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ORIGINAL ARTICLE

Functional and radiological outcomes of total knee arthroplasty using posterior-stabilized U2 knee system: A retrospective study in 560 cases at five years of follow-up

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Abstract

Purpose The purpose of this study was to assess clinical and functional outcomes as well as the prosthesis survival rates of the U2 Knee system in primary total knee arthroplasty (TKA) with a minimum follow-up of four years.

Methods We retrospectively analyzed 560 consecutively primary TKA performed between 2015 and 2019 due to osteoarthritis with a mean follow-up of 5.4 ± 1.1 years. The clinical outcomes were assessed using the knee society score (KSS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Radiographic outcomes were assessed using the American knee society's roentgenographic evaluation system. Prosthetic survival was calculated using the Kaplan–Meier method.

Results Postoperative KSS showed significant improvement at one year (Clinical: 37.4 ± 4.1 vs. 91.9 ± 3.7; $p < 0.01$; Functional: 41.2 ± 3.3 vs. 90.6 ± 4.8; $p = < 0.01$), with these improvements maintained throughout the follow-up period. The WOMAC score improved from 60 ± 10.1 preoperatively to 10.9 ± 8.3 ($p = 0.02$) at the end of the follow-up. There were 20 (3.7%) knees with radiolucent lines around the implant (< 2 mm), and none showed evidence of loosening. There were six (1.1%) revisions–four due to prosthetic joint infections and two due to periprosthetic femur fracture. The prosthetic survival was 97.8% at the study closure.

Conclusion The U2 knee system demonstrates effective and safe performance for primary TKA with significant improvements in functional scores, patient-reported outcomes, and a promising prosthesis survival rate at mid-term follow-up. We will continue with the series analysis to assess the long-term outcomes.

Keywords Knee osteoarthritis · Total knee arthroplasty · Functional outcomes · Prosthesis survival · U2 knee system

Introduction

Knee osteoarthritis is a painful joint disease that significantly impacts patients' functional capacity and quality of life [1, 2]. Total knee arthroplasty (TKA) has proven to be an effective treatment for the end stages of this condition, improving pain and function and achieving survival rates up to 95% [2–4].

The manufacturers currently offer a wide array of prosthetic options for primary TKA, each with a different design related to kinematics, patellar contact, constraint, fixation type, and instrumentation [3–5]. Knowing each implant's specific advantages and disadvantages is essential for surgeons when selecting which implant to use.

The U2 primary knee system has been available in our region since 2014. It features a femoral component discriminating between right and left, and a deep lateralized trochlear groove to promote optimal patellar tracking. The system emphasizes bone preservation philosophy by minimizing resection of the intercondylar box and posterior femoral condyles, allowing high degrees of knee flexion [5, 6].

Our department has used this implant for the past eight years, and to our knowledge, there are no medium-term reports of its performance. Therefore, this study aims to assess clinical and functional outcomes as well as the prosthesis survival rates of the U2 Knee System in primary TKA, with a minimum follow-up of four years.

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Materials and methods

Following institutional review board approval (protocol number 11978), a retrospective study was conducted on patients undergoing primary TKA consecutively between January 2015 and 2019 at a high-volume TKA center.

Patient setting

Patients were identified from our center's joint arthroplasty department database. The inclusion criteria were adult patients who underwent primary TKA in whom a U2 posterior-stabilized (PS) knee prosthesis (United Orthopaedic Corporation, Taiwan) due to end-stage osteoarthritis and had a minimum follow-up of four years. Exclusion criteria included patients with previous knee surgeries, a history of infection in the operated knee, femorotibial alignment > 20°, instability due to lack of collateral ligament integrity, oncologic disease, or incomplete clinical and radiological data.

Of 1642 primary TKAs performed during the study period, the PS U2 knee system prosthesis was implanted in 657 cases. After applying the inclusion and exclusion criteria, 97 were excluded from the study (34 due to previous knee surgeries, 35 with incomplete clinical or radiological records, 23 lost to follow-up, and five with a history of infection).

