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Functional safe zone for THA considering the patient-specific pelvic tilts: An ultrasound-based approach

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Abstract

The usual Lewinnek orientation for cup positioning in total hip arthroplasty is not suitable for all patients as it does not consider the patient mobility. We propose an ultrasound-based approach to compute a Functional Safe Zone (FSZ) considering daily positions. Our goal was to validate it, and to evaluate how the input parameters impact the FSZ size and barycentre. The accuracy of the FSZ was first assessed by comparing the FSZ computed by the proposed approach and the true FSZ determined by 3D modelling. Then, the input parameters' impact on the FSZ was studied using a principal component analysis. The FSZ was estimated with errors below 0.5° for mean anteversion, mean inclination, and at edges. The pelvic tilts and the neck orientation were found correlated to the FSZ mean orientation, and the target ROM and the prosthesis dimensions to the FSZ size. Integrated into the clinical workflow, this non-ionising approach can be used to easily determine an optimal patient-specific cup orientation minimising the risks of dislocation.

KEYWORDS

cup orientation, dislocation, functional safe zone, pelvic tilt, total hip arthroplasty

1 | INTRODUCTION

Although Total Hip Arthroplasty (THA) has become the treatment of choice for advanced hip osteoarthritis, it is still today prone to complications, such as aseptic loosening and dislocation mainly.[1] To limit the risk of dislocation, usually due to impingement and lever effect, it has been admitted for several decades that the cup should be oriented within the Lewinnek safe zone.[2] However, several studies highlighted that this safe zone is not always suitable for all patients and neither for spinopelvic pathologies.[3–6] Indeed, the lumbar-pelvic-femoral balance plays a major role on the cup orientation during daily activities hence influencing the range of motion (ROM) of the hip.[4,7] For instance, when sitting, the pelvis generally tilts posteriorly leading to an increase of the acetabular anteversion in order to improve the hip flexion. Therefore, a lumbar stiffness will have to be compensated by more hip flexion when sitting and conversely, hip stiffness will require more lumbar flexion.[8] For this reason, many authors suggested to adjust the orientation of the hip implant according to spino-pelvic mobility categories to compensate for possible stiffness and limit the risks of dislocation or impingement.[4,9–14] Yet, there is still today no consensus in the literature about the exact definition of these categories and their associated recommendations.[15]

In order to personalise the positioning of implants regarding both the patient's anatomy and pelvic kinematics, several authors have proposed biomechanical models or finite element studies, based on Computerised Tomography (CT) and X-ray images.[16–19] Nonetheless, all these methods require a significant amount of computation and engineering work for modelling and simulations, and are not therefore easy to integrate in the clinical routine. A simpler approach was proposed by Hsu et al. in 2019, to compute a safe zone based on a target ROM and the patient-specific pelvic tilt while standing, as well as several prosthetic parameters.[20] Although their approach is fast and easy to use, it does not take the pelvic mobility into account. Tang et al. proposed a similar safe zone model considering both standing and sitting positions.[21] However, their approach relies on a specific and not widely adopted EOS imaging system to measure pelvic parameters. Furthermore, while the quality of ultrasound (US) imaging may depend on the operator experience and skills, it remains an inexpensive and harmless way to digitised bony landmarks with good accuracy and reliability.[22]

We therefore propose a non-ionising approach, based on Hsu method, allowing the computation of a patient-specific functional safe zone (FSZ) for the implant positioning, that takes into account the US measurement of the pelvic tilt in different daily positions: standing, supine and sitting. The resulting FSZ would therefore ensure, given the target ROMs, that no prosthetic impingement will occur for all studied positions if the cup orientation is located within this safe zone, and would thereby limit the risks of dislocation.

The objectives of the study were (1) to validate the proposed method allowing the estimation of the FSZ based on the acquisition of the pelvic tilts in different positions, and (2) to evaluate if all the input parameters (pelvic tilts, prosthetic parameters, and target ROMs) have a significant impact on the FSZ or if any of them could be omitted to simplify the method.

2 | MATERIALS AND METHODS

2.1 | Population and pelvic tilt measurement

A prospective non-randomised clinical study was conducted to measure the pelvic tilt in supine, sitting and standing positions of patient undergoing THA. This study was approved by the French Committee for the Protection of Persons and registered under the identification number NCT03555812 in the clinicaltrials.gov database. The inclusion criteria were being over 18 years old, giving informed consent and undergoing unilateral THA for osteoarthritis or hip osteonecrosis between May 2018 and September 2019. Patients under 18 years old and unable to consent were excluded.

