Technologies for Anal Sphincter analysis and Incontinence - 2 (TASI-2)

Final Report

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SUMMARY

The aim of the TASI-2 project (Technologies for Anal Sphincter analysis and Incontinence) was to evaluate the effect of **delivery related trauma** on the external anal sphincter (EAS) muscle innervation with minimally invasive intra anal electromyography (EMG). Several studies confirmed that there is a significant correlation between anal incontinence in women and anal sphincter damage during vaginal birth with partial sphincter denervation. Knowing the location of the innervation zones and of the anatomy of the anal sphincter will allow avoiding such zone when performing episiotomy with a possibly significant reduction of its side effects.

Methods. Five hundred eleven pregnant women participated in this observational type multicenter study. Nine clinical partners from five European Countries (Germany, Italy, Latvia, Slovenia, and Ukraine) were involved in this multicenter study coordinated by the Laboratory for Engineering of the Neuromuscular System (LISiN). EMG measurements were performed, before and after child delivery, with a cylindrical disposable rectal probe with 16 silver electrodes equally spaced along the circumference. The measurements were performed at the 28th - 34th gestational week and 6-8 weeks after delivery. Only 318 women returned to the hospital to conclude the experimental protocol. Of these 249 had acceptable EMG signals and 82 had episiotomy.

The subjects were asked to perform three maximal voluntary contractions (MVC) of the EAS for 10s and the signals were acquired both during rest and during maximal voluntary contraction (MVC). The IZ of single motor units were identified by means of a recently developed surface EMG decomposition algorithm. The obstetricians were asked to draw a picture and describe the episiotomy in a standardized form.

The women were divided in **four groups** according to the delivery mode (**Caesarean section**, vaginal with **no evident damage**, spontaneous **lacerations** and **episiotomies**), and the number of IZs as well as signal amplitude were compared in each group before and after delivery respectively. All episiotomies, except three on the left and three in the midline, were performed on the right side. In the 82 women who underwent mediolateral right episiotomy, a statistically significant reduction of the number of IZs was observed, after delivery, in the **right ventral quadrant**, corresponding to the side of episiotomy, while women who had Caesarean section, spontaneous lacerations or no evident damage did not present any significant change in the innervation pattern.

Results and conclusions. The study showed that **episiotomy reduces the number of IZ** in correspondence to the side where is performed. Thus with the proposed technique the clinicians could perform a fast and reliable test which would provide indications about sphincter innervation pattern of women before delivery. This information could **help the obstetricians** to choose **which side would be preferable** if episiotomy will be deemed necessary at the time of delivery, thus preserving the sphincter innervation. The results have been presented in in 12 congresses and three articles are in prepararion. One patent has been registered.

ACRONYMS

EMG: electromyogram EAS : External Anal Sphincter MVC: Maximal Voluntary Contraction
IZ: Innervation Zone ARV : average rectified value of the EMG

1. INTRODUCTION

Anal incontinence in women is a devastating condition, especially in severe cases where women cannot hold even solid stools. Anal incontinence is underestimated due to social stigma and embarrassment and *childbirth is one of the major risk factors* in women [Sultan et al. 1993]. A study conducted in the United States showed that anal sphincter tears occur in 2–19% of vaginal deliveries [Fenner et al, 2003].
Originally, **mediolateral episiotomy** was thought to minimize pressure on the fetal head, and shorten the second stage of labor and is usually performed with scissors or scalpel on the right side of the vaginal wall since the surgical scissors are usually in the right hand of the operator [Thacker et al. 1983]. The advantages of a mediolateral episiotomy are that there is less tearing beyond the incision and the incision can be directed away from the rectum (Figure 1).

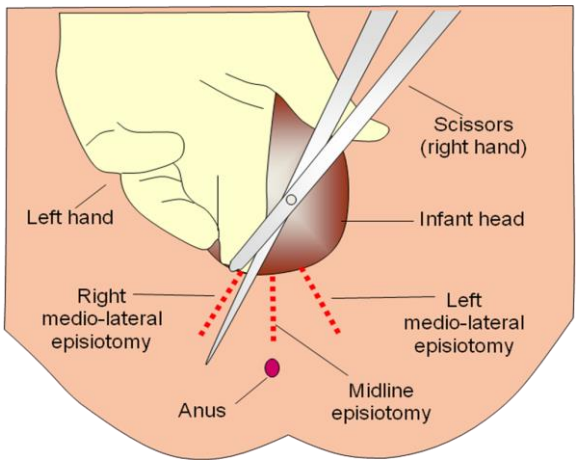

***Figure 1**. Graphical representation of the procedure to perform episiotomy (as usually shown in textbooks for midwives).*

Episiotomy is often used in association with instrumental-assisted deliveries, breech deliveries, and shoulder dystocia. The disadvantages are that there is greater blood loss and there is more perineal discomfort during healing (Sartore 2004). When compared with a spontaneous tear, episiotomy may allow more accurate tissue apposition during primary repair with potential benefits in wound healing. There is considerable variation in episiotomy rates worldwide that reflects differences in obstetric practices and schools. In Europe the lowest percentage of episiotomies is in Sweden (9%) and the highest in Italy (58%). The effect of mediolateral episiotomy is controversial; some studies showed it to be an independent risk factor [Sartore et al. 2004, Wheeler et al. 2007], whereas others found mediolateral episiotomy to be protective for fecal incontinence in primiparous women [deLeeuw et al 2001].

The risk of pudendal nerve damage during physiological delivery or obstetric trauma has been largely discussed in literature but till now **there are no indications regarding the optimal location to perform episiotomy** because of the large inter-individual variability of innervation [Merletti et al. 2004].

Multichannel surface EMG is the summation of electrical contributions from individual muscle motor units (MUs) detected with minimally invasive grids of electrodes. Recent signal processing

techniques identify the location of motor unit innervation zone (IZ) locations from multichannel EMG signals (Cescon 2006).

1.2 Objectives and research questions

The objective of this study was to evaluate the effect of delivery related trauma on the sphincter innervation with intra-anal, minimally invasive EMG. Knowing the location of the innervation zones and of the anatomy of the anal sphincter will allow avoiding such zone when performing episiotomy and a possibly significant reduction of its side effects.
The EMG probes, amplifiers and software developed during previous EU project On ASymmetry In Sphincters (OASIS) and TASI project were used for the identification of the innervation zone (IZ) distribution in the external anal sphincter (EAS).

