SCIENTIFIC PAPER

Innovative Force-PRO device to measure force and implant position in total hip arthroplasty

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Abstract

Total hip arthroplasty (THA) is the appropriate treatment for hip pain, dislocation, and dysfunction. THA refers to surgery to replace a hip implant, which is an effective way to recover normal hip function. The design of an implant imitates hip functions and allows bone growth in the implant area. However, it should be noted that the implant can dislocate after surgery. The main factor that should be considered during surgery is the correct position of the implant component. The acetabular cup of the hip implant should be positioned at $15 \pm 10°$ anteversion and $40 \pm 10°$ inclination. The evaluation of the implant inclination and anteversion during the operation decrease the risk of the implant dislocation after surgery. Developing a new innovative Force-PRO device can aid the doctor in evaluating the force on the surface of the acetabular liner and the angle of the acetabular liner during the hip implant operation. This device consists of two main sensors—force sensors and inertial measurement unit sensors. Furthermore, the 3D printings of an implant's parts should be specifically designed to integrate with these sensors. To develop the graphical user interface application, C# should be the programming language of use. The graphical user interface application communicates between the device and user via a wireless communication system. CT-based imaging and force gauge measurement are the methods to evaluate the efficiency of this device. For this purpose, the sterile method is considered.

Keywords Anteversion · CT imaging · Force sensing · Implant dislocation · Inclination · Total hip arthroplasty

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Introduction

Total hip arthroplasty (THA) is the appropriate treatments for hip arthritis. It is the most cost-effective surgical procedure to decrease severe pain in the hip, increase motion around the hip, restore hip function, and improve the quality of a patient's life [3, 9]. The common causes of severe pain in the hip are osteoarthritis, rheumatoid arthritis, and traumatic arthritis. In THA, the surgeon removes the dysfunctional bone and cartilage and then replaces them with a hip implant. This implant component consists of three parts—the acetabular component, the liner, and the femoral head. The implant component is designed to fit the bone area and allow bone growth in the implant area. However, in approximately 2–5% of patients [11], dislocation of the total hip implant can occur and may result in nearly 28% of revisions for dislocation [4]. Dislocation of the implant component poses a serious problem for both the surgeon and patient, as it increases the risk of revision surgery and the cost of treatment.

Identifying potential factors for this complication is very important, it helps surgeon to decrease the incidence of dislocation. These factors can be divided into three main categories—patient factors, which include age, gender, medical comorbidities, ligamentous laxity, revision surgeries, and patient education [21], surgeon factors, which include the number of surgical experiences and type of surgical approach [15], and implant factors, which included the design of the implant component [1]. The precision of implant placement is essential to the success of THA, as malposition of the implant results in impingement, leg-length inequality, dislocation, loosening, and implant wear [2]. The functional safe zone which is focused on functional hip motion, has been recently described as a guidance for acetabular cup placement [19]. Evaluating the orientation of the implant component can decrease the risks of hip dislocation, in order to reduce the risk of this serious complication.

Restore adequate soft tissue tension around hip joint is mandatory in terms of preventing dislocation after THA [13]. According to an intraoperative study, soft tissue laxity is a potential factor, which can affect the prevalence of dislocation after THA [18]. It should be noted that not much information is available about hip tension force, which is intraarticular force reaction [17]. The development of an innovative study design to provide useful clinical data, describing the force distribution from the femoral head on the acetabular liner. With a new innovative method to measure hip tension and hip implant position, this could be a useful device to decrease the risk of dislocation after THA.

Method

Force-PRO, the developed device, can measure the force and angle of the acetabular liner in comparison to the anterior pelvic plane (APP). Four factors were considered while developing this device—implant design, sensors, communication pathway, and user interface.

