Surgical automation reduces operating time while maintaining accuracy for direct anterior total hip arthroplasty

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ARTICLE INFO

Keywords:

Surgical automation
Total hip arthroplasty
Direct anterior
Accuracy
Efficiency

ABSTRACT

Objective: Investigate the efficiency/accuracy of surgical automation versus manual component implantation in DA THA.

Methods: Retrospective review of 111 hips: 51 hips via automation and 60 hips via manual technique for DA THA.

Results: OR time averaged 8 min faster in the Automated group, compared to Manual group ($p = 0.0009$). Average femoral size was one size larger in the Automated group compared to Manual group ($p = 0.007$). No clinically significant differences were found between Manual and Automated groups for cup position or limb-length discrepancy. One calcar fracture occurred in the Automated group.

Conclusion: Surgical automation is efficient and accurate for DA THA.

1. Introduction

Uncemented primary total hip arthroplasty (THA) has historically been performed via manual technique, using a handheld mallet and impactor.¹ While outcomes in longitudinal registry studies² are generally excellent with the manual technique, there are still some potential areas for improvement. For example, during femoral preparation, it is difficult to ensure a perfect linear vector with each impaction of the mallet and broach handle. Off-axis and misdirected forces in the proximal femur during broaching can lead to intraoperative fractures,^{3–5} and fractures of the intertrochanteric region have occurred during femoral preparation due to improper broaching.⁵ Additionally, fractures near the tip of the stem have been found to occur due to impaction of the prosthesis against an improperly prepared canal that was either reamed eccentrically or reamed for an insufficient distance.⁵ Therefore, during femoral canal preparation it is imperative to maximize force transmission along the most ideal possible vector. Particularly in trainees, it may be difficult to achieve consistency of impaction vector and strength, and the data have shown that operative experience decreases the frequency of intraoperative fractures.⁵

Furthermore, it is evident that the use of a manual mallet and impactor requires a significant burden of human effort. Previous cadaveric

studies have shown that the impaction forces necessary to broach the femur and seat the stem are as high as 3000–3900 N (N).^{6,7} With the necessity of numerous mallet strikes during the procedure (as many as 16–25 impactions per broach)⁸ it is no surprise that 66.1% of arthroplasty surgeons report a work-related injury during their career.⁹

Recently, a surgical automation system has become available that allows the surgeon to forego the manual mallet/impactor, and instead perform automated impaction under power.⁷ This technology allows the surgeon to deliver up to six impactions per second using a consistent, calibrated force, thereby reducing both variability in impaction force and vector, and potentially reducing the total operative time and workload of the surgeon.⁷ However, we are unfamiliar with any comparative study that assesses early surgical results with surgical automation, particularly regarding operative speed, accuracy, and safety of component implantation *in vivo*.

Thus, we designed the present study in order to investigate the efficiency and accuracy of surgical automation versus manual component implantation in primary hip arthroplasty, asking the following research questions: 1) Does surgical automation reduce overall skin-to-skin operating room (OR) time for primary direct anterior hip arthroplasty, compared to the handheld mallet and impactor; 2) Does accuracy of cup position, stem size, or leg length discrepancy differ with surgical

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<https://doi.org/10.1016/j.jor.2020.03.057>

Received 26 March 2020; Accepted 28 March 2020

Available online 01 April 2020

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automation, compared to using a handheld mallet and impactor; and 3) Is there a difference in the rate of intra-operative complications using surgical automation compared with the handheld mallet and impactor? We hypothesized that there would be no difference in any of the above parameters between the automated versus manual technique.

2. Methods

2.1. Study design

We retrospectively reviewed the senior author's prospectively collected arthroplasty database to identify patients undergoing direct anterior (DA) total hip arthroplasty at a high-volume specialty orthopaedic hospital. Approval for the study was obtained by the Institutional Review Board (IRB) prior to its commencement. We included all consecutive patients undergoing elective primary DA total hip arthroplasty by a fellowship-trained arthroplasty surgeon between October 2018 and April 2019. We excluded all patients undergoing revision or conversion THA, primary THA using a posterolateral approach, or primary THA as a result of an acute femoral neck fracture. Application of our inclusion and exclusion criteria yielded a total of 111 consecutive hips for final enrollment in the study population. The first 60 hips underwent surgery performed via a manual mallet and impactor technique (the "Manual" group), while the next 51 hips underwent the procedure via surgical automation (the "Automated" group) using the KINCISE™ system (Johnson & Johnson Medical Device Companies, Warsaw IN). Baseline demographic variables were recorded for the study patients and are included in Table 1.

