

'AGGA' inventor testifies his dental device was not meant for temporomandibular joint disorder or sleep apnea

January 4 2024, by Brett Kelman, Anna Werner, CBS News, KFF Health News



Credit: Kristin Vogt from Pexels

A Tennessee dentist who has been sued by multiple temporomandibular

joint disorder and sleep apnea patients over an unproven dental device he invented has said under oath that he never taught dentists to use the device for those ailments—contradicting video footage of him telling dentists how to use it.

Steve Galella, the inventor of the Anterior Growth Guidance Appliance, or "AGGA," has said in court depositions that his device had been used on about 10,000 patients, and that he trained many dentists to use the AGGA in classes around the U.S. and overseas.

At least 23 patients, some of whom described being desperate for relief from sleep apnea or temporomandibular joint disorder (TMJ), have sued Galella in recent years claiming that the AGGA damaged their mouths and, in some cases, caused tooth loss. Galella denied wrongdoing in those lawsuits and has settled almost all of them within the past few months.

Galella was deposed before he settled the largest of those lawsuits. According to a deposition transcript recently obtained by KFF Health News and CBS News, Galella said under oath that he had not represented that the AGGA could treat or cure TMJ or sleep apnea.

Video footage tells a different story.

Galella repeatedly references treating TMJ and sleep apnea patients with the AGGA, sometimes in conjunction with other devices, in footage from a training session he led with Australian dentists in 2017, which was produced in discovery in an AGGA lawsuit.

At one point in the footage, Galella can be seen displaying two versions of the AGGA to the dentists, pointing to one he says is preferred by "TMJ and sleep patients"—and then saying, "And I give it to them."

"Can you cure TMJ? Yes," Galella told dentists as his 2017 training began, according to the footage. "Can you cure mild to moderate sleep apnea? Yes."

The AGGA, which Galella recently rebranded as the Osseo-Restoration Appliance, resembles a retainer and uses springs to apply pressure to the front teeth and upper palate, according to a patent application filed in 2021. In 2023, after a joint investigation by KFF Health News and CBS News reported allegations of patients harmed by the AGGA, the FDA and the Department of Justice opened investigations into the device.

Dentists across the country have promoted the AGGA on their websites, often claiming it can "grow," "remodel," or "expand" an adult's jaw without surgery, sometimes saying it has the potential to make patients more attractive and to treat common ailments like TMJ and sleep apnea, which afflict millions of Americans. Galella has said in depositions and [video footage](#) that the AGGA causes the bones in an adult's jaw to "remodel" forward, reshaping their face.

The 2017 video footage contains other examples of Galella teaching dentists to treat TMJ and sleep apnea patients with the AGGA, which he sometimes calls a "growth appliance." In one segment, he describes using a growth appliance on "nine out of 10" of his TMJ patients. In another instance, Galella presents photos of what he says is a TMJ patient, then proceeds to describe how he treated them with an AGGA while showing photos of the patient's device and saying: "It's easy with this appliance."

The footage also shows Galella calling a growth appliance "the cure" for sleep apnea, and he later says in reference to sleep apnea that "with a growth appliance, yeah, you can fix it."

When Galella was confronted with this video footage during his recent deposition, he said his statements had been taken "out of context,"

according to the deposition transcript.

The AGGA plaintiffs alleged in their lawsuits not that Galella treated them directly but instead that he or his company consulted with their dentists and prepared AGGA "treatment plans" for each patient.

Galella said during his deposition he had reviewed more than 12,000 treatment plans but said he'd never seen one that used the AGGA to treat TMJ or sleep apnea, according to the transcript. In the AGGA lawsuits, about a dozen treatment plans are filed as exhibits, and some of those plans list the patient's "chief complaint" as TMJ or sleep apnea.

Galella's attorneys did not respond to multiple recent requests for comment, and Galella declined to be interviewed when approached in person in February. One of Galella's attorneys, Alan Fumuso, said in a written statement in February that the AGGA "is safe and can achieve beneficial results" when used properly.

