

# Comparison of conventional versus robotic-assisted total hip arthroplasty using the Mako system: An Italian retrospective study

Roberta Banchetti<sup>1</sup>, Silvia Dari<sup>2</sup>, Maria Elisabetta Ricciarini<sup>3</sup>,  
Domenico Lup<sup>3</sup>, Francesco Carpinteri<sup>4</sup>, Fabio Catani<sup>5</sup>, Patrizio Caldora<sup>6</sup>

## *Affiliations:*

<sup>1</sup> D.P.T., Prof, Department of Physical Rehabilitation, Santa Margherita Cortona Hospital, Arezzo, Italy.  
Faculty of Physical Therapy, University of Siena, Italy.

<sup>2</sup> Economist BEc, Faculty of Medicine, Department of Physical Therapy, La Sapienza University, Rome, Italy

<sup>3</sup> M.D., Department of Orthopaedics and Traumatology, Santa Margherita Hospital, Cortona and San Donato Hospital, Arezzo, Italy

<sup>4</sup> M.D., Department of Physical Rehabilitation, San Donato Hospital, Arezzo, Italy

<sup>5</sup> M.D., Prof, Department of Orthopaedics and Traumatology, University Hospital Polyclinic of Modena and Reggio Emilia, Modena, Italy

<sup>6</sup> M.D., Prof, Department of Orthopaedics and Traumatology, Santa Margherita Hospital, Cortona and San Donato Hospital, Arezzo, Italy

## *Corresponding author:*

Dr. Roberta Banchetti, S. Margherita Cortona Hospital, Southeast AUSL of Tuscany Region. Località Fratta 145, 52044 La Fratta di Cortona, Arezzo, Italy. E-mail: roberta.banchetti@uslsudest.toscana.it

## Abstract

**Introduction:** Our research aimed to evaluate differences in terms of length of hospital stay and clinical outcomes between robotic-arm assisted using MAKO system and standard manual implantation in a group of patients who underwent primary total hip arthroplasty (THA).

**Methods:** Our retrospective, cohort study was conducted between August 2014 and March 2016. From our target population of 376 patients from three hospitals of Tuscany Region, Italy, we randomly selected a sample of 220 patients, who was subdivided in two groups (MAKO system  $n = 100$ ; Standard technique  $n = 120$ ). Our evaluation was carried out before and after surgery at 24 months follow-up. Western Ontario and McMaster (WOMAC) Osteoarthritis Index, Harris Hip Modified Score (HHS), and Numeric Pain Rating Score (NPRS) scales were administered. One sample and independent sample T Student tests were used to assess eventual differences within and between groups for the continuous variables. The significance threshold was set up at  $P < 0.05$ .

**Results:** Rate of respondents was 48.6% (MAKO system  $n = 56$ , 56%; Standard technique  $n = 51$ , 42.5%). There was a significant difference in the length of hospital stay, expressed as number of days hospitalized, between the MAKO group ( $M = 5.14$ ,  $SD = 1.98$ ) and the standard group ( $M = 8.11$ ,  $SD = 1.64$ ) ( $t(105) = 15.30$ ,  $P < 0.001$ ). There were no significant differences in preoperative and post-operative scores between robotic-assisted and standard groups in all of the patient-reported outcome measures (PROMs), but we reported a statistically and clinically significant improvement in all of the post-operative PROMs scores for both surgical procedures ( $P < 0.001$ ).

**Discussion and Conclusion:** Our findings showed that the MAKO™ robotic is a valuable technology that may innovate THA. However, further long-term studies are needed to justify additional costs.

**KEY WORDS:** Arthroplasty, Hip Replacement; clinical outcomes; MAKO system; Patient Outcome Measures (PROMS) questionnaires.

## Riassunto

**Introduzione:** La nostra ricerca è stata finalizzata a valutare le differenze in termini di durata del ricovero ospedaliero e di esiti clinici tra la tecnica robotica con il sistema MAKO e quella standard convenzionale in un gruppo di pazienti sottoposti ad artroplastica totale dell'anca.

**Metodi:** Il nostro studio di coorte retrospettivo è stato condotto nel periodo Agosto 2014-Marzo 2016. Dalla nostra popolazione di riferimento composta da 376 pazienti provenienti da tre ospedali della Toscana in Italia, abbiamo selezionato un campione randomizzato di 220 pazienti che sono stati suddivisi in due gruppi (MAKO  $n = 100$ ; Tecnica standard  $n = 120$ ). La nostra valutazione è stata effettuata prima e a 2 anni di distanza dall'intervento chirurgico. Sono stati somministrati i questionari Western Ontario and Mc-Master (WOMAC) Osteoarthritis Index, Harris Hip Modified Score (HHS), and Numeric Pain Rating Score (NPRS). Il Test T di Student con un campione e con due campioni indipendenti è stato utilizzato per valutare le eventuali differenze all'interno e tra i gruppi per le variabili continue. Il livello di significatività statistica è stato fissato a  $P < 0.05$ .

