

On the Outcome of Computer-assisted Total Knee Replacement

Výsledky totální endoprotézy kolena počítačovou navigací

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ABSTRACT

A number of studies have reported a significant improvement of the postoperative alignment, when computer-navigated total knee arthroplasty (TKA) was compared with conventional techniques. However, no studies are available on the functional and patient-relevant outcomes after computer-assisted knee replacement. In a prospective, randomized trial comparing 27 computer-assisted TKAs with 25 conventional implantations, the Knee Society Score was used to assess functional status, and the WOMAC questionnaire was used to record the disease-specific, patient-relevant outcome. At a twelve-month follow-up no significant difference was detected between the two patient groups in either the scores or the number of complications and range of postoperative knee flexion. The results are in agreement with those reported in other studies on the effect of conventional TKA. With the patient group of this size it can be concluded that computer-navigated TKA gives short-term results comparable with those achieved by conventional methods of implantation.

Key words: knee, arthroplasty, computernavigation, outcome.

INTRODUCTION

Lately, a number of authors have reported on the advantages in using computer-assisted navigation in total knee replacement concerning the postoperative limb alignment, the implant positioning and implant orientation. A benefit regarding these criteria has been shown by cadaver studies as well as prospective clinical studies, a number of which were performed in a randomized manner. While there seems to be increasing evidence that computer-navigation in total knee replacement is able to improve the component positioning, so far there is no data accessible on the functional results and the patient satisfaction. Especially since long-term implant survival of conventional total knee arthroplasty has been shown to be excellent, the functional assessment and overall quality of life are becoming a more critical issue in the evaluation of success of new surgical methods. It remains unclear, if improvement of alignment has a direct beneficial effect on the functional results of the patient. In a clinical and radiological follow-up of a prospective randomized trial, we compared the outcome between patients receiving a kinematic, computer-navigated total knee replacement with patients operated with a conventional jig-based technique.

PATIENTS AND METHODS

As we have reported before, sixty consecutive patients scheduled for total knee replacement were considered for the study after the study protocol had been approved by the local ethical committee. Two patients

declined the randomization and six patients did meet one or more of the exclusion criteria. Thus, fifty-two patients were randomized with a use of a computer-program, 25 to receive a conventional total knee replacement and 27 to receive a total knee replacement assisted by kinematic computer-navigation (OrthoPilot System, Software 2.2, Aesculap, Tuttlingen, Germany). This system used active infrared receivers to track the movements of the knee and leg three dimensionally, fixed with self cutting screws to the anterior superior iliac spine, the distal femur and the tibia and to the cutting jigs. In the manual group, an intramedullary rod was used for the femoral cuts and an extramedullary tibial guide was used for the tibial resection. Patients in both groups received a cemented, total-condylar-type prosthesis with resurfacing of the patella (SEARCH Evolution, Aesculap, Tuttlingen, Germany) using a medial parapatellar arthrotomy. A tourniquet was used in both groups until the implants were cemented. In all cases, a single-shot administration of antibiotics was applied perioperatively. Physical therapy started on the day after the operation, all patients were limited to partial weight bearing until wound healing was secured. At a three months follow-up, the mechanical alignment of the leg as measured on full-leg, weight bearing, standing radiographs, had reached a straight axis in more cases with the computer-navigated implantation compared to the conventional implantations. This difference was statistically significant. The femoral- as well as the tibial mechanical ap axis and the femoral- and tibial sagittal tilt (slope) measured on sagittal x-rays had not significantly improved in the computer-assisted group.

Preoperatively and twelve months postoperatively, patients were assessed using the Knee Society Score (KSS). To measure the patient-relevant outcome, the „Western Ontario and McMaster Universities Osteoarthritis Index“ (WOMAC) was used in its localized, validated form. Weight bearing ap and non-weight bearing lateral radiographs were taken preoperatively, and at 12 months follow-up. The stages of gonarthrosis were graded according to Ahlbaek et al on the preoperative radiographs, while the postoperative radiographs were evaluated concerning the total knee replacement using the criteria defined by the Knee Society. The statistical comparisons between the two patient groups were performed using the Mann-Whitney U test with a binding correction, and a $p < 0,05$ was considered statistically significant.

