Evidence in focus
Clinical summaries

Clinical evidence summaries on VISIONAIRE Cutting Guides
Evidence in focus
Clinical summaries

VISIONAIRE® Cutting Guides

Purpose
To summarise the clinical studies aligned with the VISIONAIRE Cutting Guides (Smith & Nephew Memphis, TN, USA) meta-analysis.¹

Studies

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**Abbreviations**

- **TKA**: total knee arthroplasty
- **HKA**: hip-knee-ankle angle
- **KSS**: Knee Society Score
- **CAS**: computer-assisted surgery
- **Hb**: haemoglobin

*Studies may include other study outcomes.*
A comparison of patient-specific and conventional instrumentation for total knee arthroplasty²

Study design
• Prospective, randomised study evaluating coronal HKA alignment, assessed radiographically 3 months post primary TKA
• Procedures were performed by six surgeons using VISIONAIRE™ (n=59) or conventional instrumentation (n=67)

Key results
Accuracy
• Post-TKA HKA alignment at or within 3° of the planned mechanical axis alignment was achieved in the majority of cases with VISIONAIRE (67.8%) or conventional instrumentation (67.2%) (Figure)

Conclusion
VISIONAIRE provided good implant position accuracy comparable to conventional instrumentation.

Custom-fit total knee arthroplasty: our initial experience in 32 knees³

Study design
• Prospective study evaluating coronal mechanical axis alignment, assessed radiographically 6 weeks post TKA using VISIONAIRE (n=32)
• Ten patients had prior TKA on the other leg using conventional technique (n=4) or computer-assisted surgery (CAS; n=6)

Key results
Accuracy
• Post-TKA coronal mechanical axis alignment within 3° of neutral was achieved in 90.6% (29/32) cases using VISIONAIRE, but only 70.0% (7/10) of prior TKA cases with conventional or CAS (Figure)

Conclusion
VISIONAIRE achieved a high level of implant position accuracy.
Study design

- Retrospective review of radiographic HKA alignment 3.5 months post-TKA
- Procedures were performed by a single surgeon using VISIONAIRE (n=150) or conventional instrumentation (n=156)

Key results

Accuracy
- Post-TKA HKA alignment within 3° of 180° was achieved in significantly more cases with VISIONAIRE than conventional instrumentation (90.7% vs 78.8%; p=0.003; Figure)

Efficiency
- Mean operative time was 51 minutes using VISIONAIRE or conventional instrumentation

Conclusion

VISIONAIRE demonstrated significantly improved mechanical axis alignment compared to conventional instrumentation.

A comparison of conventional and patient-specific instruments in total knee arthroplasty


Study design

- Retrospective review of radiographic HKA alignment 3.5 months post-TKA
- Procedures were performed by a single surgeon using VISIONAIRE (n=150) or conventional instrumentation (n=156)

Key results

Accuracy
- Post-TKA HKA alignment within 3° of 180° was achieved in significantly more cases with VISIONAIRE than conventional instrumentation (90.7% vs 78.8%; p=0.003; Figure)

Efficiency
- Mean operative time was 51 minutes using VISIONAIRE or conventional instrumentation

Conclusion

VISIONAIRE demonstrated significantly improved mechanical axis alignment compared to conventional instrumentation.
Study design

- Retrospective review of TKA performed by a single surgeon using VISIONAIRE® (n=306) or conventional instrumentation (n=50) during the same period
- Operating room time and turnover, and operative complication frequency were compared

Key results

Efficiency

- VISIONAIRE resulted in a significantly shorter mean operating room time (20.4 minutes less) compared to conventional TKA, (86.8 vs 107.2 minutes; p<0.01) resulting in a cost saving of $1,326/case (Figure)
- Reduced use of surgical trays saved $240 per case with VISIONAIRE versus conventional TKA (Figure)
- VISIONAIRE also significantly reduced mean operating room turnover time by 42% (15.2 vs 21.6 minutes; p=0.022), providing additional cost savings compared to conventional TKA
- Tourniquet time was reduced by 19.9 minutes with VISIONAIRE compared to conventional TKA (63.3 vs 83.2 minutes; p=0.024)