**Risultati:** La percentuale dei rispondenti è stata pari al 48.6% (MAKO  $n = 56$ , 56%; Tecnica standard  $n = 51$ , 42.5%). C'è stata una differenza significativa nell'ospedalizzazione, espressa come numero di giorni di ricovero, tra il gruppo MAKO ( $M = 5.14$ ,  $SD = 1.98$ ) e quello standard ( $M = 8.11$ ,  $SD = 1.64$ ) ( $t(105) = 15.30$ ,  $P < 0.001$ ). Non ci sono state differenze significative nei punteggi preoperatori e postoperatori tra il gruppo operato con tecnica robotica e quello operato con la tecnica standard in tutti gli esiti clinici riferiti dal paziente, ma un miglioramento statisticamente e clinicamente significativo in tutti gli esiti clinici post-operatori riferiti dai pazienti per entrambe le tecniche chirurgiche ( $P < 0.001$ ).

**Discussione e Conclusioni:** I nostri risultati hanno evidenziato che la tecnica robotica MAKO™ è un prezioso strumento tecnologico che può innovare l'artroplastica totale dell'anca. Tuttavia, ulteriori studi a lungo termine sono necessari per giustificare i costi aggiuntivi.

### TAKE-HOME MESSAGE

*MAKO™ robotic is a valuable technology that may innovate total hip replacement.  
However, further long-term studies are needed to justify additional costs.*

**Competing interests** - none declared.

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## INTRODUCTION

Total hip arthroplasty (THA) is considered to be one of the most successful orthopedic interventions of its generation [1]. Every year, about one million patients worldwide undergo THA surgery, which is recognized as a successful, safe and cost-effective medical intervention to restore functionality of the hip joint and to regain pain-free mobility in patients suffering from severe joint disease or trauma. The number of people undergoing primary THA and revision surgery is likely to increase further due to an ageing population, decreasing average age at the first operation and the limited life span of prostheses [2, 3]. Since the first THA in 1891, research has reached advances in technology with respects to prosthesis design and materials as well as new surgical technologies such as minimally invasive surgery and computer-assisted surgery [4]. Various systems of computer-assisted orthopaedical surgery in total hip arthroplasty have been developed since the early 1990s. These include computer assisted preoperative planning, robotic devices, navigation, and patient specific surgical templates [5]. The first clinically applied system was an active robotic system called ROBODOC® (Integrated Surgical Systems Inc, Sacramento, CA), which performed femoral implant cavity preparation as programmed preoperatively. This system was developed to overcome some issues concerning postoperative thigh pain [6], intraoperative fracture [7], and failure of bony ingrowth related to first cementless femoral components [8].

ROBODOC was the first active robotic-assisted system to be designed. It consists of a preoperative planning computer workstation based on computed tomography (CT) data input linked to a robotic arm with a high-speed burr as an end effector that mills the femoral canal for the selected implant in the position chosen preoperatively on the computer workstation [9]. However, Bargar et al. in a comparison study between ROBODOC® and manual intervention groups showed the existence of significant differences concerning only the radiographic outcomes [9].

Therefore, further system improvement was made. In Europe, the first clinical use was in Germany in 1994. Since then, the system received criticism and, as a consequence, ROBODOC was not in clinical use in Europe [10]. Afterly, the ROBODOC system use was authorized by US Food and Drug Administration in 2008 [11] and robotic-assisted total hip replacement has become a common method of implantation, especially in Europe. In a 2003 randomized controlled trial, Matthias et al. showed the robotic-assisted technology had advantages in terms of preoperative planning and accuracy of the intraoperative procedure. However, they also showed some disadvantages such as the high revision rate, the amount of muscle damage, which could be responsible for the higher dislocation rate, and the longer duration of surgery. They, therefore, suggested further developments of this technology [12]. Furthermore, both Bargar et al. [9] and Honl et al. [13], in their prospective randomized studies showed no differences in clinical scores between the robotic-assisted and conventional groups. They highlighted better radiographic results in the robotic group, which, however, presented more complications like dislocation and revision than standard technique [13]. In a 2010 study of follow-up, Nakamura et al. showed that clinical score was slightly better in the robotic-assisted group at 2 and 3 years postoperatively, but this difference was no significant at 5 years follow-up [14]. Errors and complication encountered with the use of active systems, such as ROBODOC, suggested that no current active system can be considered autonomous, with the implied ability on the part of the robot or system to make decisions. In this way, surgeon training is an important issue that can minimize negative incidences due to the learning curve [5]. In recent years, improvement of surgical performance for THA was done by new machines. A most recent robotic device that was approved by US Food and Drug Administration, which is currently used in THA is Makoplasty®. The MAKOpasty® navigation system (Stryker) is an advanced surgical technique that uses a surgeon-con-

trolled semiactive robotic-assisted Robotic Arm Interactive Orthopaedic System (RIO<sup>®</sup>, MAKO Surgical Corporation), which was successfully used to achieve more precise acetabular reaming and cup placement [15] giving better results for offset, leg length, stability and range of motion [5]. Regardless of the robotic system used, some studies showed that robotic-assisted THAs have better component positioning and potentially better clinical outcomes and, therefore, long-term results than THA performed with conventional techniques [16]. Conversely, other studies highlighted an increased complication rate and costs associated with robotic techniques [10]. Moreover, there is not enough evidence in the literature about the feasibility, safety, and efficacy of the semi-active systems [5]. According to a literature review, robotic-assisted surgery is more accurate in alignment of the femoral and acetabular components and has improved reproducibility compared to conventional technique for primary THA. However, controversy still exists about clinical outcomes. In their review, Newman et al. initially identified 423 studies, of which, 15 articles met their inclusion criteria [17]. However, only two of their 15 comparison studies included employed the MAKO platform [18, 19].

