

## Original Article

# Neurophysiologic Effect of Vaginal Cone Application in Continent and Urinary Stress Incontinent Women

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**Abstract:** Simultaneous electromyographic (EMG) recordings with intramuscular wire electrodes from the left and right pubococcygeal muscles were performed to elucidate the neurophysiological effect of vaginal cones on the pelvic floor muscles. Ten continent nulliparous women (aged 22–32 years) and 20 stress urinary incontinent parous women (aged 27–60 years, average 2–4 deliveries) were examined before, during holding and after removal of the cone. All the continent nulliparous women could retain the cone in the vagina (mean weight 83.5 g (range 70–85 g). In the incontinent parous group 7 women could not hold any cone, 9 women could hold the 45 g cone, 1 the 32.5 g cone and 3 women the 57.5 g cone. There was a significant voluntary holding time difference between continent nulliparous and incontinent parous women. The study reveals that vaginal cones may induce both strengthening of muscles as well as a learning effect leading towards a better coordinated muscle activation.

**Keywords:** Continent nulliparous women; Holding time difference; Learning effect of vaginal cones; Pelvic floor coordination disturbance; Urinary stress incontinent parous women; Vaginal cone therapy

## Introduction

Pelvic floor re-education has been shown to be effective in patients with functional pelvic floor disorders suffering from stress urinary incontinence (SUI) [1]. It is

generally assumed that the efficacy of this treatment is due to strengthening of the pelvic floor muscles. To evaluate the contractile ability before and after different types of pelvic floor muscle training, various methods have been used, such as perineometers [2], cuffed catheters [3,4] or digital tests [5]. Perineometers and cuffed catheters do not allow a distinction to be made between contraction of the pelvic floor muscles or that of the abdominal wall muscles, both being registered on the meter as an increase in pelvic floor activity. Digital tests depend on the experience of the examiner, which does not permit objective evaluation.

Kinesiologic EMG recordings have been shown to demonstrate well the various activity patterns (behavior) of pelvic floor muscles [6], and revealed differences between these patterns in both continent nulliparous and incontinent parous women [7]. It was the aim of this study to evaluate how vaginal cones influence the activity of patterns of the levator ani muscles in both nulliparous continent and parous stress urinary incontinent women.

## Patients and Methods

Nulliparous women attending the Family Planning Out-patient Clinic and parous urinary incontinent women were taught the importance of the pelvic floor muscles in maintaining continence, and informed of the purpose and methodology of this study. Thirty subjects gave their informed consent and were recruited into the study.

Twenty parous women between 27 and 60 years (median 45.2 years) old, who had given birth to between 2 and 4 children (average 2.6) were examined. In all

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patients stress urinary incontinence had been diagnosed according to the ICS standards [8] and showed a urine loss of more than 30 g. Abnormalities such as hypotonic urethra or pseudocontinence caused by severe descent of the anterior vaginal wall were ruled out. Patients presenting with symptoms of urgency, urge incontinence or bladder instability were also ruled out. A control group comprised 10 healthy female nulliparous volunteers. They had no urogynecological or neurological complaints, were between 22 and 32 years old (median 27.2 years) and had not previously undergone urogenital surgery. All had normal menstruation (median cycle 29.1 days, range 27–35). Each woman was asked to empty her bladder immediately before the study. The patellar and ankle jerks, plantar reflex and sensation in lower limbs and perineum were checked. Wire electrodes were inserted under transvaginal digital control (via a 4.1 cm long steel needle, which was immediately removed) percutaneously into the left and right pubococcygeal muscle. The thin insulated wires used (manufactured by Wilburn Driver Co., Newark, NJ, 0.0031 ins, 87  $\Omega$ /foot HR enamel for insulation) had had the insulation removed for 1 mm at the tip. The quality of the EMG signal obtained was assessed both visually on the oscilloscope and also from the loudspeaker. Minor corrections (through mild pulling on one of the wires) was necessary in five cases. A Medelec M6 EMG machine (Surrey, UK) with analog EMG registration and also the integrated EMG of a Wiest Jupiter 8000 urodynamic unit (Unterhaching, Germany) was used for recording; the frequency setting of the amplifiers was 16 Hz to 10 kHz. In the Medelec M6 EMG machine the sign was continuously printed on UV-sensitive paper (Kodak Linagraph Direct-Print, Rochester, NY, USA) at a speed of 10 mm/s throughout the study, both channels being recorded simultaneously. In the Wiest Jupiter 8000 unit the integrated signal was stored on a hard drive. After the wires were introduced and the quality of the signal assessed, the loudspeaker was turned off; subjects could not observe the oscilloscope screen of the EMG machine (so that no audiovisual feedback of muscle activity was provided). We used vaginal cones as published by Plevnik (1985) (Femcon® in Irschenberg, Germany, Femina® cone in USA and GB and Femcare® in France) which are issued in sets of five cones of standard size but increasing weights (20 g, 32.5 g, 45 g, 57.5 g and 70 g) and also an extra 85 g cone in the same standardized size. The women were examined by digital vaginal palpation and the cone exercise was explained. Measurement began with a 2-minute period of complete relaxation (further periods of relaxation were obtained between activation maneuvers). The subject was then asked to contract as strongly and for as long as possible (this was repeated two or three times). The length of such a voluntary squeeze was measured by the duration of the increased EMG activity. The longest of the two or three squeezes was defined as the maximal holding time of that particular trial. Measurement of holding time length – two or three trials with interposed rest – was repeated several

times during a single session (lying down, standing up and after cone treatment). A cone of 85 g for the continent nulliparous group and of 57.5 g for the parous incontinent group was inserted, and the patient was asked to stand up. (The difference in cone weight at initial insertion was chosen according to our previous experience with cone treatment of parous women, who need a lighter cone to start training with; and a pilot trial of cone retention in healthy nulliparous women.) The subject was then asked to cough (repeated single coughs initially, followed by continuous coughing for about 5 s). The patient had to keep the cone in place for the whole time (20 min): if the cone dropped out a lighter cone was inserted. After the examination the cone was removed and measurements of holding times were then repeated in the supine position. All results were obtained as analog prints of continuous EMG activity: these were fed into a computer (Apple Macintosh® Cupertino, CA, USA) via a graphic analyser. The presence or absence of EMG activity during the maneuvers was noted and quantitatively described.

## Results

A good-quality EMG signal was obtained from both pubococcygeal muscles in 26 women during the whole examination; in 4 subjects one pair of wires became disconnected when the subject had to stand up or a cone dropped out. The women reported that the introduction of the wires caused no more discomfort than an intramuscular injection; after needle removal no discomfort was reported, even during movement.

All recordings were artefact-free, the amplitude of recorded EMG activity being from 50 to 1000  $\mu$ V. During all maneuvers, concomitant recruitment of motor units (or simultaneous inhibition of firing thereof) was observed in both pubococcygeal muscles in the nulliparous group. The durations of increased EMG activity resulting from the strongest voluntary squeeze (maximal holding time) showed good reproducibility in individual subjects. In the nulliparous group the maximal holding time ranged between 26 and 647 s (median 193.9 s) before insertion of the cone and between 34 and 340 s after cone application (median 121.6 s) with a *P* value of 0.21.

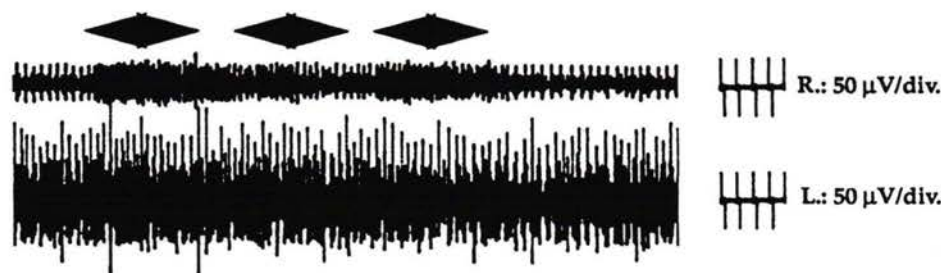
In the supine position the insertion of the intravaginal cone elicited a slight increase in the overall (continuous, tonic) motor unit activity. After standing up, the EMG activity increased and revealed either a rather consistent typical pattern of waxing and waning (crescendo-decrescendo) motor unit recruitment (Fig. 1a,b) or a maximum recruitment of activity with no variation (Fig. 1a left side).

