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In vivo kinematic comparison between an ultra-congruent and a posterior-stabilized total knee arthroplasty design by RSA

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Abstract

Purpose The aim of the present study was to compare the in vivo under weight-bearing kinematic behavior of a posterior-stabilized (PS) and an ultra-congruent (UC) total knee arthroplasty (TKA) model during a sit-to-stand motor task, a common activity of daily life.

Methods A cohort of 16 randomly selected patients (8 PS Persona Zimmer, 8 UC Persona Zimmer) was evaluated through dynamic radiostereometric analysis (RSA) at a minimum of 9 months after TKA, during the execution of a sit-to-stand. The anteroposterior (AP) translation of the femoral component and the AP translation of the low point of medial and lateral femoral compartments were compared through Student's *t* test ($p < 0.05$).

Results A significantly greater anterior translation of the femoral component was found for the PS group compared to the UC group. The flexion interval where statistical significance was found was between 30° and 0° ($p = 0.017$). Both groups showed a significantly greater anterior translation of the low point of the lateral compartment with respect to the medial one (PS: $p = 0.012$, UC: $p = 0.018$). This was consistent with a medial-pivot pattern. Furthermore, a significantly greater anterior translation of the medial compartment was found in the PS group compared to the UC group ($p = 0.001$). The same pattern was observed for the lateral compartment ($p = 0.006$).

Conclusions The TKA designs evaluated in the present study showed comparable in-vivo kinematics with regards to medial pivot pattern but differences in absolute AP translation. Specifically, the UC design showed greater AP stability than the PS design. This finding could be positive in terms of implant stability, but negative in terms of premature polyethylene wear and thus implant failure. This remains to be verified in studies with a larger sample size and longer follow-up.

Level of evidence IV.

Keywords Radiostereometric analysis · Ultra-congruent design · Posterior-stabilized design · TKA · Kinematics analysis

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Introduction

Several designs of total knee arthroplasty (TKA) have been developed in the last years to restore normal knee kinematics in osteoarthritic knee. However, data suggest that the evolution of the designs does not always translate into a restoration of the native knee kinematic behavior [1, 2].

Recently, a possible alternative to posterior-stabilized (PS) TKA has been proposed and utilized as primary implants: the ultra-congruent (UC) design. The latter replaces the function of the anterior and posterior cruciate ligament (PCL), thanks to the well-raised anterior and posterior lip and the deep-dished polyethylene insert, gaining greater conformity of the tibiofemoral joint compared to TKA with traditional inserts. This should prevent the paradoxical anterior subluxation of the femoral condyles allowing at the same time a physiological posterior femoral rollback [3]. Furthermore, its use has been recommended in young subjects with PCL insufficiency as it saves bone stock with respect to the PS design by not having a central cut-out on the femur to accommodate the box [4].

However, uncertainties were risen regarding the kinematical pattern of the UC designs. There are contrasting results regarding the knee range of motion (ROM), with some studies reporting restriction of femoral rotation, increased shearing stress on the tibia bone surface, non-physiologic femoral rollback, and reduced axial rotation in UC design which may be the cause for reduced knee flexion [5–7].

Dynamic radiostereometric analysis (RSA) is an instrument with sub-millimetric accuracy that has already been used for the in vivo kinematical analysis of TKA [8].

The aim of the study was to compare the in vivo kinematic behavior of a PS and of an UC TKA during the execution of common daily life activity, the sitting to standing motor task, to detect the presence of significant differences.

The hypothesis was that UC and PS designs would present comparable kinematics. The findings of the present study could lead to a better understanding of the in vivo behavior of the UC TKA design.

