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**Title:** Is hyperflexion possible with the solitary use of high-flexion insert in knee replacement preserving the posterior cruciate ligament? (Mid-term results)

**Running Head:** Mid-term Results of High-Flex CR TKA

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## Öz

**Giriş:** Hiperfleksiyona izin veren tasarımı total diz protezi uyguladığımız hastalarımızın erken-orta dönem sonuçlarını değerlendirmek ve özellikle fleksiyon açıklığı üzerine etkili faktörleri belirlemek.

**Yöntemler:** Hiperflex arka çapraz bağ koruyan tipi diz protezi uyguladığımız 95 hastanın 150 dizi değerlendirmeye alındı. Hastalar ortalama 8.5 yıl (3.5- 11 yıl) takip edildiler. Diz eklemleri ameliyat öncesinde ve son kontrolde Diz Cemiyeti Puanlama Sistemi ile değerlendirildi ve hareket açıklıkları kaydedildi. Komponent sağkalımı değerlendirildi. Ameliyat sonrasında yüksek fleksiyon derecesine (> 130) ulaşabilmek için ameliyat öncesinde olması gereken fleksiyon açıklığı ise ROC eğrisi (receiver-operating characteristic) analizi ile araştırıldı.

**Bulgular:** Ameliyat öncesi ortalama diz skoru  $49.1 \pm 12.0$  puan, fonksiyon skoru  $48.9 \pm 14.1$  puan ve fleksiyon açısı  $119.3 \pm 18.9$  derece olarak bulundu. Son kontrollerde aynı değerler sırasıyla  $92.9 \pm 8.2$  ( $p < 0.0001$ ),  $90.7 \pm 10.6$  ( $p < 0.0001$ ) ve  $128.0 \pm 11.5$  derece ( $p < 0.0001$ ) seviyesine yükseldi. Yetmiş (47%) dizde fleksiyon açıklığında bir artış sağlanamazken, bu hastalardan 27'sinde (18%) dizde fleksiyon değerinde azalma oldu. Ameliyat öncesi ve sonrası fleksiyon açıklıkları arasında orta seviyede korelasyon tespit edildi ( $r=0.623$ ,  $p < 0.0001$ ). Bir adet (0.6%) ara yüzey revizyonu erken dönem enfeksiyon nedeni ile yapıldı. Aseptik gevşeme gözlenmedi. ROC eğrisi analizi ameliyat öncesinde  $115^\circ$  ve üzerinde fleksiyonu olan dizlerde ameliyat sonrasında  $130^\circ$  ve üzerinde hiperfleksiyon beklenebileceğini tespit edildi.

**Sonuç:** Çalışmamızın sonucunda ameliyat sonrası fleksiyon derecesi, ameliyat öncesi fleksiyon derecesi ile ilişkili olarak bulunmuştur. Bu çalışma ile sadece yüksek fleksiyona izin veren ara yüzey kullanarak yüksek fleksiyon dereceleri elde edilemeyeceği, ameliyat öncesi fleksiyon açıklığının hiperfleksiyona ulaşmanın bu tip tasarımda bile önemli bir faktör olduğu sonucuna ulaşıldı.

**Anahtar Sözcükler:** Bağkoruyan arayüzey, hiperfleksiyon, diz artroplastisi

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## ABSTRACT

**Objective:** To evaluate the early - middle term results of our patients who underwent total knee replacement allowing for hyperflexion and to identify particularly the factors affecting the range of flexion.

**Methods:** One hundred and fifty knees of 95 patients who underwent total knee replacement with a high-flexion cruciate retaining insert were evaluated. The patients were followed up for a mean of 8.5 (3.5 to 11) years. The knee joints were assessed pre- and post-operatively and at the final follow-up with the Knee Society Scoring System and their range of motion were recorded. The component survival was also investigated.

