Efficacy of an Intra-Operative Imaging Software System for Anatomic Anterior Cruciate Ligament Reconstruction Surgery

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ABSTRACT
An imaging software system was studied for improving the performance of anatomic anterior cruciate ligament (ACL) reconstruction which requires identifying ACL insertion sites for bone tunnel placement. This software predicts and displays the insertion sites based on the literature data and patient-specific bony landmarks. Twenty orthopaedic surgeons performed simulated arthroscopic ACL surgeries on 20 knee specimens, first without and then with the visual guidance by fluoroscopic imaging, and their tunnel entry positions were recorded. The native ACL insertion morphologies of individual specimens were quantified in relation to CT-based bone models and then used to evaluate the software-generated insertion locations. Results suggested that the system was effective in leading surgeons to predetermined locations while the application of averaged insertion morphological information in individual surgeries can be susceptible to inaccuracy and uncertainty. Implications on challenges associated with developing engineering solutions to aid in re-creating or recognizing anatomy in surgical care delivery are discussed.

Keywords: ACL reconstruction, anatomy, image-guided surgery, tunnel placement

1. INTRODUCTION
The anterior cruciate ligament (ACL) is a major restraining ligament in the knee joint. ACL injuries can result in pain, joint instability, and different degrees of disability ranging from reduced participation in sports to difficulties with activities of daily living. Reconstructive surgery is the standard of care for most patients seeking for treatment for an ACL injury, and there can be as many as 175,000 such procedures performed

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annually in the United States [1]. With the direct cost of an ACL surgery being at least \$11,900 in the United States [2], the financial impact of ACL reconstruction is estimated to exceed \$2 billion per year. However, current ACL reconstruction methods are less than ideal in terms of consistency and effectiveness in restoring knee function and preventing the development of osteoarthritis (OA). Meta-analyses evaluating long-term outcome after ACL reconstruction have revealed that only in 37% of the patients was normal structure and function of the knee restored [3], and that only 65 to 70% were able to return to their pre-injury level of sports activity [3, 4]. Radiographic evidence of mild arthritic changes was found in 90% of ACL-reconstructed knees at an average follow-up of 6.6 years (ranging from 3 to 10 years) [5].

The basic understanding of ACL anatomy has advanced considerably over the past few years, revealing the shortcomings of widely employed surgical techniques for restoring the complex anatomy of the native ACL, and driving the development of more anatomic reconstruction techniques. The rationale behind such development is that increased risk for knee OA following ACL injury and surgery is due, at least in part, to failure of the procedure to restore normal anatomy and mechanics of the knee. There is a growing body of scientific evidence suggesting that anatomic reconstruction—performed by creating the bone tunnels and placing the substituting graft right at where the native ligament was attached (see Figure 1)—can better restore the joint function and deter the development of OA [6–10] .

It is however not an easy undertaking to identify the native ACL insertion or attachment sites during a surgical operation. About 85% of ACL reconstructions are done by surgeons who perform fewer than 10 cases per year [11] and are unlikely to maintain an acute awareness of the anatomy. Even for more experienced surgeons, factors including the arthroscopic distortion and disappearance of the ligament remnant (naturally or due to a notchplasty procedure reshaping the inter-condylar notch where the ACL

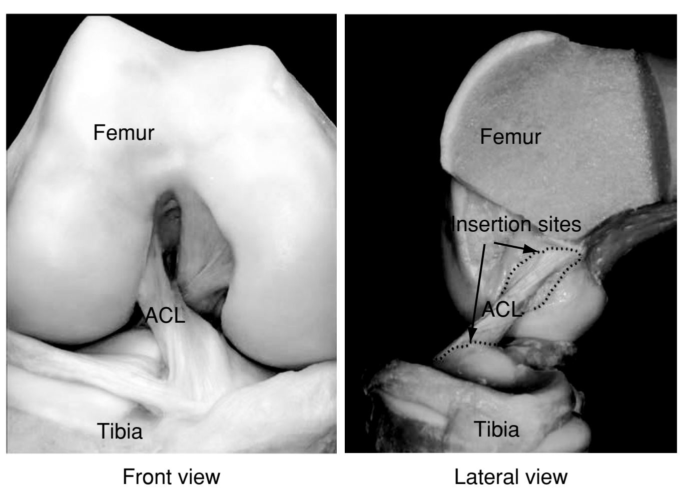

Figure 1. The anatomy of anterior cruciate ligament (ACL). The native insertion sites marked by dotted peripheries on the lateral view are where bone tunnels should be drilled and grafts be placed in an anatomic ACL reconstruction surgery.

