Experience with navigated freehand bone cutting for total knee replacement surgery

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Introduction: Previous studies in Pittsburgh [1] and Nebraska [2] investigated the concept of navigated freehand bone cutting (NFC) with Computer Aided Orthopedic Surgery (CAOS). NFC allows surgeons to cut/reshape bone without using mechanical alignment cutting blocks (jigs). Instead, the user reshares/cuts the bones while following graphical guidance from a computer while bones and cutting tools are tracked in space with navigation technology. While minimally invasive efforts in arthroplasty have aimed at reducing the size of jigs, NFC aims to fundamentally reduce the size of the incision and simplify the surgical procedure by getting rid of the cutting blocks altogether. However, the quality of the NFC cuts and their speed should at least match the conventional approach to justify use of this novel concept clinically.

An earlier pilot study [3] evaluated preliminary navigated freehand cuts and compared their speed, and quantitatively compared the surface cut quality in 3D, in the hands of local surgeons among the research team. This study reports a formal experimental evaluation in the hands of many independent surgeons with widely-varying TKR experience. Bone preparation quality was measured in terms of implant fit, alignment, and surface roughness of the bone cuts.

Materials and Methods: The subjects in this experiment were seven orthopaedic surgeons at different stages of their career, varying from the just qualified/fellowship trained, to the internationally renowned expert. Identical replicas of a right femur were molded from synthetic material to emulate the “cutting feel” of real bone. A bone-fixture was built to mount the samples on a surgical table (Figure 1). An early version of the Nebraska Orthopedics Minimally Invasive Surgery System (NoMiss) was used to navigate the bone specimen and an oscillating bone-saw fitted with passive reference frames (Figure 1). The NoMiss system was programmed with the ideal locations of the five distal-femur cuts for a widely used TKR. Preparation of each experimental run included registration of the bones prior to cutting, based on anatomical landmarks. The user interface provided real-time graphical guidance during cutting, and the surgeons where allowed to select the sequence of planes to cut based on their own preferences. Each surgeon performed five formal experiments in a one-day session, after only one non-documented trial. Each trial required the completion of all five distal cuts of one femur-specimen (and fine shaving when needed) and the placement of an implant. Timing of each test started when the users attempted to align the saw for the first cut, and ended when they verbally communicated that they would be ready to cement the implant if it was a real patient. The level of comfort and satisfaction felt by the surgeon were documented, and the quality of each cut was quantitatively assessed. An exhaustive protocol was followed for each cut bone to assess ‘quality’ of cut. Implant ‘fit’ and “alignment” were physically measured with a navigated implant trial and produced numeric fit and alignment indices. All cut bones were also digitized to compute smoothness and alignment indices representing how rotated (in 3D) and offset each bone surfaces was relative to ideal.

Results: The surgeons varied in speed but showed a steep learning-curve, with 10.2±4.3min average cutting-time. This was even faster than measured in our previous studies, which were in-turn faster than with conventional instruments, promising savings in surgeon and OR tourniquet times. From the thousands of digitized surface-points on each cut-surface, the average-roughness Ra was 0.19mm, and the difference between the highest-50-peaks and lowest-50-valleys was ±1.2mm. These confirmed previous measurements: that smoothness was reproducible and adequate, especially for cemented cases. Although tightness was not targeted for this cemented implant, 21 out of 35 bones were tight on the implant-trial, and others slightly loose (without cementation). Worst looseness was in the “flexion” sense with average range <1.6°, and ±1mm in translation. Average implant alignment error was ±1.2°, and always ±4.7° sagittally, ±3.6° frontally and ±2° axially. Linear-translation errors averaged ±1.4mm, and ±4.2mm everywhere, with some systemat-ic under-cutting evident of the distal plateau. Digitization and 3D analysis of all cut-surfaces echoed the above results, showing the extreme-outliers to be the chamfers which were treated as less important by most surgeons.

Discussion: This study showed high reproducibility of cuts and a narrow envelope of alignment error. Alignment with NoMiss in previous studies was much superior to cutting with conventional TKR cutting blocks, and this was echoed here with a wide range of independent surgeons. Neither speed nor quality had good correlation to the experience of the surgeon, which makes the technique even more promising. Surface roughness did not represent a problem for cemented implants, and it is still in the limit for acceptance established in the published literature (1 to 2mm) for non-cemented cases. Qualitative feedback from the surgeons surpassed our expectations, even with the bare-minimum level of technology used. We anticipate significant further improvements with the inclusion of novel smart software/hardware techniques under development. We now confidently believe that this technique can provide a fundamental improvement in the future for arthroplasty. Navigated freehand bone cutting can free arthroplasty from cumbersome and highly invasive bone-cutting jigs, confirming its clinical significance and promise to offer a serious alternative for easier and better minimally invasive arthroplasty.

References: