Sex-related outcome differences after implantation of low-contact-stress mobile-bearing total knee arthroplasty

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Abstract

Purpose The aim of the study was to investigate outcome differences between female and male patients after implantation of low-contact-stress (LCS) mobile-bearing total knee prostheses at a minimum follow-up of five years with respect to clinical and radiological parameters.

Methods We retrospectively analysed 128 prostheses in 126 patients (90 women and 34 men) using our hospital database. Data was extracted with respect to range of motion (ROM), the Western Ontario and McMaster Universities Osteoarthritis

Index (WOMAC) score, the Knee Society Score (KSS) and radiolucent lines on conventional X-rays.

Results At follow-up, we observed no significant differences between female and male patients after LCS total knee prostheses. Benefit after implantation of LCS total knee prostheses after five years of minimum follow-up was not significantly different between female and male patients in terms of clinical outcome or radiolucent lines.

Conclusions We found no factors in favour of gender-specific total knee prostheses.

Level of evidence Level III – retrospective comparative analysis

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Background

The scientific community has faced much debate and discussion on the topic of gender and different outcomes between female and male patients after implantation of total knee arthroplasty (TKA), and the 382 MEDLINE-listed papers for the MeSH terms gender, knee and arthroplasty prove this high interest. However, industry might try to justify the design of a gender knee without the underlying scientific proof of sex-related outcome differences after TKA in an attempt to make a gender-specific prosthesis useful or even essential. One of the most common and most successfully implanted TKA systems in Europe, the low-contact-stress (LCS) mobile-bearing total knee prosthesis (Johnson & Johnson, New Brunswick, NJ, USA; previously DePuy, Warsaw, IN, USA) was designed to provide excellent functional results at long-term follow-up analysis in both female and male patients, providing the opportunity to discuss this topic on a sensible basis [1–6]. Whereas sex-related differences in prevalence, development and characteristics of osteoarthritis of the knee joint are well covered in the literature [7–14], and previous studies have tried to elaborate these findings in other TKA designs [15], the sex-related outcome after implantation of the LCS TKA

remains elusive and has never fully been delineated in the literature. Therefore, we undertook this retrospective study and evaluated 126 consecutive patients with 128 LCS total knee prostheses with respect to sex-related outcome differences. The purpose of the study was to evaluate objective clinical and radiological outcome differences between female and male patients at minimum follow-up of five years after implantation of LCS TKA. The study hypothesis was that the outcome after implantation of an LCS total knee prosthesis differs between female and male patients with respect to clinical and radiological parameters.

Methods

Study design and patient recruitment

This study was designed as a retrospective level III comparison [16]. A consecutive series of 128 LCS implants in 126 patients was reviewed. Indications for surgical intervention, such as subjective pain level, a continuous need for analgesic and anti-inflammatory drugs and objective functional limitations [reduced walking distance and decreased range of motion (ROM)] are described in a recent publication of our study group [5] and has not been changed or altered in this analysis. Replacements were performed by three different surgeons between January 1997 and December 2002 at a single institution. We excluded patients with TKA systems other than the LCS. Anonymous clinical and radiological data for all patients were obtained retrospectively from a database of digitised patient records; and all patients in this database gave informed consent to participate in the follow-up and were aware that anonymous aggregate data would be used for research and publication.

Surgical technique and rehabilitation

Surgical technique and rehabilitation were described previously [5]. Procedures were done under general endotracheal or epidural anaesthesia with a medial parapatellar approach by three different orthopaedic surgeons using standardised methods. First, tibial osteotomies were performed, according to LCS guidelines, with a posterior slope of 5°. The femoral cut was performed with an intramedullary guide system providing 3° of external rotation using the gap-balanced technique. Patella resurfacing was not performed. Tibial and femoral cementation was performed with standardised methods according to the manufacturer's instructions. Postoperatively, patients were allowed full weight bearing, and continuous passive motion was used from the second postoperative day. All patients were discharged between ten and 14 days postoperatively and referred to an outpatient rehabilitation programme until their sixth week of follow-up. All patients had standardised pain management protocols [5] using an intravenously 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 minimum follow-up of five years, patients were clinically re-evaluated using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score [16], Knee Society Score (KSS) [17] and radiological analysis with respect to radiolucent lines according to Ewald et al. [18] (Fig. 1). In addition, complications were analysed according to Goslings and Gouma [19] and therefore rated as grade 0=no harm grade 1=temporary disadvantage without further surgery, grade 2=recovery after resurgery, grade 3=permanent damage after surgery, grade 4=death because of surgery, and grade 5=death due to another cause.

