



CORIN KneeTec DeepDish™: Functional outcomes after a follow-up of 12 months and comparison with the STRYKER Triathlon® PS

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Several competing concepts of anteroposterior stabilization have been developed for total knee arthroplasty (TKA), with an overall great success despite some differences in terms of clinical or radiological outcomes. The CORIN KneeTec DeepDish™ is a novel mobile-bearing implant, stabilized with an ultra-congruent deep-dish polyethylene insert. The aim of the present study was to report clinical and radiological outcomes of a series of patients who received the KneeTec DeepDish™ after a follow-up of 12 months, and to compare them to those of a comparable series of patients who received the STRYKER Triathlon® posterior-stabilized.

This was a retrospective comparative cohort study (level of evidence III). Demographic data, radiographic data and range of motion (ROM), as well the International Knee Society score and Oxford Knee Score were collected pre-operatively, and after a follow-up of 12 months.

106 KneeTec DeepDish™ and 80 Triathlon® PS were evaluated at follow-up. Patients who

received the KneeTec DeepDish™ had significant improvement in ROM, radiographic and clinical outcomes. There were no significant differences between the cohorts in terms of ROM, radiographic and clinical outcomes, as well as antero-posterior stability.

This study is the first to report the 12-month outcomes of the CORIN KneeTec DeepDish™. The novel KneeTec DeepDish™ achieved comparable ROM, radiographic and clinical outcomes to the Triathlon® PS after 12 months. Further studies will be necessary to evaluate the mid- to long-term outcomes of the KneeTec DeepDish™.

Keywords: Total knee arthroplasty ; Deep-dish ; Ultra-congruent ; Fonctionnal outcomes ; Radiographic outcomes.

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*Consent to participate:*All patients provided oral informed consent for participation in the study.

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INTRODUCTION

The number of total knee arthroplasties (TKA) worldwide is increasing, in part due to the ageing of the population and the associated increasing incidence of knee arthritis. Different competing methods of anteroposterior stabilization have successfully been developed for primary TKA (1-4). Ultra-congruent (UC) TKA implants have demonstrated satisfying clinical outcomes comparable to those of other designs (5), with important advantages in terms of bone-stock conservation (6) and improved congruence (7). However, they are associated with more modest ranges of motion (ROM), especially when compared to PS implants (8), and unique kinematic characteristic (9).

Further, the UC design places high levels of tension on the tibial plateau (10), which could increase shear forces and lead to implant loosening. The CORIN KneeTec DeepDish™ is a novel implant based on the CORIN HLS KneeTec™ design (11), but stabilized using a deep-dished ultra-congruent polyethylene insert rather than the usual 3rd condyle PS. To avoid excessive pressure on the tibia, it is mounted on a mobile-bearing tibial plateau (12). To our knowledge, the results of the KneeTec DeepDish™ remain unknown, and short-term outcomes remain unknown.

The purpose of this study was therefore to report the 12-month results of the KneeTec DeepDish™ implant, including ROM, radiographic and clinical outcomes. A secondary purpose was to compare these results to those of a comparable cohort who received the STRYKER Triathlon® PS, which represents a gold-standard in PS TKA (13). The hypothesis of this study was that the novel UC implant would provide comparable outcomes to the established PS implant.

MATERIALS AND METHODS

All consecutive patients who received the KneeTec DeepDish™ between February 2017 and December 2017 or the Triathlon® PS between January 2016 and December 2017 for primary TKA in one center were included in this retrospective comparative cohort study. The initial cohorts com-

prised 150 KneeTec DeepDish™ and 94 Triathlon® PS patients. However, patients with a history of infection, who could not understand the staff, or who could not be reached for a clinical and radiographic follow-up evaluation were excluded from the study (KneeTec DeepDish™, 35 patients, 25.3%; Triathlon® PS, 12 patients, 12.8%). All patients provided oral informed consent for participation in the study. Because the study did not interfere with the planned procedures for the patients due to its retrospective nature, the institutional review board (IRB) waived approval requirements for the study.

KneeTec DeepDish™ was designed from Corin's HLS KneeTec™ 3rd condyle PS implant as an ultra-congruent antero-stabilized implant with a mobile-bearing tibial plateau. This new design aims to maintain the design of the original PS variant [11], particularly in terms of patellar tracking with the advantages of UC design (6). The KneeTec DeepDish™ is made of chrome-cobalt and is always cemented. Its femoral component has a single radius and an anatomic trochlea designed 7° in valgus to facilitate patellar tracking. An ultra-congruent tibial insert provides anterior stability with an anterior lip of 10.5 mm. Patients were operated on using the anteromedial parapatellar approach. The decision to resurface the patella was left to the operator, based on intra-operative observations.

