Range of motion and functional results in three different designs of primary knee arthroplasty

Comparative study

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Abstract

Introduction: The aim of this study was to analyze functional results and range of motion and compare them between three groups of patients with total knee arthroplasty: two with high-flex prosthesis and another one with a conventional design.

Materials and Methods: Sixty-four patients were operated on with Zimmer® NexGen® total knee prostheses and 34, with high-flex Optetrack®. After patients exclusion, 22 (Group A) were treated with a high-flex Zimmer® design; 21 (Group B) with a conventional Zimmer® prosthesis and 25 (Group C) with an Optetrack ® PS prosthesis. Functional evaluation was carried out with the Knee Society Score, the Western Ontario and McMaster Universities Osteoarthritis index and the visual analogue scale.

Results: After the surgery, average maximal flexion went from 99º to 113º in Group A, with an average improvement of 14º; from 106º to 118º in Group B, with an average gain of 12º; and from 110º to 111º in Group C, with a gain of 1º. Functional results evaluated using the two scores improved in the three groups.

Conclusions: Functional evaluation is favorable in the three designs we evaluated. This study shows that there is no significant difference in reached final flexion, nor is there in functional results between the two first designs; however, these ones are significantly higher than the third group design after one-year follow-up.

Key words: Total knee prosthesis; high-flex prosthesis; conventional prosthesis; range of motion

Level of evidence: III

Rango de movilidad y resultados funcionales en tres diseños diferentes de artroplastia de rodilla primaria. Estudio comparativo

Resumen

Introducción: El objetivo de este trabajo fue analizar los resultados funcionales y el rango de movilidad entre tres grupos de pacientes con artroplastia total de rodilla: dos con prótesis de alta flexión y otro con un diseño convencional.

Materiales y Métodos: Sesenta y cuatro pacientes fueron operados con una prótesis total de rodilla Zimmer® NexGen® y 34, con una Optetrack® de alta flexión. Luego de la exclusión de pacientes, 22 (grupo A) fueron tratados con un diseño Zimmer® de alta flexión; 21 (grupo B), con una prótesis Zimmer® convencional y 25 (grupo C), con una prótesis Optetrack® PS. La evaluación funcional se realizó con el *Knee Society Score*, el *Western Ontario and McMaster Universities Osteoarthritis index* y la escala analógica visual.

Conflict of interests: The authors have reported none.

Resultados: En el posoperatorio, el promedio de flexión máxima subió de 99° a 113º en el grupo A, con un aumento promedio de 14º; de 106° a 118º en el grupo B, con una ganancia promedio de 12º y de 110° a 111° en el grupo C, con una ganancia de 1°. Los resultados funcionales evaluados con los dos puntajes mejoraron en los tres grupos.
Conclusiones: Las evaluaciones clínicas funcionales son favorables en los tres diseños evaluados. Este estudio muestra que no hay diferencias significativas en la flexión final lograda y los resultados funcionales entre los dos primeros diseños; sin embargo, estos son significativamente superiores al diseño del tercer grupo luego de un año de seguimiento.

Palabras clave: Prótesis total de rodilla; prótesis de alta flexión; prótesis convencionales; rango de movilidad.
Nivel de Evidencia: III

Introduction

Total knee replacement (TKR) is a safe and effective surgical procedure used as treatment of advanced stages of knee osteoarthritis. Designs and techniques development have got survival rates greater than 90% at 10-year follow-up.[1-3]

TKR main goal is a stable, painless knee with adequate ROM (range of motion) to perform daily activities.[4,5] Adequate function will depend on a number of factors—ROM, muscle strength, joint stability, pain, and patients'expectations.[6-8]

The post-operative ROM is an important issue in the final result. Nowadays, some patients ask for greater ROM due to their more active life-style, because they are younger or due to socio-cultural requirements.[9]

Two published reports state that 17-20% of the patients with TKR were not satisfied or reported uncertainty about TKR benefits. In 10% of the cases, the reason was poor ROM.[10,11]

The challenge of improving flexion following arthroplasty has encouraged diverse biomechanic studies that analyzed the limitations of the conventional designs to get higher degree of flexion, especial above 120º.[12-14]

In general, these new designs show changes that could help to get higher ROM avoiding the problems this could cause.[14-16]

Literature about this subject is broad and controversial, and the studies on high-flex TKRs that have been published differ in their results of ROM.[17-31]

The aim of this comparative study is to analyze knee functional results and ROM in three groups of patients with TKR using two high-flex prosthesis designs and a conventional design.

