



Original Article

Enhanced mechanical properties of a novel unsintered hydroxyapatite/poly L-lactic acid (u-HA/PLLA) screw with a reverse buttress thread design



Takuya Wakatsuki^{a,*}, Shinji Imade^a, Satoshi Furuya^b, Hiroshi Morii^c, Daishiro Oka^c, Koichiro Nakazawa^b, Kazuma Shiraishi^b, Takuya Manako^a, Masaya Sato^a, Yuji Uchio^a

^a Department of Orthopaedic Surgery, Shimane University Faculty of Medicine, 89-1 Enya, Izumo, Shimane 693-8501, Japan

^b Department of Manufacturing Technology, Shimane Institute for Industrial Technology, 1 Hokuryo, Matsue, Shimane 690-0816, Japan

^c Teijin Medical Technologies Co., Ltd., 2-3-33 Nakanoshima, Kitaku, Osaka, Osaka 530-0005, Japan

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ABSTRACT

Background: Although bioabsorbable screws offer various advantages, they also have the clinical drawback of low inherent strength. We developed a novel u-HA/PLLA screw with an innovative shape that maintains the screw function while increasing its strength. The aim of this study was to assess the mechanical properties of this novel screw in comparison to the conventional type.

Methods: Both the novel and conventional screws had a major diameter of 4.5 mm and a pitch of 1.6 mm. The conventional type had a minor diameter of 3.5 mm (with thread depth of 0.5 mm) and utilized a buttress thread design. In contrast, the novel screw had a minor diameter of 3.7 mm (with thread depth of 0.4 mm) and a reverse buttress thread. Three-point bending, shear, and torsion tests were performed to compare the screw strengths ($n = 10$). In addition, to compare their pullout strengths, the screws were inserted into two types of simulated bone, one mimicking osteoporotic bone and the other healthy bone ($n = 10$ replicates for each condition).

Results: The novel screw exhibited 33 % higher three-point bending strength ($p < 0.001$), 23 % higher shear strength ($p < 0.001$), and 24 % higher torsion strength ($p < 0.001$) than the conventional screw. The fourth parameter of mechanical strength, pullout strength, was not significantly different between the screw types, regardless of the bone conditions.

Conclusion: The novel u-HA/PLLA screw demonstrated superior mechanical strength while maintaining comparable pullout strength versus the conventional type.

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1. Introduction

There are three main types of osteosynthetic screws: metal screws, bioabsorbable screws, and bone screws. While metal screws are predominantly used at present, bioabsorbable screws have the key advantage of not requiring removal after bone union. Bioabsorbable screws also produce fewer artifacts, facilitating the use of diagnostic imaging modalities such as CT and MRI [1]. Chun et al. [2] and Nuelle et al. [3] applied bioabsorbable screws for osteochondritis dissecans and osteochondral fractures, respectively, and discussed the benefits for MRI imaging in periarticular

applications, along with the advantage of not requiring screw removal. The clinical efficacy of bioabsorbable screws has also been well documented in treatment of patellar fractures [4], foot trauma [5,6], elective foot surgeries [7], and medial epicondyle fractures in adolescents [8].

However, Pisecky et al. cautioned that bioabsorbable screws also have drawbacks that should not be overlooked, including insufficient mechanical strength and potential foreign body reactions [7]. Lee et al. similarly suggested that bioabsorbable screws are weaker than metal screws, leading to a higher incidence of breakage in clinical settings [9]. Bioabsorbable screws made from composite materials of unsintered hydroxyapatite particles and poly-L-lactide (u-HA/PLLA) have been shown to exhibit excellent bioactivity and bone conduction performance [10–12], but to suffer from the main drawback of other bioabsorbable screws—namely,

* Corresponding author.

E-mail address: waka87@med.shimane-u.ac.jp (T. Wakatsuki).

low mechanical strength. Based on these findings, bioabsorbable screws would be particularly suitable for fixing small bone fragments at the epiphysis and for relatively small bone fixations, such as those in the patella and tarsal bones. Nonetheless, the risk of screw breakage due to fragility remains a significant concern when using bioabsorbable screws.

The three main types of screw strength—bending, shear, and torsional—depend on thickness; thicker screws are less likely to break. However, screw size is limited by the site of use, with only small screws being suitable for small bones. In theory, a simple method to increase screw strength while maintaining the major diameter would be to thicken only the minor diameter. However, increasing the minor diameter would also reduce thread depth and thereby decrease screw pullout strength.

