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Original Research

Use of an Automated Surgical Impactor Reduces Femoral Broaching Time in Direct Anterior Approach Total Hip Arthroplasty: Results From a Randomized, Multicenter Study

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ABSTRACT

Background: Impaction in total hip arthroplasty has typically been conducted using a mallet. A surgical automated impactor has been developed with the goal of reducing surgeon variability, fatigue, and injury. There is also potential to reduce the variability of each impaction step in which automated impaction is used, through reproducible and consistent application of force.
Methods: Patients were randomized into either the mallet control group, or the automated impaction study group (1:1 randomization). The primary endpoint analysis was conducted to demonstrate that femoral broaching time (in minutes) with an automated impactor is noninferior to femoral broaching time with manual instruments (mallet) under a noninferiority (NI) margin of 1.25 minutes, with a subsequent test of superiority. A total of 218 patients were randomized and treated (109 in each group).
Results: Mean femoral broaching time was 5.8 minutes in the automated impaction study group (automated), and 8.1 minutes in the mallet control group (mallet), a 28.4% reduction ($P = .0005$). However, there was not a difference in surgery duration between the groups. Three fractures were reported in the mallet group and 1 in the automated group.
Conclusions: In this randomized multicenter study, an automated impactor was shown to reduce femoral broaching time in primary total hip arthroplasty, with no increase in fractures, but no decrease in operating room time was noted.

Introduction

Orthopaedic surgery is physically demanding, with occupational hazards [1-4] and injury [5-7] well-documented in the literature. Total hip arthroplasty (THA) in particular requires a large burden of human effort [8]. Cadaveric studies have shown that the forces necessary to seat the femoral stem reach as high as 3000-3900 Newtons [9,10], and requires as many as 16-25 mallet strikes per broach. It is thus unsurprising that orthopaedic surgeons may have increased incidence of musculoskeletal complaints and injuries compared with other specialties [11]. In fact, 66.1 % of arthroplasty surgeons report a work-related injury during the course of their career [1].

Impaction in total THA is typically conducted via use of a surgical mallet. Impaction steps often include the preparation of the femoral canal using broaches, insertion of the femoral stem, insertion of the acetabular cup into the prepared bone, insertion of the liner into the cup, and insertion of the femoral head onto the stem. A surgical automated impactor (Fig. 1) has recently been developed to help automate impaction steps during THA, with the goal of reducing surgeon variability, fatigue, and injury. This automated impactor delivers a calibrated force at 6 impactions per second [12], which may facilitate efficiency of surgical steps requiring impaction. Previous authors have suggested reduced

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Figure 1. Surgical automated impactor.

surgical times and comparable accuracy of component implantation compared to manual impaction [8,13]; however, these have typically been single-surgeon retrospective studies that have not reported clinical outcomes. The benefits on surgical efficiency and reduction of surgeon fatigue utilizing the surgical impactor when compared to manual femoral broaching have also been reported [14-16].

To date, there has been no prospective study that compares automated impaction to manual impaction in terms of operative time and clinical outcomes. Thus, we designed the present study as a multicenter prospective randomized controlled trial to compare automated broaching with manual broaching for primary THA. Specifically, we aimed to compare (1) duration of femoral broaching time, (2) overall operative time, and (3) clinical outcomes between the 2 study groups.

Material and methods

Study design

Institutional review board approval was obtained prior to undertaking the investigation, and signed patient consent was collected for all patients before participation in the study. All surgeries were performed by 11 surgeons at 10 study sites, all through a direct anterior approach in the supine position on a specialized traction table. Patients were randomized to either the control group (mallet): femoral broaching with a mallet; or the study group (automated): femoral broaching with an automated impactor (KINCISE, DePuy Synthes, Warsaw, IN) (See CONSORT Flow Diagram Fig. 2). All surgeons were previously familiar with the automated impactor and were considered to be beyond the learning curve with the device. In the study group, 121 were enrolled; in the control group, 122 patients were enrolled. Surgeons used the same cup for all cases, (PINNACLE, DePuy Synthes, Warsaw, IN) and 1 of 2 collared femoral stems (ACTIS or CORAIL, DePuy Synthes, Warsaw, IN).

