In-Ovation X

Self-Ligating Metal Bracket Design Features and Advantages

White Paper by
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Research & Development Team

Dentsply Sirona
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Objective

To highlight the advantages of In-Ovation X in comparison to other self-ligating brackets in terms of:
1) Calculus interference
2) Clip Retention
3) Reduced Overall Bracket profile

Introduction

Metal self-ligating brackets have become progressively favorable in orthodontic treatment due to their efficiency in treatment and advantages realized by both the clinician and patient. Various aspects of self-ligating brackets have been studied in order to evaluate their function and properties.

A key objective of self-ligating brackets is to translate adequate forces during orthodontic treatment in order to obtain optimal tooth movement and tissue response[1]. However, the bracket performance is reduced by many factors such as undesired bond failure[2], deformation of the bracket's clip resulting in inadequate force on an active archwire and overall clinically unacceptability[3]. Additionally, calculus interference on the exposed gingival end of the clip can interfere with the desired clip functionality. In order to prevent premature bracket failures, the open and close forces of the clip and the ideal profile need to be known so the occlusal bond strength can be optimized to prevent premature bond failures.[2, 4] Lastly, having insight on bracket performance due to the obstruction of calculus helps reduce the risk of clip and bracket failures.

The Dentsply Sirona Marketing Team has extensively surveyed orthodontists to find the ideal needs and improvements to current self-ligating brackets.

Currently, brackets such as the In-Ovation R and Empower 2 (American Orthodontics) are common in orthodontic care. However, through extensive voice-of-customer analysis, it was found that calculus interference was a key disadvantage to self-ligating brackets. Often the influence of calculus resulted in clip failures if not cleaned properly. In addition, it was found that orthodontists prefer a single opening mechanism versus having a secondary opening mechanism (exposure of clip whale tail on gingival end).

To our knowledge, there have been no studies in measuring clip open forces with the interference of calculus on self-ligating brackets. The aim of this investigation was to compare the opening forces between three different self-ligating brackets and measure what influence calculus may have on the forces required to open the clip. The null hypothesis of the study was that there will be significant differences amongst the group of clips tested.

Product Design

The In-Ovation X self-ligating bracket has been designed to optimize various key design parameters such as:

- Eliminate calculus interference with closed gingival end
- Reduce profile height
- Single designated opening mechanism improves resistance to deformation

Calculus

Three different metal self-ligating brackets were tested: In-Ovation X (Dentsply Sirona), In-Ovation R (Dentsply Sirona) and Empower 2 (American Orthodontics). Each one of the brackets had artificial calculus applied on the gingival end of the bracket. A key difference between the 3 brackets (Figure 1a) is, In-Ovation R and Empower 2 both have a clip design which protrudes out the body and is exposed on the gingival end of the base, whereas In-Ovation X has an enclosed clip channel resulting in no exposure of the clip.

To conduct this study, Dentsply Sirona engineers worked in tandem with clinicians to ascertain the effect of calculus on self-ligating brackets. After thoroughly researching calculus and its effect on orthodontic brackets, it was determined that there was a need for a calculus solution. The In-Ovation X solution was to close off the gingival end of the bracket and eliminate its interaction with calculus. To test this a bench test method needed to be developed in order to satisfy the need by the Dentsply Sirona engineering team. A procedure was then created and reviewed by several orthodontists to validate its clinical relevance. The test entailed the following steps for each bracket system:

- Applied artificial calculus to the bracket
- Allowed adequate drying time (3 days)
- Cleaning of brackets (depending on group, utilize a cavitron)
- Clip open tests measuring the force required to open the clip

In-Ovation X **In-Ovation R** **Empower 2**

Figure 1a: Image presents a view of each bracket on the gingival end (mesial).

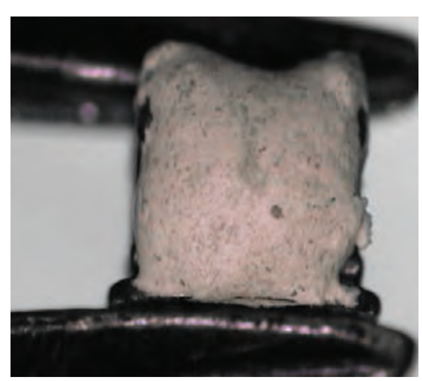


Figure 1b: Calculus buildup

The Dentsply Sirona engineering team then consulted with clinicians to identify bracket and tooth locations which are most prone to calculus build up. The feedback received together with a literature review indicated that the mandibular anterior teeth are most prone to calculus development on orthodontic brackets[5]. Therefore, lower right 1 brackets were chosen for this test.

