Intraosseous Structural Graft Technique
A new surgical concept in the treatment of superolateral defects in case of dysplastic acetabulum, during hip replacement surgery
Biomechanical and cadaver experimentations and the first clinical results

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University of Debrecen
Doctoral school of Clinical Medicine
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1. Introduction

The treatment of secondary hip arthrosis in adulthood due dysplastic hip is not completely solved even though numerous research has been performed in this field. The occurrence is Hungary is 0.5%. It occurs six times greater in newborn girls than boys. Total hip replacement for secondary hip arthrosis due to dysplasia according to the national registers is 1.8% in Sweden 7.3% in Norway and 8.9% in Hungary.

Characteristic deformities occur in the acetabular region due to the pathologic development of the hip resulting in a relative bone deficiency. This development affects not only the static components, but the muscles, circulation and innervation as well. As a result of this not only is it important to achieve good position and stability of the components, but it is equally important to have the right biological circumstances in order to get the best possible function.

Therefore it is not surprising that there are many different surgical techniques trying to realize these goals. Totally different problems arise when trying to replace the proximal femur and the acetabulum. My personal interest focuses on the later, especially pertaining to the positioning of the acetabular cup, and the bone grafting techniques associated with it. In my research I would like to elaborate on this topic from a practicing surgeons point of view. Naturally these problems generated some personal ideas which resulted in a seven year research program. The result of my research is a biological oriented surgical technique, which after biomechanical, cadaver studies, and instrument development is presently in the clinical introduction phase.

1.1. Questions pertaining to the replacement of the dysplastic acetabulum

The fundamental difficulty in the replacement of the dysplastic acetabulum is the geometric incompatibility of the hemispherical prosthesis cup and the steep, shallow, cranially extended, lateral deficient acetabulum. In slight dysplasia where the coverage of the implanted cup reaches 80% the use of a special surgical technique is not required. In the more severe cases we have to examine three problems:

1.1.1. The positioning of the cup

The position of the acetabular cup varies according to different authors. Basically the replacement can take place in the primary rotational center or outside of this. Reduction into the primary rotational center is not really a true reduction, as the hip in case of dysplasia was never in the geometrical joint rotational center.
There are numerous arguments for and against placement of the cup in the primary rotational center.

**Replacement in the primary rotational center of the hip**
If we implant the cup into the primary rotational center:

a. The rotational axis of the two hips will be parallel to the ground, gait will be more harmonic, and the load on the lumbar spine will decrease.
b. By increasing the tension of the gluteal muscles the Trendelenburg gait will cease.
c. Good stability of the replaced hip can be achieved smaller sized heads this decreases the torque on the stem which prevents early loosening.
d. The primary acetabulum has the largest bone mass in the pelvis which results in adequate bone stock for the cup even in dysplastic hips.
e. In primary cases the patients own femoral head is at our disposal for bone grafting. This is the first and only chance to perform autologous structural grafting, which can result in adequate bone stock for revision.

The primary rotational center of the hip joint can be calculated with mathematic and geometrical methods. This way the positioning of the cup can be planned and controlled.

In slight dysplasia (*Hartofilakidis A, Crowe I.-II.*) the following techniques can be used for cup implantation into the primary acetabulum:

a. Cement augmentation
   
   Long term studies showed that filling the defect with bone cement can lead to early loosening therefore the majority of the authors do not suggest this method.
b. Iliac sliding graft technique
   
   In the cranial part of the dysplastic acetabulum a cortical-spongious graft is made, which is slid distally and fixed with screws. This way the superior lateral coverage of the acetabulum is increased.

In more severe dysplasia (*Hartofilakidis B, Crowe II.-III.*) we can use:

a. Bulk bone graft techniques (Harris acetabular plasty). He coverage of the acetabulum can only be achieved with augmentation. The most common form of this is the use of the patients own resected femoral head as an autologous structural free graft.

**The Intraosseous Structural Graft (ISG) technique developed by me belongs to this group**

b. Modification of the bulk bone graft technique (Radojević technique).
c. Due to there excellent biomechanical properties trabecular metal augments are becoming increasingly popular (titanium, tantalum)
d. Special dysplastic (Oblong) cups have never gained popularity.
High hip dislocations (Hartofilakidis C, Crowe IV.) further surgical solutions are required.

