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Mid-term effect of total knee arthroplasty with and without tourniquet use on prosthesis survival, complications and functional outcome: A prospective cohort study of 511 total knee arthroplasties

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ABSTRACT

Background: A tourniquet is often used to create a bloodless surgical field during total knee arthroplasty (TKA). It is still debated whether tourniquet use improves durability of cemented implant fixation and thereby prosthesis survival. Some studies showed tourniquet application has a negative impact on post-operative wound healing, pain and function, whilst other publications contradict this. However, no previous studies evaluated the effect of tourniquet use on prosthesis survival and mid-term functional outcome specifically.
Methods: In this longitudinal observational cohort study 115 patients (116 knees) undergoing TKA without tourniquet use were compared with 374 patients (395 knees) with a tourniquet. Prosthesis survival, revision risks and complications were analysed through chart review after a mean follow-up period of 5.3 years. Additionally, patient reported outcome measures regarding knee functionality and health status (PROMs; KOOS, OKS, EQ-5D, SF-12) were collected prospectively.
Results: Both groups had an equal overall re-operation rate of 4.3% and showed similar revision rates for aseptic loosening as well as for other causes. In the tourniquet group a higher complication rate (14.7% vs 10.3%) was observed. The majority was urinary retention requiring bladder catheterization. Both groups showed comparable, improved post-operative functional results compared to the pre-operative state for all PROMs at all time points.
Conclusions: In this study TKA without tourniquet use yielded similar mid-term results as TKA with tourniquet use with regard to prosthesis survival, reoperations, complications, knee functionality and health status.

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1. Introduction

During total knee arthroplasty (TKA) a tourniquet is frequently used to achieve a bloodless surgical field [1]. However, tourniquet use during TKA remains a controversial topic. Application of a tourniquet offers better visualization of the anatomical structures, and thereby facilitates the surgical procedure [2]. Moreover, supporters of tourniquet use cite less blood loss, shorter operative time [3,4] and more robust cementation [5] as possible advantages.

Others, state that the use of a tourniquet is associated with increased direct post-operative pain [6–8], reduced early range of motion of the knee [9], wound complications and an increased risk of thrombo-embolic events [10]. In support of these findings, a recent meta-analysis [11] showed low to moderate evidence that TKA with a tourniquet is associated with an increased risk of adverse events within 30 days post-operatively and potentially higher direct post-operative pain. Additionally, a recent RCT (randomized controlled trial) [12] reported on long-term functional outcomes after TKA without a tourniquet. In contrast to the present study, no results on quality of life, reoperations and revisions were included.

Traditionally exsanguination was thought to improve cementing quality, however, a number of more present-day RCT's using RSA (radiostereometric analysis) technique have not shown any difference in prosthetic micromotion or early loosening after TKA without tourniquet use [13–15]. This raises the question what effect tourniquet use in TKA has on the durability of cemented implant fixation. Although RSA is the golden standard of implant migration, and ultimately a predictor of later implant loosening, more data and a prolonged follow-up period are needed to validate these short-term RSA data [11,16,17].

Our aim was to evaluate the differences between primary TKA with and without tourniquet use on the 5 year cumulative incidence of revision surgery, other reoperations and complications. The secondary aim was to evaluate differences in functional outcome and quality of life in both groups during follow-up.

2. Materials and methods

2.1. Study design

This study comprises a longitudinal observational cohort study. All consecutive patients scheduled for primary TKA at the Alrijne Hospital from September 2014 to January 2016 were selected for inclusion in this study. Exclusion criteria were: revision knee arthroplasty, unicompartmental knee replacement, tumor or fracture prosthesis. All patients were operated by three senior knee surgeons. One surgeon always performed TKA without a tourniquet, while the other two surgeons performed TKA always with a tourniquet. Therefore, "surgeon" can be identified as an instrumental variable for analysis, thus two groups could be identified by this pseudorandomization: tourniquet and non-tourniquet [18].

2.2. Surgical procedure

The operations were conducted in a standardized protocol, using a midline skin incision, medial parapatellar approach and a measured resection technique. A standardized bone surface preparation and cementing technique (Pulsavac, Bone Cement R, Zimmer Biomet) was used by all surgeons. A cemented posterior stabilized high flex NexGen total knee prosthesis was used in all cases (Zimmer Biomet, Warsaw, Indiana, USA).

For patients who had surgery with the use of a tourniquet, the tourniquet was inflated immediately prior to the incision and deflated after the application of sterile compression bandages. The cuff was inflated 100 mmHg higher than the patient's systolic blood pressure.

All patients were treated with a standard rapid recovery protocol of pre-operative intravenous steroids, low dose spinal anesthesia, per-operative local infiltration analgesia, tranexamic acid, and a post-operative multimodal opioid-sparing pain protocol. No wound drains, urinary catheters or patient controlled analgesia pumps were used in any of these patients. Fraxiparin was used as deep venous thrombosis prophylaxis for 4 weeks in all patients.

