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Study and development of Instrumentation for Arthroscopic Latarjet procedure

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Abstract: The aim of this study is to develop an indigenous surgical product for the arthroscopic Latarjet procedure which is precise, easy-to-use, and stable fixation device. The primary objective was to compare the clinical outcomes of patients undergoing this procedure for recurrent dislocation of the shoulder. The secondary objectives were to evaluate and compare the surgical cost, surgeon satisfaction, and complications and this also aims to serves as a sample format for the integration of engineering and medicine, showcasing the potential for collaboration between these two fields by providing insight for researchers, to understand the developments in medical instruments and devices.

We identified difficulties and failures associated with existing techniques and addressed some of these issues through the design and development of a prototype Latarjet Accurate Drilling Jig with a modified technique. The aim was to produce a more accurate and precise procedure that is easier for surgeons to perform, leading to improved outcomes for patients.

I Literature Review

A. Overview of current products and techniques used in arthroscopic Latarjet procedure

Arthroscopic Latarjet procedure is a surgical technique used to treat recurrent shoulder dislocation. The current techniques and products used in this procedure include the traditional open Latarjet procedure and various fixation devices, such as screws, sutures, or bio-absorbable implants. [1],

The traditional open Latarjet procedure involves making an incision in the shoulder to access the glenoid and transfer a piece of the coracoid process to the glenoid to create a new bony restraint for the humeral head. This procedure is effective but can be associated with a higher risk of complications and longer recovery times compared to the arthroscopic approach. [2].

In recent years, the use of arthroscopic Latarjet procedure has become more widespread, as it allows for a minimally invasive approach to treating recurrent shoulder dislocation. [3], During the arthroscopic Latarjet procedure, small incisions are made in the shoulder, and a special camera called an arthroscope is used to visualize the interior of the joint. The surgeon then uses specialized instruments to transfer the coracoid process to the glenoid and secure it in place using a fixation device, such as screws or sutures. [4],

The use of arthroscopic Latarjet procedure has several benefits over the traditional open approach, including a quicker recovery time, less pain, and a lower risk of complications. However, the accuracy and stability of the fixation devices used during the procedure can impact the success of the procedure. As such, there is ongoing research and development aimed at improving the precision and stability of the fixation devices used during arthroscopic Latarjet procedures. [5],

B. Discussion of limitations and challenges with current products and techniques

In this study, we have addressed several complications that can occur during and after the arthroscopic Latarjet procedure. Using a proto model jig and bone models, we have identified and documented these complications to guide the development of new ideas. We also recognized the benefits of the current procedure and emphasized the importance of not overlooking these advantages while exploring alternative solutions to improve the procedure.

C. Analysis of current research and development trends in the field:

After evaluating the technical aspects and parameters, we generated several ideas and modelled them using 3D software. This allowed us to review and refine our ideas for improvement. Taking into account the limitations of current devices and the challenges in development, we developed a final model of a new product for the Latarjet procedure. The following issues were addressed in the design of the new model:

i) Variations in the size of the glenoid making it difficult to use the jig.

ii)Lack of constraint in the placement of the graft.

iii) Inadequate constraint in the positioning of the holes in the graft.

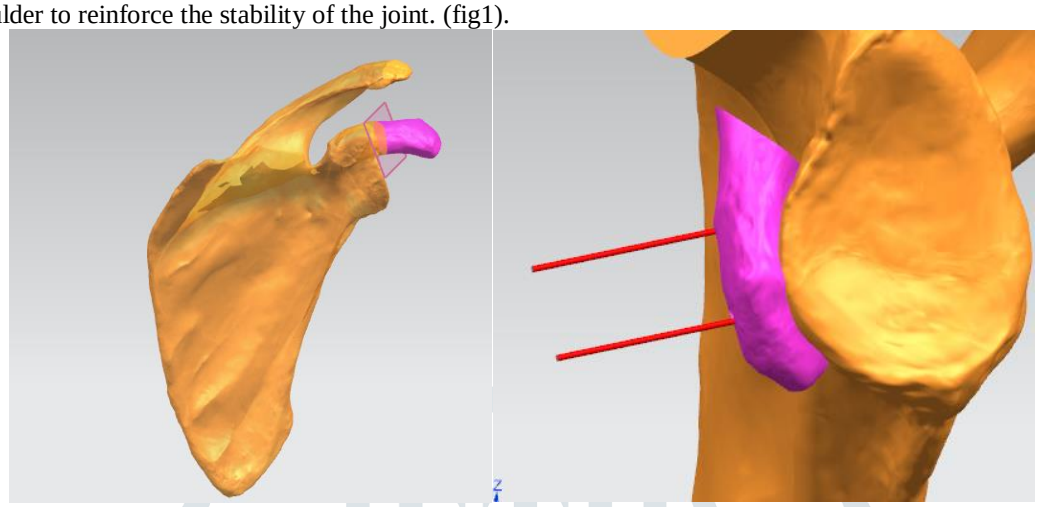
iv) Reduced bone matter in the cross-section of the graft after drilling holes.

