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ORIGINAL PAPER

Gender-specific outcome after implantation of low-contact-stress mobile-bearing total knee arthroplasty with a minimum follow-up of ten years

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Abstract
Purpose The study aim was an analysis of gender-specific outcome differences after implantation of the low-contact-stress (LCS) mobile-bearing total knee arthroplasty (TKA) with a minimum follow-up of ten years.
Methods We retrospectively analysed 138 prostheses in 108 patients (82 women and 26 men) using our hospital database and a minimum follow-up of ten years (mean 14, range 11–23). Data was extracted with respect to quality of life, clinical outcome parameters [range of motion (ROM), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, visual analogue scale (VAS), Knee Society Score (KSS), and complications.
Results At follow-up, we observed no statistically significant differences in all outcome parameters between female and male patients after LCS TKA, except for VAS score, which revealed no clinical relevance due to the low difference (1.53 vs 1.03, p=0.043).
Conclusions Ten years after implantation of the LCS TKA, gender did not influence its beneficial outcome.

Keywords Total knee arthroplasty · Gender differences · Outcome analysis

Norbert Kastner and Birgit A. Aigner contributed equally to this work as the first authors.

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Introduction

Individual solutions for individual patients have become a very interesting and much discussed topic in the field of total knee arthroplasty (TKA), leading to the development of gender-specific implants in recent years [1]. This evolution is further nurtured by patient-specific instruments, which might aid in orientation by using magnetic resonance imaging (MRI) or computed tomography (CT) scan prior to surgery, or by implants with greater size variations respecting the width of femoral condyles [2, 3]. However, there is a lack of evidence that those more individual solutions are really necessary and are not just industry driven by a product. Finally, new treatment options must yet prove their superiority over old gold standard variants, a fact often misunderstood and mislead by industry, which often claims that old, gold standard implants have to prove superiority compared with new models. Beyond individuality, the factor of gender is an important issue for our patients and raised concerns regarding TKA [4]. Whereas previous study groups demonstrate anatomical differences between female and male knee joints, our own results did not indicate necessity of a gender-specific device [5–12].

A TKA system considered as a gold standard for decades is the low-contact-stress (LCS) mobile-bearing total knee prosthesis (Johnson & Johnson, New Brunswick, NJ, USA; previously DePuy, Warsaw, IN, USA), which was designed to provide excellent functional results at long-term follow-up in both female and male patients [13–16]. It therefore provides the ideal setting in which to test any hypothesis for individual solutions for individual patients, such as differentiation between men and women.

The aim of this study was therefore to analyse gender-specific outcome differences after implantation

of LCS TKA with a minimum follow-up of ten years. The hypothesis was that the outcome differs between female and male patients with respect to quality of life (QoL), clinical outcome parameters and complications.

Patients and methods

Study design and recruitment

The authors present a retrospective level III cohort study. We searched our hospital database for patients having undergone implantation of an LCS TKA with a minimum follow-up of ten years. After exclusion of 231 patients who had already died, 108 patients were invited to our clinic for assessment. After first invitation, 66 patients (50 women and 16 men) with 84 prostheses were examined according to predefined outcome parameters. We acquired further data from another 42 patients by searching the reports of their last visits at our outpatient clinic with a minimum follow-up of ten years, revealing 108 patients with138 prosthesis in total. All patients included gave informed consent in the knowledge that anonymous data would be used for further investigations. The study protocol was approved by the local Institutional Review Board (23–284 ex 10/11).

Surgical technique and rehabilitation

All prostheses were implanted under general or epidural anesthesia in a single institution by three different orthopaedic surgeons, as previously described by the authors [12, 17]. Patients were allowed full weight bearing postoperatively. Two days after surgery, continuous passive motion was used. Between ten and 14 days after surgery, all patients were discharged. For further rehabilitation, patients were referred to an outpatient rehabilitation programme until their sixth postoperative week. Pain management was performed using an intravenously (IV) administered mixture of 75 mg diclofenac and 30 mg orphenadrine and orally administered pantoprazole 40 mg or metamizole 1 g IV, with pantoprazole orally and an intramuscular injection of piritramide 7.5 mg as an additive treatment option.

