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Our Innovation in Focus

LEGION◇ Primary Knee System for total knee arthroplasty: Design rationale and early results

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1 Research goal

To describe the design modifications to an established device in the creation of the LEGION◇ Primary Knee System, together with its early clinical results.

2 Type of evidence

3 Clinical relevance

- The GENESIS II Total Knee System was introduced in 1995 and has resulted in limited revisions,[1] with one recent study showing an excellent survivorship of 98.1% at a follow-up time of 15 years.[2]
- Complex knee disorders (e.g., varus/valgus deformities) present orthopedic surgeons with unique challenges during primary total knee arthroplasty (TKA), and often require devices that provide substantial intraoperative flexibility.[3]
- LEGION builds on the foundation of GENESIS II, with specific design changes that accommodate a wide variety of patient anatomies through surgeon-directed external rotation, the ability to add femoral augmentation, and easy intraoperative transition to a revision system when necessary.

4 Key result

- The cruciate-retaining (CR) and posterior-stabilized (PS) designs of GENESIS II and LEGION are identical, with the exception of three differences (**Figure 1a–c**, see page 3 for a full comparison with LEGION).
- These design differences are not expected to affect tibio-femoral wear performance, as both devices have comparable mean cumulative volumetric wear rates after approximately 5 million cycles of knee simulator testing.[4,5]
- Two-year results from a prospective, multicenter study of LEGION indicate that only two patients (1.4%) out of 138 underwent revision (one for infection and one for patella clunk, at 2.3 and 18.2 months, respectively).

5 Important considerations

- Further follow-up will be needed to determine the mid- and long-term performance of this device.

Figure 1a–c: Design features of the LEGION PS/CR (pictured) that differ from GENESIS◇ II.

a. Medial posterior condyle thickness (mm):
Sizes 1-6: **LEGION CR/PS (9.5)**; [GENESIS II CR/PS (7)]
Sizes 7-8: **LEGION CR/PS (11.5)**; [GENESIS II CR/PS (9)]

b. Femoral augmentation LEGION CR/PS: Threaded screw augments. [GENESIS II CR/PS: Cemented augments]

c. PS box differences
PS box wall height (mm):
LEGION PS (17.1-20.5); [GENESIS II PS (13.8-18.0)]
PS anterior wall:
LEGION PS (Yes); [GENESIS II PS (No)]

Background

The GENESIS® II system was developed in 1995 for primary TKA, and has several key design features, including:

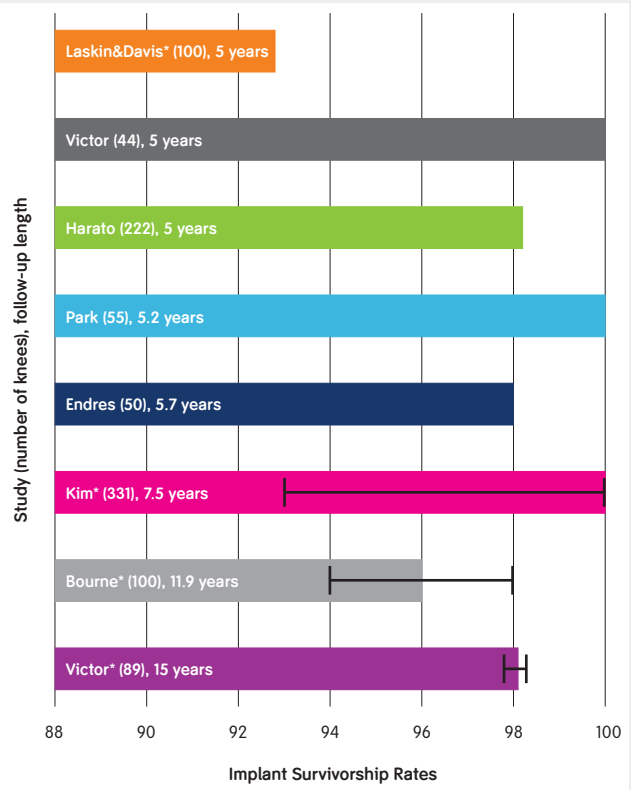
- An S-shaped trochlear groove – simulates a natural femur in its movement of the patella from a lateral position in extension to midline in flexion, thereby reducing lateral release rates to approximately 3%[6] compared with approximately 14%[7] for competitive devices;
- A bone-conserving PS box cut – removes less bone than several competitive systems[8] and leaves the critical anterior bone bridge intact;
- An asymmetric baseplate shape that matches the tibial anatomy[9] – reduces rate and severity of malrotation[10]
- VERILAST® Technology (introduced in 2008) – exhibits significantly less wear when compared with a cobalt-chromium/ultra-high-molecular weight polyethylene bearing[11] and incorporates OXINIUM® (oxidized zirconium alloy), a material that unlike cobalt-chromium has <0.0035% nickel, <0.002% cobalt, and <0.02% chromium content,[12] and highly cross-linked polyethylene (XLPE).

