

Computer-Assisted Surgery Is Not More Accurate or Precise Than Conventional Arthroscopic ACL Reconstruction

A Prospective Randomized Clinical Trial

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Background: Accurate and precise tunnel placement is critical to the success of anterior cruciate ligament (ACL) reconstruction. A new development, computer-assisted surgery, aids in placement of the ACL bone tunnels during surgery. Our hypothesis was that computer-assisted ACL reconstruction would allow more accurate and precise tunnel placement compared with conventional surgery.

Methods: In a prospective, double-blind, randomized clinical study, 100 patients eligible for ACL reconstruction with a transtibial technique were stratified by surgeon and randomized to either conventional or computer-assisted surgery. Measurement of femoral and tibial tunnel placement with use of three-dimensional computed tomography (CT) was used as the primary outcome to compare conventional ACL surgery with computer-assisted surgery.

Results: The placement of the femoral tunnel did not differ between groups (mean, 39.7% of the proximal-distal distance on the intracondylar axis [Blumensaat line] in the conventional group compared with 39.0% in the computer-assisted surgery group; $p = 0.70$). The anterior-posterior positioning of the tibial tunnel on the tibial plateau also did not differ significantly (38.9% in the conventional group compared with 38.2% in the computer-assisted surgery group; $p = 0.58$). There was no significant difference in the precision of either the femoral or the tibial tunnel placement between the two groups.

Conclusions: There was no significant difference in either the accuracy or the precision of tunnel placement between conventional and computer-assisted ACL reconstruction.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Anterior cruciate ligament (ACL) reconstruction has become standard orthopaedic practice worldwide, with an estimated 175,000 reconstructions per year in the United States¹. Although the patient desires a full recovery of the

knee after surgery, the estimated failure rate is between 10% and 25%. The majority of failures are caused by technical problems², and an estimated 80% of these technical failures are caused by malpositioning of the femoral tunnel and/or the tibial tunnel^{3,4}.

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A commentary by Stephen M. Howell, MD, Maury Hull, PhD, and David McAllister, MD, is linked to the online version of this article at jbjs.org.

Computer-assisted surgery has been shown to be of value in improving accuracy in total knee replacement by enabling the mechanical axis to be reproduced more closely⁵. Computer assistance has the potential to improve accuracy by improving closeness to the intended (true) target as well as to improve precision by improving the reproducibility of ligament positioning. Computer-assisted ACL surgery uses an infrared reference system to track the surgical tools and the tibial and femoral bone positions, thus enabling perioperative templating of the planned ACL graft position and offering an additional check of the surgical procedure.

There have been favorable reports showing some improvement in the accuracy of tunnel placement with computer assistance during ACL reconstruction⁶⁻⁸. A recently published Cochrane review of randomized clinical trials, however, showed no significant improvement in clinical outcome with use of computer-assisted surgery in ACL reconstruction⁹. The literature regarding computer-assisted ACL reconstruction contains a variety of conflicting outcome data. All previous randomized clinical trials have added important information, but they have been criticized for being underpowered and for having poor reporting, with insufficient or nonreproducible outcome measures^{6,7,10,11}. A main determinant of successful ACL reconstruction is tunnel placement, and computer-assisted surgery is directed primarily at improving the accuracy of tunnel placement and increasing reproducibility.

The present study was designed to compare computer-assisted ACL reconstruction with the traditional surgical technique. Tunnel placement was assessed with use of a three-dimensional computed tomography (CT) technique that measured the positions of the femoral and tibial intra-articular apertures^{12,13}. This novel three-dimensional measurement technique, which has been validated and is currently reported to be the most reliable outcome measurement for ACL tunnel placement, could shed more light on the value of computer-assisted ACL reconstruction^{13,14}. Our hypothesis was that computer assistance would permit more accurate and more precise femoral and tibial tunnel placement compared with conventional ACL reconstruction performed with a transtibial technique.

Materials and Methods

Study Design

A double-blind, prospective, randomized controlled study of computer-assisted compared with conventional ACL reconstruction was performed on consecutive patients between January 2007 and November 2009. The trial was registered at www.controlled-trials.com (ISRCTN40231111). Our institution's Medical Ethics Committee approved the study protocol, and all patients provided written informed consent.

