

# Use of the gentlewave system in endodontics: scoping review

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**Aim:** The objectives of this scoping review are to map the evidence available in the literature on using the GentleWave System (GWS) in endodontic treatments and to identify knowledge gaps. **Methods:** Searches were conducted in PubMed, Scopus and Web of Science. We included randomized and non-randomized clinical trials, cohort studies, case series and cross-sectional studies that evaluated or reported using the GWS. *In vitro* studies assessing the GWS versus a control group were included. Studies were independently selected by two researchers based on eligibility criteria. Two reviewers each extracted data from half of the included studies. The following data were extracted: study design, purpose, number of study groups, sample size and sample type, analyzed outcome, outcome measurement and main results. A descriptive analysis of the data was performed. **Results:** Twenty-seven studies were included. *In vitro* studies were the most frequent study design (85.2%). Of these studies, 13 evaluated root canal disinfection. The general results demonstrated that the GWS produces results superior to the observed comparison groups. Only four studies were conducted in humans (13.8%): three prospective clinical studies and one randomized clinical trial. However, the results of these studies seem to demonstrate that the GWS is a promising treatment. **Conclusion:** Available evidence demonstrates that knowledge about GWS is still very limited. Although most of the studies in our review demonstrated that the GWS performed better than or similar to other observed systems, caution should be exercised regarding its clinical recommendation, as evidence of its superiority comes only from *in vitro* studies.

**Keywords:** Endodontics. Review. Root canal preparation. Root canal therapy.

## Introduction

Endodontic diseases often result from the evolution of dental caries and are the main reasons for seeking dental care<sup>1-4</sup>. Eliminating necrotic tissue and bacteria is a crucial step of endodontic therapy and provides a better chance of achieving success and obtaining a favorable treatment prognosis<sup>5</sup>.

The chemical–mechanical preparation is a step of endodontic treatment and aims to disinfect the root canal system<sup>6,7</sup>. For this procedure, it is necessary to shape the root canal system with either manual or mechanized instruments and to use sonic and ultrasonic devices associated with irrigation solutions. These solutions aim to improve the removal of microorganisms from root canal systems<sup>5</sup>. Auxiliary solutions are used as decalcifying substances to remove the smear layer and open and expose the dentinal tubules for penetration of irrigants and intracanal medication<sup>8,9</sup>.

However, even after adequate chemical–mechanical preparation, current techniques and instruments still cannot ensure that canals are free of bacteria<sup>10</sup>. The permanence of microorganisms can result from several factors and anatomical complexities, such as curvatures, isthmuses and anastomoses, lateral canals, apical ramifications and canals of different formats, considered challenging to access by endodontic instruments<sup>11</sup>. Cases with these complexities depend mainly on the effects of irrigating solutions and intracanal medications for complete cleaning and disinfection<sup>12</sup>.

Recently, a new device known as the GentleWave System (GWS) (Sonendo, Laguna Hills, CA, USA) was developed to clean root canals. The system works through a handpiece positioned on the occlusal surface of the already accessed tooth, and it is activated from a computer console. In addition, the system contains a technology called multisonic ultra-cleaning, which is based on the energy generated by various wavelengths of sound over a wide frequency range. The irrigant solutions and chelating agents (3% sodium hypochlorite, distilled water and 8% ethylenediamine tetraacetic acid–EDTA) are associated with the sonic movement. The machine alternates the flow of irrigation fluid, which interacts with the stationary liquid inside the pulp chamber, creating a shear force that causes hydrodynamic cavitation, forming microbubbles<sup>13</sup>.

The GWS features a built-in suction that removes fluid and residual debris through a negative pressure created inside the root canal system, promoting crown–apex cleaning<sup>10,14</sup>. Furthermore, according to the manufacturer, the canals can be treated with minimal instrumentation and do not need to be enlarged beyond the ISO 15 size, thus preserving the tooth structure<sup>14,15</sup>.

Although some articles have been published over the last several years discussing the use of the GWS system, its introduction to the market is still very recent, and a better understanding of it is still necessary. In addition, no systematic literature search has been performed to map the available evidence and identify knowledge gaps. Therefore, a scoping review is an appropriate method since it is designed to

map and evaluate characteristics and evidence of a given subject based on broad research questions<sup>16</sup>. Thus, this study aimed to conduct a scoping review to map the available evidence on the use of the GWS and identify gaps in knowledge to guide future research on this technology.