Implant design

The typical modern hip implant consists of the acetabular shell, the acetabular liner, the stem, and the femoral head. The acetabular shell is attached to the hip bone, and the acetabular liner connects the acetabular shell to the femoral head. In this study, the implant prototypes were designed using a 3D computer-aided design (CAD) program. A three-dimensional printer (3D printer, Guider IIs 3D Printer from Flashforge®) was used to make the implant prototype by utilizing this CAD file.

A 3D printer is a machine that is used to print materials layer by layer until a 3D prototype is achieved. The printing precision of this 3D printer is $\pm 0.1-0.2$ mm. For making the
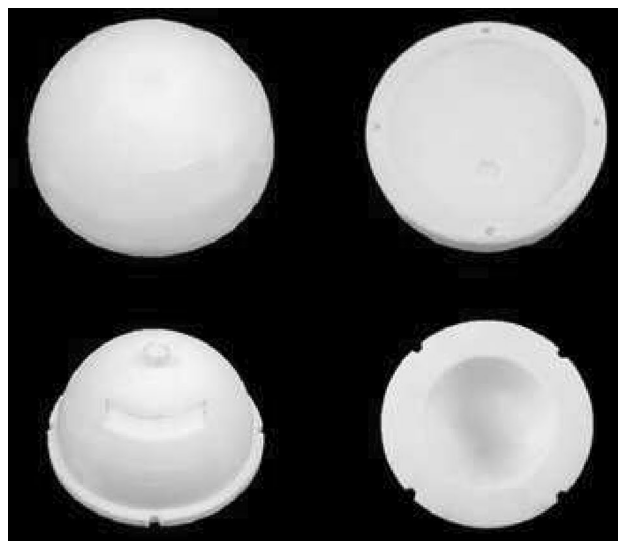

Fig. 1 Femoral head prototype

Fig. 2 Prototype of the acetabular shell and the liner developed via 3D printing

implant parts, polylactic acid (PLA) was used. PLA is a biodegradable and bioactive thermoplastic material, which can change shape when subjected to heat. To achieve a suitable prototype, prototypes were developed in various versions via 3D printing.

Hips implants have a range of femoral head sizes. The chosen implant (Monk, J&J: Fig. 1) had a 32 mm diameter head, so the 3D printed liner was designed with a 32.6 mm inner diameter to allow clearance for the force sensors (each 0.2 mm thick). The 3D printed liner was 7 mm thick, the same as a standard liner, with a slot $22 \times 17 \times 3$ mm for the IMU sensor. The 3D printed acetabular shell inner diameter was 48.6, chosen to allow easy insertion of the liner, with a wall thickness of 3 mm chosen to match the Monk metal shell. The 3D printed shells have to be printed at least for four models, due to the trial have been done with four pelvises at a time. Figure 2 demonstrates the prototypes of the acetabular shell and liner that were developed via 3D printing. The acetabular liner integrates with two types of
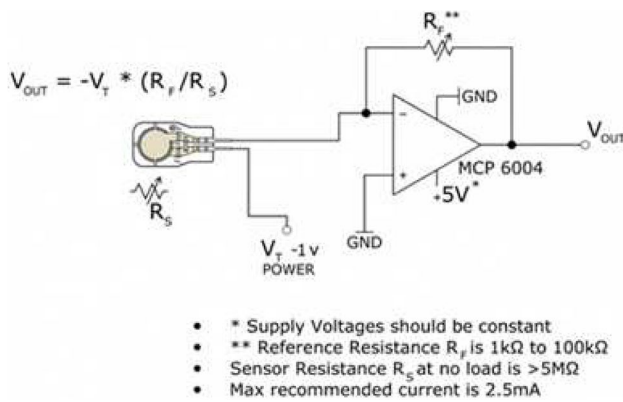
$V_{OUT} = -V_T * (R_F / R_S)$

R_F**

GND

MCP 6004

V_OUT

+5V*

R_S

V_T -1v
POWER

GND

- * Supply Voltages should be constant
- ** Reference Resistance R_F is 1kΩ to 100kΩ
- Sensor Resistance R_S at no load is >5MΩ
- Max recommended current is 2.5mA

