Applications of vibrational energy in the treatment of sinonasal disease: A scoping review

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Abstract

Background: Acoustic energy and vibration therapy are emerging as helpful adjuncts among many disease states. There has been interest in how this technology can either serve as an alternative treatment or enhance delivery of medications to treat pathology within the nasal cavity and paranasal sinuses. Our objective was to perform a scoping review of the state of the science of vibration treatment used in sinonasal disease.

Methods: A search of Embase, PubMed, and CINAHL databases was performed in November 2021. Included studies evaluated acoustic energy as a means of treatment in sinonasal diseases. Data points collected included type of technology utilized, disease state treated, and outcomes.

Results: The initial search identified 2902 studies, of which 44 met inclusion criteria. A wide array of vibrational technology such as ultrasound, sonic aerosols, and phonophoresis, with varying frequency and amplitude were described. Twenty-six studies evaluated the use of acoustic energy to treat sinonasal disease itself, while 18 studies evaluated the use of acoustic energy to facilitate drug delivery to the sinonasal cavity. Outcome measures among studies were highly varied.

Conclusions: Vibration technology used in patients with sinonasal pathology has been shown to improve pain, sinonasal symptoms, and radiologic outcome measures in small studies. Given the heterogeneous study populations and outcomes, no conclusion could be reached regarding overall effectiveness of acoustic energy as a primary treatment. Further research is required to study specific treatment indications in larger patient populations to fully understand the potential clinical benefit and to determine optimal therapeutic characteristics of sound energy.

Keywords: acoustic energy, chronic rhinosinusitis, rhinitis, ultrasound, vibration
1 | INTRODUCTION

Acoustic energy is the disturbance of energy, which passes through a medium, in the form of a wave. Vibration specifically refers to a mechanical oscillation (ie, a repetitive movement) around a point of equilibrium. Sound and vibration are closely intertwined. For example, vibration can generate a wave of sound or, vice versa, a sound wave can cause an object to vibrate. Acoustic energy and vibrational technology have been used in the treatment of many different disease states. For example, vibration has been utilized in physical therapy for improvement in muscle disorders, enhancement of wound healing, and relief of arthritic pain. Ultrasound has been used to facilitate drug delivery via phonophoresis, a process by which ultrasound increases percutaneous absorption of medication. Vibration has also been used in patients with cystic fibrosis as part of chest physiotherapy to improve patency of their lower airway and reduce mucus plugging. With the successful application of vibrational therapy to lower airway diseases, there has been an emerging interest in evaluating applications of acoustic and vibrational technology for the treatment of upper respiratory inflammatory disorders.

Sinonasal inflammatory disorders encompass a wide array of diseases, most commonly chronic rhinosinusitis (CRS), allergic rhinitis (AR), and non-AR (NAR). These disorders are characterized by chronic symptoms including nasal congestion, nasal drainage, facial pain/pressure, and hyposmia. Patients with these disorders experience detriment in quality of life, decreased productivity, and exacerbation of comorbid diseases such as asthma. Disorders of tissue remodeling, mucociliary function, host immunity, cellular metabolism, and the inflammatory cascade have been studied as mechanisms that lead to the dysfunction seen in sinonasal inflammatory disorders. Additionally, neurogenic processes have also been implicated in pathophysiology leading to tissue edema and dysfunction.

An emerging body of literature suggests that acoustic and vibrational technologies may offer therapeutic alternatives to traditional medical and surgical therapies for upper airway inflammatory conditions, or may enhance existing forms of medical therapy. We therefore performed a scoping review of the literature to evaluate the evidence for acoustic energy as a treatment of sinonasal inflammatory disorders.

2 | METHODOLOGY

The Preferred Reporting Items for Systematic reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) was followed.

2.1 | Search strategy

A literature search was performed on November 2, 2021, of Embase, PubMed, and CINAHL databases. Additional records were identified by examining the references of articles obtained for review. All databases were searched from inception to search date. The query used a combination of subject headings (eg, MeSH in PubMed) and keywords for sinonasal disease (pansinusitis, rhinosinusitis, sinus disease, sinus infection, sinus congestion, chronic rhinosinusitis, chronic sinusitis, rhinitis, sinonasal disease, facial pain, and facial neuralgia) and acoustic energy (ultrasonic, ultrasound, humming, vibrating, vibration, vibromassage, and kinetic oscillation). Full electronic search strategy is included in the supplemental material, Supplemental Table 1.

2.2 | Selection criteria

Inclusion criteria for review included articles that: (1) evaluated treatment of sinonasal disease (which broadly included facial pain) via the application of acoustic energy effectiveness (any outcome) for treatment purposes; (2) encompassed all levels of evidence; and (3) were published in all languages. Any non-English abstract was translated for screening and if inclusion criteria were met, the full article was then professionally translated for formal review. Exclusion criteria included: (1) nonsinonasal-related pathology or anatomic site, (2) use of acoustic energy for diagnostic rather than treatment purposes; and (3) reviews, commentaries, conference abstracts and proceedings, and nonhuman studies.

2.3 | Data extraction

Two authors (K.M.P. and P.R.) screened titles of identified abstracts to exclude articles that did not meet predetermined selection criteria or were duplicates. Articles that were agreed upon by both screeners to meet criteria were included for review; discordant judgments were adjudicated by a third author (P.H.H.). Following selection, two authors (K.M.P. and P.R.) independently extracted the following information when available: author, year of publication, study population, type of acoustic therapy intervention, and study outcome. Data were then synthesized, and results were divided into separate groups based on how sound energy was applied for treatment of sinonasal disease.
3 | RESULTS

3.1 | Search and study characteristics

The initial screening process returned 2902 citations. After removal of duplicates, titles and abstracts were then reviewed, which led to 131 articles for full review (Figure 1). Finally, 44 articles met our inclusion criteria and were included in the review. All studies evaluated the impact of acoustic energy on the treatment of sinonasal disease. Included studies were published between 1968 and 2021. Included articles were either originally published in English or professionally translated to English from Russian, Japanese, Polish, or German.

