

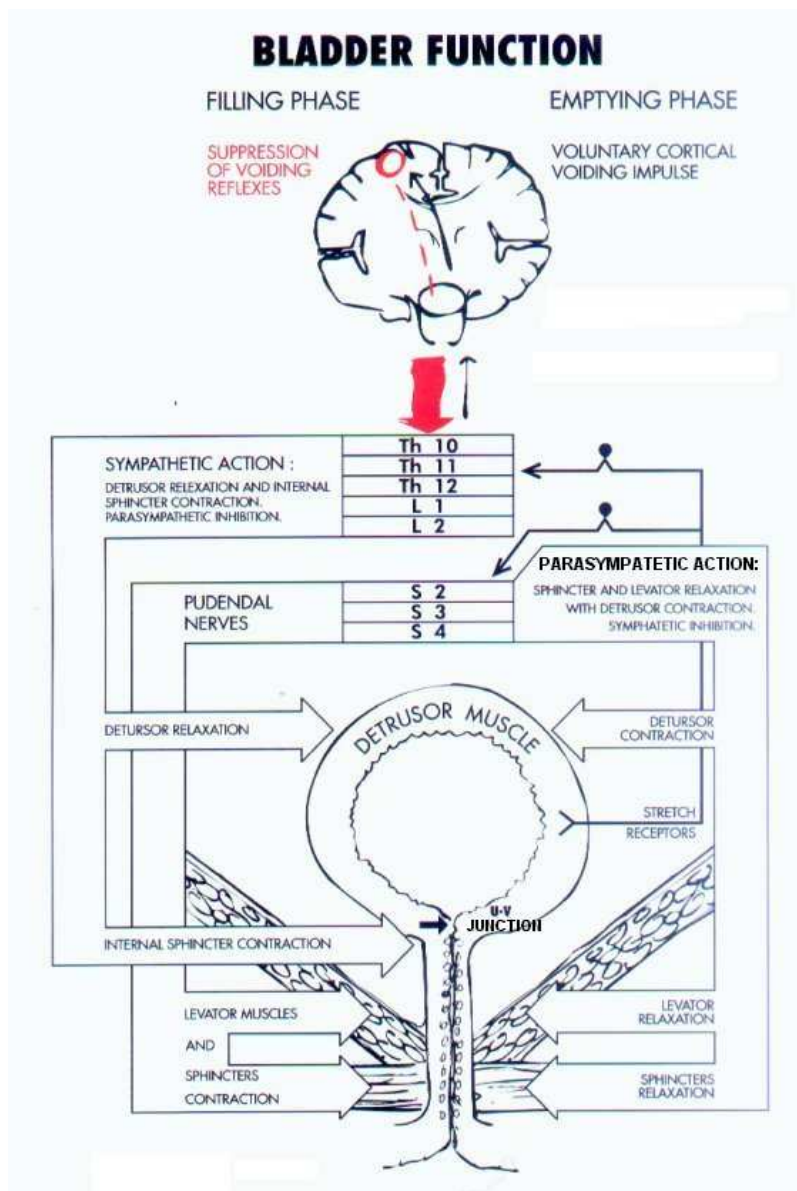
GENUINE STRESS AND URGE INCONTINENCE PROTOCOL

Using the NeuroTrac ETSTM in combination of
electrostimulation and EMG Biofeedback
in the treatment of female urinary incontinence.

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Introduction

Background Information Electrical stimulation has been shown clinically to be effective in the treatment of patients with genuine stress incontinence and detrusor instability. (see figure 3)



In 1963 Caldwell implanted electrodes in the pelvic floor of women with urinary and fecal incontinence. Later other modes of delivery were developed, including anal and intravaginal stimulation. Several studies of various intravaginal stimulation protocols were undertaken by Plevnik 1986, Eriksen and Eik-Nes 1989, Fall and Lindstrom 1991, Bent 1993, Caputo 1993, Smith JJ 1996 and Fowler 2000. The studies have shown subjective success rates in excess of 80%.

The majority of patients with incontinence are parous women and the elderly.

