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No clinical superiority of bi-cruciate retaining versus posterior stabilized total knee arthroplasty at two years follow-up

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The purpose of the present study was to evaluate and compare the clinical outcomes of two groups of patients subject to bi-cruciate retaining (BCR) or posterior-stabilized (PS) implants. It was hypothesized that patients treated with BCR prostheses would present higher flexion and better clinical and functional results than those treated with PS implants. This prospective study included thirty-two patients treated for primary knee osteoarthritis and assigned to two matched groups for their demographic characteristics and comorbidities. Those with functioning cruciate ligaments received bi-cruciate retaining prostheses. In the case of ligaments' insufficiency, the posterior-stabilised design was selected. The primary outcome was knee flexion, and secondary outcomes included the patient's reported outcomes as recorded by the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire, visual analogue scale (VAS) for pain, treatment-related complications, and surgical time. Complete data were recorded for all patients with a minimum of 2 years of follow-up. This study found a statistically significant improvement in all the analysed clinical and functional assessment tools from baseline to the latest follow-up ($p<0.05$) for both groups. However, no statistically significant difference was found between the two groups. Furthermore, bi-cruciate retaining design is surgical time. There was no evidence of clinical superiority of bi-cruciate retaining compared to posterior stabilized knee implants. Therefore, further randomized studies with more participants and a longer follow-up on comparing bi-cruciate retaining and posterior stabilized implants in primary knee osteoarthritis could be rewarding.

Keywords: bi-cruciate retaining prosthesis, total knee arthroplasty, posterior stabilized prosthesis, clinical outcomes.

INTRODUCTION

Total knee arthroplasty (TKA) is considered a successful intervention in orthopaedic surgery worldwide. However, patient satisfaction is still relevant, as up to 20% of them continue to have postoperative pain, functional limitations, and low treatment satisfaction rates[1].

To date, posterior-stabilized (PS) and cruciate retaining (CR) implants are commonly used. In both methods, the anterior cruciate ligament (ACL) is removed, affecting normal knee function, as ACL is an essential structure that assures anteroposterior knee stability[2,3]. Nevertheless, both designs demonstrated good long-term results, and low revision rates[4] but patient-reported assessment tools reveal a high number of unsatisfied patients[5].

Trying to replicate native knee kinematics could reduce the percentage of dissatisfied patients and improve clinical outcomes. In this regard, the bi-cruciate retaining design (BCR) intends to allow more physiological movement of the knee, better proprioception, and anteroposterior stability, mimicking a closer to normal knee function[6,7]. These facts are crucial, especially for younger and more active patients needing TKA. Indeed, numerous studies concluded that preservation of cruciate ligaments in total knee arthroplasty re-establishes the anatomy and kinematics of the normal knee[8,9].

The modern BCR design concept is similar to the unicompartmental knee arthroplasty (UKA), which preserves both cruciate ligaments, and it has been associated with superior outcomes in terms of

patient function compared to conventional total knee replacement[10].

Several studies demonstrated good functional results and long-term survival rates of BCR prosthesis[11,12], but this is still controversial in the literature[13]. In addition, due to the challenging and technically demanding procedure, BCR implants were abandoned for a period of time. Recently, its conception was reintroduced using a more appropriate prosthesis design and improved instruments to help with proper implantation[6,14].

The purpose of the present study was to evaluate and compare the clinical outcomes of two groups of patients subject to bi-cruciate retaining or posterior-stabilized implants. It was hypothesized that patients treated with BCR prostheses would present higher flexion and better clinical and functional results than those treated with PS implants.

MATERIALS AND METHODS

Two groups of sixteen patients were included in the study. The first group enclosed sixteen patients with efficient cruciate ligaments and received bi-cruciate retaining prostheses (Vanguard XP, Zimmer-Biomet, Warsaw, Indiana, USA). For the control group, sixteen matched for demographic characteristics and comorbidities patients presenting ligament insufficiency were selected, and they received the posterior-stabilized design (Vanguard PS, Zimmer-Biomet, Warsaw, Indiana, USA).

The inclusion criteria were male and female with tricompartmental osteoarthritis, Body Mass Index (BMI) <30 kg/m^2, and a minimum of 2-years follow-up. On the other hand, the exclusion criteria included any previous knee operation within 6 months before screening, previous ACL reconstruction, post-traumatic arthritis, varus or valgus malalignment exceeding 10°, inflammatory joint disease, septic arthritis and intra-articular injections (corticosteroid, Hyaluronic Acid, PRP, etc.) within 90 days before enrolment. All procedures were in accordance with the ethical standards of the institutional bioethics committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Written informed consent was obtained from all subjects before the study.

