Intraoperative Validation of Navigated Limb Measurements in THA Using a Pinless Femoral Array

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ABSTRACT

Appropriate limb length (LL) and femoral offset (OS) after total hip arthroplasty (THA) are crucial for a successful and lasting outcome. However, intraoperative assessment is difficult. Computed navigation is effective but the use of radiation and of invasive bone references is cause of concern. Imageless, pinless navigation systems have been shown to be accurate in experimental studies. However, almost no clinical validation has been performed. We used a minimally-invasive computer-navigated system (MICNS) in conjunction with an imageless measurement technique for implanting 60 consecutive THAs. Head/neck trial components of different size were applied, and the differences in LL and femoral OS measurements were recorded and compared to the implant manufacturer's specifications, corrected for the anatomical variations of each patient. The imageless MICNS revealed a valid and accurate intra-operative tool for measuring LL and femoral OS in vivo.

The main goals of joint replacement are to re-establish correct biomechanics and to relieve pain. In THA, the recovery of a normal gait requires a proper management of LL discrepancy and an adequate soft tissue balancing through normal femoral OS restoration. Discrepancies in LL can be a cause of discomfort and dissatisfaction for patients [1]. Additionally, LL inequality may be a source of abnormal force transmission through the replaced joint, contributing to early loosening and failure of the implants [2,3]. Not only LL but also restoration of the best possible femoral OS is critical to stability and the long term result of the procedure [4,5], and as a consequence, these two parameters play a major role in THR outcome. Although important, LL and femoral OS are difficult to assess intra-operatively for the orthopaedic surgeon.

For pre-operative measurement of LL and OS, anterior-posterior radiological images are considered as state of the art [6–8]. However, measuring LL and femoral OS on conventional X-rays can be challenging, and the accuracy is limited (for example when variation in the patient position leads to different orientations of the leg in pre- and post-operative images) [5,9,10]. This limitation hampers accurate pre-operative planning, and makes precise comparison between the pre- and post-operative images difficult, especially when accuracy should be assessed in low millimetre range.

Computer-assisted navigation during THA has proved to be an effective aid for obtaining correct implant positioning and accurately measuring LL and femoral OS [11–15]. Until recently, LL and femoral OS navigated assessment required the use of radiation (computed tomography) and pin-based femoral reference arrays [6,11,16]. The use of invasive bone pins has not been unharmful, and a number of potential complications such as pin site infections, soft tissue morbidity, or bone stress fractures have been reported [17].

In the last few years, methods have been developed which avoid this invasive fixation of the reference array into the femoral bone [18–20]. Concomitantly, there have also been substantial advances in the visualization and accuracy of imageless navigation systems. These new systems do not require pre- or intra-operative image acquisition or exposing the patient to radiation [12,18,21]. Most of the validation of the pinless femoral arrays for computer navigated measurement have been performed on cadavers [16,19] and there are almost no clinical studies that analyse the accuracy of this new technique [18].

Therefore we decided to translate these experimental experiences into the clinical setting, using a femoral pinless and imageless navigation system to determine intra-operative changes in LL and femoral OS. These changes were compared against a benchmark based on the manufacturer's trial implant specifications. This benchmark was adopted due to its theoretical accuracy, indeed, modern precision manufacturing has ensured that both trial and definitive implant specifications are accurate to .01mm.

The objective of this clinical prospective study was to assess how accurately the navigation system could record the differences in LL and OS that resulted from the use of different femoral trial components (head and neck) intra-operatively.

Materials and Methods

From November 2010 to November 2011, 60 consecutive patients requiring THR to treat primary or secondary osteoarthritis were enrolled into a prospective study. Thirteen patients were male, and 47 were female, with a mean age of 67.9 years (range: 37-84 years). The mean Body Mass Index (BMI) was 26.2 kg/m² (range: 16.4-36.7 kg/m²). All patients received press-fit femoral and acetabular components. A Trilock stem and a Pinnacle cup were implanted, with a cross linked polyethylene Marathon liner and a Biolox ceramic head (36 mm) (DePuy, Warsaw, IN).

