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Published Version:
Standardization of hemipelvis alignment for in vitro biomechanical testing / Morosato F.; Traina F.; Cristofolini L.. - In: JOURNAL OF ORTHOPAEDIC RESEARCH. - ISSN 0736-0266. - STAMPA. - 36:6(2018), pp. 1645-1652. [10.1002/jor.23825]

Availability:
This version is available at: https://hdl.handle.net/11585/722710 since: 2021-03-07

Published:
DOI: http://doi.org/10.1002/jor.23825

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J Orthop Res. 2018 Jun;36(6):1645-1652. Epub 2017 Dec 19

https://doi.org/10.1002/jor.23825

Standardization of hemipelvis alignment for *in vitro* biomechanical testing

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Submitted to: **J. Orthopaedic Research**
Version.0: 28th June 2017
Version.1: 5th October 2017

Statistics:

Word count (manuscript):	3514
Word count (abstract):	248
Figures:	7
Tables:	1
References:	45

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Author Contributions Statement: (1) all the three authors gave a substantial contribution to research design, the acquisition, the analysis and the interpretation of data; (2) all the three authors gave a substantial contribution to drafting and critically revising the paper; (3) all authors have read and approved the final submitted manuscript.

Running title: Hemipelvis alignment for biomechanical tests

ABSTRACT

Although *in vitro* biomechanical tests are regularly performed, the definition of a suitable reference frame for hemipelvic specimens is still a challenge. The aims of the present study were to: (1) define a reference frame for the human hemipelvis suitable for *in vitro* applications, based on robust anatomical landmarks; (2) identify the alignment of a hemipelvis based on the alignment of a whole pelvis (including right/left and male/female differences); (3) identify the relative alignment of the proposed *in vitro* reference frame with respect to a reference frame commonly used in gait analysis; (4) create an *in vitro* alignment procedure easy, robust and inexpensive; (5) quantify the intra-operator repeatability and inter-operator reproducibility of the procedure. A procedure to univocally identify the anatomical landmarks was created, exploiting the *in vitro* accessibility of the specimen's surface. Through the analysis on 53 CT scans (106 hemipelvises), the alignment of the hemipelvis based on the alignment of a whole pelvis was analyzed: differences between male/female and right/left hemipelvises were not statistically significant. To overcome the uncertainty in the identification of the acetabular rim, a standard acetabular plane was defined. An alignment procedure was developed to implement such anatomical reference frame. The intra-operator repeatability and the inter-operator reproducibility were quantified with four operators, on male and female hemipelvises. The intra-operator repeatability was better than 1.5°. The inter-operator reproducibility was better than 2.0°. Alignment in the transverse plane was the most repeatable. The presented procedure to align hemipelvic specimens is sufficiently robust, standardized, and accessible.

Keywords: Anatomical reference frame; *in* vitro alignment; biomechanical testing; hemipelvis; acetabular plane

1. INTRODUCTION

Reference frames and landmarks are of paramount importance in biomechanics [1; 2], to allow comparisons between different clinical, numerical or *in vitro* studies. Standardisation of the reference frame is extremely important for *in vitro* biomechanical tests [2-6]. It enables the correct alignment of the specimen and applied loads, in order to reproduce a physiological loading condition. With the definition of reproducible testing conditions, it is possible to compare different datasets of different studies.

Reference frames and landmarks for the pelvic bone are adopted in different applications [1; 2; 7-14]. Reference frames used for the analysis of medical images are qualitative in most cases [7-9]. In example, to evaluate the pelvic tilt and sacral slope surgeons generally use lateral radiographs, in combination with anatomical landmarks, assuming that the x-ray frame is aligned with the anatomical planes. However, identification of these landmarks depends on multiple factors like image quality and the position assumed by the patient. For this reason, information that can be extracted from medical images is extremely operator-dependent. *In vivo* applications (i.e. gait analysis) deal with reference frames defined by palpable anatomical landmarks [1; 10; 11]. Landmarks routinely used in clinical practice are the most accessible ones, while those that would cause patient discomfort are avoided (e.g. pubic tubercle). Identification of the landmarks is heavily affected by the presence of soft tissue. These considerations dictate some constraint to the reference frames that can be adopted for *in vivo* applications. Surgical navigation adopts reference frames both for the pre-operative planning and for intra-operative deployment [12-14]. Similarly, *in silico* applications rely on mathematical models derived from CT scans. Due to the possibility to "navigate" the bone, identification of anatomical landmarks on CT scans (which contain more detailed information) is more accurate. All the published reference frames for the human pelvis [4; 15; 16] rely on palpable landmarks that can be reached non-invasively:

- Anterior Superior Iliac Spine (ASIS) defined as the most prominent point on the iliac surface;
- Posterior Superior Iliac Spine (PSIS) defined as the upper and most posterior point of the iliac crest;
- Pubic Tubercle (PT) defined as a prominent forward-projecting tubercle on the upper border of the medial portion of the superior ramus of the pubis.

The Anterior Pelvic Plane (APP) is most widely used clinically [17-19]. It is defined by the ASISs and the PTs. Despite the physiological range of tilt of the APP, it is assumed to be roughly vertical in the standing position (anatomical neutral position, ANP) [20; 21].

