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Abstract:

Pull out tests for bone anchors used in surgical robotics were performed to prove the strength of the bone anchor -bone combination. Forces and displacement were measured to evaluate the suitability of the bone anchors as a connection between a surgical robot and bone. A universal experimental setup was designed to conduct the pull out tests. As specimens, human cranial cadaver bone, porcine cadaver hip bone and solid rigid polyurethane foams were chosen. The bone anchors were manually screwed into the specimens and then pulled out using the experimental setup. Mechanical similarities between natural bone and solid rigid polyurethane foams were found. The results suggest that the bone anchors are suitable for the attachment of surgical robotics.

Keywords: force measurement, pull out tests, bone screw, bone anchor, parallel kinematic, minimal invasive, cochlear implantation.

1 Introduction

Mechatronic assistance systems in otologic and neurotologic surgery, especially in minimally invasive cochlear implantation, have not yet found broad clinical acceptance. Requirements regarding positioning accuracy, easy handling and sterilization guidelines make the development a demanding task. In an attempt to overcome the aforementioned difficulties, a passive, parallel kinematic robot was designed [1]. Compared to other solutions, such as pre- or intraoperatively customized, patient specific microstereotactic frames [2, 3], the parallel kinematic device can be flexibly adjusted to the anatomical needs of the patient. The proposed system is directly mounted on the skull using bone anchors equipped with spherical heads (see Figure 1). It supports surgical tools attached to the end-effector in straight-line incisions, for example while drilling a hole as a minimally invasive approach to the cochlea.

However, any movements of the bone anchors while the kinematic is attached can cause accuracy loss of the endeffector pose (position and orientation), and, therefore, the surgical tool. In order to explore the limitations of skull bone anchors, pull-out tests were performed to determine the maximum applicable force load. Similar experiments regarding pull out tests on screws for dental usage were conducted in the past [4,5,6,7]. Unfortunately, the bones used in these papers are quite different from cranial bone and the results are therefore difficult to compare.



Figure 1: Figure 1: Bone anchor. (a) spherical head, (b) hexagonal, (c) bone cutting HA 2 thread.

2 Materials und Methods

The anchor used in this study is made from TiAl6V4. It is equipped with a 4 mm long, cylindrical, self-cutting HA 2 thread (ISO 5835) to ensure a rigid fixation within the skull. A spherical head, which serves as one base joint of the proposed parallel robot, is screwed onto a 4 mm long, M 1.6 thread once the bone anchor is seated. In order to screw the anchor in, a hexagonal wrench (AF 4) can be applied in between the threads (see Figure 1).

For the tests, a universal experimental setup was built, which holds different types of bone samples (artificial or natural) and allows for variations in the direction of the force applied to the bone anchor (see **Fehler! Verweisquelle konnte nicht gefunden werden.**). A load was manually induced using a handle and a thread shaft, which translated a rotational movement to a linear movement. The load was measured by a force-torque sensor (FT Mini40, ATI Industrial Automation, Inc., 500 N load range) while an inductive position encoder (WA20, Hottinger Baldwin Messtechnik, Darmstadt, Germany) detected the resulting displacement. An adapter with a cylindrical opening was used to connect the spherical heads of the bone anchors to the sensor. This also facilitated the variations in pulling direction of the applied force, simulating different poses of the mounted kinematic robot.

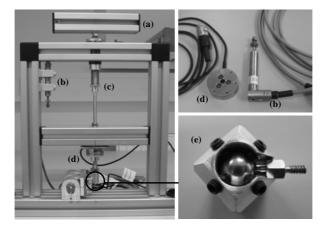


Figure 2: Experimental setup. (a) handle, (b) position encoder, (c) thread shaft, (d) force-torque sensor, (e) adapter for attaching the bone anchor.

