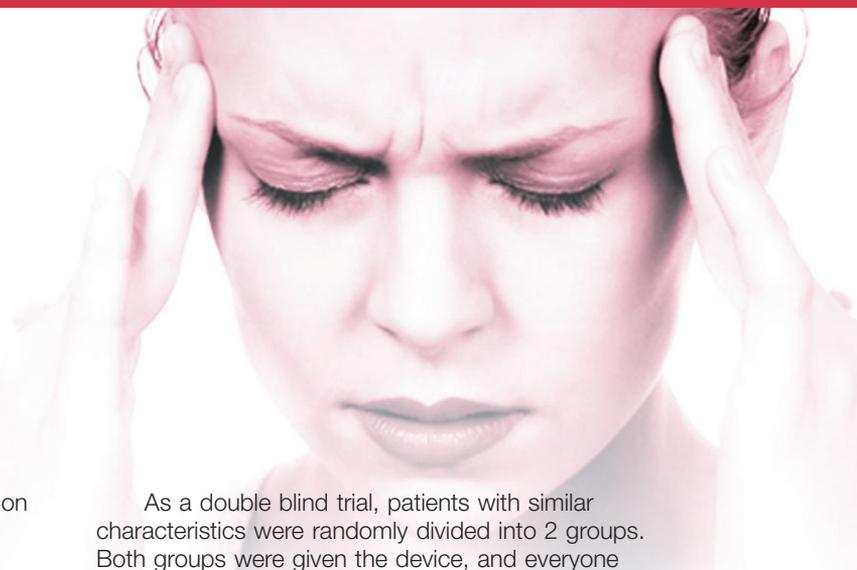


Headache Toolbox

Transcutaneous Supraorbital NeuroStimulation (tSNS)



In March of 2014, the Food and Drug Administration (FDA) approved the first medical device to be used for the prevention of migraine. This device is a 2 AAA battery-powered electrical stimulator applied to the forehead using a headband-like device manufactured by the Cefaly Technology Company of Herstal, Belgium intended for individuals with episodic migraine with or without aura, who have 2–8 attacks per month.

A self-adhesive electrode pad is positioned over the center of the forehead, and the portable device is held in place with a plastic headband that rests on top of the ears (see Fig. 1). The device activates a low level electrical current intended to stimulate the upper branches of the trigeminal nerve which transmits some of the pain associated with migraines.

In the United States, this device has one 60 hertz (Hz) setting and is to be used once per day for 20 minutes. The intensity increases to its maximum slowly, but may be maintained at a lower level with a single push of the button. Two pushes turns the device off. It is approved for patients 18 years and older, and is contraindicated in those with other implanted electrical devices such as pacemakers. In Europe and Canada, the device made by the same manufacturer has 3 stimulation settings: program 1 for acute “crisis treatment,” program 2 with 60 Hz for migraine prevention, and program 3 used for stress reduction and relaxation.

FDA approval was based upon 2 studies conducted in Europe. The first was performed in Belgium, using 67 individuals who had at least 2 migraine attacks per month and had not taken any migraine preventive medications for 3 months prior to the study. Patients who were overusing medications, had failed 3 other sound preventive trials, had frequent tension-type headaches, as well as patients who had severe neurologic or psychiatric disorders, were all excluded from the trial.

As a double blind trial, patients with similar characteristics were randomly divided into 2 groups. Both groups were given the device, and everyone received some degree of electrical stimulation, but only half of them got the same degree and type of stimulation offered by the Cefaly NeuroStimulation (tSNS) device. A 30-day baseline record was obtained during which no preventive treatment was used, and headache data were gathered, followed by 3 months in which the actual device or the sham device was used depending upon the assigned group. The 2 primary outcomes compared baseline with the third treated month, looking for:

1. A change in monthly migraine days.
2. The percentage of subjects who had at least a 50% reduction in monthly migraine days.

