Pedicle Screw Bond Strength and Resistance Characteristics With Various Mineral Quality

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***Abstract* – Abnormal quality and composition of bone mineral bonds in the spine are found in many patients with cases of idiopathic scoliosis. The data shows that poor bone quality promotes thoracic spine degenerative disc swelling and physiological anomalies. Implants in the form of pedicle screws, rods, and connectors are one of the measures for scoliosis correction. When the pedicle screws are taken out after some use poor bone quality remains. In this study, fixation strength analysis will be carried out through tensile testing of bone joints and pedicle screws with variations in bone quality. Two specimen materials were used for approach analysis: polylactic acid (PLA) and bovine backbone. Pedicle screws are classified into three types: cylindrical, conical with a single thread, and double cylindrical screws. Tensile testing revealed that PLA specimens with pedicle screw variants provided the maximum force of 7.4 N and 8.31 N with double screw cylindrical implants at PLA 70:30 and PLA 40:60. A comparison of PLA specimens with a series of cylindrical screws to double-screw cylindrical screws yielded a displacement increase of 79.6%, whereas conical screws yielded a displacement increase of 222.3%. Fixation with double-screw cylindrical screws greatly increases tensile strength. However, the conical pedicle screw model with connecting rods gives greater fixation strength.**

Keywords – Pedicle screw, single screw cylindrical, single screw conical screw, double screw cylindrical.

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1. Introduction

Abnormal quality and composition of the mineral deposits in the spine are found in many patients with idiopathic scoliosis. These abnormalities can affect the strength and biomechanical stability of the spine [1], [2]. Bones with low quality significantly affect the chances of developing scoliosis. Data show that decreased bone quality causes degeneration of the thoracic disc swelling and gives rise to physiological abnormalities of the spine [3], [4]. Bone with low quality can affect the strength and stabilization of bone biomechanics. Altered bone quality in patients with idiopathic scoliosis affects the mechanical properties and anatomic structures. The low-quality bone composition has several parameters for spine scoliosis [5], [6]. Osteoporosis can significantly reduce the quality and function of the spine. The composition of bone quality that decreases by 50% in bone composition can reduce bone strength to 25% of normal bone strength. Furthermore, the side effects of scoliosis can endanger the patient from starting to experience physiological paralysis, neurological disorders, and heart failure. These conditions depend on the degree of curvature of the scoliosis [2], [7]. In Indonesia, no data has been found on the number of people living with scoliosis, however a potential of 4% of people with scoliosis was found in elementary school-age children in one area of North Sulawesi [8].

One of the measures for scoliosis correction is the installation of implants in the form of pedicle screws, rods, and connectors. However, low bone quality causes implant failure, where the pedicle screws are pulled out after use [9], [10], [11]. A locking implant instrument is used to hold the rod in place to prevent it from slipping off the screw.

These instruments put a load on the spine in order to reduce deformity or to bring spine back to its normal position. However, the low quality of the bone is one of the reasons that causes implant failure, where the pedicle screws are pulled out after some use [1], [12].

Practitioners and researchers find several forms of failure in implant placement for scoliosis correction. These failures include dislodgement of the pedicle screw from the spine, fracture of the pedicle screw, detachment of the supporting rod from the pedicle screw, and fracture of the supporting rod [9], [13]. By using the existing implant structure, many cases of failure were found in the implant structure and at the interface between the bone connection and the pedicle screw [14], [15]. Failure of the implant structure is often found in the implant structure or at the connection interface between the bone and the pedicle screw. The failures that are often found include are: 1) Most cases are the detachment of the bolt from the bone caused by a load pulling the screw [7], [16], [17], in addition to weakness in the bone due to osteoporosis [18], 2) Fracture of the pedicle screw in the form of fatigue failure after several years of implant placement [19] and fretting of screws [20], [21], 3) Corrosion of pedicle screw and rods [21], 4) Some other forms of failure are the detachment of support rods with pedicle screws , detached and broken screw heads, and broken support rods [22].

Stress concentrations occur in fasteners such as plate cracks, loose screws, and high-rigidity implant materials [14], [17]. Giving a tensile load by reducing the coefficient of friction between the surfaces can increase the maximum stress. Maximum stress increases with increasing interfacial friction coefficient in various bone quality compositions [13], [23]. The maximum stress occurs in the cortical bone, not the pedicle screw threads [6]. The injury is caused by a failure to correct scoliosis so that the use of pedicle screws is adjusted to the quality of the bone composition to reduce the stress distribution that occurs. Using conical screws with a reduced coefficient of friction results in increased tensile loads on pedicle screw threads compared to cylindrical screws [24]. The purpose objectives are:

- To determine the fixation strength due to the influence of tensile testing on bone connections with pedicle screws with variations in the quality of mineral and bovine bone.
- Knowing the connection thread fixation pattern due to the influence of tensile testing on bone connections with pedicle screws with variations in mineral quality.

