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SYMPOSIUM: THE HIP FROM CHILDHOOD TO ADOLESCENCE

Success of Pavlik Harness Treatment Decreases in Patients ≥ 4 Months and in Ultrasonographically Dislocated Hips in Developmental Dysplasia of the Hip

Hakan Ömeroğlu MD, Nusret Köse MD, Anil Akceylan MD

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Abstract

Background Treatment of developmental dysplasia of the hip (DDH) using the Pavlik harness has been a widely used method in patients between 0 and 6 months of age for many years. However, the factors influencing the success rate of this treatment modality have still not exactly been determined as a result of the limited number of clinical studies with higher level of evidence.

Questions/purposes We, therefore, asked whether (1) patient-related variables such as age, gender, and laterality; coexisting risk factors including family history, breech presentation, intrauterine packing, first-born girl, oligohydroamnios, and swaddling; and (2) the severity of hip dysplasia, defined by ultrasonography, are associated with differences in the success rate of Pavlik harness treatment in infants with DDH.

Methods Between 2012 and 2014, we treated 153 children (≤ 6 months of age) with DDH using the Pavlik harness. Hip dysplasia apart from coexisting neuromuscular disorders, congenital abnormalities, or syndromes was our inclusion criteria. Of patients thus treated, 130 (85%) were available for the evaluation of patient- and hip-related variables against the success of Pavlik harness treatment. Mean age of these patients on day of diagnosis and initiation of treatment was 108 days. The diagnostic and followup examinations of the hips were made by ultrasonography using Graf's method. Pavlik harness treatment was initiated in Graf Type IIa- and worse hips and treatment was considered "successful" when a Graf Type I hip was achieved. Pavlik harness treatment was successful in 92 (71%) patients (130 of 181 hips [72%]).

Results Age was the only patient-related variable influencing the success rate of the treatment; the mean age of children in whom Pavlik harness treatment succeeded (97 ± 38 days; 95% confidence interval [CI], 90–112) was lower than the age of those who failed (135 ± 37 days; 95% CI, 123–147; $p < 0.001$). The highest success rate was obtained in children younger than age 3 months (37 of 40 [93%]) and the lowest one older than age 5 months (nine of 24 [37%]) ($p < 0.001$). The threshold age value related to an increased risk of failure was found to be 4 months and older, which had a sensitivity of 66% and a specificity of 77% ($p < 0.001$). A higher initial α angle was observed in the hips in which the treatment succeeded (53° ± 6°; 95% CI, 51°–53°) than in those that failed (47° ± 7°; 95% CI, 45°–50°; $p < 0.001$). The threshold α angle value related to an increased risk of treatment failure was 46° and less, which had a sensitivity of 47% and a specificity of 86% ($p < 0.001$). Dislocated hips (Graf Type III and IV hips) had the lowest rate of treatment success (five of 19 [26%] and two of four [50%], respectively), whereas Graf Type IIa- hips had the highest (27 of 29 [93%]) ($p < 0.001$).

Conclusions We conclude that Pavlik harness treatment is less effective in children at and over the age of 4 months

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

H. Ömeroğlu (✉), N. Köse, A. Akceylan
Section of Pediatric Orthopaedics, Department of Orthopaedics and Traumatology, Faculty of Medicine, Eskişehir Osmangazi University, 26480 Eskisehir, Turkey
e-mail: omeroglu.h@gmail.com; homer@ogu.edu.tr

at the time the harness is first applied as well as in hips with complete dislocations and hips with severely deficient acetabular bony roofs. In such older patients and worse hip types, the use of initial Pavlik harness treatment needs to be revisited. Future studies, comparing the outcomes of the Pavlik harness treatment and other types of interventions in such patients and hip types, are needed.

Level of Evidence Level III, therapeutic study.

Introduction

Early diagnosis provides easier treatment methods to obtain and maintain reduction, increases potential for acetabular and femoral remodeling, lessens the risk of serious complications, and reduces the costs of treatment in developmental dysplasia of the hip (DDH) [28, 33]. Arnold Pavlik initially defined "functional treatment of DDH," which included directing the dislocated femoral head into the acetabulum by an orthotic device with straps while allowing the hip to move and holding the hips in flexion, abduction, and knees in flexion [17]. The spontaneous reduction of an unstable hip in the Pavlik harness is also a result of passive abduction of the hip by the weight of lower limbs while the child is in deep sleep [12, 23]. Subsequently, treatment of DDH by the Pavlik harness (Pavlik's method) has become the universally preferred treatment method in children younger than 6 months of age [17, 28, 29]. Hip ultrasonography is a useful tool to follow the course of treatment by the Pavlik harness, besides its early diagnostic aids in DDH [20, 29]. When a normal hip sonogram is achieved after Pavlik harness treatment, no considerable difference exists between staged and immediate ending of the treatment regarding outcomes and complications [30].

The success rate of Pavlik harness treatment is known to be high before the age of 6 months, because it is difficult to effectively maintain the position of the older infant in the harness [28]. We have believed that some patient-associated variables including age, gender, and laterality; risk factors, which has been known to correlate with the occurrence of DDH such as history of DDH in relatives, breech presentation, intrauterine packing, first-born girl, oligohydroamnios, and postnatal swaddling [28] as well as ultrasonographic grading of hip dysplasia by Graf's method [8] can influence the success rate of Pavlik harness treatment in DDH. However, to our knowledge, the effect of the previously mentioned factors on the success rate of this treatment modality have still not exactly been determined, because the number of clinical studies with a higher level of evidence is limited.

In this study we, therefore, asked if (1) patient-related variables such as age, gender, and laterality; coexisting risk factors including family history, breech presentation, intrauterine packing, first-born girl, oligohydroamnios, and swaddling; and (2) the severity of hip dysplasia, defined by ultrasonography, are associated with the success rate of Pavlik harness treatment in DDH.

Patients and Methods

The institutional ethics committee approved the design and content of this retrospective study.

In the authors' hospital, DDH in children between the ages of 0 and 6 months has been treated using the Pavlik harness for many years. Between March 2012 and December 2014, Pavlik harness treatment was advised in 153 children (125 girls, 28 boys; 215 hips) with unilateral or bilateral DDH. Mean age was 108 ± 42 days (range, 21–207 days) and the affected side was unilateral in 91 (35 right, 56 left) children and bilateral in 62. Children, who had hip dysplasia as a result of coexisting neuromuscular disorders, congenital abnormalities, or syndromes in which we had been using a different treatment modality; history of prior orthosis treatment in other centers; and whose treatment was not completed while the manuscript was being written, were not included the study. Twenty-three children (15%) with DDH (34 hips [16%]) were excluded from the study as a result of refusal of Pavlik harness treatment by the parents or as a result of missing the regular followup appointments after the treatment was initiated and were lost to followup. Thus, 181 hips of 130 children (106 girls, 24 boys) with a mean age of 108 ± 41 days (range, 26–207 days) on the day of diagnosis and initiation of treatment completed the Pavlik harness treatment with either success or failure and constituted the study group. The affected side was unilateral in 79 children (28 right, 51 left) and bilateral in 51.

Risk factors known to be correlated with the occurrence of DDH [28] such as history of DDH in first-, second-, or third-degree relatives; breech presentation at the third trimester; intrauterine packing (multiple pregnancy, foot deformities, torticollis); first-born girl; oligohydroamnios; and postnatal swaddling were initially recorded in all babies. In the authors' hospital, hip ultrasonography by Graf's method [8] has been used as the primary diagnostic as well as the followup radiological tool up to 9 to 10 months of age in DDH for many years. The first two authors (HÖ, NK), who were both experienced orthopaedic surgeons, made the ultrasonographic examination of the hips using Graf's technique [8]. The hips were classified according to Graf's hip ultrasonographic classification system and the managements of all patients were realized by the same first two authors (Table 1). Pavlik harness

Table 1. Graf's ultrasonographic hip classification system [8]

Graf hip type	Bony roof α angle	Cartilaginous roof β angle	Age
Type I	Good	Covers the femoral head	Any age
Mature/normal	≥ 60°		
Type IIa+	Adequate	Covers the femoral head	0–12 weeks
Physiological immature (appropriate for age)	50°–59°		
Type IIa-	Deficient	Covers the femoral head	6–12 weeks
Physiological immature (maturational deficit)	50°–59°		
Type IIb	Deficient	Covers the femoral head	> 12 weeks
Delay of ossification	50°–59°		
Type IIc	Severely deficient	Still covers the femoral head	Any age
Critical	43°–49°	< 77°	
Type D	Severely deficient	Displaced	Any age
Decentering	43°–49°	> 77°	
Type III	Poor	Pressed upward	Any age
Dislocated	< 43°	IIIa No echoes	
		IIIb Echogenic	
Type IV	Poor	Pressed downward	Any age
Dislocated	< 43°		

