RESEARCH ARTICLE

# Patient Reported Outcomes of Total Knee Arthroplasty with Ultra-congruent Lipped Polyethylene Liners: A Randomized Study

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## Abstract

**Objectives:** The purpose of this study is to compare the Depuy curved (CVD) polyethylene insert to the curved plus (CVD+) design in TKA, which has an increased dished curve for increased articulation congruence and thus secondary anterior to posterior stability.

**Methods:** A randomized controlled trial with 100 patients was conducted to compare two knee replacement designs (CVD and CVD+ polyethylene inserts) using the Johnson and Johnson DePuy PFC Sigma total knee replacement. All participants, were randomized and blinded to reduce bias. The trial achieved 100% recruitment and maintained blinding throughout the study. Demographics, baseline characteristics, and KOOS scores were recorded pre-operatively, and at 3 and 12 months postoperatively. In addition, physical and mental component scores (PCS and MCS) were collected at 12 months post-operatively.

**Results:** Sixty patients had preoperative data, split equally into CVD and CVD+ groups. The cohort's average age was 71.47 years, and 72% were female, with no statistically significant demographic differences between groups. Preoperative measures showed no differences in Pain, ADL, or QOL. At 3 months, no significant differences were noted, though the QOL difference was 64.45 ± 16.57 for CVD and 52.94 ± 27.1 for CVD+ ($p = 0.15$). At 12 months, trends favored the CVD group, but differences in Pain, ADL, QOL, PCS, and MCS were not significant. Complications were similar, except for stiffness, with 0 cases in the CVD group and 3 in the CVD+ group at 3 months; both had 2 additional cases at 12 months.

**Conclusion:** In our study, there was no difference between designs in terms of pain, activities of daily living, and standard outcomes. Further studies are required to support the benefit of increased congruence in the CVD+ design, even though widespread adoption has been common across the industry.

**Level of evidence:** II

**Keywords:** CVD, CVD+, Liner, Total knee arthroplasty

## Introduction

Total knee arthroplasty (TKA) remains the prevalent treatment for osteoarthritis, with increasing annual incidence and prevalence.[1,2] As of 2010, there was an estimated 4.7 million patients in the U.S living with a total knee replacements.[3] Recent studies state that between 2000 and 2019, the annual volume of TKA increased by 156% on average, with an estimated annual volume of 480, 958 primary total knees in 2019.[4] At the same time, implant design has continuously changed with progression towards newer material, cementless fixation, and increased congruence. As the prevalence of osteoarthritis and TKA continues to grow with the aging population, it is important to closely monitor the changes in implant design and subsequent patient outcomes. The current literature suggests only 82% to 89% patient satisfaction after TKA, leaving significant room for improvement.[5]

TKA can vary significantly from case to case as patient

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anatomy, and severity of arthritis and deformity, factor into implant selection. A "one-size fits all" total knee prosthesis does not exist, as evidenced by continued industry efforts to market specialized subgroups such as "gender knee," "active knee," or "personalized knee".[6] As surgeons and the industry continue to strive for better outcomes, the market is flooded with different total knee designs. Ultimately, the goal of TKA is to reconstruct a "stable" knee that allows pain free motion and function. The most common causes of patient dissatisfaction include residual pain and limited function, specifically lingering pain, stiffness, abnormal kinematics compared to native anatomy.[7] Classically, the spectrum of available designs, from least to most constrained, includes posterior cruciate-retaining (CR), posterior stabilized (PS), varus-valgus constrained, and hinged designs.[6]

Specifically, CR designs have been incorporating ultra-congruent, anterior-stabilized polyethylene bearing surfaces with promising early results.[8] The Johnson and Johnson DePuy PFC Sigma total knee replacement has been in use since the late 1990s with excellent reported patient satisfaction and long term outcomes.[9,10] The sigma system offers multiple options compatible with cruciate retaining implants including the "Curved (CVD)" and "Curved Plus (CVD+)" designs, with increasing congruence [Figure 1].[6] The CVD+ design has an increased anterior lip height for increased femoral component conformity with greater anterior subluxation resistance and decreased radius of curvature.[11] Additionally, the CVD inserts allows for about 10 degrees of rotation compared to 20 degrees with the CVD+ insert.

**Figure 1. SIGMA Polyethylene designs Curved (CVD) (left) and Curved Plus (CVD+) with increased anterior lip height (right)**

With the trend towards increased congruence and our previous retrospective work raising concerns for increased pain,[6] the aim of this randomized controlled study was to compare the outcomes of primary TKA patients receiving either PFC Sigma fixed bearing CVD or CVD+ polyethylene insert. We hypothesized that there would no overall difference in patient reported outcomes from preoperative to 1-year postoperative patient reported outcomes when comparing CVD and CVD+ groups.

