The Biomechanics of Fixation via the Modified Stoppa Approach vs. the Posterior Approach for Management of Acetabular Fractures with ORIF and Acute THA in the Elderly

1. SPECIFIC AIM

This study will compare the biomechanical stability provided by fixation through the Modified Stoppa approach vs. the Posterior approach for transverse acetabular fractures that are managed with ORIF and acute total hip arthroplasty (THA) in the elderly (**Fig.1**). The Modified Stoppa approach permits the insertion of an anterior column plate along the superior surface of the pelvic brim and superior pubic ramus, a medial buttress plate along the quadrilateral plate, and a posterior column lag screw. The "gold standard" Kocher-Langenbeck method, i.e. the "Posterior" approach in this document, commonly uses a posterior column plate plus an anterior column lag screw. Although both methods are used surgically to repair transverse acetabular fractures, biomechanically no researchers have assessed fixation via the Modified Stoppa approach and only a few have evaluated the Posterior approach. Thus, an investigation into this issue is necessary. The applicants hypothesize that fixation through the Modified Stoppa approach will be mechanically superior, which may be especially desirable since it permits better surgical access to central fracture dislocations which are typically seen in the elderly.

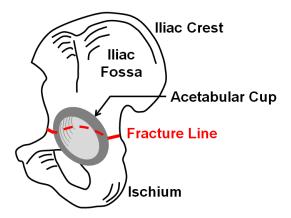


Fig.1. Transverse acetabular fracture through the hemi-pelvis managed with fixation and acute THA. The fracture fixation method is not shown here.

2. BACKGROUND AND SIGNIFICANCE

Transverse and anterior column acetabular fractures are increasing worldwide in patients over 60 years of age, particularly in men who constitute 68% of cases.¹⁻⁵ In 49.8% of cases, this injury occurs from a fall onto the greater trochanter,^{6,7} which leads to displacement of the anterior column, an associated separate fragment of the quadrilateral plate, and anterocentral displacement/dislocation of the femoral head.^{8,9} Of particular interest in the proposed study is the transverse acetabular fracture, which has been classified by the Orthopaedic Trauma Association as type 62-B1.1.¹⁰ It can be surgically approached either anteriorly, posteriorly, or both. The Posterior, i.e. Kocher-Langenbeck, method is used to fix transverse fractures, transverse plus posterior wall fractures, posterior wall fractures, and posterior column fractures while also allowing for simultaneous hip joint replacement.¹¹ The Modified Stoppa approach commonly consists of a vertical midline incision plus a lateral incision on the iliac crest¹²⁻¹⁴ and is being

increasingly used for transverse fractures, anterior wall fractures, anterior column fractures, and anterior plus posterior hemi-transverse fractures. It allows placement of reconstruction plates in different configurations across the fracture line, as well as medial buttressing of the quadrilateral plate directly to the hip joint, which is a major advantage over the Posterior method.¹²⁻¹⁴ Few biomechanical reports exist on fixing transverse acetabular fractures comparing various methods.¹⁵⁻²⁰ Four of these studies concluded that the Posterior approach of a posterior column plate plus an anterior column lag screw provided the best or equivalent fixation,¹⁵⁻¹⁷ but only 1 study used human cadaveric pelvises.¹⁹ Moreover, no biomechanical studies have determined the biomechanical properties of fixation which would be applied via the Modified Stoppa approach and compared it to the Posterior technique. Optimal biomechanical stability of fixation can allow early patient mobility, permit early weightbearing, minimize additional morbidity, and facilitate rehabilitation. Therefore, the clinical significance of this study would be to provide surgeons with the first biomechanical evidence to date about the increasingly used Modified Stoppa approach as a way for repairing transverse acetabular fractures and to compare it directly to the Posterior approach.