Fig. 3 Electrical circuit for force sensing measurement and A301 FlexiForce sensor

Fig. 4 Force gauge and the direction of force while calibrating

Table 1 Relation between force and voltage output (shown in one of four force sensors)

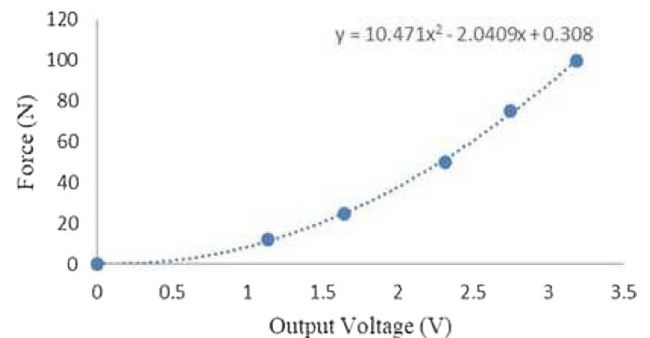| Force (N)	Average voltage output (V)
0	0
12.5	1.1328
25	1.6391
50	2.3174
75	2.7490
100	3.1849

$y = 10.471x^2 - 2.0409x + 0.308$

Fig. 5 The relationship between the force (y axis) and average voltage output (x axis) for the proposed study (shown in one of four force sensors)

sensors—force sensors and the IMU sensor. A microcontroller is used to process the sensor data. It then displays this data on the user interface via a wireless module.

Force sensors

There are various types of force sensors, such as resistive sensors, inductive sensors, and conductive sensors. The A301 FlexiForce, a resistive force sensor, was used to measure the force inside acetabular liner. When force is applied to the sensing area of the sensor, the resistance changes.

The A301 FlexiForce sensor has two pins. The diameter of the sensing area of the sensor is 9.7 mm with a length if 25.4 mm and a thickness of 0.2 mm. The force ranges between 0 and 445 N. Force sensor needs five voltages to supply its. The sensor can operate in the temperature between −40 to 85 °C. The temperature sensitivity is 0.36%/°C. The force range can be adjusted by changing the resistance of the circuit and the driving voltage by following the circuit below (Fig. 3). The response time of this sensor is lesser than 5 µs.

Before using the force sensors, a force gauge was used to find the relation of force and voltage output, as shown in Table 1. The force gauge is a highly accurate instrument

to provide precise force measurement. The direction of the force from force gauge was described in Fig. 4. The liner was attached to the base of force gauge station by using double sided sticky tape. The relation between the force and voltage output of the sensor is shown in Eq. 1 and Fig. 5.

$$y = 10.471x^2 - 2.0409x + 0.308 \qquad (1)$$

Four force sensors were attached to the acetabular liner in four separate areas by double side tape (as shown in Fig. 6). The wires of the sensors are rigid, so the sensors were positioned just below the rim of the liner to keep the lead wires out of the contact area with the head. The wires of the sensors are tiny, which do not disturb the system. The sensors are connected to the circuit, microcontroller, and wireless communication module. A microcontroller processes the data from each force sensor and converts the voltage data

Fig. 6 Positions of force sensors in the acetabular liner

into force as per the calibration graph (Fig. 5) and equation. Equation 1 shows the relation between the output voltage (V) and the force that press on the sensor (N). This equation converts the voltage output into force in Newton unit. The calibration processes are used in all numbers of force sensors. The goal of the study is to measure the total force inside the acetabular liner.

Inertial measurement unit (IMU) sensor

The GY-85 IMU sensor module (from Shenzhen Jubaolai Electronics Limited Company) has three triaxial sensors—an accelerometer, a gyroscope, and a magnetometer (compass sensor), which can all be used simultaneously to measure the sensor orientation (Fig. 7), giving nine degrees of freedom. The sensor needs a 3.3 to 5 V supply and communicates with a microcontroller via an I2C Bus. The sensor can operate in the temperature between −40 to 85 °C.

