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An in vivo and in vitro study of a new orthodontic bonding agent

Meredith S. Parks
West Virginia University

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**AN *IN VIVO* AND *IN VITRO* STUDY OF
A NEW ORTHODONTIC BONDING AGENT**

Meredith S. Parks, D.D.S.

Thesis Submitted to the School of Dentistry
at West Virginia University
In Partial Fulfillment of the Requirements for
The Degree of

Master of Science
In
Orthodontics

Peter Ngan, D.M.D., Chair
Chris Martin, D.D.S., M.S.
Elizabeth Kao, D.M.D.

Department of Orthodontics

Morgantown, West Virginia
2006

ABSTRACT

AN *IN VIVO* AND *IN VITRO* STUDY OF A NEW ORTHODONTIC BONDING AGENT

Meredith S. Parks, D.D.S

The *in vitro* study utilized 90 extracted premolars. The teeth were divided into six groups. In the first three groups brackets were bonded with Concise, Transbond XT, or APC Plus and debonded 30 minutes after bonding. In the second three groups, brackets were bonded with Concise, Transbond XT, or Concise and debonded after thermocycling. The *in vivo* study consisted of 31 patients and a split arch technique was utilized. Adhesives used were APC Plus and Transbond XT. Bond strengths for thermocycled Concise and Transbond XT were significantly greater than the other *in vitro* groups. Concise debonded after 30 minutes left significantly more adhesive on the teeth than the other *in vitro* groups, indicating that the failure occurred at the adhesive bracket interface. There was no significant difference in the bracket survival rate between APC Plus and Transbond XT *in vivo*.

TABLE OF CONTENTS

ABSTRACT.....	ii
TABLE OF CONTENTS.....	iii
LIST OF TABLES.....	v
LIST OF FIGURES.....	vi
CHAPTER I.....	1
INTRODUCTION.....	1
BACKGROUND.....	1
STATEMENT OF THE PROBLEM.....	1
SIGNIFICANCE OF THE PROBLEM.....	2
PURPOSE OF THE STUDY.....	2
HYPOTHESIS.....	2
OPERATIONAL TERMS.....	3
ASSUMPTIONS.....	4
LIMITATIONS.....	4
<i>IN VITRO</i>	4
<i>IN VIVO</i>	4
DELIMITATIONS.....	5
<i>IN VITRO</i>	5
<i>IN VIVO</i>	5
CHAPTER II.....	6
REVIEW OF LITERATURE.....	6
INTRODUCTION.....	6
DEVELOPMENT OF BONDING AGENTS.....	6
CHEMICAL CURED AGENTS.....	6
LIGHT CURED AGENTS.....	7
ADVANTAGES AND DISADVANTAGES OF VLC.....	10
BOND STRENGTH.....	11
HOW BOND STRENGTH IS TESTED.....	11
<i>IN VITRO</i> BOND STRENGTH EXPERIMENTS.....	13
EFFECTS OF FLUORIDE ADDITIVES ON BOND STRENGTH.....	14
<i>IN VIVO</i> BRACKET SURVIVAL EXPERIMENTS.....	15
PREPARATION OF THE TOOTH SURFACE FOR BONDING.....	18
CHAPTER III.....	20
METHODS AND MATERIALS.....	20
<i>IN VITRO</i> STUDY.....	20
PREPARING TEETH FOR TESTING.....	21
BONDING PROCEDURES.....	23
BOND STRENGTH TESTING.....	24
DATA ANALYSIS.....	26
<i>IN VIVO</i> STUDY.....	27
BONDING PROCEDURE.....	27
DATA ANALYSIS.....	28
CHAPTER IV.....	30
RESULTS AND DISCUSSION.....	30

RESULTS OF <i>IN VITRO</i> BOND STRENGTH STUDY.....	30
<i>IN VITRO</i> BRACKET INTERFACE ARI SCORES.....	32
RESULTS OF <i>IN VIVO</i> SURVIVAL RATE STUDY.....	33
COMPARISON OF SURVIVAL TIMES.....	34
COMPARISON OF MAXILLARY AND MANDIBULAR ARCHES.....	35
COMPARISON OF RIGHT AND LEFT SIDES.....	37
<i>IN VIVO</i> BRACKET FAILURE INTERFACE ARI SCORES.....	39
DISCUSSION OF <i>IN VITRO</i> INVESTIGATION.....	40
DISCUSSION OF <i>IN VIVO</i> INVESTIGATION.....	45
CLINICAL IMPLICATIONS.....	47
CHAPTER V.....	48
SUMMARY AND CONCLUSIONS.....	48
SUMMARY.....	48
CONCLUSIONS.....	50
RECOMMENDATIONS.....	50
REFERENCE LIST.....	52
APPENDIX A – IRB APPROVAL.....	62
APPENDIX B – CONSENT FORM.....	65
APPENDIX C- ASSENT FORM.....	69
APPENDIX D – PHI FORM.....	72
APPENDIX E – RAW DATA FOR <i>IN VITRO</i> STUDY.....	75
APPENDIX F – <i>IN VITRO</i> STATISTICAL ANALYSIS RESULTS.....	77
APPENDIX G – RAW DATA FOR <i>IN VIVO</i> STUDY.....	86
APPENDIX H - <i>IN VIVO</i> STATISTICAL ANALYSIS RESULTS.....	100
CURRICULUM VITAE.....	107

LIST OF TABLES

Table 1. Study Groups.....	20
Table 2. The modified ARI scoring scale.....	27
Table 3. Shear bond strengths for <i>in vitro</i> experimental groups measured in megapascals.....	31
Table 4. Tukey Kramer Analysis of mean shear bond strengths for the experimental groups....	32
Table 5. ARI analysis of all <i>in vitro</i> experimental groups.....	32
Table 6. Tukey Kramer analysis of mean ARI scores for the <i>in vitro</i> experimental groups.....	33
Table 7. Survival times (days) for failed brackets observed in the <i>in vivo</i> study.....	34
Table 8. <i>In Vivo</i> studies of the failure rate of Transbond XT.....	45

LIST OF FIGURES

Figure 1. Figures 1A and B. Tinted APC Plus adhesive on the back of a bracket (A) And with visible flash around bracket during bonding(B).....	21
Figure 2. A sample mounted in stainless steel ring.....	22
Figure 3. Use of surveyor to accurately place bracket on the tooth sample.....	22
Figure 4. Sample ready for testing with the Instron Mechanical testing machine.....	25
Figure 5. Close up of sample ready for testing with the Instron Mechanical testing machine....	26
Figure 6. Mean shear bond strengths (MPa) for all <i>in vitro</i> experimental groups.....	31
Figure 7. Mean ARI scores for all <i>in vitro</i> experimental groups.....	33
Figure 8. Number of brackets lost in the <i>in vivo</i> study.....	34
Figure 9. Product Limit Survival Plot of the two types of adhesives.....	35
Figure 10. Number of brackets lost in each arch in the <i>in vivo</i> study.....	36
Figure 11. Survival Plots of maxillary and mandibular brackets bonded with Transbond XT...36	
Figure 12. Survival Plots of maxillary and mandibular brackets bonded with APC Plus.....37	
Figure 13. Number of brackets lost on each side of the mouth in the <i>in vivo</i> study.....38	
Figure 14. Survival plots of right and left brackets bonded with Transbond XT.....38	
Figure 15. Survival Plots of right and left brackets bonded with APC Plus.....39	

CHAPTER I

INTRODUCTION

BACKGROUND

Orthodontic bonding agents or adhesives are used to attach fixed appliances to the enamel surface of teeth. These bonding agents have to be strong enough to hold the appliance to the teeth, but not fracture the enamel when they are removed. Excess adhesive around orthodontic brackets is usually removed before light curing. Currently, the adhesives are difficult to differentiate from enamel due to their similar coloring to both enamel and cosmetic brackets. Quite often, excess adhesive is left around the brackets and may collect plaque and promote decalcification. A new adhesive has been developed which is tinted to assist in cleanup of excess around brackets (APC-Plus, 3M Unitek, Monrovia, CA). This adhesive also contains fluoride to combat the problem of decalcification around orthodontic brackets. The aim of this study is to assess whether this new adhesive will have adequate bond strength to be used successfully clinically.

STATEMENT OF THE PROBLEM

The new bracket adhesive, APC-PLUS (3M Unitek, Monrovia, CA) which is tinted and contains fluoride to prevent decalcification, has not been tested for bond strength, bracket survival rate, and mode of bracket failure. Is the *in vitro* bond strength of this new adhesive comparable to Transbond XT and Concise? What is the bracket survival rate *in vivo*? What is the mode of bracket failure *in vivo* and *in vitro*?

SIGNIFICANCE OF THE PROBLEM

Excess adhesives left around orthodontic brackets after bonding may be difficult to remove because they have a similar color as the enamel and cosmetic brackets. Excess adhesives may collect plaque and cause decalcification and caries around brackets. A new FDA approved orthodontic bracket adhesive developed by 3M Unitek called APC PLUS, contains fluoride and changes color upon curing with visible light. If this adhesive has adequate bond strength, it will aid in cleanup of excess adhesive during bracket placement and help in reducing decalcification around brackets.

PURPOSE OF THE STUDY

The purpose of this study is to determine 1) the *in vitro* bracket debonding strength of the APC-Plus compared to two other conventional adhesives; 2) the *in vivo* bracket survival distribution using this new adhesive compared to a conventional adhesive, Transbond XT; and 3) the mode of bracket failure of these adhesives *in vitro* and *in vivo* .

HYPOTHESIS

1) There is a significant difference between the bracket debonding strengths of APC-Plus, Transbond XT, and Concise adhesives *in vitro*. 2) There is a significant difference between the mode of bracket failure of APC-Plus, Transbond XT, and Concise adhesives *in vitro*. 3) There is a significant difference between the bracket survival rate of brackets bonded with APC-Plus and Transbond XT adhesives *in vivo*. 4) There is a significant difference between the mode of bracket failure of APC-Plus and Transbond XT *in vivo*.

OPERATIONAL TERMS

1. **Bonding Materials:** A term used to indicate the materials that attach the orthodontic brackets onto the tooth surface. Synonyms: bonding adhesives, orthodontic adhesives.
2. **Composite resin:** An adhesive that consists of a polymer base resin and inorganic filler material. Coupling agents, such as silane, are often used to chemically bond these constituents together.
3. **Conventional / Standard visible light-curing unit:** A visible light producing unit, which typically uses a halogen bulb as the light source. For the purpose of this study, the Ortholux™ LED (3M Unitek) unit will be employed.
4. **Failure Interface:** Location where bond failure occurs. The bond failure could occur either between the tooth and the adhesive or the adhesive and the bracket.
5. **Fixed Appliances:** An orthodontic appliance which has attachments that are bonded or cemented to the teeth that cannot be removed by the patient.
6. **Peel Force:** A combination between tensile and shear bond strengths.
7. **Polymerization:** A chaining together of many simple molecules to form a more complex molecule with different properties.
8. **Shear:** An action or stress caused by an applied force that causes two parts of a body to slide past each other.
9. **Shear Bond Strength:** The stress required to separate a bonded bracket from a tooth when one portion is forced to slide over another portion.
10. **Survival Distribution:** Analysis to identify the time interval after bonding during which orthodontic brackets are at highest risk for bond failure.

11. **Tensile Bond Strength:** The stress required to separate a bonded bracket from a tooth when it is pulled apart with forces acting opposite and away from each other.

ASSUMPTIONS

1. Increased bond strength is essential to prevent bracket failure.
2. Addition of fluoride to adhesive affects bond strength.
3. Addition of a chemical tint to adhesives affects bond strength.
4. The consistency of the adhesive affects bond strength.
5. All operators are knowledgeable and consistent with the technique for tooth surface preparation and bonding procedures.

LIMITATIONS

In Vitro

1. There are limitations in simulating the oral environment such as saliva, occlusal forces, and temperature changes *in vitro*.
2. Forces applied by the Instron mechanical testing machine in this study include a peel force rather than a pure shear force.
3. Calcification, morphology, and fluoride content of extracted teeth may vary.

In Vivo

1. Patient may have a preferential side on which they chew.
2. Patient may brush the right and left sides differently.

3. The participant's level of understanding and compliance regarding the recommended diet and oral hygiene instructions given after placement of orthodontic brackets may vary.
4. Multiple operators involved in the bonding of orthodontic appliances may affect results in bond strength study.
5. The criteria for patient selection did not include specific type of treatment or type of malocclusion, which may affect the type of orthodontic mechanics and forces applied.

DELIMITATIONS

In Vitro

1. Samples will be limited to premolars only.
2. Only three types of bonding adhesive will be used.
3. Thermocycling will be used to simulate the oral environment.

In Vivo

1. A split mouth bonding procedure will be followed for all patients in the study.
2. All operators are trained and the technique standardized for tooth preparation and bonding procedure.
3. All patients will be given the same post-operative instructions.
4. Only two types bonding adhesives will be used.

CHAPTER II

REVIEW OF LITERATURE

INTRODUCTION

An orthodontic bonding agent is a resin which is used to bond an orthodontic appliance to the teeth. Many different kinds of agents have been developed over the years, both light and chemically activated. The bond strength of the materials measures the adhesion of the appliance to the teeth. These bonding agents should have a strength that can properly hold the appliance to the teeth, and withstand normal forces which occur in the mouth. Orthodontic appliances routinely encounter forces of mastication and forces from archwires and other auxiliary attachments, such as elastics. The bond strength should also be such that the operator can remove the appliance without damaging the underlying enamel that it is bonded to.

DEVELOPMENT OF ORTHODONTIC BONDING AGENTS

Chemical Cured Agents

In 1964, Newman ⁽¹⁾ introduced the possibility of direct bonding a plastic orthodontic bracket to the enamel surface of a tooth using an adhesive resin. He aspired to develop an esthetic attachment which would directly adhere to the enamel surface for an appropriate treatment period and be able to be removed by the operator without harmful effects to the enamel surface. While bonded to the teeth it would withstand chewing forces, stresses from the archwires, and changes in temperature. He determined that the resin needed to be non-irritating

to the oral mucosa, be able to bond under moist conditions, cure at oral temperatures, and allow for adequate working time while setting quickly enough for patient comfort.

Newman used an epoxy, which was a combination of bisphenol A and epichlorhydrin. He was able to bond this resin to the anterior teeth as well as to the plastic bracket. He used equal parts of a high molecular weight solid epoxy and a low molecular weight liquid epoxy.

In 1977, Hocevar⁽²⁾ initiated the use of Concise-Enamel Bond restorative resin for bonding orthodontic brackets. This was a four-component system consisting of two liquids and two pastes. Setting time could be altered by changing the quantity of each paste added. The two unfilled liquid resins were mixed in equal amounts and applied to etched enamel to form a mechanical bond.

In 1979, 3M developed Concise specifically as an orthodontic bonding system and decreased the necessity of adding liquid to the pastes.⁽³⁾ This simplified the bonding process, but some felt that it decreased the viscosity of the adhesive and a stiff mix could not be obtained when desired. This decrease in viscosity may have allowed brackets to slide before setting.

Light Cured Agents

In 1970, Buonocure⁽⁴⁾ introduced a bis-GMA resin to seal fissures in posterior teeth which utilized ultraviolet (UV) light to initiate polymerization. Silverman et al.⁽⁵⁾ used this same light-cured bis-GMA system along with a chemical cure adhesive to bond brackets to teeth. Once the tooth was etched, the bis-GMA sealant was placed and light-cured. A liquid-powder mixture was placed on the bracket, and the bracket was then placed on the tooth. This technique proved successful during the 6-month trial period in which it was tested.

Travas and Watts⁽⁶⁾ introduced light activated adhesives with the ability to bond orthodontic attachments in 1979. As aforementioned, Silverman et al⁽⁵⁾ used a UV light source to polymerize the bis-GMA resin sealer to the etched enamel prior to applying the chemical cured adhesive. Polymerization of these early light activated resins would occur between 320 and 380 nm of UV light. Polymerization was initiated by photo splitting of the benzoin methyl ether component of the early resins. This benzoin methyl ether was sensitive to light in the 340-nm spectrum.⁽⁷⁾ Concerns eventually arose about the safety of ultraviolet radiation and the need for better shielding, so many UV curing units were recalled.⁽⁸⁾

Manufactures then turned to the chemical industry to find a solution. In the mid-1970's, researchers started to experiment with other photoinitiators. They wanted to develop a way to activate composite resins with a safer and more effective light curing system. The introduction of visible light curing (VLC) was the addition of the photo initiator camphorquinone to composite resins.⁽⁹⁾ The curing of VLC resins is based on camphorquinone, which has a peak absorption spectrum at 470 nm.^(10;11) The visible light spectrum includes wavelengths from 400 – 700 nm. The light at the blue end of the visible spectrum polymerizes VLC resins. A wavelength range of 470 – 520 nm is emitted from the light source, and an optical filter between the bulb and the probe allows only the waves in this range to pass through.⁽¹²⁾ Only a narrow range of light centered on 470 nm is useful to activate camphorquinone.

Various other methods have been used to enhance the polymerization of bonding agents. In the late 1980's and early 1990's, the argon laser was introduced with the capability of curing filled resins in 10 seconds and unfilled resins in 5 seconds. The argon laser operates within a wavelength range of 454 – 496 nm of the visible light spectrum, with an intensity that approaches 800 mW/cm².⁽¹³⁾

The wavelength specificity of the argon laser, coupled with the ability to consistently emit visible light with substantial energy density without any wasted emissions,⁽¹³⁾ has been shown to enhance the physical properties of composite resins. This enhancement is achieved by producing a more thorough cure with up to 75% shorter exposure time compared with conventional light curing units.⁽¹⁴⁾

More recently, xenon arc light units have been introduced in restorative dentistry as alternatives for rapid light curing. The xenon arc light system is designed for high intensity (1200 mW/cm^2) curing of composite filling materials in direct resin restorations. The system has filters that narrow the spectrum of visible light to a band centered on the 470 nm wavelength for activation of camphorquinone. A high-energy, high-pressure ionized gas in the presence of an electrical current is used to create a light source strong enough to increase the curing rate of composite resins and resin modified glass ionomers.⁽¹⁵⁾ The clinical use of such light-curing units has been recently described for orthodontic bonding purposes with a cure time of two seconds per bracket.⁽¹⁶⁾

The halogen bulbs which are used in conventional curing lights have their shortcomings. They have a lifetime of only 100 hours and heat is generated during their use which degrades the bulb⁽¹⁷⁾. In 1995, Mills proposed a solid-state light-emitting diode, or LED, technology for polymerization. Instead of using hot filaments, these curing lights use junctions of doped semiconductors to generate light⁽¹⁸⁾.

LED lights have a lifetime of over 10,000 hours and have very little degradation⁽¹⁹⁾. They require little power, resist shock and vibrations, and do not require filters⁽²⁰⁾. Gallium nitride LED lights produce a narrow spectrum of light between 400 and 500 nm which falls closely within the absorption range of camphorquinone, allowing it to cure efficiently⁽²¹⁾. Dunn

⁽²²⁾ showed that composites cured with LED lights had a similar bond strength to those cured with halogen lights. Stilta⁽²³⁾ further showed that 10 seconds was the optimal cure time for orthodontic adhesives with LED light technology.

Advantages and Disadvantages of VLC

Chemically activated resins depend upon the reaction of an amine and a peroxide catalyst to form free radicals, which initiate the hardening reaction. Equal amounts of two pastes, or a powder and a liquid, are usually mixed together to initiate polymerization. Since the polymerization time continues after the setting time is reached, development of the peak physical properties of the resins can be reached in excess of 24 hours. Polymerization of the resin surface is inhibited by air which results in a tacky layer. This eases the addition of a filled resin to the unfilled bonding agent and allows a good chemical bond between the two.⁽²⁴⁾

A potential disadvantage of chemically cured adhesives is that they may not allow sufficient working time for the clinician to properly position brackets. Also, the material must reach its final set prior to removing excessive adhesive without compromising the material's maximum strength.⁽²⁵⁾ Mixing of individual pastes may allow for air to be introduced into the resin, which can compromise its physical properties.⁽²⁶⁾

One major advantage of VLC is that rapid and more complete short-term polymerization is possible with exposure to 10 – 20 seconds of light. Also, the light can cure through translucent tooth structure. VLC is more efficient than UV light curing because, unlike UV units, VLC units do not require time to heat up. Also, the output of the halogen bulb in VLC units is more than that of UV lights.

