Mako® Total Hip arthroplasty: clinical summary

Mako clinical evidence

Volume 5

1. Introduction

Total hip arthroplasty (THA) has been one of the most successful procedures within the field of orthopaedics since the late 1960s.[1] The short- and long-term outcomes of THA may be influenced by several factors, including patient demographics, surgical technique and implant features.[2] One of the most important surgeon-controlled factors is component positioning.[2] Component malposition has been linked to higher rates of hip dislocations, poor biomechanics, accelerated wear, leg length discrepancy (LLD), and revision surgeries.[2] In addition, component malposition is directly associated with dislocations and mechanical loosening, which account for approximately 40% of THA revisions.[3]

The Mako System was introduced with a goal of providing more accurate implant positioning and alignment to plan, to help restore patients' anatomy and enhance patient outcomes. This document summarizes the evidence to date that supports the use of Mako Robotic-Arm Assisted surgery for total hip arthroplasty.

2. What is the evidence that Mako Total Hip works?

Successful clinical outcomes following total joint replacement are dependent on component placement and on restoring the natural joint anatomy of the hip.[2] Instability, early mechanical failures and dislocation in hip arthroplasty continue to be primary reasons for revision.[2] The Mako System is designed to minimize the margin of error associated with component placement, and to enhance the accuracy and reproducibility of THA.

2.1 Accuracy and reproducibility in THA

In a multicenter clinical trial including 110 patients, acetabular cup position was compared between pre-operative plan, intra-operative assessment, and achieved radiographic measure.[3] Results confirmed that intraoperative robotic-arm assistance achieved greater accuracy in preparation and position of the acetabular cup during THA (Table 1).[4]

	Pre-op plan	Intra-op robotic-arm measurements	Martell radiographic measurement
Inclination	40.0°±1.2°	39.9°±2.0°	40.0°±4.1°
Version	18.7°±3.1°	18.6°±3.9°	21.5°±6.1°
Count (n)	119	119	110

Table 1. The average inclination and anteversion values of the acetabular components in the study, showing the pre-operative plan, measures recorded interoperatively, and those measured from plan radiographs using the Martell method.[2]

Figure 2a

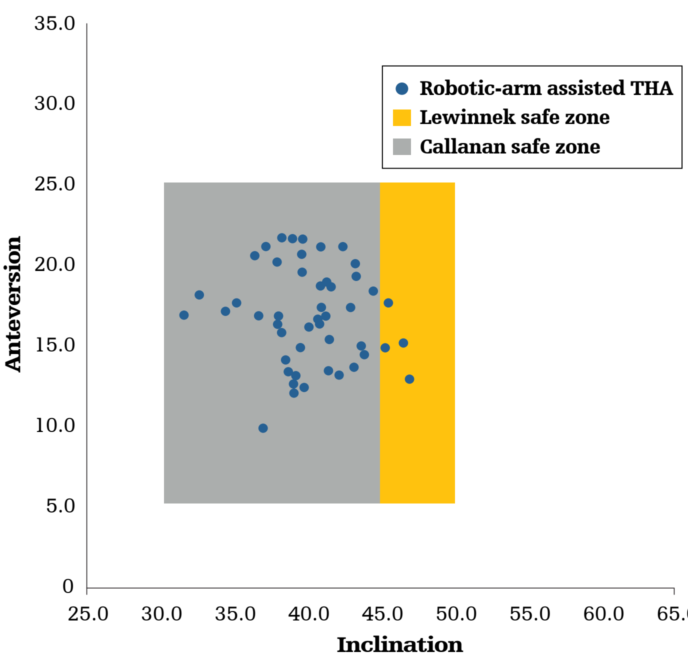
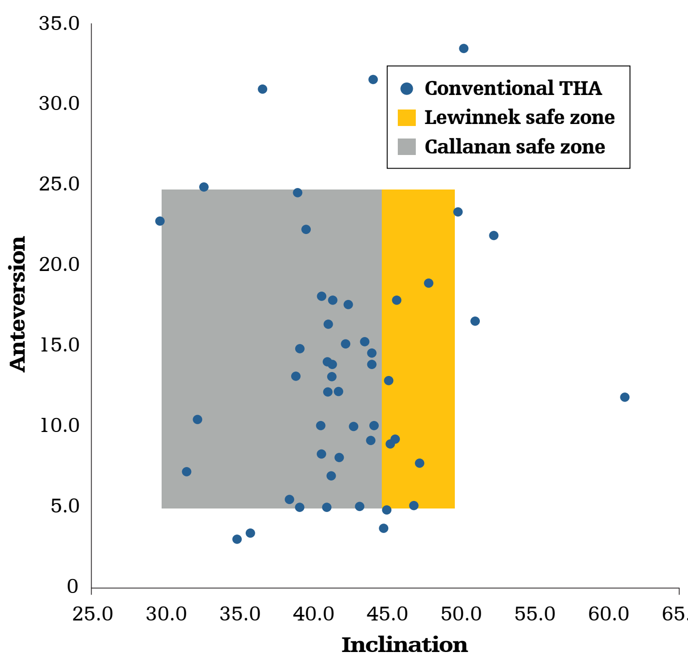


