

Bone & Joint Science

Our Innovation in Focus

JOURNEY[◇] II XR[◇] Bi-Cruciate Retaining Knee System: Design rationale and early results

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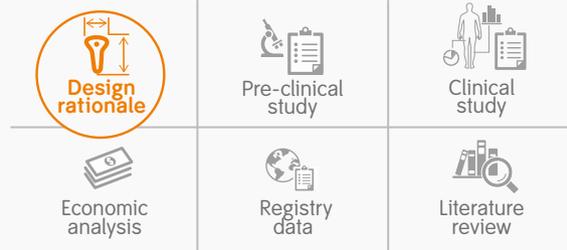
1. Smith & Nephew, Inc., Baar, Switzerland

2. Smith & Nephew, Inc., Memphis, Tennessee, USA

1 Research goal

To assess the JOURNEY II XR's (Figure 1) resistance to mechanisms that led to in vivo failure of previous bi-cruciate retaining (BCR) devices, and share the first surgeon experience with this novel design.

2 Type of evidence



3 Clinical relevance

- BCR total knee arthroplasty (TKA) allows for the preservation of the ligaments and minimization of bone resection. BCR TKA has motion patterns more similar to the normal knee than conventional TKAs,¹⁻³ and patients receiving these implants have reported significantly higher satisfaction rates than with traditional TKA.⁴
- The use of certain earlier-generation BCR devices was limited by concerns including the tibial baseplate design, wear of polyethylene (PE) components, and a relatively challenging surgical technique.⁵⁻⁷
- The JOURNEY II XR BCR knee system was designed for use in knees with a functional anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL), to enable a higher level of function for primary TKA patients. This novel design was tested in a series of mechanical analyses meant to address failure mechanisms observed in retrievals of earlier BCR designs.

4 Key result

- JOURNEY II XR had fatigue strength of nearly 2.5-times the recommended minimum strength of 202.3 lbf (Figure 2).⁸
- There was no measurable wear after six million cycles of testing.⁹
- Surgeons grading their experience with this novel device on a scale of 0 ("not satisfied") to 10 ("fully satisfied") reported high levels of overall satisfaction (8.1) and ease with baseplate coverage (7.8).¹⁰

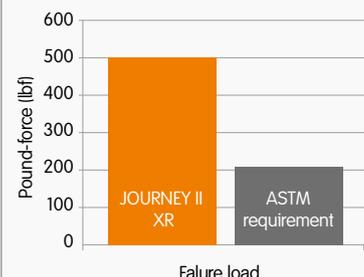
5 Important considerations

- Laboratory tests are not perfect predictors of future clinical performance. Therefore, further follow up will be needed to determine the clinical performance of this device.

Figure 1: JOURNEY II XR Bi-Cruciate Retaining Knee.



Figure 2: Fatigue strength testing.⁸



Background

Despite 10-year survivorship for TKA generally exceeding 90%,¹¹ postoperative patient dissatisfaction rates of up to 20% have been noted,^{12,13} signaling that there remains room for improving the clinical performance of TKA.

BCR TKA allows for the preservation of the ligaments and proprioception. BCR TKA has motion patterns more similar to the normal knee than conventional TKAs,¹⁻³ and has shown good long-term survivorship for implant designs that have low-conformity tibial inserts and metal-backed tibias.^{6,7} Patients who have undergone bilateral TKA with both traditional and BCR TKA have reported significantly higher satisfaction with the latter.⁴

BCR TKA was first introduced in the early 1970s. Despite the evident benefit of this approach, there were several areas of concern surrounding some earlier BCR devices, including:

- Limited flexion (<105° or manipulations)⁵
- Tibia fixation⁵
- Limited tibia implant strength⁵
- Tibia PE wear^{6,7}
- A relatively difficult surgical technique⁵

The JOURNEY° II XR° (Smith & Nephew, Inc.; Memphis, TN, USA) BCR knee system was designed for use in knees with functional ACL and PCL ligaments, to enable a higher level of function for primary TKA patients. It utilizes:

- A tibial baseplate with an asymmetric perimeter shape designed to have maximal coverage (**Figure 3**)
- An asymmetric notch, with a more anterior position medially to accept the ACL footprint (**Figure 4**)
- A continuous keel and optimized anterior bridge to provide strength and mitigate historical design concerns related to anterior implant fractures
- Highly cross-linked polyethylene (XLPE) tibial inserts using VERILAST° technology, a highly durable bearing combination shown to have low wear rates during simulator testing¹⁴

The current study tests how the JOURNEY II XR's design features performed in a series of mechanical analyses meant to address failure mechanisms observed in retrievals of earlier BCR designs. Furthermore, initial survey results from the first surgeons to implant the JOURNEY II XR are provided to gain insights into the intraoperative performance and ease of the surgical technique.

