Development of a Novel Hybrid Suture Anchor for Osteoporosis by Integrating Titanium 3D Printing and Traditional Machining

Chih-Hwa Chen¹,²,³, Wen-Jen Chang⁴,⁵, Yu-San Chen⁶, Kuan Hao Chen²,⁷, Shao-Fu Huang⁶,⁸, Hsin-Ru Hsueh⁶, Cun-Bin Li⁶, Chun-Li Lin⁶,*

¹School of Biomedical Engineering, College of Biomedical Engineering, Taipei Medical University, Taipei, Taiwan
²Department of Orthopedics, Taipei Medical University - Shuang Ho Hospital, New Taipei City, Taiwan
³School of Medicine, College of Medicine, Taipei Medical University, Taipei, Taiwan
⁴Department of Information Management, Chang Gung University, Tao-Yuan, Taiwan
⁵Department of Dentistry, Chang Gung Memorial Hospital, Taoyuan, Taiwan
⁶Department of Biomedical Engineering, National Yang Ming Chiao Tung University, Taipei, Taiwan
⁷Graduate Institute of Biomedical Materials and Tissue Engineering, College of Biomedical Engineering, Taipei Medial University, Taipei, Taiwan
⁸Innovation and Translation Center of Medical Device, National Yang Ming Chiao Tung University, Taipei, Taiwan

Abstract: The aim of this study is to develop a titanium three-dimensional (3D) printing novel hybrid suture anchor (HSA) with wing structure mechanism which can be opened to provide better holding power for surrounding osteoporotic bone. A screw-type anchor (5.5-mm diameter and 16-mm length) was designed with wing mechanism as well as micro dual-thread in the outer cortex bone contact area and macro single-thread in the anchor body. Both side wings can be opened by an internal screw to provide better bone holding power. The suture anchor and internal screw were manufactured using Ti6Al4V 3D printing and traditional machining, respectively. Static pullout and after dynamic 300-cyclic load (150 N) pullout tests for HSA with or without the wing open and commercial solid anchor (CSA) were performed (n = 5) in severely osteoporotic bone and osteoporotic bone to evaluate failure strengths. Comparison of histomorphometrical evaluation was performed through in vivo pig implantation of HSAs with the wing open and CSAs. The failure strengths of HSA with or without the wing open were 2.50/1.95- and 2.46/2.17-fold higher than those of CSA for static and after dynamic load pullout tests in severely osteoporotic bone, respectively. Corresponding values for static and after dynamic load pullout tests were 1.81/1.54- and 1.77/1.62-fold in osteoporotic bone, respectively. Histomorphometrical evaluation revealed that the effects of new bone ingrowth along the anchor contour for CSA and HSA were both approximately 20% with no significant difference. A novel HSA with wing mechanism was developed using 3D printing and the opened wing mechanism can be used to increase bone holding power for osteoporosis when necessary. Better failure strength of HSA than CSA under static and after dynamic load pullout tests and equivalence of bone ingrowth along the anchor contours confirmed the feasibility of the novel HSA.

Keywords: Suture anchor; Rotator cuff; 3D printing; Pullout; Failure strength

*Correspondence to: Chun-Li Lin, Department of Biomedical Engineering, Innovation and Translation Center of Medical Device, National Yang Ming Chiao Tung University, Taipei, Taiwan; cllin2@nycu.edu.tw

Received: May 3, 2022; Accepted: June 12, 2022; Published Online: August 26, 2022

Citation: Chen CH, Chang WJ, Chen YS, et al., 2022. Development of a Novel Hybrid Suture Anchor for Osteoporosis by Integrating Titanium 3D Printing and Traditional Machining. Int J Bioprint, 8(4):608. http://doi.org/10.18063/ijb.v8i4.608

1. Introduction

Arthroscopic rotator cuff repair using suture anchors to reattach torn rotator cuff tissue to the bone is an important surgical treatment[1,2]. However, bone holding power decreases while an anchor is inserted into osteoporotic or osteopenic bone in the proximal humerus, which increases the failure rate of anchor treatment[3-5]. Several approaches, including buddy-system anchors, bone grafting, cement augmentation, and changing anchor...
Numerous anchor constructs are available to maximize retention on the anchor-bone interface and avoid early suture anchor fixation failure. The failure strength of the suture anchor is known to be affected by its design, including fixation type, anchor material, and suture type\cite{2,4,7,9}. Anchors can be divided into screw- and impaction-type devices\cite{11}. Screw-type anchors have threads that are advanced into the bone and show higher failure strength than smaller non-screw anchors designed for glenoid repairs because screws impart increased surface area for more holding strength and efficiency compared with impaction-type devices\cite{2,7,10,11}.

