

# THE FOREMOST RESEARCHED **ROOT CANAL** TECHNOLÖGY

### Clinically and Scientifically Proven

Since the release of the GentleWave® System in 2017, a wealth of clinical research has consistently validated our claims about the technology. The subsequent peer-reviewed studies provide significant evidence that the GentleWave System is the most advanced technology in root canal tissue dissolution, debridement and disinfection.



#### **SUMMARY**

## GentleWave System Research

PEER-REVIEWED ARTICLES
PUBLISHED BETWEEN 2014-2023

OF CLINICAL STUDIES UTILIZED THE SAME

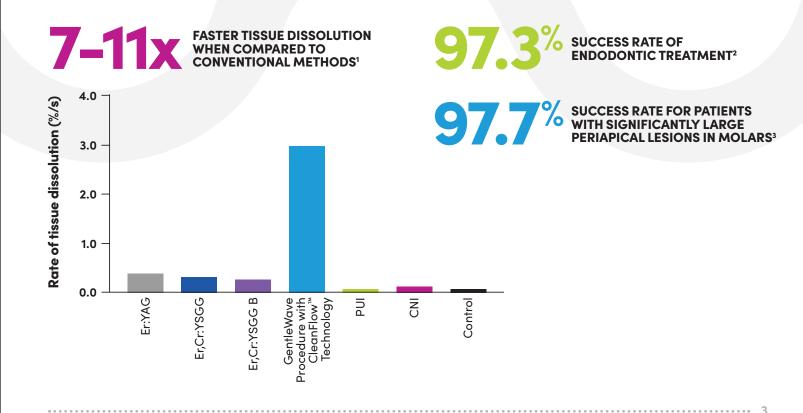
OF ARTICLES ARE PUBLISHED IN SCIENCE-RELATED PEER-REVIEWED JOURNALS

1 milion + PATIENTS TREATED



#### **CLEAN BEYOND CONVENTION**

### The Proof Is in the Numbers



#### **SUPERIOR CLEANING AND DISINFECTION**

# The GentleWave System effectively cleans canals down to the apex.

	Citation	Takeaway
1	Sharma N, Alobaid MA, Nayan K, et al. Effectiveness of Removal of Hard Tissue Debris From the Mesial Root Canal System of Mandibular Molars Using Different Supplementary Irrigation Protocols: An Original Study. J Pharm Bioallied Sci. 2023;15(Suppl 1):S151–S155. doi:10.4103/jpbs.jpbs_442_22	GentleWave achieved significant reduction of the hard tissue debris.
2	Coaguila-Llerena H, Gaeta E, Faria G. Outcomes of the GentleWave System on Root Canal Treatment: A Narrative Review. <i>Restor Dent Endod.</i> 2022 Feb 14;47(1):e11.	A total of 24 studies (20 in vitro and 4 clinical) were reviewed and described the following outcomes: the GentleWave System had a clinical endodontic success rate of 97.3%, is not associated with extrusion of the irrigant, promoted faster organic dissolution, and promoted higher penetration of NaOCI when compared to other methods.
3	Liu H, Shen Y, Wang Z, Haapasalo M. The Ability of Different Irrigation Methods to Remove Mixtures of Calcium Hydroxide and Barium Sulphate From Isthmuses in 3D-Printed Transparent Root Canal Models. Odontology. 2022 Jan;110(1):27-34.	GentleWave removed all materials faster than PF. The other method failed to remove all materials from the isthmuses.
4	Tashkandi N, Alghamdi F. Effect of Chemical Debridement and Irrigant Activation on Endodontic Treatment Outcomes: An Updated Overview. <i>Cureus</i> . 2022 Jan 23;14(1):e21525.	GentleWave is a promising tool but needs more clinical investigation to show its efficiency.
5	Montero LQ, Basrani B, Jaramillo D. Disinfection in endodontics. In: Khurshid Z, Sohail Zafar M, Najeeb S, eds. <i>Biomaterials in Endodontics</i> . Woodhead Publishing; 2022;311–356.	GentleWave is the most advanced technology in the market.
6	Jaramillo DE, Arriola AR. Histological Evaluation of Multisonic Technology for Debridement of Vital and Necrotic Pulp Tissues From Human Molar Teeth. An Observational Study. <i>Appl. Sci.</i> 2021; 11, 11002.	In histological examination, GentleWave combined with minimal instrumentation was effective in the removal of vital and necrotic pulp tissue from the root canal and inaccessible areas. For the necrotic teeth, no bacteria were detected in the main canals, isthmuses or lateral canals but were detected deep within the dentinal tubules.
7	Crozeta BM, Chaves de Souza L, Silva–Sousa YTC, Sousa–Neto MD, Jaramillo De, Silva RM. Evaluation of Passive Ultrasonic Irrigation and GentleWave System as Adjuvants in Endodontic Retreatment. <i>J Endod.</i> 2020; 46(9):1279–1285.	Both GentleWave and passive ultrasonic irrigation (PUI) were able to reduce the volume of fill material remaining with the PUI technique able to remove slightly more material. In contrast, a previous study showed GentleWave was able to remove more remaining filling material when compared to the use of EndoVac and side-vented needles.



