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Electromagnetic Navigation in Total Knee Arthroplasty—A Single Center, Randomized, Single-Blind Study Comparing the Results With Conventional Techniques

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Abstract

We report on the results of a randomized study (n = 200) to compare total knee arthroplasty performed using conventional instrumentation or electromagnetic computer assisted surgical technique. 92% of navigated and 85% of conventional knees were implanted within ± 3° from neutral mechanical alignment; there was no statistically significant difference between these proportions. There was also no difference in femoral or tibial rotation assessed by CT scan. At 1 year follow up there was no statistical difference between the two groups in American Knee Society Score, Oxford Knee Scores, patient satisfaction, quality of life, hospital length of stay, complication rates or other adverse events. Tourniquet time in the navigated group was longer. Proving value for navigation in total knee arthroplasty surgery remains a challenge.

Introduction

There remains considerable debate over the acceptable range of mechanical alignment for successful total knee arthroplasty surgery. Most authors favor placing the mechanical axis within 3° of a neutral mechanical axis 1., 2., 3. and 4. to improve implant survivorship although other studies have challenged this assumption 5., 6. and 7..

While improved implant survivorship has been linked to improved mechanical alignment, improved patient outcomes have been harder to demonstrate 8., 9., 10., 11. and 12.. Even randomized studies using imageless, optical, infra-red navigation, while demonstrating improved mechanical alignment 9., 11., 13., 14., 15., 16., 17., 18. and 19., have still been unable show improved clinical outcomes. A meta-analysis by Bauwens in 2007 suggested that there were few benefits with computer assisted navigation in knee arthroplasty surgery and that the advantages remained unclear 14. and 20..

Electromagnetic (EM) navigation systems were developed to avoid the line of site problems seen at the time of surgery with infra-red systems and the recurring contamination of reflector balls used on the reference arrays from blood and saw aerosols. The EM system under study utilizes small reference frames attached to the femur and tibia which are incorporated within the primary surgical incision, which avoids the need for additional pin sites in the tibia and femur required for infra-red trackers. A number of studies have highlighted the complications of infection and periprosthetic fracture related to the use of these bone pins 21., 22., 23. and 24.. The development of EM systems for use in Orthopaedic surgery however has had to overcome the interference of the electromagnetic field used in referencing by the presence of ferrous materials commonly seen in the theater environment including the operating table and surgical instruments [25].

The aim of the study was to assess the accuracy of implantation of components and the clinical outcome and complications with the iNAV electromagnetic navigation system compared with conventional techniques. We believe that this is the first published study to make this comparison in a randomized controlled trial.

Methods

All patients were scheduled for primary TKA at Glasgow Royal Infirmary. The study was approved by the Glasgow Royal Infirmary Local Ethics Committee and the University of Strathclyde Ethics Committee. Overall 272 patients were approached for recruitment into the trial giving a recruitment rate of 74% (Fig. 1, CONSORT flowchart). 200 patients were recruited and randomized between July 2007 and August 2010 at Glasgow Royal Infirmary. A computer generated random number table was used to randomize patients based on the order of their recruitment. Inclusion criteria included the presence of osteoarthritis suitable for total knee arthroplasty in patients capable of giving informed consent. There were no specific limits on age or the severity of disease preoperatively. Due to medical reasons one patient in the navigated and one in the conventional group had their surgery postponed. The analysis was therefore completed on 101 navigated and 97 conventional patients. Similar numbers of patients in both groups had their surgery performed by each surgeon.

