Navigation-assisted anchor insertion in shoulder arthroscopy: a validity study

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Abstract

Purpose This study aimed to compare conventional and navigation-assisted arthroscopic rotator cuff repair in terms of anchor screw insertion.

Methods The surgical performance of five operators were compared while using conventional system and the proposed navigation-assisted system in a phantom surgical model and cadaveric shoulders. The participating operators were divided into two groups: expert (n = 3) and novice (n = 2) groups. In phantom model, the experimental tasks included anchor insertion into the rotator cuff footprint and sutures retrieval. Motion analysis camera system was used to track surgeons' hand movements. Surgical performance metric included total path length, count of movements, and duration of surgery. In cadaveric experiments, repeatability and reproducibility of anchor insertion angle were compared among three experts and the feasibility of the navigation-assisted anchor insertion was validated.

Results There was no significant difference in the total path length, the count of movements and time taken, between the conventional system and the proposed system in phantom model. In cadaveric shoulders, however, the clustering of the anchor insertion angle indicated that the proposed system enabled both novice and expert operators to reproducibly insert anchor with an angle close to the predetermined target angle, resulting in an angle error of less than two degrees ($P = 0.0002$).

Conclusion The proposed navigation-assisted system improved the surgical performance of novice to expert level. All experts achieved a high repeatability and reproducibility for anchor insertion. Navigation-assisted system may help to make surgeons be familiar to insertion of suture anchors in right direction easily, even in-experienced, by providing better guidance for anchor orientation.

Level of Evidence A retrospective study (level 2)

Background

Although arthrosopic rotator cuff repair with suture anchor fixation is one of the most common orthopedic surgeries, suture anchors related complications such as anchor protrusion and anchor pullout are commonly happened and could result in failure of the surgery [14,11]. Among several factors that should be considered during anchor insertion, perhaps the most important are insertion location and angle. Whereas the first factor is related to the microarchitecture and bone density of the anatomical footprint at the greater tuberosity [13], the latter concerns the pullout strength when threaded suture anchor was used.

The insertion of the suture anchor at an optimum angle is essential for securing the rotator cuff at the footprint [18]. Itoi et al. showed that threadless and threaded suture anchors resisted pullout strength at insertion angles of 45° and 90°, respectively [1,3,5,9,2].

In the case of chronic rotator cuff tear, severe degeneration of the footprint of greater tuberosity is often found without a clear anatomic landmark. In the absence of a clear reference and limitation of 2-dimensional views, the placement and maintenance of the suture anchor at an optimal angle may be unreliable and irreproducible. Particularly in the case of a novice, the lack of experience in shoulder arthroscopic surgery can increase the chance of having an improper suture anchor insertion. There is, therefore, the need for an improvement in the current suture anchor insertion procedure to reduce errors. Micic et al. has reported a navigation-assisted anchoring technique However, the experiments were conducted only on the phantom and the accuracy was about 2 degrees [16]. The use of navigation-assisted orthopedic surgery (MAKO, Stryker®) has been applied widely for knee replacement to achieve an accurate alignment [19]. We hypothesized that the navigation system could be applied to anchor insertion and therefore, designed this study to 1) assess the construct validity of the navigation-assisted surgical system to enable a novice surgeon to perform anchor insertion procedure in the phantom model, and 2) assess the accuracy and reliability of the designated angle and location of suture anchor insertion into the humeral head for rotator cuff repair, comparing the navigation and conventional techniques in the cadaver. The outcomes expected from this study were an improvement in surgical performance and accuracy of operators in anchor insertion.

Methods

1. Navigation-assisted system for suture anchor insertion

A navigation-assisted system for rotator cuff repair was developed to guide the anchor insertion at an angle close to the preset target angle (Fig. 1-A). This system provided both arthroscopic and navigation views. Unlike typical arthroscopic view, the position of a surgical tool in the navigation-assisted arthroscopic view is marked by an arrow, which turns red and shows a virtual instrument when a surgical tool is not seen on the arthroscopic image, or green when the surgical tool is visible on the image. This augmented reality-based technique allows the operator to keep track of the direction of surgical tools even when they are invisible on the arthroscopy screen, thereby improving the hand-eye coordination of the operator during surgery. To implement this notification function, first optical tracking markers (Passive Sphere Markers, Northern Digital Inc., Waterloo, Canada) were attached to the arthroscope and surgical tools to obtain their location and direction information followed by calibrations of the arthroscope camera, hand-eye, and pivot [4].

The navigation view developed displays a 3D shoulder model and surgical tools from three perspectives, that improve 3D spatial recognition of the relative positions of the patient shoulder and the tool, while supplementing the limited depth recognition of 2D arthroscopic image. The anchor-insertion angle, defined by vertical and horizontal angles, is calculated as the angle between the humerus and the surgical tool, with each vertical and horizontal baseline as a reference, respectively (Fig. 1-B) and displayed real time for operators. The vertical baseline is a straight line that connects the greater tuberosity and the surgical neck, while the horizontal baseline is perpendicular to the vertical baseline, bisecting the lesser tuberosity on a plane that faces the glenoid in front. Defining the ideal target insertion angle against each baseline before anchor insertion, enables the operators to insert anchors at an insertion angle close to the target using the proposed navigation.

