

Electromagnetic Navigated Versus Conventional Total Knee Arthroplasty – A Five Year Follow-up of A Single-Blind Randomized Control Trial

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1. Introduction

The utilization of computer navigated surgery remains a controversial topic with little evidence to support its wider implementation in theatres. A number of studies have demonstrated that navigation improves mechanical alignment to within 3° of the neutral mechanical axis with a reduction in outliers. Although improved implant survivorship [1–4] has been demonstrated in implants placed within a 3° window from neutral, the causal relationship between computer navigation and improved survivorship in total knee arthroplasty (TKA) has been harder to prove. Data from the Australian Joint registry has demonstrated improved survivorship in younger patients following knee arthroplasty implanted using computer navigation, but these data do not allow for surgeon expertise, case volume and case mix [5]. Studies to date have also failed to demonstrate an improved clinical outcome in terms of patient reported outcome measures (PROMs) [6]. A meta-analysis performed by Panjani et al. (2003) assessed 18 studies and 3060 knees finding “limited evidence” that navigation improves functional outcome at 5 - 8 years follow-up [7].

In this current study, the iNav electromagnetic (EM) navigation system uses small reference frames attached to the femur and tibia that are incorporated into the primary surgical incision, thus avoiding the need for additional pin site incisions and drill holes in the femur and tibia that are used for reference arrays in infrared optical systems. This reduces the potential for pin site infection and/or periprosthetic fracture which has been highlighted in other studies [8]. Additionally, this system was developed to overcome the line of sight issues and the tracker-ball contamination which is often seen with infrared navigation systems.

The primary outcome of this clinical trial was to assess the accuracy of implantation of components comparing the iNav EM system in TKA versus conventional techniques. Secondary outcomes were clinical patient reported outcomes measures (PROMs) and complications. Previously, we have demonstrated that at 1 year follow-up there was; no statistically significant difference in the percentage of knees placed within $\pm 3^\circ$ of the neutral mechanical axis, no difference in femoral or tibial component rotation in the coronal, sagittal or axial planes as assessed by CT scan, and no statistically significant difference in PROMs or complications or other adverse events [9]. The only difference between the navigated and conventional groups was the increased tourniquet time seen in the navigated group which had no subsequent negative clinical effects.

We did observe that 40% of navigated participants and 26% of conventional TKA participants were within $180^\circ \pm 1^\circ$ of neutral Hip Knee Ankle Alignment (HKAA) ($p=0.043$) but the clinical benefit of such tight accuracy has not been demonstrated to our knowledge in previous studies.

In this manuscript, we present the 5 year follow-up PROMs following navigated and conventional TKA and provide evidence that navigated surgery reduces the rate of revision surgery.

2. Methods

2.1. Participants

Patients were identified by members of the research team from the Glasgow Royal Infirmary TKA surgical waiting lists. Patients were invited to participate if they had osteoarthritis of the knee suitable for TKA; were able to provide informed consent; were aged 18 or over. There were no specific limits imposed on the degree of preoperative coronal or sagittal deformity.

2.2. Randomisation

Overall 272 patients were screened and between July 2007 and August 2010. Of the 272 screened patients, 14 were excluded for other medical reasons, while 58 participant decided that they did not want to participate in a research study. The remaining 200 patients recruited and consented to the study giving a recruitment rate of 74% (Figure. 1). Patients were randomised in a 1:1 ratio to either conventional TKA or navigated TKA using a web-based computer generated random number table. Randomisation was based on the order of their recruitment and stratified to by surgeon to prevent surgeon bias and ensure that similar numbers of patients in each groups were allocated to each

surgeon. Randomisation was successful in assigning equal preoperative patient demographics between the groups. [9]

2.3. Ethical Approval

The study was approved by the Glasgow Royal Infirmary Local Ethics Committee and the University of Strathclyde Ethics Committee (07/S0704/6) and approved by NHS GGC R&D department prior to commencement of the study.