There were two main themes in which acoustic energy was used to treat sinonasal disease. The first was the application of acoustic energy to the sinonasal region to treat facial pain and sinonasal inflammation. The second theme was the use of acoustic energy to facilitate drug delivery to the nasal cavity and paranasal sinuses. The distribution of papers between the two themes, and levels of evidence are described in Tables 1 and 2 and Figure 2. For the sake of brevity, case reports are only detailed in the Tables.

3.2 | Acoustic energy applied to the sinonasal region to treat sinonasal disease

3.2.1 | Acoustic energy applied externally to address facial pain

Five studies used sound energy applied externally to address reduction in facial pain as the primary outcome of interest. The first study was a case report and is detailed in Table 1.9

Of the interventional studies, one study randomized 120 participants with myofascial pain dysfunction syndrome to medical therapy, shortwave diathermy, or ultrasound therapy (1.5 W/cm²) applied for 5 minutes daily for 2 weeks and found the most improvement in facial pain graded scales in the ultrasound group, relative to the shortwave diathermy and medical therapy groups.10 Another study followed 96 patients who were admitted to an inpatient service for orofacial acute pain secondary to dental pathology and were randomized to receive vibration stimulation of the face via a probe (n = 76) or placebo (n = 20). The authors found 71% of those who received vibration stimulation reported some pain relief (via reduction in visual analog scale [VAS]), whereas placebo stimulation was significantly less effective.11 The next study evaluated facial pain reduction in a patient population with facial pain attributed to sinonasal causes, both acute and chronic. Mechanical vibratory stimulus (100 Hz) was applied to the facial skeleton for 45 minutes, and 70% of participants reported reduction in pain.12 The last study was a single-arm interventional study of 14 patients with CRS with facial pain who underwent multimodal frequency treatment administered via the AxioSonic device. This device operated at two simultaneous frequencies and was applied at 1 W/cm² for 5 minutes on the skin overlaying the maxillary sinus and 0.5 W/cm² for 5 minutes overlaying the skin on the frontal sinus. Mean 22-item Sino-Nasal Outcome Test (SNOT-22) improvement over 2 weeks was 14.11 (p < 0.05), exceeding the minimal clinically important difference (MCID). The authors of this study were associated with the company that developed the AxioSonic device.13

3.2.2 | Acoustic energy applied externally to address bacterial sinusitis

Five studies evaluated sound energy applied externally to address treatment of bacterial sinusitis. One study was a randomized clinical trial (RCT),14 one was an observational study,15 and the remaining three were interventional studies.16–18 The 2010 RCT was conducted in the primary care setting and randomized patients with acute bacterial sinusitis to either receive transcutaneous ultrasound therapy (1.0 W/cm² in continuous mode for 10 minutes each day for 4 days) or receive amoxicillin for 10 days. At day four of intervention, the group undergoing ultrasound therapy showed a 1.5-point greater reduction in pain relative to the antibiotic group. At day 21, there were no significant differences among symptoms between the two groups.14

A study from 1997 examined the ability of pulsed magnetic field (sinusoidal field shape, frequency of 35 Hz for 12 minutes at intensity of 100% (2.5 mT) once a day for 10 days) via a Magnetronic MF-IO apparatus to improve symptoms of a sinus infection in patients with both acute maxillary sinusitis and chronic maxillary sinusitis with exacerbation. Of the nine patients with acute maxillary sinusitis, all received antibiotics and pulsed magnetic field therapy, with six patients reporting improvement in nasal symptoms. For participants with chronic maxillary sinusitis with exacerbation, they were divided into three groups—those who underwent only pulsed magnetic field therapy, those who underwent surgery and pulsed magnetic field therapy, and those who underwent antibiotics and pulsed magnetic field therapy. In the group who had pulsed magnetic therapy alone, eight of 21 reported complete improvement, seven of 21 reported some improvement, and six of 21 reported no improvement in nasal symptoms. The study was limited by lack of randomization, lack of a control group, and lack of reported participant demographics.16

The next study evaluated the effect ultrasound had on the
FIGURE 1 Flow chart of identification and screening as performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.
| Author   | Year | Country | Study population                          | Type of acoustic intervention          | Treatment group, n | Control group, n | Outcomes                                                                 | LOE |
|----------|------|---------|-------------------------------------------|----------------------------------------|--------------------|-----------------|---------------------------------------------------------------------------|-----|
| Lundeberg | 1985 | Sweden  | Facial pain attributed to sinusal cause    | Vibratory stimulus probe (100 Hz), external | 20                 | 0               | 70% reported reduction in pain via a pain graded scale                    | 4   |
| Hansson  | 1986 | Sweden  | Facial pain attributed to dental pathology | Vibratory stimulus via probe (10–200 Hz), external | 76                 | 20              | 71% in the vibration group reported significant reduction in pain via VAS | 4   |
| Talaat   | 1986 | Egypt   | Myofascial pain dysfunction syndrome       | Ultrasound (1.5 W/cm²), external        | 40                 | 80              | Better reduction in pain graded scale in the ultrasound group (2.40 ± 0.05–0.75) vs (2.10 ± 0.40–0.74, medical) and (electricity, 2.40 ± 0.67–0.78 ± 0.95) | 3   |
| Baduni   | 2017 | India   | Facial pain                               | Pulsed ultrasound (0.8W/cm²), external  | 1                  | 0               | Three-point reduction in VAS for facial pain                              | 5   |
| Smith    | 2017 | United States | CRS (facial pain) | Multimodal frequency device (low: 70–80 Hz, high: 1 MHz −0.5 to 1 W/cm²) | 14                 | 0               | Mean SNOT-22 improvement was 14.11 (p < 0.05)                              | 4   |
| Kantor   | 1997 | Poland  | Sinusitis (acute, chronic)                | Pulsed magnetic field therapy (35 Hz [acute], 50 Hz [chronic, 2.5 mT]), external | 30                 | 12              | 46% of the intervention group had complete resolution of sinusitis determined by resolution of nasal symptoms | 4   |
| Zelenkin | 1998 | Russia  | Sinusitis (acute, chronic)                | Ultrasound (64 Hz), external            | 128                | 0               | 86% of acute and 65% of chronic cases resolved determined by resolution of nasal symptoms and lack of purulence on last puncture | 4   |
| Zelenkin | 2000 | Russia  | Acute maxillary sinusitis                 | Vibratory stimulus via probe (50–100 Hz), external | 86                 | 80              | Vibration group with fewer punctures (67.8% had no purulence at second puncture) vs control (average 6 or 7 punctures) and LOS was 6 to 7 d in the vibration group vs control (8–10 d) | 4   |

