INFLUENCE OF THREADED ANCHORS DIAMETER AND INSERTION ANGLE ON TENSILE STRENGTH

ELPÍDIO DA GRAÇA[1], CLÁUDIO HENRIQUE BARBIERI[2], NILTON MAZZER[3], ANTÔNIO CARLOS SHIMANO[4]

SUMMARY

The avulsion strength of threaded anchors with 3.5 and 4.5 mm diameter was assessed by using pigs' frozen fresh femurs as a model and an assay universal machine. The major trochanter was dried and the anchors, mounted with a flexible steel wire for enabling its fixation on the assay machine, were inserted into the spongy bone near femoral head edge, at 30°, 60° and 90° with femoral diaphysis longitudinal axis. The specimens were fixed on the assay machine and traction was continuously applied at a ratio of 1 mm/ minute until assembly failure occurred. Data concerning maximum load applied, load at proportionality limit, stiffness and resiliency were recorded and compared (p<0.05). The results showed that the maximum load, the load at proportionality limit, and the resiliency were significantly higher (p=0.04, p=0.01 and p=0.02, respectively) for 4.5-diameter anchors inserted at 60°, compared to other angles and to 3.5-diameter anchors at any angle. Load at proportionality limit and stiffness were not significantly different for anchors of both diameters and for different insertion angles.

Keywords: *Shoulder; Tensile Strength; Experimental development; Swine.*

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INTRODUCTION

Reinsertion of tendons into bones has always been a problem for orthopaedic doctors, who, during many years, had only transbone sutures available, which are always hard to deal with. Then, general use staples have been made available, most of them inappropriate to reinsertion of more delicate tendons or for specific anatomical regions, such as the shoulder. Surgical anchors were designed in the late 1980's with the purpose of providing surgeons with a more appropriate means for performing most of the surgical procedures involving soft tissues fixation on bones. As known today, the first surgical anchor was designed as a self-threading titanium screw, equipped with suture made of polyester wire, which was shown to be more user-friendly and safer than the methods previously available, including transbone sutures[1,2,3].

The great advancements experienced by arthroscopic surgery, also in late 1980's, were, at least partially, due to the development of surgical anchors, which enabled the introduction of procedures such as arthroscopic repair of Bankart injuries and of the rotator cuff, allegedly more advantageous than open procedures [4-9]. After its early introduction, many different kinds of anchors have been developed, widely differing in design (threaded, hook-shaped, harpoon-like), material (stainless steel, titanium, absorbable or non-absorbable polymers) and dimensions, each one appropriate for a specific use, but always focused on the idea of enabling an easier and faster surgery.

One of the requirements for suture anchors is that it must resist to avulsion, keeping tendon or other soft tissues as next to the bone as possible for the time required for healing to occur. It has been already reported that threaded anchors' resistance to avulsion is directly proportional to its diameter [10-13] *; on the other hand, there is a generalized idea that insertion position may also play an important role in providing resistance required for fixation, but the most appropriate position does not seem to be fully determined. Particularly regarding the rotator cuff, based on the observation of the role played by the support post placed at 45º bending on farm fences ("deadmen"), Burkhart [14] suggested that anchors should be introduced at that angle to cuff's traction orientation, forming an acute angle with it. Reed et al. [15] and Gartsman and Hammerman[6] suggested that, when repairing a rotator cuff, the anchor should be inserted at 90º (perpendicular) to traction orientation, with the shoulder at 30º of abduction. Other authors suggested different orientations: 90° to joint surface [13], 45° to 60° to bone surface[16], 60° to humeral head joint surface line[17], or "less than 45º between the anchor and the traction orientation at the major tubercle juxta-articular zone" **, not specifying if oriented proximally or distally, or pointing to traction orientation or to the opposite direction. No specific references were found

* Mitek Products. Fastin®, 1998-2000. Available from http://www.mitek.com/Pages/fs-product.html. Access: October 10, 2000.

Study conducted at the Department of Biomechanics, Medicine and Locomotive Apparatus Rehabilitation (Bioengineering Laboratory). USP Medical School, Ribeirão Preto

Correspondences to: Cláudio Henrique Barbieri Departamento de Biomecânica, Medicina e Reabilitação do Aparelho Locomotor. Faculdade de Medicina de Ribeirão Preto – USP - Campus Universitário - CEP: 14049-900 - Ribeirão Preto - SP - BRAZIL - E-mail: chbarbie@fmrp.usp.br

1 - Orthopaedic doctor, Student of Post-Graduation Course, Mastery Level.
2 - Orthopaedic doctor, Chairman, Coach.
3 - Orthopaedic doctor, Associate Professor, Co-coach.
4 - Mechanical Engineer, PhD Professor, Associate.