Figure 2b



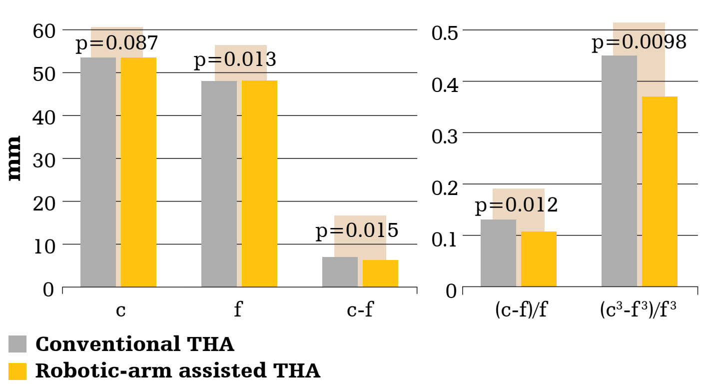
Figures 2a and 2b. Scatterplots of the (a) robotic-assisted and (b) conventional cups in the safe zones of Lewinnek et al. and Callanan et al. are shown.[5]

Domb et al. (2015) conducted a study involving six surgeons at a single institute, in which 1,980 THA surgeries were evaluated.[5] The aim of this study was to understand the influence of surgical approaches and modes of guidance.[5] Robotic-arm assisted surgery resulted in a significantly greater percentage of components placed in Callanan's safe zones (30°-45° inclination and 5°-25° version) than all other modalities, including navigation- and fluoroscopy-guided approaches ($p<0.05$).[5] This study highlighted the consistency of the robotic-arm assisted technology, based on a large patient series.[5]

In another clinical study, which compared robotic-arm assisted THA to manual THA, 100% of robotic-arm assisted THAs were within the Lewinnek safe zone (30°-45° inclination and 5°-25° version), compared with 80% of the conventional THAs ($p=0.001$).[6] A total of 92% of robotic-arm assisted THAs were in Callanan's modified safe zone, compared with 62% of conventional THAs ($p=0.001$).[6] Use of the Mako System allowed for more consistent placement of the cup in both safe zones (Figure 2a-b).[6]

Clinical evidence continues to build on the potential benefits of robotic-arm assisted THA. Investigations have demonstrated robotic-arm assisted surgery is accurate to 1.0 ± 0.7mm for leg length/offset.[7] Compared to manual THA, robotic-arm assisted THA was five times more accurate to plan in cup inclination and 3.4 times more accurate to plan in cup anteversion.[7] A recent publication highlighted the influence of head center of rotation (COR) on the risk of hip dislocation.[8] A potential benefit of robotic-arm assisted THA is that it has been shown to be significantly more accurate in reproducing COR when compared to manual implantation, which may result in reduced incidence of hip dislocation.[7]

