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## New Device Treats Arthritis Pain with Heat

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Over the ages, people have tried all sorts of things to relieve pain from arthritis – from copper bracelets, snake venom and liniment oil to acupuncture, herbal teas and narcotic painkillers.

Some work. Some don't.

Now along comes the Avacen 100, a medical device recently cleared by the U.S. Food and Drug Administration to be marketed for the temporary relief of joint pain associated with arthritis, as well as minor muscle aches, sprains and spasms.

"It worked very well for me," says Gabrielle Farrell, a 67-year old resident of Santa Barbara, California who has suffered from arthritis for over a decade. "It is such a gentle, easy treatment. It's just incredible."



Image courtesy of Avacen Medical

About the size of a bread box, Avacen uses dry heat to warm the palm of a hand. Users put their hand inside the device and rest it on a pad heated to about 106 degrees Fahrenheit.

In theory, warming the hand improves circulation throughout the body, reducing pain and inflammation non-invasively and without the use of drugs.

"They feel a slight amount of pressure because it is a vacuum chamber. They'll feel pressure as it seals around the wrist, kind of like a blood pressure cuff," said Thomas Muehlbauer, Chairman and CEO of Avacen Medical, the San Diego-based company that makes the device.

"It's actually pretty comfortable. Most people will feel very, very relaxed. I'd say 95% of the people using our machine will say they feel warmer or that they feel so relaxed."

Farrell says Avacen improves her sense of well-being and helps her sleep. She uses it for 30 minutes, twice a day, usually in the evening.

"When I do the machine in the evening, my sleep comes faster and it is definitely, definitely more restful," she told *National Pain Report*.

Because Avacen is "substantially equivalent" to a similar device made in China that's already been cleared by the FDA, the company was not required to do any studies to prove its effectiveness in treating arthritis. The FDA holds medical devices to a lesser standard than medication, which often require years of expensive clinical studies.

Avacen Medical's website does have several testimonials from people (Farrell is among them) touting the machine – which sells for \$2,495. Over 200 have been sold so far to clinics and patients.

https://youtube.com/watch?v=6i1Ufqz1QNs%3Frel%3D0

"The therapeutic claims being made for this expensive device seem far-fetched to me," said John Quintner, MD, a rheumatologist and pain medicine specialist in Australia. "Where is the evidence that increasing core body temperature can relieve pain?"

Farrell says she was also skeptical about Avacen when she started using it a year and a half ago. As a test, she stopped using it for a month and her pain returned.

"I stopped for awhile and the proof was that everything came back. A sharp pain in my fingers or stiffness. When I don't use the machine, my fingers become very stiff. And I don't play the piano well because I don't have mobility in my fingers," she said.

While inflammation has long been linked to chronic pain, the theory that blood circulation in the hands plays a role is relatively new. In 2013, researchers at Integrated Tissue Dynamics and Albany Medical College discovered that a small number of fibromyalgia patients had an unusual amount of extra nerve fibers in the capillary blood vessels of their palms. The researchers believe those extra nerve fibers act as valves, interfering with the flow of blood to muscles and organs throughout the body.

Fibromyalgia patients typically suffer from joint pain, deep tissue pain, fatigue, depression, headaches and lack of sleep. What causes that whole range of symptoms – which are difficult to treat, much less cure – has long been a mystery.

In a pilot study involving 14 fibromylagia patients who used the Avacen device twice a day, 93% reported a significant decline in widespread pain. Because of that and other anecdotal evidence, this week the company applied to the FDA for approval to market Avacen as the first medical device for the treatment of widespread pain associated with fibromyalgia. Someday it may also seek to have the device approved for treating migraines.

"We believe our mechanism of action is infusing heat into the circulatory system at an amount greater than the core body temperature," said Muehlbauer. "It drives the warmer blood which has a reduced viscosity through the capillaries. The biggest benefit there is that we're taking oxygen and protein to the deep tissues and we're taking away waste. That may not have been happening, especially for people with fibromyalgia."

Quintner would like to see more proof.

"In the absence of scientific evidence to support the claims being made for the product, it may be best for consumers to heed this wise advice, let the buyer beware (caveat emptor)," he wrote in an email to *National Pain Report*.

Gabrielle Farrell says she has all the evidence she needs.

"It works very well for me." she said. "I know I will be using the machine for the rest of my life because I don't like pills. I think if you take too many pills, eventually you're going to have problems."

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