STRYKER Triathlon® PS is postero-stabilized using a traditional post-cam system, and uses a fixed-bearing tibial plateau. This implant is considered a gold-standard in TKA, having been implanted in more than 20 million knees worldwide and the subject of numerous long-term studies (13). The Triathlon® PS is also made of chrome-cobalt, and is designed with a single radius and an anatomic trochlea. However, it is available in either cemented or uncemented versions. The majority (90%) of patients were operated on using the subvastus approach (anteromedial parapatellar approach 10%). The decision to resurface the patella was left to the operator, based on intra-operative observations.

The rehabilitation protocol was standard for both cohorts and was initiated on the day of surgery when possible. Patients were released after demonstrating their ability to walk on a flat surface

and on stairways. Patients were not immobilized, and full weight-bearing was allowed upon release. Crutches were allowed, following the patients' preference. Patients living alone were addressed to a rehabilitation center.

Demographic data and preoperative ROM, the American Society of Anesthesiologists (ASA), Devane (14) scores, were systematically collected preoperatively. Moreover, preoperative International Knee Society and Oxford Knee Scores (15) were collected from the KneeTec DeepDish™ cohort to evaluate improvement after surgery.

Further, preoperative weightbearing frontal radiographs were used to evaluate alignment and grade the osteoarthritis of the knees according to the Ahlbäck (16) classification. Skyline radiographs were used to grade the knees according the Iwano classification (17). Knee stability was evaluated in clinic at follow-up, using a goniometer to measure frontal laxity in degrees and a clinical exam to estimate anteroposterior stability in millimeters (mm).

After a follow-up of an average of 15 months (minimum 12 months), patients were evaluated in clinic and underwent radiographic examination. Their satisfaction was noted according the Likert scale, and their ROM were measured. The IKS and OKS were collected for patients of both KneeTec

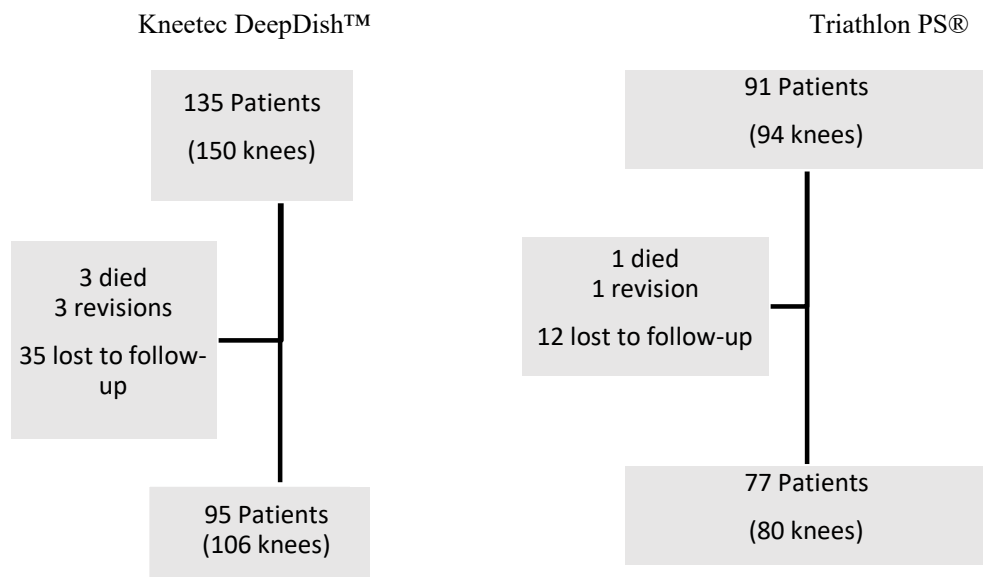
DeepDish™ and Triathlon® PS cohorts. Further, all preoperative radiographic measurements were repeated at follow-up. In addition, the patellar position was evaluated on skyline radiographs, and tibial stress-shielding was classified according to Ewald et al. (18) on frontal radiographs.

All statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC). The normality of variable distribution was evaluated using the Shapiro-Wilk test. Quantitative variables were analyzed using Student's T-Test for parametric variables or the Mann-Whitney U test for non-parametric variables. Categorical variables were analyzed using the Chi-squared test for normally distributed variables or Fisher's exact test for non-normally distributed variables. A p-value of 0.05 was considered significant ($\alpha=0.05$).

RESULTS

In the KneeTec DeepDish™ cohort, 3 patients died during follow-up, independently of their TKA, and 2 patients had revision surgery (Figure 1). The first was due to bilateral surgical site infections resulting in hematogenous translocation. The second was due to subluxation of the polyethylene insert. In the Triathlon® PS cohort, 1 patient died during follow-up, independently of his TKA, and 1 patient

Figure 1. — Flowchart detailing patient inclusion.



had revision surgery due to implant failure. The final cohorts comprised 106 KneeTec DeepDish™ (95 patients) and 80 Triathlon® PS (77 patients). Median follow-up in the Kneetec cohort was 16 months (IQR, 14-19 months), compared to 27 months (IQR, 20-35 months) in the Triathlon® cohort ($p < 0.0001$).

Both cohorts had comparable age, BMI, sex ratio, as well as surgical history and comorbidities (Table I). However, patients who received the KneeTec DeepDish™ were more sedentary, with lower Devane scores ($p = 0.004$). The main indication in both groups was primary osteoarthritis (93,8% of Triathlon® PS patients and 94,3% of KneeTec DeepDish™ patients; $p = n.s.$). Overall, the majority of patients were women (68.3%), aged over 70 years old, active, but with grade 1 obesity ($BMI \geq 31$) and an ASA score of 2.

Preoperative radiographic evaluation revealed that both cohorts had similar incidences of tibio-femoral ($p = 0.066$) and patella-femoral ($p = 0.825$) arthritis (Table II). Average frontal alignment was also equivalent in both cohorts, with median HKA angles of 175.3° (IQR, 172.2° - 182.2°) in the Triathlon® PS cohort (varus : 46 patients (57,5%); valgus 22 patients (27,5%)), and 175.7° (IQR, 170.0° - 182.0°) in the KneeTec DeepDish™ cohort (varus : 71 patients (70%) ; valgus : 15 patients (23,6%)) ($p = 0.401$). The median posterior tibial slope was 5° (IQR, 2.5° - 7.0°) in the Triathlon® PS cohort and 4.4° (IQR, 2.1° - 7.0°) for the KneeTec DeepDish™ cohort ($p = 0.711$). Finally, the pre-operative patellar position was comparable on both cohorts, although fewer subluxations were noted in the Triathlon® PS cohort (4 knees, 5.0%) than in the KneeTec DeepDish™ cohort (11 knees, 10.4%).

For patients who received the KneeTec Deep Dish™ implant, the IKS score was improved by 62.2 points (38 points on the knee subscale and 24.5 points on the function subscale) (all $p < 0.001$) (Table III). The OKS was improved by 14 points ($p < 0.001$). At follow-up, there were no statistically significant differences between the cohorts in terms of either score. The Likert Satisfaction Scale questionnaires indicated that a majority of patients were either satisfied or very satisfied with the intervention at follow-up (Triathlon® PS, 93.8%; KneeTec DeepDish™, 94.4%).

Preoperatively, ROM was greater in the Triathlon® PS cohort than in the KneeTec DeepDish™ cohort, with a larger mobility arc (105° vs 100° $p = 0.0218$), a lower extension deficit ($\mu = -2,63^\circ$ vs $\mu = -4.48^\circ$; $p = 0,0423$), and a greater flexion angle (110° vs 100° ; $p = 0,0731$) (Table III). For patients who received the KneeTec DeepDish™ the net flexion gain was 14.2° ($p < 0.001$), with a median angle of flexion at follow-up of 120° (Figure 2). Moreover, the patients' arc of mobility was increased by 17.9° ($p < 0.001$). For patients who received the Triathlon® PS, the net flexion gain was 10.8° ($p < 0.001$), with a median angle of flexion at follow-up of 120° . At follow-up, 97.5% of patients had angles of flexion of more than 100° . The patients' arc of mobility was increased by 12.8° ($p < 0.001$). ROM was comparable between the cohorts at follow-up, with no statistically significant differences in flexion and extension angles, or overall arc of motion.