To implement the navigation view, location-tracking markers were attached to a shoulder phantom or cadaver, and cadaver-to-image registration [20] was conducted to reproduce the relative positions of the shoulder and the surgical tools in a 3D virtual space. Accuracy of anchor insertion using the navigation system is determined by patient-to-image registration. Fiducial registration error and target registration error were 1.68 mm and 1.34 mm in phantom model, and 3.76 mm and 3.91 mm in cadaveric model, respectively.

2. **Experimental setup**

2.1 Surgical performance analysis in phantom model

The surgical performance using the conventional arthroscopic system and the proposed navigation-assisted system was evaluated by motion analysis (Prime 41; Natural Point, Inc., Corvallis, OR, USA) (Fig. 2-A). The conventional arthroscopic system (IM4000, IM4120; ConMed Linvatec, Utica, NY, USA) was a commercial 4-mm diameter 30 arthroscope with a viewing angle of 105 , whereas the proposed arthroscopic system with navigation technology was a 7-mm diameter 0 arthroscope with a wide viewing angle of 150 (MGB Endoscopy, Seoul, Korea). Both arthroscopic systems have an image resolution of 1920 1080 pixels, and the acquired images were displayed for the participating operators on a full-HD monitor on the experiment table.

Phantom models of the shoulder joint (Arthrex, Naples, FL, USA) were used in this study. All phantom models had same sized rotator cuff tears. All conditions and environment surrounding the participants were applied consistently. Participants included three experts who were shoulder and elbow fellowship trained orthopedic surgeons and two novices who were orthopedic residents with no experience of shoulder arthroscopy. All five operators were right-handed and handled the proposed system first and then the conventional arthroscopic system. Prior to the experiment, all participants were given instructions regarding the arthroscopic tasks and preset portals. Operators conducted a given task once with each of the two arthroscopic systems.

To ensure that the experimental environment for all participants was identical, the positions of the arthroscope, surgical tool, shoulder phantom, and both their hands were preset using an arrangement tool (Fig.2 -B). All participants began their tests by placing their hands on the palm contour of the arrangement tool and finished the tests by laying the arthroscope and surgical tool, as determined in advance. Two anchor insertion spots were marked, and an anchor was pre-inserted at one of the spots in the phantom model (Fig.2 -C).

Two reflective markers were attached on the dorsal side of the third metacarpal of each operator's hands. Four motion analysis camera were set and calibrated prior to the experiment. The motion analysis system was capable of storing 3D (x, y, z) location data with a resolution of up to 0.01 cm. Data obtained from the system were analyzed using Matlab (R2012b; MathWorks, Torrance, CA, USA). Surgical performance metric used to analyze the surgical skill of the operators included the total path length (mm) of the arthroscope and surgical tool, the count of movements, and the time taken (sec). The total path length refers to the sum of the distances of all 3D movements of the operator's hands during surgery. The count of movements was defined as the number of occasions during which the instantaneous velocity exceeded the average velocity [10]. The time taken was counted from the moment when the operator inserted an arthroscope into the portal to the moment when the operator placed it on the experiment table after the completion of the given experimental task.

The experimental tasks comprised anchor insertion and anchor suture retrieval. In the former, the operator observes arthroscopy images to find the ideal anchor insertion angle and places surgical tools accordingly. For phantom models, the ideal anchor insertion angle was preset to a single value, i.e., 135 in a vertical direction. This task was conducted twice, each at the two anchor insertion spots. The anchor suture retrieval task required the operator to pull the four sutures of the inserted anchor out of the portal one by one using an arthroscopic retriever.

2.2 Suture anchor variation analysis in cadaveric model

In the cadaveric experiment, the conventional and the proposed navigation assisted arthroscopic systems were compared for variation in the anchor insertion angles (Fig. 3-A), (B)]. The anchor insertion was conducted three times using each system. The conventional and proposed navigation assisted arthroscopic systems used in the cadaveric experiment were the same as those with the phantom model. Three optical tracking markers were used — a patient reference marker was fixed to the humerus using Steinman pins, and the other two markers were attached to the arthroscope and surgical tools, respectively. To implement the position and orientation between the surgical tool and the humerus in a virtual space, a patient-to-image registration was performed using anatomic landmarks as in the phantom setting test.

For the cadaveric experiment, three participants from experts group first conducted anchor insertion using the navigation system and then the conventional system. Anchor insertion was conducted three times each at supraspinatus (SSP) and infraspinatus (ISP) footprints on the greater tuberosity. The ideal anchor insertion angle was set to within a range between 45° and 90° from the footprint cortex by an expert surgeon with shoulder arthroscopy experience [1,2]. Using our vertical and horizontal references, the angles in the vertical and horizontal directions for the first anchor were 140 and 90 respectively, and 144 and 102 respectively, for the second anchor. The participants performed the anchor insertion task with the goal of achieving the predetermined target angles.

As in the motion analysis experiments, the operators attempted to find the ideal anchor insertion angle and place surgical tools accordingly. Once the operator determined an anchor insertion angle, the angle data were recorded.

