의학석사 학위논문

The effect of the insertion angle and pulling angle on the pullout strength of all-suture type anchors

- A biomechanical study -

All-suture type 봉합 나사의 삽입 각도와 당김 각도가 뽑힘 강도에 미치는 영향

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Abstract

Introduction:

The pullout strength of the all-suture type anchor (ASA) at the bone-anchor interface was measured based on the angles of anchor insertion and anchor pulling. Data were evaluated with regard to the deadman theory.

Materials and Methods:

Synthetic sawbones of two different densities (0.16 g/cm^2 and 0.32 g/cm^2, representing low and high bone density) with a 3-mm-thick cortical bone model attached on one side were used. ASAs for rotator cuff repair were inserted at 45º, 60º, 70º, or 90º to the surface. Sutures were pulled at two different angles from the surface: 45º (modeling the physiologic pull of the supraspinatus) and 90º (modeling pulling out during knot tying). Pullout tests were conducted using a mechanical testing machine, and the maximum load to failure (N) and failure mode were recorded. Five consecutive tests for each insertion and pulling angle combination per sawbone were conducted (80 tests total).

Results:

Pullout strength for high-density bones was significantly higher than that for low-density bones (p = 0.001). For low-density bones, there was no significant difference in ASA pullout strength for insertion angle degree. However, more vertically inserted ASAs showed stronger pullout strength for high-density sawbones. Pullout strength of anchors inserted at 90º and 75º was significantly higher than that for anchors inserted at 45º, regardless of pulling angle (all $p < 0.05$), but marginally significantly higher than that for those inserted at 60º ($p = 0.313$, 0.06). The pullout strength of anchors pulled at 45º was higher than that for those pulled at 90º (all $p < 0.05$).

Conclusions:

This study suggests that ASA's desirable insertion is vertical rather than at the deadman's angle. However, the ASA showed stronger pullout strength when pulled in the physiologic direction of the supraspinatus tendon rather than in the knot-tying direction, corresponding to the deadman theory.

Implanting ASAs vertically may be beneficial clinically when performing knot-tying during surgery and when it is pulled by the supraspinatus tendon after surgery.

Keywords: All-suture type anchor; deadman's angle; insertion angle; pullout strength

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Introduction

Rotator cuff repair by tendon re-fixation on the tuberosity of the proximal humerus has been performed to relieve shoulder pain and restore functional impairment associated with rotator cuff tears[1, 2]. Recently, due to the advancement of shoulder arthroscopy, suture anchors have gradually replaced trans-osseous sutures, which have been the “gold standard” procedure for rotator cuff repair;[3, 4] thereby, suture anchors have gradually evolved. The metallic suture anchor was a first-generation anchor that provided stable fixation but showed complications such as loosening, metallic artifacts on postoperative images, and intra-articular migration that resulted in cartilage damage[5, 6]. To avoid these problems, biodegradable suture anchors were developed as second-generation anchors[7]. They were expected to have some advantages, including easier revision, less postoperative imaging artifacts, and hardware resorption. However, complications associated with the bioabsorbable materials have been found, including foreign-body reactions, synovitis, and intra-articular inflammatory reactions[8]. In particular, the prevalence of peri-anchor cyst formation following rotator cuff surgery has been reported to reach nearly 50%[9, 10]. Newer generation, all-suture anchors (ASAs) with a reduced diameter composed of textile materials with no rigid components were developed to minimize the invasiveness and complications related to the use of rigid materials[11]. These anchors require a bone tunnel <3 mm, smaller than that required by the screw-type anchors (SAs), allowing for multiple fixations. Even though several biomechanical studies have reported that there was no significant difference in pullout strength and displacement between the ASA and SA, many surgeons have been concerned about weaker fixation of ASAs into the bone[11, 12].