The GY-85 IMU sensor was inserted into the $22 \times 17 \times 3$ mm slot in the 3D printed acetabular liner, as shown in Fig. 7. The IMU sensor connects to the circuit and microcontroller to measure the angle of the implant in comparison to the APP. The inclination and anteversion angle data of the implant, compared with the APP, is transmitted via a wireless module to be displayed on the user interface. Wang et al. define that "Anatomical inclination (AI) was the angle between the plane of acetabular face and the transverse
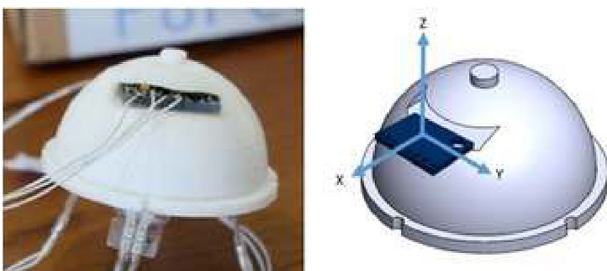
plane, whose mathematical model was the angle between the acetabular axis of the patient and the longitudinal axis. Anatomical anteversion (AA) was the angle between the acetabular axis and the coronal plane when viewed in cranio-caudal direction. The mathematic model of AA was the angle between the acetabular axis that was projected to transverse plane and transverse axis." [20].

For obtaining the roll angle (the angle that rotates around X-axis) and pitch angle (the angle that rotates around Y-axis), the data from the accelerometer (Raw_{Accel}) was converted into g unit (G_{Accel}) (g = 9.8m/s^2) and applied to the corresponding equation. Equation 2 is the general equation to calculate the acceleration [14].

$$G_{Accel} = Raw_{Accel} \times \frac{Range}{2^{resolution} - 1} \tag{2}$$

where *range* is the sensor range and *resolution* is sensor resolution. After obtaining the acceleration in g unit, Eq. 3 was used to calculate the roll angle (X) and pitch angle (Y) of the sensor [14].

$$Roll = arctan\left(\frac{-G_x}{G_y}\right), Pitch = arctan\left(\frac{G_y}{\sqrt{G_x^2 + G_z^2}}\right) \tag{3}$$

The roll equation and the pitch equation provide the following ranges [− 180, 180] and [− 90, 90]. The roll and pitch angles are calculated in terms of inclination and anteversion angles in comparison to the APP. Figure 8 shows the inclination angle and the anteversion angle.

Communication pathway

Selecting the wireless module requires many considerations, such as the range of distance between the Force-PRO devices and the laptop, the speed of communication,
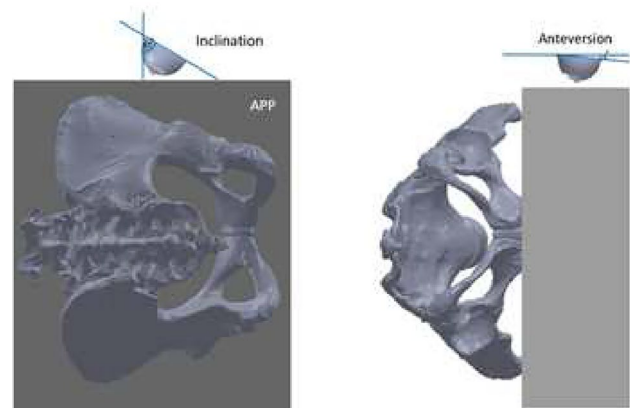

Fig. 7 IMU sensor in the gap of the acetabular liner and its axes

Fig. 8 Inclination angle (left) and anteversion angle (right)

and power consumption. The Force-PRO devices uses XBee Pro S2B. XBee is a module that has a radio frequency range of 2.4 GHz. There are many advantages of using this module; for example, it allows ultra-low power consumption, it's easy to set up, can be quickly woken up, and it's inexpensive. It has a ZigBee standard, which is IEEE 802.15.4. It supports star, tree, and mesh networks. Furthermore, it has a firmware (X-CTU program) that can configure the module. This program is designed to transmit the force data, anteversion angle data, and inclination angle data to the user interface.