Patients

All patients who were eighteen years of age or older and were eligible for primary ACL reconstruction without any additional posterior cruciate ligament or lateral collateral ligament injury were included. Exclusion criteria were insufficient grasp of the Dutch or English language and inability or unwillingness to comply with regular postoperative follow-ups.

Randomization

Participants were randomized according to a computer-generated procedure (block randomization utilizing a variable block size); the randomization codes

were held by an independent observer to ensure masked blocking. The participants were randomly allocated to computer-assisted or traditional surgery after informed consent and all baseline measurements had been obtained. The randomization was stratified according to the technique used (bone-patellar tendon-bone [BPTB] or hamstring) and the surgeon performing the reconstruction.

Surgery

Two experienced orthopaedic surgeons performed the ACL reconstructions. Each surgeon had previously performed at least 500 cruciate ligament reconstructions and was also proficient in the use of the computer-assisted surgery system, having performed more than twenty computer-assisted surgery procedures previously. The ACL reconstruction was performed with use of an arthroscopic, single-incision, single-bundle, transtibial surgical technique and either BPTB or looped semitendinosus-gracilis autograft. The choice of graft was made by the surgeon preoperatively on a case-by-case basis, depending on the athletic demands and specific wishes of the patient and on the surgeon's preference.

The computer-assisted surgery was performed with use of a stand-alone computer with infrared control (ACL reconstruction application version 1.0; Brainlab, München, Germany). This system uses reference aimers that are recognized by the infrared system. Passive infrared reflectors were fixed to the femur and to the tibia with 4-mm Steinmann pins. At the beginning of the intervention, true lateral and anteroposterior radiographs of the femur and the tibia were made with use of a calibrated c-arm connected to the computer-assisted surgery system and fitted with an infrared-reflective ring. These radiographs were then used by the computer-assisted surgery system to aid in the templating of the tibial and femoral tunnel positions. We aimed to place the tibial tunnel at 44% of the anterior-to-posterior length of the tibial plateau, as described by Stäubli and Rauschning¹⁵ (see Appendix). The lateral and anteroposterior positioning was then cross-checked with use of intra-articular landmarks on the tibial plateau whose positions were acquired and registered into the computer-assisted surgery system. These landmarks permitted comparison of the templated central point of the proposed tibial tunnel with the footprint of the ACL.

Positioning of the femoral tunnel was performed with use of the radiographic quadrant method of Bernard et al.^{13,16} (see Appendix), which locates the center of the femoral insertion of the ACL on a true lateral projection with use of sixteen rectangles (quadrants) overlaid on the medial side of the lateral femoral condyle. This point would lie approximately at the intersection of the lines defining the most posterior and most proximal quadrant, 24.8% of the distance from the most posterior contour of the lateral condyle measured parallel to the Blumensaat line and 28.5% of the height measured perpendicular to the Blumensaat line. The radiographically templated lateral and anteroposterior positioning was then crosschecked with intra-articular landmarks that were acquired into the computer-assisted surgery system, with use of a reference guide. The acquired points on the medial side of the lateral femoral condyle were then added to the computer-assisted surgery image to confirm that the central point of the proposed femoral tunnel lay within the origin of the ACL.

Finally, computer-assisted navigation was used by the surgeon in positioning the tibial and femoral tunnels. A tibial tip aimer and a femoral aimer without offset (Brainlab) were used to target the guidewire (Fig. 1).

Similar femoral and tibial bone tunnel positions within the native anatomic ACL footprint were used as the goal in the conventional ACL reconstruction. The tibial tunnel guidewire was positioned with the tibial elbow guide (ACUFEX; Smith & Nephew, Andover, Massachusetts) approximately 7 mm anterior to the most anterior border of the posterior cruciate ligament. The guidewire was positioned to give a slightly oblique tunnel direction, with a starting point on the tibia approximately 1 to 1.5 cm anterior to the medial collateral ligament, to facilitate femoral aiming. The femoral tunnel guidewire was positioned with the femoral aimer at a 2 o'clock position for the left knee and at a 10 o'clock position for the right knee. With the femur at 90°, the positioning was checked with use of a 30° arthroscope inserted either through the central portal if BPTB graft was used for the reconstruction or through the anteromedial portal if hamstring was used.

