



ALIGNER CARE

# A Giant Step to Treat, Prevent, and Cure Tinnitus

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Tinnitus can be a bothersome or painful ailment which currently has no cure. It's possible that a concurrent rise in orthodontic treatments may be responsible for tinnitus's increase. Tinnisense's novel way to move teeth has helped diminish tinnitus in some and may have prevented it in others.

# What is Tinnitus?

Tinnitus is a private auditory noise that can manifest as buzzing, hissing or other sound in one or both ears that only that person will hear.<sup>1</sup> It ranges from a mere irritation to a debilitating condition that causes severe annoyance, distraction, and frustration.<sup>2</sup> Hearing loss is a frequent comorbidity.<sup>3</sup>

While tinnitus (pronounced “**ti-nuh-tuhs**” or “**ti-nahy-tuhs**”) is affiliated with 200 health conditions, it’s rarely the primary diagnosis.<sup>4,5</sup> Those who suffer from tinnitus report problems ranging from reduced quality/quantity of sleep to concentration lapses to exacerbation of medical ailments.<sup>6</sup> Due to its lack of a definitive cure, its share of research funding, measured against the number of those who are afflicted, is sadly under-appropriated.<sup>7</sup> Most hospitals and clinics do not have tinnitus listed on the check-off portion of their registration forms; patients need to fill in “Other” to share their condition with health professionals.<sup>8</sup>

## Tinnitus’s Financial Drain on Healthcare and Workforce Systems

Tinnitus’s financial impact on healthcare (an estimated \$600 to \$1,200 per patient per year) is under-attributed.<sup>9,10</sup> When loss of work productivity is included, those figures are more than three times as high.<sup>11</sup>

Here’s a graphic example of its under-acknowledgment. Chronic sleep-deprived sufferers who’ve committed suicide almost always have their cause of death listed as depression or another biopsychosocial risk factor instead of the most likely culprit, tinnitus.<sup>12,13,14,15</sup>

Since nearly half of the estimated 25 million with tinnitus have hearing loss, a higher percentage than non-sufferers, it’s hoped that the stringent Tinnisense™ methodology will additionally help more seniors maintain their hearing acuity.<sup>16,17</sup>

While tinnitus-focused aligners (see Figure 1) and orthodontic aligners are visually indistinguishable, their usage, desired end goals, and digital tooth movement programming are very different.



**Figure 1.**  
Tinnitus-Focused Aligner

# Tinnitus: A Meteoric Rise (1983-2021)

Population of the United States (1982–2021)

Number of Patients Who Sought Medical Treatment for Tinnitus in US (1983–2021)

Number of Patients Who Received Care by a US Orthodontist (1982–2016 )

Patient Type	Period	Time-frame	US Pop. - Start	US Pop. - End	Pop. Increase	Patients - Start	Patients - End	Patients - Increase	Relative Increase
Tinnitus	1983 - 2021	38 years	234 Million	332 Million	41%	5.4 Million	16 Million	296%	705%
Orthodontist*	1982 - 2016	34 years	232 Million	323 Million	39%	2.3 Million	5.6 Million	244%*	626%**

\*Figures from multiple biannual surveys of U.S. board-eligible and board-certified members of the American Association of Orthodontists (AAO).

\*\*Traditional and aligner orthodontic therapy is also rendered by non-orthodontists; general practitioner dentists, pediatric dentists, periodontists, and prosthodontists. Verifiable and reliable orthodontic treatment figures from those clinicians are unavailable so they could not be included.

## Statistical Significance

The *p value* analysis of the statistical significance of the data confirms that increases in the number of patients who sought medical attention for tinnitus was significantly much greater (more than 99.9% certainty) than US population increase over that 38-year period.<sup>18</sup> A similar statistical significance exists (more than 99.9% certainty) with the number of patients who were treated by orthodontists over that 34-year period.