## Materials and Methods

The design of this study was based on the recommendations of Peters et al.<sup>16</sup> (2020). The study protocol is available on the Open Science Framework platform through the <https://osf.io/n5vhh/> link, and the reporting of the study is based on the PRISMA-ScR<sup>17</sup>.

### Eligibility criteria

#### *Concept*

The concept of interest was human and *in vitro* studies using the GWS, regardless of the outcome.

#### *Context*

For human studies, no restrictions were applied regarding the patient's age, study setting, endodontic technique used or outcome measured. For *in vitro* studies, no restrictions were applied regarding the laboratory analysis performed. Additionally, we included studies published in English, Spanish and Portuguese since 2014, the year the technology was developed.

#### *Types of participants*

The included human studies involved patients of any age who underwent endodontic treatment, regardless of the reason for treatment, tooth group, preparation technique and filling technique. It was only necessary that the GWS was used during the treatment.

For *in vitro* studies, any dental group was considered, regardless of the preparation and filling technique used, and it was only necessary that the GWS was used during treatment and had a comparator group.

#### *Types of sources of evidence*

Randomized and non-randomized clinical trials, retrospective and prospective cohort studies, case series and cross-sectional studies that evaluated or reported the use of the GWS were included. Furthermore, any *in vitro* study assessing the use of GWS versus a control group, regardless of the purpose of the study or the analysis performed, was included.

#### Search

Searches were performed in electronic databases (PubMed, Scopus and Web of Science) restricted from January 1, 2014 (year of technology development), to

September 1, 2022. The search strategy was developed based on terms of the PubMed MeSH and adapted to the other databases (Table 1). References of included studies were analyzed to identify additional studies.

**Table 1.** Search strategy

PubMed
"Root Canal Therapy"[Mesh] OR "Root Canal Therapy" OR "Canal Therapies, Root" OR "Canal Therapy, Root" OR "Root Canal Therapies" OR "Therapies, Root Canal" OR "Therapy, Root Canal" OR "Root Canal Treatment" OR "Endodontic Treatment" AND "Gentlewave" OR "Multisonic Ultracleaning"
SCOPUS
"Root Canal Therapy" OR "Canal Therapies, Root" OR "Canal Therapy, Root" OR "Root Canal Therapies" OR "Therapies, Root Canal" OR "Therapy, Root Canal" OR "Root Canal Treatment" OR "Endodontic Treatment" AND "Gentlewave" OR "Multisonic Ultracleaning"
Web of Science
(((((ALL=(Root Canal Therapy)) OR ALL=(Canal Therapies, Root)) OR ALL=(Canal Therapy, Root)) OR ALL=(Root Canal Therapies)) AND ALL=(Therapies, Root Canal)) OR ALL=(Therapy, Root Canal)) OR ALL=(Root Canal Treatment)) OR ALL=(Endodontic Treatment)) AND ALL=(Gentlewave)) OR ALL=(Multisonic Ultracleaning)

## Screening

The studies were selected using the Rayyan web platform (<https://www.rayyan.ai/>), where duplicate studies were removed. Initially, a pilot test was conducted to test the agreement in the selection of studies between the two reviewers (DJL and MCP) involved in this phase. The references were randomly selected using the Excel program (Microsoft Corporation, Redmond, WA, USA). Then, the two researchers independently evaluated the articles, first analyzing the titles and abstracts for the presence of the eligibility criteria. These articles were classified as "include," "exclude," or "undefined." Then, the evaluation of the full texts of the articles classified as "include" and "undefined" was conducted independently by the same two reviewers. Discrepancies in selecting titles/abstracts and full texts were resolved through discussion. In case of disagreement, the opinion of a third reviewer (RSO) was obtained.

## Data collection

A standardized data extraction form was created using Excel. First, 10% of the included studies were randomly selected in Excel to test the data extraction process and ensure consistency in interpreting the items. Next, the pilot test was conducted through discussion between the reviewers involved in this study phase. Subsequently, two reviewers (DJL and MCP) each extracted data from half of the included studies, and a third reviewer (RSO) checked the consistency of the data.

The following data were extracted: study design, purpose of the study, analyzed outcome, how the outcome was measured and main results. The number of study

groups, sample size and sample used (e.g., assessed dental group—molar, printed root canals) were also collected.

## Data analysis

Analyses were conducted in Excel. Descriptive data analysis was performed, considering the study design separately. Data were summarized in tables and figures.

