



Align Technology Shares Findings From New Clinical Study That Validates the Significant Benefits of the iTero Element 5D Imaging System as an Aid in Detection and Monitoring of Interproximal Caries Lesions (Cavities)

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- The study published in the *Journal of Dentistry* confirms that the iTero Element 5D imaging system* with iTero NIRI (Near Infra-Red Imaging) technology is more sensitive than bitewing radiography in detecting early enamel lesions and comparable in detecting dentinal lesions
- iTero NIRI technology of the iTero Element 5D imaging system was 66% more sensitive than bitewing X-ray for detection of interproximal lesions**

TEMPE, Ariz., Oct. 27, 2021 (GLOBE NEWSWIRE) -- Align Technology, Inc. ("Align") (Nasdaq: ALGN) a leading global medical device company that designs, manufactures, and sells the Invisalign system of clear aligners, iTero intraoral scanners, and exocad CAD/CAM software for digital orthodontics and restorative dentistry, today announced the findings of a multi-center clinical study, "Reflected near-infrared light versus bite-wing radiography for the detection of proximal caries: a multicenter prospective clinical study conducted in private practices," published in the peer-reviewed [Journal of Dentistry](#) (Oct. 24, 2021). The study validates and further demonstrates the significant benefits of the iTero Element 5D imaging system as an aid in detection and monitoring of interproximal caries lesions above the gingiva without harmful radiation.

The clinical study was designed to compare the detection of interproximal caries (dental cavities and decay on the proximal surface(s) of adjacent teeth) by dentists using near infra-red technology (NIRI) and bitewing radiography (a dental x-ray designed to show the crowns of the upper and lower posterior teeth simultaneously). The results demonstrated high accuracy ($p < 0.0001$) detection of early enamel lesions (88.6%***) and of carious lesions involving the dentino-enamel junction (96.9%***) (the boundary between the enamel and the underlying dentin that form a tooth).

In addition, the study compared NIRI and bitewing radiography to visual caries debridement (clinical removal of tooth decay). When compared against clinical evaluation of posterior proximal lesions observed during caries debridement, the NIRI technology of the iTero Element 5D imaging system was 66%** more sensitive than bitewing x-ray technology and demonstrated 96%** sensitivity for posterior interproximal lesions detections.

"We are pleased to see the results of these clinical findings further validate what doctors and their patients have experienced. The visualization capabilities of the iTero Element 5D imaging system helps in the early detection of cavities without x-ray radiation," said Yuval Shaked, senior vice president and managing director, iTero scanner and services business, Align Technology. "This study emphasizes the valuable role that the iTero 5D imaging system with NIRI technology is already providing doctors and their staff to support their dental assessments of patients and overall patient oral healthcare and treatment options. When combined with the ease of use and comfortable experience for a broad population of patients, the iTero 5D imaging system with NIRI technology is an essential tool for any doctor's office."

As part of the study, the iTero Element 5D imaging system was used to perform intraoral scans on 100 patients in five dental clinics across Germany and Canada. The iTero Element 5D imaging system includes NIRI technology that scans the internal structure of a tooth (enamel and dentin) in real time that aids in caries detection while simultaneously capturing 3D color images of dentition. Reflected near infra-red light images of posterior (back of the mouth) teeth were used to detect interproximal caries and the results were then compared to bitewing radiography. NIRI was found to be more sensitive than bitewing radiography in detecting early enamel lesions and comparable in detecting dentinal lesions.

Lead study author Dr. Zvi Metzger, Professor, Departments of Oral Biology and Endodontology, at The Goldschleger School of Dental Medicine, Tel Aviv University, commented on the study findings: "Reflected near infra-red light images generated simultaneously during 3D scanning of dental arches with the iTero Element 5D imaging system scanner may be used reliably for detection, screening and monitoring of proximal caries. This method for caries detection may potentially minimize the traditional use of ionizing radiation."

Dr. Peggy Bown, a participant in the study, shared that: "As a current user of the iTero Element 5D imaging system, participating in the study was very beneficial to me. I could further see the clinical value of the iTero Element 5D imaging system through its high sensitivity at detecting early enamel lesions and ease of use. Having one system, one scan, and one tip eliminates the need for multiple devices, repetitive sterilization, and minimizes the use of harmful radiation."

The study described was sponsored by Align Technology.

* iTero NIRI technology is the same across the iTero Element 5D system and some configurations of iTero Element Plus imaging systems since the wand, optics and software are the same.

** Data on file at Align Technology, September 2021

*** Data on file at Align Technology, February 2021

About Align Technology, Inc.

Align Technology designs, manufactures and offers the Invisalign system, the most advanced clear aligner system in the world, iTero intraoral scanners and services, and exocad CAD/CAM software. These technology building blocks enable enhanced digital orthodontic and restorative workflows to improve patient outcomes and practice efficiencies for over 210 thousand doctor customers and is key to accessing Align's 500 million consumer market opportunity worldwide. Align has helped doctors treat over 11.6 million patients with the Invisalign system and is driving the evolution in digital dentistry through the Align Digital Platform, our integrated suite of unique, proprietary technologies and services delivered as a seamless, end-to-end solution for patients and consumers, orthodontists and GP dentists, and lab/partners. Visit www.aligntech.com for more information.

For additional information about the Invisalign system or to find an Invisalign doctor in your area, please visit www.invisalign.com. For additional information about iTero digital scanning system, please visit www.itero.com. For additional information about exocad dental CAD/CAM offerings and a list of exocad reseller partners, please visit www.exocad.com.

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