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Evaluation of the Zimmer PSI System for Total Knee Arthroplasty Using Computer Navigation

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Summary:
The aim of this study was to determine the efficacy of patient-specific cutting blocks by comparing them to navigation, the current gold standard.

Abstract:
Introduction:
Patient-matched instrumentation is advocated as the latest development in arthroplasty surgery. Custom-made cutting blocks created from preoperative MRI scans have been proposed to achieve perfect alignment of the lower limb in total knee arthroplasty (TKA) more efficiently than current methods. The aim of this study was to determine the efficacy of patient-specific cutting blocks by comparing them to navigation, the current gold standard.

Method:
Patients were recruited (N =25) to undergo their total knee arthroplasty with a senior consultant surgeon using imageless computer navigation in the standard fashion (Orthosoft, Zimmer USA). Each participant underwent pre-operative imaging comprising a full-length MRI, which was used to produce an operative plan that was confirmed by the surgeon prior to surgery. The plan was then used to construct cutting blocks specific to the patient's anatomy (PSI, Zimmer, USA). During the arthroplasty procedure, the blocks were placed on the joint as per manufacturer's instructions and the computer navigation system was used to evaluate the alignment of the cutting blocks. The blocks were assessed intraoperatively for the alignment in the coronal and sagittal planes, as well as rotation, sizing and resection depth. The intraoperative results were compared to the pre-operative plan and the differences analysed using one-sample t-tests. The proportion of differences within +3° was also calculated, as well as the prediction interval of a single future measurement based on the data collected.

Results:
Significant differences were detected between the planned alignment and the alignment verified intraoperatively with navigation for mean femoral coronal alignment (-0.6+1.0, $p < 0.01$) and femoral rotation (3.0+3.4, $p <0.01$), but not for femoral flexion (-0.6+1.6, $p = 0.08$). In contrast, tibial frontal alignment was not significantly different to the plan (-0.4+2.4, $p = 0.87$), while the slope differed by 1.1° (+2.1, $p = 0.02$). The percentage of the sample that fell within 3° of the plan ranged from 60% (femoral rotation) to 96% (femoral coronal). Total virtual alignment in the coronal and sagittal planes were not significantly different from zero. However, of the sample measured, 76% were within +3° in the coronal plane and 80% in the sagittal plane. Importantly, 99% prediction intervals ranged from 5.9° for femoral coronal alignment to 15.8° for total sagittal alignment.

Discussion & Conclusions:
Although the results indicate that the cutting blocks do not systematically over or under-estimate alignment compared to imageless computer navigation, the variability in the differences between measurements suggests they are not yet accurate for total knee arthroplasty. The results of this investigation compare favourably to recent

reports on other available systems, particularly for alignment in the sagittal plane. However there remains a high frequency of potential limb malalignment when compared with standard computer navigation. Further investigation is warranted to identify the source of errors in the process and caution is recommended for routine clinical use without objective verification of alignment.