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ENGAGE◊ Cementless Partial Knee System achieves primary fixation and stability with its tibial bone anchor technology

Summary

- ENGAGE Cementless Partial Knee System features a novel bone fixation mechanism, the tibial bone anchor, designed to address the fixation challenges and common failure modes associated with cemented and cementless partial knee arthroplasty
- Tested rigorously in vitro in a variety of methods and compared to a press-fit keel device, the tibial bone anchor technology has been shown to be an effective method for achieving primary fixation and stability of tibial components
- ENGAGE Cementless Partial Knee System offers an innovative joint preservation solution in the management of medial compartment disease

Introduction

Widely used in orthopaedic total joint replacements for more than 50 years, cement fixation with polymethylmethacrylate (PMMA) has generally provided stability and achieved long-term implant fixation in both total knee arthroplasty (TKA)[1–4] and unicompartmental knee arthroplasty (UKA).[5,6] Recently, however, the orthopaedic community has challenged the 'gold standard' typifying PMMA cement fixation upon noting clinical limitations, such as loose cement debris, third-body wear, osteolysis, and aseptic implant loosening and tissue necrosis.[6–8] Furthermore, clinicians have reported additional technical challenges[9–12] when using cement fixation in UKAs where a smaller surgical incision and poorer visualisation may further contribute to difficulty in clearing extraneous bone cement from the posterior aspect of the tibial implant.[13]

As a result of the challenges encountered with cement fixation, a shift towards cementless fixation has been observed.[14] Cementless fixation relies upon osseointegration, a process in which patients' own bone cells grow into the implant to achieve biologic fixation.[14] To provide a stable environment for successful osseointegration, clinicians must develop a reliable fixation strategy in which they stably fix the implants to the bone, with minimal micromotion at the periprosthetic interface.[15,16] Accordingly, achieving reliable cementless fixation in minimally invasive UKAs may be perceived as technically challenging.

ENGAGE Cementless Partial Knee System technology

Overcoming the limitations of current cemented and cementless fixation in UKA, the ENGAGE Cementless Partial Knee System adopts a clinically and technically innovative method, the tibial bone anchor, to help achieve cementless implant fixation.[17] Composed of high-strength, biocompatible titanium alloy, the blade-based fixation tibial bone anchor has a T-shaped cross-section, similar to an I-beam for structural strength (Figure 1). With its fixation technology, the tibial bone anchor is capable of securely affixing the tibial component of the knee to a patient's host bone and is designed to provide several clinical benefits as demonstrated by in vitro testing:[17]

- Improved stability from compression of the baseplate against the host bone
- Greater pull-out force than a traditional press-fit keel design
- Greater resistance to bony-fracture than a traditional press-fit keel under physiological loading
- Greater implant construct rigidity than a traditional press-fit keel under physiological loading
- Reduced bone stresses induced in the adjacent bone when compared to traditional press-fit keel under physiological loading