Materials and Methods

Between March 2010 and January 2012, we evaluated 98 patients: 64 patients with Zimmer® NexGen® LPS prosthesis (Zimmer, Warsaw, Indiana, USA) and 34 patients with high-flex Optetrack® PS (Exactech, Inc., Gainesville, FL, USA). The exclusion criteria were age >75 years old, septic osteoarthritis background or neurologic disease, revision surgery, rheumatoid osteoarthritis, <12-month follow-up and impossibility of evaluating the patient.

In 22 of the 64 patients treated with Zimmer® NexGen® LPS prosthesis we used a high-flex design. Twenty of them had three-compartment osteoarthritis and, two, rheumatoid osteoarthritis; these ones were excluded. Group A was then made up of 20 patients: 15 females and 5 males aged 67 years-old on average (ranging from 54 to 75), and with an average body mass index (BMI) of 33kg/m^2 (ranging from 26 to 42).

Forty-two patients were treated with a conventional prosthesis (Zimmer® NexGen® LPS). Twenty patients were excluded because they were elder than 75, and one of them due to septic osteoarthritis background. Then, group B or control group included 21 patients, 17 females and 4 males, aged 69 years old on average (ranging from 61 to 75), and with an average BMI of 31 kg/m^2 (ranging from 25 to 44).

Thirty-four patients were treated with a high-flex Optetrack® PS prosthesis (Exactech, Inc., Gainesville, FL, USA). Nine were excluded: three due to rheumatoid osteoarthritis, one died before evaluation, and the rest of the patients were ruled out because they were lost to follow-up or because they were >75; group C was then made up of 25 patients, 14 females and 11 males, aged 71 years old on average (ranging from 58 to 75), and with an average BMI of 30 kg/m2 (ranging from 20 to 37).

In order to validate this comparative study, the demographic characteristics of the patients that were included in each of the three groups were related with one another as regards sex, age, BMI and pre-operative diagnosis (Table 1).

Patients were checked at weeks two and six, at months three and six, and at a last follow-up consultation, with a minimal follow-up of one year.

Before the surgery and at the last follow-up, we evaluated maximal flexion and extension, and then we calculated ROM as maximal flexion minus flexion contracture. Flexion was evaluated with the patient in supine position; we considered maximal patient's active flexion with 90º hip flexion and knee full flexion (Figure 1). Extension was determined with the patient in supine position too, with hips and knees fully extended. For measuring we used a manual goniometer on the lateral aspect of the knee, and two evaluators were in charge.

We evaluated function using the Knee Society Score (KSS) that includes a first knee score, which evaluates

Table 1. Demographic data of the population

	Group A	Group B	Group C
Number of patients	20	21	25
Design	Zimmer® NexGen® LPS- Flex	Conventional Zimmer® NexGen® LPS	Optetrack® PS Flex
Age (years)	67 (range 54-75)	69 (range 61-75)	71 (range 58-75)
Sex	14 females, 6 males	17 females, 4 males	14 females, 11 males
BMI (kg/m²)	32.9 (26.7-42)	31.2 (20.4-43,8)	29.8 (20.8-37,5)
Malalignment	6 valgo, 14 varo	8 valgo, 13 varo	3 valgo, 22 varo

BMI= Body Mass Index

pain, stability and ROM from 0 to 100 —where 0 represents the worst score and, 100, the best one— and a second score for knee function that uses 0 and 100 too. We also used the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) with a scale from 0 (best result) to 96 (worst result).[32,33] We evaluated pain with a visual analogue scale. We took pre-operative and post-operative anterior-posterior X-rays with monopodalic bearing and 30º-flexion lateral X-rays looking for any mechanical reason for impairment of post-operative mobility and medical evaluation (components alignment, remaining dorsal osteophytes, and signs of early prosthetic loosening, among others).

