Monitoring hip posture in total hip arthroplasty using an inertial measurement unit-based hip smart trial system: An in vitro validation experiment using a fixed pelvis model

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ABSTRACT

Intraoperative measurement of hip posture is the basis for assessing hip range of motion (ROM) and predicting postoperative functional limits allowable for activities of daily living. Although computer navigation for total hip arthroplasty (THA) has improved the accuracy of intraoperative ROM evaluation, it has not gained widespread popularity due to its complex and time-consuming protocol. We therefore developed an inertial measurement unit-based hip smart trial system (IMUHST) for intraoperative monitoring of hip posture. An in vitro validation experiment was conducted using bone models with a three-dimensional measurement model as the reference standard. The absolute mean error, Bland – Altman analysis and intra-class correlation coefficient demonstrated that the validity and reliability of this system meets the requirement for clinical application. Given that monitoring posture is the basis for evaluating the direction(s) of potential impingement, subluxation and dislocation, the IMUHST is a promising development direction of computer assisted surgery in THA.

1. Introduction

Total hip arthroplasty (THA) is increasing in popularity worldwide. One of the major goals of THA is to obtain joint stability throughout the full range of motion (ROM) as required for normal activities of daily living. Postoperative impingement between the femoral neck and metal shells or bony structures should be avoided, which frequently leads to edge loading and even dislocation. To achieve this, it is essential to ensure intraoperative component stability throughout the ROM. Despite this, other factors like patient sagittal balance, soft tissue laxity and joint deformity may still contribute to impingement and dislocation in certain cases.

Intraoperative measurement of ROM is the basis for intraoperative evaluation of impingement, subluxation, dislocation and prediction of postoperative functional outcome. The assessment of ROM relies on accurate evaluation of hip positions intraoperatively. Traditionally, intraoperative measurement of ROM was accomplished by measuring the angle of rotation between the neutral and extreme postures of the hip, with trial reduction after preparation of both the acetabular and femoral sides. In this regard, the ROM assessment largely relied on the inherent variables of surgical experience and subjective judgement. Due to the inaccuracy of measuring postural change by the traditional method of surgeon's subjective estimation, it can be ambiguous to decide if the intraoperative ROM is appropriate for postoperative function (Elson and Aspinall, 2008). Moreover, the detection of impingement and subluxation are subjective, and adjustment of component orientation after implantation requires prosthesis extraction and may jeopardize primary stability, especially in cases with inadequate bone stock.

With traditional trial reduction assessments, concerns regarding the risk for postoperative dislocation often leave surgeons and patients under worries. It is not uncommon for patients to be provided with functional restrictions after THA, which consist of suggestions to avoid some extreme postures that may increase the risk for hip dislocation. It has been reported in a national wide survey that 69–100% doctors in Netherland routinely provide patients with postoperative precautions after THA (Peters et al., 2017). However, hip precautions are associated with a slower

return to activities, significant expense and decreased patient satisfaction (Barnsley and Page, 2015). This high prevalence of postoperative precautions may be because intraoperative measurements of ROM have failed to provide an accurate assessment of truly safe ROM limits.

The accurate detection of ROM, impingement, subluxation and dislocation necessitates real-time monitoring of femoral component postures during surgery. With the progress in computed assisted surgery (CAS), optics-based navigation systems, which use charged coupled device (CCD) cameras to obtain positional information based on an infrared light, either actively emitted from a reference frame with infrared light-emitting diodes, or passively reflected from trackers attached to bones (Sugano, 2013), have been reported to improve the accuracy of component positioning, leg length measurement, dislocation and ROM detection (Inaba et al., 2016; Iorio et al., 2015; Paprosky and Muir, 2016; Ryan et al., 2010). However, navigation is used in only 1%–3% of THA procedures (Paprosky and Muir, 2016; Xu et al., 2014). Commercially available CAS systems are expensive, contain complex time-consuming protocols, and they alter surgical workflow, which has made widespread use difficult. Moreover, for the measurement of ROM, navigation systems necessitate an optic tracker fixed on the femur with one or more pins, which increase potential risks of bone fracture and neurovascular injuries, whereas the current system do not require any extra trackers and minimizes harm to patients.

Inertial measurement unit (IMU) is a collection of sensors including accelerometers, gyroscopes and magnetometers that can be used to measure the posture of bodies or surgical tools. IMU has been widely applied in urinary, abdominal and endoscopic surgeries, as well as in sports monitoring (Behrens et al., 2011; Fasel et al., 2017; O'Donovan et al., 2007; Zhang et al., 2006). In order to accurately capture intraoperative hip posture, we preliminarily developed a cost-effective inertial measurement unit-based hip smart trial system (IMUHST).

