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DYNAMIC
ULTRASONOGRAPHY IN
NEONATAL HIP INSTABILITY
AND ACETABULAR
DYSPLASIA

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To Marie,
Daniel and Hanna
Abstract

The clinical hip examination, although highly sensitive in expert hands in detecting neonatal hip instability, can lead to considerable overtreatment. Ultrasound is increasingly being used to complement the clinical examination in assessing neonatal hip instability and acetabular dysplasia, often leading to increased treatment rate. Several different ultrasound methods are in use.

In this thesis a new dynamic ultrasound method was tested using a special examination table with transducer fixing device allowing one person to perform clinical hip examination with use of the Barlow/Palmén method with simultaneous ultrasonographic visualisation.

An examination table was constructed and tested by examining 57 infants of varying ages between 1 day and 10 months (paper 1). An upper feasible limit of about three months of age was established. The hip joint was easily visualized, and the femoral head and the acetabulum were kept in the field of view during the stress test, allowing measurements of the amount of hip instability to be made.

In order to compare the dynamic ultrasound method with clinical hip examination, 1072 hips (536 infants) were examined at a mean age of 12 days (paper 2). The inclusion criteria were risk factors for DDH, clinical signs of hip instability or ambiguous clinical findings. Use of subjective dynamic ultrasound evaluation led to a reduction in calculated treatment rate from 0.85% to 0.49% as compared to the clinical examination.

To investigate the relationship between neonatal hip morphology and stability, two methods of testing hip stability, the present dynamic ultrasound method and the clinical hip examination, were compared with a static ultrasound method, the Graf method (paper 3). Acetabular morphology correlated better to stability as assessed by dynamic ultrasound than to the clinical examination results, with Cohen’s kappa = 0.381 and 0.199 respectively. Of the hips that were dysplastic by the Graf method, 97% were unstable or dislocatable by subjective dynamic ultrasound evaluation. Of the hips that were unstable or dislocatable by subjective dynamic ultrasound evaluation, 21% had normal acetabular morphology according to the Graf method and 56% were immature.

Two methods of evaluating the anterior dynamic ultrasound examination were compared (paper 4). A subjective evaluation made during the examination and an objective evaluation made later on by making measurements of the femoral head movement based on recorded loops. The results were also compared with clinical hip examination and Graf’s ultrasound method. 498 infants (996 hips) with risk factors for DDH, clinical signs of hip instability or ambiguous clinical findings were examined at a mean age of 12 days. An upper normal limit of hip laxity in this age group of 3 mm absolute value and 20% relative to the femoral head diameter was established. Use of objective dynamic ultrasound evaluation with a threshold value of 20% resulted in a reduction of abnormal hips by 63% as compared to the clinical examination and by 45% as compared to the subjective dynamic ultrasound evaluation.
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This thesis is based on the following four papers:


Definitions and abbreviations

DDH - Developmental dysplasia of the hip
CDH - Congenital dislocation of the hip
NHI - Neonatal hip instability

Hip laxity - looseness of the femoral head in the acetabulum. Can be minor, normal “physiologic” laxity or consist in varying degrees of instability or dislocatability.

Minor hip instability - “physiologic” laxity not warranting treatment.
Moderate hip instability - instability warranting treatment in hips that are not dislocatable.
Major hip instability - instability of such an extent that the hip can be dislocated

Dislocatable hip - hip with major instability, more than 50 % of the femoral head diameter can be displaced out of the acetabulum.

Late detected DDH = DDH not detected by the neonatal screening program, usually DDH detected after 4 weeks of life.

Neonatal period - first month of life
Infant - a child up to two years of age

Dynamic ultrasound - unless otherwise stated anterior dynamic ultrasound using special transducer fixing device operated by one examiner, i.e., the new method proposed in this dissertation.

Dynamic ultrasound, subjective evaluation – the abovementioned dynamic ultrasound method in which the hip stability is evaluated during the examination on the basis of the visual appearance of the hip joint on the monitor combined with the feeling in the hands.

Dynamic ultrasound, objective evaluation - the stability is determined by measuring the movement of the femoral head in relation to the acetabulum, based on recorded loops, without knowledge of the subjective findings.
1 Introduction

1.1 Definition of DDH

Developmental dysplasia of the hip (DDH) is essentially a two component disorder affecting the neonate, which if left untreated will lead to manifest hip dislocation or a subsequent chronic hip disorder, or osteoarthritis. The term DDH includes unstable, dislocatable or dislocated hips as well as malformed, or dysplastic, hips, and encompasses the two components of the disorder: abnormal formation of the hip joint (dysplasia) and hip instability (laxity). It does not include teratogenic hip dislocation, neurogenic hip disorders, or hip abnormalities caused by other diseases. Formerly DDH was called congenital dislocation of the hip (CDH). The acronym DDH was first suggested by Klisic in 1989 (66), reflecting the dynamic nature of the disease, that not all cases are diagnosable at birth, and that the condition changes over time. The large majority are unstable rather than dislocated, at least at birth. True DDH has been defined in the literature as “those neonatal hips which, if left untreated, would develop any kind of dysplasia and therefore are to be included in the determination of DDH incidence” (10).

1.2 Prevalence of DDH and instability

The prevalence of DDH varies considerably in the literature, depending on the definition and on the time and method of hip screening (10;76;118;138), with figures ranging from 1.6 to 28‰. The lack of a true golden standard for measuring instability contributes to this large variation. The number of hips requiring surgery in an unscreened population is about 1 in 1000 (49;75;81;117), which gives a clue about the true prevalence. The pathophysiology and natural history of untreated DDH is however not well understood and the number of silent DDH that may turn up as early adult osteoarthritis of the hip is unclear (30). It has been suggested that up to 9% of primary hip replacements in the adult can have DDH as underlying cause (37).

1.3 Etiology

Several different causes of NHI and DDH have been suggested such as ligamentous hyperlaxity, mechanical forces, intrauterine malposition and genetic, racial, hormonal, geographical and environmental factors (20;28;80;139).

1.4 Treatment

The choice of treatment depends upon the age of the patient at the time of diagnosis and the severity of the DDH. The goal is to obtain and maintain a concentric reduction of the hip. Regarding uncomplicated neonatal hip dysplasia, especially when diagnosed in the first month of life, the treatment usually involves abduction splinting for a period of 6 to 12 weeks. The hip is concentrically reduced and fixed in abduction for a variable length of time to allow normal development of the acetabulum and the femoral head and to allow the laxity to stabilize. Several methods of splinting are used, including rigid splints such as the von Rosen splint and the Craig splint, dynamic splints such as the Pavlik harness, or use of double or triple nappies or the Frejka pillow.
(36;68;97;98;130;134). The method carries a small but potential risk of compromising the blood supply to the femoral head, leading to avascular necrosis of the hip when excessive abduction is applied (17;59;62;71). This risk has been gradually reduced by adhering to better techniques in forming and applying the splint. Other complications of treatment include redislocation and stiffness of the hip. The treatment period varies both geographically and depending on the child’s age at the start of the treatment. In Sweden a treatment period of 6 to 12 weeks is typical for DDH diagnosed in the first month. In infants over 6 months of age application of a spica cast is needed to hold the hip in place, preceded by closed reduction and adductor release. In severe cases and in older children an open reduction may be necessary, together with surgical correction of bony deformities of the acetabulum if present.
2 History

2.1 Short history of DDH diagnosis and treatment

The existence of DDH has been known since ancient times. The disease was described by Hippocrates (460 – 370 B.C.), who stated that it might be congenital and caused by an injury to the mother’s abdomen. That the condition might be hereditary was suggested by Ambroise Paré in 1578. Paletta in Italy gave the first pathologic and anatomic autopsy description in 1783. Camper stated in 1784 that it was more common in girls. Dupuytren presented a dissertation on hip joint dislocation in Paris in 1826. Charles-Gabriel Pravaz wrote a monograph on the subject in 1847 and is believed to have been the first to have made a successful reduction, which was achieved in 1836 in a 7-year-old boy. Roser, in 1860, was probably the first to suggest that it was possible to diagnose hip dislocation in the newborn, to dislocate the hip by adduction and to reduce it by abduction, and in 1879 he proposed that an abnormal fetal position might be a cause of hip dislocation (112). Adolf Lorenz advocated in 1895 conservative treatment with manual reduction under anesthesia and a subsequent attempt to retain the femoral head in the acetabulum to facilitate normal acetabular development. He considered that a diagnosis made before the child started to walk was uncertain, and maintained that the best age to initiate treatment was in the second year.

This idea of late onset of treatment persisted far into the 20th century. However, Froelich of Nancy observed as early as in 1910 (or earlier) that a tendency to dislocation could be diagnosed in the first week of life and that the sooner the treatment began the better the results. A late onset of treatment was also opposed by Peltesohn in 1920 (100). He maintained that treatment should be started as soon as possible and that the hips of newborn babies should be examined on the first day of life. Several others, in the 1930s, suggested early diagnosis and treatment, such as Loeffler,Frauenthal,Engelman, and Hohmann (53). The name dysplasia, with or without dislocation, was suggested by Hilgenreiner in 1925 (51).

In Sweden the principle of late initiation of treatment was followed routinely until the late 1930s. The treatment was usually started at an age of 2-3 years, with poor results, as was later observed by Severin in 1941 (116). The principle of commencing treatment as soon as the diagnosis was made (preferably before the age of 1 year) was introduced in Sweden by Waldenström in about 1937. The treatment at that time was plaster fixation of the hip. Waldenström proposed that the dislocation was congenital and used an aluminium abduction splint for treatment. Putti (102;103) introduced early treatment in Italy in 1921. By early treatment he meant treatment that started before the age of one year or as soon as the diagnosis was made. He introduced the concept of “predislocation”, meaning an increased acetabular angle without subluxation. Ortolani in Italy considered that the “click” sound heard on reduction could also be heard in cases of subluxation and should be the deciding factor for diagnosis. He proposed that all babies with this sign should be treated with a pillow between the legs. Ortolani advocated early diagnosis and treatment as soon as the diagnosis was made. In 1941 Frejka (36) adapted this treatment and proposed that all with a family history of hip dislocation, breech presentation, and limited abduction should be treated. Marx of Charcow (83) carried out what was probably the first extensive systematic investigation of the hips of newborns.
He found that almost half of the cases healed spontaneously, and proposed that the most reliable sign was the presence of slipping. V Haberler of Vienna was the first to diagnose a large number of dislocations in newborns and initiate treatment immediately. In the 1940s Hart in Minnesota proposed early treatment, and in 1952 (50) he described the occurrence of a “jerk sign” when the fovea of the femoral head met and rode over the acetabular ridge.

2.2 Clinical screening

Clinical screening of the hips of newborn infants started in the 1950s. Palmén (93;94), influenced by Hart in 1950, proposed routine examination (screening) in Sweden. Screening began in Bergen in 1953 by Walther and Moe (132), in Salt Lake City in 1956, by Coleman (24), and at the Mayo Clinic in 1960 (49).
3 The clinical hip examination

3.1 Newborn infants

The clinical hip examination of the newborn consists mainly of two tests: 1) a test using a method described by Ortolani in 1937 (90), for diagnosis of dislocated hips, and 2) a method most commonly named after Barlow, which he published in 1962 (7), for diagnosis of hip instability.