However, 34% of patients who had received the KneeTec DeepDish™ had a flexion angle over 130° , compared with 22.5% of patients who had received the Triathlon® PS ($p = 0,0827$) (Figure 3).

For patients who received the KneeTec Deep Dish™, frontal knee laxity at follow-up was measured below 5° for 90.5% of patients, and anteroposterior knee laxity was measured below 5 mm for 97.2% of patients (Table 3). For patients who received the Triathlon® PS frontal knee laxity was measured below 5° for 83.8% of patients, and anteroposterior knee laxity was measured below 5 mm for 100% of patients. There was no statistically significant difference in laxity between the cohorts.

Follow-up radiographic analyses of radiolucent lines according to Ewald revealed no significant differences between the cohorts for either tibia (Anteroposterior $p = 0,8070$; Lateral $p = 0,7602$) or femur ($p = 0,5634$) (Table IV). These radiolucent lines concerned 17 patients (21.3%) in the Triathlon® PS cohort, compared with 20 patients (18.9%) in the KneeTec DeepDish™ cohort. There were no traces of radiolucency at the level of the femoro-patellar joint. There were no differences in knee alignment or femoral notching.

Table I. — Patient demographics (N=186)

	Triathlon® (N=80)			KneeTec™ (N=106)			p-value
	n	(%) / median	(IQR)	n	(%) / median	(IQR)	
							0.404
Sex							
Men	28	(35.0)		31	(29.2)		
Women	52	(65.0)		75	(70.8)		
BMI (kg/m ²)	80	29.6	(26.6-33.7)	106	29.95	(26.8-34.9)	0.744
Age (years)	80	69	(63-76)	106	69	(64-76)	0.431
Devane Score							
Sedentary	2	(2.5)		5	(4.7)		
Semi sedentary	19	(23.8)		45	(42.5)		
Leisure activity	57	(71.2)		47	(44.3)		
Moderate activity	2	(5.5)		7	(6.6)		
Professional athlete	0	(0.0)		2	(1.9)		
ASA Score							
ASA 1	10	(12.5)		10	(9.4)		0.490
ASA 2	62	(77.5)		78	(73.6)		
ASA 3	8	(10.0)		17	(16.0)		
ASA 4	0	(0.0)		1	(0.9)		

Abbr: BMI: Body-Mass Index

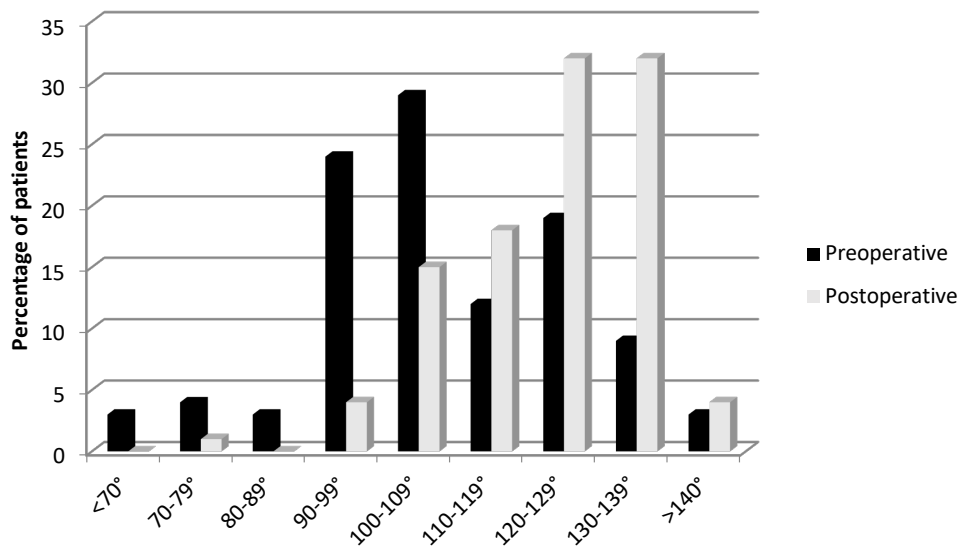


Figure 2. — Range of pre- and post-operative flexion ranges for patients who received the CORIN KneeTec DeepDish™.