The final study cohort included 401 patients with 560 TKAs (70 patients underwent simultaneous bilateral TKA and 89 underwent two-stage bilateral TKA) with a mean follow-up of 5.4 ± 1.1 years (range 4–7.5).

U2 Knee prosthesis features

The United PS primary knee system features a femoral component made of cobalt-chromium alloy, available in seven sizes. It incorporates a bone-preserving design with low femoral condylar posterior resection (9 mm) and an anterior curved intercondylar box, reducing femoral resection. The anterior tibial postface of the polyethylene is also curved, which reduces stress and allows rotational freedom of 12.5°. The single-axis radius allows high degrees of flexion (155°) with a low post-cam contact point. Additionally, it features a lateralized (4°) and extended patellar groove, enhancing patellar contact and proper tracking. The tibial component is made of titanium alloy with a single delta keel and is available in eight sizes. The modular polyethylene insert (highly cross-linked-XPE) has a posterior slope of 5°, and thicknesses ranging from 9 to 18 mm. It is milled in a nonlinear arc shape, improving congruence, stability, flexion, and rotation while reducing wear. The patellar component is made of XPE polyethylene, with three fixation pegs, available in 7 sizes varying in outer dimensions (26–44 mm) and thickness (7–10.5 mm) [6].

Surgical technique

All the surgeries were performed in a laminar-flow operation room under hypotensive spinal anesthesia. All patients received one gram of intravenous cephazolin thirty minutes before the skin incision (2 g if the patient's weight was > 80 kg) and two doses of one gram of tranexamic acid (one during anesthetic induction and the other during surgery). A median approach with a standard medial parapatellar arthrotomy was performed in all patients. Soft tissue release and balancing were performed according to the pre-existent varus or valgus deformity. Tibial osteotomy was conducted perpendicular to the tibial axis, and femoral osteotomy was done with 3–6° valgus in the coronal plane. Patellar resurfacing was decided intraoperatively based on the surgeon's preference. All components were cemented in a single stage. The extensor apparatus was routinely sutured with continuous Vicryl stitches to ensure proper patellar tracking during flexion and extension. Thromboprophylaxis consisted of administering 40 mg of subcutaneous low-molecular-weight heparin for 30 days post-surgery.

All patients followed the same rehabilitation protocol. On the first postoperative day, they began quad and calf isometric exercises and walking with full weight-bearing assistance using a walker. From the second day, they used two canes for three weeks and one cane for another two weeks.

Routine follow-up visits were scheduled at 3, 6, and 12 weeks after surgery and subsequently at 6 and 12 months, continuing annually. Radiographic examinations were performed immediately postoperatively, at 3, 6, and 12 months, and then annually.

Data collection

The recorded variables included demographic data (gender, age), the American Society of Anesthesiologists (ASA) scale, diabetes mellitus, body mass index (BMI), and femorotibial alignment. The latter was categorized as varus < 0° (negative value), neutral 0–7° valgus (positive value), and valgus > 7° [7]. Preoperative variables and the prostheses used are described in Tables 1, 2.

Clinical and functional assessment

The knee society score (KSS), including its clinical and functional subscales, was registered preoperatively, at one year, and the last postoperative visit [8]. Preoperative range of motion (ROM) was measured with a goniometer and compared to one year postoperatively [9]. Patient-reported

Table 1 Preoperative characteristics of patients included in the series

Variables	$n = 560$
Age $_{(mean, SD)}$	68.2 ± 10.3
Male $_{(n,\%)}$	290 (51.7)
Side $_{(n,\%)}$	
Right	298 (53.2)
Left	262 (46.8)
DM $_{(n,\%)}$	187 (33.4)
ASA $_{(n,\%)}$	
I	96 (17.1)
II	293 (52.3)
III	87 (15.5)
IV	84 (15.0)
BMI $_{(n,\%)}$	
< 25	164 (29.3)
25–30	295 (52.7)
31–35	86 (15.3)
36–40	13 (2.3)
> 40	2 (0.4)
Varus $_{(n,\%)}$	351 (62.6)
Neutral $_{(n,\%)}$	120 (21.4)
Valgus $_{(n,\%)}$	89 (15.9)
Patella resurfacing	392 (70.0)