A dedicated reference frame for *in vitro* biomechanical testing can rely on anatomical landmarks that are accessed directly on the specimen (after the removal of soft tissues). For this reason, *in vitro* reference frames are more robust and less operator-dependent than *in vivo* ones, in which landmarks need to be identified non-invasively.

Despite the considerations above, only a few studies can be found where a suitable reference frame is defined for the pelvis and hemipelvis [22; 23]. It is very important to underline that hemipelvic specimens are frequently adopted for *in vitro* purposes[24-26]. All the reference frames described above rely on landmarks over the whole pelvis, and cannot be implemented on a hemipelvis alone. Currently, there is no consensus on a specific procedure for aligning a hemipelvis. Hence, in order to define a reference frame for the hemipelvis, it is necessary to determine its alignment with respect to the whole pelvis. The few previous studies dealing with hemipelvic specimens lack detail about its alignment: Lewton *et al.* (2015) specified the direction of loads, defined as angles measured relative to the long axis of the pelvis but no reference frame was defined [23]. Preece *et al.* (2008) proposed a practical method based on the ANP; however more information about the alignment procedure were not stated [27].

The acetabular plane, which is defined as the plane tangent to the acetabular rim is often used clinically [28; 29]. The alignment of the acetabular plane was investigated by Murray [30]. In his work, he identified three definitions for acetabular inclination and anteversion: radiological, operative and anatomical. Surgeons usually adopt the orientation of acetabular plane as guide for surgical navigation, since it is easily identified through clinical imaging [28; 29]. The acetabular plane was also adopted in different *in vitro* tests [24-26; 31]. However, the irregular shape of the acetabular rim makes the identification of this plane subjective [32; 33].

Recently van Arkel *et al*. (2016) described an *in vitro* method to align a hemipelvic specimen, based on the reference frame recommended by the International Society of Biomechanics (ISB) [4; 22]. The proposed procedure requires first aligning the whole pelvis, using four landmarks; the authors propose a procedure to dissect the specimen to obtain two hemipelvises which preserve the same alignment previously identified for the whole pelvis. The requirement of a whole pelvis as a starting point may be a limitation, as sometimes only hemipelvic specimens are available.

The aims of the present study were to:

1. Define a reference frame for human hemipelvis that relies on robust anatomical landmarks and is suitable for *in vitro* applications.
2. Identify the alignment of the hemipelvis based on the alignment of a whole pelvis. This includes investigating differences in alignment between right and left, and between male and female.
3. Identify the relative alignment of the newly proposed *in vitro* reference frame with respect to the reference frame usually adopted in gait analysis [4].
4. Create an *in vitro* alignment procedure for hemipelvic specimens easy, robust and inexpensive.
5. Quantify the intra-operator repeatability and inter-operator reproducibility of the proposed procedure.

2. MATERIAL AND METHODS

An overview of the workflow is provided in Fig. 1. A practical *in vitro* identification of suitable pelvic landmarks was created. Computed tomography (CT) scans of human pelvises were analyzed to identify the alignment of selected landmarks of the hemipelvis with respect to the whole pelvis. An *in vitro* alignment procedure was developed for human hemipelvic specimens. The intra-operator repeatability and the inter-operator reproducibility of the procedure were measured.

2.1 *In vitro* identification of the landmarks

As shown in different areas, identification of landmarks by palpation leaves a large uncertainty and subjectivity [34]. Direct *in vitro* identification of the landmarks can be more accurate and precise. In order to implement a reproducible procedure, a robust method to identify landmarks, suitable both for pelvis and hemipelvis, was adapted from those commonly used *in vivo* [4] (Fig. 2):

- The iliac and pubic regions must be brought in contact with a plane, while the iliac wing is vertical. ASIS is found as the most external point of the iliac crest, which is in contact against the plane.
- With the bone in the same position, PT is found as the point on the pubic tubercle region, which is in contact against the plane.
- The iliac and ischial regions must be brought in contact with a plane while the iliac wing is vertical. PSIS is found as the most external point of the iliac wing, which is in contact against the plane.

2.2 Identification of the anatomical alignment of the hemipelvis based on the alignment of the whole pelvis, and comparison with ISB frame

In order to adapt to a single hemipelvis the reference frame based on the APP (which is defined for an whole pelvis), the alignment of the hemipelvis relative to the alignment of its respective whole pelvis was identified. Furthermore, the relative orientation of the proposed reference frame with respect to a reference frame commonly used in gait analysis [4] was measured based on the same landmarks. To the Authors' knowledge, this is the first time that similar analysis was made to overcome limitations related to other alignments such as those based on the acetabular plane.

2.2.1 Analysis of patient CT scans

Fifty-three CT scans were randomly selected among those taken for hip patients at Istituto Ortopedico Rizzoli between 2014 and 2017. The patients were 25 male and 28 female, 27-88 years old. The scans had a voxel size of 0.7-0.8 mm. The scans were imported and analyzed through nmsBuilder v1.0 [35]. For each scan, the landmarks (ASIS, PSIS and PT) were identified on the whole pelvis according to the description above. The pelvises were oriented in order to reach the ANP (tolerance 0.1 degrees). To measure the alignment of a single hemipelvis relative to the alignment of its respective whole pelvis, two different angles were measured (Fig. 3):

- β: the angle formed by the line connecting PT and ASIS with the transverse plane of the whole pelvis;
- δ: the angle formed by the line connecting ASIS and PSIS with the sagittal plane of the whole pelvis.