Two different biomechanical test blocks (Sawbones Europe, Sweden), composed of 15 mm thick solid rigid polyurethane foams 20 or 50 pcf, which are similar to cortical bone, were used (Figure 3). These bone substitutes were advantageous because of their known and reproducible material properties (Table 1). First, pilot holes were drilled into the test blocks and the anchors were manually implanted. Altogether, 60 pull-out tests under 0° (load case 1), 45° (load case 2) and 90° (load case 3) angle in reference to the sample surface normal were conducted. An additional set of thirty tests using twenty human cranial cadaver specimens and ten porcine cadaver hip bone specimens [4] at load case 1 were conducted to validate the suitability of the bone substitutes. Due to the limited availability of human bone and the difficult preparation of the specimens, all experiments were conducted under load case 1. The intention was to show similar characteristics between bone and bone substitute in one load case so that it can be used for the other load case.

Material	Density [g/cm3]	Compression Modulus [MPa]	Tensile Modulus [MPa]	Shear Modulus [MPa]
SR PU 20	0.32	210	248	49
SR PU 50	0.80	1148	1469	178

Table 1: Material properties of the used solid rigid polyurethane foams (20 and 50 pcf)



Figure 3: Bone substitute: solid rigid polyurethane 20 pcf.

3 Results

The results for load cases 1-3 are given in Figure 3 using boxplots. The whiskers correspond to the values inside an area of 1.5 times the length of the box. The boxplot represents the maximum forces that were determined for every test until the anchor broke free of the bone sample.

The measurements show that the maximum applicable force depends on the load direction. Considering load case 1, median values of 65.2 N for SR PU 20 and 353.8 N for SR PU 50, respectively, were determined. Furthermore, median values of 54.6 N for SR PU 20 and 249.0 N for SR PU 50 with load case 2 were measured. Under load case 3, median values of 44.9 N for SR PU 20 and 214.8 N for SR PU 50 were obtained. The median value for human cranial cadaver bone was 398.3 N and 74.3 N for porcine hip bone. It was possible to load the bone anchors with approximately 500 N at load case 1 in six tests without destroying the anchor. It is important to mention, that none of the bone anchors were visually damaged.

Measurements of displacement were also recorded for the bone substitutes in load case 1. A maximum displacement of less than 1 mm was measured for SR PU 20 and less than 1.5 mm for SR PU 50. The interpretation of these results is still in evaluation and a part of future work.

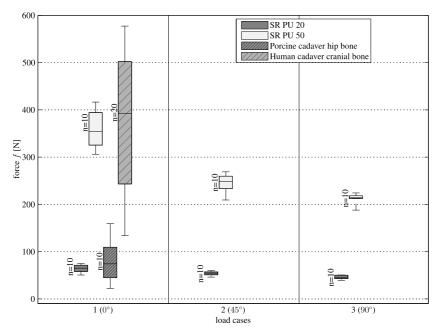


Figure 4: Boxplot of force measurement during pull-out tests.

4 Discussion

A strong variation with respect to the maximum load capability of bone anchors implanted in human and porcine bone is observed. Therefore, it is revealed that the porcine cadaver hip bone specimens are not suitable for future experiments on bone anchors for the proposed application. Comparing the results of bone and bone substitute under load case 1, similarity of human cranial cadaver bone and solid rigid polyurethane 50 pcf was found. The difference in median measurements amounts to only 44.5 N, which is acceptable for biological tissue comparison. Additionally, the median of porcine hip bone and solid rigid polyurethane 20 pcf only differs in 9.1 N, suggesting similar mechanical properties of the two materials.

Since the measurements of bone and bone substitute under load case 1 were performed under equal conditions, we hypothesize that the experimental data of the other load cases can be used to extrapolate the characteristics of human and porcine bone under load cases 2 and 3, respectively. Screws were always inserted in the same material orientation. Therefore, further experiments will be performed to prove our hypothesis whether the anisotropic bone under load case 2 or 3 behaves similar to the isotropic substitutes.

5 Conclusion

The experiments showed that special biomechanical blocks made of polyurethane foam can be used as bone substitutes in experimental load tests for bone anchoring screws with forces applied normal to the surface. A guaranteed load capacity of approximately 150 N at an angle of 90° could be experimentally determined. This unexpectedly high load capacity ensures that the tested bone anchors are suitable as rigid connection points for the passive parallel kinematic robot.

6 References

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