Anchor pullout is one of the devastating complications that can occur after arthroscopic rotator cuff repair, resulting in re-tearing, intra-articular cartilage damage, and postoperative pain. Therefore, anchors should be fixed firmly to the bone, at least during the biologic process of tendon-to-bone healing. However, not all types of anchors have the same pullout strength. Fixation strength depends on the design of the anchor, density of the bone, and insertion angle as well as the pulling angle. From the viewpoint of the insertion angle, there have been numerous studies to evaluate the ideal angle to ensure stable fixation[13]. In 1995, Burkhart proposed the deadman's angle theory, using a mathematical evaluation of the forces involved in rotator cuff repair[14]. He used trigonometric calculations to show that minimizing the angle of suture anchor insertion and the angle that the suture makes with the cuff can increase the pullout strength of the anchor and reduce tension in the suture. However, some recent biomechanical studies have failed to demonstrate the strongest pullout strength when the anchor is inserted at the deadman's angle, which has been topic of contention until now(15-19).

The fixation mechanism of the ASA is distinct from that of the conventional SA. If strands of the ASA are tensioned after being inserted into the pre-drilled hole in the bone, it would be locked in the hole by increasing its effective diameter. Accordingly, a question whether to obey the deadman theory could be presented. In spite of the increasing use of the ASA, there have been relatively few biomechanical studies on its surgical techniques, including the insertion angle of the ASA to enhance its pullout strength. Furthermore, the author has experienced some cases of ASA pullout during knot-tying and could not feel tightness in the anchor implantation, unlike with the rigid SA. There is also a need to study the ASA's load to failure with respect to surgical techniques. Therefore, these authors evaluated the pullout strength of ASAs at the bone-anchor interface with regards to the angle of anchor insertion and the angle of anchor pulling, compared with those for SAs, as reported by previous studies. The hypotheses were that the ASA would correspond to the deadman theory and therefore that 1) the pullout strength would increase as the bone density increases, 2) the ASA inserted at an acute angle to the bone surface would have stronger pullout strength than it would when inserted at a vertical angle, and 3) the ASA pulled at 45° would be harder to pull out than it would be at 90°.

Materials and Methods

Synthetic bone

Polyurethane bone blocks (Sawbones®, Pacific Research Laboratories, Vashon, WA) were used because they have been previously validated in suture anchor pullout biomechanical studies and provide lower inter-specimen standard deviation in pullout strength. Two different densities of cellular rigid polyurethane foam were used to represent cancellous bone in biomechanical testing. As the mean bone mineral density is 0.36 g/cm^3 for the greater tuberosity of the proximal humerus[20], polyurethane cellular foam blocks of 0.16 g/cm^3 and 0.32 g/cm^3, respectively, were used to simulate cancellous bone of low and high density[21-23]. For low bone density, 10 pcf (pound per cubic foot; 0.16 g/cm^3) were selected, as it is commonly used as an osteoporotic cancellous bone substitute[21]. Considering Young's modulus and yield strength values, the 0.16 g/cm^3 foam blocks may be suitable as an osteoporotic bone model for mechanical testing[24]. Previous studies demonstrated the optimum insertion angle of the SA utilizing the 0.32 g/cm^3 foam blocks to simulate non-osteoporotic cancellous bone. Therefore, 20 pcf (0.32 g/cm^3) were chosen to enhance the performance of biomechanical testing, as recommended for determining the appropriate synthetic bone density based on a measure of bone volume fraction[22, 23].

As Tingart et al. reported that the mean cortical thickness of the proximal humerus was 4.4 ± 1.0 mm, we attached a 3-mm-thick cortical bone model (short fiber-filled epoxy) on one side of the rigid bone block to mimic human cancellous bone[20, 22, 23].

All-suture type anchors application

We utilized the 2.9-mm OmegaKnot® (ARC, Seoul, Korea; Fig. 1) as an all-suture type anchor. Fixation of anchors was conducted in accordance with the manufacturers' recommendations, as below. After pre-drilled pilot holes were made, the OmegaKnot® anchor was advanced with a mallet until the proximal laser mark was flush. Then, the sutures were unwound from the anchor handle cleats, followed by removing the handle. When both suture strands were lightly pulled to be deployed into a suture ball, anchor slippage occurred until it was moved to the cortical bony undersurface and seated in the subchondral bone. The anchors were inserted at 45º, 60º, 75º, or 90º to the bone surface using a specially designed guiding apparatus made according to every insertion angle. (Fig. 2)

Fig. 1. A 2.9-mm OmegaKnot® (ARC, Seoul, Korea) was deployed until it reached the subcortical bone and formed into a “suture-ball”.

