COMPARATIVE BIOMECHANICAL STUDY AND CLINICAL APPLICATION OF SURGICAL TREATMENT OF ACETABULUM FRACTURES IN THE ELDERLY

PhD thesis

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LIST OF ABBREVIATIONS

3D	Three dimensional
A/C	Acute / Chronic
ACB	Autologous Cancellous Bone
Adm.	Admission time
Al	Aluminium
Ant.	Anterior
AP	Anteroposterior (view)
ASA	American Society of Anesthesiologists
Av.	Average
AVN	Avascular Necrosis
BCU	Blood Cell Unit (240ml)
BME	Budapesti Műszaki és Gazdaságtudományi Egyetem (Budapest University of Technology and Economics)
BMI	Body Mass Index
CCI	Charlson Comorbidity Index
CE	Conformité Européenne
CNC	Computer Numerical Control
COSMIN	COnsensus-based Standards for the selection of health status Measurement INstruments
CPRD	Clinical Practice Research Datalink
CT	Computed Tomography
DICOM	Digital Imaging and Communication in Medicine
Disloc	Dislocation
F	Force
FCA	Figure created by author – rspecially for the thesis
FEM	Finite Element Modelling
FHN	Femoral Head Necrosis
FHOA	Femoral Head Osteoarthrosis
g	Gramm
GPa	Giga Pascal
Hgb	Haemoglobin
HHS	Harris Hip Score
HO	Heterotopic Ossification
ICD	International statistical Classification of Diseases
ICH-GCP	International Conference of Harmonization – Good Clinical Practice
ID	Identification (in patient data)
Intraop.	Intraoperative
ISO	International Organization for Standardization
ISS	Injury Severity Score
IT	Information Technology
kg	Kilogram
L	Liter
LMWH	Low Molecular Weight Heparin

Max	Maximum
MDR	Medical Device Regulation
MedDev	Medical Device Directive
Min	Minimum
Mins	Minutes
MJOTRI	Manninger Jenő Országos Traumatológiai Intézet –Jenő Manninger National Institution of Traumatology
ml	Milliliter
mm	Millimeter
Mod.	Modified
MPa	Mega Pascal
MPR	Multiplanar reformation (radiology)
N	Newton
N/A	Non applicable
NCBI	National Center for Biotechnology Information
No.	Number
ORIF	Open Reduction Internal Fixation
OS	Osteosynthesis
PEO	Population Expose Outcome
PICO	Patient Intervention Comparison Outcome
PMCF	Post Market Clinical Follow up
PMID	PubMed unique Identifier
PMMA	Poly Methyl Methacrylate
PMS	Post Market Surveillance
Post.	Posterior
Postop.	Postoperative
Preop.	Preoperative
R^2	R-squared (in regression analysis)
RBC	Red Blood Cell
ref.	Reference
SPIDER	Sample Phenomenon of Interest Design Evaluation Research type
THA	Total Hip Arthroplasty
THR	Total Hip Replacement
Ti	Titanium
TIF	Tagged Image File
TMARS	Trabecular Metal Acetabular Revision System
Transv.	Transverse
UHMWPE	Ultra-high-molecular-weight polyethylene
URES	Resultant Displacement (in Finite Element Modelling)
US	United States
V	Vanadium
Vs.	versus
VX	Vortex Screw
Ys.	Years
Δ	Delta (change in result)

I. INTRODUCTION

1. Problem idnetification

A) Historical background

In the first half of the twentieth century, the standard treatment for acetabulum fractures was conservative. French orthopedic surgeons Emile Letournel and Robert Judet developed the basics of surgical treatment. Their most notable publications are the article "*Fractures of the Acetabulum: Classification and Surgical Approaches for Open Reduction: PRELIMINARY REPORT*" (1964) and the book "*Les fractures du cotyle*" summarizing their work (1974).

Judet and Letournel were the first to describe the functional anatomy of the acetabulum: they introduced terms such as the anterior and posterior columns and the quadrilateral plate. They described that the acetabulum transfers the body weight in the vertical direction through these two pillars to the lower limb. They also developed the imaging diagnostic: antero-posterior and 45° tilted ala, and obturator views were used.

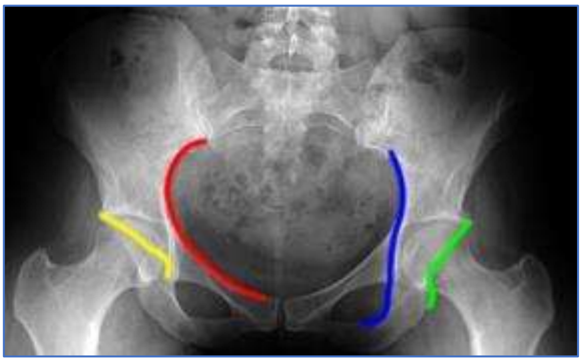

Figure 1. - Regions on the AP view (red-blue: front-rear column, yellow-green: front-rear wall) – FCA Figure Created by Author)

By analyzing 159 fractures, they developed the currently used classification. Their work is also significant because CT (Computed Tomography) was unavailable in 1964, as Godfrey Hounsfield invented it in 1972. Although CT imaging is essential in preoperative planning, the fracture classification can also be solved on a single AP pelvic view *(Figure 1)*. The classification is based on the involvement of the posterior, anterior, transverse, central region, or a combination of the above. The classification distinguishes between simple and complex fractures *(Figure 2)*. Their system does not consider the involvement of the acetabular roof however, the "gull-sign" is one of the most significant prognostic factors demonstrated later in the literature review. By examining the accident mechanism, they concluded that if the acetabulum fracture does not occur as part of a direct pelvic ring injury but by a femur-mediated force, the type of fracture is determined by the actual position of the femur at the moment of injury.

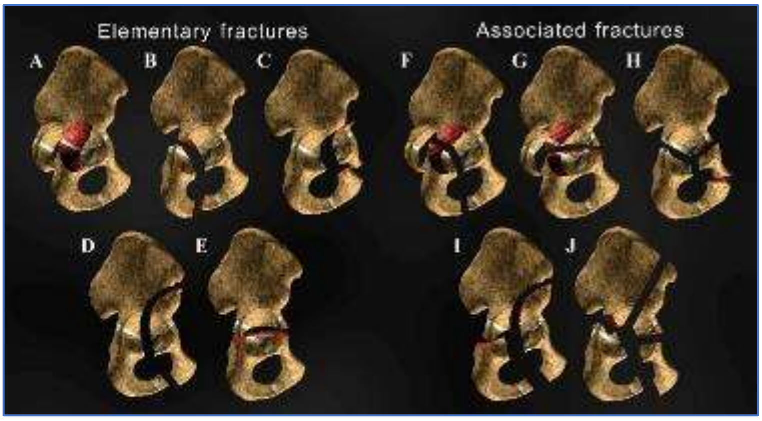

Figure 2. - Judet-Letournel Classification - FCA

They proposed surgical treatment for the fractures. The posterior fractures were explored from Kocher-Langenbeck approach, while the anterior column and quadrilateral plate fractures were treated from the ilio-inguinal approach [1].

In the following decades, research has focused on anterior approaches. The Judet-Letournel approach does not access the inner or posterior wall of the pelvis and opens the inguinal canal. Therefore other explorations were required. The first intrapelvic extraperitoneal technique is named after René Stoppa [2]. For better access to the anterior ring and quadrilateral plate, J.D. Cole and B. R. Bolhofner modified the approach and introduced it into daily use under the name “Limited intrapelvic approach.” It is known today as the modified Stoppa technique [3].

The “pararectus” or “lateral rectus” approach used at the MJOTRI (Manninger Jenő Országos Traumatológiai Intézet) was first described by M. J. B. Keel et al. Its advantage is that the anterior column, the upper stem of the pubis is easy to access, and the technique provides safety to protect the iliac arteries and veins and the corona mortis [4].

The Kocher-Langenbeck approach is standard for the posterior column and wall treatment. If a prosthesis is used to supply the acetabulum, the Hardinge and Watson-Jones techniques are also eligible.

Initially, the surgical treatment of acetabulum fracture was the percutaneous screwing or open plate fixation. The first publications mentioning a prosthesis to treat fractures appeared in the 1980s and 1990s, and had already provided encouraging results at the time of introduction [5][6][7].

B) Age distribution of acetabular fractures

The fact that increased motorization as wll as the aging of society are elevating the incidence of certain injuries has become evident today. In 1964, Letournel already mentioned: "the more cars there are on our roads, the more acetabulum fractures we have." At the Jenő MJOTRI, we observed a subtle increase in the number of acetabulum fractures in the last ten years, but we could not show a significant difference (this may also be due to the change in the admission area) – *Figure 3*.

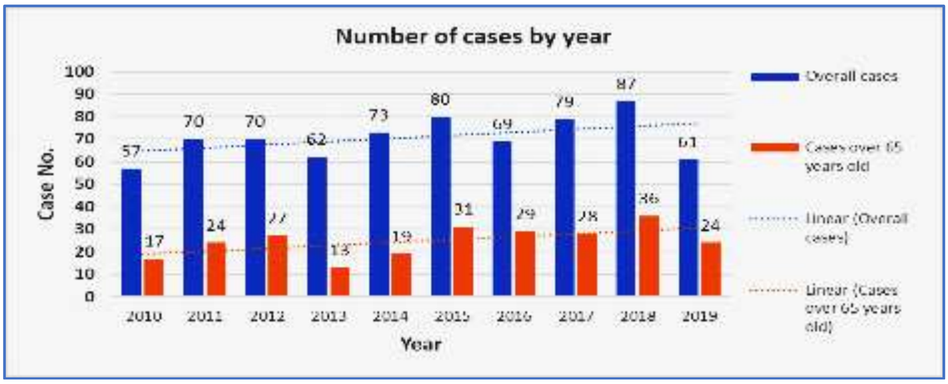

Figure 3. - Distribution of acetabulum fractures in MJOTRI

According to the literature, the incidence of acetabulum fracture averages 3-4 per 100,000 individuals per year. Fergusson and Matta provided the most reliable data in 2010. They established a prospective radiological database in 1980, acetabulum fractures were recorded for 27 years. The data of 1309 patients were divided into two groups by age (above or below 60 years). A 30% (p = 0.001) increase in the total number of cases was observed over 27 years. The mean age of new patients significantly increased (38 years before 1993, 45 after that). Even the proportion of patients above 60 years increased (10% before 1993 and 24% after that). Thus, the proportion of patients over 60 years of age (increasing with the total number of patients) increased 2.4-fold (p <0.001) [8].

Considering our institution's data, we can state that compared to any other subgroup of acetabulum fractures, the number of patients over 60 is growing the fastest. Therefore in the following years, we will have to take care of more and more acetabulum injuries in elderly patients.

Most reports concerning acetabulum fractures in the elderly begin with the following or similar-meaning sentence: "acetabulum fractures show a bimodal distribution, with high-energy injuries predominating in young age and low-energy injuries in old age." According to the data found in the literature search, this is not true. At least the distribution of injury mechanisms needs to be detailed. Indeed, due to the good general condition of lower ages and good bone mass, we find almost only high-energy injuries in the youth. However, high-energy injuries do not cease in the old age; only their rate decreases. Fractures from low energy injuries become common due to osteoporosis and poor general condition. In the literature search, we found 11 articles with percentage data pertaining zo mechanism of injury. Falling from a height higher than same position is generally considered a high-energy injury. The rate of lower-energy injuries increases with the mean age, but high-energy injuries can also be detected in the elderly group *(Figure 4)*. Due to the small number of samples, we did not find a significant correlation between mean age and high-energy injuries (p = 0.199).

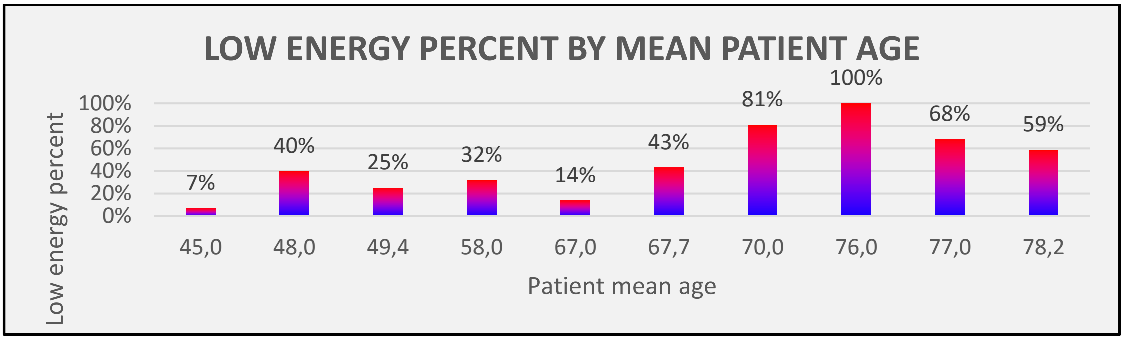

Figure 4. - The rate of low-energy injuries by mean age in the ten articles from literature research, where low energy injury rate was mentioned ([9][10][11][12][13][14][15][16][17][18])

Because injury occurs in old age by a different mechanism, we should expect different fracture types. Fergusson and Matta also found lower rates of co-injuries in the elderly (19.7% vs. 9.9%). There is also a significant difference in the distribution of fracture types: in old age, involvement of the anterior wall or column is more common (youth: 0.3% and 3.4% vs. elderly: 7.2% and 19.2%). In addition, over the age of 60, displacement or impression of the anterior wall or column is more common (63.8% vs. 43%) [8]. There is a consensus in the literature that fracture of the acetabular roof is one of the most reliable predictors of later osteoarthrosis or osteo-chondral necrosis. For this reason, more complications should be expected in older patients treated in a conservative way or with internal fixation alone.

C) Research plan and hypothesis

- International publication analysis, in which the distribution of acetabulum fracture can be determined, and the outcome and risk of currently used methods can be identified appropriately. Based on the analysis, we set up a diagnostic and therapeutic protocol.
- Demographic analysis of the MJOTRI's patient population over the past ten years.

- Biomechanical study by FEM (Finite Element Modelling) of the new revision ring acetabular shell with angular plate and comparison of its mechanical properties with the combination of quadrilateral and horizontal plate.
- Presentation and analysis of the results obtained with the indicated method in the last three years.

a) Hypothesis

- Treatment of displaced and unstable acetabulum fractures in the elderly with conservative or bone fixation techniques is less effective than the new hybrid (ORIF - Open Reduction Internal Fixation with THR – Total Hip Replacement) method or equivalent solutions.
- The new hybrid technique provides better primary stability than previous internal fixation methods.
- The new hybrid method can be used safely.
- Based on biomechanical and clinical data, assessing the need of modification of the current implant and instrumentation.

2. Literature data

A) Literature data search protocol

When developing a new technique, we need to know the existing methods and their results. We need to examine whether the developed method exists in a similar form and its results.

Literature research cannot be biased. If negative results or residual risks are found for similar methods, we should examine them for our technique. Therefore, we collected literature data from a wide range of trustworthy sources.

a) Source of literature data

We chose the American NCBI (National Center for Biotechonlogy Information) PubMed / MEDLINE search engine to perform a comprehensive search. Its advantage is that the database has more than 30 million articles at the time of writing, its search engine can be tuned appropriately, and searches can be saved and repeated.

b) Structure of search topics

We needed to base our search on the right keywords to receive the most relevant information about our method. Current search software and literature research guidelines recommend the following keyword structuring methods:

- PICO (Patient / Problem / Population; Intervention; Comparison; Outcome);
- PEO (Population; Exposure; Outcome);
- SPIDER (Sample; Phenomenon of Interest; Design; Evaluation; Research type);
- COSMIN (COnsensus-based Standards for the selection of health status Measurement INstruments).

There is considerable evidence in the literature that the results of searches based on different methods do not differ significantly. However, some reports show a higher number of results for the PICO method [19][20][21].

Accordingly, we chose the PICO procedure. The method requires that we divide our search terms into the following keyword groups:

- Patient / Problem / Population: definition of the disease and population discussed;
- Intervention: type of intervention / surgical care / treatment;
- Comparison: a method for comparison;
- Outcome: result.

The keyword groups must match the following, depending on the search engine:

- English words;
- articles do not use a standard nomenclature, so it was necessary to use an appropriate number of synonyms within keyword groups with "OR" relationship;
- keyword groups are listed with an "AND" logical relationship, as each keyword group must have at least one synonym in query;
- the selected articles must come from the last 10 years, depending on the number of results the interval can be reduced to 5 years.

The ideal number of resulting articles was a hundred, as a few results did not provide enough detailed information, and too many articles resulted in an unmanageable amount of data.

c) Management of literature data

In order to apply relevant literature results to our method, the data must be subjected to appropriate analysis. The method discussed in the articles should be examined with appropriate grouping (conservative treatment - internal fixation - prosthetics - hybrid method). The total number of cases and the actual number of cases with treatment mentioned in the article must be recorded. The methodology of the article should be examined (prospective/retrospective structure, single/multicenter study, human application/simulation/cadaver application). The reported complication of the method and the recommendation made by the article should be recorded.

B) Compiling search queries

As we examined the treatment of acetabulum fractures in the elderly, the terms (P) of the target group were given. The technique can be non-operative, prosthetic, internal fixation, or hybrid (I). We omit comparison (C), as we examined not only comparative articles. The outcome (O) may be a recovery, complication, or combination thereof (*Table 1)*.

