

Damon® Clear™ Clinical Performance Evaluation for Strength, Aesthetics and Comfort

Objective: To validate the clinical performance of Damon Clear in comparison to other self-ligating brackets in terms of strength, aesthetics and patient comfort. **Methodology:** Three multi-site *in vivo* clinical trials were conducted involving 335 patients and 2,010 Damon Clear brackets. In conjunction with the clinical trials, a series of *in vitro* design verification tests were conducted by Ormco engineers to compare various designs of Damon Clear with In-Ovation C and other Damon brackets. These tests were designed to measure torque strength and bracket ear strength, wire rotation, slide retention, occlusal and gingival loading, slide opening force, and tensile and shear debonding force thresholds. In addition, third-party researchers conducted two *in vitro* studies to simulate any *in vivo* wear and evaluate the strength of Damon Clear brackets compared with In-Ovation C and Damon 3. A separate evaluation involved two *in vitro* stain tests using Damon Clear for up to eight weeks using coffee, mustard and red wine as well as various adhesives and primers from different manufacturers. Finally, an *in vivo* debonding evaluation using two independent clinical evaluators was conducted on patients to compare debonding of Damon Clear brackets with debonding of In-Ovation C brackets in terms of ease and patient comfort. **Results:** The reported rate of Damon Clear bracket failures decreased from 3% in the first clinical trial to less than 1% in subsequent trials following adoption of proper wire sequence protocols. During *in vitro* design verification testing comparing Damon Clear with In-Ovation C, Damon Clear showed up to 70% greater rotational strength, 13% greater torque strength, 13% greater tensile debonding strength and 57% greater shear debonding strength. Compared with In-Ovation C, Damon Clear slides were less likely to open in error during treatment. Compared with earlier designs of Damon Clear brackets used in clinical trials, the final production version of Damon Clear showed 73% greater bracket ear strength and 169% more rotational strength. During *in vitro* wear and strength testing, Damon Clear experienced no structural wear after one year of simulated *in vivo* use. Damon Clear was resistant to staining during immersion in coffee, mustard and red wine while all adhesives were found to be susceptible to staining. During debonding testing, clinicians rated Damon Clear as easier to use than In-Ovation C. Patients rated Damon Clear as more comfortable during debonding than In-Ovation C. **Conclusion:** Damon Clear exceeds performance specifications established by In-Ovation C as well as other Damon brackets and is a reliable aesthetic appliance.

Aesthetic self-ligating brackets traditionally feature stainless steel lumen inserts or metallic clips in an attempt to offer the strength and functionality required for the treatment of a full range of orthodontic cases. Unfortunately, such brackets lack the aesthetics that many image-conscious patients demand, prompting them to pursue more limited treatment options such as removable aligners or foregoing treatment altogether.

The culmination of several years of research and development, the new Damon Clear bracket is a translucent passive self-ligation bracket with no metal

insert. The bracket's completely clear design is intended to meet patients' expectations for aesthetics, while its robust construction meets clinicians' needs for functionality and strength. The fully aesthetic bracket body and slide are made of sturdy polycrystalline alumina (PCA), an inert material impervious to staining or discoloration. A unique manufacturing process results in smooth, rounded contours for patient comfort, while a patent-pending laser-etching procedure on each bracket pad delivers optimal bond strength.

The slide of the SL bracket constitutes a fourth wall, which creates a passive lumen to hold the arch-

wire in place with low ligation force while facilitating rotational control. A nickel-titanium (Ni-Ti) spring mechanism maintains the slide in the open and closed positions and keeps the slide from separating from the bracket body. When the slide is opened, it employs reciprocal forces so that the spring or patient's tooth do not absorb any forces.

Based on clinical feedback regarding the performance and reliability of the Damon 3 bracket, Ormco development engineers concluded that engendering market confidence in the new Damon Clear bracket mandated that its strength, aesthetics and comfort be verified through rigorous testing before releasing the bracket to market. Consequently, a comprehensive evaluation process was conducted by in-house development engineers, independent third-party researchers and experienced clinicians. This evaluation included:

- *In vivo* clinical trials
- *In vitro* design verification tests
- *In vitro* wear simulation studies
- *In vitro* staining tests
- *In vivo* debonding evaluations

Throughout each step of the evaluation process, the data gathered helped Ormco engineers make significant improvements to the Damon Clear bracket before finally delivering an enhanced aesthetic passive SL bracket that exceeds the performance specifications of Damon 3 as well as competitive appliances such as In-Ovation C* (DENTSPLY GAC, Bohemia, NY).

***In Vivo* Clinical Evaluations**

Practicing orthodontists in North America and Europe participated in three separate clinical trials to evaluate Damon Clear in terms of strength, aesthetics and clinical performance. In total, 335 patients were bonded using 2,010 Damon Clear brackets.

The first clinical trial involved an early design of the Damon Clear bracket and began December 2008. Thirty-two independent clinical evaluators bonded 1,098 brackets on 183 patients comprised of both adolescents and adults. Each clinician received several sets of maxillary central, lateral and canine Damon Clear brackets in the standard prescription, two SpinTek™ opening/closing instruments and one Damon Clear Debonding Instrument. Clinicians employed initial round wires in one-third of the

cases bonded for the first time. In two-thirds of the cases that started Damon Clear therapy mid-treatment, various dimension finishing wires were used, including .017 x .025 TMA and .019 x .025 stainless steel.