(Figure 2)

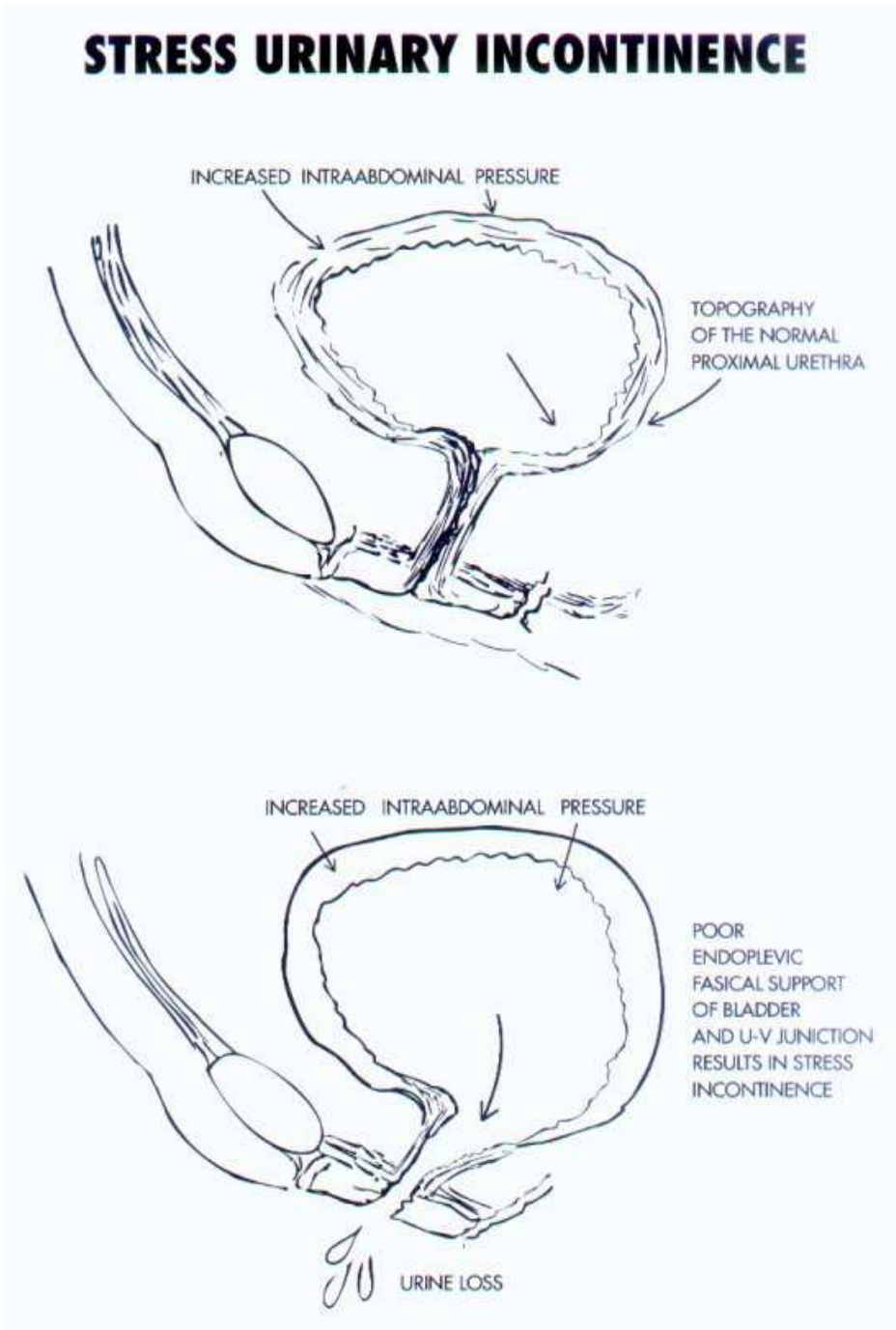
- Urinary Incontinence

Urinary incontinence – the involuntary loss of urine – affects an estimated

25 million Americans and over 3 million women in the UK.

The majority of patients with incontinence are parous women and older persons. The continence mechanism in women centers on the proximal urethra and urethrovesical junction.

Continence is maintained by multiple structural and physiologic mechanisms that regulate closure of the urethra and support of the bladder and urethrovesical junction. Actual closure of the urethra is produced by three different systems: the involuntary internal sphincter at the vesical neck, the voluntary external sphincter muscles of the urethra and mucosal coaptation produced by the urethral submucosal vascular plexus. Anatomic support for these structures primarily comes from a fascial layer, which is attached to the levator ani muscles of the pelvic floor. The terms "pelvic floor" or "pelvic diaphragm" refer to all the muscular components that close the pelvic cavity and their respective parietal fascial coverings. Unlike striated muscles in other areas of the body, the muscles of the pelvic floor are in a constant state of contraction, which allows for the efficient positioning of the urethrovesical junction. The bladder and urethra are primarily innervated by the autonomic nervous system.



