Smith+Nephew

RI.HIP MODELER
Total Hip Arthroplasty

Scientific Rationale

Background

Dislocation is one of the leading causes for THA revision

Despite the overall success and high patient satisfaction of THA, instability remains a costly and difficult problem with negative implications on quality of life. The incidence of dislocation after primary THA is approximately 2% with use of contemporary implants, exposures, and soft tissue balancing[1], yet **instability remains the leading cause for revision THA in the United States**[2,3]. Greater emphasis on patient risk-stratification, surgical technique, and component positioning is required to further reduce the burden of dislocation and revisions related to this complex multifactorial problem[1].

The primary mechanism of hip dislocation is impingement. Impingement and consequent dislocation may occur due to collision between implant components, implant and bone, and soft tissue obstruction[4,5]. Several factors, such as implant design, implant placement, and patient's comorbidities, play a role in increasing or mitigating impingement risk. Therefore, optimal implant selection and placement are paramount to avoid instability and should be tailored to the patient.

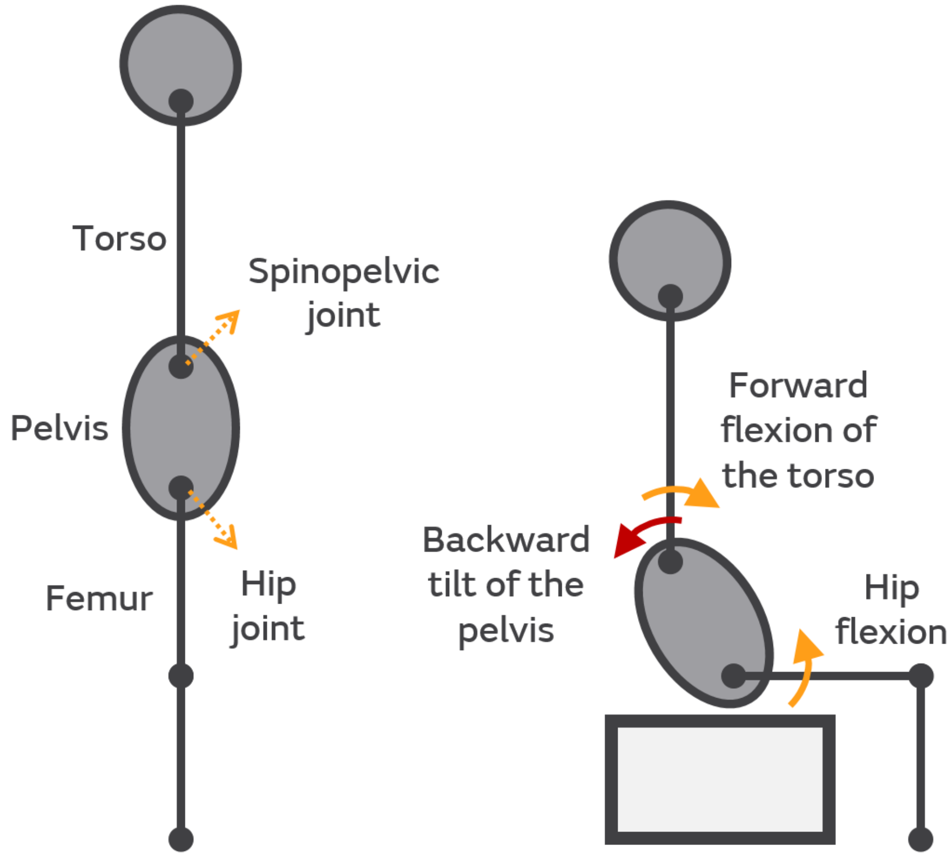
The Lewinnek safe zone needs rethinking

Surgeons typically rely on traditional safe zones for placement of the acetabular cup. The Lewinnek safe zone indicates that cup inclination and anteversion should dwell inside the 40 ± 10° and 15 ± 10° ranges, respectively, to avoid dislocation[6]. **Despite widespread implementation of a universal safe zone as proposed by Lewinnek et al.[6], several authors have recently demonstrated that the Lewinnek safe zone may not be appropriate for all patients**. Abdel et al.[7] demonstrated that in a cohort of 9,784 patients with an overall dislocation rate of 2.1%, 58% of dislocations occurred despite the acetabular components being placed within the Lewinnek's safe zone, with a mean cup inclination angle of 44° and mean anteversion of 15°. Esposito et al.[8] similarly demonstrated that in a population of 7,040 primary THA with a 2.1% dislocation rate, there was no difference in inclination and anteversion angles between dislocators and non-dislocators, implying that cup placement alone does not explain dislocation and cup angles should be tailored to the patient.

