



Improved joint awareness two years after total knee arthroplasty with a handheld image-free robotic system

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Literature into the short-term follow-up of total knee arthroplasty (TKA) using a handheld image-free robotic system are scarce. The purpose of this study was to compare the clinical outcomes and patient-reported outcome measures (PROMs) between patients operated for TKA with an image-free robotic system (robot group) or conventionally TKA (conventional group) 2 years postoperatively. A total of 147 patients were evaluated after TKA, respectively 73 in the robot and 74 in conventional group. Outcome measures included adverse events (AEs), hospital readmission rate, patient satisfaction and the following PROMs: Pain Visual Analogue Score (VAS), Oxford Knee Score (OKS), Forgotten

Joint Score Knee (FJS-12) and the EuroQOL-5D (EQ-5D). There were no statistically significant differences in the number of AEs; 8 (10.8%) in the conventional group versus 7 (9.7%) in the robot group. The FJS ($p \leq 0.05$) and OKS ($p \leq 0.05$) differed statistically in favour of the robot group. The EQ-5D and EQ-5D VAS did not statistically differ between the groups ($p=0.231$ and $p=0.373$ respectively). The VAS pain improved statically significant in both groups when comparing the pre- and postoperative values (5.8 points). Patients operated with a handheld image-free robotic system have the ability to forget their artificial knee joint in

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everyday life as measured with the FJS-12 at short-term follow-up.

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(1, 2)

INTRODUCTION

The development of surgical techniques during the past decades focussed on a way to produce more accurate placement of TKA components (1, 2). Robot-assisted surgery has been developed with the aim to help the surgeon with a more accurate component placement and an increased patient satisfaction (3-5). The NAVIO, a semi-autonomous robotic sculpting system allows for perioperative implant positioning without the need for preoperative imaging. Intraoperative evaluation makes it possible to adjust soft tissue balancing and bony alignment. This study is a continuation of previous published paper in which statistically significant less outliers were found regarding the patients operated with an image-free handheld robotic sculpting system for TKA (5). Whether this results in better clinical outcomes and improved patient satisfaction, remained to be investigated. Since kinematics of robotic TKA should be more comparable to normal knee function in theory, it is questioned whether these patients have the ability to forget their artificial joint in everyday life (6-8). In 2012, the 12-item Forgotten Joint Score questionnaire introduced a new aspect of PROMs: this is a self-administered questionnaire, specifically established for postoperative joint arthroplasty. No results are available showing that patients actually forget their artificial knee joint after robot-assisted TKA. Therefore, the objective of this study was to demonstrate that patients who were operated with use of a robot-assisted TKA have comparable or improved joint awareness when compared with patients operated with conventional TKA. The following research question was formulated: will patients operated with robot-assisted TKA forget their artificial knee joint in daily life after 2 years follow-up when compared to conventional TKA? It was hypothesized that there would be no difference in knee joint awareness and PROMs between both surgical techniques 2-years after TKA.

MATERIALS AND METHODS

This single-center retrospective case-controlled cohort study included a consecutive series of patients operated between May 2018 and March 2019 (St. Trudo Hospital, St. Truiden, Belgium) with an image-free handheld robotic system (NAVIO Surgical System, Smith & Nephew, Memphis, USA) for total knee arthroplasty (TKA). These series were matched on gender, age, type of implant (Journey II/Genesis/Legion, Smith & Nephew, USA) and follow-up time with a cohort of patients operated with conventional intramedullary rods. All TKA procedures were performed by 2 experienced knee surgeons (PB and JM), both performing a minimum of 150 TKA procedures annually. Baseline conditions, surgical procedure, perioperative outcome (e.g. operation time, blood loss) and postoperative protocol were described in detail in previous publication (5).

