

# Level of Satisfaction after Total Knee Arthroplasty with Patient Specific Implants and Instruments (Conformis I Total PS) under ultrasound guided locoregional anesthesia and motor-sparing analgesia: Clinical and functional outcomes of a Single-Center Observational Pilot Study

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## Key points

The purpose of this study is to evaluate our experience regarding the use of patient-specific instruments and implants.

## Abstract

### Introduction

Implants and prosthetic designs in total knee replacement are constantly evolving, and Patient-specific instruments and implants represent a promising innovation.

However, the literature on the supposed superiority of custom-made compared to off-the-shelf prostheses is currently wanting and very conflicting.

### Materials and Methods

Single-center observational pilot study in patients treated with Custom Made Conformis total prosthesis (I-Total PS) under ultrasound guided locoregional anesthesia and motor sparing-analgesia with 12-month follow-up using validated scores (VAS, KOOS, KSS).

### Results

The study revealed excellent results of functional and subjective scores with the use of custom-made implants and did not point out short and long-term complications.

## Conclusion

Considering the promising results that emerged, cohort studies are necessary to evaluate statistical significance

### Keyword

total knee arthroplasty; patient-specific implants; custom made; customized; individually made; individual implants; knee arthroplasty; patient-reported outcome measures; knee society score; Oxford Knee Score.

## Introduction

Total knee replacement is currently a routine procedure in Orthopedic surgery. Similarly to total hip replacement, total knee arthroplasty (TKA) has seen a remarkable improvement in survival and performance of the implant over the years. However, the level of patient dissatisfaction with the outcomes of prosthetic knee replacement is around 25-30% [1-2].

In recent years there has been a continuous effort to improve prosthetic design searching for a better adaptation and more precise “customization”. In addition to the proven CR and PS models, medial pivot models, models with asymmetric polyethylene or asymmetric “anatomical” implants have been designed in order to improve the precision of the fit. In this context, new technologies such as navigation, robotic surgery, virtual and augmented reality and patient-specific instrumentation contribute to the achievement of a personalized surgical procedure [3–6].

In particular, patient-specific instrumentation and the construction of customized implants probably represents the highest point of the continuous research for a personalized treatment in the field of arthroplasty. The implant is designed to restore the natural articular geometry of the knee. Both the dedicated disposable instruments (the positioning and resection guides of the prosthetic components, the spacer blocks, as well as the trial prosthetic components) and the implantable prosthetic components are designed with the aid of computed tomography with 3D reconstruction, with the advantage of creating a personalized implant for each individual patient. This ensures a fitting of the implant as tailored to the patient as possible, starting from its design, representing the highest form of customization.

This customized approach allows for a so accurate fit of the implant that it virtually eliminates sizing compromises, which are common with traditional total knee replacements. Standard knee implants, in fact, are designed with a series of predetermined measurements and, at the time of surgery, the “most suitable” one is chosen. They are not created for the specific anatomy of the patient and sometimes surgeons must compromise on fit, rotation and alignment of the implant. With custom made prostheses it is possible to prevent problems of protrusion, under-coverage, dimensional compromises, unnecessary bone resections and pain situations.

To date, the literature does not reveal a clear superiority of customized implants compared to off-the-shelf TKAs,

both in terms of patient satisfaction and functional results. This is partly due to the lack of comparative studies and probably to the difficult interpretation of patient-reported data collection methods (Patient-Reported Outcome Measures - PROMs) [7-9].

The aim of this pilot study is to evaluate the short-medium term clinical and functional outcomes of patients who underwent “custom made” TKA PS (Conformis I Total Ps) at our hospital using self-compiled questionnaires and both subjective and objective measures.

### Materials and Methods

In this single-center observational pilot study, 12 patients who underwent total knee joint replacement and Custom Made Conformis total prosthesis implantation (I-Total PS) at the Engles Profili hospital in Fabriano (Italy), from January 2022 to September 2023, were evaluated for short-medium term follow-up. Medial parapatellar surgical approach was used for all patients.