v) The presence of a crucial nerve near the glenoid making the procedure more complicated

II Introduction:

Background on the arthroscopic LaserJet procedure

The Latarjet procedure, also known as the Bristow-Latarjet procedure, is a surgical procedure used to treat recurrent shoulder dislocation [6]. The procedure involves transferring the coracoid process, a bony structure located near the shoulder joint, to the front of the shoulder to reinforce the stability of the joint. (fig1).



Fig(1)

In the past, the Latarjet procedure was performed as an open procedure, which required a large incision and significant disruption to the surrounding tissue. However, advances in arthroscopic surgery have led to the development of the arthroscopic Latarjet procedure, which is a minimally invasive alternative to the open procedure [7], [8].

In an arthroscopic Latarjet procedure, small incisions are made and specialized instruments, including an arthroscope, are used to visualize the joint and perform the procedure. The benefits of the arthroscopic Latarjet procedure over the open procedure include reduced pain, faster recovery, and improved cosmetic results [9], [10].

Despite these advantages, the arthroscopic Latarjet procedure is a complex procedure that requires specialized skills and expertise. The success of the procedure is dependent on proper technique, accurate placement of the coracoid transfer, and stable fixation of the transfer to the front of the shoulder. As such, the development of new devices and techniques to improve the accuracy and stability of the procedure is an important area of research in the field of shoulder surgery. [11], [12], [13].

Indications

The arthroscopic Latarjet procedure is typically indicated for patients who have recurrent shoulder dislocation, meaning the shoulder joint has popped out of place multiple times. This can result in instability and pain in the shoulder and can interfere with the patient's ability to perform daily activities.

The procedure is typically considered when conservative treatments, such as physical therapy, bracing, and rehabilitation exercises, have not been successful in preventing recurrent dislocations.

In addition to recurrent dislocation, the arthroscopic Latarjet procedure may also be indicated for patients with other conditions that cause instability in the shoulder joint, such as rotator cuff tears, instability due to previous injury or surgery, and ligamentous laxity.

It is important to note that the arthroscopic Latarjet procedure is a complex procedure and is not appropriate for all patients. The best candidate for the procedure is typically an active individual with a recurrent shoulder dislocation who has failed conservative treatment and is seeking a long-term solution for shoulder stability.

Before undergoing the procedure, a thorough evaluation by an orthopedic surgeon is necessary to determine if the arthroscopic Latarjet procedure is the best option for a particular patient.

Purpose of the article:

The purpose of this article is to present the study and development of a new product in the field of arthroscopic Latarjet procedure. The article aims to provide insight for researchers in other departments, such as engineers to understand the latest developments in medical instruments and devices. This article serves as a sample format for the integration of engineering and medicine, showcasing the potential for collaboration between these two fields.

III. Study Methodology

A. Description of the study design:

The study design for an arthroscopic Latarjet procedure would typically involve recruiting a group of patients who are undergoing the procedure for recurrent dislocation of the shoulder. The primary aim of the study would be to compare the clinical outcomes of these patients, and the secondary aims would be to assess and compare the surgical cost, surgeon satisfaction, and the rate of complications.

The study would likely involve a prospective, randomized, controlled design, where patients are assigned to either the experimental group (receiving the new device or technique) or the control group (receiving the traditional Latarjet procedure). The patients would be followed for a specific period of time to assess their clinical outcomes, and the results would be compared between the two groups.