2.3. Outcome parameters

All data regarding functional outcome were collected pre-operatively and 6, 12, 24 and 48 months post-operatively with a questionnaire. The data were obtained from the Longitudinal Leiden Orthopedic Outcome of Osteo-Arthritis Study (LOAS study). The LOAS study is an ongoing longitudinal cohort study, including patients scheduled to undergo primary THA or TKA in the Netherlands. All patients included in this study were invited to participate in the LOAS study. Functional outcome data of patients who participated in the LOAS study were combined with data obtained through chart review after a minimal follow-up period of 5 years.

The Knee Osteoarthritis Outcome Score (KOOS) and the Oxford Knee Score (OKS) were used to measure functional outcome and provide an assessment of limitations on different domains (daily living, sport and recreation, function, and health-related quality of life). More specifically, the validated Dutch versions of the KOOS and OKS (both ranging from 0 to 100, with higher scores indicating better functional outcomes) were used [19–21].

Clinically significant differences for the various PROMs were defined according to previously defined minimal important change values [22,23].

The validated Dutch versions of the Short-Form-12 (SF-12) and EuroQol 5 Dimensions (EQ-5D) were used to assess general health-related quality of life [24,25]. From the SF-12 the Physical Component Score (PCS) and Mental Component Score (MCS) were calculated (both ranging from 0 to 100, with higher scores indicating better outcomes) [26].

Missing data of the questionnaires were handled according to the suggestions in previous literature. At least 50% of the KOOS should have been completed to be included in the analysis [21]. If more than two items were missing in the OKS, items were excluded [27]. Only completed EQ-5D and SF-12 questionnaires were included in the analysis [28,29].

All other outcome measurements were extracted from the hospital electronic patient database system, after a minimal follow-up period of 5 years. All reoperations were recorded; a further distinction was made between reoperation due to infection, revision surgery and other reoperations (e.g. removal of loose bodies). A reoperation was defined as a revision surgery when a component was revised for aseptic loosening or other indications (e.g. component malrotation). In this study aseptic loosening was diagnosed according to the surgeon's clinical judgment, after thorough evaluation, including physical examination, (nuclear) imaging and laboratory evaluation.

2.4. Ethics approval

The study was approved by the local hospital review board. The patients who participated in the LOAS study (TRIAL ID NTR3348) provided informed consent. Ethical approval was obtained from the Medical Ethics Committee of Leiden University Medical Center (Protocol Number: P12.047, registration code NL39663.058.12).

2.5. Statistics

Demographic differences between the tourniquet and non-tourniquet group were evaluated with a Student's t-test in case of continuous variables or a chi-square test in case of categorical variables.

Descriptive statistics, stratified for tourniquet use were assessed to summarize the data with regard to the 5 year risk for revision surgery, reoperation and complications after primary TKA. The cumulative incidence for aforementioned outcomes was calculated for all included patients, including those deceased during follow-up, with the time at risk being 5 years. Linear mixed models were used to compare functional outcomes during a 4 year follow-up period after TKA between the tourniquet and the non-tourniquet group. Here we used a 2-level structure, i.e., repeated measurements were clustered within participants, to calculate the overall between-group differences. We did not adjust for confounding since we used an instrumental variable analysis, with surgeon as instrumental variable (i.e. pseudorandomization).

3. Results

3.1. Patient demographics

In this study 489 patients with a total of 511 total knee arthroplasty surgeries were included. The tourniquet group consisted of 374 patients (395 knees) with a mean follow-up of 5.3 (SD 0.4) years. The non-tourniquet group consisted of 115 patients (116 knees) with a mean follow-up of 5.4 (SD 0.4) years. The mean patient age of the total group was 68.1 (SD 9.1) years, 59.1% was female. There were no differences between groups for age, gender, BMI or ASA score (p = 0.84, 0.31, 0.97, 0.10, Table 1).

3.2. Revision surgery, reoperations and complications

With regard to cumulative incidence of revision surgery, reoperations and complications, results were comparable between both groups (Table 2, Table 3). In the tourniquet group 17 patients (4.3%) required reoperation, while five patients (4.3%) in the non-tourniquet group required reoperation. six patients (1.5%) in the tourniquet group needed revision surgery, of whom two patients (0.5%) underwent revision surgery due to aseptic loosening. In the non-tourniquet group three patients (2.6%) had revision surgery, one patient (0.9%) due to aseptic loosening.

In the tourniquet group 58 complications (14.7%) were observed, the majority of the complications were delayed wound healing (n = 17, 4.3%) and urinary retention which needed to be treated by bladder catheterization (n = 12, 3%). In the non-tourniquet group 12 complications (10.3%) occurred, of which delayed wound healing (n = 4, 3.5%) was the most frequent.

3.3. Patient reported outcomes

One hundred and eighty two patients participated in the LOAS study and completed the pre-operative PROMs, 144 in the tourniquet group (147 knees, 38.5%) and 38 in the non-tourniquet group (39 knees, 33%). The patients that participated in the LOAS study, and thus completed pre-operative PROMs, were younger and had a lower BMI when compared to the

Table 1
Demographics.

