THE USE OF AN ANTISIALOGOGUE IN ORTHODONTIC BONDING PROCEDURES

by

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Abstract

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The goal of the present study was to evaluate the efficacy of an antisialogogue in conjunction with conventional methods for creating a dry environment within the oral cavity during orthodontic bonding procedures versus the use of conventional methods alone as measured by the rate of bond failure. Composite resins have become the material of choice for bonding brackets. However, the use of composite resins involves a series of technique-sensitive steps which must be carried out in a dry field. Conventional methods for creating a dry field within the oral cavity include use of cotton rolls, high vacuum evacuation, dry angles and retractors. Creating a dry field using these methods can be challenging and, in many instances, ineffective, especially when bonding posterior teeth. It was hypothesized that combining antisialogogues with the conventional methods of controlling saliva would result in an increased dry field within the oral cavity, reduced risk of saliva contamination and, therefore, fewer bracket failures. The study was conducted using the antisialogogue propantheline bromide (Probanthine®).

Participants were recruited from a single orthodontic practice. Each participant had the first half of their braces placed using only conventional methods for saliva control while the second half of their braces were placed using the antisialogogue in conjunction with the conventional methods. Each of the participants was monitored over a sixty day period to evaluate the number of debonded brackets that occurred during this time. There was no significant difference in the bond failure rate for brackets bonded using conventional methods alone and those bonded when an antisialogogue was used.

DEDICATION

To my parents whose love and encouragement gave me the ability to set my goals.

To my husband Chris for his understanding and support while achieving my goals and to my baby boy Zane, the joy of my life, who puts everything in my life in perspective.

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TABLE OF CONTENTS

Page

ABSTRACT....ii

DEDICATION....iv

ACKNOWLEDGMENTS....v

TABLE OF CONTENTS....vi

LIST OF FIGURES....viii

LIST OF TABLES....ix

INTRODUCTION....1

STATEMENT OF PROBLEM....4

REVIEW OF THE LITERATURE....6

METHODS AND MATERIALS....28

Sample Selection....28

Statistical Design....28

RESULTS....33

DISCUSSION....42

SUMMARY AND CONCLUSIONS....46

APPENDIX ONE: Tables 1 through 14....49

APPENDIX TWO: Informed Consent to Participate in Research....63

APPENDIX THREE: Health History Form.....66

REFERENCES.....67

LIST OF FIGURES

Figure		Page
1.	Experimental Group: Total Brackets Bonded vs. Failed	36
2.	Experimental Group: Bond Failures in Males vs. Females	37
3.	Experimental Group: Bond Failures in Anterior and Posterior	38
4.	Number of Brackets Bonded vs. Failed	39
5.	Baseline vs. Experimental: Gender Related Bonds/Failures	40
6.	Baseline vs. Experimental: Bonds/Failures Related to Location	41

LIST OF TABLES

Table		Page
1.	Experimental Group: Total Brackets Bonded vs. Total Bracket Failures	49
2.	Experimental Group (Using Antisialogogue): Total Brackets Bonded vs. Total Bracket Failures	50
3.	Experimental Group (No Antisialogogue): Total Brackets Bonded vs. Total Bracket Failures	51
4.	Experimental Group (Females): Total Brackets Bonded vs. Total Bracket Failures	52
5.	Experimental Group (Males): Total Brackets Bonded vs. Total Bracket Failures	53
6.	Experimental Group (Anterior): Total Brackets Bonded vs. Total Bracket Failures	54
7.	Experimental Group (Posterior): Total Brackets Bonded vs. Total Bracket Failures	55
8.	Experimental Group: Listed by Gender, Age and Days until First Debond	56
9.	Baseline Group: Total Brackets Bonded vs. Total Bracket Failures	57
10.	Baseline Group (Males): Total Brackets Bonded vs. Total Bracket Failures	58
11.	Baseline Group (Females): Total Brackets Bonded vs. Total Bracket Failures	59
12.	Baseline Group (Anterior): Total Brackets Bonded vs. Total Bracket Failures	60
13.	Baseline Group (Posterior): Total Brackets Bonded vs. Total Bracket Failures	61
14.	Comparison of Bond Failure Rates	62

INTRODUCTION

The goal of the present study was to evaluate the efficacy of an antisialogogue in conjunction with conventional methods for creating a dry environment within the oral cavity during orthodontic bonding procedures. This was compared to the use of conventional methods alone as measured by the rate of bracket failure. Direct bonding of orthodontic brackets is used by the majority of orthodontists today. It is well documented in the literature in both *in vivo* and *in vitro* studies that salivary contamination is a major factor causing orthodontic bond failures. The failures caused by salivary contamination are attributed to the salivary fluid plugging the micro porosities of the enamel. This moisture contamination of the micro porosities does not allow the adhesive to effectively bond to the tooth enamel. Efforts to create a dry field within the oral cavity using conventional methods, such as high vacuum suction and cotton rolls have proven to be challenging and not always effective. Even a minuscule amount of saliva can significantly weaken the bond strength. In an attempt to decrease the chances of salivary contamination, the use of a supplemental pharmaceutical agent in conjunction with these conventional methods has been recommended in the literature. The literature recommends administering an antisialogogue one-half hour prior to the bonding of brackets to reduce salivary flow and decrease the possibility of bracket failure. By reducing the amount of saliva in the oral cavity with the use of an antisialogogue, it was

hypothesized that a dry field within the mouth would be more readily attained and maintained during the technique-sensitive bonding procedure. As a result, there would be less salivary contamination of the bonding cement and therefore fewer bracket failures. However, there has never been a study conducted that shows that a dry field created by the use of an antisialogogue in conjunction with conventional methods is more effective in preventing salivary contamination than a dry field created by conventional methods alone. This information would be very valuable to practitioners as it is important to know the factors affecting the risk/benefit ratio when administering a systemic drug for enhanced bond success.

The challenge of this study was to create a scientifically sound study design that could fairly and accurately compare both methods of creating a dry field during bonding and examine how it relates to bond failure. This was difficult considering the many variations among individuals including quality of enamel and salivary flow, type of malocclusion not to mention practitioner skill and experience. For this reason, it was evident that the study group and the control group had to be within the same individual and bonding had to be performed by the same, experienced clinician for all participants in the study. As a result of these strict requirements, we bonded one-half of the brackets on individuals using conventional methods of creating a dry field and the remaining half with the use of an antisialogogue in conjunction with conventional methods in the same appointment. This design was the most effective in allowing comparison of the two methods of bonding, taking into consideration variations that may be found among individuals. One of the major reasons as to the importance of decreasing the rate of

bracket bond failure is that fewer bracket debonds leads to fewer bracket rebonds. This can potentially equate to faster treatment time. Decreasing the length of treatment time or at least not prolonging it has many benefits. Shorter treatment time has been reported to decrease the risk of enamel decalcification, lessen the chance of gingival disease and decrease root resorption.

