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**Shear Bond Strengths of Orthodontic Auxiliaries Bonded to Clear Thermoplastic
Aligner Materials Using Three Adhesive Systems**

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**Shear Bond Strengths of Orthodontic Auxiliaries Bonded to Clear Thermoplastic
Aligner Materials Using Three Adhesive Systems**

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In Partial Fulfillment

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Andrew D. Taylor, D.M.D.

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DEDICATION

This thesis is dedicated to my family. Their love and support throughout the years has made my educational journey possible. I truly am nothing without them.

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ABSTRACT

Objective: This study compares the shear bond strength (SBS) of the adhesive/clear thermoplastic aligner (CTA) interface, using three bonding systems and three CTA materials. Methods: Tested the SBS of 90 metal buttons bonded to the CTA materials (Clear Splint Biocryl, Essix ACE®, Tru-Tain™ DX30) using different bonding systems (Bond Aligner™, Triad® Gel, Biocryl Ice Acrylic Resin). Results: The two-way ANOVA found the type of bond agent used was significant ($p < 0.01$), while CTA material ($p = 0.453$) and interactions ($p = 0.397$) were not significant. Tukey's HSD found that Bond Aligner™ had significantly higher SBS than Triad® Gel and Biocryl Ice ($p < 0.001$). Triad® Gel had significantly higher SBS than Biocryl Ice and lower SBS than Bond Aligner™ ($p < 0.001$). The Tukey's HSD test showed no significant difference in SBS with respect to the CTA material. Conclusion: There is greater SBS between the adhesive and CTA interface using Bond Aligner™ compared to Triad® Gel and Biocryl Ice.

TABLE OF CONTENTS

TITLE PAGE	i
APPROVAL.....	ii
DEDICATION.....	iii
ACKNOWLEDGEMENTS.....	iii
ABSTRACT	iv
TABLE OF CONTENTS	v
I. BACKGROUND.....	1
A. Introduction	1
B. Limitations.....	2
C. CTA Modifications and Associated Problems	3
D. Bonding to CTA	4
E. CTA Bonding Difficulties.....	7
F. Bonding Methods.....	8
II. OBJECTIVES	11
A. Purpose of Present Study	11
B. Specific Hypothesis	11
C. Null Hypothesis.....	11
III. MATERIALS AND METHODS.....	12
A. Experimental Design	12
B. Preparing Maxillary Dentition Models.....	13
C. Preparing the CTA	13
D. Bonding Metal Auxiliary Buttons to CTA	13
E. Biocryl Ice Acrylic Resin Bonding.....	14
F. Triad® Gel Bonding.....	14
G. Bond Aligner™ Bonding	15
H. Shear Bond Strength Testing	15
I. Instrumentation	16
J. Site of Failure Observation	17
K. Statistical Analysis.....	17
L. Figures of Materials and Methods Procedures.....	18

Figure 3-1. Overview of Research Design	19
Figure 3-2. Rubber impression molds used to pour up 18 maxillary dentition models using dental lab stone, Quickstone by Whip Mix®	20
Figure 3-3. Three clear thermoplastic aligner materials selected for the study.....	21
Figure 3-4. Biostar® VI with Scan Technology Positive Pressure Thermal Forming Machine used to thermoform the CTA materials to the stone maxillary models.....	22
Figure 3-5. Fine diamond flame bur used to roughen the entire buccal/facial surface of the CTA ..	23
Figure 3-6. Metal auxiliary button (3M Unitek Lingual Button Curved)	24
Figure 3-7. Three bonding adhesives that were used to attach the metal auxiliary buttons to the CTA	25
Figure 3-8. The auxiliary button placed directly onto the center of the buccal/facial surfaces of the prepared aligner.....	26
Figure 3-9. Triad® 2000 VLC unit used to light-cure Triad® Gel.....	27
Figure 3-10. The VALO™ curing light used to light cure Bond Aligner™	28
Figure 3-11. Universal testing machine by Instron® used to perform debonding shear tests	29
Figure 3-12. Single blade from Instron® machine engages the metal auxiliary button behind the button head	30
Figure 3-13. Microscope used to evaluate the site of failure after shear bond strength tests	31
IV. RESULTS	32
Table 4-1. Group 1: Bond Aligner™/Clear Splint Biocryl	34
Table 4-2. Group 2: Bond Aligner™/Essix ACE®	35
Table 4-3. Group 3: Bond Aligner™/Tru-Tain™ DX30.....	36
Table 4-4. Group 4: Triad® Gel/Clear Splint Biocryl	37
Table 4-5. Group 5: Triad® Gel/Essix ACE®	38
Table 4-6. Group 6: Triad® Gel/Tru-Tain™ DX30.....	39
Table 4-7. Group 7: Biocryl Ice/Clear Splint Biocryl	40
Table 4-8. Group 8: Biocryl Ice/Essix ACE®	41
Table 4-9. Group 9: Biocryl Ice/Tru-Tain™ DX30.....	42
Table 4-10. Mean and Standard Deviations.....	43
Table 4-11. Shear Bond Strength MPa (Stdev) Results	44
Table 4-12. Bond Failure Site Parameters.....	45
Table 4-13. Failure Site Results	46
Figure 4-1. Bar Graph of Shear Bond Strength (SBS) Results.....	47

Figure 4-2. Bonding Agent Shear Bond Strength Results..... 48
Figure 4-3. CTA Material Shear Bond Strength Results..... 49
Figure 4-4. Bond Failure Site Graph 50
V. DISCUSSION..... 51
VII. LITERATURE CITED 53

I. BACKGROUND

A. Introduction

Clear thermoplastic aligner (CTA) therapy offers an alternative treatment modality to patients who desire orthodontics without the treatment complexities of traditional metal brackets and archwires. Through the years, orthodontic providers have developed innovative techniques to use thermoformed material to efficiently move teeth in ways that are both comfortable and esthetic for the patient. In 1945, Dr. H. D. Kesling introduced a tooth positioning system that would move teeth without the use of bands, brackets, or wires. His tooth positioner was a one-piece pliable thermoformed rubber appliance that was fabricated to allow spaces to close and teeth to settle into ideal position once orthodontic bands were removed at the end of basic treatment. With an eye to the future, Dr. Kesling predicted that major tooth movements could be accomplished with a series of positioners by slightly changing the teeth on the set-up as the treatment progressed (Kesling, 1945).

Following Dr. Kesling's work, different orthodontists advanced thermoformed appliances as alternatives or supplements to fixed appliances to make major tooth movements and treat increasingly complex malocclusions. In 1971, Ponitz introduced an appliance called the "invisible retainer" that he claimed could produce limited tooth movements. The appliance was made from heated plastic sheets that were vacuum formed to a master model whose teeth were repositioned in pink baseplate wax (Ponitz, 1971). In addition to providing retention and minor tooth movement, Ponitz also described the possibilities of attaching bite planes and denture teeth to the thermoplastic material using self-curing acrylic liquid (Ponitz, 1971). McNamara

followed up on the work of Ponitz by clearly defining fabrication methods and usage for the CTA for both finishing and retention (McNamara et al., 1985). Starting in 1993, Sheridan and others introduced a series of articles that outlined various usage of thermoplastic material in orthodontics, including retention, minor tooth movements with divots and windows, molar uprighting, space maintainers, and functional and habit appliances (Sheridan et al., 1993)(Sheridan et al., 1994)(Sheridan et al., 1995).

The most recent major advancement in CTA therapy occurred in 1997 when Align Technology (Santa Clara, CA, USA) developed the Invisalign® system. Using the principles developed by Kesling and others, Invisalign® utilized 3-dimensional technologies combined with lab manufacturing technology to fabricate a series of clear aligners that moved teeth in 0.25 mm increments from beginning to end (Boyd et al., 2000). Since its introduction and wide spread marketing, CTA therapies such as Invisalign® have become an increasingly popular alternative to traditional orthodontic treatment with brackets and archwires. This popularity is due to the superior esthetics of CTA to traditional brackets and archwires, in addition to the ability of the patient to remove the aligners to eat, brush, and floss.