Characteristics	Tourniquet (n = 374, 395 knees)	Non-tourniquet (n = 115, 116 knees)	p value
Gender (n,%)			0.31
Male	118 (29.9%)	41 (35.3%)	
Female	277 (70.1%)	75 (64.7%)	
Age (years, mean (SD))	68.14 ± 9.2	67.94 ± 8.9	0.84
Laterality (n,%)			0.75
Right	207 (52.4%)	63 (54.3%)	
Left	188 (47.6%)	53 (45.7%)	
BMI (kg/m^2, mean (SD))	29.54 ± 4.7	29.04 ± 4	0.97
ASA score (n, %)			0.10
I	37 (9.4%)	19 (16.4%)	
II	323 (81.8%)	88 (75.9%)	
III	35 (8.8%)	9 (7.7%)	
IV	0 (0%)	0 (0%)	

Table 2
Five year cumulative incidence of complications after TKA.

	Tourniquet (n = 374, 395 knees)	Non-tourniquet (n = 115, 116 knees)
Complications *(n, %)*	58 (14.7%)	12 (10.3%)
Deep surgical site infection	3 (0.7%)	2 (1.7%)
Superficial surgical site infection	4 (1%)	1 (0.9%)
Delayed wound healing	17 (4.3%)	4 (3.5%)
Pulmonary embolism	2 (0.5%)	0 (0%)
Vascular and/or nerve injury	4 (1%)	2 (1.7%)
Per-operative iatrogenic injury	7 (1.8%)	2 (1.7%)
Urinary retention	12 (3%)	1 (0.9%)
Other	9 (2.3%)	0 (0%)

Table 3
Five year cumulative incidence of revision surgery and reoperations after TKA.

	Tourniquet (n = 374, 395 knees)	Non-tourniquet (n = 115, 116 knees)
Total reoperations *(n, %)*	17 (4.3%)	5 (4.3%)
Total revisions (n, %)	6 (1.5%)	3 (2.6%)
Aseptic loosening	2 (0.5%)	1 (0.9%)
Instability	3 (0.7%)	1 (0.9%)
Fracture / trauma	1 (0.25%)	0 (0%)
Malalignment	0 (0%)	1 (0.9%)
Infection (1 or 2-stage revision)	0 (0%)	0 (0%)
Total reoperations due to infection (n, %)	4 (1%)	2 (1.7%)
Debridement, antibiotics and implant retention	3 (0.7%)	2 (1.7%)
Superficial surgical site infection	1 (0.25%)	0 (0%)
Other reoperations (n, %)	7 (1.8%)	0 (0%)
Arthrofibrosis requiring manipulation under anesthesia	2 (0.5%)	0 (0%)
Fracture/trauma	3 (0.7%)	0 (0%)
Other	2 (0.5%)	0 (0%)

patients that did not complete the PROMs, with no differences in the other characteristics (responders vs non-responders 66.5 ± 8.5y vs 69.0 ± 9.4y, $p < 0.01$, and 28.5 ± 4.5 kg/m^2 vs 29.9 ± 4.5 kg/m^2, $p < 0.01$, $p > 0.05$).

PROMs for both groups are shown in Figure 1. The OKS at 6 months follow-up increased from a median of 25 (IQR 10) to a median of 42 (IQR 8) and from a median of 23 (IQR 13) to a median of 40 (IQR 10), for the tourniquet group and non-tourniquet group respectively. Thereafter, the OKS remained constant until the final follow-up point. Between both groups, no difference with regards to OKS outcome was observed (ß –2.12, 95% CI −6.67–2.39).

Post-operative, the KOOS improved for all subscales in both groups. KOOS Symptoms increased during 4 years follow-up for both groups, with the largest increase at 6 months post-operative and without a significant difference between the tourniquet (+17, 95% CI 13.9–20.9) and non-tourniquet group (+8, 95% CI −1.2–16.9).

KOOS pain, QOL and Sport increased up to 12 months for both groups. The largest increase was seen in all groups in the first 6 months post-operative, while no significant differences were observed between groups. KOOS ADL increased up to

