Article

Comparison of biomechanical gait parameters in patients after total knee arthroplasty with use of fixed-bearing medial-pivot and multi-radius design implants - randomized controlled trial

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Abstract:

Background:

Total knee arthroplasty (TKA) is considered as the most effective treatment of end-stage osteoarthritis and growing in popularity during the last years. Unfortunately a relatively high rate of unsatisfied patients is observed. Looking for the reason for that, there is an ongoing debate over the best implants design. Since introduction of total knee arthroplasty, two types of implants were designed: first with posterior stabilization (PS) sacrificing posterior cruciate ligament (PCL) and second cruciate retaining (CR). They have become two most popular nowadays. The aim of this study was to compare the clinical and functional outcomes and gait pattern following TKA with use of fixed-bearing medial-pivot (Dynamic Congruence-DC) and multi-radius design implants (PS) and compare them to the healthy subjects.

Materials:

56 consecutive patients who were qualified by a single surgeon to undergo total knee arthroplasty were involved in the study. All of them were operated in a single clinical orthopedic department by a single high-volume surgeon. All cases were primary end-stage knee osteoarthritis. 28 of them were randomly assigned to receive posterior-stabilized multi-radius implant and 28 to receive fixed-bearing medial pivot dynamic-congruence one. Every patient received rehabilitation followed by the same protocol. The patients were reviewed at six weeks, six months, one year, and three years post-operatively with routine clinical assessment. Radiographs were undertaken immediately post-operatively and at one year. Patients fulfilled WOMAC (Western Ontario and McMaster University) questionnaires preoperatively and during follow-up visits in the Biomechanical Lab at least one year after TKA. After the surgery 1 to 3 years postoperatively three-dimensional gait analysis was performed. Statistical analysis of results for both operated and healthy limb was performed. All comparisons were performed between continuous variables in unpaired groups.

Results:

Objective outcomes did not differ significantly between groups with DC and PS implants. When compared with norms for healthy knees, both in DC and PS groups the only outcomes to differ significantly from norms were length of step length both in operated. As to subjective outcomes, the only significant difference between DC and PS group was the Stiffness part of WOMAC score.

There were no significant differences in WOMAC score as a whole, Pain part of WOMAC score and Everyday Activities part of WOMAC score.

Conclusions:

To our best knowledge this is the first study to assess and compare lower limb biomechanics and gait pattern between patients undergoing total knee arthroplasty with use of fixed-bearing medial-pivot and multi-radius design implants. Results of this study show that there were no statistical differences between both types of implants and even though there was significant improvement in patient-reported outcome and gait pattern, those parameters still differ significantly in comparison to healthy volunteers. The problem with dissatisfaction after operative treatment may not lay in the procedure itself, but many different factors may contribute to it. Next studies comparing other designs of implants, as well as proper rehabilitation protocol should be performed

Keywords: knee; osteoarthritis; biomechanics

1. Introduction

Total knee arthroplasty (TKA) is considered as the most effective treatment of end-stage osteoarthritis. [1, 2] According to The National Joint Registry (NJR), 90 000 TKA surgeries are performed annually in England, Wales and Northern Ireland. Moreover, each year in the United States only, more than 700 000 such procedures are done. [3, 4] Even though those huge numbers should indicate high satisfaction among patients, about 20% of them are still unsatisfied with the outcome of the surgery while the average satisfaction rate reaches 93%. [5, 6, 7] Looking for the reason for such differences there is an ongoing debate over the best implants design, its positioning, surgical technique, alignment perioperative care, etc. [8-11] Kinematic studies show that a healthy knee is essentially a ball and socket type joint, with a more mobile lateral compartment. [12, 13, 14] Due to that fact the TKA concept of more congruent and less mobile medial compartment is considered as more anatomical and physiological and is gaining popularity nowadays.