2. Methodology

The analysis used two specimen material types: polylactic acid (PLA) and bovine backbone. Specimens with PLA material were made through 3D printing with different density levels on the outside and inside as a model of the cortical and cancellous on the backbone. In addition, testing and analysis were also carried out on the backbone of the cow. Meanwhile, there are three types of pedicle screws: cylindrical and conical with a single thread, and double cylindrical screws with different thread sizes.

The test results show that material specimens of poly lactic acid (PLA) with a specific gravity of 1.25 g/cm3 with variations in composition inner density that is 30% and 60% (cancellous equation) against the outer surface with a thickness of 3 mm with a percentage of 100% (cortical equation) which has a higher solidity and hardness than the inner part. Solidity PLA: 30% have weights 78.1 g, and PLA: 60% have weights 108.7 g. The procedure includes preparation of a tensile test specimen of 60 mm x 60 mm x 60 mm by making a binding jig during the tensile test. The behavior of this specimen being pulled out by the tensile test is to see the quality composition of the PLA material, such as the material of bone quality composition in Table 1.

Table 1. PLA specimen data

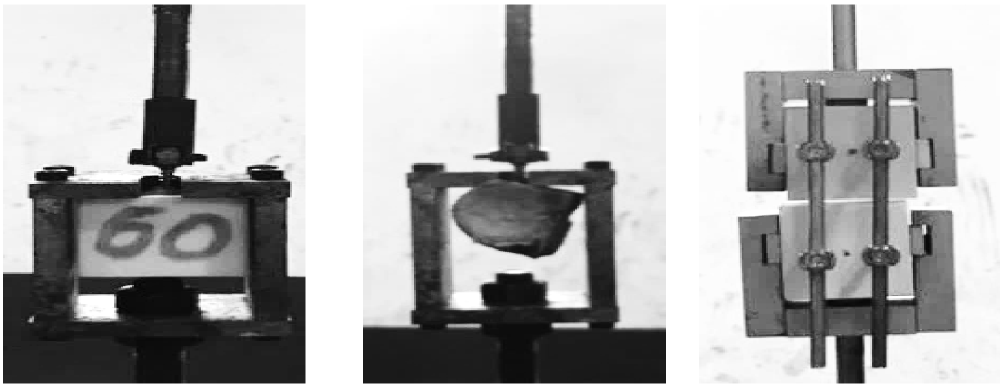
Type	Surface Thickness 3mm	Density inside	Weight (g)	Dimensions (mm)
PLA:30%	100%	30%	78.1	60x60x60
PLA:60%	100%	60%	108.7	60x60x60

Beef bone specimens were taken from the backbone of the cow (T3–T5), which was first cleaned of meat, muscle, and other parts attached to the bone, then cleaned with water for two weeks before starting the test. Pedicle implant screws in each specimen use single-screw cylindrical and conical screws and double-screw cylindrical. The use of pedicle implant screws in each specimen uses single-screw cylindrical and conical screws as well as double-screw cylindrical, as shown in Figure 1. The pedicle screw implants used are single-screw cylindrical and conical shown in Figures 1. a ,and b. and cylindrical as shown in Figure 1. c using the FJD3 type with a size of 6mm-θ5mm x 40mm Ti6A14V Young's Modulus 110 GPa and pedicle screw connecting rod ASTM C36000 (B16-92) having a tensile strength of 335 N/m^2 and hardness 80 HV.

(a) (b) (c)

Figure 1. Pedicle screw implant, a) cylindrical, b) conical, c) double-screw cylindrical

Figure 2 shows a single PLA, bovine bone, and double PLA specimen binding jig connected by a connecting rod. The tensile force and tensile speed of the tensile testing machine are adjusted in this test. Tensile test used standard ISO 12189-8 and ASTM F1717.