The pelvic tilt is defined as the angle between the vertical axis and the anterior pelvic plane (APP, plane defined by both anterior superior iliac spines [ASISs] and the pubic symphysis), and is qualified as positive when the ASISs are anterior to the pubic symphysis, and negative otherwise (Figure 1). For all patients included in the cohort, the pelvic tilt was acquired in the standing, sitting and supine positions, 1 day before undergoing THA, using a previously described and validated US based device[23] (Figure 2). The APP was determined in less than 5 min using a localised US probe and a dedicated software allowing the acquisition of the APP landmarks' position. The pelvic tilt was then determined by computing the angle between the APP and the vertical axis provided by the device's built-in accelerometer. The accuracy of this system to estimate the pelvic tilt was 1.1°.[23] All the data were stored in a dedicated authorised database.

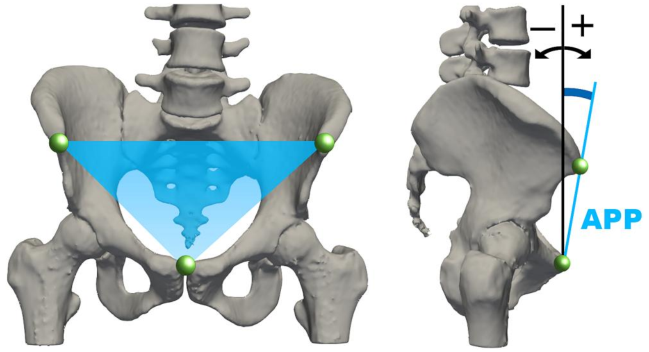

FIGURE 1 (Left) Anterior pelvic plane (APP) defined by both anterior superior iliac spines (ASISs) and the pubic symphysis. (Right) Pelvic tilt defined as the angle between the APP and the vertical axis.

2.2 | Definition of the FSZ and its input parameters

A static safe zone is computed for each studied position (standing, sitting and supine), using the approach described by Hsu.[20] Such static safe zone contains the cup orientations that enable a target ROM free of prosthetic impingement in one position. These orientations are determined by computing the position of the femoral stem when applying the target ROM (based on matrix transformations and trigonometric formulae), regarding the patient's pelvic tilt and the prosthesis design. Once determined, the three static safe zones are merged to compute the proposed FSZ (Figure 3). The FSZ thereby indicates the cup orientations safe of prosthetic impingement whatever the patient's position studied, and provides surgeons with information regarding the optimal cup orientations for the patient.

The input parameters needed to compute the proposed FSZ are: (1) the pelvic tilts in standing, sitting and supine positions, (2) the target prosthetic ROM, that is, the desired flexion/extension, abduction/adduction, internal and external rotations in the three positions, and (3) prosthetic parameters, namely the opening angle of the cup, the diameter of both the femoral neck and head, and the anteversion and inclination of the femoral neck (Figure 4). Considering only the implants and having no information on the femur, the orientation of the femoral neck is defined regarding the patient anatomical axes.

2.3 | Validation of the FSZ computation method

To validate our approach, we compared the FSZs computed for 10 patients randomly chosen from the cohort with their 'true FSZ'

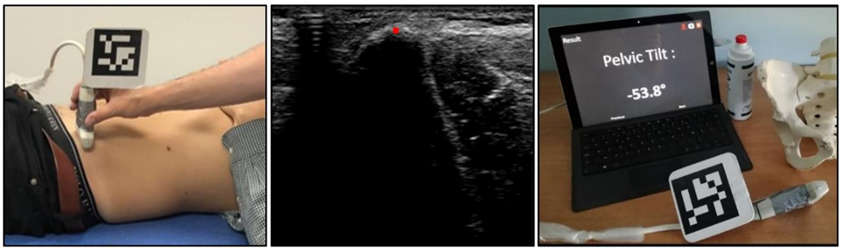

FIGURE 2 US based device used for the acquisition of the pelvic tilt.[23] First, localised US images of the APP landmarks are acquired, then the APP landmarks are accurately identified on the US images, and finally the dedicated software computes the pelvic tilt. APP, anterior pelvic plane.