For cases in therapy mid-treatment, clinicians removed their patients' maxillary brackets canine to canine, replaced them with Damon Clear appliances, and then immediately advanced treatment into rectangular wires without dropping back in wire size. Such a protocol is unrealistic in actual practice, but was made part of the evaluation to make the test as rigorous as possible. Replacing six brackets (as opposed to a single lost bracket) also precluded the use of the existing wire as a guide in placing the rebonds. To test the brackets further, some clinicians utilized staff assistants to engage wires.

There were 32 reports of breakage, a 3% breakage rate, with 41% of the evaluating practices experiencing no breakage. The majority of breaks occurred when clinicians made bends in stainless steel wires. Three breaks occurred with patients in round wires. Twenty-nine breaks occurred with patients in archwires larger than .014 x .025.

A second clinical trial began in August 2009 and was comprised of 14 orthodontists who bonded 46 patients mid-treatment with 276 brackets. The orthodontists were instructed to choose any patient whose treatment had progressed to rectangular cross-section archwires engaged in the maxilla at least second bicuspid to second bicuspid. Clinicians replaced brackets canine to canine with Damon Clear, and then progressed with recommended Damon mechanics.

For this clinical trial, doctors were provided with specific instructions on wire sequence protocols. Doctors were reminded to give each wire sufficient time to express itself before progressing to the next wire. For difficult transitions, .016 and .018 Damon Copper Ni-Ti® wires were recommended. For additional anterior torque expression, doctors were instructed to use pre-torqued nickel titanium archwires or make the appropriate bends in TMA or titanium niobium (no more than 20°). When using TMA, Doctors were instructed to use no more than half the width of the wire in any one bend (e.g., .0125 bend in a .025 dimension wire). Bends in stainless steel wires were not recommended.

Using the new wire sequence protocols, only one incident of breakage occurred, representing a failure

rate of less than 1%. A slide broke because the clinician attempted to engage elastic chain to the incisal edge of the bracket with the slide open. Protocol for placing elastic chain underneath the archwire requires that the bracket slide be closed.

The results from the first two clinical trials prompted a root-cause analysis by the Damon Clear development team. Specific attention focused on how to improve the bracket's ability to better accommodate rotational loads. Based on clinical feedback from the first two clinical trials and after analyzing the breakage that occurred, the Damon Clear development team reinforced the bracket in several key areas. These enhancements include a reinforced slide to disperse force levels across a wider surface area and increase tie-wing strength, as well as fortifying the slide window, which results in increased rotational strength.

“We participated in an extensive clinical trial to evaluate the performance of Damon Clear. Patients frequently commented that the bracket exceeded their expectations both in aesthetics and comfort.”

- Dr. Jep Paschal
Madison, GA

The Damon Clear bracket also was increased in size by approximately 5% compared with the design used in the first two clinical trials. Combined, the enhancements resulted in a bracket that delivers 169% greater rotational strength, 11% greater torque strength and 73% greater bracket ear strength than the bracket used in the first two clinical trials.

A third clinical trial was commissioned to test this “enhanced” Damon Clear bracket in April 2010. Twenty-four clinicians evaluated the bracket in terms of clinical efficacy as well as bracket placement and removable placement gauge – or “jig” – functionality.

A total of 106 patients were bonded upper 3-3 with 636 brackets in standard torque prescription. For initial bondings, clinicians could select any orthodontic patient. For rebondings, clinicians selected patients in mid-treatment with a rectangular cross-section wire. Patients were stripped of upper 3-3 brackets and replaced with Damon Clear and a rectangular Damon Copper Ni-Ti or TMA archwire was engaged.

Clinicians also were provided Damon Clear brackets with a newly designed jig on each bracket to help orient brackets. The new placement gauge design features a scaler groove and is approximately 7.1 mm in length from the center of the groove to the tail end.

At the time of this writing, no reports of breakage have been reported during the third clinical trial. In addition, clinicians evaluated the new jigs favorably compared with an earlier design previously available on Damon Q™ brackets. Clinicians pointed out that the new scaler notch aids in bracket positioning and the new tail design makes flash cleanup easier.

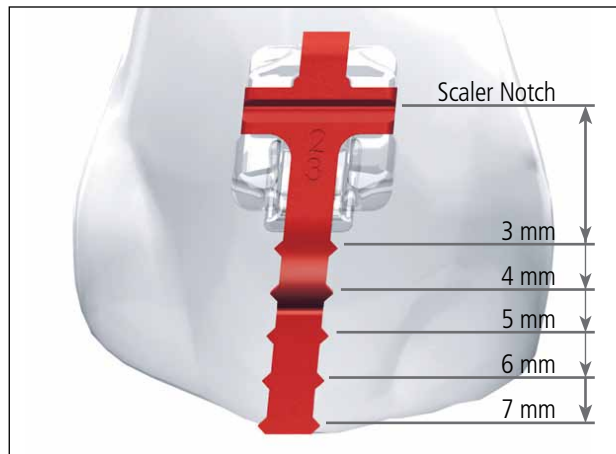


Fig.1 Damon Clear removable positioning gauge.

Table 1. Clinical Trial Summary

	<i>No. of Clinicians</i>	<i>No. of Patients</i>	<i>No. of Brackets</i>	<i>Reported Breakage Rate</i>	<i>Start Date</i>
Clinical Trial #1	32	183	1,098	3%	Dec. 2008
Clinical Trial #2	14	46	276	<1%	Aug. 2009
Clinical Trial #3	24	106	636	0%*	Apr. 2010

*No failures reported at time of publication

In Vitro Design Verification

Ormco routinely conducts rigorous *in vitro* design verification tests (engineering bench tests) on all its appliances during and after development. These tests serve two vital functions: 1) They identify under what stresses and forces these medical devices may fail; and 2) They ensure that brackets meet the design specifications established for their proper functioning in the oral environment.