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on anchor insertion angle or in other locations except at rotator cuff.

As it seems that no agreement exist about the topic, the objective of this study was to test, in an experimental model, the influence of diameter and insertion angle over threaded anchors' resistance to avulsion.

MATERIALS AND METHODS

Sixty nine fresh femurs of 5-month old Landrace pigs, of both genders, which were killed in a local slaughterhouse submitted to strict sanitary control, have been used in this experiment. Bones were carefully cleaned from all soft parts debris, and inspected for gross abnormalities, measured (average height: 17.9 cm; range: 17 - 18,5 cm), weighted (average weight: 322 g; range: 280 - 400 g), submitted to X-ray tests on two planes, in order to detect any consistency or previous fracture abnormality, identified, vacuum-packed in plastic bags and stored in freezer at -20º C for approximately two weeks [18]. They were removed from freezer 12 hours prior to experiment and allowed to unfreeze at room temperature [19]. Major trochanter and the distal condylar region were resectioned with a circular saw with thin threads; the first one was used for allowing anchors insertion directly on femoral head's spongy bone, and; the last one, for enabling an easy fixation of the bone at the assay machine.

Commercially available self-threading 3.5 and 4.5-mm diameter titanium anchors were employed. A malleable multifilament steel wire (20 cm long, 1 mm wide, maximum tensile strength 450 N) was passed through anchor's eye, forming a double loop with ends firmly attached by a simple knot, and, then, with a metal sheath manually compressed in three points for preventing sliding; a distance of 60 mm was standardized between the anchor and the knot (Figure 1).

A variable angle guide was specially made for inserting anchors always according to desired angle towards the diaphyseal longitudinal axis. A 2-mm wide hole was opened on bone, about 10 mm below femoral head's epiphyseal line, exposed by major trochanter resection, and the anchor was manually inserted directly on spongy bone, until only the steel wire was exposed (Figure 2). Control X-ray images were taken

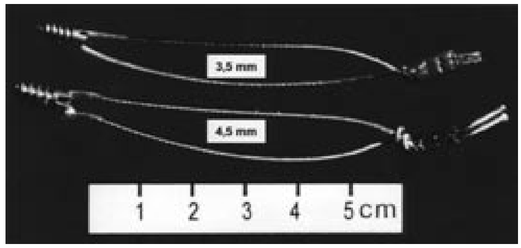

Figure 1 - *Details of the 3.5 and 4.5 mm anchors mounted with a 6-cm steel wire loop.*

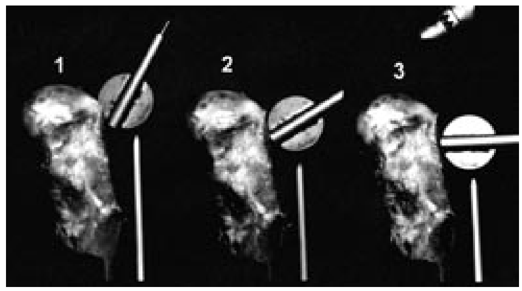

Figure 2 - *Holes perforation according to insertion angle towards femoral longitudinal axis. A) 30˚; B) 60˚; C) 90˚.*

Figure 3 - *X-ray controls of inserted anchors: A) 30˚; B) 60˚; C) 90˚; D) Insertion angles diagram.*

Figure 4 - *Specimen fixated on the universal assay machine, with longitudinal axis bent at 30˚ with horizontal line, simulating an abduction of 30˚. The steel wire connected to the anchor is attached to the machine´s upper accessory and traction orientation is strictly vertical.*

from all specimens in order to assure that the anchors were at the right angles and depths (Figure 3).

Bones were divided into six groups of ten specimens each. From Group 1 to 3, 3.5 mm anchors were used, inserted at angles 30º, 60º and 90º, respectively, the first two forming an acute angle to traction orientation, and the last, perpendicular to it. From Group 4 to 6, 4.5 mm anchors were employed, also inserted according to the same angles and orientations above.