Bioabsorbable and poly(ether-ether-ketone) (PEEK) suture anchors are rapidly evolving and supplanting metallic anchors in rotator cuff surgery. However, although bioabsorbable anchors are absorbed with time after surgery, they do not provide suture stretching force\cite{2}. Although the wing structure deployed with the PEEK impaction-type anchor subcortically provides secure fixation to the bone\cite{7}, pushout strength is significantly greater for implants with porous titanium than PEEK, with titanium being the only material showing adequate bone growth and proximity inside implant threads\cite{8,12}.

The design concept of integrating the advantage of metal screw-type anchor and deploying wing structure subcortically can improve retention between the metal anchor and the bone to increase anchor pullout strength. However, this novel design, with a complicated structure, may encounter processing difficulties that traditional metal cutting processes cannot overcome. Recently, laser powder bed fusion (LPBF), as an important laser-based additive manufacturing (AM) technique, also noted as three-dimensional (3D) printing technique for metal components, provides an opportunity to manufacture components with complex geometries in the aerospace, automotive, and medical applications\cite{13-15}. The 3D printing technique is well established for building complicated 3D constructions from computer-aided design (CAD) models for controllable of precise dimension about 20 μm and has great potential to solve the problems of creating a porous (lattice) on a dense titanium and porous titanium body for enhancing bone growth\cite{9,12}.

In this study, we deployed a novel hybrid suture anchor (HSA) with wing structure mechanism contained outer dual-threaded profile and inner hole threads with convex surface that complex geometry can be fabricated by titanium 3D printing technology. The wing mechanism can be opened by an internal milling screw according to the state of the osteoporotic bone. In vitro static/dynamic testing and animal experiments were performed to verify the feasibility of the novel HSA for failure strength and bone growth, respectively.

2. Materials and methods

2.1. Design of the novel HSA and instruments

We designed a screw-type anchor, which is 16 mm in length, 5.5 mm in diameter, and dual-thread with micro-threads in the upper compressive taper head (4-mm double-starts with 1.05-mm pitch) of the anchor for distributing stress because of supplementary contact between the micro-threads and cortical bone to improve mechanical retention (Figure 1). Macro single-threads with 2.10-mm pitch was designed in the remaining part of the anchor. Two 0.8-mm diameter holes that allow the No. 2 suture to pass through were placed symmetrically on both sides of the head. The round and undercut thread near the suture hole for suture protection and square hole at the anchor center for matching the instrument was also considered at the compressive taper head. The anchor tip was designed to enable self-drilling and positioning when inserted into the bone (Figure 1).

The HSA is designed with a symmetric wing mechanism on both sides that can be clamped to surrounding bone tissue to provide the anchor with a better holding power and failure strength between anchor and bone when required. The wing mechanism needs to be designed as axially symmetrical to allow the internal fixation screw to push the wings with an average force after insertion. However, our anchor only designed to be symmetrical with two blades because the torsional strength of the anchor entity might be too weak when over two blades were designed for the anchor. For unfolding both wings, a screw is used to push the convex surface at the anchor centric hole when inserting the 2-mm diameter internal screw into the anchor (Figure 1). The barb function can be used when both wings are expanded and the anchor is pulled out through the sutures. The space created when the wings are open helped the bone to grow inward; three holes with 600-μm diameter were also created on both sides of the anchor for bone ingrowth (Figure 1).

The instruments with HSA must be used in conjunction with arthroscopy and divided into the outer sleeve instrument and central hexagonal driver. The main function of the outer sleeve is to implant the anchor into the bone and using a square connection to strengthen the locking force. The outer sleeve instrument was also designed to be hollow to enable the central hexagonal driver to pass through to lock the internal screw such that the anchor wings can be unfolded. The implantation process involved inserting the suture anchor into the bone tissue by the outer sleeve to a suitable position and then rotating the central hexagonal driver to drive the
internal screw within the suture anchor to open the wing mechanism when necessary (Figure 1).

2.2. Manufacture of the novel HSA and instrument

It is difficult to use 3D printing technique to fabricate a mechanism that has different fitting components, because the interface between different components must be controlled to be accurate in size, the surface is free of cracks and the fit needs to be within tolerances, etc. These are related to many printing process parameters in LPBF (e.g., laser power, scanning speed, hatch space, layer thickness, and scanning strategy). Therefore, our novel HSA was fabricated by metal 3D printing system, and internal fixation screw and instrument were manufactured by traditional machining.

