# The Premier Aligner
## Clinical Evidence Summary

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# Introduction

In this document, you will find the summarized evidence that supports the claims for the Premier Aligner messaging.

## Topics Covered

**ClearQuartz™**

1. Retention of initial force
2. Retention of shape throughout wear time
3. Durability and resistance to tearing
4. Less initial force application for more comfort
5. Proven stain-resistance

**Performance Trimline**

1. Proven uniform force transmission for accurate tooth movement and root control
2. More retentive and reduced need for engagers for retention

**ClearControl™ Clinical Features**

1. ClearCorrect's Posterior Bite Ramps durability and bite opening

## Expected Use of this Information

1. Offer clinicians concise summaries of evidence that substantiate the performance and benefits of the Premier Aligner, enabling them to make informed decisions based on tests and publications

2. Equip speakers with detailed information on the Premier Aligner's distinctive qualities, such as the ClearQuartz tri-layer material, Performance Trimline, and ClearControl clinical features, to effectively convey these benefits during professional engagements and presentations

3. Equip Speakers to be able to speak through the Premier Aligner messaging related to the qualities, strengths, and differentiators of ClearCorrect's ClearQuartz tri-layer material, Performance Trimline, and ClearControl Clinical features

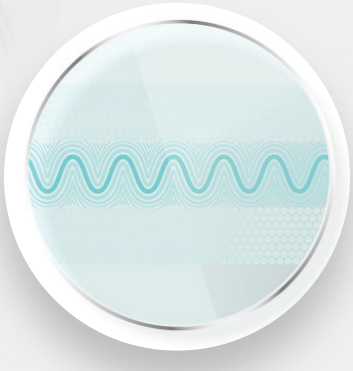
# ClearQuartz™

## Industry-leading material

**ClearQuartz**
**tri-layer material**

**Inner Layer**
**Elastomeric material**

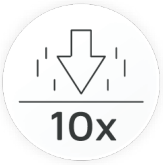
Applies gentle, consistent, and continuous force



**Outer Layers**
**Low-porosity rigid material**

For toughness and stain resistance

# ClearCorrect® aligners retain 10x more of their initial force than competitors, leading to more efficient tooth movement

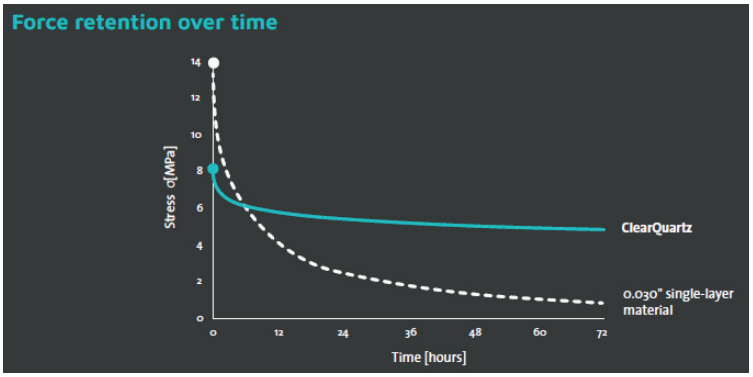



| | |
|---|---|
| **Test Type** | Bench-testing: Stress-relaxation |
| **Test Objective** | To assess the relaxation of different aligner materials (specimens) by observing the stress decrease in response to holding the specimens in a strained condition for some finite interval of time. In this specific assessment, the test specimen is kept under a fixed tensile strain. The test was performed both at room temperature (23 °C) and at simulated mouth temperature (37 °C). |
| **Test Methodology** | The test specimens were clamped with a distance of 40 mm between the grippers. These were elongated in a time window ranging from 1 s to 8 s, until a strain of 1% was obtained. The test specimens were then held in position for 72 h.<br><br>The stress measured at a fixed strain of 1% was measured continuously over time for 72 h. Stress is calculated with a constant cross-sectional area resulting in engineering stress. Mean and standard deviation is then calculated and reported for every outcome measurement and material at 13 representative time frames (0 min, 1 min, 3 min, 6 min, 12 min, 30 min, 1 h, 2 h, 5 h, 10 h, 20 h, 50 h, and 72 h). |
| **Test Publication and Date** | Internal data on file.<br>August 2020. |

