

## SACRAL NEUROMODULATION: CAN THERE BE IMPROVEMENT BY CHANGING INITIAL PARAMETER SETTINGS?

### Hypothesis / aims of study

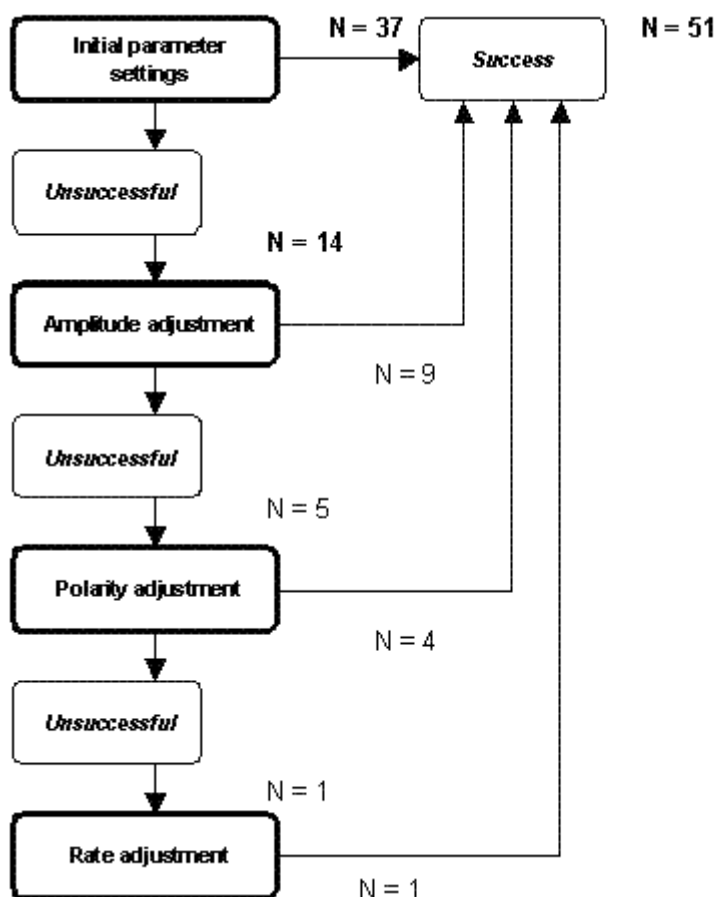
Sacral neuromodulation is considered a successful treatment for patients with urge urinary incontinence (UUI), urgency frequency syndrome and non-obstructive urinary retention, refractory to medical treatment. However, some patients initially fail to respond to this treatment and little knowledge has been gained on the influence of the stimulation parameters on the response. The aim of this study is to evaluate changes in stimulation parameters when initial settings prove unsuccessful, in order to improve the overall success rate.

### Study design, materials and methods

A group of 51 female patients with non-neurogenic severe voiding dysfunction, refractory to medical therapy were enrolled in the study. All were implanted with a unilateral Medtronic Interstim 3023 neuromodulator with a quadripolar electrode placed in the sacral foramen S3. Mean age was  $52 \pm 13$  years, 22 were complaining of urge urinary incontinence and 29 of idiopathic urinary retention. All patients had at least 70% symptom improvement during at least a 12-day peripheral nerve evaluation (PNE) test. Symptom improvement was measured by means of a voiding diary and a visual analogue scale (VAS) for the quality of life. Two days after the implant, the initial settings were applied with the N'Vision programmer and the neuromodulation was started. The first evaluation of response success was planned after 3 months. However, patients were given the possibility to return earlier to the hospital for modification of the stimulation parameters, if they felt that the treatment was unsuccessful. For patients with UUI, success was defined as a frequency < 8 times / day together with an improvement in the number of pads and leaks. For the retention group, success was defined as a residual volume < 10 ml. Stimulation parameters eligible for modification were amplitude, polarity and stimulation frequency. They were modified in a specific order as shown in the algorithm. Parameters were modified to obtain the adequate sensory response from the genito-perineal area.

### Results

After the initial settings 37 of the 51 (73%) were seen after 3 months and were considered successful based on the proposed definitions: 20 patients with urinary retention, 17 with UUI. Fourteen patients (27%) had poor response and returned at least 1 time for modification before the evaluation period of 3 months ended: 9 of them had urinary retention, 5 UUI. The first modification in these patients was an increase in amplitude with a maximum of 2.5V. After this modification, 9 patients had a successful response, the other 5 returned for adjustment of the polarity by changing the electrode configuration. All but one showed a good response. Only 1 patient with urine retention was reprogrammed with frequency adjustment, which was followed by a good result. The algorithm used is shown in table 1.



### Interpretation of results

Not all patients have a good response to the initial stimulation parameters. Modification of these parameters may improve the response. Programming should be done individually depending on the improvement and using a standardised method for changing parameter is appropriate to increase success. The sensation of the stimulation and the impedance should be checked afterwards.

### Concluding message

Further research should be done to evaluate the long term effect of these modifications.

The success rate of sacral neuromodulation can be increased by changing stimulation parameters.

<b><i>Specify source of funding or grant</i></b>	<b>NONE</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Ethics Committee of the University Hospital of Antwerpen</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>