3.1.1 The Ortolani test

Le Damany (72;73) was the first to report, in 1910-1912, systematic examinations of newborn infants to detect dislocation. He used a method similar to that later described by Ortolani, whereby attempts are made to relocate a dislocated hip. It was in 1937 that Ortolani (90;91) first published his method of diagnosing a dislocated hip. The hip was abducted in 90 degrees flexion and a click was heard when the femoral head was reduced into the acetabulum. On adducting the hip the click was heard again when the femoral head again became dislocated. This test demonstrated dislocatable hips but not unstable ones.

Ortolani wrote: “Grasp both lower extremities with the palms of the hand. Place the thumb on the medial aspect of the thigh and the index and middle fingers on the greater trochanter. The right thigh is abducted and a small resistance is felt due to the impingement of the femoral head against the limbus. At that moment the index finger pushes the greater trochanter and the femoral head is reduced into the acetabulum, producing the “click” or “clunk” sign (“segno del scatto”). The thigh is now adducted and with the pressure of the thumb in a lateral position the head is dislocated again and the “click” sign is again heard” (92).

3.1.2 The Barlow/Palmén test

A provocation method whereby an attempt is made to identify an unstable or dislocatable hip has been described by several authors (Coleman 1956, Palmén 1961, Barlow 1962) (7;24;95). In his dissertation in 1961, Palmén (95) gave a detailed description of hip examination in the newborn. This involved two stages: a) the Ortolani maneuver, and b) a subluxation provocation, which he describes as follows: “From a basic position of 90 degrees flexion and slight abduction (about 45°) the legs are held as in stage I, but with the thumbs further up against the upper femoral ends, and moderate backward pressure is exerted (dorsally), at the same time as slow adduction and slight inward rotation are carried out, as if the femoral head were to be luxated. In cases of preluxation a distinct displacement of the femoral head outwards on to the posterior acetabular edge may then be felt. If pressure is then exerted by the fingers placed against the trochanteric region, the femoral head may again be replaced, with a more or less distinct click, into its reduced position. This stage is best carried out on one leg at a time. The other hand has the same hold, but instead supports the pelvis.” A similar provocation was described by Coleman in 1956 (24) and Barlow in 1962 (7).
3.1.3 Other methods

Stanislavjevic (121) introduced the hip-knee-hip triad in hip examination of the newborn infant. Phase 1: “The examiner grasps both thighs of the newborn baby distally and extends the hips. It is difficult, almost impossible, to extend completely the hip of the newborn”. Phase 2: “The examiner grasps the upper position of the legs and tries to extend the knees. It is easier to extend the knees than to extend the hips”. Phase 3: “The examiner grasps both knees and abducts the hips. It is easier to abduct the hip joints in the newborn than to extend the knees and the hips. This is the normal hip-knee-hip triad”. If the force required for hip abduction is greater than that required to extend the hips and knees, this constitutes the abnormal hip-knee-hip triad and suggests the presence of hip dislocation.

3.2 Older infants

In the older infant after about the age of 3 months the Ortolani and Barlow/Palmén methods of examination are increasingly difficult to perform and interpret. The physical examination has to rely on other signs such as limited abduction of the hip and asymmetry of the gluteal, thigh, or labral skin folds (57;95;131). Standing or walking with external rotation can be a sign of a dislocated hip (but is usually due to contractures of the external rotators). The Galeazzi sign (or Allis sign) is useful for identifying unilateral hip dislocation: The patient lies supine with the hips and knees flexed. One leg appears shorter than the other. This is usually due to hip dislocation, but any limb length discrepancy can result in a positive Galeazzi sign.

Bilateral dislocation of the hip, especially at a later age, can be quite difficult to diagnose clinically. It can present as a waddling gait with hyperlordosis.
4 Imaging methods in hip examination

4.1 X-ray

4.1.1 Plain X-ray

Less than two years after W C Röntgen made his discovery in November 1895, several articles on dislocation of the hip in children were published in “Fortschritte auf dem Gebiete der Röntgenstrahlen” (52:137). Wolff and Hoffa (1897-98), in separate papers, presented x-ray images of hip dislocation. The technique of plain x-ray examination of the hips has remained more or less unchanged since that time. Several techniques for facilitating the identification of hip dysplasia and displacement on plain x-ray have been described (Fig. 1).

![Diagram of hip with various lines and annotations]

Fig. 1. Various helplines for use in identifying and measuring hip dysplasia and hip displacement. A horizontal baseline, Hilgenreiner’s line (51), intersects the lowest aspect of the iliac bone at the triradiate cartilage. The acetabular index or Hilgenreiner’s angle is the angle between this baseline and a line intersecting the medial and lateral edge of the acetabulum. The vertical line of Perkin (101) is perpendicular to the baseline and is drawn from the lateral edge of the acetabular roof. If the line passes medial to the femoral metaphysis the hip is dislocated. The Shenton-Menard arch (dotted line) is a curved line that can be drawn between the medial border of the proximal femur and the superior border of the obturator foramen. A broken arch indicates displacement of the femoral head.

4.1.2 Plain X-ray to investigate stability

In 1952 Hart (50) introduced the push and pull technique for investigating hip stability. Andrén, in 1962, stressed the importance of provocation and described three provocation methods using plain x-rays (3-5): a. With the hip in 45° abduction, extension and inward rotation, the longitudinal axis of the femur normally points to the bony edge of the acetabulum, but will point above the acetabulum when dislocation is present.
(Andren and von Rosen 1958) (Fig. 2); b. The femurs are forced upwards with extended legs, which leads to an interrupted Shenton-Menard line in the presence of dislocation. This second method is particularly useful in unilateral dislocation; c. The hip is imaged with the femur in outward rotation and 30° abduction.

![Hip provocation with plain x-rays as described by Andrén and von Rosen. The longitudinal axis of the femur of the left dislocated hip projects cranial to the acetabulum.](image)

### 4.1.3 Arthrography

The first arthrographies were performed in the 1920s (18;119). The method became more widespread after the introduction of water soluble iodine contrast media in the 1930s by Severin and Wiberg (115;133). Hip arthrography provided a means of evaluating the cartilaginous parts of the femoral head and the acetabulum and of assessing the shape and location of the femoral head, as well as demonstrating soft tissue abnormalities (78). Before the advent of ultrasonography, and later magnetic resonance imaging, arthrography was the best way to visualize the cartilage and other structures of the infant hip joint. In his dissertation in 1979 Lönnerholm (77) considered that arthrography was indicated in all cases of congenital idiopathic instability of the hip (CIIH) diagnosed after the neonatal period, and in those cases diagnosed neonatally where hip abduction was already restricted at birth, where primary reduction failed or was difficult, or in cases of instability persisting after 6-8 weeks of treatment. The technique was invasive, however, and besides the ionizing radiation it carried a risk of infection and hemorrhage together with risks associated with the required sedation or anesthesia.

### 4.2 Ultrasound

The advent of ultrasonography brought about a major breakthrough in the diagnosis of DDH. After the publication of the initial paper by Graf in 1980 (41), several different methods of examining the infant hip were proposed, most of which were presented in the 1980s. The methods differed regarding the view, image plane (axial, coronal or sagittal)
and direction of visualization (anterior, lateral, inferior). The methods also differed according to whether the examination was focused on visualizing the morphology or the stability of the hip.

4.2.1 Graf

Graf’s method is undoubtedly the most frequently cited method of ultrasound examination of the infant and child hip, and is widely used in different countries, mainly in Europe (19;32;46;67;99;108;125;129). Graf first published his method in 1980, and subsequently modifications and additions were made (41;42;44;45). This is a standardized technique for assessing acetabular morphology. The infant is imaged in the lateral decubitus position. A lateral coronal view of the acetabulum is acquired in the standard plane through the middle of the acetabulum, using a linear transducer. The criteria for an acceptable view are stated in detail to ensure reproducible images. The classification system is based upon subjective evaluation of the bony acetabulum and cartilage roof triangle, and upon measurements of the acetabular cartilage roof angle (β angle) and the acetabular angle of inclination (α angle). On these bases the hips are classified into four main types and nine subtypes, which dictate further management. The method requires strict adherence to the specified criteria and considerable intra- and interobserver error has been reported (6;27;89;106). There is a large variation in the reported rate of dysplasia as diagnosed with the Graf method. In unselected populations the range of dysplastic hips lies between 0.2% and 5.1%, and that of immature hips between 2.3% and 56% (8;9;31;70;108;111;126). Originally the evaluation was strictly based on the morphological findings, but Graf has also stressed the importance of stability assessment (43).

4.2.2 Rosendahl

In 1992 Rosendahl and co-workers (107) complemented Graf’s method with a stability test. Using a lateral approach with a linear probe and with the infant in the standard lateral decubitus position, a stress test with a modified Barlow maneuver was performed with one hand, while the probe was manipulated with the other hand. They found a high correlation between hip dysplasia and instability. In an unscreened population 2.3% of the hips had mild dysplasia of which 62% were dislocatable, and 1.2% had severe hip dysplasia all of which were dislocatable (109).
Fig. 3. The classification proposed by Graf is based on a coronal view of the hip in the standard plane according to detailed instructions. Line a, the baseline, is drawn parallel to the lateral iliac border. Line b, the bony roof line, is drawn tangential to the bony acetabular roof. Line c, the inclination line, is drawn from the bony rim through the center of the labrum. The angle between lines a and b measures the inclination of the acetabular roof, the α angle. The angle between lines a and c measures the inclination of the labrum, the β angle. Normal values of the α angle are above 60°. Normal values of the β angle show larger variation, with a typical value of 65° or less in type I.

4.2.3 Harcke, Morin

Harcke and coworkers introduced a combined method of static and dynamic ultrasound based on a lateral approach with the baby/infant in a supine position (47;48). The method, basically a dynamic examination method, comprised lateral transverse and coronal views with the hip in the neutral position and in flexion, without and with a Barlow stress test, a “dynamic four-step method”. The method focused on the position of the femoral head at rest and during stress testing and also took into account the configuration of the bony and cartilaginous parts of the acetabulum. The examiner held the transducer in one hand and examined the hip with the other. When the left hip was examined, the examiner used the right hand to manipulate the hip, and vice versa.

The method basically involved a subjective evaluation of the hip joint and included no measurements. A variation of the original Harcke method with measurements, however, was described by Morin et al (85;86). Measurements of the femoral head coverage were performed. A coronal flexion view showing the maximal diameter of the femoral head was chosen for measurements. A baseline drawn at the lateral iliac border, “the iliac line”, which corresponded to the Graf baseline, was used. Two lines parallel to this and tangential to the medial and lateral borders of the femoral head were drawn, and the percentage coverage of the femoral head was measured on the basis of these three lines
(d/D ratio) (Fig. 4a). They found that the d/D ratio correlated better than the alpha angle (by Graf’s method) to the acetabular index (as measured by plain x-ray).

4.2.4 Terjesen

Terjesen and coworkers (123) introduced a method of measuring the coverage of the femoral head that was a modification of the method proposed by Morin. A lateral coronal view with slightly flexed hips was used. As a baseline they used a line through the lateral bony rim of the acetabulum parallel to the long axis of the laterally placed transducer. The femoral head coverage was measured by correlating the medial and lateral borders of the femoral head to this baseline (Fig 4b). They found mean coverages of 55% and 57% in girls and boys, respectively. One comparative study in an unselected population found that 1.3% of the hips were dysplastic according to the Graf method whereas 4.1% were dysplastic using the method of Terjesen (33).

Fig. 4 A. Measurement of the femoral head coverage as described by Morin et al.. The baseline was drawn parallel to the lateral iliac line and two lines parallel to this were drawn tangential to the medial and lateral borders of the femoral head. The d/D ratio indicates the percentage coverage of the femoral head. B. The method of Terjesen differed in that the baseline was drawn parallel to the long axis of the laterally placed transducer. The a/b ratio indicates the femoral head coverage.