A selective laser melting of metal powder bed fusion machine (AM400, Renishaw, Gloucestershire, UK), also noted as 3D printing system, was used with commercial titanium alloy powder (Ti6Al4V powder ranges between 15 μm and 45 μm) to manufacture our novel HSA. The 3D printing system was operated at a laser power of 400 W, scanning rate of 0.6 m/s, and an exposure time of 125s\(^{16}\). Our 3D printer laboratory was approved by ISO13485 quality management system (Certificate Number: 1760.190828) to ensure that the anchor manufactured by 3D printing can provide a practical foundation to meet the regulations, such as printing material with biocompatibility in the context of biological safety to meet ISO10993 standard as well as demonstrating a commitment to safety and quality.

The CAD file of the HSA was imported into 3D printing system in offline state, then the build chamber was prepared with vacuum air removal and filled with argon inert gas to prevent oxidation and interstitial element contamination during the manufacturing process. With the powder being selectively scanned and melted by a laser during the process, the component can be made after the powder was crystallized. The hatching space and layer thickness in the present study were 90 μm and 30 μm, respectively. After process completion, residual 3D printing anchor particles were removed and cleaned using magnetic surface grinding and ultrasonic oscillations, respectively (Figure 2C)\(^{16}\).

Traditional machining was used to prepare the internal screw because it has a regular configuration and the thread accuracy demand was high (control within 0.04 mm accuracy) (Figure 2D). Traditional machining can control manufacturing accuracy within a small error margin and enable the internal screw to fit the anchor within acceptable error range. The instrument, including the sleeve instrument and central hexagonal driver, was composed of 304 stainless steel and fabricated using heat treatment by an ISO13485 quality management system company (A PLUS Biotechnology Co., LTD, Taipei, Taiwan).

2.3. Biomechanical static/dynamic tests

Artificial bone specimens with standardized bone densities of 0.12 g/cm\(^3\) and 0.32 g/cm\(^3\) (cellular foam with 7.5 pcf and solid rigid foam with 20 pcf) for mimicking the severely osteoporotic bone and osteoporotic bone, respectively,
were prepared by Sawbones (Sawbones; Pacific Research Laboratories, Vashon, WA) (Figure 3)\textsuperscript{[17-19]}.

To compare the effectiveness of the failure strength of the HSA with wing mechanism, 40 HSAs were prepared and each 20 HSAs was arranged for 7.5pcf and 20pcf bone blocks. Each bone type was divided into two groups with and without the wing open. A total of 20 commercial solid anchors (CSAs; CorkScrew FTII, Arthex Inc. Naples, FL, USA) of the same diameter and length were also prepared as the control group for comparing failure strength (Figure 2B). These three types of anchors were termed HSAWW, HSAWOW, and CSA for hybrid anchor with the wing open, hybrid anchor without the wing open, and commercial anchor, respectively. Subsequent subgroups were divided into two groups from these two groups, five of which were for static and after dynamic load pullout experiments (Table 1, which shows the group arrangement).

Each suture anchor was inserted into a 20 mm × 20 mm × 40 mm, Sawbone block, perpendicular (0°) to the block surface. Then, the block was clamped and mounted in a parallel position on an ElectroPulsTM E3000 testing machine (Instron Corp., Norwood, MA) with Bluehill2 software for 0.1 s sampling rate (Version 2.26, Instron Corp., Norwood, MA) pullout tests. The suture loops of the anchor were secured between the anchor and hook, leaving a constant gage of 10 cm between the hook and block surface (Figure 3). A 10 N preload was applied to each specimen and then a test load with 12.5 mm/s was applied parallel to the axis of anchor insertion for the osteoporotic trabecular bone.

For dynamic testing, a 0.5-Hz sinusoidal cyclic loading profile of 15 – 150 N for 300 cycles after a preload of 10 N was applied. Each sample was pulled to failure at a constant extension rate of 12.5 mm/s after cyclic loading to determine failure strength. Whether it was static test or dynamic test after 300 cyclic loading, failure strength and failure mode were observed, including anchor pullout or suture breakage. The

![Figure 2.](image-url)

\textbf{Figure 2.} (A) Hybrid suture anchor (HSA)s manufactured using metal 3D printing. (B) schematic diagram of commercial solid anchor. (C) The HSA without the wing open. (D) Finished product of the internal screw with front/top view scale. (E) HSA with the wing open. (F) X-ray image of HSA inserted into bone.
Kruskal–Wallis test was used to perform the statistical analysis to understand the difference of failure strength between HSAWW, HSAWOW, and CSA because sample sizes were relatively small and cannot determine if the data were normally distributed.