ACL reconstructions performed using a BPTB graft were fixed on both sides with a resorbable interference screw (BioRCL; Smith & Nephew). ACL

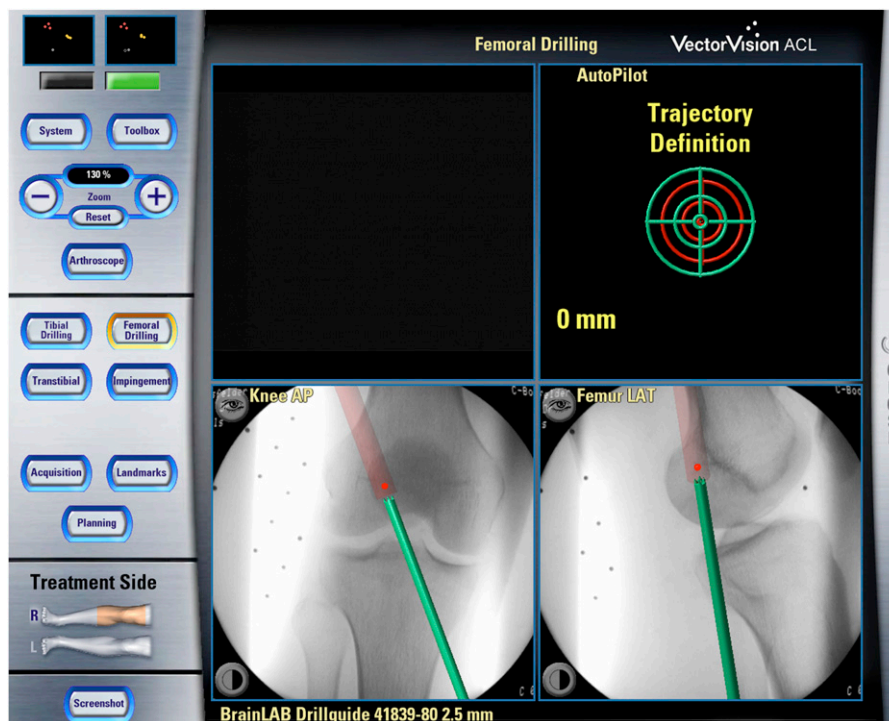


Fig. 1

Screenshot showing the femoral placement of the central guidewire. The trajectory definition is a bull's eye that aids in reaching the planned femoral position.

reconstructions in which the replacement tendon was hamstring were fixed with use of an extracortical button technique (EndoButton; Smith & Nephew) on the femoral side and a resorbable interference screw (BioRCI) on the tibial side.

Outcome Measures

The three-dimensional positioning of the intra-articular femoral and tibial tunnel apertures was chosen as the primary outcome measure. A sixty-four-channel multislice CT scanner (SOMATOM; Siemens Healthcare, Forchheim, Germany) with helical acquisition in 1.0-mm sections was used (120 kV, 160 mA, 1.0-sec rotation time). CT imaging of the knee from the top of the suprapatellar region to the superior tibial and fibular diaphyses was performed one day after the surgery. The primary study analysis was performed after the inclusion period had ended and after all patients had received postoperative follow-up including a CT of the operatively treated knee. The data were then transferred into the three-dimensional measurement software (MeVisLab version 2.0; MeVis Medical Solutions, Bremen, Germany)¹⁷ with blinding of patient information.

Measurement of the three-dimensional images was performed by two experienced observers who were blinded with regard to allocation and patient. The contours of the femur (the intracondylar axis [Blumensaat line] and medial side of the lateral femoral condyle) and of the tibia (the circumference of the tibial plateau) were mapped with use of the three-dimensional triaxial properties of the desktop version of the MeVis software¹². The tibial and the femoral tunnel were registered with use of the osseous contour of the intra-articular aperture and the extra-articular aperture. All of these data points enabled the software to calculate the position and distance to any chosen point or points and to match these points to contours or transpose them to any chosen grid (e.g., the quadrant overlay). An example of the three-dimensional visualization of the femur is shown in Figure 2.