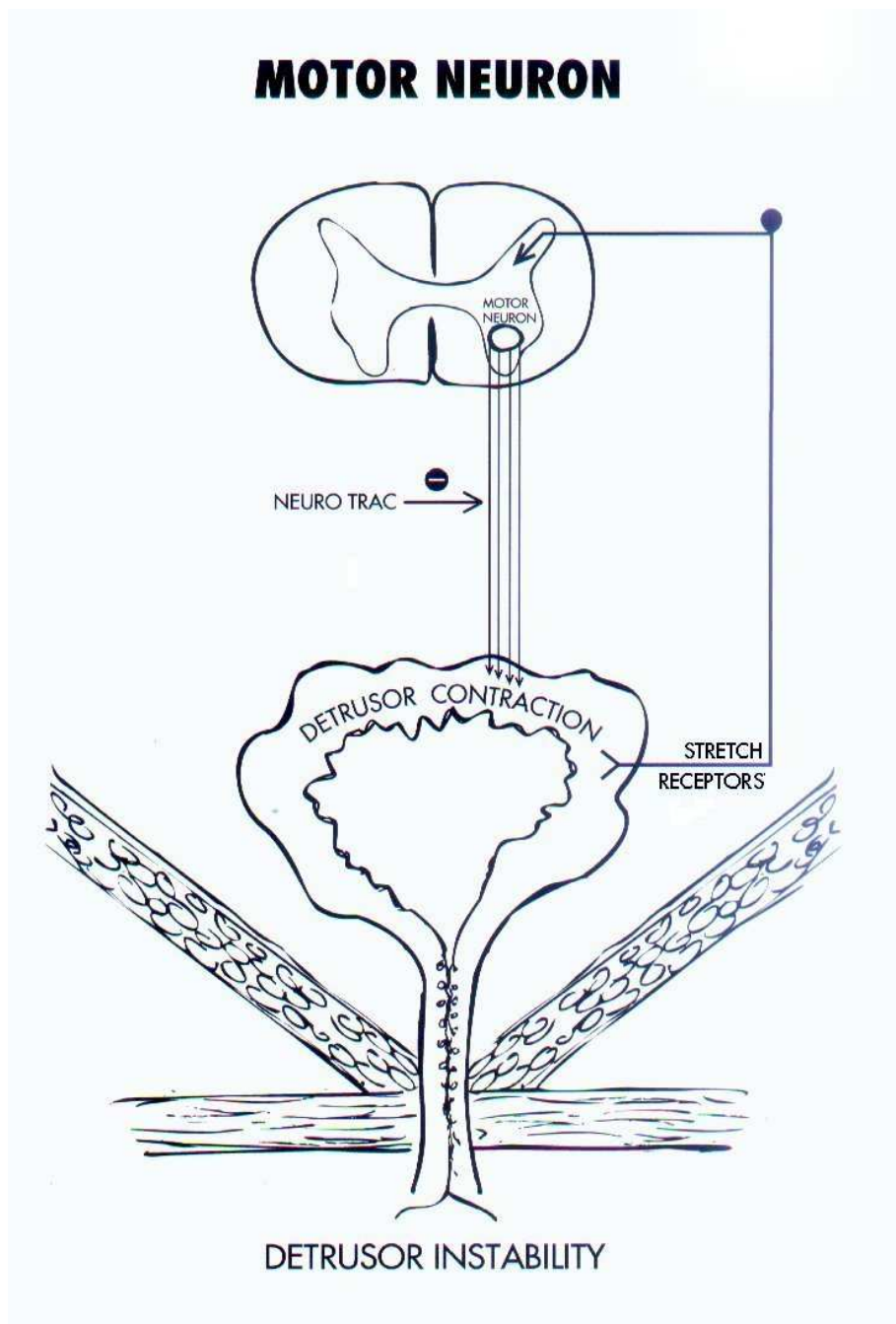
However, even activities that cause small increases in intraabdominal pressure such as walking or changing position, may produce similar symptoms.

This system can be modulated by somatic nerves that innervate the pelvic floor and external urethral sphincter. The activation of the pudendal nerve reflexes and the direct contraction of the pelvic floor and periurethral striated muscles due to electrostimulation to the pelvic floor is a simple, safe and effective way to improve incontinence.

- symptoms

Although the symptoms of incontinence are many varied, they can be classified under two broad categories: stress urinary incontinence (see figure 3) and urge incontinence. Patients may have more than one kind of symptom at the same time.