There is concern for potential eye damage as a result of exposure to blue light in the range of 435 – 440 nm. It is recommended that a shield be placed between the operator and the light source, or that the operator look away from the curing light tip during curing.⁽²⁷⁾

The greatest advantage of using VLC adhesives is the working time available to accurately position brackets prior to polymerization. A disadvantage of this approach is the time required to adequately polymerize the adhesive for each bracket with the VLC unit. The average curing time per bracket is around 20 – 40 seconds, depending upon which type of adhesive is used.

BOND STRENGTH

How Bond Strength is Tested

No matter which type of adhesive is used, the goal is to adhere the bracket securely to the tooth surface. One of the most widely used laboratory tests is shear bond strength (SBS). It measures the ability of adhesive resins to bond to tooth structure. A shearing stress is an action or a stress caused by an applied force that causes two parts of a body to slide over one another. Shear bond strength is calculated by measuring the force required to separate a bonded bracket from a tooth when one portion is forced to slide over another portion. The shear bond strength is calculated by dividing the break force applied (in Newtons) by the area of the bracket base. The resultant shear bond strength value is recorded in Megapascals (MPa). Tensile bond strength can also be measured. A tensile stress is any induced force which resists deformation caused by a load which tends to stretch or elongate a body.⁽²⁸⁾ The tensile bond strength is the stress required to separate a bonded bracket from a tooth when it is removed with forces acting in opposite directions from each other. Tensile bond strength is equal to the load (kg) divided by the square

area (cm²). To convert the kg/(cm²) to MPa, a multiplier of 0.0981 is used.⁽²⁹⁾ This procedure typically uses a chisel-shaped tool mounted in a universal testing machine to forcefully fracture a disc or bonded material (bracket) from the bonding substrate (tooth surface). A higher shear bond strength is equated with enhanced performance, and cohesive failures within tooth structure or composite resins are considered superior to failures within the adhesive layer.⁽³⁰⁾ In orthodontics, excessively high shear bond strengths pose a problem because enamel fractures can occur during debonding procedures.

Variables in testing bond strength include the modulus of elasticity and the diameter of the bonded restorative resin, the thickness of the adhesive resin, the presence of bonding adhesive flash, the contact area and shape of the chisel, and the crosshead speed of the testing machine. The variable with the widest disparity has almost certainly been the crosshead speed selected to fracture bond samples.⁽³¹⁾ The viscoelastic nature of dental adhesive suggests that SBS and failure mode could be affected by the rate of stress application. Slower crosshead speeds could allow for a deformation period during which stress and strain are compensated for by the elasticity of the bonding agent. At lower speeds, the resin behaves like a viscous material, deforming more as increased pressure is applied. This results in an increased SBS. The potential for higher shear bond strengths also exists with faster crosshead speeds. At higher crosshead speeds, the resin may perform as a brittle solid with increased energy directed toward fracture of the specimen rather than molecular deformation and flexure.^(32;33) If either statement is valid, significant differences in SBS between tested materials could result just from altering the crosshead speed. Lindemuth and Hagge⁽³⁴⁾ tested SBS of 5 groups with 10 samples each. Each group was tested using a different crosshead speed. The 5 speeds selected were 0.1, 0.5, 1.0, 5.0, and 10.0 mm/min. Their results showed that SBS and specimen failure mode (cohesive vs.

adhesive) of composite resin bonded to enamel were essentially unaffected by variation in crosshead speed. It has been suggested by Reynolds,⁽²⁵⁾ that a minimum SBS of 5.9 to 7.8 MPa is required for clinically acceptable orthodontic adhesive results.

***In Vitro* Bond Strength Experiments**

Several investigators have compared the bond strength of self-cured resins to light-cured resins. In 1984, Andreasen et al.⁽³⁵⁾ found no significant difference in shear bond strength between a light-cured resin (Heliosit) with a 40-second light exposure and a self-cured resin (Concise). However, the same study showed that Heliosit with a 20-second light exposure was weaker than Concise. In 1987, King, et al.⁽³⁶⁾ found that tensile or shear bond strength of self-cured resin (Concise and Right-On) was stronger than the tensile or shear bond strength of light-cured resin (Heliosit, Heliosit-Ortho, & Silix) with light exposure for 60, 40, or 20 seconds. A study by Greenlaw et al.⁽³⁷⁾ in 1989 determined that the shear bond strength of light-cured resin (Heliomat) was only one-half that of the chemically cured resin (Unite). These results indicated that the shear or tensile bond strength of light-cured resins was the same or weaker than that of chemical-cured resins. In 1992, Wang and Meng⁽³⁸⁾ designed a study to evaluate the ability of visible light to diffuse under the metal bracket bases to facilitate polymerization of a visible light-activated composite; to compare the tensile bond strength of light-cured resin (Transbond) at 60, 40, or 20 seconds of light exposure to self-cured resin (Concise) by use of an Instron mechanical testing machine; and to analyze the broken interface distribution. They concluded that visible light indeed had the capability to diffuse, reflect, and transmit through tooth and resin to cure the visible light-activated orthodontic composite resin under the solid metal brackets. In addition, they concluded that the bond strength of light-cured resin Transbond was stronger

(except in instances of 20 seconds or less of exposure) than that of self-cured Concise. They recommended the use of Transbond with a 40-second (20 seconds mesial and 20 seconds distal) exposure for clinical application. Finally, they reported that there was no statistical difference in bond failure interface distribution between the enamel and the resin, within the resin itself, or between the resin and the bracket. Enamel detachment occurred only rarely. The inconsistent findings between this and the previously mentioned studies may be due to the use of different light-cured resin materials or the use of different testing methods.

Effects of Fluoride Additives on Bond Strength

The addition of fluoride to orthodontic bonding agents has historically been a challenge. Several early studies have shown that adding fluoride to composite resins causes a significant decrease bond strength.⁽³⁹⁾ Glass ionomer cements were developed to release fluoride, but they were not able to exhibit adequate bond strength for orthodontic bracket bonding.⁽⁴⁰⁾ Resin was then added to the glass ionomer to attempt to increase the bond strength. Benefits of this formulation included that etching was not required for bonding, that the bonding surface could be slightly moist, and of course that the cement released fluoride. Despite the addition of resin, the glass ionomer cements still did not have bond strength equal to the composite resins.⁽⁴¹⁾ Even with etching, the bond strength of resin modified glass ionomer cements did not compare to that of composite resins.⁽⁴²⁻⁴⁵⁾ Focus was then placed on the addition of fluoride to composite resins without a compromise in bond strength.

Rawls described two methods by which fluoride is incorporated into orthodontic bonding materials: dispersions of agents of very low water solubility and diffusion from materials that are matrix bound.⁽⁴⁶⁾ In the first method, water diffuses through the matrix and dissolves the

fluoride which then diffuses out. In the second method, fluoride is released and small amounts of matrix bound agents are released to allow matrix reorganization at the molecular level. This second method using matrix-bound agents seems to provide adequate bond strength for orthodontic bonding.⁽⁴⁷⁾ Several studies have confirmed that fluoride can successfully be added to composite resin bonding agents without compromising bond strength.

Aasrum⁽⁴⁸⁾ tested VP82 (Vivadent, Liechtenstein) which is a matrix bound fluoride releasing material and found that after 24 hours it had a mean tensile strength of 5.6 N/mm², which was adequate strength for clinical use. This value was compared to a tensile strength of 11.1 for Concise and 5.1 for Transbond. In 1997, Sinha⁽⁴⁹⁾ tested 2 light-cured matrix bound fluoride releasing bonding agents, Light Bond (Reliance) and Sequence (Ormco). These 2 materials were tested for shear bond strength with an assortment of other commercially available light and self-curing resins, and no significant differences were found in the 72-hour bond strength of the bonding agents. In 2005, Bishara's⁽⁵⁰⁾ trial reported that Clearfil Protect Bond, a matrix bound fluoride releasing bonding system, had a mean shear bond strength of 11.7 MPa while Transbond XT had a mean SBS of 9.6 MPa. This result showed that there was no significant difference in shear bond strength of the two adhesives.

***IN VIVO* BRACKET SURVIVAL EXPERIMENTS**

Trimpeneers and Dermaut⁽⁵¹⁾ compared a visible light-cured fluoride releasing material (Orthon) and a chemically cured no-mix resin (Lee Insta-bond). A split mouth design was used. A total of 50 patients and 762 bonded attachments were followed for an average treatment time of 21 months (ranging from 9-33 months). A failure rate of 24.3% was reported

for the light-cured material and 12.4% for the chemically cured material. These rates were significantly different.

Fowler⁽⁵²⁾ found no statistical difference when he compared bracket failure rates between Fuji glass ionomer and an acid-etch chemically-cured two past system (Orthodontic Concise, 3M USA). A failure rate of 6.1% for the Fuji and 5.4% for the Concise was calculated after this 12 month clinical trial.

In a five year study of Transbond light cured adhesive resin, Millett et al⁽⁵³⁾ selected 548 patients and 7118 bonded brackets were analyzed. Overall, 426 brackets failed and a 6% failure rate was figured.

Galindo et al.⁽⁵⁴⁾ compared failure rates between brackets bonded with light-cured Sequence and chemically cured System 1+. Contralateral quadrants were bonded with each system respectively. A total of 32 patients were followed for a mean period of 11 months (with a range of 3-21 months). 265 brackets were bonded with the light-cured adhesive and 266 were bonded with the chemical cured material. The failure rate for Sequence was 11.3%, and 12% for System 1+. It was determined that these rates were not significantly different.

Fricker⁽⁵⁵⁾ studied 60 brackets bonded with the self-curing resin- modified glass ionomer Fuji Ortho, and 60 with the composite control System 1+. A split mouth technique was followed but only the upper and lower anterior teeth were used for evaluation purposes. The patients were followed for 12 months. A failure rate of 5% for the self-curing resin- modified glass ionomer Fuji Ortho was found. No significant difference in failure rate was found when Fuji Ortho was compared to the composite control System 1+ (8.3%).

Sunna and Rock⁽⁵⁶⁾ evaluated and compared the clinical performance of adhesive precoated brackets (APC), with that of two types of uncoated brackets. The other two adhesives

studied were Transbond XT and Right-On. 40 consecutive orthodontic patients were selected for the trial and 607 brackets were bonded. The incidence and site of first time bond failures were both recorded over a period of 1 year. The overall failure rate was 6.6%. There were no recorded significant differences between the failure rates of any of the two adhesives applied to the uncoated brackets and that of the APC precoated brackets. In addition, there were no significant differences between the upper and lower arches. The time of bonding and time of bracket failure were also recorded. It was found that there was no significant difference among the groups as to when a bracket was likely to fail. Sixty percent of the overall failures occurred within the first 6 months.

Gaworski et al. ⁽⁵⁷⁾ studied bond failure rates between a glass ionomer (Fuji Ortho LC) and a light cured composite resin (Reliance Light Bond). 149 teeth were bonded with the glass ionomer and 149 with the composite resin and patients were followed for 12-14 months. Of the 149 teeth bonded with Fuji, there were 37 failures (24.8%). There were 11 failures in the 149 teeth bonded with composite (7.9%).

Cacciafesta et al. ⁽⁵⁸⁾ compared failure rates between a Fuji glass ionomer and a System 1+ composite resin. 110 brackets were bonded with the Fuji glass ionomer cement and 110 with the System 1+ composite resin. Patients were followed for a period of 12 months. A significantly higher failure rate of 34.5% for the glass ionomer was noted, as compared to 9% for the composite resin.

Millet et al. ⁽⁵⁹⁾ compared bracket failure rates between a no-mix resin adhesive Right-On (T.P., La Porte, IN), and a light-cured 1-component compomer resin (DeTrey Dentsply, Konstanz, Germany). The compomer resin is described as a mixture of composite resin and glass ionomer cements. A split mouth technique design was used in 45 patients. A total of 426

brackets were bonded. Half were bonded with the compomer and half with the resin adhesive. Patients were followed throughout the duration of their treatment. No significant difference in bracket failure rates was found between the bonding agents. Failure rate was 20% for the resin, and 17% for the compomer.

PREPARATION OF THE TOOTH SURFACE FOR BONDING

Etching results in a discrete and preferential dissolution of the organic component of the enamel matrices creating microporosities in the enamel surface. Additionally, etching increases the wettability of the enamel surface by removal of a layer of inert, low energy, hydrophobic enamel surface structure. A fresh reactive hydrophilic surface with a greatly increased energy level is exposed, resulting in a more wettable surface. This facilitates the penetration of the polymerizing resin into the etched surface and increases the overall surface area available for bonding.⁽⁶⁰⁾

Diedrich⁽⁶¹⁾ found that the etching process goes through three stages. First, the periphery of the prism heads is delineated by microclefs of 0.1-0.2mm. The acid attack leads to a loss of substance, predominantly in the area of the prism cores, with simultaneous conservation of the marginal area. This produces a honeycomb pattern. As etching progresses, crest-like marginal ridges disappear and marginal clefs continue to widen. This is the transitional zone of the central and peripheral etching pattern in which the existing marginal ridges are elevated about 0.2-0.3 μ m. At an advanced stage, fragile prism peripheries break off. Maximum enamel loss takes place in this stage and minimum loss takes place in the honeycomb phase. Galil and Wright⁽⁶²⁾ describe an additional etching pattern, which is commonly seen in the cervical areas

and is pitted and irregular. Also noted, was an etching pattern that showed no evidence of prism outlines.

Prior to bonding, the surface layer should be free of contaminants. It was first believed that etching alone was sufficient for this removal. Miura and associates⁽⁶³⁾ showed that maximum bond strength could only be attained when an oral prophylaxis was performed prior to etching. Gwinnett and Buonocore⁽⁶⁴⁾ showed that surface contamination still existed following acid etching if not preceded by an oral prophylaxis. Following etching, the enamel surface should be adequately rinsed and dried. Beech and Jalaly⁽⁶⁵⁾ showed that when phosphoric acid is applied to enamel, calcium goes into solution. When the saturation point is reached, it precipitates as calcium phosphate. The precipitant layer has a deleterious effect on the bond strength of composite resin. Thorough washing after etching is essential to remove the precipitate and ensure optimum bonding.

CHAPTER III

MATERIALS AND METHODS

***IN VITRO* STUDY**

Ninety extracted human premolars were collected for this portion of the study. The criteria for selection included non-carious teeth with an intact buccal surface with no cracks in the enamel. The teeth were not subjected to any pretreatment chemical agents such as hydrogen peroxide or bleach. The teeth were cleaned of debris, steam autoclaved and stored in 0.1% Thymol. The 90 teeth were randomly divided into 6 experimental groups, each containing 15 teeth (Table 1).

GROUP	BONDING AGENT	THERMOCYCLING	LENGTH OF TIME BEFORE DEBONDING
I	Concise	No	30 minutes
II	Concise	Yes	After 24 hours of thermocycling
III	Transbond XT	No	30 minutes
IV	Transbond XT	Yes	After 24 hours of thermocycling
V	APC-Plus	No	30 minutes
VI	APC-Plus	Yes	After 24 hours of thermocycling

Table 1. Study Groups

Group I: Brackets were bonded with Concise, a two paste chemically cured base-catalyst composite resin system (3M ESPE, Monrovia, CA). The brackets were then debonded using the Instron testing machine (Instron Corp, Canton, MA.) within 30 minutes of bonding.

Group II: Brackets were bonded with Concise, and then debonded using the Instron testing machine after thermal cycling for 24 hours (500 cycles).

Group III: Brackets were bonded with Transbond XT, a light-cured composite resin (3M Unitek, Monrovia, CA). The brackets were then debonded using the Instron testing machine within 30 minutes of bonding.

Group IV: Brackets were bonded with Transbond XT and then debonded using the Instron testing machine after thermal cycling for 24 hours.

Group V: Brackets were bonded with APC PLUS, a light-cured color changing composite resin (3M Unitek, Monrovia, CA) (Figures 1A and B). The brackets were then debonded using the Instron testing machine within 30 minutes of bonding.

Group VI: Brackets were bonded with APC PLUS and then debonded using the Instron testing machine after thermal cycling for 24 hours.



Figure 1A



Figure 1B

Figures 1A and B. Tinted APC Plus adhesive on the back of a bracket (A) and with visible flash around a bracket during bonding (B).

Preparing Teeth for Testing

Prior to testing, a hole was drilled through each tooth approximately 5mm from the apex. A 0.040 stainless steel wire was placed through each hole for additional retention when mounted in the epoxy resin (Buehler, Lake Bluff, IL). The teeth were embedded in epoxy resin up to the

level of the cemento-enamel junction in stainless steel rings before the bonding was begun (Figure 2). A dental surveyor was used to align the facial surface of the tooth to be perpendicular with the bottom of the mold (Figure 3). This ensured that the labial surface was parallel to the force during the shear strength test. The teeth were kept moist in a humidified container while the resin dried and then were stored in water until bonding.



Figure 2. A sample mounted in stainless steel ring.



Figure 3. Use of surveyor to accurately place bracket on the tooth sample.

Bonding Procedures

The facial surface of each tooth in Groups I and II was pumiced for 10 seconds and then rinsed with distilled water for 10 seconds. Next, the enamel surface was etched with 37% phosphoric acid for 15 seconds and then rinsed for 10 seconds. The teeth were dried with a steady stream of air until the enamel surface displayed a chalky white appearance. Equal parts of Concise Enamel Bond Resin parts A and B were mixed together with a sponge applicator for 5-10 seconds and then applied in a thin layer to the etched tooth surface. Next, equal parts of Concise Orthodontic Paste parts A and B were mixed on a mixing pad with a plastic spatula for 20 seconds. The mixed pastes were then used to bond an MBT Victory Series .022 maxillary premolar bracket (3M Unitek, Monrovia, CA) to the enamel surface of the tooth. The adhesive was allowed to cure for 10 minutes before returning the samples to water.

For Groups III-VI, each tooth was pumiced for 10 seconds and then rinsed for 10 seconds with distilled water. Next, the enamel surface was conditioned with Transbond Plus Self Etching Primer (3M Unitek, Monrovia, CA). The cotton-tipped applicator saturated with the solution was rubbed on the enamel for 3-5 seconds and then gently air dried. MBT Victory Series .022 maxillary premolar brackets were bonded on the teeth with Transbond XT preloaded in a syringe in Groups III and IV. Groups V and VI were bonded with MBT Victory Series .022 maxillary premolar brackets pre-coated with APC-PLUS adhesive.

The same operator performed all of the bonding procedures in order to keep the technique consistent. In all groups, the bracket bases were completely covered with adhesive with no bubbles or voids. The brackets were placed on the tooth surface with cotton forceps. An explorer was used to deliver a constant force in order to completely seat the bracket. Excess

adhesive was removed and the bracket adhesive was then light cured if indicated. The Ortholux LED Curing Light (3M Unitek, Monrovia, CA) was used to cure the mesial side of the bracket for 5 seconds and the distal side for 5 seconds (10 seconds total). The curing tip was placed as close as possible on the mesial and distal sides of the bracket at approximately a 45-degree angle. Once cured, the teeth were ready for bond strength testing. For each of the three Groups I, III, and V, the bond strength testing was completed within 30 minutes of bonding.

Bond Strength Testing

The procedure for Groups II, IV, and VI was the same as that of the previous three groups, except that these teeth were bonded prior to being embedded in the stainless steel rings. A surveyor was used to align the brackets so they were perpendicular to the base of the potting ring and parallel to the applied debonding force. They were thermal cycled between $5^{\circ} \pm 2^{\circ}$ C and $55^{\circ} \pm 2^{\circ}$ C for approximately 24 hours or 500 cycles. A mechanical arm alternated the teeth between the two water baths. There was a one-minute dwelling time in each water bath. Following thermal cycling, the teeth were mounted in the stainless steel rings with epoxy resin. Between 22 and 24 hours after thermal cycling, the brackets were debonded.