Q a R 20 Si H M	Chong X, Shen Y, Jingzhi M, Chen W, Haapasalo M. Quality of Root Filling After Obturation With Gutta-Percha and Three Different Sealers of Minimally Instrumented Root Canals of the Maxillary First Molar. <i>J Endod</i> . 2019;45(8):1030–35.  Chan R, Versiani M, Friedman S, et al. Efficacy of Three Supplementary Irrigation Protocols in the Removal of Hard Tissue Debris from the Mesial Root Canal System of	Post GentleWave, 97.9% of canal thirds were free from debris allowing a modified single-cone technique to fill 90-99% of the canal space with root filling material.  GentleWave removed the most AHTD in canals (96.4%) and isthmus (97.9%) compared to CU
S H N	Supplementary Irrigation Protocols in the Removal of Hard Tissue Debris from the Mesial Root Canal System of	(96.4%) and isthmus (97.9%) compared to CU
	Mandibular Molars. <i>J Endod.</i> 2019;45(7):923-929.	(80.0% & 88.9%, respectively) and IU (91.2% & 93.5%, respectively)
o: E:	Vright C, Glickman G, Jalali P, Umorin M. Effectiveness of Gutta-Percha/Sealer Removal During Retreatment of Extracted Human Molars Using the GentleWave System. J. Endod. 2019;45(6):808–812.	GentleWave removed more residual obturation material (26%) compared to 16% and 9% for the side-vented needle group and EndoVac group, respectively.
Α	Mohammadi Z, Jafarzadeh H, Shalavi S, Palazzi F. Recent Advances in Root Canal Disinfection: A Review. <i>Iran Endod</i> . 2017;12(4):402–406.	GentleWave may improve the ability to disinfect the root canal system.
Fl	andrangi P. Evaluating Penetration Depth of Treatment Fluids Into Dentinal Tubules Using the GentleWave System.  Dentistry. 2016;6(3):366.	GentleWave demonstrated approximately four times greater NaOCI penetration depth in the apica region than currently employed ultrasonic systems.
Н	Ma J, Shen Y, Yang Y, et al. In Vitro Study of Calcium Hydroxide Removal from Mandibular Molar Root Canals. Endod. 2015;41:553–558.	Only GentleWave was able to efficiently remove Ca(OH) <sub>2</sub> from root canals (including the apical portion) and predictably removed the paste within 90 seconds using water irrigation alone.
E	Molina B, Glickman G, Vandrangi P, Khakpour M. Evaluation of Root Canal Debridement of Human Molars Using the GentleWave System. <i>J Endod.</i> 2015;41(10):1701–5.	GentleWave cleaned tissue debris in 97.2% and 98.1% of the apical and middle region of the MB and ML canals of mandibular molars and the MB canals of maxillary molars, respectively. In contrast, conventional instrumentation was capable of cleaning only 67.8% and 87.3% of the apical and middle region of the MB and ML canals of mandibular molars and the MB canals of maxillary molars, respectively.
N In	DiVito E, Rassoulian SA. Ex Vivo Scanning Electron Microscopy Evaluation of Cleaning Efficacy Following In Vivo Endodontic Treatment: A Report of Two Cases. Dentistry. 2017;7(3):419.	Accumulated debris and residual smear layer score were substantially lower in the patient treated with GentleWave.