**Replacement outside the primary rotational center of the hip**

Those for acetabular replacement outside the rotational center approach the problem from cost-benefit point of view. Its a fact that major acetabular defects can only be reconstructed with some sort of bone grafting. The problems with incorporation and resorption of autologous structural grafts are well known, and these increase surgical risk. Also some authors do not find that biomechanical advantage gained with replacement into the primary acetabulum is that important in the long term.

Therefore due to the high risk and relatively low benefit they replace the cups outside the primary rotational center.

a. Cranial implantation
   
   Acceptable and does not increase loosening rate if the cup is implanted 1.5-2 cm cranially as long as it is not placed laterally.

b. Medial implantation.
   
   This has numerous publication and due to its good result it became very popular, but since the point of this is controlled perforation of the acetabular cup there is an increased risk of injury to the structures of the lesser pelvis.

c. Steep implantation
   
   If the cup is implanted in increased abduction, due to decreased load surface the biomechanical wear of the cup increases and leads to early aseptic loosening.
   
   Similar effects can be seen in augmented inserts, but not to such an extent.

1.1.2. The biology of autologous structural free graft implantation

The bone graft can have osteogenic, osteoinductive and osteoconductive properties. The process of ingrowth contains the immunologic reaction of the autologous bone, cell proliferation, migration, differentiation, and revascularization. These are effected by the biological environment, the size of the contact surfaces and a stable osteosynthesis.

**Biological environment:**

a. Means the vitality and bone quality of the recipient environment. The surrounding soft tissue (muscle, periosteum, endosteum, circulation, innervation) preservation and good circulating not sclerotic spongious bone is the basis of bony ingrowth.

b. Revascularization is a fundamental element of graft incorporation, and its speed and scale depend on the size of contact surface between host and graft.

c. The instability of the osteosynthesis, due to the micro motions decreases vascularization and in this way negatively effects incorporation.
1.1.3. **Surgical risk**

The occurrence of vascular complications in primary replacement for hip arthrosis is 0.25%. Arterial injuries have a 7% mortality rate, and 15% result in amputation. Neurological complications is between 0.6–1.3%, which effects the sciatic nerve in 90% of the cases, this occurs in 0.5–2% of the cases.

In case of dysplasia the rate of complications is higher 5.2–13%.
2. Goals

2.1. Based on research pertaining to routine and dysplastic hips, the development of a new surgical technique that allows:

a. The placement of an uncemented acetabular cup in the primary rotational center.
b. The technique should be able to be used in Hartofilakidis A-B, and Crowe I-III dysplasia.
c. The primary stability of the graft should be the same or better than the most commonly used Bulk Bone Graft techniques.
d. The graft should be in a biological environment that aids in a quicker and more complete incorporation.
e. The contact surfaces should be larger than the presently known techniques.

2.2. The solution of research subtasks:

a. The examination of whether the cortico-spongy plate at the acetabular roof could be bent laterally to the extent required by the surgical technique.
b. The examination of the primary stability of the implanted graft with a material testing apparatus.
c. The examination of the contact surfaces between the graft and host bone.
d. The planning, prototyping, testing, and final manufacturing of special instruments required for the surgical technique.
e. Analysis of the surgical risk

2.3. The clinical introduction of the technique.

2.4. The results of the first surgery.
3. Materials and Methods

The research work can be grouped into five different stages and locations. The are summarized below. The details of the individual topics can be found in separate subheadings.

1. Based on X-rays and CT scans of dysplastic hips I performed measurements, geometric examinations and calculations.
2. Based on 3-D models I determined spatial relationships in dysplasia, worked out a new surgical technique, performed geometric examinations, made models and drawings.
3. Along with my research team at the University of Debrecen Department of Pathology cadaver experimentations were performed for measurements, anatomical relationships, bending tests on bone, risk analysis, and the steps of the surgical technique were worked out. Special instruments were developed for the surgical technique. Anatomical preparations were made for the stability testing.
4. Stability examinations were performed at the University of Debrecen Biomechanics Research Laboratory on anatomical preparations.
5. At the University of Debrecen, Department of Orthopedics the requirements were met for the clinical introduction of the new surgical technique.