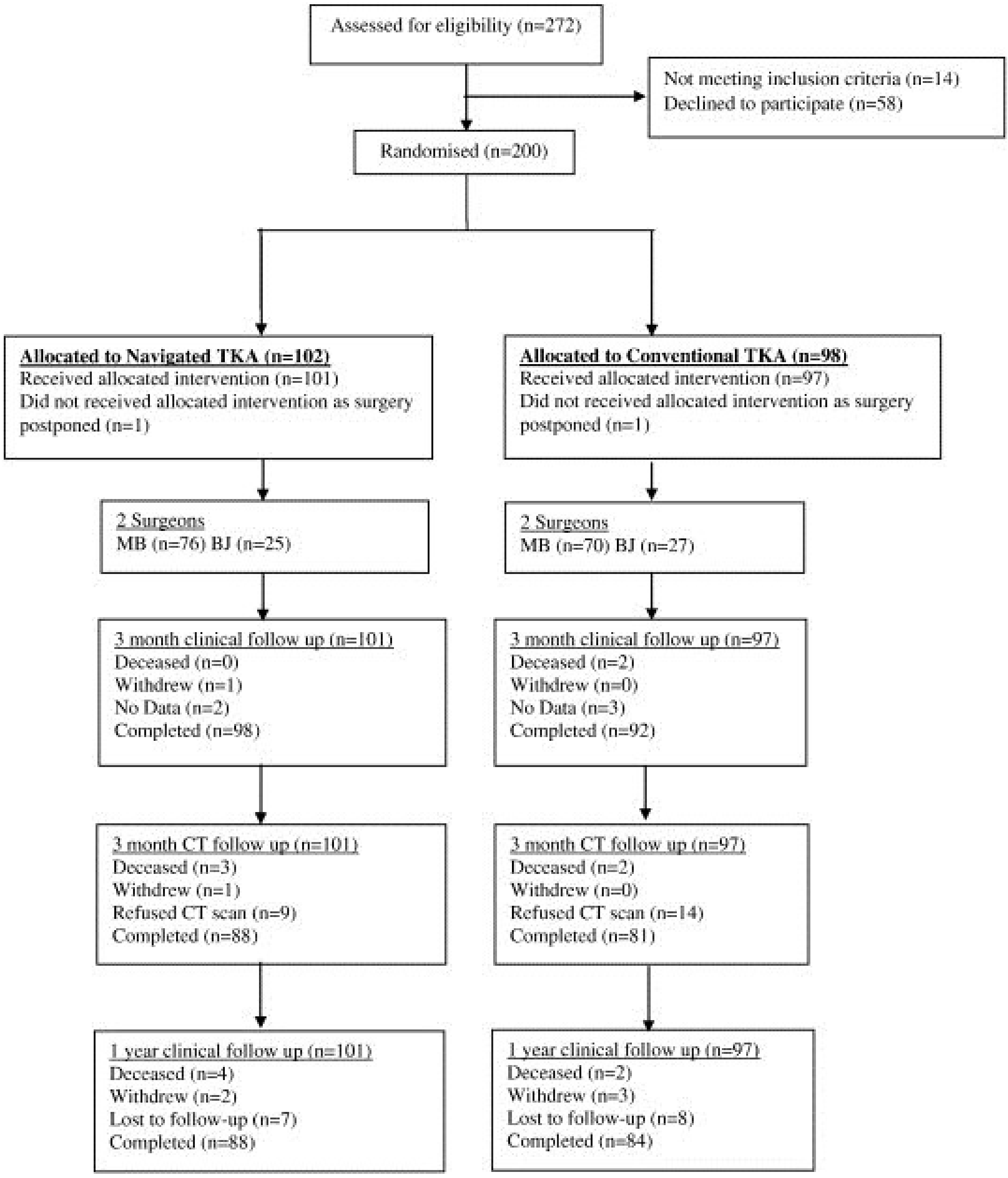

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Fig. 1.

Consort Flow Diagram for the randomized clinical study.

The iNav electromagnetic navigation system (Medtronic, Minneapolis, MN, USA) was used in the navigation group with small reference frames attached to the femur and tibia which are readily incorporated in the primary incision. A cemented posterior stabilized NexGen LPS Flex (Zimmer, Warsaw, Indiana, USA) was used in all patients. The surgery was carried out by, or under the direct supervision of one of two specialist knee surgeons, familiar with the implant and systems.

There were no differences noted between the two groups preoperatively in any of the parameters measured (Table 1). Pre operative alignment as a measure of disease severity was determined by long leg standing radiographs in bipedal stance. Tourniquet time, length of skin incision, hemoglobin drop and length of stay were analyzed along with pre-operative and post-operative complications and adverse events.

Table 1.

Pre-Operative Demographics.

	Navigated (n=101)	Conventional (n=97)	P Value
Mean Age and Range (in years)	65.6 (43–85)	65.4 (42–85)	0.87 T
Gender (ratio)	56F:45M	60F:37M	0.44 C
Mechanical axis deviation from neutral in ° (Mean 95%CI)	7.76 (20 varus to 20 valgus)	8.01 (30 varus to 25 valgus)	0.46 T
Extension ° (Median and Range)	5 (0–30)	5 (0–30)	0.93 M
ROM ° (Median and Range)	106 (65–140)	110 (40–135)	0.39 M
Oxford Knee Score (Median and Range)	16 (5–36)	16 (4–33)	0.97 M
AKSS-Knee sub score (Median and Range)	38 (17–84)	38 (2–82)	0.86 M
AKSS-Function sub score (Median and Range)	50 (3–83)	50 (0–80)	0.64 M
SF-36 Physical sub score (Median and Range)	30 (0–100)	31 (5–69)	0.95 M
SF-36 Mental sub score (Median and Range)	42 (15–90)	46 (8–94)	0.95 M

NOTE: T indicates that a 2 sample t test for normally distributed data was used, C indicates that a chi squared test was used and M indicates that a Mann Whitney non parametric test was used.