Methods

The present study was a prospective randomized clinical study, in which patients were randomly recruited from the waiting list for primary TKA at Rizzoli Orthopedic Institute and were enrolled after providing informed (1) previous corrective osteotomy on the affected lower limb, (2) post-traumatic arthritis, (3) severe preoperative varus–valgus deformity (hip knee ankle angle $> 10^\circ$); body mass index $> 40 \text{ kg/m}^2$, (4) rheumatoid arthritis; (5) chronic inflammatory joint diseases, (6) patients with a pre-pathological abnormal gait (amputated, neuromuscular disorders, poliomyelitis, developmental dysplasia of the hip), (7) severe ankle osteoarthritis (Kellgren–Lawrence grade 3 and grade 4), (8) severe hip osteoarthritis (Kellgren–Lawrence grade 3 and grade 4), (9) previous total hip or ankle replacement, (10) unwillingness to take part in this study and providing Health Insurance Portability and Accountability Act (HIPAA) authorization.

Patients were evaluated after at minimum 9-month follow-up [9] after surgery by model-based dynamic radiostereometric analysis. The RSA setup specifics were in line with previous literature studies on the same topic [10]. In short, the RSA device has two X-rays tubes and two digital flatpanels perpendicular to each other and synchronized for contemporary images acquisitions. Image post-processing was performed in a customized MATLAB (The MathWorks, Natick, US) script. The global accuracy of dynamic RSA in model positioning and orientation was evaluated in previous work and resulted to be sub-millimetric, respectively, $0.22 \text{ mm} \pm 0.46 \text{ mm}$ and $0.26^\circ \pm 0.22^\circ$ [11].

All patients performed a sit-to-stand motor task: from the sitting position, the patient had to stand up without support for the upper limbs. The chair was made of a radiolucent material and was 40 cm. The chair rising movement was not standardized to best simulate the natural movement that the patient would have done in daily life. The motion test was performed three times. In the first and the second, the patient gain comfort with the experimental setup (no X-ray exposure); in the third, data were acquired (X-ray exposure). To generate comparable data in the post-processing, all the movements were normalized from 0 to 100%, where 0% was the sitting position (before standing up), and 100% was the standing position (after the complete standing up).

From the original database, two groups of patients were selected for the present study. In the first group, patients receiving a posterior-stabilized (PS) Persona[®] (Zimmer Inc, Warsaw, Indiana, USA); in the second group, patients receiving an ultra-congruent (UC) Persona[®] (Zimmer Inc, Warsaw, Indiana, USA). The two designs share the same femoral condylar shape. The PS design has a box for housing the cam of the inlay, while the UC design requires a cruciate-retaining femoral component with an ultra-congruent inlay. All patients were operated on with the standard technique

using a medial parapatellar approach, mechanical alignment, gap-balancing technique with conventional instrumentations. In both groups, the posterior cruciate ligament was sacrificed and the patella was resurfaced.

The original groups included ten patients for the PS design and ten patients for the UC design. From these groups, four patients (two PS and two UC) dropped out from the study for personal reasons. Therefore, the final analysis was conducted on 16 patients, eight in the PS group and eight in the UC group.

The mean age of the patients was 70.0 ± 7.3 years old (95% CI). The cohort included eight right legs and eight left legs, with seven females and nine males.

This study obtained the approval of the Ethics Committee of the IRCCS Rizzoli Orthopaedic Institute (IRB statement: 0012645 approved 2014/04/03).

Statistical analysis

Statistical analysis was performed with MATLAB (The MathWorks, Natick, Massachusetts, USA). The differences in kinematic variables between the PS group and the UC group were assessed using the Student's t test for one-dimension analysis in the Statistical Parametric Mapping (SPM-1D) software [12]. The matched pair t test was used to assess the statistical differences between medial and lateral low point femoral compartments range of AP translation. The two-tailed t test was used to compare either medial or lateral low point femoral compartments between the two TKA designs, as well as the gender differences. Demographic data were collected and compared between the two TKA designs. Differences were considered statistically significant for $p < 0.05$.

The sample size was based on a power analysis consistent with previous studies performed with identical methodology and evaluated tasks [13, 8, 6–16]. The two-sample t test was used, with a true difference in AP translations of 5 mm, a standard deviation of 3 mm, and a $p < 0.05$. Given a power of 0.9, the minimum number of patients per group required was 7.