The Mako system (model RIO System -Stryker) was introduced in the USA in 2006 for use during partial knee arthroplasty surgery and in 2010 for total hip arthroplasty surgery, when a haptic-controlled semi-active robotic arm was designed to perform UKA [20]. In Italy, this technology started to work for the first time in 2014 at University-Hospital Polyclinic of Modena, in Emilia-Romagna Region and, contemporaneously, at Local Health Unit of Arezzo, in Tuscany Region. To our best knowledge, there are no studies about robotic-assisted THR using the MAKO system in Italy. Our research aimed to compare robotic-arm assisted using MAKO platform and standard manual implantation in a group of patients who underwent primary total hip replacement at three hospitals in Arezzo, Cortona and Sansepolcro, Tuscany

Region, Italy, during the period August 2014-March 2016. Our aim was to evaluate differences in terms of length of hospital stay and clinical outcomes between these two surgical procedures, before surgery and at a distance of 24 months after the index procedure.

## MATERIALS AND METHODS

### *Patients and study's protocols*

Between August 2014 and March 2016, a total of 376 patients from three hospitals underwent THA, of which 125 with the RIO system and 251 with the conventional manual technique. From our target population, we randomly selected a sample of 220 patients, who was subdivided in two groups (MAKO system  $n = 100$ ; Standard technique  $n = 120$ ). These two groups were homogeneous for age, hip disease (osteoarthritis), gender, comorbidity, race and type of surgery (i.e., elective robotic-assisted THR). In our retrospective analysis, only patients with a follow-up of 24 months and subjected to posterior-lateral approach were considered. Patients with contralateral hip or spine pathologies, bilateral THA, and important comorbidities (e.g., cardiovascular, psychiatric, oncological or rheumatic disorders) were excluded. Pre-operative and post-operative protocols for all study participants included a complete clinical assessment with the following validated Reported Patient Outcome Measures (PROMS) questionnaires: Harris Hip Score modified Questionnaire; Western Ontario and McMaster Universities Arthritis Index (WOMAC), Numerical Pain Rating Scale (NPRS) as pain scale. All patients underwent robotic-assisted THA by using the MAKO<sup>™</sup> robotic hip system (MAKOplasty<sup>®</sup> total hip application; MAKO<sup>™</sup> Stryker), which is a robotic-assisted computer navigation that uses the RIO<sup>®</sup> (Robotic Arm Interactive Orthopedic System) for reaming the acetabulum during bone preparation and cup placement. CT scans of the involved hip were obtained preoperatively for all patients. A 3-D patient-specific model was created by the robotic system that was used to guide performance of the total hip arthroplasty. For

conventional surgery, prosthetic models used were CLS® and FITMORE®, whereas for robotic-assisted surgery CORIN® and ACCOLADE II® models were implanted. The couplings were polyethylene-ceramic or ceramic-ceramic. Both the robotic and conventional THA were performed with the patient in the lateral position using the postero-lateral approach [19]. Further and importantly, all of the patients were subjected to the same rehabilitation program.

Length of hospital stay was recorded for every patient. A complete pre-operative and post-operative clinical assessment (Harris Hip Score modified, Womac, NRS and Pain Scales) was administered by telephone interviews to patients at a follow-up of 12 and 24 months after surgery. Oral informed consent was collected from each participant after explaining every detail pertaining to the study. The study content and procedures were reviewed and approved by the Institutional Ethics Review Board (IERB) of the hospitals.

### *Clinical evaluation*

To assess clinical function and daily quality life we used three questionnaires named Western Ontario and McMaster (WOMAC) Osteoarthritis Index, Harris Hip Modified Score (HHS), and Numeric Pain Rating Score (NPRS). The WOMAC questionnaire evaluates pain (during walking, climbing stairs, working and at rest) by 5 items scoring from 0 to 20, joint stiffness by 2 items that scores from 0 to 8, and activities of daily life by 17 items scoring from 0 to 68. Total score ranges from 0 to 96. The HHS specifically evaluates activities of daily life, pain and hip joint functions of the patients after hip arthroplasty. It consists of 4 sub-scales, the total score ranges from 0 to 100 (90-100 'Excellent', 80-90 'Good', 70-79 'Fairly', < 70 'Poor'). This tool was developed by Harris [22] and validated by Soderman and Malchau in 2001 [22]. In addition, other authors validated a self-administered version of the questionnaire [23]. Further, a modified version of this scale was used in our study based on adjustments proposed by several authors [24, 25]. There are

several 'Pain Scales' like the Visual Analogic Scale, the Numerical Pain Rating Scale (NPRS), and the Verbal Rating Scale (VRS). In our study, the NPRS was used because it is an excellent self-assessment measure of the pain intensity and, for this reason, it is the most commonly used in literature. Participants rated their pain on a numeric scale ranging from 0 ('No pain') to 10 ('Worst pain imaginable') [26, 27].

### *Statistical analysis*

Descriptive statistics were used for data of participants. One sample and independent sample T tests were used to assess eventual differences within and between groups for the continuous variables that are presented with their mean and standard deviation (SD). SPSS software version 12 was used. The significance threshold was set up at  $P < 0.05$ .

## **RESULTS**

Rate of respondents was 48.6% (RIO system  $n = 56$ , 56%; Standard technique  $n = 51$ , 42.5%). Mean age of the RIO system group was  $66.23 \pm 11.1$  (range 42-83), whereas it was  $69.77 \pm 10.2$  (range 42-86) for the control group. The number of male patients were 31 (55.3%) and 26 (50.9%) for the RIO system and conventional groups, respectively. Laterality of THA was on the right side (right to left) in 33 cases (58.9%) for robotic-assisted interventions and in 38 cases (74.5%) for manual standard technique. There was a statistically significant difference in the length of hospital stay, expressed as number of days hospitalized, between the MAKO group ( $M = 5.14$ ,  $SD = 1.98$ ) and the standard group ( $M = 8.11$ ,  $SD = 1.64$ ) ( $t(105) = 15.30$ ,  $P < 0.001$ ).

As shown in Table 1, preoperative values of the WOMAC scale were similar between two groups, but this difference became more slightly in the post-operative period. With regard to the Harris Score and NRS scales, preoperative values were also very similar between standard and robotic-assisted groups, before and post-intervention. Furthermore, an independent sample T-test showed nei-

ther statistically significant differences in pre-operative or post-operative scores between robotic-assisted and standard groups in all of the scales administered.

Conversely, a one-sample T test confirmed a statistically and clinically significant improvement in WOMAC scale between pre-operative and post-operative scores for both standard ( $M_1 = 68.9$ ,  $SD_1 = 11.25$ ,  $M_2 = 6.96$ ,  $SD_2 = 10.27$ ) ( $t(50) = 29.04$ ,  $P < 0.001$ ) and robotic-assisted group ( $M_1 = 70.1$ ,  $SD_1 = 14.83$ ,  $M_2 = 6.83$ ,  $SD_2 = 11.17$ ) ( $t(55) = 25.52$ ,  $P < 0.001$ ). This significant difference between pre-operative and post-operative scores was also confirmed in HHS scale for standard ( $M_1 = 46$ ,  $SD_1 = 8.77$ ,  $M_2 = 85.1$ ,  $SD_2 = 7.79$ ) ( $t(50) = 23.75$ ,  $P < 0.001$ ), and robotic-assisted group ( $M_1 = 44.3$ ,  $SD_1 = 13.80$ ,  $M_2 = 85.69$ ,  $SD_2 = 8.14$ ) ( $t(55) = 19.30$ ,  $P < 0.001$ ). With regard to NRS scale, there was also a significant improvement between pre-operative and post-operative scores for standard ( $M_1 = 8$ ,  $SD_1 = 1.13$ ,  $M_2 = 0.84$ ,  $SD_2 = 1.56$ ) ( $t(50) = 26.44$ ,  $P < 0.001$ ) and robotic-assisted group ( $M_1 = 8.6$ ,  $SD_1 = 1.20$ ,  $M_2 = 0.82$ ,  $SD_2 = 1.29$ ) ( $t(55) = 32.98$ ,  $P < 0.001$ ).

## DISCUSSION

Our retrospective, cohort study aimed to compare differences in length of hospital stay and patient-reported outcome measures (PROMs) between patients who underwent

robotic-assisted with the MAKO platform and manual total hip arthroplasty. The two homogeneous sub-groups of patients had similar pre-operative scores with no significant differences in every clinical outcomes before surgery. At 24 months follow-up, scores of both groups reported a statistically and clinically significant improvement in all of the patient-reported outcome measures (PROMs), i.e. the WOMAC, HHS and NPRS questionnaires, in comparison with preoperative conditions. This improvement was highlighted for both conventional and robotic-assisted groups. However, we showed no statistically and clinically significant differences in post-operative scores between these two groups of patients. The only significant difference that we showed was related to the length of hospital stay, for which robotic-assisted surgery performed better than conventional technique.

