Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

A Comparative Evaluation of Clinical and Radiological Outcomes of Using a New 3D Printed Tilting Suture Anchor and a Conventional Screw Anchor in Open Rotator Cuff Surgery: A Randomized Clinical Trial

Protocol summary

Study aim

To compare the clinical and radiological outcomes of a novel 3D-printed tilting suture anchor versus a conventional screw-type suture anchor in open rotator cuff repair surgery.

Design

This study is a prospective, randomized, parallel-group, superiority phase II clinical trial conducted on 88 patients. Participants will be allocated in a 1:1 ratio using block randomization. Patients and outcome assessors will be blinded to the intervention type.

Settings and conduct

This study will be conducted at Shariati Hospital affiliated with Tehran University of Medical Sciences. Eligible patients will be enrolled after obtaining informed consent and will undergo open rotator cuff repair surgery. Clinical and radiological follow-up assessments will be performed at predefined postoperative intervals.

Participants/Inclusion and exclusion criteria

Patients with full-thickness supraspinatus tendon tears who are candidates for open rotator cuff repair surgery will be included. Patients with previous shoulder surgery, advanced shoulder arthropathy, active infection, severe uncontrolled systemic disease, or unwillingness to participate will be excluded.

Intervention groups

The intervention group will undergo open rotator cuff repair using a novel 3D-printed titanium tilting suture anchor. The control group will undergo open rotator cuff repair using a conventional screw-type suture anchor. Surgical technique and rehabilitation protocol will be identical in both groups.

Main outcome variables

ASES (American Shoulder and Elbow Surgeons) score at 6 months after surgery; pain severity based on VAS (Visual Analogue Scale); Constant score; shoulder range of motion; shoulder muscle strength; MRI and CT findings; tendon retear rate; anchor-related complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210712051854N10**
Registration date: **2026-07-04, 1405/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-04, 1405/04/13**
Update count: **0**

Registration date

2026-07-04, 1405/04/13

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2028-03-29, 1407/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Evaluation of Clinical and Radiological Outcomes of Using a New 3D Printed Tilting Suture Anchor and a Conventional Screw Anchor in Open Rotator Cuff Surgery: A Randomized Clinical Trial

Public title

Evaluation of a 3D-Printed Tilting Suture Anchor in Rotator Cuff Repair Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 40 and 75 years Body mass index (BMI) less than or equal to 35 kg/m2 Complete rupture of the supraspinatus tendon, confirmed by MRI (with involvement of more than 50% of the tendon thickness as diagnosed by two musculoskeletal radiologists) and clinical examination by a shoulder specialist Failure to improve after at least 6 weeks of supervised physiotherapy Numerical Pain Rating Scale (NPRS) shoulder pain severity score equal to or greater than 6 Willingness to be randomized and adhere to the study protocol and follow-ups Use of contraceptive methods during the study for subjects of childbearing age (male or female)

Exclusion criteria:

History of severe allergic reaction or known sensitivity to metallic implant materials Presence of uncontrolled coagulation disorders or clinically significant bleeding tendency Severe and unstable cardiac or pulmonary disease that would make surgery or study follow-up risky Pregnancy or lactation at the time of study entry Contraindication to MRI (e.g., presence of incompatible implants or severe claustrophobia) History of active or recent infection of the affected shoulder Corticosteroid or PRP injection in the affected shoulder within the past 3 months History of shoulder surgery on the affected side within the past 6 months Active systemic inflammatory or autoimmune diseases (e.g., active rheumatoid arthritis) that affect tendon repair Chronic use or active immunosuppressive drugs Central or peripheral neurological disorders affecting upper limb function (such as cervical myelopathy or symptomatic radiculopathy) Severe psychiatric or cognitive disorders that prevent patient cooperation or regular follow-up Concurrent participation in another interventional clinical study

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Patients will be allocated to two intervention (titanium tilting anchor) and control (screw-type anchor) groups in a 1:1 ratio using a block randomization method. The randomization list with variable blocks (sizes 4 and 6) will be generated by an independent statistician using computer software (such as Random Allocation Software) and kept confidential. To protect confidentiality (allocation concealment), numbered, opaque, and sealed envelopes will be used, which will only be returned by an independent research assistant at the appropriate time. In this study, a two-stage randomization approach will be used to reduce the risk of selection bias and increase the internal validity of the results. Stage 1: Preoperative Screening and Informed Consent All potentially eligible patients who are clinically and MRI-confirmed to have a complete supraspinatus tendon tear and are candidates for open rotator cuff repair surgery are evaluated in the preoperative screening phase. In this phase, after providing a full explanation of the study objectives, procedure, potential benefits, and risks, written informed consent is obtained from the patients and basic information including demographic characteristics and baseline clinical variables is recorded. Stage 2: Preoperative Randomization After meeting the inclusion criteria and before the patient enters the operating room, patients are randomly assigned to one of the two treatment groups in a 1:1 ratio. Randomization is performed using a randomized block design with alternating blocks and by an independent statistician. Patient group allocation is maintained in opaque, sealed, and consecutively numbered envelopes and will not be disclosed until appropriate. Step 3: Intraoperative Eligibility Verification and Activation of Treatment Allocation After the start of surgery and direct intraoperative lesion examination, the patient’s final eligibility for entry into the interventional phase of the study is confirmed by the surgeon. Only if the intraoperative findings are consistent with the preoperative diagnosis and the patient is eligible to continue the study, will the randomization envelope be opened and the allocated intervention be implemented.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding: In this study: • Patients are blinded to the type of anchor used. • Clinical outcome assessors and statistical analysts will be blinded to the group allocation of patients. • The surgeon, operating room team, and radiologist are aware of the treatment group due to the nature of the intervention. In order to reduce bias, radiological and clinical data for statistical analysis will be provided to the statistical analyst in coded form without mentioning the type of implant. In the event of a specific clinical situation that requires immediate information about the type of implant, it will be possible to open the blinding emergency according to a

