A five to seven year follow-up comparing computer-assisted vs freehand TKR with regard to clinical parameters

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Abstract

Purpose Computer-assisted knee surgery has become established in routine clinical practice. Still, there is no study investigating midterm clinical outcome after five to seven years postoperatively. We aimed to test the hypothesis that there is no difference either for subjective [Western Ontario and McMaster Universities (WOMAC) scores] or for objective (Knee Society Score, degree of flexion) criteria between computer-assisted total knee replacement (TKR) and freehand TKR after 5.6–7.3 years.

Methods We performed a matched-pair analysis; 100 patients who received a primary TKR were investigated after a median follow-up of 6.25 years. Group A was operated on with the support of a computer system, while surgery on patients in group B was performed with the freehand technique. We determined WOMAC Score, Knee Society Score and degree of flexion.

Results Overall we found similar results for WOMAC Score [group A: 42.98 (SD 13.80); group B: 41.54 (SD

15.01; $p=0.62$)], Knee Society Score [group A: 168.20 (SD 21.94); group B: 166.60 (SD 21.44; $p=0.71$)] and range of motion [group A: 106° (SD 9.19); group B 107° (SD 7.44; $p=0.62$)].

Conclusions No significant differences in midterm clinical outcome were found after TKR performed in the freehand vs computer-assisted technique.

Introduction

Total knee replacement (TKR) has become a standard operative procedure. Long-term results show different failure modes, but good long-term results after ten years [1–3]. Still, aseptic loosening is one of the major problems connected to TKR. The establishment of conventional TKR, numerous studies focussed on tribology, metal alloys, polyethylene structure and design of implants to decrease polyethylene wear [4–8].

Axial alignment of the limb with restoration of the mechanical axis is a determinant of the outcome. A mechanical axis within a range of $\pm 3^\circ$ varus/valgus is thought to be associated with a better outcome. However, in previous studies postoperative alignment of the limb exceeded a range of $\pm 3^\circ$ in up to 30% of cases. Petersen and Engh [9] reported the radiological results of 50 primary TKAs performed using the conventional technique. In their study, 26% of TKAs failed to achieve an alignment within $\pm 3^\circ$ varus/valgus. Mahaluxmivalla et al. [10] analysed 673 TKAs. They found an alignment of more than $\pm 3^\circ$ varus/valgus in 25% of cases, independent of the surgeon's experience. Although various guiding tools for alignment have been designed to improve accuracy, several limitations of these instruments have been reported [11–14]. Errors may be due to variations in

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the bony anatomy, visual misjudgement by the surgeon or limitations of the technique.

Computer-assisted surgery (CAS) was introduced in total knee arthroplasty ten years ago. Numerous studies have shown its superiority regarding postoperative long leg alignment and component orientation [15, 16, 18, 19]. Only a few studies focussed on the clinical outcome, and most of them evaluated only a short-term outcome [19–22]. We aimed to test the hypothesis that there is no difference either for subjective [Western Ontario and McMaster Universities (WOMAC) scores] or for objective (Knee Society Score, degree of flexion) criteria between CAS TKR and freehand TKR after 5.6–7.3 years.

Method

We performed a matched-pair analysis with investigation of 100 patients who had received primary TKR 5.6–7.3 years before (68–88 months). The matching criteria age, gender, body mass index (BMI), treated side, American Society of Anesthesiologists (ASA) Score, grade of osteoarthritis (Kellgren and Lawrence Score) and sex were similar in both groups (Table 1). All patients were recruited from a cohort of 550 patients (Fig. 1). Fifty patients received a cruciate-retaining PFC Sigma® total knee prosthesis (DePuy®, Warsaw, IN, USA) with fixed bearing within a computer-assisted implantation (VectorVision®, BrainLAB®, Munich Germany). Fifty patients received a cruciate-retaining PFC Sigma® total knee prosthesis (DePuy®, Warsaw, IN, USA) with fixed bearing in the standard freehand technique. No patellar replacement was performed in either group. All the operations were performed by one team; no learning curve for computer-

assisted implantation of TKR was included. Implantation followed after standardised spinal anaesthesia with a tourniquet. The median skin incision was followed by median parapatellar arthrotomy. In both groups the tibial cut was perpendicular to the mechanical axis and the femoral component was rotated parallel to the posterior condylar axis. The only difference between the two groups was that the implantation in group B was performed under control of a navigation system. The technique of implantation has been published previously [15]. The standardised postoperative procedure consisted of full weight-bearing on day 1 after the operation with two crutches and daily continuous passive motion and physiotherapy for 3 weeks.