Debonding forces in Newtons were determined using an Instron mechanical testing machine with a crosshead speed of 1mm/minute (Figures 4 and 5). The stainless steel rings were mounted on an adjustable base jig to ensure that the applied force was parallel to the long axis of the tooth. The force was applied at the bracket-tooth interface. The force required to debond the bracket was recorded and then converted to megapascals (MPa) by dividing the force in Newtons by the area of the bracket base (11.35mm^2). Teeth that fractured during the debonding phase were excluded from the study.



Figure 4. Sample ready for testing with the Instron Mechanical testing machine.

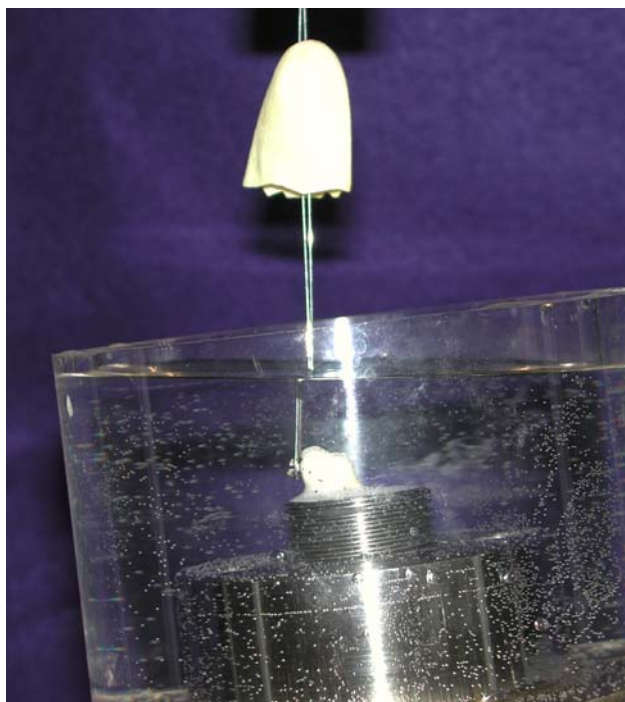


Figure 5. Close up of sample ready for testing with the Instron Mechanical testing machine.

Following debonding, all the bracket bases were examined with an optical microscope at 10x magnification to determine if the failure occurred at the enamel or the bracket adhesive interface. A modified Adhesive Remnant Index (ARI) was used to score the amount of adhesive left on each bracket following debonding (Table 2). The original ARI scale was developed by Artun and Bergland⁽⁶⁶⁾ and consists of four scoring categories, 0 to 3. The modified scale was developed to more accurately depict the amount of adhesive remaining on the bracket, and consists of five scoring categories, 0 to 5⁽⁶⁷⁾. A correlation can be made as to the amount of adhesive remaining on the enamel surface by determining the amount of adhesive remaining on the bracket base

SCORE	DEFINITION
0	No adhesive left on bracket
1	Less than 25% of adhesive left on bracket
2	25% of adhesive left on bracket
3	50% of adhesive left on bracket
4	75% of adhesive left on bracket
5	100% of adhesive left on bracket

Table 2. The modified ARI scoring scale.

Data Analysis

The Adhesive Remnant Index (ARI) was used to quantify the amount of adhesive left on the bracket after shear bond strength testing with the Instron Testing Machine. Significant differences in shear bond strength (MPa) and ARI scores between test groups were determined using ANOVA (one-way) and Tukey-Kramer Multiple comparison test.

***IN VIVO* STUDY**

The *in vivo* portion of this experiment consisted of 31 patients. IRB approval was obtained prior to the initiation of the study. Orthodontic brackets were placed by one of the designated operators, either resident or faculty in the Department of Orthodontics, West Virginia University, School of Dentistry. Criteria for patient selection were an intact permanent dentition, no decalcification on teeth, and treatment requiring comprehensive orthodontics with fixed appliances. No preference was placed on the type of malocclusion present or whether extractions were indicated.

Bonding Procedure

A split arch technique was utilized. Patients were sequentially assigned to one of two groups. In Group I, the teeth in the maxillary left and mandibular right quadrants were bonded using the Transbond XT. The teeth in the maxillary right and mandibular left quadrants were bonded with APC PLUS pre-coated brackets. In Group II, the pattern was reversed. Bonding was limited to incisors, canines, and premolars. After isolation, each tooth was pumiced for 10 seconds and then rinsed for 10 seconds with distilled water. Next, the enamel surface was conditioned with Transbond Plus Self Etching Primer (3M Unitek, Monrovia, CA). The cotton-tipped applicator saturated with the solution was rubbed on the enamel for 3-5 seconds and then gently air dried. MBT Victory Series .022 brackets were placed on the teeth. Excess cement was removed from around each bracket and the bracket was light cured. The curing tip was placed as close as possible on the mesial and distal sides of the bracket at approximately a 45-degree angle. The brackets were cured for 5 seconds on the mesial and 5 seconds on the distal with the Ortholux LED Curing Light (3M Unitek, Monrovia, CA). The LED light was calibrated before each use.

The date and quadrant of bracket failures were recorded. The failed brackets were not re-bonded, but were placed in labeled envelopes for examination in determination of bracket failure interface. The bracket failure interface was observed under light microscopy to determine if the failure occurred at the enamel or the bracket adhesive interface. A modified Adhesive Remnant Index (ARI) was used to evaluate the amount of adhesive left on the failed bracket (Table 2).

Data Analysis

The Adhesive Remnant Index (ARI) was used to quantify the amount of adhesive left on the bracket. The bracket survival distribution was analyzed using the Log-Rank and Wilcoxon

tests. These tests were applied to distinguish any significant differences in bracket survival according to the adhesive used and location of bracket (arch and side). The ARI scores were reviewed but not analyzed due to the small number of brackets collected.

CHAPTER IV

RESULTS AND DISCUSSION

RESULTS OF *IN VITRO* BOND STRENGTH STUDY

The mean shear bond strength of the six test groups is shown in Figure 6 and Table 3. ANOVA showed differences among the six test groups. Pair-wise comparisons using Tukey Kramer HSD showed significant differences between groups II and I, III, V and VI and between groups IV and I, III, V, and VI. No significant differences were found between groups II and IV and between groups I, III, V, and VI. The highest mean shear bond strengths were found with Concise composite resin thermocycled (15.103 MPa) and Transbond XT thermocycled (14.895 MPa), which were significantly higher than the rest of the groups. Similar mean shear bond strengths were found among the rest of the groups of Concise 30 minute (8.529 MPa), Transbond XT 30 minute (7.538 MPa), APC Plus 30 minute (8.654 MPa) and APC Plus thermocycled (8.303 MPa).

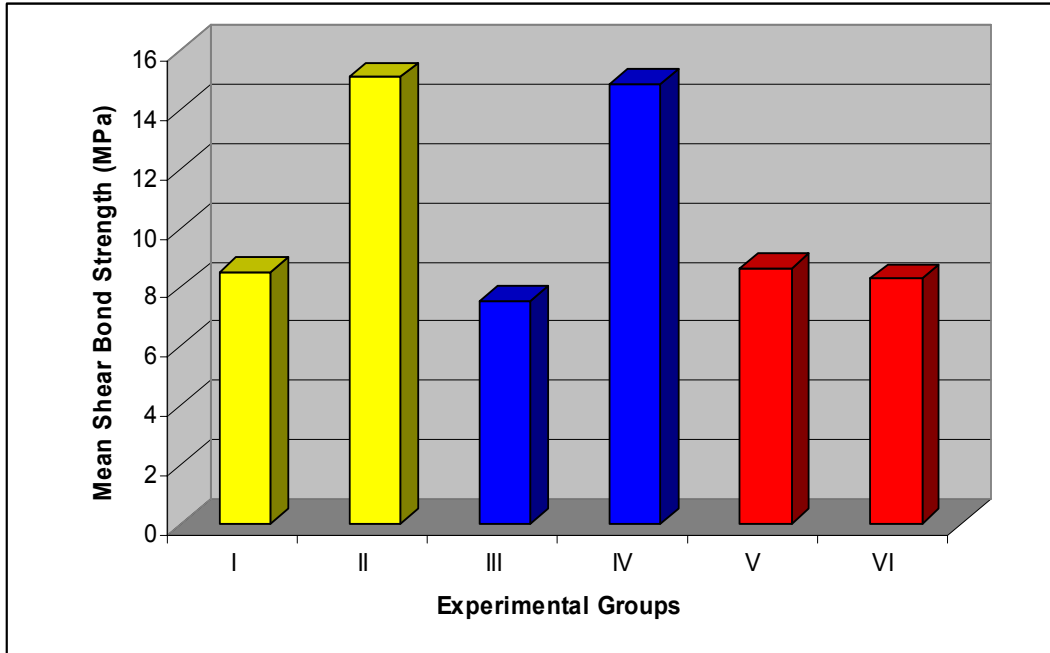


Figure 6. Mean Shear Bond Strengths (MPa) for all *in vitro* experimental groups.

Group	N	Shear Bond Strength Mean	SD	Min	Max
I (Concise 30 min)	15	8.529	2.852	5.02	13.82
II (Concise thermocycled)	13	15.103	4.470	6.76	21.25
III (Transbond XT 30 min)	15	7.538	2.841	4.19	12.33
IV (Transbond XT thermocycled)	13	14.895	3.293	9.25	20.04
V (APC Plus 30 min)	15	8.654	1.965	5.03	11.99
VI (APC Plus thermocycled)	13	8.303	3.158	3.53	14.31

Table 3. Mean shear bond strengths for *in vitro* experimental groups measured in megapascals.

Group		Mean (MPa)
II	A	15.103
IV	A	14.895
V	B	8.654
I	B	8.529
VI	B	8.304
III	B	7.538

****Groups not connected by the same letter are significantly different**

Table 4. Tukey Kramer analysis of mean shear bond strengths for the experimental groups.

***In Vitro* Bracket Failure Interface ARI Scores**

The ARI scores for the experimental groups are shown in Table 5 and Figure 7. ANOVA showed significant differences among all test groups. Pair comparisons using Tukey Kramer HSD found no significant differences between groups II, IV, V and VI and also between groups III and VI (Table 6). There were significant differences between all other possible pairs. In general, there was an increase in ARI scores with thermocycling, which indicated that more brackets failed at the enamel-adhesive interface rather than the bracket-adhesive interface. Without thermocycling, ARI scores were greater for APC Plus than Transbond XT, and Concise had the lowest ARI scores. Most brackets bonded with APC Plus failed at the enamel-adhesive interface. The brackets bonded with Concise usually failed at the adhesive-bracket interface.

Group	Mean	SD	Median	Max	Min
I (Concise 30 min)	1.600	1.765	1.0	5.0	0.0
II (Concise thermocycled)	4.800	0.414	5.0	5.0	4.0
III (Transbond XT 30 min)	3.467	1.598	3.0	5.0	0.0
IV (Transbond XT thermocycled)	4.667	0.488	5.0	5.0	4.0
V (APC Plus 30 min)	4.533	0.640	5.0	5.0	3.0
VI (APC Plus thermocycled)	4.667	0.617	5.0	5.0	3.0

Table 5. ARI analysis of all *in vitro* experimental groups.

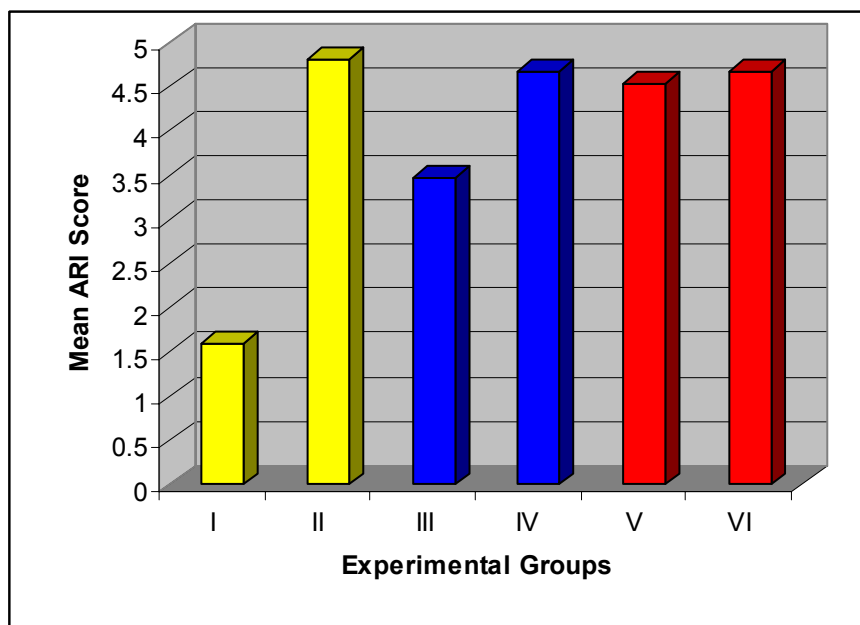


Figure 7. Mean ARI scores for all *in vitro* experimental groups.

Group		Mean ARI
II	A	4.800
IV	A	4.667
VI	A	4.667
V	A B	4.533
III	B	3.467
I	C	1.600

****Groups not connected by the same letter are significantly different**

Table 6. Tukey Kramer analysis of mean ARI scores for the *in vitro* experimental groups.

RESULTS OF *IN VIVO* SURVIVAL RATE STUDY

A total of 595 bracketed teeth were included in this study. There were 296 teeth bonded with Transbond XT and 299 bonded with APC Plus. 6.08% of the brackets bonded with Transbond XT failed (18 failures), and 7.69% of the brackets with APC Plus failed (23 failures) (see Figure 8).

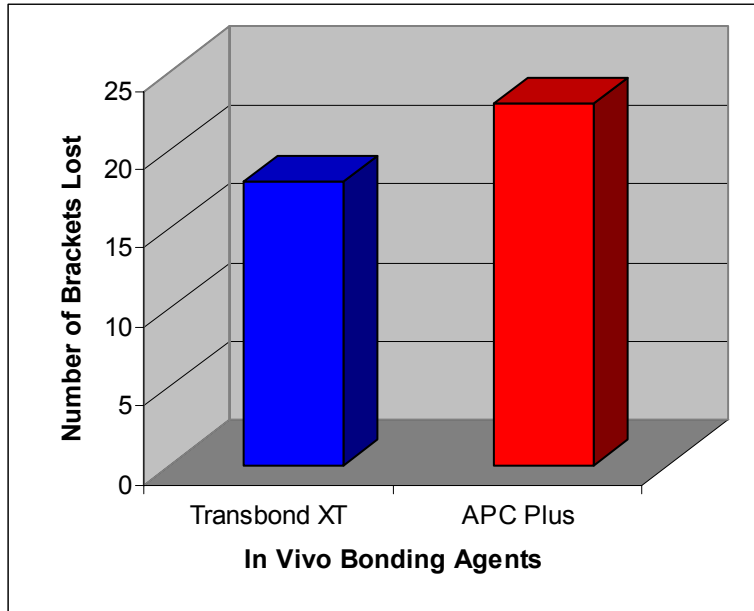


Figure 8. Number of brackets lost in the *in vivo* study.

Comparison of Survival Times

Tables 7 and 8 show the detail of the survival times of the brackets observed in the *in vivo* study. The observation period for each patient was variable. Log-Rank ($P=0.43$) and Wilcoxon ($P=0.31$) tests showed no significant differences between the survival distributions of brackets bonded with Transbond XT and APC Plus. Or, brackets bonded with one of these agents do not last longer than brackets bonded with the other.

Bonding Agent	# of Failures	Mean (days)	SD	Median	Max	Min
Transbond XT	18	160.11	137.50	112.5	480.0	28.0
APC Plus	23	145.69	97.45	153.0	337.0	28.0

Table 7. Survival times (days) for failed brackets in the *in vivo* study.

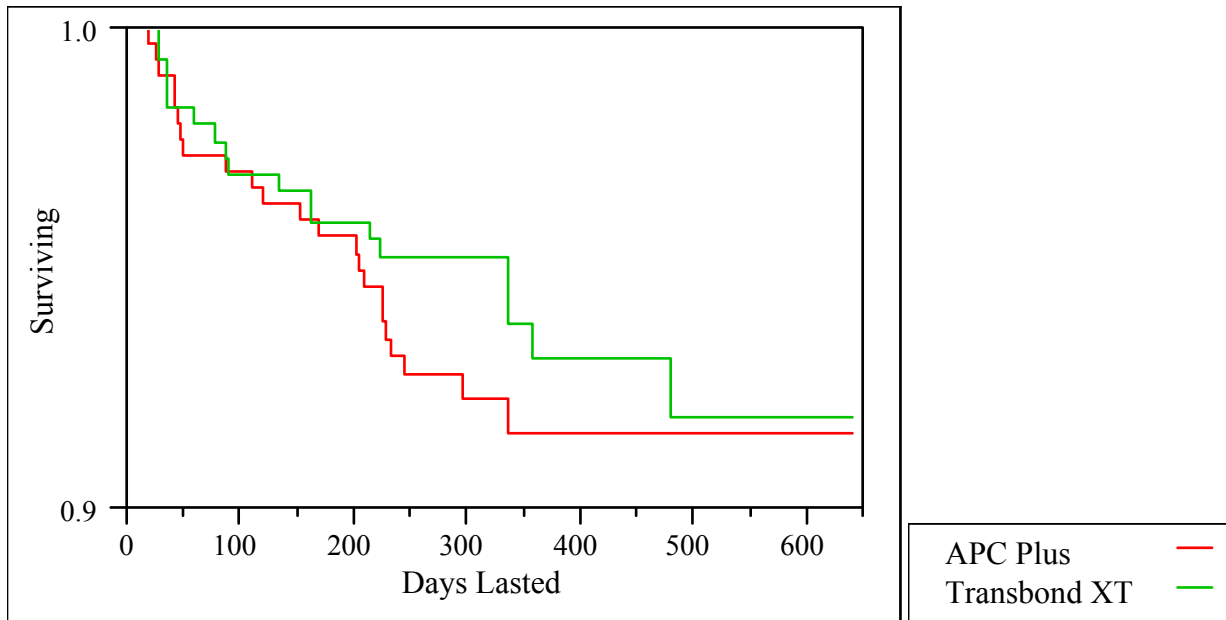


Figure 9. Product Limit Survival Plot of the two types of adhesives.

Comparison of Maxillary and Mandibular Arches

Figure 10 shows the number of brackets lost in both maxillary and mandibular arches. 148 maxillary teeth were bonded with Transbond XT and 11 were lost which indicates that 7.43% of brackets failed. 148 mandibular brackets were bonded with Transbond XT and 7 were lost which shows that 4.73% of brackets failed. Log-Rank ($p=0.31$) and Wilcoxon ($P=0.16$) tests showed that there was no significant difference between survival distributions of maxillary and mandibular arches when using Transbond XT bonding agent (figure 11). Brackets bonded with Transbond XT on a specific arch do not stay on longer as compared to the other. 148 maxillary teeth were bonded with APC Plus and 10 were lost which reveals that 6.76% of brackets failed. 151 mandibular teeth were bonded using APC Plus and 13 were lost which shows that 8.61% of brackets failed. There was no significant difference in survival distributions between arches when using APC Plus (Log-Rank $P=0.54$ and Wilcoxon $P=0.57$) (Figure 12). Brackets bonded with APC Plus on a specific arch do not stay on longer as compared to the other side.