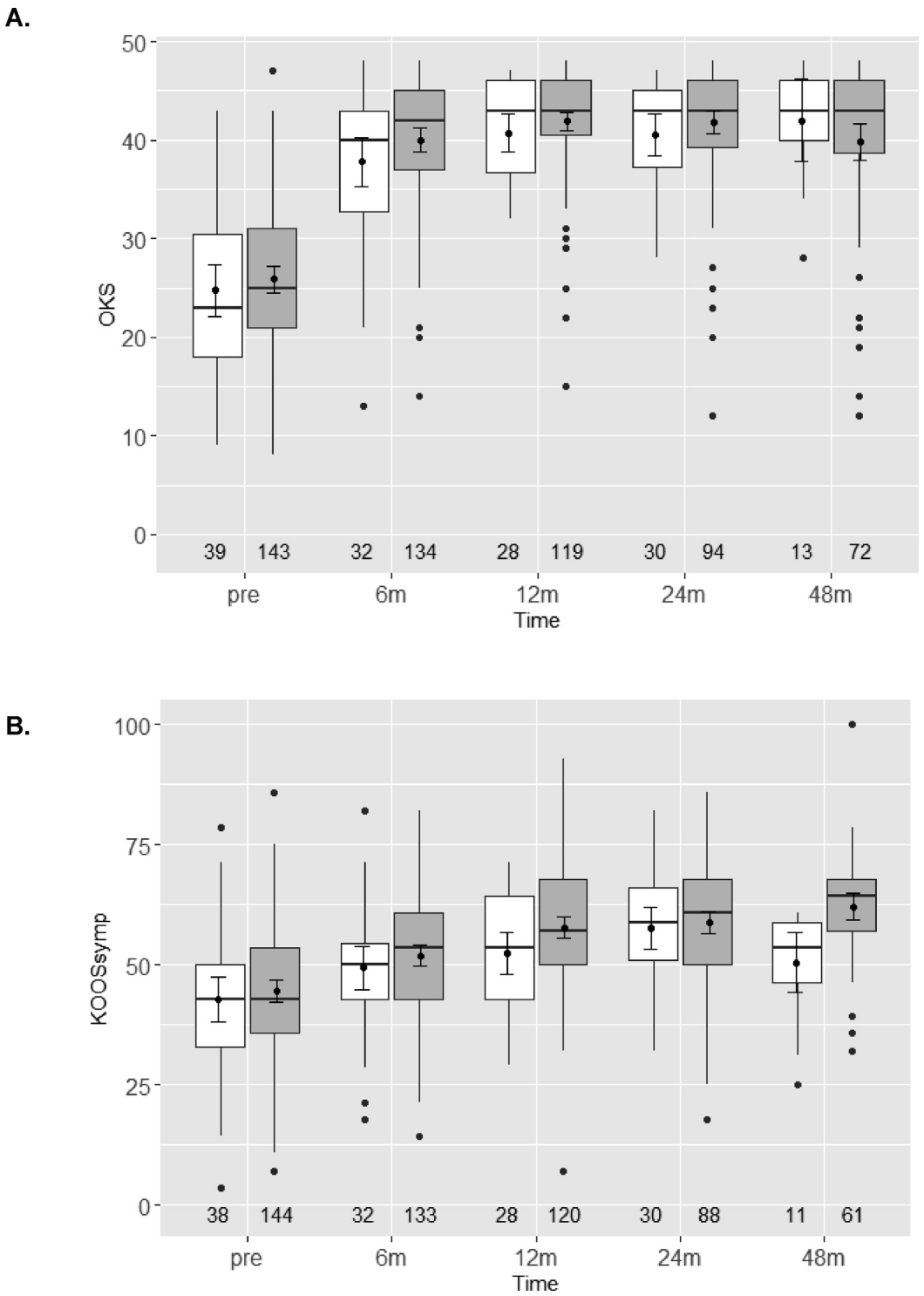

Figure 1. PROMS at each time point for the two groups (tourniquet vs non-tourniquet). For each time point the boxplot of the measured data (non-tourniquet in white, tourniquet in grey), the mean and 95% CI of the mixed models (black dot and whiskers) and the number of patients (at the bottom of the figure) are shown.