At the 2-years FU all patients were asked to complete the following four patient-reported outcome measures (PROMs): the 12-item Oxford Knee Score (OKS; 12–60, 12 being the highest score) (9), the Visual Analogue Scale for pain (VAS-pain; 0–10, 0 representing no pain), the EuroQoL-5D questionnaire (10) and the 12-item Forgotten Joint Score (FJS-12) (6). The FJS-12 identifies awareness of an artificial joint (hip or knee) during various daily life activities. High scores indicate a high degree of “forgetting” the artificial joint, that is, a low degree of awareness (0–100, 100 being the highest score). Other outcome measures evaluated included (serious) adverse events ((S)AEs), hospital readmission rate, patients were asked if they would undergo surgery on the contralateral side again (yes or no) and if they had an altered mental state during the last months (yes or no) which could impair their subjective findings.

Ethical approval was obtained by the Independent Local Medical Ethical Review Board (Nr. STZH/319). This study was conducted according to the principles of the Declaration of Helsinki (2013) and in accordance with the Medical Research Involving Human Subjects Act.

The statistical analysis were performed with the use of SPSS version 24.0 software (SPSS Inc., Chicago, USA). Statistically significant differences between both groups were analyzed with

independent-samples T-test, since data were normal distributed. Chi-square test was used for categorical variables. Effect size (i.e., Cohen's *d*) was calculated for the 2-year FJS-12, according to Kazis (11). An effect size of 1.0 is equivalent to a change of one SD in the sample, which is considered to be a very large change, and an effect size of 0.8 is considered to be large, 0.5 is moderate, and ≤ 0.3 is small. For all analyses, a *p*-value was considered to be statistically significant different at $p \leq 0.05$. Results are presented as either with mean with a standard deviation (SD) or proportions (%).

RESULTS

A total of 73 patients who were operated by means of robotic assisted TKA (robot group) for end-stage knee osteoarthritis were included out of 77. After

a 2-year follow-up, 4 patients were excluded. We were unable to contact 2 patients, the other 2 did not wish to participate. A number of 74 patients who had been operated with the conventional technique using intramedullary rods (conventional group), were included out of 77. One patient was excluded because of a recent total hip arthroplasty at the ipsilateral side which made subjective evaluation impossible. The other 2 patients did not wish to participate. This formed a total cohort of 147 patients.

A statistically significant difference for the FJS-12 ($p \leq 0.05$) and OKS ($p \leq 0.05$) was found in favor of the robot group. There were no other statistically significant differences regarding the EQ-5D and VAS pain (delta VAS pain pre- and postoperative). The PROMs are summarized in Table I. Patients in both the robot and conventional group showed high levels of satisfaction, and would undergo surgery

Table I. — Mean score of the patient reported outcome measures at 2-year postoperative evaluation

	Conventional instruments (N=74)	Robotic instruments (N=73)	P- value
FJS-12	56.4 (19.4)	75.6 (25.8)	<0.000
OKS	39.6 (7.0)	44.0 (6.0)	<0.000
EQ-5D	0.899 (0.107)	0.920 (0.100)	0.231
EQ-5D VAS	74.5 (9.3)	76.1 (13.0)	0.373
VAS pain delta*	5.8 (2.0)	5.8 (1.9)	0.932

values are given as a mean, with the standard deviation in parentheses. FJS-12=Forgotten Joint OKS: Oxford Knee Score, EQ-5D: EuroQoL-5D questionnaire, EQ-5D VAS: EuroQoL-5D visual analogue scale score, VAS: Visual Analogue Scale. * VAS pain delta: pre- and postoperative difference in pain.

Table II. — Baseline demographics and outcomes

	Conventional instruments (N=74)	Robotic instruments (N=73)
Age in years (SD)	68.9 (8.6)	69.6 (9.7)
Sex, male (%)	32 (43.2)	31 (42.5)
Operated side, right (%)	42 (56.8)	40 (54.8)
AE (%)	8 (10.8)	8 (10.9)
Hospital readmission (%)	3 (4.1)	4 (5.5)
Satisfied with TKA (%)	68 (91.9)	72 (98.6)
Would do surgery again (%)	65 (87.8)	62 (84.9)
Altered mental state of mind during the last months (%)	0	8 (11)

AE; adverse events, TKA; total knee arthroplasty

again. Patient demographics and outcome data at 2-years follow-up are shown in Table II. The effect size of the FJS-12 was high (0.8) at short-term FU.

