

Biomechanical analysis of two insertion sites for the fixation of the sacroiliac joint via an oblique lateral approach

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Roxanne Dubé-Cyr, Carl-Éric Aubin, Isabelle Villemure, Rohan-Jean Bianco, Yves Godio-Raboutet, et al.. Biomechanical analysis of two insertion sites for the fixation of the sacroiliac joint via an oblique lateral approach. Clinical Biomechanics, 2020, 74, pp.118-123. 10.1016/j.clinbiomech.2020.02.010. hal-03226860

HAL Id: hal-03226860 https://amu.hal.science/hal-03226860

Submitted on 15 May 2021

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2	oblique lateral approach
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19	Declarations of interest: Medtronic provided the implants and surgical kit for the study. Carl-Éric Aubin
20	is currently receiving funding from the Natural Sciences and Engineering Research Council of Canada
21	(Industrial Research Chair program with Medtronic of Canada). The other authors have no conflict of
22	interest to declare.
23 24	Research Ethics Committee:
25	Polytechnique Montreal: CÉR-1617-30
26	
27	Word count:
28	Abstract : 250 words
29	Manuscript: 3123 words
30	

Biomechanical analysis of two insertion sites for the fixation of the sacroiliac joint via an

Abstract

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32 Background. The sacroiliac joint is an important source of low back pain. In severe cases, sacroiliac joint 33 fusion is used to reduce pain, but revision rates can reach 30%. The lack of initial mechanical stability may 34 lead to pseudarthrosis, thus not alleviating the patient's symptoms. This could be due to the damage 35 induced to the interosseous ligament during implant insertion. Decoupling instrumentation steps (drilling-36 tapping and implant insertion) would allow to verify this hypothesis. Moreover, no biomechanical studies 37 have been published on sacroiliac joint fixation with an oblique lateral approach, while it has important 38 clinical advantages over the lateral approach. 39 Methods. Eight cadaveric human pelves with both ischia embedded were tested in three sequential states: 40 intact, drilled-tapped and instrumented with one cylindrical threaded implant with an oblique lateral 41 trajectory. Specimens were assigned one of two insertion sites (distal point; near the posterior superior iliac 42 spine, and proximal point; anterosuperior to the distal point) and tested in compression and flexion-43 extension. Vertical and angular displacements of the sacroiliac joint were measured locally using digital 44 image correlation methods. 45 Findings. In compression, instrumentation significantly reduced vertical displacements (17% (SD 22%), 46 P=0.04) but no difference was found for angular displacements or flexion-extension loads (P>0.05). 47 Drilling-tapping did not change the stability of the sacroiliac joint (P>0.05); there was no statistical 48 difference between the insertion sites (P>0.05). 49 Interpretations. Insertion of one implant through either the distal or proximal insertion site with an oblique 50 lateral approach significantly reduced vertical displacements of the sacroiliac joint in compression, a 51 predominant load of this joint. 52 53 Key words. Sacroiliac joint, sacroiliac joint fixation, sacroiliac joint fusion, arthrodesis, biomechanics, 54 minimally invasive surgery 55 56

1. Introduction

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The sacroiliac joint (SIJ) ensures the transmission of important forces from the spine and upper body to the lower limbs. The SIJ generates pain in 15 to 30% of patients suffering from low back pain ¹. Treatment options include anti-inflammatory medication, physical therapy, sacral belt, and in last resort, surgical fusion. For the latter, implants are inserted across the sacrum and ilium through the SIJ to allow mechanical stability. An osseointegration process begins and the opposing bony surfaces start to biologically fuse. In a meta-analysis evaluating five clinical outcome measures, minimally invasive SIJ fusion was proven effective for alleviating girdle pain ². Minimally invasive SIJ surgeries limit tissue exposure during surgery and only necessitate a 3-cm long incision while offering greater pain relief than open surgeries³. Still, the fusion rate ranges from 25 to 88% after 12 months ⁴⁻⁸. Patients with persistent or recurrent pain may require a revision surgery, with revision rates reaching 30% after 4 years ⁹. As the quality of the biological fusion and osseointegration is linked to the initial mechanical stability 10, researchers have investigated the effect of instrumentation on SIJ range of motion (RoM). In cadaveric studies, instrumentation with either two cylindrical and threaded implants, or three implants with a triangular cross-section significantly decreased the RoM by 27% to 54% 11-14. However, the SIJ RoM is not significantly reduced for all specimens. Counterintuitively, the SIJ RoM is sometimes increased following fixation ^{11,12,14}. In a clinical setting, an insufficient reduction in SIJ RoM may lead to pseudarthrosis, which does not alleviate the patient's symptoms. Increased RoM could be explained by the damage to the interosseous ligament (IOL), the strongest and largest of SIJ ligaments 15 during implant insertion. The IOL directly connects the SIJ surfaces together, so a modification to its integrity could lead to a loss of stability greater than the stability gain provided by the implants. This hypothesis could be verified by isolating the effects of drilling and tapping on SIJ stability, which has not been done before. Decoupling instrumentation steps (drilling-tapping and implant insertion) would allow a better understanding of SIJ biomechanics and SIJ fixation. SIJ initial mechanical stability also depends on certain surgical choices like the surgical approach and implant trajectory, as well as the type, size, and number of implants. For instance, the two main surgical approaches for minimally invasive SIJ fixation are the direct lateral and the oblique lateral approaches,

respectively referred to as lateral and oblique in the text for simplicity. Compared to the oblique approach, the lateral approach requires considerably more dissection of the gluteal muscles (medius and maximus). However, most of the recent clinical studies have used the lateral approach with triangular dowel implants and are industry-sponsored ¹⁶. Recently, two retrospective studies have compared the lateral and oblique approaches, using triangular implants and cylindrical threaded implants respectively. Majd et al. found the oblique approach to be superior for some clinical outcomes (higher rate of significant improvement on the visual analogue scale (VAS) (65% vs 45%), lower estimated blood loss (33cc vs 60cc), lower adverse event rate (6.7% vs 20%) ¹⁷. However, significance was not mentioned. Claus et al. found that both approaches led to a significant improvement of the Oswestry Disability Index (ODI) and SF-12 (Short Form-12 health survey) scores, without a significant difference between the two techniques ¹⁸. Length of stay, estimated blood loss were not statistically different between the groups but the oblique approach had a significantly longer surgery (60 min vs 41 min) 18. Revision rate was higher for the oblique approach compared to the lateral approach (6.1% vs 2.4%), but the difference was not statistically significant. Many experimental and numerical studies have been conducted on the lateral approach 11-14,19-21 compared to only one numerical study on the oblique approach 22. Bruna-Rosso et al. simulated an oblique SIJ instrumentation using a finite element model of the pelvis with one to two threaded implants and compared two insertion sites and two implant orientations ²². Placing the implant farther from the SIJ center of rotation (CoR) (located at the axial interosseous ligament according to Farabeuf's theory ²³) and using an orientation more parallel to the SIJ CoR led to a better stabilization of the SIJ subjected to compression loads. No cadaveric studies have been published on this approach, but such study would allow a better understanding of oblique fixation and help further reduce revision rates.

Hence, the current study aimed to experimentally measure the isolated effects of drilling and tapping as well as the effects of oblique SIJ fixation on SIJ RoM while comparing two possible insertion sites. It was hypothesized that instrumenting the SIJ with one implant would lead to significant motion reduction and that there would be a significant difference between the two tested insertion points.

2. Methods

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2.1 Specimen preparation

The pelves (sacrum and iliac bones) of eight human specimens (age ranged from 73 to 94 years old; Table 1) embalmed with a zinc chloride solution were harvested. They were thawed at room temperature and cleaned of muscle tissue while keeping the ligaments of the SIJ intact (anterior, posterior, IOL, sacrotuberous and sacrospinous ligaments). CT-scans were taken to ensure there were no anomalies like bone bridging. Bone mineral density was measured with a calibration phantom (Model 062M Electron Density Phantom, CIRS Inc., Virginia, USA). Specimens were wrapped in saline-soaked gauze, placed in plastic bags and stored at -20 °C. The day before testing, they were thawed at room temperature and placed in neutral position (i.e. anterior superior iliac spine in line with the pubic symphysis in the vertical plane). The inferior part of the specimens was embedded in a bloc of fast-curing resin (1:1 mixture of F18 Polyol and F18 Isocyanate, Axson Technologies, Cergy, France) up to the obturator foramina in a double-leg stance model (Fig. 1A). They were wrapped in saline-soaked gauze and put in a refrigerator (4 °C) until the next day. Right before the beginning of the tests, a random speckle pattern was produced on the anterior SIJ surfaces using a black spray paint over uniform white paint (Fig. 1A).

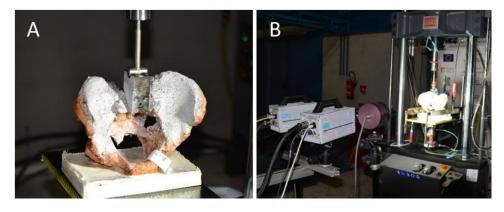
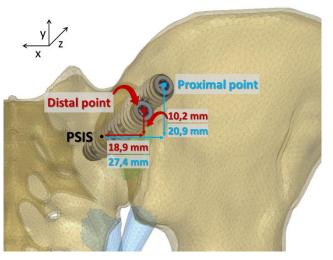


Fig. 1 Experimental set-up: A) Double-leg stance model and B) camera position

2.2 Test procedure

Specimens were randomly divided into two equal groups (n=4/group) and assigned one of two insertion sites. The distal point was located near the posterior superior iliac spine (PSIS) (Fig. 2). The proximal point was positioned anterosuperiorly to the distal point ²².



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Fig. 2 Insertion points tested and implant trajectory - Posteroanterior view

Metal bars and clamps rigidly fastened the resin bloc to a 370.02-15kN MTS servohydraulic system (MTS Systems, Créteil, France) (Fig. 1B). A custom metal piece was firmly fixed on the endplate of S1 with wood screws. The displacements between the sacrum and the ilium were measured in three states. First, the specimens were tested in the "intact state" under compression and flexion-extension (FE) loads (see next paragraph) to obtain a reference RoM and allow subsequent comparison. Next, using a posteromedial approach (Fig. 2)²², we positioned a guidewire using a template to ensure repeatability of the insertion sites. Then, a drill and a depth-stop were used over the guidewire to drill a 12-mm diameter hole for a 50-mm long threaded, cannulated and fenestrated implant (RIALTOTM Sacroiliac Joint Fusion System, Medtronic, Memphis, TN, USA). With a surgical tap, we threaded the insertion hole and tested the specimens for the "drilled state". Finally, the implant was inserted and specimens were tested again in the "instrumented state". All implants were inserted on the right side. Implant position was confirmed with a CT-scan after testing. Specimens were tested in compression and FE under quasi-static loads (10 N/s) preceded by 15 preconditioning cycles (0.5 Hz) of 40 N. The compression loads (i.e. vertical axis) reached 500 N and were applied with a hinge joint (Fig. 3A). The two cycles of FE (i.e. sagittal plane) ranging from -7.5 Nm to 7.5 Nm were applied with a pivot joint. The FE moments were achieved with a lever arm and a 5-kg weight, resulting in a combined compression ranging from 25 to 175N respectively (Fig. 3B). A total of six tests were performed for each specimen. On average, it took 120 minutes to perform the tests (time ranged from 80 to 185 minutes). To avoid dehydration during testing, saline-soaked gauzes were applied posteriorly on the sacrum, covering the posterior portion of the SIJs. It was not possible to apply saline-soaked gauzes on the anterior portion of the SIJs because of the speckle pattern.

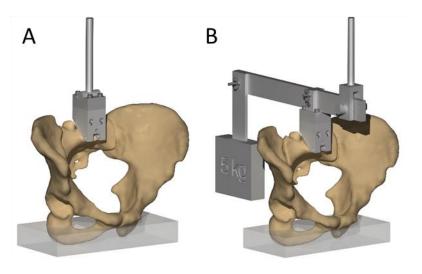


Fig. 3 Experimental devices for A) compression and B) flexion-extension loads (combined with compression)

2.3 Data measurement and analysis

Two 1MP cameras (FASTCAM SA3 Model 120K, Photron Europe Limited, West Wycombe, UK) were placed with a 20° to 25° angle between them (Fig. 1B). The intra-articular displacements were measured locally with the Correlated Solutions VIC-3D measurement system (Correlated Solutions Incorporated, Columbia, SC, USA). This system calculated the three-dimensional displacements on the surface nearby the joint based on the principle of digital image correlation (DIC). In-plane precision was under 0.005 mm while out-of-plane precision was 0.01 mm.

Using the VIC-3D software, we numerically selected sets of three points along the right SIJ (three on the ilium and three on the sacral ala) for a total of six points (Fig. 4). The relative vertical displacements (VD) (z-axis) of the sacrum was computed with regards to the ilium. The vertical displacement of the ilium (pt. 2) was subtracted from the vertical displacement of the sacrum (pt. 5) throughout loading, and the maximum value over time was reported. To measure the relative angular displacements (AD) in the sagittal (x-z) plane, lines connecting the top and bottom points for each set of points (1-3; 4-6) were virtually drawn. Next, the angle between the sacral ala and the ilium was computed before (θ_B) and throughout loading (θ_A) using the lines' slopes. The angle difference over time ($\Delta AD = \theta_A - \theta_B$) was measured. For

the FE loads, the values reported represent the total RoM, i.e. the maximum AD in flexion added to the maximum AD in extension. Both VD and AD were computed for each loading scenarios.

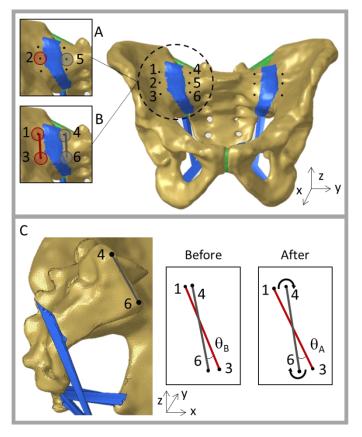


Fig. 4 Representation of the selected points for the measurement of SIJ relative A) vertical displacements (VD) and B) angular displacements (AD). C) Side view of the sacrum for the measurement of AD. For visualization purposes only.

2.4 Statistical analysis

Statistical analysis was made with Statistica (v13.3; TIBCO Software Inc., Palo Alto, CA, USA). A Wilcoxon signed rank test was applied to compare the "drilled state" and the "instrumented state" to the "intact state" and check for significant differences. This type of analysis takes into account the intervariability that is inherent to cadaveric testing. The two insertion sites were compared by applying a Mann-Whitney U test on the normalized data (percentage change with regards to the "intact state" of each specimen). For all statistical tests, the significance level was set at 0.05.

3. Results

Seven specimens completed the testing protocol (Table 1). One specimen (ID1) deteriorated at the end of the second test and was therefore not included in the analysis. The age ranged from 73 to 94 years. No bone bridging was detected from the CT-scans.

187 Table 1 Specimen information

Specimen	Sex	Age (yr)	Bone mineral density (mg/cm³)
*ID1	Н	88	90
ID2	F	74	155
ID3	Н	73	200
ID4	Н	73	105
ID5	Н	76	90
ID6	Н	83	35
ID7	Н	94	95
ID8	F	83	80
*Mean		79.4	108.6
SD		7.8	53.7

Note: *Means and SD calculated without ID1

Intra-articular displacements of adjoining sacrum and ilium of the "intact state" ranged from 0.08 mm to 2.20 mm for VD (translation) and from 0.15° to 2.83° for AD (rotation) (Table 2). No significant difference was found in compression or in FE between the "intact state" (CI: 0.14 - 1.36 (compression, VD), 0.05 - 0.40 (FE,VD), CI: 0.01 - 1.70 (compression, AD), 0.16 - 0.75 (FE, AD)) and the "drilled state" (CI: 0.14 - 1.19 (compression, VD), 0.06 - 0.41 (FE,VD), CI: -0.01 - 1.52 (compression, AD), 0.14 - 0.79 (FE, AD), (P > 0.05). In compression, insertion of the implant led to a significant decrease of VD compared to the "intact state" (CI: 0.08 - 1.16, P = 0.04). It had no significant effect on AD (CI: 0.001 - 1.56) (P > 0.05). In FE, the implant had no significant effect on VD (CI: 0.06 - 0.36) or AD (CI: 0.21 - 0.68) (P > 0.05). There was no significant difference between the two insertion sites in compression (CI: -37.37 - 2.96 (VD), CI: -33.25 - 19.81(AD)) or in FE (CI: -35.50 41.33 (VD), CI: -22.41 - 35.94 (AD), P > 0.05) (Table 3).

Table 2 Relative SIJ displacements of the instrumented side

	Insertion - point _	Compression			Flexion-extension		
Specimen		Intact	Drilled	Instrumented	Intact	Drilled	Instrumented
		Vertical displacement - VD (mm)					
*ID1	1	0.21	-	-	0.04	-	-
ID2	2	0.55	0.37	0.33	0.10	0.12	0.10
ID3	1	0.49	0.48	0.25	0.19	0.23	0.11
ID4	2	0.56	0.42	0.46	0.16	0.14	0.20

ID5	1	0.48	0.49	0.45	0.19	0.16	0.11
ID6	2	0.72	0.71	0.67	0.25	0.28	0.30
ID7	1	0.23	0.28	0.27	0.08	0.08	0.13
ID8	2	2.20	1.91	1.90	0.64	0.63	0.53
*Mean		0.75	0.66	0.62	0.23	0.24	0.21
SD		0.66	0.56	0.58	0.19	0.19	0.16
			Angular displacement - AD(°)				
*ID1	1	0.23	-	-	0.33	-	-
ID2	2	0.27	0.36	0.32	0.15	0.20	0.23
ID3	1	0.97	0.48	0.48	0.42	0.50	0.29
ID4	2	0.48	0.56	0.54	0.42	0.21	0.49
ID5	1	0.41	0.36	0.47	0.36	0.36	0.50
ID6	2	0.82	0.75	0.79	0.50	0.59	0.48
ID7	1	0.20	0.17	0.21	0.22	0.20	0.19
ID8	2	2.83	2.58	2.64	1.13	1.19	0.94
*Mean		0.85	0.75	0.78	0.46	0.46	0.45
SD		0.91	0.83	0.84	0.32	0.36	0.25

Note: *Means and SD calculated without ID1

Table 3 Comparison of the RoM change (%) for the insertion points tested (average, and each specimen values)

Percentage change (intact vs. instrumented) (%)

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Load	Displacement	Distal insertion point (n=4)	Proximal insertion point (n=3)	P-value (Mann-Whitney U)
G	VD	-20 (-41; -19; -6; -14)	-14 (-49; -6; +14)	0.63
Compression	AD	+4 (+16; +13; -4; -7)	-10 (-50; +17; +4)	0.63
	VD	+9 (+6; +25; +20; -17)	-5 (-44; -43; +72)	1.00
FE	AD	+12 (+55; +15; -3; -17)	-1 (-31; +41; -12)	0.63

4. Discussion

We experimentally measured the isolated effects of drilling and tapping as well as implant insertion on SIJ stability and compared two insertion sites using image correlation methods. The VD of the intact SIJs agree with previous studies, which reported means ranging from 0.32 to 0.7 mm ²⁴⁻²⁶. The measured AD are in line with rotations measured *in vivo* (means of 0.5° and 0.8°, respectively) ^{27,28} but are below AD reported in most *ex vivo* studies (means ranging from 1.3° to 4.5° for similar FE loads) ^{11-14,26}. Those *ex vivo* studies had younger subjects and higher female to male ratios, both factors increasing SIJ mobility. Moreover, the single-leg stance model used in these studies increases the shear force ²⁹ and thus leads to larger SIJ displacements. The rehabilitation guidelines by Dall et al. recommend to avoid single-leg stance until bony fusion has occurred, which is usually within 6 to 8 weeks ²⁹. Cadaveric testing aims to simulate the initial

postoperative stabilization; therefore, a double-leg stance model was deemed appropriate. The distance from the SIJ to the reference point on the ilium may also influence the reported RoM. Lindsey et al., Soriano-Baron et al. and Jeong et al. placed their marker on the iliac wings, near the anterior superior iliac spine, while Shih et al. placed it near the acetabulum ^{11-13,21}. Hammer et al. quantified the RoM of the ilia during compressive loading of L5 and showed motion was present between the SIJ and the pubic symphysis ²⁶, meaning the ilium should not be considered as a rigid body. Using a double-leg stance model, they found a negligible AD of the sacrum with regards to the ilium of 0.01°. In the present study, DIC allowed to select iliac reference points millimeters away from the articulation, which may give a better representation of the actual relative displacements of the SIJ. The loads used in this study do not represent all possible loads present in the pelvis. Compression is the most important load of the SIJ because it is almost always present in most diurnal postures and motions (i.e. upper body weight) and contributes to the stability of the pelvic ring ³⁰. FE is also involved in several tasks, and puts even more loads on the SIJ. In this study, it was modeled with a lever-arm that led to a combination of FE and compression. This type of loading may be more realistic than pure moments, which do not take into consideration the stability provided by the compression and force-closure mechanisms. Lateral bending and axial rotation were not included, but could be tested in future studies to assess a wider variety of possible loadings. Drilling and tapping for one implant unilaterally did not destabilize the SIJ. Therefore, the damage to the IOL created to insert an implant does not explain why some specimens lose stability after instrumentation. The maximum cross-section area of IOL that was cut (≈115 mm²) remains relatively small compared to its total section of approximately 750 mm² ³¹. In a study by Dall et al., transecting the entire posterior ligament complex (including the IOL) led to a significant, but relatively small increase of motion, with AD staying under 2°29. This could be because form-closure mechanisms such as the self-locking arrangement of the pelvis and the fitting ridges and grooves of the articular surfaces provide great stability to the SIJ ³⁰. Thus, SIJ stability relies only partially on the IOL. Another possible explanation for the lack of initial mechanical stability could be poor bone quality, but additional testing needs to be done.

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Implant insertion significantly decreased VD for the compression load, with an average reduction of 17% (SD 22%), which is likely not enough to lead to an osseointegration. Instrumentation with one implant contributed relatively little to the stabilization of the SIJ, and had no significant effect on AD and for FE loads. Likewise, Jeong et al. did not find a significant decrease of AD in FE following instrumentation with three triangular implants ²¹. Contrastingly, similar studies have reported a significant decrease of AD in FE using two or three implants ¹¹⁻¹⁴. However, most of them compared the RoM of the instrumented state to a "destabilized" state (posterior ligaments and/or pubic symphysis cut) ¹¹⁻¹³, which may amplify the action of the implants. In the current study, the "instrumented state" consisted of only one implant and was compared to the "intact state". Because of the rotatory nature of the SIJ biomechanics, one fixation point may not be enough to successfully restrain different types of movements, especially given the proximity of the implant to the CoR of the SIJ, located near S2 ²³. Adding more implants may reduce this effect and further increase stability, but additional testing is necessary.

The position of the two clinically plausible insertion sites tested did not lead to statistically different RoM reduction in the case of a one-implant scenario, as opposed to the previous numerical study of Bruna-Rosso et al ²². The distance between the two tested sites was less than 15 mm, which might be too small to have an impact on the RoM. Hence, both insertion points provided a comparable SIJ stabilization.

Some mobility always remains *ex vivo* following instrumentation ^{11-14,21}, and it is hard to define a clinically significant RoM reduction. Muscular activity further stabilizes the SIJ *in vivo*, but remaining micromovements may hinder the osseointegration process. The ideal RoM restriction threshold to allow proper SIJ fusion is not known. Such threshold would be relevant to define clinical significance and assess the proper action of SIJ fusion implants and how it relates to the patient's pain.

This experimental study has some limitations. Results may have been influenced by freeze-thaw cycles, the duration of the tests and embalmment. Tan et al. studied the effect of freeze-thaw cycles, and multiple within- and between-day testing on human cadaveric lumbosacral spine ³². They found that the initial four freeze-thaw cycles had no significant effect on the RoM of the segments and that cumulative testing (8 tests; up to 12 hours) within a single day did not lead to significant differences in RoM. In the present study, each specimen went through two freeze-thaw cycles and testing was done in a single day, in under 3

hours, so the impact on the results are thought to be minimal. However, because of the paint and speckle pattern, it was not possible to keep the anterior part of the SIJ moist with saline-soaked gauzes once the tests started. The anterior ligaments may have dried up and stiffened, possibly contributing to the small displacements measured. Given that the tests were performed in 120 minutes on average, we believe that the ligament of interest, the IOL, was deep enough to stay hydrated throughout testing. As for embalmment, it may also have stiffened the ligaments of the SIJ, which may have affected the results, especially regarding the effect of drilling through the IOL. However, unlike a true synovial joint, the biomechanics of the SIJ relies largely on form-closure mechanisms of the pelvis (i.e. shape of the bones) that are independent of soft tissues, thus we believe the effect of soft tissue stiffening was limited. The specimens were old with varying bone quality and this might have affected the SIJ RoM. However, the CT-scans showed no bone bridging or other anomalies. In addition, the measured effect of the implants was obtained on the basis of comparison, so the conclusions drawn likely remain valid.

5. Conclusions

This is the first biomechanical study to investigate SIJ fusion via an oblique approach. We measured the isolated effects of drilling-tapping and instrumentation on SIJ stability and compared two different insertion sites. Drilling through the IOL did not increase the intra-articular displacements of the SIJ, and thus this hypothesis is rejected. Our main hypothesis was only partly accepted, as instrumenting the SIJ with one implant significantly decreased vertical displacements in compression but led to no motion reduction in flexion-extension and no significant difference between both insertion sites.

6. Acknowledgments

The authors acknowledge the support of Dr Kathia Chaumoître, MD, and the Assistance Publique-Hôpitaux de Marseille, (Hôpital Nord, Marseille, France) for their radiologic expertise. The authors would also like to thank: the A*MIDEX foundation, MITACS Globalink, the Fonds de recherche du Québec – Nature et technologies and the Natural Sciences and Engineering Research Council of Canada (Industrial Research Chair program with Medtronic of Canada – grant number: PCIPJ-346145) for their financial support and Medtronic for providing the implants and surgical kit for the study.

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