

PhD SCHOOL

PH.D. THESIS

**The Contribution of Non-Invasive
Imaging Techniques in the Diagnosis
and Treatment of Developmental
Dysplasia of the Hip (DDH) in
Newborn and Infant**

Ph.D Candidate **Dan Vasilescu**

Thesis Coordinator Prof.dr. **Sorin Marian Dudea**



Dedication

*My whole appreciation,
to all who supported and trusted me,
but especially to my wonderful mother,
whose love for children
determined me to get to this point of my career.*

LIST OF PUBLICATIONS

Articles published in extenso as a result of the PhD research

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ABBREVIATIONS USED IN THE TEXT

DDH	Developmental Dysplasia of the Hip
US	Ultrasound
CT	Computer Tomography
MRI	Magnetic Resonance Imaging
WHO	World Health Organization

INTRODUCTION

DDH is the most common dysplastic disease in newborns and infants, having a malformative potential it may be present at birth or may occur at any time during the development of the coxofemoral joint.

The presence of the disease in newborns, but also the late DDH repercussions, have forced DDH to be considered a public health problem worldwide. In the last decades, many studies have been dedicated to this condition, both for a correct diagnosis and for the most effective treatment. Thus, from the classical pelvis radiography indicated for diagnosis at the age of several months and the use of rudimentary methods of conservative orthopedic treatment or of traumatic and large surgical interventions, now it is possible to diagnose DDH in the first days of life, as well as to use minimally invasive treatment methods.

The impact of the correct management of DDH is not only on the individual and his family but also has a socio-economic component by avoiding long-term disability and/or complex surgery.

Despite to all advances in recent years, the optimal management of DDH diagnosis and treatment is still in scientific debate. Data on incidence, diagnosis, optimal treatment are still contradictory in many issues.

Even though it is widely accepted that an early diagnosis has an extremely favorable impact on treatment and evolution towards healing, there is controversy over the optimal age at which to diagnose, choose the method, but also on the therapeutic attitude.

Hip ultrasonography in the newborn has been imposed over the last 2-3 decades as the method of choice in DDH detection. WHO recognized hip US as being chronologically the first DDH diagnostic method. Early studies and applications of US diagnosis began in the 1980s. Several techniques and principles of US diagnosis have been developed over the years, each with supporters and contesters.

Perhaps the most widespread and exact technique is the one developed and perfected by Professor Graf in Austria. Although highly accurate and based on a set of

defining elements for correctness, this technique is subject to critics of some researchers, who incriminate both the elevated rate of positive diagnosis and the existence of late DDH detected cases.

On our national level, the lack of extensive multicenter studies leads to the lack of national statistical data, as well as the lack of a unified protocol in DDH management.

The present theses, as well as the activity carried out during the last years on the scientific and clinical level, are intended to contribute to the quality of the diagnostic act with the inherent repercussions on the therapeutic attitude. Multidisciplinary collaboration with orthopedic pediatric surgeons and neonatologists has led to a series of clinically validated ultrasound observations. The result of these studies lies in the implementation of a new criterion of fairness on the ultrasound image, but also in the imposition of a more accurate clinical-ultrasound management. Thus, it is desirable to increase the accuracy of the diagnostic ultrasound method, while reducing the late detection of DDH cases in patients who were initially considered healthy.

The original elements present in the thesis are represented by the description of some new hip ultrasounds signs mentioned for the first time in the literature. Also, is presented a particular way of integrating clinical and ultrasound data to reduce the risk of late DDH diagnosis.

CURRENT STATE OF THE ART

1. Developmental Dysplasia of the Hip. Clinical, Epidemiological and Therapeutic Considerations

1. 1. Definition and general data

DDH is a common disorder among newborns and infants. It may be present at birth or may occur at any time during the maturation of the coxo-femoral joint. It may be represented by several forms from acetabular dysplasia to the malposition of the femoral head in the hip joint and from an unstable hip to the subluxation stage or the worst, complete dislocation [1].

DDH defines a multitude of anatomical hip modifications, secondary to poor or stopped joint development. Developmental disorders may begin from embryonic life and may continue until childhood, during which time the hip changes its configuration to reach the mature form around the age of 15 [2].

DDH is a continuous affection of the coxo-femoral joint, which can start from an immature hip, to progress towards moderate acetabular dysplasia, so that ultimately the articulation leads to severe dysplasia and displaced hip. DDH is the main cause of premature coxarthrosis requiring complete prosthesis at a young age [3].

1.2. Epidemiological data

The incidence of DDH among the population is an internationally widely discussed topic, with data suggesting a high degree of variability.

This variability has several explanations: differences between target populations, study methods, diagnostic methods used and national health programs.

In the United States, there are reported incidences of 1.5 per 1000 newborns for the Caucasian race and significantly lower for the African race. Regarding the gender, females are reported to be affected in a proportion of 4-8 times higher than males [1]. Among the same population, other studies reports that the incidence of DDH would be 1.4-35 per 1000 newborns [4].

A study in Israel indicates an incidence of clinical suspicion of 9.5 per 1000 newborns and a DDH confirmation by imaging methods of 6.5 per 1,000 newborns [5].

In Austria and Central Europe data from literature indicate an incidence of DDH of 2.5%. Concurrently, 9% of hip prostheses in Austria are in young patients suffering from early coxarthrosis due to the late DDH diagnosis [6].

There are no extensive national studies in Romania, and those performed in some centers indicate an incidence of 6 per 1,000 newborns detected by clinical and radiological examination [2].

The DDH etiology is multifactorial, Dimeglio being among the first to systematize the incriminated risk factors:

- family history
- breech presentation
- cesarean delivery
- oligoamnios
- maternal hypertension
- delayed intrauterine growth
- primacy and gemelarity
- high birth weight
- clubfoot
- torticollis
- limited hip abduction
- muscles tonus disturbances
- female sex
- ethnicity, habits
- the presence of any other malformation.

Most of these factors can be explained by genetic load, reduced mobility (oligoamnios, breech presentation, primiparity or multiple pregnancy, muscle contraction - iliopsoas, adductors), maternal (relaxin) and feminine hormones which can induce excessive ligament laxity, local habits of inferior limbs immobilization of the newborn or its transport mode.

Studies have shown a higher prevalence in the left hip, which can be explained by the fetus position with the left hip towards the mother's spine, which would lead to the limitation of abduction (in the case of normal cranial presentation).

The natural evolution of untreated DDH is dependent on the degree of affection and the age of the patient. While the more severe stages of dysplasia (IIc, D, III and IV) are progressing towards worsening, a particular problem is related to the evolution of mild and moderate dysplasia. Immature hips or light dysplasia can also evolve to spontaneously healing during joint maturation. But, this evolution can not be

predicted, with the real risk of worsening and implicitly of a late initiated therapy. A number of studies show evolutionary variability. Thus, some cases may remain clinically silent or may lead to coxarthrosis, some cases diagnosed at infancy may develop spontaneously towards healing (80% of clinically diagnosed and approximately 90% of those diagnosed with ultrasound) [1].

Most commonly diagnosed are moderate dysplasia cases, often being underestimated, resulting in a lack of treatment or inappropriate treatment. In such cases, premature degenerative hip joint damage may be the first sign of disease [7].

1.3. Clinical diagnosis

Clinical examination is the first stage of DDH diagnosis management. Initially, a correct anamnesis should be considered to identify the presence of any risk factors. Based on their identification, several diagnostic protocols may indicate the need for selective ultrasound screening or other imaging technique according with the patient's age.

The severity of DDH may increase with bone and joint maturation. Studies have shown that bone maturation does not occur with a linear progression, during the first 12 weeks of life the speed of maturation being much faster. This time interval has to be speculated to significantly reduce the duration of treatment, but also its restrictiveness. Therefore, it is extremely important that the diagnosis should be made as soon as possible and afterwards the treatment to be instituted immediately.

There are several internationally debated theories about optimal age when this clinical examination is more conclusive, and whether it should be the basis for the diagnosis, or it could be associated by a radio-imaging method.

It should be noted that in newborn babies a slight instability may be present in the first few days after birth (considered physiological by several authors), leading to an increased rate of false positive diagnosis in the absence of imaging confirmation. At the same time, it is necessary to consider the gradual decrease of the clinical examination sensitivity with the advancement in the joint maturation process.

F. Grill mentions in a 2008 study that approximately 75% of type IIc, 58% of type D and, respectively, 30% of type III hips are stable on clinical examination.

Regarding how to approach the diagnosis according to the national programs, eloquent data are obtained by grouping into three categories these protocols and the reported incidence of open reductions surgery in 1,000 newborns:

- 1) Countries where clinical screening is used (Ireland, New Zealand, Northern Ireland, UK) show a rate of 0.78 - 1.3.
- 2) Countries with selective clinical and ultrasound screening (England, Norway, Italy and France) with rates of 0.57-0.70.
- 3) Countries with clinical and ultrasound universal screening (Austria, Germany, Czech Republic) report the lowest rates, 0.07-0.26 [6,8,9].

A negative diagnosis does not rule out the possibility of subsequent dysplasia, knowing that aggression factors can disrupt the normal development of the hip at any time until maturation. Practically, the hip should be checked periodically, especially up to the age of 1 year when there is a maximum risk of developing dysplasia. Because the clinical examination is very dependent on the physician's experience, it is recommended, at the newborn age (in the first 2 weeks of life), at 2, 4, 6, 9 and 12 months, to perform the clinical check-up by an physician experienced in the hip consult [1].

Clinical examination and clinical signs are different depending on the patient's age and can be classified into 3 categories:

- a) up to the age of 3 months;
- b) 3 months - 8 months;
- c) over 8 months [2].

1.3.1. Clinical examination in the child up to 3 months of age

For the quality of the examination, it is essential to pay attention some general principles. The clinical examination should be performed on a durable consultation table to reduce the risk of false results. The patient should feel comfortable by ensuring his food, quietness and adequate temperature.

The hip joint condition can not be seen only at the simple inspection. Therefore, it should be evaluated through the clinical examination. In the three-month-old infant, we can see the external rotation of the inferior limb on the lesioned hip side, that being a more obvious sign at a higher age. Signs of asymmetry present in the hip or thigh have an inconsistent value, being present only in the case of unilateral or bilateral but asymmetric lesions [2].

1.3.1.1. Asymmetry signs

The Peter-Bade sign is the appearance on the injured side of an extra skin fold on the thigh, fold produced by the relaxation of the abductor muscles. Also, the vulvar slit is inclined on the injured side, the intergluteal cleft is tilted to the same side and the gluteal fold is elevated on the side with the lesion [2].

1.3.1.2. Signs of articular laxity

Ortolani sign shows ligamentary or capsular laxity that denotes hip instability. In principle, it is only present in the first 2 months of life, after which the muscles are so strong that they no longer allow the reduction of the dislocation. It can also be found at a higher age if it is a disorder in the normal development of the muscles or if a neurological disorder is present (spina bifida, polio sequela, paraplegia etc).

In order to perform the Ortolani sign maneuvers, infant should be placed on a robust examination plan. The physician will perform the flexion of the thigh on the abdomen and flexion of the calf on the thigh, with the patient's knee fixed in the examiner's hand. The physician will fix his medius and index on the infant's greater trochanter. There will be an abduction movement of the thighs (abduction can be done up to 90 degrees) by pushing the big trochanter forward. If the abduction is blocked, a trochanter pressure is applied down and towards the median line. The positive Ortolani sign implies unblocking the abduction and continuing up to 90 degrees, producing a low click. It is the noise caused by the penetration of the femoral head into the acetabulum.

When executing the reverse motion, the adduction, the femoral head is output from the acetabulum, passing it over the edge of the cotiloid cavity will sometimes produce the same click. If it's well learned, the maneuver is relatively easy to be performed and is characteristic of the diagnosis. Sometimes, a diagnostic confusion can be caused by the mobilization of the baby's knees wich can produce a similar noise to that of the Ortolani sign.

Barlow sign is another evidence of articular laxity and can be found by the age of 6 months. The infant's position is basically the same as that of producing the Ortolani sign, but with a 60° hip flexion.

Holding the infant's knee in his hand, the doctor will perform the abduction movement by pulling the patient's thigh against him and by the same time, a movement towards the midline of the body is imprinted on the femoral head. The examination continues with the reverse movement. While hip adduction is performed, a presure will be applied along the axis of the thigh in a direction as to push the femoral head outside from the acetabular cavity. If the maneuvers are possible with an ample movement in the hip joint, with the slight exit and entry of the femoral head in the joint, it signifies positivity, meaning a sign of laxity and a hip instability, which is a sign of hip dysplasia. The Barlow test reveals a dislocation followed by a reduction, helping to identify seemingly healthy hips in the Ortolani test.

Other higher amplitude movements are internal and external rotation of the hip and thigh adduction.

Signs of mobility limitation are due to the excessive muscle of the adductors. This is an important sign, especially after 1 month of age. In principle, when abduction is very limited, especially when is unilateral, a hip ultrasound is required [2].