**Results:** The mean preoperative knee score was  $49.1 \pm 12.0$ , the mean functional score was  $48.9 \pm 14.1$  and the mean range of flexion was  $119.3 \pm 18.9$  degrees. The same values at the follow-up improved to  $92.9 \pm 8.2$  ( $p < 0.0001$ ),  $90.7 \pm 10.6$  ( $p < 0.0001$ ) and  $128.0 \pm 11.5$  degrees ( $p < 0.0001$ ), respectively. A moderate correlation was detected between the preoperative and postoperative ranges of flexion ( $r = 0.623$ ,  $p < 0.0001$ ). There was insert revision in one knee (0.6%) due to early infection. No revision due to aseptic loosening. Analysis with the ROC revealed the probability postoperative hyperflexion of  $130^\circ$  or above in knees that had a preoperative range of flexion of  $115^\circ$  and above.

**Conclusion:** The postoperative range of flexion was found to correlate with the preoperative range of flexion. The results of our study showed that higher range of flexion is not possible with the solitary use of high-flex CR insert and the preoperative range of flexion is an important factor in attaining hyperflexion even with the use of such inserts.

**Keywords:** Cruciate retaining, knee replacement, hyper-flex knee

## Introduction

Total knee arthroplasty (TKA) is a successful and reliable method that has been often employed in arthrosis of the knee recently (1). The rate of patient satisfaction reaches 80% and above (2). The increasing mean age of the community and the successful survival outcomes of TKA in young people

has doubled the number of TKA applications in the last 10 years (3, 4). Postoperative range of

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motion is an important determinant of the functional outcomes following TKA(2). For this reason, in an attempt to attain a higher range of motion, new designs with modifications in the femoral component and polyethylene geometry were developed to allow hyperflexion. The benefit from the femoral component designs allowing hyperflexion is however debatable (5-7). Studies on increasing the range of motion after TKA and on the modified designs of the polyethylene insert in prostheses substituting or retaining the posterior cruciate ligament (PCL) are limited in the literature (8-10). The range of motion has been shown to increase with the modification of the polyethylene insert in PS (PCL-substituting) prostheses(8) whereas no clinical difference was found in a randomized controlled study(9). Advantages of modifications in the design of high-flexion CR (Cruciate Retaining) insert have also been shown(10).

In our study, we aimed to evaluate the early - middle term results of our patients who underwent PCL-preserving TKA with high-flexion insert in our clinic and the relationship between the preoperative and postoperative ranges of motion.

## Methods

One hundred and sixty-two knees of 103 patients underwent a PCL-preserving TKA, using only high-flexion inserts (Genesis II; Smith & Nephew, Memphis, TN, USA), performed by a single senior surgeon between 2006 and 2014. One hundred and fifty knees of 95 patients (88 females, 7 males) were included in the study. Eight patients were lost to follow-up. The study protocol was performed in compliance with the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013). The mean age of the patients was 71 (22 to 85) years. The patients had a mean weight of 78 (64 to 104) kg and a mean height of 157 (145 to 168) cm. Four patients (seven knees) were diagnosed with rheumatoid arthritis, two patients (two knees) with systemic lupus erythematosus, three patients (three knees) with posttraumatic arthritis and others with primary osteoarthritis. Bilateral TKA was performed on 71 patients during the same session and on four patients in successive sessions. Ten patients of the bilateral TKA group had a PS type prosthesis on their contralateral side. Of them, only those with a CR prosthesis was included in the study. The mean follow up period was 8.1 (3.5 to 11) years.

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Preoperative and postoperative ranges of motion of the knees were recorded using the neutral zero method and the patients were evaluated with the Knee Society Scoring System(4). Progressive radiolucency between the bone and the components, loosening or migration of the implant were evaluated observed in the follow up radiographs (anteroposterior – lateral and patella tangential views).

