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**Prevention of peri-neural fibrosis after neurolysis and carboxy-methyl-cellulose/ poly-ethilene-oxide barrier agent for the treatment of recalcitrant postsurgical neuropathic pain: experimental study on mice and preliminary clinical results**

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**INTRODUCTION:**

The surgical treatment of recalcitrant pain due to scar formation around a nerve is represented by the neurolysis of the nerve and the covering with a gliding and/or well vascularized tissue (adipo-fascial flap, synovial flap, etc), a vein wrapping or a barrier agent to prevent the scar formation. We show the result of an experimental and a clinical study on the use of a barrier agent. The aim of the experimental study is to assess the efficacy in reducing the adhesions in a mouse model by means of the anti-adhesion gel composed of carboxy-methyl- cellulose and poly-ethilene-oxide (Dynavisc® Gel) after induction of a perineural lesion (experimental mice model of epi-neural fibrosis was used). This barrier agent has been widely employed in spine surgery but never tested in peripheral nerve surgery.

In the meantime we assess the outcome of eight patients operated with a neurolysis and the application of CMC and PO for a recalcitrant neurological pain.

**MATERIALS AND METHODS:**

25 adult mice were employed in the experimental study. The animals were divided into two groups: in both the bed muscle around the sciatic nerve was burned by dia-thermo coagulator (model to create a scare around the nerve); in a group was applied the anti-adhesion gel. After 3 weeks the peri-neural fibrosis was assessed by means of a biomechanical test (measurement of the maximum force required to detach the nerve from the muscle) and by histological evaluation (amount of fibrous tissue and collagen around the nerve).

In the clinical study we assess 8 patients operated for a recalcitrant pain after previous surgical procedures on nerves (7 females and 1 male – average age 47.5 Pre-operative VAS from 6 to 8). In all eight patients a neurolysis and combined application of CMC&PO gel was performed. The painful component of the syndrome was assessed by means of the VAS scale pre –operatively and post-operatively at one day, one month and six months.

**RESULTS:**

**EXPERIMENTAL:** According to the results obtained by means of histological and biomechanical analysis CMC&PO gel is able to reduce peri-neural scarring. The group of burned muscle bed shows adhesion force of 68g, CMC&PO group of 48g, control group 38g. There is a statistically significant difference between the control group and also with the CMC&PO gel. The qualitative histological analysis shows the reduction of the scar tissue after the gel application.

**CLINICAL:** In all cases analyzed there were no observed adverse effects due to surgery after the application of CMC&PO. In 7 out of 8 cases satisfactory results were obtained with reduction (difference $\geq$ 4 VAS) of pain in both the short and long term. In 6 of the 8 cases the pain regressed to a level compatible with the performance of regular daily routine (VAS $\leq$ 2).

**CONCLUSION:** The experimental study showed that CMC&PO gel can reduce peri-neural scar formation in the mice model. In clinical setting no adverse effect are noted, and it seems to give satisfactory results after a neuro-lysis reducing pain probably for the reduction of the fibro-genesis around the nerve. This is a TYPE IV of evidence; no double blind study was performed – we didn't compare the results with a simple neurolysis.

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