(a) (b) (c)

Figure 2. Pedicle–jig screw tensile test image, a) Single PLA and b) Cow bone, c) Double PLA with connecting rod

Figure 2 (a) and (b) shows the tensile testing of specimens PLA: 30%, PLA: 60%, and bovine bone, which have been fitted with cylindrical and conical pedicle screws with single screw and double screw cylindrical which are attached with a jig to the tensile testing machine. This tensile test was carried out with the aim to produce data on tensile strength, displacement, and surface pattern of variations in the pedicle screw detached from the specimen due to variations in the level of density on the inside of the specimen. Whereas bovine bone specimens subjected to tensile testing as a living bone approach yield data on tensile strength, displacement, and surface pattern of pedicle screw variations regardless of the specimen.

Figure 2 (c) shows the tensile testing of PLA: 30% and PLA: 60% specimens which have been fitted with cylindrical and conical screw pedicles with single-screw and double-screw cylindrical, then a connecting rod is attached to each of the pedicle screws, and a jig is attached to the tensile testing machine. This tensile test was carried out with the aim to produce data on the tensile strength of the effect of attaching the connecting rod to the specimen, displacement, and surface pattern of variations in the pedicle screw detached from the specimen due to variations in the level of density on the inside of the specimen.

The behavior of this specimen being pulled out by the tensile test is to see the quality composition of the PLA material, such as the bone quality composition.

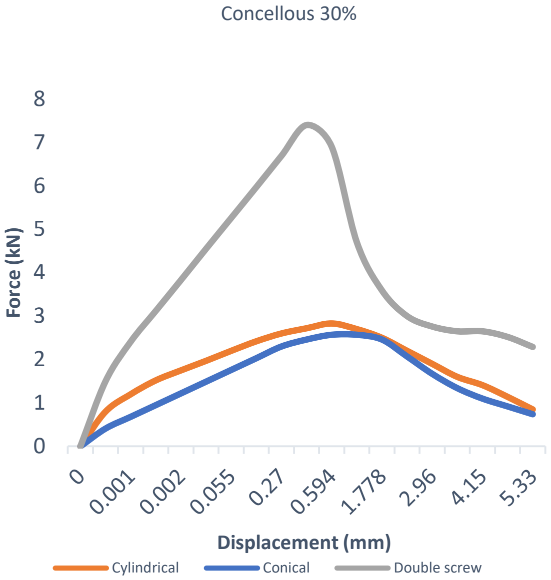
3. Results

Tensile testing was carried out to produce the fixation strength of the pedicle screw connection with variations in the mineral quality of PLA and bovine bone as well as displaying the fixation screw connection pattern with variations in mineral quality

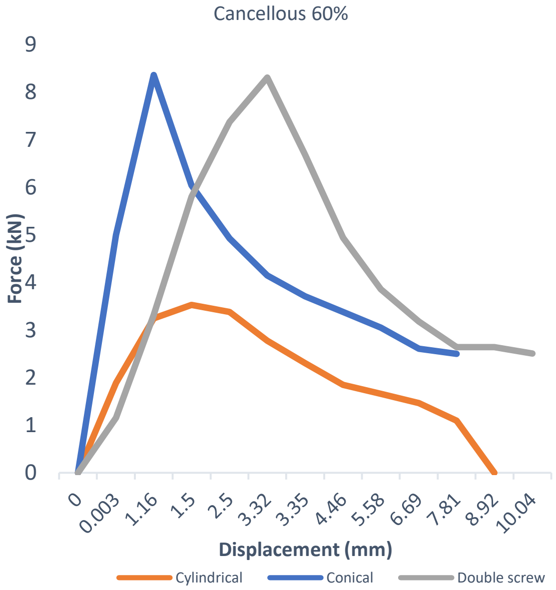
3.1. Interfacial Tensile Strength Test on PLA and Bovine Bone Specimens with Variations of Pedicle Screws

A tensile testing machine was carried out to obtain the interface contact response for variations in the PLA specimen model with variations in external loads whose characteristics are close to the mechanical properties of bone and the use of bovine bone specimens. The trial was successfully carried out by loading each single PLA material specimen with a tensile load of 5 kN with a tensile speed of 5 mm/min. Figure 3 shows the results of the tensile test of the two material compositions; PLA: 30%, PLA: 60%, and bovine bone fixed with single screw and conical screw implants as well as double cylindrical screw.

The difference in the density composition of PLA is equated with the quality composition of bone, while the bovine bone is a biological bone approach. The test is performed first on less dense PLA specimens and then on more dense specimens. Furthermore, bovine bone material specimens, fastened with variations of pedicle screws, were subjected to a tensile test with a tensile load of 5 kN at a tensile speed of 5 mm/min on a tensile testing machine.



