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Observational Study of the Complications, Functional Results, and Survival of a Rotating Bearing Cruciate Retaining Ultra-Congruent Total Knee Prosthesis at 5 years of minimal follow-up.

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Summary

2 senior surgeons in 2 private hospitals in France have reviewed a consecutive series of patients admitted for primary TKA surgery and implanted with a cruciate sacrificing rotating bearing Ultra-Congruent type of knee prosthesis. A large proportion (84%) of fully cementless components were used. 108 patients were included in the study and evaluated at a minimum of 5 years of follow-up. The mean follow-up was at almost 7 years. A complete complication analysis was made including the co-morbidities with or without impact on the final outcomes. There had been a proportionally high number of complications related to post-operative trauma, which can be considered as usual for a population of this age. The results demonstrate that the use of cementless components have had no impact of the survival rates with a final KM rate for implant related retrieval at 97.1% at 9.15 years of FU. The clinical and functional outcomes demonstrate a high level of subjective satisfaction (95.05%) and 95% of Good or Excellent results. Almost 92% of the patients live with a pain free knee, and 90% have a perfectly oriented (within +/-2° from target HKA) and stable knee. The use of this TKA has delivered satisfactory long-term outcomes in the 2 institutions and has proved to be safe for use.

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Introduction

We report the survival analysis, the functional performance and an analysis of the complications of a **multicentric observational study of 2 consecutive series** of total knee arthroplasty implants (*Rolflex UC, Evolutis, Briennon, France*) for a total of 108 arthroplasties at 5 years of minimal follow-up (*mean FU of 6.94 years*).

The data was collected prospectively in one centre (operator Dr Rifai, *Clinique Mathilde, Rouen, France*) and retrospectively using the patients' files held in the hospital for the preoperative and the short-term follow-up data and prospectively for the latest follow-up data in the other centre (operator Dr Bouxin, *Institut Orthopédique Calot / Fondation Hopale, Berck-sur-Mer, France*).

The data was recorded on a dedicated hip and knee clinical study database (*OrthoWave™ V6, ARIA sarl, 6 rue G.Clémenceau, Houdain, France*). The collection of data included the epidemiologic information, the operation notes with the characteristics of the implants used, the complications and the status of the devices at any period of the evaluation, and the IKDC (*International Knee Documentation Committee*) score and the OXFORD Knee score. The IKDC was calculated when the patient was available for physical evaluation, and the OXFORD was calculated when the patient could not return for physical evaluation.

Casuistic

The patients operated in the Clinique Mathilde (group 1) by Dr Rifai were admitted for surgery between January 18, 2007 and January 6, 2011 for a total of 62 TKA procedures for 57 patients.

The patients operated in the Institut Calot (group 2) by Dr Bouxin were admitted for surgery between November 25, 2010 (date of first use of the device) and December 17, 2013 for a total of 46 TKA procedures for 45 patients.

The mean age at the operation for the 102 patients was at 70.2 years, ranging from 43 to 90. The gender proportion was standard with 68.6% of female patients (n=70) versus 31.4% of males (n=32), and with 53 right sides versus 55 left sides.

The aetiology was also standard with a large proportion of arthritis (90.8%), metabolic and neurologic for 3.7%, post-trauma for 3.7%, and necrosis for 1.8%.

Method

The TKA device evaluated in the study has been in clinical use since 2007. It is a UC (Ultra-Congruent) and rotating bearing cruciate sacrificing primary total knee prosthesis. The device can be implanted with or without acrylic bone cement for both the femoral condyles or the tibial baseplate. The patella resurfacing is not compulsory and is dependent on the decision of the operator, but when selected for implantation the component can only be used with cemented fixation.

The inclusion of patients and the collection of clinical and functional data for the series of the Clinique Mathilde began from this initial date of use and was terminated at the end of year 2010. The second centre (*Institut Calot*) began using the device in 2010 and included patients up to end of 2013. The average follow-up for the 2 centres is at 6.94 years (6 years and 11 months) for the 101 arthroplasties that could be evaluated either with an IKDC score or an Oxford questionnaire, or both.