Figure 3: JOURNEY II XR tibial baseplate.

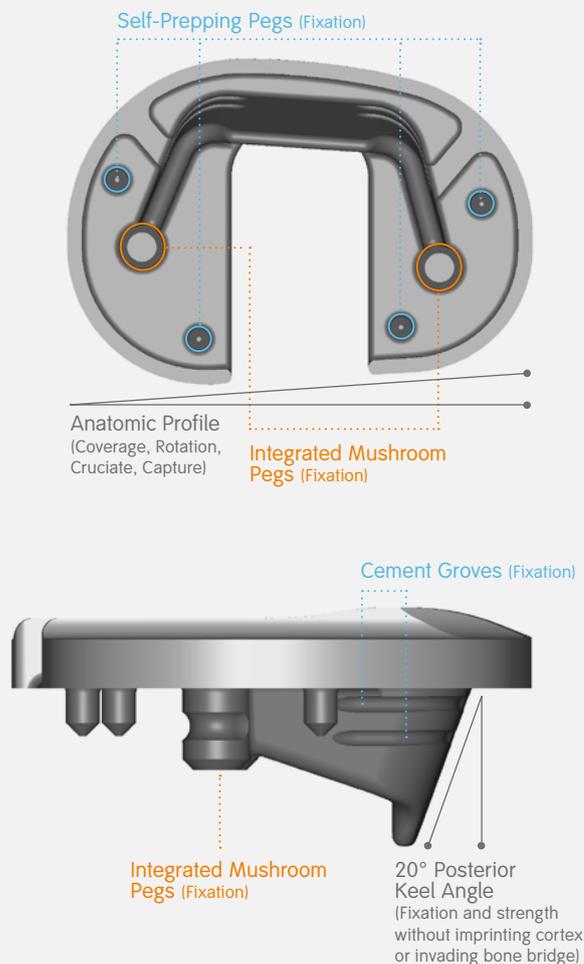
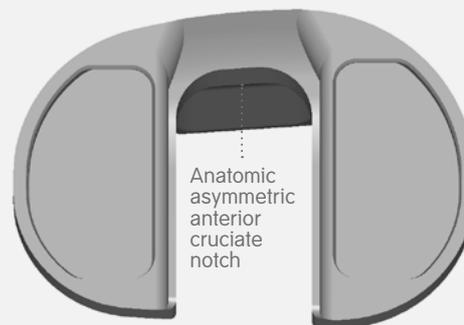


Figure 4: Asymmetric notch.



Methods

Retrieval analysis of previous BCR designs

- Twenty earlier-generation BCR implants (16 Ti-6Al-4V tibial trays, two cast cobalt-chrome tibial trays, and two all PE tibial implants) clinically retrieved after six to 20 years in vivo were evaluated using light microscopy and scanning electron microscopy to determine mechanisms of failure. All metal tibial trays were uncemented, porous designs. Eighteen of the PE inserts were sterilized by gamma irradiation in air.¹⁵

JOURNEY[®] II XR[®] mechanical testing

- Tibial tray fatigue strength (ASTM F1800-12; **Figure 5**)
 - Compared to the recommended strength specified in ASTM F2083-08.^{8,15}
- Tibial fixation (**Figure 6**)
 - Compared to short (20mm) and long (50mm) stemmed cemented implants. The implants were cemented into specially prepared foam that had the posterior medial quadrant removed to create an unsupported condition and loading posteromedial until failure.^{15,16}
- Wear
 - Six million cycles simulated under displacement control with inputs based on ISO 14243-3 and healthy knee kinematics.⁹

Analysis of surgeon experience

- To date, more than 200 cases with JOURNEY II XR have been performed by 30 surgeons, who responded to surveys on the degree of difficulty in implanting this novel device. Their qualitative feedback was collected and assessed.¹⁰

Figure 5: Tibial tray fatigue strength test setup.