All patients underwent THR performed by a single surgeon (MU) using a postero-lateral approach. For all landmark acquisition and navigation steps, the Ci Hip 2.1 software (Brainlab AG, Feldkirchen, Germany) was used. During the preparation of the patient, a non-invasive pinless femoral reference array was attached to the proximal part of the thigh. The reference array consisted of marker spheres and a plate which was fixed on the soft tissue with an incision foil. After positioning the patient on the table in a lateral decubitus position, a second pin-based reference array was fixed on the pelvis with two Schanz screws. Then, the skin, the subcutaneous layer and the fascia lata were incised and the external rotator muscles were released from the femur. A posterior capsulotomy was performed before a 3.5mm short screw was inserted into the greater trochanter to define a reproducible proximal landmark for LL and femoral OS measurements. The screw was placed approximately 2 cm distally to the tip of the greater trochanter at its lateral side. The leg was placed in a roughly neutral position (i.e. only slightly flexed and without significant ab-/adduction and internal/external rotation). This defined a reference position for LL and OS measurements which was later reproduced after hip joint relocation. The proximal landmark defined by the screw was acquired by a pointer device as a reference for the native position of the leg.

Then the femur was dislocated and the neck osteotomy performed. Before the acetabulum was prepared, one landmark on the anterior and one on the opposing side of the acetabular rim was acquired to define the centre-of-rotation of the hip. Subsequently, the acetabulum was prepared and the definitive cup was introduced and positioned with two stabilization screws. The trial polyethylene liner was put in place, and then the medullary canal was reamed with the trial rasp until a firm fit was achieved.

Then a standard neck was inserted, and the shortest head was applied. After relocation, the leg was realigned to the initial neutral position and a LL and OS measurement were recorded using the navigation system. The procedure was repeated with the next combination (standard neck, medium head) and then, if possible, with the final combination (standard neck, long head). All three heads were of 36 mm diameter. The navigation system calculated the LL changes from variations in the cranial-caudal position of the proximal landmark, along the mechanical axis. OS changes were calculated from the variations in orthogonal distance from the centre of rotation of the hip to the mechanical axis. The changes in LL and OS for each trial implant combination were noted and stored in a log file for later evaluation (Fig 1).

After determining the ideal implant combination, the definitive components were implanted.

Post-operatively, in order to assess the accuracy of the measurement of these differences (and thus of the navigation system itself) they were compared to the femoral trial component sizing information provided by the implant manufacturer. Changes between different trial component sizes are given as integer mm values, following the stem shaft axis. It is important to note that the stem shaft axis usually deviates from the cranial-caudal mechanical axis, whereas the navigation system bases its measurement of LL and OS on the mechanical axis. Therefore, before the implant specification values could be used as a benchmark for the navigation system, they needed to be corrected for the anatomical variations (femoral varus/valgus) of each patient. As a first step, the individual femoral varus-valgus angles were estimated from the immediate post-operative anterior-posterior X-ray images. An indirect method was applied since no weight bearing, full length radiographs were available. The X-rays only contained approximately the upper half of the femur, and were calibrated based on the size of the head implant that was finally used. The length of the femur was estimated using a statistical relationship between body height and femur length according to Hauser et al. [22]. Fig. 2 shows a sample evaluation.

Once the individual patient's varus-valgus angle was determined, a trigonometric correction was made, which reflected the transition from the trial implant reference system to the navigation reference system (based on the mechanical axis). This was applied to the values given by the manufacturer (see Appendix), giving the changes in LL and OS (varus/valgus-corrected values) for each trial head/neck combination used, for each patient. These were compared to the actual differences observed in the navigation measurements.

Descriptive statistics including arithmetic mean ± standard deviation, and 95% confidence interval (CI) were calculated. All statistical calculations were performed using Microsoft Excel (Microsoft, Redmont, WA).

Results

In total, there were 104 intra-operative navigation-based measurements of LL and OS. The mean VV angle measured on the anterior-posterior x-rays was -6.3° ± 0.63° (95% CI: [-5.1°, 7.6°]). The mean

Fig. 1. Navigation software screenshots showing the difference in limb length and femoral offset measurement when a longer head/neck trial implant was inserted.
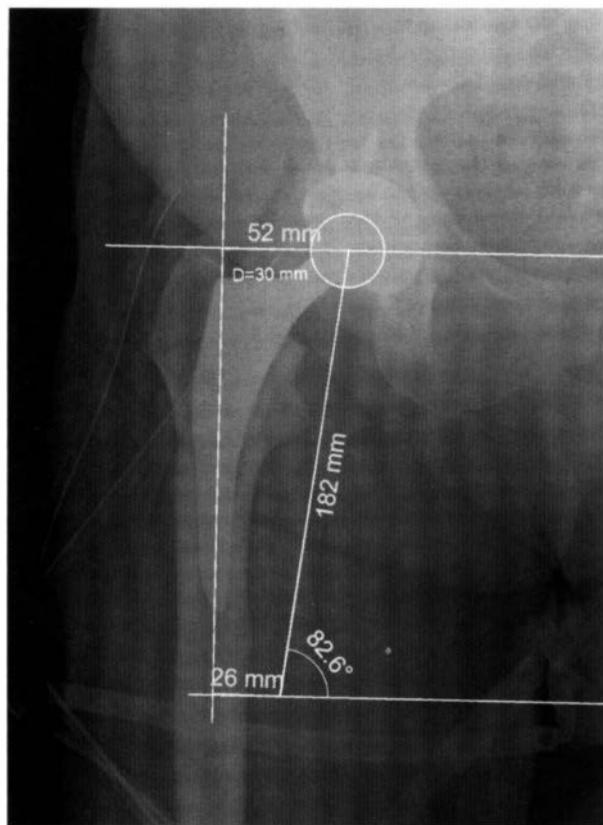
Fig. 2. X-ray based determination of varus-valgus angles. The individual varus-valgus angle is calculated by 90° minus the depicted angle (here: 7.4°).

difference between the intra-operative navigation measurements and the VV-corrected values was 0.00 ± 1.16mm (95% CI: [-2.27mm, 2.28mm]) for limb length and -0.20 ± 1.21mm (95% CI: [-2.58mm, 2.18mm]) for offset.

Discussion

The most common technical problems associated with THA are component malpositioning and postoperative limb length (LL) discrepancy. Intraoperative navigation systems have proved effective in achieving adequate implant component positioning and LL management [12–15,23–25]. Although LL discrepancy is a result of both cup and stem positioning, most of the studies concerning navigation have been focussed on cup orientation and very little has been published about stem positioning and its role in LL discrepancies. Only relatively recently has stem alignment come to be regarded as an essential factor for optimal range of motion, reduced rate of dislocation and mechanical problems, and proper LL adjustment [26,27]. LL discrepancy after THA may lead to patient complaints such as back pain, gait disorders, and dissatisfaction with the procedure [3,28]. Indeed, better functional outcome has been reported when LL discrepancy was absent or minimal [29,30]. In the same way, re-establishing a proper femoral OS gives better functional results in terms of strength, motion and stability. This in turn decreases rates of wear and aseptic loosening [31].

Various methods have been used as a gold standard for the comparison between pre- and post-operative LL, although there is no technique available which achieves accuracy levels in the submillimetric range. Radiation-based measurements are more precise than clinical measurements [7,8,32,33], however X-ray techniques still may have limitations in terms of accuracy [9,10,34,35]. CT showed good clinical precision in LL measurements [6,36] but the dose of

radiation is a concern. Computer navigated measurement has proved to be relatively accurate for assessing LL, but it is an invasive technique. Pinless referencing could significantly reduce the risk of bony and soft tissue morbidity caused by femoral pin fixation, although it has potentially reduced accuracy due to the direct translatory and rotational variations between the pinless array and the femoral bone [20]. Therefore a specific measurement technique that compensates for such variations is required if pinless referencing is to achieve precise LL and OS measurement.

In our study, the navigation measurements were found to be in a high accuracy range, although there were potential sources of inaccuracy in our methodology. In particular, the varus-valgus angles could only be estimated indirectly, since it was not feasible to have post-operative weight bearing, full length X-ray images. The trial component specifications are only related to changes on the femoral side, whereas the calculations for global LL and femoral OS changes can be affected by the position of the acetabular component. Although the position of the cup was not changed during the measurement procedure, the navigation-based measurements can be indirectly influenced by the position of the trunk in relation to the orientation of the femur. One could claim that the trial femoral components are usually not perfectly fixed which may cause additional changes in LL and OS measurements. However, we believe that our methodology avoided this, as broaching was performed until an absolutely firm trial rasp setting was reached. Although each of these potential sources of inaccuracy might result in only submillimetric variations, their combined effects are not completely negligible.

Obvious as it may seem, the values specified by the implant manufacturer should not directly be used to assess LL and femoral OS changes, since the specifications only refer to a stem coordinate system (however precise) and do not directly reflect anatomical features. Differences between the stem and anatomical co-ordinate systems can reach up to 1.3mm, and therefore to create a valid benchmark, we used trigonometry to adjust the implant specifications to the individual anatomy. According to our benchmark, we observed an accuracy of below 1mm (95% confidence interval) for the minimally-invasive computer-assisted navigation system, which for clinical purposes is a very satisfactory level of precision.