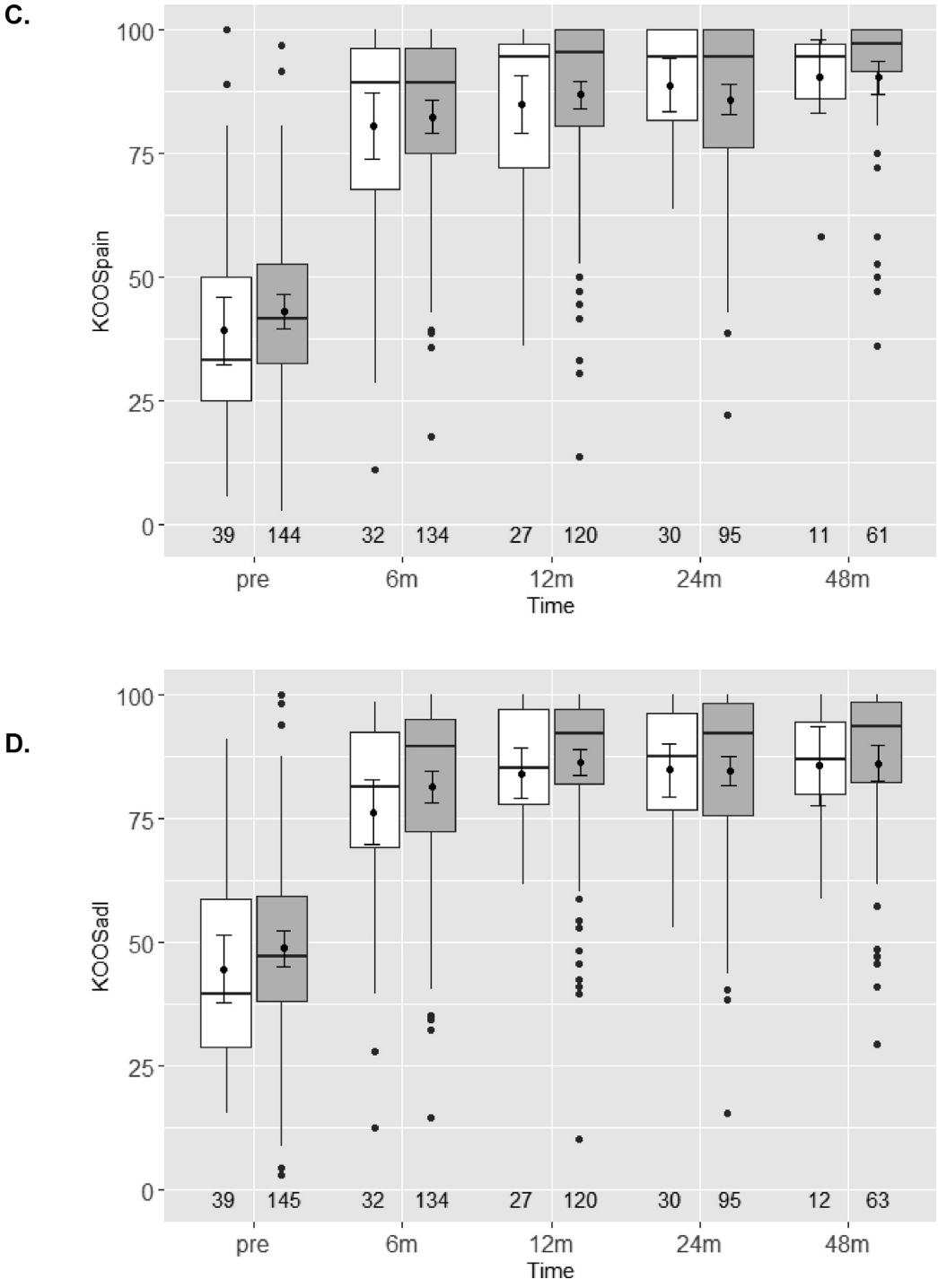

Fig. 1 (*continued*)

6 months post-operative, without a significant difference between the tourniquet (+37, 95% CI 32.6–42.3) and non-tourniquet group (+41, 95% CI 32.2–49.8).

The only significant difference observed in the KOOS subscales was for KOOS symptoms at 4 years follow-up, in favour of the non-tourniquet group (ß 11.53, 95% CI 4.6–18.44). The median KOOS symptoms was 53.6 (IQR 14.3) in the non-tourniquet group compared to 64.3 (IQR 10.7) in the tourniquet group.