(a)



(b)

Figure 3. Graph of tensile testing Force (kN) – Displacement (mm) of the pedicle screw on the specimen material composition a) PLA: 30%,b) PLA: 60%

The results of the tensile test force on bovine bone can be seen in Figure 4 double-screw cylindrical screw implants fixed on bovine bone produced the highest tensile force of 2.46 kN and a displacement of 4.073 mm compared to single-screw cylindrical or conical pedicle screws.

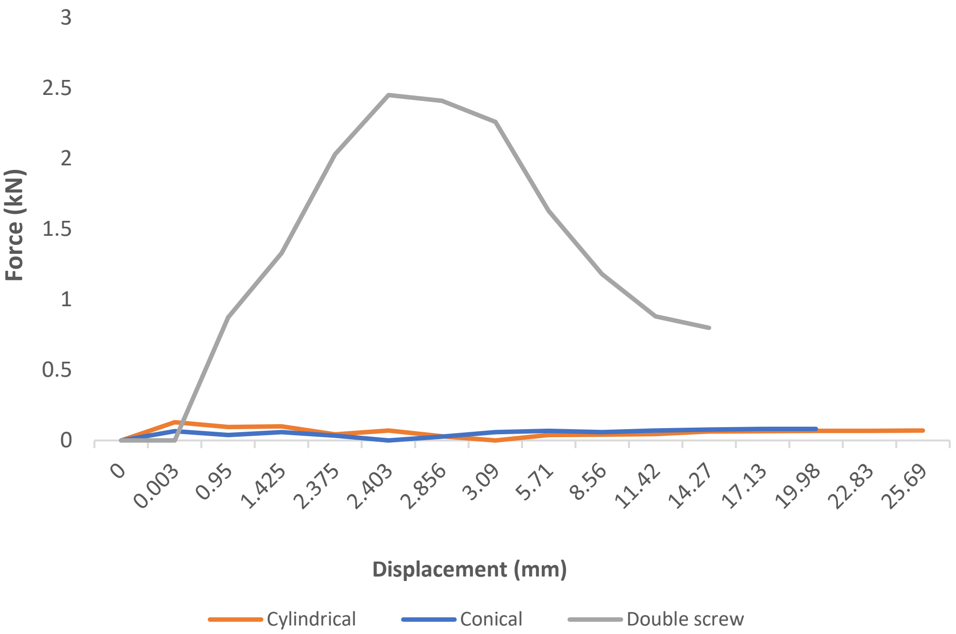
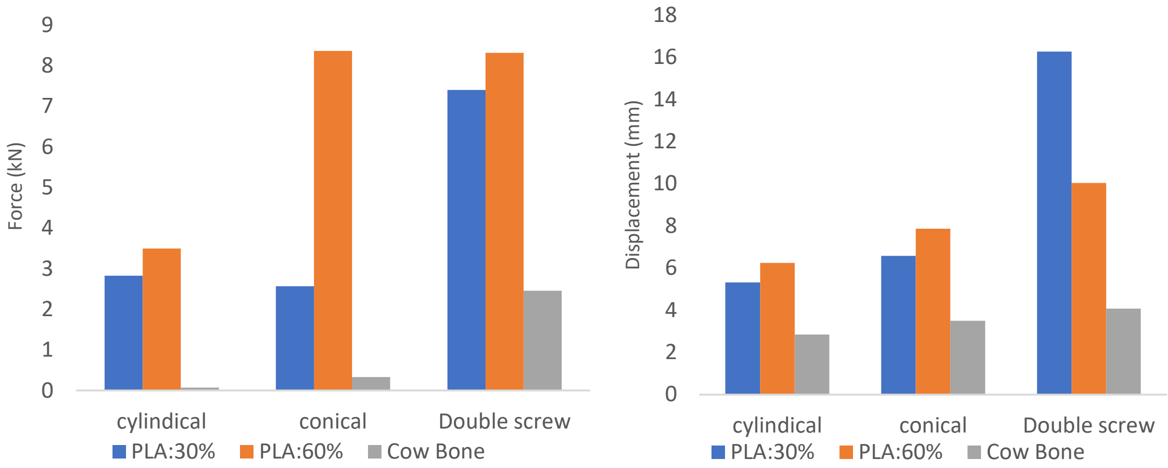


Figure 4. Graph of tensile testing Force (kN) – Displacement (mm) of the pedicle screw on the specimen bovine bone