DM, diabetes mellitus; ASA, American Society of Anesthesiologists; BMI, body-mass index

Table 2 Protheses used in the series

Variables	*n* (%)
Femoral size	
2	
3	10 (1,8)
4	95 (16.9)
5	232 (41.4)
6	141 (25.2)
7	77 (13.7)
	5 (0.9)
Tibial size	
2	11 (1.9)
3	170 (30.3)
4	175 (31.2)
5	118 (21.1)
6	86 (15.3)
Patella size	
29	199 (49.4)
32	195 (48.4)
36	9 (2.2)
Polyethylene insert	
9	360 (64.3)
11	154 (27.5)
13	34 (6.1)
15	12 (2.1)

outcomes (PROMs) were assessed using the Western Ontario and McMaster Universities Osteoarthritis Index score (WOMAC) at the last visit [10]. These values were completed by two orthopedic fellows trained in knee arthroplasty during routine patient visits.

Radiographic assessment

Anteroposterior and lateral standing radiographs of the knee and patellar axial view (30° of flexion) were reviewed using the Knee Society's roentgenographic evaluation system to assess radiological alignments [11]. Measurements included the femorotibial angle, the coronal alignment of the femoral and tibial components, and the alignment of the femoral component (flexion or extension) and tibial component (posterior slope) in lateral views. These measures were performed using the Synapse software (Fujifilm Corporation, USA).

The knee society TKA evaluation and scoring system was used to assess the presence of radiolucent lines (RLL). Aseptic loosening was defined as RLL > 2 mm around prosthetic components, migration > 2 mm, or progression of linear RLL [12]. The first author of this study, a trained orthopedic surgeon specializing in knee arthroplasty, performed a radiological assessment.

Complications, revision, and prosthesis survival rates

Intraoperative and postoperative complications, including deep vein thrombosis (DVT), pulmonary embolism (PE), and periprosthetic fracture (PPF) (using the Rorabeck and Taylor classification), were recorded [13]. Acute and chronic periprosthetic joint infection (PJI) was assessed according to the MuskuloSkeletal Infection Society (MSIS) criteria [14]. Prothesis survival was analyzed based on endpoint revision for any cause.

Statistical analysis

Numerical variables were described as mean and standard deviation or median and interquartile range according to their distribution, while qualitative variables were described as frequencies or percentages. Assessment of categorical variables was performed by using the Chi-square test (or Fisher's exact method if necessary). Also, continuous variables were evaluated with the "t" student test. Prosthesis survival rate analysis was performed with the Kaplan-Meir methods. A difference of $p < 0.05$ was considered significant. All data were registered into an Excel (Redmon, USA) spreadsheet, and statistical calculations were performed with the use of the software GraphPad Prism 9.0 (LaJoya, CA, USA).

Results

Clinical assessment

The KSS showed significant improvement from baseline to one-year post-surgery: Clinical score increased from 37.4 ± 4.1 to 91.9 ± 3.7 ($p = < 0.01$,) and Functional score improved from 41.2 ± 3.3 to 90.6 ± 4.8 ($p = < 0.01$). This improvement was sustained over four years, with no significant differences between the Clinical and Functional Scores of KSS at one year and four years ($p = 0.84$). The mean ROM improved significantly from 90° ± 25 preoperatively to 112° ± 18 ($p = 0.006$) at the final follow-up. By the end of the study, the average flexion was 125° (range 95–130°), with 92% of the knee achieving more than 120° flexion.

The mean WOMAC score improved from 60 ± 10.1 preoperatively to 10.9 ± 8.3 at the last follow-up. The pain subscale was 6.7 ± 4.4, stiffness was 2.8 ± 1.1, and the function subscale was 16.7 ± 10.