B. Limitations

There are many different uses for thermoplastic appliances in dentistry today. CTA are used as aligners for major and minor tooth movement. They are used as retainers following comprehensive orthodontic treatment. They are also used as removable functional and habit appliances. Soon after the widespread introduction of Invisalign® to the market in 1999 as a comprehensive orthodontic appliance, specific limitations

affecting their ability to correct certain types of malocclusions were identified. These limitations included crowding and/or spacing over 5mm, skeletal discrepancies of more than 2mm, centric-relation and centric-occlusion discrepancies, severely rotated teeth, open bites, extrusion of teeth, severely tipped teeth, teeth with short clinical crowns, and arches with multiple missing teeth (Phan, 2007). These limitations were due to the CTA's limited control over root movements such as root paralleling, rotation correction, tooth uprighting, and tooth extrusion (Phan, 2007). Certain desired tooth movements made it difficult to maintain aligner retention and adaptation to the teeth, and, as a result, prevented application of the necessary force for tooth movement.

C. CTA Modifications and Associated Problems

Once clinicians began experiencing these treatment difficulties, they simultaneously began developing methods to address them. Modifications to the CTA are commonplace. The appliances can be modified with slits, hole-punching tools, elastic hook forming pliers, or by auxiliaries bonded directly to the appliance or teeth. However, it should be noted that significant modifications can weaken the thermoplastic appliance (Guarneri et al., 2009). While clinicians report the ease of using scissors to cut slits in the material for the attachment of elastics, this type of modification weakens the material and often leads to appliance breakage when subject to the forces exerted by the attached elastics (Guarneri et al., 2009). In addition, the sharp edges of the slits when subject to elastic forces can cause discomfort to the patient, as the appliance loosens with wear and the gingival borders become ill-fitting. Bonding auxiliaries directly to the teeth and removing the corresponding CTA material is another method of

attaching elastics. With the auxiliary bonded directly to the tooth, it is very possible for unwanted tooth movement to occur at this anchorage site. In addition, removing the thermoplastic material to accommodate the bonded auxiliary is time consuming and creates sharp edges in the material causing discomfort for the patient (Guarneri et al., 2009). The reduction in adaptation of the thermoplastic appliance to a tooth at an area of modification, from either a button bonded directly to a tooth or slits for elastics, adversely affects the biomechanical forces acting at that site. As a result, this further reduces the aligner's ability to function as desired and facilitate tooth movement. In contrast, bonding auxiliaries directly to the surface of the thermoplastic appliance avoids the above mentioned problems, providing an effective means to achieve appliance retention. As a result, this improves tooth movement with this appliance.

D. Bonding to CTA

The orthodontic literature provides many examples of modifications to CTA to achieve desired results. First and foremost, thermoplastic appliances need good retention and adaptation so that the appliance can deliver the forces desired without becoming dislodged (Rinchuse, 2002). Undercut enhancing thermopliers have been used to add retentive undercuts in the embrasures of the thermoplastic appliances. These retentive undercuts can be further strengthened by bonding a reinforcing material into the undercut (Rinchuse, 2002). Mild Class II or Class III molar correction was achieved by using interarch elastics between bonded auxiliary buttons on maxillary and mandibular thermoplastic appliances (Guarneri et al., 2009). Bonded auxiliary buttons have been used to derotate bicuspids by bonding a button to the surface of the bicuspid

and another button to the thermoplastic appliance near the molar, with the appliance material relieved around the bonded bicuspid button (Kuo). Root movement has been achieved by relieving the thermoplastic material and bonding power arms directly to the tooth needing root movement and to the thermoplastic appliance surface of the adjacent tooth. An elastic connecting the two power arms generates a movement force (Gange, 2013). Thermoplastic appliances with inter or intra-maxillary elastics have been used to treat minor 2-3mm anterior open bite patients (Park, 2009). Auxiliary buttons were bonded directly to the teeth to be extruded and intermaxillary elastics were used to connect to buttons bonded to the aligner on the opposite arch. Intramaxillary elastics can also be used if buttons are bonded to the lingual side of the aligner (Park, 2009).

Minor tooth movement up to three millimeters can be produced by modifying thermoplastic appliances with force-generating divots placed in the thermoplastic material with special heated devices (Sheridan et al., 1994). A window is cut in the thermoplastic material opposite the divot to allow for unimpeded movement. The divots are then progressively deepened throughout treatment to continue to produce movement. Successive deepening can create a thin and flimsy divot that is unable to generate the force necessary for tooth movement. When this occurs, the divot has traditionally been reinforced with a bonded composite to convert the hollow divot into a shaft of solid plastic (Sheridan et al., 1994).

In addition to the examples listed above, thermoplastic appliances with auxiliary modifications have been used for intrusion, habit appliances, bite planes, anterior crossbite correction, ectopic canine correction, and palatal expanders. Tooth intrusion has been documented using a thermoformed plastic appliance with auxiliary buttons

bonded to the buccal and lingual surfaces. This intrusion method was developed to address the problem of disproportionate extrusive forces that fixed appliances placed on adjacent teeth in their attempt to intrude a single tooth (Armbruster, 2003). A thermoplastic retainer was fabricated with the plastic removed over the crown of the tooth to be intruded with buttons bonded to the buccal and lingual surface, and an elastic attached to deliver light intruding forces across the occlusal surface of the extruded tooth (Armbruster, 2003).

Sheridan and others documented their use of thermoplastic material with bonded modifications to fabricate molar uprighting appliances, bite planes, and habit appliances (Sheridan et al., 1995). Rinchuse followed up on Sheridan's work and documented how thermoplastic material with bonded modifications could be used for anterior crossbite correction, ectopic canines, and palatal expanders. For anterior crossbite correction, a finger spring was attached to a thermoplastic aligner with cold-cure acrylic and activated twice to correct an anterior crossbite of the maxillary incisor (Rinchuse, 1997). An ectopic maxillary canine was moved into the arch by bonding a bracket with a hook to the ectopic canine and then using a thermoplastic appliance with two metal attachments, one bonded lingual to the ectopic tooth and the other bonded posterior and facial to the ectopic tooth (Rinchuse, 1997). Various sizes and configurations of elastics were used in conjunction with the bonded auxiliaries to control the movement of the ectopic tooth into the arch (Rinchuse, 1997). A hybrid thermoplastic nickel titanium removable palatal expander was constructed with cold-cure acrylic resin on a working cast. An eight year old female with posterior crossbite and a Class III malocclusion wore the expander full time for six weeks and achieved a stable expansion (Rinchuse,

1997). The introduction of temporary anchorage devices opens up even more possibilities to more effectively treat malocclusions using thermoplastic appliances with bonded modifications (Sparaga).

E. CTA Bonding Difficulties

Thermoplastic appliances with bonded modifications used to correct various malocclusion are available as another tool for clinicians to treat patients with esthetic concerns (Sergl et al., 1998), fear of pain and discomfort associated with general orthodontic treatment (Sergl et al., 1998), or patients with confounding hygiene and periodontal health factors (Boyd and Vlaskalic, 2001). In order for these appliances to work effectively, not only does the patient need to be compliant with wear, but the thermoplastic material and the bonded auxiliaries need to maintain their integrity, adaptation and strength while resisting debonding, fractures, and tears. Many clinicians have reported frustration and difficulty associated with bonding auxiliaries to thermoplastic appliances, mainly due to unpredictable bond strength, and the resultant increase in emergency visits as a consequence of auxiliary debonds.

The primary challenge for bonding auxiliaries to the thermoplastic material is getting them to stick to the material. Conventional dental adhesive are inadequate due to the smooth surface of the plastic creating inadequate micromechanical retention (Kuo). Plastic primer has been used to enhance retention, but it does not address the potential problem of flexural failure of the rigid adhesive-thermoplastic material interface during insertion and removal (Kuo). Medical grade cyanoacrylate adhesive has sufficient bond

strength but it requires a 1-2 hour cure time which is unacceptable for chairside addition of buttons (Kuo).

F. Bonding Methods

Currently, using cold-cure acrylic resin offers the highest bond strength for attaching auxiliaries to thermoplastic appliances (Pendleton et al., 2008). However, the use of cold-cure acrylic resin chairside is cumbersome and time consuming, requiring time to surface roughen the material, mix the monomer and polymer, and allowing time for the material to cure. Light-cured acrylic resin has also been used to attach auxiliaries. The light-cured resin demonstrates weaker bond strength to thermoplastic material (Pendleton et al., 2008) and it still requires surface preparation and approximately ten minutes of total light cure time per manufacturer's instructions. In an effort to address the clinical inefficiency of cold-cure acrylic for bonding auxiliaries, Invisalign® introduced ClearLoc™, a proprietary moisture-resistant light-activated plastic adhesive for bonding plastic auxiliary buttons to the thermoplastic appliance (Kuo). The material was advertised as not requiring preparation of the bonding surface and curable in less than 30 seconds with a standard light-cure unit (Kuo). No studies are available that document the material's bond strength, and the material is no longer available or sold by Invisalign®. Invisalign® training and education material no longer advocates the bonding of auxiliaries directly to the thermoplastic material, instead clinicians can prescribe that elastic hook or button window modifications be added to the thermoplastic appliances in the treatment planning stage by use of Invisalign® proprietary software, ClinCheck®. There is no documentation available that explains

that these changes were a result of time consuming and unpredictable auxiliary bonding.

Recently, a new adhesive material for bonding auxiliaries to thermoplastic material was introduced by Reliance Orthodontic Products called Bond Aligner™. The material is composed of Tricyclohexane dimethanol diacrylate and N,N-Dimethyl acrylamide (Reliance, MSDS). In 2013, the company documents filed with the Food and Drug Administration described the new bonding material as “a light cure, orthodontic adhesive for metal, composite and porcelain brackets and for appliances (auxiliaries) to bond to thermoplastic aligners. The Clear Aligner Adhesive (Bond Aligner™) is formulated in a viscosity that flows easily from the syringe and bonds chemically to a, typically difficult to adhere to, surface, a thermoplastic aligner now common in the dental industry. This adhesive, upon polymerization, is clear and virtually indistinguishable from the thermoplastic aligner thereby making it aesthetically pleasing to the patient. The light cure property of the adhesive allows the user to determine the polymerization time required by simply exposing the adhesive to an LED light source until set.” (Reliance, 510 (k) Summary). Company President, Paul Gange, Jr., has advertised the product as a reliable auxiliary bonding method to “any clear thermoplastic aligner material, including, but not limited to, Invisalign®, Essix®, and Tru-Tain™. He also emphasizes that Bond Aligner™ does not require the extra step of applying a primer material, as required for both light-cure and cold-cure acrylic resin bonding systems (Gange, 2013). Bond Aligner™ has been advertised as a way for the clinician to troubleshoot cases with bonded auxiliaries similar to the way clinicians troubleshoot

traditional bracket and wire treatment modalities to achieve optimal treatment results (Gange, 2013).

In addition to Bond Aligner™, cold-cure and light-cured acrylic resin are advocated methods for bonding auxiliaries to thermoplastic appliances currently in use today. Cold-cure acrylic is a two part bonding system composed of a separate monomer liquid and a powder polymer. The combination of the monomer and polymer creates an exothermic reaction that produces a strong and durable acrylic material (PMMA) (Driscoll et al., 1991). Triad® Gel is a visible light cure urethane-dimethacrylate resin, that doesn't contain methylmethacrylate monomer (De La Cruz et al., 2002). Light-activated materials polymerize faster and exhibit less polymerization shrinkage compared to cold-cure autopolymerizing PMMA resins (Craig, 2002). Cold-cure and light-cured resins have been compared in a few studies of denture base repairs with mixed results (Stipho and Talic, 2001) (Dar-Odeh et al., 1997), and only one comparative test involving acrylic-bonded auxiliaries to thermoplastic materials, also with mixed results (Pendleton et al., 2008). It is important to note that these studies were conducted using an earlier generation of Triad light-cure material, Triad® VLP which was composed of a matrix of urethane dimethacrylate plus small amounts of microfine silica to control its elastic properties (Stipho and Talic, 2001).

II. OBJECTIVES

A. Purpose of Present Study

The purpose of this present study is to compare the shear bond strengths of the adhesive/clear thermoplastic appliance interface, using three different bonding systems and three different thermoplastic aligner materials. The bonding systems selected for this study are Triad® Gel by Dentsply, a clinically accepted light cured adhesive systems for clear thermoplastic materials, Biocryl Ice Acrylic Resin by Great Lakes Orthodontics, a fast setting clear cold cure acrylic, and Bond Aligner™ by Reliance Orthodontics Products, a recently developed bonding adhesive for clear thermoplastic aligners.

B. Specific Hypothesis

There is greater bond strength between the adhesive and thermoplastic material interface using the newly developed bonding system, Bond Aligner™, compared to currently accepted light-cure and cold-cure acrylic resin bonding systems.

C. Null Hypothesis

There is no significant difference in bond strength between the adhesive and thermoplastic material interface using the newly developed bonding system, Bond Aligner™, compared to currently accepted light-cure and cold-cure acrylic resin bonding systems.

III. MATERIALS AND METHODS

A. Experimental Design

This study is designed to test the shear bond strength of an orthodontic button auxiliary bonded to a clear thermoplastic aligner. Three adhesive bonding systems will be used to bond an auxiliary button to three different clear thermoplastic aligner materials.

For this study, sample groups have been categorized according to the bonding adhesive and the thermoplastic aligner material used. Three bonding adhesives and three thermoplastic aligner materials will be used, resulting in nine sample groups. Each group will consist of two aligners made from the same clear thermoplastic material, with five (5) auxiliary buttons bonded to each of the aligners with the same adhesive bonding system. The groups are as follows:

Group	Thermoplastic Material	Bonding System
1	Clear Splint Biocryl (Great Lakes)	Bond Aligner™ (Reliance Orthodontic Products)
2	Clear Splint Biocryl (Great Lakes)	Triad® Gel (DENTSPLY)
3	Clear Splint Biocryl (Great Lakes)	Biocryl Ice Acrylic Resin (Great Lakes)
4	Essix ACE® Plastic (DENTSPLY)	Bond Aligner™ (Reliance Orthodontic Products)
5	Essix ACE® Plastic (DENTSPLY)	Triad® Gel (DENTSPLY)
6	Essix ACE® Plastic (DENTSPLY)	Biocryl Ice Acrylic Resin (Great Lakes)
7	Tru-Tain™ DX30 (Tru-Tain)	Bond Aligner™ (Reliance Orthodontic Products)
8	Tru-Tain™ DX30 (Tru-Tain)	Triad® Gel (DENTSPLY)
9	Tru-Tain™ DX30 (Tru-Tain)	Biocryl Ice Acrylic Resin (Great Lakes)

B. Preparing Maxillary Dentition Models

Multiple rubber impression molds of the same maxillary dentition were used to pour up 18 maxillary dentition models using dental lab stone, Quickstone by Whip Mix® (Figure 3-2).

C. Preparing the CTA

The three .040" clear thermoplastic aligner materials selected for this study were Essix ACE® Plastic (DENTSPLY Raintree Essix Glenroe), Tru-Tain™ DX30 (Tru-Tain Orthodontic and Dental Supply), and Clear Splint Biocryl (Great Lakes Orthodontics) (Figure 3-3). Each material was used to make six clear thermoplastic aligners. The Biostar® VI with Scan Technology Positive Pressure Thermal-Forming Machine by Scheu Dental will be used to thermoform the clear thermoplastic materials to the stone maxillary dentition in accordance with the manufacturer's instructions (Figure 3-4).