3. **Statistical analysis**

Statistical analysis of the surgical performance and anchoring angle was performed using OriginPro software (ver. 9b; OriginLab Corp., Northampton, MA, USA). Data homogeneity of the three surgical performance metrics (total path length, count of movements, and time taken) and anchoring angle errors was evaluated by the Shapiro-Wilk normality test. Since all data were not normally distributed, the paired-sample Wilcoxon signed rank test was used to determine the statistical significance of each measurement (total path length, count of movements, and time taken) using the proposed navigation system, compared to the conventional arthroscopic system. Additionally, Mann-Whitney U test was used to confirm significant differences between the expert and novice groups. The level of significance was set at $P < 0.05$, * for $P < 0.05$ and ** for $P < 0.01$. Lastly, a post-experiment power analysis was performed at a 0.05-significance level to determine the power to detect a significant difference between the two systems.

Results

1. **Surgical performance evaluation using motion analysis in the phantom experiment**

The average of the total path length of the arthroscope in the expert group decreased from 439 mm to 362.5 mm while average of the total count of movements and time increased from 261.5 to 293.5 and from 126 sec to 145.8 sec (Fig. 4-A). However, there were no significant differences in these metrics. The experts handled the arthroscope similarly with both the systems and surgical performance with the surgical instrument was similar as well (Fig. 4-B). The average of the total path length of the surgical instrument decreased from 834.9 mm to 828 mm, and the count of movements increased from 340.9 to 357.6. These differences were not significant.

In the novice group, there was a difference in operating skills with both the arthroscope and surgical tool. As depicted in Figure 4, there was a reduction in the average total path length of the arthroscope and surgical tool, the count of movements, and the time taken when using the proposed system. In surgical performance regarding the arthroscop manipulation, the average of the total path length, the count of the movements, and time decreased from 761.1 mm to 257.5 mm, from 860.4 to 254, and from 637.8 sec to 226.4 sec. In surgical performance regarding the surgical instrument manipulation, the average of the total path length and the count of the movements decreased from 1748.4 mm to 757.7 mm and from 1379.6 to 409.6. However, there were no significant differences in these metrics.

Errors in anchor insertion from the target insertion angle of 135 using the conventional arthroscopic and the proposed systems, at two different spots were compared (Fig. 5). The errors for first and second anchors in the expert group, who conducted anchor insertion solely based on conventional arthroscopic images, were 3.4 and 11.6 on average, respectively. These errors decreased to 1.2 and 0.5 , respectively using the proposed system. Similarly, the errors decreased from 7.7 and 16.7 to 0.4 and 0.6 , respectively in the novice group. There was a significant difference between the conventional and the proposed navigation systems ($P = 0.002$), and a result of the power analysis using 20 samples showed a power of 86.03 %. Whereas the angle error significantly decreased ($P = 0.031$) in the expert group, there was no difference in the novice group.

2. **Comparison in anchor insertion angles in cadaveric experiment**

Anchor screw insertion angles were tested using cadaveric experiments. It showed that the proposed navigation system reduced deviations in the insertion angles measured when all three experts performed the three anchor insertion trials with each of the first and second anchors (Fig. 6). Each expert obtained significant improvement ($P = 0.031$) in vertical and horizontal angles using the proposed system, which allowed anchor insertion at an insertion angle closer to the target angle with high reproducibility when compared to the conventional system (Fig. 7). Significant improvements of first and second anchors were powered at 99.88 % and 99.99 %, respectively. Furthermore, the angle deviations decreased significantly ($P = 0.0002$), not only for each expert but also among participating experts (Table 1).

Discussion

Experimental results suggests that the navigation-assisted arthroscopic rotator cuff repair could improve operators' surgical performance that allowed anchor insertion close to the target angle in target area. The anchor insertion angle was measured consistently both in phantom and cadaveric experiments.

Quantitative assessments of the surgical skill of operators have been evaluated using various criteria in previous studies [6-8,10,17]. Based on previous studies [15,12], we assessed three criteria — total path length of the arthroscope and surgical tool, the count of movements, and the duration of the operation. In the phantom-based motion analysis experiments, the usability of the navigation-assisted system on surgical skill improvement varied between the experts in arthroscopy and the novices. However, there was no significant difference between the conventional arthroscopic and the proposed systems in the three surgical performance metrics. The results indicate that the experts performed their surgical tasks while maintaining their surgical skills, regardless of the system applied. In contrast, the two novices improved their surgical skills when the tracking system and the navigation system were used. A comparison of surgical skills using the conventional system showed a large gap between the experts and the novices, which disappeared with the navigation-assisted system, indicating that the novices improved their surgical skills with the proposed system. However, there was no significant difference between groups in the motion analysis experiments, which may be attributed to the small sample size.

Compared to the conventional system, variation in the anchor insertion angle was narrower, within two degrees, in both groups when the proposed system was used. The maximum anglular error of 1.2 degrees showed improved results compared to a previous study with an average angular error of 2 degree [16]. The error may belong to the acceptable range of anchor insertion. In addition, deviations in the anchor insertion angles were narrower among the experts compared to the novices when the conventional system was used. However, the gap between the two groups was minimal when the proposed system was used, similar to the observations made with surgical skill evaluation. A similar trend was observed in cadaveric experiments. The surgical task performance of novice was improved to expert level by the proposed navigation-assistant system.

The navigation-assisted system allowed high reproducibility of anchor insertion for both the first and second anchors, with reduction in deviations observed not only for experts but also among all participating novices. Since the proposed system enabled the experts to insert anchors at an insertion angle closer to the single target angle, it was concluded that the proposed navigation-assisted aided the operators to insert anchors at a predetermined insertion angle.