Several studies used WOMAC questionnaire as the main patient self-reported outcome of 'joint perception' to compare hip and knee replacement surgery [28–30]. Functional outcome after total hip replacement is affected by accurate component positioning and restoration of hip biomechanics. In a recent (2017) retrospective cohort study on outcomes of robotic-assisted total hip arthroplasty, Illgen et al. showed that robotic-assisted total hip arthroplasty improved acetabular component

**Table 1.** Comparison between robotic-assisted and standard surgery groups in preoperative and postoperative scores ( $n = 107$ ).

| Type of surgery ( $n = 107$ ) |                               |                       |              |
|-------------------------------|-------------------------------|-----------------------|--------------|
| Scales                        | Robotic-assisted ( $n = 56$ ) | Standard ( $n = 51$ ) | P            |
| <i>WOMAC</i>                  |                               |                       |              |
| Pre-operative                 | 70.1 (SD 14.8)                | 68.9 (SD 11.2)        | $P = 0.6256$ |
| Post-operative (24 months)    | 6.8 (SD 11.1)                 | 6.9 (SD 10.2)         | $P = 0.9536$ |
| <i>NRS</i>                    |                               |                       |              |
| Pre-operative                 | 8.6 (SD 1.2)                  | 8 (SD 1.1)            | $P = 0.084$  |
| Post-operative (24 months)    | 0.82 (SD 1.5)                 | 0.84 (SD 1.5)         | $P = 0.9377$ |
| <i>Harris Hip Score</i>       |                               |                       |              |
| Pre-operative                 | 44.3 (SD 13.8)                | 46 (SD 8.7)           | $P = 0.4386$ |
| Post-operative (24 months)    | 85.6 (SD 8.1)                 | 85.15 (SD 7.7)        | $P = 0.7276$ |

Significant at  $P < 0.05$

accuracy and reduced dislocation rates when compared with manual total hip arthroplasty. Comparisons included also operative time, estimated blood loss and infection rate. The study showed no statistically significant differences in the rate of infection between groups. However, authors called for larger multicenter studies using alternative surgical approaches [31].

Domb et al. [19] stated that use of the robot allows for improvement in placement of the cup in the safe zones described by Lewinnek et al. [32] and Callanan et al. [33], which is an important parameter in long-term success of THA. However, whether the radiographic improvements observed can translate into clinical benefits for patients, such as reductions in component impingement, acetabular wear, and prosthetic dislocations, or in terms of improved longevity, has to be still demonstrated. A recent study by Bukowski et al. compared operative time, estimated blood loss, postoperative complications and patient-reported outcome measures (PROMs), such as Short-Form 12 Health Survey (SF-12), UCLA activity score, WOMAC and modified HHS, between patients who either underwent robotic THR or manual THR. In that research, the robotic THR cohort demonstrated significantly higher mean postoperative UCLA and mHHS scores at a minimum one-year follow-up. However, authors showed neither significant differences in SF-12 or WOMAC scores, nor in overall complication rates between the two groups. Only estimated intraoperative blood loss was significantly reduced for robotic THR group [34].

Most of the studies comparing robotic-assisted and conventional THA were based on ROBODOC. There were a few studies on MAKO platform. Alignment of the femoral and acetabular components was shown to be statistically superior in the robotic groups, regardless of type of robotic technique. Domb et al. (50 robotics versus 50 controls) reported results of using the MAKOplasty® and found it was significantly more likely to obtain correct acetabular cup alignment ( $P = 0.001$ ), inclination ( $P = 0.004$ ), and anteversion ( $P$

$= 0.002$ ) compared to controls [19]. Nawabi et al. using a very small sample (12 cadaveric hip, 6 robotics and 6 control) reported that the robotic-assisted devices allowed for increased accuracy and precision for the acetabular cup to have the correct orientation and center of rotation [18].

The main improvement introduced by the use of robotic hip technique is the reduction of the prosthesis placement errors. The preoperative planning is planned by a software, starting from a CT scan, which reproduce in 2D and 3D the anatomy of the subject to operate. The computer system controls and guides, allowing the surgeon to work with millimeter accuracy thanks to an infrared camera; the seat of the prosthesis is reamed to achieve the final socket size because the software is planned on areas of bone to be removed, by determining the coupling of stem centre of rotation in order to optimize the leg length and offset. Therefore, the surgical gesture is displayed even before making the incision. The final result is personalized for each patient. Conversely, with the standard technique, the surgeon follows the anatomic reference trusting by own experience [35].

The Robotic Arm Interactive Orthopedic (RIO) system (Mako Surgical Corp., Fort Lauderdale, FL, USA) assisted THA uses patient's CT scan data to create 3D surgical plan ensuring implant placement specific to the anatomy. Therefore, RIO robotic arm guidance and real time 3D visual feedback gives precision of bone preparation of femur and acetabulum. Robotic technology improves the human performance by ensuring accurate placement of the surgical tools and reducing surgical errors. In this way, the accurate combined component placement of cup and stem is closely related to stability, functionality and wear in total hip arthroplasty (THA) [36].

The MAKO™ robotic is a valuable technology that may innovate THA. This robotic system guides navigation giving precision of bone preparation of the femur and acetabulum. It provides quantitative knowledge of component position and biomechanical reconstruction of leg length and offset and

has a safe mechanism for acetabular preparation and cup implantation [37]. In comparison with standard surgical techniques, the MAKO Tactile Guidance System has many advantages concerning an increased surgical accuracy, reproducibility and optimization of component position in both unicompartmental knee and hip arthroplasty procedures.

However, in accordance with Werner et al., although the benefits of this new technology are noticeable, real improvement of patient outcomes have to be shown to justify the added financial burden requested [38].