The TASI-2 project started on May 2009. The research questions of TASI-2 were:

- Is the IZ distribution of the external anal sphincter uniform around the anal canal?
- Does episiotomy affect the IZ distribution?
- Does caesarean section preserve the IZ distribution?
- What is the effect of spontaneous tears on the IZ distribution?

2. METHODS

2.1 Clinical partners

The protocol was initially performed in collaboration with 16 clinical partners who were instructed and were provided with amplifiers and probes between November 2009 and February 2010.

These partners were instructed and were provided with amplifiers and probes in August 2010. Many clinical partners who joined the TASI-2 group soon abandoned the project because of difficulties in recruiting patients.

After some drop-offs in the group of clinical partners involved in the TASI-2 project, the **final list of partners** is the following:

1. Hospital of Cantù: Diego Riva, Eleonora Ester Raimondi
2. Hospital of Riga: Dace Rezeberga, Vita Zacesta, Olesja Zelenova
3. Hospital of Cuneo: Pier Dino Rattazzi, Luigi Spagna
4. Hospital of Ljubljana: Adolf Lukanovic, Kristina Drusany Staric
5. Hospital of Cagliari: Anna Maria Paoletti, Donatella Marongiu, Konstantinos Martsidis
6. Hospital of Asti: Maggiorino Barbero, Vicky Rabino
7. Hospital of Vinnitsa: Olexander Protsepko, Lena Martynshyn, Marina Storoshuk
8. Hospital of Berlin: Kaven Baessler, Milena Ludescher

Figure 2 shows the map of Europe with indication of clinical partners involved in the TASI-2 project.

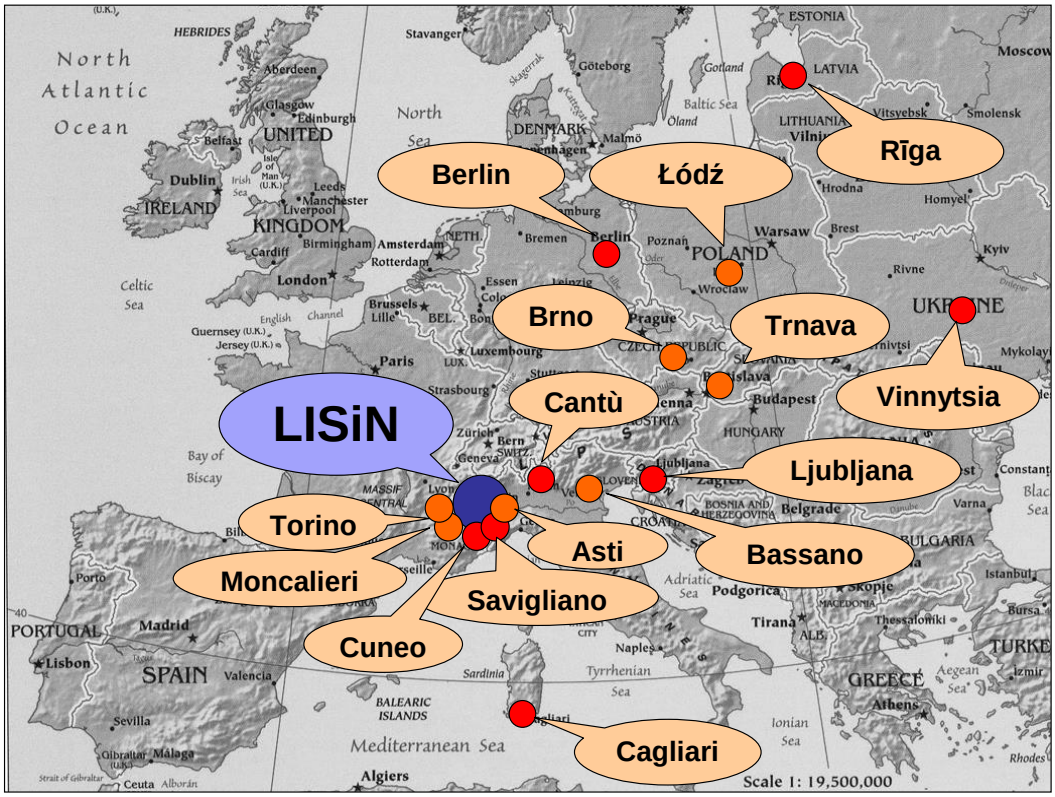

Figure 2. *Map of Europe including the clinical partners initially involved in TASI-2.*

2.2 Subjects and inclusion criteria

The inclusion criteria for the patients participating to the EMG measurements of TASI-2 project were:

1. Between 28th and 34th week of gestation
2. Primiparous (or with no previous vaginal deliveries)
3. Intact anal sphincter
4. No previous phenomena of anal incontinence
5. No planned Caesarean Section
6. No diabetes
7. Cephalic presentation of the infant

After two extensions of the project, the final number of pregnant women recruited in the TASI-2 study was 511. The number of women who returned for the second measurement after the delivery were 318. The percentage of drop-off of patients was 37%. No explanation is available for such a high drop-off.

3. RESULTS

3.1 Visual analysis and signal quality assessment

The signals from the 318 patients were visually inspected and classified in five different classes according to the overall signal quality.
The criteria used to assess the quality of the signals were: 1) presence of artefacts due to movement of the probe, 2) power line interference, 3) short circuits between electrodes, 4) saturation of the EMG channels and 5) presence of high noise. The classes were: Q1) Very bad quality: contact problems present in more than eight channels Q2) Bad quality: contact problems present in four to seven channels Q3) Sufficient quality: contact problems present in two or three channels Q4) Good quality : contact problems present in one channel and Q5) Very good quality: no contact problems. The signal quality was assessed for each of the two sessions (pre-post partum) and the minimum of the two values was considered in order to be conservative.

The channels with contact problems of the signals of quality Q3 and Q4 were reconstructed by interpolating the adjacent good channels. The patients with signals of quality Q1 and Q2 (bad signals) were discarded from the analysis and **the final number of patients included in the statistical analysis was 249.**

3.2 Classification of patients according to the type of delivery

The patients with signals of quality Q3, Q4 and Q5 were divided In 4 groups according to the type of delivery:

1. Caesarean section (this group was considered as the control group in the following analysis)
2. Vaginal delivery with no visually evident damage
3. Spontaneous lacerations
4. Episiotomy (three mediolateral left and three midline episiotomies were not considered in the following analysis in order to consider only mediolateral right episiotomy).