By reducing the deviation of multiple anchor insertions performed by one surgeon and the deviation between multiple surgeons, thus providing a consistent, high accurage surgery for many patients. The proposed system was used for arthroscopic rotator cuff repair in this study, but it is applicable to elbow, knee, and hip arthroscopy that require stable and precise anchor insertion.

Limitations

The current study has limitations. First, the number of participating operators is small. Since the participating operators used the proposed system first and then the conventional system, the operators may have learned from the proposed system, thereby creating a ceiling effect which may have affected their performance using the conventional system. Second, in both the phantom and cadaveric experiments, anchors were not actually fixed and surgical tools were positioned at spots determined by the operators. The possibility of any change in the angles that might have occurred during insertion of the anchor was not considered. Third, while the results produce significant differences with the techniques, the differences may not be significantly different from a biomechanical or clinical perspective. Lastly, for practical use of the navigation-assisted system in the surgery, a less- or non-invasive reference marker should be attached to the patient. In addition, a reliable patient-image registration should be performed to cope with the joint motion due to water circulation and shoulder traction.

Conclusions

A navigation-assisted system was developed to guide anchor insertion angle and thereby improving the surgical skills of less experienced operators. Experts in arthroscopy used this system to demonstrate high reproducibility for anchor insertion with a deviation of less than two degrees from the target angle. These findings suggest that the proposed system may contribute to improved surgical performance and anchor insertion for arthrosopic rotator cuff repair.

Declarations

Ethics approval and consent to participate Not applicable

Consent for publication Not applicable

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions :

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Idea conception IHJ, JSH, KHK

Data acquisition HJK, KHJ, HSC, SPL

Data interpretation HJK, KHJ, DJP, MJS, DMK

Drafting manuscript HJK, KHJ, EK

Revise and final approval of manuscript HJK, KHJ, KHK, IHJ

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Table

Table 1. Mean and standard deviation of anchor insertion angle errors in the expert group

	Anchor	Conv				Navi			
		V		H		V		H	
Mean and standard deviation of angle	First	8.6	8.7	12.2	7.7	**0.8**	**0.5**	**0.7**	**0.4**
error(	Second	14.6	10.1	12.2	5.6	**0.7**	**0.6**	**0.7**	**0.6**

Figures

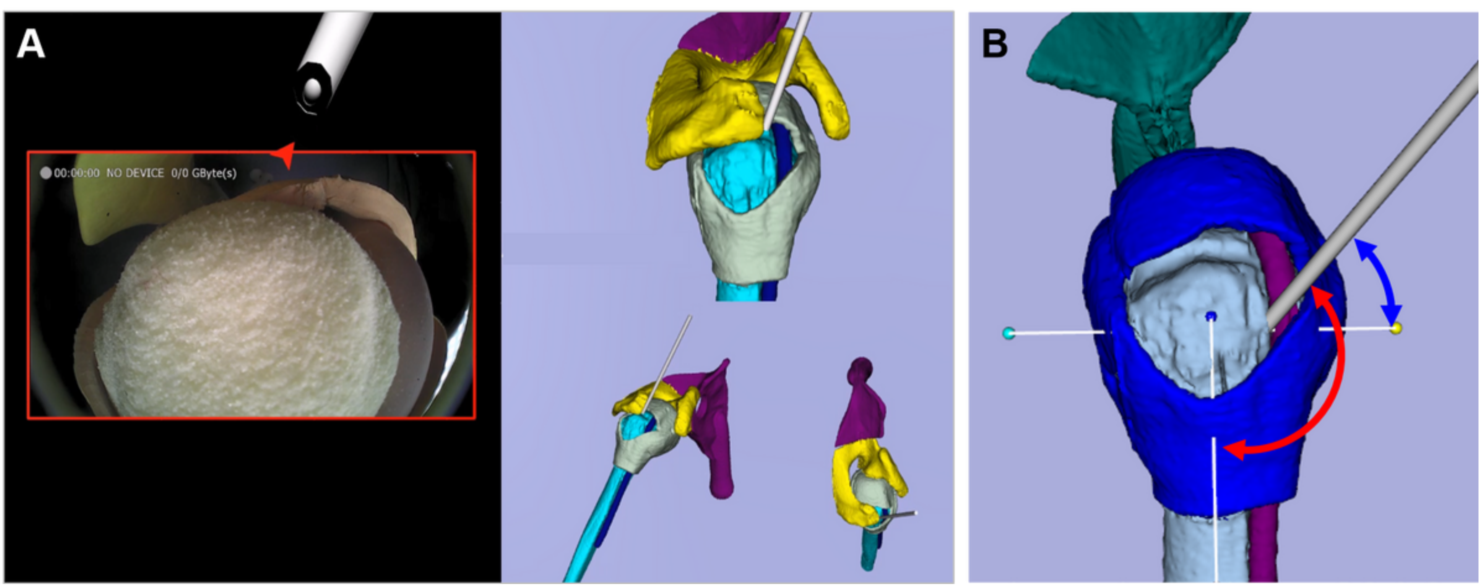

Figure 1

Angle-guided navigation system for a shoulder anchor insertion: (A) screen configuration of the developed navigation system that simultaneously shows surgical instrument and a shoulder phantom on augmented reality and virtual reality screens and (B) definition of baselines for anchor insertion angle guides.

