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RESEARCH ARTICLE

Mechanical characterisation of polylactic acid-alendronate bioscrew in different concentrations of glutaraldehyde

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Abstract

Background: Bioscrew is a developing innovation as a substitute to avoid re-surgery for screw removal; one of the bioscrew materials is polylactic acid (PLA). Alendronate plays a role in reducing osteoclastic activity, causing a decrease in osteoclast-mediated bone resorption, thereby accelerating the process of bone union. **Objective:** This study determines adding various glutaraldehyde concentrations to the bioscrew mechanical characteristics. **Method:** This study used the PLA bioscrew immersed into bovine hydroxyapatite (BHA)-gelatin (GEL)-alendronate (ALE) solution, then added with 0% (F1), 1% (F2), and 1,5% (F3) glutaraldehyde (GTA) as cross-link agent. **Result:** The pore diameter for F1, F2, and F3 were: 38.90±15.34; 29.01±8.94; and 30.58±7.40 µm, respectively. The flexural strength for F1, F2, and F3 were: 1.00±0.22, 1.18±0.13, and 1.11±0.16 MPa, respectively. The pull-out strength for F1, F2, and F3 were: 4.88 ± 0.79; 7.87 ± 0.24; and 7.65±1.02 N, respectively. The degradation rate for F1, F2, and F3 were: 14.40±2.08; 3.81±0.67; and 4.97±0.58 %, respectively. This study has found that glutaraldehyde concentrations significantly affect pull-out strength and degradation rate. The highest mechanical strength and slowest degradation rate for % weight loss was F2. **Conclusion:** Adding glutaraldehyde may enhance the mechanical characteristics of the bioscrew.

Introduction

Bone fracture is a human health issue, with 178 million cases in 2019 worldwide (Wu *et al.*, 2021). Fracture repair can usually return damaged skeletal organs to their pre-injury cellular composition, structure, and biomechanical function. However, about 10% of fractures will not heal normally (Einhorn & Gerstenfeld, 2015).

In orthopaedic applications, PLA-based materials have been widely used as fixation devices, such as bioscrews, pins, washers, arrows, and arrows in reconstructive surgeries, including on the mandibular joint (Narayanan *et al.*, 2016). PLA-based materials are used for manufacturing surgical internal fixations due to their good mechanical strength and absorbency, which reduces pain and risks associated with secondary surgery in patients (Narayanan *et al.*, 2016).

Bioscrews were designed to create radiation-friendly screws, capable of being securely fixed until the graft is combined, then undergoing destruction to be replaced by bone. Bioscrews are associated with good clinical outcomes and are possibly equivalent to metal screws (Pinczewski & Salmon, 2017). Material filling for bioscrew is carried out to accelerate bone growth and neutralise acidic pH due to PLA degradation. The bioscrew filling materials used are bovine hydroxyapatite as a base, gelatin, and alendronate. Bovine hydroxyapatite comes from bovine bone, which consists of 93% hydroxyapatite and 7% β-tricalcium phosphate (Budiatin *et al*., 2022). Gelatin is a biopolymer that can strengthen both hydroxyapatite and BHA. Further, gelatin beneficially influences the scaffold's in vivo performance (Gani *et al*., 2023). Gelatin is hydrophilic to facilitate drug release by diffusion, but it dissolves readily in aqueous solutions, so cross-linking agents must be added (Bigi *et al*., 2001).

Preliminary research shows that cross-linking agents such as glutaraldehyde have advantages such as being soluble in water, forming covalent bonds, having a low boiling point, and only being required in low concentrations (Budiatin *et al*., 2014). Alendronate, a natural modulator of bone metabolism (Capra *et al*., 2011). The primary mechanism of action of alendronate is to reduce osteoclastic activity, causing a decrease in osteoclast-mediated bone resorption, thereby accelerating the process of bone union (Olszynski & Davison, 2008).

