Concurrent Validation of a Novel Intraoperative Navigation Platform for Total Knee Arthroplasty: Assessing Implant Alignment and Collateral Ligament Elongation

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INTRODUCTION: Despite the significant success rate of total knee arthroplasty (TKA) exceeding 90% and the inherent superiority of computer assisted navigation systems over conventional techniques in achieving targeted implant alignment, around 20% of patients still remain dissatisfied. This is primarily due to factors such as reduced joint motion and ligament instability. Therefore, a novel intraoperative navigation platform (Next-Ar, Medacta International) was recently introduced to assist surgeons in achieving targeted implant alignment precisely while providing real-time feedback of tibiofemoral kinematics and medial collateral ligament (MCL) and lateral collateral ligament (LCL) elongation using a motion tracking unit. The goal of this study was to validate the accuracy of the Next-Ar system in terms of implant alignment parameters, tibiofemoral kinematics and collateral ligament elongations compared to gold standard measurement tools in an *ex-vivo* set-up.

METHODS: Computed tomography (CT) of 7 native fresh-frozen full legs were collected following approval from an Ethics Committee and the CT images were used for designing patient specific cutting guides, including the housing for the Next-Ar motion trackers (single camera and receiver). The CT-based bony landmarks and collateral ligament insertions were identified to generate virtual single line bundle and these input parameters were imported into Next-Ar system to provide real-time feedback for bone resection, orientation of TKA, tibiofemoral kinematics and collateral ligament elongation intraoperatively. Following, each specimen was implanted with a cemented total knee arthroplasty (GMK Sphere, Medacta International) based on a mechanical alignment technique and mounted into a physiological ex-vivo knee simulator. The specimens were then subjected to quasistatic squatting at various knee flexion angles, while actively controlling the quadriceps and bilateral hamstrings (50N each) to a maintain constant vertical ankle load of 110N. The Next-Ar based tibiofemoral kinematics, relative change in medial collateral ligament and lateral collateral ligament elongations were acquired and these measurements were compared to reference values that were synchronously acquired with bone-pin mounted markers and a six-camera optical motion tracking system (MTS, Vicon). Furthermore, the MCL and LCL insertions were identified in reference to the bone-pin mounted markers using a wand and defined as anterior, middle and posterior bundles (each single line). Following, post-op CT images were collected to analyze hip knee ankle angle (HKA), femoral varus, femoral flexion, femoral rotation, tibial varus and tibial slope. A generalized mixed model was used to compare the tibiofemoral kinematics and collateral ligament elongations obtained from Next-Ar and MTS systems. In addition, a paired t-test was performed to compare the post-op CT based implant alignment parameters to its targeted values ($p<0.05$).

RESULTS SECTION: In terms of alignment, mean differences (diff = target – post-op CT) of hip knee ankle angle (target vs post-op, p=0.08), femoral varus (p=0.21), femoral flexion (p=0.87), femoral rotation (p=0.78), tibial varus (p=0.12) and tibial slope (p=0.4) measured 1.5° (±1.9°), -0.5° (±1°), -0.1° (±1°), -0.1° (±1.2°), -0.8° (±1.1°) and 0.4° (±1°), respectively. In terms of kinematics, knee flexion (p=0.35) and valgus orientation (p=0.14), obtained from both Next-Ar and MTS systems were comparable. Nevertheless, the tibial internal rotation exhibited a significant difference (p=0.001, Table 1) between Next-Ar (%CI, 0.9 – 3.5) and the MTS (-6.3 – -3.8). Finally, collateral ligament elongations obtained from the Next-Ar (CI=-2mm – 4.3mm and -2.9mm – 1mm) demonstrated similar values for the anterior bundle of the MCL (p=0.3) and the LCL (Fig. 1) in-anterior, middle and posterior bundles (p>0.96).

DISCUSSION: These findings show that Next-Ar system could potentially help achieving targeted implant alignments, while providing objective and realistic real-time tibiofemoral kinematics and collateral ligament elongation for both the native and implanted knee. Although the tibiofemoral kinematics obtained from both systems were comparable, this was not the case for tibial internal rotation, which might be associated with potential differences in anatomical landmark definition between Next-Ar and MTS systems. Moreover, care must be taken while assessing collateral ligament elongation, especially for MCL elongation which due to its larger insertion area, might not be well represented by a single-line definition. One notable limitation of this study is that Next-Ar motion tracker unit was unable to collect dynamic data during the experiment due to infrared light interferences between both systems in certain positions throughout the flexion-extension range

SIGNIFICANCE/CLINICAL RELEVANCE: The novel intraoperative navigation platform, Next-Ar system, can potentially aid clinicians in achieving more precise target implant alignment. Furthermore, the real-time tibiofemoral kinematics and collateral ligament elongation feature could potentially help restoring natural knee joint motions and ligament stability.

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Table.1 The confidence intervals (95%) and associated p-values values for tibiofemoral kinematics.

	MTS (%CI)	Next-Ar (%CI)	p-value
Knee flexion	42.4 – 43.7	42 – 43.3	0.35
Tibial internal rotation	-6.3 – -3.8	0.9 – 3.5	0.001
Valgus	-2.8 – 0.7	-1 – 2.6	0.14

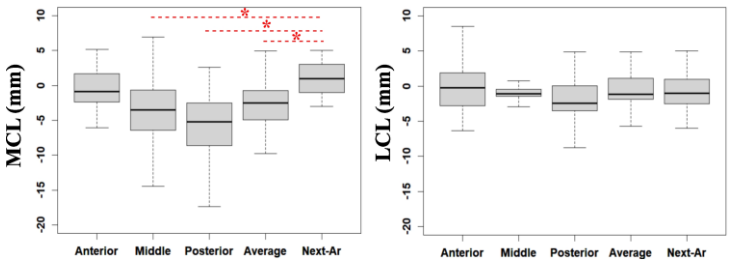

Fig. 1. The medial collateral ligament and lateral collateral ligament elongations obtained from MTS (anterior, middle, posterior and avarage) and Next-Ar systems. The average represents the mean value of anterior, middle and posterior. Red dotted line with asterisk indicates statistical difference ($p<0.05$).