TANYX® CLINICAL TRIALS ACTUAL FINAL REPORT

TANYX® - THE PORTABLE TENS DEVICE

TANYX® is a disposable, portable, thin, 15x5 cm device with a low cost when compared to the other devices available in the Brazilian market.

With 4 buttons, the on/off button works by simply pressing it for 3 seconds. The pulse is adjusted to 55 Hz, with a pulse width of 80 µs and intensities adjusted by manually pressing buttons “L”, “M” and “H”.

TANYX® battery is enough for at least 10 hours of use before being disposed of. It means that the same device may be used for, e.g. 20 minutes´ sessions, and kept to be used again until the end of the battery.

A patient is free to use it firstly with the “L” intensity and, if necessary, he/she can increase the intensity of use to “M” and, then, to “H”.

The sticky plaster must be ideally placed perpendicularly to the line of the pain area. After turning the device on by simply pressing the upper button, choose the desired intensity, beginning by “L”. The intensity may be increased, but in case of localized muscle contraction during the selection, the intensity should be lowered so that the threshold is below the one of the muscle contraction in order to avoid muscle fatigue and secondary pains. If the intensity selected is already the minimum one, “L”, the plaster must be slightly moved on the skin for a little change in position so that the sensation disappears and the muscle contractions are not seen anymore.

The electrode positioning is very important to get to an optimal analgesia. They may be applied directly to the affected area, nerve roots, peripheral nerves, acupuncture points, trigger points or even to the dermatome region corresponding to the pain area. Two or more of those regions may be stimulated simultaneously.

THE EXPERIENCE OF TANYX® IN SEVERAL PATHOLOGIES (CLINICAL TRIALS)

Low back pain

Low back pain is one of the most frequent causes of chronic pain and the most common concerning spinal column. In a prospective and controlled study, TANYX® was evaluated by being applied for 30 minutes, twice a day, for 14 days, in 21 patients with low back pain. The application provided an expressive reduction in the intensity of the lumbar facet pain (example of nociceptive somatic pain), improvement of sleep quality and welfare state upon waking and a reduction in the consumption of rescue analgesics. Neuropathic pain was not improved. Side effects were not described.

(Lauretti GR e cols. The Journal of Chemical and Pharmaceutical Research. 2016; 8 (8): 486-490)

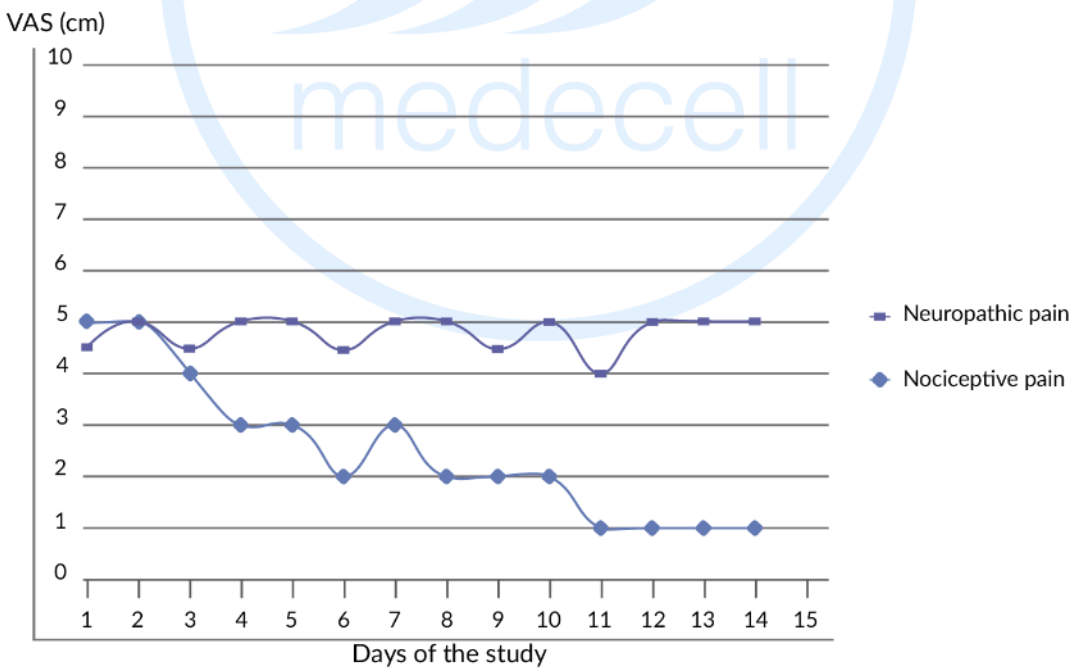

Figure 1: Decrease of the nociceptive pain, according to the VAS scale (visual analogue scale), with the use of TANYX® along the 14 days of treatment.