Table 1.- Proper keyword combination for the final search

P	patient and / or problem	Elder patients acetabular fracture	Elder, older, old, elderly, aged, high age	Fracture, fractures, injury, injuries	Acetabular, acetabulum
I	intervention / treatment	Total hip arthroplasty or internal fixation	THA, THR, total hip replacement, total hip arthroplasty, endoprosthesis, prosthesis, arthroplasty	ORIF, internal fixation, plating, osteosynthesis, synthesis, fixation	
C	comparison	empty			
O	outcome	Outcome result as arthrosis, necrosis or recovery	recovery, osteoarthrosis, arthrosis, AVN (avascular necrosis), arthritis		
Release Date			2010/01/01	2020/01/01	

C) Results of literature review

a) Completion of results

Even with a well-structured search, we can miss important information. After the primary selection of articles, we should check to see if the search engine offers a related publication based on the selected article that may be relevant.

b) General results and inclusion of literature data

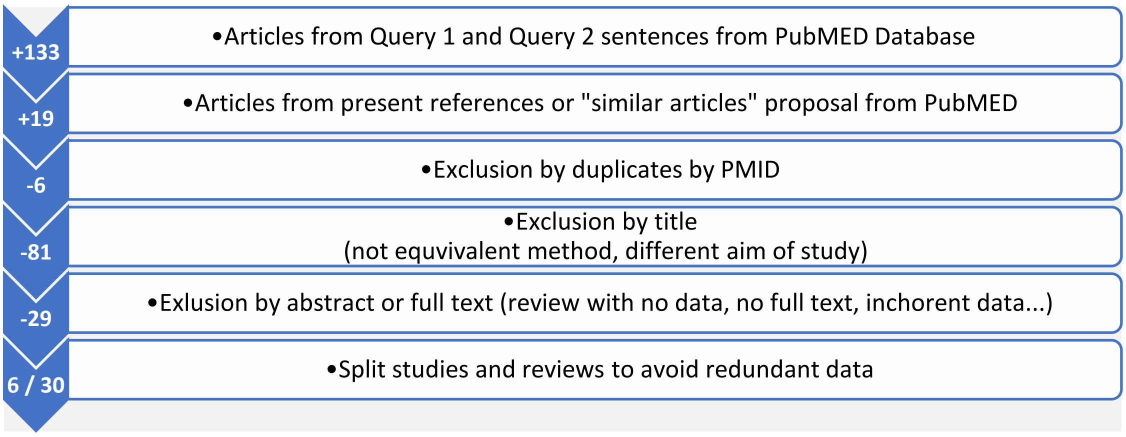

Figure 5. - The collection and inclusion process of articles

Based on the multiple searches and their aggregation, we found 152 publications. The search conditions were English, period 2010-2020, and online full-text availability. The studies were then analyzed by title, abstract, and full text (exclusion/inclusion process: *Figure 5*).

We evaluated review or meta-analytic publications separately. Of the remaining 30 articles, seven were prospective, and 23 were retrospective. Unfortunately, most articles did not exceed the Level III Evidence level. Most publications had only Level IV evidence.

After including the articles, we checked the method discussed, the follow-up period, the age and gender of the patient groups, the proportion of complications related to the method and the number of recovered cases, intraoperative complications, average blood loss, and functional results (most dissertations use the HHS – Harris Hip Score system). The types of study centers, longitudinal time structure, and methods tested are listed in *Table 2*.

Table 2.- Methodological distribution of the publications in the literature search

<table>
<tr><th colspan="2" rowspan="2">Center type</th><th colspan="2">Method build</th></tr>
<tr><th>Single</th><th>Multiple</th></tr>
<tr><td colspan="2">Multicenter</td><td></td><td>[8][15]</td></tr>
<tr><td colspan="2">Review</td><td></td><td>[22][23][24][25][26][27]</td></tr>
<tr><td rowspan="2">Single center</td><td>Retrospective</td><td>[28][29][17][14][10][30][31] [9][32][13][33][34][35][36] [37][16]</td><td>[18][38][39][11][12]</td></tr>
<tr><td>Prospective</td><td>[40][41][42][43][44][45][46]</td><td></td></tr>
</table>

c) Demographics

A total of 3324 cases were discussed in the thirty articles (11-1309, average 114.6). Publications with lower case numbers usually introduce a new method.

Only ten of the papers dealt especially with acetabulum fractures in the elderly, thus the age of the studied patient groups were varied (11-101 years by individuals, 37.8-81 years average). The case-number-weighted mean age in the articles was 40.9, so the presence of young patients in non-elderly-targeted publications is predominant.

The mean age (weighted by method-specific case numbers) was as follows (averaging all articles): ORIF 49.82, THR 48.63, and 75.4 years in the case of hybrid technique. The difference between the mean ages of the internal fixation and pure prosthetic patients was minimal. There was a significant difference ($p < 0.001$) between the patient groups of conventional and hybrid methods, which was not surprising since hybrid techniques had been developed especially for fractures in the elderly. We observed a higher ratio of male patients: the minimum male / female ratio was 1:2, and the maximum was 7.2:1. Based on the case-weighted average, the overall male/female ratio was 1.3:1.

d) Method-specific data

While all of the six reviews/meta-analyses papers examined several treatment methods, the thirty dissertations included one or several methods *(Figure 6)*.

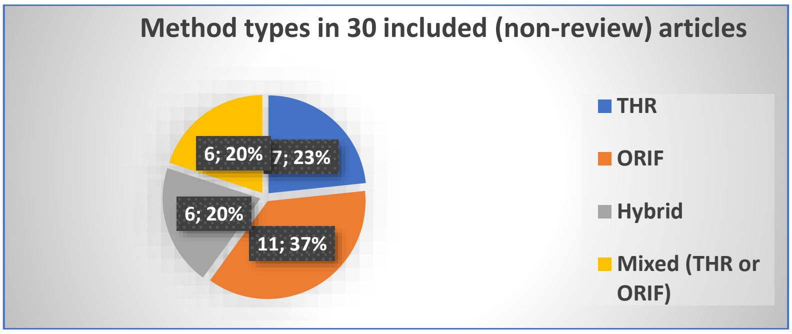

Figure 6. - Distribution of the surgical methods examined by the thirty non-review articles

We can compare results and complications only after an appropriate follow-up time. We could identify the follow-up period in 26 papers. Since many publications consider follow-up time as zero for perioperative death, the minimum follow-up period was 0, and the maximum was 276 months. The case-weighted follow-up time was 32.7 months. The follow-up time of the ORIF method lagged behind the hybrid and prosthetic methods (30.8 months vs. 75.4 months; p = 0.01). The 22-month follow-up average of articles examining hybrid methods was not high either, but the relatively recent introduction of implants could explain this. Complications are shown in *Table 3*.

Table 3. - Complications in the 30 non-review articles

	ORIF	THR	Hybrid	Non-operative
Exit	0,6%-7,5%	11,10%	9,9%-20%	3,40%
FHOA	6,52%-36%			
FHN	2%-9%			6,40%
Septic	4.34%-10%	3%-11%		4,20%
Dislocation	2%-5,2%	3%-12%	6%	
HO	7,5%-22%		5%-20%	

The expected amount of blood loss is essential. The mean was 782 ml for ORIF, 1182 ml for THR, and 1150 ml for the hybrid method. Due to the low number of cases, the difference between the data had a low significance (ORIF-THR: p = 0.11; ORIF-Hybrid: p = 0.5).

Functional results were predominantly determined by HHS values. We found HHS interpreted in 11 articles. There was no significant difference between ORIF (78.1), THR (86.3), and hybrid technique (94) (p = 0.41). The high value described for the hybrid method was only read in one article, so its significance could not be evaluated.

e) Analysis and conclusion of metanalytical and review publications

The six papers processed a total of 6006 cases, averaging 1201, examining several surgical or conservative methods without exception, with a mean follow-up of 44 months. There was no significant difference in the distribution of demographics and complications compared to the previously described data.

Demographic conclusions [8**][**24**]:**

- The number of acetabulum fractures increased. The number of patients over the age of sixty grew the fastest. Therefore our method may be used more frequently in the future.
- The higher male ratio was constant and unchanged in recent decades

Mechanism and classification [8**][**26**]:**

- Acetabulum injuries resulting from low-energy injuries were mostly elementary fractures that predominantly affected the anterior wall and column.
- Due to the higher rate of low-energy injuries, co-injuries were also lower, usually with lower ISS values.

Expected results and complications of procedures for acetabulum fractures in elderly:

- Conservative therapy was only appropriate for stable fractures without displacement [15].
- Percutaneous screw fixation should only be a palliative technique, especially in patients with poor conditions [24].
- Opinions rgearding the ORIF method were divided. Although several papers reported good results, follow-up time was short. The rate of loosening and displacement were higher in this group, and the combined rate of osteoarthrosis and necrosis is over forty percent. Based on the radiological analysis, the most significant predictor of this was the damage of the acetabular roof ("gull-sign") [14] [24].
- THR results with a conventional prosthesis were worse than surgery for primary coxarthrosis due to lower stability. Hybrid methods are recommended for patients with good general conditions. In the case of THR, degenerative joint lesions as AVN or osteoarthrosis may not occur, but heterotopic ossification reached 20 percent. According to long-term results, it did not cause significant any functional loss [22].
- Blood loss was higher in the THR and hybrid groups. The risk should be considered in preoperative planning [23] [24].

f) Conclusion of literature data

The method we have introduced is expected to have a lower complication rate and better functional results than other procedures.

Later, in order to represent our results properly and to compare them with international publications, we need to collect the following data prospectively:

Demographics: age, gender, mechanism, history (based on CCI – Charlson Comorbidity Index) and additional injuries (ISS), fracture classification (Judet-Letournel classification + presence of "gull sign").

Surgical care: time since injury, type and time of surgery, blood loss, type of approach, complications.

Hospital care: length of stay, postoperative complications, amount of transfusion, initiation of mobilization and exercise, HHS.

Data from follow-up assessments: wound condition, gait and walking aid use, HHS, pain, complications, and imaging results.

II. OBJECTIVES

1. Introduction

From the second half of the twentieth century, the treatment of acetabulum fractures shifted to the surgical method. The literature agrees that conservative treatment of stable fractures without displacement has good results.

Based on literature analysis, displaced fractures (especially in the case of acetabular roof involvement) have a high rate of degenerative complications (necrosis or arthrosis) with conventional treatment (15-40% in ORIF or conservative therapy). Thus, it is necessary to use a procedure that precludes degenerative joint complications when choosing surgical treatment. A long-term complication of THR is implant loosening, which must be considered. There is evidence that a higher chance of prosthesis loosening can be expected at a younger age. Lee E. Bayliss studied 63,158 hip prosthetic patients in a retrospective analysis of CPRD (Clinical Practice Research Datalink) data. Ten-year implant survival was 95.6% and 89.7% at twenty-year follow-up. He found a correlation between the age at surgery and the expected risk of revision. Over 70 years, the revision rate ranged 1-6%, while it ranged 20-30% at a lower age. The difference in the number of revisions between the youngest and oldest age groups shows an increase of up to three times in women and up to five times in men [47]. Thus, a lower risk of the revision can be expected with prosthetics performed at an older age.

If THR is chosen as the primary solution to avoid degenerative complications in elderly acetabulum fractures, we have to face acetabular instability. Due to the acetabulum fracture, a pressure-based "press-fit" method cannot be used. It could be obvious that we provide the stability of the acetabular shell with cement. However, the loaded cement flows into the fracture gaps during the impaction of the shell, making the fracture impossible to heal.

Ensuring primary stability, i.e., avoiding the prolonged bed-ridden state, is an outstanding task in the elderly. Complications due to hypostasis, such as pneumonia, thromboembolism, decubitus, and mental changes are well known [48] [49] [50].

During the treatment of unstable acetabulum fractures in the elderly with a prosthesis, we must ensure the primary stability of the acetabular shell, which provides immediate mobilization, weight-bearing and later secondary stability. Internal fixation is a procedure that achieves bone stability and remodeling by bridging the bone discontinuity. It is understandable to combine this treatment principle with joint replacement. Our literature analysis examined several studies that use osteosynthetic and prosthetic techniques not as a linked procedure but as a separate ORIF and THR solution in one or more sessions. Because of the complexity of the method and the multi-step care, those procedures have more complications. With older age and more underlying diseases, short- and long-term complications of surgical care also clearly increase [51] [52]. We modify our hypothesis: can we develop a new, hybrid method to provide acetabular stability that does not increase surgical invasion and strain.

2. Surgical considerations

Considering patient safety, we need to develop a surgical method that provides sufficient stability through ORIF without significantly increasing the surgical invasion and avoids degenerative complications through THR. Accordingly, the process assumes a single-session use and a fixed physical connection between the ORIF and THR components.

If we can build such a system based on previous results, we must evaluate it to meet theoretical biomechanical considerations before the clinical use. Based on the literature analysis, we need to check what complications we can expect. Since the idea of a mechanically attached hybrid (ORIF + THR) method in a single session is not unprecedented, we need to examine the safety of the methods already known. After the clinical introduction, it is necessary to check the results of the introduced method. We can compare our results with data from literature and previous patient data from our institution.

3. Implant design

Introducing a new implant on the market is a complex task, especially if the implant is under the authorization procedure Class III (implantable trauma devices). The European Union makes the medical device certification subject to strict rules. The directive until May 2020 named ‘MedDev’ (https://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/en/renditions/native), allowed new implant certification based on its similarity to a previous device. From May 2021 (MDR–: https://eur-lex.europa.eu/eli/reg/2017/745/oj), the new regulation no longer allowed similarity-based certification, medical devices shall only be authorized based on a clinical study according to ICH-GCP (International Conference of Harmonization – Good Clinical Pratice).

In the implant planning period, we followed the MedDev (Medical Device Directive) principles: we modified an already existing implant to address a similar problem and combined this with other devices already used in pelvic fixation. The process of modification or testing presupposed a well-functioning relationship with the manufacturer.

Based on the listed criteria, we chose to combine and modify the ConeTact R-2 (ref .: Zoltán Csernátony, Tamás Moser) and Vortex Pelvis (ref .: László Vámhidy, Endre Varga, Ferenc Tóth, Béla Turchányi) systems produced by Sanatmetal Ltd. The porous plasma-coated ConeTact R-2 cup provides several dome-screwing options. A threaded ring can be attached to the rim of the cup, into which angular-stable screws with a diameter of 3.5 mm can be inserted. With the help of special screws, an additional plate can be secured to the ring, into which additional angular-stable screws can be placed *(Figure 7)*. We hypothesized that the screws placed in the ring and U-plate provided sufficient primary stability (osteosynthetic principle), and the use of a plasma-coated cup and autologous cancellous bone facilitateg subsequent integration.

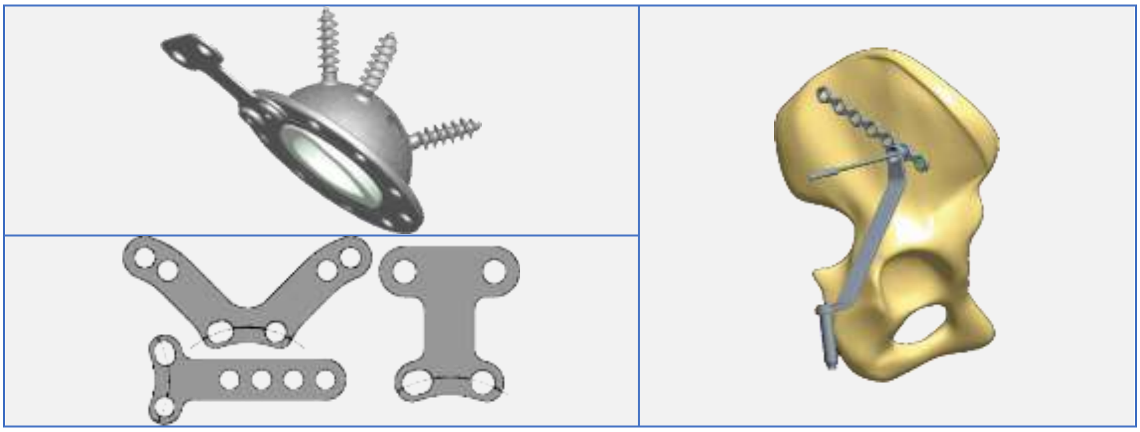

Figure 7. - Original systems (ConeTact R-2, plates, and Vortex Pelvis) - courtesy of Sanatmetal LTD.

Rationale: Monitoring results with Sanatmetal ConeTact and Vortex Pelvis (PMS – Post Market Surveillance and PMCF – Post Market Follow Up), which have been on the market for more than ten years, did not reveal any common complications or device-specific risks.

4. Preclinical evaluation of implant safety and efficacy

A) Comparison of the implant with international results

There are several examples of combining internal fixation and prosthetic techniques. Based on appropriate equivalence, the results of different similar techniques can be applied to our system. We can predict efficacy. The complication rate can be reduced by considering known difficulties and applying modifications. Based on our literature search, the following implants were considered eligible for the hybrid resolution of acetabulum fractures in the elderly:

- Zimmer Trabecular Metal Acetabular Revision System;
- Stryker / Howmedica Restoration GAP II;
- J&J Depuy Synthes Acetabulum Roof Reinforcement Plate.

Rationale: The European Union had authorized the use of medical devices based on equivalence, so the equivalence method was sufficiently rigorous and well-founded to test new implants properly.

B) Biomechanical evaluation of the implant by FEM

The FEM is a computer method used in design processes. Taking into account the the solid body characteristics of the object to be examined, it decomposes the object into a finite number of units and simulates the dynamic behavior of the object under force. The implant and bone are bodies considered to be linear-elastic, homogeneous, and isotropic, so Hooke's law describes their behavior. Accordingly, if the Young modulus of elasticity (change in length per unit force) and Poisson coefficient (cross-sectional change per unit force) of the alloy and bone are known, we can simulate where a displacement or stress occurs in the bone-implant model. We can calculate where loosening or implant breakage can occur so the structure of the implant can be optimized.

Rationale: by the third quarter of the twentieth century, use of FEM exceeded natural load experiments and became overwhelming by the end of the century (99% simulation - 1% true measurement) [53], so the method is commonly accepted. As a medical explanation, we can present the results of Tamás Bodzay's Ph.D. thesis. He compared the biomechanical behavior of surgical implants (transsacral plate, SI screwing, omega plate synthesis) used for unstable pelvic dorsal ring injuries with FEM, cadaver experiments, and clinical results. His most important result correlating to our research is that the biomechanical experiments performed with different methods were consistent with each other and with the clinical results [54]. Accordingly, we developed a similar pelvic model, and the material characteristics of the bone were drawn from the same source.