Spinopelvic mobility should be considered in THA placement

A growing body of literature on the dynamic relationship between the hip, pelvis, and spine has revealed that **limitations in spinopelvic mobility are linked to higher risk of THA dislocation**[9]. One study noted a 1.55% dislocation rate in THA without previous spinal fusion, a 2.73% dislocation rate in short spinal fusions (one to two levels), and a 4.62% dislocation rate in fusion of three or more intervertebral disc levels[10]. Multiple studies have also demonstrated that the relative risk of revision THA in patients with spinal disease is at least 62% higher and up to 700% higher than in a primary THA population without spinal disease[11–14].

When performing activities of daily living in which the torso and the femur move with respect to each other, both the spinopelvic joint (i.e. the articulation between the spine and the pelvis) and the hips contribute to the overall motion. For example, when a healthy subject moves from a standing position (femur and torso approximately parallel) to a sitting position (femur and torso approximately perpendicular), the hips flex and, at the same time, the pelvis tilts backwards, producing an anterior bending of the spinopelvic articulation (figure below). The lack of rotation at the spinopelvic joint that occurs in patients with spinopelvic mobility limitations forces larger rotations at the hips, which, in turn, might bring the implant closer to impingement between components. Anterior impingement and, consequently, posterior dislocation are mostly associated with activities of daily living with large hip flexion angles, such as rising from a chair, whereas posterior impingement and anterior dislocation occur typically in hip extension, like at the end of the stance phase during walking[9,15].