inserts) may still cause misidentification of the natural insertion or attachment sites. A conceivable engineering solution is to provide a navigational aid in identification of the insertion sites, which nevertheless entails usability and implementation challenges. There remain acceptance and cost issues associated with the use of a sophisticated surgical navigation system in orthopaedic surgeries in general [12]. Simple, easy-to-use, and surgeon-friendly navigation aid systems are more desirable. Simple or complex, a system must specify the target insertion locations. Acquisition of this information in a patient-specific manner (using, e.g., magnetic resonance imaging (MRI)) and its quick retrieval for intra-operative use are still technically challenging. Use of information synthesized from literature data would lead to questions concerning the individual variability in ligament insertion morphology and inaccuracy or uncertainty associated with applying group-averaged or another person's data to a specific case.

The objectives of the present study are (1) to examine whether an imaging software system presenting the ACL insertion locations on fluoroscopic views is effective in guiding orthopaedic surgeons intra-operatively to predetermined insertion site locations, and (2) to evaluate the accuracy as well as uncertainty associated with using literature-based data to represent individual ligament insertion morphology. To achieve these objectives, we recruited 20 orthopaedic surgeons to perform simulated arthroscopic ACL reconstructive surgeries in our laboratory on 20 cadaveric knee specimens, with and without the aid of the fluoroscopic imaging system, and recorded the surgeons' performances in identification of the insertion sites. We then measured the ACL insertion site morphology on both the femur and tibia of each specimen, and statistically compared the measurements with the literature data on digitally simulated radiographs.

2. METHODS

2.1. Imaging Software System

The imaging software system, developed by Smith & Nephew, Inc. (Andover, MA), is designed for use with intra-operative fluoroscopy. As shown in Figure 2, the software

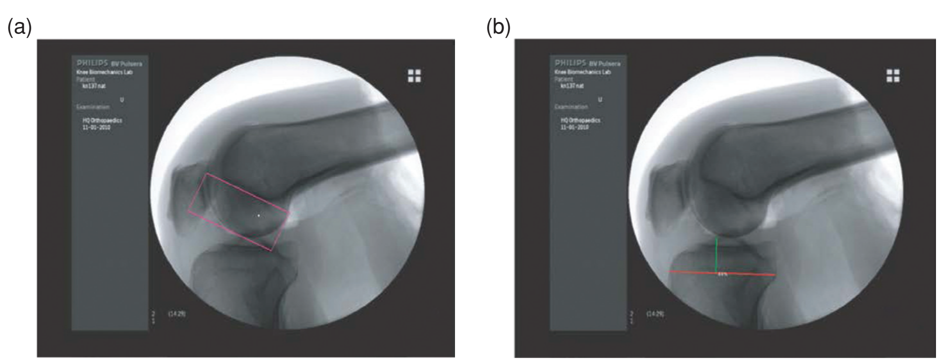

Figure 2. The ACL insertion site locations determined by the present imaging software on lateral fluoroscopic views of the knee. On the femoral side (a), the insertion site position (white dot) is defined with respect to a two-dimensional reference frame (purple rectangle); on the tibial side (b), the insertion site location (green line) is defined based on a reference line (red line) known as the Amis-Jakob line [17].

establishes on a lateral fluoroscopic view of the knee a reference frame on the femur and a reference line on the tibia, both patient-specific, and predicts the ACL insertion site location based on a synthesis of the existing literature data [13–15]. The two-dimensional (2D) reference frame on the femur is defined by the most anterior and posterior points on the Blumensaat's line [16] and a perpendicular line drawn to the distal edge of the femoral condyles; the tibial reference line is defined by the most anterior and posterior points on the Amis-Jakob line [17]. The literature data express the locations of ACL insertions as percentages of the corresponding reference frame and line dimensions. The imaging system therefore allows a surgeon during an operation to take a fluoroscopic image with a lateral view of the current drill guide position, visually compare it with the predicted target position, and make an adjustment if needed. This process can be repeated until the surgeon is satisfied with the position.