Results: Bone stock



c-f = bone thickness lost over course of surgery

(c-f)/f = bone thickness lost through surgery per width of the femoral head

$(c^3-f^3)/f^3$ = volume of bone lost through surgery

Figure 3. Illustrates the Mako System's single reaming technique preserves bone as compared to conventional THA's sequential reaming technique.[9]

The amount of bone stock reamed during primary THA can also have an important influence on the recreation of the center of rotation, as well as on the preservation of bone stock in primary THA patients.[9]

Suarez-Ahedo et al. (2017) studied bone preservation during primary THA and performed a matched pair control study which demonstrated that when compared to conventional THA (n=57), robotic-arm assisted THA (n=57) allowed for more precise reaming. This led to the use of smaller acetabular cups in relation to the patient's femoral head size.[9] Using acetabular cup size relative to femoral head size as a surrogate measure of acetabular bone resection, these results suggested greater preservation of bone stock using robotic-arm assisted THA compared to conventional THA.[9] This may reflect increased translational precision during the reaming process (Figure 3).[9]

The potential benefits of using CT-based robotic technology, such as Mako, to assess the influence of native femoral version on final stem version (SV) and combined anteversion when using a straight, uncemented stem, was researched by Marcovigi et al. (2018).[10] Three hundred and sixty-two patients who underwent Mako Total Hip were enrolled from three different orthopaedic centers.[10] All patients underwent CT planning with measurement of femoral neck version (FNV) and intraoperative measurement of SV, acetabular component version (AV), and combined version (CV), with robotic instrumentation.[10] Results showed that the mean FNV was 5.0° ± 9.6°, and SV was 6.4° ± 9.7°.[10] A strong correlation was found between SV and CV ($R = 0.89$, $P < .001$) and a significant difference in SV was found between the three centers ($P < .001$). CV was <25° in 109 patients (30.1%) with relative risk of CV < 25° being 8.6 times greater with SV < 5° ($P < .001$) (Figure 4).[10]

From this data, it is important to note that when using an uncemented, single-wedge, straight stem, SV is highly variable.[10] Thus, the greater variability of FNV in patients with osteoarthritis is confirmed.[10] Despite being moderately correlated with native FNV, SV can be partially influenced by the surgeon.[10] The authors concluded that knowledge of pre-operative and intra-operative stem version is fundamental to avoid abnormal combined version and therefore reduce risk of impingement, dislocation or acetabular uncoverage.[10] They also emphasized that CT-based planning and robotic technology may be useful tools to have in the operating room, combined with stem designs which facilitate the achievement of desired version angles.[10]