### **Surgical technique**

All patients were administered a combination of spinal-epidural anesthesia and the epidural catheter was left in place for 48 hours after surgery for patient-controlled analgesia (PCA). Antibiotic prophylaxis was initiated with IV injection of 2 g of cefazolin half an hour before skin incision and was continued for 48 hours with IV injections of 1 g every 6 hours. No tourniquet was used during surgeries. Following the anterior longitudinal cutaneous-subcutaneous incision, the joint was exposed with medial parapatellar arthrotomy. Bone incisions were performed with incision guides after necessary soft tissue releases. Intramedullary guides were used on the femur side and extramedullary guides were used on the tibia side in all cases. As the type of the high-flexion tibial polyethylene insert was the PCL-retaining type, the PCL was preserved in all cases. Cemented femoral and tibial components were used in all cases. Cemented, polyethylene biconvex patellar component was used in 137 knees. The remaining 13 knees were performed circumpatellar denervation, osteophyte resection and ‘aggressive patelloplasty’, which we describe as the dome-shaped correction of the patella and its decompression by drilling. The skin was closed and the knee was bandaged. No drains were used.

Low-molecular-weight heparin and thromboembolic prophylaxis were administered in all patients. Prophylaxis was initiated 10 to 12 hours after epidural catheter application with subcutaneous injection of 0.4 ml of enoxaparin and was continued throughout the hospitalization period for a mean of 4.8 (3 to 7) days. Patients continued receiving the same dose of enoxaparin for a minimum of four weeks.

Rehabilitation was started with leg swings over the side of the bed on the day of surgery and mobilization in the room about 6 to 18 hours after surgery. A continuous passive motion (CPM) device was used for flexing the knee for 30° to 60° on the day of surgery and the exercises continued for a mean of 4.8 (3 to 7) days throughout the hospitalization period, 2 to 3 sessions a day and for 2

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hours per session. The range of flexion was increased 30° to 40° each day, depending on the tolerability of the patient.

### Statistical evaluation

The mean pre- and postoperative values were compared using paired, two-sample Student's t-test. The effect of age, preoperative knee scores and ranges of motion on the range of flexion was analyzed with correlation tests. In cases where the sampling size was low as in the patellar surface replacement group, the Mann-Whitney U test was used for comparisons. Receiver operating characteristic (ROC) curve analysis was used in investigating the required preoperative range of flexion to achieve a high postoperative range of flexion (>130°). The value of the identified level was measured with the Fisher's exact x2 test. SPSS v.21 (International Business Machines Corp. - IBM, USA) statistical software was used for statistical evaluation. The statistical significance level was set at  $p < 0.05$ .

### Results

The mean knee score was  $49.1 \pm 12.0$  (25 to 84) preoperatively and  $92.9 \pm 8.2$  (38 to 100) at the final follow-up ( $p < 0.0001$ ). The mean functional score also improved from the preoperative value of  $48.9 \pm 14.1$  (20 to 90) to  $90.7 \pm 10.6$  (55 to 100) postoperatively ( $p < 0.0001$ ). The mean preoperative flexion of  $119.3^\circ \pm 18.9^\circ$  (70° to 145°) showed a significant increase and reached  $128.0^\circ \pm 11.5^\circ$  (100° to 155°) after surgery ( $p < 0.0001$ ) (Table1). The mean increase in flexion was  $8.6^\circ \pm 15.9^\circ$  (-35° to 45°). No increase in range of flexion was achieved in 70 knees (47%) while the range decreased in 27 patients (18%). The mean range of flexion of the patients (seven knees) diagnosed with rheumatoid arthritis was  $127.1^\circ$  (110° to 140°) at the final follow-up.

Anterior knee pain developed in seven (4%) knees of six patients, one bilaterally, which did not have a significant effect on daily activities. Four of these knees had undergone patellar replacement and

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aggressive patelloplasty had been performed on the other three. The patellar surface was kept in 13 patients. No significant difference was found between the two groups in terms of age ( $p=0.06$ ), the preoperative and postoperative ranges of flexion ( $p=0.88$  and  $p=0.88$ ), increase in range of flexion ( $p=0.86$ ), and the preoperative and postoperative knee ( $p=0.21$  and  $p=0.51$ ) and functional ( $p=0.82$  and  $p=0.11$ ) scores (Mann-Whitney U test).