Table 3 Comparison of axis modification after surgery

Mechanical Axis	Before Surgery	After Surgery	*p*-value
Varus $_{(mean, SD)}$	− 10.2° ± 4.7	5.3° ± 1.2°	0.02*
Valgus $_{(mean, SD)}$	9.4° ± 3.9	5.9° ± 0.8	< 0.01*
Neutral $_{(mean, SD)}$	3.6° ± 2.0	2.3° ± 1.6	0.54

SD, standard deviation; negative value: varus

*Significant *p*-value

Radiographic analysis

Postoperative femorotibial alignment averaged 5.3° for knees with preoperative varus deformity and 5.9° for knees with preoperative valgus. (Table 3, Fig. 1) The median tibial component alignment was 89.0° (range 82–92) in the coronal plane, with a median posterior slope of 1° (range 0–4) in the lateral plane. The median femoral component alignment was 4.4° (range 3–6) in the coronal plane and 1.2° flexion (range 0–5) in the lateral plane.

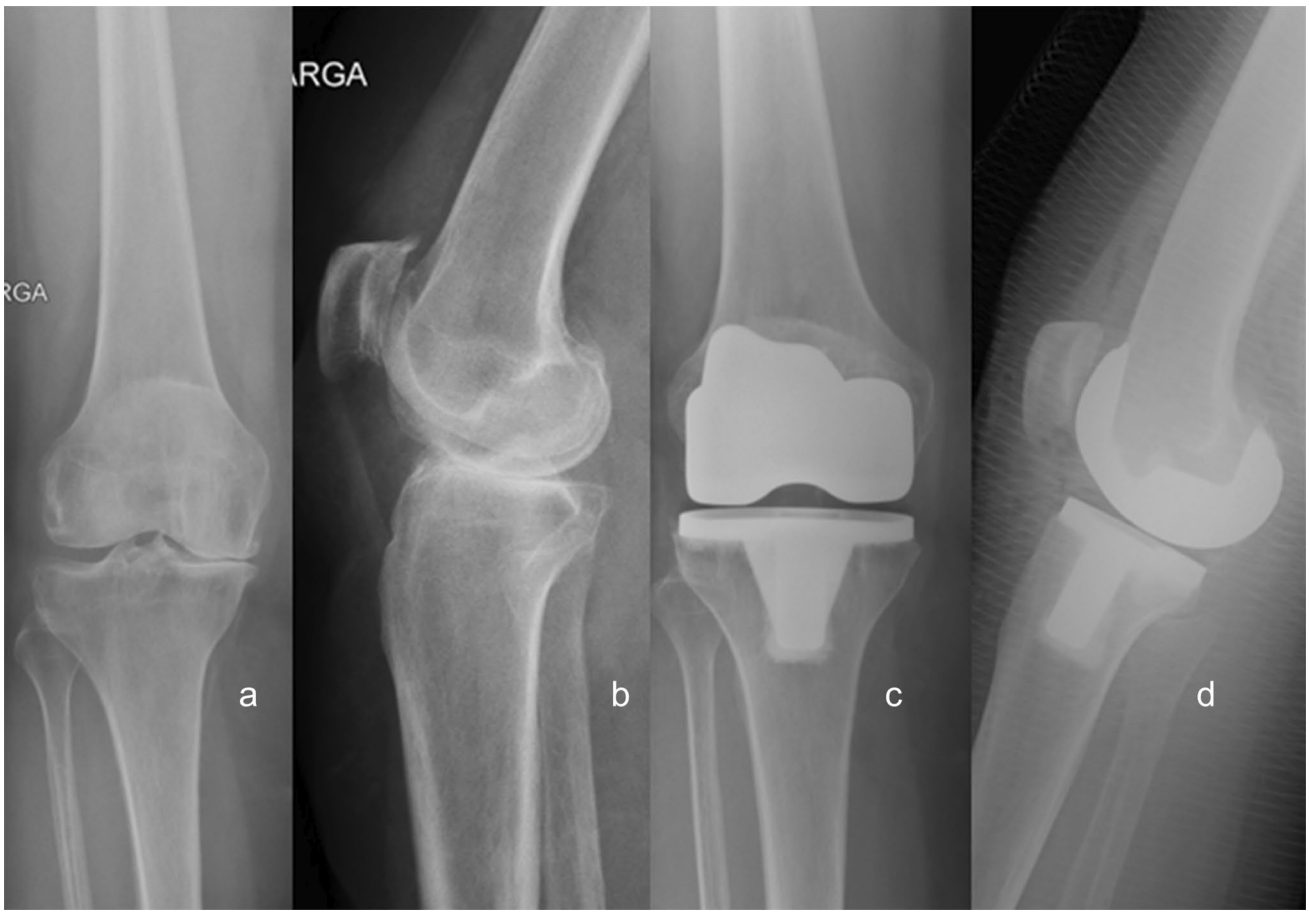

Fig. 1 Case: **a, b**: preoperative AP and L view weight-bearing radiographs showing varus arthrosis. **c, d**: postoperative AP and L radiograph at 5-year follow-up showing proper femorotibial alignment, with no radiolucent lines present

At the end of the follow-up, RLLs were observed around the implants in 20 patients (3.7%). Of these, 14 knees had RLL in one zone and six in two zones, with the most affected zones being 1 and 2 of the tibia in the AP view. No RLL was ≥ 2 mm or progressive.

Complications and revision

No intraoperative complications were registered. Postoperatively, we recorded seven (1.2%) DVTs, one (0.2%) non-fatal PE, ten (1.7%) PJIs, and four (0.7%) PPFs.

The four (0.7%) patients who developed acute PJI were treated with debridement, implant retention, polyethylene exchange, and systemic antibiotic therapy, evolving successfully.

The median onset for the six patients who experienced chronic PJI was eight months (range 4–14). All of them were treated with a two-stage revision and systemic antibiotic therapy, with no recurrences registered by the end of the study.

