Sassoon A, Nam D, et al. Systematic Review of Patient-specific Instrumentation in Total Knee Arthroplasty: New but Not Improved. Clin Orthop Relat Res 2015;473:151–158

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° or more of deviation from neutral, Bellemans 2013 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
- 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:

Bellemans J, Colyn W et al. Is Neutral Mechanical Alignment Normal for All Patients? The Concept of Constitutional Varus. Clin Orthop Relat Res 2012;470:45–53

Chareancholvanich K, Narkbunnam R, Pornrattanamaneewong C. A prospective randomised controlled study of patient-specific cutting guides compared with conventional instrumentation in total knee replacement. Bone Joint J. 2013;95:354–359.

Hamilton WG, Parks NL, Saxena A. Patient-specific instrumentation does not shorten surgical time: a prospective, randomized trial. J Arthroplasty. 2013;28(Suppl):96–100.

Noble JW Jr, Moore CA, Liu N. The value of patient-matched instrumentation in total knee arthroplasty. J Arthroplasty 2012;27:153–155