Based on the description above, research is needed to prove that there was an effect of adding glutaraldehyde as a cross-linking agent on the character of the PLA bioscrew containing BHA-GEL-ALE suspension through mechanical tests: flexural strength, pull-out strength, and degradation test.

Methods

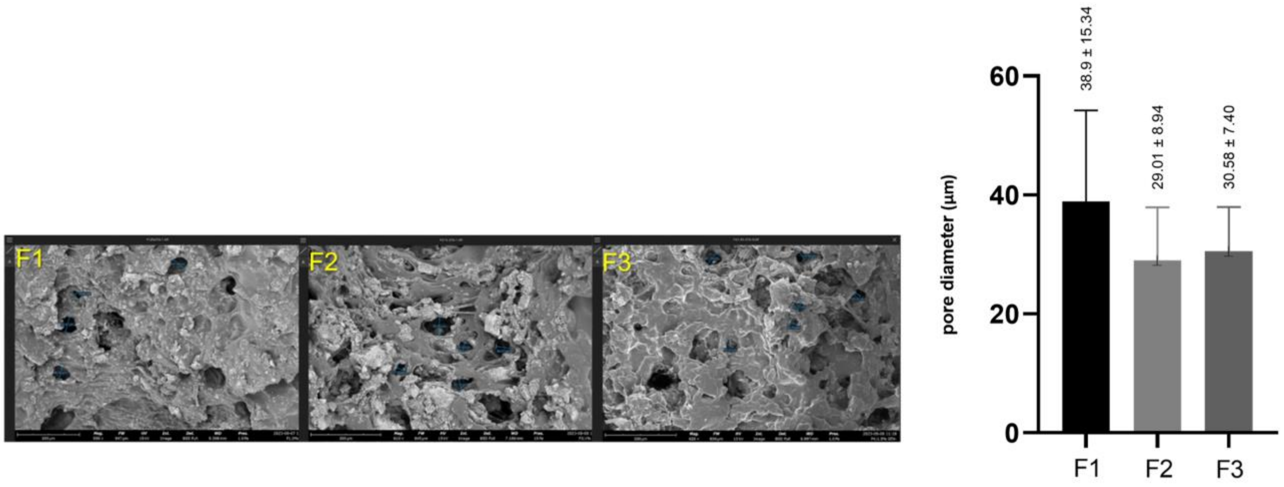
PLA-based bioscrew was made by 3D printing with the dimension of ±32 mm length and ±6 mm screw body diameter. The PLA-based bioscrew was immersed into BHA:GEL:PVA:HPMC (6:1:2:1) suspension and 1% w/w ALE with various concentrations of GTA 0,0% (F1), 1% (F2), and 1,5% (F3). Characterisation tests were pore diameter, flexural strength, pull-out strength, and degradation rate.

The pore diameter of the bioscrew was observed using a Scanning Electron Microscope (SEM). The flexural strength (Autograph Shimadzu AG-10TE) was performed by placing the bioscrew horizontally between two stacking points, then giving a compressive load at a speed of 5 mm/minute from one point above to the centre of the screw until the screw was damaged. The pull-out test (Autograph Shimadzu AG-10TE) used polyurethane foam as a bone-like media for insertion by the bioscrew. Then, the bioscrew head was given a pull-out at 8 mm/minute speed until the bioscrew was removed from the polyurethane media. The degradation test is performed by immersing the bioscrew in phosphate buffer saline (PBS) solution with pH 7.4 ± 0.2 and at 37°C. The weight changes were observed for 28 days.

The data was presented as mean ± standard deviation (SD). Study data was statistically analysed using SPSS software (SPSS Inc., Chicago, IL, USA). The result was analysed with ANOVA, and a p-value less than 0.05 was considered statistically significant.

Results

The pore diameters of the F1, F2, and F3 were 38.90±15.34, 29.01±8.94, and 30.58±7.40 µm respectively, did not significantly differ (Figure 1).