In developing the final production version of the Damon Clear bracket, Ormco engineers worked in tandem with clinicians during the clinical trials to ascertain root causes of any breakage that occurred. Brackets that failed were analyzed to determine fracture points and to measure the stress levels that resulted in breakage.

Ormco engineers fabricated a number of bracket iterations, all of which underwent the same design verification tests described in this section of the paper. For each iteration, the performance of Damon Clear was compared with other orthodontic brackets that included Damon Q, Damon 3, Inspire ICE™ and In-Ovation C. Damon Q is an all-stainless steel appliance. Damon 3 is a hybrid polycarbonate and stainless steel bracket. Inspire ICE is a conventional twin aesthetic bracket constructed of a monocrystalline alumina. In-Ovation C is an active self-ligating ceramic bracket with a metal clip while Damon Clear is made entirely of aesthetic polycrystalline alumina except for a metallic spring.

The performance statistics of Damon Clear and In-Ovation C reflect actual testing data (average for all brackets in the test) and are recorded in comparison with the specifications for other Ormco brackets as applicable. The following *in vitro* design testing indicates that the final production version of Damon Clear surpasses its established specifications for strength and functionality and compares favorably with the testing data or specifications of comparison appliances.

TORQUE

The purpose of the torque test is to determine the strength of the gingival and occlusal walls of the Damon Clear lumen when a compressive torque load is applied. A critical element of a fully aesthetic ceramic bracket — especially Damon Clear, which for aesthetic purposes has no metal insert — is its ability to withstand torquing bends.

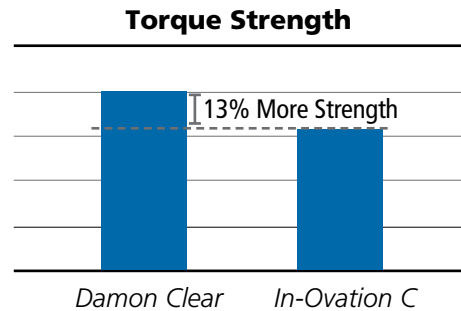


Fig. 2. Damon Clear and In-Ovation C torque strength (in Newtons).

For each test, a bracket was epoxied into a carrier with the occlusal wall of the bracket aligned with the horizontal plane. The slide was removed and a .021 x .025 stainless steel archwire (not recommended for Damon mechanics) secured in the slot with an elastomer. (A .019 x .025 stainless steel archwire will not break a bracket because there is too much play between it and the .022 x .028 slot.) With the carrier secured to a base fixture, a torquing arm was advanced so that it clamped onto the archwire at either end. A symmetrical compressive torquing load was applied to the archwire facially and occlusally until the bracket broke, and the maximum load was recorded.

For the purposes of this test, In-Ovation C was used as the benchmark. The torque strength of the Damon Clear bracket used in the first two clinical trials was comparable to the torque strength of In-Ovation C. After design improvements, the final production version of Damon Clear was 13% stronger than In-Ovation C. The final production version of Damon Clear also exceeded the torque strength of Inspire ICE by 51%.

BRACKET EAR STRENGTH

The purpose of this test is to determine the strength of Damon Clear bracket ears (irrespective of the strength of the slide) when a labial load is applied to the slide in a closed position. The strength of bracket ears is essential when translating teeth while correcting in/out discrepancies. It is important to test the ears independent of the slide (and vice versa) to ensure that each is sufficiently strong.

For each test, the polycrystalline slides of Damon Clear brackets were replaced in the bracket assembly with metal slides designed for testing purposes. The bracket was clamped into a carrier with a vice. Tape was placed

over the assembly and carrier to ensure that the slide remained in its closed position. A .012 ligature wire was engaged through the archwire slot with its ends braided together. The braided ends were clamped into the pneumatic jaw of the loading piston of the force-measuring instrument. A symmetrical tensile load was then applied at a rate of 2 mm/min until the bracket ears failed and the maximum load was recorded (Fig. 3).

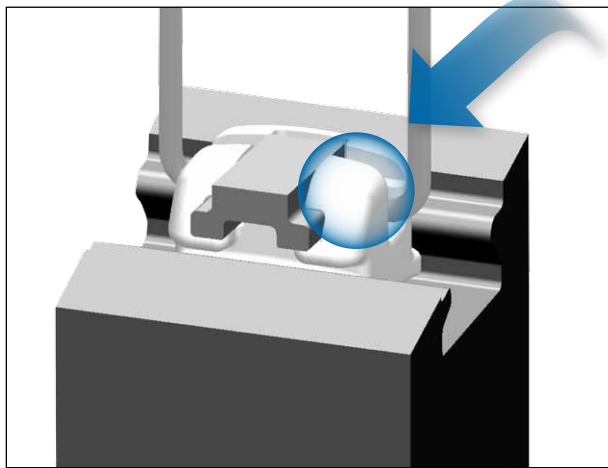


Fig. 3. Bracket ear strength test.

Compared with Damon Clear brackets used in the first two clinical trials, the final production version of Damon Clear was 73% stronger. In-Ovation C was not tested.

