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In vivo femorotibial kinematics of medial-stabilized total knee arthroplasty correlates to post-operative clinical outcomes

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# **In-vivo femorotibial kinematics of medial-stabilized total knee arthroplasty correlates to postoperative clinical outcomes**

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## **Conflict of interest**

Authors declare that they have no conflict of interest.

# In-vivo femorotibial kinematics of medial-stabilized total knee arthroplasty correlates to postoperative clinical outcomes

3

## 4 ABSTRACT

5 **Purpose:** To evaluate if there was a correlation between in vivo kinematics of a medial-stabilized (MS) total knee  
6 arthroplasty (TKA) and post-operative clinical scores. We hypothesized that (1) a MS-TKA would produce a medial pivot  
7 movement and that (2) this specific pattern would be correlated with higher clinical scores.

8 **Methods:** 18 patients were evaluated through clinical and functional scores evaluation (Knee Society Score clinical and  
9 functional, Womac, Oxford), and kinematically through dynamic radiostereometric analysis (RSA) at 9 months after MS-  
10 TKA, during the execution of a sit-to-stand and a lunge motor task. The anteroposterior (AP) Low Point translation of  
11 medial and lateral femoral compartments were compared through Student's t-test ( $p < 0.05$ ). A correlation analysis between  
12 scores and kinematics was performed through the Pearson's correlation coefficient  $r$ .

13 **Results:** A significantly greater ( $p < 0.0001$ ) anterior translation of the lateral compartment with respect to the medial one  
14 was found in both sit-to-stand (medial  $2.9 \text{ mm} \pm 0.7 \text{ mm}$ , lateral  $7.1 \text{ mm} \pm 0.6 \text{ mm}$ ) and lunge (medial  $5.3 \text{ mm} \pm 0.9 \text{ mm}$ ,  
15 lateral  $10.9 \text{ mm} \pm 0.7 \text{ mm}$ ) motor tasks, thus resulting in a medial pivot pattern in about 70% of patients. Significant  
16 positive correlation in sit-to-stand was found between the peak of AP translation in the lateral compartment and clinical  
17 scores ( $r = 0.59$  for Knee Society Score clinical and  $r = 0.61$  for Oxford). Moreover, we found that the higher peak of AP  
18 translation of the medial compartment correlated with lower clinical scores ( $r = -0.55$  for Knee Society Score clinical,  $r =$   
19  $-0.61$  for Womac and  $r = -0.53$  for Oxford) in the lunge. A negative correlation was found between Knee Society Score  
20 clinical and VV laxity during sit-to-stand ( $r = -0.56$ ) and peak of external rotation in the lunge motor task ( $r = -0.66$ ).

21 **Conclusions:** The MS-TKA investigated produced in-vivo a medial pivot movement in about 70% of patients in both  
22 examined motor tasks. There was a correlation between the presence of medial pivot and higher post-operative scores.

23 **Level of evidence:** IV

24 **Keywords:** medial-stabilized, TKA, dynamic RSA, medial pivot

25

26

## 27 **Introduction**

28

29 Nowadays, about 20% of patients who underwent total knee arthroplasty (TKA) is not fully satisfied in terms of pain  
30 relief and functional outcomes [11]. Despite good coronal and sagittal alignment, the restoration of normal knee  
31 kinematics, which is supposed to be a crucial factor, is not always reached [2, 9]. Many studies focusing on the motion of  
32 the native knee joint revealed that the lateral compartment performs a wider anterior-posterior (AP) translation during  
33 flexion-extension compared to the medial one. This type of motion is known as “medial pivoting” movement of the knee  
34 [9, 13].

35 Several TKA designs have been developed with the aim of reproducing this pattern as much as possible. A new concept  
36 of TKA, the medial-stabilized (MS) knee prosthesis, has been developed trying to mimic distal femur and tibial plateau  
37 geometry, thus reproducing the natural knee motion. The MS-TKA guarantees anteroposterior (AP) stability of the medial  
38 compartment thanks to the “ball-in-socket” geometry, coupling with a greater AP translation of the external compartment  
39 during knee flexion allowed by the flat lateral surface of the insert [18].

