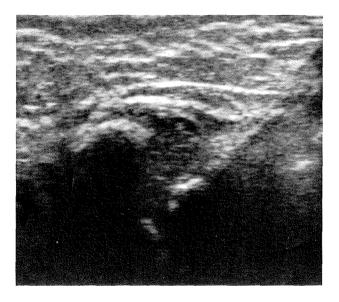
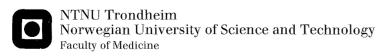
### Agnar Tegnander, MD

# DIAGNOSIS AND FOLLOW-UP OF CHILDREN WITH SUSPECTED OR KNOWN HIP DYSPLASIA





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### CONTENTS

	Page
Acknowledgements	7
List of Papers	9
Terminology and abbreviations	10
Introduction	13
Anatomy	13
Etiology and epidemiology	14
Natural history	15
Normal growth and development	15
Neonatal hip instability	16
Dysplasia and subluxation	17
Dislocation	19
Diagnosis	19
Clinical	19
Radiography	20
Ultrasound	24
Neonatal screening	28
Treatment and follow-up	30
Aims of the study	33
Review of Papers I - VI	34
General discussion	37
Patients	37
Methods	38
Clinical	38
Ultrasonography	39
Radiography	40

### Page

Results	41
Neonatal screening	41
Natural history of US abnormalities	43
Treatment results in NHI	44
Imaging methods	45
General conclusions	48
References	49
Papers I-VI	61

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To my Macintosh IIci, which I trusted through all the years.

To my parents, who always have supported me.

But most of all to Unn-Merete, Jonas, Aurora and Amalie. I love you.

Trondheim, June 7, 1999

Agnar Tegnander

#### LIST OF PAPERS

- I. Agnar Tegnander, Terje Terjesen, Tobias Bredland, Ketil Jarl Holen. Incidence of late-diagnosed hip dysplasia after different screening methods in newborns. J Pediatr Orthop Part B 1994;3:86-8.
- II. Ketil Jarl Holen, Agnar Tegnander, Terje Terjesen, Tobias Bredland, Ole Jakob Johansen, Ola D Sæther, Sturla H Eik-Nes. General or selective neonatal hip joint screening using ultrasound? A prospective, randomized study of 15 529 newborns. Submitted for publication.
- III. Agnar Tegnander, Terje Terjesen. Ultrasound measurements in hips of children above 2 years of age. Normal variations in 232 hips. Acta Orthop Scand 1995;66:229-33.
- IV. Agnar Tegnander, Terje Terjesen. The reliability of ultrasonography in the follow-up of hip dysplasia in children above 2 years of age. Acta Radiol 1999;40:619-24.
- V. Agnar Tegnander, Ketil Jarl Holen, Terje Terjesen. The natural history of hip abnormalities detected by ultrasound in clinically normal newborns. A 6-8 year radiographic follow-up study of 93 children. Acta Orthop Scand 1999;70(4):335-7.
- VI. Agnar Tegnander, Ketil Jarl Holen, Svein Anda, Terje Terjesen. Good results after treatment with the Frejka pillow for neonatal hip instability. A 3-6 year follow-up study. Submitted for publication.

#### **TERMINOLOGY AND ABBREVIATIONS**

**Hip Dysplasia (HD):** All types of dysplasia of the hip joint (acetabular dysplasia, subluxation and dislocation). HD in this work is synonymous with congenital dislocation of the hip (CDH) which was used earlier and developmental dislocation of the hip (DDH) which is used in most papers during the last decade.

Acetabular dysplasia: A shallow acetabulum with an increased acetabular index (Hilgenreiner 1925b, Faber 1937, Burger et al. 1990).

**Subluxation:** Partial dislocation. The femoral head is still in contact with the acetabulum, although the area of contact is decreased compared to dysplasia.

Dislocation: The whole femoral head is located outside the acetabulum.

**Neonatal hip instability (NHI):** Any degree of abnormally mobility of the femoral head in the first month of life.

Late-diagnosed hip dysplasia: Hip dysplasia diagnosed after one month of age (Dunn et al. 1985, Bjerkreim 1974, Heikkilä 1984, Bialik et al. 1986).

**Screening:** A presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly.

**General screening:** Screening of whole population groups, where no selection of high risk groups is made.

Selective screening: Screening of selected high risk groups.

#### **Ultrasound measurements:**

Femoral head coverage (FHC): The coverage of the femoral head by the bony acetabulum, in percent.

**Lateral head distance (LHD):** The distance from the lateral tangent of the ossification center of the femoral head to the lateral bony acetabular rim.

Lateral cartilage distance (LCD): The distance from the lateral tangent of the cartilaginous femoral head to the lateral bony acetabular rim.

Anterior head distance (AHD): The distance from the anterior tangent of the bony femoral epiphysis to the anterior bony acetabular rim.

Anterior capsule distance (ACD): The distance from the midportion of the femoral neck to the anterior joint capsule.

#### **Radiographic measurements**

Lateral head distance by radiography (LHDR): Similar measurement as LHD, but measured on radiographs.

**Migration percentage (MP):** The percentage of the femoral head lateral to the bony acetabular roof (Reimers 1980).

**Center edge angle (CE angle):** The angle between a line through the center of the femoral head parallel to Perkins' line and a line through the center of the femoral head and the lateral bony rim of the acetabulum (Wiberg 1939).

Acetabular index (AI): The angle between a horizontal line connecting the two triradiate cartilages (Hilgenreiner's line) and a line connecting the medial and lateral edges of the acetabular roof.

#### **INTRODUCTION**

#### Anatomy of the hip joint

The acetabular cartilage complex is a 3-dimensional structure that is triradiate medially and cup-shaped laterally. The triradiate cartilage is interposed between the ilium, the ischium, and the pubis (Weinstein 1987). In the embryo, the hip joint components (femoral head and acetabulum) develop from the same mesenchymal cells. At 7 weeks of gestation, a cleft develops in the precartilage cells defining the femoral head and acetabulum (Bardeen and Lewis 1901, Gardner and Gray 1950, Strayer 1943, Strayer 1971). At 11 weeks of gestation the hip joint is fully formed (Strayer 1971, Watanabe 1974). The fetal development consists of further growth and early enchondral ossification of the iliac, ischial and pubic nuclei. These nuclei subsequently fuse, though separated by the triradiate cartilage (the Y-cartilage, Figure 1), to form the bony part of the acetabulum (Ogden 1983).

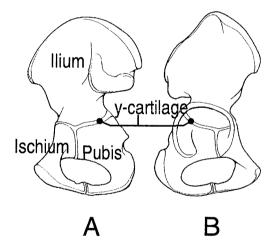


Figure 1. The triradiate cartilage viewed from the medial (A) and from the lateral (B) side

The triradiate cartilage is the physeal plate of the acetabulum and is therefore important in the growth and remodeling of acetabulum (Ponseti 1978). At birth, the femoral head is deeply seated in the acetabulum and held there by the surface tension of the synovial fluid. It is difficult to dislocate a normal infant hip even after division of the joint capsule (Dunn 1969, Ponseti 1978). The cartilaginous part of the acetabulum consists of an outer, circular fibrocartilaginous rim, the labrum acetabulare, and an inner hyaline cartilage. Each flange of the triradiate cartilage is composed of very cellular hyaline cartilage containing cartilage canals and growth plates. Interstitial growth within the triradiate cartilage complex causes the hip socket to expand during growth. At birth, the femoral head coverage by the bony acetabulum is relatively low, but increases as the hyaline cartilage ossifies. This ossification, or maturation of the acetabulum, depends on normal containment of the femoral head as a stimulus for growth (Smith et al. 1958, Harrison 1961, Tönnis 1987). At completion of growth, the growth plates of the acetabulum and femoral head ossify.

#### Etiology and epidemiology

The cause of HD remains unknown, but there is no doubt that genetic, ethnic, and mechanical factors play a role. The incidence of HD has been reported to be as high as 2.5 - 5 % in Lapps and North American Indians (Coleman 1968, Getz 1955, Rabin et al. 1965, Wedge and Wasylenko 1979) while HD is almost nonexisting among Chinese and blacks (Edlestein 1966, Coleman 1968, Hoagland et al. 1973, Pompe Van Meerdervoort 1977). This could partly be explained by the different traditions in carrying the infants with the legs in adduction as the Lapps and Indians, or abduction as the Chinese and the blacks.

The genetic factor has been demonstrated in twin studies (Idelberger 1951). In monozygotic twins, the reported prevalence of HD in the twin of an index case is 34 - 50%, in contrast to about 3% in dizygotic twins. In family studies an increased prevalence of HD is seen within families (Record and Edwards 1956, Wilkinson and Carter 1960, Woolf et al. 1968, Wynne-Davies 1970). Wynne-Davies reported that the risk of early and late HD in siblings of a child with HD and with normal parents was 6% (brothers 1% and sisters 11%). With an affected parent and one affected child, the risk to the second child was 36%. Females account for approximately 80% of the cases of HD (Bjerkreim and van der Hagen 1974, Coleman 1968, Wynne-Davies 1970, Holen et al. 1994).

Causes to the increased incidence in females are not well documented, but hormonal influence might be responsible (Palmén 1984). The genetic effects may be manifest as acetabular dysplasia, joint laxity or both.

The intrauterine environment, reflecting mechanical factors, may influence the development of the hip. In white infants there is increased incidence of HD in firstborn children (Dunn 1969, Wynne-Davies 1972, Bjerkreim 1974, Dunn 1976, Hadlow 1988), probably caused by an unstretched primi gravida uterus and abdominal muscles, whereas others could not verify this (Holen et al. 1994). This crowding phenomenon is also seen in oligohydramnion (Dunn 1969, Dunn 1976). Breech presentation is associated with higher risk of HD (Carter and Wilkinson 1964, Salter 1968, Bjerkreim 1974, Holen et al. 1994). High birth weight also seems to be a risk factor (Bjerkreim 1974, Holen et al. 1996). Dunn (1976) stated that foot deformities is a risk for HD, but Holen et al. (1996) could not confirm this in their study.

#### Natural history

#### Normal growth and development

The growth and maturation of acetabulum depends on a proper stimulus from a well contained femoral head. With a normally developed acetabulum at birth and a normal stimulus from the femoral head, the ossification of the femoral head and the acetabulum continues. Delayed ossification of the femoral head is a common sign in HD (Ponseti 1978). Appearance after 10 months of age is considered abnormal (Tönnis 1987). The femoral neck elongates considerably during the first 2 years of life (Tönnis 1987), while the neck-shaft angle (CCD-angle) decreases from 150° in newborns to about 135° at 15 years of age. The mean femoral anteversion angle decreases from 40° in newborns to about 12° in adults (Tönnis 1976).

The acetabulum continues to ossify after birth. At about 8-9 years of age, ossification centers appear at the acetabular margin (Ponseti 1978). They are believed to play an important role in further growth of the acetabulum, and subsequently fuse with the pelvic bone at about 18 years of age.

The depth increases during development as a result of interstitial growth in the acetabular cartilage, appositional growth in the periphery of the cartilage, and periosteal new bone formation at the acetabular margin (Harrison 1961, Ponseti 1978).

At puberty, the depth of the acetabulum is further increased by the development of three secondary centers of ossification in the hyaline cartilage surrounding the acetabular cartilage. These centers are homologous with other epiphyses in the skeleton (Ponseti 1978).

#### Neonatal hip instability (NHI)

The majority of unstable hips at birth stabilize within weeks (Barlow 1962, Coleman 1978, Jones and Wood 1977, Pratt et al. 1982, Holen et al. 1999). The remaining hips are the truly dysplastic and will persist or subluxate/dislocate without treatment. Barlow (1962) found that one in 60 neonates had instability of one or both hips. More than 60% of these hips stabilized in the first week of life, and 88% stabilized within the first 2 months. Pratt et al. (1982) followed 18 dysplastic hips in children, diagnosed in the first 4 years of life. After an average period of 11.2 years, 15 of 18 hips had become radiographically normal. Coleman (1968) followed 23 untreated patients with NHI and found that 5 became normal, 9 retained dysplastic features, 3 subluxated, and 6 were dislocated. Yamamuro and Ishida (1984) and Ackermann and Kupper (1984) found that when clinically unstable hips (positive Ortolani) at birth were left untreated, approximately 50% normalized and the rest developed manifest dysplasia. Holen et al. (1999) followed 99 newborns with NHI diagnosed clinically and with ultrasound. After two weeks 33 infants (31%) had persisting dysplasia and were treated with the Frejka pillow. Of the remaining 68 infants not treated, 5 infants needed treatment with an abduction orthosis after 4-5 months, because of persisting acetabular dysplasia. Thus, a total of 36% needed treatment. It is therefore difficult to predict the outcome of neonatally unstable hips.

#### Dysplasia and subluxation

After the neonatal period, hip dysplasia (HD) refers to inadequate development of the acetabulum, the femoral head, or both. All subluxated hips have acetabular dysplasia. Radiographically, the differences between these two entities are the coverage of the femoral head by the acetabular roof and the intactness of Shenton's line (Shenton 1911). In subluxation, Shenton's line is disrupted and the femoral head is laterally and/or superiorly displaced (Wedge and Wasylenko 1978, Cooperman et al. 1983, Weinstein 1987). Shenton's line can be misleading because it could be disrupted in coxa valga (Severin 1941) and it changes with varying amounts of femoral rotation (Schoenecker et al. 1995). The measurements can also be difficult to reproduce (Stoker 1993). In acetabular dysplasia the femoral head is not displaced and Shenton's line is intact (Figure 2).

In the literature, acetabular dysplasia and subluxation are often not separated (Herring 1992). In addition, secondary degenerative changes may convert a dysplastic hip into a subluxated hip (Weinstein 1987).

It has been estimated that 20-50% of arthrosis (degenerative joint disease) of the hip is secondary to subluxation or acetabular dysplasia (Wiberg 1939, Lloyd-Roberts 1955, Wedge and Wasylenko 1978, Cooperman et al. 1983, Harris 1986). Wiberg suggested that there is a direct relation between onset of radiographic arthrosis and the

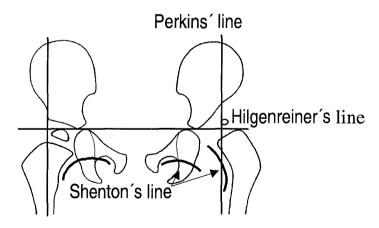


Figure 2. Shenton's line disrupted in the left hip showing subluxation

17

amount of dysplasia as measured by a decrease in the center edge (CE) angle. Cooperman et al. (1983) reviewed the radiographs on which Wiberg based his conclusions. They demonstrated that 7 of the 17 hips were actually subluxated. These hips were the most dysplastic, with an average CE angle of  $2^{\circ}$ , and had arthrosis by the age of 42 years. The other 10 hips were dysplastic with intact Shenton's line and average CE angle of  $10^{\circ}$ . They had arthrosis by an average age of 57 years.

Thus, in Wiberg's series the decrease in CE angle was associated with both increasing acetabular dysplasia and the increased likelihood that the hip was subluxated. Subluxation was the primary factor in the development of arthrosis.

Cooperman et al. (1983) reported on 20 patients with 32 hips with evidence of acetabular dysplasia (CE angle less than 20°) but without subluxation. All the patients developed arthrosis, but there was not a linear correlation between the CE angle and the rate of development of arthrosis as had been suggested by Wiberg.

Cooperman et al. (1983) found that conventional radiographic parameters used to describe dysplasia (CE angle, acetabular index, percent coverage, depth, inclination) could not predict the rate at which the hip joint would develop arthrosis. Murphy et al. (1995) reported in a radiographic study of 286 patients with untreated dysplasia, that no patients in whom the hip functioned well until the age of 65 years had a CE angle of less than 16° or MP of more than 31%. Stulberg and Harris (1974) demonstrated that there is no radiographic picture of arthrosis uniquely associated with preexisting acetabular dysplasia. The CE angle, the most commonly used parameter to quantify dysplasia, could be affected by several parameters, not only radiographic positioning, but also the changes accompanying the development of arthrosis.

In conclusion, the natural history of acetabular dysplasia cannot be exactly predicted, but there is an association between dysplasia and arthrosis. Subluxation of the hip predictably leads to the development of arthrosis and clinical disability from the second decade of life (most severe subluxations) to menopause or later (minimal subluxation) (Wedge and Wasylenko 1978 and 1979). The unfavorable natural history of acetabular dysplasia and subluxation indicates the importance of follow-up of children with HD and of treating these conditions in order to avoid later development of arthrosis.

#### Dislocation

In untreated dislocation there may be little functional disability, although all have gluteal muscle insufficiency and quite pronounced limping gait. The natural history is mainly dependent on two factors: the presence or absence of a well-developed false acetabulum and bilaterality. Wedge and Wasylenko (1979) reported on 32 patients with 42 complete dislocations. They were 16-86 years of age and were evaluated using a modified Harris hip score. Forty-one percent of the patients had good rating, 14% were fair, and 45% had poor clinical rating. They demonstrated a 24% chance of a good clinical result with a well developed false acetabulum, while with moderately developed or absent false acetabulum, there was a 52% chance of a good clinical result. Crawford and Slovek (1978) reported on 10 patients (18 hips) with untreated complete dislocations. All patients were doing well at follow-up. Two 50-year-old patients with unilateral dislocations complained of low back pain, but had no hip pain. Three 55-year-old patients complained of hip pain with more than one mile of walking.

In patients with bilateral dislocations, low back pain may occur. In unilateral complete dislocations, secondary problems of limb length inequality, ipsilateral knee deformity and pain, scoliosis, and gait disturbances are common (Wedge and Wasylenko 1979).

#### Diagnosis

#### Clinical examination

The diagnostic test for HD was originally described by LeDamany (1912) as the "signe de ressaut". In 1936 Ortolani described the pathogenesis of this sign and called it "segno dello scatto" (1948) or the "click sign" as translated to English. Later, the test has usually been called Ortolani's test. Palmén (1961) and Barlow (1962) supplemented this test with a test of subluxatability; i.e. detecting less degrees of instability. In a newborn, the term hip dysplasia refers to any hip with a positive Ortolani or Barlow sign, i.e. any hip that may be provoked to subluxate or dislocate, or a hip that is subluxated or dislocated and may be reduced. In newborns, this is usually called neonatal hip instability (NHI). These diagnostic tests have been used in the clinical examination of newborns for decades.