## Raw Data

1983: 5.4 million patients sought treatment for tinnitus (National Institutes of Health).<sup>19</sup>

2021: 16 million sought treatment for tinnitus.<sup>20</sup>

This 296% increase in Americans seeking medical help for tinnitus was **7x times** the US population increase (42%) over those 38 years.<sup>21</sup>

1982: 2.3 million patients were treated by a US orthodontist for tinnitus.<sup>22</sup>

2016: 5.62 million were treated by a US orthodontist.

This 244% increase in Americans being treated by an orthodontist for tinnitus was more than **6x times** the US population increase (39%) over those 34 years.<sup>23</sup>

## Chart:

**Patients Who Received Dental Care by an Orthodontist (US)**  
**Patients Who Sought Medical Treatment for Tinnitus (US)**

Time Span	% Patients Increase vs. % US Population Increase
1982 - 2016	+625% in the # of dental patients treated by an orthodontist***
1983 - 2021	+705% in the # of tinnitus patients who sought medical care

\*\*\* Over the past couple of decades, a third of the orthodontic procedures have been provided by non-orthodontists. Combining those figures would raise the rate of increase in orthodontic treatments beyond the **8x** level, similar to the observed rise in tinnitus.

Researchers need to investigate whether there's a connection, between an unintended impact from orthodontic treatment and the eerily sharp rise in tinnitus. Is it possible that there has been a direct negative impact? Tinnisense™ Solutions, LLC (Tinnisense) believes that once the successful implementation of its novel approach becomes the standard of care, the astonishing increase in those suffering from tinnitus will be tamed.

# Pertinent Questions - Thoughts - Suggestions

1. Amongst tinnitus sufferers: Is there a measurable difference between those who've had orthodontic care and those who haven't?
2. Medical questionnaires and health history reviews taken by surgeons (e.g., otolaryngologists – ear, nose, and throat [ENT] head and neck surgeons), physicians (e.g., primary care physicians [PCPs]), and audiologists should be asking if the patient has had in the past or is currently receiving orthodontic therapy.<sup>24, 25</sup>
3. Medical questionnaires and health history reviews in dental and orthodontic offices and clinics would improve if they asked whether the patient currently or has in the past experienced tinnitus or hearing loss.<sup>26, 27</sup>
4. When a patient discloses that they have tinnitus:
  - a. A Tinnitus Functional Index (TFI) should be completed to establish the baseline of their condition.<sup>28</sup>
  - b. A Tinnitus and Hearing Survey (THS) should be completed to establish whether hearing loss may be contributing to their condition.<sup>29</sup>
5. If it's determined that those who've received orthodontics have tinnitus at a greater level than those who've never received that care:
  - a. Orthodontists and dentists should embrace the tinnitus-focused aligner protocol.
  - b. Tinnitus should be a part of informed consent discussions prior to the start of an orthodontic treatment.

