

Clinical efficacy of OrthoPilot navigation system versus conventional manual total hip arthroplasty: A systematic review and meta-analysis

Journal of International Medical Research

2019, Vol. 47(2) 505–514

© The Author(s) 2019

Article reuse guidelines:

sagepub.com/journals-permissions

DOI: 10.1177/0300060518819378

journals.sagepub.com/home/imr



Cheng-long Chen^{1,*}, Peng-fei Han^{1,*},
Zhi-liang Zhang¹, Xiao-juan Sun^{2,3} and Zhi Lv⁴

Abstract

Objective: This study was performed to compare the clinical efficacy between the OrthoPilot navigation system and conventional manual surgery in patients undergoing total hip arthroplasty.

Methods: The Embase, PubMed, CINAHL, and Cochrane databases were searched for clinical trials. The outcome measurements were the anteversion angle, inclination angle, and complications. Review Manager 5.3 statistical software was used for the data analysis.

Results: Significant differences were found in the femoral offset and overall complication rate between the conventional and navigation groups. Additionally, the conventional group had significantly less anteversion than the navigation group. However, the navigation group had significantly better inclination. The operation time was significantly shorter in the conventional than navigation group.

Conclusion: Both the OrthoPilot navigation system and conventional total hip arthroplasty result in significant improvements in patient function with similar overall complication rates and have their own advantages in achieving good cup position. The conventional procedure has a shorter operation time than does use of a navigation system.

¹Department of Orthopaedic Surgery, the Second Clinical Medical College of Shanxi Medical University, TaiYuan, China

²Department of Orthopaedics, The Alpert Medical School of Brown University, Providence, RI, USA

³Department of Orthopaedics, the Second Hospital of Shanxi Medical University, Shanxi Key Laboratory of Bone and Soft Tissue Injury Repair, TaiYuan, China

⁴Department of Orthopaedics, the Second Hospital of Shanxi Medical University, TaiYuan, China

*These authors contributed equally to this work.

Corresponding author:

Zhi Lv, Department of Orthopaedics, The Second Hospital of Shanxi Medical University, 382 Wuyi Road, Taiyuan 030001, PR China.

Email: shellingfordbk221b@163.com



Keywords

Arthroplasty, replacement, hip, meta-analysis, patient navigation, surgery, computer-assisted

Date received: 12 July 2018; accepted: 23 November 2018

Introduction

Total hip arthroplasty (THA) is one of the most effective and frequently performed operations worldwide to relieve pain and restore function in patients with hip joint disorders.¹⁻³ Every year, more than 1 million people worldwide undergo THA for severe osteoarthritis with intractable or permanent pain and dysfunction, and this number is expected to double within the next 20 years.^{1,2,4} THA has completely changed the treatment method for hip disease with arthritis that was performed in the 1960s and has achieved excellent long-term efficacy.^{2,5} Many scholars have devoted themselves to prolonging the service life of artificial joints in patients undergoing THA by accurately positioning the prosthesis, reducing wear, and reducing the fretting of the prosthesis.^{6,7} With the breakthroughs in computer and artificial intelligence technology in recent years, imageless navigation systems have become important in the clinical setting⁸ and are now used successfully in total knee arthroplasty, unicompartmental knee arthroplasty, hip arthroplasty, and shoulder arthroplasty.⁹ Imageless navigation systems are used to collect anatomic data, calculate the mechanical axis of the limbs, or determine the position of the joint intraoperatively through a three-dimensional optical positioning device and without the use of preoperative or intraoperative images (computed tomography, magnetic resonance imaging, C-arm fluoroscopy, and X-ray images).^{9,10} In January 1997, Saragaglia et al.¹⁰ first introduced the OrthoPilot imageless navigation system (Aesculap AG, Tuttlingen, Germany) to total knee arthroplasty. Since then, many clinical trials have shown that

navigation-assisted operations using such systems improve precision and accuracy over conventional manual surgery.¹¹⁻¹⁵ However, whether imageless navigation or traditional surgery should be performed in THA remains controversial.¹⁶ This study was performed to systematically compare the clinical efficacy between these two methods through a meta-analysis and thus provide theoretical guidance for clinical practice.