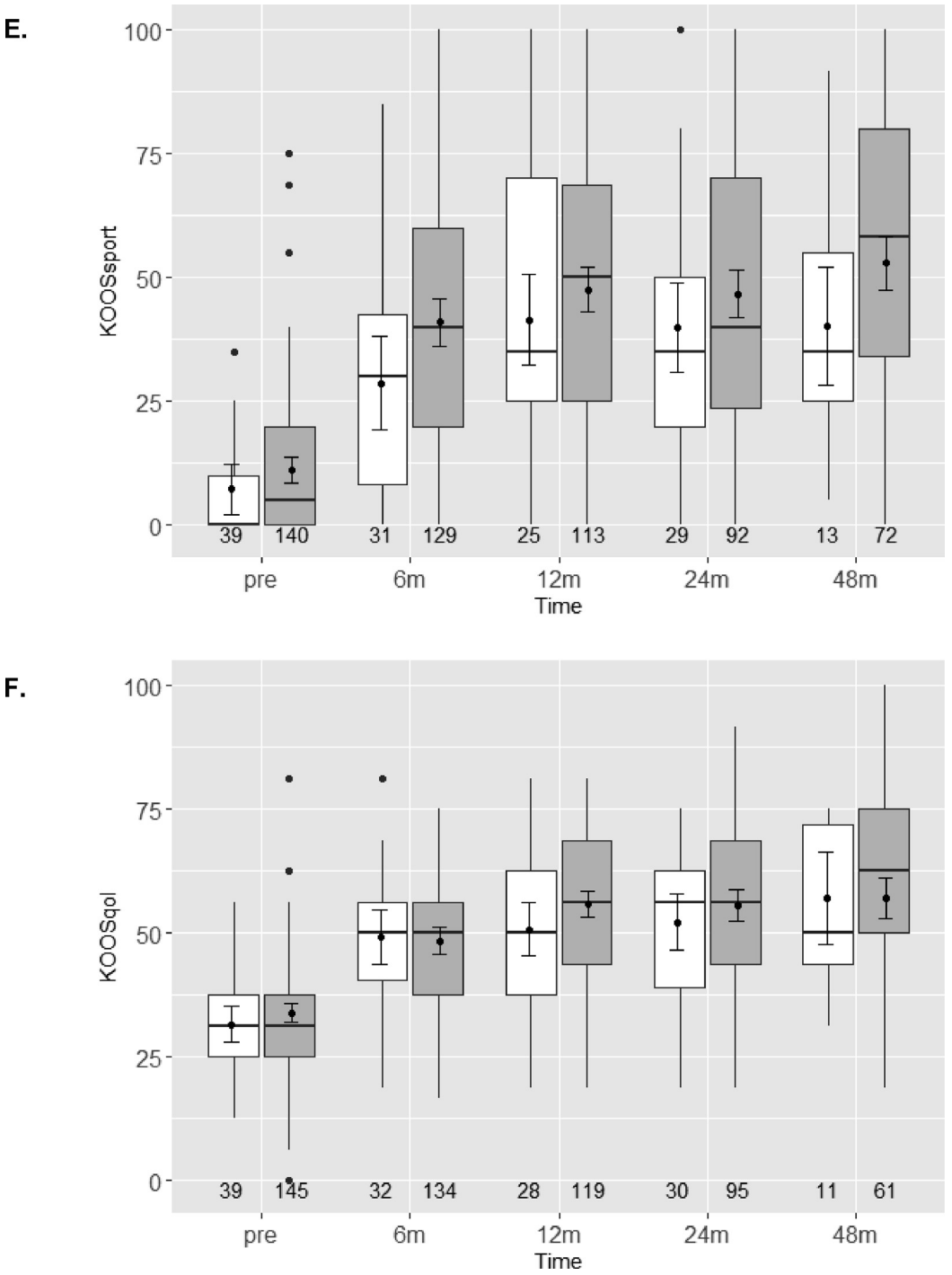

Fig. 1 (*continued*)

The EQ-5D increased during the first 6 months in both groups, 0.19 points (95% CI 0.14–0.24) and 0.23 points (95% CI 0.09–0.36) for the tourniquet and non-tourniquet group respectively. A significant effect of group was observed (ß 0.09, 95% CI 0.01–0.17), with a measured pre-operative median score of 0.68, IQR 0.48 for the non-tourniquet group compared to a median score of 0.78, IQR 0.12 for the tourniquet group.

For the SF-12, the mental score showed no effect of time or group for the tourniquet group (ß −0.52, 95% CI −2.24–1.19) or non-tourniquet group (ß 1.54, 95% CI −1.75–4.84). The physical score showed improved scores for the tourniquet group up to 12 months post-operative, with the largest increase up to 6 months post-operative (ß 13.57, 95% CI 11.2–16.0), while the non-tourniquet group improved 15 points (95% CI 10.2–19.8). There was no effect of group (ß 3.18, 95% CI −1.04–7.40).