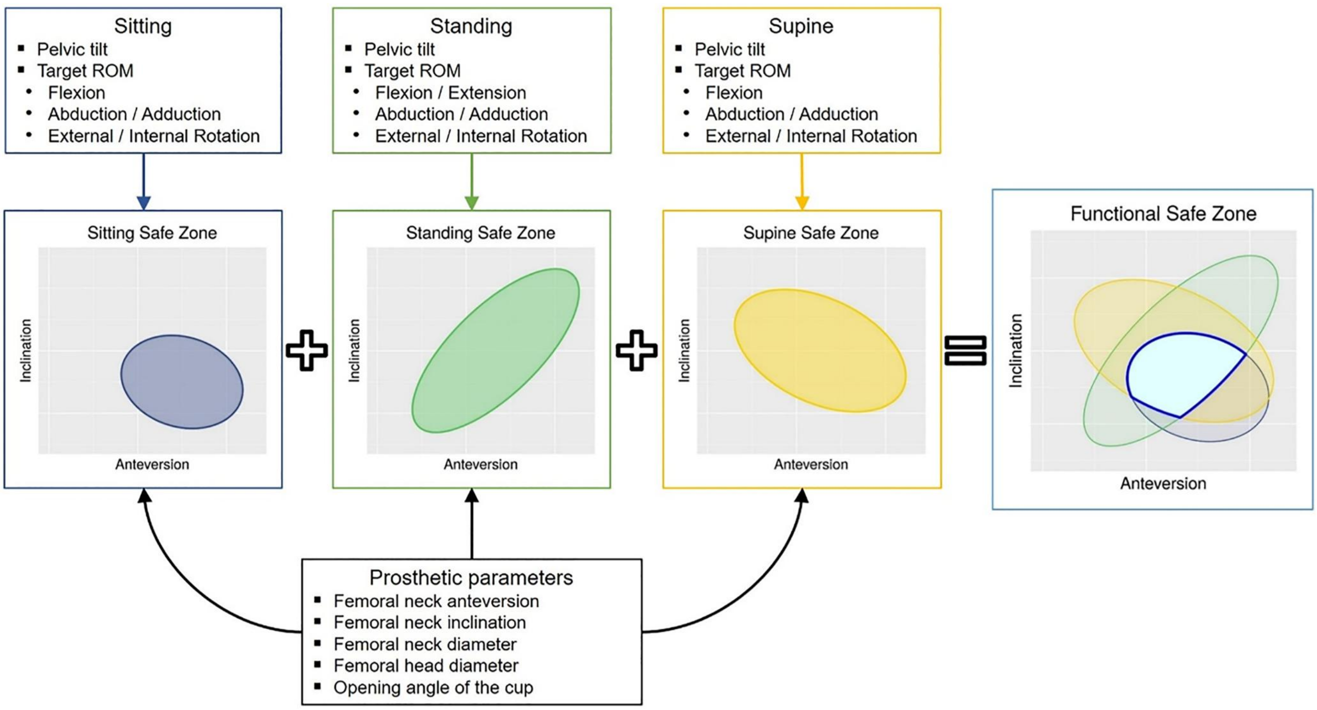

FIGURE 3 Concept of the FSZ: merging of the supine, standing and sitting static safe zones. The FSZ indicates the cup orientations enabling a target ROM safe of prosthetic impingement in the studied positions regarding the patient's pelvic tilt and the prosthetic parameters. FSZ, functional safe zone; ROM, range of motion.

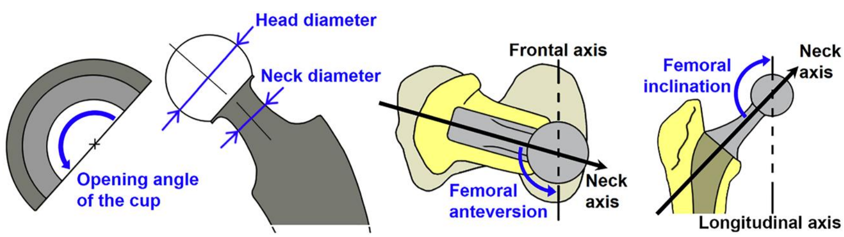

FIGURE 4 Prosthetic parameters used to compute the functional safe zone.

determined by a 3D simulation model. This modelling consisted in applying a target ROM on a 3D mesh of a total hip prosthesis[24] loaded into SolidWorks (Dassault Systèmes).

For each patient, we screened the cup orientations for which an impingement occurred when performing a target ROM, regarding the patient's pelvic tilt in supine, sitting and standing positions. All cup orientations from −89° to 90° of inclination and anteversion were tested, to ensure that the cup orientation at the impingement limit would be identified. The 'true FSZ' was then defined as the sets of cup orientations which did not cause any impingement for the target ROM in the three positions.

Finally, this 'true FSZ' was compared to the FSZ computed (for the same target ROM) by our software, in terms of (1) barycentre of the FSZ, that is, the mean inclination and mean anteversion, (2) distance between edges, and (3) intersection over union (IoU) coefficient. The latter is used to measure the similarity between sample sets and is defined as the size of the intersection divided by the size of the union of the sample sets. The closer the IoU is to 1, the more similar the sample sets are.

The prosthetic parameters used for the FSZ validation are described in Table 1. For each patient, a target ROM was arbitrarily defined within ±20° around a default target ROM (Table 2).[25–30]

2.4 | Significance of the input parameters

To assess the significance of the input parameters and their impact on the FSZ, numerous FSZs were computed using several values for each parameter. The tested pelvic tilts were those of the 30 patients and the tested prosthetic parameters are detailed in Table 3. Five target ROMs were tested and defined as −10°, −5°, +0°, +5° and +10° for all movements around the default target ROM (Table 2). This led to more than 450 000 combinations of parameters tested (30 pelvic tilts × 5 target ROMs × 5^5 prosthetic parameters). The mean anteversion, mean inclination and size of the generated FSZs have been computed and a principal component analysis (PCA) was performed to study the relationships between these characteristics of the FSZ and the input parameters.