4.2.5 Dahlström

A dynamic ultrasound method with an anterior approach was introduced by Dahlström and co-workers in 1986 (25;26). The method focused on diagnosing hip instability and was designed to closely copy the standard clinical examination for hip instability as described by Palmén and Barlow. Two examiners carried out the examination, usually an orthopedist and a radiologist. While one examiner performed the provocation test, the other handled the ultrasound probe and apparatus. A sector probe was used. The ultrasound probe was placed anterior to the hip joint and parallel to the femoral neck, with a section midway between sagittal and transverse. The direction of the ultrasound beam
was in the alleged direction of displacement of the femoral head, i.e., posterolateral. In this way the movement of the femoral head during the stress test could be reliably visualized. The method is in use in Sweden but otherwise is not widely applied (2;29). This method is purely a test for instability, and does not include any morphologic evaluation. Very low treatment rates have been reported using this method (2).

4.2.6 Other methods

Saies and coworkers (114) added measurement of the femoral head dislocation to the Harcke method. With the infant supine and the hips flexed a transverse lateral view of the hips was obtained. Posterior pressure similar to the Barlow maneuver was applied in an attempt to displace the femoral head posteriorly, and an image was obtained with a view similar to the pre-stress view. This procedure required two examiners, a sonographer to operate the transducer and stabilize the pelvis and a radiologist to perform the stress test.

Several other methods of ultrasound imaging of the hips have been proposed (12;40;87;122). Novic and coworkers (87) reported on a dynamic multiplanar approach. Suzuki and coworkers (122) introduced a technique with an anterior axial view of both hips simultaneously, using a transverse linear transducer. They claimed that by this means lateral displacement could be detected. The infant was examined in the supine position with the hips in an extended position and in flexion/abduction. When there was displacement in extension they found that the direction of the displacement was anterior-lateral.

Three-dimensional ultrasonographic visualization of the hip was introduced in 1990 and has been described in several reports (35;39;120;128) but has not yet been widely established.
5 The new anterior dynamic ultrasound method

The idea to the present dynamic ultrasound method with transducer fixing device came about after working for some time with the ultrasound method described by Dahlström and coworkers in 1986 (26). The Dahlström method was the first and to the authors knowledge the only published ultrasound method to date that tried to closely copy the standard clinical examination as described by Barlow and Palmén with simultaneous visualization with ultrasound. The idea behind this was that by adding another dimension to the clinical hip examination, the visual sense, the examiner’s confidence should increase, and thus positively affect the sensitivity and specificity of the examination.

Several disadvantages were noted performing the dynamic ultrasound examination according to the principle of Dahlström, which involved two examiners, one who performed the clinical stress test and one who manipulated the ultrasound transducer. It was often difficult and problematic to keep the femoral head in the image when the clinician performed the Barlow/Palmén maneuver. During the clinical examination the infant (along with the hip joint) moves in different directions and rotates, and all this is augmented by the resisting infant. This makes it difficult for the assisting examiner who manipulates the transducer to predict how the clinician will apply the force to the hip and to know how he himself should incline and position the transducer for the best results.

This led to the design of an examination table with a transducer fixation device. This means that the whole examination is performed by one examiner that has both hands free to perform the classic Barlow/Palmén maneuver with the added ultrasonographic visualization of the hip joint. The fact that one examiner alone controls both the clinical examination and the ultrasound is important, as he or she is able to move and adjust the hip joint and the femoral head in the ultrasonographic field of view, thus keeping the femoral head in the field of view during the maneuver. The examiner is also able to adjust the direction or inclination of the transducer so that the maximal displacement is visualized. By adding the visual sense as a second dimension the examiner is now able to visually confirm or double-check what he feels with his hands.

In the early stages of the project the working name given to the method was the Three Sensory Method (3SM), as the idea was to incorporate a third sense, sound, in the hip instability diagnosis. This was to be achieved by applying a microphone to the hip during the provocation maneuver. This idea was abandoned, however, because of the questionable correlation between hip instability and the “click” sound (16;63;63;64).

To the authors knowledge the use of a transducer fixing device in the performance of dynamic hip examinations has not been described previously, at least regarding humans. However, a fixation device for use in the diagnosis of canine hip instability has been patented (88). This works the other way round, i.e., instead of fixing the transducer, the device is used to apply pressure to the hips to test for instability, leaving one hand free to manipulate the ultrasound transducer.
6 Aims of the thesis

The principal aims of this research were:

1. To design and construct an examination table with a probe fixation device.
2. To investigate the applicability of this device in examining infants of various ages.
3. To compare this dynamic ultrasound method with clinical assessment of hip instability.
4. To compare the hip stability as assessed with this method with the acetabular morphology as assessed with static ultrasound, the Graf method.
5. To establish normal values of hip laxity in the newborn at two weeks of age.
6. Using the dynamic ultrasound method, to compare subjective evaluation of hip stability with objective evaluation based on measurements.
7 Material and methods

7.1 The examining table with the transducer fixation device

The requirement was a stable light table, easily movable. The table should be small enough to be easily moved and placed near the ultrasound machine, but large enough to accommodate the infant safely. The height of the table should allow the examination to be carried out with the examiner standing. Furthermore, the transducer fixing device should not be in the way or obstruct the conduct of the Barlow/Palmén hip provocation maneuver. After several prototype tests, a table with aluminium legs and framework was constructed (Fig. 5). A transverse armature across the middle of the examination table was fastened to both sides of the table, to ensure stability, and the transducer fixing device was fastened to the middle of the transverse armature. The transducer fixing device was designed to hold a 5-7 MHz sector transducer that was used at the radiology department. A spring coil mechanism ensured constant moderate pressure on the surface anterior to the hip during the examination, and furthermore a comfortable examination condition for the infant. The transducer could be angulated in all directions and rotated to obtain an optimal field of view.

Fig.5. a. The examination table. b. The anterior dynamic ultrasound examination is performed by one examiner that uses both hands for the Barlow/Palmén provocation. The ultrasound transducer is fastened to a transverse armature across the examining table with a special device, and can be rotated and angulated in all directions.
Fig 6. The examination technique during stress testing of the left hip. A posterior force is applied to the femur with one hand, while the other hand stabilizes the pelvis. The sequence is monitored and video-recorded with the transducer placed in the groin, giving an oblique anterior view parallel to the femoral neck. The direction of dislocation can easily be visualized.

7.2 Initial study (paper 1)

The main goal was to test the feasibility of using the examination table with a fixed transducer to examine newborn and older infants. The following questions were addressed:

1. Was it possible to manipulate and hold the infant in place, and at the same time perform a Barlow/Palmén provocation test and keep the femoral head and acetabulum in the sonographic field of view? Could this be achieved with minimal outside help from the parent or other accompanying person?

2. Did the instrumentation, i.e., the transducer fixation device, interfere with the normal conduct of the clinical hip stress test? The idea was that the clinical Barlow/Palmén test could be carried out as usual, where the examiner was able to test the stability with the hip in the standard position of half abduction and approximately 90 degrees of flexion. The instrument should not be in the way and the added dimension of the ultrasound visualization should come easily and naturally.

3. What was the upper infant age limit for a feasible examination? A minimum of one month was considered essential for the method to be of practical use. After one month of age the role of instability diminishes and the importance of morphologic imaging increases in the evaluation of DDH.
The above described examination table with the transducer fixation device was used. The ultrasound equipment was an Acuson 128™ (Siemens Medical Solutions USA Inc., Mountain View, California, USA), with a 5 or 7 MHz sector probe for the dynamic studies, and a 5 or 7.5 MHz linear probe for the Graf method. The study comprised 57 infants, of ages between one day and ten months. The mean age was 54 days and the median age 36 days. The infants were referred to the pediatric radiology department because of an abnormal or ambiguous clinical hip examination or because of risk factors for DDH (family history of DDH, breech presentation, foot anomalies). Twenty-one of the infants were referred by an orthopedist who had performed a clinical examination of the hips prior to the ultrasound examination.

All the ultrasound examinations were conducted by the same examiner. The Graf examination was performed according to the standard description, with the infant in lateral decubitus, and at least two images of each hip in the standard plane were documented on film. The images were analyzed by the examiner and classified into types according to the Graf method. The dynamic ultrasound examination was documented on video with continuous recording during the examination. The provocation maneuver was repeated until satisfactory recordings were established. Representative images demonstrating the femoral head in the neutral position and during maximal displacement, and also an image showing the maximal diameter of the head, were selected and printed on film. The femoral head diameter and the distance between the center of the femoral head and anterior acetabular rim at rest and during maximal displacement were measured from these images using a digitizer tablet. The hips were assigned to three groups as normal, unstable, or dislocatable on the basis of the results of the dynamic ultrasound examination measurements. The threshold values were set to <20% as normal, 20 - <50 % as unstable and 50% or more as dislocatable. The threshold value of 20% was derived from the values published by Dahlström and coworkers (25).

From the clinical examination the hips were categorized into three groups as a) normal, b) unstable or showing indeterminate results (that would warrant treatment if not otherwise contradicted), and c) dislocatable.

### 7.3 The second study (papers 2-4)

The study was performed between September 2001 and March 2005. The main goals were:

1. to compare the results of hip stability evaluation made by clinical hip examination by orthopedists, with those obtained by dynamic ultrasound using our method;
2. to study the relation between hip stability as assessed by dynamic ultrasound and clinical examination, and acetabular morphology as assessed by static ultrasound using Graf’s method;
3. to establish normal and pathologic values of hip laxity in the newborn at 2 weeks of age;
4. to compare subjective and objective evaluation of hip stability using the dynamic ultrasound method.
A flowchart of the study is presented in Figure 7.

![Flowchart](image)

Fig. 7: A flowchart of the second study (paper 2-4).

All newborn infants born at the Karolinska University Hospital Solna, Stockholm, underwent clinical hip screening, performed by the maternity unit pediatricians, on the first day of life. Infants with confirmed hip instability, hip dislocation or ambiguous findings, and those with risk factors such as breech delivery, foot deformity, torticollis or a family history of DDH were referred for pediatric orthopedic consultation. During the study period newborn babies referred for this orthopedic consultation with risk factors or with ambiguous or abnormal clinical findings were included in the study.

The study comprised the following stages:

1. **Clinical hip screening at the maternity ward.** Within 24 hours after birth all infants born at the hospital were examined by an experienced pediatrician. Hip stability was assessed with the Ortolani and Barlow/Palmén methods and the hips were classified as normal, unstable, or dislocatable/dislocated. All infants with abnormal or ambiguous hips, and all those with risk factors for DDH were referred for orthopedic consultation.

2. **First orthopedic examination.** At the orthopedic consultation a clinical hip examination was performed by a senior pediatric orthopedist, who graded the hips into three groups based on the hip stability as assessed by the Barlow/Palmén and
Ortolan tests: a. stable hips which also included hips with minor instability that did not require treatment; b. unstable hips, i.e., hips with moderate instability requiring treatment but not dislocatable; c. hips with major instability, i.e., hips that were dislocatable or dislocated.

