A Study on Designing, Development and Testing of an Innovative External Jig for the Percutaneous Screw Fixation of the Acetabular Column Fractures

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Abstract

Background: Operative treatment of acetabulum fractures often requires open surgical fixation. Minimally invasive surgery (MIS) with percutaneous screw fixation can be done is some acetabular column fractures which are amenable to closed reduction. This can be done free hand using intraoperative fluoroscopy or with the help of advanced 3D navigation system. Free hand technique exposes the operative staff to considerable intraoperative fluoroscopy,has a steep learning curve and there is a risk of screw malpositioning. Even though 3D navigation is highly accurate, the affordability of the navigation system in a rural set up is not feasible. Use of an external universal modular jig which has been routinely used for the fixation of long bone fracture, can give similar results in the fixation of undisplaced/minimally displaced acetabular column fractures amenable to close reduction. Currently such jigs are not available for the management of acetabular fractures.

Objectives: With this study we aim to design a modular jig for the percutaneous fixation of the acetabular column fracture fixation. Also we will validate in vitro efficacy and safety on cadaveric models. To test the clinical efficacy on minimally displaced acetabular column fractures.

Methodology: It will be an observational study conducted at the Department of Orthopaedics, JNMC, Sawangi and Wardha, India. A 3 D model of the pelvis will be made based on the CT scan data of 40 patients using Mimics 10.01 software (Materialize, Leuven, Belgium) software. After the desired jig is made,its accuracy will be checked on the saw bone and cadaveric model. Once the accuracy of the jig has been established, it will be used on the suitable patient population and the results will be compared with the matched patient population who have been operated using the traditional free hand technique under fluoroscopy control.

Results: The results will be compared based on the operating time,radiation exposure,hospital stay and postoperative outcome. During follow up,patients in both the groups will be evaluated clinically with Harris hip score (HHS) and radiologically with Matta outcome grading. To evaluate functional outcome patients the patients will be categorized into excellent (HHS, 90-100), good (HHS, 80-90), fair (HHS, 70-80) and poor (HHS, <70).

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Conclusion: This study will help in designing and development of an universal external modular jig for the MIS and percutaneous fixation of acetabular column fracture.

Keywords: *Acetabulum column Fracture, Minimally invasive surgery (MIS) Universal external modular Jig, Percutaneous screw Fixation.*

Introduction

Minimally invasive surgery (MIS) for fixation of acetabular fractures is possible with the advances in intraoperative fluoroscopic imaging.[1] Percutaneously inserted screws in medullary pubic ramus, iliac wing and iliosacral bone can stabilize pelvic or acetabular disruptions directly mean while can diminish operative blood loss, shorten operative time and allow patient's early activity.[1–3] Complications associated with open surgical procedures are similarly avoided by using percutaneous techniques. Several biomechanical studies have shown that screw fixation gives good stability as obtained with plate fixation for certain varieties of acetabular fractures with the added advantage of being minimally invasive thereby reducing blood loss,operative time and patient morbidity.

Stable and safe percutaneous fixation techniques depend on accurate closed reduction, excellent intraoperative fluoroscopic imaging and detailed preoperative planning.[4–6] A thorough knowledge of pelvic osseous anatomy, injury patterns, deformities and the related intraoperative imagery techniques are essential for the surgeon to fulfil the operation of percutaneous acetabular fixation.[7,8]

Although percutaneous screw fixation has several advantages over open surgical procedure in minimally displaced acetabular fractures, there is always a risk of injury to the surrounding neurovascular pelvic structures.[9,10] The learning curve for free hand percutaneous fixation is steep, requires expertise and the intraoperative fluoroscopic exposure to the surgeon is more as compared to open procedure. Image guided Orthopaedic surgery has the potential to be a widely used, minimally invasive and intelligent option.[9] But cost is a major issue for their use on a larger scale in Indian scenarios.

Background: Management of the acetabular fractures is a challenging situation for the orthopaedic surgeon worldwide. Percutaneous fixation is a preferred modality of treatment for certain varieties of minimally displaced acetabular fractures which are amenable to closed reduction. Traditionally percutaneous fixation is done using free hand technique,which requires considerable expertise,is time consuming and requires significant radiation exposure.Navigation guided percutaneous fixation is emerging as a promising treatment option but cost is a major issue for its use in Indian setup.Use of a modular universal jig can significantly overcome the current difficulties,will be cost effective and can improve the postoperative outcome in this patient population. Currently there is no commercial jig available for the percutaneous fixation of acetabular column fractures.

Background/Rationale: Surgical jigs are being traditionally used in the management of long bone diaphyseal fracture of femur, tibia and humerus. They reduce the operative time, intraoperative fluoroscopic exposure and also the surgeon-based errors thereby improving the surgical safety and assuring more predictable outcomes. Use of a modular external jig in the percutaneous fixation of the acetabular column fracture can give similar results. Such jigs are currently not available for the surgical fixation of acetabular column fracture.

Objectives:

1. To design an external jig with modularity for the percutaneous fixation of anterior and posterior acetabular fracture fixation, facilitating accurate insertion of antegrade and retrograde lag screws in the fixation of minimally displaced acetabular column fractures on pelvic specimens.
2. To develop the designed jig into a model through 3D printing (CAD).
3. To validate in vitro efficacy and safety on cadaveric models.
4. To test the clinical efficacy on minimally displaced acetabular fractures.

