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Original Article

Radiographic Prediction of the Results of Long-term Treatment with the Pavlik Harness for Developmental Dislocation of the Hip

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In 1957, Pavlik introduced the Pavlik harness as a useful treatment for developmental dislocation of the hip (DDH), and subsequent studies have documented favorable outcomes among patients treated with this device. However, there are only a few articles reporting how early radiographic measurements can be used to determine the prognosis after treatment with the Pavlik harness. In this study, 217 hips from 192 patients whose DDH treatment with the Pavlik harness was initiated before they were 6 months old and whose follow-up lasted at least 14 years (rate, 63.8%) were analyzed using measurements from radiographs taken immediately before and after harness treatment, and at 1, 2, and 3 years of age. Severin's classification at the final follow-up was I or II in 71.9% and III or IV in 28.1% of the hips, respectively. Avascular necrosis of the femoral head (AVN) was seen in 10% of the hips. Stepwise multiple regression analysis was performed to retrospectively determine whether any radiographic factors were related to the final classification as Severin I/II or III/IV. Receiver operating characteristic (ROC) curves were drawn for these factors, and a Wiberg OE angle (Point O was the middle point of the proximal metaphyseal border of the femur) of 2° on the 3-year radiographs was found to be the most useful screening value for judging the acetabular development of DDH cases after treatment with a Pavlik harness, with a sensitivity of 71% a specificity of 93%, and a likelihood ratio of 10.1.

Key words: developmental dislocation of the hip, long-term follow up, radiographic measurement, stepwise multiple regression analysis, acetabular development

In 1957, Pavlik [1] introduced the Pavlik harness to as an effective treatment for developmental dislocation of the hip (DDH), and subsequent studies have documented favorable outcomes among patients treated with this device [2-4]. The Pavlik harness consists of straps for the legs and, when it is appropriately applied, prevents adduction and extension of the hip joint at the same time that it promotes flexion, abduction, and rotation. This positioning and motion limitation aids in the spontaneous reduction of the dislocated hip. Since a report was published in 1963 regarding a series of DDH patients treated from 3 to 6 months of age [12], the Pavlik harness has been the preferred method of DDH treatment and is a

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commonly used orthotic device worldwide.

However, Mubarak *et al.* [5] reported the failure to obtain sufficient reduction using the Pavlik harness. Avascular necrosis (AVN) of the femoral head is a common problem [2, 3, 5, 6], and the occurrence of post-therapeutic acetabular dysplasia continues to be a major issue [4, 7-9]. To date, there have only been a few articles reporting how radiographic measurements can be used for the prognosis of DDH treated with the Pavlik harness [10-12]. The present study included 217 hips of 192 patients treated only with the Pavlik harness who were followed up for over 14 years. Various radiographic parameters were measured and statistically analyzed to determine possible predictors for long-term results.

Patients and Methods

The Pavlik harness has been used as the initial treatment for developmental dislocation of the hip (DDH) and subluxation of the hip (SDH) since 1963. A total of 442 DDH hips initially treated with the Pavlik harness from 1963 to 1992 at our institution were studied. Cases of subluxation, acetabular dysplasia, or atypical dislocation, as well as those treated at another hospital, were excluded from the study. In 356 of the 442 hips, reduction was achieved with the sole use of the Pavlik harness (reduction rate: 80.5%, Fig. 1); this figure included 16 hips treated with supplementary surgery after reduction. In terms of follow-up, there were 192 patients with 217 hips with DDH who were followed for more than 14 years (recall rate: 63.8%), excluding the 16 hips with supplementary surgery. Of these 217 hips, 19 were in males and 198 were in females. Twenty-five patients had bilateral involvement while 167 patients had unilateral dislocation. The patients' average age at the final follow-up examination was 20 years (range: 14 to 33 years).

Antero-posterior radiographs of the hip joints were taken before the use of the harness, 1 month after harness removal and at 1, 2 and 3 years of age. The α-angle [7] and the OE angle [13], as well as Yamamuro's distance a [7] and distance b' (modified Yamamuro's distance b) were measured (Fig. 2). Radiographs taken at the final follow-up examination were assessed according to Severin's classification [14] and the Kalamchi and MacEwen classification [15]. At the final follow-up radiographic evaluation, Severin I and II were considered to be a satisfactory level, while Severin III and IV were unsatisfactory.

