The introduction of robotic-arm assisted Total Hip Arthroplasty: Learning curve and effect on theatre utilization.

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Keywords: Robotic surgery, MAKO, Total hip arthroplasty, Theatre utilization, total case time

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Abstract

Background

The objective of this study was to report on the learning curve associated with the introduction of robotic-arm assisted Total Hip Arthroplasty with a focus on operating theatre utilization.

Methods

A total of 339 primary THA cases (225 robotic-arm assisted, 114 conventional) were eligible for inclusion in this retrospective observational study. All patients underwent hybrid THA by a single surgeon using a posterolateral approach. The anaesthetic, intraoperative, and postoperative protocols remained unchanged during the study. Total case time was defined as the interval from arrival to the operating theatre complex to entering the recovery area.

Results

281 cases were included in the theatre utilization analysis. There were no differences in the demographics between the robotic-arm assisted and conventional THA cases in terms of age (p=0.463) or gender (p=0.953). Total case time for conventional THA was 100 minutes (95% CI: 98.04 to 102.06) and 127.6 minutes (95% CI: 125.5 to 129.63) for robotic-arm assisted. Robotic-arm assisted THA (n=188) cases were analysed in sequential groups of 50 (Groups A to D). Robotic arm THA total case time decreased by 16 minutes between Group A (mean 135.44, 95%CI:131.21 to 139.6) and Group D (mean 119.45, 95%CI: 115.88 to 123.01). Robotic THA cases were associated with a 35% increase in total case time in the early phase which reduced to a 19% increase after 150 cases.

Conclusion

Operating theatre utilization analysis revealed increased total case time in robotic-arm assisted cases which gradually improved over the duration of the study.

Keywords:

Robotic arm-assisted THA; total hip arthroplasty; total case time; learning curve; MAKO; theatre utilization and staffing; surgical care practitioner; robotic surgery.

1. Introduction

Robotic-arm assisted Total Hip Arthroplasty (THA) using the Mako™ system was introduced in 2012 aiming to improve the accuracy of acetabular component implantation[1]. The orientation of the acetabular and femoral components is considered critical for the stability of THA although the concept of an acetabular component safe zone is no longer universally accepted[2,3].

Robotic-arm assisted technology aims to improve component positioning and avoid the implantation variation associated with conventional instrumentation[4]. The ability to accurately execute the THA component plan has the potential to achieve the optimal balance between stability and longevity[5]. When compared with conventional instrumentation as well as other guidance methods, robotic-arm assisted technology has been shown to significantly improve the accuracy and precision of implantation of THA components within a safe zone [6,7].

The introduction of this technology is associated with significant acquisition and running costs which can be accounted for when planning a business case. Its effect on the operating theatre utilization has not been clearly reported. The purpose of this study was to report on the effect of the introduction of the robotic-arm assisted technology on operating theatre workflow in a hip arthroplasty practice.

The primary aim of this study was to compare the case duration of robotic-arm assisted THA to conventional instrumentation THA. Secondary aims included defining the operating department team learning curve and investigating the operating room session duration.

2. Patients and Methods

2.1 Patient selection

All patients undergoing surgery in the senior author's (RGM) Nuffield Health Bournemouth Hospital practice from 1st October 2016 to 31st June 2019 were included in this retrospective observational study. . Robotic-arm assisted technology was introduced at the Bournemouth Nuffield Hospital in October 2017. Patient demographic and operating department workflow data were prospectively and independently recorded for all surgical procedures (Table 1). All patients undergoing primary THA prior to October 2017 underwent conventional hybrid THA. From October 2017, all patients undergoing primary THA were offered the option of robotic-arm assisted THA and were able to opt for either conventional or robotic-arm assisted surgery. Informed consent to patient data collection was gained on admission. Analysis of anonymised data was covered under institutional policy. The NHS Health Research Authority decision tool was used and determined that NHS research ethics committee approval was not required for this study [8]. This assessment is based on questions on patient randomisation, change of treatment from acceptable standards and generalizability in keeping with the UK policy framework for health and social care research[9]. This was additionally reviewed by our Research Development & Support department who advised that HRA approval or NHS REC favourable opinion was not required for this study.

2.2 Inclusion and exclusion criteria

All patients undergoing primary total hip arthroplasty during the study period were included. From October 2017, all patients were given the option to proceed with robotic-assisted or conventional surgery. There was no case selection by the surgeon. Patients undergoing additional procedures at the time of surgery (e.g. removal of metalwork, bone grafting) or coded as complex primary THA cases were excluded. For theatre utilization analysis, all THA cases that were performed on a list that included non-primary THA cases were excluded. For session duration and case load analysis, all THA cases performed in mixed robotic and conventional THA lists were excluded.

2.3 Outcome variables

We opted to analyse the Total Case Time (TCT) defined as the time from the patient arrival to the operating theatre department until the time the patient was ready for transfer to the recovery area. This was used over other time intervals (such as start to end of surgical procedure) in order to account for the robot setting up time and the laying up of the scrub team which are different in the robotic arm-assisted THA cases. Session duration was defined as the time from arrival of the first patient to the operating theatre complex until the time the last patient was ready to enter recovery. Case load was the number of THA cases in a single operating list.

2.4 Surgical Technique

All THA cases were performed by the senior author (RGM) in a single operating room. A MAKO product specialist was present in all cases, confirmed the pre-operative plan with the surgeon and supported the perioperative practitioners. In all cases, the patient was anaesthetised and positioned in the lateral decubitus position in the anaesthetic room. The scrub team prepared the instruments and the MAKO product specialist ensured the robot was in position and ready for use prior to the patient being transferred into the operating room. In all cases, hybrid THA was performed using a previously described technique[10].

2.5 Robotic-arm assisted Total Hip Replacement

All robotic arm assisted THA were performed by the senior author using the MAKO™ system (Stryker, Kalamazoo, MI, USA). The surgical approach was identical to the conventional THA cases. All patients underwent CT imaging for pre-operative planning. The registration was performed and verified as previously described[11]. The express workflow system was used intraoperatively in all cases. This provides robotic arm guidance during reaming and implantation of the acetabular component, as well as leg length and offset data.

2.6 Intra and postoperative care

The anaesthetic team and technique remained unchanged during the study period. Our routine anaesthetic protocol includes spinal anaesthesia, sedation and local anaesthetic infiltration. In cases where spinal anaesthesia was not possible, general anaesthesia was used.

2.7 Statistical analysis and reporting guidelines

Analysis of theatre utilization was done using Statistical Process Control (SPC)[12,13], a process supporting the interpretation of measures presented over time and endorsed by NHS Improvement[14]. SPC charts sequentially chart each case as an individual point as well as the mean, upper and lower control limits. Control limits were set at 3 SD. Statistical theory states that 99.73% of all data points should fall between the two control limits when a process is stable or unchanged[15]. The SPC rules used in interpretation help identify if a process exhibits common cause (predictable) variation or whether there are special causes. The control rules assessed (Nelson's rules) were: Point more than 3SD from mean, nine or more points in a row on the same side of the mean, six or more points are continually increasing or decreasing, 14 or more points in a row alternating (increasing then decreasing), 4 of 5 points in a row are more than 1SD from the mean in the same direction, two or three of last three points in a row +/- 2 SD in the same direction, 15 points in a row all within 1 SD of the mean or either side of the mean, eight points in a row exist but none are within 1SD of the mean and the points are in both directions of the mean[16]. . Descriptive statistics were used in the presentation of the data. Data was analysed using IBM SPSS Statistics for Macintosh, Version 25.0. Armonk, NY: IBM Corp. Control Charts were designed using Microsoft Excel for Macintosh, Version 16. The revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were used to inform the preparation of the manuscript[17,18].

3. Results

3.1 Demographics

There was no difference in age (p=0.463, independent t-test) or gender (p=0.953, Chi Squared) between the robotic-arm and conventional groups. The patient flow diagram is included in Figure 1.

3.2 Operating theatre utilization analysis

Theatre utilization analysis was restricted to operating lists consisting purely of primary THA cases. A Total of 93 conventional THA and 188 Robotic arm-assisted THA cases were included. Mean total case time was 100 minutes (95% CI:98.04 to 102.06) for conventional THA and 127.6 minutes (95% CI: 125.5 to 129.63) for robotic-arm assisted. Statistical Process Control analysis revealed the conventional THA process to be in control with a single violation of the control rules (Figure 2). The SPC analysis of the robotic-arm assisted cases revealed a process out of control with a total of 11 violations when analysed as a whole. We proceeded with further exploratory SPC analyses to subdivide the robotic-arm assisted cases. A split in groups of 100 revealed a significant difference between the first and second group (t-test, $p<0.001$). The split in sequential groups of 50 (Groups A to D) revealed better process control within groups with reduced number of control rule violations (Group A two violations, Group B one violation, Group C four violations, Group D no violations). The SPC chart depicting mean and control limits per 50 robotic-arm assisted THA cases can be seen in Figure 3. The descriptive statistics of case duration per group can be seen in Table 2. Between Group A and Group D there was a decrease in the mean total case time of 16 minutes. Total case time was compared between groups using ANOVA. Post hoc tests revealed Group A to be statistically different to all other groups. Group B was not statistically different to group C (p=0.827) but was different to groups A (p=0.026) and D (p=0.021). Group C was not statistically different to group D (p=0.154).

3.3 Case load and Session duration analysis

The median number of robotic arm-assisted THA cases per operating list was 3 (IQR 2,4). Robotic arm assisted cases were initially performed in mixed robotic and conventional THA lists. To demonstrate the case list load during the learning curve, the number of robotic arm-assisted cases per list (including cases performed in mixed lists) is demonstrated in chronological fashion in Figure 4. Session duration was analysed in cases consisting purely of robotic arm-assisted (n=165) or conventional THA cases (n=81). The number of THA cases per list as well as the mean total session duration are listed in Table 3. The mean operative session duration per THA by session case load can be seen in Figure 5.

3.4 Intraoperative problems/complications

Two significant intraoperative complications occurred in the robotic-arm assisted THA during the study period. In one case the pelvic registration marker was hit by the acetabular reamer and displaced. Image intensifier was used to locate and remove the displaced marker. As a result, the total case time was high as seen in Figure 3. (Group C, point above upper control line). In a different case the pelvic array loosened and displaced after the implantation of the acetabular component. As a result, the assessment of offset and leg length was not possible and was completed using conventional THA technique.

4. Discussion

The introduction of robotic-arm assisted technology in our study was associated with an increase in the time each patient spends in the operating theatre department. New technology is rapidly introduced into arthroplasty procedures with multiple robotic systems currently in use in the United Kingdom for joint replacement surgery[19,20]. Operating theatre patient flow and utilization is directly related to the cost of delivering joint replacement surgery and is therefore of paramount importance in systems of bundled payments[21].

Our study revealed a mean increase of 27 minutes in the time each THA patient spends in the operating department when compared to conventional THA. This additional time per case was more pronounced in the first 50 robotic-arm assisted cases (group A additional 35.39 minutes) and gradually improved after 150 cases to an additional 19.4 minutes in group D. Redmont et al. reported on the learning curve with robotic-arm assisted THA with cases split in groups of 35 [22]. They reported operating time defined as the interval from the incision to the time closure began. They reported a maximum improvement of 16.6 minutes in the mean operating time. This is consistent with the improvement seen in our study between group A and group D.

We feel that the interval reported by Redmont et al. does not fully reflect the effect of the introduction of the robotic-arm assisted technology on theatre workflow. This is due to the fact that positioning and set up of the robotic arm and preparation of optical trackers is done prior to the surgical incision and is not reflected in the incision to closure time. Those additional steps performed by the operating department team (patient docking, scrub preparation, robot preparation and positioning) are subject to a learning curve when a new technology is introduced. We therefore feel that more extended time intervals, such as the total case time reported in our study, should be used to assess the impact of new technology. A breakdown of the operating team learning curve would be of interest for future studies.

The effect of the learning curve on the time each patient spent in the operating theatre was analysed using SPC analysis in our study. There was a significant reduction of when analysing robotic-arm cases in group A compared to group D with a reduction of 16 minutes. Furthermore, group D total case time showed spread similar to the conventional THA (group D SD: 10.8 and conventional THA SD: 9.8). This suggests that after the learning curve, robotic case duration variability is similar to conventional cases. Operating departments can therefore schedule lists efficiently without increased unpredictable over-runs.

