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Abstract

Background: The purpose of the present study was to report the improved efficacy of Abduction Orthosis for the treatment of developmental dysplasia of the hip, with the use of Entry Angle monitoring. The hypothesis is that when the entry angle is zero, then acetabular remodelling is induced and the time needed to wear the abduction splint is half the time normally expected in order to achieve favourable outcomes. The entry angle could help adjust and direct the ideal degree of splint abduction.

Materials: A total of 81 patients with developmental dysplasia of the hip, with a total of 120 dislocated hips, who underwent nonoperative management with the Papadimitriou method (modification of the Hoffmann-Daimler method) from 1971 to 2017 were retrospectively reviewed. In Phase A of the Papadimitriou method, the patient wears a flexion harness which allows the femoral head to be gradually reduced. This is followed by Phase B, during which the patient wears an abduction splint in order for the reduced hip to Undergo remodelling.

The study group included 15 boys and 105 girls. The average age of the patients was 14 months (range, 4 - 44 months) at the time of treatment and the mean follow up was 9 1/2 years (range, 2 - 30 years).

Radiographs were obtained in order to assess the acetabular index, the Entry Angle, the Severin classification and the presence of evidence of osteonecrosis of the proximal femoral epiphysis. Acetabular remodelling during phase B was evaluated by observing the change in the acetabular index (AI) over time with the use of serial X-ray measurements. We measured the acetabular index prior to treatment and at the end of treatment. The end of treatment was defined as the time when the acetabular index reached the normal range for the age and gender of the child. The patients were divided into two groups, according to the time needed to remodel the dysplastic acetabular remodellers (FR), where acetabular remodelling ensued in less than 6 months and the normal acetabular remodellers (NR), where acetabular remodelling occurred in the usually expected 12 to 15 months. Entry angles were calculated from the first days of Phase B.

Results: Gender, side of involvement, bilateral involvement, the presence or absence of the ossific nucleus, the age at the onset of treatment, the appearance of osteonecrosis, the average acetabular index before and after treatment, the duration of Phase A, the degree of displacement of the femoral head (Tönnis grade), the final Severin grade of deformity and the appearance of osteonecrosis showed no statistically significant difference between Fast remodellers (FR) and normal remodellers (NR).

The mean duration of phase B in the FR group (n = 36) was 6 months compared to 15 months in the NR group (n = 84). The mean entry angle for the FR group was $2 \pm 1,5$ degrees compared to 16 ± 5 degrees in the NR group (p < 0,01).

Conclusions: The EA could help the surgeon adjust the degree of abduction in the abduction splint in order to expedite the remodelling of the dysplastic acetabulum. When the entry angle approaches values near zero, it means that the degree of abduction of the hip is biomechanically optimal and the pressure exerted by the femoral head inside the dysplastic acetabulum is uniform and concentric. This stimulates the deepening of the dysplastic acetabulum and as a result, a reduction of the treatment duration is expected.

Keywords: Entry; Angle; Developmental; Dysplasia; Hip; Treatment; Abduction; Orthosis; Index

Introduction

An established method for the treatment of developmental dysplasia of the hip (DDH) is the use of an abduction splint [1,2], even in walking children [3]. To achieve a favourable outcome in treating DDH, the abduction splint [4] has to position the leg in such a degree of abduction, which would allow concentric distribution of pressure [5] of the femoral head [6] inside the dysplastic acetabulum [7] and induce acetabular remodeling [8,9] of the acetabulum [10] until it reaches normal levels. One drawback of the abduction splint in children is the long duration that it must be worn, usually more than a year.

