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Bilateral Total Knee Replacements using Two Different Implant Designs - Preliminary Report

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Objectives: To evaluate the results and advantages of using two different implant designs for total knee replacement arthroplasties.

Design: Prospective randomized study.

Setting: Orthopaedic Department, SMC, Bahrain.

Methods: Between January 2000 and December 2002, nine patients with advanced osteoarthritis, with the indication of bilateral total condylar replacements, had one knee replaced with design 'A' and the other side with design 'B'.

Results: The nine patients with designs A and B were critically analyzed to compare the results of the two designs in the same group of patients by the same medical team.

The nine patients compromised of six women and 3 men with a mean age of 66.5 at the time of replacing the first knee. The follow-up period ranged from 18 to 42 Months.

All patients were satisfied and showed improvement of pain, deformity and function. The mean pre-operative scores were 48.5 and 48.3 while the follow-up scores were 89.1 and 88.7 for knees with designs 'A' and 'B' respectively.

Conclusion: The results of the knees with either design 'A' or 'B' are similar. Purchasing two designs will not affect the results, but it will reduce cost and improve technical support.

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Significant evolution of total knee replacement arthroplasty (TKR) took place during the last three decades. Due to improvement of the instruments, materials and implant designs, it became possible to obtain appropriate implant positioning and fixation provided accurate surgical technique is followed[1,2].

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Many of the currently marketed designs provide painless, stable and mobile knee for more than 10 and 15 years[3,4]. Some of the early-introduced designs were further developed, modified over the years and dominated the market. Domination of few manufacturers created several problems. One of the problems is a state of monopoly that in turn increased the cost and on occasions delayed the delivery of implants[5]. With hundreds of different implant designs available in the medical market, surgeons, especially in the developing countries may find it difficult to choose an implant design. The appropriate selection should be based on implant's developmental history, instruments reliability, independent published results and price[6].

In our department a total condylar design 'A' has been in use since the early 1990's. A state of monopoly occurred and reflected on the cost, availability and technical support. In 1999 a second total condylar design 'B' was selected and introduced to our unit. Both designs 'A' and 'B' have documented histories of development and published results[7-9].

The aim of this paper is to compare the results of the two implants ('A' & 'B') when used for bilateral knee replacement arthroplasties by the same surgical team.

METHODS

Between January 2000 and December 2002, all patients with osteoarthritic knees with the indication of bilateral TKR were randomized for using two different implant designs 'A' and 'B'. During that period, nine patients had design 'A' on one knee and design 'B' on the other.

The decision for surgery was based on severity of pain, functional disability and radiological changes (Figure 1).

Figure 1. Radiograph of osteoarthritic knees showing decreased joint spaces, osteophyes, sub-chondral sclerosis and varus deformity

All the knees were explored through straight mid-line skin incision and curved para-patellar incision for the muscles and capsule. The preparation of the tibial and femoral condyles was performed with the instrument systems for either design 'A' or 'B'. The appropriate size trial implants were positioned and tested for alignment, range of movement and stability. The appropriate pre-sterile components were selected and cemented. The patella was not replaced in any of the knees.

Wound was closed in layers and drained. Prophylactic antibiotics and anticoagulants started on the day of surgery and continued for three to five days. Standard post-operative programme was followed for mobility and rehabilitation of the patients.

All the patients were assessed before and after surgery according to the Knee Function Assessment Chart of the British Orthopaedic Association[10]. For the sake of comparison on reporting the results of this study, the assessment was transformed to the 100 points Bristol Scoring System that resembles that of the Hospital for Special Surgery[11].

RESULTS

The nine patients with design 'A' on one knee and design 'B' on the other were six women and three men. The mean age at the time of replacing the first and second knees was 66.5 (59 to 73) and 67.1 (60 to 74) respectively.

The sizes of the implants required for the patients were mostly of small and medium sizes. One patient required large size. The thickness of the tibial inserts required was 8 and 10 mm.

At a follow-up period of 18 to 42 months, the nine patients were satisfied with the results on both knees. On assessment, there were improvements in pain; movement and deformities .The improvements in the overall scores were remarkable as demonstrated in Table 5.

Pre-operatively, the pain was severe in all patients. Post-operatively, one knee with 'B' design had moderate pain while the other knees from both groups were either pain free or with mild ache (Table 1).

Table 1. Pre- and post-operative pain

Pain	Pre-operative		Post-operative	
	'A'	'B'	'A'	'B'
None/ mild	0	0	9	8
Moderate	1	0	0	1
Severe	8	9	0	0
Total	9	9	9	9

Most of the patients were satisfied with the range of movement obtained following surgery. Pre-operatively, two knees from group 'A' and three from group 'B' had range of flexion more than 100 degrees while the other knees had flexion less than 100 degrees. Post-operatively eight knees from each group had flexion more than 100 degrees (Table 2). Fifty per cent of the knees reached 120 degrees of flexion.

Table 2. Pre- and post-operative flexion

Flexion/degrees	Pre-operative		Post-operative	
	'A'	'B'	'A'	'B'
100 or more	2	3	8	8
81 to 100	6	6	1	1
60 or less	1	0	0	0
Total	9	9	9	9

Pre-operatively, most of the knees had flexion deformity more than 10 degrees. Post-operatively, one patient from each group had flexion deformity more than 10 degrees (Table 3).