Figure 3

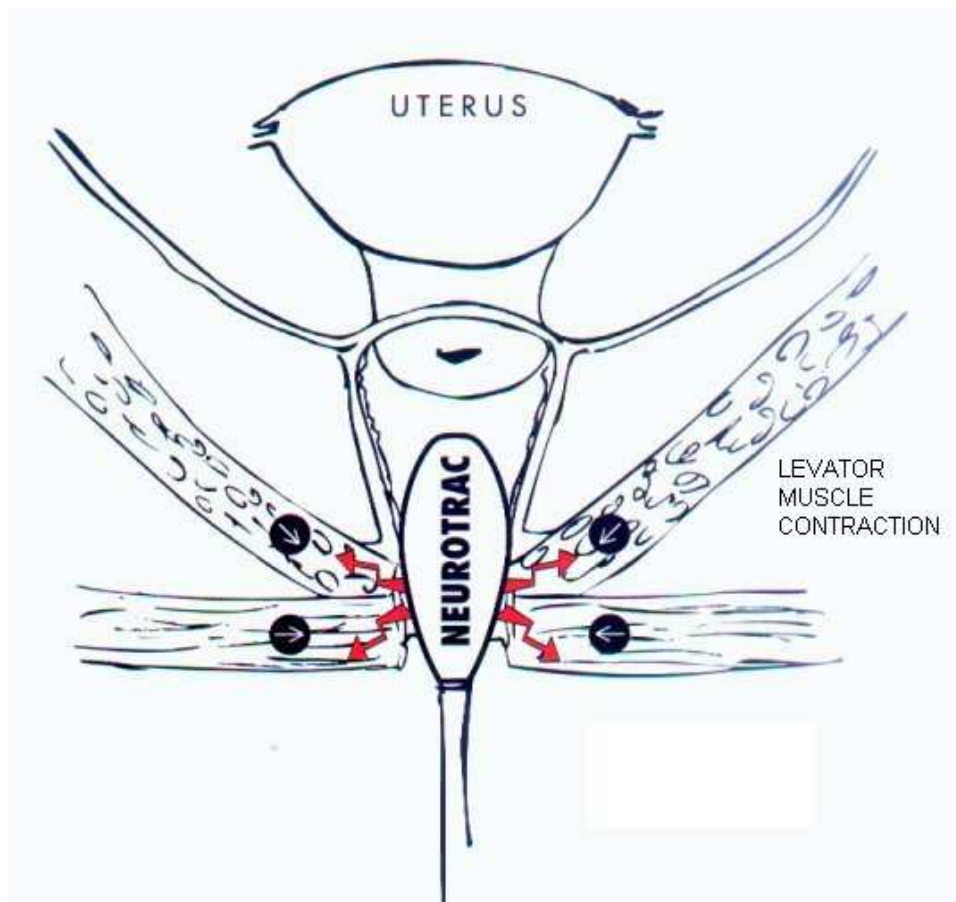


Stress urinary incontinence involves leakage of urine with an elevation in intraabdominal pressure. It is commonly produced by coughing, laughing and sneezing. However even activities that cause small increases in intraabdominal pressure such as walking or changing position, may produce similar symptoms. (see figure 4, page 4)

Urge incontinence is the involuntary loss of urine associated with a strong desire to void, whether or not the bladder is full. Many women with urge incontinence complain of not being able to reach the bathroom in the time, or they may experience urinary dribbling or leaking when they see the washroom or toilet or put the key in the door upon returning home. Urge incontinence is associated with a spectrum of voiding symptoms: frequency (>7 times/day), urgency (the strong desire to void) and nocturia (>1time/night). Usually, involuntary detrusor contractions (detrusor instability) produce the symptom complex of urge incontinence. There are many causes of the problem which essentially is an imbalance

The receptor signals overwhelm the inhibitory reflex before the bladder is full.

Electrostimulation using the NeuroTrac



between the signals from the parasympathetic nerve receptors in the bladder and the inhibitory sympathetic reflex to the detrusor muscle. The receptor signals overwhelm the inhibitory reflex before the bladder is full.

Stress and urge incontinence are not diagnoses but rather symptom complexes that the patient reports to the healthcare practitioner. A diagnosis identifies the causes of urinary incontinence and is made by demonstrating objective evidence of urine loss, usually with diagnostic testing (urodynamics). Distinguishing between symptoms and diagnoses is vital because therapy – particularly surgical treatment – is based on an

Treatment results for genuine stress incontinence take about 12 weeks; detrusor instability may improve in less time.

accurate diagnosis of the cause of incontinence. Urodynamics is required to be certain of the specific diagnosis of most forms of incontinence.

Diagnosis of incontinence; Kauppila & Kujansuu diagnostic questions

Questionnaire

Distinguishing stress and urge incontinence from the answers to 10 question developed by Kauppila & Kujansuu is simple guide for diagnosing the type of incontinence. The questionnaire is as follows. All that needed is to give the indicated points to each question and total them. A score below 7 shows stress incontinence. Above 7 indicates treatment in the URGE electrostimulation mode – Programme 2.

