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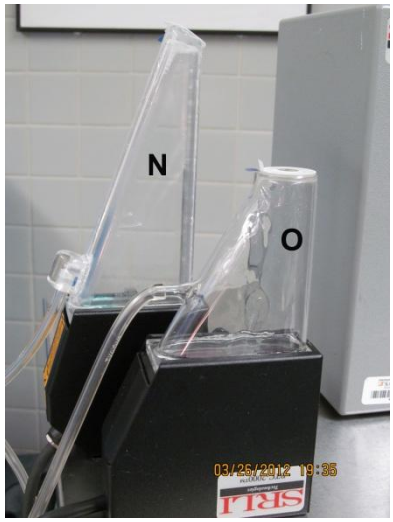
A NEW CUTOMETER-LIKE DEVICE FOR INVIVO MEASUREMENTS OF HUMAN VAGINAL WALL BIOMECHANICAL PROPERTIES

Hypothesis / aims of study

Human vaginal wall biomechanical properties have been tested ex vivo in frozen/thawed tissue samples (1), and more recently in fresh anterior vaginal wall samples (2). In vivo testing of human tissues with a cutometer-like device originated with the study of wound healing in plastic surgery. Application to the human vaginal wall is under investigation with inconclusive reports so far. We report on the validation steps for a new prototype designed for office testing.

Study design, materials and methods

Following IRB approval, women scheduled for advanced stage (stage ≥ 2) anterior compartment prolapse repair underwent combined measurements of their anterior vaginal wall biomechanical properties using an original cutometer-like device (O)(BTC-2000 from SRLI) and a newer version (N) designed for better vaginal fitting. The new device is narrow-shaped at its extremity, has a slightly oblique aperture of same diameter (10mm) as the original version, and can measure tissue deformation during a 6 seconds suction phase by laser altimetry as did (O). A methodology identical to the one used in a prior study (3) investigating the reliability of the (O) cutometer-like device was applied. First, measurements were made in duplicate by the primary surgeon (R1) and a neutral observer with no prior training in the use of the device (R2). Intra (IaR) and inter-rater (IrR) reliability testing was performed for the anterior vaginal wall measurements at the level of the bladder neck as indicated by the balloon of a Foley catheter for reproducibility purposes, and at a reference point, the suprapubic region on the midline about 1 cm above the pubic symphysis. All measurements were obtained after complete bladder drainage and at the start of the procedure following patient intubation to minimize variability and patient interference. Second, data obtained with the (O) device was compared with data obtained with the (N) device for the anterior vaginal wall and suprapubic regions. Biomechanical parameters displayed by the instrument were assessed for reliability using an intra-class correlation coefficient (ICC), with 0.6 as the cuff-off for reproducibility.



Results

Five women were tested sequentially with both devices, both suprapubically (SPR) and vaginally (V). For the new prototype, intra-rater reliability was high for the primary, more expert tester (R1), and lower for any other tester selected at random in the operating room (R2). Because of this difference between tester experience, inter-rater reliability was lower than IaR. The highest level of reliability was obtained for the suprapubic region over the anterior vaginal wall (Table 1).

When comparing O and N devices, a very good correlation was noted for laxity, elastic deformation, and elasticity both for anterior vaginal wall and suprapubic measurements (Table 2).

Interpretation of results

Comparison of an original cutometer-like device with a novel version more adapted for anterior vaginal wall measurement of in vivo biomechanical properties revealed a good correlation for laser-altimetry measurements related to laxity and elastic deformation during the suction phase, and to elasticity when the tissue returns to baseline at the end of the suctioning effect. Expert performance was better than a neutral observer performance, suggesting a learning curve. Future users are encouraged to study their intra-rater reliability performance.

Conclusion

A novel cutometer-like prototype modeled after the BTC-2000 original device indicates suitable performance for women with a large anterior vaginal wall prolapse. The high IaR for an expert tester, good O vs N correlation and improved probe design suggest that the N device warrants further testing in the office setting..

Table 1 Intra- and Inter-Rater Reliability Testing of New Prototype (N)

Measurement (mm)		Intra-Rater R1		Intra-Rater R2		Inter-Rater R1 v R2		
		IaR R 1 ICC	IaR R1 p-value	IaR R2 ICC	IaR R2 p-value	IrR ICC	95% CI	p- value
Laxity	**V**	0.82	0.01	0.20	0.32	0.42	-0.61, .94	0.20
	SPR	0.68	0.04	0.70	0.03	0.74	-0.04, .96	0.03
Elasticity	**V**	0.50	0.13	0.78	0.03	0.15	-0.76, 0.9	0.37
	SPR	0.93	0.001	0.64	0.06	0.45	-0.76, .90	0.15
Elastic Deformation	**V**	0.73	0.03	-0.10	0.53	0.60	-0.42, .96	0.10
	SPR	0.87	0.005	0.70	0.04	0.74	-0.04, .96	0.03

V – Anterior Vaginal Wall; SPR – suprapubic region

Table 2 Comparison of anterior vaginal wall and suprapubic region measurements for the original (O) device and new prototype (N) in same patients

				Anterior vaginal wall		Suprapubic region	
Measurement (mm)	**Machine**	**Mean**	**Std. Dev.**	**p-value**	**Mean**	**Std. Dev.**	**p-value**
Laxity)	O	1.39	0.43	0.68	1.64	0.36	0.79
	N	1.54	0.63		1.58	0.24	
Elastic	O	2.23	0.36	0.50	2.04	0.42	0.74
Deformation	N	2.50	0.76		1.96	0.30	
Elasticity	O	0.80	0.22	1.00	1.28	0.25	0.32
	N	0.80	0.34		1.12	0.25	

References

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Disclosures

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