Since introduction of total knee arthroplasty, two types of implants were designed: first with posterior stabilization (PS) sacrificing posterior cruciate ligament (PCL) and second cruciate retaining (CR). They have become two most popular nowadays. [15, 16] It was proved that PS designs achieve stability during flexion by stopping the posterior translation of the tibia with „post and cam" mechanism. It results in a non-natural anterior shift of the tibia by preventing the posterior translation of the tibia on the femur, thanks to a post and cam, allowing a non-natural anterior shift of the tibia known as "paradoxical movement". [17]

The design of medial pivot TKA with cruciate retaining technique was aimed to restore native knee kinematic by avoiding any paradoxical movement. It was believed that thanks to such design patients will have not only better functional results, but also better gait pattern and lower risk of polyethylene wear. In several systematic reviews and meta-analysis [18, 19] no superiority of any design was proved, however in systematic review by Longo et al. [18] some significant differences were observed in range of movement favorable for PS design. So far, there is a limited number of randomized-controlled studies analyzing gait pattern following total knee arthroplasty with different prosthesis designs.

It is well proved that the gait following TKA hardly comes back to normal. It is estimated that only one third of patients show biphasic pattern of sagittal plane moments which is considered as physiological. [20] To our best knowledge there was only one study analyzing gait pattern following TKA with use of medial pivot design in comparison to single radius design. [21] 45 patients were randomized and no statistically significant differences were found by researchers in terms of functional outcome and gait parameters with a little favorable results for the single radius design group.

The aim of this study was to assess potential differences in gait patterns following TKA with use of either fixed-bearing medial-pivot (MP) design or posterior-stabilized multi-radius design 1-3 years after the surgery. Our hypothesis is that, even though patient-reported outcomes might be not different, gait pattern might be more similar to the healthy native one with use of medial-pivot design.

2. Materials and Methods

This study was conducted according to the Consolidated Standards Of Reporting Trials (CONSORT) and an appropriate checklist was presented to the editors of the Journal. [22] CONSORT flowchart is depicted in the Figure 1. Study protocol was designed as a prospective, blinded, parallel-group, superiority trial, with balanced randomization [1:1]. This study was registered on ClinicalTrials (Registration number: NCT04524312). Institutional Ethics Committee approval was obtained and every participant signed written consent to participate.