The patients were followed up for one year, with clinical assessments by a blinded independent assessor (Research Nurse); range of motion was determined using a hand held goniometer, and knee specific outcome measures included the American Knee Society and Oxford Knee Scores with the SF 36 score used as a general health measure. Overall patient satisfaction was determined and pain was recorded using a visual analogue pain score.

Post-operative CT scans were used to determine the accuracy of implantation. CT scan analysis was conducted using Mimics 12.0 software (Materialise, Leuven, Belgium). Measurements of the femoral and tibial component position in the coronal (varus/valgus), sagittal (flexion/extension) and axial (rotational) planes were made. The overall mechanical alignment was also calculated from the addition of the femoral and tibial coronal angles. The combined component rotation was calculated from the addition of the femoral and tibial rotation angles. The rotations were measured using the methods detailed in Berger et al (1998) [26]. In the coronal plane we aimed to position both femoral and tibial implants at 90° to the mechanical axis. In the sagittal plane we aimed to position the femoral component with a 5° slope relative to the mechanical axis, in line with the anterior cortex of the distal femur. The tibial component was aimed to be positioned at a 7° slope, as per the manufacturer's guidelines. For femoral rotation we aimed to implant the femoral component in line with the surgical trans-epicondylar axis of the femur. The reference for tibial rotation was a line from the geometric center of the tibia to the center of the tuberosity. Rotational measurements were calculated from a perpendicular line drawn from the posterior surface of the implant. As the tuberosity is 18° externally rotated, we considered an 18° internal rotation of the implant to be a neutral position [27]. (No obvious deformities of the tibia or previous fractures were noted in the study cohort that could have influenced this value.) We considered the desired mechanical axis alignment to be 0° with a range of ± 3°.

Statistics

A power calculation was performed based in data provided by a randomized controlled trial using infra red optical tracking systems. Bathis et al reported 96% of patients with mechanical leg alignment within 3° of neutral using navigation compared to just 78% with conventional instrumentation [16]. In order to detect a difference of this magnitude with a power of 90% at alpha = 0.05, we would require 82 patients per group, 164 in total. As the primary outcome measure was based on post-operative CT scan we anticipated a higher than average loss to follow-up for the primary outcome measure. We therefore allowed an additional 25% for loss to follow-up, giving a total of 103 patients in each group.

Statistical analysis was performed using SigmaPlot 11.0 (Systat Software Inc). To evaluate differences between the surgical groups either a two sample t test (normally distributed data) or a Mann Whitney test (non parametric data) was performed. A Chi Squared test was used to analysis the male: female ratio. A P value of less that 0.05 was considered significant.

Results

Surgical Differences

There was a small but statistically significant difference in skin incision length of 1 cm noted between the 2 groups with longer incisions reported in the navigated group. Tourniquet times were also statistically significantly longer in the navigated group; median 80 min for the navigated group compared to a median of 65 min for the conventional group (P = 0.001).There were no differences in mean drop in hemoglobin or length of hospital stay between the two groups (Table 2).

Table 2.

Surgical Data for the Navigated and Conventional Groups.

	Navigated (n = 101)	Conventional (n = 97)	P Value
Mean length of skin incision	18.2cms	17.0cms	0.0021T

	Navigated (n = 101)	Conventional (n = 97)	P Value
Median tourniquet time (range)	80 min (45–130)	65 min (40–120)	0.001M
Median drop in Hb (range)	3.2 g/dl (0.5–6.9)	3.1 g/dl (1.5–10.0)	0.599 M
Median length of stay (range)	5 days (2–30)	5 days (2–15)	0.567 M

NOTE: T indicates that a 2 sample t test for normally distributed data was used, M indicates that Mann Whitney Test used.

Clinical Outcome Scores

Although the navigated group had statistically significantly better absolute Oxford scores compared to the conventional group at 3 months and a showed a trend for better AKSS scores at 3 months (Table 3) the change in score from pre-operative values was not significantly different (P = 0.088). At 1 year post-operatively both groups had further improved their OKS and AKSS scores, with no significant difference detected between the groups at this time point (Table 4). There was also no significant difference in range of motion, pain VAS or SF-36 scores (Table 4). Table 5 shows that there was no difference in the patient satisfaction ratings between the two groups. Overall there was a 12% incidence of patients who were unsure, unsatisfied or very unsatisfied at 1 year post surgery.