All surgeries were performed through a medial parapatellar approach in a supine position under general anaesthesia without tourniquet application. The surgical procedure followed the basic principles of total knee arthroplasty. The distal femoral cut was done using an intramedullary guide with 5-8^o of valgus angle based on each individual anatomy and 2-4^o of external rotation. Concerning the tibia, an extramedullary guide was used to perform a unique cut for the PS design, whereas multiple cuts preserving the tibial island were performed in the BCR design. For the latter, a special instrumentation was used to protect the tibial island and recreate the anatomic slope. Patellar resurfacing was systematically performed. For the BCR design, resurfacing was done as the first step, while in the PS design, it was the last step. The cementation technique was performed in one stage for both groups starting with cleaning the bone thoroughly with pulse lavage, vacuum mixing of cement, and pressurized injection with a cement gun. Cement was enforced on both implants and bone and the knee was retained in extension while the cement was set up.

The primary outcome, knee flexion, was measured using a manual goniometer while the patient was supine from the lateral side. Secondary outcomes, which provided a comprehensive view of the patient's condition, included the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire and the visual analogue scale (VAS) for pain, surgical time, and treatment-related complications. Standard radiological evaluation was performed in all the follow-up intervals. All patients agreed to follow the same rehabilitation protocol.

All data were analyzed by an independent statistician. Statistical analysis was conducted using SPSS 24.0 (IBM Corp, Armonk, NY). For all the values, the mean and SD are provided. The paired t-test was performed to analyze outcomes between preoperative and post-operative findings, respectively. P-values less than 0.05 were considered statistically significant.

RESULTS

All patients included in this study were prospectively followed for at least 24 months (range 24-41months). Complete data were recorded for all patients. Analytical demographic characteristics are provided in Table I.

Statistically significant improvement was found in all clinical and functional assessment tools analyzed from baseline to the latest follow-up ($p<0.05$) for both groups. However, no statistically significant difference was found between the two groups. All outcomes are demonstrated in detail in Table II.

Major complications were defined as cases needing revision surgery. One early implant failure in the BCR group required reoperation. On the other hand, a minor complication in the PS group was observed, consisting of one wound dehiscence. Finally, the mean

Table I. — Patient's Demographic Characteristics

Characteristic	BCR Group	PS Group
Participants	16	16
Gender	Female, n=7 Male, n=9	Female, n=7 Male, n=9
Age	70.6 years (range 55-85)	70.8 years (range 56-87)
BMI	27.92 ± 2.42 kg/m2	27.87 ± 2.34 kg/m2
ASA Classification	II, n= 10 III, n= 6	II, n= 9 III, n= 7
Kellgren-Lawrence	III, n= 11 IV, n= 5	III, n= 10 IV, n= 6

Table II. — Summary of Outcomes

	Preoperative		24 Months FU		P- value		
Variables	BCR Group	PS Group	BCR Group	PS Group	BCR Group Final FU versus Preoperative	PS Group Final FU versus Preoperative	BCR vs PF Groups Final FU
Knee Flexion	$107^0 \pm 4^0$	$106^0 \pm 4^0$	$121^0 \pm 2^0$	$120^0 \pm 1^0$	p<0.05	p<0.05	NS
KOOS pain	39.85 ± 6.45	39.86 ± 6.51	76.79 ± 5.13	76.82 ± 4.19	p<0.05	p<0.05	NS
KOOS symptoms	38.08 ± 5.19	38.15 ± 5.12	76.42 ± 4.57	76.23 ± 4.22	p<0.05	p<0.05	NS
KOOS ADL	40.91 ± 4.76	40.87 ± 4.74	78.73 ± 4.44	78.64 ± 3.93	p<0.05	p<0.05	NS
KOOS Sports/Rec	25.58 ± 14.06	25.62 ± 14.07	48.92 ± 7.14	49.08 ± 6.71	p<0.05	p<0.05	NS
KOOS QOL	24.12 ± 13.86	23.17 ± 9.17	48.72 ± 7.93	48.64 ± 7.73	p<0.05	p<0.05	NS
VAS pain	7.62 ± 0.81	7.64 ± 0.83	2.17 ± 0.66	2.16 ± 0.68	p<0.05	p<0.05	NS
Complications Major/Minor			1/0	0/1			
Surgical Time (min)			84.20 ± 7.10	69.15 ± 3.20			p<0.05
All outcome values are described as mean ± standard deviation							

operative time for the BCR group was 84.20 min instead of 69.15 for the PS group, with a statistically significant difference (p<0.05). It should be noted an intraoperative bone island fracture in the bi-cruciate group that was converted to a CR prosthesis was considered a treatment-related complication, but it was excluded from further analysis.