40 Multiple studies reported favourable outcomes for the MS-TKA, with satisfactory results at medium to long-term follow-  
41 up [5, 8, 12, 14]. Nevertheless, to authors’ knowledge, there is lack of evidence of better clinical outcomes in presence of  
42 specific kinematic patterns. In particular, just few investigations have been focused on the correlation between in-vivo  
43 kinematics of MS prosthesis and post-operative clinical outcomes [19].

44 Hence, the aim of the present study was to evaluate if the in vivo kinematics of a MS total knee arthroplasty, designed to  
45 produce medial pivot pattern, was somehow correlated with post-operative clinical scores. The hypotheses were that (1)  
46 the MS-TKA would be able to produce medial pivot movement during the examined motor tasks, that (2) this specific  
47 pattern would be correlated with higher clinical scores.

48

## 49 **Materials and Methods**

50 A cohort of 18 randomly selected not consecutive patients in waiting list for TKA at our institution was enrolled in this  
51 study after providing an informed consent. The randomization was carried out using a random number generator, available  
52 on the web site of National Health System, which generated 18 casual numbers within the interval (1, 45). These numbers  
53 were used to select the patients from the waiting list for TKA. The inclusion criteria were: (1) age (50-85 years old); (2)  
54 severe radiographic primary osteoarthritis (Kellgren-Lawrence grade 3 and grade 4); (3) patients scheduled for a primary  
55 TKA. The exclusion criteria were: (1) previous corrective osteotomy on the affected lower limb; (2) post-traumatic  
56 arthritis; (3) severe preoperative varus-valgus deformity (Hip Knee Ankle angle > 10°); Body Mass Index > 40 kg/m<sup>2</sup>;  
57 (4) rheumatoid arthritis; (5) chronic inflammatory joint diseases; (6) patients with a pre-pathological abnormal gait  
58 (amputated, neuromuscular disorders, poliomyelitis, developmental dysplasia of the hip); (7) severe ankle osteoarthritis  
59 (Kellgren-Lawrence grade 3 and grade 4); (8) severe hip osteoarthritis (Kellgren-Lawrence grade 3 and grade 4); (9)  
60 previous total hip or ankle replacement; (10) unwillingness to take part in this study and providing Health Insurance  
61 Portability and Accountability Act (HIPAA) authorisation.

62 The mean age of the patients was  $72.1 \pm 7.4$  years old (95% CI). The cohort included 7 right legs and 11 left legs, with 9  
63 females and 9 males. All patients were operated with the standard technique (medial parapatellar approach, adjusted  
64 mechanical alignment)[21] receiving a cemented MS-TKA (GMK Sphere, Medacta International, Switzerland) with  
65 patellar resurfacing. Patients were evaluated after a minimum 9-month follow-up by Model-based dynamic

66 radiostereometric analysis (RSA). The RSA set-up was analogous to the ones already published in previous articles from  
67 the same study group [3, 4, 6, 15].

68 All patients performed two motor tasks that represent common daily activities, a sit-to-stand and a lunge movement:

- 69 - Sit-to-stand: from the sitting position, the patient had to stand up, without support for the upper limbs. The chair  
70 was made of a radiolucent material and was 40 cm high. The chair rising movement was not standardised to best  
71 simulate the natural movement that the patient would have done in daily life.
- 72 - Lunge: from the standing position, the patient made a bending with the operated limb, reaching their maximum  
73 flexion according to their possibilities, then returned in the standing position. Patients were not allowed to use  
74 supports for the upper limbs. Also, this motor task was not strictly standardised.

75

76 The global accuracy of dynamic RSA in model positioning and orientation, evaluated in terms of “trueness  $\pm$  precision”,  
77 resulted to be sub-millimetric, respectively  $0.2 \text{ mm} \pm 0.5 \text{ mm}$  and  $0.3^\circ \pm 0.2^\circ$ . Data are presented as mean  $\pm$  standard  
78 error.

79 Moreover, pre-operative and post-operative visit at 9 months, patients were clinically evaluated by one single expert  
80 orthopaedic surgeon which calculated the clinical and functional Knee Society Score (KSSC and KSSF), Womac and  
81 Oxford scores. These scores are commonly used to assess patients’ clinical status in terms of pain and functionality. For  
82 the KSSC, KSSF and Womac, the scores range from 0 to 100, and is considered good over 69. The Oxford score ranges  
83 from 0 to 48 and is considered good over 39.