Table 3.

Clinical Scores for the Navigated and Conventional Surgical Groups 3 Months Post-Surgery.

3 Months Clinical Scores	Navigated (n = 98)	Conventional (n = 92)	P Value
Median ROM (Range)	105 (68–130)	100 (43–133)	0.24
Median Oxford (Range)	32 (7–46)	29 (6–46)	0.031
Median AKSS-Knee (Range)	78.5 (38–95)	76 (15–94)	0.067
Median AKSS-Function (Range)	60 (10–100)	55 (0–55)	0.098

NOTE: Mann Whitney test used for P value.

Table 4.

Clinical Scores at 12 Months Post-Surgery.

1 Year Clinical Scores	Navigated (n = 88)	Conventional (n = 84)	P Value
Median ROM (Range)	110 (80–135)	110 (75–135)	0.309
Median Oxford (Range)	34 (12–48)	36 (5–47)	0.682

1 Year Clinical Scores	Navigated (n = 88)	Conventional (n = 84)	P Value
Median AKSS-Knee (Range)	85 (33–95)	86 (32–100)	0.910
Median AKSS-Function (Range)	70 (15–100)	65 (0–100)	0.274
Median SF-36 Physical (Range)	53 (3–99)	46 (9–96)	0.611
Median SF-36 Mental (Range)	69 (18–100)	70 (15–97)	0.529
Median Pain VAS (Range)	20 (0–90)	16 (0–98)	0.916

NOTE: Mann Whitney test used for P value.

Table 5.

Satisfaction Ratings at 12 Months Post-Surgery.

1 Year Satisfaction Rates	Navigated (n = 88)	Conventional (n = 84)	P Value
% Very Satisfied	64	56	
% Satisfied	26	30	
% Don't Know	7	6	0.34
% Unsatisfied	1	5	
% Very Unsatisfied	1	3	

Accuracy Study

There was no statistically significant difference between the two groups in accuracy of placement of either the femoral or tibial component in the coronal plane (Fig. 2 and Fig. 3). Nor was any significant difference observed between the accuracy of placement in the sagittal plane (Fig. 4 and Fig. 5) or the axial plane (Fig. 6 and Fig. 7).

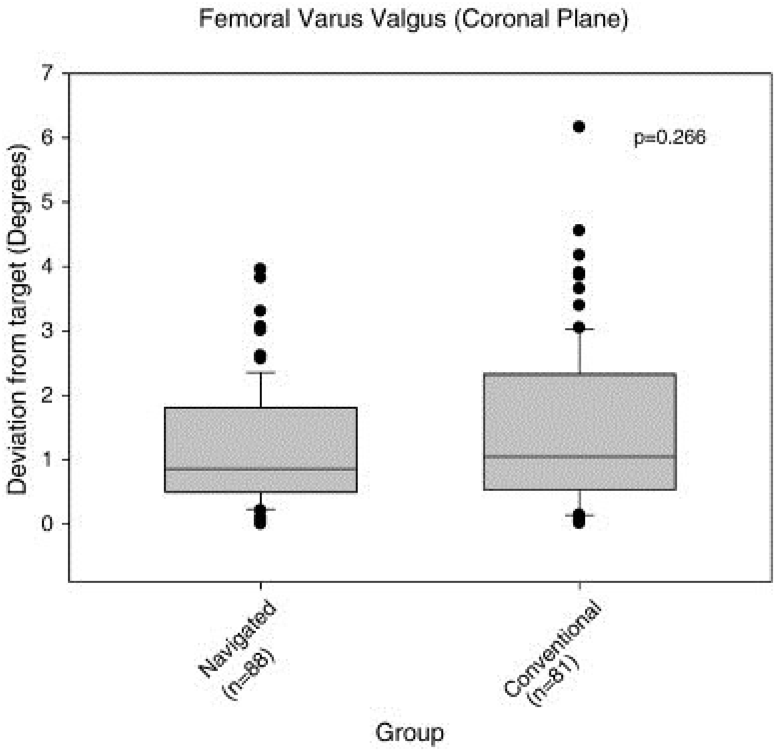

Fig. 2.

Femoral coronal alignment deviation from target.

