100%)	0.49
	2	No (5%)	0	No	
2 YR Acetabular Index (By Hip)	30	22.5 ± 5.5 (12–39)	30	21.4 ± 4.0 (14–28)	0.49
2 YR Radiograph Success (By Hip)	28	Yes (93%)	30	Yes (100%)	0.49
	2	No (7%)	0	No	

Table 2
Comparison of 23 vs. 24 Hour Daily Wear Time by Hip.

	23 Hour		24 Hour		
Variable	n	Mean ± SD (Range)	n	Mean ± SD (Range)	p Value
Age at PH treatment (Days)	48	15 ± 12 (4–58)	17	18 ± 17 (4–69)	0.56
# Visits in 1st 4 weeks	48	3 ± 0.9 (1–4)	17	3 ± 0.7 (1–4)	0.54
# Ultrasounds in 1st 4weeks	48	1.9 ± 1.1 (0–4)	17	1.6 ± 0.9 (1–3)	0.39
Clinical Success Rate (By Hip)	54	Yes (97%)	19	Yes (100%)	> 0.99
	2	No (3%)	0	No	
2 YR Acetabular Index (By Hip)	45	22.7 ± 4.9 (12–39)	15	19.9 ± 4.1 (12–27)	0.05
2 YR Radiograph Success (By Hip)	43	Yes (97%)	15	Yes (100%)	> 0.99
	2	No (3%)	0	No	

Table 3
Patients with pre-treatment hip ultrasound data.

Pavlik Wear			Number of Visits		
	Hips	Patients		Hips	Patients
23 Hour	24	21	≤2 Visits	25	21
24 Hour	14	12	> 2 Visits	13	12
Total	38	33	Total	38	33

clinical successes as PH treatment achieved hip stability and the abduction brace was initiated to treat residual ultrasonic dysplasia.

Of the original 75 hips, 60 (80%) had AP pelvis radiographs at 2 years (Figs. 1–4). No significant difference in the radiographic success rate was observed between different PH protocols (duration of PH wear or number of clinic visits, Tables 1–2). The intraclass correlation coefficient (ICC) for acetabular index measurements by two independent observers was 0.87 indicating a strong inter-observer agreement.

5. Discussion

The major conclusions of this study are that daily PH wear duration (23 vs 24 h) and the frequency of follow up visits in the first 4 weeks of PH treatment (weekly visits vs every other week) do not affect the clinical or radiographic outcomes for Barlow + hips. These conclusions are based on the following evidence. First, clinical success, defined as a stable hip that did not require closed or open reduction or the use of an abduction orthosis to obtain stability, was not significantly different between the 23-h vs. 24-hour wear duration groups or frequent vs. Less frequent follow-up groups ($p > 0.99$, $p = 0.49$). Next, radiographic success, defined as a lack of residual acetabular dysplasia on radiograph at 2 years of age, was also not significantly different between the 23-h vs 24-h wear duration groups or frequent vs. Less frequent follow-up groups ($p > 0.99$, $p = 0.49$). Collectively the PH clinical and radiographic success rates in Barlow + hips were excellent (> 90%) regardless of PH treatment regimen chosen (Tables 1 and 2).

As previously mentioned DDH encompasses a wide range of hip pathology. It has been previously recommended that reported DDH outcomes be subcategorized by the type of hip pathology as we did in our study.[3] To our knowledge this subcategorization is uncommon and there are no studies in the literature comparing the clinical outcomes of different PH treatment protocols specifically for Barlow + hips. The results of this study are similar to another study from our group that examined the clinical and radiographic outcomes of specifically Ortolani + hips treated with different PH regimens. In that study, the clinical and radiographic success rates were also excellent for different PH treatment regimens used.[10]

Although it has been clearly shown in the literature that clinical follow up for patient's treated with PH is essential in both confirming the reduction and assuring parental compliance, the optimal frequency of follow up has not been defined.[13] Based on these results, strict weekly visits for the first 4 weeks of PH treatment are not necessary for a successful clinical or radiographic outcome of Barlow + hips. Benefits of fewer visits include reduced medical costs and decreased inconvenience for parents.