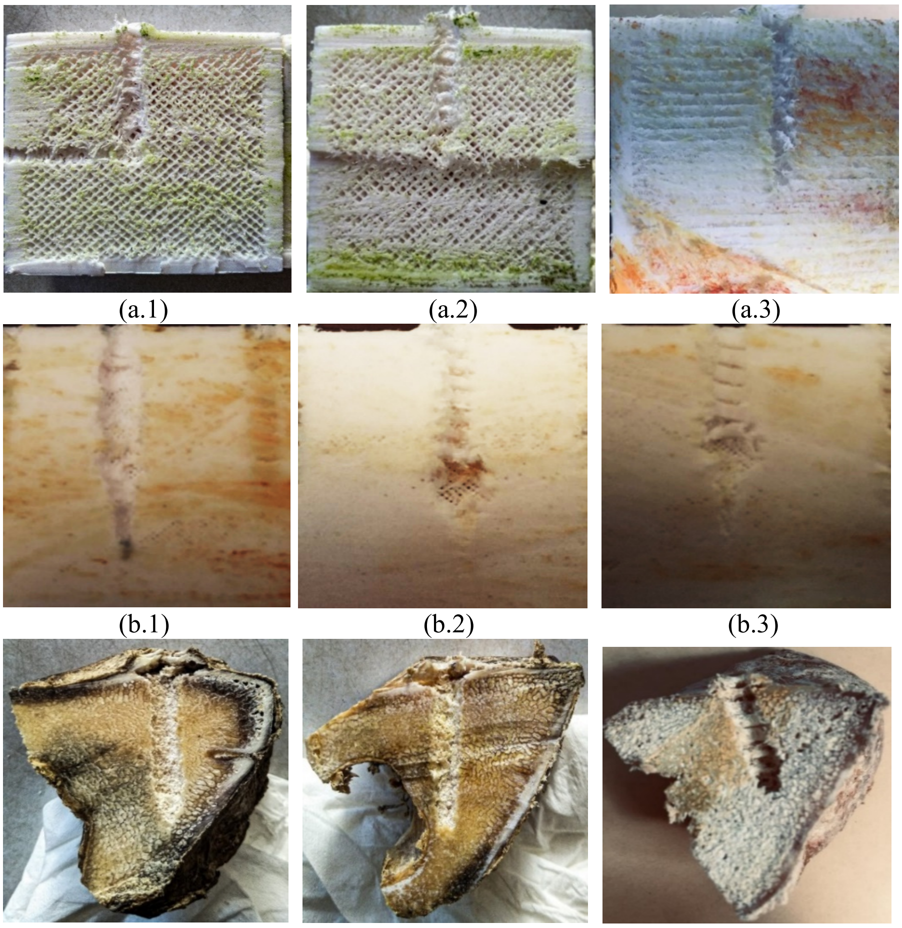
The results of the PLA specimen tensile test: 30% with variations in the pedicle screw in Figure 5 (a) produced the highest tensile strength of 7.4 kN using double-threaded cylindrical screw fixation, and PLA: 60% specimen had a tensile strength of 8.36 kN with single-threaded conical screw fixation.



(a) (b)

Figure 5. Graph of tensile testing Force (kN) – Displacement (mm) of the pedicle screw on the composition of specimen material a) Force (kN), b) displacement (mm)

Figure 5 (b) shows the deformation that occurs at the interface of various PLA specimens with variations of pedicle screws, resulting in the highest displacements of 16.28 mm and 10.04 mm using double cylindrical screws at PLA: 30% and PLA: 60% compared to using screws single screw cylindrical and conical.



(a.1) (a.2) (a.3)

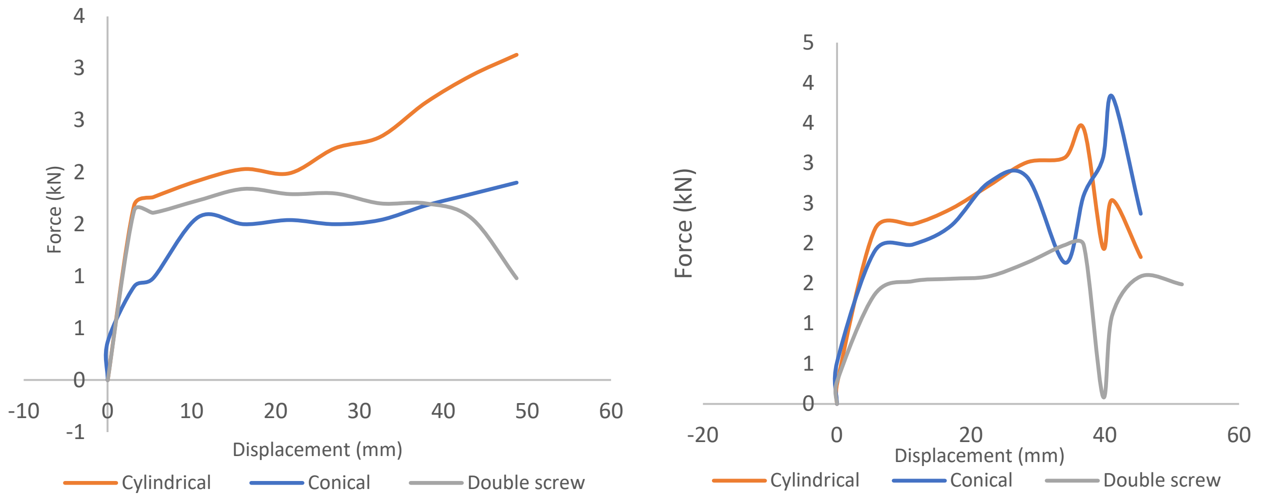
(b.1) (b.2) (b.3)

