Introduction

In the human body, two main muscular structures are basically arranged transversely, while all others are arranged mostly longitudinally: the diaphragm and the pelvic floor, both important in compartmentalize two adjacent structures but different. Like all muscles, so that...
to preserve muscle tone they must be continuously “trained”, as well as with skeletal muscle whose tone is maintained and enhanced by constant exercise. As regards the diaphragm, this is a partition muscle between the chest and abdomen and it is constantly activated because, for its strategic functional role, allows the continuous and rhythmic lung expansion as well as the rhythmic cardiac excursions, for which his tone is always preserved. The pelvic floor instead is, from the strictly anatomical viewpoint, composed of 3 fibromuscles overlapping layers (Figure 1):

1. **Pelvic diaphragm** is the deepest layer, made up of the elevator ani with its bundles ischio-coccigeal, pubo-coccigeal (medially to whom shall run bundles of the two pubo-rectal muscle) and ischiolum-coccigeal. The Pelvic Diaphragm bundles are arranged bilaterally to fan, whose spindle is constituted by the coccyx. Two parts of elevator ani muscle bundles, which in fact constitute a single functional unit, converge on the so-called central tendinous of perineum, aponeurotic structure stretched between the vaginal canal and the rectum. Within the midline of the pelvic diaphragm there is the hiatus genitalis, that is a continuity solution of the same one which both the rectum, vagina, and urethra pass through. Pelvic diaphragm is inserted anterolaterally on the tendineous arch, a fibrous structure stretched between the pubis and ischial spine. Below the elevator ani muscle is the ischio-rectal fossa.

2. **Urogenital diaphragm** is a triangular shaped structure upper side the elevator ani, in anterior perineum. It is composed by bischiatic line, that ideally is its base, and by ischiolum-pubic branches, that are the lateral sides; the vertex consists in the pubic symphysis. The urogenital diaphragm consists in deep perineal transverse muscle and pubourethral ligaments. Within the midline of the pelvic diaphragm there is the hiatus genitalis, that is a continuity solution of the same one which both the rectum, vagina, and urethra pass through.

3. The outer layer is formed instead of the sphincters floor composed by 4 muscles: the ischio cavernous muscle (from the ischiolum to the clitoris root); the vaginal constrictor muscle (from tendinous centre of perineum to clitoris); the superficial transverse of perineum muscle (from tendinous centre of perineum to ischial tuberosity); the sphincter ani muscle (place around the anal canal). The front of the sphincters floor is the clitoris bulbar lodge in which there are the clitoris cavernous bodies and the vestibular bodies.

During the pregnancy there is a gradual sliding, though slight, of these 3 layers due to the increased gravitational load and to the hormonal changes of gestational season; in fact there is a significant increased production of progesterone supported by the persistence of the corpus luteum induced by chorionic gonadotropin of trophoblastic sourcing before and placental later, as well as estrogen-derived placental rather than ovarian; moreover the placenta and the decidua basalis produce a peptide hormone, relaxin, which is produced by the ovary in childbearing age (1).

Relaxin is structurally similar to insulin and acts by counteracting the action of oxytocin on myometrial cells and inhibiting collagen synthesis due to increased collagen matrix metalloproteinases (MMP) (1, 2). This new hormonal statement, deliberately limited to changes that occur in the pelvic floor, allowing a greater trophism and a hypervascularization of all pelvic organs, induced by placental estriol, as well as greater flexibility of fibrous components and joints due to MMP chondrocytic enhancement, induced by synergism of estriol and relaxin. Progesterone, produced by the placenta with pregnancy progresses, antagonizes the contractile myocytes effect estriolo-induced and actuates neoangiogenesis in the pelvic floor with soaking of individual muscles in synergy with functional relaxin with increased muscles-aponeurotic cleavage (5, 7) (Figure 2).

Progesterone also induces an increase in cervicovaginal glands mucus with increased viscosity and elasticity of secretions and making of cervical mucous plug that protects the amniotic fluid by infections. Near by term of pregnancy the placental relaxin reaches the highest production levels (6, 7), to detriment of progesterone that is no longer able to antagonize myotonic effect of oestradiol and onset contractions. The progesterone production drop effect during labor results in a significant intracellular MMP decrement and hyaluronidase increment, with marked reduction of hyaluronic acid especially in the vaginal extracellular matrix, which explains the vaginal dryness during la-
bor often responsible for spontaneous tears of varying degrees (1, 2, 6). For a long time the best remedy to counteract the vaginal elasticity decreased was considered preventive routine episiotomy, in order to reduce the damages caused by the unpredictable spontaneous lacerations. These practices, even if properly executed, produce inevitably loss of structural integrity in pelvic floor, with possible annoying functional aftermath sometimes disabling (3). The purpose of our study, which lasted over two years, has been to demonstrate that adequate vaginal-perineal preparation near the labor is very effective to prevent spontaneous tears during childbirth and avoid the routine episiotomy if not strictly necessary.