Based on our results, a strict 24 h/day PH regimen does not appear to be necessary to achieve stable hips for Barlow + hips. This is likely due to the increased stability of Barlow + hips compared to other less stable forms of DDH. Due to the high effectiveness of the PH for both mild and severe forms of DDH, an additional hour of wear per day for Barlow + hips does not appear to have an effect on clinical outcomes. Although the authors of this study conclude that weekly clinic visits for the first 4 weeks of PH treatment and strict 24-h wear are not required, the PH treatment regimen should be determined on a case by case basis with ultimate goal of achieving a stable hip joint as soon as possible while providing the greatest convenience for patients and families.

Strengths of this study include prospectively enrolled patients, a high 2-year radiographic follow up rate (80%), and assessment of both clinical and radiographic outcomes. Limitations of this study include lack of pre-treatment hip sonography in all patients. Fifty-one percent of patients had pretreatment sonography based on surgeon's preference. In our institution, the diagnosis of a Barlow positive hip and initiation of a PH treatment is based on a clinical exam by a fellowship trained pediatric orthopedic surgeon, which is the standard of care at many centers in the US.[14] Another weakness is that PH compliance was not objectively measured. To the author's knowledge there are no studies in the literature objectively determining PH compliance, although there is a study utilizing parental surveys that showed 96% compliance.[15] It has previously been suggested that a more strict treatment regimen with 24-h wear can lead to worse compliance due to difficulty with bathing and clothing changes. Regardless of this possibility, both groups (23-h vs 24-h wear) had a clinical success rate over 90% which supports the notion that PH wear does not have to be a strict 24-h regimen to be successful in Barlow + hips. Future studies would benefit from objectively measuring PH compliance with an instrument such as a heat sensor incorporated in the brace.

In summary, this study sought to determine if frequency of follow-up visits in the first 4 weeks of PH treatment and the daily PH wear duration (23-h vs. 24-hour) affected the outcome of obtaining stable and reduced hips in infants with Barlow + hips. The findings of the study suggest that it may not be necessary to have a strict weekly clinic visit or require 24-h harness wear in the first 4 weeks of PH treatment in order to have satisfactory clinical and radiographic outcomes for infants < 6 months of age with Barlow + hips.

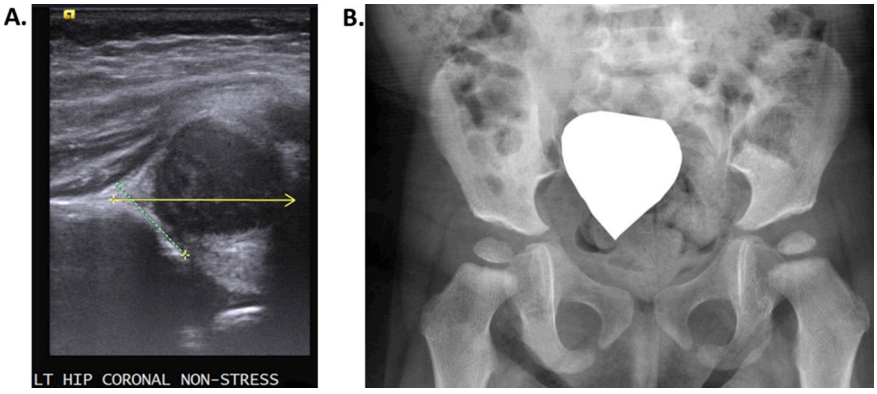

Fig. 1. Eight week old girl with a left Barlow positive hip dislocation treated with 24 h PH wear regimen and less frequent clinic visits.
A. A non-stress coronal view of pre-treatment left hip ultrasound. B. A standing AP radiograph of pelvis obtained at 26 months showing normal left hip.