Graphical user interface

The graphical user interface is the part of the design that allows the user to communicate with the device. The user interface is designed with the aim of making it user friendly or easy to understand. The Visual Studio C# program is used to develop the graphical user interface application.

The graphical user interface application (as shown in Fig. 9) comprises three parts—force data part, angle data part, and com-port setting part. The force data part displays the amount of force and the location of each force sensor. The angle data part displays the anteversion and inclination angles. It has a calibrate button to all angles to zero before measuring the angle of the implant in comparison with the APP. The com-port setting part is designed to select the com port of the XBee receiving module. It has a connect button to connect the user interface to the device.
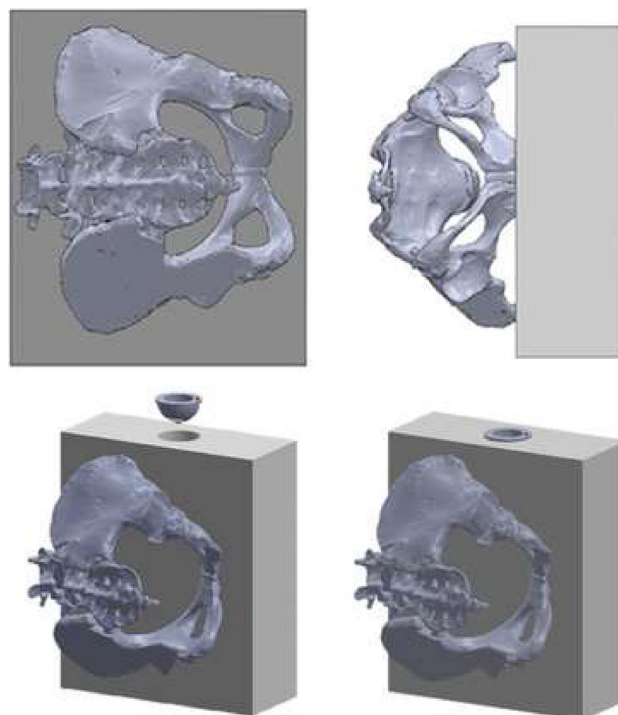

Fig. 9 User interface on Visual Studio

Fig. 10 The alignment box with pelvic bone model

Experiment

To test the performance of the device, the number of sample size (N) was calculated using Eq. 4 with the data from a preliminary study. In the preliminary study, the cup was set to have 45° inclination angle and 15° anteversion angle. Force-Pro was used to measure the angle of the cup 20 times to find the mean absolute difference and the standard deviation. The mean absolute difference ± standard deviation is 2.85° ± 2.23° for inclination and 3.05° ± 2.96° for anteversion. According to the result, the minimum requirement of the sample size is 11. In this experiment, the sample size is equal to 14. Therefore, 14 pelvic bone models were used in the measurement. Four pelvic bone models were separated for each measurement.

$$N = \frac{z_{\frac{\alpha}{2}}^2 \times 3sd^2}{\Delta^2} \tag{4}$$

($\alpha = 0.05$, $sd = 2.96$, Difference of mean(Δ) = 3.05).