Assays were performed with a universal tests machine equipped with a high-precision load cell up to 200 Kgf attached to an extensiometer for applied load readings, and with a high-precision comparative clock for measuring deformations produced by traction. Specimens were fixed to the machine with a bent diaphyseal longitudinal axis at 30º to the horizontal one, simulating a 30º abduction [20] the anchor's steel wire was connected to the movable upper portion of the machine, so that traction orientation was strictly vertical, just as the rotator cuff would be pulling at the corresponding angle (Figure 4). A 20-N pre-load was applied for 60 seconds for system accommodation purposes, and then, a real load was applied, at a speed of 1 mm/minute, until a sudden drop occurred to the recorded load value, indicating system failure. Applied load values were recorded at 0.1 mm deformations, being expressed as SI units (Newtons for loads and meters for deformations).

Graphs for load vs. deformation were obtained for all assays in order to enable calculation of the mechanical properties of each specimen, namely: maximum load, load at proportionality limit, stiffness and resiliency. An average value was calculated for each parameter in each group, and data were submitted to statistical analysis by Kruskal-Wallis' non-parametric test, comparing results achieved with same diameter anchors and the results achieved with anchors of two different diameters inserted at the same angle.

RESULTS

Ninety six assays were performed, 20 of which with the purpose of establishing technical details, such as

* * Cooper AE. Restoring motion. Orthopedic Technology Review, vol. 2, number 5, 2000. Available at www.orthopedictechreview.com/issues/may00/pg42.htm.

specimens preparation, kind and dimensions of the accessories required for fixing specimens on machine, fixation position and load application speed. The results of those assays were not considered for final calculations. Sixteen assays were discarded due to technical problems, leaving a total of 60 valid assays, which results are summarized on Tables 1 and 2.

Gross examination of specimens after assay showed that, with system failure, the anchor migrated into the hole, always towards traction, but it has been completely avulsioned in no cases. In fact, it rotated around a cross-sectional axis located somewhere between the middle of its length and the end, but it was firmly stuck inside bone, being impossible to manually remove it.

Statistical analysis

Considering the diameter of anchors separately, there was no significant difference between maximum loads for 3.5 and 4.5 mm anchors inserted at any angles (p=0.44 and p=0.06, respectively). Considering insertion angles separately, maximum loads were significantly different between 3.5 and 4.5 mm anchors inserted at 60º (p=0.04), but not at 30º or at 90º (p=0.31 and p=0.57, respectively).

For load at proportionality limit, no significant difference was found between 3.5 and 4.5 mm anchors inserted at any angle (p=0.09 and p=0.60, respectively). When insertion angles were separately considered, there was a significant difference between 3.5 and 4.5 mm anchors inserted at 60º (p=0.01), but not at 30º or 90º (p=0.33 and p=0.17, respectively).

Stiffness was not significantly different angle by angle for anchors of both diameters (p=0.38 and p=0.61, respectively), as well as no significant difference was found between anchors of both diameters (p=0.62 for 30°, p=0.47 for 60°, and p=0.97 for 90°) for each insertion angle separately.

Lastly, resiliency was not significant angle by angle for anchors of both diameters (p=0.06 and p=0.08, respectively). Similarly to what was found for maximum load and load at proportionality limit, there was no significant difference between 3.5 and 4.5 mm anchors only for 60º insertion angle (p=0.02), but not for 30º or 90º (p=0.09 and p=0.16, respectively).

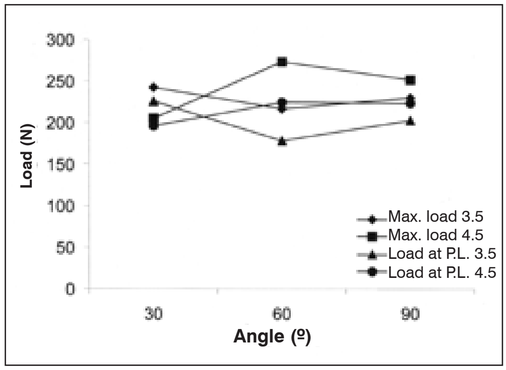

Figure 5 - *Graph representing the behaviors of maximum load and load at proportionality limit, showing higher resistance of 4.5 mm anchors as opposed to the lower resistance of 3.5 mm anchors at 60º.*

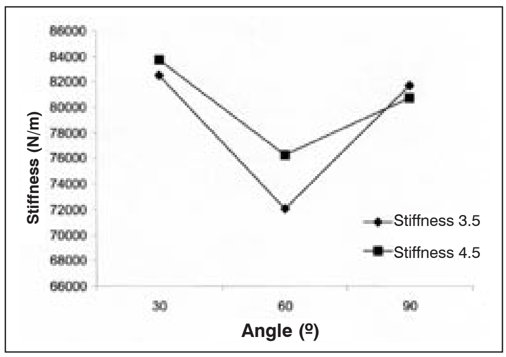

Figure 6 - *Graph representing stiffness behavior, showing a great reduction for 3.5 and 4.5 mm anchors at 60º, evidencing the higher flexibility of both at this angle.*