Materials and methods

In the period January 2013-December 2016 we observed the effects on the birth canal of a topical product based on hyaluronic acid and protectol on a sample of 236 pregnant who got to our ambulatory.

This product, available as vaginal ovules, has been made to apply every night from the 34th week until delivery. The reason that led us to use that product, is inherent in the pharmacodynamic properties of its components (1, 2, 4-7).

Hyaluronic acid is the main component of connective tissue; it is a glycosaminoglycan devoid of a proteic structure that confers a defined spatial arrangement, for which thanks to the free carboxyl groups is capable of complexing with a large number of water molecules giving to the connectival amorphous matrix elevated characteristics of hydration, plasticity and viscosity (14). The extreme molecular length along with its high degree of hydration allows more polymers of hyaluronic acid to organize themselves to form a structure of reticular type that has two main functions:

- create a molecular framework to maintain the shape and tone of the tissue;
- function as a filter against diffusion in the tissue of particular substances, bacteria, infectious agents. Only substances with a low molecular weight to pass through the “mesh” of this network will be able to spread freely in the tissue; all substances with high molecular weight, as well as bacteria or viruses, will remain entangled in the network. Substances of which protectol consists have a low molecular weight, so easily pass through the mesh made by hyaluronic acid, expounding its action.

Protectol is a polymer composed of various substances with a protective and moisturizing that contributes synergistically to amplify the action of hyaluronic acid in addition to explicate their peculiar effect:

- *Betula alba extract*: it is obtained from the *Betula alba* leaf, plant belonging to the Betulaceae family, and mainly it consists of flavonoids (iperoside, quercetin and myricetin-3-galactoside) and in smaller amounts from tannins, ascorbic acid, fenolcarbossilic acids, resins, terpene alcohols and essential oil. It shows excellent decongestant effect thanks high levels of flavonoid content.

- *Scrophularia nodosa extract*: scrophularia nodosa is a medicinal plant which grows in moist soil and temperate. From its roots you get a substance containing saponins, cardiac glycosides, flavonoids, resins, sugar and organic acids; this principle has diuretic and cardioactive actions (5, 6) and in oriental medicine is still used today for anti-inflammatory purposes, pain-relieving and skin disorders. In popular medicine, the scrofularia was known to heal wounds and other diseases such as hemorrhoids and liver, kidney and stomach problems. In the official medicine of XVI century, the plant was considered an excellent therapy against the scrofula, or more properly *adinitis tuberculosi*, an infection of the lymphonodes by mycobacterium tuberculosis. A recent indexed study has shown a potent spasmyloytic effect of scrophularia extract of whose action is expressed by the activation of muscarinic receptors (7, 9).

Among the other substances contained in our used product we include lactic acid, essential constituent
pregnant women who have agreed to undergo the vaginal ecosystem, and that by effect of increased levels of estriol as from the 32nd week decreases for direct inhibition on MPS of Lactobacillus cell wall, as well as Aloe barbadensis, prevalently consisting of polysaccharides containing D-glucose and D-mannose, as well as phytosterols (cholesterol, campesterol, and 3-sitosterol), vitamins, enzymes, trace elements and aminoacids. Aloe extract acts primarily as a skin moisturizing and soothing, but also has antifungal and antimicrobial; aloe gel made a protective film layer on the skin, with the function of excellent moisturizing agent.

Traditionally Aloe has healing, soothing and decongestants; the phytoelements of Aloe are also able to stimulate the production of collagen and elastin, helping to counteract the effects of the loss of tissue elasticity.

The assumption from which we started in experimenting a method that would make it less traumatic event “birth” and thus would increase the compliance of pregnant women against this procedure, especially if their first experience, is the axiom that spontaneous delivery it must be considered the main mode of giving birth to a child; if there is a problematic medical impediment for vaginal delivery, there is an indication to perform cesarean section (17). This explanation is unfortunately made necessary due to excessive number of cesarean sections, often solely due to the demonization of the phenomena that accompany the labor and physiological delivery and decreased tolerance in the acceptance of women in labor time and commitment needed to traval and the physiological birth (so called natural right to underline the epistemological significance of the event) (14, 17).

Adequate preparation of muscle-perineal floor is essential to minimize the tearing effects resulting from mechanical stress caused by progression of fetal body through the birth canal (3, 8).