Methods

Search strategy

Following the recommendations of the Cochrane Collaboration, studies were retrieved from the following online databases: Embase, PubMed, Central, CINAHL, PQDT, CNKI, CQVIP, WanFang Data, Cochrane Library, and CBM from January 2008 to October 2018. The magazine catalogs and references were manually searched in an effort to find gray literature such as unpublished academic papers and chapters in monographs. All pertinent papers were searched without restricting the language, and articles were translated if necessary. The keywords for both the Chinese and English searches were “total hip arthroplasty,” “THA,” “imageless,” “navigation,” “conventional,” “manual,” and “freehand.” The search strategy was: total hip arthroplasty OR THA AND imageless OR navigat* AND conventional OR manual OR freehand.

Inclusion criteria

The inclusion criteria for the study were (1) adults with severe hip disease (osteoarthritis,

developmental dislocation of the hip, avascular necrosis of the femoral head, rheumatoid arthritis, Paget's disease, and similar conditions); (2) controlled trials, prospective studies, retrospective studies, and cohort studies; (3) performance of THA in all patients; and (4) comparison of the clinical efficacy of the OrthoPilot navigation system with conventional manual approaches.

Exclusion criteria

The exclusion criteria were (1) duplicate publications; (2) letters, comments, editorials, case reports, proceedings, personal communications, and reviews; (3) cadaveric studies; (4) failure of the study objective or intervention measures to meet the inclusion criteria; (5) imprecise original documents of the experimental design; and (6) incomplete data.

Data extraction and quality assessment

The data in all included trials were extracted by two independent investigators (C.-L.C. and P.-F.H.). Disagreement between the two reviewers was settled by discussion and consultation with a third reviewer. The extracted information were (1) the basic characteristics of the included studies, including the article title, authors, journal title, journal volume, and publication date; (2) methodological characteristics of the research (e.g., randomized, controlled, blinded); (3) patient characteristics (general information about the patients, such as sex, age, and race, as well as baseline characteristics such as disease course and severity); and (4) sample size, intervention methods, follow-up time, and outcome measurements.

The risk-of-bias assessment tool outlined in the Cochrane Handbook was used to assess the methodological quality of the clinical controlled trials. Six domains were evaluated: (1) random sequence generation,

(2) allocation concealment, (3) blinding of patients and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, and (6) selective reporting risk. The modified Jadad scale was used to assess the quality of cohort studies, and the full score was 7 points. Trials with a score of >4 points were considered high-quality studies. Relevant data recorded for the analysis included the first author's name, published year, and sample sizes of the OrthoPilot navigation system and conventional manual approaches for THA.

Outcome measures

The outcome measurements were the anteversion angle, inclination angle, complications (leg length discrepancy [LLD] and femoral offset), and operation time.

Statistical analysis

All data analyses were conducted using Review Manager 5.3 software (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). Dichotomous outcomes are expressed as odds ratios (ORs), and the weighted mean difference (WMD) or standard mean difference (SMD) was used for continuous outcomes, both with 95% confidence intervals (95% CIs). Heterogeneity was tested using both the chi-square test and I^2 test. A fixed-effects model was chosen when there was no statistical evidence of heterogeneity ($I^2 < 40\%$), and a random-effects model was adopted if significant heterogeneity was found ($I^2 > 75\%$). If heterogeneity was found, we checked the study population, treatments, outcomes, and methodology to determine the source of heterogeneity. If it could not be quantitatively synthesized or the event rate was too low to be measured, we used a qualitative evaluation. Some of the studies were eliminated for a sensitivity analysis, and

funnel plots were created to assess the bias. Differences were statistically significant at $p \leq 0.05$.

Results

Search and selection

In total, 583 articles were retrieved based on the online and manual search strategy. By reading the titles and abstracts, 349 articles that were unrelated to the purpose of the study were excluded, and 62 related articles

were preliminarily screened out. The full texts were read and the inclusion and exclusion screening criteria were strictly followed. Finally, 6 trials involving 779 patients were included.^{6,17-21} The patients' characteristics and conditions in the included studies were compared (sex, age, and baseline characteristics), but no statistically significant differences were found. The literature screening process and the results are shown in Figure 1. The modified Jadad scale was used to assess the quality of the included studies. The basic characteristics

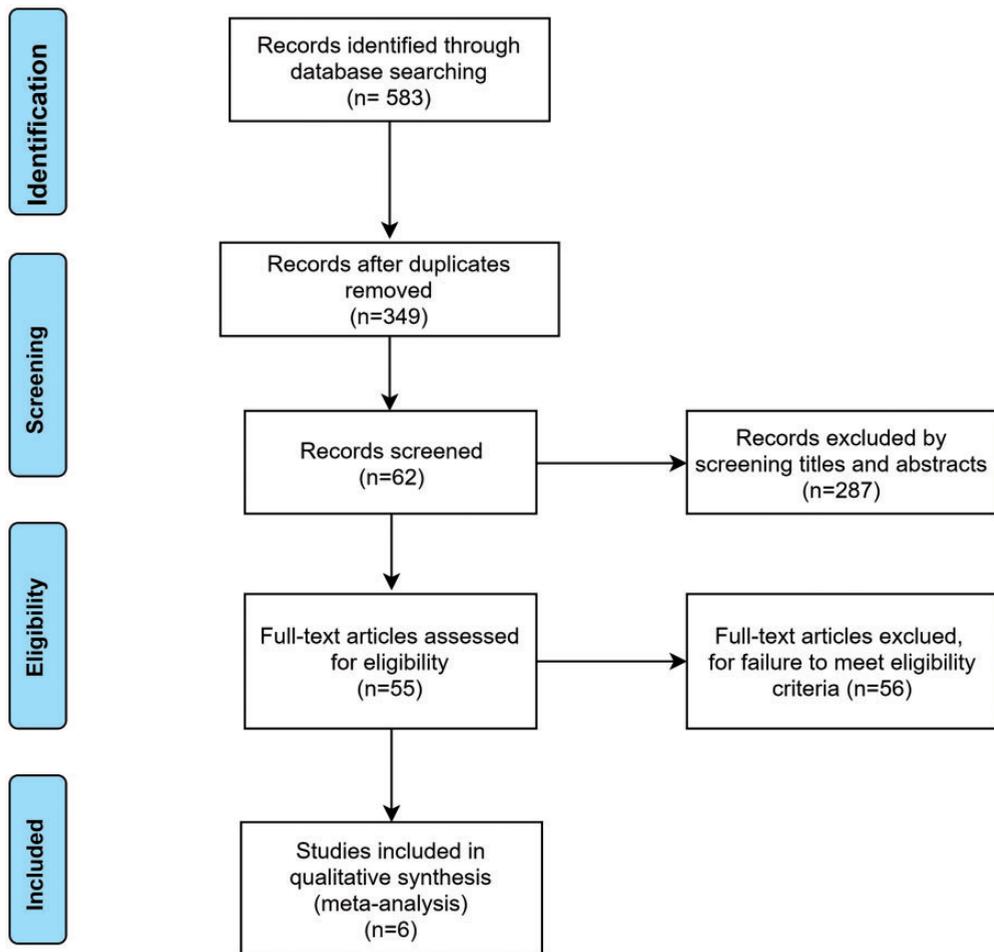


Figure 1. Flow diagram of the search strategy.

of the included literature are presented in Table 1.

Six studies were included in this meta-analysis, and the heterogeneity of the studies was estimated by the I^2 test. The methodological quality of all included clinical controlled trials was high, and the possibility of bias was low (Figure 2).

Precision of anteversion

Four trials compared the anteversion angle between the OrthoPilot navigation system and conventional manual surgery. A fixed-effects model was employed in the meta-analysis with no heterogeneity ($I^2 < 75\%$) among the three study results. The results showed a significantly lower anteversion angle in the conventional manual group than in the navigation group (95% CI, 3.05–5.22; $p < 0.00001$) (Figure 3).

Precision of inclination

Four studies compared the inclination angle between the OrthoPilot navigation system and conventional manual surgery. A random-effects model was employed in

the meta-analysis because the heterogeneity between the studies was significant ($I^2 = 91\%$). The meta-analysis showed that the inclination angle was significantly smaller in the OrthoPilot navigation group than in the conventional manual group (95% CI, -7.03 to -0.56 ; $p = 0.02$) (Figure 4).

Complications

The data were divided into three groups according to the preoperative LLD, postoperative LLD, and femoral offset. A random-effects model was employed in the meta-analysis because the heterogeneity between the studies was significant ($I^2 = 74\%$). All six trials were included, and two groups of data showed no significant difference between the preoperative and postoperative LLD. However, the femoral offset was significantly lower in the OrthoPilot navigation group than in the conventional manual group (95% CI, -3.90 to -1.61 ; $p < 0.00001$), and the total complication rate was significantly different between the two procedures (95% CI, -3.13 to -0.49 ; $p = 0.07$) (Figure 5).

Table 1. General characteristics of included studies.

First author	Year	Study design	Group	Cases (n)	Age (y)	Sex (M/F)	Outcomes	Modified Jadad scale score
Confalonieri ¹⁷	2018	Retrospective	ON	20	60.4	–	(3)	5
			CM	22	60.8			
Ellapparadja ¹⁸	2016	Retrospective	ON	152	67	70/82	(3)	5
			CM	57	72	12/45		
Girard ⁶	2014	Randomized	ON	20	51.3	10/10	(1)(2)(3)	7
			CM	20	54	3/17		
Mainard ¹⁹	2008	Randomized	ON	42	63.3	18/24	(1)(2)	7
			CM	42	60.5	22/20		
Shah ²⁰	2017	Prospective	ON	194	67.2	93/109	(1)(2)(3)	4
			CM	150	58.3	93/80		
Oh ²¹	2018	Retrospective	ON	30	62.2	29/1	(1)(2)(4)	5
			CM	30	62.1	29/1		

Outcomes: (1) Anteversion angle, (2) Inclination angle, (3) Complications, (4) Operation time. M, male; F, female; ON, OrthoPilot navigation; CM, conventional manual.

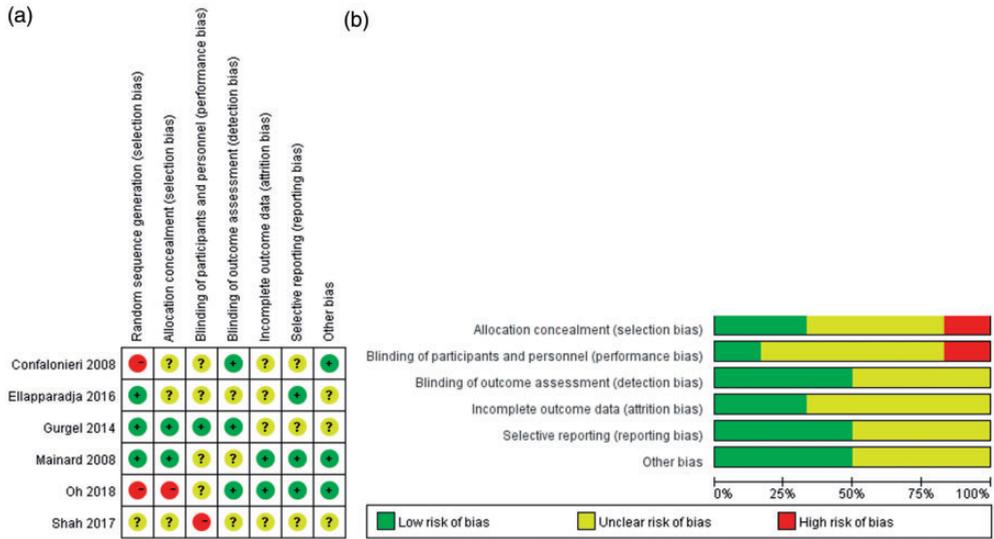


Figure 2. (a) Risk-of-bias graph and methodological quality of the included studies. This risk-of-bias tool incorporates the assessment of randomization, blinding, completeness of outcome data, selection of outcomes reported, and other sources of bias. The items were scored with “yes,” “no,” or “unclear.” (b) Risk-of-bias summary. Each risk-of-bias item is presented as a percentage across all included studies and indicates the proportional level of each risk-of-bias item.

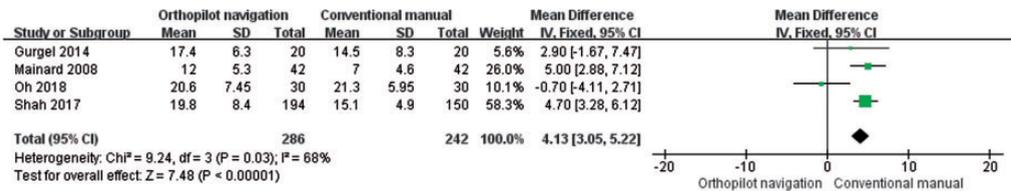


Figure 3. Postoperative anteversion between the two procedures.

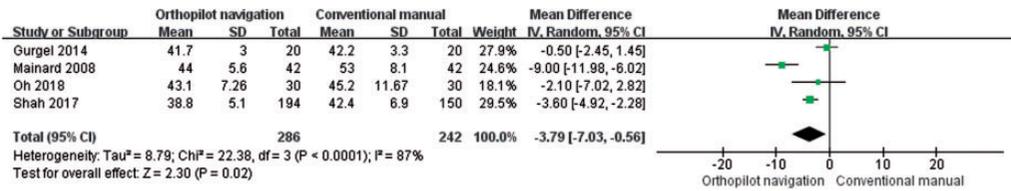


Figure 4. Postoperative inclination between the two procedures.

Operation time

Two studies compared the operation time between the OrthoPilot navigation system and conventional manual surgery.

A fixed-effects model was employed in the meta-analysis because of the absence of heterogeneity ($I^2 < 75\%$) between the two study results. The operation time was significantly shorter in the conventional

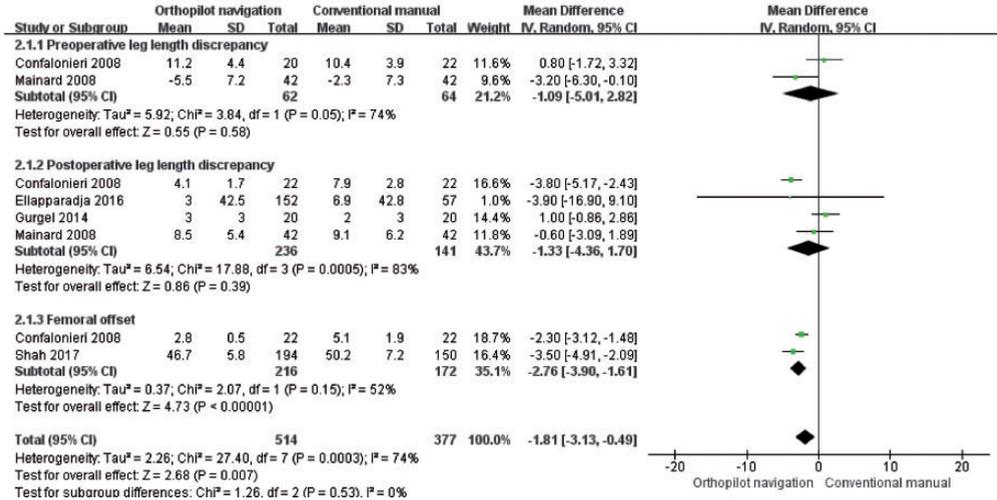


Figure 5. Complications between the two procedures.

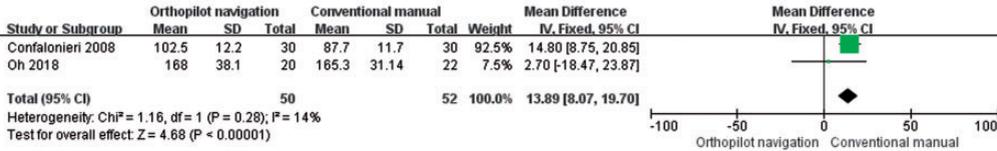


Figure 6. Operation time between the two procedures.

manual group than in the OrthoPilot navigation group (95% CI, 8.07–19.7; $p < 0.00001$) (Figure 6).

Discussion

THA is a relatively mature and widely used procedure in orthopedic surgery.^{13,22} The key to a high long-term success rate of THA is accurate placement of the prosthesis.^{23,24} Inaccurate placement of the prosthesis will lead to false femoral head and acetabular impact and limited mobility.²⁵ Accurate mounting of the prosthesis requires the surgeon to accurately position the patient’s pelvic and femoral locations.²⁶ In traditional surgery, preoperative imaging and template measurements assist in the intraoperative placement of the prosthesis.^{27,28} However, because of the large

number of factors affecting preoperative imaging and the unstable position of the intraoperative patient, the positions of pelvis and femur change,²⁹ causing deviations between the intraoperative and preoperative results and ultimately affecting the placement of the prosthesis.²⁸ Imageless navigation technology uses computer technology to accurately correlate the preoperative imaging data with the intraoperative anatomy of the patient, tracks the surgical instruments in real time by detecting markers and displaying them in a virtual scene,^{10,30} and transmits the information to the surgeon in real time. Several clinical studies have shown that imageless navigation can improve the accuracy of prosthesis placement, thereby reducing the occurrence of complications such as postoperative dislocation^{31,32} compared with traditional THA surgery.

Imageless navigation (OrthoPilot system) can obtain three-dimensional image data and simulate the degree of hip movement before surgery, which facilitates preoperative planning;^{16,22,33} it can also track and guide the operation during surgery and assess the placement of the prosthesis.³³ However, because of the high cost of computer navigation equipment, complex application of the system, and the time it takes to perform the navigation,³⁴ the performance of THA under navigation remains controversial.

We selected four outcomes (anteversion, inclination, complications, and operation time) to fully compare the efficacy between the two procedures. We found statistically significant differences in the femoral offset, overall complications, anteversion, inclination, and operation time between the two groups. The results indicated that use of the OrthoPilot navigation system can achieve lower femoral offset and better inclination than conventional THA; however, the conventional manual method showed advantages with respect to more effective anteversion and a shorter operation time.

This systematic review included six trials, and the methodological quality was high for all studies. However, this analysis also has several limitations, such as a slight risk of bias remaining in some studies. This might have been related to the fact that patients should be informed about which surgical method can be chosen and what medical ethical problems are involved. Incomplete outcome data, a lack of large-sample controlled trials, and the various skill levels among clinical surgeons may also lead to low methodological quality and could affect the reliability of meta-analysis results. In the same outcome measurements system, we analyzed up to six studies for some outcomes and at least two studies for other outcomes; this increased the heterogeneity between groups. Because of the insufficient number of included studies, we only compared two important indexes (precision of

anteversion and inclination) to evaluate the two different procedures. Additionally, considering the effects of variation in the assessment methods on the assessment of THA,³⁵ we excluded some outcome measurements. Therefore, the above conclusions still require further verification. This will depend on the emergence of more randomized controlled trials with higher quality and larger sample sizes in the future.