In order to identify any factors related to the final radiographic outcomes, a stepwise multiple regression

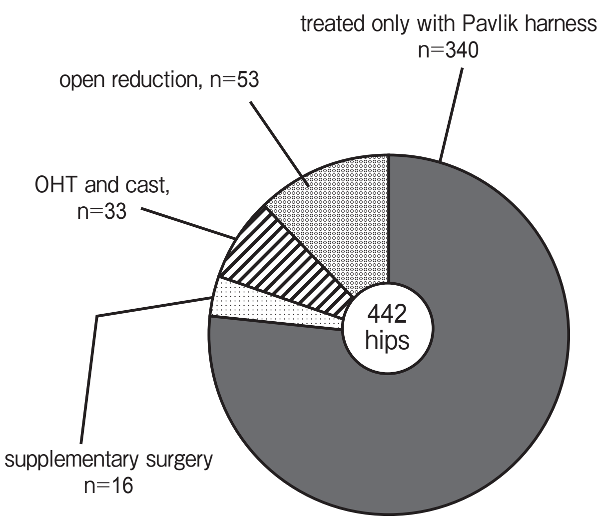

Fig. 1 Among a total of 442 hips with DDH initially treated with the Pavlik harness in our department from 1963 to 1992, the reduction rate was 80.5%. Among patients in whom DDH could not be reduced by the Pavlik harness, 53 hips were treated with open reduction, and 33 hips were treated with overhead traction (OHT) and cast immobilization.

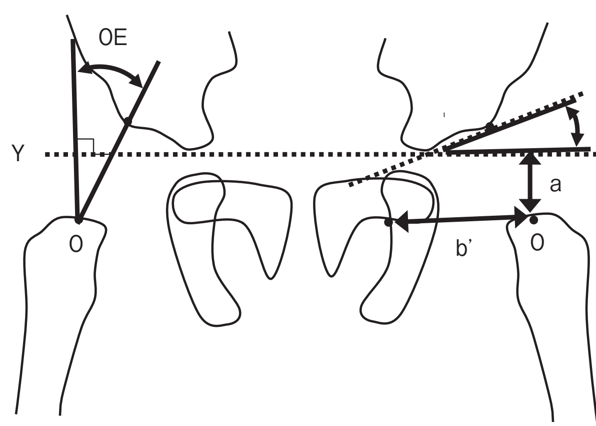

Fig. 2 Radiographic measurements. Point O is the middle point of the proximal metaphyseal border of the femur. Point E is the lateral edge of the acetabulum. The Y-line connects the lowest ends of both iliacs. The a angle is the acetabular angle reported by Yamamuro [6]. The OE angle and center-edge angle are the angles reported by Wiberg [7]. Yamamuro's distance a [6] is the length from the point O to the Y-line, and we defined the distance b' as the length from the medial edge of the ischium to the point O.

analysis was performed using the CE center edge angle in the final follow-up radiographs and the presence of AVN at the final follow-up examination as criterion variables, and early the radiographic measurements as explanatory variables. A receiver operating characteristic (ROC) curve was drawn for each factor and the cut-off value, likelihood ratio, sensitivity and specificity were calculated statistically. All analyses were conducted using SPSS software for Windows, version 16.0.1. A significance level of 5% was chosen for all tests ($p < 0.05$).

Results

At the final follow-up examination, 156 hips (71.9%) were classified into the Severin I or II groups and 61 hips (28.1%) into the Severin III or IV groups (Table 1). According to the Kalamchi and MacEwen classification, AVN was observed in 22 hips (10%), of which 13 were classified as group I and 3 each were classified as group II, III and IV (Table 2). There were significant differences in the α angle and the OE angle in the radiographs 1 month after the harness removal between hips classified as Severin I/II and III/IV at the final follow-up examination (Fig. 3A, B). There were also significant differences between the 2 groups (I/II and III/IV) in the distance a from pre-treatment radiographs and in the distance b' from the 1-year radiographs (Fig. 4A, B). A stepwise multiple regression analysis was performed to identify any factors (the OE angle, the α angle, the distance a and the distance b') related to the CE angle at the final follow-up examination; the degree of correlation was the strongest for the OE angle in the age of 3-year radiobraph, followed in order by the distance b' at the age of 3 years and the α angle in the age of 3-years radiograph. The intercorrelations among the factors were evaluated. While no strong correlation was found between distance b' and the OE angle or between distance b' and the α angle, there was a correlation between the OE angle and the α angle. An