Table II. — Preoperative patient knee characteristics

	Triathlon® (N=80)		n	KneeTec™ (N=106)	p-value
	n	(%)		(%)	
Genu Flexum					0.091
No	55	(68.7)	60	(56.6)	
Yes	25	(31.3)	46	(43.4)	
HKA angle (°)					0.118
<170	10	(12.5)	23	(21.7)	
[170-178[36	(45.0)	48	(45.3)	
[178-182]	12	(15.0)	10	(9.4)	
]182-190]	15	(18.7)	15	(14.2)	
>190	7	(8.8)	10	(9.4)	
Patellar position					0.302
Centered	72	(90.0)	90	(84.9)	
Tilted	4	(5.0)	3	(2.8)	
Subluxated	4	(5.0)	11	(10.4)	
Dislocated	0	(0.0)	2	(1.9)	
Tibiofemoral OA (Ahlbäck Classification)					0.066
Stage 1	1	(1.3)	2	(1.9)	
Stage 2	28	(35.0)	31	(29.2)	
Stage 3	32	(40.0)	60	(56.6)	
Stage 4	19	(23.8)	13	(12.3)	
Patellofemoral OA (Iwano Classification)					0.825
Stage 1	32	(40.0)	41	(38.7)	
Stage 2	29	(36.3)	40	(37.7)	
Stage 3	12	(15.0)	19	(17.9)	
Stage 4	7	(8.8)	6	(5.7)	

Abbr: HKA: Hip-Knee-Ankle; OA: Osteoarthritis.

DISCUSSION

The primary purpose of this study was to report the 12-month ROM, as well as clinical and radiographic outcomes of the CORIN KneeTec DeepDish™. A secondary purpose was to compare these results to those of a comparable cohort who received the STRYKER Triathlon® PS. We report satisfactory 12-month ROM, clinical and radiographic outcomes of the KneeTec DeepDish™, with no statistically significant differences when compared to 12-month outcomes of the Triathlon® PS. The original non-

inferiority hypothesis is therefore demonstrated for a follow-up of 12 months. In the literature, UC implants are associated with successful short-term clinical and radiographic outcomes compared to PS implants (Table V), although there is more controversy regarding their success in terms of kinematics or stability (8, 9). In our cohorts, patients had comparable 12-month ROM between KneeTec DeepDish™ and Triathlon® PS. Further, there were no differences in frontal or anteroposterior laxity at follow-up between the cohorts, suggesting the KneeTec DeepDish™ provides adequate

Table III. — Clinical outcomes

	Triathlon® (N=80)			KneeTec™ (N=106)			p-value
	N	median	IQR	N	median	IQR	
Knee Society Score (IKS)							
Preoperative					112.0	(86-129)	
Postoperative	80	170.0	(157-189)	106	172.5	(145-92)	0.580
IKS knee							
Preoperative					47.0	(36-57)	
Postoperative	80	89.0	(80-98)	106	91.5	(77-97)	0.662
IKS function							
Preoperative					60.0	(45-75)	
Postoperative	80	85.0	(70-100)	106	87.5	(70-100)	0.814
Oxford Knee Score (OKS)							
Preoperative					23.0	(19-29)	
Postoperative	80	40.0	(35-42)	106	40.0	(33-43)	0.880
Flexion (°)							
Preoperative	80	110	(100-120)	106	100	(90-120)	0.073
Postoperative	80	120	(115-125)	106	120	(110-130)	0.784
Extension (°)							
Preoperative	80	0	(-5-0)	106	0	(-10-0)	0.042
Postoperative	80	0	(0-0)	106	0	(0-0)	0.853
Mobility Arc (°)							
Preoperative	80	105	(90-120)	106	100	(85-120)	0.032
Postoperative	80	120	(115-120)	106	120	(110-130)	0.402
Frontal laxity (°)							0.197
< 5	67	83.8		96	90.5		
5 – 9	13	16.2		9	8.5		
10–14	0	0.0		1	0.9		
Anteroposterior Laxity (mm)							0.510
< 5	80	100.0		103	97.2		
5 – 9	0	0.0		2	1.9		
≥ 10	0	0.0		1	0.9		