The IMUHST system was developed by incorporating specifically designed circuits containing IMU sensors into the plastic femoral head trial, whereby hip posture can be dynamically captured and displayed on the terminal in real-time after trial reduction (Figs. 1 and 2). By monitoring hip posture, this novel system has the potential to qualitatively record ROM during THA surgery, thereby providing confidence to surgeons and patients as a means of avoiding unnecessary postoperative precautions and to accelerate rehabilitation.

In this study, an in vitro experiment was conducted to examine the validity and reliability of posture monitoring of the hip joint by the IMUHST system. A mechanical goniometer measurement system was used as the reference standard.

Fig. 2. The IMUHST is composed of a hallow trial head containing circuits and IMU sensors within it and the system is mounted onto a trial stem and reduced into the joint to capture the posture of hip joints intraoperatively.

2. Materials and methods

2.1. Inertial measurement unit-based hip smart trial system

The IMUHST system proposed in this study was composed of measurement hardware in a hollow, plastic femoral head and application software in a terminal computer. The trial femoral head and terminal computer were connected via a USB cable (Figs. 1 and 2). During THA surgeries, the IMUHST system is intended to be mounted to the trial stem after preparation of both the acetabulum and femur, and then the hip joint will be reduced to evaluate the safe ROM, impingement, and dislocation of the joint without disturbance to the traditional THA workflow (Fig. 2).

In the trial femoral head of 36 mm in diameter, a three-axis accelerometer, three-axis gyroscope and three-axis magnetometer
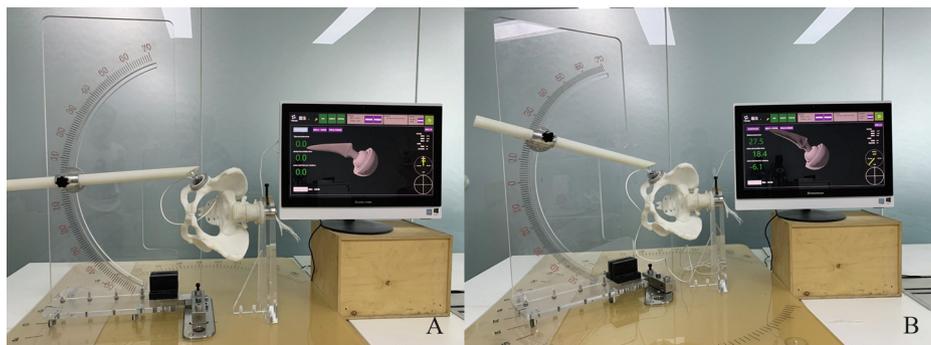

Fig. 1. A-B. The experimental setup of the mechanical measurement reference and Inertial Measurement Unit based Hip Smart Trial system with A. in the neutral posture and B. in a flexion, abduction, internal rotation posture.

were incorporated in the electronic chips to build an IMU system. Instant posture was captured by the accelerometer, gyroscope and trigonometry to calculate hip ROM after setting of the neutral posture (Fig. 3). The gyroscope and magnetometer were used to get geographic orientation for determination of hip ROM coordination system and to improve the accuracy of the attitude algorithm of ROM measurement of the accelerometer by constant calibration and correction of accumulated errors.

Kalman filtering and 9-axis fusion algorithms were employed to compute the rotation angle on a microprogrammed control unit (MCU). The zero-input offset drift of system-in-package 3D digital accelerometer and 3D digital gyroscope was 0.1 mg/s and 0.015 deg/s respectively, and the root mean square (RMS) of rate noise of the gyroscope was 0.075 deg/s. The ultra-low offset drift of the 3D digital magnetometer was 0.017uT. To reduce drift, oversampling and medium filtering were employed for data-processing to reduce zero bias instability and random walk noise. For the

magnetometer, both hard and soft ferromagnetic calibration algorithms were integrated in the MCU for adaptation to the complex magnetic field environments in operation theaters (Pengfei Guo, 2008). Besides, calibration operations were conducted before each measurement. An error model Kalman filter was employed in the MCU, and sensor drift threshold mechanism was used for every raw sensor data with dynamic threshold determination. The flow chart of Kalman filter algorithm implementation is shown in Fig. 4.