Moreover, the impact of each input parameter was analysed independently by computing a FSZ for multiple values of the studied parameter, all other parameters being fixed to default values (see Tables 1 and 2 for the prosthetic parameters and the target ROM respectively). The default pelvic tilts in supine, standing and sitting positions were defined as the cohort average pelvic tilts for the three different positions.

TABLE 1 Prosthetic parameters used for the functional safe zone validation

Anteversion of the femoral neck (°)	117
Inclination of the femoral neck (°)	125
Opening angle of the cup (°)	180
Diameter of the neck (mm)	11.5
Diameter of the head (mm)	28

TABLE 2 Target range of motion default values

Position	Supine	Standing	Sitting
Flexion (°)	120	120	80
Extension (°)	-	20	-
Abduction (°)	40	30	70
Adduction (°)	30	20	30
Internal rotation (°)	40	30	30
External rotation (°)	30	20	20

TABLE 3 Prosthetic parameters used for the significance analysis

Anteversion of the femoral neck (°)	105	110	115	120	125
Inclination of the femoral neck (°)	115	120	125	130	135
Opening angle of the cup (°)	170	175	180	185	190
Radius of the neck (mm)	4	5	6	7	8
Radius of the head (mm)	12	13	14	15	16

2.5 | Statistics

The quantitative data were summarised by their mean, standard deviation, and range.

The PCA allows to study the data variability according to new variables, namely the principal components (PC), in order to highlight the multifactorial correlations between the studied parameters through their coordinates on the PCs. These coordinates correspond to the correlation coefficient r of a Pearson linear correlation. Thus, two parameters correlated to the same PC will be correlated with each other. A coefficient of $0.0 \le r < 0.2$ indicates a negligible positive correlation, $0.2 \le r < 0.4$ a weak positive correlation, $0.4 \le r < 0.6$ a medium positive correlation, $0.6 \le r < 0.8$ a high positive correlation, and $0.8 \le r \le 1.0$ a very strong correlation.[31,32] The same scale is considered for negative coefficients indicating thus negative correlations. A Student t-test was used to identify non zero r coefficients with significance level set at $p < 0.05$. All statistical computations were performed using R (version 3.6.3).

3 | RESULTS

3.1 | Population and pelvic tilt measurement

Thirty patients were included in the cohort corresponding to 17 women and 13 men. The mean age was 66 ± 14 years old (range: 18–85 years old) and mean BMI was 25.5 ± 3.1 kg/m^2 (range: 19.5–32.3 kg/m^2). No patient had had a lumbar surgery before and seven (23%) had a contralateral total hip prosthesis. For the 30 patients, the average pelvic tilt standing was −6.0 ± 10.3° (range: −30.6 to 11.7°), supine was 1.7 ± 5.1° (range: −9.3 to 11.3°) and sitting was −44.5 ± 6.1° (range: −53.8 to −23.9°).

3.2 | Validation of the FSZ computation method

The pelvic tilts of the 10 patients randomly chosen from the cohort are presented in Table 4.

The FSZs computed by our software and the 'true FSZs' obtained by 3D modelling for the 10 patients are shown in Figure 5. The average difference between the barycentres of the true and the computed FSZs was −0.2 ± 0.3° (range: −0.6 to 0.4°) for mean anteversion and

TABLE 4 Pelvic tilts (in °) in the supine, standing and sitting positions of the 10 patients randomly chosen for the functional safe zone validation

Patient	A	B	C	D	E	F	G	H	I	J
Supine position	6.1	5.0	11.3	−4.3	−9.3	7.3	−4.4	−0.5	3.6	8.6
Standing position	−25.8	−2.1	9.4	11.7	−12.1	3.8	−9.5	−7.5	−7.4	6.5
Sitting position	−43.8	−31.1	−23.9	−49.2	−49.4	−34.2	−44.6	−45.7	−51.6	−49.4