Data analyses

The primary endpoint analysis was conducted to investigate whether femoral broaching time (in minutes) with an automated impactor is noninferior to femoral broaching time with manual instruments (mallet) under a noninferiority (NI) margin of 1.25 minutes. Based upon input from key opinion leaders and data from

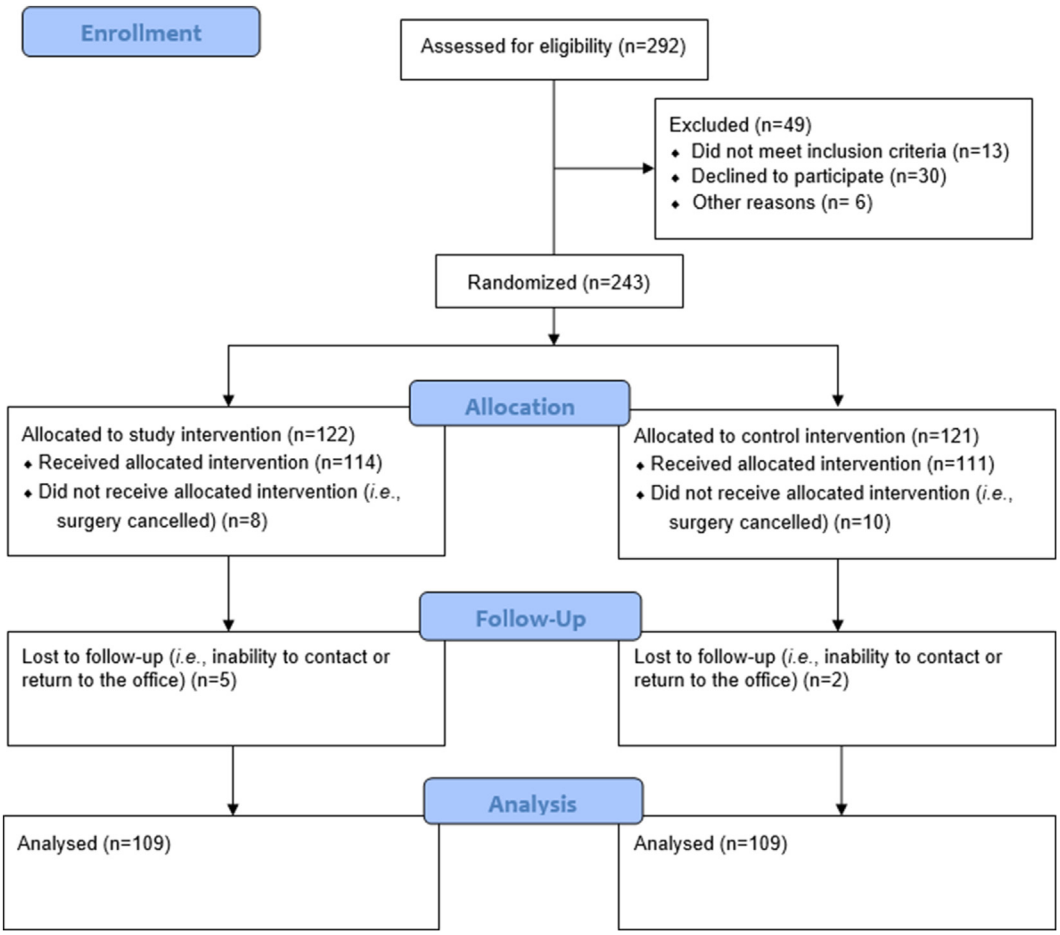

Figure 2. CONSORT diagram outlining patient flow and analysis sets.

previous studies [12-16], typical femoral broaching time with manual instruments is anticipated to have a range of 5 to 15 minutes, which implies a standard deviation of approximately 2.5 minutes (1/4 of the range). Moreover, key opinion leaders suggest that a difference of 10 minutes in femoral broaching time (increase for a single patient) is clinically meaningful. The noninferiority margin of 1.25 minutes was established because it is half of the anticipated standard deviation and is much less than a clinically meaningful difference. Under a 1-sided test with 5% alpha, a sample size of N = 88 per group would be sufficient to demonstrate noninferiority with 95% power.

If NI was successfully demonstrated, then a test for superiority would be conducted. Additionally, if the primary endpoint analysis successfully demonstrated NI, then a NI test of skin-to-skin time with an NI margin of 3.75 would be conducted. Regarding the primary endpoint analysis, it was estimated that there was greater than 97% statistical power to demonstrate noninferiority in femoral broaching time with the enrolled sample sizes in the automated impaction and mallet control groups. Standard descriptive summaries for continuous data were reported, and for categorical data, the count and percent were reported.

Patient demographics and surgical details

A total of 218 patients were randomized and treated (109 in each group). The mean age was 64.7 (standard deviation 9.0) years, mean body mass index was 28.1 (standard deviation 5.4), and 121 (55.5%) hips were women. Primary diagnosis was osteoarthritis in 204 (93.6%) hips. Intraoperatively, the surgeon was instructed to classify the patient's subjective bone quality (both proximal and distal) as per the following scale: "Normal," "Good," "Fair," "Poor," "Osteopenia," "Osteoporosis," or "Sclerotic." Femoral bone class was reported as normal or good in 203 (93.5%) hips. No differences in patient demographics were noted between groups. Additional patient demographic and surgical detail is presented in Tables 1 and 2. Patient-reported outcome measures were obtained at predetermined time points (preoperatively, 6-week follow-up, 24-week follow-up) and included Harris Hip Score, EuroQol - 5 dimension (EQ-5D), and Forgotten Joint Score (Table 3). We also administered a questionnaire at these same time points to determine patient-reported satisfaction, pain level, and leg length discrepancy (Table 4).

Table 1
Patient demographic details.

Variable	Automated	Mallet	*P* value
Mean age (y)	64.8 (43 to 83)	64.6 (36 to 85)	.89
Gender			
Women	59 (54.1%)	62 (56.9%)	.79
Mean BMI (kg/m^2)	28.1 (17 to 50.8)	28.1 (19 to 44.3)	.96
ASA risk			
I	6 (5.5%)	3 (2.8%)	.69
II	68 (62.4%)	70 (64.2%)	
III	35 (32.1%)	36 (33.0%)	
IV	0	0	
Primary diagnosis			
Avascular necrosis	4 (3.7%)	7 (6.4%)	.31
Degenerative joint disease	5 (4.6%)	8 (7.3%)	
Hip dysplasia (CDH/DDH)	0	2 (1.8%)	
Osteoarthritis	99 (90.8%)	92 (84.4%)	
Rheumatoid arthritis	1 (0.9%)	0	
Operative side			
Left	46 (42.2%)	47 (43.1%)	1.0
Bone class (proximal femoral)			
Normal	64 (58.7%)	66 (60.6%)	.50
Good	35 (32.1%)	38 (34.9%)	
Fair	8 (7.3%)	5 (4.6%)	
Poor	2 (1.8%)	0	
Osteoporotic	0	0	
Sclerotic	0	0	
Bone class (distal femoral)			
Normal	65 (59.6%)	68 (62.4%)	.92
Good	37 (33.9%)	36 (33.0%)	
Fair	6 (5.5%)	5 (4.6%)	
Poor	0	0	
Osteoporotic	0	0	
Sclerotic	0	0	
DORR type			
A	31 (28.4%)	34 (31.2%)	.77
B	77 (70.6%)	75 (68.8%)	
C	1 (0.9%)	0	

Results

Broaching time and operative time

Mean femoral broaching time was 5.8 minutes in the automated study group and 8.1 minutes in the mallet control group. Femoral broaching time for automated THA was found to be noninferior under a noninferiority margin of 1.25 minutes ($P < .0001$) and superior in a subsequent test of superiority ($P = .0005$). However, the planned NI test of skin-to-skin time did not successfully show noninferiority between the groups (automated group 71.0 minutes; manual group 70.2 minutes), nor was mean anesthesia time different between groups (automated group 117.3 minutes; manual group 116.3 minutes) (Table 2).