WIRE ROTATION

The purpose of wire rotation testing is to challenge the strength of each Damon Clear bracket ear individually with asymmetrical loading, the type of loading that occurs clinically when making rotational corrections. For each test, a bracket was secured into a carrier with a .019 x .025 stainless steel archwire engaged. The carrier assembly was placed onto a torquing gage and the torquing arm advanced so that it clamped onto the archwire at either end. A rotating load was applied to the archwire until the bracket broke and the failure angle and maximum load was recorded (Fig. 4). The process was repeated using different types of wires of the same cross section.

The wire rotation test included the early design of Damon Clear used in the first two clinical trials as well as the final production version of Damon Clear and In-Ovation C. Tooth-specific brackets tested included U1R and U3R.

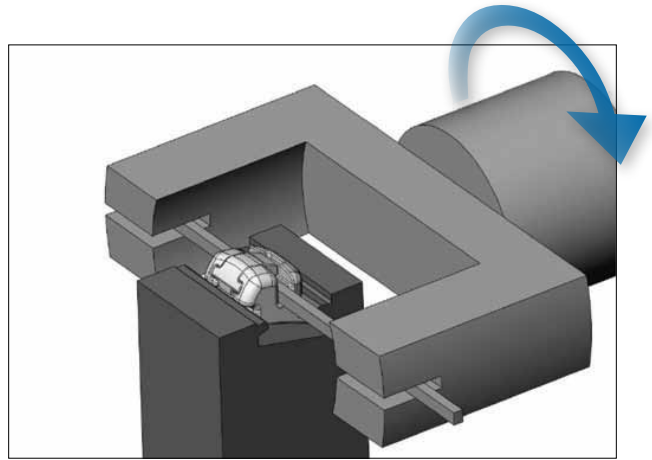


Fig. 4. Wire rotation strength test.

Compared with In-Ovation C, the final production version of Damon Clear withstood up to 70% greater rotational force levels than In-Ovation C. The final production version of Damon Clear also is up to 169% stronger than the earlier design of Damon Clear used in the first two clinical trials. However, while this enhanced version of Damon Clear can withstand substantially greater rotational force than the earlier design, clinicians must continue to be cognizant of the limitations of ceramic material versus stainless steel.

SLIDE RETENTION

The purpose of the slide retention test is to determine the strength of the Damon Clear spring mechanism that maintains the slide in position when the slide is forced beyond its open position. Use of the SpinTek™ Opening/Closing Tool is essential, since it ensures the slide is never forced beyond the open position while allowing the slide opening mechanism to employ reciprocal forces on opening. When using the SpinTek tool, it is impossible to force the slide beyond its open position because there is more travel in the slide than what the opening tool can engage when abutting one side of the slot. This assessment is designed to test for the occasion when another tool (e.g., a Damon 3MX opening tool) is inadvertently employed (not recommended).

For each test, the gingival tie-wings of a Damon Clear bracket were ground off with a diamond grinding wheel. The bracket assembly was epoxied onto a metal ball clamped into a holding fixture with the slide aligned so that the direction of the slide movement was perpendicular to the loading piston of the force measuring instrument. With the slide open, a compressive load

was applied to the slide at the rate of 1 mm/min until the slide spring pin broke, and the maximum load was recorded.

Damon Clear was compared with Damon Q, the only other bracket with the same type of opening configuration. Both the early clinical trial version as well as the final production version exceeded Damon Q slide retention by 13%.

OCCUSAL LOADING

The purpose of this test is to determine the strength of the entire occlusal surface of Damon Clear bracket assemblies when the assemblies are subjected to an occlusal load akin to heavy masticatory forces, especially when a patient chews something hard. For each test, a Damon Clear bracket assembly was epoxied onto a metal ball clamped into a holding fixture so that the occlusal edge was perpendicular to the shearing piston of the force measuring instrument. A compressive load was applied to the occlusal surface of the bracket at a rate of 1 mm/min until the bracket broke, and the maximum load was recorded.

The bracket assembly of Damon Clear withstood 317% greater occlusal forces than Damon Q, 298% greater forces than Damon 3, and 90% greater forces than Inspire ICE. The occlusal loading strength of In-Ovation C was not measured.

GINGIVAL LOADING

The purpose of this test is to determine the strength of the entire gingival surface of Damon Clear bracket assemblies (bracket housing including tie-wings, slide and spring/pin mechanism) when experiencing a heavy gingival load. It is primarily designed to test for brackets that may be bonded upside down (which offers additional torque options, although clinicians would seldom do so with this particular bracket). This test also serves to assess the strength of the bracket under unusual loading, such as when a heavy force is applied to the gingival aspect of the tie-wings via attachment.

A Damon Clear bracket assembly was epoxied onto a metal ball clamped into a holding fixture with the bracket aligned so that the gingival edge was perpendicular to the shearing piston of the force measuring instrument. A compressive load was applied to the gingival surface of the bracket at a rate of 1 mm/min until the bracket

broke, and the maximum load was recorded. Note that the bracket was epoxied in place so that the bracket assembly was tested, not the adhesive bond.

The bracket assembly of Damon Clear withstood 109% greater gingival forces than Damon Q, 52% greater forces than Damon 3 and 4% greater forces than Inspire ICE. The occlusal loading strength of In-Ovation C was not measured.

