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Conventional Versus Computer-Assisted Technique for Total Knee Arthroplasty: A Minimum of 5-Year Follow-up of 200 Patients in a Prospective Randomized Comparative Trial

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ABSTRACT

In the literature, studies of computer-assisted total knee arthroplasty (TKA) after mid-term period are not conclusive and long-term data are rare. In a prospective, randomized, comparative study 100 conventional TKAs (group REG) were compared with 100 computer-assisted TKAs (group NAV). Minimum follow-up was 5 years. No difference in implant failure was found with 1.1% in group NAV versus 4.6% in group REG ($P = 0.368$). Group NAV showed a significantly less mean deviation of mechanical limb axis ($P = 0.015$), more TKAs (90% versus 81% in group REG) were within 3° varus/valgus and a higher tibial slope and lateral distal femoral angle (LDFA) accuracy was found ($P \leq 0.034$). Clinical investigational parameters showed no differences ($P \geq 0.058$). Insall and HSS score total were also higher in group NAV ($P \leq 0.016$).

Computer-assisted navigation systems for total knee arthroplasty (TKA) were introduced to improve clinical outcome, to achieve higher postoperative implantation accuracy and to enhance TKA long term-survival. Component alignment within ±3° varus/valgus accuracy from neutral mechanical axis is recognized as fundamental for long-term survival [1–3]. However, recent published studies [4,5] found no direct influence of exact reconstructed mechanical axis within ±3° varus/valgus on long-term survival rate following TKA. Nevertheless, until biomechanical interrelations of components' orientation in coronal, sagittal and axial planes are better understood a neutral mechanical limb axis remains the golden standard.

Conventional, non-navigated TKA has been compared with computer-assisted technique several times [6–10]. Different authors [11–14] found better radiological results for navigated TKA. In other trials [8,15,16] a significant improved mechanical axis after navigated TKA could not be obtained. Several studies also reported better clinical outcomes for computer-assisted technique [17,18]. In contrast, Lüring et al [19] verified no significant differences in WOMAC Score, Knee Society Score or range of motion (ROM) between both study groups 2 years postoperative. Also other trials did not find statistical differences in clinical evaluations and score results [8,10,20–23].

For most of the trials published to date, the postoperative follow-up term is too short to provide reliable answers as to whether navigation leads to better clinical results and higher implant survival rates. Even recent published meta-analyses [7,24–26], verifying a significant reduction of malalignment risk over ±3° from neutral mechanical leg axis by using navigation systems, are mostly based on literature with short postoperative follow-up periods. Only a small number of trials with a mid- to long-term follow-up rate of 5 years or more are available [17,27–30]. Hernández-Vaquero et al [29] reported no difference of implant survival rate between navigated and conventional TKA after a mean follow-up term of 8.3 years. This was in keeping with the findings of Kim et al [30] after 10.8 years. However, both authors [29,30] found no differences in tibiofemoral mechanical axis alignment in frontal plane. This may explain their equal TKA survival results. Only one prospective randomized mid-term trial [27] is available comparing TKA survival rate between navigated and conventional procedure based on a better postoperative mechanical limb alignment in computer-assisted group. Harvie et al [27] found no TKA revision in both study groups 5 years after primary implantation.

Most recently published mid- to long-term follow-up trials are limited by a retrospective [29] or a prospective but non-randomized

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study design [17], an incomplete follow-up rate [17] below 65% or statistically insignificant number of patients (under 25 patients per study group) after 5 years [27].

The objective of our study was to answer following questions: (1) Can computer-assisted technique for TKA influence the survivorship of the implant? (2) Is there a difference in radiologic results and (3) in clinical outcome parameters? (4) Might navigation affect the results of Insall scores, HSS scores and WOMAC scoring?

Materials and Methods

A total of 200 patients (200 TKAs) were enrolled in this prospective, randomized, comparative study. One hundred patients (100 TKAs) underwent surgery with the conventional non-navigated implantation technique (regular TKA group–group REG). In 100 patients (100 TKAs) the CT-free VectorVision knee navigation system (BrainLAB, Munich, Germany) (navigated group–group NAV) was used [13]. Patients were randomized based on an assigned patient code. Patients with even-numbered codes had the conventional implantation procedure, and patients with odd-numbered codes had the computer-assisted operation. The randomization procedure was performed by an independent secretary in the hospital's administration office [13]. At final postoperative clinical and radiological follow-up the investigator did not know which procedure was used for TKA.

Preoperative demographic data, diagnoses, leg deformities, Insall knee scores and range of motion (ROM) were similar between study groups. The preoperative body mass index was 28.2 in group REG and significantly lower compared to 30.2 in group NAV ($P = 0.002$). Patients provided consent before having a TKA and before being included in our institutional review board-approved study.

The surgical procedures were performed by three experienced orthopedic surgeons using a standard medial parapatellar exposure. A lateral approach [31] was used for severe valgus deformities in conjunction with pre-implantation ligament balancing when indicated. We implanted the NexGen Mobile Bearing Knee (MBK; Zimmer Inc., IL, USA) and the NexGen Legacy Posterior Stabilized Flex Mobile (LPS Flex; Zimmer Inc., IL, USA) in both study groups with equal distribution [13].