Real time data of posture was calculated at a frequency of 100 Hz. With the real-time data, hip posture can be read and recorded on the smart trial software. Neutral position in the measurement system was defined as the position where the mechanical axis of femur is parallel with both the anterior pelvic plane and the horizontal plane, and the trans-condylar axis of distal femur is perpendicular with the horizontal plane (Fig. 3). Hip posture was defined as the rotation angles based on the local femoral coordinate system from the neutral position (Miki et al., 2012). The first
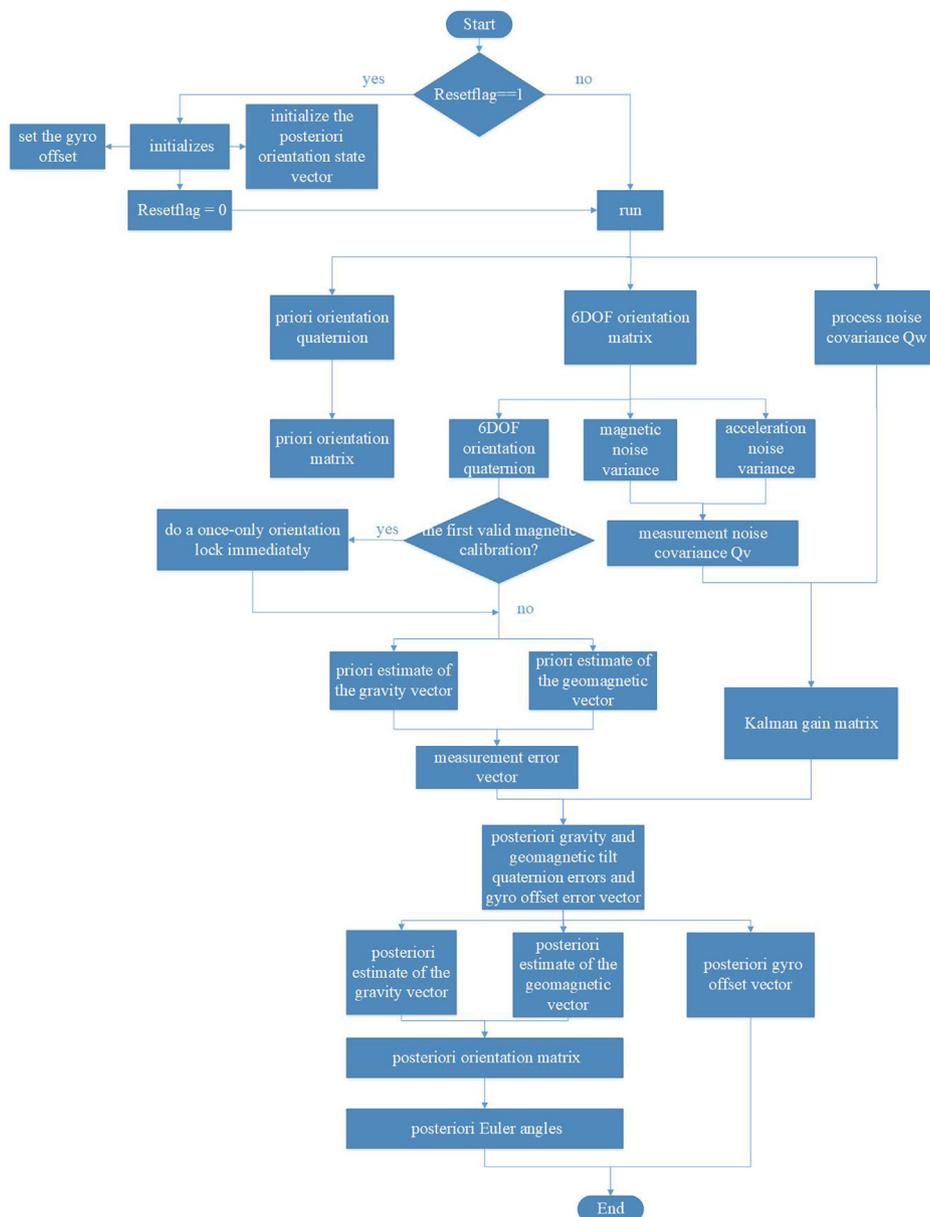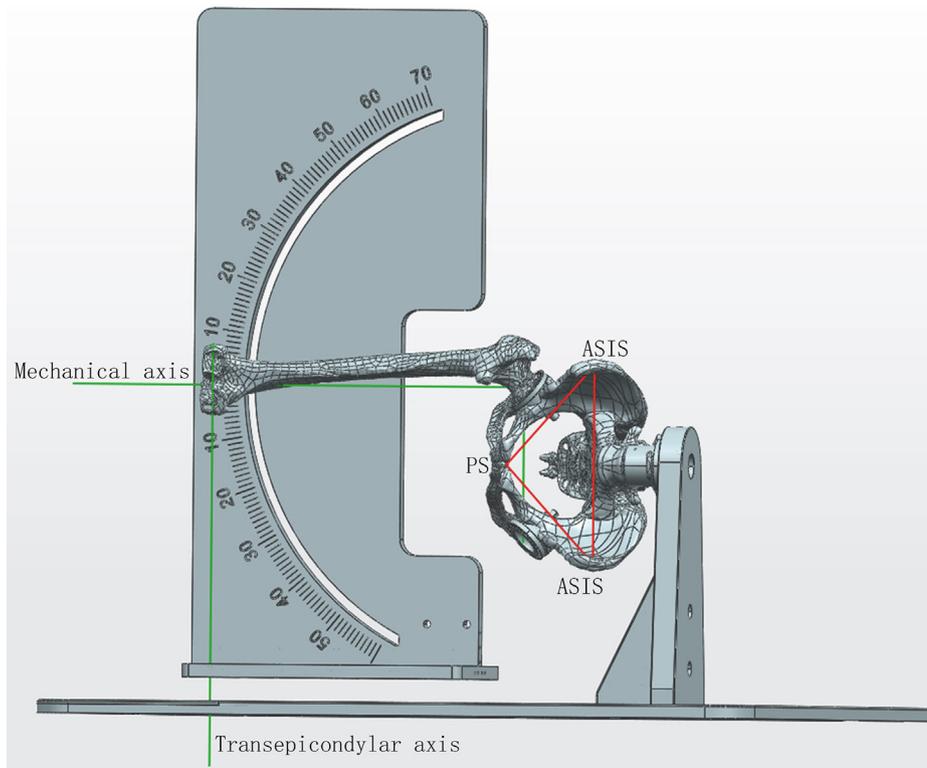