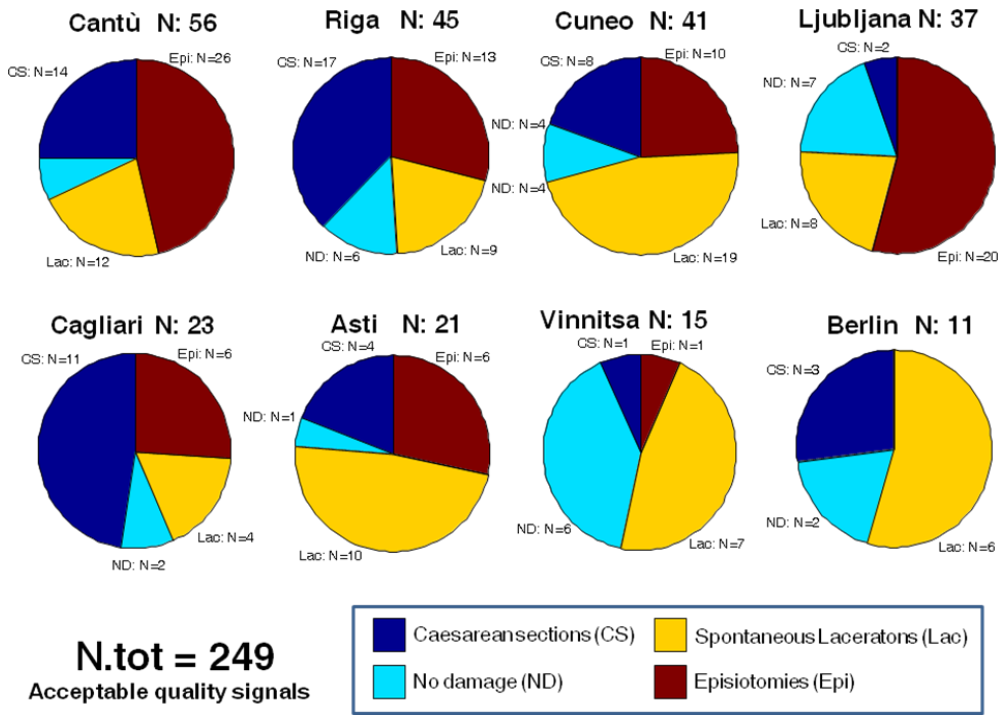

Figure 3. *Pie-charts of the delivery type of patients for each of the eight clinical partners.*

Figure 3 shows the distribution of patients according to the type of delivery for each of the eight clinical partners. It is interesting to notice how the percentages of Caesarean sections and episiotomies varies considerably according to the hospital. The total distribution of delivery types is represented in figure 4.

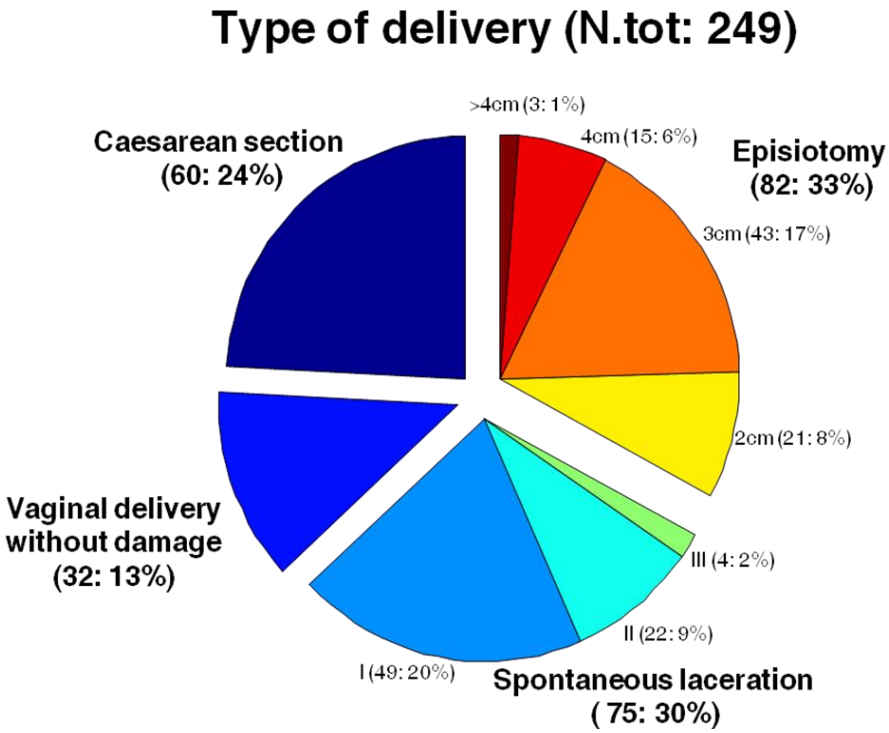

Figure 4. *Pie-chart of the delivery types for all the patients.*

3.2 Examples of distribution of IZ before and after delivery

The following figures (5a, 5b, 5c, 5d, 5e, and 5f) show six examples of innervation zone distribution before and after delivery in women who had mediolateral right episiotomy. The representation of the position of episiotomy is shown in the panels on the left. The motor units are represented as red arches while their innervation zones are shown as dark spots. It is evident in these six patients that the episiotomy caused a dramatic variation of the innervation pattern with a reduction of innervation zones in the right ventral quadrant and, in some cases, also affecting other quadrants.