3. **A static ultrasound** examination according to Graf’s method (45). After the orthopedic examination the infant was referred to the ultrasound department for static and dynamic ultrasound examinations, in most cases at the same visit to the hospital, usually within a few hours. The Graf examination was performed either by an experienced pediatric radiologist or by a sonographer who had received special training in the Graf method. The findings at the first orthopedic examination were not known to the ultrasound examiner. The examination was carried out in a standard manner as described in the literature, with the infant in the right and left lateral decubitus positions. At least two images of each hip were acquired in the standard plane. The ultrasound equipment used was an Acuson Sequoia™ (Siemens Medical Solutions USA Inc., Mountain View, California, USA) with a 5 or 7 MHz linear transducer. The hips were graded according to Graf's classification and allocated to three groups (Fig.8): Group A: normal acetabular morphology, type Ia and Ib, with an alpha angle of 60° or more. Group B: borderline or immature hips, type IIa, with an alpha angle of 50-59°. Group C: dysplastic hips, type IIc and worse, with an alpha angle of below 50°. The examiner noted the findings and these were included in a report directly after the examination.

4. **Anterior dynamic ultrasound** examination using the method developed at the department (34), which was based upon the principle described by Dahlström and co-workers in 1986 (25;26). This was performed directly after and by the same examiner as the Graf examination. The ultrasound examinations were carried out either by an experienced pediatric radiologist or by a sonographer who, prior to the study, had received special training in clinical hip examination and dynamic ultrasound. The ultrasound equipment used was an Acuson128XP™ (Siemens Medical Solutions USA Inc., Mountain View, California, USA) with a 5 MHz sector transducer. The dynamic examination was documented with video recording and directly

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**Fig. 8.** Hip sonogram in the standard plane according to Graf illustrating the different groups: A. Normal hip type Ia. B. Immature hip type IIa. C. Dysplastic hip type IIc.
to the radiology department PACS (picture archiving and communication system) with cine loops. The examiner evaluated the hip stability on the basis of the visual information from the ultrasound together with the tactile perception during the stress test, and the hips were classified as normal, unstable, or dislocatable (Fig. 9). These findings were included in a report to the orthopedic surgeon. The dynamic ultrasound classification was subjective. No measurements were used to decide the degree of displacement of the femoral head. A hip that was seen or felt to be displaced out of the acetabulum was classified as dislocatable. A hip that was considered to show significant instability requiring treatment, but not to be dislocatable, was assigned to the unstable group. Hips with minor (insignificant) instability, together with completely stable hips, were assigned to the stable group.

Fig. 9: Anterior dynamic ultrasound. A sagittal sonogram of the right hip parallel to the femoral neck with the anterior approach. The hip was imaged during the Barlow/Palmén maneuver. A. Stable hip with the femoral head in the acetabulum. B. Unstable hip with posterior subluxation of the femoral head. C. Dislocatable femoral head; a = anterior acetabular rim, b = posterior acetabular rim, c = femoral head, d = femoral neck/diaphysis.

5. Second orthopedic examination. After the ultrasound examinations the infant was returned to the orthopedic unit, where a second clinical hip examination was performed by the orthopedist, with the same classification into normal, unstable, and dislocatable. The second orthopedic examination was carried out within hours after the ultrasound examination, even when the sonography was performed on a different day than the first orthopedic examination. On the basis of the clinical findings together with the ultrasound report, the orthopedist made a diagnosis and decided about treatment.

6. Dynamic ultrasound measurements. Later on measurements on the images from the dynamic ultrasound were performed on the basis of the recorded cine-loops and video recording. This secondary assessment was made after the study was closed, at least several months after the primary evaluation, and without access to the report from the first evaluation. Scrolling through the loops, an image that was considered to show the maximal diameter of the femoral head was chosen and the diameter was measured. An image in the neutral position and an image showing maximal displacement of the femoral head were identified and an anatomical landmark at the
anterior acetabular rim was selected. This was usually a point at the junction between the anterior acetabular labrum and the bony anterior acetabular rim (Fig. 10). The distance between the center of the femoral head and this anatomical landmark was measured in the neutral position and with maximal displacement of the femoral head. The magnitude (degree) of hip laxity or instability was expressed as the difference in the distance from the acetabular rim to the center of the femoral head between the neutral position and the position during maximal stress, and the relative instability was calculated by dividing this figure by the diameter of the femoral head, in percent.

![Diagram](image)

**Fig. 10. Dynamic ultrasound measurements.** The distance between the anterior acetabular rim and the center of the femoral head was measured in neutral position (a1) and during maximal displacement (a2). The diameter of the femoral head (b) was measured in order to calculate the relative instability.
8 Statistical methods

All statistical analyses were carried out with SPSS for Windows® version 10.0.1, and Amos version 6.0, SPSS Inc., Chicago, Illinois, USA.

The statistical analysis was based on univariate and multivariate linear models. These were used to describe the correlation between repeated measurements using the same method, and between repeated measurements with different methods.

The agreement between repeated measurements using the same method was assessed using Cohen’s kappa (categorical ratings) or with intraclass correlation (continuous ratings). Values with continuous data also allowed determination of the size of the measurement error relative to the total variation. This was done by comparing the distribution within the measurements with the distribution between the measurements.

The agreement between repeated measurements performed with different methods is calculated by different multivariate methods, namely multiple regression analysis, exploratory factor analysis, and hypothesis-testing factor analysis (or path analysis). All three methods are related. They are either based on correlations (non-comparable ratings) or covariations (with comparable rating). There are several variations of each multivariate method.

A multiple regression analysis is used to test whether a relation is better explained by several variables combined than by an individual variable. Explorative factor analysis is used to group variables into subgroups based on the criterion that the covariation is larger within than between the subgroups. In hypothesis-testing factor analysis (or path analysis) the relationships between the variables are defined in advance.

In paper 3, path analysis (15) was used for modeling cause and effect based on a covariance matrix. A semi-exploratory path analysis based on a covariance matrix was applied. First those paths which the study design rendered unfeasible were excluded. The remaining paths were determined by stepwise exclusion of non-significant paths. The direction of the causation was determined by the study design; cause preceded effect.

In paper 2 and 3 Cohen's kappa was used to measure the agreement between the Graf examination, the dynamic ultrasound examination and the clinical examination. In the study in paper 3 path analysis was used to assess the way in which different diagnostic tests of hip stability influenced the orthopedist’s decision regarding treatment.

In paper 4 intraclass correlation was used to measure the agreement between repeat measures of the same value, exploratory factor analysis was performed using principal axis factoring, and multiple regression was also used. The error variance ($S^2_{error}$) and the intraclass correlation ($r_{intraclass}$) were calculated according to the equations (69)
\[ \bar{x} = \frac{1}{2N} \sum_{n=1}^{N} (x_{n,1} + x_{n,2}) \]

\[ s^2 = \frac{1}{2N} \left\{ \sum_{n=1}^{N} (x_{n,1} - \bar{x})^2 + \sum_{n=1}^{N} (x_{n,2} - \bar{x})^2 \right\} \]

\[ r = \frac{1}{Ns^2} \sum_{n=1}^{N} (x_{n,1} - \bar{x}) (x_{n,2} - \bar{x}) \]
9 Results

9.1 The first study, paper 1

The table design and transducer fixation device proved feasible. The device did not interfere with the normal conduct of the Barlow/Palmén maneuver. The transducer could easily be adjusted in all planes so as to obtain an optimal image of the acetabulum and the femoral head in the neutral position and during stress testing. The direction of displacement of the femoral head, posterior and lateral, was easily visualized and the acetabulum and the femoral head were maintained in the sonographic field of view during the maneuver. Infants under 1 month of age were found to be easily examined. The stress test became increasingly difficult to perform with increasing infant age and an upper feasible limit of about three months of age was established.

This first study included 57 infants and 114 hips. According to the dynamic ultrasound examination 4 hips were unstable and 1 was dislocatable (Table 1). Of the 109 hips that were stable, all but three were classified as normal or borderline by Graf’s method. According to Graf’s method 6 hips needed to be treated and 14 additional hips required a follow-up examination before treatment could be decided upon, in contrast to 5 hips requiring treatment as assessed by the dynamic ultrasound.

Table 1 The outcome of the dynamic ultrasound examination compared with that of the Graf method. N = 57 patients (114 hips).

<table>
<thead>
<tr>
<th>Graf type</th>
<th>Stable</th>
<th>Unstable</th>
<th>Dislocatable</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal (I)</td>
<td>93</td>
<td>1</td>
<td></td>
<td>94</td>
</tr>
<tr>
<td>Borderline (IIa)</td>
<td>13</td>
<td></td>
<td>1</td>
<td>14</td>
</tr>
<tr>
<td>Pathologic (IIc+)&lt;sup&gt;1&lt;/sup&gt;</td>
<td>3</td>
<td>3</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>109</td>
<td>4</td>
<td>1</td>
<td>114</td>
</tr>
</tbody>
</table>

<sup>1</sup> Type IIc or worse

Of the 57 infants included in the study, 21 infants (42 hips) underwent clinical hip examination by an orthopedist prior to the ultrasound examination. The agreement between the clinical examination and the dynamic ultrasound examination was 71%. The main difference concerned 10 hips that were judged to be normal at dynamic ultrasound but were considered unstable or indeterminate on clinical examination and thus to need treatment. With the Graf method seven of these were assessed as normal (type 1) and two were borderline (type 2a). According to the standard clinical protocol at our hospital at the time of the study four of these hips required treatment as judged from the dynamic ultrasound examination results, in contrast to 13 hips according to the clinical examination.
Table 2. Forty-two hips (21 patients) examined with dynamic ultrasound and clinically by an orthopedist.

<table>
<thead>
<tr>
<th>Clinical examination</th>
<th>Dynamic ultrasound</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stable</td>
</tr>
<tr>
<td>Stable</td>
<td>28</td>
</tr>
<tr>
<td>Unstable/indeterminate</td>
<td>10</td>
</tr>
<tr>
<td>Dislocatable</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>38</td>
</tr>
</tbody>
</table>

1) Type IIc according to Graf’s method. 2) Seven hips were type I and two were type IIa according to Graf’s method. 3) Type IIc with the Graf method.

### 9.2 The second study

In papers 2 and 3 a total of 536 infants (1072 hips) were included. The mean gestational age at birth was 39.0 weeks (SD 1.8 weeks), with a range of 28 to 43 weeks. The mean birth weight was 3375 g (SD 608 g). The mean age at the time of the ultrasound examination was 12.2 days (SD 4.8 days), range 2-30 days. The static and dynamic ultrasound examinations were performed at the same visit to the radiology department. In most instances they were done on the same day as the orthopedic examination, but in 14 cases there was an interval exceeding 7 days between the first orthopedic examination and the ultrasound examinations.

In paper 4 there were 498 infants (996 hips) included. The mean gestational age of the infants at birth was 39 weeks (SD 1.8 weeks), with a range of 28-43 weeks. The mean age at the time of the first orthopedic examination was 12.2 days (SD 4.9 days), with a range of 2-30 days. The mean time interval between the first orthopedic examination and the ultrasound examinations was 0.66 days (SD 2.6 days).

The second orthopedic examination following the ultrasound examinations was always performed during the same visit to the hospital, on the same day.

### 9.2.1 Gender

There was an overrepresentation of females in the second study with a female : male ratio of 1.8:1. As seen in Table 3, the ratio was higher in infants with abnormal hips, and this was most evident regarding the objective dynamic ultrasound.
Table 3. The female: male ratio in different groups of infants.