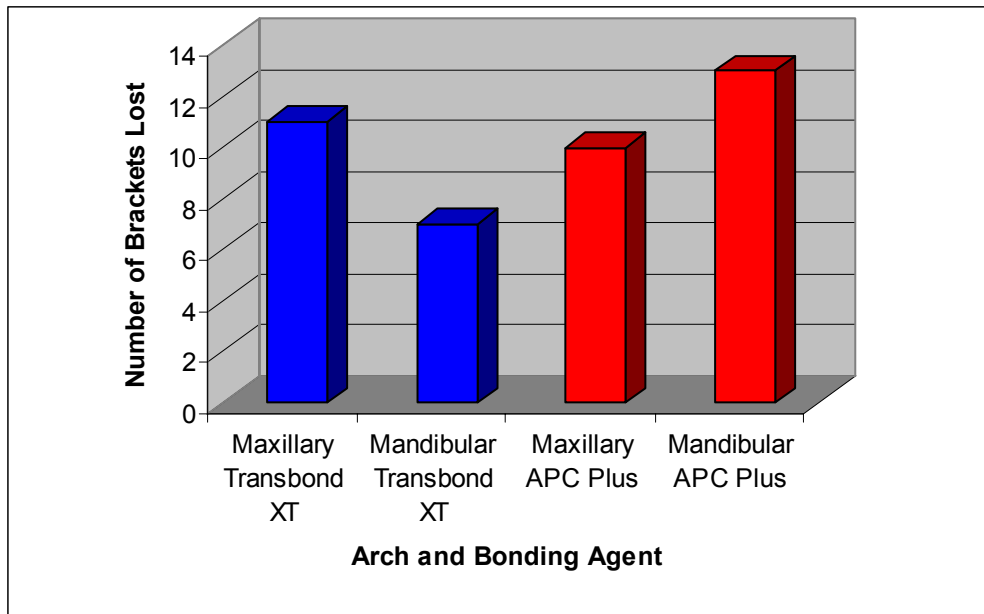


Figure 10. Number of brackets lost in each arch in the *in vivo* study.

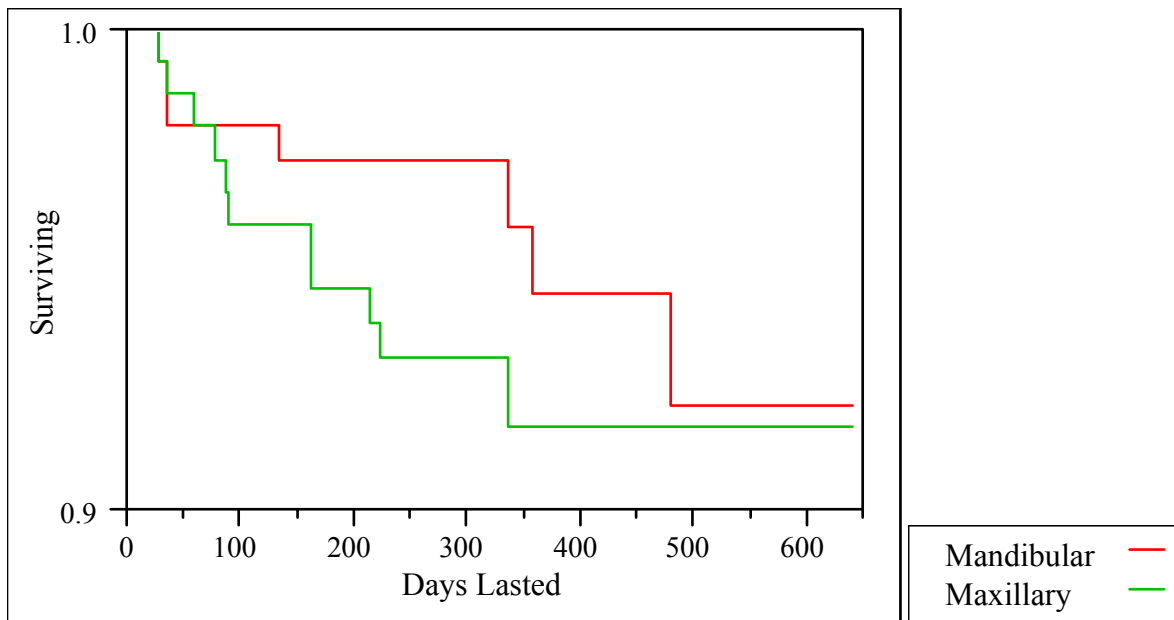


Figure 11. Survival Plots of maxillary and mandibular brackets bonded with Transbond XT.

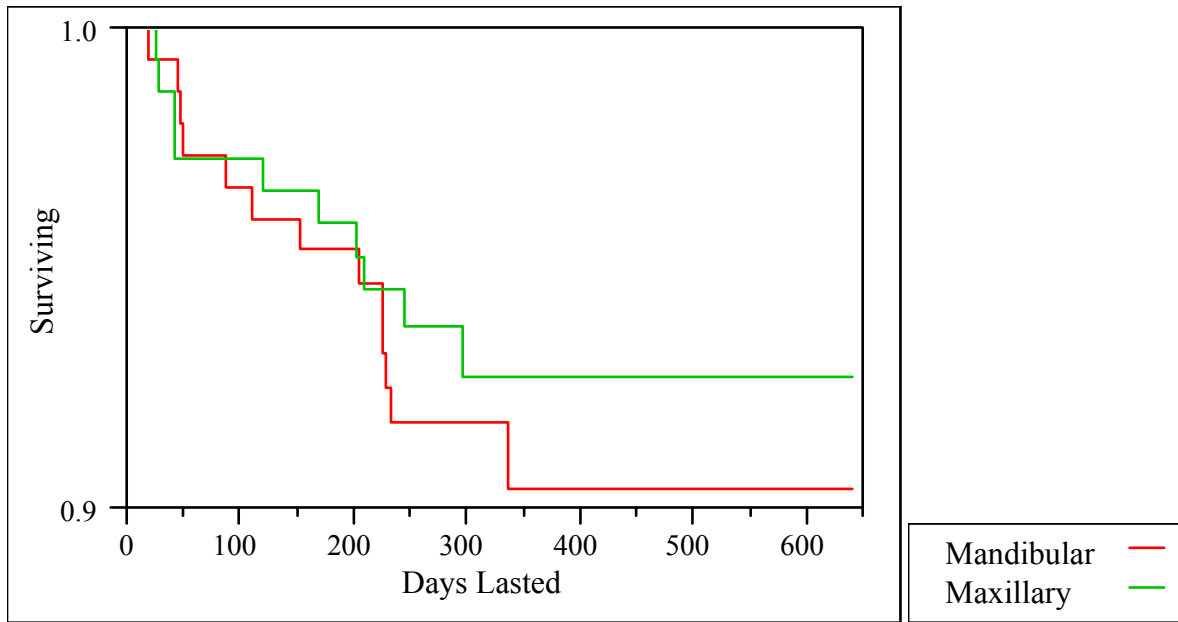


Figure 12. Survival Plots of maxillary and mandibular brackets bonded with APC Plus.

Comparison of Right and Left Sides

Figure 13 details the number of brackets lost from the right and left sides of patients' mouths. 149 teeth on the right side were bonded with Transbond XT adhesive and 10 were lost indicating that 6.71% failed. 147 teeth on the left side were bonded with Transbond XT and 8 were lost pointing to a 5.44% failure rate. Log-Rank ($P=0.33$) and Wilcoxon ($P=0.38$) tests showed that there was no significant difference between the survival distributions of the left and right sides bonded with Transbond XT (Figure 14). Therefore, we surmise that brackets bonded with Transbond XT on a specific side of the mouth do not last longer than those bonded to the other side. 150 brackets on the right side were bonded with APC plus and 9 failed. This indicates that 6.00% failed. 149 brackets on the left side were bonded with APC Plus and 14 were lost, which shows that 9.40% failed. Log-Rank ($P=0.28$) and Wilcoxon ($P=0.36$) tests

showed that there was no significant difference between the survival distributions of the left and right sides bonded with APC Plus (Figure 15). Brackets bonded with APC Plus bonded on a specific side of the mouth do not last longer than those bonded to the other side.

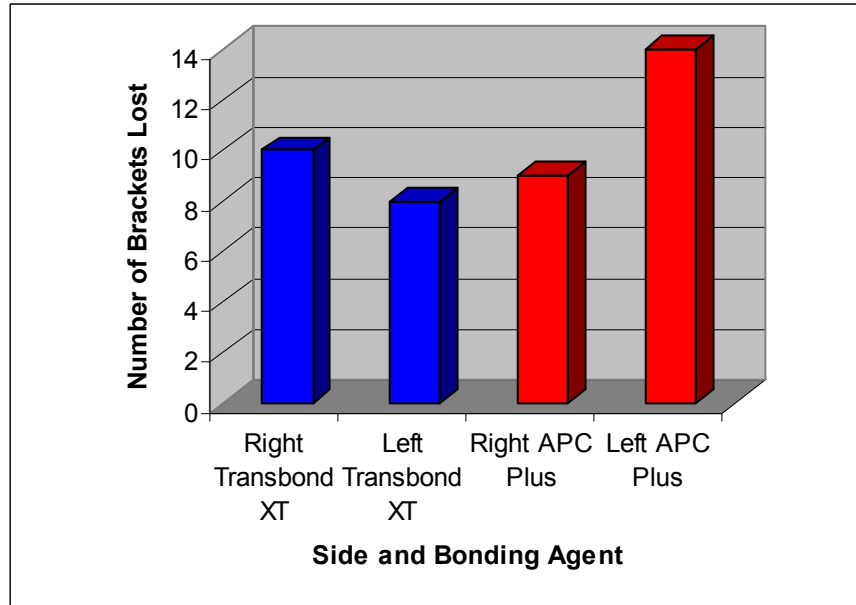


Figure 13. Number of brackets lost on each side of the mouth in the *in vivo* study.

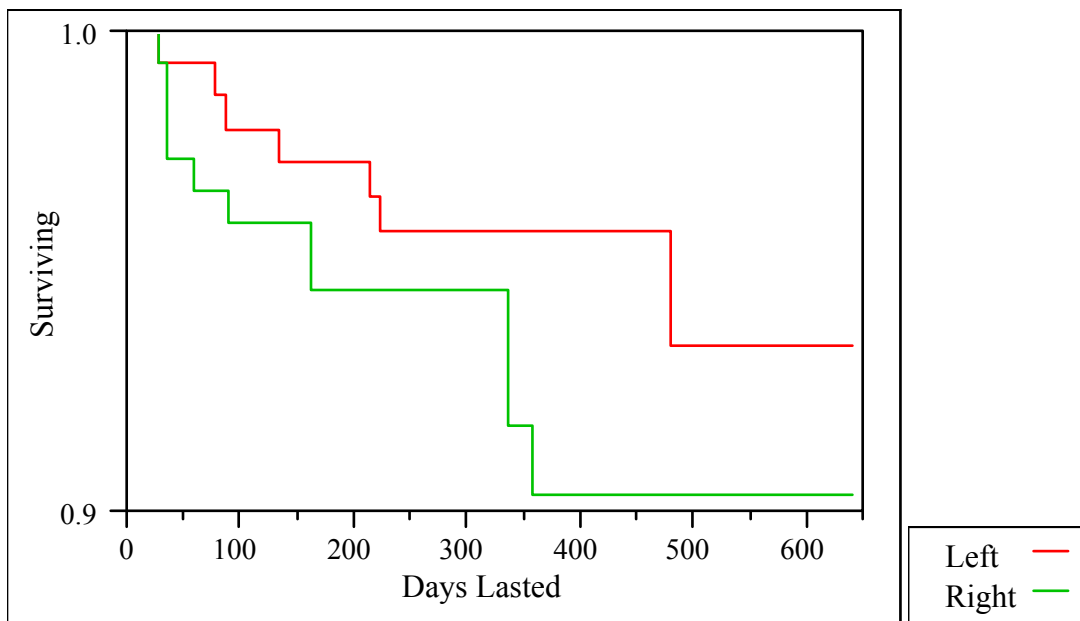


Figure 14. Survival plots of right and left brackets bonded with Transbond XT.

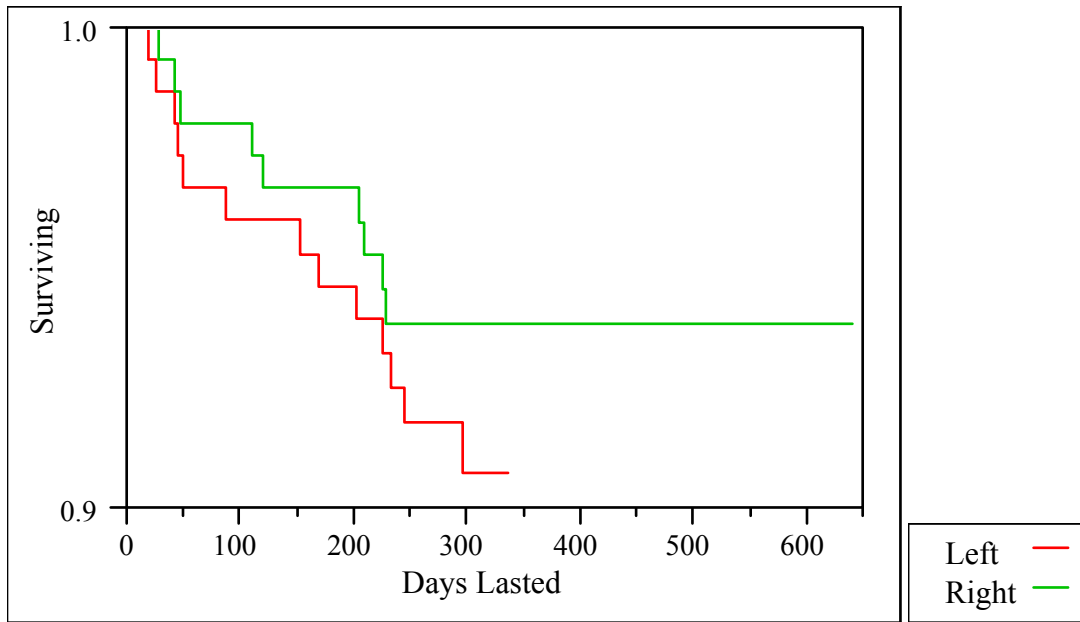


Figure 15. Survival Plots of right and left brackets bonded with APC Plus.

***In Vivo* Bracket Failure Interface ARI Scores**

The sample size of the failed brackets was too small to justify an analysis of ARI scores. Failed brackets bonded with Transbond XT had a mean ARI score of 4.2. Failed brackets bonded with APC Plus had a mean ARI score of 3.9.

DISCUSSION OF *IN VITRO* INVESTIGATION

In this study, the shear bond strength is not a pure shear force but a shear peel mechanism. The mean shear bond strength after 30 minutes of bonding were found to be 8.529 MPa for Concise, 7.538 MPa for Transbond XT, and 8.654 MPa for APC Plus. Reynolds⁽²⁵⁾ reported that a range of 5.9 to 7.8 MPa is adequate for bond strength to withstand occlusal forces clinically. The mean shear bond strength of Concise at 8.529 MPa was slightly lower than those reported by Willems⁽⁶⁸⁾ (9.9 MPa), Fajen⁽⁶⁹⁾ (11.27 MPa after 24 hours), and Mimura⁽⁷⁰⁾ (14.81 MPa after 24 hours).

The mean shear bond strength of Transbond XT (7.538 MPa) was in agreement with several studies which examined the shear bond strength of Transbond XT when used with the self-etching primer. Romano⁽⁷¹⁾ found a mean bond strength of 6.4 MPa, Owens⁽⁷²⁾ found 7.9 MPa, and Bishara⁽⁷³⁾ reported 7.1 MPa as a mean shear bond strength for Transbond XT.

This study reported that the mean shear bond strengths of Transbond XT and Concise were not significantly different. This is in agreement with Chamda⁽⁷⁴⁾ who found that there was no significant difference in the bond strengths of Transbond and Concise at intervals of 10 minutes and 24 hours after bonding. Grandhi⁽⁷⁵⁾ also found that Transbond XT and Concise had similar bond strengths after 7 days.

The bond strength of APC Plus adhesive has not been reported in the literature. In this study, the mean shear bond strength for APC Plus after 30 minutes was 8.654 MPa. This value was not significantly different from the Concise and Transbond XT groups. According to Reynolds, this value will produce adequate strength for initial placement of orthodontic wires.

For the groups that were subjected to thermocycling and longer storage time, this study showed a significant increase in shear bond strength for Concise (15.103 MPa) as compared to

those that were debonded after 30 minutes. This is in agreement with Bulut⁽⁷⁶⁾ who reported a shear bond strength for Concise of 20.6 MPa, Surmont⁽⁷⁷⁾ who reported 16.7 MPa and Coreil⁽⁷⁸⁾ who reported 20.13 MPa. On the other hand, several studies of other bonding agents compared debonding after 24 hours to debonding after thermocycling and reported a significant decrease in bond strength in the groups that were thermocycled⁽⁷⁹⁻⁸²⁾.

Transbond XT had a mean shear bond strength of 14.895 MPa after the thermocycling process and 24 hour storage, which was a significant increase from the 30 minute group. After thermocycling, Lalani⁽⁸³⁾ found the mean shear bond strength for Transbond XT to be 13.31 MPa, Schanefeldt⁽⁸⁴⁾ reported 14.82 MPa, and Rix⁽⁸⁵⁾ reported 20.19 MPa. As was the case with Concise, the trend of increased bond strength after thermocycling did not apply to the Transbond XT group. Transbond XT's bond strength significantly increased after thermocycling and the values that were reported are comparable to those in previous studies.

The fact that Concise and Transbond XT had increased bond strength after thermocycling and 24 hour storage may be explained by the fact that more time for polymerization elapsed before debonding was performed. In the 30 minute groups, not as much time was allowed to elapse before debonding, so these brackets did not get the benefits of increased time for polymerization. The bond strengths of the thermocycled Concise and Transbond XT may have significantly increased because of increased polymerization.

The mean shear bond strength of APC Plus was 8.303 MPa after thermocycling. This had a very slight decrease in mean shear bond strength from the 30 minute group, though not significant. It was found to be not significantly different from all 3 of the 30 minute groups and significantly less than the Transbond XT and Concise thermocycling groups. One reason for this decreased strength is that it may not have increased polymerization over time as Transbond XT

and Concise do. Also, this lack of increase in strength after thermocycling and longer storage time may have something to do with the addition of fluoride or dye to the adhesive. In addition, this material may have more shrinkage and expansion during thermocycling which may affect bond strength. This study showed that APC Plus had adequate bond strength for orthodontic purposes after thermocycling and it performs the same as other commercially available adhesives.

The adhesive remnant index (ARI) enables the clinician to determine the bracket failure interface. The modified ARI scale used for this study ranged from 0-5. A score of zero indicates that all of the adhesive remained on the enamel surface after debonding while a score of five indicates that all of the adhesive remained on the bracket base. A low score would be interpreted as a failure between the adhesive and bracket interface, or a strong bonding of adhesive to enamel. A high score would indicate a failure at the adhesive enamel interface or a weak bonding of adhesive to the enamel. Clinically, the clinician would prefer the failure to occur between the adhesive and the enamel at the time of debond because this would allow for easier resin removal from the enamel surface. Yet, the clinician would like the bonding between the enamel and the adhesive to be strong enough for the bracket to remain bonded to the tooth throughout treatment.

In this study, brackets bonded with Concise had a mean ARI score of 1.60 30 minutes after bonding. These results are concurrent with studies performed by Sinha⁽⁸⁶⁾ which showed Concise with a mean ARI of 1.7 ± 0.6 meaning half of the adhesive was left on the tooth and a fairly strong bonding of the adhesive to the enamel. Mimura⁽⁸⁷⁾ found in his study that most of the brackets bonded with Concise left all of the adhesive on the enamel. Carstensen⁽⁸⁸⁾ found that most brackets bonded with Concise scored an ARI of 1 or 2 which meant that more than

half of the adhesive was left on the tooth. The results from this study indicate that the majority of the adhesive remained on the tooth after debonding, therefore the failure occurred between the adhesive and the bracket interface. This result may be due to the fact that the self-cure material did not set well, it had increased porosity from mixing, or that the material did not flow well into the undercuts of the mesh bracket base.