Figure 6: Tibial fixation test setup.



Results

Retrieval analysis of previous BCR designs¹⁵

- In general, there were four modes of failure in the retrieved implants of earlier BCR designs
 - Six implant fractures: 2 Ti-6Al-4V trays, 2 all-PE tibial implants, and 2 tibial inserts
 - Two tibial inserts dissociated
 - Seven tibial trays loosened
 - Tibial inserts had oxidized PE resulting in delamination and wear

Mechanical testing

- Tibial tray fatigue strength^{8,15}
 - JOURNEY II XR had fatigue strength of nearly 2.5-times the recommended minimum strength (**Figure 7**)
- Tibial fixation^{15,16}
 - JOURNEY II XR: 8% higher ($p=0.76$) than short keel design and 47% lower ($p=0.036$) than long keel design (**Figure 8**)
- Wear⁹
 - No measurable wear at 6 million cycles

Analysis of surgeon experience¹⁰

- Surveys for 130 (65%) of the available cases were returned. Surgeons graded their experience on a scale of 0 ("not satisfied") to 10 ("fully satisfied")
- Overall satisfaction was 8.1, but increased to 8.4 when rating surgeon's most recent case
- Baseplate coverage was rated as 7.8 on average
- Surgeons said that 88% of cases met their expectations in terms of difficulty

Figure 7: Fatigue strength testing.^{8,15}

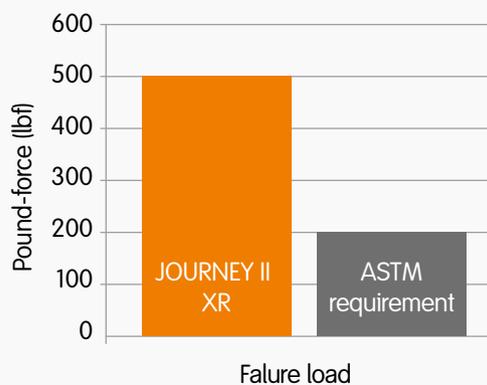
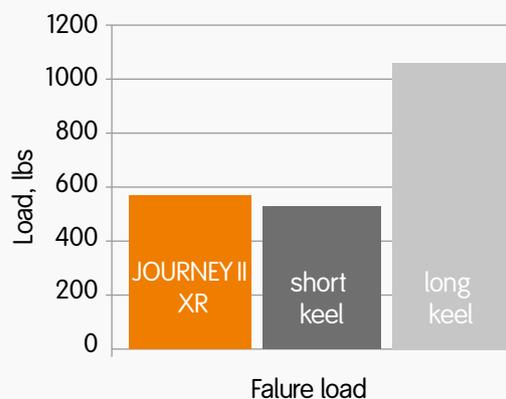


Figure 8: Fixation testing.^{14,15}



Conclusions

Retrieval analyses of earlier-generation BCR TKAs identified their main modes of failure. They determined that their design and material features contributed to implant fracture/dissociation, tibial loosening, and PE delamination. Mechanical testing of JOURNEY[®] II XR[®] showed that its three main design features address these past failures. A titanium baseplate with a deeper, multi-directional, cemented keel that has grooves and pegs provides greater implant strength than other designs.* It also has equivalent fixation to the bone as a previous short keel design, while the articular surface has lower conformity which should lower fixation demands. Fully captured, independent medial and lateral locking features increase lock strength between the tibial insert and tray. Re-melted, ethylene oxidesterilized, 7.5 Mrad cross-linked PE addresses the tibial insert delamination and wear. This study indicates that it is feasible to design a new BCR TKA to address the failures of historical designs. Early clinical results indicate that surgeons can implant the novel JOURNEY II XR system with ease, satisfaction, and encouraging baseplate coverage. Additional studies could be necessary to assess the performance and survivorship of this knee system.

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- * Compared to Vanguard XP[®] Total Knee System tested following ASTM F1800 fatigue testing to 1000N (225 lb). Reported in Vanguard XP design rationale: Form No. BMET0923.0-ENG;REV1114;2014.

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