Papadimitriou., *et al.* [3,11,12] modified the original Hoffmann-Daimler method [13-15] in 7 critical points [16]. In Phase A of this modified method, the patient wears a flexion harness (Figure 1a) which allows the femoral head to be gradually reduced [12,17]. This is followed by Phase B, where the patient wears an abduction splint in order for the reduced hip to undergo remodelling. By wearing the abduction splint in phase B (Figure 1b), the femoral head inside the shallow/dysplastic acetabulum exerts pressure which stimulates the remodeling of the acetabulum [12]. As a result, the dysplastic acetabulum increases its depth [18]. If the distribution of pressure is even and concentric [5,8], remodeling ensues quicker and the patient has to wear the abduction splint for less time. The deepening of the acetabulum finds place gradually and this is monitored by the improvement of the Acetabular Index (AI) in serial follow up X-rays. The abduction splint is worn for 24 hours a day and allows the patient to walk (Phase B). The acetabular remodeling during phase B lasts usually around 12 - 15 months (AI returns to normal values according to patients age).

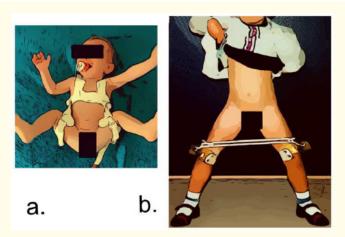


Figure 1: a. The flexion harness in phase A and b. the abduction splint in phase B. This device maintains abduction of the hips and is suitable for children at the crawling and walking stages.

Retrospective examination of our cases allowed us to identify a group of 36 patients who recovered faster (less than 6 months) than the usually expected 15 months or more. Seeking for plausible explanations for the unexpectedly fast remodeling, we drew the hypothesis that in this group of patients, the mean entry angle (EA) was different. This Entry Angle could be an indirect index of the ideal position of the femoral head inside the acetabulum, which produces fast remodeling compared to the other patients with the normal remodeling speed.

The degree of splint abduction is usually set arbitrary, according to surgeon's preference. The question arose in terms of what is the optimum degree of hip abduction in order to achieve faster acetabular remodeling and, as a result, reduce the duration of splint wearing. The purpose of the study was to retrospectively investigate whether the EA could be an index of quick remodeling. When one changes the abduction of the hips in the abduction splint, the EA (as it is measured on pelvic X-rays) changes respectively. Our hypothesis states that if, at the beginning of Phase B, one abducts the hips in the splint in such degrees that the entry angle takes values around zero (EA = 0), then the acetabulum would remodel faster than normal. The EA could be an indication that the hip is placed in a biomechanically favorable position and, as a result, it could explain the shorter Phase B treatment time required (less than 6 months) in fast remodelers when

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compared to the EA values measured at the start of phase B in normal remodelers. By validating the EA angle, the implications would be very wide; an Index to monitor and directly objectify every functional conservative treatment for DDH where an abduction splint is worn. By measuring the EA, the surgeon can adjust the degrees of abduction of the hips in the splint to the point of the most advantageous biomechanical position, simply by aiming for the ideal EA measured on follow up X-rays (EA towards 0) and thus speeding up the normalization of the acetabular obliquity.

Materials and Methods

The medical records of 167 patients with the diagnosis of developmental dysplasia of the hip, treated between January 1971 and December 2017, were reviewed. 114 patients were excluded because their radiographs or medical records were being inadequate. Patients previously managed with open hip surgery, or those where the dysplasia was secondary to arthrogryposis or to neuromuscular disease, septic arthritis or a teratological condition, and those whose dislocation was associated with a congenital anomaly or syndrome, were also excluded. Patients who were previously managed unsuccessfully with a Pavlik or Freijka harness were included in the study. 81 patients with a total of 120 dislocated hips were included in the study (Table 1). The study group included 15 boys and 105 girls. The average age of the patients was 14 months (range, 4 to 44 months) at the start of treatment and the mean follow up was 9,5 years (range, 2 - 30 years). All patients in the study period were treated conservatively with the functional Papadimitriou method [3] (modified Hoffmann-Daimler method [13,14]). With this method, the patient wears a flexion harness (Phase A), during which time the femoral head is gradually reduced, followed by an abduction splint (Phase B), during which time the reduced hip remodels [3,12].

Forty-eight patients had unilateral involvement, whereas the rest of them had bilateral involvement. For the statistical analysis, we considered each hip separately. The duration of treatment in the harness (phase A) and the duration in the abduction splint (phase B) were recorded. During phase B, the children wore the abduction splint continuously and were radiographically followed-up with X-rays every 2 months.