Our study has some limitations. It was a retrospective analysis and the sample was small, due to low rate of respondents. We did not compare early or late post-operative complications such as blood loss, leg length discrepancy, offset, instability, impingement, "edge-loading" and wear; moreover, for this study we compare neither surgical time nor radiological outcomes. As a matter of fact, past studies showed that robotic-assisted surgery requires more surgical time than standard and results in a wide range of rates of complications (from 0 to 55%), despite better radiographic outcomes. However, there is not enough evidence in the literature that better radiographic outcomes correspond to better clinical outcomes [5, 17–19]. Furthermore, some scholars tried to study the learning curve of the operating surgeons, because learning procedures and surgical practices could play an important role for the final results, improving the outcomes of the robotic-assisted THR. For instance, Illgen described the learning curve of results of surgeons which operated with Mako technology, showing a significantly higher score in both HHS and UCLA scales, both for standard and robotic-assisted procedures [39]. Stryker offers the so called 'Electric Learning', with innovative learning techniques at various levels, by a continuing training to determine the best learning curve. It is not mentioned the minimum number of patients to become proficient [40]. Before starting using the robotic arm, however, the surgeon must carry out the rating course to be allowed to perform robotic-assisted THA.

Therefore, this curve cannot be standardized for a minimum number of operations, but it is much more complex and multifaceted than reported in the specific orthopedic literature [41, 42].

Conversely, our study has also some strengths. Our patients were randomized and our 2-years follow-up study was longer than some of past comparison studies. Furthermore, this was the first Italy-based study and one of the few about robotic technique of THA using the MAKO platform.

Although computer-assisted total hip replacement utilizes digital image systems helping surgeons to obtain reproducible and accurate placement of implants, and improving the accuracy of prosthesis positioning, this has not yet been showed to have clinical benefits [4]. Actually, it leads to an increased surgical time, elevated costs and operative complexity [43]. Manzotti et al. in a matched-pair study comparing 48 computer-assisted THRs with 48 THRs performed using a traditional freehand alignment method, showed no statistically significant difference in the Harris Hip Score or normalized WOMAC Arthritis index, no incidence of prosthetic dislocation or significant intra-operative complications in both groups. However, the surgical time was statistically longer in the computer-assisted group, even if using computer navigation of both the femoral stem and acetabular cup in THR represents a practical way to achieve a more 'anatomical hip arthroplasty' [44]. Some studies about hip biomechanics have demonstrated that durability of prostheses is negatively affected by instability, edge-loading and impingement, regardless of the type of coupling and design of prosthesis. The robotic technique by tackling these adverse effects could potentially increase the prosthetic survival. In the next future, long-term studies concerning data for the prosthetic survival will be able to benefit from specific national registries.

In Italy, the national register named as R.I.A.P. was developed by Ministry of Health to collect more information, but not all Italian Regions chose to take part to it [45].

Therefore, this register can provide only partial information, by drawing up data from hospital discharges based only on ICD-9-CM Classification.

The International Society of Arthroplasty Registries (ISAR) Patient-Reported Outcome Measures (PROMs) Working Group does not make specific recommendations about which PROMs to use in arthroplasty registries. However, according to the Working Group, registries should choose PROMs instruments, which were previously developed with a relevant patient population and have evidence of good measurement properties for patients who have arthroplasty [46]. Our study confirms the importance of the PROMs Questionnaires as validated and powerful tools, which are increasingly important for optimizing health care resources [47].

In conclusion, our study showed that both the robotic-assisted and standard total hip arthroplasty are able to give greater benefits and advantages to patients in terms of patient satisfaction and return to daily life, which are part of the prosthesis consolidation process.

We found no any clinically and statistically significant differences in clinical outcomes of THA surgery between MAKO robotic-arm assisted and manual conventional groups, except for length of hospital stay, for which robotic-assisted surgery performed better than conventional technique.

According to 2017 Stryker's data [48], MAKO robot would allow surgeons to achieve the best precision in the positioning of the component with a subsequent improvement of clinical outcomes, leading to important benefits and better quality of life for patients [27, 49]. However, studies showed that robotic-assisted technology lead to an increasingly anesthesia and operating time, probably due to intraoperative issues concerning the surgeon-robot interaction; furthermore, additional equipment in the operating room requires more operatory space, and skilled and trained workforce; other concerns include the high costs of equipment and prostheses. For all these reasons, further long-term studies focusing on prosthesis survival are needed to justify additional costs.

