

Executive Summary

Publication	First clinical study of a novel complete metal-free ceramic total knee replacement system. Meier E, Gelse K, Trieb K, Pachowsky M, Hennig FF, Maurer A. J Orthop Surg Res. 2016 https://www.ncbi.nlm.nih.gov/pubmed/26857704 (PMC free full text)
Study	Prospective, non-randomized, single-arm, open-label, observational; Level of Evidence 4
Implant	BPK-S Integration Ceramic (PETER BREHM GmbH; BIOLOX delta ceramic, CeramTec GmbH)
Patients	34 patients with a mean age of 66.87 ± 9.76 (range, 46-83) years were enrolled in this study. The study group included 38 TKA with 21 TKA (55.2%) in female and 17 TKA (44.7%) in male patients. Out of these, 28 patients (32 TKA) completed the 3- and 12-month follow-up examination. The mean BMI was 31.4 ± 5.6 (22.7-47.8) kg/m ² .
Follow-up	12 months
Methods	The clinical outcome was evaluated pre- and postoperatively at 3 and 12 months using KSS, Oxford Knee Score, EQ-5D-VAS Score.
Results	Postoperatively, the KSS, Oxford Knee Score and EQ-5D-VAS Score improved significantly at 3 and 12-months ($p < 0.001$). There were no device-related complications or failure of the BPK-S ceramic TKA system during surgery or reported follow-up period. There were no intraoperative or postoperative periprosthetic bone fractures. There was no aseptic loosening of the BPK-S Integration Ceramic TKA in any of the patients. .
Key Points	This is the first study investigating the clinical outcome and safety of a completely metal-free TKA system. The metal-free BPK-S Integration Ceramic TKA proved to be safe and clinically efficient alternative to metal TKA in the short-term follow up period. The mid- and long-term follow-up will have to approve this favourable clinical outcome.

	The BPK-S Integration Ceramic TKA meets the functional performance of established primary standard metal TKA in the short-term follow up period. All patients significantly gained benefit from the implantation of the metal-free BPK-S Integration Ceramic TKA by improved or restored knee function, mobility, quality of life and pain situation. The fact that none of the patients developed an allergic reaction to the BPK-S Integration Ceramic system or exacerbation of existing hypersensitivities underlines the rationale of a metal-free TKA for the use in patients with known hypersensitivities. For the surgeon, the implantation of the BPK-S Integration Ceramic system does not require any differential inclusion nor exclusion criteria. According to the authors, the switchover to the BPK-S Integration Ceramic TKA appears to be completely unproblematic, since surgical technique and target alignment are comparable to the current BPK-S Integration CoCr system.
Abbreviations	CoCr - cobalt chromium, TKA - total knee arthroplasty, BMI - body mass index, KSS - Knee Society Score