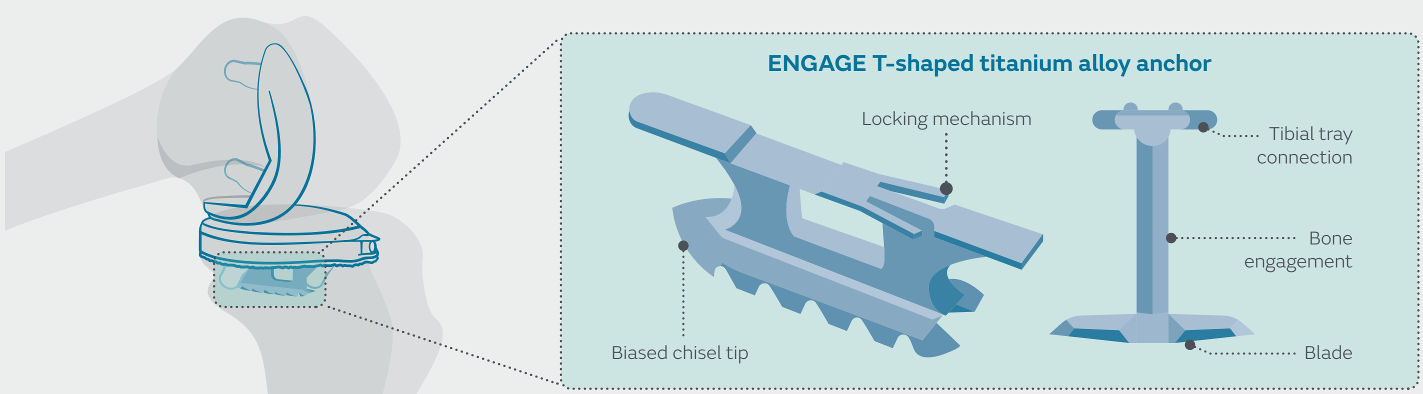

Figure 1. ENGAGE Cementless Partial Knee System anchor technology

Its profile is configured to comprise a bladed area on the horizontal crossbar of the T cross-section of the anchor for engagement into the host bone, as well as a solid rail at the other end, which fits into a conforming slot in the primary body of the tibial component. A biased chisel tip is also included on the superior surface of the leading blade edge of the anchor (Figure 1). This is designed to draw the bone between the anchor's horizontal surface and the inferior surface of the tibial component, generating a compressive force at the periprosthetic interface (Figure 2).

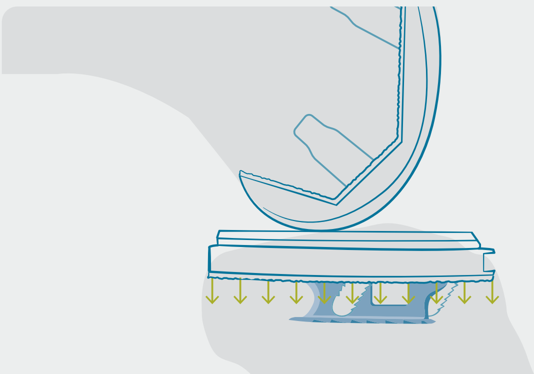

Figure 2. Design of chiselled tip of the ENGAGE Cementless Partial Knee System anchor. Arrows show direction of compressive forces once anchor is inserted

Assessing the mechanical performance of the ENGAGE◊ Cementless Partial Knee System anchor technology

In order to assess the mechanical performance of the ENGAGE tibial bone anchor, a series of tests has been conducted. The following sections provide the details and outcomes of each evaluation, namely an anchor compression test, a pull-out test, a static loading test and a finite element analysis.

Anchor compression

To assess the magnitude of the compressive force generated by ENGAGE Cementless Partial Knee System, the anchor compression test[18] measured the force generated by the tibial anchor between the ENGAGE tibial component and a foam block (Figure 3).

A grade-15 polyurethane (PU) foam block* was prepared using a modified anchor guide and pilot cutter. Two strips of medium-grade pressure film (Fuji Prescale™†) were placed on the foam block (Figure 3a). A size-3, left medial tibial component was positioned on the pressure film, interposing the pressure film between the foam block and the tibial component (Figure 3b). A size 3–4 tibial anchor stem was then inserted into the tibial component and the foam block (Figure 3c). The ENGAGE system was then removed, and effects on the exposed pressure film were used to determine the force generated by the anchor (Figure 3d). The test was repeated with six samples.

