



HIGHER REVISION RATES AND ASEPTIC LOOSENING WITH POSTERIOR-STABILISED TOTAL KNEE ENDOPROSTHESIS COMPARED TO THE CRUCIATE-RETAINING TYPE OF THE SAME IMPLANT MODEL- A SINGLE-CENTRE RETROSPECTIVE STUDY ANALYSING 580 TOTAL KNEE ARTHROPLASTIES

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SUMMARY – The purpose of this study was to evaluate the 4-year survivorship of total knee arthroplasty (TKA) of a single manufacturer and determine whether failure rates differ between the cruciate-retaining (CR) and the posterior-stabilised (PS) type of implant. In addition, possible causes of revision were analysed as well. A retrospective analysis of 580 TKAs, with either the CR or the PS type of the Biotech Future Knee endoprosthesis (BIOTECH GmbH, Garbsen-Berenbostel, Germany) was performed. The 4-year survivorship for revision of any cause in all cases was 89.14%, with aseptic loosening being the most common cause of revision (53.9%). Regarding the type of implant model, the revision rate was higher in the PS group compared to the CR group (13.7% to 8.0%, respectively, $p=0.027$). The Cox regression models suggested that the type of prosthesis was a significant predictor of the need for revision (HR, 0.442; 95% CI, 0.234–0.833). In conclusion, our study has shown higher revision rates with the PS implant type when compared to the CR implant type with a higher rate of aseptic loosening in the PS group. Further studies are needed to determine the cause of these results and to investigate whether the problem is specific to the implant.

Keywords: *Aseptic loosening, Cruciate-retaining, Posterior-stabilised, Revision surgery, Total knee arthroplasty*

Introduction

Total knee arthroplasty (TKA) is a well-established treatment modality for patients with end-stage knee osteoarthritis. It is a frequently performed and successful surgical procedure that provides pain relief

and improvement of knee function with a 10-year survivorship greater than 90%¹⁻³. In cases of TKA failure, revision surgery is required. Recent studies report changes in the aetiology of failure mechanisms, i.e., the rate of TKA failure due to polyethylene wear decreased, whereas the rate of infection increased⁴. Nowadays, the most common causes of TKA failure are aseptic loosening, infection and instability⁴⁻⁸. Proper follow-up of the TKA outcomes in terms of revision rates, causes and risk factors determination, is mandatory for coming to definitive conclusions which will eventually lead to better outcomes.

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In order to evaluate TKA outcomes in our Department we conducted a retrospective study with several goals. The main goal was to reveal the 4-year survivorship of TKA of a single implant model and to determine whether the failure rates differed between the CR and the PS implant type. Additional goals were to detect the causes of these TKA failures as well as risk factors that led to revision.

Materials and methods

From February 2014 to August 2016, 580 primary TKAs were performed in our department using either the CR or the PS type of the same cemented knee implant model - Biotech Future Knee endoprosthesis (BIOTECH GmbH, Garbsen-Berenbostel, Germany).

After the approval from the hospital's Ethical committee was obtained, a retrospective analysis was done, comparing the CR and PS implant models. A hand search of operation logs as well as an analysis of digitised data was performed. The main aim was to determine the survivorship for the 4-year period with revision for any cause as the endpoint. Risk factors and the mean time from index surgery to revision were also determined.

Demographic data, including age, sex, body mass index (BMI), operated side, and the length of the follow-up period were recorded. Reasons for revision surgery were determined as aseptic loosening, periprosthetic infection, and "other" (including fracture of the patella, periprosthetic fracture, pseudomeniscus syndrome, loosening of the screw used for fixation of the polyethylene to the tibial baseplate and knee stiffness).

The analysis of preoperative and two postoperative knee x-rays (on surgery day and at the final follow-up) was done. The knee alignment and the tibial slope were measured on the preoperative x-rays. The knee alignment was defined as the angle between the mechanical axis of the femur and the tibia. On the first postoperative x-ray, the difference between the width of the tibial component and the width of the tibia at the tibial cut was measured, as well as the knee alignment and the tibial slope. On the last available X-rays, the knee alignment was measured once again and the presence of osteolysis around the implant was noted.