1.3.2. Clinical examination in the 3-8 month old infant

It is the time interval in which most cases are diagnosed in our country.

At inspection, the severe dysplastic hip (luxated) appears with an elevated contour and the same side lower limb presents an external rotation. Because of the tendency of the femoral head to luxate from the acetabulum, there is a shortening of the thigh.

1.3.2.1. Asymmetry signs

At this age asymmetry signs described in the previous age group may also be present.

The **Ombredanne sign** can be highlighted starting from this age group. In a patient with hip dysplasia or dislocation which is lying on a rough plane with the feet soles fixed on the plane surface, the knee level will be asymmetric. At this age, we can see also the prominence of the trochanteric region on the same side as the lesion and the slight external rotation of the affected inferior limb.

1.3.2.2. Signs of articular laxity

They are highlighted when the adduction degree is exaggerated on lesioned side, as the thigh can get overlapped on the opposite one.

The Gourdon sign is the exaggeration of internal hip rotation, which can reach 100°; normally being 45°-60° at this age.

The Lance mark consists in exaggerating external hip rotation to approximately 100°.

The femoral telescopic sign or the "piston" sign consists of the exit and entry of the femoral head into the acetabulum during the traction of the calf in the thigh axis. The traction and then pushing in the opposite direction is performed with the child in

supine position, with the calf flexed on the thigh and the pelvis immobilized on the plane surface by one of the physician's hands.

1.3.2.3. Signs of mobility limitation

The abduction limitation can be examined with both the inferior limbs in the extension, but also with them flexed from the hip and knee.

The sign of Ortolani is rarely encountered in this age group and only when the muscles are insufficient or even paralyzed: spina bifida, polio sequelae etc.

In the healthy infants from this age group, the more developed muscles will not allow the femoral head to enter into the acetabulum and thereby to reduce the dislocation [2].

1.3.3. Clinical examination in the child over the age of 8 months and after starting the walking

If the DDH is present the onset of the orthostatic position is delayed due to the lack of muscle development on the affected side. There will also be limping walk, manifested both by shoulder inclination on the same side with the affected hip as well as by the "toe walking" on the affected side. Waddle walking is present when the hip is bilaterally affected.

The **Trendelenburg sign** is an expression of the failure of the gluteus medius muscle. Normally, in unilateral support, the pelvis and shoulder axis are parallel. In support on the dislocated limb, the thorax tilts on the same side and the basin leans towards the healthy side.

Nelaton - Roser line is obtained with the patient in lateral decubitus on the healthy side, with the affected side hip in flexion to 145°. In a normal hip, the tip of the big trochanter, the antero-superior iliac spine and the tuberosity of the ischion are on an uninterrupted straight line.

The Schömacker line. Normally, in dorsal decubitus, with the hip in extension, the umbilicus, antero-superior iliac spine, and the tip of the big trochanter are on a straight line [2].

1.4. Therapeutic considerations

The desideratum of the therapeutic attitude, regardless of its type, is to obtain a stable and centered hip until the age of 3 months. The idea of early therapy is universally accepted.

The recommended treatment for patients with changes in the hip configuration depends on at least three factors:

- the degree of DDH;
- the age of the patient from the time of diagnosis and the institution of the treatment;
- in case of dislocation - the degree of the femoral head displacement relative to the acetabulum.

However, internationally there is controversy over the DDH level from which orthopedic treatment variants should be considered. These debates mainly refer to so-called moderate degrees of dysplasia or immature hips.

Tschauner et al. in an extensive retrospective study by analyzing 3 patient groups of 725 surgically treated cases, revealed the importance of a diagnosis as early as possible in the case of severe dysplasia (IIc, D, III and IV - according to Graf classification). In all three groups the initial therapeutic intention was either the use of abduction methods or the closed reduction. Lot I was represented by patients whose diagnosis was established at an average age of 5.5 months (the period prior to the introduction of hip ultrasound in clinical practice). 75% of the patients included in this group had soft-structure contractions, 66% had associated also contracture of adductor muscles, aspects that were opposed to conservative orthopedic treatment and require preparatory treatment by bed extensions and percutaneous tenotomy of adductors or iliopsoas. Only 88% of patients in this group achieved therapeutic success, the rest required complex surgery of femur and pelvic osteotomy. Lots II and III showed the same average age for diagnosis, approximately 2 months. In these cases, less than 10% required pre-therapeutic preparatios, none of the patients recording contraction of adductor muscles, and the incidence of osteotomy interventions being 0% [6].

Didactically and practically, the best treatment differentiation is based on the age of the patient, and then the type of therapy is individualized according to the other criteria.

1.4.1. Therapeutic considerations by age group

Depending on age, there are 5 age groups, the treatment being relatively similar:

- Age group up to 1 month;
- Age group 1-3 months;
- Age group 3-6 months;
- Age group from 6 to 18 months;
- Age group over 18 months.

In patients in the first month of life, the most frequent treatment is a preventive one, as indicated by the clinical examination. Thus, the abductor pantyhose or abductor diaper is best suited for hip flexion and abduction. In severe, ultrasound confirmed dysplasia, more restrictive abduction devices may also be used.

Treatment of the age group up to 3 months is simple, with extremely good prognosis and healing in more than 90% of cases. It consists in the central repositioning of the femoral head into the acetabulum, a position that can be gradually obtained by applying various types of abductor devices. In the first two age groups, very good results can be obtained by using pelotas (or more modern versions). The pelota is of square or rectangular shape, made of plastic or more rigid textile being contained in pantyhose. Due to it, hip flexion and abduction guides and centers the femoral head into the acetabulum.

It is also worth mentioning the increased attention that should be paid to borderline hips (border values for ultrasound examination), with the establishment of preventive measures in the first two age groups.

After the age of 3 months, the baby's muscles being more developed, the abduction diaper becomes insufficient for proper abduction. Therefore, the use of abductor devices, which can create abduction and progressive limited hip flexion, is essential for good morphological and functional results. Of historical value is the Von Rosen device, as the Freyka pillow.

Modern abduction devices must be easy to use (both worn and mounted), to allow abduction up to 60°, flexion up to 100° and at the same time to allow hip movements. These allowed motions contribute to joint development and helps to avoid complications. One of the most widespread abduction devices is the Pavlik harness. It allows a progressively positioning to the ideal position: flexion to 90-100° and abduction up to 60°. At the same time, the device allows properly hygiene of the infant, without suppressing the contention.

In the age groups up to 6 months, a 6-8 week treatment for moderate DDH has about 80-90% rate of success. The lack of a favorable response to this treatment scheme will require more advanced therapeutic stages: spica cast, tenotomies etc [2].

As the severity or age of the patient increases, the rigidity degree of the abduction system will also have to increase as: abduction diaper - abduction device - Pavlik harness - spica cast.

In choosing the right treatment, parents' compliance with treatment should also be considered by accepting the diagnosis and therapy proposed and by assessing their possibilities to care and to manipulate the device.

After 6 months of age, conservative orthopedic therapeutic results can only be applied to mild or moderate dysplasia. Even in these cases, there is often a need for preparatory treatment for closed reduction.

Also in this age group, desideratum is the congruence between the acetabulum and the femoral head. The use of abductor devices results in weaker results in this age group, because of the well developed pelvic belt muscles and relatively retraction of those muscles close to the hip joint. To overcome the muscle tone and to prevent excessive pressure on the femoral head, the bed extension with progressive abduction should be used [9].

The late diagnosis, followed by the late institution of therapy, involves, in addition to complex surgery procedures and increased failure rate risks, also, possible complications such as avascular necrosis of the femoral head. The avascular necrosis, major treatment complication, is not mentioned in untreated patients; the therapeutic methods with an increased incidence of avascular necrosis are: Pavlik harness, closed or open reduction and osteotomies [4].

Cost-effective economic studies have balanced both on time or late diagnostic and therapeutic costs. The conclusion was that a slight increase in diagnostic costs would lead to a significant decrease in the cost of therapy, claiming as the optimal diagnostic protocol to be the combined clinical and ultrasound screening for DDH [10].

2. DDH Positive Diagnosis, Staging and Monitoring Therapy by Radio-Imaging Methods

2.1. DDH positive diagnosis and staging

The DDH diagnosis is a clinical and radio-imaging multidisciplinary one, requiring corroboration of anamnesis and clinical examination data with those obtained from radio-imaging investigations.

While clinical diagnosis involves classical examinations subjected to subjectivity, imaging diagnosis provides data that will convey the positive diagnosis.

Although indispensable for a complete and accurate diagnosis, imaging examination methods vary according to several factors:

- patient age;
- loco-regional protocols;
- the complexity of the case.

The age of the patient - in accordance with WHO recommendations, hip ultrasound is the first chronological investigation indicated for the DDH diagnosis. Subsequently, at the age of 4 months, the classical pelvic radiography starts to increase its contribution. This is also useful in the diagnosis of late DDH cases as well as in the operator planning. Presently, in more and more countries, diagnosis of DDH by radiological methods, especially after 3-4 months of age, is considered malpractice.

Local and regional protocols - are established at national, university or clinic level. There is no worldwide valid protocol related to the investigation timing and the type of radio-imaging method to be used. There is no national standard in Romania, but ultrasound is increasingly recommended to be performed in the first few weeks of life.

The complexity of the case - may require the use of more imaging methods when there are more complex malformations including DDH as a related disorder or when preoperative planning is required. When surgical interventions requiring overall bone imaging, complex calculations related to the proximal femoral or acetabular cavity, but also to the muscular, tendon and cartilage structures involved, MRI or CT can provide more complete information. Multi-plane and 3D reconstructions can really help orthopedic surgeons.

Since the doctoral thesis is intended to be a plea for an early and non-invasive diagnosis, the ultrasound diagnosis will be more widely presented.

2.1.1. The ultrasound diagnosis of DDH

Ultrasound examination of the hip is universally accepted as the first imaging method used in DDH diagnosis.

Currently, there are several ultrasound methods that address both to the morphological and functional study of the joint (dynamic study).

The most common, known and accepted method is the one described by Professor Graf (Stolzalpe, Austria). The method was developed in the late 1970s and was clinically implemented for the first time in the early 1980s. The method was later improved by several changes, last in 2006.

Other popular but less standardized and less common echographic methods are those described by Harcke, Terjesen and Suzuki.

2.1.1.1. Graf hip ultrasound method

The hip ultrasound examination according to Graf method aims at the morphological study of the hip joint, assessing the degree of bone and cartilage coverage of the femoral head by the bony acetabulum as well as by the acetabular and periacetabular fibrocartilage structures. The method is qualitative, reproducible and standardized.

To perform the hip ultrasound examination according to the Graf method, a linear transducer with frequencies ranging from 5-10 MHz is required.

The following accessories are also recommended to be used: a foam/sponge concave cradle that will help hold the patient in the lateral decubitus position; as well as a transducer mounting system formed by metal arms, which will help to obtain a perfectly coronal sectional plane by avoiding the unwanted tilting of the transducer in the cranio-caudal and/or antero-posterior plane.

Ultrasound examination of the hip according to the Graf method can be performed even immediately postnatally and up to 7 months of age when the dimensions of the femoral head ossification nucleus will obstruct the ultrasound beam from spreading to the depth of the acetabular cavity making it impossible to visualize the elements necessary for diagnostic. Practically there is no age limit, bone maturation, the conformation and positioning of the ossification nucleus being the ones limiting the examination.

The approach is one in the coronal plane, using the greater trochanter (being cartilaginous in the newborn and infant age) as an ultrasound window. The ultrasound

plan will cross the greater trochanter, the femoral neck and the femoral head reaching the depth of the acetabular cavity. Of the many possible images, only one can be used for the morphological study of coverage degrees. This standard image must meet a multitude of fairness criteria: mandatory anatomical elements, as well as image orientation criteria.

The anatomical elements required to be identified are: 1) the femoral head (may contain the ossification nucleus), 2) the deepest point of the acetabular roof – lower limb of the bone ilium, 3) the perichondrium-periost junction (on the surface of the iliac bone), 5) the joint capsule, 6) the acetabular labrum, 7) the osteochondral plate or chondro-osseous junction (corresponding to the transition zone between the femoral head and the femoral neck), 8) the synovial fold joint (synovial), 9) the acetabular cartilage roof, 10) the bony rim – a point on the acetabular bony roof where the concavity of the acetabulum to the femoral head, turns into convexity.

The standard imaging plan is a coronal one, which has to cross the middle of the acetabular cavity, by cutting the femoral head through its maximum diameter. The main conditions for obtaining this image are:

1) the presence of the acetabular labrum - a triangular on the section fibrocartilage structure with increased ecogenity, being attached medial to the joint capsule and immediately below to the acetabular cartilage roof.

2) the iliac bone surface must be parallel to the surface of the transducer;

3) the presence of the lower limb of the bone ilium - appears on the image as a small round-oval, hyperechoic area that is located in the most caudal portion of the acetabular bony roof, being delimited inferior by triradiated cartilage (hypoechoic / transonic);

4) the presence of the osteochondral plate - appears on the ultrasound image in the form of an interrupted line formed by hyperecogenic points (palisades), starting from the metaphyseal region and continuing on the lower edge of the femoral head; line that is recommended to appear as long as possible and to show a trajectory that is perpendicular to the surface of the transducer.