Each fabricated CTA was then prepared for the bonding of metal auxiliary buttons by roughening the entire buccal/facial surfaces of each aligner with a high-speed handpiece and a fine diamond flame bur (Matchbox Diamonds, Size 862-016, DENTSPLY Midwest) in accordance with the manufacturer's instructions (Figure 3-5).

D. Bonding Metal Auxiliary Buttons to CTA

The bonding adhesives that will be used to attach the metal auxiliary button (Curved Bondable Button- 3M Unitek)(Figure 3-6) auxiliaries are Triad™ Gel with Triad® VLC Bonding Agent (DENTSPLY), Biocryl Ice Acrylic Resin (Great Lakes

Orthodontics), and Bond Aligner™ (Reliance Orthodontic Products) (Figure 3-7). These adhesives will each be used in accordance with their manufacturer's instructions.

The metal auxiliary buttons will be bonded to the group's respective clear aligner material using their respective bonding adhesive system. The auxiliary button will be placed directly onto the center of the buccal/facial surfaces of the prepared aligner (Figure 3-8), adjacent to five teeth on the thermoplastic aligner (#2, #5, #8, #11, and #14). Excess bonding agent will be removed with a dental explorer prior to curing. Only five sites per aligner were selected for shear bond strength testing in order to reduce potential distortion of the adjacent bonding sites during Instron testing.

E. Biocryl Ice Acrylic Resin Bonding

Bonding with the cold-cure resin, Biocryl Ice Acrylic Resin (Great Lakes Orthodontics), will be conducted by first placing the liquid monomer on the roughened buccal/facial surfaces of each clear aligner material. After two minutes, a second layer of monomer will be applied to the bonding surfaces of the aligner and the base of the metal auxiliary button. Small amounts of monomer and polymer will then be mixed to syrup like consistency, per the manufacturer's instructions, and applied to the base of the metal auxiliary button. The button will then be carefully positioned on the thermoplastic aligner material. The acrylic will then be allowed to cure for 24 hours.

F. Triad® Gel Bonding

Bonding with the light-cure resin, Triad® Gel by DENTSPLY will be conducted by first applying Triad® VLC Bonding Agent to the facial/buccal surfaces of each thermoplastic aligner and then placing the aligner in the Triad® 2000 VLC unit for 2

minutes. Next, Triad® Gel will be applied to the base of the metal auxiliary button and the button will then be carefully positioned on the thermoplastic aligner material. The aligner will then be placed in the Triad® 2000 VLC Unit to cure for four minutes (Figure 3-9).

G. Bond Aligner™ Bonding

Bonding with the new light-cure adhesive Bond Aligner™, by Reliance Orthodontic Products, will be conducted by applying the adhesive to the base of the metal auxiliary button and then carefully positioning the auxiliary buttons on the thermoplastic appliance material. The bonding adhesive will then be cured using a VALO™ (ULTRADENT) curing light. The VALO™ (ULTRADENT) curing light is a light emitting diode that produces high intensity light at 395-480nm. The Plasma Mode setting will be used with a power level of 4500mW. Each metal auxiliary button with its corresponding bonding adhesive will be cured for three seconds on the four sides of the button's base. (Figure 3-10)

H. Shear Bond Strength Testing

A universal testing machine by Instron® (NORWOOD, MA) will be used to perform debonding shear tests on 10 buttons for each sample group. A total of 90 buttons will be tested (Figure 3-11).

The CTA model base was placed occlusal side up on the universal testing machine (Instron 5943R9153, Norwood, Maine) (Figure 3-24). A straight blade was mounted onto the 1 KiloNewton load cell. Prior to the initiation of the test, a crosshead

speed of 1mm/min was designated to the Instron. The blade was placed against the flat surface of CTA behind the button head (Figure 3-12).

Once the Instron machine setup was complete and the specimen was in position, the test was initiated and the blade descended vertically and was perpendicular to the metal auxiliary button until bond failure occurred. The Instron machine records, in Newtons, the maximum force required to create shear bond failure. Based on the maximum force at the time of the failure, shear bond strength was determined for each sample in megapascals (MPa). Shear bond strength in MPa was calculated from the peak load of failure in Newtons and divided by the metal auxiliary button's surface area (0.024 in²). The mean and standard deviation was determined per group and subgroup.

I. Instrumentation

The specifications of the Instron 5943, Norwood, MA are:

- 1 kN (225 lb) capacity
- 1123 mm (44.2 in) vertical test space
- Load measurement accuracy: +/- 0.5% of reading down to 1/1000 of load cell capacity option (2580 series load cells)
- Up to 2.5 kHz data acquisition rate option simultaneous on load, extension, and strain channels
- Speed range of 0.05 - 2500 mm/min (0.002 - 100 in/min)

J. Site of Failure Observation

Following shear bond strength (SBS) testing, the specimens were examined under a 20x stereomicroscope (Nikon Microscope Model #553730, Japan) (Figure 3-13) to determine the site of bond failure as either: 1) CTA material ripping with the auxiliary still bonded to the CTA 2) Auxiliary debonds with no bonding agent remnants on the CTA 3) Auxiliary debonds with bonding agent on both the CTA and auxiliary base 4) Auxiliary debonds with no bonding agent remnants on auxiliary base.

K. Statistical Analysis

Prior to conducting this research, a power analysis was calculated to determine if 10 samples per group would yield sufficient strength and significant effect to accept or reject the null hypothesis. The power analysis found that a sample size of 10 per group provides 80% power to detect a moderate effect size of 0.335, or approximately .077 standard deviation difference among means for the main effects of both bonding agent type and CTA material, and a moderate effect of 0.37 for the interaction between the effects (NCSS PASS 2002).

The Instron Universal Testing Machine (Instron®, Norwood, MA) was used to measure shear bond strength in Newtons (N) required to debond each of the 10 samples per group. The Megapascals required to debond each sample was calculated by dividing Newtons by the surface area of the auxiliary button (0.024 in²). This information was then used to calculate the mean and standard deviation descriptive statistics for each of the nine groups in both Megapascals (MPa) and Newtons (N) (Table 4-1 thru Table 4-9).

In addition, bond failure site scores were collected for each tested sample. This data was organized into a chart, according to predetermined bond failure site parameters (Figure 4-12), where it clearly illustrates the predominant site of failure for each type of bonding agent (Table 4-13 and Figure 4-4).

Statistical analysis included a two-way analysis of variance (ANOVA) and Tukey's Honestly Significant Difference (HSD) test. The means of shear bond strength in MPa were compared using the two-way ANOVA model that included main effect factors for both bonding agent type (Bond Aligner™, Triad® Gel, Biocryl Ice) and CTA material (Clear Splint Biocryl, Essix ACE®, Tru-Tain™ DX30), and a factor to account for the interactions between both factors. Once a significant difference was found between the factors the Tukey's Honestly Significant Difference (HSD) test criteria was applied to screen for pairwise comparisons between the groups to determine where the significant differences were located. Our level of significance was defined when $p < 0.05$.

L. Figures of Materials and Methods Procedures.

The images of the research procedures are listed and documented in order of their occurrence.