After the initial relaxation of the newborn hip has disappeared (Barlow 1962, MacKenzie 1981), limitation of abduction, leg length inequality, and asymmetric skinfolds of the thighs are possible signs of HD (Palmén 1961, von Rosen 1962, MacKenzie 1972, Wilkinson 1985).

#### Radiography

Radiography has been the standard imaging method in the diagnosis and follow-up of HD. However, in newborns and in the first months of life there may be difficulties assessing the hip joints because of the lack of ossification center of the femoral head and the immature pelvic bones. The limits between the different subgroups of HD (acetabular dysplasia, subluxation, and dislocation) have usually been based on subjective evaluation (Bjerkreim 1974, Palmén 1984, Visser 1984). Consequently, different authors may have used somewhat different criteria in the evaluation of the hips. Two reference lines are commonly used to make the interpretation of the radiographs more reliable. On the frontal view of the pelvis and proximal femurs, Hilgenreiner (1925a) described a horizontal reference line connecting the two triradiate cartilages, while Perkins (1928) introduced a vertical line perpendicular to Hilgenreiner's line through the lateral edge of the acetabulum (Figure 3).

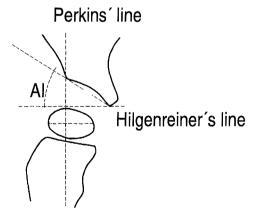


Figure 3. Hilgenreiner's and Perkins' lines. Acetabular index (AI)

Numerous measurements have been proposed as valid indicators of HD in newborns and infants. The "Pfannendachwinkel" or the acetabular index (AI) is measured as described originally by Hilgenreiner (1925a) or later by Kleinberg and Lieberman (1936). This is the angle between Hilgenreiner's line and a line drawn between the medial and lateral edges of acetabular roof (Figure 3). This angle is a valid measure of the acetabular inclination in children before ossification of the triradiate cartilage, but it may vary considerably according to the position of the pelvis (Kleinberg and Liebermann 1936, Tönnis 1987).

To express the percentage of the metaphysis lateral to Perkins' line, the distances from the lateral margin of the metaphysis to Perkins' line (l) and the width of the metaphysis parallel to Hilgenreiner's line (m) are measured, and the metaphyseal percentage (MEP,  $l/m \times 100$ ), is calculated (Figure 4)(Terjesen et al. 1989b).

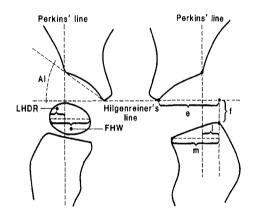


Figure 4. Radiographic measurements in infants. See text.

In addition, the vertical distance from the lateral metaphysis to Hilgenreiner's line is measured (f), as is the distance along Hilgenreiner's line from the lateral metaphysis to the inferior bony margin of the acetabular roof (e).

In hips where the ossification center of the femoral head has appeared, the distance from the lateral tangent of the ossification center to Perkins' line (lateral head distance, LHDR) is measured, as is the width of the ossification center (femoral head width, FHW) parallel to Hilgenreiner's line.

When the whole ossification center is medial to Perkins' line, LHDR is given a minus sign. When the ossification center is larger than 10 mm, the migration percentage (MP) is calculated according to the formula *LHDR/FHW x 100* (Reimers 1980) (Figure 4). This expresses the percentage of the femoral head lateral to Perkins' line. Based on these measurements every hip can be classified as either normal, dysplasia, subluxation, or dislocation, as proposed by Terjesen et al. (1989b) (Table 1).

Table 1. Radiographic criteria for three subsets of HD in children under 2 years of age according to Terjesen et al. (1989b)

 Dysplasia	Subluxation	Dislocation
Bony defect of lateral	1. Metaphyseal percentage (MEP)	1. MEP > 100
acetabular rim, or	> 70 at 2-5 months	2. Unilateral cases
flattened rim	> 60 at 6-11 months	Side diff. in
Acetabular index	> 50 at 12-23 months	e or $f > 7 mm$
$\geq 32^{\circ}$ at 2-11 months	2. Distance e above upper normal	
$\geq 30^{\circ}$ at 12-23 months	limit, or f below lower normal	
	límit	
	3. Unilateral cases:	
	Side difference in e or $f > 3 mm$	

The distances e and f are shown in Figure 4

In children older than 2 years of age the most common measurements regarding femoral head coverage are the MP and the center edge angle (CE angle). The CE angle of Wiberg quantifies the degree of lateral coverage of the femoral head (Wiberg 1939). This is the angle between a line through the center of the femoral head parallel with the Perkins' line and a line through the center of the femoral head and the lateral bony rim of acetabulum (Figure 5).

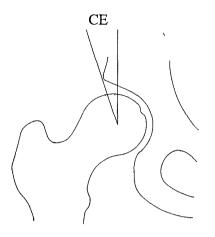


Figure 5. Center edge angle (CE) of Wiberg

This measurement was originally described in adult hips, but has later been used also in children (Severin 1941). The CE angle is less reliable in young children because their femoral ossification centers are small. If the acetabular anteversion is abnormal, the second line would not pass through the midlateral bony rim, but rather the posterolateral rim, and will not give the correct CE angle. Despite this, radiographic criteria for normal hip joints and subgroups of HD have been proposed (Table 2).

Table 2. Radiographic criteria for normal hip joints and subgroups of HD in children older than 2 years of age according to Terjesen et al. (1991)

Age				
(years)	Normal	Dysplasia	Subluxation	Dislocation
2	AI < 28°	AI≥28°	MP 33%-99%	MP ≥100%
3	AI < 26°	AI ≥26°	MP 33%-99%	MP ≥100%
4 - 7	$CE \ge 15^{\circ}$	CE 10°-15°	CE < 10° and MP 33%-99%	MP ≥100%
8 - 12	CE ≥20°	CE 10°-20°	CE < 10° and MP 33%-99%	MP ≥100%
≥13	CE ≥25°	CE 15°-25°	CE < 15° and MP 33%-99%	MP ≥100%

AI, acetabular index; MP, migration percentage, CE, center edge angle

#### Ultrasound

Ultrasound examination of the hip was first introduced by Graf as a way of assessing surface contour of the pelvis (Graf 1980). It was soon apparent that ultrasound could image not only bony structures, but also non-osseous components of the infant hip, such as the cartilaginous femoral head and acetabulum, and information could be gained about the anatomy of the hip joint. He thoroughly described the sonoanatomy of the normal as well as of the abnormal hip and standardized the technique (Graf 1980, 1981, 1984). Graf's technique is static and relies on the morphological appearance of the osseous and cartilaginous acetabulum. Two angles are measured; the alpha angle defines the slope of the superior part of the osseous acetabulum (acetabular roof) while the beta angle evaluates the cartilaginous acetabular roof component (Figure 6).

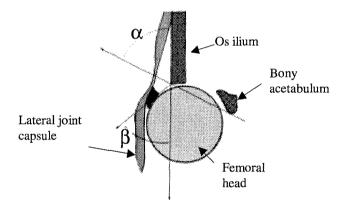


Figure 6. The alpha and beta angles of Graf

He classified the hips into 4 main types (Graf 1993). Graf's type I is a normal mature hip, type IIa is an immature hip, and the types IIb-c, III and IV are classification of hips from acetabular dysplasia to dislocation.

Harcke and coworkers (1984 and 1990) presented a dynamic sonographic approach. This consists of a multipositional evaluation that resembles the physical examination. While the dynamic approach does not ignore acetabular development, it places greater emphasis on position and stability.

Morin et al. (1985) used tangential lines to the lateral and medial aspects of the femoral head parallel to the iliac line to define the coverage of the femoral head. Terjesen and coworkers (1989b) modified this evaluation as they emphasized that the most important parameter in abnormal hips was the coverage of the femoral head. The bony rim percentage (BRP) (Figure 7), later called the femoral head coverage (FHC), is based on the distances from the floor of the acetabulum to the lateral bony rim (a) and to the lateral joint capsule (b).

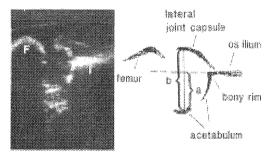


Figure 7. Longitudinal ultrasound image and schematic drawing of a normal hip in a newborn.  $\Delta$ = bony acetabular rim, F = femur, I = os ilium. Note that the anatomic structures are rotated 90° in relation to those on a radiograph

Both measurements are taken perpendicular to the long axis of the transducer and thus parallel to Hilgenreiner's line and perpendicular to the long axis of the infant when the transducer is correctly positioned. The FHC is calculated as  $a/b \times 100$  and expresses the percentage of the femoral head covered by the bony acetabulum. In cases with subluxation or dislocation, the floor of the acetabulum is difficult to define, and the measurements are taken from the medial tangent of the femoral head. The mean FHC in newborns is 55% (Terjesen et al. 1989a, Holen et al. 1994). In children with neonatal hip instability the FHC is reduced to a mean of 36-37%. In addition to the ultrasound measurements, a dynamic subjective evaluation is done. This is important because we can image in real-time the instability of the hip, which can be difficult to assess with the clinical examination. With the hip in abduction and flexion we can simulate treatment with an abduction device.

A normal FHC in abduction means that the hip has been reduced and that the anatomy of the acetabulum is normal (Terjesen 1998). Based on this evaluation, criteria for the 3 subgroups of HD have been outlined (Terjesen et al. 1989b) (Table 3).

In children where the ossification center of the femoral head has appeared, the distance from the lateral tangent of the bony nucleus to the lateral bony rim of the acetabular roof (lateral head distance, LHD) is measured (Terjesen et al. 1989b). LHD corresponds to LHDR by radiography. It is an indirect expression of the acetabular coverage of the femoral head. The larger the LHD, the less is the head coverage.

Dysplasia	Subluxation	Dislocation
1. Bony defect of lateral	1. Bony defect of lateral	1. FHC < 10
acetabular rim, or	acetabular rim or	2. LHD > 10 mm at 2-11 months
rounded bony rim	rounded bony rim	and $> 12 \text{ mm}$ at 12-23 months
2. Femoral head coverage	2. FHC 10-40	
(FHC) 40-50	3. Lateral head distance (LHD)	
	5-10 mm at 2-5 months	
	6-10 mm at 6-11 months	
	7-12 mm at 12-23 months	
Both criteria	Two of three criteria	Criterion 1 is used only if the
must be present	must be present	ossification center of the femoral
		head has not appeared

Table 3.Ultrasound criteria for three subgroups of HD in children under 2 years of age according to<br/>Terjesen et al. (1989b)

There has been a widespread opinion that ultrasound is not appropriate for diagnosis of HD in children older than 1-2 years of age (Graf 1984, Clarke et al. 1985, Suzuki et al. 1987, Millis and Share 1992). The reason is that most of the acetabulum cannot be seen behind the large ossification center of the femoral head. However, Terjesen et al. (1991) showed that other important anatomic structures are clearly visualized on the lateral longitudinal scan in older children. Depicting the lateral outline of the ossification center, the lateral joint capsule, and the lateral acetabular rim, the

coverage of the femoral head can be indirectly assessed by measurement of LHD, exactly as described for infants (Figure 8).

Terjesen et al. (1991) documented a good accordance between LHD and both the corresponding radiographic distance LHDR and the migration percentage. The larger the LHD, the more serious is the hip abnormality (Figure 9).

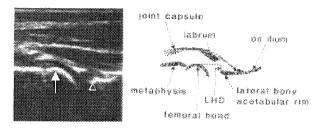


Figure 8. Normal longitudinal scan and schematic drawing of a normal hip in a 6-year old boy.  $\triangle$  = bony acetabular rim,  $\uparrow$  = femoral head, LHD = lateral head distance

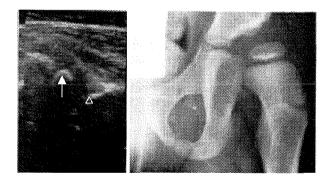


Figure 9. Subluxation of a hip in a 3-year old girl both seen on ultrasound and radiography. $\Delta$ = bony acetabular rim,  $\uparrow$ = femoral head.

In addition they described an anterior scan. With the transducer applied anteriorly along the central parts of the femoral head and neck, the anterior head distance (AHD) was measured in a similar way as described for LHD (Figure 10).

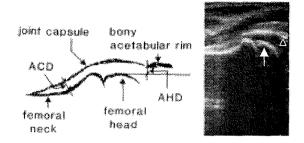


Figure 10. Anterior scan and schematic drawing of a normal hip in a 6-year old boy.  $\triangle =$  bony acetabular rim,  $\uparrow =$  femoral head, ACD = anterior capsule distance, AHD = anterior head distance.

Anterior subluxation is diagnosed by an abnormally increased AHD and any posterior subluxation will also be detected.

On the anterior scan, the anterior capsule distance, ACD, was measured as the distance between the femoral neck and the anterior capsule. This parameter is important in transient synovitis and other conditions with increased fluid content in the hip joint (Terjesen and Østhus 1991). When the hip is examined with both a lateral and an anterior scan, the combination represents a 3-dimensional evaluation of the hip.

Ultrasound examination in older children aimed at diagnosis of HD has hitherto only been described in one study (Terjesen et al. 1991), and further evaluation of this method was therefore an important aim of the present work.

#### Neonatal screening

A good screening program should fulfill certain demands. It has to be a well known disease to screen, a good screening method has to be available, the disease has to be curable, and the screening should be economically acceptable (Parkin 1981, Morrissy and Cowie 1987). These demands are fulfilled regarding HD.

Several authors have calculated the incidence of established hip dislocation in an unscreened European population to approximately 1 per 1000 live births (Getz 1955, Carter and Wilkinson 1964, Leck et al. 1968, MacKenzie and Wilson 1981). Because

the treatment is easier and the results are better when HD is detected at an early age, clinical screening of newborn hips was organized in many countries in the early 50's . Systematic clinical screening showed encouraging results with few cases of late diagnosed HD (Palmén 1961, Von Rosen 1962, Barlow 1962, Fredensborg 1976a), although reports from Norway and other countries were more discouraging (MacKenzie 1972, Williamson 1972, Bjerkreim 1974, Cyvin 1977, Bialik 1986) (Table 4).

Author	Year	Country	Material	Late HD
Von Rosen	1962	Sweden	24 000	0.04
Fredensborg	1976	Sweden	58 759	0.1
Palmén	1961	Sweden	12 394	0
Barlow	1962	England	19 625	0.2
Smaill	1968	New Zealand	6 000	0.7
Bjerkreim	1974	Norway	82 574	2.4
Cyvin	1977	Norway	19 864	2.2
Tredwell & Bell	1981	Canada	32 000	0.2
Bialik et al.	1986	Israel	12 891	2.8
Bower et al.	1987	Australia	67 689	2.2
McKibbin	1988	England	15 561	0.6
MacNicol	1990	Scotland	117 256	0.5
Lennox et al.	1993	Scotland	67 093	1.3

Table 4. Prevalence of late HD (patients per 1000 persons) in clinically screened populations

Williamson (1972) reported an increase of treated newborns after starting the screening program, whereas a decrease in late-detected cases in the same period was not obtained. It was also pointed out the difficulty in learning the examination procedures of Ortolani and Barlow. Catford et al. (1982) who suggested that the varying incidence of HD in different populations could be caused by different diagnostic criteria, wrote that "despite the introduction of neonatal screening in the early 1960s in Southampton we have failed to make a substantial impact on avoiding the late diagnosis of cases". Bjerkreim (1974) also found a high frequency of late-detected cases after screening for neonatal HD.

These varying results of clinical neonatal screening was the reason for introducing new techniques like ultrasonography in the screening. In Austria and Germany, general ultrasound screening has been established (Graf and Tschauner 1994), whereas the effectiveness of such screening is still debated (Clarke et al. 1989, Hauck and Seyfert 1990, Jones and Powell 1990, Rosendahl et al. 1994). Since there is no agreement on the most effective screening policy, we wanted to examine this question in the present investigation.

It seems that the introduction of ultrasound has reduced the incidence of late detected HD (Eggl et al. 1993, Stöver et al. 1993, Marks et al. 1994), but the amount of overtreatment has increased (Berman and Klenerman 1986, Clarke et al. 1989, Graf et al. 1993). Therefore, one of the aims of the present study was to evaluate the natural history of abnormal and suspicious hips in order to reduce overtreatment.

#### Treatment and follow-up

During the last decades of the 19th century surgical reduction of dislocated hips was afflicted with high numbers of complications (Lorenz 1892, Hoffa 1895). This lead the Austrian orthopedic surgeon Lorenz to develop a method of closed reduction of hip joint dislocation (1895). He stated that normal development of the acetabulum was achieved by reducing the femoral head into the acetabulum and by keeping it reduced by a plaster-of-Paris hip spica (Lorenz 1920). He recommended treatment start at 2-3 years of age, but this was opposed by others who recommended early treatment start (Froelich 1932, Hilgenreiner 1935, Frejka 1941). Later experience has established consensus regarding the benefits of early treatment start, preferably during the neonatal period.

The treatment of HD in neonates involves several practical problems and difficult decision makings. Which hips require treatment ? What is the best treatment regimen for the neonate in terms of outcome and avoidance of complications ? When can treatment be safely stopped ? How should failures of early treatment be managed ?

Almost all authors agree that Ortolani positive hips should be treated (Herring 1992). In slightly unstable hips (positive Barlow test) the treatment is controversial. Barlow, in his initial report (1962), documented the outcome in 15 such hips without treatment. Thirteen returned to normal, but two became dislocated and were as

difficult to treat as those in which the initial diagnosis was missed. Barlow concluded that all hips prone to dislocation should be treated.

The Pavlik harness (Pavlik 1957) is currently the most widely used abduction device in the initial treatment of HD (Herring 1992), and is the subject of most recent follow-up reports. Rates of success and complications depend on the type of hip abnormality being treated. In the Barlow positive (subluxable) hip treated during the neonatal period, virtually 100% success is likely (Herring 1992). In the older infant, the success rate drops and the complication rate rises as the proportion of dislocations increases. Grill et al. (1988) reviewed a large European cohort and found a direct correlation between the level of displacement and the likelihood of successful harness treatment. In Sweden and Finland the von Rosen splint (von Rosen 1962) has gained success with minimal complications (Hansson et al. 1983, Heikkilä 1988).