Surgery was performed by 12 different surgeons but did not differ greatly regarding surgical technique. All patients were under spinal anaesthesia and antibiotic prophylaxis was applied with either cefazoline or

clindamycin (in cases of confirmed beta-lactam antibiotic allergies). A thigh tourniquet was applied to all patients. The medial parapatellar approach was used in most of the cases (73,4%, 426/580 cases), while the midvastus approach was used in all other cases. The surgery continued with a tibial cut performed first using an extramedullary rod for guidance, followed by femoral and patellar cuts. The implant type (PS or CR) was determined by surgical preference. The cementing technique was done by most surgeons by hand-mixing and hand-packing, while a single surgeon used the cement gun or the syringe cement pressurisation (modification of the technique described by Matthews *et al.*) for mixing and application of the cement⁹. Polymethyl methacrylate (PMMA) cement with medium viscosity was used in all patients. The cement was placed on the implant as well as interdigitated or pressurised on the bone in all cases. Special attention was given not to move the knee during cementation, and to place the cement when it was not too viscous or too hardened. Both the femoral component and the tibial baseplate were made of cobalt chrome alloy, while the tibial insert was made of standard ultra-high molecular weight (UHMW) polyethylene and was fixed to the tibial baseplate with a 3.5mm screw. The patellofemoral alignment was determined by the "no thumb test" and lateral release was performed if necessary¹⁰. The tourniquet was always released after cementing and was followed by hemostasis and irrigation with hydrogen peroxide and sterile saline. Afterward, a single drain was placed intra-articularly and wound closure was performed. The drain was removed either on the first or second postoperative day and the patients started with a range of motion exercises, as well as walking with crutches, bearing weight as tolerated. All data regarding surgery was analysed using the operation logs. Tibial and femoral component sizes were noted to look for a possible tibiofemoral component mismatch.

Statistical analysis was performed using SPSS v21.0. Normality of distribution was tested by Shapiro-Wilk's test and skewness, and kurtosis was inspected, while homogeneity of variance was tested using Levene's test. The differences between groups of independent continuous variables were analysed using independent samples t-test or Mann-Whitney test, depending on the data nature. The differences in the occurrence of individual conditions were compared using the chi-square test. Survival analysis was performed for a period of 48 months. The Log Rank

Mantel-Cox test was used for testing the differences between groups. Cox regression analysis was performed for predicting the probability of the need for revision surgery. The predictors included in the regression analyses were the type of prosthesis, tibial width, and tibial component width difference, change of tibial slope after surgery, age, and BMI. An error threshold of $\alpha=0.05$ was used in the interpretation of the results.

Results

The study included a total of 580 knees. The demographic data are shown in Table 1. There were no differences between the groups with regard to sex, age and BMI, while the difference of borderline significance was found regarding the follow-up period ($p=0.055$).

Table 1. Demographic features of patients who underwent total knee arthroplasty with either cruciate-retaining (CR) or posterior-stabilised (PS) implant

	Endoprosthesis model		p value
	CR	PS	
No.	288	292	/
Sex (male / female) ^a	81/207	78/214	0.703
Age (years) ^b	68±8	69±8	0.393
BMI (kg/m ²) ^b	31.67 ±4.83	31.61±5.36	0.885
Side (left / right) ^a	134/154	148/144	0.317
Follow-up (months) ^c	57.09±7.22	55.9±7.68	0.055

Data are N or mean (±SD); a- analysed with chi-square test; b- analysed with independent samples t-test; c- analysed with Mann-Whitney test. CR- cruciate-retaining, PS- posterior-stabilised.