STATEMENT OF THE PROBLEM

In the field of orthodontics, bonding of brackets to teeth is a very technique-sensitive procedure. Salivary contamination of the bracket adhesive and/or tooth enamel contributes to bond failure of the bracket. Bond failures can delay treatment time and create excess overhead expenditures by consuming unnecessary practitioner and staff time.

In an effort to reduce salivary contamination, many orthodontists use antisialogogues in conjunction with conventional methods for creating a dry field during bonding of brackets. The assumption is that a pharmaceutical agent that reduces salivary flow will help reduce salivary contamination and increase bonded bracket success. This appears to have been done on blind faith since, according to a thorough review of the literature, there are no scientific studies that indicate whether or not this assumption is valid. The study undertaken here is critical as it is important for practitioners to know whether or not use of a pharmaceutical agent is warranted when bonding brackets. Either a positive or a negative result of this study is valuable information for a practitioner. If the outcome is positive, and it is shown that antisialogogues can reduce bracket failure, then orthodontists can administer the drug with confidence knowing that treatment time and overhead expenses may be reduced. On the other hand, if the outcome is negative and it is shown that antisialogogues do not help reduce bracket failure, then orthodontists can discontinue administration of such drugs and eliminate any potential drug reaction or drug

related complications to the patient.

LITERATURE REVIEW

Direct bonding of brackets is currently used by the majority of orthodontists throughout the world. This type of bonding is a direct consequence of the pioneering work of Buonocore (1955) and Newman (1964). Newman incorporated the acid etch procedure developed by Buonocore for the bonding of orthodontic brackets to enamel surface. Modern orthodontic resins have been proven both experimentally and clinically to have adequate strength to withstand orthodontic tooth moving forces (Retief, 1974; Wiltshire 1994). Direct bonding of orthodontic brackets using composite resin cements requires attention to many details if successful bonding is to be achieved. Factors that affect bonding strength include adaptation of the bracket base to the tooth surface, bracket preparation, type of adhesive used in bonding (light cure vs chemical cure), condition of the enamel, tooth preparation, contamination or mechanical disturbances during placement of the bracket, microbial attack and water diffusion into resin cement once the bracket is cemented, forces of occlusion and practitioner experience.

A post-treatment evaluation of the direct bonding technique was done by Zachrisson, (1977). His study examined 705 bond attachments in forty-six children over an average treatment time of seventeen months. It was concluded that bond failures are probably attributable to four main factors:

1. moisture contamination (gingival fluid, saliva)

2. forces exceeding the bond strength (too heavy ligation, forces of mastication, and occlusion trauma)

3. inadequate adaptation of bracket to tooth surface (judged from an uneven or thick layer of adhesive on the contact surface of several loose brackets)

4. individual variation (hyper salivation, differences in enamel composition and response to etching).

The investigator also noted that bond failures decreased as practitioner experience in bonding increased. A study conducted by Fox et al., (1991) concluded that, in addition to the type of cement used in orthodontic bonding, other factors, such as the nature of enamel, bracket base, continuity of material under bracket and nature of the mix when a two component bonding system is used (i.e., accuracy of composite ratio) should also be considered as important factors in the bonding procedure. In a review of direct orthodontic bonding by Reynolds et al., (1977) three factors were considered important in creating a successful bond; tooth surface, adhesive and bracket backing. In analyzing bond failures the authors concluded that if the tooth and attachment surface have been properly prepared, failures in direct bonding are attributable to poor moisture control or forces that exceed the bond strength acting on the attachment.

Adaptation of Bracket to Tooth Surface

There are several factors that influence the adaptation of a bracket to the tooth surface. One of these factors which relates to posterior teeth is the nonuniformity of resin thickness beneath the bracket due to buccal grooves. An *in vitro* study conducted by Knoll et al., (1984) compared shear bond strengths between orthodontic brackets bonded to anterior teeth and that of posterior teeth. They found a higher bond failure rate among

brackets bonded on posterior teeth. They concluded that the higher failure rate occurred due to thick adhesive joints in the buccal groove area which weakened bond strengths due to the increased polymerization shrinkage that occurs in thicker areas of resin. These findings are in agreement with a study conducted by Evans and Powers, (1985) which concluded that a minimal film thickness on the base of the bracket is important since complete polymerization is unlikely to occur in thicker films. In a study that examined shear strengths of various types of bracket bases (Lopez 1980) sixteen different commercially available metal bracket attachment bases were examined. The study concluded that the mesh size of the bracket base as well as bracket design significantly influence the adaptability of the bracket to the tooth surface which in turn influences the retentive properties of the bracket. It is also noted in the literature that during the placement of the bracket on the tooth, the bracket should be pressed firmly onto the tooth surface to ensure a thin layer of adhesive for the above mentioned reasons (Zachrisson 1977).

Bracket Preparation

Prior to bonding, several steps should be taken to improve shear bond strength. The backing of the bracket must be kept perfectly clean in order to insure proper adhesion of the composite resin to the wire mesh of the bracket (Reynolds 1975). Reynolds (1975) also described various methods for cleaning the bracket bases. These methods included sandblasting or electrolytic etching of the bracket followed by an alcohol wash and oven drying. Newman et al., (1995) showed that the shear bond strengths of metal brackets was increased by sandblasting the metal bonded surface. This study claimed that

sandblasting improved shear bond strength not only by cleansing surface contaminants on the bracket base, but also by creating micro-fine undercuts which increased the surface area where the composite resin could adhere. Another method for increasing shear bond strength as it relates to bracket preparation is the use of adhesion promoters also known as silanes (polymellitic glycerol dimethacrylate - PMGPM). Several coats of silane are placed on the etched enamel surface as well as to the metal backing of the bracket to be bonded. Both enamel and bracket surfaces are allowed to air dry for five seconds. A study conducted by Newman et al., (1995) using this silating technique on sandblasted brackets noted increased shear bond strengths when compared to sandblasting alone. This study advocated using this technique on teeth that may need increased bond strength, such as in cases of fluoroses, hypocalcification or when bonding posterior teeth. It is well documented that premolars and molars may require increased bond strength due to the higher forces of occlusion in posterior segments and to the difficulty in isolation from salivary contamination during bond placement (Zachrisson, 1977; Newman, 1978; Lovius et al., 1987). When preparing brackets for bonding, care should also be taken to compact the adhesive thoroughly into the mesh backing. Air entrapment can result from haphazard adhesive placement which may lead to decreased shear bond strengths (Bradburn and Pender 1992).