GENESIS II has produced positive clinical results over the last two decades (**Figure 2**). A 2012 systematic analysis collected data from 11 clinical studies (1,201 knees in total) with this device; 14 revisions were identified, resulting in a 96.0% implant survivorship rate at a maximum follow-up of 11.9 years.[1] One recent study with the longest-yet follow-up for GENESIS II (15 years) reported an excellent survivorship of 98.1%. This was a single-surgeon study in which the choice for a CR or PS implant was made after assessment of deformity and ligament status, and both cemented and uncemented femoral fixation were used.[2]

GENESIS II has proven successful in conventional TKA for standard indications; however, surgeons also perform TKAs in patients whose cases can be considered relatively complex, such as those with extra-articular deformities, posttraumatic arthrosis, and neuropathic arthritis.[3] For such demanding cases it is necessary to customize TKA device component choice, positioning, and technique in order to achieve optimal postsurgical results.[3]

The LEGION® Primary Knee was introduced in 2005 (originally under the name GENESIS® II SPC), and later became part of the LEGION Total Knee System, which also includes LEGION Revision and LEGION Hinge Knees. LEGION builds on the design foundation of GENESIS II, with specific changes to accommodate a wide variety of patient anatomies. This analysis provides an overview of these design changes, as well as the early results from a prospective, multicenter study with LEGION.

Figure 2: Kaplan-Meier implant survivorship estimates for GENESIS II at final assessment in eight studies (991 knees) with ≥5 years follow up.[2,6,13-18]



*Indicates a study in which Kaplan-Meier survivorship estimates were reported. Other studies had survival extrapolated from revision information (e.g., lack of revisions = 100% survival).

H 95% confidence interval (with exception of Bourne[13], which reports standard deviation)

Methods

Design background

- LEGION® is a total knee system, with options in both CR and PS designs, as well as constrained and hinged knee components.
- LEGION CR and PS have designs similar to GENESIS® II CR and PS, with three differences shown in **Figure 3a-c**.

Wear analyses (AMTI 6-station knee simulator)

- First analysis: wear of LEGION CR 7.5 Mrad XLPE tibial inserts articulating against GENESIS II CR OXINIUM® femoral components was measured. The test was conducted for 5.19 million cycles.[5]
- Second analysis: the wear of LEGION CR 7.5 Mrad XLPE tibial inserts articulating against LEGION CR OXINIUM femoral components was measured. The test was conducted for 45 million cycles, with wear assessed at 5.19 million cycles.[4]

Figures 3a-c: Design features of the LEGION CR/PS that differ from GENESIS II CR/PS.

