Smith-Nephew

VISIONAIRE[•] Patient-Specific Instrumentation (PSI) vs conventional instrumentation in total knee arthroplasty (TKA): results from a systematic literature review and meta analysis

Summary

Compared to TKA carried out with conventional instrumentation, VISIONAIRE TKA:

- Significantly reduced the odds of an outlier in the mechanical axis by 40% (p<0.0001)
- Led to significantly more efficient operations, with reductions in operating room time (p=0.02), turnover time (p=0.022) and tourniquet time (p=0.01)
- Significantly reduced the odds of requiring a blood transfusion by more than 50% (p=0.01)

Background

Malalignment following TKA remains a challenge which is associated with reduced patient satisfaction and postoperative complications.¹⁻³ Patient-specific instrumentation has been developed to try to address this problem. VISIONAIRE Cutting Guides use the patient's MRI and X-rays to design cutting blocks which are specific to the patient's anatomy. VISIONAIRE PSI has been extensively published on allowing for a robust analysis through a systematic literature review and meta-analysis of multiple outcomes.

Methods

A systematic review of the literature using EMBASE, PubMed and Google Scholar was carried out to identify all VISIONAIRE studies (Figure 1).⁴

Studies were only included in the final analysis if they were written using English language, compared the clinical outcomes of VISIONAIRE TKA and conventional instrumentation and reported on alignment accuracy, intraoperative outcomes or postoperative outcomes:

- Alignment accuracy: mechanical axis outliers, coronal component alignment outliers, sagittal component alignment outliers and femoral component rotation outliers
- Intraoperative outcomes: operating room time, operating room turnover time, tourniquet time; incidence of blood transfusion and number of instrument trays
- Postoperative outcomes: incidence of postoperative complications, patient length of stay and return to function

Meta-analyses were performed on all outcomes except number of trays, operating room turnover time and return to function, due to not being a formal outcome, low number of studies and differences in reporting respectively.

The systematic literature review identified 24 studies which met the eligibility criteria and were included in the meta-analysis,⁴ 11 of which were randomized controlled trials (Figure 1).

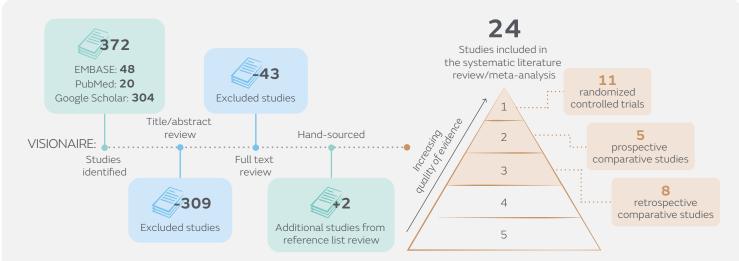


Figure 1. Search strategy and overview of VISIONAIRE TKA evidence showing number of studies by level of evidence

Results

Accuracy

- Fifteen studies reported on the number of mechanical axis outliers⁵⁻²⁰
 - VISIONAIRE[•] reduced the odds of an outlier by 40% compared to conventional instrumentation (odds ratio [OR], 0.60; 95% confidence interval [CI]: 0.47–0.77; p<0.0001; Figure 2)
- Six studies reported on the number of coronal plane outliers after TKA with VISIONAIRE or a conventional technique^{6-8,12,14,15}
 - There was no significant difference in the overall odds of an outlier in the coronal plane, or for the tibial or femoral component when assessed separately
- Five studies reported on the number of sagittal plane outliers^{6-8,12,15}
 - There were no significant differences in overall odds of an outlier in the sagittal plane or for the tibial component when assessed separately
 - The odds of an outlier in the sagittal plane was significantly higher for the femoral component with VISIONAIRE compared to conventional instrumentation (OR, 1.88; p=0.0059)
- Five studies reported on the number of rotational component alignment outliers^{6,8,12,15,29}
 - There were no significant differences between VISIONAIRE and conventional instrumentation

Intraoperative outcomes

Operating room time

- Seventeen studies reported on the length of time spent in the operating room^{6-9,11-14,17,18,20-26}
 - VISIONAIRE resulted in a significant reduction in mean operating room time of 6.16 minutes (7.3% less time) compared to conventional techniques (95% CI: -0.89, -11.42; p=0.02; Figure 3)

