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Total knee arthroplasty: do newer CR implants yield better results? A single center prospective study

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The aim of this study was to compare whether the newest TKA prosthesis (Persona) gives improved clinical outcomes due its more anatomical design in comparison to older prostheses (balanSys). This study included a total of 89 patients planned for TKA from June 2018 to September 2019. Outcomes such as Knee Injury and Osteoarthritis Outcome Score (KOOS), range of motion (ROM), numeric pain rating scale (NRS), analgesics and alignment were recorded next to patient characteristics and complications. Our results showed a significant improvement in NRS, ROM and functional scores postoperatively compared to preoperatively for both the Persona and the balanSys implants. Although the flexion ROM for the Persona group was higher at 6 and 12 months postoperative compared to the balanSys, this was mainly a regaining of the preoperative ROM. Throughout all timepoints, there were no statistically significant differences observed in NSAID and opioid usage between the balanSys and Persona groups. Both implants are safe and efficient to use in the treatment of knee osteoarthritis. Although Persona had an improved postoperative flexion, this did not have an impact on any of the patient-reported outcomes.

Keywords: Total knee arthroplasty, prospective, Persona, ROM, knee implant, patient reported outcomes.

Abbreviations: TKA (Total Knee Arthroplasty), ROM (Range of Motion), PO (Post Operative), CR (Cruciate Retaining), CPM (Continuous Passive Motion), IQR (InterQuartile Range), MCID (Minimal Clinically Important Difference), PCL (Posterior Cruciate Ligament), numeric pain rating scale (NRS), Knee Injury and Osteoarthritis Outcome Score (KOOS), CR (cruciate retaining), PS (posterior-stabilized).

INTRODUCTION

End-stage osteoarthritis patients often experience high amounts of pain, discomfort and a restriction in their daily activities[1]. Many studies have shown the effectiveness of a total knee arthroplasty (TKA) in alleviating this pain and improving knee function in daily life[2-5]. However, it is worth noting that even though TKA is beneficial, the functional scores following the procedure are still lower compared to healthy individuals[6]. This deficit could be attributed to the implant design and could be improved by using implants that can mimic the natural kinematics of the knee[7,8]. A wide range of total knee implants are on the market nowadays and the development of new implants is still ongoing. As knee implants and our knowledge about knee physiology, kinematics, and technology keeps evolving, it is important to monitor the differences between implants and their effect on the functional outcome scores of patients.

In our hospital, the Persona (Zimmer Biomet, Warsaw, USA)[9] and balanSys (Mathys Ltd Bettlach, Switzerland)[10] implants are commonly used. The balanSys bicondylar fixed-bearing implant has been available since 1998 and has yielded excellent results so far with a rise in both objective functional capabilities and a range of motion (ROM) of 113°[11]. Moreover, studies have reported significant subjective enhancements with a mean numeric pain rating score (NRS) of 1.48 and a mean WOMAC (Western ontaria and McMaster universities osteoarthritis score) of 87[12]. In contrast, the Persona implant is relatively new, with its first introduction in Belgium in 2014. The Persona knee implant system has an anatomical shape of the tibial component of the prosthesis, which might result in a better fit and less overhang of the tibial tray. In

addition, the femoral component comes as standard or narrow to avoid overhang of the femoral component. The large availability of component sizes including 1 mm thickness increment of the inlays, might lead to improved knee stability post-surgery[13]. The femoral component, with asymmetric posterior condyles, was designed to fit the native anatomy of the tibial plateau. Studies have shown that the implant gives good clinical results with an improvement in pain, function (ROM 123°) and quality of life (KOOS QoL 79)[13-15]. A study by Dai et al., showed that the anatomical design of the tibial baseplate increased the tibial coverage and restored the shape of tibia more accurately than standard knee designs[16]. The available data of both the balanSys and Persona implant are consistent with the objective and subjective findings reported in other studies involving a TKA procedure[17-19].

