Descriptive results of 41 rotating highly congruent and posterior-stabilized total knee arthroplasties with a mean follow up of 3.55 years

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Abstract

Rotation highly congruent TKA have been recorded for over 6 years on a routinely basis on Orthowave 6 CRO database for evaluation and post-market surveillance purposes. The present study analyses the preliminary results at a mean 3 years and 6 months of this TKA prosthesis with goals of assessing the functional scores, the complications, and the survival curve of the implant.

41 consecutive TKA have been implanted between 2007 and 2009 by the author operator. The casuistic is fully comparable to existing literature for usually elected patients for TKA on arthritis and necrosis indications.

Patients aged on average 70 years old at time of surgery, with a majority of female patients, and with an initial global IKS score of 77/200, were handicapped by severe pain and HKA deformity (34 varus vs 5 valgus).

2 TKA had to be revised within the evaluation period. One was a global revision for failure consecutive to a lack of constitutional varus deformity correction. The second was a fracture/collapse failure of the medial tibial plateau that would probably have been avoided if the original implant had been cemented.

The final IKS score reaches 194 on average, including one bad result for the global revision patient. The mean HKA value is close to the 180° "normal" value, yet leaving some selected varus cases with a slight hypo-correction. The flexion score is very satisfactory with a mean 119° translating into an improvement of close to 25° on average from pre-op situation.

In conclusion, the results need classically to be confirmed at longer follow-up, but despite 2 revision cases that could have been avoided by using a more adapted material, the improvement in pain and function from the pre-op situation is very positive and confirms the author in his use of this implant for the majority of his TKA indications.

Résumé

41 prothèses totales de genou rotatoires à stabilisation par congruence et de première intention ont été revues par l'auteur au recul moyen de 3 ans et demi. Les données cliniques sont reportées en routine sur une base de données de type CRO dans l'objectif d'évaluer le dispositif implantable et d'assurer sa sécurité clinique dans sa phase post-marketing.

L'étude vise à analyser les performances fonctionnelles, les complications et le taux de survie des implants au plus grand recul.

41 PTG (38 patients) ont été implantées entre 2007 et 2009 par l'auteur. La casuistique de la série est strictement comparable aux études disponibles dans la littérature scientifique pour des patients atteints de gonarthrose ou de nécrose.

Les patients, majoritairement des femmes, étaient âgés en moyenne de 70 ans à l'intervention. Le score global IKS était de 77 points en per-opératoire, justifié par une douleur intense et une difformité axiale marquée (34 génu-varum et 5 génu-valgum).

2 patients ont subi une révision partielle ou totale de leurs implants. Une révision globale a été consécutive au descellement du plateau tibial expliqué par une insuffisance de correction d'une difformité constitutionnelle majeure fixée en varus.

Une révision partielle sur fracture/tassement du compartiment tibial interne aurait probablement été évitée par la mise en place initiale d'un plateau tibial cimenté.

Le score global IKS moyen s'établit au dernier recul à 194 points, incluant un mauvais résultat correspondant au patient ayant bénéficié de la révision globale.

La valeur HKA moyenne pour l'ensemble de la cohorte s'établit en léger varus proche du normo-axe de 180°, mais incluant plusieurs cas laissés volontairement en hypo-correction.

La flexion moyenne est à 119° et constitue une amélioration significative de près de 25° en moyenne par rapport à la mesure pré-opératoire.

En conclusion, les résultats restent à confirmer sur le long terme, mais malgré les 2 cas de révision qui auraient pu être évités par l'utilisation d'un matériel plus adapté, l'amélioration de la douleur –dans tous les cas- et l'amélioration de la fonction confirme l'auteur dans son utilisation de cet implant pour la majorité de ses indications de genou prothétique de première intention.

Introduction

This study is part of a Post Market Surveillance review of patients. The evaluator records the initial patient data at time of surgery and at each clinical follow-up review on a remote CRO database (Contract Research Organization: Orthowave 6) on a prospective registry basis.

The main goal of the evaluation is for the surgeon to evaluate his practice with this new rotating platform total knee prosthesis after more than 5 years of use. In addition the results of the study will provide the post-market surveillance data required by the notified bodies in the CE mark renewal procedures.

Material and method

The current review is based on the following data collection methodology:

- The CRO database is completed on a prospective and non-interventional basis: the surgeon creates a new patient file each time a new patient is admitted for total knee surgery. The data is recorded within a standard follow-up procedure.
- The initial file includes patient data, patient's surgical history and aetiology.
- The surgery report is completed in the immediate post-op time, and includes surgery complications –if any- and implants references. The file is usually completed the same day with immediate post-op x-rays.
- Patients are invited to follow a review calendar delivered when leaving the hospital. The review periodicity is normally 3 months, 1 year and every following year. It can be different in cases of complications, or adversely when the patient feels excessively confident in his prosthesis.
- At each follow up period, the patient is evaluated for IKS score (*chart 1*), x-ray analysis, and complications. Data is recorded in real time on the CRO database.

Apart from the initial follow up calendar, the patients are not re-summoned. Patients are reviewed as they come. Motivations for patients to come for the review appointments are of 2 types: either the patient strictly follows the review calendar, or the patient experiences problems or difficulties with their implant and visit the surgeon for a solution. The second motivation can have negative statistical effects on follow-up results.