5. Evaluation of clinical data

If promising results in the preclinical study could be obtained, the newly created implant could be applied in the surgical treatment of unstable acetabulum fractures in the elderly (over 65 years, osteoporosis, ASA (American Society of Anesthesiologists) II or higher).

We prospectively collected all data types previously included in international publications during the application. Thus, we recorded demographic data, general conditions, all parameters of the surgical process, postoperative results, and then long-term follow-up data.

6. Objective Summary

- Modification of the implant system in use according to our indication and application.
- Identification of on-market devices equivalent to our implant and predicting the possible results and complications from their data.
- Carrying out FEM simulation using our implant design and previous pelvic models (developing possible implant optimization and positioning).
- Analysis of data obtained during the clinical use, development of final indication, and therapeutic strategy.

III. METHODS

1. The implant and the surgical technique

A) Biomechanical considerations

As we specified the unstable acetabular fracture in the elderly as the indication of the hybrid system, we faced numerous biological and mechanical problems. Bone mass decreases by aging. Because there is a clear relation between cortical thickness, cancellous density, and anchoring force of screws, less stability can be achieved in porotic bone [55] [56]. In old age, bone and muscle mass decrease, and bone healing becomes slower. These events delay the development of secondary stability, thus exposing the implants to a more extended mechanical load [57].

In the case of insufficient bone mass, stability can be increased with an angular-stable system, a larger support surface, and cement augmentation [58]. By introducing the screws in altered directions, the stability can be enhanced [59]. As we will see, due to anatomical characteristics, a complete implant-bone contact is not available. The stability of dynamic compression systems relies on bone-plate friction, so in our case, it was necessary to design an angluar-stable system. With some increase in the plate-bone distance, the stress distribution in the system can be improved [60].

We attach a threaded ring to the ConeTact R-II cup and then attachrd a "U" plate. Both the ring and the plate have angular-stable holes. As a result of this structure, we met our previous requirements for both angular stability as well as for buttressing, as the ring formed a fixing and a supporting surface *(Figure 8)*.

Figure 8. - Contact between the cup, ring, and "U" plate - FCA

The implant had to be modelable to achieve the ideal bone-plate distance. A polyaxial design was necessary to achieve the diverging screw directions discussed earlier. The Vortex Pelvis system used in the ORIF of pelvic fractures fulfilled both conditions: the plate could be modeled, and the screws could be placed into the hole within 15° multidirectional angulation *(Figure 9)*.

Figure 9. - "U" plate modeling and polyaxiality- FCA

B) Surgical steps

The surgical process was not performed immediately, but after a short delay to avoid complications from hypostasis. The surgery was performed on a radiolucent table to allow C-arm views. We performed surgery in supine position and used a Watson-Jones approach.

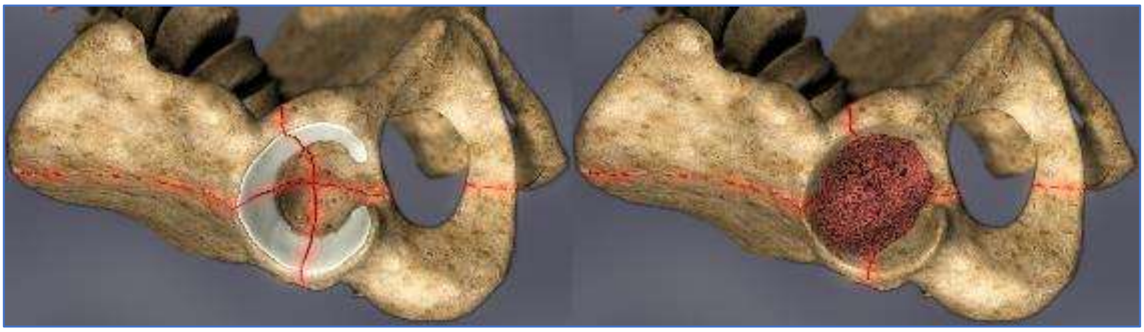

Figure 10. - Cartilage removal and ACB (autologous cancellous bone) fill - FCA

After joint exploration and resection, we harvested cancellous bone from the femoral head. Unlike the "press-fit" method, we did not ream the acetabulum totally. Our goal was to remove most of the cartilage and create enough space to insert the shell without any tension after the cancellous bone impaction *(Figure 10)*. The appropriate size was determined by probing. After the proper size was chosen, the ConeTact R-II shell was attached to the ring. After careful insertion, the shell was secured with 6.5 mm diameter cancellous screws *(Figure 11)*. During screw introduction, it was necessary to ensure that the plane of the shell was kept in good position.

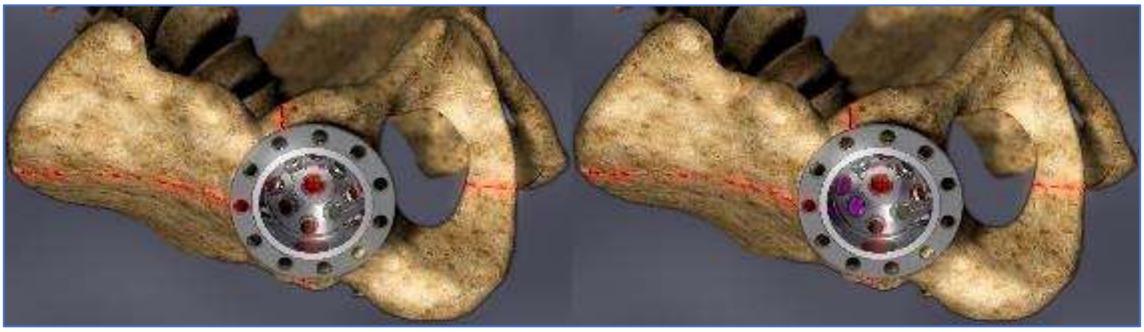

Figure 11. - Ring insertion, dome screw introduction - FCA

Following the introduction of 6.5mm screws, the ring was fixed with angle-stable 3.5mm (VX) screws. Since either a VX screw or a screw securing the "U" plate could be inserted in the grooves of the ring, the position of the "U" plate must be determined before inserting the ring VX screws. The plate's ideal position was the acetabular roof so that the two forks of the plate were preferably on either side of the fracture on the iliac wing. VX screws must be introduced in altered directions through the deepest bone mass possible. After tightening of the ring screws, the plate was modeled and then attached to the ring with securing screws. The plate had 2x4 holes. The plate can be shortened with a cutting device *(Figure 12)*.

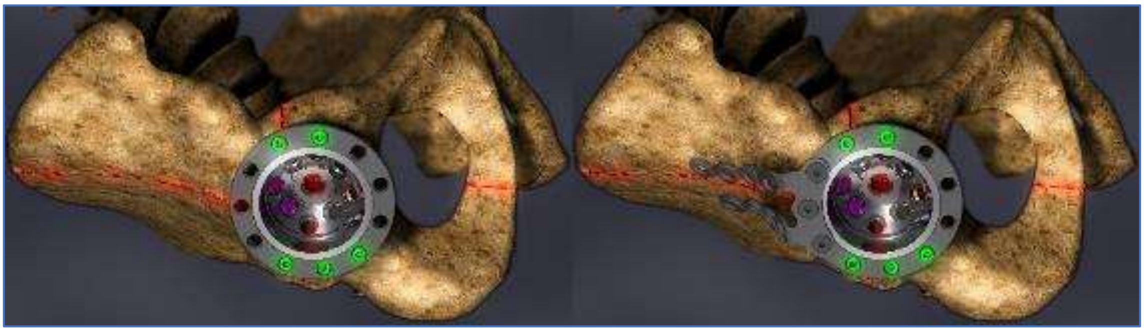

Figure 12. - Ring screw introduction and plate securing - FCA

After mounting the plate, we inserted angular-stable 3.5mm diameter screws into the "U" plate. The altering direction already used for the ring screw was also recommended here. We checked the stability after introducing the screws, and an intraoperative X-ray qas taken. If the shell plane was not ideal (small anteversion or too high inclination), a 10 or 20° insert could be used *(Figure 13)*.

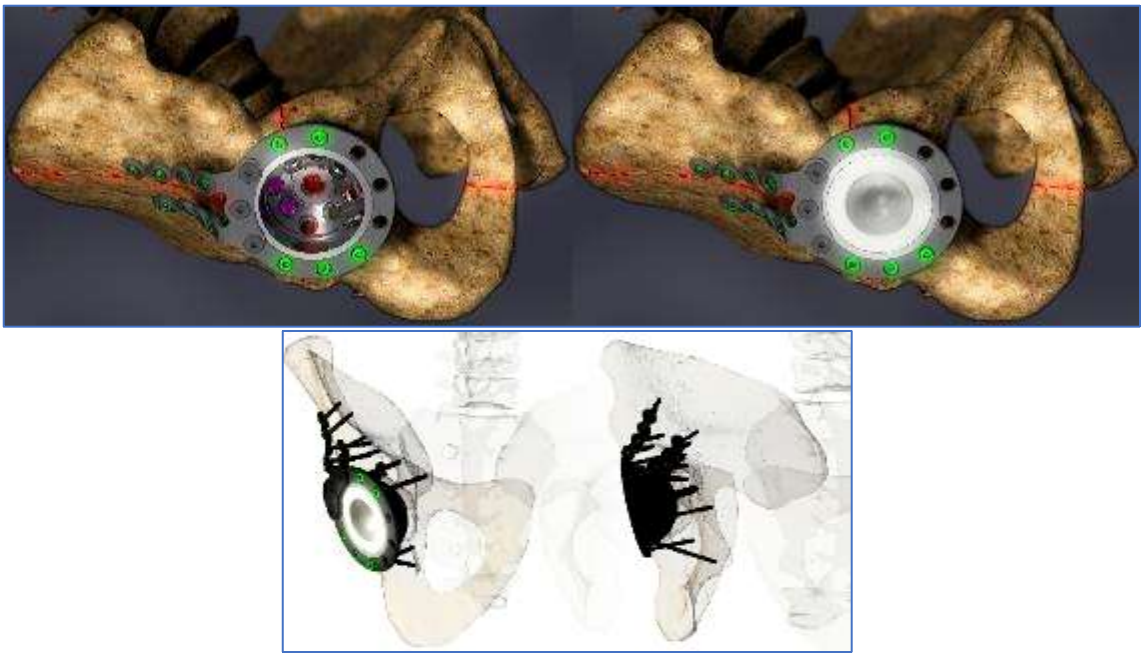

Figure 13. - Plate screws introduction, liner insertion, X-Ray on Judet views - FCA

The femur shaft insertion was carried out according to the general principles of THR. Postoperative care was similar to the aftercare guidelines of THR. Walking with an aid limited to limb weight load and passive movement of the joint should begin no later than the second postoperative day. Suture removal was performed at 10 to 14. days postoperatively and LMWH (Low Molecular Weight Heparine) is administered for at least six weeks after the surgery. Follow-up visits were at the postoperative 6th and 12th week, 6th and 12th monthd, then we assessed patients every two years.

2. Data evaluation from equivalent devices

A) Criteria for demonstrating equivalence

In order to compare the results of the two instruments, we needrf to prove their similarity. For this, the following should be similar for the two instruments:

- clinical use (same group of patients, same purpose of care, same anatomy);
- technical characteristics (design, raw material, use with similar principles);
- biological activity (in contact with human tissues)

B) Comparison of equivalent assets

Table 4. - Identification of similar devices

Tested feature	Sanatmetal ConeTact R-2	DePuy, Synthes Roof-Reinforcement Plate	Zimmer Biomet TMARS (Trabecular Metal Acetabular Revision System)	Stryker Restoration Gap II
				
Clinical characteristics				
Purpose	Acetabular fracture Revision	Identical	Identical	Similar
Anatomical location	Hip joint	Identical	Identical	Identical
Age	Adult	Identical	Identical	Identical
Technical characteristics				
Diameter	40-74mm/2mm	Similar	Similar	Similar
Plate length	2x4 holes	Identical	Similar	Identical
Special coating	Yes	Different	Similar	Different
Plate connection	Modular	Different	Different	Different
Insert connection	Direct	Different	Different	Different
Angular stable	Yes	Identical	Different	Different
Ring surface	Yes	Identical	Different	Different
Ring screwing	Yes	Identical	Different	Different
Biological characteristics				
Alloy	Ti	Identical	Identical	Identical
Biologic activity	None	Identical	Identical	Identical

Table 4. examines the similar devices found under current EU legislation [61]. Zero, one, and two points can be awarded for the given compliance (different-similar-identical). Crucial properties are weighted twice (marked in red). Accordingly, of the maximum 38 points available, Depuy / Synthes scored 31 points, Zimmer Biomet 19 points, and Stryker 17 points. Thus, the Roof Reinforcement Plate results can be applied to our technique.

3. Development of a finite element model for mechanical simulation

We performed the designing and testing of FEM with the help of Károly Váradi (Professor Emeritus – BME (Budapest University of Technology and Economics), Faculty of Mechanical Engineering, Department of Mechanical and Product Design) and Gábor Szalai (student - BME, Faculty of Mechanical Engineering).

A) Material properties

The system included artificial and biological components. Unlike manufactured elements, the physical properties of bones and ligaments were challenging to determine. The characteristics of the artificial elements are given in *Table 5*.

Table 5. - Material properties of implants - Sanatmetal LTD.

Component name	Raw material	Elasticity modulus [GPa]	Poisson ratio	Yield point [MPa]
ConeTact R-2 Cup	Ti6Al4V	113.8	0.324	880
Ring and „U" plate	CP Ti Grade2	103.4	0.33	345
Inlay	UHMWPE	0.689	0.46	24.1
VX and securing screw	Ti6Al4V	103.4	0.33	345

The material properties of the biological elements were drawn from the summary of Hiroyuki Abe et al. [62] – *Table 6*.

Table 6. - Material properties of bony elements

Element name	Elasticity modulus [GPa]	Poission ratio
Cortical layer	17	0.3
Cancellous stock	0.150	0.2

The layers of bone differ from each other in terms of phyisical caracteristics. The pelvis is not long bone, so a significant presence of cancellous stock is expected. Previously, calculations were performed with the help of the Faculty of Mechanical Engineering of the Budapest University of Technology and Economics: the ratio of cortical and cancellous bone was analyzed on CT scans, and then a homogeneous model was created [63] [64]. Accordingly, a cancellous-cortical ratio of 90-10% was determined, assuming a homogeneous distribution. Thus, the modulus of elasticity was changed to 2,060 GPa and the Poisson's ratio to 0.21. The new homogeneous model showed realistic behavior based on FEM simulations [65].

B) Design and subdivision of the 3D (three dimensional) model for FEM

After defining the material properties, we needed to develop models for the FEM simulation. The fundamental problem of FEM is the number of subdivided elements. A model subdivided into a few elements results in inaccurate data. As we increase the number of elements, the result becomes more accurate, but it means exponentially demanding computing capacity and computing time. An accepted method during FEM is to increase the number of elements and perform new simulations until the new measurements do not deviate significantly from the previous ones. Increasing the number of items also makes a remarkable difference *(Figure 14)*.

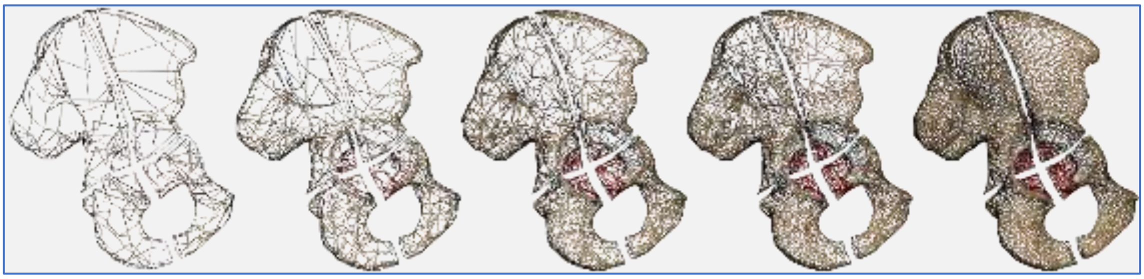

Figure 14. - Variation of the model saturation with the number of elements - FCA

The basic mesh was created from 3D imaging of a previous composite pelvic model. After importing the model into Solidworks 2018 3D design software, FEM was performed with Solidworks Simulation. The mesh was automatically decomposed into 3D tetrahedral elements. After reaching the appropriate number of elements and Jacobian evaluation, the model was composed of 508162 elements (size 1.98–9.9mm), 776494 nodes, in the presence of zero distorted elements [65].

After designing the mesh, we needed to make our model "definite," so we had to determine the fixed suspension points. In the absence of these, our model "flies away" under the influence of forces. This point fell on the posterior surface of the SI joint. The weight transfer point was the upper-end plate of the first sacral segment, and the load was 600 N.

We defined the tight joints as static bonds and the fracture lines as friction surfaces. The behavior of the pelvic model (von Mises force and URES displacement) proved to be nearly identical to the previously validated models (model – *Figure 15*).