For each study patient, direct anterior THA was performed using a previously described technique.¹⁰ In all cases, the acetabulum was prepared with a 1-mm (mm) press-fit for an uncemented acetabular component with a neutral polyethylene liner (PINNACLE®, Depuy Synthes, Warsaw IN), and the femur was prepared using an all-broach technique for an uncemented, fully hydroxyapatite-coated, triple-tapered stem with a collar (ACTIS®, Depuy Synthes, Warsaw IN). For each case, we reviewed the electronic medical record and noted the total

"skin-to-skin" OR time (defined as the duration of time starting with the skin incision and ending with placement of the postoperative dressing, in minutes), implant sizes, and whether acetabular screws were used. Additionally, we reviewed post-op digital standing anteroposterior radiographs and measured cup anteversion (degrees), cup inclination (degrees), and leg-length discrepancy (mm) using our institutional PACS software, consistent with previously described methodology.¹¹ Finally, we recorded whether any intra-operative complications were observed, such as calcar fracture.

The primary outcome for the present study was the difference in average "skin-to-skin" OR time between the Manual and Automated groups. As secondary outcomes, we determined whether there were any differences in average femoral stem size (there are 12 possible femoral stem sizes in this implant system, ranging from #1 to #12), incidence of acetabular screw augmentation, average cup position (inclination and anteversion), or average post-op leg-length discrepancy between the two groups. Finally, as an additional secondary outcome, we determined whether there was any increase in intra-operative complications reported between the Manual and Automated groups.

2.2. Description of surgical automation technique

Following exposure of the patient's acetabulum, the native socket was sequentially reamed with hemispherical reamers under fluoroscopic visualization until good chatter was achieved, and the reamer size and position was deemed appropriate on the fluoroscopic images. The acetabular component was then opened onto the sterile field and threaded into the insertion handle for the automated system (Fig. 1). Again under fluoroscopic control, the acetabular component was impacted on power using the automated system until the cup was fully seated and deemed clinically stable. Acetabular screws were placed on a case-by-case basis at the discretion of the senior surgeon, for hips in which the patient's bone quality was subjectively deemed to require screw augmentation. The polyethylene liner was provisionally placed by hand into the acetabular component, then impacted into the locking mechanism under power using the automated system (Fig. 2).

Following exposure of the femur, a box osteotomy was used to remove cancellous bone from the posterolateral femoral neck, and the femoral canal was entered using an angled blunt canal finder. The femur was then sequentially broached under power, using the

Table 1

Pre-operative patient demographic variables. ASA = American Society of Anesthesiologists.

	Manual (n = 60)	Automated (n = 51)	p Value
Age (years), mean	64 (range 39–83)	63 (38–84)	0.66
Gender			
Male (n, %)	34 (56.7%)	27 (52.9%)	0.85
Female (n, %)	26 (43.3%)	24 (47.1%)	
Operative Side			
Left (n, %)	31 (51.7%)	23 (45.1%)	0.28
Right (n, %)	29 (48.3%)	28 (54.9%)	
Height (inches), mean	67.8 (range 58.0–75.5)	67.2 (range 60.0–79.0)	0.49
Weight (pounds), mean	188 (range 91–294)	185 (range 107–296)	0.70
Body Mass Index (BMI) (kg/m ²), mean	28.5 (range 16.9–38.9)	28.2 (range 15.8–38.6)	0.77
Pre-Operative Diagnosis			
Osteoarthritis (n, %)	54 (90.0%)	45 (88.2%)	0.77
Avascular Necrosis (n, %)	4 (6.7%)	5 (9.8%)	0.73
Rheumatoid Arthritis (n, %)	1 (1.7%)	0 (0.0%)	1.00
Perthes Disease (n, %)	1 (1.7%)	0 (0.0%)	1.00
Hip Dysplasia (n, %)	0 (0.0%)	1 (2%)	0.46
ASA Classification, mean	2.2 (range 1–4)	2.2 (range 1–3)	0.68

Fig. 1. The acetabular component threads into an impactor attachment for the automated system.

Fig. 2. A ball-tipped impactor attachment seats the polyethylene liner into the metal-backed acetabular component.

Fig. 4. A blunt-tipped impactor attachment is used to seat the final femoral component.

Fig. 3. Automated broaching is performed via an offset attachment that connects to the femoral broach.

Fig. 5. The head impactor attachment is used to seat the femoral head onto the trunnion of the femoral component.

automated system (Fig. 3). Broaching was considered complete when no further distal advancement of the broach was observed with respect to the calcar, and good fit and fill of the metaphyseal area was achieved. Calcar planing was then performed and trial components were placed. Stem position, femoral size, and leg length/offset were now confirmed via fluoroscopy, and the final implant was opened onto the sterile field. The femoral stem was placed provisionally by hand, then impacted under power until the collar was fully seated (Fig. 4). Finally, the femoral head was impacted under power onto the trunnion of the stem, again using the automated system (Fig. 5).

2.3. Statistical analysis

All data were entered, stored, and analyzed using Microsoft Excel

(Microsoft Corporation, Redmond, WA, USA), StatTools (CUHK, Hong Kong, China), and GraphPad QuickCalcs (GraphPad Software, San Diego, CA, USA). Continuous variables were analyzed using Student's t-test, while categorical variables were analyzed using Fisher's exact test. In all cases, statistical significance was set at $p = 0.05$.

3. Results

Pre-operative patient demographic variables are displayed in Table 1; no differences were observed between the Manual and Automated groups for age, gender, operative side, height, weight, body mass index (BMI), pre-operative diagnosis, or American Society of Anesthesiologists (ASA) classification.

Average “skin-to-skin” OR time was 96.6 min in the Manual group,

Table 2
Perioperative Variables. LLD = limb length discrepancy.

	Manual (n = 60)	Automated (n = 51)	p Value
Operating Room Time (minutes), mean	96.6 (range 69–126)	88.5 (range 69–123)	0.0009
Femoral Component Size, mean	5.9 (range 2–11)	6.9 (range 3–11)	0.007
Acetabular Position, mean			
<i>Inclination (degrees[°])</i>	40.3° (range 33°–52°)	43.7° (range 38°–52°)	0.00002
<i>Anteversion (degrees[°])</i>	25.1° (range 16°–34°)	25.4° (range 12°–33°)	0.669
Post-operative LLD (mm), mean	0.6 (range –3.9 – 4.3)	0.8 (range –3.2 – 4.4)	0.80
Acetabular Screw Fixation (n, %)	5 (8.3%)	3 (5.9%)	0.72
Intra-operative Complications			
<i>Calcar Fracture (n, %)</i>	0 (0.0%)	1 (2.0%)	0.46

compared to 88.5 min in the Automated group ($p = 0.0009$). The average femoral size was 5.9 in the Manual group, compared to an average femoral stem size of 6.9 in the Automated group ($p = 0.007$). Post-operative cup inclination averaged 40.3° in the Manual group, compared to 43.7° in the Automated group ($p = 0.00002$). No significant differences were found between Manual and Automated groups in terms of average cup anteversion, use of acetabular screws, or average post-operative limb-length discrepancy [Table 2].

One intra-operative nondisplaced calcar fracture was reported during broaching in the Automated group (1/51, 2.0%), in a thin 72-year-old female with a history of osteoporosis. No intra-operative complications were reported in the Manual group (0/60, 0.00%), ($p = 0.46$). The fracture in question was secured with two Luque wires, and the decision was made to convert to a cemented stem due to her poor bone quality. The patient was allowed weight bearing as tolerated post-operatively, with no change in the standard rehabilitation protocol.

4. Discussion

Although primary THA has historically excellent results using the manual mallet and impactor technique, the advent of surgical automation has the potential to improve operative efficiency and reduce surgeon workload. However, we are not familiar with any previous study that has investigated the intra-operative efficacy and safety of this innovative technology. To our knowledge, the present work is the first study to compare the historical manual technique to surgical automation for THA. Our investigation finds that the Automated technique 1) reduces OR time, 2) increases femoral stem size, and 3) achieves similar accuracy of acetabular positioning compared with the Manual technique. There was one intra-operative complication (calcar fracture) in an osteoporotic female in the Automated group; this patient was treated with a cerclage wiring and a cemented stem with no disruption of the post-operative protocol.

This study had several limitations. First, we cannot rule out some effect of selection bias which is inherent to any retrospective study. We attempted to mitigate this bias by enrolling a consecutive series of patients with a standard set of inclusion/exclusion criteria, all of whom underwent DA THA using identical implants and surgical technique, in order to make both groups as comparable as possible. In addition, we analyzed pre-operative patient demographic variables to ensure there were no major differences between groups. A second limitation is that our study is reporting results from a single fellowship-trained arthroplasty surgeon at a high-volume specialty orthopaedic hospital. Thus, our results may not be as applicable to other centers or to other surgeons using different implants or technique. Third, since our aim was only to assess intra-operative variables and not follow patients longitudinally, we cannot assess whether functional performance differs

over time between the two groups. Additional future studies with longitudinal follow up would be required to determine if there are differences in patient outcomes long-term. Lastly, it is arguable that with our study population of 111 THAs, the investigation could have been underpowered to detect differences between groups for relatively rare variables, such as calcar fracture or incidence of acetabular screw fixation. However, the study was still adequately powered to determine significant differences between groups for the primary and secondary outcomes, and the rate of calcar fracture in our study was consistent with the reported literature.^{12–15} We feel the strength of this study is that it is to our knowledge the first report demonstrating the intra-operative efficacy and safety of surgical automation for THA, compared with the manual technique.