All nulliparous women could retain the cone in the vagina (mean weight 83.5 g; range 70–85 g). Three out of 20 parous stress incontinent women could hold the 57.5 g cone; a further 9 could hold a 45 g cone and 1 a 32.5 g cone whereas 7 patients could not retain any cone.





a) 25y Nullipara (S.A.), holding cone



b) 33y Nullipara (Z.A.), holding cone

Fig. 1. Continuous EMG recordings from the right and left pubococcygeal muscles in 2 nulliparous continent women. Patterns of waxing and waning (crescendo–decrescendo, ♦) motor unit recruitment from the right and left pubococcygeal muscles holding the 85 g cone (a). On the left side of the 33-year-old woman (b) there is full recruitment.

Table 1. Comparison of the maximum voluntary activation time between nulliparous continent and stress urinary incontinent parous women with differentiation between cone holders and non-cone holders

Nulliparous continent women (n=10)	Before cone application 26–647 s (193.9 s)*	After cone application 34–340 s (121.6s)†
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Cone holders (n=13)	20–132 s (59.2 s)§	
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P values: \* $P=0.022$ ; † $P=0.04$ ; § $P=0.04$  ( $P\leq 0.05$ )

Measurements of the maximal holding time (ability of prolonged strong voluntary activation) showed that the maximum holding time was significantly less in the parous group than in the nulliparous group (Table 1). The stress urinary incontinent women were able to activate the pelvic floor for between 2.6 and 132 s (median 43.7 s) before, and between 2 and 140 s (median 49.4 s) after cone testing, with a  $P$  value of 0.9. By splitting the urinary stress incontinent women into 'cone holders' and 'noncone holders' it is interesting to see the significant difference in the voluntary maximum holding times: in the cone holders it was 59.2 s and in the non-cone holders it was 15.1 s (mean). Waxing and waning patterns as well as maximum recruitment patterns were persistent in all parous women capable of retaining the cone. Muscle 'behavioral abnormalities',

in the sense of qualitative differences between the right and left levator parts, were found in 15 women; 5 women showed unilateral absence of reflex recruitment on one side; and in 10 women inappropriate (paradoxical) inhibition of firing of motor units during voluntary and reflex activation was demonstrated (accompanied by appropriate recruitment on the other side). In 3 women with unilateral absence of reflex recruitment we found a direct effect of the vaginal cone (Fig. 2): before cone application they showed a unilateral inhibition of motor unit recruitment during maneuvers of reflex activation. After holding a 45 g cone for 20 minutes with the demonstrated waxing and waning recruitment pattern, a consistent reappearance of appropriate bilateral recruitment of motor units during coughing and repetitive coughing was found.