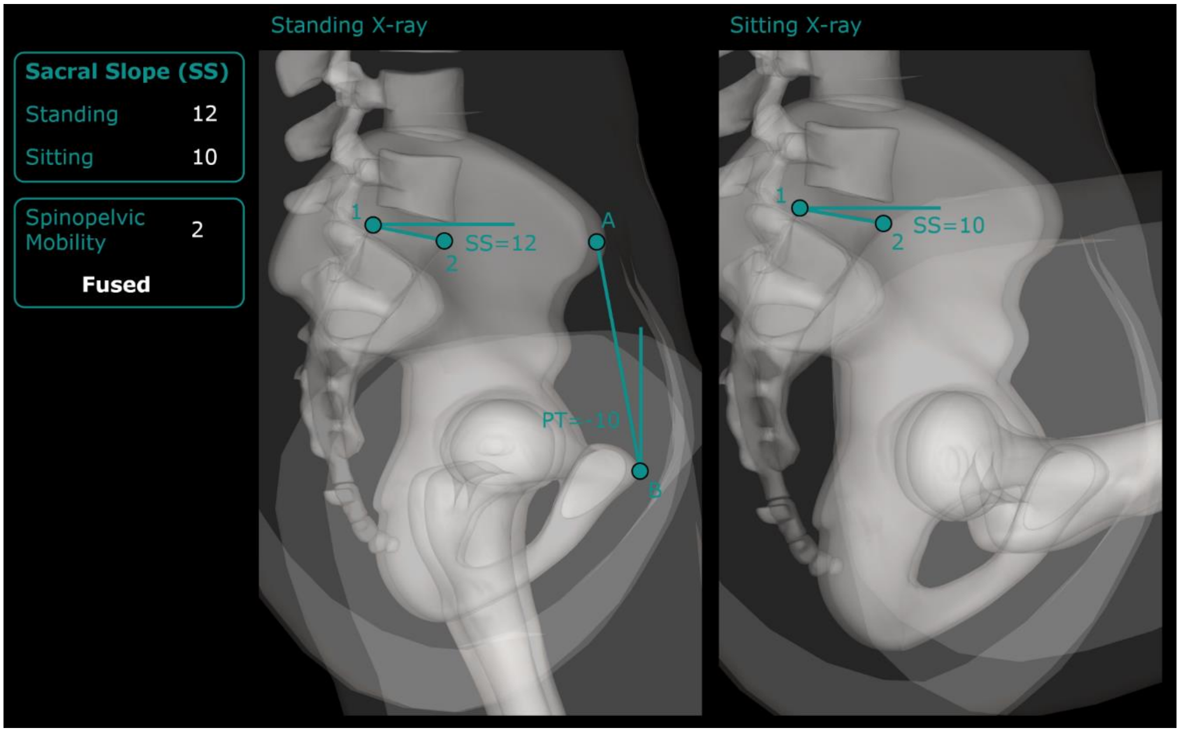
Rationale

Spinopelvic classification

Several **classifications** of the spinopelvic condition of THA patients have been proposed in the literature. Attenello and Harpstrite[16] provide a succinct summary of the different approaches. All methods rely on lateral radiographs of the spine-pelvis-femur in standing and sitting positions. Although different measurements are utilized by different research institutes, the most recurrent parameter used to classify patients is spinopelvic mobility. **Most classification strategies measure spinopelvic mobility by measuring the change in position of the pelvis between the standing and sitting positions**[15,17,18]. The Hip-Spine Workgroup, initiated in 2018 at the American Academy of Orthopedic Surgeons (AAOS) Annual Meeting to provide consensus on terminology and concepts relative to spinopelvic mobility and THA, advocated for the **use of sacral slope (SS) to measure spinopelvic mobility, as it is the easiest to calculate and measure on a radiograph**[19]. SS can be measured as the angle between a horizontal line and the line connecting the anterior and posterior aspects of the sacral plate (figure below). The difference between SS measured on standing and sitting radiographs (ΔSS = standing SS – sitting SS) is a quantification of the backward pelvis tilt occurring when transitioning from standing to sitting (figure below). Assuming that the torso is vertically aligned in both standing and sitting positions, ΔSS coincides with the anterior flexion of the spinopelvic joint and is used to quantify spinopelvic mobility. RI.HIP MODELER incorporates the classification presented by Stefl et al.[17] and McKnight et al.[18], which defines four main spinopelvic mobility categories based on standing and sitting SS:

- Normal: 10° < ΔSS ≤ 30°
- Stiff: 5° < ΔSS ≤ 10°
- Fused: ΔSS ≤ 5°
- Hypermobile: ΔSS > 30°