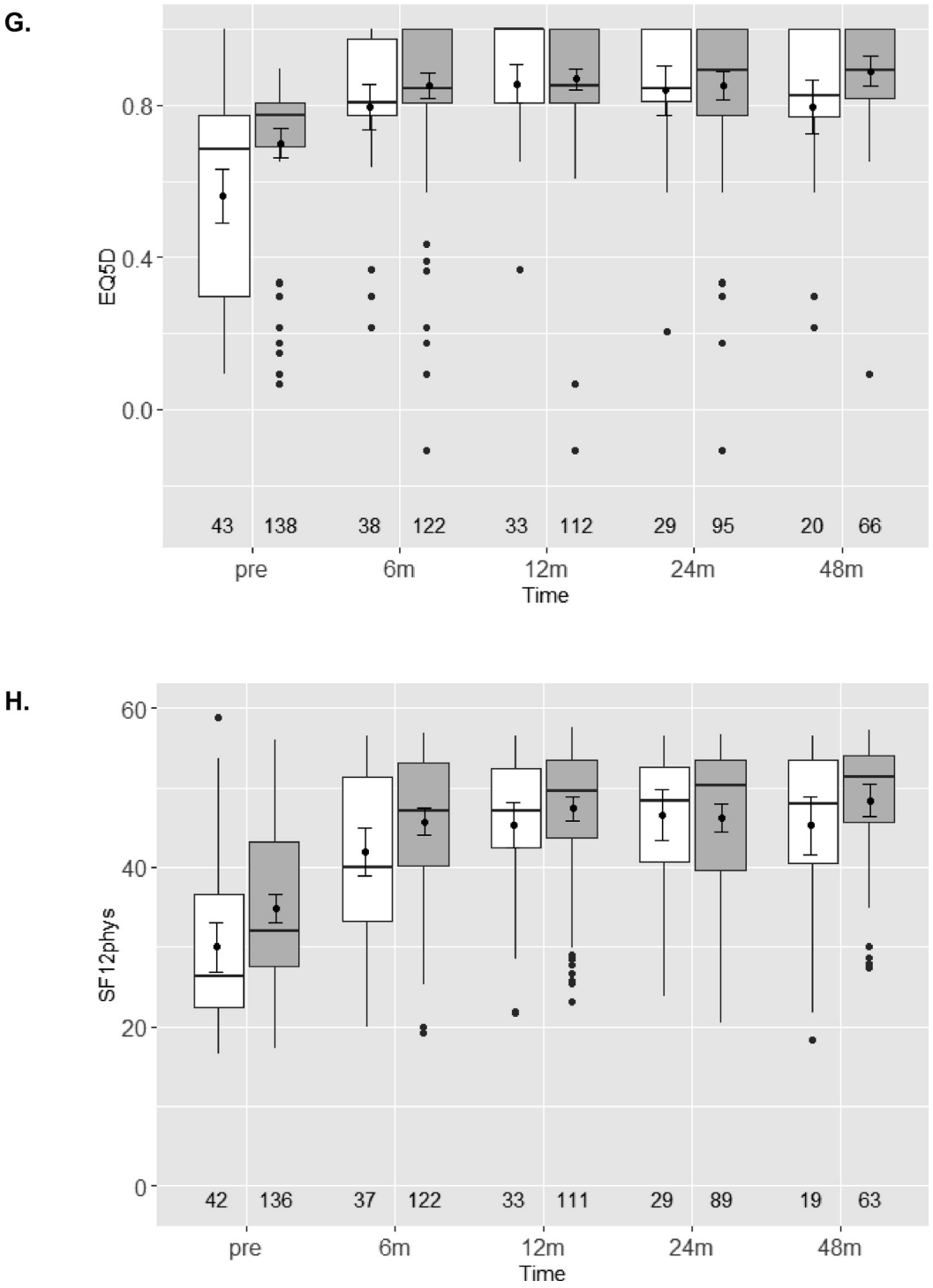

Fig. 1 (*continued*)

4. Discussion

The 5 year cumulative incidence of revision surgery after TKA was comparable between both the tourniquet and non-tourniquet group. Furthermore, patient reported outcome scores and quality of life scores were almost similar between both the tourniquet and non-tourniquet group.

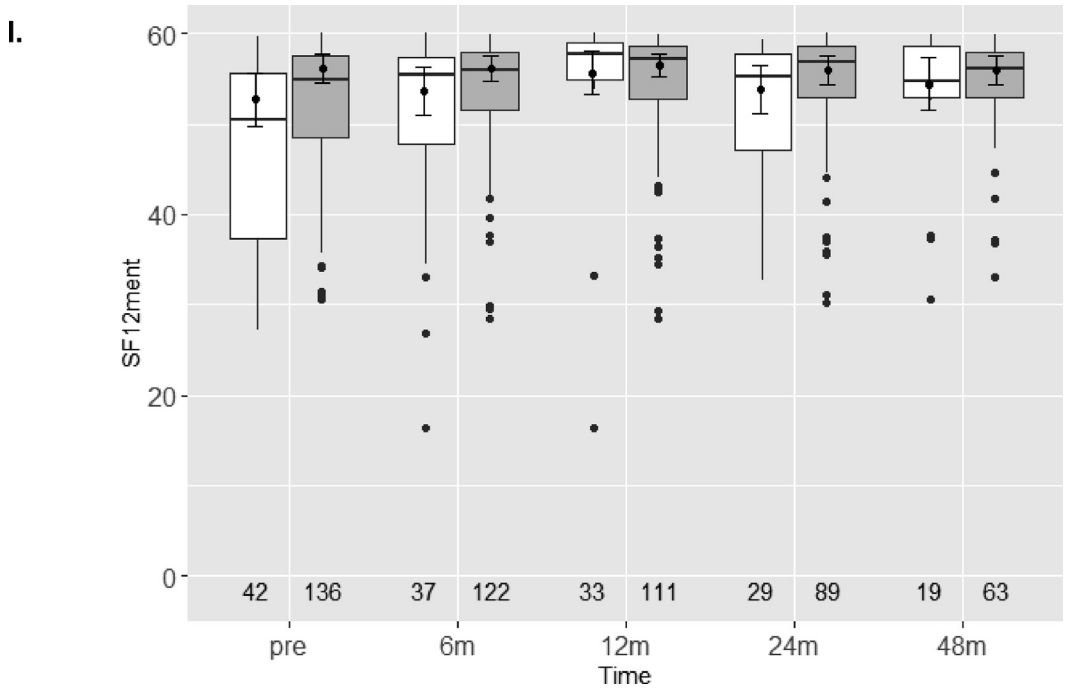

Fig. 1 (*continued*)

Our study is the first to report on a combination of mid-term results of TKA with and without the use of tourniquet, including revision rates for aseptic loosening, complications, patient reported outcome scores and quality of life scores. The short-term effect of a bloodless surgical area (i.e. use of a tourniquet) on cemented TKA fixation has been studied previously, using a surrogate end-point like bone-cement penetration [5,30] as well as using direct implant migration using RSA [13–15]. Neither of these end-points showed any effect on implant fixation, which is line with our findings.

Previous research showed higher revision risks for aseptic loosening (1.1%, vs 0.5% in our study), for the cemented NexGen total knee prosthesis when using a tourniquet. In the aforementioned study aseptic loosening occurred after a mean duration of 67.4 months post-operatively [31]. This warrants that the follow-up duration of the current study was adequate to assess the occurrence of aseptic loosening.

The majority of reported complications in this study were cases of delayed wound healing, with a slightly higher incidence in the tourniquet group. The latter has been studied extensively in the past, although no consensus on the actual effect of a tourniquet on wound healing was found in recent a review [16]. Remarkably, a high number of patients with urinary retention requiring bladder catheterization were observed in the tourniquet group. Although in the current study all patients were treated with a standardized rapid recovery protocol, this finding may indicate earlier post-operative mobilization in the non-tourniquet group. In other studies early mobilization has been shown to reduce the incidence of urinary retention [32].