Results

All the patients were able to perform the sit-to-stand motor task. The average time of follow-up evaluation was 13.0 ± 6.9 months. The sex distribution was not found to statistically influence the kinematics ($p < 0.05$). The post-operative ROM was higher ($p = 0.001$) in the PS group compared to the UC group (Supplementary A).

A significantly greater anterior translation of the femoral component was found for the PS group compared to the UC group. The flexion interval where statistical significance was found, was between 30° and 0° ($p = 0.017$) (Fig. 1). Both groups showed a significantly greater anterior translation of the low point of the lateral compartment with respect to the medial one (PS: $p = 0.012$, UC: $p = 0.018$). This was consistent with a medial-pivot pattern (Figs. 2 and 3). Furthermore, a comparison of the anterior translation of the medial compartment between the PS group and the UC group was statistically significant and showed a greater excursion in the PS group ($p = 0.001$). The same pattern was observed for the lateral compartment ($p = 0.006$) (Table 1).

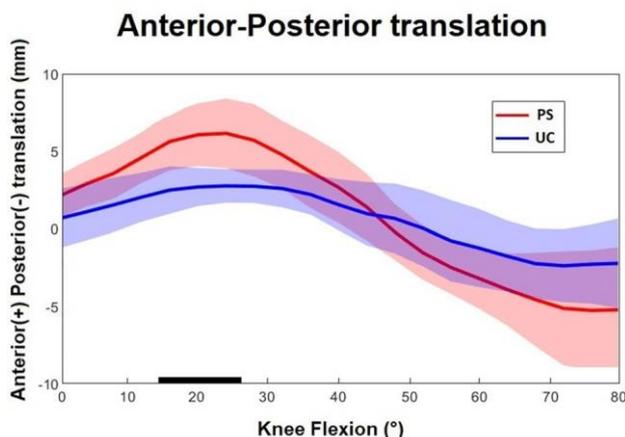


Fig. 1 Average of AP translation of the femoral component during a sit-to-stand. From the sitting position (80° of flexion) the patients stand-up. Significant values are indicated by the black line on the bottom of the figure

Discussion

The most important finding of the present study was that both PS and UC TKA showed significantly greater anterior translation of the low point of the lateral compartment with respect to the medial one (PS: $p = 0.012$, UC: $p = 0.018$), thus resulting in a medial pivot movement during the examined motor task. The UC group showed less lateral and medial condyles AP translation compared to the ones of the PS group ($p = 0.006$ and $p = 0.001$). This means that UC femoral component showed a reduced femoral rollback as also shown in two recent studies [17, 18]. Moreover, at the peak knee flexion, the UC showed a less posterior medial compartment contact point compared to the one of the PS, but no difference was present for the lateral compartment (Figs. 2 and 3). Pizza et al. recently demonstrated that a tighter medial compartment is associated with lower clinical score [10]. This might imply that, if correctly balanced, the congruence of the UC insert can control the movement of the condyles, but at the expense of non-physiological kinematics, as also demonstrated by Daniilidis et al. [6].

Fig. 2 Average of the AP translation of the low point of medial and lateral compartment during sit-to-stand of the PS group. On the right are represented the knee flexion angles