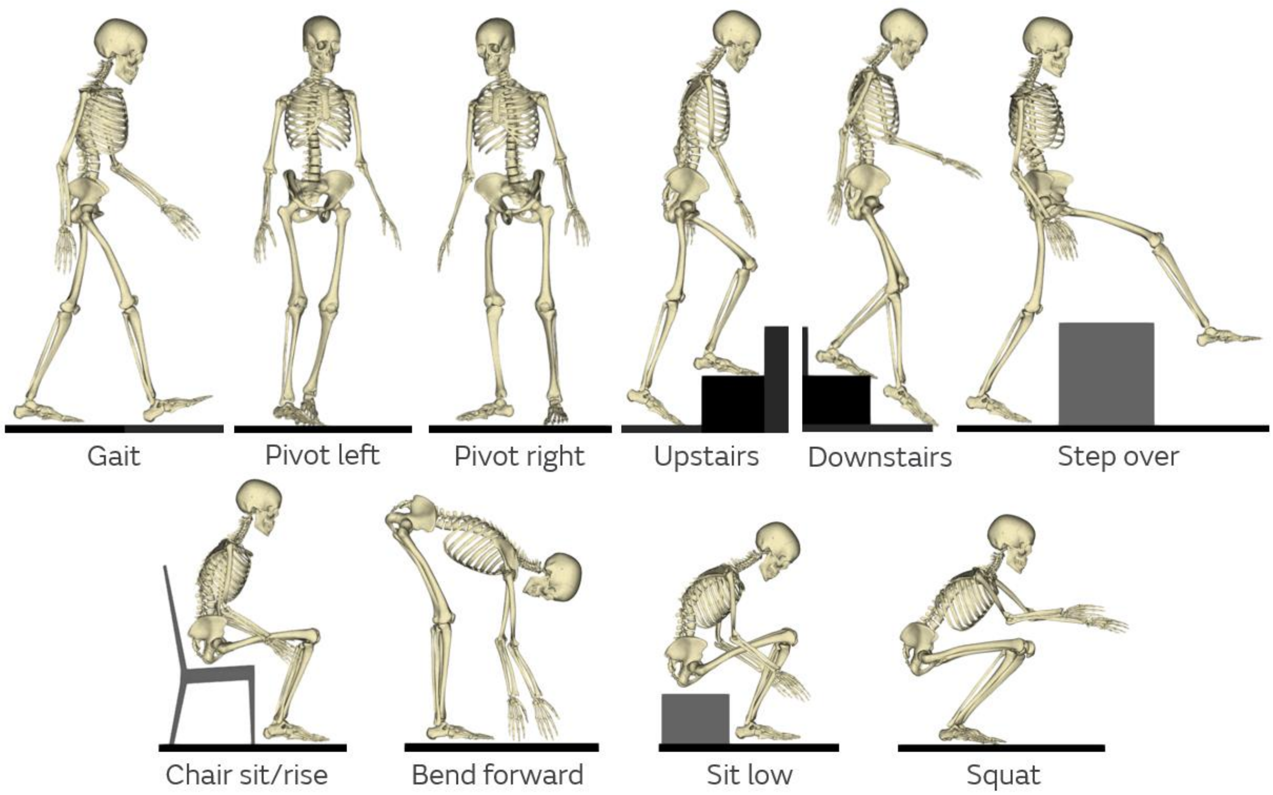
Average standing and sitting SS for a patient with normal spinopelvic mobility are 40° and 20°, respectively, indicating that the pelvis tilts backwards of approximately 20° when transitioning from standing to sitting, and, consequently, hip flexion is approximately 70° [17]. On the contrary, **patients with a fused/stiff spinopelvic joint will present larger hip flexion angles in the sitting position (≥ 80°), increasing the proximity between stem and cup rim**. Hypermobile may be considered a variant of normal seen primarily in younger female patients[18]. It provides protection against impingement because the increased pelvic motion requires less femoral motion with changes in posture.



RI.HIP MODELER requires the user to only measure SS in both standing and sitting radiographs, from which spinopelvic mobility is quantified as the difference between the two (ΔSS) according to the definition from Stefl et al.[17]. Based on this parameter, the patient is assigned to one the following four categories: normal, stiff, fused, or hypermobile.