Type of Adhesive

Many types of bonding agents can be used for direct bonding of orthodontic brackets. The two basic choices of bonding systems include a light activated bonding agent and a chemically activated bonding agent. The use of visible light cured materials for

orthodontic bonding was first described by Tavas et al., (1979). During the direct bonding technique, the adhesive material is cured by transillumination through tooth structure (Tavas 1980; Tavas and Watts 1984). Laboratory investigations carried out by Tavas et al., (1984) showed that light-activated adhesives have similar shear bond strengths to that of chemically cured adhesives. Also, a study examined residual debris on the enamel surface after bracket removal and showed that light cure material tends to leave less residual debris than chemically cured material (O'Brien 1988). A clinical trial conducted by Lovius et al., (1987) compared bond strengths of light cured material to that of chemically cured material and it was found that the failure rate for chemically cured material was 16% compared to 23% for the light cured material over an eighteen month period. Both materials showed a higher failure rate for posterior teeth than for anterior teeth. Another clinical trial conducted by O'Brien et al., (1988), compared the clinical performance of a visible-light cured material with that of a chemically cured material over a six month period. Their findings were different than earlier reports by Lovius et al., in that the light cured material had a slightly lower failure rate (4.7%) than the chemically cured material (6.0%). These failure rates were also significantly lower for both materials than those found in the study by Lovius et al., (1988). Advantages of light cure adhesives compared to chemical cure adhesives as summarized in this study included maximum polymerization of the adhesive after exposure to the visible light source as opposed to gradual cure with chemically cured materials. This allows immediate placement of arch wires. Earlier studies by Mizrahi and Smith (1969) recommended that no stress be applied to the cement bond for at least thirty minutes to allow full tensile strength of the cement to

develop. Another advantage of the light cure resin mentioned in this study is the ability to have more time to properly position the bracket on the tooth surface. These investigators also found the handling properties of the visible light-cured materials to be superior to the chemically cured materials. Light-cured materials are more viscous which prevents drifting of the brackets once they are placed on the enamel surface. Keizer et al., (1976) in their study of direct bonding of orthodontic brackets, emphasized the importance of the setting process of the adhesive. A very slow setting time has increased risk of contamination which can result in incomplete setting (polymerization) and potential premature fracture of the bracket/adhesive bond. On the other hand, a very fast setting adhesive may not allow enough time for the adhesive to flow into the etched enamel therefore making the adaptation to the tooth surface incomplete resulting in weaker shear bond strength (Gwinnett et al., 1967). The fact that light cure material is cured on demand is a definite advantage over chemically cured materials that have fixed rate curing times. Keizer et al., (1976) also noted the importance of proper mixing ratios when a two paste chemically cured system is used. The ratio of the two components of the adhesive system will influence the setting time. This is a disadvantage since it requires the operator to correctly portion the materials manually. Light cure systems on the other hand are typically one paste systems that do not require mixing of two components. According to a laboratory evaluation done by Delport and Grabler, (1988) one-paste systems have less waste, debond easier and have a longer working time when compared to two paste systems. One factor influencing the success of light cured materials is the amount of penetration of the light source. The depth of polymerization and degree of hardness of

light cure composite resins is influenced by the amount of exposure time to the visible light source (Baharav et al., 1988). This study by Baharav et al., showed that resin can be polymerized through one millimeter of enamel and that the composite resin nearer the light source undergoes more complete polymerization. This same study also concluded that most of the polymerization is completed within the first ten seconds of light exposure and that increased exposure time results in greater depth of polymerization up to a certain point. Another factor influencing shear bond strength as it relates to the type of adhesive used is the particle size of the filler in the resin (Buzzitta et al., 1982). Buzzitta et al., conducted an *in vitro* study in which three types of direct bonding cements (unfilled, medium filled & highly filled) with three types of brackets (polycarbonate, stainless steel, and ceramic) were examined. They found that unfilled acrylic cement gives the highest bond strength value for both polycarbonate (plastic) and ceramic brackets while the highly filled diacrylate cement gives highest bond strength values for stainless steel brackets. Another choice of adhesives for direct bonding of orthodontic brackets is glass ionomer cement. Glass ionomer cements were first introduced by Wilson and Kent, (1972) and are commonly used in general dentistry as cavity liners bonding to both dentin and enamel without etching or drying. An advantage of glass ionomer cements over composite resins is that they have the ability to not only release fluoride but also to absorb fluoride from fluoridated tooth paste acting as a rechargeable slow release fluoridation device (Silverman et al., 1995). This may help decrease the chance of demineralization around brackets. Another advantage is that glass ionomer cements form a physiochemical bond to enamel as opposed to a mechanical interlocking bond, therefore eliminating the need for

acid etching of enamel. The newer glass ionomers which are resin reinforced (80% glass polyalkenoate cement and 20% light cured resin) tolerate the presence of moisture on the enamel surface during the curing process (Fricker 1994). A twelve month clinical trial conducted by Fricker (1994) compared light activated, resin reinforced glass ionomer cement to composite resin bonding adhesives. His study showed no significant differences in failure rates of directly bonded orthodontic brackets cemented with light cure resin reinforced glass ionomer (3.3%) compared with composite resin (1.6%). Because no statistical failure rate was found in this study, it was concluded that this type of glass ionomer was a satisfactory adhesive for direct bonding of orthodontic brackets. A study conducted by Silverman et al. (1995) had similar results to those of Fricker (1994). One hundred fifty full arch cases were bonded with resin reinforced glass ionomer from first molar to first molar and observed during an eight month period. They reported a 96.8% success rate, they noted that bracket failures were related to occlusal interferences, diet and bonding technique but only failures due to occlusal interferences and diet were counted against the "success" rate. Had bracket failure from all causes been included, the success rate would be lower. The results of the aforementioned studies are not in agreement with a study conducted by Wiltshire (1994). Wiltshire, examined the shear bond strengths of glass ionomer cements on etched and non-etched enamel surfaces as compared to composite resin cements. The results of his study clearly showed that the composite resins have a significantly higher bond strength than resin reinforced glass ionomer cement. Based on this result, continued use of composite bonding resins was advocated instead of glass ionomer cements. These findings are in agreement with Cook

(1988) who compared the *in vitro* bond strength of glass ionomer cement to that of a composite resin. His results indicated that the bond strength of glass ionomer cement was inferior to that of composite resin. Although there are differences in opinion regarding the adequate bond strength of an orthodontic bonding material, it has been suggested that the bond strength of glass ionomer cements may be adequate for orthodontic bracket bonding (Compton et al. 1992).