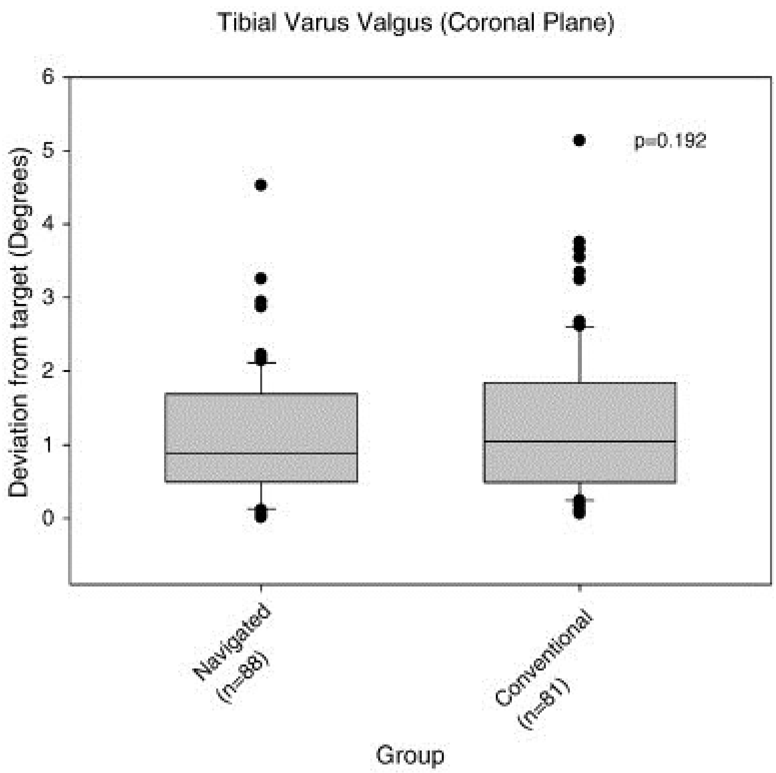

Fig. 3.

Tibial coronal alignment deviation from target value.

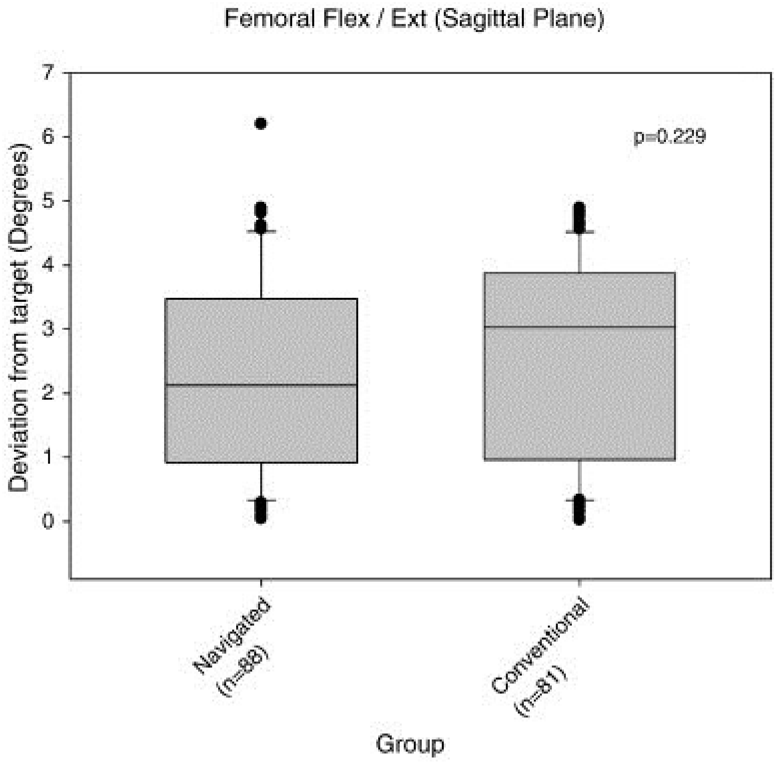

Fig. 4.

Femoral sagittal alignment deviation from target value.