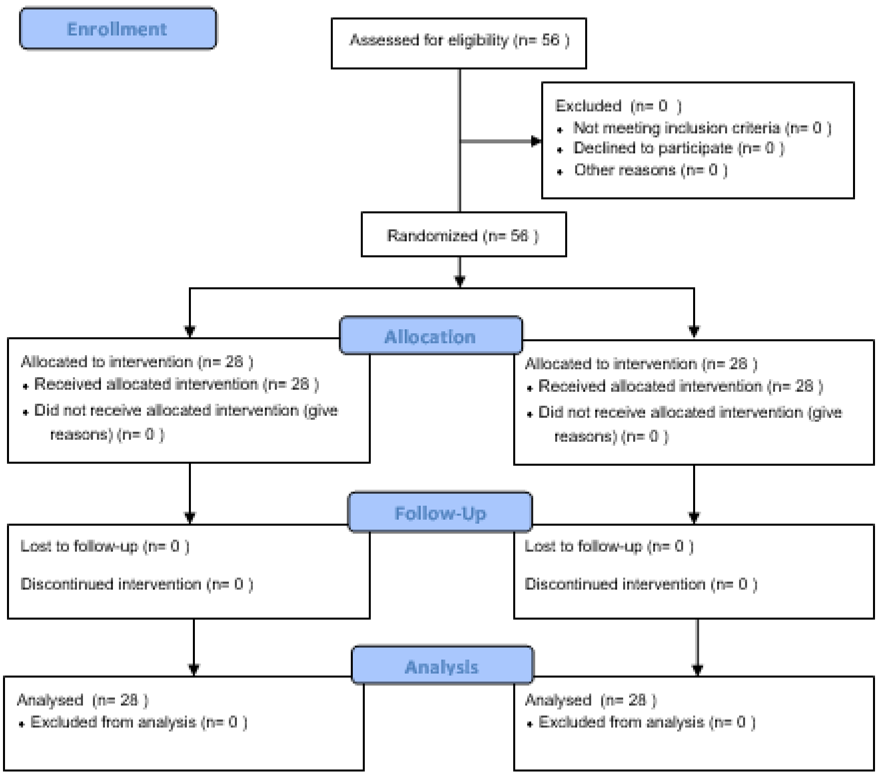

Figure 1. CONSORT flowchart

To this study 56 consecutive patients who were qualified by a single surgeon (AS) to undergo total knee arthroplasty were recruited. All cases were primary end-stage knee osteoarthritis. 28 of them were randomly assigned to receive posterior-stabilized multi-radius implant (Nexgen, Zimmer Biomet, Warsaw, IN, USA): PS group and 28 to receive fixed-bearing medial pivot dynamic-congruence one (K-Mod, Biomplanti, Italy): DC group. Mean age of all participants was 69,9 years (52-80). No baseline characteristics differences were found between groups. (Table 1)

Participants characteristics

	PS group	DC group	p-value
BMI (body mass index - kg/m2)	31.97 (SD=5.17)	32.76 (SD=5.07)	> 0.05
Age (years)	68.0 (SD=6.5)	71.0 (SD=5.0)	> 0.05
male:female	21:7	19:9	>0.05
right:left	17:10	17:10	>0.05

Table 1. – baseline characteristic of participants

All patients were operated through standard anterior parapatellar approach with patella lateral dislocation. No patellar resurfacing was performed in all cases. All surgeries were performed with use of tourniquet and postoperative closed seduction drainage left for at least 12 hours. All operations were performed by the senior author (AS), who is a highly trained total joint replacement surgeon and performed more than 3000 of such surgeries in professional career. All surgeries were performed using a standard midline incision and medial parapatellar arthrotomy. Cruciate sacrificing implants were used and tibial cuts were done first using extramedullary alignment jigs. These were made perpendicular to the long axis of the tibia with a posterior slope of between 0° and 7°. The femur was prepared using intramedullary alignment with a valgus angle of between 5° and 7° and external rotation of 3°.

Femoral bone cuts were made in the sequence as recommended by the surgical protocol of the K-MOD knee system and NexGen LPS system. After removal of posterior and peripheral osteophytes, soft-tissue balance was assessed using the Tibial insert trial. Flexion and extension gaps were balanced. No patella resurfacing was performed. All components were implanted using cement. The post-operative protocol included chemical and mechanical thromboprophylaxis unless specifically contraindicated. All patients received one dose of parenteral antibiotics at the induction of anaesthesia and two further doses post-operatively. Flexion and extension exercises of the ankle and isometric quadriceps contraction exercises were started on the first post-operative day, with full weight-bearing as tolerated. The aim of mobilisation with a physiotherapist was to obtain flexion of the knee of 90° mobilising with a walker and walking with crutches by the third post-operative day.

The patients were reviewed at six weeks, six months, one year, and three years post-operatively with routine clinical assessment. Radiographs were undertaken immediately post-operatively and at one year.

Patients fulfilled WOMAC questionnaire preoperatively and during follow-up visits in the Biomechanical Lab at least one year after TKA, when they felt that their rehabilitation protocol is fulfilled and function of their knee is the best possible. Inclusion and exclusion criteria are depicted in Table 2.