An intraoperative patellar fracture developed in one knee (0.6%) and superficial wound site infection was observed in two knees (1.3%) which healed with antibiotic treatment. Acute deep periprosthetic infection treated with changing of the liner and debridement on the 10<sup>th</sup> day was seen in one knee (0.6%).

One patient (1%) had to undergo treatment due to pulmonary embolism and three other (3%) due to deep vein thrombosis. No advancing radiolucency between the bone and implant, implant loosening or displacement were observed at the follow-ups. Considering the aseptic loosening the final reference point, the survival rate of the whole system %100.

A statistically significant difference was detected between the preoperative ranges of flexion of the knees those achieved hyperflexion postoperatively and those did not (Table 2). Statistical evaluation showed a moderate correlation between the preoperative and postoperative ranges of motion [ $r=0.623$ ,  $p<0.0001$ ]. ROC curve analysis confirmed that the knees expected to have a postoperative range of flexion of 130° or above must have a preoperative range of flexion of 115° or above (sensitivity 82%; specificity 72%) (Figure 1). Seventy-four of the 91 knees with a preoperative range of flexion of 115° or above reached a postoperative range of flexion of 130° or above whereas only 16 of the 59 patients with a preoperative flexion of below 115° reached a postoperative flexion of 130° ( $p<0.001$ ). (Table.3)

No significant relationship was found between age and postoperative range of flexion or increase in range of motion. The preoperative range of flexion was inversely related to the amount of increase in flexion [ $r= (-0.776)$ ,  $p<0,001$ ]. No significant correlation was observed between the functional and knee scores and the postoperative flexion results.

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## Discussion

The aim in TKA treatment is to obtain a painless knee joint with adequate and lasting capability of flexion. In our daily lives, we need a flexion range of 60° for walking on a flat road, 85° for climbing the stairs, 90° to 95° to go down the stairs, and 100° to 110° to stand up from the sitting position or to tie shoe laces (11, 12). However, considering the social and cultural structures of the eastern populations like ours, high ranges of flexion of 130° or above is required to perform many moves, such as sitting cross-legged or squatting.

Several total knee prostheses specifically designed for high-flexion have been shown to reach 113° to 139° of flexion in the short term and these values are significantly higher than those reached by the standard designs(5, 8, 13, 14) . In studies investigating the high-flexion inserts as in ours, the PS designs were mostly investigated (8, 9, 15). In their study, Laskin et al. found that the PS type high-flexion prosthesis had a mean postoperative flexion of 133° and reported that this value was significantly higher than those achieved with standard PS design prostheses (8). However, some authors suggested that there was no difference between the same high-flex PS type prostheses with postoperative flexion values of 120° to 133° and the standard ones (9, 15). On the other hand, Crow et al. used a high-flexion CR insert that we used in our series and found a mean flexion of 119°. This value was significantly higher than the mean flexion obtained using a standard insert in their series (10). Our mean flexion of 127° was higher than the previously reported results of similar design.

In the literature, the age of the patient, tibiofemoral varus-valgus alignment, body mass index, the surgical technique and the prosthetic design were reported to have a relationship with the postoperative range of flexion (16-18). Our postoperative flexion results were found to correlate with the preoperative flexion values. In addition, there was a negative linear relationship between the increase in postoperative range of flexion and the preoperative range of flexion.