The patients included in the study were selected based on the following inclusion criteria: male or female patients aged between 50 and 80 years; clinical and radiographic diagnosis of tricompartmental gonarthrosis (grade III-IV according to Kellgren-Lawrence classification); at least 6 months of ineffective conservative treatment with infiltrative therapy with hyaluronic acid; informed consent.

The patient must undergo CT scan approximately 25 days before the operation, to acquire a series of images necessary to carry out a three-dimensional reconstruction of the joint.

The result of the radiological examination is sent to the prosthesis manufacturing company, where the instrumentation and implantable components are made.

During the clinical evaluation, the functional values according to the KOOS (Knee Injury and Osteoarthritis Outcome Score) and KSS (Knee Score Society) scales, as well as the evaluation of the pain using the Visual Analog Scale (VAS), were taken into consideration in their authorized editions.

The follow-up of the patients was carried out by compiling the aforementioned score systems, already used at time zero and repeated 30 days and one year from the date of surgery.

Operative anesthesia was achieved under ERAS protocol with side-selective subarachnoidal injection of iperbaric bupivacaine 1%, 12 mg, using 27 gauge Whitacre atraumatic needles. Sonographic assistance to estimate anterior complex position and depth was used in patients over a BMI score of 28 to maximize comfort and minimize number of attempts.

Post-operative analgesia was granted by a combination of ultrasound guided motor-sparing blocks (IPACK block – see figure 1, and adductors canal block – see figure 2, with a grand total of 3mg/kg ropivacaine adjuncted with betamethasone 8mg) and EV ketoprofene 160mg (maximum 320mg/die) + paracetamol 1g (maximum 3g/die).

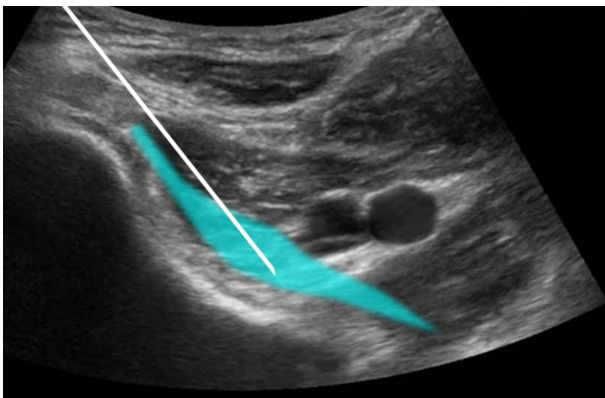


Figure 1. IPACK Block

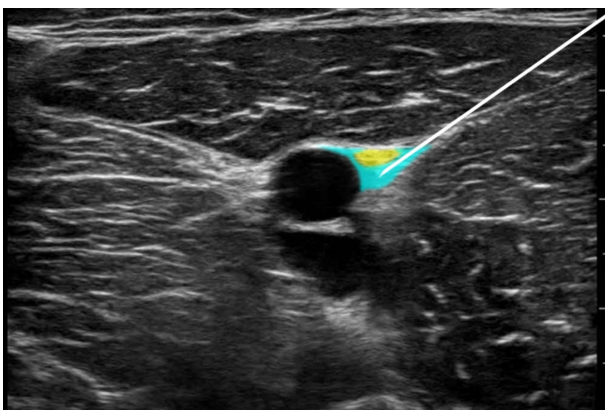


Figure 2. Adductors canal block

Preoperative intravenous antibiotic prophylaxis was used for all patients (2 g of cefazolin or if contraindicated 1 g of vancomycin two hours before the incision).

Subcutaneous low molecular weight heparin was administered as anti-DVT prophylaxis to all patients (LMWH at a dose of 4000 IU once daily by subcutaneous injection starting 12 hours after the end of the surgery).