# Dental-Medical Consequences

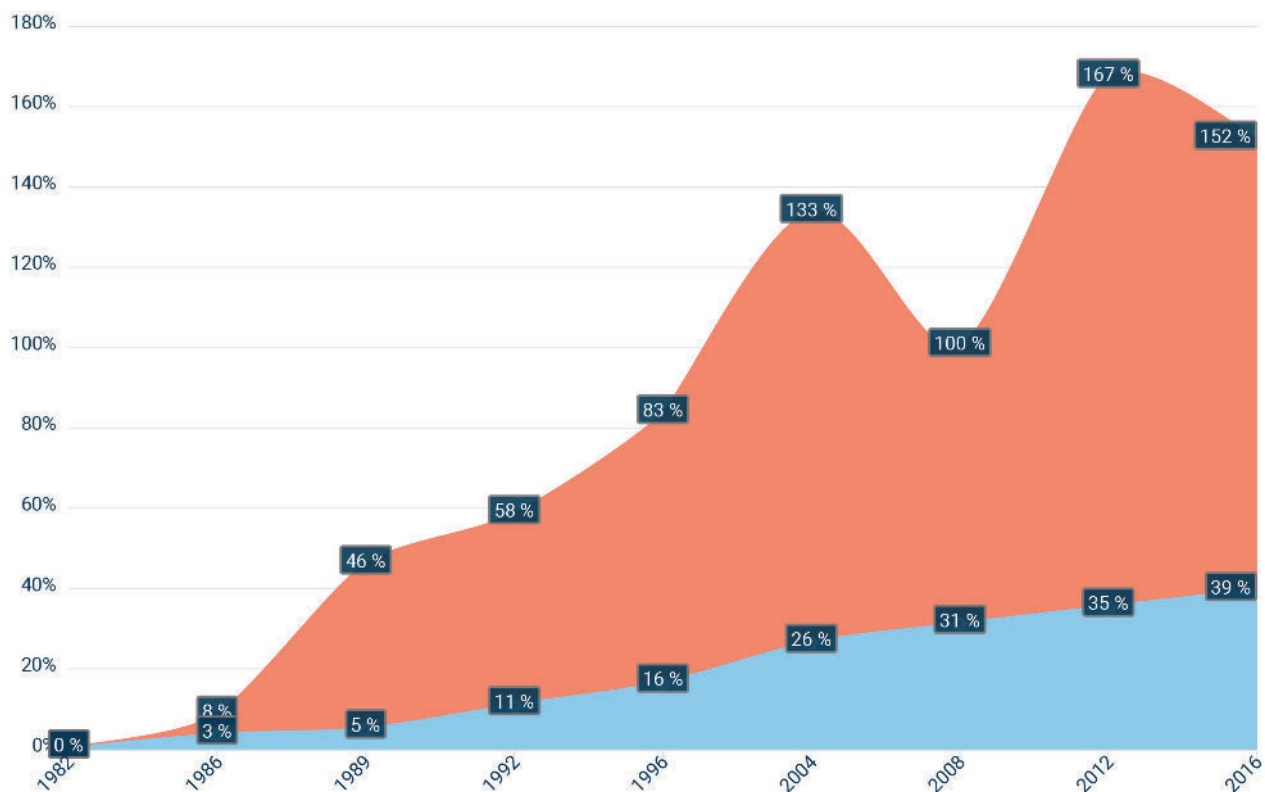
It's not uncommon for patients with chronic malocclusion (bad bite) to experience acute dental and medical consequences.<sup>30</sup> Some examples are fractured teeth, excessive grinding, cracked fillings, temporomandibular joint dysfunction (TMD) and tinnitus.<sup>31</sup>

Dentists provide custom mouthguards, and patients can obtain self-moldable over-the-counter (OTC) versions to diminish grinding. Sometimes, this lessens tinnitus episodes, especially for those who experience TMD.<sup>32, 33</sup>

Since being widely introduced in the late 1990's, orthodontic aligners – a series of clear, flexible removable oral devices to treat misaligned teeth – have seen extraordinary increases in popularity.<sup>34, 35</sup>

## Orthodontic Treatments in United States

Number of Orthodontist Patients (US) 1982-2016  
US Population 1982-2016



# Raw Data: Orthodontic Treatments in United States

Number of Orthodontist Patients 1982–2016  
US Population 1982–2016

Year	1982	1984	1986	1989	1992	1994	1996	2004	2006	2008	2010	2012	2014	2016
Patients (millions)	2.23	2.33	2.42	3.25	3.53	3.72	4.09	5.21	4.84	4.46	4.56	5.58	5.04	5.62
US Population (millions)	232	236	240	247	257	263	270	293	298	304	309	314	318	323

## Are Medical and Dental Scopes of Practice Unintentionally Impeding Tinnitus Research?

Currently, tinnitus-focused aligner therapy resides in a “no man’s land” of therapeutic solutions. That’s because this novel tinnitus treatment does not fit neatly within the domain of medicine (ENTs) or dentistry (orthodontists). ENTs receive extensive surgical and non-surgical training, but none of it focuses on tooth health, periodontal health, or occlusion health.<sup>36,37</sup> Orthodontists do not receive any training on how to examine, measure, or treat their patients’ auditory capabilities and related conditions.<sup>38,39</sup>

It’s incumbent upon each healthcare discipline to establish workable treatment parameters to allow this care to reach the many patients who would greatly benefit by having their tinnitus suffering reduced or eliminated.