Table 1 - *3.5 mm anchors.*

Average maximum load 242.68 N (range: 124.07 N – 332.02 N) at 30° 216.30 N (range: 139.94 N – 321.34 N) at 60° 230.07 N (range: 204.43 N – 275.28 N) at 90°
Load at proportionality limit 225.29 N (range: 119.36 N – 314.68 N) at 30° 178.03 N (range: 131.61 N – 258 N) at 60° 202.67 N (range: 170 N – 255.68 N) at 90° (Figure 5)
Average Stiffness 82.536 N/m (range: 49.734 N/m – 121.600 N/m) at 30° 72.067 N/m (range: 45.153 N/m – 107.892 N/m) at 60° 81.719 N/m (range: 65.200 N/m – 97.731 N/m) at 90° (Figure 6)
Average resiliency 0.281 J (range: 0.084 J – 0.457 J) at 30° 0.198 J (range: 0.105 J – 0.389 J) at 60° 0.219 J (range: 0.176 J – 0.360 J) at 90° (Figure 7)

DISCUSSION

The use of metallic implants for tendons reinsertion into bones was introduced aiming to provide a faster and safer procedure compared to transbone sutures. Due to the high degree of complications, such as laxity and migration [21,22,23], the staples that were initially used have been progressively replaced by suture anchors [2], which enable an easier surgical procedure and provide as much safety to tendon reinsertion as transbone sutures do [2,13].

Despite of the introduction of other designs, threaded anchors seem to have a superior performance, a characteristic that would be directly proportional to its dimensions, especially regarding diameter, because a wider diameter provides a larger contact surface to the surrounding bone, and, theoretically, a higher tensile strength and avulsion resistance [10,13,24]. A technical detail related to anchors use, apparently as important as diameter, but not fully clarified, is the insertion angle, which was the motivation for our study. Common sense seems to indicate that the insertion at 90º with traction orientation would provide a stronger resistance to avulsion. However, this is not entirely true, because mechanical properties of the bone in which they are inserted may influence anchors behavior, according to insertion angle. Different opinions seem to indicate that the insertion angle does not significantly influence resistance to avulsion, provided it is between 30º, forming a obtuse angle, and 90º with traction orientation (“deadmen”) and forming with that an acute angle as suggested by Burkhart[14,25], would theoretically add more resistance to fixation. This is a specific recommendation in cases of rotator cuff reinsertion, which does not apply to other tendons, and, even so, considering humeral head curvature, this angle results in an anchor being positioned almost in parallel to joint surface, thus leaving a small amount of bone tissue between each other, especially at entrance, which might reduce its resistance. However, such hypothesis was not tested in the present investigation, because the authors understood that screws in general, such as the threaded anchor, are intended to resist particularly to axial loads, oriented according to its longitudinal axis and tend to avulse them, with curving tensions being of secondary interest. Thus, anchors inserted at 30º and 60º were distally oriented in order to form an obtuse angle to traction orientation, instead of the acute angle suggested by Burkhart. Furthermore, it was decided that the insertion angle should range from 30º to 90º, at 30º intervals, because the majority of authors report insertion angles within this range; additionally, shorter intervals (15º and 20º, for example) would be less applicable from a surgical point of view.

The geometric reference for determining an insertion angle also varies according to the author, with some reporting an estimated traction orientation in the cuff [6,14,15,25], and others, the orientation of bone surface at insertion site. In the present investigation, the first step was to determine the lateral cortical of the bone as a geometrical reference for anchors insertion angle, even because this is easier to determine. Following, 3.5 and 4.5 mm anchors were selected because these are the most frequently used ones on the shoulder, despite of the introduction of 6 mm anchors.

Pig femur was chosen as a model because the consistency of spongy bone at the neck region is close to human spongy bone [15,18]. Although this model could be criticized, as any other experimental model in the same situation, this is certainly better than wood models, which could be an alternative, especially when obtaining human bones is very difficult, both from logistic and standardization perspectives. The major trochanter was resectioned on models aiming to expose a spongy bone just below femoral head's growth plate [10], so that the anchors were inserted in a similar way to what is performed on human beings, in cases of rotator cuff reinsertion. The femur was fixated to the assay machine at a 30º angle with horizontal simulating a slight abduction [20] and the steel wire connected to the anchor was tractioned vertically, tangentiating femoral head as a pulley, in a way that mimicked traction orientation of the supraspinal tendon [13,14].