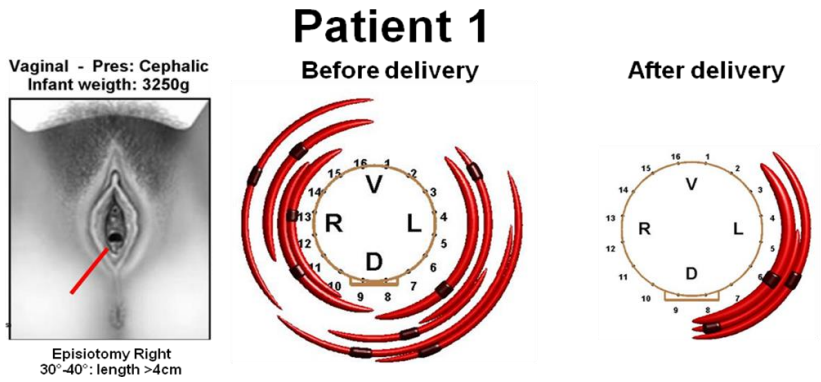

Figure 5a. *Position of episiotomy, distribution of motor units and innervation zones of Patient 1 before and after delivery. A reduction of the number of active motor units is visible on the right ventral side after the delivery.*

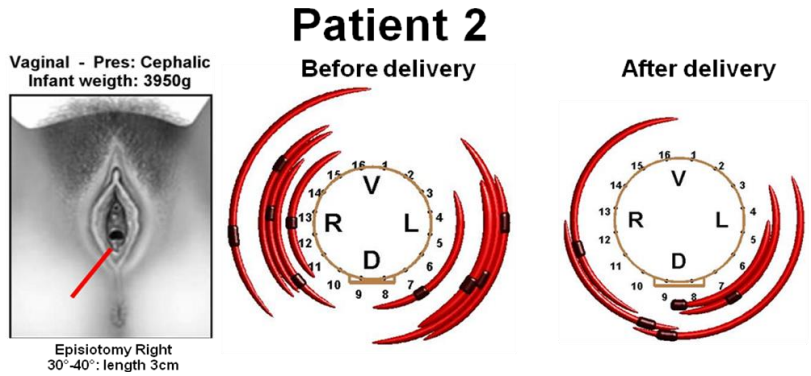

Figure 5b. *Position of episiotomy, distribution of motor units and innervation zones of Patient 2 before and after delivery. A reduction of the number of active motor units is visible on the right ventral side after the delivery.*

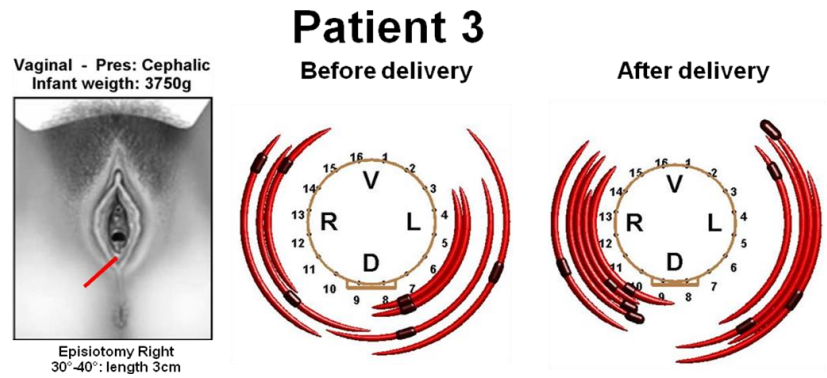

Figure 5c. *Position of episiotomy, distribution of motor units and innervation zones of Patient 3 before and after delivery. A reduction of the number of active motor units is visible on the right ventral side after the delivery.*

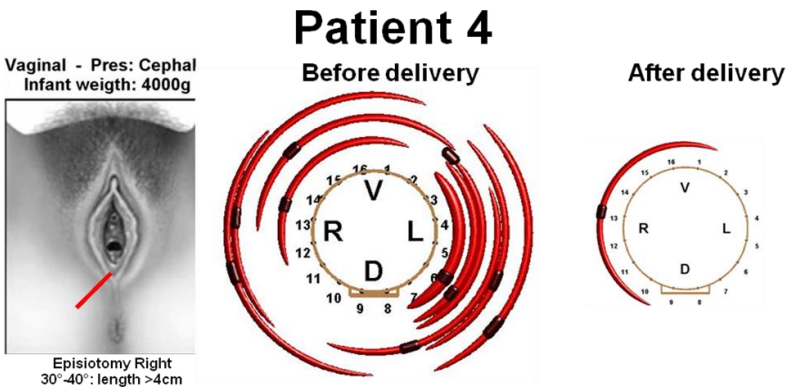

Figure 5d. *Position of episiotomy, distribution of motor units and innervation zones of Patient 4 before and after delivery. A reduction of the number of active motor units is visible on the right ventral side after the delivery.*

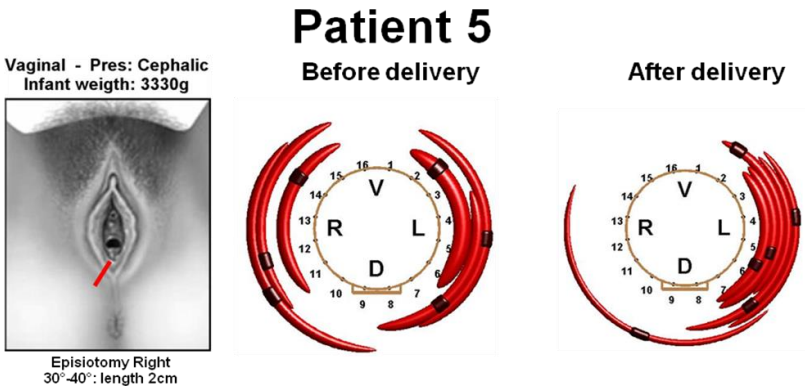

Figure 5e. *Position of episiotomy, distribution of motor units and innervation zones of Patient 5 before and after delivery. A reduction of the number of active motor units is visible on the right ventral side after the delivery.*

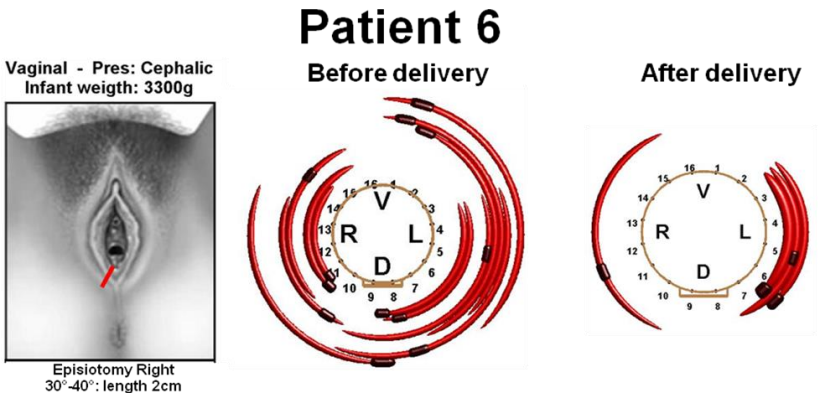

Figure 5f. *Position of episiotomy, distribution of motor units and innervation zones of Patient 6 before and after delivery. A reduction of the number of active motor units is visible on the right ventral side after the delivery.*

These examples are representative for the group of patients who had mediolateral right episiotomy.