The four distal femoral PPFs were recorded at 2.4, 4.1, 4.5, and 6.1 years after TKA, all of them caused by low-energy trauma. One fracture was fixed with a distal femur-locked plate and another with a retrograde intramedullary nail (Rorabeck and Taylor type II), achieving bone union. The other two fractures required prosthesis revision due to affected femoral fixation (Rorabeck and Taylor type III).

Prosthetic survival

At the end of the study, we recorded eight (1.4%) prosthesis revisions: six (1.1%) due to septic causes and two (0.3%) due to PPF. No aseptic revision for implant loosing was noted. Prosthesis survival data are summarized in Fig. 2.

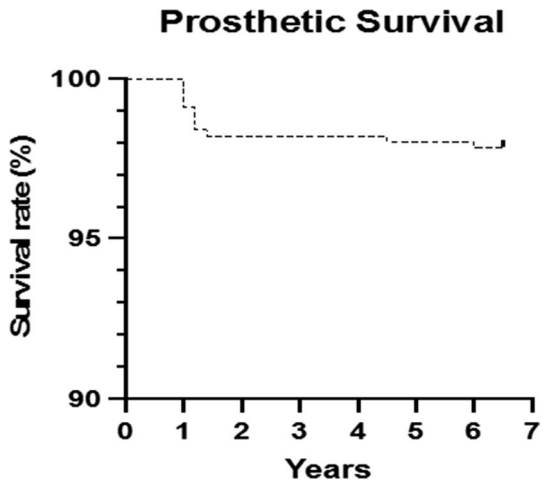

Fig. 2 Kaplan-Meyer survival curve showing 99.1% survival at 1 year, 98% at 4.5 years, and 97.8 at 6.5 years of follow-up

Discussion

This study's main finding was that using the U2 knee system in primary TKA, we observed a significant improvement in knee function and a promising prosthetic survival rate, with follow-up extending beyond five years. Our results, reflecting improvements in functional scores measured by the KSS, are consistent with findings from previous studies using different commercially available prosthetic models. Harwin et al. [15] assessed 713 TKA using the Thriatlon system (Stryker®) and reported improvement in clinical KSS from 48 to 96 and KSS function from 63 to 85 at more than two years of follow-up. Similarly, Hopley et al. [16], in their systematic review of the PS Sigma implant (Depuy-Synthes®), reported a 45% improvement in KSS (from 43 to 89 points) and a 36% improvement in function (from 45 to 82 points) when comparing preoperative and postoperative scores. In our series, the significant functional score improvements observed one year post-arthroplasty remained stable through the last examination. PROMs also showed consistent results, aligning with those reported by Yoon et al. [17] using the Nexgen LPS-flex (Zimmer-Biomet®), which showed an improvement from 59 to 15 at seven years of follow-up.