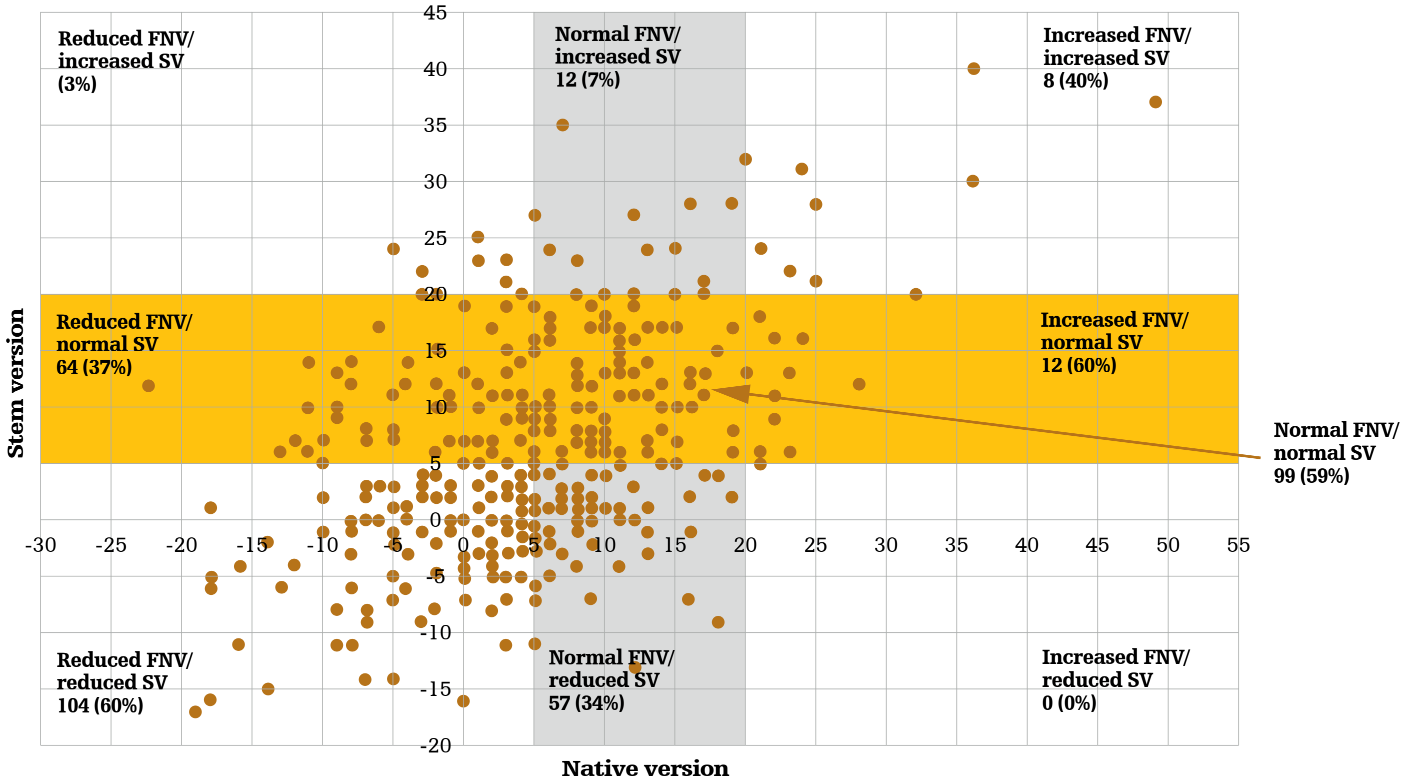


Figure 4. Scatter graph of SV in respect to FNV. The stem "safe zone" was highlighted in green.[10] When FNV was <5°, stem version was "increased" 3% of the time, "normal" 37% of the time, and "reduced" 60% of the time, meaning that the surgeon was not always able to correct femoral retroversion.[9] Also with a "Normal" FNV, the stem was positioned with a SV <5° 34% of the time.[10]

2.2 Surgical team learning curve

In a retrospective, single-surgeon review of 100 consecutive Mako Total Hips, Bukowski et al. (2016) studied the effects of learning curve on the outcome of three groups of patients: 1) the surgeon's first 100 manual THA cases (2000-2001); 2) the surgeon's last 100 manual THA cases (2010-2011); and 3) the surgeon's first 100 Mako Total Hip cases (2011-2012).[11,12] Dislocation was more frequent in group one (5/100, 5%) and group two (3/100, 3%) than in group three (0/100, 0%) ($p<0.05$) at the one year follow-up interval.[12]

Similarly, Redmond et al. (2015) researched the learning curve during the adoption of robotic-arm assisted THA as measured by component position, operative time, and complications.[13]

The first 105 robotic-arm assisted THAs performed by a single surgeon were divided into three groups based on the order of surgery: 1) Group A consisted of the first 35 patients who underwent Mako Total Hip by the senior surgeon, 2) Group B consisted of patients 36–70; and 3) Group C consisted of patients 71–105.[13] The authors reported a decreased risk of acetabular component malpositioning with Mako experience ($P < 0.05$).[13] Operative time appeared to decrease with increasing surgical experience with the Mako System ($P < 0.05$).[13] A learning curve of 35 cases was observed, as a decreased incidence of acetabular component outliers and decreased operative time were noted with increased surgical experience with Mako.[13]

