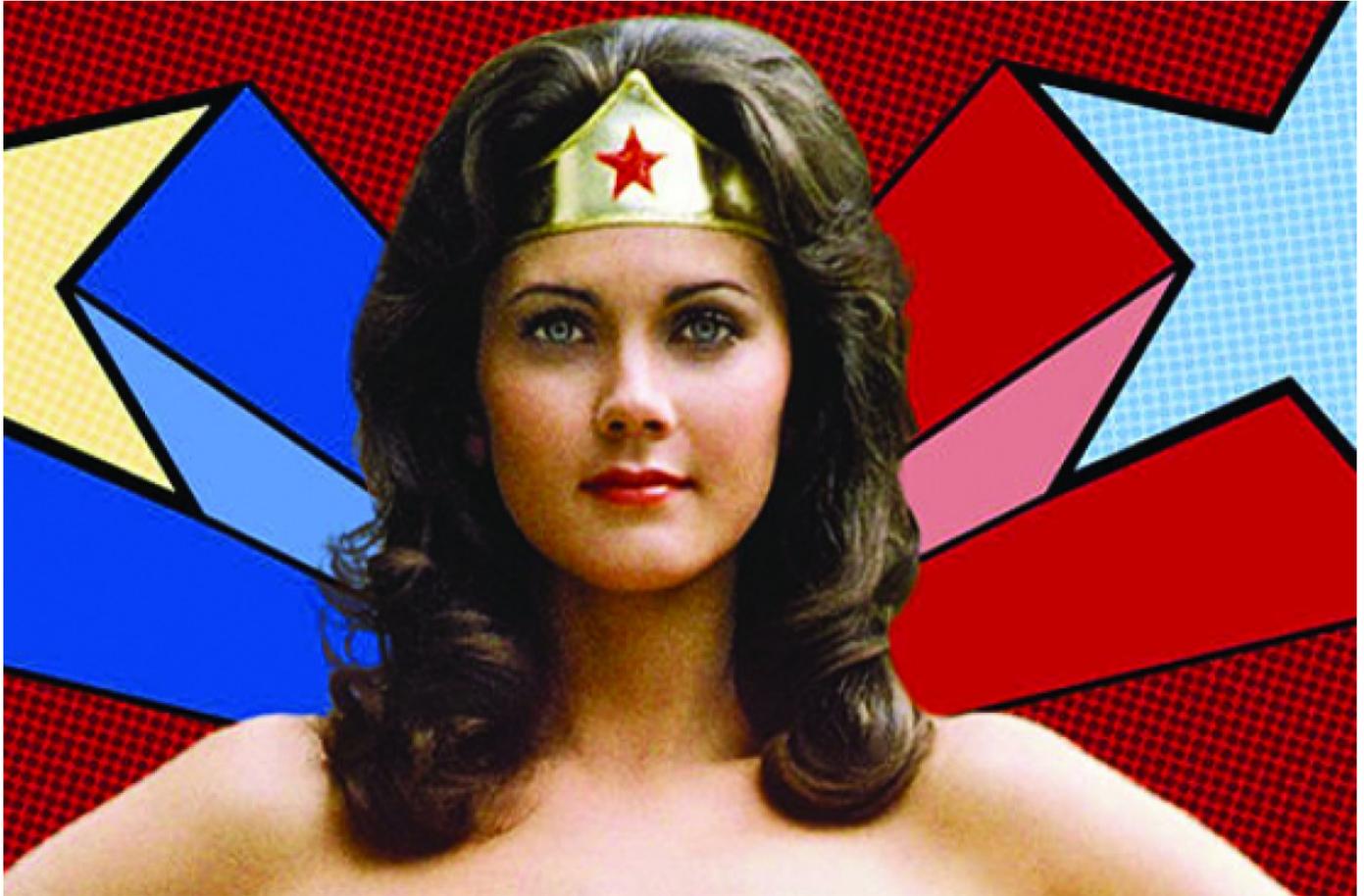


# Headache device gains qualified support - The Medical Republic

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Posted by

A Wonderwoman-like headband device for migraine is gaining acceptance as a non-interventional and non-toxic alternative or adjunct to traditional therapies, an expert says

The supraorbital transcutaneous stimulator, Cefaly, sits on the forehead above the eyes and delivers electric impulses to the trigeminal nerves, acting in a similar way to TENS therapy.

Associate Professor Richard Stark, acting head of neurology at the Alfred Hospital in Melbourne, said the device had originally been met with scepticism.

However, it was essentially risk free and might be of benefit for patients averse to medication because of real or perceived side effects.

In 2014, Cefaly was the first prophylactic migraine device approved by the US FDA after a Belgian randomised controlled trial of 67 migraineurs recruited in tertiary headache clinics found the mean number of headache days decreased significantly in the treatment group over three months, but not in the sham group.<sup>1</sup>

The number of monthly migraine attacks and monthly acute migraine drug intake were also significantly reduced in the treatment group.

There were no adverse events in either group.

The study provided Class III evidence that treatment with a transcutaneous stimulator was effective and safe as a preventive treatment for migraine, the study authors said. Another study of 2300 people with headache who rented the device online for 40 days found the device was safe, with minor and reversible adverse events occurring in around 4% of participants.<sup>2</sup>

After a testing period of 58 days on average, 47% of renters were not satisfied and returned the device, although a compliance check showed they had used it for only 48% of the recommended time.

Pain specialist Dr Michael Vagg said the device had the benefit of being non-invasive and non-toxic, which could be a drawcard for patients who had disabling symptoms but wanted to avoid drugs that could have unpleasant side effects.

“They can at least point to FDA approval and studies showing it has at least some efficacy.”

“We still don’t know if they’re better for milder, severe, daily, episodic migraines, so there’s a lot of that sort of data we need to know more about,” he said.

While the \$400 battery-powered device is not PBS-listed, a number of private health insurers allow patients to claim the cost.

There was some evidence the device also had a sedative effect, Professor Stark said.

*References:1: Neurology 2013; 81(12):11022: J Headache Pain 2013; 1;14:95Professor Stark received funding for an educational video for Cefaly, but has no other financial ties with the company*

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