Condition of the Enamel

The morphology of the enamel plays an important role in the success of orthodontic bonding. Sheykholeslam and Brandt (1977) wrote:

> "Morphologically, enamel consists of microscopic units called enamel prisms. The greater mass of enamel is made of these prisms, except for a few microns on the outer surface which is frequently "prismless".

Each prism contains many small units called hydroxyapatite crystals and in cross-section they resemble "key-holes". These crystals, which are dissolved during the acid etching process leave behind "resin projections". In a comparison of prismless and prismatic enamel following etching by Gwinnet, (1973) a significant difference in topography existed between the two types of enamel layers. Gwinnett, found that the length of resin projections in the prismless layer of enamel after etching was significantly shorter than those of the prismatic enamel when viewed by scanning electron microscope. He describes the orientation of the crystals within the prismless layer to be unidirectional and dense in arrangement. This arrangement is said to be responsible for the uniform dissolution of crystals during the acid etch procedure, limiting the amount of porosity created in the enamel. Because of the shorter resin projections and limited porosity,

Gwinnett, describes resin penetration of the prismless enamel during the bonding process as "limited". Ripa et al., (1966) examined 128 teeth at various ages and found that 100% of deciduous teeth had a prismless layer (erupted and unerupted) and 70% of the permanent teeth had a prismless layer. The groups of teeth were not separated in anterior or posterior in this particular study. In a study by Sheykholeslam and Buonocore (1972), the degree of resin penetration on the enamel surface of older permanent and deciduous teeth was examined after various etching times via scanning electron microscope. Their results showed significantly greater amount of resin tag lengths in the older enamel (20-50 years old) when compared to the deciduous teeth. They concluded that the relative absence of tags in the deciduous teeth after etching resulted in loss of mechanical retention which adversely affects bonding for these teeth. They recommended the removal of the prismless layer followed by acid etching in order to produce resin penetration into enamel with formation of resin tags similar to that of prismatic enamel. Sheen et al. (1993) compared bond strengths of younger and older permanent teeth with varying etching times. Their results showed that older permanent teeth (48-69 years old) had a stronger bond than younger permanent teeth (9-16 years old) with either a fifteen or sixty second etching time. Their results also showed that the shear bond strength of older teeth was the same with either fifteen or sixty seconds etching time. The same was found for young permanent teeth indicating that prolonged etch times may not enhance bond strength of these teeth. Also indicated in this study is that prolonged etching time dissolves the prismless layer which should increase the retention of resins according to previous studies (Gwinnett 1973). However, this was not the case in the study by Der Horng et al., (1993).

As mentioned, the young permanent teeth had the same bond strength for short (fifteen seconds) and long (sixty seconds) etching times. This indicates that the prismless layer on the enamel surface of younger permanent teeth may not influence retention of bonded resins. This study is in agreement with Wang and Lu (1991) who studied bond strength on young permanent teeth with various etch times. The results of their study indicated that there was no statistical differences in the tensile bond strength among the etching times of fifteen, thirty, sixty or ninety seconds. There was a significant difference in the 120 second etch time group which showed the lowest tensile bond strength. This indicates that removing the prismless layer does not necessarily increase bond strength leading to the conclusion that the prismless enamel may not influence retention. Wang and Lu (1991) offer an explanation for differences in the literature regarding retention of the prismless enamel layer. They explained that previous studies, such as that by Sheykholeslam and Buonocore (1972) judged quality of mechanical retention by examining surface irregularities with use of the scanning electron microscope. The electron beam used with this microscope cannot penetrate deeply into the narrow depressions in the enamel; hence surface irregularities cannot indicate magnitude of bond strength.

Another way in which enamel morphology may be influenced is by external bleaching of teeth for cosmetic purposes. A study conducted by Titley et al. (1988) attempted to determine if bleaching teeth with 35% hydrogen peroxide would effect the adhesion of commonly used composite resin bonding systems. They immersed bovine teeth in 35% hydrogen peroxide for sixty minutes. The teeth were rinsed with water and bonded with composite resin to preflattened labial surfaces. The results indicated a

significant reduction in bond strength when compared to a control group that was not bleached. Examination of the bond failures under scanning electron microscope indicated that the reduction in bond strength resulted principally from the inability of the bonding resin to adhere properly to the etched enamel surface. A study conducted by Miles et al. (1994) examined the effects of carbamide peroxide on the tensile bond strength of orthodontic brackets. They concluded that:

1. Use of carbamide peroxide bleaching immediately before bonding significantly reduces bond strength
2. Immersion of bleached teeth in water for one week prior to bonding results in a return of bond strength to that of the non-bleached control group.

They postulated that water immersion most likely eliminates the residual bleaching agent which would negatively affect the bonding process. From this result they hypothesized that saliva may have a similar action on bleached teeth, suggesting that bleaching should be ceased one week prior to orthodontic bonding to ensure adequate bonding strengths. Findings by Bishara et al. (1993) do not support the aforementioned studies. In their study, human molar and premolar teeth were subjected to 10% carbamide peroxide for one week. The bleaching gel was changed every eight hours in an effort to approximate instructions usually given to patients undergoing bleaching. Their results showed no significant difference in mean debonding strength of bleached teeth when compared to that of non-bleached teeth.

Tooth Preparation

Preparation of the tooth prior to orthodontic bonding plays an important role in the success of the bond. By implementing a proper technique with careful cleaning,

etching and drying of the teeth prior to placement of the bonding adhesive, relatively low failure rate can be expected (Zachrisson 1977). A study by Brannstrom et al. (1978) evaluated various methods of enamel preparation. They compared differences between liquid versus gel forms of etchant, mechanical versus chemical cleaning of enamel prior to etching and the effect of fluoride treatment prior to orthodontic bonding procedures. The evaluation of each of the treatments was done with the use of scanning electron microscope photographs. The quality of retention among the various treatment groups was not determined. However, the degree of surface irregularities on the enamel surface was evaluated. The results of this study were summarized as follows:

1. There was no difference in the appearance of the enamel when acid etched either with a liquid or a gel.

2. There was no significant difference in the appearance of the enamel mechanically cleaned with a diamond bur versus the enamel cleaned with a medium aluminum oxide disc.