Abbr: IQR: Inter-Quartile Ran

Table IV. — Radiographic evaluation at follow-up

	Triathlon® (N=80)	KneeTec™ (N=106)	
	n (%)	n (%)	p-value
Angle HKA (°)			0.762
<170	0 (0.0)	1 (0.9)	
[170-178[18 (22.5)	30 (28.3)	
[178-182]	44 (55.0)	54 (50.9)	
]182-190]	18 (22.5)	20 (18.9)	
>190	0 (0.0)	1 (0.9)	
Femoral notching	4 (5.0)	5 (4.7)	0.701
Radiolucent lines according to Ewald			
Tibial anteroposterior			0.807
None	71	91	
Zone 1-2	8	12	
Zone 3-4	1	3	
Zone 5	0	0	
Zone 6	0	0	
Zone 7	0	0	
Tibial lateral			0.760
None	78	104	
Zone 1	1	0	
Zone 1'	0	0	
Zone 2	1	2	
Zone 2'	0	0	
Zone 3	0	0	
Femoral			0.563
None	70	89	
Zone 1	8	14	
Zone 2	2	1	
Zone 3	0	0	
Zone 4	1	4	
Zone 5-7	0	0	
Patellar			1
Yes	0 (0.0)	0 (0.0)	
No	80 (100.0)	33 (100.0)	

stability. Nevertheless, further studies are therefore necessary to investigate knee kinematics using the CORIN KneeTec DeepDish™.

The PS design is well-known for its advantageous ROM. Despite equivalent clinical results to PS, several authors report inferior ROM with UC

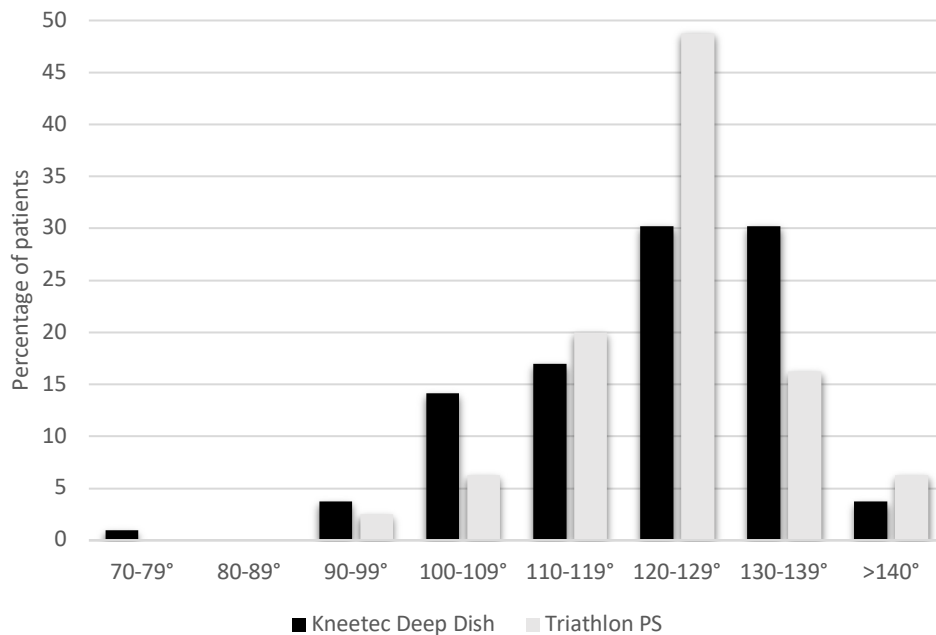


Figure 3. — Comparison of the postoperative flexion ranges of patients who received the CORIN KneeTec DeepDish™ with those of patients who received the STRYKER Triathlon® PS.

implants (8), while other find no difference (19). In a meta-analysis, Bae et al. (8) report that UC implants in general have greater external femoral rotation and less posterior rotation than PS implants, which they argue may impact knee kinematics. Further, they found UC implants had greater anteroposterior tibial laxity and less ROM than PS implants. However, femoral rollback is not in itself correlated with superior clinical outcomes (6). In the present study, there were no differences in ROM between the cohorts, with median flexion ranges of 120°. Furthermore, 95,3% of patients who received the KneeTec DeepDish™ implant had arc-of-motions of more than 100°, which allow the majority of daily activities (20), and a third (34%) had arc-of-motions of over 130°, which is considered a normal range. Nevertheless, because only 22.5% of patient with the Triathlon® PS achieved arc-of-motions of over 130°, the KneeTec DeepDish™ may have an advantage over the former in terms of allowing deep flexion. A large cohort study with a similar UC implant (21) reported an average flexion of 115° at a follow-up of 5 years, suggesting the good ROM observed in the present study could be extended to longer follow-up.