<table>
<thead>
<tr>
<th></th>
<th>Female/male ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>All infants in the study population</td>
<td>1.8 : 1</td>
</tr>
<tr>
<td>All infants treated during the study period</td>
<td>2.5 : 1</td>
</tr>
<tr>
<td>Abnormal judged by 1st orthopedic exam</td>
<td>2.7 : 1</td>
</tr>
<tr>
<td>Abnormal judged by subjective dynamic ultrasound</td>
<td>3.8 : 1</td>
</tr>
<tr>
<td>Abnormal judged by objective dynamic ultrasound</td>
<td>4.3 : 1</td>
</tr>
</tbody>
</table>

1) Unstable hips 3.5:1 and dislocatable hips 4.1:1

9.2.2 Subjective evaluation of dynamic ultrasound vs clinical examination (paper 2)

At the first orthopedic examination 196 hips were considered to be abnormal as compared to 131 hips on the dynamic ultrasound (Table 4). The two examinations were in agreement concerning 867 hips out of 1072 (kappa = 0.284).

At the first orthopedic examination 81.7% of the hips were diagnosed as normal, 14.5% as unstable, and 3.8% as dislocatable or dislocated. With the dynamic ultrasound method the corresponding figures were 87.8%, 10.4%, and 1.8% respectively. 125 hips were considered stable according to dynamic ultrasound and unstable or dislocatable according to the first orthopedic examination. Of these, none was pathologic according to the Graf method, 93 were normal (type 1) and 32 were borderline (type 2a).

Table 4 The results of the first orthopedic examination compared with those of the subjective dynamic ultrasound evaluation. N = 1072 hips.

<table>
<thead>
<tr>
<th></th>
<th>Dynamic Ultrasound</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stable</td>
</tr>
<tr>
<td><strong>1st orthopedic exam.</strong></td>
<td></td>
</tr>
<tr>
<td>Stable</td>
<td>816</td>
</tr>
<tr>
<td>Unstable</td>
<td>116</td>
</tr>
<tr>
<td>Dislocatable or dislocated</td>
<td>9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>941</td>
</tr>
</tbody>
</table>

1) The assessment of this hip was changed to dislocatable at the 2nd orthopedic examination

The second orthopedic examination, performed with access to the dynamic ultrasound results, showed an increase in agreement between the two methods from 867 (80.9%) to 897 hips (83.7%) (kappa = 0.375) (Table 5). But there were still 107 hips that the ortho-
pedest considered unstable, dislocatable or dislocated but that were classified as stable on dynamic ultrasound. Fifty hips that were classified as unstable on dynamic ultrasound were judged to be stable at the orthopedic examination.

Table 5  The second orthopedic examination compared with the subjective dynamic ultrasound evaluation. N = 1072 hips.

<table>
<thead>
<tr>
<th>2nd orthopedic exam.</th>
<th>Dynamic Ultrasound</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stable</td>
</tr>
<tr>
<td>Stable</td>
<td>834</td>
</tr>
<tr>
<td>Unstable</td>
<td>99</td>
</tr>
<tr>
<td>Dislocatable or dislocated</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>941</td>
</tr>
</tbody>
</table>

9.2.3 Instability in relation to acetabular morphology (paper 3)

In paper 3 the relation between the acetabular morphology as assessed by the Graf method and the hip stability as assessed by subjective dynamic ultrasound evaluation and by clinical examination (Tables 6-8). Graf's examination showed the smallest number of normal hips, but also the fewest pathologic hips, with many indeterminate results that needed follow-up. According to Graf's method 77% of the hips were normal, 20% borderline/immature, and 3% pathologic. At the 1st orthopedic hip examination 82% were stable, 14% unstable and 4% dislocatable. The outcome of the subjective dynamic ultrasound evaluation was 88% stable hips, 10% unstable and 2% dislocatable.

The distribution of the 1072 hips according to the Graf type is shown in Table 6, together with the number (and percentage) of hips that were found to be unstable, dislocatable or dislocated on dynamic ultrasound and at the first orthopedic examination.
Table 6 Distribution of sonographic types according to the Graf classification, and the number (and percentage) of hips that were unstable, dislocatable or dislocated according to the dynamic ultrasound and the first orthopedic examination.

<table>
<thead>
<tr>
<th>Graf type</th>
<th>n</th>
<th>Dynamic ultrasound</th>
<th>1st orthopedic examination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Unstable</td>
<td>Dislocatable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Unstable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dislocatable or dislocated</td>
</tr>
<tr>
<td>Ia</td>
<td>724</td>
<td>20 (2.8%)</td>
<td>1 (0.14%)</td>
</tr>
<tr>
<td>Ib</td>
<td>97</td>
<td>7 (7.2%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Ia</td>
<td>220</td>
<td>66 (30.0%)</td>
<td>7 (3.2%)</td>
</tr>
<tr>
<td>Ic</td>
<td>20</td>
<td>17 (85.0%)</td>
<td>2 (10.0%)</td>
</tr>
<tr>
<td>Ild</td>
<td>6</td>
<td>1 (16.7%)</td>
<td>5 (83.3%)</td>
</tr>
<tr>
<td>IIIa</td>
<td>2</td>
<td>0 (0%)</td>
<td>2 (100%)</td>
</tr>
<tr>
<td>IIIb</td>
<td>3</td>
<td>1 (33.3%)</td>
<td>2 (66.7%)</td>
</tr>
<tr>
<td>IV</td>
<td>0</td>
<td>0 (0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Total</td>
<td>1072</td>
<td>112 (10.4%)</td>
<td>19 (1.8%)</td>
</tr>
</tbody>
</table>

¹ One hip that was classified as type 3b according to Graf's examination (and dislocatable according to dynamic ultrasound) was considered stable at the first orthopedic examination. This hip was re-assessed as being dislocatable at the second orthopedic examination.

Table 7 The results of dynamic ultrasound compared with those of the Graf examination (n = 1072 hips). A, normal hips (type Ia and Ib); B, borderline (type IIa); and C, abnormal (type IIc and worse). Kappa = 0.381

<table>
<thead>
<tr>
<th>Graf’s examination</th>
<th>Dynamic Ultrasound</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td></td>
<td>793</td>
<td>147</td>
<td>1</td>
<td>941</td>
</tr>
<tr>
<td>Unstable</td>
<td></td>
<td>27</td>
<td>66</td>
<td>19</td>
<td>112</td>
</tr>
<tr>
<td>Dislocatable</td>
<td></td>
<td>1</td>
<td>7</td>
<td>11</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>821</td>
<td>220</td>
<td>31</td>
<td>1072</td>
</tr>
</tbody>
</table>
Table 8  The results of the first orthopedic examination compared with those of the Graf examination (n = 1072 hips). A, normal hips (type Ia and Ib); B, borderline (type IIa); and C abnormal (type IIc and worse). Kappa = 0.199

<table>
<thead>
<tr>
<th>1st orthopedic examination</th>
<th>Graf’s examination</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Normal</td>
<td>716</td>
<td>150</td>
</tr>
<tr>
<td>Unstable</td>
<td>100</td>
<td>47</td>
</tr>
<tr>
<td>Dislocatable</td>
<td>5</td>
<td>23</td>
</tr>
<tr>
<td>Total</td>
<td>821</td>
<td>220</td>
</tr>
</tbody>
</table>

9.2.3.1 Subjective dynamic ultrasound evaluation

The correlation between the acetabular morphology and the stability as assessed by subjective dynamic ultrasound evaluation was 0.381 according to Cohen’s kappa. Of the hips in group A with normal acetabular morphology, 3.4% were unstable or dislocatable as assessed by dynamic ultrasound. In the borderline group B, 33% were unstable or dislocatable, and among the dysplastic hips, group C, 97% (all but one) were unstable or dislocatable. Of the 131 hips that were unstable or dislocatable according to dynamic ultrasound, 21% were normal according to the Graf classification, 56% were immature, and 23% were dysplastic.

9.2.3.2 Orthopedic hip examination

The correlation (Cohen’s kappa) between the acetabular morphology and the stability as assessed at the first orthopedic examination was 0.199. Of the hips with normal morphology (group A), 13% were found to be unstable or dislocatable on clinical examination. In the borderline group B, 32% were judged to be unstable or dislocatable, and in group C 68% were unstable or dislocatable. Of the 196 hips that were considered unstable or dislocatable on clinical hip examination, 53% were normal, 36% were immature and 11% were dysplastic according to the Graf method.

9.2.3.3 Dynamic ultrasound and orthopedic examination in agreement

The dynamic ultrasound results were in agreement with those of the first orthopedic examination regarding 867 hips (Table 9). Of the 816 hips that were judged as stable with both methods, only one (0.1%) proved to be dysplastic (type IIc) according to the Graf classification, and 115 (14%) of the hips were borderline. One half of the hips that were judged to be unstable with both methods were allocated to Graf group B. Of the 15
hips that were dislocatable with both methods, two thirds were dysplastic according to the Graf method and none was normal.

Table 9. The results of the Graf examination in the 867 hips regarding which the dynamic ultrasound and the first orthopedic examination were in agreement.

<table>
<thead>
<tr>
<th>Graf group</th>
<th>Dynamic ultrasound agrees with 1&lt;sup&gt;st&lt;/sup&gt; orthopedic exam</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Unstable</td>
<td>11</td>
<td>18</td>
</tr>
<tr>
<td>Dislocatable</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>711</td>
<td>138</td>
</tr>
</tbody>
</table>

9.2.4 Influence of ultrasound on clinical decision (paper 2)

The orthopedic examinations performed before and after the dynamic ultrasound were compared (paper 2). The two orthopedic examinations were in agreement in 96.8% of the hips, with kappa = 0.878 (Table 10). In 34 hips the assessment was changed at the second orthopedic examination; 22 of these, which were judged as unstable or dislocatable at the first orthopedic examination, were given a normal rating, which was in agreement with the dynamic ultrasound examination in all but one. Twelve hips received a worse rating, which was in accordance with the dynamic ultrasound in 10 cases.

Table 10. Comparison of the first and second orthopedic examinations. N = 1072 hips. At the second orthopedic examination the number of pathologic hips is decreased from 196 to 188.

<table>
<thead>
<tr>
<th>1&lt;sup&gt;st&lt;/sup&gt; orthopedic examination</th>
<th>2&lt;sup&gt;nd&lt;/sup&gt; orthopedic examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stable</td>
<td>Stable</td>
</tr>
<tr>
<td>Stable</td>
<td>861</td>
</tr>
<tr>
<td>Unstable</td>
<td>22</td>
</tr>
<tr>
<td>Dislocatable or dislocated</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>884</td>
</tr>
</tbody>
</table>
The decision regarding further management was based upon the findings at the second orthopedic examination in the light of the results of the first orthopedic examination and the dynamic and static ultrasound examinations. All in all 144 patients received treatment, of whom 111 were given a Frejka pillow and 33 a von Rosen splint. Nine patients were treated with a Frejka pillow even though both hips were classified as stable after the first and also after the second clinical orthopedic examination. All nine showed pathologic results on ultrasound examination. Four of these were found to be unstable in at least one hip on dynamic ultrasound, and the remaining five had one hip categorized as immature (type IIa) with the Graf method. Twelve patients with clinically determined instability in at least one hip were not treated. In ten of these infants both hips were judged to be stable on dynamic ultrasound. Nine were graded as normal on Graf’s examination, 2 had unilateral type IIa and one had bilateral type IIa.

A path analysis (12) was performed (Fig. 11) to investigate how the different estimates of hip instability or pathology influenced the orthopedist’s choice of treatment (paper 3). The orthopedists were influenced in three steps, as illustrated by the significant regression coefficients in each step.

1. The orthopedist's first estimate, the outcome of the first clinical orthopedic examination, was influenced by the results of the clinical examination in the maternity ward (b=0.35).

2. The orthopedist's second estimate, the outcome of the second clinical orthopedic examination, was influenced by the orthopedist’s first estimate (b=0.83) and by the result of the dynamic ultrasound (b=0.23).