3.1. The Intraosseous Structural Graft (ISG) technique

The procedure was worked out at the Biomechanics Laboratory of the University of Debrecen on dysplastic hips, using rapid prototyping technique on 3-D models, and the Institute of Pathology of the University of Debrecen, on 19 hips of 10 cadavers.

The point of the ISG technique is that due to the dysplasia in the deficient cranial part of the acetabulum, a proximally attached cortico-spongyous plate is made, which is bent in the lateral direction. In the space thus formed a wedge-shaped graft is cut from femoral head is impacted from the distal direction and is stabilized by one or two screws depending on the graft size.

The graft s modeled with the reamer and an uncemented cup is inserted.

A detailed description of the process:
1. The surgical exposure is according to Watson-Jones.
2. The reaming is carried out in the primary rotational center.
3. After the acetabulum is prepared the uncovered part of the properly placed trial implant will designate the acetabular defect. Accordingly with a chisel the proximally attached cortico-spongyous plate is made.
4. The bone block is gently bent in the lateral direction, to the extent until the trial cup is covered appropriately. The final position is measured.
5. From the resected femoral head a corresponding base height wedge-shaped graft is prepared.
6. The graft is impacted under the plate.
7. Adequate stability is achieved by compression cortical screws with washers.
8. The graft is modeled to the reamed acetabulum.
9. The uncemented cup is impacted.
10. If necessary, the cup can be further stabilized with screws.

3.2. In vitro and ex vivo experiments

3.2.1. Analysis of the bending capability of the cortico-spongious plate
An essential condition for the feasibility ISG technique is that the proximally attached plate could be bent to the extent required by the technique. Based on experiments and measurements on the 3-D models of Hartofilakidis and Crowe classified hips, by rapid prototyping a lateral bending of 15 mm is sufficient for the execution of the technique. The flexibility was tested on 19 hips of 10 cadavers. As a first step we developed with a chisel the cortico-spongious plate. The bending was carried out by a flat chisel placed under the plate, a special measuring instrument noted the distance before flexibility was lost.

3.2.2. Instrument development
The ISG technique can be performed with traditional bone surgical instruments, but based on the cadaver studies however, it was decided to develop special tools so the preparation of the cortico-spongious plate can be done more efficiently and accurately. The idea was launched with two developments. Both went through the modeling and cadaver experimentation phase. During the development great emphasis was paid the protection of the gluteal muscles and avoidance of pelvic perforation.

Designed for the "one-step" concept was a U-shaped, three edged chisel that allows the creation of the plate in one step.

The "three-step" concept consists of two chisels. A T shaped rasp-chisel serves for the frontal, and a flat chisel for the horizontal plane osteotomies. The T rasp-chisel works like a rasp on the outer cortical of the plate. Thereby this avoids damage to the gluteal muscles during detachment, and on the other hand the fixed size of the vertical blade avoids pelvic perforation.

The flat chisel was developed for the sagittal plane. The chisel head is characterized by that the edge is asymmetrical, therefore during chiseling it has the tendency to move towards the outer cortical. This configuration serves to reduce the risk of pelvic perforation.
Modifications

The basis of the development work was that the instruments were designed using available pelvic models and the finished pieces were tested on similar models and cadavers. As each phase of the work - including the preparation of prototypes – was done by me, I did not deter from significant change from the basic concept.

During the cadaver experiments, we found that the straight chisel makes the supraacetabular region difficult to approach, so a 30-30° sagittal and frontal plane bayonet-shaped break was added to the stem of the chisel.

In addition to this change the flat chisel head was also re-planned. The new, sharp design allows better control of the tool and a more secure opening. The asymmetrical head was kept because of the good experience.

In prototype testing it was found that the U shaped chisel even with the improved mechanical conditions, because of its size, shape was difficult to maneuver in the acetabulum. After evaluation I decided to reject the one-step approach.

Based on the prototypes plans were drawn up and a precision engineering firm produced the chisel able to be used in the surgical setting.

3.2.3. The questions about autologous free bone graft transplantation

Free autologous graft placement is the most important element of the ISG technique. The process will focus on three issues:

1. What is the proportion of the contact surfaces between the host and graft?
2. What are the biological qualities of the bones in contact?
3. What is the primary stability of the graft?

