In-Ovation X

A Story of Design, Development and Ingenuity

White Paper by
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Introduction

Since the introduction of the In-Ovation R bracket over a decade ago, other manufacturers have been unsuccessful in their attempts to improve on its form, fit, and functionality until now.

Dentsply Sirona Orthodontics, the leader in orthodontic brackets, has taken a quantum leap forward with the new In-Ovation X bracket system. The project started with GAC assembling a group of noted orthodontists throughout the world to meet in Philadelphia, Pennsylvania, their task was to define clinical design inputs for the “ultimate orthodontic bracket”. The result was the In-Ovation X orthodontic bracket system.

The Story of In-Ovation X

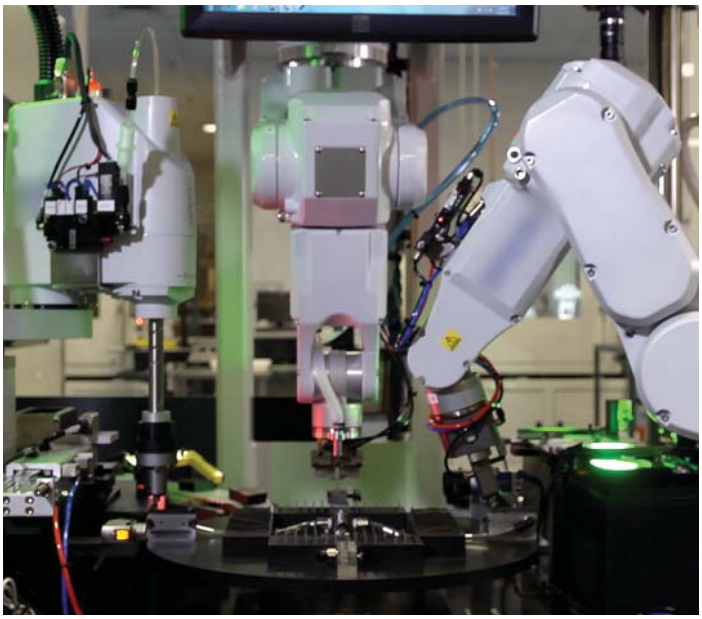
That first meeting in Philadelphia, Pennsylvania was an organized collaborative effort to design an orthodontic bracket. The doctors attending this meeting included: myself, Antonino Secchi, Celestino Norbrega, Luis Nunez, Julia Garcia-Baeza, Ryan Tamburrino, Shalin Shah, Dan Fishel, Raffaele Spena, and Sam King (short biographies on these key contributors can be found in the appendix section towards the end of this paper). Critical to the design process were the members of the Dentsply Sirona Orthodontics Marketing and Research and Development Teams. For two days this group discussed the pros and cons of traditional edgewise verses self-ligating brackets, the design features of all the brackets presently available in the market place, the strong points and weaknesses of each of the brackets, and identified the characteristics that would be present in the "ultimate bracket". It was unanimously decided that self-ligation was the bracket design of choice.

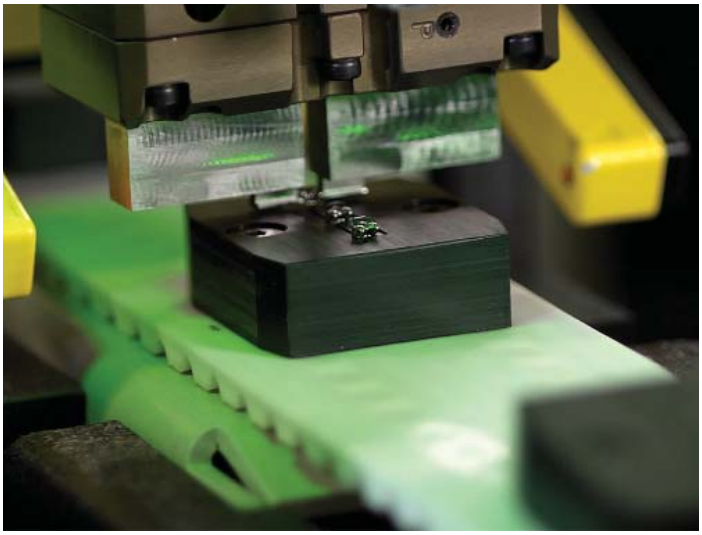
The members of the Marketing and Research and Development Teams presented numerous design concepts for the "new" ultimate orthodontic bracket. The meeting was recorded, copious notes were taken, and all input was recorded and assimilated by the Research and Development Team to be used in designing the new bracket. This was the first time in my experience, such an exhaustive collaborative process had been utilized in the design of an orthodontic bracket. Less than a month later the team of doctors reconvened in New York to see the prototype that teams had developed. The doctors were amazed. In a short period of time the design engineers at Dentsply Sirona Orthodontics were 90% of the way finished with the bracket design. Several small suggestions and changes were then incorporated into the final design and In-Ovation X bracket was born.