We checked admission medical histories and the IT records of office check-ups to enumerate complications.

Surgical technique

All the patients were operated on using a haemostatic cuff. We always used a knee anterior approach followed by medial parapatellar arthrotomy and lateral patellar dislocation. We removed the cruciate ligaments. Then we performed bone cuts in femur and tibia checking size, stability and mobility of the trial components, to finally insert the definite ones, which in all the cases were cemented.

No patient received the patellar component. Surgical drains were removed at post-operative 24-48 hours. Post-operative rehabilitation started 24 hours after the surgery with flexion-extension exercises, quadriceps isometric contraction and waking at average post-operative 48 hours with walker or Canadian cane. Patients in the three groups followed the same rehabilitation protocol.

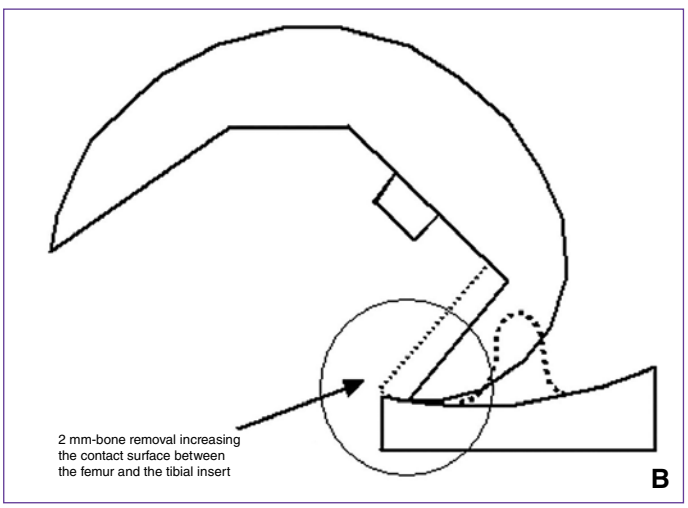
Prosthesis design

With respect to the prosthesis design, the high-flex Zimmer® NexGen® LPS prosthesis differs somewhat from the conventional design.[9,17,18] The LPS-Flex bone cutting femoral guide was designed to cut 2 additional mm on the back of the femoral condyles to increase the curvature of the joint surface in high degrees of flexion and, this way, increase back femoral roll and flexion range.

Therefore, the width of the back of the prosthetic femoral condyles increases 2 mm (Figure 2). The tibial component has a frontal slope or notch to avoid impingement over the patellar tendon during maximal flexion. The design of the tibial post shows an increase in the jumping distance to avoid prosthetic dislocation during maximal

Figure 1. Evaluation of maximal knee flexion with goniometer with the patient in supine position with 90º-flexion hip.

flexion (Figure 3). The form of the frontal part of the polyethylene insert changes too, with a notch where it contacts the patellar tendon in higher degrees of flexion to avoid impingement.[14,15]