## Results

The search resulted in the identification of 177 studies. Forty-eight duplicates were removed, resulting in 129 articles. After analyzing the titles and abstracts, 102 articles were removed. Twenty-seven studies were assessed for eligibility through their full texts, and two articles were excluded (see Supplementary Material). After analyzing references from other studies, two additional articles were included. Thus, 27 studies were included in this scoping review. Figure 1 presents a flowchart depicting study selection. Twenty-three (85.2%) studies were classified as *in vitro* and four (14.8%) as human studies.

Table 2 presents the characteristics of *in vitro* studies. The sample size ranged from one to 900, and only one study evaluated 900 models of 3D-printed root canals; the majority (64.0%) of studies used molar teeth. Thirteen studies (56.5%) tested canal disinfection and measured different outcomes and used different verification methods. Most of these studies demonstrated that the GWS was superior to the systems used for comparison<sup>10,18-23</sup>. In four studies, there was no difference between the GWS and the compared groups<sup>24-27</sup>, and, in two studies, the GWS was shown to be inferior<sup>8,28</sup>.

Three articles evaluated the effectiveness of removing filling material (gutta-percha, cement and calcium hydroxide<sup>29-31</sup>), and, in only one study, the GWS failed to remove the filling material completely<sup>31</sup>. Even the first published study on the GWS, which evaluated its effectiveness at tissue dissolution, demonstrated that the system dissolved tissues at a significantly faster rate than conventional irrigation devices<sup>32</sup>.

Several studies evaluated other outcomes. Wang et al.<sup>33</sup> (2016) demonstrated that the GWS caused minimal erosion in root dentin, as did the NaOCl group, followed by final irrigation with EDTA. In another study, the anatomy of the dentin of the root canal wall was examined using scanning electron microscopy, and a wide variety of structures, especially in the middle and apical regions, were observed to have no remnants of organic tissue or dentin<sup>34</sup>.

One study found that the GWS and Endovac irrigations were not associated with apical extrusion<sup>14</sup>. Three other studies evaluated apical pressure while using the GWS and employed the same analysis method. Ordinola-Zapata et al.<sup>35</sup> (2021) reported that the GWS produced negative pressure, and closed needles generated lower apical pressure than open needles. According to Chen et al.<sup>36</sup> (2021), a larger apical size did not result in higher apical pressure than smaller sizes for needle irrigation, and the GWS and negative pressure during irrigation contrib-