### 2.4. In vivo anchor implantation and histomorphometrical evaluation

The study was reviewed and approved by the ethics review committee of the Institutional Animal Care and Use Committee of Chi-Mei Medical Center (No.: 110011201). Two female, skeletally mature, Yorkshire pigs, weighing around 20 kg (mean ± SD: 20.25 ± 0.695 kg), with an average age of 4 months, were used for the *in vivo* implantation study. The pig model was chosen due to its similarity in bone quality, density, anatomy, and size with human humerus. Moreover, cost and variability are lower in this model than others[11]. Bone mineral density was not calculated in this study because all pig shoulders were young and of the same age (4 months ± 1 week).

The pigs were fasted for 12 h before surgery. For sedation and anesthesia, zoletil-50 5 mg/kg, xylazine 2 mg/kg, atropine 0.03 mg/kg, and ketoprofen 2 mg/kg were given by intramuscular injection. Anesthesia was maintained with 3% isoflurane through endotracheal inhalation, with oxygen 2 L/min. The pig was placed in the lateral position and the skin was disinfected with povidone-iodine. A 5–6-cm long skin incision was made at the upper shoulder area. Deltoid and other superficial muscles were separated with bleeding control. The infraspinatus muscle was identified by anatomical

**Table 1.** Numbers of HSA/CSA for static/dynamic pullout test and *in vivo* animal experiment

| Anchor type                  | *In vitro* biomechanical test (number) | *In vivo* animal experiment (number) |
|------------------------------|---------------------------------------|-------------------------------------|
|                              | 20 pcf  | 7.5 pcf | Pig shoulder |                             |
| HSA (n=44)                   |         |         |             |                             |
| With the wing open (HSAWW)   |         |         |             |                             |
| Static pull out              | 5       | 5       |             |                             |
| Dynamic pull out             | 5       | 5       |             |                             |
| Animal experiment            |         |         |             |                             |
| Without the wing open (HSAWOW)|         |         |             |                             |
| Static pull out              | 5       | 5       |             |                             |
| Dynamic pull out             | 5       | 5       |             |                             |
| CSA                          |         |         |             |                             |
| Static pull out              | 5       | 5       |             |                             |
| Dynamic pull out             | 5       | 5       |             |                             |
| Animal experiment            |         |         |             |                             |
| CSA (Arthex) (n=24)          |         |         |             |                             |
| Static pull out              | 5       | 5       |             |                             |
| Dynamic pull out             | 5       | 5       |             |                             |
| Animal experiment            |         |         |             |                             |

HSA, Hybrid suture anchor; CSA, Commercial solid anchor
landmarks and tendonectomy was performed as close to the insertion footprint as possible.

A total of eight suture anchors for animal experiments, two HSAs with high-strength force fiber suture of No. 2 ultra-high molecular weight braided polyethylene (UHMWPE), and two CSAs with 5.5 mm fully threaded metallic suture anchors, were inserted into the left and right humeral head at an angle of 45°. A specific central hexagonal driver was applied to drive the internal screw to unfold the mechanism of anchor wing after the HSA was driven into suitable bone depth using the outer sleeve instrument. Reattachment of the tendon was performed by single-row suturing with fiber wires threaded on both types of anchors. Finally, the wound was closed in layers without a visible bleeding point. A topical antibiotic (penicillin 3000 IU/kg) was applied before wound closure to control surgical site infection. A prophylactic antibiotic (enrofloxacin 5 mg/kg) was administered IM, QD for 5 d. Once analgesia was no longer required, the animals were monitored once daily. Eight weeks after surgery, under deep general anesthesia, the pigs were euthanized with heart exanguinations. Bilateral humerus was then removed from the shoulder joint and tendon stumps of rotator cuff muscles were kept with the sample.

Each anchor and its surrounding hard tissue were sectioned and dehydrated in a graded series of alcohol (20 – 40 – 60 – 80 – 100%). The sample was then embedded, sliced, and ground for dyeing in blue for bone tissue and anchor identification. Images of sliced sections were taken under ×12.5 magnification and analyzed using an image processing software (ImageJ 1.53a for MacOS, National Institutes of Health, USA). Using hue adjustment in the color threshold function, the ratio of the stained (blue) to total area was calculated along the anchor contour 1 mm outward to quantify bone growth. Statistical Mann–Whitney U test was performed to compare bone growth variation between CSAs and novel HSAs with the wing open.

