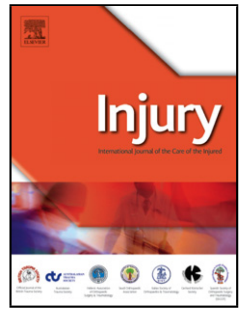

Title: Percutaneous Iliosacral Fixation in External Rotational Pelvic Fractures. A Biomechanical Analysis

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TITLE PAGE.

PERCUTANEOUS ILIOSACRAL FIXATION IN EXTERNAL ROTATIONAL PELVIC FRACTURES.
A BIOMECHANICAL ANALYSIS.

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Conflict of interest statement.

There are no conflicts of interest.

Keywords: biomechanic, pelvis, open-book fracture, Young-Burgess fracture, screw, minimally invasive fixation.

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ABSTRACT.

Introduction: Although the gold standard in open book pelvic fractures remains the pubic symphysis (PS) plate fixation, the clinical outcomes are not satisfactory, despite the excellent anatomical reduction assessed radiologically. Some authors suggest that residual instability of the posterior pelvic elements may be responsible for the chronic pain and the early osteoarthritic changes in the sacroiliac joint (SIJ).

Objective: To evaluate whether the isolated posterior fixation with one or two iliosacral screws (ISSs) is sufficient to provide adequate stability for the treatment of Burgess Young APC-II (YB APC-II) type of pelvic ring injuries.

Methods: Biomechanical experimental study using 7 fresh human pelvises, where an YB APC-II pelvic injury was previously implemented. The isolated posterior fixation of the pelvic ring with 1 or 2 ISSs directed in the S1 vertebra body was analysed in each specimen following an axial load of 300N. The different displacement of the SIJ and of the PS were analysed in all three spatial axes, using the validated optical measurement system 3D PONTOS 5M. A multivariate version of Friedman test (non-parametric ANOVA for repeated measures) was performed.

Results: The isolated fixation of the SIJ with 1 ISS did not show any differences with respect to the intact pelvis (p = 0,851). Regarding the PS, both type of fixations (with 1 or 2 ISSs) confirmed an acceptable correction and adequate control of the PS even though with some differences compared to the intact pelvis (p = 0,01). The presence of the second ISS found not to offer any significant additional benefit. The three-dimensional analysis of the behaviour of the pelvic elements, in these two different types of fixation, did not show any statistical significant differences (p = 0.645).

Conclusion: The posterior fixation with ISS can represent an alternative option for treatment of pelvic injuries associated with rotational instability. Further prospective clinical studies are necessary to determine, the influence of the residual pubic symphysis mobility in the every day life, when the above-mentioned technique is applied.

KEYWORDS.

Biomechanic, pelvis, open-book fracture, Young-Burgess fracture, screw, minimally invasive fixation.

INTRODUCTION.

Pubic symphysis (PS) plating is considered nowadays the gold standard of treatment of open book pelvic lesions with partial preservation of the posterior anatomical structures (Young Burgess APC-II (YB APC-II)[1] or AO/Tile B1[2,3]) [2,4,5]. In spite of a high rate of radiologically confirmed anatomic reduction of the symphysis joint, clinical outcomes reveal that 32.2% of patients report persistent pelvic back pain in the long-term[6]. These clinical results are analogous to those pelvic lesions characterised by complete disruption of the posterior pelvic ring elements[7,8].

Residual pain and secondary arthritis of the sacroiliac joint (SIJ)[4,9] have been reported in patients who sustained antero-posterior compression pelvic injuries with partial lesion of the SIJ treated solely by plating of the PS. Not surprisingly, several authors questioned whether this strategy of stabilisation of these pelvic ring lesions is sufficient[10,11,12,13,14,15] to adequately control the SIJ. It was argued that the potential micro-instability component in SIJ[10,15,16] following the injury may represent the cause of the contradictory results between optimal post-operative radiological findings of the anatomical reduction, with respect to the less satisfactory functional outcome during the long term follow up. Osterhoff[17] et al. have recently concluded that "percutaneous sacroiliac screw fixation alone is a sufficient technique for the stabilization of rotationally unstable pelvic fractures". The authors of the study underlined the importance of restoring the integrity of the posterior pelvic arch.

Considering that pain is mainly located in the posterior region of the pelvic ring, precisely at the SIJ, is one incorrect to postulate whether anterior fixation of the PS is insufficient to guarantee stability of the posterior elements of the pelvic ring? Moreover, is it possible to restore the pelvic ring anatomy and prevent the micro-movements of the SIJ by solely posterior fixation? The literature regarding this clinical situation remains obscure. The aim of this study therefore is to determine the degree of pelvic stability after isolated posterior fixation using one or two iliosacral screws (ISSs) as definitive treatment in pelvic external rotation injuries (Young Burgess APC-II (YB APC-II) or AO/Tile B1).

MATERIALS AND METHODS.

Seven female human freshly-frozen anatomical specimens were used, (i.e. not embalmed cadavers) for this study. The mean age of the specimens was 73,9 (SD ±13,85) years. None of the donors had any previous medical history of skeletal disorders. The cadaveric specimens were dissected in such way as to obtain a configuration including the L4-L5 vertebrae, the whole pelvis and also the lower third of both femurs. In all specimens the articular capsule and ligaments of the PS and SIJ were spared, including the sacrospinous and the sacrotuberous ligaments. The soft tissues of the lumbar spine and of the hip joints were spared as well.

After preparation, the anatomical specimens were frozen to below -20 °C[10,12,18,19,]. Before running the tests, the specimens were defrosted and hydrated by immersion in room temperature water for 16-20 hours. In this way the mechanical changes of the bone and the ligaments due to the freezing process and the dehydration were minimised. For the same reason the anatomic specimens were moistened with water before and during the experiments[12,19].

For the purposes of this study an electromechanical machine type Zwick / Roell Z100 (BT1-FB100TN), able to apply vertical loads, controlled by the test Xpert II software, was used. A patented and registered device[12,20] was attached to the electromechanical machine in order to appropriately anchor the pelvis specimens and simulate the standing position and alignment in the same sagittal plane of the anterior superior iliac spines and of the pubic tubercles[19]. Due to the properties of this specific device, it was possible to analyze the biomechanical behavior of the fractured pelvis. The specimens were fixed proximally at an angle of 130° on a metallic plate attached on the vertebral bodies with 4 screws, 4 mm each, and 6 mm screw bolts for the sacrum. The remaining space between the metallic angled plate and the bone was filled with surgical cement polymethylmethacrylate (PMMA) Palacos LV®. Both femurs were distally fixed at 15° of anteversion and 10° of valgus, using a bi-component polyurethane resin type fast setting (Feropur®) (PR55-E55).

In all cadaveric specimens an YB APC-II pelvic injury was simulated (Table 1). Each specimen underwent a cyclic axial load of 300N in 3 phases: (A) Intact pelvis, (B) injured pelvis with iliac-sacral synthesis by one screw at the lower portion of the S1 level (F1S), and (C) injured pelvis with iliac-sacral synthesis, adding a second screw to the previous fixation scheme, also in the S1 level (2FS), positioned superiorly with respect to the first screw. Following the YB APC-II type of injury pelvis reduction was achieved by manual manipulation until complete alignment was externally visualized around the anterior edge of the sacroiliac joint and the anterior-posterior pubic symphysis margins. X-rays were then used to both confirm reduction and perform osteosynthesis using Kirschner guide wires and titanium cannulated screws (Synthes®, Oberdof, Switzerland) of 7.3 mm diameter with washer as recommended by Kraemer[21]. Over each specimen, radiographic control was performed in inlet, outlet and lateral sacral views to ensure the proper position of the implant and reduction of injury (figure 1).

In order to study the three-dimensional directions of the different components of the pelvic ring, the PS and SIJ were marked with special adhesive markers. The movement and the characteristics of the pelvis under axial load in each phase of the study, were analyzed, using a validated system for micro mobility biomechanical studies, PONTOS 5M system[22] (GOM System, Optical Measuring Techniques). On the other hand, minor axial load cycles of 80N were performed after every main axial load cycle of 300N, with the final objective of verifying that the axial load of 300N had not determined any bone fracture or that the repeated axial loads had not negatively influenced the overall mechanical behaviour of the specimens, which would have invalidated the study[12].

The displacements (measured in millimetres) were analyzed and compared between the following structures: The superior and inferior level of the PS, the superior and inferior level of both sacroiliac injured joints, and the rotational movements (measured in degrees) of the whole injured hemipelvis with reference to the sacrum, in the three spatial axes. In order to achieve a more thorough analysis of the data obtained, a complementary elaboration of the overall deformity of the pelvis was performed, analyzing the data acquired during the minor axial load cycles of 80N. This data was expressed in a regression line diagram, illustrating the deformation of the whole pelvis under the load applied.

A multivariate version[23] of the Friedman test (non-parametric ANOVA for repeated measures) was done to compare the overall effect of the independent variable injury status of the pelvis (with 3 levels: Physiological, injured and fixed with 1 ISS and injured and fixed with 2 ISS) on the 7 dependent variables (4 displacements and 3 rotations). Basically, this test consists in performing a MANOVA on the ranks. There was a special interest in comparing the dependent variables separately. This way, the multivariate test was performed three times: a) For the two displacements at the right SIJ, b) for the two displacements at the PS and c) for the three rotations of the right iliac bone relative to the sacrum.

RESULTS.

Tables 2 and 3 show the variations in marker position for the different specimens in each test relative to the initial position with no load in an intact pelvis, osteosynthesed injured pelvis with one and two ISSs respectively.

Regarding the displacements at the SIJ, the Box´s M test for homogeneity of covariance matrices was not significant (p= 0.484). Then, the multivariate version of the Friedman test revealed a non-significant multivariate main effect for injury status, Wilks' λ = 0.925, F (4,34) = 0.337, p = 0.851, partial eta squared = 0.038. Power to detect the effect was 0.117 (Table 2).

With regard to the displacements at the PS (Table 3) the Box´s M test for homogeneity of covariance matrices was not significant (p= 0.002). The multivariate version of the Friedman test revealed a significant multivariate main effect for injury status, Wilks' λ = 0.466, F (4,34) = 3.954, p = 0.010, partial eta squared = 0.317. Power to detect the effect was 0.860. Given the significance of the overall test, the univariate main effects were examined. Significant univariate main effects for injury status were obtained for the displacement at the upper part of the symphysis, *F* (2,18) = 5.917, *p* = 0.011, partial eta square = 0.397, power = 0.814; and for the displacement at the lower part of the symphysis, *F* (2,18) = 9.629 , *p* = 0.001 , partial eta square = 0.517, power = 0.959. Additionally, post-hoc pair wise comparisons for each displacement at the symphysis were made. The p-values of those comparisons are shown in Table 5 and the significant differences (applying Holm's sequential Bonferroni correction) are indicated in boldface.

In the comparison of the rotations of the right iliac bone (Table 4), the Box´s M test for homogeneity of covariance matrices was not significant (p= 0.645). Then, the multivariate version of the Friedman test revealed a non-significant multivariate main effect for injury status, Wilks' λ = 0.669, F (6,32) = 1.186, p = 0.339, partial eta squared = 0.182. Power to detect the effect was 0.396.

When comparing distance variations and their signs, no significant differences were found in the SIJ (p = 0.851); however, there was a significant difference in the lower symphysis (p = 0.001) and upper symphysis (p = 0.011). Comparing rotations of the right iliac bone no significant differences were found between intact pelvis and osteosynthesed injured pelvis. Overall, no significant differences were found between one or two ISSs.

DISCUSSION.

The management of pelvic ring injuries has evolved over the years and the work of Letournel has significantly contributed to the advances that have been made[24]. While it is widely accepted that lesions with complete ligamentous disruption both anteriorly and posteriorly (YB APC-III), necessitate anterior and posterior reconstruction, the management of lesions with partial posterior ligamentous disruption (YB APC-II) remains a point of vivid discussion[10,11,25]. The fact that the published radiological results on this type of injury do not reflect the clinical outcome which is less satisfactory, but is comparable to clinical results related to more severe injuries where all the soft tissue elements of the posterior pelvic ring are completely disrupted[8] has led some authors to consider whether the long term pain reported is the sequelae of residual instability of the posterior pelvic elements. This argument has been supported by the observation of the development of early arthritic changes in the SIJ[4,9]. Consequently, there is an open debate whether the routine plating of the PS should be additionally enhanced with stabilisation of the SIJ[10,11,12,13,25]. It is of note that recently, a clinical study by Osterhoffet al[17], supported the view that the ISS fixation alone could be sufficient for the treatment of an injury with rotational instability. The results of this study revealed that isolated posterior fixation with ISS managed to restore the physiological stability/mobility on the SIJ in YB APC-II injuries. With respect to the PS movements, the displacement was restored with a minimal residual mobility.

Very few studies have examined the biomechanical behaviour of the PS following isolated fixation of the posterior pelvic ring. Simonian et al[11]performed fixation of the SIJ using ISS or sacro-iliac plate in a YB APC-II injury model without PS fixation. They observed a significant decrease in displacement in the pelvic symphysis with respect to the intact pelvis, in both cases without anterior fixation. Nevertheless, authors concluded that the isolated posterior fixation of the pelvic ring can not affect the mobility of the PS. Regarding the two configurations of SIJ fixation tested in our study, the correction of the displacement achieved was 90% approximately (90.9% median with 16,4% Interquartile Range (IQR) in upper PS and 88.4% (IQR 22,4%)in lower PS with one ISS; two ISSs showed 85,9% (IQR 18,3%) and 84.8% (IQR 22,3%) median of reduction in upper and lower PS, respectively) allowing minimal displacements anteriorly (maximum gap measured in the superior and inferior PS was 1,47 mm and 1,86 mm respectively). No statistically significant differences were observed between one or two sacroiliac screws.

The necessity of the posterior fixation of the SIJ additionally to the standard stabilisation of the PS, in case of YB APC-II injury, represents a topic under debate still to be confirmed. Van den Bosch et al[25] performed a biomechanical study evaluating the posterior fixation additionally to the PS standard fixation in open book injuries. Its influence in the pelvic ring stability was analysed and it wascompared to the intact pelvis behaviour. The outcome of the study revealed that the SIJ fixation did not provide any greater stability, and that the behaviour of the injured pelvic ring was similar with respect to intact pelvis. The pelvic damage caused by these authors was potentially less severe than the one in the present work, in order not to injure the sacrotuberous, sacrospinous, and interosseous ligaments. Conversely, Simonian[11] and Dujardin[10]determined that the complete injury of the interosseous ligament, is able to increase significantly the mobility of the SIJ, in case of YB APC-II type of injury. They concluded that the combination of anterior and posterior fixation is necessary to restore the physiological mobility of the pelvic ring. Regarding the biomechanical study carried out by our group, the isolated posterior fixation with ISS managed to restore the physiological mobility of the SIJ, which represents the main biomechanical fulcrum for the axial loads of the human body. With respect to the PS movements, the displacement was restored by 90%, with a minimal residual mobility restricted in a millimetric range. Given that the mobility of PS was reduced and restricted in a narrow range of motion following SIJ fixation and also that an up to 2.5 cm PS diastasis is considered relatively stable and can be conservatively treated [1,26,27], results herein presented suggest that the isolated posterior fixation with ISS may represent a therapeutic option in these type of injuries. Furthermore, the isolated fixation of the injured hemipelvis with a single ISS did not present significant differences regarding to the physiological mobility of the hemipelvis in all spatial axes. The addition of a second ISS was not associated with any substantial improvement.

A registered and patented system was used to analyse experimentally the mechanical behaviour of injured pelvis[20]. The model was designed to allow the simulating standing upright position described by Simonian[11] and Comstock[28], so that the anterior superior iliac spine and PS tubers were aligned in the coronal plane and femurs could be placed in 15º anteversion and 10º valgus. Therefore, the axial load direction passes through the PS and provides a biomechanical model for studying the effects of sacroiliac fixation in the PS. The versatility of this system allows specimens to be positioned and set correctly despite having a distinct separation between femurs. These goals were achieved through the use of a proximal bearing, which corrects angles and allows the correct inclination of the pelvis and a rolling system of linear motion guide lower, which allows the distance between femurs to be adjusted.

This study presents limitations related to the unfeasibility to reproduce the real conditions of the mechanism of injury of the patient in a laboratory environment. In order to minimize the limitations, fresh specimens were used to preserve the biomechanical characteristics of all the osteo-capsular and ligamentous structures. Additionally, the data analyzed were obtained at a single moment in time (cross-sectional study). Another potential limitation relates to the possible biomechanical stress modifications of the specimens due to the repeated axial load cycles. To minimize this bias, the overall stiffness was analysed between the different phases of the study and it was statistically verified that the mechanical capabilities were not affected by the load cycles[12]. Given the characteristics of the study and the use of human pelvises, it was not possible to select randomly the cadaveric specimens. In order to obtain a more homogeneous sample of data, all seven specimens used were females, but with heterogeneous ages. This condition can potentially influence the outcomes and lead to bias. Due to the nature of this study it was not possible either to evaluate in a later stage the biomechanical impact of the physiological healing process that would happen in real conditions after trauma.

It is still unknown whether the reported pain after this kind of injuries and the development of SIJ arthritis is merely due to SIJ instability and whether mechanical stability is only to be achieved by rigid fixation of SIJ which in turn leads to arthritis despite excellent radiologic results. The discrepancy between radiological and functional outcomes in case of YB APC-II injuries, treated surgically by isolated anterior fixation, could be due to a residual SIJ micro-instability[10,12,28]. The isolated fixation of the SIJ appears to show sufficient stability of the posterior elements of the pelvic ring, and could be able to re-establish the physiological biomechanical behaviour of the SIJ. Nevertheless, this type of fixation has limitations to control the anterior displacement, allowing residual movements in a region with less biomechanic solicitation as the PS. Despite this, prospective clinical studies are necessary to determine whether these minimum displacements of PS are relevant from the clinical perspective.

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FIGURE LEGENDS.

Figure 1. Radiographic control. Inlet (a), lateral sacral (b) and outlet (c) views.

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Table 1: Overview of the experimental phases of the study in chronological order.

Experimental Phases	Description
PHASE A	Cycle of axial load of 300N applied on intact pelvis
PHASE A'	Cycle of axial load of 80N applied on intact pelvis
1st MANIPULATION	**Anteriorly:** complete dissection of all ligaments of pubic symphysis **Posteriorly:** simulation of Young Burgess APC-II injury by dissection of ipsilateral sacrotuberous, sacrospinous, anterior sacroiliac and interosseous ligaments. The posterior sacroiliac ligaments were spared
2nd MANIPULATION	Reduction and osteosynthesis with 1 ilio-sacral screw (F1S): The entry point of the first screw, was located 1.5 cm above the gluteal crest, at the midpoint between the iliac crest and the greater sciatic notch. The screw was positioned with an inclination of 30 ° in the coronal plane (cranial direction) and 15 ° in the axial plane, directed to the anterior portion of the S1 vertebral body
PHASE B	Cycle of axial load of 300N applied on pelvis with F1S
PHASE B'	Cycle of axial load of 80N applied on pelvis with F1S
3rd MANIPULATION	Osteosynthesis with 2 ilio-sacral screws (F2S): The entry point of the second screw was located 1 cm above the first screw, with an inclination of 0 ° in the coronal plane and 15 ° in the axial plane, directed to the anterior portion of the S1 vertebral body
PHASE C	Cycle of axial load of 300N applied on pelvis with F2S
PHASE C'	Cycle of axial load of 80N applied on pelvis with F2S
4th MANIPULATION	Removal of ilio-sacral screws
PHASE C''	Cycle of axial load of 80N applied on injured pelvis

Table 2: Displacement (mm) between the markers placed at the right sacroiliac joint.

Subject	Upper displacement at the SI joint			Lower displacement at the SI joint		
	A	B	C	A	B	C
1	0.002	-0.084	-0.038	-0.006	-0.267	-0.139
2	-0.103	-0.139	-0.128	0.012	0.053	0.089
3	-0.011	-0.006	-0.010	-0.022	0.046	0.031
4	-0.182	-0.078	-0.127	-0.059	0.155	0.062
5	-0.013	-0.060	0.020	-0.037	0.052	0.015
6	-0.112	-0.171	-0.160	-0.198	-0.217	-0.201
7	-0.289	-0.201	-0.265	-0.202	-0.128	-0.074
Median	-0.103	-0.084	-0.127	-0.037	0.046	0.015
IQR	0.135	0.086	0.120	0.115	0.225	0.153

Table 3: Displacements (mm) between the markers placed at the symphysis.

	Upper displacement at the symphysis			Lower displacement at the symphysis		
Subject	Physiological	Fixed 1 screw	Fixed 2 screws	Physiological	Fixed 1 screw	Fixed 2 screws
1	-0.048	0.071	0.047	0.010	0.198	0.245
2	-0.050	-0.059	-0.091	0.073	0.096	0.038
3	-0.064	0.750	0.382	0.050	0.800	0.501
4	-0.114	1.454	1.474	0.075	1.740	1.861
5	-0.137	1.023	0.968	0.000	1.107	1.024
6	-0.069	0.112	-0.093	-0.029	0.236	0.094
7	-0.072	0.437	1.055	0.120	0.772	1.242
Median	-0.069	0.437	0.382	0.050	0.772	0.501
IQR	0.036	0.795	1.034	0.069	0.737	0.964

Table 4: Rotations (degrees) of the right iliac bone relative to the sacrum.

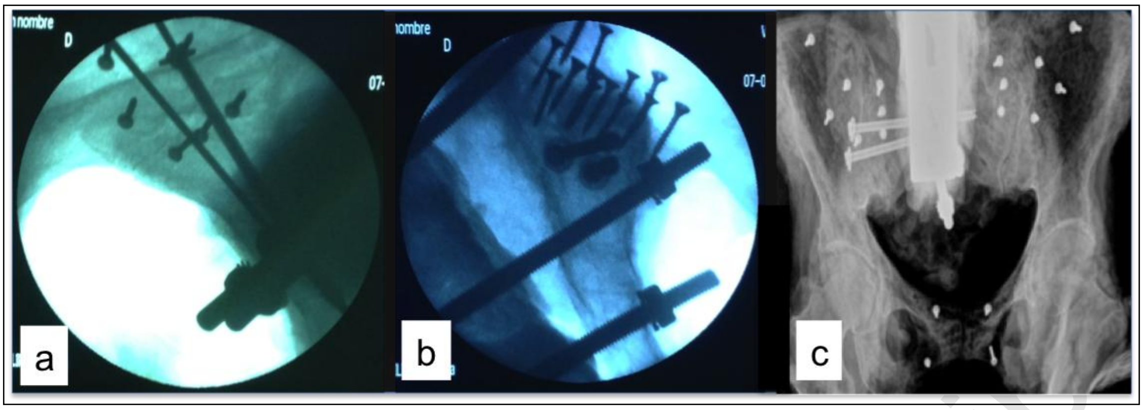
Subject	Sagittal plane			Transversal plane			Coronal plane		
	A	B	C	A	B	C	A	B	C
1	-0.208	-0.757	-0.617	0.038	0.306	0.290	-0.004	-0.155	-0.133
2	-0.881	-0.491	-0.902	0.284	0.236	0.077	0.004	-0.013	0.092
3	-0.491	-0.289	-0.217	0.070	-0.230	-0.013	-0.016	-0.144	-0.101
4	-1.718	-1.114	-1.060	0.015	-0.172	0.074	0.180	-0.302	-0.270
5	-0.244	-0.709	-0.274	-0.446	0.007	-0.570	0.204	-0.210	-0.023
6	-1.097	-0.518	-0.552	0.067	0.071	0.197	0.090	-0.015	0.040
7	-0.844	-0.555	-0.766	0.182	0.253	0.213	-0.191	-0.110	-0.092
Median	-0.844	-0.555	-0.617	0.067	0.071	0.077	0.004	-0.144	-0.092

Table 5: p-values of the pairwise comparisons for each displacement at the symphysis. Significant differences (applying Holm's sequential Bonferroni correction) are indicated in boldface.

Upper disp. Physiol.-1 Screw	Upper disp. Physiol.-2 Screws	Upper disp. 1Screw-2 Screws	Lower disp. Physiol.-1 Screw	Lower disp. Physiol.-2 Screws	Lower disp. 1Screw-2 Screws
.011	0.048	.776	**.003**	**.005**	.954

Table 6: Correction (%) between the markers placed at the symphysis.

	Correction at the upper symphysis		Correction at the lower symphysis	
Subject	B	C	B	C
1	90,9%	92,7%	88,4%	85,5%
2	99,7%	98,5%	99,1%	98,6%
3	3,9%	47,3%	18,6%	51%
4	85,9%	85,7%	68,4%	66,1%
5	67,3%	68,5%	67,4%	69,9%
6	92,3%	98,1%	89,4%	95,1%
7	93,6%	85,9%	91,1%	84,7%
Median, IQR	90,9%	85,9%	88,4%	84,8%
IQR	16,4%	18,3%	22,4%	22,3%


a
b
c