Table 3. Pre- and post-operative flexion deformity

Flexion deformity	Pre-operative		Post-operative	
	'A'	'B'	'A'	'B'
30 degrees or more	1	1	0	0
21 to 30	1	1	0	0
11 to 20	6	5	1	1
Less than 10	1	2	8	8
Total	9	9	9	9

Figure 2. *Radiograph of knees following total knee replacement that demonstrates appropriate positioning of implants in valgus. The right knee shows slight varus tilt associated with pre-existing rotational deformity*

All the knees showed improvement of the alignment after operation. Pre-operatively all the knees were in varus. After operation (Figure 2), the knees became within the required valgus angle (Table 4).

Table 4. Pre- and post-operative varus/ valgus angle

Angle	Pre-operative (varus)		Post-operative (valgus)	
	'A'	'B'	'A'	'B'
20 degrees or more	1	1	0	0
11 to 20	6	5	0	0
Less than 10	2	3	9	9
Total	9	9	9	9

All patients admitted improvement after surgery. However, patients with flexion less than 100 degrees expressed concern as it restricted their socio-religious requirements, especially with preying and squat setting.

Clinical deep vein thrombosis occurred once in each group. A knee from group 'B' developed wound haematoma that required aspiration and another knee from group

'A' showed delayed wound healing. None of these complications affected the follow-up scores.

Scores out of 100 pints: the mean pre- and post-operative follow-up scores were 48.5 and 89.1 for group 'A', and 48.3 and 88.7 for group 'B' respectively (Table 5).

Table 5. Pre- and post-operative scores (out of 100 points)

Knee score	Pre-operative		Post-operative	
	'A'	'B'	'A'	'B'
1	46	47	90	91
2	50	50	91	91
3	52	51	93	92
4	48	46	84	83
5	47	47	92	90
6	51	50	82	81
7	48	50	84	86
8	46	46	94	93
9	49	48	92	92
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Mean score	48.5	48.3	89.1	88.7

DISCUSSION

The objectives of surgical treatment of osteoarthritic knee are to relieve pain, correct deformity and to restore a mobile knee. In advanced stages of the disease, these objectives are achieved by knee replacement surgery.

Total replacement of both femoral and tibial articulating surfaces with a simple metal hinge implant developed in the 1950's. The design showed early satisfactory results. However, the knee joint is more complex than a simple hinge. The normal knee permits few degrees of rotation, sliding, and abduction-adduction, besides the wide range of flexion-extension. Therefore, the concept of simple hinge implants failed to provide long-term satisfactory results especially in active patients[12-14].

Significant evolution of knee replacement arthroplasty took place in the 1970's when the concept of low friction arthroplasty was applied by using a metal femoral component and a polyethylene tibial component. Further development provided metal-backed ultrahigh density polyethylene tibial component[15-17].

Soon after the evolution of TKR in the 1970's, the importance of reproducible correct positioning of the implants with balanced ligaments was recognized. Improvement in surgical techniques and developments of instrumentations for current implants were of great help to achieve these objectives. Both design 'A' and 'B' used in this study have reliable instrumentation systems.

Many of the currently marketed implants give acceptable results. However, it is possible that many of the implants are selected and purchased without sound basis.

There are criteria for selection of implants including results, reliability and cost[6,18]. To facilitate comparing the results of different implants, there is a need for universal system for assessment and scoring. Despite this requirement, there are more than thirty different systems for assessments identified in the literature[19]. In this study an easy to use system of scoring was used.

Many published reports demonstrated comparison between different replacement arthroplasties in different patients and few were compared in the same patient[20-23]. In our department we have been using the same implant design for bilateral TKA until this study started. The current study compared the results of two different implant designs used in the same group of patients where the operations were performed by the same surgical team.

Since our early days of performing knee replacement arthroplasties, we have been adopting the Knee Function Assessment Chart of British Orthopaedic Association that was introduced in 1978[10,24]. For the sake of comparing results of different implant designs, we transformed our assessment to a system with scoring out of 100 points[11].

The replaced knees in this study showed acceptable tibio-femoral valgus angle within 10 degrees. The recommended tibio-femoral valgus angle following TKR range is 7 degrees[25]. However, there are variations related to the gender, reliability of the instruments and surgeons judgment. A valgus angle between 4 and 10 degrees is acceptable[26,27].

Besides achieving acceptable alignment, the results showed reduction of pain, improved movement and function. The mean pre-operative score of approximately 49 points improved on follow-up to 89.1 for design 'A' and 88.7 for design 'B'. The follow-up scores are comparable to other published reports from specialized centers[8,9,28].

CONCLUSION

Total Knee Replacement arthroplasty is a well-established technique for treatment of joints with advanced osteoarthritic changes. Many of the currently marketed implant designs if appropriately selected can give equally good results.

Based on appropriate selection criteria, a second total condylar implant design was introduced to our department. That achieved a state of competition between the manufacturers with positive impact on technical support, delivery and reduction of cost.

In this study, we demonstrated that the results and scoring of both designs are equally good. The drawbacks of this study are the small number of patients and the short-term follow-up period.

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