

学位論文の要旨

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- 学位論文名 Enhanced Mechanical Properties of a Novel Unsintered Hydroxyapatite/Poly L-lactic Acid (u-HA/PLLA) Screw with a Reverse Buttress Thread Design
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論文内容の要旨

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. However, bioabsorbable screws possess notable drawbacks, most importantly insufficient mechanical strength. Previous studies have similarly reported that these screws are mechanically weaker than their metallic counterparts and show a higher incidence of breakage in clinical use. Although bioabsorbable screws composed of unsintered hydroxyapatite and poly-L-lactide (u-HA/PLLA) exhibit excellent bioactivity and osteoconductivity, they share the principal limitation of other bioabsorbable implants—namely, low mechanical strength.

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 potential solution to this problem is to increase only the minor diameter while preserving a thread depth of up to 0.4 mm, within which pullout strength is relatively maintained, and to adopt a reverse buttress thread—reported to provide superior

pullout resistance.

By combining these two design strategies, it is theoretically possible to enhance screw strength while maintaining adequate pullout strength. Based on this background, we developed a novel u-HA/PLLA screw. The aim of this study was to evaluate the mechanical and pullout strength of this new screw in comparison with those of the conventional design.

MATERIALS AND METHODS

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 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. 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. 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 AND DISCUSSION

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. 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 ($p < 0.001$).

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.

In the pullout test, the median (interquartile range [IQR]) pullout strength in the 10-pcf foam was 149.8 N (143.1–153.8) for the conventional screw and 151.3 N (138.7–160.4) for the novel screw, with no significant difference between the two.

In the 20-pcf foam, the median pullout strength was 516.8 N (506.7–558.9) for the conventional screw and 564.4 N (515.4–590.9) for the novel screw, again showing no significant difference between the screw types.

The most important finding of this study was that the novel screw exhibited approximately 20%–30% greater three-point bending, shear, and torsional strength than the conventional screw, with no difference in pullout strength. The mechanical strength of bioabsorbable screws remains inferior to that of metallic screws, representing a significant 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. 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. 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. 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. 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. 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 approach presented in this study is applicable not only to u-HA/PLLA screws but also to other non-metallic screws. Furthermore, given the emerging evidence that bone screws manufactured from autogenous and allogenic bone are promising alternatives to both metal and bioabsorbable polymer screws, we anticipate that our novel screw design could also be effectively applied to these bone screws.

CONCLUSION

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.