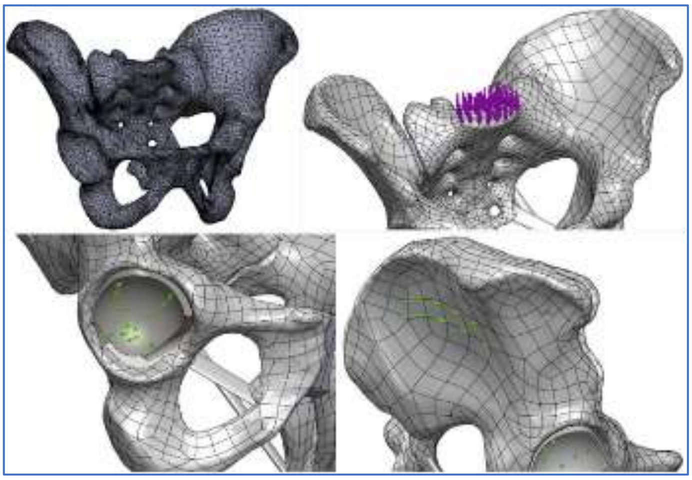

Figure 15. - Basic mesh, axial and femoral loading, determination of the FEM model [65]

C) Development of a final (damaged) pelvic and implant model

In the elderly, the most common fracture is a hemitransverse pattern involving the anterior wall or column. The more unstable the fracture, the greater the displacement is expected during the simulation. Accordingly, the hemitransverse fracture was completed with a horizontal component of the "T"-shape fracture extending to the anterior wall. This configuration allowed the radial forces to "shatter" the pieces of the acetabulum during simulation, resulting in femoral head protrusion *(Figure 16)*.

Figure 16. - Force directions acting through the head, pelvic displacement - FCA

We inserted the ring- and plate-mounted shell into the fracture model. For proper comparison, we chose a bone fixation method corresponding to the same fracture pattern: horizontal plating supplemented with an "L" -shaped "quadrilateral plate." The threaded part of the screws was simplified, and the forces acting on the threads were replaced by friction force *(Figure 17)*.

We evaluated the stability by simulating normal daily life. Based on Bergmann's work, the forces that occur in the general activities of a person weighing 80 kg are included in *Table 7* [66]. The axes are: 'x' horizontal - the line joining the two femoral heads, 'y' the sagittal axis - the line joining the sacrum and symphysis, and 'z' the longitudinal axis of the body - a vertical line in standing position.

Figure 17. - FEM elements: horizontal plate, hybrid method, screw [65]

Table 7. - Forces rising during daily activities

Activity	Standing on two feet	Climbing stairs	Rising from a chair
$F_{x\,(max)}$	162.3 N	470.5 N	423.5 N
$F_{y\,(max)}$	-45.5 N	470.5 N	94.1 N
$F_{z\,(max)}$	578.1 N	1858.7 N	1411.7 N

We examined the displacement and stress with these forces on the models (fractured model without implant, hybrid method, plate synthesis). We attempted to optimize the new implant system and compare it with clinical data based on the stress distribution.

4. Clinical and additional data collection

Although the FEM provides detailed data on the system's physical behavior, it does not model the process of bone healing nor material fatigue. Secondary stability cannot be predicted from the simulation. Similar devices also showes several differences, so the data obtained from their use should be considered, but no clear conclusions could be drawn for our system. Accordingly, although our case numbers are still low, the development of secondary stability, surgical risk, and recovery can only be analyzed by clinical evaluation of our patient population.

- Demographics: gender, age, medical history, concomitant injuries;
- Fracture characteristics: side, fracture classification, degree of displacement;
- Surgical data: surgery time, blood loss, intraoperative complication, implant;
- Radiological analysis of surgical outcome: acetabular plane, bone-plate relationship, residual displacement;
- Postoperative period: number of nursing days, blood transfusion, mobilization;
- Follow-up period: radiological analysis, remodeling evaluation, gait assessment, Harris Hip Score

According to the literature review, almost half of the elderly acetabulum fractures treated without surgery or bone fusion ended with a degenerative lesion, there was no control (conservative) group formed in our study.

IV. RESULTS

1. Clinical results

A) Demographic data

We performed the first surgical application in 2018. Until the close of the dissertation, 14 surgeries were performed with the evaluated method.

We adopted the indication based on the data of similar systems in literature: we used our device in case of unstable, displaced acetabular fracture in the population over 65 years. Three "off-label" use were performed: it was used for revision of acetabular loosening and bone loss due to the earlier infection in two cases, and in one case, we treated an acetabular non-union. The average age was 70, with a higher proportion of men (71% vs. 29%). Side distribution was not significant (left-right ratio 43% vs. 57%). The demographics are shown in *Table 8*.

Table 8. - Patient demographic and anamnestic data

ID	AGE AT ADM.	GENDER	SIDE	ADM. DAYS	TRAUMA ENERGY	DIAGNOSE	CCI (age mod.)	Proven porosis	ISS	BMI	ASA
	Av.: 70,3	*M/F: 71%/29%*	*L/R:43% /57%*	*Av.: 15,4*	*High: 64%*	*A/C:79/21 %*	*Av.: 6,3*	*Yes: 21%*	*Av.: 19,1*	*Av.: 28,6*	*Av.: 2,4*
01	71	Male	Left	13	High	Chronic	9	Yes	18	27,6	2
02	90	Male	Right	13	Low	Acute	8	No	18	25,4	3
03	35	Male	Left	23	High	Chronic	2	No	29	42,2	2
04	69	Female	Right	32	High	Chronic	6	Yes	18	23,7	2
05	63	Male	Left	16	High	Acute	9	No	21	24,8	3
06	71	Male	Left	26	High	Acute	8	No	20	27	3
07	76	Female	Right	18	Low	Acute	9	No	16	25,4	3
08	67	Female	Left	15	Low	Acute	9	Yes	16	28,3	2
09	75	Female	Right	14	Low	Acute	4	No	24	31,4	2
10	76	Male	Left	6	High	Acute	6	No	21	27,3	2
11	82	Male	Right	17	Low	Acute	9	No	16	26,8	2
12	67	Male	Right	8	High	Acute	8	No	16	34,7	2
13	75	Male	Right	15	High	Acute	1	No	16	24,7	2
14	66	Male	Right	0	High	Acute	0	No	18	30,4	3

B) Anamnestic data and injury mechanism

Due to the higher age, our patients had several comorbidities: the most common was hypertension (100%), followed by a 25% presence of type II diabetes, cerebrovascular or peripheral vascular disease, and liver cirrhosis. Diseases were classified by age-corrected values of CCI (mean of 6.3). Patients were mostly ASA grade 2 (mean 2.4) *(Table 8)*.

As discussed above, acetabulum fractures in the elderly were not necessarily the result of low-energy injury: 64% of cases occurred in high-energy trauma.

Based on imaging analysis, we treated almost exclusively complex fractures (a simple fracture in only one case). Due to the high age, the anterior column or wall involvement was 86%. The so-called "Gull-sign" was observed in 64% of patients, with at least 5 mm displacement on the primary CT scans *(Table 9)*.

Table 9. - Primary radiological findings

ID	ANT. COLUMN	ANT. WALL	POST. COLUMN	POST. WALL	TRANSV. PART	TYPE	GULL SIGN	PRIMARY GAP >5mm	PRIMARY DISLOC >2mm
	86%	*57%*	*43%*	*14%*	*21%*	*Assoc.: 93%*	*64%*	*100%*	*7%*
01	Yes	Yes	No	No	No	Associated	No	Yes	No
02	Yes	No	Yes	No	Yes	Associated	Yes	Yes	No
03	Yes	No	Yes	No	Yes	Associated	No	Yes	Yes
04	No	No	No	No	No	Elementary	Yes	Yes	No
05	Yes	Yes	Yes	Yes	No	Associated	Yes	Yes	No
06	Yes	No	Yes	No	Yes	Associated	Yes	Yes	No
07	Yes	Yes	No	No	No	Associated	Yes	Yes	No
08	Yes	Yes	No	No	No	Associated	No	Yes	No
09	Yes	Yes	No	No	No	Associated	Yes	Yes	No
10	Yes	Yes	No	No	No	Associated	No	Yes	No
11	Yes	Yes	No	No	No	Associated	Yes	Yes	No
12	Yes	No	Yes	No	No	Associated	No	Yes	No
13	Yes	Yes	No	No	No	Associated	Yes	Yes	No
14	No	No	Yes	Yes	No	Associated	Yes	Yes	No

C) Surgical results

Our institution set up a workgroup to introduce the new technique, and four doctors performed the surgeries. The mean time of surgery was 138 minutes, and there were two (14%) severe intraoperative complications (significant bleeding).

We scheduled surgeries in a delayed manner due to the preoperative evaluation and preparation. The average number of pre-surgical hospital days was 4.5.

The most frequent shell size was 54mm, with an average of 54 mm (50-56 mm). As we performed only aminimal reaming and then filled the acetabulum with cancellous bone, the shell was positioned further away from the lamina interna. The resulting position of the shell reduced the required length of the artificial femoral neck, so in most cases, a short head was used.

The acetabular plane was defined by the ring's fit, not by the expected plane. Thus, the shell inclination could become too steep, therefore a 10 ° or 20 ° offset liner was used to maintain good position (in 71% of the cases we used 20° liner). Despite the expectation of a too steep cup position, the mean inclination angle was 39 ° (27–51 °) based on X-ray evaluation.

Table 10. - Surgical and nursing outcomes

ID	DELAY (DAYS)	HOSP DAYS	TIME (MIN)	COMPLIC	CUP SIZE (mm)	HEAD SIZE	INLAY (°)	SCREWS Cup-Ring-Plate	INCLINATION / VERSION
	Av.: 4,5	*Av.: 15,4*	*Av.: 138,2*	*Yes :14%*	*Av.: 54*	*Av.: -1*	*10°: 29%; 20°: 71%*	*Av.: 1-3-3*	*Av.: 39°/18°*
01	Secondary	13	155	No	52	-3	20	C0-R3-P4	43°/14°
02	2	13	145	No	56	-5	10	C0-R4-P4	38°/2°
03	Secondary	23	115	No	54	-5	20	C0-R4-P3	47°/22°
04	Secondary	32	160	bleeding	54	0	20	C2-R3-P0	51°/12°
05	3	16	130	No	56	-3	20	C0-R3-P4	29°/-7°
06	4	26	150	No	54	-3	20	C2-R3-P4	44°/24°
07	6	18	150	No	54	0	20	C1-R3-P4	27°/28°
08	6	15	100	No	54	0	20	C1-R3-P3	29°/26°
09	4	14	185	No	56	0	20	C4-R3-P2	°/°
10	1	6	125	bleeding	56	-3	10	C2-R2-P2	41°/6°
11	7	17	125	No	54	3	20	C3-R4-P5	33°/25°
12	3	8	140	No	50	-5	20	C2-R4-P4	52°/31°
13	10	15	115	No	54	3	10	C1-R4-P4	33°/27°
14	3	0	140	No	52	5	10	C2-R4-P3	43°/19°

The 6.5mm cancellous dome screws were used in 10 cases (with an average of 2 screws). An average of 3 angular-stable VX screws were placed in the ring, and an average of 3 screws were used in the U-plate *(Table 10)*.

D) Outcomes of the hospital period after surgery

Following surgery, patients were admitted to the postoperative ward. The average blood loss during surgery was 1136 ml. Excluding the two surgeries with high blood loss (patients 04 and 10), the average blood loss decreased to 825 ml. Acute, displaced acetabulum fractures were also associated with continuous blood loss in the preoperative period. The average decline in Hgb (Haemoglobin) between the time of injury and surgery was 19g/l. Preoperative transfusions were given in three cases, intraoperatively in eight cases, and postoperatively in seven cases, so an average of 3.14 units of packed RBC (Red Blood Cell) was administered per patient during the initial treatment *(Table 11)*.

Depending on the baseline conditions and surgical load, patients were mobilized two days after the surgery with walking aids, and then the treatment continued in a rehabilitation ward. The average number of hospital days was 15.4 (range 6-32). A prosthetic head dislocation was detected in two cases in the perioperative period, both cases were solved by head replacement. In one case, an early infection occurred, the treatment was still ongoing during the writing of dissertation (no implant removal performed).

Table 11. - Blood loss data during the initial treatment

ID	INITIAL HGB (g/l)	PREOP. HGB (g/l)	PREOP. BLOOD Δ	PREOP. BCU.	INTRAOP. BLOOD LOSS	INTRAOP. BCU.	POSTOP. BCU.	SUM OF BCU.
	Av.: 129	*Av.: 121*	*Av.: -19,6*	*Av.: 0,43*	*Av.: 1136*	*Av.: 1,36*	*Av.: 1,36*	*Av.: 3,14*
01	N/A	143	N/A	0	1600	2	0	2
02	110	106	-4	0	1500	2	0	2
03	N/A	187	N/A	0	1000	0	0	0
04	N/A	124	N/A	0	3000	4	6	10
05	136	90	-46	2	400	1	0	3
06	120	120	N/A	0	1000	2	4	6
07	124	105	-19	0	400	2	0	2
08	129	117	-12	0	350	0	0	0
09	123	117	-6	0	800	0	3	3
10	154	154	N/A	0	3000	4	2	6
11	128	87	-41	2	350	0	2	4
12	134	128	-6	0	750	0	0	0
13	100	85	-15	2	350	0	0	2
14	156	129	-27	0	1400	2	2	4

E) Follow-up results

Patients were follow up for assessment at the postoperative 6th and 12th weeks than 6th and 12th months. After that, in the absence of complications, follow-up was performed annually. AP and axial images of the affected hip and AP x-ray images of the pelvis were taken. We evaluated general and wound conditions and functional results. The range of movement, pain, and daily activity were measured based on HHS. During the early follow-up period (within six weeks), the patient was only mobilized with a walking aid, resulting in a low score for early functional outcomes. Therefore, the latest score for that patient was reported in subsequent data.

The median follow-up was 43 weeks. One patient died at the fifth postoperative week, and another patient did not show up for the follow-up (based on a telephone visit, her hip was asymptomatic). In two other patients, follow up studies have not been performed at the close of the dissertation.

To quantify the textual data, the results were divided into categories:

- radiology: visible fracture; blurred fracture; no visible fracture; consolidation;
- ability to walk: not able walk; walking with frame; with crutches; with a cane; normal walking;
- pain: continuous pain, pain on movement; pain on weight-bearing; no pain;

- implant condition: stable; loosening; loosening and breakage; unstable shell.

Table 12. - Patient follow-up data - time achieved in parentheses (weeks)

ID	FOLLOW UP	BONE HEALING	WALKING	PAIN	IMPLANT	LAST HHS
	Av.: 43					*Av.: 83*
01	140	Blur fracture (6)	Normal (48)	No pain (6)	Screw breakage+loosening (14)	91
02	0					
03	87	No fracture line (15)	Stick (31)	Weight bearing (15)	Stable (15)	75,3
04	78	No fracture line (12)	Normal (36)	No pain (41)	Stable (12)	80
05	77	No fracture line (13)	Normal (42)	Weight bearing (42)	Stable (10)	57,5
06	75	No fracture line (12)	Stick (38)	No pain (12)	Screw Loosening (38)	93
07	59	No fracture line (59)	Stick (59)	Weight bearing (59)	Screw Loosening (59)	83,8
08	54	No fracture line (12)	Stick (12)	No pain (33)	Stable (12)	90,8
09	0					
10	25	Consolidate (25)	Normal (11)	Weight bearing (5)	Stable (5)	92
11	9	Blur fracture (9)	Crutches (9)	No pain (9)	Stable (9)	84
12	1	Blur fracture (1)	Crutches (1)	No pain (1)	Stable (1)	
13	0					
14	0					

The different categories received scores starting from 1 in ascending value (1 point - worst possible category, e.g., continuous pain, 4 points - best possible category - no pain). Accordingly, we could recorded the best results in particular patients and the time when the result were achieved. The best results achieved by patients and the time of its achievement are shown in *Table 12*.

2. Results achieved by the equivalent instrument

As already described in Chapter *III.2.B)*, we can compare our method to the “roof reinforcement plate” developed by Herbert Resch. Their most comprehensive results were summarized in 2017 [41].

A) Demographics

Between 2009 and 2014, 30 patients underwent surgery, 25 had primary acetabulum injuries. Our follow-up period was shorter, and our study was limited to one center, so our case numbers were not comparable (14 own patients). They set the lower age limit to 65 years. The mean age of their patients was higher (79.9 years vs. 70.3 years). Their gender distribution were balanced (50% male) compared to our population (70.3% male). There was a significant difference in the mechanism of injury: they treated 86.6% of patients with low-energy injuries in contrast to our patients (36%). The anterior column or wall and T-shaped or transverse pattern affecting the anterior region were also higher among their patients (66.6%). Due to the low-energy injuries, the preoperative Hgb value in their material would be expected to be higher but actually is lower (Resch: 114 g / l, ours: 121 g / l). Their older and higher-risk patients could explain this difference.

B) Surgical and follow-up data

The preoperative hospital days was higher in their report (average 9.4 vs. 4.5 days). Their implant was custom-made, the manufacturing time may increase the preoperative delay. In terms of the average surgery time (Resch: 154.4 minutes, own: 138.2 minutes), their results are slightly longer, but this was probably due to the cement setting time (the acetabular cup must be cemented into the rooftop plate). The mean of intra- and postoperative blood transfusions was almost the same: they used an average of 1.2 units pre / intraoperative, and 1.9 units in the postoperative period, resulting in an average of 3.1 units of packed RBC in their total patient population (our data: 1.36; 1.36, and 3.14 units, respectively).

According to their older age group (mean ASA 3), mortality was higher: one patient died in the perioperative period, and five patients died within the first six months after surgery. Their early rehabilitation plan differed from ours: they started immediate weight-bearing depending on the patient's condition. Among the patients followed for more than six months (24), one became unable to walk (4.2%), 25% walked without aids, 50% with a cane, 4% with a crutches, and 16.8% with a frame. In our material, our patients with similar follow-up time showed a similar distribution: 40% can walk without an aid, 40% with a cane, 20% with crutches. In our material, no inability to walk was observed.