SLIDE OPENING FORCE

The purpose of this test is to determine the minimum force required to open Damon Clear slides. A sufficient minimum force is required to ensure that slides do not inadvertently open during treatment. The gingival tie-wings of a Damon Clear bracket were ground off using a diamond grinding wheel. The bracket assembly was epoxied onto a metal ball, which was clamped into a holding fixture so that the direction of the slide movement was perpendicular to the loading piston of the force measuring instrument. Beginning with the slide closed, the slide was opened and closed one time at the rate of 1 mm/min with an approximate travel of .026. The minimum force to open the bracket was recorded.

The slide opening force in the early design of Damon Clear used in the first two clinical trials was comparable to Damon Q. After design improvements, the final production version of Damon Clear was 155% stronger than the early design, which means that slides are less likely to open during treatment. In-Ovation C slides required 32% less force, which means they are more likely to open in error during treatment.

TENSILE DEBONDING

The purpose of this test is to determine the bond strength of the Damon Clear laser-etched bonding base when a symmetrical tensile (vertical) load is applied to the slide in a closed position. Clinically, this protocol tests the adhesive bond when translating teeth while correcting in/out discrepancies.

For each test, a Damon Clear bracket assembly was bonded onto a bovine tooth (which were potted in stone within an acrylic ring) with Ortho Solo™ bonding primer/sealant and Enlight™ adhesive, and light-cured for 40 seconds on the mesial and distal sides. A u-shaped .016 round archwire was engaged in the lumen with its ends braided together and clamped into the pneumatic jaw

of a torquing gage. A symmetrical tensile load was applied until the bracket bond failed, and the maximum load was recorded.

The final production version of Damon Clear withstood 13% greater tensile forces than In-Ovation C.

SHEAR DEBONDING

The purpose of this test is to determine the bond strength of the Damon Clear laser-etched bonding base when a shear load is applied to the entire occlusal edge of the bracket assembly with the slide in the closed position. Clinically, this test simulates the bracket under heavy masticatory forces to determine the point at which it will debond when clinicians employ standard bonding practices.

For each test, a Damon Clear bracket assembly was bonded onto a bovine tooth (potted in stone within an acrylic ring) with Ortho Solo bonding primer/sealant and Enlight adhesive, and light-cured for 40 seconds on the mesial and distal sides. With the potted tooth clamped into a holding fixture, the bracket was aligned so that the occlusal edge was perpendicular to the shearing piston of a force measuring instrument. A compressive load was applied to the occlusal surface of the bracket until the bracket debonded, and the maximum load was recorded.

Compared with In-Ovation C, the final production version of Damon Clear had 57% greater shear debonding strength.

In Vitro Wear Simulation Testing

Third-party researchers at the University of Minnesota (Minnesota Dental Research Center for Biomaterials and Biomechanics/Minneapolis) conducted rigorous *in vitro* testing to simulate the oral environment for *in vivo* wear and strength of Damon Clear. This “artificial mouth” accelerates life testing of dental materials. In the span of 42 hours, it can conduct 300,000 cycles of chewing to accurately replicate a one-year time period within the mouth.

The researchers conducted two rounds of tests. The purpose of the first round was to establish a baseline for the testing rigor of round two. Round one testing included Damon 3 and Damon Clear. Given the extent of the clinical experience with Damon 3, it was used

during the first round to correlate the *in vitro* simulation protocol with *in vivo* experience.

After establishing a baseline for the adequacy of the testing rigor in round one, the researchers appreciably increased the occlusal forces for round two in order to stress the brackets to an even greater extent. Round two was expanded to include In-Ovation C. Damon 3 would again be used as a control to judge the rigors of the testing protocol.

WEAR TESTING PROTOCOL

The researchers performed wear tests using a proprietary laboratory testing machine constructed specifically for testing dental materials. The testing machine employs a mixture of three abrasive ingredients and simulates mastication in the oral environment (Fig. 5).

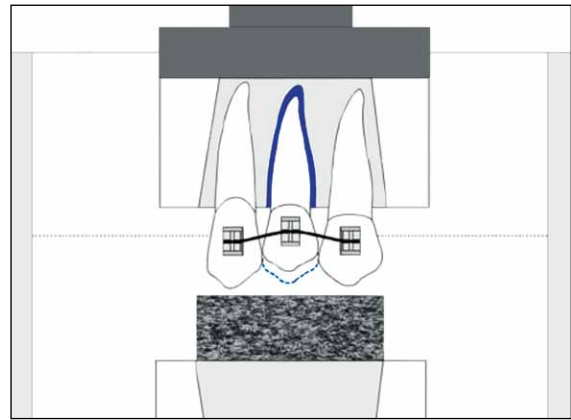


Fig. 5. Schematic of laboratory wear testing apparatus.

For each test, three bovine teeth were potted in a mounting ring using orthodontic resin, and then affixed to the upper, moveable platen of the testing machine. The upper moveable platen comes in contact with a compliant element in the lower portion of the environmental chamber during the test. The teeth were aligned at an angle to ensure that when the brackets contacted the opposing compliant element, they experienced sufficient abrasion and force in both transverse and occlusal direction.

The compliant element captured the abrasive materials from the solution against which the teeth and brackets (when bonded) came into contact. The solution was comprised of two highly abrasive materials: ceramic beads 1.0 mm in diameter and fractured ceramic cubes of approximately 0.1 to 3.0 mm in size mixed in

deionized water. Brackets were bonded using orthodontic adhesive without primer/sealant. A .019 x .025 stainless steel wire was engaged to tax them with appropriate force.