Fig. 3. Flow chart for the error model Kalman filter algorithm.

Fig. 4. Neutral position of the mechanical range of motion measurement model: the mechanical axis of femur is parallel with both the anterior pelvic plane and the horizontal plane, and the trans-condylar axis of distal femur is perpendicular with the horizontal plane.

rotation (flexion or extension) was moved about the z-axis of femur, whereas the second (abduction or adduction) and third (external or internal rotation) rotations were about the y-axis and x-axis, respectively (Fig. 5).

2.2. Mechanical hip range of motion measurement model

To simulate total hip arthroplasty, we employed pelvis and femur bone models, implanted a 60-mm trial cup into the right acetabulum and a femoral stem into to the femoral canal after broaching (Accolade II, Stryker, Warsaw, IN). The IMUHST system,

incorporated in a 36-mm diameter trial femoral head, was then assembled onto the femoral trial stem and reduced into the cup.

During in vivo surgeries, the pelvis is put in a neutral position and stabilized during THA surgeries with various types of positioners (Schwarzkopf et al., 2017). To simulate the condition, a real size pelvic model was then fixed onto a plastic scaffold, which was designed to ensure that the anterior pelvic plane was perpendicular to the ground, thereby mimicking the lateral decubitus position utilized in a posterior approach for THA. There is potential movement of the pelvis during in vivo surgeries (Schwarzkopf et al., 2017), but this is simplified with a fixed pelvis in the current mechanical ROM measurement model to calculate the accuracy
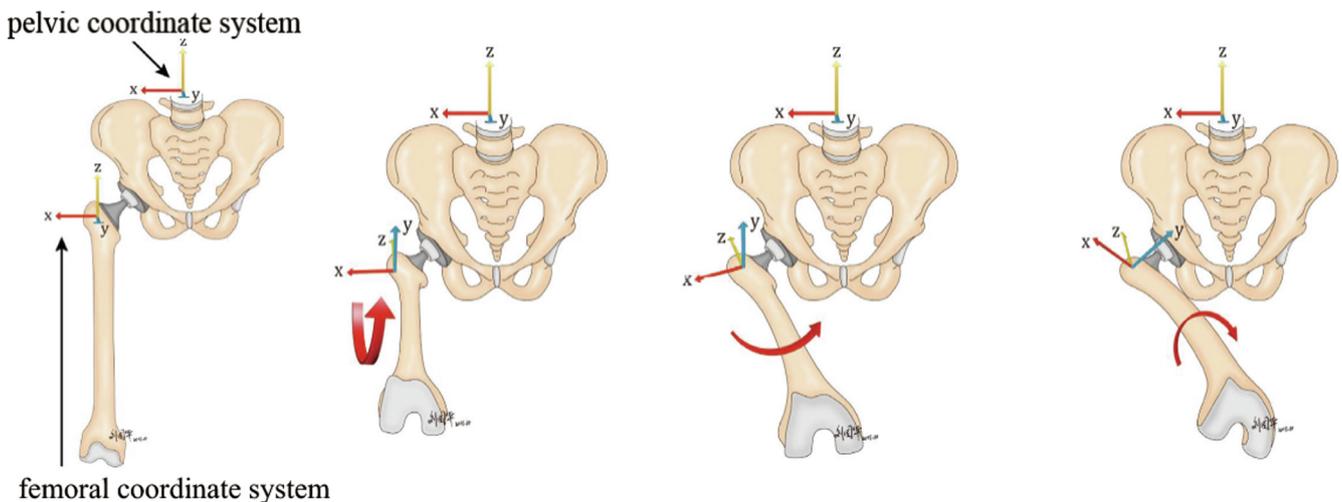
Fig. 5. Definition of the coordinate systems and anatomical hip posture. The femoral coordinate system is defined according to the retro-condylar plane; the pelvic coordinate system is based on the anterior pelvic plane. The posture of the hip joint is calculated by a rotation matrix of the two coordinate systems.