3. Results obtained from FEM analysis

A) Results obtained by comparing the horizontal plating and hybrid method

The greatest strength awakens in the hip joint during normal daily activities when rising from a chair or climbing stairs. We examined the three-axis maximal displacement and von Mises forces in the implant system for both treatment techniques during these two activities. Since conservative therapy was not the object of our dissertation, the mechanical behiavor of the native pelvis is not detailed. However, it is essential that without stabilization, a displacement of more than 1 mm occurs between the fragments, even when standing on two legs. This cyclical displacement does not allow the fracture to heal [67].

a) Comparison of maximum displacement between hybrid method and plate OS

We observed the maximum displacement on the iliac crest: 3.8 and 5.5 mm for the hybrid method and 3.1 and 4.5 mm for the plating (Figure *18.* - [65]).

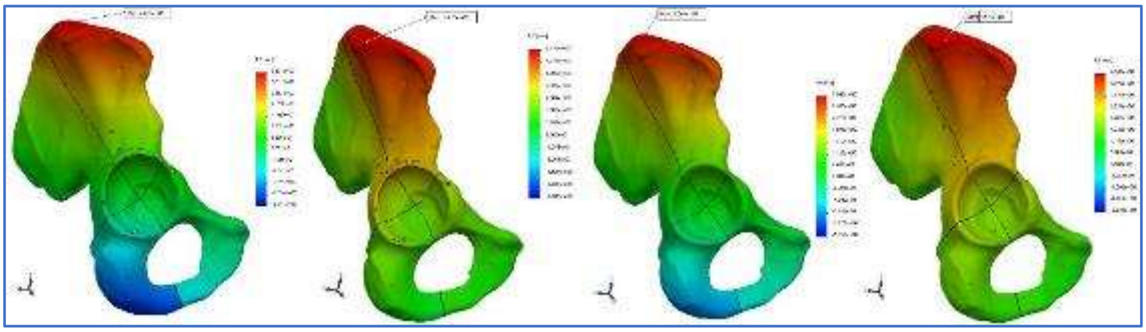

Figure 18.- Displacement under load (hybrid method - plate OS rise, and stair climbing) [65]

In the case of our implant, the maximum displacement at the crest was more significant. A former report has previously demonstrated that eliminating the motion at the crest does not improve stability [63], so this was not considered a mechanical problem. In the substantial part of the fracture, the displacement between the surfaces of the acetabulum fragments was less in the hybrid system: 0.04 versus 0.36 mm in the case of stair climbing and 0.013 mm versus 0.1 mm displacement in the case of rising from a chair. Less displacement provides a better condition for bone healing and integration between the cancellous stock and plasma surface.

b) Maximum von Mises forces for hybrid method and plate fixation

The stress distribution was surprising for the hybrid method: there was a significant difference between the screws in the "U" plate and the ring. The maximal load forces used in the study of bone displacement were modeled. In the hybrid system, stress accumulation was detected on the angular-stable screws placed in the roof-top region of the ring facing the anterior and posterior columns (maximum value 480.8 MPa, which was below the yield point of the screw alloy 880 MPa).

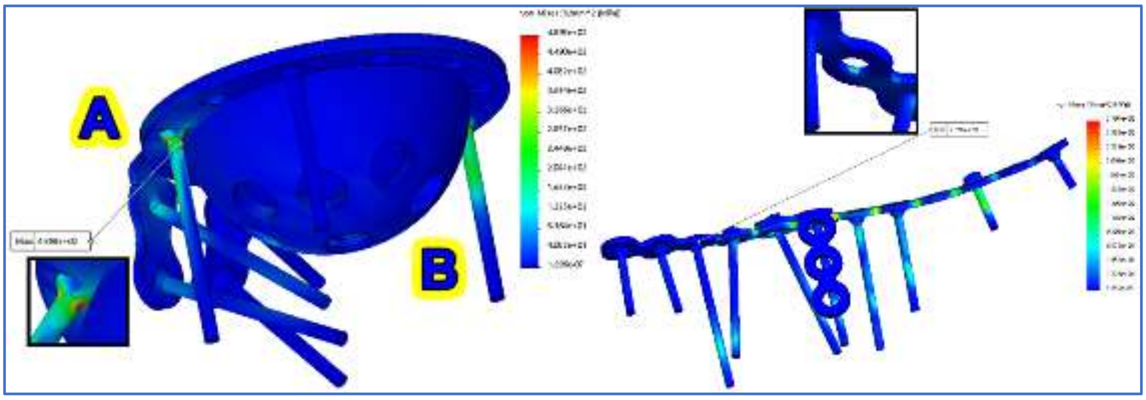

Figure 19.- Von Mises stress forces of the hybrid and plate system during stair climbing [65] [67]

In plate fixation, the average stress was lower, mainly affecting the plate (maximum value 279.1 MPa), which approached the yield point of the plate alloy (345 MPa). The stress distribution is shown in *Figure 19* [67][65]. The most loaded ring screws are marked "A" and "B" as they play a significant role in subsequent optimization.

c) FEM optimization of the hybrid method

Finite element optimization improved stress distribution and reduced maximum von Mises forces. This method can enhance stability without increasing surgical invasion. The ring and shell diameter depended on the size of bony acetabulum, therefore no optimization experiment was performed on them. The diameter of the screws previously marked "A" and "B", and the length and thickness of the plate were increased, and then the tests presented earlier were performed on the modified models.

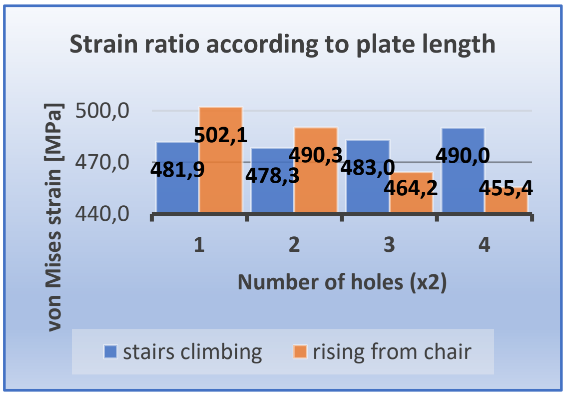

Figure 20. - Stress data for optimized models based on plate grooves number

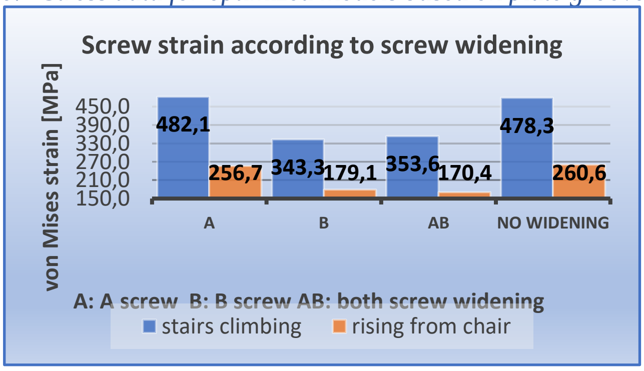

Figure 21. - Stress data for optimized models (based on plate grooves, screw size increase, or full optimized model)

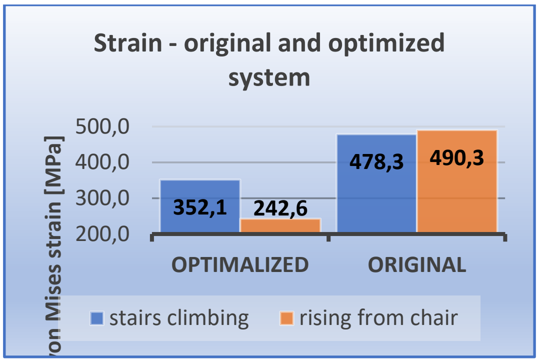

Figure 22. - Stress data for overall optimized models (optimalized: 3 groove holes, A and B screws with increased diamater)

The presentation of the results of all combination series would exceed the scope of the dissertation, so only the data of the combinations proved to be optimal are given. Since increasing the length of the plate would require a larger approach, and more than five plate screws were not used in any case, the length of the plate was also optimized. Better stress distribution was not achieved by increasing the diameter of the screws placed in the plate. We did not get better results by increasing the thickness of the plate either. The stress distribution improved by increasing the core size of screws "A" and "B" to 5.1 mm. *Figures 20, 21, 21* show the data after optimization [65] [67]. To achieve the lowest strain in the "U" plate, we need to use 3x2 screws. The core diameter needed to be increased for the ring screws "A" and "B". By doing so also reduced the stress on the entire system.

V. DISCUSSION

1. Overview of the preoperative period

Our patients with acute, displaced acetabular fractures over 65 years of age underwent surgery on the fifth day after injury (on average). In Hungarian practice, it is not unknown that patients undergo surgery even 6-8 weeks after injury. Based on our results, we disegaree with this. Acetabulum fractures are considered not only a fracture which require fixation but the are also a source of hemorrhage. We checked the initial and preoperative hematology panels. We found a clear correlation between the length of the preoperative period and preoperative blood loss: the blood loss increased in proportion to the number of preoperative days. In the case of an anticoagulated patient, the decrease in Hgb was faster *(Figure 23)*.

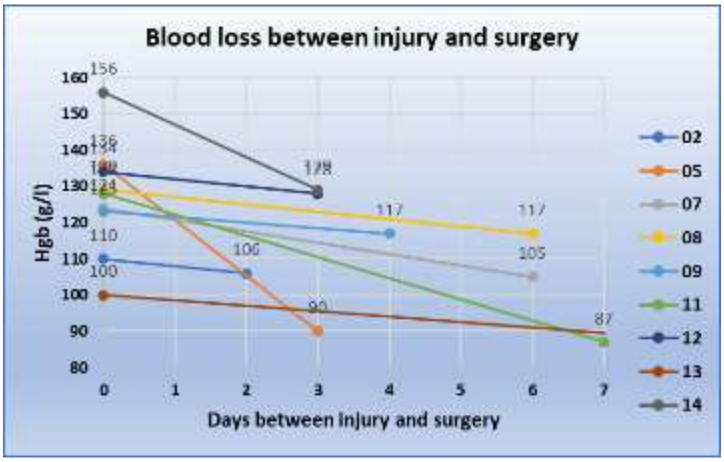

Figure 23.- Relationship between injury and surgery time and preoperative blood loss in acute patients

The rate of high-energy injuries was higher among our patients (64%). Accordingly, a higher rate of posterior region involvement was found compared to the usual anterior wall or column fractures typical to old age. The anterior region involvement did not disappear despite the high number of high-energy injuries. While five (56%) of the nine high-energy injuries had a posterior wall or column involvement, one patient (20%) of the five low-energy injuries had the same involvement. Anterior involvement was observed in 12 cases (86%), 100% in the low-energy group, and 78% in high-energy cases.

2. Overview of surgical method

A) Surgical process, technical difficulties, and possible pitfalls

The placement of retractors is usually a problem during surgery. Fracture of the anterior column usually shows sufficient stability in a supine position, so the anterior retractor insertion is not challenging. However, in the event of a fracture of the posterior column or wall and anterior wall, the anterior and/or posterior portion of the bony ring becomes unstable to make the retractor insertion difficult. In this case, exploration can be done using either a Langenbeck retractor or another tool, but this increases the operating time. In the case of an unstable posterior wall, an additional difficulty may occur. The resistance at the posterior edge of the acetabulum is missing during reaming and cup insertion, resulting in eccentric reaming or cup insertion. If this happens, the shell may displace in retroposition and retroversion. Despite the difficulties, acceptable shell planes were achieved *(Figure 24)*. A 10 or 20 ° insert was used in the case of too steep inclination or insufficient anteversion.

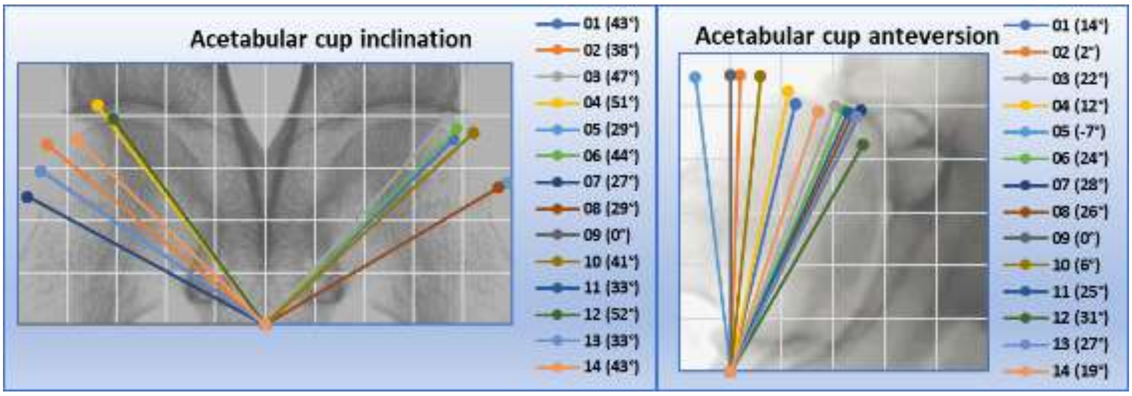

Figure 24. - Acetabular cup inclination and anteversion

In contrast to the standard prosthetic procedure, the cup size is not determined by the bony acetabular diameter but by the size of the ring chosen. The surface of the ring serves as a support, so it is ideal to achieve an extensive buttressing surface with the bony acetabular rim. According to FEM, the screws placed in the ring play an essential role, thus a sufficiently wide cancellous stock is required behind the ring in the projection of both columns.

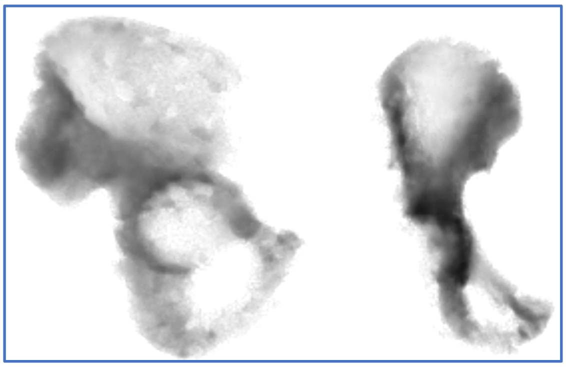

Figure 25. - Average density in ala and obturator views – FCA

The average density of the intact hip based on the superimposed CT scans is shown in *Figure 25*. It can be seen that only the upper part of two columns and the posterior part of ischial bone are suitable for stable screw placement. The upper stem of pubic bone has sufficient density, but according to the ring plane, angular-stable screws cannot be inserted in this direction.

The final macroscopic and radiological images did not differ significantly from the results of the acetabular revision systems *(Figure 26)*:

Figure 26. - Intraoperative and X-ray (AP and axial) images

B) Assessment of surgical risk and complications

As instability made the surgical approach, reaming, and cup positioning complicated, we predicted a longer-than-average surgery. The maximum length of surgery was 160 minutes, so the procedure can be performed within three hours even in difficult cases. It can be performed within a few days after the patient's admission.

Because blood loss is more difficult to tolerate in older age, we investigated a possible correlation between various factors and surgical blood loss. The relationship between coagulation disorders or their pharmacological influence and hemorrhage was not the subject of our dissertation. Surprisingly, no clear correlation was found between body weight and BMI (body mass index) data: higher body weight or body mass index did not indicate a higher intraoperative blood loss *(Figure 27)*. However, as the time of surgery increased, blood loss also increased. Although the significance of the correlation was low, this was due to the low number of cases *(Figure 27)*. It is important to emphasize that oversizing of the cup and the consequent secondary displacement resulted in significant intraoperative blood loss (3000ml in subjects 04 and 10).

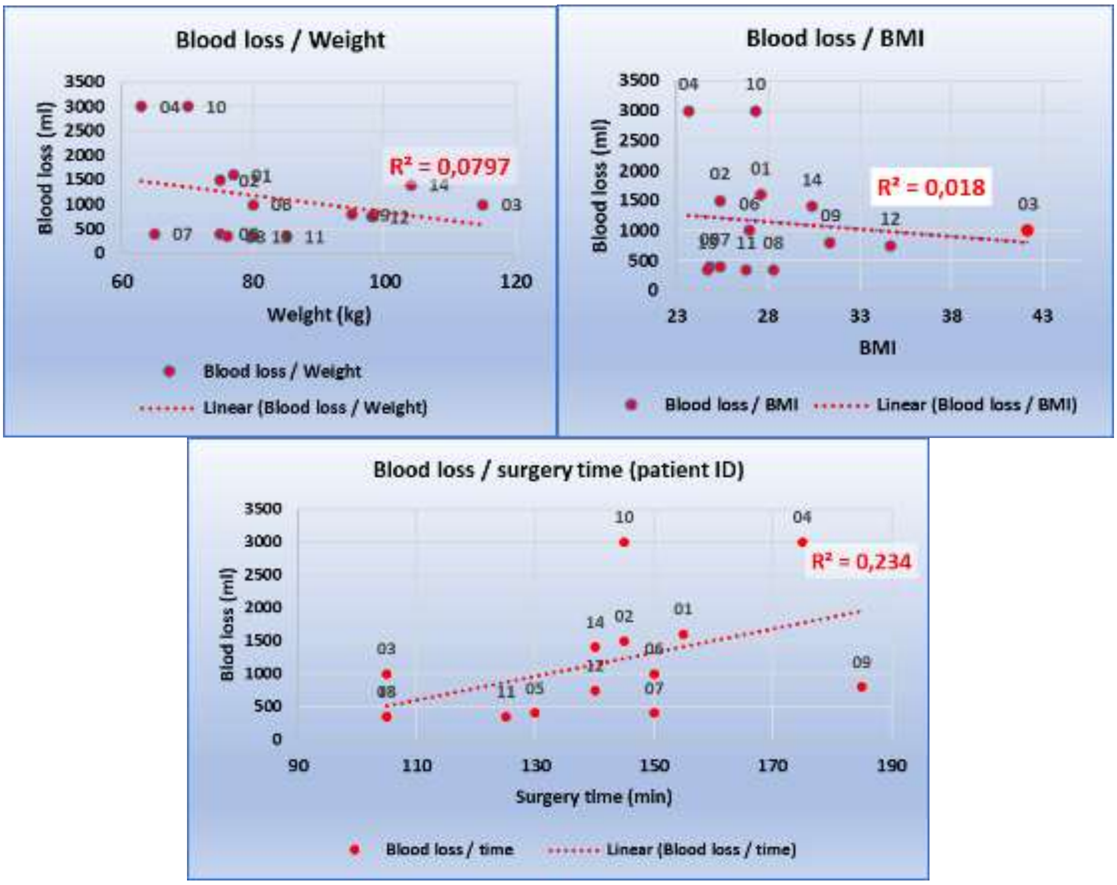

Figure 27. - Relationship between blood loss and body weight, BMI, time of surgery

With a new technique, the initial application is slower and requires practicing. The insertion of a ring- and plate-mounted shell required a more difficult, special maneuver (inserting along the surface of the rear retractor). Preparing the place of the "U" plate was not a problem, but securing it to the already attached ring sometimes required several attempts.

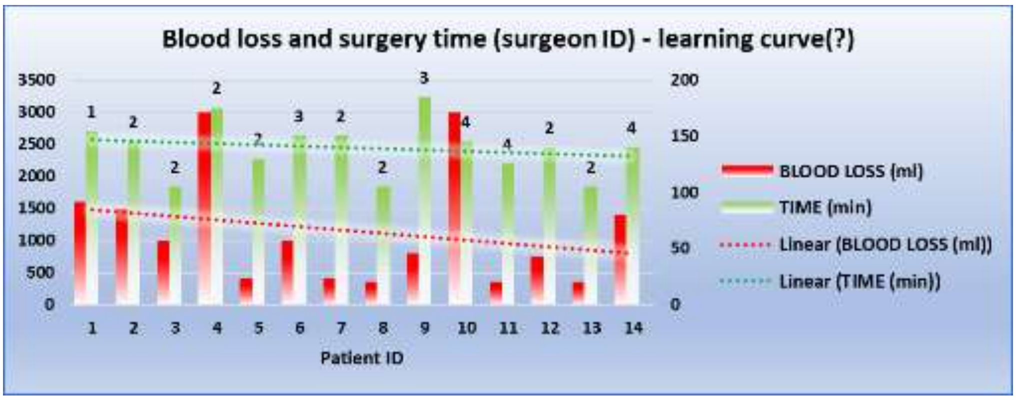

Figure 28. - Learning curve in chronological order in terms of blood loss and surgical time

The operations were performed by four surgeons, with the first assistant coming from other team members in each case. Accordingly, we can assume collective practical development. If the patients are plotted in chronological order, we can see a modest development in terms of surgery time and decreasing blood loss *(Figure 28)*.

C) Options of implant modification based on clinical results

We also wanted to modify the original implant based on FEM, surgical and radiological evaluation. The original plate has 2x4 holes, has no side characteristics, and is symmetrical. Based on surgical experience, the plate required more bending between the ring connection and the first pair of holes for the ideal bone-plate distance. No plate breakage was observed in any cases, but solving the large-scale bending during production would be desirable. Imaging data also confirmed the need for modification.

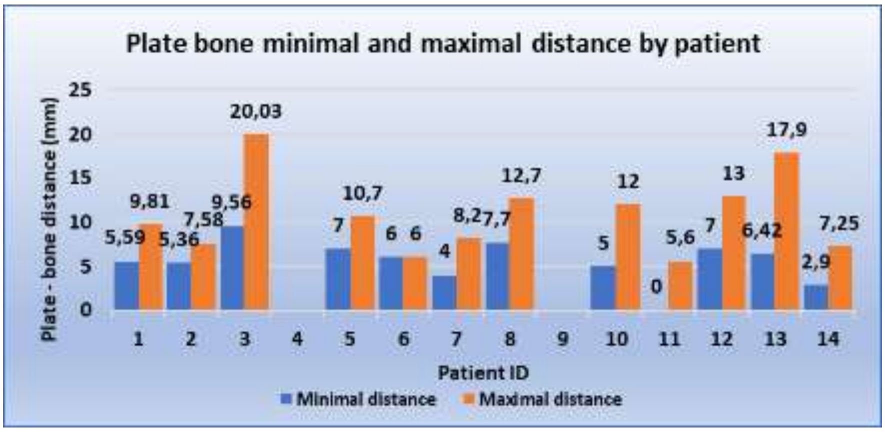

Figure 29.- Minimum and maximum distance between plate and bone per patient

In postoperative CT scans, the minimum and maximum of bone-plate distances at the level of the angular-stable holes were measured in a plane perpendicular to the plate *(Figure 29)*. The result was surprising: the average of the minimum distance is larger than five, the maximum is more than ten millimeters. Therefore, the plate should be bent during manufacturing, not during the surgery. Examination of optimal bending was performed based on CT scans (according to bone and metal Hounsfield values). Images were projected on each other at standard position and magnification, and the metal and bone densities were recolored and then averaged *(Figure 30)*.

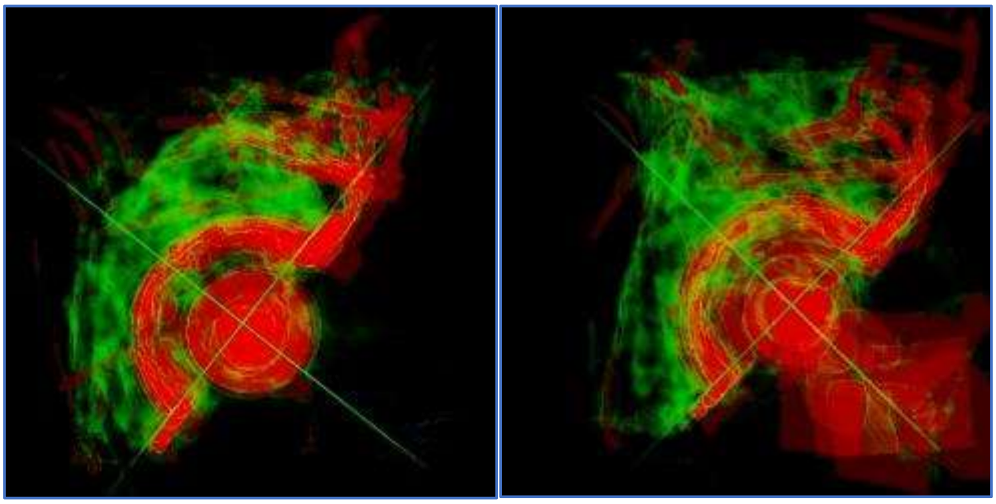

Figure 30.- Average projected density (green - bone, red - metal; anterior fork, dorsal fork)

Based on the averaged images, the shape of the anterior and dorsal forks of the plate should be completely different. The anterior fork should be convex, while the dorsal fork should be concave. According to the anatomy of the pelvis, the anterior fork was placed on the convex surface of the anterior inferior iliac spine, and the posterior fork was in contact with the concave surface of the posterior part of the acetabulum. However, different plates need to be produced for the left and right sides. Considering the previous FEM optimization (increasing the size of the ring screw), the following shape modifications are planned *(Figure 31)*:

Figure 31. - Planned modifications - bending and beveling of the plate, increasing the ring hole - FCA

3. Follow-up overview

The results of postoperative follow-up have been reported previously (*chapter IV.1*). Although our patient numbers were still low, we have achieved good results in walking and function compared to the results of Herbert Resch's team. Follow up CT scans were performed in the patient population followed for at least half a year. A ring screw breakage was observed in one case, and screw loosening in two cases. The complications of the screws did not affect the stability of the acetabular cup in any case. No signs of loosening were observed around the acetabular cup with x-ray or CT scans (Example - *Figure 32*).

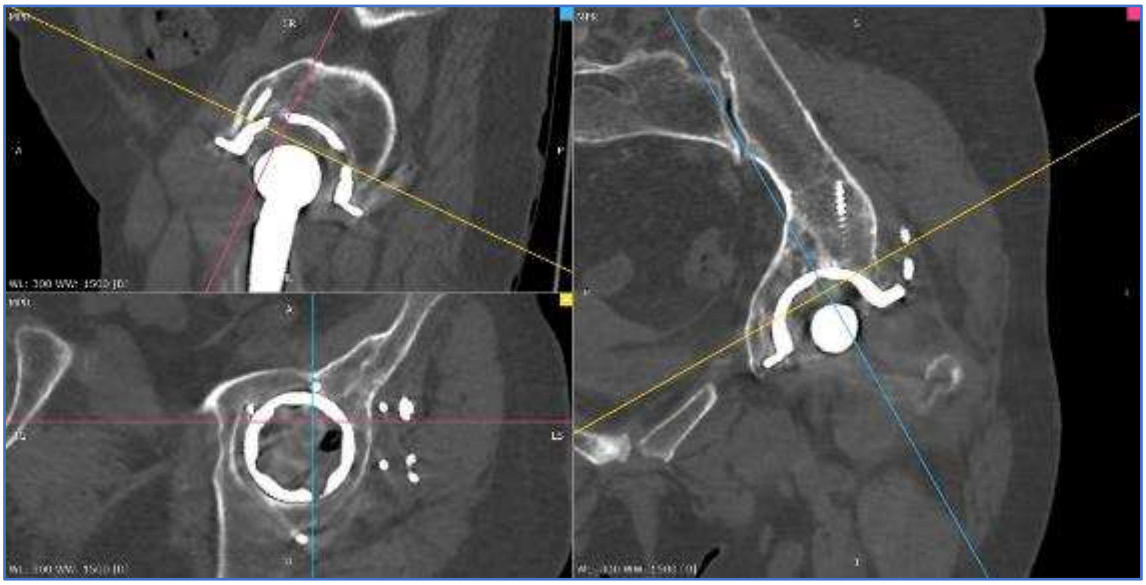

Figure 32. - Example of a remodeling CT image (ID 08 – postoperative 6th month follow up)

VI. CONCLUSIONS

The literature review clarified that plate fixation may also have sufficient stability in elderly acetabulum fractures, but 15-40% of patients developed AVN or arthrosis due to the joint involvement. In addition, symptomatic heterotopic ossification was more than 20%, therefore osteosynthesis was inappropriate in treating unstable acetabulum fractures with significant displacement in the elderly. According to the literature, degenerative joint complications are sure to occur in the case of significant "gull-sign". In most cases, that specific form of injury was identified. Accordingly, the bone fixation method was not suitable for managing unstable acetabulum fracture with displacement, joint replacement was also required.

Primary prosthetic procedures, are not eligible for the treatment of unstable acetabulum fractures. Due to the instability, the press-fit method cannot be used, and "overstuffing" of the unstable fracture carries a significant risk of intraoperative hemorrhage. Thus, the joint replacement must be supplemented with bone fixation. The screws placed in the ring and U-plate act as internal fixation, providing primary stability and promoting bone healing. In the postoperative period, secondary stability is achieved due to fracture healing and the incorporation of cancellous stock.

For the hybrid procedure, a combined device was developed according to the capabilities of on-market implants. We achieved good results during the application.

The preoperative period was also examined, and we recommend the earliest possible surgical care due to the continuous blood loss. There were no significant issues with the application. With a proper technique, uncontrollable blood loss did not occur. In case of anterior or posterior wall instability, we needed to be prepared for difficulties in surgical approach and positioning of the cup which resulted in a longer time of the surgical process.

The initial weight bearing should be adjusted to the patient's condition in the postoperative period. Our patients were usually admitted to a rehabilitation ward after a maximum of two weeks of hospitalization. Our long-term follow-up ended with good results: all the patients followed for more than six months were able to walk, most of them without aids, and a smaller proportion with a cane. Pain occurred in a few patients, but only during prolonged exercise without aids. The final HHS score for our patients was above 80 points in all cases, with an average of 90 points. It is an excellent outcome according HHS classification.

Comparing the efficacy of our system with an equivalent device (roof reinforcement plate), we can report good results. The time of surgery and blood loss comparing to the international data were almost the same *(Table 13)*. Their older and higher risk patient population can explain their higher mortality rates. Although the surgery was performed with a longer delay, this was probably because their implant was "custom-made", which required a longer manufacturing process. The polyethylene insert was glued to the customized shell. The loosening caused by the tension arising on the contact surfaces with different mechanical characteristics is now evident. We consider our system's cementless, metallic securing feature to be beneficial. Custom designing and manufacturing are time-consuming and expensive processes. If the production could be arranged at the location of care, it would not be a reason for further delay of the operation anymore.

Table 13. - Patient follow-up data - time achieved in parentheses (weeks)

	Hybrid system	**„Roof reinforcement plate"**
Recruitment period	2018-2021	2009-2014
Case number	14 (10 male / 4 female)	30 (15 male / 15 female)
Patient age (min – max) (years)	70 (35-90)	79.9 (65-92)
Surgery time / average packed red cell units	138.2 min / 3.14 units	154.4 min / 3.1 units
Postoperative death	1 (7.1%)	6 (20%)
Walking	40% free – 40% cane – 20% crutches	25% free – 50% cane – 4.16% crutches – 16.7% frame – 4.16% wheelchair

FEM evaluation showed higher stability of the system we developed. No acetabular loosening was observed during the follow-up, and CT scans showed the integration between the bony surface, implanted cancellous stock, and plasma surface. The implant provided sufficient primary stability to develop secondary stability and bone healing. Further modifications based on FEM optimization, surgical procedure, and radiological outcomes will improve system stability, therefore this was recommended to the manufacturer.

VII. SUMMARY

Based on a literature review, we have developed a new implant system to treat unstable, displaced acetabulum fractures in the elderly.

Prior to clinical use, the system was subjected to FEM analyses. The simulation tests have shown a clear advantage of our system over the previously used purely bone fixation procedures.

Since 2018, we operated on 14 patients with this system. Eleven of the patients had an acute fracture, and three patients underwent surgery for chronic causes (one case due to acetabulum non-union, and two cases due to acetabular loosening and bone loss after THR). One patient died during the follow-up period, and one patient did not show up for follow-up. All of our patients were able to walk, with a minority using a cane. CT scans proved the plasma cup and bone surface integration, and no acetabular loosening occurred.

Although the initially designed system provided sufficient stability, further modifications can improve the primary stability based on FEM analysis, surgical experience, and CT scan analysis.

The weakness of our study was the low number of patients, but we will continue our prospective data collection, and we will modify our treatment strategy consequently.

Based on the theoretical design, FEM analysis, and clinical results, the procedure we have developed can be a possible technique to treat unstable, displaced acetabulum fracture in the elderly, even based on CE (Conformité Européenne) criteria.

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Comparison of different fixation methods of bicolumnar acetabular fractures

Çift kolonlu asetabulum kırıklarının farklı tespit yöntemlerinin karşılaştırılması

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ABSTRACT

Objectives: This study aims to investigate if the stabilization of iliac wing fractures influences the stability of the acetabular osteosynthesis, if surgical fixation is the choice of treatment, and which technique to be used.

Materials and methods: In the study, measurements were performed with an improved finite element model. Tension and displacement values were measured in bicolumnar acetabular fractures in the following cases: combination of cranial and medial plate fixation through the linea terminalis, or combination of cranial plate and quadrilateral surface plates. The iliac wing fracture was either not fixed, or fixed with screws or with a plate.

Results: In cases where osteosynthesis was performed through the linea terminalis, 0.01 mm fracture gap displacement was observed with the use of a combination of cranial and quadrilateral surface plate fixations. In the combination of cranial and medial positioned plates, the displacement in the fracture gap was 0.088 mm. The fixation of the iliac wing fracture did not improve the stability of the osteosynthesis of the linea terminalis. Plate fixation of the iliac wing fracture was more stable than screw fixation alone.

Conclusion: In double column fractures, if the reduction does not require an anterior approach, it is not necessary to fix the iliac wing fracture only to improve the stability of the fixation. If the reduction does require an anterior approach, it is worth fixing the iliac wing fracture with the technically less demanding screw fixation.

Keywords: Acetabular fracture; cranial plate; iliac wing fracture; medial plate; quadrilateral surface plate.

ÖZ

Amaç: Bu çalışmada iliyak kanat kırıklarının stabilizasyonunun asetabüler osteosentezin stabilitesini etkileyip etkilemediği, cerrahi tespitin tercih edilen tedavi olup olmadığı ve kullanılacak tekniğin hangisi olduğu araştırıldı.

Gereç ve yöntemler: Çalışmada ölçümler iyileştirilmiş bir sonlu eleman modeli ile yapıldı. Çift kolonlu asetabulum kırıklarında gerginlik ve displasman değerleri aşağıdaki olgularda ölçüldü: Linea terminalis boyunca kraniyal ve medial plak tespiti kombinasyonu veya kraniyal plak ve dörtgen yüzeyli plak kombinasyonu. İliyak kanat kırığı ya tespit edilmedi ya da vidalarla veya bir plak ile tespit edildi.

Bulgular: Osteosentezin linea terminalis boyunca yapıldığı olgularda kraniyal ve dörtgen yüzeyli plak tespitlerinin kombinasyonunun kullanılması ile 0.01 mm'lik kırık boşluğu displasmanı gözlemlendi. Kraniyal ve medial konumlu plakların kombinasyonunda kırık boşluğundaki displasman 0.088 mm idi. İliyak kanat kırığının tespiti linea terminalisin osteosentezinin stabilitesini iyileştirmedi. İliyak kanat kırığının plak tespiti sadece vida tespitinden daha stabil idi.

Sonuç: Çift kolonlu kırıklarda eğer redüksiyon anterior yaklaşım gerektirmiyorsa iliyak kanat kırığını sadece tespitin stabilitesini iyileştirmek için tespit etmek gerekli değildir. Eğer redüksiyon anterior yaklaşım gerektiriyorsa iliyak kanat kırığını teknik olarak daha az zorlayıcı olan vida tespiti ile tespit etmeye değerdir.

Anahtar sözcükler: Asetabulum kırığı; kraniyal plak; iliyak kanat kırığı, medial plak, dörtgen yüzeyli plak.