The mean difference between the navigation measurements and the expected values (after correction to the anatomical coordinate system) was 0.00 ± 1.16mm (LL) and -0.20 ± 1.21mm (femoral OS). These results compare favourably with reports in the literature that analyse the accuracy of computer navigated measurements of LL and OS. Various techniques have been used, including radiography, CT scans, pin-based and pinless femoral arrays. Murphy et al. [19] analysed a technique using a pin-based femoral reference array and reported an accuracy of -0.5 ± 1.77mm for LL measurements. Dastane et al. [3] focused on the question of whether they could reliably reconstruct femoral OS, and found deviations between a pin-based and the X-ray measurement technique of 0.6 ± 3.6mm for LL and 1.4 ± 6.4mm for femoral OS. In a cadaver study Renkawitz et al. estimated LL and femoral OS changes with the pin-based version of the navigation technique we used in this study [24]. Results were compared with pre- and post-operative CT measurements. The Authors found mean LL and femoral OS differences less than 1 mm with a substantial correlation between intraoperative navigation values and CT measurements. In a second cadaveric study [23], they tested the same pinless femoral reference array as we used in our study, with accuracy values of 0.5 ± 1.22mm (LL) and 0.5 ± 0.9mm (OS). In a further experimental study, the same Authors compared the pin-based and femoral pinless technique and found maximum deviations of 1.3mm for LL and 1.2 mm for femoral OS [25].

Based on our results, we conclude that LL and femoral OS measurements with a minimally-invasive femoral reference array and an imageless navigation system are accurate and favourably compare with the reported, pin-based LL and femoral OS measurements during

THA. Nevertheless, as to our knowledge this is the first study on the use of this minimally invasive reference system in a clinical setting, further clinical studies are advisable to confirm the favourable outcome of our recent experience.

Appendix

Trigonometric correction of trial implant specifications.
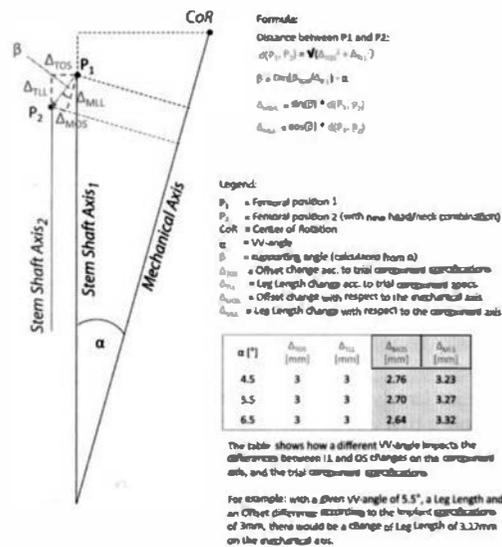
References