The Frejka pillow (Frejka 1941) has been the major abduction device in the treatment of neonatal HD in Norway (Figure 11).

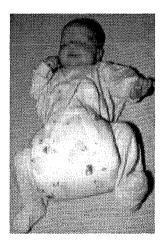


Figure 11. Newborn with the Frejka pillow

This seems to have been a satisfactory treatment (Medbø 1961, Hinderaker et al. 1992) although some authors have stated that the pillow should be abandoned because of an unacceptable high rate of treatment failures and complications (Hansson et al. 1983,

Danielsson and Nilsson 1984, Heikkilä 1988, Herring 1992). In Trondheim we have had the clinical impression that the Frejka pillow has been successful. However the discouraging reports by others made us reconsider the effectiveness of the treatment, which was one of the aims of the present work.

The long-term problems and complications associated with treated HD are residual subluxation, dysplasia, and avascular necrosis of the femoral head (AVN) (Wiberg 1939, Wedge and Wasylenko 1978, Wedge and Wasylenko 1979, Cooperman et al. 1983). Persisting subluxation and acetabular dysplasia should be surgically corrected in order to escape their unfavorable natural history. Although hips that are anatomically imperfect may function well for many years, they will eventually lead to arthrosis (Severin 1941, Gibson and Benson 1982, Malvitz and Weinstein 1988).

AVN is an iatrogenic complication caused by treatment of HD. The reported incidence varies from 0-73% (Bucholz and Ogden 1978, Kalamchi and MacEwen 1980, Malvitz and Weinstein 1988). Total epiphyseal necrosis is usually apparent during the first year after reduction. However, certain patterns of physeal damage, particularly the lateral growth arrest pattern secondary to partial physeal plate injury, may not be radiographically evident until several years after reduction (Bucholz and Ogden 1978). Therefore, the incidence of AVN may not be adequately assessed until some years after treatment, and the patients should be followed until skeletal maturity. With early treatment start, the incidence of AVN has dramatically decreased (Palmén 1994).

#### AIMS OF THE STUDY

- 1. To evaluate the efficiency of different screening policies of the hips in newborns.
- 2. To evaluate whether or not general ultrasound screening is rational and necessary.
- 3. To establish the limits of normal variation of ultrasound measurements in children above 2 years of age.
- 4. To evaluate whether ultrasound is a reliable method for assessment of HD in the follow-up of treated children.
- 5. To establish the natural history of hips with abnormal or suspicious findings by ultrasound, but with normal clinical findings, at the neonatal hip examination.
- 6. To assess the efficiency of the Frejka pillow in the treatment of neonatal hip instability.

#### **REVIEW OF PAPERS I - VI**

#### PAPER I

Three different screening approaches for detecting HD were compared. The effectiveness of the screening was based on the incidence of late-detected HD. Group A consisted of 15 950 children examined by a pediatrician with the Barlow and Ortolani methods. Group B consisted of 5 403 children who, in addition to clinical screening by a pediatrician, also were examined with ultrasound. Group C consisted of 6 411 children, born in 2 district hospitals or a district delivery ward, and who were clinically examined by doctors inexperienced in HD, using the Ortolani method.

We found significant differences between all the 3 groups in the incidence of latedetected HD. The incidence was significantly less in group B (0.7 per 1000) than in group A (2.6 per 1000) and group C (5.3 per 1000). This indicates that ultrasound screening for HD in newborns is more effective than clinical screening alone and that experienced clinical examiners are more effective than inexperienced examiners.

#### PAPER II

The aim of this study was to evaluate whether ultrasound screening of hips should be recommended for all newborns or only for those with risk factors for HD. In a prospective, randomized trial of 15 529 newborns during the 5-year period 1988-92, approximately half the newborns were clinically examined at birth by experienced pediatricians, whereas the other half had additional ultrasound screening. The efficacy of the 2 screening policies was measured in late presenting cases of HD.

After a follow-up period of 6-11 years, only one case of late detected HD has been found in the ultrasound group, as compared to 5 in the group with clinical screening only. This represents a rate of 0.13 and 0.65 per 1000, respectively. With a relative risk of 0.21 (Ci 0.03-1.45), the difference in late cases of HD in the 2 study groups was not significant (p = 0.22).

We conclude that the effect of additional ultrasound examination, measured in late detected HD, is marginal when the clinical screening is of high quality.

Therefore, general ultrasound screening is not necessary. We recommend, however,

selective ultrasound screening for infants with risk factors for HD and neonates with abnormal or suspicious clinical findings.

#### PAPER III

The hips of 116 children and adolescents aged 2 years or more were examined with ultrasound to establish the normal variation in different age groups. All had been referred to the outpatient clinic for various complaints from the lower extremities, but were found to have clinically normal hip motion and had ultrasound measurements within the limits of normal variation proposed by Terjesen et al. (1991).

All children were examined with a lateral and an anterior scan of each hip. The bony femoral head coverage was assessed by measurements of LHD (lateral head distance). The coverage of the cartilaginous femoral head was measured by LCD (lateral cartilage distance.

The LHD increased with age. The upper normal limits (mean + 2SD) increased from 3.5 mm at age 2-3 years to 6.7 mm in adolescents older than 11 years. The LCD which did not change with age, hardly provided any useful additional information regarding lateral coverage. The AHD was somewhat larger in the adolescents older than 11 years than in the younger age groups, with upper normal limits of 2 mm and 1 mm, respectively. Radiographs were available in 15 of the patients and confirmed the ultrasound findings regarding femoral head coverage.

We conclude that ultrasound is a reliable method in children above 2 years of a ge and should replace radiography as the primary imaging technique in clinical suspicion of HD.

#### PAPER IV

Ultrasound and radiography were compared in the follow-up of children treated for neonatal or late-detected HD. A total of 53 patients were examined. We compared the parameters used for assessment of femoral head coverage: LHD by ultrasound and LHDR, MP and CE angle by radiography.

We found a good accordance between sonographic LHD and the radiographic parameters MP and CE angle in the different age groups. There was also a high

35

correlation between LHD and LHDR (r = 0.85). In 11 hips with normal ultrasound, dysplasia or possible dysplasia was found by radiography. With further follow-up, 9 of 9 examined hips became normal also by radiography, indicating that the evaluation by ultrasound had been reliable. We recommend that ultrasound is used as the primary imaging technique in the routine follow-up of children with HD. Radiography is needed only when LHD is above the normal limits or the hip looks suspicious on sonography.

#### PAPER V

The natural history of children with clinically normal hips at birth, but with abnormal ultrasound findings, was evaluated. In the 3-year period 1988-90 we found 170 children with this combination. 93 of these children attended a follow-up examination with radiography 6-8 years later. At follow-up, all hips were normal with a mean CE angle of 24° and a mean MP of 13%. We therefore conclude that these children do not need treatment from birth because spontaneous resolution occurs in the great majority. Postponement of treatment in the few with persisting dysplasia does not seem to affect the outcome.

#### PAPER VI

During the 3-year period 1988-90, the Frejka pillow was used in 108 newborns with clinical NHI verified by ultrasound. 42% of the hips were Ortolani positive, and 58% were Barlow positive. The pillow was used for 4 months, and all the infants were followed for 12 months or until normalization of the hips. At 4-5 months of age all but 5 infants had normal hips. Spontaneous normalization occurred in 2 of these infants, but 3 girls with bilateral NHI, high birth weights, and low femoral head coverage by ultrasound, needed additional treatment with an abduction orthosis (2 patients) or a hip spica cast (1 patient). One of these girls developed avascular necrosis (AVN) of her left hip. The overall treatment failure was 2.8% and one patient (0.9%) developed AVN.

At an age of 3-6 years 85 children (79%) attended a follow-up examination to evaluate the mid-term results with the Frejka pillow. Clinical and radiological examinations were performed. In the oldest children (49 patients) the femoral anteversion angles were measured with radiography according to Rippstein (1955).

There were no significant differences in the radiographic measurements between the previous unstable hips and the stable contralateral hips in unilateral cases. All children had CE angles and MP within the normal range, although somewhat decreased femoral head coverage was found compared to a control group examined by Cyvin (1977). The mean femoral AV angle was slightly increased compared to normal hips, but only 3 patients had abnormally increased anteversion. In conclusion, the results with the Frejka pillow were good, with few treatment failures and complications.

#### **GENERAL DISCUSSION**

#### Selection of patients

In Paper I, which was a retrospective study, we compared patients from different time periods. Thus, although groups A and C were partly from the same period (1980-85), as were the groups B and C (1986-87), the results were not directly comparable. However, the study showed a trend towards differences between the efficiency of various screening procedures. This made the background for a new study with an improved design, which was the prospective, randomized study in Paper II, where clinical screening performed by pediatricians was compared to screening with additional ultrasound.

All the requirements of a prospective, randomized clinical study were met in Paper II. The study protocol was outlined before the investigation, the aim of the study was clearly defined, the sample size was mathematically calculated, and the statistical power was defined. The study was approved by the ethical committee, and a written consent from the parents of the children was obtained.

In Paper III a random sample of normal children would be the optimal study material. Instead we examined children who had been referred to the outpatient clinic for various complaints from their lower extremities, and whether this represented a normal population could be questioned. We used, however, strict inclusion criteria, defining the hips as normal when there were no previous history of hip disorders, normal range of motion (Bjerkreim 1974, Cyvin 1977), normal anatomic structures of the hip by ultrasound and ultrasound measurements within the normal range proposed by Terjesen et al. (1991). Using these criteria, children with abnormal hips would be excluded from the study.

In Papers V and VI we did not have 100 % attendance at the follow-up examinations, but 55% and 79% respectively. This could make it difficult to draw reliable conclusions. On the other hand, there were no significant differences in FHC at birth and risk factors for HD between the children attending the follow-up examinations and those not attending.

Children with normal hips at 12 months were not routinely followed any further at that time, and they were therefore difficult to locate years after. Moreover, children with clinical problems or radiographic abnormalities would routinely be followed up and included in Papers V and VI, making it less likely that any cases of persisting HD would be missed.

# **Methods**

## Clinical examination

At the neonatal hip examination, cases of hip instability may be missed for several reasons:

1. Inexperienced examiner

In all but the best organized centers this is probably the commonest cause of failure (Moore 1974). The Barlow and Ortolani tests are difficult to perform properly, and close supervision is therefore necessary before sufficient expertise is reached. Several reports show better results with experienced examiners in clinical screening (Fredensborg 1976a, Lehman and Street 1981, Danielsson and Nilsson 1984, Macnicol 1990) and this was confirmed in Paper I.

2. Difficult interpretation

A dislocated hip is not always easily detected in a large child (Smaill 1968). A child who is crying and struggling is also difficult to examine.

3. Irreducible hip dislocation

The clinical diagnostic tests are based on the fact that a dislocated or subluxated hip can be felt to reduce (Ortolani) or that an unstable hip can be manually subluxated (Barlow). When the hip is irreducible the diagnosis could be missed in the hands of an inexperienced examiner. Restricted abduction should, however, arise suspicion of HD. Irreducible dislocation is very rare (McKibbin et al. 1988), and we found no such cases in the randomized study (Paper II).

4. Later dislocation of a primary stable hip

There are some evidence that children with normal hip joints at birth could develop acetabular dysplasia, subluxation or dislocation later (Townsend and Tolo 1994), although such cases probably are very rare.

These problems make the clinical diagnosis of hip dysplasia difficult or even unreliable in inexperienced hands. The results of previous studies (Williamson 1972, Catford et al. 1982) indicate that a screening program may lead to an increase in treated newborns, but still the same or increased frequency of late-detected cases. This means overtreatment, that the treatment is offered to children with normal hips.

# Ultrasonography

In Papers I, II, V and VI ultrasound of the newborn hip was done according to Terjesen et al. (1989a). The measurements of femoral head coverage (FHC) and lateral head distance (LHD) were preferred rather than Graf's method of measuring angles, although in Paper I a dynamic evaluation only was done during the first year (1986) of ultrasound examination.

Various investigators have found Graf's method impractical or unreliable in the newborn because of difficulties in selecting the reference points (Morin et al. 1985, Zieger et al. 1986, Harcke and Grissom 1990). The beta angle has proven especially unreliable (Zieger et al. 1986, Niethard and Roesler 1987, Millis and Share 1992). In an interobserver study, Rosendahl et al. (1994) found a moderate agreement between 2 examiners measuring the alpha and beta angles. This corresponds well with the studies of Zieger et al. (1986) and Niethard and Roesler (1987).

Our technique is a combination of static and dynamic assessment. This method was chosen because we think that the coverage of the femoral head is the most important measurement in HD, irrespective of the age of the patient. In an interobserver study, Holen et al. (1994) found a 95% confidence limit for interobserver variation in FHC of  $\pm$  8%, which is acceptable. This method has also been studied by other authors. Dias et al. (1993) found poor intra- and interobserver agreement both with our method and with the method of Graf, whereas Czubak et al. (1998) found a better interobserver

agreement with our method. In addition they stated that our classification system was simpler.

The method of ultrasound examination in children older than 2 years of age was introduced by Terjesen et al. (1991). Unfortunately, no other groups have evaluated this method. Therefore we felt that another study was needed to evaluate the method in normal hip joints (Paper III) and in the follow-up of hips with known HD (Paper IV). The method can be used in children of all age groups if corrected for the natural growth of the femoral head and acetabulum.

Ultrasound evaluation is an adequate method when HD is suspected, but if an osseous tumor or other skeletal diseases in the hip area is suspected, this is not always detectable with ultrasound. For such evaluation a radiograph or examination by other imaging methods should be obtained.

# Radiography

Radiography is not sufficiently reliable in the newborn because of their immature skeleton, making the interpretation difficult. Also in older children there are problems concerning the interpretation of the radiographs. The acetabular index (AI), which is the main measurement for assessing acetabular dysplasia in small children, has shown quite large variability in interobserver and intraobserver studies (Bolton-Maggs and Crabtree 1983, Kay et al. 1997). The AI varied as much as 12° in the intraobserver study of Kay et al. (1997). Others have, however, found good agreement of the AI in an inter- and intraobserver study among experienced examiners (Spatz et al. 1997).Smith et al. (1997) showed, in a follow-up study after treatment of HD in infants, that a change in AI of more than 5° was independent of the outcome of the treatment, and therefore of limited predictive value.

There have also been different suggestions regarding the normal variation of the AI. While Kleinberg and Lieberman (1936) considered an AI above 30° in newborns and infants as pathologic, others have found this limit too narrow. According to Caffey et al. (1956) and Tönnis (1976), the upper normal limits are approximately 33° in girls at 5-6 months of age and 30° at 12 months. These values correspond well with the results of Terjesen et al. (1989b). Despite this, many authors have stated that the diagnosis of hip dysplasia cannot be based on a high AI only (Caffey et al. 1956, Laurenson 1959, Komprda 1984). Bony defect of the lateral acetabular rim is also a sign indicating dysplasia (Komprda 1984, Terjesen et al. 1989b).

The CE angle of Wiberg (1939) has been difficult to reproduce in children less than 5 years of age (Fredensborg 1976b, Tönnis 1976, Weintroub et al. 1979, Schoenecker et al. 1995). Tönnis (1976) said that during the first years of life, differences in measurements could be caused by difficulties in defining the center of the femoral head. The reduced reliability of the CE angle in young children was the reason why we also assessed the coverage of the femoral head by an additional radiographic measurement, the migration percentage (MP) (Papers I - VI). This parameter is easily measured in all children above one year of age.

# **Results**

## Neonatal screening

We confirmed the experience of previous studies that the results were better when the neonatal clinical screening was performed by experienced examiners as compared with inexperienced examiners (Paper I). However, there was an unacceptably high rate of late detected HD, 2.6 per 1000 even in the group where pediatricians performed the examination, which is similar to results from Norway presented earlier (Bjerkreim 1974, Cyvin 1977). The introduction of ultrasound screening in 1986 improved the screening with a late detected frequency of 0.7 per 1000.

We changed the ultrasound technique in 1987 to include measuring the femoral head coverage in addition to dynamic evaluation. This seemed to improve the screening further, as no late detected cases in children born in 1987 have occurred. These results were interesting, but not conclusive, since comparison of different time periods is hardly

sufficiently reliable. We therefore started a randomized controlled prospective study in 1988 to evaluate whether or not screening was more effective when US was used (Paper II). During the 5-year-period 1988-1992 we randomized 15 529 children to clinical examination by experienced pediatricians and ultrasound screening by orthopedic surgeons (group 1) or clinical examination only (group 2).

During a follow-up period of 6-11 years only one case of late-detected HD in the ultrasound group (0.13/1000) and 5 cases in the group with clinical screening (0.65/1000) were found. The difference was not statistically significant (p=0.22)(Paper II). These results are in accordance with the experience of Rosendahl et al. (1994). In a prospective randomized trial of 11 925 newborns, they found no significant difference (p = 0.1) in late presenting hip dysplasia between newborns with clinical examination only and newborns with additional ultrasound examination.

In Paper II, we experienced that the number of late-detected HD decreased during the study period in the clinical screening group. This was also a trend in the study of Rosendahl et al. (1994), who reported a reduction in late detected HD from 2.6 to 1.3 per 1000 during the study period. Dwyer (1987) also reported better screening results when special attention was drawn to the problem. The improved quality of the clinical screening in Paper II could also be explained by the fact that most of the clinical examinations were performed by one very experienced examiner with special interest in HD, as shown earlier by Macnicol (1990). This was probably the main reason for the reduced frequency of late-detected cases of HD in group 2 (Paper II) as compared with the clinical screening in Paper I.

Ultrasound screening involved other benefits. First there was a substantial reduction in newborns that underwent treatment during the study period (Paper II). Secondly, a few infants with normal clinical findings as newborns, but having HD that needed treatment, were detected by ultrasound at the neonatal screening (Terjesen et al. 1996, Paper V).

In Paper I we found that 59% of the children with late detected dysplasia had risk factors for HD. Jones and Powell (1990) added ultrasound examination to the clinical screening for high-risk infants. They had no cases of late-detected HD and concluded that ultrasound examination of infants at risk would reduce the problem with

late HD, since most of the infants developing late HD were in the high-risk group. This has been supported by others (Walter et al. 1992, Stöver et al. 1993). Also Clarke et al. (1989), Boeree and Clarke (1994) and Rosendahl et al. (1994) found a reduction of late detected cases when high risk infants had additional ultrasound. Therefore, ultrasound of high risk newborns seems advisable.