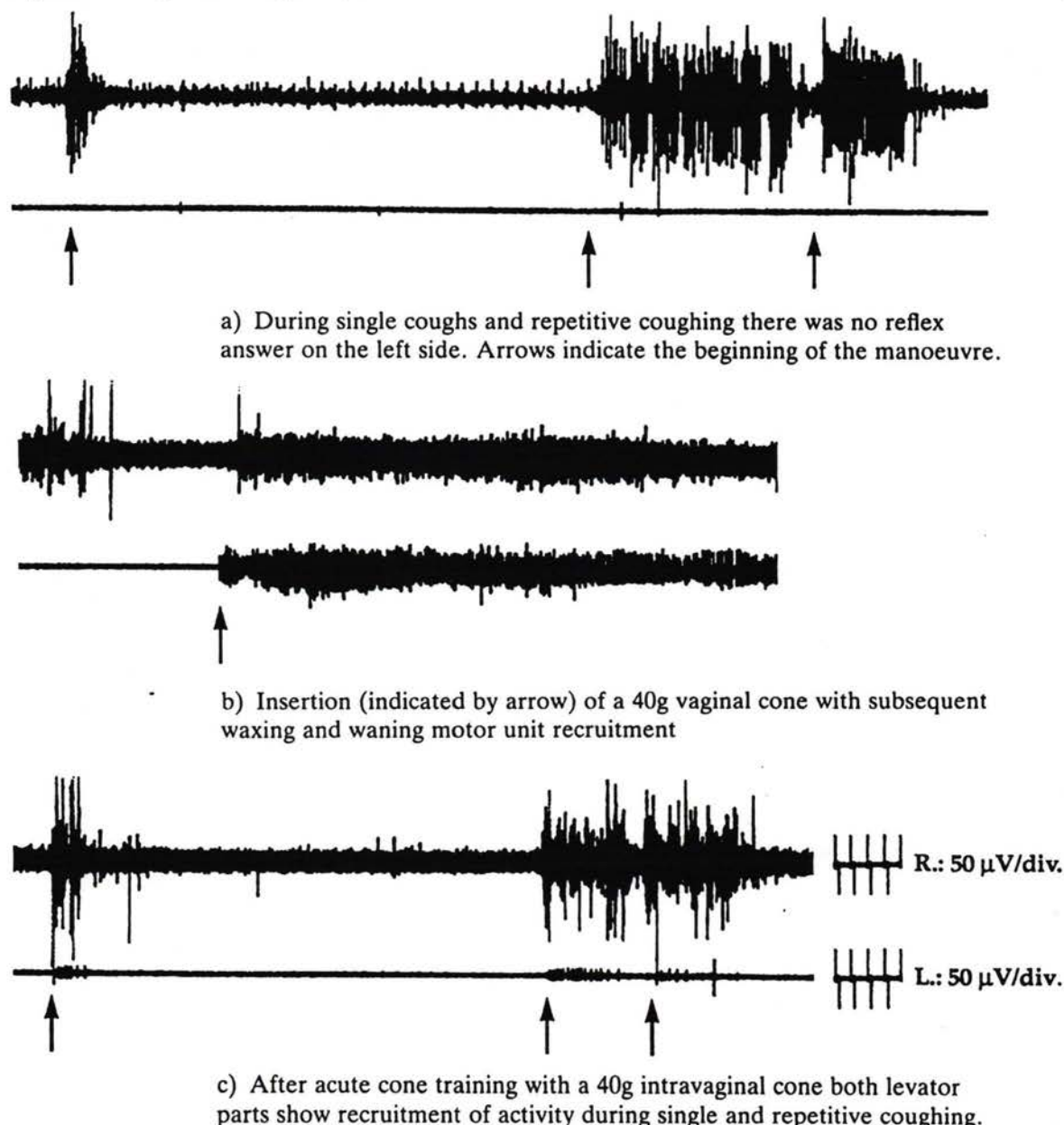


Fig. 2. Continuous EMG recordings from the right and left pubococcygeal muscles of a 50-year-old stress urinary incontinent woman after two vaginal deliveries.

## Discussion

At the introduction of vaginal cones for conservative treatment of stress urinary incontinence their mode of action was described as providing sensory feedback due to the feeling of losing the cone, which makes the pelvic floor contract around the device [8]. Our results reveal that in women capable of holding a cone in the upright position, the insertion of a cone leads to an intermittent type of activity, reflecting repetitive pushing up of the cone, which tends to slip out of the vagina. This pattern was typically found at these recording sites, which showed a tonic pattern of EMG activity [6]. At recording sites with a phasic pattern we occasionally found

prolonged uniform maximal recruitment with no variation. These patterns were independent of whether minimal or maximal cone weight was being used. In those women not able to hold the cone there was still a recruitment of activity, although palpation showed no evidence of muscle contraction.

In our study all the nulliparous continent women, but only 13 out of 20 parous stress incontinent women, were able to retain the cone. The maximal voluntary activation times was significantly longer in the nulliparous women: in the parous women (Table 1) there was a difference between cone holders and non-cone holders, reflecting the insufficiency of pelvic floor muscles in stress incontinent patients. Apart from the fact that



there are anatomical reasons why some women are not able to hold a cone (a wide introitus and/or vagina), we would suggest that there is also a necessary starting condition of pelvic floor muscles, reflected by our measure of maximal holding time. Findings from our study suggest that this should be above 20 s for a woman to be a candidate for cone therapy. For conventional pelvic floor exercises to be effective it is essential that the patient should understand which muscles should be consciously, voluntarily activated. However, the vaginal cone treatment activates the appropriate muscles reflexly. The waxing and waning EMG pattern corresponds to repetitive activation of muscle and represents a quite effective exercise program. As we were able to show, there was also a reappearance of recruitment of reflex activity after acute cone exercise in patients with unilateral absence of such 'normal' behavior; in our opinion this demonstrates that cones may also train reflex coordination of the pelvic floor muscles, which may not be the case with voluntarily performed exercises [9]. In conclusion, vaginal cones may induce both strengthening of muscles as well as a learning effect leading towards a better coordinated muscle activation.

