Journal of Orthopaedics 23 (2021) 264–272

Contents lists available at ScienceDirect

Journal of Orthopaedics

journal homepage: www.elsevier.com/locate/jor

Comparison between patient specific instrumentation and traditional technique in patients with total knee arthroplasty: An observational perspective study

Sergio Rigoni [a,*], Martina Dalla Libera [a], Diego Pigatto [b], Davide Conte [b], Alessandro Ceccato [b], Cesare Chemello [a]

[a] Hospital of Asiago, Health Units 7 "Pedemontana", Italy
[b] Hospital of Bassano, Health Units 7 "Pedemontana", Italy

ARTICLE INFO

Keywords:
Patient specific instruments (PSI)
Knee arthroprothesis
Gait analysis
Knee society score (KSS)
SF-36 score

ABSTRACT

Background: Total knee arthroplasty surgery (TKA) using prenavigated Patient Specific Instruments (PSI) technique represents one of the most recent technological evolutions in development of prosthetic surgery. The aim of this study was to evaluate kinematic and functional recovery of patients operated with prenavigated PSI technique compared to those operated with traditional technique.

Methods: A cohort of 20 patients is divided in two groups; some are operated with traditional technique (with NexGen Knee system) and others with prenavigated PSI technique (with eMP Knee system) at Asiago Hospital. Limb circumferences are measured for edema evaluation and different evaluation forms are provided to patients: SF-36, KSS pre-surgery (T0), KSS 15 (T1) and 45 days after surgery (T2). *Gait Analysis* is performed 60 days post-surgery, after leaving crutches.

Results: The analysis of KSS and SF-36 evaluation forms shows a greater improvement in PSI Evolution group in terms of articulation (comparison between T0 and T1), knee function and early return to physical and social activities. Pain is lesser in NexGen group, in an earlier phase, but 45 days after surgery (T2) there are no significant differences between two groups. Perception of general state of health improves more and earlier in NexGen. In NexGen group edema evaluation had significant differences at the level of prosthetic leg, but not in knee and thigh. Overall: the walking pattern is more physiological in PSI Evolution group.

Conclusions: The present study highlighted the superiority of prenavigated PSI technique over traditional technique in recovering functionality of prosthetic knee and in restoring a more physiological path pattern.

1. Introduction

Since the 1970s, arthroplasty has been recognized to be an effective treatment for advanced knee osteoarthritis, capable of relieving pain in 90% of operated patients.[1] Currently TKA represents the Gold Standard for treatment in advanced osteoarthritis and all other surgical procedures are compared with it in terms of efficacy: TKA long-term follow-up studies show 90% of good results and 92–93% survivorship at 15-year.[2] Nonetheless, misalignment represents the main cause of failure[3] and in literature it is acknowledged that 30% of TKA has a misalignment greater than 3°. Over the years, patient expectations increased considerably: nowadays the two biggest factors of after-surgery patient dissatisfaction are persistence of pain and delay in functional recovery.[4] In order to meet increasing request to shorten post-op recovery and return to active lifestyle as early as possible, surgical technique has been refined several times. Especially over the last ten years, a lot of interest focused on less invasive approaches and prosthetic designs optimizing joint kinematics.[2]

Prosthetic knee surgery with prenavigated PSI technique represents the latest technological evolution in the development of Total Knee Arthroplasties.[2]

PSI system provides three-dimensional preoperative planning. Hafez's group was among the first to describe this new technique: use of patient-specific cutting guides (or templates) instead of traditional instruments and no need for medullary canal drilling. Several companies have recently exploited the idea of customized cutting guides, but

* Corresponding author. Department, SC Recovery and Functional Rehabilitation, Via Martiri di Granezza 42, 36012 Asiago (VI), Italy.
E-mail address: Sergio.rigoni@aulss7.veneto.it (S. Rigoni).

https://doi.org/10.1016/j.jor.2021.01.013
Received 11 December 2020; Accepted 31 January 2021
Available online 11 February 2021

although no evidence based study has been yet published to demonstrate the benefit to use PSI guide as a part of the surgical routine, positive clinical results obtained by several researches allowed PSI technique to increasingly spread out also in Italy[5]

Compared to traditional technique, PSI technique is based on a preoperative knee study using computed tomography (CT) or MRI with scans including not only knee, but also hip and ankle. These are used to evaluate limb axes in frontal, coronal and sagittal plane and therefore even rotational deformities. Data acquired are uploaded and processed thanks to a specific CAD (Computer-Aided-Design) software, and then they are sent to the provider company (prosthesis supplier) for processing an accurate preoperative computer-assisted planning. *Planning* is based on the principles of mechanical or anatomical alignment on frontal plane in accordance with individual surgeon's philosophy (since there are no statistically significant differences in literature). Regarding femur external rotation and femoral and tibial slope, PSI reproduces patient's anatomy thanks to CT scans. This technique is the only one that requires an accurate and precise evaluation of these parameters. Surgeon has an active role in preoperative planning, approving or integrating default settings and sending data back to provider company through an interactive website. Once *planning* is approved, two virtual shapes are designed, one for femur and one for tibia, which are subsequently transformed by means of rapid prototyping technology into real cutting templates specific for each single patient. These guides are necessary to lead precise femoral and tibial resections to obtain the correct positioning of the prosthetic components.[5] PSI guides are used only once because they are specifically designed to adapt to each single patient's anatomy.

Another fundamental difference between the two prostheses is pivot positioning: traditional pivot rotates around a central axis while in prenavigated it is in a medial position allowing an increase of asymmetrical roll-back.

Overall, PSI technique shows numerous benefits compared to regular surgery, some proven and others theoretical: first of all it simplifies ancillary instruments (reducing number of guides and bulky tools) and surgical steps (measurement, alignment, cutting). Secondly it is less invasive because it does not require perforation of femoral medullary canal with intramedullary alignment guides (reducing the risks of bleeding, infection and gas embolism). It reduces surgical time, it improves matching between the femoral and tibial surfaces and it corrects severe extra-articular deformities. Furthermore, it improves accuracy of implant size and positioning (errors less than 3°) and it optimizes limb alignment attempting to better respect the physiological arthrokinematics of patient's knee in its pre-arthritic state.