A possible solution to this problem involves two key factors of pullout strength. First, the relationship between thread depth and pullout strength is a biphasic, positive, and approximately linear one, with pullout strength being relatively maintained up to a thread depth threshold of 0.4 mm [13,14]. Second, while the buttress thread, which has a small proximal flank angle and a large distal flank angle, has long been the predominant thread shape in surgical applications, the reverse buttress thread, which has a large proximal flank angle and a small distal flank angle, has recently been shown to offer greater resistance to loosening and higher pullout strength from a stress dispersion perspective [15,16]. Therefore, by increasing only the minor diameter up to 0.4 mm in thread depth and adopting a reverse buttress thread, it is theoretically possible to improve screw strength while maintaining pullout strength.

Based on the background outlined above, we have developed a novel u-HA/PLLA screw. This novel screw maintains the pitch and 4.5-mm major diameter of the u-HA/PLLA screw in current clinical use, but features an increased minor diameter, a reverse buttress thread, and a low-profile screw head. We anticipate that increasing the minor diameter will improve the mechanical strength, while the reverse buttress thread will maintain the pullout strength. The aim of our study was thus to assess the mechanical and pullout strength of the novel screw relative to those of the conventional screw.

2. Materials and methods

2.1. u-HA/PLLA screws

Two designs of all-thread u-HA/PLLA screws were prepared for this study, both with 4.5 mm diameter, 1.6 mm pitch, and 30 mm length. The conventional screw was the Osteotrans Plus™, and the novel one was the Osteotrans Plus LRT™, both manufactured by Teijin Medical Technologies Co., Ltd. (Osaka, Japan). The screws differ in two key aspects: minor diameter and thread shape. The conventional screw has a minor diameter of 3.5 mm (with a 0.5 mm thread depth) and features a buttress thread (distal and proximal flank angle of 44° and 28°, respectively). In contrast, the novel screw has a 3.7 mm minor diameter (with a 0.4 mm thread depth) and incorporates a reverse buttress thread (distal and proximal flank angles of 0° and 30°, respectively). The details of both screws are shown in Fig. 1.

2.2. Mechanical properties of the screws

To investigate their resistance to failure, we comparatively evaluated three factors of the conventional screw (conventional type) and novel screw (novel type): the bending strength, shear strength, and torsional strength.

2.2.1. Three-point bending test

To determine the bending strength of the screws, a three-point bending test was conducted for each group (n = 10 replicates per group). Two custom-made fixtures were attached to a mechanical loading device (model 5565; Instron, Canton, MA). The upper fixture featured a semicircular projection (R: 2 mm) at the tip, while the lower fixture had two bases with a 4.5 mm diameter groove for positioning the screw, spaced 20 mm apart (Fig. 2A). The specimens were placed at the center of the lower fixture, a preload of 5 N was applied, and the upper fixture was lowered onto the specimen at a constant rate of 5 mm/min. The maximum load was recorded when the upper fixture was displaced by 8 mm due to contact between the fixtures or when the load decreased by more than 50 % after reaching the maximum load, which was defined as the screw's bending strength.

2.2.2. Shear test

Shear strength was assessed using the same Instron mechanical loading device as used in the three-point bending test. A custom-made pair of sliding semi-cylindrical fixtures with a 4.5 mm diameter hole in the center were used (Fig. 2B). The specimens were positioned in the hole, a preload of 5 N was applied, and the upper fixture was slid upward at a constant rate of 5 mm/min to apply a shear load. This test was performed 10 times for both screw groups. The shear strength of the screw was defined as the load at which the force decreased by more than 40 % after reaching the maximum load.

2.2.3. Torsion test

Custom-made fixtures consisting of two components were prepared. One component was a 50 × 50 × 15 mm polyether ether ketone (PEEK) block with a threaded hole for either the conventional screw or the novel screw in the center of the 50 × 50 mm face. The other component was a 50 × 50 × 12 mm SUS304 block. Both components were securely fixed face to face. The PEEK block was used only once and replaced after each test. Each screw was inserted into the corresponding custom-made fixture until it reached the bottom of the hole (15 mm). An automatic rotating torque screwdriver (NTS-6-S10; Sugisaki Seiki, Ibaraki, Japan) was then connected to each screw head using a custom-made attachment device (Fig. 2C). A torsion load was applied until the screw broke, and the maximum torque value recorded was defined as the torsion strength.