In addition, the relative orientation of the proposed reference frame with respect to the ISB reference frame [4] (which is commonly used in gait analysis) was measured in all scans after identifying the mid-point of the two PSIS (mid PSISs): this consisted in a single rotation (ξ), in a sagittal plane (Fig. 3).

To exclude outliers, Peirce's criterion was applied [36; 37]. Suspect data were checked among subjects, for both angles. To test the procedure, three skilled operators processed three CT scans three time each. To avoid any bias, the scan elaboration was performed on different days between repetitions, so that the operator could not recognize previous elaborations. To assess the intra-operator repeatability (i.e. when the same operator repeatedly elaborates the same CT scan), the standard deviation between the three repetitions was computed, for each of the operators and each CT scan. The repeatability was computed as the root-mean-square-average between CT scans and operators. To assess the inter-operator reproducibility (i.e. when different operators elaborate the same CT scan), for each of the operators and each CT scan, the average value was computed out of three repetitions. The reproducibility was computed as the standard deviation between the operators.

The significance of differences between the right and left hemipelvises was tested with a paired t-test for β and δ. Differences between male and female for β and δ were tested with an unpaired t-test. A threshold of $p=0.05$ was assumed. Statistical analyses were performed using MatLab (2009 Edition, MathWorks, Natick, MA, USA).

2.3 Alignment procedure for the human hemipelvis

In order to separately control the rotations, the hemipelvises were equipped with a dedicated handle, which was clamped in a 6-degrees of freedom manipulator. The first part of the procedure required aligning the landmarks with respect to horizontal and vertical planes (Fig. 4):

- Vertical adjustment: the three landmarks were positioned at the same height (i.e. using an adjustable plate and plasticine);

- Horizontal adjustment: ASIS and PT were positioned parallel to the edge of the reference plane.

At this point the hemipelvis had a known alignment. To overcome the limitations of defining the acetabular plane based on the acetabular rim [30], a *standard acetabular plane* was defined (SAP, see Appendix I). With the aim of aligning the hemipelvis with the SAP horizontal, the specimen was subsequently rotated by two angles (Fig. 5) (see Appendix I):

- Rotation in the posterior direction by $\Phi = 51°$;
- Rotation in the medial direction by $\Omega = 10°$.

2.4 Assessment of the intra-operator repeatability and inter-operator reproducibility

To test the alignment procedure, hemipelvic bone specimens in solid foam (ERP Mod.1291, ERP Mod.1294, Sawbones, Malmö, Sweden) were adopted. In order to measure the alignment achieved, a squared plastic block was rigidly fixed on the hemipelvises; the absolute orientation of its faces was measured, after the alignment, through a goniometer (Art. 06.07503, IDF, Pontoglio (BS), Italy; precision: 0.1 degrees).

Four operators aligned the two specimens three times each. In order to evaluate the robustness of the procedure two skilled operators (who performed at least one alignment procedure) and two inexperienced operators were chosen. To avoid any bias, the specimen orientation was modified between repetitions. To assess the intra-operator repeatability, the standard deviation between the three repetitions was computed, for each of the operators and each specimen. The repeatability was computed as the root-mean-square-average between specimens and operators. To assess the inter-operator reproducibility, for each of the operators and each specimen, the average value was computed, out of three repetitions. The reproducibility was computed as the standard deviation between the operators. Statistical analyses were performed using MatLab (2009 Edition, MathWorks, Natick, MA, USA).

3. RESULTS

3.1 Alignment of hemipelvis based on the alignment of whole pelvis

The landmarks could be easily identified in all the CT scans. Based on the Peirce's criterion, five cases were excluded for β and none for δ. The intra-operator repeatability was below 0.6° for β, and below 0.5° for δ. The inter-operator reproducibility was better than ±2.6° for β and better than ±3.8° for δ.

The difference between right and left hemipelvises was on average 0.3° for β ($p>0.7$) and 0.2° for δ ($p>0.7$). In none of the 53 pelvises examined, a difference greater than 9° was observed between the left and right hemipelvis for β and δ. The values of β in the female subjects were 0.6° larger than for the males, but this difference was not statistically significant ($p=0.4$, Table 1). The values of δ were 0.1° larger for the female subjects than for the males ($p=0.9$, Table 1). The relative orientation of the proposed reference frame with respect to the ISB reference frame in the sagittal plane was on average $\xi=10.7°$. The difference between male and female for ξ was 0.6° and not statistically significant ($p=0.6$, Table 1).

3.2 Alignment procedure

All operators performed successfully the alignment, for all the specimens. The time required was about 15 minutes for each specimen. The intra-operator repeatability was generally below 1.5° for each angle (Fig. 6). The inter-operator reproducibility was less than ±2.0° for each angle. Alignment in the transverse plane was most repeatable.

4. DISCUSSION

The aim of this study was to define a reference frame suitable for *in vitro* biomechanical testing of the human pelvis, based on robust anatomical landmarks. As *in vitro* tests are often performed on hemipelvises, the procedure was devised for a hemipelvis (rather than relying on a whole pelvis). To enable comparisons and registrations with other studies, the alignment with respect to a reference frame commonly used in movement analysis was measured. Finally, we aimed at evaluating the reliability of the protocol in terms of intra-operator repeatability and inter-operator reproducibility.