Outcome assessment

At a minimum follow-up of ten years, all patients were clinically assessed with respect to QoL, clinical outcome and complications. We therefore measured active and passive range of motion (ROM), the Knee Society Score (KSS) [18], the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [18], and the visual analogue scale (VAS). In order to objectively analyse complications, we used the grading system described by Goslings and Gouma [19].

Statistical analysis

We performed a descriptive and explorative data analysis. Thereafter, independent *t* tests were used to compare demographic parameters across groups. Previous publications [4, 12] were chosen for sample-size estimation, and we calculated post hoc power in case of significant differences according to Hoening and Heisey [20]. All calculations were performed using SPSS 16.0 (SPSS Inc., Chicago, IL, USA), and a p value < 0.05 was considered significant.

Results

Demographic data

Mean patient age was 80 (range 49–95) years at follow-up (14 years, range 11–23). Eighty-two female (76 %) and 26 male (24 %) patients were included in our study, having undergone surgery on their right knee in 49 % and on their left knee in 51 % of cases. These data are presented in Table 1.

Quality of life and clinical outcome parameters

We found no statistically significant differences with respect to ROM, KSS and WOMAC scores between female and male patients (Table 2). With respect to VAS, we found a significant difference in pain levels, ranging from 1.53 for women to 1.03 for men ($p=0.042$). However, this statistical difference was insignificant; therefore they were not further analysed according to Hoening and Heisey [20]. These data are reported in Table 2.

Table 1 Demographic data (mean, range) of 82 female and 26 male patients with 84 low-contact-stress total knee arthroplasties at a minimum follow-up of 10 years

	Female patients ($n=82$)	Male patients ($n=26$)	P value
age in years	81, (53–95)	77, (49–92)	>0.05
height in cm	163, (147–177)	177, (156–188)	<0.005
weight in kg	73, (59–116)	87, (77–104)	<0.005
Overall groups			
follow-up in years	14, 11–23		
Side	Right knees (49 %)	Left knees (51 %)	>0.5

Table 2 Comparative outcome (mean, standard deviation) in 108 patients with 138 low-contact-stress total knee arthroplasties at a minimum 10 years of follow-up

	Female patients (n=82)	Male patients (n=26)	P value
Range of motion (passive)	99; 20.2	101; 17.9	0.962
Range of motion (aktive)	96; 16.7	95; 17.3	0.860
Knee Society Score (function)	69; 30.2	79; 24	0.172
Knee Society Score (pain)	69; 20.9	76; 24.4	0.442
WOMAC	81; 15.2	84; 16.4	0.253
Visual analogue scale	1.53; 0.38	1.03; 0.26	0.043

WOMAC Western Ontario McMaster Universities Osteoarthritis Index

Complications

There were 13 complications (9.4 %) in 138 TKAs: five case of aseptic loosening, which were treated with a one-stage exchange; three cases of late infections, which were treated with two-stage exchange; three cases of inlay wear, which were treated with inlay exchange; one instability, which could be addressed by revising the case and implanting a higher inlay; one periprosthetic fracture, which was treated with one-stage exchange. Interestingly, we found one female patient with inlay significant wear after only one year, who was successfully treated with exchange; we believe this wear was caused by a technical error and incorrect implantation, with possible immediate damage to inserted inlay. All cases had to undergo revision surgery and were rehabilitated according to grade 2, described by Goslings and Gouma [19]. These results are further illustrated in Table 3.

Discussion

The aim of this study was to analyse gender-specific outcome differences after implantation of LCS TKA with a minimum follow-up of ten years. The hypothesis was that the outcome differs between female and male patients with respect to QoL, clinical outcome parameters, and complications. We found that the beneficial outcome after LCS TKA was not significantly influenced by gender with respect to QoL, clinical outcome parameters and complications 10 years after implantation.