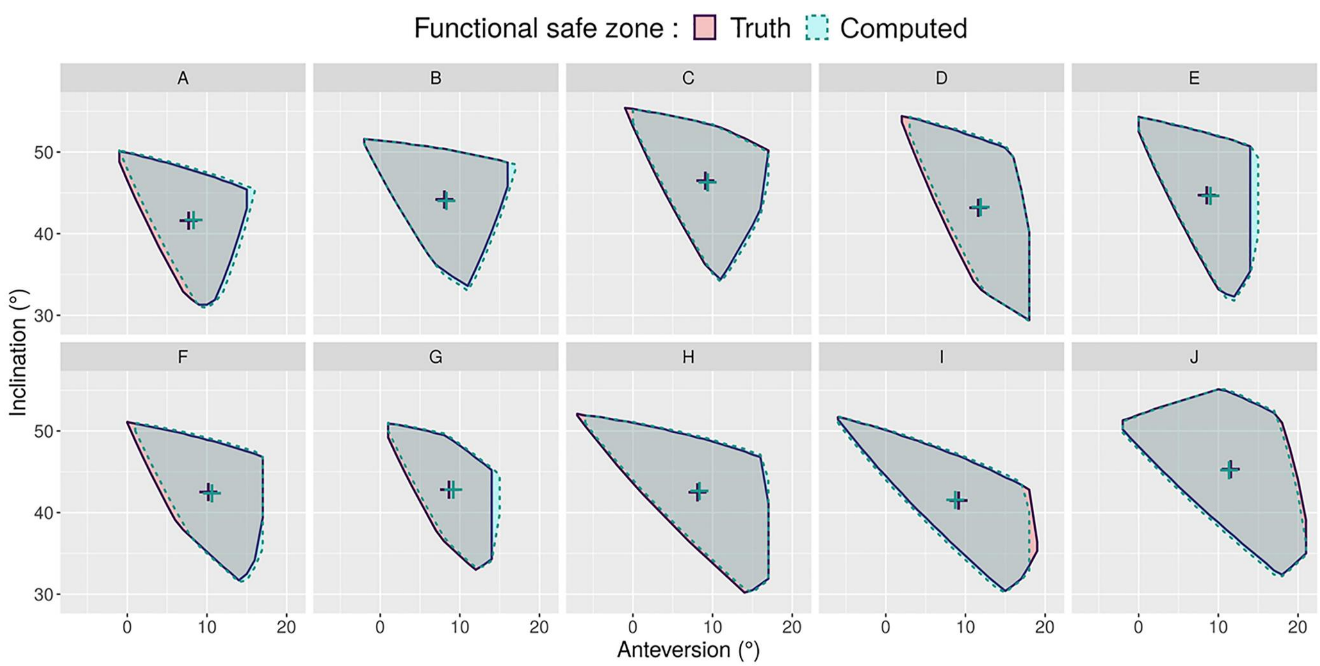

FIGURE 5 FSZ validation: true and computed FSZs for the 10 patients. Crosses indicate the FSZs' barycentres. FSZ, functional safe zone.

0.0 ± 0.1° (range: −0.1 to 0.2°) for mean inclination. The average distance between edges of both zones was 0.2 ± 0.2° (range: 0.0–1.0°) and the average IoU coefficient was 92 ± 3% (range: 86%–95%).

3.3 | Significance of the input parameters

The correlation coefficients to the PCA components of the FSZ's input parameters and characteristics are presented in the Figure 6. All coefficients were significantly different from zero (all *p*-value < 0.001).

The impact of each input parameter on the FSZ can be visualised in the following sections. Each time, the dotted line indicates the FSZ computed for the default value of all input parameters.

3.3.1 | Impact of the pelvic tilts on the FSZ

The pelvic tilts in sitting, standing and supine positions are weakly to highly correlated to the FSZ mean anteversion and inclination, according to the second principal component of the PCA (PC2) (see Figure 6). The Figure 7 shows the impact of each pelvic tilt on the FSZ.

3.3.2 | Impact of the neck orientation on the FSZ

The neck inclination and anteversion are weakly to very strongly correlated to the FSZ mean inclination and anteversion, according to the first and second principal components of the PCA (PC1 and PC2) (see Figure 6). The Figure 8 shows the impact of the neck inclination and anteversion on the FSZ.

3.3.3 | Impact of the prosthesis geometry on the FSZ

The head/neck diameters ratio and the opening angle of the cup are weakly to highly correlated with the size of the FSZ, according to the third principal component of the PCA (PC3) (see Figure 6). The Figure 9 shows the impact of these parameters on the FSZ.

3.3.4 | Impact of the target ROM on the FSZ

The PC3 also indicates a moderate correlation between the target ROMs and the area of the FSZ (see Figure 6). The Figure 10 shows the impact of some target ROMs on the FSZ.

	Pelvic Tilt Supine	Pelvic Tilt Standing	Pelvic Tilt Sitting	Neck Antev.	Neck Incli.	Head Neck ratio	Cup opening angle	ROM	FSZ Mean Antev.	FSZ Mean Incli.	FSZ Size
PC1	-0.09	0.18	-0.05	0.15	0.96	0.08	-0.04	0.07	0.56	-0.90	-0.14
PC2	0.62	0.29	0.61	-0.67	0.12	0.00	0.00	-0.02	0.78	0.37	0.00
PC3	-0.05	0.11	-0.04	-0.01	-0.03	0.65	-0.38	-0.58	0.00	0.04	0.95

-1 -0.8 -0.6 -0.4 -0.2 0 0.2 0.4 0.6 0.8 1

FIGURE 6 PCA results: correlation coefficients *r* of the input parameters of the algorithm (pelvic tilts, prosthetic parameters and target ROM) and the FSZ characteristics (barycenter and size) relative to the PCA principal components (PC). Coefficients *r* close to 1 (or −1) indicate strong correlations, close to 0 negligible correlations. FSZ, functional safe zone; PCA, principal component analysis; ROM, range of motion.

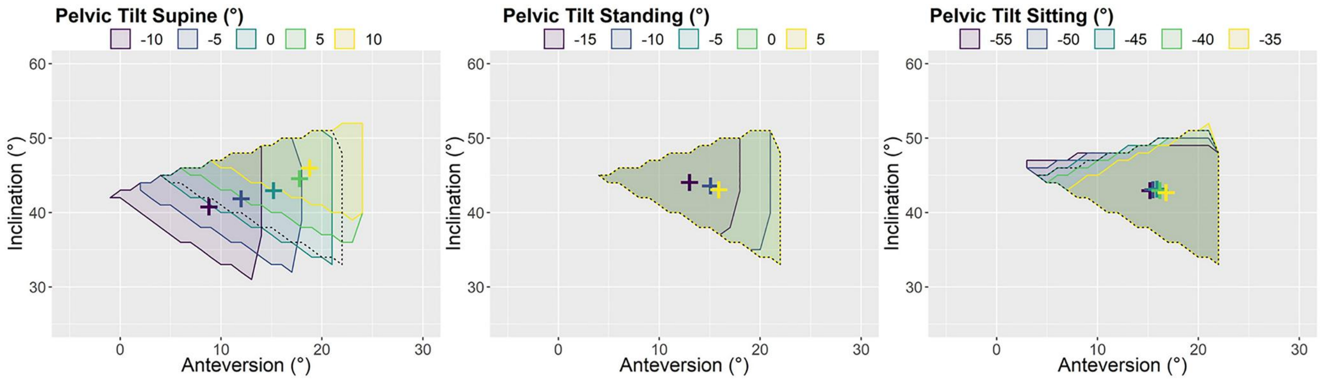

FIGURE 7 Impact of the pelvic tilts on the functional safe zone.

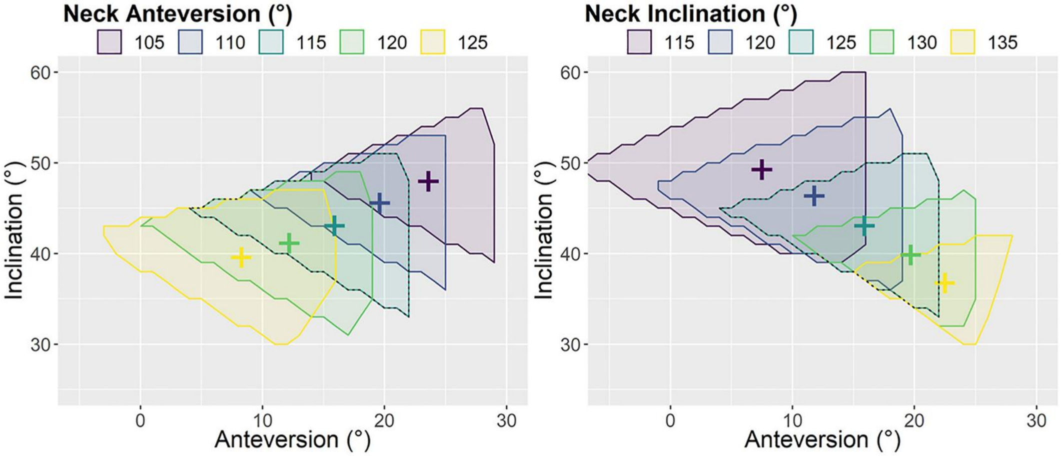

FIGURE 8 Impact of the neck orientation on the functional safe zone.

4 | DISCUSSION

The present study proposes a non-ionising workflow to compute a new FSZ for the cup orientation in THA adapted to the patients' motions. This FSZ can be used to accurately determine the cup orientations safe from prosthetic impingement as well as to evaluate the impact of the patient specific pelvic tilts, or the target ROM and prosthetic parameters, on the optimal orientation. Such US-based approach can be easily integrated in clinical routine, as it is fast and simple to perform (around 5 min to acquire the pelvic tilts and