To compare our three-dimensional measurements with previously published CT measurements, we translated our data to a true medial view of the lateral femoral condyle and a true proximal-to-distal view of the tibia¹³. The

position of the center of the tibial tunnel aperture was then calculated as a percentage of the dimension of the tibial plateau in the medial-lateral direction and in the anterior-posterior direction. The position of the center of the femoral tunnel aperture was calculated as a percentage with use of a modified quadrant method^{13,16}. The position measurements were plotted separately for the femoral and the tibial tunnel. This method compares the central point of the intra-articular femoral tunnel aperture with the contour of the medial side of the lateral femoral condyle on a CT image, rather than with the contour of the

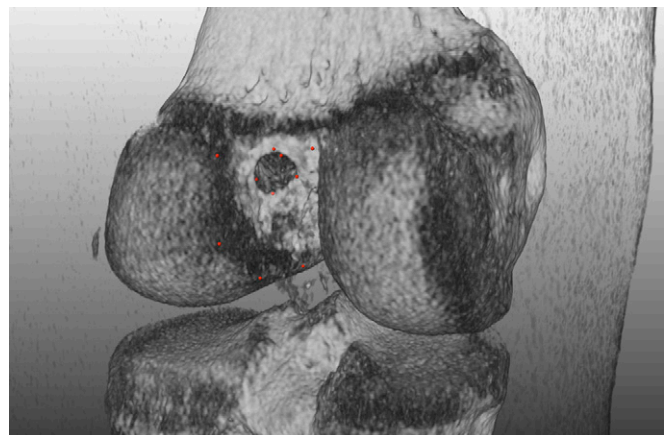


Fig. 2

Posterolateral view of a three-dimensional computed tomogram of a left knee after ACL reconstruction. The red dots (identified with use of MeVis software) show the three-dimensional measurement points of the femoral tunnel opening and the intracondylar contour of the lateral femoral condyle.