Patient reported outcome measures and quality of life scores showed almost no differences during the follow-up of the current study. Previously, contrasting results were published on this subject. Alexandersson et al. [33] reported a small positive effect of tourniquet-less surgery on rehabilitation after 3 months, while Wang et al. [34] described better clinical outcomes and less pain during the early stages of rehabilitation. In contrast, Jawhar et al. [30] noted no effect of tourniquet use on functional outcome, muscle strength and health status after a follow-up of 6 months. Recently, Hamawandi et al. [12] reported results similar to our study. They found improved early functional outcome after TKA without the use of a tourniquet, with no difference on functional outcome after prolonged follow-up. In the present study significant improvements in all clinical outcome measures were observed. The largest improvement was seen up to 1 year post-operative. A possible explanation for the lack of difference in clinical outcome scores may be the timing of our first follow-up point. As reported in previous studies, the most prominent positive effect of tourniquet-less surgery on clinical outcome mainly exists within the first couple of months after surgery, and may be non-detectable at our first follow-up point of 6 months post-operatively.

Although this study had a prospective design for data collection, we did not have a randomized design. However, pseudorandomization by conducting an instrumental variable analysis was used. Additionally, our study included all consecutive patients eligible for TKA from the same hospital according to the same perioperative protocol, except for tourniquet use, thus minimizing the risk of bias.

The patients who participated in the LOAS study, and thus completed the pre-operative PROMs, were younger and had a lower BMI compared to the patients who did not complete the PROMs. However, the observed differences are modest and

the clinical significances of these findings are probably negligible. It is more likely a reflection of characteristics of patients who are willing to actively participate in clinical research than that it will influence the results in the present study.

Additionally, besides a difference in pre-operative EQ-5D and SF-12 PCS scores no baseline imbalances were observed. These differences, although statistically significant, most likely do not hold clinical relevance.

The only post-operative PROMs differences were observed in favour of the non-tourniquet group for KOOS symptoms at 4 years follow-up and a significant effect of group for the EQ-5D at 6 months follow-up. These differences are probably present due to the lack of power and low number of patients available for follow-up at 4 years.

Some limitations exist in the current study. First, the current study lacks power to statistically test the cumulative incidence of revision surgery, reoperations and complications after 5 year follow-up. However, since tourniquet use currently is not part of national arthroplasty registries, thus large registries with data regarding tourniquet use are not available. Therefore, this study may prove to be a first step towards evaluating mid-term effects of tourniquet use during TKA.

Secondly, there is a possibility that patients underwent revision surgery or additional treatment outside of our hospital and outside the scope of this study. However, these cases would likely be evenly distributed between the tourniquet and non-tourniquet groups. Moreover, part of the PROMs questionnaires were directed at possible revision surgery, and no cases of revision surgery or additional treatment outside of our hospital were reported.

Thirdly, due to the loss of follow-up at the final follow-up points, less data was available for the different PROMs. The mixed model analysis however, used in analyzing the clinical outcomes is able to take into account these missing data. Furthermore, the missing data were evenly distributed between both groups. In addition to the loss of follow-up, there is also a risk of selection bias for patients who choose to participate in the LOAS study and thus the PROMs data. However, as mentioned earlier, no clinical significant differences were observed between patients who completed the pre-operative PROMs and patients who did not.

Fourthly, since different surgeons performed TKA with and without tourniquet, differences in results may be due to the difference in surgeon. As discussed in the methods section, in this study "surgeon" was used as an instrumental variable for analysis, thus two groups (tourniquet and non-tourniquet) could be identified for pseudorandomization. When using "surgeon" as instrumental variable, one of the assumptions is that outcomes between surgeons did not differ. Similar outcomes between surgeons were expected since all had training within the same residency program. Furthermore, all surgeries were performed using a standardized surgical, as well as rapid recovery perioperative protocol. Thereby ensuring that observed differences can most likely be attributed to the variable tourniquet use.

Although revision surgery is generally considered an end-point in arthroplasty surgery, this endpoint is severely biased by the indication for surgery, and as such by the surgeon. For that matter radiological evaluation of arthroplasties will add value as a more objective measure of outcome after TKA. The latter was not done in the current study, because no standardized clinical follow-up, including clinical and radiological evaluation was planned. To optimize analysis of prosthesis survival, future research should also incorporate long-term radiological analysis of the incidence of aseptic loosening in non-tourniquet TKA.

This study presents the first evidence on mid-term effects of tourniquet use during TKA on prosthesis survival, aseptic loosening, functional outcome and quality of life. Previous research has investigated short term results of tourniquet use on wound healing, blood loss, deep venous thrombosis and other subjects, but no mid-term effects of TKA on the combination of our results without the use of a tourniquet were previously published. Considering the lack of power of the current study, it is however not feasible to draw far-reaching conclusions.

5. Conclusion

The 5 year cumulative incidence of revision surgery, other reoperations and complications after primary total knee arthroplasty was comparable when comparing TKA performed with and without the use of a tourniquet. Patient reported outcome measures were comparable between groups during mid-term follow-up as well. As a result of this study and considering previously published effects of tourniquet use during total knee arthroplasty on wound healing and immediate post-operative pain, routine application of a tourniquet should be carefully considered.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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