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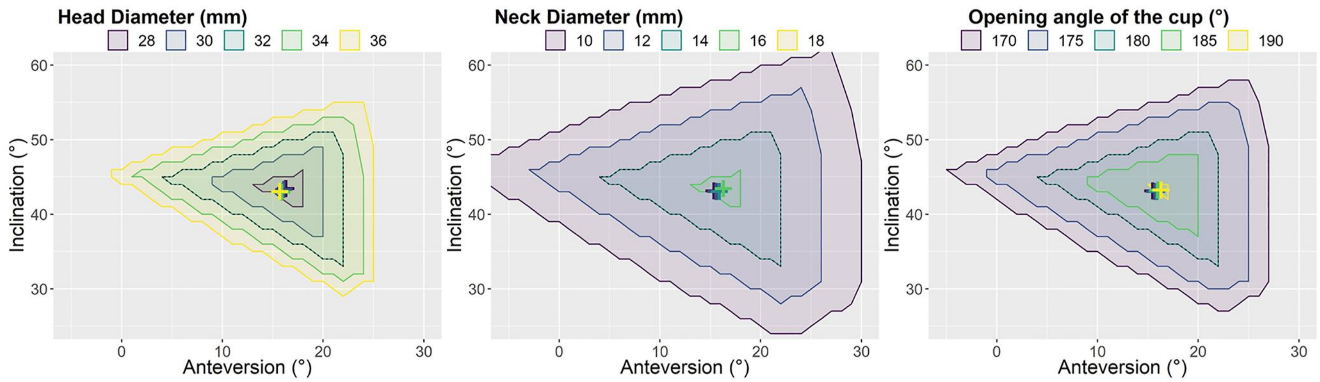

FIGURE 9 Impact of the prosthesis geometry on the functional safe zone.

compute the FSZ) and does not require any X-ray or CT images unlike other solutions.[16,17,21]

A first study allowed the validation of the proposed approach for the computation of a FSZ by using a dedicated application software. Both the position error, that is, the error on the mean anteversion and inclination, and the error at borders were inferior to 1°, which is clinically acceptable. The IoU coefficient was very high for all patients (>85%), highlighting the excellent similarities between both true and computed FSZ.

As part of a clinical study, we measured the pelvic tilts in standing, supine and sitting positions on 30 patients using our US-based device. We further computed their FSZs using the proposed approach and analysed the impact of each input parameter on the FSZ. All the parameters allowing the computation of the FSZ were found to have a significant impact on it. The PCA reveals that the mean orientation of the FSZ is strongly influenced by the patient's pelvic tilts as well as the orientation of the femoral neck. On the other hand, the FSZ size is mainly impacted by the geometry of the prosthesis and the target ROM. Although the PCA indicates moderate to strong correlations between the pelvic tilts and the FSZ mean anteversion, the impact of the pelvic tilt might depend on the considered position. For instance, in Figure 7, the supine pelvic tilt has a stronger impact on the FSZ mean orientation than the sitting pelvic tilt, when the PCA results show that both supine and sitting pelvic tilt have similar impacts on the FSZ. Such result suggests that the impact of the pelvic tilts also depends on their relative values. Thus, the pelvic tilts in sitting, standing and supine positions should be accounted for, as omitting one position would not be sufficient to estimate the FSZ precisely. The orientation of the femoral neck is a significant factor influencing the mean orientation of the FSZ (Figure 8). When the anteversion of the neck increases, the FSZ mean anteversion decreases, maintaining a quite stable combined anteversion as recommended by several authors.[33–35] Similarly, the mean inclination of the FSZ decreases as the femoral neck inclination increases, thus maintaining a rather stable relative inclination between both prosthetic components. The PCA analysis also confirms that the geometry of the prosthesis, namely the diameters of the femoral head and neck and the opening angle of the cup, has a direct influence on the FSZ size (Figure 9). These results support the idea that the higher the head/neck diameters ratio, the larger the safe zone.[36] Finally, regarding the target ROM, it can be observed that if a large target ROM is requested, the area of the FSZ is smaller (Figure 10). More specifically, the FSZ limits seem to be influenced by abduction and adduction for inclination, and internal and external rotations for anteversion. Although these observations have been previously done by several authors, this approach allows the easy implementation of all these observations in the clinical routine.

The determination of the most suitable target ROM for a given patient is still today an open question, as there is no clear consensus in the literature.[20] Yet, it should be probably adapted to the patient's age, daily activities and potential pathologies. The proposed method for the FSZ computation could also be very important for patients having extreme spino-pelvic kinematics, since it could be used to optimise safely the prosthetic ROM given the patient's pathological situation and it could give to the surgeon a clear overview of the margin of error available around the optimal cup orientation when implanting the prosthesis.

Our study presents however several limitations. The first one is that the proposed approach only takes into account prosthetic impingement. But to consider potential bony or soft tissue impingements, additional image acquisitions would be necessary, making the global process more intrusive and probably more expensive. In addition, the estimation of such FSZ relies especially on one parameter, the pelvic tilt, which could be modified postoperatively. This point is still today controversial,[37–43] but could be overcome by adjusting the FSZ to the uncertainty of the postoperative pelvic tilt as recently proposed by Fischer et al.[44] Furthermore, no spinal parameter is considered in the proposed FSZ, and the US measurement of the pelvic tilts in several positions may not be equivalent to X-ray images for determining the lumbar-pelvic balance. Nevertheless, it gives a real insight of the pelvic behaviour during movements. Finally, the proposed FSZ remains to this day theoretical, since other parameters may interfere in hip stability such as soft tissue elasticity, abductors lever arm and efficiency, or postoperative femoral offset. Further clinical studies should be conducted to confirm that the lumbar-pelvic complex can be evaluated through US measurements

