Major trial casts doubt on leading device to heal bone fractures

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*A*n ultrasound device meant to speed healing of bone fractures is ineffective, according to a new [clinical trial](http://www.bmj.com/content/355/bmj.i5351) — though it has been on the market for 22 years and has rung up hundreds of millions of dollars in sales.

The trial at sites in Canada and the United States involved 501 patients who had surgical repair of fractures of the tibia — the larger of two leg bones between the knee and ankle. It found that patients treated with “low-intensity pulsed ultrasound” healed at the same rate as those given a sham treatment. (Their healing was assessed by X-rays and by how quickly they could bear full weight and return to normal activities.)

It was by far the largest randomized, controlled clinical study of the technology. And it raised questions about how rigorously the device was vetted before going on the market. Earlier trials showing some benefit were methodologically suspect, said Jason Busse, a researcher at McMaster University in Hamilton, Ontario. Some of those studies were coauthored by the inventor of the device**.**

“The device industry perhaps needs to be held to a higher standard before approval is given by regulatory bodies for marketing,” said Busse, a coauthor of the study, published Tuesday in the BMJ.

The study was launched in 2008 with funding from Smith & Nephew, which made the leading hand-held device for delivering low-intensity pulsed ultrasound. Smith & Nephew later spun off that division into a separate company, Bioventus.

In 2012, the year the last patients were enrolled, Bioventus conducted an unplanned early review of the data. Upon learning that the treatment had no apparent benefits, the company yanked funding for the trial, Busse said.

“They didn’t see an obvious reason to continue to support a study that would not be supportive of their product,” Busse said. Bioventus said the funding was pulled to prevent inconvenience to patients and to reduce their exposure to X-rays.

Researchers continued to follow up with patients and analyze the data. Then, in 2015, Bioventus retroactively inserted a [new condition](https://clinicaltrials.gov/archive/NCT00667849/2015_12_07/changes) into the study protocol, according to ClinicalTrials.gov, the National Institutes of Health database of trial information. The company said that for an adequate test,patients had to use the treatment at least 18 minutes a day, and they had to do that at least four out of every five days for a full year.

As it turned out, just 43 percent of patients met that standard.

Dr. Peter Heeckt, chief medical officer of Bioventus, said that “dismal compliance” rate invalidated the study. He said internal company data and findings from an unpublished study show good results when patients use the device regularly. Heeckt also criticized the patient population used by the researchers as relatively healthy — with few participants who had risk factors for slow bone healing, such as [obesity](https://www.statnews.com/2016/04/03/weight-loss-procedure/), [diabetes](https://www.statnews.com/2016/10/11/diabetes-technology/), and a history of [smoking](https://www.statnews.com/2016/10/24/us-cancer-deaths-smoking/). (One-third of the participants were active smokers and 6 percent had diabetes.)

Busse, however, rejected the criticism. He said the trial was meant to mimic the real-world patient experience for compliance. And he pointed out that a sizable portion of the patients in the trial did, indeed, use the device as often as the company recommends. Yet they didn’t heal faster than those who got a sham treatment.

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