2.2. Subjects

Twenty participants included six senior orthopaedic residents (post-graduate year 4–6), three orthopaedic sports medicine fellows, one attending orthopaedic surgeon, and 10 visiting fellows who are attending orthopaedic surgeons or fellows in foreign countries. The experimental protocol, which was approved by the University of Pittsburgh Institutional Review Board, was explained to each participant, and informed consent was then obtained.

2.3. Specimen Preparation

Before each participant performed arthroscopic ACL reconstruction surgery on a randomly assigned knee specimen, the specimen went through several preparation steps as follows. Each specimen was first carefully dissected such that skin and soft tissues were removed while the joint capsule was kept intact. Six spherical fiducial markers (precision Nylon spheres, radius 9.525 mm) were rigidly affixed to the femur and tibia, three on each bone. The ACL was arthroscopically transected to simulate an injury, and removed of most of its substance to leave approximately a 2 mm remnant ("stump") on both the femur and tibia. The peripheries of the ACL native insertions sites ("footprints") on both the femoral and tibial sides were then digitized using a surgical navigation system (Polaris Spectra, NDI). Twenty to twenty-five evenly distributed points along the periphery of each insertion site were digitized. In addition, the spherical surfaces of six fiducial markers were "painted" by the digitization stylus such that "point-clouds" were formed to facilitate the co-registration procedure later needed. The preparation concluded with a high-resolution CT scan (slice spacing: 0.625 mm) of the specimen with the fiducial markers attached at a University of Pittsburgh clinical radiology facility.

2.4. Simulated ACL Reconstruction Surgery

With a specimen arthroscopically prepared (e.g., portals created) and in a typical surgery position (the femur secured in a fixture and the tibia freely movable), each participating surgeon was asked to perform a simulated ACL reconstruction surgery using a transportal technique. Specifically, the surgeon was required, through a standard anteromedial portal, to identify and mark with an awl or drill guide the locations on the femur where the femoral tunnel should start and on the tibia where the tibial tunnel should exit for an anatomic single-bundle ACL reconstruction. Once the surgeon completed an attempt and was satisfied with the position, a lateral fluoroscopic image of the knee was obtained, on which the patient-specific reference frame and reference line were defined and corresponding target insertion locations displayed. The surgeon could then adjust the tunnel placement to best match the target locations displayed by the imaging system, or choose not to if he or she was satisfied with the current positions. The tunnel positions after each placement attempt were documented using the fluoroscope.

2.5. Data Analysis

The digitized insertion site "footprints" were mapped on the corresponding three-dimensional (3D) CT-based bone model via the fiducial markers using an image reconstruction and data co-registration procedure previously established by our group [18]. This procedure minimized the residual error in fitting the "point-clouds" to the surfaces of spherical markers and the effect of target registration error [19]. The 3D bone model, along with co-registered insertion sites as digitized points, was projected to the lateral plane consistent with that of the fluoroscopic imaging (Figure 3). The

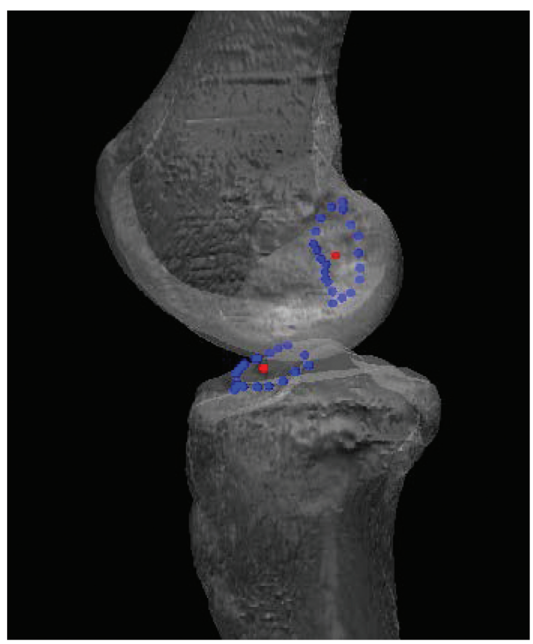

Figure 3. The lateral plane projection of a CT-acquired 3D bone model along with the digitized ACL insertion sites (blue dots are the individual digitized points; red dots are the geometric centers).

