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PERINEAL ELASTICITY METER

Hypothesis / aims of study

To present the development of a new equipment (perineal elasticity meter) from its idealization through development.

Study design, materials and methods

It was initially designed and produced a prototype consisting of one central circular millimeter stem 1; a cursor 2 with a leaked area 3 that demonstrates the formed circumference by the opened expanders 4, that are fixed at 7 and 8 stems on the 9 and 10 hinges. When traction is made in the cursor 2, it demonstrates the circumference measurement and the expanders open the circumference to the maximum of 12 centimeters of diameter (Figure 1)

The second model that was projected consists of two stems, fixed in their proximal extremities through hinge 2. In the distal extremity, there is a millimeter stem which can be fixed or moved through the hinge 4. It has a similar form to a gynecological speculum, but with a more superficial exam (only the middle third of vagina, will not have contact with the uterine cervix (Figure 2 and Figure 3).

After the development, we have filed a Brazilian patent number 018080032067 and an International Patent by PCT (Patent Cooperation Treaty) numbered 000178.

The next step was to discover which could be considered as a good elasticity opening of the stems. Then, we compared a good *Epi-no*® perimeter of 21 centimeters ¹ to the opening of our equipment.

Results

The first developed equipment did not prove to be applicable to measure perineum extensibility because of the great resistance of the vaginal walls (anterior, posterior, laterals) simultaneously stretched. It was used experimentally in the researches. So, we improved the idea of the perineal elasticity meter, experiencing the vaginal speculum action of antero posterior opening that can reach a maximum of 12,5 centimeters.

The second equipment was then developed and applied again in the researches, and then it worked well.

When compared one of researcher with a good perineal elasticity, to *Epi-no*® perimetry of 21 centimeters, it was equivalent to 10 centimeters of opening stems (the inner measure) of the perineal elasticity meter.

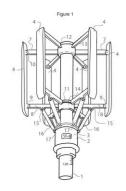
Interpretation of results

Selective episiotomy seems to be more beneficent than it's routine use (1). Natural birth without surgical procedure has been advocated worldwide, but the concern about the parturients' safety exists. For this reason, procedures that can reduce the use of episiotomy have been studied such as *Epi-no*® use during pregnancy (2). Evaluating quantitatively pelvic floor extensibility or elasticity could be useful in deciding to use or not an episiotomy. *Epi-no*® showed to be an efficient measurer of pelvic floor extensibility, but this equipment was not developed for this purpose. Our elasticity perineal meter, on the other hand, was developed with this purpose and it should be uncomplicated to manipulate and financially accessible, with a low cost involved. Our next project is to produce the elasticity perineal meter in disposable plastic and to conduct a large clinical study, to prove the efficacy and safety of the equipment.

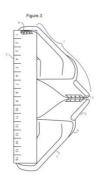
Concluding message

It is really difficult to create a new equipment nowadays, due to lots of technology available with high costs. But the need to use an accessible perineal elasticity meter in our studies prompted us to develop this presented equipment. There is a long study that must be done before it become ready to be commercialized.

Fig. 1- First equipment Fig. 2- Second equipment closed Fig.3- Second equipment opened







References
1. Zanetti, MRD- Quantitative evaluation of perineal extensibility. PhD thesis. 2010

Specify source of funding or grant	None
Is this a clinical trial?	No
What were the subjects in the study?	NONE