To achieve the greatest possible bracket wear, the simulated chewing employed a tangential motion. Occlusal forces were increased throughout the tests to tax the brackets with greater abrasion. The force levels documented represent total force. Because the total occlusal force is distributed over three teeth, the approximate force applied to each tooth is the total force divided by three. The excursion depth is 1.0 mm and the chewing frequency (set at 1.0 to 2.0 Hz) was increased once during the testing to shorten testing time.

The researchers photographed the brackets and took 3-D digital surface scans (the entire bracket and a cross-section) of each one in position prior to testing, at various increments throughout testing and at the end of each test. The 3-D scans taken during testing demonstrated subtracted surfaces for wear comparison analysis not discernable to the naked eye.

A light coat of Magnaflux* Spotcheck SKD-S2 (Magnaflux, Glenview, IL) was applied to the brackets prior to scanning. This coating is a reflective material detectable when exposed to the optical scanner.

Wear in the ranges designated by turquoise and blue fall within the margin of error (tolerances) for the scanner. Wear in the ranges designated by purple and fuchsia represent a significant decrease in height relative to the baseline and signify considerable wear.

Black indicates areas that are out of the range of the scanner. Out-of-range readings usually occur for one of two reasons: 1) There are concave bracket contours the surface scanner cannot read (e.g., the space between

the Damon Clear slide and the bracket body; or 2) The wear is so excessive that it is off the measurement scale. The depth at which the scan is projected is determined based on the extent of the wear being analyzed.

The 3M* ESPE* Lava* ST (3M/ESPE, St. Paul, MN) scanner employed for these tests is a non-contact, optical 3D-scanning device. Its operating principle is based on fringe projection combined with triangulation methods. A fringe pattern is projected onto the surface of the bracket and imaged by a video camera under a certain angle. Different views are superimposed to capture the entire surface, a procedure that captures high-density data for optimal accuracy.

**ROUND ONE TESTING:
DAMON CLEAR AND DAMON 3**

Two consecutive tests were run with the same brackets, teeth and setup. Damon 3 was bonded upside down so that the polycarbonate surface would experience the most abrasion. At 400,000 cycles and a load of 2 N, the Damon 3 bracket began to exhibit wear. Since Damon 3 was used to determine that the *in vitro* testing is sufficiently aggressive, the mean occlusal load was increased from 2 N to 10 N for the next 540,000 cycles. After 940,000 cycles (400,000 cycles at ~2 N and 540,000 cycles at ~10 N), Damon 3 exhibited wear similar to that seen clinically. The 3-D surface scans exhibited significant wear on the Damon 3 bracket exceeding 0.25 mm, specifically on the acrylic tie-wings. This wear indicates that the aggressiveness of the test was sufficient to simulate the extent of wear seen clinically with Damon 3 in the oral environment. Damon Clear showed no visible wear even at the end of the 940,000 cycles, which was corroborated by 3-D surface scans.



Fig. 6. Wear comparison at ~40 N.

**ROUND TWO TESTING:
DAMON CLEAR AND IN-OVATION C**

Given that the round one testing methodology was sufficient to produce wear on the Damon 3 bracket similar to that experienced clinically, the researchers increased the aggressiveness of the next round of experiments to test three brackets beyond what clinicians would expect to see *in vivo*. Damon 3 served as the control for testing Damon Clear and In-Ovation C. For the second test, the mean occlusal load was increased to ~40 N for 300,000 cycles.

Photographs and 3-D surface scans (entire brackets and cross-sections) were taken before the test and at various cycles. Fig. 6 depicts the three brackets in position before the test and after 200,000 cycles and 300,000 cycles at ~40 N. Fig. 7 depicts Damon Clear after 200,000 cycles at ~40 N and Fig. 8 after 300,000 at ~40 N. The photographs demonstrate the clarity and translucency of Damon Clear even after such rigorous wear testing.

After 300,000 cycles, the Damon 3 bracket demonstrated significant wear although it neither delaminated nor debonded. Fig. 9 depicts the 3-D scan of the sub-



Fig. 7. Damon Clear after 200,000 cycles at ~40 N.



Fig. 8. Damon Clear after 300,000 cycles at ~40 N.

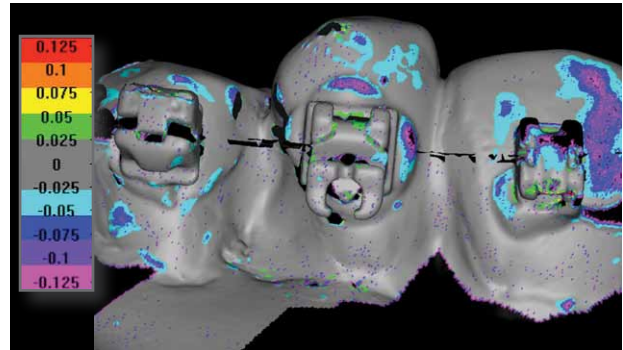


Fig. 9. 3-D scan of subtracted surfaces after 150,000 cycles at ~40 N.

tracted surfaces of all brackets after 150,000 cycles at ~40 N with a depth range from -0.125 to +0.125 in increments of 0.025. This scan indicates Damon 3 wear consistent with that seen in the photographs including significant wear (purple and fuchsia) on various aspects of the bracket as well as areas so worn on the maxillary tie-wings and above the slide that they are out of range (black). Neither In-Ovation C nor Damon Clear exhibited wear, although the slide coating of In-Ovation C wore off. (The black out-of-range areas on Damon Clear are at the slide opening and where the wire had been engaged in the lumen)