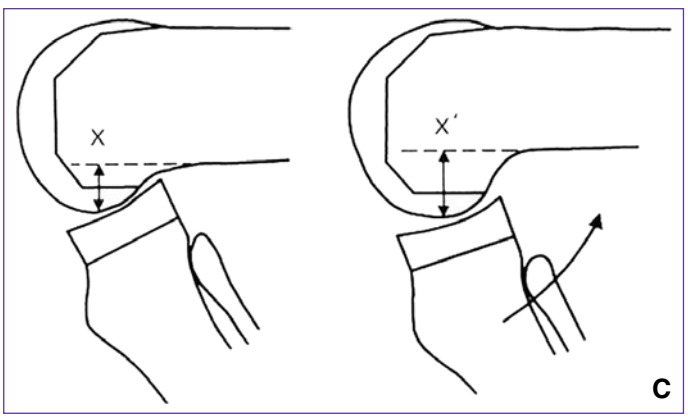


Figure 2. Characteristics of the Zimmer® NexGen® LPS-Flex and the conventional Zimmer® NexGen® prostheses. **A.** Lateral X-rays in two patients with high-flex and conventional Zimmer® total knee arthroplasty. We can see greater width (2 mm) on the back of the condyles. **B.** Comparative scheme where we can see the 2 mm-increase in the width of the dorsal wall. **C.** Representative scheme of the effect the increase of the femoral offset has, avoiding impingement of the femoral dorsal cortex on the polyethylene insert.

The high-flex Optetrack® PS model shows similar changes. The cam effect and the design of the tibial insert offer controlled back roll up to 145º-flexion without dorsal pinching. Moreover, it has a slight slope on the back of the polyethylene insert to avoid impingement in the highest degrees of flexion. The tibial insert shows an angular dorsal slope which increases the jumping height and improves back femoral roll and resistance to dislocation in high degrees of flexion.

Statistical analysis

We described quantitative variables as average and standard deviation, even the non- normal variables, because what we are interested in is interpretation and comparison with other series. Categorical variables are describes as proportions.

For inter-groups comparison we used the Mann-Whitney test by distribution. The value we considered as statistically significant was $p<0.05$. We used the IBM SPSS v 17.00 statistical program.

Results

Average follow-up was 15 months (ranging from 13 to 18) in Group A or study group (high-flex Zimmer® NexGen®), 17 months (ranging from 13 to 21) in Groups B (conventional Zimmer® NexGen®) and 20 months (ranging from 14 to 28) in Group C (high-flex Optetrack®)

Pre-operative maximal flexion was 99º ± 10.97º (ranging from 90º to 120º) in Group A, 106º ± 11.95º (ranging from 90º to 130º) in Group B and 110° ± 11.95º (ranging from 90º to 125°) in Group C. At last evaluation after

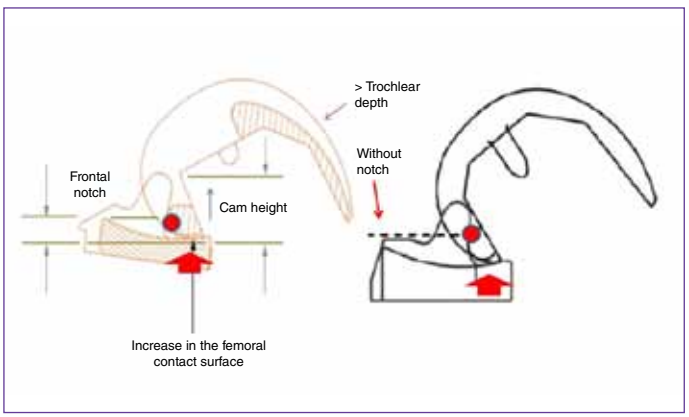


Figure 3. The tibial component has a frontal slope to avoid impingement on the patellar tendon during maximal flexion. The design of the tibial post shows an increase in the jumping distance to avoid prosthetic dislocation in maximal flexion.

the surgery, average maximal flexion increased to 113º ± 12.89º (ranging from 95º to 140º) with average increase of 14º in Group A, to 118º ± 11.24º (ranging from 90º to 130º) with average gain of 12º in Group B, and to 111° ± 12.52º (ranging from 83° to 135°) in Group C. Here we did not detect statistically significant differences while comparing the post-operative values in the two first groups ($p<0.05$). However, at the time of comparing the two first designs with the third one, Groups A and B showed statistically significant pre-operative/post-operative improvement in flexion ($p<0.005$).