The patients were admitted for surgery according to the standard indications of primary TKA indications: bi-compartmental or tri-compartmental arthritis of the knee joint, with less than 15° of varus or valgus deformity for patients of all age or weight, in capacity to be compliant with the usual post-operative recommendations, with a reasonable level of autonomy (excluding patient living in a healthcare institution), benefiting from the national health insurance scheme, and having understood and accepted the conditions of the study. Revision cases were a priori excluded unless the bone stock and the status of the collateral ligaments could be considered as intact and functional. Patients admitted for trauma and/or presenting co-morbidity risks (infection, general health status, neurologic disease…) were also excluded.

The group 1 patients were recalled for evaluation between December 15, 2016 and March 3, 2017. They were evaluated by their surgeon (*Dr Y.Rifai*). In this group, 4 patients were not recalled as they had previously been evaluated at more than 5 years of FU in the general control procedure of the arthroplasty. 5 other patients had the opportunity to return for longer term evaluation between May and November 2018.
The group 2 patients were recalled for evaluation by a resident doctor (*Dr Jad Chbib Abi Raad*) between April 25, 2018 and October 14, 2018. In this group, 2 patients did not need to be reviewed as they had already been evaluated at 5 years of FU in 2017.
Following this procedure 102 patients could be questioned for evaluation. 3 patients had deceased, and 3 patients could not be contacted following the recall procedure including 3 phone calls and a written mail invitation. The 3 patients were finally considered as lost-to-follow-up.
The reviewed patients have been questioned according to the study plan for the status of the arthroplasty at the latest follow-up, for the complications if any, and for the functional performance of their articulation.
The functional evaluation was made primarily with an IKDC score when the patient could be physically evaluated, or could be questioned with an OXFORD knee score for a subjective evaluation of the patient when the patient could not return for physical evaluation.
The data collected aimed primarily at calculating the revision rate of the TKA through the recording of the revision procedures for partial or total revision and including the causes of failure of the arthroplasty. The survival calculation was made according to the Kaplan-Meir methodology for failure of the arthroplasty for any cause of failure for the total or any partial component as endpoint and for implant related failure only as endpoint.
The evaluator was also requested to record all complications reported by the patient at any period of the follow-up. The complications have been analysed in details and classified for relation to the performance and survival of the arthroplasty.

Results

According to the selection criterions 108 arthroplasties were identified for inclusion to the study. Despite the high mean age at time of operation (70.2) and a correlated high mean age of 76.67 years at time of evaluation, there had only been 3 patients deceased and 3 patients lost-to-follow-up, leaving 102 patients available for the 5 years minimum analysis (mean FU 6.94 years [4.42-10], sd:1.46).
The implants used were mainly implanted without cement and with a patellar component. A patellar component was used in 92.6% (n=8) of the cases. On the femoral side 84.2% (n=91) of the condyles were uncemented versus 15.7% (n=17) of cemented versions. On the tibial side 77.7% (n=84) of the baseplates were uncemented versus 22.2% (n=24) of cemented versions.
As a result, there was a majority of cementless TKA (77.7%, n=84), 15.7% (n=17) of cemented TKA, and 6.5% (n=7) of hybrid TKA.

Complications

29 patients (28.7%) were recorded for complications *(Table 1)*. There was no intra-operative complication reported.
5 patients (4.9%) were recorded for complications related to co-morbidities such as post-operative haemorrhagic anaemia, pulmonary embolism, or deep vein thrombosis. After a short recovery period all these 5 patients (were able to proceed with the standard post-operative care protocol and at the final evaluation all of them were measured with an Oxford score ranging between 13 and 17, and an IKDC score at 199 for three of them. None of them required revision of the implants.
17 more patients (16.8%) were also concerned with co-morbidities, but with direct effects on the performance of the arthroplasty. These are classified “Surgery associated with co-morbidities” in the complications table *(Table 1)* presented below. Among these 16 patients the main symptoms were either a persistent pain (9 cases) or the development of a Sudek’s atrophy (5 cases) with an