In conclusion, the results from the present (Paper II) and the above mentioned studies indicate that general ultrasound screening is not necessary if the clinical screening is of high quality. If not, an improvement of the clinical screening or general ultrasound screening should be aimed at.

# Natural history of ultrasound abnormalities

A new method like ultrasound in the hip screening does not only provide better answers to unsolved questions; it also raises new questions. One question is the natural history of clinically normal hips with ultrasound findings suggesting dysplasia. Few studies have addressed this problem, but the short term results have indicated that most of these hips normalize without any treatment (Castelein et al. 1992, Terjesen et al. 1996). In Paper V we found that such hips were still developing normally after a mean follow-up time of 7 years. Despite this the MP and CE angle indicated somewhat decreased femoral head coverage compared to normal hip joints. Whether this is of any clinical importance is uncertain.

In Paper V (neonates with normal clinical findings but abnormal or uncertain ultrasound findings), the mean FHC at birth was higher than in hips with NHI (Holen et al. 1999). These hips with borderline values or slightly reduced FHC at birth may represent hips that are immature and not really dysplastic. The challenge is to define the hips which need treatment as soon as possible after birth. Our study (Paper V) did not provide any conclusive answers, but showed that it was safe to follow suspicious hips until normalization or until treatment was considered necessary at 4 - 5 months of age. This policy had no adverse effects on the outcome of the treatment.

Studies of normal hip joints in children show that the CE angle increases somewhat with age (Severin 1941, Fredensborg 1976b). Weintroub et al. (1979) showed that this increase was larger in hips recovering from HD than for normal hips. Therefore it is important to follow children with manifest or possible HD to skeletal maturity, to see if the hips follow a normal developmental pattern and if the measurement results improve to reach the normal range of hips in the general population.

# Treatment results in NHI

The main goal in the treatment of HD is to obtain reduction and maintain the hip reduced until it has become sufficiently stable. The Frejka pillow (Frejka 1941) has been one of the most commonly used devices to achieve this goal. After several reports with many treatment failures and AVN (Hansson et al. 1983, Danielsson and Nilsson 1984, Heikkilä 1988, Herring 1992), other devices such as the Pavlik harness (Pavlik 1957) and the von Rosen splint (Hansson et al. 1983, Heikkilä 1988) have been preferred by many authors.

Several reports dealing with the treatment of HD do not distinguish between treatment immediately after birth and treatment start some weeks or months after birth. We found (Paper VI) that if treatment with the Frejka pillow is started one of the first days after birth, the results are comparable to those reported with Pavlik harness and von Rosen splint regarding both treatment failures and AVN. As pointed out in the Paper VI, newborns with pronounced clinical instability and a very low FHC seem to reflect a more severe form of HD. This has also been stated by other authors who suggest close follow-up of these children and a change in treatment to a more rigid device if instability persists after a few weeks (Herring 1992).

Holen et al. (1999) followed all Ortolani and Barlow positive hips for 1 - 2 weeks with clinical and ultrasound examinations before decision regarding treatment was taken. They showed that 29 of 52 infants with positive Ortolani test, but only 2 of 47 Barlow positive hips, needed treatment. They therefore recommended delayed treatment start for NHI in order to reduce overtreatment. This probably means that there was a certain degree of overtreatment in Paper VI because 58% of the neonates had less pronounced instability (Barlow positive). Despite this we feel that our results of the Frejka pillow can be compared to other studies, because until now there has been broad agreement that all Barlow positive hips should be treated (Herring 1992).

There have been few reports on the long term results of hips treated from birth, especially in the Pavlik harness group, although Weinstein (1992) stated that treated

hips should be followed to skeletal maturity to detect residual dysplasia and AVN. Bjerkreim (1974) and Cyvin (1977) followed children treated with the Frejka pillow for several years and found abnormally high AV angles and decreased range of motion in many children corresponding with the findings in Paper VI. A comparable study on the von Rosen splint was presented by Fredensborg (1976a), although AV angles were not measured. At an average age of 10 years, all children had normal range of hip motion and no child had any complaints. The reduction in range of motion in Paper VI was, however, small and did not seem to influence the physical activities of the children.

# Imaging methods in children > 2 years of age

Subluxation and dislocation are readily detected with both ultrasound and radiography. Minor degrees of HD are, however, more difficult to assess. The limits between normal and slightly abnormal hips are not easily drawn for various reasons. First, the applied measurements may not be optimal as prognostic factors. Secondly the limits may vary somewhat according to age.

A problem with all diagnostic procedures in HD is to define the limits of normal variation and to define the different subgroups. In order to evaluate whether ultrasonography was useful for this purpose, comparison with radiography as the "gold standard" was necessary. This raised a problem because no generally accepted classification for the measurements of children's hips has been established. Terjesen et al. (1991) had previously proposed radiographic criteria for normal hip joints and for the subgroups of HD (Table 2) and this classification was used in the present investigation (Papers I - VI). Well known radiographic measurements like AI, MP, and CE angle were included and the normal ranges for these variables were based on the experience of many authors (Tönnis 1976, Wiberg 1939, Severin 1941, Kasser et al. 1985, Reimers 1980, Eklöf et al. 1988, Fredensborg 1976b).

Although the classification in Table 2 hardly represent the "true" and final limits between the 4 categories normal, acetabular dysplasia, subluxation, and dislocation, it is easy to apply and was found suitable for the present papers. Moreover, after using these criteria for several years, we have not found it necessary to modify the classification. Whether or not the limits of normal range for the 2 variables (MP and CE angle) used for assessing femoral head coverage are completely reliable as prognostic factors, should be evaluated by further follow-up to skeletal maturity of the children in Papers IV, V, and VI. So far, the lower normal limit of  $15^{\circ}$  for the CE angle and the upper limit of 25% for MP seem adequate in distinguishing between normal and abnormal hips.

By radiography, we defined hips with abnormal CE and normal MP or vice versa as "possible" or "uncertain" (Papers IV and V) dysplasia. This definition could be discussed because most of these hips normalized after some time, confirming the trend towards spontaneous resolution in mildly dysplastic hips previously reported (Pratt et al. 1982, Severin 1941, Wiberg 1939). As a consequence of the results in Paper IV we suggest that these "uncertain" hips are defined as normal.

Of the ultrasound measurements LHD is the most important variable in the diagnosis of HD in older children. In Paper III, where the normal range of ultrasound measurements was assessed, we used the criteria from the previous paper of Terjesen et al. (1991). The results of Paper III showed slightly lower values for LHD in the youngest age groups. Based on both these papers, we think the normal ranges for lateral and anterior femoral head coverage by ultrasound according to Table 5 should be fairly reliable.

 Age		
(years)	LHD	AHD
2-3	4	1
4-7	5	1
8-11	6	1
≥12	7	2

Table 5. Suggestion of upper normal limits of LHD and AHD (mm) by ultrasound in children older than two years of age.

LHD, lateral head distance; AHD, anterior head distance

The upper limit of LHD increases from 4mm to 7mm in adolescents above 11 years of age. When ultrasound is performed as the primary examination, LHD values below these levels with normal sonographic anatomic landmarks on the lateral and anterior scans

indicate a normal hip, and radiography can be omitted. If the hip is abnormal or suspicious by ultrasound, additional radiography is performed. The aim should not be to abandon radiography, but to reduce its use to the necessary minimum.

Which imaging method should be used as the primary method in the follow-up of HD? In Papers III and IV we showed that the femoral head coverage was reliably assessed with ultrasound. These children will be exposed to a relatively high amount of radiation if they are followed with radiography. These factors combined with the possibility of the orthopedic surgeon to perform sonography as an integral part of the clinical examination, make us conclude that ultrasound should be the primary imaging method in the follow-up of HD (Paper IV).

# **CONCLUSIONS**

- Experienced examiners achieve better results than inexperienced examiners in the neonatal hip screening. Ultrasound was more efficient than clinical because significantly fewer cases of late-detected HD occurred after ultrasound screening (Paper I).
- General ultrasound screening of the hip joints in newborns is not necessary if the clinical screening is of high quality. Selective screening of risk groups is recommended (Paper II).
- 3. Lateral head distance (LHD) is the most important ultrasound parameter for evaluation of HD in children older than 2 years of age. The upper normal limit of LHD increases from 4 mm at age 2-3 years to 7 mm in adolescents above 11 years of age (Paper III).
- 4. Ultrasound is a reliable imaging method in the follow-up of children with HD and in the evaluation of children referred for clinically suspected HD. Sonography is therefore recommended as the primary imaging method (Papers III and IV).
- 5. The great majority of hips with abnormal or suspicious ultrasound findings but with normal clinical findings at the neonatal examination, spontaneously develop normally. Treatment from birth is therefore not necessary, but a close follow-up is important (Paper V).
- Good results and few complications were obtained with the Frejka pillow as treatment for NHI. Thus, a change to other methods is hardly advisable (Paper VI).

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# PAPER I

Agnar Tegnander, Terje Terjesen, Tobias Bredland, Ketil Jarl Holen. Incidence of late-diagnosed hip dysplasia after different screening methods in newborns. J Pediatr Orthop Part B 1994;3:86-8



# Incidence of Late-Diagnosed Hip Dysplasia After Different Screening Methods in Newborns

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Summary: We compared the effectiveness of different approaches to hip screening in newborns. Three groups were studied: children born in our hospital from 1980 through 1985 who were clinically examined by pediatricians (group A), children born in 1986 and 1987 who were examined by ultrasound (US) in addition to clinical examination (group B), and children born in three district hospitals where neonatal clinical screening had not been performed by pediatricians (group C). There were significant differences between the three groups in the incidence of late-diagnosed hip dysplasia (HD): 2.6 in 1,000,

There is no agreement with regard to the efficacy of neonatal clinical screening for congenital or developmental hip dysplasia (HD). Whereas some investigators have reported somewhat discouraging experiences (3,4), with the methods of Ortolani (13) and Barlow (1), others have obtained excellent results, with an incidence of late-diagnosed HD of <0.5 in 1,000 (1,8,12,17). In Norway, the incidence of late-diagnosed HD varies from 2.0 to 3.5 in 1,000 (2,6). The great discrepancy in incidence between countries and between hospitals in the same country indicates that neonatal screening in many hospitals needs improvement.

Ultrasonography (US) has been established as a reliable technique in diagnosis of HD in infants (5, 9,15), but its usefulness as a screening method in newborns is still debated (5,10,11). In 1986, we began to use US for hip screening in newborns. The main purpose of the present study was to evaluate whether screening became more efficient after US was introduced. We also wished to determine whether any difference existed in the clinical screening and results of experienced and inexperienced physicians.

0.7 in 1,000, and 5.3 in 1,000, respectively. We conclude that US screening of hips in newborns was more effective than clinical screening alone and that clinical screening by pediatricians was superior to screening by doctors with less experience in examining children. US appears to have the potential to eradicate late-diagnosed dislocations, but milder degrees of HD still occur. With regard to the US method, measurement of femoral head coverage appears to be more adequate than subjective evaluation only. **Key Words:** Hip dysplasia—Screening methods— Ultrasound.

#### PATIENTS AND METHODS

We divided 27,764 children born in four different institutions in our county into the following groups according to approaches to hip examination (Table 1). Group A consisted of 15,950 children born at the University Hospital in the 6-year period from 1980 through 1985. These newborns were examined by a pediatrician or a pediatrician resident under supervision using the methods of Ortolani and Barlow. Group B consisted of 5,403 children born at the University Hospital in the 2-year period from 1986 to 1987, when we used US in addition to clinical examination in all newborns. Group C consisted of 6,411 children born at two district hospitals and one district delivery ward from 1980 through 1989. They were examined by obstetricians, surgeons, or general practitioners using the Ortolani method.

We included only the 2-year period from 1986 to 1987 in group B, because the US screening was changed in 1988 when we began a randomized controlled prospective study.

During the first year of US screening (1986), the evaluation was performed as a dynamic examination only, aimed at detecting unstable hips. Beginning in 1987, we measured the coverage of the femoral head by the bony acetabular roof (14). All US examinations were performed by orthopedic surgeons, who also performed the Ortolani and Barlow tests.

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#### LATE-DIAGNOSED HD

TABLE 1. Incidence of late-diagnosed HD according to screening policy

					Late-diagnosed HD		
Hospital	Period	No. of newborns	Method	Examiner	No.	Incidence per 1,000	
Trondheim University Hospital	1980–1985	15,950	Clinical	Pediatrician	42	2.6	
Trondheim University Hospital	1986–1987	5,403	Clinical and ultrasound	Pediatrician and orthopedic surgeon	4	0.7	
District hospitals	19801989	6,411	Clinical	Doctor	34	5.3	

HD, hip dysplasia.

The effectiveness of neonatal screening was measured by the incidence of late-diagnosed HD (detected after age 1 month). All children born in our county with late-diagnosed HD were recorded. Our hospital is the only one with an orthopedic department in our area, and all children with HD are treated there.

For patients with late-diagnosed HD, we recorded sex, year of birth, age at diagnosis, affected side, and any risk factors for HD. Radiographic severity was classified as dysplasia, subluxation, or dislocation according to the method of Terjesen et al. (15). Classification was based on measurements of the acetabular index and lateral and/or proximal displacement of the femoral epiphysis and metaphysis. The  $\chi^2$  test of independence was used for comparison of the groups. Significance level was set at p < 0.05.

#### RESULTS

Eighty children (89 hips) with late-diagnosed HD were detected: 42 children in group A, four in group B, and 34 in group C. The incidence at our hospital before US was introduced (group A), was 2.6 in 1,000 (Table 1). In group B with US screening, the incidence was reduced to 0.7 in 1,000. The difference between group A and group B was significant (p < 0.02). The incidence in group C (district hospitals) was 5.3 in 1,000. This incidence was significant group A (ifferent from that in both group B (p < 0.01) and group A (p < 0.01).

The diagnosis of the four missed HD in group B was acetabular dysplasia in three children and subluxation in one; none had dislocation. The four babies were born in 1986 when we performed a subjective and dynamic US examination only. In 1987, when the coverage of the femoral head was measured, there were no cases of late-diagnosed HD.

Mean age at diagnosis of late HD was 7.7 months (range 1–49 months). There were 75 (94%) girls and five (6%) boys. The right side was affected in 39 cases and the left side in 32; nine patients had bilateral disease (11%). According to the radiographic classification, the numbers of patients with dislocation, subluxation, and acetabular dysplasia were 16, 29, and 35, respectively (Table 2).

Twenty-six children had a family history of HD (33%), and 12 (15%) were born in breech position. Nine children (11%) had both a family history of HD and were born in breech position. Thus, 33 children (41%) had no known risk factors.

#### DISCUSSION

Opinion differs with regard to the effectiveness of hip screening by US in newborns. Tschauner et al. (16) maintained that US screening was the only tool to detect all hips requiring therapy. Hauck and Seyfert (10) examined newborns at risk for HD and concluded that US screening would detect more hips requiring therapy than did clinical screening. Jones and Powell (11) examined newborns with risk factors and detected no late-diagnosed dislocations. On the other hand, Clarke et al. (5) used US in newborns with either clinical abnormality of the hip or risk factors and noted no effect on the incidence of late-diagnosed HD. They emphasized that the usefulness of US as a screening method in newborns must be assessed cautiously. Our results in

TABLE 2. Incidence of late-diagnosed HD according to severity of disease

	Screening method	No. of patients	Dislocation		Subluxation		Dysplasia	
Hospital			n <sup>a</sup>	Incidence per 1,000	nª	Incidence per 1,000	n <sup>a</sup>	Incidence per 1,000
Trondheim University Hospital	Clinical	42	7	0.4	18	1.1	17	1.1
Trondheim Universrity Hospital	Clinical and ultrasound	4	0	0	1	0.2	3	0.6
District hospitals	Clinical	34	9	1.4	10	1.6	15	2.3

HD, hip dysplasia.

" The most severely affected side is given in patients with bilateral HD.

J Pediatr Orthop Part B, Vol. 3, No. 1, 1994

dicate that US screening for HD in newborns was more effective than clinical screening only. US screening apparently eliminates late-diagnosed dislocations, whereas milder degrees of HD still occur. Only randomized prospective studies can solve the question of the optimal method for screening of newborns' hips, however. The study we began in 1988 is still in progress.

All four missed cases of HD were in infants born during the period when only a subjective and dynamic ultrasound examination was performed. After we began measuring femoral head coverage, no late-diagnosed cases were detected. Thus, our results indicate that such measurement is more adequate than subjective evaluation only. Measuring head coverage is rapid and relatively simple (14), and the method is recommended in newborns and small infants.

Several groups of investigators have emphasized the importance of experienced examiners in clinical screening (4,7,8), which is in accordance with our results, as the incidence of late-diagnosed HD was highest when less experienced doctors performed the examination. The screening would probably be more effective if only a few experienced examiners were involved (7). Pediatricians or orthopedic surgeons with special interest and knowledge of HD should perform the examinations, both the clinical and the US screening.

Cyvin (6) reported that 34% of the children with late-diagnosed HD had a family history of HD and that 7% of the children were born in breech position. Bower et al. (3) reported that 8% of the children were born in breech position. We also included children born by cesarean section in breech position, which may explain the higher frequency (15%) of breech position in our study. The high frequency of infant with risk factors supports the common policy of routine follow-up several months after their birth.

The great difference in incidence of latediagnosed HD in different countries and in different areas of the same country may be explained in part by the difference in the efficacy of neonatal clinical screening performed by experienced as compared with less experienced examiners. Furthermore, different diagnostic criteria probably were used (4). Because subjective evaluation of radiographs only tends to yield unreliable results, standardized measurements of the radiographs should be made (15). Measurement of several parameters provides more objective radiographic evaluation and would make comparison of results of studies of different investigators more reliable.