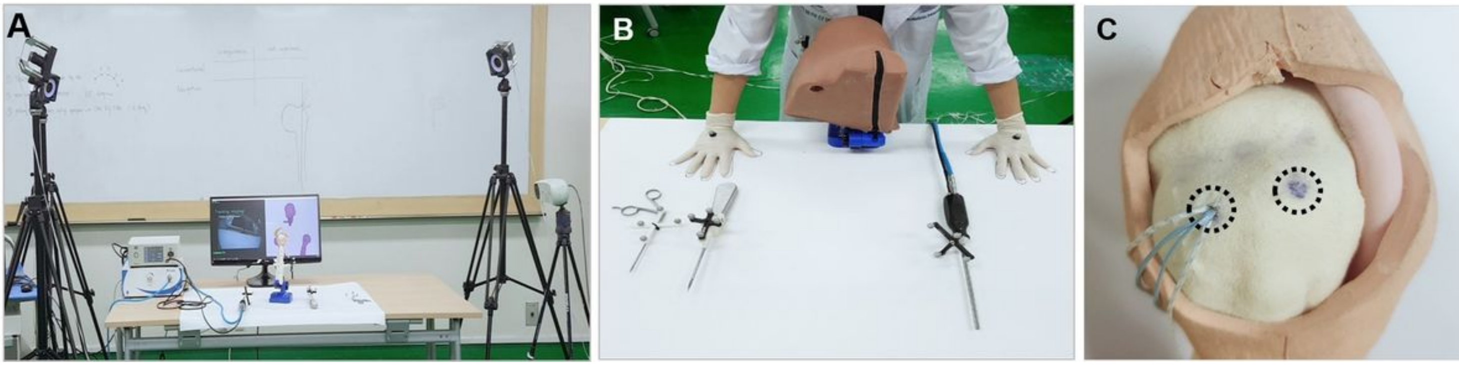

Figure 2

Experimental setup for motion analysis: (A) motion analysis camera and phantom-based experimental setup; (B) standardized position of arthroscopes and surgical instruments used for the anchor insertion experiment and reflective markers are attached on dorsum of hands, the arthroscope and the instruments; (C) two anchor insertion spots on shoulder phantom.