3. There was no difference in the appearance of the enamel cleaned with three different chemical pretreatment solutions prior to etching.

4. There was no difference in the appearance of the etched enamel after various modes of fluoride treatment prior to etching.

Gerbo et al. (1992) examined the pretreatment cleansing of enamel using an air-powder polisher versus cleansing with a standard rubber cup and flour of pumice. After the teeth were cleaned using either of the two techniques, the teeth were etched and bonded with orthodontic brackets. Tensile strength was tested for both groups. Results showed that there was no statistical difference in the tensile bond strength between the teeth cleaned with the air polisher and those cleaned with the standard rubber cup with flour of pumice.

Contamination

Direct bonding of orthodontic brackets using a composite resin cement requires that the orthodontist creates and maintains a virtually dry field within the oral cavity to prevent saliva contamination of the adhesive. Saliva contamination is considered to be a major factor influencing bond failure (Dijkman et al. (1972); Hormati et al. (1980); O'Brien et al. (1988); Pender et al. (1988); Silverman et al. (1972). Hormati et al. (1980) examined the effects of moisture contamination on shear bond strength using freshly extracted permanent teeth. The labial surfaces of all teeth were flattened, pumiced and etched for sixty seconds. After initial preparation, they compared the following experimental conditions:

1. control group which had no moisture contamination
2. resin applied directly to wet surface contaminated with saliva for sixty seconds
3. resin applied after saliva contamination surface was dried with air for fifteen seconds
4. saliva contaminated surface washed with water for fifteen seconds and dried with air for fifteen seconds
5. same as group four but re-etched for ten seconds
6. same as group five but re-etched for sixty seconds.

The results showed that composite resins applied directly to wet, saliva contaminated surface had significantly less shear bond strength than any of the other resins. When this group (group two) was viewed under scanning electron microscope, it was evident that most of the porosities created in the enamel as a result of etching were plugged by moisture. It was concluded that moisture made the depth of the resin tags insufficient for

adequate retention. Furthermore, etched enamel samples that were only dried with air after saliva contamination showed significantly less shear bond strength than etched enamel samples that were re-etched after contamination. Based on these results, the following conclusions were made regarding proper clinical technique as it relates to bonding:

1. avoid saliva contamination of etched enamel surface by use of a rubber dam

2. contaminated surfaces should be re-etched for ten seconds, rewashed and redried prior to bonding.

In a review of direct bonding by Reynolds, (1975) moisture contamination was the leading cause of bond failures and should be avoided by implementing the following:

1. all teeth should be dried with hot dry air from a filtered dental unit or hair dryer since oil and water contamination via the air hose tubing may compromise tooth preparation (Sheykholeslam and Brandt, 1977)

2. high and low volume suction should be used as needed

3. drying agents can be applied

4. a rubber dam may be used where possible

5. antisialogogues can be used to reduce salivary flow

Mechanical Disturbance

There are two types of mechanical disturbances that can potentially effect the bond strength of orthodontic brackets. These are disturbance of the prism tags on the surface of the enamel during the etching process and mobilization of the bracket by the operator while cement is still polymerizing. In regard to mechanical disturbance of the enamel rods, it is documented in the literature that freshly etched enamel surface is very fragile

(Dennison and Craig, 1978). In a report on acid etching procedures by Gwinnett (1978) for the American Dental Association Council on Dental Materials and Devices, moisture contamination and rubbing (as opposed to dabbing) of the enamel during the etching process were condemned. Hormati et al. (1980) studied the effects of contamination and mechanical disturbance on acid etched enamel. In order to evaluate the effect of mechanical disturbance of the prism tags, the shear bond strengths of enamel that was etched with a dabbing technique was compared to that of enamel that was etched by rubbing with a cotton pledget. Their results showed no significant difference in shear bond strength between the groups. However, scanning electron microscope photographs showed observable differences in the etched patterns. With respect to mobilization of the bracket, care must be taken by the operator not to mechanically disturb bracket position during the polymerization process of the cement. This type of disturbance can lead to bond failure as indicated in a study by Silverman et al. (1995). They attributed 1.4% of the overall 4.6% bond failures to mechanical disturbance of the bracket by the operator during polymerization of the adhesive.

Microbial Attack

A study by Matasa (1995) indicated that composites used as orthodontic direct bonding adhesives can host and nurture a variety of aerobic and anaerobic microorganisms. This study examined batches of used brackets that were sent in by practitioners for resale or reconditioning. On average, at least one in five of the lots received had some brackets exhibiting adhesive decay. It was concluded that microbial attack of adhesive should be considered as a cause for bracket debonds.

Water Diffusion

Newman et al. (1968) evaluated the effect of water immersion on bond strength. It was shown that water immersion substantially reduces shear bond strength of orthodontic brackets. The results of the study concluded that the average strengths of the adhesive bond was considered to be acceptable and able to form bonds at six and twelve month time intervals. This result is similar to that of Meng et al. (1995) who also examined orthodontic resin under water immersion at various time intervals. Their results showed that the greatest loss in bond strength occurs initially followed by a period of relative stabilization and then a weaker reduction after twenty-four weeks. It was concluded that debonding of orthodontic composite resin may gradually and automatically occur under water immersion due to characteristics of the composite resin.

Antisialogogue

Experience shows that the use of conventional techniques to achieve and maintain a dry field within the mouth are not always adequate for bonding procedures. The percentage of bond failures reported in the literature ranges from 7-20% in clinical trials (Mizrahi and Smith 1971). In an attempt to create a dry field, some orthodontists have advocated the use of a rubber dam during the bonding procedure (Silverman et al. 1972; Newman 1973). This of course is impractical as rubber dams are often a hindrance and more practical techniques need to be explored and developed. The use of pharmaceutical agents to dry saliva during bonding procedures has been recommended as a more certain method of saliva control. A pharmaceutical agent that chemically blocks parasympathetic activation of salivary glands is called an antisialogogue. Three of the most popular

antisialogogues used in dentistry are (Banthine®) methantheline bromide, (Probanthine®) propantheline bromide and (Sal-tropine®) atropine sulfate. The use of the antisialogogues Banthine® or Probanthine® have been advocated for use during orthodontic bonding procedures. The antisialogogue, Sal-tropine® is the latest to be introduced to the market and no orthodontic related trials have been published to date. Silverman et al. (1975) suggested oral dosages of 100-150mg of Banthine® thirty minutes prior to bonding for effective saliva control however, Banthine® is no longer manufactured. White (1975) and Sapkos (1984) recommended 30mg of Probanthine® one half hour prior to the bonding of orthodontic brackets. Probanthine® is currently the most widely used pharmaceutical agent used in orthodontic offices. At this time, no scientific clinical trial has been conducted to determine if the use of antisialogogues in orthodontic bonding leads to fewer bracket bond failures. The impact of antisialogogues in reducing saliva contamination and therefore reducing bracket bond failure is unknown. The present study was designed to determine if the use of antisialogogues in conjunction with conventional methods of saliva control is more effective than the use of conventional dry field methods alone with regard to bracket failure.