Limits of this technique are mainly due to logistic, because of the delay of a few weeks from *planning* acceptance to cutting guides production and delivery. In long-term cost-effectiveness ratio (additional costs for imaging and production of customized guides) is expected to be beneficial. However, it is not yet clear whether the differences between the two surgical techniques also imply functional improvements and a faster rehabilitative recovery.

Based on the premises made, our study has to be considered on one hand as an efficacy comparison study between two surgical techniques, and on the other hand as a prospective comparative longitudinal study. Our main objective is to evaluate and compare short-term functional recovery of patients operated with prenavigated PSI compared to those operated with traditional technique using objective and subjective measurement scales. Furthermore, using *Gait Analysis* we aimed to identify whether knee behavior during walking is more similar to physiological movement in patients operated with one or the other surgical technique.

2. Materials and methods

2.1. Subjects

Patients were recruited from the operating list of Orthopedics and Traumatology ward of Asiago Hospital (Table 1).

2.2. Randomization

20 subjects were randomly extracted from the list using a simple randomization with dedicated software and following, in the same way, they were divided in two groups. 12 subjects were assigned in "PSI" group, 8 in "NexGen" control group. Therefore, it is a polycentric study not balanced in parallel.

3. Methods

Subjects were informed of risks and benefits of this study and they were conscious of the opportunity to withdraw at any time. In order to be involved, all patients signed hospital Informed Consent form. Hospital competent bodies authorized the study.

One group undergoes TKA with traditional technique (*NexGen Zimmer®*) and the other one with prenavigated techniques (*PSI eMP Microport®*) in Orthopedics and Traumatology ward of Asiago Hospital, ULSS 3. In both techniques, knee exposure was performed through traditional medial parapatellar access which requires medial incision and medial patellar arthrotomy. In both cases the cruciated ligaments are sacrificed;

tibial component is cemented, femoral component is not cemented and patella not resurfaced. Both prostheses use a UC (ultracongruent) polyethylene insert, without post-cam mechanism, in order to save femoral bone stock. Patients were not aware about which surgical procedures they underwent, undergoing a standardized rehabilitative treatment using times and methods in accordance with guidelines (protocol) of Asiago Hospital. During 18-day rehabilitation pathway, the same physiotherapist, unaware of which type of intervention was performed, followed both groups. Daily sessions take place in the gym, an hour and a half in the morning from Monday to Saturday. On Sunday, a passive mobilization is performed in the ward.

Short-term comparison of functional recovery, between patients operated with standard technique and those operated with prenavigated PSI technique, is valuated with evaluation forms given to patients: SF-36 and KSS pre-surgery (T0), 15 (T1) and 45 days after surgery (T2). At 15 and 45 days after surgery, edema of lower limb is assessed by circumferential measurement: femoral component landmark is set at 18 cm from the upper pole of patella, and tibial component landmark is at 15 from the lower pole of patella, in accordance with guidelines of the Italian Society of Physical Medicine and Rehabilitation (SIMFER). At Bassano Hospital *Gait Analysis* is performed 60 days after surgical procedure and leaving crutches, in order to evaluate space-time, kinematic

Table 1
Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Caucasian patients (male and female) with gonarthrosis	Presence of neurological pathologies
Age between 50 and 80 years	Patients with joint prosthesis elsewhere
Unilateral knee symptoms	Preoperatively non-ambulatory patients
Arthrosis ≥ grade III according to K&L classification	Bedridden patients
Axial deviations greater than 3°	Postoperative infection disease complications
BMI *(Body Mass Index)* between 18 and 35	
Mini Mental State Examination normal evaluation	

and kinetic parameters of walking. Again, examiners were not aware of which type of surgical procedure was performed. To compare outcomes between the two study groups (NexGen vs PSI eMP a statistical analysis is carried out.

After having analysed data available in literature[6] and having considered our study purposes, we decided to take into account the following parameters from *Gait Analysis:*

- Space-time parameters: frequence (steps/min), speed (m/s), step and half-step length (m), step and half-step execution time (s), duration of single and double foot support (% cycle step), moment of foot detachment from the ground (% cycle of the step), moment of contact and lift off of contralateral foot from the ground (% cycle of the step);
- Kinematic parameters: hip, knee, ankle and foot joint degrees on three planes of movement during the gait cycle (°);
- Kinetic parameters: *Ground Reaction Force* (N) and knee joint angular momentum (N·m/kg).

Acquired data are then compared with normal values taken from an analysis carried out in the same laboratory. This comparison seeks to obtain useful reference values for the interpretation of walking tests. Several studies[7] have confirmed that walking kinematics depends on the subject's speed and therefore is necessary to compare pathological path with curves and reference values of healthy subjects moving at similar speed.

3.1. Statistical analysis

Before comparing the PSI eMP group with the NexGen one, a descriptive analysis of the sample will first be carried out in order to evaluate homogeneity of the two groups. A parametric study is performed in order to compare outcomes of SF-36 evaluation form, Knee Society Clinical Rating System and of edema measurement. Therefore, "*t*-test" is used to verify equality of two groups comparing it with the different average values taken into account. A descriptive statistical analysis and a parametric analysis (*t*-test) for some kinematic and kinetic step components and for all space-time parameters are performed to compare the walking pattern of the two groups with the normal one. Since sample is composed of less than 30 subjects, the *t*-test is compared with t student distribution and p-value is computed to assess significance level.

4. Results

Analyzing the sample, the most of subjects are female and the average age is 69 years, slightly lower in NexGen group than in PSI eMP one, but this difference is not statistically significant ($p \geq 0.30$). The two groups are homogeneous for anthropometric characteristics (a p-value of 0.13 for height parameter and a p-value of 0.67 for body weight parameter). The average BMI of the sample is 27.69 (minimum 24.3-maximum 31). The average duration of surgical procedure with PSI eMP technique is 102.9 min while with NexGen one is 109.9 min (p-value 0.37). The majority of patients underwent surgery on the right knee (thirteen subjects) and had preoperative varus deformity of the limb (sixteen subjects).

Z test is used to compare improvement of limb alignment in two groups. Comparing proportion of patients with varus/valgus deviations between 0° and 15°, it is evident that the two groups are homogeneous before surgical procedure. Alignment improves significantly after both interventions, but much more in the pre-navigated technique group (z test equal to −4.14 with p-value of 0.001 in the PSI eMP group and z test equal to −2.51 with p-value of 0.01 in the NexGen group).