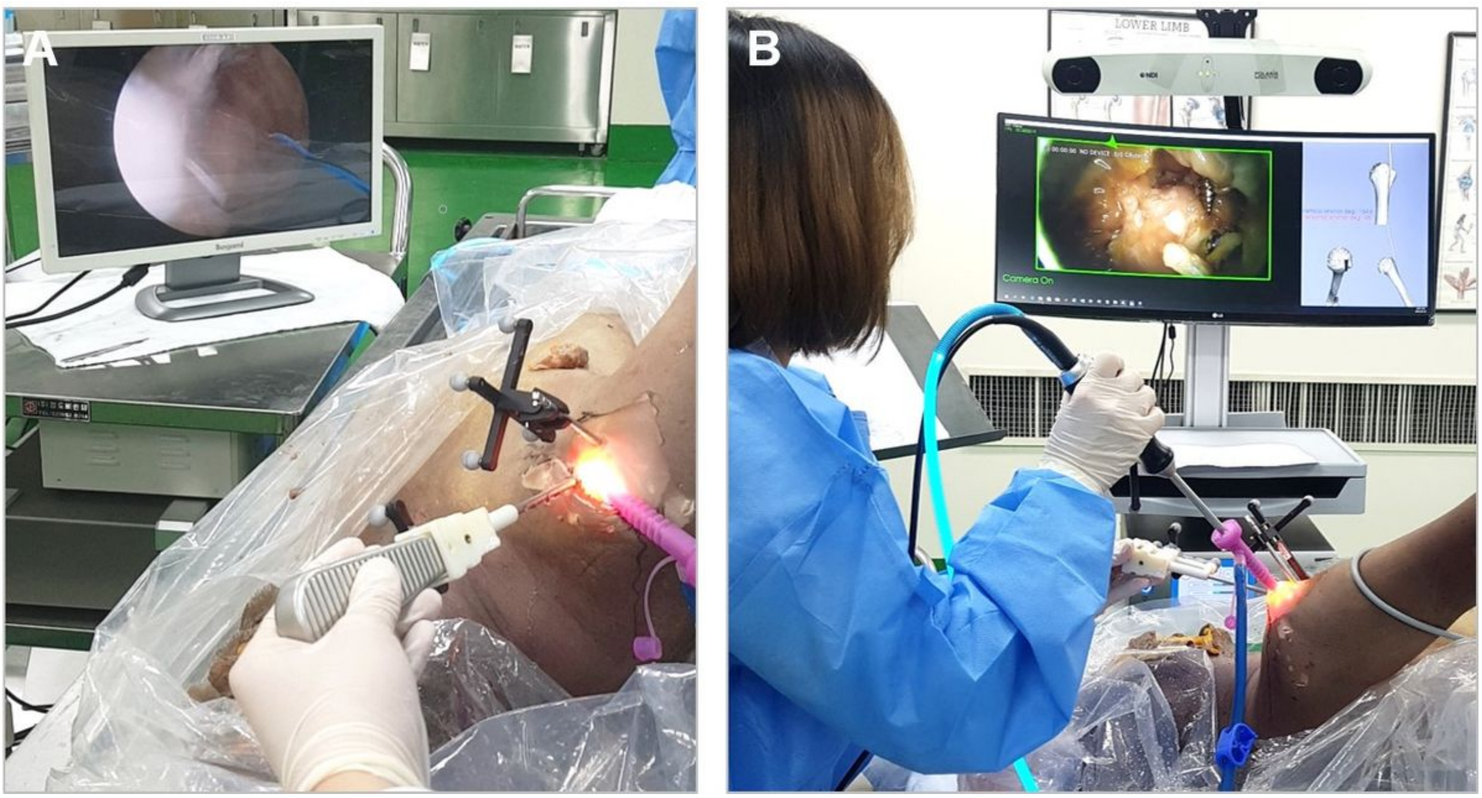

Figure 3

Cadaveric experiment: (A) conventional arthroscopic system; (B) proposed navigation system.

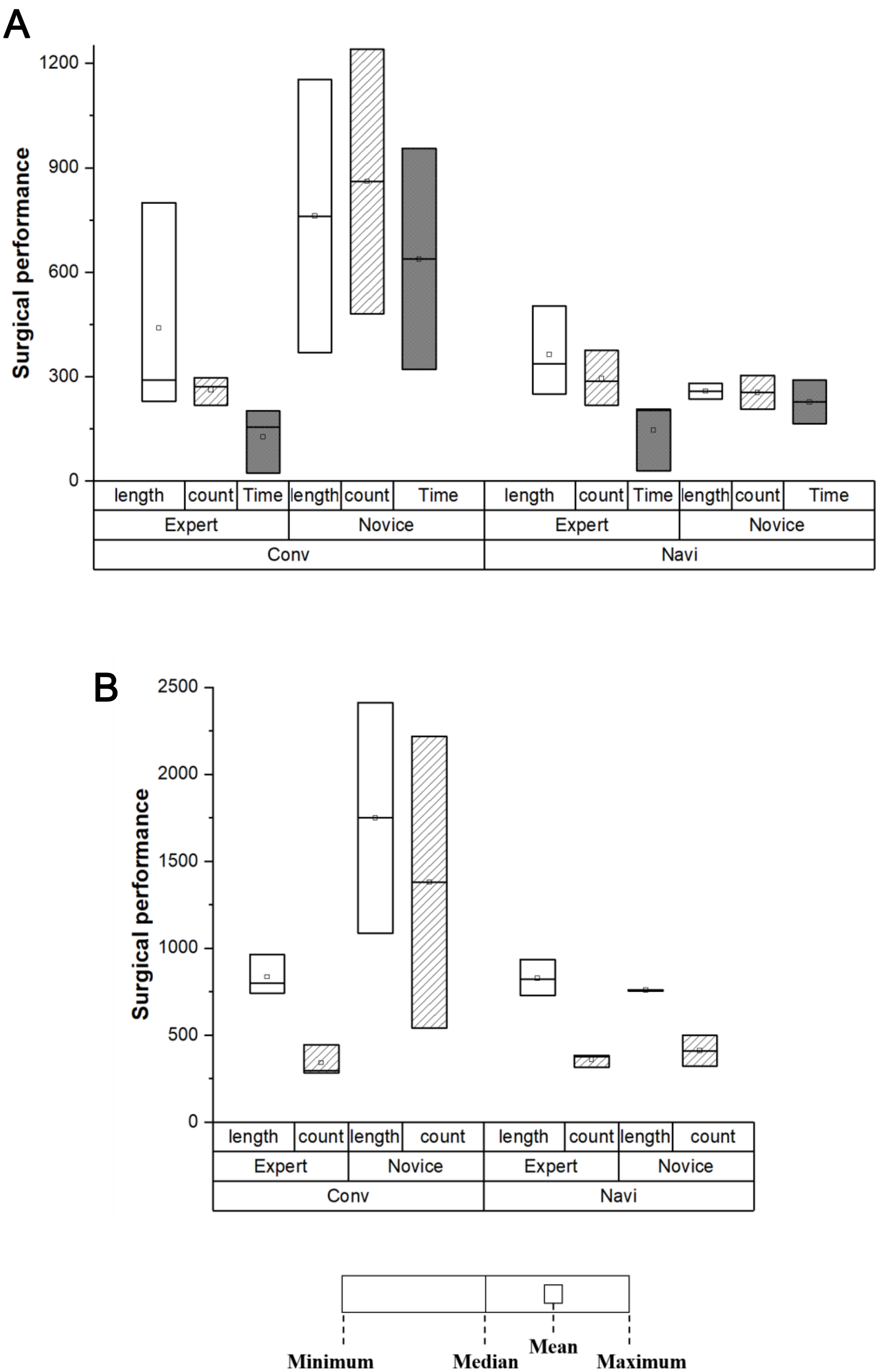

Figure 4

Comparative surgical performance between conventional (Conv) and navigation-assisted system (Navi) among experts and novices for (A) arthroscope handling motion and (B) surgical instrument handling motion in phantom model. (Box-and-whisker plot indicates minimum, median, mean, and maximum.)