RESULTS

The groups had been well balanced concerning demographic data preoperatively. Differences in the age, the body mass index and the radiographic grading were not statistically significant (table 1). The preoperative diagnosis had been primary osteoarthritis in 18 cases in the computer-navigated and in 21 cases in the manual group, posttraumatic arthritis in 6 computer-navigated and 2 manual cases, and rheumatoid arthritis in 3 computer-navigated and 2 manual cases. There were 14 operations on the right and 13 on the left side in the computer-assisted group, compared with 10 on the right and 15 left in the manual group. There were no statistically evident differences in the preoperative Scores of the Knee Society and the WOMAC (table 2). In the postoperative course, we already reported four wound infections with skin necrosis, two in each group. Three of the wounds had to be revised surgically within six weeks after the index operation (one in the computer-navigated, and two in the conventional group); all wounds were unsuspecting at a three months follow-up. There were no other operative revisions on any of the knees followed in the year after the operation. None of the patients in the computer-navigated group experienced problems with the skin incision at the iliac crest. There had been no evident signs of a deep infection at or before the twelve month follow-up-visit in any of the patients. There had been no signs of a clinically evident thrombosis in either group.

Twelve months after the operation, all 52 patients were available for a complete clinical and radiographic assessment. On roentgenographic evaluation, no lysis greater than 2mm was recorded in any of the cases. Radiolucent lines (smaller than 2mm) that were not progressing in comparison with x-rays taken at a 3-months visit were noted in four patients in the computer-navigated group and in two patients of the manual group in the zones 3 and 4 of the tibial baseplate. One patient in the manual group showed a non-progressive radiolucent line in the femoral zones 1 and 4. There were no radiolucent lines on the lateral views of the patella.

The mean knee flexion for the entire study group was

Table 1

	Patients included n (% female)	Age Mean (SD)	Body Mass Index Mean (SD)	Radiographic grade Ahlbaek III/IV/V
Computer-navigated	n= 27 (67% female)	64,7 (9,4)	27,9 (3,55)	7 / 17 / 3
Manual	n= 25 (68% female)	67,3 (6,3)	30,2 (4,95)	8 / 14 / 3
		p=0,3	p= 0,08	p=0,91

Table 2

	KSS preoperative Mean (SD)	WOMAC preoperative		
		Pain Mean (SD)	Stiffness Mean (SD)	Physical Function Mean (SD)
Computer-navigated	96,1 (23,9)	5,6 (1,6)	6,3 (1,9)	5,8 (1,4)
Manual	103,2 (24,3)	5,4 (1,9)	6,3 (2,0)	5,6 (1,5)
	p=0,30	p=0,62	p=0,89	p=0,53

Table 3

	KSS at 12 months Mean (SD)	WOMAC at 12 months		
		Pain Mean (SD)	Stiffness Mean (SD)	Physical Function Mean (SD)
Computer-navigated	176,2 (17,2)	0,9 (0,9)	2,0 (2,1)	1,6 (1,5)
Manual	168,4 (24,9)	1,2 (1,0)	2,0 (1,8)	1,9 (1,8)
	p=0,46	p=0,67	p=0,78	p=0,36

109 degrees (standard deviation: SD: 15 degrees). One patient in the manual group only reached a maximum flexion of 75° (with all other patients able to flex equal or more than 90°), while in the computer navigated group, all patients reached a minimum of 90° of flexion. The differences in the knee flexion between the group that had a manual implanted prosthesis compared to those who had a computer-navigated procedure were not found to be significant ($p=0,77$). And even though the mean values of the Knee Society Score and the WOMAC showed slightly better results in the computer-navigated group, there was no statistical significant difference concerning the combined score of the Knee Society ($p=0,46$) or the subscores of the WOMAC (subscore pain $p=0,67$; subscore stiffness $p=0,78$, subscore physical function $p=0,36$) when comparing the two patient groups (table 3).