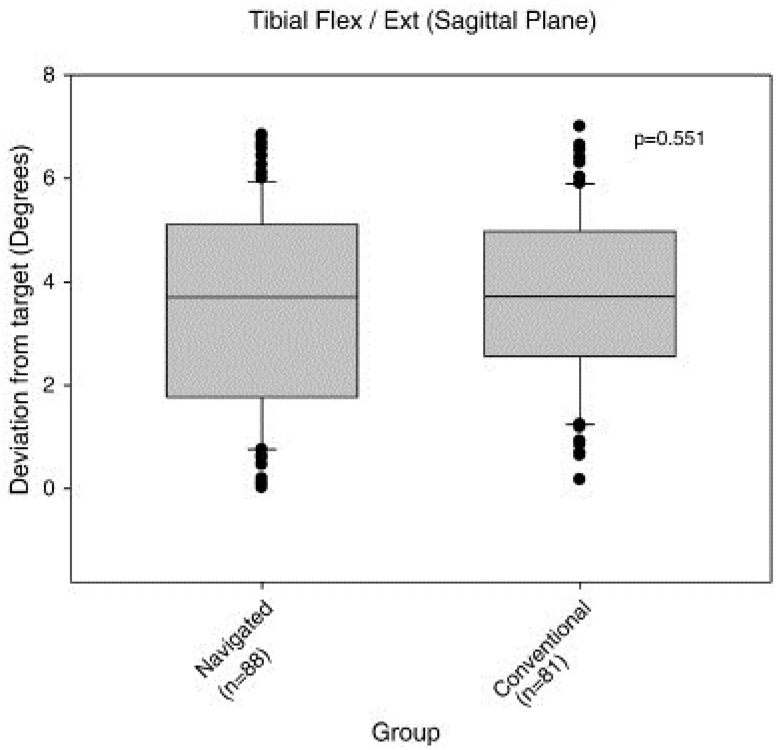

Fig. 5.

Tibial sagittal alignment measured from CT scans.

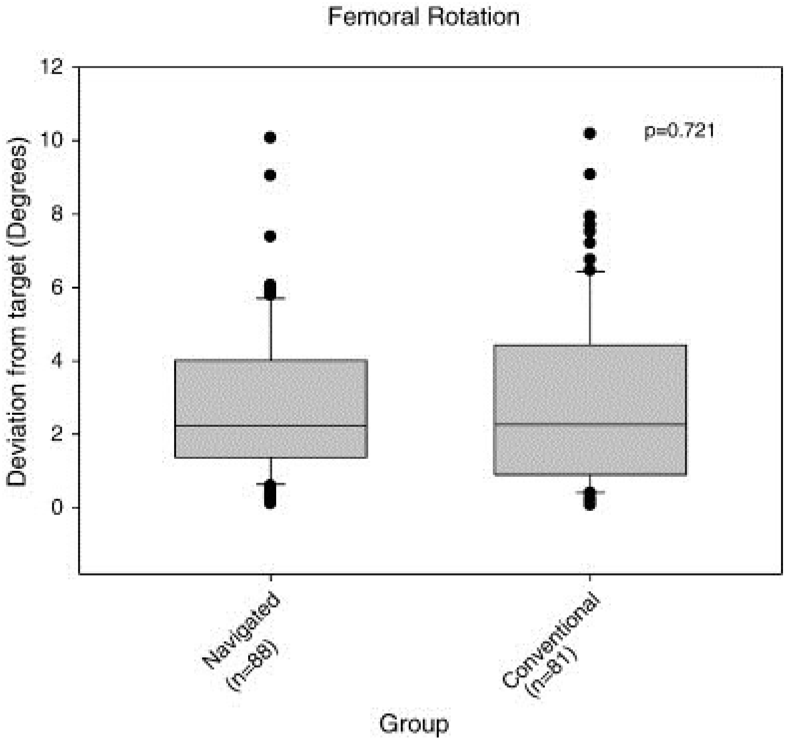

Fig. 6.

Femoral rotation deviation from target value.