According to the 2017 report of the Belgian national TKA database the average age of patients undergoing total knee arthroplasty (TKA) ranged from 60 to 79 years old, with 37% being male and 63% female. Additionally, a significant majority (95%) of these patients suffered from osteoarthritis[20]. The posterior stabilized (PS) construct was the most prevalent, accounting for 61% of cases, followed by posterior cruciate retaining (CR) at 19%, and ultra-congruent (UC) constructs at 15%. The remaining 6% comprised of other types such as constrained condylar, hinge, and bicruciate retaining constructs. No significant advantage of one design over the other has been established except for a slightly higher risk of anteroposterior instability in the CR construct[21,22]. Both the Persona and the balanSys implants have PS and CR designs. So far, no studies have shown that TKA implants with an anatomical shape significantly improve the functional outcomes scores postoperatively compared to existing im-plants, although radiological assessments have shown a better fit for these implants[23].

The main goal of this study was to assess and compare patient reported outcomes (NRS and KOOS), ROM, analgesic usage and radio-graphic imaging preoperatively and at 1 year postoperatively for two groups of patients under-going primary total knee arthroplasty, with one group receiving the Persona CR implant and the other receiving the balanSys CR implant. Based on the potential anatomical and biomechanical advantages associated with the Persona implant design, our hypothesis was that patients receiving this implant would exhibit enhanced functional outcome scores and improved ROM compared to patients receiving the balanSys design.

MATERIALS AND METHODS

A single centre, prospective randomized study was conducted. A total of 89 patients were recruited during the preoperative visit between June 2018 and November 2019 and were assigned an implant. Six patients cancelled their surgery (1 Persona implant (P), 5 balanSys implant (B)). Of the remaining participants, 45 patients were assigned group P and 38 patients group B. All patients were operated by a senior surgeon (TM). Exclusion criteria consisted of revision surgery, bilateral TKA in one stage, extreme varus (>20°) or valgus (>25°) alignment, morbid obesity (BMI>40 kg/m²), deficient PCL and comorbidities inhibiting normal revalidation (including but not limited to COPD (Chronic Obstructive Pulmonary Disease) stage 3-4, NYHA (New York Heart Association) stage 3-4, pre-existing deformities and recent foot and ankle surgery). Randomization was applied in a block-fashion. A random number allocating each patient to each group was generated by Microsoft Office Excel. The local ethics committee approved the study April 2018.

Patient follow-up times were at 6 weeks (6w PO), 6 months (6m PO) and 1 year (1y PO). On each visit, including the preoperative visit, various measurements were taken. These included the KOOS questionnaire (validated in Dutch) [24], which consists of 5 subscales ($KOOS_{pain}$, $KOOS_{symptoms}$, $KOOS_{adl\ (Activities\ of\ Daily\ Life)}$, $KOOS_{sport}$ and $KOOS_{qol\ (Quality\ Of\ Life)}$), NRS[25] and the ROM, measured with the Easy Angle digital goniometer[26]. In the KOOS questionnaire, a Likert scale was used for each question with 5 possible answer options. Scores were then transformed to a 0-100 scale, a score of 100 indicating no problems[27]. The analgesic usage of paracetamol, NSAIDS and opioids, as well as postoperative complications were also registered.

At the 6w PO visit, a varus (positive degrees) or valgus hip/knee mechanical angle (negative degrees), was measured on standing postoperative radiographs[28,29]. Standard demographics such as sex, age, weight, height and smoking habits were recorded.

All patients received spinal anaesthesia with a femoral nerve block. Preoperatively, the implants were planned using standard knee (frontal, lateral and axial) and full leg radiographs. All TKA implantations were performed using the standard subvastus approach with a medial paramedian skin incision. During this approach, the MPFL (Medial PatelloFemoral Ligament) was cut and the interval to the knee joint was developed medial of the vastus medialis obliquus muscle belly. Alignment was checked using an intramedullar femoral device and an extramedullar tibial device. All implants used were

cruciate retaining (CR) with patellar resurfacing, no standard difference in cuts were made between the two implants and re-cutting was guided by trial implants.

