Liste-73

SPINAL CORD STIMULATION IN PATIENTS WITH PAIN IN BACK OR LOWER LIMBS USING A NEW TRANSVERSE TRIPOLAR LEAD (TTL) AND TEMPORARY DUAL PULSE GENERATOR. THE LEUVEN EXPERIENCE.

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Purpose: To evaluate the efficacy of a transverse tripolar lead (TTL) and to test computer predictions on steering of paraesthesia. This lead has three electrodes oriented transversely to the spinal cord axis, and a fourth electrode on the midline close to the center electrode. By computer modeling, it has been predicted to bias recruitment in favor of dorsal column fibers, and with a new dual pulse stimulator may steer paraesthesia in a finely controlled manner.

Methods: In patients with chronic intractable pain in one or more limbs from non-malignant origin a TTL was implanted and trial stimulation was performed using a new dual pulse stimulator All patients had had multiple stimulation devices before with good results if the paraesthesia could be delivered to the site of pain. They were -- so to speak -- the worst possible "stimulation cases" drawn from a large practice with patients having had electrical stimulation of the spinal cord. The study was performed after approval by an ethical committee and with respect for European Standard of Clinical Investigation on Medical Devices for Human Subjects (EN 540).

Results: In a first study a TTL prototype (Model A, 12 mm wide) was implanted in four patients. Using the dual pulse stimulator, steering of paraesthesia could be demonstrated in all but one patient whose central contact was too close to the cord.
Three out of four patients were satisfied after implant of the TTL. However, after 12 months only one patient remained with good effect from the stimulation, mainly due to technical problems with lead shifting and lead wire breakage. In a second study two patients received another type of TTL (Model B, 10 mm wide). These also did not last long due to unsolved technical drawbacks. The inclusion of patients was stopped and the leadwas totally redesigned. 12 months later, in a third study nine patients received a new TTL (Model 3991A, 10 mm wide). No technical defects of the lead were encountered. Steering could be demonstrated and 6 patients have received valuable benefit 1 year after implant, which was considered to be a good result in these selected worst possible patient population.

Conclusions: Steering of paraesthesia is possible when the lead is near physiological midline and not too tilted. One concern is a more than doubling of the current needed over 12 weeks, sometimes to the limit of the stimulation device. The TTL Model 3991A can now be called reliable. A five center trial is underway with patients having the lead implanted as their first implantable stimulating device.