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Intermediary Multicentric Prospective and Comparative Analysis of 435 Mobile Bearing Total Knee Arthroplasties of Ultra Congruent Stabilization Mechanism Versus Peg and Cam Stabilization Mechanism. A Point-in-Time Analysis of the Orthowave™6 Database

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Introduction

The Rolflex TONIC total knee implant was launched in early 2016. It is a cruciate sacrificing design and offers a choice of 2 cruciate substituting mechanism according to the UC (Ultra-Congruent) concept or to the PS (Postero-stabilisation with peg and cam) concept. The PS choice can be associated to a fixed tibial bearing or to a mobile tibial bearing, while the UC choice can only be associated to a mobile tibial bearing. The international use of UC total knee prosthesis is low: according to the 2019 AJRR report the UC variant was up at 4.5% of use in 2018, while the PS variant accounted for the largest frequency of use at 51.6%. The second most used type of TKA was the cruciate retaining (CR) variant at 43.8% of use. There is currently no CR variant in the Rolflex TONIC portfolio.

In order to inform of any differences in terms of etiology, indications, patient profile, surgical choices, and clinical and functional performance between the PS and the UC cruciate substituting mechanisms, this document will analyze only the mobile bearing variants of the Roflex TONIC UC and PS. The patients implanted with Fixed bearing PS will not be included in this analysis.

A prospective clinical follow-up of the Rolflex TONIC has been organized by the sponsor (Evolutis, Briennon, France) to evaluate the safety and performance of this new device. This study includes the implants used since June 2016 and up to December 2018. The study design will review the patients at 2, 5 and 10 years of follow-up. At the date of this intermediary report, the 2 years review is not yet terminated. The 2 years report is expected for early 2021 when all patients included will show more than 2 years of FU. Therefore, this intermediary analysis should only be viewed as a security control analysis in search for any anticipated deviation in the expected results. The average length of follow-up will remain short until all patients will be reviewed at 2 years of minimal FU, yet it will evidence if any short or mid-term complication occurred, and how good is the recovery of the patients estimated through an IKS and an OXFORD scores.

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Patients

Between June 2016 and December 2018, the 5 evaluators operating in 4 orthopaedic centers, have recorded 435 total knee prosthesis (412 patients) with a mobile bearing in the Orthowave™6 database. The patients were admitted for primary surgery in 99.5% of the cases, and for revision in 0.5% (4 cases). The mean age of the patients at operation time was 74.5, and when comparing the PS versus the UC group, there is an extremely significant difference for age between the 2 groups: 79.1 for the PS group versus 70 for the UC group (*PS Group mean Age 79.12 (38 -> 94), standard deviation 6.45, UC Group mean Age 70.02 (48 -> 89), standard deviation 7.43, Test Student-Fischer (t): -13.649, p value: 1.620909e-35 (+++) : p < 0,001: extremely significant difference between groups*).

The etiology was rather conventional with 95.8% of arthritis, 1.9% of necrosis, 0.9% of revision, 0.7% of inflammatory arthritis, and 0.7% of post-trauma sequalae.

The patients were ASA 1 in 10.05% of the cases, ASA 2 in 56.44%, and ASA 3 in 35.51%. There was no ASA 4 or 5 in the group.

There were 58.3% of female patients versus 41.7% of males, with average size of 163.8cm (140-195) and weight at 80.6kg (41-134), resulting in a BMI at 30.0 (16.4-50.4). 16.3% of the patients were classified "normal", 37.7% with a "slight" obesity, 40.7% with a "medium" obesity, and 5.3% with a "severe" obesity. And the comparison of the 2 groups show a highly significant difference of BMI between the PS and the UC group: PS Group mean BMI at 29.3 ((20 -> 45.2) standard deviation 5.08) versus UC group mean BMI at 30.77 ((16.4 -> 50.47) standard deviation 5.56).

Methodology

The data presented in this document have been extracted from a Monitored Data Base (MDB) hosted in the Orthowave™6 database, and analyzed on April 15, 2020. Orthowave™6 is dedicated to the recording, protection, and analysis of clinical and functional follow-up data of hip and knee arthroplasty procedures. Any participation of an evaluation center in the database requires the purchasing of a license and the use of dedicated access codes.

The data is recorded by each evaluator on his own Orthowave™6 account, and is later transferred to the MBD database which is accessible to the sponsor of the study (Evolutis). The data accessible through the MDB is fully confidential and compliant with all European regulations for medical research. The sponsor has no access to the personal data of the patients, and cannot modify the patient files.