The alignment protocol revolved around anatomical landmarks, which could be accurately identified on the physical *in vitro* specimens. The analysis of 53 patients' CT scans allowed identifying the average alignment of a hemipelvis based on the alignment of its original whole pelvis. No significant differences were detected between right and left sides and between male and female specimens. Furthermore, the relative alignment of the newly proposed *in vitro* reference frame for the hemipelvis was measured with respect to a reference frame commonly used in gait analysis [4]. Thus, even if the rationale of this study drove us to choose a different reference frame, it is possible to refer our *in vitro* frame to the one used in gait analysis.

When the landmarks were identified *in silico* on CT scans, the intra-operator repeatability was 0.5° in the frontal plane, and 0.5° in the transverse plane; the inter-operator reproducibility was 2.6° in the frontal plane and 3.8° in the transverse plane. When the alignment procedure was applied to physical hemipelvises *in vitro*, the intra-operator repeatability was generally below 1.5°, and the inter-operator reproducibility was less than ±2.0°. The variability mainly depends on the uncertainty in the identification of the landmarks. Due to the limited resolution of the CT scans, it is not surprising that the uncertainty of the *in silico* alignment was worse than the *in vitro* one.

Past studies, where a reference frame was defined for other bone segments (tibia [6], and vertebra [5]), reported errors of the order of 1°-3°, comparable to the present one. Only few studies expressly defined a reference frame for the human pelvis *in vitro* [22-26; 31; 38]. Comparisons with the present study are difficult, as the reproducibility of such references has only seldom been quantified. For instance, Anderson *et al.* performed an *in vitro* alignment of a whole pelvis based on the ASIS and pubic symphysis: while they focused on relative rotations, they did not report the accuracy of their original alignment [39]. A reference frame based on the acetabular plane is often adopted for *in vitro* purposes [24-26; 31]. However, identification of this plane is complex due to the irregular shape of the acetabular rim [32; 33]. To overcome this problem, we defined the alignment for a standard acetabular plane (SAP) based on the advice of a group of hip surgeons.

To the Authors' knowledge, this is the second study in which a reference frame for the hemipelvis was derived from the reference frame of the whole pelvis. In fact, van Arkel *et al*. developed a procedure to apply the ISB reference frame to the whole pelvis before bisecting it, and then apply the same reference when the hemipelvises were used for *in* *vitro* testing [4; 22]. They found that after bisection, the hemipelvis had a misalignment compared to the original whole pelvis. The error was 1.5±1.6° for the adduction, 0.5±1.1° for the internal rotation, and 0.6±1.7° for the flexion. However, as this error does not include the intra- and inter-operator uncertainty in identifying the landmarks and initially aligning the whole pelvis, the resultant total error of their procedure is larger (i.e. the sum of such errors, and of the uncertainties in aligning the whole pelvis). Furthermore, for some applications it might be preferable not to drill the large screw holes required to hold the specimen during bisection [22].

The main limitation of our approach is probably that, in order to standardize the reference frame, and to be able to implement it on isolated hemipelvises, we were forced to make a number of simplifications such as applying to any specimen the same average values of the angles. We assumed that the anterior pelvic plane was vertical. However, the inter-subject variability has been reported due to patient's anatomy and pose (i.e. when changing from supine to standing position) [40; 41]. Consistently with our aim of standardizing the alignment procedure, we assigned the alignment that corresponds to the average reported in the literature (around 0° [21; 41; 42]). Similarly, the alignment of the standard acetabular plane was defined based on angle values agreed upon by a pool of surgeons. In principle, the proposed alignment procedure can be implemented also with different angles for the acetabular plane: one just needs to change the final couple of rotations.

The procedure has been tested on synthetic models of the pelvis. To include the variability, both male and female specimens were used. Such models provide detailed anatomy, including the presence and shape of the landmarks. This allowed testing the intra-operator repeatability and inter-operator reproducibility of the alignment procedure.

An *in vitro* implementation of a procedure to identify robust anatomical landmarks allows objectively determine the reference points for the alignment. It is important to underline that reproducibility and repeatability of an alignment procedure strongly depend on the identification of the anatomical landmarks; hence practical rules to identify these landmarks should be always taken in consideration for *in vitro* purposes. The reference frame and alignment procedure developed can be applied each time a hemipelvic specimen is studied, both *in vitro* and *in silico*. Furthermore, the proposed reference frame can be easily registered to match a reference frame commonly used in gait analysis. Moreover, the intra-operator repeatability and inter-operator reproducibility quantified in the present study are sufficient for most *in vitro* applications. For these reasons, the presented procedure to align hemipelvic specimens is sufficiently robust, standardized, and accessible, hence can be easily replicated in other laboratories. The proposed reference frame can therefore be assumed as a starting point for numerous pre-clinical *in vitro* tests e.g. to test implant stability of acetabular reconstructions.

APPENDIX I: Standard acetabular plane (SAP)

To overcome the known uncertainties and limitations of defining the acetabular plane based on the acetabular rim [30], a *standard acetabular plane* was defined (SAP). Standard values for acetabular inclination (45 degrees) and anteversion (20 degrees) were chosen according to a pool of experienced hip surgeons. Both values are within the Lewinnek "safe zone" (inclination = 40°±10°; anteversion = 15°±10°) [17], which represents the goal for most surgeons during cup implantation [17; 19; 43; 44]. It was demonstrated that prosthesis implanted within the "safe zone" better resist to dislocation and impingement [17; 45].

The angles necessary to align the SAP horizontal were calculated combining the alignment of the hemipelvis based on the whole pelvis, and the inclination and anteversion of the SAP (Fig. 7):

- Rotation in a quasi-transverse plane:

  $\Phi = \text{Acetabular anteversion} + \delta = 20° + 31° = 51°$

- Rotation in the frontal plane:

  $\Omega = \text{Acetabular inclination} - \beta = 45° - 35° = 10°$

where:

- β and δ are the average values of the angles measured from the 53 CT scans, to align the hemipelvis based on the whole pelvis (see Par. 3.1).
- Φ and Ω are the final angles to align the hemipelvis with the SAP horizontal.
- All values were rounded to the closest integer.

Acknowledgments

The Authors wish to thank Aesculap AG Research & Development for the financial support. The authors gratefully acknowledge the advice of the pool of hip surgeons, namely Prof. Vollkmar Jansson, Prof. Maximilian Rudert, Prof. Heiko Graichen and Prof. Cesare Faldini.

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TABLES

Table 1 – Values of β, δ and ξ measured in the CT scans of 53 subjects (Fig. 3). Average and standard deviation are reported, after excluding outliers, for all subjects, and split by gender. The last column shows the average difference, and statistical significance (unpaired t-test).

Angles	All	Male	Female	Difference between Male and Female
β	35.5° ± 4.0°	35.2° ± 4.9°	35.9° ± 2.6°	0.6° (p=0.4)
δ	31.3° ± 3.8°	31.4° ± 3.8°	31.3° ± 3.9°	0.1° (p=0.9)
ξ	10.7° ± 5.8°	11.0° ± 6.2°	10.3° ± 5.4°	0.6° (p=0.6)

CAPTIONS TO FIGURES

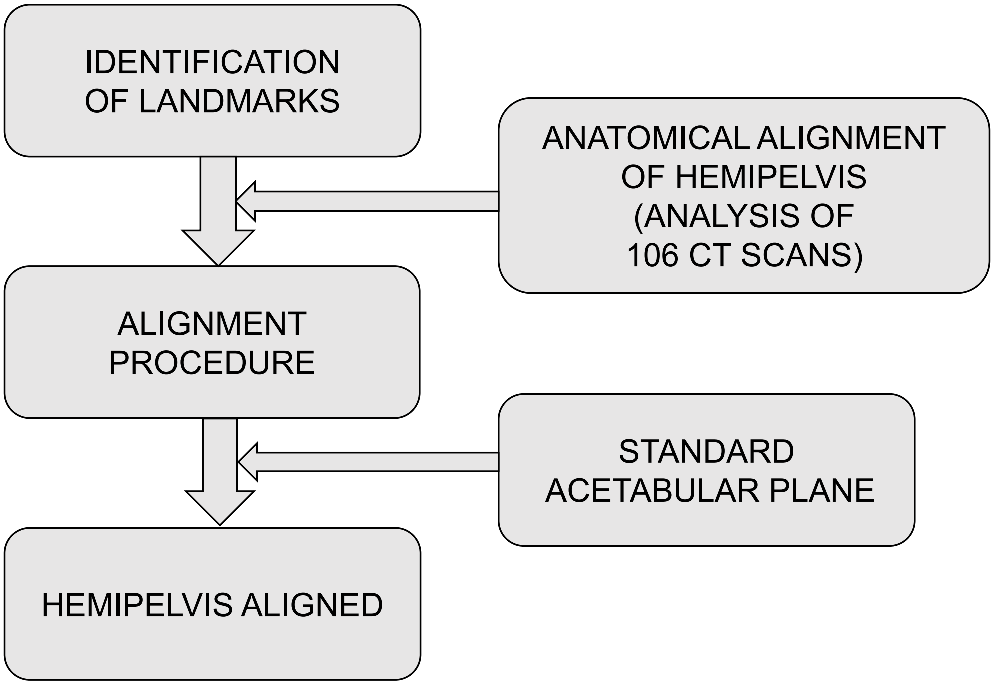

Fig. 1 - Workflow of the proposed alignment procedure for the hemipelvis.

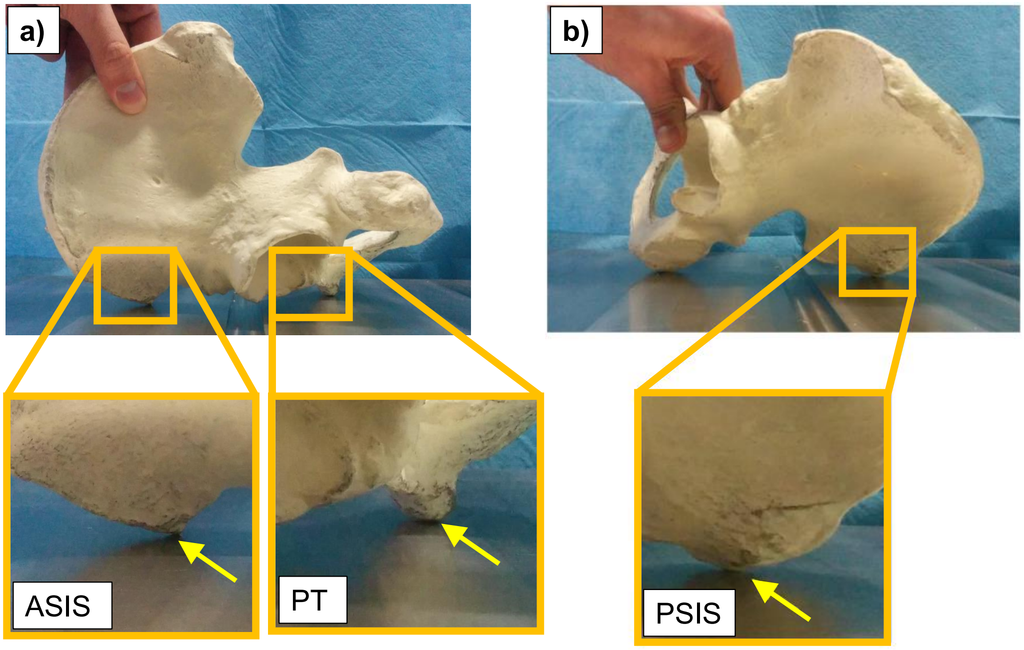

Fig. 2 – *In vitro* identification of the landmarks on a hemipelvis: a) ASIS and PT, b) PSIS.

A left specimen is shown in these pictures.

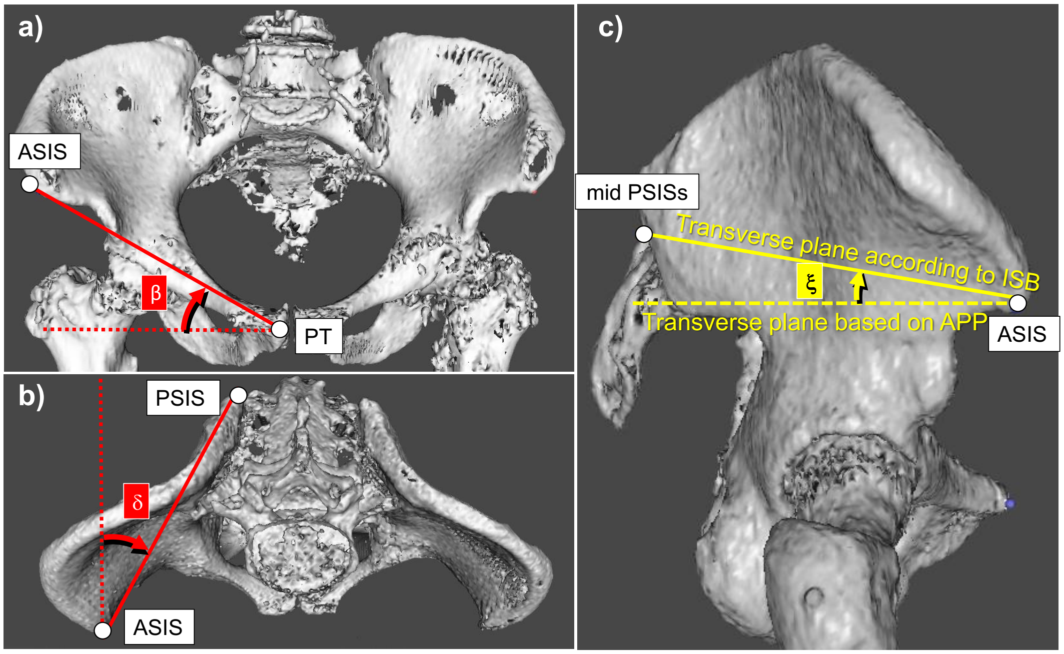

Fig. 3 - Three different angles were measured in the 53 patient CT scans using nmsBuilder. a) The angle (β) formed by the line connecting PT and ASIS with the transverse plane of the whole pelvis was measured in a frontal view. b) The angle (δ) formed by the line connecting ASIS and PSIS with the sagittal plane of the whole pelvis was measured in a transverse plane. c) The angle (ξ) between the proposed reference frame (based on the APP) and the ISB reference frame was measured in a lateral view.

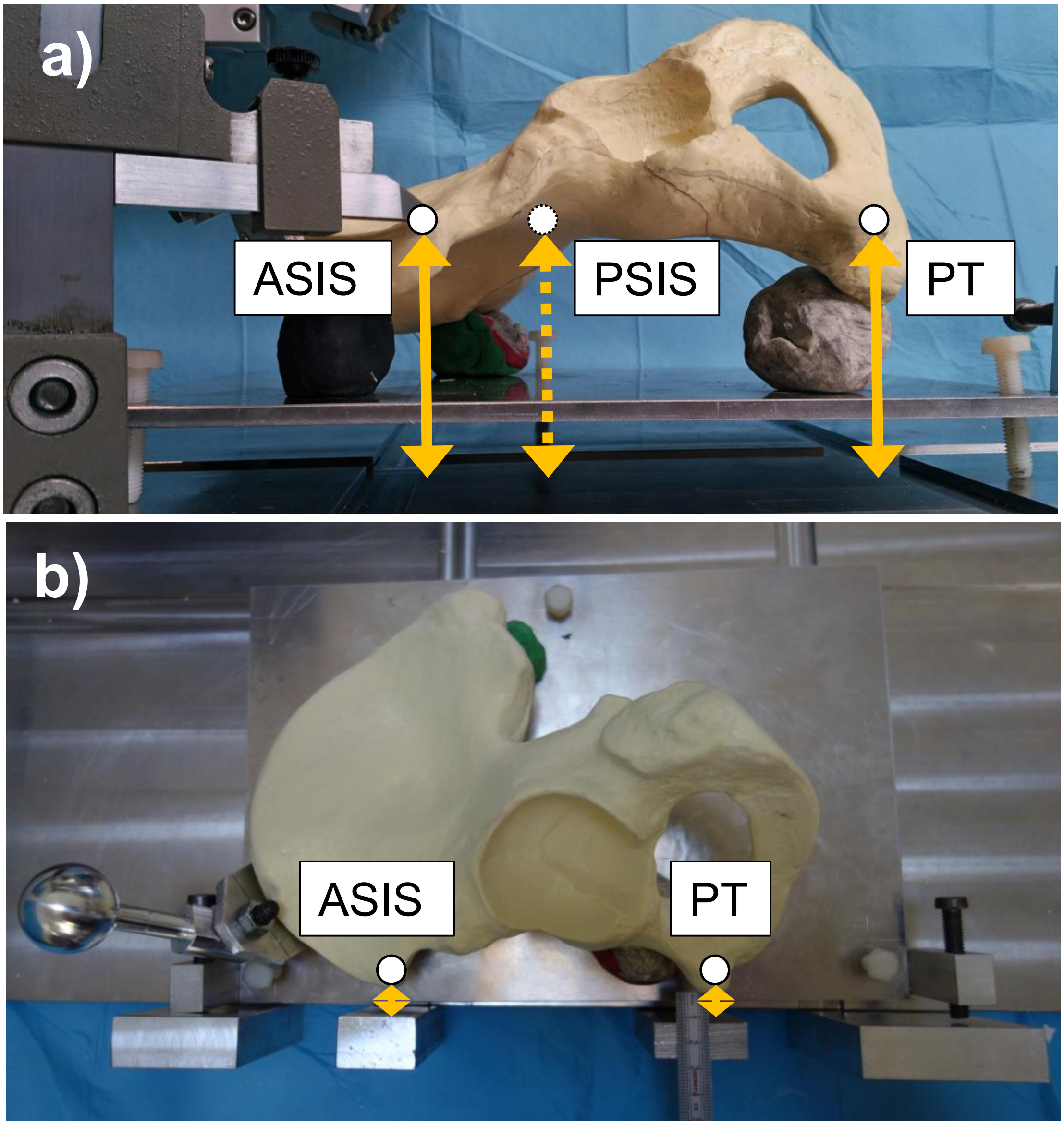

Fig. 4 – Alignment of a left hemipelvis: a) Vertical adjustment of the three landmarks. Quasi-frontal view, with the ASIS, PT and PSIS (hidden by the hemipelvis) at the same height, as measured with the vertical ruler (visible in the far left of the picture). Also visible is the spherical handle mounted on the hemipelvis. b) Horizontal adjustments of the landmarks. Lateral view of a left hemipelvis with ASIS and PT aligned with the edge of the reference plane.

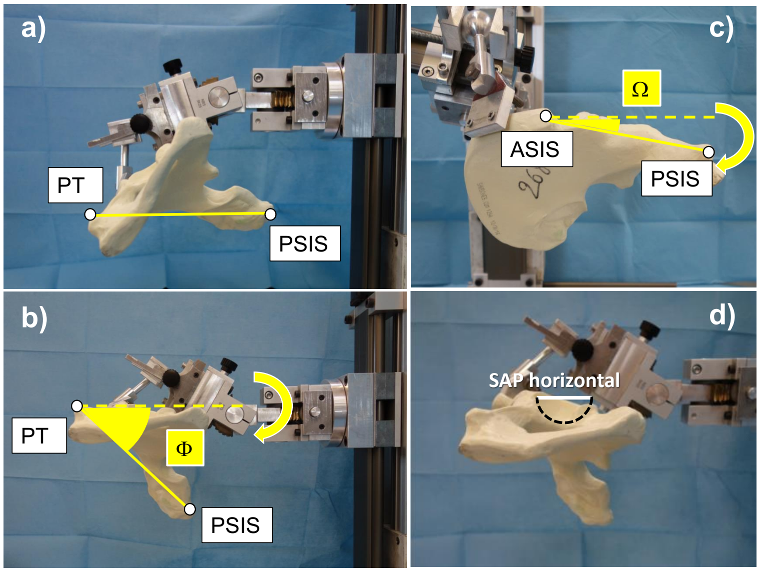

Fig. 5 – Hemipelvis clamped in the 6-degrees of freedom manipulator through the handle rigidly fixed to the bone. a) Left hemipelvis viewed from distally (i.e. in a quasi-transverse plane) aligned as in Fig. 4, and lifted from the plane. b) Rotation of the specimen by Φ in the medial direction. c) Rotation of the specimen by Ω in the anterior direction. d) The standard acetabular plane (SAP) is horizontal once the specimen is aligned.

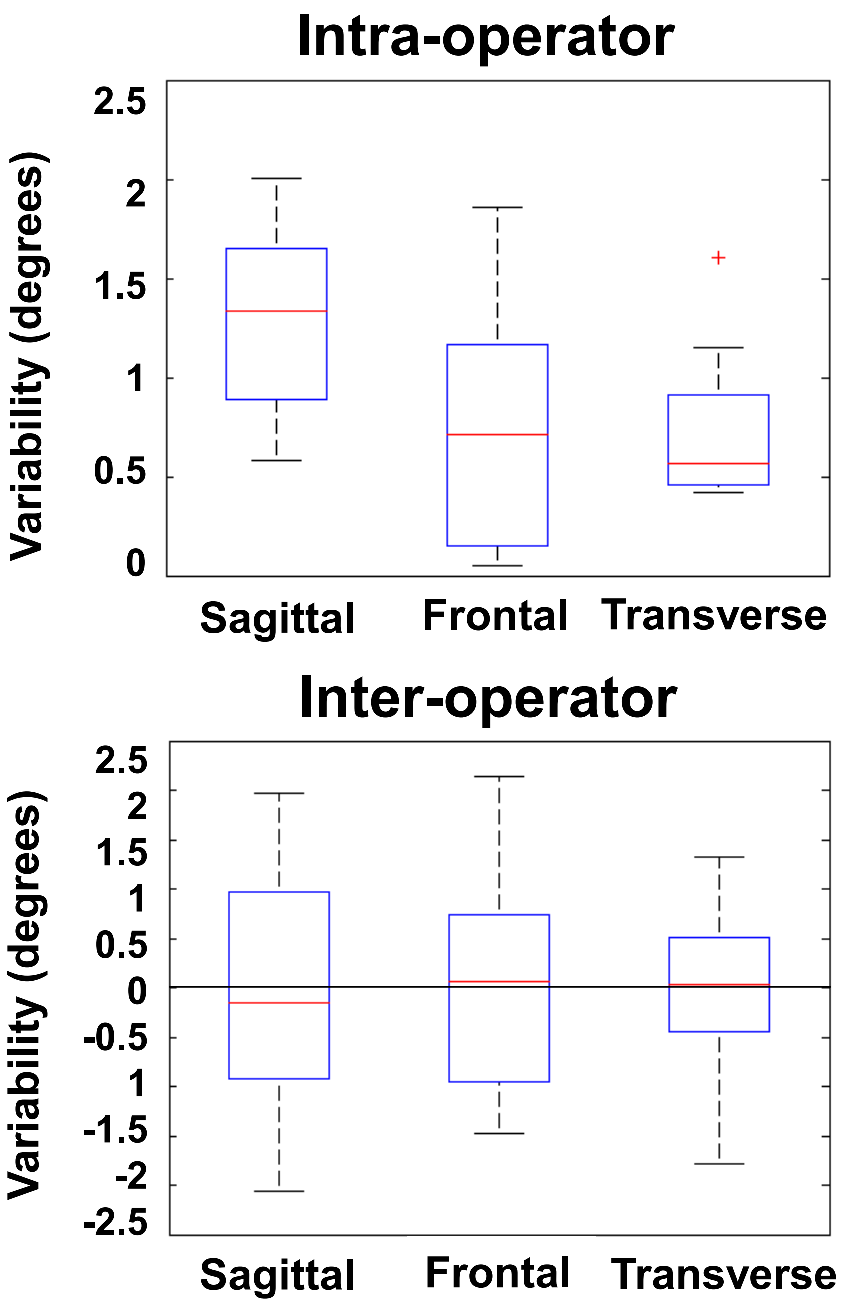

Fig. 6 - Variability of measured angles on the hemipelvic specimens in each plane: intra-operator repeatability (top) and inter-operator reproducibility (bottom). The red mark indicates the median; the blue boxes includes the 25th –75th percentile; the whiskers extend to the most extreme data points. The outliers are marked with red crosses, and were excluded from the analysis.

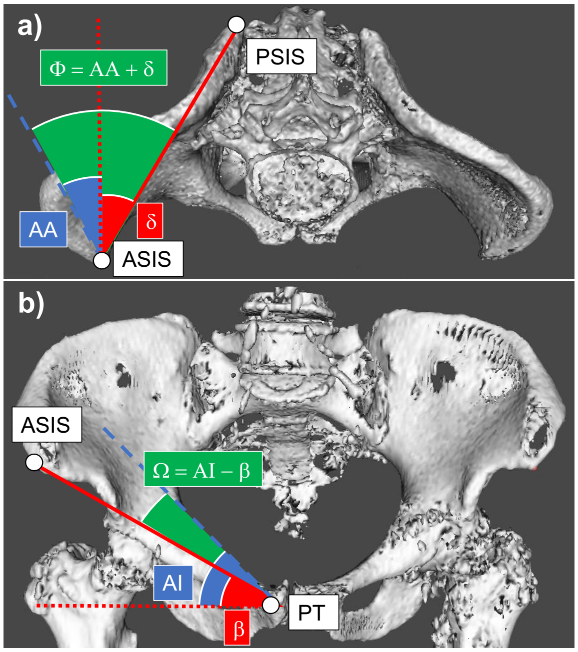

Fig. 7 – Combination of angles to align a hemipelvis with the standard acetabular plane (SAP) horizontal: (a) Top view of a CT scan of human pelvis showing the angle (Φ), which is calculated as the sum between the angle corresponding to the acetabular anteversion (*AA*) and δ; (b) Frontal view showing the angle (Ω), which is calculated as the difference between the angle corresponding to the acetabular inclination (*AI*) and β.