At the same time, on the internal surface of the acetabular roof should be identified the "deflection point" known as "the bony rim". It is identified as the place where the curvature of the acetabular roof changes from the concave aspect to the acetabular cavity, towards the convex, further the curvature following the trajectory of the acetabular angle.

The joint conformation should be defined by assessing the degree of bone or cartilage coverage of the femoral head. These will be achieved by determining the alpha (α) and beta (β) angles. To determine them, it is necessary to identify 4 points:

1. Point located at the perichondrium-periost junction, placed on the surface of the iliac bone, immediately cranial to the acetabular angle;
2. The bony rim - from the acetabular roof, being described above;
3. The point tangent to lower limb - marked lower and towards the inside of the acetabular cavity;
4. The point located in the center of the acetabular labrum.

Through these points, there will be drawn three lines, which by their intersection will determine α and β angles:

A. the **base line** - the line that passes through point 1 and will be parallel to the surface of the transducer, practically following and continuing to caudal the surface of the iliac bone;

B. the **bony roof line** - will pass through points 2 and 3;

C. the **cartilage roof line** - will pass through points 2 and 4.

The α angle will be determined by the intersection of lines A and B. To define a hip with a normal configuration, the α angle should have a value of at least 60° . Depending on the obtained value, the hip would be classified in one of the four types: I - IV, where type I is the one considered normal and type IV is the most affected stage.

The intersection of A and C lines will determine the β angle. It has values considered normal when it is less or equal to 55° .

According to the α and β angles values on the Graf nomogram, as well as to the age of the patient, the hips are classified into 4 types:

Type I - defines the hip with a normal morphological configuration, the α angle being greater or equal than 60° . Depending on the value of β angle, two subtypes are described: **type Ia** for $\beta \leq 55^\circ$ and **type Ib** when $\beta > 55^\circ$. In both situations, the acetabular cavity is deep, the acetabular angle is sharp and well defined, the acetabular bony roof having a profound conformation. The bone coverage of the femoral head is optimal, exceeding 50% of its upper surface.

Type II - Depending on the patient's age and α and β angles values, type II includes several subtypes: IIa (IIa-, IIa+), IIb, IIc and D.

Subtype IIa is characteristic at patients aged <3 months. It is considered to be an immature hip with α value in the range 50° - 59° . Depending on the α angle value the evolutionary prognosis of the hip is considered as in the absence of therapeutic intervention, so that until the age of 3 months (12 weeks) the hip evolves to maturation and the desideratum is that α angle would be greater or equal to 60° . It is believed that in a very large proportion the immature hips exhibit a spontaneous healing evolution, with the improvement of the angle α at a rate of about 1° / week. According to this algorithm a hip with an angle $\alpha \geq 50^\circ$ at birth has a favorable

prognosis. Similarly, an angle $\alpha \geq 55^\circ$ at 6 weeks is credited with favorable evolution. Using the same algorithm, for example, if α value is $\leq 55^\circ$ at 6 weeks, the hip evolution to healing is having a negative prognosis. Therefore, this evolution prognosis will subdivide type IIa into **IIa+** (immature hip with favorable prognosis) and **IIa-** (intense immature hip with poor prognosis and dysplastic potential).

Type IIb - is characteristic in patients older than 3 months with α angle value being in the same interval as for the hips IIa, 50° - 59° . It is considered as the lowest degree of dysplasia.

Hips type IIa and IIb are morphologically characterized by viewing a less defined rounded acetabular angle, a more oblique oriented acetabular eyebrow and a lower degree of femoral head coverage.

In the case of preterm newborns, staging will be done using the corrected age. This is calculated by subtracting from the number of life weeks the weeks of prematurity.

Type IIc - is a severe dysplastic hip. It is characterized by values of α angle between 43° and 49° and it can be identified at any age. The acetabular bony roof is more oblique, with barely enough bone coverage to support the femoral head. β angle is less than 77° .

Type D - is a hip characterized by the same values of angle α as type IIc, but which in dynamic maneuvers can be dislocated. This implies, in addition to the reduced α angle value, also a large and deficient cartilage coverage of the femoral head with β angle value greater than 77° . Type D represents the first decentered hip.

Type III - is a subluxated hip. α angle value is less than 43° . The acetabular cartilage roof is superior and lateral deflected in relation to the acetabular bone angle. The femoral head is still at the same level with the acetabulum. This elevation of the femoral head will cause pressure on the acetabular cartilage. Increased and / or prolonged pressure will lead to structural changes in the cartilage structure. Thus, the acetabular cartilage roof normally has a highly hypoechogenic, almost transonic, ultrasound appearance. This is found in **type IIIa**. Structural changes will be identified echographically by changing ecogeneity, the appearance of cartilaginous tissue becoming more echogenic, thus characterizing **type IIIb**. The favorable progression of type IIIb treatment will, in a first phase, involves the passage through type IIIa.

Type IV - is the most severe stage and involves the hip luxation. α angle is less than 43° . The static ultrasound diagnosis includes the visualization of the femoral head in a position outside the acetabulum. The acetabular cartilage roof is deflected medio-caudal. This positioning, corroborated with the positioning of the labrum near the acetabular angle and the development of the pulvarium (fibro-adipose tissue filling the

acetabular cavity in the absence of the femoral head) in the depth of the acetabular cavity, represent factors that oppose the reduction of the dislocation by non-invasive orthopedic methods and impose surgery the most times. The standard image can not be obtained in such a way that all anatomical and correct elements to be present, due to the lack of normal anatomical relationships at the articular level [11].

2.1.1.2. Harcke method

The Harcke method - was designed by Professor Theodore Harke and is based on the combined hip study in a neutral position (morphological study) and under stress (the study in dynamics). Thus, a series of images are required in the coronal and transversal plane, respectively in a neutral position as well as under stress. The name of the obtained image will include both the section plane and the hip relaxation or flexion (stress) state.

The neutral coronal image - is the basic image for the morphological study. It is similar to the standard image of Graph technique, including measurements of α and β angles.

Coronal image in flexion it is obtained with the hip flexed at 90° . In this position, maneuvers will be performed on the femoral head to assess the articular stability and the degree of femoral head movement: piston and Barlow maneuvering with the hip in flexion and also in adduction.

Transverse image in flexion it is obtained with the hip flexed at 90° . The relations of the femoral head with the acetabulum will be followed when going from maximum adduction to maximum abduction. Barlow and Ortolani maneuvers will be performed with the hip in adduction position, respectively in abduction.

The neutral transverse image will appreciate the positioning of the femoral head in relation to the depth of the acetabulum, while also assessing the presence of pulvarium in the case of luxated or subluxated hips [12].

2.1.1.3. Terjesen method

It was described by Professor Terje Terjesen at the end of the 1980s. It requires a static and dynamic examination, in the coronal and transversal plane, with the patient in supine position. The degree of the femoral head coverage will be assessed, with a minimum of 50% considered normal in patients up to 1 month of age. It is also used to measure the distance between the tangent at the acetabular angle and the tangent at the external surface of the femoral head ossification nucleus. If the obtained image allows, α angle can also be calculated according to the Graf method. Terjesen technique has limitations in that it assumes the sphericity of the femoral head (which actually has the shape of a sphere flattened at the poles) and the central location of the ossification nucleus in the femoral head (in fact its position can be eccentric) [13,14].

2.1.1.4. Suzuki method

It was described by Shiego Suzuki in the early 1990s. The method involves, for the first time, the simultaneous both hips examination through the anterior approach with the help of a large linear transducer. The location of the femoral head is appreciated in relation to the horizontal tangent line to the anterior edge of the pubic bone surface and the perpendicular line on it that passes through the lateral portion of the pubic bones. Depending on the relationship of the femoral head with these lines, it is determined whether the hip is normal, subluxated or dislocated. The method allows examination of patients in orthopedic contention systems with hips in flexion and abduction [15].

2.1.2. Radiological diagnosis

Classic pelvis radiography has been widely used for DDH diagnosis until the 1990s when, with the introduction of the hip ultrasound, its indication has been reduced, with preference given to early diagnosis and avoiding irradiation.

Pelvis radiography is indicated after the age of 6-7 months when the hip ultrasound is limited by the degree of bone maturation, which by the increased dimensions of the ossification nucleus will prevent visualization of the whole acetabular cavity. Therefore, at present, the pelvis radiography is used for: the diagnosis of late DDH cases, in patients who have not performed the hip ultrasound, in those who have walking disorders or hip pain, to follow the cases diagnosed and treated at younger age and for the primary diagnosis when the ultrasound was normal but hip dysplasia developed subsequently. It may also be indicated in particular cases when more complex malformations of the entire pelvis and / or the proximal femur are present.

Typically, the pelvis radiography will be performed with the lower limbs extended and in the adduction position.

It will appreciate:

- continuity of the Menard-Shenton line;
- normal positioning of the femoral head in the inferomedial quadrant formed by the Hilgenreiner and Perkins lines, respectively lateralization or ascending femoral head position in pathological conditions;
- acetabular cover angle.

In children and teenagers with undiagnosed and untreated DDH or with residual dysplasia, signs of degenerative changes may occur, as: subchondral osteosclerosis in

the acetabular bony roof, narrowing of the articular space, bone cysts in the femoral head and acetabulum etc. Major complications include deformation of the femoral head secondary to avascular necrosis, version and structure modifications of the acetabulum [14,16,17].

2.1.3. Arthrography

It is generally used intraoperative in older children. It allows both the anatomical evaluation of the joint and the possible presence of the factors that oppose the reduction, as well as post-reduction for the appreciation of its quality. The contrast injection will be performed under radioscopic control, with attention being paid to the concentration and amount of intraarticular injection of the contrast product [17].

2.1.4. CT diagnosis

The CT examination gives superior visibility of the acetabular anatomy as well as of the reduction quality. The correct evaluation of the femoral head position in the acetabular cavity is due to the axial plane sectional images. An additional advantage is conferred in the case of children immobilized postoperatively in the spica casts. But it is always necessary to consider the high degree of irradiation involved by the CT examination.

On the axial sections obtained through the center of the acetabulum, the anterior and posterior acetabular angles, which define the degree of inclination of the anterior and posterior acetabulum, can be calculated. The acetabular axial index is given by the sum of the two angles and defines the degree of the whole acetabular cavity depth.

The acetabular version angle is an important parameter to be determined especially for planning the pelvic osteotomy. On the axial image passing through the center of the acetabular cavity, this angle is calculated by the intersection of the line joining the anterior and posterior acetabular margins and the perpendicular raised from the point where the acetabular line intersects the horizontal line tangent to the posterior aspect of the bony pelvis.

The CT scan also determines the ante or retroversion of the proximal femur. For this purpose, it is necessary to obtain the axial line through the femoral neck and head, respectively the line tangent to the rear aspect of the femoral condyles; the angle formed between them, by superimposing the images, will determine ante or retroversion of the femur.

3D CT images are also useful for the overall study of acetabular morphology [17,18].

2.1.5. MRI diagnosis

The use of MRI in the diagnosis of DDH is limited due to increased costs, but also to the need for sedation. In particular cases, MRI can have an important contribution through increased visualization of soft structures: acetabular cartilage, femoral head, acetabular labrum, excess pulvinar, etc.

2.2. DDH ultrasound screening

An aspect under international debate in recent years, including nowadays, is the use of ultrasound diagnosis for DDH detection as a general screening method or only in selected cases [19].

Use as screening also involves discussion of the timing of the first ultrasound. There are authors who recommend taking the ultrasound in the first few days after birth in order to get a diagnosis as early as possible. Others are supportive of the idea to do it at the age of 4-6 weeks for better correlation with the clinical diagnosis, but also with any aspects encountered in the dynamic examination. The hip becomes stable at this age, avoiding erroneous instability diagnostics (there may be a high degree of articular hyperlaxity in the first 4 weeks of life) [20].

National universal ultrasound screening for DDH has been introduced in several European countries since the 1990s: Austria, Switzerland and Germany.

Selective ultrasound screening involves performing ultrasound examination only in patients presenting risk factors (breech delivery, twin pregnancy, family history, other associated musculoskeletal disorder) and / or clinical suspicion.

The main opponents of the universal screening claim the method's high rate of false positive diagnosis which is leading to an increased rate of treatment, as well as the lack of reproducibility and the operator's dependence [21].

Other studies support the opposite by statistics indicating a nearly double treatment rate when the diagnosis is only clinically formulated compared to the ultrasound diagnosis [22]. Another study in Norway shows that 92% of young people in need of total hip prosthesis showed healthy hips in postnatal clinical examination. Therefore, there is a poor correlation between clinical suspicion and ultrasound diagnosis. The screening based only on clinical data is supposed to be a source of late diagnosed DDH [23,24].

Part of the increased rate of positive diagnosis generated by ultrasound screening may be induced by the inclusion of immature hips (IIa+, IIa-), but whose therapy is a minor and not aggressive one. Poor correlation of ultrasound and radiographic diagnosis is also showed by some studies [25].