Standard postoperative protocols already in use in our hospital were used for postoperative revalidation and pain management. This consisted of early mobilization with physiotherapy assisted with CPM (Continuous Passive Motion), cyclic compressive cooling, antithrombotic prophylaxis and standard pain protocols according to the WHO pain ladder guidelines.

The R-program (A language and environment for statistical computing; R Development Core Team, R Foundation for Statistical Computing; Vienna, Austria) was used for all statistical analyses. A power analysis was conducted in advance with G-power and suggested a minimal total population of 75 subjects or 38 patients in each treatment group[30]. This was in concordance with studies of similar design[31-33]. Descriptive statistics (means and standard deviations) of patient related data and radiographic data was performed using Excel 2019®. A linear mixed-effect model was used for repeated measures over time of the clinical scores between the balanSys and Persona implant group. Alpha was set at .05 for all tests.

RESULTS

The average age in both groups was 69 years (IQR Persona 63-78; IQR balanSys 63-75). Among the Persona group, 59% of the patients were female, while 41% were male. In contrast, the balanSys group had 71% female patients and 29% male patients. The average BMI was similar between the Persona (29.8 kg/m², IQR 27.1-32.5) and the balanSys group (30.9 kg/m², IQR 27.2-35.3) regardless of sex. Specifically, the BMI for Persona male patients was 29.5 kg/m² and 30.01 kg/m² for Persona female patients, while balanSys male patients had an average BMI of 29.8 kg/m² and balanSys female patients had an average BMI of 31.5 kg/m².

Operative risk represented by the ASA score was on average 2 for both groups and 8 patients admitted to active smoking habits (3 Persona, 5 balanSys).

Both implant groups had an average preoperative pain score of 6.4/10 ($IQR_{Persona}$ 6-7, $IQR_{balanSys}$ 5-8) and a significant reduction in NRS pain score was noted for both implants from pre-operative to 6 weeks postoperative ($NRS_{persona}$: 3.2, $NRS_{balanSys}$: 3.9) $p<0.0001$). For the balanSys implant a second decrease was also found between 6 weeks and 6 months postoperative ($NRS_{balanSys\ 6m}$: 1.6) ($p<0.0001$). No significant differences were found between the implants at any timepoint (Fig. 1).

No statistical differences were found between the Persona or balanSys implants concerning the KOOS scores (Fig. 2). However, both im-plants showed significant improvements in all KOOS scores preoperatively compared to 1-year PO. Notably, the $KOOS_{pain}$, $KOOS_{symptoms}$ and $KOOS_{adl}$ scores of both implants showed a significant improvement between preop and 6w PO ($p<0.05$). Additional improvements were observed between 6w and 6m PO for the $KOOS_{pain}$ score of both implants. The Persona implant also showed significant improvement in $KOOS_{symptoms}$ ($p<0.05$) between these two time intervals, while the balanSys implant demonstrated significant improvement in $KOOS_{adl}$ ($p<0.05$).

Regarding $KOOS_{sport}$, there were significant improvements for the Persona implant between the preoperative and 6 weeks postoperative intervals and 6 weeks and 6 months interval (resp. $p<0.05$; $p<0.05$) and for the balanSys implant between 6 months and 1 year postoperative (1y PO) ($p<0.001$). A significant improvement was also noted for the $KOOS_{qol}$ scores for the balanSys implant for all timepoints ($p<0.05$). In contrast, a statistical significance was only found for the first ($p<0.0001$) and second interval ($p<0.001$) for the Persona implant.

Postoperative alignment represented by the mechanical axis measurements on full leg radio-graphs at 6w PO showed no statistical difference between the Persona (1.4°; IQR 0°-4°) and balanSys implant (1.1°; -1°-2.5°).