84 This study obtained the approval from Institutional Review Board (IRB) of the IRCCS Rizzoli Orthopaedic Institute (ID:  
85 003603 February 16<sup>th</sup>, 2016).

## 86 **Statistical Analysis**

87 Statistical analysis was performed with MATLAB®. For each of the two movements, the AP translation of medial and  
88 lateral compartments was compared in order to assess the presence of medial pivot pattern: a “pivoting ratio” was  
89 assessed within  $(-1, 1)$  for each task. In all tasks with ratio between 0 and 1, prostheses were considered to perform  
90 consistent medial pivot.

91 The matched pairs Student’s t-test was used to assess the statistical differences, with  $p < 0.05$ . Furthermore, a ratio  
92 between medial and lateral AP translation was calculated to evaluate how many knees showed the medial pivot pattern.

93 A correlation analysis between post-operative clinical scores and kinematic parameters was performed for each of the  
94 two tasks through the Pearson’s correlation coefficient  $r$  ( $p < 0.05$ ). A correlation coefficient  $r < 0.4$  was considered poor,  $r$   
95 between 0.4 and 0.75 was considered fair,  $r > 0.75$  was considered good.

96 In order to calculate the sample size, an a priori power analysis was performed. The two sample T-test was used with  $p <$   
97  $0.05$ . Based on previously published studies with the same technology, the true difference of means between medial and  
98 lateral compartment was set to 3 mm for both motor tasks [6, 15], while the standard deviation was considered 3 mm.  
99 The power value was 0.95. Based on this analysis, the number of patients resulted to be 16.

100

101 **Results**

102 All the patients were able to perform the sit-to-stand motor task, while all the patients except one were able to perform  
103 the lunge motor task. The average time of follow-up evaluation was  $10.0 \pm 1.8$  months. The sex distribution was not found  
104 to statistically influence the kinematic and outcome analyses ( $p < 0.05$ ).

105 Regarding the sit-to-stand, the kinematic analysis showed the presence of medial pivot, with a significantly greater  
106 ( $p < 0.0001$ ) anterior translation of the lateral condyle ( $7.1 \text{ mm} \pm 0.6 \text{ mm}$ ) compared to the medial one ( $2.9 \text{ mm} \pm 0.7 \text{ mm}$ )  
107 on average (Fig.1 and Tab.1). A consistent medial pivot pattern was found in 12 patients out of 18 (67%). Thus, the  
108 kinematic analysis was repeated in the sub-group of patients performing medial pivot and in the sub-group of patients not  
109 performing it. A significantly greater anterior translation of lateral condyle ( $p < 0.0001$ ) was found in the sub-group of  
110 patients performing medial pivot, while no statistical difference was found in the sub-group of patients not performing  
111 medial pivot. Also, regarding the lunge motor task, the lateral condyle showed a significantly larger ( $p < 0.0001$ ) anterior  
112 translation ( $10.9 \text{ mm} \pm 0.7 \text{ mm}$ ) with respect to the medial one ( $5.3 \text{ mm} \pm 0.9 \text{ mm}$ ) (Fig.2 and Tab.1) on average. A  
113 consistent medial pivot pattern was found in 11 patients out of 17 (65%). As for the sit-to-stand, the initial cohort was  
114 split in two sub-groups, and the same trend was found (Tab.1). The Freeman graphics regarding the kinematical results  
115 split in two groups of patients, performing a consistent medial pivot or not, are provided in supplementary material A.

116 Regarding the post-operative clinical outcomes, significant correlations ( $p < 0.05$ ) were found between clinical outcomes  
117 and knee kinematics (Tab.2). In particular, a positive correlation was found between the peak of AP translation in the  
118 lateral compartment and both the KSSC ( $r = 0.59$ ) and the Oxford ( $r = 0.61$ ) scores in the sit-to-stand motor task. In  
119 addition, we found that the higher the peak of AP translation in the medial compartment the lowest the KSSC score ( $r =$   
120  $-0.55$  lunge), the WOMAC ( $r = -0.60$  lunge), and the Oxford ( $r = -0.53$  lunge). We found also a negative correlation  
121 between KSSC score and VV laxity regarding the sit-to-stand ( $r = -0.56$ ) motor task and between the peak of external  
122 rotation and the KSSC ( $r = -0.66$ ) regarding the lunge motor task. A specific post-hoc power analysis for the clinical  
123 outcomes was performed. Using a sample size of 18 patients and the correlation coefficient with the lowest absolute  
124 magnitude, i.e.  $r = 0.53$ , the power resulted 0.81. The complete list of patients' outcomes in relation to the medial pivot  
125 pattern is provided in the supplementary material B.