Personalized biomechanical models and implant range of motion signatures

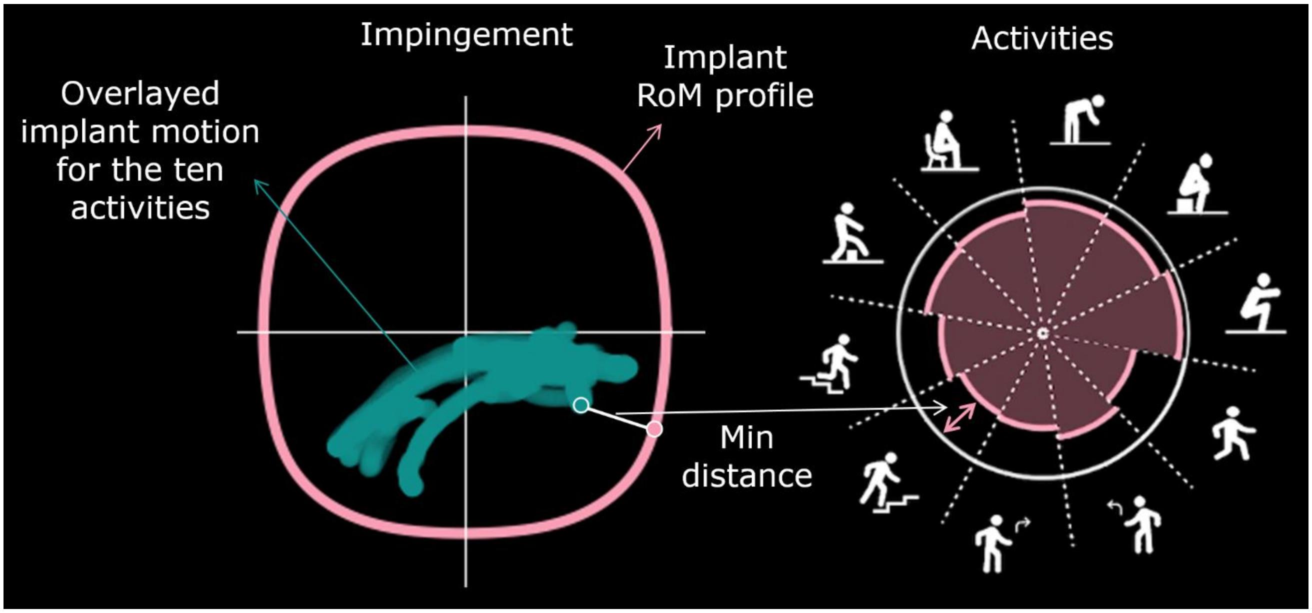
Physics-based biomechanical models of the human body can be used to quantify joint angles during motion. One of the most common techniques to drive skeletal models and estimate realistic motion patterns is to use marker-based motion capture data. Virtual markers drive the motion of the computer model via springs that track the motion of the experimental markers collected on a test subject in the laboratory. This methodology, called inverse kinematics, was used to simulate ten activities of daily living with an average skeletal model and estimate hip and spine motion. Model predictions were validated against in vivo fluoroscopy measurements on THA patients performing the same set of activities. Subsequently, the joint angles estimated with this technique were conditioned to obtain motion patterns for the stiff, fused, and hypermobile spinopelvic conditions.



RI.HIP MODELER provides the user with a set of simulation-based motion patterns for ten activities of daily living consistent with the spinopelvic condition of the patient. Condition-specific motion of the implant during activities of daily living can be used to identify an optimal cup placement that reduces risk of impingement.

Risk of impingement is not influenced by implant placement alone, but also implant design. Several studies have investigated how implant component design and parameters affect impingement-free range of motion (RoM)[5,20,21]. Although a qualitative understanding of how RoM changes between implant designs is simply achieved (e.g. dual mobility devices have larger RoM than single mobility devices), it is hard to have a quantitative understanding of how these changes affect distance to impingement during activities of daily living.

The combination of simulation-based hip motion during activities of daily living and implant RoM signatures provides a platform to quantify distance to impingement between implant components. As shown in the figure below, the distance between implant motion profiles and RoM signature for the a given implant corresponds to the distance to impingement. Distance to impingement can be calculated separately for each activity and displayed in the activity wheel, as shown below. The closer the activity arc gets to the white circle, the closer the stem gets to impingement with the cup.

