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Title of Paper: Accuracy and repeatability of quantitative fluoroscopy for the measurement of sagittal plane translation and instantaneous axis of rotation in the lumbar spine

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Work on human beings that is submitted to *Medical Engineering & Physics* should comply with the principles laid down in the Declaration of Helsinki; Recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989. You should include information as to whether the work has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work.

Competing Interests

The authors have performed research for the Ortho Kinematics Company, which is commercialising a version of this technology in the United States..

Please state any sources of funding for your research

No external funding was obtained for this research.

DOES YOUR STUDY INVOLVE HUMAN SUBJECTS? Please cross out whichever is not applicable.

Yes

If your study involves human subjects you MUST have obtained ethical approval.

Please state whether Ethical Approval was given, by whom and the relevant Judgement's reference number

Ethical approval was given by the National Research Ethics Service (REC reference 0/H0502/99).

This information must also be inserted into your manuscript under the acknowledgements section prior to the References.

1 **Accuracy and repeatability of quantitative fluoroscopy for the measurement of sagittal**
2 **plane translation and finite centre of rotation in the lumbar spine**

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9

10 **Abstract**

11 Quantitative fluoroscopy (QF) was developed to measure intervertebral mechanics *in vivo*
12 and has been found to have high repeatability and accuracy for the measurement of
13 intervertebral rotations. However, sagittal plane translation and finite centre of rotation
14 (FCR) are potential measures of stability but have not yet been fully validated for current QF.
15 This study investigated the repeatability and accuracy of QF for measuring these variables.
16 Repeatability was assessed from L2-S1 in 20 human volunteers. Accuracy was investigated
17 using 10 consecutive measurements from each of two pairs of linked and instrumented dry
18 human vertebrae as reference; one which tilted without translation and one which translated
19 without tilt. The results found intra- and inter-observer repeatability for translation to be
20 1.1mm or less (SEM) with fair to substantial reliability (ICC 0.533-0.998). Intra-observer
21 repeatability of FCR location for inter-vertebral rotations of 5° and above ranged from 1.5mm
22 to 1.8mm (SEM) with moderate to substantial reliability (ICC 0.626-0.988). Inter-observer
23 repeatability for FCR ranged from 1.2mm to 5.7mm, also with moderate to substantial
24 reliability (ICC 0.621-0.878). Reliability was substantial (ICC>0.81) for 10/16 measures for
25 translation and 5/8 for FCR location. Accuracy for translation was 0.1mm (fixed centre) and
26 2.2mm (moveable centre), with an FCR error of 0.3mm(x) and 0.4mm(y) (fixed centre). This
27 technology was found to have a high level of accuracy and with a few exceptions, moderate
28 to substantial repeatability for the measurement of translation and FCR from fluoroscopic
29 motion sequences.

30

31

32 Introduction

33 The *In vivo* measurement of intervertebral motion in the lumbar spine in individuals has been
34 progressing. This information has traditionally been obtained as displacement on flexion-
35 extension radiographs, however, this has been consistently found to be prone to large errors
36 and variability between observers [1-5]. The method also suffers from the inability to detect
37 the true end-range during motion and lack of standardised measurement methods [6].

38 Studies of quantitative fluoroscopy (QF) for measuring lumbar spine intervertebral
39 kinematics using continuous motion tracking began in the 1980s [7]. QF measures
40 continuous intervertebral motion and extracts end of range measurement from wherever it
41 occurs in the bending sequence, giving a radiation dose similar to a conventional
42 radiographic examination [8, 9]. Various iterations have been found to have good
43 repeatability and accuracy for measuring intervertebral rotations at lumbar and cervical
44 levels [5, 9-12]. However, excessive translation is thought to be more closely associated
45 with back symptoms [13]. Translation also affects the finite centre of rotation (FCR) and the
46 latter is an expression of the distribution of loading between the disc and facets during
47 upright flexion-extension motion [14]. It is also said that the centre of reaction force (CR)
48 can be extrapolated from the FCR [14].

49 QF technology employs standardised image registration and analysis protocols with
50 relatively straightforward and inexpensive hardware in contrast to specialist MR, CT or dual
51 fluoroscopic systems which are not as readily available in hospital settings. However, the
52 literature addressing the repeatability and accuracy of translation and FCR measurement
53 from fluoroscopy is based on different techniques. For example, Cerciello et al determined
54 the accuracy of measuring intervertebral rotation and FCR location in 2-D using stepped
55 positions in a calibration specimen rather than from continuous motion [15]. Wang et al and
56 Lin et al determined the accuracy of translation measurement in ovine specimens using 2D-
57 3D dual fluoroscopic systems where the geometry was informed by magnetic resonance or
58 CT-based vertebral models of the same participant rather than a calibrated reference [16,
59 17]. These studies also found excellent accuracy - and in the case of Wang et al good
60 repeatability - for translation measurement. However, they involved greater radiation dose
61 and expense, while Yeager et al found good repeatability for pooled vertebral levels using a
62 less elaborate low-dose 2-D clinical QF system, but did not assess levels individually [5, 18].

63 The validation of QF technology for *in vivo* translation and FCR measurement from
64 continuous motion sequences is therefore incomplete. The aim of this study was to
65 determine the current accuracy and repeatability of 2-D QF for measuring lumbar inter-

66 vertebral translation and FCR location during motion using a standardised patient motion
67 protocol. This research involved the use of two calibrated human cadaveric specimens to
68 assess accuracy during sagittal plane motion in a prescribed pathway and repeatability in
69 twenty volunteers executing a standardised bending protocol.

70 **Methods**

71 ***Accuracy study***

72 Two sets of dry cadaveric vertebral pairs were used to provide reference data. Specimen A
73 (Fig 1A) consisted of L4 and L5 vertebrae joined at their end-plate centres by a universal
74 joint 4mm high, representing a fixed centre of rotation with zero translation. Specimen B (Fig
75 1B) comprised of L3 and L4 vertebrae. These were joined at their end-plate centres by a
76 plastic linkage which allowed translation of the upper vertebra without rotation. It was driven
77 by an actuator motor and controller (Arduino Software Ltd. UK – resolution 0.01mm)
78 providing anterior to posterior translation across the lower vertebral end-plate during the
79 rotation.

80 Both specimens were mounted on rigid bases and positioned 15 cm from a motion frame
81 which incorporated a rotating disc (Fig 1 A and B). The central ray of a C-arm digital
82 fluoroscope (Siemens Arcadis Avantic – Siemens GMBH, Germany) was positioned so as to
83 pass through the centre of the disc space. A block of animal soft tissue was interposed
84 between the X-ray source, the models and the fluoroscope's image intensifier to degrade the
85 images by generating soft tissue scatter.

86 Fig 1A and B about here

87 The superior vertebra of specimen A was rotated to 18° of flexion and return representing an
88 arbitrary physiological maximum measured using a tilt sensor (Axminster instruments UK–
89 resolution +/- 0.002 degrees) [19]. This was done using a rod driven by a vertical rotating
90 disc embedded in a vertical motion frame (Fig 1A). It was controlled and driven by a laptop
91 computer using bespoke software (Daqfactory VSC – Heatherose Electronics Ltd. UK). The
92 superior vertebra of Specimen B was translated posteriorly across 50% of the lower
93 vertebral end-plate and back again. This was an arbitrary range designed to allow direct
94 comparison between the reference and index values, which should apply, within reason, no
95 matter how large or small the translation. Rotation was at 3°/sec and translation at
96 1.5mm/sec. These procedures were repeated 10 times for each specimen. Images were

97 recorded at 15 frames per second during the 10 sequences for each specimen. All image
98 sequences were analysed by one trained observer.

99 ***Repeatability study***

100 Data were obtained from a parallel study of twenty volunteers being examined for passive
101 recumbent lumbar motion [9]. These were recruited using the eligibility criteria described in
102 Table 1 and following a favourable opinion from the National Research Ethics Service (REC
103 reference 0/H0502/99). Each participant was positioned in the lateral decubitus position on
104 a horizontal motion frame with the central ray of the fluoroscope positioned to pass through
105 the L4 vertebra (Fig 2). The inferior section of the motion frame was rotated through 40° of
106 flexion over a 12 second interval using the motion controller (Daqfactory VSC – Heatherose
107 Electronics Ltd, UK). This was immediately followed by 40° of extension. The effective
108 radiation dose for this procedure has been estimated as 0.24mSv [18].

109 Table 1 about here

110 Fig 2 about here

111 After transfer of images from the fluoroscope to an image processing workstation, two
112 trained observers (a senior radiographer and a medical physicist) analysed the same 40
113 image sequences for inter-observer repeatability (two sequences per participant for the 20
114 participants). Five repeated mark-ups of flexion and extension images of intervertebral
115 levels from L2-S1 took approximately 20 minutes. Observers were blinded to each other's
116 image registrations. The second observer also analysed each image sequence twice for
117 intra-observer repeatability.

118 ***Kinematic data extraction***

119 The fluoroscopic sequences were transferred to a desktop computer and Image J (v 1.47 for
120 Windows OS) was used to separate the individual images from the digital sequences. The
121 images underwent user defined edge enhancement, after which templates were manually
122 placed five times around each vertebral body (L2–S1) in the first image. Bespoke software
123 written in Matlab (V R2007b, The Mathworks Inc.) used a cross-correlation method to obtain
124 automated frame to frame image tracking of the vertebral bodies in subsequent images [20].
125 Co-ordinates were placed on the vertebral body corners in the first image, linked to the
126 tracking templates and used to register the vertebrae in two dimensional space in each

127 frame. Tracking was verified for quality assurance by viewing all sequences and repeating
128 any tracking that failed.

129

130 The displacements between each pair of tracked positions were calculated using Distortion
131 Compensated Radiographic Analysis [21]. These were averaged over 25 registration
132 combinations and output as data series'. (Fig 3). Each data series was inspected for
133 tracking failure using video playback. Any failed tracking data were removed and if all
134 templates failed, the data were not used in the analysis.

135 Fig 3 about here

136 ***Translation calculation***

137 Frobins method [21] for calculating translation (shown in Figures 4 and 5 A & B) is based on
138 landmarks identified on the vertebral body 'corners'. Vertebral midlines (Fig. 4) are defined
139 as lines passing through the midpoints between corners 1-2 and 3-4 respectively.

140 Fig 4 about here

141 The average gradient and y axis crossover of the two midlines are calculated for a vertebral
142 pair. The resultant line is called the bisectrix and normally passes through the inter-vertebral
143 disc space.

144 Using the method depicted in Figure 5, a line is drawn from the centre of each vertebra to
145 the coinciding bisectrix. These lines intersect the bisectrix at 90 degrees to the bisectors'
146 gradient.

147 Fig 5 A and B about here

148 Translation was calculated as the distance along the bisectrix between the points at which
149 these two lines independently cross the bisectrix (Fig 5). To standardise this measurement
150 this is given as a proportion of the mean vertebral body depth of the superior vertebra, where
151 1 VBU (vertebral body unit) is the mean of the upper and lower vertebral body end plate
152 depth of the superior vertebra. For the *in vivo* studies VBUs were converted to millimetres
153 based on a standard vertebral depth of 35mm and for the specimens by their actual
154 measurement.

155 ***FCR calculation***

156 The FCR position and distance from the posterior superior corner of the inferior vertebral
157 body was calculated by finding the least squares solution between the four corners and the
158 corresponding co-ordinates on the subsequent image [22] (Fig 5 A and B).

159 The four corner reference template positions for two adjacent vertebrae were taken and re-
160 positioned so that the inferior vertebral position was superimposed. From these coordinate
161 positions, the centre of rotation between the two images was calculated by finding the least
162 squares solution between each of the four corners and their partners from the second image.
163 The least squares solution was taken as described by McCane et al [22] which gives the
164 Matlab script used to execute this calculation. The positions at which each of these least
165 squares solutions meet was taken as the FCR for those two vertebrae between those two
166 images. The axis of rotation was then displayed relative to the inferior vertebra in a pair as a
167 function of the four- corner template on the inferior vertebra. The superior-posterior corner of
168 the inferior vertebra was taken as the origin for this reference field where the X-axis is along
169 the template on the superior vertebral border and the Y-axis perpendicular to the X-axis
170 passing through the origin. The unit of distance used was the proportion of the average
171 vertebral body depth of superior vertebra (due to the non-uniform shape of the sacral
172 template) where the origin of this co-ordinate system is the anterior-superior corner of the
173 inferior vertebra.

174 FCR positional data were calculated at the maximum rotation angle between any two
175 template positions where the inter-vertebral angle was greater than 5 degrees as a cut-off -
176 as when intervertebral rotation interval decreases, the variation in FCR position increases.
177 This is a systematic error due to the way in which the FCR positions are calculated. FCR
178 was measured continuously between the first frame of the image sequence and the image
179 frame where angular rotation was at its maximum $\pm 0.5^\circ$. The limit of $\pm 0.5^\circ$ was selected
180 as this was the increment through which the tracking templates rotated when calculating
181 vertebral body position within each image. The results were taken as the average position of
182 the FCR in X and Y co-ordinates over the 5 trackings.

183 Fig 6 A and B about here

184 ***Statistical analysis***

185 For the accuracy study, 10 sets of markings were performed for each specimen. Measured
186 translation was compared with zero translation reference data in the fixed centre specimen
187 (end plate depth 28.77mm) and with translation across 50% of the inferior end plate (depth
188 34.66mm) in the moveable centre specimen. Disagreement was expressed as the root-

189 mean-square (RMS) differences between measured and reference values for both
190 translation and FCR. 95% limits of agreement (LoA) were calculated and expressed in VBU
191 [23].

192 For the repeatability studies, 4 intervertebral levels (L2-S1) were analysed for both flexion
193 and extension translation for each of the 20 participants. For FCR location, data were
194 removed from FCR analysis when rotation did not reach 5°. This range has been suggested
195 as the lowest over which intervertebral FCRs should be calculated from radiographs without
196 unacceptable error [24]. Therefore, in anticipation that not all levels would reach the
197 necessary 5°, the levels were pooled to give a maximum possible 80 observations for each
198 of flexion and extension. Intra and inter-observer reliability were expressed as intraclass
199 correlation coefficients ($ICC_{consistency(3,1)}$) using adjectives proposed by Shrout and Fleiss and
200 revised from the original scale of Landis and Koch [25, 26]. In the Shrout and Fleiss scale,
201 reliability as denoted by an ICC of 0.00-0.01 is considered as “virtually none”, 0.11-0.40
202 “slight”, 0.41-0.60 “fair”, 0.61-0.80 “moderate” and 0.81-1.00 “substantial”.

203 **Results**

204 ***Accuracy***

205 The proportion of vertebral body depth that was translated in the moveable centre specimen
206 as measured by the actuator motor was 0.52 VBU (17.95mm). Table 2 shows the RMS
207 differences and 95% LoAs between the reference and measured translation and FCR
208 locations.

209 Table 2 about here

210 For the fixed centre of rotation specimen, the average discrepancy (RMS) in translation
211 range between reference and image data was 0.004 VBU (0.10mm) (LoA 0.01mm). For the
212 translating specimen, the discrepancy when the superior vertebra was translated across
213 50% of the end-plate of the lower one was 0.062 VBU (2.16mm) (LoA 0.52mm). For FCR,
214 the RMS x and y co-ordinate location differences between the reference and measured
215 locations in the fixed centre specimen were 0.009 VBU(x) or 0.25mm (LoA 1.30mm) and for
216 0.014 VBU(y) or 0.40mm (LoA 1.20mm). (Table 2). Bland-Altman plots for these are shown
217 in Fig 7 (A-D).

218 Fig 7 about here

219

220 **Repeatability**

221 The participant sample was made up of 9 females and 11 males aged 26 to 46 (mean age
222 35.7, SD 7.20). Their mean body mass index was 24.71 (SD 2.22).

223 Between 6 and 14 observations for each level in the 20 subjects were visible and tracked
224 successfully for translation. Not all levels and directions were visible or trackable in all
225 subjects. Artefacts due to the movement of bowel gas across images and tall patients
226 whose upper vertebral levels did not fit the image field) were the main causes of this. Intra
227 and inter-observer repeatability for each intervertebral level are shown in Table 3. All levels
228 and directions showed at least fair agreement and reliability. The best agreement was
229 between observers at L2-3 in extension (SEM=0.17mm) and the worst within observers at
230 L5-S1 in extension (SEM=1.14mm). The best reliability was within observers at L2-3 in
231 flexion ((ICC=0.998 (0.958-0.997)) and the worst within observers at L3-4 in flexion
232 ((ICC=0.533 (0.406-0.849)).

233 Table 3 about here

234 Repeatability results for FCR are shown in Table 4. Five degrees of rotation was reached by
235 30 intervertebral pairs. For both translation and FCR location, within observer disagreement
236 did not exceed 2mm for either flexion or extension. Inter-observer disagreement was high
237 for FCRy in extension (5.67mm). All directions otherwise showed moderate to substantial
238 reliability, the smallest ICC being 0.621 (0.429-0.813) for FCRx flexion between observers.

239 Table 4 about here

240 **Discussion**

241 Where mechanical impairment of intervertebral motion in the spine is at issue, its assessment
242 will depend on the availability of technology with which to perform standardised
243 measurements in patients during motion and to provide reference values and error estimates
244 for the various parameters. This study is the first to assess the accuracy and level by level
245 repeatability of the measurement of sagittal plane translation and FCR location from moving
246 vertebral images using low dose 2-D QF. Its results indicate where the current strengths
247 and weaknesses in the technique lie when reporting results of patient studies to clinicians.

248 The accuracy of techniques for radiographic measurement of intervertebral kinematics has
249 been determined using calibration models for roentgen stereophotogrammetry, (which
250 although highly invasive, is sometimes considered the gold standard), biplanar radiography

251 and QF [10, 15, 27, 28]. In this study, idealised conditions were also avoided by degrading
252 the images with animal soft tissue and in the upright position, although It is not uncommon
253 for such studies to be undertaken with no loading or in an animal model with no tissue
254 degradation [16, 29, 30]

255 In this study, we compensated for radiographic image distortion using distortion-
256 compensated roentgen analysis and used an image intensifier that incorporated automatic
257 distortion correction [21]. Measurement is virtually independent of distortion of the
258 radiographic image resulting from central projection, axial rotation, lateral tilt, and off-centre
259 position with an error for translation of between 0.4 and 0.8mm. Measurement of translation
260 was determined from the vertebral body centres, making it independent of rotation. Previous
261 QF studies have also shown that degrading the alignment by axially rotating it 10° out of
262 plane and inclining the X-ray beam inclined 10° inferiorly results in minimal loss of accuracy
263 in rotational studies [10]. Thus the technique should be sufficiently accurate to give useful
264 information about ranges and motion patterns. However, this technique is not thought to be
265 possible in scoliotic spines due to failure of image tracking.

266 This study found the current QF method to have fair to substantial repeatability for all levels
267 and directions using the current protocol. It also found acceptable accuracy *in vitro* for the
268 measurement of FCR location and translation during continuous spinal motion. Reliability
269 was mainly good, but at some levels and directions suggests that training and quality
270 assurance are needed when applying the measurement to comparisons between individuals
271 and reference standards [31].

272 The inter-observer y-error in determination of FCR in extension (5.67mm) and the intra-
273 observer ICC (0.644) for extension translation at L5-S1 point to a need for caution. Closer
274 inspection of the data revealed that the former was also greatest at L5-S1, where image
275 quality and consequently co-ordinate placement may be rendered problematical by the
276 super-imposition of the ilia and/or lack of perfect orthogonal alignment of the central X-ray
277 beam with the vertical axis of the vertebrae. Previous work found radiographic positioning to
278 be more important than tracking accuracy as a contributor to the variability in measurement
279 of angular position, but that this does not preclude high repeatability and accuracy of
280 measurement of rotation [19, 48]. However, for translation and FCR this may be more
281 critical.

282 FCR was once thought to be promising as a way of assessing abnormal loading during
283 intervertebral motion in patients [32, 33] but fell out of favour owing to high errors in
284 measurement and the intrinsic computational errors that occur when rotational range is low

285 [24, 34-36]. The suggestion that it might be used to measure stability has therefore also not
286 generally been taken up [14]. However, the present study has shown that despite the use
287 of continuous motion data, as is necessary in patient studies, greater accuracy was achieved
288 for determining the FCR (average error 0.3mm_x, 0.4mm_y) than was found in a previous study
289 with such a specimen that used stepped rotation positions (average error 2mm)[15].

290 The repeatability study utilised information from participants undergoing passive recumbent
291 and not weight bearing motion. It may be thought that weight bearing information would have
292 been preferable to study the repeatability of translation and FCR measurement. However,
293 this would have meant irradiating additional participants to obtain the same data and
294 differences in motion patterns associated with weight bearing should not affect their
295 measurement. Indeed, Wood concluded that the lateral decubitus position was superior for
296 the detection of instability in patients with spondylolisthesis and Yeager et al used these
297 interchangeably for their repeatability analysis of rotation and translation at pooled levels [37]
298 [5].

299 FCR, at least in the sagittal plane, could therefore be used to inform both patient care and
300 patient-specific mathematical models. However, further studies are needed to establish
301 normative *in vivo* reference standards at individual levels using QF. It would also be
302 beneficial to explore the effects of spinal geometry and muscle contraction on FCR location,
303 to add coronal plane validation and to confirm whether the FCR locus might be used to
304 assess relationships between structural change and the *in vivo* biomechanical performance
305 characteristics of discs under load. Finally, rotational cut-offs for accurately locating the FCR
306 should be revisited in the light of the greater standardisation offered by QF protocols.

307 Diagnostic advances in spine biomechanics have also been made using kinetic MRI [37-41]
308 and SPECT-CT imaging [42, 43]. However, although kinetic MRI locates points of
309 encroachment on neural tissues and SPECT-CT contributes to the identification of potential
310 sites of pain generation, neither can extract end-range or continuous inter-vertebral motion.
311 In addition, the radiation dosage from SPECT-CT is considerably larger than that of QF.

312 Improvements in repeatability and accuracy are ongoing requirements for any diagnostic
313 test, which means that reference standards will always be imperfect. Validation of QF will
314 therefore require that scientists and practitioners also examine the extent to which test
315 results are meaningful in practice [44]. This may be appreciated from patient register data. In
316 parallel with this, technology development should address any measurement deficiencies.

317 **Limitations**

318 Participants with a BMI over 31 or aged over 51 were excluded from the study and none had
319 osteoporosis, osteoarthritic change, vertebral deformities or curvatures; which may
320 precipitate tracking failures. In the accuracy study, the translation error was considerably
321 higher (2.10mm) in the translating specimen than in the fixed specimen (0.10mm). This
322 may have been due to the resolution of the actuator motor in the latter (0.01mm), or by a
323 small amount of out of plane motion due to imperfections in the mechanical linkage of this
324 specimen. However, this discrepancy is well below the generally accepted cut-off of 4mm
325 for excessive translation [45-48].

326 Distortion that changes during motion is not correctable if the templates that track the images
327 from frame to frame do not change to accommodate it. In the future, this could be provided
328 by adaptations to the tracking codes [8]. The US versions of this technology image the upper
329 and lower lumbar levels separately to minimise out of plane images and ensure inclusion of
330 all lumbar levels. While this increases the X-ray dose, it also makes for better
331 reliability in the measurement of translation than was found here [5].

332 Future studies of accuracy and repeatability are needed to substantiate the present work.
333 These could use a larger number of examiners, a range of rotational angles for FCR
334 accuracy and a more elaborate calibration set up that combines rotation and translation. A
335 larger number of human participants would overcome the problem of low angles of rotation
336 and enable determination of the level by level repeatability of FCR location at 5° and above.
337 For example, poorer agreement was found at L5-S1 than other levels, possibly owing to
338 lower image quality resulting from superimposition of both ilia on the vertebral images.

339 **Conclusion**

340 Quantitative fluoroscopy was found to have a high level of accuracy as well as moderate to
341 substantial observer agreement and reliability for the measurement of FCR and translation.
342 Exceptions were in the reliability of measuring translation at L3-4 and agreement between
343 observers in locating the FCR in extension. The development of reference standards and
344 analysis quality assurance measures will be essential for optimal clinical use [6].

345

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349 List of Figures

350 Figure 1. Lumbar intervertebral motion specimens. (A) Fixed centre specimen (B) Movable
351 centre specimen

352 Figure 2. Diagram of patient positioning for fluoroscopic imaging (Ortho Kinematics Inc.,
353 with permission)

354 Figure 3. Example of translation data for extension at L5-S1 (live participant). Solid line
355 shows filtered average of 25 trackings. Shaded area represents all data.

356 Figure 4. Graphical representation of two lumbar vertebrae undergoing extension in the
357 sagittal plane with a four-point reference template marked on the corner of each vertebra to
358 calculate the bisectrix. The bisectrix is to be used as a basis of calculation of translation
359 changes.

360 Figure 5 A and B. Depiction of translation measurement calculation between two adjacent
361 lumbar vertebrae in (A) full extension (B) full flexion

362 Figure 6 A and B. Examples of computer-generated measurements of: (A) FCR in fixed
363 centre specimen (B) translation in movable centre specimen

364 Figure 7 A to D. Bland-Altman plots: (A) Translation in fixed centre specimen (B)
365 Translation in movable centre specimen (C) FCR_x in fixed centre specimen (D) FCR_y in
366 fixed centre specimen

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375 **Acknowledgements**

376 This article presents independent research and the views expressed are those of the
377 author(s) alone. The authors wish to acknowledge the contributions of the participants and of
378 Fiona Mellor for sharing some of her participant image sequences and contributing to the
379 participant image registration.

380 **Competing Interests**

381 The authors have performed research for the Ortho Kinematics Company, which is
382 commercialising a version of this technology in the United States.

383 **Sources of funding**

384 No external funding was obtained for this research.

385
386 **Ethical Approval**

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388 Ethical approval was given by the National Research Ethics Service (REC reference
389 0/H0502/99).

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519

1 **Accuracy and repeatability of quantitative fluoroscopy for the measurement of sagittal**
2 **plane translation and finite centre of rotation in the lumbar spine**

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9

10 **Abstract**

11 Quantitative fluoroscopy (QF) was developed to measure intervertebral mechanics *in vivo*
12 and has been found to have high repeatability and accuracy for the measurement of
13 intervertebral rotations. However, sagittal plane translation and finite centre of rotation
14 (FCR) are potential measures of stability but have not yet been fully validated for current QF.
15 This study investigated the repeatability and accuracy of QF for measuring these variables.
16 Repeatability was assessed from L2-S1 in 20 human volunteers. Accuracy was investigated
17 using 10 consecutive measurements from each of two pairs of linked and instrumented dry
18 human vertebrae as reference; one which tilted without translation and one which translated
19 without tilt. The results found intra- and inter-observer repeatability for translation to be
20 1.1mm or less (SEM) with fair to substantial reliability (ICC 0.533-0.998). Intra-observer
21 repeatability of FCR location for inter-vertebral rotations of 5° and above ranged from 1.5mm
22 to 1.8mm (SEM) with moderate to substantial reliability (ICC 0.626-0.988). Inter-observer
23 repeatability for FCR ranged from 1.2mm to 5.7mm, also with moderate to substantial
24 reliability (ICC 0.621-0.878). Reliability was substantial (ICC>0.81) for 10/16 measures for
25 translation and 5/8 for FCR location. Accuracy for translation was 0.1mm (fixed centre) and
26 2.2mm (moveable centre), with an FCR error of 0.3mm(x) and 0.4mm(y) (fixed centre). This
27 technology was found to have a high level of accuracy and with a few exceptions, moderate
28 to substantial repeatability for the measurement of translation and FCR from fluoroscopic
29 motion sequences.

30

31

32 Introduction

33 The *In vivo* measurement of intervertebral motion in the lumbar spine in individuals has been
34 progressing. This information has traditionally been obtained as displacement on flexion-
35 extension radiographs, however, this has been consistently found to be prone to large errors
36 and variability between observers [1-5]. The method also suffers from the inability to detect
37 the true end-range during motion and lack of standardised measurement methods [6].

38 Studies of quantitative fluoroscopy (QF) for measuring lumbar spine intervertebral
39 kinematics using continuous motion tracking began in the 1980s [7]. QF measures
40 continuous intervertebral motion and extracts end of range measurement from wherever it
41 occurs in the bending sequence, giving a radiation dose similar to a conventional
42 radiographic examination [8, 9]. Various iterations have been found to have good
43 repeatability and accuracy for measuring intervertebral rotations at lumbar and cervical
44 levels [5, 9-12]. However, excessive translation is thought to be more closely associated
45 with back symptoms [13]. Translation also affects the finite centre of rotation (FCR) and **the**
46 **latter** is an expression of the distribution of loading between the disc and facets during
47 upright flexion-extension motion [14]. It is also said that the centre of reaction force (CR)
48 can be extrapolated from the FCR [14].

49 QF technology employs standardised image registration and analysis protocols with
50 relatively straightforward and inexpensive hardware in contrast to specialist MR, CT or dual
51 fluoroscopic systems which are not as readily available in hospital settings. However, the
52 literature addressing the repeatability and accuracy of translation and FCR measurement
53 from fluoroscopy is based **on** different techniques. For example, Cerciello et al determined
54 the accuracy of measuring intervertebral rotation and FCR location in 2-D using stepped
55 positions in a calibration specimen rather than from continuous motion [15]. Wang et al and
56 Lin et al determined the accuracy of translation measurement in ovine specimens using 2D-
57 3D dual fluoroscopic systems where the geometry was informed by magnetic resonance or
58 CT-based vertebral models of the same participant rather than a calibrated reference [16,
59 17]. These studies also found excellent accuracy - and in the case of Wang et al good
60 repeatability - for translation measurement. However, they involved greater radiation dose
61 and expense, while Yeager et al found good repeatability for pooled vertebral levels using a
62 less elaborate low-dose 2-D clinical QF system, but did not assess levels individually [5, 18].

63 The validation of QF technology for ***in vivo*** translation and FCR measurement **from**
64 **continuous motion sequences** is therefore incomplete. The aim of this study was to
65 determine the current accuracy and repeatability of 2-D QF for measuring lumbar inter-

66 vertebral translation and FCR location during motion using a standardised patient motion
67 protocol. This research involved the use of two calibrated human cadaveric specimens to
68 assess accuracy during sagittal plane motion in a prescribed pathway and repeatability in
69 twenty volunteers executing a standardised bending protocol.

70 **Methods**

71 ***Accuracy study***

72 Two sets of dry cadaveric vertebral pairs were used to provide reference data. Specimen A
73 (Fig 1A) consisted of L4 and L5 vertebrae joined at their end-plate centres by a universal
74 joint **4mm high**, representing a fixed centre of rotation with zero translation. Specimen B (Fig
75 1B) comprised of L3 and L4 vertebrae. These were joined at their end-plate centres by a
76 plastic linkage which allowed translation of the upper vertebra without rotation. It was driven
77 by an actuator motor and controller (Arduino Software Ltd. UK – resolution 0.01mm)
78 providing anterior to posterior translation across the lower vertebral end-plate during the
79 rotation.

80 Both specimens were mounted on rigid bases and positioned 15 cm from a motion frame
81 which incorporated a rotating disc (Fig 1 A and B). The central ray of a C-arm digital
82 fluoroscope (Siemens Arcadis Avantic – Siemens GMBH, Germany) was positioned so as to
83 pass through the centre of the disc space. A block of animal soft tissue was interposed
84 between the X-ray source, the models and the fluoroscope's image intensifier to degrade the
85 images by generating soft tissue scatter.

86 Fig 1A and B about here

87 The superior vertebra of specimen A was rotated to 18° of flexion and return representing an
88 arbitrary physiological maximum measured using a tilt sensor (Axminster instruments UK–
89 resolution +/- 0.002 degrees) [19]. This was done using a rod driven by a vertical rotating
90 disc embedded in a vertical motion frame (Fig 1A). It was controlled and driven by a laptop
91 computer using bespoke software (Daqfactory VSC – Heatherose Electronics Ltd. UK). The
92 superior vertebra of Specimen B was translated posteriorly across 50% of the lower
93 vertebral end-plate and back again. This was an arbitrary range designed to allow direct
94 comparison between the reference and index values, which should apply, within reason, no
95 matter how large or small the translation. Rotation was at $3^\circ/\text{sec}$ and translation at
96 1.5mm/sec. These procedures were repeated 10 times for each specimen. Images were

97 recorded at 15 frames per second during the 10 sequences for each specimen. All image
98 sequences were analysed by one trained observer.

99 ***Repeatability study***

100 Data were obtained from a parallel study of twenty volunteers being examined for passive
101 recumbent lumbar motion [9]. These were recruited using the eligibility criteria described in
102 Table 1 and following a favourable opinion from the National Research Ethics Service (REC
103 reference 0/H0502/99). Each participant was positioned in the lateral decubitus position on
104 a horizontal motion frame with the central ray of the fluoroscope positioned to pass through
105 the L4 vertebra (Fig 2). The inferior section of the motion frame was rotated through 40° of
106 flexion over a 12 second interval using the motion controller (Daqfactory VSC – Heatherose
107 Electronics Ltd, UK). This was immediately followed by 40° of extension. The effective
108 radiation dose for this procedure has been estimated as 0.24mSv [18].

109 Table 1 about here

110 Fig 2 about here

111 After transfer of images from the fluoroscope to an image processing workstation, two
112 trained observers (a senior radiographer and a medical physicist) analysed the same 40
113 image sequences for inter-observer repeatability (two sequences per participant for the 20
114 participants). Five repeated mark-ups of flexion and extension images of intervertebral
115 levels from L2-S1 took approximately 20 minutes. Observers were blinded to each other's
116 image registrations. The second observer also analysed each image sequence twice for
117 intra-observer repeatability.

118 ***Kinematic data extraction***

119 The fluoroscopic sequences were transferred to a desktop computer and Image J (v 1.47 for
120 Windows OS) was used to separate the individual images from the digital sequences. The
121 images underwent user defined edge enhancement, after which templates were manually
122 placed five times around each vertebral body (L2–S1) in the first image. Bespoke software
123 written in Matlab (V R2007b, The Mathworks Inc.) used a cross-correlation method to obtain
124 automated frame to frame image tracking of the vertebral bodies in subsequent images [20].
125 Co-ordinates were placed on the vertebral body corners in the first image, linked to the
126 tracking templates and used to register the vertebrae in two dimensional space in each

127 frame. Tracking was verified for quality assurance by viewing all sequences and repeating
128 any tracking that failed.

129

130 The displacements between each pair of tracked positions were calculated using Distortion
131 Compensated Radiographic Analysis [21]. These were averaged over 25 registration
132 combinations and output as data series'. (Fig 3). Each data series was inspected for
133 tracking failure using video playback. Any failed tracking data were removed and if all
134 templates failed, the data were not used in the analysis.

135 Fig 3 about here

136 ***Translation calculation***

137 Frobins method [21] for calculating translation (shown in Figures 4 and 5 A & B) is based on
138 landmarks identified on the vertebral body 'corners'. Vertebral midlines (Fig. 4) are defined
139 as lines passing through the midpoints between corners 1-2 and 3-4 respectively.

140 Fig 4 about here

141 The average gradient and y axis crossover of the two midlines are calculated for a vertebral
142 pair. The resultant line is called the bisectrix and normally passes through the inter-vertebral
143 disc space.

144 Using the method depicted in Figure 5, a line is drawn from the centre of each vertebra to
145 the coinciding bisectrix. These lines intersect the bisectrix at 90 degrees to the bisectors'
146 gradient.

147 Fig 5 A and B about here

148 Translation was calculated as the distance along the bisectrix between the points at which
149 these two lines independently cross the bisectrix (Fig 5). To standardise this measurement
150 this is given as a proportion of the mean vertebral body depth of the superior vertebra, where
151 1 VBU (vertebral body unit) is the mean of the upper and lower vertebral body end plate
152 depth of the superior vertebra. For the *in vivo* studies VBUs were converted to millimetres
153 based on a standard vertebral depth of 35mm and for the specimens by their actual
154 measurement.

155 ***FCR calculation***

156 The FCR position and distance from the posterior superior corner of the inferior vertebral
157 body was calculated by finding the least squares solution between the four corners and the
158 corresponding co-ordinates on the subsequent image [22] (Fig 5 A and B).

159 The four corner reference template positions for two adjacent vertebrae were taken and re-
160 positioned so that the inferior vertebral position was superimposed. From these coordinate
161 positions, the centre of rotation between the two images was calculated by finding the least
162 squares solution between each of the four corners and their partners from the second image.
163 The least squares solution was taken as described by McCane et al [22] which gives the
164 Matlab script used to execute this calculation. The positions at which each of these least
165 squares solutions meet was taken as the FCR for those two vertebrae between those two
166 images. The axis of rotation was then displayed relative to the inferior vertebra in a pair as a
167 function of the four- corner template on the inferior vertebra. The superior-posterior corner of
168 the inferior vertebra was taken as the origin for this reference field where the X-axis is along
169 the template on the superior vertebral border and the Y-axis perpendicular to the X-axis
170 passing through the origin. The unit of distance used was the proportion of the average
171 vertebral body depth of superior vertebra (due to the non-uniform shape of the sacral
172 template) where the origin of this co-ordinate system is the anterior-superior corner of the
173 inferior vertebra.

174 FCR positional data were calculated at the maximum rotation angle between any two
175 template positions where the inter-vertebral angle was greater than 5 degrees as a cut-off -
176 as when intervertebral rotation interval decreases, the variation in FCR position increases.
177 This is a systematic error due to the way in which the FCR positions are calculated. FCR
178 was measured continuously between the first frame of the image sequence and the image
179 frame where angular rotation was at its maximum +/- 0.5°. The limit of +/- 0.5° was selected
180 as this was the increment through which the tracking templates rotated when calculating
181 vertebral body position within each image. The results were taken as the average position of
182 the FCR in X and Y co-ordinates over the 5 trackings.

183 Fig 6 A and B about here

184 **Statistical analysis**

185 For the accuracy study, 10 sets of markings were performed for each specimen. Measured
186 translation was compared with zero translation reference data in the fixed centre specimen
187 (end plate depth 28.77mm) and with translation across 50% of the inferior end plate (depth
188 34.66mm) in the moveable centre specimen. Disagreement was expressed as the root-

189 mean-square (RMS) differences between measured and reference values for both
190 translation and FCR. 95% limits of agreement (LoA) were calculated and expressed in VBU
191 [23].

192 For the repeatability studies, 4 intervertebral levels (L2-S1) were analysed for both flexion
193 and extension translation for each of the 20 participants. For FCR location, data were
194 removed from FCR analysis when rotation did not reach 5°. This range has been suggested
195 as the lowest over which intervertebral FCRs should be calculated from radiographs without
196 unacceptable error [24]. Therefore, in anticipation that not all levels would reach the
197 necessary 5°, the levels were pooled to give a maximum possible 80 observations for each
198 of flexion and extension. Intra and inter-observer reliability were expressed as intraclass
199 correlation coefficients (ICC_{consistency}^{3,1}) using adjectives proposed by Shrout and Fleiss and
200 revised from the original scale of Landis and Koch [25, 26]. In the Shrout and Fleiss scale,
201 reliability as denoted by an ICC of 0.00-0.01 is considered as “virtually none”, 0.11-0.40
202 “slight”, 0.41-0.60 “fair”, 0.61-0.80 “moderate” and 0.81-1.00 “substantial”.

203 **Results**

204 ***Accuracy***

205 The proportion of vertebral body depth that was translated in the moveable centre specimen
206 as measured by the actuator motor was 0.52 VBU (17.95mm). Table 2 shows the RMS
207 differences and 95% LoAs between the reference and measured translation and FCR
208 locations.

209 Table 2 about here

210 For the fixed centre of rotation specimen, the average discrepancy (RMS) in translation
211 range between reference and image data was 0.004 VBU (0.10mm) (LoA 0.01mm). For the
212 translating specimen, the discrepancy when the superior vertebra was translated across
213 50% of the end-plate of the lower one was 0.062 VBU (2.16mm) (LoA 0.52mm). For FCR,
214 the RMS x and y co-ordinate location differences between the reference and measured
215 locations in the fixed centre specimen were 0.009 VBU(x) or 0.25mm (LoA 1.30mm) and for
216 0.014 VBU(y) or 0.40mm (LoA 1.20mm). (Table 2). Bland-Altman plots for these are shown
217 in Fig 7 (A-D).

218 Fig 7 about here

219

220 **Repeatability**

221 The participant sample was made up of 9 females and 11 males aged 26 to 46 (mean age
222 35.7, SD 7.20). Their mean body mass index was 24.71 (SD 2.22).

223 Between 6 and 14 observations for each level in the 20 subjects were visible and tracked
224 successfully for translation. Not all levels and directions were visible or trackable in all
225 subjects. Artefacts due to the movement of bowel gas across images and tall patients
226 whose upper vertebral levels did not fit the image field) were the main causes of this. Intra
227 and inter-observer repeatability for each intervertebral level are shown in Table 3. All levels
228 and directions showed at least fair agreement and reliability. The best agreement was
229 between observers at L2-3 in extension (SEM=0.17mm) and the worst within observers at
230 L5-S1 in extension (SEM=1.14mm). The best reliability was within observers at L2-3 in
231 flexion ((ICC=0.998 (0.958-0.997)) and the worst within observers at L3-4 in flexion
232 ((ICC=0.533 (0.406-0.849)).

233 Table 3 about here

234 Repeatability results for FCR are shown in Table 4. Five degrees of rotation was reached by
235 30 intervertebral pairs. For both translation and FCR location, within observer disagreement
236 did not exceed 2mm for either flexion or extension. Inter-observer disagreement was high
237 for FCRy in extension (5.67mm). All directions otherwise showed moderate to substantial
238 reliability, the smallest ICC being 0.621 (0.429-0.813) for FCRx flexion between observers.

239 Table 4 about here

240 **Discussion**

241 Where mechanical impairment of intervertebral motion in the spine is at issue, its assessment
242 will depend on the availability of technology with which to perform standardised
243 measurements in patients during motion and to provide reference values and error estimates
244 for the various parameters. This study is the first to assess the accuracy and level by level
245 repeatability of the measurement of sagittal plane translation and FCR location from moving
246 vertebral images using low dose 2-D QF. Its results indicate where the current strengths
247 and weaknesses in the technique lie when reporting results of patient studies to clinicians.

248 The accuracy of techniques for radiographic measurement of intervertebral kinematics has
249 been determined using calibration models for roentgen stereophotogrammetry, (which
250 although highly invasive, is sometimes considered the gold standard), biplanar radiography

251 and QF [10, 15, 27, 28]. In this study, idealised conditions were also avoided by degrading
252 the images with animal soft tissue and in the upright position, although It is not uncommon
253 for such studies to be undertaken with no loading or in an animal model with no tissue
254 degradation [16, 29, 30]

255 In this study, we compensated for radiographic image distortion using distortion-
256 compensated roentgen analysis and used an image intensifier that incorporated automatic
257 distortion correction [21]. Measurement is virtually independent of distortion of the
258 radiographic image resulting from central projection, axial rotation, lateral tilt, and off-centre
259 position with an error for translation of between 0.4 and 0.8mm. Measurement of translation
260 was determined from the vertebral body centres, making it independent of rotation. Previous
261 QF studies have also shown that degrading the alignment by axially rotating it 10° out of
262 plane and inclining the X-ray beam inclined 10° inferiorly results in minimal loss of accuracy
263 in rotational studies [10]. Thus the technique should be sufficiently accurate to give useful
264 information about ranges and motion patterns. However, this technique is not thought to be
265 possible in scoliotic spines due to failure of image tracking.

266 This study found the current QF method to have fair to substantial repeatability for all levels
267 and directions using the current protocol. It also found acceptable accuracy *in vitro* for the
268 measurement of FCR location and translation during continuous spinal motion. Reliability
269 was mainly good, but at some levels and directions suggests that training and quality
270 assurance are needed when applying the measurement to comparisons between individuals
271 and reference standards [31].

272 The inter-observer y-error in determination of FCR in extension (5.67mm) and the intra-
273 observer ICC (0.644) for extension translation at L5-S1 point to a need for caution. Closer
274 inspection of the data revealed that the former was also greatest at L5-S1, where image
275 quality and consequently co-ordinate placement may be rendered problematical by the
276 super-imposition of the ilia and/or lack of perfect orthogonal alignment of the central X-ray
277 beam with the vertical axis of the vertebrae. Previous work found radiographic positioning to
278 be more important than tracking accuracy as a contributor to the variability in measurement
279 of angular position, but that this does not preclude high repeatability and accuracy of
280 measurement of rotation [19, 48]. However, for translation and FCR this may be more
281 critical.

282 FCR was once thought to be promising as a way of assessing abnormal loading during
283 intervertebral motion in patients [32, 33] but fell out of favour owing to high errors in
284 measurement and the intrinsic computational errors that occur when rotational range is low

285 [24, 34-36]. The suggestion that it might be used to measure stability has therefore also not
286 generally been taken up [14]. However, the present study has shown that despite the use
287 of continuous motion data, as is necessary in patient studies, greater accuracy was achieved
288 for determining the FCR (average error 0.3mm_x, 0.4mm_y) than was found in a previous study
289 with such a specimen that used stepped rotation positions (average error 2mm)[15].

290 The repeatability study utilised information from participants undergoing passive recumbent
291 and not weight bearing motion. It may be thought that weight bearing information would have
292 been preferable to study the repeatability of translation and FCR measurement. However,
293 this would have meant irradiating additional participants to obtain the same data and
294 differences in motion patterns associated with weight bearing should not affect their
295 measurement. Indeed, Wood concluded that the lateral decubitus position was superior for
296 the detection of instability in patients with spondylolisthesis and Yeager et al used these
297 interchangeably for their repeatability analysis of rotation and translation at pooled levels [37]
298 [5].

299 FCR, at least in the sagittal plane, could therefore be used to inform both patient care and
300 patient-specific mathematical models. However, further studies are needed to establish
301 normative *in vivo* reference standards at individual levels using QF. It would also be
302 beneficial to explore the effects of spinal geometry and muscle contraction on FCR location,
303 to add coronal plane validation and to confirm whether the FCR locus might be used to
304 assess relationships between structural change and the *in vivo* biomechanical performance
305 characteristics of discs under load. Finally, rotational cut-offs for accurately locating the FCR
306 should be revisited in the light of the greater standardisation offered by QF protocols.

307 Diagnostic advances in spine biomechanics have also been made using kinetic MRI [37-41]
308 and SPECT-CT imaging [42, 43]. However, although kinetic MRI locates points of
309 encroachment on neural tissues and SPECT-CT contributes to the identification of potential
310 sites of pain generation, neither can extract end-range or continuous inter-vertebral motion.
311 In addition, the radiation dosage from SPECT-CT is considerably larger than that of QF.

312 Improvements in repeatability and accuracy are ongoing requirements for any diagnostic
313 test, which means that reference standards will always be imperfect. Validation of QF will
314 therefore require that scientists and practitioners also examine the extent to which test
315 results are meaningful in practice [44]. This may be appreciated from patient register data. In
316 parallel with this, technology development should address any measurement deficiencies.

317 **Limitations**

318 Participants with a BMI over 31 or aged over 51 were excluded from the study and none had
319 osteoporosis, osteoarthritic change, vertebral deformities or curvatures; which may
320 precipitate tracking failures. In the accuracy study, the translation error was considerably
321 higher (2.10mm) in the translating specimen than in the fixed specimen (0.10mm). This
322 may have been due to the resolution of the actuator motor in the latter (0.01mm), or by a
323 small amount of out of plane motion due to imperfections in the mechanical linkage of this
324 specimen. However, this discrepancy is well below the generally accepted cut-off of 4mm
325 for excessive translation [45-48].

326 Distortion that changes during motion is not correctable if the templates that track the images
327 from frame to frame do not change to accommodate it. In the future, this could be provided
328 by adaptations to the tracking codes [8]. The US versions of this technology image the upper
329 and lower lumbar levels separately to minimise out of plane images and ensure inclusion of
330 all lumbar levels. While this increases the X-ray dose, it also makes for better
331 reliability in the measurement of translation than was found here [5].

332 Future studies of accuracy and repeatability are needed to substantiate the present work.
333 These could use a larger number of examiners, a range of rotational angles for FCR
334 accuracy and a more elaborate calibration set up that combines rotation and translation. A
335 larger number of human participants would overcome the problem of low angles of rotation
336 and enable determination of the level by level repeatability of FCR location at 5° and above.
337 For example, poorer agreement was found at L5-S1 than other levels, possibly owing to
338 lower image quality resulting from superimposition of both ilia on the vertebral images.

339 **Conclusion**

340 **Quantitative fluoroscopy was found to have a high level of accuracy as well as moderate to**
341 **substantial observer agreement and reliability for the measurement of FCR and translation.**
342 **Exceptions were in the reliability of measuring translation at L3-4 and agreement between**
343 **observers in locating the FCR in extension.** The development of reference standards and
344 analysis quality assurance measures will be essential for optimal clinical use [6].

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366 fixed centre specimen

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375 **Acknowledgements**

376 This article presents independent research and the views expressed are those of the
377 author(s) alone. The authors wish to acknowledge the contributions of the participants and of
378 Fiona Mellor for sharing some of her participant image sequences and contributing to the
379 participant image registration.

380 **Competing Interests**

381 The authors have performed research for the Ortho Kinematics Company, which is
382 commercialising a version of this technology in the United States.

383 **Sources of funding**

384 No external funding was obtained for this research.

385
386 **Ethical Approval**

387
388 Ethical approval was given by the National Research Ethics Service (REC reference
389 0/H0502/99).

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Figure legends

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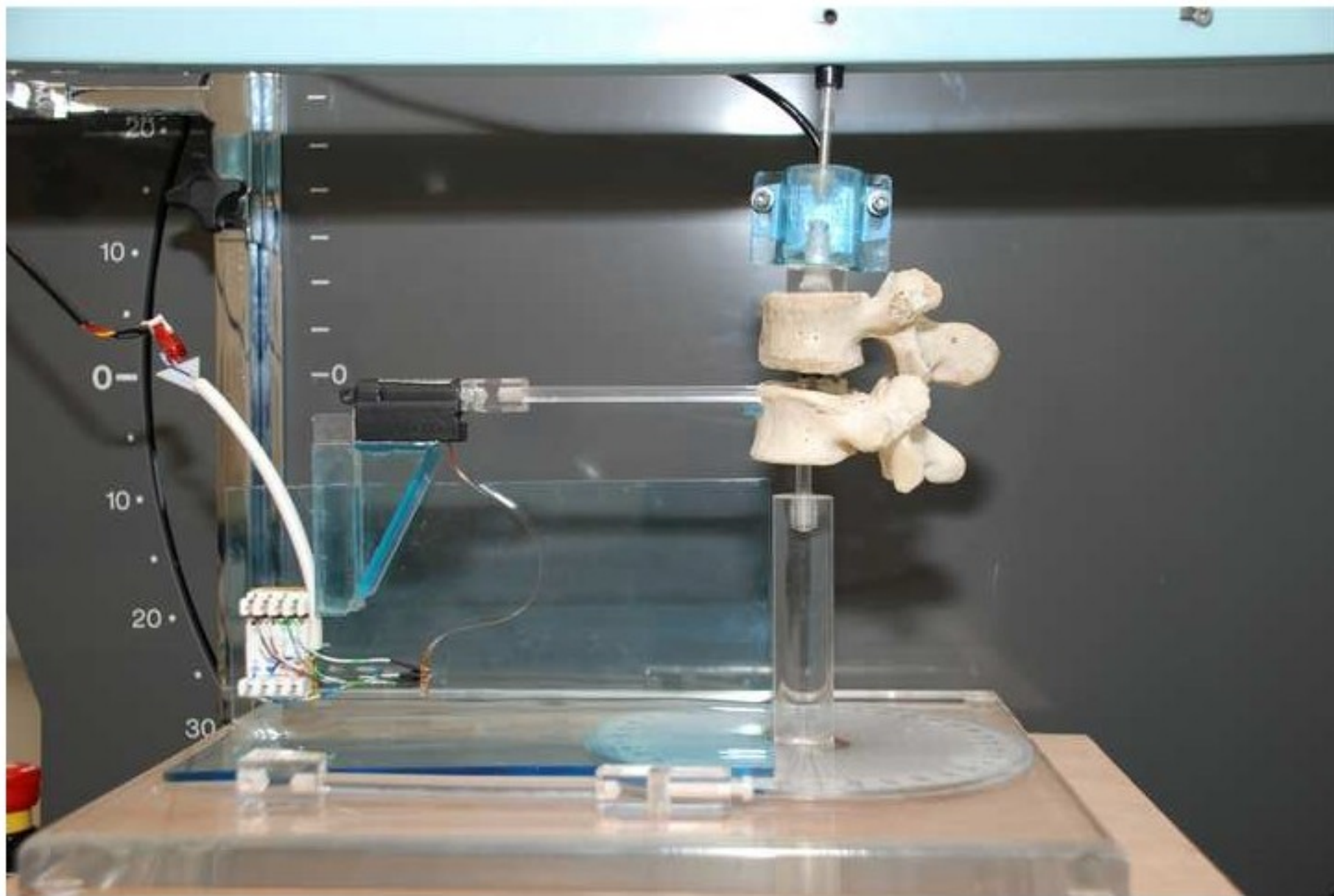
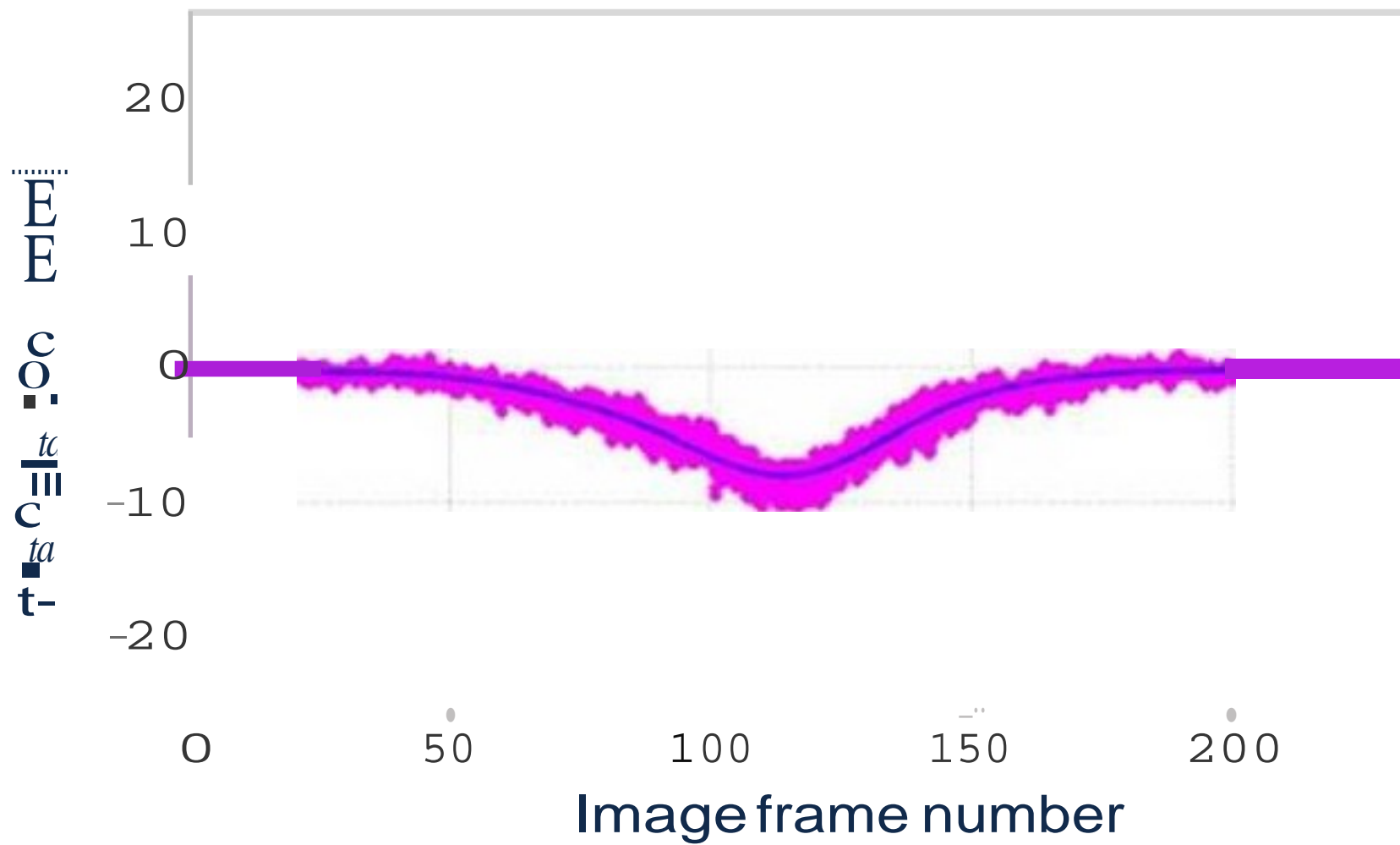


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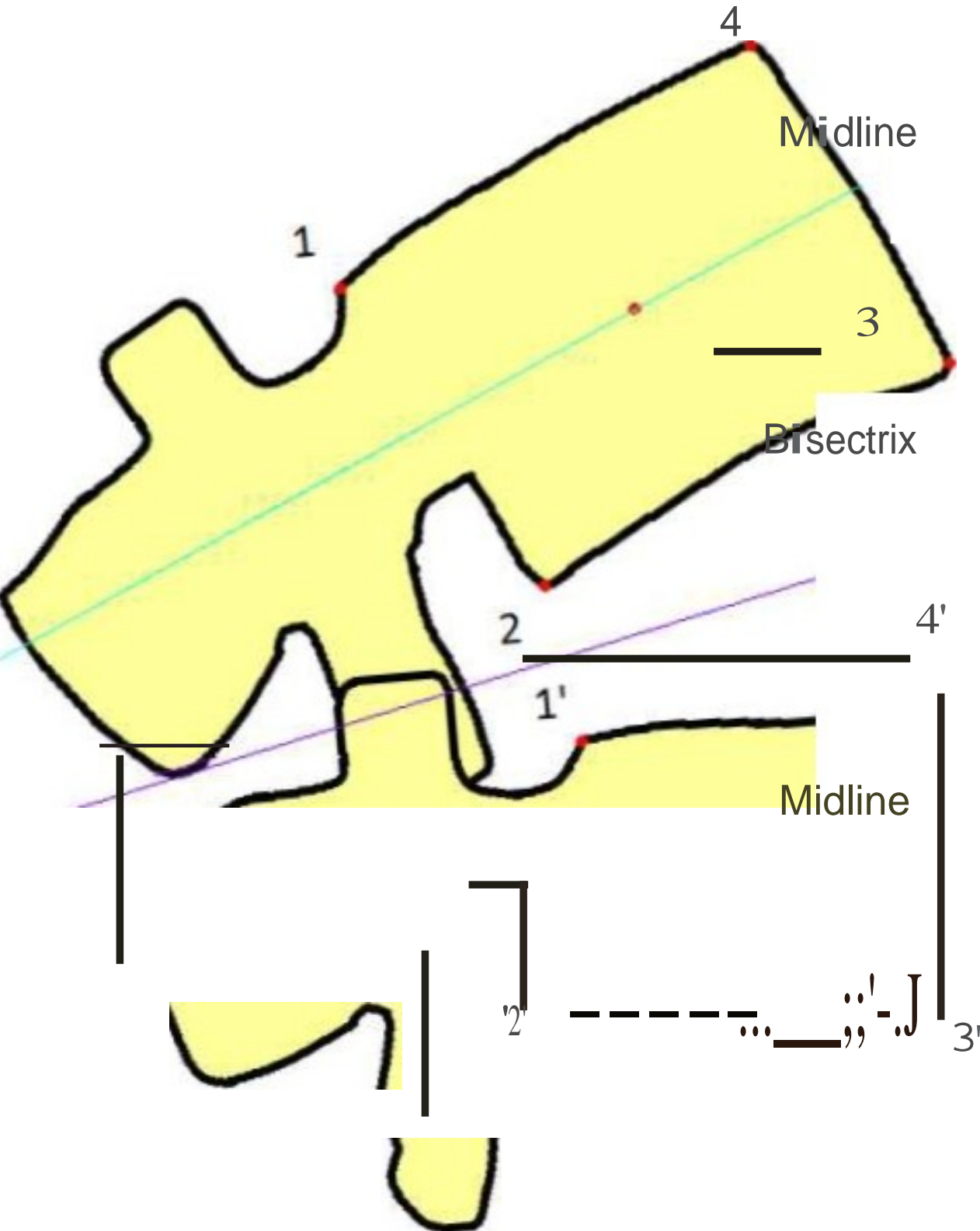
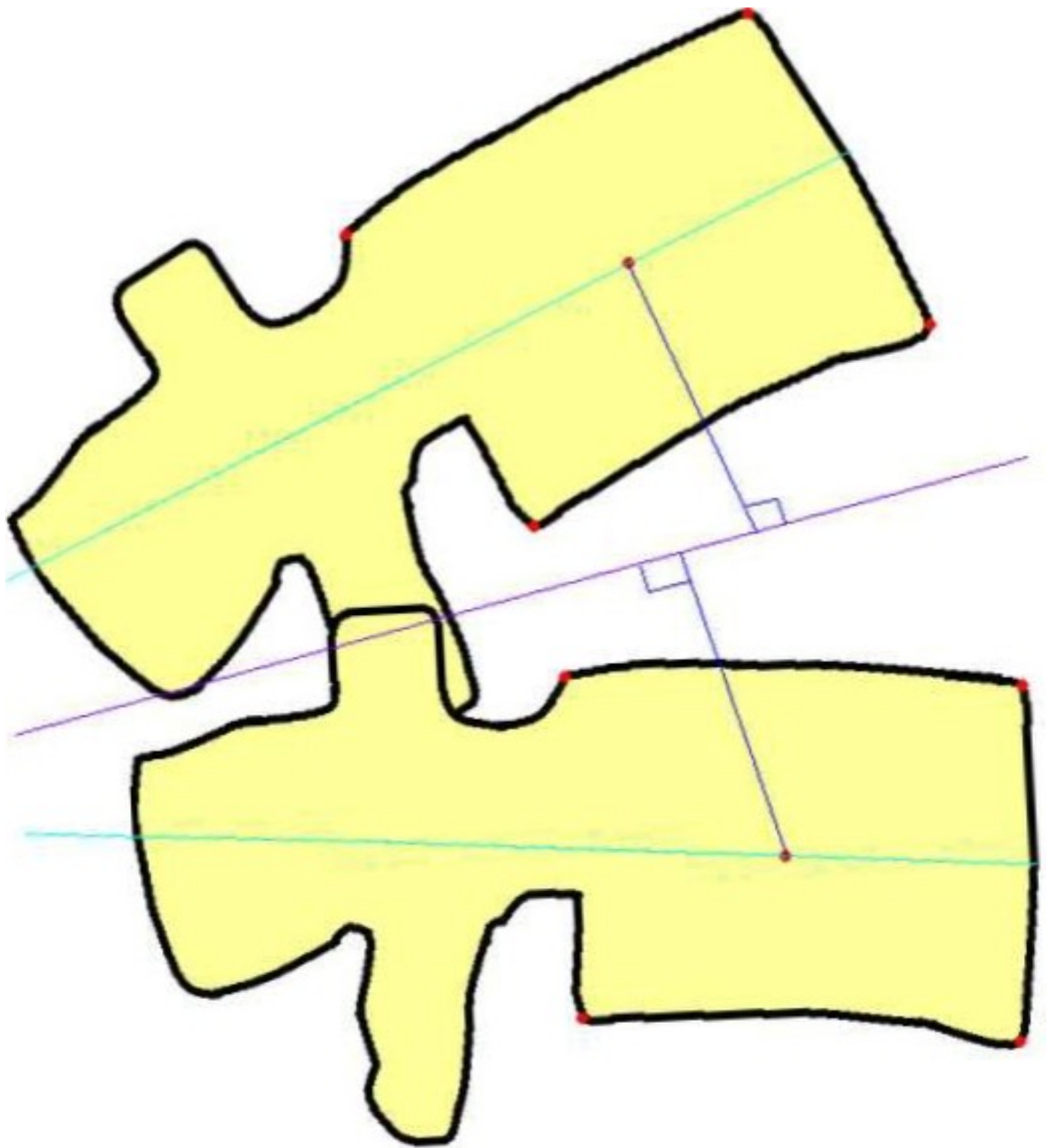


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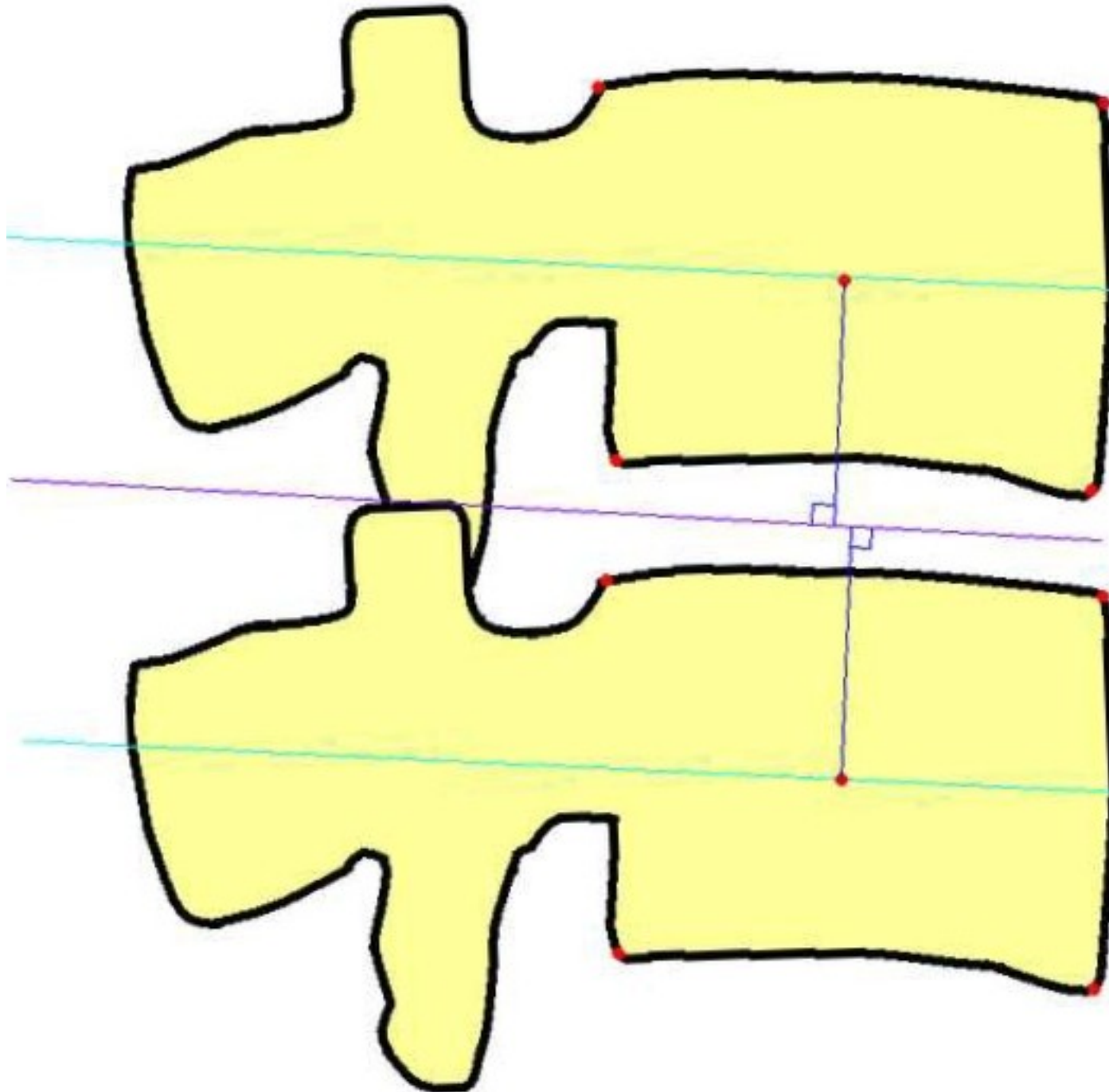


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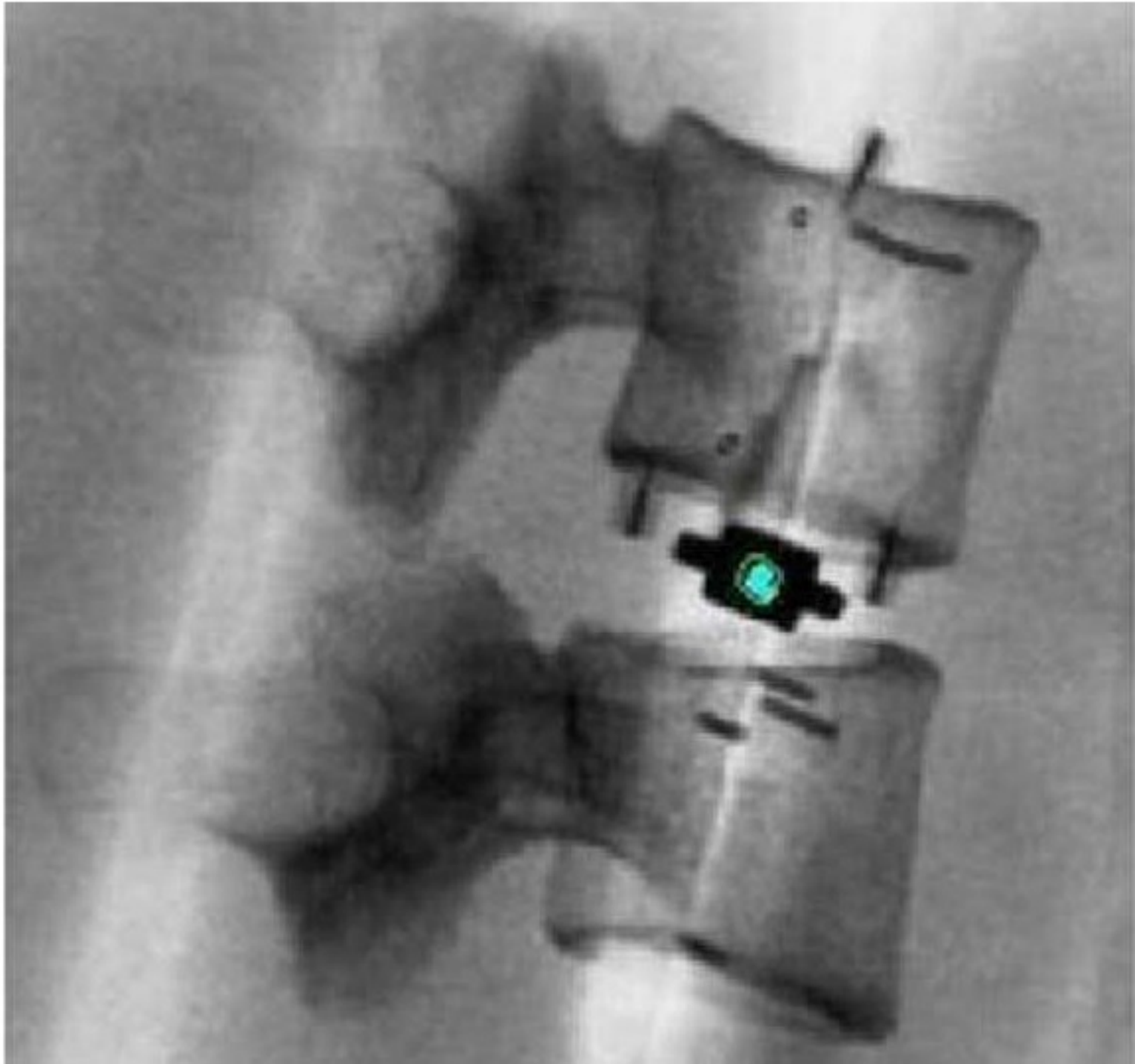


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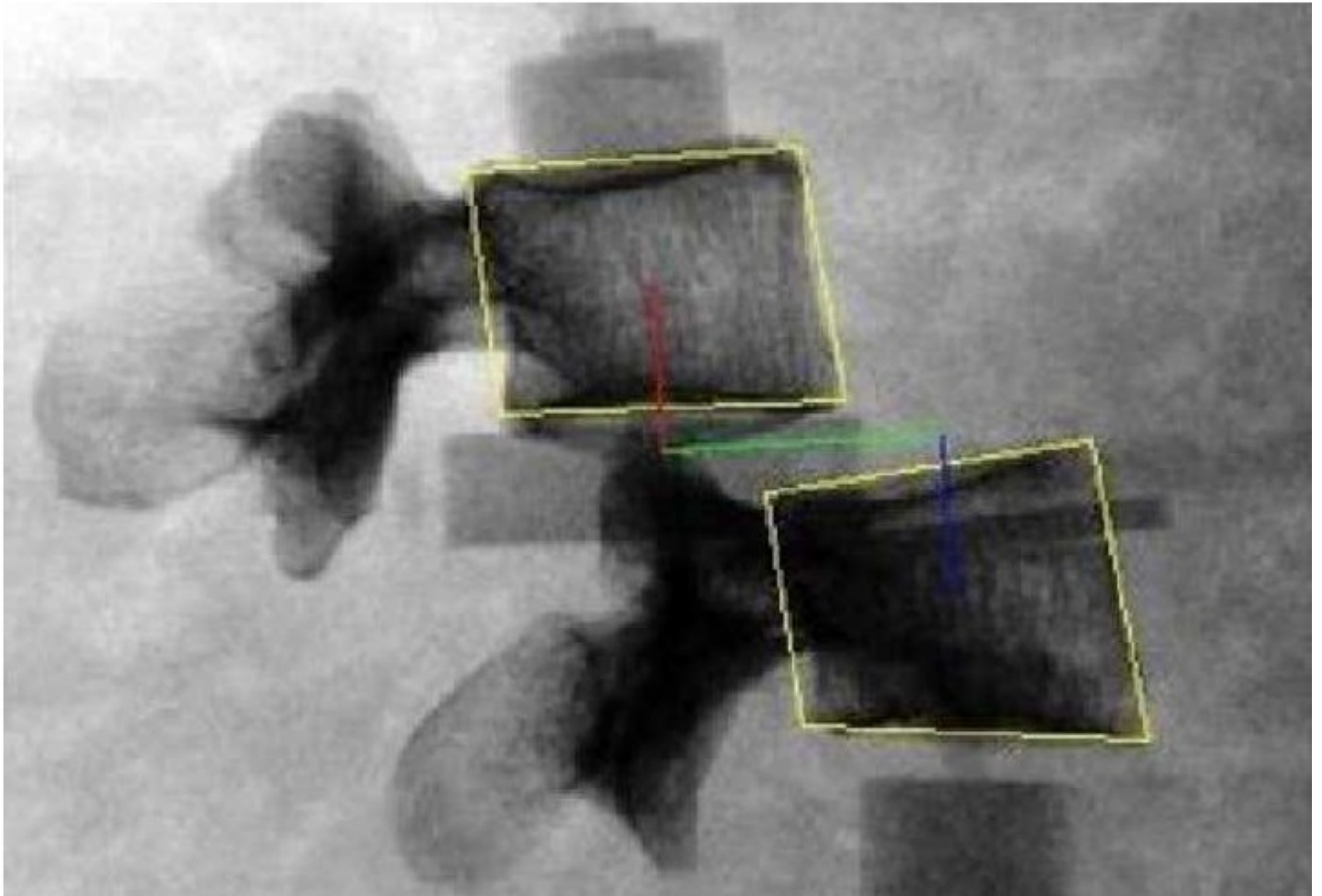
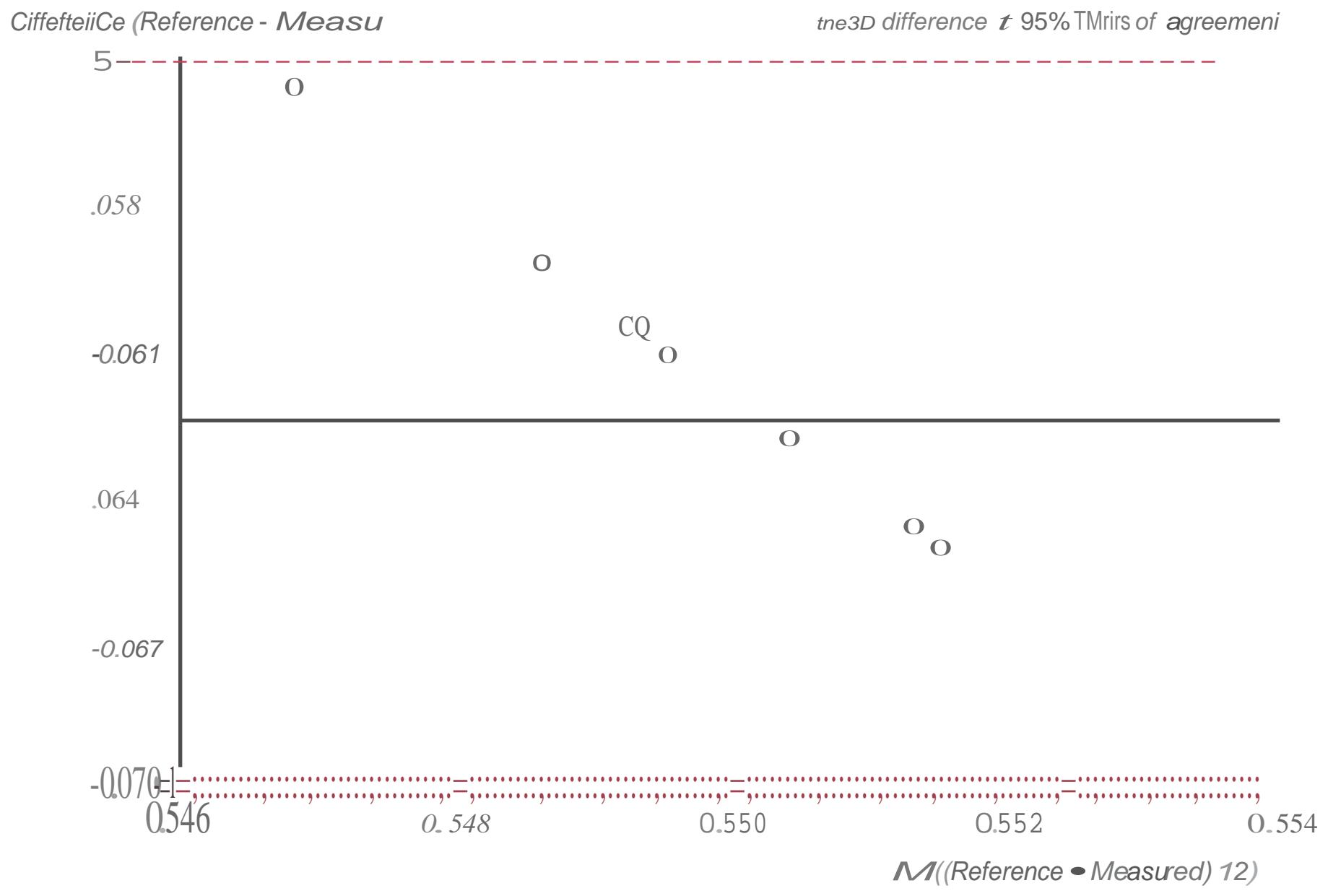
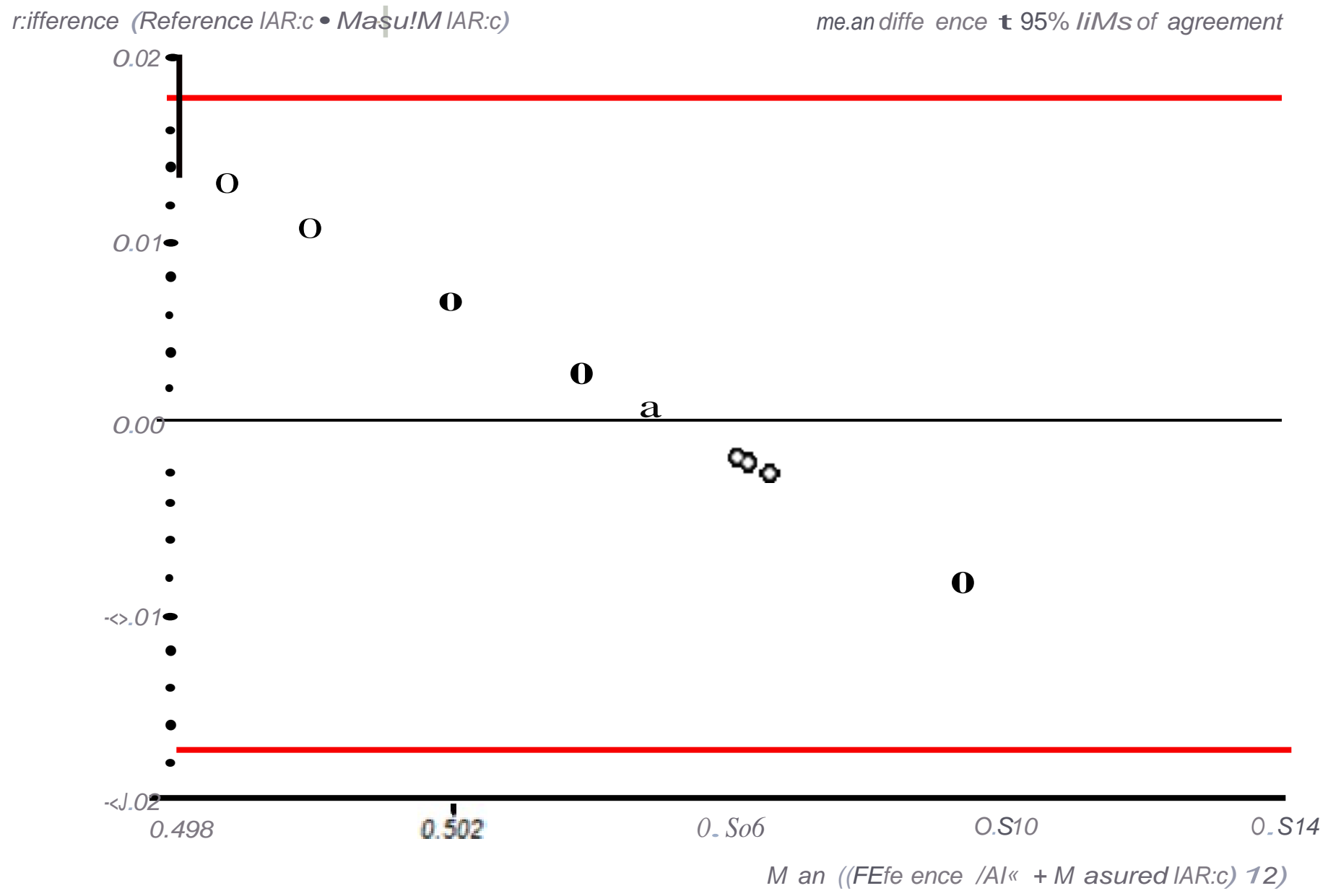
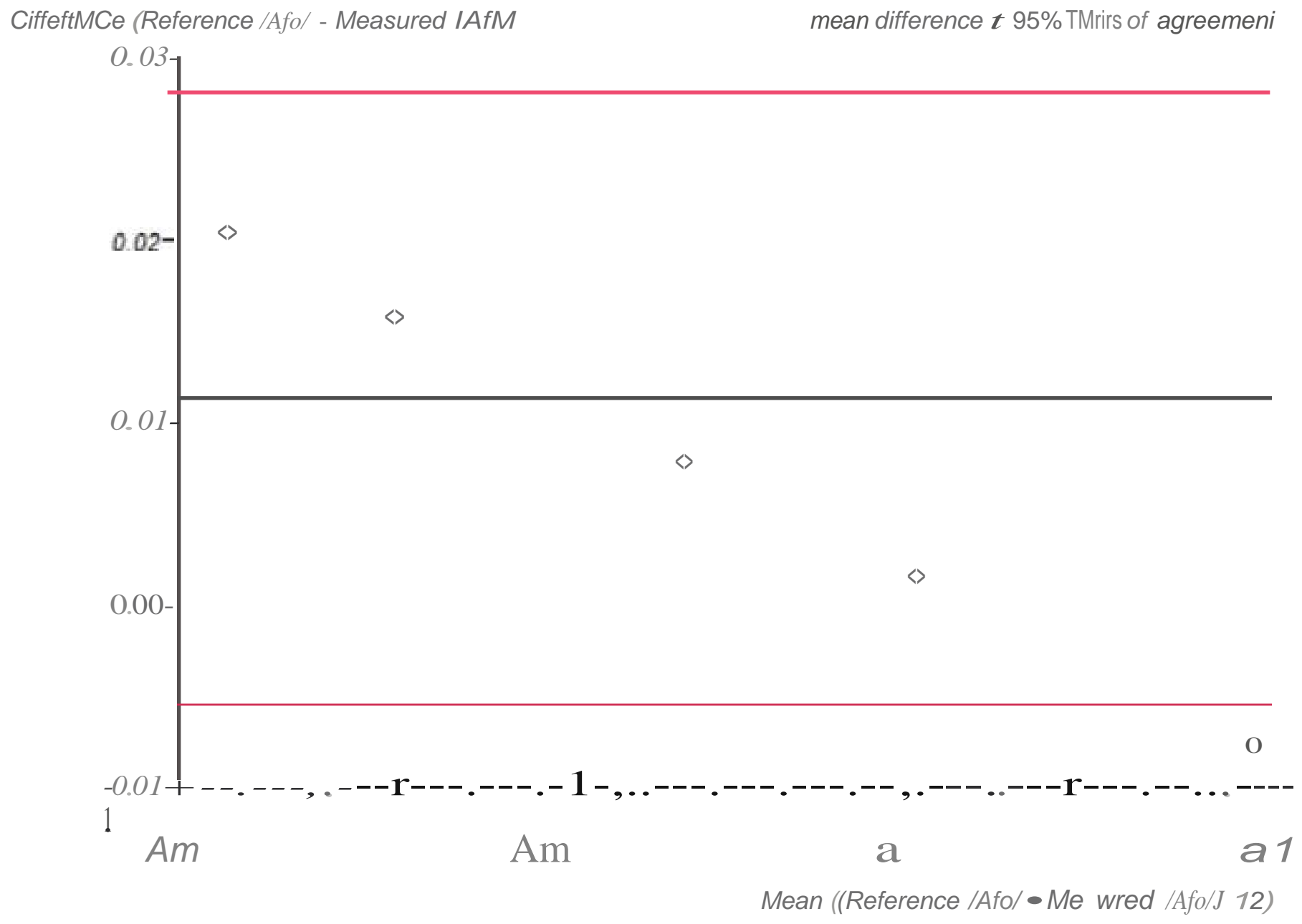


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Tables

Table 1. Participant inclusion and exclusion criteria for repeatability study

Inclusion criteria	Exclusion criteria
<p>Male and female. Age 21–51 years. Able to understand written information. Willing to participate Able to freely give informed consent. Menstruation within last 28 days, or evidence of contraceptive use, or sterility (females). Consent to GP being informed of inclusion in study. Able to tolerate 80 degrees of flexion–extension passive trunk motion</p>	<p>Pregnancy Mental illness Poor understanding of English Recent abdominal or pelvic surgery. Previous mid-lumbar spinal surgery Body mass index (BMI)>31 Medical radiation exposure in the past 2 years with a dose of greater than 8 mSv (defined as CT scan of chest, abdomen or pelvis or interventional procedures under radiological control, i.e. angiography). Current involvement in any other research study. Hyper-mobility syndrome Pathology such as fracture, infection, neoplasm. Spinal stenosis. Spondylolisthesis. Radicular pain. Litigation or compensation pending</p>

Table 2. RMS differences between reference and measured translation and FCR locations

	Fixed specimen			Translating specimen		
	VBU	mm	95% LoA (VBU)	VBU	mm	95% LoA (VBU)
Translation	0.004	0.10	0.001 to 0.006	0.062	2.16	0.055 to 0.070
IARx	0.009	0.25	-0.017 to 0.018	–	–	–
IARy	0.014	0.40	-0.028 to 0.005	–	–	–

Table 3. Intra and interobserver repeatability of translation by level and direction

Level	n	Flexion						Extension					
		Intraobserver			Interobserver			Intraobserver			Interobserver		
		SEM (mm)	ICC (95%CI)	n	SEM (mm)	ICC (95%CI)	n	SEM (mm)	ICC (95%CI)	n	SEM (mm)	ICC (95%CI)	
L2-3	11	0.18	0.988 (0.958-0.997)	11	0.51	0.865 (0.499-0.964)	7	0.21	0.935 (0.671-0.989)	6	0.17	0.932 (0.514-0.990)	
L3-4	14	0.43	0.533 (0.406-0.849)	14	0.46	0.570 (-0.339-0.862)	13	0.40	0.742 (0.185-0.920)	12	0.35	0.809 (0.337-0.945)	
L4-5	11	0.39	0.853 (0.483-0.947)	11	0.62	0.700 (-0.115-0.919)	10	0.56	0.899 (0.619-0.975)	7	0.65	0.916 (0.512-0.982)	
L5-S1	13	0.77	0.828 (0.456-0.947)	12	0.75	0.844 (0.458-0.955)	10	1.14	0.644 (-0.344-0.910)	8	0.64	0.910 (0.553-0.931)	

Table 4. Intra and interobserver repeatability of FCR location (pooled data)

Flexion							Extension					
Intraobserver			Interobserver				Intraobserver			Interobserver		
	n	SEM (mm)	ICC (95%CI)	n	SEM (mm)	ICC (95%CI)	n	SEM (mm)	ICC (95%CI)	n	SEM (mm)	ICC (95%CI)
IARx	30	1.72	0.816 (0.678-0.953)	24	2.03	0.621 (0.429-0.813)	21	1.82	0.852 (0.680-1)	21	1.19	0.876 (0.727-1)
IARy	30	1.75	0.626 (0.421-0.830)	24	1.86	0.690 (0.497-0.882)	21	1.51	0.999 (0.833-1)	21	5.67	0.878 (0.659-1)