The personal recorded data is limited to the gender, the size and the height of the patient, and his(her) birth date. The information related to the surgery include the date of surgery, the description of the implants used, the duration of surgery, the ASA score of the patient. Complications are recorded at any delay of occurrence from intra-operative to late complication. Revisions are recorded through the modification of the status of the patient in the study. And finally, the patient is physically evaluated through an IKS score, and is asked to answer a PROM (Oxford) score at each of the post-operative evaluation.

The IKS score was developed in 2011 by the Knee Society in order to evaluate the results of the total knee arthroplasties on the basis of objective clinical data and the function of the knee, but also on the expectations and on the satisfaction of the patients. The score ranks on a total of 200 including 100 for the knee score and 100 for the function score. A 200 score indicates a perfect knee.

The Oxford Knee Score is a patient self-completion PRO (Patient Reported Outcomes) containing 12 questions on activities of daily living. The OKS has been developed and validated specifically to assess function and pain after TKR. The Oxford score rank between 12 and 60. The lower the score, the better are the results of the assessed knee: 12= perfect knee, 60 = fully disabled knee.

Orthowave™6 include a statistic calculation modulus that enables to calculate descriptive data of the studied population, make group comparison statistics, and calculate a Kaplan-Meier survival curve.

Implants

All bearings were mobile. For the Rolflex TONIC knee, the mobile bearing tibial baseplate is identical for PS or for UC use. The femoral condyles and the polyethylene insert are both PS or UC depending on the choice of stabilization mechanism, but in both cases the size of the insert is equal to the size of the condyles.

In this analysis the PS to UC ratio was 51 to 49%. Concerning the fixation mode of both the femoral condyles and the tibial baseplates, both groups have a larger share of cementless fixations (Condyles: 64.4% for the PS vs 77.5% for the UC, Tibial baseplate 66.5% for the PS vs 78.4% for the UC), but the statistical comparison of the groups show an extremely significant difference between the groups (*Condyles: Pearson (khi2): 51.863, p value: 3.203633e-11 (+++), Tibial baseplate: Pearson (khi2), p value: 1.921669e-10 (+++): 48.21, p < 0,001: extremely significant difference*), meaning that the use if cementless components is significantly more frequent in the UC variant.

A patellar resurfacing was associated in 93.8% of the cases and not resurfaced in only 6.2% of the cases.

In mobile bearing Rolflex TONIC total knee arthroplasties, the polyethylene inserts are of the same size as the size of the femoral condyles. This sizing method enables the best congruency possible between the condyles and the insert to the benefit of stability, kinematics and wear. The only possible adaptation is on the selection of the thickness of the insert.

In this analysis, the 10mm (minimal thickness) inserts have been used in 56.4% of the surgeries, the 12.5mm in 34.9%, and the 15mm in 8.7%. No insert of 18mm of thickness has been used. The comparison of insert thickness use between groups is highly significant: in the PS group, 61.6% of the inserts used are of 10mm, 34.2% are of 12.5mm, and only 4.1% are of 15mm. In the IC group, the comparative frequencies are respectively 50.5%, 35.6% and 13.4%. The statistical comparison demonstrates a highly significant difference between the PS and the UC (*chart and table 1*).

Results

371 patients had been evaluated with an IKS questionnaire at a mean 10.4 months after surgery (1.5 – 37.4). Of which 125 patients had been evaluated at a minimum of 12 months.

The IKS score for the full group was at a mean 172.2 ((64-200) standard deviation 26.01) including a knee score at 91.3 ((39-100) standard deviation 10.27), and a function score at 80.8 ((0-100) standard deviation 20.02).

For the 125 patients with more than 12 months of Follow-up, the IKS score was at a mean 182.3 (108 -> 200) standard deviation: 20.28.