The inclusion criteria include all usual indications for total knee replacement for patients aged 50 to 90 years old. These indications were mainly osteoarthritis of one or more articular compartments of the knee including genu-valgum, genu-varum and femoro-patellar. The clinical symptoms generally are an important cartilage wear combined with an axial deformity of the limb exceeding 10°, a flessum exceeding 10°, and a ligamentary instability.

The patients' data have been extracted from the database in May 2013. The extraction criterion was any primary total knee procedure included in the database from the beginning of the experience in January 2007 to December 31st, 2009. It was decided to retrieve no learning curve from the inclusion period.
The final cohort includes 41 total knee arthroplasties for 38 patients.

The average follow-up period of the cohort is 3 years, 6 months and 18 days. The minimum follow-up is 2.25 year (2 year and 3 months), the maximum is 5 years and 7 months *(chart 2).* 5 patients (12.2%) had more than 5 years of follow-up.

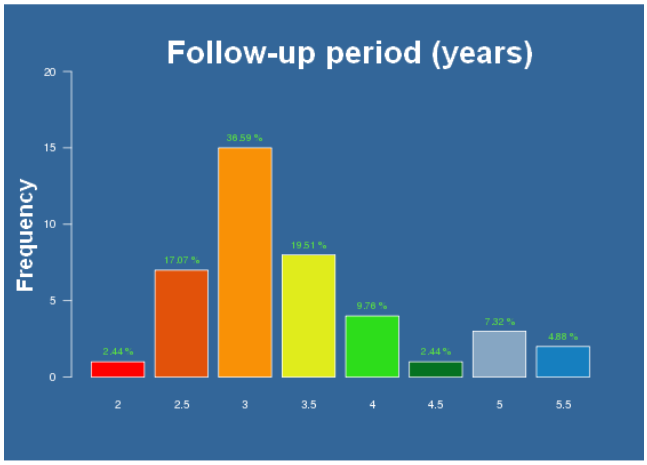


Chart 2: frequency of follow-up period

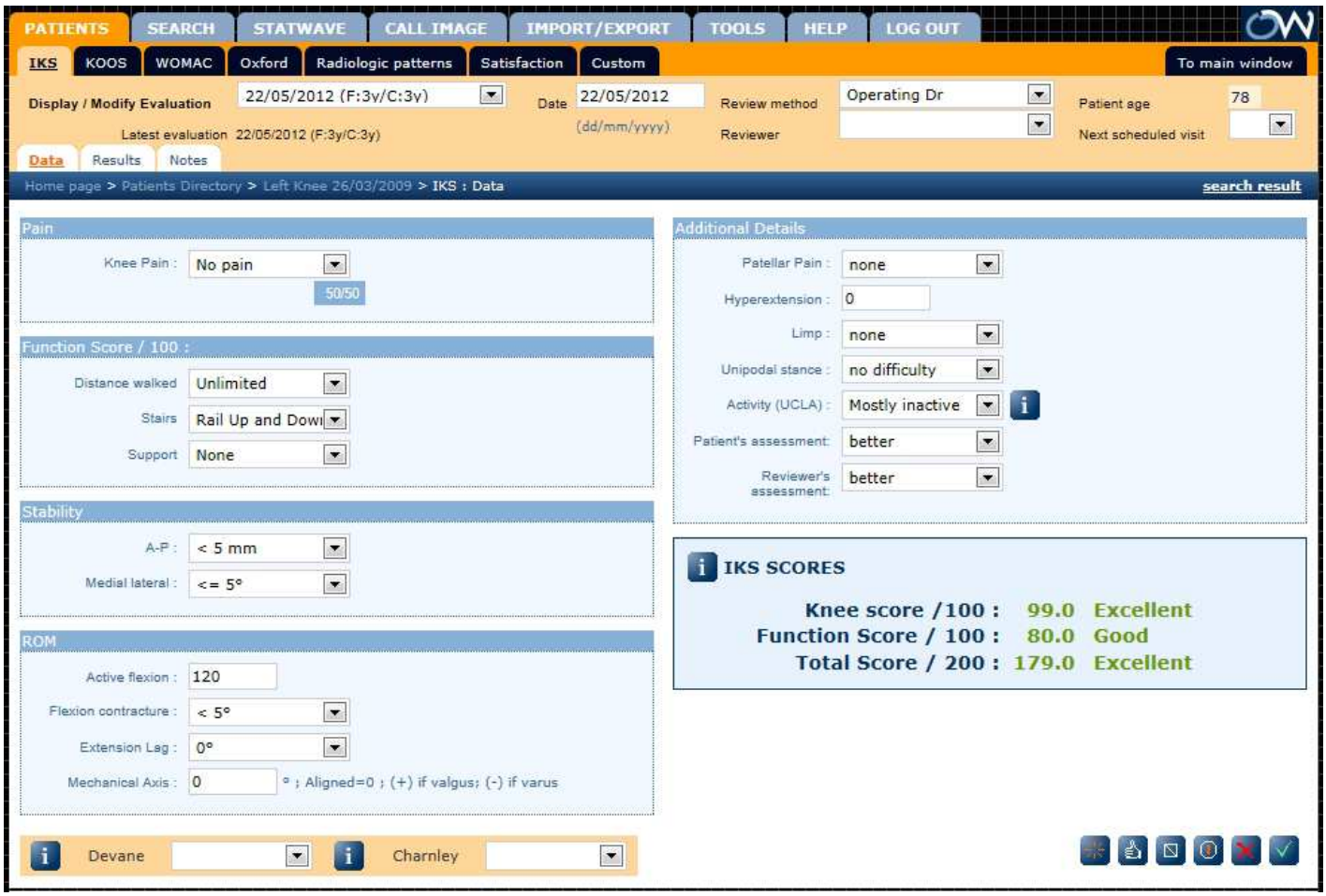


Chart 1: HKS Knee and Function score questionnaire on Orthowave CRO.