Sample size calculation

We decided to investigate 50 patients in each group. It was done pragmatically, to be able to match enough patients according to the desired matching criteria, age, gender, BMI, treated side, ASA Score, grade of osteoarthritis (Kellgren and Lawrence Score) and sex.

Follow-up measurement

After approval of the local Ethics Committee, written and informed consent was received from all participants. All patients were invited to take part in a clinical follow-up 5.6–7.3 years (median follow-up 75 months) after TKR. The WOMAC Osteoarthritis Index [23] as well as the Knee Society Score [24] and the degree of flexion were obtained from all patients. Complications were monitored from the patient's records. In detail we monitored the following: wound infection, venous thrombosis, deep infection, loosening and reoperation.

Table 1 Demographic parameters of both treatment groups (mean values, standard deviation and *p* values)

Parameter	Group A (CAS)	Group B (freehand)	<i>p</i> value
<i>n</i>	50	50	1
Age (years)	70.8±7.33 (58–83)	69.3±8.68 (58–82)	0.37
Weight (kg)	84.2±14.67 (55–115)	88.6±19.32 (33–120)	0.21
Height (m)	1.65±0.08 (1.48–1.81)	1.64±0.11 (1.38–1.82)	0.9
BMI (kg/m ²)	31.1±5.03 (25.22–41.12)	32.7±6.19 (20.70–43.73)	0.17
Sex	35 female, 15 male	35 female, 15 male	1
Treatment side	30 right, 20 left	30 right, 20 left	1
ASA Score	1.92±0.67 (1–3)	1.86±0.67 (1–3)	0.26
Degree of osteoarthritis (Kellgren & Lawrence Score)	3.08±0.67 (2–4)	3.14±0.67 (2–4)	0.65
Type of arthritis: primary 1, rheumatoid arthritis 2, others 3	1: 47, 2: 3, 3: 0	1: 46, 2: 3, 3: 1	–
Preoperative leg axis	Varus: 43, valgus: 7	Varus: 43, valgus: 7	1
Degree of varus deformity	10.44±4.46° (4–22°)	10.61±3.94° (5–20°)	0.85
Degree of valgus deformity	9.57±2.94° (7–15°)	9.33±2.42° (7–14°)	0.88

Fig. 1 Flow chart illustrating patient selection for this study

Statistical analysis

Assessment of all patients in both groups was performed by two orthopaedic surgeons. Statistical analysis was performed using the paired Student's *t* test. Two-tailed values of $p < 0.05$ were considered statistically significant. For comparing WOMAC Score, Knee Society Score and range of motion, box plots were used. The box height is the inter-quartile range which represents half of all values; 25% of values are higher and 25% of values are lower than the box. The median is displayed as a horizontal line across each box. The minimum and maximum values are represented by the vertical lines. Analysis of the data was performed using SPSS software (version 11.5, SPSS Inc., Chicago, IL, USA).

Results

WOMAC Score

In the navigated group the WOMAC A (pain) revealed no statistically significant differences: A: 7.72 (SD 3.22, 95% confidence interval of difference -1.33 ± 1.13); B: 7.82 (SD 2.97; $p=0.87$). Similar results were found for WOMAC B (stiffness): A: 3.90 (SD 1.53); B: 3.52 (SD 1.58; $p=0.22$) and WOMAC C (function) A: 31.36 (SD 10.55); B: 30.20 points (SD 11.65; $p=0.6$). In total the WOMAC Score

demonstrated good results without any statistically significant differences: WOMAC total: A: 42.98 (SD 13.80); B: 41.54 (SD 15.01; $p=0.62$) (Fig. 2).

Fig. 2 Box plots for WOMAC Score representing the lower quartile (25th percentile) and upper quartile (75th percentile), the inter-quartile range and the median

Knee Society Score

No significant differences were found for the Total Knee Score. On average, patients in group A reached 168.20 (SD 21.94) points and patients in group B 166.60 (SD 21.44; $p=0.71$) points (Fig. 3). In detail, the values of the Knee Score were: A: 93.12 (SD 4.35) and B: 92.58 (SD 6.98; $p=0.64$) and the results of the Function Score A: 84.3 (SD 15.02) and B: 83.2 (SD 14.56; $p=0.71$).

Degree of flexion

When focussing on range of motion (Fig. 4) slightly different but no statistically significant values were found. Mean flexion in group A was 106° (SD 9.19) and in group B 107° (SD 7.44; $p=0.62$).

Complications

In this cohort we did not see any complications in terms of wound infection, venous thrombosis, deep infection, loosening or re-operation.