(c.1) (c.2) (c.3)

Figure 6. The pattern of specimen material pedicle screw tensile test results: a) PLA: 30%; b) PLA:60%; c) Cow bone (1. cylindrical,2.conical,3.double screw cylindrical)

3.2. Testing the interfacial strength of the PLA:30% and PLA:60%

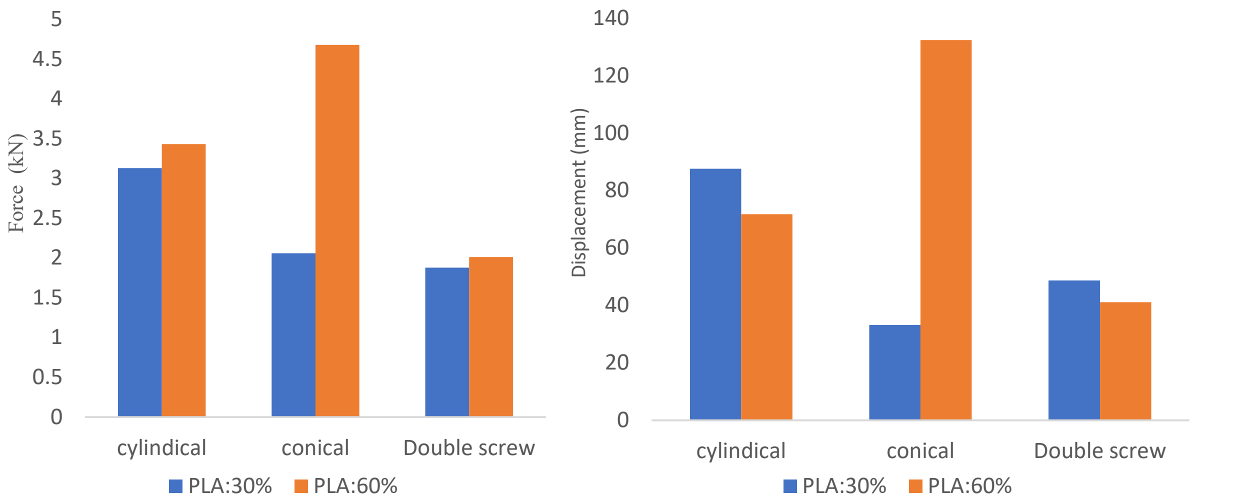
Specimens of the material composition PLA: 30% and PLA: 60% were strung together and then fixed with two rows of pedicle screws, then connecting rods were attached to each screw. The fixed specimens are subjected to a tensile test with a tensile load setting of 10 N with a displacement speed of 20 mm/min to produce a force (kN) and displacement (mm) graph, as shown in Figure 7.



(a) (b)

Figure 7. Graph of Force (N) – displacement (mm) tensile test of pedicle screw series on specimen material composition a) PLA:30 and b) PLA:60

