
Design: systematic review of randomized trials and nonrandomized studies

Purpose of study: to compare patient-specific cutting blocks with conventional methods of total knee arthroplasty with respect to (1) neutral mechanical alignment, (2) cost, and (3) clinical results

PICOS:
- Patient population: patients undergoing total knee arthroplasty (TKA)
- Intervention: patient-specific cutting guides (PSI) during the operation
- Comparison: conventional instrumentation for TKA
- Outcomes:
  - Mechanical alignment such as the hip-knee-ankle (HKA) angles or the number of outliers (deviation from neutral of 3° or more) on postoperative radiographs
  - Cost of the operation in terms of operating time and operating room resource use
  - Clinical outcomes such as postoperative pain and function
- Study types: any study published in a peer-review journal was eligible for inclusion, but greater weight was attached to randomized clinical trials
  - Conference proceedings and abstracts were excluded from consideration because they had not been vetted through a peer-review process

Study selection:
- Databases were searched through January 2014 and included MEDLINE and EMBASE, and a second search was conducted in June 2014
- The first author performed the literature searches and the results were agreed upon by a consensus of the other authors
- Of 22 studies meeting the inclusion criteria, only 3 were randomized clinical trials

Results:
- Among the 3 randomized trials, the reporting of the data did not lend itself to pooling, and the authors decided not to attempt a meta-analysis of findings
- However, there was consistency among the 3 RCTs with respect to main conclusions regarding joint alignment
  - One study (Hamilton 2013) reported no difference between groups in joint alignment
A second study (Chareancholvanich 2013) reported no difference in tibiofemoral or femoral component alignment but did note a difference in tibial component alignment with PSI being closer to neutral than standard instrumentation (89.8° vs 90.5°), which was considered clinically insignificant by the authors.

The third study (Noble et al. 2012) favored PSI with respect to neutral alignment (1.7° vs 2.8°) but again the small angular difference was considered unlikely to be clinically significant.

The lower level studies were generally consistent with the randomized trials in not showing a clinically significant difference in joint alignment with PSI over conventional instrumentation.

With respect to cost analysis, the studies showed a reduction on the number of surgical trays used in the operation, but this appeared to be offset by the frequency with which PSI-generated surgical plans had to be altered during the course of the operation, requiring secondary checks on cut thickness, component sizing, and component position.

Only two non-randomized studies compared clinical patient-reported outcomes of pain and function such as the Knee Society scores, and no conclusions could be drawn favoring PSI over conventional instrumentation.

Authors’ conclusions:

- The available literature does not clearly support PSI over conventional cutting blocks for any outcomes of TKA.
- The literature search may have been biased by including only studies published in English, and by the fact that most of the studies were done by high-volume arthroplasty surgeons.
- Although fewer instrument trays were used during PSI than during conventional instrumentation TKA, there was no real difference in procedural speed and efficiency.
- PSI has not been shown to offer any clinical benefit with respect to patient satisfaction, range of motion, or knee function.
- PIS offers no advantage over standard instrumentation in the hands of a well-trained surgeon.

Comments:

- Three RCTs were included in the review, all of which did measure radiographic alignment, but the three studies had three different primary outcomes.
  - For Chareancholvanich 2013, mechanical axis alignment was the primary outcome.
For Noble 2012, the primary outcome was the use of economic resources such as instrument tray set-up time, operative time, blood loss, instrumentation requirements, and discharge disposition.

For Hamilton 2013, the primary outcome was operative time from first incision to final skin closure.

The RCTs are entered as Level I studies without an attempt to estimate risk of bias using the Cochrane or other method of assessing internal validity of RCTs.

The description of the randomization is weak in two of the three RCTs; Noble and Hamilton report nothing about the method of randomization, and Chareancholvanich reports that randomization was done in blocks of four without specifying allocation concealment.

The data on joint alignment are given as means and ranges but without standard deviations, preventing any attempt to pool the data in a meta-analysis.

Although not discussed as an issue, the importance of alignment in terms of “outliers” being classified as $3^\circ$ or more of deviation from neutral, Bellemans 2013 reported that 32% of men and 17% of women have natural varus alignment of $3^\circ$ or more, and restoration of alignment to neutral would not necessarily be desirable for them.

Chareancholvanich allocated 40 patients to PSI and 40 to conventional instrumentation; Hamilton allocated 26 patients to each intervention, and Noble analyzed 15 PSI patients and 14 conventional instrumentation patients.

Collectively, the results can support a “good” evidence statement of the lack of a clinically important difference in joint alignment using PSI over conventional instrumentation.

It is best for a systematic review to have at least two authors independently rating studies for inclusion and for quality; only one author selected the studies, and the other authors consented to the selection, but did not work independently of the first author.

Assessment: marginally adequate systematic review which will support a statement that there is good evidence that in the setting of total knee replacement, the use of patient-specific cutting instrumentation does not offer benefits over conventional instrumentation in terms of postoperative radiographic joint alignment.

References:

