

Five Facts to Know About Clear Aligner Therapy

Clear aligner therapy has revolutionized orthodontic treatment and has been embraced by practitioners and patients around the world – a revolution made possible by digital technology and newer materials¹ that are simultaneously rigid enough to move teeth, but still flexible enough to be comfortably and easily inserted and removed from a patient's mouth.

Information about clear aligner therapy can be obtained from many sources, not all of which accurately convey important facts that patients and potential patients should know about this orthodontic treatment option. As the category creator and continuous technological innovator, Align Technology takes pride in supporting dental health professionals to help drive progress in dentistry and provide relevant information on clear aligner therapy so patients can make more informed decisions regarding their treatment options. Align markets its products and services to licensed dentists and orthodontists and promotes responsible clear aligner therapy which requires the supervision of a licensed healthcare professional throughout treatment. It does not sell its clear aligners directly to consumers or patients.

1. Moving teeth is a medical treatment

Orthodontic treatment is a medical treatment that moves teeth through the bone of the jaw. This is true of treatment designed to make simple tooth movements and true even if one of the patient's primary goals is improved appearance.

Not all patients are good candidates for orthodontic treatment, including clear aligner therapy. Patients must be assessed for such things as cavities or underlying conditions such as periodontal disease that must be resolved before orthodontic treatment can safely commence. Only an in-person exam by a trained, accredited dentist or orthodontist can make this determination.

If not properly supervised and monitored by a trained, accredited dentist or orthodontist, 'simple' treatments may improve a patient's smile but simultaneously create potentially serious dental problems (even tooth loss)² that may have long term health implications.

2. Clear aligners are medical devices in the same classification as brackets and wires

Just like fixed brackets and wires and braces, clear aligners are medical devices, recommended and fitted by a healthcare professionals and treatment must therefore be planned and regularly monitored by an accredited dentist or orthodontist. The Invisalign® System is classified as a Class IIa medical device in Europe and cleared by both the U.S. Food and Drug Administration and the Australian Therapeutic Goods Administration. In the European Union, the Invisalign System and Vivera™ retainers both bear the CE mark and the 0344 Notified Body number of DEKRA certification, CE 0344.

Treatment using the Invisalign System enables dentists and orthodontists to effectively treat all classes of malocclusions (including complex Class II and III malocclusions) and to efficiently prepare for restorative procedures where relevant to preserve healthy tooth mass and minimize need for extraction and other dental procedures).

¹ Invisalign clear aligner's patented multi-layer aligner material, SmartTrack, is the result of almost 8 years of development and testing 260 different materials.

² Without in-person evaluation of a patient's mouth, gums, teeth and underlying structures by an accredited dentist before treatment begins, careful treatment planning and regular oversight, orthodontic treatment can cause changes in dentition that may harm patients -- negatively affect the bite or soft tissues, or even cause loss of tooth vitality (compromised blood flow that can eventually lead to tooth loss).

3. The Invisalign System can provide effective treatment for a broad range of conditions and a wide range of patient age groups

The product of more than two decades of innovation, Align's Invisalign System is the most advanced clear aligner system in the world³ – able to address a broad range of orthodontic case complexity (including bite corrections and functional changes) and with other devices such as the Invisalign® Palatal Expander System, is able to treat virtually all patient cases for adults, adolescents and children as young as 6 years old.⁴

Clear aligner treatment for younger patients like Invisalign First™ can address necessary functional corrections of the teeth, jaws and arches. Designed specifically for patients with a mix of primary and permanent teeth, these treatments address challenges such as correcting positioning of the upper and lower teeth and providing predictable arch expansion.⁵

4. Patients should have a thorough clinical examination before undertaking any orthodontic treatment, including clear aligner therapy

All orthodontic treatment, including clear aligner therapy, moves a patient's teeth through the bone of their jaw, so before treatment, it is essential that a trained, accredited dentist or orthodontist review the patient's most recent radiographs (x-rays) or other equivalent bone imaging studies to clearly visualize the patient's teeth in the bone of the jaw. This requires an initial, in person office visit. 3D digital scans alone cannot provide data on the conditions of structures below the gumline.

5. Clear aligner therapy requires continuous direct doctor supervision

When used responsibly by trained, accredited dental healthcare providers, digital technologies and tools, including remote doctor-patient consultation (teledentistry) have enormous potential to extend professional care and enhance both patient outcomes and convenience. However, because orthodontic treatment is a complex discipline that involves the movement of a patient's teeth through bone, it is essential that trained orthodontists or dentists are directly involved in patient treatment after the initial examination and assessment. This includes all aspects of treatment planning, prescription and fitting of clear aligners and ongoing monitoring throughout treatment. This oversight is particularly relevant to clear aligner treatment because unlike with removable appliances, the monitoring of patient compliance with the required daily wear time for their clear aligners is essential to achieve the desired outcome.

About Align

Align Technology designs and manufactures the Invisalign® System, the most advanced clear aligner system in the world, iTero™ intraoral scanners and services, and exocad™ CAD/CAM software. For additional information about the Invisalign system, please visit www.invisalign.com.

Company Owned Marks

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³ Data on file at Align Technology, as of September 23, 2020

⁴ Q2 Earnings, July 24, 2024

⁵ Invisalign First Clear Aligners [<https://www.invisalign.com/the-invisalign-difference/invisalign-first>]