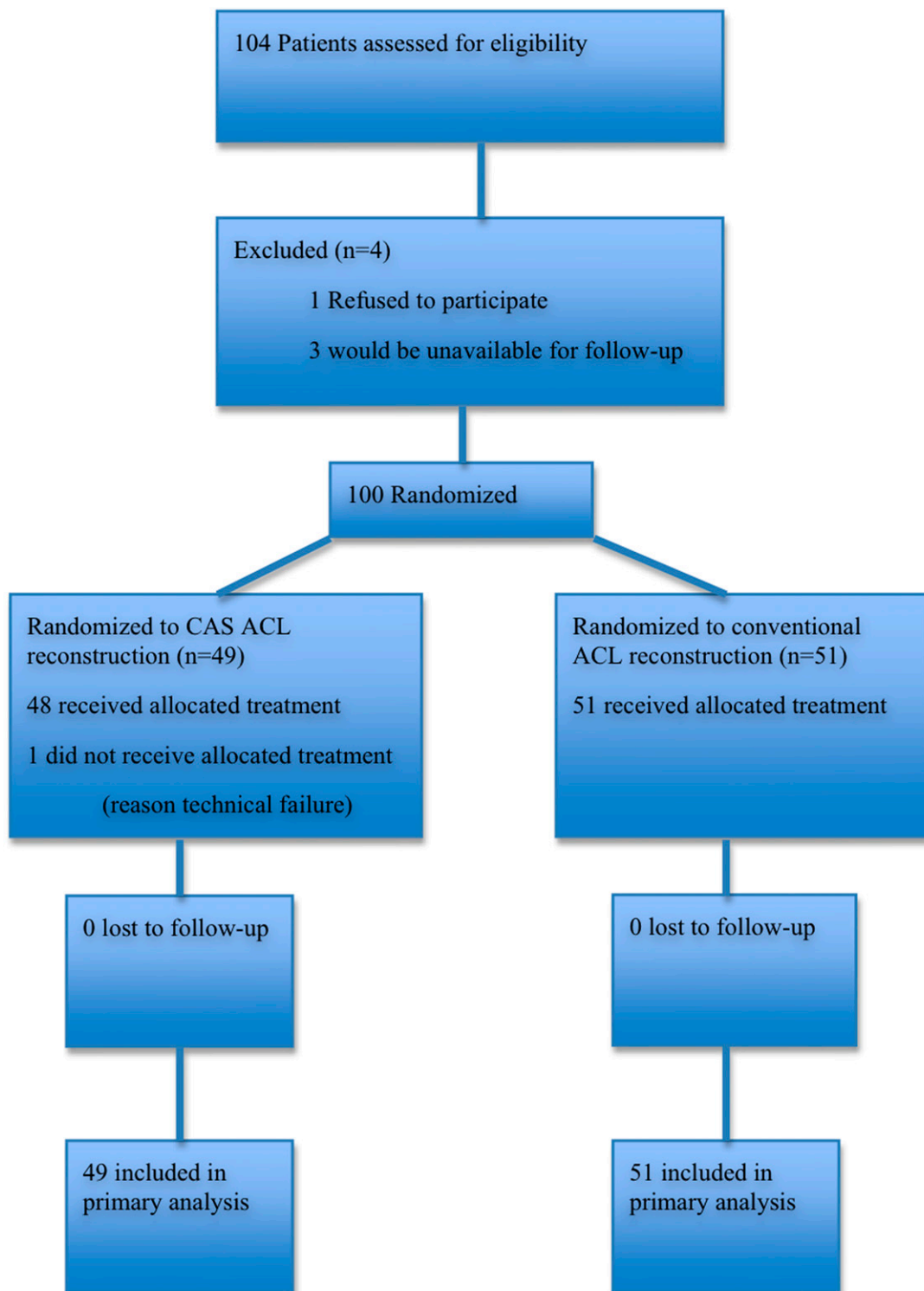


Fig. 3
Flow of patients through the study. CAS = computer-assisted surgery.

lateral femoral condyle on a radiograph. This choice was made because this contour can be measured reliably on the CT image and because the intra-condylar contour of the lateral femoral condyle is the contour that is visualized during arthroscopy and is referenced for the tunnel placement¹⁶.

Patient age, weight (in kg), and height (in cm) as well as the time between trauma and surgery were recorded. Each patient completed the International Knee Documentation Committee (IKDC) subjective forms¹⁸ and the Tegner¹⁹, Knee injury and Osteoarthritis Outcome Score (KOOS)^{20,21}, and

Lysholm²² questionnaires preoperatively. A second Tegner questionnaire was also completed for the pretrauma state. The objective IKDC form was completed, and laxity measurements were performed with use of a KT1000 arthrometer (MEDmetric, San Diego, California). Intraoperative findings were recorded, the surgical procedure was timed, and any adverse events that occurred were recorded.

Statistical Analysis

The tunnel positioning on the femoral and tibial sides was chosen as the primary outcome measure. We considered a 1.5-mm difference to be clinically important, taking into account the minimum tunnel thickness necessary to prevent a posterior blowout of the tunnel with interference screw fixation²³. It was calculated that twenty-five patients would be required to detect a minimum difference of 1.5 mm in the femoral tunnel position given a standard deviation of 1.9 mm, and thirty-eight patients would be required to detect a minimum difference of 1.5 mm in the tibial tunnel position given a standard deviation of 2.3 mm (one-sided test with $\alpha = 0.05$ and $\beta = 0.20$)²⁴. A minimum of forty-five patients per group would therefore be necessary to allow for a possible 20% loss to follow-up.

Statistical analysis was performed primarily with use of SPSS software (version 15.0; SPSS, Chicago, Illinois). The Shapiro-Wilk test confirmed that each variable had a normal distribution, and the results are therefore presented as the mean and the standard deviation. The primary analysis was by intention to treat. Two observers measured the femoral and tibial tunnel placement independently for each patient. An intraclass correlation coefficient (ICC) and accompanying 95% confidence interval (CI) was calculated for each variable to assess the interobserver agreement. Calculation of the ICC was based on an analysis of variance (ANOVA) model and used the two-way mixed model for absolute agreement. The mean positions of the femoral and tibial tunnel apertures in two dimensions were also compared between the groups.

Source of Funding

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Results

The flow of patients through the study is shown in Figure 3. The baseline and intraoperative characteristics of the study population are presented in the Appendix. The majority of the participants were male (71% in the computer-assisted surgery group compared with 80% in the conventional group).