Neck pain (cervicalgia)

Neck pain is another example of recurrent chronic pain with difficult treatment that compromises the top of the spinal column. In a prospective, double-blind, randomized and comparative study with sham therapy (inactive) involving 44 patients, TANYX® was applied to the cervical region for 20 minutes, twice a day, for three days on end, resulting in improvement of facet and cervical muscle pain, bigger column mobility and lower consumption of rescue analgesics. Analgesia lasted for 30 days, at least. Side effects were not reported.
(Lauretti GR e cols. The Journal of Biomedical Science and Engineering. 2016; 9: 451-459)

Table 2. Pain measurements.

	Prior VAS *(cm)**	VAS after *TENS**	Prior n°. of *diclofenac tablets**	N°. diclofenac *tablets after TENS**
PG	*8 (7 - 9)*	*8 (6 - 9)*	*2 (2 - 3)*	*2 (2 - 3)*
TG	*8 (7 - 9)*	*3 (2 - 4)*	*2 (2 - 3)*	*1 (0 - 2)*
p (between groups)	*p > 0.05*	*p < 0.01*	*p > 0.05*	*p < 0.05*

*Data expressed as mean (25% - 75% percentile); VAS: visual analog scale.

Table 3. Neck disability and capacity of performing routine daily activities after 3-day TENS device.

	Capability of neck rotation	Capability of neck lateral extension	Capability of neck retroflexion	Capacity of performing routine activities
PG	*15 (maintained)* *4 (worsened)* *2 (improved)*	*14 (maintained)* *5 (worsened)* *2 (improved)*	*15 (maintained)* *4 (worsened)* *2 (improved)*	*15 (maintained)* *4 (worsened)* *2 (improved)*
TG	*20 (improved)* *2 (worsener)*	*20 (improved)* *2 (worsener)*	*20 (improved)* *2 (worsener)*	*20 (improved)* *2 (worsener)*

PG: placebo group; TG; TENS groups; $p<0.05$ between groups.

Figure 2: Tables 2 and 3 of the study, presenting data about pain improvement by means of VAS (visual analogue scale) and decrease in the consumption of rescue analgesics (top) and bigger mobility of the neck and improvement of the capacity to perform daily activities (bottom) with the use of TANYX®.

Fibromyalgia

In a prospective study with 39 patients with fibromyalgia, the comparison between using 1 or 2 TANYX® devices was made by means of simultaneous application to the cervical and/or lumbar region. The applications were carried out for 20 minutes, twice a day, for 7 days. The simultaneous use of 2 devices was more effective than the isolated application of each one of them, which, in its turn, was more effective than not using TENS, resulting in pain and fatigue relief, sleep and life quality improvement and lower consumption of rescue analgesics. Side effects did not occur.

(Lauretti GR e cols. Rheumatology Int. 2013; 2: 1-6)