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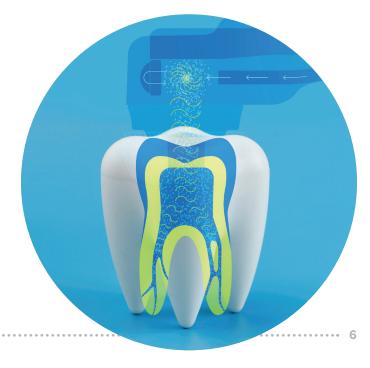
#### PREVENTS APICAL EXTRUSION

# Vortical flow generated by the GentleWave System creates negative pressure<sup>4</sup> within the root canal that prevents apical extrusion<sup>5</sup>.

	Citation	Takeaway
16	Chen B, Shen Y, Ma J, Haapasalo M. Effect of Apical Size on Apical Pressure During Syringe–Needle and Multisonic Negative Pressure Irrigation. <i>Odontology.</i> 2021;109(3): 625–631.	With GentleWave, the apical pressure stayed negative regardless of the apical size and there was no significant difference in the apical pressure measured at different apical sizes. For SNI and NPSNI, positive pressures were observed at all apical sizes. For GentleWave and NPSNI, no significant difference in apical pressure was found between the palatal, distobuccal and the two mesiobuccal canals. Since both the GentleWave and NPSNI had apical pressures below the human central venous pressure, both are safe regarding the risk of extrusion up to apical sizes as large as #110.
17	Ordinola-Zapata R, Crepps JT, Arias A, Lin F. In Vitro Apical Pressure Created by Two Irrigation Needles and a Multisonic System in Mandibular Molars. <i>Restor Dent Endod.</i> 2021;46(1):e14.	Positive apical pressure is generated through conventional irrigation by open-end or closed-end needles. The size and shape of the canal affect the apical pressure for syringe irrigation. GentleWave generated negative apical pressure for both canals.
18	Haapasalo M, Shen Y, Wang Z, et al. Apical Pressure Created During Irrigation With the GentleWave System Compared to Conventional Syringe Irrigation. <i>Clin Oral</i> <i>Investig.</i> 2016;20(7):1525–34.	GentleWave creates negative pressure at the apical foramen during root canal cleaning irrespective of the canal size.
19	Charara K, Friedman S, Sherman A, et al. Assessment of Apical Extrusion During Root Canal Irrigation With the Novel GentleWave System in a Simulated Apical Environment. <i>J Endod</i> . 2016;42(1):135–9.	GentleWave and irrigation with the Endovac system was not associated with extrusion. Extruded irrigation mass using the open-ended 30-G needle depended on the canal type and enlargement.

### Apical protection with the GentleWave System with CleanFlow™ Technology

As the irrigant stream passes over the endodontic access, vortical flow is created, producing negative pressure<sup>4</sup> that guards against apical extrusion<sup>5</sup>.





#### **FAST HEALING**

### The healing success rate for patients with significantly large periapical lesions treated with the GentleWave System was

	Citation	Takeaway
20	Sigurdsson A, Garland RW, Le KT, Rassoulian SA. Healing of Periapical Lesions After Endodontic Treatment With the GentleWave Procedure: A Prospective Multicenter Clinical Study. <i>J Endod.</i> 2018;44(3):510–517.	Patients with significantly large periapical lesions in molar teeth were treated with GentleWave. The success rate for healing at 12 months was 97.7%.
21	Garland RW. Bone Regrowth and Healing of Periapical Lesions Nine Months After Removal of Silver Points and Retreatment With the GentleWave Procedure. <i>Int J Dent</i> <i>Oral Health.</i> 2017;3(4).	At the nine-month follow-up visit post GentleWave, clinical evaluation showed the tooth was asymptomatic and CBCT imaging revealed significant bone regrowth and periradicular healing.
22	Sigurdsson A, Le KT, Woo SM, et al. Six-Month Healing Success Rates After Endodontic Treatment Using the Novel GentleWave System: The PURE Prospective Multicenter Clinical Study. <i>J Clin Exp Dent.</i> 2016;8(3):e290- 8.	77 GentleWave patients were evaluated at six months, with a follow-up rate of 86.5%. The cumulative success rate of healing was 97.4%.
23	Sigurdsson A, Garland RW, Le KT, Woo SM. 12–Month Healing Rates After Endodontic Therapy Using the Novel GentleWave System: A Prospective Multicenter Clinical Study. <i>J Endod</i> . 2016 Jul;42(7):1040–8.	Only 3.8% of the patients experienced moderate postoperative pain within 2 days and no incidence of pain at 14 days, 6 months and 12 months after treatment with GentleWave. The cumulative success of endodontic therapy was 97.3%.
24	Le K. Six-Month Healing of a Mandibular First Molar With Complex Anatomy Using a Novel Endodontic Procedure. <i>J Dent Health Oral Disord Ther.</i> 2016;4(4):1–3.	At the 6-month recall post GentleWave, radiographs revealed complete healing of apical periodontitis. Radiographs at 18 months provide verification of healing.