3. RESEARCH DESIGN AND METHOD

3.1. General Strategy

This study has 2 stages (**Fig.2**). Stage 1 will be non-destructive stiffness testing of 10 matched pairs of intact human cadaveric hemi-pelvises as a baseline. Stage 2 will be destructive testing of transversely fractured hemi-pelvises that are reduced and repaired with 2 methods, as well as being equipped with an acetabular component. The optimal method will have higher stiffness, higher failure parameters, and lower interfragmentary motion.

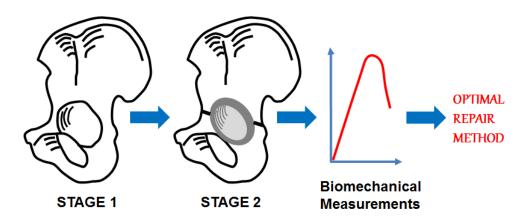


Fig.2. Proposed plan to determine the optimal repair method. Repair method details are not shown. The diagram is not to scale.

3.2. Hemi-Pelvis Preparation

Ten matched pairs of fresh-frozen human cadaveric hemi-pelvises will be obtained upon approval of the applicants' institution. Specimens will have no prior pathology or fracture and will be from males older than 60 years.³ Dual energy x-ray absorptiometry (DEXA) scans will provide BMD and clinical T-scores. For Stage 1, each intact hemi-pelvis will be potted in 2 steel cubes filled with anchoring cement by its iliac tuberosity and auricular surface (i.e. simulating the sacro-iliac joint) and also by its symphyseal surface and part of the pubic rami (i.e. simulating the symphysis pubis). For Stage 2, complete transverse acetabular fractures will be created using an alignment jig and industrial band saw. In left hemi-pelvises, the Modified Stoppa approach will involve a supra-pectineal anterior column plate fixed with 6 cortical screws along the superior surface of the pelvic brim and superior pubic ramus, a medial buttress plate fixed with 4 cortical screws along the quadrilateral plate, and a posterior column lag screw (**Fig.3**). In right hemi-pelvises, the Posterior approach will involve a posterior column plate secured using 6 cortical screws plus an anterior column lag screw (**Fig.3**). After ORIF, each pelvis will undergo insertion of a properly-sized multi-hole acetabular component after reaming, with fixation using 3 cancellous screws and placement of a polyethylene liner.

3.3. Mechanical Testing

Specimens will be mounted using a clamping system to the Instron tester (Model 8874, Instron, Norwood, MA, USA) (Fig.3). Stage 1 will be a non-destructive stiffness test of the intact hemi-pelvis. Stage 2 will be a destructive test of the hemi-pelvis after creating and repairing a transverse acetabular fracture with the acetabular component in place, in order to obtain stiffness, failure force, failure displacement, failure energy, and relative interfragmentary displacement. The force applicator will be a steel acetabular reamer's hemi-spherical end or a steel ball, respectively, pressed into the intact acetabulum or acetabular cup to replicate a THA. The force will be applied at angles of 45 deg superomedially and 15 deg posteriorly in the sagittal plane to simulate femoral neck orientation during standing. The force regime will be a pre-load of 50 N to remove "mechanical slack" followed by 3 cycles of force rampup-rampdown at 10 mm/min up to a subclinical level of 250 N (Stage 1) and then a single continuous force rampup at 10 mm/min until specimen structural collapse (Stage 2). Prior to Stage 2 tests, 4 adhesive colored circular markers will be attached 2 mm apart and 5 mm away from either side of the fracture line along the posterior column. The relative movement of the markers will be recorded using a highresolution digital video camera (Sony Cybershot W Series) with a ruler in the field of view for later analysis using VLC media player 4.2 (VideoLAN, Paris, France).

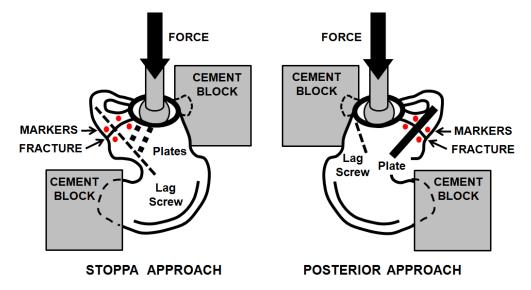


Fig.3. Test setup for experiments on the repaired transverse acetabular fracture. Dashed lines (- - -) indicate hidden structures. The same setup will be used for Stage 1 and 2. The diagram is not to scale.