Fig. 1 Radiolucent lines according to Ewald et al. [18] were classified in 128 patients (90 women and 36 men) after implantation of low-contact-stress total knee prosthesis and analysed with respect to potential sex-related differences. The figure illustrates the classification dividing the tibial plateau into seven different zones indicative for poor implant seating

Statistical analyses

Independent *t* tests were used to compare demographic parameters across groups. Previous publications [15] were chosen for sample size estimation; in case of significant differences, we evaluated post hoc power according to the method by Hoening and Heisey [20]. All calculations were done using SPSS 16.0 (SPSS Inc., Chicago, IL, USA). A *p* value <0.05 was considered significant.

Results

Demographic data

At a minimum follow-up of five years (mean 7, range 5–11), the mean age of patients in both groups was 78 (range 47–98) years. We included 90 women (72.8%) and 36 men (23.2%) in this analysis; 47.7% of prostheses were implanted in right knees and 52.3% in left knees. All LCS prostheses were totally cemented (tibial and femoral). No revision surgery was performed in any patient at the time of the last follow-up. We observed significant differences with respect to height and weight between female and male patients. Patient demographic data with *p* values is reported in Table 1.

Outcome assessment

At minimum follow-up of five years, we observed no significant differences in clinical scores between female and male patients after LCS total knee prostheses (WOMAC *p*=0.772; KSS for pain *p*=0.863; and function *p*=0.723). The 128 prostheses averaged an active ROM of 102.4° (range 5°–145°), with no significant difference between groups (*p*=0.799). For the 90 female patients, mean age was 79 (range 47–98) years, mean WOMAC score was 24.9 (range 0–85) points, and mean KSS score was 83 (range 0–100) points for pain and 70.05 (range 0–100) points for function. The mean active ROM was 95.5° (range 5°–40°). Thirty-four male patients had a mean age of 75 (range 49–92) years, a mean

WOMAC score of 32.1 (range 0–84) points and a mean KSS score of 80.6 (range 0–100) for pain and 59.9 (range 0–100) for function. The mean active ROM was 95.7° (range 75°–145°). Regarding the presence of radiolucent lines, the distribution was typical, as previously published [5], and we observed no different patterns between female and male patients (*p*=0.89). These results are illustrated in Fig. 1 and Table 2.

There were five complications: There were two cases of flexion instability (one man and one woman), which did not require revision surgery (grade 1), were conservatively treated with muscle strengthening and regained sufficient stability after training. One case of rupture of the medial collateral ligament was caused by an adequate trauma in a female patient. This case was successfully revised (grade 2). There were two cases of infection followed by two-stage revision surgery (one man and one woman). One of these cases, a woman, remained as a functional arthrodesis with ROM of 0–5–10 (grade 3) and one case, a man, was revised successfully (grade 2). These complications were not statistically significant different between female and male patients (*p*>0.5).

Discussion

The purpose of this study was to evaluate outcome differences between female and male patients at minimum of five years follow-up after implantation of LCS total knee prostheses. The study hypothesis was that the outcome after implantation of an LCS mobile-bearing total knee prostheses at minimum follow-up of five years differs between female and male patients with respect to clinical and radiological parameters. We found that benefit at a minimum of five years of follow-up was not significantly different between female and male patients in terms of clinical outcome, pain, active ROM or distribution of radiolucent lines. Anatomical differences between female and male knee joints are documented in the literature, indicating women have a tendency towards a more valgus alignment and a narrower mediolateral dimension in

Table 1 One-hundred and twenty-eight low-contact stress (LCS) total knee arthroplasties (TKA) were implanted in 90 female and 34 male patients in a consecutive series. Statistical analysis revealed no

significant difference in terms of age between groups. We observed statistically significant differences with respect to height and weight between female and male patients