Discussion

Computer assisted surgery has gained very much interest in total knee arthroplasty, with superior results concerning axial leg alignment compared to the conventional technique [15–18]. There is, however, little information about the clinical outcome [19–22]. This study was conducted to test

Fig. 3 Box plots for Knee Society Score representing the lower quartile (25th percentile) and upper quartile (75th percentile), the inter-quartile range and the median

Fig. 4 Box plots for range of motion representing the lower quartile (25th percentile) and upper quartile (75th percentile), the interquartile range and the median

the hypothesis that there are differences for subjective (WOMAC Score) as well as for objective (Knee Society Score, degree of flexion) criteria between CAS TKR and freehand TKR after 5.6–7.3 years. To the best of the authors' knowledge the longest clinical outcome study focusses on five years. The authors aimed to present five to seven year results and focussed on the WOMAC Score as a validated patient-oriented subjective score, the Knee Society Score as a validated clinical knee score and range of motion.

Martin and coworkers investigated the CAS TKR imageless vs image-based technique [21]. They did not find a statistically significant difference two years after implantation. This is in agreement with previous results. In a two-year follow-up comparing image-guided vs freehand TKR in 50 cases, no difference in WOMAC and Knee Society Scores were found between the two groups [20]. In the most recent literature Molfetta and Caldo reported on a case-control study comparing 30 CAS TKRs to 30 freehand TKRs at a 5.4-year follow-up [22]. They recorded radiological data, complications, limb alignment, Knee Society Score and range of motion. According to their data the only difference between the two groups was a statistically significant improvement in the restoration of the mechanical axis of the lower limb alignment. Kamat et al. carried out a retrospective analysis of 673 TKRs of five consecutive years which were either operated on with standard instrumentation or with computer assistance. The authors did not find any statistically significant difference between the two groups for the Oxford Knee Score up to five years postoperatively [19].

In our study, no significant differences between the groups were found for the WOMAC Score ($p=0.62$). Further, the Knee Society Score described by Insall and coworkers [24] was comparable to other studies in the current literature [25]. No statistically significant difference for either the Knee Score or the Function Score could be seen. When focussing on the degree of flexion as an outcome criterion the results showed similar values in both groups (mean 106

vs 107°) without a statistically significant difference ($p=0.62$). Other authors describe a similar degree of flexion in their freehand outcome studies [5]. For these data, the hypothesis to be tested is not proven. There was no difference between group A and group B in our study.

When comparing the results to previously published studies one can summarise that similar results were found. Up to the current date, there is no study which evaluates a statistically significantly different clinical outcome between computer-assisted and freehand total knee arthroplasty.

Apart from this, our study has some limitations. The study has a retrospective and matched-pair character with a limited number of subjects. However, when we performed post hoc statistical calculations of sample size, it was found that between 150 and 770 subjects per group would be needed for most bony parameters to detect a statistically significant difference between the study group and the control group. However, the clinical question is whether it would be worthwhile and possible to enroll these additional subjects in order to attain statistical significance if the difference between the two groups is that small and probably of no clinical relevance. It is obvious that a prospective randomised study is still the gold standard for comparing two different techniques. Nevertheless, our study represents one of the first midterm reports comparing the clinical outcome in computer-assisted vs freehand TKR.

Although the postoperative leg alignment has been proven to be superior when using computer assistance in numerous studies, the clinical outcome will still be a matter of ongoing debate. As far as the authors are concerned, the long-term difference between CAS TKR and freehand TKR needs further investigation on a larger time scale.

We could verify our tested hypothesis: There is no difference either for subjective (WOMAC Score) or for objective (Knee Society Score, degree of flexion) criteria between CAS TKR and freehand TKR after 5.6–7.3 years.

The authors conclude that the hypothetical advantages of computer assistance in TKR for functional parameters and patient's satisfaction are still not yet proven. A clinical investigation has to be performed on a larger time scale in terms of loosening as the endpoint.

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Conflict of interest The first author is a member of the professional training team of Johnson & Johnson.