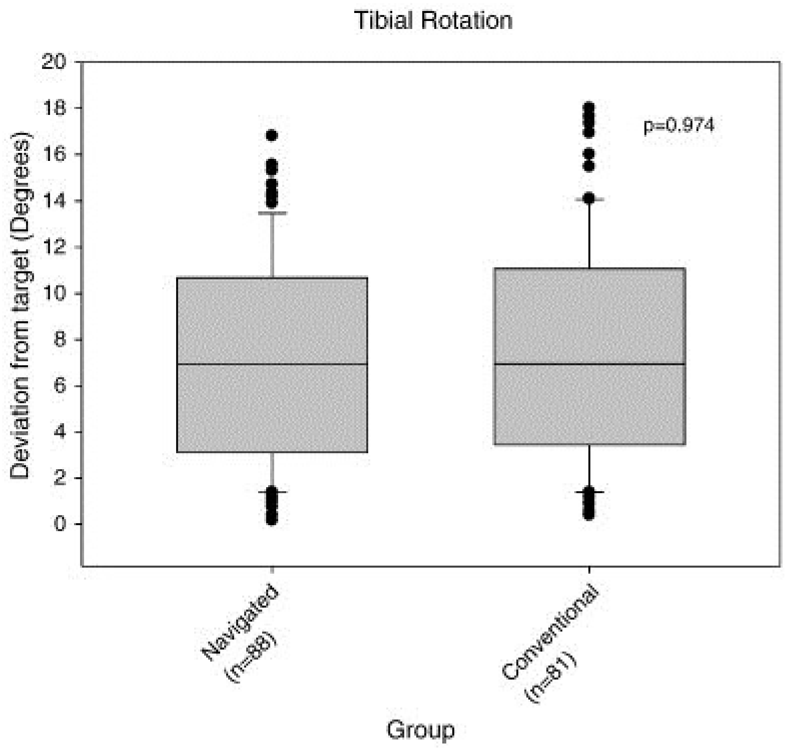

Fig. 7.

Tibial rotation deviation from target value.

92% of navigated and 85% of conventional mechanical axis alignments were within the desired range of 0°–3° of neutral (Fig. 8). Although there was an improvement in the overall accuracy of mechanical axis alignment in the navigated group, it did not reach statistical significance (P = 0.063).

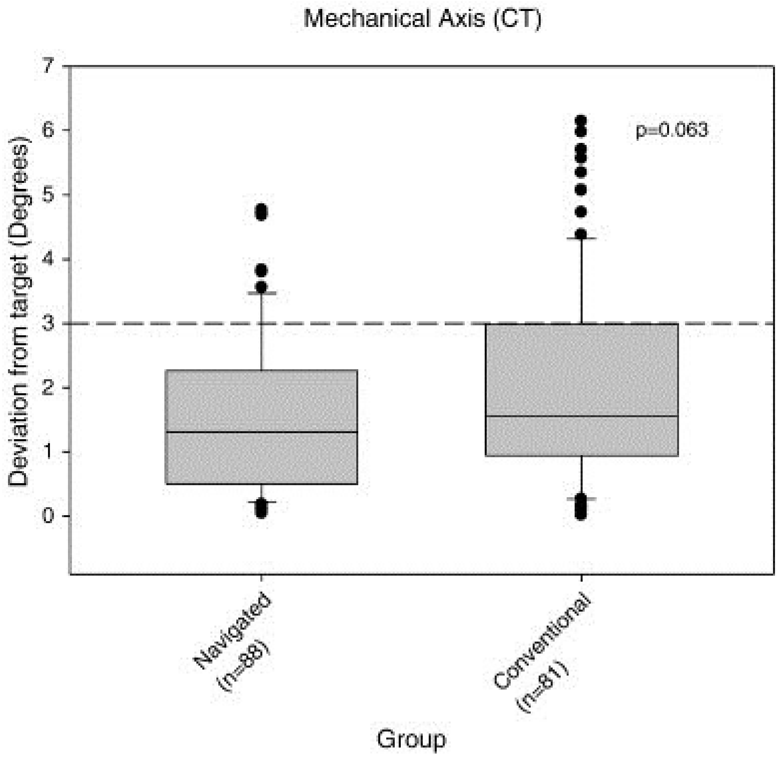

Fig. 8.

Post operative mechanical axis alignment — deviation from target value of 0° (measured from CT scan). Dotted line represents the 3° target window for the mechanical axis.

Complications

Complications were low in both groups. There was only one deep infection in the study in a patient in the conventional group. In the conventional group there has been one revision surgery for deep infection and one patient required a MUA at 4 months post operation. There were similar numbers of proven thromboembolic complications (navigated = 2, conventional = 2). This was reassuring in view of the longer surgical time observed in the navigated group. In keeping with the similar drops in hemoglobin between the 2 study groups, transfusion was required in 11 patients in the navigated group and 8 patients in the conventional group. There were no complications specific to the femoral and tibial reference array used in the navigated group.

Discussion

This study is the first to report the results of electromagnetic navigation in total knee arthroplasty in a randomized controlled study. The results have failed to show any benefit in clinical or radiological outcome using navigation compared with conventional techniques.

A slightly longer incision was employed in navigated surgery. This is likely to have occurred as a distal extension of the wound was required to insert the tibial array. The 1 cm of additional length is unlikely to be of any clinical significance however.