Analysis variable: Insert thickness
Bar chart | Stack chart | Mosaic plot

Group 1 Samples : 219/601

AND Date d'intervention <= 2018-12-31
AND Femoral component = ROLFLEX TONIC
PS

Group 2 Samples : 208/601

AND Date d'intervention <= 2018-12-31
AND Femoral component = ROLFLEX TONIC
UC

Insert thickness	Count	%	Count	%
10	0	0	1	0.48
10mm	135	61.64	105	50.48
12.5mm	75	34.25	74	35.58
15mm	9	4.11	28	13.46

Pearson (khi2): 14.24
Degrees of freedom: 3
P-value: 0.002596575 (++)
p < 0,01 : highly significant difference according to the two studied groups (++)

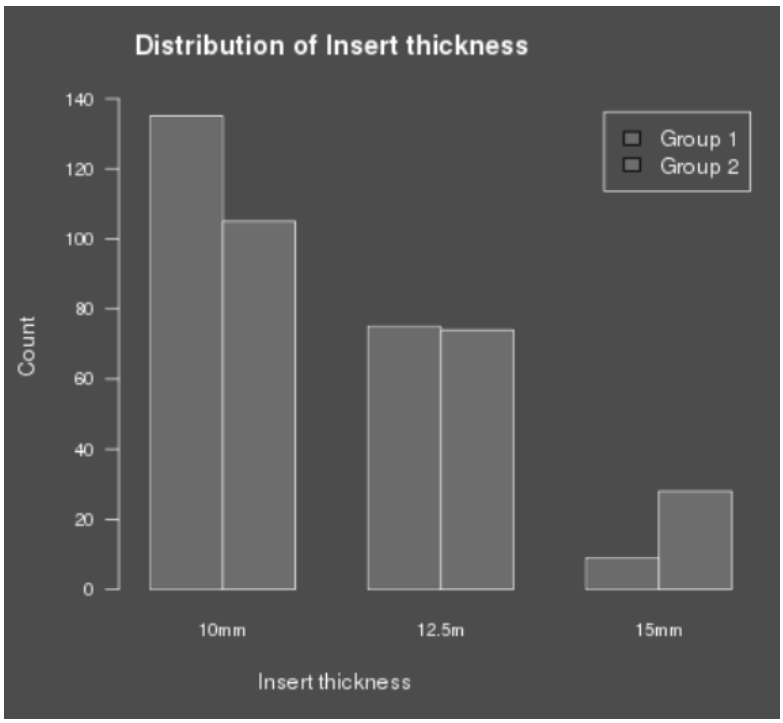


Table 1 and chart: *comparative distribution of the thickness of the polyethylene inserts used for the PS versus the UC variants of the Rolflex TONIC*

When compared between PS and UC group, the IKS score difference is very highly significant: PS Group at mean value 167.54 (80 -> 200) sd 26.01 versus UC Group at mean value 177.15 (64 -> 200) sd 25.14. The student -Fischer test (t) is calculated 3.615 with a P-value at 0.0003419222 (+++), demonstrating a very highly significant difference according to the two studied groups ($p < 0,001$), and meaning that the knee and function results for the UC patients are significantly better than for the PS patients.

There were less patients to answer the Oxford questionnaire but at a longer follow-up: 157 patients at 15.5 months of average FU. The mean OXFORD score for the full group is at 18 (12-36) sd 4.47. (Reminder, the Oxford score is rated on a total of 60, and the lower the score the better the resultsof the assessed knee: 12= perfect knee, 60 = fully disabled knee).

Again, when compared between PS and UC groups, the difference is significant: PS Group mean value at 18.64 (12 -> 36) standard deviation 4.91 versus UC group mean value at 17.13 (12 -> 29) standard deviation 3.66. The Student-Fischer test (t) at -2.116 and with P-value 0.03595311 (+) demonstrate a significant difference according to the two studied groups ($p < 0,05$).

Twenty-five (25) complications at each step of the implants use (3 intra-operative, 17 early or 5 late-follow-up) have been recorded. The complete list of complications at each stage of follow-up is listed in table 2 below. This list includes also the cases that have been revised:

The analysis of the status of the patients indicates that 2 patients (0.5%) died, and 3 patients (0.7%) have been lost to follow-up including 2 that had been evaluated at 17 and 19 months after surgery.

The Lost-to-follow-up patients are patients that are identified and have been contacted, but that refuse to return for evaluation.

There have been 7 revision surgeries. The status of each revision per type of implant is reported in the table 3. The low number of revisions in each group does not allow to conclude to any statistical difference of revision rates between groups.

The reasons for revision are presented in the table 4 below. 2 of the 3 patients lost-to follow-up had previously been evaluated at 17 and 19 months with very good and excellent IKS score. Among the 7 revisions (1.6%), the documentation indicates that 3 revisions occurred for cause of infection (0.7%), and 1 for trauma (0.2%) on a defficient osteoporotic patient, leaving 3 revisions (0.7%) analyzed as implant related.