3.3 Statistical analysis

A team of statisticians led by a professor of Statistics at Politecnico di Torino (Prof. Mauro Gasparini) contributed to this work in order to identify the optimal tool for the analysis of the EMG data.
The following data were also presented at a conference (Gasparini 2012).

The first consideration is that the TASI-2 project is an observational study thus the statistical methods that need to be applied are different with respect to methods for randomized protocols (like clinical trials).

3.3.1 Response variable

We decided to focus the analysis of EMG signals on the number of innervation zones identified in the anal sphincter and on EMG amplitude. These two variables can be computed for each electrode allowing a circular analysis of the sphincter muscle. We decided, after a discussion with the statisticians, to divide the sphincter in four quadrants:

- Left Ventral (LV) upper right observing the sphincter in gynecological position
- Left Dorsal (LD) lower right observing the sphincter in gynecological position
- Right Dorsal (RD) lower left observing the sphincter in gynecological position
- Right Ventral (RV) upper left observing the sphincter in gynecological position

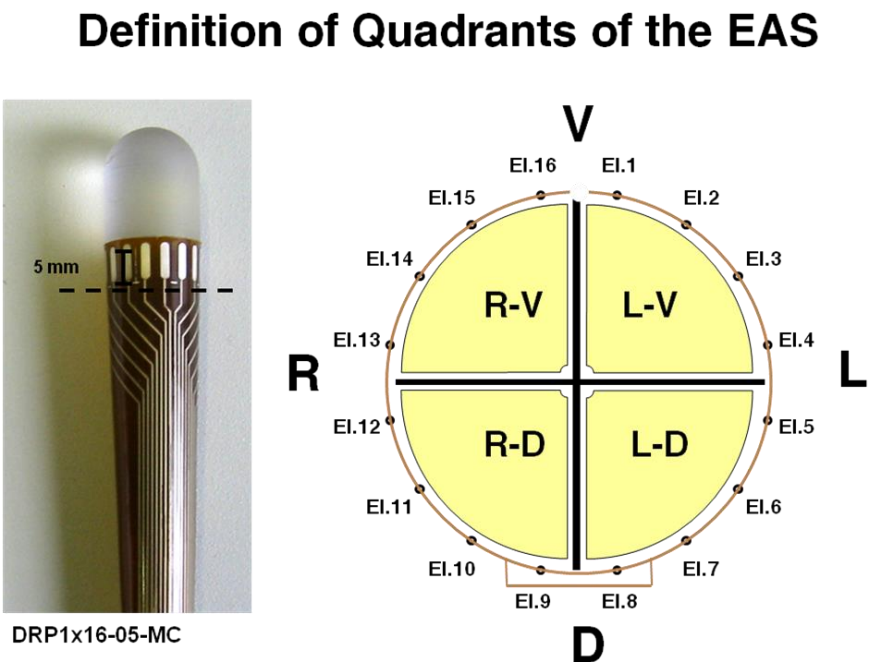

Figure 5. *Rectal probe used in the TASI-2 project and schematic image of the probe section with the indication of electrode numbers and the four quadrants (Left Ventral - LV, Left Dorsal - LD, Right Dorsal - RD, Right Ventral - RV).*

The last quadrant (right ventral - RV) is the quadrant of interest for the patients who had episiotomy because it is the quadrant closest to the episiotomy site (when performed on the right side) and then the most vulnerable to innervation zone reduction.

Two possible responses were investigated:
• ***iz:*** the number of innervation zones, a discrete (count) variable
• ***arv***: the average rectified value of the EMG signal, a continuous variable, measuring the intensity of electrical signal.
Some preprocessing is needed for ***iz*** because it is a discrete variable which is more difficult to analyze with standard statistical methods, but it is a more interesting variable because has stronger physiological relevance.

3.3.2 Response and predictors in regression
The response variable can be either ***iz*** or ***arv***.
Possible predictors of interest are:

• factors, i.e. categorical predictors:
    type (1=Caesarean section; 2=No damage; 3=Spontaneous lacerations; 4=Episiotomy)
    time (before/after delivery, also indicated as pre/post)
    quad (LV/LD/RD/RV)
• their interactions.

The present database is a standard setup for linear models, which include, as special cases, regression, ANOVA and ANCOVA situations. **Generalized linear models** are suitable generalizations, e.g. for binary data, count data and survival regression and will be used in the following analysis (Zuur et al. 2009).

3.3.3 Significance of interactions
Two nested models were built and compared in order to test the significance of the three-way interaction for variable ***iz***. The "big" model includes three way interactions (which are the interactions in which we are interested. The "small" model includes only two-way interactions. The significance of the difference between the model will indicate that there are contrasts which are of interest for the study.
Result: good significance of the three-way interaction, i.e. of the need to use the "big" model (p-value = 0.003). This result indicates that there is a relationship between type of delivery and quadrant before and after delivery.

3.3.4 Same analysis for the continuous response ARV
Can we obtain the same results with ***arv*** treated as a Gaussian-distributed response, rather than Poisson? The same analysis applied to ***arv*** is not significant, indicating that there are no significant three-way interactions. This result is interesting because it suggests that the analysis of innervation zones is more informative than ***arv***, and then the advanced signal processing applied in order to obtain the location of innervation zones (***iz***) is more indicative of changes as opposed to the simple EMG amplitude analysis. Thus, in the following section, only the variable ***iz*** will be analyzed.