Between the preop and 1y PO ROM measurements a significant increase in mobility was found for both implants (Persona $p<0.0001$, balanSys $p<0.05$). Significant differences were found between the two implants at 6m (Persona= 127º, balanSys= 119º ($p=0.0093$)) and 1y PO (Persona= 128º, balanSys= 121º($p=0.0094$)) (Fig. 3).

At 6w PO the PCM usage of the balanSys group significantly decreased compared to preop ($p<0.05$) levels and was lower than in the Persona group ($p=0.06$). A second decrease in PCM usage between 6w and 6m PO was present for both balanSys ($p=0.07$) and Persona ($p<0.05$) (Fig. 4A). For the NSAID usage a decrease was found for the Persona group between preop and 6w PO although this decrease was not significant ($p= 0.09$) (Fig.4B). Throughout all timepoints, there were no statistically significant differences observed in NSAID and opioid usage between the balanSys and Persona groups.

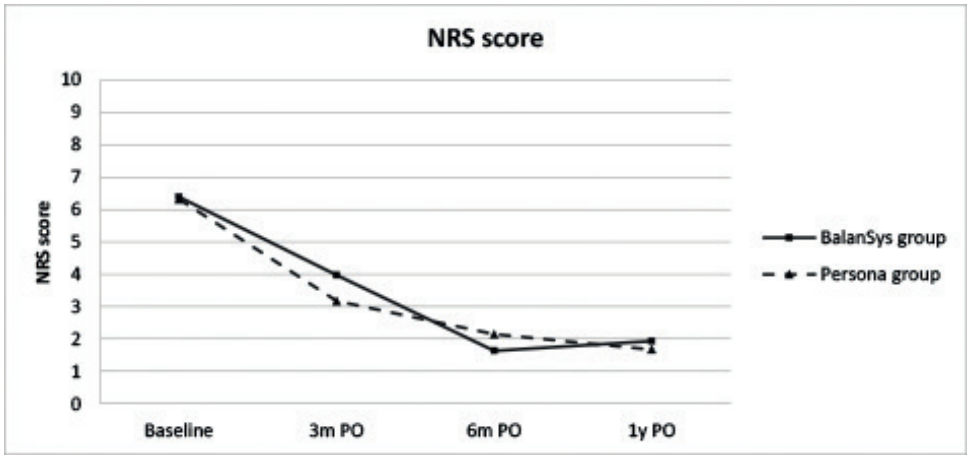

Fig. 1. — NRS pain score for all timepoints (pre-operatively, 6 weeks [6w PO], 6 months [6m PO] and 1 year postoperatively [1y PO]) for both patient groups (balanSys andPersona).