Difficulty with accurate visualization of the femoral reference guide occurred during one procedure in the computer-assisted ACL reconstruction group. This procedure was continued successfully with use of the conventional femoral guide. This patient was analyzed in the allocated group, in accordance with the intention-to-treat principle. Tunnel positioning within 1 mm of the templated position was achieved in the remaining forty-eight computer-assisted surgical procedures. No other perioperative complications occurred.

Assessment of the interobserver agreement of the three-dimensional measurements showed an almost perfect ICC of 0.90 (95% CI, 0.85 to 0.93) for the position of the intra-articular aperture of the femoral tunnel and 0.99 (95% CI, 0.98 to 0.99) for the position of the intra-articular aperture of the tibial tunnel.

The mean position of the femoral tunnel aperture measured parallel to the Blumensaat line was $39.0\% \pm 9.6\%$ of the

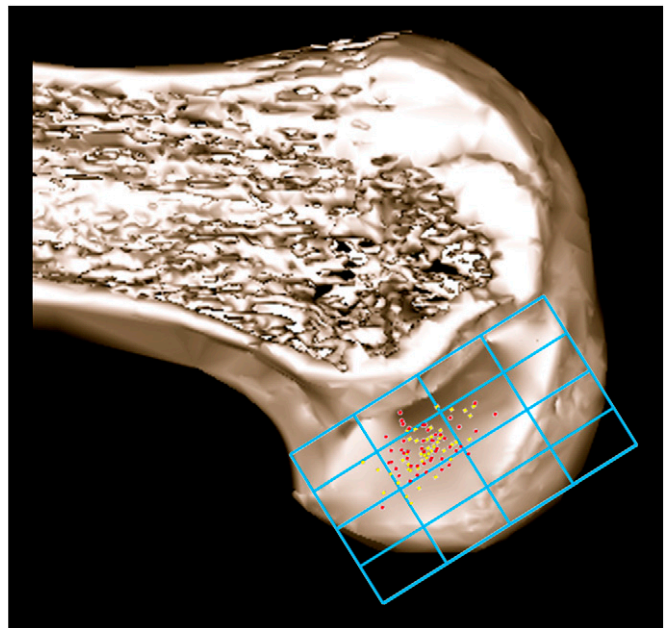


Fig. 4

Position of the intra-articular aperture of the femoral tunnel in computer-assisted surgery (red dots) compared with conventional surgery (yellow squares). The positions and the quadrant overlay are displayed on a sagittal computed tomography image of the lateral condyle of a randomly chosen knee viewed from the medial side.

distance from the most proximal point for the computer-assisted surgery group and a slightly more distal $39.7\% \pm 9.1\%$ for the conventional group. This difference was not significant ($p = 0.70$). The mean anterior-posterior height on the lateral femoral condyle, measured perpendicular to the Blumensaat line, was $39.1\% \pm 8.4\%$ for the computer-assisted surgery group and slightly closer to the Blumensaat line at $37.9\% \pm 9.7\%$ for the conventional group. This difference was also not significant ($p = 0.51$). There was no significant difference in the precision of the femoral tunnel aperture between the two groups ($p = 0.76$) (Fig. 4).

The mean position of the tibial tunnel aperture in the anteroposterior direction did not differ significantly between the groups ($p = 0.58$). The anteroposterior tunnel position on the tibial plateau, according to the measurement technique described by Stäubli and Rauschning¹⁵, was $38.2\% \pm 5.8\%$ for the computer-assisted surgery group and $38.9\% \pm 6.8\%$ for the conventional group. The medial-lateral position also did not differ significantly between the groups ($p = 0.89$). The distance from the most medial edge was $42.7\% \pm 3.6\%$ for the computer-assisted surgery group and $42.6\% \pm 5.7\%$ for the conventional group. There was no significant difference in the precision of the intra-articular tibial tunnel aperture position between the two groups ($p = 0.87$) (Fig. 5).

Other factors that could have affected tunnel placement (earlier compared with later surgery, hamstring compared with BPTB graft, and surgeon) did not significantly affect accuracy or precision.