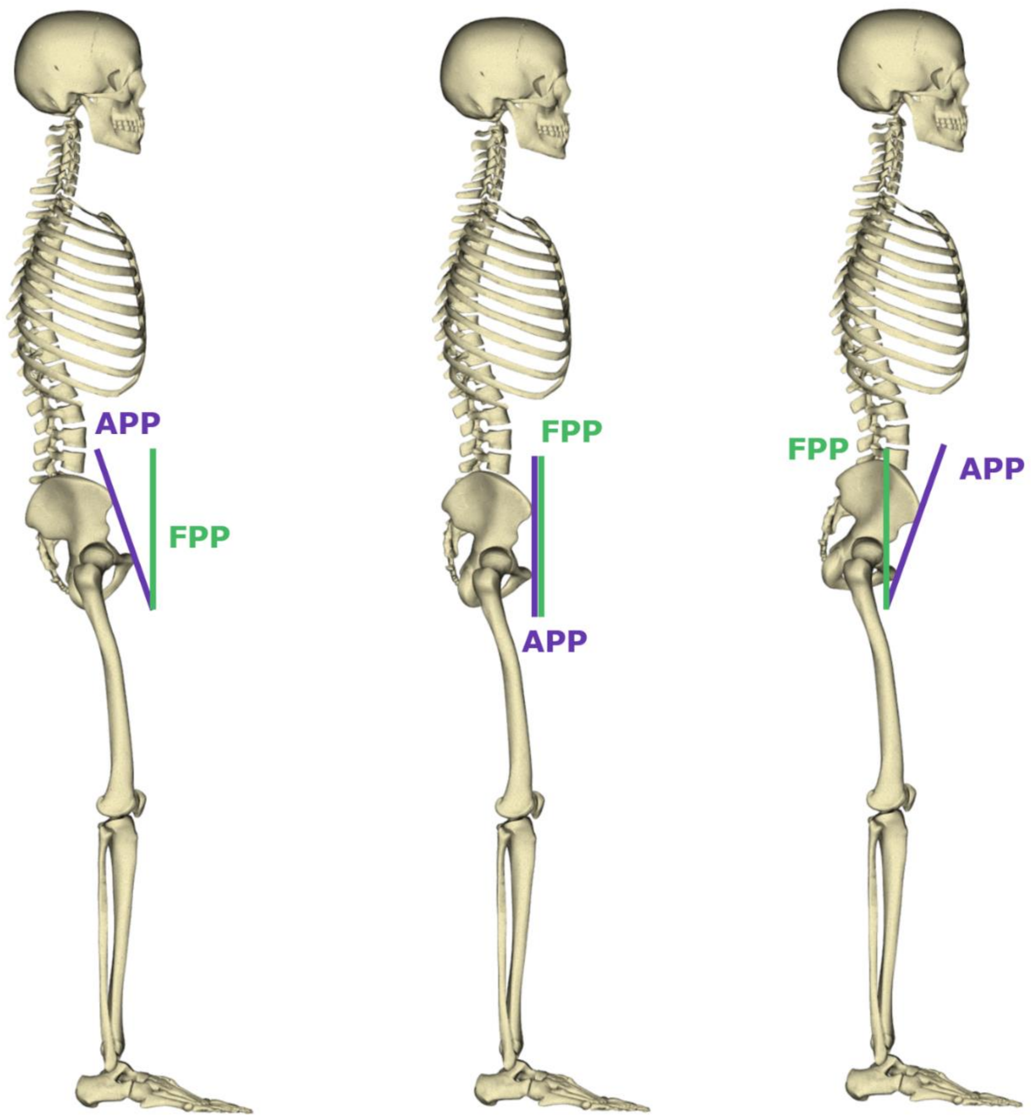


RI.HIP MODELER provides the user with the ability to compare RoM profiles between implant designs by superimposing the impingement-free regions and visualize the change in distance to impingement. In combination with the classification of the patient's spinopelvic mobility, this feature can facilitate the selection of a particular design given the mobility of the patient (e.g. a dual mobility device for a high-risk patient).

