Does the Implant Design Influence the Outcome after Total Knee Arthroplasty?

Ebrahim Khamis, MRCS, CABS* Mohammed Hussain, BSc, MD**
Shaker Al Asheeri, BSc, MD** Ali Zainaldeen, MBBS**Abdulla Malki, MD, FRCS***

Objective: To compare the outcome of the two different TKA implant designs used at SMC and to derive an estimate for the cost-effectiveness of using different implants.

Design: A Retrospective Study.

Setting: Department of Orthopedics, Salmaniya Medical Complex, Bahrain.

Method: Two hundred ninety-eight patients who had TKA from January 2011 to June 2014 at SMC were reviewed. Patients with different implant designs were compared for pain severity, the range of motion (ROM), walking distance and satisfaction.

Result: There were no significant statistical differences in pain severity, ROM, walking distance or patient's satisfaction between the two implant designs used at SMC.

Conclusion: Selection of the implant design from the known manufacturers should be based on appropriate criteria.

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Total Knee Arthroplasty (TKA) is an established and reliable way of treating advanced knee osteoarthritis (OA)[1,2]. It is designed to improve the function and quality of life. It is an effective, but costly surgical procedure for the healthcare system. The success of TKA depends on multiple factors including proper patient selection, good surgical technique, implant design and post-operative rehabilitation[3-5]. The outcomes of TKA have improved with the use of careful preoperative planning, the availability of a variety of implant designs and operative technique guided by accurate instrumentation sets that help the surgeon to position and fix the implants more accurately and reproducibly[6].

Many implant designs for TKA are available in the market. Manufacturing companies are advocating the use of their implants, each claiming better result. The Swedish and British Joint Registries list many of these implants as being used in Sweden and UK respectively[7,8]. However, it does not compare its use to each other regarding the functional outcome of patients undergoing TKA[9].

The aim of this study is to compare the outcome of the two different implant designs (Scorpio NRG and PFC Sigma) used at SMC and to derive an estimate for the cost-effectiveness of TKA using the less expensive implant type if no effect on the outcome has been found.

METHOD

Three hundred fifty-one patients who had TKA from January 2011 to June 2014 were reviewed. TKA is performed using two implants (Scorpio NRG and PFC Sigma). The selection of these two implant designs was primarily based on their place in the Swedish and British Joint Registries[7,8]. They were performed by three arthroplasty surgeons at SMC, working independently of each other.

Fifty-three patients were excluded from the study due to loss of follow-up visits, the death of a patient, infection requiring revision within one year postoperatively and incomplete documentation.

Two hundred ninety-eight patients were included in the study; 145 (48.66%) were males and 154 (51.34%) were females. Mean age was 65.9 years (57-74 years). The mean duration of symptoms was 3.3 years (1-9 years).

The criteria for surgical intervention were primarily based on pain severity, functional disability and radiological advanced OA changes.

In this study, pain severity was stratified into three categories: mild (1 to 3 on the numeric pain rating scale), moderate (4 to

* Consultant
Department of Orthopedics
** Senior Orthopedic Resident
*** Consultant Orthopedic Surgeon
Salmaniya Medical Complex
Professor
Arabian Gulf University
Kingdom of Bahrain
Email: drebrahim@live.com; dr-ortho@hotmail.com

7 on the numeric pain rating scale) and severe (8 to 10 on the numeric pain rating scale).

The surgical procedure was performed through a medial parapatellar arthrotomy approach using the instrument systems for either implant design (Scorpio NRG or PFC Sigma), see figures 1 and 2. The postoperative rehabilitation program was similar for all patients. Patients were discharged from the hospital when they were able to walk independently using a walking frame or crutches.