The age and gender of the patients admitted for TKA surgery was in compliance with the generally admitted criteria: no TKA before 50 years old, very seldom depending on the global health level above 90 years old and of course a majority of female patients. In the reviewed cohort, the patients were aged between 55 and 88 years old at time of surgery *(chart 3)*. The mean age was 70.34 years old, the standard deviation was 9.19. Female patients outnumbered the male patients: there were 29 women (76%) for 9 men.

Due to this high ratio of female patient, the mean height is low at 1.67m, ranging from 1.55m to 1.79m (sd: 7.2cm).

The mean weight at 73.6kgs includes a widespread distribution ranging from 53 to 105kgs. The wide weight range translates into a high mean Body Mass Index ratio of 26, with extremes ranging from 20.8 (1 female patient measuring 1.67m) to 40.0 (1 female patient measuring 1.62m) *(chart 4)*.

There was no ascendancy for any operated side: 21 TKA were implanted on a left knee (51%), and 20 on a right knee (49%).

All 41 TKA were initially indicated for primary implantations on degenerative arthritic diseased knees in 97.5% (40 cases) or necrosis (1 case: 2.5%).

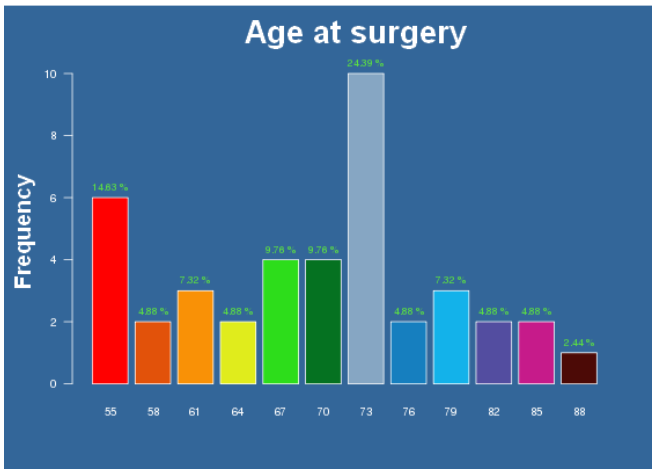


Chart 3: Frequency of age of patients at surgery time

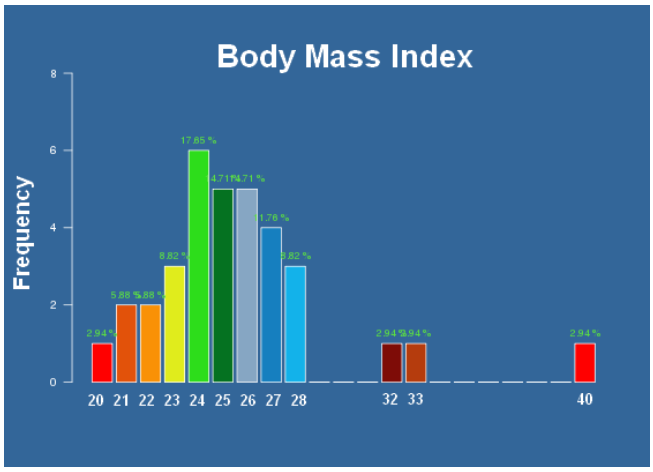


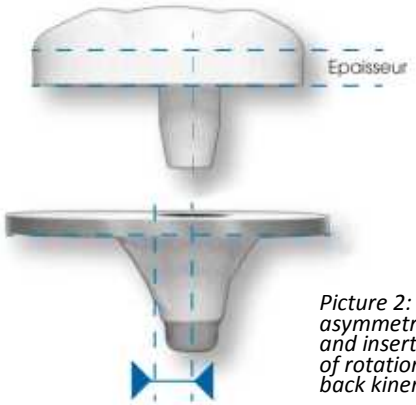
Chart 4: Frequency of body mass index

34 knees had a deformity in genu-varum. 5 knees presented genu-valgum deformity. 2 knees only had a 180° HKA before surgery.
8 patients had a varus deformity exceeding 10° (HKA 169° or less), while the valgus deformity, technically more demanding when considering prosthetic balance, were superior to 5° in 4/5 of the cases.
The surgeries occurred in 2007 for 11 of them, 2008 for 12 of them, and in 2009 for the remaining 18.

The implant used is a rotating platform "highly congruent postero-stabilized" total knee replacement prosthesis available in either anatomic *(picture 1)* or universal version, and in cemented or cementless components depending of the version.

Picture 1: Rolflex "Anatomic": a highly congruent stabilized rotating platform total knee prosthesis.