The Kaplan Meier survival analysis for Retrieval of all type (status C1 + CT + CF + B3 + B4 + BT + BF) shows no difference between the PS and the UC group (*Table 5*), with a survival estimated at 98.4% at 3.51 years of maximal FU for the PS group (95% Confidence Interval: 0.966-1) versus 97.8% at 3.36 years of maximal FU for the UC group (95% Confidence Interval: 0.957-1). The calculated P-value at 0.673 (NS) $p>0.05$ shows a not significant difference.

Table 2.

List of complications at each stage of follow-up

Period	PS or UC	Delay (months)	Gender	Age	Complication	Revision
Intra operative (0.7%)	PS	0	Male	82	Mis-introduction of the intra-femoral rod	No
	UC	0	Male	49	Tibial crack next to the anterior tuberosity osteotomy	No
	PS	0	Male	86	Tibial crack occurred during the impaction of the implant	No
Early post-operative (3.9%)	UC	3	Female	67	Knee stiffness that required a mobilization	No
	UC	4	Female	72	Knee stiffness that required a mobilization	No
	UC	7	Female	72	Fascia-lata syndrome treated by physiotherapy	No
	UC	0.7	Male	89	Rupture of the quadricipital tendon with infection requiring lavage, implant retrieval and repair	Yes
	PS	18	Female	75	Lateral neuropathy pain with fascia-lata syndrome that healed spontaneously	No
	UC	4	Female	70	Secondary valgus locking of the tibial implant following lateral plateau collapse at 4 months Revised for a cemented implant	Yes
	UC	0.7	Female	62	Carential osteoporosis by bypass at 3 weeks	Yes
	UC	9	Male	49	Metaphyseal tibial fracture after 9 months treated with conservative treatment	No
	PS	2	Male	78	Implant subsidence (revised)	Yes
	PS	2	Female	80	Hemarthrosis	No
	PS	0.7	Male	79	Infection at streptococus dysgalactiae (revised)	Yes
	PS	3	Female	75	Patellar dislocation: repair of the medial tendon	No
	PS	6	Female	71	Crepitus of a non-resurfaced patella	No
	UC	11	Female	69	Patellar tendinopathy	No
	UC	1	Female	64	Skin necrosis with exposure of implants requiring amputation of the thigh	No
	PS	3	Female	86	Cicatricial scarring	No
	PS	6	Female	79	Progressive chondromalacia patellar pain on a non-resurfaced patella requiring a secondary patellar replacement	No
Late post-operative (1.15%)	UC	21	Male	67	Revision of the prosthesis for absence of fixation of the tibial component	Yes
	PS	15	Female	82	Crepitus of a non-resurfaced patella	No
	PS		Female	89	Saphenous nerve syndrome	No
	PS	18	Male	85	Hematogenous staphylococus lugdunensis infection	Yes
	PS	21	Female	84	Patellar crepitus and quadricipital tendinopathy	No

The Kaplan Meier survival analysis for Implant related revision (C1 + CT) also shows no significant difference between the PS and UC groups (*Table 6*) although no C1, CF or CT status was attached to the PS group. But since only 2 implant related failures were recorded within the UC group, the number is not significant enough to calculate a statistical difference. For the PS group the survival estimate is 100% at 3.51 years of maximal FU versus 98.9% at 3.36 years of maximal FU for the UC group (95% Confidence Interval: 0.974-1). The calculated P-value at 0.155 (NS) $p>0.05$ shows a not significant difference.

For the full group, the Kaplan Meier analysis for Retrieval of all type (status C1 + CT + CF + B3 + B4 + BT + BF) calculates a survival rate at 98.3% (95% Confidence Interval: 0.97-0.995) at 3.54 years of maximal FU (*Table 7*), while when restricted to the Implant related failures, the survival rate is at 99.5% (95% Confidence Interval: 0.988-1) (*Table 8*).

Table 3.