Additionally, the study may include surveys or interviews with the surgeons to gather their feedback on the ease of use, stability, and precision of the new device or technique. The results of the study would be analyzed statistically to determine the effectiveness of the new product and its impact on patient outcomes, surgical costs, and surgeon satisfaction.

The study design should adhere to ethical principles, such as informed consent from the patients, protection of their privacy, and avoiding any harm to the patients. The study design and methods should also be reviewed and approved by an institutional review board or ethics committee to ensure that the study is conducted in an ethical and responsible manner

B. Explanation of the study population and sample size:

The outcome of the arthroscopic Latarjet procedure is generally positive, however, there have been instances of complications. These include infection, frozen shoulder, formation of hematoma, symptomatic implants, fracture or non-union of the coracoid graft, neurological complications, arthritis, and recurrence of instability. Among these issues, the fifth one (fracture or non-union of the coracoid graft) is particularly relevant to mechanical engineering and will be the focus of the solution.

C. Details of the intervention (the new product) and control group:

There are various jigs and instruments available in the global market, however, they tend to be expensive to import. In India, the following model (fig2) is commonly used in the Latarjet procedure.

Fig(2)

During the review of the procedure's technical issues, the following problems were identified:

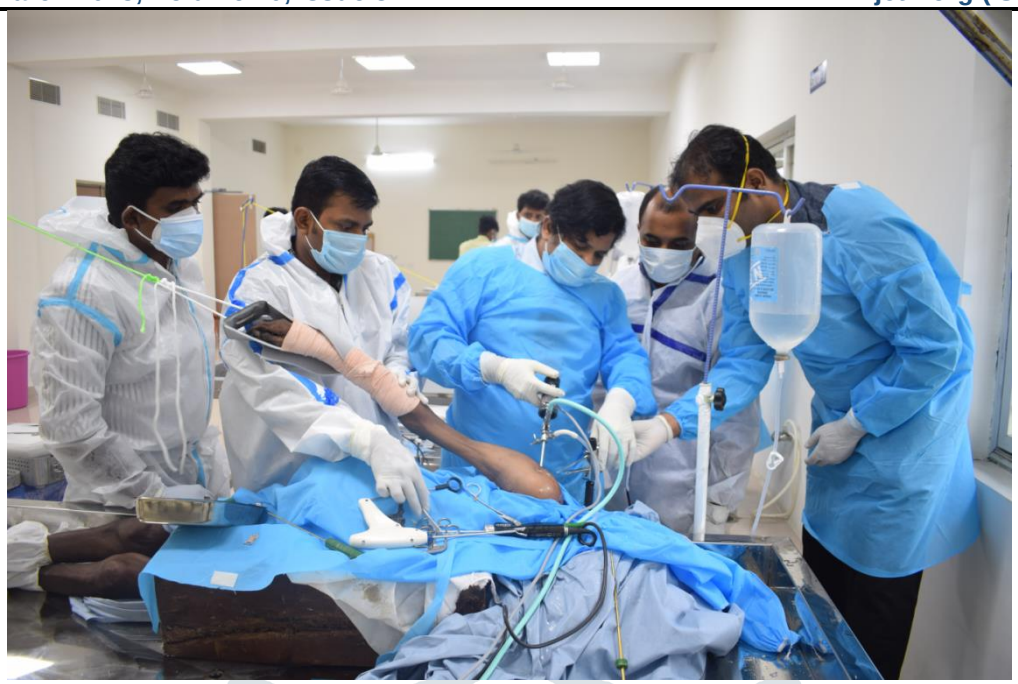
1. Variations in Glenoid size leading to an improper fit with the jig.
2. Insufficient constraint of the placement of the graft.
3. Inconsistencies in the positioning of the holes drilled in the graft.
4. Cross-sections of the drilled graft revealing insufficient bone matter.
5. The presence of a crucial nerve near the glenoid making the procedure complex.

"The new product design has been compared to the existing procedure and has shown the following benefits:

1. The hole size of the graft has been reduced, reducing the risk of fracture during fixation.
2. No implants, such as endo buttons or screws, are required. Instead, only fiber wire or fiber tape is used to secure the graft, which reduces cost and benefits the patient.
3. The positioning, fixation, and repeatability of the jig are accurate and precise.
4. The jig is flexible and can be adjusted to accommodate variations in glenoid size without compromising precision and accuracy.

