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# Sagittal alignment in patients with flexion contracture of the hip before and after total hip arthroplasty

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## Abstract

**Introduction** In hip osteoarthritis, hip flexion contracture can severely alter the patient's alignment, and, therefore, affect the patient's quality of life (QOL). Hip contracture is not well-studied, partly because of the difficulties of its diagnosis. The aim of this study was to propose a quantitative definition of hip flexion contracture, and to analyse sagittal alignment in these patients compared to non-contracture ones, before and 12 months after total hip arthroplasty (THA).

**Materials and methods** Consecutive patients with hip arthrosis and an indication for THA were included ( $N=123$ ). Sagittal full-body radiographs were acquired in free standing position and in extension. QOL questionnaires were administered before and after surgery. Spinopelvic parameters were measured, including the pelvic–femur angle (PFA). Patients with low pelvic incidence ( $<45^\circ$ ) were included in the hip contracture group if  $PFA > 5^\circ$ , or  $PFA > -5^\circ$  when pelvic incidence  $\geq 45^\circ$ .

**Results** 29% of patients were in the hip flexion contracture group, and they showed lower pelvic tilt than the no-contracture group ( $p < 0.001$ ), larger lumbar lordosis (LL) and smaller PI-LL ( $p < 0.001$ ), as well as a forward position of the head. 16% of patients still had hip contracture 12-months postop. Contracture patients showed higher QOL scores after surgery.

**Conclusions** The proposed method to diagnose hip contracture group allowed to define a group of patients who showed a specific pattern of sagittal spinopelvic alignment. These patients improved their alignment and quality of life postoperatively, but their hip mobility was not always restored. Diagnosing these patients is a first step toward the development of more specific surgical approaches, aiming to improve their surgical outcome.

**Keywords** THA · Surgery · Alignment · Spinopelvic alignment

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## Introduction

The hip is a key element of the sagittal chain of alignment which allow the patient to maintain an erected posture and horizontal gaze while minimizing energy expenditures. Hip osteoarthritis can be accompanied by hip flexion contracture and reduced range of motion, which can severely alter the patient's alignment [1, 2]. Hip flexion contracture can be associated with compensation mechanisms which recruit the whole sagittal chain of compensation, from the cervical spine to the lower limb and the ankle [3]. However, such sub-optimal posture can have a negative effect on the patient's quality of life (QOL): relationships between reduced hip and spine range of motion and disability or osteoarthritis progression were reported [4, 5].

Extension and flexion contractures of the hip have been described in association with a number of pathologies, such as cerebral palsy, ankylosing spondylitis and osteoarthritis

[1, 2, 6–8]. Different compensation mechanisms can be deployed by the patient depending on the underlying pathology. For instance, Lamartina and Berjano [9] described “pelvic kyphosis” in patients with neurological disease. These patients were characterized by an increased sagittal vertical axis (SVA) without pelvic compensation and normal spine for a given pelvic incidence. These authors also suggested that hip disease with flexion contracture could be a cause of pelvic kyphosis. Indeed, hip flexion contracture is considered a common characteristic for hip osteoarthritis patients [2]. However, not all patients present limited hip range of motion corresponding to flexion contracture, and therefore, such limitation could represent a specific category of patients.

One of the challenges of describing patients with flexion hip contracture is the diagnosis of this condition. Hip flexion contracture is usually estimated with physical examination through the Thomas test [10]: the contralateral limb of the supine patient is flexed to eliminate the lumbar lordosis, and the angle between the axis of the thigh and the horizontal is measured to quantify hip flexion contracture. Alternatively, femoral version can be measured in lateral full-body radiographs, as the angle subtended by the femoral axis and the vertical, and provide a qualitative assessment of contracture [11]. However, these methods do not consider the orientation of the pelvis, which is an important aspect when assessing hip mobility. Several alternatives of this test were proposed to better control hip motion, such as the modified Thomas test with lumbo-pelvic stabilization and the Staheli test [8, 12]. These approaches are reproducible and non-invasive, but they can only partially account for pelvis motion and morphology, or for the potential soft tissue artifacts when estimating limb motion.

The aim of this work was to establish a classification criterion to detect those patients with hip osteoarthritis and hip flexion contracture, and to determine their postoperative outcome, in terms of contracture and sagittal alignment, by comparison with patients with hip osteoarthritis and normal hip extension.

## Materials and methods

### Patients

This is a prospective and consecutive cohort of patients. Patients with hip arthrosis and with an indication for THA were included between July 2019 and December 2020 at Kyoto City Hospital (Japan). Exclusion criteria were: spinal implant with iliosacral screws, spinal fusion of more than two vertebral levels or scoliosis with coronal Cobb angle higher than 25°. Institutional review board approved the data collection (authorization N. 621).

### Data collection and radiographic analysis

Full-body standing lateral radiographs were acquired in free standing position and in extension (Fig. 1). For the extension radiograph, patients were asked to hold on to a horizontal bar slightly higher than shoulder level, and they were instructed to extend their pelvis and spine as much as possible. Acquisitions were obtained preoperatively and postoperatively after 6 and 12 months.

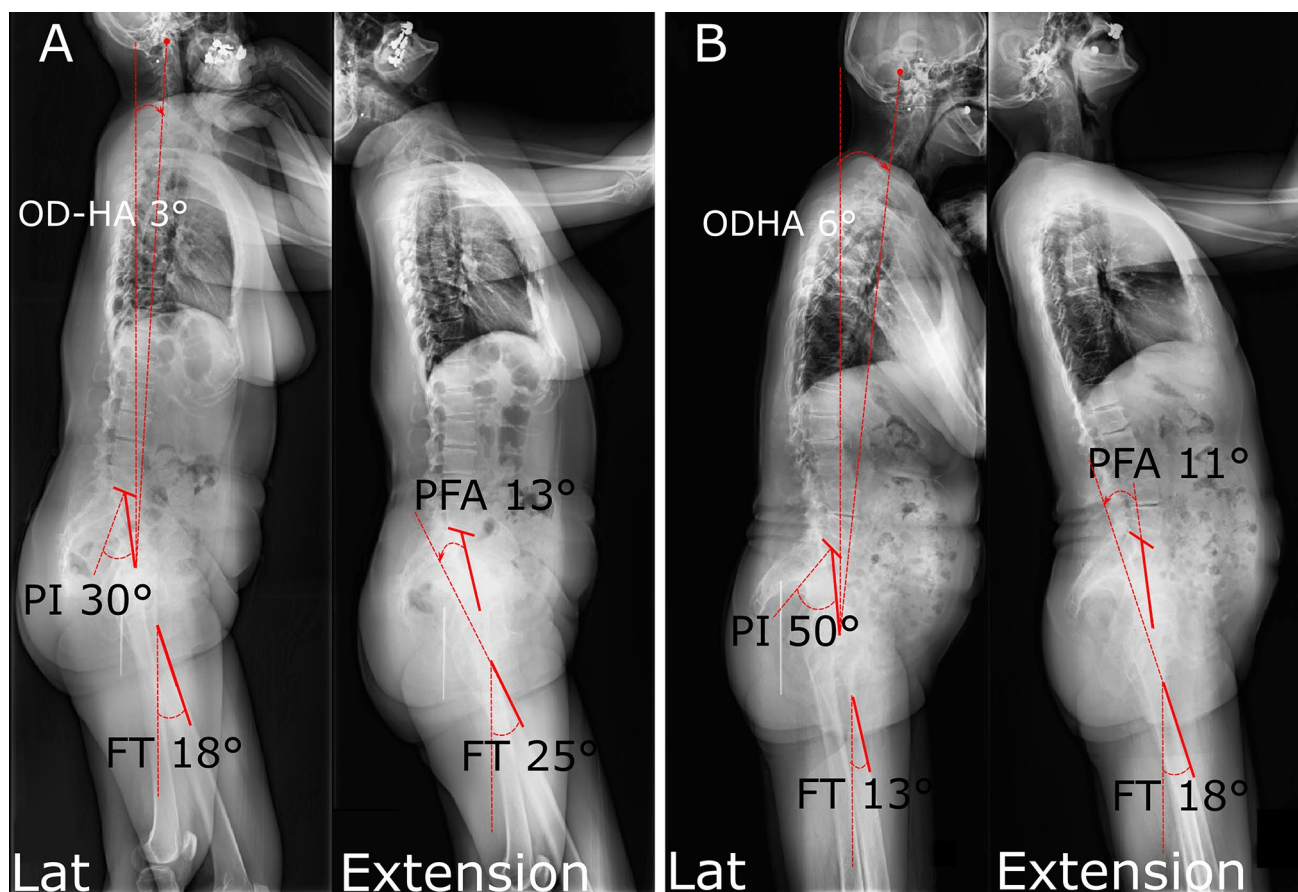
The following standard parameters were measured by an experienced operator in both radiographs: pelvic tilt (PT), pelvic incidence (PI), L1–S1 lumbar lordosis (LL), pelvic incidence minus lumbar lordosis (PI-LL), sagittal slope of the upper plateau of T1, and the T1-pelvic angle (TPA, Fig. 2) [13]. In addition, the following parameters were computed: femur sagittal tilt, as the angle between the vertical and a line along the frontal aspect of the first third of the femur diaphysis (Fig. 1). The angle was considered positive toward flexion and negative toward extension [2]. Pelvic–femur angle (PFA), i.e., the angle between the femur and a line drawn from the middle of the sacrum endplate to the centre of the interacetabular hip axis. In free standing position, OD-HA angle was also measured: it is the angle between the vertical and the line between the C2 odontoid process and the interacetabular hip axis [14].

### Flexion contracture of the hip

Hip range of motion in extension was quantified by measuring PFA of the pathological limb in the extended position X-ray. Then, contracture of the hip was defined as a reduced range of motion of the pathological side of the hip in extension. However, to define a threshold to characterize a “reduced” range of motion, it was hypothesized that range of motion depended on patient’s pelvic incidence. Hence, Patients with low PI ( $<45^\circ$ ) were included in the hip contracture group if their PFA was higher than  $5^\circ$ , while the threshold was  $-5^\circ$  for patients with standard or high PI ( $PI \geq 45^\circ$ ), as detailed in Table 1.

### Quality-of-life assessment

Patients were administered the Japanese Orthopaedic Association Hip Disease Assessment Questionnaire [15] preoperatively and 6-month postop. The JHEQ is a QOL assessment method that takes into account squatting and sitting on the floor, two common activities in Japanese lifestyle, and it allows to quantify the patient’s QOL on a scale from 0 to 28 points (increasing with QOL) related to three categories: pain, movement and mental state.



**Fig. 1** Lateral (Lat) and extension radiographs of typical patients with low (A) and high pelvic incidence (B). Pelvic incidence (PI), femoral tilt (FT) and OD-HA in free standing position, and pelvic-femoral angle (PFA) in extension, are reported on the radiographs

## Statistics

Preliminary cohort size analysis suggested that a cohort of 40 patients would allow to detect an improvement of  $10^\circ$  in the group with contracture of the hip ( $\alpha=0.05$ ,  $\beta=0.9$ ) [16]. Since the definition of contracture relies on the PFA angle, a reproducibility study was conducted on this parameter: two experienced operators (one surgeon, one engineer) repeated the measurement on eight patients, in free-standing position and extension, and both preop and postoperatively, for a total of 128 measurements. Intra-observer repeatability and inter-observer reproducibility were assessed in terms of standard deviation of the uncertainty.

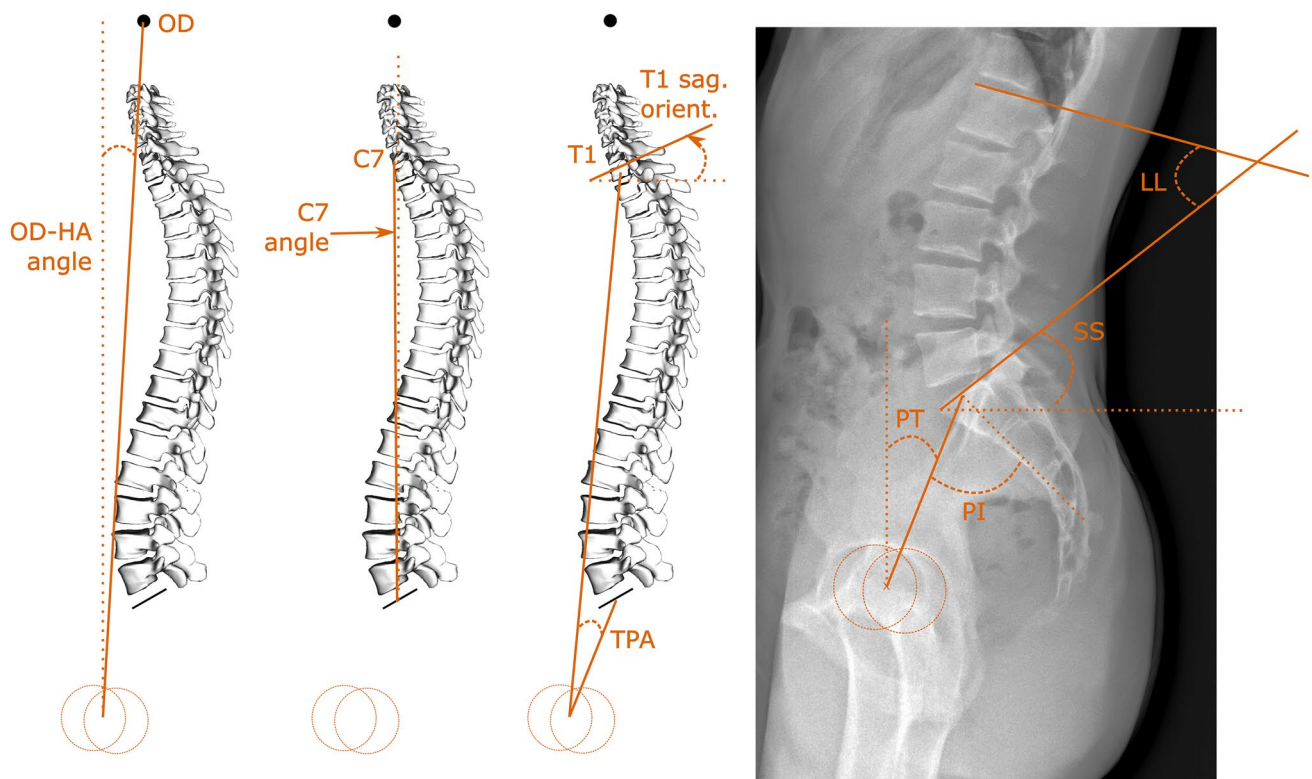
Differences between contracture groups were assessed with Mann–Whitney  $U$  test, while paired Friedman’s test for multiple comparisons were employed when comparing preop and postop values, followed by post-hoc Tukey–Kramer analysis. Correlations were analysed with Spearman’s rank test. Significance was set at  $p < 0.05$  and data were reported as median [quartiles]. Calculations were performed with Matlab 2020b (The Mathworks, Natick, USA).

## Results

One-hundred twenty-nine patients were included, 105 women and 24 men, median age 70 [63; 76] years. Twelve-month postop radiographs were available for 102 patients. Twenty-three patients presented femoral head subluxation (Crowe classification III and IV), which was not statistically associated to flexion contracture ( $p=0.8$ , Fisher’s test).

Thirty-seven patients were in the hip flexion contracture group (29%). Table 2 reports the demographics data of the cohort and the contracture and non-contracture groups, while Fig. 1 shows typical examples of patients with hip contracture. The definition of hip contracture can also be appreciated in Fig. 3, which shows the relationship between PI and PFA in extension before and after surgery. Intra-observer uncertainty of PFA measurement was  $1.5^\circ$ , while inter-observer uncertainty was  $2.2^\circ$ . The uncertainty was virtually identical in free standing and extension, as well as preoperatively and postop (less than  $0.2^\circ$  differences).





**Fig. 2** Spinopelvic parameters: Odontoid-hip angle (OD-HA), C7 angle, T1-pelvic angle (TPA), pelvic tilt (PT), pelvic incidence (PI), sacral slope (SS), lumbar lordosis L1-S1 (LL)

**Table 1** Definition of flexion hip contracture according to pelvic incidence (PI) and pelvic-femoral angle (PFA) in extension

Pelvic incidence	Flexion hip contracture	No contracture
PI < 45°	PFA > 5°	PFA ≤ 5°
PI ≥ 45°	PFA > -5°	PFA ≤ -5°

**Table 2** Demographics of the cohort

	Cohort	Contracture	No contracture
Number	129	37	92
Female/male	105/24	32/5	73/19
Age	70 [63; 76]	69 [59; 72]	70 [64; 78]
Preop subluxation (number)	23	7	16
Pelvic incidence [°]	47 [40; 55]	48 [37; 54]	46 [40; 55]

### Comparison between contracture and no contracture patients

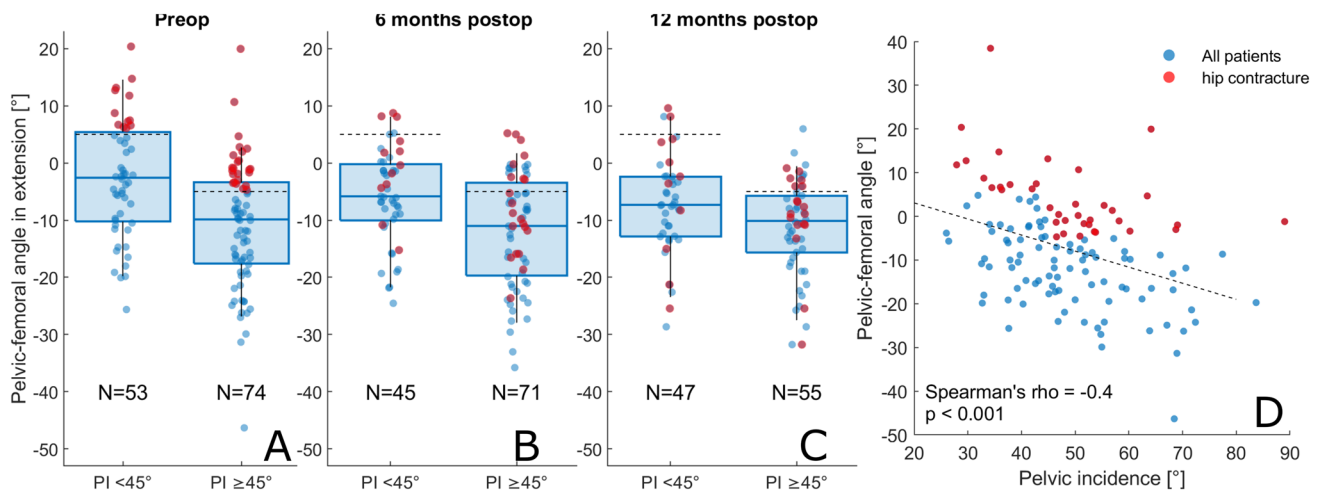
PFA in extension decreased with pelvic incidence ( $p \leq 0.001$ , Fig. 3), and the hip contracture patients corresponded to the highest values of PFA. PFA was higher

in contracture vs no contracture group ( $p < 0.001$ ), which is consistent with the definition of this group. PFA in free standing position was 5° [1; 10] in contracture group and -9° [-15; 1] in no contracture group ( $p < 0.001$ ). Contracture patients also showed higher femoral tilt ( $p = 0.02$ ).

Flexion hip contracture patients showed a specific pattern of sagittal spinopelvic alignment (Table 3). They had lower PT than the no-contracture group ( $p < 0.001$ ), both in the low and high PI group, although the relationship between PI and PT was similar in the two groups (Fig. 4). Vialle et al. [17] reported a normal range for the relationship between PT and PI in asymptomatic subjects: the percentage of patients outside this normal range was similar in contracture and no contracture groups (20 vs 35%,  $p = 0.1$ , Fig. 4).

Pelvic anteversion of the flexion contracture patients was correlated with a larger lordosis and smaller PI-LL ( $p < 0.001$ ), as well as a forward position of the head relative to the pelvis (OD-HA,  $p = 0.03$ ). Interestingly, C7 angle was similar between the two groups.

QOL questionnaires were only available for 49 patients preoperatively and 83 6 months postoperatively. Both groups showed similar QOL before surgery (Fig. 5), and they both significantly improved their QOL score after surgery



**Fig. 3** Relationship between pelvic incidence in free standing position and pelvic femoral angle in extension preop (A) and 6 (B) and 12-month postop (C). Patients with preoperative flexion hip contracture are plotted in red, while the thresholds of pelvic-femoral angle

for the definition of the contracture are represented as horizontal dashed lines ( $5^\circ$  for  $PI < 45^\circ$  and  $-5^\circ$  for  $PI \geq 45^\circ$ ). The correlation between pelvic incidence and pelvic-femoral angle in extension is also shown (D)

**Table 3** Spino-pelvic alignment of the patients in standing position according to flexion hip contracture

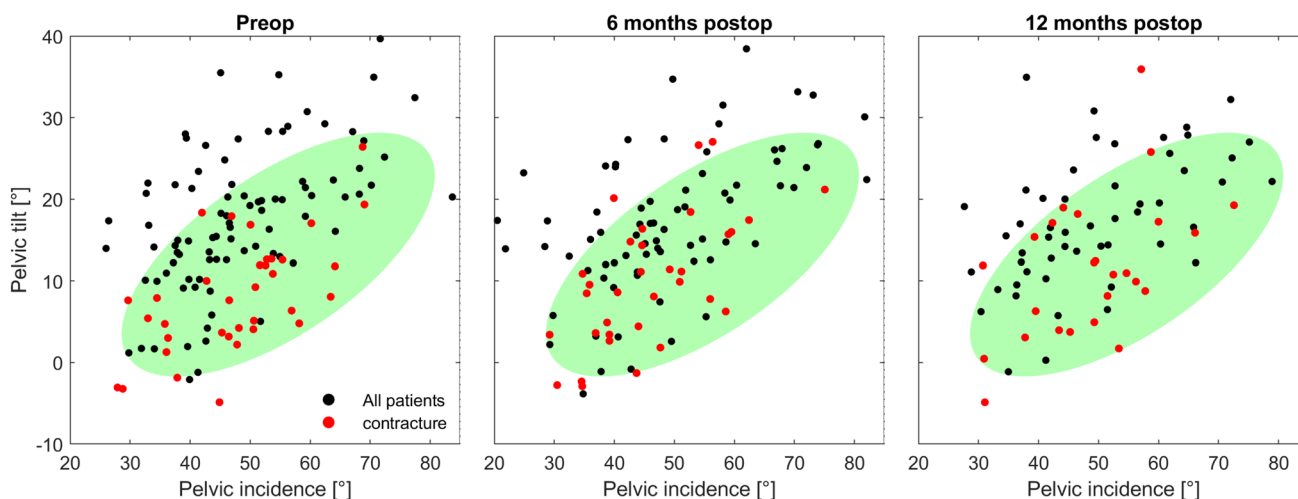
Parameter	Preop			6 months postoperatively			12 months postoperatively		
	Contracture group	No contracture group	<i>p</i> value	Contracture group	No contracture group	<i>p</i> value	Contracture group	No contracture group	<i>p</i> value
Pelvic-femur angle (sta.) [°]	5 [1; 10]	-9 [-15; -1]	<i>p</i> < 0.001	0 [-4; 6]	-6 [-14; -2]	<i>p</i> < 0.001	2 [-3; 5]	-5 [-11; -2]	<i>p</i> < 0.001
Pelvic-femur angle (ext.) [°]	2 [-2; 8]	-12 [-18; -5]	<i>p</i> < 0.001	-3 [-11; 2]	-8 [-19; -2]	0.004	-4 [-10; -1]	-9 [-14; -5]	0.01
Femoral tilt [°]	13 [10; 17]	10 [7; 14]	<i>p</i> = 0.02	10 [5; 12]	11 [7; 14]	-	-10 [-13; -6]	-11 [-14; -7]	-
Pelvic incidence [°]	48 [37; 55]	46 [40; 55]	-	44 [38; 52]	47 [40; 58]	-	49 [41; 55]	49 [41; 57]	-
Pelvic tilt [°]	8 [3; 12]	18 [13; 23]	<i>p</i> < 0.001	9 [4; 15]	17 [13; 24]	<i>p</i> < 0.001	9 [4; 12]	17 [12; 22]	<i>p</i> < 0.001
Lumbar lordosis [°]	50 [45; 57]	39 [27; 48]	<i>p</i> < 0.001	52 [42; 56]	38 [27; 50]	0.002	50 [43; 54]	40 [28; 52]	0.03
PI-LL [°]	0 [-11; 5]	10 [2; 23]	<i>p</i> < 0.001	-2 [-11; 4]	13 [3; 24]	<i>p</i> < 0.001	1 [-4; 4]	9 [-2; 22]	0.01
T1 slope [°]	21 [19; 25]	25 [19; 31]	-	23 [16; 31]	22 [16; 35]	-	24 [16; 30]	28 [21; 33]	-
T1-pelvis angle [°]	10 [1; 16]	18 [11; 27]	<i>p</i> < 0.001	9 [2; 12]	18 [12; 26]	<i>p</i> < 0.001	9 [3; 14]	19 [12; 26]	<i>p</i> < 0.001
C7 angle [°]	6 [0; 8]	5 [2; 9]	-	2 [-2; 5]	6 [2; 9]	0.004	4 [2; 6]	6 [3; 10]	-
OD-HA [°]	3 [0; 5]	1 [-1; 3]	0.04	1 [-1; 3]	2 [-1; 4]	-	2 [0; 4]	2 [0; 4]	-

Femur-pelvic angle was reported both in standing (sta.) and in extension (ext.). Values are reported as median [quartiles], and *p*-values are reported for significant differences between contracture and no contracture group

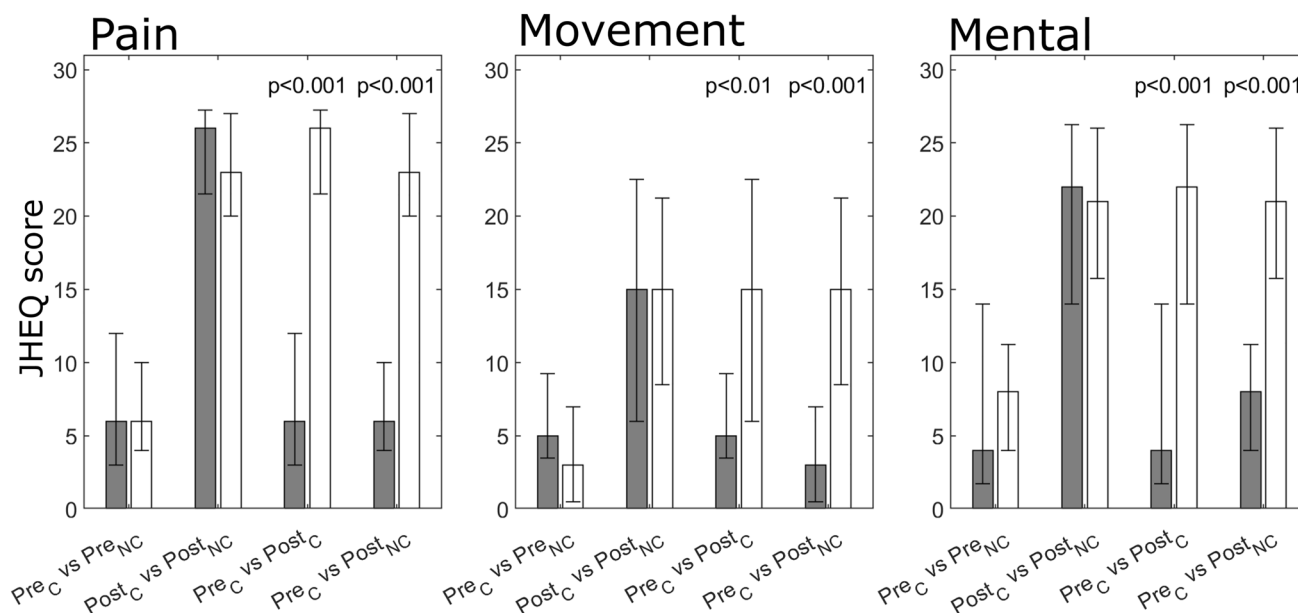
(*p* < 0.001). However, contracture patients had significantly higher QOL score postoperatively in the “movement” and “mental” categories (*p* < 0.001 and *p* < 0.05, respectively).

### Comparison between preop and postop parameters

In contracture patients, PFA decreased 6 months after surgery (*p* = 0.004), i.e., their range of motion in extension increased, and it remained unchanged 12-months postop. This corresponded to decrease of the percentage of patients



**Fig. 4** Relationship between pelvic incidence and pelvic tilt in a control population (green ellipse, data from Vialle et al. [17]) and in the present cohort before and 12 months after surgery. Patients with flexion hip contracture are plotted in red



**Fig. 5** Comparisons of Japanese Orthopaedic Association Hip Disease Assessment Questionnaire (JHEQ) score before (“Pre”) and after total hip arthroplasty (“Post”) in contracture (C subscript) and non-contracture patients (NC subscript). *P* values of significant differences are reported

presenting contracture, from 29% preop to 14% postop, to 16% 12-months postop. Eight patients (16% of the hip contracture group) still showed contracture 1 year postoperatively, while five patients (6% of non-contracture group) developed a contracture postop. However, these five patients were above the threshold for hip contracture by only 3° or less. TPA also increased 6-months postop in contracture patients ( $p = 0.02$ ), while femoral tilt decreased ( $p < 0.001$ ). Figure 6 shows typical examples of a patient that resolved

the contracture postoperatively, and a second one who did not.

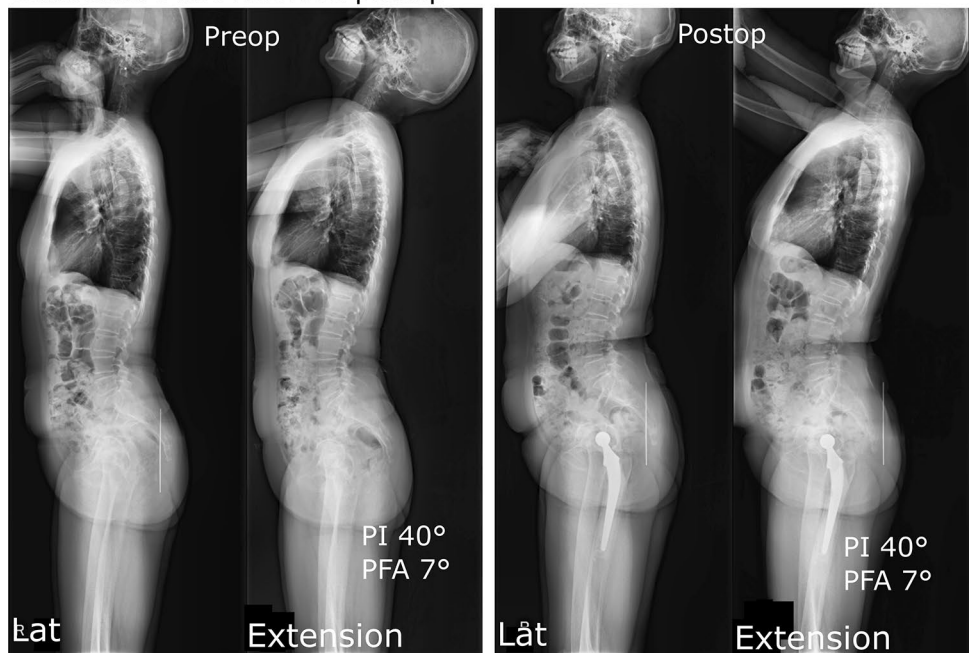
Conversely, PFA did not significantly change postoperatively in the no contracture group ( $p > 0.05$ ), nor did the other parameters (Table 3). Although PI-LL did not change postoperatively, 50% of patients in both groups showed PI-LL mismatch preop, and this percentage was reduced 6-months postop to 12% and 30% for the contracture and no contracture group, respectively.

**Fig. 6** Examples of patients where the hip contracture was resolved or not. Pelvic-femoral angle (PFA) improved by  $23^\circ$  in the resolved patients, while no change was measured in the non-resolved one

**Contracture resolved postop**



**Contracture not resolved postop**



More in general, even if most parameters did not change between preop and postop stages, large changes could be observed in several patients. For instance, 40% of the patients changed their LL by more than  $5^\circ$  both between preop and 6-months postop, as well as between this timepoint and 12-months postop. However, only 28% of patients changed their PT 6-months post-op (half of them increased and the other half decreased) and only 5% patients changed their PT thereafter.

**Discussion**

In the present work, a method was proposed to identify patients with hip contracture in a cohort of hip osteoarthritis patients. This method is based on the measurement of PFA in extension sagittal radiographs: high PFA in extension, corresponding to reduced hip range of motion, was associated with hip flexion contracture. Interestingly,



this classification of patients based on a single hip parameter allowed to highlight a group of patients showing a specific spinopelvic alignment and benefitting from a better improvement of QOL after surgery. It is possible that contracture patients were living with a higher degree of disability than no-contracture patients before surgery, and therefore, they perceived a better improvement after surgery.

QOL was quantified using the JHEQ [15], which is a validated evaluation tool for hip-joint disease [18, 19]. The score represents the overall QOL as the sum of three items evaluating the patient's hip-related pain, his/her activity, and mental state. The questionnaire takes into account squatting and sitting on the floor, two activities that are common in Japanese lifestyle. For instance, it contains items, such as "it is difficult for me to get up from the floor and tatami", but most of its questions and statements could be applied to the global population (such as "even when I am at rest, my hip is painful", or "It is difficult to cut my toenails", "Because of hip-joint disease, I sometimes get irritated or feel nervous"). Therefore, the QOL-related results of the present work should be relevant beyond the Japanese population.

Hip pathology (and the accompanying pain) can affect the patient's sagittal alignment [2, 20, 21]. One of the aims of this work was to highlight the further balance alterations induced by hip contracture. These patients had an anteverted pelvis, hyper-lordosis, small TPA and forward position of the head (high OD-HA, Table 3). Interestingly, C7 angle was similar between groups; this suggests that the difference in TPA is mostly due to the anteversion of the pelvis rather than to a posterior movement of T1 in the contracture group. Since the definition of hip contracture was adapted to PI, this parameter was similar in the contracture and non-contracture group. This corroborates the fact that the differences of sagittal alignment between groups are indeed due to contracture, and not to pelvis morphology.

Hence, contracture patients showed an overall less harmonious spinopelvic alignment than non-contracture patients, and they exacerbated the already altered alignment of hip osteoarthritis patients, when compared to asymptomatic subjects. For instance, asymptomatic subjects usually have an OD-HA of  $-2 \pm 2^\circ$  (mean  $\pm$  SD) [22], while non-contracture group showed a forward position of the head (OD-HA  $1^\circ$  [ $-1$ ;  $3$ ]), and contracture group an even more advanced head position ( $3^\circ$  [ $0$ ;  $5$ ]). Further down the sagittal compensatory chain, TPA in both groups was similar to previously published values in asymptomatic elderly patients ( $13.7^\circ$  [ $10$ ;  $18.5$ ] [23]), with the contracture group showing smaller values than asymptomatic, probably because of pelvic anteversion.

The values chosen as threshold to define hip contracture corresponded to the 75% percentile observed in the cohort, rounded to the nearest five. Therefore, 29% of the cohort

was in the contracture group. The threshold to define hip contracture was adapted to the patient's PI to account for the correlation observed between PFA and PI: patients with higher PI theoretically have higher PFA in extension (Fig. 3), because they have higher PT in standing position. Standard and high PI ( $> 60^\circ$ ) were considered together, because no difference of PFA was observed for higher PI. Analysis of a larger cohort might highlight differences between standard and high PI patients.

Not all patients resolved their hip flexion contracture post-operatively. Hence, the surgical strategy could be adapted to improve these patients' outcome. However, patients were not assessed for knee arthrosis or knee flexion contracture: it is possible that some of these patients also suffered from knee contracture, which could induce similar sagittal alterations by hip compensatory flexion.

More in general, sagittal alignment was only marginally affected by THA. For instance, only 40% of patients changed their LL postoperatively, while only 28% changed their PT. This is consistent with previous results reporting significant but small changes of PT [3]. Nevertheless, contracture patients were able to improve their posture by increasing their femoral tilt, even without PT changes. It is often considered that retroversion of the pelvis is a compensation mechanism for the postoperative release of contracture, which in turn could increase the risk of anterior dislocation. Although only a few patients increased their PT, the general improvement of PFA could still lead to an increased risk of anterior dislocation because of the increased angle between the femur and the hip cup.

PFA was previously measured by McKnight et al. [24], who reported that a standing angle lower than  $-25^\circ$  could be at risk of posterior impingement and anterior dislocation. It can be noted that those authors measured the supplementary angle to the one reported here (i.e.,  $180^\circ$ —PFA in the present work). In the present work, standing PFA was more negative in non-contracture patients than in contracture, with three patients showing  $PFA < -25^\circ$ . Postoperatively, two patients still showed such low standing PFA (3% of patients).

Weng et al. [2] reported a range of  $8.8^\circ \pm 7.9^\circ$  (mean  $\pm$  SD) for standing PFA in asymptomatic subjects, and significantly smaller values in osteoarthritis ( $-0.6^\circ \pm 9.7^\circ$ ). Similar values were reported in coxarthrosis patients by Philippot et al. [25] ( $-0.5^\circ \pm 15.4^\circ$ ). The medians in the present work were  $-9^\circ$  [ $-15$ ;  $-1$ ] for no contracture group and  $5^\circ$  [ $1$ ;  $10$ ] in the contracture group (Table 3). The sign of the angles in the two studies are opposite, because in the present work, it was decided to define a positive angle in case of hip flexion, which is consistent with the clinical functional examination [4]. With that in mind, the non-contracture patients in the present study showed a similar PFA angle when standing than controls in Weng et al. However, in their osteoarthritis group, those authors did not differentiate

contracture patients. The median PFA angle of the total cohort in this work was  $-3^\circ$  [ $-13$ ;  $4$ ], which is closer to the values reported by previous authors for osteoarthritis patients. However, this median value mixes two very different populations of contracture and non-contracture patients (Table 3). Furthermore, the relationship between PFA and PI which was analysed in the present work allowed to observe that hip mobility depends on PI; this dependency should, therefore, be taken into account when assessing hip joint.

The main limitation of the proposed method of classification is that it requires performing an additional radiograph of the patient in extension position. This position is difficult to standardize, much like other position, such as sitting, which nevertheless have been showing their clinical relevance in the last few years [26–28]. However, the measurement of the PFA on radiographs showed an uncertainty of  $2.2^\circ$ , which is consistent with other radiographic measurements.

A second limitation of this study was the definition of the angular threshold to define contracture:  $5^\circ$  for low PI and  $-5^\circ$  for mid-to-high PI. These values were selected as the 75% percentile of the PFA distribution observed in the total cohort, and they allowed to define a consistent group of patients showing a specific pattern of alignment. However, these thresholds could be refined by further studies on the physiological limitations leading to hip flexion contracture.

## Conclusions

A new type of osteoarthritis patients was defined in the present work: they combine the degenerative joint disease with a flexion contracture of the hip. These patients present a specific pattern of sagittal alignment, with significant differences at all levels of the sagittal chain of balance, from the hip to the head, when compared to non-contracture patients. Furthermore, these patients maintain a sagittal imbalance postoperatively, and their contracture is not always resolved. Therefore, further studies are necessary to better understand the aetiology of the contracture, and how the treatment can be improved to solve it postoperatively. The validation of a quantitative method to diagnose them is an important first step in this direction.

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**Author contributions** CV: concept and design, obtaining of funding, analysis and interpretation of the data, drafting of the article, and final approval of the article. CV was the main investigator of this study, and performed all of the measurements. YK: provision of study patients, obtaining of funding, collection, analysis and interpretation of data, participation in the reproducibility study, critical revision of the article for important intellectual content and final approval of the article. MT: concept and design, analysis and interpretation of data, critical revision

of the article for important intellectual content, and final approval of the article. YS: provision of study patients, analysis and interpretation of data, critical revision of the article for important intellectual content, and final approval of the article. CT: provision of study patients, analysis and interpretation of data, critical revision of the article for important intellectual content, and final approval of the article. SF: provision of study patients, analysis and interpretation of data, critical revision of the article for important intellectual content, and final approval of the article. SF: provision of study patients, analysis and interpretation of data, critical revision of the article for important intellectual content, and final approval of the article. SM: concept and design, obtaining of funding, analysis and interpretation of data, critical revision of the article for important intellectual content, and final approval of the article.

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**Availability of data and materials** Data are available on an as-requested basis.

## Declarations

**Conflict of interest** There are no conflicts of interest to declare.

**Research involving Human Participants** Institutional review board approved the data collection (authorization N. 621).

**Informed consent** Patients informed consent was collected.

**Consent to publish** Not applicable.

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