## Materials and Methods

### *Study Design and Patient Selection*

Following IRB approval to investigate knee designs, we conducted a randomized controlled trial involving 100 patients who were reviewed alongside an analysis of patient characteristics, patient-reported outcomes and operative data. All patients received a Johnson and Johnson DePuy PFC Sigma total knee replacement with either the CVD or CVD+ polyethylene insert. The study included patients who were scheduled for total knee arthroplasty (TKA) between 7/10/2019 and 1/29/2020. Inclusion criteria encompassed adult patients indicated for primary TKA, while exclusion criteria included previous knee surgeries and significant comorbid conditions affecting surgical outcomes. Recruitment achieved 100% participation within the specified timeframe.

### *Randomization and Blinding*

Patients were randomized into two groups, receiving either the CVD or CVD+ polyethylene insert, using a computer-generated randomization program. This program produced a predetermined randomization sequence, which was then concealed from the surgical team until the time of surgery. This concealment ensured that the surgical team remained blinded to the allocation group during the peri-operative period, thus maintaining the integrity of the blinding process. This blinding was maintained throughout the peri-operative period and data analysis to minimize bias.

### *Data Collection*

Demographic metrics, including age, gender, BMI, race, and tobacco use status, were recorded using the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) database (Worcester, Massachusetts). Patient-reported outcome measures included the Knee injury and Osteoarthritis Outcome Score (KOOS) for activities of daily living (ADL), quality of life (QOL), and pain, recorded pre-operatively, and at 3-month, and 12-month post-operative intervals. Additionally, a physical component score (PCS) and a mental component score (MCS) from the Short Form-12 (SF-12) questionnaire were recorded at 12 months postoperatively. Complications, such as infections, stiffness, and blood clots, occurring within one year post-surgery were documented.

### *Statistical analysis*

Means and standard deviations were calculated for continuous variables, and frequencies and percentages for categorical variables. Comparative analysis between the CVD and CVD+ groups was performed using Student's t-test for continuous variables and Chi-square test for categorical variables. A p-value of $< 0.05$ was considered statistically significant. Confounding factors, such as age, gender, and BMI, were controlled for in the analysis through stratification and multivariate regression models if deemed necessary.

## Results

Of the 100 patients reviewed, 60 patients had preoperative outcome measures available in the FORCE-TJR registry, 30 in each group [Figure 2]. There were no significant differences in the demographics of the cohort. The average age of the cohort was 71.47 ± 8.63 years and was 72% female [Table 1].

### *Patient-Reported Outcome Measures*

Preoperatively there were no differences between the CVD and CVD+ cohorts in Pain, ADL, or QOL measures [Table 2]. Similarly, there were no significant differences in scores at 3 months. The QOL measures had the largest difference however, 64.45 ± 16.57 in the CVD group and 52.94 ± 27.1 in the CVD+ group ($p = 0.15$). At 12 months post-operatively, there were trends favoring Pain, ADL, or QOL scores in the CVD group over the CVD+ group. However,

they did not reach statistical significance [Table 3]. Additionally, at 12 months there were no significant differences in the PCS or MCS scores [Table 4].