The experiment of measuring anteversion and inclination of the hip implant by Force-PRO device was set. The aim of the experiment was to compare the result of anteversion angle and inclination angle between the Force-PRO device and the CT image. Four pelvic bone models with four alignment boxes were attached to the CT scanner bed. The pelvic bone position was set with the alignment box in the lateral decubitus position that correlates with the world sagittal

Fig. 11 Four pelvic bone models with randomized attaching acetabular cup in different angles
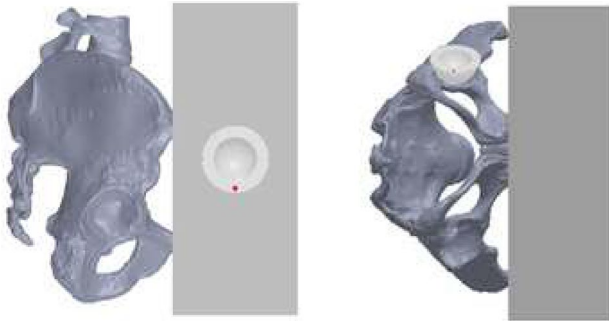

Fig. 12 The red marker and the position of Force-PRO on the pelvic bone model

plane. The Force-PRO device was set with the alignment box, as shown in Fig. 10. Therefore, the device will relative synchronizes its zero position with the pelvic bone model. The device can interpret its position related to its aligned position to determine cup position using an anterior pelvic plane as a reference plane. The cup position was randomly set up, as the common position in the clinical practice, varied from 40° to 60° for inclination, and 0° to 25° for anteversion. Standard goniometer was used to assist cup positioning. The acetabular shells were fixed to four pelvic bone models, which were presented on the bone models in different angles (as shown in Fig. 11). Four Force-PRO devices

(integration of acetabular liner, sensors, and circuit) were prepared using four alignment boxes to set the angle to be zero compared with CT bed (Fig. 11). Each device has identical preparation. Force-PRO devices were attached to four acetabular shells on the pelvic bone models to record the inclination and anteversion angles of four models each time. The inclination and anteversion angles are recorded from the device one time per one pelvic bone model. The red marker on the Force-PRO device (Fig. 12) is used to be the reference point when rotating the device. The red marker is fixed to align at the bottom position of the cup while measuring to avoid the swap of the inclination and anteversion angle. After the angle was recorded from the developing devices, the pelvic bone models with the acetabular cups was sent to the CT scanner to allow the production of cross-sectional images by using the APP as the reference plane.

After CT scanned imaging was completed, then orthopedist and radiologist independently measured the cup anteversion and inclination for each scan. The measurement process was repeated after 4 weeks later, resulting in four times measurements (two inclination measurements and two anteversion measurements per hip, totaling to $14 \times 4 = 56$ units). Inter- and intra-observer reliability were analyzed for each measurement parameter. The inclination angle and the anteversion angle of the implant were measured with reference to the APP in the CT image. The first procedure in measuring the inclination and anteversion angle involved selecting the largest section of the acetabular component in the CT axial and coronal view. A straight line was drawn from the anterior and posterior edges of the implant cup. The angle of the straight line and the sagittal plane of the pelvis was the anteversion angle. The angle of the line tangential to the edges of the implant cup and the line perpendicular to the points on two sides of the pelvis was the inclination angle (see Fig. 13).

Another experiment was conducted to evaluate the force sensors' efficiency. Different force levels from the

Fig. 13 Measurement of the anteversion and inclination angles from the CT coronal image
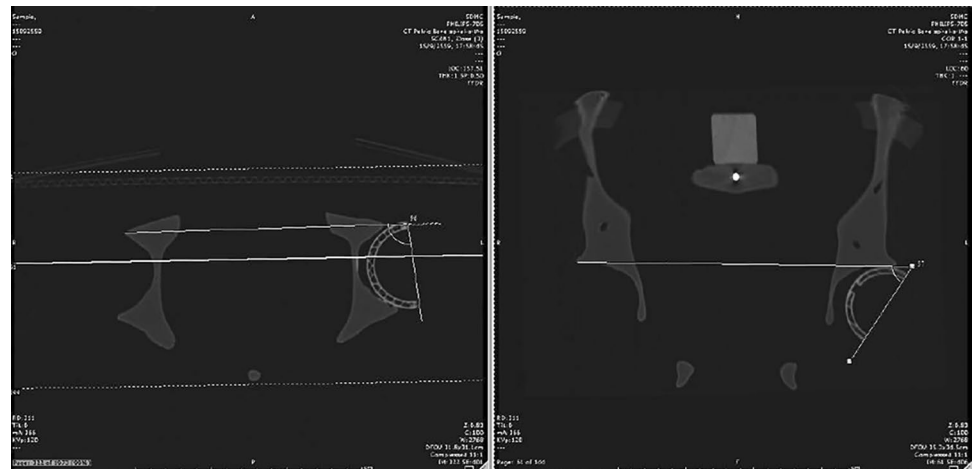
force gauge were placed on the sensors. The user interface recorded the force data from the calibration equation (Eq. 1). Each force was tested 20 times to identify the percent error.