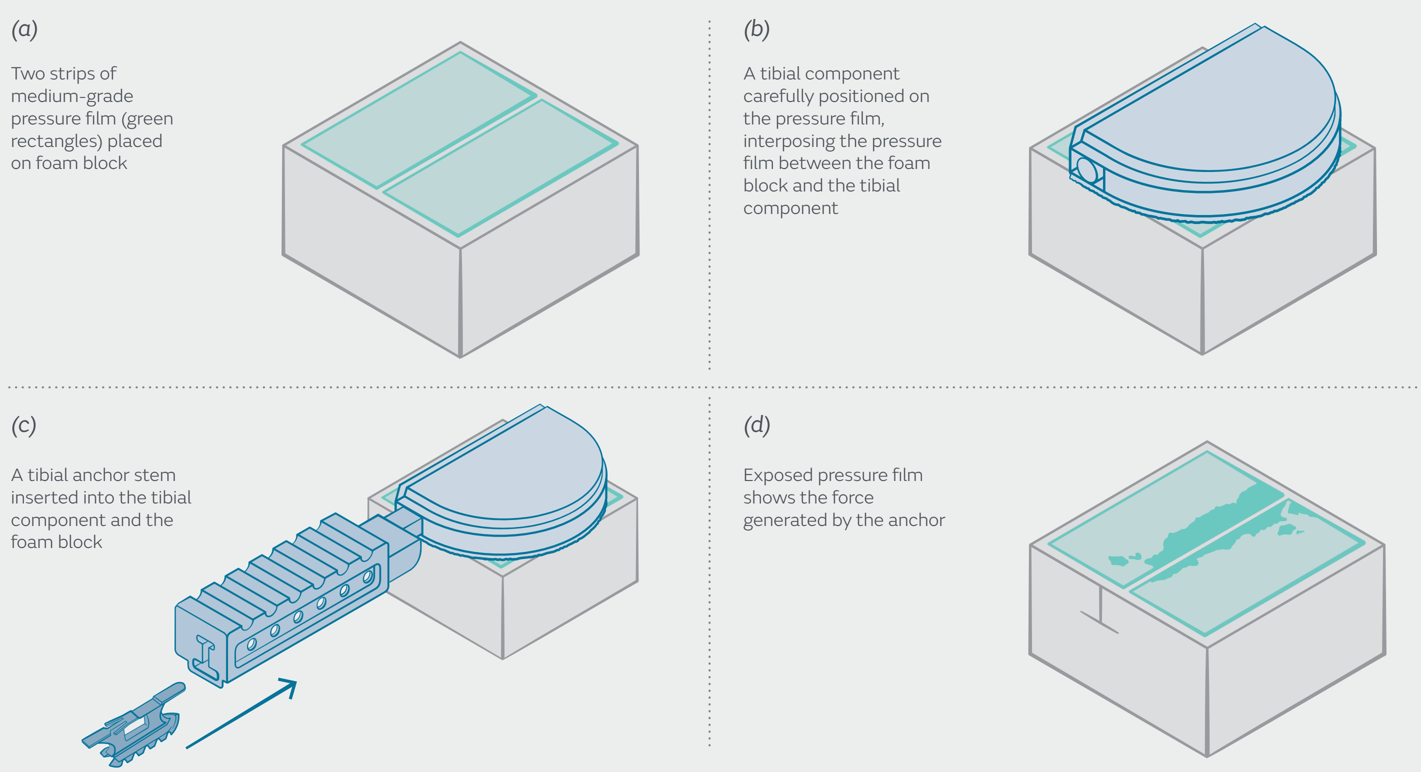

Figure 3. Anchor compression test[18] preparation conducted with six samples

*Pacific Research Laboratories, WA, USA. †Sensor Products, Inc., NJ, USA.

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Test results demonstrated a range of pressures under the tray, translating to an average of a **340N (76.4lbs)** force generated via tibial anchor insertion for the size 3–4 anchor into a size-3 tray (Figure 4). This represents the average force that is induced during the insertion of the tibial anchor component in simulated bone media (grade-15 PU; sawbones) for a medium-sized implant. The findings indicate the substantial compressive force generated by the tibial anchor between the ENGAGE◊ tibial component and the foam block.

Pull-out test

Another test used to measure the mechanical strength of the tibial bone anchor was the pull-out test.[19,20] This test compared the performance of the ENGAGE Cementless Partial Knee System technology to that of a cementless UKA device with a press-fit keel.