Acetabular remodelling on radiographs during phase B was evaluated by observing the change in the acetabular index [19] (AI) over time on serial X-ray measurements. We measured the AI prior to treatment and at the end of treatment. We defined the end of treatment as the point where the acetabular index was in normal range for the age and gender of the child. The patients were divided into two groups, according to the time required to remodel the dysplastic acetabulum completely: the Fast Remodellers (FR), where acetabular remodeling ensued in less than 6 months and the Normal acetabular Remodellers (NR), where remodeling ensued in the normally expected 12 to 15 months.

At the beginning of phase B, the Entry angle was calculated and recorded according to radiographs. The EA can be estimated using the following procedure (Figure 2): The superior lateral acetabular rim is marked as Point E, whereas the acetabular teardrop is marked as Point D. Point V is defined as the lowest and most lateral point of the acetabular margin, namely the point where the lower contour of the head intersects with the posteroinferior acetabular margin, the latter being easily identified on most X-rays. Lines are drawn between Points E and V (EV line) and between Points E and D (ED line). The subtend angle VED is bisected by the EW line, which represents the projection of a "mean acetabular inlet plane". The perpendicular line on EW (green line) forms an angle with the femoral neck axis (purple line). That angle is the Entry Angle (EA).

The measurement of the Entry Angle on X-rays is time-consuming and cumbersome. We therefore developed an application called the "Papadimitriou Abduction Splint App" in order to expedite the procedure. The application is available on the itunes Apple store [20] (https://itunes.apple.com/us/app/papadimitriouabductionsplint/id1437808634). For more information on how to calculate the Entry Angle please refer to the tutorial video (Video 1).

The goal of the functional conservative treatment of DDH is to induce remodeling and deepening of the dysplastic acetabulum by placing the hip in abduction using the splint. The EA is changed according to the position of the femoral head inside the acetabulum (Figure 3a and 3b). The EA could be an indirect radiological index of evenly distributed pressure inside the acetabulum.

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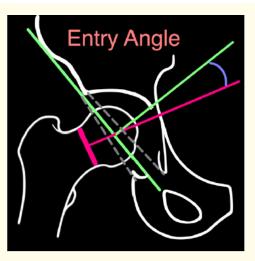


Figure 2: The method to estimate the entry angle (EA).

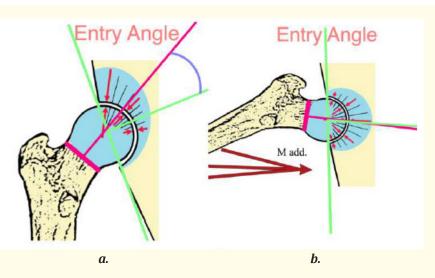


Figure 3: Entry angle measured at a. neutral and b. abduction hip position. Pressure vectors arranged over the acetabulum are depicted in neutral (a) and abduction position (b). The entry angle is reduced by the abduction of the hip and according to the position of the femoral head in relation of the acetabulum there is a certain position of hip abduction where EA takes a favourable zero value.

The type and severity of subluxation and dislocation were classified on the basis of anteroposterior pelvic radiographs according to the system presented by Tönnis [21]. The final results were evaluated according to the Severin classification system [22,23]. Radiographs were evaluated for signs of osteonecrosis as described by Salter, *et al.* [24] and femoral head growth disturbances were classified according to the criteria described by Bucholz and Ogden [25].

Statistical analysis

The data were analyzed with the use of the nonparametric Mann-Whitney test. The level of significance was set at *p < 0.05 and **p < 0.01. All analyzed variables showed a nonparametric distribution. The chi-square test was used for qualitative data. The Spearman correlation coefficient was used to examine correlations between multiple factors. Statistical analysis was performed using SPSS software (version 25.0; SPSS, Chicago, Illinois).