Anterior pelvic plane vs. Functional pelvic plane

The definition of a universally valid safe zone is complicated by the fact that cup inclination and anteversion have been defined in different ways: according to Murray et al.[22], cup angles can be described according to anatomical, operative, and radiographic **definitions**. Although the radiographic definition is the most frequently used to measure cup angles from an anteroposterior (AP) x-ray, the definition used in each investigation is not always clearly reported. In addition, the definition of a **reference plane** needs to be specified. The same cup angles might produce a different placement of the device, when different reference planes are used. For example, although the Lewinnek safe zone was defined with respect the APP, which is an anatomical plane containing the two anterior superior iliac spines (ASIS) and the pubic symphysis, the same safe-zone angles are used as reference for placement on coronal plane AP x-ray, which does not necessarily coincide with the APP of the patient[23]. The APP and the supine coronal plane of the body (captured with a radiograph when the patient is on the operating table) are often used as reference planes to position the cup. However, none of the two provides any information on the alignment of the pelvis when the patient is walking and performing other motor tasks. Recently, to address this limitation of current techniques, the use of the standing coronal plane as reference for cup angles has been strongly advocated, as it best mimics the position of the pelvis during daily activities[15,19,24]. This plane has been defined functional pelvic plane (FPP). Since several comparisons demonstrated that the orientation of the pelvis with respect to the coronal plane of the body may differ considerably between the supine and standing (functional) positions[25–27], a lateral standing radiograph is recommended to identify the relative orientation between the FPP and APP.

RI.HIP MODELER allows the user to landmark the ASIS and pubic symphysis in the standing x-ray, so that APP tilt can be measured. Knowledge of the APP tilt provides with the ability to easily convert cup angles between the APP and FPP, so that cup angles can be defined with respect to the FPP, and then converted to the APP, which can be identified during surgery with navigation techniques.

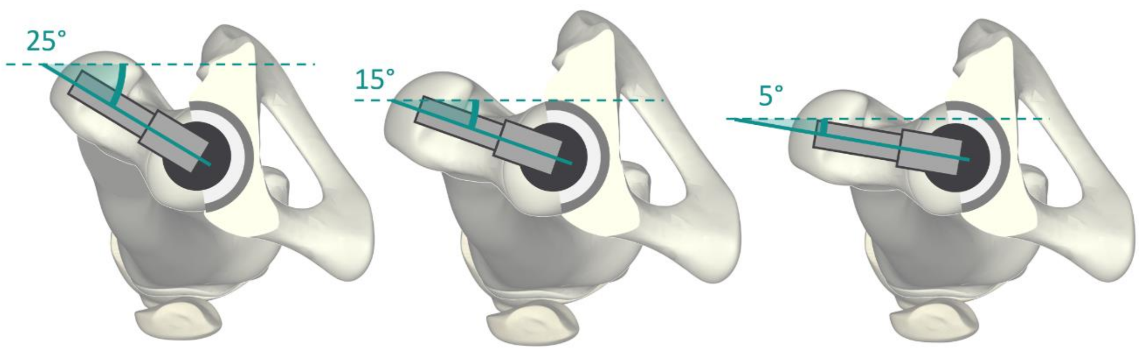


Considerations on stem anteversion

An additional factor that should be taken into account when planning cup placement to minimize impingement risk is the contribution of stem anteversion. Since the position of the stem relative to the cup in a neutral standing pose will affect the range of motion (RoM) of the device, some investigators advocate for a relationship of dependency between stem and cup anteversion. These considerations are particularly relevant with uncemented femoral stems, which must have a stable press fit to obtain bone fixation. A stable press fit means that the stem must adapt to the femoral bone geometry, which is highly variable. Accordingly, there is often less ability to adjust the stem anteversion in uncemented compared to cemented stems. Stem anteversion angles ranging from -15° (retroversion) to 45° have been previously reported[28–30]. Therefore, Dorr et al.[31]

proposed a safe zone based on **combined anteversion** (the sum of cup and stem anteversions), that should lie inside the 25°-50° range. Mathematical models have previously confirmed that combined anteversion should be considered to avoid impingement[32,33].