126

127 **Discussion**

128 The most important findings of the present study were that (1) the MS TKA produced medial pivot movement during  
129 both sit-to-stand and lunge motor tasks in the 70% of patients; that (2) higher values of AP translation of the lateral  
130 compartment correlated with higher clinical scores, while the higher values of AP translation of the medial compartment  
131 correlated with lower clinical scores. Moreover, higher values of VV laxity during sit-to-stand and peak of external  
132 rotation during the lunge motor task were correlated with lower clinical scores.

133 The medial pivot motion of the healthy knee joint has been widely described in literature [7, 10, 13, 16]. The restoration  
134 of normal knee biomechanics is a crucial point of TKA surgery, but it can be highly related to implant design and patients  
135 activity [1]. The MS prosthesis evaluated in this study (GMK Sphere, Medacta International, Switzerland) demonstrated  
136 a consistent medial pivot movement both in the sit-to-stand and in the lunge motor tasks, two common activities of daily  
137 life with different levels of engagement. This prosthetic design is intended to reproduce posterior femoral rollback and

138 medial pivot motion, avoiding paradoxical anterior sliding or rolling forward of the femoral component with respect to  
139 the tibia during flexion-extension.

140 The medial pivot pattern was found in about 70% of patients for both motor tasks, thus confirming the average trend. Our  
141 kinematic results are in line with the ones of different authors, reproduced in either an in-vivo or in-vitro setting.  
142 Steinbrück A. et al. [18] tested the GMK Sphere MS TKA in an in-vitro setting during loaded squat from 20° to 120° of  
143 flexion. They found a combination of anterior translation of the lateral compartment (14.7 mm ± 6 mm) with a lower  
144 anterior translation on the medial one (3.5 mm ± 4.8 mm), concluding that the specific TKA was able to mimic the  
145 physiological knee kinematics. Also Scott G. et al.[17] reported a greater AP translation on the lateral side (8 mm ± 4  
146 mm) with respect to the medial one (2 mm ± 3 mm) in 16 knees implanted with the same prosthesis during in-vivo lunge  
147 movement. The range of AP translation of the present study resulted lower than the one presented by Steinbrück A. et al.  
148 and similar to the one of Scott G. et al. This difference could be explained by the higher range of knee flexion (20-120°)  
149 reached in-vitro and in the absence of patients' active muscle control [18].

150 On average, the cohort of patients reported good clinical and functional outcomes. Regarding the correlation between the  
151 clinical outcomes and AP Low Point translations of medial and lateral compartments, it seems that the medial pivot  
152 movement has a positive effect on the clinical and functional outcomes of the patients. Analogue results were found in a  
153 recent paper by Van Onsem et al. The authors reported that patients with poor post-operative patient-reported outcomes  
154 (PROMs), after a Posterior-Stabilized (PS) TKA implantation experienced more anterior translation on the medial side  
155 and less posterior translation on the lateral side during deep flexion activities. Meanwhile the patients who reported good  
156 clinical outcomes showed a greater AP stability on the medial compartment with respect to the lateral one [21]. It must  
157 be outlined that the TKA model examined by Van Onsem is substantially different from the one of the present study,  
158 since AP stability of PS-TKA relies more on the post-cam mechanism. However, the concept of higher congruency of the  
159 medial compartment with respect to the lateral one seems to be equally important to ensure AP stability of the implant.