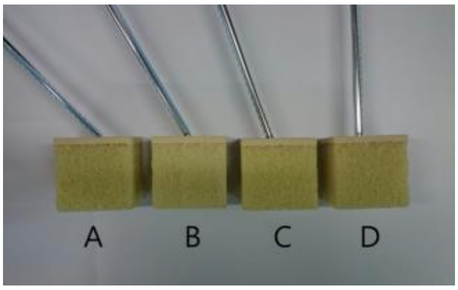

Fig. 2. Various insertion angles of the all-suture anchor to the synthetic bone are shown. A) 45º; B) 60º; C) 75º; D) 90º.

Mechanical test protocol

After the synthetic bone blocks were set up in a special jig, pullout tests were conducted using a mechanical testing machine (Z005, Zwick/Roell®, Germany). Sutures were hand-tied around the hook of the load cell to make the tensioned strings the same length (20 cm). Sutures were pulled at two different angles from the surface: 45º, corresponding to the physiologic pull of the supraspinatus tendon after rotator cuff repair, and 90º, corresponding to the situation for pulling out in the direction of knot-tying during rotator cuff surgery (Fig. 3). Anchors were preloaded at 10 N and pulled at 0.8 mm/s. Failure was defined as anchor disengagement from the bone or breakage of the suture strand. The maximum load to failure (N) and the mode of failure were recorded.

Fig. 3. Two directions in which the all-suture anchor was pulled in the using universal testing machine are shown. A) 45º, corresponding to the physiologic pull of the supraspinatus tendon; B) 90º, corresponding to the situation for pulling out during knot-tying.

Statistical analysis

The sample size calculation was performed with a significance level (a) =

0.05 and power (1-b) = 0.90. On the basis of a previous report by Strauss et al., we estimated a relevant clinical difference for the load to failure of 0.2 and a predicted standard deviation (SD) of 0.1[16]. The total required sample size in each group was 5; thus, 5 consecutive tests were conducted at each insertion angle and pulling angle per sawbone density, making 80 tests in total. All statistical analyses were performed using the SPSS Statistics software program (version 22; IBM, Armonk, NV). Differences in pullout strength between pulling angles and insertion angles for 2 different synthetic bones were analyzed using the unpaired t-test. *P* values of < 0.05 were considered statistically significant.

Results

Pullout strength of all-suture type anchors

The pullout strength of anchors inserted at various angles with pulling at 45º and 90º for both the low- and high-density synthetic bones are displayed in Table 1. The pullout strength of anchors inserted at 45º, 60º, 75º, and 90º on the low-density bone and pulling at 45º was 167.82 ± 45.56 N, 205.50 ± 46.74 N, 185.62 ± 33.86 N, and 195.66 ± 49.45 N, respectively. When the anchors were pulled at 90º from the surface, their pullout force was 170.67 ± 42.91 N, 206.27 ± 52.35 N, 169.29 ± 29.20 N, and 181.89 ± 30.72 N, respectively. There was no significant difference in the pullout strength of ASAs in the low-density bone in terms of pulling angle and insertion angle (Fig. 4).

Table 1. Average pullout strength at each insertion angle, pulled angle, and bone density

Pulling angle (º)	Insertion angle (º)	Pullout strength at low bone density (N)	Pullout strength at high bone density (N)
45	45	167.82 ± 45.56	381.14 ± 19.84
45	60	205.50 ± 46.74	427.56 ± 29.24
45	75	185.62 ± 33.86	467.21 ± 28.07
45	90	195.66 ± 49.45	464.09 ± 35.08
90	45	170.67 ± 42.91	297.69 ± 40.64
90	60	206.27 ± 52.35	351.40 ± 64.63
90	75	149.29 ± 29.20	408.438 ± 20.52
90	90	181.89 ± 30.72	411.69 ± 87.31