Figure 3-1. Overview of Research Design

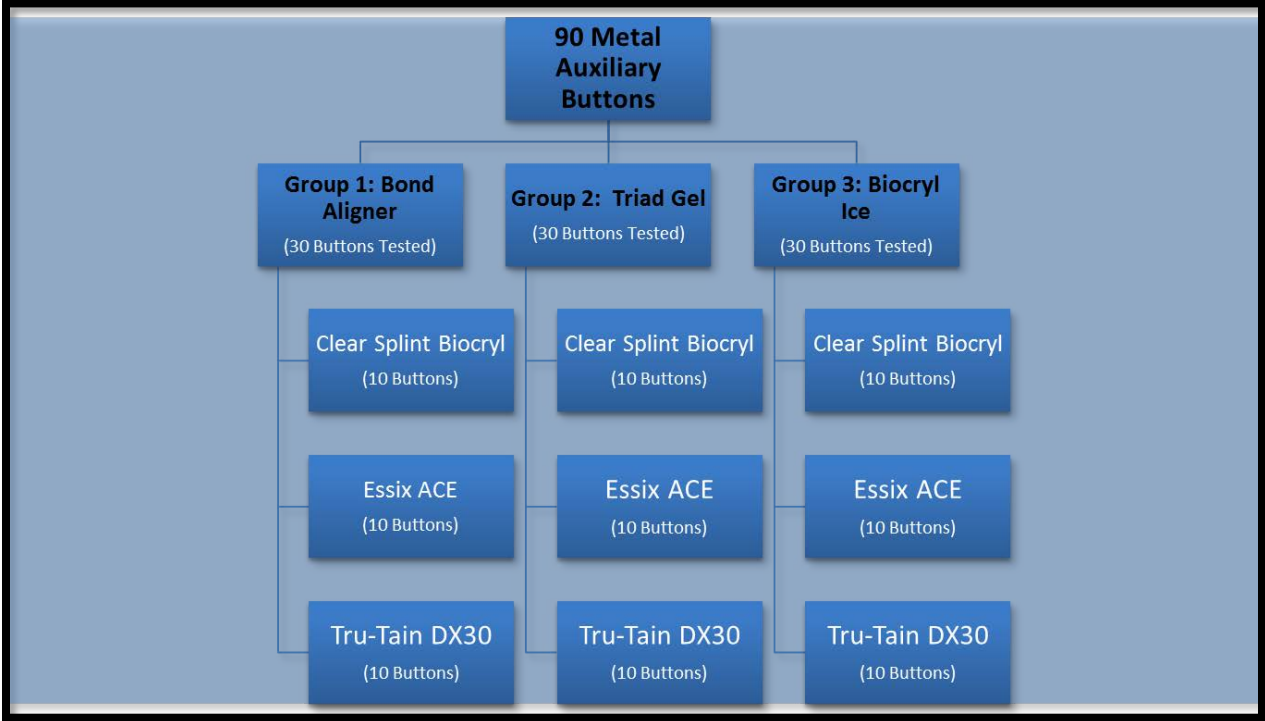


Figure 3-2. Rubber impression molds used to pour up 18 maxillary dentition models using dental lab stone, Quickstone by Whip Mix®



Figure 3-3. Three clear thermoplastic aligner materials selected for the study



Figure 3-4. Biostar® VI with Scan Technology Positive Pressure Thermal Forming Machine used to thermoform the CTA materials to the stone maxillary models



Figure 3-5. Fine diamond flame bur used to roughen the entire buccal/facial surface of the CTA



Figure 3-6. Metal auxiliary button (3M Unitek Lingual Button Curved)



Figure 3-7. Three bonding adhesives that were used to attach the metal auxiliary buttons to the CTA



Figure 3-8. The auxiliary button placed directly onto the center of the buccal/facial surfaces of the prepared aligner



Figure 3-9. Triad® 2000 VLC unit used to light-cure Triad® Gel



Figure 3-10. The VALO™ curing light used to light cure Bond Aligner™

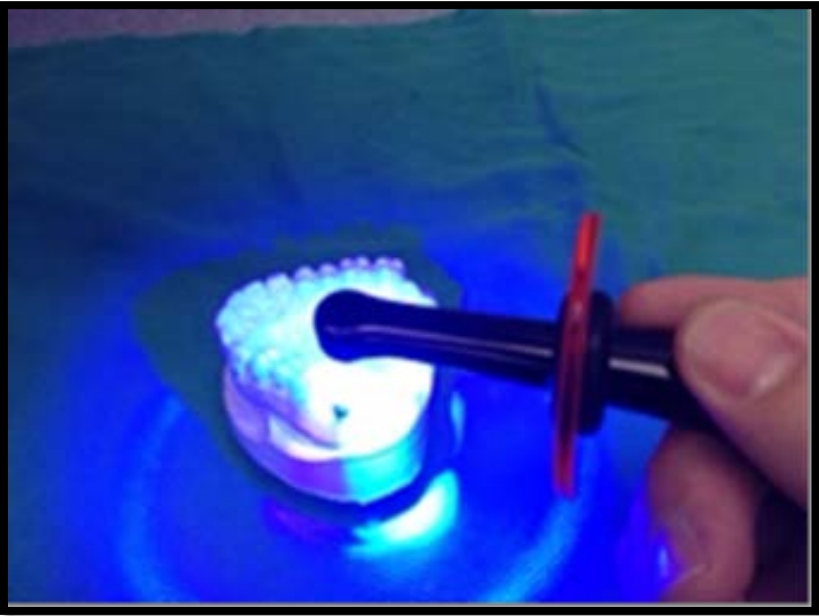


Figure 3-11. Universal testing machine by Instron® used to perform debonding shear tests



Figure 3-12. Single blade from Instron® machine engages the metal auxiliary button behind the button head



Figure 3-13. Microscope used to evaluate the site of failure after shear bond strength tests



IV. RESULTS

Our study results were collected after completing the shear bond strength tests with the Instron® universal testing machine on the auxiliary buttons bonded with different bonding agents to different CTA materials. An attached blade on the load cell of the Instron machine descended at a cross-head speed of 1mm per minute and engaged the auxiliary button bonded to the CTA. The force on the load cell was recorded as the blade continued its downward movement. Once the load cell recorded a significant drop in force in its downward movement, the blade stopped and the load cell recorded, in Newtons (N), the maximum force applied. The force in Newtons was then divided by the surface area of the auxiliary button base (0.024in²) to give the shear bond strength of the test sample in megapascals (MPa). The shear bond strength for each group is recorded in the following tables, as well as the average shear bond strength and standard deviation for each group and subgroup (Table 4-1 to Table 4-11). The auxiliary buttons and CTA material were then manually examined under a microscope to determine the site and mode of failure.

The two-way ANOVA results found that the type of bonding agent used was significant ($p < 0.001$), while the type of CTA material ($p = 0.453$) and the interaction between bonding agent and CTA material ($p = 0.397$) were not significant. Further analysis of the independent variables with the Tukey HSD test found that Bond Aligner™ had significantly greater shear bond strength than both Triad® Gel and Biocryl Ice (Table 4-11 and Figure 4-1). Triad® Gel was found to have a significantly greater shear bond strength than Biocryl Ice and significantly lower shear bond strength than Bond Aligner™ (Table 4-11 and Figure 4-1). Biocryl Ice was found to have significantly

lower shear bond strength than both Bond Aligner™ and Triad® Gel (Table 4-11 and Figure 4-1). Lastly, the Tukey HSD test showed there was no significant difference in shear bond strength in regards to CTA material (Table 4-11 and Figure 4-2).

Additional non-parametric data was collected based on the bond failure site of the auxiliary buttons. There were four possible failure sites noted when conducting the shear bond strength tests. The CTA material could fail and rip with the auxiliary button still bonded to the CTA. The auxiliary button could debond with no bonding agent remnants on the CTA material. The auxiliary button could debond with bonding agent remnants on both the CTA and auxiliary base. And lastly, the auxiliary button could debond with no bonding agent remnants on the auxiliary base. A comparison was done to evaluate the site of failure of each group and there were differences noted between the groups (Table 4-13 and Figure 4-4). Auxiliary buttons bonded with Bond Aligner™ experienced a majority (60%) of their failure due to the CTA material ripping with the auxiliary still bonded to the CTA. Auxiliary buttons bonded with Triad® Gel experienced an equal distribution of failure among the first three failure sites. Auxiliary buttons bonded with Biocryl Ice experienced a majority (90%) of their failure due to the auxiliary debonding from the CTA with no bonding agent remnants on the auxiliary base.

