Clinical validation of novel patient specific cut guides for total knee replacement.

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Abstract

This prospective randomized controlled study was designed to validate a novel design of CT-based patient specific instruments (PSI) for total knee replacement. Accurate alignment of implant components are crucial for ensuring long-term performance of knee implants. It has been shown that patient-specific instrumentation can provide accurate alignment but the placement of the blocks can be challenging in surgery and accurate and reliable positioning may be difficult. A novel design of CT-based cutting blocks was developed that provides additional guiding structures to allow a more simple and reliable placement of the patient specific cut guides on the bone. In 31 cases the accuracy of placement was checked with computer navigation and the intra-operative use and stability was judged by the operator using a questionnaire. The alignment of the instruments was measured to be in average below 1° of the preoperatively planned alignment with a maximum deviation of 3° for the varus/valgus angle. The questionnaire showed good performance of the blocks regarding intra-operative handling and surgical placement.

Key words: arthroplasty, replacement, knee; patient-specific; instrumentation; surgery, computer-assisted

Introduction

The goal of this clinical study was to investigate the placement and accuracy of CT-based PSI during total knee replacement (TKR) [1-5]. As the success of a TKR is mostly related to the correct positioning of the prosthetic components, various different guides have been proposed to support the surgeon in performing the relevant bony cuts [6-17]. The guides have predefined slots, which indicate the ideal cut planes to achieve a specific preoperative planning. Such patient-specific cutting guides have recently been developed by Medivation AG. The novel design features structures to support the surgeon in finding the correct position of the block during surgery. At the femur cut guide these structures are arms that are designed to go anterior and distal along the border of the joint surface (figure 1). For the tibia cut guide a structure along the anterior edge of medial plateau is used (figure 2). In order to prove the clinical validity of the patient specific instrumentation, a first clinical study was conducted. The goal of this study was to verify the matching of the cutting guides to the patient's anatomy and to measure the reliability and accuracy of the alignment using these guides. The matching of the cutting guides was graded by the operating surgeons and recorded in terms of a questionnaire, while the accuracy of the alignment was determined using a navigation system.