treatment was immediately initiated in Graf Type IIa- and worse hips [8]. Type IIa-, IIb, and IIc hips were further classified as "stable" and Types D, III, and IV hips were classified as "unstable" as initially defined by Graf [8]. Mean initial α angle of all hips was 51° ± 7° (range, 25°–58°). An orthopaedic resident applied the Pavlik harness under the supervision of experienced surgeons. The parents were then strictly informed about the use of the harness and were not allowed to remove the harness. If the parents removed the harness for bathing the baby or in case of any inconvenience, then a resident applied it under supervision as soon as possible. The ultrasonographic followup examination intervals were set at 3 to 4 weeks. The ultrasonographic followup examinations were made while the harness was not worn. Pavlik harness treatment was immediately discontinued and considered "successful" when a Graf Type I hip was achieved (Fig. 1). Pavlik harness treatment was considered "unsuccessful" if an initially Graf Type D, III, or IV hip did not progress into a better ultrasonographic hip type within each 3- to 4-week followup interval and type of treatment was changed (mostly closed/open reduction under general anesthesia, rarely rigid abduction orthosis) or an initially Graf Type IIa-, IIb, or IIc hip did not progress into a better ultrasonographic hip type within 8 weeks of followup and this was followed by transition to another treatment method, preferably a rigid abduction orthosis. In bilateral cases, if the treatment of one hip failed, then Pavlik harness treatment of the patient was considered "unsuccessful." In six bilateral cases, the harness treatment failed in one hip (all but one were unstable hips) and was successful (all but one were stable hips) in the contralateral hip. In the remaining 13 bilateral cases, the harness treatment failed in both hips; bilateral stable hips in seven patients, bilateral unstable hips in three, and one unstable/one stable hip in three. Immediate cessation of Pavlik harness treatment as a result of femoral nerve palsy was also considered as "failure of the treatment." Femoral nerve palsy was observed in two patients in which the return of femoral nerve function was observed within 4 weeks after the immediate cessation of the harness. Mean treatment period of 130 children was 59 ± 31 days (range, 16–168 days). Pavlik harness treatment was successful in 92 (71%) patients (130 of 181 hips [72%]). All patients were invited for radiographic examination at 1 year of age and then at least once annually.

For the assessment of the correlation between the success rate of Pavlik harness treatment and patient-related variables, data of the patients in whom the treatment succeeded and failed were compared. For the assessment of the correlation between the success rate of Pavlik harness treatment and grade of hip dysplasia including Graf hip type and α angle, data of the hips in which the treatment succeeded and failed were compared.

The chi-square and Fisher's exact tests were used to compare the frequencies of the variables in different groups. The receiver operating characteristic (ROC) curve was used to assess the edge values for age and α angle. The Mann-Whitney U test was used to compare the mean values of two different groups because of having unequal variances. A p value < 0.05 was considered significant.

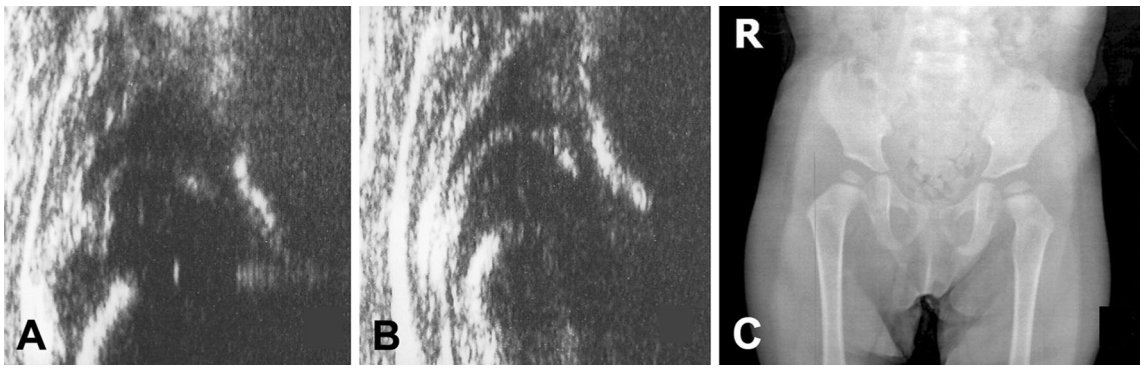

Fig. 1A–C Right (**A**) and left (**B**) hip sonograms of a 110-day-old first-born girl with a history of breech presentation at the third trimester are seen. α angle was measured as 25° on the right side and 30° on the left side and the cartilaginous roof was pressed downward on both sides. Both hips were considered Graf Type IV. Graf Type I hip was achieved after 149-day-long Pavlik harness treatment in both hips. Radiographic examination at 26 months of age (**C**) revealed an acceptable short-term outcome in both hips.