Heng et al. (2018) carried out a retrospective comparison of a single surgeon's last 45 conventional THAs performed prior to changing to the robotic-arm assisted system, and compared them with the first 45 robotic-arm assisted THAs.[14] When comparing surgical times between the two groups, they found that the average surgical time was 96.7 minutes for the robotic-arm assisted group and 84.9 minutes for conventional group.[14] Upon further analysis, the authors determined that each robotic-arm assisted operation was approximately one minute shorter than the previous robotic operation and the average time for the last 10 cases was reduced to 82.9 minutes, which was quicker than the average time of the conventional group.[14] It was concluded that surgical time is comparable with conventional techniques after the initial learning curve of approximately 35 cases.[14]

3. What are the clinical benefits of Mako Total Hip?

Clinical benefits resulting from increased accuracy and precision afforded by Mako Total Hip have been investigated, including functional outcomes and levels of patient satisfaction. Results of studies in this area are promising.

3.1 Clinical and functional outcomes in THA

In the research conducted by Bukowski et al. (2016), outcomes for three groups of 100 consecutive THAs (first 100 manual THAs; last 100 manual THAs; and first 100 Mako Total Hips), were reviewed. Mako Total Hip resulted in significantly higher modified Harris Hip scores (92.1 ± 10.5 vs. 86.1 ± 16.2, p = 0.002) and University of California, Los Angeles (UCLA) activity level (6.3 ± 1.8 vs. 5.8 ± 1.7, p = 0.033) than manual THA, at minimum one-year follow-up (Figure 5 and 6, Table 2).[11]

Perets et al. (2018) have reported on minimum two-year outcomes and complications for Dr. Benjamin Domb's patients who underwent a Mako Total Hip procedure.[15] Dr. Domb is a high-volume, fellowship-trained surgeon.

For the 162 cases Mako Total Hip cases included in their analysis, the average time of surgery was 76.7 minutes which is comparable to times reported in literature for manual surgeries.[12, 15] Patients reported average Harris Hip Score of 91.1.[15]

The Forgotten Joint Score (FJS-12) questionnaire has evidence of low ceiling effects and is suitable for assessing longer term outcomes in well-performing groups after THA.[16] The literature has reported a FJS-12 ranging from 50.9 ± 25.3 to 80 ± 24 for patients who received manual THA.[15,16] For the 162 cases in this study, Perets et al. reported a FJS-12 of 83.1 which, to date, is the highest found in literature on THA.[15] Additionally, at two years, there were no leg length discrepancies or dislocations reported.[15] Post-operatively, six patients reported fractures (greater trochanteric n=3 and calcar n=3) and six had complications such as deep vein thrombosis and infection.[15]

These patients continued to be followed and Stoker et al. (2019) recently presented on minimum five-year outcomes on this patient cohort.[19] When compared to a manual THA control group, the Mako Total Hip cases reported significantly higher Harris Hip (p<0.001), FJS-12 (p=0.002), Veterans RAND (VR)-12 Physical (p=0.002) and Short Form Health Questionnaire (SF)-12 Physical (p=0.001) scores

Patient-reported outcomes (PROMs) comparing rTHA and mTHA patient groups[11]

	Group (rTHA n=100, mTHA n=100)	Preoperative	Postoperative	PROMs (postoperative-preoperative)	p-value
mHHS (mean and standard deviation)	rTHA	49.6 (16.3)	92.1 (10.5)	43.0 (18.8)	<0.001
	mTHA	49.2 (14.8)	86.1 (16.2)	37.4 (18.3)	<0.001
	p-value	0.865	0.002	0.035	
SF12-MCS (mean and standard deviation)	rTHA	54.1 (10.4)	54.6 (9.1)	0.4 (9.7)	0.629
	mTHA	53.1 (9.6)	53.0 (10.2)	0.5 (11.5)	0.970
	p-value	0.459	0.245	0.962	
SF12-PCS (mean and standard deviation)	rTHA	33.5 (9.6)	46.0 10.5)	12.5 (11.8)	<0.001
	mTHA	30.3 (8.0)	44.4 (11.0)	14.0 (11.9)	<0.001
	p-value	0.010	0.282	0.404	
WOMAC (mean and standard deviation)	rTHA	45.6 (18.9)	16.0 (14.9)	-29.6 (21.4)	<0.001
	mTHA	47.1 (14.7)	17.3 (15.5)	-28.5 (18.3)	<0.001
	p-value	0.536	0.538	0.618	
UCLA (mean and standard deviation)	rTHA	5.1 (1.9)	6.3 (1.8)	1.2 (1.7)	<0.001
	mTHA	4.8 (1.8)	5.8 (1.7)	1.0 (1.9)	<0.001
	p-value	0.227	0.033	0.429	