**Figure 2.**

This is a view of the lower jaw of an elderly woman who has tinnitus, sleep apnea, and signs of grinding. Lots of periodontal plaque builds up within weeks after every professional prophylaxis.



**Figure 3.**

Partway through her tinnitus-focused aligner therapy, she no longer needed a CPAP to sleep safely. Her breath no longer had a foul odor, and there was much less plaque accumulating. Those tinnitus episodes have become fewer and milder and no longer interfere with her ability to fall asleep or prematurely awake her from her sleep.

## Tinnitus-Focused Aligner Care: A Novel Solution

Tinnisense Solutions, LLC, a health technology startup based in New York City and founded by Elliot Davis, D.D.S., a prolific inventor and general practitioner dentist in Manhattan and the Bronx, utilizes a multi-patented, never previously attempted process to alleviate and prevent tinnitus.

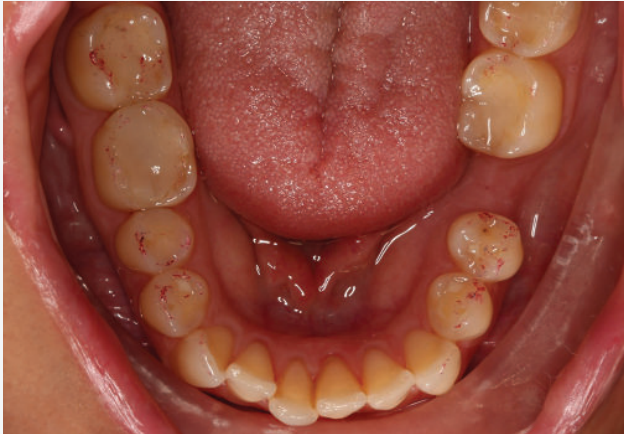
Tinnitus-focused intraoral aligners minimize the deleterious force of teeth on the supporting bone.<sup>40</sup> Lingering reverberations in the maxilla (top jaw) and mandible (lower jaw) from undesirable occlusal (bite) forces are sufficient to initiate or exacerbate tinnitus. As prudent tooth repositioning progresses, bad bite forces are gradually diminished to the point where they become subclinical (barely perceptible or imperceptible).<sup>41, 42</sup> Please refer to Figures #2,3. Programmed movements of teeth within the tinnitus-focused aligner design are distinct from those within orthodontic-focused aligner designs.

Tooth structure weakened by enamel chips, cleaves, and excessive wear of dentin is repaired non-invasively (no dental shot, no drilling) with the patented enamel replacement process.<sup>43</sup>



Enamel replacement, which has never been a part of the braces process, helps to secure a stable result, one more likely to ward off orthodontic relapse and tinnitus. Relapse, which occurs more often than not, is undesirable because as teeth positions worsen and occlusion health gradually declines, it often leads to unwelcomed medical and dental consequences, including tinnitus.<sup>44, 45, 46</sup>

There are aspects frequently included in orthodontic treatments that Dr. Davis believes are deleterious: fixed lingual splints (metal glued to the backs of teeth), extractions of healthy teeth (those with no infection nor decay), irreversible removal of healthy enamel (esthetic incisal shaving, bite adjustments and interproximal reduction [IPR]). These likely problematic inclusions are excluded from his multi-patented protocol.<sup>47, 48, 49, 50</sup> Other proprietary advances include enhancements aimed at strengthening the supportive bone, creating healthier gums, achieving 3-D tooth parallelism, bringing about asymmetry reduction, promoting enamel/dentin reinforcement, and obviating the need to remove non-infected wisdom teeth.<sup>51, 52, 53</sup> Please refer to Figures #4,5.



**Figure 4.**

This is the view of a middle-aged woman's lower jaw. Poor occlusion health from badly positioned teeth posed an elevated risk for developing tinnitus.