[a] [b]

Figure 1: [a] The representative photograph showing surface morphology and [b] the pore diameter of the bioscrew in the different formulas. The results are expressed as mean ± SD.

The flexural strength for F1, F2, and F3 were 1.00±0.22, 1.18±0.13, and 1.11±0.16 MPa, respectively, did not significantly differ. The pull-out strength for F1, F2, and F3 were 4.88 ± 0.79, 7.87 ± 0.24, and 7.65±1.02 N, respectively, significantly different. The degradation rate for F1, F2, and F3 were: 14.40±2.08; 3.81±0.67; and 4.97±0.58 % respectively, significantly differ. The flexural strength, pull-out strength, and degradation rate (Table I).

Table I: The mechanical strength of the bioscrew in different formulas. The results are expressed as mean ± SD

Bioscrew	Flexural strength σ (MPa)	Pull-out strength F (N)	Degradation rate (%)
F1	1.00 ± 0.22	4.88 ± 0.79	14.40 ± 2.08
F2	1.18 ± 0.13	7.86 ± 0.24	3.81 ± 0.67
F3	1.11 ± 0.16	7.65 ± 1.02	4.97 ± 0.58
Average	1.10 ± 0.18	6.80 ± 1.58	7.73 ± 5.16

Discussion

Aliphatic polyesters, like poly(-caprolactone), poly (lactic acid), poly (glycolic acid), and copolymer PLGA, have received the most significant attention in recent years as synthetic degradable polymers. These substances are biocompatible, degrade at a controlled rate, and produce degradation byproducts that are not hazardous to tissues when used in vivo. Additionally, by manually adjusting the design and synthesis settings, polymers with superior mechanical properties can be created (Wei *et al*., 2020). In this study, the pore diameter of the PLA bioscrew for F2 and F3 had a lower pore diameter than F1. This is in line with previous research showing that a small addition of GTA reduces the porosity, which makes the structure denser (Khabibi *et al*., 2021). The pore diameter increased in F3 compared to F2, and previous research demonstrated that an increase in glutaraldehyde increases the pore diameter (Putra *et al*., 2018).

The flexural strength of each group did not differ, with an average of 1.10±0.18 MPa. The previous research of miniplate specimens made of PLA with 34 mm length, 6.1 mm width, and 1.2 mm thickness, respectively, which have been subjected to flexural strength tests, has an average of 4.43 ± 0.1 MPa (Whulanza *et al*., 2022).

In the present study, the pull-out strength for F2 was higher than F1 and decreased in F3. Previous research showed that GTA at 0.5 and 1.0% increases pull-out strength and decrease at 1.5% (Arianita *et al*., 2018).

The degradation rate of the bioscrew showed that within 28 days, the F1 treatment group had a faster degradation rate and significant change in weight compared to the F2 and F3. Another study shows that adding GTA increases resistance to degradation, demonstrating that GTA inhibits degradation (Putra *et al*., 2018).

The PLA bioscrew shell in the F1 treatment group was intact in 28 days because only the BHA-GEL-ALE layer was degraded. As for the treatment groups F2 and F3, there was still quite a lot of BHA-GEL-ALE composite left to coat the PLA bioscrew shell. PLA can be completely degraded for over a year (Whulanza *et al*., 2022). Bioscrews were required to have a reasonable degradation rate to match the rate of bone tissue regeneration and provide mechanical support for new bone tissue (Wei *et al*., 2020). This study showed that F2 and F3 had lower degradation rates than the control group (F1), which means that glutaraldehyde could suppress the degradation rate of bioscrew.

Conclusion

The glutaraldehyde concentration as a cross-linking agent significantly affects pull-out strength and degradation rate. However, pore diameter and flexural strength are not significantly affected. The F2 shows the highest mechanical strength and slowest degradation rate. In conclusion, the addition of glutaraldehyde enhances the mechanical characteristics of bioscrew.

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