### 3. Results

**Figure 2** shows the HSA after metal 3D printing manufacturing, the manufacturing accuracy, and the status of functional test. **Figure 2C and 2E** show anchor wings in unexpanded and opened states, respectively. The manufacturing accuracy of 3D printing can be controlled <6% for five random samples between the design parameter and the actual measurement after printing (**Table 2**). **Figure 2D** shows the finished product of the internal screw by machine milling, with front/top view scale and accuracy can be controlled at 0.04 mm. The X-ray image shows that the wings of the HSA can be opened smoothly while inserted into the bone under the operation of the specific instrument after the anchor is inserted into the Sawbone (**Figure 2F**).

The static pullout test results showed that the HSA failure strengths with and without the wing open were significantly higher \((P < 0.05)\) than CSA regardless of severely osteoporotic bone and osteoporotic bone. The average failure strength was 2.50 (105.43N/42.16N) and 1.95 (82.41N/42.16N) folds for HSA with and without the wing open than CSA in severely osteoporotic bone (**Figure 4**), respectively. The corresponding folds were 1.81 (464.55N/256.27N) and 1.54 (394.5/256.27) for osteoporotic bone. A similar trend was observed in the pullout test after dynamic load was applied; average failure strength was 2.46 (128.01N/52.13N) and 2.17 (113.12N/52.13N) folds for HSA with and without the wing open than CSA in severely osteoporotic bone, respectively. The corresponding folds were 1.77 (532.74N/301.53) and 1.62 (489.39N/301.53N) for osteoporotic bone. **Table 3** shows that failure modes of pullout tests for suture anchors.

**Figure 5** shows the histomorphometrical images for CSA and HSA. Stained area (blue region) along the anchor contour indicates the amount of bone growth with newly formed lamellar bone directly in contact with the anchor. **Table 4** lists percentage of stained area to total area along the anchor contour, 1 mm outward for histomorphometrical evaluation, with average value ± standard deviation being 19.802% ± 2.08% for CSA and 18.21% ± 1.30% for HSA. No statistically significant difference between wing-open hybrid anchors and commercial anchors was observed.

### 4. Discussion

Rotator cuff tear repairs are more challenging among the elderly population with osteoporotic or osteopenic bone in the proximal humerus\(^6\). Understanding the pullout strength of suture anchors in relation to their design is important for surgeons to avoid early suture anchor fixation failure and for designers to improve suture anchor performance\(^6\). Making higher demands on the structural design of the anchor to increase contact area between anchor and bone interface for enhancing the interfacial retention strength is necessary. Therefore, we propose a novel suture anchor with micro-threads in the cortical bone contact area and an open wing auxiliary structure that can enhance pullout performance in the osteoporotic state. **Figure 6** shows that internal matching sliders were designed originally as cone and cylinder ball head. However, adaptation interface fitness between matching slider and anchor was difficult to control accurately in size, free crack, and tolerances when an anchor with matching slider is printed together. Therefore, the inserted internal screw, manufactured using traditional machine milling, was later selected to drive the convex surface of the wing mechanism because the slider was prone to binding and unable to function due to the...
manufacturing imprecision of metal 3D printing. The internal screw is a standard machine part and suitable for manufacturing using machine milling because its accuracy can be set to 0.04 mm. The internal thread of the anchor can be fitted with the internal screw thread when the manufacturing accuracy of the 3D printing machine was controlled under 0.1 mm. Therefore, the convex curved surface inside the anchor can be pushed out slowly to achieve wing opening when the internal screw is inserted gradually.

Obtaining samples with a consistent degree of osteoporosis is challenging. We performed our novel anchor pullout testing on synthetic, standardized physiological and osteoporotic bone specimens because they had consistent mechanical and microstructural properties, better availability, minimal material degradation over time, and lower cost compared with cadaveric bone. Synthetic polyurethane foams are frequently used in biomechanical testing. Polyurethane foams are manufactured in a range of densities (grades) to achieve mechanical properties in the range of the human trabecular bone. Studies comparing the microstructure of polyurethane foam and human vertebrae for screw pullout testing found that polyurethane grade 7.5 and 20 pcf can be used to mimic the severely osteoporotic bone and osteoporotic bone[17,18,20].

A pullout constant extension rate of 12.5 mm/s was set according to the literature to be approximately one-third of the 33 mm/s rate of arm movement used in daily activities[21]. A pullout test angle of 0° was the worst condition of possible pullout force in clinical use. The dynamic load of 150 N was based on two-

### Table 2. Errors of five random samples between the design parameter and the actual measurement after printing

| Random sample | Suture hole | Bone growth hole | Pitch (anchor body) | Pitch (taper head) | Anchor Length | Anchor diameter |
|---------------|-------------|------------------|---------------------|-------------------|---------------|-----------------|
| Design value (mm) | 0.800 | 0.600 | 2.10 | 1.05 | 16.00 | 5.50 |
| RS1 | 0.792 | 0.630 | 2.14 | 1.00 | 15.96 | 5.79 |
| RS2 | 0.783 | 0.629 | 2.21 | 1.07 | 15.92 | 5.73 |
| RS3 | 0.788 | 0.626 | 2.05 | 1.02 | 15.91 | 5.75 |
| RS4 | 0.792 | 0.653 | 2.21 | 1.01 | 15.94 | 5.69 |
| RS5 | 0.783 | 0.622 | 2.07 | 1.05 | 15.89 | 5.72 |
| Ave | 0.7876 | 0.6336 | 2.136 | 1.03 | 15.924 | 5.736 |
| Std | 0.0045 | 0.0123 | 0.075 | 0.0291 | 0.0270 | 0.0371 |
| Err (%) | 1.55 | 5.6 | 1.7 | 1.9 | 0.5 | 4.3 |

**Figure 4.** Comparison of static and after dynamic pullout tests for hybrid suture anchor (HSA)s and commercial solid anchors. (A) For severely osteoporotic bone. (B) For osteoporotic bone. The * and ** symbols indicated significant difference between groups, that is, $P < 0.05$.

**Figure 5.** Representative histomorphometrical images for (A) commercial solid anchor and (B) hybrid suture anchor (HSA).
thirds of the average arm strength of a 20-year-old adult as the load condition\textsuperscript{[22]}. A dynamic load cycle of 300 refers to the average number between 107 and 408 load cycles that could induce maximum displacement after surgery\textsuperscript{[22]}.

The results of static and dynamic pullout testing showed that the failure strength between the new anchor and bone, with or without the wing open, regardless of osteoporotic bone types was higher than that of the control group. The reason may be that for the newly-designed anchor, without the wing open, the double-thread design was used to increase the contact area with the cortical bone, thereby increasing failure strength under the same 5.5-mm diameter compared with the control anchor. Consequently, the failure strength of the newly-designed anchor was better after the wings were open because wing clamping of the bone increased holding strength. When compared HSA static failure strength to control group, it can be found that the severe osteoporosis folds (2.50 for with the wing open and 1.95 for without the wing open)

### Table 3. Failure mode of pullout tests under static and after dynamic loads

| Fracture mode                               | CSA (Arthex) | HSAWOW | HSAWW |
|----------------------------------------------|--------------|--------|-------|
| Static (7.5 pcf sawbone)                    |              |        |       |
| Fracture mode                               |              |        |       |
| Static (20 pcf sawbone)                     | AP           |        |       |
| After dynamic load (7.5 pcf sawbone)        |              |        |       |
| Fracture mode                               |              |        |       |
| After dynamic load (20 pcf sawbone)         |              |        |       |
| Fracture mode                               |              |        |       |

SB, Suture broken; AP, Anchor pull out; CSA, Commercial solid anchor

### Table 4. The percentage of the stained area (blue) to the total area along the anchor contour 1 mm outward for the histomorphometrical evaluation

| No.   | CSA (Arthex) | HSA with the wing open | P-value |
|-------|--------------|------------------------|---------|
| Pig 1 | 16.147       | 19.934                 | <0.05   |
| Pig 1 | 19.243       | 17.050                 | <0.05   |
| Pig 2 | 20.716       | 18.485                 | <0.05   |
| Pig 2 | 20.384       | 17.394                 | <0.05   |
| Ave±Std p | 19.802±2.08 | 18.21±1.30             |         |

HSA, Hybrid suture anchor; CSA, Commercial solid anchor
were higher than that of the normal osteoporosis (1.81 for with the wing open and 1.54 for without the wing open). A similar trend was also found in the dynamic tests. This result implied that our new design was more effective in the severe osteoporosis case. The more interesting part of the pullout test was that after the dynamic test, failure strength was higher than static failure strength for both the control group and the newly-designed anchor. This was because the UHMWPE fiber of the suture was affected by high temperature and high strain rate, and the tensile strength of the suture increased as the strain rate increased.