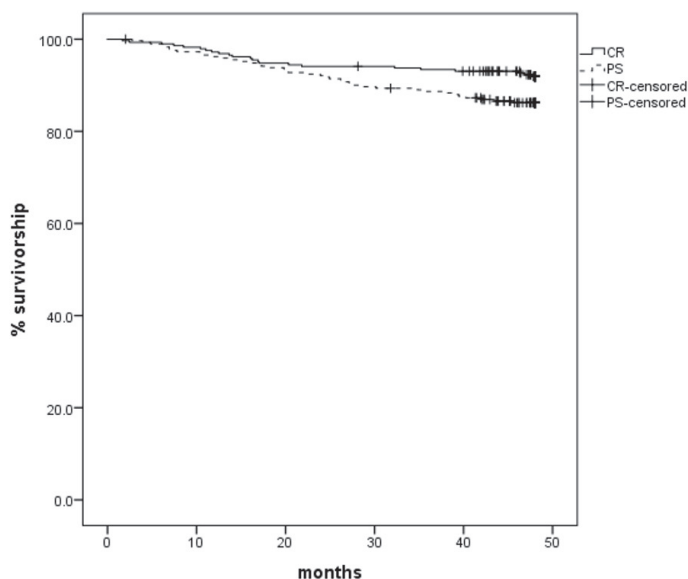


Figure 1. Kaplan-Meier survivorship estimates, using revision TKA for any reason as an endpoint, show the 4-year survivorship estimates 92.01% (95% confidence interval, 88.10–94.76) for the cruciate-retaining (CR) group and 86.30 (95% confidence interval, 81.69– 89.92) for the posterior-stabilised (PS) group. The log-rank Mantel Cox test revealed a statistically significant difference between the groups ($p=0.028$).

During the 4-year period after the index surgery, the revision surgery was performed in 63/580 cases (10.8%). The overall 4-year survivorship for revision of any cause was 89.1% (95% confidence interval [CI], 86.2 – 91.5). Survivorship was 92.01% (95% CI, 88.1 – 94.7) for the CR group and 86.3% (95% CI, 81.6 – 89.9) for the PS group (Figure 1).

The most common cause of revision in all cases was aseptic loosening (34/580 of all cases, 5.8% and 34/63 of revision cases, 53.9%), followed by periprosthetic infection (18/580 of all cases, 3.1% and 18/63 revision cases, 28.5%). The leading cause of revision was different between the groups (Table 2). Regarding the implant model type, most of the revision cases were performed in the PS group (40/63 cases, 63.4%) and the revision rate was significantly higher in this group when compared to the CR group (40/292 cases, 13.7% to 23/288 cases, 8.0%, respectively, $p=0.027$). The median time between index and revision surgery was 16.03 months (range, 1.6–47.8) in the CR group and 20.2 months (2.7–45.5) in the PS group. In the CR group, the leading cause of revision was periprosthetic infection (10/23 cases, 43.5%), while in the PS group infection was found in 8/40 cases (20%), respectively. In the PS group, the leading cause of revision was aseptic loosening (26/40 cases, 65%) and was more prevalent than in the CR group (8/23 cases, 34.8%), which revealed a statistically significant difference ($p=0.021$).

No differences were noticed among the CR and the PS groups regarding the possible tibiofemoral components mismatch (86 vs 96 cases, respectively, $p=0.784$) which was always within the manufacturer's guidelines (difference of one size was allowed between the tibial and the femoral component). Furthermore, no differences were found among the groups regarding x-ray analysis and the preoperative or postoperative knee alignment, change of the tibial slope, or difference in width of the tibial component and the tibial cut (Table 3). The difference was noticed regarding the number of patients with osteolysis, which was found in 53/580 cases (21,2%) in the PS group and 33/580 cases (13.3%) in the CR group, respectively ($p=0.020$).

The Cox regression suggested that the type of implant was a significant predictor of the need for revision (HR, 0.442; 95% CI, 0.234–0.833, $p=0.012$). The models suggested no influence of age (HR, 0.977; 95% CI, 0.947–1.008, $p=0.15$), BMI (HR, 0.976; 95% CI, 0.924 – 1.032, $p=0.40$), change of tibial slope (HR, 0.961; 95% CI, 0.850 – 1.087, $p=0.525$) or difference in width between the tibial component and the tibial cut (HR, 1.128; 95% CI, 0.972– 1.309, $p=0.114$).