Results

The main objective of the study was to assess how the Force-PRO device can evaluate the positioning of the acetabular cups by comparing the device's measurement of the inclination and anteversion angles with the inclination and anteversion angles that were interpreted using freehand techniques

and CT-based imaging in a previous study, as shown in Tables 2 and 3.

The mean absolute error between the acetabular inclination that was recorded from the device and the result from the CT data was 2.14° (range 0.5°–6°, standard deviation: 1.77, 95% CI − 1.12 to 3.16).

The mean absolute error between the acetabular anteversion that was recorded from the device and the result from the CT data was 4.25° (range 0°–9.5°, standard deviation: 3.02, 95% CI − 2.51 to 5.99).

With respect to position assessment, a device system can also analyze the force distribution on the surface of the acetabulum cup in real time. Following this system, surgeons

Table 2 Results of mean and standard deviation of inclination angle reading by Orthopedist, Radiologist, and Force-PRO device

Sample No.	Mean (SD)		Device inclination (degree)	Inclination error (degree)
	Orthopedist inclination (degree)	Radiologist inclination (degree)		
1	51 (0)	51.5 (0.71)	51	0.5
2	50 (0)	51 (0)	51	1
3	47.5 (0.71)	48 (0)	51	3.5
4	49 (0)	50 (0)	55	6
5	50.5 (0.71)	51.5 (0.71)	51	0.5
6	59 (0)	60 (0)	59	1
7	49 (0)	49.5 (0)	51	2
8	58 (0)	59 (0)	60	2
9	40.5 (0.71)	40.5 (0.71)	44	3.5
10	44.5 (0.71)	45 (0)	45	0.5
11	38 (0)	37.5 (0.71)	42	4.5
12	37.5 (0.71)	37.5 (0.71)	41	3.5
13	53 (0)	52.5 (0.71)	52	1
14	56.5 (0.71)	56.5 (0.71)	56	0.5

Table 3 Results of mean and standard deviation of anteversion angle reading by Orthopedist, Radiologist, and Force-PRO device

Sample No.	Mean (SD)		Device anteversion (degree)	Anteversion error (degree)
	Orthopedist anteversion (degree)	Radiologist anteversion (degree)		
1	10 (0)	10 (0)	3	7
2	12.5 (0.71)	13 (1.41)	9	4
3	20.5 (0.71)	20.5 (0.71)	18	2.5
4	22 (0)	22.5 (0.71)	25	3
5	8 (0)	8 (0)	5	3
6	10 (0)	10 (0)	10	0
7	12.5 (0.71)	13.5 (2.12)	4	9.5
8	11.5 (0.71)	11 (0)	10	1.5
9	3.5 (0.71)	4 (1.41)	3	1
10	20 (0)	20 (0)	14	6
11	10 (0)	9.5 (0.71)	2	8
12	15.5 (0.71)	15.5 (0.71)	7	8.5
13	− 3 (0)	− 2.5 (0.71)	− 6	3.5
14	− 4 (0)	− 4.5 (0.71)	− 6	2

can evaluate the soft-tissue tension around the hip joint and select the best suitable by using the principle of force sensor (conversion of the differences of voltage into force recording by using an Eq. 1 after the calibration process), as shown in Table 1 and Fig. 5.