Sal-tropine® and Probanthine® are all synthetic cholinergic blocking drugs, also known as antimuscarinic drugs. Cholinergic blocking drugs act on the heart, eyes, smooth muscle, glandular secretion, and central nervous system. Atropine and scopolamine are classic examples of cholinergic blocking drugs. They are competitive antagonists of postganglionic (muscarinic) receptors located at the afferent junction of the parasympathetic system. Atropine and scopolamine differ quantitatively in antimuscarinic

action. Scopolamine (use to prevent motion sickness), has a strong effect on the iris, ciliary body, and certain secretory glands, such as salivary, bronchial, and sweat glands. Atropine is more effective on the heart, intestines, and bronchial muscles, and has prolonged duration of action. Salivary secretion is more sensitive to scopolamine. However, scopolamine depresses the central nervous system in clinical dosages and therefore Atropine is usually preferred over scopolamine. Scopolamine also has an anamnestic effect that does not occur with atropine. Although scopolamine produces sedation and amnesia at therapeutic levels, higher doses cause excitement, delirium, difficulty in fixing attention, euphoria, fatigue, motor incoordination, disorientation, and auditory and visual hallucination (Goodman and Gilman 1975).

Atropine-like drugs, such as Sal-tropine® can dilate the pupil of the eye (mydriasis) and paralyze accommodation (cycloplegia). Atropine-like drugs, when administered systemically, have little influence on intraocular pressure, except in patients with narrow angle glaucoma, in which case pressure can occasionally rise to dangerous levels (Goodman and Gilman, 1975).

Probanthine® differs from atropine in that it is two to five times more potent in antimuscarinic activity and about 1.5 times more potent as a ganglionic blocking agent. Its action is more prolonged than that of atropine with effective therapeutic dose lasting a maximum of six hours. Because Probanthine® is a more potent antimuscarinic drug (nerve to target), smaller doses can be utilized with less ganglionic blocking (Goodman and Gilman, 1975). For the aforementioned reasons, Probanthine® is the drug of choice for the present study.

In most cases, Sal-tropine® and Probanthine® are administered orally. Unfortunately, results of oral administration of these drugs can be unpredictable. Oral medication effectiveness is often dependent upon many factors that are beyond the clinician's control, such as the absorptive ability of the patient's intestinal tract, the presence or absence of food in the stomach as well as the psychological status of the patient. White (1975) suggested that a more certain and effective way to deliver antisialogogues to orthodontic patients is by intraoral, submucosal injections. Although submucosal injections can target localized areas involving minor salivary glands, the large salivary glands, such as the sublingual and parotid are not effected. Salivary secretions from these major glands can lead to pooling of saliva in the posterior area of the oral cavity, especially around the lower first and second molars rendering submucosal injections useless. Consequently, oral dosing is the method of choice in this study and is the method of choice within the orthodontic community.

In conclusion, the pharmaceutical effects of antisialogogues have been thoroughly investigated and established. However, the very important question as to whether the use of antisialogogues can significantly decrease the number of bracket failures has not been established.

Practical Significance

The practical significance of the present study was to determine if the number of orthodontic bond failures can be significantly reduced. By reducing the number of bond failures, treatment time can be decreased since for every appointment that a bracket must be rebonded, treatment does not progress. The reason that treatment does not progress is

because the orthodontist can never exactly rebond the bracket to its original position. As a result of this, a smaller diameter wire must be placed in order to easily engage it into the newly positioned bracket slot. After the bracket has been rebonded, it takes approximately four weeks or one appointment for the tooth to be re-aligned perfectly within the wire once again. Therefore, further progression of the treatment with larger diameter wires necessary for completing treatment is delayed.

By reducing the duration of treatment or by not prolonging treatment, the patient will be at less risk for several side effects that can be related to long term wear of orthodontic appliances such as decreased chance of demineralization of the enamel due to plaque accumulation, decreased risk of root resorption or shortening of the roots, and decreased risk of gingivitis associated with plaque accumulation. In order to evaluate the efficacy of the use of an antisialogogue during orthodontic bonding and subsequent bond failure, the participants had one-half of their braces placed without the drug and one-half placed after administration of the drug. The number of bond failures was recorded for both groups over a two month period.

Theoretical Significance

The antisialogogue ProBanthine® is the pharmaceutical agent of choice in the present study due to its ability to block a higher ratio of muscarinic receptors (nerve to target) to ganglionic receptors (nerve to nerve). By blocking activation of muscarinic receptor sites as opposed to ganglionic sites, the drug is more concentrated at the desired target site needed. The theory is that if saliva production can be blocked, it will be easier to maintain a dry environment during orthodontic bonding procedures. If a dry mouth can

be maintained, there will be less chance of salivary contamination of the bonding cement and, therefore, fewer bond failures.

METHODS AND MATERIALS

An experimental group of twenty-five participants was selected during a four month period from the private orthodontic practice of Dr. Donald Gustovich, Bellvue, Ohio. Dr. Gustovich's office was chosen because he had experience using the antisialogogue for orthodontic bonding procedures and he bonded all teeth including first and second molars. The participants in the experimental group were selected based on the following criteria:

1. all of the patients were to undergo full-bonded orthodontic treatment with brackets on all posterior and anterior teeth for a minimum of three months during the study period
2. they did not have any medical problems as outlined in the participant consent form
3. they did not have crowns, composite or amalgam restorations that interfered with bracket placement
4. patients would not be pregnant or nursing
5. they could not be incarcerated and
6. they had to have full permanent dentition including first and preferably second molars present.

