Evidence Table

Clinical Area: **Pulsed electrical stimulation for treatment of osteoarthritis of the knee**
Reference: **Zizic TM, Hoffman KC, Holt PA et al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. *J Rheumatol* 1995; 22: 1757-1761.**

Study Type: Randomized controlled trial.
Study Aim: To evaluate the safety and effectiveness of pulsed electrical stimulation for treatment of osteoarthritis (OA) of the knee.

Outcomes
- *Primary:* Physician global evaluation; patient assessment of pain, patient assessment of function.

Design
- *Number of subjects:* N=78 (n=41 active treatment; n=37 placebo)
- *Description of study population:* Demographic characteristics were not reported.
- *Inclusion criteria:* ≥20 years old; Confirmed diagnosis of OA in the knee.
- *Exclusion criteria:* Other orthopedic conditions such as asceptic necrosis of the femoral condyle; juxtaarticular Paget's disease and chondrocalcinosis.
- *Power:* Not discussed.
- *Method of randomization:* Not discussed.
- *Intervention:* Patients were randomized to receive an active pulsed electrical stimulation device (Bionicare Stimulator) or an identical placebo device. Prior to treatment, there was a 2-week period during which the patient was seen twice to obtain baseline measurements. The treatment period took place during the following 4 weeks; patients were advised to use the device for 6-10 hours a day. The device delivered a low frequency (100 Hz) low amplitude signal to the knee via skin surface electrodes. NSAID therapy was permitted if patients remained symptomatic with NSAID treatment.
- *Blinding:* Double-blind.
- *Source of outcome data (e.g. patient self-report, doctor report, lab results):* Clinical examination, patient self-report.
- *Length of follow-up*: 8 weeks for efficacy; 6 months for adverse effects.
- *Completeness of follow-up:* 7/78 (9%) were lost to follow-up.

Validity
- *Is the study type appropriate for the questions being asked?* Yes.
- *Was the study population typical of patients with this disease?* Yes.
- *Were the treatment/control groups comparable at baseline?* The authors reported that there were no significant differences between groups in demographic data, and no significant baseline difference in radiographic severity..
- *Was the intervention compared to placebo and/or best accepted intervention?* Yes.
- *Was there compliance with the intervention?* The authors did not report the number of hours per day the devices were used.

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- *Was there equal intensity of observation of study and control subjects?* Yes.
- *Was the process of observation likely to affect the outcome?* No.
- *Intention to treat analysis?* No.
- **Conclusions regarding validity of methods:**

The statistical analysis may have been biased. The authors used one-sided p-values at the p=0.05 level. It is generally accepted to cut the p-value in half when doing a one-sided test (i.e. if the two-sided p-value cut-off were 0.05, the one-sided cut-off should be 0.025). The p-value used in the study doubles the chances that a significant result will be found. Other methodological limitations are that the method of randomization and statistical power were not reported and analysis was not intention to treat. In addition, the authors did not control for concomitant NSAID use.

Results

Primary efficacy variables (percentage change from baseline, adjusted mean)

	Active device (n=38)	Placebo device (n=33)	p-value
Physician global evaluation	38.6	24.0	0.023
Patient evaluation of pain	31.3	19.0	0.040
Patient evaluation of function	30.3	19.4	0.045

Adverse effects

24% of the active device group and 21% of the placebo group experienced mild skin reactions.

Authors' Conclusions

"The improvements for pain and function found in this study suggest that pulsed electrical stimulation is effective for treating OA of the knee. Studies of longterm effects are warranted."

Reviewer's Conclusions

According to the authors' criteria, all three primary efficacy variables were statistically significant, favoring the active device group. However, if the p-value had been cut in half for the one-sided test that was performed, only one of the three variables would have been statistically significant. The clinical significance is unclear. For example, there is a 10% difference in the change from baseline to 8 weeks in patient perception of pain. Long-term efficacy was not reported. The authors did not control for NSAID use during the treatment period.

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