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KNEE ARTHROPLASTY

Primary TKA in patients with major deformities and ligament laxities: promising results of an intermediate constrained implant at mid-term follow-up

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Abstract

Background Total knee arthroplasty (TKA) in major deformities with ligament insufficiency may require a higher constraint, with bone sacrifice and concerns about long-term survivorship. Mid-level constraint liners have been recently introduced, but few studies described their outcomes. The aim of this study is to evaluate the short to mid-term outcomes of a constrained postero-stabilized (CPS) insert for primary TKA in moderate to severe deformities.

Methods All patients who underwent TKA using a CPS liner in two centers between 2015 and 2017 were included in the study. The indications were: (1) valgus deformity type 2–3 partially correctable; (2) severe varus deformity with varus thrust; (3) post-traumatic deformity with major ligamentous insufficiency and any case of intra-operative ligament insufficiency. Patients were evaluated according to the Knee Society Scoring System (KSS), the Hospital for Special Surgery score (HSS), the Western Ontario and Mc Master University (WOMAC) and the Oxford Knee score (OKS). X-rays were evaluated according to the Knee Society Roentgenographic Evaluation System.

Results Forty-seven TKA were included, with an average age of 66.1 ± 10.3 years and an average follow-up of 68.4 ± 6 months. All patients demonstrated a moderate to severe pre-operative mediolateral instability. All the scores significantly improved ($p < 0.0001$). In 71.4% of cases, the outcomes were excellent or very good. There were no failures due to aseptic loosening but one failure due to a traumatic ligament rupture. The cumulative survivorship was $97.9\% \pm 2.1\%$ at 84 months.

Conclusions This mid-range constraint total knee replacement demonstrated promising outcomes and survival at mid-term follow-up.

Level of evidence IV (case series).

Keywords Total knee arthroplasty · Mid-range constraint · Major deformities · Ligament laxity · Constrained posterior-stabilized

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Introduction

Total knee arthroplasty (TKA) in moderate to severe deformities can be a surgical challenge and may require an upgrade of the polyethylene liner constraint to address pre or intra-operative laxity. In particular, severe varus or valgus deformities, even if they could be addressed with primary components, may deserve an increased level of constraint [1, 2]. Stability is achieved by limiting varus–valgus and torsional movement, the extent of which varies across different designs [3]. In the past, the way to increase the constraint was to use a Varus–Valgus Constrained (VVC) or a hinged implant, which implies the use of stems and carifying a bigger amount of bone, with some concerns for long-term survivorship due to higher stresses [4] and potential difficulties in secondary revisions.

A mid-range constraint mechanism, in between a posterostabilized (PS) and a VVC liner, could be a solution in some cases of moderate to severe deformities. The constrained posterior-stabilized (CPS) liner has a wider post than a standard PS liner, but a narrower and shorter post compared to a VVC liner, conforming to a standard PS femoral box. The advantages compared to a VVC liner are the reduced bone removal and the use of primary components without long stems. At present time there are few studies in literature describing the outcomes of mid-level constrained liners, which represent a relatively new implant solution [5, 6] showing promising results, on short-term follow-up and small cohorts of patients using a different implant with the one presented in this study.

The aim of this study is to evaluate the mid-term outcomes of the Persona® Constrained Posterior Stabilized implant (CPS Zimmer-Biomet®, Warsaw Indiana), a mid-range constraint liner that can be used with the Primary Persona PS femoral component and a standard tibial tray (added with a short standard stem) to address some major deformities or post-traumatic cases with major ligament laxities that in the past would have required a VVC liner.

Hypothesis of this study was that this mid-range constraint implant would allow to achieve a post-operative mechanical alignment of the knee with good clinical outcomes and survivorship at mid-term follow-up.