Knee flexion is an important functional outcome measure in post-TKA evaluations and holds an important place in scoring in several assessments(19). Recently, evaluations filled by the patients have come to the forefront (20, 21). These evaluations inquire the expectations of the patients before surgery, their postoperative thoughts on the success of the surgical outcome, whether the patient is affected by the movement of the joint if any, and whether the patient thinks an additional treatment is necessary. Postoperative range of flexion has been shown to have no relationship with

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patient satisfaction in some studies (22). However, increased range of flexion meets the expectations of the patient from the knee, renders the knee functionally capable and improve the evaluation results of advanced flexion levels ( $\geq 130^\circ$ ) (23). In another study with similar mean flexion and Knee Society (knee and function) scores, a higher degree of flexion and Knee Society score is directly related with higher patient satisfaction and their data confirmed that high post-operative range of knee flexion improve patient-rated outcome (24). On the other hand, Thomsen et al. had similar results with high-flexion and standard prosthesis designs in terms of patient satisfaction even high-flex TKA showed increased flexion (25). There was no correlation observed between the range of flexion and the knee and functional scores in our study.

Although the new design features help to increase flexion, its advantages and usability are arguable. Our femoral component was not a special design; it had a CR insert and required no additional bony cuts. Decreasing the radius of curvature of the posterior femoral condyle, shortening or increasing the thickness of the femoral condyle have been considered in creation of some other new designs (3, 13, 26). It is obvious that more bone cuts are required to utilize these design features. Ranawat asserted that this will complicate the performance of a revision surgery in the years to come (27). In addition, possible increases in polyethylene wear and patellofemoral complication rates might be another drawback of the attained high flexion. We did not observe any aseptic loosening or advancing radiolucency in our mid- term follow-up.

There were some limitations in our study. This was a retrospective study without any control group. Nevertheless, the surgical technique was identical for all knees, which were performed by a single senior surgeon.

## **Conclusion**

One of the main deductions of our study was that one can expect a postoperative movement above  $130^\circ$  in patients who had a preoperative range of flexion of  $115^\circ$ . Using the high-flex CR insert is not

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a sufficient modification to achieve hyperflexion on its own. The preoperative range of flexion is also an important parameter even for such specially designed implants in achieving hyperflexion.

**Ethical Committee Approval:** Authors declared that the research was conducted according to the principles of World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013).

**Informed Consent:** Written informed consent was not received due to the retrospective nature of this study

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**Hasta Onamı:** Çalışmanın retrospektif tasarımından dolayı hasta onamı alınmamıştır.

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**Table 1.** The mean pre- and post-operative flexion degrees (°) and Knee Society (Knee and Function) Scores

	Preoperative	Postoperative	
Flexion (°) (Mean ± •SD) [Minimum- maximum]	119.3±18.9 [70-145]	128±11.5 [100-155]	p<0.0001*
Knee Score (Mean ± •SD) [Minimum- maximum]	49.1±12.0 [25-84]	92.9±8.2 [38-100]	p<0.0001*
Function Score (Mean ± •SD) [Minimum- maximum]	48.9±14.1 [20-90]	90.7±10.6 [55-100]	p<0.0001*

• Standart  
Deviation

\*Student t -  
test

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**Table 2.** Comparison of mean pre-operative flexion degrees of the knees that achieved hyperflexion ( $\geq 130^\circ$ ) and those did not.

Postoperative Flexion ( $^\circ$ )	Knee (n)	Mean Preoperative Flexion ( $^\circ$ )
<130	60	106 $\pm$ 17
$\geq 130$	90	128 $\pm$ 14
		*p< 0.0001, <i>Student t-test</i>