(Continues)
| Author     | Year | Country     | Study population          | Type of acoustic intervention   | Treatment group, n | Control group, n | Outcomes                                                                 | LOE |
|------------|------|-------------|---------------------------|---------------------------------|--------------------|------------------|--------------------------------------------------------------------------|-----|
| Hosoien    | 2010 | Norway      | Acute bacterial sinusitis | Ultrasound (1.0 W/cm²), external | 24                 | 24               | 1.5-point higher reduction in pain in the ultrasound group vs the control group | 2   |
| Feizabadi  | 2018 | Iran        | CRS and healthy controls  | Ultrasound (0.5–1 W/cm²), external | 22                 | 0                | 87% reduction in *Staphylococcus aureus* bacterial copy number after treatment | 3   |
|           |      |             |                           |                                 |                    |                  |                                                                          |     |
| Acoustic energy applied intranasally to address bacterial sinusitis |
| Zelenkin   | 1998 | Russia      | Acute frontal sinusitis   | Vibration stimulus (50 Hz), intranasal | 52                 | 0                | 85% resolution of sinusitis by day 3 determined by patency of the frontal sinus tract via irrigation | 4   |
| Khudiev    | 2003 | Russia      | Chronic maxillary sinusitis | Ultrasound (3 W/cm², 26.5 Hz) external | 61                 | 10               | 72% of the ultrasound group had complete recovery, 40% had complete recovery in antibiotics alone | 4   |
|           |      |             |                           |                                 |                    |                  |                                                                          |     |
| Acoustic energy applied externally to address CRS symptoms |
| Ansari     | 2004 | Iran        | CRS                       | Ultrasound (1 W/cm², 1 MHz) external | 1                  | 0                | Resolution of symptoms and CT findings of sinusitis                     | 5   |
| Eby        | 2006 | United States | CRS                     | Humming (130 Hz, 18 hums per min) | 1                  | 0                | Resolution of symptoms of sinusitis by day 4                            | 5   |
| Ansari     | 2007 | Iran        | CRS                       | Ultrasound (0.5–1 W/cm²), external | 57                 | 0                | 81.3% improvement in sinus symptoms                                     | 4   |
| Ansari     | 2007 | Iran        | CRS                       | Ultrasound (0.5–1 W/cm²), external | 10                 | 10               | 86.56% (SD 20.76) improvement in sinus symptoms in the ultrasound group relative to 37.14% (SD 46.37) in control | 3   |
| Ansari     | 2010 | Iran        | CRS                       | Pulsed Ultrasound (1 MHz, 1 W/cm²), external | 1                  | 0                | Resolution of symptoms and CT findings of sinusitis                     | 5   |
| Young      | 2010 | New Zealand | CRS                       | Pulsed Ultrasound (1 MHz, 0.5–1.0 W/cm²), external | 22                 | 0                | Median percent improvement in SNOT-20 was 34.1% after the sixth treatment session | 4   |

(Continues)
### TABLE 1 (Continued)

| Author          | Year | Country    | Study population | Type of acoustic intervention | Treatment group, n | Control group, n | Outcomes                                                                                     | LOE |
|-----------------|------|------------|------------------|-------------------------------|--------------------|------------------|---------------------------------------------------------------------------------------------|-----|
| Rocha           | 2011 | Brazil     | CRS              | Ultrasound (1 MHz, 1 W/cm²), external | 14                 | 12               | 64% objective decrease in nasal obstruction in the intervention group vs. placebo             | 3   |
| Ansari          | 2012 | Iran       | CRS              | Pulsed vs. Cont. Ultrasound (1 MHz, 0.5–1 W/cm²), external | 15                 | 15               | No difference among the two groups in change in sinusitis symptom score                     | 3   |
| De Castro       | 2017 | Philippines | CRSwNP           | Pulsed ultrasound (1 MHz, 1.0 W/cm²), external | 21                 | 21               | At week 3, SNOT-22 score of controls was 16.57 (SD, 1.78) and of ultrasound was 10.45 (SD, 1.19) (p = 1.07E-80)  | 2   |
| Ansari          | 2021 | Iran       | CRS (with olfactory dysfunction) | Pulsed ultrasound (1 MHz, 1 W/cm²), external | 15                 | 0                | Smell Identification Test improved from 13.1 (SD, 1.8) to 22.0 (SD, 1.3) SNOT-20 improved 49.3 (SD, 18.4) to 22.2 (SD, 16.4) | 4   |
| Khanwalkar      | 2021 | United States | Nasal congestion | Vibrational headband and individualized sound file | 50                 | 0                | 90% with improved TNSS, facial pain VAS from 1.3 to 0.9, p = 0.01                              | 4   |

Abbreviations: CRS, chronic rhinosinusitis; CT, computed tomography; LOE, level of evidence; LOS, length of stay; NAR, nonallergic rhinitis; NOSE, nasal obstruction symptom evaluation scale; PNIF, peak nasal inspiratory flow; RQSS, Rhinitis Questionnaire Symptom Score; SD, standard deviation; SNOT-20, 20-item Sino-Nasal Outcome Test; SNOT-22, 22-item Sino-Nasal Outcome Test; TNSS, Total Nasal Symptom Score; VAS, visual analog scale.