Materials and methods

This is a two-centres retrospective evaluation of a prospectively collected data of a consecutive series of primary TKA performed between January 2015 and June 2017 using a constrained postero-stabilized liner with the Persona PS implant (CPS Fig. 1). The main indications for a CPS liner and recruitment criteria were:

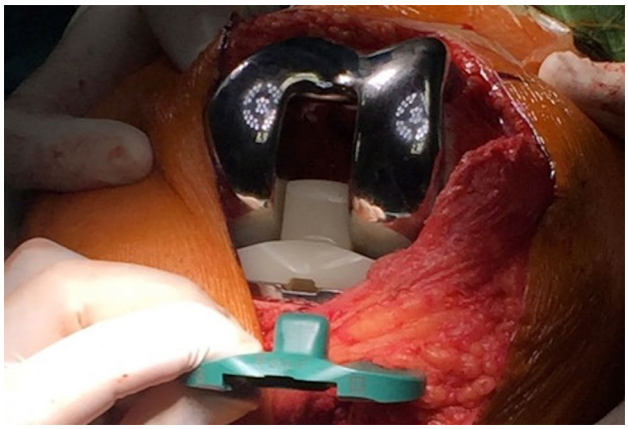

Fig. 1 CPS insert compared to a standard PS insert (green)

- severe valgus deformities, type 2–3 according to the classification described by Krackow, or type 3, 4, 5 of Mullaji and Shetty classification, which may require extensive soft tissue release with a possible residual varus–valgus laxity [2, 7, 8]
- severe varus deformity (fixed intra-articular deformity according to the Thienpont and Parvizi classification [9]) with varus thrust which requires a soft tissue release resulting in a mild medial instability
- post-traumatic deformities with major ligamentous insufficiency and any case of intra-operative MCL mild instability [1, 10].
- a CPS liner was used when there was a difference in medial and lateral gap opening equal or greater than 4 mm after manually testing it in extension, mid flexion, and deep flexion

Exclusion criteria were: for the valgus cases, a valgus deformity > to 20 °C on long standing x-rays associated with a ligament laxity of more than 6 mm at manual testing and a deformity of more than 25 °C for the varus cases. Patients with Rheumatoid Arthritis (RA) were not excluded.

The decision to use a CPS insert was planned preoperatively for all cases and then confirmed intra-operatively, after different trials using both a PS and a CPS liner. All the demographics, pre-operative, intra-operative data, as well as complications and failures were collected. All the procedures were performed by one of the senior authors or under their direct supervision. A standard anteromedial approach with a medial parapatellar capsulotomy was performed in all cases. In both centres an anatomical tibial alignment was performed, and the tibial slope followed the surgical technique. The distal femoral cut was performed at 3–6 on the

coronal plane, using a lower valgus angle in case of valgus knee, according to the pre-operative planning on long-leg x-rays, to obtain a mechanical alignment. If necessary, a medial or lateral soft tissue release was performed using the pie-crusting technique, to obtain equal gaps according to the technique described by Ranawat [11]. The patella was selectively replaced in one centre and always replaced in the other. The indication to patellar replacement were maltracking and severe symptomatic osteoarthritis (grade 3 or 4) [12]. All the implants were cemented with the same technique (fully cemented). In all the cases, a short tibial stem (width 14 mm, length 30 mm) was used as suggested by the manufacturer.

Post-operatively, all patients were allowed for full weight-bearing, and they began rehabilitation (including continuous passive motion) the same day of the operation, with the same protocol in both the centres.

Post-operative clinical and radiological evaluation were planned at 3 months, 6 months, 1 year, and annually thereafter. The Knee Society Scoring System (KSS) [13], the Hospital for Special Surgery (HSS) knee scores [14], the Western Ontario and Mc Master University (WOMAC) score [15] and the Oxford Knee score [16] were used for the clinical evaluation; Range of Motion (ROM) was also recorded. Furthermore, patients were asked to grade the results dividing it into excellent, very good, good, fair, or poor. All the patients underwent pre- and post-operative complete series of weight-bearing x-rays. Limb alignment, component positioning, and presence of radiolucent lines were evaluated according to the Knee Society Roentgenographic Evaluation System [17]. The minimum follow-up was 60 months.

Data were collected with Excel® Microsoft and presented with average and standard deviation (SD) and t test and chi-squared test were performed with Medcalc to analyse differences in continuous and categorical variables, respectively.