Average pre-operative ROM was 94° in Group A, 102° in Group B and 104° in Group C, and post-operatively it respectively reached 113°, 118° and 111° ($p<0.05$). Average differences in ROM were 19° ± 15.7º in Group A, 16° ± 11.46º in Group B, and 7° ± 17º in Group C. Pre-operative/post-operative differences in ROM only were statistically significant in Groups A and C.

Pre-operative flexion contracture was 5º ± 5.7º decreasing to 1º ± 2.2º in Group A; 4º ± 5.38º decreasing to 0º ± 4.7º in Group B, and 6.4° ± 6.97º in Group C decreasing to 0° ± 2.2º by last follow-up.

In the groups we verified statistically significant improvement in the WOMAC and functional KSS scores, but not in the KSS score for pain (Figure 4). Pre-operative KSS was 36/50 (knee/knee function score) in Group A, and improved to 89/92; 46/49 in Group B, and improved to 93/90; and 48/53 in Group C with improvement to 87/76. Statistically significant differences were only seen in Groups A and B while comparing them with Group C ($p<0.005$).

Average WOMAC score in Group A was 48 ± 8.2 (ranging from 35 to 62) before the surgery and 3 ± 4.1 (ranging from 0 to 16) after the surgery, what represents 19 patients with excellent results and one patient with good results. In Group B, WOMAC score went from 54 ± 12.8 (ranging from 34 to 96) before the surgery to 5 ± 4.78 (ranging from 0 to 18) after the surgery. This implies 20 patients with excellent results and one patient with good results. In Group C, pre-operative WOMAC was 53 ± 18.21 (ranging from 13 to 85) and it was 20 ± 19 (ranging from 1 to 76) at last evaluation; 11 patients had excellent results; three patients, bad results, and the rest of the patients had good to fair results. We did find significant differences in post-operative WOMAC score results in Group B while comparing them with Group C ($p<0.005$) (Figure 4).

Pain evaluation using the visual analogue scale showed the following results: in Group A, it averaged 8 ± 1.3, and it decreased to 1 ± 2 after the surgery. In Group B, the pre-operative score also averaged 8 ± 1.3, and it decreased to 1 ± 2 at last follow-up; Group C showed an average of 8 ± 2 that decreased to 3 ± 1 at last evaluation. Here differences were only statistically significant while comparing Groups A and B with Group C ($p<0.05$).

With respect to the X-ray evaluation, we detected neither signs of early loosening nor other X-ray changes which could affect post-operative ROM in any of the patients (Figures 5 and 6).

We did not verify complications by the last follow-up in Group A. There were two complications in Group B: one patient with wound dehiscence that required a second surgical procedure to close the wound, and another one with deep venous thrombosis who was given anticoagulant therapy. These two patients did well with good functional scores at one-year follow-up. In Group C, there was one complication: a superficial infection of the wound that was successfully treated with surgical toilet and antibiotics. We believe that these complications are not related to the prosthetic component used.