The universal component has a symmetrical trochlea on the femoral side, and a symmetrical tibial baseplate. The universal condyles and the baseplates can be used either on a left or on a right knee. The congruency and articulation of the universal condyles to the tibial insert is identical to the anatomic version so that there is no functional difference in between the versions, except for the length of the lateral trochlear bank. The universal components are of interest when inventory size and implant cost are a major issue.
The anatomic components have asymmetrical designs and cannot be used for both articulation sides. The femoral trochlea of the anatomic component has a longer lateral bank for improved patellar tracking. The tibial baseplate has a narrower lateral compartment and the rotating center of the tibial insert is slightly medial to increase the lateral gliding-sliding path during flexion, and reduce the "paradox" anterior move of the medial femoro-tibial contact *(picture 2)*.



Picture 2: Rolflex asymmetrical tibial baseplate and insert: medialized center of rotation for improved roll-back kinematics.

The ROLFLEX knee is designed and manufactured by Evolutis (Briennon, France). The **rotating and highly congruent TKA** market segment is very important in France as this sub-segment accounts for more than ¼ (27%) of the total French knee market (1).
Some other European countries like Germany, Italy, Austria and Switzerland also have a significant market sub-segment with this type of TKA, while UK, Spain and most north-European countries mostly prefer other type of postero-stabilization devices.

Among the cohort evaluated, the components used for the femoral side were mainly non- cemented (61%: 25 implants). On the tibial side 22 implants were cemented (53.7%) and 19 were non-cemented (46.3%). The choice of tibial fixation was made intra-operatively based on the quality of the bone stock.

The sizes used are in compliance with the female influence within the cohort: femoral sizes 1 & 2 were used in the large majority of cases (17 cases each size: 41.5%), while only 4 sizes 3 (9.8%) and 3 sizes 4 (7.3%) were used, all sizes 3 and 4 but one for male patients. The female influence is not so obvious on the tibial component side: a short majority of size 2 was used in

16 cases (39%), a size 3 in 12 cases (29.3%), a size 1 in 10 cases (24.4%) and a size 4 in 3 cases.
The tibial trays were in majority associated with 8mm thickness polyethylene inserts (35 cases: 85%). 10mm thickness inserts were used in 4 cases and 12mm in 2 cases.
All 10mm inserts were used for patients with initial varus HKA between -6° (174°) and -12° (168°), all 4 patients were corrected to a 180° HKA.
Both 12mm inserts are associated with post-operative complication and partial or total revision: the 2 patients had similar tibial plateau fracture and collapse at mid-term after surgery. For both cases, the initially 8mm insert component was changed for a 12mm insert to compensate for lower secondary tibial resection.
The patella resurfacing with a polyethylene component was decided in 34 cases (82.9%). 7 were left non-resurfaced. There was no statistical difference between the 2 groups for pain or function.

There was no intra-operative complication reported.

Results
41 arthroplasties were available for review with a mean follow-up period of 3 years and 6 months ([2.25 – 5.58] sd: 0.85).
39 have had no complication at either short or long term post-operatively.
2 (4.8%) cases were associated with implant failure leading to isolated tibial component replacement at 14 in one case and to total revision of both tibial and femoral component at 27 months after surgery:
The 14 months post-op complication was a 74 years old female patient at time of surgery, suffering from a severe medial tibio-femoral osteoarthritis induced by a constitutional genu-varum > 10°. The constitutional varus was due to epiphyseal deformity of both femur and tibia. It was decided initially to keep some varus in the prosthesis. Both components were cemented. The tibial resection was calculated to leave 5° of epiphyseal varus. A standard 7° valgus femoral component was implanted with correction of the distal cut to compensate for an important femoral valgus. The tibial insert had a 12mm thickness (initially 8mm).
At the one year evaluation review, the x-ray images showed a progressive tibial loosening associated with a fracture / collapse of the medial plateau, which was analyzed as the result of an excess of medial compartment loading *(picture 3)*.

Picture 3: Partial failure case: tibial baseplate loosening and collapse due to lack of genu-varum correction and consecutive overloading of medial compartment

It was decided to revise the total prosthesis with custom “adapted” implants: a new tibial baseplate was manufactured including a 4mm augment to compensate from the effects of the 90° tibial resection on the lateral tibial cortex, and a keeled femoral component was designed with a 12° valgus angle. The surgery evidenced a loosened tibial baseplate that was very easy to retrieve, but the femoral condyles were well fixed and it was decided intra-operatively not to change the femoral component. The tibial resection was aligned at 90° of the intramedullar axis and a long intra-medullar keel was fitted to the baseplate to resist potential remaining medial loadings *(picture 4)*. The final HKA axis is close to 180° and the patient aged 77 at time of latest evaluation scores at 199 according to IKS with a Function score at 100 and a Knee score at 99 with active knee flexion at 120°: she claims being pain free and better than before surgery.

Picture 4: Partial failure case: replacement of failed tibial baseplate with custom made baseplate including 4mm augment and long intra medullar keel.

The 27 months post-op complication was a 76 years old male patient who has been readmitted following an identical medial plateau fracture and collapse episode. The resulting genu-varum situation led to implant loosening. Only the tibial component was loosened but it was decided intra-operatively to revise the femoral component also. Both initially cementless components were revised with cemented implants. Since the revision the patient has not returned for follow-up.

Most patients had been reviewed in 2012 for 60% of the cohort (23 patients) and in 2011 for 26% of the cohort (10 patients). 5 patients were reviewed in early 2013.
The mean age at time of latest review is 74.1 years old, ranging from 58 to 91.