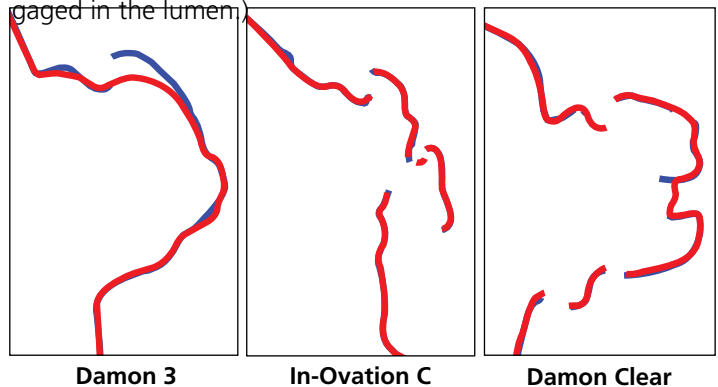


Fig. 10. Cross section of 3-D scans of subtracted surfaces after 150,000 cycles at ~40 N. Damon 3 bracket shows wear while In-Ovation C and Damon Clear show no wear.

Fig. 10 depicts the 3-D subtracted surfaces scan of a cross section of Damon 3 after 150,000 cycles at ~40 N. The blue outline indicates the original surface prior to testing. The red outline is the surface after cycles and demonstrates significant wear. In the cross-sectional graph, wear was estimated to be approximately .5mm — or roughly twice as much as what was seen during the first

round of tests. Neither In-Ovation C nor Damon Clear demonstrated any appreciable wear at any stage of the testing. Fig. 10 depict the 3-D scans of the subtracted surfaces of In-Ovation C and Damon Clear, respectively, after 150,000 cycles at ~40 N with a depth range from -.0.125 to +0.125, validating lack of wear in either of these two brackets.

The results of the artificial mouth study demonstrate that Damon Clear has much greater structural integrity than Damon 3 and is comparable to In-Ovation C after one year in the oral environment.

***In Vitro* Stain Testing**

Two *in vitro* stain tests were conducted with Damon Clear using various adhesive primers and light-cured adhesives from different manufacturers:Ormco, 3M Unitek (Monrovia, CA), DENTSPLY GAC and Reliance Orthodontic Products (Itasca, IL).

The first stain test lasted eight weeks and involved bonding 32 Damon Clear brackets using eight different primer/adhesive combinations to bovine teeth. The teeth were pumiced, etched for 40 seconds with phosphoric acid, primed and bonded with one of the eight primer/adhesive combinations, and then light-cured for 40 seconds on each side, mesially and distally.

Once bonded, each primer/adhesive type was placed in each of four testing mediums: room temperature (70° F) tap water (as a control), coffee, mustard and marginal staining fluid used for materials testing in a laboratory setting. The staining fluid is permanganate, a general name for a chemical compound containing the manganate (VII) ion. It is deep red in color and significantly more potent than red wine.

For each of the testing periods, the teeth were removed from the fluids, rinsed with water, brushed with a soft toothbrush and Colgate* toothpaste (Colgate-Palmolive, NY, NY), rinsed again, blown with air to dry quickly, and analyzed for visible staining with the naked eye and under a microscope.

The stain test employed the following adhesive/primer combinations:

- Transbond* XT adhesive and Transbond MIP primer (3M Unitek)
- Transbond LR adhesive and Transbond MIP primer (3M Unitek)
- Enlight adhesive and Ortho Solo primer (Ormco)

- Blüglöo™ adhesive and Ortho Solo primer (Ormco)
- Neobond* (DENTSPLY GAC) and Ortho Solo primer
- Pad Lock* adhesive (Reliance) and Ortho Solo Primer
- Pad Lock adhesive with Fluoride (Reliance) and Ortho Solo primer
- FlowTain* adhesive (Reliance) and Ortho Solo primer

No brackets, slides or adhesives exhibited any discoloration when placed in room-temperature tap water.

For brackets placed in mustard, no adhesive exhibited staining visible to the naked eye nor did mustard stain any bracket or slide.

For brackets placed in coffee, neither Transbond LR, Transbond XT, Blüglöo nor Enlight exhibited adhesive discoloration. Neobond, Pad Lock, Pad Lock with Fluoride and FlowTain exhibited adhesive staining visible to the naked eye. Coffee did not stain any bracket or slide.

The marginal staining liquid significantly stained each of the adhesive types. It did not stain the brackets or slides. However, after sustained immersion for eight days and two months, respectively, fluid was observed in two brackets between the mesial/distal sides of the slides and the bracket body where some patients may experience difficulty brushing or flushing clean with water.

A second *in vitro* stain test was conducted with Damon Clear for four weeks and again involved various adhesive combinations: Blüglöo with MIP primer, Transbond XT with Fluoride and MIP primer, and Pad Lock with Fluoride and MIP primer. This time, Inspire ICE brackets were added as a control group. The sample size consisted of 180 Damon Clear brackets.

Three brackets from each combination were removed at one-week intervals for observation. After one week of submersion, adhesives showed signs of staining around the bracket base where adhesives are often exposed to coffee, mustard and wine. No staining of either Damon Clear or Inspire ICE was observed at any time during the study.