2.3. Measurement of pullout strength

2.3.1. Simulated bone

Polyurethane foam blocks (Sawbones, PRL, WA, USA) with densities of 10 and 20 pounds per cubic foot (PCF) (0.16 g/cm³ and 0.32 g/cm³, respectively) were used as simulated bone. The 10 pcf foam density mimics osteoporotic bone, while the 20 pcf density represents normal cancellous bone [16]. Composite blocks were used to minimize inter-specimen variability and met the American Society for Testing and Materials (ASTM) standard #F1839-08. The blocks were cut to dimensions of 40 × 28 × 28 mm, with 10 small blocks prepared for each density. Pre-drilled holes were made in the center of the bottom surface of the blocks using a drill press; the diameters were 3.5 mm for the conventional type and 3.7 mm for the novel type (10 holes in each).

2.3.2. Single pullout test

After tapping, screws were inserted into the pre-drilled holes so that their heads extended 15 mm from the upper surface of the block. A single pullout test was then performed for each combination of screw type and simulated bone density (n = 10 replicates

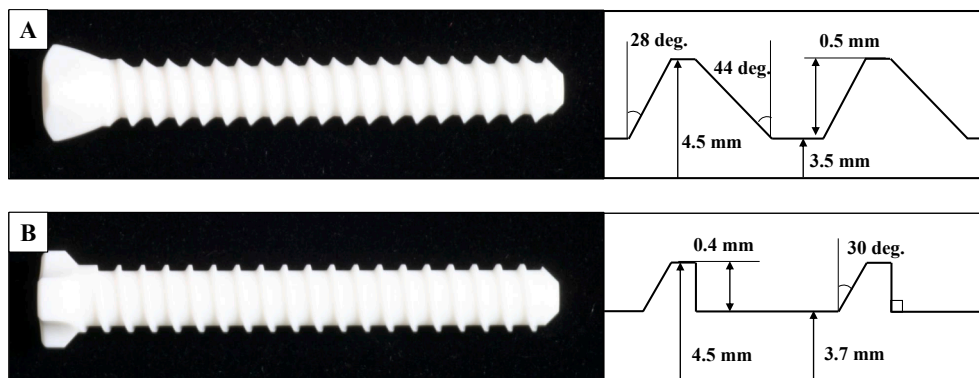


Fig. 1. Photographs (left) and design schematics (right) for the conventional and novel u-HA/PLLA screws. The upper row depicts the conventional screw and the lower row the novel screw.

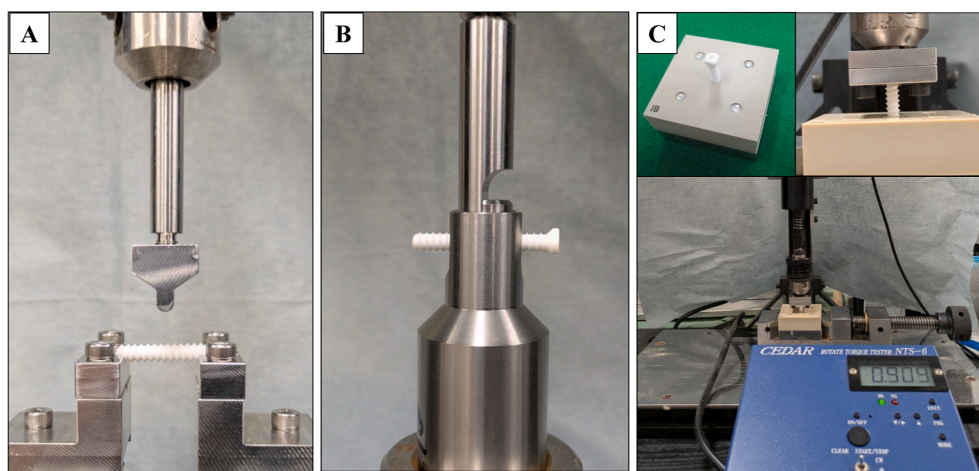


Fig. 2. Custom-made fixtures for measuring screw strength. **A:** Three-point bending test. **B:** Shear test. **C:** Torsion test.

for each condition). Two custom-made fixtures were connected to the same mechanical loading machine described above (Fig. 3). The upper fixture had a 4.5-mm-diameter hole in the center for attaching the screw head. The lower fixture was a rectangular plate with a 10-mm-wide hole on the top surface. A simulated bone block was positioned under the lower fixture, and the tested screw was secured to the upper fixture through the gap. After applying a 5 N preload, the screw pullout test was conducted in a direction parallel to the screw axis at a speed of 5 mm/min, as specified by ASTM F543. The pullout strength was recorded as the maximum value observed immediately before screw pullout.