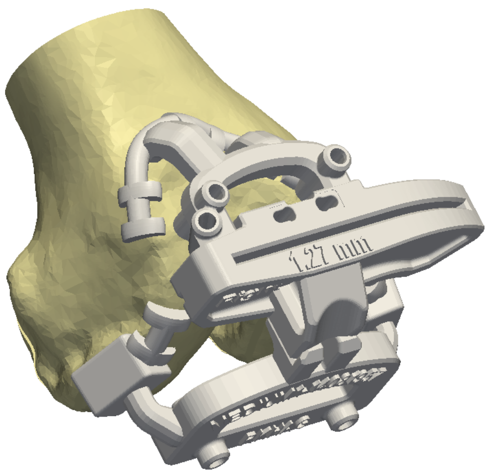


Fig. 1 Femur cut guide

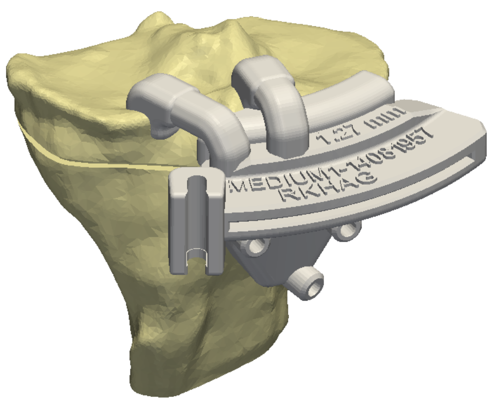


Fig. 2 Tibia cut guide

Materials and Methods

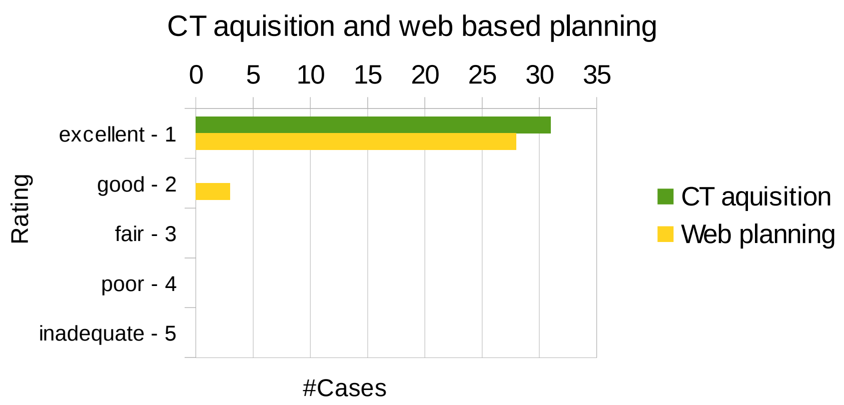
31 patients scheduled for TKR were recruited for this study. Ethical approval was obtained by hospital Märkisch Oderland (Wriezen, Germany). The study was performed in accordance to the Declaration of Helsinki and informed consent was obtained from all individual participants. For each patient, a preoperative computed-tomography (CT) scan of the concerned leg was obtained using a Brilliance 6 scanner (Phillips, Netherlands). In order to reduce x-ray exposure to the patients, a special acquisition protocol was applied (distal femur and proximal tibia: slice distance of 0.5 mm; proximal femur and distal tibia: slice distance of 2.0 mm). Each CT-dataset was further processed to retrieve a three-dimensional (3D) model of the leg anatomy. The semi-automatic segmentation step was performed using in-house developed software (Medivation AG). The resulting 3D models were consequently used to plan and design the patient-specific cut guides. The cutting guides consist of a femoral and a tibial component and are constructed using in-house developed, certified software (Medivation AG). The cutting guides specifically couple to osteophytes and bone structures at the border of the joint surface and thus provide a stable fit to the patient's anatomy. The cutting slots were arranged to achieve a neutral mechanical alignment of the leg (varus-valgus and flexion-extension angle of 0°). The resultant planning together with the designed patient-specific cutting guides were presented to the surgeon via a CE-certified website (Webplanning, Medivation AG). The website shows a 3D visualization of all bones and cut planes and enables the surgeon an adjustment of the planning. Upon confirmation by the surgeon, the cutting guides were produced using additive manufacturing technique using biocompatible material (3D System, Duraform PA). The guides have been sent to the respective hospital and were steam sterilized in the hospital for intra-operative use.

The TKR was then conducted according to the normal clinical routine. In order to measure the accuracy of the alignment of the patient-specific guides, a navigation system (Brainlab AG, Germany - Alignment verification workflow) was used. The cutting guides were matched onto the particular bone. The fit of the guides was graded by the surgeon for each individual component. The precision of the guides to achieve the desired planning was intra-operatively measured using the navigation system by fixing the tracking markers to the femur and tibia cut guides using a slot adapter. The registration was performed by collecting the required anatomical landmarks. The intra-operative measurements were subsequently compared with the preoperative plan. Besides the matching of the guides, certain other criteria like soft-tissue stress were recorded by the surgeon. The entire process of CT-acquisition, data upload, web-based planning and delivery status was recorded in a questionnaire. Thereby, the grades ranged from 1 (excellent) to 5 (inadequate).

Results

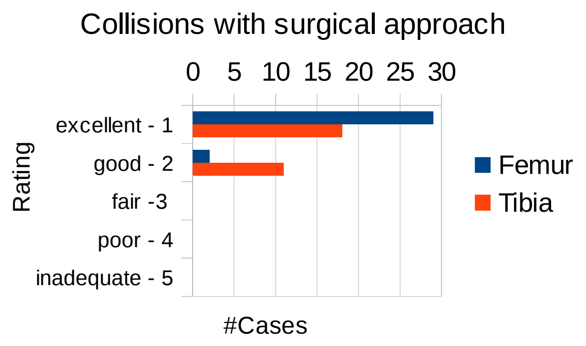
31 patients (13 male, 18 females; mean age: 69 ± 9.8) were enrolled in this study. The right knee joint was operated in 16 cases, the left knee joint in 15 cases. In most of the cases (29 patients) a varus malposition was corrected, while valgus malposition was corrected in two patients.