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Isolated iliac wing fractures usually do not influence the stability of the pelvic ring and typically do not require osteosynthesis; therefore, nonoperative treatment is generally the choice of therapy. Exceptions include open fractures, widely displaced fractures, long-lasting persistent pain (3-4 weeks), or increasing secondary displacement.[1] The case is different if the iliac wing fracture is an associated injury of an acetabulum fracture or if the fracture line crosses the linea terminalis influencing the stability of the pelvis ring. In fractures of the anterior column or in bicolumnar fractures, we often see the fracture line "running" to and through the iliac wing. If we chose to use the Judet-Letournel approach to operate on these fractures, the iliac wing can usually be exposed through an anterior window. If a Stoppa or pararectus approach is used for the intrapelvic surgery,[2-3] the exposure to the anterior window is performed only in cases when the acetabulum fracture requires reduction, i.e. reducing the displaced iliac wing fracture aids us in the reduction of the acetabulum.

In these cases, we have a possibility of fixing the iliac wing component. For the fixation of the iliac wing fracture, two different techniques exist: plate or screw fixation.[1]

Concerning the osteosynthesis of the bicolumnar fracture, a question arises regarding which fixation provides greater stability of the fracture: the combination of cranial and medial plate to the linea terminalis, or the combination of cranial and quadrilateral surface plates? The second question is whether to additionally perform fixation of the iliac wing or not, and which technique should we use?

To answer these questions, it helps to know whether the surgical fixation of the iliac wing will influence the stability of the osteosynthesis of the acetabulum fracture.[4] Therefore, in this study, we aimed to investigate if the stabilization of iliac wing fractures influences the stability of the acetabular osteosynthesis, if surgical fixation is the choice of treatment, and which technique to be used.

MATERIALS AND METHODS

The numeric simulation was performed in 2016, in the Institute of Machine Design, Faculty of Mechanical Engineering, University of Technology and Economics, Budapest. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Anatomic model: we used the previous, realistic-geometry pelvis model from our earlier experiments for this study.[5] We simulated a bicolumnar acetabulum fracture with one of the following fixation methods: combination of cranial and medial plate fixation through the linea terminalis, or combination of cranial and quadrilateral surface plates. The fracture running through the iliac wing was either not fixed, fixed with screws only, or fixed with a plate.

Geometric model: In the realistic geometric model, we modeled node-to node contact in the hip joint and at the fracture site, whereas a bonded contact was modeled in all other intact joints (symphysis and sacroiliac joints).

Material model: we used a linear elastic material model; the material properties can be seen in Table I.[5] The used material properties are the elastic modulus and the Poisson's ratio. These material properties are dedicated for the description of the deformity of elastic, rigid bodies under pressure. We removed the cancellous bone elements of so-called hollow bone model, since our previous experiments have demonstrated that the cancellous bone layer does not significantly partake in the loading; therefore, it can be neglected without causing misinterpretation of the results.[6] For this reason, we only modelled the cortical layer, thus the table only contains those material properties. It can be seen that the elastic modulus of the ligaments is about five times greater than that of the joints, thus demonstrating their

TABLE I

Material properties in model

	Elastic modulus (MPa)	Poisson ratio (-)	Rated maximal tension (MPa)
Corticalis	17 000	0.3	70
Ligament	355	0.2	-
Symphysis	50	0.2	-
Sacroiliac joint	68	0.2	-
American Iron and Steel Institute 316L	200 000	0.265	500
Contact material	100	0.4	-

importance in their attachment to the bone; hence, the disregard of this is unacceptable. Among the joints, the symphysis is less stiff. Although the degree of this is not too significant, we nonetheless took it into consideration since it did not affect the measuring time, yet gave more accurate results. We simulated a catalogue indexed American Iron and Steel Institute 316L stainless steel type implant in our experiments. The validation of the model was performed on cadaver experiments, as mentioned in our previous publication,[7] that is, we modeled Denis type I sacrum fracture and symphysiolysis; the symphysiolysis was fixed with a four-hole plate and the sacrum fracture was fixed with either a transsacral plate or direct plate synthesis.

Load and rim parameters

Case 1- Bicolumnar acetabular fracture, weight bearing on both lower extremities: load on the promontorium, in the Z-axis, 500 N, both femurs fixed, the pelvis is posteriorly supported against displacement in the Y-axis; node-to node contact in both hip joints and at the fracture site; bonded contact in other joints; neighboring the acetabulum-cranial and medial plate fixations through the linea terminalis; no fixation of the iliac wing fracture.

Case 2- Bicolumnar acetabular fracture, weight bearing on both lower extremities: load on the promontorium, in the Z-axis, 500 N, both femurs fixed, the pelvis is posteriorly supported against displacement in the Y-axis; node-to node contact in both hip joints and at the fracture site; bonded contact in other joints; neighboring the acetabulum-cranial plate and quadrilateral surface plate fixation through the linea terminalis; no fixation of the iliac wing fracture.

Case 3- Bicolumnar acetabular fracture, weight bearing on both lower extremities: load on the promontorium, in the Z-axis, 500 N, both femurs fixed, the pelvis is posteriorly supported against displacement in the Y-axis; node-to node contact in both hip joints and at the fracture site; bonded contact in other joints; neighboring the acetabulum-cranial and medial plate fixations through the linea terminalis; screw fixation of the iliac wing fracture.

Case 4- Bicolumnar acetabular fracture, weight bearing on both lower extremities: load on the promontorium, in the Z-axis, 500 N, both femurs fixed, the pelvis is posteriorly supported against displacement in the Y-axis; node-to node contact in both hip joints and at the fracture site; bonded contact in other joints; neighboring the acetabulum-cranial plate and quadrilateral surface plate fixation through the linea terminalis; screw fixation of the iliac wing fracture.

Case 5- Bicolumnar acetabular fracture, weight bearing on both lower extremities: load on the promontorium, in the Z-axis, 500 N, both femurs fixed, the pelvis is posteriorly supported against displacement in the Y-axis; node-to node contact in both hip joints and at the fracture site; bonded contact in other joints; neighboring the acetabulum-cranial and medial plate fixations through the linea terminalis; plate fixation of the iliac wing fracture.

Case 6- Bicolumnar acetabular fracture, weight bearing on both lower extremities: load on the promontorium, in the Z-axis, 500 N, both femurs fixed, the pelvis is posteriorly supported against displacement in the Y-axis; node-to node contact in both hip joints

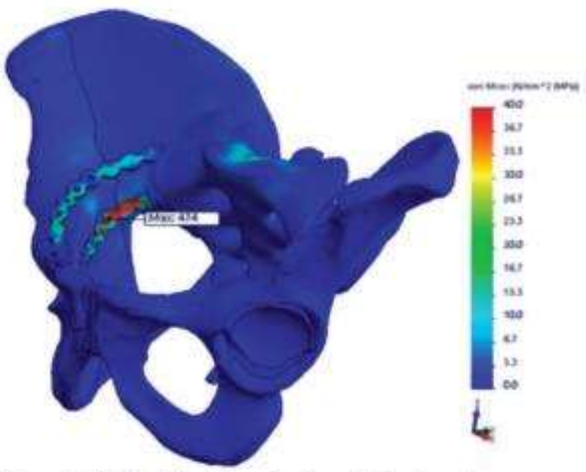

Figure 1. Distribution of tension in model in Case 1.

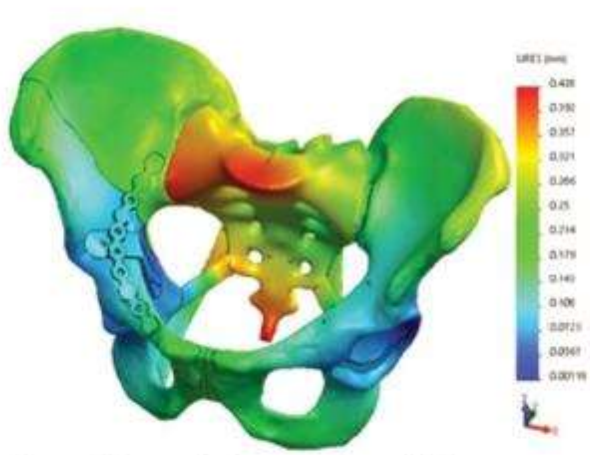

Figure 2. Movement in fracture gap in model in Case 2.

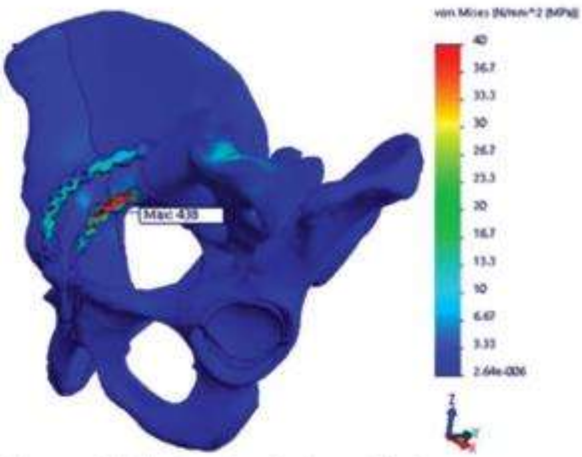

Figure 3. Distribution of tension in model in Case 3.

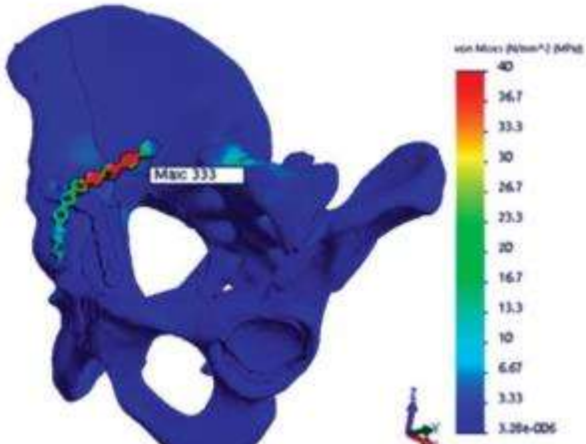

Figure 4. Distribution of tension in model in Case 4.

and at the fracture site; bonded contact in other joints; neighboring the acetabulum-cranial plate and quadrilateral surface plate fixation through the linea terminalis; plate fixation of the iliac wing fracture.

Statistical analysis

SolidWorks 2016 program was used for the finite element analysis. Automatic mesh generation was used for the finite element mesh, except in the sacrum, where 29 Jacob point Tetra elements were used for greater accuracy.

RESULTS

Case 1- Bicolumnar acetabular fracture, cranial and medial plate fixations through the linea terminalis; no fixation of the iliac wing fracture. Maximum tension in the bones was 197 MPa, in the metals was 474 MPa; displacement in the fracture gap of the linea terminalis was 0.088 mm, displacement in the fracture gap of the iliac wing was 0.12 mm (Figure 1-tension).

Case 2- Bicolumnar acetabular fracture, cranial plate and quadrilateral surface plate fixation through the linea terminalis; no fixation of the iliac wing fracture. Maximum tension in the bones was 128 MPa, in the metals was 317 MPa; displacement in the fracture gap of the linea terminalis was 0.01 mm, displacement in the fracture gap of the iliac wing was 0.14 mm (Figure 2-movement).

Case 3- Bicolumnar acetabular fracture, cranial and medial plate fixations through the linea terminalis; screw fixation of the iliac wing fracture. Maximum tension in the bones was 190 MPa, in the metals was 438 MPa; displacement in the fracture gap

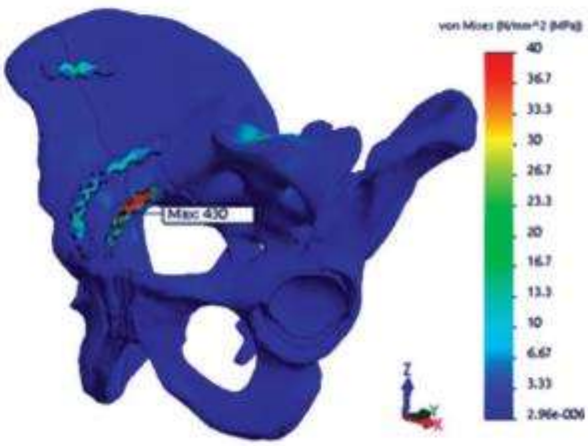

Figure 5. Distribution of tension in model in Case 5.

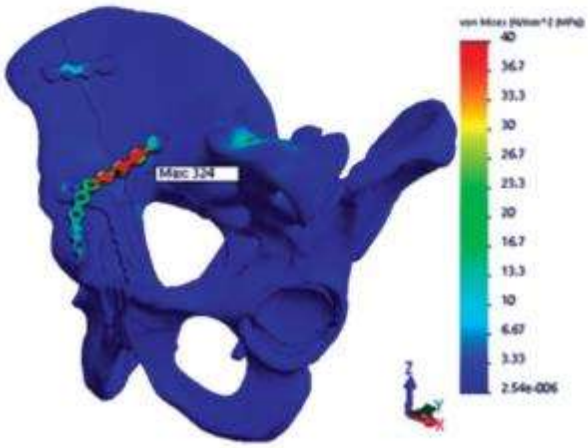

Figure 6. Distribution of tension in model in Case 6.

TABLE II

Maximum tension and displacement values in six models

	Displacement; linea terminalis (mm)	Displacement; iliac wing (mm)	Stress; bone (MPa)	Stress; implant (MPa)
Case 1	0.09	0.12	197	474
Case 2	0.01	0.14	128	317
Case 3	0.09	0.11	190	438
Case 4	0.01	0.12	140	333
Case 5	0.09	0.04	187	430
Case 6	0.01	0.05	116	324

of the linea terminalis was 0.087 mm, displacement in the fracture gap of the iliac wing was 0.11 mm (Figure 3-tension).

Case 4- Bicolumnar acetabular fracture, cranial plate and quadrilateral surface plate fixation through the linea terminalis; screw fixation of the iliac wing fracture. Maximum tension in the bones was 140 MPa, in the metals was 333 MPa; displacement in the fracture gap of the linea terminalis was 0.01 mm, displacement in the fracture gap of the iliac wing was 0.12 mm (Figure 4-tension).

Case 5- Bicolumnar acetabular fracture, cranial and medial plate fixations through the linea terminalis; plate fixation of the iliac wing fracture. Maximum tension in the bones was 187 MPa, in the metals was 430 MPa; displacement in the fracture gap of the linea terminalis was 0.087 mm, displacement in the fracture gap of the iliac wing was 0.04 mm (Figure 5-tension).

Case 6- Bicolumnar acetabular fracture, cranial plate and quadrilateral surface plate fixation through the linea terminalis; plate fixation of the iliac wing fracture. Maximum tension in the bones was 116 MPa, in the metals was 324 MPa; displacement in the fracture gap of the linea terminalis was 0.005 mm, displacement in the fracture gap of the iliac wing was 0.05 mm (Figure 6-tension). The results can be seen in Table II.

DISCUSSION

Indications for the surgical treatment of acetabulum fractures include articular surface incongruence greater than 1 mm, fracture gap displacement greater than 2 mm, or if the "roof arc angle" is less than 45 degrees on at least one of the AP-ala-obturator views on the radiographs. Generally, an anterior approach is used for all acetabular fractures, except in posterior wall, posterior column or certain transverse fractures.

The disadvantages of the Judet-Letournel approach[8] are well-known: it is a rather invasive technique, where the abdominal muscles are detached from the iliac crest and the destruction of the inguinal canal. In addition, the reduction and positioning of the plate can only be performed from a cranial direction. The modified Stoppa approach is less invasive, the quadrilateral surface can be visualized, and reduction can be performed through this exposure. However, positioning of the plate and screws applied on the cranial side is more difficult. The pararectus approach-following mobilization of the external iliac artery and vein-combines the advantages of both the Judet-Letournel and Stoppa approaches.[9] Using this approach, a plate can be positioned either cranially or medially, and in cases of bicolumnar acetabulum fractures, a quadrilateral surface plate can also be used instead of a medial plate.

The question arises which fixation allows for greater stability: the combined use of cranial and medial plate or cranial and quadrilateral surface plate? Additionally, should we perform fixation of the iliac wing if the bicolumnar acetabular fracture line reaches it and if so, should we choose plate or screw fixation?

We tried to answer these questions in our study using pelvis finite element model experiments.[10] In our current study, we used the same plastic pelvis model, which we had used in our previous research. Computed tomography images were used to model the different thicknesses of the cortical layers of the bone, but we neglected the role of the cancellous layer, as other authors have also done.[11] We modelled the symphysis and sacroiliac joints to be less stiff. We modelled a bicolumnar fracture of the acetabulum. Either cranial and medial plate fixation through the linea terminalis or cranial plate and quadrilateral surface plate was used for osteosynthesis of the fracture. The fracture running through the iliac wing was not fixed in the first two cases and was fixed with screw or plate fixation in the further cases. The bonded connection between the plate and screws corresponds to the plate-screw contact in locked plate fixation. As in our previous studies, we modelled smooth, frictionless fracture surfaces. The measurements were performed with the model standing upright on both lower limbs.

In conclusion, the cranial and quadrilateral surface plate combination offered a relatively more stable fixation than cranial and medial plate combination, with or without the fixation of the iliac wing fracture; however, the differences in the displacement values were not significant. The fixation of the iliac wing fracture did not significantly improve the stability of the osteosynthesis through the linea terminalis. Less displacement was observed in the iliac wing fracture when plate fixation was used compared to screw fixation. Based on the tension values measured in the bones and metals, the stability of the fixation was adequate, and implant failure or loosening is not anticipated. Based on the results, in bicolumnar acetabular fractures, if the reduction does not require an anterior approach, it is not necessary to fix the iliac wing fracture only to improve the stability of the fixation. If the reduction does require an anterior approach, it is worth fixing the iliac wing fracture with the technically less demanding screw fixation.