References

- Glant TT, Jacobs JJ (1994) Response of three murine macrophage populations to particulate debris: bone resorption in organ cultures. *J Orthop Res* 12:720–731
- Rodriguez JA, Bhende H, Ranawat CS (2001) Total condylar knee replacement: a 20-year followup study. *Clin Orthop Relat Res* 388:10–17
- Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM (2002) Insall Award paper. Why are total knee arthroplasties failing today? *Clin Orthop Relat Res* 404:7–13
- Chen FS, Scher DM, Clancy RM, Vera-Yu A, Di Cesare PE (1999) In vitro and in vivo activation of polymorphonuclear leukocytes in response to particulate debris. *J Biomed Mater Res* 48:904–912
- Font-Rodriguez DE, Scuderi GR, Insall JN (1997) Survivorship of cemented total knee arthroplasty. *Clin Orthop Relat Res* 345:79–86
- Jacobs JJ, Gilbert JL, Urban RM (1998) Corrosion of metal orthopaedic implants. *J Bone Joint Surg Am* 80:268–282
- Kubo T, Sawada K, Hirakawa K, Shimizu C, Takamatsu T, Hirasawa Y (1999) Histiocyte reaction in rabbit femurs to UHMWPE, metal, and ceramic particles in different sizes. *J Biomed Mater Res* 45:363–369
- Woolson ST, Northrop GD (2004) Mobile- vs. fixed-bearing total knee arthroplasty: a clinical and radiologic study. *J Arthroplasty* 19:135–140
- Petersen TL, Engh GA (1988) Radiographic assessment of knee alignment after total knee arthroplasty. *J Arthroplasty* 3:67–72
- Mahaluxmivala J, Bankes MJ, Nicolai P, Aldam CJH, Allen PW (2001) The effect of surgeon experience on component positioning in 673 press fit condylar posterior cruciate-sacrificing total knee arthroplasties. *J Arthroplasty* 16:635–640
- Delp SL, Stulberg SD, Davies B, Picard F, Leitner F (1998) Computer assisted knee replacement. *Clin Orthop Relat Res* 354:49–56
- Laskin RS (2003) Instrumentation pitfalls: you just can't go on autopilot! *J Arthroplasty* 18:18–22
- Novotny J, Gonzalez MH, Amirouche FM, Li YC (2001) Geometric analysis of potential error in using femoral intramedullary guides in total knee arthroplasty. *J Arthroplasty* 16:641–647
- Reed SC, Gollish J (1997) The accuracy of femoral intramedullary guides in total knee arthroplasty. *J Arthroplasty* 12:677–682
- Bäthis H, Perlick L, Tingart M, Lüring C, Zurakowski D, Grifka J (2004) Alignment in total knee arthroplasty. A comparison of computer-assisted surgery with the conventional technique. *J Bone Joint Surg Br* 86(5):682–687
- Bauwens K, Matthes G, Wich M, Gebhard F, Hanson B, Ekkernkamp A, Stengel D (2007) Navigated total knee replacement. A meta-analysis. *J Bone Joint Surg Am* 89(2):261–269
- Bolognesi M, Hofmann A (2005) Computer navigation versus standard instrumentation for TKA: a single-surgeon experience. *Clin Orthop Relat Res* 440:162–169
- Jenny JY, Clemens U, Kohler S, Kiefer H, Konermann W, Miehle RK (2005) Consistency of implantation of a total knee arthroplasty with a non-image-based navigation system: a case-control study of 235 cases compared with 235 conventionally implanted prostheses. *J Arthroplasty* 20:832–889
- Kamat YD, Aurakzai KM, Adhikari AR, Matthews D, Kalairajah Y, Field RE (2009) Does computer navigation in total knee arthroplasty improve patient outcome at midterm follow-up? *Int Orthop* 33(6):1567–1570
- Lüring C, Oczipka F, Perlick L, Tingart M, Grifka J, Bäthis H (2009) Two year follow-up comparing computer assisted versus freehand TKR on joint stability, muscular function and patients satisfaction. *Knee Surg Sports Traumatol Arthrosc* 17(3):228–232
- Martin A, von Strempel A (2006) Two year outcomes of computed tomography-based and computed tomography free navigation for total knee arthroplasties. *Clin Orthop Relat Res* 449:275–282

22. Molfetta L, Caldo D (2008) Computer navigation versus conventional implantation for varus knee total arthroplasty: a case-control study at 5 years follow-up. *Knee* 15(2):75–79
23. Bellamy N, Campbell J, Stevens J, Pilch L, Stewart C, Mahmood Z (1997) Validation study of a computerized version of the Western Ontario and McMaster Universities VA 3.0 Osteoarthritis Index. *J Rheumatol* 24(12):2413–2415
24. Insall JN, Dorr LD, Scott R, Scott WN (1989) Rationale of the Knee Society clinical rating system. *Clin Orthop Relat Res* 248:13–14
25. Bachmeier C, March L, Cross M, Lapsley H, Tribe K, Courtenay BG et al (2001) A comparison of outcomes in osteoarthritis patients undergoing total hip and knee replacement surgery. *Osteoarthritis Cartilage* 9:137–146