Inclusion criteria	**Exclusion criteria**
Knee flexion angle > 90 °	Unwillingness to participate
BMI <40	Revision surgeries before and after TKR
Ability to walk for 10 meters	Any other lower limbs surgeries
60-80 years of age	Secondary OA
Leg discrepancy < 5mm	Neurological disorders
Hip extension angle < 0°	Cardiac disorders
Hip flexion angle > 90°	Severely impaired balance
No residual pain associated with the surgery	Severe dizziness

Table 2. Inclusion and exclusion criteria

After the surgery 1 to 3 years postoperatively three-dimensional gait analysis were performed with use of BTS SMART device (BTS Bioengineering, Quincy, MA, USA). At least one year time was chosen as authors of this manuscript assumed that proper rehabilitation protocol improves function of the operated knee after such a period of time. This device uses passive markers technology and registers the movement by six cameras. To perform full gait analysis several data concerning patients anthropometry were collected (lower limb length, knee and ankle joint width, width and depth of the pelvis). All measurements and analysis were performed according to the Davis protocol. [23]

Participants were asked to walk for 10 meter distance in their normal tempo four times. During walking their movement was recorded with use of markers placed on the base of the sacral bone, both anterior superior iliac spines, both greater trochanters, both lateral sides of the femur (half distance between greater trochanter and lateral femoral condyle), both sides on the fibular head, both lateral sides of the shin (half distance between head of the fibula and lateral malleolus), both bases of 5th metatarsal bone and calcaneal tuberosity.

Immediately before measurements every participant was asked to walk through a marked route as many times as they wanted to feel fully comfortable with markers to minimize potential influence on their lower limb biomechanics. Analyzed parameters were divided into spatio-temporal and kinematic ones (Table 3). The Assessor was not aware of the type of implants used in every participant.

Spatio-temporal parameters	**Kinematic parameters**
• time of swing phase [%] • time of stance phase [%] • time of double-stance phase [%] • step length [m] • cadence [number of strides per minute] • mean gait velocity [m/s]	• Range of pelvic drop in frontal plane on the opposite site of the bearing limb [°]

Table 3. Spatio-temporal and kinematic parameters analyzed in the study

Statistical analysis of results for both operated and healthy limb was performed. All comparisons were performed between continuous variables in unpaired groups. Therefore, according to the normality of distribution, either t-student test for unpaired groups or U Mann-Whitney test were used. Distribution normality was examined using Shapiro-Wilk test. Significance level was set at p value below 0.05.

3. Results

Objective outcomes did not differ significantly between groups with K-MOD and NexGen implants. Time of the single-stance phase in the operated limb was 66.3% vs. 64.1%, accordingly, p=0.123 and in healthy limb it was 65.8% vs. 64.0%, p=0.213. Time of swing phase in the operated limb was 33.7% vs. 35.9%, p=0.178 and in the healthy limb it was 34.2% vs. 36.0%, p=0.245. double-stance time was 15.3% vs. 16.4%, p=0.098. Step length in the operated limb was 0.43m vs. 0.5m, p=0.087 and in the healthy limb it was 0.54m vs. 0.6m, p=0.12. Mean gait velocity was 0.62 m/s vs. 0.7 m/s, p=0.111. Walking cadence was 85.4 steps/minute vs. 87.3 steps/minute, p=0.115. (Table 4)

	DC	PS	p

single stance phase [%]	OL	66.3	64.1	0.123
	HL	65.8	64.0	0.213
swing phase [%]	OL	33.7	35.9	0.178
	HL	34.2	36.0	0.245
step length [m]	OL	0.43	0.50	0.087
	HL	0.54	0.60	0.120
double stance phase [%]		15.3	16.4	0.098
mean gait velocity [m/s]		0.62	0.70	0.111
walking cadence [steps/minute]		85.4	87.3	0.115

Table 4. Gait characteristics. OL – operated limb, HL – healthy limb.

When compared with norms for healthy knees, both in DC and PS groups the only outcomes to differ significantly from norms were length of step length both in operated (norm=0.73m vs. DC=0.43m, p=0.012; vs. PS=0.5m, p=0.02) and healthy limb (norm=0.73m vs. DC=0.54m, p=0.021; vs. PS=0.6m, p=0.019), mean gait velocity (norm=1.39 m/s vs. DC=0.62 m/s, p=0.008; vs. PS=0.7 m/s, p= 0.007) and walking cadence (norm=113.8 steps/minute vs. DC=85.4 steps/minute, p=0.01; vs. PS=87.3 steps/minute, p=0.003).