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Hybrid solution combining osteosynthesis and endoprosthesis for double column acetabular fractures in the elderly provide more stability with finite element model

Yaşlılarda çift kolon asetabuler kırıklar için osteosentez ve endoprotez hibrid kombinasyonu "finite element" yöntemi ile daha çok stabilite sağlar

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ABSTRACT

Objectives: This study aims to compare mechanical stability of osteosynthesis (plate and screw fixation) alone versus the same method supplemented with hip arthroplasty (hybrid solution) for double column fractures in elderly.

Patients and methods: Mechanical investigations were performed on an advanced finite element pelvis model developed for double column fractures. The following simulated implant combinations were analyzed: modular acetabular basket with a ring with polyaxial screws and U-plate; plates with polyaxial screws placed on the medial-horizontal (linea terminalis) and quadrilateral bone surfaces; modular acetabular cup with U-plates; and polyaxial screws in sizes optimized based on a finite element model (FEM). Using the models, the possible shifts in peak load positions arising in different movement patterns caused by load and tension and implant deformation were measured.

Results: Hybrid systems resulted in minimal deformation of the implants already available on the market. We observed less possible shifts and greater stability in the acetabular fracture zones, compared to conventional osteosynthesis alone. Optimization with available and compatible implant sizes led to a further significant increase in stability.

Conclusion: Hybrid method combining osteosynthesis and prosthesis implantation provide more stability in biomechanical models in the treatment of double column fractures in elderly.

Keywords: Acetabular fracture, acetabulum, finite element model, pelvic trauma, plate osteosynthesis, total hip replacement.

ÖZ

Amaç: Bu çalışmada yaşlılarda çift kolon kırıklarında osteosenteze (plak ve vida tespiti) kıyasla kalça artroplastisi ile desteklenen aynı yöntemin (hibrid çözüm) mekanik stabilitesi karşılaştırıldı.

Hastalar ve yöntemler: Çift kolon kırıkları için geliştirilen ileri sonlu eleman pelvis modelinde mekanik araştırmalar yapıldı. İncelenen simüle edilen implant kombinasyonları şunlardı: poliaksiyel vidalı ve U plaklı, halkalı, modüler asetabüler sepet; medial horizontal (linea terminalis) ve kuadrilateral kemik yüzeylerine yerleştirilen poliaksiyel vidalı plaklar; U plaklı, modüler asetabüler kap ve çeşitli ebatlarda sonlu eleman modeline (FEM) göre optimize edilen poliaksiyel vidalar. Bu modellerde yük, gerilim ve implant deformasyonuna bağlı farklı hareket paternlerinden doğan pik yük pozisyonlarındaki muhtemel kaymalar ölçüldü.

Bulgular: Hibrid sistemler, piyasada bulunan implantlarda minimum deformasyona neden oldu. Tek başına konvansiyonel osteosenteze kıyasla, asetabüler kırık bölgelerinde daha az muhtemel kayma ve daha yüksek stabilite gözlendi. Mevcut ve uygun implant ebatlarına göre optimizasyon yapıldığında, stabilitede anlamlı düzeyde ilave bir artış izlendi.

Sonuç: Yaşlılarda çift kolon kırıklarının tedavisinde biyomekanik modellerde osteosentez ve protez implantasyonunu içeren hibrid yöntem daha fazla stabilite sağlamaktadır.

Anahtar sözcükler: Asetabüler kırık, asetabulum, sonlu eleman modeli, pelvik travma, plak osteostentezi, total kalça replasmanı.

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The annual increase of the incidence of acetabular fractures still follows a bimodal pattern. The first spike is represented by pelvic and acetabular fractures in young individuals caused by high-energy impacts, and the second by injuries of the elderly combined with pelvic fractures due to low-energy traumas (>65 years, household accidents).

Both surgical and conservative treatment of pelvic fractures in elderly is a significant challenge for the surgeon due to existing osteoporosis and comorbidities.[1] Osteoporosis (i.e., decreased mineral substance of the bone) developing in elderly has a distinct impact both on the primary and long-term stability of the osteosynthesis.[1]

The positioning and stability of any type of implants in the osteoporotic bone is questionable and their long-term anchorage strength is clearly lower, compared to that of the average age population with appropriate bone density.[2] Conservative therapy may fail due to pneumonia, thromboembolism, and mental disorders with frequent occurrence.

In addition to difficulties with reduction and achieving appropriate stability, treatment of acetabular fractures in elderly produce early post-traumatic femoral head necrosis and osteoarthritis of the hip joint, resulting in a considerably compromised walking pattern, and weight-bearing and walking ability. These complications have a significant impact on the short-term results of the osteosynthesis alone procedures.[3-4]

There are antecedent references in the international literature for the so called hybrid procedures (i.e., osteosynthesis combined with joint replacement in a single session). Resch et al.[5] developed a special kind of hybrid intervention taking into consideration the circumstances mentioned above: acetabular fractures in the osteoporotic bones treated in a single session with the so called roof reinforcement plate, applying osteosynthesis and prosthesis implantation in the same session. The main principle of the method is that a custom-made plate is designed and produced based on the computed tomography (CT) scan of the injured acetabulum and the cup is cemented into this plate. The results are improved, compared to osteosynthesis alone. In a case study of 30 patients, 70% of them were able to be mobilized immediately, half of the patients regained their former walking ability very soon and, despite a burdening surgical intervention, the ratio of general surgical complications was not higher than that of patients of similar age treated by osteosynthesis alone.[5]

In the light of literature data, in the present study, we aimed to compare mechanical stability of osteosynthesis (i.e., plate and screw fixation) alone versus the same method supplemented with hip arthroplasty (i.e., hybrid solution) for double column fractures in elderly and to theoretically determine the ideal position and size of the implants.

PATIENTS AND METHODS

The exposition of theory and practice of finite element modelling (FEM) of biomechanical systems is beyond the limits of our publication, thus we delineate its development only schematically.

It is obvious that the accuracy of computed measurements is significantly influenced by the capacity of the system, which is limited also in the 21st century. The main point is to rigorously consider the biomechanical incidences and the constant values observed in real-life setting, as well.

After planning the model, rasterization (i.e., increase of the resolution) is required until the point, after which increase of resolution does not produce any considerable improvement in the results. For the development of a model representing -or at least being similar to- the real biomechanical situation, appropriate and empirically defined material constants are required.

There are no calculation difficulties in cases of implants produced according to licensed manufacturing standards, as the International Organization for Standardization (ISO) standards of the design of the implants and pureness of alloys and basic materials provide a homogenous, exactly definable and traceable static value.

Biological systems pose a harder problem in case of FEM analysis. In the pelvis, the osseous frame (os coxae, i.e. os ilei, ischii, and pubis) and the ligament structures are non-homogeneous systems with several solid-state physics constants, requiring complex calculations or averaging.

However, according to our former calculations and measurements, the system may be properly simplified: the cancellous bone mass with lower stress resistance cannot be considered negligible, compared to the predominant cortical bone substance; however, it may be averaged, and the ligament system not providing any physical stress transmission due to the injury can be neglected.[6] Accordingly, solid-state physics constants applied in our measurements are represented (Table I).

For the simulation, an actual pathological simulation model is required. In our study, we applied

TABLE I
Physical constants of used materials

Part	Elastic modulus [MPa]	Poisson ratio	Yield stress [MPa]
Cortical bone	17	0.3	
Cancellous bone	0.15	0.2	
Acetabular cup (Ti6Al4V)	113.8	0.342	880
Acetabular inlay (UHMWPE)	0.689	0.46	24.1
Acetabular ring (CP titanium grade 2)	103.4	0.33	345
V-shaped plate (CP titanium grade 2)	103.4	0.33	345
Plate fixing screw (Ti6Al4V)	113.8	0.342	880
Angular-stable screw (Ti6Al4V)	113.8	0.342	880

MPa: Megapascal

a model of a double column fracture combined with a transversal component, as this represents one of the most unstable fracture configurations. The fracture planes were designed to cross each other at the load transmission point of the acetabulum (Figure 1).

Imaging of the interaction between the fracture planes rendered calculation more difficult. The friction between the fracture planes was calculated with coefficients applied for rough surfaces.

Our model was boundary; fixation surfaces were modelled according to the following: in regard to the fact that we were unable to analyze sacrum fractures or iliosacral lysis in our model, we considered these contact surfaces as an inertia system, thus our model became defined.

Friction constants used for rough surfaces were applied in the fracture gap and calculated with axial fixation in the case of bone-screw connections (considering the computing capacity). Also, the lamellae of the screws were simplified due to computing capacity and rendering times.

We considered screw-plate connections as bounded due to the principles of angular stable screw heads and absolute stability. The uncemented cup-acetabulum connection was a pure non-friction surface transmitting the radial load direction.

After construction of the static model, only testing of mechanical loads occurring during everyday activities is relevant. Due to limited computing capacity, we simulated exclusively movement patterns indispensable for everyday life, but producing high power transmission (i.e., impulse): standing on two feet, standing up from a chair, climbing stairs, and the force impacts exerted on the femoral head and acetabulum.

We retrieved the resulting data and the occurring torque values from the relevant publication.[7]

In the following part, we described the implant models applied in the FEM. We supplemented the modular revision acetabular cup system (Sanatmetal Conetact R) developed by our team with a U-shaped system bridging the fracture line in the cranial direction. The ring is connected to the plasma-coated acetabular cup with a thread, and the U-shaped plate may be fixed to this with separate screws.

Into the empty grooves in the ring and the grooves of the plate, 3.5-mm and 5.1-mm polyaxial screws can be inserted. The plate can be shaped and shortened by grooves (2×4 grooves) without causing damage. The figure depicts the ideal insertion of the implant system (Figure 2). The design similar to the reconstruction plate allows shortening the plate, although screws may not be inserted into all grooves of the ring due to the absence of periacetabular bone substance suitable for screw anchorage.

Of note, both the anterior and posterior columns can be stabilized thanks to the rotation-centric groove of the ring. According to the options listed above

Figure 1. Lateral and internal views of artificial fracture lines.

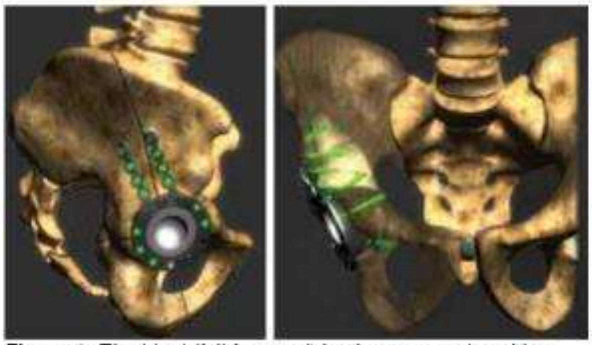

Figure 2. The ideal (full featured) implant use and position.

and the licenses obtained, we also started surgical treatments in addition to biomechanical stability investigations.

The horizontal + quadrilateral surface model using an L-shaped plate (Figure 3) perfectly represents our practical results and, thus, these do not require further explanation.

The results obtained from the biological model were evaluated in the SolidWorks system. We registered predominantly the multidirectional, mostly vertical shifts, tension and deformation arising from the implants in different anatomical regions (i.e., ala, acetabular bottom, anterior column).

Figure 3. An internal view of quadrilateral surface plate.

RESULTS

We analyzed the shifts in a native fracture model (i.e. without implant) mentioned above in the first calculation cycle. For as much as conservative therapy was out of the scope of our investigations, no detail is given here. It is important that shifts close to the acetabulum were larger than 1 mm in the model without implants, which is not compatible either with the biological, or with the mechanical prerequisites of fracture healing.

Osteosynthesis alone (i.e., plate fixation) produced acceptable shift values (considering that we performed a single calculation, not a cyclic one). Another important result is that in the horizontal plate and screws, in cases of minimal shift and any type of load pattern, such a high amount of stress arose which was significantly close to the yield-point of the implant (difference <20%), thus considering the cyclic load and material fatigue, the chance of immediate implant breakage was extremely high. Our self-developed system -even in the case of an idealized model taking into account all fixing options- produced surprising results. The screw fixation of the grooves in the U-shaped plate and in the ring was performed according to the fracture pattern and bone quality.

However, even if we choose the idealized model for the finite element measurements (regardless of surgical exposure and invasiveness), we may draw some essential biomechanical consequences: similarly to the stabilizing pseudopodia or the fixation of a Burch-Schneider basket,[8] the maximal stress was measured in the direction of the screws inserted into the os ischii and ramus ossis pubis (Figure 4).

The screws inserted into the U-shaped plate and the acetabular perimeter zones mentioned above represented only minimal stabilizing factors, despite the fracture gaps running between them. The role of the spherical acetabular cup component

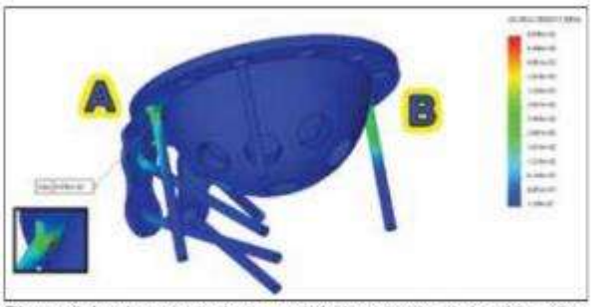

Figure 4. Implant strain during weight-bearing (main load-bearing screws noted with "A" and "B").

(plasma-coated socket) did not take any part in the load bearing, and this was defined as an advantage, namely this was considered the exact main benefit of the hybrid system.

DISCUSSION

Shift tests performed with the system showed more stability around the acetabulum (i.e., less shift between the fragments). However, computed mechanical experiments verified a larger shift in the region of the iliac bone, probably as the acetabulum was the center of the motion. This might be a considerable factor influencing fracture healing, although we proved in our previous experiments that after fixation of the anterior column (our system is suitable also for this thanks to the grooves), the iliac bone did not require any additional fixation.[6]

As a supplement, we provided CT scans taken under load three months after surgery. According to the results of simulation, the screw exposed to the strongest stress broke. We optimized the implants based on the practical results and in accordance with our primary objectives.

The main point of each FEM is optimization. However, in the case of biomechanical implants, we need to take into consideration the compatibility of the already existing implants and their availability on the market, in addition to optimal mechanical manufacturing. If we perform optimizing measurements on such implants, time-consuming licensing procedures can be avoided.

Based on these facts, possible optimization calculations of our hybrid system were determined as follows: Can the length of the U-shaped plate and the number of the 3.5 mm screws be reduced?; Can we increase the size of the screws inserted into the ring; and Does this increase stability? Stability can be increased by the reduction of the length of the plate (decreased invasiveness) and by the increase of the core diameter of the main load bearing screw (Figure 5, 6, and 7).

The stress on the implants is decreased (significantly under the yield-point), the number of required implants is reduced (less invasion and bone loss), and the possible shift is less; therefore, we can achieve higher stability with less invasiveness and bone loss. It is unambiguously proven that the hybrid method of fixation (osteosynthesis + prosthesis) provides fewer shifts (i.e., warrants higher stability) during load patterns, compared to plate osteosynthesis alone.

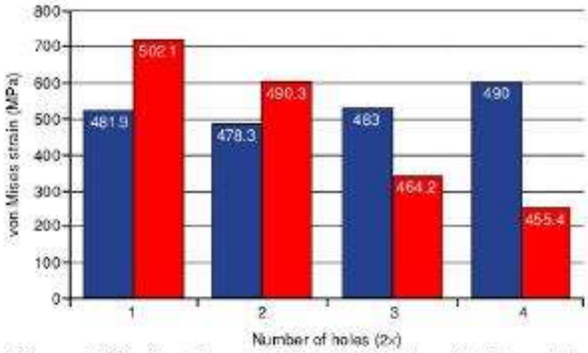

Figure 5. Strain ratio according to plate length (blue: stairs climbing; red: rising from a chair).

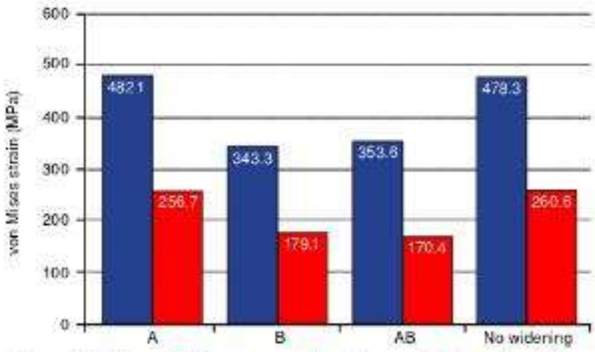

Figure 6. "A" and "B" screw strain during weight-bearing (blue: stair-climbing; red: rising from a chair).

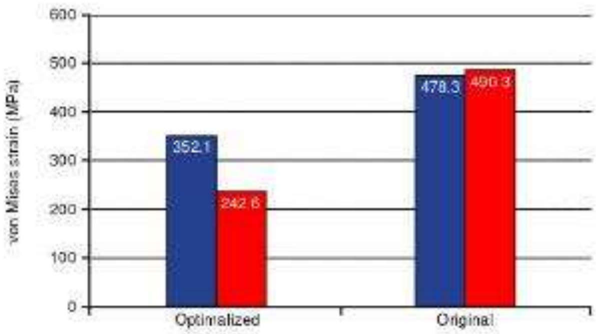

Figure 7. Peak strain comparison between original and optimized implants (blue: stair-climbing; red: rising from a chair).

Our measuring system indicated lower stress and less shifts in the most involved acetabular zone in the hybrid system, compared to those after plate osteosynthesis. The larger shift in the iliac bone had no impact on stability. Furthermore, the optimized implant model did not reach the safety limits of the implanted materials.

In conclusion, based on the results of the biomechanical investigations, hybrid solutions (osteosynthesis + prosthesis) provide higher stability and improved biomechanical results, compared to other surgical procedures for double column fractures in elderly. With regard to the joint replacement, complications such as necrosis of the femoral head and osteoarthritis can be avoided, but cannot be modelled in a FEM.

Declaration of conflicting interests

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