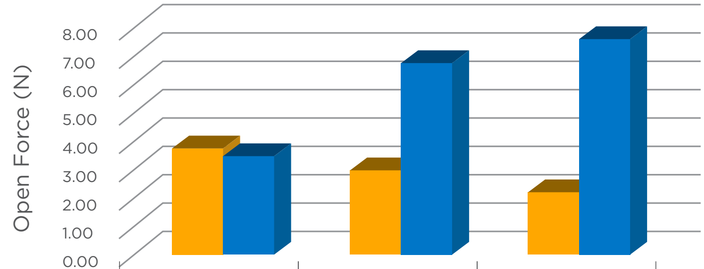
To evaluate the initial opening forces of the clips a valid design verification test procedure was conducted. In this test the bracket is securely fastened to the lower crosshead of the Instron using a custom fixture (Model 5943, Instron Industrial Products, Grove City, PA USA). A specified tool (scaler or wire) was used as an opening for each individual bracket on the Instron test procedure.

To evaluate the opening forces with the presence of calculus the same validated design verification test procedure and equipment were used with the presence of calculus. (Artificial calculus, produced internally by a division of Dentsply Sirona - Dentsply Professional, York, PA USA). The resulting calculus solution was then evaluated by Dr. Celestino Nobrega to confirm its equivalence in texture, form and adhesion to that of actual calculus. A consistent amount of calculus was then applied for each bracket on the gingival end (Figure 1b). It was then weighed to ensure it was within specification. Each bracket was then allotted a drying period of 3 days for the calculus to fully harden. Finally, the samples were prepped for the clip opening test. Initial clip opening force and post calculus application forces were evaluated.

Results:
A significant increase in forces were found between initial and post open forces for Empower 2 (up to ~225%) and In-Ovation R (350%). However, there was no significant increase in force before and after the application of calculus for In-Ovation X.

Clip Retention

The purpose of this study was to focus on the clip retention force between the three self-ligating brackets. A correlation was created by Dentsply Sirona Engineers between the minimum force required to apply force on a common active archwire (.018x.025" for 0.022" slot brackets) and the clip opening force requirement.



	In-Ovation X	Empower 2	In-Ovation R
Control	3.73	2.99	2.18
Calculus	3.47	6.73	7.60

Figure 2: In-Ovation X had no significant change in open force post application of calculus. Empower 2 increase force by 225% post application of calculus. In-Ovation R increase force by 350% post application of calculus.

Figure 3: Clip resting on active archwire (0.019" x 0.025").

Figure 4: Displays position of clip in open state.

The function of self-ligating clips is to enclose orthodontic archwires in the slot of the bracket. More importantly, active self-ligating clips also need to keep the active archwires in the corner of the slot by exerting forces higher than the archwire forces (See Figure 3) [1,3].

Clinically, clip open force is an indicator of clip force on the archwire (see Figure 4). Qualitatively, the stiffer the clips are, the higher the force they apply on the archwires. Therefore, a higher open force is experienced. If clinicians feel the open forces are adequate, they reasonably assume the clips have enough force to hold the archwires in place. If they feel the open forces are too low, they assume the clips are too loose and the clips are not able to hold the archwires appropriately.

The test method included:

- Quantitative relations between the clip forces on active archwires and the clip open forces are derived.
- The minimum open forces needed to hold the BioForce® PLUS archwire are calculated.
- The clip open force lower limit specifications are set based on the theoretical calculation.

Force relations are illustrated in Figure 5. The definitions below will be used:

Horizontal direction	Parallel to bottom of the clip.
Vertical direction	Perpendicular to the horizontal direction.
Fo	Clip open force, horizontal direction.
N	Normal force on clip by the archwires.
F1	Component of N at vertical direction when the clip is on the archwire at the closed position.
F2	Component of force on the clip at vertical direction when the clip is at clip stop.
u	Coefficient of friction.
f	Friction force at clip stop and bottom of bracket, horizontal direction same as open force.
K	Stiffness of clip.