Clinical outcomes

Hospital stays were less than 24 hours for 172 patients (78.9%) (Table 2). Length of stay was a mean of 0.7 (standard deviation 0.7) days and not statistically different between groups. One intraoperative fracture was reported in the automated group, while 3 fractures were reported in the mallet group ($P = .36$). Two intraoperative calcar fractures were reported, one in each group, and both were treated with cerclage wires. There were 2 additional intraoperative fractures reported in the mallet group: a greater

Table 2
Operative and perioperative information.

Variable	Automated	Mallet	*P* value
Mean stem size (CORAIL)	12.1 (9-15)	11.4 (9-15)	.10
Mean stem size (ACTIS)	5.9 (1-12)	5.5 (2-10)	.19
Difference from templated stem size	0.2 (−2 to 6)	−0.3 (−4 to 5)	**.003**
Mean femoral broaching time	5.8 (0.7-19.9)	8.1 (1.7-31.6)	**<.0001**[a] **.0005**[b]
Mean skin-to-skin time (min)	71.0 (43-137)	70.2 (43-117)	.73
Mean anesthesia time (min)	117.3 (64-186)	116.3 (65-175)	.79
Mean length of stay (d)	0.8 (0-5)	0.7 (0-2)	.44
Fracture	1 (0.9%)	3 (2.8%)	.36
Discharge disposition			
Home	80 (73.4%)	78 (71.6%)	.88
Home health care	27 (24.8%)	31 (28.4%)	
Short-term rehab facility	0	0	
Short-term rehab facility with skilled nursing	2 (1.8%)	0	
Narcotic use (patient reported at 6 wk)			
None	11 (10.1%)	6 (5.5%)	.17
1 d	8 (7.3%)	6 (5.5%)	
1-3 d	23 (21.1%)	19 (17.4%)	
<1 wk	12 (11.0%)	10 (9.2%)	
1 wk	12 (11.0%)	16 (14.7%)	
2 wk	11 (10.1%)	20 (18.3%)	
>2 wk	24 (22.0%)	21 (19.3%)	

Bold values indicate statistical significance.
[a] Test of noninferiority.
[b] Test of superiority.

Table 3
Clinical outcomes.

Variable	Preoperative			6-wk (14-60 d)			24-wk (61-180 d)		
	Automated	Mallet	*P* value	Automated	Mallet	*P* value	Automated	Mallet	*P* value
Mean Harris Hip Score (SD)	56.4 (13.7)	55.8 (15.0)	.77	85.3 (13.3)	83.9 (13.3)	.45	94.8 (8.2)	95.7 (7.0)	.40
Mean EQ-5D-5L (SD)	0.65 (0.17)	0.64 (0.15)	.63	0.83 (0.11)	0.80 (0.12)	.12	0.91 (0.10)	0.90 (0.14)	.49
Mean EQ-5D VAS (SD)	72.5 (18.2)	74.9 (17.1)	.30	84.9 (10.4)	85.3 (10.6)	.79	86.1 (10.7)	86.6 (10.6)	.76
Mean Forgotten Joint Score (SD)	N/A	N/A	N/A	51.2 (26.7)	48.1 (30.1)	.45	73.9 (26.1)	71.4 (28.9)	.52

EQ-5D, EuroQol - 5 dimension.

trochanteric fracture that required no additional treatment and a proximal femur fracture that was treated with ORIF. Harris Hip scores, EQ-5D-5L, EQ-5D visual analog scale, and Forgotten Joint scores were similar between groups (Table 3). Pain and patient satisfaction were also not statistically different between cohorts (Table 4).

Discussion

While primary THA historically has excellent outcomes using the manual impaction technique, the introduction of automated impaction has the potential to improve operative efficiency while maintaining clinical and radiographic outcomes. In the present multicenter prospective randomized controlled trial, we demonstrate that automated impaction significantly reduces femoral broaching time compared to the historical manual impaction technique, while there were no differences found between groups in terms of overall operative time or patient-reported outcomes. Fewer total intraoperative fractures were reported in the automated group compared with the manual group; however, this difference was not statistically significant with the numbers available.