Similar to what occurred in the first stain study, particles in the slides of a few Damon Clear brackets were observed. This often occurred as a result of the slide remaining open during prolonged immersion. Brushing the bracket and flushing the slide with water were often effective at removing the particles. However, particles on a small number of brackets (4%) were extremely difficult to remove and required sonication in acetone and alcohol.

It is important to note that submerging brackets 24 hours a day, seven days a week for eight weeks in mustard, coffee and red wine is not representative of patients' everyday activities. While normal consumption of foods and staining liquids may have no actual effect on the inert ceramic material of Damon Clear brackets themselves, popular adhesives on the market are all susceptible to staining. Damon Clear is resistant to staining, but its translucent properties may reflect visible staining of teeth or adhesives. In addition, patients who do not practice proper hygiene may be more likely to experience food particles and staining liquids stuck in the slide channels of Damon Clear. Consequently, clinicians need to alert Damon Clear patients to the importance of proper hygiene and to limit or even eliminate their consumption of liquids that may stain adhesives.

In Vivo Debonding Testing

The objective of the debonding evaluation was to assess the debonding of Damon Clear brackets compared with In-Ovation C in terms of ease and patient comfort.

Two independent clinical evaluators (an orthodontist and a clinical assistant) and 22 volunteer patients with acceptable oral hygiene participated in the evaluation. The volunteers had six brackets direct-bonded to their upper incisors and cuspids and were debonded approximately two weeks later. Each evaluator debonded 11 patients.

The evaluators bonded each patient with three Damon Clear brackets and three In-Ovation C brackets. Half the patients had Damon Clear brackets bonded to the maxillary left quadrant and In-Ovation C brackets bonded to the maxillary right quadrant, while the other half had the reverse combination. The brackets types were not identified to the patients. The evaluators used the new Damon Clear Debonding Instrument for debonding Damon Clear. They followed the In-Ovation C debonding protocol prescribed by DENTSPLY GAC. Instruments were collected and inspected upon completion of the clinical trial for evidence of any wear at the tips.

The clinical evaluators rated their debonding experience with each bracket based on ease, efficiency (number of attempts) and overall experience on a rating scale of 1 to 5 with 1 being difficult and 5 being easy.

Patients rated their debonding experience with each bracket based on comfort, efficiency (number of attempts)

and overall experience on a rating scale 1 to 5 with 1 being very uncomfortable and 5 being very comfortable.

Evaluators rated Damon Clear as 82% easier to debond than In-Ovation C brackets (Table 2).

Table 2. Clinician Ease of Debonding

	<i>Damon Clear</i>	<i>In-Ovation C</i>
UR3	4.73	3.00
UR2	4.65	2.27
UR1	4.50	3.00
UL1	4.83	2.50
UL2	4.64	1.91
UL3	4.82	2.82
Average	4.70	2.58

(1=Difficult – 5=Easy)

In terms of comfort during debonding, the patients rated Damon Clear as 38% more comfortable than In-Ovation C brackets (Table 3).

Table 3. Patient Comfort During Debonding

	<i>Damon Clear</i>	<i>In-Ovation C</i>
UR3	4.64	3.64
UR2	4.45	2.91
UR1	4.30	3.67
UL1	4.67	3.10
UL2	4.00	3.10
UL3	4.27	3.64
Average	4.39	3.19

(1=Very Uncomfortable – 5=Very Comfortable)

The length of time involved to debond brackets was found to be up to three times longer for In-Ovation C brackets, which required flash removal using a burr or scaler prior to debonding as recommended by DENTSPLY GAC. In contrast, the Damon Clear Debonding Instrument does not require flash removal prior to removing brackets.

In-Ovation C brackets also were more prone to bracket fractures during removal. In some cases, a diamond burr was used to remove remnants of fractured bracket-

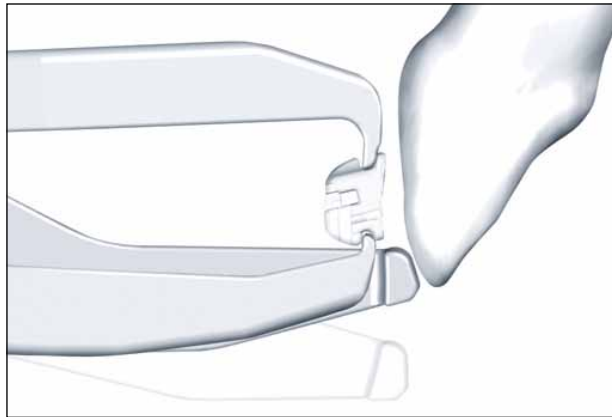


Fig. 11. Damon Clear Debonding Instrument1.

ets from patients' teeth. Clinicians need to be cognizant of the risk of enamel damage during this process. Damon Clear brackets were found to be less susceptible to bracket fractures for improved patient safety.

Finally, because no flash removal using a burr or scaler is required prior to removing Damon Clear brackets,

the Damon Clear debonding process was found to be considerably more efficient than In-Ovation C.

Conclusion

A series of clinical trials, third-party laboratory testing and design verification tests demonstrate that Damon Clear surpasses established specifications in all clinical performance categories including wear and strength, torque and rotational control, resistance to staining, and debonding ease and patient comfort. The Damon Clear bracket outperformed design specifications of the Damon 3 bracket as well exceeded many performance specifications of In-Ovation C. Furthermore, the final production version of the Damon Clear bracket offers increased wire rotational strength compared with the earlier designs used in the first two clinical trials. Damon Clear is a reliable appliance for clinicians looking to offer patients aesthetic treatment.