To evaluate the efficiency of a force sensor (the four sensors are identical, so the results are similar), the convert calibration process is used. Table 4 infers that the percent error of the force sensor in the Force-PRO device is $0 - 2.272\%$. The percent error in Table 4 was calculated from Eq. 5.

$$\frac{Apply\ force - Average\ force}{Apply\ force} \times 100 \qquad (5)$$

Discussion

THA is the treatment to relieve severe pain, restore motion, increase hip function, and improve the quality of a patient's life. However, improper positioning of the acetabular cup in THA results in various complications, such as a limited range of motion, increased wear, and implant dislocation. This research aims to develop the device to evaluate the force on the surface of the acetabular liner and the angle of the acetabular liner during the hip implant operation. The correct position of the implant component was concerned.

At present, there are various techniques to adjust the position of the acetabular cup; for example, the conventional free-hand technique and imageless navigation. However, these techniques have different advantages and limitations.

With respect to the conventional free-hand technique, the results are rarely satisfactory. Hassan et al. found that despite using mechanical alignment guides, the acetabular component is positioned in the safe zone only 58% [7]. DiGioia et al. reported that the free-hand method can lead to mispositioning 78%, as measured using intra-operative computer-assisted measurement [6]. Saxler et al. have reported that the free-hand method positions the acetabular component in the safe zone only 26% [16].

An imageless navigation system has been developed for THA. It is a high-precision technique compared to traditional

methods [5, 10]. Although it is as accurate as the CT-based method, it has some limitations, such as complicated usage, expensive, time-consuming procedure, and high risk of contamination from pin placement [12].

In the Force-PRO device, the IMU sensor is used to measure the inclination and anteversion angles. It is classified under the broader group of computer-assisted surgery (CAS). The performance of Force-PRO device is reliable, especially in terms of the acetabular cup's inclination angle. This device is accurate on average and has a smaller standard deviation compared to other devices. Bony landmarks are used as a reference point to determine the APP for the calibration process. The Force-PRO device works on the calibration plane (APP). Although this study was performed on the pelvic bone model, the results, in Tables 2 and 3, still indicate that the Force-PRO device is accurate. The results, in Tables 2 and 3, were compared to a CT-based study. Furthermore, a standard radiographic analysis was used to evaluate the position of the implant cup in the CT image. The effects of the anteversion were determined to have significant errors [8].

The limitation of the developed device in comparison with other advanced CAS systems is that it has moderate accuracy in terms of assessing anteversion. Due to three dimensions of the acetabular cup's placement, it is easy to lose the orientation on one of these planes. In other words, this device depends on the pelvis position. Another limitation is that this device compromises the sterility.

With respect to force sensors, the developed device is a real-time measurement. This device can display force distribution on the acetabular cups surface during surgery. However, the limitation of the device is that the area of the measurement is four areas, which cannot cover the total force from the femoral head. It estimates the approximate total force just from four sensors.

Conclusion

Integrating an IMU sensor and force sensors in the Force-PRO device is useful in terms of estimating soft tissue tension in intra-operative surgery. Furthermore, this integration is essential for selecting the best implant length. Force-PRO can also decrease post-operative complications such as dislocation and loosening of the implant.

Furthermore, clinical in-vivo studies are required to evaluate the accuracy of the Force-PRO device in THA and to examine the improvement in implant placement achieved by sensors. The study results in the reduction of post-operative complications and increases the mid- and long-term survival of the total hip implant in hip arthroplasty.

Table 4 Mean, SD, range of force and percent error from 20 repeats (reading from program)

Apply force (N)	Mean (N)	SD (N)	Range of force (N)	Percent error
12.5	12.228	0.203	11.937–12.542	2.18
25	24.432	0.532	23.341–25.053	2.27
50	50.545	0.34	50.349–51.824	1.09
75	75.532	0.643	74.943–77.390	0.71
100	100.431	0.831	99.304–102.492	0.43

Compliance with ethical standards

Conflict of 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. This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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