The learning curve duration reported in previous robotic arm-assisted joint replacement studies have been shorter than in our study. Redmond et al. reported an improvement in operative time and alignment outliers after 35 robotic-arm assisted THA cases[22]. Kayani et al. reported an initial learning curve of seven cases for TKA[23]. Both of those studies reported on the surgical time (incision to closure) which is different to the interval reported in our study. The improvement in the total case time in our study was more gradual and continued for longer. We feel that the use of total case time rather than incision to closure time is in part responsible for this difference. The exposure of the operating department staff to robotic cases may differ between centres and this can affect the duration of their learning curve. We further reported the number of THA cases per operating list to further demonstrate the effect of the practice volume on the learning curve. We feel that despite batching the robotic-arm assisted THA cases and often performing six THA in a single list, the improvement in total case time was slow. Doing low volume sporadic cases can increase the duration of the operating room team learning curve even further.

The introduction of new technologies to the operating theatre can lead to reduction in productivity. Our study revealed that when the learning curve of the whole team was investigated, the curve was longer when compared to previous reports focusing on incision to closure time. We feel that during introduction of new techniques, the education of the whole surgical team is key. Case selection and volume should be appropriate and the operating department team should remain together during the learning curve. The true cost of robotic assisted surgery can only be assessed when capital expenditure, maintenance and consumable costs as well as loss in case volume during and after the learning curve are taken into account.[24,25]. Our study is the first to report on the session duration between conventional and robotic assisted hip arthroplasty indicating the case volume loss in the early phases. The variability of total case duration after the learning curve was small and similar to conventional THA. Further research is needed to investigate the cost-effectiveness of the technology[26].

4.1 Limitations

Our study has several limitations. It is observational in nature. Patients were given the option to proceed with robotic-assisted or conventional surgery and were not randomized. The patient data we collected did not include Body Mass Index or ASA score. We were therefore not able to compare these variables between the conventional and robotic groups. However, we do not have any reasons to believe that there would be bias on BMI or ASA between the groups as all patients were recruited form the senior author's clinic with no restrictions on BMI or ASA placed for either conventional or robotic-assisted THA. This is a single surgeon study and therefore the results of the learning curve analysis might not be generalisable to all surgeons. The senior author has had experience with computer navigation and robotic assisted surgery prior to this study which was felt to be beneficial during introduction of the robotic-arm technology. Finally, we did not collect patient reported and radiographic outcomes as part of this study. We feel that there have been numerous reports in the literature focusing on patient reported and imaging outcomes of robotic-arm assisted joint replacement surgery. We therefore decided to focus our study on operating theatre utilization and efficiency. Further research is needed to investigate the cost effectiveness of the technology.

5. Conclusion

Operating theatre utilization analysis revealed increased total case time in robotic-arm assisted cases which gradually improved over the duration of the study. Robotic THA cases were associated with a 35% increase in total case time in the early phase which reduced to a 19% increase after 150 cases.

Table 1

Unique identification number
Date of Birth
Procedure
Anaesthetist
Operation Date
Admission to hospital
Arrival to Operating theatre complex
Anaesthetic start
Surgical procedure start
Recovery ready time
Discharge

Demographic and operating department workflow data recorded.

Table 2

	Conventional	All Robotic	Group A	Group B	Group C	Group D
Mean	100.05	127.77	135.44	127.84	125.54	119.45
Std. Deviation	9.76	14.43	14.90	11.41	15.32	10.84
Upper bound 95% CI	102.06	129.63	139.67	131.08	129.90	123.01
Lower bound 95% CI	98.04	125.48	131.21	124.60	121.18	115.88

Total Case Time in minutes. Group A: Patients 1-50, Group B: patients 51-100, Group C: patients 101-150, Group D: patients 151-188

Table 3

Cases per list	One THA	Two THA	Three THA	Four THA	Five THA	Six THA
Conventional THA lists	3	6	9	8	1	0
Session duration mean (min)	99	219.7	325.3	414	606	
Robotic THA lists	1	15	5	6	3	8
Session duration mean (min)	131	287.8	405.6	544.2	643.3	766.3

Operative session duration (minutes) and number of THA cases on operating list. Only sessions consisting exclusively of robotic assisted or exclusively conventional THA were included.