Patient outcomes

- No significant difference in operative blood loss between VISIONAIRE and conventional TKA (120.8 and 116.7ml, respectively)

Conclusion

VISIONAIRE significantly reduced operating room time and turnover by a combined mean time of 26.8 minutes, resulting in cost savings of more than $1,500 per case compared to conventional TKA.
Study design

• Retrospective analysis of femoral component rotation, assessed using magnetic resonance imaging approximately 6 months post-TKA
• A single surgeon performed the procedures using VISIONAIRE™ (n = 46) or conventional instrumentation (n = 48)

Key results

Accuracy

• There were significantly fewer outliers >3° in the VISIONAIRE group compared to conventional instrumentation (2.2 vs 22.9%; p = 0.003; Figure)

Conclusion

VISIONAIRE significantly improved femoral component rotation compared to conventional instrumentation.

Component alignment and clinical outcome following total knee arthroplasty: a randomised controlled trial comparing an intramedullary alignment system with patient-specific instrumentation


Study design

• Prospective, randomised study evaluating HKA alignment by computed tomography scan approximately 6 weeks post-TKA
• Procedures were performed by two surgeons using VISIONAIRE (n = 69) or conventional instrumentation (n = 64)

Key results

Patient outcomes

• At 3 months post-TKA, 12 complications were reported for VISIONAIRE and 18 were reported for conventional instrumentation

Efficiency

• Mean operative time was 49.8 minutes for VISIONAIRE and 52.3 minutes for conventional instrumentation (Figure)

Conclusion

VISIONAIRE has a mean operative time of approximately 50 minutes, with fewer complications reported at 3 months post TKA.
Stability and alignment do not improve by using patient-specific instrumentation in total knee arthroplasty: a randomized controlled trial\textsuperscript{10}

Study design

- Prospective, randomised study evaluating stability and alignment radiographically 12 months post-TKA
- Procedures were performed by three surgeons using VISIONAIRE\textsuperscript{®} (n=21) or conventional instrumentation (n=21)

Key results

Patient outcomes

- No reoperations were performed (Figure)
  - Four adverse events were reported in both the VISIONAIRE group and in the conventional group

Efficiency

- Mean operative time was 66 minutes for VISIONAIRE compared to 68 minutes for conventional TKA

Conclusion

VISIONAIRE achieved a reduced mean operative time compared to conventional TKA, with no reoperations at 12 months post-TKA.

A multi-planar CT-based comparative analysis of patient-specific cutting guides with conventional instrumentation in total knee arthroplasty\textsuperscript{11}

Study design

- Retrospective analysis of implant alignment and component rotation post-TKA, assessed using computed tomography
- Two surgeons performed the procedures using VISIONAIRE (n=115) or conventional instrumentation (n=185)

Key results

Accuracy

- Mean post-TKA HKA alignment within $\pm 3^\circ$ of neutral was achieved in the vast majority of cases with VISIONAIRE (86.1%) or conventional instruments (83.2%) (Figure)

Efficiency

- Mean operative time was reported as 72.5 minutes for VISIONAIRE and 75.0 minutes for conventional TKA
- Mean tourniquet time was reported as 13.5 minutes for VISIONAIRE and 13.1 minutes for conventional TKA

Conclusion

VISIONAIRE provided accurate implant alignment, comparable to conventional instrumentation.
Contribution of patient-specific cutting guides to lower limb alignment for total knee arthroplasty


Study design
• Prospective, observational study evaluating implant alignment radiographically more than 3 months post-TKA
• Procedures were performed by multiple surgeons using VISIONAIRE™ (n=57) or conventional instrumentation (n=11)

Key results

Accuracy
• Mean post-TKA HKA alignment at or within 3° of neutral was achieved in 41/57 (71.9%) cases with VISIONAIRE (Figure) and 9/11 (81.8%) cases with conventional instrumentation

Conclusion
VISIONAIRE provided good implant position accuracy, comparable to conventional instrumentation.