Categorical analysis of modified Harris Hip Score

	rTHA	mTHA	
90-100	75.0% (75)	61.0% (61)	0.034
80-89	13.0% (13)	15.0% (15)	0.684
70-79	6.0% (6)	5.0% (5)	0.756
<70	6.0% (6)	19.0% (19)	0.005

Table 2

(Table 3).[19] While revision rates between these cohorts were similar (p=0.479), the acetabular component placement for the Mako Total Hip cases were more consistently placed within the Lewinnek (p=0.002) and Callanan (p=0.001) safe zones.[19] This study used multiple validated functional hip outcome scores in combination with pain and satisfaction to determine patients who received Mako Total Hip reported favorable outcomes at a minimum 5-year follow-up.[19]

Patient reported outcomes	Robotic-assisted THA	Manual THA	p-value
HHS	90.57±13.46	84.62±14.45	<0.001
FJS-12	82.69±21.53	70.61±26.74	0.002
VAS	1.27±2.20	1.07±1.87	0.45
Satisfaction	8.91±2.00	8.52±2.62	0.35
VR-12 mental	60.76±5.94	58.97±6.03	0.17
VR-12 physical	50.30±8.83	45.92±9.44	0.002
SF-12 mental	56.59±5.60	56.20±6.62	0.81
SF-12 physical	48.97±9.21	44.01±10.26	0.001

Table 3. Minimum 5-year patient reported outcomes for a Mako Total Hip and manual THA cohort.[19]

A similar trend was observed in a retrospective review of 45 Mako Total Hips and 45 conventional THA cases, as conducted by Heng et al. (2018), where complications rates were found to be comparable.[14] The conventional group had three intra-operative complications compared to one in the robotic group.[14] The three intraoperative complications experienced by the conventional group related to acetabular fractures, while the robotic group had none.[14] The authors suggested that this could be due to the single ream, minimal bone resection technique utilized by the robotic system, which may decrease the risk of acetabular fractures.[14]

In a separate study, significant improvements in postoperative patient-reported outcome measures (PROMs) such as Western Ontario and McMaster (WOMAC), modified Harris Hip Score (HHS) and Numeric Pain Rating Score (NPRS) were observed when comparing Mako Total Hip to conventional THA.[18] Banchetti et al. (2018) carried out a retrospective cohort study of a target population of 376 patients from three hospitals, from which 220 patients were randomly selected (Mako Total Hips cases, n= 100; standard technique THA cases, n=120).[18] A total of 107 patients responded at 24 months follow-up (Mako cases, n= 56; and standard technique cases, n=51).[18] The study reported a statistically and clinically significant improvement in all the outcome measures in comparison to pre-operative conditions for both cohorts.[18]

3.2 Patient satisfaction

THA has been one of the most successful surgeries in medicine, having demonstrated favorable short- and long-term outcomes and resulting in more than 95% survivorship in 10 years.[1] In addition, patient satisfaction post-THA is high, as demonstrated in Perets et al. (2018) study, where patient satisfaction at a minimum of two years follow-up was assessed.[15] For the 162 Mako Total Hip cases considered in this study, mean patient satisfaction was a high 9.3 out of 10.[15]