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**EDITORIAL COMMENT.** This paper gives more clarification as to the (good) effect of vaginal cones. Even though Plevnik and co-authors suspected some kind of reflex activity in 1985, this study demonstrates nicely the electromyographic effects, including intermittent activation as well as possible recruitment of motor units even in previously unilateral inhibited motor units. A prerequisite of this treatment is good compliance and the ability to retain the cones, which was impossible in 7 out of 20 women.

## Review of Current Literature

### Long-Term Analysis of the Surgical Management of Pelvic Support Defects

R. F. Porges, S. W. Smilen

Department of Obstetrics and Gynecology, New York University School of Medicine, 530 First Ave, New York, NY 10016, USA  
*Am J Obstet Gynecol* 1994; 171:1518-1528

Of 486 patients managed surgically for pelvic support defects over a 23-year period, 433 were followed for a mean of 31 months. The classification system for defects was based on the introitus as a reference point, and defects were characterized as mild, moderate or severe. Urinary incontinence was not evaluated. Recurrence correlated directly with the severity of the original defect. There were indications that the addition of sacrospinous vault suspension reduced the likelihood of recurrence in those patients with severe defects, e.g. procidentia. Recurrences occurred as early as 4 months and as late as

20 years. It was perceived that the success of the sacrospinous ligament fixation depended less on the suspending sutures than on the attachment over a levator muscle. Anterior repair was more effective than posterior repair in preventing recurrences at their respective sites. A double plication of the vesicovaginal connective tissue maintains an adequate length of anterior valve plate.

### Comment

This is a descriptive study and should be viewed in this light. The International Continence Society method of analysis for pelvic muscle defects uses the hymenal ring as a reference point and measures from there. No mention is made of incontinent disorders, before or after surgery. In follow-up, consideration should be given to patient reporting of symptoms. Recurrences were rare with cystocele repairs (2%-3%) and slightly more common with rectocele repairs (6%). The techniques used in this study are effective in preventing long-term recurrences.



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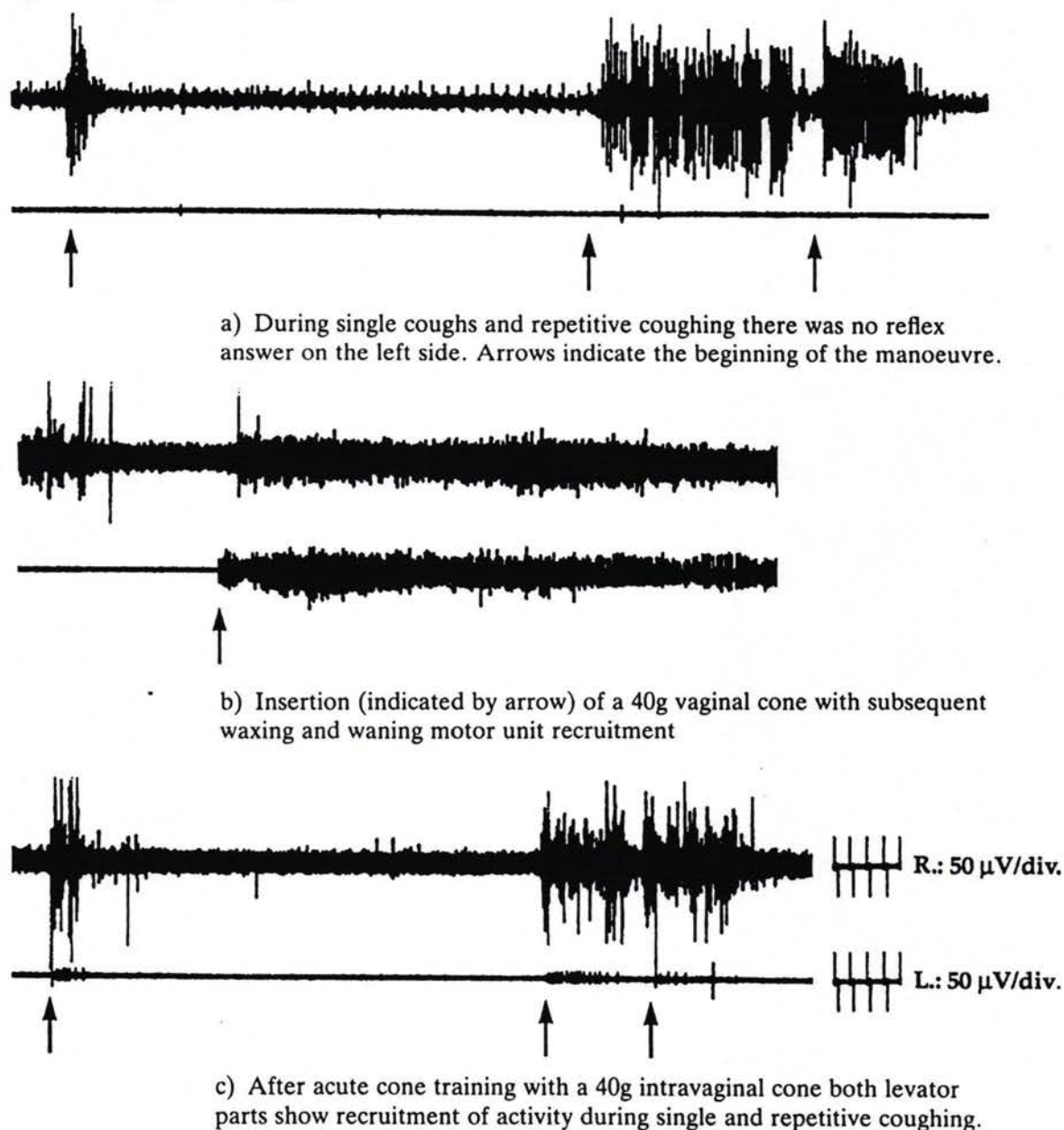