With Transbond XT, a mean ARI score of 3.47 was found when debonded 30 minutes after bonding. These results show that approximately half of the adhesive was left on the tooth after debonding. This is similar to the results reported by Bishara⁽⁸⁹⁾ and Vicente⁽⁹⁰⁾, who both reported that of the Transbond XT brackets debonded, the majority had an ARI score of 2.0. Owens⁽⁹¹⁾ also reported that most Transbond XT brackets debonded had an ARI score of 2.0. For all three previously mentioned studies, a score of 2 indicated that more than half of the adhesive was left on the tooth.

APC Plus has not previously been reported in the literature. In our study, APC Plus brackets had a mean ARI score of 4.53. The results would suggest that most of the adhesive remained on the bracket after debonding which indicates that the failure occurred between the tooth and adhesive interface.

When comparing all of the 30 minute groups, the brackets bonded with Concise left the most adhesive remaining on the enamel. Concise's mean ARI score was significantly lower than the other two groups. Transbond XT and APC Plus left similar amounts of adhesive on the enamel, an amount significantly less than Concise. This situation is desirable in orthodontics because it allows for easier cleanup after debonding brackets.

After thermocycling, the Concise group had a mean ARI score of 4.80. This suggests that most of the adhesive remained on the bracket after debonding. Failure occurred at the

enamel adhesive interface. Bulut⁽⁹²⁾ showed that Concise had a mean ARI score of 2.0 in his studies of shear bond strength which meant that half of the adhesive was left on the bracket base. Our findings concur with this study. As Concise's bond strength increased with longer storage, its ARI score also increased which is not what was expected. The Concise had increased bonding to the enamel but also a firm bond with the bracket. These two groups of specimens were prepared separately so, though there was one operator, there may have been variation in the way that the teeth were etched or the adhesive was mixed.

Transbond XT had a mean ARI score of 4.67 after thermocycling. Most of the adhesive was left on the bracket after debonding, suggesting that the failure occurred between the enamel-adhesive interface. These findings are in agreement with Schanefeldt⁽⁹³⁾ and Rix⁽⁹⁴⁾, who both conveyed that debonded brackets with an ARI score of 2.0 were the majority in their studies. Lalani⁽⁹⁵⁾ also reported that most of the brackets bonded with Transbond XT in his study scored a 2.0 in the ARI evaluation. In each of the previous 3 studies, an ARI score of 2.0 meant that 50% of the adhesive was left on the tooth after debonding.

After thermocycling, APC Plus had a mean ARI score of 4.67, which was not significantly different than Concise and Transbond XT's ARI after thermocycling. Most of the adhesive was on the bracket after debonding which is desirable in orthodontics. It means that there is less adhesive left on the tooth for the operator to clean up. All 3 thermocycling groups had similar scores, suggesting that they are comparable clinically.

DISCUSSION OF *IN VIVO* INVESTIGATION

A total of 31 patients were used in the *in vivo* portion of this study. Of the 595 teeth, 296 were bonded with Transbond XT and 299 with APC Plus. Sixteen of the brackets bonded with Transbond XT failed, for a failure rate of 6.08%, while 23 brackets bonded with APC Plus failed indicating a failure rate of 7.69%. The failure rates published in the literature for Transbond XT varied from 0.94% to 12.0%^(56;96-108). When evaluating these studies, multiple variables must be taken into consideration, such as primer used, type of light-curing, and duration of observation. Table 7 lists the *in vivo* failure rate studies for Transbond XT. The failure rates reported in this study are comparable to studies performed by Cal-Neto⁽¹⁰⁹⁾ and Ireland⁽¹¹⁰⁾ who used self-etch primer and a halogen light similar to those used in this study. According to previous studies, the failure rates for Transbond XT and APC Plus reported in this study are appropriate for a successful light-activated adhesive. In addition, it seems that both adhesives had the majority of their failures within the first 250 days after bonding. This suggests that most failures will occur towards the beginning of treatment.

Author	Failure Rate	Primer	Light Curing	Duration of Study
Pandis ⁽¹¹¹⁾	2.62%	Self-Etch Primer	Plasma Arc	12 months
Pandis ⁽¹¹²⁾	0.94%	Self-Etch Primer	Halogen	14 months
Ireland ⁽¹¹³⁾	10.99	Self-Etch Primer	Halogen	6 months
Ireland ⁽¹¹⁴⁾	4.95%	Conventional Acid Etch	Halogen	6 months
Manzo ⁽¹¹⁵⁾	3.9%	Conventional Acid Etch	Halogen	11 months
Manzo ⁽¹¹⁶⁾	3.9%	Conventional Acid Etch	Plasma Arc	11 months
Sfondrini ⁽¹¹⁷⁾	4.3%	Conventional Acid Etch	Plasma Arc	12 months
Sfondrini ⁽¹¹⁸⁾	5.4%	Conventional Acid Etch	Halogen	12 months
Wong ⁽¹¹⁹⁾	6.68%	Conventional Acid Etch	Halogen	6 months
Sunna ⁽⁵⁶⁾	10.7%	Conventional Acid Etch	Halogen	12 months

Littlewood ⁽¹²⁰⁾	6.8%	Conventional Acid Etch	Halogen	6 months
Cal-Neto ⁽¹²¹⁾	5.08%	Self-Etch Primer	Halogen	6 months
Cal-Neto ⁽¹²²⁾	2.54%	Conventional Acid Etch	Halogen	6 months
Elaut ⁽¹²³⁾	2.4%	Conventional Acid Etch	Argon Laser	12 months
Elaut ⁽¹²⁴⁾	5.7%	Conventional Acid Etch	Halogen	12 months
Frost ⁽¹²⁵⁾	10.0%	Conventional Acid Etch	Halogen	3 months
Aljubouri ⁽¹²⁶⁾	1.6%	Self-Etch Primer	Halogen	12 months
Aljubouri ⁽¹²⁷⁾	3.1%	Conventional Acid Etch	Halogen	12 months
Petteimerides ⁽¹²⁸⁾	12.0%	Conventional Acid Etch	Plasma Arc	6 months
Petteimerides ⁽¹²⁹⁾	12.0%	Conventional Acid Etch	Halogen	6 months

Table 8. *In Vivo* studies of the failure rate of Transbond XT.

When comparing survival times with Log-Rank and Wilcoxon tests, no significant difference was found between the survival distributions of Transbond XT and APC Plus. That is, brackets bonded with one of the two agents do not last longer than those bonded with the other. Brackets bonded with APC Plus adhesive will not have a higher failure rate. The tests also did not show a significant difference in survival distributions between the arch and the side of the mouth on which the bracket was bonded. That is, brackets were not more prone to failure on a specific arch or side. Arch and side of the mouth do not play a factor in whether or not the bracket is likely to fail. APC Plus is unique because it contains fluoride and also a dye to aid in cleanup of flash around brackets. According to this study, the addition of these components does not affect the survival rate of brackets bonded with this adhesive when compared to Transbond XT. Traditionally, mandibular brackets fail more often than maxillary ones due to occlusal forces. This trend was evident in the APC Plus brackets but not for brackets bonded with

Transbond XT. Perhaps the lower shear bond strength of APC Plus found *in vitro* plays a role in these results.

CLINICAL IMPLICATIONS

This investigation shows that APC Plus has adequate bond strength to withstand occlusal forces in clinical situations. This particular adhesive is tinted for easier and more effective cleanup which could possibly lead to decreased plaque accumulation around brackets. APC Plus also releases fluoride to help combat decalcification around direct bond brackets. Since decalcification is a problem in many orthodontic patients, this new bonding agent could prove to be very useful in reducing decalcification.

CHAPTER V

SUMMARY AND CONCLUSIONS

SUMMARY

This project was an *in vitro* and *in vivo* study of the shear bond strength and survival rate of a new orthodontic bonding agent, as compared to two conventional ones. The *in vitro* portion of the experiment compared the shear bond strength of three different adhesives. The adhesives used in this study were Concise, Transbond XT, and APC Plus. The *in vivo* portion determined the bracket survival rate and distribution of failed brackets bonded with two adhesives. The adhesives used in this part of the study were Transbond XT and APC Plus.

For the *in vitro* portion of the study, ninety extracted premolars were divided into six groups of 15 teeth each. Brackets that were bonded with Concise and Transbond XT were used as control groups. Brackets bonded with APC Plus were the experimental groups. The shear bond strength of the adhesives was tested with an Instron mechanical testing machine at either 30 minutes or after 500 cycles of thermocycling and 24 hour storage. The bracket failure interface was determined using the modified Adhesive Remnant Index (ARI).

Significant differences in shear bond strength and ARI score were determined using ANOVA. Paired comparisons were made using Tukey-Kramer Multiple Comparison analysis at $P < 0.0001$. This study showed that there was no significant difference in bond strength of Concise, Transbond XT, and APC Plus 30 minutes after bonding. After thermocycling and 24 hour storage, Concise and Transbond XT had significantly higher bond strengths than all of the other groups. The rest of the groups had lower bond strengths, but their values were still

considered adequate for orthodontic bonding. 30 minutes after bonding, Concise had a significantly lower ARI score than Transbond XT and APC Plus. Concise was more likely to fail at the adhesive-bracket interface while Transbond XT and APC Plus were likely to fail at the enamel-adhesive interface.

Increased time for curing and thermocycling caused the ARI score to significantly increase in Concise and Transbond XT. APC Plus's ARI score after thermocycling and 24 hour storage was not significantly different. Results showed that Concise, Transbond XT, and APC Plus had similar ARI scores after thermocycling, therefore, they would have similar modes of failure. Score indicated that they were likely to have a failure in the enamel-adhesive interface.

For the *in vivo* part of the study, two bonding agents were used in a split arch technique to bond the maxillary and mandibular teeth of 31 patients with adult dentitions. The date of bonding, date of bracket failure, location of bracket failure and the type of adhesive used were recorded for each patient. At the end of the variable observation periods, the Log-Rank and Wilcoxon tests were applied to determine if any differences existed in survival distributions. No significant differences in bracket survival distribution were shown between the two bonding agents. There was also no significant difference in arch or side for the adhesives. Thus, APC Plus was shown to have similar survival properties to those of Transbond XT.

CONCLUSIONS

1. From the findings of this study, it was concluded that there was no significant difference among Concise, Transbond XT, and APC Plus in shear bond strength 30 minutes after bonding.
2. There was a significant increase in bond strengths after thermocycling for Concise and Transbond XT, but not for APC Plus.
3. There was a significant difference in ARI score between Concise and Transbond, and Concise and APC Plus, but there was no difference after thermocycling.
4. *In vivo*, there was no significant difference in the survival rates of Transbond XT and APC Plus.

Brackets bonded with APC Plus were found to have adequate bond strength for orthodontic bonding. These brackets had similar bond strengths compared to those bonded with Concise and Transbond XT. The site of bracket failure for the APC Plus brackets was similar to that of the Transbond XT brackets.

Clinically, there was no statistically significant difference in the survival rate of brackets bonded with APC Plus and Transbond XT. Brackets can be bonded clinically with APC Plus without any risk of increased bracket failure rate.

RECOMMENDATIONS

Further clinical studies could assess the bracket failure rate of this new bonding agent. A larger sample size could be used, bonding could be limited to one type of adhesive, and one operator performing the bonding could help to minimize error. The fluoride releasing benefits of

APC Plus could also be assessed with further *in vitro* and *in vivo* trials. The effectiveness of the released fluoride in preventing decalcification could be tested in the laboratory and in patients.

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APPENDIX A
IRB APPROVAL



DATE: July 26, 2004

This research will be monitored for re-approval annually.
APPROVAL PERIOD: June 23, 2004 to June 22, 2005

NOTICE OF APPROVAL FOR PROTOCOL: IRB #16276

TO: Meredith Parks
Peter Ngan, Chris Martin, Michael Bagby, Elizabeth Kao, & Glenn Boyles

TITLE: An *In Vivo* Study to Evaluate the Bond Strength of a New Unitek Orthodontic Adhesive

AGENCY: 3M Unitek

The Institutional Review Board for the Protection of Human Research Subjects (IRB) has approved the project described above. Approval was based on the descriptive material and procedures you submitted for review. Should any changes in your protocol/consent form be necessary, **prior approval must be obtained from the IRB.**

According to the Code of Federal Regulations, Section 312.32, investigators are required to notify the FDA and the study sponsor of any adverse experience associated with the use of an investigational drug that is serious and unexpected. A serious adverse experience is considered any event that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose. An unexpected adverse experience is an event that is not identified in nature, severity, or frequency in the current investigator brochure. Any experience reportable to FDA and the sponsor must also be reported immediately to the IRB. If the study is funded, initiation of the protocol may not begin until the contract is finalized.

Chestnut Ridge Research Building

886 Chestnut Ridge Road
PO Box 6845
Morgantown, WV 26506-6845

Phone: 304-293-7073
Fax: 304-293-7435

Equal Opportunity/Affirmative Action Institution

Date: July 26, 2004
Page -2-
Parks
IRB #16276

A consent form* X is ___ is not required of each subject.

An assent form X is ___ is not required of each subject.


A recruitment ad has ___ has not X been approved.

A consent form waiver has ___ has not X been approved.

An authorization form to use PHI has X has not ___ been approved.

A PHI waiver has ___ has not X been approved.

Only copies of the consent and/or assent form with the IRB's approval stamp may be used with human subject research. It is the responsibility of the investigator to submit a revised consent form for the IRB's approval should funding be obtained. This stamped consent form must then be used for subjects enrolled. A copy of each subject's signed Consent/Assent Form must be retained by the investigator and accessible to federal regulatory authorities for at least three years after the study is completed.


LILLO A. ASU
Senior Program Coordinator for
Research Compliance

LAA/clg

APPENDIX B
CONSENT FORM



**PARENTAL OR GUARDIAN CONSENT
AND INFORMATION FORM**

**An *In Vivo* Study of a New
Orthodontic Bonding Agent and the
Effect of Fluoride Varnish on Enamel
Decalcification**

WEST VIRGINIA UNIVERSITY
Institution Review Board for the
Protection of Human Research Subjects

JUL 26 2004

X _____
EXPIRES _____
H.S. # 16276

Introduction. I, _____, have been asked to allow my child _____ to participate in this study. Meredith Parks, D.D.S. and Glenn Boyles, D.D.S., Peter Ngan, D.M.D., Chris Martin, D.D.S., Michael Bagby, D.D.S., and Elizabeth Kao, D.M.D., M.S., are conducting this research to fulfill the requirements for a master's thesis in the Department of Orthodontics at West Virginia University. Dr. Parks and/or Dr. Boyles have explained the study to me.

Purpose of the study. The purpose of the study is to test the bracket survival of a new FDA approved adhesive used to bond brackets on the teeth. "Bracket survival" refers to how many brackets stay bonded to the teeth during orthodontic treatment. This adhesive has a tint, or color, which allows the doctor to clean up the excess adhesive during bracket placement. This study will also test an FDA approved fluoride varnish that may possibly prevent cavities due to the application of braces and white spot decalcification. This study is being sponsored by 3M Unitek, Monrovia, CA.

Description of Procedures. This study will be done at West Virginia University, Department of Orthodontics. Sixty patients between the ages of 12-17 will be participating in this research project. My child's involvement will include bonding of his/her braces with either the new colored adhesive or the conventional orthodontic adhesive that is tooth colored. If one of his/her brackets comes off, the failure will be noted and the bracket will be saved and analyzed. The tooth involved will then be excluded from the study, rebracketed, and treatment will resume. Also, my child's teeth will be painted with a protective fluoride varnish coating and any white spot decalcification will be noted.

Submission Date 7/20/04

Page 1 of 3

Initials

Date

An *In Vivo* Study of a New Orthodontic Bonding Agent and the Effect of Fluoride Varnish on Enamel Decalcification

Risks and Discomforts. My child should have no additional discomforts or risks other than those normally experienced by patients undergoing orthodontic treatment

Benefits. I understand that there may be no clinical benefit to my child but that the knowledge gained from this study may be of benefit to clinicians and other dental patients.

Contact Persons. For more information about this research, I can contact Dr. Parks or Dr. Boyles at 304-293-5217. For more information regarding my child's rights as a research subject, I may contact the executive secretary of the Institutional Review Board at 304-293-7073.

Financial Considerations. There are no special fees for participating in this study.

Alternatives. I understand that my child does not have to participate in this study.

Confidentiality. I understand that any information obtained as a result of my child's participation in this research will be kept as confidential as legally possible. I understand that these research records, just like hospital records, may be subpoenaed by court order or may be inspected by federal regulatory authorities. In any publications that result from this research, neither my child's name nor any information from which my child might be identified will be published without my consent.

Submission Date 7/20/04

Page 2 of 3

Initials

Date

An *In Vivo* Study of a New Orthodontic Bonding Agent and the Effect of Fluoride Varnish on Enamel Decalcification

Voluntary Participation. Participation in this study is voluntary. I understand that I may withdraw my child from this study at any time. Refusal to participate or withdrawal will not alter my child's treatment. I have been given the opportunity to ask questions about the research, and I have received answers concerning areas I did not understand. Upon signing this form, I will receive a copy. I willingly consent for my child to participate in this study.

Signature of parent or guardian

Date

Signature of investigator

Date

Initial of Subject

Date

Submission Date 7/20/04

Page 3 of 3

APPENDIX C
ASSENT FORM



ASSENT FORM

An *In Vivo* Study of a New Orthodontic Bonding Agent and the Effect of Fluoride Varnish on Enamel Decalcification

WEST VIRGINIA UNIVERSITY
Institution Review Board for the
Protection of Human Research Subjects

JUL 26 2004

X
EX
H.S. # 16276

Introduction. I, _____, have been asked to be in this research study, which had been explained to me by Dr. Meredith Parks and/or Dr. Glenn Boyles.

Purpose of the study. I have been told that the purpose of the study is to test how the braces stay on the teeth with the new colored "glue" or adhesive. The doctor has explained that the new colored glue is easier to clean than the clear one. The study also will test a fluoride tooth coating that may prevent me from getting cavities or the "white spots" that Dr. Parks and/or Dr. Boyles have explained to me.

Description of Procedures. This study will be done at West Virginia University, Department of Orthodontics during my regularly scheduled appointments. My involvement will include gluing of half of my braces on with the new colored glue and the other half with the regular clear glue. If any of my braces fall off, Dr. Parks or Dr. Boyles will keep them and put new ones back on. Also, half of my teeth will be painted with the fluoride coating while my braces are on, and Dr. Parks or Dr. Boyles will check my teeth periodically for white spots.

Risks and Discomforts. There should be no additional discomforts or risks other than those normally experienced by patients that have braces.

Submission date 7/20/04 Page 1 of 2 _____
Initials Date

An *In Vivo* Study of a New Orthodontic Bonding Agent and the Effect of Fluoride Varnish on Enamel Decalcification

Benefits. I understand that the knowledge gained from this study may be of benefit to other dental patients.

Confidentiality. I have been promised that anything they learn about me in the study will be kept as secret as possible.

Voluntary Participation. I have been told that I do not have to do this study. No one will be mad at me if I choose not to be in it or if I decide to quit. I have been allowed to ask questions about the research, and all of my questions have been answered. I will receive a copy of this form after I sign it.

I willingly agree to be in this study.

Signature of participant

Date

Signature of investigator

Date

Submission Date 7/20/04

Page 2 of 2

APPENDIX D

PHI FORM

Authorization to Use or Disclose Protected Health Information (PHI)

West Virginia University

I hereby voluntarily authorize the use or disclosure of my individually identifiable health information as described below.

Patient Name: _____ ID Number: _____
Date of Birth: _____ IRB Protocol #: 16276

Persons/organizations providing the protected health information (e.g. hospitals):

Patients from the West Virginia University School of Dentistry Department of Orthodontics

Persons/organizations receiving the information (e.g. investigators, clinical coordinators, sponsor, FDA):

Meredith Parks DDS, Glen Boyles DDS, Peter Ngan DMD, Chris Martin DDS, Michael Bagby DMD, Elizabeth Kao, DMD

The following information will be used:

Location of bracket failure and assessment of failed bracket will be recorded. Location of decalcification will be recorded. All PHI will be coded to protect the privacy of participating patients.