3. The choice of treatment was influenced by the orthopedist's second estimate (b=0.85), by the dynamic ultrasound (b=0.07), by Graf’s method (b=0.07) and by the clinical examination in the maternity ward (b=0.05). In general the path analysis indicated that if any of the estimates suggested a need for treatment, the infant was treated.
Fig. 11. Path analysis based on the variance-covariance matrix of five estimates of hip pathology (coded as 1=normal, 2=unstable, 3=dislocatable) and treatment (coded as 1= no treatment, 2= Frejka pillow, 3= von Rosen splint). N=1072 hips. Numbers within circles are residual variances not accounted for in the model. Double-ended arrows are covariances between these residuals caused by the study design. Single-ended arrows are significant regression coefficients (p≤5 %) that are part of the model. Computations were performed using Amos version 6.0 from SPSS Inc.

9.2.5 Treatment rate (papers 2 and 3)

The theoretical treatment rate was calculated on the basis of the outcome of five different diagnostic tests, including the initial hip examination at the maternity ward on day one, and the Graf examination. The hip with the worst score decided treatment. Regarding the clinical examination and the dynamic ultrasound, all infants in whom at least one hip was considered unstable or dislocatable were assumed to undergo treatment. Regarding the Graf method, hips of type IIa were considered indecisive cases that needed a follow-up for decision, and hips of type IIc or worse were assumed to undergo treatment without further investigation. The calculated treatment rate was based on the number of infants born at our hospital during the study period, a total of 18031.

As seen in Table 11, the first orthopedic examination classified 154 infants as having at least one hip unstable or dislocatable, and thus being in need of treatment. The dynamic ultrasound suggested that 89 infants should be treated. The use of Graf's method resulted in 132 borderline cases needing a follow-up examination before a decision on treatment could be taken, which meant that the number of infants considered to require treatment was between 21 and 153.

A combination of Graf's examination and dynamic ultrasound was also tested, where all infants that met the criteria for treatment with one or both methods were considered in need of treatment. Of the 536 infants, 363 were normal at both examinations. Eighty-four had stable hips bilaterally but had an immature/borderline acetabulum in at least one hip and thus needed follow-up. Eighty-nine infants had at least one hip that was unstable or dislocatable or had acetabular dysplasia type IIc or worse according to the Graf classification and thus needed treatment. Owing to the large number of indecisive cases resulting from the Graf examination, the calculated treatment rate had a wide range, between 4.9‰ and 9.6‰.
Table 11. *The theoretical treatment rates calculated for the different methods of diagnosis, based on the hip with the worst score. The difference in treatment rate between the first and second orthopedic examinations was not statistically significant, but the difference in treatment rate between the subjective dynamic ultrasound evaluation and each of the two orthopedic examinations was highly significant. N = 536 infants. The treatment rate was based on the total number of infants born during the study period, i.e., 18031. The actual treatment rate during the study period was 8.0‰ (144 infants).*

<table>
<thead>
<tr>
<th>Stability/acetabular development based on the hip with worst outcome in test</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical exam. maternity unit</td>
<td>Normal 413</td>
<td>Borderline Graf 123</td>
<td>Unstable or Dislocatable Graf 123</td>
<td>Number to be treated</td>
<td>Treatment rate 6.8‰</td>
</tr>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; orthopedic exam.</td>
<td>382</td>
<td>154</td>
<td>154</td>
<td>8.5‰</td>
<td></td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; orthopedic exam.</td>
<td>389</td>
<td>147</td>
<td>147</td>
<td>8.2‰</td>
<td></td>
</tr>
<tr>
<td>Subjective dynamic ultrasound evaluation</td>
<td>447</td>
<td>89</td>
<td>89</td>
<td>4.9‰</td>
<td></td>
</tr>
<tr>
<td>Graf's method</td>
<td>383</td>
<td>132</td>
<td>21</td>
<td>1.2–8.5‰</td>
<td></td>
</tr>
<tr>
<td>Dynamic ultrasound combined with Graf's method</td>
<td>363</td>
<td>84</td>
<td>89</td>
<td>4.9–9.6‰</td>
<td></td>
</tr>
</tbody>
</table>

<sup>1)</sup> The wide range was due to a large number of borderline cases (group B) at the Graf examination that needed a follow-up examination before a decision could be taken on further management.

### 9.2.6 Objective evaluation of dynamic ultrasound using measurements; basic statistics (paper 4)

The mean absolute hip displacement or laxity was 1.1 mm in the right and 1.4 mm in the left hip. The relative hip displacement or laxity was 7.0% in the right and 9.0% in the left hip, and the mean for both hips was 8.0% (SD 7.7). The correlation between absolute and relative dislocation was almost perfect, with r=0.99. The frequency distribution of the relative displacement is illustrated in Figure 12. The distribution of hip laxity in relation to chronologic age is shown in Figure 13.
Fig 12. Histogram showing the distribution of the relative instability or laxity in 2.5% intervals. Number of hips = 996.

Fig 13. Distribution of relative hip laxity (in percent) in relation to age (in days). N = 996.
The mean diameter of the femoral head was 15.5 mm (SD 1.1 mm) on both sides. The femoral head diameter had a medium positive correlation to the corrected gestational age (chronologic age at time of examination plus gestational age at time of birth), r=0.42. There was no significant correlation between femoral head diameter and absolute or relative instability (r=0.01, P=0.85, n=996 and r=-0.06, P=0.04, n=996 respectively).

9.2.7 Normal values of hip laxity

Two approaches were used to calculate the upper normal limit of hip laxity (paper 4).

1) A group of normal hips was defined. This group comprised hips that were assessed as stable at the first and second orthopedic stress tests and also at the subjective dynamic ultrasound evaluation, and that were classified as type I with the Graf method. Totally there were 640 such hips, and the mean infant age at the time of the first orthopedic examination was 12.7 days. The mean relative laxity in this group was 6.0% (SD 4.2 %), with a mean absolute laxity of 0.9 mm (SD 0.65 mm; range 0 - 4.2 mm). With the upper normal limit set at the mean plus 2 SDs, a relative laxity value of 14.4% and an absolute laxity value of 2.2 mm were obtained.

2) The whole study population (n=996 hips) was used as the basis for the upper normal limit calculation. This gave a mean absolute laxity of 1.23 mm (SD=1.2 mm) and a mean relative laxity of 8.0% (SD=7.7 %). Based on mean values plus 2 SD, the upper normal limits for absolute and relative laxity were 3.6 mm and 23.4% respectively.

9.2.8 Measurements correlated to orthopedic examination and dynamic ultrasound results

Depending on the method of calculation as described above, two different upper normal limits of relative hip laxity were derived, 15% or 25%, rounded upwards. By using 15% as the upper normal limit, the number of hips considered to require treatment was reduced by 40 % as compared to the first orthopedic examination and by 9% as compared to the subjective dynamic ultrasound evaluation (Table 12). By using 25% as the threshold the number of hips requiring treatment dropped to 37, a reduction of 81% and 71% respectively.
Table 12. The number of hips that were unstable or dislocatable, i.e., requiring treatment, with use of different upper thresholds. The results were compared with those of the first orthopedic examination, performed prior to the ultrasound examination, and with the primary, subjective evaluation of the dynamic ultrasound examination. The third column shows the number and percentage of female hips in the different groups.

<table>
<thead>
<tr>
<th></th>
<th>Unstable or dislocatable hips, requiring treatment</th>
<th>Female hips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study population</td>
<td>644 (65%)</td>
<td></td>
</tr>
<tr>
<td>1st orthopedic examination</td>
<td>193</td>
<td>140 (73%)</td>
</tr>
<tr>
<td>Dynamic ultrasound, subjective evaluation</td>
<td>128</td>
<td>101 (79%)</td>
</tr>
<tr>
<td>Measurements, threshold 15%</td>
<td>117</td>
<td>86 (74%)</td>
</tr>
<tr>
<td>Measurements, threshold 20%</td>
<td>71</td>
<td>55 (78%)</td>
</tr>
<tr>
<td>Measurements, threshold 25%</td>
<td>37</td>
<td>30 (81%)</td>
</tr>
</tbody>
</table>

9.2.9 Measurements in relation to other diagnostic tests

The outcome of the dynamic ultrasound measurements was studied in relation to that of five diagnostic tests. Four of these were tests of hip stability (the maternity ward examination, the two orthopedic examinations and the dynamic ultrasound subjective evaluation), and the fifth was a sonographic assessment of the acetabular morphology (Graf’s examination). Multiple regression analysis showed that the method that best correlated to the measured instability was the subjective dynamic ultrasound evaluation with r=0.67 (Table 13).
Table 13. The mean hip laxity in the three different categories, stable, unstable, and dislocatable. Objective dynamic ultrasound evaluation with measurements compared with results from five different diagnostic tests. Regarding the static Graf examination the hip categories were normal (type I), borderline (type 2a), and dysplastic (type 2c and worse). The results are given as hip laxity in relation to the diameter of the femoral head in percent, and within brackets as the absolute value of hip movement in millimeters. Number of hips = 996.

<table>
<thead>
<tr>
<th></th>
<th>Objective dynamic ultrasound evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal</td>
</tr>
<tr>
<td></td>
<td>% (mm)</td>
</tr>
<tr>
<td>Clinical exam. maternity unit</td>
<td>7.0 (1.1)</td>
</tr>
<tr>
<td>1st orthopedic exam.</td>
<td>6.8 (1.0)</td>
</tr>
<tr>
<td>2nd orthopedic exam.</td>
<td>6.7 (1.0)</td>
</tr>
<tr>
<td>Subjective dynamic ultrasound evaluation</td>
<td>6.2 (1.0)</td>
</tr>
<tr>
<td>Graf’s method</td>
<td>6.3 (1.0)</td>
</tr>
<tr>
<td>All methods combined¹</td>
<td>6.0 (0.9)</td>
</tr>
</tbody>
</table>

¹ Classification using all methods in combination: Normal = normal with all methods; Dislocatable = dislocatable/dislocated with any method; Unstable = all others.

9.2.10 Sensitivity and specificity of the different diagnostic tests

The sensitivity and specificity of five diagnostic tests was calculated using the dynamic ultrasound measurements as golden standard (Tables 14 and 15) (paper 4).

Three different threshold limits for instability were used, 15, 20 and 25%. Based on the results of the different diagnostic tests the hips were allocated to two groups, a) normal and b) pathologic, which comprised the unstable, dislocatable or dislocated hips. At the Graf examination hips of type 2a were classified as pathologic.
Table 14. The sensitivity of five different diagnostic tests using dynamic ultrasound measurements as the reference.

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity Threshold 15%</th>
<th>Sensitivity Threshold 20%</th>
<th>Sensitivity Threshold 25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical exam. maternity unit</td>
<td>41</td>
<td>55</td>
<td>73</td>
</tr>
<tr>
<td>1st orthopedic exam.</td>
<td>56</td>
<td>70</td>
<td>84</td>
</tr>
<tr>
<td>2nd orthopedic exam.</td>
<td>55</td>
<td>63</td>
<td>86</td>
</tr>
<tr>
<td>Dynamic ultrasound</td>
<td>68</td>
<td>86</td>
<td>95</td>
</tr>
<tr>
<td>Graf’s method</td>
<td>65</td>
<td>83</td>
<td>95</td>
</tr>
<tr>
<td>All methods combined1</td>
<td>61</td>
<td>96</td>
<td>97</td>
</tr>
</tbody>
</table>

1) Classification using all methods in combination: Normal = normal with all methods; Pathologic = all others.