In conformity with usual principles of good practice in total knee arthroplasties, no patient were left with any valgus in post-op *(chart 5b)*. The accuracy of the instrumentation allows the operator to reproduce

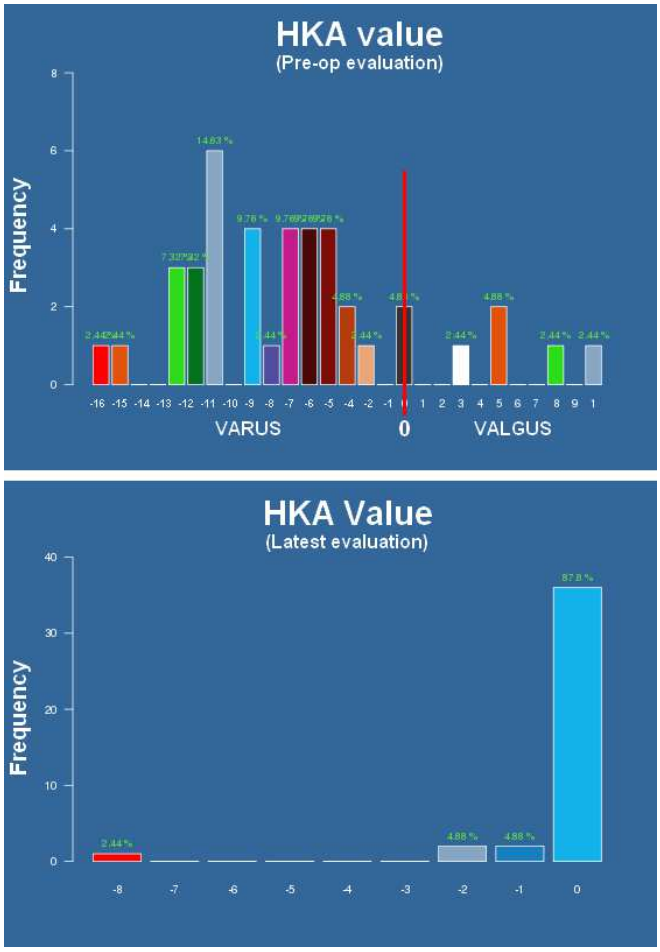
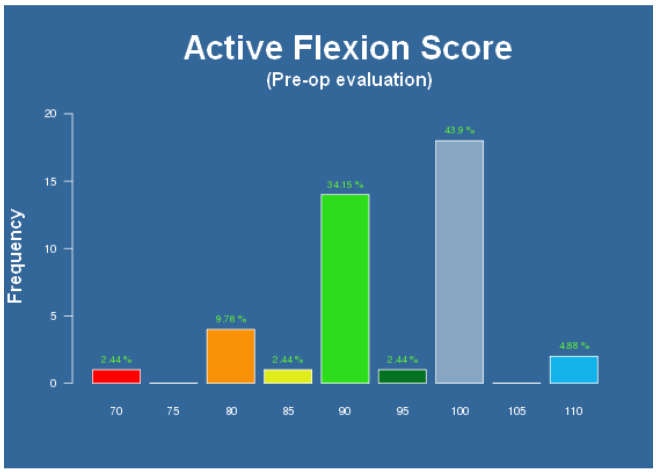


Chart 5a and 5b: Distribution of mechanical axis (HKA) at pre-operative and at latest evaluation

180° HKA when considered as possible according to the reducibility of the deformity. In the valgus group, all patients were re-aligned along the 180° HKA line. In the varus group, and except for the fully revised implant case, all patients but 4 (-1 and -2°) were intra-operatively aligned on the conventional 180° HKA. These 4 patients had an initial deformity ranging from -4 to -8°, and it was decided intra-operatively not to fully correct the deformity.
The mean HKA deviation is set in slight hypo-correction of varus deformity at -0.3° from 180°.
The patient which was revised for both components is the only one to keep an important varus (-8°) associated with a poor knee result (39/100). Despite a good flexion at 120°, his total IKS is only fair at 99/200.

In the pre-operative evaluation, the mean flexion for the group was set at 94° ([70-110], sd: 8.4).The mean active flexion value at latest evaluation was up to 118.8°, ranging from 100° to 130° with a standard deviation of 6.59 *(chart 6a & b)*. The average flexion gain from the pre-operative evaluation is 24.9°.
More significant: all patients but 2 are able to flex at minimum value of 110°, while at pre-operative evaluation, in the same group, all patients but 2 had a maximum flex capacity of 100°, and half of the total group could not flex more than 90°.
At latest evaluation, 30 patients (73.2%) have an active flexion of 120° or more. 3 patients – 2 women and 1 man (4 arthroplasties, 9.7%) - reach an active flexion of 130°.
At the other end 2 patients have an active flexion limited to 100°: all 2 are female patients with final IKS of 185 at 2 and 3 years of review. These patients aged 76 and 84 have otherwise good function and no pain, good walking ability and no need for assistance.
Despite a bad IKS score, the total revision patient is able to flex at 120°. The second revision case reaches the same flexion score.

In the details of the knee score *(chart 7a & b)*, all patients evaluated at the latest follow-up (41 cases, 100%) had less than 5mm antero-posterior and less than 5° medio-lateral stability assessment.
Most (40 cases, 97.5%) had a good extension with less than 5° of flessum, which is a significant improvement from the pre-operative situation where 9 patients (21.9%) had a flessum superior to 5° (including 2 patients with more than 16° of flessum).
At latest FU 1 case only had a slight flessum of less than 10°.