The ENGAGE fixture features a porous tibial component, left medial size 1 (representing the most challenging case), impacted onto a foam block with a tibial anchor. The competitor fixture has a porous tibial component,* with a press-fit keel as the only fixation method, impacted onto the foam block. Both fixtures used grade-15 PU foam blocks.† The test was repeated with six samples for each device.

Test results (Figure 5) showed that the mean pull-out force of the ENGAGE fixture was 364.1N (81.9 lbs), whereas the mean pull-out force of the comparator fixture was 24.6N (5.5 lbs). The ENGAGE Cementless Partial Knee System, therefore, demonstrated a pull-out force **14.8 times greater** than the press-fit keel design.

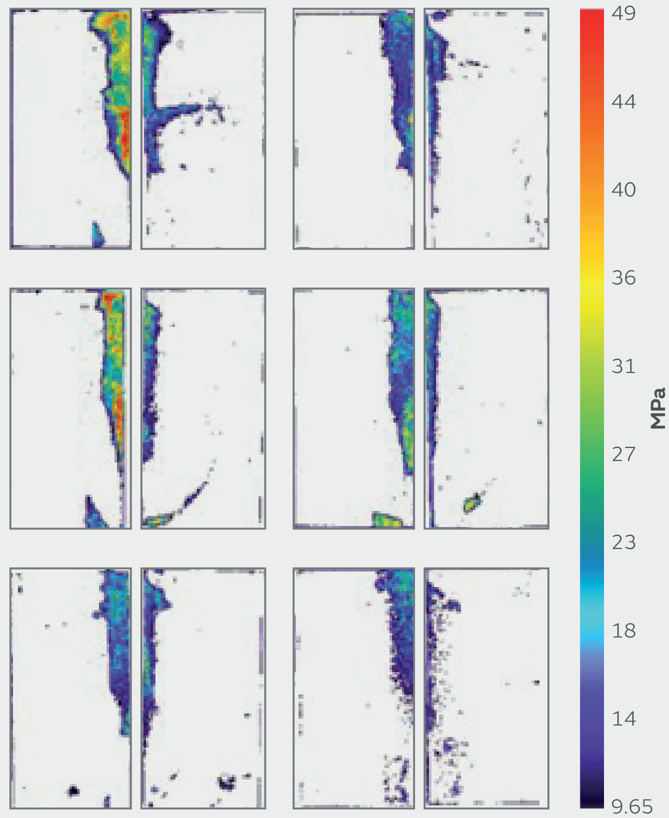

Figure 4. Pressure film of the six anchor pressure samples, showing the force generated by the ENGAGE anchor[18]