opacity of model was adjusted such that the Blumensaat's line and relevant landmarks were clearly identifiable for establishing the references describe above.

The basic measure of tunnel placement accuracy was the distance from the drill guide tip to the target insertion site location prior to use of the fluoroscopic imaging system (i.e., without the actual display of target insertion site) and at the conclusion of each adjustment under the visual guidance of the fluoroscopic imaging system. The distance was measured off the fluoroscope and determined via a calibrated pixel-distance conversion procedure. Regardless of the number of adjustments, which varied from 0 to 4, the beginning and final distances were used to represent the tunnel placement accuracy, without and with the aid of the imaging system, respectively. A *t*-test was employed for a comparative analysis.

The literature-based average ACL insertion site locations [13–15] displayed by the imaging software were compared to the individually measured native insertion locations. The difference (δ) was quantified as the distance from a predicted location based on literature data to the geometric center of the digitized points along the periphery of an insertion site, in a lateral projection (two-dimensional for the femoral side and one-dimensional for the tibial side). In addition, the native insertion site size was characterized compactly by the mean of the distances (*d*'s) from individual digitized points to their corresponding geometric center. A normalization of the difference (δ) by this mean distance (μ_d) resulted in a dimensionless, non-biased measure (γ) of the accuracy of literature-based data in representing individual-specific insertion site locations.

The difference between the native ACL insertion site and the initial tunnel position on the femoral side of each knee was also analyzed in order to evaluate surgeons' performance without the aid of the fluoroscopic imaging system. This was assessed by the distance between the geometric center of digitized points and the tunnel position recorded. For the tibial side, the difference was one-dimensional and could be derived from the other two distance measures described above.

3. RESULTS

Most participating surgeons (16 out of 20) made at least one adjustment after receiving the visual feedback of their initial tunnel placement position relative to the target position, and most adjustments (14 out of 16) resulted in an improvement. The average tunnel placement accuracy as measured by the distance between the selected tunnel position and the target position improved from 3.9 (SD: 2.2) mm to 1.6 (SD: 1.6) mm on the femoral side and from 3.7 (SD: 2.4) mm to 1.5 (SD: 0.8) mm on the tibial side; the differences were statistically significant ($p < 0.01$ for both). Figure 4 shows a representative example of a surgeon's improvement towards the target insertion positions displayed by the imaging system. The average number of adjustments was 2.1 (SD: 1.7) and the average added time by the adjustments was 72 seconds (SD: 98 seconds). An interesting observation was that the improvement was more pronounced in the orthopaedic residents and sports medicine fellows than in visiting foreign fellows who were associated with an ACL clinical research group at University of Pittsburgh and were better versed in the anatomic concept for ACL reconstructive surgery: the