2.4. Surgical Procedure

All patients received a cemented posterior stabilized NexGen LPS Flex (Zimmer, Warsaw, Indiana, USA). Participants randomised to the conventional group received a TKA implanted using standard instrumentation whilst those randomised to the navigated group had surgery using the iNav EM navigation system (Medtronic, Minneapolis, MN, USA). The iNav EM system is imageless and uses small reference frames attached to the femur and tibia which are readily incorporated in the primary incision. There is then a process of joint registration which maps the surface anatomy of the joint. All surgery including joint surface registration was carried out by, or under the direct supervision of, one of two knee arthroplasty surgeons. Alignment targets were similar in both groups with a neutral hip-knee-ankle alignment (HKAA) and the aim to implant both femur and tibial components perpendicular to this in the coronal plane. The post-op HKAA for both groups were; Navigated TKA = $179.8^{\circ} \pm 2.0^{\circ}$ (175.2° - 184.7°) and Conventional TKA = $179.7^{\circ} \pm 2.5^{\circ}$ (173.8° - 185.9°), with 92% of Navigated and 85% of Conventional TKA patients achieving $180^{\circ} \pm 3.0^{\circ}$, and 40% of Navigated and 26% of Conventional TKA patients achieving $180^{\circ} \pm 1.0^{\circ}$ as measured by CT. [9]

Ligament balancing was carried using clinical assessment during the surgical procedure in both groups. In the navigated group additional information was provided by the system with real time feedback of the gap in mm between the femoral and tibial component and of the overall HKAA during varus and valgus stress.

2.5. Patient Reported Outcome Measures and Revisions

Patients were followed up to five years (Navigated TKA; n = 66 and Conventional TKA; n = 61), with clinical assessments by a blinded independent assessor; range of motion was determined using a hand-held goniometer, and knee specific outcome measures included the American Knee Society Score (AKSS)

and Oxford Knee Scores (OKS) and the SF 36 score used as a general health measure (both Physical and Mental).

Revision surgery was also assessed by analysing the Scottish PACS Global Worklist. This image archiving system stores all imaging for patients undertaken in the National Health Service (NHS) in Scotland since 2008. It acts as a valuable resource for identifying patients lost to follow-up who have undergone revision surgery in other NHS hospitals in Scotland which may have not been identified.

2.6. Statistics

The primary outcome measure for this study was alignment within 3° of neutral at 3 months following surgery. In order to detect a difference of this magnitude with a power of 90% at $\alpha = 0.05$, the initial power calculation indicated that we required 82 patients per group, 164 in total. A post-hoc power calculation, based on the secondary endpoint of OKS at 5 years, suggested that a sample size of 58 per group was required to detect a 5 point difference with a power of 80%. Over the 5 year period, there has been a 34.6% and 37.7% LTFU rate in the navigated and conventional groups, respectively (Figure 1). Paired t-tests were performed to compare the change in each outcome measure from 1 year to the 5 year, as well as comparing the difference between navigated and conventional groups overall at 5 years (Table 1). In addition to this, a Kaplan Meir survivorship graph has been created to compare the all cause revision rates between navigated and conventional TKA surgeries which was analysed using a Mantel-Cox Log Rank test on GraphPad Prism (v6).

3. Results

3.1. Clinical Outcomes

In both treatment groups, OKS, AKSS Knee Score and Range of Movement improved over time and this improvement was statistically significant between 1 year and 5 year follow-up (Table 1). The pre-operative demographics of these patients were previously reported [9] and there were no significant differences in pre-operative scores between the Navigated and Conventional TKA in the 5 year follow-up cohort (data not shown). Interestingly, the SF-36 and AKSS Knee Function scores showed no significant improvement over the same time period. Importantly, no statistically significant difference in any of the clinical outcome measures for navigated versus conventional TKA at the 5 year time point (Table 1) were observed.

3.2. Revision Rate

In the 5 years following surgery, there were three revision surgeries performed. All of these were in the conventional group (4.9%); two were for deep infection and one was for instability (Figure 2) with no revision surgeries in the navigated group (0%). This difference in revision rate failed to reach statistical significance ($p = 0.08$). The revision for instability was carried out for symmetrical flexion instability with no obvious malalignment seen in any of the 3 femoral and 3 tibial planes measured on post-operative CT scans. No additional revision surgeries were identified in the original cohort from the analysis of the PACS Global Worklist.

4. Discussion

This prospective randomised controlled trial is one of only a handful of studies to publish clinical outcome data comparing EM navigation with conventional TKA surgery. In 2019, Cho et al (2018) published a retrospective analysis of 40 knees, comparing conventional techniques with EM navigation and demonstrated an improvement in KSS score and ROM at 8-10 year follow up [10]. However, this small retrospective study is alone in demonstrating long term benefits of EM navigation as other studies utilising navigation have failed to find any significant clinical benefit from utilisation of the technology [5,11,12].

