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Mechanical characterization of bone anchors used with a bone-attached, parallel robot for skull surgery

Jan-Philipp Kobler[a,*], Lenka Prielozny[b], G. Jakob Lexow[b], Thomas S. Rau[b], Omid Majdani[b], Tobias Ortmaier[a]

[a] *Institute of Mechatronic Systems, Leibniz Universität Hannover, 30167 Hanover, Germany*
[b] *Hannover Medical School, 30625 Hanover, Germany*

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ABSTRACT

Bone-attached robots and microstereotactic frames, intended for deep brain stimulation and minimally invasive cochlear implantation, typically attach to a patient's skull via bone anchors. A rigid and reliable link between such devices and the skull is mandatory in order to fulfill the high accuracy demands of minimally invasive procedures while maintaining patient safety. In this paper, a method is presented to experimentally characterize the mechanical properties of the anchor–bone linkage. A custom-built universal testing machine is used to measure the pullout strength as well as the spring constants of bone anchors seated in four different bone substitutes as well as in human cranial bone. Furthermore, the angles at which forces act on the bone anchors are varied to simulate realistic conditions. Based on the experimental results, a substitute material that has mechanical properties similar to those of cranial bone is identified. The results further reveal that the pullout strength of the investigated anchor design is sufficient with respect to the proposed application. However, both the measured load capacity as well as the spring constants vary depending on the load angles. Based on these findings, an alternative bone anchor design is presented and experimentally validated. Furthermore, the results serve as a basis for stiffness simulation and optimization of bone-attached microstereotactic frames.

1. Introduction

Precision skull surgery requires specialized instrumentation to satisfy demanding requirements in minimally invasive cochlear implantation, deep brain stimulation electrode placement and related applications. Surgical robotics for use in these fields must provide the surgeon with an instrument guidance of submillimetric accuracy [1]. Recently, promising results have been achieved with microstereotactic frames and miniaturized robots that attach directly to the skull of the patient.

An example of a commercialized system is the SpineAssist® by Mazor Surgical Technologies Inc. (Caesarea, Israel and Norcross, GA, USA), which is rigidly mounted onto the patient using a fixation frame. The hexapod-based guidance assistant (formerly known as MARS) has been developed for spine surgery [2,3] but could potentially be used for incisions at the skull as well [4]. The StarFix™(FHC, Inc., Bowdoin, ME) [5–7] is a passive, customized microstereostatic frame, made via rapid prototyping based on a predefined drill guidance model. It is mounted on preoperatively implanted anchors, whose locations are derived by obtaining a CT scan and subsequent automatic segmentation during intervention planning. Moreover, Labadie et al. proposed a bone-attached, customized, microstereotactic frame serving as a drill guide [8–10] which is milled intraoperatively using a CNC machine. Recently, Kratchman et al. developed an automated parallel robot for minimally invasive cochlear implantation and deep brain stimulation, which is mounted on a rigid pre-positioning frame attached to the skull of the patient [11]. Furthermore, a microstereotactic frame that is adjusted by a robot, immobilized, and then used as a tool guide in deep brain stimulation was presented previously by Kratchman and Fitzpatrick [12].

In order to provide enhanced flexibility during the surgical procedure, the authors propose a passive parallel robot (Stewart-Gough platform) which can be directly attached to bone anchors, eliminating the need for a rigid fixation frame. An illustration of the proposed mechanism is given in Fig. 1. The main idea is to use the spherical heads of the bone anchors both as fiducials during task planning and as base joints of the robot. Manually adjustable struts connect the platform, i.e., the linear drill guide, to the base points and serve as prismatic joints to align the surgical tool with a predefined trajectory.

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* Corresponding author. Tel.: +49 51176217840.
E-mail addresses: jan-philipp.kobler@imes.uni-hannover.de (J.-P. Kobler), lexow.jakob@mh-hannover.de (G. Jakob Lexow).

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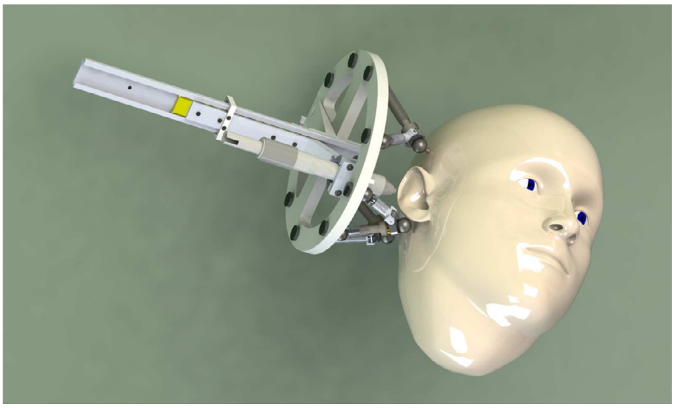

Fig. 1. Concept of a passive parallel robot which serves as a drill guide in minimally invasive cochlear implantation. The mechanism attaches to bone anchors with spherical heads implanted in a patient's skull.

Due to the direct attachment, neither intraoperative navigation nor explicit point-based registration between patient and device is required. The accuracy of the mechanism is further increased by implementing reconfigurability and by exploiting redundant degrees of freedom of the mechanism during incision planning: considering a drilling task, two redundant degrees of freedom, i.e., platform height and rotation around the drill axis, can be exploited in order to optimize certain performance criteria of the manipulator with respect to stiffness and singularity avoidance. A detailed description of the device and the surgical workflow has been presented elsewhere [13].