DISCUSSION

The most important finding of this study was that both BCR and PS prosthesis significantly improved the clinical and functional outcomes. Nevertheless, bi-cruciate retaining knee implants did not demonstrate clinical superiority compared to posterior-stabilized design. Moreover, they were associated with a higher number of complications and a slightly prolonged surgical time. Consequently, the results did not verify the hypothesis of the study.

The bi-cruciate retaining total knee arthroplasty, with its unique design that allows retention of both cruciate ligaments, presents an intriguing concept. The main goals of this design are to preserve normal femoral rollback and proprioception, enhance stability, and maintain a close-to-normal knee motion. Indeed, Halewood et al. in a cadaveric study, demonstrated that the BCR design preserves an anteroposterior stability closer to normal and reduces laxity compared to the CR design. Moreover, possible reasons for unsatisfied patients have altered kinematics, including paradoxical anterior femoral translation and decreased proprioception after TKA[15]. Another cadaveric model showed that the rotational kinematics of the native knee is reproduced after BCR TKA with the medial constrained insert. They concluded that constraint of the medial side in BCR TKA is a crucial factor for restoring native kinematics, which may lead to better clinical outcomes[16].

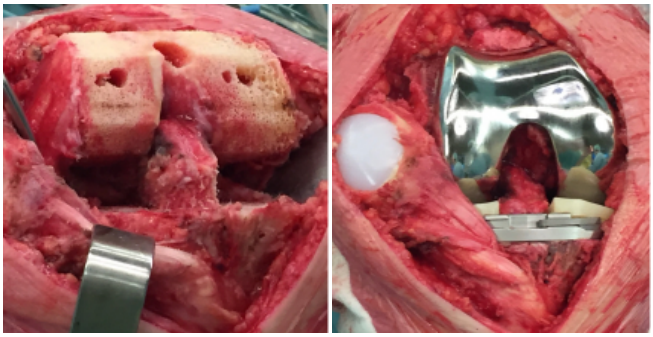

Fig. 1 — Intraoperative pictures of bi-cruciate retaining total knee arthroplasty procedure

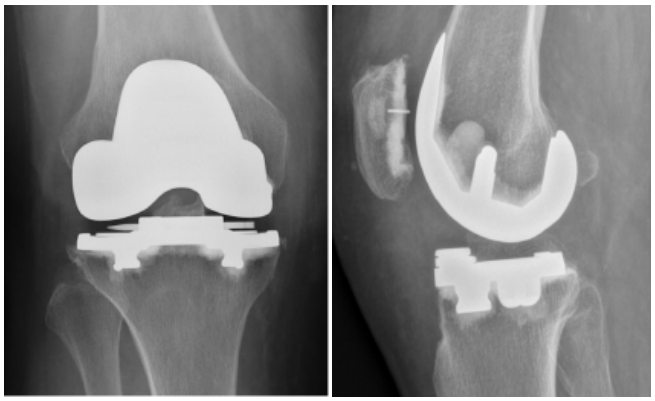

Fig 2 — Postoperative X-rays of bi-cruciate retaining total knee arthroplasty

Tsai et al.[17] demonstrated no statistically significant differences in anterior-posterior translation as well as varus rotation of BCR-TKA when compared to normal healthy knees during the stance phase. Heyse et al.[18] concluded that as both cruciate ligaments are preserved with BCR TKA the unloaded knee closely resembles native knee kinematics including preserving the rollback mechanism. Hence, conserving cruciate ligaments in total knee arthroplasty could be associated with better clinical outcomes.

Sabouret et al.[11], in a case series of 163 BCR implants, described excellent clinical results with a survival rate of 82% at 22 years of follow-up. In addition, Pritchett et al.[12] reported survival and functional outcomes in the largest long-term series of bicruciate-retaining total knee arthroplasty, which includes 214 knees in 160 patients with a minimum follow-up of 20 years. The Kaplan–Meier survivorship was 89% (95 % CI, 82-93 %) with revision for any reason as the endpoint. The main reason for the revision was polyethylene (PE) wear of a non-cross-linked PE. Excluding these revisions, the 20-year survivorship rate rises to 96%. Alnachoukati et al.[19], in their retrospective study, reported short-term results after 146 primary total knee arthroplasties using BCR implants. They noted 2 revisions (1.4%) and 1 reoperation (0.7%), which was a manipulation under anesthesia. They concluded that the new BCR design results in great patient-reported satisfaction, function, and short-term outcomes.