Previous authors have investigated the use of automated impaction to improve operative efficiency. Bhimani et al [8] retrospectively reported an overall operative time savings of 8 minutes and Thalody et al [13] retrospectively showed an overall operative time savings of 12 minutes using the same automated impactor for direct anterior THA. Interestingly, while we demonstrated reduced broaching time using automated impaction, the overall operative time between study groups was similar. One possible explanation is that automated impaction was only required for the broaching sequence in the study group and not necessarily used for all impaction steps during the case. Conversely, for the control cases, manual impaction was only required for broaching so automated impaction could have been used for other impaction steps in the procedure; however, this only occurred in 3 manual cases for cup impaction and liner impaction and in 1 case for head impaction.

While previous authors have not investigated clinical outcomes after automated impaction for THA, our data demonstrate no difference in patient-reported outcomes measures for automated compared to manual impaction THA. There were fewer intraoperative fractures in the automated group (1/109, 0.9%) compared to the manual group (3/109, 2.8%); however this difference was not statistically significant. This observed fracture data are consistent with those reported by previous authors. Fritz et al [17] reported 6 calcar fractures in a series of 510 THAs (6/510, 1.2%) all of which were implanted using automated impaction. Strait et al [18] reported a fracture rate of less than 1% in a cohort of 1248 hips, while Osondu et al [19] reported a fracture rate of 1.6% in a cohort of 1453 direct anterior approach hips with use of automated impaction. The reported calcar fracture rate in the manual impaction THA literature ranges from 0.9% to 4.4% [20,21].

Stem sizes in our study trended higher with automated broaching, but this correlation was not statistically significant.

Table 4
Patient reported satisfaction, pain, and perceived leg length discrepancy.

n (%)	Preoperative			6-wk (14-60 d)			24-wk (61-180 d)		
	Automated	Mallet	*P* value	Automated	Mallet	*P* value	Automated	Mallet	*P* value
Would you have this procedure again?	-					.49			.24
Yes				98 (97.0)	91 (94.8)		94 (100)	89 (97.8)	
No				3 (3.0)	5 (5.2)		0	2 (2.2)	
Patient satisfaction			.64			.16			.96
Extremely	80 (73.4)	78 (72.2)		80 (79.2)	66 (68.0)		78 (82.1)	77 (82.8)	
Very	29 (26.6)	28 (25.9)		15 (14.9)	23 (23.7)		13 (13.7)	12 (12.9)	
Moderately	0	2 (1.9)		5 (5.0)	6 (6.2)		2 (2.1)	2 (2.2)	
Slightly	0	0		0	2 (2.1)		1 (1.1)	0	
Not at all	0	0		1 (1.0)	0		1 (1.1)	2 (2.2)	
Groin pain			.79			.96			.45
None	23 (21.1)	23 (21.1)		57 (56.4)	60 (61.2)		78 (82.1)	72 (77.4)	
Mild	24 (22.0)	27 (24.8)		38 (37.6)	27 (27.6)		15 (15.8)	18 (19.4)	
Moderate	39 (35.8)	37 (33.9)		6 (5.9)	11 (11.2)		1 (1.1)	2 (2.2)	
Severe	23 (21.1)	22 (20.2)		0	0		1 (1.1)	1 (1.1)	
Buttock pain			.84			.52			.68
None	31 (31.0)	36 (37.5)		66 (64.7)	61 (62.2)		81 (85.2)	80 (86.0)	
Mild	33 (33.0)	24 (25.0)		31 (29.4)	30 (30.6)		11 (11.6)	11 (11.8)	
Moderate	36 (36.0)	36 (37.5)		5 (4.9)	6 (6.1)		2 (2.1)	2 (2.2)	
Severe	9 (9.0)	13 (13.5)		0	1 (1.0)		1 (1.1)	0	
Leg length			.25			.59			.42
Equal	71 (65.7)	73 (70.9)		82 (85.4)	79 (82.3)		85 (90.4)	76 (84.4)	
Right side longer	19 (17.6)	10 (9.7)		5 (5.2)	9 (9.4)		6 (6.4)	10 (11.1)	
Left side longer	18 (16.7)	20 (19.4)		9 (9.4)	8 (8.3)		3 (3.2)	4 (4.4)	

Notably, Bhimani et al [8] have reported a mean increase of a full stem size with use of automated impaction, and Thalody et al [13] reported a mean stem size of 5.67 for automated compared with 4.82 for mallet ($P = .006$). While the final size for each unique stem may depend on differences in broach design and strategy for each surgeon, larger stem size could potentially be due to more consistent filling of the canal with broaches with the use of automated impaction.