All patients began the physiotherapy rehabilitation program starting from the day after the surgery, thanks to efficacy and motor-sparing features of ultrasound guided blocks and multimodal analgesia.

Post-operative treatment includes:

- start of passive mobilization with Kinetec CPM and off-load physiotherapy upon return to the ward.
- start of weight-bearing physiotherapy on first day after surgery
- first medication seven day after surgery
- removal of stitches fifteen day after surgery
- radiographic control in A-P and L-L projection performed immediately post-operatively, 30 days, 6 months and one year after surgery.

The Student's T test for paired series was used to compare the means of the data obtained at the pre-operative visit and each of the follow-up visits.

## Results

The patients included in the study who underwent total knee replacement at the Orthopedics and Traumatology department of the Engles Profili Hospital in Fabriano (Italy) are 12, for a total of 10 men (83.3%) and 2 women (16.7%). The average age at the time of surgery was 56.71 (min. 52, max. 74), the average BMI was 28.04 kg/m<sup>2</sup> (min. 26.73, max. 29.4) (see table 1).

	Value	Range
N=12		
Age	56.71	52-74
Gender, n (%)	10 (83,3%)	
- Male	2 (16,7%)	
- Female		
BMI, kg/m <sup>2</sup>	28,04	26,73-29,4

Table 1. Age, gender, BMI values and range.

	Time 0	1 Month	Δ 1M	12 Months	Δ 12M
KOOS	36,8	57,28	20,48 p-value >0,05	96	59,2 p-value >0,05
KSS knee score	41,8	61,57	19,77 p-value >0,05	96,66	54,86 p-value >0,05
KSS function	50	64,64	14,64 p-value >0,05	100	50 p-value >0,05
VAS	8	2,2	5,8 p-value >0,05	0,2	7,8 p-value >0,05

Table 2. KOOS, KSS Knee score, KSS function, VAS scores.

The KOOS increased on average from a value of 36.8 at pre-operative time 0, to an average value of 57.28 at the first check-up after 1 month, with an average Δ of 20.48. The difference in improvements with a p value > 0.05 was not statistically significant.

In the 12-month follow-up the average KOOS was 96 (Δ=59.2).

Also in this case there was no statistically significant difference, with p>0.05 (see figure 3)

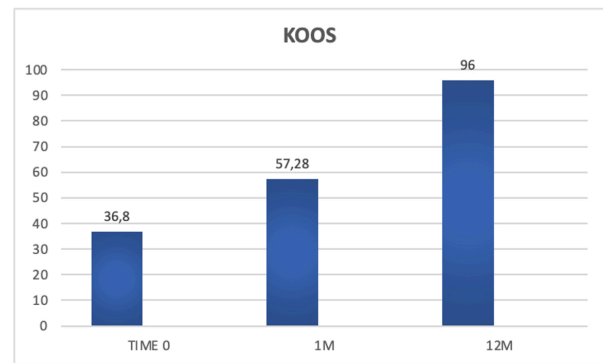


Figure 3. KOOS increase at time 0, 1 month, 12 months.

The KSS can be divided into two sections: knee score and functional score.

The knee score showed an increase from 41.8 (pre-operative value) to 61.57 (1M value) with Δ=19.77, with a non-statistically significant difference in values.

At the one-year follow-up, the patients obtained an average score of 96.66 with an average Δ of 54.86. Also, in this case there was no statistically significant difference with p> 0.05.

The functional KSS showed an increase from 50 (pre-operative value) to 64.64 (1 month value) with Δ = 14.64 with a non-statistically significant difference in values.

At the one-year follow-up, the patients obtained an average score of 100 with Δ=average equal to 50. Also, in this case there was no statistically significant difference with p>0.05 (see figure 4).