Previously, our study showed that tourniquet times were significantly longer in the navigated group (median 80 vs 65 minutes, $p = 0.001$) compared with conventional surgery[9]. This increase in surgical time associated with navigated surgery does not appear however to have increased the infection rate or length of stay in keeping with other studies [13,14]. Additionally, navigation did not appear to affect long term PROMS as there were improvements in most clinical outcome measures between 1 and 5 years (ROM, OKS, AKSS Knee Score) in both the conventional and navigated groups in keeping with normal recovery following surgery. However, no differences in clinical function between surgical interventions were observed suggesting that both treatments provide equivalent clinical outcomes up to 5 years following surgery.

The rate of all-cause revision at 5 years was higher in the conventional group, but it is difficult to be certain of the role of navigation in this difference. Two of the revisions were for infection (one late, the other haematogenous) and overall the numbers involved are too small to draw any meaningful conclusions. Although longer follow-up beyond 10 years might demonstrate differences in late failures from causes such as aseptic loosening, we are not optimistic that the use of navigation in this study will prove beneficial given the similar coronal alignment seen between the two groups post-operatively.

The largest outcome study looking at revision rates and the contribution of navigation comes from the Australian Registry [5] and which showed a decrease in revision rates in patients under the age of 65 who underwent navigated versus conventional TKA, (with evidence of aseptic loosening/lysis). In contrast data from a Norwegian Registry study [15] has shown an increased revision rate at a mean follow up time of less than 2 years in computer assisted TKA.

In conclusion this study has shown no difference in clinical outcomes comparing conventional versus EM navigation TKA at 5 years follow-up. Although an increase in revision rates was seen in patients undergoing conventional surgery, a causal link with navigation is difficult to prove and unlikely. The results of this study apply to surgeons with experience in knee arthroplasty and we are unable to determine whether navigation may be helpful in less experienced hands. Given the increased costs associated with navigated surgery, evidence for the routine use of navigation in TKA remains difficult to justify at the current time.

5. Acknowledgements

N/A

6. Author Contributions

M.B., B.J., and P.R. conceived the study and were involved in planning the study. P.M. conducted follow-up appointments on all patients. S.O'D, and J.D. carried out the data management and trial oversight. A.C., A.H., J.D. and M.B. contributed equally to the writing of the manuscript and all authors were involved in reviewing the manuscript prior to submission.

7. Conflict of Interest

The authors declare no competing interests.