2.3. Monitoring of the therapy

The use of imaging techniques is essential in monitoring the treatment, both during the course of the procedure and at longer intervals to supervise the evolution over time and the possible occurrence of complications.

During treatment applied in the first few months of life, ultrasound is considered the optimal investigation. Using the same Graf method as for the diagnostic, ultrasound has the advantage of accurate tracking the evolution of the studied parameters (angles α and β), but also by appreciating morphological changes.

Ideally, ultrasound monitoring of the therapy evolution would be done at 4-6 weeks intervals. Thus, according to the data provided, the effectiveness of the treatment will be appreciated and the optimal abductor attitude will be chosen according to the disorder severity and the patient's age. Monitoring is indicated throughout the whole treatment, until a normal, stable and symmetrical parameters hip is achieved.

Even though treatment has been completed with the desired, healthy, stable hip, several authors support the need to monitor morphological changes that may occur up to the age of adolescence. These changes include those that may occur at the level of the femoral head (changes in structure and joint surface that can go up to avascular necrosis), acetabulum and labrum, with side effects of impingement or labral rupture [17,24].

After the age of 6-7 months, the monitoring will be performed by classical pelvis radiography. This may reveal possible bone changes and, in some cases, residual remissions or dysplasia [26].

CT has an extremely limited use due to the high irradiation and the need for repeated investigations will considerably increase the irradiation of patients.

MRI and arthro-MRI are particularly useful for evaluating postoperative progression, impingement diagnosis and labral lesions. MRI is also the most sensitive imaging technique for the detection of femoral head avascular necrosis, one of the most serious abductor treatment complications [17].

PERSONAL CONTRIBUTION

1. Working hypothesis / objectives

The studies conducted and presented in the part dedicated to personal contributions focused on the use of ultrasound examination for DDH diagnosis. Among the methods presented in the general part, we chose the method most representative internationally, the Graf method.

Although it is an extremely widespread and widely used method, it is still the subject of numerous controversies in the scientific environment. The incriminated existence of late DDH cases, as well as the false positive cases, requires the analysis of the factors that can generate these situations.

The next working hypotheses were formulated for the studies included in the thesis:

- there is a variability of α values depending on the osteochondral plate position on standard hip ultrasound image;
- borderline and asymmetric hips may be a cause for late DDH cases;
- concave iliac bone surface can be an ultrasound sign to be found in hip limited abduction cases due to muscle hypertonia;

The working hypothesis focused on improving the diagnostic quality of the Graf method through a better correlation of the imaging and clinical aspects. Thus, two new signs were taken into account in the standard ultrasound image: the osteochondral plate orientation and the concave sign of the iliac bone. Also, two new clinical-ultrasound situations have been described that are generating late DDH cases: asymmetric and borderline hips.

Observations were based on multidisciplinary collaboration between the ultrasound examiner and the pediatric orthopedic surgeon. Retrospectively, ultrasound images, as well as clinical data, were analyzed to better integrate information and optimally apply them in practice.

The set objectives:

- standard ultrasound hip images analysis;
- identification of the different values of α angle for different positions of the osteochondral plate;
- correlation of clinical and ultrasound data for borderline and asymmetric hips;

- ultrasound follow-up for borderline and asymmetric hips during the treatment;
- identification of curve iliac bone surface on the ultrasound images;
- correlations between ultrasound findings and clinical data for patients presenting limited hip abduction.

The underlying objectives of this thesis were the improvement of the current state of clinical and ultrasound management of DDH, both in terms of diagnosis and treatment. Thus, statistically sustained observations were generated regarding: optimization of the standard image acquisition according to the Graf method and ultrasound information integration into the clinical practice.

2. General methodology

The studies were based on common elements regarding the clinical and imaging study methodology.

For all cases undergoing clinical examination, the same tests were applied: Ortolani, Barlow and assessment of hip abduction. Clinical examination was performed by an orthopedic pediatric surgeon with clinical experience of at least 15 years in the hip examination of newborn and infant. All data resulting from clinical evaluation were recorded in individual reports.

Due to the diagnostic capacity in the first few weeks of life, ultrasound examination according to the Graf was chosen the imaging method of hip analysis. The examination methodology was unitary, regardless of the ultrasound equipment used, this being represented by a Hitachi EUB 8500 and a Hitachi Noblus. Both have linear transducers with variable frequencies of 5-13 MHz. In both situations the images were stored in the internal memory of the ultrasound and later transferred for processing.

The actual screening methodology included the successive evaluation of the two coxo-femoral joints with the child sitting in the lateral decubitus, with his mother maintaining the position and also ensuring the lower limb contention.

Obtaining the standard image characteristic of the Graf method was validated, for each case included in the studies, by identifying the anatomical and mandatory correctness elements (Figures 1 and 2).

The ultrasound examination ended with a written report that included the value of α and β angles, as well as other particular aspects. These reports have also been archived.

In patients monitored during therapy, reevaluations were performed at intervals of 4-6 weeks.

In cases that did not benefit from clinical examination, the doctor who performed the ultrasound made a brief anamnesis for identifying possible risk factors.

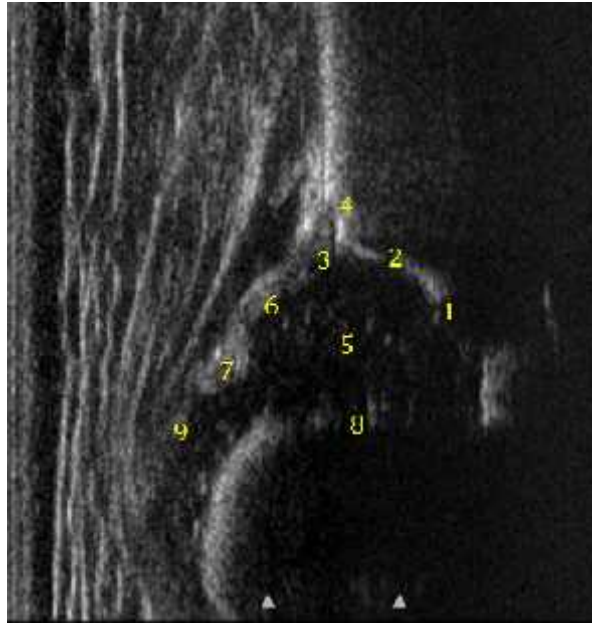


Fig. 1. Anatomical landmarks on hip ultrasound standard image according to Graf method: 1 – lower limb, 2 - acetabular bony roof, 3 - acetabular cartilage roof, 4 - perichondrium-periost junction on iliac bone, 5 – femoral head (after the age of 3 months the ossification nucleus may be visible), 6 – labrum, 7 – synovial fold on joint capsule, 8 – osteochondral plaque, 9 – greater trochanter.

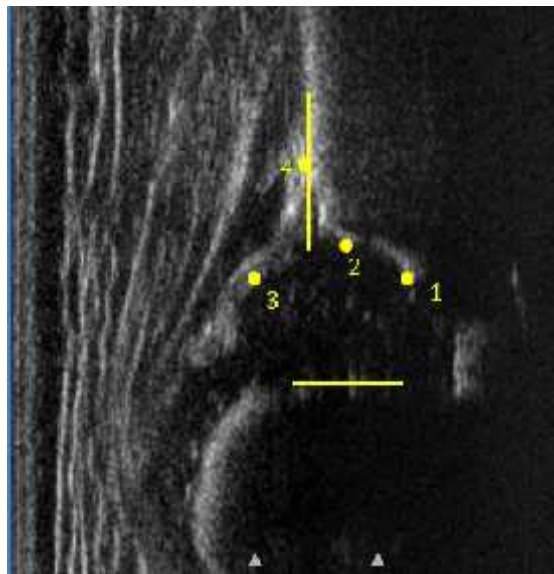


Fig. 2. Correctness elements: 1 – lower limb, 2 – bony rim, 3 - labrum, 4 - perichondrium-periost junction, vertical line – surface of the iliac bone parallel with the surface of the transducer, horizontal line – osteochondral plate – perpendicular on the surface of the transducer.

3. Study I. A new sign in the standard hip ultrasound image of the Graf method

3.1. Introduction

Developmental dysplasia of the hip (DDH) is a well-known and studied condition, which can affect the hip joint throughout its development. Although numerous studies have focused on the issue of diagnosis, there is still no widespread consensus on the approach [27,28]. The literature presents many concepts ranging from purely clinical diagnosis to complex screening programs [28,29].

One of the most popular hip ultrasound diagnostic methods is the Graf method. Although the most commonly used, this method continues to generate discussion on the sensitivity and specificity, based on the rate of false positive or false negative diagnosis [30,31,32].

The Graf method is based on obtaining the standard image of the hip joint. In this image it is mandatory to see the elements that certify the accuracy: lower limb (lower extremity of the bony acetabular roof), the plane of the iliac bone surface parallel to the surface of the transducer and the labrum. It is also necessary to correctly identify: the femoral head (with the ossification nucleus when present), perichondrium-periosteum junction, joint capsule (with a characteristic fold), greater trochanter, convexity-concavity deflection point and the osteochondral plate (visible in the inferior aspect of the femoral head) [11].

The main drawback incriminated is over-diagnosis leading to unnecessary treatment and increased health costs [33]. Some studies propose alternative ultrasound methods to the Graf technique and some countries and centers are adherent to these alternative methods [34,35,36,37].

Extensive studies have been conducted to assess the correlations between clinical and ultrasonographic diagnosis or between ultrasound and classic hip radiography [38].

The outcome of these complex studies is influenced by: long duration (the Graf method has last time been improved in 2006 [11]), the lack of a golden standard and the ethical conflict in using an irradiating technique like radiography. The common criticisms of the Graf method are: the high rates of over-diagnosis and the dependence on the examiner's experience [30,31,39].

The present study aims to assess the usefulness of an additional element of accuracy for the standard image of the Graf ultrasound method. The standard image of the Graf method requires the identification of three marks that certifies the presence of the mid acetabular roof plane [40]. But, interobserver variations in the measurements had been reported [30,31,39]. This study investigated whether an additional accuracy criterion may contribute to a better tailored diagnosis of DDH using Graf method.

3.2. Working hypothesis

The working hypothesis was based on the idea of a better correlation between the ultrasound image and the clinical data, due to the incriminated high rate of over diagnosis of the Graf hip ultrasound method.

Based on the observations from the ultrasound practice, it was noticed the possibility of the osteochondral plate being caught in different positions, also fulfilling all the criteria of correctness required by the Graf method.

Thus, the working hypothesis formulated for this study was: "There are variations in the angle α values depending on the position of the osteochondral plate".

Objectives:

- the α angle mean values variation before and after using the horizontal osteochondral plate criteria;
- analysis of incidence of false positive diagnosed cases without the use of horizontal osteochondral plate criteria;
- analysis of the therapeutic evolution compared to mild types dysplasias or immature hips.

3.3. Material and methods

The study was conducted in the Radiology Department of the Emergency County Clinical Hospital Cluj-Napoca, by retrospective analysis of the database containing 2356 reports of the subjects presented for DDH assessment January 2008 – December 2014. For all abnormal cases a clinical examination by an experienced orthopedic surgeon was performed in the Orthopedic Department of the Rehabilitation Clinical Hospital Cluj.

In all cases hip ultrasound was performed according to Graf method by using Hitachi EUB 8500 ultrasound equipment with a 6.5-13 MHz linear transducer.

The study inclusion criteria were: subjects presenting for ultrasound hip screening for which the ultrasound diagnosis was either normal (Ia, Ib), immature hips or mild dysplasia (IIa+, IIa- and IIb) according to Graf method hip staging criteria [33]. Patients with risk factors (family history, breach or transverse presentation, gemelarity, oligohydramnios, associated neuromuscular and musculoskeletal

pathology: clubfoot, metatarsus adductus, torticollis, cerebral palsy) and with prior clinical examination or indication for hip ultrasound due to suspected DDH were excluded. Patients with severe DDH (IIc, D, IIIa, IIIb and IV) were also excluded.

From the total 2356 subjects examined between January 2008 and December 2014, 1278 patients were excluded. The study group was limited to 1078 patients (2156 hips). The study group was divided into two groups, according to the period of time and the examination technique.

Group I consisted of patients examined between January 2008 and December 2011 (402 patients - 804 hips), who underwent ultrasound examination of the hip according to the classic standards of the Graf method.

Group II consisted of patients examined from January 2012 to December 2014 (676 patients - 1352 hips), who underwent ultrasound of the hip according to the Graf method with an additional quality criterion developed by our group, named the perpendicular osteochondral plate. Technique and description of the criterion under investigation: while obtaining the quality criteria of the Graf image, special attention was paid to angulate the transducer to a point where the osteochondral plate is visible on its width and the angle between a plane passing through the osteochondral plate and the surface of the transducer is 90° (Fig. 3).