There were no statistically significant differences between norms for healthy knees and both DC and PS groups for the following outcomes: time of single stance phase in operated limb (norm=61.0% vs. DC=66.3%, p=0.076; vs. PS=64.1%, p=0.08); time of single stance phase in healthy limb (norm=61.0% vs. DC=65.8%, p=0.069; vs. PS=64.0%, p=0.078); time of swing phase in operated limb (norm=39.0% vs. DC=33.7%, p=0.059; vs. PS=35.9%, p=0.068); time of swing phase in healthy limb (norm=39.0% vs. DC=34.2%, p=0.075; vs. PS=36.0%, p=0.063); double-stance time (norm=13.0% vs. DC=15.3%, p=0.55; vs. PS=16.4%, p=0.071.) (Table 5)

		norm	DC	norm vs. DC p-value	PS	norm vs. PS p-value
step length [m]		0.73	0.43	**0.012**	0.5	**0.020**
mean gait velocity [m/s]		1.36	0.62	**0.008**	0.7	**0.007**
walking cadence [steps/minute]		113.8	85.4	**0.010**	87.3	**0.003**
double stance phase [%]		13.0	15.4	0.550	16.4	0.071
single stance phase [%]	OL	61.0	66.3	0.076	64.1	0.080
	HL		65.8	0.069	64.0	0.078
swing phase [%]	OL	39	33.7	0.059	35.9	0.068
	HL		34.2	0.075	36.0	0.063

Table 5. OL – operated limb, HL – healthy limb.

As to subjective outcomes, the only significant difference between DC and PS group was the Stiffness part of WOMAC score (3.0 vs. 1.133, p=0.049). There were no significant differences in WOMAC score as a whole (29.33 vs. 24.6, p=0.59), Pain part of WOMAC score (3.73 vs. 3.467, p=0.967) and Everyday Activities part of WOMAC score (22.6 vs. 19.6, p=0.59). (Table 6)

WOMAC	DC	PS	P
total	29.33	24.6	0.59
function	22.6	19.6	0.59
pain	3.73	3.467	0.967
stiffness	3.0	1.133	**0.049**

Table 6. WOMAC subscales results

4. Discussion

The aim of this study was to compare the clinical and functional outcomes and gait pattern following TKA with use of fixed-bearing medial-pivot and multi-radius design implants and compare them to the healthy subjects.

There was a study reporting excellent patient-reported outcomes following TKA with use of the same DC design implants. [24] Authors have followed almost 300 patients for 5 years with 98,2% survivorship of the implants. However in this particular study no comparison to other implants design was performed what makes the study less reliable. Results of our study show similar great outcomes of use of this prosthesis, even though follow-up and number of participants was much shorter.

Summarily, none of the outcomes of gait pattern analysis in DC group differed significantly from PS group. To our best knowledge there was only one study analyzing gait patterns between these two types of implants designs. Benjamin et al. compared single radius and medial pivot designs the same as in this study in terms of functional results and patient-reported outcome in the group of 90 patients. There were no statistically significant differences in any analyzed parameters, such as KSS (Knee Society Score), OKS (Oxford Knee Score) and cadence, walking speed, stride length and stance time, peak stride, mid support and push-off forces. However in this particular study all patients underwent TKA surgery with patellar resurfacing. That might contribute to overall results and may be the reason for such outcomes.