predefined procedure. Blinding assessment test: At the end of the study, assessors and patients can be asked which group they think they received (a simple blinding index question) to assess the success of blinding. Emergency Unblinding • In the event of a serious complication requiring knowledge of the implant type (e.g. for therapeutic decision-making or if there is a risk to the patient), there is a controlled procedure for unblinding: 1. A formal request for unblinding should be made in writing by the surgeon or treating physician and should include a compelling clinical reason. 2. The randomization officer (independent statistician) or allocation list keeper should provide specific information after recording the time/reason. 3. Each unblinding should be recorded in the study file with the reason, time, and identity of the requester and reported in the final study report. 4. It is preferable to unblind only when absolutely necessary and to the minimum extent necessary to minimize damage to the validity of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Dr. Shariati Hospital Educational, Research and Treatment Center - Tehr

Street address

Dr. Shariati Educational, Research and Treatment Center, opposite the Faculty of Economics, Jalal Al-Ahmad Intersection, North Kargar Street, Tehran.

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.565

Health conditions studied

1

Description of health condition studied

Rotator cuff tear

ICD-10 code

M75.12

ICD-10 code description

Complete rotator cuff tear or rupture not specified as traumatic

Primary outcomes

1

Description

The American Shoulder and Elbow Surgeons (ASES) score is the primary outcome measure used to assess overall shoulder function, pain, and disability after rotator cuff repair. Differences between groups reflect the effectiveness of the intervention.

Timepoint

Baseline (preoperative), 3 months postoperatively, and 6 months postoperatively

Method of measurement

Assessed using the standardized ASES Shoulder Score questionnaire, which includes pain (VAS-based) and activities of daily living. Scores range from 0 to 100, with higher scores indicating better shoulder function.

2

Description

Rotator cuff re-tear rate after surgery, reflecting biological and mechanical integrity of tendon healing.

Timepoint

6 months postoperatively (and 12 months if available)

Method of measurement

Assessed using shoulder MRI (T2-weighted and fat-suppressed sequences) evaluated by a blinded musculoskeletal radiologist. Re-tear is recorded as a binary outcome (yes/no).

Secondary outcomes

1

Description

Shoulder pain intensity as a clinical indicator of treatment effectiveness.

Timepoint

Preoperative, 6 weeks, 3 months, and 6 months postoperatively

Method of measurement

Visual Analog Scale (VAS), scored from 0 (no pain) to 10 (worst pain)

2

Description

Active range of motion of the shoulder including flexion, abduction, internal and external rotation.

Timepoint

Preoperative, 3 months, and 6 months postoperatively

Method of measurement

Measured in degrees using a standard orthopedic goniometer

3

Description

Shoulder muscle strength, particularly rotator cuff muscle performance.

Timepoint

3 months and 6 months postoperatively

Method of measurement

Manual Muscle Testing (MMT) and/or hand-held dynamometer

4

Description

Quality of tendon healing and tendon-to-bone interface integrity.

Timepoint

6 months postoperatively

Method of measurement

MRI evaluation by a blinded musculoskeletal radiologist using standardized healing criteria (intact, partial healing, failure)