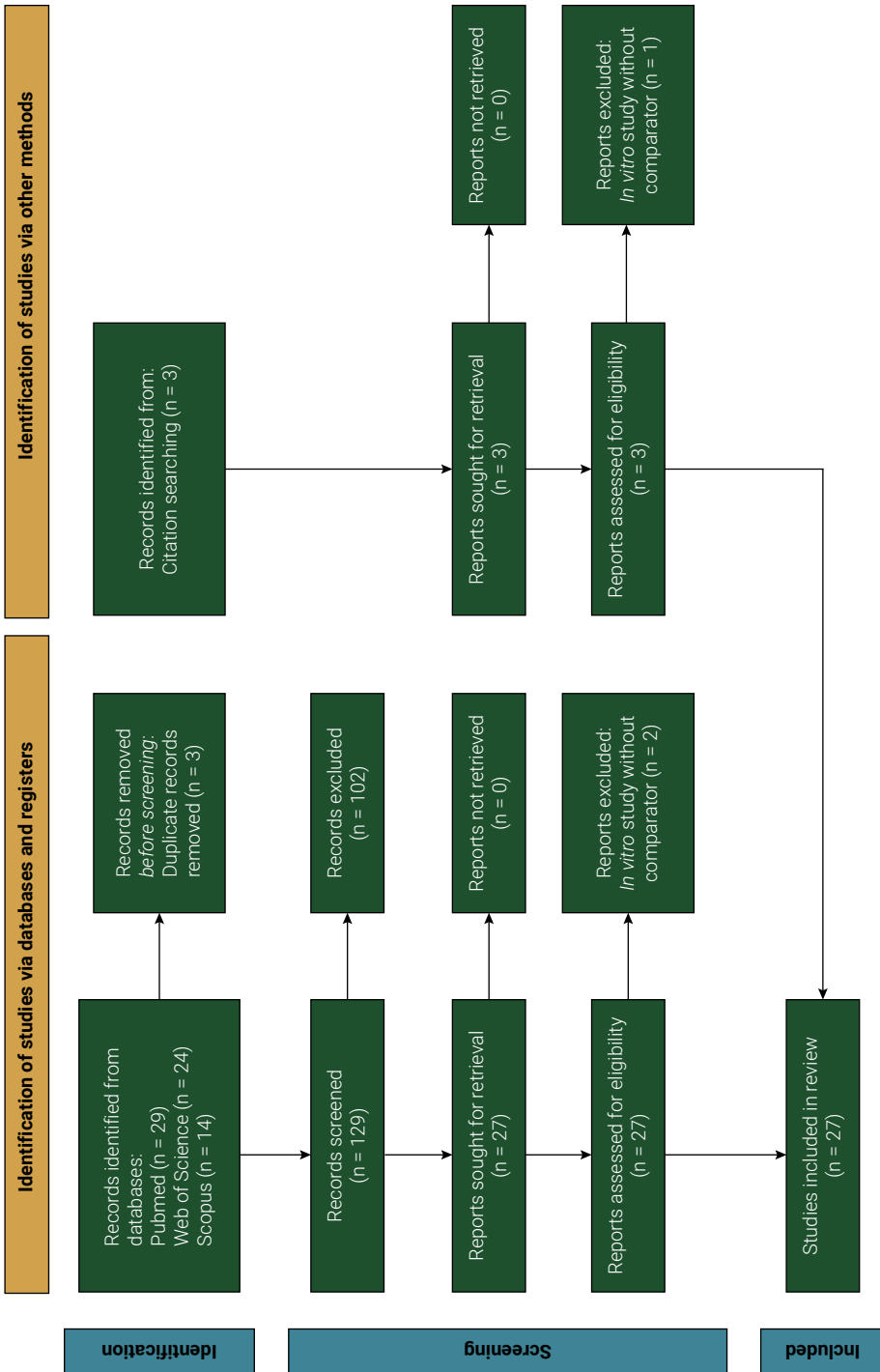


Figure 1. Study selection flow diagram

**Table 2.** Characteristics and results of the in vitro studies included.

Study	Study design	Study groups	N	Tissue used	Objective	Outcome	Outcome measurement	Result
Charara K et al. 2016	In vitro	18	16	Molars	To evaluate apical extrusion during treatment with GentleWave system, open conventional 30-G needle or Endovac in root canals enlarged to different dimensions with and without apical constriction.	Apical extrusion	Extrusion frequency and average extruded mass through the apical extrusion measuring device - airtight chamber	Root canal treatment with GentleWave System and irrigation with Endovac was not associated with extrusion. Extruded irrigation mass using the open-ended 30-G needle depended on the canal type and enlargement.
Chan R et al. 2019	In vitro	3	24	Molars	To assess the efficacy of the GentleWave system in comparison with intermittent and continuous ultrasonically activated irrigation in the removal of accumulated hard tissue debris in root canals and isthmuses within mesial roots of mandibular molars using micro-computed tomographic imaging.	Removal of accumulated hard tissue debris in root canals and isthmuses	Micro-computed tomographic imaging	GentleWave system achieved greater efficacy in the removal of accumulated hard tissue debris from the mesial root canal system of mandibular molars compared with continuous ultrasonic but not intermittent ultrasonic. The efficacy of continuous ultrasonic and intermittent ultrasonic was comparable.
Chen B et al. 2021	In vitro	27	1	Molars	To examine the effect of apical size on the apical pressure by positive and negative pressure syringe-needle and multisonic negative pressure irrigation.	Apical pressure	Pressure transducer	Large apical size of the canal did not result in higher apical pressure values compared to small sizes for syringe-needle irrigation and multisonic negative pressure irrigation, regardless of different canal anatomies.
Choi HW et al. 2019	In vitro	3	39	Molars	To compare disinfection and the biofilm removal efficacy of the GentleWave system with passive ultrasonic activation method.	Disinfection and the biofilm removal efficacy	Histological tissue processing. Modified Brown and Brenn stained sections and Hematoxylin and Eosin stained sections were visualized using a stereomicroscope.	The GentleWave System demonstrated significantly greater reduction in biofilm within the mesial roots of mandibular molars and mesiobuccal roots of maxillary molars than those treated with conventional rotary instrumentation and passive ultrasonic activation protocol.
Coaguila-Llerena H et al. 2022a	In vitro	2	22	Molars	To assess biofilm removal efficacy of GentleWave System and passive ultrasonic irrigation.	Biofilm removal efficacy	Quantitative real-time polymerase chain reaction (qPCR) and 16S ribosomal RNA gene sequencing (next-generation sequencing—NGS).	Bacterial reduction in mesial roots of mandibular molars prepared with passive ultrasonic irrigation was similar to those prepared with a GentleWave system. The reduction estimated that both groups were equivalent.

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Crozeta BM et al. 2020	In vitro	2	20	Molars	Efficacy to remove remaining filling materials from oval-shaped root canals	Effectiveness of removing remaining filler materials	Scanning electron microscope and Micro-CT Scanning	GentleWave system and passive ultrasonic irrigation were able to reduce the remaining filling material volume. None of these techniques completely removed all remaining filling material. Passive ultrasonic irrigation showed a better performance by removing.	
Dash S et al 2020	In vitro	5	75	Premolars	To compare the effectiveness of erbium: yttrium–aluminum–garnet laser, GentleWave irradiation, photodynamic therapy, and sodium hypochlorite in smear layer removal and dentin permeability with a scanning electron microscope.	Smear layer removal and dentin permeability	Scanning electron microscope	All tested agents are effective in smear removal at coronal, middle, and apical third, however, it was found that Er:YAG laser-activated conventional root canal preparation was comparatively efficient in cleaning the smear layer and opening dentinal tubules.	
Haapasalo M et al 2016	In vitro	4	4	Molars	To measure the apical pressure by the GentleWave System	Apical pressure	Pressure transducer	The GentleWave system produced lower apical pressure than syringe irrigation under all experimental conditions.	
Haapasalo M et al 2014	In vitro	5	6	Pieces of bovine muscle tissue	Assess tissue dissolution	Effectiveness in tissue dissolution	Tissue dissolved as judged visually in less than 5 minutes	The GentleWave system used with sodium hypochlorite (NaOCl) at different concentrations dissolved tissue at a significantly faster rate when compared with the conventional irrigation devices examined under the conditions in the present study.	
Jaramillo DE et al. 2021	In vitro	3	24	Molars	To evaluate the efficacy of a multisonic technology for the debridement of vital and necrotic pulp tissues in freshly extracted human mandibular molar teeth compared to untreated teeth.	Efficacy of a multisonic technology for the debridement of vital and necrotic pulp tissues	Examined under the microscope the presence of pulp tissue remnants e bacteria	The GentleWave system combined with minimal instrumentation was effective for removal of vital and necrotic pulp tissue from the root canal system and inaccessible areas.	
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Liu H et al. 2022	In vitro	90	900	3D printed root canal models	To evaluate the efficacy of different irrigation techniques in the removal of various calcium hydroxide [Ca(OH) <sub>2</sub> ] and barium sulfate [BaSO <sub>4</sub> ] formulations from three isthmuses in 3-dimensional (3D) printed molar root canal models.	Removal of residual material from the three isthmuses of the printed models.	Mean removal times were recorded from activation of irrigation procedures to completion of removal	The GentleWave system removed all materials faster than PiezoFlow, whereas Open-ended irrigation needle 5mL/min and 15mL/min, Double-side-vented irrigation needle 5mL/min, EndoUltra NITI activator tip failed to remove all materials from the isthmuses. Pure Ca(OH) <sub>2</sub> and the mixture with BaSO <sub>4</sub> paste in the proportion 8:1 were removed in less time than the other mixtures by the GentleWave system, PiezoFlow and Open-ended needle irrigation systems using 15 mL/min.
Ma J et al. 2015	In vitro	3	30	Molars	To evaluate the removal of calcium hydroxide [Ca(OH) <sub>2</sub> ]	Assessment of calcium hydroxide [Ca(OH) <sub>2</sub> ] removal from channels root	Micro-CT scans were acquired for each specimen after instrumentation and before and after the removal of calcium hydroxide [Ca(OH) <sub>2</sub> ]	All 20 mesial canals of the GentleWave system were completely free of calcium hydroxide [Ca(OH) <sub>2</sub> ] after cleaning
Molina B et al. 2015	In vitro	3	45	Molars	To compare the debridement efficacy of the GentleWave system with a traditional method for cleaning root canals	The efficacy of tissue debris removal from root canals	Percentage of debris remaining in the root canal space through cross sections with photomicrographs	GentleWave System showed a significantly greater cleaning capacity and reduction in residual debris within the mesiobuccal and mesiolingual canals of mandibular molars and the mesiobuccal canals of maxillary molars than those cleaned conventionally.
Park SY et al. 2020	In vitro	6	66	Molars	To assess the efficacy of different final root canal irrigation activation methods in removing debris and smear layers in the apical and middle portions of root canals during retreatment.	Removing debris and smear layers in the apical and middle portions of root canals	Scanning electron microscopic	The GentleWave system showed a more optimal cleaning efficacy of the root canal debris but did not differ significantly with the tested passive ultrasonic or sonic irrigation method.