Conclusion

This meta-analysis has demonstrated that the OrthoPilot navigation system is superior to conventional THA in terms of femoral offset, precision of inclination, and total complications. However, conventional manual surgery showed better results in terms of precision of anteversion and the operation time. These results indicate that using the OrthoPilot navigation system can achieve lower femoral offset and better precision of inclination than conventional THA. However, conventional THA saves more time during the surgery than does the OrthoPilot navigation procedure. Studies with larger sample sizes and longer-term results are needed in the future.

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

Funding

This study was supported by the Natural Science Foundation of China [8177103120].

References

1. Pivec R, Johnson AJ, Mears SC, et al. Hip arthroplasty. *Lancet* 2012; 380: 1768–1777.
2. Learmonth ID, Young C and Rorabeck C. The operation of the century: total hip replacement. *Lancet* 2007; 370: 1508–1519.
3. Liang C, Wei J, Cai X, et al. Efficacy and safety of 3 different anesthesia techniques used in total hip arthroplasty. *Med Sci Monit* 2017; 23: 3752–3759.
4. Shan L, Shan B, Graham D, et al. Total hip replacement: a systematic review and meta-analysis on mid-term quality of life. *Osteoarthritis Cartilage* 2014; 22: 389–406.
5. Weber M, Woerner M, Springorum R, et al. Fluoroscopy and imageless navigation enable an equivalent reconstruction of leg length and global and femoral offset in THA. *Clin Orthop Relat Res* 2014; 472: 3150–3158.
6. Girard J, Lavigne M, Vendittoli PA, et al. Biomechanical reconstruction of the hip: a randomised study comparing total hip resurfacing and total hip arthroplasty. *J Bone Joint Surg Br* 2006; 88: 721–726.
7. Saucedo JM, Marecek GS, Wanke TR, et al. Understanding readmission after primary total hip and knee arthroplasty: who's at risk? *J Arthroplasty* 2014; 29: 256–260.
8. Chang JD, Kim IS, Prabhakar S, et al. Revision total hip arthroplasty using imageless navigation with the concept of combined anteversion. *J Arthroplasty* 2017; 32: 1576–1580.
9. Zagra L. Advances in hip arthroplasty surgery: what is justified? *EFORT Open Rev* 2017; 2: 171–178.
10. Saragaglia D, Picard F, Leitner F. An 8- to 10-year follow-up of 26 computer-assisted total knee arthroplasties. *Orthopedics* 2007; 30(10 Suppl): S121–S123.
11. Brown ML, Reed JD and Drinkwater CJ. Imageless computer-assisted versus conventional total hip arthroplasty: one surgeon's initial experience. *J Arthroplasty* 2014; 29: 1015–1020.
12. Rebal BA, Babatunde OM, Lee JH, et al. Imageless computer navigation in total knee arthroplasty provides superior short term functional outcomes: a meta-analysis. *J Arthroplasty* 2014; 29: 938–944.
13. Inori F, Ohashi H, Yo H, et al. Accuracy of cup height and medialization in THA for dysplastic hip osteoarthritis using an imageless navigation system. *Orthopedics* 2012; 35: 7–12.
14. Hohmann E, Bryant A and Tetsworth K. A comparison between imageless navigated and manual freehand technique acetabular cup placement in total hip arthroplasty. *J Arthroplasty* 2011; 26: 1078–1082.
15. Lass R, Kubista B, Olischar B, et al. Total hip arthroplasty using imageless computer-assisted hip navigation: a prospective randomized study. *J Arthroplasty* 2014; 29: 786–791.
16. Renkawitz T, Weber M, Springorum HR, et al. Impingement-free range of movement, acetabular component cover and early clinical results comparing 'femur-first' navigation and 'conventional' minimally invasive total hip arthroplasty: a randomised controlled trial. *Bone Joint J* 2015; 97-B: 890–898.
17. Confalonieri N, Manzotti A, Montironi F, et al. Leg length discrepancy, dislocation rate, and offset in total hip replacement using a short modular stem: navigation vs conventional freehand. *Orthopedics* 2008; 31: orthosupersite.com/view.asp?rID=35541.
18. Ellapparadja P, Mahajan V, Atiya S, et al. Leg length discrepancy in computer navigated total hip arthroplasty - how accurate are we? *Hip Int* 2016; 26: 438–443.
19. Mainard D. Navigated and nonnavigated total hip arthroplasty: results of two consecutive series using a cementless straight hip stem. *Orthopedics* 2008; 31: orthosupersite.com/view.asp?rID=35528.
20. Shah SM, Deep K, Siramanakul C, et al. Computer navigation helps reduce the incidence of noise after ceramic-on-ceramic total hip arthroplasty. *J Arthroplasty* 2017; 32: 2783–2787.
21. Oh KJ, Kim BK, Jo MI, et al. Which one is more affected by navigation-assisted cup positioning in total hip arthroplasty: anteversion or inclination? A retrospective matched-pair cohort study in Asian physique. *J Orthop Surg (Hong Kong)* 2018; 26: 2309499018780755.
22. Renner L, Janz V, Perka C, et al. What do we get from navigation in primary THA? *EFORT Open Rev* 2016; 1: 205–210.