3.3.5 Simultaneous confidence intervals

Simultaneous confidence intervals were computed with the *R* package *multcomp*.
With overall 95% confidence (default value), we can estimate the following differences of innervations zone numbers (post-pre):
For the episiotomy group (82 subjects) the decrease of ***iz*** after delivery in the ventral right quadrant is estimated at -0.624 with confidence interval between -0.962 and -0.287, it is significant because the difference is negative with 95% confidence.

If we consider the Caesarean sections, the difference of the number of ***iz*** is estimated at 0.173, with confidence interval between -0.181 and 0.527. The same analysis in the same quadrant for the Caesarean section subjects does not show significant differences because the confidence interval includes the zero.

3.3.6 Computing more intervals

Table 1 shows the confidence intervals for the change in the number of innervation zones in the four different quadrants for all the patients grouped according to the type of delivery.

Table 1. Estimates and confidence intervals of the difference between the number of innervations zone number after and before delivery.

Delivery type	Quadrant	Estimate	95% CI Lower	95% CI Upper
Caesarean Sections (N=60)	DL	0,08	-0,32	0,49
	DR	0,17	-0,29	0,63
	VL	0,12	-0,47	0,70
	VR	0,31	-0,23	0,84
Vaginal delivery with no visible damage (N=32)	DL	-0,16	-0,72	0,40
	DR	-0,04	-0,60	0,53
	VL	-0,27	-1,18	0,63
	VR	-0,50	-1,41	0,41
Spontaneous Lacerations (N=75)	DL	-0,32	-0,76	0,11
	DR	0,00	-0,50	0,50
	VL	0,28	-0,30	0,85
	VR	-0,13	-0,67	0,41
Episiotomy (N=82)	DL	-0,01	-0,34	0,31
	DR	0,22	-0,12	0,57
	VL	-0,15	-0,56	0,27
	VR	**-0,55**	**-1,01**	**-0,09**

Figure 6 shows in a graphical way the confidence intervals for the four groups of patients of interest (Caesarean section as control group and Episiotomy as cases) for the change in the number of innervation zones in four different quadrants.

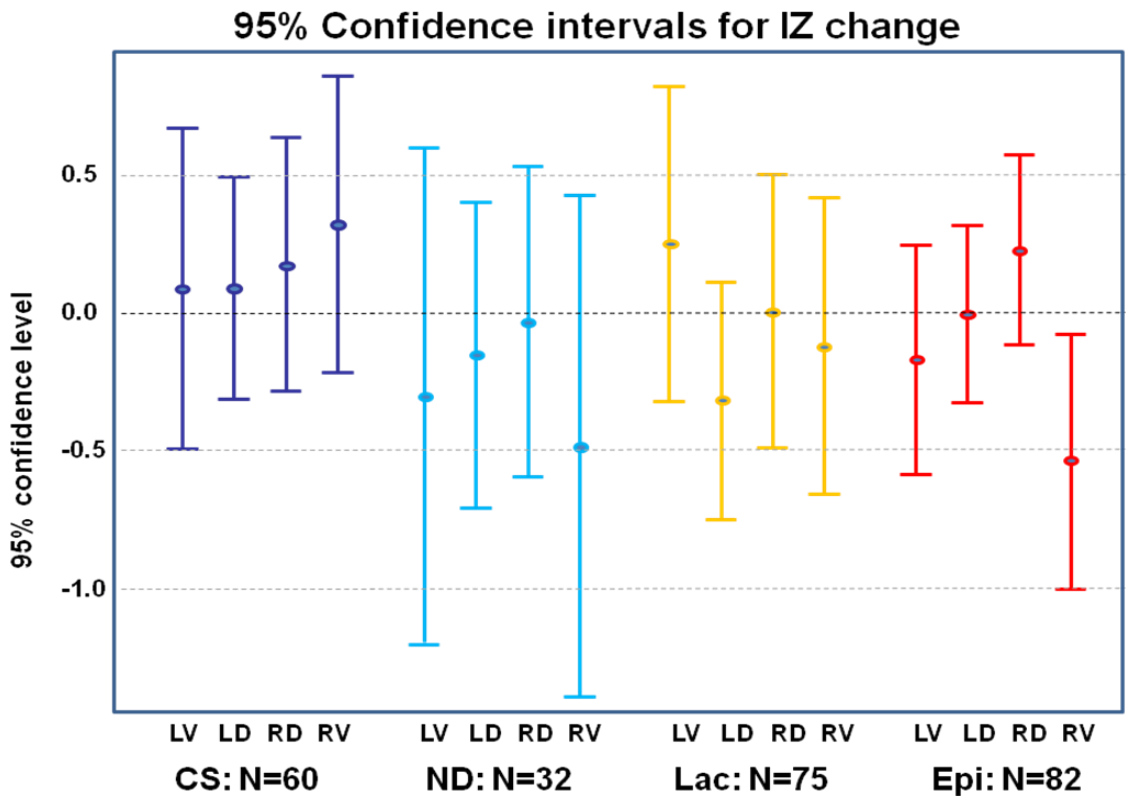

Figure 6. *95% confidence intervals of the change of innervation zones of the patients grouped according to the factors: type(Caesarean section CS, Vaginal delivery with no visually evident damage - ND, Spontaneous lacerations - Lac, Episiotomy - Epi), quad (LV, LD, RD, RV).*

Both from table 1 and figure 6 we can notice that the only definitively negative interval remains the one for the episiotomy patients, in the ventral right quadrant. We can say (with 95% confidence) that **episiotomy causes a significant decrease of the number of innervation zones in the RV quadrant** of the EAS quantified between 0.21 and 1.03 innervations zones and that **no other significant decrease or increase is observed for other quadrants and other types**.

4. DISCUSSION

The surface EMG detection technique based on the probe depicted in Fig. 5 and adopted in this study does not identify all motor units of the EAS and their innervations. It priviledges the largest and closest to the detection system. The technique has been demonstrated to provide reapeatable results [Enck et al, 2010] and has been described in intermediate reports and previous publications (merletti et al 2004). The fact that only the closest portion of the EAS motor units is detected implies that the damage to motor units further from the electrode array might indeed be undetected. The conclusions of this work are therefore conservative.

Cesarean section did not modify the number of innervation zones in any quadrant in a statistically significant way. The same results can be observed for the vaginal delivery with no evident perineal damage and for the spontaneous laceration group. **An increase of the number of cases would not likely modify this conclusion**.