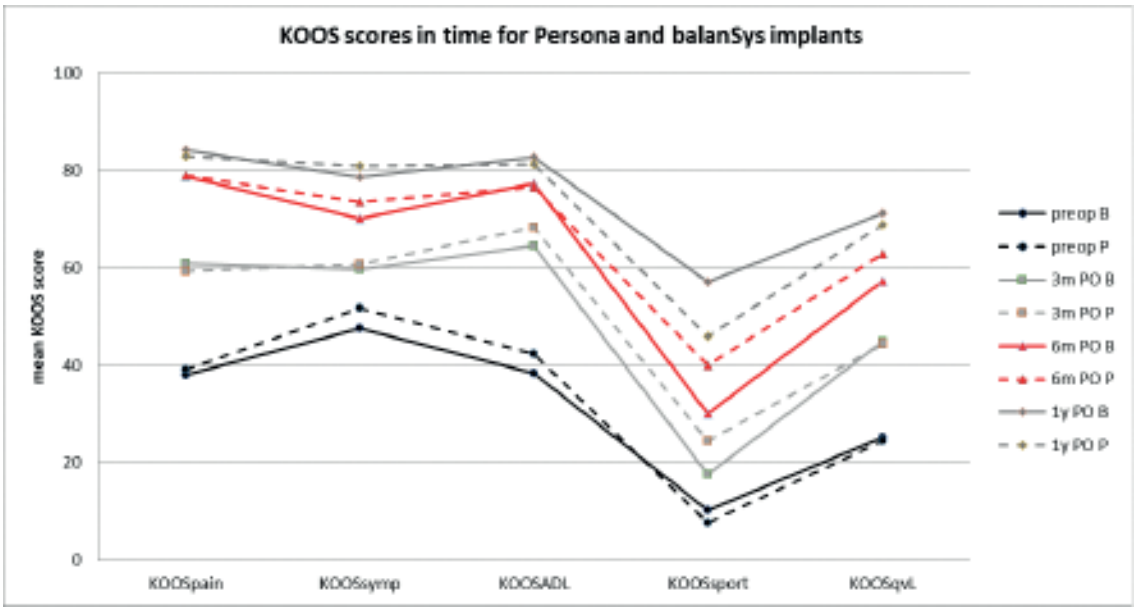

Fig. 2. — KOOS subscale scores (pain, symptoms, activities of daily living (ADL), sport and quality of life (QOL)) for all timepoints (pre-operatively (preop - black), 6 weeks (6w PO - light grey), 6 months (6m PO -red) and 1 year postoperatively (1y PO - dark grey)) for both patient groups (full line B = balanSys and dotted line P = Persona).

In the Persona group, two serious complications were recorded. One patient experienced skin necrosis and persisting wound healing difficulties requiring wound revision surgery and one patient had a periprosthetic femur fracture within 2 weeks postoperative requiring surgical fixation with plate and screw osteosynthesis. No casualties within 1y PO follow-up were registered.

DISCUSSION

In this randomized study, we aimed to explore potential biomechanical and clinical benefits of an anatomical design (Persona) compared to an older TKA design (balanSys). Our hypothesis suggested that the anatomical design of the Persona prosthesis might lead to improved results in both KOOS and ROM assessments. Interestingly, our hypothesis was supported by the data concerning ROM, as the Persona group displayed superior flexion ROM compared to the balanSys implant at 6 and 12 months postoperative. However, despite this improvement in ROM, it did not translate into enhanced functional outcomes, as no significant differences in KOOS scores were found between the two groups.

Patient characteristics, including age and sex, did not exhibit any significant differences from the 2017

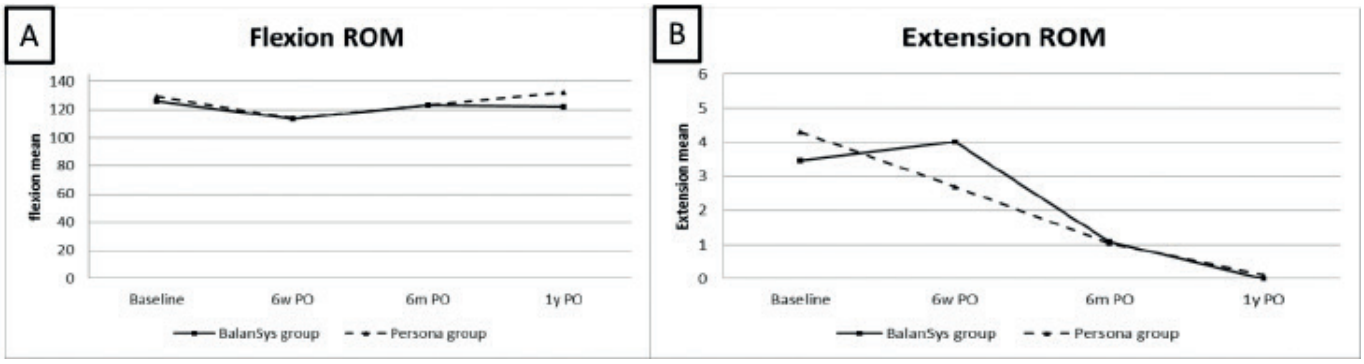

Fig. 3. — Extension ROM (left) and flexion ROM (right) for all timepoints (pre-operatively, 6 weeks [6w PO], 6 months [6m PO] and 1 year postoperatively[1y PO]) for both patient groups (full line = Persona and dotted line = balanSys). Significant differences (p<0.05) between implants are shown with a red asterisk at 6m and 1y PO.