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Results

Gender, side of involvement, unilateral or bilateral involvement, the presence or absence of the ossific nucleus, the age at the onset of treatment, the appearance of osteonecrosis, the average acetabular index before and after treatment, the duration of Phase A, the degree of displacement of the femoral head (Tönnis grade), the final Severin grade of deformity and the presence of osteonecrosis were not statistically significantly different between Fast Remodelers (FR) and Normal Remodelers (Table 1).

Variable	Fast Acetabular Remodelers (N = 36)	Normal Acetabular Remodeller (N = 84)	Significance
Gender (female\male)	30/6	75/9	n.s.
Age at onset of treatment (mths)	12 ± 10	16 ± 8,6	n.s.
Duration of phase A (days)	41 ± 26	49 ± 31	n.s.
Duration of phase B (mths)	6 ± 2	15 ± 4	**
Severity of dislocation Tonnis grade N (%)			n.s.
Ι	4	0	
II	19	34	
III	9	29	
IV	4	21	
Acetabular Index before treatment (Albt)	36,33 ± 6,77	41 ± 7,75	n.s.
Acetabular Index after treatment (AIat)	22,64 ± 4,54	23,82 ± 5,67	n.s.
Severin Class I or II (satisfactory) (N = 112)	33	79	n.s.
Severin Class III or IV (unsatisfactory) (N = 8)	3	5	
Entry Angle	2 ± 1,5	16 ± 5	**
AVN Necrosis	2	7	n.s.
Classification -Bucholz Ogden type			n.s.
Ι	1	0	
II	0	5	
III	1	1	
VI	0	1	

Table 1: Statistical analysis of measured variables with respect to remodelling of the acetabulum. Fast Acetabular Remodelers
(FR, remodeling <6 months) versus Normal Acetabular Remodellers (NR) at follow-up.
*p < 0.05 ** p < 0.001 n.s. = Not Significant.

The mean duration of phase B in the FR group (N = 36) was 6 months (SD \pm 2) compared to 15 months (SD \pm 4 months (N = 84) in the NR group. The mean entry angle (EA) for the FR group was 2 \pm 1,5 degrees compared to 16 \pm 5 degrees in normal remodelers which was statistically significant (p < 0,01).

Discussion

Normal endochondral ossification [8] on the epiphyseal primordial cartilage is active if the direction of the pressure is in agreement with the axes of the bone-forming cartilage cell columns [5,9,26] and if the magnitude of the pressure changes regularly and within bio-

logical limits [2,8,9]. Ossification is inhibited if the pressure magnitude is not within a certain physiologic range, but the phenomenon is dynamically reversible [5,8,27]. To achieve a favorable outcome in the treatment of DDH, the abduction splint has to place the leg in such abduction [28], that it would allow the concentric distribution of the pressure of the femoral head inside the dysplastic acetabulum [8]. This process would induce remodeling that would eventually allow normalization of the acetabulum [2,10,29,30]. One of the major disadvantages of conservative functional treatments, especially in older walking children, is the prolonged wearing of abduction orthoses - usually more than 15 months, the period where acetabular remodeling is expected to ensue. Various abduction orthoses have been used in an effort to induce acetabular remodeling and all share the same concept [2,8,29].

The optimal degree of abduction of the hips, which is imposed mechanically by the splint's degree of abduction, is in close correlation with the duration of phase B. In other words, optimal degree of abduction means less time of splint wearing for the patient.

The purpose of our study was to investigate whether or not changing the degree of abduction of the lower extremity in the abduction splint and aiming towards a near-zero EA by adjustment of the femoral head in the acetabulum would induce remodeling sooner and thus a reduced duration of wearing the abduction splint (phase B).