Operating room turnover time

- One study reported on operating room turnover time²⁰
 - Turnover time between cases was 42% shorter with VISIONAIRE (6.4 minutes shorter; p=0.022; Figure 4) than conventional techniques

Tourniquet time

- Seven studies reported on tourniquet time^{8,17,20,22,23,27}
 - Mean time in tourniquet was significantly reduced by 12.94 minutes (15.9% less time) with VISIONAIRE compared to conventional instrumentation (95% CI: 3.10–22.79; p=0.01; Figure 5)



Figure 2. Reduction in odds of an outlier in the mechanical axis alignment of VISIONAIRE TKA, compared to conventional instrumentation

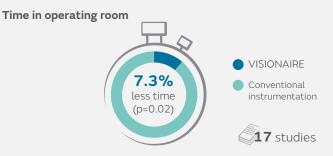


Figure 3. Percentage reduction in operating room time for VISIONAIRE compared to conventional techniques



Figure 4. Percentage reduction in operating room turnover time for VISIONAIRE compared to conventional techniques. No meta-analysis was conducted on this outcome as only one study was identified.

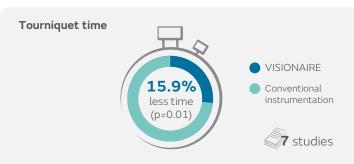


Figure 5. Percentage reduction in tourniquet time for VISIONAIRE compared to conventional techniques

Number of trays

- Although not a formal outcome in most studies, six studies commented on the number of trays^{5,16,17,20,23,26}
 - All commented on the reductions in the number of trays seen with VISIONAIRE^o compared to conventional instrumentation

Blood loss

- Eight studies reported mean values of blood lost during TKA;^{5,7,11,14–16,20,26} however, the absence of standard deviations or ranges prevented a meta-analysis from being performed
- Six studies reported on the odds of a blood transfusion^{5,13,14,20,22,28}
 - The odds of requiring a blood transfusion were 53% lower with VISIONAIRE compared with conventional instrumentation (OR, 0.47; 95% CI: 0.26-0.83; p=0.01; Figure 6)

Postoperative outcomes

Postoperative complications

- Six studies reported on postoperative complications^{6,17,18,22,24,27}
 - No significant difference in the odds of a postoperative complication between VISIONAIRE and conventional instrumentation

Length of stay

- Nine studies reported on length of stay^{7,13,18,21,22,25-28}
 - Mean length of stay was significantly reduced by 0.39 days (11.1% less time) with VISIONAIRE compared to conventional instrumentation (95% CI: 0.25-0.53; p<0.0001; Figure 7)

Return to function

- Eleven studies reported on assessment of postoperative return to function^{5–7,12,14,16–18,24,25,28}
 - In general, the balance of evidence suggests there is no significant difference between VISIONAIRE and conventional instrumentation
 - One study reported significantly higher KSS clinical scores compared to conventional instrumentation at 6 weeks post-TKA (90 vs 65; p=0.02), but no significant differences were observed at 3 or 12 months²⁴

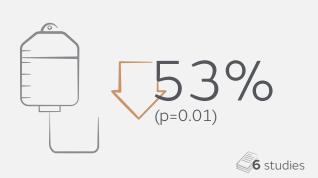


Figure 6. Percentage reduction in odds of requiring a blood transfusion with VISIONAIRE, compared to conventional instrumentation



Figure 7. Comparison of mean number of days spent in hospital

Conclusions

VISIONAIRE PSI has been extensively published on in the literature. Results from this systematic literature review and meta-analysis show that its use leads to improvements in mechanical axis accuracy, efficiency in surgical procedures and length of hospital stay in comparison with conventional instrumentation.

Additional health economic data

Health economic analysis to assess the impact on hospital costs of VISIONAIRE⁶ TKA compared to conventional TKA was outside of the scope of this systematic literature review and meta-analysis. However, a recent retrospective, real-world study has shown that hospital costs associated with VISIONAIRE were significantly lower than conventional instrumentation (\$14,910 vs \$16,018; p<0.0001; Figure 8).³⁰

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Figure 8. Mean estimated cost saving with VISIONAIRE compared to conventional instrumentation

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