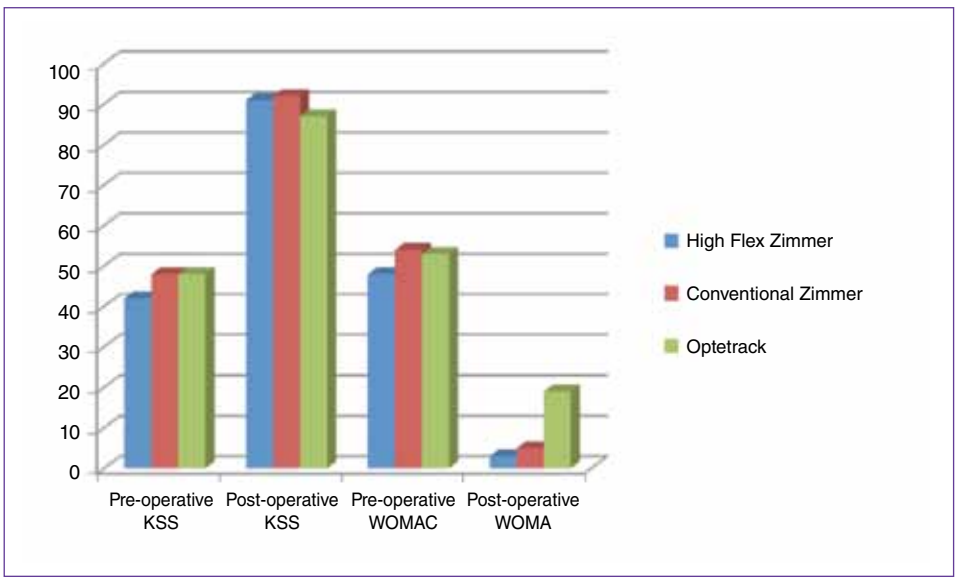


Figura 4. Comparative representation of medical evaluation in the three designs.

Discussion

TKR post-operative ROM depends undoubtedly on several factors—the patient, the pre-operative ROM, the surgical technique and the implant design, among others.[34-37]

Over the latest decade, implants designs have improved with the aim of increasing ROM and bettering function.

In our study, we compared three groups of patients we gave three different prosthesis designs to. The two groups with Zimmer® NexGen® showed no significant ROM improvement between the conventional design group and the high-flex design one, but both models did certainly better in achieved ROM differences than the high-flex Optetrack® model. Patients improved, on average, 19º with the Zimmer® NexGen® Flex, 16º with the conventional Zimmer® NexGen®, and only 7º with the high-flex Optetrack® prosthesis.

Final ROM also involves the pre-operative/post-operative degree of extension, variable that can be misleading at the time of evaluating the true effect that is necessary to assess with these implants, which is *maximal final flexion*. As regards this parameter, we did not verify statistically significant differences while comparing the post-operative values in the two first groups ($p<0.05$). However, when we compared the two first designs with the third one, Groups A and B did significantly better in the pre-operative/post-operative flexion differences ($p<0.005$).

Numerous articles comparing these high-flex prostheses with conventional designs have been published; however, it is still unclear if these designs will actually improve ROM on the grounds of higher final flexion (Table 2).[17-31]

A systematic revision carried out by Murphy et al. which included nine studies and 399 high-flex prosthesis in 370 patients, focused on studying high-flex prosthesis results, reports lack of evidence to determine if high-flex prosthesis will improve ROM and patients' functional performance.[38]

A meta-analysis published in 2009 shows that high-flex prosthesis did better than conventional ones, contrarily to what was published in a 2011 meta-analysis.[29,30]

Another meta-analysis suggests that the Flex prosthesis does not increase maximal post-operative flexion while compared to the conventional implant. Average differences between the two implants were just 2.1º (-0.2-+4.3 95%CI, p=0.07), which are not only statistically non-significant, but also medically non-significant. Additional flexion of 2º or even 4.3º does not give functional advantages to the patient.[24]

A more recent meta-analysis that was published in 2015 includes 16 studies with 2643 knees and reports that high-flex prostheses are better than the conventional ones at the time of improving ROM, both posterior-stabilized prosthesis and prosthesis that keep the posterior cruciate ligament. Nevertheless, there were no significant differences in functional results among designs.[31]

Several factors are involved in post-operative ROM following TKR. The most important is pre-operative ROM. Other alleged factors are female sex, the contra-lateral knee status, personal attitude towards rehabilitation, BMI, surgical technique, restoration of the joint line, femoral condyle back offset, and the implants. Therefore, it is difficult to evaluate only one variable, such as the implant, in such multi-factorial context.[26-34]