In both groups minimum follow-up was 5 years after primary implantation. In group REG mean follow-up was 5.7 years. From the 100 patients (100 TKAs), 79 patients (79 TKAs) were available for follow-up. Nine patients had died of causes unrelated to TKA surgery, 4 patients were unavailable for follow-up and remaining 8 patients were interviewed by telephone. In group NAV mean follow-up was 5.4 years. Overall 74 patients (74 TKAs) were available for follow-up. Eight patients had died unrelated to TKA surgery, 5 patients were not available and 13 patients followed a telephone interview.

Thus to determine TKA survival, 87 patients (87 TKAs) in both groups (96% versus 95% in group NAV) were available for review. Follow-up x-rays were possible in 86.2% (75 TKA) in group REG versus 80.2% (73 TKA) in group NAV. Clinical examination was done at 85.7% (72 TKA) in group REG versus 79.8% (71 TKA) in group NAV. Study endpoints were defined as revision for any reason. Patients who had undergone revision or with serious co-morbidity unrelated to TKA (e.g. cerebral stroke with immobilizing hemiparesis) were not included in radiological and clinical analysis (Table 1).

Age, gender, body mass index (BMI), mean weight (kg) and height (cm), side of implantation and ASA (American Society of Anesthesiologists) classification [32] of every patient were noted at 5-year follow-up. Clinical investigation included examination for effusion, ROM, subjective feeling of instability and ligament laxity in full extension and 30° flexion [33]. Instability was classified by opening angle of the limb (Grade 1 = 6°–9°, Grade 2 = 10°–14° and Grade 3 > 14°) [33]. Similarly anterior drawer test (Grade 1 = 5–7 mm; Grade 2 = 8–10 mm; Grade 3 = over 10 mm) and anterior knee pain were evaluated [33].

Table 1
Follow-up Overall Survival, Clinical and Radiological Examination.

	Group REG: 100 TKA	Group NAV: 100 TKA
Follow-up: overall survival		
Died due to unrelated TKA causes	−9	−8
Available for follow-up	91 (100%)	92 (100%)
Not reached	−4	−5
Follow-up rate	87 (95.6%)	87 (94.6%)
Follow-up: clinical examination		
Died due to unrelated TKA causes	−9	−8
Revision	−4	−1
Serious co-morbidity unrelated to TKA	−3	−2
Available for follow-up	84 (100%)	89 (100%)
Not reached	−4	−5
Telephone interview only	−8	−13
Follow-up rate	72 (85.7%)	71 (79.8%)
Follow-up: radiological examination		
Died due to unrelated TKA causes	−9	−8
Revision	−4	−1
Available for follow-up	87 (100%)	91 (100%)
Not reached	−4	−5
Telephone interview only	−8	−13
Follow-up rate	75 (86.2%)	73 (80.2%)

Additionally Insall Knee Score [33], Western Ontario Mac Master University Index (WOMAC Score) [34] and Hospital for Special Surgery Knee Score (HSS Knee Score) [35] were measured on every patient.

Radiological examination was performed by standard radiographs including a long-leg weight-bearing x-ray. We evaluated mechanical axis of the limb, lateral distal femoral angle (LDFA) and medial proximal tibial angle (MPTA) in frontal plane [36] (Fig. 1A). A mechanical axis of the limb within ±3° varus or valgus was seen as optimum [1–3]. Lateral view was used for posterior tibial slope evaluation. Tibial slope of 7° (within 4° to 10°) respectively 83° (86° to 80°) in relation to mechanical axis of tibia was seen as optimum (Fig. 1B). A tangential patellar radiograph in 45° flexion was taken measuring patella alpha (α) angle [37,38] (Fig. 1C). Positive angles were interpreted as normal, 0° or negative angles as subluxation of patella [37,38]. For detection of radiolucent lines, the standardized Roentgenographic Evaluation and Scoring System of Knee Society was used [37].

Statistical analysis was performed with SPSS software (Version 17; IL, USA). Significance was defined by $P < 0.05$. Mean, range, minimum, maximum and standard deviation were measured for every parameter. We used Fisher's exact test for analysis of nominal data (e.g. gender, side of implantation). Unrelated *t*-test was performed to analyze normal distributed data (e.g. age, BMI, ROM). Mann–Whitney *U*-test was used for ASA classification and HSS classification. For measuring the distribution of mechanical axis of the limb in neutral, varus or valgus position Chi-Square-test was performed.

Results

After a minimum follow-up of 5 years, no significant difference in TKA survival rate within either study group was found (95.4% versus 98.9% in group NAV; $P = 0.368$). Rate of revision was 4.6% (4 TKA) in group REG versus 1.1% (1 TKA) in group NAV. In group REG, two patients were revised due to late onset infection of TKA (1.3 and 1.5 years after primary implantation), one patient sustained a traumatic periprosthetic fracture 1.9 years postoperatively and one patient complained about ligament instability. As a consequence a polyethylene (PE) inlay exchange from 12 to 14 mm 2 years after primary TKA implantation was performed. In group NAV there was one implant loss due to trauma (periprosthetic femoral fracture) 0.4 years after implantation.

For the reconstruction of the mechanical axis of the limb, for the tibial slope and in part for the LDFA measurement, we found significantly lower accuracies in group REG. With a mean deviation