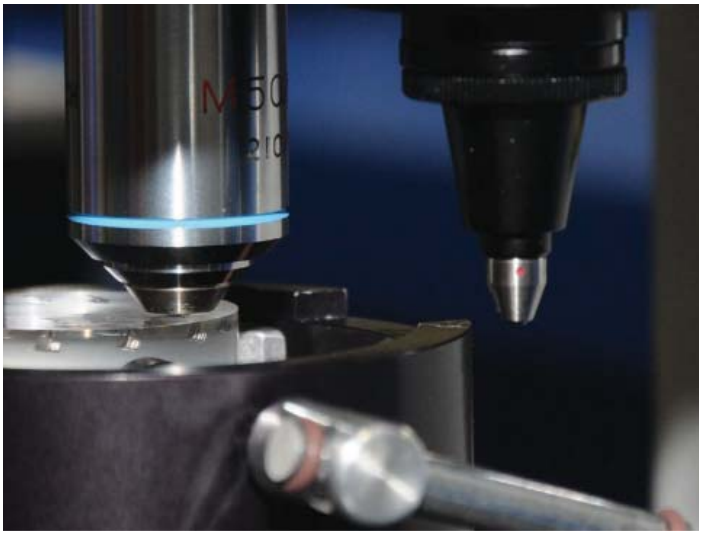
The challenge then was to figure out how to manufacture the brackets since no off-the shelf machinery existed that could produce an orthodontic bracket to the tolerances desired by Dentsply Sirona Orthodontics.

The company's vision in making this considerable investment was to re-invent the way orthodontic brackets are manufactured in order to significantly improve the quality, precision, and accuracy of the finished orthodontic bracket. In order to manufacture these state of the art brackets, a brand new wing was added to the high-tech manufacturing facility in Sarasota, Florida. The production team customized manufacturing robots and developed processes that enabled them to produce orthodontic brackets with a degree of quality, precision, and accuracy never before attained in this industry.

Dentsply Sirona Orthodontics didn't stop there. They believed that in order to ensure the bracket was everything it was designed to be, clinical trials were initiated to prove the design concept. And now, after over 2 years of successful clinical trials the bracket is available for introduction into the marketplace.







The Manufacturing Process

With the release of the In-Ovation X bracket, Dentsply Sirona Orthodontics has revolutionized the way orthodontic appliances are manufactured. They have done this through the development and utilization of flexible robotic assembly systems and customized upstream manufacturing processes. This state of the art facility utilizes metal injection molding technologies as well as custom manufactured robotic systems with in-process vision inspection to build orthodontic brackets with precision and quality assurance unmatched in the industry. These robotic systems are capable of assembling the brackets to a 20 micron tolerance and then automatically inspect them to ensure they are within those tolerances before they leave the manufacturing station. From the raw materials to finished assemblies, the brackets are precisely formed, assembled, welded, polished and inspected using the most advanced automated technology available. No other orthodontic bracket available on the market today is produced with this degree of quality, precision and accuracy. In my assessment, the ingenious design of the bracket combined with the state of the art manufacturing process, will ensure a better treatment experience for both the patient and the clinician.

Traditional Edgewise Brackets vs. Self-ligating Brackets – A Brief Review of the Literature

Over the past 20 years a tremendous amount of research has been published in orthodontic journals about self-ligating brackets and the purported benefits in improving the efficiency of orthodontic treatment. Exhaustive studies have been conducted comparing virtually every aspect of the treatment of cases with traditional edgewise brackets versus self-ligating brackets[5,6,7,8,19,21,22,23,24,26,27,28,29,30,33,34,40]. Length of treatment time, number of patient visits, patient chair-time, and other treatment parameters have been examined and reported on in the literature. Many other studies[8,9,10,12,38] have compared friction, binding and the sliding abilities of self-ligating brackets when compared to traditional edgewise brackets.

The surprising results of all these studies are that there is really no industry consensus on which type of bracket will provide the best treatment for our patients. Many studies come to the conclusion that self-ligating brackets offer "no benefits" to the patient. Other studies show that there is less friction and binding, patient discomfort is reduced, teeth do move faster, treatment is completed faster, less chair-time is needed, and fewer appointments are necessary for the successful completion of an orthodontic case. In the bibliography of this White Paper Report I have listed many articles addressing this very question, "Are there any real treatment benefits that would justify the use of self-ligating brackets?" I urge the reader examine these articles and draw their own conclusions. Over the upcoming years I am sure many more studies will be performed and eventually we will have a clearer understanding of the true benefits of self-ligating brackets.