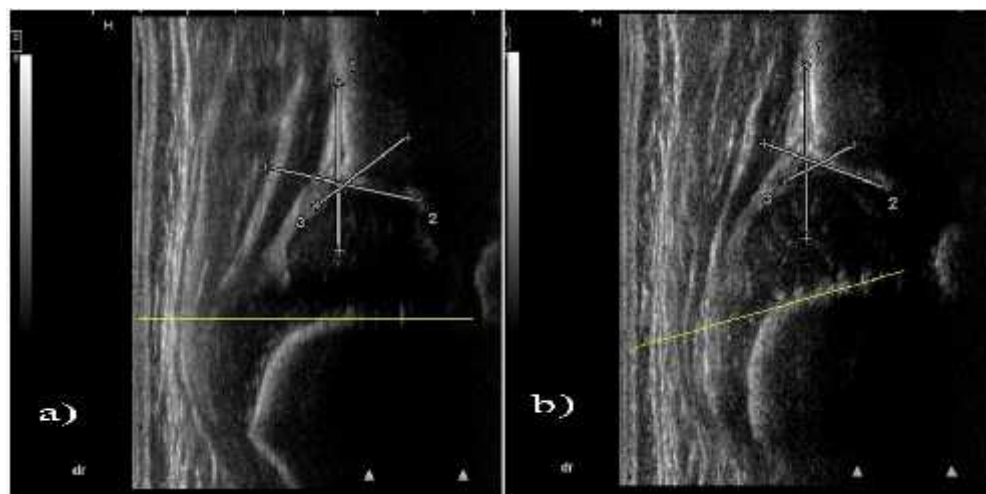


Fig. 3. Standard ultrasound images of the same right hip. It can be seen the variation in the direction of the osteochondral plate - yellow line: a) horizontal; b) superior oblique. On the left side of the images are included the angles measurements.

The institutional ethics committee approval was obtained and, due to the retrospective character of the study, written consent was waived.

Statistical analysis was performed using SPSS 13.0 for Windows software (SPSS Inc., Chicago, IL, USA) and the statistical tests were chosen according to the studied data type: descriptive statistics (Means, std. Dev, std. Error 95 % CI, Min, Max), Kolmogorov-Smirnov test, the Mann-Whitney U test and Z test. The Kolmogorov-Smirnov test was used to determine the normality of the distribution in the study groups. The Mann-Whitney U test was used to assess not normally distributed data (average alpha angle values in the two groups). Z test was used to compare two population groups' proportions. P was considered statistically significant at a value $p < 0.05$ for Mann-Whitney U test, respectively $p < 0.01$ for the Z test.

3.4. Results

The demographic analysis of the two groups is presented in table I.

Table I. Comparative demographic data of group I and II

	Total no.	Gender			Age (weeks)			
		m	f	f:m ratio	Av.	Std. dev	Min	Max
Group I	402	156 (38.7%)	246 (61.3%)	1.57	12.1	6.86	2	40
Group II	676	300 (44.4%)	376 (55.6%)	1.25	9.9	5.35	2	40

The distribution of the values of the alpha angle in the two groups is illustrated in figures 4 and 5.

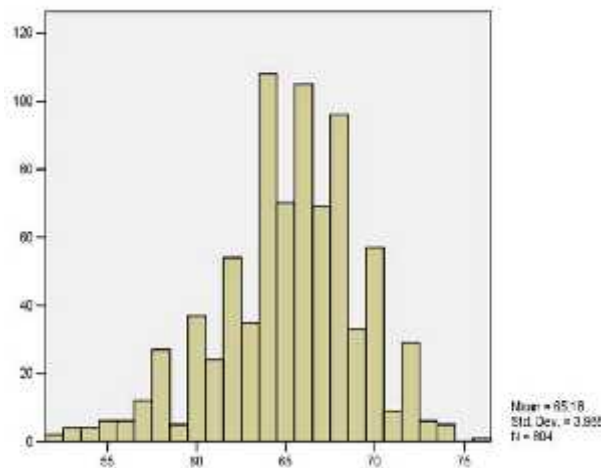


Fig. 4. Non normal distribution of the alpha angle values in Group I

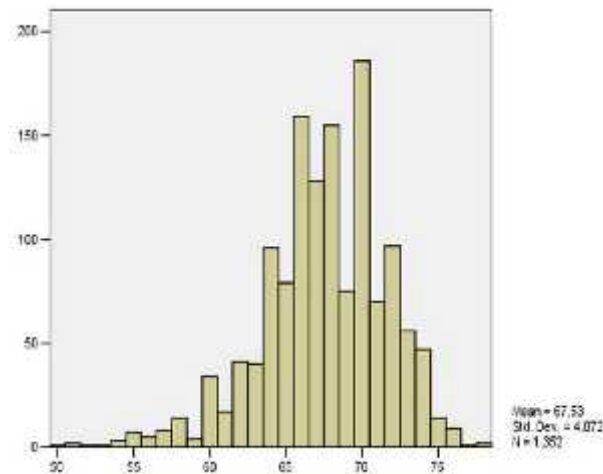


Fig. 5. Non normal distribution of the alpha angle values in Group II

The Kolmogorov-Smirnov test applied to both groups showed non normal distribution of the data ($p < 0.05$).

The alpha angle average of all hips from group I and II are showed in table II.

Table II. Descriptive data analysis of the alpha angle for all subjects from group I and II

	N	Mean	Std. Dev	Std. Error	95% Confidence Interval for Mean		Min	Max
					Lower Bound	Upper Bound		
Group I	804	65.18	3.965	.140	64.90	65.45	52	76
Group II	1352	67.53	4.072	.111	67.31	67.75	50	78
Total	2156	66.65	4.189	.090	66.47	66.83	50	78

The Mann-Whitney U test showed significant difference between the means of the two groups ($p = 0.000$).

The alpha angle average was computed separately for the hips labeled as normal and for the abnormal hips, in both groups (table III).

Table III. Descriptive data analysis of the alpha angle for normal and abnormal subjects from Group I and II

		No.	Mean	Std. Dev	Std. Error	95% Confidence Interval for Mean		Min	Max
						Lower Bound	Upper Bound		
Normal	Group I	738	65.93	3.137	.115	65.71	66.16	60	76
	Group II	1306	67.92	3.515	.097	67.73	68.12	60	78
	Total	2044	67.21	3.516	.078	67.05	67.36	60	78
Abnormal	Group I	66	56.71	1.846	.227	56.26	57.17	52	59
	Group II	46	56.26	2.245	.331	55.59	56.93	50	59
	Total	112	56.53	2.022	.191	56.15	56.91	50	59

Statistical analysis showed significant difference between the average alpha angle of normal labeled hips in groups I and II ($p=0.000$, Mann-Whitney U test). There was no statistical difference between the average alpha angle of the abnormal hips in the two groups ($p=0.497$).

The incidence of abnormal alpha value diagnosed patients / hips was calculated in each group (Table IV).

Table IV. Comparative incidence of normal and abnormal patients / hips in group I and II

	Total No. patients / hips	Normal patients / hips	Abnormal patients / hips
Group I	402 / 804	347 (86.3%) / 738 (91.8%)	55 (13.7%) / 66 (8.2%)
Group II	676 / 1352	638 (94.4%) / 1306 (96.6%)	38 (5.6%) / 46 (3.4%)

There was significant difference of incidence of the abnormal hips between the two groups ($p=0.000$, Z-test).

The data shown in table III implies that the addition of the new quality criterion increases the average value of the obtained alpha angle by 2° . To assess this effect of the new quality criterion, a recalculation of all alpha angles in group I was performed by adding 2 units to the original value. Reclassification of the hips with the new values (group IR) provided an incidence of the abnormal labeled patients of 7.4% (30 patients). Comparing groups IR and II yielded no significant difference in incidence of the abnormal patients ($p = 0.115$, Z-test).

Evaluation of the obtained osteochondral plate sign in the archived images of the patients from group II showed a 87% success rate.

3.5. Discussions

The introduction of hip ultrasound for DDH diagnosis was equally a great progress in pediatric clinical practice and created a distinct niche of uncontested clinical application of ultrasound examination. For more than 30 years the ultrasound Graf method is widely used for this purpose [41].

The main criticisms on the Graf method are represented by: variability and examiner dependency. Graf described the quality criteria needed to produce interpretable and reproducible images [11].

One further criticism of the Graf method is the over-diagnosis.

This study aimed to analyze the impact of an additional quality criterion in obtaining the standard image. For this purpose, the allotment of the subjects in one of the two patient groups based was on two considerations: the period of time and the method of investigation used. Although unequal, the chosen time intervals aimed at the inclusion of a sufficient number of patients to allow significant statistical studies. Since ultrasound is used as a screening method, only patients who were presented in department for this purpose were included in the study groups. This is the reason why patients presenting risk factors, with previous clinical exam or indication for hip ultrasound were excluded. Given the sporadic and unpredictable occurrence and the potential influence on the population average values, ultrasound diagnosed severe dysplasia (IIc, D, IIIa, IIIb and IV) cases were also excluded from the study. The final difference between the 2 groups consisted only in that for group I classic Graf method was applied and for group II was used Graf method with the additional accuracy criterion. In evaluating the results, it was assumed non-variable DDH incidence in the constant ethnic population over a few years as stated by Randall et al [27].

The demographic study revealed a difference in females / males ratio of 1.57:1 in group I compared with 1.25:1 in group II. This can be explained by the wider acceptance, in the last years, of universal ultrasound screening idea without taking into account the baby's gender. In the same context, better information on the need to perform hip ultrasound led to a decreased of the average age at first presentation in the second group, closer to the recommended age of 4 – 6 weeks [43].

Initial comparison between the two groups showed statistically significant differences in the alpha angle value of the patients labeled as normal. A 2° higher average value of the patients from group II than group I was calculated (67° vs 65°).

There was a statistically significant difference between the number of patients diagnosed having a less than 60° alpha angle hips in the two groups: more normal hips diagnosed in group I as compared to group II. The 2° angle difference may exert a major repercussion on borderline hips: type IIa-, IIa+ or IIb with alpha angle value close to 60° . This category of patients is the main cause for controversial literature data on the increased rate of over-diagnosis [32,37,43,44].

The average alpha angle value of both normal and abnormal hips was calculated separately for both groups. For the normal labeled hips the difference of 2° persisted and was validated by statistical analysis. There was no statistically significant difference between the average values of the abnormal hips in the two groups. These results infer that the perpendicular osteochondral plate sign may add an average value of 2° at the measured alpha angle. Higher absolute value of the alpha angle may in its turn contribute to the reclassification of some of the borderline abnormal hips. As there was significant difference in the percentage of abnormal hips in groups I and II (lower percentage in group II) and as this observation contradicts the original study assumption as stated above an attempt was made to validate the observation by reclassifying the abnormal hips in group I by adding 2° to the initially measured value. In newly formed group IR, all hips from original group I and with alpha angles of 58° and 59° were relabeled as normal. From the 55 patients initially diagnosed as having abnormal hips, only 30 remained abnormal in group IR when using the new criterion. The newly obtained incidence of abnormal hips in group IR was 7.4%, with no statistically significant difference from group II (5.6%, $p>0.1$). A large numeric study of Caucasians examined for DDH by hip ultrasound mentioned an incidence of 7.15% [45], similar to group II and IR from the present study (5.6% and 7.4%). The relatively increased number of abnormal cases does not mean an equal incidence of DDH. The incidence reported for group II and IR includes also immature hips.

Some limitations of the present study must be acknowledged. A limitation of the present study could be the success rate in obtaining the new criterion on the standard image. This is difficult or sometime impossible for very advanced mature hips when the osteochondral plate is located in the acoustic shadow generated by the ossified lateral part of the plate. In this situation the direction of the osteochondral plate is either perfect horizontal, or slightly oblique to inferior [11]. Therefore, when acquiring the standard image the osteochondral plate might be visible having a horizontal trajectory in an image immediately before obtaining the standard one. However, due to the constantly decreasing age at the presentation these were not considered a major limitation and as shown the success rate in group II was 87%.

Due to the retrospective character of the study, interobserver and intraobserver variability assessment of the new criterion was not performed.

The study refers strictly to ultrasound hip approach and not to the overall management of the case. Complete management of a DDH case is more complex and subject to further studies.

3.6. Conclusions

The present study suggest that the addition of a new quality criterion for the Graf method standard image may contribute to a better tailored approach to the ultrasound diagnosis of DDH by lowering the number of over-diagnosed cases. This criterion may be useful especially in cases with borderline values of the alpha angle. Further studies are mandated to confirm these observations and fully assess the clinical usefulness.

The presence of the osteochondral plate sign in the standard image of the Graf method leads to a decreased number of diagnosed DDH cases. This lowered cases number comes to remedy the over-diagnosis complain of those who oppose ultrasound screening for DDH. As a consequence, it will reduce cases of unnecessary treatment, especially in patients diagnosed with mild or moderate DDH. Future studies on more meaningful numeric groups may confirm or refute our observation.

