Use of an automated surgical impactor reduces femoral broaching time in direct anterior approach total hip arthroplasty: results from a randomized, multi-center study

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INTRODUCTION

Impaction in THA has typically been conducted using a mallet. A surgical automated impactor (KINCISE™, DePuy Synthes, Warsaw, IN) 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. 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 two study groups.

METHODS

Patients were randomized into either the mallet control group (MALLET), or the automated impaction study group (KINCISE) (1:1 randomization). The primary endpoint analysis was conducted to demonstrate that femoral broaching time (in minutes) with an automated impactor is non-inferior to femoral broaching time with manual instruments (mallet) under a non-inferiority (NI) margin of 1.25 minutes, with a subsequent test of superiority. Standard descriptive summaries for continuous data were reported, and for categorical data, the count and percent were reported.

RESULTS

A total of 218 patients were randomized and treated (109 in each group). No differences were noted between groups for age, BMI, and other demographic details. Mean femoral broaching time was 5.8 minutes in the KINCISE group, and 8.1 minutes in the MALLET group, a 28.4% reduction. Femoral broaching time for KINCISE group THA was found to be superior compared with manual broaching (p=0.0005). However, there was not a difference in surgery duration between the groups. Three Intra-operative fractures were reported in the MALLET group, and one in the KINCISE group. Hospital stays were less than 24 hours for 172 patients (78.9%) **See Table 1 for additional detail**. All clinical outcomes – Harris Hip Scores*, EQ-5D-5L, EQ-5D VAS, Forgotten Joint Score, pain and patient satisfaction - were similar between groups at 6 weeks and 24 weeks post-operatively.

*Range of motion was not required to be collected at 6 weeks post-op

Table 1 - Operative and Perioperative Information

	KINCISE	MALLET	p-value
Mean Stem Size (CORAIL™)	12.1 (range 9 to 15)	11.4 (range 9 to 15)	0.10
Mean Stem Size (ACTIS™)	5.9 (range 1 to 12)	5.5 (range 2 to 10)	0.19
Difference from templated stem size	0.2 (range -2 to 6)	-0.3 (range -4 to 5)	0.003
Mean Femoral Broaching Time (minutes)	5.8 (range 0.7 to 19.9)	8.1 (range 1.7 to 31.6)	<0.0001§ 0.0005£
Mean Skin-to-Skin Time (minutes)	71.0 (range 43 to 137)	70.2 (range 43 to 117)	0.73
Mean Anesthesia Time (minutes)	117.3 (range 64 to 186)	116.3 (range 65 to 175)	0.79
Mean Length of Stay (days)	0.8 (range 0 to 5)	0.7 (range 0 to 2)	0.44
Fracture	1 (0.9%)	3 (2.8%)	0.36

§Test of non-inferiority
£Test of superiority

CONCLUSIONS

In this randomized multi-center study, an automated impactor was shown to reduce femoral broaching time in primary THA, with no increase in intra-operative fractures, but no decrease in overall OR time was noted.