D. Outcome measures and statistical analysis methods:

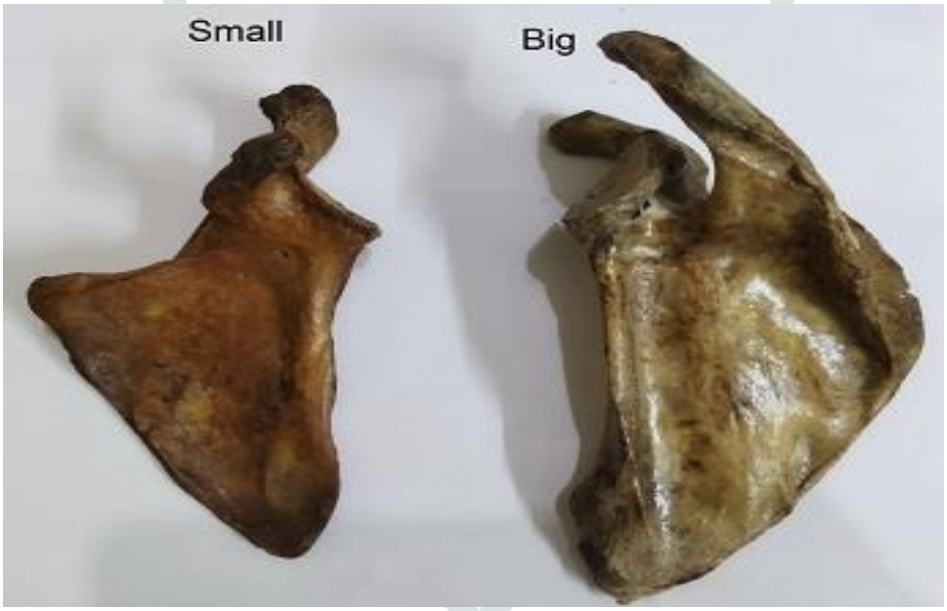
The above-mentioned benefits may not have been fully realized yet as the new product design has only been tested using model bones and cadavers (fig3). Further corrections and revisions may be necessary to ensure that the benefits can be achieved in a real-world scenario. However, some benefits have been observed, such as a reduced risk of fracture during fixation due to reduced hole size, the jig being flexible and able to accommodate variations in the glenoid size and no implants are used which reduces cost and benefits the patient.



Fig(3)

Statistical analysis methods:

1. **Sample Size**: The sample size of the study could be determined by calculating the minimum number of patients required to obtain statistically significant results fig (4).



Fig(4)

2. **Demographic Data**: Demographic data such as age, gender, and body mass index of the patients can be collected and analysed.
3. **Preoperative Data**: Data on the patients' preoperative clinical status, such as pain level, range of motion, and stability, can be collected and analysed.
4. **Outcome Measures**: Outcome measures such as postoperative pain level, range of motion, and stability can be collected and analysed at various time points (e.g., 6 weeks, 3 months, 6 months, 1 year).
5. **Complications**: The incidence of complications such as infection, frozen shoulder, hematoma formation, symptomatic implants, and recurrence of instability can be recorded and analysed.
6. **Return to Work**: The time to return to work can be recorded and analysed.
7. **Patient Satisfaction**: Patient satisfaction with the procedure can be measured using a standardized questionnaire and analyzed.
8. **Comparison with Other Techniques:** The results of the Arthroscopic Latarjet procedure can be compared with other surgical techniques, such as open Latarjet procedure, to determine the relative benefits and drawbacks of each technique.
9. **Cost Analysis:** The cost of the procedure can be compared with the cost of other surgical techniques to determine the economic benefits and drawbacks of each technique.

IV. Results

A. Summary of the results of the study

A new design for the arthroscopic Latarjet procedure has been proposed, which offers significant benefits compared to the existing technique. The study has shown positive results in terms of shoulder stability, function, and strength. This was achieved through an implant-free coracoid fixation with a smaller hole size, which benefits the patient and reduces costs. The study involved developing a model and simulation, redefining specifications, creating a new device, proposing a new procedure and process, and using alternative materials.