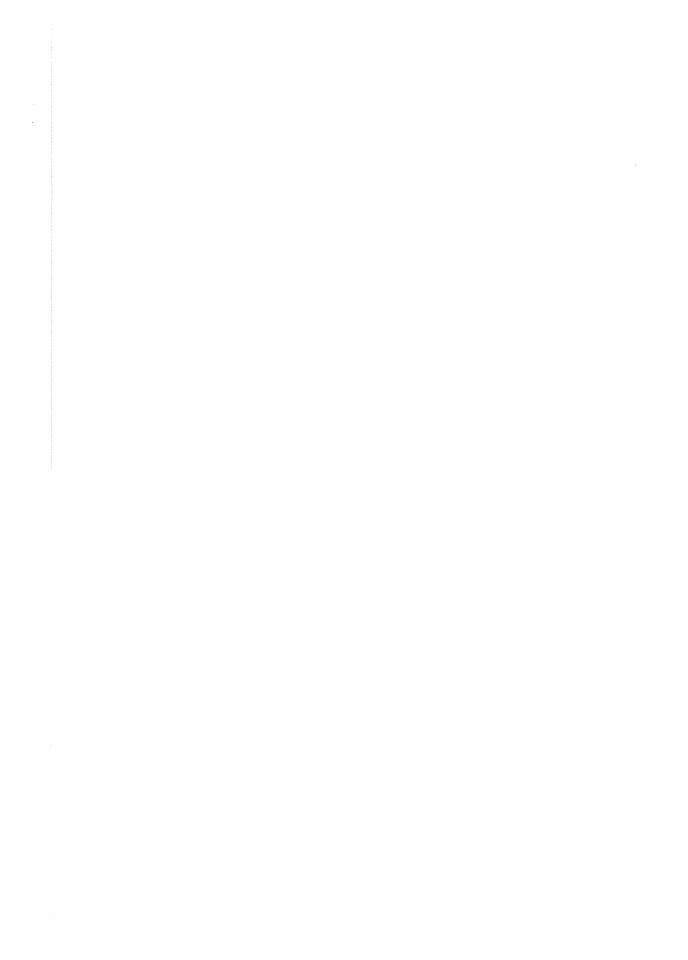
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# PAPER II

Ketil Jarl Holen, Agnar Tegnander, Terje Terjesen, Tobias Bredland, Ole Jakob Johansen, Ola D. Sæther, Sturla H. Eik-Nes. *General or selective neonatal hip joint screening using ultrasound? A prospective, randomized study of 15 529 newborns. Submitted for publication.* 



# General or selective neonatal hip joint screening using ultrasound? A prospective randomized study of 15.529 newborns

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# Summary

**Background** Because there is no consensus whether general (all neonates) or selective (neonates belonging to the risk groups) ultrasound screening of the hip joints in newborns should be recommended, the aim of the present study was to evaluate this important question.

**Methods** We performed a non-selected prospective, randomized study during the 5-year period 1988-92, including all newborns at our hospital. A total of 15.529 newborns were randomized to either clinical examination by experienced pediatricians or to ultrasound examination of the hip joints in addition to the clinical screening. The effect of the screening was measured as the rate of late detected cases of congenital or developmental hip dysplasia (HD) in the 2 groups.

**Findings** During a follow-up period of 6-11 years, only one case of late detected HD has been detected in the ultrasound group, as compared to 5 cases in the group with clinical screening, representing a rate of 0.13 and 0.65 per 1000, respectively. The difference in late cases between the two groups was not statistically significant (p=0.22).

**Interpretation** When the clinical screening is of high quality, as in the present study, the effect of an additional ultrasound examination, measured as late presenting cases of HD, is marginal. Under such circumstances, general ultrasound screening is not necessary. We recommend, however, selective ultrasound screening, including neonates with abnormal or suspicious clinical findings and those with well-known risk-factors for HD.

# Introduction

The Ortolani (1937) and Barlow (1962) clinical tests for neonatal hip instability (NHI) can, in inexperienced hands, be unreliable and result in relatively high numbers of false positive and false negative results (Bjerkreim 1974, Palmén 1984, Macnicol 1990). False positive tests may lead to overdiagnosis and overtreatment, whereas false negative tests lead to late detected hip dysplasia or dislocation.

During the last decade ultrasound has become widely used in the diagnosis of hip disorders in infants, especially in the detection of neonatal hip instability (NHI) (Graf 1984, Harcke et al. 1984, Morin et al. 1986, Castelein & Sauter 1988, Terjesen et al. 1989a). There is no consensus with regard to whether ultrasonography should be performed in all neonates or only in those with risk-factors for neonatal or developmental hip dysplasia (HD). In Austria, a general ultrasound screening of the hip joints in newborns has been established (Graf & Tschauner 1994). In other regions a selective screening policy is preferred (Jones and Powell 1990, Boeree and Clarke 1994). To solve this question, large, randomized clinical trials (RCT) are required (Berman and Klenerman 1986, Terjesen et al. 1989a, Harcke and Kumar 1991). So far, only one randomized study addressing the efficacy of ultrasound screening in neonates has been published (Rosendahl et al. 1994).

The aim of the present study was to answer the following question: is general ultrasound screening of all newborns rational and desirable, or should a selective screening policy be preferred?

# **Patients and methods**

During the 5-year period 1988-92 all parents at the University Hospital of Trondheim were invited to have their newborns participate in a non-selected RCT addressing the possible benefit of ultrasonographic screening of the neonatal hip joint. The study protocol was approved by the Ethical Committee at the University Hospital of Trondheim.

# Working hypothesis

Our working hypothesis was that there is no difference in the incidence of late detected HD between a group where all newborns are examined by ultrasound and a group where ultrasound examination is performed for clinical reasons only.

# Sample size calculations

The sample size calculation was performed according to Fleiss (1981). With a alphavalue of 0.05 and a beta-value of 0.10 and a strength of 0.90 in the study, it was calculated that we needed at least 12194 infants (6097 infants in each group) to prove a significant difference in late detected cases of HD in the 2 study groups. Based on the yearly number of births at our hospital, a 5 years study was planned.

# Inclusion and exclusion criteria

The parents were given written information about the study and gave their written consent to participate. Babies of parents who refused consent were registrated and not included. Newborns with permanent address outside our county were not included in the study because they could not easily be followed up at our hospital. Newborns with low birth weight were included and examined later when their general health condition had improved.

The information form included a questionnaire, which was distributed and collected by the midwives. The parents were asked for any family history of HD. Other risk factors were registered from the birth protocol (breech position) or from the pediatricians examinations of the newborns on the first day of life. The following risk-factors would lead to ultrasound examination for clinical reasons: NHI, doubtful clinical findings, HD in the family, breech position, and foot deformities.

# The randomization and study groups

On the second day after the birth of the child, the orthopedic surgeon evaluated the answers on the questionnaires and the results of the pediatricians' examinations. After including the newborns according to the protocol, the orthopedic surgeons performed the randomization by the method of random sampling numbers (Armitage and Berry 1987). From a table of random sampling numbers between 00 and 99, with a total of 2500 numbers, the newborns were given numbers consecutively according to the birth protocol. When all the 2500 numbers were expended, we started from the beginning of the table again. Numbers between 00 and 49 were assigned to Group 1, whereas newborns with numbers between 50 and 99 were assigned to Group 2.

In Group 1 ultrasound examination of the hip joints was performed in addition to the clinical screening by the pediatrician, whereas Group 2 only had clinical screening by the pediatrician. Newborns randomized to Group 2 with clinical instability or uncertain clinical findings or with the previously mentioned risk-factors for HD had ultrasound examination for clinical reasons.

Throughout the study period, the randomization and examinations went on continuously. Infants who were randomized to ultrasound examination, but not examined, were registrated.

# Clinical and ultrasound examinations

All newborns were clinically examined on the first day of life by a senior pediatrician. From September 1989 almost all clinical examinations were performed by the same experienced pediatrician (OJJ). The examination included the Ortolani (1937) and Barlow (1962) tests. These tests were also performed by the orthopedic surgeons at the time of the ultrasound examination.

The ultrasound examination was performed, usually at day 3 after birth, by the orthopedic surgeons involved in the study (TT, AT, TB, KJH). All newborns in Group 1,

and newborns in Group 2 with the specified risk-factors for HD, were examined. The ultrasound method described by Terjesen et al. 1989a and Holen et al. 1994, was used. The method is based on measurement of the percentage coverage of the femoral head by the acetabular roof (femoral head coverage, FHC), but a subjective, dynamic evaluation was also performed. We used a 5 MHz linear transducer and 2 scan plains were obtained, one longitudinal and one transverse scan plain. The measurements were performed on the longitudinal scan. In a previous interobserver study we found that the 95% confidence limits of FHC was  $\pm$  8% indicating that the method is reliable in the hip joint screening of newborns (Holen et al. 1994).

### Neonatal hip instability (NHI)

Newborns in need of treatment were equipped with a Frejka pillow after the ultrasound examination. The treatment period was 4 months. Measurements of the lateral head distance (LHD) by ultrasonography and radiography were important parameters in the evaluation of the hips during follow-up (Terjesen et al. 1989b, Holen et al. 1994). The trial profile is shown in Figure 1.

## Registration of late detected cases of HD

Late detected cases of HD were defined as patients with HD diagnosed after one month of age. Since our hospital is the only hospital treating patients with late-detected HD in our county, all late detected cases would be registered. However, due to possible migration in the study groups, some infants included in the study could have been treated elsewhere for late HD. Therefore, information was requested from all hospitals in Norway involved in treating late detected HD, concerning patients born in Trondheim in the study period.

If treatment was started during follow-up in cases followed from birth, they were not registrated as late detected cases of HD.

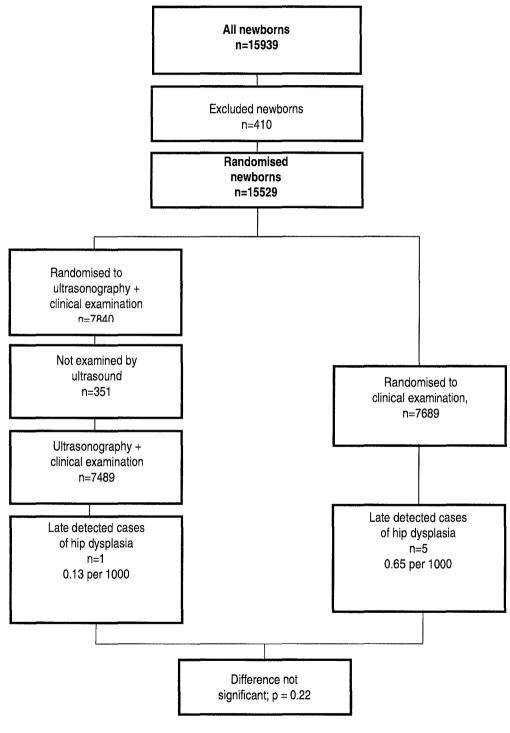


Figure 1. Trial profile

## Data registration and statistics

For all newborns pre-, peri-, and postnatal data were prospectively registered in a database at the National Center for Fetal Medicine. Additional information from the ultrasound examination of the hip were added to this database.

Student's t-test, Chi-square test and Fischer's exact test were used in the statistical analysis. The relative risk of detection of late hip dysplasia was calculated as the rate in the ultrasound group divided by the rate in the control group, and precision was given with 95 % confidence interval (Ci), p-values below 0.05 were considered significant.

## Results

Of the 15.939 live births in the 5-year period, 410 newborns (2.6%) were not included because of addresses outside our county (n=339) or parental denial (n=71).

A total of 7840 newborns were randomized to Group 1 (ultrasound examination group), whereas 7689 newborns were randomized to Group 2 (clinical examination group). Due to risk factors, a total of 872 newborns in Group 2 (11.3%) had ultrasound examination.

In Group 1, 7489 of the 7840 newborns who had been randomized, were examined by ultrasound. The remaining 351 newborns were missed for ultrasound examination because they died, or were sent to other hospitals or home from the neonatal intensive care unit without our knowledge (n=334), or because the parents agreed to participate and were randomized, but left the maternal ward before the ultrasound examination (n=17).

There were no significant differences between the 2 randomized study groups concerning sex, birth weight and birth rank (Table 1). Concerning NHI and risk-factors for HD, the two groups also were similar (Table 2). There were a significantly higher number of foot-deformities in Group 1.

During the follow-up period of 6 to 11 years (mean 8.5), only one infant in Group 1 developed late detected HD, representing a rate of 0.13 per 1000 births. This infant was a girl where limited hip abduction was detected at 3 months of age by a physiotherapist who treated her for a mild foot deformity. Because of the foot deformity this infant should have been routinely followed up by ultrasound, but the protocol was for some reason departed from.

Ultrasound and radiography showed left-sided hip dysplasia. She was treated with an abduction splint and the hip normalized.

Table 1. Characteristics of the randomized neonates in group 1 (ultrasound
and clinical examination) and group 2 (clinical examination)

<u>Characteristics</u>	Group 1(n=7489) (n=7489)	<b>Group 2</b> (n=7689)	<u>Difference</u>
Girls (n)	3673(49%)	3752(48.8%)	n.s.
Boys (n)	3816(51%)	3937(51.2%)	n.s.
Birth weight (g, mean)	3490	3472	n.s.
Birth rank 1 (n)	3490(46.6%)	3598(46.8%)	n.s.
Birth rank 2 (n)	2644(35.3%)	2722(35.4%)	n.s.
Birth rank 3 or more (n)	1355(18.1%)	1369(17.8%)	n.s.

n = number; g = grams; n.s. = non-significant.

Table 2: Risk factor	distribution among	the infants in	n the 2 randomized groups

Group 1	Difference	
(n=7489) (	n=7689)	
73	66	n.s
332	331	n.s.
351	338	n.s.
140	40	0.001
2	2	n.s.
	(n=7489) ( 73 332 351 140	(n=7489)       (n=7689)         73       66         332       331         351       338         140       40

NHI = neonatal hip instability; HD = hip dysplasia or dislocation; n.s. = non-significant;

\* = family history with confirmed hip dysplasia

Five infants in Group 2 have presented with late detected HD, which gives a rate of 0.65 per 1000. Four of these children were treated with an abduction splint, and their hips developed normally. One infant with dislocation needed tenotomy of the adductor longus tendons, closed reduction and hip spica cast. One of these infants was detected at another hospital because the parents had moved to a neighboring county. Apart from this patient, no other cases of late detected HD were reported from the other orthopedic departments in Norway.

The relative risk for late detected HD in the ultrasound group was 0.21 (95% Ci: 0.03 - 1.45), the difference in late detected cases between the 2 randomized groups was not statistically significant (p=0.22, Fisher's exact test).

## Discussion

This study met the classical demands of a RCT, such as:

- 1. The protocol should be clarified before the start of the study
- 2. The aims of the study should be defined
- 3. There should be a sufficient sample size
- 4. The statistical power should be given
- 5. Informed consent must be obtained
- 6. The study should be approved by the ethical committee
- 7. The method of randomization should be acceptable.

The two study groups were similar concerning number of infants, sex, NHI and risk-factors (except for foot deformities) (Table 2). The significantly higher number of foot deformities in Group 1 occurred because the orthopedic surgeons noted several foot deformities which not were registrated by the pediatricians. Most of these deformities were minor foot deformities such as pes adductus and pes calcaneovalgus. With no breaks in the study during the 5-year period, we concluded that no significant bias in the design of the study would occur.

Despite the lack of scientific evidence on the efficacy of ultrasonography in the examination of the hip joints in newborns, as measured in RCT, the method has been widely accepted as an improvement of the newborn hip joint examination (Graf 1984, Harcke et al. 1984, Castelein et al. 1988, Terjesen et al. 1989a). All newborns in Austria are hip-examined by ultrasound (Graf & Tschauner 1994). Several authors have asked for RCT's as a basis for screening policy, should ultrasound screening be general (all newborns) or selective (risk groups)? (Berman and Klenerman 1986, Terjesen et al. 1989a, Harcke and Kumar 1991).

In a RCT of 11.925 newborns, Rosendahl et al. (1994) found no statistically significant difference in late presenting cases of HD (including subluxation, dislocation and acetabular dysplasia) between newborns with clinical examination and newborns with additional ultrasound examination, indicating that general ultrasound screening of the hip joint in newborns is not necessary. Based on their, and the present study, which to our knowledge are the only RCT's until now, it seems reasonable to conclude that a

dedicated and very experienced clinical examiner is sufficient for an adequate quality of hip joint screening in newborns. The advantage effected by ultrasound screening is, however, evident when such screening is compared to clinical screening by less experienced examiners (Tegnander et al. 1994).

It seems possible that a few children with normal hips at birth might develop late dysplasia or dislocations (Palmén 1984). It has also been reported that some hips with normal clinical findings but abnormal sonography do not resolve spontaneously (Castelein et al. 1992, Terjesen et al. 1996). Therefore, an incidence of late HD up to 0.5 per 1000 should be acceptable for clinical screening.

Previous reports from our hospital and from other parts of Norway have shown a relatively stable incidence of late detected cases of HD of approximately 2-3 per 1000, including frank dislocation, subluxation, and acetabular dysplasia (Bjerkreim 1974, Cyvin 1977, Tegnander et al. 1994). In the years previous to this study, Bredland and Terjesen (1987) found an incidence of 3 per 1000 at our hospital. The goal of our study was a reduction of late detected cases to below 0.5 per 1000. Unexpectedly, the incidence of late detected cases in the clinical examination group was substantially reduced during the study period. The number of late detected cases of HD in Group 2 was reduced from the expected 15-20 cases to only 5 cases. Improvement in the clinical screening was the main reason for the lack of a statistically significant difference in the incidence of late detected HD between Group 1 and Group 2. Others have reported the same tendency towards better results when attention is focused on a special problem through a clinical study (Dwyer 1987), and Rosendahl et al. (1994) also experienced the same kind of reduction. The reduction in late detected cases of HD in Group 2 also confirms previous reports that dedicated and experienced clinical screening can almost eliminate late detected HD (Palmén 1953, Fredensborg 1976, Macnicol 1990). In most of the study period a highly skilled and experienced pediatrician performed most of the clinical examinations.

Our results in Group 1 shows that ultrasonographic screening probably has the potential to eradicate late presenting cases of HD. The only late detected case of HD in this group could have been avoided if the follow-up protocol had been followed carefully. Our results are supported by Marks et al.(1994), who had no cases of late detected HD in a

group of 14.050 infants screened neonatally with ultrasound. Rosendahl et al. (1994) found that there were no late detected cases with dislocations of the hip in their ultrasound group, as compared to one case with late dislocation in the selective screening group and 2 cases of late dislocation in the clinical screening group. Our results concerning late detected dislocations are in accordance with the findings of Rosendahl et al. (1994), with additional ultrasound screening late detected cases with subluxation or acetabular dysplasia might occur, but it seems that the serious cases of late dislocations will be avoided.