**Figure 5.**

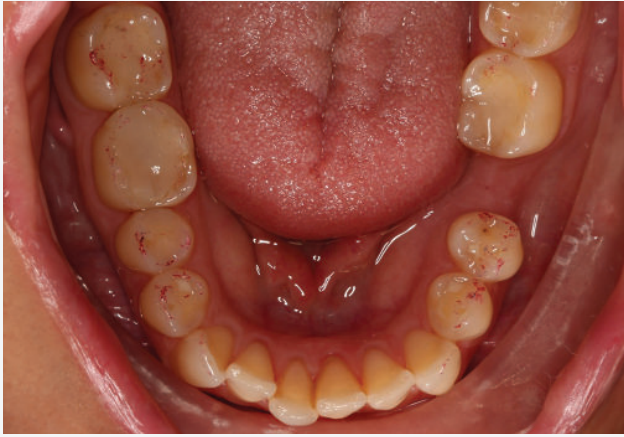
Her wisdom tooth went from worthless to valuable as it was elegantly and strategically moved forward along with the molar in front of it. She avoided the need for dental implant surgery and the surgical extraction of a wisdom tooth. The likelihood of her developing tinnitus remained reduced years after tinnitus-focused aligner care elevated her periodontal health and occlusion health.

# Orthodontic Care vs. Tinnitus-Focused Aligner Care: Why Does Only One Help with Tinnitus?

Topic	Orthodontic Aligner Care	Tinnitus-Focused Aligner Care
<b>Reasons for Therapy</b>	Malocclusion (based on classification, asymptomatic, symptomatic), smile dissatisfaction, facial asymmetry.	Periodontal disease, <sup>54</sup> TMD, tinnitus*, sleep apnea, malocclusion (symptomatic), facial asymmetry.
<b>Aligner Design</b>	Shapes, materials, and temporary protrusions on teeth have been used for decades.	Materials have been used for decades. Shape and design are unique and have a patent pending.
<b>Improvement Goals by the End of Therapy</b>	Smile improvement, bite health, asymmetry reduction.	Gum health, sleep health, tinnitus health, TMD health, bite health, asymmetry reduction, smile improvement.
<b>Enamel Replacement<sup>55</sup></b>	Has never been a part of treatment. Excessively worn and chipped enamel, dentin, and fillings are infrequently repaired during treatment.	Missing dentin and excessively worn and chipped enamel and fillings are reinforced during treatment. Diminishes thermal and occlusion force sensitivities.
<b>Extractions of Healthy Teeth</b>	Not uncommon. Entire healthy teeth (no infection, no decay) are routinely extracted by an oral surgeon or general dentist at the request of the orthodontist.	Healthy teeth are never extracted. The supporting bone is modified to make room for each part of every tooth.
<b>Irreversible Removal of Portions of Teeth</b>	Interproximal Reduction (IPR), the irreversible removal/shaving down of healthy tooth structure, is performed about half of the time.	IPR is not a part of this therapy because it impedes maximum bone reformulation and optimal tinnitus benefits from being achieved.
<b>Retention Goal</b>	To keep teeth in their current locations after the active phase of care has been completed and final settling has occurred.	Subtle, but valuable tooth movements during the post-active, passive movement/retention phase help ensure a stable result.
<b>Retention Methodology</b>	Options include permanent/semi-permanent glued splints and/or removable retainers.	Removable retainers additionally, albeit slightly, guide teeth to ensure long-term stability. Glued splints would inhibit obtaining the top result so they are not used.

1. Orthodontic care, from the AAO website (November 2023):
  - a. “Orthodontists are specialists who focus on your bite and alignment of your teeth. Their job is to not only make sure that your smile looks great, but your bite feels good and functions properly, too.”<sup>56</sup>
  - b. There is no expectation for an orthodontic treatment to improve one’s tinnitus health status.
2. Tinnitus-focused aligner care expects the benefits to tinnitus health to start during treatment and continue after treatment has finished.