2.4. Statistical analysis

Data were analyzed using JMP 16 (SAS Institute, Cary, NC, USA). The Mann–Whitney *U* test was employed for all comparisons. *P*-values less than 0.05 were considered statistically significant.

3. Results

3.1. Mechanical properties of the screws

The median (interquartile range [IQR]) values from the three-point bending strength test and shear strength test were 164.2 N (155.9–166.0) and 859.3 N (848.3–868.4) for the conventional screws, and 215.4 N (211.7–217.5) and 1072.2 N (1003.2–1107.4) for

the novel screws (Fig. 4A and B). Significant differences were observed between the groups for both measurements ($p < 0.001$ and $p < 0.001$, respectively). The median torsion strength was 0.600 Nm (IQR, 0.593–0.617) for the conventional type and 0.741 Nm (0.727–0.764) for the novel type, revealing a significant difference between the types ($p < 0.001$) (Fig. 4C).

The percentage increases in the novel type compared to the conventional type were 33 % in three-point bending strength, 23 % in shear strength, and 24 % in torsion strength.

3.2. Pullout strength

During the tests, there were no unintended breaks or cracks in either the threads or heads of screws of either type. The median (interquartile range [IQR]) pullout strength in the 10-pcf form was 149.8 N (143.1–153.8) for the conventional type and 151.3 N (138.7–160.4) for the novel type, with no significant difference (Fig. 5A). In the 20-pcf form, the median pullout strength was 516.8 N (506.7–558.9) for the conventional type and 564.4 N (515.4–590.9) for the novel type, again showing no significant difference between the types (Fig. 5B).

4. Discussion

The most important finding of this study was that the novel screw exhibited approximately 20 %–30 % greater three-point



Fig. 3. Custom-made fixtures for the screw pullout test.

bending, shear, and torsional strength than the conventional screw, with no difference in pullout strength.

Bioabsorbable screws offer the advantage of not requiring removal after bone union and have been utilized in various clinical settings. However, their mechanical strength remains inferior to that of metallic screws, which is a major limitation. To address this issue, we first aimed to enhance the mechanical strength of the screw by increasing its minor diameter. However, enlarging the minor diameter inevitably reduces thread depth, which may lead to decreased pullout strength. To compensate for this potential drawback, we adopted a reverse buttress thread design to improve pullout resistance despite the shallower threads. Consequently, we developed a novel screw geometry that incorporates two key modifications compared to the conventional screw.

The underlying rationale for the first enhancement—the change in minor diameter—was as follows. A screw’s strength is influenced by its minor diameter, assuming the major diameter

remains constant [14]. In addition, there is an inversely proportional relationship between minor diameter and thread depth: as the former increases, the latter decreases. A shallower thread depth results in lower pullout strength [18–20]. Therefore, it is essential to find a compromise point between screw strength and pullout strength, which are also inversely related. Previous studies have demonstrated that, regardless of the material (metal or u-HA/PLLA), the relationship between thread depth and pullout strength exhibits a biphasic linear correlation, with a boundary at a thread depth of 0.4 mm [13,14]. Based on this result, we modified the minor diameter of the u-HA/PLLA screw, which has a major diameter of 4.5 mm, from 3.5 mm (0.5 mm thread depth) to 3.7 mm (0.4 mm thread depth), while leaving the major diameter and pitch unchanged. As a result, the novel screw design demonstrated statistically significant increases of more than 20 % in three-point bending, shear, and torsion strength compared to the conventional screw.