The information is being disclosed for the following purposes (Start with the Title of the study and include additional information e.g. screening and recruiting subjects; analyzing research data, or other specified purposes):

For the master's thesis project titled "An *In vitro* and *In vivo* Study to Evaluate the Bond Strength of a New Unitek Orthodontic Adhesive"

I may revoke this authorization at any time by notifying the Principal Investigator in writing at:

Meredith Parks DDS, 1076 Health Sciences North, P.O. Box 9480 Morgantown, WV 26506

If I do revoke my authorization, any information previously disclosed cannot be withdrawn. Once information about me is disclosed in accordance with this authorization, the recipient may redisclose it and the information may no longer be protected by federal privacy regulations.

Authorization to Use or Disclose Protected Health Information (Contd.)

I may refuse to sign this authorization form. My clinical treatment may not be affected by whether or not I sign this form. I may not be allowed to participate in the research if I do not sign the form.

This authorization will expire on the date that the research study ends. (Other options for expiration include an actual date of expiration, occurrence of a particular event, or "none" if the authorization will have no expiration date.)

Expiration date: None

I will be given a copy of this authorization form.

Signature of subject or subject's legal representative (Form MUST be completed before signing) Date

Printed name of subject's legal representative
Relationship to the subject Initials

<input type="checkbox"/>	Parent	_____
<input type="checkbox"/>	Medical power of attorney/representative	_____
<input type="checkbox"/>	Legal guardian	_____
<input type="checkbox"/>	Health care surrogate	_____

WEST VIRGINIA UNIVERSITY
Institution Review Board for the
Protection of Human Research Subjects

JUL 26 2004



X
EXPIRES 6-30-04
H.S. # 16216

APPENDIX E
RAW DATA FOR THE *IN VITRO* STUDY

30 Minute Groups

Group I (Concise)			Group III (Transbond XT)			Group V (APC Plus)		
sample	SBS (mPa)	ARI	sample	SBS (mPa)	ARI	sample	SBS (mPa)	ARI
1	6.54	0	1	4.36	3	1	6.96	5
2	6.13	0	2	4.19	4	2	8.45	4
3	5.81	0	3	4.83	0	3	7.71	5
4	5.02	0	4	4.52	3	4	8.66	5
5	7.37	2	5	5.46	2	5	8.78	4
6	8.46	0	6	7.03	5	6	10.3	5
7	9.14	0	7	7.15	5	7	5.03	4
8	8.09	4	8	10.49	5	8	6.36	3
9	12.95	3	9	12.33	3	9	9.03	5
10	13.82	4	10	4.31	3	10	7.58	5
11	13.63	3	11	9.45	5	11	11.99	5
12	8.5	1	12	10.71	3	12	11.62	5
13	6.34	1	13	10.32	1	13	7.04	5
14	9.44	1	14	10.17	5	14	9.51	4
15	6.7	5	15	7.75	5	15	10.79	4

Thermocycling Groups

Group II (Concise)			Group IV (Transbond XT)			Group VI (APC Plus)		
sample	SBS (mPa)	ARI	sample	SBS (mPa)	ARI	sample	SBS (mPa)	ARI
1	9.77	5	1	18.23	4	1	12.43	3
2	21.25	5	2	15.64	4	2	2.91	5
3	6.76	5	3	16.03	5	3	4.86	5
4	5.21	5	4	16.38	5	4	14.31	5
5	25.59	5	5	19	5	5	8.55	5
6	13.07	4	6	15.13	4	6	7.94	5
7	16.18	5	7	11.69	5	7	7.89	4
8	17.4	5	8	13.22	5	8	9.72	5
9	12.17	5	9	24.9	4	9	11.28	5
10	21.25	4	10	3.88	5	10	3.53	5
11	16.83	5	11	10.1	5	11	9.64	4
12	12.24	5	12	9.25	5	12	7.5	4
13	16.57	4	13	13.19	5	13	12.22	5
14	12.54	5	14	15.73	5	14	4.45	5
15	20.31	5	15	20.04	4	15	6.05	5

APPENDIX F
***IN VITRO* STATISICAL ANALYSIS RESULTS**

IN VITRO.

SBS. Compare groups 1, 2, 3, 4, 5, and 6.

*The following Table gives the min, max and the median for each group.

Group	Minimum	Median	Maximum
1	5.02	8.09	13.82
2	6.76	16.18	21.25
3	4.19	7.15	12.33
4	9.25	15.64	20.04
5	5.03	8.66	11.99
6	3.53	7.94	14.31

**Oneway Anova
Summary of Fit**

Rsquare	0.518042
Adj Rsquare	0.487147
Root Mean Square Error	3.142857
Mean of Response	10.34202
Observations (or Sum Wgts)	84

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Group	5	828.1306	165.626	16.7679	<.0001
Error	78	770.4488	9.878		
C. Total	83	1598.5794			

*There is significant difference between the groups. $P < 0.0001$.

*The following table gives the means and standard deviations for each group

Means and Std Deviations

Level	Number	Mean	Std Dev
1	15	8.5293	2.85181
2	13	15.1031	4.47030
3	15	7.5380	2.84107
4	13	14.8946	3.29252
5	15	8.6540	1.96477

Level	Number	Mean	Std Dev
6	13	8.3031	3.15767

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

Level		Mean
2	A	15.103077
4	A	14.894615
5	B	8.654000
1	B	8.529333
6	B	8.303077
3	B	7.538000

Levels not connected by same letter are significantly different

*There is no significant difference between the groups 2 and 4.

*There is no significant difference between the groups 1, 3, 5, and 6.

*There is a significant difference between the groups 1 and 2.

*There is a significant difference between the groups 2 and 3.

*There is a significant difference between the groups 2 and 5.

*There is a significant difference between the groups 2 and 6.

*There is a significant difference between the groups 1 and 4.

*There is a significant difference between the groups 3 and 4.

*There is a significant difference between the groups 4 and 5.

*There is a significant difference between the groups 4 and 6.

SBS. Compare only the groups 1,3, and 5.

Oneway Analysis of SBS By Group

Excluded Rows45

Oneway Anova

Summary of Fit

Rsquare	0.038404
Adj Rsquare	-0.00739
Root Mean Square Error	2.586171
Mean of Response	8.240444
Observations (or Sum Wgts)	45

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Group	2	11.21870	5.60935	0.8387	0.4394
Error	42	280.90769	6.68828		
C.	44	292.12639			
Total					

*There is no significant difference between the Groups 1, 3, and 5. P=0.43.

Means and Std Deviations

Group	Number	Mean	Std Dev
1	15	8.52933	2.85181
3	15	7.53800	2.84107
5	15	8.65400	1.96477

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

Group		Mean
5	A	8.6540000
1	A	8.5293333
3	A	7.5380000

Levels not connected by same letter are significantly different

SBS. Compare only the groups 2,4 and 6.

(Observations 4,5 in Group 2; 9,10 in Group 4; 1,2 in Group 6, on SBS are deleted)

Excluded Rows

6

Oneway Anova

Summary of Fit

Rsquare	0.442677
Adj Rsquare	0.411714
Root Mean Square Error	3.687596
Mean of Response	12.76692
Observations (or Sum Wgts)	39

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Group	2	388.83795	194.419	14.2972	<.0001
Error	36	489.54108	13.598		
C. Total	38	878.37903			

*There is a significant difference between the groups. P<.0001

Means and Std Deviations

Level	Number	Mean	Std Dev
2	13	15.1031	4.47030
4	13	14.8946	3.29252
6	13	8.3031	3.15767

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

Level	Mean
2 A	15.103077
4 A	14.894615
6 B	8.303077

Levels not connected by same letter are significantly different

*There is no significant difference between the groups 2 and 4.

*There is a significant difference between the groups 2 and 6.

*There is a significant difference between the groups 4 and 6.

ARI. Compare groups 1, 2, 3, 4, 5, and 6.

*The following Table gives the min, max and the median for each group.

Group	Minimum	Median	Maximum
1	0	1	5
2	4	5	5
3	0	3	5
4	4	5	5
5	3	5	5
6	3	5	5

Oneway Analysis of ARI By Group Summary of Fit

Rsquare	0.550405
Adj Rsquare	0.523644
Root Mean Square Error	1.069787
Mean of Response	3.955556
Observations (or Sum Wgts)	90

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Group	5	117.68889	23.5378	20.5670	<.0001
Error	84	96.13333	1.1444		
C. Total	89	213.82222			

*There is a significant difference between the groups. $P < 0.0001$.

*The following table gives the means and standard deviations for each group.

Group	Number	Mean	Std Dev
1	15	1.60000	1.76473
2	15	4.80000	0.41404
3	15	3.46667	1.59762
4	15	4.66667	0.48795
5	15	4.53333	0.63994
6	15	4.66667	0.61721

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

Group	Mean
2 A	4.8000000
4 A	4.6666667
6 A	4.6666667
5 A B	4.5333333
3 B	3.4666667
1 C	1.6000000

Levels not connected by same letter are significantly different

*There is no significant difference between the groups 2, 4, 5, and 6.

*There is no significant difference between the groups 3, and 5.

*There is a significant difference between the groups 1 and 2.

*There is a significant difference between the groups 1 and 3.

*There is a significant difference between the groups 1 and 4.

*There is a significant difference between the groups 1 and 5.

*There is a significant difference between the groups 1 and 6.

*There is a significant difference between the groups 2 and 3.

*There is a significant difference between the groups 2 and 5.

*There is a significant difference between the groups 4 and 5.

*There is a significant difference between the groups 4 and 6.

ARI. Compare only the groups 1, 3 and 5.

Oneway Analysis of ARI By Group

Excluded Rows 45

Oneway Anova

Summary of Fit

Rsquare	0.43739
Adj Rsquare	0.410599
Root Mean Square Error	1.423164
Mean of Response	3.2
Observations (or Sum Wgts)	45

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Group	2	66.13333	33.0667	16.3260	<.0001
Error	42	85.06667	2.0254		
C. Total	44	151.20000			

*There is significant difference between the groups. $P < 0.0001$.

Means and Std Deviations

Group	Number	Mean	Std Dev
1	15	1.60000	1.76473
3	15	3.46667	1.59762
5	15	4.53333	0.63994

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

Group	Mean
5 A	4.5333333
3 A	3.4666667
1 B	1.6000000

Levels not connected by same letter are significantly different

*There is no significant difference between the groups 3 and 5.

*There is a significant difference between the groups 1 and 3.

*There is a significant difference between the groups 1 and 5.

ARI. Compare only the groups 2, 4 and 6.

Oneway Analysis of ARI By Group

Excluded Rows 45

Oneway Anova

Summary of Fit

Rsquare	0.01581
Adj Rsquare	-0.03106
Root Mean Square Error	0.513315
Mean of Response	4.711111
Observations (or Sum Wgts)	45

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob > F
Group	2	0.177778	0.088889	0.3373	0.7156
Error	42	11.066667	0.263492		
C.	44	11.244444			
Total					

*There is no significant difference between the groups 2, 4 and 6. P=0.71.

Means and Std Deviations

Group	Number	Mean	Std Dev
2	15	4.80000	0.414039
4	15	4.66667	0.487950
6	15	4.66667	0.617213

Means Comparisons

Comparisons for all pairs using Tukey-Kramer HSD

Group	Mean
2 A	4.8000000
4 A	4.6666667
6 A	4.6666667

Levels not connected by same letter are significantly different

APPENDIX G
RAW DATA FOR THE *IN VIVO* STUDY

Patient	Tooth #	Adhesive	Arch	Side	Failed?	Days Lasted	
A	4	APC Plus	Maxillary	Right	No	457	
	5	APC Plus	Maxillary	Right	No	457	
	6	APC Plus	Maxillary	Right	Yes	120	
	7	APC Plus	Maxillary	Right	Yes	42	
	8	APC Plus	Maxillary	Right	No	457	
	9	Transbond XT	Maxillary	Left	No	457	
	10	Transbond XT	Maxillary	Left	Yes	87	
	11	Transbond XT	Maxillary	Left	No	457	
	12	Transbond XT	Maxillary	Left	No	457	
	13	Transbond XT	Maxillary	Left	Yes	214	
	20	APC Plus	Mandibular	Left	No	457	
	21	APC Plus	Mandibular	Left	No	457	
	22	APC Plus	Mandibular	Left	No	457	
	23	APC Plus	Mandibular	Left	Yes	233	
	24	APC Plus	Mandibular	Left	Yes	87	
	25	Transbond XT	Mandibular	Right	No	457	
	26	Transbond XT	Mandibular	Right	No	457	
	27	Transbond XT	Mandibular	Right	No	457	
	28	Transbond XT	Mandibular	Right	No	457	
	29	Transbond XT	Mandibular	Right	No	457	
	B	4	Transbond XT	Maxillary	Right	No	453
		5	Transbond XT	Maxillary	Right	No	453
		6	Transbond XT	Maxillary	Right	No	453
		7	Transbond XT	Maxillary	Right	Yes	90
		8	Transbond XT	Maxillary	Right	No	453
		9	APC Plus	Maxillary	Left	No	453
		10	APC Plus	Maxillary	Left	No	453
		11	APC Plus	Maxillary	Left	No	453
		12	APC Plus	Maxillary	Left	No	453
13		APC Plus	Maxillary	Left	No	453	
20		Transbond XT	Mandibular	Left	No	453	
21		Transbond XT	Mandibular	Left	No	453	
22		Transbond XT	Mandibular	Left	No	453	
23		Transbond XT	Mandibular	Left	No	453	
24		Transbond XT	Mandibular	Left	No	453	
25		APC Plus	Mandibular	Right	No	453	
26		APC Plus	Mandibular	Right	No	453	
27		APC Plus	Mandibular	Right	No	453	
28		APC Plus	Mandibular	Right	No	453	
29		APC Plus	Mandibular	Right	Yes	48	
C		4	APC Plus	Maxillary	Right	Yes	28
		5	APC Plus	Maxillary	Right	No	271
		6	APC Plus	Maxillary	Right	No	271
		7	APC Plus	Maxillary	Right	No	271
		8	APC Plus	Maxillary	Right	No	271
		9	Transbond XT	Maxillary	Left	No	271
		10	Transbond XT	Maxillary	Left	Yes	28

	11	Transbond XT	Maxillary	Left	No	271
	12	Transbond XT	Maxillary	Left	No	271
	13	Transbond XT	Maxillary	Left	No	271
	20	APC Plus	Mandibular	Left	Yes	18
	21	APC Plus	Mandibular	Left	No	271
	22	APC Plus	Mandibular	Left	No	271
	23	APC Plus	Mandibular	Left	No	271
	24	APC Plus	Mandibular	Left	Yes	153
	25	Transbond XT	Mandibular	Right	No	271
	26	Transbond XT	Mandibular	Right	No	271
	27	Transbond XT	Mandibular	Right	No	271
	28	Transbond XT	Mandibular	Right	Yes	28
	29	Transbond XT	Mandibular	Right	No	271
D	4	APC Plus	Maxillary	Right	No	499
	6	APC Plus	Maxillary	Right	No	499
	7	APC Plus	Maxillary	Right	No	499
	8	APC Plus	Maxillary	Right	No	499
	9	Transbond XT	Maxillary	Left	No	499
	10	Transbond XT	Maxillary	Left	No	499
	11	Transbond XT	Maxillary	Left	No	499
	13	Transbond XT	Maxillary	Left	No	499
	20	APC Plus	Mandibular	Left	No	499
	21	APC Plus	Mandibular	Left	No	499
	22	APC Plus	Mandibular	Left	No	499
	23	APC Plus	Mandibular	Left	Yes	337
	24	APC Plus	Mandibular	Left	No	499
	25	Transbond XT	Mandibular	Right	No	499
	26	Transbond XT	Mandibular	Right	Yes	337
	27	Transbond XT	Mandibular	Right	No	499
	28	Transbond XT	Mandibular	Right	No	499
	29	Transbond XT	Mandibular	Right	No	499
E	4	Transbond XT	Maxillary	Right	No	526
	6	Transbond XT	Maxillary	Right	No	526
	7	Transbond XT	Maxillary	Right	No	526
	8	Transbond XT	Maxillary	Right	No	526
	9	APC Plus	Maxillary	Left	Yes	169
	10	APC Plus	Maxillary	Left	No	526
	11	APC Plus	Maxillary	Left	No	526
	13	APC Plus	Maxillary	Left	No	526
	20	Transbond XT	Mandibular	Left	No	526
	22	Transbond XT	Mandibular	Left	No	526
	23	Transbond XT	Mandibular	Left	No	526
	24	Transbond XT	Mandibular	Left	No	526
	25	APC Plus	Mandibular	Right	No	526
	26	APC Plus	Mandibular	Right	No	526
	27	APC Plus	Mandibular	Right	Yes	227
	29	APC Plus	Mandibular	Right	No	526
F	4	Transbond XT	Maxillary	Right	No	362

	5	Transbond XT	Maxillary	Right	No	362
	6	Transbond XT	Maxillary	Right	No	362
	7	Transbond XT	Maxillary	Right	No	362
	8	Transbond XT	Maxillary	Right	Yes	58
	9	APC Plus	Maxillary	Left	No	362
	10	APC Plus	Maxillary	Left	No	362
	11	APC Plus	Maxillary	Left	No	362
	12	APC Plus	Maxillary	Left	No	362
	13	APC Plus	Maxillary	Left	No	362
	20	Transbond XT	Mandibular	Left	No	362
	21	Transbond XT	Mandibular	Left	No	362
	22	Transbond XT	Mandibular	Left	No	362
	23	Transbond XT	Mandibular	Left	No	362
	24	Transbond XT	Mandibular	Left	No	362
	25	APC Plus	Mandibular	Right	No	362
	26	APC Plus	Mandibular	Right	No	362
	27	APC Plus	Mandibular	Right	Yes	111
	28	APC Plus	Mandibular	Right	No	362
	29	APC Plus	Mandibular	Right	No	362
G	4	APC Plus	Maxillary	Right	No	414
	5	APC Plus	Maxillary	Right	No	414
	6	APC Plus	Maxillary	Right	No	414
	7	APC Plus	Maxillary	Right	No	414
	8	APC Plus	Maxillary	Right	No	414
	9	Transbond XT	Maxillary	Left	No	414
	10	Transbond XT	Maxillary	Left	No	414
	11	Transbond XT	Maxillary	Left	No	414
	12	Transbond XT	Maxillary	Left	No	414
	13	Transbond XT	Maxillary	Left	No	414
	20	APC Plus	Mandibular	Left	No	414
	21	APC Plus	Mandibular	Left	No	414
	22	APC Plus	Mandibular	Left	No	414
	23	APC Plus	Mandibular	Left	No	414
	24	APC Plus	Mandibular	Left	No	414
	25	Transbond XT	Mandibular	Right	No	414
	26	Transbond XT	Mandibular	Right	Yes	35
	27	Transbond XT	Mandibular	Right	No	414
	28	Transbond XT	Mandibular	Right	No	414
	29	Transbond XT	Mandibular	Right	Yes	35
H	4	Transbond XT	Maxillary	Right	No	321
	6	Transbond XT	Maxillary	Right	No	321
	7	Transbond XT	Maxillary	Right	No	321
	8	Transbond XT	Maxillary	Right	No	321
	9	APC Plus	Maxillary	Left	No	321
	10	APC Plus	Maxillary	Left	Yes	42
	11	APC Plus	Maxillary	Left	No	321
	13	APC Plus	Maxillary	Left	No	321
	20	Transbond XT	Mandibular	Left	No	321