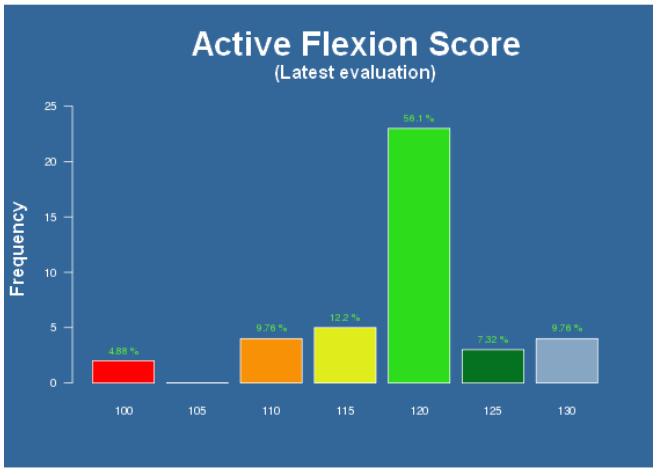
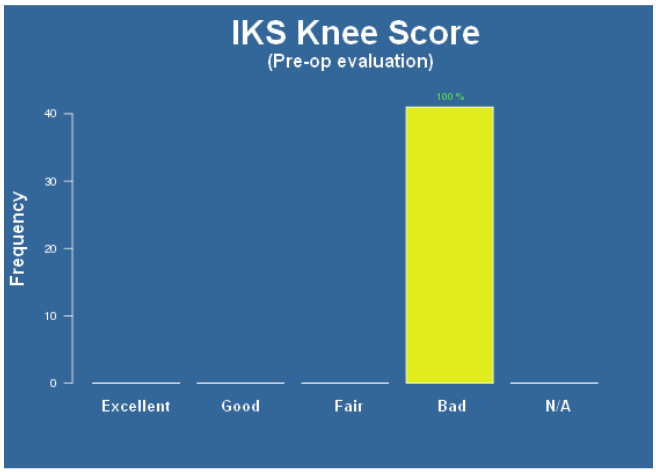


Chart 6a & 6b: Distribution of flexion score at pre-op and at latest evaluation



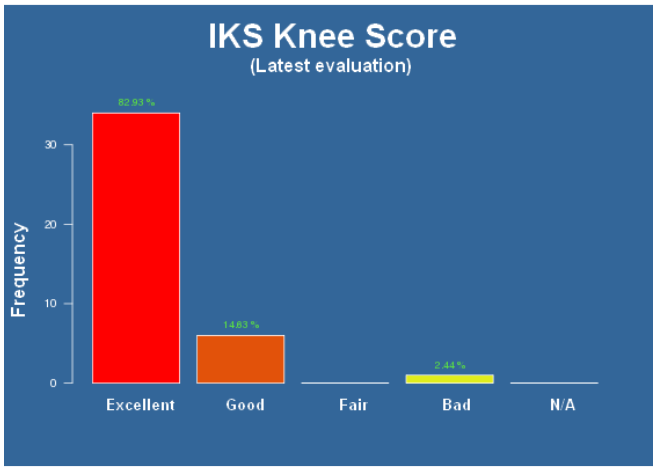


Chart 7a & b: IKS knee score at pre-op and at latest evaluation

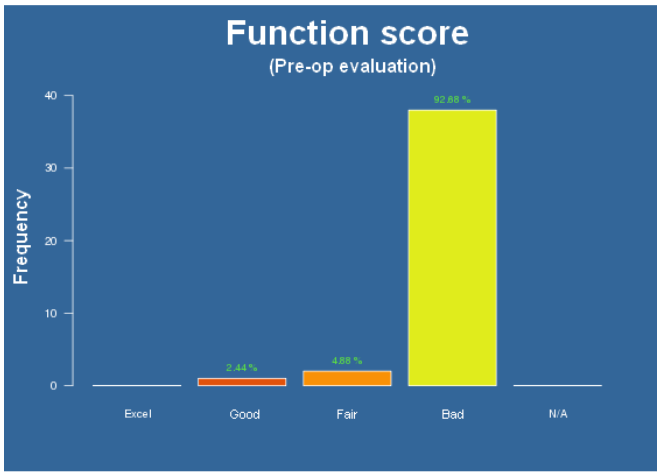
Consequently none were in recurvatum.

At the latest FU evaluation, 34 cases (82.9%) scored an "excellent" knee score, 6 cases (14.6%) scored "good", and 1 patient only (the total revision patient) scored "bad". Considering the initial pre-op evaluation where all 41 cases had been scored "bad", the results are very satisfactory.

When considering the function score *(chart 8a & b),* while 92.7% (38 cases) were scored Bad at the pre-op evaluation (2 scored "fair" and 1 scored "good"), most cases (36 cases, 87.8%) scored excellent at the latest follow-up, the remaining 5 cases (12.2%) were either good (4) or fair (1).
While only 1 patient was able to walk for an unlimited distance at the pre-op evaluation (36 could walk less than 500m, and 1 was limited to his residence), at the latest evaluation review, a large majority of the cohort (38 cases, 92.6%) could have an unlimited walk (according to age of patient), 2 patients (7.3%) could walk within a 1km perimeter, and 1 could walk within the 500m to 1km range.