For any of the parameters assessed, the results achieved in the present investigation showed that threaded anchors are very resistant to avulsion in a similar way for both diameters tested, with differences between both being not significant at 30º e 90º. However, at 60º the resistance to avulsion (maximum load, load at proportionality limit, and resiliency) was significantly higher for 4.5 mm anchors (Table 2, Figure 5), a phenomenon that was accompanied by stiffness reduction for both diameters (Figure 6).

The reason for resistance to avulsion to be reduced for 3.5mm anchors and to be increased for 4.5 mm anchors at 60º is not fully understood. The authors of this study interpreted that the maximum performance of 3.5 mm anchors occurs when traction is transversally oriented, or, inversely, almost parallel to insertion angle, because resiliency is provided both by surrounding bone mass at 90º - which holds it firmly - and for the thread in close contact with the bone at 30º (screws resistance to previously mentioned axial load). Between these end points, none of the two mechanisms is totally efficient for 3.5 mm anchors, of which smaller surface cuts through the bone, making it to rotate around a cross-sectional axis located between its medial third and its end; the addition of 1 mm in 4.5 mm anchors makes all the difference. The fact that stiffness was reduced for anchors of both diameters at 60º shows that both are more flexible at this angle, with 4.5 mm anchors absorbing more energy (resiliency) before system failure. These results somehow conflict to those by other authors and producers, who state that an anchor's resiliency to avulsion always increase with diameter.

Table 2 - *4.5 mm anchors.*

Average maximum load 205.49 N (range: 87.61 N – 294.69 N) at 30° 273.29 N (range: 223.64 N – 324.28 N) at 60° 251.39 N (186.40 N – 352.71 N) at 90°
Load at proportionality limit 195.72 N (range: 79.28 N – 280 N) at 30° 223.75 N (range: 183.75 N – 283.42 N) at 60° 223.68 N (range: 179.34 N – 295 N) at 90° (Figure 5)
Average stiffness 83.759 N/m (range: 38.852 N/m – 127.314 N/m) at 30° 76.267 N/m (range: 56.706 N/m – 102.826 N/m) at 60° 80.760 N/m (range: 65.360 N/m – 96.689 N/m) at 90° (Figure 6)
Average resiliency 0.203 J (range: 0.104 J – 0.337 J) at 30° 0.295 J (range: 0.171 J – 0.417 J) at 60° 0.278 J (range: 0.149 J – 0.406 J) at 90° (Figure 7)

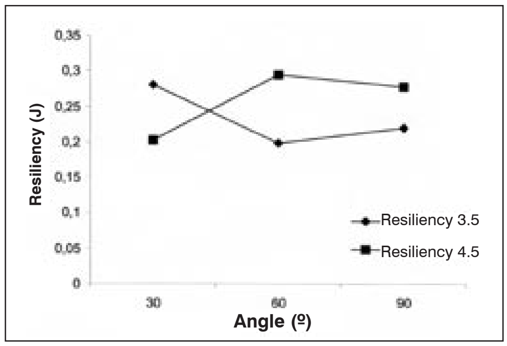

Figure 7 - *Graph representing resiliency behavior, showing its increase for 4.5 mm anchors and its reduction for 3.5 mm anchors from 30° to 60° and 90°, evidencing that 3.5 mm anchors absorb more energy at 30° and 4.5 mm anchors, at 60° and 90°.*

Barber and cols.[10] discussed about what would be better in terms of number of anchors to be used for reinserting rotator cuff: would two smaller gauged anchors result in stronger resistance to avulsion than a wider one? Based on the results achieved here, the first alternative would probably be more appropriate, because smaller gauged anchors produce less damage to receptor bones, while a higher number of anchors would provide a better load distribution, as evidenced by Burkhart and cols.[26].

Surgeons must be aware that, from a surgical perspective, neither anchors diameter nor insertion angle can assure, either alone or in conjunction, fully satisfactory results [15], because the reinsertion's resistance to avulsion depends on other factors, such as a proper adhesions release, the quality of injured tendinous tissue and bone, suture technique and material, healing process, and others [23,27,28]. For example, the same anchors and angles studied here would certainly have a different performance on an osteoporous bone in the elderly.

Considering the results achieved, the authors conclude that both 3.5 mm and 4.5 mm anchors may be used at 30º or 90º, with similar performance; for insertions at 60º, 4.5 mm anchors should be preferred because of their superior performance. Although the results refer to the use of a single anchor, this conclusion is probably also true when two or more anchors are required.

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