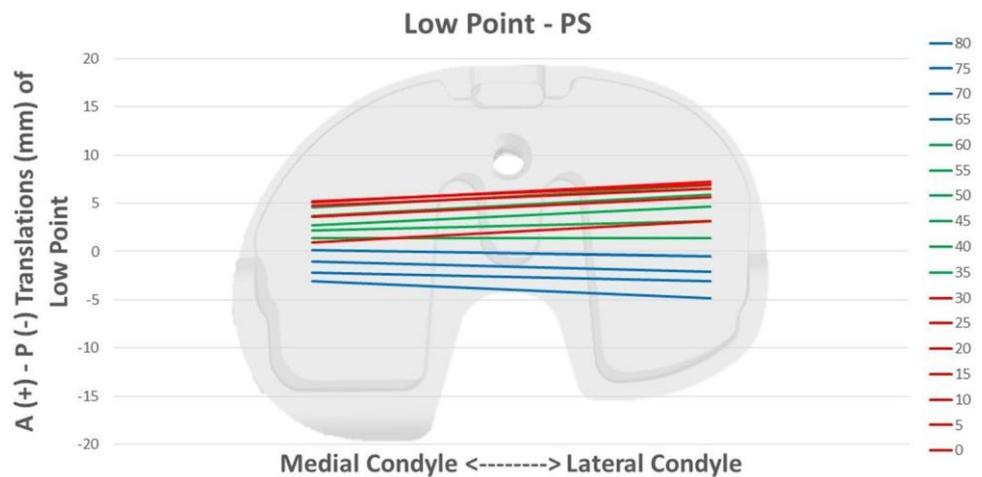


Fig. 3 Average of the AP translation of the low point of medial and lateral compartment during sit-to-stand of the UC group. On the right are represented the knee flexion angles

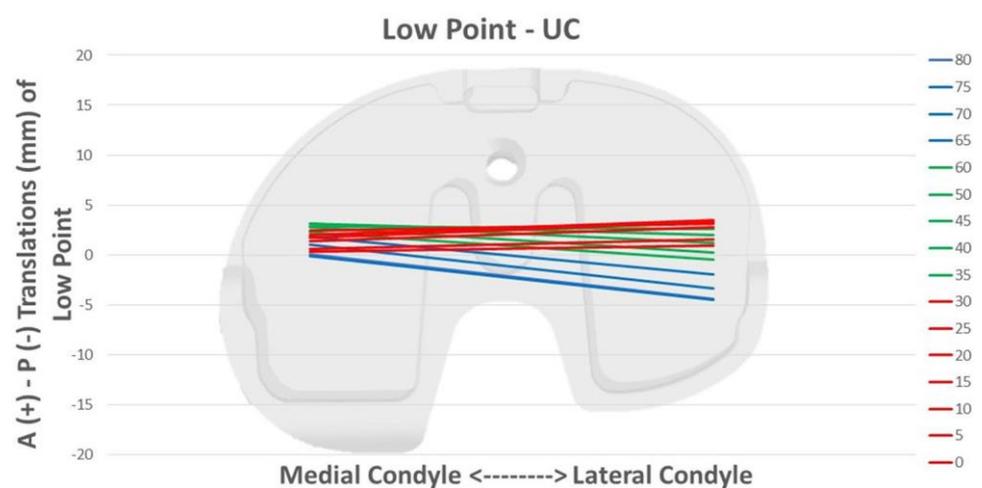


Table 1 Kinematical data obtained from the comparison between the PS and UC groups

Kinematic assessment	PS	UC	<i>p</i> value
AP translation (mm)	11.4±2.4	5.1±2.2	0.017*Low point translation (mm)
Medial compartment	9.2±2.9	3.3±3.2	0.001*
Lateral compartment	13.4±2.9	8.0±3.8	0.006*
<i>p</i> value	0.012*	0.018*	

*Statistically significant results

On the other hand, PS implants have intrinsic stability that requires more generous resections due to the cam-box system that engages around 60° of flexion, preventing ante-rior femoral translation as the flexion increases. From 0° to 60°, however, a greater AP translation of the PS group compared to the UC group has been shown in the present study. This implies that the femoral condyles move with a greater AP freedom and may adapt better to muscle activa- tion and weight-bearing stresses than a UC implant, whose movement is more closely guided by the shape of the insert [3], but this freedom could also result in patient perceived instability.