Another study that analysed patient-reported outcomes after bi-cruciate retaining arthroplasty was conducted recently by Baumann et al.[20]. The authors evaluated three groups of 34 patients who underwent a bicruciate-retaining total knee arthroplasty, a posterior stabilized total knee arthroplasty or a medial unicompartmental knee arthroplasty. The forgotten joint (FJS) score was used to describe patient satisfaction. They recorded a higher FJS for the BCR group and the UKA group compared to the PS group with a statistically significant difference between the bi-cruciate retaining implants (BCR and UKA) compared to the cruciate-sacrificing implant. In the present study, the KOOS score was used to quantify functional outcomes. A significant improvement was found in all the analyzed subscales from baseline to the latest follow-up ($p<0.05$) for both groups. However, no statistically significant difference was found between the two groups.

Preserving anterior cruciate ligament insertion into the tibia is another challenging issue, as the multiple tibial cuts may weaken the bone island. Hence, knee manipulations and, notably, a forced extension with the implants in place could provoke an avulsion fracture of the island. Thus, attention should be given, especially in the very first cases during the surgeon's learning curve. Indeed, Lombardi[21] reported a prospective multicenter study with early-stage results (90 days post-operative) of 383 patients with a BCR total knee arthroplasty. He described 11 cases of island fracture in the first 119 patients and only five cases in the following 264 patients. He interpreted this as a sign of a learning curve. In this study, one intraoperative bone island fracture (8%) was converted to a CR prosthesis, considered a treatment-related complication, and excluded from further analysis.

Various studies conducted with first-generation BCR implants demonstrated limited ROM and pain due to significant ligamentous tension. Cloutier et al.[22] reported that the average flexion range was 107° in 104 BCR knees after 10 years of implantation. In another study of 163 consecutive bi-cruciate retaining knee replacements, the same authors reported a mean flexion of 103°[11]. Jenny et al.[23], in their study of 32 ACL-retaining with a follow-up time of 2-3 years, reported 102° of flexion.

However, these outcomes did not align with recent studies with first or second-generation BCR implants. For example, the studies conducted by Pritchett[24,25] reported in 201 prostheses with preservation of both cruciate ligaments a mean range of motion of 119° after 8 and 11 years. Some years later, Alnachoukati et al.[19], in a case series of 146 knees using the same device of bi-cruciate retaining arthroplasty as the present study reported also a mean flexion of 121° but in a short-term review of 12 months. Baumann et al.[26], reported that the BCR group presented a mean flexion of 115.5°. Nevertheless, this value was lower than the mean flexion of the PS group, which was approximately 125°. Christensen et al.[13] reported a relatively higher mean average flexion of 122° for BCR group whilst 120° was observed in the CR group. The previous outcomes are in accordance with the results of the current study. In fact, a relatively higher mean average flexion of 121° was found in the BCR group instead of 120^0 in the PS group.

Another crucial point in bi-cruciate retaining design is the tibial component fixation. Various studies described a higher reoperation rate in BCR prostheses due to tibial component issues. For instance, Pelt et al.[27] found 12% of revision rate at 3 year follow-up with primary reason for revision the isolated tibial loosening. Christensen et al.[13] reported as well a higher overall risk of revision with BCR compared to CR implants. In details, they described one septic revision and two tibial revisions for ACL impingement in one case and aseptic tibial loosening with suspected metal allergy in the other. Similarly, in the present study, a higher reoperation rate was found in the BCR group again with one aseptic loosening of the tibial implant revised with primary components.

Two are the main contributions of the present study to the discourse of the bi-cruciate retaining total knee arthroplasty for primary osteoarthritis. First, the prospective comparative character of the study and collection of the data. To our best knowledge, there is a lack of recent literature comparing the functional results of similar types of implants. Second, the matched for demographic characteristics and comorbidities groups.

There are also specific limitations that have to be considered in the current study. The main limitation is that part of BCR procedures included in the study was performed during the surgeons' learning curve for this type of implant. That could explain the longer surgical time or the higher reoperation rate. In our institution, PS design is the gold standard; thus, this design was selected as the control group. Second, a prospective non-randomized comparative study predisposes to selection bias. However, as bi-cruciate retaining implants are not yet a standard treatment option for ethical reasons, it was decided to avoid randomization. Third, only a small number of patients are included in each group.

CONCLUSION

This study does not illustrate evidence of the clinical superiority of bi-cruciate retaining knee implants. Furthermore, it seems to be associated with a higher number of revision surgeries and prolonged surgical time. Therefore, further randomized studies, excluding learning curve procedures, with more participants and a longer follow-up on comparing bi-cruciate retaining and posterior stabilized implants in primary knee osteoarthritis, could be rewarding.

Compliance with ethical standards

Conflict of Interests: The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethical Approval: All procedures were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Participate and publish: Written informed consent was obtained from all subjects before the study and patients signed regarding publishing their data.

Data availability: The data that support the findings of this study are available on request from the corresponding author

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