The following geometric parameters were obtained from CAD models.

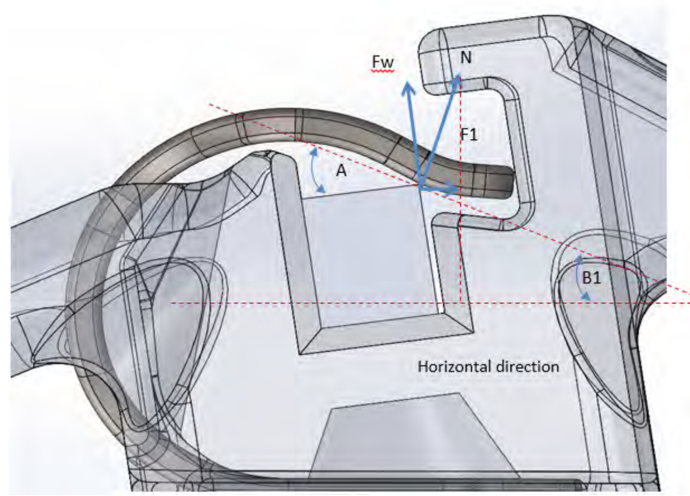


Figure 5: In-Ovation X bracket theoretical calculation markup.

C0	Initial clip span
C1	Clip span when clip is on the archwire
A	Angle between bottom of slot and tangent line at clip touch point when the clip is on the archwire at close position.
B1	Angle between the tangent line and horizontal line when the clip is on the archwire at close position.
B2	Angle between the tangent line and horizontal line when the clip is at clip stop.

The clip open forces were obtained using the following equation steps:

$$N = Fw / \cos A$$
$$F1 = N \cos B1$$
$$K = F1/(c1-c0)$$
$$F2 = K(c2-c0)$$
$$f = 2uF2$$
$$Fo = F2 \cdot \tan B2 + f = F2(\tan B2 + 2u)$$

The reactive force on a BioForce® PLUS active archwire (0.019" x 0.025") was obtained through a 3 point bend test. The resulting forces of the archwires are summarized in Table 1.

	Posterior	Bicuspid	Anterior
0.5mm	1.47	1.13	0.80
1mm	1.76	1.40	1.03
2mm	2.34	1.83	1.49

Table 1: Summary of the reaction forces on a 0.019" x 0.025" active BioForce ® PLUS Archwire.

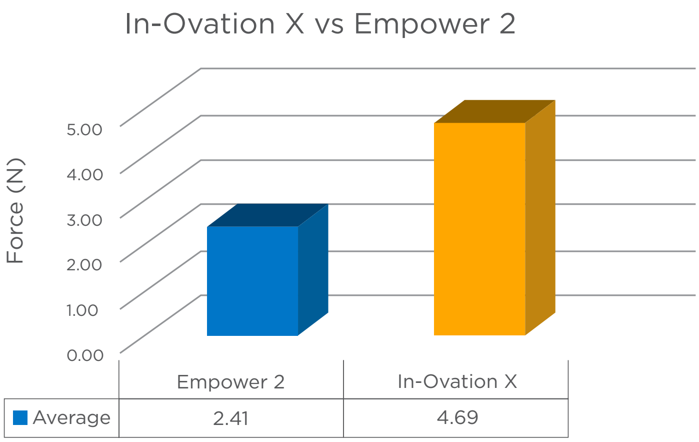


Figure 6: In-Ovation X presented to have 194% more clip open force compared to Empower 2 post fatigue.

A bench test was created by the Dentsply Sirona Engineering team to compare active archwire engagement and the clip open force comparisons between In-Ovation X and Empower 2. Samples were tested at an initial and post fatigue status. The initial force was established using the similar clip open procedure highlighted in the calculus section. The fatigue portion was conducted using manual cycling of opening and closing the clip 100 times. The manual cycling was conducted using an appropriate scaler for each product (In-Ovation X and Empower 2). A post open force was conducted using the same procedure as initial.