Results from histomorphometrical evaluation revealed that the effects of new bone ingrowth along the anchor contour, 1-mm outward for the control and newly-designed anchor were both approximately 20%, with no statistically significant difference. Thus, our newly-designed anchor can achieve initial osseointegration on the anchor-bone interface after surgery and be used in the clinic. However, the newly-designed anchor, with the wing open and three surface holes of 600-μm diameter, did not exhibit better osseointegration in animal experiments and requires long-term evaluation.

Our study has some limitations. The central hexagonal driver within the specific sleeve instrument was used to drive the internal screw to open the wing mechanism. However, only 2-mm hexagonal head of the central driver must be carefully under appropriate insertion force to prevent the head from slipping or breaking and make it impossible to push the wings away. Furthermore, our animal experiments focused on the normal bone to evaluate the functionality of osseointegration after anchor implantation. A detailed animal model of osteoporosis needs to be used to evaluate whether the failure strength of the newly-designed anchor is improved and the state of osseointegration.

5. Conclusion

A novel HSA with wing structure mechanism with dual-threaded was developed integrating 3D printing and mechanic milling and the wing of HSA can be opened by an internal screw to increase the holding power for osteoporosis patient when necessary. Results of static and after dynamic load pullout tests for severe and normal osteoporosis showed that the failure strengths of HSA with and without the wing open were significantly higher (P < 0.05) than that of CSA. Histomorphometrical evaluation revealed that the effects of new bone ingrowth along the anchor contour for CSA and HSA were both approximately 20%, with no statistically significant difference.

Funding

This study is supported in part by MOST 109-2314-B-038-026-MY3 and 109-2221-E-010-002-MY3, Taiwan.

Conflict of interest

No conflict of interest was reported by all authors.

Author contributions

Supervision: Chun-Li Lin
Conceptualization: Chih-Hwa Chen and Chun-Li Lin
Investigation: Yu-San Chen, Kuan Hao Chen, Shao-Fu Huang, Hsin-Ru Hsueh, Cun-Bin Li
Methodology: Yu-San Chen, Kuan Hao Chen, Shao-Fu Huang Hsin-Ru Hsueh and Cun-Bin Li
Formal analysis: Wen-Jen Chang and Yu-San Chen
Writing – original draft: Chih-Hwa Chen and Chun-Li Lin
Writing – review and editing: Chih-Hwa Chen and Chun-Li Lin

References

1. Chaudhry S, Dehne K, Hussain F, 2019, A Review of Suture Anchors. *Orthop Trauma*, 33:263–70.
http://doi.org/10.1016/j.mporth.2016.12.001

2. Ma R, Chow R, Choi L, et al., 2011, Arthroscopic Rotator Cuff Repair: Suture Anchor Properties, Modes of Failure and Technical Considerations. Expert Rev Med Devices, 8:377–87.  
http://doi.org/10.1586/erd.11.4

3. Braunstein V, Ockert B, Windolf M, et al., 2015, Increasing Pullout Strength of Suture Anchors in Osteoporotic Bone using Augmentation—a Cadaver Study. Clin Biomech, 30:243–7.  
http://doi.org/10.1016/j.clinbiomech.2015.02.002

4. Horoz L, Hapa O, Barber FA, et al., 2017, Suture Anchor Fixation in Osteoporotic Bone: A Biomechanical Study in an Ovine Model. Arthroscopy, 33:68–74.  
http://doi.org/10.1016/j.arthro.2016.05.040

5. Rosso C, Weber T, Dietschy A, et al., 2020, Three Anchor Concepts for Rotator Cuff Repair in Standardized Physiological and Osteoporotic Bone: A Biomechanical Study. J Shoulder Elbow Surg, 29:e52–9.  
http://doi.org/10.1016/j.jse.2021.07.032

6. Chae SW, Kang JY, Lee J, et al., 2018, Effect of Structural Design on the Pullout Strength of Suture Anchors for Rotator Cuff Repair. J Orthop Res, 36:3318–27.  
http://doi.org/10.1002/jor.24135

7. Barber FA, Herbert MA, Hapa O, et al., 2011, Biomechanical Analysis of Pullout Strengths of Rotator Cuff and Glenoid Anchors: 2011 Update. Arthroscopy, 27:895–905.  
http://doi.org/10.1016/j.arthro.2011.02.016

8. Tingart MJ, Apreleva M, Lehtinen J, et al., 2004, Anchor Design and Bone Mineral Density Affect the Pull-out Strength of Suture Anchors in Rotator Cuff Repair: Which Anchors are Best to Use in Patients with Low Bone Quality? Am. J. Sports Med, 32:1466–73.  
http://doi.org/10.1177/00002789042644