1. Determination of the ratio of the contact surfaces

It grafts required for each technique were developed from 3x2x2 cm bone blocks. Given the dimensions I have laid out the grafts used in each bulk bone graft techniques. All sides of the grafts that come into contact with the host bone was determined based on measurements of the 3D models, and then their territory was calculated.

2. The biological quality of bones in contact

The analysis of these diverse factors are beyond the scope and possibilities of my work, so in this direction measurements, experiments have not been conducted. The theoretical aspects of the topic is discussed in the introduction.
3. Examination of the primary stability of osteosynthesis

The cadaver experiments were carried out at the University of Debrecen, Institute of Pathology, and the measurements were done in the Biomechanics Laboratory with a Instron 8874 material testing apparatus. 20 hemipelvises were removed from 10 cadavers, of which 10 were prepared according to the ISG technique and 10 according to Harris.

Five basic categories of questions had to be clarified during the examinations:

a. **Determination of the direction of the compressive strength on the graft**

On implanted uncemented cups the force arises at a 45 ° angle in the frontal plane, which may be divided into two vectors one parallel and one perpendicular to the body. For the instability of the graft the cranial direction component is responsible, therefore, the force emerging parallel to the longitudinal axis of the body was measured.

b. **The change in the magnitude** of compressive force on the graft was examined with a test speed of 10 mm / min consistently until establishment of the desired movement while measuring the force required.

c. **Determination of the level of displacement to be measured**

In uncemented cup implantation (depending on the size) the acetabulum is under reamed of 12 mm in the conventional technique. This means that the bone in the acetabulum receiving the cup gets compressed 1-2 mm. The graft – if adequate primary stability is achieved – is also compressed the same amount. If the stability is not sufficient, then the graft will not get compressed, but moves in cranial direction. Accordingly the force required for 1 mm displacement was recorded by the material testing device.

d. **Elimination of undesirable shifts in the measurement system**

We had to make sure that no other movements took place besides the displacement between the graft and the pelvis. The possibility of movement between the specimen and the recording surface of the material testing apparatus was annulled by placing the model into a plaster cast. The blocks were firmly held in a vice. During the measurement, to prevent movement between the graft and the steel presser foot surface of the vice, we used the largest possible contact surface.

e. **Ensuring the same measurement conditions**

The same types of grafts were made each of the surgical techniques. In every case cortical screws with washers were used under compression. The screws were tightened 1,5 Nm with a torque screwdriver. During the modeling of the two techniques, for better comparability same right and left hemipelvises were used with the corresponding femoral head in the 10 cases. The measurement was carried out on prepared models as noted above. Results were presented graphically. For statistical analysis the two-sample t-test and non-parametric Mann-Whitney U test was performed.
3.2.4. Analysis of surgical risk

For surgical analysis cadaver experimentations were made, from which I gained experience, and illustrations were made. During the cadaver experimentations the acetabular region was explored in order to verify the location of neurovascular structures in the surgical area, and its relation to the bone and musculature. Special emphasis was placed on specific surgical risk posed in Harris plasty and the ISG technique, and safety requirements. Photo documentation and hand drawings were made.
4. Results

4.1. The Intraosseous Structural Graft Technique
Our main result is the development of the ISG technique. Since its clinical introduction 3 surgeries were performed. No complications occurred. The longest follow up is 11 months.

4.2. The bending capability of the cortico-spongious plate
During the bending measurements 17 out of 19 cases surpassed the desired 15mm.

4.3. Instrument development
The results are composed of a 3 chisel set, which contains the following:
- 1 right sided T headed rasp-chisel
- 1 left sided T headed rasp-chisel
- 1 sharp flat chisel

4.4. The ratio of the contact surfaces
Based on surface area calculations the following results were obtained for the contact area of grafts:
Graft contact surface for the two techniques:
- Harris plasty: 6 cm$^2$
- ISG technique: 13 cm$^2$
Ratio: the ISG technique has a 2.26 times larger graft-host contact surface compared to Harris plasty.

4.5. The primary stability of the osteosynthesis
Based on the two tailed t test with a 5% significance level, the primary stability of the osteosynthesis on the performed 10 Harris plasty and 10 ISG techniques did not show significant differences. Due to the low number of cases we performed the non parametric Mann-Whitney U test. At 5% significance level no significant difference was found.