Table 2. The correlation between the success rate of Pavlik harness treatment and the patient related variables

Patient-associated variables	Rate of successful treatment	p value
Age group (days)	≤ 60; 16/17 (94%)	< 0.001*,†
	61–90; 21/23 (91%)	
	91–120; 34/45 (76%)	
	121–150; 12/21 (57%)	
	> 150; 9/24 (37%)	
Gender	Girls; 77/106 (73%)	0.456†
	Boys; 15/24 (63%)	
Laterality	Unilateral; 60/79 (76%)	0.118†
	Bilateral; 32/51 (63%)	
Coexisting risk factor	At least 1; 37/52 (71%)	1.0†
	No; 55/78 (71%)	
History of DDH in relatives	Yes; 14/22 (64%)	0.446†
	No; 78/108 (72%)	
Breech presentation	Yes; 14/18 (78%)	0.585†
	No; 78/112 (70%)	
Intrauterine packing	Yes; 3/3 (100%)	0.555‡
	No; 89/127 (70%)	
First-born girl	Yes; 27/37 (73%)	1.0†
	No; 50/69 (73%)	
Oligohydroamnios	Yes; 6/9 (67%)	0.720‡
	No; 86/121 (71%)	
Swaddling	Yes; 8/16 (50%)	0.076‡
	No; 84/114 (74%)	

* Significant difference; †chi-square test; ‡Fisher's exact test; DDH = developmental dysplasia of the hip.

Results

Younger patients were more likely to succeed with Pavlik harness treatment. There was a difference between mean treatment starting ages of children in whom Pavlik harness treatment succeeded (97 ± 38; range, 26–207 days; 95% confidence interval [CI], 90–112) and failed (135 ± 37; range, 47–197 days; 95% CI, 123–147; $p < 0.001$). The highest success rate was obtained in children younger than age 3 months (37 of 40 [93%]) and the lowest one older than age 5 months (nine of 24 [37%]) (Table 2). An age of 120 days and older was found to be the threshold for having an unsuccessful result in Pavlik harness treatment and this age range had a sensitivity of 66% (95% CI, 49%–80%) and a specificity of 77% (95% CI, 67%–85%; $p < 0.001$) (Fig. 2). A correlation between the remaining patient-related variables and the success rate of Pavlik harness treatment could not be observed ($p > 0.05$) (Table 2).

There was a difference between the mean initial α angles of the hips in which the treatment succeeded (53° ± 6°; range, 25°–58°; 95% CI, 51°–53°) and failed (47° ± 7°; range, 35°–58°; 95% CI, 45°–50°; $p < 0.001$). An initial α angle of 46° and less was found to be the threshold for having an unsuccessful result. This angle range had a sensitivity of 47% (95% CI, 33%–62%) and a specificity of 86% (95% CI, 79%–92%; $p < 0.001$) (Fig. 3).

Graf Type IIa- hips had the highest rate of success (27 of 29 [93%]), whereas Graf Type III and IV hips had the lowest (five of 19 [26%] and two of four [50%], respectively) ($p < 0.001$) (Table 3). The stable hips had a higher rate of treatment success than the unstable hips (112 of 142 [79%] versus 18 of 39 [46%]; $p < 0001$) (Table 3). Among the unstable hips, the treatment success rate was lower in dislocated hips (seven of 23 [30%]) than in decentering hips (11 of 16 [69%]) ($p < 0.001$) (Table 3).

Among 18 initially unstable hips in which the subsequent Pavlik harness treatment failed (three unstable hips with coexisting femoral nerve palsy were not included), the femoral head could not be reduced into the acetabulum in 14 hips (D: four, III: nine, IV: one). The femoral head was reduced, but the deficiency in the acetabular bony roof did