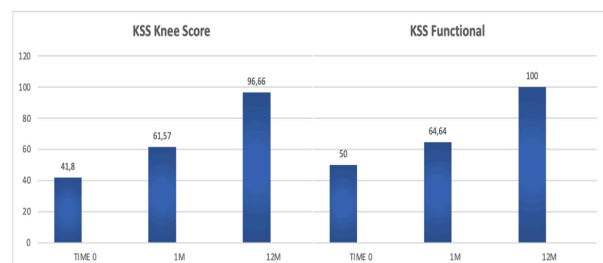
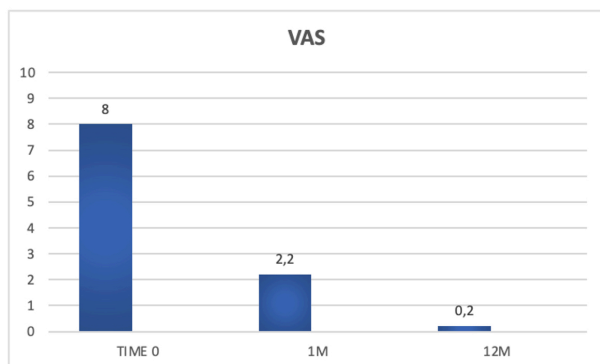


Figure 4. KSS Knee Score and KSS Functional increase at time 0, 1 month, 12 months.

The average VAS found pre-operatively was 8. At the first check-up they decreased to 2.2 respectively ( $\Delta=5.88$ ). At the second check, an average value of 0.2 was found ( $\Delta=7.8$ ).

Also, in this case there were no statistically significant improvements ( $p>0.05$ ) (see figure 5).



**Figure 5.** Average VAS decrease at time 0, 1 month, 12 months.

## Discussion

This study examined the use of ConforMIS implants (ConforMIS Inc) in its iTotal PS version.

The ConforMIS system differs from other PSI systems because, in addition to creating customized cutting masks based on the three-dimensional model of the knee, a patient-specific implant is also produced.

In fact, the femoral and tibial components, as well as the polyethylene tibial inserts, are built using the same three-dimensional model of the patient's knee and are delivered together with the PSI instruments.

The literature on implants with PSI instrumentation and on entirely customized ones such as ConforMis is constantly growing and currently there is no standard reference indication for their use compared to conventional implants.

In literature there is no unanimous consensus on the advantages and disadvantages of PSI for what concerns surgical time [15-21], intra- and postoperative blood loss [11-13, 16-18, 20, 22], the potential improvement in range of motion (ROM) or duration of hospitalization [11,15,20].

The existing literature is therefore currently very conflicting: there are several studies that have shown promising results and in general a superiority regarding the functional scores for custom made TKAs [23-32].

However, a 2023 review by Müller et al. showed no significant advantages over off-the-shelf knee implants [33], partly due to the lack of quality studies.

However, it must be said that recent studies in favor of custom-made prostheses were not yet included in Müller's review [23-25, 30-31].

Although the long-term survival rates of total knee arthroplasty are today very satisfactory, the literature points out a degree of dissatisfaction, linked in particular to the young age of the patients and the increasingly greater functional demands compared to the past [34-36].

In this context, the research's effort in the prosthetic field in recent years has mainly been aimed at the necessary improvement in terms of postoperative satisfaction scores.

The relatively high percentage of unsatisfied patients certainly has multifactorial reasons, but a possible cause must be found in the lack of a precise anatomical correspondence in the adaptation of the prosthetic components. In fact, many studies show that an imprecise adaptation of the implant, such as protruding areas or rotation defects, correlates with greater pain and inferior functional results even in the long term [37-44].

Over the years, numerous efforts have been made in this sense, improving the possibility of adapting the various off-the-shelf prosthetic models to the individual patient, such as a greater number of sizes available, "gender" specific implants, the possibility of "narrow" femoral implants or the production of asymmetric "anatomical" components. However, to date the introduction of individual "custom made" implants potentially represents the maximum level of specific anatomical adaptation to the individual patient.