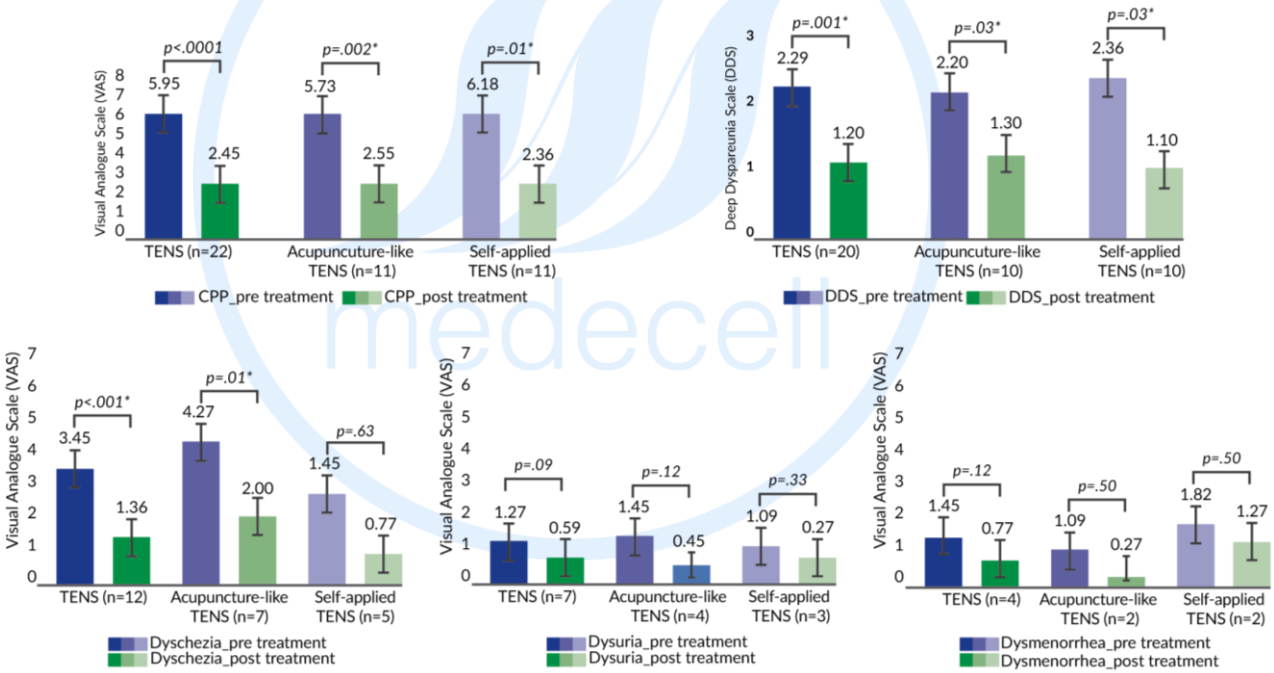

Figure 3: Decrease of chronic pelvic pain, dyschezia and dysmenorrhea by means of VAS (visual analogue scale) and deep dyspareunia by DDS (deep dyspareunia scale) after the use of TANYX®.

Dysmenorrhea

A very usual condition that corresponds to the pain related to women's menstrual cycle. In a prospective, double-blind, randomized and comparative study with sham therapy (inactive), 40 women with dysmenorrhea were divided into 2 groups. In the active group, TANYX® was applied to the pelvic region every 8 hours for an average of 4 days (up to 7 days). The use resulted in immediate and significant decrease in dysmenorrhea and consumption of rescue analgesics, with improvement in the quality of life of patients, in comparison to sham. Three months later, most of patients were still using TANYX® for pain relief. Side effects did not occur.

(Lauretti GR e cols. Neuromodulation: technology at the neural interface. 2015; 18: 522-527)

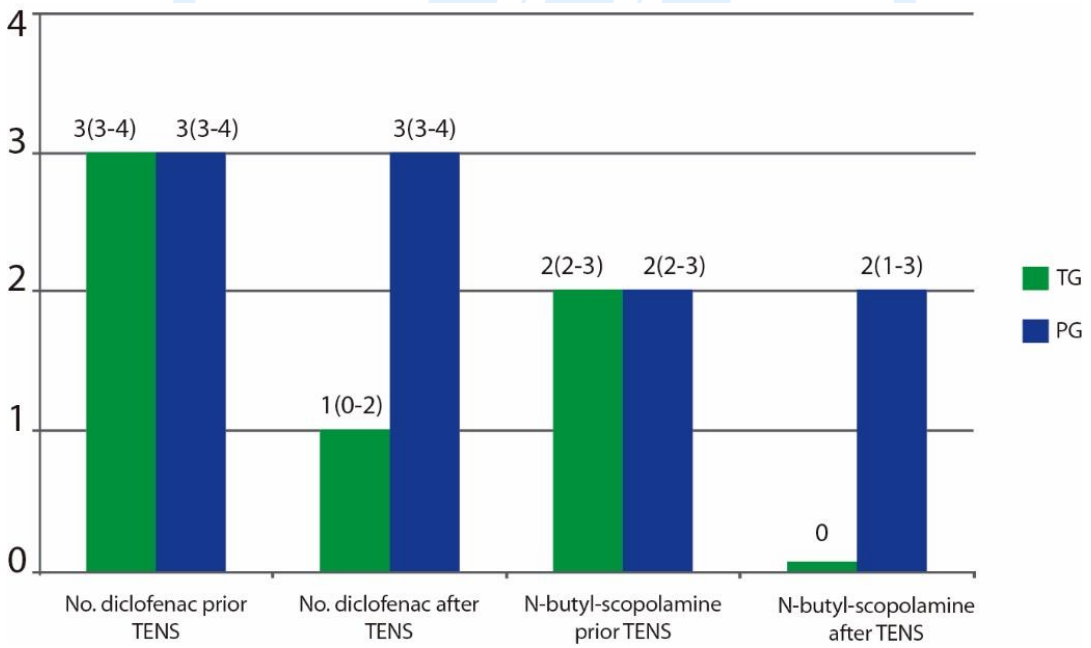

Figure 4: Reduction in the consumption of rescue analgesics with the use of TANYX®.