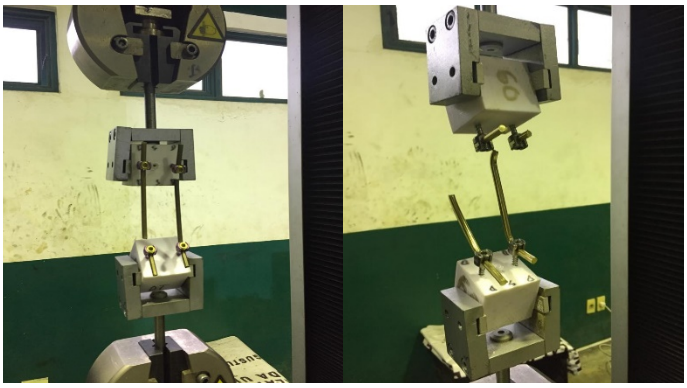
Figure 8 (b) shows the deformation at the interface with the highest PLA variation of 87.59 mm using a cylindrical screw and 132.41 mm deformation using a conical screw on PLA: 30% and PLA: 60% specimens. A comparison of PLA specimens with cylindrical screws to double-screw cylindrical screws saw an increase in displacement of 79.6%, while conical screws with double-screw cylindrical screws increased displacement by 222.3%. This deformation reflects the effect of pedicle screw fixation on the specimen as an effect of its interfacial strength.



(a) (b)

Figure 8. Graph of tensile test Load (kN) – L (mm) pedicle screw assembly on specimen material composition a) Force (kN) and b) Displacement (mm)

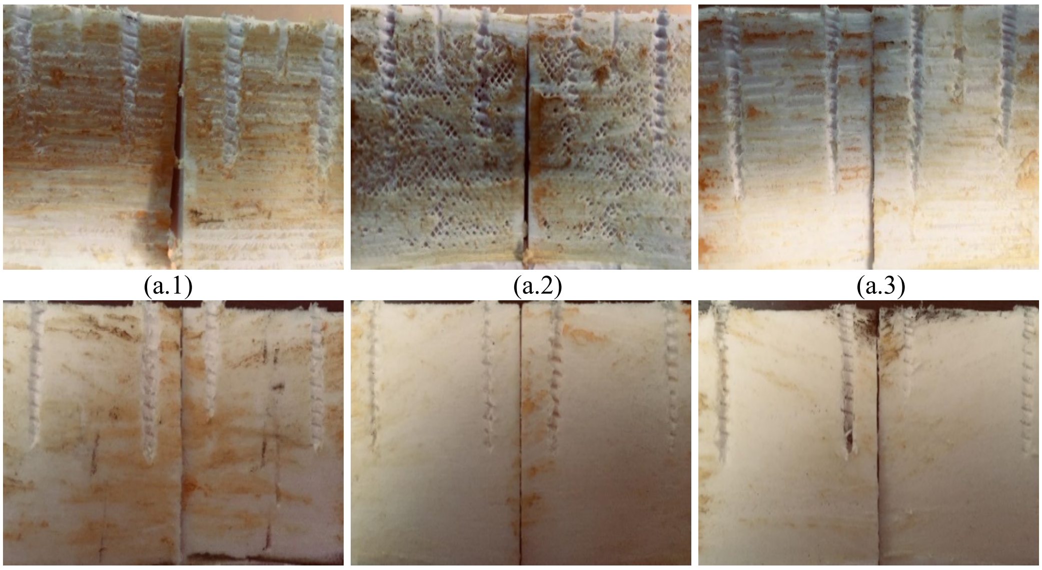
Figure 9 shows the results of the tensile test of the fracture mechanism during the tensile testing of the PLA: 30 % and PLA: 60 % specimens which had been broken in the position of the connecting rod which was fastened between cylindrical and conical pedicle screws with single thread and cylindrical with double thread. Figure 9 (a) and (b) show specimens broken by axial force in the direction of the connecting rod and fracture of the connecting rod near the screw pedicle, which occurs at the beginning of the screw nut fastening.



(a) (b)

Figure 9. Fracture form of tensile test of PLA specimen pedicle screw assembly a) PLA: 30% , b) PLA: 60%

Figure 10 presents the cut pattern of a bovine bone specimen that had its pedicle screw removed during a tensile test. The pattern of the loose surface of the pedicle screw with the PLA material specimen: 30% (Figure 10 (a)) it, appears that the fine fiber is formed by a cylindrical screw groove which indicates that the screw is more difficult to remove than the other screws. The PLA material specimen: 60% (Figure 10 (b)) shows quite fine fibers formed by conical screw grooves with a rough interfacial surface pattern, indicating that the screw is more challenging to remove.