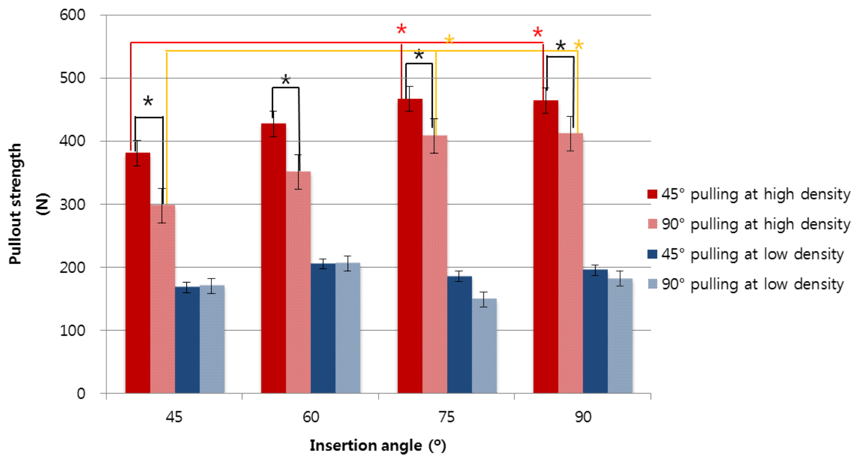

Fig. 4. Pullout strength at various all-suture anchor insertion angles and pulling angles for two types of sawbones (high-density and low-density) are shown. The asterisk indicates a statistically significant difference.

The pullout strength of anchors inserted at 45º, 60º, 75º, and 90º into the high-density bone and pulling at 45º was 381.14 ± 19.84 N, 427.56 ± 29.24 N, 467.21 ± 28.07, and 464.09 ± 35.08 N, respectively. For the anchors pulled at 90º from the high-density synthetic bone, the load to failure was 297.69 ± 40.64 N, 351.40 ± 64.63 N, 408.438 ± 20.52 N, and 411.69 ± 87.31 N, respectively. The pullout strength with the high-density sawbones was significantly higher than that of the low-density sawbones (p <0.001). The pullout strengths of anchors inserted at 90º and 75º were significantly higher than those for anchors inserted at 45º, regardless of the pulling angle (all $p < 0.05$), but were only marginally significant compared to those inserted at 60º ($p = 0.313$, 0.06). With regard to the pulling angle, the pullout strength of anchors pulled at 45º was significantly higher than that at 90º (all $p < 0.05$, Fig. 4).

Failure mode and traction-force curve

The reason for finishing the biomechanical test in the low-bone-density group was anchor pullout in 40 cases, and no thread rupture occurred. Four anchors under the conditions of 75º and 90º insertion angle with high bone density failed from suture breakage due to strong pullout fixation at the bone-anchor interface, whereas the others failed by being pulled out from the synthetic bone. Figure 5 represents graphically the force-strain curve in the 45°

pullout condition for the synthetic bone of high bone density at the various insertion angles. Analysis of the traction-displacement curves for the ASAs displayed a long, elastic phase representative of the movement of the suture anchor within the drill hole, following a short plateau phase during elastic deformation, which has also been described in a previous study[11]. These phases reflected the manual preload performed by the surgeon to place the anchor under the subcortical bone. Therefore, the amount of displacement measured at the breakpoint would be primarily due to stretch deformation of the suture loop in an *in vivo* situation.

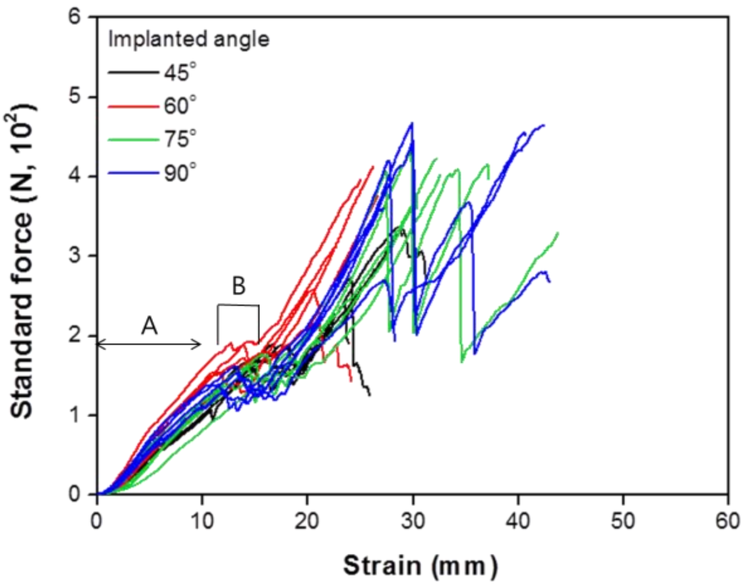

Fig. 5. Traction-force curves for all-suture type anchors (ASAs) in the condition pulled at 45º on the synthetic high-density bone are shown. Analysis of traction-displacement curves for the ASA displays a long, elastic phase representative of

movement of the suture anchor within the drill hole (A), followed by a short plateau phase during elastic deformation (B).

Discussion

We postulated that the ASA would act in accordance with the deadman theory, because the ASA fixed under cortical bone without properties of threads seemed to be more similar to a block buried in the ground, which is postulated in the deadman theory. However, the current biomechanical study revealed that the fixation strength of the ASA was more stable in the higher density bone, when it was inserted at a vertical angle, and when it was pulled in the physiologic direction.

Bone density plays an important role in determining the pullout strength of conventional suture anchors as well as screws for traumatic fracture. Poor bone quality and osteoporotic bone may lead to anchor loosening and inhibit tendon-to-bone healing[25]. Meyer et al. reported that cancellous bone mineral density had a linear relationship with the pullout strength of conventional suture anchors[26]. Another study showed that a 50% increase in trabecular bone density resulted in a 53% increase in fixation strength[27]. Additionally, Pietschmann et al. demonstrated a significant decrease in maximum failure load for SAs inserted into a osteopenic humerus[28]. Tingart et al. found that the failure load of metal suture anchors was significantly related to the cortical bone mineral density of tuberosities of the humerus[20]. The current results, in which higher failure loads of the ASA were revealed in the bones with higher bone mineral density (BMD), are in agreement with those of previous biomechanical studies using conventional suture anchors. In the present study, the ASA inserted into low-bone-density models was too low to have differentiated value at various insertion angles and pulling angles. During pulling of the ASA, anchors were moved to subchondral bone, following transformation into suture balls resistant to cortical bone, shown as the short plateau phase in the traction-force curve. The quality of subchondral and cortical bone is critical in determining the pullout strength of the ASA. Usually, the subchondral bone plate had decreased thickness under osteoporotic conditions(23). Additionally, the greater tuberosity of the proximal humerus has been reported to have different values of vBMD depending on the location. Tingart et al. demonstrated that the proximal part of the greater tuberosity had greater trabecular vBMD in the posterior part but greater cortical vBMD in the middle part via a cadaveric biomechanical study(20). Oh et al. showed that bone density in the greater tuberosity was the highest in the posterolateral portion and the lowest in the medial portion by measuring region-specific BMD with quantitative computed tomography(29). Therefore, as with the conventional SA, the ASA should be used with caution for anchor locations and osteoporotic bone.

According to the current data, the pullout strength of the ASA inserted at 90º or 75º from the bone surface was stronger than that for anchors inserted at 45º in high-density sawbones, in contrast to predictions made based on the deadman theory. Since Burkhart demonstrated with the deadman theory that the ideal insertion angle of suture anchors was 45º to the bone surface, most surgeons have believed that inserting suture anchors at the deadman's angle had the strongest pullout strength(14). However, several recent studies did not demonstrate the strongest load to failure for anchors inserted at the deadman's angle. Liporace et al. conducted the first biomechanical test using 20 matched pairs of humeri with SAs inserted at 30º, 45º, 75º, and 90º relative to the cortical surface of the greater tuberosity(15). Their results showed no significant difference between groups with various insertion angles, which was not in accordance with the deadman theory. Strauss et al. evaluated what effect the angle of SA insertion has on pullout force at the suture-tendon interface using supraspinatus tendons from 7 matched pairs of cadaveric shoulders(16). They demonstrated that suture anchors placed 90º to the greater tuberosity provided improved soft-tissue fixation compared to that for anchors placed at the deadman's angle of 45º. Sano et al. simulated stress concentration between the proximal anchor threads and the bony surface on the traction side via the 3-dimensional finite element method(19). They reported that insertion of an anchor at 90° reduced the stress concentration more than did 45° in the middle range of traction angles. Insertion of the SA at 90º reduced stress concentration and micro-motion at the bone-anchor interface, resulting in stronger pullout force than that at 45º[18]. These biomechanical studies using conventional SAs showed similar results to those in the current study using ASAs with respect to the insertion angle. However, the reasons for these results for ASAs are understood differently. After the ASA was deployed to reach the subcortical bone and formed a suture-ball, the status of the subchondral bone was one of the most important factors for determining the pullout strength of the ASA. If the ASA was inserted at an acute angle, an ellipse-shaped hole was made on the subcortical bone, causing the suture-ball to pull out more easily than with a circular hole, which developed when the ASA was inserted at a vertical angle (Fig. 6). It is likely that the shape of the suture-ball affects the pullout strength as well.