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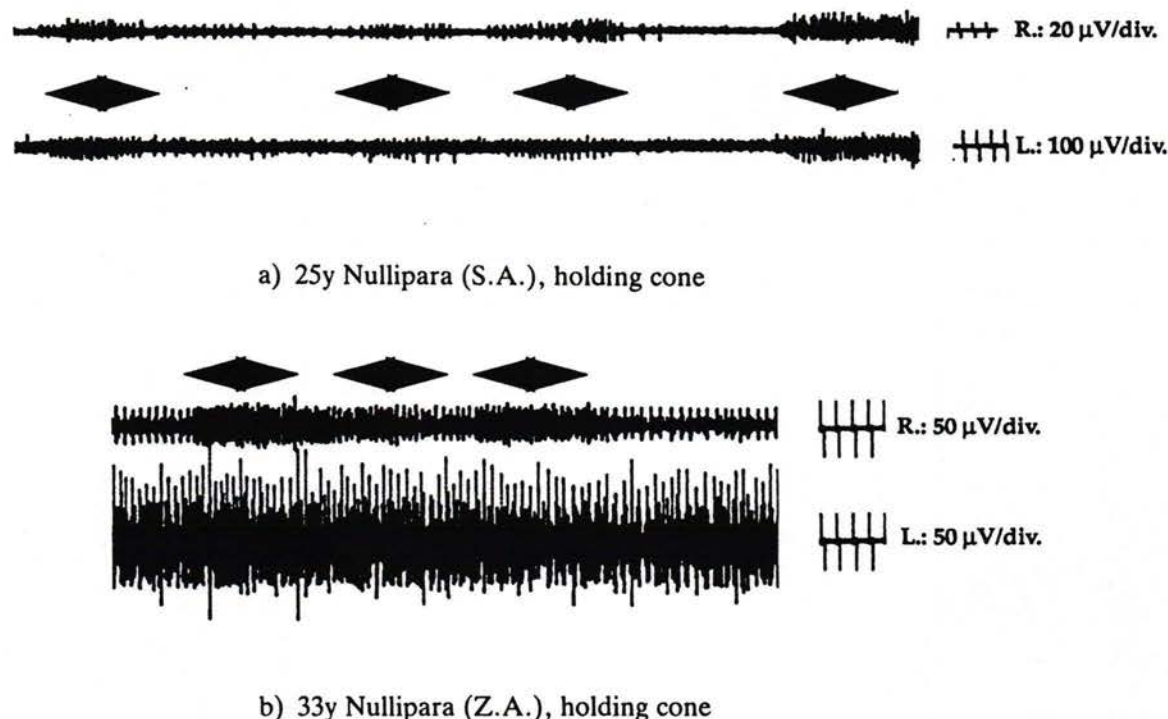


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A good-quality EMG signal was obtained from both pubococcygeal muscles in 26 women during the whole examination; in 4 subjects one pair of wires became disconnected when the subject had to stand up or a cone dropped out. The women reported that the introduction of the wires caused no more discomfort than an intramuscular injection; after needle removal no discomfort was reported, even during movement.