Our study comes with multiple limitations. For purposes of this study, use of the assigned impaction method was only required for the femoral broaching, rather than throughout all impaction steps (femoral broaching, stem impaction, cup impaction, impaction of the head onto the stem, liner impaction, and so on). This is a limitation for the study, particularly in assessing secondary endpoints (skin-to-skin time and cup positioning). There are also limitations in verifying differences in bone preparation between groups. While we report on stem size compared with preoperative plan, we were not able to assess any differences in the preparation of the femoral canal between groups.

Another limitation is that 2 separate femoral stems were used in this multicenter study, according to the preference of the surgeon. While these stems have similar workability (broach-only, collared, hydroxyapatite-coated tapered stems), differences in workflow could potentially affect the calculated broaching and overall operative time between groups. Additionally, another limitation is that total operative time is influenced by many other factors that could be controlled for in this multicenter study, such as surgical technique, deformity, soft tissue releases necessary, and surgeon experience, which may explain why total operative time was not different between groups despite there being a significant difference in broaching times. Finally, it was not possible for the surgeons themselves to be blinded to the randomization process. Since the surgeons performing the operation by definition knew which patients were in the study group and which were in the control group, this could theoretically have biased the study outcomes (either consciously or unconsciously), particularly in an industry-funded investigation. While a prospective, multi-center, randomized study design should help to blunt the observer bias, this remains an important limitation to our investigation.

Conclusions

In this randomized multicenter study, an automated impactor was shown to reduce femoral broaching time in primary THA. Continued study is needed to determine the overall value of automated impaction for OR efficiency, bone preparation, and clinical outcomes. Perhaps even more important are the effects on the surgeon compared to the traditional use of the mallet in terms of muscle strain, fatigue, and stress. In fact, it is the opinion of the authors that the reduced physical workload afforded by automated impaction is perhaps the most important facet of its use; additional studies are ongoing to assess this burden of effort directly.

Funding

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Conflicts of interest

Brian Gladnick reports being a board member of American Association of Hip and Knee Surgeons; being a part of medical/orthopaedic publications editorial/governing board for Journal of Arthroplasty; and being a paid consultant for and receiving research support from DePuy Synthes. David Fawley reports being a paid employee for DePuy Synthes, a Johnson & Johnson company; and reports having a stock or stock options in Johnson & Johnson. Thierry Bernard reports being a paid employee for DePuy Synthes, a Johnson & Johnson company. John Redmond reports receiving research support from and being a paid consultant for DePuy Synthes and Stryker and reports being a part of speakers bureau for Arthrex, Inc. Henry Clayton Thomason reports being a board member of Southern Orthopaedic Association; reports receiving research support from DePuy Synthes; and reports being a part of speakers bureau for Heron Therapeutics. J. Craig Morrison reports being a board member of American Association of Hip and Knee Surgeons; receiving research support from DePuy Synthes, Biomet, and Exactech, Inc; and a paid consultant for DePuy Synthes and HealthTrust; is a part of speakers bureau for DePuy Synthes.

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CRediT authorship contribution statement

Henry Clayton Thomason: Writing – review & editing, Investigation. **John Redmond:** Writing – review & editing, Investigation. **J. Craig Morrison:** Writing – review & editing, Investigation. **David Fawley:** Writing – original draft, Visualization, Project administration, Methodology, Conceptualization. **Thierry Bernard:** Writing – review & editing, Methodology, Formal analysis, Data curation. **Brian P. Gladnick:** Writing – original draft, Supervision, Investigation.

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