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Ordinola-Zapata R et al. 2022	In vitro	2	22	Incisors	To assess the efficacy of a non-instrumentation technique to disinfect root canals infected by a human dental plaque-derived multispecies biofilm.	Effectiveness in the disinfection of root canals infected by multispecies biofilm.	Culture and 16S rRNA gene sequencing	Significant shifts in composition were observed following cleaning by using both regimens (conventional technique and the non-instrumentation technique -GentleWave System) but the impact of this change was greater following a conventional cleaning technique.		
Ordinola-Zapata R et al. 2021	In vitro	6	12	Molars	To evaluate the apical pressure generated by 2 endodontic irrigation needles and the GentleWave system in lower molars.	Apical pressure	Current (mA) from the pressure transducer	Close-ended needles generated less apical pressure than open-ended needles. Irrigation induced less apical pressure in mesial than in distal root canals. The GentleWave system procedure produced negative apical pressure.		
Vandurangi P. 2016	In vitro	4	40	Molars	To evaluate the penetration depth of sodium hypochlorite (NaOCl) in dentinal tubules using the GentleWave system versus ultrasonic agitation	Depth of sodium hypochlorite penetration into dentinal tubules	Examined and imaged with a stereo microscope	GentleWave System demonstrated at least four times deeper cleaning in the apical region than active ultrasonic system and was effective throughout the root canal system.		
Velardi JP et al. 2022a	In vitro	5	60	Premolars	To compare the effectiveness of the GentleWave system and passive ultrasonic irrigation in removing lipopolysaccharides from infected root canals after minimally invasive techniques and conventional instrumentation.	Effectiveness in removing lipopolysaccharides from infected root canal	LAL assay (KQCL test)	GentleWave system was the most effective protocol against lipopolysaccharides in infected root canals using minimally invasive techniques and conventional instrumentation techniques.		
Velardi JP et al. 2022b	In vitro	5	60	Premolars	To evaluate the effectiveness of the GentleWave System and passive ultrasonic irrigation in removing Enterococcus faecalis lipoteichoic acid from infected root canals with a minimally invasive and conventional instrumentation technique.	Effectiveness in removing Enterococcus faecalis lipoteichoic acid from infected root canals	Samples were cryogenically ground for intraradicular lipoteichoic acid (LTA) analysis. LTA was quantified with an LTA ELISA kit enzyme-linked immunosorbent assay kit	GentleWave System + minimally invasive technique and conventional instrumentation technique were the most effective protocols against E. faecalis LTA, with no difference between them.		
Wang Z et al. 2016	In vitro	7	35	Molars	To examine the level of erosion in root dentin caused by different irrigation methods and protocols	Level of erosion in root dentin	Energy-dispersive X-ray spectroscopy and scanning electron microscopic images.	Scanning electron microscopy showed canal wall erosion when an additional final irrigation with NaOCl was done. NaOCl followed by final EDTA irrigation performed either by syringe needle or the GentleWave System caused minimal dentin erosion.		

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Wang Z et al. 2018	In vitro	2	24 Premolars	<p>To examine root canal wall anatomy in premolar teeth cleaned by a noninstrumentation method after #10 K-file patency examination</p> <p>Examine root canal wall anatomy</p> <p>Scanning electron microscopic</p> <p>Root canal wall dentin in premolars cleaned with GentleWave system showed a wide structural variety, especially in the middle and apical region. No organic tissue remnants or dentin debris were detected. In the control group untreated teeth, tissue remnants covered most of the dentin surface.</p>
Wright CR et al. 2019	In vitro	3	30 Molars	<p>Effectiveness of the removal of residual obturation material (gutta-percha and sealer)</p> <p>Effectiveness of filling material removal</p> <p>Digital radiographs in the buccolingual and mesiodistal angles and posttreatment micro-computed tomographic scans</p> <p>None of the irrigation protocols assessed could completely remove residual obturation material from the root canal system. Both the side-vented needle and GentleWave system groups were able to remove more residual obturation material than the EndoVac group; however, the differences were not significant</p>
Zhang D et al. 2019	In vitro	2	20 Molars	<p>Effectiveness of irrigant and root canal system cleaning in removing multispecies oral biofilms from root canals</p> <p>To determine the effectiveness of two irrigation and cleaning systems in removing multispecies oral biofilms from root canals.</p> <p>Both groups, GentleWave System and Ultrasonic System, showed reduced bacterial DNA. GentleWave showed a more constant and significantly greater reduction of total microbial DNA than PiezoFlow Ultrasonic</p>

uted to improved safety compared to positive pressure. This result corroborates a study by Haapasalo et al.<sup>37</sup> (2016), in which the GWS was shown to create negative pressure in the apical foramen during root canal cleaning, regardless of the size of the canal instrumentation.