#### **REDUCED POSTOPERATIVE PAIN**

# 96.6% of patients treated with the GentleWave System reported mild to no pain post procedure.<sup>6</sup>

	Citation	Takeaway
25	Grigsby D Jr, Ordinola-Zapata R, McClanahan SB, Fok A. Postoperative Pain After Treatment Using the GentleWave System: A Randomized Controlled Trial. <i>J Endod.</i> 2020;46(8):1017-1022.	The GentleWave group showed a lower level of postoperative pain than the conventional group.



#### **BIOFILM AND SMEAR LAYER REMOVAL**

# The research supports that the GentleWave Procedure removes multispecies biofilm and smear layer.

	Citation	Takeaway
26	Coaguila-Llerena H, Ordinola-Zapata R, Staley C, Dietz M, Chen R, Faria G. Multispecies Biofilm Removal by a Multisonic Irrigation System in Mandibular Molars. <i>Int Endod J.</i> 2022 Nov;55(11):1252–1261.	GentleWave reduced the amount of biofilm by 100% (median) and PUI reduced it by 78.5% (median). GentleWave preserved pericervical dentine through minimized instrumentation.
27	Velardi JP, Alquria TA, Alfirdous RA, Griffin IL, Tordik PA, Martinho FC. Efficacy of GentleWave System and Passive Ultrasonic Irrigation With Minimally Invasive and Conventional Instrumentation Technique Against Enterococcus Faecalis Lipoteichoic Acid in Infected Root Canals. <i>J Endod</i> . 2022 Jun;48(6):768–774. doi: 10.1016/j. joen.2022.01.021. Epub 2022 Mar 3. PMID: 35247369.	E. faecalis LTA was recovered from 100% of the root canals after passive ultrasonic irrigation (PUI) + minimally invasive techniques (MIT) and PUI + conventional instrumentation techniques (CIT). In contrast, no E. faecalis LTA was recovered from 42% of the root canals after GentleWave + MIT and GentleWave + CIT. In conclusion, GentleWave + MIT and GentleWave +CIT were the most effective protocol against E. faecalis in infected root canals, in both the canal and intraradicular dentin.
28	Ordinola–Zapata R, Mansour D, Saavedra F, Staley C, Chen R, Fok AS. In Vitro Efficacy of a Non–Instrumentation Technique to Remove Intracanal Multispecies Biofilm. <i>Int Endod J.</i> 2022 May;55(5):495–504. doi: 10.1111/iej.13706. Epub 2022 Mar 8.	GentleWave, with the APM procedure instrument and non-instrumentation technique, and the conventional technique with PUI were able to remove an intracanal multispecies biofilm from mandibular incisors. The conventional technique caused a greater change in the biofilm communities present after treatment than the non-instrumentation technique.
229	Velardi JP, Alquria TA, Alfirdous RA, et al. Comparison of GentleWave System and Passive Ultrasonic Irrigation With Minimally Invasive and Conventional Instrumentation Against LPS in Infected Root Canals. <i>Sci Rep.</i> 2022 Mar 22;12(1):4894.	Lipopolysaccharides (LPS) were recovered from 100% of the root canals after passive ultrasonic irrigation (PUI) + minimally invasive techniques (MIT) and PUI + conventional instrumentation techniques (CIT). In contrast, no LPS was recovered from 42% of the root canals after GentleWave + MIT and 50% after GentleWave + CIT. In conclusion, GentleWave + MIT and GentleWave + CIT were the most effective protocol against LPS in infected root canals, in both the canal and intraradicular dentin.
30	Park SY, Kang MK, Choi HW, Shon W-J. Comparative Analysis of Root Canal Filling Debris and Smear Layer Removal Efficacy Using Various Root Canal Activation Systems During Endodontic Retreatment. <i>Medicina</i> (Kaunas). 2020; 56(11):615.	GentleWave showed cleaner canals among the treatment groups. The number of debris removed from the root canal systems were greater with GentleWave than with ultrasonic or sonic activation. In the middle regions, GentleWave showed lower smear scores and in the apical regions, showed similar scores to the other techniques.