Table 15. The specificity of five different diagnostic tests using dynamic ultrasound measurements as the reference. N =996 hips.

<table>
<thead>
<tr>
<th></th>
<th>Specificity Threshold 15%</th>
<th>Specificity Threshold 20%</th>
<th>Specificity Threshold 25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical exam. maternity unit</td>
<td>88</td>
<td>88</td>
<td>87</td>
</tr>
<tr>
<td>1st orthopedic exam.</td>
<td>85</td>
<td>85</td>
<td>83</td>
</tr>
<tr>
<td>2nd orthopedic exam.</td>
<td>87</td>
<td>86</td>
<td>85</td>
</tr>
<tr>
<td>Dynamic ultrasound</td>
<td>95</td>
<td>93</td>
<td>90</td>
</tr>
<tr>
<td>Graf’s method</td>
<td>82</td>
<td>81</td>
<td>79</td>
</tr>
<tr>
<td>All methods combined1</td>
<td>66</td>
<td>65</td>
<td>63</td>
</tr>
</tbody>
</table>

1) Classification using all methods in combination: Normal = normal with all methods; Pathologic = all others.

9.2.11 Measurement error

In order to calculate the measurement errors (paper 4), 30 examinations were selected by randomization and remeasured. For the diameter of the femoral head (mean=15.7 mm) the measurement error was 0.38, and for the absolute and relative hip laxity (mean 1.27 mm and 8.16% respectively) the measurement errors were 0.32 and 1.94, respectively (Table 16).
Table 16. Mean values of the old and new measurements, measurement error ($s_{\text{error}}$), and the intraclass correlations ($r_{\text{intraclass}}$) based on old and new measurements. N=30.

<table>
<thead>
<tr>
<th></th>
<th>Mean value</th>
<th>$s_{\text{error}}$</th>
<th>$r_{\text{intraclass}}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter of femoral head</td>
<td>15.7 mm</td>
<td>0.38</td>
<td>0.70</td>
</tr>
<tr>
<td>Absolute hip laxity in mm</td>
<td>1.27 mm</td>
<td>0.32</td>
<td>0.72</td>
</tr>
<tr>
<td>Relative hip laxity in %</td>
<td>8.16%</td>
<td>1.94</td>
<td>0.76</td>
</tr>
</tbody>
</table>
10 Discussion

10.1 Introduction

Developmental dysplasia of the hip is in essence a two component disease. On the one hand there is hip joint laxity or instability, and on the other hand there is acetabular dysplasia (morphological changes of the acetabulum). Whether the instability or the dysplasia is the dominating aspect of neonatal DDH is debated. As causative mechanisms of DDH hormonal factors, ligament laxity, mechanical forces, intrauterine malposition and genetic, racial, geographical and environmental factors have been suggested (20;28;80;136;139). The pathophysiology has not been agreed upon and several factors are probably involved. Despite numerous studies on the subject we still do not know the ideal way to detect DDH in the infant. Should we look for all morphologically abnormal hips or should we concentrate on finding hip instability? There is evidence in the literature that stable and morphologically normal hips in the newborn can develop DDH. And furthermore there is indication that some hips with presumably DDH induced premature osteoarthritis are morphologically normal and stable in the infant (30). The best method to detect stable hips with morphologic DDH in the infant is to perform ultrasound screening with a static method such as Graf’s method or a modification of this method (Terjesen or Harcke/Morin). This may lead to considerable overtreatment. There are several studies indicating that general ultrasound screening is not cost effective, or not to be recommended, and selected screening has been advocated (14;54;110;127).

This means selection based on risk factors. This is complicated by the fact that several studies have shown that only a minority of infants with diagnosed DDH have identified risk factors (except for the female gender) (13;56;60;113). It is not the aim of this thesis to answer all these questions, but to focus primarily on the diagnosis of neonatal hip instability.

The clinical hip examination of newborn infants has been performed systematically in screening since the middle of the previous century and in expert hands has proved sensitive in detecting instability, as is reflected in the low figures of late detected DDH shown in our study. The specificity, however, is low. The second study was conducted in a setting of a very low rate of missed or late detected DDH. During the study period one case of DDH was missed by the screening program at our institute (this infant was not examined with ultrasound and was not in the study). With 18031 babies born during the study period, this corresponds to a rate of late detected DDH of 0.006%. The neonatal hip screening program at our institute consists of clinical hip examination performed on day one of life by a small group of experienced pediatricians. Infants with ambiguous findings and those with manifest instability, together with infants with risk factors for DDH, are referred for orthopedic consultation, usually during the first or second week of life.

Although there is no consensus on the true prevalence of neonatal DDH, it seems credible that the range is somewhere between the reported prevalence of DDH in need of surgery in an unscreened population, and the lowest reported values of treatment in successful screening programs; i.e., between 0.1% and 0.3%. However, the treatment rate at our institute during the study period was 0.8%.
10.2 Initial study, study 1

The main object of the initial study (paper 1) was to explore the feasibility of using the examination table that allowed the examiner to have both hands free. The study population was chosen to encompass a large range of ages from newborn to 10 months, which is far above the practical age of testing stability with the Barlow/Palmén method.

We found that infants up to the age of 3 months were easily examined by one person with simultaneous clinical examination and ultrasonographic visualization.

In the Barlow/Palmén test the direction of dislocation of the femoral head is posterolateral. As the ultrasound beam with the anterior dynamic method is pointed in that direction, we found it easy to visualize and follow the femoral head during the stress maneuver, keeping the femoral head and the acetabulum in the field of view. During several years of previous experience with the Dahlström method we often encountered problems in visualizing the displacement and the hip joint during the provocation maneuver by reason of the fact that two examiners were involved in the procedure, one that performing the stress test and another that manipulating the ultrasound probe. If the two examiners did not cooperate closely there were problems in keeping the femoral head and the acetabulum in the field of view during the provocation. This was not the case in our method, where one examiner both steered the ultrasound probe and performed the Barlow/Palmén maneuver. We found it easy to keep both the femoral head and the acetabulum in the field of view during the stress maneuver.

10.3 General remarks on the second study setup, papers 2-4

The population of study 2 (paper 2-4) was enrolled in the study during a period of 3 years 6 months, out of a population of 18031 infants born at the maternity unit during the study period. The selection for the study was made by the orthopedist at the first orthopedic consultation, with the instructions to include all infants with a clinically abnormal or ambiguous hip examination, together with infants with risk factors for DDH.

The point of time for the clinical orthopedic examination and the ultrasound examinations was set at the second week of life, usually between the 10th and the 14th days. This was considered late enough for the “physiologic instability” to have settled and early enough to ensure optimal treatment results. This has support in the literature (7;38;55;79;82;84). The aim was to perform the clinical orthopedic examinations and the ultrasound examinations at the same visit to the hospital or on the same day, in order that the results would not be biased by the time interval between the examinations; i.e., so that any hip instability diagnosed at the clinical examination would not have spontaneously normalized by the time the ultrasound examination was performed. The mean time delay between the first orthopedic examination and the ultrasound examination was 0.68 days and the delay in the cases where the orthopedic and ultrasonographic results differed was even shorter.

Owing to possible risks associated with repeated stress tests of the hip (22;61;96;105), the hip stress test was limited to four occasions; the maternity ward examination, the two orthopedic examinations, and the dynamic ultrasound.
10.4 Golden standard

As previously discussed, no golden standard examination has been defined for detection of hip instability. Prior to the ultrasound era the clinical examination was the only practical examination for investigating hip stability. The accuracy of the clinical examination has been reported to be very variable and highly operator dependent (8;11;21;23;55;58;126). The clinical examination is a highly subjective test of instability with no means of quantification, as the magnitude of femoral head displacement cannot be measured, the force used is not standardized, there are individual variations in the examination technique, and the sensation of instability is appreciated differently by different examiners. Furthermore the success of the Barlow/Palmén test depends on a relaxed infant.

If, on the other hand a means of visualization of the hip joint is added to the clinical examination, there will be a possibility not only of measuring and quantifying the amount of femoral head displacement, but also of verifying that what is felt with the hand is indeed a laxity or instability of the femoral head. This is achieved with our dynamic ultrasound method, and this method may be a step towards a golden standard method of assessing and visualizing hip instability. But further studies are needed to validate this.

10.5 The correlation between hip stability and morphology

Inconsistency between hip stability and hip morphology is widely cited in the literature, but ultrasound investigations on this issue are sparse (104;124). Rosendahl and co-workers (9) compared the Graf examination with dynamic ultrasound using a lateral approach, and found that 49% of the sonographically unstable hips had either normal (Graf type I) or immature (Graf type Ila) acetabular morphology. In our study using a different dynamic ultrasound method, 77% of the sonographically unstable or dislocatable hips were normal or immature according to the Graf classification (see Table 7). The study by Rosendahl and coworkers is not directly comparable to the present study because of the different technique in the stress test and the different ultrasonographic approach. But the result of both studies can be summarized by stating that dysplastic hips are unstable, but that a considerable proportion of unstable hips are not dysplastic. Our study, however, is biased in this regard. We can assume that all unstable or dislocatable hips in infants born during the study period were included in the study, but we do not know how many hips that were clinically normal, but pathologic according to Graf’s examination, were left out of the study.

10.6 Measurements of hip stability

Both the absolute and the relative instability or laxity of the femoral head were measured (paper 4). Measuring the relative instability meant an additional measurement of the diameter of the femoral head. The advantage of this was that it was not dependent on the size of the infant. But our results showed almost perfect correlation between the two measurements, and measurement of the relative stability, i.e., measurement of the femoral head diameter, can thus be omitted.
10.7 Normal hip laxity

Reports on quantitative findings regarding normal hip laxity are sparse. A literature search revealed two comparable dynamic ultrasound studies. Dahlström and coworkers (25) measured the distance between the center of the femoral head and the anterior acetabular brim at rest and during the Palmén/Barlow maneuver in an unselected population of 108 consecutive newborns (216 hips). They measured this distance in relation to the diameter of the femoral head and found a mean relative laxity of 4% at birth and 2.1% at 5 days of age. At one month they found no displacement at all. They concluded that the upper limit of normal hip laxity at birth was 16%, with a gradual decline with age. Andersson (1) examined 455 neonates less than 2 days old. He measured the distance between the anterior acetabular brim and the surface of the femoral head and found a mean movement of 2.2 mm. He defined the upper normal limit of hip laxity as 6.0-6.8 mm, depending on weight.

In our study, carried out at a mean age of 12.2 days, hips considered normal at five diagnostic tests (stable at three clinical examinations and subjective dynamic ultrasound, and normal with the Graf method) showed a mean relative laxity of 6.0% and a mean absolute laxity of 0.9 mm. When the upper normal limit was set to two standard deviations, it was found to be 14.4% and 2.3 mm. Based on the whole study population the corresponding results were 23.4% and 3.6 mm. Our values for normal relative hip laxity were considerably higher than those in the study by Dahlström and coworkers, even though the infants were examined at a younger age in the latter study, with an expected high ratio of “physiologic hip laxity”. In our study the mean laxity was between 6.0% and 8.0% at the age of 12 days, as opposed to 2.1% at the age of 5 days in the Dahlström study. Our results are in greater agreement with those reported by Andersson. The mean absolute laxity was between 0.9 and 1.2 mm in our study, which is below the figure of 2.2 mm obtained by Andersson. However, the infants were examined at an age of less than 2 days in Andersson’s study, and the mean laxity can be expected to have decreased at 12 days of age.