The decision underlying the second improvement, the change of thread profile from buttress type to reverse buttress type, was also informed by previous research. For example, recent studies have revealed that reverse buttress threads, characterized by a smaller distal flank angle compared to the proximal flank angle, offer better stability due to stress dispersion [15,16]. Feng et al. found that reverse buttress threads had a 30.5 % higher pullout strength than buttress threads, and their finite element method (FEM) analysis revealed that reverse buttress threads exhibited larger compressive strain but smaller tensile strain than their buttress counterparts [15]. They concluded that reverse buttress threads are well-suited for osteosynthetic screws, as they are designed to reduce bone failure during pullout by exploiting the biomechanical characteristic that bone exhibits greater compressive strength than tensile strength. Additionally, Ye et al. suggested through FEM analysis that screws with reverse buttress threads had the smallest maximum displacement and relatively lower maximum equivalent stress at the bone–screw interface, making this thread shape the most appropriate [16]. Wang et al. conducted pullout experiments using bone screws, which possess mechanical properties similar to those of bioabsorbable screws. Their results demonstrated that the reverse buttress thread design exhibits superior pullout strength. Furthermore, micro-computed tomography (μ CT) analysis showed that, in the reverse buttress group, bone was attached only between the threads, whereas in the buttress group, the trabecular structures of the recipient cancellous bone remained intact. Collectively, the findings of Wang et al. indicate that stress was concentrated at the thread tips in the buttress design, leading to failure of the surrounding bone [17]. In this study, the novel screw demonstrated pullout strength

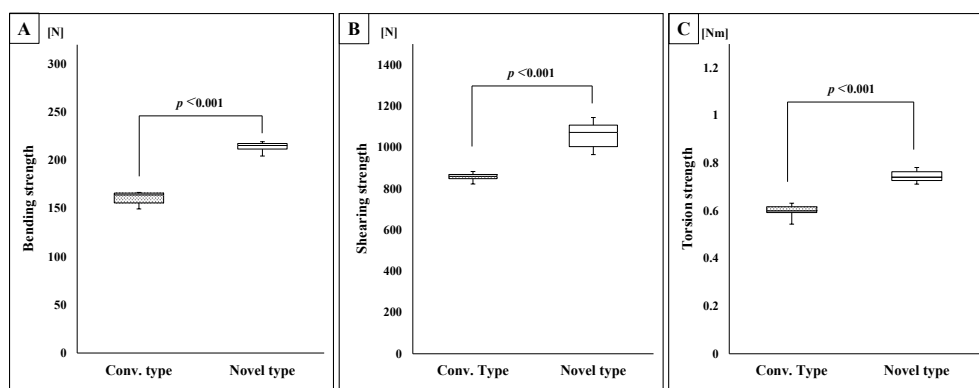


Fig. 4. Box plot of screw strength for each screw type. A: Bending strength. B: Shear strength. C: Torsion strength.

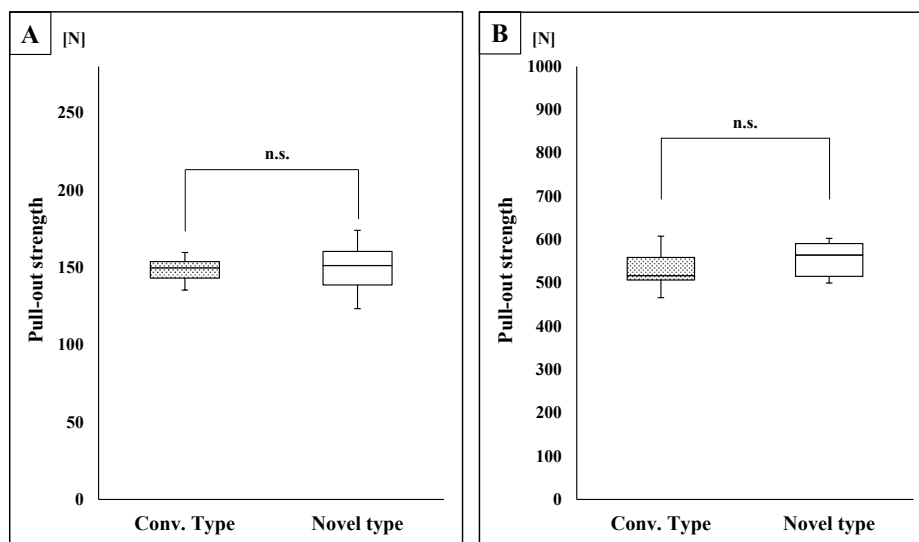


Fig. 5. Box plot of pullout strength for each screw type. A: For 10 pcfs. B: For 20 pcfs.

comparable to the conventional screw, irrespective of the density of the simulated bone. We attribute this result to the reverse buttress thread design, which compensates for the reduction in pullout strength associated with decreased thread depth.