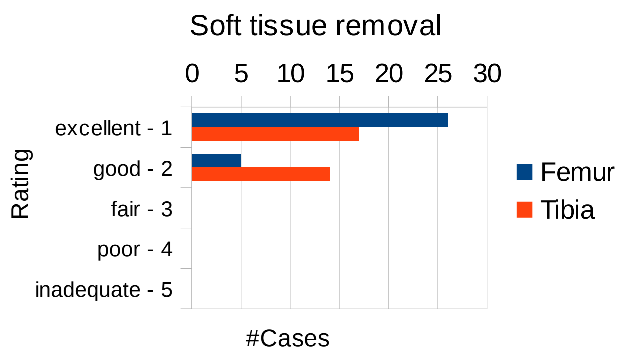
The first part of the questionnaire dealt with the image acquisition and the planning process. The image acquisition was graded with 1 for all patients. The data upload and web-based planning process were both graded with 1 in 28 cases and with 2 in three cases.



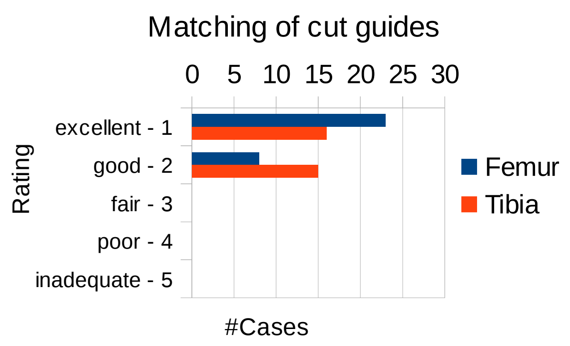
The second part of the questionnaire dealt with the intra-operative application of the patient-specific guides. The delivery of the cutting guides was judged with a grade of 1 in 28 cases and with a grade of 2 in three cases. The general quality of the 3D printed guides scored similar grades (grade 1 in 26 cases, grade 2 in four cases and grade 3 in one case).

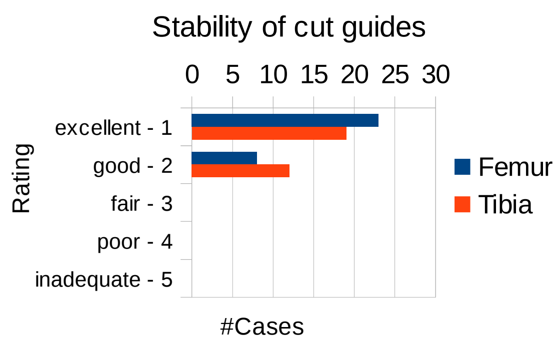
In the next step, potential collisions of the cutting guide with the operative approach was assessed. On average, collisions occurred more frequently for the tibial than for the femoral component (average grade for femoral component: 1.1, average grade for tibial component: 1.5). But no grade worse than 2.5 was recorded. Similar results were found for judging the amount of soft tissue needed to be removed. On the tibial side, more tissue had to be removed (average grade of 1.5) than on the femoral side (average grade of 1.3) to allow a proper placement of the guide.

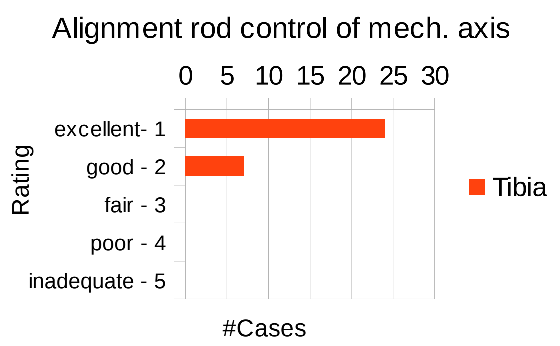




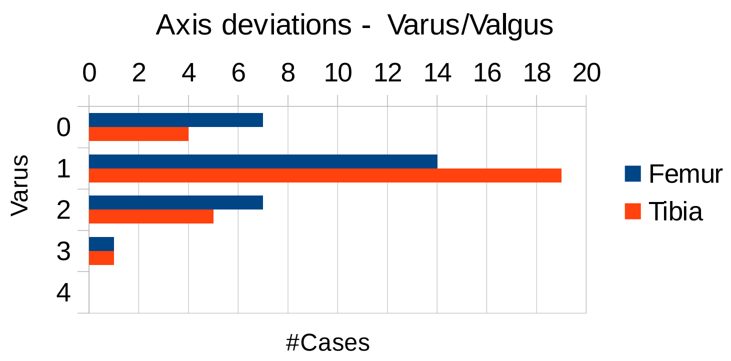
The actual matching of the cutting guides was judged with an average grade of 1.3 for the femoral side and 1.5 for the tibial side. But most importantly, all matching were assessed with either a grade of 1 or 2. Moreover, the fixation and the stability of the cutting guides was evaluated. Again no grade different than 1 or 2 was assigned for either the tibial or femoral component. On average, grades of 1.3 (femoral component) and 1.4 (tibial component) were observed. In the last step of this second part, the control of the leg axis using an alignment rod attached to the tibia guide was evaluated. On average the leg axis was estimated with a grade of 1.27 (range: 1-2).