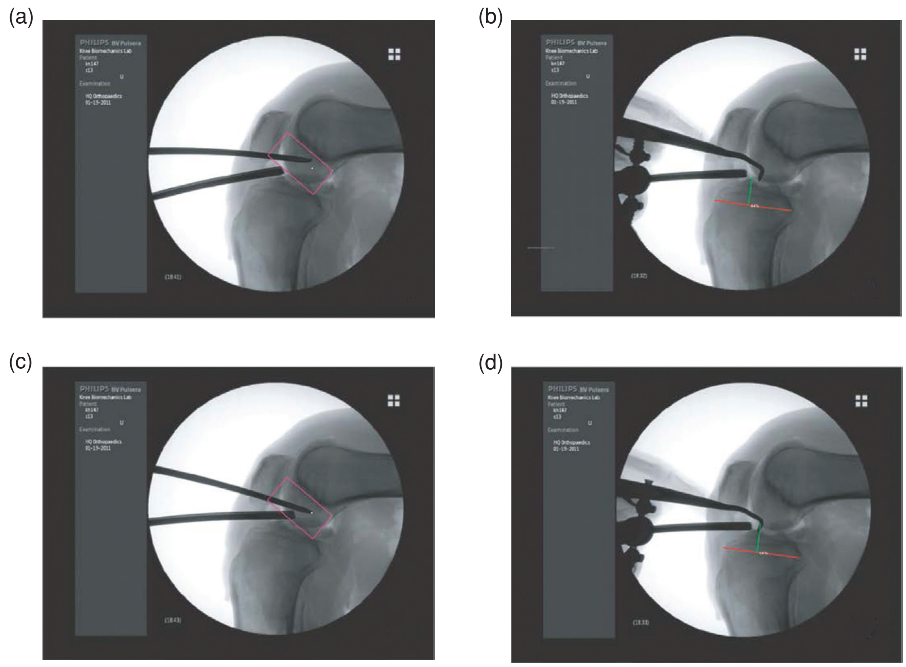

Figure 4. A surgeon's tunnel placements on the femur (a, c) and tibia (b, d), before (a, b) and after (c, d) adjustment made under the visual guidance of the intra-operative imaging system.

accuracy measure changed from 4.2 mm (SD: 2.6 mm) to 1.6 mm (SD: 0.8 mm) for the former group (n = 9) and 3.5 mm (SD: 1.9 mm) to 1.9 mm (SD: 2.1 mm) for the latter group (n = 10).

Table 1 summarizes selected parameters describing the native insertion sites and measures of accuracy of literature-based prediction of individual-specific insertion site locations. Note μ_d and σ_d are statistical measures—they are, respectively, the mean and standard deviation of *d*, the distances of digitized insertion site points to their geometric center, as simple measures of the size and shape of an insertion site (e.g., a very circular-shaped insertion site would have a very small σ_d value). On average, the literature-based insertion site locations on both the femoral and tibial sides were within the boundary defined by the mean insertion site distance (μ_d). Of note, however, is that the literature-based predetermined insertion site location is intended to be the center of a drill or tunnel. The discrepancy on the tibial side was less than that on the femoral side. The coefficient of variation (SD/mean ratio) for the discrepancy was 0.61 and 0.57 for the femoral and tibial side, respectively.

The distances from the initial tunnel positions placed without the aid of the fluoroscopic imaging to the geometric center of corresponding native ACL insertion sites had a mean (±SD) of 4.53 (±2.59) mm on the femoral side and 3.20 (±2.11) mm

Table 1. Statistical summary (n = 20) of native insertion site parameters and measures of accuracy of literature-based predictions of the individual-specific insertion locations. μ_d: the mean of distances from individual digitized insertion periphery points to their geometric center; σ_d: the standard deviation of distances from individual digitized insertion periphery points to their geometric center; δ: the distance from a predicted location based on literature data to the geometric center of the digitized points; γ: the ratio of δ to μ_d.

	μ_d (mm)	σ_d (mm)	δ (mm)	γ
		Femoral side		
Mean	4.13	1.43	2.60	0.62
SD	0.84	0.30	1.59	0.32
		Tibial side		
Mean	3.59	1.90	1.53	0.45
SD	0.74	0.39	0.88	0.30

on the tibial side. Note in particular that the mean distance on the femoral side was greater than the mean insertion site distance (μ_d) as a measure of insertion site size.