4. Study II. Ultrasonographic Borderline and Asymmetric Infant Hips - a Challenge in Developmental Dysplasia of the Hip Management

4.1. Introduction

DDH is a condition with invalidity potential. Its diagnosis is based on the identification of risk factors, clinical examination and the appropriate use of imaging methods according to the age of the patient: hip ultrasound and classic pelvic radiography. Diagnosis method and complexity still remain in the international debate. It is widely accepted that for optimal therapeutic results the early diagnosis must be formulated until the age of 6 weeks [46,47].

Although subjective, clinical examination is somewhat standardized in terms of tests performed: Ortolani, Barlow, assessment of abduction. Clinical examination results are influenced by many factors: patient age, the examiner's experience, degree of muscle tone, the status of the opposite hip etc [48].

The use of ultrasound as first intention imaging method is universally accepted. However, there is still a debate regarding the optimal time when it should be performed and about the target group. Examination protocols differ depending on the country or center. Two concepts are most widespread: 1) hip ultrasound only in patients with present risk factors and / or those with a clinical suspicion; 2) hip ultrasound as screening method for DDH, independent from clinical examination [49,50,51].

Graf method is the most common and standardized ultrasound technique. It is based on a standard image that must meet several criteria of correctness. This image serves to determine α and β angles, which represents bone and respectively cartilage coverage of the femoral head. Although widely used, Graf method has contesters. They report an increased rate of positive diagnosis, but also late diagnosed DDH cases by radiography in patients considered healthy on first ultrasound examination [50,52,53,54].

Empirical observations of our group revealed that borderline and asymmetric hips might have unfavorable outcome. Although asymmetric and border hips are not a rare discovery in ultrasound practice, literature is deficient in information.

The purpose of the paper is to assess the degree of risk of the evolution of these hips.

4.2. Working hypothesis

The work hypothesis was based on improving the correlation between the ultrasound aspect and the clinical data for the reduction of the late DDH cases.

Both from previous clinical experience and from literature data, we found the existence of cases that although they were declared healthy at a first ultrasound examination, they subsequently developed DDH. Analyzing the ultrasound images we found that some of these cases had α angle values equal or slightly greater than 60° . Another group of patients presented marked asymmetries of α angle values at bilateral comparative look of the hips.

These ultrasound findings were combined with clinical and anamnestic data.

Following this analysis, the working hypothesis was drawn up: "The existence of a lower limit of normal or of asymmetry can lead to late DDH cases".

4.3. Material and methods

The study focuses on investigating two possible sources of missed cases by clinical-ultrasound management of DDH: borderline and asymmetric hips.

Borderline hips are those with α angle value of 60° and 61° , in patients considered healthy according to Graf method.

Asymmetric hips in a patient are considered when the values of α angle are greater than 60° , but left to right difference between the α angle values exceeds 4° . The study was conducted in the Radiology Department of the Emergency Clinical County Hospital Cluj-Napoca, by retrospective analysis of the database containing 3013 reports of the subjects presented for DDH assessment January 2008 to December 2014. In all cases, hip ultrasound was performed according to the Graf method using Hitachi 8500 EUB US equipment with a 6.5-13 MHz linear transducer. A single operator having two years experience in hip ultrasound at the date of the onset of the study period performed all the examinations.

Due to the retrospective nature of the study the organization ethics committee waved informed consent.

Inclusion criteria consisted of: subjects presented for the first time to hip ultrasound with or without prior clinical examination and for whom examination data and ultrasound images were available.

Exclusion criteria were: severe dysplastic hips (IIc, IIIa, IIIb and IV), patients for whom either report data or images were missing.

Of the initial 3013 reports analyzed, after applying the above criteria, data for 2517 subjects represented the study group.

The age of the patients included in the study ranged from 2 weeks to 6 months (26 weeks), with a mean age value of 10.7 weeks.

Three independent groups were formed according to α angle values:

Group I included 1985 healthy considered subjects with bilateral $\alpha > 60^\circ$ and without a difference greater than 4° between the hips α angle values.

Group II included 250 patients with borderline and/or asymmetric hips as defined above.

Group III included 282 patients having at least one hip classified as DDH or immature (IIa-, IIa+ and IIb) according to Graf method.

On all groups II and III patients, abduction devices were used according to the orthopedic surgeon decision. The same ultrasound operator using the same Graf method performed at follow-up examinations after 4-6 weeks of treatment for most of the patients of Group II and III.

Patients with follow-up were considered for comparing the outcome of groups II and III.

A favorable evolution was considered when an improvement of α angle values was discovered and at the end of the follow-up period, the patient was considered healthy complying with the following criteria: no borderline values or no asymmetry (fig. 6,7).

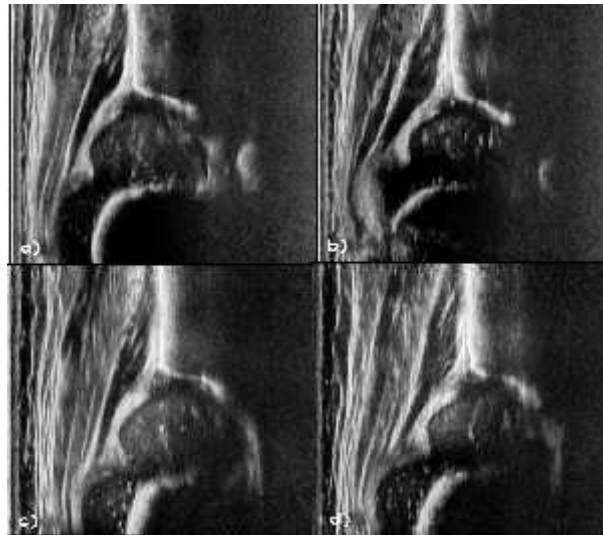


Fig. 6. Asymmetric hips in evolution. a) and b) show the initial stage at the age of 5 weeks – 8° difference between right and left hips alpha angle values (alpha angle measured for right and left hip were 71°, respectively 63°). c) and d) present the evolution after 5 weeks of abduction attitude (use of 2 diapers), 3° difference (72°, respectively 69°), it shows an improved alpha angle on the left hip (from 63° to 69°).

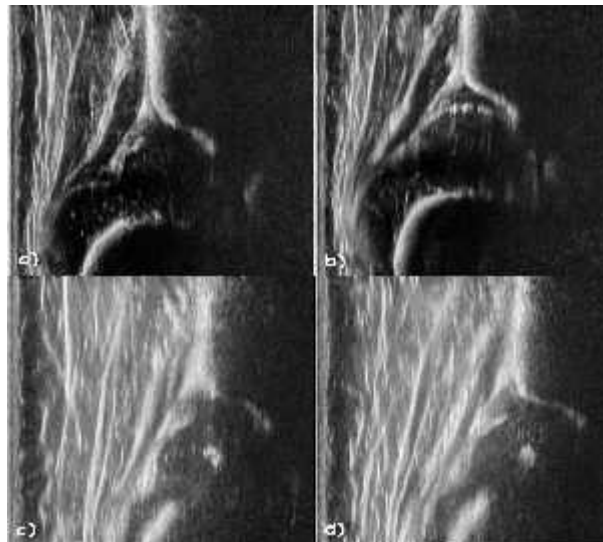


Fig. 7. Bilateral borderline hips. a) and b) represent the initial stage at the age of 6 weeks. Both hips had an alpha angle value of 60°. c) and d) after 6 weeks of abduction treatment attitude it was observed an improvement by 3° and respectively 4° on the alpha angle values. Appearance of the ossification nucleus in both femoral heads represents an indirect sign of favorable evolution.

Unfavorable evolution is defined as: staying or involution at a stage considered dysplastic (IIb or worse), obtaining or maintaining the asymmetry or a hip as border type (fig. 8).

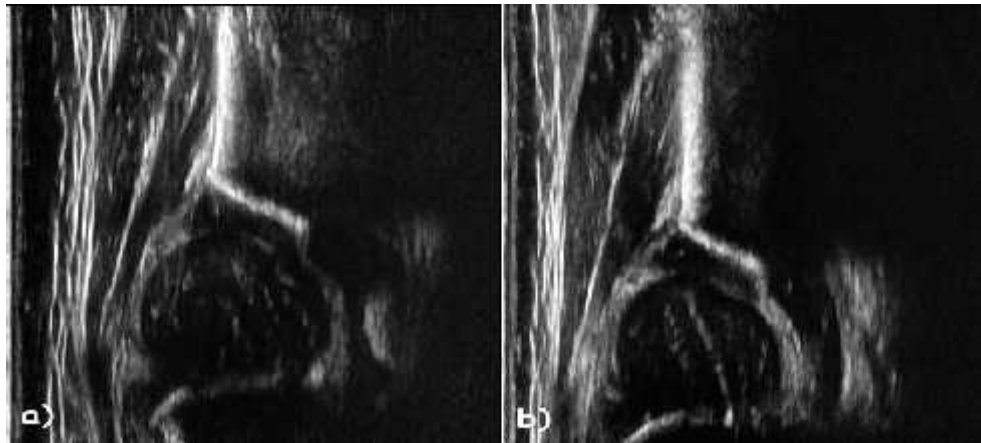


Fig. 8. a) Borderline 60° alpha angle left hip, b) stationary evolution to 61°, after 6 weeks of abduction treatment attitude, 2 diapers.

In order to find any correlation between the new supposed abnormal condition (asymmetric and borderline hips) and the known pathological conditions (immature and dysplastic hips), the incidence of risk factors (breech delivery, prematurity, family DDH history, twin pregnancy and associated musculoskeletal disorders as: club foot, torticollis, metatarsus adductus), clinical suspicion and the success of therapy were evaluated (Table V, VI).

Statistical software used was Social Science Statistics with free acces on <http://www.socscistatistics.com>. The Z-test was used, as recommended test to compare the population group's proportions and to assess the possible correlation between the same conditions presented in two different groups. P was considered statistically significant at a p value < 0.05.

4.4. Results

The incidence of risk factor for DDH in Group I was 19.24% (382 patients). From the total 1985 patients, 1231 were clinically examined firstly. After the clinical examination in 512 from these patients (41.5%) a clinical suspicion of abnormal hip was formed.

In Group II the incidence o risk factors was 16.8% (42 patients). 179 patients from the Group II performed initially clinical examination and indication for ultrasound evaluation was formulated in 55.3% cases (99 patients). There was follow-up available on 94 patients and on 7.44% (7 patients) of them an unfavorable evolution was observed.

Group III risk factor incidence was 18.79% (53 patients). From 191 patients examined clinically on 71.2% (136 patients) a suspicion was formulated.

From 38 patients recorded with at least one hip IIa- type, on 29 follow-up data showed 6.89% (2 patients) treatment failure rate.

In 196 patients having at least one hip IIa+ type, follow-up was recorded on 114 patients. The unfavorable treatment rate was 8.77% (10 patients).

Dysplastic hips IIb type was identified in 55 patients with follow-up on 27. 22.22% (6 patients) presented unfavorable evolution on treatment.

4.5. Discussions

Among the criticisms leveled by opponents of the Graf method, late detected cases that initially were considered healthy on ultrasound examination, is probably the most difficult accusation [52,53,55].

The purpose of this study is to identify two possible causes and to propose a solution for resolving them.

According to Graf, the inter-observer variation allowance is 2° , therefore we considered borderline hips those type I hips included into this limit of 2° (α angle: 60° and 61°). Those hips could become type II if another examiner performs the ultrasound (α angle: 58° or 59°).

The asymmetry finding between the two hips is based on the same principle of interobserver variation of 2° for each hip. Therefore, a difference of more than 4 degrees could be considered having a pathological substrate.

Analyzing the incidence of the risk factors in Group II and III, comparing with Group I, there is no significant difference. For Group I vs. Group II the Z-Score is 0.929. The p-value is 0.17619. The result is not significant p being greater than 0.05. For Group I vs. Group III the Z-Score is 0.1796. The p-value is 0.85716, the result being not significant for p value greater than 0.05. No significant difference was observed when comparing the incidence of the risk factors in Group II vs. Group III. The Z-Score is -0.5994. The p-value is 0.5485. The result is not significant p being greater than 0.05.

There were no significant differences between the three groups regarding the role of the risk factors in DDH pathogenesis (Table V).

Comparing pathological suspicion based on the clinical examination in Group I vs. Group II the Z-Score is -3.4599. The p-value is 0.00027. The result is significant at $p < 0.05$. Similar significance was proofed comparing Group I vs. Group III; the Z-Score is -7.6455. The p-value is 0. The result is significant at $p < 0.05$. Comparing the incidence of pathological suspicion in Group II vs. Group III, also, significant difference was observed: the Z-Score is -3.1744. The p-value is 0.00076. The result is significant at $p < 0.05$. Those data reveal a high suspicion rate after the clinical examination, in groups II and III, comparing with the healthy population. That means that from this point of view, Group II might be considered having at least a dysplastic prognostic (Table V).