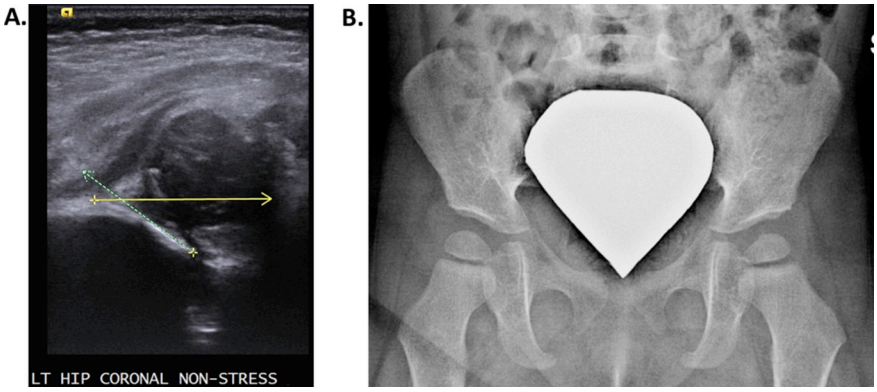

Fig. 2. Six week old girl with a left Barlow positive hip dislocation treated with 24 h PH wear regimen and frequent clinic visits.
A. A non-stress coronal view of pre-treatment left hip ultrasound. B. A standing AP radiograph of pelvis obtained at 25 months showing a normal left hip.

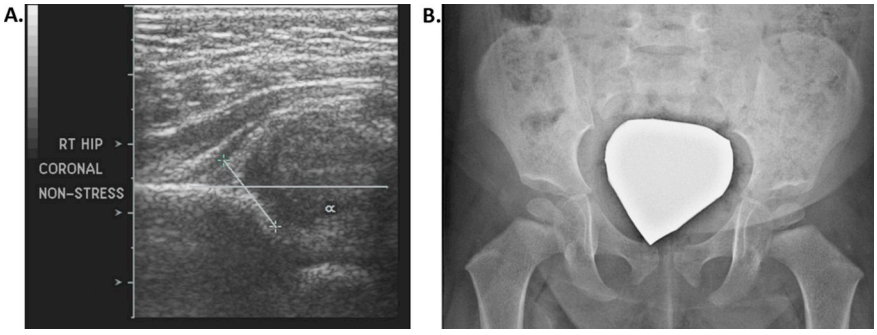

Fig. 3. Eight week old girl with a right Barlow positive hip dislocation treated with 23 h PH wear regimen and less frequent clinic visits.
A. A non-stress coronal view of pre-treatment right hip ultrasound. B. A standing AP radiograph of pelvis obtained at 25 months showing a normal right hip.

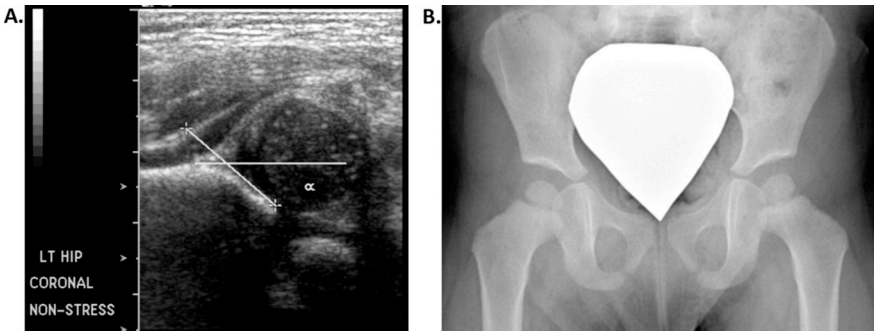

Fig. 4. Four week old girl with a left Barlow positive hip dislocation treated with 23 h PH wear regimen and frequent clinic visits.
A. A non-stress coronal view of pre-treatment left hip ultrasound. B. A standing AP radiograph of pelvis obtained at 21 months showing a normal left hip.