The experimental group was comprised of patients who met these criteria and were gathered consecutively until twenty-five participants agreed to participate in the study. In addition to the experimental group, a baseline group, also comprised of patients who met the inclusion criteria, was selected retrospectively to determine a general overall bond

failure for Dr. Gustovich's office. Subjects in the baseline group were also selected consecutively and consisted of a total of twenty-three individuals. Baseline subjects had braces bonded prior to the recruitment of the experimental group and were examined for bond failures retrospectively. The dates and locations of all bond failures are meticulously recorded at Dr. Gustovich's office which allowed simple collection of this data. The bond failures of the baseline group were compared to that of the experimental study. The principal investigator met with the patient or guardian and discussed the risks and benefits of the study. A detailed medical history was obtained at the time. Once the patient or guardian signed the consent form, the patient was scheduled for a one and a half hour bracket placement appointment. Brackets were placed on the teeth in two steps. Each patient was seated in the dental chair, and all teeth to be bonded were pumiced with pumice. Cheek retractors (Spand/eez® by Glenroe Technologies, Bradenton, FL) were placed and moisture removed by high volume suction. The teeth were etched for sixty seconds with 3M Unitek Transbond Gel Etch® and then rinsed with tap water for ten seconds per tooth. The teeth were then dried for ten seconds per tooth using an air syringe and sealed with Single Bond®, by 3M Unitek. The mouth was divided into four quadrants (upper left, upper right, lower left and lower right from central incisor to last erupted molar). Two quadrants were prepared and bonded in each of the two steps. The quadrants chosen for each step were alternated between upper left, lower right and upper right, lower left sides. In the first step, one half of the brackets were placed on the teeth in two quadrants (e.g., upper left and lower right) without the use of the antisialogogue and in the second step the remaining brackets were placed on the teeth in the opposite two

quadrants (e.g., upper right and lower left) with the use of the antisialogogue. The bracket placement always began in one of the lower quadrants, and the orthodontist alternated the starting location between the lower left and lower right quadrant for each subsequent subject. There was a half hour wait between the first and second steps as it takes approximately one-half hour for the antisialogogue to be absorbed into the bloodstream.

After initial bonding of the two quadrants, the participant was orally administered two, 15 mg tablets of ProBanthine® (provided their weight was within the range of forty-five and two hundred fifty pounds) and was seated in the waiting room. During this time the patient viewed a twenty minute video on oral hygiene instructions and non- acceptable foods to eat while wearing orthodontic appliances. One half hour after the administration of the drug, the patient was seated and prepared for the second stage of bonding.

Initial arch wires (0.016 Nickel Titanium, 3M Unitek®) were placed and ligated using A-1 AlastiK® ligatures (manufactured by 3M Unitek®, Monrovia, CA) after all appliances were bonded. After administration of the drug the patient was monitored for one hour for symptoms of overdose, such as curare-like action (i.e., neuromuscular blockade leading to weakness and possible paralysis), CNS disturbances, such as restlessness or psychotic behavior and flushing. If any of the above symptoms had occurred, the following measures would have been taken:

1. immediate induction of emesis using ipecac syrup or stomach lavage
2. injection of 0.5-2 mg physostigmine intravenously up to 5 mg
3. monitoring and managing of vital signs.

The orthodontic appliances used in this study were manufactured by A-Company®, San Diego, CA, 0.022 slot, Roth prescription and bonded to the teeth using Transbond light cure bonding materials from 3M Unitek®. Participants were seen four weeks after initial study participation for their regularly scheduled orthodontic appointment. Charts were marked with red stickers to indicate patient participation in the study. Location of bond failures and dates were carefully recorded by the orthodontist at each visit, which is a standard office procedure. Bond failure was defined as a bracket that has been fully detached from the tooth. Patients were asked to call the orthodontist immediately to report any bond failures that occurred between regularly scheduled appointments.

Once all of the data were collected, means were calculated for patient age, overall number of bond failures and number of bond failures with and without the drug. A paired t-test was performed to determine if there was a statistical difference between the mean bond failures of both groups. Mean bond failures were also calculated and compared for anterior (cuspid to cuspid) and posterior (premolars and molars) segments. The percentage of males and females that participated in the study was tabulated and mean bond failure of the two groups were also compared. The mean overall bond failures from the study were compared to the baseline group, who met all the criteria the study group did, chosen retrospectively from the same orthodontic practice. The retrospective data for the baseline group was collected from the patient charts. Data was collected from patients who had braces placed on the teeth for a minimal of sixty days and began treatment prior to the recruitment of the experimental group. Data collection began from the most

recently bonded cases and was consecutively collected until a sufficient sample size was achieved. This was done in order to establish a general overall bond failure rate for Dr. Gustovich's practice. This baseline failure rate was compared to the bond failure rate of the experimental group. A Chi-Square test was used to determine if there was a statistical difference in bond failures between the experimental and baseline groups.

RESULTS

Bracket failures were recorded for each tooth over a sixty day period. The details for the sample size including mean age, sex distribution, bracket failure location, drug failure and number of bond failures in each group are shown in Appendix 1, Tables 1 through 13. A total of 576 brackets were bonded in the experimental group. This total included brackets bonded with and without the use of an antisialogogue. Of the 576 brackets, 272 were placed on the anterior teeth and 304 were placed on the posterior teeth.. A total of five bond failures were observed in the anterior and posterior groups combined. This equates to less than l% (0.86%) overall bond failure rate for the experimental group (see Figure 4). Of the 576 brackets bonded in the experimental group, 287 were bonded without the use of an antisialogogue. Of the 287 brackets placed, there was a total of three bond failures that equate to a 1.04% failure rate as shown in Figure 1. Of the 289 brackets bonded with the use of an antisialogogue, there were two bond failures that equate to a 0.692% failure rate also shown in Figure 1. A paired t-test was used to compare the means between the failure rates with and without the use of an antisialogogue. The result was calculated to be $\rho = 0.64$ which indicates there is no significant difference in bond failure between the two groups (see Table 14). The total bracket failures for anterior and posterior teeth bonded with and without the use of antisialogogues were evaluated. Anterior was defined as cuspid to cuspid and posterior