## Test Results

| Temperature | 37 °C | |
|---|---|---|
| **Time / Material** | **ClearQuartz** | **Single Layer 0.030** |
| 0 min (Start) | **8.02** ± 0.15 | **13.29** ± 0.30 |
| 72 h | **4.85** ± 0.13 | **0.80** ± 0.08 |
| | Tf/Ti = 0.60 | Tf/Ti = 0.06 |
| | **10x more** | |

Tf: Time final (72 h)
Ti: Time initial (0 min)




Conclusion: ClearCorrect aligners made with ClearQuartz retain 10x more of its initial force than competitors (0.030" single layer polyurethane material).

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# ClearCorrect® aligners retain their shape throughout wear time of the aligner, increasing movement predictability

| | |
|---|---|
| **Test Type** | Bench-testing: Dimensional stability |
| **Test Objective** | To validate the dimensional changes of aligners after cyclic insertion/removal aging by in vitro simulation. A use life of 2 months needs to be validated. The number of insertion/removal cycles was calculated assuming an average of 6 insertions and removals per day. Hence, the average number of insertion/removal cycles per aligner is calculated as 6 times 61 (maximum days of use), i.e. 366. This number was then rounded up to 500. |
| **Test Methodology** | All evaluated samples were produced at ClearCorrect following the validated production workflow. All samples were created with thermoformed ClearQuartz. The aligner samples were conditioned for at least 48 h in deionized water at (37 ± 1) °C. The insertion/removal aging simulations were performed by hand by two operators. For the insertion/removal simulation, each aligner was coupled to a different model, so that for each aligner, a fresh model was used.<br><br>The dimensional stability was assessed by digital analysis of surface mesh data obtained via x-ray computer tomography (CT). CT measurements were performed before and after the aging protocol, thus allowing to estimate the dimensional changes due to repeated insertion/removal of the aligner from a dentition model.<br><br>Acceptance criteria was defined in terms of Average distance ≤ 0.3 mm at 80$^{th}$ percentile. |
| **Test Publication and Date** | Internal data on file.<br>July 2020. |

## Test Results

| Sample | Fit | |
|---|---|---|
| | Avg Distance (mm) | % points ≤ 0.3 mm |
| Aligner 1 | 0.001 | 94.72 |
| Aligner 2 | 0.001 | 94.77 |
| Aligner 3 | 0.001 | 99.94 |
| Average | 0.001 | 96.48 |
| Std Dev | N/A | 3.00 |

Conclusion: ClearQuartz retained its shape throughout wear time of the aligner.

# ClearQuartz™ has proven durability, demonstrating 4x tear resistance


| | |
|---|---|
| **Test Type** | Bench-testing: Determination of tear-resistance |
| **Test Objective** | To determine the ability of a test specimen to resist tearing by pulling two close extremities of a test specimen with a notch in it from each other. It is typically used for testing of plastic film and other polymers. |
| **Test Methodology** | The test was performed at a tensile speed of 200 mm/min until complete rupture of the specimen in two parts. The outcome measurements include tear strength and tear force. Several material specimens were evaluated, including ClearQuartz. |
| **Test Publication and Date** | Internal data on file.<br>August 2020. |

## Test Results

| Material | Tear strength [N/mm] | Tear force [N] |
|---|---|---|
| **ClearQuartz** | **119** ± 21 | 89.0 ± 17.3 |
| **0.030" Single layer material** | **27.0** ± 3.7 | 18.4 ± 3.4 |
| CQ: ClearQuartz<br>SL: 0.030" Single layer material | CQ/SL= 4.41 | |

Conclusion: ClearQuartz has proven durability with 4x tear resistance than 0.030" single layer polyurethane material.