Table V. p-values obtained when comparing the incidence of DDH risk factors and DDH clinical suspicion in the three groups

	Group I vs. Group II	Group I vs. Group III	Group II vs. Group III
Risk factors	0.17619	0.85716	0.5485
Clinical suspicion	0.00027	0	0.00076

Regarding the unsuccessful treatment rate Group II is compared with IIa-, IIa+ and IIb subgroups from Group III. In the first two situations, there is no significance between treatment of borderline and asymmetric hips and immature ones: Z-Score=0.0995, p-value=0.46017, respectively Z-Score=-0.3472. p-value=0.36317; the result is not significant, p being greater than 0.05.

But, comparing unsuccessful treatment rate from Group II with subgroup IIb, true DDH hips, a significant difference is observed: Z-Score=-2.1852, p-value=0.01426, the result being significant at $p < 0.05$. Data reveals an increased correlation in the therapeutic results between Group II patients and those from mild delayed maturation subgroups from Group III (IIa-, IIa+) (Table VI).

Table VI. p-values obtained when comparing the incidence of unsuccessful treatment rate of Group II vs. subgroups from Group III.

	Group III, IIa-	Group III, IIa+	Group III, IIb
Group II	0.46017	0.36317	0.01426

This study supports the idea of using ultrasound Graf method for diagnosing and monitoring the evolution of DDH.

The management of borderline and asymmetric hips should be performed in collaboration with an orthopedic physician. Even if the subjects in one of those situations are not considered having DDH, abductor attitude should be considered as a preventive method for a possible unfavorable evolution. We suggest that a minimal

therapeutic intervention in borderline and asymmetric hips might lead to a decrease in the late detected cases number.

Further studies on larger scale are required to validate these observations.

The study presents a few limitations. Because a single examiner conducted the ultrasound study, the interoperability variability could not be analyzed. The study is longitudinal retrospective and so the examiner was in the learning curve during the study period so that intraoperative variability cannot be analyzed. The therapeutic approach to the abnormal hip changes over time and tends to give up some old devices such Pavlik harness. The treatment has been instituted by several pediatric orthopedists in the absence of a standardized treatment protocol. There is no way to analyze the parent's compliance with the recommended therapy.

4.6 Conclusions

The study main observation could mean that borderline and asymmetric hips should be managed similar to immature and potential dysplastic hips (IIa+ and IIa-), showing a potential pathological condition.

Borderline and asymmetric hips could represent a cause for late diagnosed DDH.

5. Study III. A Possible Ultrasound Correspondence of Limited Abduction in Infants Screened for Developmental Dysplasia of the Hip

5.1. Introduction

DDH is the most common dysplastic disorder diagnosed in newborn and infant. However, the methodology for diagnosis hip dysplasia is still a controversial issue. It is accepted that all newborns and infants should undergo clinical examination in the first few weeks of life [56]. The use of ultrasound as a universal or selective screening method is still questionable [57].

The clinical examination includes maneuvers designed to evaluate joint stability as well as the degree of abduction. The abduction may be exaggerated, in the case of hyperlaxity, or limited, most frequently as an expression of adductor muscles hypertonia. The clinical examination is generally influenced by the subjectivity of the examiner. If clinically hip instability can sometimes be evidenced by ultrasound during dynamic examination methods, hypertonia can not be evaluated, staying only at the clinical observation stage.

The Graf method is the most widespread ultrasound technique for infant hip examination. This is a static examination, which uses a standard image for assessing the degree of bone and cartilage coverage of the femoral head. The Graf method is considered to be the most reproducible and standardized technique. The difficulty of the method is to obtain a correct standard image, for which there are some mandatory criteria to be fulfilled: the iliac bone surface to be parallel to the surface of the transducer, the presence of the deepest point of the acetabular roof and the acetabular labrum on the image and the perpendicularity of the osteochondral plate on the transducer's surface [58].

In ultrasound practice, the correct orientation of the iliac bone surface is the first of the above mentioned criteria to be highlighted in order to obtain the standard image. If this is generally easy, there are situations where this parallelism is impossible with all the examiner's efforts, the bone surface describing a slightly overturned or concave appearance to the transducer. In this case, the time for examination is extended and there is also the doubt of a technical error.

From our empirical observations there is a plausible explanation for this particular situation, in correlation with the observations obtained from the clinical examination.

5.2. Working hypothesis

The existence of the particular aspect of concave contours of the iliac bone surface, encountered in rare cases in the ultrasound examination, required verification of the coexistence of a possible clinical cause. The frequent association of this sign with the limitations of hip abduction led to the formulation of the working hypothesis: "There is a correlation between the muscular hypertonia of the clinically diagnosed pelvic region and the ultrasound aspect of the iliac bone's concave surface."

Objectives:

- the incidence of clinically diagnosed hypertonia;
- analysis of incidence of concave appearance on the iliac bone surface;
- analysis of the existence of a correlation between hypertonia and concavity.

5.3. Material and methods

The study focused on the retrospective analysis of the archived images and the identification of the concave sign of the iliac bone. This concavity is not assimilated to situations in which the bony plane is deflected to the anterior or posterior by technique mistakes.

The study was conducted in the ultrasound department of a private clinic by retrospective analysis of images from 534 patients investigated between January 2017 and March 2018.

In all cases, hip ultrasound was performed according to the Graf method using Noblus Hitachi-Aloka US equipment with a 5-13 MHz linear transducer. A single operator having nine years experience in hip ultrasound at the date of the onset of the study period performed all the examinations.

The clinical examination was performed by a single pediatric orthopedic surgeon with more than thirty years of clinical experience.

Due to the retrospective nature of the study the organization ethics committee waved informed consent.

Inclusion criteria consisted of: subjects presented for the first time to hip ultrasound with prior or after clinical examination and for whom examination data and ultrasound images were available.

Exclusion criteria were: patients for whom either clinical data or images were missing and also high degree DDH patients (type III and IV according to Graf staging).

Of the initial 534 reports analyzed, after applying the above criteria, data for 478 subjects represented the study group (956 hips).

The age of the patients included in the study ranged from 3 weeks to 6 months (24 weeks), with a mean age value of 10.2 weeks.

The study group consisted of 328 female subjects, respectively 150 males.

Ultrasound examination and clinical evaluation were performed independently of each other.

From a clinical point of view, subjects were included in 2 groups:

- Group A - 417 subjects with no abduction limitation and no signs of hypertonia;
- Group B - 61 subjects with abduction limitation and presence of hypertonia on muscle adductor groups.

The ultrasound examination focused on identifying the concave appearance of the iliac bone and led to the formation of two groups of subjects:

- Group I - 467 subjects where it was possible to obtain the linear aspect of the iliac bone surface;
- Group II - 11 subjects to whom at least the standard hip image showed the concave appearance of the iliac bone.

Statistical software used was Social Science Statistics with free acces on <http://www.socscistatistics.com>. A chi-square calculator test was used for association between two categorical variables. P was considered statistically significant at a p value < 0.05.

5.4. Results

In the Group A considered clinically healthy from the point of view of abduction degree, of the 417 patients, only 5 presented the concave appearance of the iliac bone, on 4 of them only one-sided. For the rest of 412, the standard image was obtained appropriately.

In the Group B of patients with abduction limitation and adductor muscle hypertonia, of the total of 61 patients, 6 had concave appearance, in 5 cases being bilateral. For the remaining 55 subjects with limited abduction at clinical examination, the linear aspect of the iliac bone surface was possible to be obtained.

Table VII - The contingency table

	Normal abduction	Limited abduction - Hypertonia	Marginal Row Totals
Linear iliac bone surface	412 (407.4) [0.05]	55 (59.6) [0.35]	467
Concave iliac bone surface	5 (9.6) [2.2]	6 (1.4) [15.05]	11
Marginal Column Totals	417	61	478 (Grand Total)

The chi-square statistic is 17.6568. The p-value is 0.000026; this result being significant for $p < 0.05$.

5.5. Discussions

The statistical results of the bony concave surface sign incidence in the patient's two groups, with or without abduction limitation, indicate an increased prevalence of bone changes in the group of patients clinically suspected with DDH [Table VII].

Since DDH presents a possibility of occurrence throughout the maturation and development of the hip joint, the presence of abduction limitation may influence these processes over time. So, this clinical condition may represent a source of late DDH [59,60].

Many clinicians consider that limited abduction of the hip is a predisposing risk factor for the onset of DDH. According to recent studies, it is considered to be the third important clinical sign for the relevance of DDH clinical diagnosis, after the positive Barlow and Ortolani tests [61,62].

Therefore, consideration of this ultrasound sign, in conjunction with clinical data, may avoid some late DDH diagnosis cases with initial normal considered ultrasound [Fig. 9].

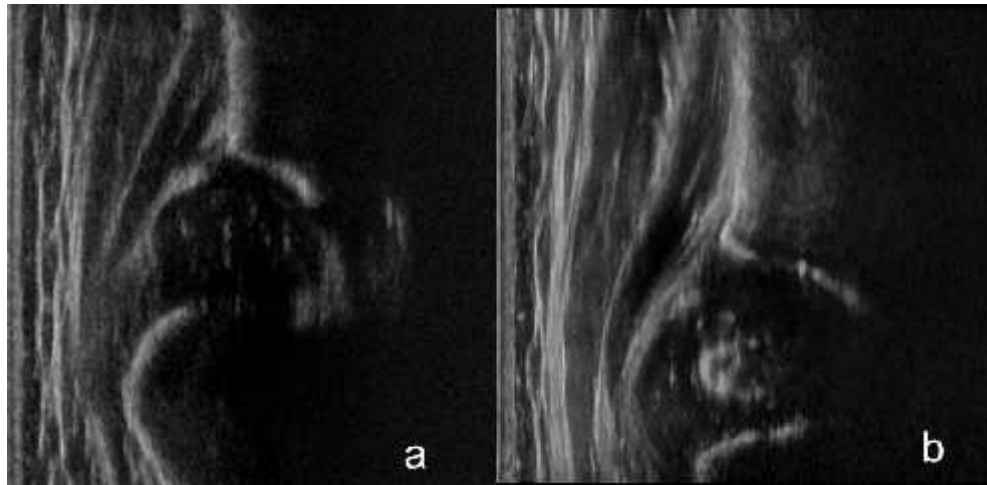


Fig. 9. a) Normal standard hip image; b) Concave iliac bone surface

Muscles having iliac insertions that could lead to this particular aspect are: iliacus, rectus femoris and sartorius. While sartorius and rectus femoris muscles have the main action the hip flexion, the iliopsoas muscle through its hypertonia, could lead to limiting abduction from hip flexion [Fig. 10]. Consequently it can modify the insertion area as well as influence the configuration of adjacent bone anatomy due to its trajectory. The abduction limitation produced by iliopsoas muscle hypertonia makes the iliopsoas tendon the target of some surgical release procedures in order to reduce the hypertonic effect and for better reduction of hip luxation and subluxations.

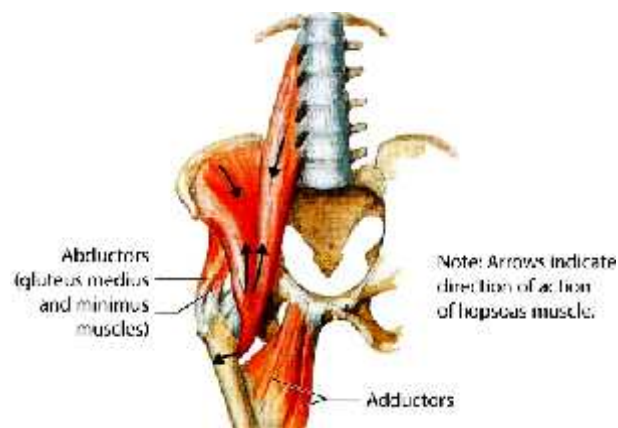


Fig. 10. Anatomic image of muscles insertions on the iliac bone [63].

Some studies which monitored the hip joint evolution over time in patients presenting limited hip abduction, considered that therapeutic intervention is not required in patients with type I hips according to the Graf classification.

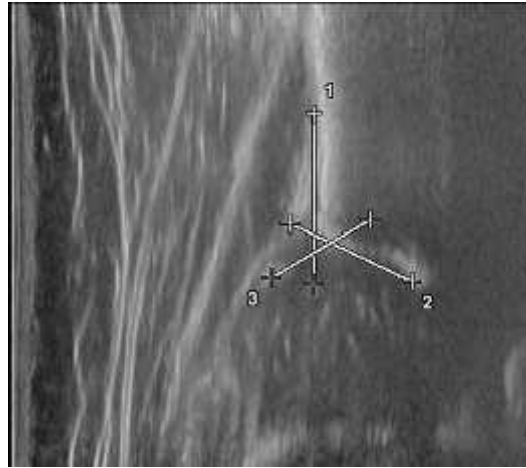


Fig. 11. Concave iliac bone surface sign in an infant with limited unilateral abduction. Asymmetric hips were also found, on the affected side α angle value being lower by 6° comparing to the opposite side.

A large number of studies suggest that unilaterally restricted abduction as having an increased risk for DDH versus bilateral limitation [64].

Also, the borderline hips ultrasound identification associated with a degree of abduction limitation requires, in the first few weeks of life, a minimal orthopedic abduction therapy to avoid the late DDH diagnosis [Fig. 11].