However, further studies with longer follow-up are necessary to verify this hypothesis.

In the present study, there was operator-dependent difference between the cohorts. The KneeTec DeepDish™ cohort was operated on using the anteromedial parapatellar approach, while the Triathlon® PS was operated on using mainly the midvastus approach. Using different surgical approaches is not expected to have had an impact on outcomes in this study.

The follow-up of 12 months is sufficient to study short-term functional results of TKA. Indeed, several studies demonstrated the stability of these functional results from 1 year to 5 years after TKA. The rate of patients lost to follow-up of 24% may appear high. It can be explained by the old age of the patients and a relatively high rate of sedentary patients (38,2%).

The KneeTec DeepDish™ demonstrated excellent functional results, with 94.4% of patients satisfied or very satisfied. This satisfaction rate is notably higher than the 75% reported by Shan (22) in their study on satisfaction after TKA. UC design presents certain advantages that make it an important alternative for arthroplasty. Indeed, despite its

Table V. — Comparisons of the outcomes of UC implants with PS implants in the literature

Author	Year	Journal	Implant	Follow-up (years)	Clinical outcomes	Radiographic outcomes	Stability and kinematics
Han	2020	KSSTA	Triathlon	2	AS (UC) worse	AS (UC) worse	-
Lee	2019	JOS	Columbus	5	same	same	same
Bae	2018	KSSTA	-	meta-analysis	same	UC worse	UC worse
Fritzsche	2017	KSSTA	Columbus	intraoperative	-	UC worse	UC worse
					KSS same, OKS		
Lützner	2017	KSSTA	Columbus	1	UC better	same	UC different
					KSS same, OKS		
Lützner	2016	KSSTA	Columbus	1	UC better	same	UC different
			Natural				
Singh	2016	JCOT	Knee	3 months	UC worse	-	UC worse
Kim	2015	KSSTA	E-motion	3	same	-	UC different
Machhindra	2015	JoA	E-motion	2	same	UC worse	-
			Triathlon				
Sur	2015	JoA	(CS)	5	same	-	UC worse
							UC more
Appy Fedida	2015	OTSR	Triathlon		-	-	laxity
Bignozzi	2014	KSSTA	Gemini	2	same	-	same
Argenson	2013	OTSR	mixed	10	same	same	-
Uvehammer	2001	JoA	AMK (CS)	2	same	same	same
Laskin	2000	CORR	Genesis II	3 months	same	same	same

Abbr: UC: Ultracongruent; PS: Posterior-Stabilized; KSSTA: Knee Surgery, Sports Traumatology, Arthroscopy; JOS: Journal of Orthopaedic Science; JCOT: Journal of Clinical Orthopaedics and Trauma; JoA: The Journal of Arthroplasty; OTSR: Orthopaedics & Traumatology: Surgery & Research; CORR: Clinical Orthopaedics and Related Research.

widespread use, PS TKA is susceptible to several issues including breakage or dislocation of the post-cam and the patellar clunk syndrome (9). In contrast, UC designs preserve bone stocks, which is important due to the rise of younger, more obese patients (23). Further, UC implants require shorter surgical time and allow faster patient recovery (24).

To the authors' knowledge, this is the first study reporting short-term outcomes of the CORIN KneeTec DeepDish™. Due to the presence of a comparable cohort in the same center who received the STRYKER Triathlon® PS, we were able to compare these outcomes with those of this gold-standard of PS TKA. Despite minor peri-operative differences, both cohorts were remarkably similar in terms of demographics, which lends weight to the

comparison. However, this study has limitations. The large number of patients excluded in the KneeTec DeepDish™ cohort due to loss to follow-up compared to that of the Triathlon® PS cohort (25.3% vs 12.8%) may have caused us to overestimate outcomes. Moreover, the comparison between the implants is imperfect due to different operative approaches and average follow-up time.

CONCLUSION

This study is the first to report the 12-month outcomes of the CORIN KneeTec DeepDish™. In our practice, the KneeTec DeepDish™ demonstrated equivalent radiographic and clinical outcomes to those obtained with the Triathlon®

PS. Moreover, there were no differences at follow-up in terms of knee laxity or ROM between the two implants. Patient satisfaction in the KneeTec DeepDish™ reached 94.4%. Further studies will be necessary to evaluate the mid- to long-term outcomes and survival of the KneeTec DeepDish™.

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