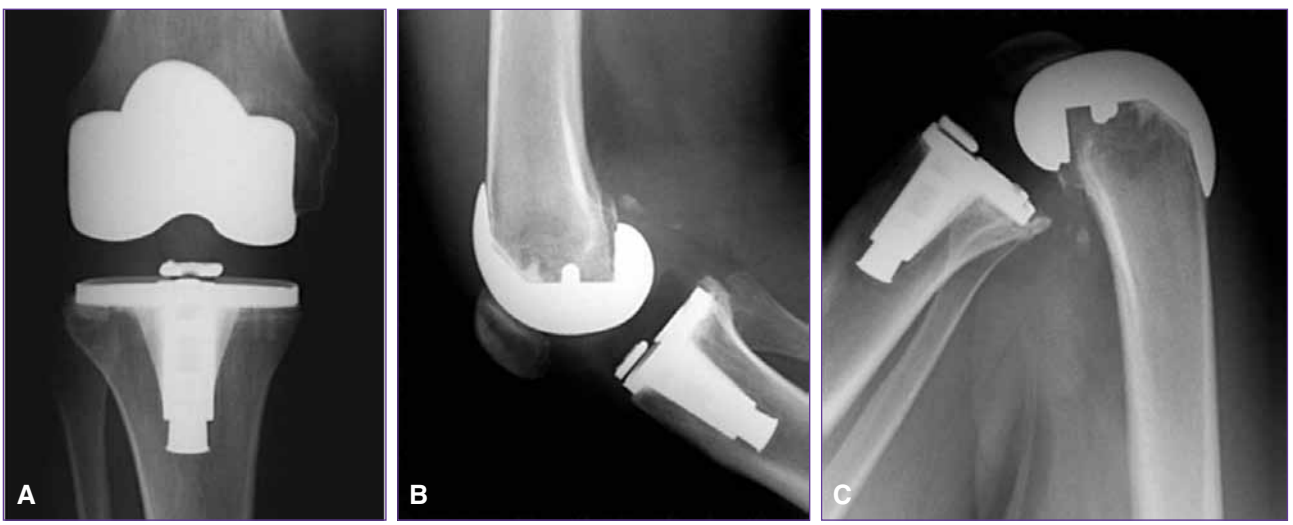


Figure 5. Post-operative X-rays of high-flex Zimmer® NexGen® LPS prosthesis. **A.** Front view that shows good alignement. **B.** 30º- flexion lateral view that shows a 2 mm-increase in width on the back of the femoral condyles. **C.** 140º-maximal flexion lateral view.

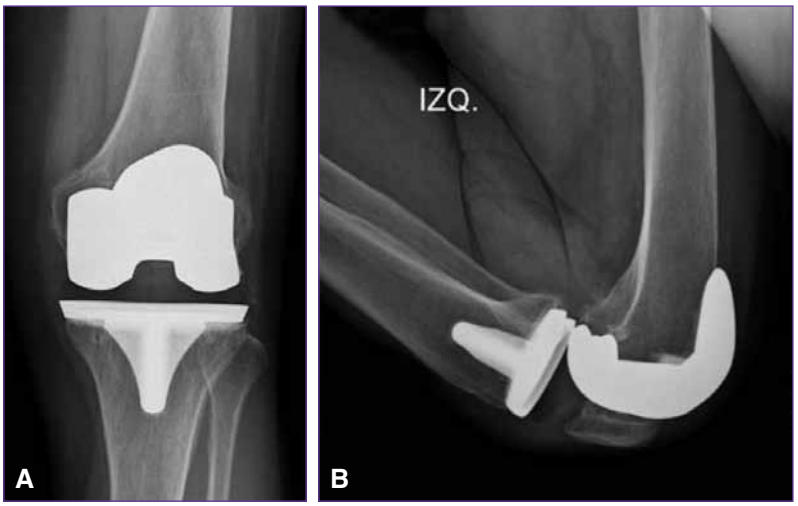


Figure 6. Post-operative X-rays of high-flex Optetrack® prosthesis. **A.** Front view that shows right position and alignement. **B.** 124°-maximal flexion lateral view.