Intervention groups

1

Description

Intervention group: 1. Operative DetailsAll patients undergoing open rotator cuff repair surgery (based on the surgeon's diagnosis and discretion) are placed in the beach-chair position. Debridement of the torn tendon edges and preparation of a bone bed (footprint) in the greater tuberosity are performed. Bed preparation includes removal of superficial fibrotic tissue and creation of superficial spot hemorrhage to facilitate biological repair.The supraspinatus tendon repair is performed using a 3D printed titanium tilting suture anchor. The number of anchors used is determined by the size of the tear and the surgeon's judgment. The use of other auxiliary devices or standard suturing techniques is permitted according to the center's usual protocol and the surgeon's discretion.2. Anchor Insertion TechniqueAfter preparing the bone bed, a bone channel with a standard diameter and depth corresponding to the dimensions of the designed anchor is created in the footprint area. The anchor is inserted longitudinally (inline) into the bone channel. After initial placement, by applying controlled tension to the threads connected to the anchor, the tilting mechanism is activated, so that due to the difference in length and width of the anchor, transverse placement is created within the channel and its direct exit is mechanically limited.After activating the tilting mechanism, the initial stability of the anchor is checked manually by applying gentle tension to the threads. If proper placement is confirmed, the threads are used to perform tendon repair sutures. In the event of unsatisfactory anchor placement or technical difficulties in anchor placement, removal and reinsertion or rescue techniques may be performed at the surgeon's discretion, which will be fully documented.3. Intraoperative AssessmentsDuring surgery, the following assessments are systematically recorded:1. Ease of insertion based on surgeon judgment and recorded on a descriptive scale (easy, moderate, difficult).2. Success of initial anchor placement after activation of the tilt mechanism (successful/needs revision/unsuccessful).3. Initial anchor stability with controlled manual tension on the threads.4. Approximate time required for placement of each anchor.5. Any intraoperative complications related to the anchor, including bone fracture, canal dilation, instrument failure, or the need for a change in technique.6. Need for rescue techniques (such as additional anchor placement or repositioning).All of this data will be recorded on pre-designed forms.Postoperative rehabilitationAll patients will follow the same rehabilitation protocol:• Weeks 0-4: Use of a sling with an abduction pad; passive shoulder movements, pendulum exercises, and elbow range of motion; limitation of end extension and overhead movements• Weeks 4-12: Initiation of active shoulder assisted movements, supervised physical therapy, and gradual strengthening of the rotator cuff, deltoid, and scapular stabilizer muscles• Months 3-6: Continued structured rehabilitation; return to heavy overhead activities will be prohibited until strength is restored (usually about 12 months)

Category

Treatment - Devices

2

Description

Control group: 1. Operative DetailsAll patients undergoing open rotator cuff repair surgery (based on the surgeon's diagnosis and discretion) are placed in the beach-chair position. Debridement of the torn tendon edges and preparation of a bone bed (footprint) in the greater tuberosity are performed. Bed preparation includes removal of superficial fibrotic tissue and creation of superficial spot hemorrhage to facilitate biological repair. Supraspinatus tendon repair is performed using screw-type anchors. The number of anchors used is determined based on the size of the tear and the surgeon's judgment. The use of other auxiliary devices or standard suturing techniques is permitted according to the center's usual protocol and at the surgeon's discretion.2. Anchor insertion techniqueAfter preparation of the bone bed, the anchor is inserted into the bone using the accompanying wrench. The initial stability of the anchor is then checked manually by applying gentle tension to the threads. If adequate placement is confirmed, the sutures are used to perform tendon repair sutures. In the event of unsatisfactory placement or technical difficulties in anchor placement, removal and reinsertion or rescue techniques may be used at the discretion of the surgeon, which will be fully documented.3. Intraoperative AssessmentsDuring surgery, the following assessments are systematically recorded:1. Ease of insertion of the anchor based on the surgeon’s judgment and recorded on a descriptive scale (easy, moderate, difficult).2. Success of initial anchor placement after activation of the tilt mechanism (successful/needs revision/unsuccessful).3. Initial anchor stability with controlled manual tension applied to the sutures.4. Approximate time required for placement of

each anchor.5. Occurrence of any intraoperative complications related to the anchor, including bone fracture, canal dilation, instrument failure, or need for technique change.6. Need for rescue techniques (such as additional anchor placement or repositioning). All of this data will be recorded on pre-designed forms.Postoperative rehabilitationAll patients will follow the same rehabilitation protocol:• Weeks 0 to 4: Use of a sling with an abduction pad; passive shoulder movements, pendulum exercises, and elbow range of motion; limitation of end extension and overhead movements• Weeks 4 to 12: Initiation of active shoulder assistive movements, supervised physical therapy, and gradual strengthening of the rotator cuff, deltoid, and scapular stabilizer muscles• Months 3 to 6: Continue structured rehabilitation; return to heavy overhead activities will be prohibited until strength is restored (usually about 12 months)

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital
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Dr. Hossein Nematian
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Vice Chancellor for Research and Technology, Sixth Floor, Central Organization of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Deidentified participant data including demographic information, clinical outcome variables, imaging results, and implant related complications will be shared. The final study protocol and informed consent form will also be available upon request.

When the data will become available and for how long
The data will be available from 6 months after publication of the study results until 5 years after publication.

To whom data/document is available
Academic investigators, researchers from scientific institutions, and individuals with a valid research proposal may request access to the data.

Under which criteria data/document could be used
The data will be available only for scientific research purposes and academic analyses. All shared data will be deidentified and commercial use will not be permitted. Applicants must submit a formal request including the study objective and analysis plan and must agree to maintain data confidentiality

From where data/document is obtainable
Applicants may request access by contacting the principal investigator of the study. Contact information of the principal investigator will be available in the study registry and at Tehran University of Medical Sciences.

What processes are involved for a request to access data/document
Requests will be reviewed by the principal investigator and the research team. If approved, deidentified data will be provided within 4 weeks after receipt of a complete request.

Comments