The KFF Health News-CBS News investigation of the AGGA was based on interviews with 11 people who said they were hurt by the device and dental specialists who said they'd witnessed severe complications in AGGA patients. The investigation found no record of the AGGA being registered with the FDA and no peer-reviewed evidence showing the device "expands" or "remodels" the jaw as Galella and other dentists have claimed.

"The entire concept of this device, of this treatment, makes zero sense," said Kasey Li, a maxillofacial surgeon and sleep apnea specialist who has published research on AGGA patients. "It doesn't grow the jaw. It doesn't widen the jaw. It just pushes the teeth out of their original position."

In the wake of the KFF Health News-CBS News investigation, the FDA

announced it was "evaluating safety concerns" about the AGGA and a similar device, the Anterior Remodeling Appliance. The agency said the devices had been used to treat TMJ and sleep apnea even though they were not cleared by the FDA and their safety and effectiveness had not been established.

Weeks later, the criminal investigation into the AGGA was disclosed in [court filings](#) by Galella and device manufacturer Johns Dental Laboratories, who said the U.S. attorney's office in Memphis, Tennessee, was "potentially bringing criminal charges" against them. In another court filing, Johns Dental provided a copy of a grand jury subpoena seeking a wide variety of AGGA documents, including "any complaints received from any source whatsoever regarding the AGGA."

Since then, Galella has resolved lawsuits from at least 19 AGGA plaintiffs through out-of-court settlements without any public admission of fault. Additional AGGA lawsuits were filed in Indiana, Pennsylvania, and Washington, with all plaintiffs alleging they were harmed while being treated for TMJ or [sleep apnea](#).

Alice Runion, a 30-year-old IT consultant living outside Indianapolis, alleged in one of those lawsuits that wearing an AGGA as part of her TMJ treatment resulted in "permanent impairment and disfigurement" and "caused severe damage to the roots of [her] teeth."

In an interview, Runion added that the AGGA caused lingering migraines that have left her unable to work on a computer for long stretches, forcing her out of her job. Runion said that even after corrective jaw surgery that cost tens of thousands of dollars, some of her teeth may still be at risk.

"My surgeon and my [health care providers](#) have told me that it is possible that I could lose teeth in the future still because of the treatment

I received," Runion said.

The AGGA is also being studied by orthodontists Neal Kravitz and Jeffrey Miller, who said they intend to publish a research paper next year on how the device hurts patients. Miller, who has been a paid consultant for some AGGA plaintiffs, said he has examined dental scans from at least 30 patients who were "damaged" by the AGGA.

"It's not difficult to see the pattern," Miller said. "The patients lose bone that supports the housing of their teeth."

Miller and Kravitz said that they bought an AGGA in May for their research and that the Department of Justice sent an official to photograph the unboxing of the device for the criminal investigation.

Miller and Kravitz added that Johns Dental was willing to sell them the AGGA only if they did not refer to the device by name while purchasing it. They provided KFF Health News and CBS News with a copy of an email in which a Johns Dental employee writes: "To order the growth appliances from here on out, you'll need to avoid using the names of those appliances or Dr. Galella's name."

A Johns Dental facility was inspected by the FDA in July, according to online inspection records. Those records show the company was issued seven citations pertaining to medical devices, but do not specifically mention the AGGA or any specific device.

One citation was for an unspecified device whose "design history file does not demonstrate that the design was developed following the requirements" of federal law. Johns Dental declined to comment through its attorney, Jeffrey Oberlies.

Ten days after that FDA inspection, Johns Dental owner Jerry

Neuenschwander was deposed in an AGGA lawsuit, court records show. He pleaded the Fifth in response to every question, according to a deposition transcript obtained by KFF Health News and CBS News.

Spokespeople for the Justice Department and the FDA declined to comment on the AGGA. Attorneys for Neuenschwander did not respond to requests for comment.

2024 KFF Health News. Distributed by Tribune Content Agency, LLC.

Citation: 'AGGA' inventor testifies his dental device was not meant for temporomandibular joint disorder or sleep apnea (2024, January 4) retrieved 29 April 2024 from <https://medicalxpress.com/news/2024-01-agga-inventor-testifies-dental-device.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.