From our experience, we consider that only staging the hips as being type I is not sufficient, the comparative look of the two hips being also necessary to identify asymmetries on ultrasound and on the abduction degree at clinical examination [Fig. 12].

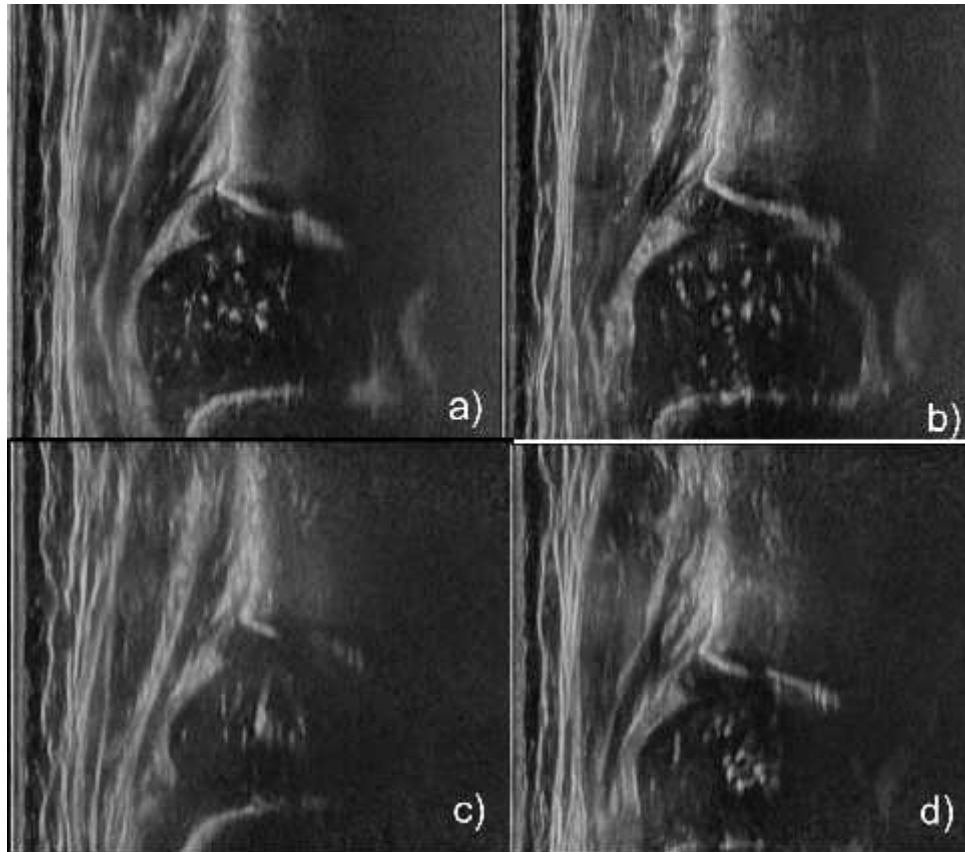


Fig. 12 Evolution of bilateral concave iliac surface sign in a child presenting bilateral hip abduction limitation. a), b) Initial aspect at the age of 13 weeks. c), d) the same case after 5 weeks of orthopedic abduction device (abduction diaper). Left hip is presented in the left side of the images. Slightly improvement is seen in the concave aspect, but also in the α angle values. A more restrictive abduction device might have a better result.

The present study is just at the first observations stage presenting some limits as:

- relatively low number of investigated subjects, especially those with abduction limitation;
- reduced scale of this observations by attendance of just one ultrasound practitioner and one pediatric orthopedic surgeon;
- lack of longer time follow-up.

Further larger studies are necessary to confirm our suppositions and to validate the concave iliac bone surface sign.

5.6. Conclusions

Hypertonia of hip adduction action muscle groups is proven to be an important clinical sign and an important risk factor for DDH. The concave appearance of the iliac bone may be an important sign indicating an increased degree of iliac muscle hypertonia. The sign of the bone surface concavity, added to clinical information, may require the initiation of preventive abduction therapy.

6. General discussions

Being one of the most common malformative diseases in newborns and infants, DDH has been extensively studied over the past 30-40 years. Studies have been carried out on all continents, being the concern of researchers from several medical specialties: pediatricians, pediatric orthopedists, radiologists, neonatologists.

With all these concerns, there are currently many debates and opinions about the diagnostic and therapeutic attitude.

The studies presented in the thesis focused on the description of some echographic signs, which in close correlation with the clinical data, designed to bring an improvement of the ultrasound hip examination method. The results of the studies presented in the thesis aim to improve both the technique of obtaining the standard image and the way of interpretation and integration in the clinical context of the ultrasound data. Even being the most popular and widely used method, Graf hip ultrasound method is the target of several controversies.

The main controversies regarding the Graf technique relate to the following:

- the use of ultrasound investigation as a universal or selective screening;
- the optimal time for the first ultrasound examination;
- increased rate of over-diagnosed DDH cases;
- the relatively constant number of late DDH cases [65,66].

The issue of screening is extremely controversial, both medical and financial. The studies presented in the thesis, through the permanent correlation of the clinical data with the ultrasound, come to support the idea of a multidisciplinary clinical and ultrasound screening. Recent studies indicate a poor effectiveness of the isolated clinical diagnosis, but also an increased over-diagnosis rate in the isolated use of the ultrasound screening [65,66]. The criterion of the horizontal position of the osteochondral plate is to bring about a substantial improvement in diagnostic accuracy and the avoidance of staging as pathological of a healthy group of hips [67]. Therefore, the practical application of this new sign will lead to increased rigor in obtaining the standard image, resulting in reducing the incidence of DDH and, implicitly, unnecessary treatment. Although it is the most reproducible ultrasound method, the Graf method has a large interobserver variability of 40% in calculating α angle, requiring improvement in technique [68].

Consequences will also be recorded financially by reducing the costs of diagnosing and treating DDH. Costs considered high in the case of universal screening

are incriminated by those who contest this diagnostic attitude [65,69]. Studies to the contrary indicate a low incidence of large surgical interventions among patients included in the universal screening programs [70,71].

Through the proposed diagnostic and therapeutic modalities, the thesis encourages the early diagnosis of DDH. Optimal clinical and ultrasound correlation is performed at the age of 4-8 weeks. Avoiding ultrasound screening in the first 4 weeks of life will result in a reduction of diagnosed cases of immaturity, especially in of dynamic ultrasound methods [70,72,73].

Clinical integration of ultrasound information is supported by the presentation of borderline and asymmetric hips [74]. Diagnosis of these particular situations can lead to a significant reduction of late detection of DDH cases, while the first ultrasound is considered normal. As can be seen from study data, cases diagnosed in the optimal interval for ultrasound screening, would benefit from a minimal preventive treatment similar to immaturity. Very recently, international literature has shown a concern for these situations, proposing 3D examination models to better visualize acetabulum conformation [75].

The study of risk factors criticized for DDH appearance is still of interest [76]. Even though genetic models that predispose to develop DDH are currently under investigation, there are contradictory views of "classical" risk factors. The abduction limitation appears more and more frequently as an important clinical sign for the diagnosis of DDH [77,78]. This limitation of abduction may be due to the hypertonia of the iliopsoas muscle. Study 3 shows a possible correlation between the clinical examination and the ultrasound image, indicating a possible influence of hypertonia on the iliac bone configuration, by the appearance of the concave aspect of the bone surface.

By contributing to the quality of the DDH ultrasound diagnosis by refining the Graf method, the thesis also addresses international demands for a better correlation between clinical and imaging diagnosis and the introduction of new diagnostic criteria [79].

The researches conducted in the studies presented in the thesis are subject to several limits:

- the impossibility of using another technique to confirm ultrasound observations, ultrasound being the golden-standard in the DDH diagnosis;
- the impossibility of following cases over a longer period of time, including after starting the race;
- lack of interobervatory analysis both on the ultrasound diagnosis side and on the clinical examination side;

- the unicentral development of the study;
- the lack, for reasons of medical ethics, of controlling batches to be analyzed from the perspective of natural evolution in clinical situations of asymmetrical or asymmetric balances and marked hypertonia balances to validate the observations recommending the establishment of preventive treatment;

Further studies are mandated to confirm these observations and fully assess the clinical usefulness.

7. General conclusions

The thesis was based on improving the quality of the diagnostic act in DDH. The results of the studies come to give a qualitative contribution to the ultrasound examination of the hip by the Graf method. Input is brought to the points for which the method is incriminated by certain authors: increased rate of positive diagnosis and cases of late DDH.

Observations from studies generated the following general ideas:

- Addition of a new quality criterion for the Graf method standard image, represented by the horizontal osteochondral plate position, may contribute to a better tailored approach to the ultrasound diagnosis of DDH by lowering the number of over-diagnosed cases.
- The horizontal osteochondral plate sign may be useful especially in cases with borderline values of α angle: light immaturity or borderline hips.
- The use of the horizontal osteochondral plate sign in the hip ultrasound practice may increase the overall average of α angle values by at least 2° .
- In clinical practice is needed a better correlation between ultrasound and clinical examination data. Those can not be separated and using one of them for diagnostic purposes will not exclude the other. Our research suggests the need for clinical-ultrasound screening for DDH detection.
- Borderline and asymmetric hips are real special conditions neglected when pursuing unilaterally as a hip to have strictly just an α angle greater than 60° .
- Borderline and asymmetric hips should be managed similar to immature and potential dysplastic hips (IIa+ and IIa-), showing a potential pathological condition.
- In borderline and asymmetric hips the treatment is minimal when the diagnosis is formulated early, being necessary to follow the evolution in time at intervals of 4-6 weeks.
- Borderline and asymmetric hips could represent a cause for late diagnosed DDH cases.

- The concave surface of the iliac bone may be an important sign indicating an increased degree of iliac muscle hypertonia.
- The sign of the bone surface concavity, added to clinical information, may require the initiation of preventive abduction therapy.

8. Originality and innovative contributions of the thesis

Although it addresses a long-term internationally debated issue, DDH diagnosis and treatment, the thesis brings some novelty aspects, both in terms of diagnosis and clinical integration of information from ultrasound investigation.

Graf technique is considered to be the most well-known and improved echographic method of hip investigation for DDH diagnosis. Despite these considerations, as presented in previous chapters, the method requires extra rigor. This need is borne out by the multitude of studies with contradictory results.

A first element of originality is the premiere presentation of the osteochondral plate sign. Until now, it was only necessary that the osteochondral plate to be present on the standard image of the Graf method. There are no references in the literature on how it should be visualized and whether it can influence subsequent measurements. The research undertaken within the thesis proves scientifically, the influence that this element can bring on the quality of the diagnosis. By using this new sign of corectness on the standard image, along with the three above mentioned: the parallelism between the surface of the iliac bone and the transducer surface, the lower limb and the presence of the acetabular labrum, a significant improvement in the diagnosis is achieved in the case of the hips immediately below the border of 60° α angle value.

A second element of originality is related to the premiere presentation of borderline and asymmetrical hips. There are no references in the literature to mention these particular aspects. We believe that the DDH ultrasound diagnosis should not be limited to simply calculation of α and β angles values. An overview should be given by assessing the degree of symmetry on one side and the other. The existence of major differences greater than 4° between the two hips may mean one of the following situations: presence of a history conditions that led to asymmetry or the present existence of factors that induce the decrease of the α angle value with the risk of evolution to dysplasia. Correlation with clinical data may require the initiation of a preventive treatment that will lead to the correction of the asymmetry. Also, the presentation of borderline hips raises for the first time a problem related to the therapeutic approach in this situation. Even if strictly according to Graf staging these hips are classified as healthy, there is a risk that a minimal regression of the α angle value will turn them into pathological hips. Also, the clinical-ultrasound monitoring of these hips without any therapeutic measures, shows the risk of DDH being detected

at a higher age when treatment becomes more difficult, sometimes involving surgery. The studies conducted within the thesis recommend the establishment of a minimal therapeutic, preventive attitude, to improve the parameters and to obtain hips outside the risk area.

A third element of originality is the presentation of the concave sign of the iliac bone. Although, seen in the ultrasound practice and generating the difficulty in obtaining the standard image according to the Graf method, this sign was not previously described, and there was no correlation with the clinical signs. Although the study involved a relatively small number of cases, a possible correlation with the hypertonia of the adductor muscles with proximal insertion on the iliac bone is demonstrated. The iliac muscle, component of the iliopsoas muscle, shows the strongest adductor action at this level. Being also the target of the surgical release surgery, the sign described for the first time can bring an important benefit by establishing a therapeutic attitude that will relax the increased tone of the iliac muscle and implicitly to avoid subsequent surgical interventions in DDH cases due to muscular hypertonia. While unilateral hypertonia is highly predictable for the presence of DDH, bilateral ones are likely to omit a high number of positive cases and also raising many clinical suspicions in cases with no pathological correspondence. The sign of the concave bone of the iliac bone brings a better correlation between the clinical and ultrasound examinations, validating clinically diagnosed hypertonia.

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