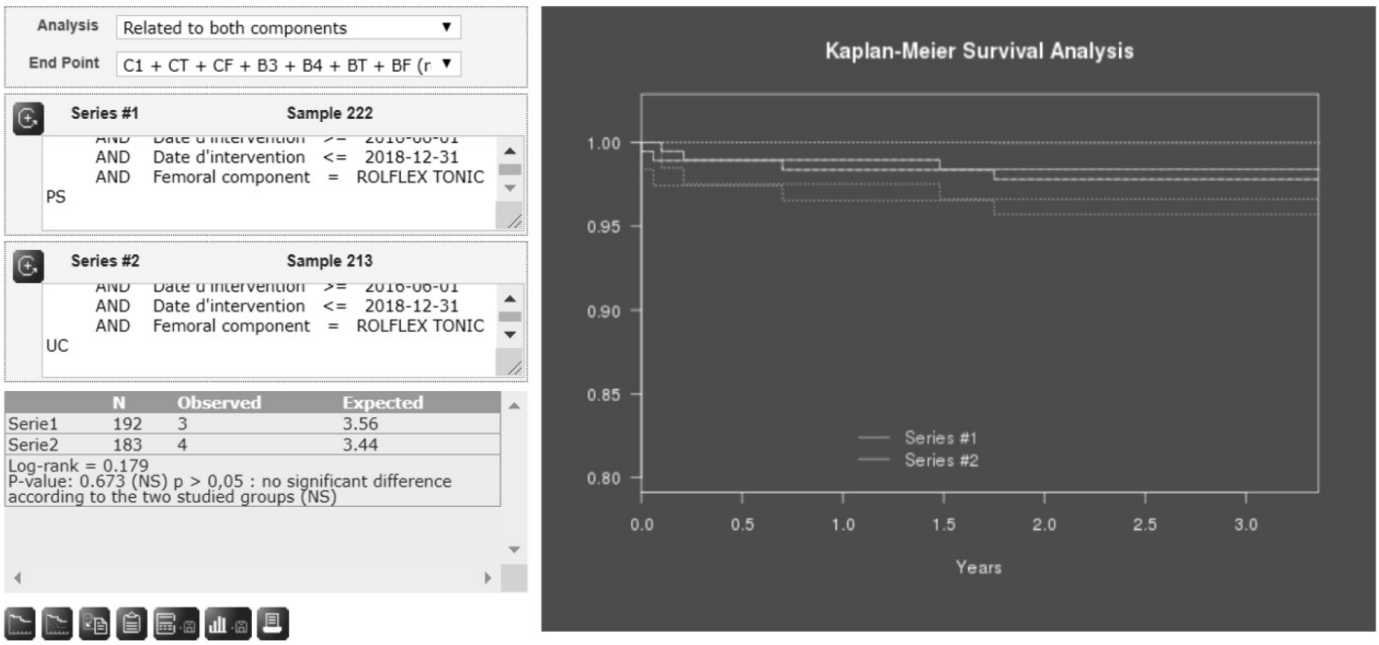
Status and frequency of patient per variant of implant

Status	PS		UC	
	Number	%	Number	%
A: on file	216	97.3	207	97.18
B1: Lost to Follow-up	1	0.45	2	0.94
B2: Dead	2	0.9	0	0
B3: Retrieval (infection/not implant related)	2	0.9	1	0.47
B4: Retrieval (trauma/not implant related)	0	0	1	0.47
B5: Out of study	0	0	0	0
BF: Femoral retrieval (not implant related)	0	0	0	0
BT: Tibial retreival (not implant related)	1	0.45	0	0
C1: Failure (retrieval)	0	0	1	0.47
C2: Failure (clinical)	0	0	0	0
C3: Failure (radiological)	0	0	0	0
CF: Femoral failure (implant related)	0	0	0	0
CT: Tibial failure	0	0	1	0.47

Table 4.