B. Discussion of the findings in relation to the literature review, current trends and advanced method.

S.No	Antiquated Procedure	Advanced Procedure
01	Implant used may cause hardware related complications and may require second surgery for removal.	No such complications
02	More possibility of inaccuracy due to fixed jig size	Less possibility of inaccuracy due to adjustment in jig size
03	As implants are used cost of the procedure is high	Cost of the procedure is comparatively low
04	Graft fracture rate is higher because of diameter of drill and screw size (screw hole diameter ranges 3 to 4 mm)	Low rate of fracture in graft fixation (reduced screw hole diameter ranges 2 to 3mm)
05	Procedure complications are more	Procedure complications is less
06	Recovery or healing rate is normal	Recovery or healing rate is relatively fast

V. Conclusion

A. Summary of the main findings and implications

The arthroscopic Latarjet procedure has generally positive outcomes, but there have been reported complications such as infection, frozen shoulder, hematoma formation, symptomatic implants, fracture or non-union of the coracoid graft, neurological complications, arthritis, and recurrence of instability. The focus of the study is on the fifth issue, fracture or non-union of the coracoid graft, which is of particular importance to mechanical engineering. In India, a commonly used jig for the procedure has been identified, but during a review of its technical issues, problems such as variations in glenoid size leading to an improper fit with the jig, insufficient constraint of graft placement, inconsistent graft hole positioning, insufficient bone matter in the drilled graft, and the presence of a crucial nerve near the glenoid were identified.

A new product design has been compared to the existing procedure and has shown benefits such as reduced hole size in the graft, reducing the risk of fracture during fixation, and the use of only fiber wire or fiber tape instead of implants to secure the graft, reducing cost and benefiting the patient. The jig is also precise and accurate in positioning, fixation, and repeatability and can be adjusted to accommodate variations in the glenoid size without losing precision. However, these benefits have not been fully realized yet as the new product design has only been tested on model bones and cadavers and may require further revisions for practical implementation

B. Discussion of the limitations and potential limitations of the study:

In any research study, there are inherent limitations that must be taken into consideration. It is important to acknowledge these limitations as they can impact the validity and reliability of the results. Here are some limitations that are commonly encountered in medical studies:

Sample size: The sample size of the study may be small, which can limit the generalizability of the results to a larger population.

Selection bias: The study participants may not be representative of the general population, and this can introduce selection bias into the results.

Observer bias: The results may be affected by observer bias, particularly if the assessments are subjective in nature.

Lack of control group: A lack of a control group, or a comparison group, can make it difficult to determine the effectiveness of the treatment being studied.

Confounding factors: Confounding factors, such as other treatments or underlying medical conditions, can influence the results of the study and make it difficult to determine the impact of the treatment being studied.

Follow-up time: The follow-up time of the study may be limited, which can affect the long-term outcomes of the treatment being studied.

Technical limitations: Technical limitations, such as the availability of equipment or software, can impact the results of the study.

These limitations must be taken into consideration when interpreting the results of the study. It is also important to note that potential limitations may arise during the conduct of the study, and these must also be addressed in the discussion of the results

C. Suggestions for future research and development in the field:

The field of arthroscopic Latarjet procedure can benefit from future research and development efforts in several ways. These may include:

i) Fine-tuning the jig with various bone models to improve accuracy and precision.

ii)Revising and improving the design of the device to address all the needs of the procedure.

iii) Analysing the product and evaluating its performance through various tests and simulations.

iv) Offering cadaver courses and training to familiarize surgeons with the new device and procedure.

v) Conducting clinical trials to calibrate the product and gather valuable data and feedback.

vi) Monitoring patients' recovery and collecting feedback to analyse the effectiveness of the procedure and identify areas for improvement. By implementing these measures, the arthroscopic Latarjet procedure can continue to advance and deliver better results for patients

D. Final thoughts and recommendations for clinicians and patients:

In conclusion, the new design of the arthroscopic Latarjet procedure shows promise in terms of stability, function, and strength compared to the existing procedure. While further research and development is necessary, clinicians and patients can benefit from the new design's cost-effectiveness and improved results. It is important for clinicians to stay updated on the latest developments in the field and for patients to be informed about the potential risks and benefits of the procedure before making a decision. Additionally, it is recommended for clinicians to closely monitor the recovery process and gather patient feedback to ensure the best possible outcome

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