160 Furthermore, the negative correlation between VV laxity and peak of external rotation with clinical outcomes suggests  
161 that excessive coronal and rotational laxity could play a role in knee function after TKA. To our knowledge, no article  
162 has been published about correlation between dynamic rotational or coronal laxity with clinical outcomes. In addition,  
163 this correlation seems to highlight the importance of soft tissue balancing during surgery. Medial compartment stability  
164 and lateral compartment wider AP translation allow proper implant function. On the medial side, the stability is provided  
165 by the high congruency of the inlay with the medial condyle and by the integrity of medial soft tissues (superficial medial  
166 collateral ligament). On the lateral side, the flat surface of the inlay facilitates the rollback, thus, lateral soft tissue release  
167 is more likely to be done. However, to avoid excessive lateral compartment laxity, the anterior fibers of the ileo-tibial  
168 band should remain intact, as suggested also by Van Overschelde et al.[20]. However, the ranges of VV laxity found for  
169 the patients of our study were always below 5°, thus suggesting that intraoperative stability was achieved properly. As  
170 recently confirmed by Watanabe et al., valgus laxity averaging 3.6° correlates with good PROMs after PS TKA, while  
171 increasing joint laxity reversely affected some of the clinical outcomes [22].

172 The present study has some limitations. First of all, the RSA evaluation was performed only after surgery, as specifically  
173 required by our IRB in order to reduce x-rays exposure. Thus, it was not possible to compare joint kinematics before and  
174 after implantation. Anyway, joint kinematics of an arthritic knee cannot be assumed as the one of the native joint. Second,  
175 a strict standardization of patients' movement in terms of movement magnitude and velocity was not performed. Patients  
176 were required to perform the motor tasks in the most natural way as possible, in order to mimic daily life conditions.

177 However, to generate comparable data, all the movements were normalized in the post processing (see Methods for  
178 details). Furthermore, the correlation analysis between the clinical outcomes and the kinematical data did not allow us to  
179 define a cut-off for laxity, over which the clinical outcomes becomes poor. This aspect is more likely to be investigated  
180 in a wider cohort of patients. Finally, all the pre-operative and post-operative clinical evaluations was carried out by one  
181 single expert surgeon (who did not participate to surgeries nor to dynamic RSA analysis) to avoid inter-rater variability.

182 The results of this study have an important clinical relevance. In fact, the knowledge that a medial pivot kinematics after  
183 the implantation of a MS-TKA leads to better clinical results will push research in obtaining it in a higher ratio of patients.

184

## 185 **Conclusions**

186 The MS-TKA investigated produced in-vivo a medial pivot movement in about 70% of patients in both examined motor  
187 tasks. There was a correlation between the presence of medial pivot and higher post-operative scores.