(a.1) (a.2) (a.3)

(b.1) (b.2) (b.3)

Figure 10. The pattern of the results tensile test section of the pedicle screw assembly of the specimen material a) PLA: 30% b) PLA: 60% (1.cylindrical, 2.conical, 3.double screw)

4. Discussion

The results of tensile testing of PLA specimens with a variety of pedicle screws are shown in Figure 10a.3 and b.3 The maximum tensile strength produced by the tensile test was 7.4 kN and 8.31 kN using double cylindrical screw implants at PLA: 30%, and PLA: 60% compared to using cylindrical screws and conical screws. Comparison of PLA specimens with cylindrical screw fixation to double-screw cylindrical screws shows an average increase in force of 82% whereas using conical screws compared to double-screw cylindrical screws, there is an average increase in force of 35%. The results of the tensile test with variations in pedicle screws and variations in PLA composition resulted in the highest interfacial forces using PLA: 60% specimens compared to 30% PLA specimens.

Comparison of PLA specimens with double-screw cylindrical screws to single-screw cylindrical screws showed an increase in tensile strength of 27.63%, while the comparison of single-screw conical screws to single-screw cylindrical screws showed an increase in tensile strength of 29.5%.

The results of the tensile test with variations in pedicle screws and variations in PLA composition showed that the highest interfacial forces occurred using PLA: 60% specimens compared to PLA: 30% specimens. These results indicate that the density composition of the specimen layer can increase the tensile strength so that the characteristics of the various test specimens can be compared to human bone material that has variations in bone composition.

Cylindrical to cylindrical double-threaded screws have an average displacement increase of 97% at PLA: 30%. Whereas in PLA: 60% with conical screws to double cylindrical screws, there is an average displacement increase of 40.5%. Specimens of bovine bones using double-screw cylindrical screws have an average displacement increase of 29.6%. This deformation causes the pedicle screw to produce an indication of its interfacial strength.

In comparison of PLA specimens with cylindrical screws against double-screw cylindrical screws showed an average displacement increase of 97% in PLA: 30% while PLA: 60%, compared to cylindrical and conical screws. Comparison of PLA specimens with cylindrical screws against double screw cylindrical screws, there is an average displacement increase of 97% at PLA: 30%. Whereas in PLA: 60% with conical screws to double cylindrical screws there is an average displacement increase of 40.5%. Specimens of bovine bones using double screw cylindrical screws have an average displacement increase of 29.6%. This deformation causes the pedicle screw to produce an indication of its interfacial strength.

The asymmetrical cut pattern of the tensile test specimens of the PLA variety and bovine bone with the pedicle screw removed showed that the material specimens were PLA: 30% (Figure 6. a) and PLA: 60% (Figure 6. b) surface of the specimen using double cylindrical screws. This condition indicates that cylindrical double threaded screws are more easily pulled out compared to cylindrical and conical screws with a rough interfacial surface pattern indicating that the screws are more difficult to pull out. The surface pattern of the bovine bone material specimen, as shown in Figure 6.c, shows that the fibers are quite smooth, forming screw grooves on the double cylindrical thread, which indicates that the screw is easier to pull out compared to cylindrical and conical screws, which have a rough interface surface pattern, which indicates that the screw is more difficult to pull out.

The results of the PLA specimen tensile test with variations of the pedicle screw in Figure 8 (a) produced the highest tensile strength of 3.13 kN using cylindrical screw fixation and 4.68 kN with conical screw fixation at PLA: 30% and PLA: 60%. The comparison of PLA specimens with double-screw cylindrical screws to cylindrical screws showed an increase in tensile strength of 39.9%, while the comparison of double-screw cylindrical screws with conical screws showed an increase in tensile strength of 57.1%. The tensile test results with variations in pedicle screws and variations in PLA composition showed that the highest interfacial forces occurred using PLA: 60% specimens compared to PLA: 30% specimens. These results indicate that the density composition of the specimen layer can increase the tensile strength so that the characteristics of the various test specimens can be compared to human bone material with variations in bone composition.

5. Conclusion

Testing of the pedicle screw interfacial withdrawal mechanism on PLA and bovine bone specimens, which describes the quality composition of human bones, is likened to variations in the composition of different densities. Fixation using double-screw cylindrical screws can significantly increase tensile strength compared to cylindrical and conical pedicle screws with axial tensile loads. While, the high-density PLA quality composition variation model with a pedicle screw connected by a connecting rod has better tensile strength. Bending force testing using a conical pedicle screw model coupled with a connecting rod produces better fixation strength than other pedicle screws with variations in material quality composition. Testing the bending force using a series of conical pedicle screws coupled with connecting rods resulted in better fixation strength than other pedicle screws with variations in material quality composition. Scoliosis spine surgery can be performed with a better selection of pedicle screws to support the spine and the load is only limited to the direction of the pedicle screw pulling force so it is necessary to carry out additional testing of the load in different directions.

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