Pre-treatment factors like gender, side of involvement, bilateral involvement, the presence or absence of the ossific nucleus, the average acetabular index before treatment, the severity of dislocations, the age at the onset of treatment, were not found to be significantly different between the FR and NR groups (Table 1). Similarly, post-treatment factors like the presence of osteonecrosis after treatment, the duration of Phase A, the final Severin grade of deformity, the appearance of osteonecrosis or the final outcome after follow up were not significantly different. The fast remodellers take half the time usually needed for normal remodellers in phase B. The entry angle was the only statistically significant difference (p < 0.001) found between the two groups. The entry angle, as mentioned above (Figure 2), seems to be a good indirect index for monitoring and adjusting the treatment of children with abduction orthoses. When the values of the entry angle measured at the start of phase B are adjusted to approach values near zero (Figure 4 and 5) the patient could be converted to fast acetabular remodeler and the concept, could explain the reduced treatment time required (less than 6 months) for Phase B in fast remodelers.

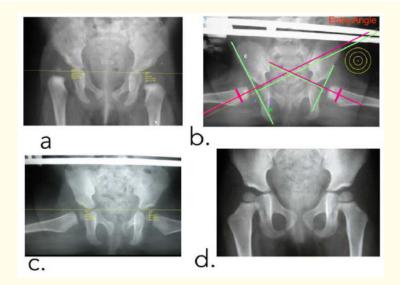


Figure 4: a. Anteroposterior radiograph of the pelvis of a six month-old girl with unilateral Tönnis grade-III hip dislocation. Initial X-rays measure an Acetabular Index of 40 degrees. Complete reduction after two months (phase A). b. Starting phase B with abduction splint. Entry angle is zero on X-ray. c. Anteroposterior radiograph, five months later, Acetabular Index now 25 degrees showing that the acetabulum has strongly remodelled. Notice and compare the improvement in the acetabular index. d. Anteroposterior radiograph, 21 months later, showing that the acetabulum has remodelled completely and the femoral head is spherical and concentric.

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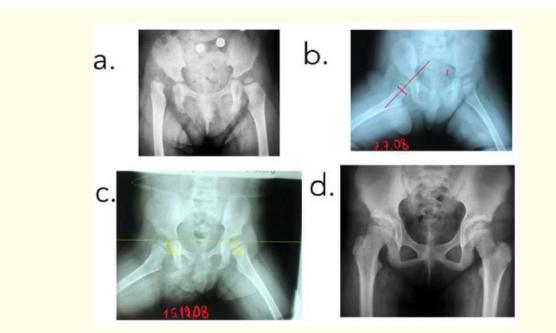


Figure 5: a. Initial Anteroposterior radiograph of the pelvis of a 30 month-old girl with unilateral Tönnis grade-III hip dislocation. b. Starting phase B with abduction splint. Entry angle is zero on X-ray. c. Anteroposterior radiograph 5 months later, Acetabular Index now 25 degrees showing that the acetabulum has remodeled quickly. d. Anteroposterior radiograph, at 10 years of age. Complete recovery.

Pressure of the femoral head inside the acetabulum [5,9] is considered to be an essential prerequisite for normal acetabular growth (Remodelling). It must be intermittent, in an axial direction within a normal range magnitude and evenly distributed inside the acetabulum [2,5,9,10]. The surgeon is usually faced with the following dilemma: how much abduction is necessary in order to induce acetabular remodelling? The degree of abduction of the splint is usually chosen according to surgeon's experience by assuming which is the optimal biomechanical position of the leg on static X-rays. Most of the times, one has to repeat the X-ray with the child in different abduction positions and measure again in a trial-and-error effort in order to find the most advantageous position; which most of the times is based on plain surgeon's experience. The EA offers an easy and objective measurable index which allows the adjustment of the abduction degree by the splint in the best position for the patient.

By adjustment of the abduction degrees of the splint, one can change the EA, and by aiming to bring the EA to near zero values, the distribution of pressure inside the dysplastic acetabulum is concentric. This stimulates acetabular remodeling at maximal speed and reduces the need for wearing the abduction orthosis from 15 months to less than 6 months. This procedure may help quickly decide what the optimal abduction position of the extremity is, by adjusting the abduction of the brace to the suggested ideal degrees.