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# ClearQuartz™ applies 1/3 less initial force, enhancing patient comfort during aligner treatment

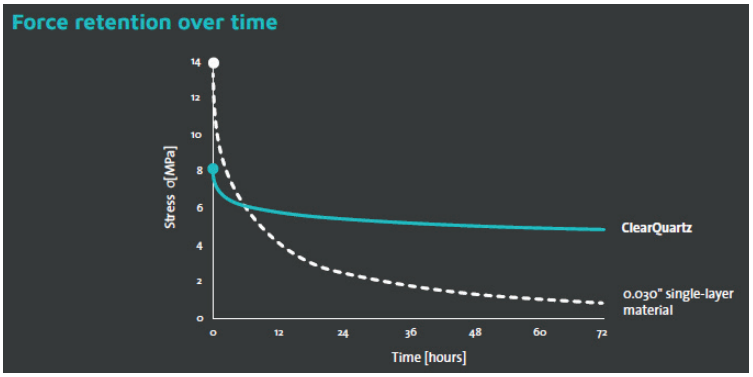
| | |
|---|---|
| **Test Type** | Bench-testing: Stress-relaxation |
| **Test Objective** | To assess the relaxation of different aligner materials (specimens) by observing the stress decrease in response to hold the specimens in a strained condition for some finite interval of time. In this specific assessment, the test specimen is kept under a fixed tensile strain. The test was performed both at room temperature (23 °C) and at simulated mouth temperature (37 °C). |
| **Test Methodology** | The test specimens were clamped with a distance of 40 mm between the grippers. These were elongated in a time window ranging from 1 s to 8 s, until a strain of 1% was obtained. The test specimens were then held in position for 72 h.<br><br>The stress measured at a fixed strain of 1% was measured continuously over time for 72 h. Stress is calculated with a constant cross-sectional area resulting in engineering stress. Mean and standard deviation is then calculated and reported for every outcome measurement and material at 13 representative time frames (0 min, 1 min, 3 min, 6 min, 12 min, 30 min, 1 h, 2 h, 5 h, 10 h, 20 h, 50 h, and 72 h). |
| **Test Publication and Date** | Internal data on file.<br>August 2020. |

## Test Results

| Temperature | 37 °C | |
|---|---|---|
| Time / Material | ClearQuartz | Single Layer 0.030 |
| 0 min (Start) | **8.02** ± 0.15 | **13.29** ± 0.30 |
| 72 h | 4.85 ± 0.13 | 0.80 ± 0.08 |

CQ/SL-1= 0.39

CQ: ClearQuartz
SL: 0.030" Single layer material




Conclusion: ClearCorrect aligners made with ClearQuartz apply 1/3 less initial force than 0.030" single layer polyurethane for enhanced patient comfort during treatment

# ClearCorrect® aligners have been proven to be more stain-resistant than the leading aligner brand

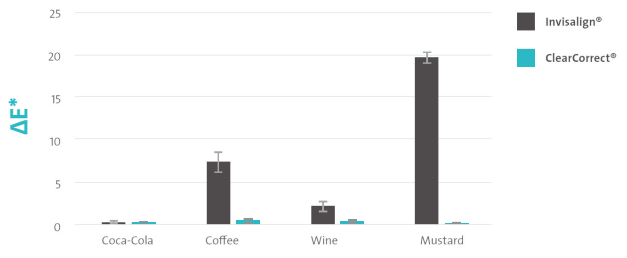
| | |
|---|---|
| **Test Type** | Bench-testing: Stain-resistance |
| **Test Objective** | To assess in vitro the tendency of staining of clear aligners from Invisalign using the SmartTrack® material, and ClearCorrect using the ClearQuartz™ material. |
| **Test Methodology** | Different staining media was used to condition the aligners by full immersion at 37 °C for 24h. Staining agents utilized were: Coffee, Mustard, Cola, and Red Wine. For each staining medium, one Invisalign aligner and one ClearCorrect aligner were fully immersed in the medium and kept at 37 °C for 24h. Samples conditioned in deionized water were used as reference.<br><br>After the staining, sections of aligners were cut on either the incisors or the last molars. These regions allowed collection of relatively flat samples approximately 1 cm x 1 cm, suitable for color measurement in transmission mode. |
| **Test Publication and Date** | Internal data on file.<br>March 2022. |

## Test Results


Aligners immersed in their respective substances for 24 hours at 37° C.