Inevitably descending of fetal body involves the stretching of the various planes of the pelvic floor; perineum relaxes, directs and guides the baby’s head progression to opening for the childbirth. It is understandable therefore the importance of minimizing the modifications hormonal-induced in the vagina due to the decrease of MMP with intracellular increase of hyaluronidase and decrease of hyaluronic acid in extracellular matrix, with onset of hyperviscosity of vaginal fluid that predisposing to dryness often responsible for spontaneous lacerations of various degree (3, 11). The product we tested is commercially available with other indications, for which its use off-label has required an appropriate counseling with acquisition of informed consent duly compiled; it was purchased by the patient and daily independently applied from the 34th week until such time of childbirth. The 236 pregnant women who have agreed to undergo the study were all aged between 20 and 42 years; 132 of them (p=55,9%) were in their first pregnancy, while the remaining 104 (p=44,1%) have already had other pregnancies.

Among 9/104 multiparous (p=8,7% t=3,9%) had undergone 1 previous cesarean section, whereas the 95/104 remaining (p=91,3% t=40,2%) just had spontaneously birth to one or more. In agreement with current ministerial guidelines for pregnant women with single previous cesarean section, the enrollment in the study group was subdivided to the acquisition of a second informed consent on acceptance of delivery labor, obtained by adequate and complete counseling including the explanation of all the risks and possible benefits. Exclusion criteria were the rejection of delivery labor by patients with previous cesarean section, breech presentation, ultrasound evidence of a large V-shaped, hymenoele by previous cesarean section, maternal and/or fetal problems dissuading a long term termination of pregnancy (severe oligohydramnios, maternal hypertension, marked IUGR, placenta praevia or placenta accreta suspicion), anatomic pelvis defects (12). All pregnant women applied a suppository in the vagina every night and performed perineal massage with special oil.

At the 34th week all pregnant of our study were initiated in a operated by us course of preparation for childbirth in which, in addition to instilling the correct psychological approach to the event labor/delivery, much attention was given to the perineum massage working, with the help of specific media such as pilates or massage balls, which the patients then purchased to independently carry out the exercises at home (3, 8, 12, 14).

Results

All pregnant women in our study recruited have come to the end of pregnancy (37,1-41,5 ws).

In 16/236 childbirths (p=6,8%) it was performed cesarean section for various problems occurred, the analysis of which is not covered in our discussion but still independent from the use of the device object of our study, while in 220/236 (p = 93,2%) have completed the vaginal delivery.

It is interesting to note that among the 9 patients previously undergone cesarean section only in 4 cases it was necessary a second cesarean section, while the other 5 were able to give birth naturally. In 98,3% of patients (232) have come to labor with the proper mental approach, while in the remaining 4 (p = 1.7%) prevailed anxiety and fear in our opinion influenced by environmental and familiar adverse factors; 3 of them had a previous c-section and 1 pregnant for the first time, all then
came out to caesarean section. Instead the results obtained with the 220 pregnant came out to perform spontaneous delivery have fully supported our initial conviction of validity to use, in terms of reduction of childbirth’s tears prevention, a product containing hyaluronic acid and protectol in association with an effective, targeted perineal massage.

For purely illustrative purposes (Figure 3), we have divided the spontaneous childbirth’s tears in 2 classes:
1. **superficials**, similar to the canonical classes I and II in which there is involvement cutaneomucosal or muscle superficial perineal plans without involvement of the anal sphincter;
2. **deeps**, equivalent III (A, B and C) and IV classes in which there is involvement in various thickness of the anal sphincter.

The effects of the deep perineal tears in short, medium and long term, are essentially summarized as follows (10, 11):
- **PELVIC CHRONIC PAIN**: painful symptoms in the pelvis, abdomen, and/or perineum, whose symptoms are caused by involuntary hypertonicity of the pelvic floor muscles.
- **VULVODYNIA**: pain and/or burning in vestibular site you can also radiate to the rest of the pelvis, dyspareunia, vestibular erythema of various degrees.
- **URINARY INCONTINENCE**: passage of urine through the urethra is not mediated by the will.
- **ANAL INCONTINENCE**: loose stools or gas uncontrollably.
- **PROLAPSE**: descent or herniation of one or more pelvic organs inside or outside the vagina.