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Declaration of Conflicting Interests

One of the authors (RGM) declares a paid educational consultancy with Stryker. The authors declare Institutional Research Funding from ZimmerBiomet and Stryker outside the submitted work.

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Figure 1

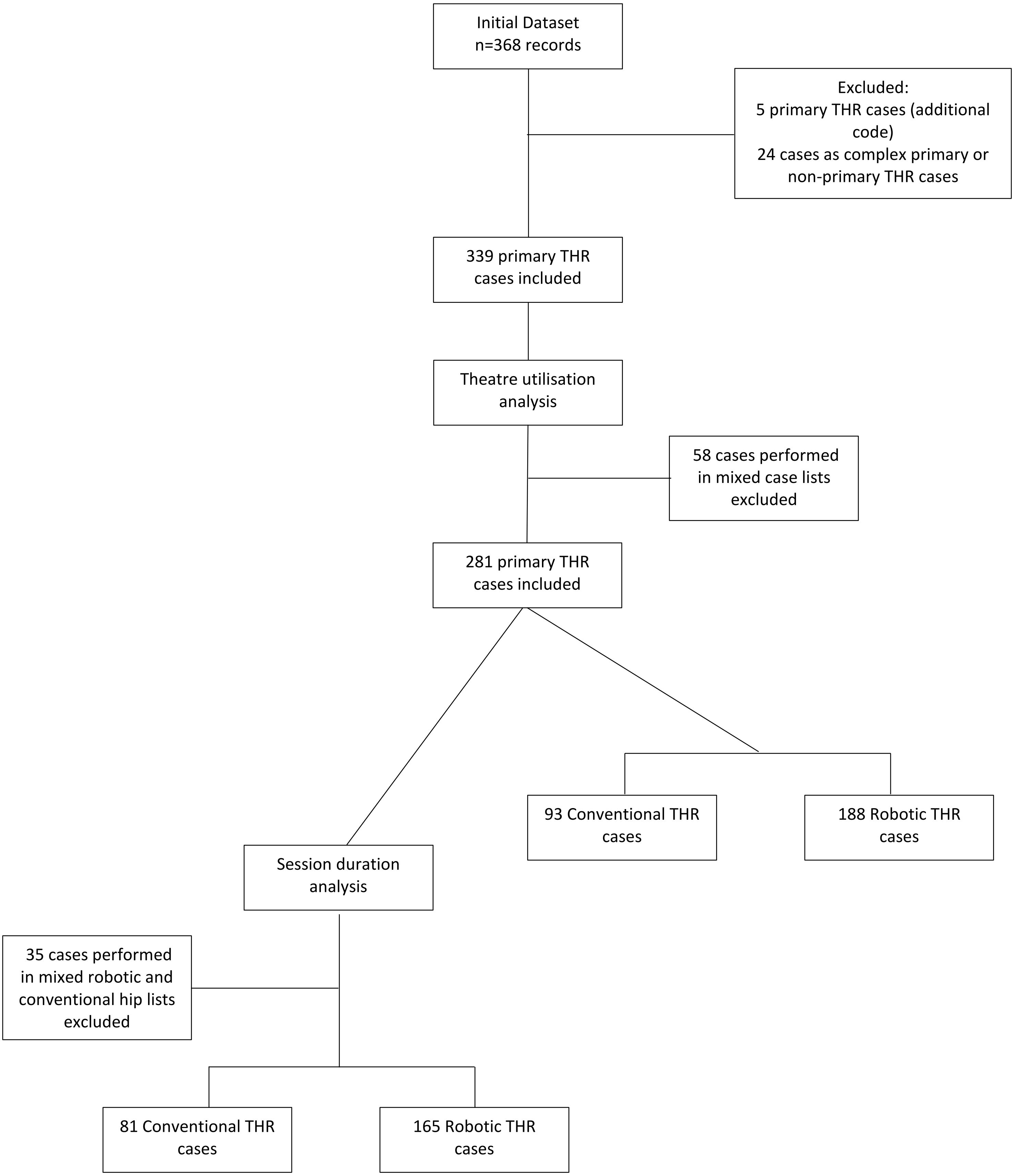
Initial Dataset
n=368 records
Excluded:
5 primary THR cases (additional code)
24 cases as complex primary or non-primary THR cases
339 primary THR cases included
Theatre utilisation analysis
58 cases performed in mixed case lists excluded
281 primary THR cases included
93 Conventional THR cases
188 Robotic THR cases
Session duration analysis
35 cases performed in mixed robotic and conventional hip lists excluded
81 Conventional THR cases
165 Robotic THR cases