Although the obvious conclusion would be that episiotomy should be avoided in order to preserve external anal sphincter innervations, clinicians must take into account other risk factors related to Caesarean section and the benefits of episiotomy during vaginal delivery.

The fact that spontaneous tears (lacerations) did not result in a statistically significant change in the number of active motor units suggests that may be preferable to episiotomy. However this finding deserve further investigation and considerations concerning the issue of surgical repair.

A Cochrane review to determine the possible **benefits and risks** of the use of restrictive episiotomy versus routine episiotomy during delivery (Carroli, 2009) found that:
"*The restrictive use of episiotomy shows a lower risk of clinically relevant morbidities including severe perineal trauma (relative risk (RR) 0.67, 95% confidence interval (CI) 0.49 to 0.91), posterior perineal trauma (RR 0.88, 95% 0.84 to 0.92), need for suturing perineal trauma (RR 0.71, 95% CI 0.61 to 0.81), and healing complications at seven days (RR 0.69, 95% CI 0.56 to 0.85). No difference is shown in the incidence of major outcomes such as severe vaginal and perineal trauma nor in pain, dyspareunia or urinary incontinence.*"

The following guidelines on the use of episiotomy or prevention of third and fourth degree tears were identified:

- The **Royal College of Obstetricians and Gynaecologists** (**RCOG**) green-top guideline on the management of third and fourth degree perineal tears:
  "Can obstetric anal sphincter injury be predicted and prevented?
  Clinicians need to be aware of the risk factors for obstetric anal sphincter injury but also recognize that known risk factors do not readily allow its prediction or prevention.
  Studies are required to investigate the effect of interventions to prevent third-degree tears in women with risk factors. "
- The **British National Institute for Health and Clinical Excellence** (**NICE**) guideline on intrapartum care. Recommendations:
  "*A routine episiotomy should not be carried out during spontaneous vaginal birth.*
  An episiotomy should be performed if there is a clinical need such as instrumental birth or suspected fetal compromise. "

In our studies all the episiotomies were performed because of suspect fetal compromise or threat of severe perineal tears, and no episiotomy was performed as a routine practice. In this case we cannot predict the degree of spontaneous lacerations that would have occurred if episiotomy had not been performed, but according to the literature (Carroli 2009) the lacerations would have likely been of III or IV degree.
In our group of patients the spontaneous lacerations are mostly of I or II degree, thus these lacerations do not affect the external anal sphincter muscle. In addition occult laceration or sphincter injuries could be occurring also in the group of vaginal delivery without evident damage.
Indeed this might be suggested by the large variability of number of motor units observed in the ND group- For this reason the cases considered in the final analysis were only episiotomies (as cases) and Caesaren sections (as controls).
The present study does not concern the issue of possible reinnervation and the relationship between EAS damage and incontinence. It does not give indications of the type of delivery that a gynecologists should select according to many factors. However, since episiotomy causes a loss of innervations on the side where it is performed, **the doctors could decide the side** which is less innervated in order to reduce possible development of anal incontinence due to the loss of innervation.

5. CONCLUSIONS AND LIMITATIONS OF THE STUDY

A rigorous statistical analysis (Generalized mixed linear model) was applied in order to evaluate interaction between factors such as quadrant, type of delivery and time for the count variable "*iz* number". The main conclusions of the TASI-2 study can be summarized as follows:

1. A fast and reliable **test** to identify the **distribution of innervation zones** in the external anal sphincter of pregnant women has been developed and tested on **more than 500 patients**.
2. It is possible to **count the number of active motor units innervated in each of the four quadrants** of the EAS and detected by the sensor, and thus identify if there is an asymmetry in innervation zone distribution of such active and detected motor units before and after some intervention (including rehabilitation interventions).
3. There is a **statistically significant decrease** of the number of innervation zones (95%CI [-1.03:-0.21]) in the **right ventral quadrant** of women who had mediolateral right episiotomy.
4. Knowledge of the distribution of innervations zones provides the gynecologists and obstetricians with the information needed either to choose the side **where to perform episiotomy** in case it is necessary, or accept the risk of lacerations, or consider other alternatives.

Issues such as possible reinnervation of denervated motor units and the relationship between EAS damage and incontinence were not within the objectives of the project and have not been investigated. These issues require a follow-up study which is highly desirable.

REFERENCES

1. Andrews V, Sultan AH, Thakar R, Jones PW Occult anal sphinter injury: myth or reality? Br J Obstet. and Gynecol. 2006; 113. 195-200.
2. Carroli G, Mignini L. Episiotomy for vaginal birth. Cochrane Database of Systematic Reviews 2009, Issue 1. Art. No.: CD000081.
3. Cescon C. "Automatic location of muscle innervation zones from multi-channel surface EMG signals". Proceedings of the IEEE International Workshop on Medical Measurement and Applications (MeMeA2006), April 20-21 2006, Benevento, Italy.
4. De Leeuw JW, Vierhout ME, Struijk PC, Hop WC, Wallenburg HC. Anal sphincter damage after vaginal delivery: functional outcome and risk factors for fecal incontinence. Acta Obstet Gynecol Scand. 2001 Sep;80(9):830-4.
5. Enck P, Franz H, Davico E, Mastrangelo F, Mesin L, Merletti R. Repeatability of innervation zone identification in the external anal sphincter muscle. Neurourol. Urodyn. 2010;29:449-457.
6. Fenner DE, Genberg B, Brahma P, Marek L, DeLancey JO. Fecal and urinary incontinence after vaginal delivery with anal sphincter disruption in an obstetrics unit in the United States. Am J Obstet Gynecol. 2003 Dec;189(6):1543-9; discussion 1549-50.
7. Merletti R, Bottin A, Cescon C, Farina D, Mesin L, Gazzoni M, Martina S, Pozzo M, Rainoldi A, and Enck P, "Multichannel surface EMG for the non-invasive assessment of the anal sphincter muscle," Digestion, 2004, 69:112–122,
8. National Collaborating Centre for Women's and Children's Health. Intrapartum Care: care of healthy women and their babies during childbirth. London: RCOG Press, 2007