In our series only 5/220 cases (p = 2.27%) (Table 1) there were deep tears, of which 4 in primiparous, 1 in multiparous; none of 5 patients with previous c-section have incurred in deep tears, but one superficial lacerations and 4 to complete absence of lacerations (note that in this class we included those little lacerocontusive lesions limited to the most superficial layers of the skin or

![Figure 3 – Fetal head crowning.](image)

### Table 1 - Laceration Types

<table>
<thead>
<tr>
<th>Group</th>
<th>No tears</th>
<th>Superficial tears</th>
<th>Deep tears</th>
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<tbody>
<tr>
<td>G1</td>
<td>93</td>
<td>26</td>
<td>4</td>
</tr>
<tr>
<td>G+P0</td>
<td>4</td>
<td>1</td>
<td>0</td>
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<tr>
<td>G+P+</td>
<td>78</td>
<td>13</td>
<td>1</td>
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Perineal injury by birth: how to prevent it to reduce C-sections

Table 2 - Recruited pregnant women.

<table>
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<th>Outcome</th>
<th>Total</th>
<th>Primiparous</th>
<th>Multiparous with previous Caesarian section</th>
<th>Primiparous</th>
<th>Multiparous</th>
<th>Caesarian sections</th>
<th>Vaginal deliveries</th>
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</thead>
<tbody>
<tr>
<td>Caesarian section before labour</td>
<td>252</td>
<td>106</td>
<td>146</td>
<td>100</td>
<td>52</td>
<td>47</td>
<td>112</td>
</tr>
<tr>
<td>Arrived to labour</td>
<td>252</td>
<td>120</td>
<td>132</td>
<td>120</td>
<td>122</td>
<td>8</td>
<td>244</td>
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Table 2 - Recruited pregnant women.

<table>
<thead>
<tr>
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<th>Vaginal deliveries</th>
<th>Previous Cesarian section</th>
<th>Previous vaginal delivery</th>
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mucous membranes that did not require suturing).

International literature states that the factors predisposing to spontaneous childbirth’s tears, regardless of their size, are considered to be (11, 12, 14, 17):
- Asian ethnic origin (OR 8.9 IC 4.2 - 18.9);
- First time childbirth (OR 2.4 IC 1.5 - 3.7);
- Occiput posterior position (OR 2.1 IC 1.0 - 4.5);
- Operative delivery with vacuum extractor (OR 2.7 IC 1.6 - 4.6);
- High weight of newborn (OR 1.001 IC 1.0 - 1.001).

In our series patients, properly prepared, than the previous factors are:
- 29/220 Asian ethnic origin: no deep tears (OR 0.5747 IC 0.0310 - 10.6668 – not significant);
- 123/220 first time childbirth: 4 deep tears (OR 3.2269 IC 0.3548 - 29.3490 – not significant);
- 1/220 occiput posterior position: no one deep tears (OR 13 IC 0.4744 - 356.2296 – not significant);
- No one operative delivery with vacuum extractor;
- Maximum weight of newborn was 4300 g: no one deep tears.

By these data we can deduce that identified predisposing factors in Gruptz A. et al. study group (11) are not applicable to our pregnant model previously prepared (Table 2).

Apart notation is any failure to mention the pregnant BMI compared to the control group; despite the relative paucity of spontaneous childbirth’s tears in our series (45/220 vaginal births=20.45%), most of them (38/45 p=84.4%) are in BMI≥28 pregnant (55/220 p=25%). A BMI≥28 is a powerful risk factor (OR 50.4538 IC 19.5367 - 130.2976); reduce BMI below this limit in an absolute risk reduction about 64.8%.

It has been demonstrated that preventive routine episiotomy does not reduce the incidence of deep childbirth’s tears (10, 13, 14); in our series we were performed 12/220 episiotomy (p=5.45%) most of which are due to inadequate preparation of the perineum, often by negligence of the patient.

Usefulness of the perineal massage from the 34th to 35th weeks there is opinion unanimity in international literature: it is estimated that perineal massage reduce the risk of tearing of 25% (8, 11, 12). From our compiled data using the product containing hyaluronic acid and protectol, this risk strikes further to 20.45%, thus revealing the real usefulness of it.

In accordance with the main Guidelines on labor we try to apply some recognized unanimously measures such as factors favoring the success of labor (14-17):
- Encourage to press only at fully dilation;
- Respect the physiological timing of the second stage although prolonged;
- Promote free positions also during the second stage of childbirth;
- Facilitate the free pushed;
- Avoid Kristeller maneuver.

Together with the initial informed consent were distributed judging sheet products. The responses have been very encouraging and promising (Figure 4), and it is our hope that these precautions can be transposed on a larger scale in order to increase compliance of pregnant against the spontaneous delivery and reduce the number of not strictly necessary caesarean sections.
Figure 4 - Final judgment on the product.

References