	22	Transbond XT	Mandibular	Left	No	321
	23	Transbond XT	Mandibular	Left	No	321
	24	Transbond XT	Mandibular	Left	Yes	135
	25	APC Plus	Mandibular	Right	No	321
	26	APC Plus	Mandibular	Right	No	321
	27	APC Plus	Mandibular	Right	No	321
	29	APC Plus	Mandibular	Right	No	321
I	4	Transbond XT	Maxillary	Right	No	621
	5	Transbond XT	Maxillary	Right	No	621
	6	Transbond XT	Maxillary	Right	No	621
	7	Transbond XT	Maxillary	Right	No	621
	8	Transbond XT	Maxillary	Right	No	621
	9	APC Plus	Maxillary	Left	Yes	203
	10	APC Plus	Maxillary	Left	No	621
	11	APC Plus	Maxillary	Left	No	621
	12	APC Plus	Maxillary	Left	No	621
	13	APC Plus	Maxillary	Left	No	621
	20	Transbond XT	Mandibular	Left	Yes	480
	21	Transbond XT	Mandibular	Left	No	621
	22	Transbond XT	Mandibular	Left	No	621
	23	Transbond XT	Mandibular	Left	No	621
	24	Transbond XT	Mandibular	Left	No	621
	25	APC Plus	Mandibular	Right	No	621
	26	APC Plus	Mandibular	Right	No	621
	27	APC Plus	Mandibular	Right	No	621
	28	APC Plus	Mandibular	Right	No	621
	29	APC Plus	Mandibular	Right	No	
J	4	APC Plus	Maxillary	Right	No	379
	5	APC Plus	Maxillary	Right	No	379
	6	APC Plus	Maxillary	Right	No	379
	7	APC Plus	Maxillary	Right	No	379
	8	APC Plus	Maxillary	Right	No	379
	9	Transbond XT	Maxillary	Left	No	379
	10	Transbond XT	Maxillary	Left	No	379
	11	Transbond XT	Maxillary	Left	No	379
	12	Transbond XT	Maxillary	Left	No	379
	13	Transbond XT	Maxillary	Left	No	379
	20	APC Plus	Mandibular	Left	No	379
	21	APC Plus	Mandibular	Left	No	379
	22	APC Plus	Mandibular	Left	No	379
	23	APC Plus	Mandibular	Left	No	379
	24	APC Plus	Mandibular	Left	Yes	49
	25	Transbond XT	Mandibular	Right	No	379
	26	Transbond XT	Mandibular	Right	No	379
	27	Transbond XT	Mandibular	Right	No	379
	28	Transbond XT	Mandibular	Right	No	379
	29	Transbond XT	Mandibular	Right	No	379
K	4	APC Plus	Maxillary	Right	No	544

	6	APC Plus	Maxillary	Right	No	544
	7	APC Plus	Maxillary	Right	No	544
	8	APC Plus	Maxillary	Right	No	544
	9	Transbond XT	Maxillary	Left	No	544
	10	Transbond XT	Maxillary	Left	No	544
	11	Transbond XT	Maxillary	Left	No	544
	13	Transbond XT	Maxillary	Left	No	544
	20	APC Plus	Mandibular	Left	No	544
	22	APC Plus	Mandibular	Left	No	544
	23	APC Plus	Mandibular	Left	No	544
	24	APC Plus	Mandibular	Left	No	544
	25	Transbond XT	Mandibular	Right	Yes	359
	26	Transbond XT	Mandibular	Right	No	544
	27	Transbond XT	Mandibular	Right	No	544
	29	Transbond XT	Mandibular	Right	No	544
L	4	APC Plus	Maxillary	Right	No	534
	5	APC Plus	Maxillary	Right	No	534
	6	APC Plus	Maxillary	Right	No	534
	7	APC Plus	Maxillary	Right	No	534
	8	APC Plus	Maxillary	Right	No	534
	9	Transbond XT	Maxillary	Left	No	534
	10	Transbond XT	Maxillary	Left	No	534
	11	Transbond XT	Maxillary	Left	No	534
	12	Transbond XT	Maxillary	Left	No	534
	13	Transbond XT	Maxillary	Left	Yes	77
	20	APC Plus	Mandibular	Left	No	534
	21	APC Plus	Mandibular	Left	No	534
	22	APC Plus	Mandibular	Left	No	534
	23	APC Plus	Mandibular	Left	No	534
	24	APC Plus	Mandibular	Left	No	534
	25	Transbond XT	Mandibular	Right	No	534
	26	Transbond XT	Mandibular	Right	No	534
	27	Transbond XT	Mandibular	Right	No	534
	28	Transbond XT	Mandibular	Right	No	534
	29	Transbond XT	Mandibular	Right	No	534
M	4	Transbond XT	Maxillary	Right	No	641
	5	Transbond XT	Maxillary	Right	Yes	35
	6	Transbond XT	Maxillary	Right	No	641
	7	Transbond XT	Maxillary	Right	No	641
	8	Transbond XT	Maxillary	Right	No	641
	9	APC Plus	Maxillary	Left	No	641
	10	APC Plus	Maxillary	Left	No	641
	11	APC Plus	Maxillary	Left	No	641
	12	APC Plus	Maxillary	Left	No	641
	13	APC Plus	Maxillary	Left	No	641
	20	Transbond XT	Mandibular	Left	No	641
	21	Transbond XT	Mandibular	Left	No	641
	22	Transbond XT	Mandibular	Left	No	641

	23	Transbond XT	Mandibular	Left	No	641
	24	Transbond XT	Mandibular	Left	No	641
	25	APC Plus	Mandibular	Right	No	641
	26	APC Plus	Mandibular	Right	No	641
	27	APC Plus	Mandibular	Right	No	641
	28	APC Plus	Mandibular	Right	No	641
	29	APC Plus	Mandibular	Right	No	641
N	4	APC Plus	Maxillary	Right	No	504
	5	APC Plus	Maxillary	Right	Yes	209
	6	APC Plus	Maxillary	Right	No	504
	7	APC Plus	Maxillary	Right	No	504
	8	APC Plus	Maxillary	Right	No	504
	9	Transbond XT	Maxillary	Left	No	504
	10	Transbond XT	Maxillary	Left	No	504
	11	Transbond XT	Maxillary	Left	No	504
	12	Transbond XT	Maxillary	Left	No	504
	13	Transbond XT	Maxillary	Left	No	504
	20	APC Plus	Mandibular	Left	No	504
	21	APC Plus	Mandibular	Left	No	504
	22	APC Plus	Mandibular	Left	No	504
	23	APC Plus	Mandibular	Left	No	504
	24	APC Plus	Mandibular	Left	No	504
	25	Transbond XT	Mandibular	Right	No	504
	26	Transbond XT	Mandibular	Right	No	504
	27	Transbond XT	Mandibular	Right	No	504
	28	Transbond XT	Mandibular	Right	No	504
	29	Transbond XT	Mandibular	Right	No	504
O	4	APC Plus	Maxillary	Right	No	274
	5	APC Plus	Maxillary	Right	No	274
	6	APC Plus	Maxillary	Right	No	274
	7	APC Plus	Maxillary	Right	No	274
	8	APC Plus	Maxillary	Right	No	274
	9	Transbond XT	Maxillary	Left	No	274
	10	Transbond XT	Maxillary	Left	No	274
	11	Transbond XT	Maxillary	Left	No	274
	12	Transbond XT	Maxillary	Left	No	274
	13	Transbond XT	Maxillary	Left	No	274
	20	APC Plus	Mandibular	Left	Yes	44
	21	APC Plus	Mandibular	Left	No	274
	22	APC Plus	Mandibular	Left	No	274
	23	APC Plus	Mandibular	Left	No	274
	24	APC Plus	Mandibular	Left	No	274
	25	Transbond XT	Mandibular	Right	No	274
	26	Transbond XT	Mandibular	Right	No	274
	27	Transbond XT	Mandibular	Right	No	274
	28	Transbond XT	Mandibular	Right	No	274
	29	Transbond XT	Mandibular	Right	No	274
P	4	APC Plus	Maxillary	Right	No	253

	5	APC Plus	Maxillary	Right	No	253
	6	APC Plus	Maxillary	Right	No	253
	7	APC Plus	Maxillary	Right	No	253
	8	APC Plus	Maxillary	Right	No	253
	9	Transbond XT	Maxillary	Left	Yes	223
	10	Transbond XT	Maxillary	Left	No	253
	11	Transbond XT	Maxillary	Left	No	253
	12	Transbond XT	Maxillary	Left	No	253
	13	Transbond XT	Maxillary	Left	No	253
	20	APC Plus	Mandibular	Left	No	253
	21	APC Plus	Mandibular	Left	No	253
	22	APC Plus	Mandibular	Left	No	253
	23	APC Plus	Mandibular	Left	No	253
	24	APC Plus	Mandibular	Left	No	253
	25	Transbond XT	Mandibular	Right	No	253
	26	Transbond XT	Mandibular	Right	No	253
	27	Transbond XT	Mandibular	Right	No	253
	28	Transbond XT	Mandibular	Right	No	253
	29	Transbond XT	Mandibular	Right	No	253
Q	4	Transbond XT	Maxillary	Right	No	572
	6	Transbond XT	Maxillary	Right	No	572
	7	Transbond XT	Maxillary	Right	Yes	337
	8	Transbond XT	Maxillary	Right	No	572
	9	APC Plus	Maxillary	Left	No	572
	10	APC Plus	Maxillary	Left	No	572
	11	APC Plus	Maxillary	Left	No	572
	13	APC Plus	Maxillary	Left	No	572
	20	Transbond XT	Mandibular	Left	No	572
	21	Transbond XT	Mandibular	Left	No	572
	22	Transbond XT	Mandibular	Left	No	572
	23	Transbond XT	Mandibular	Left	No	572
	24	Transbond XT	Mandibular	Left	No	572
	25	APC Plus	Mandibular	Right	No	572
	26	APC Plus	Mandibular	Right	No	572
	27	APC Plus	Mandibular	Right	No	572
	28	APC Plus	Mandibular	Right	No	572
	29	APC Plus	Mandibular	Right	No	572
R	4	Transbond XT	Maxillary	Right	No	291
	5	Transbond XT	Maxillary	Right	No	291
	6	Transbond XT	Maxillary	Right	No	291
	7	Transbond XT	Maxillary	Right	No	291
	8	Transbond XT	Maxillary	Right	No	291
	9	APC Plus	Maxillary	Left	No	291
	10	APC Plus	Maxillary	Left	No	291
	11	APC Plus	Maxillary	Left	No	291
	12	APC Plus	Maxillary	Left	No	291
	13	APC Plus	Maxillary	Left	No	291
	20	Transbond XT	Mandibular	Left	Yes	

	21	Transbond XT	Mandibular	Left	No	291
	22	Transbond XT	Mandibular	Left	No	291
	23	Transbond XT	Mandibular	Left	No	291
	24	Transbond XT	Mandibular	Left	No	291
	25	APC Plus	Mandibular	Right	No	291
	26	APC Plus	Mandibular	Right	No	291
	27	APC Plus	Mandibular	Right	No	291
	28	APC Plus	Mandibular	Right	No	291
	29	APC Plus	Mandibular	Right	No	291
S	4	APC Plus	Maxillary	Right	No	311
	5	APC Plus	Maxillary	Right	No	311
	6	APC Plus	Maxillary	Right	No	311
	7	APC Plus	Maxillary	Right	No	311
	8	APC Plus	Maxillary	Right	No	311
	9	Transbond XT	Maxillary	Left	No	311
	10	Transbond XT	Maxillary	Left	No	311
	11	Transbond XT	Maxillary	Left	No	311
	12	Transbond XT	Maxillary	Left	No	311
	13	Transbond XT	Maxillary	Left	No	311
	20	APC Plus	Mandibular	Left	No	311
	21	APC Plus	Mandibular	Left	No	311
	22	APC Plus	Mandibular	Left	No	311
	23	APC Plus	Mandibular	Left	No	311
	24	APC Plus	Mandibular	Left	No	311
	25	Transbond XT	Mandibular	Right	No	311
	26	Transbond XT	Mandibular	Right	No	311
	27	Transbond XT	Mandibular	Right	No	311
	28	Transbond XT	Mandibular	Right	No	311
	29	Transbond XT	Mandibular	Right	No	311
T	4	APC Plus	Maxillary	Right	No	301
	5	APC Plus	Maxillary	Right	No	301
	6	APC Plus	Maxillary	Right	No	301
	7	APC Plus	Maxillary	Right	No	301
	8	APC Plus	Maxillary	Right	No	301
	9	Transbond XT	Maxillary	Left	No	301
	10	Transbond XT	Maxillary	Left	No	301
	11	Transbond XT	Maxillary	Left	No	301
	12	Transbond XT	Maxillary	Left	No	301
	13	Transbond XT	Maxillary	Left	No	301
	20	APC Plus	Mandibular	Left	No	301
	21	APC Plus	Mandibular	Left	No	301
	22	APC Plus	Mandibular	Left	No	301
	23	APC Plus	Mandibular	Left	No	301
	24	APC Plus	Mandibular	Left	No	301
	25	Transbond XT	Mandibular	Right	No	301
	26	Transbond XT	Mandibular	Right	No	301
	27	Transbond XT	Mandibular	Right	No	301
	28	Transbond XT	Mandibular	Right	No	301

	29	Transbond XT	Mandibular	Right	No	301
U	4	APC Plus	Maxillary	Right	No	315
	5	APC Plus	Maxillary	Right	No	315
	6	APC Plus	Maxillary	Right	No	315
	7	APC Plus	Maxillary	Right	No	315
	8	APC Plus	Maxillary	Right	No	315
	9	Transbond XT	Maxillary	Left	No	315
	10	Transbond XT	Maxillary	Left	No	315
	11	Transbond XT	Maxillary	Left	No	315
	12	Transbond XT	Maxillary	Left	No	315
	13	Transbond XT	Maxillary	Left	No	315
	20	APC Plus	Mandibular	Left	No	315
	21	APC Plus	Mandibular	Left	No	315
	22	APC Plus	Mandibular	Left	No	315
	23	APC Plus	Mandibular	Left	No	315
	24	APC Plus	Mandibular	Left	No	315
	25	Transbond XT	Mandibular	Right	No	315
	26	Transbond XT	Mandibular	Right	No	315
	27	Transbond XT	Mandibular	Right	No	315
	28	Transbond XT	Mandibular	Right	No	315
	29	Transbond XT	Mandibular	Right	No	315
V	4	APC Plus	Maxillary	Right	No	239
	5	APC Plus	Maxillary	Right	No	239
	6	APC Plus	Maxillary	Right	No	239
	7	APC Plus	Maxillary	Right	No	239
	8	APC Plus	Maxillary	Right	No	239
	9	Transbond XT	Maxillary	Left	No	239
	10	Transbond XT	Maxillary	Left	No	239
	11	Transbond XT	Maxillary	Left	No	239
	12	Transbond XT	Maxillary	Left	No	239
	13	Transbond XT	Maxillary	Left	No	239
	20	APC Plus	Mandibular	Left	Yes	227
	21	APC Plus	Mandibular	Left	No	239
	22	APC Plus	Mandibular	Left	No	239
	23	APC Plus	Mandibular	Left	No	239
	24	APC Plus	Mandibular	Left	No	239
	25	Transbond XT	Mandibular	Right	No	239
	26	Transbond XT	Mandibular	Right	No	239
	27	Transbond XT	Mandibular	Right	No	239
	28	Transbond XT	Mandibular	Right	No	239
	29	Transbond XT	Mandibular	Right	No	239
W	4	Transbond XT	Maxillary	Right	No	517
	6	Transbond XT	Maxillary	Right	No	517
	7	Transbond XT	Maxillary	Right	No	517
	8	Transbond XT	Maxillary	Right	No	517
	9	APC Plus	Maxillary	Left	No	517
	10	APC Plus	Maxillary	Left	No	517
	11	APC Plus	Maxillary	Left	No	517

	13	APC Plus	Maxillary	Left	No	517
	20	Transbond XT	Mandibular	Left	No	517
	22	Transbond XT	Mandibular	Left	No	517
	23	Transbond XT	Mandibular	Left	No	517
	24	Transbond XT	Mandibular	Left	No	517
	25	APC Plus	Mandibular	Right	No	517
	26	APC Plus	Mandibular	Right	No	517
	27	APC Plus	Mandibular	Right	No	517
	29	APC Plus	Mandibular	Right	No	517
X	4	Transbond XT	Maxillary	Right	No	390
	5	Transbond XT	Maxillary	Right	No	390
	6	Transbond XT	Maxillary	Right	No	390
	7	Transbond XT	Maxillary	Right	No	390
	8	Transbond XT	Maxillary	Right	No	390
	9	APC Plus	Maxillary	Left	No	390
	10	APC Plus	Maxillary	Left	No	390
	11	APC Plus	Maxillary	Left	No	390
	12	APC Plus	Maxillary	Left	No	390
	13	APC Plus	Maxillary	Left	No	390
	20	Transbond XT	Mandibular	Left	No	390
	21	Transbond XT	Mandibular	Left	No	390
	22	Transbond XT	Mandibular	Left	No	390
	23	Transbond XT	Mandibular	Left	No	390
	24	Transbond XT	Mandibular	Left	No	390
	25	APC Plus	Mandibular	Right	No	390
	26	APC Plus	Mandibular	Right	No	390
	27	APC Plus	Mandibular	Right	Yes	206
	28	APC Plus	Mandibular	Right	No	390
	29	APC Plus	Mandibular	Right	No	390
Y	4	Transbond XT	Maxillary	Right	Yes	162
	5	Transbond XT	Maxillary	Right	No	302
	6	Transbond XT	Maxillary	Right	Yes	162
	7	Transbond XT	Maxillary	Right	No	302
	8	Transbond XT	Maxillary	Right	No	302
	9	APC Plus	Maxillary	Left	No	302
	10	APC Plus	Maxillary	Left	No	302
	11	APC Plus	Maxillary	Left	No	302
	12	APC Plus	Maxillary	Left	No	302
	13	APC Plus	Maxillary	Left	Yes	279
	20	Transbond XT	Mandibular	Left	No	302
	21	Transbond XT	Mandibular	Left	No	302
	22	Transbond XT	Mandibular	Left	No	302
	23	Transbond XT	Mandibular	Left	No	302
	24	Transbond XT	Mandibular	Left	No	302
	25	APC Plus	Mandibular	Right	No	302
	26	APC Plus	Mandibular	Right	No	302
	27	APC Plus	Mandibular	Right	No	302
	28	APC Plus	Mandibular	Right	No	302

	29	APC Plus	Mandibular	Right	No	302
Z	4	Transbond XT	Maxillary	Right	No	272
	5	Transbond XT	Maxillary	Right	No	272
	6	Transbond XT	Maxillary	Right	No	272
	7	Transbond XT	Maxillary	Right	No	272
	8	Transbond XT	Maxillary	Right	No	272
	9	APC Plus	Maxillary	Left	No	272
	10	APC Plus	Maxillary	Left	Yes	245
	11	APC Plus	Maxillary	Left	No	272
	12	APC Plus	Maxillary	Left	No	272
	13	APC Plus	Maxillary	Left	No	272
	20	Transbond XT	Mandibular	Left	No	272
	21	Transbond XT	Mandibular	Left	No	272
	22	Transbond XT	Mandibular	Left	No	272
	23	Transbond XT	Mandibular	Left	No	272
	24	Transbond XT	Mandibular	Left	No	272
	25	APC Plus	Mandibular	Right	No	272
	26	APC Plus	Mandibular	Right	No	272
	27	APC Plus	Mandibular	Right	No	272
	28	APC Plus	Mandibular	Right	No	272
	29	APC Plus	Mandibular	Right	No	272
AA	4	Transbond XT	Maxillary	Right	No	258
	5	Transbond XT	Maxillary	Right	No	258
	6	Transbond XT	Maxillary	Right	No	258
	7	Transbond XT	Maxillary	Right	No	258
	8	Transbond XT	Maxillary	Right	No	258
	9	APC Plus	Maxillary	Left	No	258
	10	APC Plus	Maxillary	Left	No	258
	11	APC Plus	Maxillary	Left	No	258
	12	APC Plus	Maxillary	Left	No	258
	13	APC Plus	Maxillary	Left	No	258
	20	Transbond XT	Mandibular	Left	No	258
	21	Transbond XT	Mandibular	Left	No	258
	22	Transbond XT	Mandibular	Left	No	258
	23	Transbond XT	Mandibular	Left	No	258
	24	Transbond XT	Mandibular	Left	No	258
	25	APC Plus	Mandibular	Right	No	258
	26	APC Plus	Mandibular	Right	No	258
	27	APC Plus	Mandibular	Right	No	258
	28	APC Plus	Mandibular	Right	No	258
	29	APC Plus	Mandibular	Right	No	258
BB	4	Transbond XT	Maxillary	Right	No	254
	5	Transbond XT	Maxillary	Right	No	254
	6	Transbond XT	Maxillary	Right	No	254
	7	Transbond XT	Maxillary	Right	No	254
	8	Transbond XT	Maxillary	Right	No	254
	9	APC Plus	Maxillary	Left	No	254
	10	APC Plus	Maxillary	Left	No	254