A possible source of error is to try and estimate the exact real size of the normal femoral head. The transparency of the non-ossified cartilage can mislead the surgeon into estimating the EA incorrectly (Figure 6). To avoid this and in order to measure objectively, we adopted the method of Amador., *et al.* [31], where the head circumference is always related to the distal point of the medial and lateral metaphyseal curvatures. By connecting these two points we obtain a secant, which is perpendicular to the femoral neck axis. The perpendicular line runs through the center and in the direction of the femoral neck.

Another limitation could be the narrow range of EA values (Table 1). Meticulous examination of the above mentioned guidelines about the point selection as well as diligent preparation and drawing of the lines over the X-rays could eliminate the potential error of measurements. The use of the Papadimitriou Abduction Splint App [20] proved to be helpful, especially in expediting these measurements.

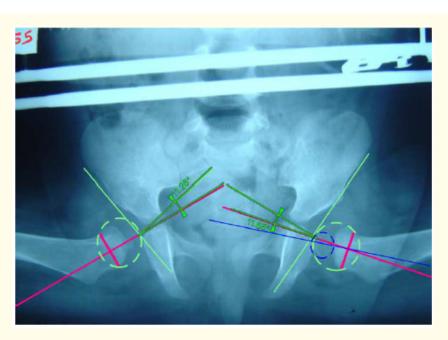


Figure 6: The head circumference drawn with green. Purple line: a secant line is drawn from points where the metaphyseal femur curvature intersects medially and laterally the femur head- dotted line circumference. By connecting these two points we obtain a secant. A perpendicular line to the secant runs through the center of the femoral head and gives the neck axis direction. Notice that the femoral neck axis line is off center (blue line - left hip), which is a potential source of error during the measurement of the entry angle.

The concept of the entry angle measurement could be theoretically applied to every conservative treatment method of dysplasia of the hip which utilises any kind of abduction splint. By monitoring the EA in plain follow-up pelvic X-rays, one could adjust the therapy and improve the outcome. Adjusting the degree of the splint abduction in order to aim for near-zero EA values, would offer confidence that the degree of abduction of the hip is in the optimal biomechanical position. As a result, the pressure exerted by the femoral head inside the dysplastic acetabulum is uniform and concentric. The latter would stimulate the deepening of the dysplastic acetabulum even further, which results to the reduction of treatment time.

Conclusion

In conclusion, entry angle measurements can help the surgeon adjust the degree of abduction of the hip in order to expedite the remodelling of the dysplastic acetabulum. At near-zero EA values, the remodelling pressures are evenly distributed and result in a reduction of treatment time.

Videos

Tutorial video: How to calculate the Entry angle with the "Papadimitriou Abduction Splint App".

The app is available on the Apple store: https://itunes.apple.com/us/app/papadimitriouabductionsplint/id1437808634

Video description: To achieve a favorable outcome in the treatment of DDH, the abduction splint has to place the leg in such abduction to allow concentric distribution of pressure of the femoral head inside the dysplastic acetabulum. This would induce remodelling of the acetabulum towards normal. The surgeon is usually faced with the dilemma of how much abduction is necessary in order to induce the acetabular remodelling. The "Papadimitriou Abduction splint Application" calculates the whole range of measurements and the entry angle. The current abduction or adduction of the hip is measured and by scrolling, one can virtually change the position of the legs. By increasing or decreasing abduction, the app concurrently calculates the load, the pressure and its distribution in the new position, which is projected in real time over the X-ray. Every time one changes the degrees, the distribution of pressure is projected for the corresponding degree of

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abduction. With this procedure, all data are recalculated live on the screen, which allows easy identification of the biomechanically ideal position (concentric distribution of pressure inside the acetabulum; more black/green arrows inside the acetabulum). This procedure helps quickly decide on the optimal position of abduction of the extremity, by changing the abduction of the brace to the suggested ideal degree of abduction, without having to repeat the X-rays. This will promote uniform remodeling of the dysplastic acetabulum towards normal and will speed up the process. For the treatment of DDH, the "Papadimitriou Abduction hip splint App" makes a real time biomechanical analysis in order to identify the optimal positioning for both legs in the Abduction splint. The blinking arrow is showing the EA which is changed by changing the position of the hip.

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