A power analysis was performed using a 2-sided test at an alpha level of 0.05 with a power or 80% to determine the required sample size for statistical significance according to our main endpoints with a medium effect size. Based on the power analysis, 45 patients were needed to detect a significant difference.

The study was performed in accordance with the ethical standards in the 1964 Declaration of Helsinki and with the HIPAA regulation. The Institutional Review Board (IRB) of the author's institution defined this study as exempt from IRB approval (prospective study on a well-established surgical procedure and commercialized insert).

Level of Evidence IV: cohort studies.

Table 1 Baseline characteristics and clinical pre/intra-operative evaluation

Gender (male%/female%)	16 (34%)/31 (66%)
Average age (years)	66.1 ± 10.3
Average BMI (kg/m^2)	23.9 ± 3.7
Average follow-up	68.4 ± 6
Side (right%/left%)	24 (51.1%)/23 (48.9%)
Diagnosis (%)	Primary idiopathic knee arthritis 40 (85.1%) Rheumatoid arthritis 3 (6.5%) Post-traumatic 4 (8.4%)
Alignment (%)	Valgus (type 2–3) 23 (48.1%) Varus 17 (37%) Neutral 7 (14.9%)
Pre-op HKA alignment (Mean and SD)	Valgus knees: 12.1° (2,3) Varus knees: 15.3° (3.3) Neutral alignment 1.3° (3) *(neutral defined within ± 5° HKA)*
Pre-op ROM (°)	110° ± 13.9°
Patella replacement	Replaced 76.6% Not replaced 23.4%

BMI body mass index, *ROM* range of motion, *SD* standard deviation

Results

Demographics

Between January 2015 and March 2017, 47 TKA were performed in 45 patients using the Persona with CPS insert® (Zimmer, Warsaw). No patients were lost to follow-up, so 47 implants were included in the study. There were 31 female (66%) and 16 males (34%), with an average age of 66.1 ± 10.3 years and an average Body Mass Index (BMI) of 23.9 ± 3.7 kg/m^2. The average follow-up was 68.4 ± 6 months, with a minimum follow-up of 5 years. Essential demographics and pre-op data are summarized in Table 1.

The diagnosis was primary idiopathic knee arthritis in 40 cases (85.1%), rheumatoid arthritis in 3 cases (6.5%), post-traumatic arthritis in the remaining 4 cases (8.4%). Ten patients underwent previous surgery on the same knee (21.3%), including ligaments reconstruction, meniscectomy and high tibial osteotomy. In 23 cases (48.1%) the pre-operative alignment was valgus (grade 3–4) and in 17 cases (37%), there was a varus alignment with a varus thrust and associated flexion deformity in one third of these cases. In the remaining cases (7, 15%) the lower limb had an overall neutral alignment (defined as ± 5 °C on the mechanical axis) but there was a major ligamentous instability mainly due to post-traumatic sequelae. The average pre-operative flexion was 106.3° ± 13.1°, with 29 patients (61.7%) having a loss of extension with an average of 4.3° ± 4°. All the patients demonstrated a mild to severe pre-operative mediolateral

Table 2 Summary of outcomes

Outcomes	Pre-operative	Post-operative	*P*-value
ROM	106.3° ± 13.1°	119.8° ± 8°	$p < 0.0001$
KSS objective	41.8 ± 18	84.7 ± 11	$p < 0.0001$
KSS functional	35.5 ± 21.4	87.9 ± 13.2	$p < 0.0001$
HSS score	54.4 ± 12.5	91.7 ± 3.5	$p < 0.0001$
OKS	40.1 ± 12.5	17.2 ± 6.3	$p < 0.001$
WOMAC			
Pain	19.9 ± 5.7	3.2 ± 3.8	$p < 0.0001$
Stiffness	5.8 ± 2.4	1.5 ± 1.4	$p < 0.0001$
Function	50 ± 14.1	10.6 ± 10.5	$p < 0.0001$
Rated outcomes	N/A	Excellent 50% Very good 21.4% Good 26.2% Fair 2.4%	N/A