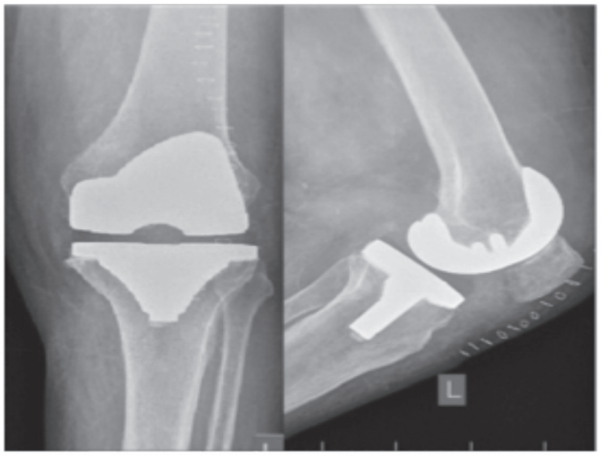

Figure 1: A Radiograph of TKA Using Implant Scorpio NRG

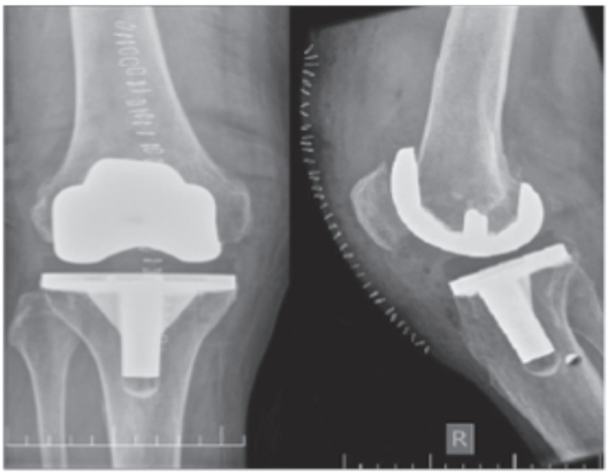

Figure 2: A Radiograph of TKA Using Implant PFC Sigma

Patients were assessed preoperatively, six to ten weeks postoperatively, and a final visit after one year. Pain severity using the numeric pain rating scale, ROM measurement (flexion deformities and maximum flexion achieved), walking distance, and patient satisfaction were assessed preoperatively, post-operatively and during follow-up.

RESULT

One hundred forty-seven (49.33%) patients had TKA using Scorpio NRG and 151 (50.67%) patients underwent TKA using PFC Sigma. Data were analyzed using SPSS version 20 and Chi-square test was performed for pain severity, maximum flexion, flexion deformity, walking distance and patients' satisfaction, see tables 1 to 5.

Table 1 deals with pain severity; the P-value was 0.829 which indicates no significant statistical difference between Scorpio NRG and PFC Sigma implants.

Table 1: Pre and Postoperative Pain Severity

Implant Design	Pain Severity	Preoperatively	Postoperatively
A	None	0	19 (12.93%)
	Mild	0	117 (79.59%)
	Moderate	0	11 (7.48%)
	Severe	147 (100%)	0
	Total	**147 (100%)**	**147 (100%)**
B	None	0	16 (10.6%)
	Mild	0	122 (80.8%)
	Moderate	1 (0.66%)	13 (8.6%)
	Severe	150 (99.34%)	0
	Total	**151 (100%)**	**151** (100%)

Table 2 deals with maximum flexion; the P-value was 0.785 which indicates no significant statistical difference between Scorpio NRG and PFC Sigma implants.

Table 2: Pre and Postoperative Maximum Flexion

Implant Design	Flexion Deformity	Preoperatively	Postoperatively
A	70^o or less	2 (1.36%)	1 (0.68%)
	71^o to 100^o	15 (10.2%)	9 (6.12%)
	More than 100^o	130 (88.44%)	137 (93.2%)
	Total	**147 (100%)**	**147 (100%)**
B	70^o or less	3 (1.99%)	2 (1.33%)
	71^o to 100^o	12 (7.95%)	11 (7.28%)
	More than 100^o	136 (90.06%)	138 (91.39%)
	Total	**151 (100%)**	**151 (100%)**

Table 3 deals with flexion deformity; the P-value was 0.974 which indicates no significant statistical difference between Scorpio NRG and PFC Sigma implants.

Table 3: Pre and Postoperative Flexion Deformity

Implant Design	Flexion Deformity	Preoperatively	Postoperatively
A	15^o or less	119 (80.95%)	144 (97.96%)
	16^o to 30^o	21 (14.29%)	3 (2.04%)
	More than 30^o	7 (4.76%)	0
	Total	**147 (100%)**	**147 (100%)**
B	15^o or less	122 (80.79%)	148 (98.01%)
	16^o to 30^o	20 (13.25%)	3 (1.99%)
	More than 30^o	9 (5.96%)	0
	Total	**151 (100%)**	**151 (100%)**

Table 4 deals with walking distance; the P-value was 0.506 which indicates no significant statistical difference between Scorpio NRG and PFC Sigma implants.