In addition, the ultrasound screening provided other benefits. First, a substantial reduction in newborns that needed treatment was achieved (Holen et al.1997). The overall 5-year treatment rate was 8.7 per 1000, which is considerably lower than previous reports from our hospital (Cyvin 1977). Moreover, a few infants with normal clinical findings as newborns, but having HD that needed treatment, have been detected by ultrasound (Terjesen et al.1996). The ultrasound screening has led to higher treatment rates in other studies (Rosendahl et al. 1994, Tönnis et al.1990). Tönnis et al. (1990) found that sonographic screening resulted in doubling the number of treated infants, because all sonographically abnormal hips were treated from birth. Our markedly lower treatment rate is explained by the policy of treating only sonographic abnormalities that do not settle spontaneously (Terjesen et al. 1996).

It has been reported that prematurity could increase the risk for late HD (Hansson et al. 1983). In an ultrasonographic evaluation of premature hips, Gardiner et al. (1992) found no differences in Graf's angles in preterm and term infants. This might indicate that prematurity alone should not represent a higher risk for late HD. In our study, 351 infants randomized to ultrasound examination were not examined, most of these infants were referred to the neonatal intensive care unit because of prematurity. All infants had normal findings after clinical screening at birth. In addition, they were followed closely by pediatricians during their first years of life because of their prematurity. Therefore, it is unlikely that any of these infants have developed late detected HD which has not yet been discovered, and they should therefore not influence our results. A best case (0.13 per 1000) - worst case (3 per 1000) analysis of late HD among these 351 infants,

suggests no influence upon our results because of these cases missed for ultrasound examination.

Our conclusion will therefore be: 1. If the clinical screening is of high quality, general ultrasound screening is not needed; selective ultrasound screening should then be recommended. 2. If the quality of the clinical screening is not satisfactory, general ultrasound screening by experienced examiners should be recommended. If experienced ultrasound examiners are not available, the clinical screening may be improved by more skilled and experienced clinical examiners.

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## PAPER III

Agnar Tegnander, Terje Terjesen. Ultrasound measurements in hips of children above 2 years of age. Normal variations in 232 hips. Acta Orthop Scand 1995;66:229-33.

# Ultrasound measurements in hips of children above 2 years of age

Normal variations in 232 hips

## Agnar Tegnander and Terje Terjesen

In order to find the limits of normal variation of ultrasound measurements in children over 2 years of age, we examined 116 children and adolescents with normal hip joints. The children had been referred for various complaints from their lower extremities. Longitudinal ultrasound scanning from the lateral and anterior aspects was performed by the orthopedic surgeon as an integral part of the clinical examination. The most relevant parameters regarding hip dysplasia are those assessing the coverage of the femoral head: the lateral head distance (LHD, the distance from the lateral tangent of the bony epiphysis to the lateral bony acetabular rim) and the anterior head distance (AHD, measured as LHD, but from the anterior scan). The LHD increased with age; the upper normal limit (mean + 2 SD) increased from 4 mm at age 2-3 years to 7 mm at age 12–16 years. The AHD was larger in adolescents 12–16 years of age than in younger patients. The upper normal limit was 1 mm in the youngest and 2 mm in the oldest children. The mean (SD) differences (right minus left) in LHD and AHD were 0.3 (1.1) mm and 0.2 (1.0) mm, respectively.

Radiographs were available in 15 of the patients and confirmed the ultrasound findings regarding femoral head coverage. Our findings should be of value in interpreting ultrasound measurements in older children.

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The benefit of ultrasound in evaluating congenital hip dysplasia (HD) in newborns and infants has become well established during the past decade (Graf 1984, Clarke et al. 1985, Terjesen et al. 1989). In older children, most of the acetabulum cannot be seen because of the large ossification center of the femoral head, but other bony and soft structures of the hip joint are visible, allowing assessment of the extent of femoral head coverage by the acetabulum (Terjesen et al. 1991).

Although most patients referred by clinicans on suspicion of HD are under 2 years of age, there are also many children above this age with symptoms indicating possible HD. We examined the limits of normal variation for the ultrasound measurements in children aged 2 years or more.

## Patients and methods

During the period 1988 through 1992, we examined at the outpatient clinic the hips of 116 children and adolescents aged 2 years or more. There were 60 boys and 56 girls, with a mean age of 5 (2–16) years. Most of the children had been referred for suspicion of HD or other hip diseases. The reasons for referral were intoeing gait (60), pain in the hip or knee (29), click or crepitation in the hip (17), limping (6), and out-toeing gait (4). The criteria for including patients in the study were: no previous hip disorder, normal range of motion of both hips, normal anatomic structures of the hip by ultrasound assessment, and ultrasound measurements within the range of normal hips in our previous study (Terjesen et al. 1991). Thus, patients with HD, transient synovitis, Perthes' disease, slipped capital femoral epiphysis, and neuromuscular disease were not included.

We examined all children with ultrasound from the lateral and anterior aspects of the hip joint, according to the method of Terjesen et al. (1991). Real-time ultrasound with a 5 MHz linear transducer was used. The patient was supine and the lower limb was in neutral position. During the lateral longitudinal scan, the baseline of the transducer was kept parallel to the long axis of the patient. The anatomic structures on the ultrasound image are depicted 90° rotated in relation to those on a radiograph (Figure 1). The distance from the lateral tangent of the ossification center of

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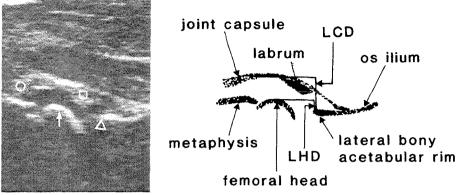


Figure 1. Longitudinal lateral ultrasound image and schematic drawing of a normal right hip in a 6-year-old girl, showing the lateral outline of the ossified epiphysis (arrow), lateral bony acetabular rim (triangle), joint capsule (circle), and labrum (square). Lateral head distance (LHD) and lateral cartilage distance (LCD) are indicated on the schematic drawing.

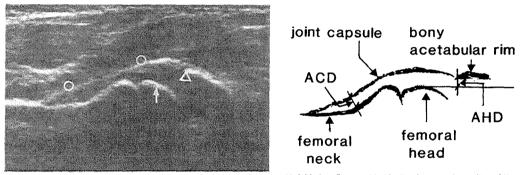


Figure 2. Anterior ultrasound image and schematic drawing of a normal left hip in a 5-year-old girl, showing anterior outline of the femoral head (arrow) and neck, anterior bony acetabular rim (triangle), and joint capsule (circle). Anterior head distance (AHD) and anterior capsule distance (ACD) are indicated on the schematic drawing.

the femoral head to the lateral bony acetabular rim (lateral head distance, LHD) was measured. When the entire ossification center was medial to the acetabular rim, the LHD was given a negative sign. During the last 2 years of the study, including 39 patients under 12 years of age, the distance from the lateral tangent of the cartilaginous femoral head to the lateral bony acetabular rim, was also measured (lateral cartilage distance, LCD) (Terjesen 1993). LHD and LCD express the lateral position of the femoral head relative to the acetabulum and represent the uncovered part of the epiphysis. Based on the measurements of LHD and LCD the thickness of the lateral femoral head cartilage was calculated (LCD minus LHD).

During the anterior scan the transducer was kept over the central part of the femoral head and the long axis of the femoral neck, also depicting the anterior acetabular rim and the anterior joint capsule (Figure 2). Two distances were measured: from the anterior tangent of the bony epiphysis to the anterior bony acetabular rim (anterior head distance, AHD) and from the midportion of the femoral neck to the anterior joint capsule (anterior capsule distance, ACD). The AHD expresses the anterior covering of the bony femoral head and was given a minus sign when the entire bony epiphysis was posterior to the acetabular rim.

Conventional anteroposterior radiographs, which had been ordered beforehand by the referring general practitioner, were available in 15 of the children with a mean age of 5 (2-14) years. The ultrasound examiner did not see the radiographs until after the sonography. The distance from the lateral tangent of the femoral head to the lateral acetabular rim (lateral head distance by radiography, LHDR) was measured. measurement was The made parallel to Hilgenreiner's line. The LHDR corresponds to LHD by ultrasound and expresses the coverage of the femoral head.

Age Number years of hips					AHD	ACD		
	·	Mean	Mean +2SD	Mean	Mean +2SD		Mean +2SD	
2-3	126	0.8	3.5	-1.5	1.1	3.7	5.1	
4-7	58	1.5	4.3	-1.8	0.7	4.4	5.9	
8-11	30	2.6	5.7	-1.9	0.6	4.4	6.3	
12-16	18	3.1	6.7	0.7	1.5	5.1	7.3	

Table 1. Ultrasound findings in 116 patients with normal hip joints

LHD lateral head distance, mm, AHD anterior head distance, mm, ACD anterior capsule distance, mm

We used analysis of variance (ANOVA) and Scheffe's F-test to compare group means. The significance level was set at p < 0.05. The correlation between various parameters was expressed as Pearson's correlation coefficient (r).

### Results

The mean LHD was 0.8 mm in the youngest children and 3.1 mm (p 0.0001) in the oldest (Table 1). The upper normal limit (mean + 2 SD) increased from 3.5 mm at age 2–3 years to 6.7 mm at age 12–16 years. The mean side difference (right minus left) was 0.3 mm (SD 1.1).

The mean LCD in patients under 12 years of age was 5.2 mm and no difference with age occurred (Table 2). There was a high correlation between LHD and LCD (r 0.69). The thickness of the lateral femoral cartilage was 3–4 mm in most hips and was smaller in the age group 8–11 years than in younger children (p 0.001).

The mean AHD had a minus sign in all the age groups, showing that the whole ossification center was posterior to the anterior acetabular rim in most hips (Table 1). The AHD was larger in adolescents 12-16 years of age than in younger patients (p 0.009), whereas there were no differences between the 3 youngest groups. The mean (SD) side difference (right minus left) was 0.2 (1.0) mm.

The ACD was 4–5 mm in most hips and increased with age (p 0.0001, Table 1). The upper normal limit increased from 5 mm at age 2–3 years to 7 mm in the oldest group. The mean difference between the right and left side was 0.3 (SD 1.0) mm.

No differences in LHD, AHD and ACD between the different groups of complaints and correlated to age were found. Nor were there any differences in these parameters between affected and contralateral hips in children with unilateral complaints.

All 15 radiographs showed normal hips, confirm-

ference between LHD and LHDR (LHD–LHDR) was –0.3 (-4.0–2.4) mm, and the difference was 3.0 mm or less in 28 of the 30 hips.

ing the ultrasound findings. The correlation coeffi-

cient between lateral head distance measured by

ultrasound and radiography was 0.59. The mean dif-

Table 2. Lateral cartilage distance (LCD, mm) and thickness of the lateral femoral head cartilage (mm) by ultrasound

	Number	LC	D	Cartilage thickness		
years	of hips	mean	SD	mean	SD	
2-3	50	5.2	1.3	4.4	0.9	
4–7	18	5.2	1.3	4.0	0.8	
8–11	6	5.4	0.9	2.6	0.4	

## Discussion

Our study showed that all relevant lateral and anterior anatomic structures of the hip joints in older children can be reliably visualized by ultrasound. With regard to hip dysplasia, a decreased coverage of the femoral head is considered to be the most important parameter, irrespective of the age of the patient. Thus, it is essential to establish the limits of normal variation of LHD in the various age groups. The present results showed somewhat smaller values for the upper normal limit of LHD in the two youngest age groups than did our previous study (Terjesen et al. 1991). Based on both these studies, the following upper normal limits are suggested: 4 mm at age 2-3 years, 5 mm at 4-7 years, 6 mm at 8-11 years, and 7 mm in adolescents above 11 years of age. In patients with LHD lower than these limits, hip dysplasia can be excluded. When LHD is higher, radiography should also be used for the evaluation. The same policy can be used in the follow-up of patients previously treated for hip dysplasia (Figure 3).

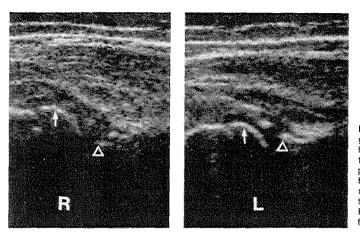


Figure 3. Longitudinal lateral ultrasonograms (labels as in Figure 1) of both hips in a 6-year-old girl (not included in the present material) during follow-up of previously treated hip dislocation. The femoral head is laterally displaced in the right hip (R), indicating slight subluxation, whereas the left hip (L) is normal. Radiography confirmed the ultrasound findings.

A comparison between ultrasound and radiography was performed in 15 children. The results confirmed our experience of a good accordance regarding extent of femoral head coverage (LHD and LHDR), indicating that the ultrasound evaluation is reliable (Terjesen and Østhus 1991, Terjesen et al. 1991). Although ultrasound (like radiography) entails potential measurement errors due to patient positioning, transducer position, and identification of anatomic landmarks on images, the moderate interobserver variation of  $\pm 1$  mm (Terjesen et al. 1991) confirms our experience that the technique is appropriate in clinical practice.

In addition to LHD, the exposed lateral part of the femoral head was also measured as the lateral cartilage distance (LCD) in patients under 12 years of age. Little useful additional information was gained by determining this parameter which is in accordance with experience based on arthrography (Gallagher et al. 1983). Moreover, the outline of the bony femoral head is more easily identified than that of the cartilaginous part. We therefore recommend LHD as the main parameter regarding femoral head coverage.

The anterior head distance showed that the whole bony femoral head was totally covered by the acetabulum in most hips. If a hip with HD has anterior protrusion or subluxation, this will be detected by an increased AHD.

The anterior capsule distance (ACD) is of little importance in hip dysplasia. However, all conditions with effusion or blood in the hip joint increase the ACD. This is therefore the main ultrasound parameter in transient synovitis (Kallio et al. 1985, Wingstrand 1986, Terjesen and Østhus 1991). The side difference was less than 2 mm in all normal hips, and the ACD increased somewhat with age, in keeping with our previous results (Terjesen et al. 1991).

We have adopted sonography as the primary imaging technique in all patients, regardless of age, referred for possible hip dysplasia. If that sonography is performed by an experienced examiner, the evaluation takes no more than about 5 min in most patients. If performed by the orthopedic surgeon as an integral part of the clinical examination, as was done in our study, we think ultrasound examination is time-saving and probably less expensive than separate radiographic and clinical examinations.

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## PAPER IV

Agnar Tegnander, Terje Terjesen. *The reliability of ultrasonography in the follow-up of hip dysplasia in children above 2 years of age.* Acta Radiol 1999;40:619-24.

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## RELIABILITY OF ULTRASONOGRAPHY IN THE FOLLOW-UP OF HIP DYSPLASIA IN CHILDREN ABOVE 2 YEARS OF AGE

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#### Abstract

*Purpose:* The aim of the present study was to assess whether ultrasonography (US) was reliable in the follow-up of children above 2 years of age who had previously been treated for congenital or developmental hip dislocation or dysplasia (HD).

Material and Methods: As part of the routine follow-up, we examined 53 children (106 hips), aged 2–12 years (mean 6 years). Using US, the coverage of the femoral head was assessed by the distance from the lateral tangent of the ossified femoral head to the lateral bony acetabular rim (lateral head distance, LHD). The corresponding distance was measured on radiographs (LHDR). The radiographic femoral head coverage was assessed by the migration percentage (MP) and the center-edge (CE) angle.

**Results:** We found a good accordance between sonographic LHD and the radiographic parameters MP and CE in all age groups, indicating that femoral head coverage was reliably assessed by US. There was also a high correlation between LHD and LHDR (r=0.85). All hips with subluxation were detected by US. In 11 hips that appeared normal on US, but with dysplasia or uncertain findings by radiography, the condition spontaneously normalized in 9 out of 9 examined hips with further follow-up.

*Conclusion:* Because a reliable assessment of the hip is obtained, we recommend that US should be used as the primary imaging technique in the routine follow-up of children above 2 years of age with previous HD. Radiography should be omitted when US shows normal findings and is only needed when the US LHD is above the upper normal limit or the hip looks abnormal or suspicious by subjective evaluation.

The use of ultrasonography (US) in the diagnosis and follow-up of infants with congenital and developmental hip dislocation and dysplasia (HD) has been widely accepted during the last decade. In follow-up of older children, however, US has so far been tested by our group only (10). Taking into account the high amount of radiation these children are exposed to during conventional diagnosis, treatment, and follow-up, the availability of alternative imaging techniques would be advantageous (7). Correspondence: Agnar Tegnander, Department of Orthopedics, Trondheim University Hospital, N-7006 Trondheim, Norway. FAX +47 73 86 87 22.

Key words: Hip joint, congenital hip

dysplasia; ultrasonography;

radiography, radiation dose;

pediatric.

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Irrespective of the patient's age, femoral head coverage is the most important measurement in HD (3), because maintained concentric reduction is a prerequisite of normal development of the hip. Residual subluxation or dysplasia leads to arthrosis (11). Femoral head coverage is routinely measured by radiography, but can also be assessed by US. Thus, the aim of the present study was to evaluate the reliability of US in determining femoral head coverage in older children during followup of previously treated HD.

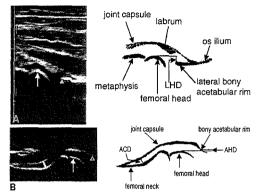


Fig. 1. Ultrasonograms and schematic drawings of a normal right hip. A) Lateral view. The lateral head distance (LHD) is indicated on the schematic drawing. LHD is 4 mm in this hip. The ossification center of the femoral head is marked by an arrow and the lateral bony acetabular rim by a triangle. B) Anterior view. The anterior head distance (AHD) and the anterior capsule distance (ACD) are indicated on the schematic drawing. The ossification center of the femoral head is marked by an arrow, the anterior bony acetabular rim by a triangle, and the ACD is marked with a bar on the US image.