associated reduction of the functional performance of their knee: articular stiffness, reduction of walking range, stop of the physiotherapy program. In some case there was a suspicion of associated back-pain. And for 3 patients the complication was related to a post-operative flexum of 10°, a peri-articular heterotopic ossification, and an infection that was treated with an antibiotherapy. For this group of complications none required the revision of the implants, but the final outcomes were diverse. For 9 of them the final OXFORD score was evaluated between 12 and 17 at a period of evaluation ranging from 4 to 6 years, and including one patient presenting a severe obesity at 43.8 of BMI. When available the IKDC score for these 9 patients ranged between 141 (51+90) to 199 (99+100). For the remaining 8 patients in this group the Oxford evaluation range between 21 at 6 years of Fu and 54 at 4 years of FU. The worst result was also measured at 46 on the IKDC score and concerns the younger patient of the series which was implanted at the age of 43 and following a previous surgical failure of tibial osteotomy associated with an anterior tibial tuberosity transposition. This 1.80m and 110 kg patient had a limited knee function immediately following the surgery with a fixed flexum at 10° and soon after developed a Sudek's atrophy. The cementless implants have not been revised despite a suspicion of migration of the patellar component. Part of the other patients in this complication group were also characterized by a high BMI (at 40 for one patient) or a high age (superior to 80 for 2 patients).

In the remaining 7 patients with complications, 2 were classified C1 (Failure/Retrieval), 1 B4 (Failure trauma or not implant related), and 2 BT (Not implant related tibial retrieval). The remaining 2 patients had been victim of a post-operative trauma affecting the patella only, one was treated orthopaedically and the other surgically. For this latter the bone healing was not achieved and the patellar component loosened, despite which the patient was evaluated with an Oxford score at 15 at the 5 years FU review. The other patient aged 76 at the operation was evaluated at Oxford 28 and IKDC 145 at the latest FU review (4years).

3 patients (2.9%) required complete revision of the total arthroplasty at post-operative periods ranging from 1 to 5 years. The 1-year total exchange was justified by the rupture of a lateral ligament of the knee for a 76 years old female patient. This complication was classified B4 as the rupture of a collateral ligament cannot be implant related. Following the rupture, the articulation became unstable. The implant was retrieved and replaced by a hinged prosthesis. The $2^{1/2}$ years total exchange was a bi-component aseptic loosening of a cementless prosthesis at a 76 years old male patient, the TKA was exchanged for the same components with cemented fixation. The polyethylene insert initially of 8mm thick was exchanged for a 12mm new one. And the 5 years total revision was in fact the long-term conclusion of a complication initiated 2 years before with a scintigraphic examination showing that the instability felt by the patient could be related to the loosening of the femoral and patellar components. The severe obesity female patient with a BMI at 43.8 (115 kgs) waited for her knee to dislocate intermittently to decide for the revision.

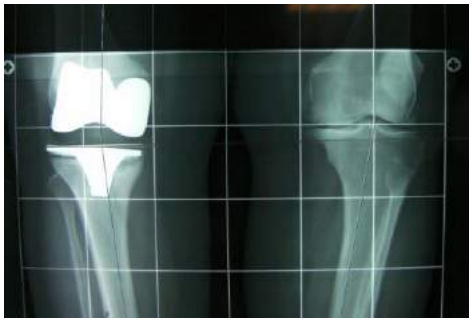
One medium obesity (BMI 31.2) but young (55years at operation) female patient required an

Table 1: Complications table.