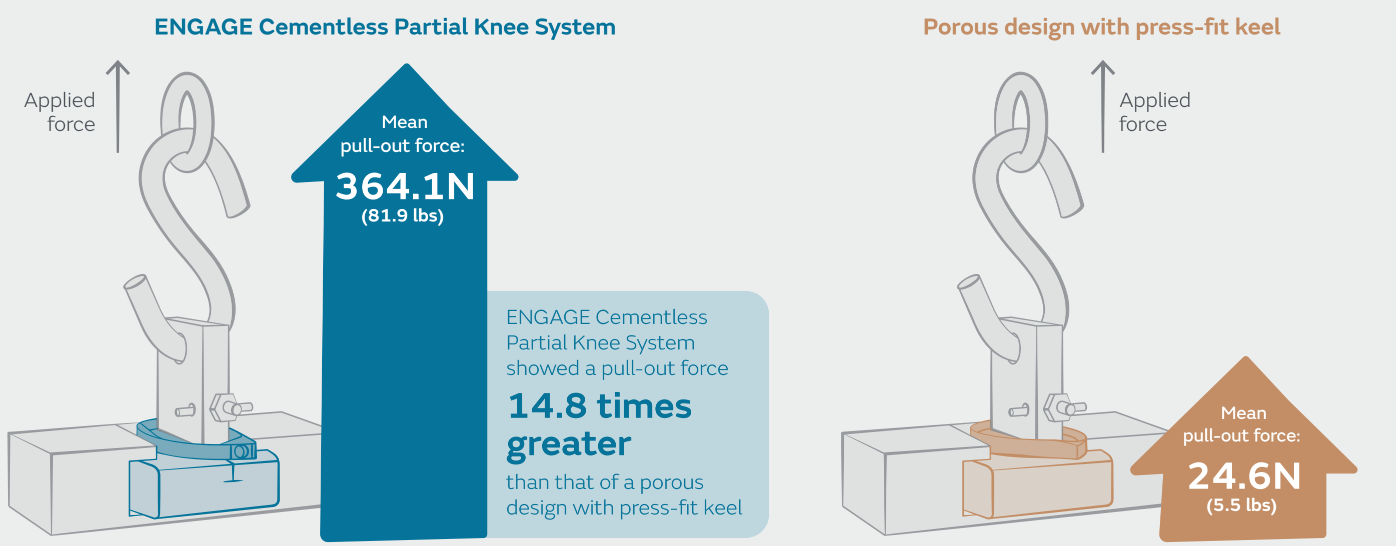

Figure 5. Pull-out test[19,20] measuring the mean pull-out force in six samples for the ENGAGE Cementless Partial Knee System and a press-fit keel device

*Not available in the US. †Pacific Research Laboratories, WA, USA.

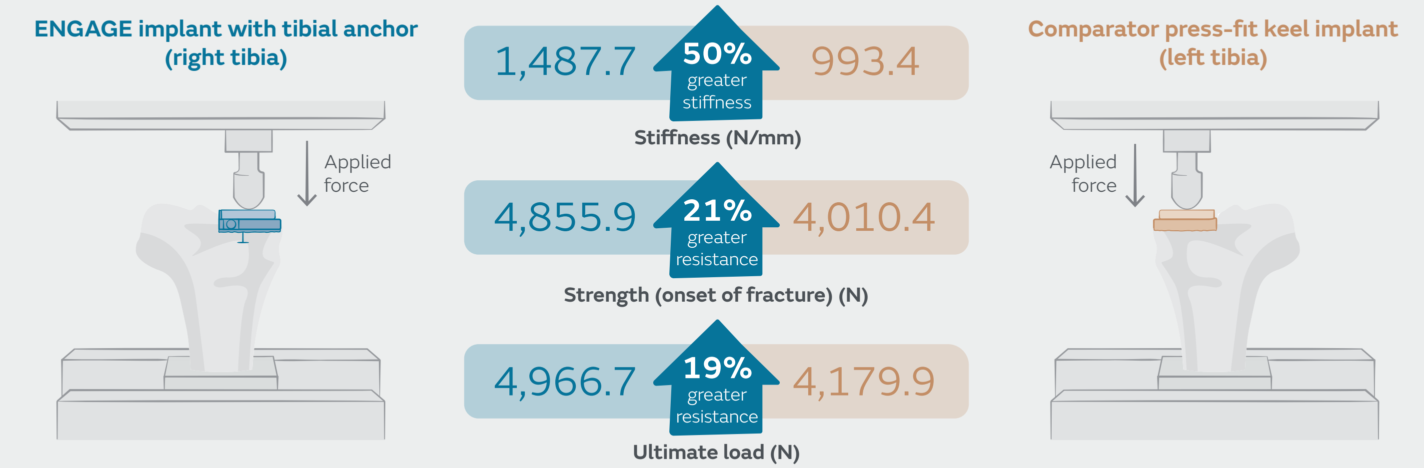

Figure 6. Static loading test[21] assessing the stiffness, strength and ultimate load of the ENGAGE Cementless Partial Knee System and a comparator system on four matched human cadaveric bone

Static loading test

A static loading test on human cadaveric bone[21] was performed on the ENGAGE◊ Cementless Partial Knee System and a press-fit keel system to assess their respective stiffness, strength (highest force before the onset of a fracture) and ultimate load (highest load before failure mode).