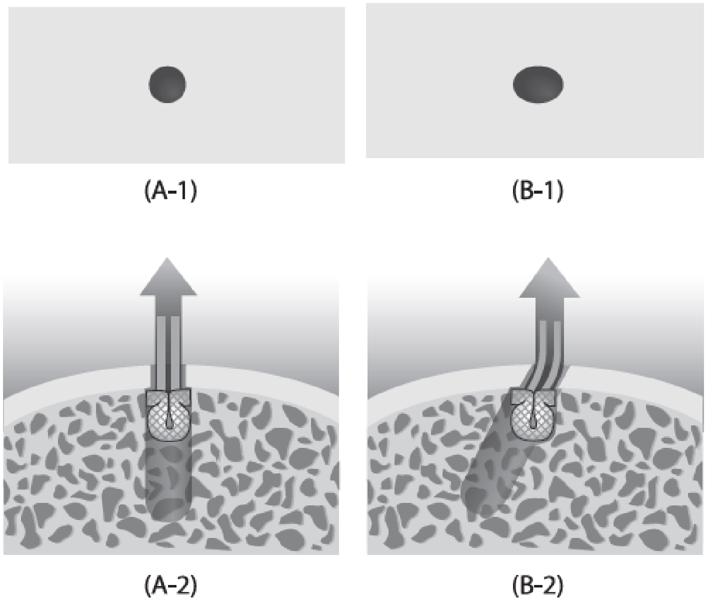

Fig. 6. If the all-suture anchor (ASA) is inserted at a vertical angle, a circular hole was made on the subcortical plate (A-1), causing the “suture-ball” to be compressed evenly to the bony surface area (A-2). However, if the ASA is inserted at an acute angle, an ellipse-shaped hole slightly larger than the circular hole was made (B-1), and it was therefore pulled out more easily (B-2).

Regarding the pulling angle of anchors, the ultimate pullout force for conventional SAs seemed to be greatest when inserted at an angle similar to the angle of the applied load, which is in contract to the deadman theory. Green et al. inserted screw-in metallic suture anchors at 30º, 45º, 60º, and 90º into synthetic cancellous bone blocks(18). Various pulling angles, ranging between 0º and 180º, were applied, and they assessed the effect of the insertion angle and the applied angle on pullout strength. They demonstrated that the pullout strength for each insertion angle was strongest when the angle of pull was similar to the angle of insertion. To explain these results, they focused on the importance of the biomechanical properties of suture anchors. Because a threaded anchor had multiple disks surrounding a central peg, disks were more perpendicular to the direction of pull in the deadman's condition. On the other hand, when inserted at an obtuse angle and pulled parallel to the insertion angle, disks were more in line with the direction of pull; then, much greater surface area of disks could withstand the pulling force. However, the ASA showed higher pullout strength if pulled in the physiologic direction of the supraspinatus tendon (45°) rather than in the direction of knot-tying (90°), which matched the deadman's angle. Thus, using the ASA is expected to have an advantage, especially during the postoperative period, once sutures are passed and tied securely, as the ASA would be more secure than SAs would be with respect to supraspinatus pull.