### Test Results: Color change (ΔE) between the aligners after staining

| Aligner system | Staining medium | ΔE* | Color change rating |
|---|---|---|---|
| **Invisalign** | Coke | 0.23 ± 0.21 | Trace – Extremely slight change |
| | Coffee | 7.45 ± 1.17 | Much – Extremely marked change |
| | Wine | 2.17 ± 0.52 | Noticeable – Perceivable change |
| | Mustard | 19.86 ± 0.66 | Very much – Change to other color |
| **ClearCorrect** | Coke | 0.16 ± 0.14 | Trace – Extremely slight change |
| | Coffee | 0.42 ± 0.21 | Trace – Extremely slight change |
| | Wine | 0.34 ± 0.19 | Trace – Extremely slight change |
| | Mustard | 0.14 ± 0.08 | Trace – Extremely slight change |




Conclusion: ClearCorrect ClearQuartz aligners demonstrated to be more stain-resistant than Invisalign SmartTrack aligners. The result of this test may support the hypothesis that the polyurethane elastomer layer (middle layer in ClearCorrect aligner) is responsible for the absorption of staining compounds, as suggested by previous studies.[1,2]

1. Liu, C.-L. et al. Colour stabilities of three types of orthodontic clear aligners exposed to staining agents. Int. J. Oral Sci. 8, 246–253 (2016).
2. Bernard G, Rompré P, Tavares JR, Montpetit A. Colorimetric and spectrophotometric measurements of orthodontic thermoplastic aligners exposed to various staining sources and cleaning methods. Head Face Med. 16, 1–11 (2020).

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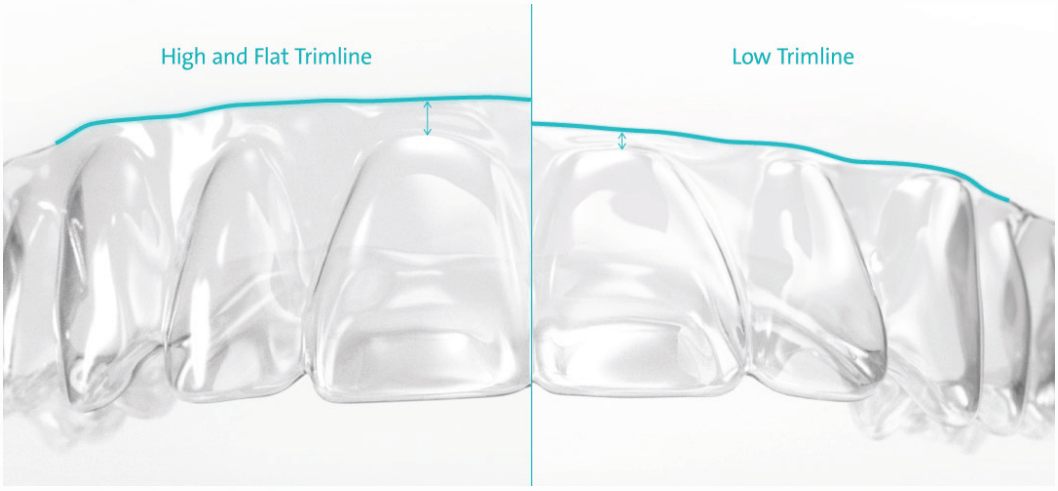
# ClearCorrect