3. Orthodontic research and surveys of orthodontists' retention methods in Australia, Canada, Croatia<sup>57</sup>, Hungary, India<sup>58</sup>, Iraq<sup>59</sup>, Lithuania, Netherlands, New Zealand, Poland<sup>60</sup>, Norway, Switzerland<sup>61, 62</sup>, Turkey<sup>63</sup> and the United States have shown
  - a. Retention procedures are variable and dependent largely on personal preferences. There does not seem to be any consistent ... retention methodologies." (Australia, New Zealand)<sup>64</sup>
  - b. "59% of the orthodontists believed that a practice guideline for retention after orthodontic treatment needs to be developed..." (Netherlands)<sup>65</sup>
  - c. "There is a need to identify all causative factors of inadvertent tooth movement in relation to bonded retainers and to prevent the onset of unintentionally active retainers." (Netherlands)<sup>66</sup>
  - d. "It is difficult to find statistical data about the frequency and the average degree of the relapse, but some ... is observable in 70-90% of the cases." (Hungary)<sup>67</sup>
  - e. "There is an urgent need ... to identify the most effective and safe method for managing the relapse..." (Cochrane Collaboration – multinational)<sup>68</sup>
  - f. "... there was no evidence ... to show that one intervention was superior to another to manage the relapse of the alignment of lower front teeth..., aesthetic assessment by participants and practitioners, treatment time, patient's discomfort, quality of life, cost-benefit considerations, stability of the correction, and side effects including pain, gingivitis, enamel decalcification, and root resorption."(Cochrane Collaboration – multinational)
  - g. "No retainer is proved to guarantee a perfect stability of dental alignment..." (Poland)<sup>69</sup>
  - h. "For patients with removable retainers, most orthodontists instruct them to wear their retainers forever... do not instruct patients to have fixed lingual retainers removed at a specific time...indicating lifetime retention." (United States)<sup>70</sup>
  - i. "Evidence-based guidelines are desired for a common retention protocol." (Lithuania)<sup>71</sup>
  - j. "There seems to be a potential dichotomy between orthodontists being uncomfortable about allowing general dental practitioners to manage retention and orthodontists unwilling to provide retention care indefinitely." (Canada)<sup>72</sup>
4. These professional surveys confirm that, after more than 200 years, orthodontists and dentists worldwide are still waiting for the development of "that reliable method" which will consistently yield a stable and lasting result.
5. The increasing popularity of orthodontic braces and aligners and the instability that often follows might explain why dentists, PCPs, audiologists and ENTs are seeing many more patients with undesirable dental and medical consequences, including tinnitus.
6. Tinnisense incorporates a multi-patented protocol for tooth movement and retention that has provided comfort to patients. Its unique methodology seems particularly well-suited for those with periodontal disease, sleep disorders, and tinnitus. Please refer to Figures #6,7.



**Figure 6.**

Decades after finishing with braces as a teenager, his occlusion health deteriorated as orthodontic relapse set in. Widespread poor tooth positioning led bad bite forces to be passed through to the bone. That elevated the risks to his sleep health and for developing tinnitus.



**Figure 7.**

Years after his tinnitus-focused aligner therapy concluded, those "new" tooth positions have stayed stable. His occlusion health remains improved - bad bite forces haven't returned. The likelihood that he will experience tinnitus episodes has remained greatly reduced.

## Conclusion

The startling rise in tinnitus suffering shows no signs of abatement. Despite the many millions who suffer from tinnitus, the ailment has received far too little funding and seen scant progress from researchers over the past 50 years. The number of people hampered by tinnitus increased seven times faster than the population grew over the past few decades, an unsustainable pace for any healthcare system.

The possibility that an important connection exists between orthodontic therapy and tinnitus must be explored. If an upgrade to the current method for prudently moving teeth could help stem the surge of tinnitus, it would make sense to incorporate these principles into our care as soon as possible. Medical, dental, and national institutions need to embrace tinnitus-focused aligner care so this remedy can bring relief and ward off suffering to many in the US and around the world.

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