We believe that the novel screw shape represents a viable option for non-metallic screws, achieving both breakage resistance (via the strength of the screw itself) and functionality (via the pullout strength). The 4.5 mm diameter u-HA/PLLA screw used in this study would be particularly effective for treating ankle and foot injuries, such as fractures of the medial or posterior malleolus and syndesmotic fixation. In addition, its clinical application is expected in settings where favorable outcomes with bioabsorbable screws have already been reported, including for patellar fractures [4] and medial epicondyle fractures in adolescents. Furthermore, applying this screw geometry to screws of different diameters may expand the indications for bioabsorbable screws. For example, increasing the diameter to 6.5 mm may enhance mechanical strength and allow use in weight-bearing fractures, such as proximal femoral or distal femoral condylar fractures. Conversely, using screws of smaller diameters such as 3 mm may enable application in fractures of the hand or phalanges, taking full advantage of the no-removal benefit of bioabsorbable screws. In this way, bioabsorbable screws have already demonstrated a certain degree of clinical utility, and the adoption of this novel thread geometry is expected to further improve clinical outcomes and broaden indications.

We anticipate that our approach would be applicable not only to u-HA/PLLA but also to other non-metallic screws made from poly-glycoside, poly-dioxanone, and poly-lactide/ β -tricalcium phosphate. In addition, in light of emerging evidence that bone screws made from autogenous [21] or allogenic bone [22,23] are suitable alternatives to metal screws and bioabsorbable polymer screws, we expect that our novel screw design could also be effectively applied to these bone screws.

Because bioabsorbable screws are gradually resorbed *in vivo*, changes in their mechanical properties over time remain a potential concern. The screw material used in the present study, u-HA/PLLA, is known to exhibit an initial bending strength of approximately 270 MPa, which exceeds that of human cortical bone. Previous *in vitro* studies have reported that the bending strength decreases by approximately 15% at 12 weeks and by 25% at 24 weeks [10]. Similar trends have been observed in *in vivo* animal studies using rabbits. Nevertheless, these studies also

indicate that sufficient mechanical strength is retained even at 24 weeks, which is generally considered the time frame required for complete bone union [24].

In our current study, the novel screws demonstrated approximately 20% greater mechanical strength compared to the conventional screws. This enhancement is expected to compensate for the 25% strength reduction observed at 24 weeks, thereby maintaining adequate fixation strength throughout the critical healing period.

Furthermore, previous animal studies on u-HA/PLLA screws have shown that macrophage-mediated phagocytosis of HA and PLLA degradation products is not observed within the first 1–2 years after implantation. Phagocytosis and resorption are reported to begin approximately 3 years post-implantation [25]. Based on these findings, it is considered that both the mechanical strength and the thread morphology of the screw are maintained during the bone healing period, and that the pullout strength does not significantly decrease.

There are several limitations to this study. First, the screw functional evaluation was conducted solely through a pullout test along the screw axis. This approach was chosen to comply as closely as possible with the ASTM Standard (#F543) and to align with similar methods employed in previous studies on screw evaluation [26]. The reduced thread depth in the novel screw may lead to loosening under cyclic loading. However, Schliemann et al. investigated whether locking screws with a large core diameter and a low thread pitch provide increased stability under cyclic load and reported that such screws are associated with less motion at the bone–implant interface, resulting in greater fixation strength compared to conventional locking screws [27]. A similar effect is anticipated for the novel u-HA/PLLA screw.

Second, this study did not include *in vivo* testing. Therefore, the screw strength and pullout strength in an actual clinical setting might differ from those found here. Nonetheless, because the relative relationship between the novel and conventional screws would be expected to remain consistent, the findings of this study remain meaningful. However, *in vivo* performance evaluation is a crucial aspect of implant assessment. Therefore, future studies should include animal experiments to comprehensively evaluate not only fixation strength under dynamic loading but also screw breakage, bone healing progression, and long-term biological responses such as stability.

Third, the screw head shape was not evaluated in this study. Preliminary tests during the development process confirmed that the novel screw exhibited the same functionality as the conventional type, and no damage to the head occurred during the pullout tests. Thus, no serious clinical issues are expected. In contrast, a thinner head may offer clinical benefits, such as reduced irritation to surrounding tissue. In the future, we plan to report on the outcomes of treatments using the novel screw in actual clinical settings.

5. Conclusions

The novel u-HA/PLLA screw demonstrated greater strength and comparable pullout strength when compared to the conventional type. This shape effect may be universal, such that similar benefits could be realized by its application to other non-metallic screws.

Ethical approval

Not required.

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Declaration of competing interest

This research was not supported by any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. But we own the design rights (JPS-1700438, 1700439, 1700490) for the novel screw investigated in this paper.

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