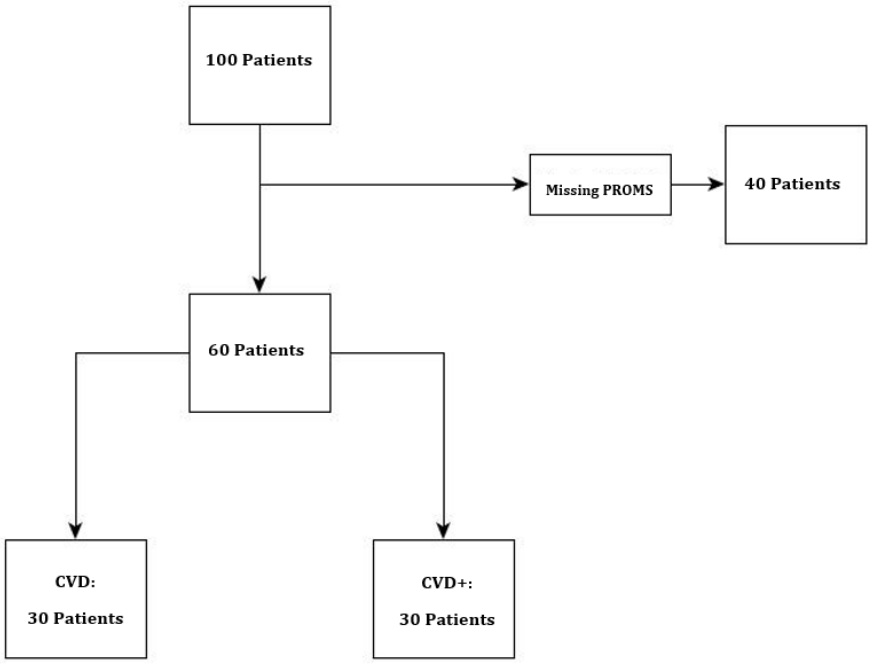


**Figure 2. Flowchart of the included patients**

| Table 1. cohort demographic breakdown | | | |
|---|---|---|---|
| | **Cohort** | **CVD** | **CVD+** |
| ***n*** | ***60*** | ***30*** | ***30*** |
| Age +/- SD (years) | 71.47 ± 8.63 /Range = 52-90 | 72.03 ±8.58 /Range = 57-88 | 70.9 ±8.79/ Range = 52-90 |
| Female Total (% of total) | 43 (72) | 20 (66.7) | 23 (76.7) |
| BMI +/- SD | 32.15 ± 5.71 | 31.82 ± 5.80 | 32.46 ± 5.71 |
| Race Total White (% of total) | 54 (90) | 27 (90) | 27 (90) |
| Cigarette Use Total (% of total) | 5 (8.3) | 3 (10) | 2 (6.7) |

| Table 2. Outcome measures compared between the two groups at the pre-operative time point | | | |
|---|---|---|---|
| | **CVD** | **CVD+** | **P-value** |
| **Pain** | 36.04 ± 16.14 | 36.04 ± 19.12 | 1 |
| **ADL** | 38.96 ± 19.33 | 35.63 ± 18.87 | 0.50 |
| **QOL** | 25.83 ± 16.47 | 24.38 ± 18.88 | 0.75 |

ADL: Activities of Daily Living/ QOL: Quality of life/ Analysis d0one using Student's t-test

| Table 3. Outcome measures compared between the two groups at the 3-month time point | | | |
|---|---|---|---|
| | **CVD** | **CVD+** | **P-value** |
| **Pain** | 69.53 ± 17.66 | 62.87 ± 19.45 | 0.31 |
| **ADL** | 76.56 ± 18.33 | 70.96 ± 24.70 | 0.46 |
| **QOL** | 64.45 ± 16.57 | 52.94 ± 27.1 | 0.15 |

ADL: Activities of Daily Living/ QOL: Quality of life/Analysis d0one using Student's t-test

| Table 4. Outcome measures compared between the two groups at the 12-month time point | | | |
|---|---|---|---|
| | CVD | CVD+ | P-value |
| **Pain** | 77.99 ± 18.83 | 75.99 ± 15.77 | 0.71 |
| **ADL** | 83.97 ± 17.15 | 78.29 ± 17.35 | 0.30 |
| **QOL** | 70.65 ± 25.24 | 67.76 ± 15.77 | 0.65 |
| **PCS** | 45.91 ± 9.00 | 39.95 ± 11.55 | 0.10 |
| **MCS** | 47.92 ± 13.14 | 51.74 ± 8.63 | 0.26 |

ADL: Activities of Daily Living/ QOL: Quality of life/ PCS: Physical component score/ MCS: Mental component score/ Analysis d0one using Student's t-test

***Complications***

Total complications including ED visits, infections, stiffness, and blood clots were similar between the CVD and CVD+ cohorts at 3 and 12 months postoperatively aside from stiffness which had 0 cases at 3 months in the CVD group and 3 cases in the CVD+ group. At 12 months both had 2 additional cases of stiffness, however the difference did not reach statistical significance [Table 5].

| Table 5. Comparison of complications between the two groups | | | | |
|---|---|---|---|---|
| | | CVD | CVD+ | P-value |
| **Total Infections** | *3 months* | 0 | 1 | - |
| | *12 months* | 1 | 1 | 1.00 |
| **Total Cases of Stiffness** | *3 months* | 0 | 3 | - |
| | *12 months* | 2 | 5 | 0.23 |
| **Total Blood Clots** | *3 months* | 0 | 0 | - |
| | *12 months* | 0 | 1 | 1.00 |