1. Gurney B. Leg length discrepancy. Gait Posture 2002;15:195.
2. Gofton JP. Studies in osteoarthritis of the hip IV. Biomechanics and clinical considerations. Can Med Assoc J 1971;104:1007.
3. Parvizi J, Sharkey PF, Bissett GA, et al. Surgical treatment of limb-length discrepancy following total hip arthroplasty. J Bone Joint Surg Am 2003;85-A:2310.
4. Charles MN, Bourne RB, Davey JR. et al. Soft-Tissue Balancing of the Hip. The Role of Femoral Offset Restoration. J Bone Joint Surg Am 2004;86:1078.
5. Lecerf G, Fessy MH, Philippot R, et al. Femoral offset: anatomical concept, definition, assessment, implications for preoperative templating and hip arthroplasty. Orthop Traumatol Surg Res 2009;95:210.
6. Murphy SB, Ecker TM. Evaluation of a New Leg Length Measurement Algorithm in Hip Arthroplasty. Clin Orthop Relat Res 2007;463:85.
7. Sabharwal S, Kumar A. Methods for Assessing Leg Length Discrepancy. Clin Orthop Relat Res 2008;466:2910.
8. Sabharwal S, Zhao C. McKeon JJ, et al. Computed radiographic measurement of limb-length discrepancy. Full-length standing anteroposterior radiograph compared with scanogram. J Bone Joint Surg Am 2006;88;2243.
9. Kjellberg M, Al-Amiry B, Englund E, et al. Measurement of leg length discrepancy after total hip arthroplasty. The reliability of a plain radiographic method compared to CT-scanogram. Skeletal Radiol 2012;41:187.
10. Meermans G, Malik A, Witt J, et al. Preoperative radiographic assessment of limb-length discrepancy in total hip arthroplasty. Clin Orthop Relat Res 2011;469:1677.
11. Oastane M, Dorr LD, Tarwala R, et al. Hip offset in total hip arthroplasty: quantitative measurement with navigation. Clin Orthop Relat Res 2011;469:429.
12. Hohmann E, Bryant A, Tetsworth K. A comparison between imageless navigated and manual freehand technique acetabular cup placement in total hip arthroplasty. J Arthroplasty 2011;26:1078.
13. Jolles BM, Genoud P, Hoffmeyer P. Computer-assisted cup placement techniques in total hip arthroplasty improve accuracy of placement. Clin Orthop Relat Res 2004;426:174.
14. Kalteis T, Handel M, Bathis H, et al. Imageless navigation for insertion of the acetabular component in total hip arthroplasty: is it as accurate as CT-based navigation? J Bone Joint Surg Br 2006;88;163.
15. Kalteis T, Handel M, Herold T, et al. Greater accuracy in positioning of the acetabular cup by using an image-free navigation system. Int Orthop 2005;29:272.
16. Renkawitz T, Schuster T, Herold T, et al. Measuring leg length and offset with an imageless navigation system during total hip arthroplasty: is it really accurate? Int J Med Robot 2009;5:192.
17. Wysocki RW, Sheinkop MB, Virkus WW. et al. Femoral fracture through a previous pin site after computer-assisted total knee arthroplasty. J Arthroplasty 2008;23:462.
18. 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.
19. Renkawitz T, Schuster T, Grifka J, et al. Leg length and offset measures with a pinless femoral reference array during THA. Clin Orthop Relat Res 2009;468:1862.
20. Renkawitz T, Wegner M, Gneiting S, et al. Experimental validation of a pinless femoral reference array for computer-assisted hip arthroplasty. J Orthop Res 2010;28:583.
21. Snyder GM, Lozano Calderón SA, Lucas PA, et al. Accuracy of computer-navigated total hip arthroplasty. J Arthroplasty 2012;27:415.
22. Hauser R. Smolinski J, Gos T. The estimation of stature on the basis of measurements of the femur. Forensic Sci Int 2005;147:185.
23. Beckmann J, Stengel D, Tingart M, et al. Navigated cup implantation in hip arthroplasty. Acta Orthop 2009;80:538.
24. Dorr LD, Malik A, Wan Z, et al. Precision and bias of imageless computer navigation and surgeon estimates for acetabular component position. Clin Orthop Relat Res 2007;465:92.
25. Ryan JA, Jamali AA. Bargar WL. Accuracy of computer navigation for acetabular component placement in THA. Clin Orthop Relat Res 2010;468:169.
26. Widmer KH, Zurfluh B. Compliant positioning of total hip components for optimal range of motion. J Orthop Res 2004;22:815.
27. Yoshimine F. The safe-zones for combined cup and neck anteversions that fulfill the essential range of motion and their optimum combination in total hip replacements. J Biomech 2006;39:1315.
28. Maloney WJ, Keeney JA. Leg length discrepancy after total hip arthroplasty. J Arthroplasty 2004;19(Suppl 1):108.
29. Konyves A. Bannister GC. The importance of leg length discrepancy after total hip arthroplasty. J Bone Joint Surg Br 2005;87:155.
30. Nakamura N, Sugano N, Nishii T, et al. A comparison between robotic-assisted and manual implantation of cementless total hip arthroplasty. Clin Orthop Relat Res 2010;468:1072.
31. Sakalkale DP, Sharkey PF, Eng K, et al. Effect of femoral component offset on polyethylene wear in total hip arthroplasty. Clin Orthop Rel Res 2001;388:125.
32. Takigami I, Itokazu M, Itoh Y, et al. Limb-length measurement in total hip arthroplasty using a calipers dual pin retractor. Bull NYU Hosp Jt Dis 2008;66;107.
33. Terry MA, Winell JJ, Green DW, et al. Measurement variance in limb length discrepancy: clinical and radiographic assessment of interobserver and intraobserver variability. J Pediatr Orthop 2005;25:197.
34. Franken M, Grimm B, Heyligers I. A comparison of four systems for calibration when templating for total hip replacement with digital radiography. J Bone Joint Surg Br 2010;92:136.
35. Robb C. Harris R, O'Dwyer K, et al. Radiographic assessment of biomechanical parameters following hip resurfacing and cemented total hip arthroplasty. Hip Int 2009;19:251.
36. Ecker TM, Tannast M, Murphy SB. Computed tomography-based surgical navigation for hip arthroplasty. Clin Orthop Relat Res 2007;465:100.