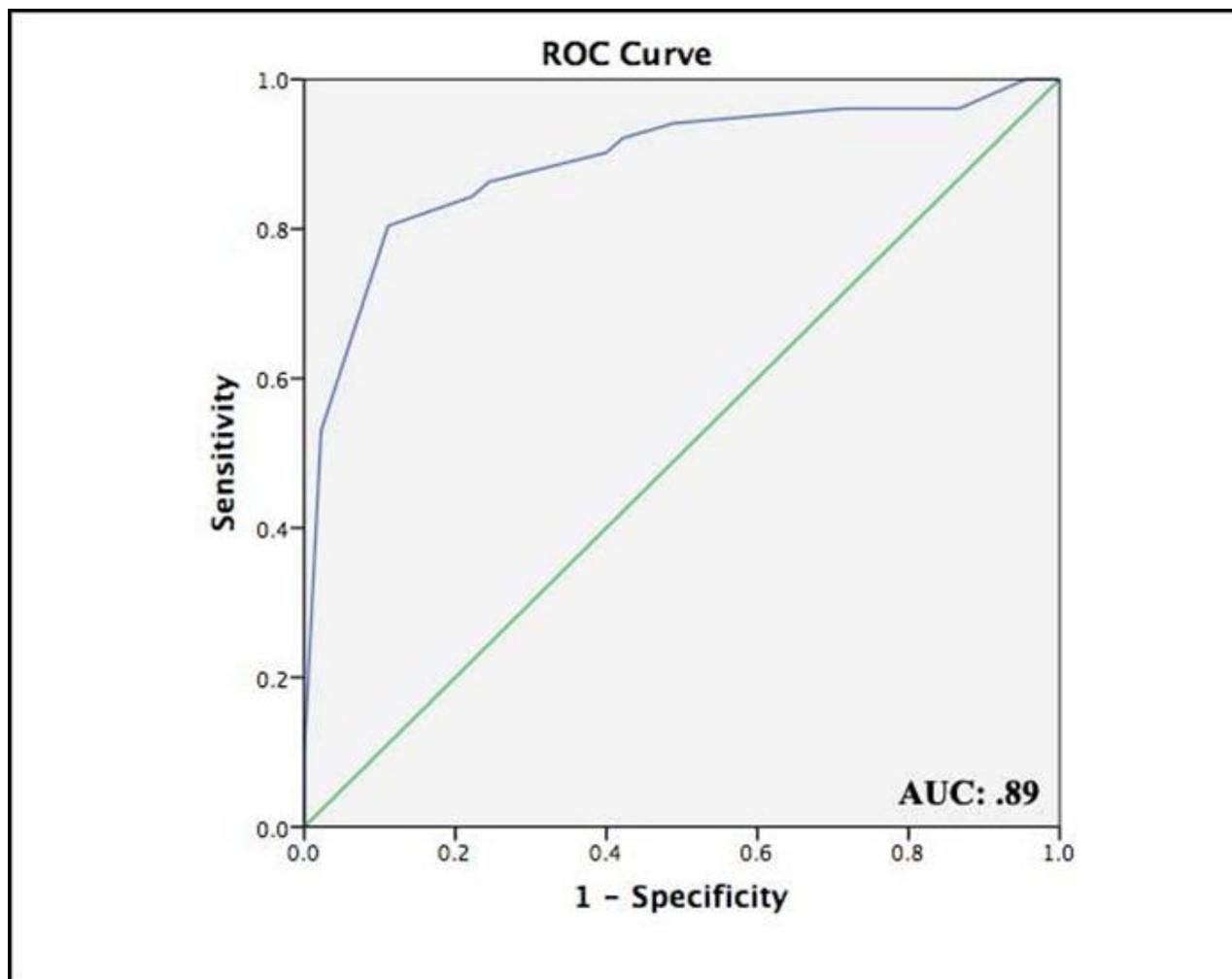
**Table 3.** Comparison of knees that had preoperative range of flexion of  $115^\circ$  and above with below degrees that reached postoperative hyperflexion ( $\geq 130^\circ$ ).

		Postoperative Hiperflexion $\geq 130^\circ$		Total
		-	+	
Preoperative flexion $\geq 115^\circ$	-	43	16	59
	+	17	74	91
Total		60	90	150

Fischer Exact test, p <0.001

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**Figure 1.** Receiver operating characteristic (ROC) curve analysis; investigating the required preoperative range of flexion to achieve a high postoperative range of flexion (AUC:0.89)



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