Because of the diverse findings and the vast differences of opinion, several years ago I decided to do a study of my own to try to determine if, in my practice, I noticed any real benefits to the utilization of self-ligating brackets. I decided to compare cases in my practice that were treated using traditional edgewise brackets with cases that were treated using In-Ovation R brackets. It was a simple study that compared three parameters of treatment:

- Number of appointments necessary to complete treatment
- Amount of chair-time required to complete treatment
- Length of treatment

This study was later published as a White Paper Report entitled, "Increasing Practice Efficiency and Profitability Utilizing In-Ovation Self-Ligating Brackets" and is available from the Dentsply Sirona website at: https://www.dentsply.com/content/dam/dentsply/pim/manufacturer/Orthodontics/Brackets/Self_Ligating/In_Ovation_R/In_Ovation_R/120-089-04-r2-WP-Clark-qn8qvxd-en-1412.pdf

In short, the use of self-ligating brackets in my practice resulted in 40% fewer appointments, up to 3 less hours of chair time per patient, and a reduction of 4.14 months of active treatment time. This report was also published in Ortho-The International C.E. Magazine of Orthodontics Vol.3 – Issue 1/2014 under the same title.

Appointments

9.6 vs 16.26

In-Ovation averages 40% fewer appointments than traditional brackets with ties.

Time

302.55 minutes vs 476.76 minutes

With In-Ovation* doctors realize a chairside time savings of approximately 3 hours per patient.

Months in Treatment

19.83 months vs 23.97 months

In-Ovation finishes equivalent cases approximately 4 months sooner than traditional brackets with ties.

*Jerry R. Clark, DDS, MS, Jack Gebbie, BS, Datatex Market Research Report Summary: Increasing Practice Efficiency and Profitability Using In-Ovation Self-Ligating Brackets, March, 2007. Datatex is a member of CASRO® - Council of American Survey Research Organizations

Incontrovertible Benefits of Self-Ligation

Elimination of "round tripping" of teeth

As was documented in the literature on numerous occasions by: Sherruff[8], Pizzoni[9], Heano and Kusy[10], Parkin[12] and many others, teeth are freer to slide on self-ligating brackets thereby creating significantly less binding and friction as the teeth move. When bringing in a high canine the wire can easily slide through the canine bracket as well as the bicuspids and molars thereby allowing the tooth to move occlusally without protruding the incisors.

Quicker archwire changes

It takes far less time to change archwires when using self-ligating brackets. The bracket door or clip is opened, the old wire is removed and the new wire is placed and the door or clip is closed. Some studies indicate a time savings of 7 minutes or more when self-ligating brackets are used as compared to using traditional brackets and ligating with metal or elastic ties.

Consistency of archwire engagement

Every self-ligating bracket, no matter whether the doctor or assistant engages the archwire in the bracket, produces a consistent amount of force on the tooth thus producing more predictable tooth movement. With steel or elastic ties there can be an inconsistency of force on the tooth after the wire is engaged in the bracket depending upon who is engaging (tying) the wire into the bracket and the method of engagement.

Security of archwire engagement

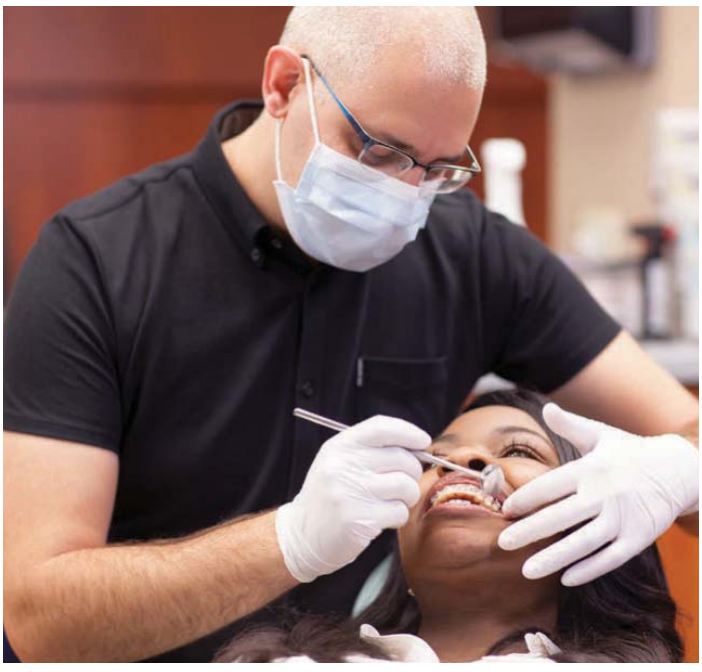
With traditional edgewise brackets if an elastic chain breaks, or an elastic tie comes off the tooth or a metal tie is loose and not properly securing the wire into the bracket sometimes significant undesirable tooth movement can occur. This does not occur with self-ligating brackets since once the door or clip is closed the archwire is secured into the bracket.