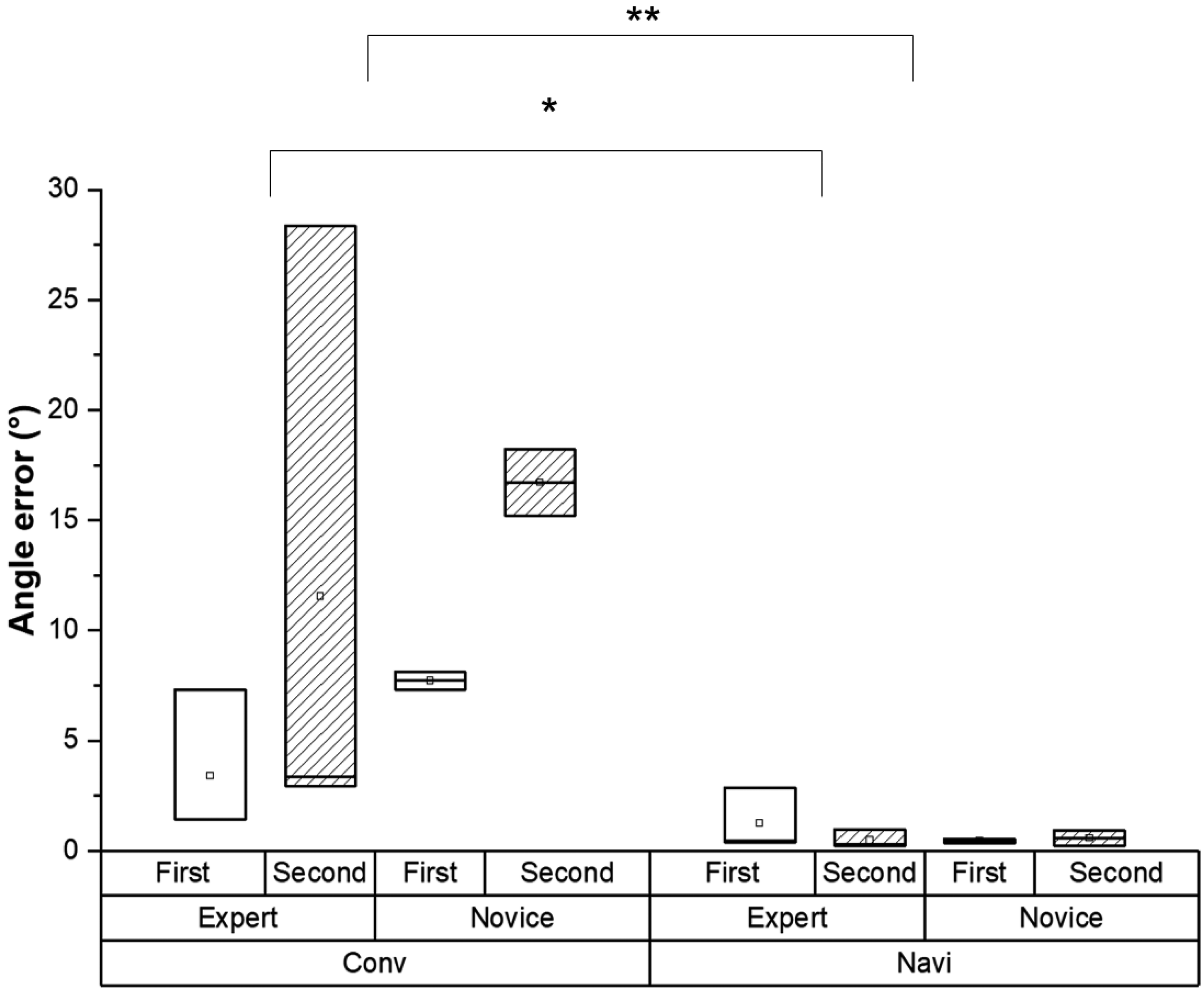

Figure 5

Comparison of vertical angle errors at first and second anchor spots in phantom-based anchor insertion experiments. An anchoring angle error of the expert group significantly decreased when they used the proposed navigation system (*). Average of the every participants including expert and novice group shows a significant difference between the conventional and the proposed navigation systems in terms of anchoring angle error (**).

