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FEASIBILITY AND CORRELATION OF IN VIVO MEASUREMENT OF VAGINAL BIOMECHANICAL PROPERTIES USING A PURPOSE DESIGNED VAGINAL PROBE

In the field of dermatology, non invasive aspiration devices that can measure the biomechanical properties of skin are clinically used. They are presumed to measure properties of the dermal component of the skin, consisting of collagen and elastin fibers. It seems logical that these devices could be applied for similar measurements at the level of the vaginal wall. One such device (DermaLab skin probe; Cortex Technology, Hadsund, Denmark) has already been used for that purpose. The aspiration device, has a diameter of 2cm and a height of 1.5cm. The probe suctions at a preset vacuum pressure the vaginal wall into an opening of a 10 mm diameter (=aperture). During this process it measures the actual pressure (stress) and vaginal wall displacement (strain). In Epstein's study [(1)],a single location was measured, i.e. on the left lateral vaginal wall, 2cm above the hymenal ring. That device was not designed for intravaginal use, so that we searched for an alternative. Also, a 10 mm aperture may cause aspiration of compliant vaginal tissue into the probe, causing uninterpretable recordings. Last, prolapse is a site specific condition so that one may need site specific measurements. Herein we tested a prototype device, derived from the Cutometer MPA 580 (Courage and Khazaka Electronic GmbH, Cologne, Germany). This device which is designed for intravaginal use, has a length of 20 cm and the largest diameter of the device is 3 cm. It's prototypes have either a 6 or 8 mm aperture.

Study design, materials and methods

In total 45 consecutive patients, referred for pelvic floor ultrasound with a variety of pelvic floor problems, first underwent clinical assessment using the POP-Q classification. This was followed by a first elasticity measurement (aperture:6mm), whereafter the pelvic floor ultrasound was done, followed again by a second measurement (aperture:8mm). First outcome variable was the ability to introduce the probe for measurement. If it failed, the reason for it was noted. If successful, a typical vaginal elasticity measurement consisted of a single cycle with an aspiration pressure of 300 mbar, an aspiration pressure comparable to dermal measurements. Both suction and relaxation time consist of 5 sec after an initial 10 sec pretime without aspiration. The measurements were taken at four places: two on the anterior vaginal wall, at point Aa and 5 cm above the hymenal ring (=Aa-2 cm), and two on the posterior wall, at point Ap and 5 cm above the hymenal ring (=Ap-2 cm). The Cutometer MPA580 software displays a series of plots and parameters (=recording), among which R0: firmness of the vaginal wall; R2: overall elasticity and R7: ratio of elastic recovery to the total deformation, which are representative for the entire measurement. After measurement, the recording was judged to be interpretable or not, based on its quality. If not, up to three attempts were made to obtain a better recording. In its absence, the entire measurement for this location was classified as failed. Descriptive statistics and factor analysis were done using, JMP®7 software (SAS Institute Inc., Cary, NC, 2007). Factor analysis allows to determine which experimental conditions affect the measurements in a significant way and which experimental conditions could be considered as irrelevant.

Results

Introduction failure: of the 45 patients (range 28-83yrs) enrolled, in 11 patients (24.4%) the probe could not be inserted either because of pain or discomfort (n=8) or because of vaginal bleeding that particular day (n=3). Though at first glance invasiveness of elasticity measurement is no different from that of transvaginal ultrasound, the need for measurements without lubrification gel in an atrophic vagina of a patient without prolapse is difficult (failure rate in ≤grade I resp. grade II+ prolapse: 15.5% vs. 0%: p0.003). Once the elasticity measurement probe could be introduced, the second insertion, after the pelvic floor ultrasound was always successful.

Measurement failure and interpretable results: This left us with 34 patients, and up to 4*34=136 measurements with the 6 mm resp. the same for the 8 mm device. Elasticity measurements typically took less than 5 min. The usability of the recordings with each of the apertures are displayed in table 1. The overall usability rate of recordings was (165/272; 60.66%), but that with the 6 mm aperture device were more frequently usable than those with the 8 mm.

Table 1: Measurements which could be interpreted

	6 mm n	8 mm n
Stage 0	2	1
Stage I	12	5
Stage II	11	4
Stage III or more	8	6
Measurement at Aa	34 (100%)	14 (41.18%)
Measurement at Aa- 2cm	25 (73.53%)	10 (29.41%)
Measurement at Ap	30 (88.24%)	11 (32.26%)
Measurement at Ap-2cm	30 (88.24%)	11 (32.26%)
All measurements :	119 (87.5%)	46 (33.82%)
Minimum 1 measurement	31 (91.18%)	15 (44.12%)
All four measurements:	110 (84.03%)	7 (5.15%)

Correlation study*:*

Factor analysis: In 16 patients measurements could be obtained with both devices in at least one site. The results of a factor analysis of the measurements using Device and Site as main factors are displayed in Table 2. This was possible for 13 (81.2%) observation pairs at Aa, for 10 (62%) at Aa-2cm, for 11 (68.75%) at Ap and 11 (68.75%) at Ap-3. In brief, the effect of using an aperture of 6 or 8 mm (Device) is highly significant. Conversely the effect of measuring at different locations (Site) is not

significant (p>0.05). There was no significant interaction between Device and Site. These effects are most pronounced for R0, R2 and R7.

Table 2.Effect test performed by factor analysis.

	Device 6-8 p value	Site p value
R0	< 0.001	0.0681
R2	0.002	0.6293
R7	0.002	0.3398

Interpretation of results

In one out of four patients, we could not introduce the probe, hence start measuring, mainly because of pain. This was however confined to patients without prolapse. In other words, in prolapse patients we had a 100 % success rate for introduction of the probe. After introduction, measurements turned out to be uninterpretable in 17/136 (6 mm) and even more for the 8 mm device (110/136), its reasons being undetermined. Further, the two apertures give significantly different measurements, so measurements cannot be interchanged. On the other hand, measurements from one site were representative for the other tested sites, at least in this population.

Concluding message

It seems that the current prototype can be improved, to diminish the introduction failure rate. This is particularly relevant for patients without prolapse, which will be required to do normative studies. In this respect, it is fortunate that the smaller aperture provides less interpretation problems, so that a device with smaller diameter could be constructed.

The high measurement failure rate is another problem, which remains unexplained. Most probably it is due to aspiration of vaginal mucus, or an abnormally compliant vagina. For that purpose a device that provides visual feedback of the vaginal displacement may be helpful.

We were surprised that measurements were not different between sites, although prolapse is at times site specific. Also we need to obtain measurements in severe prolapse patients, which most probably have more compliant vaginas as well as patients with more discrepancy in prolapse per site. Also it may be that elasticity measurements are not indicative of the deeper vaginal structures.

References

1. Epstein LB, Graham CA, Heit MH. Systemic and vaginal biomechanical properties of women with normal vaginal support and pelvic organ prolapse. Am J Obstet Gynecol 2007;197:165.e1-165.e6.

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of the University Hospitals Leuven.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**