	Citation	Takeaway
3′	Zhang D, Shen Y, de la Fuente-Nunez C, Haapasalo M. In Vitro Evaluation by Quantitative Real-Time PCR and Culturing of the Effectiveness of Disinfection of Multispecies Biofilms in Root Canals by Two Irrigation Systems. <i>Clin Oral Investig.</i> 2019;23(2):913–920.	GentleWave consistently removed high levels of bacterial DNA more predictably than the Ultrasonic System and was able to achieve this in minimally instrumented (#15.04) molar canals.
3:	Choi HW, Park SY, Kang MK, Shon W-J. Comparative Analysis of Biofilm Removal Efficacy by Multisonic Ultracleaning System and Passive Ultrasonic Activation. <i>Materials (Basel)</i> . 2019;12(21):3492.	GentleWave demonstrated significantly greater reduction in biofilm within mesial roots of mandibular molars and mesiobuccal roots of maxillary molars than those treated with conventional rotary instrumentation and PU activation.

#### **DENTIN PRESERVATION**

# The GentleWave System maintains the integrity of the tooth by preserving more tooth structure.<sup>7</sup>

	Citation	Takeaway
33	Alquria TA, Alfirdous RA, Gupta S, et al. Comparison of Conventional and Contemporary Root Canal Disinfection Protocols Against Bacteria, Lipoteichoic Acid (LTA), and Lipopolysaccharide (LPS). <i>Sci Rep.</i> 2023 Jan 21;13(1):1206.	With minimal instrumentation, GentleWave was the most effective disinfection protocol for bacteria, LTA and LPS removal from the main canal and intraradicular dentin.
34	Woo SM. Periapical Healing of a Mandibular Molar With Middle Mesial Canal: A Case Report. <i>J Interdiscipl Med Dent Sci.</i> 2017;5(2):209.	GentleWave cleaned the middle mesial canal without instrumentation, helping to preserve dentin and promote long-term sustainability of the tooth. Conventional root canal treatment would have required dentin removal and risked file separation, strip perforations and ledges, jeopardizing the long-term outcome of the tooth.
35	Shon W-J. Introducing the GentleWave System. <i>Restor Dent Endod.</i> 2016 Aug;41(3):235.	The GentleWave system provides a better solution to endodontic challenges and improves treatment outcomes while maintaining the integrity of the tooth.
36	Kishen A, Peters OA, Zehnder M, Diogenes AR, Nair MK. Advances in Endodontics: Potential Applications in Clinical Practice. <i>J Conserv Dent</i> . 2016 May–Jun;19(3):199–206.	The GentleWave Procedure shows promise for disinfection with minimally instrumented canals.
37	Wang Z, Maezono H, Shen Y, Haapasalo M. Evaluation of Root Canal Dentin Erosion After Different Irrigation Methods Using Energy–Dispersive X–ray Spectroscopy. <i>J Endod</i> . 2016;42(12):1834–1839.	NaOCI followed by final EDTA irrigation performed by the GentleWave System caused minimal dentin erosion.

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#### SUPERIOR OUTCOMES IN COMPLEX ANATOMY