4.6. Surgical risk
Based on the literature and cadaver studies we obtained the following results for the surgical risk of the ISG technique:

1. Risks at the outer surface of the iliac crest
The outer surface of the supra-acetabular region is covered by the gluteus medius and minimus muscles. The blood supply of these muscles is from the superior gluteal artery and vein exiting the suprapiriform hiatus, and the innervation is by the superior gluteal nerve. The bifurcation of these structures is cranial and superficial from the surgical site, so their risk of injury is low.
2. Risks on the inner surface of the iliac crest

The neurovascular structures in the lesser pelvis were localized according to the *Wasielewski* quadrant system. The ISG technique involves the safest posterior superior quadrant. The thickness of the acetabulum in this quadrant surpasses 35 mm.
5. Discussion

In my thesis I demonstrate a new surgical technique for the replacement of the dysplastic acetabulum, and the previous biomechanical and cadaver experimentations.

Both the literature and clinical practice has similar solutions to the ISG technique. These are partly incomplete pelvic osteotomies used in pediatric orthopedics and partly acetabular augmentations used during adult hip replacement. The similarity is obvious as both of these surgeries have the same goal: in children to increase the coverage of the femoral head, and in adult hip replacement to increase the coverage of the acetabular component.

Pediatric orthopedic solutions – although may show similarities – have basic theoretical and technical differences compared to the ISG technique. The most important being due to the sensitivity of the femoral head circulation is that most of those technique are extraarticular, with completely different chiseling direction and osteosynthesis solutions.

In adult reconstruction the major difference in the ISG and other bulk bone graft techniques is that in the ISG technique the graft is placed intraosseally in a better biological and biomechanical environment.

We can not discuss intra-operative experience due to the low number of cases, but it can already be said that the technique meets all the expectations gained from the cadaver and laboratory experimentations. I would like to emphasize the advantages of the safe chiseling technique and the more than satisfactory primary stability of the graft. From a surgical point of view it is very important that the width of the graft should be measured very precisely. This aids in the tight impaction in the frontal plane and provides good rotational stability. For the osteosynthesis cortical screws with washers should be used under compression. The number of screws used is determined by the graft size. If possible two screws should be used, but in small grafts, or thin cortico-spongious plate one screw can be sufficient. The bleeding from the acetabular region after chiseling is greater than expected, but controllable. In the intra-operative setting the proximal fixation of the cortico-spongious plate fractured more often then experienced during the cadaver experiments, we believe this is due to the sclerotic, rigid bone in the superior acetabular region caused by the secondary arthrosis. Nevertheless the preservation of the periosteiun and musculature provides enough stability to continue the surgery. During the cadaver experimentations we found that a large enough wedge can be cut from the femoral head, but in a dysplastic hip, due to the deformity, and degenerative changes of the head, and the osteolytic cysts within, this is not always true. Based on this it can be concluded that detailed preoperative planning is crucial. Preoperatively it must be determined that an adequate graft can be made from the femoral head. For this CT examination can give the most precise answer. It is also very important to make sure adequately thick inner pelvic wall is present for the stable
fixation of the graft. This can be achieved by chiseling the thinnest possible outer cortico-spongious plate possible. Therefore preoperative measurements and planning on CT is a must.

In vitro and ex vivo experiments were done for the ISG technique. A part of our cadaver studies focused on the lateral bending capability of the cortico-spongious plate. This had to be examined separately as no one in the literature measured this before. Fracture test on long bones were performed previously and it is accepted that the fracture threshold is 25 microstrains. 1000 micro-strains means the 0.1% deformity of the bone against pulling power. In the present study we did not use this number, but defined a minimal threshold the plate has to bend laterally in millimeters. Out of the 19 examined cadaver hips 17 surpassed this threshold. This supports the fact that the ISG technique is feasible. It must be taken into account that these examinations were performed on healthy non dysplastic cadavers. This explains why the fracture of the proximally fixed cortico-spongious plate occurred more often in the surgical setting.

During the modeling and cadaver studies we encountered difficulties that we felt could be made more safe and precise with special instruments. Out of the two instrument development concepts, based on the 3D models and cadaver experimentations I decided to stick with the three step method. The manufactured instruments performed up to expectations in the intraoperative setting.