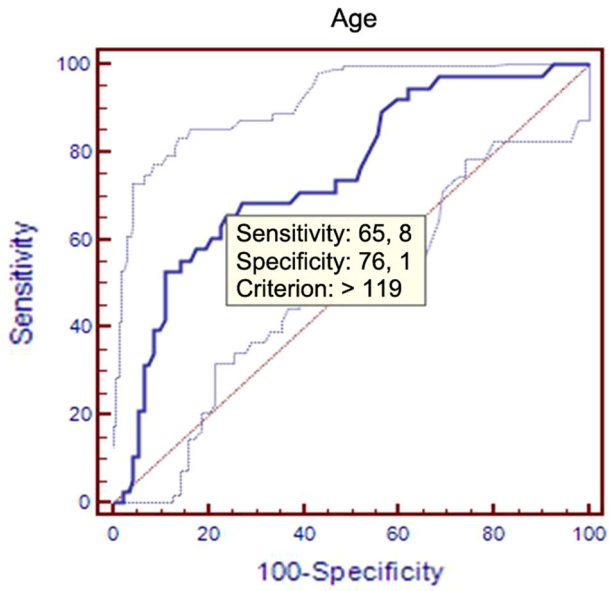

Fig. 2 ROC curve of the age of the patients is seen.

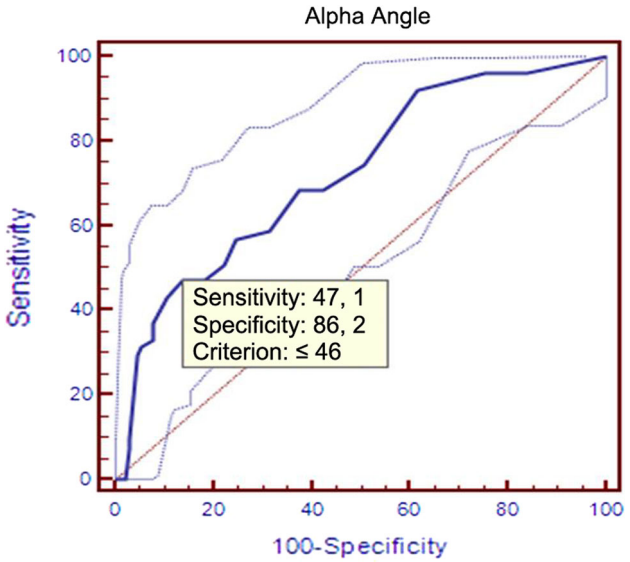

Fig. 3 ROC curve of the α angle is seen.

not show any improvement within 8 weeks after femoral head relocation and a rigid abduction orthosis was then applied in four hips (D: one, III: two, IV: one).

Discussion

Treatment of DDH using the Pavlik harness is a widely preferred method in children younger than age 6 months. The short- or long-term success rate of Pavlik harness treatment is known to depend on some patient-related variables as well as the radiological grade of hip dysplasia [28, 29]. Nevertheless, as a result of lack of a higher number of studies with a high level of evidence, the exact effect of the some factors on the success rate of the Pavlik harness treatment seems to be controversial. We sought to assess the effect of patient-dependent variables and ultrasonographic hip type on the efficacy of Pavlik harness treatment in children younger than age 6 months.

Table 3. The correlation between the success rate of Pavlik harness treatment and the hip types in ultrasonography

Rate of successful treatment	
Hip type	Hip stability
Type IIa-; 27/29 (93%)	
Type IIb; 75/98 (77%)	Stable; 112/142 (79%)
Type IIc; 10/15 (67%)	
Type D; 11/16 (69%)	
Type III; 5/19 (26%)	Unstable; 18/39 (46%)
Type IV; 2/4 (50%)	
$p < 0.001$*,†	$p < 0.001$*,†

* Significant difference; †chi square test.

There are some limitations of the present study. First, there might be a bias in exclusion criteria of the patients because the exact number of patients whose parents refused the treatment and who were lost to followup after the treatment was initiated could not exactly be provided. The ratio of excluded patients is approximately 15% among the entire population and we believe that it did not significantly influence our main findings. Second, the present study only focused on the instant success rate of Pavlik harness treatment and did not include midterm or long-term followup radiological and clinical outcomes. Third, defining the success of the treatment as "sonographic improvement of the dysplastic hip in a certain time period" could be against Pavlik's own philosophy, which had encouraged individualizing the treatment of each hip and avoided time limitations during treatment [4]. Fourth, the correlation between the success rate of Pavlik harness treatment and initial clinical findings was not assessed to avoid bias because the same physician did not perform all clinical examinations. Finally, we could not exactly determine the compliance of the parents to the treatment protocol, although all of them were initially informed in detail. It is well known that parents' poor compliance in maintaining the harness on their children is one of the most important failure reasons of Pavlik harness treatment [18].