All recordings were artefact-free, the amplitude of recorded EMG activity being from 50 to 1000  $\mu$ V. During all maneuvers, concomitant recruitment of motor units (or simultaneous inhibition of firing thereof) was observed in both pubococcygeal muscles in the nulliparous group. The durations of increased EMG activity resulting from the strongest voluntary squeeze (maximal holding time) showed good reproducibility in individual subjects. In the nulliparous group the maximal holding time ranged between 26 and 647 s (median 193.9 s) before insertion of the cone and between 34 and 340 s after cone application (median 121.6 s) with a *P* value of 0.21.

In the supine position the insertion of the intravaginal cone elicited a slight increase in the overall (continuous, tonic) motor unit activity. After standing up, the EMG activity increased and revealed either a rather consistent typical pattern of waxing and waning (crescendo-decrescendo) motor unit recruitment (Fig. 1a,b) or a maximum recruitment of activity with no variation (Fig. 1a left side).

All nulliparous women could retain the cone in the vagina (mean weight 83.5 g; range 70–85 g). Three out of 20 parous stress incontinent women could hold the 57.5 g cone; a further 9 could hold a 45 g cone and 1 a 32.5 g cone whereas 7 patients could not retain any cone.



## Original Article

# Neurophysiologic Effect of Vaginal Cone Application in Continent and Urinary Stress Incontinent Women

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**Abstract:** Simultaneous electromyographic (EMG) recordings with intramuscular wire electrodes from the left and right pubococcygeal muscles were performed to elucidate the neurophysiological effect of vaginal cones on the pelvic floor muscles. Ten continent nulliparous women (aged 22–32 years) and 20 stress urinary incontinent parous women (aged 27–60 years, average 2–4 deliveries) were examined before, during holding and after removal of the cone. All the continent nulliparous women could retain the cone in the vagina (mean weight 83.5 g (range 70–85 g). In the incontinent parous group 7 women could not hold any cone, 9 women could hold the 45 g cone, 1 the 32.5 g cone and 3 women the 57.5 g cone. There was a significant voluntary holding time difference between continent nulliparous and incontinent parous women. The study reveals that vaginal cones may induce both strengthening of muscles as well as a learning effect leading towards a better coordinated muscle activation.

**Keywords:** Continent nulliparous women; Holding time difference; Learning effect of vaginal cones; Pelvic floor coordination disturbance; Urinary stress incontinent parous women; Vaginal cone therapy

## Introduction

Pelvic floor re-education has been shown to be effective in patients with functional pelvic floor disorders suffering from stress urinary incontinence (SUI) [1]. It is

generally assumed that the efficacy of this treatment is due to strengthening of the pelvic floor muscles. To evaluate the contractile ability before and after different types of pelvic floor muscle training, various methods have been used, such as perineometers [2], cuffed catheters [3,4] or digital tests [5]. Perineometers and cuffed catheters do not allow a distinction to be made between contraction of the pelvic floor muscles or that of the abdominal wall muscles, both being registered on the meter as an increase in pelvic floor activity. Digital tests depend on the experience of the examiner, which does not permit objective evaluation.

Kinesiologic EMG recordings have been shown to demonstrate well the various activity patterns (behavior) of pelvic floor muscles [6], and revealed differences between these patterns in both continent nulliparous and incontinent parous women [7]. It was the aim of this study to evaluate how vaginal cones influence the activity of patterns of the levator ani muscles in both nulliparous continent and parous stress urinary incontinent women.

## Patients and Methods

Nulliparous women attending the Family Planning Out-patient Clinic and parous urinary incontinent women were taught the importance of the pelvic floor muscles in maintaining continence, and informed of the purpose and methodology of this study. Thirty subjects gave their informed consent and were recruited into the study.

Twenty parous women between 27 and 60 years (median 45.2 years) old, who had given birth to between 2 and 4 children (average 2.6) were examined. In all

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