Using off-the-shelf prostheses, the choice of size of the components and their adaptation to the specific anatomy of the patient is often a compromise between over- or

under-sizing (generally preferable) of the component itself, chosen by the surgeon during the operation. However, the "manual" choice of size and position of the components is a potential source of errors regarding the optimal dimensional and rotational adaptation.

Furthermore, Meier et al., analyzing more than 24,000 CT scans, showed a wide variation in the asymmetry of the posterior offsets (medial and lateral) in the natural knee joint, which can reach up to 8 mm [44]. Even with regards to the tibial plateau there may be inter-individual variability that is difficult to reproduce with off-the-shelf prosthetic implants. In another study by Meier et al, on over 15,000 CT scans, an asymmetry of more than 5 mm existed between the medial and lateral tibial plateau in 22% of cases [45].

This individual variability obviously cannot be taken into consideration in off-the-shelf prosthetic models. In conclusion, we can say that in cases where the specific anatomy of the patient differs from the standard one, even modern off-the-shelf implants with numerous possibilities for variations in terms of sizes and dimensions may not guarantee an adequate adaptation [46].

Due to the need to find a series of compromises intraoperatively that guarantee the best possible adaptation while respecting the need for a symmetrical flexion and extension balance, the position of the components in off-the-shelf TKAs differs more from the position planned preoperatively compared to the implantation of custom-made prostheses. Bugbee et al. have in fact demonstrated how the use of custom-made instrumentation and implants helps to achieve the pre-operatively planned positioning, with a potential favorable effect on joint function and overall, on the patient's final satisfaction [47].

In this context, it does not seem surprising that the present study has highlighted an excellent functional performance of custom-made implants, and it is reasonable to hypothesize a certain superiority in terms of functional scores and probably patient satisfaction

compared to off-the-shelf prostheses. At the basis of the excellent results obtained there is certainly a greater respect for the native biomechanics and kinematics of the knee, as well as the optimization of the adaptation of the individual prosthetic components.

Despite the excellent results emerging from this and other studies, it is not possible today to recommend the use of custom-made prostheses in all patients, also partly considering the cost of the implant which is significantly higher than off-the-shelf models.

The use of patient-specific implants currently seems to have an elective indication, especially in the presence of anatomical deformities (congenital or acquired) and in patients with extreme dimensions of the femoral and tibial segments. Another field of application is represented by the impossibility of using an intramedullary guide (presence of axial deformities, occlusion of the medullary canal, presence of synthesis devices), as an alternative to navigated and robotic surgery or the use of extra medullary alignment systems. There are several limitations in this study, first of all the low number of patients analyzed. However, this is a pilot study conducted by a single surgical team. The collection and analysis of pre- and post-operative data allows us to evaluate the potential improvement 12 months after surgery.

Currently, the functional and subjective data from this study have not been compared with a control group to better evaluate their significance and to evaluate the real difference in terms of improvement at defined time intervals.

Following the interesting data emerging from this study, we plan to conduct a study in the future with a larger sample and with a control group consisting of conventional TKAs implanted by the same surgical team following a mechanical alignment technique.

### **Conclusion**

Considering that the patient-specific prosthesis plays a role in some particular cases (presence of bone deformities and extreme dimensions of the tibia and

femur, impossibility of using the intramedullary guide...), among the questions that a more comprehensive study with a larger number of cases and with a control group may want to answer, it could be whether the patient-specific prosthetic can play a relevant role even in the larger case of the population that undergoes knee prosthesis in the absence of particularly complex anatomical situations; but simply as an alternative (perhaps more performing) compared to off-the-shelf prosthetic models.

In this study we analyzed preliminary data regarding our excellent experience with ConforMIS (ConforMIS Inc) implants in its iTotal PS version. Further quality studies are needed to define the field of application of this type of prosthesis and the real differences in results with off-the-shelf prostheses.

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