9. RCOG. The management of third- and fourth-degree perineal tears. Green-top guideline 29. London: RCOG, 2007
10. Sartore A, De Seta F, Maso G, et al. The effects of mediolateral episiotomy on pelvic floor function after vaginal delivery. Obstet. Gynecol. 2004; 103: 669-673.
11. Sultan AH, Kamm MA, Bartram CI, Hudson CN. Anal sphincter trauma during instrumental delivery. Int J Gynaecol Obstet. 1993 Dec;43(3):263–270.
12. Thacker SB, Banta HD. Benefits and risks of episiotomy: an inter-pretative review of the english language literature.1860-1980. Obstet Gynecol Surv 1983;38:322–38.
13. Wheeler TL, Richter HE. Delivery method, anal sphincter tears and fecal incontinence: new information on a persistent problem. Curr Opin Obstet Gynecol. 2007 Oct;19(5):474-9.
14. Zuur AF, Ieno EN, Walker NJ. Saveliev AA. Smith GM. Mixed effects models and extensions in ecology with R (Statistics for Biology and Health). Springer-Verlag Gmbh (march 2009), ISBN-10: 0387874577
15. http://lme4.r-forge.r-project.org/

PUBLICATIONS (subsequent to the end of the project)

1. Cescon C, Mesin L, Nowakowski M, Merletti R. Geometry assessment of anal sphincter muscle based on monopolar multichannel surface EMG signals. J. Electromyogr. Kinesiol. 2011;21:394-401.
2. Cescon C, Raimondi EE, Zacesta V, Drusany-Staric K, Martsidis K, Merletti R. Characterization of the motor units of the external anal sphincter in pregnant women with multichannel surface EMG. Int Urogynecol. J. 2014 Aug; 25(8): 1097-103.
3. Cescon C, Riva D, Zacesta V, Drusany-Staric K, Martsidis K, Protsepko O, Baessler K, Merletti R. Effect of vaginal delivery on the external anal sphincter muscle innervation pattern evaluated by multichannel surface EMG: results of the multicentre study TASl-2. lnt Urogynecol J. 2014 Nov;25(11): 1491-9.
4. Ullah K, Cescon C, Afsharipour B, Merletti R. Automatic detection of motor unit innervation zones of the external anal sphincter by multichannel surface EMG. J Electromyogr. Kinesiol. 2014; 6: 860-867.

PRESENTATIONS AT CONGRESSES

1. Cescon C, Merletti R. Design and development of a disposable rectal probe for high density multichannel surface EMG of the external anal sphincter muscle. “XVIII Congress of the International Society of Electrophysiology and Kinesiology”, Aalborg, Denmark, June 16–19, 2010.

2. Cescon C, Baessler K, Drusany K, Raimondi E, Riva D, Marongiu D, Martsidis K, Rezeberga D, Zacesta V, Merletti R. Evaluation of child delivery trauma on the external anal sphincter muscle by means of surface electromyography (preliminary results of a multicenter study). “7th International Pelvic Floor Dysfunction Society World Congress and FIGO task force meeting”, Palermo, Italy, May 10–12, 2010.

3. Baessler K, Cescon C, Drusany K, Martsidis K, Merletti R, Raimondi E, Rezeberga D, Riva D, Zacesta V. Distribution of innervation zones of the external anal sphincter and changes after vaginal delivery: preliminary results of a multicenter study - TASI-2 (Technologies for Anal

Sphincter Analysis and Incontinence). “Joint Annual Meeting of the International Continence Society (ICS) and International Urogynecological Association (IUGA)”, Toronto, Canada, August 23–27, 2010.

4. Riva D, Cescon C, Baessler K, Drusany K, Raimondi EE, Marongiu D, Martsidis K, Zacesta V, Merletti R. Evaluation of delivery trauma on the external anal sphincter (EAS) by means of surface electromyography. “XX Congresso Nazionale AIUG”, Alghero, Italy, October 7-9, 2010 [published in: Urogynaecologia International Journal 2010;24:1].

5. Martsidis K, Marongiu D, Cescon C, Mais V, Melis GB, Paoletti AM. Un nuovo metodo di valutazione oggettiva non invasiva dell’incontinenza anale post-partum. Fattori di rischio, fisiopatologia, prevenzione: risultati preliminari. “XXI Congresso Nazionale AIUG”, Torino, Italy, November 6-8, 2011 [published in: Urogynaecologia International Journal 2011;25:2].

6. Cescon C. Riva D. Raimondi EE. TASI-2 Project – 2009-2011. International Genoa Incontinence 2012. 27-28 Gennaio 2012 - Genova.

7. Gasparini M. Statistical Issues in the Analysis of Count EMG Data from a study on Obstetric Trauma During Delivery. Texas A&M Univ. Department of Statistics College Station Feb 9th, 2012

8. Cescon C, Zacesta V, Riva D, Drusany K, Raimondi EE, Martsidis K, O.Protsepko, Baessler K, Merletti R.: Effect of vaginal delivery on external anal sphincter innervation. ISEK 2012, Brisbane, Australia, 20 July 2012

9. Cescon C, Zacesta V, Riva D , Drusany K, Raimondi EE, Martsidis K, O.Protsepko, Baessler, K Merletti R.: Characterization of motor units of the external anal sphincter in pregnant women ISEK 2012, Brisbane, Australia, 20 July 2012

10. K.Baessler, Cescon C, Drusany-Starič K., D.Riva , V.Začesta, K.Martsidis, Merletti R.: IUGA 2012, Brisbane, Australia, 04-08 Sept 2012

11. C. Cescon , D. Riva, E.E. Raimondi V. Začesta , K. Drusany-Starič , K. Martsidis, M. Barbero, O. Protsepko, K. Baessler, R. Merletti. Multichannel EMG evaluation of anal sphincter pre and post vaginal delivery: results of an international study. FIGO 2012, Rome, Italy, 7-12 October 2012

12. Drusany-Starič K., Lukanovic A. Cescon C, D.Riva,EE Raimondi, V.Začesta, K.Martsidis, O.Protsepko, K.Baessler, Merletti R. Changes of external anal sphincter innervation pattern after episiotomy evaluated with multichannel EMG. (Results of the multicenter study TASI-2): ICS 2012, Beijing, China, 15-19 October 2012

PATENTS

Cescon C, Merletti R. “Sensore per l’acquisizione di segnali bioelettrici da un muscolo anulare, in particolare per elettromiografia di superficie multicanale”, 2009 (Patent number: TO2009A000814).