### **Case Reports: Outcomes in Complex Anatomy**

	Citation	Takeaway
38	Chen B, Szabo D, Shen Y, et al. Removal of Calcifications From Distal Canals of Mandibular Molars by a Non- Instrumentation Cleaning System: A Micro-CT Study. <i>Aust</i> <i>Endod J.</i> 2020;46(1):11–16.	GentleWave significantly reduced the volume of calcifications in 100% of the non-instrumented distal canals of mandibular molars.
39	Wang Z, Shen Y, Haapasalo M. Root Canal Wall Dentin Structure in Uninstrumented but Cleaned Human Premolars: A Scanning Electron Microscopic Study. <i>J</i> <i>Endod.</i> 2018;44(5):842–848.	No organic tissue remnants or dentin debris was detected in uninstrumented premolars treated with GentleWave.
40	Ford MW. Utilizing the GentleWave System for Debridement of Undetected Apical Anatomy. <i>J Contemp Dent Pract.</i> 2018;19(3):345–351.	This case report highlights the clinical significance of utilizing GentleWave to clean and debride undetected complex apical anatomy often inaccessible with standard endodontic therapies.
41	Ford MW. Complex Apical Anatomy Revealed Following Endodontic Treatment of a Maxillary Molar Using the GentleWave System: A Case Report. <i>Dentistry</i> . 2017;7(8):446.	Post GentleWave, the previously diagnosed symptomatic apical periodontitis had fully resolved by the three-week follow-up visit. A final radiograph revealed a clinically significant obturation with previously unseen lateral canals and an isthmus within the apical third.
42	DiVito EE, Le KT. Maxillary Molar Healing After Treatment of an Uninstrumented Canal With a Novel Root Canal Procedure: A Case Report. <i>Clin Case Rep.</i> 2017;5(10):1676– 1681.	This case illustrates dentin preservation of a molar with an uninstrumented mesiobuccal-3 canal revealed post-GentleWave and maintained healing at 18 months.
43	Pullen RV. Root Canal Treatment of a Maxillary First Molar With an Uninstrumented Fifth Canal: A Clinical Case Report. J Oral Hyg Health. 2017;5(1):219.	GentleWave was able to clean an unidentified and uninstrumented canal in a maxillary first molar, contributing to the fast healing of the tooth.
44	Vandrangi P, Basrani B. Multisonic Ultracleaning in Molars With the GentleWave System. <i>J Oral Health: Endodontics</i> . 2015;72–86.	GentleWave is more effective in areas with anatomical complexities and in apical thirds compared to conventional treatment methods.



Pre-GentleWave Procedure. Image



courtesy of

Post-GentleWave Procedure. Image Michael Ribera,



GentleWave Procedure Image courtesy of



Pre-GentleWave Procedure. Image courtesy of Karen



Post-GentleWave Procedure. Image courtesy of Karen



post-GentleWave Procedure. Image courtesy of Karen

#### **ACCELERATED TISSUE DISSOLUTION**

The rate of tissue dissolution using the GentleWave System was 7 to 11 times higher than that of conventional methods, including syringe needle irrigation, passive ultrasonic irrigation and laser irrigation.<sup>1</sup>

	Citation	Takeaway
45	Liu H, Shen Y, Haapasalo M. Effectiveness of Six Irrigation Techniques With Sodium Hypochlorite in Tissue Dissolution. <i>Cureus</i> . 2023;15(5): e39208.	GentleWave with CleanFlow was the fastest at dissolving tissue compared to Er:YAG and Er,Cr:YSGG lasers and conventional irrigation.
46	Haapasalo M, Wang Z, Shen Y, Curtis A, Patel P, Khakpour M. Tissue Dissolution by a Novel Multisonic Ultracleaning System and Sodium Hypochlorite. <i>J Endod</i> . 2014;40(8):1178–81.	GentleWave achieved a significantly faster tissue dissolution rate when compared with three other systems examined in vitro.

#### SEPARATED INSTRUMENT REMOVAL

### Evidence of the GentleWave System's ability to remove instruments during treatment.

	Citation	Takeaway
47	Portela NN, Rech JP, Marchionatti AME, Barasuol JC. Techniques to Address Fractured Instruments in the Middle or Apical Third of the Root Canal in Human Permanent Teeth: A Systematic Review of the In Vitro Studies. <i>Clin Oral Investig.</i> 2022 Jan;26(1):131–139.	The removal success rate with GentleWave was lower than that achieved with the ultrasonic technique. However, the GentleWave System method does not compromise dentinal integrity.
48	Wohlgemuth P, Cuocolo D, Vandrangi P, Sigurdsson A. Effectiveness of the GentleWave System in Removing Separated Instruments. <i>J Endod.</i> 2015;41(11):1895–8.	Success rate when the separated files were engaged in the apical region was 61% and midroot region was 83%, with a median time of 10 minutes 44 seconds. Curvature of <30° showed a 91% success rate, while curvature greater than 30° showed a 42% success rate.



Take a closer look at the clinical evidence from GentleWave System studies and case imagery from your peers.

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<sup>1</sup> Liu H et al. (2023) Cureus. 15(5):e3920

<sup>3</sup> Sigurdsson A et al. (2018) J Endod. 44(3):510-517 <sup>4</sup> Haapasalo M et al. (2016) Clin Oral Investig. 20(7):1525-34

<sup>5</sup> Charara K et al. (2016) J Endod. 42(1):135-9

<sup>6</sup> Data on file. Sonendo, Inc. <sup>7</sup> Sigurdsson A et al. (2016) J Endod. 42:1040-48

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