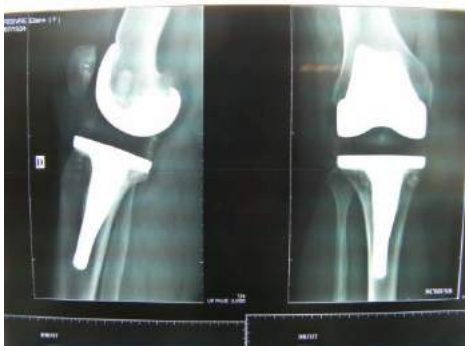
Series number	Patient details	Delay	Complication type	Classification complication	Status	Latest FU
6	Aged 74 at operation	Permanent since the operation	Persisting pain. Back pain at 4 months. Persistant at 44 months with reduction of walking ability.	Surgery associated with co-morbidity	A: On-file	Oxford 39 at 5 years FU.
10	BMI at 39.2 Medium obesity. Aged 70 at operation	1 week	Pulmonary embolism, anemia, asthma	Co-morbidity	A: On-file	IKDC 99+100 at 5 years of FU. Oxford 13.
11	BMI at 38.6 Medium obesity.	3 months	Heat / inflammation	Co-morbidity	A: On-file	IKDC 99+100 at 6 years of FU. Oxford 16.
18		Permanent since the operation	Immediate post-op thrombosis. Sudeck's atrophy. Permanent pain	Surgery associated with co-morbidity	A: On-file	Oxford 36 at 5 years FU.
21	Aged 76 at operation	14 months	Peri-prosthetic proximal tibial fracture following a fall on the knee. Undisplaced. Treated orthopaedically.	Post-operative trauma	A: On-file	IKDC 75+70 at 4 years of FU. Oxford 28.
22	Aged 74 at operation	Immediate post-op	Deep vein thrombosis	Co-morbidity	A: On-file	Oxford 13 at 4 years FU.
23		4 months and 3 years	Articular stiffness treated by physiotherapy. Associated with back pain.	Surgery associated with co-morbidity	A: On-file	Oxford 13 at 4 years FU.
25		6 weeks	Stiffness associated to Sudeck's atrophy	Surgery associated with co-morbidity	A: On-file	Oxford 15 at 5 years FU.
32	BMI at 33,2 Medium obesity. Aged 70 at operation	Immediate - 6 months	Post-operative anemia, painful inflammation at 4 months, Sudeck's atrophy at 6 months	Surgery associated with co-morbidity	A: On-file	IKDC 85+90 at 6 years of FU. Oxford 16.
35		Immediate and permanent	Post-operative anemia, painful scar and articular stiffness after 1 year, Sudeck's atrophy at 16 months, persisting pain	Surgery associated with co-morbidity	A: On-file	Oxford 27 at 7 years FU.
38	BMI at 38.7 Medium obesity	1 month	Articular stiffness treated by mobilization	Surgery associated with co-morbidity	A: On-file	Oxford 13 at 4 years FU.
43	Aged 72 at operation	1 week	Pain, infection, stiffness. Local treatment.	Surgery associated with co-morbidity	A: On-file	Oxford 30 at 4 years FU.
45	BMI at 40.4 Severe obesity	1 week	Infection Escherichia Coli + Klebselia pneumonia. Antibiotherapy.	Surgery associated with co-morbidity	A: On-file	Oxford 15 at 6 years FU.
46	BMI at 43.8 Severe obesity	15 days - 57 months	15 days pain. 2 years pain + stiffness. 3 years Vein thrombisis + pain. 40 months implant instability with femoro-patellar dislocation. 4 years femoro-tibial subluxation. 57 months complete retreival of implant.	Implant aseptic loosening	C1: Failure (retrieval)	IKS 43+0 at 3 years.
50	BMI at 32.4 Medium obesity. Aged 73 at operation	Immediate	Deep vein thrombosis	Co-morbidity	A: On-file	IKDC 99+100 at 6 years of FU. Oxford 17.
54	Aged 80 at operation	18 months / 5 years	15 months stiffness and pain, reduction of walking ability. 5 years persistent chronic pain.	Surgery associated with co-morbidity	A: On-file	Oxford 26 at 6 years.
59	Aged 76 at operation	1 year	Knee instability, lateral ligament rupture. Exchange of primary TKA for a hinged prosthesis	Implant failure	B4: Retrieval (Trama./Not implant related)	IKDC 20+65 at 9 months.
63	Aged 74 at operation	14 months	Exchange of tibial implant for intercurrent cause (technical error in the orientation and positioning of the component). Component did not have the opportunity to fix. Exchanged for cemented and keeled component.	Technical error	BT: Tibial retrieval (Not implant related)	IKDC 99+100 at 7 years FU.
65	Bilateral TKA with Rolflex UC	4 months	Persistent pain (right knee)	Surgery associated with co-morbidity	A: On-file	IKDC 96 + 100 at 4 years. Oxford 16.
67	Aged 77 at operation	Post-op / 3 months	Deep vein thrombosis immediate post-op. 3 months avulsion of the patella and fracture. Surgical repair did not consolidate and patella component loosened at 1 year.	Post-operative trauma	A: On-file	Oxford 15 at 5 years FU.
68		3 months	Articular stiffness. Mobilization under anesthesia. At 5 months pain is persitant.	Surgery associated with co-morbidity	A: On-file	Oxford 17 at 5 years FU.
69	BMI at 33.9 Medium obesity. Aged 43 at operation	2 months / 1 year	Flexum at 10° 2 months. 1 year development of Sudek's atrophy.	Surgery associated with co-morbidity	A: On-file	IKDC 46+0 at 4 years. Oxford 54.
75	BMI at 34.6 Medium obesity. Aged 72 at operation	Immediate post-operative	Hemorragic anemia	Co-morbidity	A: On-file	Oxford 17 at 5 years FU.
78	Aged 80 at operation	21 months	Heterotopic peri-articular ossification treated surgically.	Surgery associated with co-morbidity	A: On-file	Oxford 21 at 6 years FU.
90		3 months	Persistent pain	Surgery associated with co-morbidity	A: On-file	IKDC 51+90 at 5 years. Oxford 17.
91	Aged 73 at operation	29 months	Failure retrieval of complete cementless prosthesis. Replaced by same cemented prosthesis.	Implant failure	C1: Failure (retrieval)	IKDC 99+100 at 3 years after replacement.
98	BMI at 31.2 Medium obesity. Aged 55 at operation	9 years	Tibial insert was exchanged after 8 1/2 years of implantation for trauma induced instability and replaced with a 4mm thicker insert.	Post-operative trauma	BT: Tibial retrieval (Not implant related)	IKDC 100+100 at 9 years FU.
99	BMI at 40 Severe obesity. Aged 70 at operation	Post-op / 3 months	Post-operative hemorragic anemia + diabetes mellitus. 3 months stop of physiotherapy for pain.	Surgery associated with co-morbidity	A: On-file	Oxford 28 at 6 years FU.
104	Aged 76 at operation	Post-op	Persistent pain.	Surgery associated with co-morbidity	A: On-file	IKDC 99+100 at 5 years. Oxford 12.