Author Contribution

David Neal: Study design, data collection and analysis, drafting and revision of manuscript
Terri Beckwith: Study design, data collection and analysis, drafting and revision of manuscript
Adam Hines: Study design, data collection and analysis
Wei Chun Lee: Data collection
Bekir Eray Kilinc: Data collection
ChanHee Jo: Study design, data analysis, drafting of manuscript
Harry Kim: Study design, data collection, drafting and revision of manuscript

Disclosure of potential conflicts of interest

The authors declare they have no conflict of interests in this work.

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Research involving human participants and/or animals

All procedures performed in studies involving humans were in accordance with the ethical standards of the institution at which the studies were conducted. This study was approved by our IRB. This article does not contain any studies with animals performed by any of the authors.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Declarations of interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jor.2019.06.027.

References

1. Roposch A, Protopapa E, Cortina-Borja M. Weighted diagnostic criteria for developmental dysplasia of the hip. *J Pediatr.* 2014;165(6):1236–1240 e1231.
2. Tibrewal S, Gulati V, Ramachandran M. The Pavlik method: a systematic review of current concepts. *J Pediatr Orthop B.* 2013;22(6):516–520.
3. Nakamura J, Kamegaya M, Saisu T, Someya M, Koizumi W, Moriya H. Treatment for developmental dysplasia of the hip using the Pavlik harness: long-term results. *J Bone Joint Surg Br.* 2007;89(2):230–235.
4. Cashman JP, Round J, Taylor G, Clarke NM. The natural history of developmental dysplasia of the hip after early supervised treatment in the Pavlik harness. A prospective, longitudinal follow-up. *J Bone Joint Surg Br.* 2002;84(3):418–425.
5. Ramsey PL, Lasser S, MacEwen GD. Congenital dislocation of the hip. Use of the Pavlik harness in the child during the first six months of life. *J Bone Joint Surg Am.* 1976;58(7):1000–1004.
6. Johnson AH, Aadalen RJ, Eilers VE, Winter RB. Treatment of congenital hip dislocation and dysplasia with the Pavlik harness. *Clin Orthop Relat Res.* 1981(155):25–29.
7. Guille JT, Pizzutillo PD, MacEwen GD. Development dysplasia of the hip from birth to six months. *J Am Acad Orthop Surg.* 2000;8(4):232–242.
8. Heeres RH, Witbreuk MM, van der Sluijs JA. Diagnosis and treatment of developmental dysplasia of the hip in The Netherlands: national questionnaire of paediatric orthopaedic surgeons on current practice in children less than 1 year old. *J Child Orthop.* 2011;5(4):267–271.
9. Mulpuri K, Song KM. AAOS clinical practice guideline: detection and nonoperative management of pediatric developmental dysplasia of the hip in infants up to six months of age. *J Am Acad Orthop Surg.* 2015;23(3):206–207.
10. Authors Blinded. A comparison of Pavlik harness treatment regimens for dislocated but reducible (Ortolani+) hips in infantile developmental dysplasia of the hip. *J Pediatr Orthop.* 2017 Aug 2. https://doi.org/10.1097/BPO.0000000000001052 [Epub ahead of print] , PMID:28777280.
11. Tonnis D. Normal values of the hip joint for the evaluation of X-rays in children and adults. *Clin Orthop Relat Res.* 1976:39–47 119.
12. Spatz DK, Reiger M, Klaumann M, Miller F, Stanton RP, Lipton GE. Measurement of acetabular index intraobserver and interobserver variation. *Journal of pediatric orthopedics.* 1997;17(2):174–175.
13. Jones GT, Schoenecker PL, Dias LS. Developmental hip dysplasia potentiated by inappropriate use of the Pavlik harness. *J Pediatr Orthop.* 1992;12(6):722–726.
14. White KK, Sucato DJ, Agrawal S, Browne R. Ultrasonographic findings in hips with a positive Ortolani sign and their relationship to Pavlik harness failure. *J Bone Joint Surg Am Vol.* 2010;92(1):113–120.
15. Hassan FA. Compliance of parents with regard to Pavlik harness treatment in developmental dysplasia of the hip. *J Pediatr Orthop B.* 2009;18(3):111–115.