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THE REPEATABILITY OF SONOGRAPHIC MEASURES OF FUNCTIONAL PELVIC FLOOR ANATOMY.

Hypothesis / aims of study
Ultrasound is increasingly being used in the diagnostic evaluation of patients with symptoms and signs of pelvic floor dysfunction(1). While the repeatability of measurements obtained during post-processing of volume data sets and of measurements obtained on the same day seems high, there is little data on the reproducibility of measurements obtained at longer intervals. This is relevant due to the potential confounding effect of bowel filling and stool consistency, muscle resting tone and neuromuscular activation status, the varying effectiveness of patient instruction and investigator performance. Due to the nature of clinical practice at our unit, patients undergoing surgical management for urinary incontinence or female pelvic organ prolapse are assessed twice- once at the time of the initial visit in a public hospital, and again after urodynamic testing in a private setting. The aim of this study was to determine the short to medium-term repeatability of translabial ultrasound (US) measures of prolapse and pelvic floor anatomy by comparing archived volume US datasets obtained at those two appointments.

Study design, materials and methods
This is a retrospective study analysing archived US volume datasets obtained in the context of routine clinical practice at a tertiary urogynaecological unit. Patients with two separate assessments prior to surgical management of pelvic floor dysfunction between Jan. 08 and Nv. 2012 were included. At both assessments participants had undergone an interview and 4D translabial US with a Voluson type system with RAB 4-8 Mhz transducer, after voiding and in the supine position as previously described (2), by a total of approx. 20 individual examiners, under the supervision of the senior author or five other staff trained by him for 3 months or more. US data analysis was performed by the first author on a desktop PC using the software 4D View v10, blinded to all other data. Bladder neck descent, cystocele, uterine descent, presence of a true rectocele and rectocele depth, hiatal area on valsalva and levator avulsion were determined by tomographic US as previously described (3; see Figure 1). We used Cohen's kappa and Intraclass correlation statistics (absolute agreement definition) to define repeatability of measurements. We did not perform power calculations due to the absence of pilot data and the retrospective nature of this research.
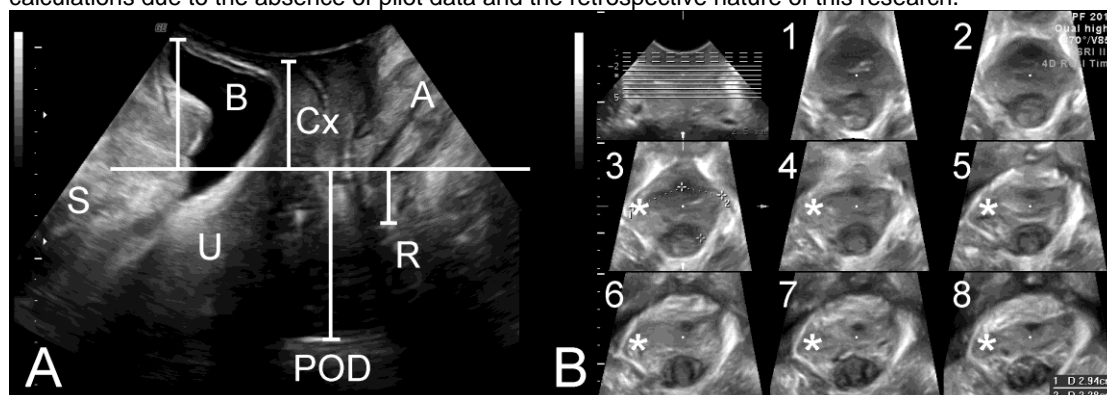

Figure: Assessment of prolapse (A) and levator avulsion (B) by translabial 4D US. S= sym-physis pubis, B= bladder, Cx= cervix, U= uterine corpus, R= rectal ampulla, POD= pouch of Douglas, A= anal canal. In image B '*' mark the location of a full right- sided avulsion.

Results
A test retest series of the postprocessing of 20 US volume datasets showed good to excellent inter-observer repeatability for the postprocessing analysis of bladder neck descent (ICC 0.82, CI 0.60- 0.93), cystocele (ICC 0.82, CI 0.51- 0.93), Uterine descent (ICC 0.81, CI 0.53- 0.93), area at valsalva (ICC 0.92, CI 0.80– 0.97), rectal ampulla position (ICC 0.73, CI 0.39– 0.89), rectocele depth (ICC 0.75, CI 0.48– 0.89), true rectocele (Kappa 0.69, CI 0.29– 1.09) and levator avulsion on tomographic US (Kappa 0.77, CI 0.47- 1.0). 155 patients with two available US volume datasets between Jan. 2008 and Nov. 2012 were identified from the institutional databases. 40 cases with interval greater than 6 months and 10 with missing volume datasets were excluded, leaving 106 for analysis. All reported data pertains to those 106 patients. The interval between assessments was a mean/ median of 73 days (range, 1-178). The mean age of participants was 58 years (SD 12.8, range 27-87), mean BMI was 30.4 (SD 5.5), median parity was 3 (range, 1-10). All patient had had at least one vaginal delivery. 53 (50%) had a previous hysterectomy and 34 (32.1%) had previous surgery for pelvic organ prolapse or stress incontinence.
71 (67%) patients suffered from symptoms of prolapse, 83 (78.3%) of stress incontinence, 80 (75.5%) of urge incontinence, 46 (43.4%) of symptoms of voiding dysfunction, 36 (34%) from constipation and 61 (57.5%) of obstructed defecation (OD) symptoms; 17 (16%) had fecal incontinence. 96 (90.6%) women were diagnosed with significant prolapse (ICS POP-Q Grade 2+) 73(68.9%) in the anterior compartment, 64 (60.4%) in the posterior compartment, and 13 (12.3%) in the central compartment.
Table 1 shows a comparison of US measurements for the first and second appointments, with means, ranges, Intraclass correlation and confidence intervals for the same, and bias. There was no appreciable systematic bias, with the difference between assessments showing mean differences of 0.9 mm for Bladder neck descent and cystocele descent and 1.2 mm for uterine descent.

Parameter	First assessment		Second assessment		Intraclass correlation	Confidence Interval	Systematic bias	
Bladder neck descent (mm)	28.4	(1.3 to - 58.4)	29.3	(1.3- 61)	0.74	0.57- 0.83	-0.9 mm	(-3.1 to 1.4)
Cystocele descent (mm)	-9.4	(25.9 to -59.4)	-8.5	(28.8- -54.2)	0.81	0.73- 0.87	-0.9 mm	(-3.3 to 1.6)
Uterine descent (mm)	-2.5	(45.8 to -49.5)	-1.3	(41.2 to -52.6)	0.79	0.66- 0.87	-1.2 mm	(-5.4 to 2.9)
Rectocele descent (mm)	-16.3	(16 to -45.6)	-12.1	(26.5 to -42.9)	0.44	0.26- 0.58	-4.2 mm	(-6.8 to -1.7)*
Rectocele depth (mm)	18.7	(10 to 35.4)	19.4	(10.1 to 45.1)	0.73	0.45- 0.86	3.4 mm	(1.4 to 5.4)**
Hiatal area (cm2)	33.5	(15.5- 66.3)	33.4	(12.7 to 70)	0.93	0.90- 0.95	+0.1 cm2	(-0.7 to +1.0)

Table 1: Repeatability of sonographic measures of pelvic floor functional anatomy (n= 106).

As regards qualitative findings such as the diagnosis of levator avulsion and true rectocele, agreement was very high (agreement in 101/ 106 cases, kappa 0.91 for avulsion (CI 0.77- 0.94) and agreement in 92/ 106 cases, kappa 0.73 (0.56- 0.84) for true rectocele.

Interpretation of results
In this series of 106 patients assessed twice by translabial 4D US at an average interval of 73 days, we found high repeatability of all tested parameters of pelvic floor function. The most repeatable qualitative measure was diagnosis of avulsion by tomographic US with a kappa of 0.91 and agreement in 95% of cases. Hiatal area on Valsalva was highly repeatable as were most measures of pelvic organ descent. The least repeatable measures related to the posterior compartment, likely due to variation in stool quality and rectal filling. These results are reassuring, especially given that volumes were obtained by a large number of different trainees under direct supervision, and given that offline analysis was performed by a trainee after less than two weeks of training.

Concluding message
Both qualitative and quantitative assessment of pelvic floor anatomy by 3D pelvic floor US is highly repeatable.

References
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