Discussion

Our study has shown overall 4-year survivorship for TKA with the Biotech Future Knee model (BIOTECH GmbH, Garbsen-Berenbostel, Germany) with

Table 2. Number and causes of revision surgeries during 4 years after total knee arthroplasty with either cruciate-retaining or posterior-stabilised implant

		Endoprosthesis model		ALL	p value
		CR	PL		
Cause of revision, No. (%) ^a	Infection	10/23 (43.5%)	8/40 (20%)	18/63 (28.5%)	
	Aseptic loosening	8/23 (34.8%)	26/40 (65%)	34/63 (53.9%)	0.021
	Other ^b	5/23 (21.7%)	6/40 (15%)	11/63 (17.6%)	
No. of revisions (% of revision rate) ^a		23/288 (8%)	40/292 (13.7%)	63/580 (10.8%)	0.027
Time to revision (months), median (range) ^c		16.03 (1.67–47.80)	20.28 (2.77–45.50)	18.15 (1.67–47.80)	0.408

Data are N (%) and median (range); a- analysed with chi-square; b- Other- stiffness, periprosthetic fracture, fracture of the patella, pseudomeniscus, and instability of the tibial component fixation screw; c- analysed with Mann-Whitney test. CR- cruciate-retaining, PS- posterior-stabilised.

Table 3. Radiographic assessment of patients who underwent total knee arthroplasty with either cruciate-retaining or posterior-stabilised implant

	Endoprosthesis model		p value
	CR	PS	
PREOPERATIVE VARUS (degrees) ^a	10 (0-25)	10 (0-28)	0.105
PREOPERATIVE VALGUS (degrees) ^a	9 (0-19)	10 (0-17)	0.826
POSTOPERATIVE VARUS (degrees) ^a	0 (0-9)	0 (0-5)	0.240
POSTOPERATIVE VALGUS (degrees) ^b	1 (0-9)	2 (0-9)	0.861
LAST FOLLOW-UP VARUS (degrees) ^a	3 (0-10)	2 (0-20)	0.664
LAST FOLLOW-UP VALGUS (degrees) ^a	2 (0-6)	2 (0-5)	0.362
TIBIAL COMPONENT- TIBIAL CUT WIDTH DIFFERENCE (mm) ^a	2 (-8 to 13)	1 (-4 to 8)	0.373
TIBIAL SLOPE DIFFERENCE (degrees) ^a	2 (-4 to 7)	2 (-8 to 10)	0.067

CR- cruciate retaining, PS-posterior-stabilised. Varus and valgus were determined on x-rays as the angle between the mechanical axis of the femur and the tibia; in cases where the angle was zero, the patient was added to both groups. Preoperative varus and valgus- measured on an x-ray taken on the day before surgery; Postoperative varus and valgus- measured on an x-ray taken immediately after surgery; Last follow-up varus and valgus- measured on the last available x-ray after surgery; Tibial component-tibial cut width difference- measured as the width of the tibial component retracted by the width of the proximal tibia at the tibial cut; Tibial slope difference- measured as the postoperative tibial slope retracted by the preoperative tibial slope. Data are median (range); a- analysed with independent samples t-test; b- analysed with Mann-Whitney test.

revision of any cause as the endpoint of 89.14 %, while the aseptic loosening was the main cause for revision (53.9%). In addition, TKA with a PS implant type has been shown to result in higher revision rates compared to TKA with a CR implant type. Furthermore, a significant difference was found between causes of revision, with aseptic loosening being the most common cause in the PS group compared to that in the CR group.

This is the first study comparing the Biotech Future Knee PS and CR implant models and this is the main advantage of the study. No other studies regarding the same implant model have been published until today and the implant was not found in any of the available joint replacement registries. We were, therefore, unable to make a valid comparison between the survivorship in this study and with survivorship of the same implant in other hospitals. When compared to the available results from the literature, our results are similar to some published data regarding the main reasons for revision surgery but differ regarding survivorship of implants, which is, in our case, comparable to some longer survivorships from the literature 3¹¹.

