
Design: meta-analysis of controlled clinical trials

Study question: In the setting of reconstruction of the anterior and posterior cruciate ligaments of the knee, are outcomes improved over conventional operating techniques when computer technology is used for the surgery?

PICOS:

- Patients: Skeletally mature people undergoing reconstruction of the ACL, PCL, or both ligaments, or of skeletally immature people undergoing reconstruction, provided that these were few in number and balanced between treatment groups
- Intervention: Computer assisted surgery (CAS) in ACL or PCL reconstruction
- Comparison: Conventional ACL or PCL reconstruction
- Outcomes: Validated self-reported quality of life measures, such as SF-36, Tegner Scale, Lysholm Scale, International Knee Documentation Committee (IKDC) subjective scales, Cincinnati knee scales, Knee injury and Osteoarthritis Outcome Score (KOOS), and the ACL Quality of Life outcome measure
  - Objective assessment of knee function, such as the IKDC objective scales, were also used as primary outcomes
  - Secondary outcomes could include range of motion, static stability, graft positioning, development of radiographic osteoarthritis, re-rupture of the ACL, duration of surgery, and reoperation
- Study types: Both randomized and quasi-randomized (such as allocation by hospital record number or date of birth) comparing CAS with conventional operating techniques

Study selection:

- Databases included MEDLINE, EMBASE, the Cochrane Central Register, and CINAHL through July 2013
- Two authors independently assessed potentially eligible articles for inclusion in the analysis
- Risk of bias was assessed using criteria of randomization method, allocation concealment, blinding, completeness of outcome data, and avoidance of selective reporting of outcomes, taking into account possible biases arising from surgeons’ level of experience with the operative techniques (study done when CAS was newly introduced versus when surgeons had past experience with CAS)

Results:
- The authors included five studies with 366 participants (all from Europe), all of which compared computer assisted ACL reconstruction with conventional surgery (no studies of PCL were included)
  - There were some variations in the technical details of the computer assistance
- Two studies with 120 patients reported subjective IKDC scores at 2 or more years followup; there were no statistically or clinically differences between groups (2.05 points on the 100 point IKDC); the minimal clinically important difference (MCID) is considered to be 6.3 at 6 points and 16.7 at 12 months
  - The same two studies also reported Lysholm scores, for which there also were no differences between groups
- Three studies reported IKDC objective scores, and all but three patients had examination scores which were graded by the examiners as normal; scores of CAS and conventional ACL surgery were identical
- Similarly, for secondary outcomes such as rotational stability on the pivot shift test, three studies showed nearly identical outcomes between the two surgical techniques
- Arthrometric testing in three studies, either with the KT-1000 or with the Telos device, similarly showed no differences between groups
- Anatomical and technical outcomes such at tunnel placement were reported by all five included studies; tibial tunnel placement was not reported to have different accuracy in any study, and the one study reporting more accurate femoral tunnel placement for the CAS group reported equal IKDC subjective and objective outcomes
- Adverse events such as tendon ruptures, thromboembolic events, infections were not observed with either technique
- CAS added time to the operation, varying between 9.3 and 27 additional minutes

Authors’ conclusions:

- There is insufficient evidence from randomized trials to draw conclusions about the effectiveness of CAS, but the currently available evidence does not indicate that CAS in knee ligament reconstruction improves outcome
- The studies tended to be small and were not without risk of bias, meaning that the current state of the evidence is only of moderate quality (future research is likely to have an important impact on the estimate of effect, and may change the estimate
- The reporting of the trials is generally poor, and more rigorous trials are needed to establish whether CAS plays a valuable part in ACL reconstruction

Comments:

- Although the authors are correct to say that the studies were somewhat small and possibly underpowered, the 95% confidence intervals for the pooled IKDC outcomes did not include a value exceeding the minimal clinically important difference; small
sample sizes of the included studies is not likely to account for the failure to find a contribution of CAS to the surgical outcomes.

The IKDC is widely used as an outcome assessment tool, but it has a feature which deserves expert comment for its interpretation:

- The subjective scale runs from 0 (worst score) to 87 (best score); this scale is then normalized to a 100 point scale for purposes of reporting.
- Two scales deal with pain on a familiar 10 point VAS.
- Several of the scales have a low score of 0 and a high score of 4, with one point for each gradation of improvement:
  - The items on the IKDC ask patients to rate such things as the highest level of activity they can perform without significant pain, without significant swelling, without significant giving way, and on a regular basis.
  - It also asks for the degree to which the knee affects the patient’s ability to perform nine common activities.
- There is one item asking for whether, during the past 4 weeks, the patient’s knee locked or caught; this is a yes/no item worth one point.
- Thus, the difference between a knee which does or does not lock carries equal weight as that between a pain VAS of 5 and a VAS of 6, or between having minimally difficult and moderately difficult ability to sit with the knee bent.
- Because locking of the knee is an important consideration for some decision-making, the IKDC does not appear to give it nearly as much weight as it should have:
  - If the surgical approach made a difference in knee locking/catching, the IKDC would almost never detect a difference between groups; it could easily be buried amid the other items of the overall subjective score.

Assessment: good meta-analysis of several imperfect studies supporting a statement that current evidence does not indicate that in the setting of knee ligament reconstruction, computer assisted surgery improves outcomes over conventional surgery, but may add to operating time.