



# Results of open reduction internal fixation versus percutaneous iliosacral screw fixation for unstable pelvic ring injuries: retrospective study of 36 patients

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## Abstract

**Introduction** Surgical stabilization of posterior pelvic ring fractures can be achieved by closed reduction and percutaneous fixation (CRPF) or by open reduction and internal fixation (ORIF). The aim of the present study is to compare the clinical results of both methods.

**Material and methods** Medical records of 36 patients consecutively operated for unstable pelvic ring injuries were retrospectively reviewed. We compared 22 patients treated with CRPF versus 14 patients stabilized by using ORIF between 2007 and 2017. The Majeed and Pohlemann scores were used to evaluate postoperative functional outcomes. Complications like blood loss, infection rate, Neurological injury, the operative time and the length of hospital stay were analyzed.

**Results** The median Majeed pelvic score was 87 points for the CRPF technique compared with 69 points for the ORIF technique. The median Pohlemann score, operative time and length of hospitalization were similar between the two groups. The median blood loss for the CRPF technique was 300 ml compared to 500 ml for the ORIF technique. CRPF and ORIF procedure had each one neurological lesion. There was one case of infection in the ORIF group and none in the CRPF group. No measurements except for the blood loss have reached the significance threshold.

**Conclusion** The CRPF technique shows a clear decrease in blood loss. There was no statistically significant difference in the functional results, infection rate, neurological injury, operative time and hospital stay between both techniques.

**Keywords** Percutaneous iliosacral screw fixation · Unstable pelvic ring injury · Iliosacral fracture/dislocation · Majeed score · Pohlemann score

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## Introduction

Posterior pelvic ring injuries are complex, often unstable, and difficult to treat. Sacroiliac fractures are a variant of pelvic injury associated with high energy. One of the multiple factors associated with poor functional outcomes is residual posterior displacement [1]. The goal of operative treatment for displaced, unstable pelvic ring fractures and sacroiliac dislocations is anatomic reduction and rigid fixation to facilitate early mobilization.

Depending on the type of fracture, there are different surgical approaches, reduction techniques, and fixation methods. Examples of fixation methods include iliosacral screws, trans-sacral screws, sacral bars, vertebropelvic internal fixation, posterior tension band plating, and anterior sacroiliac (SI) joint plating.

Pelvic fractures can be reduced in an open or closed fashion followed by percutaneous and/or internal fixation. Open

reduction and internal fixation (ORIF) with anterior plating have traditionally required extensive surgical exposure of the pelvic deep structures which can be associated with nerve damage [2, 3], elevated surgical blood loss [2] and infection rates of about 25% [4].

Posterior plating risks include wound complications with deep infection reported to be between 14 and 25% [2, 4, 5].

Closed reduction and percutaneous fixation (CRPF) has been recommended by Roult et al. and has demonstrated good results [6]. Malreduction of the pelvic ring can lead to significant long-term problems like pain, non-union or mal-union with leg length discrepancy and delayed neurological compromise [2]. Iliosacral or trans-sacral screw fixation of pelvic ring fractures can be technically demanding procedures with the use of an intraoperative simple 2D fluoroscopically assisted imaging, or with a CT navigated system.

Roult et al. described the CRPF technique for sacroiliac fractures and dislocations with an iliosacral screw in the first sacral vertebral body demonstrating it to be biomechanically stable [7]. This method allows also a reduction in operating time [8], diminished surgical bleeding [8] and decreased infection rate ranging from 0 to 1% [9].

Our primary outcome is the functional results of ORIF and CRPF for posterior pelvic ring injuries using the Majeed [10] and Pohlemann [11] scores. Secondary outcomes analysis include complications (blood loss, infection rate, and Neurological injury), operative time and length of hospitalization.

## Material and methods

The present retrospective study was conducted between September 2007 and December 2017. During this time, fifty patients sustained an unstable posterior pelvic ring injury at an academic level-1 trauma center.

Of these 50 patients, 36 adult patients were treated with iliosacral fixation. The patients were classified into two groups: the CRPF group had 22 patients stabilized under fluoroscopic (59%) or O-Arm guidance (41%) and the ORIF group had 14 patients.

The median follow-up was 6 months for the CRPF group and 10.5 months for the ORIF group (Table 1).

One patient in the CRPF group and one patient in the ORIF group were lost to follow-up.

Fourteen patients had to be excluded due to the following: patients under 18 years of age, patients whose initial posterior stabilization used a method other than CRPF and ORIF, H-shaped sacral fractures, and those treated only with external fixation.

Fractures of the pelvis were classified according to the AO-Tile classification [2]. In the CRPF group, 19 patients had a Tile C and 3 patients a Tile B fracture. In the ORIF group, 8 patients were classified according to Tile C and 6 according to Tile B (Table 1).

The median age was 35.5 years with 25th–75th percentiles (27; 59) in the CRPF group versus 42.5 years median age with 25th–75th percentiles (26; 54) in the ORIF group. The gender distribution was similar between the two groups

**Table 1** Patients characteristics. Assessments of CRPF and ORIF techniques. Median (IQR)

|                                                  | CRPF ( <i>n</i> =22)        | ORIF ( <i>n</i> =14)         | <i>p</i> value |
|--------------------------------------------------|-----------------------------|------------------------------|----------------|
| Age (years), median (IQR)                        | 35.5 (27; 59)               | 42.5 (26; 54)                | 0.85           |
| Female sex                                       | 4 (18%)                     | 2 (14%)                      | 0.50           |
| Type B2/3 AO-Tile classification                 | 3 (14%)                     | 6 (43%)                      | –              |
| Type C AO-Tile classification                    | 19 (86%)                    | 8 (57%)                      | –              |
| Majeed score (points), median (IQR)              | 87 (59; 96) <sup>c</sup>    | 69 (64; 86) <sup>a</sup>     | 0.23           |
| Majeed (percent of good to excellent results)    | 15 (71%) <sup>c</sup>       | 6 (46%) <sup>a</sup>         | 0.14           |
| Pohlemann score (points), median (IQR)           | 5 (4; 6) <sup>c</sup>       | 5 (3; 6) <sup>a</sup>        | 0.74           |
| Pohlemann (percent of fair to excellent results) | 15 (71%) <sup>c</sup>       | 9 (69%) <sup>a</sup>         | 0.89           |
| Operative time (min)                             | 139 (93; 179) <sup>d</sup>  | 138 (116; 160)               | 0.82           |
| Duration of hospitalization (days)               | 23 (13; 32)                 | 25 (20; 41)                  | 0.31           |
| Blood loss (ml)                                  | 300 (100; 450) <sup>e</sup> | 500 (240; 1000) <sup>b</sup> | 0.03           |
| Infections                                       | 0 (0%) <sup>c</sup>         | 1 (7%)                       | 0.40           |
| Neurological injury after surgery                | 1 (5%) <sup>c</sup>         | 1 (7%) <sup>c</sup>          | 0.76           |
| Neurological injury related to trauma            | 8 (38%) <sup>c</sup>        | 3 (23%) <sup>c</sup>         | 0.36           |
| Follow-up (months)                               | 6 (4; 12)                   | 10.5 (7; 12)                 | 0.07           |
| Radiological score (points)                      | 2 (1; 3)                    | 2 (2; 3)                     | 0.33           |
| Anterior approach and fixation                   | 16 (71%)                    | 6 (38%)                      | 0.07           |
| Anterior pelvic injury                           | 22 (100%)                   | 13 (92%)                     | 0.20           |

<sup>a</sup>*n* = 13; <sup>b</sup>*n* = 11; <sup>c</sup>*n* = 21; <sup>d</sup>*n* = 20; <sup>e</sup>*n* = 17

with 18% female in the CRPF group and 14% in the ORIF group (Table 1).

### Surgical techniques

Two experienced orthopedic surgeons (OB and ET), specialists in pelvic and acetabular surgery, performed all the procedures.

ORIF technique was favored in patients with crescent fractures and when closed manipulative reduction failed. Over the last years, most of the patients had a percutaneous fixation as our surgeons acquired experience and familiarity with this technique.

A single dose of antibiotic prophylaxis (1.5 g of cefuroxime i.v.) was given in all the cases.

#### Closed (CRPF)

The patient was placed supine on a radiolucent table, and an image intensifier was moved between inlet, outlet and lateral views to facilitate reduction and screw placement. Closed reduction was performed by longitudinal traction and closed manipulation. Reduction was held manually, while cannulated, percutaneous iliosacral screws were placed. All screws were partially threaded and used with washers. Moderate compression was applied across the SI joint, but in the case of vertical sacral fractures, screws were tightened only until the fracture surfaces were approximated.

The posterior lesions were fixed with Depuy Synthes® 7.3 mm cannulated cancellous screws (San Juan Capistrano, California, United States) (Fig. 1).

The anterior pelvic ring injuries were fixed with 3.5 mm curved stainless steel R75 pubic symphysis plates Stryker®.



Fig. 1 CRPF technique

#### Open (ORIF)

The open reduction technique involved supine and prone positioning on a radiolucent fracture table. A gluteus maximus sparing method for the posterior approach was used to allow for direct visualization and reduction of the posterior pelvic injury.

Intraoperative fluoroscopy was used to confirm reduction and guide the placement of iliosacral screws.

In ORIF technique, the posterior pelvic ring injuries were fixed with 3.5 mm Matta pelvic plates Stryker®, 5 mm condyle screws with a nut of a T2 femoral nailing system Stryker®, Depuy Synthes® 3.5 mm reconstruction plates DCP, 3.5 mm locking compression plates LCP, bolted sacral bars, and 7.3 mm cannulated cancellous screws (San Juan Capistrano, California, United States) (Fig. 2).

The anterior pelvic ring injuries were fixed with 3.5 curved stainless steel R75 pubic symphysis plates Stryker®.

#### The postoperative assessment

The Majeed Score is based on pain, work performance, sitting, sexual intercourse and standing. The total score ranks the clinical outcomes as excellent (> 85), good (70–84), acceptable (55–69) or poor (< 55) in patients who were working before the injury [10]. The Pohlemann score is divided into clinical, radiological, and social reintegration outcomes [11]. For radiological results, we measured vertical, antero-posterior and symphyseal displacements on the last antero-posterior radiographic view of the pelvis using the technique described by Henderson et al. [12]. The measurements were performed by three distinct observers.

For the posterior displacement, the Pohlemann radiological score was rated as three points for anatomical posterior healing, two points for maximal posterior displacement of



Fig. 2 ORIF technique

5 mm and one point for posterior displacement above 5 mm [11].

To evaluate the pelvic outcome, the ratings of the radiological and clinical results were assessed as a single score on a 7 points scale, where the maximum of 7 points represented an excellent result, 6 points a good result, 5 and 4 points a fair result, and 3 and 2 points a bad result [11].

The complications (blood loss, infection, and neurological injury), operative time, and length of hospitalization were analyzed.

## Statistical analysis

Descriptive statistics were used to characterize the population. Continuous variables were expressed as the median and interquartile range (IQR) [25th–75th percentiles]. Categorical variables were summarized as a percentage.

Chi-squared tests were used to assess significant differences between observed frequencies. Wilcoxon signed-rank tests were used to compare scores and measurements between both groups of patients. All statistical analyses were performed with Stata 15.0 (StataCorp, College Station, TX, USA). The limit for statistical significance was set as usual at  $p < 0.05$ .

## Results

In the CRPF group, 18 patients were fixed with a single screw in S1, 2 patients with two screws in S1, 1 patient with a screw in S1 and S2, and 1 patient with one screw in S1 and S3.

Twenty-two patients of the CRPF group had an anterior pelvic injury ( $p = 0.07$ ). Sixteen of them required a simultaneous anterior approach and fixation ( $p = 0.20$ ) (Table 1).

In the ORIF group, eleven patients were fixed with pelvic plates, one patient with one screw in S1 and S2, one patient with sacral bars, one patient with 2 condylar screws of a distal femoral nail.

Thirteen patients of the ORIF group had an anterior pelvic injury ( $p = 0.07$ ). Four of them required a simultaneous anterior approach and fixation, whereas two of these patients were fixed few days later ( $p = 0.20$ ) (Table 1).

## The functional scores outcomes

Majeed and Pohlemann scores were obtained between April and September 2018 in 21 patients for the CRPF group and 13 patients for the ORIF group. The median follow-up for the CRPF group was 6 months with 25th–75th percentiles (4; 12). The median follow-up for the ORIF group was 10.5 months with 25th–75th percentiles (7; 12) (Table 1).

The median Majeed score was 87 points with 25th–75th percentiles (59; 96) for the CRPF group compared to median score of 69 points with 25th–75th percentiles (64; 86) for the ORIF group (Table 1). The percentage of good to excellent results with the Majeed score was 71% for the CRPF technique against 46% for the ORIF technique.

The median Pohlemann score was 5 points with 25th–75th percentiles (4; 6) for the CRPF group compared to a median score of 5 points with 25th–75th percentiles (3; 6) for the ORIF group (Table 1). The percentage of fair to excellent results with the Pohlemann score was 71% for the CRPF technique against 69% for the ORIF technique.

The results did not reach significant threshold.

## Radiological score

The median radiological score was 2 points for the CRPF group with 25th–75th percentiles (1; 3) and 2 points for the ORIF technique with 25th–75th percentiles (2; 3). The  $p$  value ( $p = 0.33$ ) was not significant (Table 1).

## Blood loss

Sixteen of the twenty-two patients treated with the CRPF method had simultaneous anterior fixation and four of the fourteen patients treated with the ORIF method had simultaneous anterior fixation. The CRPF group had a median blood loss of 300 ml with 25th–75th percentiles (100; 450) compared to 500 ml with 25th–75th percentiles (240; 1000) for the ORIF group. The  $p$  value ( $p = 0.03$ ) was significant (Table 1).

## Infection

There was one case of infection in the ORIF technique out of fourteen patients and none in the CRPF technique. The  $p$  value ( $p = 0.40$ ) was not significant (Table 1).

## Neurologic lesions

For neurological injuries, the CRPF technique had one lesion versus one lesion for the ORIF technique. The  $p$  value ( $p = 0.76$ ) was not significant (Table 1).

With the CRPF method, one patient had neuropathic pain in the territory of S1 and S3 due to malpositioning of the screws. After changing the screws, the patient fully recovered without sensory or motor loss.

With the ORIF method, the neurologic complication was due to a malpositioned guide wire in the L5 nerve root causing a permanent steppage gait requiring an orthosis.

## Operative time and length of hospitalization

The median operative time was 139 min with 25th–75th percentiles (93; 179) for the CRPF technique versus 138 min with 25th–75th percentiles (116; 160) for the ORIF technique. The  $p$  value ( $p=0.82$ ) was not significant (Table 1).

The two cases in the CRPF group with unilaterally posterior-only fixation procedures had an operative time of 47 min and 56 min.

The median length of hospitalization was 23 days with 25th–75th percentiles (13; 32) for CRPF technique compared to 25 days with 25th–75th percentiles (20; 41) for ORIF technique. The  $p$  value ( $p=0.31$ ) was not significant (Table 1).

## Discussion

Unstable pelvic injuries have been associated with high rates of morbidity and mortality [5]. The operative management of unstable pelvic ring fractures can be technically difficult and necessitates accurate reduction with rigid fixation. The treatment method is an important factor that can influence the functional outcomes [1]. Optimal treatment for unstable fractures of the pelvis is not yet defined [13]. The ORIF technique includes anterior and posterior approaches. The anterior approach to the SI joint with subsequent ORIF provides better exposure of the anterior SI joint with a direct visualization of the injury in some cases. However, it is difficult to assess reduction in pure SI joint dislocations through this approach. The ideal assessment of a reduced SI joint dislocation is via the posterior approach and determination at the region of the inferior SI joint near the greater sciatic notch. With this anterior approach, injury to the L5 nerve root is a risk and the medial access is limited to apply a plate.

The sacroiliac screw is a well-recognized choice of implant for posterior stabilization of pelvic injuries. Fixation was most commonly carried out using an open posterior approach until recently with the development of the percutaneous approach [6]. CRPF technique is certainly a more difficult and demanding method that requires experienced surgeons because of the particularity of pelvic and sacral anatomy [14] with a risk of injury to the cauda equina, L5 and S1 nerve roots.

## Functional scores

Very few studies have compared the functional results of the two techniques. Elzohairy et al. retrospectively reviewed 70 patients treated with CRPF and ORIF. Using the Pohlemann score, he found no significant difference

in the functional outcomes between the two methods with good to excellent results in 86% of cases for the CRPF against 80% for the ORIF [15].

In our study, we also found no significant difference in the functional outcomes with the Pohlemann score in both techniques. We didn't obtain as much as good to excellent results than M.M. Elzoheiry et al.; however, we had 86% and 57% of Tile C pelvic fractures for the CRPF and ORIF technique compared to 26% for both techniques in their study [15].

Based on the Majeed's grading score for pelvic fractures, we had better functional outcomes using the CRPF technique with a Majeed's median score of 87 points compared to 69 points for the ORIF technique. We found 71% of good to excellent results with the CRPF group versus 46% with the ORIF group.

Schweitzer et al. [9] obtained better functional outcomes using the CRPF method with 91% of good to excellent results.

The main limitation of this score is that it is influenced by the characteristics of the fracture and associated injuries and not determined by the stabilization method [9].

Various authors affirm that good functional results after stabilization of sacroiliac lesions depends on the quality of the posterior reduction [4, 11, 12, 16, 17].

We found in our study a better quality of reduction in the ORIF technique with 42.8% anatomical reduction according to the Pohlemann radiological score compared to 27.2% in the CRPF technique.

Anatomic reconstruction of the pelvic ring is an important factor for good to excellent clinical results, but even when this goal is met, other parameters (sacral fractures, sacroiliac dislocations, primary neurological/urological injuries) can lead to an unsatisfactory result [18].

We observed also in our study that some patients in the CRPF group had good or excellent clinical results despite the poor quality of reduction.

Of the twenty-two patients, eight had a radiologic score of 1 point. Five of them had good to excellent results with the Majeed outcome scale and six of them had fair results using the Pohlemann score.

These outcomes correlate with other studies where the concept of bad functional results and non-anatomical reduction of the posterior pelvic injury has been questioned [19].

Controversy still remains regarding the factors that affect the functional result in the treatment of unstable pelvic ring fractures [1]. Several studies like Suzuki et al. and Kokubo et al. showed that nerve damage has a significant relationship with unsatisfactory functional outcome [1, 20]

We did not find in our study a direct relationship between bad results and neurologic lesions.

Seven out of nine patients in the CRPF group with operative and non-operative neurologic injuries had good to

excellent results according to the Majeed score. The other two patients had poor results.

In the ORIF group, three out of five patients had good to excellent results. One patient had a fair result and the other patient had a poor result.

According to the Pohlemann score, the nine patients with associated neurologic injuries had fair results with the CRPF technique knowing that four of them had a radiologic score of 1 point which tends to decrease the overall score.

For the ORIF technique, three out four patients had fair results with a radiologic score of 2 points for two of them. The fourth patient had an excellent result.

The majority of the patients treated by CRPF and ORIF method with the worst Majeed and Pohlemann functional outcomes were young males (21 to 44 years old) with associated traumatic injuries (brain, thoracic, abdominal, upper and lower extremities).

In the CRPF technique, the three patients had C2 fractures without neurological lesions. Two of them had associated injuries and a radiological score of 1 point. The other patient had no associated injury and had a radiological score of 2 points.

In the ORIF technique, the two patients had a B3 fracture with associated injuries. One of them had a traumatic neurological lesion. Both patients had associated injuries. One patient had a radiologic score of 1 point and the other had a radiological score of 3 points.

## Blood loss

The disadvantage of the ORIF technique includes a major risk of bleeding due to the extensive surgical exposure to reach deep structures. The percutaneous technique popularized by Routt in the 1990s resulted in a decreased blood loss [8, 21]. The main factors are the lack of decompression of the intrapelvic hematoma and the decrease in intraoperative bleeding [22]. Our study confirms these observations with blood loss reduced by nearly half using the percutaneous technique knowing that the bleeding amount was probably overestimated in the CRPF group due to the simultaneous anterior approach and fixation (71%).

## Infection

Percutaneous sacroiliac screw fixation seems to be an attractive option for the infection rate. In the literature, the infection rate is undoubtedly high in the open method with reports of up to 25% [4]. In the ORIF technique, we found a rate of infection of 7.1% and none in the CRPF. These results for the CRPF technique correspond to the infection rate between 0 and 1% described in the Schweitzer et al. publication [9].

## Neurologic lesions

One of the potential disadvantages of percutaneous technique is the proximity of neurovascular structures, especially L5-S1 and iliac vessels [23], when inserting the screws [24]. Our study found one neurological lesion in the CRPF technique with a full recovery after changing the length of the malpositioned screws and one for the ORIF technique with a permanent L5 root palsy requiring an orthosis.

The CRPF method has well-recognized risks of nerve injury [25] but when performed with high-quality image intensification, the complication rates have been low [5, 7]. According to Giannoudis et al. [8], the risk of neurological damage in the CRPF technique was estimated between 0.5 and 7.7%.

Neurological assessment for pelvic fractures is essential but often difficult to perform in a polytrauma patient in the emergency room. Particular attention should be paid to the lumbosacral plexus (especially L5), the upper gluteal nerve and the pudendal nerve [25].

## Operative time and length of hospitalization

A comparison of operative time for CRPF versus ORIF technique is difficult due to the diverse types of pelvic ring injuries (non-versus displaced anterior or posterior pelvic ring fractures). In our study, the operative time is practically similar with an average of 139 min for the CRPF method versus 138 min for the ORIF method. In other studies, like Giannoudis et al. and Routt et al. the percutaneous technique shows a reduced operative time [8, 22]. In the Shuler et al. study, the mean operative time was of 52 min in 35% of the patients with only percutaneous screws without additional procedures [23]. However, the overall range was of 170 min.

No studies have compared the length of hospital stay between the two techniques. We found a median hospital stay of 23 days for the CRPF group versus a median hospital stay of 25 days for the ORIF group. The days of hospital stay for acute care were shortened by the transfer to other centers or to the clinical rehabilitation. Severe polytrauma patients had longer length of stay in both groups.

## Fluoroscopic and O-Arm

Screws can be inserted via an open approach in the prone position, or percutaneously in the supine position. The CRPF procedure is considered to be technically challenging and is associated with high screw malpositioning rates of up to 24% [26]. The first report of an open screw fixation of a sacroiliac dislocation was by Lehmann et al. (1934) [27]. Since then, the technique has undergone several modifications, based on Matta's widely established and standardized fluoroscopic projections (inlet and outlet) to evaluate the pelvic

ring lesion and control the screw placement intraoperatively [25]. Due to the limitations of 2D-fluoroscopic images, a repetitive change of the c-Arm projection (90° to another) is mandatory to visualize the guide wire position in all three dimensions during drilling. Furthermore, the experience of the surgeon in pelvic surgery and in navigation procedures is an important factor, which may further influence these parameters. As the experience of our team increased with the O-Arm, the operative timing decreased. It is also important to utilize a drill-tip guide wire as opposed to threaded. Further, important to advance the drill bit on oscillate and tap the bone to ensure the tip is in bone the entire way, i.e., and not out the sacral ala, in the foramen or in the sacral canal. Sometimes, proprioceptive manual feedback is difficult in patients with poor bone stock.

We have lately abandoned the use of the O-Arm because of the excessive long time for positioning of the patient and time spent to acquire intraoperative images. Instead, we are now using two fluoroscopies (inlet and outlet) during introduction of the guide wire with antero-posterior and lateral views control before inserting the cannulated screw [28].

The main limitation of this study is the small number of patients analyzed, faced in previous literature, which allows us only to affirm a decrease in intraoperative bleeding with CRPF method. There was no statistically significant difference between both techniques for the functional outcomes, the rate of infection, neurological injury, the operative time and the hospital stay.

## Conclusion

Closed reduction and percutaneous iliosacral screw fixation is a potential treatment for posterior pelvic ring injuries including minimally displaced SI joint dislocations, vertical sacral fractures and/or SI joint fracture-dislocations.

This technique has lately gained in popularity for its benefits including shorter operative time, decreased blood loss, lower infection risk, and ease of anterior surgery when indicated. Moreover, this method has increased interest and familiarity among early career orthopedic trauma surgeons.

In our study we found more than 70% of good to excellent results using the Majeed's score without a better quality of reduction compared to the ORIF technique and a statistically decrease of blood loss.

However, we could not affirm a clear superiority of this technique over the ORIF for functional results, neurologic lesions, infection rates, operative time and hospital stay.

We will need larger comparative studies in the future before the standardization of the percutaneous technique for unstable pelvic ring injuries.

## Compliance with ethical standards

**Conflict of interest** All authors declare that they have no conflict of interest.

**Ethical approval** The ethics committee approved the study (2017-02091).

**Human and animal rights** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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

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