Question Points

Do you feel urgency before leaking?

No(0), Some (1), Strong (2)

Do you leak when lifting something heavy or in other strenuous situations?

Yes (0), Even without strenuous activity (2)

Do you leak when doing something strenuous, or seconds afterwards?

At the same time (0), seconds after (2)

What quantity of urine leaks?

A little (0), moderate amount (1), a large amount (2)

Can you interrupt urination without leaking?

Yes (1), No (2)

Do you feel pain when urinating?

No (0), Yes (2)

Do you feel strong urgency in stressful situations?

No (0), Fairly strong (1), Yes (2)

How many times per day do you urinate?

5 times (0), 6-7 times (1), 8 or more times (2)

How many times do you urinate at night?

0-1 times (0), 2-3 times (1), 4 or more (2)

Have you had medication for urinary infections?

0-1 times (0), 2 or more times (1), chronic (2)

If the total is less than 7, stress incontinence is most likely.

Most patients with higher scores will respond quickly to electrostimulation with the NeuroTrac 5TM set in the URGE programme 2.

Treatment

Treatment of incontinence should be started only after a complete history and physical examination. The therapy choices must consider all aspects of the woman's life. Since conservative therapy requires active participation by the patient and surgery necessitates a long recuperation, the patient must be involved in the choice of treatments. Conservative management of incontinence is appropriate for women who seek improvement of their symptoms rather than a cure. All forms of conservative therapy are safer, less invasive and less costly than surgical options. Pelvic floor exercises, first described by Kegel 60 years ago, can diminish episodes of stress incontinence by strengthening the levator muscles. Many clinical studies show that simple verbal instruction is usually inadequate. Many multiparous women cannot isolate and contract their levator muscles and only 30% of women who receive verbal instruction can perform pelvic floor exercises correctly. It is important to learn to do the exercises in the right way. A typical regiment of pelvic floor exercises is based on sets of short and long contractions performed 2 to 3 times a day. Patients can expect 70 – 80% improvement in symptoms in about 12 weeks. Pelvic floor exercises can be enhanced with biofeedback. With NeuroTrac 5 EMG biofeedback the patient quickly learns to clench the right muscles. A contractile levator muscles can be strengthened with NeuroTrac

GENUINE STRESS INCONTINENCE PROTOCOL.

electrical stimulation (Programm 3). (see figure 2) Direct electrical stimulation of these muscles causes hypertrophy and increased strength and may inhibit inappropriate detrusor contractions in patients with an intact neural pathway. Therefore, electrical stimulation can be used to treat mixed incontinence. Electrical stimulation is applied by a probe placed into the vagina. The probe is then connected to a small home device NeuroTrac. Electrical stimulation is usually given twice daily for 20 minutes (Programm 3). Treatment results for genuine stress incontinence take about 12 weeks; detrusor instability may improve in less time. (See Figure 1)The main treatment of urge incontinence is still an anticholinergic drug but today electrostimulation has proven to be a more acceptable treatment. Anticholinergic drugs reduce the neurotransmissive capability of the entire parasympathetic nervous system, not just of the bladder nerves. This may reduce urgency and frequency, but instead causes nausea, dry mouth, blurred vision and other unpleasant side effects. Drugs do not cure urge incontinence.

TREATMENT OPTIONS FOR URGE INCONTINENCE

DRUGS OR NeuroTrac 5TM

Oxybutynin hydrochlorid	Maximal Electrostimulation
EFFICACY	
% Improvement in symptoms compared to pre-treatments or placebo: Cardozo (1) 63,5% Moisey (2) 69% Kirkali (3) 79% Barry (4) 69%	Cure or significant improvement: Eriksen (5) 83% Shepard (6) 87% Plevnik (7) 77%
SIDE EFFECTS	
Dry mouth, constipation, blurred vision, nausea, facial flushing, abdominal discomfort and difficulty in micturition.	No side effects (5)
CONTRA – INDICATIONS	
Patients with obstruction of the bowel, bladder outflow obstruction, intestinal atony, severe ulcerative colitis or toxic megacolon, myasthenia gravis, glaucoma. Breast feeding mothers.	Patients with heart – pacemakers. Pregnancy.
PRECAUTIONS	
Use with caution in: the elderly frail, autonomous neuropathy, hepatic or renal disease, reflex oesophagitis, hyperthyroidism, coronary artery disease, congestive heart failure, cardiac arrhythmias, tachycardia, pragnancy.	Patients with urinary tract infections.
ANNUAL COST	

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