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Accuracy, Reliability, and Repeatability of Navigation Systems in Clinical Practice

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Navigation in orthopedic surgery is now a widely accepted technique for the measurement of in vivo knee kinematics and has been proposed to possibly improve final outcome during surgery. In vivo results of navigated kinematic tests during surgery are affected by external factors, such as surgeon-subjective variability, limb positioning, and patient-specific laxity. The purpose of this study was to assess the reliability of navigation technology to assess knee laxities during an in vivo setup and to evaluate intraobserver reliability and interobserver repeatability. Intraoperative evaluation was performed on more than 70 consecutive anterior cruciate ligament surgical reconstructions. Intratester reliability and intertester repeatability were evaluated by correlating the results of repeated tests of antero-posterior translation, varus–valgus and internal–external rotations. Percentage standard error, the α-Crombach test, and interclass correlation (ICC) were used to estimate the measurement variability. The results showed repeatability on anteroposterior translation (1.2-mm repeatability) and good correlation (ICC > 0.60). Repeatability of Varus–valgus rotation was 0.9° (ICC > 0.46) in knees with small laxities, and repeatability of internal–external rotation was 2.4° (ICC > 0.72). Navigation systems have shown to be reliable, complete, and objective in intraoperative kinematic evaluations.
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The importance of the evaluation of passive knee laxity in the assessment of both knee anterior cruciate ligament (ACL) injuries and the efficacy of relative surgical reconstruction has been widely discussed and validated.[1-5] The necessity of quantifying this laxity led to the development of several instruments and methodologies used for objective measurements. In particular, arthrometers,[6,7] bioimages (radiological methodologies,[8,9] roentgenstereophotogrammetry analysis (RSA),[10] dynamic magnetic resonance imaging,[11,12] and fluoroscopy[13]), electrogoniometers,[14] electromechanical devices,[15] and 3-dimensional trackers[9,16] have been widely used. Navigation in orthopedic surgery is now a widely accepted technique for measuring in vivo knee kinematics and has been proposed to possibly improve final outcome during surgery.[17,18]

The advantage of these systems is their ability to precisely quantify the 6 degrees of freedom kinematics of the knee during standard clinical testing in the intraoperative setting. This additional information may refine the surgeon's ability to diagnose specific instability patterns by identifying pathological coupled motions intraoperatively as well as evaluating ligament reconstruction constructs.[19] Navigation is being used in an increasing number of research articles not only to validate or to compare different surgical strategies but also to compare the contribution of different bundles in vivo in controlling knee laxity or to identify additional clinical tests that could better describe patient constitutional laxity.

This technology has been validated in vitro by the use of a controlled setup or robotic simulators for its accuracy and for its usability in the surgical environment, demonstrating an overall accuracy of approximately 1 mm or 1°[20-23] and a high correlation with motion applied by robotic manipulators.[19]

However, in vivo results of navigated kinematic test during surgery are affected not only by the nominal accuracy of localizing technology or the experimental setup but also by other external factors, such as surgeon-subjective and manually applied loads, limb positioning during the test, and patient-specific laxity. Therefore, it is important to quantify possible biases that may occur during in vivo tests to define

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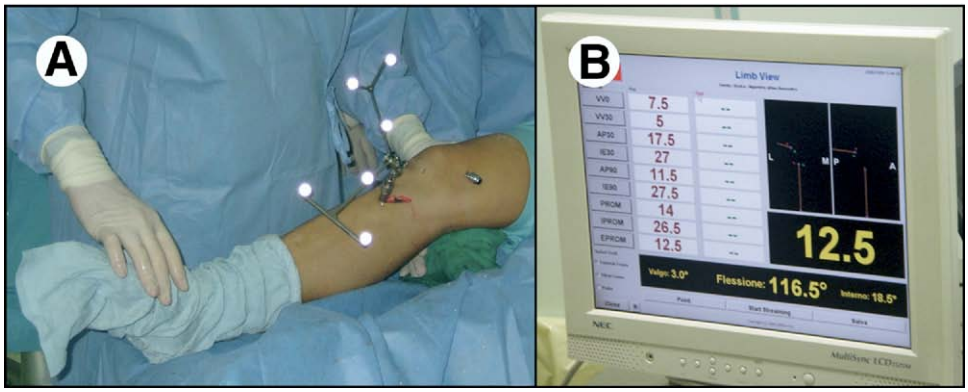

Figure 1 In vivo marker setup (A) and software interface (B) of navigation system.

the reliability of such technologies in the in vivo setup. The purpose of this study was to assess the reliability of navigation technology in assessing knee laxities during an in vivo setup and to evaluate intraobserver reliability and interobserver repeatability.