#### Material and Methods

During the period 1988–1995, we used US in the follow-up examinations of 53 patients above 2 years of age (48 girls, 5 boys), who had previously been treated for neonatal (12 cases) or late-detected (41 cases) HD. Late-detected HD was HD detected after 1 month of age. The diagnosis was made with radiography and US. The primary treatment methods were Frejka pillow (11 patients), abduction splint (2 patients), closed reduction and plaster bandage (38 patients), and open reduction (2 patients). Four hips developed avascular necrosis (AVN) and 2 hips redislocated. A total of 17 hips needed additional treatment (femoral osteotomy in 7 hips, femoral and pelvic osteotomy

in 5, pelvic osteotomy in 1, and other procedures in 4 hips). The children had several follow-up examinations, and one random examination of each child at the age of 2 years or later, including both US and radiography, was used in the present study. The mean age at this follow-up was 5.9 (range 2– 12) years. The patients were divided into 3 age groups: 2–3 years of age (14 patients), 4–7 years (24 patients), and 8–12 years (15 patients).

The US method of TERJESEN et al. (10) was used: the patient was lying in the supine position with extended hips and the legs in neutral position regarding rotation and abduction/adduction. Scanning was performed from the lateral and anterior aspects of the hip region with a 5 MHz linear transducer. With the transducer kept parallel with the long axis of the body, a lateral longitudinal scan was employed showing the lateral anatomic landmarks of the hip joint. When depicting the central part of the femoral head, the distance from the lateral tangent of the ossification center to the lateral bony acetabular rim was measured (Fig. 1a). This was called the lateral head distance (LHD), which is an indirect measure of the femoral head coverage by the acetabulum. The less the femoral head is covered, the larger the LHD is; thus, this measurement indicates the degree of severity of HD. When the whole ossification center was medial to the lateral bony rim, the LHD was given a minus sign. For classification of hips as normal or abnormal, our previous studies on the limits of normal variation were used (8, 10). Thus, the upper normal limits of LHD were 4 mm at the age of 2-3 years, 5 mm at age 4-7 years, 6 mm at age 8-11 years, and 7 mm for children 12 years or older.

The anterior scan was employed with the transducer parallel with the long axis of the femoral neck, visualizing the central parts of the hip joint (Fig. 1b). Two parameters were measured: the distance from the anterior tangent of the ossification center of the femoral head to the anterior bony

Table 1           Mean values and SD of the US and radiographic measurements													
Age Hips, groups, years n	Hips,			US	5		_			Radiog	raphy		
	n	LHD,	LHD, mm		AHD, mm		ACD, mm		, mm	MP, %		CE, °	
			Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean
2–3	28	3.3	1.7	-1.9	1.0	4.0	0.6	3.7	1.8	21.9	11.2	15.8	6.6
47	48	3.5	2.2	-1.3	1.2	4.2	0.7	3.4	2.6	14.5	9.8	20.4	5.6
8-12	30	4.4	2.7	-0.8	1.4	4.3	0.9	6.5	4.1	18.1	8.6	23.0	7.4

LDH=lateral head distance, AHD=anterior head distance, ACD=anterior capsule distance, LHDR=radiographic LHD, MP=migration percentage, CE=center-edge angle.

Table 2           Comparison of sonographic LHD and radiographic LHDR in the 3 age groups									
Age groups, years	Hips, n	Differer (LHDR-I		Limits of agreement*	Correlation coefficient				
		Mean mm	SD	-					
23	28	0.4	0.8	-1.2-2.0	0.89				
4–7	48	-0.1	1.1	-2.3-2.1	0.90				
8-11	30	2.1 1.8		-1.5-5.7	0.87				

rim of the acetabulum (anterior head distance, AHD), and the width of the anterior joint space (anterior capsule distance, ACD). When the tangent of the femoral head was posterior to the anterior bony rim, the AHD was given a minus sign. The ACD was measured as the distance between the anterior joint capsule and the femoral neck at the level of the neck concavity (10).

On conventional a.p. radiograms obtained with the patient in the supine position with parallel legs and no hip rotation, the distance from the lateral tangent of the femoral head to the lateral acetabular rim was measured. This was called lateral head distance by radiography (LHDR) and is similar to the LHD by US. We used a substraction factor of 10% for the measured LHDR to correct for magnification. The femoral head coverage was assessed by measurements of the migration percentage (MP) (4) and the center-edge (CE) angle (12). CE angles of 15° or greater and an MP of 25% or less were recorded as normal. A hip was classified as normal when both the MP and the CE angle

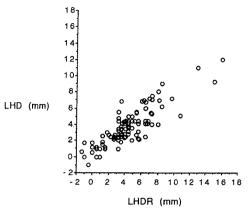


Fig. 2. Scatterplot of the lateral head distance by US (LHD) and radiography (LHDR). The correlation coefficient is 0.85.

were normal, as uncertain when one of the measurements was abnormal and the other was normal, and as abnormal when both measurements were abnormal.

Statistics: We used one-way analysis of variance (ANOVA) with Scheffe's F-test to compare group means. The significance level was set at p < 0.05. The correlation between various parameters was expressed as Pearson's correlation coefficient (r) and limits of agreement.

#### Results

US and radiographic measurements are shown in Table 1. The mean difference between LHDR and

Table 3           US and radiographic measurements in 11 hips that were normal by US but abnormal or uncertain           by radiography								
Age groups, years	Case	Pres	ent examina	tion	Femoral head coverage as			
		LHD	MP	CE	latest follow-up			
23	5	3.6	27	13	Normal			
	6	2.4	20	13	Not attended			
	10 right hip	2.8	31	10	Normal			
	10 left hip	3.5	28	11	Normal			
	11	3.7	24	14	Normal			
	12 right hip	2.5	30	*	Normal			
	12 left hip	3.5	30	*	Normal			
	13	3.8	27	15	Not attended			
47	31	4.1	30	10	Normal			
	36	4.4	25	13	Normal			
8-11	52	5.1	29	15	Normal			

LHD=lateral head distance, mm. MP=migration percentage, %. CE=center-edge angle, °. \*CE angle not measured because of small ossification centers (13 mm width bilaterally).

Fig. 3. A–C) Ultrasonograms and radiograph of both hips in a 3-year-old girl. Symbols as in Fig. 1. F is femur; I is os ilium. The right hip (R) is normal, whereas the left hip is subluxated (LHD 6 mm, MP 42%).

LHD (LHDR-LHD) of the 106 hips was 0.7 mm (SD 1.6). Pearson's correlation coefficient (r) was 0.85 (Fig. 2). The limits of agreement ( $\pm$ 2SD) was from -3.9 to 2.5 mm. The mean difference was somewhat higher in the oldest age group than in the two younger groups (Table 2).

The correlation coefficient between LHD and MP was 0.79 in the youngest age group, 0.82 in the middle, and 0.83 in the oldest group. There was also a high correlation between LHD and CE angle: -0.82, -0.66, and -0.73, respectively, in the three age groups.

The correlation coefficient between LHDR (the radiographic parameter) and MP was 0.90 to 0.96 in the 3 groups. Between LHDR and CE angle, the correlation coefficients were -0.91, -0.79 and -0.82, respectively. The correlation coefficients between MP and CE were -0.95, -0.88, and -0.91, respectively, in the three age groups.

By radiography, 80 hips were assessed normal, 17 abnormal, and 9 uncertain. Eighty-two hips were normal and 24 were abnormal by the US evaluation. Of the 17 radiographically abnormal

#### A. TEGNANDER AND T. TERJESEN

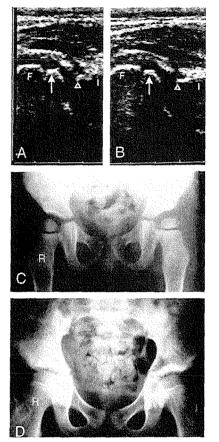


Fig. 4. A-C) Ultrasonograms and radiograph of both hips in a 2-year-old girl (case no. 10). Symbols as in Fig. 3. Both hips are normal by US but dysplastic by radiography. No treatment was started. D) Radiograph of the same patient at 11 years of age, showing normal development of the hips (MP 10% and 15%).

hips, 13 were also abnormal (true-positive) by US (Fig. 3), whereas 4 were normal (false-negative) (Fig. 4). Of the 80 radiographically normal hips, 71 were also normal by US (true-negative), whereas 9 were abnormal (false-positive).

The specificity of US was 89% and the negative predictive value was 95%. A recent follow-up of the 9 patients (11 hips) with normal US and abnormal (4 hips) or uncertain (7 hips) radiography has been performed. Two patients did not appear at this follow-up. All the other patients (9 hips) had developed femoral head coverage regarded as normal without any treatment (Table 3).

#### Discussion

Apart from avascular necrosis, the coverage of the femoral head is the most important parameter during follow-up of previously treated cases of HD. Although radiography is appropriate for measurement of femoral head coverage, patients treated for HD often need many radiographic examinations during childhood and adolescence, exposing them to a considerable amount of radiation. This was the obvious reason why we started to use US in the follow-up, not only of infants, but of all children.

An indispensable condition for replacing radiography with US in the routine follow-up is that the US measurements are reliable. There was a good accordance between the US LHD and the radiographic measurements of MP and CE angle, confirming our previous experience that femoral head coverage can be reliably assessed by US (8, 10).

If US is used as the primary imaging method, the measurement limits between normal and abnormal hips are important because radiography is omitted when the US evaluation shows normal hip joints. Based on our previous studies (8, 10), we defined the upper normal limit of LHD as a mean value+2SD of normal hips. The present results did not indicate that these limits should be changed. Thus, reasonable limits are 4 mm in children 2–3 years, 5 mm in those aged 4–7 years, 6 mm in those aged 8–11 years, and 7 mm in children 12 years or older.

Another prerequisite for recommending US as the primary imaging method is that all hips with true pathology can be detected. Hips with frank dislocation are easily diagnosed by US (but there were no such hips in the present material). All the radiographically subluxated hips were also abnormal by US. However, among those with acetabular dysplasia only or uncertain radiographic findings, there was some discrepancy between the methods. This was not unexpected, considering that both techniques involve certain sources of error. First, the lateral acetabular rim, which is an important anatomic landmark in both US and radiography, can be rounded and difficult to define exactly, especially in dysplastic hips. Secondly, the CE angle is not consistently reproducible in children below 5 years of age (2, 5).

In children, the CE angle has to be below  $15^{\circ}$  to be classified as abnormal (2, 6). A sharp distinction between dysplasia only and subluxation is hard to establish, but  $10^{\circ}$  seems to be a reasonable limit. With regard to MP, REIMERS (4) used 33% as the limit for subluxation, whereas EKLÖF et al. (1) recommended a somewhat lower limit. Based on these reports and our previous results in normal hips, we consider the limits of 25% for dysplasia and 33% for subluxation to be appropriate.

These reservations to the accuracy of radiographic evaluation should be kept in mind when radiography is used as the "gold standard", and when designating the US results as "true-" and "false"-positives and -negatives. The consequence of false-positives is not serious, because a radiograph would then be obtained and reveal no real pathology. False-negatives, however, could represent a more serious problem, as slight degrees of dysplasia would not be detected. If spontaneous resolution occurs, as has been reported in many such hips (6, 12), there is no harm done. On the other hand, if the abnormality is persistent, a falsenegative US would entail a delay in diagnosis and treatment. This was the reason why further followup was performed in the patients with normal US and abnormal or uncertain radiography. Not unexpectedly, considering that these hips had minor degrees of radiographic abnormalities, 9 of 9 examined hips developed femoral head coverage regarded as normal, with both MP and CE angle within normal range. One of these hips had a known avascular necrosis at the time of the primary study. Two patients with uncertain radiography at 2-3 years of age did not show up for this late follow-up examination. If we assume that these 2 hips developed normally as did the other hips with discrepancy, the true number of falsenegatives was zero, confirming the reliability of the US evaluation.

The anterior US measurements AHD and ACD were normal in all our patients, thus giving limited additional information. Nevertheless, we always included the anterior scan because an anterior subluxation would be detected by an increased AHD and exudate and other types of fluid in the joint are diagnosed by an increased ACD. In avascular necrosis, the development of fragmentation of the femoral head can be seen, as previously described in Perthe's disease (9).

The practical consequence of the present study is that US should replace radiography as the routine imaging method in follow-up of HD. Radiography is required only when US shows abnormal or suspicious findings. Because the majority of the hips develop normally, this policy will greatly reduce the radiation dose to this patient group. We have a US unit available at the out-patient clinic and the orthopedic surgeon performs US as an integral part of the clinical examination. This represents a rational and time-saving policy compared with the traditional procedure of separate radiographic and clinical examinations.

623

#### A. TEGNANDER AND T. TERJESEN

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## PAPER V

Agnar Tegnander, Ketil Jarl Holen, Terje Terjesen. *The natural history* of hip abnormalities detected by ultrasound in clinically normal newborns. A 6-8 year radiographic follow-up study of 93 children. Acta Orthop Scand 1999; 70(4): 335-7.

# The natural history of hip abnormalities detected by ultrasound in clinically normal newborns

A 6-8 year radiographic follow-up study of 93 children

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Ultrasound screening for hip dysplasia or dislocation has revealed a group of children with clinically normal hips, but with abnormal or suspicious ultrasound. During the 3-year period 1988–90, we found 170 children with this combination. We evaluated the natural history of these hips.

93 children were examined clinically and with standard radiography 6–8 years after birth. The center edge (CE) angle of Wiberg and migration percentage (MP) were measured on the radiographs.

87 children had not undergone any treatment, whereas treatment with an abduction orthosis had been initiated at approximately 4 months of age because of persisting dysplasia in 6 cases. All hips were radiographically normal at this follow-up. The mean CE value was 24 degrees (SD 6.5) and the mean MP was 13% (SD 5.2). 73 children had no complaints in their lower extremities, whereas 12 had intoeing gait, 1 had outtoeing gait, 2 had hip or knee pain, and 5 had other complaints not relevant to hip dysplasia.

We conclude that infants with sonographically abnormal or suspicious hips, but with normal clinical findings, do not need immediate treatment because spontaneous resolution occurs in most of them. Postponement of treatment in the few with persistent dysplasia does not seem to affect the outcome.

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With the introduction of ultrasound screening for hip dysplasia and dislocation (HD) in newborns, a group of children with clinically normal hips, but with abnormal ultrasound, has been identified (Berman and Klenerman 1986, Clarke et al. 1989, Terjesen et al. 1989, Castelein et al. 1992, Graf et al. 1993). There is no agreement as to whether these infants should be treated from birth or be followed without any treatment initially. We have previously found that most of these hips will normalize spontaneously (Terjesen et al. 1996), but the follow-up period was limited to the first 4–5 months of life. The aim of the present study was to determine whether such hips would continue to develop normally.

## Patients and method

During the 3-year period 1988–90, we examined 4,973 children with ultrasound as part of a pro-

spective randomized study, to evaluate the efficiency of ultrasound screening for HD. The newborns were examined with the Ortolani and Barlow tests by an experienced pediatrician on the first day of life. Ultrasound examination was performed by the orthopedic surgeon 2–4 days after birth, when we also repeated the clinical examination. We used the ultrasound technique of Terjesen et al. (1989), which is based mainly on measurement of the femoral head coverage (FHC).

170 (3.4%) children (134 girls) with normal hips at the clinical examinations had pathologic ultrasound findings (FHC < 50%) at birth. The mean FHC at birth in these hips was 44% (34–48). The infants were not treated from birth, but were examined at 2–3 months of age (ultrasound and clinical examinations) and at 4–5 months (ultrasound, radiographic and clinical examinations). At 4–5 months of age, 10 infants, all girls, had persistently abnormal hips on ultrasound and radiographs. They were treated with an abduction

				CE			MP	
Number of hips	US at birth	Treatment <sup>a</sup>	mean	SD	range	mean	SD	range
122	Abnormal	No <sup>b</sup>	24	5.3	1537	13	6.5	-524
52	Normal	No	25	4.9	17–36	11	6.1	0-22
8	Abnormal	Yes	21	4.7	17–30	19	4.9	10-25
4	Normal	Yes <sup>c</sup>	19	4.4	1525	18	7.6	7–25

Radiographic results in the 93 children at the follow-up examination at 6-8 years of age

<sup>a</sup> From 4–5 months of age. <sup>b</sup> Not treated because of normalization.

<sup>c</sup> Treated because contralateral side showed persistent dysplasia.

US ultrasound, CE center edge angle, MP migration percentage, SD standard deviation.

orthosis and developed normally (Terjesen et al. 1996). The remaining infants developed normally without treatment, and no further routine followup was performed.

All 170 patients were asked to attend a followup examination 6-8 years after birth. A clinical examination was performed and a standard supine anteroposterior pelvic radiograph was obtained to evaluate the development of the hips. We recorded any pain in the hip, thigh or knee and gait disturbances, and performed a hip motion examination. The range of hip motion was measured to the nearest 5 degrees. On the radiographs, we measured the migration percentage (MP, Reimers 1980) and the center edge (CE) angle (Wiberg 1939). MP of 25% or less and CE angle of 15 degrees or more were considered normal. A hip was classified as abnormal when both the CE angle and the MP were outside these limits. When one of the measurements was abnormal and the other normal, the hip was classified as having "possible dysplasia".

## Statistics

The difference between groups was calculated with the chi-square test. The difference between means was calculated with the Student's t-test or with one-way analysis of variance (ANOVA) using the Scheffe test. The significance level was set at 0.05.

## Results

93 (55%) children (70 girls) attended the followup examination after 6–8 years. Their mean age was 7.1 (6–8) years. The mean FHC of the affected hips (130) at birth in this group was 44%, the same as in the group not attending the follow-up examination (92 affected hips) (p = 0.8). The two groups were also similar regarding risk factors for HD (family history and breech position) and birth weight.

73 children had no complaints about their lower extremities, whereas 12 had intoeing gait, 1 had outtoeing gait, 2 had hip or knee pain, and 5 had other complaints not relevant to HD. The range of motion (ROM) of the hips was slightly reduced compared to a normal population.

All the children attending the follow-up examination had normal radiographs (Table).

Of the 93 children, 87 had not undergone treatment, whereas 6 had been treated with an abduction orthosis from approximately 4 months of age, because of persisting dysplasia (Terjesen et al. 1996). The mean CE angle of the treated hips was 21 (17–30) degrees, and the mean migration percentage was 19 (10–25)%. The MP of the pathologic hips in the treatment group was significantly larger than that of normal hips in the untreated group.