Several other studies with hip laxity measurements have been reported, but owing to different techniques these are not directly comparable with our method. Saies et al (114) measured the posterior movement of the femoral head during provocation with a lateral approach, in infants of ages below 3 months. They found a mean movement of 1.4 mm in clinically normal hips, 4.5 mm in hips with moderate instability, and 5.1 mm in those with major instability, and suggested classification into two groups: a physiologic group with less than 5.0 mm laxity, and a pathologic group with laxity of 5 mm or more. Keller et al (65) examined 40 normal infants on day 1 with a lateral approach using the Harcke method (48), and found the normal posterior movement of the femoral head to be 3.2 mm in the left hip and 2.3 mm in the right hip, with mean upper limits of 6 and 4 mm respectively. On day two these limits were reduced to 2.7 and 1.9 mm respectively. Rosendahl and coworkers (107) did a modified Barlow maneuver using the Graf projection in the lateral decubitus position and found a mean lateral movement of 1.5 mm (10.2%) in hips with minor instability, 2.6 mm (18%) in those with major instability, and 5.5 mm (40.1%) in dislocatable hips.

We arrived at two different values as the upper normal limit of hip laxity. The lower of these two values of 2.2 mm and 14.4% was based on measurements on hips that had been considered stable at five different diagnostic tests, and was obtained by adding two
standard deviations to the mean value. The normal value derived by this method is probably far too low, as a score of abnormal by any method meant that the hip was excluded from the normal group. The other method of calculating the upper normal limit, by using the mean value + 2 SD of the whole study population, assumed a normal population with a normal distribution. The population in this study was a selected population with an increased proportion of abnormal hips, and the results of 3.6 mm and 23.4% are presumably exaggerated. The true upper limit of normal hip laxity, in infants 12 days of age, can thus be assumed to lie between 2.2 and 3.6 mm in absolute figures, and between 15 and 25% (rounded upwards) relative to the femoral head diameter. We suggest using 3 mm and 20% as the upper normal limits of absolute and relative hip laxity respectively.

10.8 Clinical examination vs ultrasound

The number of hips considered to be unstable was considerably reduced when dynamic ultrasound was used as compared to the clinical examination. In the case of subjective ultrasound evaluation the number of hips requiring treatment was reduced by 33% and the number of infants requiring treatment by 42%. With use of measurements, the dynamic ultrasound examination reduced the number of hips requiring treatment by 63% as compared to the first orthopedic examination. This is a considerable reduction in treatment rate.

The lack of a true golden standard diagnostic test for DDH makes it difficult to evaluate the rate of false negative dynamic ultrasonography results. A large proportion of the hips considered normal by the ultrasound methods received treatment. How many of these were cases of true DDH and actually in need of treatment is not known. Three observations strengthen the validity of the dynamic ultrasound results:

1. The findings at Graf’s examination. Of the 125 hips that were stable according to dynamic ultrasound and unstable or dislocatable according to the first orthopedic examination, none was dysplastic with the Graf method and 32 were borderline (type IIa).

2. The female : male ratio of pathologic hips was more in agreement with the figures reported in the literature regarding dynamic ultrasound.

3. Although lower than the orthopedic results, the frequency of pathologic hips as found with dynamic ultrasound was still far above the alleged true prevalence of 1-3‰.

Owing to the mild side effects of treatment there is a tendency to treat when in doubt, and it may be argued that it is better to treat than to risk missing abnormal hips. However, the risk of complications of treatment, such as avascular necrosis, and pressure sores (17:59:62:71), although small, cannot be ignored. Added to this is the cost of the treatment, both to the health sector/society and to the individual families. The lowest possible treatment rate should be aimed for.

How do we explain the discrepancy between the clinical examination results and the findings at dynamic ultrasound regarding instability?
a. Indecisiveness or lack of confidence on the part of the clinical examiner. The examiner may not be sure if the hip is stable or not, and may choose to give treatment rather than miss an unstable hip.

b. What the examiner feels with the hand as movement of the femoral head (relative to the acetabulum) may be incorrect.

c. The perceived movement of the femoral head is exaggerated.

d. The orthopedic examination may have higher sensitivity.

10.9 Dynamic ultrasound: subjective versus objective assessment

The number of hips considered unstable was reduced by 40% when subjective evaluation with dynamic ultrasound was used to determine hip stability as opposed to clinical hip examination (paper 2). It was shown that by making measurements an additional decrease in the number of hips judged to be in need of treatment was achieved, by a factor of between 9% and 71% depending on the definition of the upper normal limit of hip laxity (paper 4). As compared to the subjective evaluation of the dynamic ultrasound, use of measurements led to a decrease in the number of unstable or dislocatable hips by between 9% and 71% depending on the level of the upper normal limit. With the upper normal limit of relative hip laxity set at 20%, midway between the upper and lower value, the number of abnormal hips requiring treatment was reduced from 128 to 71 hips, or by 44%.

The discrepancy between the results of the subjective and objective evaluation of the dynamic ultrasound examination can be caused by several factors:

a. Inaccuracy of the optical recognition (perception), by the examiner, of the movement of the femoral head on the ultrasound monitor.

b. It is possible that the tactical perception during the provocation maneuver, which is missing on the recorded cine-loops, is misleading and causes an increased number of false positive results.

10.10 Error of measurement

To estimate intraobserver error and the quality of the measurement data, 30 cases were selected by randomization and remeasured. The intraclass correlation, i.e., the correlation between individual pairs of data, was 0.76 for the relative hip laxity and 0.72 for the absolute laxity, indicating that the measurement data were of good quality. All measurements, however, were made by one person with long experience in this type of examination. This means that the results are probably not generalizable and that less experienced examiners will probably get poorer results.
10.11 Sensitivity/Specificity

How do we evaluate sensitivity and specificity when there is no golden standard diagnostic test? The average prevalence in the unscreened European population has been used in the literature to evaluate this (74). We chose to use the objective dynamic ultrasound evaluation as a golden standard and to look at how the other diagnostic tests measured against it.

The sensitivity and specificity of five different diagnostic tests in finding hips in need of treatment were measured with use of objective dynamic ultrasound results as a golden standard. As expected use of all methods combined led to a high sensitivity but a low specificity. The two ultrasound methods, subjective dynamic ultrasound evaluation and Graf’s method, had a similar sensitivity that was considerably higher than that obtained with the clinical examination. Of interest is that the specificity of the maternity ward examination was high - comparable to or higher than that of the examination by the pediatric orthopedists examination - but that the sensitivity was lower than that noted with the other tests.

10.12 Gender

Girls are reported to have an approximately four times higher risk than boys of being diagnosed with DDH, with some variation depending on the method of diagnosis (76;135). The results of our study are in agreement with this finding, particularly regarding the results of the dynamic ultrasound with a ratio around 4:1. There was a tendency towards a higher ratio with an increased threshold level of the dynamic ultrasound measurements. It is of interest that the female: male ratio was lower regarding the outcome of the orthopedic examination (2.7:1) and among those that received treatment (2.5:1). The reasons for this are not clear from the study, but it may be due to a higher proportion of normal hips among those considered unstable or dislocatable at the orthopedic examination.

10.13 Who should perform the dynamic ultrasound examination?

In this study the examinations were performed by several pediatric radiologists with long experience in pediatric ultrasonography, and one ultrasonographer who was specialized in pediatric ultrasonography and had also received training in performing the clinical hip examinations by the Barlow/Palmén method. Over 50% of the ultrasound examinations were carried out by the ultrasonographer and more than half of the remainder by the pediatric radiologist with the longest experience in ultrasonography of the hip (the author). No significant difference in the correlation between the subjective and objective dynamic ultrasound was observed between the ultrasonographer and the pediatric radiologist with the longest experience. Since the end of the study period the ultrasonographer has continued to conduct the vast majority of infant hip ultrasound examinations made at this pediatric x-ray department, both as sole performer of the dynamic ultrasound examination and with the Graf examination.

We believe that the most important factor in performing this dynamic ultrasound examination with success is the clinical skills in carrying out the Barlow/Palmén hip stress
test, which means that orthopedists or other clinicians doing infant hip examinations can after appropriate ultrasonographic training perform the dynamic ultrasound examination.
11 Conclusions

A combined clinical examination and ultrasound visualization can be performed by one person, using the present specially constructed examination table with a transducer fixation device, in infants up to about 3 months of age (paper 1).

Use of the subjective evaluation of the dynamic ultrasound as a basis for the decision regarding treatment reduced the treatment rate by over 40%, resulting in a calculated treatment rate of 0.49% (paper 2).

Acetabular morphology assessed by the Graf examination correlated better to stability as assessed by dynamic ultrasound than to the clinical examination results, with fair to moderate agreement. (paper 3).

Graf’s examination resulted in a large number of indeterminate results that needed follow-up, but when used as the sole criterion for deciding treatment it did not lead to a higher treatment rate than when the decision was based on clinical hip examination (paper 3).

In infants at 2 weeks of age almost all dysplastic hips are unstable, but a considerable proportion of unstable hips are not dysplastic. (paper 3).

Dynamic ultrasound examinations of the infant hip with the anterior approach should be documented with continuous recording in order to allow measurements. This will reduce the percentage of hips considered to require treatment as compared to using subjective evaluation (paper 4).

The upper normal limit of hip laxity in infants of an average age of 12 days is 20% when measured as relative laxity and the absolute figure is 3 mm (paper 4).

There is no significant difference between use of absolute and relative measurements of hip laxity, and measurement of the femoral head diameter can thus be omitted (paper 4).
12 Clinical applications

How should the results of these studies be interpreted regarding the clinical application? The fact that clinical hip screening, which is primarily concerned with detecting hip instability, can be quite successful and will almost eliminate late detected cases, as was found in our study, suggests that detecting hip instability should be the main concern of neonatal hip screening. Our knowledge of the pathophysiology of early adult hip osteoarthritis is, however, quite limited. We do not know the natural history of stable hips with undetected dysplasia.

The dynamic ultrasound method presented in this thesis is a clinical method that relies on good clinical skills in performing the Barlow/Palmén provocation as well as skills in ultrasonography. We see our dynamic ultrasound method as a direct extension of the clinical hip examination. The static methods of Graf and Terjesen, on the other hand are not dependent on clinical examination skills, but are more like conventional diagnostic imaging with strictly defined criteria of a standard image and projection.

In this thesis it is shown that the treatment rate will be considerably reduced by using the outcome of dynamic ultrasound to rule treatment. The true extent of the false negative results is not known. None of the hips with negative dynamic ultrasound and a positive clinical examination were dysplastic according to the Graf method. This suggests a low false negative rate.

Several different settings are suggested for use of the present dynamic ultrasound method:

a) As a direct extension of the clinical examination, the clinical hip examination is performed with use of our examination table and ultrasound method.

b) As a secondary method or complement to the clinical examination, used for examining infants with indeterminate or unstable/dislocatable hips according to the clinical examination.

c) To further reduce the number of hips considered to require treatment Graf´s examination can be used when the dynamic ultrasound shows instability.

d) In our experience the dynamic ultrasound method can be an aid in learning to perform clinical examination of the infant hip, as the examiner can visualize the hip joint while carrying out the Barlow/Palmén maneuver (in exactly the same position as without ultrasound).

Finally it should be stressed that the success of the method depends on good clinical skills in performing the Barlow/Palmén maneuver as well as ultrasonographic skills.
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(77) Lönnherholm T. Radiological studies of the hip joint in children with special reference to congenital idiopathic instability. Uppsala University; 1979.