of measuring ROM in a stable pelvis by IMUHST. The center of rotation of the right hip was superimposed using the origin of two goniometers: the vertical one for measurement of abduction and adduction, and the horizontal one for measurement of flexion and extension. Internal and external rotation of the femur was measured through a circular goniometer fixed onto the femoral shaft. The whole construct was then fixed onto a horizontal table. The upper side hip joint was reamed and implanted with a 54 mm outer diameter hemispherical cup model with an inner diameter of 36 mm. A femoral model with an IMUHST system contained within a 36 mm diameter head was reduced to the joint. The abduction/adduction, flexion/extension and internal/external rotation degrees are measured simultaneously by the three mechanical goniometers and the IMUHST system (Fig. 1). A universal clamp was used to support the weight of the femur model and to stabilize hip posture for repeated measurements and static drifts.

The hip joint model was then placed into 195 different postures to record angulation measured by the smart trial around the three axes of flexion/extension, abduction/adduction, and internal/external rotation (Table 1). In order to measure the accuracy of the IMUHST device in each single rotating axis and during compound movements, postures were grouped into four types: three simple posture groups with the femur rotating around a single axis while the two other axes were maintained at the origin, and one compound posture group with the femur rotating around all three axes. Each posture measurement took less than 10 s, with the femur starting from the original neutral position and rotated at a constant speed to the target position to read the data. In order to examine reliability, the IMUHST measurements were repeated 6 times with 10 s intervals between each time point and for all of the postures. Four randomly chosen postures were held static by the universal clamp and monitored continuously for 5 min with the IMUHST system to evaluate the static drift of each axis.

2.3. Statistics

With the mechanical posture measurement outcome as the reference standard, the mean absolute error (MAE) for posture monitoring by the IMUHST system was calculated with a 95% confidence interval. A Bland-Altman analysis was used to calculate the 95% limits of agreement within which the angle estimation errors falls with a 95% probability. The intra-class correlation coefficient (ICC) was calculated for each group of postures as the assessment of reliability. All statistical analysis was performed using SPSS software (version 15.0; IBM, Armonk, NY, USA) and Medcalc software (Medcalc, Mariakerke, Belgium). Significance was set at $p < 0.05$.

3. Results

The 95% confidence interval of MAE in measuring posture in the three axes was as follows: $2.5 \pm 4.9°$ for flexion/extension, $2.5 \pm 4.4°$ for adduction/abduction, and $1.0 \pm 2.0°$ for internal/external rotation in all tested postures, respectively. For postures rotating around each single axis, the accuracy was $0.6 \pm 0.9°$ for flexion/extension, $0.8 \pm 1.2°$ for abduction/adduction, and $2.1 \pm 2.8°$ for internal/external rotation, respectively. For compound postures rotating encompassing all three axes, the accuracy was $3.3 \pm 5.5°$ for flexion/extension, $3.2 \pm 4.3°$ for abduction/adduction, and $0.9 \pm 1.6°$ for internal/external rotation (Table 1).

The Bland-Altman analysis revealed that, in comparison to mechanical measurements, the means of errors in the IMUHST measurements were $-0.3°$ in flexion/extension, $-0.5°$ in abduction/adduction, and $0°$ in internal/external rotation. The limitations of agreement were between $-7.2°$ to $6.6°$ in flexion/extension, $-7.0°$ to $6.1°$ in abduction/adduction, and $-2.6°$ to $2.7°$ in internal/external rotation (Fig. 6).

The ICC values for posture measurement by the IMUHST system for 6 times with 10 s intervals ranged from 0.929 to 1.000 for the different rotation axes in the four groups of positions tested (Table 1).

The static drift measurement revealed that the drift of the current IMUHST ranged between $-0.004°/s$ to $-0.001°/s$ for flexion/extension, $<0.001°/s$ to $0.001°/s$ for abduction/adduction, and $-0.001°/s$ to $<0.001°/s$ for internal/external rotation.