ROM range of motion, *KSS* knee society scoring system, *HSS* Hospital for Special Surgery, *WOMAC* Western Ontario and Mc Master University, *OKS* Oxford Knee score, *N/A* not applicable

instability mainly related to the deformity or to the sequelae of a traumatic event. In 76.6% of the patients the patella was replaced. All the post-operative outcomes were evaluated at the last available follow-up. Post-operatively, the ROM significantly increased from 106.3° ± 13.1° to 119.8° ± 8° ($p < 0.0001$). Objective and subjective KSS, HSS, OKS and WOMAC scores significantly improved from pre-operative to last follow-up, as shown in Table 2. Thirty patients rated their outcomes as excellent or very good (71.4%) and only one patient was unsatisfied with the result (2.4%). All the knees resulted stable at the clinical evaluation at the different follow-up visits (clinical evaluation and score assessment). There were no major complication or deep infection. Minor complications were detected in 17.3% of the cases, such as moderate bleeding (6 patients,), loss of extension (1 case) and one case of superficial infection treated with antibiotics.

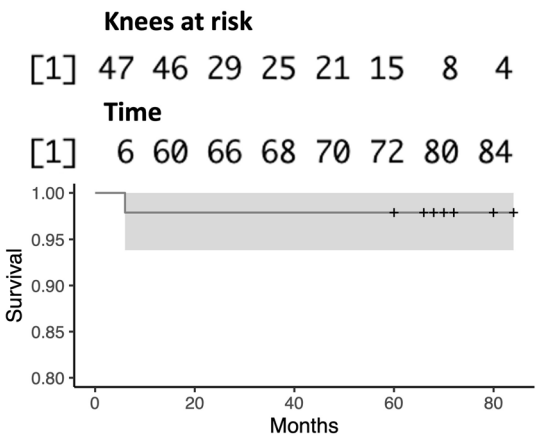

Fig. 2 Cumulative survivorship (revision as endpoint)

One patient underwent revision for severe instability due to a fall with ligaments failure 6.2 months after the first implant using a VVC implant. With revision as an endpoint, the cumulative survivorship calculated with the Kaplan–Meier method was 97.9 ± 2.1% (Fig. 2) at 84 months.

At the radiological evaluation, performed according to the Ewald classification [17], there were no progressive significant radiolucent lines. One patient demonstrated two non-significant (< 2 mm) and non-progressive radiolucent lines around the femur (zone 3 and 4 according to the classification) and 4 patients had non-significant non-progressive radiolucent lines below the tibial component (zone 1–2–3–4–6–7 according to the classification); in three of these cases the radiolucent lines were already detectable in the immediate post-operative x-ray control, probably due to a not perfect cementation technique.

Implant positioning was evaluated according to the angles described by Ewald [17]. All the implants resulted well positioned (Table 3), and the average Hip–Knee–Ankle (HKA) angle was 179.1° ± 3.1°. Figure 3 shows a post-operative x-ray (A) and the radiographic result 60 months after surgery (B). No signs of implant instability was detected on ap and ll views nor on long standing x-rays.

Discussion

The main finding of this study is that this mid-range constrained implant showed favorable results and good survivorship at a mid-term follow-up in primary total knee replacement for the treatment of moderate to severe deformities.

Total knee arthroplasty in major deformities and ligament laxity sometimes requires increasing the level of constraint [18]. There are few studies published about primary TKA with increased constraint (VVC), with promising outcomes and high patient's satisfaction, but the survival rate can be lower than with primary implants, as shown by Martin et al. [19]. Furthermore, due to the increased surgical time, bone sacrifice and use of hardware, infection may play a role in reducing the survival rate of these implants as stated and showed by Badawy et al. [20].