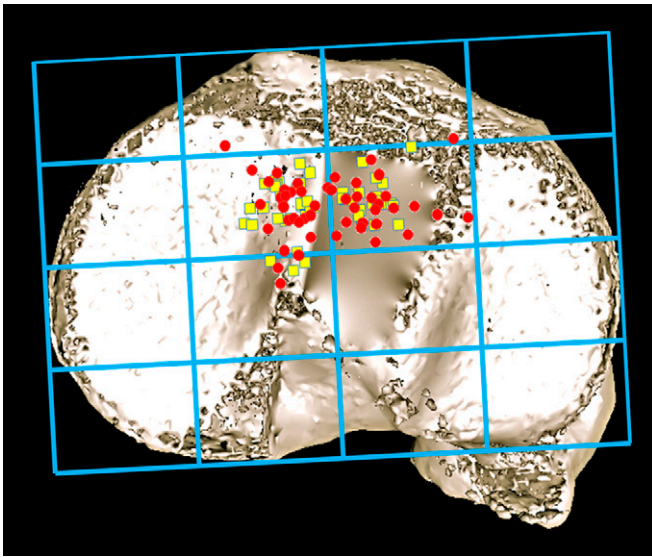


Fig. 5
Position of the intra-articular aperture of the tibial tunnel in computer-assisted surgery (red dots) compared with conventional surgery (yellow squares). The positions are displayed on a cranial computed tomography image of a fitted tibial plateau of a randomly chosen right knee.

Discussion

The results of this randomized controlled trial involving ACL reconstruction did not show better femoral or tibial tunnel placement in computer-assisted surgery compared with conventional surgery. There was no significant increase in either accuracy or precision of the tunnel placement at the femoral origin or the tibial insertion of the ACL graft. The study used three-dimensional CT imaging for measurement of this primary outcome because computer-assisted ACL reconstruction should be judged on its capability to aid in more precise and accurate placement of reference tools.

Four previous randomized clinical trials of computer-assisted ACL reconstruction were identified in a recently published meta-analysis⁹. None of these trials revealed a significant difference in clinical outcome after computer-assisted compared with conventional ACL reconstruction. The study by Chouteau et al. found more accurate placement of both the femoral and the tibial tunnel⁸. The study by Mauch et al. found that the tibial tunnel placement was closer to the reference point of 44% in the computer-assisted surgery group than in the conventional ACL reconstruction group²⁵. The previous studies included no data on the precision of the tunnel placement during ACL reconstruction. All four studies used smaller sample sizes than the present study, and none of them used CT or three-dimensional CT measurement tools to visualize and measure the ACL tunnel placement postoperatively⁹. The CT measurements used in the present study were more accurate than the radiographic measurements used in the previous studies, and this may provide an explanation for the difference in results¹². Our larger study using a validated three-dimensional CT measurement technique did not confirm the superior results

previously described for tunnel placement in computer-assisted ACL surgery.

The computer-assisted surgery system used a gold standard defined by Stäubli and Rauschning¹⁵, 44% of the anterior-posterior length of the tibial plateau on a true lateral knee radiograph, as the target for the tibial tunnel placement. Although the anatomic attachment sites of the ACL have been well described, the optimal bone tunnel placement for ACL grafts remains controversial. However, current surgical practice focuses on placing the bone tunnels within the anatomic insertion sites of the native ACL (anatomic placement). Defining a universal optimal position is therefore not possible, making an individualized approach necessary.

The mean difference between the actual tibial tunnel position and the defined gold standard was 4.4% for the conventional group and 5.1% for the computer-assisted surgery group. Since the mean tibial plateau length in the operatively treated knees was 54 mm, a 5% difference in the tunnel position would have equaled approximately 3 mm of anterior displacement from the perioperatively determined central position of the ACL footprint. A range of error in the tibial tunnel position equal to twice the standard deviation of 5.8%, or 11.6%, in the computer-assisted surgery group would represent a difference of 6.3 mm in the anterior or posterior direction between the actual position and the intended target on the tibial plateau. In some cases, this would make the tunnel too posterior and vertical on the tibia or too anterior and would cause severe roof impingement.

It has been suggested that experienced surgeons perform conventional arthroscopic ACL surgery with greater precision and possibly achieve more accurate tunnel placement than less experienced surgeons^{26,27}. All of the previous randomized clinical trials and the present trial that compared computer-assisted surgery with conventional ACL reconstruction were performed by experienced ACL surgeons⁹. It is possible that the further improvement that computer-assisted ACL reconstruction can provide experienced surgeons was too small to establish significance.