4. Discussion

This study evaluated the validity and reliability of a novel inertial measurement unit-based hip smart trial system (IMUHST) used for intraoperative monitoring of hip posture in total hip replacement surgery. The current IMUHST system is intended to be used as a temporary modular trial head mounted onto the trial stem

Table 1
The MAE and ICC results of the in vitro validation experiment.

| Hip postures tested	Measured range	Number of postures tested	95% CI of MAE	ICC
All postures				
Flexion/extension	$-80° \sim 120°$	195	2.5 ± 4.9	1.000
Abduction/adduction	$-40° \sim 70°$		2.5 ± 4.4	1.000
Internal/external rotation	$-90° \sim 90°$		1.0 ± 2.0	1.000
Flexion/extension axis only				
Flexion/extension	$-80° \sim 120°$	41	0.6 ± 0.90	1.000
Abduction/adduction	$0°$		0.4 ± 0.54	0.947
Internal/external rotation	$0°$		0.4 ± 0.62	0.929
Abduction/adduction axis only				
Flexion/extension	$0°$	21	1.7 ± 2.0	1.000
Abduction/adduction	$-36° \sim 70°$		0.8 ± 1.2	1.000
Internal/external rotation	$0°$		1.2 ± 2.0	0.988
Internal/external rotation axis only				
Flexion/extension	$0°$	19	2.0 ± 3.8	1.000
Abduction/adduction	$0°$		4.5 ± 4.3	1.000
Internal/external rotation	$-90° \sim 90°$		2.1 ± 2.8	1.000
Compound posture				
Flexion/extension	$-30° \sim 120°$	114	3.3 ± 5.5	1.000
Abduction/adduction	$-40° \sim 65°$		3.2 ± 4.3	1.000
Internal/external rotation	$-70° \sim 50°$		0.9 ± 1.6	1.000

Hip extension, adduction, and internal rotation were noted as negative for each rotating axis, respectively; MAE = mean absolute error; CI = Confidence Interval; ICC = Intraclass Correlation Coefficient.

during THA operations to capture hip postures in real time, and needs to be removed before implantation of real prostheses. Capturing hip posture lays down the very foundation for developing more complex clinical applications of the intraoperative IMUHST, such as measurement of hip joint ROM, navigation of component orientation, as well as detecting adverse situations, including impingement, subluxation and dislocation. These particular situations are of paramount importance to identify and improve during THA surgeries in order to optimize postoperative hip function and survivorship. The traditional method utilized for this purpose relied on the surgeons' intraoperative palpation, visual estimation and subjective judgement, which are influenced by numerous additional factors, including patient positioning, obesity, surgical approaches and viewpoint. The subjective evaluation of hip joint ROM, component position, impingement and subluxation have low reliability and accuracy (Meermans et al., 2015).

Computer assisted total hip arthroplasty surgeries are reported to be more accurate than traditional, manual tools in terms of positioning the prosthesis. However, most studies pertaining to accuracy have evaluated component position during surgery (Jolles et al., 2004; Paprosky and Muir, 2016). Very little literature has reported the accuracy of an optical navigation system in measuring posture. Kendoff et al. reported that a rotational deviation of 3 degrees was obtained with a noninvasive optic tracker system (Kendoff et al., 2007). According to our in vitro experimental data, the average MAE of the IMUHST system ranges from 1.0 to 2.5°, depending on the axis of motion evaluated, and is comparable with the traditional optics-based navigation systems in measuring hip posture. This is in concert with previously published reports that the mean absolute error of IMU-based joint angle measurement systems reached 2° (Brennan et al., 2011; Chardonnens et al., 2012; Faber et al., 2013).