Considering results referred to individual items of Knee Society Score (Table 2), it is clear that both approaches are effective for pain parameter. There is no superiority of one over the other, but simply a difference in terms of timing: NexGen allows an earlier reduction in pain while PSI eMP requires more time. Regarding articular mobility parameter, *t*-test establishes the superiority of PSI eMP over NexGen, especially in the early post-op period. This gap is less evident, but still confirmed in T2.

Knee score subsection, consisting of pain, joint and stability parameters, shows instead that two methods are equally effective both in quantitative terms (results are statistically significant) and in qualitative terms: temporal trend is similar both in the first and in the second interval (see Table 2).

Score's functional component demonstrates meaningful value only for PSI eMP, showing superiority of PSI Evo over NexGen; it is also confirmed by unique analysis of measuring instrument, as seen in final part of Table 2.

As far as physical activity is concerned, in NexGen group the only significant improvement occurs between T0 and T2, while for PSI eMP group there is a significant improvement already fifteen days after surgical procedure (Table 3).

Regarding **physical pain**, at time T0 the two groups are not homogeneous: the PSI eMP group shows a higher score than the NexGen one (36.67 vs 27.14 points, p-value equal to 0.07). NexGen group seems to have a faster improvement than PSI eMP one, and this is due to the fact that already at time T1 it reports a score significantly different from score at T0. However, the improvement between T0 and T2 is very relevant in both groups and there is no significant difference between two groups at T2.

Regarding the perception of **general health conditions**, both groups improve from T0 to T2 (average score of the sample varies from 59.81 to 80.62 points) but NexGen group appears to have a greater improvement than PSI eMP one (p-value of 0.06), already found at T1 with p-value of 0.04.

As for **social activities**, both groups improve from T0 to T2 (the overall score varies from 49.94 to 82.75 points). However it can be noticed that for PSI eMP group both comparisons (T0 to T1 and T0 to T2) are meaningful, showing a greater recovery speed.

Another parameter in SF36 score analyzes **limitations due to emotional health**: no significant differences are observed between the two groups at either T0, T1 or T2. In patients operated with traditional

Table 2
Knee Society Score single/multiple item results.

Pain perception		
Comparison	T test	p-value
***NexGen: T0 vs T1**	−5,83	**0,0004**
***NexGen: T0 vs T2**	−9,31	**0,014**
***PSI eMP: T0 vs T1**	−2,1	**0,05**
***PSI eMP: T0 vs T2**	−7,25	**0,008**
Improvement from T1 to T2: PSI eMP vs NexGen	1,02	0,34
Articular mobility		
Comparison	T test	p-value
T2: PSI eMP vs NexGen	2,67	**0,01**
***NexGen: T0 vs T1**	0,54	0,6
***NexGen: T0 vs T2**	−0,22	0,82
***PSI eMP: T0 vs T1**	2,42	**0,02**
***PSI eMP: T0 vs T2**	0	1
Knee Score (KS)		
Comparison	T test	p-value
***NexGen: T0 vs T1**	−5,51	**0,0004**
***NexGen: T0 vs T2**	−9,57	**0,01**
***PSI eMP: T0 vs T1**	−1,78	**0,09**
***PSI eMP: T0 vs T2**	−7,31	**0,009**
Improvement from T1 to T2: PSI eMP vs NexGen	1,21	0,25
KS + FS		
Comparison	T test	p-value
***NexGen: T0 vs T1**	−0,6	0,56
***NexGen: T0 vs T2**	−4,59	**0,001**
***PSI eMP: T0 vs T1**	−0,8	0,43
***PSI eMP: T0 vs T2**	−6,71	**0,01**
****Improvement from T0 to T2: PSI eMP vs NexGen**	1,7	**0,09**

Table 3
SF-36 single item results.

General health conditions		
Comparison	T test	p-value
T2: PSI eMP vs NexGen	−2,01	**0,06**
***NexGen: T0 vs T1**	−4,12	**0,0014**
***NexGen: T0 vs T2**	−6,01	**0,0001**
***PSI eMP: T0 vs T1**	−1,51	0,14
***PSI eMP: T0 vs T2**	−1,99	**0,065**
Improvement from T0 to T1: PSI eMP vs NexGen	−2,23	**0,04**
Social activities		
Comparison	T test	p-value
***NexGen: T0 vs T1**	−1,67	0,12
***NexGen: T0 vs T2**	−3,78	**0,0028**
***PSI eMP: T0 vs T1**	−2,33	**0,03**
***PSI eMP: T0 vs T2**	−3,58	**0,002**
Emotional limitation		
Comparison	T test	p-value
***NexGen: T0 vs T2**	−2,48	**0,02**
***PSI eMP: T0 vs T2**	−0,67	0,51
Improvement from T0 a T2: PSI eMP vs NexGen	0,31	0,75
Mental health status		
Comparison	T test	p-value
NexGen: T0 vs T1*	−3,39	**0,007**
NexGen: T0 vs T2*	−4,11	**0,001**
Improvement from T0 to T2: PSI eMP vs NexGen	−0,12	0,9

technique there is a significant improvement between T0 and T2 (score varies from 23.71 to 76.14 points), not found in patients operated with pre-navigated PSI technique.

The last criterion of SF-36 score examines **mental health**: the only significant improvements are highlighted in NexGen group.

Considering changes in edema over time, *t*-test is computed to compare evolution between 15 and 45 days after surgery, and there are no significant differences between the two groups at thigh or at knee level of the operated limb.

Gait analysis highlights differences in several aspects. Both groups show substantial differences comparing to normal population in space-time parameters. As easily predictable: frequency, execution time, stance and double support duration are alterned in negative terms. There is no superiority in one or the other technique regarding these parameters. The only significant element is that in NexGen group the difference between the two half-steps is more evident, while in PSI Evo they are proportionally reduced (Table 4).

From a kinetic point of view, there is a clear reduction in maximum knee flexion and extension in both groups (see Fig. 1). Flexion is reduced in NexGen group, with a significant difference compared to PSI eMP one, while for the extension the exact opposite occurs. Red line represents PSI eMP trend, the green line shows trend of NexGen while the black line is for control group (Fig. 2)

Rotations in transverse plane are significantly reduced in NexGen group (Fig. 3).