3.4. Data Analysis

For Stage 1, stiffness (i.e. slope of force-vs-displacement graph) will be double-checked for linearity R^2 to ensure specimens were not damaged and remained within the linear elastic range. For Stage 2, stiffness (i.e. slope of initial linear segment of the force-vs-displacement graph), failure force (i.e. peak force just before failure), failure displacement (i.e. displacement at peak force), failure energy (i.e. area under the curve up to the peak force), and relative interfragmentary motion (i.e. from image analysis at 50 N, 250 N, and failure) will be obtained.

3.5. Statistical Analysis

For each parameter (e.g. stiffness), all data from both Stage 1 and 2 will be combined into a single data array and compared using one-way ANOVA set at p<0.05. If ANOVA yields p<0.05, post hoc pairwise analysis will be done with Tukey's method set at p<0.05 to determine which specific pairwise comparison(s) caused the statistical difference. This permits statistical comparison between stages for each repair method, but also between repair methods for each stage. Pearson linear correlation coefficients (R) for all measured parameters will be computed with respect to BMD, T-score, and age.

3.6. Justification

First, human cadaveric hemi-pelvises will come from male donors over 60 years of age, since this is the predominant population group that incurs transverse acetabular fractures.³

Second, quasi-static loads at rates similar to the current 10 mm/min have been used previously on pelvic fixation, it will minimize time-related viscoelastic effects, and it will yield lower conservative data levels.^{15,16,19,20}

Third, the 250 N sub-clinical force for Stage 1 allows stiffness measurement while avoiding specimen damage, so Stage 2 constructs can be implanted and tested properly. This value was chosen since repaired hemi-pelvises may fail at a force as low as 500 N.¹⁸

Fourth, applied force will be at 45 deg superomedially and 15 deg posteriorly in the sagittal plane. This replicates femoral neck orientation while the patient is standing.^{15,18,20}

Fifth, markers along the fracture line help visualize whether fracture fragments move perpendicular to the fracture line to create a gap, parallel to the fracture line to generate shear, or by angulation to create a wedge shape.¹⁶⁻¹⁸

4. ROLE OF THE RESIDENT

The orthopaedic surgery resident will be involved in all aspects of the study. The resident will be responsible for day-to-day project execution, while supervised by the co-applicants, namely, a senior orthopaedic surgeon and a senior research bioengineer. The resident will secure all materials to give them experience in dealing with industrial suppliers and administrative personnel. The resident will have the human specimens scanned using DEXA to allow them to interact with this technology and hospital radiology staff. The resident will prepare specimens and perform biomechanical tests assisted by a junior research assistant to enhance their grasp of biomechanics. The resident will collect all data and perform all statistical analysis to deepen their knowledge of statistics. The resident will take the lead in writing a journal article to develop their skills in writing, data interpretation, and literature review. The resident will submit the article to a journal for peer-review to give them experience with the publication process.

5. REFERENCES

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Nov 20, 2014

Dear OTA Committee,

Please note that the current submission is a revised version of a study proposal submitted last year in 2013, which was rejected. We felt the proposal was clinically relevant and addressed an important issue faced by surgeons in managing this injury pattern, thus, we are re-submitting a new version of the study plan. Since no feedback about the reason(s) for rejection was received from the OTA committee, we have carefully re-assessed the original submission ourselves and made the following changes.