All the above mentioned concepts require a rigid and reliable link between the skull and the drill guide to ensure patient safety and maximum accuracy. Especially firm placement of the bone anchors is essential since any movement must be avoided. Thus, their mechanical load capacity as well as their resilience play a crucial role considering the design of future prototypes. Furthermore, during the surgical procedure, forces and torques act on such devices, resulting from both manual operation and the bone drilling process. Such loads are transmitted through the rigid mechanisms and result in tensile or compressive forces applied to the bone anchors [13].

In previous work, the authors have presented a method to optimize the design of the parallel robot for kinematic accuracy [14]. Furthermore, a study focused on loads, occurring during guided drilling, revealed that the maximum interaction force applied by the surgeon, oriented perpendicular to the drilling axis, is approximately 12 N [15]. If this force is applied 5 cm above the platform, a simulation according to the method presented elsewhere by Kobler et al. [13] yields that the resulting forces acting upon the bone anchors can be up to 50 N. Deflections of the bone anchors under load, in turn, lead to deviations of the drill from its desired trajectory. With respect to patient safety, such deviations must be minimized. In the worst case, the screw connection can fail due to overload. Possible failure modes of the self-tapping fasteners are either associated with the screws (bolt breaking, thread stripping) or the material into which they are inserted (thread stripping) [16]. In this context, several researchers have reported on the mechanical characterization of bone screws for dental implantation [17,18]. Furthermore, the load capacity of monocortical screws in osteoporotic bone [19] and the pullout strength of suture anchors [20] have been studied. However, both the screw design as well as the bone samples used in these studies differ significantly when compared to the application considered here.

Hence, the mechanical properties of the anchor–bone linkage need to be determined under conditions that match the intended use with a bone-attached robot. Therefore, in this contribution we present the results of comprehensive studies that have been conducted in order to experimentally assess the pullout strength of bone anchors as well as their spring constants when seated in bone. The remainder of the paper is organized as follows. In Section 2 the specifications of the considered bone anchor are given. Furthermore, the experimental setup is presented as well as the proposed test procedure. The resulting pullout strength and spring constants of the anchor-bone linkage are listed in Section 3. Section 4 discusses the results in the scope of the intended application and gives an outlook on future work.

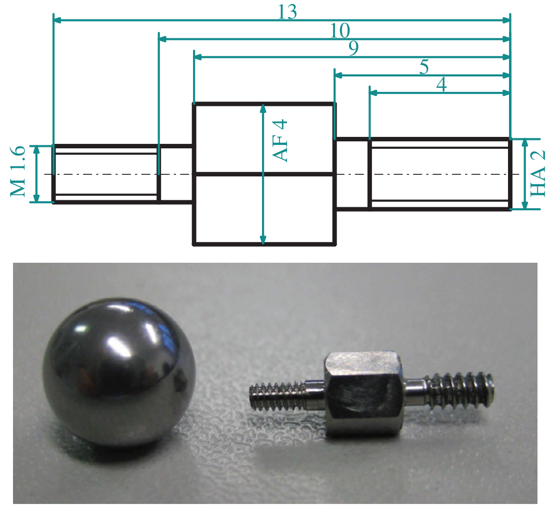

Fig. 2. Technical drawing (top) and photograph (bottom) of the bone anchor used in this study. All dimensions given in mm.

2. Materials and methods

2.1. Specifications of the investigated bone anchors

The dimensions of the bone anchors being investigated in this paper are given in Fig. 2. Given the assumption that a deeper insertion leads to stronger fastening, the screw thread is designed to be as long as reasonably possible limited only by the thickness of the bone. Measurements of the skull thickness in clinical CT data using a custom-made software [21] showed sufficient positions for bone anchors assuming a maximum insertion depth of up to 5 mm, thus defining the dimensions of the initial design. The bone screw is equipped with a cylindrical, self-cutting HA 2 thread manufactured according to ISO 5835. In order to facilitate handling, the middle part of the anchor has a hexagonal shape adapted to an off-the-shelf hexagon wrench key. The spherical head, which serves as the base joint of the proposed parallel robot, is screwed onto the M 1.6 thread bar once the bone anchor is seated in bone.

The bone anchors are machine-made from TiAl6V4 titanium alloy (titanium grade 5), which has a tensile strength of 850–1120 N mm^{-2}, a fatigue strength of 440–690 N mm^{-2} and a breaking elongation of 10–15%. The strength of this material is superior to surgical steel (e.g. X2CrNiMo1812) while being both biocompatible and resistant to corrosion. Furthermore, it is well known that the number of artifacts in computed tomography (CT) images is generally lower compared to anchors made from stainless steel [22].

2.2. Measurement of pullout strength and spring constants

Considering the proposed concept of a bone attached parallel robot, forces and torques occurring at its end effector are transmitted through the rigid mechanism, resulting in tensile and compressive forces being applied to the bone anchors. Such forces and torques mainly result from the surgeon interacting with the instrument guidance during surgery, and from the drilling process itself. Unfortunately, any motions of the bone anchors lead to spatial deviations