In the conventional group, a number of 5 patients required postoperative transfusion. A further 2 developed a superficial wound infection. One patient developed a Sudeck's dystrophy or complex regional pain syndrome (CRPS). In the robot group, 3 patients required postoperative transfusion. Two patients developed a transient injury to the peroneal nerve. One patient experienced a secondary bleeding and 2 patients developed a significant mobility deficit which required mobilisation under narcosis. There were 3 patients who were readmitted in the conventional group (4.1%), 2 patients were admitted for extensive pain and/or nausea which required intravenous analgesia. One patient was admitted for a wound problem which required superficial debridement. In the robot group there were 4 readmissions (5.5%), 2 patients were readmitted for extensive pain and/or nausea which required intravenous analgesia. The other 2 patients were readmitted for heavily restricted motion which required mobilization under narcosis.

DISCUSSION

The most important finding of the present study is the statistically significant improved joint awareness in the robot group compared to the conventional group at 2-years postoperatively as measured by the FJS-12 and the OKS. In contrast, the VAS pain and EQ-5D did not show significant differences. The null hypothesis stating there would be no difference between the 2 groups at 2 years was therefore rejected.

In the past, the high level of patient dissatisfaction reported after TKA, up to 20%, was contributed to inaccurate implant positioning, joint line restoration and/or limb alignment (12-15). However, recent studies found no significant effect of component and/or limb malalignment on PROMs after TKA (16-18). Robotic TKA already showed more accuracy for the planned placement of TKA components and limb alignment when compared to conventional TKA (5,7,19). But in previous studies, this ability of robotic TKA for accurate implant positioning has not produced any

differences in the middle- or long-term clinical and functional outcomes when compared with a conventionally placed TKA (7, 20-22).

With the FJS-12, we are able to evaluate the concept of joint awareness or the ability to forget the artificial joint in daily life (6). Following TKA, the FJS-12 and thus joint awareness is mainly affected by pain in the initial months, later followed by quadriceps strength during the long-term follow-up (23). As shown for unicondylar knee arthroplasty, less invasive surgical approaches with minimal bone resection and less soft tissue dissection preserve proprioceptive fibers and result in better joint awareness compared with TKA (24-26). In the same way, robotic surgery for TKA allows for optimal preservation of the periarticular soft tissue envelope, possibly causing less inflammation and postoperative pain. It combines patient-specific intraoperative dynamic soft tissue balancing and implant positioning. This personalized hybrid alignment of the NAVIO could explain the good joint awareness. Although this was not studied in the present study.

We may not oversee the multifactorial nature of patient satisfaction. These include multiple preoperative, surgical and postoperative factors (27-29). For example, older patients often report better FJS-12 scores because of their lower demand for daily activities (30, 31). Likewise there is also a negative effect of a high BMI on the FJS-12 (30). Adequate patient selection and education to achieve realistic patient expectations remains very important for a good outcome (28, 29).

Furthermore, we found no statistically significant differences regarding adverse events. This is in line with other studies comparing robotic-assisted TKA placement with conventionally placed TKA (32).

To our knowledge, this is the first study reporting functional outcomes and PROMs at short-term follow-up after image-free handheld robotic surgery for TKA. The present study has indeed several limitations. First, there are no preoperative PROMs available (OKS and EQ-5D). This makes it impossible to follow the intra-patient evolution during the postoperative years. Secondly, it is a retrospective cohort study with relatively small groups, the findings in this study should therefore be

confirmed in a prospective randomized controlled trial with long-term follow-up focusing on function, PROMs and implant survival.

CONCLUSION

Based on the findings in the present study we can conclude that patients operated with a handheld image-free robotic system for TKA have the ability to forget their artificial knee joint in everyday life when compared to patients with conventional placed TKA two years after initial surgery.

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