

COMPARISON OF THE TENSILE STRENGTH OF THREADED METAL ANCHORS INSERTED ON CORTICAL AND SPONGY BONES

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SUMMARY

Rotator cuff rupture is a common affection causing an impact on the daily lives of patients, resulting in functional disability and pain. A reasonable number of patients need tendinous repair. Current trends on shoulder surgery are the use of minimally invasive techniques with lower per-operative morbidity and earlier rehabilitation. From the 1990's on, shoulder arthroscopy was largely developed, as well as the use of anchors for tendinous sutures fixation. This technical

evolution has allowed for arthroscopic surgery outcomes comparable to those in open surgeries.

One of the potential problems for the use of anchors in shoulder arthroscopic surgeries is related to its loosening from bone surface. The present study has as an objective to compare the tensile strength of threaded metal anchors inserted on cortical and spongy bones.

Keywords: Rotator Cuff; Rupture; Tensile strength; Biomechanics.

INTRODUCTION

In the last decades, medicine as a whole and particularly orthopaedics has achieved a deep knowledge on the development of less invasive surgical techniques and more adequate bone fixation systems ^(1,2,3,4).

Arthroscopy provides less aggressive approaches, with lower surgical morbidity rates ^(3,4), and shoulder surgery is one of the most benefited areas as a result of this advancement.

In open surgery for rotator cuff repair, tendinous sutures are possible, with quite adequate bone fixation. The most famous reinsertion technique is performed by building a bone trough at the major tuberosity of the humerus with trabecular bone exposure (considered as the best place

for bone-tendon integration). Tendon is placed closer and sutured by transbone stitches fixed at the lateral cortical of major tuberosity ^(2,8). An adequate approach of the tendon to the bone is achieved, and suture keeps its tensile strength, allowing for tendon's reinsertion to the bone ⁽⁵⁾.

Literature related to techniques for repairing rotator cuff injuries is varied and shows quite positive values in traditional surgeries – open – and in arthroscopic surgeries ⁽⁶⁾. Many methods of tendons reinsertion to humeral head and using different fixation materials are described. Today, bone fixation anchors are mostly used.

The arthroscopic technique has differences compared to the open technique. Bone fixation anchors are used, and

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those are inserted through arthroscopic portals. Bone trough is not performed (7), and the tendon is directly apposed on a minimally scarified cortical bone (7,8). Bone trough is not performed because spongy bone is thought to be unable to promote an adequate anchor fixation (6,9-12). The advantage of the open technique relies on a higher contact between bone surface and tendon (13).

In the arthroscopic technique, the tendon is reinserted to the humeral major tuberculum region after scarification of the bone surface and fixed by suture wires attached to the threaded metal anchor on bone surface. Such bone fixation must have a biomechanical stability that enables reinsertion and the subsequent rotator cuff healing.

This study aims to improve the arthroscopic technique for rotator cuff reinsertion, with the objective of achieving a tendinous fixation with similar biomechanical characteristics as those of the open surgery by comparing the tensile strength of threaded metal anchors on cadavers' cortical and spongy bones.

MATERIALS AND METHODS

Twenty shoulders of 10 human cadavers (10 pairs) were selected from São Paulo City Death Examination Service (SVOC). All studied shoulders presented with tendinous injuries at the rotator cuff or any other anatomical change seen at the moment of dissection. Shoulders were divided into two groups.

Group A – (cortical bone) Consisting of 10 cadaver proximal humeri.

Group B – (spongy bone) Consisting of 10 cadaver proximal humeri.

This was a randomized study, with the same number of right and left humeri in each group.

Methodology for preparing cadaver pieces

After a macroscopic evaluation of the piece at SVOC ruling out any pathology that could preclude the use of the shoulder, this was removed with the scapula, a portion of distal clavicle and humeral proximal half, so that all its capsular-ligamentar structure remained intact. Subsequently, all musculotendinous structure was removed from each shoulder, leaving only the bone struc-

ture. All shoulders were identified and properly packed. Pieces were frozen at -20°C and allowed to unfreeze to room temperature 12 hours prior to assays, with gauze soaked in saline solution, following previous hydration care. After shoulders were randomly assigned, those were submitted to the protocol for anchors insertion on the same day and by the same surgeon. Inclusion criteria are shown on Chart 1.