Although optics-based navigation systems provided improved accuracy of component positioning, leg length control and ROM detection, navigation is utilized in only 1–3% of THA procedures (Paprosky and Muir, 2016; Xu et al., 2014). Potential reasons for this include the high cost of hardware, time-consuming protocols and workflow disturbances, which decreased its popularity among surgeons and hospitals. The novel system of IMUHST described in the current study features several advantages; it is minimally invasive without the need for bone pins, as well as convenient and easy to use and it does not require complex and expensive optic navigation hardware (Inaba et al., 2016; Jassim et al., 2014; Xu et al., 2014). The cost effectiveness of IMU sensor navigation systems has been reported to be significantly advantageous over conventional optics-based navigation system, as there is a lower disposable cost and no capital cost (Goh et al., 2016; Novak et al., 2007). The current solution is more suitable than optics-based nav-
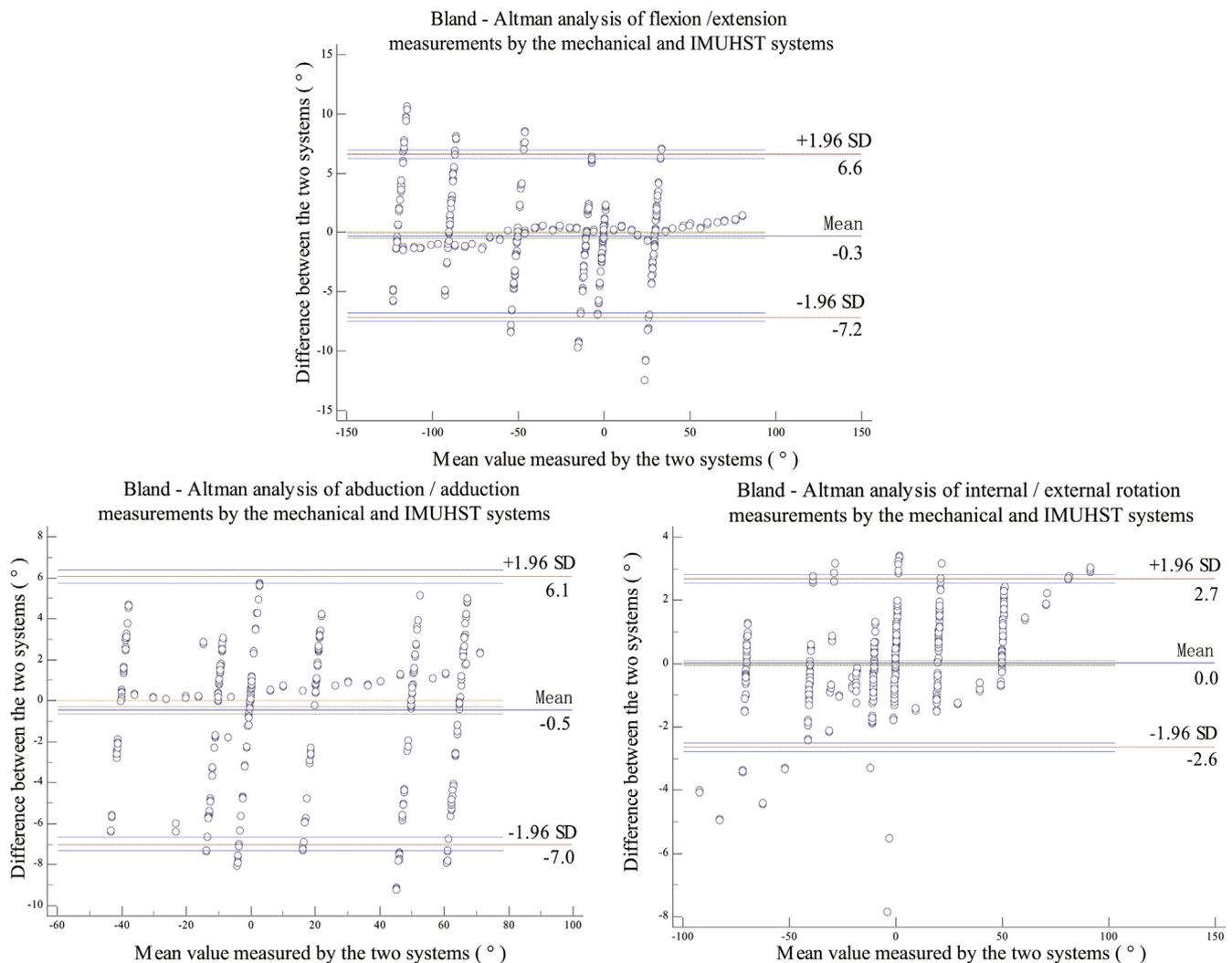
Fig. 6. Bland – Altman analysis of the measured results of the mechanical and inertia measurement unit-based hip smart trial (IMUHST) systems in A. flexion/extension axis; B. abduction/adduction axis; and C. internal/external rotation axis.

igation systems for hospital and surgeons with a low annual THA volume, who were reported to complete the majority of THA surgeries with higher risks of complications and cannot afford to expensive hardware investments (Haeberle et al., 2018).

IMU-based tools were introduced into the field of arthroplasty recently. Several accelerator-based systems have been developed for total knee arthroplasty and have achieved good results (Gharaibeh et al., 2017; Iorio et al., 2015; Nam et al., 2013). Silvio reported the development of an IMU-based navigation system for periacetabular osteotomy and obtained a mean difference of within 4 degrees (Pflugi et al., 2016). To our knowledge, an intra-articular IMU-based intraoperative smart trial system to monitor the hip posture has not been reported previously. This is likely due, in part, to challenges associated with incorporating circuits, sensors and the battery into limited space within the femoral head; this requires advanced component design and accurate assembly to place the sensor in the exact rotation center and orientation.