Endometriosis

Relatively common, it is one of the causes of secondary dysmenorrhea. In a prospective, randomized and comparative study with sham therapy (inactive), 22 women with deep endometriosis resisting to hormone treatment were treated with the application of TANYX® to the pelvic region for 8 weeks, in self-applied or acupuncture mode. The use resulted in significant improvement of chronic pelvic pain, dyspareunia and quality of life of the patients, in comparison to the isolated hormone therapy. Both kinds of applications were efficient for pain relief. Side effects did not occur.

(Mira TAA e cols. European Journal of Obstetrics & Gynecology and Reproductive Biology. 2015; 194: 1-6)

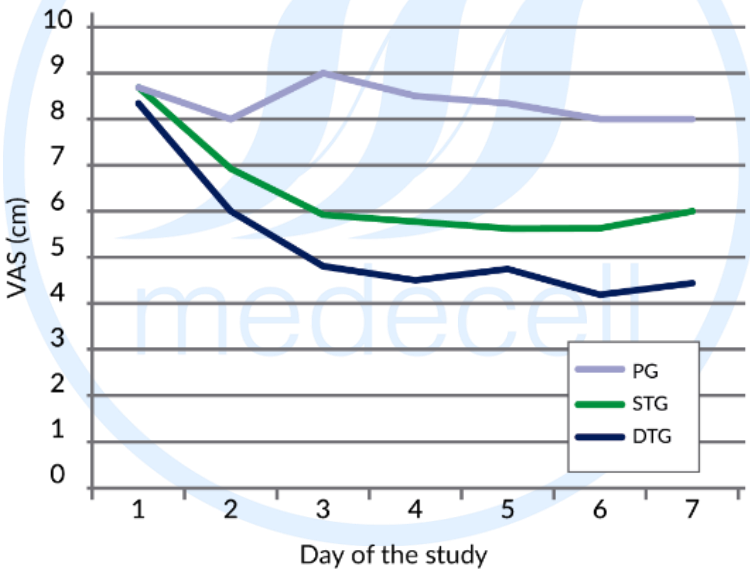

Figure 5: Pain relief by VAS (visual analogue scale) along the study with the use of 2 TANYX® (DTG) devices, 1 TANYX® (STG) device and no devices (PG).

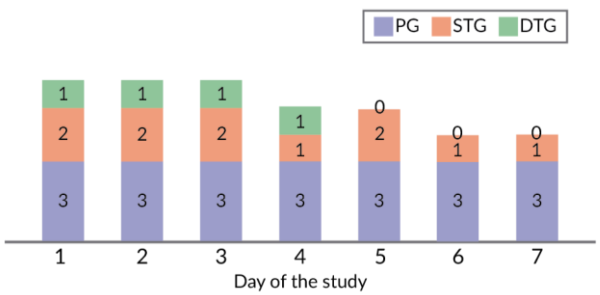

Figure 6: Number of rescue analgesic pills used by each group along the treatment period.

CONCLUSION

Clinical studies performed with Tanyx® and published in indexed journals confirm its efficacy and safety in the treatment of patients with low back pain, neck pain, fibromyalgia, dysmenorrhea and endometriosis.
Considering that the etiopathophysiology of most musculoskeletal diseases is similar (acute inflammatory process, with or without trauma, or chronic degenerative process with periods of exacerbation) and the existence of a large bibliography proving the efficacy and safety of the use of conventional TENS in this class of diseases, the use of Tanyx® may be recommended in these diseases.
The same rationale is valid for dysmenorrhea, be it primary or secondary, including here patients with endometriosis.
So, Tanyx® can be indicated as an efficacious and safe tool for the treatment of all the indications contained in its registration dossier.

São Paulo, 02/25/2019

Carlos Alberto Morales Paris, MD, PhD

REG: 62.957 (São Paulo – BR)