## References

1. Callaghan JJ, Albright JC, Goetz DD, Olejniczak JP, Johnston RC. Charnely total hip arthroplasty with cement. Minimum twenty-five-year follow-up. *J Bone Joint Surg Am.* 2000;82:487-497.
2. Holzwarth U, Cotogno G. Total hip arthroplasty. State of the Art, Challenges and Prospects. Luxembourg: Joint Research Centre, Institute for health and Consumer protection, European Commission; 2012.
3. Torre M, Romanini E, Zanoli G, Carrani E, Luzi I, Leone L, et al. Monitoring Outcome of Joint Arthroplasty in Italy: Implementation of the National Registry. *Joints.* 2017;5(2):70-78.
4. Knight SR, Aujla R, Biswas SR. Total hip arthroplasty-over 100 years of operative history. *Orthop Rev.* 2011;3:e16.
5. Sugano N. Computer-assisted orthopaedic surgery and robotic surgery in total hip arthroplasty. *Clin Orthop Surg.* 2013;5:1-9.
6. Callaghan JJ, Dysart SH, Savory CG. The uncemented porous-coated anatomic total hip prosthesis. Two-year results of a prospective consecutive series. *J Bone Joint Surg.* 1988;70A:337-346.
7. Mallory TH, Kraus TJ, Vaughn BK. Intraoperative femoral fractures associated with cementless total hip arthroplasty. *Orthopedics.* 1989;12:231-239.
8. Engh CA, Bobyn RM. Biological fixation in total hip arthroplasty. Thorofare, NJ: Slack Inc; 1985.
9. Bargar WL, Bauer A, Börner M. Primary and revision total hip replacement using the ROBODOC<sup>(R)</sup> system. *Clin Orthop Relat Res.* 1998;354:82-91.
10. Schulz AP, Seide K, Queitsch C, von Haugwitz A, Meiners J, Kienast B, et al. Results of total hip replacement using the Robodoc surgical assistant system: clinical outcome and evaluation of complications for 97 procedures. *Int J Med Robot.* 2007;3:301-306.

11. ROBODOC, a CUREXO Technology Corporation [cited 2017, Dec 15]. Available from: <http://www.robodc.com>.
12. Matthias H, Oliver D, Christian G, Volker C, Frank L, Sebastian D, et al. Comparison of robotic-assisted and manual implantation of a primary total hip replacement: a prospective study. *J Bone Joint Surg Am.* 2003;85(8):1470–1478.
13. Honl M, Dierk O, Gauck C, Carrero V, Lampe F, Dries S, et al. Comparison of robotic-assisted and manual implantation of a primary total hip replacement: a prospective study. *J Bone Joint Surg Am.* 2003;85:1470–1478.
14. Nakamura N, Sugano N, Nishii T, Kakimoto A, Miki H. A comparison between robotic-assisted and manual implantation of cementless total hip arthroplasty. *Clin Orthop Relat Res.* 2010;468:1072–1081.
15. Dorr LD, Jones RE, Padgett DE, Pagnano M, Ranawat AS, Trousdale RT. Robotic guidance in total hip arthroplasty: the shape of things to come. *Orthopedics.* 2011 Sep 9;34(9):e652–655.
16. Paul HA, Bargar WL, Mittlestadt B, Musits B, Taylor RH, Kazanzides P, et al. Development of a surgical robot for cementless total hip arthroplasty. *Clin Orthop Relat Res.* 1992;285:57–66.
17. Newman J, Carroll K, Cross M. Robotic-assisted total hip arthroplasty: a critical appraisal. *Robot Surg Res Rev.* 2014;1:37–42.
18. Nawabi DH, Conditt MA, Ranaway AS, Dunbar NJ, Jones J, Banks S, et al. Haptically guided robotic technology in total hip arthroplasty: a cadaveric investigation. *Proc Inst Mech Eng H.* 2013;227(3):302–309.
19. Domb BG, El Bitar YF, Sadik AY, Stake CE, Botser IB. Comparison of Robotic-assisted and Conventional Acetabular Cup Placement in THA: A Matched-pair Controlled Study. *Clin Orthop Relat Res.* 2014;472(1):329–336. doi:10.1007/s11999-013-3253-7.
20. Roche M. Robotic-assisted unicompartmental knee arthroplasty: The MAKO experience. *Clin Sports Med.* 2014;33(1):123–132.
21. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. *J Bone Joint Surg Am.* 1969 Jun;51(4):737–755.
22. Söderman P, Malchau H. Is the Harris hip score system useful to study the outcome of total hip replacement? *Clin Orthop Relat Res.* 2001 Mar;(384):189–197.
23. Mahomed NN, Arndt DC, McGrory BJ, Harris WH. The Harris hip score: comparison of patient self-report with surgeon assessment. *J Arthroplasty.* 2001;16(5):575–580.
24. Edwards PK. Are range of motion measurements needed when calculating the Harris Hip Score? *J Arthroplasty.* 2016;31(4):815–819.
25. Hirvonen J. The Effect of Waiting Time on Health-Related Quality of Life, Pain, and Physical Function in Patients Awaiting Primary Total Hip Replacement: A Randomized Controlled Trial. *Value Health.* 2009;212(6):942–947.
26. Hjermstad MJ, Favers PM, Haugen DF, Caraceni A, Hanks GW, Loge JH, et al. Studies comparing Numerical Rating Scales, Verbal Rating Scales, and Visual Analogue Scales for assessment of pain intensity in adults: a systematic literature review. *J Pain Symptom Manage.* 2011;41(6):1073–1109.
27. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *J Clin Nurse.* 2005;14(7):798–804.
28. Collins M, Lavigne M, Girard J, Vendittoli PA. Joint perception after hip or knee replacement surgery. *Orthop Traumatol Surg Res.* 2012;98:275–280.
29. Ethgen O, Bruyere O, Richy F, Dardennes C, Reginster JY. Health-related quality of life in total hip and knee arthroplasty. *J Bone Joint Surg Am.* 2004;86:963–969.
30. Marx RG, Jones EC, Atwan NC, Closkey RF, Salvati EA, Sculco TP. Measuring improvement following total hip and knee arthroplasty using patient-based measures of outcome. *J Bone Joint Surg Am.*

2005;87:1999–2010.