The rationale for a gender solution in TKA is anatomical difference between female and male knee joints, which is objectively documented in the literature [21–24]. One of these differences is the Q-angle, which is measured by drawing an imaginary line from the anterior superior iliac spine to the centre of the patella and constructing an angle between the patellar tendon and this imaginary line [21]. Physiological values for women with < 18° and for men with < °15 are reported [22]. Another difference is the anterior condyle height, which is reported to be smaller in women, with an average value of 10.1 mm compared with 10.9 mm for the lateral condyle [22]. The difference regarding medial condyles is even larger, with average values from 5.1 mm in women vs 6.4 mm in men [21]. Furthermore, the aspect ratio of the mediolateral (ML) to anteroposterior (AP) dimension was shown to be different between genders [23, 24] as, regardless of AP dimension, women are reported to have smaller ML dimensions. In addition, Conley et al. [22] found that the average female distal femur had a more trapezoidal shape than the more rectangular male distal femur.

These anatomical differences were postulated to have significant impact on prosthetic design with respect to

Table 3 Analysis of 13 complications in 108 patients with 138 low-contact-stress total knee arthroplasties at a minimum 10-year follow-up

Patient number	Sex	Complication	Procedure	At follow-up	Grade
1	male	aseptic loosening	1-stage exchange (tibia only)	4 years	2
2	female	infection	2-stage exchange	1 year	2
3	female	periprosthetic fracture	1-stage exchange	5 years	2
4	female	wear (inlay)	inlay exchange	1 year	2
5	female	infection	2-stage exchange	4 years	2
6	female	aseptic loosening	1-stage exchange (tibia and femur)	1 year	2
7	female	wear (inlay)	inlay exchange	7 years	2
8	female	aseptic loosening	1-stage exchange (tibia only)	7 years	2
8	same patient, other side	instability	inlay exchange	5 years	2
9	female	aseptic loosening	1-stage exchange (tibia only)	8 years	2
10	female	wear (inlay)	inlay exchange	10 years	2
11	male	infection	2-stage exchange	15 years	2
12	female	aseptic loosening	1-stage exchange	1 year	2

differences between sexes and between individual knee joints in general, as the femoral shield might overlap after implantation in case of imbalance between ML and AP dimension [25]. In addition, another anatomical type for a more individual TKA would be a small ventral overhang of the femur, because the femoral shield for female knee joints might be thinner [25].

As the AM to PL dimension is not optional in the LCS design, it is perfectly suitable for detecting inferior outcomes between sexes. Previous investigators have reported on 27,372 patients following TKA and found 18 % of women and 16 % of men were unsatisfied or uncertain after implantation, with no statistically significant difference [26]. This correlates with our findings, as patient satisfaction, documented by the KSS and WOMAC scores, did not differ between sexes. Harrysson et al. [27] performed a register research of 35,857 TKAs in Sweden with a focus on revision rates and found no differences between genders. This also correlates with previous findings of our study group using register data sets [28] and with the presented data, which also show no significant difference in outcome between genders. We therefore believe that various different sizes of tibial plateaus and femoral shield are needed, as prosecuted by the market, in order to address our patients' individual needs. However, no gender-specific implant is needed to do so.

We emphasise the following limitations of our analysis: the stratification process on preoperative demographic data with respect to patient height and weight was not possible, as these parameters are substantially different between sexes. Therefore, this systematic bias is totally valid and did not need to be eliminated. Furthermore, operations were performed by three different surgeons, which could have possibly led to further bias. However, all procedures were performed at a single institution under direct supervision of the head clinician of the division of knee surgery using standardised methods. Lastly, our study might be underpowered, as we performed a sample-size estimation according to the literature [4, 12] and post hoc power analysis, which was not applicable due to insignificant differences between groups. However, it should be noted that we present data from patients in a continuous series of a previous report [12] with a new minimum follow-up of 20 years. We believe this further strengthens our findings.

Conclusion

Ten years after implantation of the LCS TKA, the factor of gender does not influence its beneficial performance with respect to QoL, clinical outcome and complications.

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