Another finding was that the kinematic behavior between the two implants showed a lower AP translation of the UC TKA between 30° and 0° of knee flexion with respect to the PS TKA. This finding differs from the con- cept shown in other studies, which show that UC implants have less posterior translation than PS implants during flexion [19, 6, 7, 20]. As the patients started the task from the sitting position, it was not possible to investigate the posterior translation in full flexion. However, the findings of the present study showed that the high congruence in the polyethylene of the UC insert reduces AP translation during a knee extension under weight-bearing, such as standing up from a chair. Indeed, the femorotibial kinemat- ics of the UC design relies only on the high congruence of the insert. On the one hand, this high congruence should control femoro-tibial translation throughout the ROM, preventing antero-posterior mid-flexion instability. On the other, it may cause posterior impingement of the femur on the posterior raised lip of the insert at high degrees of flex- ion and therefore limits the femoral rollback [20]. In the present study, this phenomenon was not verified because the task studied did not allow the analysis of deep flexions. Some studies found UC implants to limit maximum flexion due to the conflict between the posterior portion of the femoral condyles and the raised posterior lip of the polyethylene [6, 7, 20]. In fact, in a recent meta-analysis, Bae et al. analyzed the results of intraoperative kinemat- ics of PS and UC TKAs, concluding that the PS inlay is preferable to the UC one due to more favorable kinemat- ics and stability, even though no clinical differences were detected [19]. In the present study, post-operative ROM was higher in the PS design compared to the UC, thus confirming the literature.

The design of the present study did not allow to draw any conclusion about the superiority of one implant over another. Given the lower antero-posterior translation of the medial compartment showed in UC group, there may be a higher peak pressure on the polyethylene associated with an early wear and a reduced survival rate of the implant. However, the methods of the present study did not allow this parameter to be investigated, but it would be interesting to evaluate this aspect in future studies.

This study has several limitations. First, the small sample size. This was due to the strict inclusion criteria and the radiographic setup of the study. Moreover, the sample size was in line with previous studies conducted using the same technology [8, 21, 16]. The RSA evaluation was conducted at minimum 9 months after surgery. Thus, it was not pos- sible to conduct a longitudinal kinematical analysis to assess the differences with pre-operative kinematics at longer term follow-up. The absence of pre-operative investigation was required by our IRB with the specific aim of reducing overall X-ray exposure per patient. Moreover, although 9 months can be considered a short-term follow-up, it is in line with literature on the first post-operative TKA kinematical analy- sis [9, 10]. The motor task investigated was not standard- ized in terms of velocity and starting knee flexion angle to allow patients moving naturally and investigate daily life kinematics as much as possible. Data were normalized in post-processing based on the time elapsed. Moreover, the investigated task did not stress the knee joint to the maxi- mum ROM. Therefore, the inferences drawn could not be extended to the highest degrees of knee flexion.

Lastly, the height of the chair was within the standards for commercially available products. Such height allowed anadequate knee flexion in the starting position [22].

The clinical relevance of this study is that the two differ-ent implants showed slightly different kinematic behaviors but, in this case series, did not show substantial criticisms that could lead to a preference.

Conclusion

The TKA designs evaluated in the present study by dynamic RSA showed comparable in-vivo kinematics with regards to medial pivot pattern but differences in absolute AP translation. Specifically, the UC design showed greater AP stability than the PS design. This finding could be positive in terms of implant stability, but negative in terms of premature polyethylene wear and thus implant failure. This remains to be verified in studies with a larger sample size and longer follow-up.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00167-021-06629-1>.

Author contributions TRDS participated in study design, data interpretation, and drafted the manuscript; DA participated in study design, data interpretation, and drafted the manuscript; SDP contributed in methods development and data interpretation, helped to draft the manuscript and performed statistical analysis; RZ participated in kinematics data collection and analysis, and helped to draft the manuscript; NP contributed in data interpretation and helped to draft the manuscript; GMMM supervised the clinical interpretation; SZ and LB participated in study design, coordinated activities and helped to draft the manuscript. All the authors read the final manuscript and approved it.

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Declarations

Conflict of interest The authors have no conflicts of interest to declare that are relevant to the content of this article.

Ethical approval Ethics Committee of the IRCCS Rizzoli Orthopaedic Institute (IRB statement: 0012645 approved 2014/04/03).

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

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