Microbiome in the nasal cavity by culturing nasal swabs both before and after treatment with ultrasound (1 MHz, 1 W/cm² applied to the skin overlying the maxillary sinus and 0.5W/cm² applied to the skin overlying the frontal sinus). Using polymerase chain reaction as a detection method, *Staphylococcus aureus* was detected in 15 of the 22 patients. After ultrasound treatment, 87% of participants who had *S aureus* detected were found to have a quantitative reduction in bacteria copy number.18

The remaining two studies were from the same group in Russia. The first was a study of 128 patients admitted to an inpatient service with acute maxillary (n = 60) and acute maxillary and ethmoid sinusitis (n = 68) treated first with sinus puncture and drainage, followed by
**TABLE 2**  
Acoustic energy used to facilitate drug delivery to sinonasal cavity

| Author    | Year | Country | Study population | Type of acoustic intervention | Treatment group, n | Control group, n | Outcomes                                                                 | LOE |
|-----------|------|---------|------------------|-------------------------------|--------------------|-----------------|--------------------------------------------------------------------------|-----|
| Ansari    | 2013 | Iran    | CRS              | EP (pulsed ultrasound, 1 MHz, 1 W/cm²) | 1                  | 0               | Resolution of symptoms and CT findings of sinusitis                     | 5   |
| Ansari    | 2015 | Iran    | CRS              | EP (pulsed ultrasound, 1 MHz, 1 W/cm²) | 30                 | 30              | Percent improvement in symptom score was greater in the EP group (67.2 vs 49.3%, p = 0.03) | 3   |
| Zippel    | 1968 | Russia  | Chronic maxillary sinusitis | Ultrasonic drug delivery | 10                 | 10              | Mean (drug) in maxillary was $3.86 \times 10^{-2}$ in the control group and $4.97 \times 10^{-2}$ in the ultrasound group | 4   |
| Dañiak    | 1989 | Russia  | Chronic maxillary sinusitis | Vibrating device (26 KHz) with irrigation | 65                 | 35              | Decreased need for repeat puncture, decreased duration of days until improvement, and greater resolution in bacterial culture in the vibration vs control groups | 4   |
| Saijo     | 2000 | Japan   | CRS              | Ultrasonic nebulization vs jet nebulization | 6                  | 6               | More drug delivered to maxillary with jet (average 16.66 ug/mL) vs ultrasound (average 6.5 ug/mL) | 4   |
| Gerber    | 2003 | Russia  | CRSwNP           | Ultrasound probe intranasal  | 109                | 0               | 2.5% had relapsed disease (of note: 28% were lost to follow-up)         | 4   |
| Maniscalco| 2006 | Italy   | Healthy volunteers | Sonic enhancement of nebulized drug delivery | 6                  | 0               | After delivery of L-NAME, 22% to 35% reduction in nasal NO after humming | 4   |
| Valentine | 2008 | Australia | Cadavers with maximal sinus surgery | PARI SINUS device (44-Hz vibration to aerosol) | 7                  | 7               | Increase in intensity (2.06 vs 0.26), percentage of stain (49.96% vs 4.19%), and circumference stained (76.59% vs 12.7%) in the nasal rinse vs the PARI SINUS groups | 3   |
| Katsumi   | 2008 | Japan   | CRS              | PARI SINUS device (44-Hz vibration to aerosol) | 56                 | 0               | 75% reported some level of symptom improvement relative to their baseline | 4   |
| Moller    | 2010 | Germany | Healthy volunteers with normal anatomy | PARI SINUS device (44-Hz vibration to aerosol) | 5                  | 0               | 6.5% of drug in the sinuses with PARI, not seen with nasal spray 3x longer clearance with PARI vs spray | 4   |

(Continues)
| Author     | Year | Country      | Study population          | Type of acoustic intervention                                                                 | Treatment group, n | Control group, n | Outcomes                                                                 | LOE |
|------------|------|--------------|----------------------------|------------------------------------------------------------------------------------------------|--------------------|--------------------|---------------------------------------------------------------------------|-----|
| Patel      | 2012 | United States| Cadavers after sinus surgery | Pulsed ultrasound (25–27 KHz) drug delivery device                                             | 6                  | 0                  | Drug in maxillary and sphenoid sinus 12 of 12, posterior ethmoid 8 of 12, and frontal 4 of 11 | 4   |
| Goektas    | 2013 | India        | CRS olfactory dysfunction  | AMSA device uses vibration (100 Hz) and pressure (10–50 mbar)                                   | 18                 | 15                 | Improvement in olfactory function in both systemic steroid control group and topical steroid via drug delivery device groups | 3   |
| Ohki       | 2013 | Japan        | CRS                        | PARI SINUS device (44-Hz vibration to aerosol)                                                  | 5                  | 0                  | All patients deemed recovered at follow-up visit, and no specific outcome measures reported | 5   |
| Moller     | 2013 | Germany      | CRSsNP                     | PARI SINUS device (44-Hz vibration to aerosol)                                                  | 11                 | 0                  | Maxillary deposition was 4.0% ± 1.7% (before surgery) and 6.1% ± 2.2% (after) | 4   |
| Mainz      | 2014 | Germany      | CF-associated CRS          | PARI SINUS device facilitated dornase alfa vs isotonic saline                                   | 23                 | 23                 | SNOT-20 score improved after dornase alfa compared with isotonic saline (p = 0.017) | 2   |
| Raychler   | 2015 | France       | CRS (olfactory dysfunction) | Sonic enhancement of nebulized drug delivery                                                   | 10                 | 20                 | Objective olfactory tests (SST) improved (5.5, 5.8, and −1.1, p = 0.01) in the nebulization, oral, and nasal spray groups, respectively | 3   |
| Mainz      | 2016 | Germany      | CF-associated CRS          | PARI SINUS device facilitated hypertonic vs isotonic saline                                     | 69                 | 69                 | No statistical or clinical significance between the two groups in SNOT-20 | 2   |
| Poletti    | 2017 | Germany      | CRS (olfactory dysfunction) | AMSA device uses vibration (100 Hz) and pressure (10–50 mbar)                                   | 13                 | 16                 | Improvement in objective olfactory function in both groups at 2 weeks (2.2 with AMSA, 2.6 with nasal spray) | 3   |

Abbreviations: CF, cystic fibrosis; CRS, chronic rhinosinusitis; CRSsNP, chronic rhinosinusitis with nasal polyps; CRSwNP, chronic rhinosinusitis without nasal polyps; CT, computed tomography; EP, erythromycin phonophoresis; L-NAME, nitric oxide synthase inhibitor; LOE, level of evidence; NO, nitric oxide; SNOT-20, 20-item Sino-Nasal Outcome Test; SST, Sniffin’Sticks Test.

Low-frequency ultrasound (64 Hz for 2 minutes on consecutive days) applied to the external face. In the acute maxillary sinusitis group, 86% of patients had resolution of sinusitis at discharge. In the maxillary and ethmoid sinusitis patients, 65% had resolution of sinusitis at discharge. This study was limited by lack of a control group, eg, those receiving puncture and drainage only. The same group then studied patients who were admitted to an inpatient service with acute sinusitis and underwent sinus puncture and drainage and then compared traditional treatment of sinusitis with antibiotics (n = 86) with intervention with vibrotherapy (n = 80), which was applied both extranasally and intranasally. The vibration therapy was performed with a Russian apparatus, Tonus-3, which requires a 220-V
circuit, and has an oscillation frequency of 50 Hz to 100 Hz with an amplitude of 0.2 mm to 0.5 mm. The patients who underwent vibrotherapy had a decreased incidence of purulence on second sinus puncture and had a decreased length of stay relative to the group who received antibiotics. The participants were not randomized, which may have introduced selection bias. 17

3.2.3 Acoustic energy applied intranasally to address bacterial sinusitis

Two studies in this category focused on the intranasal application of acoustic energy to treat bacterial sinusitis. The first study was an interventional study of 71 patients with chronic maxillary sinusitis. Sixty-one participants received intranasal low-frequency ultrasound (modified UZR-M ultrasound apparatus, which was set to 3 W/cm² with a working frequency of 26.5 Hz in amplitude for a duration of 3 minutes for 5 to 7 treatments) placed via maxillary sinus puncture; and 10 controls were given antibiotics only. Complete recovery (which was based on symptoms, repeat sinus puncture results, nasal endoscopy, bacterial culture data, and cytological evaluation of blood counts—although these data were not provided in the article) was noted in 72% of patients who received ultrasound alone and in 40% who received antibiotics alone. The study was limited by lack of reported clinical characteristics specific to each group, lack of randomization, and the absence of criteria constituting “complete recovery.”19

The second study was an observational investigation of 52 patients with acute frontal sinusitis who underwent puncture of their frontal sinus with removal of purulence, irrigation with an antibiotic solution, and then mechanical low-frequency (50 Hz) vibration via a device placed intranasally along the middle turbinate. Of the 52 patients, 85% had resolution of symptoms by day 3 and 93% of patients had patency of their frontal sinus tract at discharge. This study was limited by the lack of a comparison group who underwent treatment with antibiotics and puncture without vibration.20

3.2.4 Acoustic energy applied externally to address CRS symptoms

Eleven publications addressed the application of acoustic energy to the external face to treat sinonasal symptoms in patients with CRS. One Iranian research group produced 6 of the 11 studies evaluating various forms of externally applied ultrasound therapy as it pertains to the treatment of chronic rhinosinusitis. This group published two separate case reports described in Table 1.21,22 The same group published a prospective interventional study that enrolled 57 patients with medically refractory CRS to receive low-intensity pulsed ultrasound (1 MHz) to the skin overlying the maxillary sinus (1W/cm² for 5 minutes) and to the skin overlying the frontal sinus (0.5 W/cm² for 4 minutes). The total improvement in sinonasal symptoms was 81.3%. Of the individual symptoms assessed, the greatest improvement was seen in the report of patients with nasal discharge, facial pain, and postnasal drip.23 Next, the same group performed a placebo-controlled single-blinded RCT of 20 patients with medically refractory CRS to compare treatment with continuous ultrasound (1 MHz with similar settings to that described above regarding maxillary and frontal sinus settings) to placebo (mock ultrasound simulation). The authors reported an increased improvement in mean total sinus symptom score in the intervention group relative to placebo 1 month after intervention.24 The group then conducted a double-blind RCT to compare the effects of continuous and pulsed ultrasound (same settings as above) in 30 patients with medically refractory CRS. No statistically significant difference was found in the main treatment outcome—change in sinusitis symptom score. Of note, this study was reported as a pilot study, as slow recruitment prevented the study from achieving adequate statistical power.25 Finally, the last study evaluated 15 patients with CRS with olfactory dysfunction who under-
went treatment with therapeutic pulsed low-frequency ultrasound (same regimen as above) for 10 sessions, 3 days a week. Mean Smell Identification Test improved from 13.1 (standard deviation [SD], 1.8) at baseline to 22.0 (SD, 1.3) after 10 treatments and persisted at 1-month follow-up at 22.0 (SD, 1.3). Mean 20-item Sino-Nasal Outcome Test (SNOT-20) improved from 49.3 (SD, 18.4) to 22.2 (SD, 16.4) after 10 treatments and persisted at 1-month follow-up (21.0; SD, 15.9). No funding was disclosed. 26

Another group from New Zealand conducted a prospective interventional study of 22 patients with medically refractory CRS where participants underwent six sessions of pulsed ultrasound therapy (1 MHz, 0.5 W/cm² for 4 minutes overlying the frontal sinuses and 1 W/cm² for 5 minutes overlying the maxillary sinus). Median percent improvement in SNOT-20 was 34.1% after the sixth treatment session. Two patients reported worsening of symptoms, one of whom went on to develop acute bacterial sinusitis requiring antibiotics. 27 In Brazil, Rocha et al 28 conducted a cohort placebo-controlled study of 26 patients with medically refractory CRS where patients were randomized to ultrasound therapy (1 MHz, 1 W/cm² applied to the maxillary sinus) versus a sham procedure. The authors found improvement in reported nasal symptoms and an objective 64% decrease in nasal obstruction in the intervention group relative to the placebo group. From the Philippines, a single-blinded RCT of low-frequency ultrasound (n = 21) versus placebo (n = 21) was conducted in 42 patients with CRSwNP with medically refractory CRS who had undergone sinus surgery. The ultrasound regimen was started at 1 week postoperatively and low-frequency ultrasound (1 MHz) overlying the skin of the maxillary and frontal sinus was applied for 5 minutes for two sessions per week for a total of 3 weeks. The SNOT-22 and modified Lund-Mackay endoscopic scores were statistically improved relative to the sham group. No conflict of interest was disclosed. 29

Another study evaluated the efficacy of audible sound frequencies applied to the external face for the treatment of nasal congestion. A prospective, nonrandomized interventional study was performed in 50 patients with nasal congestion using the SoniFlow vibrational headband device. With the aid of a mobile phone application, the SoniFlow device generated an individualized sound file representing the resonant frequency of the sinuses, calculated from an individual’s facial surface landmarks. Participants underwent two sequential 10-minute treatments. After two treatment cycles, 90% of patients showed improvement in Total Nasal Symptom Score, with statistically significant and clinically meaningful differences achieved. The nasal congestion subscore was significantly reduced and mean facial pain VAS also significantly decreased from baseline. Two of the authors did have equity stake in the device company. 30

The last study in this category was a case report of a patient who utilized humming as a CRS treatment strategy and is described in Table 1. 31

3.2.5  |  Acoustic energy applied intranasally to address chronic sinonasal symptoms

The following category describes three studies that evaluated acoustic energy applied intranasally to address chronic sinonasal symptoms. The first study was a single-blinded RCT of 71 patients with NAR that compared treatment with intranasal kinetic oscillation stimulation (KOS) with a sham procedure. Participants placed a device into their nasal cavity and inflated the device to 0.05 atm at home once daily for 2 weeks. Active treatment with KOS consisted of mechanical vibrations created using regular pressure oscillations at a frequency of 50 Hz. Improvement in Rhinitis Questionnaire Symptom Score (RQSS) was significant for the treatment group but not the placebo group. There was no significant difference in baseline peak nasal inspiratory flow (PNIF), but, after treatment, the placebo group had higher PNIF. Of note, one of the authors was a major shareholder in the company active in development of KOS products. 32

Two studies evaluated the SinuSonic device, which delivers a combination of acoustic vibration (128 Hz at 80 decibels) and oscillating expiratory pressure to the nasal cavity via a handheld nasal mask. The first was a pilot study that evaluated 14 participants with a history of nasal congestion who underwent application of the SinuSonic device for 2 to 5 minutes. Participants reported statistically improved NAS measures for congestion and ease of breathing after application. 33 The next study was an observational study of 40 participants with chronic nasal congestion who used the device for 3 minutes twice daily over 5 weeks. At 5-minute follow-up, improvement in PNIF and VAS symptoms (statistically and clinically significant) was noted. At the 2-week follow-up, PNIF showed a 31% increase. At the 5-week follow-up, all PROMs reached MCID improvement. No adverse effects were reported, although 10% of participants reported mild discomfort with the device. 34 Of note, both SinuSonic studies were funded by the device company.

3.3  |  Acoustic energy used to facilitate drug delivery for treatment of sinonasal disease

3.3.1  |  Acoustic energy applied externally with phonophoresis

Two studies investigated applications of phonophoresis in the treatment of CRS. Phonophoresis is a process in
which ultrasound is used to facilitate transcutaneous drug delivery. Ansari et al.\(^3\) published a case report described in Table 2. In 2015, the same group published a double-blind RCT comparing treatment of patients with medically refractory CRS who had pulsed ultrasound only versus pulsed ultrasound (1 MHz, 1 W/cm\(^2\) for 5 minutes) with phonophoresis using 5% erythromycin ointment applied topically to the skin overlying the maxillary sinuses. Both groups had improvement in total symptom score relative to baseline, but the phonophoresis group had a statistically greater improvement relative to the ultrasound-only intervention group. There was no difference between the two groups in posttreatment computed tomography (CT) findings, although not all participants had a posttreatment CT.\(^3\)

3.3.2 Acoustic energy applied to intranasal drug delivery devices to facilitate drug delivery

To understand whether sound energy can improve drug delivery to the paranasal sinuses, various groups have creatively conducted studies to evaluate this question. In one 2006 study, sonic enhancement of nebulized drug delivery (via a nebulizer connected to a rubber duck call that yielded sound with a pulsating airflow) was assessed by the efficacy of delivery of a nitric oxide (NO) synthase inhibitor (L-NG-Nitro arginine methyl ester, L-NAME) to the paranasal sinuses, where NO is synthesized. Nasal NO was induced in six healthy adults through the act of humming, which increases nasal NO levels via improved ventilation of the paranasal sinuses. When L-NAME was delivered transnasally via jet nebulizer without sonic enhancement, NO levels in the nasal cavity rose as expected after humming. Yet, when the same participants were then given L-NAME via the nebulizer with sonic enhancement, there was a 22% to 35% reduction in nasal NO after humming, likely as a result of L-NAME reaching the paranasal sinuses and blocking NO formation.\(^3\) This study provided proof of concept for further drug delivery devices utilizing acoustic energy.

In 2012, a cadaver study used low-frequency ultrasound (25–27 KHz) through a handpiece inserted into the nasal vestibule to compare delivery of solution in cadaver heads before and after sinus surgery. Before sinus surgery, the drug was able to reach the central nasal cavity and ethmoids reliably. After surgery, the pulsed ultrasound device was able to deliver drug to the maxillary and sphenoid sinus reliably and the frontal sinus and skull base some of the time. Of note, this study had two authors with ownership interest in the device and another author on the advisory board of the device company.\(^3\)

A study then evaluated 20 patients with maxillary sinusitis, 10 of whom received ultrasonic aerosol drug delivery to their nasal cavity while the other 10 patients received aerosolized drug without ultrasound. All patients then underwent surgery, and their maxillary sinus tissue was sampled. The mean concentration of the drug was found to be 3.86 $\times$ 10\(^{-2}\) for those patients without ultrasound and 4.97 $\times$ 10\(^{-2}\) for those who had received the ultrasound-facilitated aerosolization before surgery.\(^3\)

On the contrary, in another study that evaluated six patients who had previously had sinus surgery, nebulized medication was administered first via an ultrasound nebulizer and then 2 days later administered via a jet nebulizer. Drug concentrations at the anterior head of the inferior turbinate, maxillary sinus, and posterior ethmoids were measured after each treatment. Both methods allowed good drug delivery to the aforementioned sites, with significantly more drug delivered to the anterior inferior turbinate and maxillary sinus in the jet nebulizer application relative to the nebulizer aided by ultrasound.\(^3\)

The next study described details of 109 patients with CRS with nasal polyps (NPs) who underwent a Caldwell-Luc procedure and intraoperatively had their maxillary sinus filled with a chlorhexidine solution to which ultrasonic energy was applied using the LORA-DON apparatus. Depending on the cause of sinusitis (infectious or inflammatory), the sinus was then infused with either an antibiotic- or dexamethasone-impregnated solution after the device was turned off. Of these 109 patients, long-term follow-up (6 months) was available for 78 patients. The main outcome followed was relapse of disease, which, while vaguely defined, was nevertheless reported in 2.5\% of the study population at long-term follow-up.\(^3\) Another study then evaluated 100 patients with acute or chronic maxillary sinusitis and divided the participants into three treatment arms: (1) sinus puncture with application of a vibrating device (LORA apparatus, 26 KHz) using saline; (2) puncture, vibrating device with antibiotic irrigation; or (3) control, puncture and rinse with antibiotics only. The authors found decreased need for repeat puncture, shorter duration of days until improvement in symptoms, and greater resolution in bacterial culture in the vibration groups relative to control. There were no significant differences between the two vibration groups (saline and antibiotic solution). No funding sources were disclosed.\(^3\) Reichler et al.\(^3\) performed a prospective RCT of 30 patients with CRS with hyposmia who were randomized to treatment with oral steroids, budesonide nasal spray, or sonic nebulization of budesonide for 16 days. Objective olfactory tests improved with statistical significance in all three groups over baseline, but only the oral steroid and sonic nebulization groups achieved MCID. The study was funded in part
by the medical device company who made the sonic nebulizer.

The following two studies evaluated the AMSA nebulizer device, which provides vibration (100 Hz) and pressure impulses of 10 to 50 mbar. The first study evaluated 33 patients with CRS who had olfactory dysfunction. Eighteen participants were given pressure-pulsed inhalation of prednisolone for 20 minutes for six sessions, and 15 participants were given oral steroids. Both groups had improvement in VAS of olfactory function and objective measures of olfactory function at 2 months and 6 months. No funding source was disclosed.\(^4^4\) The second study of the device by a different group, randomized patients with CRS to either receive conventional nasal spray (dexamethasone) or to pressure-pulsed nasal inhalation of dexamethasone for 12 days. Improvement in olfactory function was seen at 2 weeks in both groups, although MCID was not reached and decline in olfactory function was seen at 6 weeks relative to the 2-week mark. The AMSA device was provided by the company for the study.\(^4^5\)

The final studies evaluated the PARI SINUS drug delivery device, which works via vibration aerosol with 44-Hz vibration added to a spray aerosol. In 2008, a study of cadavers that had undergone maximal sinus surgery compared drug delivery with standard nasal douching to nebulization with the PARI SINUS device and found greater distribution and drug concentration to all sinuses with the standard nasal douching relative to the PARI SINUS device. This study was not funded by the drug device company.\(^4^6\) Next, the device was studied in 56 patients with CRS who used the device to deliver topical steroids and antibiotics to the sinonasal cavity. Of all participants, 75% reported some improvement relative to baseline. This study was limited by lack of a comparison or control group. No funding source was listed for this study.\(^4^7\) A case series of five patients using the device is detailed in Table 2.\(^4^8\) Next, a group published two separate studies, the first a case series of five healthy patients with normal sinonasal anatomy who underwent drug delivery via a nasal spray and then via the PARI SINUS device on two separate occasions. Outcomes are shown in Table 2. Funding of the study was supported by the device company.\(^4^9\) The same group went on to study the device in 11 patients with CRS without NPs before and after sinus surgery. Total nasal deposition was 56.7% ± 13.3% and 46.7% ± 12.7% before and after sinus surgery, respectively. Maxillary sinus deposition (as a percentage of nasal dose) was 4.0% ± 1.7% and 6.1% ± 2.2% before and after sinus surgery, respectively. No significant distribution was seen in the frontal sinus. This study was funded in part by the device company.\(^5^0\)