An evaluation of the need for blood transfusion when using patient specific instrumentation for total knee arthroplasty


Study design
• Retrospective review of complications and operative outcomes for TKA procedures performed by a single surgeon using VISIONAIRE (n=21) or conventional instrumentation (n=24)

Key results

Patient outcomes
• Mean length of hospital stay (bilateral TKA) was significantly shorter (18.4%) with VISIONAIRE versus conventional instrumentation (3.1 vs 3.8 days; p=0.01; Figure)
• Postoperative blood transfusion was not required in any VISIONAIRE patients, but was required by five conventional TKA patients
• One patient experienced a complication with VISIONAIRE, compared to three patients with conventional TKA

Efficiency
• Mean operative time per knee (unilateral TKA) was significantly shorter with VISIONAIRE versus conventional instrumentation (89.6 vs 116.1 minutes; p<0.01; Figure)
• Mean tourniquet time (unilateral TKA) was significantly shorter with VISIONAIRE versus conventional instrumentation (57.6 vs 91.8 minutes; p<0.01)

Conclusion
VISIONAIRE significantly reduced operative time, tourniquet time and length of hospital stay, compared to conventional instrumentation.
Study design

- Prospective, randomised study evaluating mechanical implant alignment post-TKA

Key results

Patient outcomes

- VISIONAIRE achieved significant reductions in mean length of hospital stay compared to conventional instrumentation (59.2 vs 66.9 hours; p=0.43; Figure 1)

Accuracy

- Mean post-TKA mechanical alignment was significantly closer to neutral with VISIONAIRE versus conventional instrumentation (1.7 vs 2.8°; p=0.03; Figure 2)

Efficiency

- VISIONAIRE resulted in significant reductions in mean operative time compared to conventional instrumentation (121.4 vs 128.1 minutes; p=0.048; Figure 3)
- Mean number of instrument trays used per case was significantly reduced with VISIONAIRE compared to conventional instrumentation (4.3 vs 7.5; p<0.0001; Figure 4)

Conclusion

VISIONAIRE significantly improved mechanical alignment and operative efficiency compared to conventional instrumentation, along with significant reductions in length of hospital stay.

Study design

- Prospective evaluation of the accuracy of bone resection in TKA performed by multiple surgeons using VISIONAIRE™ (n=41)

Key results

Efficiency

- Compared to historic data from 45 TKAs with conventional instruments
  - Mean operative time was 84 minutes for VISIONAIRE and 88 minutes for conventional instrumentation (Figure)
  - Mean tourniquet time was 82 minutes for VISIONAIRE and 85 minutes for conventional instrumentation (Figure)

Conclusion

VISIONAIRE demonstrated a slightly reduced mean surgical and tourniquet time compared to conventional instrumentation.
Small improvements in mechanical axis alignment achieved with MRI versus CT-based patient-specific instruments in TKA: a randomized clinical trial


### Study design

- Prospective, randomised study evaluating alignment accuracy radiographically post-TKA performed by a single surgeon
- Procedures used VISIONAIRE™ (n = 30), computed tomography (CT)-based patient-specific instrumentation (PSI, n = 30) or conventional instrumentation (n = 30)

### Key results

#### Accuracy

- Mean post-TKA mechanical limb alignment at or within 3° of the planned alignment was achieved more frequently with VISIONAIRE (93%) versus CT-based PSI (70%) or conventional instrumentation (57%) (Figure)

#### Conclusion

VISIONAIRE provided highly accurate mechanical alignment more frequently than both CT-based PSI and conventional instrumentation.

