STOP Neuroma Trial

Surgical Treatment Of symPtomatic NEUROMA

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NEUROCAP®, Data driven efficacy

One year animal implantation data strongly stresses out NEUROCAP®'s key mode of action acting as barrier for further nerve outgrowth and the accompanying unwanted signals and stimuli thereof. Additionally, one year of post-implant follow up data with the clinical STOP Neuroma cohort study emphasize the clinical utility and sustainability of NEUROCAP® in reducing painful neuroma in the patient.

Animal data NEUROCAP®

The outcome of the animal implantation study comparing treatment of rat sciatic nerve-ends with a 1,5 mm NEUROCAP® with a control group (cut and bury technique) strongly shows NEUROCAP® to perfectly act as mechanical barrier to prevent axonal sprouting.
Histological comparison at 3, 6 and 12 months post-implantation clearly shows a tendency towards nerve-end maturation in the NEUROCAP® group with no neuroma formation. Moreover, the nerves are less tethered to the surrounding tissues in the NEUROCAP® group suggesting less traction neuritis and pain as observed in the behavior of the test animals.

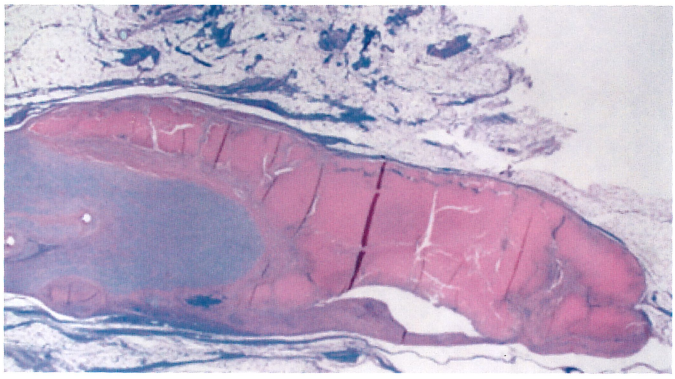

Figure-1. Luxol fast blue stain image of NEUROCAP® and nerve stump in rat sciatic nerve injury model; 12-month post-implant: NEUROCAP® with organized nerve

STOP NEUROMA cohort study

The STOP NEUROMA study was designed to provide surgeons with clinical evidence about NEUROCAP®'s benefits in the much needed management of symptomatic neuroma pain. The 12-months follow-up data undoubtedly indicate the effectiveness of NEUROCAP® in terms of reducing pain symptoms, improving patients' daily life and functioning. NEUROCAP®, as first-in-kind device can be used in prevention of neuroma pain in the long term, following amputations or accidental damage.

PROTECT NEURO study

The PROTECT Neuro study, a global multicenter post-market trial investigating the long-term efficacy and safety of NEUROCAP® in upper and lower limb end-neuroma is currently enrolling patients. Eighteen sites were recruited in the EU and US to originally enroll 92 patients in total.
The enrollment rate and initial follow up data in this study are that satisfactory that the inclusion will be stopped at 69 patients. Main outcome measures are VAS pain score, QuickDASH or functioning, Elliot Neuroma score and recurrence with follow-up visits at 3, 6, 12 and 24 months after surgery. Currently, mean VAS Pain scores have decreased by more than 70% and functionality scores have decreased significantly in patients at 12-months follow-up. No recurrence of neuroma has yet been confirmed.

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Table 1 Final data VAS Pain score STOP Neuroma trial

Patient (gender-age)	Neuroma	NEUROCAP® size	Pre-op VAS (0-100 mm)	Post-op 6 wks VAS (0-100 mm)	Post-op 3 mths VAS (0-100 mm)	Post-op 6 mths VAS (0-100 mm)	Post-op 12 mths VAS (0-100 mm)
F27	SRN neuroma	2,5 mm	81	1	1	1	1
F66	SRN neuroma	3,0 mm	93	9	25	30	8
F42	Dorsal branch ulnar nerve and SRN	2,5 mm	79	6	1	3	6
F25*	Dorsal branch ulnar nerve	2,0 mm	64	1	1	72	60
F21	SRN neuroma	2,5 mm	80	26	27	27	30
M59	SRN neuroma	3,0 mm	9	30	30	14	62
F41**	Radial nerve	3,0 mm	78	13	12	72	21
F33	SRN neuroma	1,5 mm	80	1	9	1	1
F37	Median nerve	1,5 mm	78	1	0	1	1
M41***	Sens. branch median nerve	1,5 mm	91	85	72	NA	NA
MEDIAN (range)	-	-	79 (9-93)	8 (1-85)	11 (0-72)	14 (1-72)	8 (1-62)

* *Recurrent neuroma at 6 months after external trauma (hit on operational site). Surgically treated between 6- and 12-month follow-up.*

** *Patient indicates variable pain rates, sometimes spontaneous and sometimes when carrying heavy load. Pain is much less frequent than before surgery.*

*** *SAE after external trauma (bumped on table corner); severe seroma formation at operational site. Re-operated and NEUROCAP® removed; study exit after removal.*