Table 3 presents the characteristics and results of the human studies included. Three were classified as prospective clinical studies, and one was a randomized clinical trial. These studies had sample sizes between 36 and 77. Three studies evaluated molar teeth, and only one article considered premolars. Three articles evaluated the success rate based on signs, symptoms and radiographic evaluations. Of these, two articles considered the same sample but used different follow-up times: 6 and 12 months. The GWS had a healing success rate of 97.4% after 6 months<sup>38</sup> and 97.3% after 12 months<sup>39</sup>. In the other study, treatment with the GWS considerably reduced periapical lesions, with a success rate of 97.7% at the 12-month reassessment<sup>13</sup>.

Of all included studies, only one was a randomized clinical trial<sup>40</sup>. The study compared the use of the GWS to endodontic treatment with conventional irrigation and evaluated the incidence and intensity of postoperative pain using a pain scale. The study found no significant difference in the incidence or intensity of pain with the two methods. However, patients on both evaluated systems that were evaluated reported a significant decrease in pain within 6 hours of treatment.

**Table 3.** Characteristics and results of the included human studies.

Study	Study design	Study groups	N	Tissue used	Objective	Outcome	Outcome measurement	Result
Grigsby D Jr et al. 2020	Human, Randomized clinical trial	2	36	Premolars or Molars	To determine if the GentleWave system significantly decreases the incidence and intensity of postoperative pain.	Incidence and intensity of postoperative pain	0-100 numerical rating scale (NRS)-41 for pain	There was no significant difference in the incidence or intensity of postoperative GentleWave system and endodontic treatment with conventional side-vented needle irrigation and ultrasonic activation. However, both groups reported a statistically significant decrease in pain with time 6-hour posttreatment time point.
Sigurðsson A et al. 2016a	Human, Prospective Clinical Study	1	77	Molars	To evaluate healing rates of molars after root canal treatment employing the GentleWave system	Cumulative success rate of healing	Clinical signs and symptoms and signs of apical periodontitis through radiographs	In this six-month clinical study, the cumulative success rate of healing was 97.4% when patients were treated with the GentleWave system.
Sigurðsson A et al. 2016b	Human, Prospective Clinical Study	1	75	Molars	To evaluate healing rates of molars 12 months after endodontic therapy using the GentleWave system	Cumulative success rate of healing	Clinical signs and symptoms and signs of apical periodontitis through radiographs	In this 12-month prospective multicenter clinical study, the GentleWave system showed a high level of success after a 12-month follow-up, 97.3%.
Sigurðsson A et al. 2018	Human, Prospective Clinical Study	1	44	Molars	To report the results of a group of patients with significant periapical lesions who were treated and evaluated in two prospective, multicenter, single-arm, non-significant risk clinical studies.	Cumulative success rate of healing	Clinical signs and radiographic evaluations	Treatment of sizable periapical lesions with the GentleWave system procedure resulted in a success rate of 97.7% at 12-month re-evaluation.

## Discussion

This study is the first to use a complete knowledge synthesis method to improve understanding of the available evidence on using the GWS. The main result was that the evidence regarding the use of this technology is still limited, since most of the included studies were *in vitro*, and there were only four clinical studies of the GWS. However, some aspects should be highlighted: 1) most *in vitro* studies demonstrated the superiority of GWS compared to other methods, mainly for cleaning and disinfection of the root canal<sup>10,18-23</sup>; 2) a significant portion of the remaining *in vitro* studies and the only randomized clinical trial included in this scoping review revealed similar results between the GWS and its comparators<sup>14,24-27,31,33,36,40</sup>; and 3) most of the clinical studies included did not establish a control group, which hinders a clear understanding of the GWS.