188



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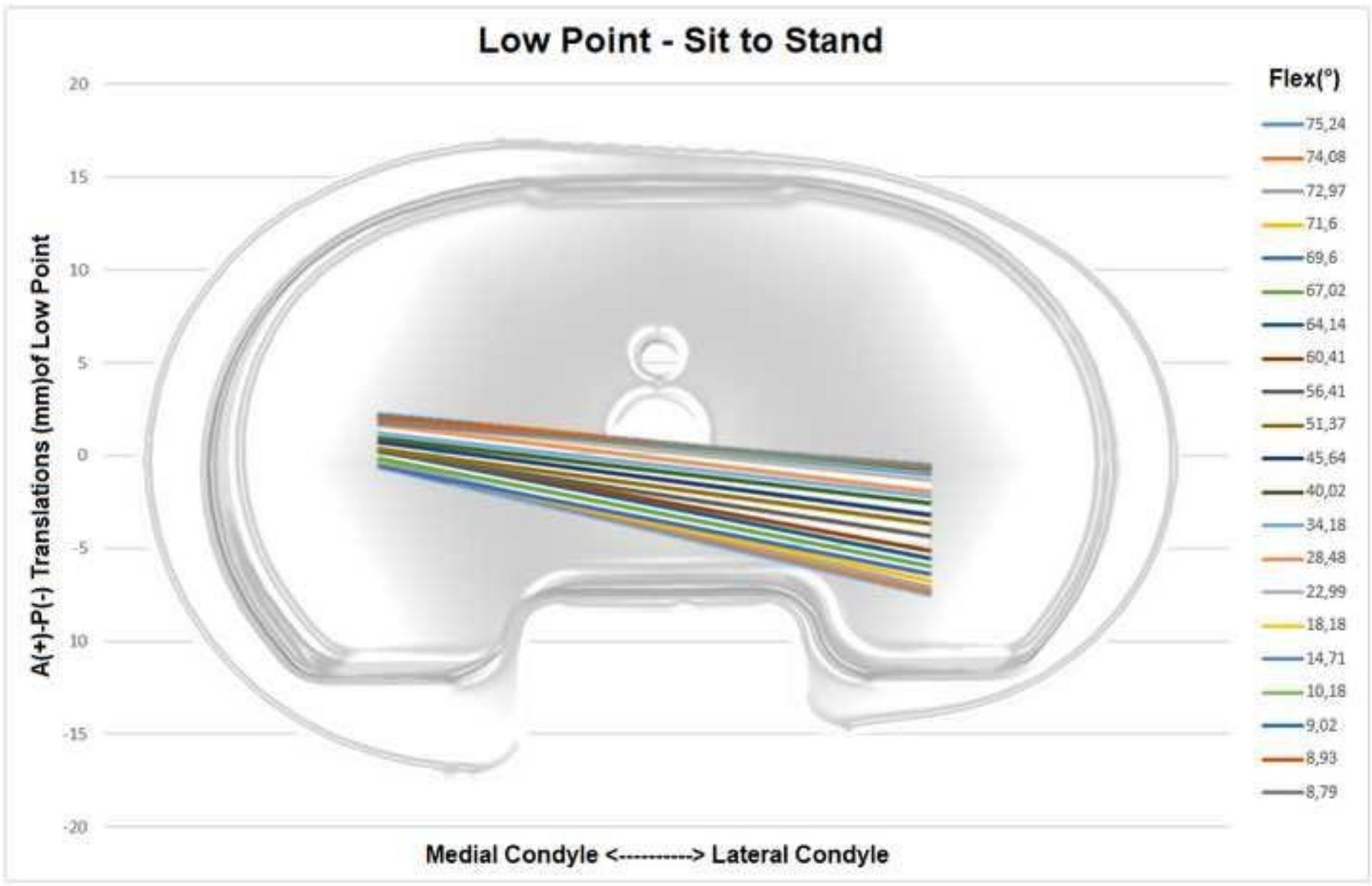
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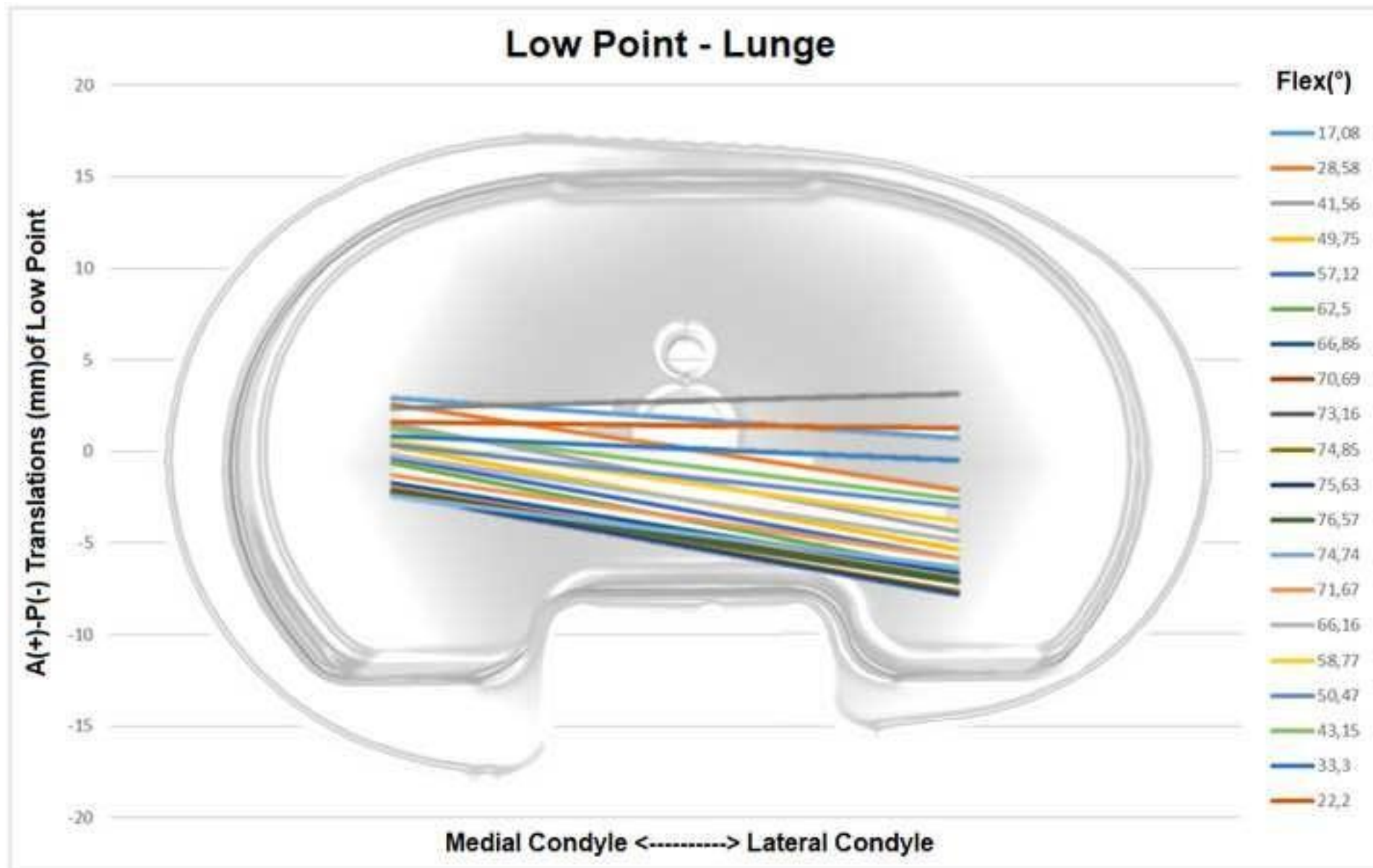
245 **Figure captions**