There are several limitations in the study. First, the current study was a mechanical laboratory test using artificial polyurethane bones; thus, the models may not correspond with the physiologic biomechanics of a dynamic shoulder joint. However, several previous studies reported the biomechanical similarity between the synthetic bones and human cadaveric bones. Furthermore, the pullout strength was tested only at the bone-anchor interface, instead of using the construct of the repaired tendon in human shoulders. Though *in vivo* or cadaveric verification is needed, the current data were meaningful, as this is the first report on the ideal surgical technique (such as the insertion angle) for the ASA. Pullout strength at the tendon-suture interface after rotator cuff tendon repair should be analyzed in a cadaveric study in the future. Second, the conventional SA under the same conditions was not tested and compared with the ASA; therefore, it was not possible to make direct comparisons between the ASA and the SA. However, there have been numerous mechanical pullout strength studies using conventional SAa published in the literature, so indirect comparison seems justified.

In conclusion, the current biomechanical study suggests that the desirable insertion of ASAs should be vertical rather than at the deadman's angle. However, the ASA showed stronger pullout strength when pulled in the physiologic direction of the supraspinatus tendon rather than in the knot-tying direction, which is in accordance with the deadman theory. Therefore, implanting the ASA vertically may be clinically more beneficial when performing knot-tying during surgery and pulled by the supraspinatus tendon after surgery.

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국 문 초 록

배경: 본 연구는All−suture type (ASA) 봉합 나사의 삽입 각도와 당김 방향에 따라 뽑힘 강도가 어떻게 달라지는가를 알아보고, 기존의 deadman 이론과 부합하는지 알아보고, 실제 수술 시 All−suture type (ASA) 봉합 나사의 바람직한 삽입 방법을 제시하고자 한다.

방법: 저밀도와 고밀도를 나타내 는2개의 다른 강도(0.16 g/cm2, 0.32 g/cm2)를 가진 해면골 모형의 한쪽 면에 3mm 두께의 피질골 모형을 붙여 실험에 사용하였다. 회전근 개 봉합술에 쓰이는ASA를 45° , 60° , 70° , 90° 각도로 삽입한 뒤, 봉합사를 수술 후 생체 내에서 극상근이 작용하는 방향인 45ㅇ와 봉합 매듭을 지을 때의 방향인 90° 로 각각 당겨보면서, 최대 뽑힘강도(N) 와 뽑히는 양상을 기록하였다. 2가지 강도의 골 모형에 여러 삽입 각도와 당김 방향에 따른 조합으로 각 조건당 5번의 연속적인 실험하여, 전체 80번의 실험을 수행 하였다.

결과: 이번 연구에 따르면 저밀도에서보다 고밀도의 골 모형에서 뽑힘 강도가 유의하게 크게 나타났다(p = 0.001). 저밀도의 골 모형에서는 삽입 각도 및 당김 방향에 따른 뽑힘 강도 간 차이가 없었으나, 고밀도의 골모형에서는 수직에 가깝게 삽입할수록 뽑힘 강도가 큰 경향을 보였다. 90° 와 75° 로 삽입했을 때가 45° 로 삽입했을 때보다 두 가지 당기는 방향 모두에서 뽑힘

강도가 유의하게 크게 측정되었고(all $p < 0.05$), 60° 보다는 유의하지 않지만 큰 경향을 보였다(p = 0.313, 0.06). 당김 방향에 따라 살펴보면, 고밀도의 골모형에서 90° 로 당길 때보다 45° 방향으로 당길 때 유의하게 뽑힘 강도가 증가하였다(all $p < 0.05$).

결론: 본 연구에서 ASA는 극상근 방향과 봉합 매듭 방향 모두에서 삽입 각도가 수직일수록 뽑힘 강도가 증가하므로 수직에 가깝도록 삽입하는 것이 유리하다는 결론을 얻을 수 있었고, 이는 기존의 deadman의 이론과는 다른 결과이다. 그러나, 당김 방향에 따라 살펴보았을 때, 삽입 각도에 상관없이 수술 중 봉합 매듭을 짓는 방향보다 수술 후 극상근이 당기는 방향에서 뽑힘 강도가 증가하는 것으로 나타났다. 이는 deadman 이론에 부합하는 결과이고, ASA가 수술 중 안정적으로 잘 삽입되었다면 수술 후 뽑힐 가능성이 낮을 것임을 시사한다고 할 수 있다.

주요어: 봉합나사; 데드맨 각도; 삽입각도; 뽑힘 강도

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