Comparison of PS and CR total knee implants has been thoroughly analysed in literature 17⁻¹⁹. In a recent study, Longo et al. published a systematic review and meta-analysis based on 37 studies to compare PS and CR total knee implant¹⁷. No differences were found regarding postoperative functional scores and complication rates. Our study has shown statistically significantly more revisions after TKA with PS than with the CR implant model (13.7% to 8.0% respectively, $p=0.027$) and more aseptic loosening in the same group (65% to 34.8% respectively, $p=0.021$).

According to Puloski et al., the reason for more frequent aseptic loosening in the PS group could be the cam-post articulation which could represent an additional source of wear debris, contributing to osteolysis and aseptic loosening²⁰. The authors analysed standard UHMW polyethylene wear in 23 retrieved total knee components and developed a "post-wear score" to quantify it. The score depended on the area and type of surface damaged with the maximum score of 20 points, which presented the worst result. The highest score among the revised implants was 12.4, in a case

where osteolysis was the reason for revision, while in all other cases, the score was much lower, suggesting osteolysis as an important sign of cam-post wear. It is noteworthy that the retrieved polyethylene in the study by Puloski *et al.* was made by 4 different manufacturers and sterilised in different ways - gamma irradiated in the air (14/21), sterilised with ethylene oxide (5/21) or with gas plasma (2/21)²⁰. In our study, a similar standard UHMW polyethylene, sterilised with gamma vacuum foiled method, was used in all patients. Due to the retrospective design of our study, scoring of the post wear could not be performed, but more cases of osteolysis were noticed in the PS than in the CR group (21,2% vs 13.3%, respectively), in our study as well. According to another study, conducted by Furman *et al.*, the design of the tibial post also affects the cam-post wear²¹. The authors showed that the more anterior placement of the post leads to greater wear at the anterior surface of the post²¹. Finally, a study by Pang *et al.* suggests that other factors could also lead to greater cam-post wear²². The authors suggest that joint line elevation, femoral and tibial component malposition, and anterior tibial slope could result in significantly more wear²². Regarding the results from the literature and our results, it seems possible that the type of polyethylene used in our study may have led to more frequent aseptic loosening and revisions with PS implants.

Delanois *et al.* published a study in 2017, revealing reasons for the revision of primary TKA¹². Based on their study, infection was the most common aetiology for revision TKA (20.4%), followed by mechanical loosening (20.3%). This is in contrast with our study, where aseptic loosening was the leading aetiology for revision TKA (53.9%), followed by infection (28.5%). The most common revision TKA procedure in our study was the revision of all implant components, which is in accordance with the study of Delanois *et al.*¹². During the revision of cases with aseptic loosening in our study, bonding failure was noticed at the implant-cement interface, while the bonding at the cement-bone interface was good, implicating possible unsatisfactory tibial component surface roughness (Figure 2). An in-vitro study by Grupp *et al.* compared implant fixation strength after cementation by a push-out test between three tibial base plates with different surface roughnesses, while five different types of bone cement were used for fixation¹³. The tibial implant with the lowest roughness showed lower push-out force,



Figure 2. Extracted tibial prosthesis at the revision surgery due to aseptic loosening of the total knee endoprosthesis. The figure shows good bonding at the cement-bone area, while bonding failure is present at the implant-cement area.

with a bonding failure at the implant-cement interface. Thus, the authors suggested that surface roughness is the uppermost factor affecting the binding of the implant-cement interface¹³. In addition, Deen *et al.* suggested in their study that the cobalt chrome tibial base plates may lead to stress shielding and bone resorption, especially in men and patients with preoperative varus deformity¹⁴. Both the femoral and tibial components used in our study were made of cobalt chrome alloy which may have, in addition to the relatively long tibial stem (Figure 2), led to aseptic loosening¹⁴.