Table 1 Severin's classification at the final follow-up examination

Severin classification	I	II	III	IV	Total
	152	4	56	5	217 hips
	Satisfactory group 156 (71.9%)		Unsatisfactory group 61 (28.1%)		

Table 2 Kalamchi & MacEwen classification at the final follow-up examination

Kalamchi & MacEwen classification	I	II	III	IV	Total
	13	3	3	3	22 hips/ 217 hips (10%)

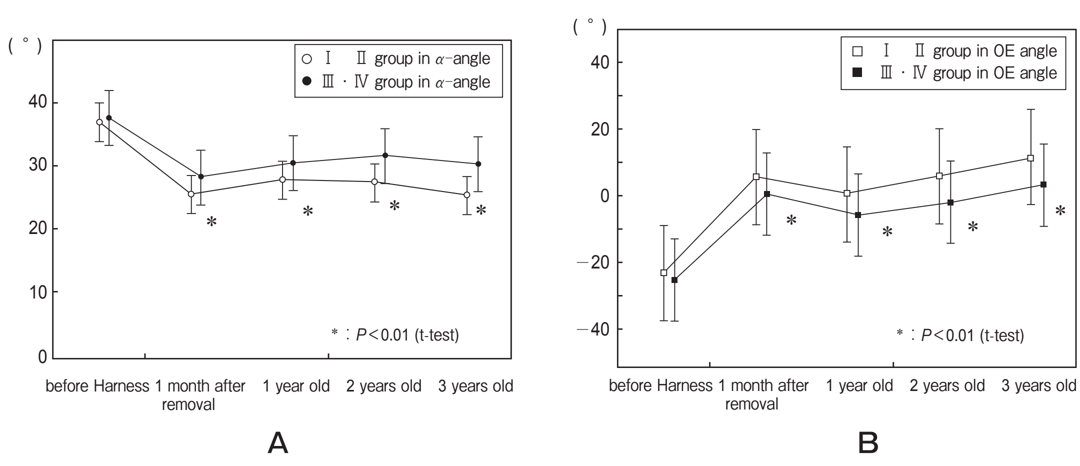

Fig. 3 A, The angles for the Severin I/II and III/IV groups at the time before harness, 1 month after harness removal, and at 1, 2, and 3 years of age; B, Changes in the OE angles for the Severin I/II and III/IV groups. There were significant differences in the α angle and the OE angle at 1 month after the Pavlik Harness removal between the Severin I/II and III/IV groups at the final follow-up examination.

ROC curve was drawn for the OE angle and the distance b' at the age of 3 years; the cut-off value of 2° for the OE angle was shown to be most useful, with a likelihood ratio of 10.1, a sensitivity of 71% and a specificity of 93% (Fig. 5A, B). Therefore, the results indicate that 3-year-old children with an OE angle of 2° or less are likely to have a poor outcome at the end of their growth period. In the same manner, stepwise multiple regression analysis was performed to identify the factors related to AVN; the distance a and the OE angle before the use of the harness were extracted. There was no correlation between the distance a and the OE angle before the use of the harness. ROC curves were drawn for the distance a and the OE angle before the use of the harness, and cut-off values of −35° for the OE angle and 5 mm for the distance a were obtained: the former had a sensitivity of 53%, specificity of 76%, and likelihood ratio of