	Female patients with LCS TKA (<i>n</i> =90)	Male patients with LCS TKA (<i>n</i> =34)	<i>P</i> value
Age in years*	79, (47–98)	75.8, (49–92)	> 0.82
Height in cm*	162, (147–177)	178, (156–194)	< 0.005
Weight in kg*	72, (48–115)	88, (78–105)	< 0.005
Overall (female and male)	Right knees 47.7%	Left knees 52.3%	> 0.5

*Mean (range)

Table 2 Clinical and radiological results after implantation of 128 low-contact-stress (LCS) total knee arthroplasties (TKA) in 126 patients (90 women and 34 men) in a consecutive series at minimum follow-up of 5 years. We observed no significant differences in clinical scores between female and male patients with respect to range of motion (ROM), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, Knee Society Score (KSS) (pain or functional score) and patterns of radiolucent lines

	Female patients (<i>n</i> =90)	Male patients (<i>n</i> =34)	<i>P</i> value
Range of motion	95.5, 5–140	95.7, 75–145	<i>p</i> >0.799
WOMAC score	24.9, 0–85	32.1, 0–84	<i>p</i> >0.772
Knee Society Score (pain)	83, 0–100	80.6, 0–100	<i>p</i> >0.863
Knee Society Score (function)	70.05, 0–100	59.9, 0–100	<i>p</i> >0.723
Radiolucent lines according to Ewald (tibial plateau)			<i>p</i> >0.89
Zone 1	24.7%	25.3%	
Zone 2	19.2%	20.1%	
Zone 3	12.4%	12.2%	
Zone 4	26.2%	24.9%	
Zone 5	12.5%	11.5%	
Zone 6	2.9%	2.8%	
Zone 7	<1%	<1%	

comparison to the anteroposterior dimension [21, 22]. These anatomical differences were postulated to have significant impact on prosthetic design with respect to differences between sexes and between individual knee joints in general, as the femoral shield might overlap after implantation in case of a misbalance between the mediolateral and anteroposterior dimension [23]. 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 [23]. However, LCS prostheses cannot contribute to these anatomical differences, as different sizes vary with respect to the mediolateral aspect but not the anteroposterior aspect. As the relation from the mediolateral to the anteroposterior aspect is therefore not optional in the LCS design, we could not and did measure a correlation with clinical outcome, but we assessed and compared the prosthesis performance in general. However, these aspects are only striking in the event of outcome differences between female and male patients after implantation of TKA. Robertson et al. [24] reported on 27,372 patients following TKA and found 18% of women and 16% of men were unsatisfied or uncertain after implantation, which did not reach statistical significance. This is in line with our findings, as patient satisfaction, documented by the WOMAC score [17], did not differ between sexes. Harrysson et al. [25] assessed results of 35,857 TKAs in the Swedish Arthroplasty Registry with a focus on revision rates. Results were in line with our experience (two revisions in women and one in men), with no significant difference in outcome between genders.

We emphasise the limitation of our findings: preoperative demographic data was inconsistent with respect to height and weight, as these parameters could not be matched in this analysis. However, height and weight differences are typical between sexes [25], and therefore, this

systematic bias is totally valid and did not need to be eliminated. Furthermore, operations were performed by two different surgeons, which could have possibly led to further bias. However, operations were all performed at a single institution under direct supervision of the head clinician of the division of knee surgery and using standardised methods. Patients in this study had relatively long hospital stays (average two weeks), which is typical for the authors' countries, but might differ from other European or US countries. Also, we report data of 90 female and 34 male patients, which might add to a systematic bias. However, this sex ratio is consistent with our patient population and further corresponds to findings of other authors investigating continuous series [15]. In addition, we were able to reach all patients for follow-up but not at exactly the same time, with a cutoff at a minimum of five years after implantation. Lastly, our study might be underpowered, as we performed a sample-size estimation according to the literature [15] and post hoc power analysis, which was not applicable due to insignificant differences between groups. However, it should be noted that we present radiological and clinical data from all patients of this continuous series, with no patient lost to follow-up at a representative minimum of five years.

Conclusion

We conclude that benefit after implantation of LCS total knee prostheses after five years of minimum follow-up is not significantly different between female and male patients in terms of clinical outcome, pain, active ROM or radiolucent lines. We therefore found no factors in favour of gender-specific total knee prostheses.

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