Table 4
Average values of normalised step length parameter in NexGen Group, PSI eMP group and control group.

Normalised Step Length AVG VALUES	Normality	Lower Limb	NexGen	PSI eMP
	0,73	Operated	0,62	0,65
		Healthy	0,58	0,61
Confronti			*t*-test	p-value
Operated NexGen vs PSI eMP			−0,53	**0,6**
Operated NexGen vs Normality			−2,85	**0,078**
Operated NexGen vs Healthy			1,94	**0,07**
Operated PSI vs Normality			−1,57	0,15
Operated PSI vs Healthy			0,74	0,49
Healthy PSI vs Normality			−2,39	**0,04**
Healthy NexGen vs Normality			−3,79	**0,02**

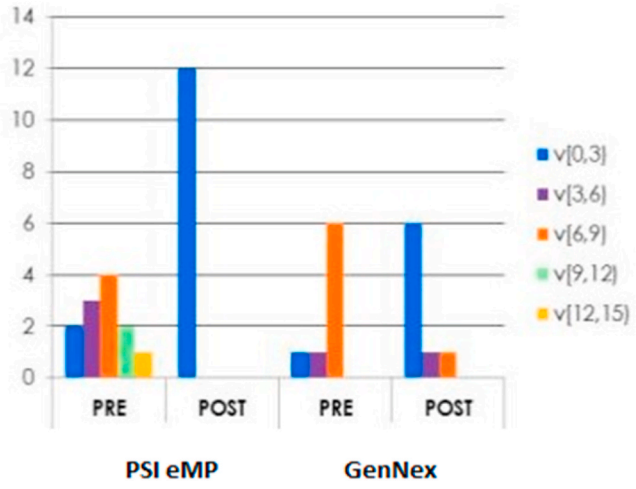

Fig. 1. Frequencies in X-ray: deformities of lower limb in PSI eMP and NexGen groups, pre-op and post-op.

The kinematic analysis highlights several aspects. In the beginning of step phase, there is a reduction of knee flexion momentum on sagittal plane for both techniques, but in NexGen group the reduction is statistically lower than in PSI eMP one. Moreover, it is notable the trend of forces in the mid-stance phase: flexor momentum increased in both techniques, but increase is higher in PSI eMP group (Fig. 4).

The mid-stance rotating momentum establishes the superiority of PSI eMP (Table 5, Fig. 5).

Regarding vertical (Fig. 6) and horizontal (Fig. 7) component of ground responses, we report a statistically significant reduction in both groups, even more accentuated in the group with traditional prosthesis.

5. Discussion

Pre-navigation in TKA is a quite recent surgical technique. For this reason, literature is rather sparse, while scientific production analyzing outcomes after TKA with gait analysis instrumentation is more substantial.

Our study presents innovative features in the analysis of PSI eMP's behavior and it confirms what other researchers had already discovered regarding traditional prostheses.

The use of PSI eMP is particularly effective for post-op frontal plane limb alignment: misalignment of most of the patients falls within the range of 0–3°. According to different studies, misalignment represents the main cause of failure in knee.[8]

From the comparison between scores of PSI eMP group and NexGen group within *American Knee Society Clinical Rating System*, a specific rating scale for knee, there was a benefit of both techniques in the reduction of pain, as well results analyzed with *KSS* didn't show a superiority of one surgical technique over the other. Even if there were no statistically significant differences between two groups 45 days after surgery, pain improvement occurred earlier in the NexGen group than in the PSI eMP one. This data is also confirmed by outcomes analysis of "physical pain" item in SF-36 scale (Table 3).

A significant difference was found in favor of pre-navigated PSI technique concerning the knee articular movement, which increased significantly already 15 days after surgery. The statistical analysis confirmed that 45 days after the surgery, patients' joint mobility operated with PSI technique is greater than the one of patients operated with traditional technique (Table 2).

Knee flexion is greater in pre-navigate technique also considering *Gait Analysis*: during limb oscillation phase (60–100%), the knee operated with NexGen flexes about ten degrees less than the contralateral (44.26° vs 54.09°) while in PSI eMP group the difference is minimal

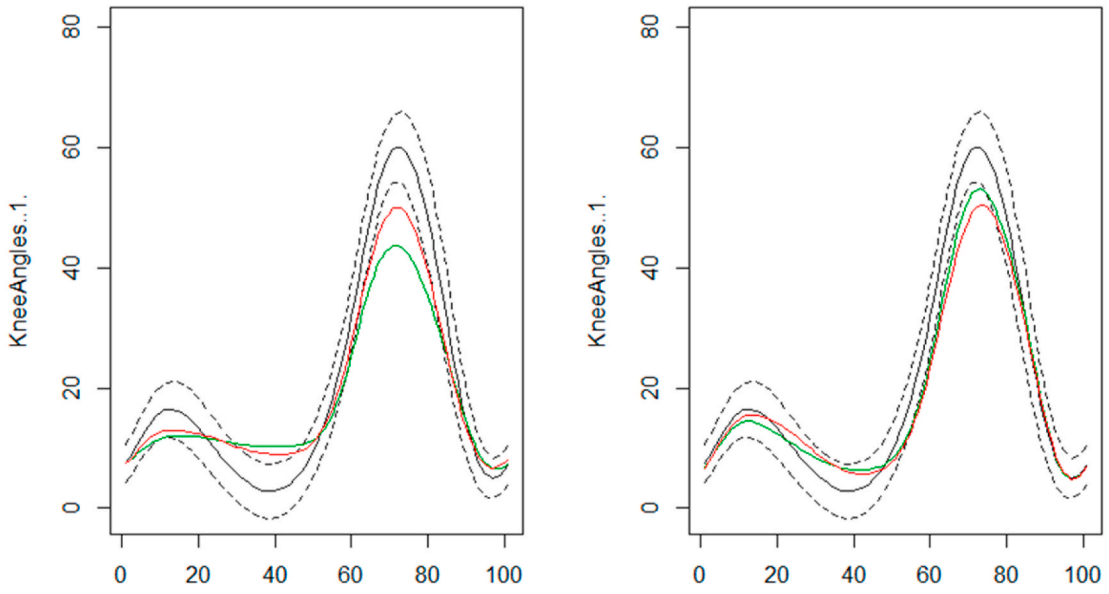

Fig. 2. Knee movement curve on the sagittal plane of NexGen group, PSI eMP group and Control group.