8. Funding Source

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9. Figures

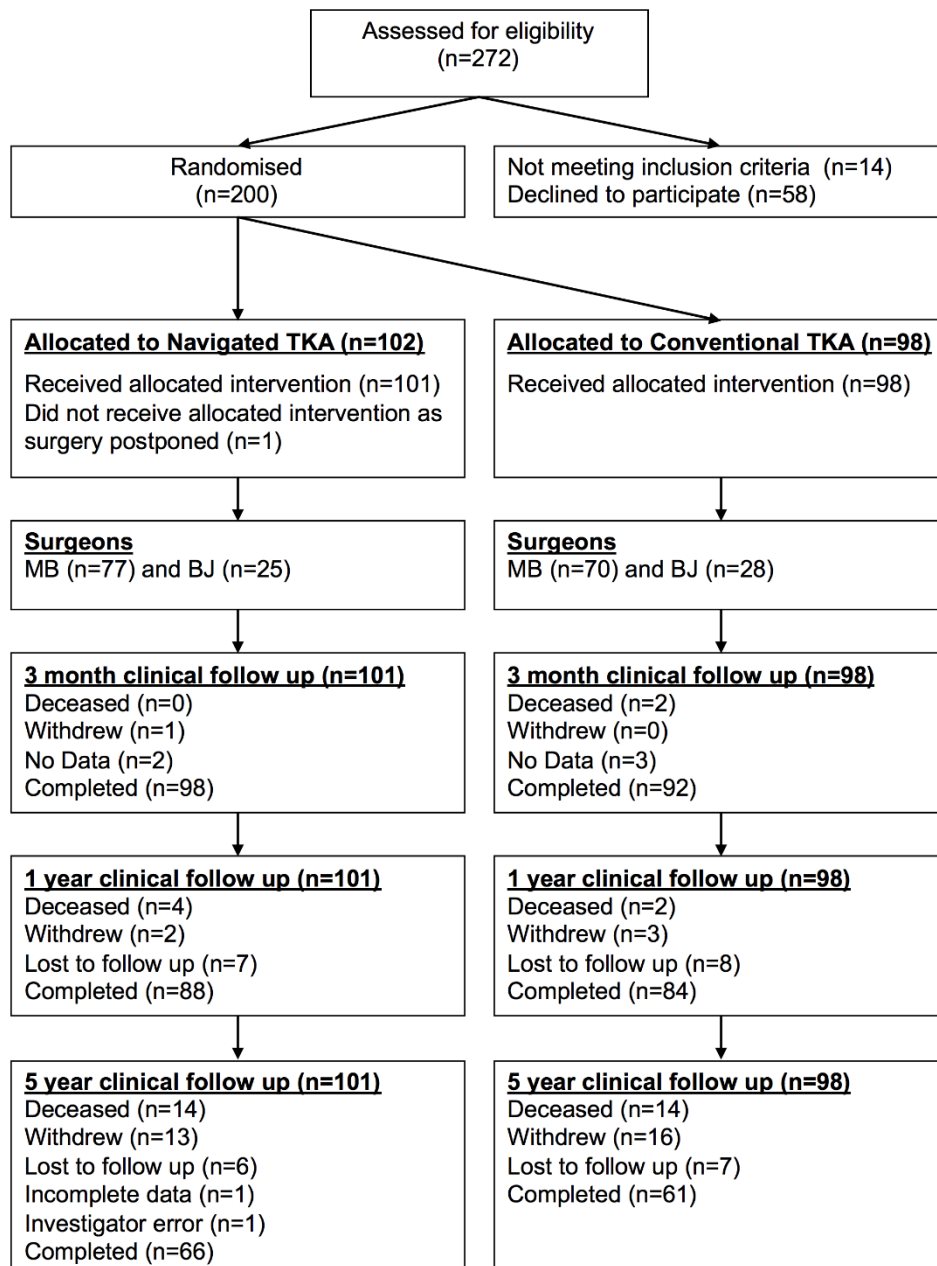


Figure 1 - CONSORT (Consolidated Standards of Reporting Trials) Flow Diagram demonstrating the flow of patients through the randomised clinical study.

Parameter	Navigated TKA			Conventional TKA			5 Year Comparison
	1 year (n=88)	5 year (n=66)	p values	1 year (n=84)	5 year (n=61)	p values	p values
ROM	110 (80-135)	120 (90-135)	0.001	110 (75-135)	120 (80-135)	0.001	0.77
Oxford	34 (12-48)	37 (5-48)	<0.001	36 (5-47)	38 (10-47)	<0.001	0.46
AKSS - Knee Score	85 (33-95)	93.5 (60-100)	<0.001	86 (32-100)	94 (34-100)	<0.001	0.35
AKSS - Function	70 (15-100)	65 (50-100)	0.13	65 (0-100)	70 (15-100)	0.33	0.3
SF36 Physical	53 (3-99)	38.6 (3.7-93.7)	0.34	46 (9-96)	49.37 (5-92.5)	0.26	0.19
SF36 Mental	69 (18-100)	69.5 (5-98.7)	0.34	70 (15-97)	75.6 (0-100)	0.38	0.32

Table 1 – Patient Reported Outcome Measures at 1 and 5 year’s following Navigated or conventional Total Knee Arthroplasty. Paired t tests comparing 1 and 5 year outcomes in each group, and two-tailed t-tests were used comparing 5 year outcomes between navigated and conventional groups were performed using GraphPad Prism v6.0. Data shown represents median (and range), and a p value of < 0.05 was deemed significant.

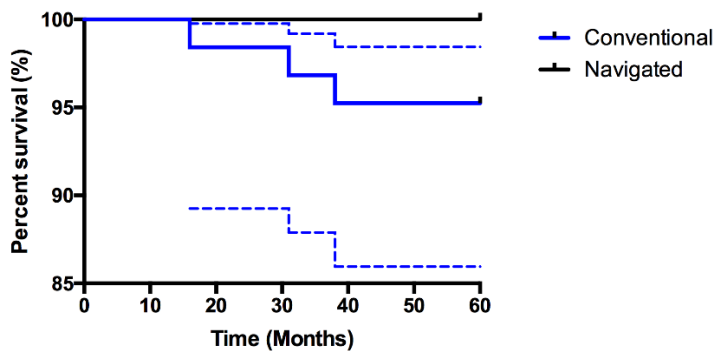


Figure 2 – Kaplan-Meier survival curve with 95% Confidence Intervals for Total Knee Arthroplasty revision rate at 5 years following surgery comparing navigated (0% - 0/66 patients) versus conventional surgery (4.9% - 3/61 patients).

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