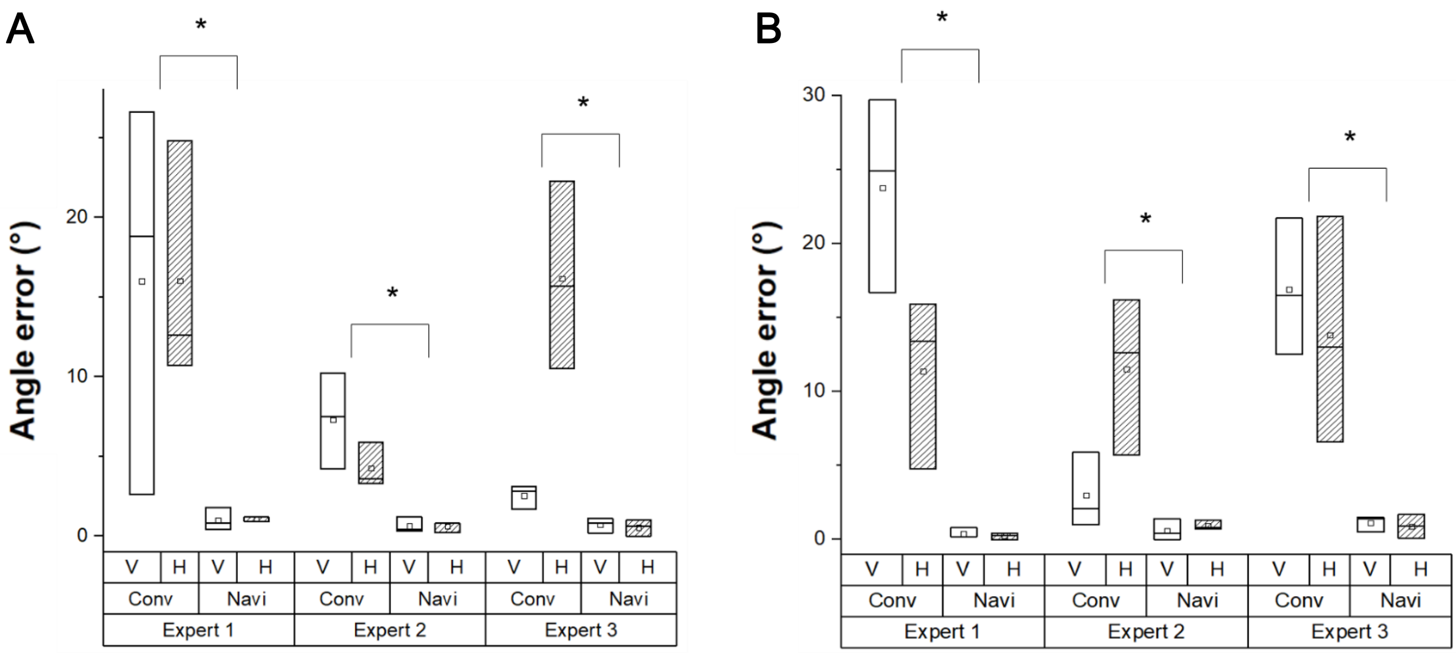

Figure 6

Comparison of vertical (V) and horizontal (H) angle errors in cadaver-based anchor insertion experiments: (A) first anchor and (B) second anchor. The angle error of the each expert significantly decreased when using the proposed navigation system (*)

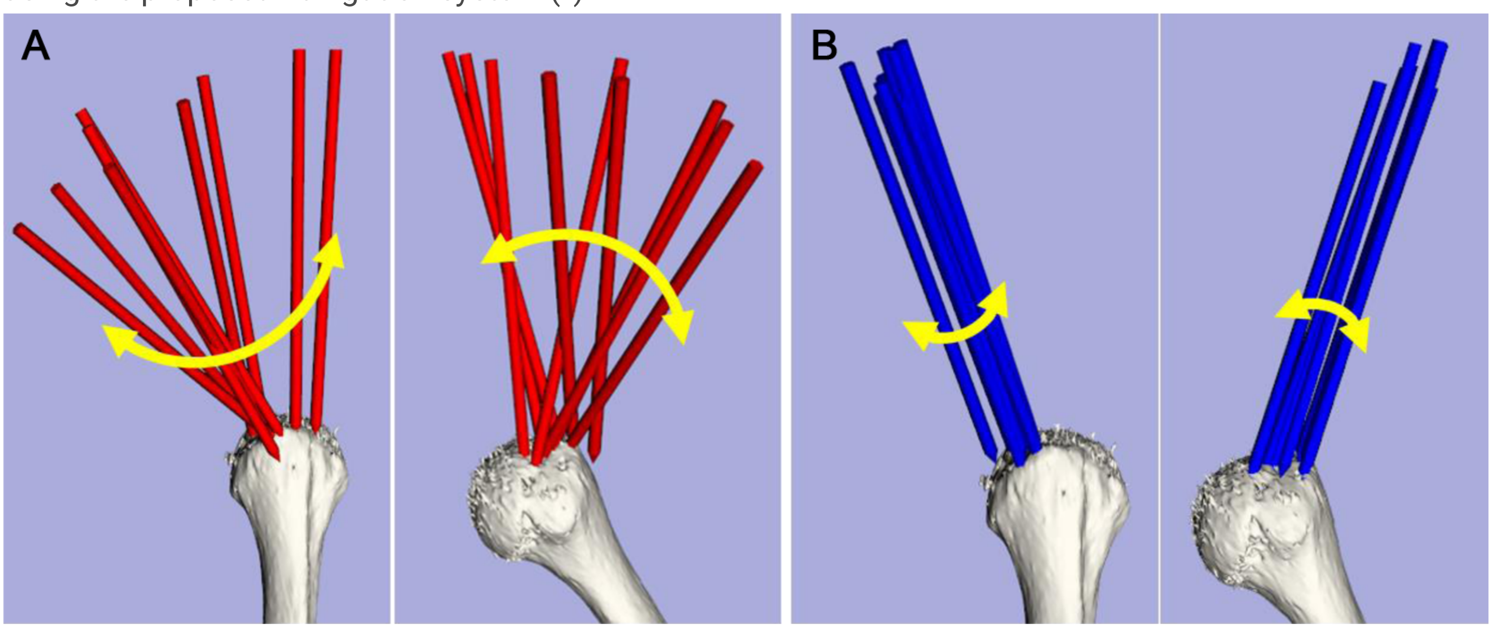

Figure 7

Comparison of anchor insertion angles for first anchor (A) Results of conventional system and (B) results of proposed navigation system