GENESIS II CR/PS	LEGION CR/PS
	

a. Medial posterior condyle thickness (mm):
Sizes 1-6: GENESIS II CR/PS (7); LEGION CR/PS (9.5)
Sizes 7-8: GENESIS II CR/PS (9); LEGION CR/PS (11.5)

Rationale: Femoral components for GENESIS II CR/PS have built-in 3° external rotation, whereas for LEGION CR/PS external rotation is surgeon directed.

b. Femoral augmentation
GENESIS II CR/PS: Cemented augments
LEGION CR/PS: Threaded screw augments

Rationale: GENESIS II CR/PS utilizes cemented GENESIS II femoral augments, whereas LEGION CR/PS utilizes screw-on LEGION femoral augments

c. PS box differences
PS box wall height (mm):
GENESIS II PS (13.8-18.0), LEGION PS (17.1-20.5)

Rationale: LEGION PS is used in conjunction with constrained inserts, whereas GENESIS II PS is not.

PS anterior wall:
GENESIS II PS (No), LEGION PS (Yes)

Rationale: Anterior wall prevents anterior cement migration during surgery with LEGION PS, as compared with GENESIS II PS.

Prospective study

- A prospective study was initiated across five institutions in the United States, in which 138 patients (**Table 1**) received LEGION° Primary and were followed for two years.
- One patient died and seven were terminated early due to other reasons.

Results

Design changes

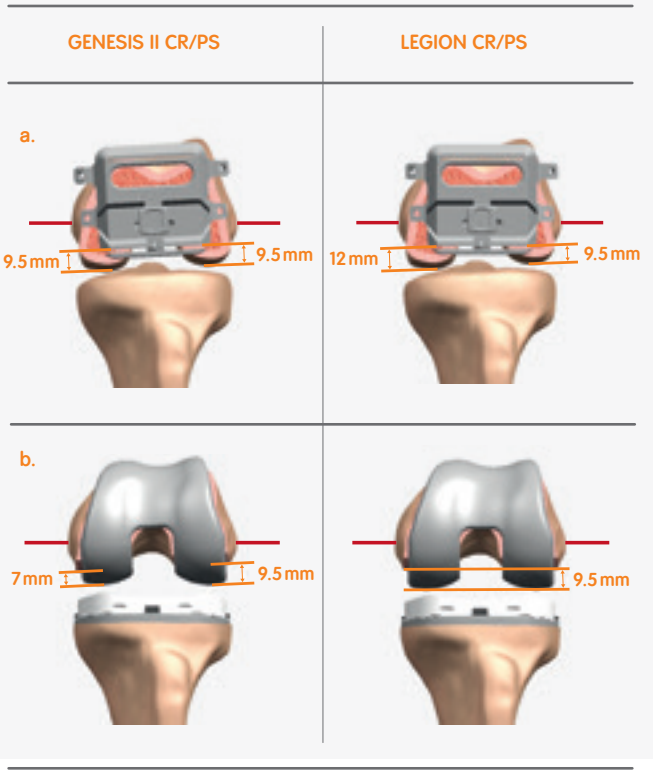
- GENESIS° II employs built-in 3° external rotation useful for the basic surgeries needed for most primary TKAs. LEGION does not incorporate built-in external rotation. Instead, the surgeon externally rotates the femoral component to match the patient's anatomy (**Figure 4a-b**). This is achieved by the posterior-medial condyle being the same thickness as the posterior-lateral condyle
- Both GENESIS II and LEGION employ the same instrumentation with the exception of the rotation of the sizing guide
- Design changes provide for more seamless intraoperative transition to revision TKA if necessary. This is because all versions of the LEGION Knee utilize the same articulating geometry, femoral cuts, and A/P box, making the need for additional bone resection unnecessary
- Ream-through femoral trials that allow the surgeon to move easily from a CR to PS design, as well as locate the correct medial/lateral position for the PS box
- Only one design change involves an articulating surface (**Figure 3a**). Both GENESIS II and LEGION have a tibiofemoral conformity ratio of 1:1.05 in the coronal plane and the same kinematic contact throughout the range of motion in the sagittal plane. This would explain the comparable results of the wear analysis below. The patellofemoral articular surfaces are identical between GENESIS II and LEGION femorals.