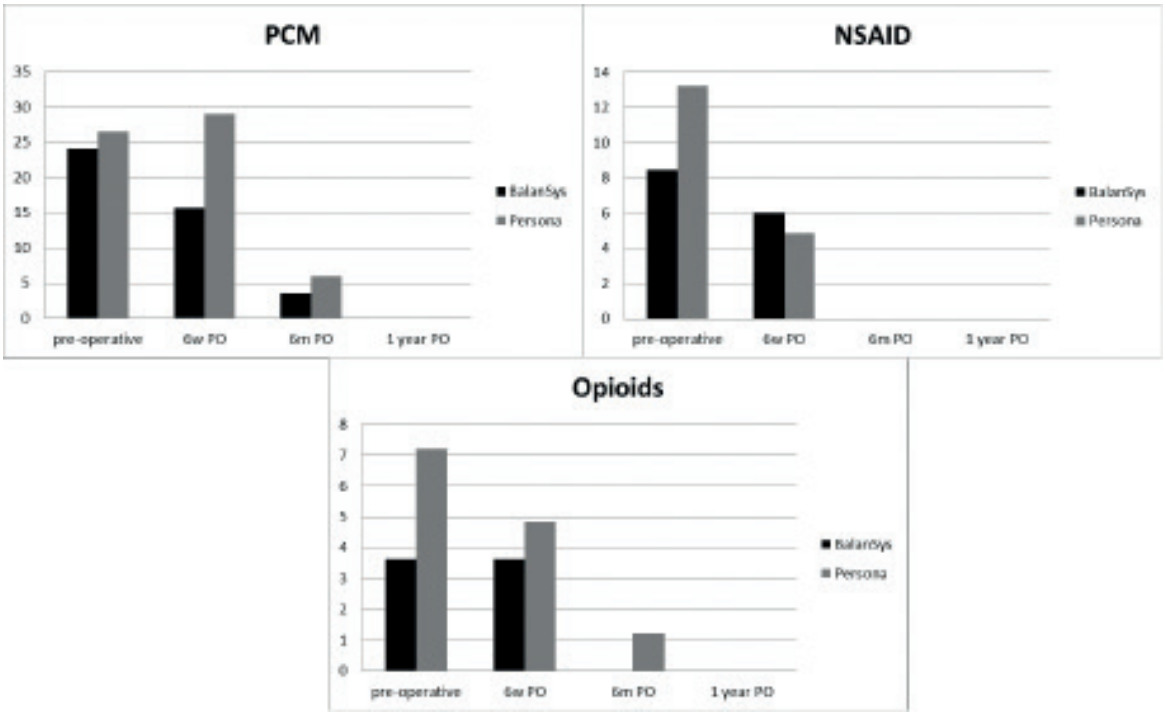

Fig. 4. — PCM (A), NSAID (B) and Opioid (C) usage percentages for the balanSys (black) and the Persona implant (grey) at all timepoints (pre-operatively, 6 weeks [6w PO], 6 months [6m PO]and 1 year [1y PO] postoperatively). Statistical differences in time for the balanSys group are shown with full black lines and for the persona group with dotted, grey lines. Statistical differences between balanSys and Persona are shown with a red line.

report of the national TKA database, making our study a representative sample of the population. All patients included in this study were treated with a CR construct based on surgeon's preference. This design bears a higher risk of anteroposterior instability if contraindications are not accounted for (PCL insufficiency, posterolateral instability, extensor mechanism deficiency)[13,34]. Our study recorded no instances of persistent instability or revision surgery due to excessive anteroposterior instability, indicating favorable outcomes with the CR construct used in this patient cohort.

