Punch vs. Drill

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Researcher and Protocol Identification:

Title: Punch vs. Drill tunnel use for anchor tunnel creation and correlation with post-operative pain

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Objective:

To determine if different techniques used in the creation of suture anchor socket creation can influence post-op pain following rotator cuff repair

Hypothesis:

We propose that the use of an arthroscopic drill for creation of anchor socket will result in less pain post-operatively when compared to the use of the punch.

Clinical significance:

Arthroscopic rotator cuff repair has become a mainstay of treatment for rotator cuff tears requiring surgical intervention and has been reported to decrease pain and increase function to levels similar to open approaches while requiring smaller incisions and less soft

tissue disruption.[3-5] Development of reliable and effective procedure-specific instrumentation, primarily in the form of suture anchor systems, has been a key reason for the successful progression in arthroscopic rotator cuff repair.[1-3,5-7]

Even with advanced instrumentation, it has become evident that a subset of patients experience pain and functional limitations in the acute post-operative period.[4,8,9] Studies have demonstrated that rotator cuff tear size does not correlate with post-operative pain in patients,[10] and that pain scores may not be improved by using an arthroscopic repair versus an open repair.[4,19] Austin et. al. observed that 56 patients having undergone rotator cuff repair for full thickness rotator cuff tears suffered sleep disturbances for up to 3 months after surgery.[18] The causes for increased post-operative pain in patients following rotator cuff repair remain poorly understood. As such, all relevant variables, including technical components of the repair, should be critically evaluated in an effort to optimally address post-operative pain for patients.

Because arthroscopic rotator cuff repair most commonly uses suture anchors inserted into proximal humeral bone to re-attach tendon(s), the authors sought to examine technical components of suture anchor insertion. The sockets for insertion of suture anchors used in rotator cuff repair are made most often with use of a surgical punch that, in theory, corticates the socket to optimize anchor thread purchase and pull-out strength. However, use of a punch may cause significant micro-trauma to proximal humeral bone as it fractures trabeculae to create the socket, as opposed to use of a drill bit which cuts and removes trabeculae to create the socket. These fractures occurring as the result of stress-induced microtrauma to bone have a well-documented role in causing pain.[11-14] These microfractures are also associated with bone marrow lesions seen on MRI. Importantly, bone marrow lesions in the greater tuberosity have been reported to occur after arthroscopic rotator cuff repair using punch-socket suture anchors, and can remain present for 6 – 12 months.[15-17] Taken together, these findings give credence to the theory that punch-induced microfractures may contribute to postoperative pain after arthroscopic rotator cuff repair.

Study Design:

- Randomized prospective cohort study.

1. Inclusion criteria
    a. Patient's aged 18-80 years old with diagnosis of rotator cuff tear having failed non-operative management and being indicated for surgical intervention with use of suture anchors.
2. Exclusion criteria
    a. Glenohumeral arthrosis
    b. Previous shoulder surgery
    c. Psychiatric diseases
    d. Rheumatologic diseases
    e. Fibromyalgia
    f. Spine diseases

- 50 Patients will be randomized to have bone sockets formed with either a punch (25) or a drill (25) at the time of surgery.
- Patients will follow up at their standard of care visits at 2 weeks, 6 weeks, 3 months, and 6 months
- PROMIS SF v2.0 – Physical Function 10a, PROMIS SF v1.0 – Pain Interference 6a, SANE, ASES, VAS scores will be collected at each visit for research purposes.

- Patients will record their pain levels and number of pain pills they took for three days post-op for research purposes.
- MRI of the shoulder of the first 5 patients in each group will be obtained at 2 weeks post-op for evaluation of bone marrow edema pattern in the proximal humerus for research purposes.

Training in the policies protecting the rights and welfare of human subjects in research:
All staff involved in this study has had IRB-approved training according to The University of Missouri Healthcare guidelines

Publication of private information:
Investigators intend to publish the results of this study without identifying the subjects; and every attempt will be made to follow strict confidentiality. The results of this research may appear in scientific publications without identifying the patients.

Future contact with research patients:
Research patients/caregivers may be contacted to participate in future research.

Possible risks to research patients:
Potential for loss of confidentiality. Each patient will be assigned a random subject number. The key linking numbers to subjects will be locked away in the offices of University of Missouri, Missouri Orthopedic Institute. All published information will be through de-identified subject numbers. The key linking the patient and all identifiable personal information will be destroyed 10 years post-study completion to allow for complete data analysis and use of data for publication writing.

Patients will be randomized 1:1 into either the punch or drill. The surgeon does not determine the procedure; there is always the potential risk that the other procedure may result in more post-op pain.

Possible benefits:
Research patients enrolled in the study will not benefit directly from this study itself; however, information gained from this study could benefit patients being treated in the future. Specifically it may help determine a new standard of care for patients with upper extremity injuries with resultant hand stiffness.

Costs to subjects:
No costs will be incurred by the subjects above and beyond the standard medical practice.

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