Table 1 Patient demographics (n=138)*

Gender, patients (%) Male Female	 49 (35.5) 89 (64.5)
Age, years (range)	66.4 (24-88)
Height, centimeters (range)	167.3 (144.7-193.0)
Weight, kilograms (range)	87.2 (43.1-128.8)
Body mass index, kg/m² (range)	31.1 (17.4-51.9)

*All variables except gender presented as means.

Figure 4a-b: Femoral rotation, as evidenced from placement of cutting block (a) to ultimate implantation (b).



Wear analysis

– Separate analyses[4,5] revealed comparable wear between the LEGION® CR and GENESIS® II CR (**Table 2**).

Table 2 Results of separate wear analyses at 5.19 million cycles (AMTI 6-station knee simulator).

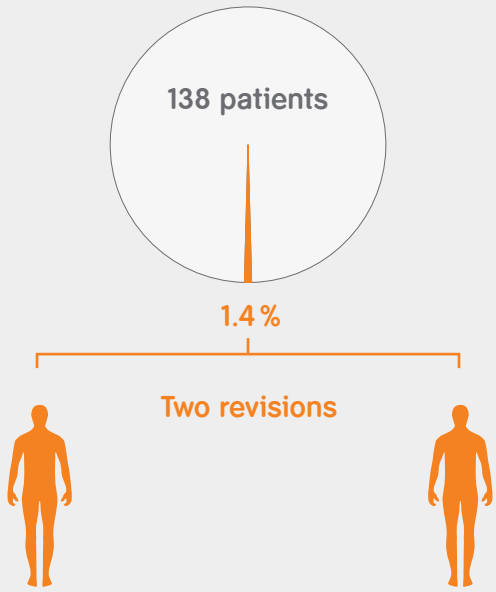
Articulating components	Mean cumulative volumetric wear ± SD
LEGION CR 7.5 Mrad XLPE tibial inserts against GENESIS II CR OXINIUM femoral components[5]	2.51 ± 1.93 mm^3
LEGION CR 7.5 Mrad XLPE tibial inserts against LEGION CR OXINIUM femoral components	2.67 ± 1.20 mm^3

SD = standard deviation; XLPE = crosslinked polyethylene.

Prospective study

– At two years follow up, there were two revisions noted in 138 patients (1.4%; **Figure 5**)

Figure 5: Revisions reported in prospective study.



– Reason: Severe infection
– Age/gender: 69 years, male
– BMI: 31.6
– Treatment: Tibial insert revision 2.3 months after primary TKA

– Reason: Moderate patella clunk
– Age/gender: 50 years, male
– BMI: 37.4
– Treatment: Patellar revision 18.2 months after primary TKA

Conclusions

LEGION° builds upon the well-established GENESIS° II designs, which have achieved excellent survivorship of 98.1% at 15 years follow up.[2] LEGION and GENESIS II achieve equivalent articulation but do so via different surgical approaches to femoral external rotation. GENESIS II offers built-in external rotation by having asymmetric posterior condyles, whereas LEGION allows surgeon-directed external rotation with symmetric posterior condyles. The differing techniques are used with the same tibial implants for both systems and produce comparable implant tibio-femoral kinematics and wear performance after approximately 5 million cycles of knee simulator testing. Based on laboratory wear simulation testing at 45 million cycles,[11] the LEGION Primary CR Knee System with VERILAST° Technology completed 45 million cycles of in vitro simulated wear testing, which is an estimate of 30 years of activity.* Other LEGION design modifications provide surgeons with a more seamless system during surgery, allowing the ability to convert from CR to PS, from PS to constrained, and from primary to revision TKA, as well as the ability to use any tibial insert variant without having to remove the femoral component, all using a common instrument system. Early clinical results with LEGION indicate that it has an acceptable revision rate at two years; however, additional follow-up is needed to gauge whether these results will continue in the medium to long-term.

* The results of in-vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance. Also, a reduction in total polyethylene wear volume or wear rate alone may not result in improved clinical outcomes as wear particle size and morphology are also critical factors in the evaluation of the potential for wear mediated osteolysis and associated aseptic implant loosening. Particle size and morphology were not evaluated as part of the testing.

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