Despite patellar resurfacing being performed in 70% of the cases, no revision was observed during the follow-up due to AKP or patellar maltracking. Patellofemoral maltracking is a well-known cause of knee pain following TKA, with reported rates ranging from 1 to 20% [18, 19]. Although some authors argue that it is more common in patients with retained patellae, others claim the opposite, indicating that no solid evidence supports the necessity of patellar replacement [18, 19]. It may be influenced by many factors, such as proper alignment and balancing of soft tissues and correct seating of components, as well as by the prosthetic design [16, 18]. In this series, the U2 design features an enlarged and lateralized patellar groove that provides a larger contact area between the femoral component and the patella, potentially optimizing patellar tracking.

Assessing new implant designs that offer greater flexion is crucial, as increased flexion has been associated with early failures due to higher loading at the femoral implant cement interface [20]. Despite the U2 implant capacity for high degrees of flexion, no prosthetic loosening was registered at the study closure. It contrasts with the 21% revision rate reported for other high-flexion prosthesis systems at two years [21]. Potential factors contributing to this difference could include the low post-cam contact point at maximum flexion, the extensive contact area between

the posterior condyles and the polyethylene, the rounded shape (not rectangular) of the polyethylene post, and the rotational freedom provided by the design. Additionally, the custom milling of the XPE polyethylene might contribute to reducing component stress and wear.

The incidence of DVT and PE in our series was consistent with rates of 1.8% and 0.6% reported by Chiu et al. after reviewing 1,263,351 electives TKAs [22].

The prosthetic survival rate at five years was 98.9%, consistent with 96.6% and 97.3% reported for the Duracon and Triathlon (Stryker®) implants according to the Australian Registry [23], and in line with the 98.5% survival rate at five years for the Sygma implant (Depuy-Synthes®) [16]. In this study, PJI was the leading cause affecting prosthetic survival, accounting for 1.1% of cases. It agrees with the findings described by Kurtz et al. and Weinstein et al., who reported cumulative incidence of PJI of 1.5% and 2.0%, respectively, after 24 months [24, 25]. The periprosthetic fracture was the other leading cause of revision in this series, accounting for 0.7% of cases, all due to low-energy trauma (fall of patient's heights). These rates are lower than the 4.5% reported by Postler et al. or the 10.0% described by Abdel et al. [26, 27].

Our study has limitations, including its retrospective nature, the small sample size, and the lack of a control group. Another limitation is that it was conducted in a high-volume knee arthroplasty center by experienced surgeons, and an accurate method (such as radiographic assessment) to measure knee ROM was not employed. However, the goniometer measurement has been accepted and used in similar studies.

Conclusions

Our findings suggest that the U2 knee system is an effective and safe option for primary TKA, providing improved functional scores and patient-reported outcomes, along with a promising prosthesis survival rate at mid-term follow-up. Therefore, the U2 knee system demonstrates comparable results to other available designs. Further analysis of this series will continue to assess the long-term outcomes.

Author contributions All authors contributed to the study's conception and design. Material preparation, data collection, and analysis were performed by GG, JAR, and LPA. The first draft of the manuscript was written by GG, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability All data generated and analyzed during this study are included in this published article and are available from the corresponding author upon reasonable request.

Declarations

Conflict of interest The authors have no relevant financial or non-financial interests to disclose.

Ethical approval All procedures performed in studies involving human participants 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. (Project number 11978). This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of the British Hospital of Buenos Aires (Protocol number 11978).

Consent to publish The authors affirm that human research participants provided informed consent for the publication of the images in Fig. 1.

Informed consent Informed consent was obtained from all individual participants included in the study.

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