# First clinical trial with successful results

Renens, 07.10.2022. Today, Lumendo announced that they have successfully completed their first clinical trial (ClinicalTrials.gov Identifier: NCT05374434). The single-center, 2-arm randomized controlled clinical trial was conducted at Istanbul Medipol University, Turkiye in collaboration with Prof. Dr. Tan Fırat Eyüboğlu, Istanbul Medipol University, Turkiye and Prof. Dr. Dr. h.c. Mutlu Özcan, University of Zurich, Switzerland, where five patients were treated with inertial cavitation-generating device where the other five received the conventional treatment.[1]

Lumendo has developed the new product in response to the urgent need for a simpler and better debridement and disinfection method for root canals, with the aim to clean root canals even in the deepest portions and the most complex anatomies of the root canals. The goal of the trial was to find out whether patients would develop any pain during and after the treatment as obviously the pulp in the exposed root canal is a highly sensitive area. Finally, the 5 patients whose teeth (all premolars or molars) were treated with the inertial cavitation-generating device did not report more pain than the control group, which was a great success. Although not significant ($p > 0.05$) due to the relatively small sample size of the pilot trial group, the treated patients reported on average 12% less post-operative pain than the control group.

About Lumendo: Incorporated in Switzerland in 2018 as Spin-off of the two Swiss Federal Institutes of Technology – École Polytechnique Fédéral de Lausanne (EPFL) and Eidgenössische Technische Hochschule Zürich (ETH) – Lumendo is a well-recognized upcoming disruptor in the field of endodontics. Focusing on product excellence and a strong innovation stream, the goal of Lumendo is to develop easy-to-apply, reliable, and novel products to treat unsolved medical challenges.

About Istanbul Medipol University, Turkiye: İstanbul Medipol University is highly specialized in clinical and fundamental medical sciences and one of the leading Universities both academically and scientifically in Turkiye. The university's research center "Research Institute for Health Sciences and Technologies" (SABITA) provides a comprehensive research environment that hosts multiple centers and facilities that encompass a wide spectrum of scientific, technical and applied topics from regenerative medicine to neuroscience and drug development to cancer research. Prof. Dr. Tan Fırat Eyuboglu and his team particularly focus on clinical research in Department of Endodontics, collaborating with different academic and non-academic parties around the world.

About University of Zurich, Switzerland: Division of Dental Biomaterials, Center of Dental Medicine at the University of Zurich is specialized in translational and clinical research on studying numerous aspects of biomaterials for tooth-, implant- and mucosa-borne reconstructions. Division of Dental Biomaterials under

[1] Comparative Evaluation of the Effectiveness of Root Canal Preparation After Irrigation Using Endodontic Needle and Inertial Cavitation, [https://clinicaltrials.gov/ct2/show/record/NCT05374434], Aug. 2022.

the leadership of Prof. Dr. Dr. h.c. Mutlu Özcan has also excellent collaboration with the Swiss Federal Institute of Technology in Zurich (ETH) through which various innovative initiatives were realized over the years. In addition to the clinical expertise, her research team focuses on primarily on the development and application of advanced dental biomaterials and devices.

About the technology: Root canal treatments are one of the most difficult treatments for dentists, traditionally with success rates ranging between 46-91%.[2] With more than 60 million annual treatments worldwide, these failures lead to a substantial increase in healthcare costs and many tooth extractions.

One major cause of the treatment failure is the use of endodontic files that may result in root or instrument fractures. Another issue is the inefficient identification and disinfection of the often very complex root canal anatomy. Finally, a major other problem is the obturation of such anatomically complex morphologies with viscous or rubber-like materials that are difficult to be distributed adequately in narrow canals, leading to voids that can be reinfected.

The goal of Lumendo's technology platform is to offer better treatment options to dentists and their patients. The company's first products will be launched in 2024.

Disclaimer: Lumendo's devices are in development and not approved for clinical use under any jurisdiction.

For further information please contact:

Lumendo AG
Chemin du Closel 5
1020 Renens
Switzerland
info@lumendo.ch
www.lumendo.ch

[2] S. Friedman, "Prognosis otooth-, f initial endodontic therapy." Endod. Top., vol. 2, no. 1, pp. 59–88, Jul. 2002.