The problems with autologous structural free grafts can be divided into three groups.

1. The basis of bony ingrowth is revascularization of the graft form the host bone. This depends among other things on the size of the contact surface between host and graft, as revascularization proportional increases with increased contact surface area. Based on the surface area calculations the ISG bone graft has over 2 times as large contact surface compared to Harris plasty. Our expectation is that due to this the graft will remodel quicker and more completely.

2. The ratio between good spongious bone and sclerotic cortical bone is also important in the host site. In Harris acetabular plasty the femoral head is fixed partly to the sclerotic supraacetabular region and partly to the lateral cortex of the pelvis. It true that this area is roughened before fixation, but the effect of this is hard to measure. On the other hand in the ISG technique the graft is placed under the cortical bone intraosseally, into spongious bone with good biological qualities.

3. One of the primary expectations from the ISG technique was that the osteosynthesis of the graft should be as stable as the reference Harris plasty. This was realized, as shown by the material testing apparatus that there is not a significant difference in stability.
Looking through the literature, modeling, cadaver studies, and intra-operative experiences show that the risk factors for the ISG technique is not much different from the reference Harris plasty.
6. Summary

In my thesis I discussed the research performed at the University of Debrecen, Department of Orthopedics between 2008.-2014. My main interest was the replacement of the dysplastic acetabulum. With over 50 years of experience at our Department, review of the national and international literature it can be said that this problem is still not completely solved. Despite the numerous studies, the proper placement of the acetabular cup is not clarified. The majority agree with placement in the primary rotational center, but due to the complications associated with graft placement many surgeons moved toward cranial or medial placement. It is agreed upon that the lateral placement of the cup causes early loosening. The use of graft is still under argument. Lack of ingrowth and reabsorption are unfortunate facts. Nowadays it's becoming more obvious that the use of an autologous structural graft combined with a uncemented cup provides the best results, but bio-mimetic synthetic materials can change this concept.

At our Department, due to the biomechanical advantages we prefer to implant the cup into the primary rotational center. During my experiments I concluded that the problems with the graft are partly mechanical, partly biological in origin. Instability prevents revascularization, which in turn prevents ingrowth. From a biological perspective the size of the surface area in contact, and the biological quality and activity of the bone is very important.

Based on this I worked out the Intraosseous Structural Graft technique keeping in mind the above mentioned perspectives.

With the aid of 3D models we clarified the important anatomical and biomechanical questions. Cadaver studies prove that the proximally fixed cortico-spongyous plate can be bent laterally to the desired length.

Special instruments were developed, which were manufactured for clinical use.

A material testing apparatus proved that the stability of the ISG technique is not significantly different from the Harris acetabular plasty.

Geometrical methods were used to calculate that the contact surface area of the ISG technique is twice as much as that used in Harris plasty.

Risk analysis was performed which showed that the complication rate of ISG is not greater than in Harris plasty.

During the experimentations we used over 20 3D models, and 39 hips of 20 cadavers for measurement, dissection, and surgical technique development.

Clinical introduction started, and three successful surgeries were performed.
7. My New ascertainments, results

1. Evaluating the difficulties with autologous structural free grafts I developed the Intraosseous Structural Graft (ISG) technique, which provides a better biological environment and contact surfaces than the known Bulk Bone Graft techniques, and the same primary stability.

2. Taking into consideration the most important parameters of hip dysplasia, based in the literature – following my own idea – I set up the therapeutic algorithm of the disease. I placed the ISG technique in this algorithm.

3. With cadaver experimentations I proved that the cortico-spongious plate in the supraacetabular region can bent laterally to the desired extent.

4. I set up the technique for primary graft stability measurements. With this method – using a material testing apparatus – comparable and reproducible studies can be made.

5. I designed and produced the prototypes of special instruments required for the surgical technique, then tested them on models and cadavers. The final versions were manufactured and I started using them in the intra-operative setting.

6. I summarized the complications that can occur during acetabular replacement. Based on my cadaver studies I supplemented the data found in the literature. Targeted examinations were performed by me to clarify the expected complications in the supraacetabular region during the ISG technique.

7. I began clinical introduction of the technique. I operated three patients without complications. Longest follow up time 11 months.
List of publications related to the dissertation


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