Patient specific instrumentation versus conventional knee arthroplasty: comparative study


### Study design

- Observational study evaluating HKA alignment radiographically 6 weeks post-TKA
- Procedures were performed by a single surgeon using VISIONAIRE (n = 40) or conventional instrumentation (n = 40)

### Key results

#### Patient outcomes

- Mean Hb loss (g/dl) was 3.5 for VISIONAIRE and 4.2 for conventional TKA (Figure)

#### Accuracy

- Mean post-TKA HKA alignment at or within 3° of neutral was achieved in all cases

#### Conclusion

VISIONAIRE achieved accurate alignment, with less Hgb loss than conventional TKA.
Reducing blood loss in bilateral total knee arthroplasty with patient-specific instrumentation


**Study design**
- Retrospective study evaluating surgical time for bilateral TKA
- Procedures were performed by a single surgeon using VISIONAIRE (15 patients) or conventional instrumentation (14 patients)

**Key results**

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<tr>
<th>Group</th>
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<th>Pulmonary embolism</th>
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<th>Manipulation under anaesthesia (stiffness)</th>
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<tr>
<td>VISIONAIRE</td>
<td>1</td>
<td>0</td>
<td>1 (haematoma)</td>
<td>2</td>
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<tr>
<td>Conventional instrument</td>
<td>1</td>
<td>0</td>
<td>0</td>
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Table. Post-TKA complications

**Conclusion**
Use of VISIONAIRE resulted in few post-TKA complications.

Comparison of customized cutting block and conventional cutting instrument in total knee arthroplasty: a randomized controlled trial


**Study design**
- Prospective, randomised controlled trial evaluating HKA alignment radiographically 3 months post-TKA
- Procedures were performed by a single surgeon using VISIONAIRE (n=51) or conventional instrumentation (n=51)

**Key results**

**Patient outcomes**
- 37% (19) of patients required a blood transfusion in the VISIONAIRE group compared to 51% (26 patients) in the conventional TKA group

**Accuracy**
- Mean post-TKA HKA coronal alignment within 3° of the mechanical axis was achieved in 94% of cases (48/51) using either VISIONAIRE or conventional instruments

**Efficiency**
- Mean operative time was 11 minutes (10.6%) shorter with VISIONAIRE versus conventional instruments (93 vs 104 minutes; Figure)

**Conclusion**
VISIONAIRE reduced operative time compared to conventional instrumentation, while achieving fewer blood transfusions and highly accurate limb alignment.
Patient-specific instrumentation in total knee arthroplasty: simpler, faster and more accurate than standard instrumentation – a randomized controlled trial


Study design
- Prospective, randomised controlled trial evaluating coronal alignment radiographically post-TKA
- A single surgeon used VISIONAIRE® (n=47) or conventional instrumentation (n=48)

Key results

Patient outcomes
- VISIONAIRE significantly reduced mean length of hospital stay by 0.7 days (5.0 vs 5.7 days; p=0.005) compared to conventional instrumentation
- Significantly fewer mean blood units were used (0.02 vs 0.2; p=0.024), and patients were less likely to require blood transfusion (1.1 vs 7.7%; p=0.024), with VISIONAIRE compared to conventional instrumentation (Figure)

Accuracy
- VISIONAIRE achieved mean post-TKA coronal alignment at or within 3° of neutral in significantly more cases than conventional instrumentation (88.1 vs 64.1%; p=0.011)

Efficiency
- VISIONAIRE significantly reduced mean surgical time by 18 minutes (24.8%; 54.4 vs 72.4 minutes; p=0.00) compared to conventional instrumentation

Conclusion
VISIONAIRE achieved significantly more accurate coronal alignment and reduced surgical time, length of hospital stay and blood loss complications compared to conventional instrumentation.

Study design
- Prospective study evaluating radiographic alignment and functional outcomes for TKA
- Two surgeons were randomly assigned to perform procedures using VISIONAIRE (n=31) or conventional instrumentation (n=31)

Key results

Patient outcomes
- No significant differences in length of hospital stay or blood loss between VISIONAIRE and conventional TKA (6.68 vs 6.06 days, respectively)
- VISIONAIRE required a mean of 4 units of blood for transfusion compared to 6 units for conventional TKA (Figure)

Conclusion
VISIONAIRE may reduce the number of units of blood required for transfusion compared to conventional TKA.
References


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