Finally, another group published two separate studies evaluating the PARI SINUS device in patients with cystic fibrosis (CF). The first study was a double-blind crossover RCT. Twenty-three patients with CF were randomized to inhale either dornase alfa or isotonic saline (placebo) for 28 days with the PARI SINUS device. Participants then underwent a 28-day washout period and then crossed over to the alternative treatment. The authors found that primary nasal symptoms (via the nasal subdomain of SNOT-20) improved significantly with dornase alfa compared with no treatment, while a small improvement with isotonic saline did not reach significance. The SNOT-20 overall score improved significantly after dornase alfa compared with isotonic saline (\(p = 0.017\)). The device company did partially fund the study.\(^5^1\) The same group then went on to perform a multi-institutional RCT of 69 patients with CF who had CRS. Participants were randomized to receive sinonasal vibrating inhalation via the PARI SINUS device of either NaCl 6.0% or NaCl 0.9% for 28 days. Both therapeutic arms were well tolerated and showed trends towards significance in improvement of SNOT-20 scores (NaCl 6.0%: 

\[ \text{NaCl 6.0%: } −3.1 ± 6.5 \text{ points, NaCl 0.9%: } −5.1 ± 8.3 \text{ points} \]

although did not reach statistical or clinical significance. This study was funded by the Association Luxembourgoise de Lutte contre la Mucoviscidose and the German Cystic Fibrosis Association, although the device company provided the devices and medications.\(^5^2\) Notably, in both studies, the vibration-enhanced nebulizer was used in both treatment arms, so there was no ability to determine the specific contribution of the vibration component of therapy to the clinical outcome.

4 | DISCUSSION

Our scoping review found two main methods in which acoustic and vibrational technology was being utilized for chronic sinonasal disorders: (1) using the acoustic energy itself to treat the disease, and (2) using the technology to facilitate drug delivery.

In the first category where acoustic energy itself was used to treat sinonasal inflammation or facial pain, several studies reported success using ultrasound to treat facial pain, to aid in clearance of bacterial infections and to decrease CRS symptoms. There are several mechanisms of action that may explain the benefit of acoustic energy and vibration on sinonasal inflammation and infection as well as facial pain. First, it is known that sinonasal inflammation has a neurogenic component leading to autonomic nervous system dysfunction thought to be secondary to sympathetic hypofunction.\(^5^3\) This autonomic dysfunction is hypothesized to cause tissue edema, increase mucus secretion within the sinonasal airway, and heighten sensation of pain.\(^5^4\) Vibration and acoustic energy have been shown to modify neuromodulators and reduce pain. A study in a rat model found that therapeutic ultrasound is
able to decrease upregulation of neuromodulators associated with pain including neurokinin 1 receptor, substance P, tumor necrosis factor α, and interleukin 6, with associated decreased pain behavior in rats.54 Furthermore, there is evidence that vibration may help to eliminate biofilms—certainly a cause that may propagate or exacerbate sinonasal disease in some cases. In an in vitro study of patients with NPs, the polyps treated with low-frequency ultrasound showed decreased inflammatory cell count in the subepithelial layer and removal of bacterial biofilm from the surface of the epithelial layer relative to the control tissue not treated with ultrasound.55 Moreover, ultrasound has also been shown to have an intrinsic antibacterial effect beyond disrupting biofilms.56 Finally, vibration is also thought to mechanically reduce viscoelasticity of sputum and enhance mucociliary clearance and expectation of mucus in the lower airway—as seen in CF.57 It is reasonable to hypothesize that this might have a similar effect in the upper airway in patients without CF.

Limitations of the articles identified in this portion of the scoping review include small sample size, frequent lack of a control group, and heterogenous outcome measures, which made it difficult to compare interventions. Three separate devices, two that utilized acoustic vibration and the other that used KOS, had success in treating rhinitis symptoms. Yet, the sample size in the studies were small, and different outcomes measures were used, making comparisons difficult. In addition, some authors in each study had a financial interest in the success of the device.

In the second category—the use of acoustic energy and vibration to facilitate drug delivery—there were mixed results. In the L-NAME study, the authors found implied evidence that vibration-enhanced nebulizer devices improved delivery of pharmacologically active compounds to the sinuses compared with nebulizer alone—an important proof of concept for the potential success of this technology.37 Yet, subsequent studies of vibration-enhanced drug delivery have shown varied outcomes. Only one study compared vibration-enhanced nebulization to standard nasal saline irrigations, in which saline irrigation achieved better drug delivery in patients who had previously undergone sinus surgery.45 Other well-designed studies did show success in drug delivery to the sinuses and improved sinonasal symptoms, but these studies were often funded by the device company, therefore introducing a risk of bias. Phonophoresis with erythromycin applied transdermally overlying the maxillary sinus did show improvement in symptoms in the RCT,36 yet the sample size of the study was small and no other group has successfully reproduced the results. Overall, articles reviewed for this component of the scoping review were limited by small sample size, different disease states studied, different outcomes measured, different technology utilized, and conflicts of interest present in many of the device studies.

An additional consideration to be noted regarding this review is that two of the authors (K.M.P. and P.H.H.) have equity stake in a company focused on utilizing acoustic technology for sinonasal disease.

Despite the shortcomings of the body of evidence reviewed, this scoping review did identify 44 separate studies on this topic, of which provide mostly level 3 and 4 evidence.58 The studies included in this review represented heterogenous device technologies, study designs, and clinical outcomes, and therefore no conclusion could be reached regarding the overall effectiveness of acoustic energy as primary treatment for sinonasal disease and facial pain, or for enhancement of drug delivery. However, there are well-designed studies that show promise in this field and speak to the potential for future growth of this emerging area of study towards the development of novel therapies. Studies directed at further elucidating underlying mechanisms of action and measuring rigorous clinical outcomes are needed to address current gaps in the existing body of evidence.

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CONFLICT OF INTEREST
Phillips: equity interest in Third Wave Therapeutics; Roozdar: none; Hwang: equity interest in Lyra Therapeutics, Tivic Health, and Third Wave Therapeutics.

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**Supporting Information**

Additional supporting information may be found in the online version of the article at the publisher’s website.

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