Several previous studies have investigated “skin-to-skin” OR time for total hip arthroplasty procedures using the direct anterior approach with the manual mallet and impactor. Our OR time averages are consistent with those reported in the arthroplasty literature, which in several studies range from 78 to 141 min.^{16–19} Importantly, it has been previously reported that prolonged OR time is an independent risk factor for deep surgical site infection after primary hip arthroplasty.^{20–23} This would suggest that any intervention which enables the surgeon to reduce operative time may potentially reduce the risk of periprosthetic infection. In the present study, surgical automation reduced average OR time by approximately 8 min, however future longitudinal studies would be required to determine if this improvement in OR time would have any significant effect on reducing infection risk.

Multiple authors have previously investigated the importance of acetabular positioning during THA.^{24,25} In 1978, Lewinnek et al.²⁶ defined a radiographic “safe zone” for acetabular position as anteversion of 15° (°) (± 10°) and inclination angle of 40° (± 10°). This work demonstrated that anterior THA dislocations were correlated with increased cup anteversion,²⁶ and subsequent authors have also reported similar findings.^{27,28} Biedermann et al. have reported that anteversion of 15° and abduction of 45° to be the lowest risk values for dislocation.²⁹ Buller et al. used imageless navigation to enhance accuracy during THA for acetabular component orientation in obese patients, and defined the senior author’s “safe zone” as cup anteversion 25° ± 10°, and cup inclination 40° ± 10°.³⁰ In the present study, the radiographic cup position in both Manual and Automated groups was consistent with these previous studies. Interestingly, the Automated group average cup inclination was 3° more vertical than the Manual group, which was a statistically but not clinically significant difference as both groups were well within the acetabular “safe zone” as defined by previous authors.^{26,30} Importantly, in our study all acetabular components were placed under fluoroscopic guidance, which has been shown to result in decreased variability of acetabular cup inclination and anteversion using the direct anterior approach.¹⁸

The importance of adequate femoral sizing has been previously reported, particularly regarding the DA approach. Angerame et al. investigated causes for revision after direct anterior THA and found a higher incidence of femoral component loosening as the reason for early revision when compared to other approaches.³¹ The authors suggest that this might be due to femoral under-sizing, leading to inadequate osseointegration or aseptic loosening.³¹ Similarly, Rivera et al. have found that femoral under-sizing is more common in the direct anterior approach, likely due to the technical difficulty of femoral exposure and preparation.³² In the present study, patients who underwent DA THA using surgical automation had on average a full stem size larger than patients in the Manual group. This ability to maximize femoral stem size may have implications for improved femoral survivorship with THA using the direct anterior approach, however future longitudinal studies are needed to determine this definitively.

In our study we encountered one patient who sustained an intraoperative calcar fracture using surgical automation. Previous authors have associated osteoporosis, which is more common in elderly females, with perioperative periprosthetic hip fractures.^{13,15} Several authors have evaluated intraoperative fracture rates using cementless stems particularly in the direct anterior approach. Hartford et al. reported an intraoperative fracture rate of 2.6% (13/500) and a 1.2% (6/500) calcar fracture rate.¹³ Berend et al. have reported an intraoperative calcar fracture rate of 4.4% (58/1320),¹² and Matta et al. reported 4 intraoperative calcar fractures out of 442 hips (0.9%).¹⁴ The present study had an intraoperative calcar fracture rate of one out of 51 hips (2.0%) in the automation group, consistent with the above reports. The authors caution that while our fracture rate was indeed low and consistent with the cementless stem literature, surgical automation is not a panacea for avoiding calcar fractures, and care should be taken with patients who have osteoporosis or subjectively poor bone quality.

In conclusion, the present investigation finds that direct anterior THA using a surgical automation system reduces OR time and maximizes femoral sizing, while maintaining accuracy of acetabular cup positioning. The authors believe this is a safe and effective technology for improving OR efficiency. Moreover, while the present study was not designed to evaluate the burden of effort on part of the surgeon, it is the opinion of the senior author that the use of surgical automation subjectively reduces the physical workload necessary to complete the operation. Future studies would be useful in quantifying the degree to which this burden of effort is eased, and whether over time this may effect a reduction in surgeon fatigue and work-related injuries.

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