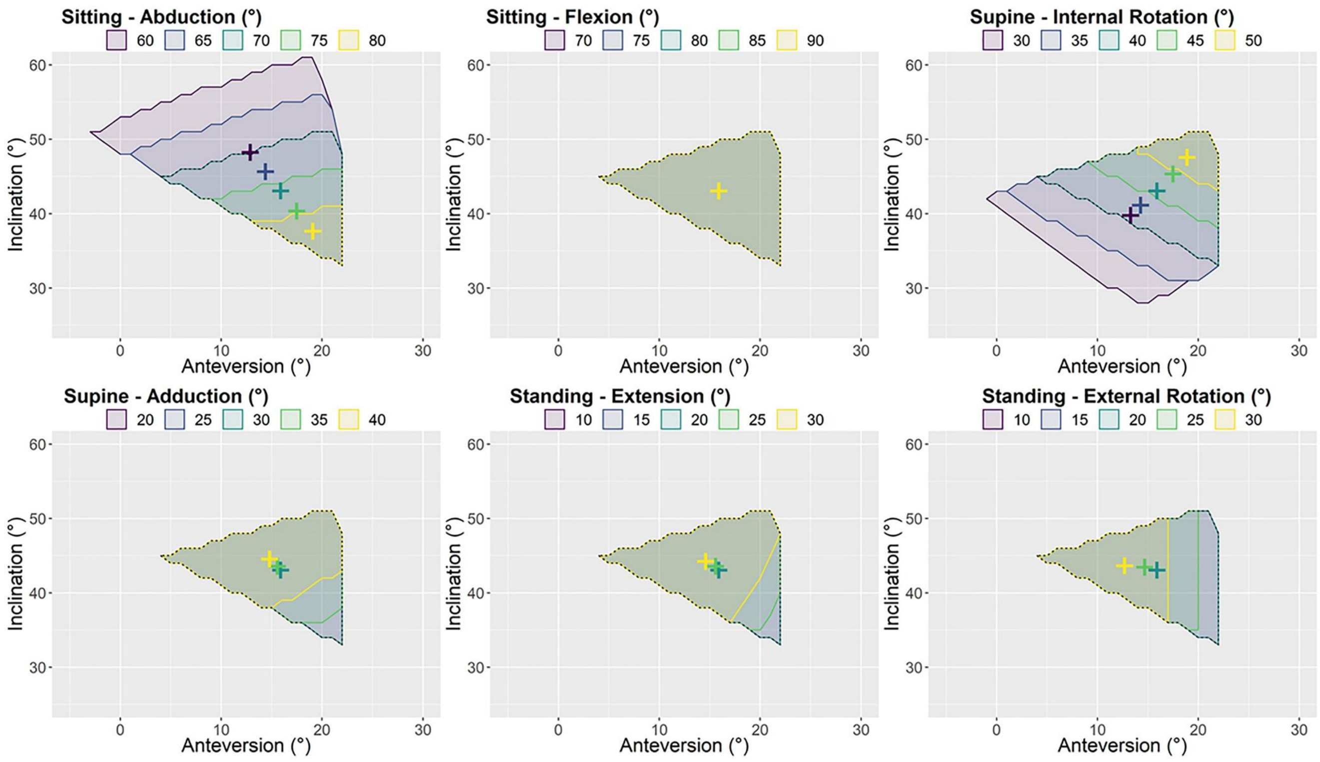

FIGURE 10 Impact of some movements' target range of motion on the functional safe zone.

of pelvic tilts and that no prosthetic impingement would occur when the prosthesis is oriented within the proposed FSZ.

In conclusion, the proposed method allows the non-ionising acquisition of the pelvic tilt in different daily positions and the determination of a FSZ accurate enough to be used in a clinical context. The FSZ's sensitivity to its input parameters, confirms the necessity of taking into account the pelvic tilts in standing, sitting and supine positions, as well as the femoral neck orientation, the implants dimensions and the prosthetic ROM. This approach does not need additional X-ray or CT images and can be used to easily compute an optimal cup orientation for THA considering the patient-specific pelvic mobility.

AUTHOR CONTRIBUTIONS

Aziliz Guezou-Philippe contributed to the research design, analysis of the data, drafting and critical revision of the paper. Arnaud Clavé contributed to the analysis of the data and critical revision of the paper. Wistan Marchadour, Hoel Letissier, Christian Lefèvre and Eric Stindel contributed to the research design and analysis of the data. Guillaume Dardenne contributed to the research design, analysis of the data, drafting and critical revision of the paper. All authors have read and approved the final submitted manuscript.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare that are relevant to the content of this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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