exchange of the polyethylene insert following a trauma 8 ½ years after implantation. The patient fell and immediately after her knee began to subluxate. In order to avoid retrieving the well-fixed tibial and femoral components and exchange with a more constraint device, it was decided to simply reduce the articular gap with a thicker new insert. 6 months after the exchange of the insert, the patient is back to full function and no pain with a passive flexion at 125° and an unlimited walking range.
The last complication patient was revised for exchange of the tibial cementless baseplate after 14 months of implantation. This case was classified as a technical error: the X-ray images show that the articular deformity in varus alone increased by the medial compartment wear was a possible contra-indication to a low stabilization PS TKA such as the Rolflex UC. The post- operative control x-ray (*Pict 1*) evidences the wrong positioning of the implant which is properly sized but maintained in varus orientation and shifted laterally from the tibial epiphysis by around 5mm. Such lateral shift was responsible for persistent pain and reduction of mobility: for this female patient of 74 years old and at the 11 months review, the active flexion was limited at 100° and the pain was moderate but permanent. The tibial baseplate loosening was confirmed by the 12 months radiographic exam *(Pict 2)*. When revised, the tibial baseplate positioning was corrected for orthogonality with the tibial axis and its stabilization was completed with a long intramedullary keel *(Pict 3)*. At the latest review (7 years of FU) the knee of this patient was perfectly fixed, and the 82 years old patient was benefiting from a stable knee (less than 5mm of A/P slide and less than 5° of medio-lateral swing) and could bend her knee up to 120° in active flexion. The corresponding IKDC score at 7 years of FU was at 199/200.

Pict 1: Immediate post-operative control for patient 63.



Pict 2: 12 months control x-rays for patient 63.



Pict 3: Revision post-operative control x-rays for patient 63.