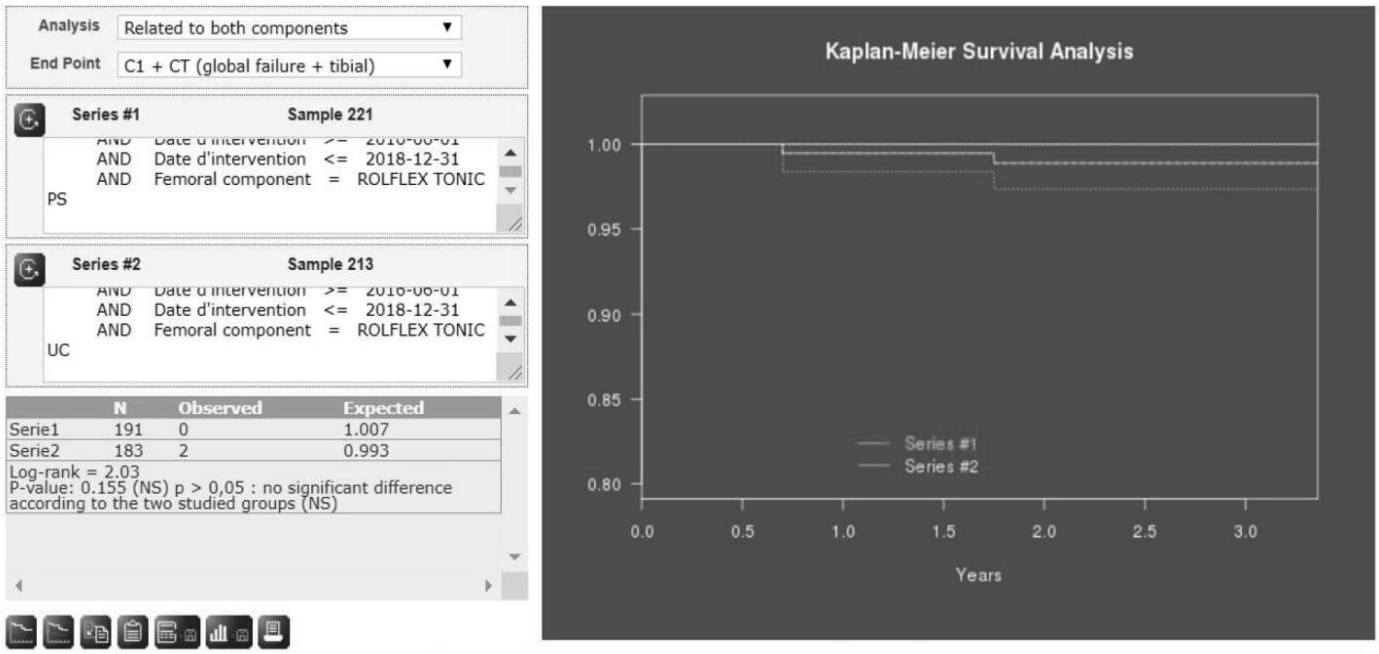
Details of status for each patient excluded of the study

Patient Number	Status	Surgery date	Femur	Surgeon	Last eval	Comments
000462664445	**Lost to FU**	09/06/2016	ROLFLEX TONIC UC	JLC	30/01/2018	Female Medium obesity 77 yo Refuses to return IKS 189 at 19 mois
000462705940	**Lost to FU**	16/06/2016	ROLFLEX TONIC UC	JLC	13/12/2017	Female 65 yo Refuses to answer IKS at 200 at 17 months
001131883992	**Lost to FU**	04/06/2016	ROLFLEX TONIC PS	PV	04/06/2016	Female Medium obesity 83 yo Never evaluated
001133052915	**Deceased**	26/04/2018	ROLFLEX TONIC PS	JMD	10/08/2018	
001133106203	**Deceased**	14/12/2018	ROLFLEX TONIC PS	PV	14/12/2018	
001132625441	**B3 retrieval (infection/not imp. related)**	10/10/2016	ROLFLEX TONIC PS	JMD	01/09/2017	Male Mild obesity 79 yo Arthroscopic lavage at 1 month Evidence of streptococus dysgalactiae Negative evolution Removal of implants
001182663780	**B3 retrieval (infection/not imp. related)**	18/03/2017	ROLFLEX TONIC UC	PM	18/03/2017	Female Normal weight 64 yo Skin necrosis with exposure of implants at 1 month Thigh amputation
001132627337	**B3 retrieval (infection/not imp. related)**	22/12/2016	ROLFLEX TONIC PS	JMD	19/04/2019	Male Medium obesity 85 yo Hematogenous staphylococus lugdunensis infection at 18 months
001132105519	**B4 retrieval (trauma./not imp. related)**	01/02/2018	ROLFLEX TONIC UC	JMD	22/02/2018	Female Medium obesity 62 yo Carential osteoporosis by bypass at 3 weeks
001132286867	**BT tibial retrieval (not imp. related)**	15/06/2018	ROLFLEX TONIC PS	PV	31/08/2018	Male Medium obesity 78 yo Subsidence at 2 months
001132126705	**C1 failure (retrieval)**	27/11/2017	ROLFLEX TONIC UC	JMD	09/08/2018	Female Medium obesity 70 yo Secondary valgus locking of tibial implant following lateral plateau collapse at 4 months Revision at 10 months for a cemented Revision implant
001132644336	**CT tibial failure**	16/01/2017	ROLFLEX TONIC UC	JMD	26/05/2017	Male Mild obesity 67 yo Revised at 21 months for absence of fixation of the tibial component confirmed in July 20818