## Performance Trimline

**High and Flat &**
**Low Trimline**



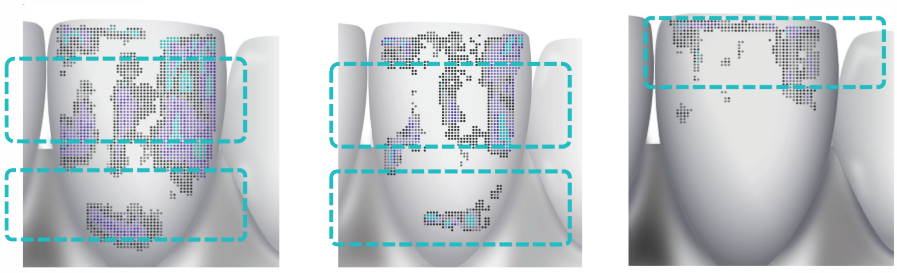
# ClearCorrect's Performace Trimline

## Proven uniform force transmission for more accurate tooth movement and enhanced root control

| | |
|---|---|
| **Test Type** | External Publication: University Hospital Bonn, Bonn, Germany |
| **Test Objective** | To investigate how the stress distribution and forces transmitted from orthodontic aligners to the tooth surface are affected by the geometry and extension of the trimming line.<br><br>The trimming line design could have a significant impact on the clinical outcome of orthodontic aligner treatment. |
| **Test Methodology** | Thirty-six (36) aligners were thermoformed with Zendura FLX sheets (0.75 mm thick) and divided into four groups based on the design of the trimline: Scalloped, Scalloped extended, Straight, and Straight extended. Fuji pressure- sensitive films were used for pressure measurement. The pressurized films were scanned and evaluated. Pressure and forces were measured over the entire facial surface of an upper right central incisor (Tooth 11) and at 7 different locations [cervical, middle, incisal, mesio-incisal, mesio-cervical, disto-cervical, and disto-incisal). In addition, the thickness of the aligners at these 7 sites was measured with a digital caliper. |
| **Test Publication and Date** | Journal of Dentistry: Effect of trimming line design and edge extension of orthodontic aligners on force transmission: An in vitro study - ScienceDirect<br>August 2022. |

# Test Results

**Stress distribution areas over the upper right central incisor using different trimline designs.**



Extended
High and flat

Straight
Low

Scalloped

Conclusion: The extended and straight trimline design exhibited more uniform force transfer and stress distribution across the tooth surface than the other designs. More specifically, applying more forces to the middle and cervical areas, suggesting that due to the increased forces to these areas closer to the center of resistance, it can have an enhanced root control and more accurate tooth movement vs the scalloped design, that applies more forces to the incisal edge of the tooth.

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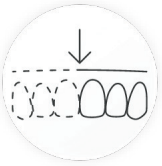
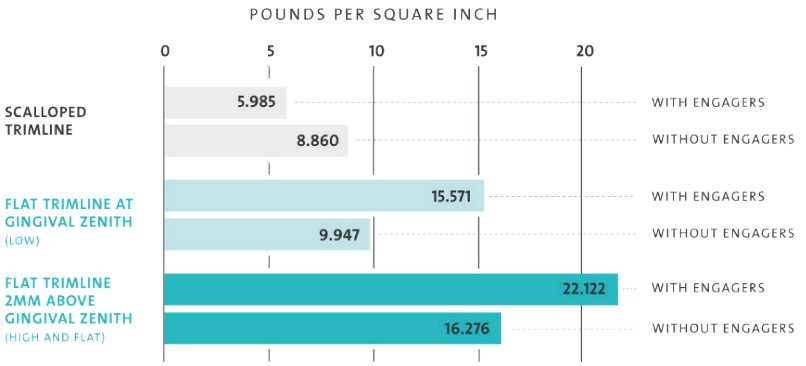
# ClearCorrect® aligners are up to 2.5x more retentive than scalloped aligners, reducing the need for engagers used for retention



| | |
|---|---|
| **Test Type** | External Publication: Thesis, University of Nevada, Las Vegas |
| **Test Objective** | To evaluate the effect of gingival margin design (scalloped vs straight cut at gingival zenith vs straight cut 2 mm above gingival zenith) on the retention of thermoformed aligners. Retention of aligners is a critical requirement for efficient tooth movement. |
| **Test Methodology** | Six aligner designs were fabricated for each of the two used aligner materials (12 total aligner designs). Aligners designs are scalloped, straight cut at gingival zenith (0 mm), and straight cut 2 mm above gingival zenith on a model with attachments. These designs were tested with and without attachments. Three aligners were made for each of the 12 aligner designs for a total of 36 aligners. A Universal Testing Machine was used to pull each aligner off of a Kilgore dentoform in a direction perpendicular to the occlusal plane. The force needed to pull each aligner off of the dentoform was recorded as the retentive force of the aligner. |
| **Test Publication and Date** | University of Nevada, Las Vegas: "Effect of Gingival Margin Design on Retention of Thermoformed Orthodon" by Daniel P. Cowley (unlv.edu)<br>August 2012. |

