
Design: Systematic review of randomized trials

Study question: When total knee arthroplasty is done, does computer-assisted navigation improve outcomes?

PICOS:
- Patient population: adults undergoing TKA
- Intervention: Computer-assisted navigation when TKA is done
- Comparison: Conventional TKA
- Outcomes: Coronal alignment, knee clinical scores, cost, patient satisfaction, component axial rotation, AP and mediolateral stability, and long-term durability
  - Although coronal alignment is the outcome most commonly reported in randomized trials, the authors questioned the relevance of that variable to clinical outcomes of knee function and also of implant durability (frequency of revision surgery)
  - Coronal alignment within 0-3° are considered to be mechanically aligned; coronal alignment outside 3° (either varus or valgus) is classified as an “outlier”
- Study types: Focus on randomized trials, meta-analyses, and registry data

Study selection:
- MEDLINE was the only online database, and was searched for English publications “within the past 10 years”
  - Search date not specified, but a 2012 study appears in the bibliography
- Some national registries (e.g. the Norwegian Registry) were also searched
- Search herms were total knee arthroplasty, navigation, computer assisted, and complications
- No specification of whether risk of bias was assessed in the analysis of articles

Results:
- Meta-analysis was not done, because most recent meta-analyses have pooled data on coronal alignment, and results are presented descriptively
- The general state of the literature leaves much to be desired, since many randomized trials show a greater frequency of mechanical alignment with navigated TKA, but these studies do not evaluate the associations between patient characteristics and knee function beyond the degree of malalignment shortly after surgery
One meta-analysis of studies published before 2008 reported improved coronal alignment with navigated TKA (95%) compared with conventional TKA (66%).

However, no differences in knee function or complications were found.

A Norwegian arthroplasty register reported a higher rate of revision at two years with navigated TKA compared to conventional TKA, attributing the difference to the recent introduction of navigated arthroplasty and the resultant learning curve associated with the technical aspects of navigated TKA.

RCTs (e.g., Harvie 2012) which have reported better coronal alignment have not found differences between navigated and conventional TKA for outcomes such as Knee Society, SF-36, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and patient satisfaction scores five years after surgery.

The pattern that emerges is one of studies reporting fewer alignment outliers with TKA, but not showing (and often not even reporting) differences with respect to clinical outcome scores.

Costs of navigated TKA are greater than for conventional TKA because of increased operating room time, additional computer processing time, pin and tracker placement, and analysis of intraoperative data.

Authors’ conclusions:

- Computer navigation of TKA improves coronal alignment and reduces the frequency of radiographic outliers.
- Despite this fact, improvements in functional outcomes, revision rates, or implant survival have not been shown.
- The search was restricted to the past 10 years to exclude studies of nascent technology and include only contemporary literature with improved technique.
- Sagittal plane and axial alignment have been less studied than coronal alignment.
- Alignment goals of a neutral mechanical axis are not the correct goal, since individual patient anatomical factors require that adjustments be made.
- Factors other than limb alignment may affect the long-term durability of TKA; dynamic loading of the knee is multifactorial, and the criteria of 0-3° may not predict long-term survival of the implant.
- Future clinical trials should document clinical function and revision rates with long-term outcome data.

Comments:

- The authors searched only a single online database and a single national registry, and did not specify the date of the search; since studies dated 2012 were included in the references, the search was probably done close to the publication date.
- Despite the marginal quality of the search strategy and the lack of discussion of risk of bias, the authors did identify a general weakness of the literature on navigated
TKA: there has been a focus on coronal alignment and a lack of emphasis on knee function and implant durability
- The authors question that neutral mechanical axis alignment should be a goal of treatment, citing Bellemans 2013, which reported that 32% of men and 17% of women have natural varus alignment of 3° or more, and restoration of alignment to neutral would not necessarily be desirable for them
  o They also cite Parratte 2010, which used 15 year data for cemented total knee arthroplasties from the Mayo clinic, and compared 292 neutrally aligned TKA cases (within 0-3° of neutral) with 106 “outliers” with alignment 3° or more from neutral: the survival curves of the ideally aligned implants and the outliers were nearly identical
- Although there are some weaknesses of the systematic review’s search strategy, the authors identify a major weakness of the relevant literature’s outcome reporting; they do make a good argument that navigated TKA has not been shown to improve functional outcomes of most patients; those with extra-articular deformity, retained implants, or other factors precluding conventional alignment guides are outside the scope of the review, which applies to a vast majority of candidates for TKA

Assessment: Adequate for an evidence statement that navigated TKA improves coronal alignment compared to conventional TKA, increasing the likelihood that the implant will have alignment within 3° of neutral, but that there is no evidence that this alignment leads to improved knee function or implant durability compared to conventional TKA in patients who do not have considerations of extra-articular deformity, retained implants, or other factors precluding conventional alignment guides

References:

