

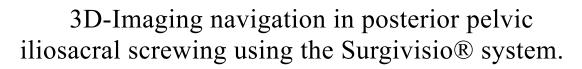
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#### Abstract

The recent studies about iliosacral screws performed with navigation systems show promising results. The Surgivisio system is a new generation of intraoperative 3D imaging technique used in our institution since two years. The aim of this prospective study was to evaluate the accuracy of iliosacral screw placement and radiation exposure with the Surgivisio® system.

Between January 2018 and December 2019, every patient operated for percutaneous iliosacral screwing using the Surgivisio® system were included in this prospective single center study. Accuracy of screw placement was assessed with post-operative high-resolution CT-scan. Operative time, radiation exposure and complications were assessed.

A total of 32 patients were included with 49 iliosacral screws. Using the modified Gras classification, 2% (1/49) were rated as misplaced and 2% (1/49) were repositioned. The mean operative time was 26 min for the whole procedure. The mean dose area product was 7.98 Gy.cm<sup>2</sup>. Two complications were recorded (neurological pain treated by removal of the misplaced screw, an asymptomatic cement leakage with one augmented iliosacral screw).

The Surgivisio® system is an efficient navigation tool for iliosacral screwing in minimal invasive surgery. It improves the accuracy of screw placement with an acceptable radiation exposure and operative time.

### 1 Introduction

Correct placement of iliosacral screws remains a surgical challenge. With conventional fluoroscopy the percutaneous procedure is associated with high screw misplacement rates of up to 24% [1,2]. The presence of dysmorphic sacral foramina or increased alar slopes is known to increase the incidence of

screw malpositioning [3]. Some authors recommend the use of computer navigation in iliosacral screw placement with promising results [4].

The Surgivisio® system is an all-in-one 2D/3D imaging and real-time navigation device which enables pedicle navigation in minimal invasive spine surgery and for which no clinical series have been published yet.

The aim of this prospective study was to evaluate the accuracy of iliosacral screw placement and radiation exposure with the Surgivisio® system.

#### 2 Materials and Methods

Between January 2018 and December 2019, every patient operated for percutaneous illosacral screwing using the Surgivisio® system were included in this prospective single center study.

Demographic data such as age, sex, body mass index, surgical indications (traumatic or neoplastic) For traumatic indications, energy of the trauma, fracture pattern according to the Tile classification, and surgical management were collected [5]. Sacral bones were classified as dysmorphic according to the Kaiser criterias [6]. Several surgeons performed the surgical procedure. The operative time for the whole procedure was recorded. Radiation exposure was calculated for the whole procedure thanks to the final dose area product (DAP) in Gy.cm2. A 1-mm pelvic CT scan was performed post-operatively and accuracy of screw placement was assessed using the modified Gras classification by an independent observer as follow: I.secure positioning, completely in the cancellous bone; II. secure positioning, but contacting cortical bone structures; III. malplaced positioning, penetrating the cortical bone; IV. Necessity of surgical removal [7].

Patients were operated under general anesthesia in a prone position on a standard operating carbon table (Allen, Massachusetts, USA).

The Surgivisio device (Surgivisio Company, Gières, France) is a unique system offering the possibility to perform 2D/3D imaging and real time navigation through a single platform.

Three main steps are required to perfom the navigation :

• Placement of the patient reference fixed to the spine process in L4, L5 and S1 or to the posterior iliac crest (Fig.1).

• Images acquisition and 3D reconstruction with an optimized C-arm trajectory to maximize the reconstruction volume and reduce the X-ray dose. The surgical staff goes outside of the room during this image acquisition and therefore is not subject to X-ray radiation. The calibration phantom is detected automatically on all projections. The set of projections is automatically calibrated intrinsically and extrinsically with respect to the calibration phantom. Using this auto-calibration method, the 3D image is reconstructed by compensating any patient motion, breathing or any deformation of the C-arm (Fig.1).

• Navigation: the calibration phantom is replaced by a patient optical tracker at a precisely known location, using a magnetic reproducible fixation on the patient reference. The surgeon uses a factory-calibrated single use trocar equipped with a tracker and can immediately visualize the trocar position on reconstructed slices in the 3D image and navigate (Fig.1).

Ilio-sacral screw fixation was performed using 7.3 cannulated titanium screws (Depuy Synthes, Switzerland) with cement augmentation using Vertaplex HV (Stryker, Pusignan, France) when necessary.

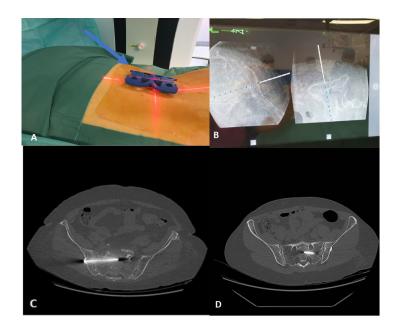


Figure 1: The "Butterfly" single-use calibration phantom placed on the patient reference (blue narrow) (A). 3D images reconstruction, axial, coronal and sagittal slices (B). Post-operative pelvic CT-scan of a patient with bilateral screwing (C and D).

Statistical analysis used StatView 5.5 software (SAS Institute, Cary, NC, USA).

## 3 Results

A total of 32 patients (15 women, 17 men) with a mean age of 55.4 years were included. A total of 49 iliosacral screws were navigated. The main indication was high-energy trauma accident (71.4%). The mean operative time was 26 min. Eighty-two percent of the screws (40/49) were performed in "difficult" sacrum (dysplasia, bilateral screwing and/or cement augmentable screwing). Using the modified Gras classification 98% (48/49) were rated as acceptable. The mean dose area product was 7.98 Gy.cm<sup>2</sup> (1.27-24). Two complications (4%) and one re-intervention (2%) were recorded during the follow-up. The results are summarized in Table 1.

Mean	Whole serie (n=32)	lliosacral screws (n=49)
Sex ratio		
Male	17	
Female	15	
Age, years (range)	54.4 (19-88)	
BMI (kg/m2)	23.24 (15.4-39.2)	
Surgical indication		
Traumatology	28	42
Tumoral	4	7
Surgical time, minutes (range)		
whole procedure	95 (39-180)	95 (39-180)
Tile classification		
A3 (H or U shape sacral fracture)	15	30
В	15	15
С	2	4
Iliosacral screwing difficulties		
Sacral dysmorphism	13	24
bilateral screwing	15	30
cement augmentable screwing	6	8
Screw placement (modified Gras classification)		
Grade I		35
Grade II		12
Grade III		1
Grade IV		1
Radiation exposure		
DAP (Gy.cm2)	7.98 (1.27-24.0)	7.98 (1.27-24.0)

Table 1: Demographical data, radiological results and radiation exposure

#### 4 **DISCUSSION**

This study is the first clinical series that evaluates accuracy of iliosacral screw insertion and radiation exposure with the Surgivisio system. Although the majority of screwings were difficult due to sacral dysmorphism, bilateral screwing and/or cement augmentation, the rate of screw malpositioning is remarkably low. Our results are similar to the literature, showing an interest of navigation in iliosacral screwing, without increase of the operative time and radiation exposure compare to other navigations devices [8].

The Surgivisio® system is an efficient navigation tool for iliosacral screwing in minimal invasive surgery. It improves the accuracy of screw placement with an acceptable radiation exposure and operative time.

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Conflicts of interest: Delphine Carmagnac has no conflicts of interest to disclose, in relation to the present study or elsewhere. Mehdi Boudissa, Gael Kerschbaumer and Jérôme Tonetti are consultants for the Surgivisio® Company