	11	APC Plus	Maxillary	Left	No	254
	12	APC Plus	Maxillary	Left	No	254
	13	APC Plus	Maxillary	Left	No	254
	20	Transbond XT	Mandibular	Left	No	254
	21	Transbond XT	Mandibular	Left	No	254
	22	Transbond XT	Mandibular	Left	No	254
	23	Transbond XT	Mandibular	Left	No	254
	24	Transbond XT	Mandibular	Left	No	254
	25	APC Plus	Mandibular	Right	No	254
	26	APC Plus	Mandibular	Right	No	254
	27	APC Plus	Mandibular	Right	No	254
	28	APC Plus	Mandibular	Right	No	254
	29	APC Plus	Mandibular	Right	No	254
CC	4	Transbond XT	Maxillary	Right	No	218
	5	Transbond XT	Maxillary	Right	No	218
	6	Transbond XT	Maxillary	Right	No	218
	8	Transbond XT	Maxillary	Right	No	218
	9	APC Plus	Maxillary	Left	No	218
	11	APC Plus	Maxillary	Left	No	218
	12	APC Plus	Maxillary	Left	No	218
	13	APC Plus	Maxillary	Left	No	218
	20	Transbond XT	Mandibular	Left	No	218
	21	Transbond XT	Mandibular	Left	No	218
	22	Transbond XT	Mandibular	Left	No	218
	23	Transbond XT	Mandibular	Left	No	218
	25	APC Plus	Mandibular	Right	No	218
	26	APC Plus	Mandibular	Right	No	218
	27	APC Plus	Mandibular	Right	No	218
	28	APC Plus	Mandibular	Right	No	218
	29	APC Plus	Mandibular	Right	No	218
DD	4	Transbond XT	Maxillary	Right	No	272
	5	Transbond XT	Maxillary	Right	No	272
	6	Transbond XT	Maxillary	Right	No	272
	7	Transbond XT	Maxillary	Right	No	272
	8	Transbond XT	Maxillary	Right	No	272
	9	APC Plus	Maxillary	Left	No	272
	10	APC Plus	Maxillary	Left	No	272
	11	APC Plus	Maxillary	Left	No	272
	12	APC Plus	Maxillary	Left	No	272
	13	APC Plus	Maxillary	Left	No	272
	20	Transbond XT	Mandibular	Left	No	272
	21	Transbond XT	Mandibular	Left	No	272
	22	Transbond XT	Mandibular	Left	No	272
	23	Transbond XT	Mandibular	Left	No	272
	24	Transbond XT	Mandibular	Left	No	272
	25	APC Plus	Mandibular	Right	Yes	229
	26	APC Plus	Mandibular	Right	No	272
	27	APC Plus	Mandibular	Right	No	272

	28	APC Plus	Mandibular	Right	No	272
	29	APC Plus	Mandibular	Right	No	272
EE	4	Transbond XT	Maxillary	Right	No	166
	5	Transbond XT	Maxillary	Right	No	166
	6	Transbond XT	Maxillary	Right	No	166
	7	Transbond XT	Maxillary	Right	No	166
	8	Transbond XT	Maxillary	Right	No	166
	9	APC Plus	Maxillary	Left	No	166
	10	APC Plus	Maxillary	Left	Yes	27
	11	APC Plus	Maxillary	Left	No	166
	12	APC Plus	Maxillary	Left	No	166
	13	APC Plus	Maxillary	Left	No	166
	20	Transbond XT	Mandibular	Left	No	166
	21	Transbond XT	Mandibular	Left	No	166
	22	Transbond XT	Mandibular	Left	No	166
	23	Transbond XT	Mandibular	Left	No	166
	24	APC Plus	Mandibular	Right	No	166
	25	APC Plus	Mandibular	Right	No	166
	26	APC Plus	Mandibular	Right	No	166
	27	APC Plus	Mandibular	Right	No	166
	28	APC Plus	Mandibular	Right	No	166
	29	APC Plus	Mandibular	Right	No	166

APPENDIX H
***IN VIVO* STATISTICAL ANALYSIS RESULTS**

IN VIVO.

Censored brackets are those have not failed yet.

Uncensored brackets are those have failed.

Uncensored brackets:

*The following table gives the mean, standard deviation, min and max of survival time for each bonding agent.

<u>Bonding Agent</u>	<u>n</u>	<u>Mean</u>	<u>Std. dev</u>	<u>Median</u>	<u>Min</u>	<u>Max</u>
APC Plus	23	145.69	97.45	153.0	18.0	337.0
Transport XT	18	160.11	137.50	112.5	28.0	480.0

Censored brackets:

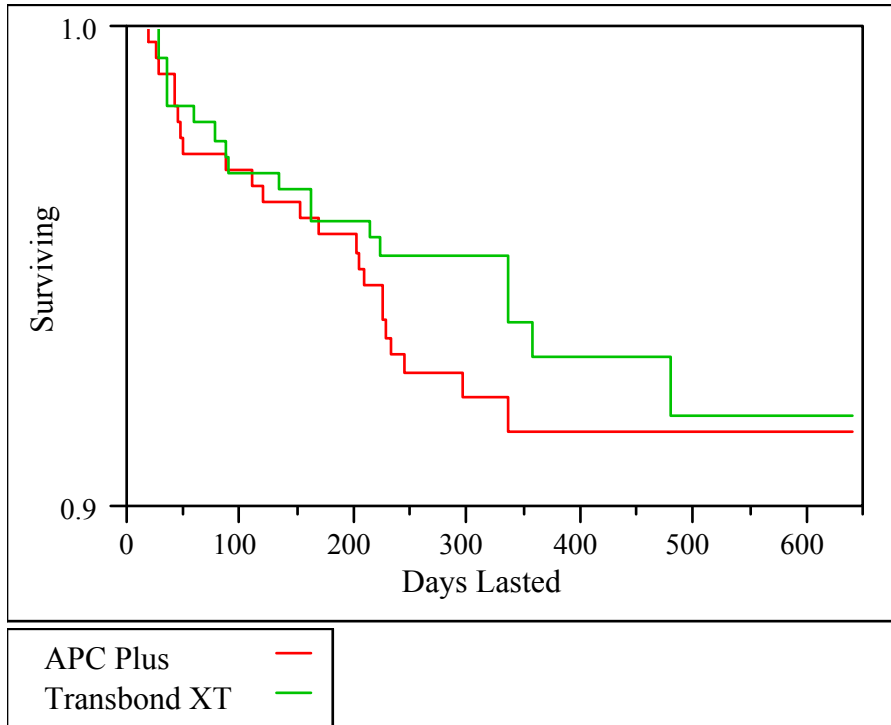
*The following table gives the mean, standard deviation, min and max of survival time for each bonding agent.

<u>Bonding Agent</u>	<u>n</u>	<u>Mean</u>	<u>Std. dev</u>	<u>Median</u>	<u>Min</u>	<u>Max</u>
APC Plus	276	373.19	129.23	315.0	166.0	641.0
Transport XT	278	373.53	127.85	315.0	166.0	641.0

Comparison of the bonding agents:

*The graph below gives the survival plot for the bonding agents.

Product-Limit Survival Fit Survival Plot



Summary

Group	N Failed	N Censored	Mean	Std Error
APC Plus	23	276	322.002	3.42017
Transbond XT	18	278	458.945	5.19442
Combined	41	554	455.92	3.80199

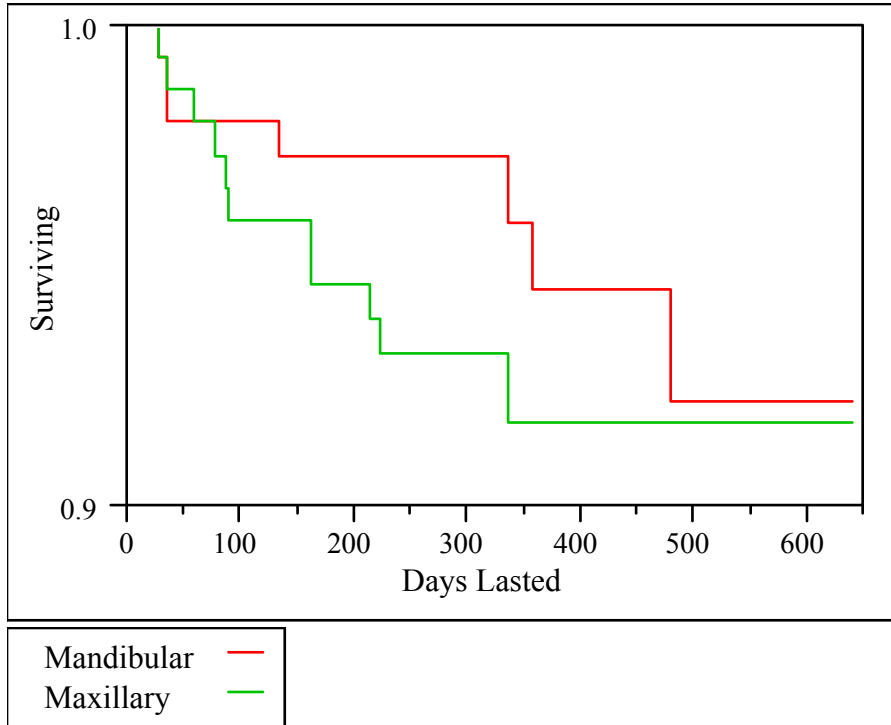
Tests Between Groups

Test	ChiSquare	DF	Prob>ChiSq
Log-Rank	0.6194	1	0.4313
Wilcoxon	0.9995	1	0.3174

*There is no significant difference between the survival distributions of APC and XT. Log-Rank test $P=0.43$, Wilcoxon test $P=0.31$. That is, brackets bonded with one agent do not last longer than brackets bonded with the other agent.

Comparison of upper and lower arch for Transbond XT brackets.

**Product-Limit Survival Fit
Survival Plot**



Summary

Group	N Failed	N Censored	Mean	Std Error
Mandibular	7	141	464.932	6.65734
Maxillary	11	137	321.822	5.08006
Combined	18	278	458.945	5.19442

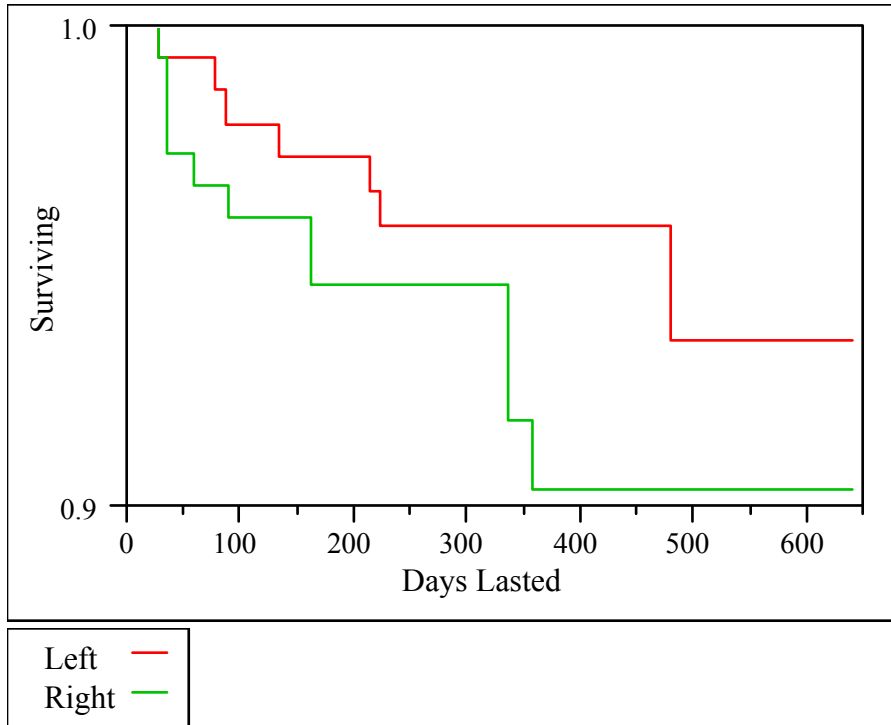
Tests Between Groups

Test	ChiSquare	DF	Prob>ChiSq
Log-Rank	1.0049	1	0.3161
Wilcoxon	1.9019	1	0.1679

*There is no significant difference between the survival distributions of Mandibular and Maxillary in Transbond XT brackets. Log-Rank test P=0.31, Wilcoxon test P=0.16.

Comparison of left and right sides of Transbond XT brackets.

Product-Limit Survival Fit Survival Plot



Summary

Group	N Failed	N Censored	Mean	Std Error
Left	7	140	465.449	6.39728
Right	11	138	343.154	5.5959
Combined	18	278	458.945	5.19442

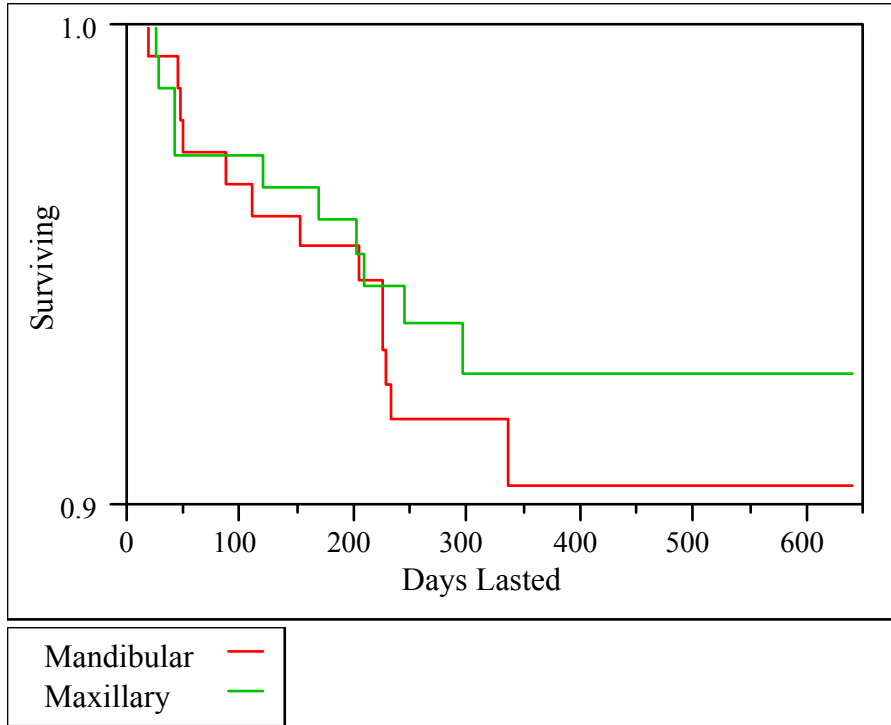
Tests Between Groups

Test	ChiSquare	DF	Prob>ChiSq
Log-Rank	0.9370	1	0.3330
Wilcoxon	0.7566	1	0.3844

*There is no significant difference between the survival distributions of left and right side of Transbond XT brackets. Log-Rank test P=0.33, Wilcoxon test P=0.38.

Comparison of upper and lower arch for APC brackets.

**Product-Limit Survival Fit
Survival Plot**



Summary

Group	N Failed	N Censored	Mean	Std Error
Mandibular	13	138	320.751	5.0413
Maxillary	10	138	286.174	4.07549
Combined	23	276	322.002	3.42017

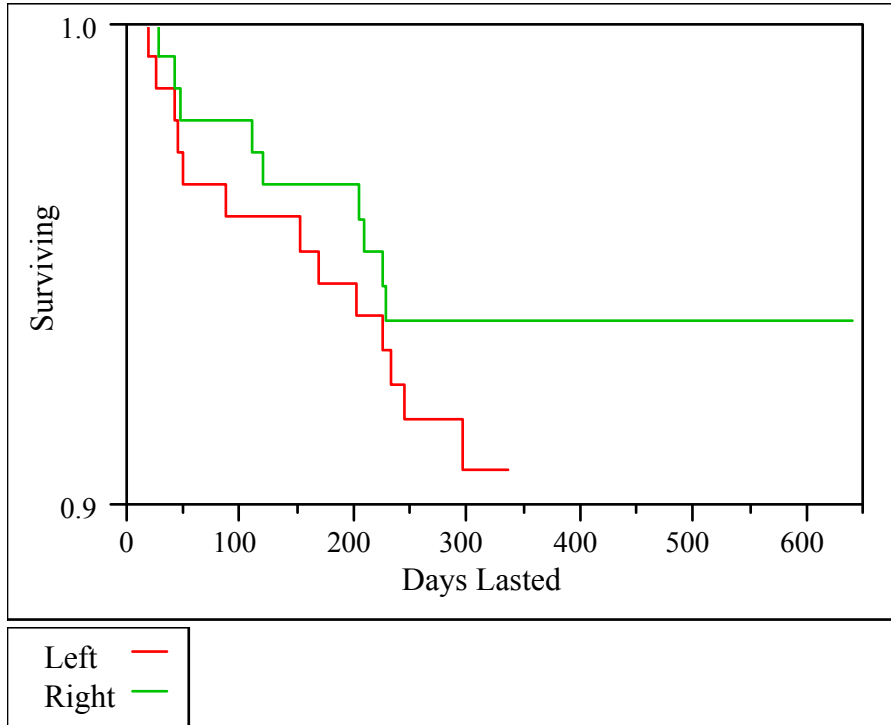
Tests Between Groups

Test	ChiSquare	DF	Prob>ChiSq
Log-Rank	0.3675	1	0.5444
Wilcoxon	0.3194	1	0.5719

*There is no significant difference between the survival distributions of Mandibular and Maxillary in APC Plus brackets. Log-Rank test P=0.54, Wilcoxon test P=0.57.

Comparison of left and right sides of APC Plus brackets.

**Product-Limit Survival Fit
Survival Plot**



Summary

Group	N Failed	N Censored	Mean	Std Error
Left	14	135	319.291	5.35747
Right	9	141	223.38	2.5516
Combined	23	276	322.002	3.42017

Tests Between Groups

Test	ChiSquare	DF	Prob>ChiSq
Log-Rank	1.1253	1	0.2888
Wilcoxon	0.8106	1	0.3679

*There is no significant difference between the survival distributions of left and right side of APC Plus brackets. Log-Rank test P=0.28, Wilcoxon test P=0.36.

CURRICULUM VITAE

Name: Meredith S. Parks
Date of Birth: December 20, 1975
Place of Birth: Newport News, Virginia

EDUCATION

August 1994 – May 1998 Wake Forest University
Winston-Salem, North Carolina
Bachelor of Science, Biology

August 1998 – May 2003 Virginia Commonwealth University
School of Dentistry
Richmond, Virginia
Doctorate of Dental Surgery

July 2003 – April 2006 WVU School of Dentistry
Department of Orthodontics
Morgantown, West Virginia
Master of Science

PROFESSIONAL MEMBERSHIPS

American Association of Orthodontists
American Dental Association