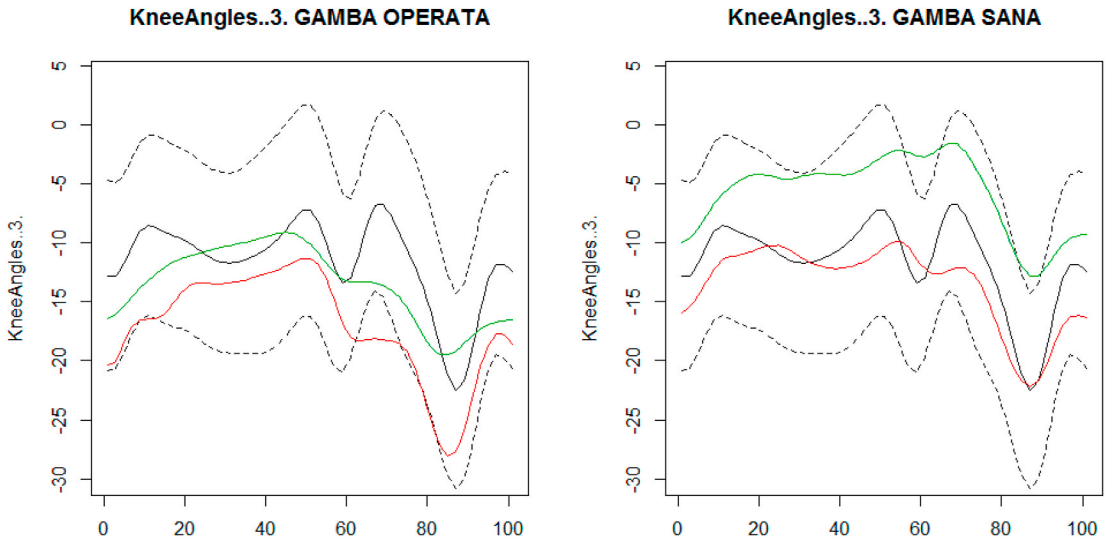

Fig. 3. Knee movement curve on the transverse plane of NexGen group, PSI eMP group and Control group.

(53.05° vs 54.48°), although it is less than maximum flexion of control group (61.35°). In literature several studies[9] confirm the reduction of post-operative maximum TKA knee flexion during limb swing.

This fact is also confirmed by a significant difference in vertical GRF dip between the healthy limb of NexGen group and the one of control group. The central dip of the vertical GRF is related to the ability of unloading force platform during the swing of the contralateral limb. Therefore, a significant reduction in dip seems to be consequence of a simultaneous greater difficulty in oscillating the operated limb for NexGen group, while this feature is not found in PSI eMP one.

Considering that there were no significant differences between the two groups in terms of edema at knee level, likewise for scar impact (medial pararotuleal surgical incision), a less joint mobility in NexGen group during oscillation of the operated limb could depends on greater knee stiffness or from less proprioception. On the contrary, greater knee mobility in PSI eMP group could depend on a greater congruence between the femoral and tibial surfaces and/or on the asymmetric roll back movement, which occurs beyond 45° of knee flexion.

Another important parameter for evaluating the effectiveness of TKA surgery is knee functionality[1]: a significant improvement of this item was found only in PSI eMP group. Considering overall the full evaluation scale KSS, 45 days after surgery PSI eMP patients improved significantly more than patients who underwent surgery with traditional technique (Table 2).

Comparison of the SF-36 scores shows a faster improvement in physical activity and in social activities in the PSI eMP group, although there are no significant differences between the two groups 45 days after surgery (Table 3). This early improvement of the knee could be associated with lower blood loss in PSI technique compared with conventional one, therefore there is a lower postoperative anemia. There is on the contrary a greater improvement in the perception of general health conditions in patients operated with the traditional technique, highlighted already 15 days after surgical procedure. This phenomenon is probably associated with the early improvement of pain, of mental health status and of role limitations due to emotional health. No significant differences were found in “vitality” and “role limitations due to physical health” parameters.

From *Gait Analysis* data: evaluation of space-time parameters shows

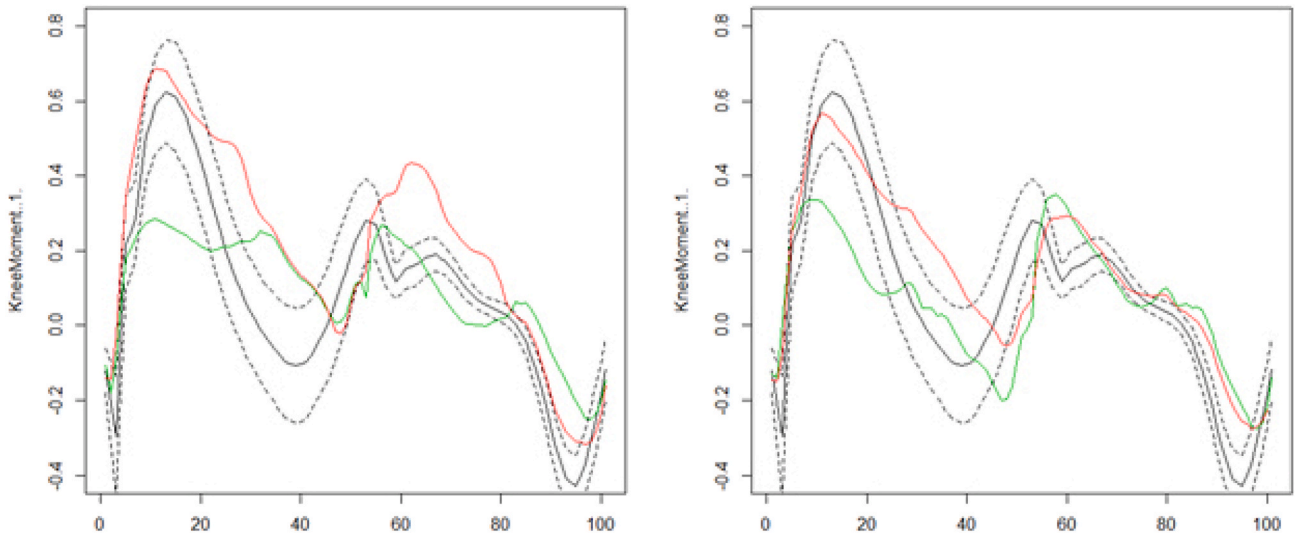

Fig. 4. Knee momentum curves on the sagittal plane of NexGen group, PSI eMP group and Control group.