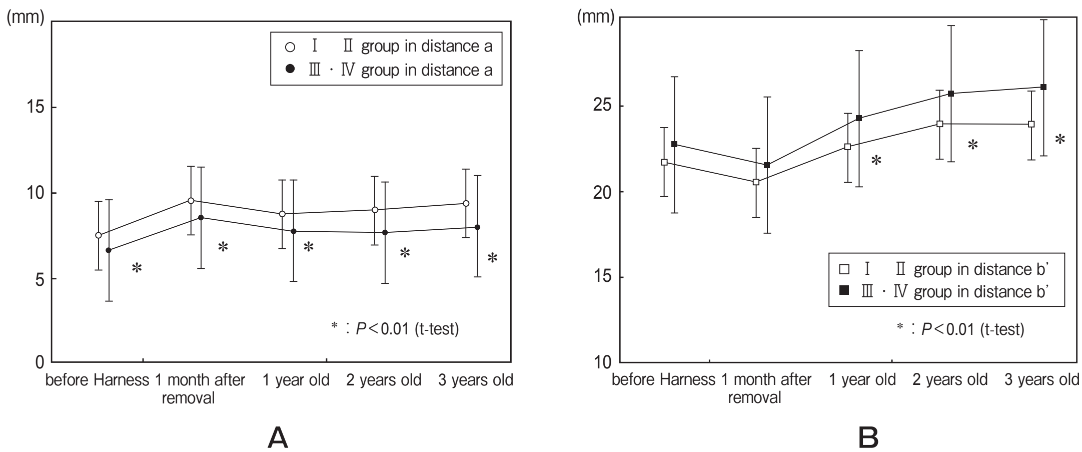

Fig. 4 A, Changes in the distance a for the Severin I/II and III/IV groups; B, Changes in the distance b' for the Severin I/II and III/IV groups. There were also significant differences between the 2 groups in the pre-treatment distance a and in distance b' at 1 year of age.

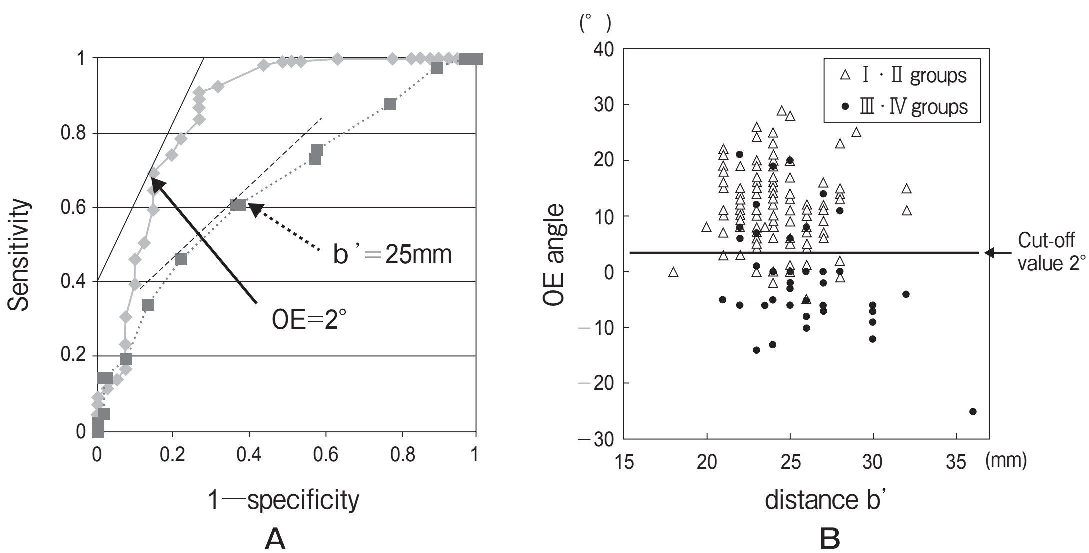

Fig. 5 A, The ROC curve and the cutoff value for the OE angle and the distance b' at the age of 3 years. No useful cut-off value was identified for the distance b'. The cut-off value for OE of 2° had a sensitivity of 71%, specificity of 93%, and likelihood ratio of 10.1; B, The relationship between the OE angle and the distance b' at the age of 3 years. In 125 of the 137 hips of the Severin I/II group and 12 of the 42 hips in the Severin III/IV group, the OE angle at the age of 3 years was more than 2°. In 12 of the 137 hips in the Severin I/II groups and 13 of the 42 hips in the Severin III/IV groups, the OE angle at the age of 3 years was under 2°.