9. Trindade R, Albrektsson T, Galli S, et al., 2018, Bone Immune Response to Materials, Part I: Titanium, PEEK and Copper in Comparison to Sham at 10 Days in Rabbit Tibia. J Clin Med, 7:526.  
http://doi.org/10.3390/jcm7120526

10. Alan Barber F, Boothby MH, Richards DP, 2006, New Sutures and Suture Anchors in Sports Medicine. Sports Med. Arthrosc, 14:177–84.  
http://doi.org/10.1097/00132585-200609000-00010

11. McFarland EG, Park HB, Keyurapan E, et al., 2005, Suture Anchors and Tacks for Shoulder Surgery, Part I: Biology and Biomechanics. Am J Sports Med, 33:1918–23.  
http://doi.org/10.1177/0363546505282621

12. Guyer RD, Abitbol JJ, Ohnmeiss DD, et al., 2016, Evaluating Osseointegration into a Deeply Porous Titanium Scaffold: A Biomechanical Comparison with PEEK and Allograft. Spine, 41:E1146–50.  
http://doi.org/10.1097/brs.0000000000001672

13. Huang S, Narayan RL, Tan JH, et al., 2021, Resolving the Porosity-unmelted Inclusion Dilemma during in-situ Alloying of Ti34Nb Via Laser Powder Bed Fusion. Acta Mater, 204:116522.  
http://doi.org/10.1016/j.actamat.2020.116522

14. Wang D, Liu L, Deng G, et al., 2022, Recent Progress on Additive Manufacturing of Multi-material Structures with Laser Powder Bed Fusion. Virtual Phys Prototyp, 17:329–65.  
http://doi.org/10.1080/17452759.2022.208343

15. Yu W, Xiao Z, Zhang X, et al., 2022, Processing and Characterization of Crack-free 7075 Aluminum Alloys with Elemental Zr Modification by Laser Powder Bed Fusion. Mater. Sci Addit Manuf, 1:4.  
http://doi.org/10.18063/msam.v1i1.4

16. Li CH, Wu CH, Lin CL, 2020, Design of a Patient-specific Mandible Reconstruction Implant with Dental Prosthesis for Metal 3D Printing using Integrated Weighted Topology Optimization and Finite Element Analysis. J Mech Behav Biomed Mater, 105:103700.  
http://doi.org/10.1016/j.jmbbm.2020.103700

17. Arslan AK, Demir T, Ormeci MF, et al., 2013, Postfusion Pullout Strength Comparison of a Novel Pedicle Screw with Classical Pedicle Screws on Synthetic Foams. Proc Inst Mech Eng H, 227:114–9.  
http://doi.org/10.1177/0954411912463323

18. Hsu JT, Huang HL, Chang CH, et al., 2013, Relationship of Three-dimensional Bone-to-Implant Contact to Primary Implant Stability and Peri-implant Bone Strain in Immediate Loading: Microcomputed Tomographic and in vitro Analyses. Int J Oral Maxillofac Implants, 28:367–74.  
http://doi.org/10.11607/jomi.2407

19. Nagaraja S, Palepu V, 2016, Comparisons of Anterior Plate Screw Pullout Strength between Polyurethane Foams and Thoracolumbar Cadaveric Vertebræ. J Biomech Eng, 1:138.  
http://doi.org/10.1115/1.4034427

20. Bateman AH, Balkovec C, Akens MK, et al., 2016, Closure of the Annulus Fibrosus of the Intervertebral Disc using a Novel Suture Application Device-in vivo Porcine and ex vivo Biomechanical Evaluation.. Spine J, 16:889–95.  
http://doi.org/10.1016/j.spinee.2016.03.005
21. Burkhart SS, Diaz Pagán JL, Wirth MA, et al., 1997, Cyclic Loading of Anchor-based Rotator Cuff Repairs: Confirmation of the Tension Overload Phenomenon and Comparison of Suture Anchor Fixation with Transosseous Fixation. Arthroscopy, 13:720–4.

22. Ikai M, Fukunaga T, 1968, Calculation of Muscle Strength Per Unit Cross-sectional Area of Human Muscle by Means of Ultrasonic Measurement. Int Z Angew Physiol, 26:26–32.

http://doi.org/10.1016/s0749-8063(97)90006-2

http://doi.org/10.1007/bf00696087

Publisher’s note

Wioce Publishing remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.