246

247 **Fig.1** Average of the AP translation of the Low Point of medial and lateral compartment during sit-to-stand over the entire  
248 cohort of patients, represented as Freeman graphic. On the right are represented the knee flexion angles.

249 **Fig.2** Average of the AP translation of the Low Point of medial and lateral compartment during lunge over the entire  
250 cohort of patients, represented as Freeman graphic. On the right are represented the knee flexion angles.





LOW POINT KINEMATICS		Medial Condyle AP translation (mm)	Lateral Condyle AP translation (mm)	p-value
<b>Sit to stand</b>	<i>Entire cohort (n=18)</i>	2.9 ± 0.7	7.1 ± 0.6	< 0.0001 *
	<i>Medial pivot pt (n=12)</i>	1.2 ± 0.8	8.2 ± 1.1	< 0.0001 *
	<i>No medial pivot pt (n=6)</i>	5.1 ± 1.4	4.7 ± 1.7	n.s
<b>Lunge</b>	<i>Entire cohort (n=17)</i>	5.3 ± 0.9	10.9 ± 0.7	< 0.0001 *
	<i>Medial pivot pt (n=12)</i>	5.7 ± 0.8	11.9 ± 0.8	< 0.0001 *
	<i>No medial pivot pt (n=5)</i>	6.3 ± 2.4	6.6 ± 1.9	n.s

*Table 1 – Anteroposterior (AP) Low Point translation of medial and lateral condyles during sit to stand (top) and lunge (bottom) evaluated through dynamic RSA. Data are reported as entire cohort, patients performing consistent medial pivot and patients not performing consistent medial pivot. \* represent statistically significant differences ( $p < 0.05$ ).*

CORRELATION COEFFICIENT [r]	Sit to Stand				Lunge			
	<i>KSSC</i>	<i>KSSF</i>	<i>WOMAC</i>	<i>OXFORD</i>	<i>KSSC</i>	<i>KSSF</i>	<i>WOMAC</i>	<i>OXFORD</i>
<b>Peak of AP translation lateral compartment</b>	0.59 *	n.s.	n.s.	0.61 *	n.s.	n.s.	n.s.	n.s.
<b>Peak of AP translation medial compartment</b>	n.s.	n.s.	n.s.	n.s.	-0.55 *	n.s.	-0.60 *	-0.53 *
<b>VV laxity</b>	-0.56 *	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
<b>Peak Ext-rotation</b>	n.s.	n.s.	n.s.	n.s.	-0.66 *	n.s.	n.s.	n.s.

Table 2 – Pearson's correlation coefficients ( $r$ ) between kinematical parameters and patient-reported outcomes. \* represent statistically significant differences ( $p < 0.05$ ).