## Test Results




HF_NoE / S_WithE= 2.72

HF_NoE: High and flat trimline, without engagers
S_WithE: Scalloped trimline, with engagers

Conclusions:
- The 2mm straight gingival margin design (equivalent to ClearCorrect's High and Flat design) had the highest retentive forces.
- The straight cut at gingival zenith design (equivalent to ClearCorrect's Low Trimline design) also had higher retentive forces as compared to the scalloped design.
- It also suggested that the trimline design above or at gingival margin will require less engagers for the purpose of retention.

# ClearControl™

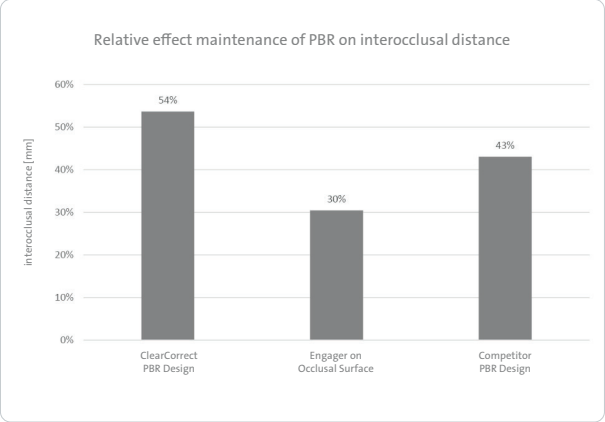
Scientifically-proven
Clinical Features

# ClearCorrect's Posterior Bite Ramps retain 25% more of its shape during stress testing vs other designs in the market and provides 1.7x bite opening area*

| | |
|---|---|
| **Test Type** | Bench testing |
| **Test Objective** | To evaluate the interocclusal distance changes in various Posterior Bite Ramp designs when subjected to worst-case simulated loading conditions (biting on one Posterior Bite Ramp feature). This test aims to compare ClearCorrect's new design with two other designs. This assessment complements a broader lifetime performance verification study to ensure the devices' durability throughout their intended usage duration. |
| **Test Methodology** | The study evaluated three different Posterior Bite Ramp (PBR) designs based on the ClearCorrect dentition model, including the new ClearCorrect design, the use of engagers on the occlusal surface, and a simulated competitor's version. Using the Arcon Articulator Artex CR, the interocclusal distance of these aligner test samples was measured with precision gauge blocks. After preconditioning the samples in deionized water, stress tests simulated a patient biting on a PBR, with specific loading and unloading parameters. Finally, digital microscopic imaging was employed before and after stress testing to inspect the Bite Ramps for any deformations or defects. |
| **Test Publication and Date** | Internal data on file.<br>November 2022. |

## Test Results

| PBR Design | Interocclusal distance (mm) | Effect PBR (mm) |
|---|---|---|
| Reference | 3.65 | - |
| ClearCorrect Three Arch Design | 4.88 | 1.23 |
| Engager on Occlusal Surface | 4.34 | 0.69 |
| Competitor Design | 5.30 | 1.65 |




Conclusion: the initial measurement (T0) showed the competitor's design having the highest interocclusal distance, followed by the new ClearCorrect design, and the engagers on the occlusal surface exhibiting the lowest. Results were as expected due to the placement of the features, where the competitors' PBR were placed on both upper and lower molars and ClearCorrect only on lower molars. Interocclusal distance between the new ClearCorrect design was double vs using engagers on the occlusal surface. After stress testing (T1), all designs showed deformation leading to reduced interocclusal distances. However, relative assessments indicated that the new PBR design from ClearCorrect best maintained its interocclusal distance, showcasing the lowest relative deformation by retaining 25% more of its shape during stress testing.