Table 5
Average values of normalised maximum flexor and rotational knee momentum in NexGen Group, PSI eMP Group and Control Group.

Maximum Rotational Knee Momentum AVG VALUES	Control Group	Lower Limb	NexGen	PSI eMP
	0,22	Operated	0,15	0,18
		Healthy	0,19	0,21
Comparison			*t*-test	p-value
Operated PSI eMP vs Control Group			−0,97	0,35
Operated GenNex vs Control Group			−2,77	**0,02**

that knee osteoarthritis and subsequent surgery significantly alter the entire locomotor pattern of patients. Neverthless, no significant differences were found between NexGen group and PSI eMP one. According to Pethes,[10] a reduction in the variability of angular parameters leads to an increase in the variability of the space-time parameters in the first postoperative period. In particular, it can be observed in both groups an increase in walking cadence, a reduction in the step execution time, an extension of the stance phase and an increase in the double support time; these parameters are aimed at increasing stability while walking. The significant differences between healthy limb and operated one highlight the tendency in both groups to avoid load in the limb with prosthesis. The only difference identified between the two groups concerns the length of half-step, confirming the difficulty in the oscillatory phase, as previously reported (Table 4).

According to literature, it is highlighted that during load acceptance phase (0–15% of gait cycle) the operated knee of both groups flexes less than the knee of control group (16.68°), but no significant difference was found between PSI eMP group (16.15°) and NexGen one (12.55°). We confirm this data, but comparing knee flexion momentum during load acceptance (Fig. 4), there is a significant reduction in NexGen group compared to the control group, in both limbs. The alteration of this parameter after TKA is also highlighted by other studies[1,9], The reduction of knee flexion momentum indicates a lower eccentric contraction of quadriceps and it could depend on an analgesic attitude or on a lower strength developed by the muscle. Alternatively, this reduction could be likely related to arthrogenic muscle inhibition, in particular of the vastus medialis oblique (VMO), particularly active in the last degrees of knee extension and frequently post-surgery inhibited. In absence of adequate muscles absorption, it is assumed that the load impact transfers the weight directly from the femoral to the tibial prosthetic component with the consequent risk of predisposing prosthesis for earlier wear.

The graph of the vertical GRF (Fig. 6) and table IX show a significant

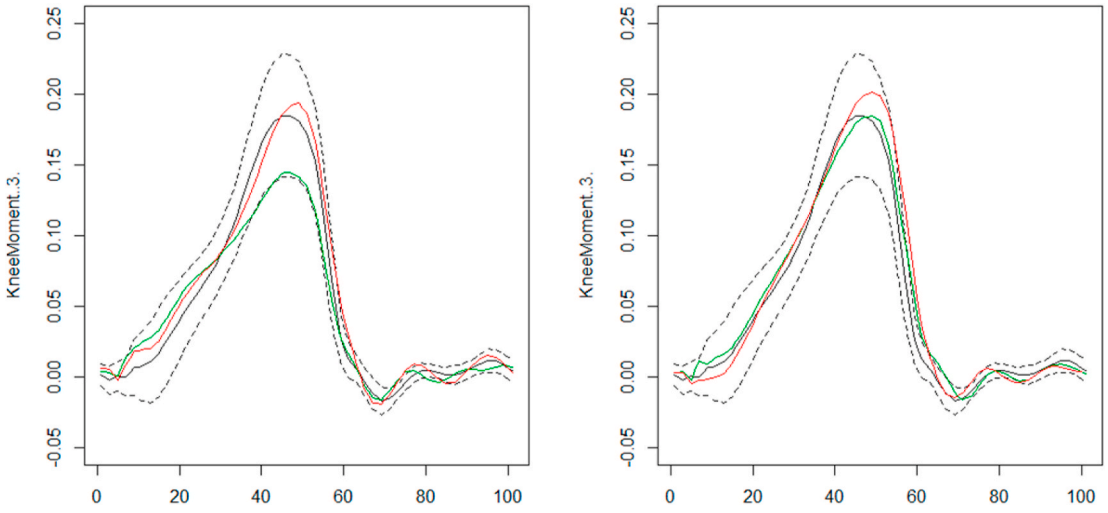

Fig. 5. Knee rotating momentum curves of NexGen group, PSI eMP group and Control group.

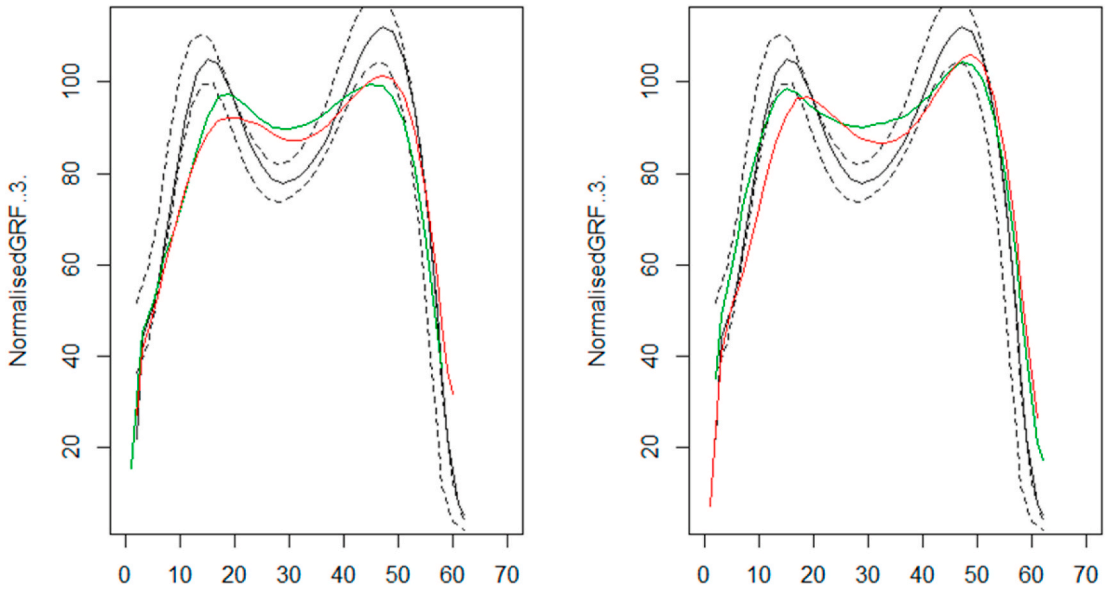

Fig. 6. Ground Reaction Force (vertical component) curves of NexGen group, PSI eMP group and Control group.