DISCUSSION

While we have been unable to locate publications reporting on the clinical outcome of computer-assisted total knee arthroplasty, the data presented compares

well to other publications assessing the outcome of conventional total condylar-type knee replacement. The average flexion reached by patients after twelve months in 684 conventional Kinemax prosthesis implanted in a number of centers in the United Kingdom, the United States and Australia was reported to be 108,4° (SD 17,9). And at an average of 30 months after implantation of 58 Miller Galante II Implants with patella resurfacing, Barrack and Coworkers reported on a mean Range of Motion of 110°, compared to a mean of 108° in the computer-navigated and 109° in the manual group at the twelve months follow-up in our trial. And the combined score of the knee society in the same 58 patients reached values between 168 and 178,6, compared to the data presented here with 168,4 in the manual, and 176,2 in the computer-navigated group. In 2001, the Kinemax outcomes group published the WOMAC subscores "pain" and "function" for the preoperative and twelve months evaluation of 862 TKA-patients. After transformation to the scale used for the WOMAC in the present study the preoperative pain score of 5,5 (SD 1,9) improved to a postoperative score at a 12 months follow-up of 1,7 (SD 1,8), compared to the preoperative scores of 5,7 and 5,4 (computer-navigated / manual) and the postoperative scores of 0,9 and 1,2 (computer-navigated / manual) in our patient-collective. And the preoperative WOMAC function score of 5,3 (SD 1,8) in the Kinemax study group improved to 2,6 (SD 2,0), postoperatively (WOMAC function preoperative: computer-navigated 5,7, manual 5,4; postoperative: computer-navigated 1,6, manual 1,9). Thus, with the numbers available, kinematic computer-assisted total knee replacement is able to match results of the conventional jig-based technique in our study, but also compared to conventional procedures performed in other centers.

Computer-assisted total knee replacement has been the object of some debate. Our data does not support the hypothesis that improvement in leg axis and reduction of the number of cases with a higher deviation from an "ideal" alignment automatically leads to a better functional result and a better outcome, as measured with the recommended outcome scores. The number of patients included in our study might be too small for this discrimination. For example, to show a significant difference in the postoperative WOMAC subscore for "physical function" with a power of 90% and alpha set at 5%, using power analysis we retrospectively calculated that 1102 randomized patients would be needed in the follow-up. Since alignment in total knee arthroplasty can so far only be regarded as a surrogate outcome indicator, it still remains to be seen if the improvement in this criteria will lead to reduced failure-rates and improved long-term outcomes. On the other hand, the ongoing development of computer-navigation-systems seeks to increasingly incorporate features like soft-tissue balancing and rotational alignment, which might result to a more precise control and a better understanding of the influences of these parameters on the function and the outcome in the future.

ZÁVĚR

V řadě studií je popsáno významné zlepšení pooperačního postavení implantátu při srovnání totální endoprotézy kolena s použitím počítačové navigace a konvenčních technik. Nejsou však dostupné studie, které popisují funkční výsledky a subjektivní hodnocení pacientů po počítačem navigované implantaci endoprotézy. V prospektivní randomizované studii srovnávající 27 operací s použitím navigace s 25 operacemi konvenčním postupem bylo pro hodnocení funkčního stavu použito Knee Society skóre a pro subjektivní hodnocení pacientů byl použit dotazník WOMAC. Ve sledovaném období deseti měsíců nebyly nalezeny žádné významné rozdíly ve výši skóre ani v počtu komplikací a rozsahu pooperační flexe mezi těmito dvěma skupinami. Výsledky jsou v souladu se zjištěním ostatních studií, které se zabývají náhradou kolenního kloubu prováděnou konvenčními technikami. S ohledem na počty pacientů zahrnutých do studie lze uzavřít, že počítačem navigovaná implantace protézy kolenního kloubu přináší v krátkodobém sledování výsledky srovnatelné s konvenčními metodami.

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