## Discussion

The trend towards increased congruence and the utilization of anterior lipped high congruence (HC) total knee inserts has become increasingly popular, as reflected by the numerous available options offered by the major manufacturers. The traditional PS design has some advantages over CR, which include simplified balancing and stability at the cost of less physiological kinematics, more bone loss, and post-operative complications and wear.[12] The congruence of the HC design has proposed advantages of distributing surface loads better, thus reducing wear and increasing knee stability.[13] In essence, the HC liners were designed with the goal of optimizing both the CR and PS designs, stability and kinematics without the posterior-cam mechanism. Previous studies have shown promising results in regards to patient outcomes of anterior-lipped HC inserts when compared to both CR and PS designs.[14,15] Additionally, HC inserts have equivocal survivorship and revision rates when compared to traditional CR and PS inserts.[16] As the HC inserts have been shown to be promising, manufacturer such as Depuy, Zimmer, and Stryker have developed their high congruence inserts with a larger anterior lip to further resist anterior subluxation similar to a PS design and improve anteroposterior and rotational stability.

Our previous work has examined the use of Johnson and Johnson DePuy Sigma liners, suggesting significantly increased pain with the use of high congruence liners.[6] Nevertheless, the work was retrospective thus limited by the indications of using increased constraint. The original polyethylene designs were quite flat and thus difficult to balance, relying purely on ligamentous stability for ultimate mechanics. With improving materials and the invention of highly crosslinked polyethylene which resists shear forces better, a more congruent design allowed the kinematics to be dictated further by the implant, with good survival results. Surgeons can choose increasing level of anterior to posterior constraint in a CR design, without having to cut a box and loose further femoral bone. That decision though used to be driven by perceived difficult balance, PCL insufficiency, or other technical difficulties during surgery, thus biasing the outcomes towards worse satisfaction, function, and pain. Nevertheless, the increased pain may also be attributed to the increased congruence of the polyethylene insert. This finding could be quite concerning when newer generations of total knee implants have selected high congruence as their baseline design, and no options for flat or less congruent inserts.

To better understand the difference in patient reported outcomes and eliminate the patient or surgery factor, we hypothesized no differences between the CVD and CVD+ cohorts in pain, ADL, or QOL measures when randomized, which was then further supported by scores at 3 months. Our previous retrospective study also noted a statistically insignificant increase in KOOS-ADL improvement scores in the curved cohort compared to curved plus.[6] A possible explanation for this difference in improved patient outcomes at 3 months could be related to the increased constraint with the larger anterior lip, resulting in altered joint mechanics and increased pain. Interestingly, even the current study sees a trend towards the less congruent design in a randomized group of patients, even though statistical significance could not be achieved.

Ultimately, patient reported outcomes can be subjective. An examination of implant survival, radiographic analysis, and complications showed similar distributions at 1 year. Both cohorts had one case of infection during the data collection, which is higher than expected considering historic rate of infection in this population of less than 0.3%. The CVD+ group had 1 case of DVT and 3 cases of knee stiffness compared to 0 DVTs and no knee stiffness at 3 months. Even though no statistical significance can be drawn, the increased anterior to posterior constraint may explain the higher rate of stiffness. Technically, the fate of the PCL in high congruence designs is not clear. In review of different design philosophies – some designs suggest sacrificing the PCL when using high congruence, and others preserve the ligament. The current study did not evaluate the presence or function of the PCL, which may be relevant to ultimate knee function. While any complication is significant to patient care there were too few numbers in this study to make statistically supported claims on differences between the two groups.

The current randomized controlled study had the benefits of eliminating inherent biases associated with retrospective studies, including varying indications, technical limitations, and surgical or patient parameters. However, due to the difficulty with long term randomization, the study is limited by a smaller sample size and response rate. Assessing equivalence or no difference is very difficult from a statistical standpoint, which ultimately affected the power of the current study. Leveraging the current sample size and perceived effect size, no statistical differences were detected in patient reported outcomes when comparing the CVD vs CVD+ inserts. While our focus was on patient outcomes and complications, it is important to consider additional variables including implant longevity and long-term outcomes. Typical implant survival is expected beyond 20 years, and higher congruence may affect such longevity. Future studies should include increased sample sizes with long term follow-up to support benefit and safety in higher congruence liners, even though wide-spread use is inevitable.

## Conclusion

With continued advances in implant design and efforts to improve TKA outcomes, it is imperative to critically analyze new designs and validate safety and outcomes with quality studies before implementing widely. In the PFC sigma CR total knee system, we are unable to give definitive recommendations regarding the superiority of the CVD vs CVD+ liner based on short-term patient outcomes, even though trends in pain and stiffness can be concerning. The anterior lipped high congruence liners are potentially beneficial but require more investigation to optimize their use and indications in total knee arthroplasty.

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