The surgical procedure (common to all shoulders) followed the order below:

1. The removal of humeral proximal half without its tendinous and ligamentar insertions was performed.
2. In Group A humerus with cortical bed, fixation anchors were inserted (one in each humerus) at 0.5 cm laterally and distally to the lateral end of the humeral head joint surface on major tuberosity medium third, with a 45° orientation to humeral axial shaft.
3. In Group B shoulders the same procedure was performed, preceded by bone trough of approximately 0.7 cm deep at 0.5 cm from the lateral end of humeral head joint surface, 1 cm long. Thus, anchors were fixed right to the spongy bone, with one anchor being used in each tested humerus.
4. In each anchor, a steel wire was passed, which was attached to a traction machine.

Exclusion criteria are shown on Chart 2.

Implant material employed

We employed anchors made of a titanium alloy, 5.0 mm wide (reference 7210181, "Dyonics"[®]) as those used in arthroscopic surgeries. They consist of a handle and a shaft, in which tip the anchor already prepared with the steel wire is positioned (Figure 1).

Methodology for biomechanical evaluation.

Pieces were then taken to Biomechanics Laboratory LIM 41 of IOT-FMUSP and assayed on the Kratos K-5002 mechanical assays universal machine, featuring a 100Kgf load cell. Bone segments were fixed to the assay machine's

Gender: Male
Age group: 20 – 50 years old
Absence of previous traumatic or non-traumatic pathology on proximal humerus musculotendinous and/or bone structure.
Absence of macroscopic anatomical changes.
Causa mortis with no anatomical and/ or local bone quality changes.

Chart 1 - Shoulders inclusion criteria

Humeral anatomical injury during pieces preparation.
Surgical technique error (bad positioning of anchors)

Chart 2 – Shoulders exclusion criteria

wise, remaining at a 10-cm standard distance from traction hook, where wires were fixed (k). Traction test was then initiated to each anchor separately, from zero Newton, at a speed of 20mm/min, until maximum tensile strength was achieved, with force measurement recorded in Newtons and deformation in millimeters. Traction alignment, as well as traction direction was parallel to anchor's axis, in which no forces dissociation exist. Each implant was submitted to the same experimental sequence.

Parameters analyzed at elasticity limit were maximum force (N), maximum deformation (mm) and stiffness(N/mm). (Johnson's method) (Figures 2 and 3).

Statistical Analysis of Results

Values obtained in mechanical evaluation were compared by using previously standardized simulations, at a significance level of 5%. That is, if when studying spongy vs. cortical paired data we had parametric data we would use the paired t statistical test. Since data were not parametric, we used the Wilcoxon's test.

RESULTS

The results achieved show that there was no significant difference on maximum force for loosening anchors both in cortical and spongy bone. The average loosening force at cortical bone was 291.8 N with minimum force of 156.8 N and maximum 482.9 N. Standard deviation was 125.7 N. At the spongy bone, the average loosening force was 287.1 N with minimum force of 125.9 N and maximum 526.4 N. Standard deviation was 133.5 N. (Table 1)