It was slightly more difficult for the same 3 patients to climb stairs: while the 37 TKA of the 34 "unlimited walkers" had no difficulty normally climbing stairs, 2 of the "limited walkers" required the help of a rail to go both up and down the stairs. The last case had no data recorded for this item.
Nevertheless, none of the 37 patients needed the help of any walker, crutches or canes.

The global pre-op IKS mean score *(chart 9a)* was very low at 77.02/200, ranging from 21 to 119. The female patient scoring a 21/200 global score at pre-op evaluation was a 72 years old lady with normal weight, but suffering from severe pain, low flexion ability, HKA at 169°, housebound, unable to use stairs and assisted by a walker. At latest evaluation, this patient aged 76 years old has no functional difficulty left and has a global IKS score of 199.
At the latest review the global IKS score *(chart 9 b)* of the 38 patients (41 TKA) aged 74.1 years old on average, with a mean 3.55 years FU period, reaches 194.2, ranging from 99 to 200, standard deviation of 15.99. The standard deviation is high due to the global



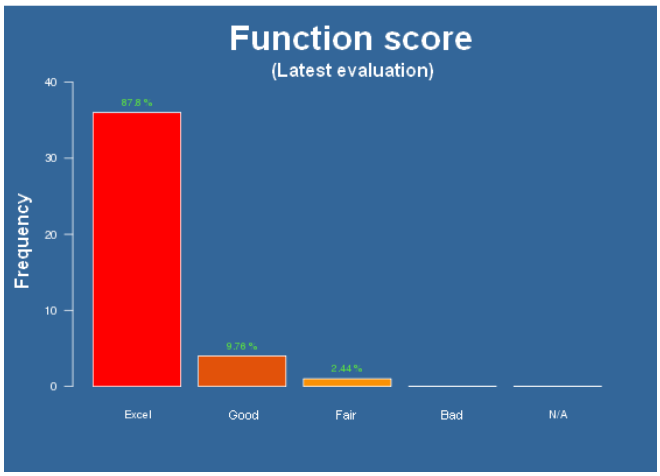
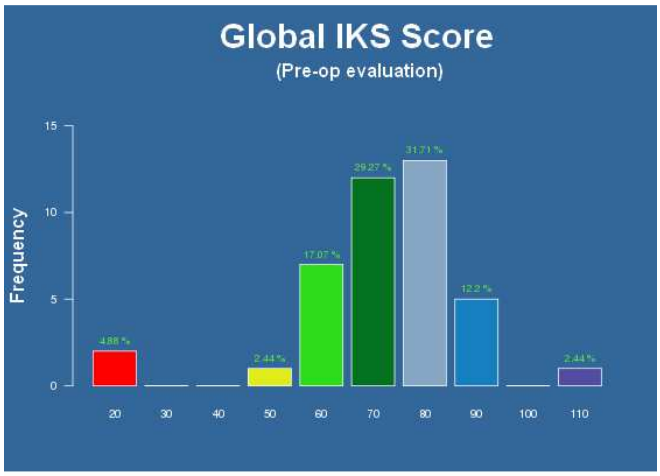


Chart 8a & b: IKS function score at pre-op and at latest evaluation



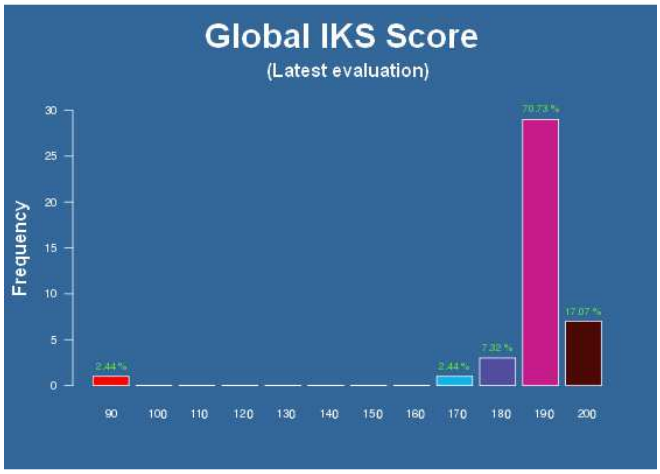


Chart 9a & b: IKS GLOBAL score at pre-op and at latest evaluation

revision patient with a 99 overall IKS score. All the other patients, except one have a global IKS score equal or superior to 185. One male patient aged 78 years old at latest review has a 179 global IKS score due to a slight function difficulty when going up and down the stairs.

Concerning the patella resurfacing, and despite the fact that a fraction of the cohort (7 cases, 17.1%) has not beneficiated from a patellar resurfacing, the patella related pain is identical for both groups: none of the patient claims any patellar pain.

All reviewed patient are graded "excellent" results according to the IKS criteria.
This is confirmed by the patient's assessment as all except the global revision case (37 patients, 40 cases) consider that their living has been improved by the surgery.

At the latest review, while 2 patients where initially dependant, the majority is autonomous in their daily activities, 2 patients have some moderate activities, and 2 patients have regular moderate activities. No patient considers being dependant any more.
34 cases consider having no remaining pain at all, while 6 cases continue to have mild and occasional pain. One case only (the global revision case) keeps complaining about moderate, yet continual pain.