- 1. Focus on the Elderly. This new proposal intentionally focuses on the elderly, since this is a more clinically-relevant population that experiences this type of injury pattern. Specifically, the title has been amended by the addition of the term "...in the elderly." Also, the opening statement in section 1 now reads "This study will compare the biomechanical stability provided by fixation through the Modified Stoppa approach vs. the Posterior approach for transverse acetabular fractures that are managed with ORIF and acute total hip arthroplasty (THA) in the elderly." Consequently, the choice of hemi-pelvises from donors greater than 60 years of age has been retained in this new proposal.
- 2. Clinically-relevant Test Groups. The original submission proposed three test groups: intact acetabulum (Stage 1), intact acetabulum with a THA acetabular component (Stage 2), and the fractured/repaired acetabulum equipped with a THA acetabular component (Stage 3). Upon reconsideration, we recognized that insertion of a THA acetabular component would actually be part of the operative management of this injury (rather than existing prior to injury). As such, the new proposal now only evaluates the two clinically realistic test groups that would be encountered, namely, the intact acetabulum which represents the pre-injury condition (Stage 1) and the fractured/repaired acetabulum equipped with a THA acetabular component which would be the final post-operative condition (Stage 2). Thus, all instances of the original Stage 2 have been removed both from Figure 2, as well as all text in subsections 3.1 to 3.6.
- **3.** Clinically-relevant Surgical Procedure. As a direct result of point 2 above, we have amended the sequence in which the surgical procedures take place in order to be more clinically realistic. Thus, a new sentence has been added in subsection 3.2 Hemi-Pelvis Preparation: "After ORIF, each pelvis will undergo insertion of a properly sized multi-hole acetabular component after reaming, with fixation using 3 cancellous screws and placement of a polyethylene liner."

We hope the above alterations are satisfactory. Accompanying this cover letter, please find all the other requested documents, including a study plan, study budget, and support letter. Thank you again for your due consideration.

Sincerely,

Applicants

The Biomechanics of Fixation via the Modified Stoppa Approach vs. the Posterior Approach for Management of Acetabular Fractures with ORIF and Acute THA in the Elderly

OTA Resident Research Grant Budget Sheet

Budget cannot exceed \$20,000

Submitting a budget over this amount disqualifies your application for consideration

- <u>Salaries and Wages</u>: Enter name, percentage of time on project and salary requested as well as fringe benefits charged to the grant. Please also state what each person will be doing.
- <u>Permanent Equipment</u>: Justification to be appended.
- <u>Consumable Supplies</u>: Excludes animals and animal care.
- <u>Animals and Animal Care</u>: Justify all requests where need is not apparent.
- <u>All Other Expenses</u>: Charges for overhead are not covered by OTA Grants. No indirect costs will be funded.

SALARIES AND WAGES (List all personnel for whom money is requested)	on this	Requested from OTA Funds
Not applicable since all salaries are already paid	project %	(Omit Cents) n/a
Fringe Benefits% of Salaries and Wages	/0	
Salaries and Wages plus Fringe Benefits	TOTAL	0

PERMANENT EQUIPMENT (Justification to be appended)		
Not applicable since all equipment is already in place		n/a
	Subtotal	0

CONSUMABLE SUPPLIES (Exclude animals and animal care)		
20 Acetabular cups @ \$500 / cup		10,000
30 Plates @ \$200 / plate		6000
10 Human cadaveric pelvises @ \$400 / pelvis		4000
	Subtotal	20,000

ANIMALS AND ANIMAL CARE		
Not applicable since no animals involved		n/a
	Subtotal	0

ALL OTHER EXPENSES		
Not applicable since overhead costs already covered		n/a
	Subtotal	0

TOTAL DIRECT COSTS \$20,000 ***

*** Additional direct costs for 160 screws for plates (@\$25/screw=\$4000), 60 screws for acetabular cups (@\$25/screw=\$1500), 20 lag screws (@\$50/screw=\$1000), 80 markers (@\$5/marker=\$400), 40 steel cubes for cement potting (@\$10/cube=\$400), and 10 buckets of potting cement (@\$20/bucket=\$200) amount to \$7500. This will be covered by a funding source at the applicants' institution. Details of this funding source can be provided upon request.