2.2, and the latter had a sensitivity of 53%, specificity of 83%, and likelihood ratio of 3.1. Thus, neither an OE angle of −35° nor a distance a of 5 mm before the use of the harness was shown to be a useful prognostic indicator for AVN.

Discussion

The Pavlik harness has been widely used in Japan, but there have been few reports regarding the long-term outcome of treatment with Pavlik harness for DDH. In the present study, the long-term results with respect to the ratios of Severin I/II (successful treatment) and AVN were essentially comparable with those reported by Kumasawa [8] and Fujioka [9].

Several reports have described acetabular development in DDH patients treated with the Pavlik harness. Rosen *et al.* [10] evaluated the radiographs of 103 hips with DDH and analyzed them statistically. They reported that the Tönnis grade of dislocation determined from the initial radiograph before the use of the Pavlik harness was useful as a prognostic indicator of the final outcome of treatment with the Pavlik harness. However, the mean age of their patients at the time of the final follow-up was only 65 months. Chen *et al.* [11] evaluated the radiographs of 75 hips with unilateral DDH and performed a retrospective statistical analysis. They reported that the center-head distance discrepancy measurement the first 1 year after reduction with the Pavlik harness was the best predictor of the outcome of acetabular development in unilateral DDH. In their study, the mean follow-up time was less than 10 years.

In our institute, Mitani *et al.* [12] investigated 96 hips with unilateral DDH until the patients reached the age of 15 years and performed a retrospective multivariate analysis of the radiographic measurements. They reported that the acetabular shape can be accurately predicted by observing plain radiographs of patients at the age of 3 years. However, the prediction formula determined by that study proved to be complex. The 217 hips of 192 patients with DDH enrolled in the present study had at least 14 years of follow-up. There were significant differences between the Severin I/II and III/IV groups, as evaluated in the final follow-up examination, in the α-angle, the OE angle, the distance a and the distance b' on 1-, 2- and 3-year radiographs. The CE angle at the final follow-up examination was related to the OE angle, the distance b' and the α-angle at 3 years. When the cut-off values for these factors were set, an OE angle of 2° or less at the age of 3 years was shown to be the most useful predictor of the final outcome, with a sensitivity of 71% and a specificity of 93%.

The causes of the poor outcomes following the use of the Pavlik harness included poor reduction and the presence of AVN. Mitani [16] noted that incorrect attachment of the Pavlik harness may be the major cause of AVN. Suzuki *et al.* [6] reported that the incidence of AVN rose with the grade of the dislocation and the risk was high in hips in which distance a was less than 8 millimeters in the initial radiograph before reduction. Inoue *et al.* [17] divided 100 hips with DDH into successful and unsuccessful reduction groups and evaluated the risk factors for predicting unsuccessful reduction and AVN. In their study, a pre-treatment distance a of 7 millimeters or less and acetabular angle of 36° or more were found to be risk factors for unsuccessful reduction and AVN. In the present study, stepwise multiple regression analysis also showed that AVN was related to the OE angle and the distance a obtained prior to the use of the Pavlik harness. The cut-off values for the OE angle and the distance a obtained prior to the use of the Pavlik harness were −35° and 5 mm, respectively; however, they proved not to be useful for predicting AVN. Among the cases analyzed in present study, it would be difficult to predict AVN based on the radiographic results regarding the severity of dislocation prior to reduction.

On the other hand, Kumasawa *et al.* [8] and Fujioka *et al.* [9] reported that some intrinsic factors influence the long-term outcome in DDH patients because of the presence of dysplasia in the uninvolved side. Nakamura *et al.* [18] reported a high incidence of secondary osteoarthritis with DDH or acetabular dysplasia. In the present study, it was hypothesized that an earlier acetabularplasty based on a prediction at age 3 would provide a better outcome for prognosis of DDH after the reduction using the Pavlik harness.

There are several limitations in the present study. First, our method requires an adequate antero-posterior radiograph to clarify the landmarks. Second, the mean length of follow-up time was not sufficient to evaluate the final outcome of hip joint maturation.

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