The opening force of clips was directly correlated to the amount of force required by the clip to apply on the active arch-wire. The LR4 bracket presented the highest required minimum load to apply on an active archwire throughout treatment. By quantitative analysis of the proposed correlation and design, the worst case scenario was selected by lower posterior position lower right 4.

Results:
After the test was conducted and 100 times cycling was analyzed, In-Ovation X presented almost ~200% greater force than Empower 2 in clip opening force. The minimum force required on the active archwire was found to be 2.00N of load. In-Ovation X provides ~235% more force than the required minimum load compared to Empower 2.

Lower Profile:

The purpose of this study was to evaluate the reduction of the gingival and overall profile comparing In-Ovation R to In-Ovation X. Measurements were conduct by CT Scans and CAD (Solidworks 2014). The overall profile is the measurement from the base of the bracket to the most protruding feature on the bracket.

Results:
The lower right 1 bracket was found to have the largest profile between In-Ovation X and In-Ovation R. There was an overall reduction of ~14% found comparing In-Ovation X to In-Ovation R. This overall reduction results in a shorter moment, potentially reducing undesired bond failures, as well as improved comfort to patients.

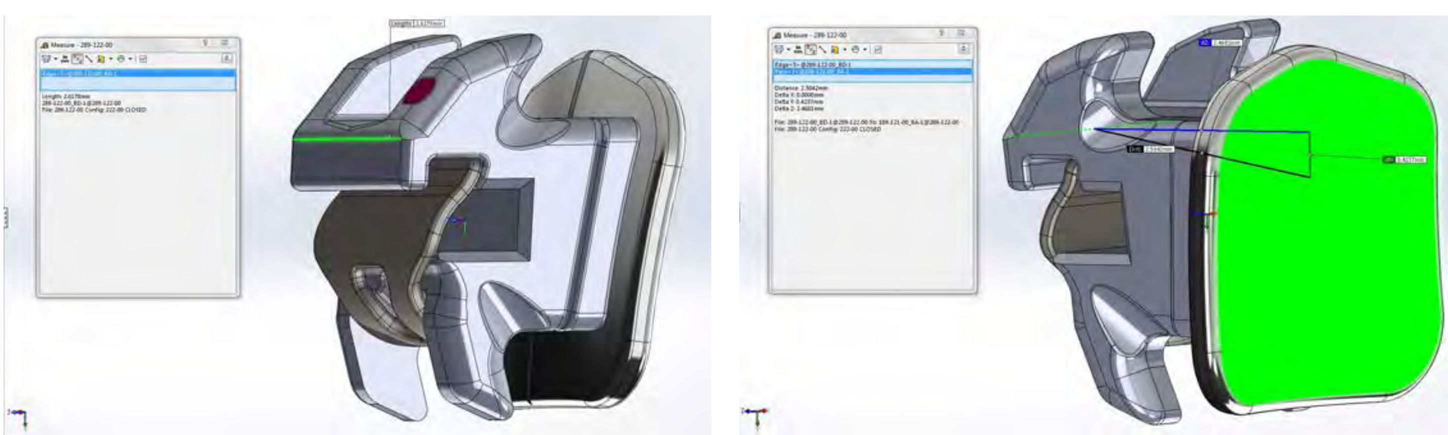


Figure 7: Left image presents outer most labial point and right image represents outer most lingual point.

Conclusion:

The ultimate limitation in self-ligating brackets has been calculus interference on the opening of clips. From our research and analysis using in-vitro bench testing, In-Ovation X had no effect on calculus interference on the opening of the clip. However, In-Ovation R and Empower 2 both increase forces by over 200% to their nominal forces when calculus is present on the gingival end. The data speaks with confidence that eliminating a biological interference of calculus will help the longevity and performance of In-Ovation X by allowing the orthodontist to open brackets without the risk of over exerting force in opening clips, and ultimately deforming the clip. In addition, having a reduced profile compared to the current In-Ovation R bracket ensures the bracket delivers an advantage of increased patient comfort, improved aesthetics and reduction in undesired de-bonding failures with a lower profile. Lastly, comparing clip integrity has been a major factor in orthodontic treatment. Understanding the minimum force requirements to apply adequate torque expression on active archwire is essential in effective treatment. In-Ovation X has presented its ability to have great clip integrity and less degradation compared to its competitor Empower 2.

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