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Hypothesis / aims of study
Recent studies demonstrated that there is a significant correlation between anal sphincter damage during vaginal birth, with or without episiotomy, and subsequent development of anal incontinence in women. Knowledge of the location of the innervation zones (IZs) of the external anal sphincter (EAS) would allow better protection of the innervation. Avoiding the innervation zones during episiotomy could presumably significantly reduce the incidence of sphincter dysfunction. The aim of this study is to evaluate the distribution of the innervation zones and the effect of delivery related trauma on the innervation of the EAS employing surface electromyography (EMG).

Study design, materials and methods
This is a multicenter study that aims to recruit 500 patients. Seven clinical partners from European Countries (Germany, Italy, Latvia, and Slovenia) are currently involved (Berlin, Cagliari, Cantù, Como, Hildesheim, Ljubljana and Riga). Thirty primiparous women concluded the experimental protocol up to date. Measurements were performed during the third trimester of pregnancy and 6-8 weeks after the delivery. Included were only nulliparous women older than 18 years. Measurements were performed with a disposable rectal probe including 16 silver electrodes (see Figure 1). The time shift of the EMG signals from these electrodes reveal the innervation of active motor units and how the action potentials propagate along the fibers [3].

Figure 1. A) Disposable rectal probe with 16-electrodes (code: DRP1x16-05MC). Diameter 14 mm. B) Example of multichannel surface EMG signals detected on the external anal sphincter. Black circles indicate the innervation zone location of the active motor units and straight lines indicate the propagation of the potentials.

For each of the two investigations, surface EMG signals were amplified in single differential configuration using an EMG-USB amplifier (LISiN OT-Bioelettronica, Torino, Italy), sampled at 2048 Hz, and stored on a PC after 12bit A/D conversion. Slow signals produced by active smooth muscles (if any) were rejected because of the high pass filter at 10 Hz. The probe was lubricated with a drop of glycerol and inserted into the anal canal. The women were asked to perform a maximal voluntary contraction (MVC) of the EAS for 10s. EMG signals were acquired for 50s including 10s and 20s of rest before and after the MVC contraction. Signals were divided in epochs of 0. 5 seconds. For each channel and epoch ARV was computed. The ARV values were averaged along the epochs in order to have one value for each channel and extract the ARV map. The activity of single motor units was identified by means of a surface EMG decomposition algorithm.

Results
The signals showed a large variability of IZ distribution around the sphincter without a standard pattern confirming previous observations [3]. In almost all women who underwent episiotomy or who had perineal lacerations the distribution of IZs was located at the dorsal side after delivery. Figure 2 shows an example of distribution of motor units in a woman after vaginal delivery with mediolateral episiotomy on the right side. The motor units on the ventral right side of the external anal sphincter do not appear in the second measurement post partum.
Figure 2. Schematic representation of the motor unit distribution in the subcutaneous portion of the external anal sphincter of a woman who had a right lateral episiotomy before and after delivery. Healthy primigravida, 24 years old, 172 cm, 65 kg. Dark spots indicate positions where IZs were identified. (V=ventral=12 o'clock, D=dorsal, R=right, L=left)

Interpretation of results
There is a wide variation of innervation zones of the anal sphincter. Perineal damage (laceration or episiotomy) results in a change of innervation towards more dorsal nerve entries. Whether this change is due to activation of previously not recruited muscle fibres or due to real re-distribution remains unclear. The latter seems unlikely because of the short time frame after delivery. The results of the present study show that a simple and reliable clinical test could be performed in pregnant women revealing the location of innervation zones of the anal sphincter. Theoretically, if the IZs are better protected and avoided during episiotomy, the risk of neurogenic damage should decrease as well as the incidence of anal incontinence.

Concluding message
Low-cost, disposable and minimally invasive EMG probes will enable preventive screening of anal sphincter innervation zones to avoid iatrogenic denervation during episiotomy and subsequently minimize the risk of anal incontinence.

References

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| Is this a clinical trial? | Yes |
| Is this study registered in a public clinical trials registry? | No |
| Is this a Randomised Controlled Trial (RCT)? | No |
| What were the subjects in the study? | HUMAN |
| Was this study approved by an ethics committee? | Yes |
| Specify Name of Ethics Committee | Comitato Etico dell’ A.S.O. San Luigi Gonzaga di Orbassano |
| Was the Declaration of Helsinki followed? | Yes |
| Was informed consent obtained from the patients? | Yes |