Table 4-1. Group 1: Bond Aligner™/Clear Splint Biocryl

Group 1: Bond Aligner™/Clear Splint Biocryl

Date Tested: 20 March 2013

	N	MPa	Failure Site
1	82.500	5.32	3
2	115.400	7.45	1
3	59.780	3.86	1
4	97.340	6.28	1
5	80.030	5.16	3
6	84.120	5.43	4
7	114.830	7.41	1
8	33.890	2.19	3
9	77.390	4.99	1
10	59.870	3.86	1
avg	80.52	5.19	
st dev	25.24	1.63	

Failure Site Key

- 1 CTA Material
- 2 CTA/Bonding Agent Interface
- 3 Bonding Agent
- 4 Bonding Agent/Auxiliary Interface
- 5 Auxiliary Button

Table 4-2. Group 2: Bond Aligner™/Essix ACE®

Group 2: Bond Aligner™/Essix ACE®

Date Tested: 20 March 2013

	N	MPa	Failure Site
1	76.340	4.93	2
2	93.450	6.03	2
3	56.810	3.67	3
4	74.600	4.81	3
5	43.880	2.83	2
6	64.600	4.17	2
7	89.870	5.80	1
8	57.180	3.69	1
9	72.670	4.69	1
10	61.140	3.94	3
avg	69.05	4.46	
st dev	15.39	0.99	

Failure Site Key

- 1 CTA Material
- 2 CTA/Bonding Agent Interface
- 3 Bonding Agent
- 4 Bonding Agent/Auxiliary Interface
- 5 Auxiliary Button

Table 4-3. Group 3: Bond Aligner™/Tru-Tain™ DX30

Group 3: Bond Aligner™/Tru-Tain™ DX30

Date Tested: 20 March 2013

	N	MPa	Failure Site
1	68.190	4.40	1
2	109.010	7.03	1
3	41.220	2.66	1
4	53.320	3.44	1
5	48.540	3.13	3
6	65.460	4.22	1
7	102.530	6.61	1
8	61.050	3.94	1
9	78.410	5.06	1
10	60.660	3.91	1
avg	68.84	4.44	
st dev	22.10	1.43	

Failure Site Key

- 1 CTA Material
- 2 CTA/Bonding Agent Interface
- 3 Bonding Agent
- 4 Bonding Agent/Auxiliary Interface
- 5 Auxiliary Button

Table 4-4. Group 4: Triad® Gel/Clear Splint Biocryl

Group 4: Triad® Gel/Clear Splint Biocryl

Date Tested: 20 March 2013

	N	MPa	Failure Site
1	46.990	3.03	4
2	75.670	4.88	1
3	39.550	2.55	2
4	54.120	3.49	3
5	44.220	2.85	3
6	52.540	3.39	2
7	87.750	5.66	1
8	36.240	2.34	2
9	50.920	3.29	2
10	48.140	3.11	2
avg	53.61	3.46	
st dev	16.06	1.04	

Failure Site Key

- 1 CTA Material
- 2 CTA/Bonding Agent Interface
- 3 Bonding Agent
- 4 Bonding Agent/Auxiliary Interface
- 5 Auxiliary Button

Table 4-5. Group 5: Triad® Gel/Essix ACE®

Group 5: Triad® Gel/Essix ACE®

Date Tested: 20 March 2013

	N	MPa	Failure Site
1	50.790	3.28	3
2	57.930	3.74	3
3	29.360	1.89	3
4	45.090	2.91	3
5	46.790	3.02	3
6	52.510	3.39	3
7	64.720	4.18	3
8	31.040	2.00	3
9	44.440	2.87	3
10	46.500	3.00	3
avg	46.92	3.03	
st dev	10.82	0.70	

Failure Site Key

- 1 CTA Material
- 2 CTA/Bonding Agent Interface
- 3 Bonding Agent
- 4 Bonding Agent/Auxiliary Interface
- 5 Auxiliary Button

Table 4-6. Group 6: Triad® Gel/Tru-Tain™ DX30

Group 6: Triad® Gel/Tru-Tain™ DX30

Date Tested: 20 March 2013

	N	MPa	Failure Site
1	46.980	3.03	1
2	78.880	5.09	1
3	36.570	2.36	1
4	34.980	2.26	1
5	39.920	2.58	2
6	42.640	2.75	2
7	70.040	4.52	1
8	28.980	1.87	2
9	52.190	3.37	1
10	35.940	2.32	1
avg	46.71	3.01	
st dev	16.13	1.04	

Failure Site Key

- 1 CTA Material
- 2 CTA/Bonding Agent Interface
- 3 Bonding Agent
- 4 Bonding Agent/Auxiliary Interface
- 5 Auxiliary Button

Table 4-7. Group 7: Biocryl Ice/Clear Splint Biocryl

Group 7: Biocryl Ice/Clear Splint Biocryl

Date Tested: 20 March 2013

	N	MPa	Failure Site
1	19.770	1.28	4
2	33.110	2.14	4
3	16.670	1.08	4
4	38.980	2.51	4
5	13.020	0.84	4
6	8.960	0.58	4
7	47.490	3.06	4
8	12.820	0.83	4
9	22.600	1.46	4
10	9.880	0.64	4
avg	22.33	1.44	
st dev	13.23	0.85	

Failure Site Key

- 1 CTA Material
- 2 CTA/Bonding Agent Interface
- 3 Bonding Agent
- 4 Bonding Agent/Auxiliary Interface
- 5 Auxiliary Button

Table 4-8. Group 8: Biocryl Ice/Essix ACE®

Group 8: Biocryl Ice/Essix ACE®

Date Tested: 20 March 2013

	N	MPa	Failure Site
1	35.830	2.31	4
2	27.050	1.75	4
3	21.590	1.39	4
4	17.400	1.12	4
5	23.000	1.48	4
6	20.140	1.30	4
7	31.820	2.05	4
8	21.280	1.37	3
9	28.230	1.82	3
10	23.430	1.51	4
avg	24.98	1.61	
st dev	5.69	0.37	

Failure Site Key

- 1 CTA Material
- 2 CTA/Bonding Agent Interface
- 3 Bonding Agent
- 4 Bonding Agent/Auxiliary Interface
- 5 Auxiliary Button

Table 4-9. Group 9: Biocryl Ice/Tru-Tain™ DX30

Group 9: Biocryl Ice/Tru-Tain™ DX30

Date Tested: 20 March 2013

	N	MPa	Failure Site
1	10.470	0.68	4
2	43.430	2.80	4
3	20.220	1.30	4
4	45.310	2.92	4
5	25.960	1.67	4
6	45.700	2.95	4
7	39.610	2.56	4
8	34.490	2.23	4
9	21.680	1.40	4
10	14.050	0.91	1
avg	30.09	1.94	
st dev	13.29	0.86	

Failure Site Key

- 1 CTA Material
- 2 CTA/Bonding Agent Interface
- 3 Bonding Agent
- 4 Bonding Agent/Auxiliary Interface
- 5 Auxiliary Button

Table 4-10. Mean and Standard Deviations

Descriptive Statistics

Dependent Variable: MPA

AGENT	TRAY	Mean	Std. Deviation	N
Bond Aligner™	Clear Splint Biocryl	5.195	1.6288	10
	Essix ACE®	4.456	0.9936	10
	Tru-Tain™ DX30	4.44	1.4247	10
	Total	4.697	1.374	30
Triad® Gel	Clear Splint Biocryl	3.459	1.0356	10
	Essix ACE®	3.028	0.7008	10
	Tru-Tain™ DX30	3.015	1.0408	10
	Total	3.1673	0.9303	30
Biocryl Ice	Clear Splint Biocryl	1.442	0.8516	10
	Essix ACE®	1.61	0.3676	10
	Tru-Tain™ DX30	1.942	0.8571	10
	Total	1.6647	0.7346	30
Total	Clear Splint Biocryl	3.3653	1.953	30
	Essix ACE®	3.0313	1.3774	30
	Tru-Tain™ DX30	3.1323	1.509	30
	Total	3.1763	1.6195	90

Table 4-11. Shear Bond Strength MPa (Stdev) Results

Bonding Agent	Shear Bond Strength MPa (St Dev)*			
	CTA Material			
	Sub-Group 1	Sub-Group 2	Sub-Group 3	
	Clear Splint Biocryl	Essix ACE®	Tru-Tain™ DX30	Total %
Bond Aligner™	5.20 (1.6) ^a	4.46 (1.0) ^a	4.44 (1.4) ^a	4.70 (1.4) ^A
Triad® Gel	3.46 (1.0) ^b	3.03 (0.7) ^b	3.02 (1.0) ^b	3.17 (0.9) ^B
Biocryl Ice	1.44 (0.9) ^c	1.61 (0.4) ^c	1.94 (0.9) ^c	1.66 (0.7) ^C
Total	3.37 (2.0) ^d	3.03 (1.4) ^d	3.13 (1.5) ^d	

*Groups with the same lower case letter by row or column are not significantly different. Groups with the same upper case letter per column are not significantly different.