The reported overall success rate of Pavlik harness treatment in DDH ranges from 58% to 100% [1, 3, 6, 7, 9–16, 24, 25, 27]. In the present study, Pavlik harness treatment resulted in a favorable outcome in 71% of the

patients. The results of the previous studies have shown that considerably higher success rates can be obtained if Pavlik harness treatment is started before the age of 2 to 3 months [3, 6, 9–11, 26, 31]. Bilateral involvement [3, 13, 26], having two or more risk factors for DDH [12], and male gender [5] are the reported patient-related variables that correlated with a higher rate of failure in Pavlik harness treatment. The results of the present study revealed that the treatment-starting age was the only patient-related variable, with older patients being much more likely to fail treatment. More than 90% of children younger than 3 months of age (37 of 40) were treated successfully, but that number dropped to approximately one-third when the patients were older than 5 months of age (nine of 24). An age of 4 months and older was found to be the threshold value that would increase the rate of failure in Pavlik harness treatment, and this cutoff had a sensitivity of 66% and a specificity of 77%.

The reported ultrasonographic predictors of failure or complications in DDH treated by the Pavlik harness are an initially lower α angle (< 43°), higher β angle, and a worse hip type (Graf Types III and IV hips) [1, 14, 31]. The reported success rate of Pavlik harness treatment in Graf Type III and IV hips is not as high as the other Graf hip types [3, 16, 21, 22, 25, 31]. The results of the present study revealed that both a lower initial α angle and a worse Graf hip type decrease the Pavlik harness treatment success rate. An initial α angle of 46° and less increases the possibility of failure and it has high specificity (86%). Pavlik harness treatment failed more than two-thirds of Graf Type III hips and two of four Graf Type IV hips in the present study. The cartilaginous acetabular roof is pushed downward by the dislocated femoral head toward the acetabulum in Graf Type IV hips, whereas it is pushed upward by the dislocated femoral in Graf Type III hips [8]. Besides, adductor muscles adversely influence the reduction of a highly dislocated hip while the hip is in flexion and abduction in a Pavlik harness and a higher success rate of treatment should not be expected in such a hip [2, 12, 23]. These pathoanatomical differences explain the greater difficulty to succeed in dislocated hips [16]. In a comparative study, better ultrasonographic outcome and lesser secondary treatment need were achieved by von Rosen splint treatment than by Pavlik harness treatment in Graf Types III and IV hips under the age of 4 months [32]. Because controversy still exists on the efficacy of Pavlik harness treatment in Graf Type III and especially in Type IV hips, prospective comparative studies with larger samples seem to be needed for assessing whether primary Pavlik harness treatment is routinely indicated and for comparing the efficacy of different treatment modalities in such hips. There are few data on the success rate of Pavlik harness treatment in ultrasonographic hip types other than Graf Type III and IV hips. The reported treatment success rate with the Pavlik harness is higher in such hips [3, 9, 31]. The success rate of Pavlik harness treatment was more than 90% in Graf Type IIa- hips, approximately three-fourths in Type IIb hips, and approximately two-thirds in Types IIc and D hips in the present study. Besides, there was a considerable difference between the treatment success rates of stable and unstable hips. Approximately three-fourths of the unstable hips could not accurately be reduced within the required time by Pavlik harness treatment. In the remaining one-fourth, the deficiency in the acetabular bony roof did not heal within a certain time, although the femoral head was properly relocated into the acetabulum. Although Graf Type D hips were initially considered to be unstable, the treatment success rate in such hips was close to the one of stable hips in the present study. Because the acetabular bony roof in a Type D hip is not as deficient and the femoral head is not as displaced as in a dislocated hip, the difference between the treatment success rates of stable and unstable hips was mainly the result of Graf Types III and IV hips in the present study.

Femoral nerve palsy is one of the failure reasons of Pavlik harness treatment and has a reported incidence of 2.5% [19]. In the present study, femoral nerve palsy was seen in two patients in whom complete recovery was observed after discontinuation of the harness.

We conclude that Pavlik harness treatment is more likely to fail in older infants, in hips having dislocation, and in hips with severely deficient acetabular bony roofs. The threshold age and α angle values associated with an increased risk of failure are 4 months and older and 46° and less, respectively. The parents of such patients should be informed about the high risk of treatment failure. We believe that, in such older patients and worse hip types, the use of an initial Pavlik harness treatment needs to be revisited. Future studies, comparing the outcomes of the Pavlik harness treatment and other types of interventions in such patients and hip types are needed.

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