RI.HIP MODELER provides the user with the ability to visualize how a change in stem anteversion angle modifies the stem-cup relative position during activities of daily living.



Cup placement recommendations based on spinopelvic mobility

Cup placement recommendations specific to each spinopelvic condition are provided in the literature. The general consensus is that patients with normal mobility and balance do not require any ad hoc adjustment and can be treated according to the traditional safe zone from Lewinnek[15,17,34]. Stefl et al.[17], in accordance with Kanawade et al.[35], indicates that stiff hips require cup inclination near 45°, and cup anteversion of 20-25°, to open the orientation of the acetabulum to compensate for loss of pelvic movement. On the contrary, hypermobile hips require less inclination (35-40°) and less anteversion (15-20°) to prevent excessive verticality of the acetabular component with sitting, which increases the risk of drop-out dislocation. For fused patients, Stefl et al.[17] recommends that the acetabular component should be mechanically opened with high inclination and anteversion angles. If inclination exceeds 45°, there must be a trade-off of potentially increasing wear, so the surgeon must balance the risk of dislocation with the age and activity level of the patient. Similarly, McKnight et al.[18] recommend higher inclination and anteversion angles for patients in the neutral stiff group (40-45° and 20-25°, respectively), and lower inclination angles for hypermobile patients (35-45°). In addition, Stefl et al.[17]

and McKnight et al.[18] recommend the use of the combined anteversion paradigm, as cup placement alone cannot provide a full picture in terms of impingement risk. Specifically, Stefl et al.[17] recommends a combined anteversion of 25° to 45° for patients with normal spinopelvic mobility, and of 35° to 50° for stiff/fused spines. Luthringer and Vigdorchik[15] strongly advocate for the use of the functional pelvic plane (FPP) and recommend cup anteversion angles of 25-30° for patients with limited spinopelvic mobility and the use of dual mobility devices for stiff patients that also present a flatback deformity (posterior tilt of the pelvis in the standing position), as these are the patients most at risk of dislocation. In summary, we can isolate the following recommendations:

- **Increased** cup **inclination** and **anteversion** angles for **stiff/fused** patients.
- **Decreased** cup **inclination** for **hypermobile** patients.
- Use of the **FPP** as reference to better capture the patient-specific behavior during activities of daily living.
- Use of the **combined anteversion** paradigm to take into account the patient-specific anatomy of the femur that might require a stem positioning far from the average.

Given a spinopelvic category and a stem anteversion angle, RI.HIP MODELER provides cup angle recommendations based on placement protocols from the scientific literature. However, these recommendations are only based on the spinopelvic condition of the patient and do not take into considerations other factors such as bone coverage, soft tissue integrity, patient activity level, etc. Therefore, **RI.HIP MODELER allows the user to change cup angles and stem anteversion based on the surgeon's experience and visualize how these changes modify the device's estimates of distance to impingement.**

X-ray protocol

Indications on how to take the standing and sitting **radiographs** have been provided in the literature, so that patient classification can be performed correctly and measurements can be compared between patients. **The following indications should be followed when taking x-rays to be used for spinopelvic classification in RI.HIP MODELER**:

- Both x-rays:
  - Patient's arms resting at 90° on a support.

  - X-ray should include the spine-pelvis-femur complex from L3 to the proximal femur (approximately one third of the femur).
  - The x-ray beam should be centered at the greater trochanter perpendicular to the patient's axial line.
  - a high-quality lateral x-ray is obtained with overlap of the left and right ASIS.
- Standing X-Ray:
  - Patient standing naturally.
- Sitting X-Ray:
  - Patient sitting naturally with his/her back straight, and with an angle between the thighs and trunk of 90° (the use of an adjustable-height stool is recommended to ensure the 90° angle).

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