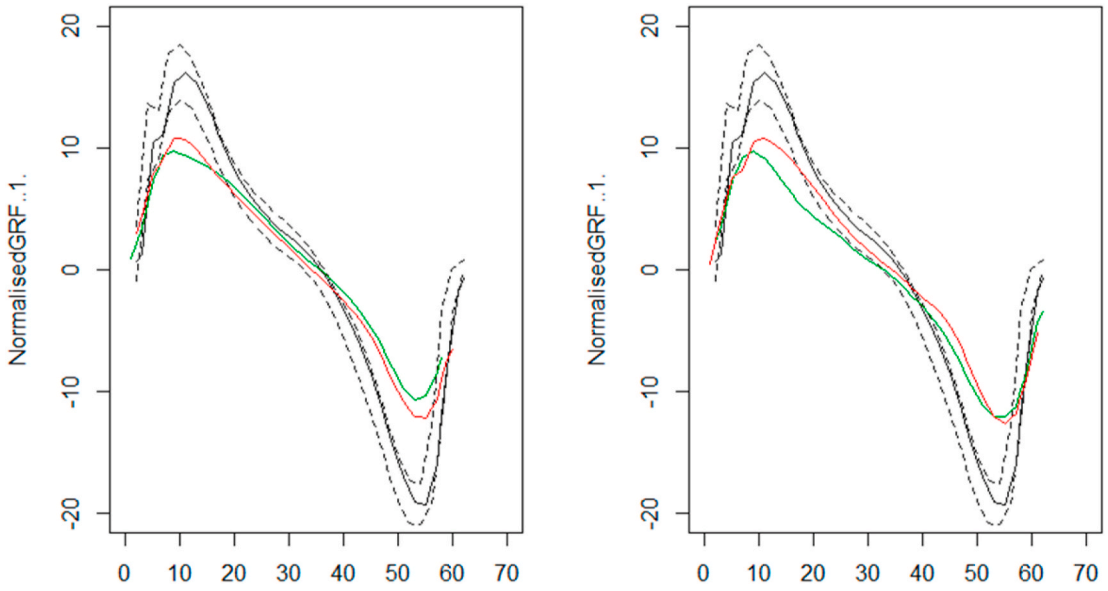

Fig. 7. Ground Reaction Force (anteroposterior component) curves of NexGen group, PSI eMP group and Control group.

reduction of the first peak in both groups compared to the control one and a significant difference between the two limbs only in the NexGen group. This information would indicate an asymmetrical pattern of the load capacity in front step, in accordance with the hypothesis of analgesic attitude or a less dynamic stabilization of the knee during this step cycle.

Analyzing the video recording of patients during load acceptance, in PSI eMP group the projection of the GRF vector passes behind the articular center of the knee generating an almost normal flexion momentum, while in NexGen group this vector passes near the articular center and it generates a reduction of the momentum. It seems that patients' strategy for reducing the contractile demand at the quadriceps level is to flex the trunk by moving anteriorly center of gravity and consequently reducing the lever arm, thus they assume a compensatory postural attitude (Fig. 8) (see Fig. 9).

A significant reduction in the maximum rotator moment was found between the prosthesis knee in the GenNex group and the healthy knee in the Control Group (Fig. 5, Table 5); this data is hypothesized to be due to a greater arthrogenic muscle inhibition in this group compared to PSI eMP group. The following factors could be fundamental for extending life of the prosthesis: a greater dynamic stabilization of the knee and a greater degree of total rotation on the transverse plane.

6. Conclusions

Most of the studies that used *Gait Analysis* to evaluate TKA post-surgery ambulatory functions were limited to investigate the kinetic and kinematic parameters on the sagittal plane. Few studies have investigated knee movements on the transverse plane, knee rotational momentum and Ground Reaction Force because the interpretation of these parameters is complex and further researches are needed to confirm the hypotheses developed by various authors[2,6,9]

Overall, considering the kinetic and kinematic parameters analyzed so far it seems that values and curves of PSI eMP group approximate

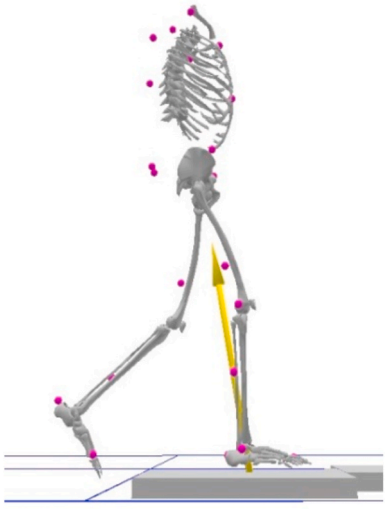

Fig. 8. Load acceptance in "PSI eMP" group.

more to those of the control group. This would indicate a faster recovery of the physiological path pattern in the PSI eMP group compared to NexGen one. Functional items too highlighted the superiority of pre-navigated PSI technique over traditional technique. Nevertheless, NexGen group seems to be superior in the reduction of pain in the first postoperative period and in subjective parameters.