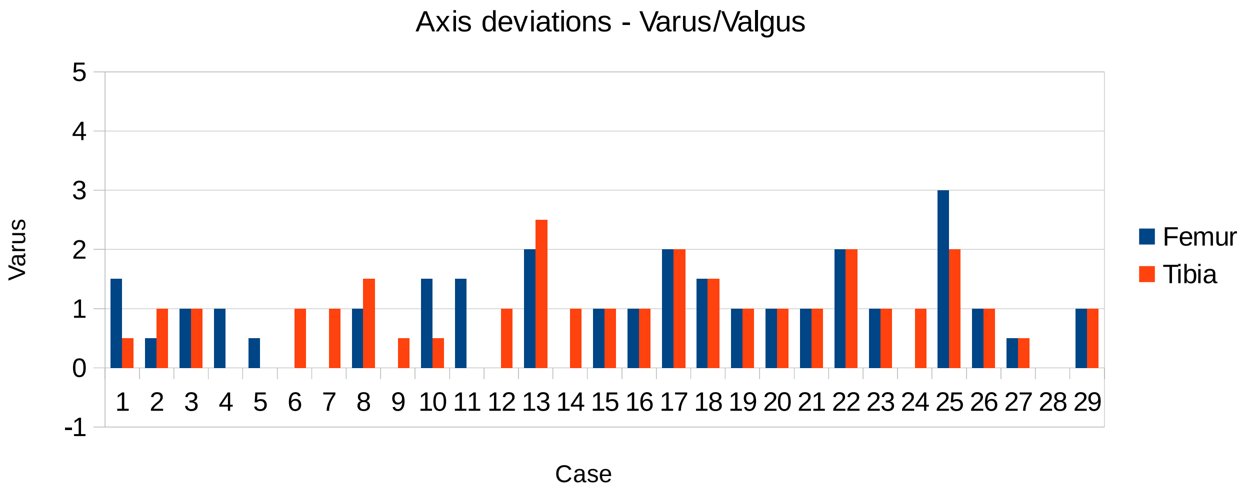






The third part of the questionnaire is about the measurements using the navigation system. The fixation of the tracking markers and the navigation measurements were judged, on average a grade of 2.19 was found (range: 1-4). Moreover, several comments emphasized the instability of the tracking markers. For two cases navigation measurements with poor rating (>=4) have been excluded due to instability of the trackers. The alignment of the femoral cutting guide was measured in terms of varus/valgus alignment. On average, a deviation of 0.95° (varus) was measured for the varus/valgus alignment (maximum deviation of 3°). The alignment of the tibial cutting guide showed a deviation of 0.98° (varus) in the varus/valgus alignment (maximum deviation of 2.5°).





Conclusion

The primary goal of this study was to investigate the validity of the patient specific instrument system. Two different measures were defined to judge the validity: A questionnaire was used to record the grades of the surgeon for the whole process of image acquisition until the final alignment of the cutting guides. An image-free navigation system was used to quantitatively measure the alignment of the guides. The grades in the questionnaire proved the general usability and applicability of the PS-Knee system. Except for one single case with a grade of 3 (general quality of cutting guide) the grades were all in the range of 1-2.5. Most importantly, the matching of the cutting guides was graded in the range of 1-2, demonstrating the robustness and reliability of the cutting guide placement.

In average a very good alignment was measured (0.95°/0.98°). The angles of femoral and tibial varus/valgus alignment were all in an acceptable range with a maximum error of 3° in component placement. However, for some measurements, the values recorded by the navigation system seemed to be not reliable. Several comments by the surgeons indicated, that the actual intra-operative alignment was not reflected by the values measured by the navigation system.

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