

Electrostimulation with FREMS is effective in therapy-refractory painful Diabetic Neuropathy

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ABSTRACT

Neuropathy common complicates Diabetes Mellitus (DM), and often converts from sensory loss to painful neuropathy (pDN). In these patients standard pharmaceutical strategies often are ineffective or cause side-effects.

We assessed the efficacy of Frequency Rhythmic Electro Magnetic neural Stimulation (FREMS) in patients with therapy-refractory pDN in a phase-IV conducted study evaluating the effects of a 2-weeks treatment on 3 months of pain relief. Two validated scorings systems were used; the Neuropathic Pain Symptom Inventory (NPSI), and the EQ-5d quality of Life score.

Upon a call in local newspapers and the internet 307 subjects were screened of which 236 subjects were included with pDN without co-morbidities and unsuccessful medical treatment: 8 subjects cancelled FREMS. So 228 subjects received 10 daily 40 min FREMS stimulations within 2 weeks. FREMS is executed on 2 legs below the knees with 4 pairs of electrodes/leg. The stimulations is unique and differs from conventional treatments in a randomised stimulation with changing frequencies and amplitudes.

The results are given as %- changes in NPSI and changes in visual EQ-5D score from baseline to 1 and 3 months after day-1 of treatment.

FREMS induced significant changes in absolute NPSI from baseline to M1 and M3 (ANOVA).

An at least 50% fall in NPSI was seen in 71/228 subjects at M1 and in 68/228 at M3. In 102/228 subjects at M1 or M3. If a 33% fall was considered these data were 102/228; 100/228 and 115/228.

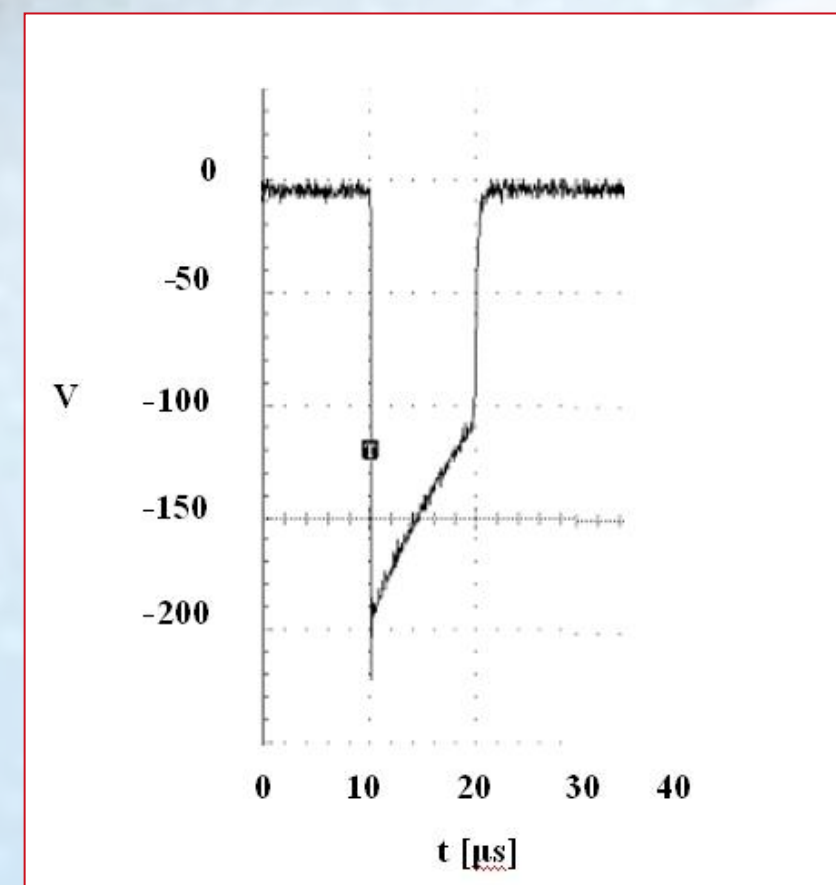
The average EQ-5D visual score (0-100) increased from baseline 53 ± 16 to 62 ± 14 at M1 and 63 ± 16 at M3.

In Clinical practice electro stimulation with FREMS is effective in therapy-refractory pNP. The method needs further investigation but is a promising alternative for difficult to treat patients.

BACKGROUND

- Neuropathy is a common complication in Diabetes Mellitus (DM), it effects 25-50% of diabetic patients and often converts to painful Diabetic Neuropathy (pDN)
- Pharmacological treatments in pDN is insatisfactory in clinical practice.
- FREMS was suggested as an alternative treatment in 2005 (Bosi et al, Diabetologia)

METHODS AND MATERIALS



- Electrostimulation different from TENS.
- Specific large negative Voltage with restphase
- Continuously changing signal (Randomiser)
- Both Legs, 4 channels, 16 electrodes
- 10 days/2 weeks, a 40 min period.
- Stimulation threshold: just not painful

OBJECTIVE

Aim Study:

To assess the efficacy of a standard 10 days/40 min/two-legs/4 channel treatment with FREMS in patients with pDN who did not respond to pharmacological treatment.

Measures of effect:

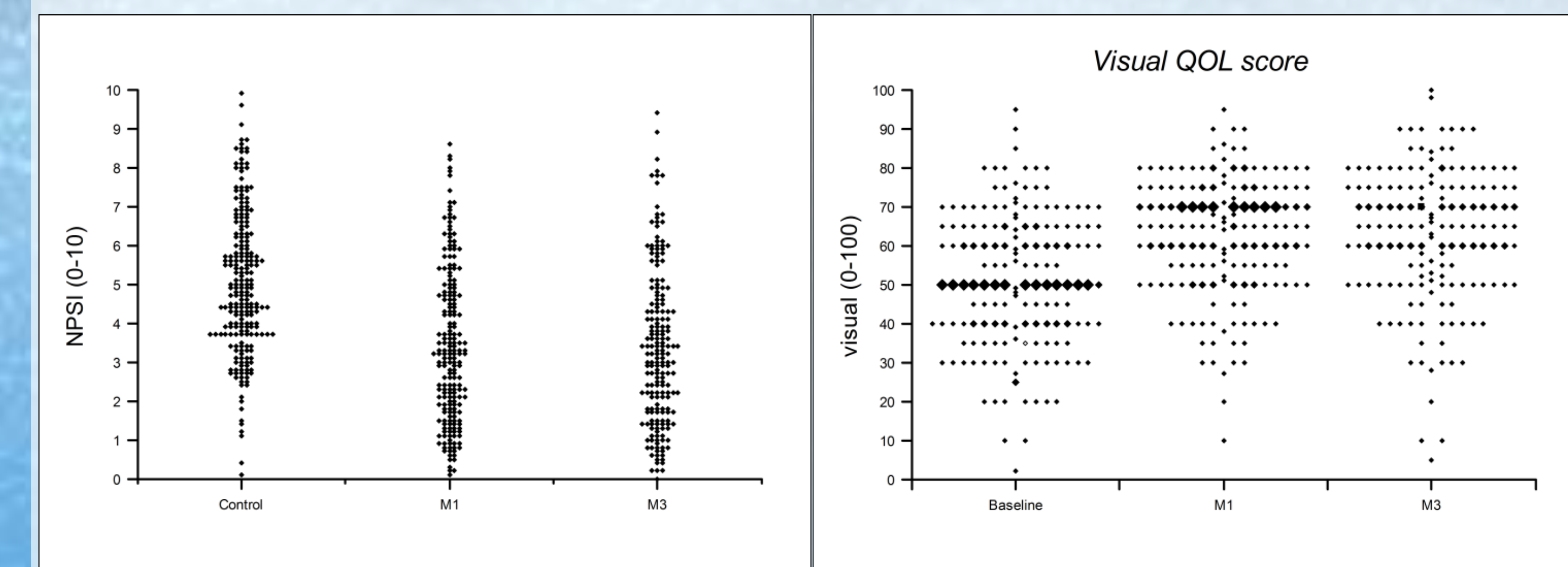
- Neuropathic Pain Symptom Inventory score (NPSI) (12 questions, 10 with 0-10. Score: 0-100 Max)
- EQ-5D Quality of Life (liniair 0-100 scale)

Subjects:

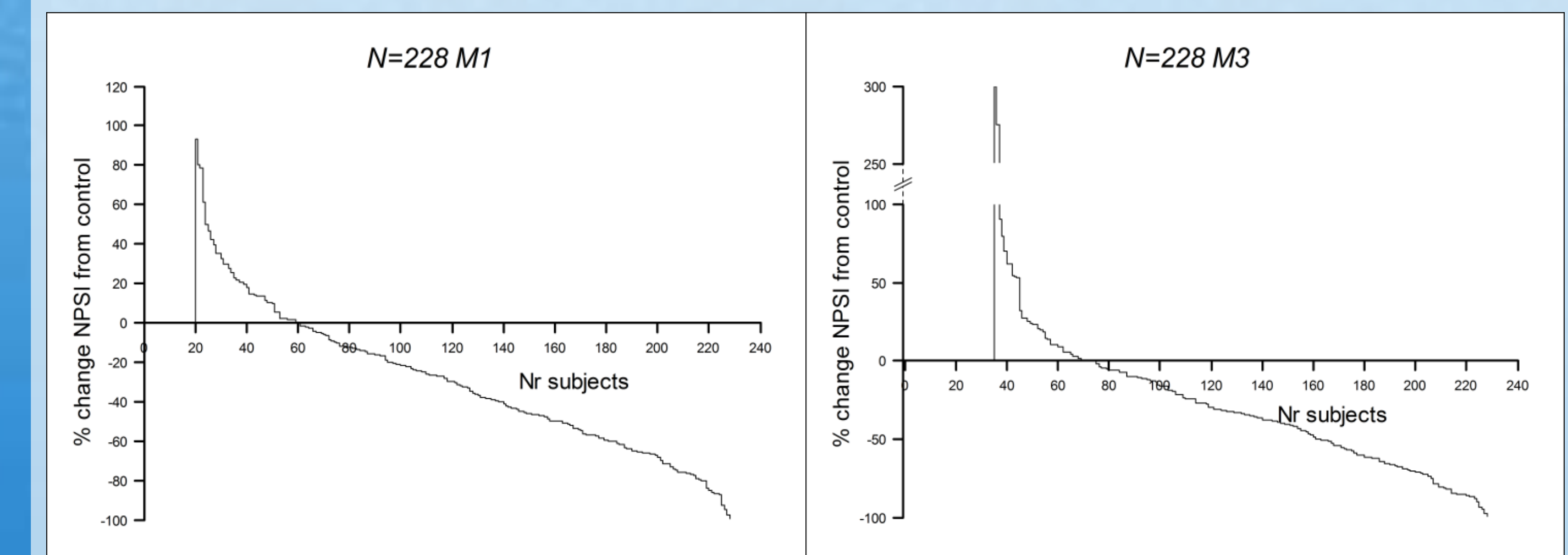
- Responded upon a call in local newspapers and the internet
- N=307 screened
- N=236 subjects eligible, having (clinically) proven pDN without co-morbidities and unsuccessfull medical treatments.
- Data are presented from N=228, 8 subjects canceled their treatment.

RESULTS

Absolute NPSI and visual EQ-5D (N=228)



Percentage fall in NPSI at M1 and M3:



Classical Response ($\geq 50\%$ fall in NPSI)

At M1: 71/228 subjects (31,1%)
At M3: 68/228 subjects (29,8%)
M1 or M3: 102/228 subjects (44,7%)

If a 33% fall is considered clinically relevant:

At M1: 102/228 (44,7%); At M3 100/228 (43,8%)
M1 or M3 in 115/228 (50,4%)

CONCLUSION OR DISCUSSION

- FREMS was feasible in patients with painful Diabetic Neuropathy (pDN)
- FREMS electro-stimulation is effective in pain relief assessed with objective scores in patients with therapy-refractory pDN
- This promising therapy needs a blinded head-to-head comparison with alternative electrostimulation (e.g. TENS)