ACCURACY VALIDATION OF SEMI-ACTIVE ROBOTIC APPLICATION FOR PATELLOFEMORAL ARTHROPLASTY

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ABSTRACT

Patellofemoral arthroplasty (PFA) is a delicate and challenging procedure [5]. A PFA application has been developed for the Navio semi-active robotic platform ("NavioPFA"), to facilitate both planning and bone preparation. NavioPFA combines image-free navigation and planning with robotically assisted bone shaping, and is open to any implant design, provided that the feasibility and accuracy is confirmed in sawbones and cadaver tests. In this abstract we describe the accuracy tests of NavioPFA, with results for four different implant designs. The accuracy of prosthesis placement with Navio is evaluated by independent measurements that compare the final placement to the planned position.

INTRODUCTION

The Navio system incorporates a hand-held robotic instrument for bone shaping [2-4]. After successful development and clinical introduction of a unicondylar knee replacement (UKR) application, a PFA application was developed to address the isolated arthritis of the patellofemoral compartment. NavioPFA uses an image-free approach in which both direct and kinematic referencing, along with articular surface mapping, is used to define all parameters relevant for planning. After the implant placement plan is finalized, the bone cutting plan is generated, and the bone is prepared with the handheld, robotically controlled handpiece. The real-time control loop controls the depth or speed of a cutting bur, thus resulting in the planned bone preparation. In this study we evaluate the performance of NavioPFA in femoral bone surface preparation as evidenced by the implant position. The described tests evaluate the accuracy of implant placement on synthetic (sawbones) and cadaveric knees in a simulated clinical setting.

MATERIALS AND METHODS

Simulated PFA surgeries were performed for four different commercial implant designs. Two designs were "inlay" and two were "onlay" type. For each implant design, a minimum of 3 synthetic bones ("Sawbones", Pacific Research) and two cadaver knees were prepared. Implant CAD files were modified to include 8-9 conical divots distributed across the articulating surface, and implants were printed in using a direct metal laser sintering (DMLS) procedure. At the beginning of each surgery, in order to establish a reference frame that can be shared between the intraoperative position tracking system and the postoperative measurement device, a four conically devoted fiducials are screwed into each bone. After the fiducials are attached, the procedure follows the regular NavioPFA protocol. An optical tracking frame was rigidly attached to femur. The image-free procedure proceeded including landmark localization, articulating surface mapping, implant location planning and cutting preparations. Exposure Control (i.e. controlling the depth of cut relative to a stationary guard) was the primary mode of operation for bone cuts, while Speed Control (i.e. controlling the speed of the bur based on position relative to the cutting plan) was used mostly to prepare the peg holes. Then, the implants were inserted in their prepared places. Using separate software running on a laptop computer, an independent data collection is then performed to evaluate the accuracy of implant placement. Positions of the conical divots on the PFA implant and on the four fiducial screws were measured using a Microscribe digitizing arm with a 3mm spherical tip tracked probe. As the same fiducial points were collected at the beginning of surgery relative to the respective bone trackers, by registering the two sets of points, we can directly compare the final implant position with the planned implant position.

RESULTS

A Total of 24 tests were performed for four different implant designs (11 cadavers, 13 sawbones), with a minimum of 5 cases (2 cadavers) per implant design. Nine users prepared the bone cuts: 4 surgeons performed the cadaver surgeries, and 5 engineers prepared all synthetic bone cuts. All implants were placed within a maximum RMS error of 0.87 mm from the target position in any particular direction (cadavers 0.88mm, sawbones 0.86mm). Maximum rotation RMS error in any particular direction was 1.20 degrees (cadavers 1.36 degrees, sawbones 1.04 degrees).

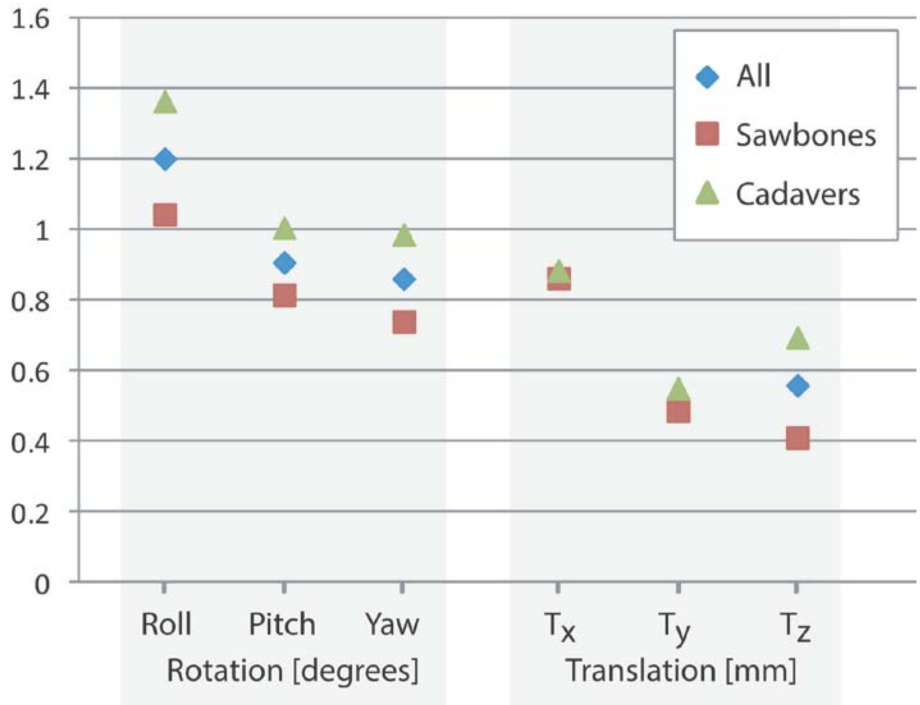

Figure 1. Rotational and translational RMS accuracy of implant placement

DISCUSSION

The results of sawbones and cadaver tests of NavioPFA accuracy, are in accordance with previously reported accuracy results for UKR surgery [2, 3]. There was no significant difference in accuracy between various implant designs. The accuracy of sawbones preparation was slightly higher than that of cadaver bones (Fig 1.).

Conventional PFA surgery is often intimidating for surgeons because of difficulties planning and bone preparation. The task becomes even more complex in the case of bicompartmental procedures, considered as a less invasive and tissue preserving alternative for combined medial and patellofemoral arthritis [1]. Because of increased complexity, many surgeons elect instead a TKR as a simpler, although not always optimal solution. The use of Navio in PFA allows surgeons to assess the patellofemoral compartment geometry and the implant fit and to confidently plan the implant selection and position. It eliminates the need for conventional instrumentation and may allow access to the bone through a reduced incision. With the precision and reproducibility of the robotic procedure, it is expected that surgeon confidence in performing a more predictable and reliable PFA will increase.

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DISCLOSURES

All authors are employees of Blue Belt Technologies.