Computers in Biology and Medicine 39 (2009) 280 – 285

Contents lists available at ScienceDirect

Computers in Biology and Medicine

journal homepage: www.elsevier.com/locate/cbm

Reliability of a navigation system for intra-operative evaluation of antero-posterior knee joint laxity

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ARTICLE INFO

Article history:
Received 18 June 2007
Accepted 5 January 2009

Keywords:
Knee laxity
ACL lesion
Navigation systems
Arthrometer
Rolimeter
KIN-Nav

ABSTRACT

Background: The purpose of this study was to investigate about the reliability of measuring antero-posterior laxity within-subjects for *in-vivo* studies using a navigation system.
Methods: The analysis was performed by enroling 60 patients undergoing anterior cruciate ligament ACL reconstruction, and assessing AP laxity during the Lachman and drawer tests.
Results: For the navigation system standard deviation for intra-trial measures was 0.7 mm, thus the intra-trial repeatability coefficient was 2.2 mm; standard deviation for intra-trial measure was 1.2 mm, while the reference inter-trial repeatability coefficient between expert surgeons was 3.4 mm.
Conclusions: In conclusion, this study suggests that KIN-Nav may represent a new method to measure and document AP laxity intra-operatively with improved accuracy and test the effect of surgical treatment *in-vivo* with higher sensitivity than in the past and this study quantify its reliability for within-subjects studies performed by a single expert surgeon.

1. Introduction

The importance of the evaluation of passive antero-posterior (AP) knee laxity in order to assess both knee anterior cruciate ligament (ACL) injuries and the efficacy of relative surgical reconstruction has been widely discussed and validated [1–3]. The necessity to have a quantification of this laxity led to the development of several instruments and methodologies used for objective measurements; in particular arthrometers [4], bioimages (radiological methodologies [5,6], RSA [7], dynamic MRI [8,9], and fluoroscopy [10]), electrogoniometers [11], electromechanic devices [12] and 3D trackers [13] were widely used.

Nevertheless, only a few techniques have proven to be suitable for intra-operative use, basically due to the strict restraints for the equipment that can be used in the operating room (OR), including the need to be sterilisable and the requirement to minimise surgeons' fatigue, additional surgical time and patient morbidity. At present the most widely spread tools used to quantify manually AP displacement of the tibia with respect to the femur are basically arthrometers that can be used either at maximum stress [14–16] or with a known force [17–19]. These devices are very simple and are able to provide an objective quantitative evaluation of AP laxity, both before and after surgical treatment.

However the measurements performed using these devices are affected by several sources of errors, such as the impossibility to fix the tool directly on bones during acquisition, the uncertainty about the initial knee position (degree of flexion/extension), test conditions during the evaluation, and variability due to tester's experience [4,12,16,18,20,21]. Therefore, further studies on these devices or on new methodologies that quantify AP laxity would be useful to improve reliability of knee kinematics estimation. Recently, the use in the OR of 3D tracking devices, and in particular their application in navigation systems, seems useful to overcome some of the problems reported with arthrometers. Since their intrinsic accuracy is high (0.350 mm is the highest threshold in the identification of optical marker position) and the trackers are directly fixed on bones, they can be used to assess the relative displacement of bones without concern for soft tissue artefacts; in addition navigation systems are suitable to improve the test reproducibility, allowing the surgeon to check knee placement and test execution [22–24].

Although this methodology is expensive and slightly invasive (due to the need to use sensors that are fixed to the bones),

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0010-4825/$ - see front matter © 2009 Elsevier Ltd. All rights reserved.
doi:10.1016/j.compbiomed.2009.01.001

navigation systems-having the robust capability to evaluate joint kinematics-are very promising in this field of application and therefore deserve further investigation. Previous studies have assessed their reliability in the acquisitions of anatomical landmarks or in the evaluation of specific surgical techniques [25–29], but the analysis of their performance for measuring kinematic values is still lacking.

The objectives of this study were thus to statistically determine the reliability of a navigation system in the measurement of AP laxity clinical tests (Lachman and drawer tests) performed by the same surgeon (intra-tester reliability) and by different operators (inter-tester reliability), and also to compare the computer-assisted procedure with a known widely used method, such as the clinical evaluation performed with a commercial knee arthrometer (Rolimeter©, Aircast Europe, Germany) in the same test conditions. A preliminary validation of the navigation system for translational and rotational laxity measurements was also performed by the authors in [30], however the statistical analysis and the experimental design was improved in this study for AP laxity in order to understand how to interpret clinical results obtained with navigation systems and compare them with those obtained in literature with other methodologies. Therefore the major novelty of this work is to provide a complete analytical method, able to assess the clinical coherence of the data coming from different measuring system and to evaluate the degree of consistency between the measurements performed both by the same examiner and by different examiners too.

2. Material and methods

2.1. Subjects and testers

This study involved a cohort of 60 consecutive patients that underwent arthroscopic ACL reconstruction performed in our institute between January and September, 2005. All patients were recruited if they complained of anterior knee instability, with a diagnosis of isolated ACL ligament injury and no previous surgery on the affected knee. Patients were included also if a torn meniscus was associated with the ACL injury (12 cases); however, they were excluded if they had any co-existing disease in the knee. Among this group of patients, all those who voluntarily agreed to take part in the research protocol were enroled. The sample set included 53 men and 7 women; the mean age of study patients was 31.0 ± 10.8 years (range: 16–59 years); 32 knees were right and 28 left; all lesions were considered as sub-acute or chronic lesions of traumatic origin with a mean time from injury to surgery of 12 ± 10.8 months (range: 3–48 months).

This study design was preferred to a randomised trial with a much longer completion time to minimise biases introduced by the learning curve, differences in surgical equipment, and the operating environment.

All patients underwent an arthroscopic double-bundle or single-bundle ACL reconstruction with hamstring tendon graft [31,32]. All ACL lesions were arthroscopically confirmed to match the inclusion criteria of this study.

Three investigators from the surgical team of the institute were selected for the necessary examinations used for this study. The first examiner (surgeon A) was an experienced surgeon, who has been in charge of regular clinical routine and research services for more than 10 years and 200 navigated interventions; he was considered to be an *expert* user of both the navigation system and other clinical evaluation methods. The second examiner (surgeon B) was an experienced surgeon with more than 5 years' experience in clinical practise and 50 navigated interventions; he was considered to be an *intermediate* user of the navigation system and an *expert* user of the clinical evaluation methods. The third investigator (surgeon C) was considered to be a *novice* user of all evaluation methods, as he was medically qualified but had little experience with diagnostic and surgical examinations (less than 2 years) and no previous experience with the navigation system.

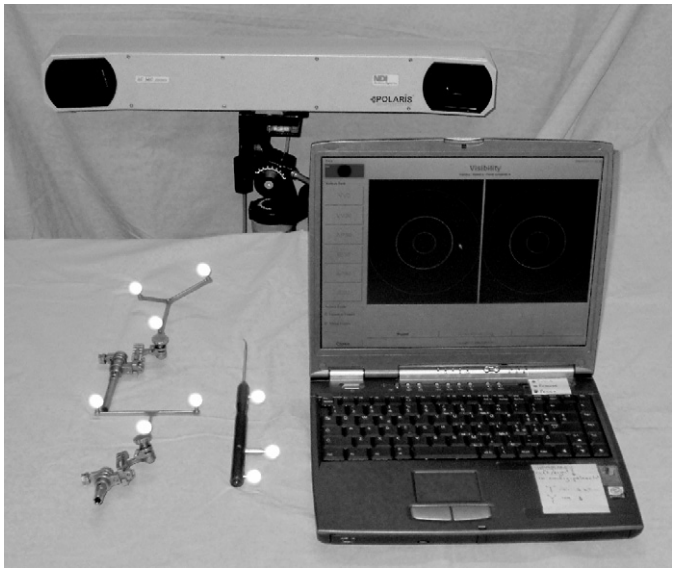

Fig. 1. KIN-Nav set-up.

The study design was approved by the Institutional Ethical Review Board of the Institute prior to data collection, and all patients gave their informed consent.

2.2. Experimental procedure

After spinal anaesthesia and with tourniquet inflated, a preliminary clinical pre-operative knee evaluation was performed using a Rolimeter knee arthrometer before entering the OR. The evaluation was performed by a single examiner, the most experienced investigator.

ACL reconstruction was performed arthroscopically by the same, most experienced surgeon, using or a single-bundle or a double-bundle technique with hamstring tendons.

The intra-operative assessment of the knee AP laxity was performed using the KIN-Nav navigation system, developed at our institute, consisting of an optical localizer (Polaris, Northern Digital, Waterloo, ON, Canada) and dedicated software running on a commercial laptop (Fig. 1). This system was tested and optimised prior to this study and was deemed suitable for surgical routine [23,24,26,33].

In this study we recorded Lachman and drawer tests in ACL-deficient and reconstructed knees, thus estimating AP laxity, respectively, at 30° and 90°. The surgeon performed the evaluation of knee stability as in clinical practise, by applying maximum manual load at the level of the tibial tuberosity perpendicular to the tibial axis, similarly to tests with the Rolimeter [14–16]. The leg was positioned at the corresponding degree of flexion supported by a sterile drape, placed under the thigh, and the corresponding flexion angle was checked in real-time on the KIN-Nav interface (Fig. 2).

AP laxity was measured also after the reconstruction, as in ACL-deficient state, both with KIN-Nav and the Rolimeter. The mean interval time between the pre-operative Rolimeter evaluation and the first KIN-Nav evaluation of the knee was 30 minutes, while, due to OR necessity, post-operative evaluations were consecutive. All surgeons witnessed the measures and were blinded to the laxity values obtained with KIN-Nav and Rolimeter.

In order to estimate KIN-Nav's ability to assess AP laxity we tested inter-trial and intra-trial repeatability. In an effort to limit the additional surgical time required for this study the intra-trial and