So far, only a few studies comparing medial-pivot knee design with posterior-stabilized implants. [25-28] In the study by Vikas Kulshrestha et al. authors followed for 2 years 80 patients randomly allocated to receive medial-pivot design total knee implant ADVANCE MP Knee System in comparison to NexGen LPS. There were no statistically significant differences in terms of FJS (Forgotten Joint Score) and KSS. However patients with PS implant had significantly better postoperative ROM. In this particular study significant differences were found in terms of many biomechanical parameters such as timed up and go, stair climb test, self-paced walk test favoring medial-pivot design. Those results might indicate that MP design restores more native knee biomechanics, sacrificing postoperative knee flexion. Observations from this study only partially correspond to our results. As authors stated the mean degree of deformity was lower in the MP group, but the difference was not statistically significant ($p < 0.068$). When it comes to the severity of deformity in the PS group, 13 (32.5%) had mild, 10 (25%) had moderate, and 17 (42.5%) had severe deformity, whereas in the MP group, 20 (50%) had mild, seven (17.5%) had moderate, and 13 (32.5%) had severe deformity, and difference between two groups was not significant ($p = 0.280$). Such differences, even though they were not significant, might have influenced the results of this study.

When comparing both these groups to the healthy knees, the same variables differed from norms both in DC and PS group. Therefore, it may be concluded that dynamic congruence TKA yields spatio-temporal characteristics non-inferior to the better known posterior stabilized TKA. On the other hand, the fact that significant difference was found in the stiffness part of WOMAC subscale might indicate that dynamic congruence might have inferior influence on knee biomechanics and lowering patients reported outcome following the surgery.

5. Conclusions

To our best knowledge this is the first study to assess and compare lower limb biomechanics and gait pattern between patients undergoing total knee arthroplasty with use of fixed-bearing medial-pivot and multi-radius design implants. Results of this study show that there were no statistical differences between both types of implants and even though there was significant improvement in patient-reported outcome and gait pattern, those parameters still differ significantly in comparison to healthy volunteers. So far there are no scientific proofs for superiority of fixed-bearing medial-pivot over multi-radius design implants and vice versa. The choice of implant types should be done by a well experienced surgeon, based on many variables. All of them should be taken into account, so as to give satisfactory results in as many cases as possible. Although 20% of patients are unsatisfied after TKA, the problem may not lay in the procedure itself but many different factors may contribute to it. We believe that to perform a surgery with satisfactory results the key is proper qualification, then implant choice and surgical technique and after all good postoperative care including rehabilitation. Even the best implant could not give a satisfactory result when one of the things mentioned above were not considered.

Next studies comparing other designs of implants, as well as proper rehabilitation protocol should be performed to improve outcome of the surgery, patients satisfaction and gait more similar to the pre-osteoarthritic level. Further research concentrating on improving or developing new designs of total knee implants must be undertaken to get closer to the native knee biomechanics. Total knee arthroplasty nowadays still does not remind anything close as the tire change in the car, but rather implanting a run-on tire.

Author Contributions:

Conceptualization, Artur Stolarczyk, Magda Stolarczyk, Bartosz M. Maciąg and Igor Jarzemski; Data curation, Marcin Mostowy and Kuba Radzimowski; Formal analysis, Kuba Radzimowski and Maciej Świercz; Investigation, Artur Stolarczyk, Magda Stolarczyk, Bartosz M. Maciąg and Piotr Stępiński; Methodology, Artur Stolarczyk, Magda Stolarczyk, Bartosz M. Maciąg and Igor Jarzemski; Project administration, Artur Stolarczyk, Bartosz M. Maciąg and Grzegorz Maciąg; Resources, Magda Stolarczyk, Igor Jarzemski and Marcin Łapiński; Supervision, Magda Stolarczyk; Validation, Igor Jarzemski, Grzegorz Maciąg, Piotr Stępiński, Jakub Szymczak, Maciej Świercz and Krystian Żarnovsky; Visualization, Jakub Szymczak and Maciej Świercz; Writing – original draft, Artur Stolarczyk, Bartosz M. Maciąg and Piotr Stępiński; Writing – review & editing, Artur Stolarczyk, Bartosz M. Maciąg, Grzegorz Maciąg, Piotr Stępiński and Krystian Żarnovsky

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