Period	N° at risk	N° censored	N° event	N° at end	Survival	Revision Burden	Std.err	-0.05	+0.05
0 - 0.1	222	0	0	222	1	0	0	1	1
0.1 - 0.21	222	0	1	221	0.995	0.005	0.005	0.985	1
0.21 - 1.48	221	11	1	209	0.99	0.01	0.007	0.975	1
1.48 - 3.51	209	178	1	30	0.984	0.016	0.009	0.966	1
0 - 0.06	213	0	1	212	0.995	0.005	0.005	0.984	1
0.06 - 0.7	212	0	1	211	0.989	0.011	0.008	0.974	1
0.7 - 1.75	211	3	1	207	0.984	0.016	0.009	0.965	1
1.75 - 3.36	207	176	1	30	0.978	0.022	0.011	0.957	1

Table 5 and chart: *Kaplan-Meier analysis – PS vs UC group - Retrieval of all type (C1 + CT + CF + B3 + B4 + BT + BF)*



Period	N° at risk	N° censored	N° event	N° at end	Survival	Revision Burden	Std.err	-0.05	+0.05
0 - 3.51	221	191	0	30	1	1	0	1	1
0 - 0.7	213	2	0	211	1	0	0	1	1
0.7 - 1.75	211	3	1	207	0.994	0.006	0.006	0.984	1
1.75 - 3.36	207	176	1	30	0.989	0.011	0.008	0.974	1

Table 6 and chart: *Kaplan-Meier analysis – PS vs UC group - Implant related revision (C1 + CT)*

Table 7.

Kaplan Meier analysis – Full group - Retrieval of all type (C1 + CT + CF + B3 + B4 + BT + BF)

Period	N° at risk	N° censored	N° event	N° at end	Survival	Revision Burden	Std.err	-0.05	+0.05
0 - 0.06	435	0	1	434	0.998	0.002	0.002	0.993	1
0.06 - 0.1	434	0	1	433	0.995	0.005	0.003	0.988	1
0.1 - 0.21	433	0	1	432	0.993	0.007	0.004	0.984	1
0.21 - 0.7	432	2	1	429	0.99	0.01	0.005	0.981	1
0.7 - 1.48	429	9	1	419	0.988	0.012	0.005	0.977	0.998
1.48 - 1.75	419	6	1	412	0.985	0.015	0.006	0.973	0.997
1.75 - 3.54	412	381	1	30	0.983	0.017	0.007	0.97	0.995

Table 8.

Kaplan Meier analysis – Full group - Implant related revision (C1 + CT)

Period	N° at risk	N° censored	N° event	N° at end	Survival	Revision Burden	Std.err	-0.05	+0.05
0 - 0.7	434	5	0	429	1	0	0	1	1
0.7 - 1.75	429	16	1	412	0.997	0.003	0.003	0.993	1
1.75 - 3.54	412	381	1	30	0.995	0.005	0.004	0.988	1

Discussion

Despite the short follow-up associated to the analyzed dataset, and the fact that the collection of data is still under way, the comparison of the complications, clinical results, and survival of the Rolflex TONIC PS with the Rolflex TONIC UC is made possible thanks to the high number of patients included by the 5 surgeon-evaluators since June 2016. The analysis is based on 219 PS implants versus 209 UC implants with an average follow-up of 10.5 months.

The data analysis demonstrates that there are some significant differences in the casuistic of the 2 groups: in comparison to the UC patients, the PS patients are: - Older by 9 years on average: 79.1 for the PS group versus 70 for the UC group - Have a lower average BMI: 29.3 for the PS group versus 30.77 for the UC group.

The age difference is not a surprise as the UC mechanism is best adapted to healthier knees and efficient quadricipital muscle moment. The UC design is also less constrained and requires a good ligamentary status of the knee where the PS more constrained design provides more security in deviated knees. Some of the participating surgeons do not adapt the stabilization design to the profile of each patient, but others, accounting for 80.9% of the full group, select the stabilization mechanism of the implant according to the patient's profile, including some isokinetic pre-operative measures: for Dr Jean-Marc Durand, a patient with a quadricipital moment of less than 1.6kg/N before surgery is best indicated for a PS variant of the Rolflex TONIC knee.

The BMI difference is more surprising and is not explained by the available dataset. For the average adult population, a BMI less than 25 indicates a "normal weight". When the BMI is above 25 and less than 30 the concerned population is "overweight", and above 30, the population is "obese". Therefore, this highly significant difference will need to be taken into account when comparing the clinical and survival results of the 2 groups as an increased BMI can potentially reduce the outcomes and increase the complications.