Table 4: Pre and Postoperative Walking Distances

Implant Design	Walking Distance	Preoperatively	Postoperatively
A	Indoors only	13 (8.84%)	0
	Up to 0.5 km	120 (81.63%)	35 (23.81%)
	0.5 to 1.0 km	11 (7.48%)	96 (65.31%)
	More than 1.0 km	3 (2.04%)	16 (10.88%)
	Total	**147 (100%)**	**147 (100%)**
B	Indoors only	19 (12.58%)	0
	Up to 0.5 km	112 (74.17%)	41 (27.15%)
	0.5 to 1.0 km	15 (9.94%)	89 (58.94%)
	More than 1.0 km	5 (3.31%)	21 (13.91%)
	Total	**151 (100%)**	**151 (100%)**

Table 5 deals with patients' satisfaction; the P-value was 0.506 which indicates no significant statistical difference between Scorpio NRG and PFC Sigma implants.

Table 5: Postoperative Patients' Satisfaction

Implant Design	Satisfaction	Patients
A	Satisfied	139 (94.56%)
	Unsatisfied	8 (5.44%)
	Total	**147 (100%)**
B	Satisfied	144 (95.36%)
	Unsatisfied	7 (4.64%)
	Total	**151 (100%)**

DISCUSSION

Early designs for knee replacement arthroplasties were metal-on-metal that created many complications on follow-up. In the early 1960s, Sir John Charnley introduced the concept of low-friction arthroplasty of the hip; metal femoral component and plastic acetabulum made of Ultra High Molecular Weight Polyethylene (UHMWPE) was used. The components were fixed using acrylic bone cement[10,11]. Ten years later, Gunston used the same concept for knee replacement arthroplasties[12]. Since then, the number of primary TKA performed annually has increased significantly. Outcomes have improved with the use of proper patient selection, better prosthesis design, meticulous surgical technique including proper soft tissue balancing and limb alignment and postoperative rehabilitation[6,13,14].

The main objectives of TKA are reduction of pain, improvement of function and correction of deformities[15]. Many studies have shown clearly that these objectives are mostly fulfilled following properly performed TKA[16-18].

TKA has been performed using many implant designs. Some of the implants were regularly used in Sweden and UK and were listed in the Swedish and British Joint Registries[7,8].

Patients with knee OA could be assessed using many of the available rating systems. Unfortunately, there is no ideal rating system. However, all systems include measurement of pain severity, evaluation of function and assessment of the range of motion[16,18,19]. In our study, we have used these three assessment tools for evaluating patient's outcome postoperatively and preoperatively. Patients' satisfaction evaluation tool was included[18].

Hamilton et al found that patient outcome after TKA could be influenced by the prosthesis used; while Redha et al demonstrated that the results are equally good for the different appropriately selected implants[20-21].

Patients in this study demonstrated no significant difference in all scores used (pain severity, walking distance, flexion contracture, maximum flexion range and patient satisfaction). Results have shown a reduction of pain, improvement in movement and better function post-operatively. Using appropriately selected different implant designs has no influence on the surgical outcome. Sharkey et al stated that appropriate selection of implants should be based on criteria of implants' developmental history, the instruments' reliability, reproducibility of the technique, independently published results and price[22].

The limitations of this study were as follows: the limited follow-up, comparison of same implants in different patients; because it is retrospective, the records were not designed for the study, potential confounding factors were not recorded and no randomization.

This study supports the strategy of using implants based on their availability and cost. Less expensive implant designs would produce an equally good outcome. Consequently, more implants could be purchased resulting in a shorter patients' waiting list and improved medical care. Moreover, the cost difference between implants could be significant, which could be utilized to improve other deficient areas in the health system.

CONCLUSION

Total knee arthroplasty is a cost-effective surgical intervention for the treatment of advanced knee osteoarthritis. Appropriately selected and performed, the results of TKA using many of the marketed implant designs are generally good.

A selection of the implant design from the known manufacturers should be based on appropriate criteria.

A multicentric study with convenient sample size and long period of follow-up is recommended to evaluate different implant designs for TKA.

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