PETER BREHM
Die Präzision in Titan
für den Menschen

Executive Summary

Publication	**A novel ceramic tibial component is as safe as its metal counterpart.** Trieb K. Biomed Tech (Berl), 2017 Aug 3. DOI https://doi.org/10.1515/bmt-2016-0231 [Epub ahead of print]
Study	Biomechanical examination according to the standards ISO 14879-1 and ASTM F1800-07 in order to examine the safety of the tibial component of the novel all-ceramic TKR.
Implant	BPK-S Integration Ceramic (PETER BREHM GmbH; BIOLOX delta ceramic, CeramTec GmbH)
Patients	-
Follow-up	-
Methods	The standards ISO 14879-1 and ASTM F1800-07 describe the test set-up for the experimental strength verification in the approval process of the tibia component from knee implants with a significantly increased maximum load of 5300 N (900 N are required) and post-fatigue burst strength testing. Although the strength of the tibia component was already verified by passing the alternating load test according to approval requirements, the post-fatigue burst strength testing carried out after alternating load test in the same embedding and with the same test set-up reveals the component reserves against fracture after 10 million load cycles. An *in vivo* lifetime of 10 years was simulated for the tibial component. The tibial component of the BPK-S Integration Ceramic is available in sizes 3-6. For the tests, five size 3 components and two size 6 components were evaluated.
Results	**All specimens were able to prove their mechanical strength against fracture in the alternating load test** which simulated the worst-case conditions regarding component size, embedding and external load**.** There was **no material fracture** in any of the included tibial components. The subsequent post-fatigue burst strength testing revealed the maximum strength against fracture of all tibial components. With at least 9.7 kN for size 3 and at least 12.1 kN for size 6, **all tibial components showed large strength reserves to the stress in the alternating load test**, even for the particularly critical embedding with a one-sided free-floating tibial component which is only expected in vivo in especially unfavorable individual cases.

	The comparison of the burst loads of the tested tibial sizes 3 and 6 confirmed the result of the FEM calculation of the worst-case size determination, which states that the largest stress occurs in tibial size 3.
Key Points	The biomechanical testing according to the standards ISO 14879-1 and ASTM F1800-07 showed **no evidence for increased risk of component failure or any other complications concerning safety** of the BPK-S Integration Ceramic. The tibial component of the BPK-S Integration Ceramic showed **high component strength** under standardized laborytory conditions in an alternating load test, even if simulating a worst-case scenario. The subsequent post-fatigue burst strength testing showed **large strength reserves**. Studies have to evaluate properties and clinical results of the BPK-S Integration Ceramic TKR under clinical conditions.
Abbreviations	TKR - total knee replacement

PETER BREHM GmbH | Am Mühlberg 30, 91085 Weisendorf | Tel.: 09135 71 03 – 0 | peter-brehm.de
info@peter-brehm.de | LinkedIn