The statistical comparison of patellar resurfacing is not possible due to the low number of resurfaced patellae: 6.2% within the PS group and 6.4% within the UC group (*Table 9*).

But the comparative analysis provided an unexpected information: the proportion of polyethylene insert thicknesses turned out to be highly significantly different between the PS group and the UC group. In the PS group the large majority of the cases (61.6%) use a 10mm thick insert: the minimal thickness available, and only 4.1% are associated with a 15mm thick insert: the highest one available. The PS prosthesis is more constrained than the UC prosthesis, and due to the higher "jump distance" required to subluxate the prosthetic joint (minimum of 14mm included in the

Table 9.

Frequency of patellar replacement per variant of Rolflex TONIC

Patellar Replacement	PS Group	%	UC Group	%
None	196	93.8%	190	93.6%
PE implant	13	6.2%	13	6.4%

design), the PS implant can be used more securely in some deviated primary knees and in some low stage revisions: within the 4 Rolflex TONIC used to treat revision cases in this analysis, only one was a UC type, and was associated with a 15mm insert. The 3 others were of PS type with one 10mm insert and two 12.5mm inserts.

In comparison the UC group used only 51% of 10mm thick inserts, 35.6% of 12.5mm inserts, and as many as 13.4% (28 cases) of 15mm thick inserts.

The available dataset does not provide any information to explain this statistical difference, especially considering that both types of implant are implanted with the exact same instrumentation set. However, it will be highly interesting in the longer follow-up analysis to examine the possible correlation between the increased use of thicker inserts for the UC design, and clinical, functional or survival outcomes.

Both IKS and Oxford score comparison indicate that the clinical and functional outcomes of the UC group are better than the outcomes of the PS group: IKS and Oxford of the PS Group at 167.54 and 18.64 versus IKS and Oxford of the UC Group at 177.15 and 17.13, both differences are statistically relevant. This difference can be justified by the age difference between the 2 groups with a significant difference of 9 years on average, but can be contradicted by the BMI difference between the 2 groups with a 1.47 point of increased BMI for the UC group. The difference cannot be explained by a different average follow up: the average follow-up for the PS group is 10.4 months for the IKS and 15.9 for the Oxford, versus for the UC group respectively 10.4 and 15.0.

The Kaplan Meier survival analysis have shown no statistical difference between the 2 groups, would it be for any cause of revision or for implant-related reasons. For any cause of revision, the PS group survival rate is 98.4% at 3.51 years of maximal FU versus 97.8% at 3.36 years for the UC group. The statistical difference is not significant. And when the analysis is restricted to the "implant-related" causes alone, the estimate of the PS group is 100% at 3.51 years of maximal FU versus 98.9% at 3.36 years of maximal FU for the UC group. In the analysis also the statistical difference is not significant.

Conclusion

The current analysis document is for regulatory information purpose only. It has to be considered only as a snapshot of the clinical status of the Rolfex TONIC mobile bearing patients at mid-way of a 2 years review of a multicentric study. The complete results will be available once all patients included in the study up to December 2018 will have been evaluated at 24 months of minimal follow-up, which is expected in semester 1 2021. This document is intended for demonstration of the on-going study, and provides a partial view of the clinical and functional results and an analysis of the complications that have been recorded during the short use of a large number of surgeries. Under this aspect it already provides useful information regarding the safety of use of the device.

The analysis demonstrates very good clinical and functional performance of both variants of the Mobile bearing device. At closely identical length of follow-up the UC variant shows better IKS and Oxford results, but the results of the PS variant are also very good, especially considering that the average age of the patients in the PS group is nearly 10 years older than the average age of the patients in the UC group. And in both groups, the frequency and type of complications, and the survival analysis with a Kaplan-Meier methodology show identically good results with 0.5% of implant-related revision for the full group at the maximal follow-up of 3.51 years (mean FU at 10.4 months).

Logically this intermediary analysis will need to be confirmed by the full 2 years review planned for availability in 2021. The full 2 years review will also be an opportunity to evaluate the outcomes related to 2 specific differences that have been identified between the PS and the UC group: the comparative thickness of the polyethylene liners used which showed a tendency for thicker inserts in the UC group, and the average BMI of the patients in each group which showed that the patients selected for a UC variant of the Rolflex TONIC knee are more obese on average than the patients in the PS group. Both of these statistically significant differences will have to be assessed specifically for correlation on the outcomes of the device.