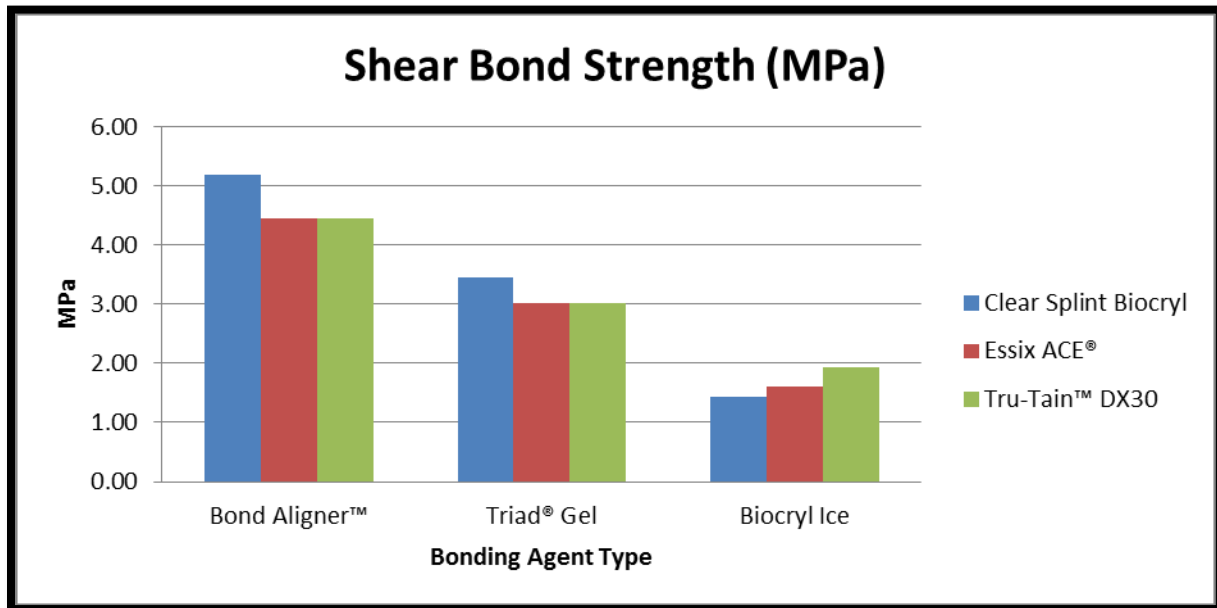
Table 4-12. Bond Failure Site Parameters

Failure Site Key	
1	CTA Material Rips- Auxiliary Still Bonded to CTA
2	Auxiliary Debonds- No Bonding Agent Remnant On CTA Material
3	Auxiliary Debonds- Bonding Agent On Both CTA And Auxiliary Base
4	Auxiliary Debonds- No Bonding Agent Remnant On Auxiliary Base

Table 4-13. Failure Site Results

Fracture Mode	Failure Site Percentage(Number out of 10)			
	Bond Aligner™	Clear Splint Biocryl	Essix ACE®	Tru-Tain™ DX30
<i>CTA Material</i>	60% (6)	30% (3)	90% (9)	60%
<i>CTA/Bonding Agent Interface</i>		40% (4)		13%
<i>Bonding Agent</i>	30% (3)	30% (3)	10% (1)	23%
<i>Bonding Agent/Auxiliary Interface</i>	10% (1)			3%
Triad® Gel				
<i>CTA Material</i>	20% (2)		70% (7)	30%
<i>CTA/Bonding Agent Interface</i>	50% (5)		30% (3)	27%
<i>Bonding Agent</i>	20% (2)	100% (10)		40%
<i>Bonding Agent/Auxiliary Interface</i>	10% (1)			3%
Biocryl Ice				
<i>CTA Material</i>			10% (1)	3%
<i>CTA/Bonding Agent Interface</i>				
<i>Bonding Agent</i>		20% (2)		7%
<i>Bonding Agent/Auxiliary Interface</i>	100% (10)	80% (8)	90% (9)	90%

Figure 4-1. Bar Graph of Shear Bond Strength (SBS) Results



Bond Aligner™ had significantly greater bond strengths ($p < 0.001$) to each CTA material compared to Triad® Gel and Biocryl Ice with no significant interaction ($p = 0.397$). Triad Gel was found to have significantly greater shear bond strength ($p < 0.001$) than Biocryl Ice and significantly lower shear bond strength than Bond Aligner. Lastly, Biocryl Ice was found to have significantly lower shear bond strength than Bond Aligner and Triad Gel.