Survival analysis

The survival analysis has been calculated according to the Kaplan-Meir methodology for different endpoints.
When calculated for failure related to implant (C1), the survival rate is at 98.6% after 5 years and at 97.1% after 9.15 years *(Table 2 and Chart 1)*.

Période	N en cours	N censurés	N sortis	N final	Taux de survie	Charge révisionnelle	Erreur standard	-0.05	+0.05
0 - 2.38	107	3	0	104	1	0	0	1	1
2.38 - 4.99	104	8	1	95	0.986	0.014	0.013	0.961	1
4.99 - 9.15	95	64	1	30	0.971	0.029	0.02	0.933	1

Table 2: Kaplan Meir table for survival of Rolflex UC TKA for failure related to implant

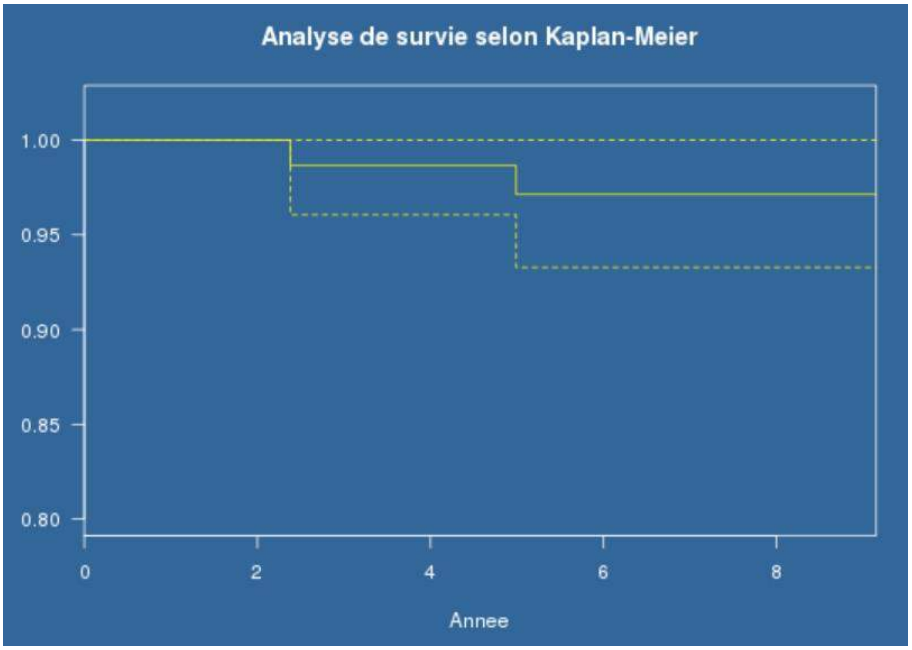


Chart 1: Kaplan Meir chart for survival of Rolflex UC TKA for failure related to implant

There had been 2 isolated revisions involving to the tibial component (1 for technical error, 1 for long term polyethylene wear) and no revision involving the isolated femoral component.
When considering the survival rate for any reason as endpoint (C1+CT+CF+B3+B4+BT+BF) *(Table 3)* including the non-implant related failures, the survival rate lays at 96.1% at the 5 years milestone on the basis of 96 TKA analysed, and at 88.4% at the 9.15 years of maximum follow-up but on the analysis of only 30 implants. The large confidence interval for this data indicates the low statistical value of this figure.

Période	N en cours	N censurés	N sortis	N final	Taux de survie	Charge révisionnelle	Erreur standard	-0.05	+0.05
0 - 1.04	109	1	0	108	1	0	0	1	1
1.04 - 1.14	108	0	1	107	0.987	0.013	0.013	0.963	1
1.14 - 2.38	107	1	1	105	0.974	0.026	0.018	0.94	1
2.38 - 4.99	105	8	1	96	0.961	0.039	0.022	0.919	1
4.99 - 8.58	96	50	1	45	0.947	0.053	0.026	0.897	0.999
8.58 - 9.15	45	14	1	30	0.884	0.116	0.066	0.764	1

Table 3: Kaplan Meir table for survival of Rolflex UC TKA for failure related to any cause

