

## THE EFFECTIVENESS OF SUB-SENSORY THRESHOLD IN PATIENTS WITH A CHRONIC NEUROMODULATION IMPLANT

### Hypothesis / aims of study

More than two decades ago neuromodulation was introduced in the clinic. However, beside the different malfunctions of the lower urinary tract and rectum, which became treatable, and technical improvements, the patient is asked to feel the electrical impulse for the nerve modulation. This instruction might be the reason why the amplitude is often increased over time. A different training of the patient might help to avoid this and increase a longer battery life.

### Study design, materials and methods

Over the last 6 years (1999-2005) 52 neuromodulators (46 IPGs (7 bilateral electrodes connected to the implant by a y-connector, 39 with a unilateral electrode) and 6 TWINS) were implanted. All treated patients had at least previous three other attempts of treatment before they were evaluated for neuromodulation. 14 men and 38 women (age 26 – 69 years) received an implant after successful peripheral nerve evaluation with a documented improvement of at least 70%. The heterogenic group of patients had the following urological malfunctions: urge urinary incontinence (UI) (n=25), urine retention (UR) (n=17), reflex bladder (n=1), pelvic pain (n=3), neurogenic bladder (n=2) and stool incontinence (n=4).

At the time of the adjustment of the chronic implant the patient was asked to pinpoint the stimulation, which caused by changing all other parameters except the amplitude the strongest sensation. Afterwards the amplitude was decreased to the sub-sensory threshold.

### Results

The majority of the patients were implanted on the level of S3 uni- or bilateral (85%). The last 16 patients were provided with new TINE®-lead electrode. Before the patients were released the implant was adjusted. The amplitude needed in 47 of these patients was at a mean of 1V (0.5-1.5V). For 45% of the patient a significant reduction of the amplitude was reached by reverse the polarity. There was no difference in the parameters dependent to the implant or number of electrodes. Subsensoric neuromodulation is an effective treatment. Of these patients, in addition to the two who experienced stool incontinence, the bowel function normalized in 6 patients. In 6 patients the implants lost their effect within the first 3-8 months postoperatively and could not be improved through a parameter re-adjustment or new location of the electrodes (4 UR, 1 UI, 1 neurogenic); 2 devices were removed.

### Interpretation of results

Optimized setting of a neuromodulator improves the outcome at a relative low amplitude (mean 1V). The sub-sensory threshold still provides the patient with an effective long-lasting therapy.

### Concluding message

The best adjustment improves comfort and will increase the battery life. Optimized parameters help to avoid scaring at the electrode. In addition, other reasons than a higher amplitude might be the reason for the fading effect or even failure.

### References

**FUNDING:** None

**HUMAN SUBJECTS:** This study did not need ethical approval because Not required but followed the Declaration of Helsinki Informed consent was obtained from the patients.