*As compared to engager shapes on the occlusal surface
Bite ramp loading simulation. Stress loading force level of 195N±5N for first molars and 203 N ± 5 N for second molars for 100 cycles every 0.5 seconds.

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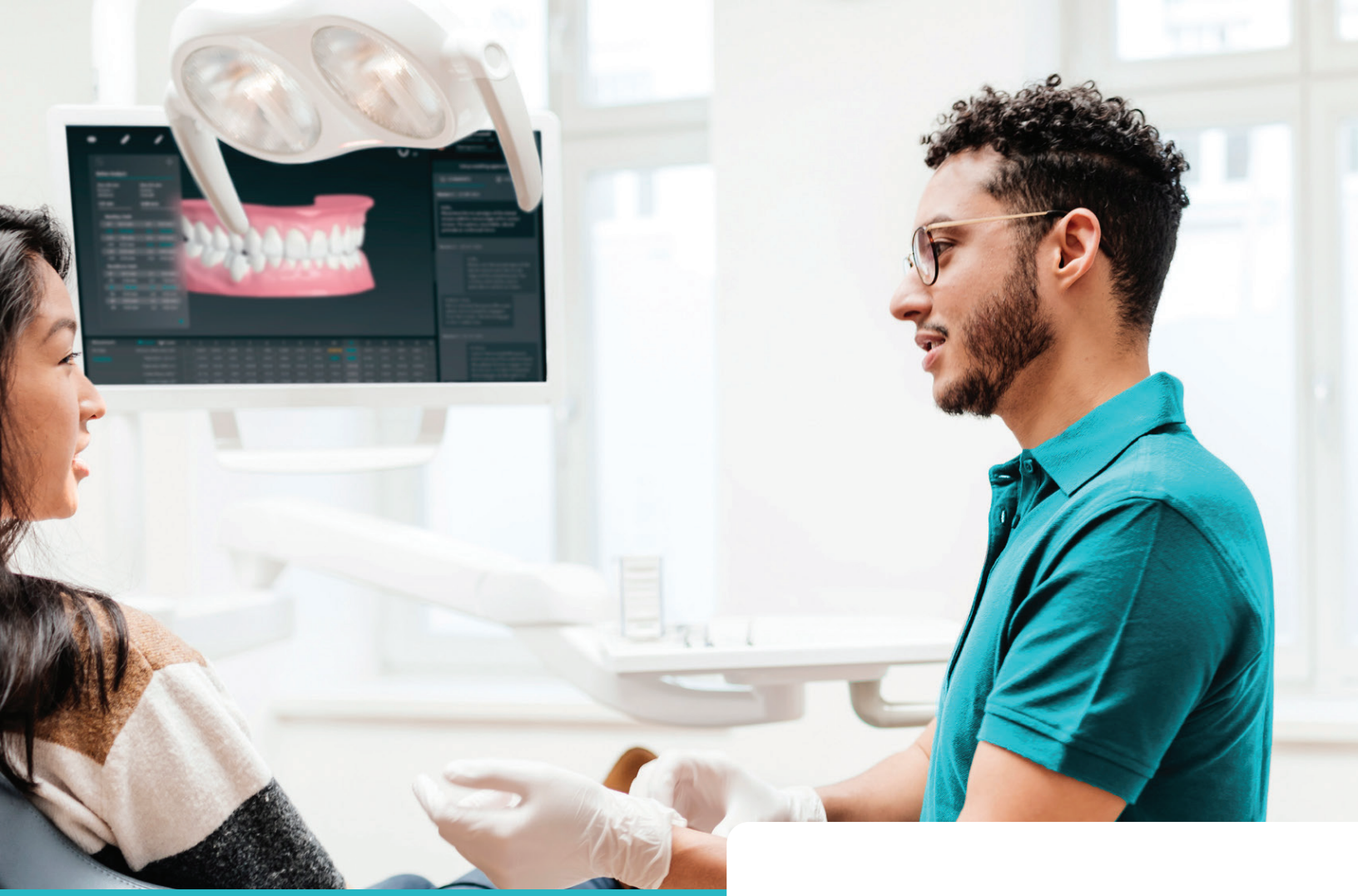

## Get answers.

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