Figure 4-2. Bonding Agent Shear Bond Strength Results

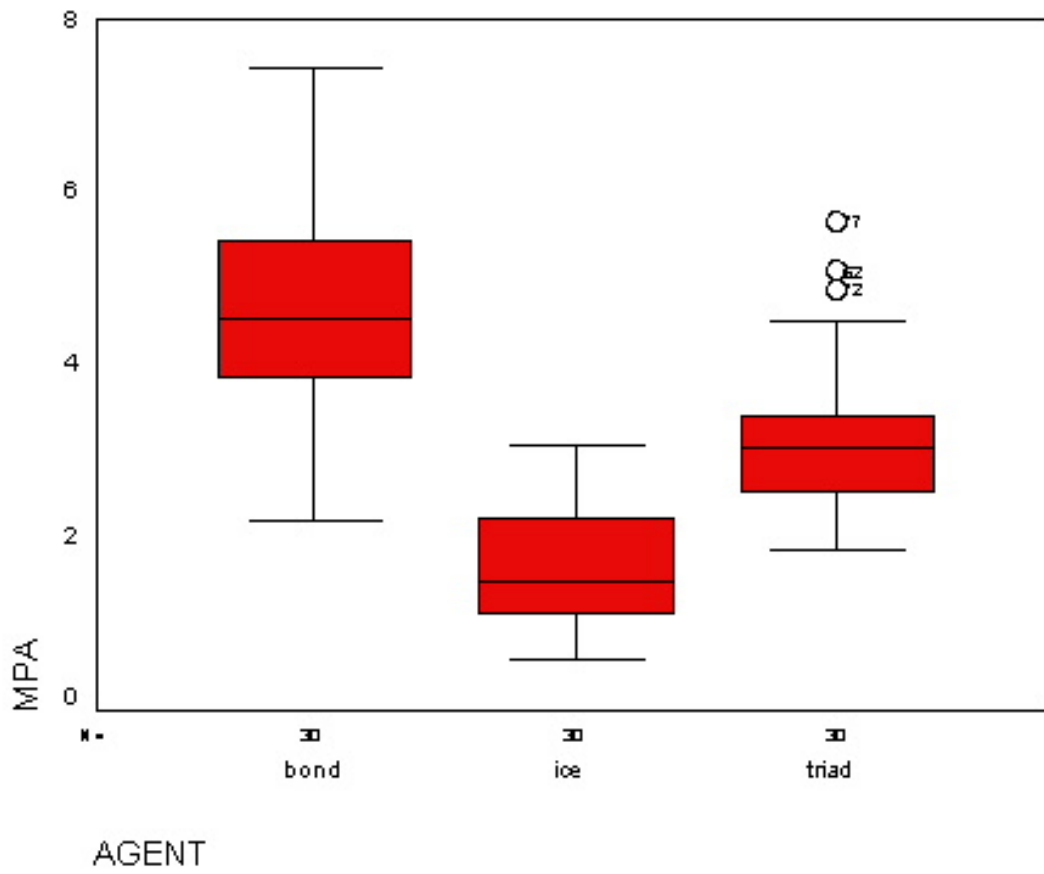


Figure 4-3. CTA Material Shear Bond Strength Results

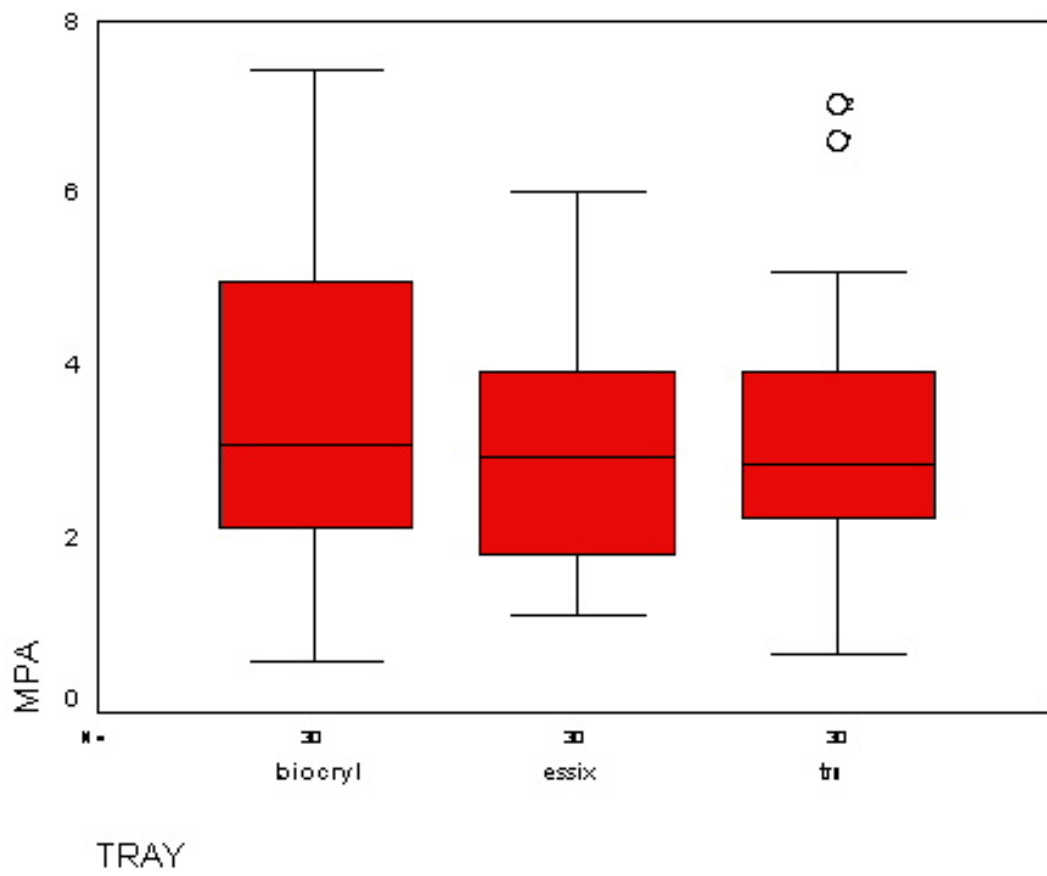
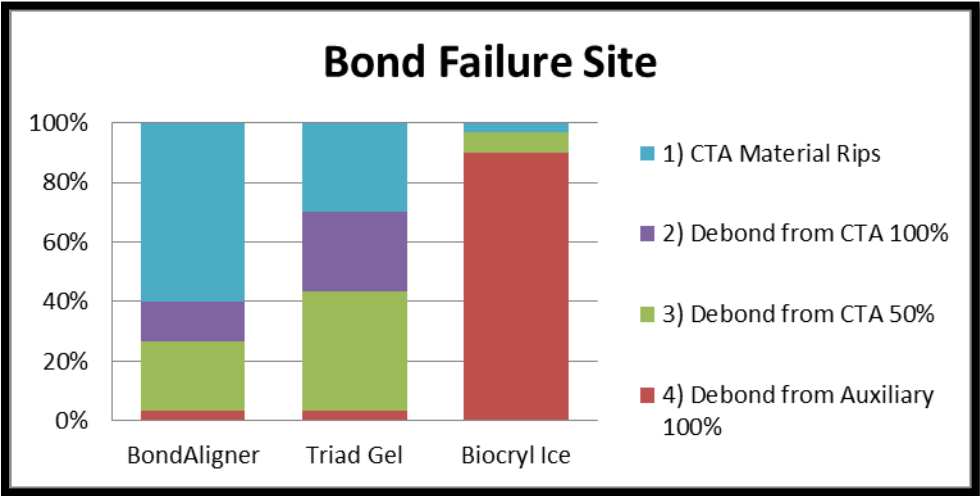


Figure 4-4. Bond Failure Site Graph



V. DISCUSSION

The results of this study indicate that metal auxiliary buttons bonded to clear thermoplastic aligner materials with Bond Aligner™ are more durable than those bonded with Biocryl Ice, a cold cure acrylic, and Triad® Gel, a light cure acrylic.

Many limitations are evident with this study. The sample size of ten auxiliary buttons tested for each group tested was small. However, the sample size for each group was adequate to determine significant differences. Future studies should look at including additional attachment methods, bonding materials, types of auxiliary attachments, and CTA materials to further add to the results of this study. Future shear bond strength tests on bonded auxiliaries should better approximate intraoral conditions and use elastics to remove the bonded attachments instead of the rigid Instron® blade.

This study was conducted in vitro and therefore impossible to truly evaluate the various effects that saliva, food, occlusal forces, and repeated removal, insertion and long-term wear of elastics have on bonded auxiliaries. Other studies have demonstrated that polymers can be degraded by various intraoral conditions. For example, alcohol plasticizes certain polymers, water causes filler leaching, and some microorganisms produce esterase enzymes that can degrade polymers (Soderholm and Richards, 1998).

VI. CONCLUSION

1. There is greater bond strength between the adhesive and clear thermoplastic material interface using the newly developed bonding system, Bond Aligner™, versus the currently accepted light-cure and cold-cure acrylic resin bonding systems.
2. Bond Aligner™ had significantly greater shear bond strength than both Triad® Gel and Biocryl Ice.
3. Triad® Gel was found to have a significantly greater shear bond strength than Biocryl Ice and significantly lower shear bond strength than Bond Aligner™.
4. Biocryl Ice was found to have significantly lower shear bond strength than both Bond Aligner™ and Triad® Gel.
5. There was no significant difference in shear bond strength in regards to the CTA material used ($p=0.453$). In addition the interaction between bonding agent and CTA material ($p=0.397$) was not significant.
6. A majority of auxiliary buttons bonded to CTA material with Bond Aligner™ did not experience bond failure when subjected to the shear bond strength test due to the CTA material ripping and failing before debonding could occur.
7. This study supports the claims that Bond Aligner™ is a reliable bonding system that allows providers the ability to bond auxiliaries to any clear thermoplastic aligner material, including, but not limited to Clear Splint Biocryl, Essix ACE®, and Tru-Tain™ DX30. Bond Aligner™ does not require the extra step of applying a primer material, as required for both light-cure and cold-cure acrylic resin bonding systems. Bond Aligner™ now allows clinicians to confidently troubleshoot cases with bonded auxiliaries without worrying about auxiliary debond failures.

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