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# IMPROVING NEUROMODULATION TECHNIQUE: PRELIMINARY RESULTS OF MINIMALLY INVASIVE IMPLANT WITH TINED LEAD

### Aims of Study

Aim of this report is to present the first experience of a minimally invasive technique for sacral neuromodulation using a new tined lead.

#### Methods

A new tined lead (fig. 1) has been specifically designed to allow a minimally invasive placement of chronic lead for sacral neuromodulation.

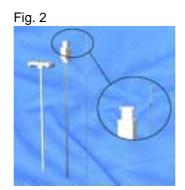
The foramen needle is inserted into the foramen to a desired location (S3 usually), then the technique consist of using a introducer kit (fig. 2) inserted over a metal stylet inserted through the needle, the lead is inserted through the plastic sheath of the introducer kit.

The position and depth of the lead is adjusted to obtain the best sensory and motor response.

From September '01 9 consecutive patients (6 female, 3 male, mean age 34, range 27-56), underwent minimally invasive staged implant of permanent lead (in local anaesthesia with ropivacaine) for sacral neuromodulation all 9 pts skipped the PNE phase.

The procedure was performed in local anaesthesia. Indications for sacral neuromodulation were: urinary retention 4 pts (neurogenic 2), urge incontinence 5 pts (neurogenic 1).

Fig. 1



#### Results 1 4 1

The average time necessary to complete the procedure was 45 minute (range 25-60). In all the patients x-ray is taken during the implant and at the last follow-up to check the correct positioning of the lead.

Six pts underwent second stage (implant of IPG) after 12-36 days of screening phase, 2 that report an improvement lower than 50% were not selected for implantable pulse generator (IPG) implant and lead removed (in local anesthesia) and 1 patients is currently in the screening phase. The mean follow-up is 5 months. There were no displacement of the lead.

All the six pts that underwent second stage implant maintain the good results: restoring continence in 3 pts with urge incontinence and recovery of spontaneous voiding in the 3 pts suffering from voiding disturbances

## Conclusions

The use of a tined lead allows a minimally invasive implant of chronic sacral neuromodulation lead. Our still preliminary results shown that the new tined fixation system is a reliable way to allows a real minimally invasive placement of chronic lead.

A minimally invasive approach to implantation has a number of benefits.

- Our experience showed that the staged, percutaneous approach with local anesthesia is feasible, allows for the elimination of the sub-chronic phase of the test stimulation, is quicker than the traditional implant and may reduce adverse events associated with the surgical procedure required to implant the lead.
- The use of local anesthesia lets the implanting physician use the patient's conscious sensory response to stimuli as an aid in accurately placing the stimulation lead.
- Tined lead allows a true percutaneous approach without skin incision and fascial fixation
- The explant of the lead is simple quick and safe and we can define this method the new PNE