31. Illgen RL, Bukowski BR, Abiola R, Anderson P, Chughtai M, Khlopas A, et al. Robotic-assisted total hip arthroplasty: outcomes at minimum two-year follow-up. *Surg Technol Int.* 2017;30:365–372.
32. Lewinnek GE, Lewis JL, Tarr R, Compere CL, Zimmerman JR. Dislocations after total hip-replacement arthroplasties. *J Bone Joint Surg Am.* 1978;60:217–220.
33. Callanan MC, Jarrett B, Bragdon CR, Zurakowski D, Rubash HE, Freiberg AA, et al. The John Charnley Award: risk factors for cup malpositioning: quality improvement through a joint registry at a tertiary hospital. *Clin Orthop Relat Res.* 2011;469:319–329. doi: 10.1007/s11999-010-1487-1.
34. Bukowski BR, Anderson P, Khlopas A, Chughtai M, Mont MA, Illgen RL. Improved functional outcomes with robotic compared with manual total hip arthroplasty. *Surg Technol Int.* 2016;29:303–308.
35. Dorr LD, Malik A, Dastane M, Wan Z. Combined anteversion technique for total hip arthroplasty. *Clin Orthop Relat Res.* 2009 Jan;467(1):119–127. doi: 10.1007/s11999-008-0598-4.
36. Patil VK, Wan Z, Dorr L. *Robotic Surgery: Applications and Advances*; March 2013. doi:10.2217/ebo.12.252.
37. Tarwala R, Dorr LD. Robotic assisted total hip arthroplasty using the MAKO platform. *Curr Rev Musculoskelet Med.* 2011;4:151–156.
38. Werner SD, Stonestreet M, Jacofsky DJ. Makoplasty and the accuracy and efficacy of robotic-assisted arthroplasty. *Surg Technol Int.* 2014;24:302–306.
39. Illgen R. Robotic Arm Assisted THA Improved Accuracy, Reproducibility, and Outcomes Compared to Conventional Technique. 43<sup>rd</sup> - Annual Course: Advances in Arthroplasty, October 22-25, 2013, Boston, MA.
40. Stryker. OUS 2017 Clinical Dossier - MKOSYM-CG-3\_13144\_2017 / Mako Partial Knee and Total Hip clinical summary. [Cited 2017, Dec 15]. Available from: <http://strykerlearn.com/events/>.
41. Nzeako O, Back D. Learning curves in arthroplasty in orthopedic trainees. *J Surg Educ.* 2016;73(4):689–693.
42. Wilson MD, Dowsey MM, Spelman T, Choong PF. Impact of surgical experience on outcomes in total joint arthroplasties. *ANZ J Surg.* 2016;86(12):967–972.
43. Reininga IH, Zijlstra W, Wagenmakers R, Boerboom AL, Huijbers BP, Groothoff JW, et al. Minimally invasive and computer-navigated total hip arthroplasty: a qualitative and systematic review of the literature. *BMC Musculoskelet Disord.* 2010;11:92.
44. Manzotti A, Cerveri P, De Momi E, Pullen C, Confalonieri N. Does computer-assisted surgery benefit leg length restoration in total hip replacement? Navigation versus conventional freehand. *Int Orthop.* 2011;35:19–24.
45. Torre M, Luzi I, Romanini E, Zanolli G, Tranquilli Leali P, Masciocchi M, et al. Il Registro Italiano Artroprotesi (RIAP): stato dell'arte. *Ital J Orthop Traumatol.* 2013;39:90–95.
46. Rolfson O, Bohm E, Franklin P, Lyman S, Denissen G, Dawson J, et al. Patient-reported outcome measures in arthroplasty registries Report of the Patient-Reported Outcome Measures Working Group of the International Society of Arthroplasty Registries Part II. Recommendations for selection, administration, and analysis. *Acta Orthop.* 2016 Jul;87 Suppl 1:9–23. doi: 10.1080/17453674.2016.1181816. Epub 2016 May 26.
47. Rolfson O, Rothwell A, Sedrakyan A, Chenok KE, Bohm E, Bozic KJ, et al. Use of Patient-Reported Outcomes in the Context of Different Levels of Data. *J Bone Joint Surg Am.* 2011 Dec 21; 93(Suppl 3): 66–71.
48. Jerabek SA, Carroll KM, Maratt JD, Mayman DJ, Padgett DE. Accuracy of Cup Positioning and Achieving Desired Hip Length and Offset Following Robotic THA.; 14th Annual CAOS Meeting, June 18-21, 2014, Milan, Italy.