Four matched pairs of fresh-frozen cadaveric tibias were prepared with the ENGAGE implant with the tibial anchor (right tibia) and a competitor press-fit keel implant (left tibia) and subjected to static compressive loading (Figure 6).

Results showed that the mean stiffness of the ENGAGE Cementless Partial Knee System fixtures was 1487.7N/mm, whereas that of the press-fit keel device was 993.4N/mm. As such, the ENGAGE implant showed **50% greater stiffness** compared to its comparator. The onset of a fracture for the ENGAGE fixtures was recorded at a mean force of 4,855.9N, compared to 4,010.4N for the comparator design. The ENGAGE implant, therefore, showed a **21% greater resistance** to the force needed to initiate a fracture. Finally, the mean ultimate load for failure of the ENGAGE specimens was 4,966.7N, while that of the press-fit keel device specimens was 4,179.9N. This result indicated that the ENGAGE Cementless Partial Knee System had a **19% greater overall resistance** to the ultimate load that caused a fracture, compared to the press-fit keel system.

Finite element analysis (FEA) of tibial interface stresses

A detailed FEA[22] was conducted to compare the stresses at the tibial bone-to-implant interface for ENGAGE Cementless Partial Knee System and a press-fit predicate implant, under normal physiologic gait loading. The calculated Von Mises and maximum compressive principal stress show a difference in the way the forces are introduced into the tibial bone between the two fixation methods.

The FEA (Figure 7) indicated that stresses directly adjacent to the tibial anchor demonstrated a maximum compressive principal stress that was **0.55MPa** for the ENGAGE Cementless Partial Knee System and therefore **35% less** than the press-fit keel-device which was recorded at 0.84MPa.[22]

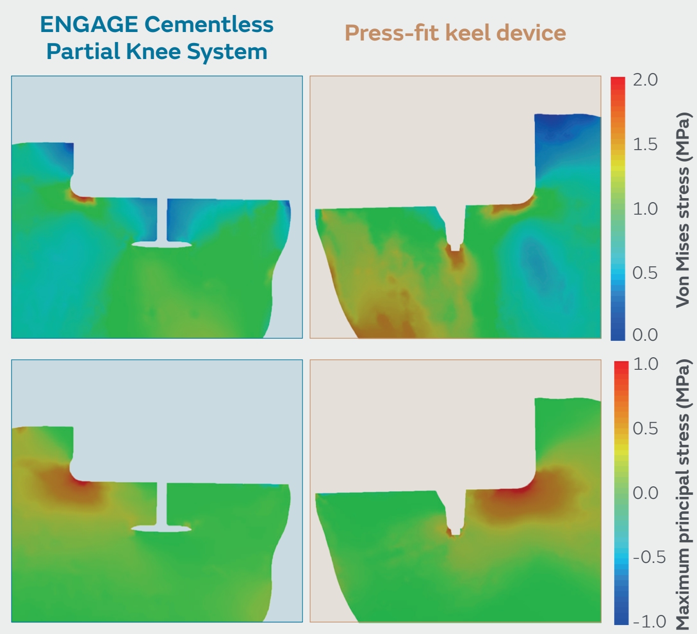

Figure 7. Comparison of tibial interface stresses[22] under normal physiologic gait loading for ENGAGE Cementless Partial Knee System and press-fit keel device

Conclusion

ENGAGE Cementless Partial Knee System features a novel bone fixation method, the **tibial bone anchor, which has been documented to outperform a cementless UKA device with a press-fit keel design in a variety of rigorous in vitro tests**. The tibial anchor technology provides effective primary fixation, as well as stability of the tibial components, supporting the use of the ENGAGE system in managing medial compartment disease.

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