Figure 2

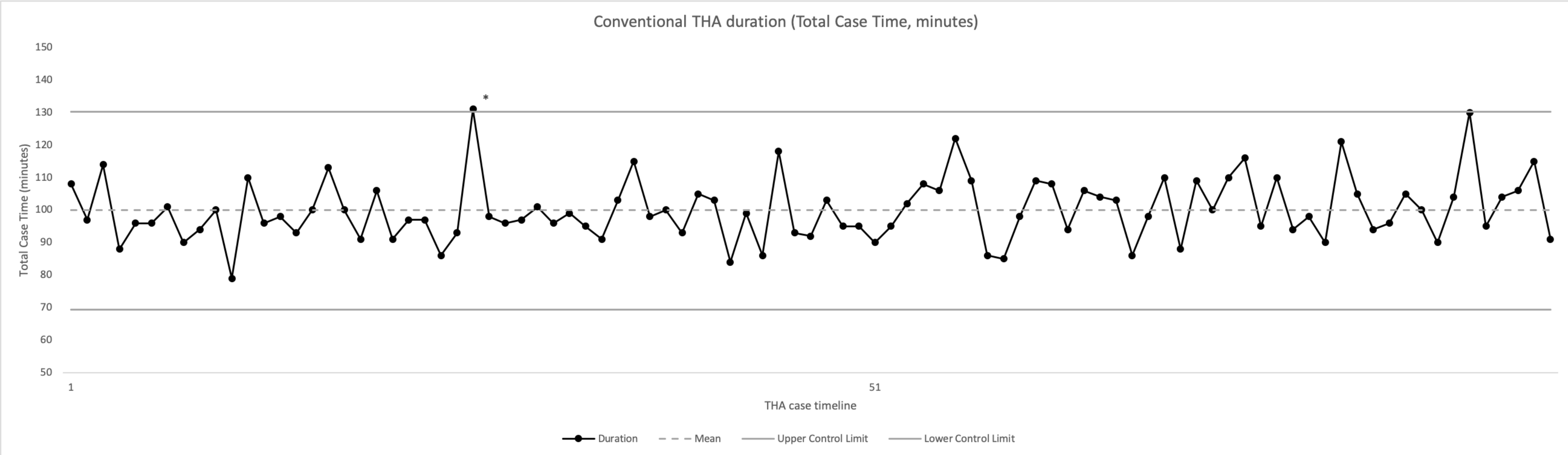

Figure 2: Conventional THA Statistical Process Control chart. Total case time in minutes. Control limits set at 3 SD. Control rule violations: * over 3 SD from mean.