Fewer emergency visits for patients

Since the archwire is securely engaged in the self-ligating bracket, broken elastic ties or chains have no effect on the engagement of the wire into the bracket and therefore adverse tooth movement will not occur, thus eliminating the need for additional emergency visits to the office to replace them or tuck in protruding ligature ties that are sticking the patient.

Less discomfort for the patient

In a study published in Clinical Impressions entitled "Orthodontics from Good to Great" Dr. Derick Tagawa states, "The average pain-level response from patients with conventional brackets was 4 (pain was measured with 0 being no pain and 10 being severe pain) while the average pain-level from the Damon System patients with the self-ligating brackets was 1.3 with no pain reported higher than 4[15]".



Other Potential Benefits of Self-Ligation

Reduction of root resorption

Several studies indicate that the use of lighter forces and the elimination of "round tripping of teeth" may reduce the amount of root resorption experienced during orthodontic treatment, although other studies maintain this advantage is still up for debate[31,36], more studies need to be done.

Fewer patient appointments are necessary to complete treatment

Another potentially significant benefit for the patient is the reduction in the number of visits necessary to complete treatment when self-ligating brackets are used. Although there are some studies that indicate no time savings, reduced patient visits, or shorter treatment time, there are numerous published articles documenting that the use of self-ligating brackets does reduce the number of patient visits necessary to complete treatment .

Reduced chair-time to complete treatment

Another possible significant benefit of self-ligating brackets is the reduced chair-time necessary to complete treatment. Some studies demonstrate a reduction in patient chair-time up to 30% AND appointments can be shorter due to the efficiency of quicker archwire changes .

Reduced treatment time

There are many conflicting research studies concerning the reduction of treatment time when self-ligating brackets are utilized. Some studies indicate a time saving of up to 5 months[5,6]. Other studies show no reduction in treatment time. Since self-ligating brackets are in essence edgewise brackets with a clip or a door, all should be able to agree that treatment should NEVER take longer when utilizing self-ligating brackets.

Increased practice profitability

If any time is saved in treating patients then that saving can impact the practice's bottom line. Noted and respected orthodontic practice consultant Mary Beth Kirkpatrick states the following: "Practices that consistently used self-ligating brackets for one year or more report the following:

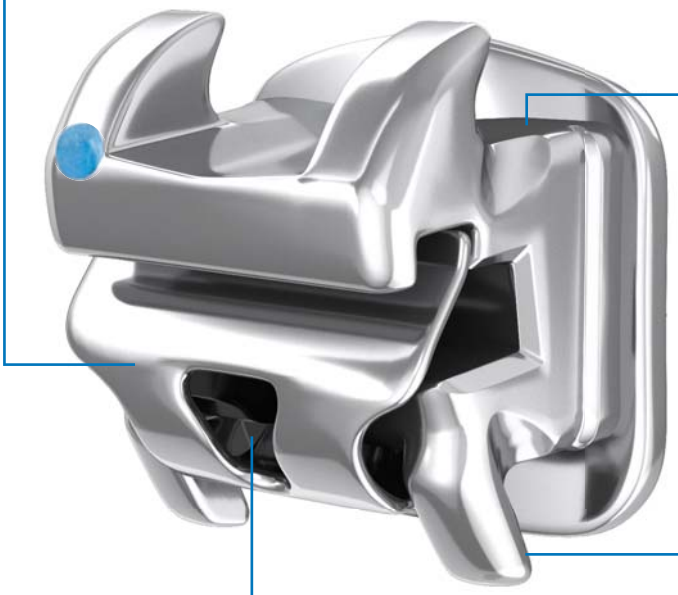
- Collections/Production per doctor hour INCREASES
- Cost to complete treatment per patient DECREASES
- Schedule is less stressful for doctor, staff and patients
- Patients are pleased to complete treatment in less time
- Treatment Efficiency and profit per patient INCREASES

"Treatment efficiency is directly related to the number of visits. A commonly used measure of efficiency is to divide the treatment fee by the number of visits. With fewer visits, a practice whose efficiency quotient was previously $240 per visit is now reporting that value to be upward of $350 per visit."