Functional outcomes

The patients have been evaluated for pain and function at the latest follow-up period on the basis of an IKDC score or on the basis of an OXFORD Qualitative questionnaire, or both when possible.
74 patients could be evaluated totally with an IKDC score and 39 were completed with an OXFORD questionnaire. The methodology of calculation of the OXFORD questionnaire in the Orthowave database is the “genuine” methodology: the lowest the figure, the best the result. The maximum score for a perfectly painless and fully functional patient is 12, while the worse result is 54.
The mean age at the latest evaluation period was at 76.6 for the IKDC group and 73.4 for the OXFORD group. The latest follow-up global mean IKDC score was at 194.5 (range [46-200], sd.19.18) which translates in 91.4% of Excellent results, 3.6% of Good results, 1.2% of Fair results, and 3.6% of Bad results. On a subjective scale of evaluation 95.05% of the patients claimed that they felt the performance/pain of their knee had improved since the previous evaluation, 1.98% felt it was unchanged, and 2.97% felt is had degraded.
The OXFORD qualitative global mean score was at 19.7 (range [12-54], sd.8.89).
In the details of the IKDC score analysis 91.9% of the patients had no pain at all (5.4% occasional, 1.35% mild when walking, and 1.35% severe pain), and the same proportion could benefit from an

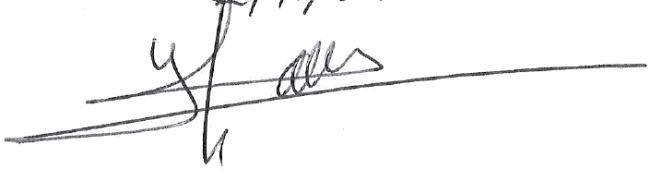
unlimited walking range and without need for assistance. Only one patient was in need for the help of crunches to walk up to 500m of distance.
90.5% of the patients had a final HKA value (Hip-Knee-Ankle axis) within the +2/-2 range. The mean HKA value was calculated at -0.3° from the 180° target (range [-6-12] sd.2.04). In the OXFORD questionnaire, 89.8% of the patients claimed that their knee was perfectly stable. The remaining (10.2%) were also satisfied with only slight instability felt during the beginning of use.
The mean passive flexion was at 117.9°, with 68.3% of the patients able to flew at 120° or more.

Conclusions

This observational study aimed at confirming the security of use through a complications and Kaplan-Meir survival analysis, and at evaluating the long-term functional outcomes of a cruciate sacrificing Ultra Congruent rotating bearing primary TKA. 2 consecutive series of patients in 2 hospitals operated by 2 senior surgeons have been evaluated at a minimum of 5 years after surgery and the collected data has been reported on a hip and knee clinical study database.
Despite the high average age of the patients at time of surgery (70.2 years), there was a limited number of patients deceased and a limited number of patients lost for follow-up recall, allowing for a large cohort to be evaluated.
The complications were duly recorded, including a large proportion of complications related to co-morbidities with or without impact on the outcomes of the arthroplasty. No intra-operative complication was recorded.
The mean follow-up for 102 patients is close to 7 years. 6 patients required revision including 3 for 1 total and 2 partial replacement for post-operative trauma causes. One other had a patellar complication (fracture) without component exchange and despite the worse outcomes of the series, the patient has not applied for revision.
The Kaplan Meier analysis for implant related causes demonstrates a 97.1% survival rate at 9.15 years of follow-up. And when considered for revision for any cause (including the post-operative traumas), the 5 years survival rate is at 96.1%.
The functional scores demonstrate a high level of subjective satisfaction (95.05%) and 95% of Good or Excellent results. Almost 92% of the patients live with a pain free knee, and 90% have a perfectly oriented (within +/-2° from target HKA) and stable knee.
Despite the high ratio of use of fully cementless components (77.7%), the functional, clinical, and radiological outcomes of the Rolflex UC used in the 2 hospitals participating to this study, are satisfactory and confirm that the device is safe for use in primary TKA indications for any patient of any age not presenting an unreducible varus or valgus deformity, and eligible for knee replacement.

Approvals

Dr Yasser Rifai
Date: 22/11/2018



Dr Jad Chbib Abi Raad
Date: 22/11/2018