Figure 3

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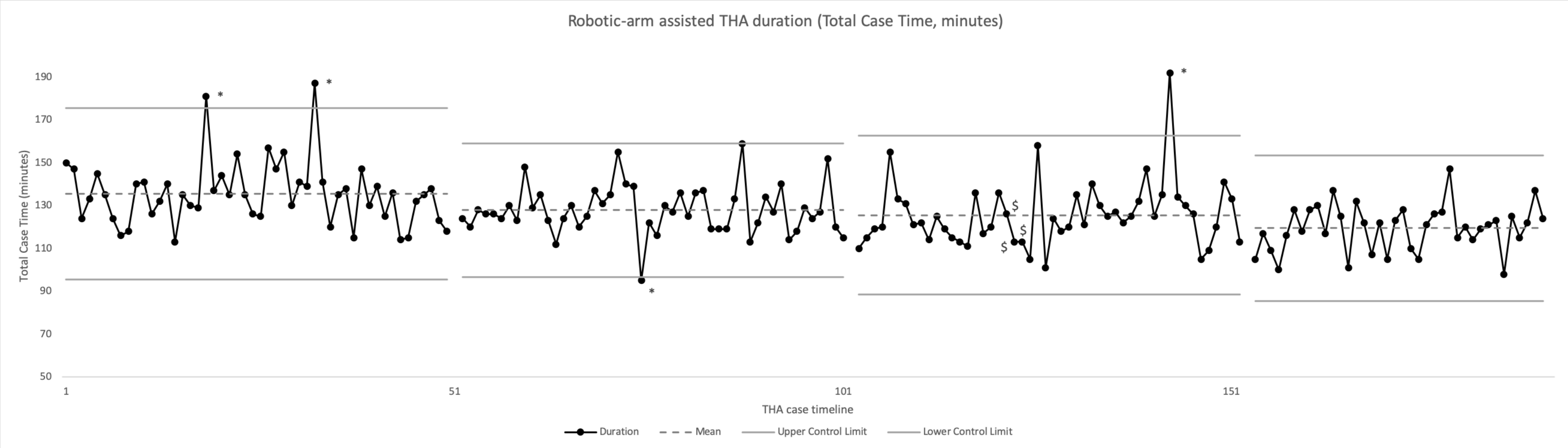

Figure 3: Robotic-assisted THA Statistical Process Control chart. Total case time in minutes. Control limits set at 3 SD. Control rule violations: * over 3 SD from mean, $15 points in a row all within 1SD of the mean

Figure 4

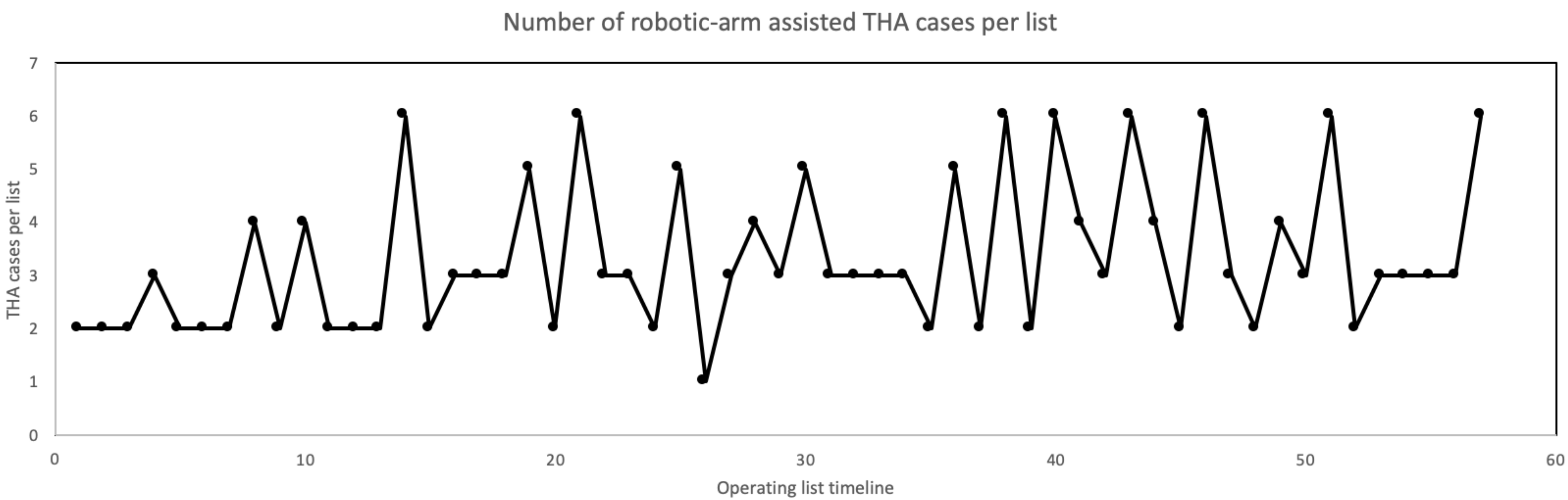

Figure 4: Number of robotic-arm assisted THA cases per operating list.