The possibility to use a mid-level constraint may be helpful on both sides, improving survival rates and reducing

Table 3 Average angles calculated according to the Knee Society total knee arthroplasty roentgenographic evaluation and scoring system [17]

	Alfa (α)	Beta (β)	Gamma (γ)	Delta (δ)	HKA
Average angle	92.7°	88.6°	2.9°	87.9°	179.1°
Standard deviation	2.8	1.2	2.3	2.4	3.1

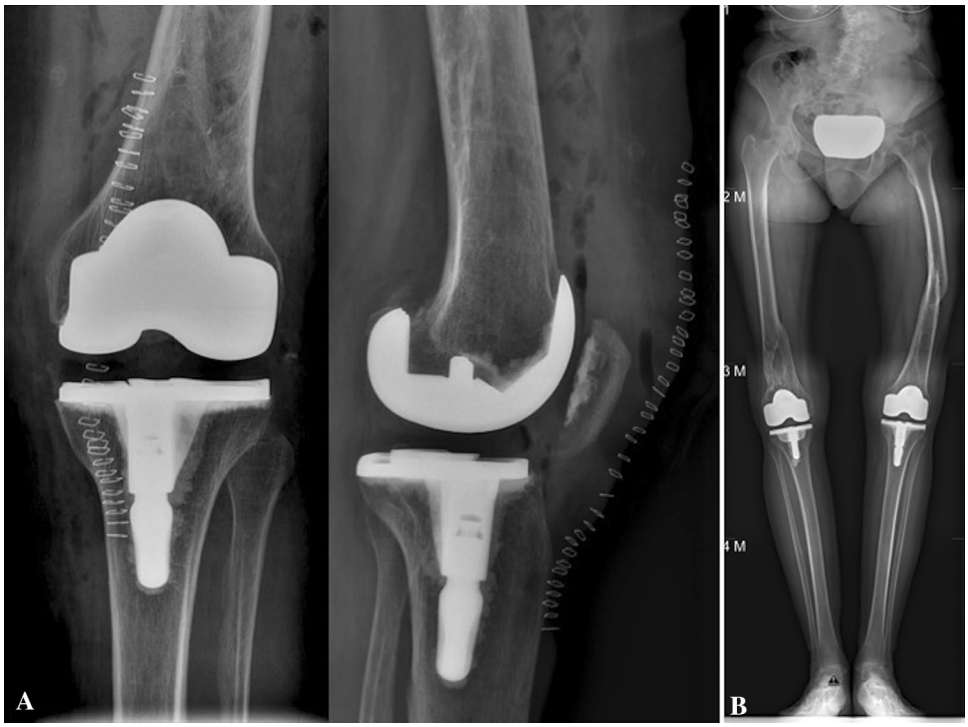

Fig. 3 Post-operative x-ray of a left knee (**A**, antero-posterior view on the right and lateral view on the left) and the radiographic result of the same knee at 60 months of follow-up (**B**)

infection due to an easier surgical technique compared to more invasive implants. Furthermore, a mid-level constrained liner allows for a smaller amount of bone removal and can be used in association with a primary implant. These features may make easier a potential future revision reducing the need of hardware such as augments, cones and stems [21].

In this study, a CPS liner was used, which has a broader, taller, and not angled spine compared to PS design, providing the femoral component with an increased level of varus- valgus stability, to supply some insufficiency of the collateral ligaments. Particularly, the liner is designed to provide ± 1.5° varus/valgus constraint and ± 5.5° internal/external rotation constraint, with a decreased rotational freedom compared to normal PS post.

The CPS liner can be used with a primary femoral component; the box cut for PS must be augmented in the roof by 2 mm. However, the box is still smaller compared to the one needed for a VVC implant. On the tibial side, it requires an additional short tibial stem (30 mm length, 14 mm diameter).

The switch from PS to CPS can be decided intra-operatively for whatever reason, and it can be performed even without the dedicated instrumentation.

Konopka et al. [22] showed increased wear in the post region of CPS inserts when compared to PS inserts, corresponding to more surface deformation in posterior and medial post regions. However, the increased damage and deviation of the post surfaces was minimal and likely clinically insignificant in short-term retrievals.