Mary Beth Kirkpatrick

The Next Generation of Orthodontic Brackets

In the designing of the In-Ovation X bracket many of the proven positive qualities and design features of the In-Ovation R bracket were incorporated into the new In-Ovation X bracket. The new design also employs many features that were desired by orthodontists. Reduced curvature of the clip improves clip strength and increased wire retention forces, enclosed clip channel design mitigates calculus accumulation that can interfere with clip opening, opening and closing the clip without the need of a special instrument, tactile feedback when opening and closing the inter-active clip, full archwire/clip engagement during the working phase of treatment for maximum torque control, reduced bracket profile without reducing interactivity between the bracket and the archwire, smoothly contoured bracket wings and edges for maximum patient comfort, and increased tie wing clearance for ease of elastic placement without increasing the bracket's footprint or profile are just some of the design changes that make the In-Ovation X bracket unique.



New Design Features

Stronger Interactive Clip Deisgn

By reducing the curvature of the clip, the new In-Ovation X clip design has produced a much stronger clip, making it less vulnerable to strength degradation or distortion upon opening, while still maintaining its flexibility. This property allows for increased force to seat square and rectangular archwires securely into the base of the In-Ovation X bracket.

Enclosed Clip Mechanism

Calculus build-up also produces the undesirable effect of clogging the spring clip mechanism. This sometimes made the opening of self-ligating bracket clips difficult or even impossible. Now with the In-Ovation X clip mechanism completely encased in the bracket this is no longer a problem.

Lower Bracket Profile

In an effort to increase patient comfort, reduce occlusal interferences and decrease bond failures, the profile of the In-Ovation X bracket has been reduced by up to 14.3%.

New Facial Keyhole Opening Mechanism

The spring clip now has an easily accessible keyhole opening located at the top of the clip. To open the In-Ovation X bracket no special tool is needed, a traditional scaler is all that is necessary to engage the keyhole opening. Due to the strategic placement of the keyhole it is easy to engage the opening and almost impossible to deform the clip during the opening process. Finger pressure is all that is needed to securely close the In-Ovation X clip.

Clip Design

Clip retention feature	Greater clip disassembly force.
Redesigned clip	Delivers tactile feedback when clip is closed

Body Design

Tapered occlusal tie-wings	Designed to minimize occlusal interference.
Optimal mesial-distal span	Provides optimal rotational control.
Metal injection molded	Enhances consistency, accuracy and strength.
Triple chamfered slot walls	Facilitates easy wire insertion reducing the chance of archwire binding or crimping.

Base Design

80 Gauge single mesh	Delivers proven bond strength.
Anatomical base design	Compound contoured to minimize rocking.

Usability

Placement

Vertical scribe line	Facilitates accurate bracket placement.

Ligation

Enhanced tie-wing	Accommodates double elastomeric chain or chain undercuts and a tie.
Redesigned body contours	Designed to accommodate accessories.

Identification

Color ID, Laser etched	Simplifies identification and bracket inventory management. Palmer Notation

Conclusion

Dentsply Sirona Orthodontics has invested millions of dollars in order to redefine the manufacturing process by which orthodontic brackets are produced. By taking the bold approach of creating a totally new orthodontic bracket from concept to its final introduction to the marketplace, the company has made an investment in the future of orthodontics and the way it is practiced by doctors throughout the world.

In coupling the benefits of active self-ligation as well as its new innovative product design features, the In-Ovation X system has ensured that both patient and clinician have the best possible treatment experience available.

Dentsply Sirona Orthodontics invites all orthodontists to avail themselves and their patients of the opportunity to use what the company believes is the finest orthodontic bracket ever created, In-Ovation X.

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Dr. Shalin Shah earned his Bachelor of Arts, Doctorate of Dental Medicine, Certificate in Orthodontics, and Masters of Science in Oral Biology from the University of Pennsylvania. He is also on the faculty at the University of Pennsylvania and lectures nationally and internationally for Complete Clinical Orthodontics and Roth-Williams Center for Functional Occlusion.

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Dr. Ryan Tamburrino, grew up in Pittsburgh, and his tinkering and technical interests during his early years led him to Duke University where he received degrees in Biomedical Engineering and Mechanical Engineering/Materials Science. Wanting to also to be involved in healthcare, he enrolled at the University of Pennsylvania where he received his Doctorate of Dental Medicine and was Chief Resident while obtaining his specialty Certificate in Orthodontics. In addition to private practice, Dr. Tamburrino is on the faculty at the University of Pennsylvania in the Department of Orthodontics.

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