3.3 Patient recovery

When exploring a patient's road to recovery, their length of stay in hospital after surgery is a key factor to consider. Heng et al. (2016) retrospectively compared the length of stay of 45 patients who underwent Mako Total Hip against those who received conventional THA (n=45).[14] They reported similar results in both groups, however once the patients who required inpatient rehabilitation were excluded, the robotic group had a shorter hospital stay (5.93 days vs. 4.22).[14]

This finding was further validated by another study conducted by Banchetti et al. (2018) who retrospectively analyzed 107 patients at 24 months follow-up (Mako Total Hip, n= 56; standard technique THA, n=51).[18] They found a significant difference in the length of hospital stay, defined by number of days hospitalized, between the Mako group (M=5.14. SD=1.98) and the standard group (M=8.11, SD=1.64).[18]

Overall, early data from these studies suggest that patients who undergo Mako Total Hip may be able, on average, to return home sooner after surgery than those who undergo conventional THA. This may pose a great advantage for the patients' well-being, as well as offers financial benefits to healthcare institutions since a reduction in length of hospitalisation has the potential to reduce economic burden to hospitals.[18] Furthermore, these findings have the potential to offer financial benefits to Healthcare Institutions since a reduction in the length of stay post Mako Total Hip surgery potentially reduces the economic burden to hospitals. This is a key area being investigated by various surgeons worldwide.

4. Conclusions

Mako Total Hip offers the potential for surgeons to achieve component placement and alignment accuracy, as well as to enhance clinical outcomes.[4-18] Patients have reported tangible benefits of Mako robotic-arm assisted procedures, including treatment satisfaction and return to activities of daily living.[11, 19] Surgeons are empowered to achieve their target pre-operative plans with precision, helping distinguish them within their medical communities. Ultimately, the benefits of Mako Robotic-Arm Assisted THA may be experienced by all key players – patients, surgeons, and health systems.

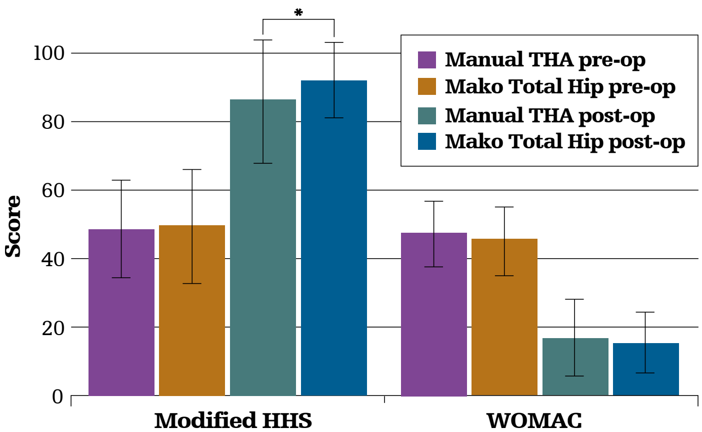


Figure 5. Statistically higher modified HHS were shown for Mako Total Hip patients.[11]

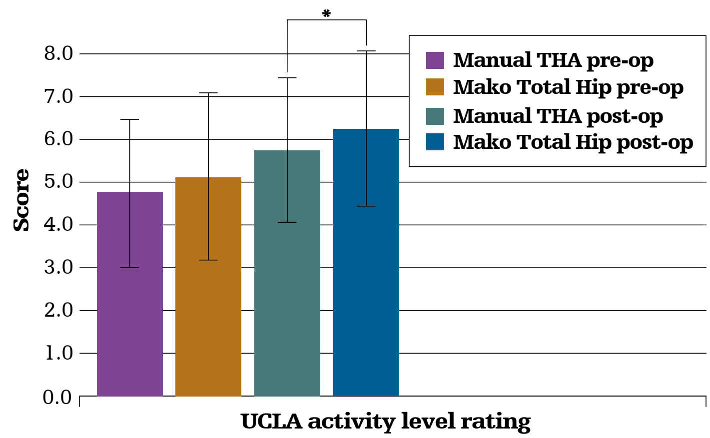


Figure 6. Statistically higher UCLA scores were shown for Mako Total Hip patients.[11]

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