Whether the component and knee axis malalignment actually lead to shorter survival of implants is controversial. On one hand, it is suggested by Kim *et al.* that the anatomical axis should be placed in a slight valgus position of 3°-7.5°¹⁵. On the other hand, Howell *et al.* conducted a study to determine if varus alignment adversely affects implant survival and function 6 years after kinematically aligned TKA. The authors suggest that varus alignment of the tibial component, knee or limb showed no adverse effect on implant survival or function after a mean of 6.3 years¹⁶. The results of preoperative or postoperative knee alignment did not differ between the groups in our study. The median angle between the mechanical axis of the femur and the tibia was between 0° and

2° of valgus on the early postoperative x-ray and between 3° of varus and 2° of valgus at the last available follow-up x-ray.

A single surgeon (the corresponding author) used only the CR implant and was the one who implanted most of them (28% of all CR implants, 81/288). This surgeon always used the cement pressurisation technique (modification of the technique described by Matthews *et al.*) or the cement gun for cementation of both the tibia and femur and this could have also led to the lower revision rates in the CR group⁹. No differences were noticed between the PS and CR implant groups with regard to the preoperative severity of the deformities.

The main strength of this study is that there was no designer-surgeon influence, as the surgeons did not take part in implant development and production. Furthermore, the Biotech Future Knee endoprosthesis was the only available total knee endoprosthesis for surgeons at that time. All data in the study were analysed by the authors that were not among the 12 surgeons performing the TKA with the Biotech Future Knee model. We are aware that our study has several limitations. Our results are implant specific and are related only to the Biotech Future Knee model. Furthermore, the TKA was performed by 12 different surgeons. Additional surgeon analysis revealed that most of them either preferred the PS implant or that they used equally PS and CR implants.

Our study has shown higher revision rates with the PS implant type that was used for TKA and higher rates of aseptic loosening as the cause of revision in the same group, when compared to the CR implant type. Further studies are required to determine the cause of such results and to investigate if the problem is implant specific.

Disclosure of conflict of interest

The authors declare that they have no conflict of interest.

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Sažetak

VEĆA UČESTALOST REVIZIJSKIH ZAHVATA I ASEPTIČKOG RAZLABAVLJENJA TOTALNIH ENDOPROTEZA KOLJENA SA STRAŽNjom STABILIZACIJOM U USPOREDBI S TOTALNOM ENDOPROTEZOM KOLJENA S OČUVANIM STRAŽNjim KRIŽNIM LIGAMENTOM ISTOG TIPA ENDOPROTEZE – RETROSPEKTIVNA STUDIJA JEDNOG CENTRA NA 580 KOLJENA

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Primarne endoproteze koljena razlikuju se u dizajnu s obzirom je li stražnja ukrižena sveza održana (CR) ili žrtvovana (PS). Cilj istraživanja bio je ispitati 4-godišnje preživljenje totalne endoproteze koljena jednog proizvođača te utvrditi postoje li razlike s obzirom na CR ili PS dizajn endoproteze. Također, analizirani su mogući uzroci revizijskih zahvata. Retrospektivno je analizirano 580 koljenskih (PS i CR) endoproteza Biotech Future Knee (BIOTECH GmbH, Garbsen-Berenbostel, Germany). Ukupno 4-godišnje preživljenje ispitivanih endoproteza je 89.14%, a kao najčešći uzrok revizijskog zahvata zabilježeno je aseptičko razlabavljenje endoproteze (53.9%). S obzirom na dizajn endoproteze, postotak revizijskih zahvata je bio viši u PS nego u CR grupi (13.7% i 8.0%, $p=0.027$). Coxov regresijski model upućuje na dizajn endoproteze kao značajan prediktor potrebe za revizijskim zahvatom (HR, 0.442; 95% CI, 0.234-0.833). U zaključku, ovo istraživanje utvrdilo je viši postotak revizijskih zahvata kod PS dizajna u usporedbi s CR dizajnom endoproteze. Potrebne su dodatne studije kako bi se utvrdilo je li opažena razlika specifična za dizajn endoproteze ili ispitivani implantat.

Ključne riječi: *aseptičko razlabavljenje endoproteze, totalna endoproteza koljena, uzroci revizijskih zahvata*