Method

Study Design: Observational Case Control Study

Setting: The study will be conducted at the Department of Orthopaedics, JNMC, Sawangi, between June 2020 to June 2022. The complete helical CT data will be collected from 40 adult patients (20 males and 20 females) aged between 18 to 75 years without any bone lesions or anatomic abnormalities,who have been advised CT abdomen pelvis for other any medical reason apart from Orthopaedic trauma at JNMC Hospital. The data collected will be used for the reconstruction of 3 D Pelvic model. The entry site for screw insertion will be determined using Mimics software.

Participants: Informed consent will be obtained from all participants. After the jig has been devised and it's validity and accuracy has been checked on cadaveric models,it will be checked on the appropriate patient population.

Eligibility Criteria: All the patients with fresh (less than 05 days old) minimally displaced acetabular column fracture amenable to closed reduction will be included in the study.

Exclusion Criteria:

1. Both column fracture with intra articular component requiring open reduction
2. Old fractures(more than 02 weeks old) not amenable to closed reduction

Variables: We will be checking the accuracy of the jig on the Pelvic Saw bone models and cadavers. Accuracy will be checked based upon the deviation between planned and executed screw at respective screw entry and tip.

Once accuracy has been identified then it will be checked on suitable patient population and the results will be compared with matched patient population in terms of radiation exposure to Operation theatre personnel, operative time and hospital Stay.

Data Sources/Measurement: During follow up,patients in both the groups (MIS using Jig vs MIS using free hand technique and conventional fluoroscopy) will be evaluated clinically with Harris hip score (HHS) and radiologically with Matta outcome grading. To evaluate functional outcome the patients will be categorized into excellent (HHS, 90-100), good (HHS, 80-90), fair (HHS, 70-80) and poor (HHS, <70).

Bias: None

Study Size: Because of the novelty of the current research and as there are no prior previous published similar studies, the sample size cannot be calculated methodically. So purposive or convenient sampling method will be used and the efficacy of the jig will be first checked on 05 cadavers (10 Hips) first. If found to be suitable and accurate then the jig will be used on all the suitable cases as per the inclusion criteria of the current study.

Quantitative Variables: The Student's t-test will be used in evaluating the statistical significance of differences in means. The unpaired t-test will be used in the comparison of mean surgery time between the two groups.

Statistical Method: Data will be imported to Microsoft excel sheet. The level of significance of the Universal modular jig as compared to conventional fluoroscopy for percutaneous fixation, will be measured using Chi square test.

Discussion

Acetabular fracture accounts for 10–22% of all fractures. They are traditionally managed surgically using open reduction internal fixation (ORIF) using plate osteosynthesis.[13,15]

ORIF is a preferred but requires extensive surgical exposure,have higher incidence of soft tissue complications, prolongs hospital stay and increases risk of heterotopic ossification and avascular necrosis of femoral head due to exposure per se. Minimally invasive surgery (MIS) and percutaneous screw fixation is an equally effective alternative in the management of certain variety of acetabular fractures which are amenable to close reduction.[13,16,17]

In the pelvi acetabular surgery,there is a very narrow pelvic corridor with the neurovascular structure in close proximity of the fracture surface and also the overlapping bowel shadow makes the intraoperative fluoroscopic visualization difficult.[14] MIS and percutaneous screw fixation can be done with the traditional free hand method using intraoperative 2D fluoroscopy or with the help of 3D navigation system in the management of certain varieties of minimally displaced pelvi acetabular fractures. Free hand technique is technically

demanding, has a steep learning curve, has a high risk of screw malplacement and exposes the operative staff to prolonged radiation.[17] 3D navigation based MIS is an excellent upcoming option with encouraging results, high safety margin but is very expensive and not a cost effective option in a rural setup.[17]

External jig aided intramedullary interlocking nailing has been used in the management of long bone fractures in Orthopaedic trauma routinely. The advantage of the use of an external jig is that it makes the surgery reproducible, is relatively cheap and decreases the operative time and complications.

We have hypothesized that the use of an universal modular jig would give similar benefits in the management of indicated acetabular column fractures which are amenable to closed reduction and percutaneous screw fixation. Also the use of this new jig would help in decreasing the operative time, surgical exposure, blood loss and would improve the patient outcome and reduce the hospital stay. Such jigs are not available for the fixation of acetabular columns fractures. So through this study we aim to design and develop an innovative external jig for the percutaneous screw fixation of the acetabular column fractures and then check its accuracy first on saw bone and cadaveric specimen. Once its accuracy and safety is established we will use the jig on selected patient population which are suitable for percutaneous acetabular fracture fixation and will compare the outcomes on the matched patient population treated with the current free hand technique using intraoperative fluoroscopy in terms of operative time, functional outcome and radiation exposure.

Key Results: This study will help in the designing, development and testing of an innovative external jig for the percutaneous screw fixation of the acetabular column fractures.

Limitations: It will be a single centre study so reproducibility of the current device would not be possible to check during the current study. A multicentric study comparing the efficacy of the jig will be required subsequently.

Interpretation: This will be the first study to design, develop and test the efficacy of a universal modular jig for the fixation of the acetabulum column fracture. We hypothesize that the development of this jig will help in successful management of the acetabular column fractures in terms of decreased operative time, reduced radiation exposure and improved patient functional outcome.

General is Ability: Once developed and validated a multicentric study will be done to determine the reproducibility and accuracy of the jig.

Ethical Clearance: Taken from institutional ethics committee.

Source of Funding: Self.

Conflict of Interest: Nil.

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