23. Nishio S, Fukunishi S, Fukui T, et al. Adjustment of leg length using imageless navigation THA software without a femoral tracker. *J Orthop Sci* 2011; 16: 171–176.
24. Renkawitz T, Worner M, Sendtner E, et al. [Principles and new concepts in computer-navigated total hip arthroplasty]. *Orthopade* 2011; 40: 1095–1102.
25. Renkawitz T, Tingart M, Grifka J, et al. Computer-assisted total hip arthroplasty: coding the next generation of navigation systems for orthopedic surgery. *Expert Rev Med Devices* 2009; 6: 507–514.
26. Fukunishi S, Nishio S, Fujihara Y, et al. Accuracy of combined anteversion in image-free navigated total hip arthroplasty: stem-first or cup-first technique? *Int Orthop* 2016; 40: 9–13.
27. Hoorntje A, Janssen KY, Bolder SBT, et al. The effect of total hip arthroplasty on sports and work participation: a systematic review and meta-analysis. *Sports Med* 2018; 48: 1695–1726.
28. York PJ, McGee AW Jr, Dean CS, et al. The relationship of pelvic incidence to post-operative total hip arthroplasty dislocation in patients with lumbar fusion. *Int Orthop* 2018; 42: 2301–2306.
29. Nganga M, Bramwell D, Monaghan J, et al. Evaluation of the multi-attribute prioritisation tool for total joint replacement. *J Orthop* 2018; 15: 242–247.
30. Jones CW and Jerabek SA. Current role of computer navigation in total knee arthroplasty. *J Arthroplasty* 2018; 33: 1989–1993.
31. Kim HJ, Yoon JR, Choi GW, et al. Imageless navigation versus conventional open wedge high tibial osteotomy: a meta-analysis of comparative studies. *Knee Surg Relat Res* 2016; 28: 16–26.
32. Wada H, Mishima H, Yoshizawa T, et al. Initial results of an acetabular center axis registration technique in navigated hip arthroplasty with deformed acetabular rims. *Open Orthop J* 2016; 10: 26–35.
33. Deep K, Shankar S and Mahendra A. Computer assisted navigation in total knee and hip arthroplasty. *SICOT J* 2017; 3: 50.
34. Lin F, Lim D, Wixson RL, et al. Limitations of imageless computer-assisted navigation for total hip arthroplasty. *J Arthroplasty* 2011; 26: 596–605.
35. Snijders TE, Willemsen K, van Gaalen SM, et al. Lack of consensus on optimal acetabular cup orientation because of variation in assessment methods in total hip arthroplasty: a systematic review. *Hip Int* 2018. doi: 10.1177/1120700018759306. [Epub ahead of print].