Discussion

Total knee replacement is one of the most common joint replacement surgery procedures. Within the last decade the available implantable "solutions" have been improved to provide satisfaction to younger and more demanding patients. The general rationale of total knee prosthesis have not been changed, instead improvements have been brought to the range of implants to provide a better physiologic adaptation to the bones, while the ancillary instrumentations became more accurate and helped the surgeon to include soft-tissue balancing in the surgical procedure. This evolution translates clinically in improved function.
JJ.Callaghan (2), in a clinical review of 119 TKA similar to the Rolflex implanted in the late 1980's, and with

patients of mean age 70 years old, was satisfied with a mean IKS score that rose from 74 at the pre-op evaluation to 165 at the latest follow-up of 9 to 12 years. In addition the mean active flexion for the cohort was at 102°.
Our review is similar in patient casuistics with the same mean age at surgery (70 years old) and an initial IKS score at 77. Our length of follow-up remains comparatively short but our flexion results close to a mean 119° and a global IKS at 194 compares very favorably to JJ Callaghan's results.

J.Witvoet (3), in his review of 315 TKA with a mean follow-up of 6.3 years, implanted in the early 1990's, and with patients of mean age 70.5 years old, was equally satisfied with a mean IKS score that rose from 54 at the pre-op evaluation to 152 at the latest follow-up. The mean active flexion he recorder in the study was 110.5°.

Between the early 1990's and today, the implants and the instrument sets have improved. The patients also have changed with more demand for improved function, unlimited ability to walk and increased comfort in everyday activities.

This study remains short in terms of length of follow-up. Nevertheless some results are promising for the longer term outcomes. The age, gender and BMI sampling of this cohort is in conformity with the general indications for TKA, and similar to the available bibliography. Yet, the IKS Knee score shows an interesting reproducibility of the surgical technique and/or of the instrumentation: the HKA results are in the normal axis ([2° varus to 3° valgus] interval according to Ewald) in all cases but one, and all cases have good antero-posterior and medio-lateral stability, with no case in recurvatum and only one case remaining with a slight flessum of less than 10°.

General bibliography teaches that a perfect knee joint alignment is not predictive of improved results, but good balancing and stable knee joint is predictive of improved results and long term survivorship.

In addition, the mean active flexion value at 119° of our cohort is in conformity with recent bibliography and patients' expectations for more mobility. G.Demey (4) in his review at one year of follow-up of 130 HLS (Tornier, France) TKA, with a gender repartition of 95 women for 30 men, and admitted for surgery between 2004 and 2005, came out with a mean flexion of 120° for the cemented femur population and 124° for the cementless femur population. The difference between cemented and uncemented population came out to be not statistically significant. There was no more significance in the IKS global scores between the 2 groups: the global score rose from 106 to 177 [101; 200] for the cemented group, and 109 to 181 [119; 200] for the cementless group.

In our analysis, the mean global IKS is 194.2. This result is less due to the knee score with a good mean flexion and good stability as described earlier in this document, than to the reproducibility of the results for all patients: no patient has any residual pain either globally or on specific zones such as the femoro-patellar joint. All patients have recovered full autonomy in their daily activities, 4 (9.7%) of them even have occasional or regular moderate activities. None require any kind of help; all but 3 (7.3%) are able to climb stairs up and down without the need of rail, and all but 3 (7.3%) take benefit from an unlimited ability to walk.

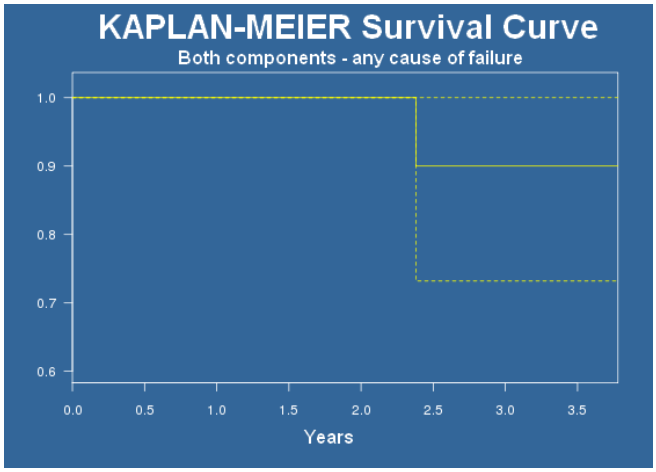


Chart 10: Kaplan-Meier survival curve at latest follow-up for femoral and tibial component, evaluated for any cause of failure

Regarding the survival curve *(chart 10)*, the results are distorted by 2 medium term complications associated with tibial fracture and collapse. If one of the 2 cases was probably contra-indicated for a primary TKA implant, and would have benefited from keeled implants because of the constitutional deformity of both tibia and femur, the second case could probably have been avoided with the use of a cemented tibial tray. This recalls that the use of cementless tibial implants for TKA remains successful and possible, but requires some caution in the selection of patients:

prosthetic balance and resulting HKA need to be mastered by the operator, but most of all the bone quality needs to be accurately assessed before selecting this cementless option.

Although these results need to be confirmed by a longer follow-up analysis, the conclusion of this study is that we are reassured by the reproducibility of the global solution including implant sizing and design, and instrumental efficiency.

Control X-ray at 11 months of FU.

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