The KOOS scores of both implants were comparable to the reported scores in literature[13,35,36] More important than the statistical significance is the MCID (Minimal Clinically Important Difference) of the KOOS results. Similar MCIDs of the KOOS subscales are reported in literature for both HTO (High Tibial Open-Wedge)[37] and TKA procedures[38]. Our results show that the MCIDs for $KOOS_{pain}$, $KOOS_{adl}$ and $KOOS_{qol}$ were already reached at 6w PO for both implants. For the $KOOS_{symp}$ the MCIDs were reached at 6w PO for the balanSys group but only at 6m PO for the Persona group. This was

reversed for the $KOOS_{sport}$, where the Persona group reached MCID at 6w PO and the balanSys group only at 6m PO. In conclusion, both implants achieved a clinical important difference for four KOOS subscores at 6w PO. In parallel with the KOOS scores, at 6w PO a significant reduction in pain scores was noted for both implants. Our results, showing a mean reduction of 4.5 and 4.7 for respectively the balanSys and Persona group, were comparable to literature[2,9,25]. Associated with these results is the analgesics usage of patients. Although the only statistical difference in analgesics was the PCM usage at 6 weeks postoperative, a trend could be seen of prolonged analgesics usage of both PCM and opioids in the Persona group compared to the BalanSys group. Although we adhere to the WHO Pain Ladder recommendations, in reality analgesic usage in patients is highly multifactorial and depends on compliance of the patient, contraindications, intolerances, recommendations of other medical professionals and many more. To our knowledge, no other studies have been conducted that describe the usage of oral analgesics postoperatively following a TKA procedure. Therefore, there are no comparisons available in literature for reference.

Considering anatomical prostheses boast about their biomechanical advantage, a difference in ROM results would be expected. Our results showed a significant reduction of flexion ROM at 6w PO compared to preop for both implants, followed by a regaining of this ROM during the following months. These results are concordant with studies of a similar design[9,11,26]. At both 6m and 1y PO the Persona implant outperformed the balanSys implant in flexion ROM. It is important to note that the flexion preop and 1y PO did not significantly differ, meaning the improvement of total ROM is mainly a regaining of the preoperative ROM. As such, the balanSys group did not completely regain their previous ROM compared to the Persona group.

Certain limitations need to be taken into consideration for this study. Although included, the construct validity of the $KOOS_{sport}$ subscale has been found to be weak with a low reliability (intraclass correlation coefficients) concerning rehabilitation after a TKA procedure[39]. Although the single-surgeon nature of this study is a strength, essentially eliminating intersurgeon variability, this inevitably led to smaller patient groups. Nonetheless the minimum sample inclusion of patients, as indicated by our power analysis, was reached for statistical analysis. Due to excessive cancellations in the balanSys group and an over-representation of Persona implants in the last batch, this last subgroup was overrepresented in this study. This did not lead to a selection bias as demonstrated by our demographic statistics. Our follow-up period ended, as standard in our hospital, at the 1 year PO timepoint. For better understanding of the long term biomechanical effects and its impact on patient reported outcomes, long-term studies are needed.

CONCLUSION

This prospective randomized study found that both the balanSys and Persona TKA CR implants are safe and, most importantly, effective in treating patients with osteoarthritis. Our results showed significant improvements in all categories, including pain, ROM and functional scores, for both implants. Interestingly, although the Persona group displayed higher flexion at 6 and 12 months postoperative, this did not translate into an enhancement of knee function (KOOS) and primarily represented a recovery of preoperative ROM. Moreover, no other significant differences were observed between the two implants, indicating that the biomechanical design of the Persona did not provide a major clinically significant advantage over the balanSys implant.

Level of Evidence (Sackett): III

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