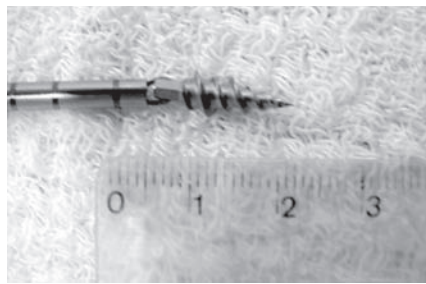


Figure 1- Smith and Nephew (Dyonycs®) anchor

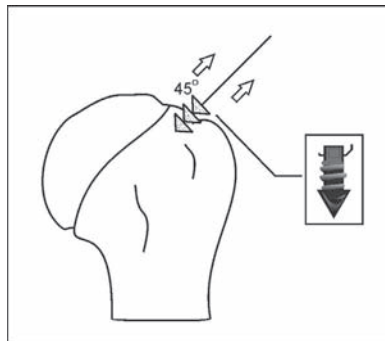


Figure 2 - Anchor insertion on cortical bone

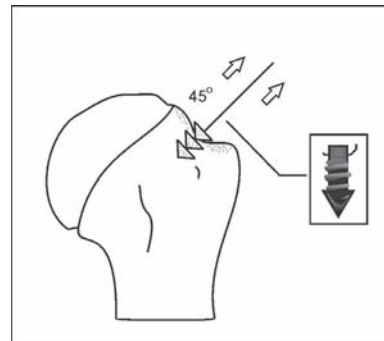


Figure 3 - Anchor insertion on spongy bone with bone trough performance

	Maximum force [N]	
	Cortical	Spongy
Pair 1	442.4	482.7
Pair 2	295.3	153.9
Pair 3	243.5	292.9
Pair 4	455.4	417.0
Pair 5	156.8	280.4
Pair 6	198.5	207.9
Pair 7	284.1	218.8
Pair 8	482.9	526.4
Pair 9	281.2	184.0
Pair 10	284.8	125.9
A	291.8	287.1
SD	125.7	133.5
ASE	37.9	40.2
Min	156.8	125.9
Max	482.9	526.4
N	10	10

Wilcoxon's test $p = 0.9658$ n.s. (non significant)
A=Average SD=Standard deviation
ASE=Average standard error
Min=minimum value Max=maximum value
N = sample number

Table 1 - Descriptive statistics of cortical and spongy groups' maximum force. Comparison by Wilcoxon's test.

DISCUSSION

Suture metal anchors currently constitute the main implant used in rotator cuff repair surgeries, allowing for a lower level of per-surgical morbidity and shorter surgical time ⁽⁶⁾.

Even with its increasing use and with improvements of surgical techniques, anchors fixation in humeral bone

technique is still a significant problem in rotator cuff injuries repair ⁽⁷⁾. There are some studies reporting biomechanical studies on tensile strengths of tendon sutures with the use of bone fixation anchors (either threaded or not) comparing them to transbone sutures. However, there

are few studies showing only resistance tests of anchors on bone surface ⁽⁶⁾.

Anchors loosening before tendon healing may cause surgical failure due to a gap between the tendon and the bone, precluding rotator cuff reinsertion ⁽⁷⁾.

The edges of an injured rotator cuff are fibroid and non-vascularized. Those must be repaired up to an area where the tendon is strong and vascularized. A vascularized bone bed favors reinsertion and promotes a better lever arm, keeping an adequate level of tension for the reinserting tendon ⁽¹³⁾.

Studies show that the insertion of anchors with 45° bending to humeral head bone surface is the most stable and tensile-strong biomechanical position of the rotator cuff ⁽¹⁴⁾. Therefore, in the present study, anchors were inserted with 45° bending, as traditionally performed in surgeries.

Traction direction of the anchor was in parallel to its insertion axis, corresponding to the maximum stressed force for loosening. In clinical situations, this stress tends to be lower.

Another discussion point is regarding the best kind of anchor and the best place to insertion. Recent studies show that threaded

anchors present a better bone fixation than the hook-type ones. Other studies also show that the major tuberosity peak (in its medial and proximal portion) is the place with the highest bone density, and where the highest tensile strength was found. In our study, threaded metal anchors were placed at that site targeting a higher fixation strength ⁽¹⁵⁾.

We observed that the mean loosening force on cortical bone was 291.8 N and on spongy bone, 287.1 N, not evidencing any significant difference between each other. It is important to highlight that those loosening values, both in cortical and spongy bones, are much higher than deforming forces of in vivo rotator cuff fibers, which makes us believe that those implants warrant a good fixation in both beds ⁽¹⁵⁾.

In the present study, we pursued the evaluation of all variants susceptible to bias (best kind of anchor, best insertion site, best insertion and traction angle) in order to achieve a result reliable and reproducible to clinical needs.

CONCLUSION

No difference was observed on the resistance to loosening of anchors fixated both in cortical and spongy bones after performing a bone trough. The tendinous reinsertion on bone trough may benefit cuff's integration without losing anchor's fixation resistance, and could combine the advantage of a minimally invasive technique, as arthroscopic surgery, with a rotator cuff fixation and integration as seen in open surgeries.

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