The most influential limit of this study is the reduced sample size due to the complexity of the study itself. Furthermore, it was not possible to measure edema extension at T0 or few days after surgical procedure, nor to perform *Gait Analysis* before surgical procedure in order to evaluate the modification of gait pattern for each single patient. The choice of the "Plug-In Gait" marker set represents another critical element: this acquisition protocol, although being internationally recognized and used by many laboratories, lacks in precision in defining knee joint center and frontal plane of the corresponding body segment. We propose to develop and validate a new protocol to improve accuracy of this measurement, using a greater number of markers to separately calculate the rotation center of the tibial and femoral components. In addition, markers positioning can be influenced by the body mass index and skin trophism. In order to reduce errors inherent in gait biomechanical analysis, markers positioning and detection of anthropometric parameters were carried out always by the same technician for all subjects involved in this study.

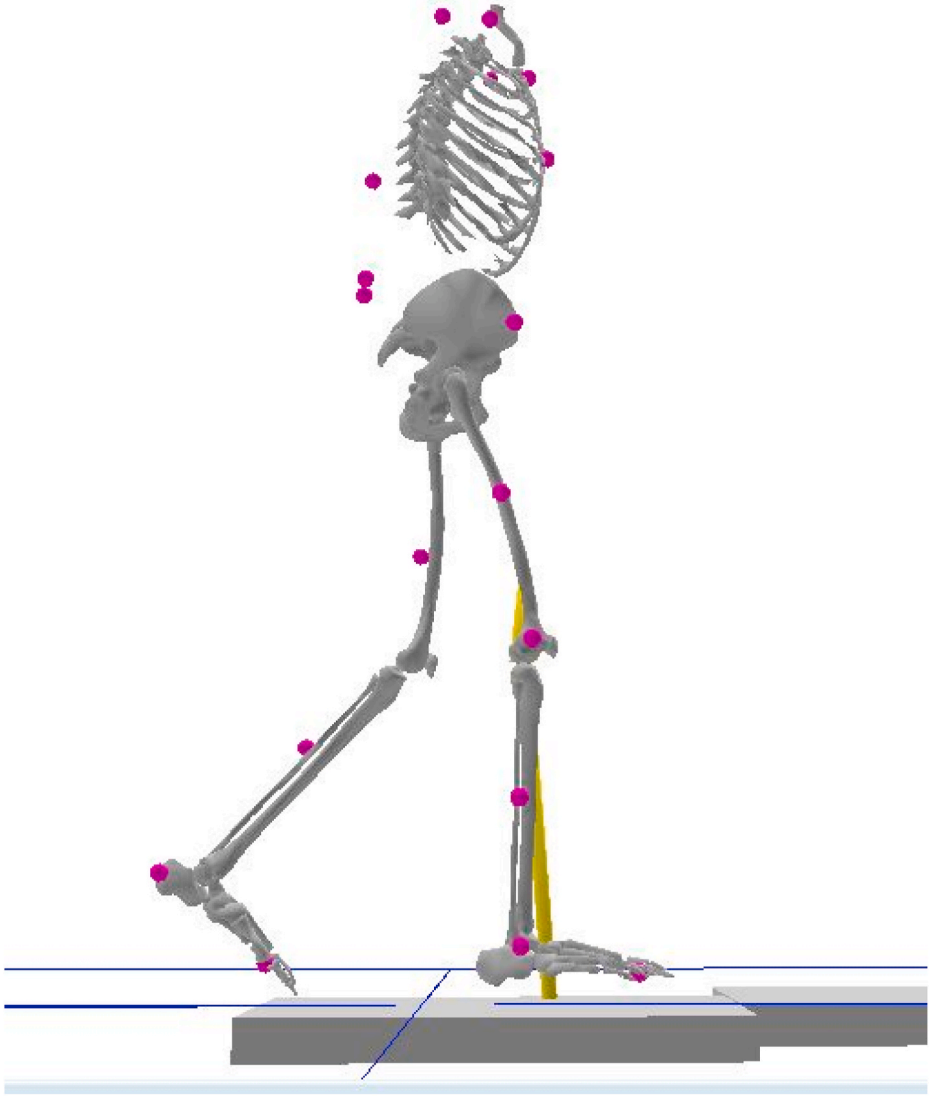

Fig. 9. Load acceptance group in "NexGen" group.

Funding resources

"This research did not receive any specific grant from funding agencies in the public, commercial, or not for profit sectors".

CRediT authorship contribution statement

Sergio Rigoni: Conceptualization, Investigation, Project administration. **Martina Dalla Libera:** writing, Data curation. **Diego Pigatto:** Formal analysis, Resources. **Davide Conte:** Methodology, Software, Validation. **Alessandro Ceccato:** Formal analysis, Resources. **Cesare Chemello:** Conceptualization, Investigation.

Declaration of competing interest

No conflicts of interests are present.

References

1 Sosdian L, Dobson F, Wrigley TV, et al. Longitudinal changes in knee kinematics and moments following knee arthroplasty: a systematic review. *Knee*. 2014;21:994–1008.
2 Insall JN, Dorr LD, Scott RD, Scott WN. Rationale of the knee society clinical rating system. *Clin Orthop Relat Res*. 1989;248:13–14.
3 Lotke PA, Ecker ML. Influence of positioning of prosthesis in total knee replacement. *J Bone Joint Surg Am*. 1977;59(1):77–79.
4 Wegryzyn J, Parratte S, Coleman-Wood K, Kaufman KR, Pagnano MW. No benefit of minimally invasive TKA on gait and strenght outcomes. A Randomized Controlled Trial. *Clin Orthop Relat Res*. 2013;471, 46-5.
5 Slamin J, Parsley B. Evolution of customization design for total knee arthroplasty. *Curr Rev Musculoskelet Med*. 2012;5:290–295.
6 McClelland JA, Webster KE, Feller JA. Gait analysis of patients following total knee replacement: a systematic review. *Knee*. 2007;14:253–263.
7 Schwartz MH, Rozumalski A, Trost JP. The effect of walking speed on the gait of typically developing children. *J Biomech*. 2008;41:1639–1650.
8 Bargren JH, Blaha JD, Freeman MA. Alignment in total knee arthroplasty. Correlated biomechanical and clinical observations. *Clin Orthop Relat Res*. 1983;173:178–183.
9 Milner CE. Is gait normal after total knee arthroplasty? Systematic review of the literature. *J Orthop Sci*. 2009;14:114–120.
10 Pethes A, Kiss RM, Szendröi M. Variability of gait in the early postoperative period of total knee arthroplasty with different surgical technique. *Int Orthop*. 2014;38:517–523.