The utilization of mechanical goniometers as the reference standard can help ensure that the coordinate system matrix are identical to that of the IMUHST (Brennan et al., 2011). This is achieved through the design of the three goniometers and accurate manufacturing to enable the superimposition of the origin points and rotation axes. This represents an advantage over optic navigation systems as the reference standard, which have been reported to calculate rotation of the matrices using tracking clusters fixed on proximal and distal parts of a joint (different from the anatomical framework used by IMU sensors) and require either pre-trial or post-trial alignment with the IMU-based systems to measure accuracy (Chardonnens et al., 2012; Faber et al., 2013; Li and Zhang, 2014).

According to our data, accuracy in the flexion/extension and adduction/abduction planes were relatively lower when compared to the internal/external rotation plane with the goniometer measurements as the reference standard. This might be because the internal/external rotation results in rotation of the coordinate system and cause interferences in the results of the other two axes. In our study, the motion sequence was not controlled, which has the potential to introduce intra-trial variability among different postures and potentially increase the measurement errors of compound postures by IMUHST. Another source of variation may come from the earth frame alignment drift caused by local magnetic field alteration (Brennan et al., 2011; Brodie et al., 2008; Godwin et al., 2009). The ICC values of repeated measurements (0.929–1.000) showed very good reliability of IMUHST (Table 1).

The static drift measurement revealed a small amount of drift in the system, which means a maximal drift of 1.2° over 5 min duration and acceptable to clinical applications (Table 2). This small drift amount is achieved by the 9-axis IMU sensor utilized in the current IMUHST, which encompasses constant correction of drift according to dynamic monitoring of the gravity and magnetic field axes. Drifts in the internal/external rotation axis were found to be higher than that in other axes, which are the result of poorer accuracy in the "z" axis in IMU sensors.

Magnetometers have been widely used in sensor based surgical navigation systems, and Kalman filter algorithms were commonly employed to reduce the noise of magnetometers. Silvio et al. reported a Kalman filter algorithm which did not compensate for disturbed magnetic field (Pflugi et al., 2016). However, the Kalman filter in the current IMUHST system employed a compensation for both soft and hard magnetic disturbances during processes of initial calibration, because the IMU sensors is mounted onto a trial stem which is possibly ferromagnetic (Fig. 2), and we hold an assumption that the magnetic field in operation theaters was complex but stayed constant during short time application of IMUHST (Pengfei Guo, 2008). However, as the IMUHST system is intended to be used temporally for less than 10 min in each THA surgery,

Table 2
Sensor drift at static postures in five minutes.

Posture	Drift °/s		
	Flexion/ extension	Abduction/ adduction	Internal/ external rotation
Flexion 0°, abduction 0°, rotation 30°	−0.001	0.001	−0.010
Flexion 0°, abduction 40°, rotation 0°	−0.003	0.004	−0.019
Flexion 40°, abduction 0°, rotation 0°	<0.001	<0.001	−0.010
Flexion 40°, abduction 40°, external rotation 10°	−0.004	<0.001	<0.001

the influence of environment magnetic field changes can be reasonably minimized because the operation theater system is designed to work smoothly and steadily during THA surgeries, providing a stable hard magnetic environment.

We acknowledge that this research has several limitations. First, the in vitro study was unable to fully simulate the intraoperative situation as there were no soft tissues or body fluid surrounding the bone model. Second, a THA navigation system was not used in the current study. Further study including a navigation system as the reference is required and its matrices of rotation need to be realigned to the IMUHST system to eliminate systemic errors caused by distinctions in angle definition. Third, the current study assumed that the pelvis remain stationary during measurement. For in vivo scenarios, however, there is coordinated movement between the spine, pelvis and hip (Miki et al., 2012), which requires a tracker on the pelvic side to measure the anatomical range of motion of the hip. The current study evaluates the posture capture function of the IMU sensors on the femoral side, which provides a mechanism for potential real-time posture monitoring in combination with pelvic trackers. A fourth limitation is that the design of the current mechanical measurement system does not allow real-time monitoring of posture during motion. As such, dynamic drifts were not assessed in this study. However, the 9-axis IMU employed in the current system features the advantage of reducing dynamic drift by constant calibration compared with the traditional 6-axis IMU sensors (Madgwick et al., 2011).

The IMUHST system provided accurate, real-time monitoring of hip posture in this in vitro experiment and represents a promising system for assessing intraoperative range of motion in THA surgeries.

Disclosures

Dr. Yixin Zhou and Dr. Hao Tang collaborated with the Beijing Yiemed Medical Technology Co. Ltd to develop this system and conducted the validation experiment.

Declaration of Competing Interest

The authors declared that they have no conflicts of interest to this work. We declare that we do not have any commercial or associative interest that represents a conflict of interest in connection with the work submitted.

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