Although the two surgeons in the present study were highly experienced in ACL surgery, there was a considerable and unexpected lack of precision in tibial and femoral tunnel placement in both groups. We had expected to achieve greater precision in both groups. Also, we had expected to achieve greater precision in the computer-assisted surgery group than in the conventional group, but there was no significant difference. A possible explanation for the lack of precision is the great anatomic variety in intercondylar and femoral condylar shapes. The Blumensaat line is not actually a straight line, as one might believe on the basis of lateral radiographs; in reality, it is an S-shaped curve. Also, the angular orientation of the Blumensaat line is variable, and its location relative to the intercondylar axis can be more posterior, central, or more anterior on the femoral condyle. Because of this great anatomic variation, evaluating the outcome by means of percentages relative to fixed chosen references (such as the length and height of the femoral condyle and tibial plateau) might

introduce a measurement bias and could explain some of the variance. The study by Sudhahar et al. showed poor correlation between the intraoperatively expected anteroposterior position of the tibial tunnel and the actual position measured postoperatively on lateral radiographs²⁷. Both anatomic variations and intraoperative inaccuracies could contribute to the poor measured precision in the present study.

Another way of looking at the precision involves comparing outliers in the groups. Topliss and Webb arbitrarily defined outliers in tunnel positioning as being more than 7% away from a femoral sagittal position of 27%, more than 4% away from a tibial sagittal position of 44%, and more than 5% away from a tibial coronal position of 45%²⁸. We transposed the radiographic criteria in that study to our three-dimensional CT data, which introduced a possible bias in adapting the intracondylar CT contour of the lateral femoral condyle to the radiographic contour of that condyle. Approximately 40% of the tibial tunnel positions and nearly 60% of the femoral tunnel positions in both groups in the present study were outliers. This is only slightly better than the 59% rate of tibial tunnel malpositioning and 64% rate of femoral tunnel malpositioning reported by Topliss and Webb on sagittal radiographs²⁸. A possible explanation for the high rate of malpositioning involves the previously mentioned anatomic variations, which were more notable on the three-dimensional CT images, especially on the femoral side. In a 1994 study of five cadavers, Stäubli and Rauschning described a range of 38.7% to 47.9% for the position of the center of the ACL on the tibial side¹⁵. Despite the small sample size, the actual center of the native ACL would have been classified as an outlier in one of the five specimens. We feel that there is still much to learn about the size, shape, and position of individual ACLs, especially in relation to the landmarks that we used as references in the reconstructed knee, and that this could explain the observed frequency of outliers.

Our study was designed in 2007, at a time when transtibial drilling was considered the gold standard and was the most commonly used technique. There is, however, a growing consensus that attaining a femoral tunnel position within the anatomic footprint of the ACL often needs to be done independently of attaining a tibial tunnel position within the footprint, necessitating an accessory anteromedial portal²⁹.


We agree that use of the transtibial technique could steer the positioning of the femoral drill hole in a particular direction and limit the positioning possibilities³⁰. However, this would have been true for both arms of the present trial.

It should be noted that use of the computer-assisted ACL reconstruction system also has several drawbacks. Greater costs are associated with the 26.7-minute increase in operative time and with use of the disposable reflective reference balls. Also, the intraoperative imaging is cumbersome and results in additional radiation exposure.

The primary limitation of our study lies in the fact that there is no universally accepted gold standard for the positioning of a single-bundle ACL reconstruction. The conventional technique is based on arthroscopic recognition of intracondylar anatomic landmarks, whereas the computer-assisted surgery system also uses an additional radiographic knee-contour template. This could be considered to introduce an outcome bias in favor of the computer-assisted surgery group since the primary outcome was based on three-dimensional CT measurements.

In conclusion, this study showed no significant difference in precision or accuracy between conventional ACL reconstruction and computer-assisted ACL reconstruction utilizing intraoperative radiographic data acquisition. Further investigations into improving the accuracy and precision of tunnel placement are required.

Appendix

 Tables showing baseline and intraoperative characteristics of the study population and figures demonstrating intraoperative templating of the tunnel apertures are available with the online version of this article as a data supplement at jbjs.org. ■

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