The first outcome measure, change in the number of migraine days, showed improvement, but not sufficient change to be considered significant. The second outcome, that is the percentage of those having at least a 50% reduction, was positive, meaning that if individuals did respond to the device, they had a significant decrease in the number of headache days, seen in about 26% of subjects. Almost a third of subjects who did respond experienced a 25% reduction in headache days.

The investigators also studied attack frequency, mean headache severity per migraine day, monthly intake of acute, as-needed medications, occurrence of migraine-associated symptoms per migraine day (nausea, light, and noise sensitivity), and percentage of very or moderately satisfied patients. There was a slight decrease in mean headache severity if individuals followed the protocol, and a highly significant almost 75% decrease in monthly acute migraine medications taken. Patient satisfaction was rated as 70% with the actual device com-



Figure.—Transcutaneous Supraorbital NeuroStimulation device as it is worn. Each electrode pad lasts 15-30 sessions.

pared with 40% with the sham device. There was no change in nausea, light, and noise sensitivity.

The study results were clearly affected by compliance issues with the device, that is, by whether those using it did so according to the instructions of daily use for 20 minutes each day. The trial was set up to capture changes in migraines after 3 months totaling 90 daily sessions of 20 minutes each. However, 1 problem in determining the effectiveness of this device is that subjects in the actual trial failed to turn it on reliably and daily. Overall, participants only did an average of 56 sessions in 3 months. One can see where the commitment of 20 minutes each and every day for 3 months can be difficult in busy lives, although the device is battery powered, and wearers can do their usual activities while it is operating.

By comparison, this device appears not to match the preventive benefits seen with topiramate, another FDA-approved migraine medicine. Topiramate can decrease the number of migraine days by 44% as opposed to this device, use of which resulted in a 25% reduction of days. The number of migraine attacks with topiramate was reduced by 48%, while the device reduced the attack number by 19%.

However, the side effects from topiramate can be very problematic, and result in many patients abandoning the medication because of memory problems, numbness and tingling, or kidney stones. Side effects of the device occurred in less than 5% of individuals, and were mild and temporary, with irritation or pain at the site of the electrode pads, tension headache, or mild drowsiness being most common. Some sleepiness or fatigue was reported in fewer than 1% of subjects, but that effect may have been incorporated into the stress reduction

and relaxation program built into the program 3 setting of the European model.

A much larger follow-up study was performed to gauge safety and satisfaction in users of this supraorbital neurostimulation device, obtained from 2313 subjects who rented the device for a 40-day trial period through the internet. Satisfaction was found in 53.4% of subjects, and they were willing to purchase the device, while 46.6% of the subjects were not satisfied and returned it. The returned devices were downloaded, and it was found that the users only had them turned on 48.6% of the required daily time.

As of now, in the United States, the device is not generally covered by insurance, and costs about \$299 plus \$35 for shipping. A prescription must accompany each order. A 3 pack of electrodes is \$25, with an additional \$5 for shipping. Each electrode pad lasts between 15 and 30 sessions. The company does not accept credit cards, and only accepts payment through PayPal as of June 2014. Some patients have been able to get insurance reimbursement if transcutaneous electrical stimulation devices units are covered on their plan. There is not yet a US billable code specific to this device, and the company has said that patients must seek this reimbursement from the insurance company on their own. In the United Kingdom and Ireland, individuals buy the device for full price and get a refund of all but 49 pounds if they return it at 2 months, amounting to what the company calls a 2-month rental fee.

In summary, the tSNS Cefaly device for headache treatment provides a promising, safe, low side effect option for the prevention of migraine. As of now, in the United States, it is only approved for daily 20-minute use for prevention, but in other countries, it is marketed with 3 settings allowing for acute and preventive treatment, as well as stress reduction. The effectiveness of this device appears not to match other accepted oral migraine prevention options, but it has fewer side effects and is generally well tolerated by those who do use it. Monthly migraine days were reduced by about 30% with the device, and the monthly intake of acute, as-needed migraine medications decreased by about 37%. More than half of users were either very or moderately satisfied with the device. Taking into account modest but proven effectiveness, the supraorbital stimulator provides a new low side effect option for the prevention of migraine.

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