There was no reduction in hemoglobin loss with navigated surgery. The avoidance of intra-medullary instrumentation has been suggested as a mechanism to reduce blood loss [17] and cerebral emboli [28]. In the conventional group we used intramedullary instrumentation in the femur only and used a bone plug to occlude the end of the femoral canal which might explain the failure to observe any difference in change in post-operative hemoglobin.

Complications remained low in both groups however, with no increased rate of infection from the increased tourniquet time in the navigated group. A previous meta-analysis [29] suggests that increased operative times for navigated surgery in total knee arthroplasty are 20 min on average; slightly longer than our increase of 15 min. Some of our increased time was associated with data collection for the study to assist in post-operative analysis but the majority results from array insertion, landmark registration and inevitable, although uncommon software glitches. This increase in surgical time allied to the additional costs of hardware, software and disposables required to carry out the surgery all put pressure on navigation techniques to deliver better surgical outcomes 11., 14., 15., 16., 17., 19., 30., 31., 32., 33., 34., 35. and 36..

Although a slight reduction in mechanical axis outliers was seen in patients post-operatively at 3 months, this failed to reach statistical significance. This in part may be due to the good results seen with conventional techniques with 85% of cases within the 3° desired range. Our power calculation had been based on conventional techniques achieving implantation within the 3° window in only 78% of cases. Based on our actual study results we would have required 463 patients per group to detect a statistically significant 7% difference, with a power of 90%. Other potential reasons for the failure of the navigation system to achieve significantly better post-operative alignment might lie with the single point landmark registration system employed, with errors in landmark registration creating errors in the software algorithms. Our assessment of overall accuracy of implantation of both femoral and tibial components in the sagittal, coronal and axial planes revealed no significant increase in accuracy achieved using navigation compared to conventional instrumentation in any of these individual parameters. Again this may in part be due to single point registration system and it is possible that other registration techniques may provide more accurate navigation and consequently greater precision in implant placement.

A potential weakness of our study is the methodology used to measure tibial rotational errors. There is no universally accepted methodology for measuring tibial rotation. We have used as a reference a line drawn from the geometric center of the tibia to the center of the tuberosity as previously described by a number of authors 26., 27., 37. and 38.. However, other authors have argued that use of the tibial tuberosity may give rise to errors as the position of the tuberosity is variable [39].

Deflection artifact with electromagnetic systems in an in vitro study has been suggested in the presence of ferrous materials within 10 cm of the localizer and is another potential source of system error [25]. Our experience was that in the presence of ferrous materials the system would go 'blind' and prior to loss of signal, no unexplained change in the system readout values was noted. Other in vitro and in vivo studies looking at the results of electromagnetic navigation have confirmed that system accuracy is not problematic, with good results comparable to infra-red systems 35.,

40. and 41.. Two clinical studies have compared the electromagnetic technique directly with traditional infra-red navigation systems and found similar, high degrees of accuracy 42. and 43., although the numbers in these studies were small. Our much larger study has demonstrated good results with EM navigation, comparable with other optical systems. Dutton et al have previously reported 92% of patients achieving post-operative mechanical axis alignment within 3° of neutral, Johnson et al 96% and in a meta-analysis of 29 studies Mason et al reported 91% 44., 45. and 46..

Although improvements in alignment have been demonstrated to be correlated with improvements in implant survivorship in some studies 47., 48. and 49., improvements in function with navigation have been harder to prove. This is possibly because the differences in alignment seen over conventional surgery are not great enough. Our study reinforces others in the literature with no difference seen in any of the patient centered, knee specific or general health measures used.

Improvements in the outcomes of knee arthroplasty surgery are needed however as our study results mirror the majority of others, with some 12% of patients either unsure or dissatisfied with their surgery. Dissatisfaction following knee arthroplasty surgery is multifactorial however and it is perhaps simplistic to think that poor outcomes can be eliminated by surgical technique alone.

The advantages of navigation at the current time therefore remain unclear. A potential reduction in revision burden 10 years following arthroplasty surgery from a reduction in outliers is a difficult argument with which to engage health providers to justify increased costs of surgery, particularly in the current financial climate. The difficulty that navigation faces is that total knee joint survival in modern knee arthroplasties exceeds 97% at 10 years with aseptic loosening as the end point using conventional techniques 50. and 51. which is a difficult benchmark to surpass. Indeed a recent study by Kim in 520 patients comparing navigated and conventional techniques in simultaneous bilateral total knee arthroplasties in the same patient revealed greater than 98% survivorship for both groups at a mean of 10 years [52].

Work has been done to promote the teaching and training benefits of navigation 53. and 54., but its value in routine total knee arthroplasty surgery remains under scrutiny.

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