This study did not show radiographic or clinical evidence of loosening at mid-term follow-up. In literature, there are only two studies describing the outcome of a midlevel constraint insert, but the authors used different implants and liners [5, 6]. Crawford et al. showed good patient reported outcomes as well as objective outcomes, comparable to those reported in literature [5], with no evidence of aseptic loosening at short- to mid-term follow-up.

Dubin and Westrich in a recent publication showed [6] promising results with a mid-level constraint implant in patients with severe osteoarthritis at a 4 years follow-up, with equal or improved functional outcomes comparing to a matched group treated with a PS liner.

The results of the present study are in line with those of this two cited studies but with a longer follow-up and a different type of implant used.

Before the introduction of a midlevel constrained implant, the choice in these patients was between a semi-constrained implants or a primary implant such as CR or PS implants. As previously said, early reports have demonstrated favorable outcomes of primary semi-constrained TKAs in patients with severe deformity or ligamentous laxity but different potential downsides, such as early loosening due to higher constraint, were also described [23].

The amount of instability that need a more constrained implant is not clearly defined. Some authors suggest that a persistent laxity exceeding 7 mm needs a semi-constrained

TKA [4], but the introduction of this midlevel constraint liners may change this paradigm, especially in young patients where a lower level of constraint may be desirable in terms of implant survival. Conversely, the risk for less experienced surgeons, may be to encounter some surgical mistakes with CPS liners. A badly balanced knee will fail, so this liner must be used only with correct indications and a correct surgical technique. These are the reasons why the CPS liner may be indicated in knees with severe varus or valgus deformity, with incompetent lateral or medial collateral ligaments respectively, and those with significant flexion contractures that cannot be appropriately balanced intra-operatively and may benefit from a more constrained TKA [24].

In this case series, the average age was 66.1 years, and good or excellent outcome were obtained in most patients, with very good improvement of PROM's scores, confirming the possibility to use this insert in young patients. Both objective and subjective post-operative outcomes showed significant improvement comparing to the pre-operative and results that are in line or better with those presented in the literature with more constrained implants [25, 26].

Despite concerns for implant loosening and survivorship due to the increased level of constraint, there was no evidence of clinical or radiological loosening at mid-term follow-up. The only case of revision was not related to the implant, but due to a fall with subsequent ligaments instability needing a revision with a constrained implant.

This study has several limitations. First, population size is small, but comparable to previous studies with more constrained implants in primary TKA [19, 20, 27] and with the only other two studies on midlevel constrained implant [5, 6]. Another limitation of this study is the mid-term follow-up (mean 68.4 months). However, the insert is relatively new on the market, and the promising results shown with this implant may deserve further studies with longer follow-up. Finally, there is no control group to compare the outcomes, particularly to compare the rate of aseptic loosening between CPS insert and VVC implants. Further studies may increase the level of evidence adding a control group with a VVC implant considering the type of cohort evaluated in the current research.

Conclusions

This study showed promising outcomes and survivorship of primary TKA for major deformities with moderate to severe ligamentous instability using a mid-level constraint implant (CPS liner), with no evidence of loosening and high patients' satisfaction in a prospective evaluation at a minimum 5 years. Longer follow-up and studies with higher sample size are needed to confirm these results.

Author contributions SMPR and FR designed the study. FB, RR and SMPR performed the surgeries. MG, FR and DLB collected the data. FR drafted the manuscript. SMPR critically revised it. FB and RR gave final approval before submission. This manuscript is original and not published elsewhere.

Declarations

Conflict of interest R. Rossi is a teaching consultant for Arthrex, Zimmer-Biomet, Lima, Medacta, Smith and Nephew, De Puy. F. Benazzo is a teaching consultant for Zimmer Biomet, Limacorporate and Ceramtec. D.E. Bonasia is a teaching consultant for Arthrex and Zimmer-Biomet; (2) Editorial royalties for Elsevier and Springer; (3) Editorial board "The Knee" Journal, Elsevier. The other authors certify that they have no commercial associations that might pose a conflict of interest in connection with the submitted article.

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. Informed consent: for this type of study formal consent is not required. All patients signed an informed consent for the surgical procedure.

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