Table 2. Comparative results in different published articles

Study	Number of patients (per group)	Follow-up (years)	Age (years)	ROM (°)		Maximal flexion (°)		p
				Pre-operatorio	Post-operative	Pre-operatorio	Post-operative	
Weeden et al.[28]	25 Zimmer® NexGen® LPS	1	62	119	120	121	120	
	25 Zimmer® NexGen® LPS-Flex			120	132	122	133	
Bin et al.[9]	90 Zimmer® NexGen® Conventional	1	66	115	123		124	p <0.009
	90 Zimmer® NexGen® LPS-Flex			117	129		130	
Kim et al.[20]	50 Zimmer® NexGen® LPS	2	68	126	136			p 0.41
	50 Zimmer® NexGen® LPS-Flex			127	139			
Nutton et al.[26]	28 Zimmer® NexGen® LPS	1	68	107	108			p >0.05
	28 Zimmer® NexGen® LPS-HF			106	110			
Mc Calden et al.[23]	50 Genesis® II PS	2	71				123	p 0.811
	50 Genesis® II PS Flex						124	
Laskin et al.[22]	40 Genesis® II	2				116	118	p <0.01
	40 Genesis® II Flex					117	133	
Bonifacio et al. *(not published)*	21 Zimmer® NexGen® LPS-Flex	1	69	94	113	99	113	p <.005
	20 Zimmer® NexGen® LPS			102	118	106	118	
	25 Optetrack® Flex			104	111	110	111	p >0.05

In our series, post-operative functional results and the pain scale improved significantly in the groups. We found a positive correlation in the achieved ROM, since the two first groups showed significantly higher maximal flexion with functional results significantly higher in the WOMAC and functional KSS scores than the third group.

Although intuitively, patients' satisfaction and function after the surgery can be associated with the achieved degree of flexion, literature is controversial.[18,20,21,26] Park et al. analyzed ROM and functional results using the KSS, WOMAC and SF-36 scores in 207 Korean patients (333 knees) one year after TKR. They report a weak correlation between maximal post-operative flexion and pain relief, function and life quality.[39] In another study, the KSS scores of pain while walking, stairs use and rest were similar in the groups with conventional prosthesis and in those ones with high-flex prosthesis one year after the surgery (p=0.68; p=0.37; p=0.35; p=0.57, respectively).[40]

X-rays showed significant changes in neither group regarding the components position, knee alignment and patellar level, nor did they find signs of early loosening. There were no intra-operative serious complications related to the implants in the follow-up.

The aim of these implants, apart from trying to give higher mobility, is to achieve safer maximal flexion avoiding the complications that could be associated with this advantage. It is necessary to carry out a longer follow-up to determine if this new prosthetic biomechanics could affect wear or loosening of the components. This greater degree of flexion increases patellar-femoral contact pressure, what potentially causes front pain, greater wear, patellar fracture and loosening.[41,42] Moreover, high degrees of flexion show greater femoral back roll, what could be associated with greater wear.

Hans et al. reported prevalence of femoral component loosening of 38% in high-flexion LPS prosthesis after an average follow-up of 2.7years.[41]

Other of the reported disadvantages of this high-flex design is the need of greater bone removal on the back of the femoral condyles, which is a worrying factor in case of prosthetic revision. The other disadvantage is that it is more expensive.[27,28]

The disadvantages of our study were the fact that we did not allocate the patients randomly, the scarce number of patients and the short follow-up. However, this series compares three different designs with a statistically compared sample. The three designs were evaluated longer than one year, a key condition at the time of assessing ROM because, in general, this time is considered to be enough—after one-year follow-up, it is hardly frequent that ROM changes in patients with TKR.

Literature is controversial and confusing at the time of comparing high-flex TKR prosthesis to conventional ones. Most probably, results depend on several factors such as surgical techniques, the different designs, patients' inherent factors and the methodology of the published studies.

Conclusion

Regarding functional results, these ones were better in Groups A and B than in Group C. Final ROM and degree of flexion did no differ between Groups A and B, but they were significantly higher in Groups A and B than in Group C.

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