4. DISCUSSION

As engineering innovations continue to improve and transform how surgical care is delivered, one of the most important missions is to help the surgeons achieve a better understanding and awareness of the anatomy intra-operatively. Re-creating or recognizing the anatomy is a fundamental principle for orthopaedics as well as surgical care in general. It is easy to appreciate and accept this principle but it is challenging to follow it in clinical practices. The present study demonstrated, using anatomic tunnel placement in ACL reconstruction as an example, that there was indeed room for improvement in surgeons' performance. The discrepancies between the initial tunnel positions and native insertion sites on individual knees indicated that the surgeons' performance on average deviated substantially from being anatomic. Results from this study also suggested that the proposed imaging software system was an effective means for guiding surgeons to a predetermined location for tunnel replacement while the application of averaged insertion site location information for individual surgeries can be susceptible to significant inaccuracy and uncertainty. If the tunnel radius—which typically varies from 3.5 mm to 5 mm—is used as a criterion for "being anatomic," the intra-operative imaging software system can potentially change a tunnel placement from non-anatomic to anatomic.

Development of engineering solutions to aid in recognizing and maintaining awareness of patients' anatomy must address several challenges or issues, as exemplified by the current study. First of all, acquisition of accurate quantitative knowledge of the anatomy is not a trivial undertaking. To date, a robust quantitative database of insertion site morphology in relation to the bone (to which a reference frame is usually attached) has been lacking—the literature data used by the imaging software in this study were based on moderate sample sizes. Part of the challenge arises from the difficulty of acquiring insertion and bone morphological data accurately with a single imaging modality or with two modalities combined seamlessly. We have previously established a method for mapping digitized ligament insertion sites on CT-based bone models [18], and in the current study were able to adapt this method for arthroscopic application (i.e., without the need to disarticulate the specimens).

In addition, the issue of "one-size-fits-all" versus individual-specific aiding information persists as a problem in surgical engineering innovations. While making an average prediction is simple, the applicability of such a prediction to a specific individual depends upon the inherent variability in the parameter being predicted and the sample data on which the prediction was based. An empirical evaluation as done in the current study would provide quantitative assessment of the accuracy and, perhaps more importantly, the uncertainty associated with the use of averaged information. Ideally, pre-operative knowledge of patient-specific insertion site location in relation to the bone geometry and/or consistently identifiable landmarks would best facilitate intra-operative navigation. However, this would stipulate accurate non-invasive characterization of insertion site morphology via existing imaging modalities as well as expeditious automated extraction of tissue structure geometric information [20], neither of which is fully viable with the existing technology.

Furthermore, practicality and usability are important considerations in developing clinical tools for intra-operative use. Although our study did not feature a rigorous comparison between a surgical navigation system and the proposed simple imaging software system, it involved the former in the procedure of acquiring the insertion site morphology data, which was time-consuming and labor-intensive. It can be concluded from this empirical evaluation that routine intra-operative use of a surgical navigation system for identifying ligament insertions would still require further improvement on system practicality and usability. The simple imaging system was viewed favorably by most of the participating surgeons: ten out of the 20 surgeons found the system "useful," nine found it "somewhat useful," and one found it "not useful;" seven out of 20 surgeons considered the overall system use "very easy," eleven considered "somewhat easy," and two considered "not easy."

We recognize two major limitations of the current study that motivate future investigative efforts. First, the change or difference in tunnel placement was only examined statistically. We did not address how much change in tunnel position would translate into a meaningful joint mechanics alteration so as to affect functional outcome. Our group is developing musculoskeletal models based on in vivo dynamic data of ACL-reconstructed knees with distributed tunnel placements. Such models will establish a mechanistic relationship between the tunnel placement position as a surgical parameter and the biomechanical functional outcome. Second, this study did not include a condition in which the surgeons were presented with fluoroscopic imaging without the indication of insertion site location. While it is conceivable such a condition would result in greater variability in tunnel placement as compared to one with a clearly indicated target, an evaluation of the ‘net’ effect of the insertion site overlay would be a worthwhile endeavor.

5. CONCLUSIONS

We completed an empirical study participated by 20 orthopaedic surgeons evaluating a newly developed imaging software system for improving tunnel placement in anatomic ACL reconstruction surgery. The study concluded that the imaging software system was effective in leading surgeons through visual guidance to a predetermined tunnel placement location, while the use of averaged ACL insertion morphological information as the basis for predetermining the location in individual surgeries can be subject to non-negligible inaccuracy and uncertainty.

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CONFLICT OF INTEREST

The authors indicated no potential conflicts of interest.

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