Materials and Methods

Surgical Protocol

The intraoperative evaluation was performed during 8 months of consecutive anterior cruciate ligament (ACL) surgical reconstructions, with 70 patients being examined. ACL reconstruction was performed arthroscopically by the same, most-experienced surgeon, who used a single-bundle or a double-bundle technique with hamstring tendons.[24,25] An experimental protocol was established during the first 10 cases of the trial, which were excluded from this study. Patients were recruited for the study if they complained of anterior knee instability and had a diagnosis of isolated ACL ligament injury and no previous surgery on the affected knee. Patients also were included if a torn meniscus was associated with the ACL injury (12 cases); however, they were excluded if they had any coexisting pathology in the knee.

Among this group of patients, all those who voluntarily agreed to take part in the research protocol were enrolled. The sample set included 53 men and 7 women; the mean age of study patients was 31.0 ± 10.8 years (range, 16 to 59 years); 32 knees were right and 28 left; and all lesions were considered as subacute or chronic lesions of traumatic origin with a mean time from injury to surgery of 12 ± 10.8 months (range, 3 to 48 months). This study design was preferred to a randomized trial, which would have a much longer completion time, to minimize biases introduced by the learning curve, differences in surgical equipment, and differences in the operating environment.

The evaluation of clinical reliability of navigation was performed on a commercially available system (BLU-IGS, Orthokey, Lewes, DE), which uses optoelectronic technology for 3-dimensional localizing. Reference frames of the navigation system were fixed on bones with 3-mm bicortical Schantz screws implanted in tibial and femoral incisions, near the tunnel's external hole (Fig. 1); then, the surgeon acquired the hip center (by pivoting the leg) and femoral transepicondylar line, tibial mediolateral axis, and malleoli percutaneously. These points were automatically recorded by the navigation system to compute the joint reference frame and display the instantaneous position of femur and tibia axes according to the classical conventions for navigation systems and biomechanics.[26,27]

The surgeon performed the kinematic evaluation at 0°, 30°, and 90° of flexion manually at maximum force, as is usual in clinical practice, examining the state of the knee on the computer display. Laxity test consisted of varus–valgus (VV) stress at 0° and 30° of knee flexion, anteroposterior (AP) translation at 30° and 90° of flexion, and internal–external (IE) rotation at 30° and 90° of flexion. The relative movement of the tibia and femur are recorded by the navigation system, and rotational and translational laxities are computed and displayed in real-time, allowing the surgeon to quantify the behavior of the ACL-deficient knee. Tests were repeated before and after insertion of the ACL graft. The procedure for navigated kinematic evaluations was used during surgery after approval by the local ethics committee and written informed consent was obtained from all volunteers.

Experimental Setup

The intra- and intertester evaluation of the measured laxity was performed in blinded conditions (ie, hiding the results of the measured laxity and maintaining the display of the knee state during kinematic tests). For measuring intratester reliability, in 30 cases an expert surgeon performed the kinematic tests, at maximum force, 3 times consecutively at extension, 30° knee flexion and at 90° knee flexion, both before and after ACL reconstruction.

For measuring intertester repeatability, in the other 30 cases 3 different surgeons performed laxity tests on the same patient. One of the 3 examiners was an expert surgeon and an expert user of the navigation system; the second examiner was an expert surgeon and an intermediate user of the navigation system; and the third examiner was a young surgeon with no previous experience with the navigation system.

We used percentage standard error (SE%) to estimate the measurement variability and the α-Crombach test with within-subject standard error and inter-class correlation (ICC) test to