*In vitro* studies are performed to simulate biological conditions in the laboratory, providing researchers with information useful for the development of further studies. These studies have been widely used to test new materials and therapeutic or preventive procedures within the field of dentistry, especially in endodontics<sup>41</sup>. However, *in vitro* studies have some limitations, such as the difficulty of extrapolating results to human beings<sup>42</sup>. Despite the caution needed when interpreting *in vitro* studies, the available evidence seems to demonstrate that the GWS is a promising treatment. However, it is important to note that the GWS works through a hand-piece positioned on the occlusal surface of the already accessed tooth. This condition requires the system to reach the occlusal position, which is problematic if the patient has restricted mouth opening capability and is probably difficult to simulate in *in vitro* studies. Regardless, *in vitro* studies are performed to assess the reduction of bacterial DNA and the dissolution of organic matter, although it is impossible for them to reproduce a clinical scenario and its associated challenges.

Only four clinical studies were identified in this review. Only one was a randomized clinical trial<sup>40</sup>, which is considered the ideal study design for testing health interventions<sup>43</sup>, and the other three were prospective clinical studies<sup>13,38,39</sup>. Grigsby et al.<sup>40</sup> (2020) showed no significant difference in the incidence or intensity of pain after using irrigant solutions with the GWS versus conventional irrigation. The other three clinical studies did not include a control group<sup>13,38,39</sup>, which makes it impossible to compare the results produced using the GWS with those produced with other instrumentation systems. This fact corroborates the conclusion that the evaluation of the GWS is still in the very early stages.

Recently, a narrative review describing the results of the GWS in endodontic treatment was published. In general, the results demonstrated that the GWS promoted the reduction of bacterial DNA, faster dissolution of organic matter and greater penetration of sodium hypochlorite into dentinal tubules<sup>44</sup>. However, narrative reviews do not use explicit and systematic criteria for the search and critical analysis of the literature, making it difficult for other researchers to reproduce their results. Searching for sources does not involve the application of a predetermined and specific strategy and is often less comprehensive. Furthermore, the selection of studies and interpretation of information may be influenced by the subjectiv-

ity of the authors and selection bias<sup>45</sup>. The present study performed a scoping review, which mapped the main concepts of the GWS. A scoping review examines the extent, scope and nature of investigations, summarizes and disseminates the investigation data systematically, reproducibly and transparently and identifies gaps in existing research<sup>46</sup>.

It is essential to note that the GWS is expensive, reaching up to 70,000 USD<sup>47</sup>, and this may make the development of clinical studies unfeasible, especially because they are already considered more expensive than other types of studies. However, the success rate of the GWS seems to be similar to that of other root canal instrumentation systems, which may not justify the use of this technology and the development of new studies. Thus, analyses that consider the cost-effectiveness of the GWS are still necessary for a better understanding of the viability of its use. Maybe the cost of the GWS explains why only four studies used the GWS in patients. In addition, it is necessary to train personnel to use the system since dentistry schools teach only the conventional methods for endodontic treatment. As a result, few professionals can apply this new technology.

This study has some important limitations. First, a search in the gray literature was not conducted because it was understood that the technology is still in the very early stages; therefore, articles on the subject were expected to be indexed in the searched databases. Second, data extraction was not performed in duplicate, but prior training of the researchers was performed to reduce possible errors.

Knowledge about mechanized systems to aid chemical–mechanical preparation contributes to the success of endodontic therapy. This process is essential for bio-film removal and root canal disinfection. In the future, more randomized clinical trials should be performed to compare the GWS with two or more root canal cleaning systems, and they should consider cost-effectiveness analyses during study development. Furthermore, clinical studies already published on the subject must continue their follow-ups to obtain long-term evidence.

In conclusion, the evidence available on the GWS is mostly based on *in vitro* studies and four clinical studies and demonstrates that knowledge about using the technology is still very limited. Caution should be exercised regarding the clinical recommendation of the GWS, as evidence of its superiority comes only from *in vitro* studies, and there is still no evaluation of its cost-effectiveness, which seems essential due to its high cost compared to other systems available on the market.

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## Conflict of Interest Statement

The authors deny any conflicts of interest related to this study.

## Data Sharing

Data, analytical code, or other materials will be shared upon request.

## Author Contribution

**Daiana Jacobi Lazzarotto** – Data curation, Methodology, Writing-review & editing. **Mayara Colpo Prado** - Data curation, Methodology, Writing-review & editing. **Lara Dotto** - Data curation, Methodology, Writing-review & editing. **Rafael Sarkis Onofre** – Conceptualization, Project administration, Supervision, Writing-original draft.

All authors actively participated in the manuscript findings, revised, and approved the final version.

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