## Discussion

Since most authors recommend immediate treatment in newborn infants with abnormal ultrasound findings, but normal clinical findings (Hauck and Seyfart 1990, Tönnis et al. 1990, Ganger et al. 1992, Millis and Share 1992, Graf et al. 1993), there are few reports on the natural history of such hips. Short-term results have shown that most of these hips normalize without treatment (Castelein et al. 1992, Terjesen et al. 1996). We found that the hips have remained normal when reviewed after 6–8 years. Thus, the assessment by ultrasound during the first 4–5 months of life proved to be sufficient, as no hips in the untreated group had deteriorated at further followup.

Compared to normal children of the same age (Terjesen et al. 1991), our study showed that the untreated children had somewhat lower coverage of the femoral head (lower average CE angles and higher MP). CE angles between 15 and 20 degrees were found in several cases, indicating that the final result is still somewhat uncertain and that these children should be reviewed at the end of the growth period. Previous studies have shown an increase in the CE angle with age in normal children (Severin 1941, Fredensborg 1976), resulting in a lower normal limit of 20–25 degrees in adults (Wiberg 1939). Whether all children reported here will eventually reach this level remains to be seen.

Several children had a slightly reduced range of motion. Apart from the trend towards intoeing gait, they had no complaints and had normal physical activity. Thus, the decrease in range of motion had little, if any, clinical significance.

The 6 children who had been treated with an abduction orthosis from 4-5 months of age also had radiographically normal hips at the follow-up examination. However, the CE angle in this group was lower than that in the untreated children. This indicates that the treated children represent a subgroup with true HD, whereas the remaining children had slight abnormalities that spontaneously resolved or never had any real abnormalities, but only "immature" hips during the first months of life. We have found that the postponement of decision regarding treatment had no negative effects on the outcome. Unless the hip becomes obviously dislocated or severely subluxated-in which case treatment should be started immediatelythe expectant attitude that we adopted seems advisable. This policy will reduce overtreatment of neonatally abnormal hips diagnosed with ultrasound in clinically normal children. It should be emphasized that a prerequisite for this expectant attitude is that the clinical examination be performed by examiners with great experience.

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## PAPER VI

Agnar Tegnander, Ketil Jarl Holen, Svein Anda, Terje Terjesen. Good results after treatment with the Frejka pillow for neonatal hip instability. A 3-6 year follow-up study. Submitted for publication.

# Good results after treatment with the Frejka pillow for neonatal hip instability A 3-6 year follow-up study

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## Abstract

Because there is no consensus with regard to the efficiency of the Frejka pillow in the treatment of neonatal hip instability (NHI), the aim of the present study was to evaluate our results with this device. During the 3-year period 1988-90, the Frejka pillow was used in 108 newborns with clinical NHI verified by ultrasonography. There were 3 treatment failures (2.8%), defined as infants who needed additional treatment with an abduction splint or hip-spica cast. Avascular necrosis (AVN) of the femoral head occurred in one patient (0.9%).

At an age of 3-6 years, 85 of the children attended a follow-up examination. An intoeing gait was observed in 17% and slightly reduced hip mobility in 20% of the patients. As compared with normal children, the patients had somewhat lower coverage of the femoral head by radiography, indicated by a lower center-edge angle and a higher migration percentage, but the coverage was within the normal range in all cases. The mean anteversion (AV) angle was larger than that of normal children but only 3 patients had abnormally high AV angles.

In conclusion, the results with the Frejka pillow were good, with few treatment failures and complications. More rigid devices like the von Rosen splint seem to involve a slightly lower failure rate, but a higher risk of AVN. Therefore, we still recommend the Frejka pillow when treatment is started within few days after birth.

# Introduction

Since neonatal hip screening was introduced in Norway about 40 years ago, the Frejka pillow has been the standard treatment for neonatal hip instability (NHI). This seems to have been a satisfactory treatment (17,23). However, controversy exists with regard to its effectiveness, and some authors have maintained that the Frejka pillow should be abandoned because of an unacceptable high rate of treatment failures and complications (7,13,14,15). A considerable frequency of abnormal radiographic findings in follow-up at age 4-7 years has also been published (5,6).

In the present study, our clinical and radiographic results after treatment with the Frejka pillow have been evaluated. The purpose was to reconsider the effectiveness of the Frejka pillow; should it still be recommended or should it be replaced by other, more rigid abduction devices?

# Patients and methods

During the 3-year period 1988-90 there were 9514 live births at our hospital. All newborns were examined clinically by a pediatrician with the Ortolani (27) and Barlow (2) tests on the first day of life. Infants with unstable hips were additionally examined by an orthopedic surgeon both clinically and by ultrasound after 1-3 days. All infants with neonatal hip instability (NHI) and subluxation or instability by ultrasound were treated with the Frejka pillow for 4 months. The treatment started immediately after the ultrasound examination.

All children were routinely followed with clinical and ultrasound examinations. The first follow-up examination was performed at 2-3 months of age. At the second follow-up at age 4-5 months a standard pelvic radiograph was also obtained. The last regular follow-up was at 12-14 months of age. For those with persisting pathologic or suspicious findings, further follow-up was carried through.

The ultrasound examination was done according to the techniques described previously by Terjesen et al. (35,36), mainly based on measurement of femoral head coverage (FHC) in newborns and infants and lateralization of the femoral head in older children. The radiographs were assessed by measurements of the acetabular index and coverage of the femoral head.

# Follow-up examination

The parents of all children treated with the Frejka pillow were asked by letter to participate in a clinical and radiographic follow-up study 3-6 years after the treatment period to evaluate the medium-term treatment results. We registered any pain in the hip, thigh, or knee and gait disturbances, and performed a clinical examination. The range of hip motion was measured to the nearest  $5^{0}$ . Normal range of motion included flexion of more than  $130^{0}$ , abduction of at least  $45^{0}$ , and a minimum of  $85^{0}$  internal plus external rotation. Internal rotation of  $75^{0}$  or more and external rotation of less than  $30^{0}$  was considered as internal rotation deformity (34).

All children were examined by radiography. An antero-posterior radiograph with the child supine and the legs in neutral position was obtained. The femoral head coverage was assessed by the migration percentage (MP)(29) and the center-edge (CE) angle (38). CE-angles of  $15^0$  or larger and MP of 25 % or less were recorded as normal.

A hip was classified as abnormal when both the CE-angle and the MP were outside these limits. When one of the measurements was abnormal and the other was normal, the hip was classified as "possible dysplasia". In the oldest children (49 cases), the anteversion (AV) angle of the femur was measured according to Rippstein (30). The upper normal limit of AV-angle (mean + 2SD) in this age group is  $46^{\circ}$  in boys and  $48^{\circ}$  in girls (6). The occurrence and degree of avascular necrosis of the femoral head (AVN) was classified after Kalamchi and McEwen (20).

# Statistics

Comparison of mean values in neonatally stable and unstable hips was carried out by the two-sample t-test. The significance level was set at p < 0.05. The correlation between various parameters was expressed as Pearson's correlation coefficient (r).

# Results

108 neonates (1.1% of all live births) were treated with the Frejka pillow (94 girls and 14 boys). Since 36 infants had bilateral NHI, a total of 144 hips were abnormal. Clinical grading of the instability was positive Ortolani test in 42% of the hips and less pronounced instability (positive Barlow test) in 58% (19). The mean FHC by ultrasound at birth was 37% in the unstable hips and 47% in the stable hips. At 4-5 months of age, all except 5 infants had normal hips by both ultrasound and radiography. Of those with abnormal findings, spontaneous normalization occurred in 2 babies, whereas treatment with abduction orthosis was started some months later in 2 infants because of persisting dysplasia, and with hip-spica cast in one patient because of slight subluxation (Fig. 1).

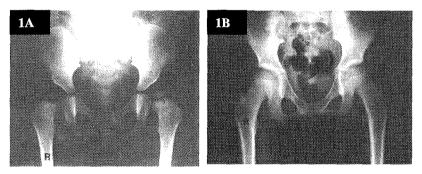


Figure 1a. Radiograph of a 12-mont-old girl who needed additional treatment because of recurrent dysplasia.

Figure 1b. At the last follow-up examination at 9 years of age, there is still somewhat low coverage of the right femoral head (CE angle  $17^{0}$ , MP 27%).

There were no cases of severe subluxation or frank dislocation. The three patients with additional treatment were girls with high birth weights (3789 g, 4129 g, and 4540 g) and with bilateral NHI, and low sonographic FHC at birth (31 and 33%, 29 and 40%, and 38 and 30%). One of these girls developed AVN of the left hip, grade 3 (Fig. 2).

## Follow up

Of the 108 children, 85 (79 %) appeared at the follow-up examination at age 3-6 years. There were 74 girls and 11 boys with a mean age of 4 years and 4 months (36-75) months).

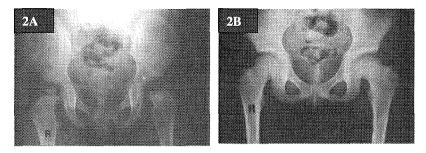


Figure 2a. Radiograph at 20 months of age of the girl who developed avascular necrosis of her left femoral head.

**Figure 2b.** At the last follow-up (6 years of age), the hip has developed satisfactorily, although the femoral head is larger and the neck is shorter and broader as compared with the contralateral hip.

Seventy-nine (93%) children had no complaints from their lower extremities. Four had minor complaints not relevant to hip dysplasia (HD). Two children had an internal rotation deformity and complaints because of the intoeing gait. Thirteen other children with intoeing had no complaints, neither had one child with outtoing gait.

The range of hip motion (Table 1) was normal in 68 children (80%) and slightly reduced in 17 (20%).

Table 1. Range of hip motion in 85 children treated with the Frejka pillow

Flexion		Extension		Abduction		Int. Rot		Ext. rot	
Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
138	4.8	22	3.2	59	12.4	66	14.9	35	5.2

Int. rot, internal rotation. Ext. rot, external rotation. SD, standard deviation.

The most frequent abnormality was decreased total rotation in 9 children  $(75^{\circ}-85^{\circ})$ . Reduced abduction was seen in 4 children  $(25^{\circ}-45^{\circ})$  and 2 children had reduced flexion  $(120^{\circ}-130^{\circ})$ . The radiographic results are shown in Table 2. Table 2. Radiographic results at age 3-6 years in 85 children treated with the Frejka pillow from birth

Hip status		CE		MP		AV		CCD	
at birth	n	mean	SD	mean	SD	mean	SD	mean	SD
NHI	131	26	6.2		6.1	36	7.8	136	8.2
Normal	39	27	5.3	10	5.8	34	8.0	139	8.2

n, number of hips. NHI, neonatal hip instability. CE, center edge angle. MP, migration percentage. AV, anteversion angle. CCD, neck-shaft angle. SD, standard deviation.

There were no significant differences between the previously stable and unstable hips. All the patients had CE angles of  $15^{\circ}$  or higher and MP of 25 % or lower, indicating femoral head coverage within the normal range. The femoral AV-angles were abnormally increased bilaterally in two girls ( $53^{\circ}/53^{\circ}$  and  $55^{\circ}/55^{\circ}$ ) and in one boy ( $47^{\circ}/47^{\circ}$ ).

The 3 girls who needed additional treatment had no complaints from their lower extremities. The girl with avascular necrosis of her left hip had slightly reduced total rotation  $(80^{0})$  and  $10^{0}$  lower abduction on the left side  $(50^{0} \text{ versus } 60^{0})$ . At the last follow-up at 6 years of age, the size of the left femoral head was slightly increased, but the CE angle and MP ( $20^{0}$  and 17%) were within the normal limits (Fig. 2). The femoral neck was shorter and broader than normal. One of the two other girls, who had CE and MP within normal limits at 6 years of age, had somewhat reduced femoral head coverage of her right hip at an additional follow-up at 9 years of age (Fig. 1).

### Discussion

The aim of the treatment is to obtain and maintain adequate reduction of the femoral head. Treatment failure, defined as displacement of the femoral head (subluxation or dislocation) and acetabular dysplasia (abnormally high acetabular index), can occur during the treatment period or the subsequent months. Patients with treatment failure need additional treatment with abduction orthosis or hip spica plaster cast, and in severe cases even closed or open reduction. Some authors have reported that the Freika pillow involves an unacceptable high rate of treatment failures as compared with the von Rosen splint (13, 14, 16). Heikkilä (14) had 6% treatment failures with the Frejka pillow but only 0.6% with the von Rosen splint. However, the two methods were used during different periods and the results are therefore not directly comparable. Hiertonn and James (16) had 3% treatment failures with the Frejka pillow and advocated change to von Rosen splint. Almby and Rehnberg (1) evaluating the results from a later period at the same hospital when both the Frejka pillow and the von Rosen splint were used, found that the failure rates were similar (4% and 3.6% respectively). Hansson et al. (13) reported failure rates of 5.5% after Frejka treatment and 0.6% after the von Rosen method. These figures, based on Hansson's thesis (12) on the treatment of NHI in Gothenburg, refer to a subgroup and not to the total material. If all infants needing additional treatment because of acetabular dysplasia or displacement are included, the failure rates were similar (Frejka pillow 2.8% and von Rosen splint 3.8%). Hinderaker et al. (17) found no difference between the two methods in the acetabular index at the end of treatment.

According to previous reports and including the present results, the median rate of treatment failures with the Frejka pillow is 4%, with a range of 2.8 - 9.7% (1, 6, 12, 13, 14, 16, 17, 23). The corresponding figures with the von Rosen splint (including similar abduction splints) are 2.7 (0 - 6.7) % (1, 3, 4, 9, 10, 11, 12, 13, 14, 17, 31, 32). Although slightly in favor of the von Rosen splint, the difference is small and hardly of clinical significance. We therefore do not agree with Hansson et al. (13) who maintained that the Frejka pillow does not provide reliable retention of the femoral head in the reduced position.

One matter that might have contributed to our low failure rate is the size of the abduction pillow. This should be the same as the distance between the knees in maximal unforced abduction of the flexed hips. We mostly used a 20 cm pillow in newborns of normal birth weight. If a too small pillow is used, the correcting effect will be reduced and the rate of treatment failures will probably rise.

The three patients who needed additional treatment had pronounced clinical instability and very low FHC by ultrasound at birth. It seems that particularly low femoral head coverage at birth reflects a more severe form of NHI, which needs more careful follow-up than routine procedure. In such cases, change of treatment from Frejka pillow to a more rigid abduction splint or plaster cast should be considered if the hips are persistingly abnormal or suspicious during the first months of life.

The most serious complication is avascular necrosis (AVN) of the femoral head. This is caused by the treatment and has been reported with the use of all types of abduction devices. In a review article on conservative treatment in newborns and infants, Herring (15) maintained that the Frejka pillow had a too high rate of AVN and therefore should not be recommended, referring to previous studies (14, 37) to support this view. However, these references are not relevant for judging the Frejka pillow as treatment in NHI, because the reason for an unacceptable high rate of AVN was inclusion of infants with treatment start after the neonatal period in one study (37) and cases with additional traction and plastering due to treatment failures in the other (14).

Including only patients where treatment started during first week of life, the median AVN rate of the present and 5 previous studies is 0.5 % with a range of 0 - 2 % (6, 8, 18, 24, 28). The median AVN rate with the von Rosen splint (including similar abduction splints) is 3.3 %, with a range of 0 - 6.7 % (3, 4, 9, 10, 11, 12, 25, 31, 33). This indicates a somewhat greater risk of AVN with the more rigid abduction splints as compared with the Frejka pillow, which is an important reason why we still prefer the Frejka method.

Currently, the Pavlik harness seems to be the most widely used treatment in infants below 6 months of age (15, 28). The advantage with the harness are that it allows some hip motion and that the child remains in the device during diaper changes. The disadvantages are the need of weekly visits to the hospital to adjust the straps as the

child grows, and that serious, though rare, complications like femoral nerve palsy and inferior dislocation have been reported (26).

At follow-up the frequency of intoeing gait was 17%, which accords well with previous reports of 10% (24) and 17% (6). Although this rate is higher than that of controls at the same age (6), few children had complaints because of the intoeing. With regard to range of hip motion (ROM), Cyvin (6), examining children in the same area as we did, found that 20% of the girls and 10% of the boys had abnormal ROM; the most common deviation was increased internal and reduced external rotation. Other follow-up studies of various treatment devices including the Frejka pillow have found normal range of motion in all the children (10, 22, 24). This hardly corresponds with our frequency of 20% with reduced ROM. However, the reduction in mobility was small and did not influence on the children's daily activities.

As compared with a control group 4 - 6 years of age, Cyvin (6) reported 6 -  $7^{0}$  higher mean AV angle,  $2^{0}$  higher neck - shaft angle, and  $2^{0}$  lower CE angle in children who had been treated with the Frejka pillow. Compared with Cyvin's treatment group, we found similar results regarding AV and neck - shaft angles, but  $4^{0}$  lower CE angle. The CE angle was, however, higher than  $15^{0}$  and thus within the normal range in all our patients. When assessing the coverage of the femoral head, the migration percentage (MP) is an adequate supplement to the CE angle. The mean MP of 11% in hips with NHI is somewhat higher than the 8% found in normal children at the same age (36), but all our patients had MP less than 25% and thus whithin the normal range.

We found that only 3.5 % of the children had abnormally high AV angles at follow-up, whereas Cyvin (6) and Bjerkreim (5) had 14% and 12%, respectively. We have no explanation for this difference, but our mean AV angle of  $36^{0}$  confirms the trend towards increased anteversion in hip dysplasia (5,6).

The Frejka pillow is simple to use and only one follow-up examination at approximately 2 months of age is necessary to see whether the pillow has to be changed to a larger size and to confirm by ultrasound that the treatment is effective. The pillow has to be removed every time diapers are changed. Whether this theoretical disadvantage represent any true unfortunate effect, is uncertain. Although it could increase the risk of displacement of the femoral head, it could also decrease the risk of AVN. When using von Rosen splint, there is an increased risk of skin irritation and pressure sores (14, 22). Thus, more careful supervision is necessary and the infant has to go to the hospital once a week for follow-up and bathing. Because of practical problems with the splint, its use has been discontinued in some centers (22, 23). In our country with relatively long distances to hospitals for people from sparsely populated areas, the Frejka pillow seems to be the preferable device for practical reasons. Because we have had good results and few complications, we see no strong arguments for a change to other methods.

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