was defined as premolars and molars. Anterior versus posterior failures were evaluated. Of the 272 brackets bonded in the anterior, there was only one bracket failure (0.36%) (see Figure 3). Of the 304 brackets bonded in the posterior, there were 4 bracket failures (1.3%) (see Figure 3) The experimental group consisted of 16 females (64%) and 9 males (36%). Of the total 576 brackets bonded in the experimental group, 361 were bonded in females and 215 were bonded in males. Of the 361 brackets bonded in females, only 1 bond failed (.28%) which was less than the failure rate found in the males as shown in Figure 2. Of the 215 brackets bonded in males, 4 bonds failed (1.86%) also shown in Figure 2. The mean age of the experimental group was fifteen years old with the oldest being 39.4 years old and the youngest being 10.8 years old. In addition to bracket bond failures recorded from our experimental group, bracket failures from the baseline group were also recorded. This was done to establish the average bond failure rate at this particular office for patients undergoing routine bonding procedures. The baseline group consisted of twenty-three subjects with a total of 578 brackets bonded. There was a total of 15 females (66%) and 8 males (34%) (see Table 9). Of the 578 brackets placed, a total of 13 bond failures were tabulated over a 60 day period for this group equating to a 2.2% overall bond failure rate (see Table 9). Of the 578 brackets placed, 380 were placed in females and 198 placed in males as shown in Tables 7 and 8. There was a total of thirteen bond failures in the baseline group, nine bond failures were found in males and four were found in females as shown in Tables 10 and 11 This equates to a 4.5% bond failure rate in males and a 1.05% failure rate in females. When examining anterior versus posterior in the baseline group, a total of eleven posterior and two anterior bracket failures was

recorded as shown in Tables 12 and 13. This equates to a 3.6% failure rate in the posterior and a 0.73% failure rate in the anterior. Failure rates in male versus female and anterior versus posterior was very similar for both experimental and baseline groups (see Figures 5 and 6). A Chi-Square Test was calculated at the 0.05 confidence level to determine if there was a significant difference in overall bond failures between the baseline and experimental groups. The result of the Chi-Square test was 1.33 which indicated no significant difference between the two groups (see Table 14). To compare the mean bracket failure rate between the groups who did and did not use an antisialogogue, a paired t-test was performed. The result was $\rho = 0.645$ which indicated that there was no statistical difference between the mean bracket failure rates of both groups (see Table 14).

Figure 1. -- Experimental Group: Total Brackets Bonded vs. Failed

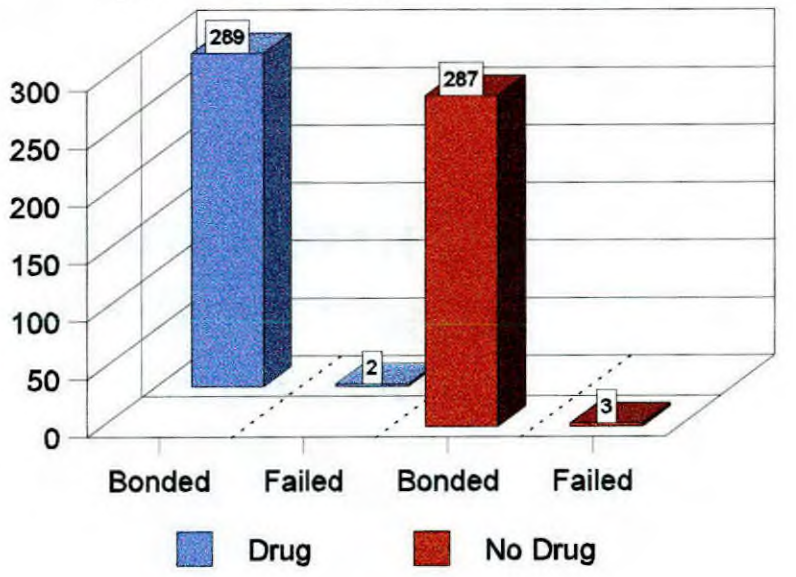


Fig. 2.-- Experimental Group: Bond Failures in Males vs. Females

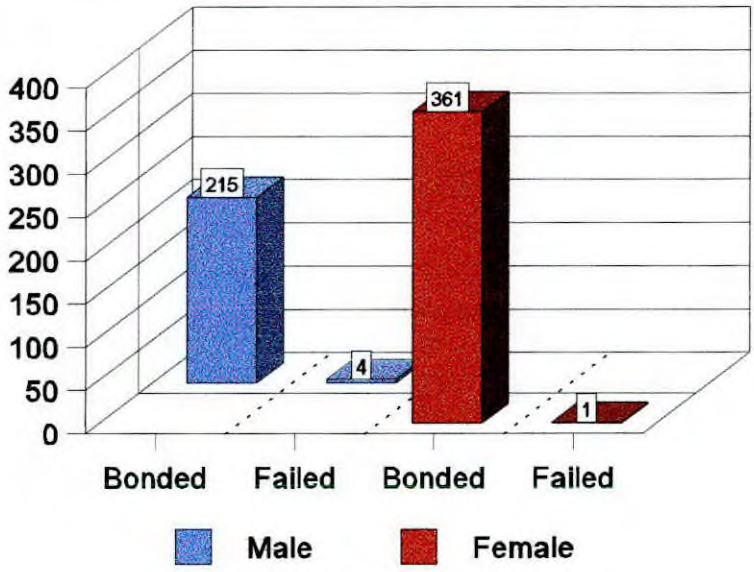


Fig. 3. -- Experimental Group: Bond Failures in Anterior and Posterior

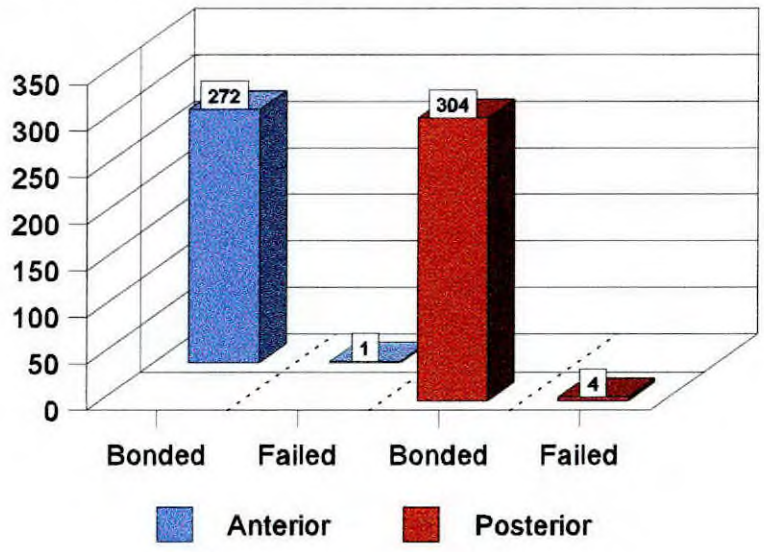


Fig. 4.-- Number of Brackets Bonded vs. Failed

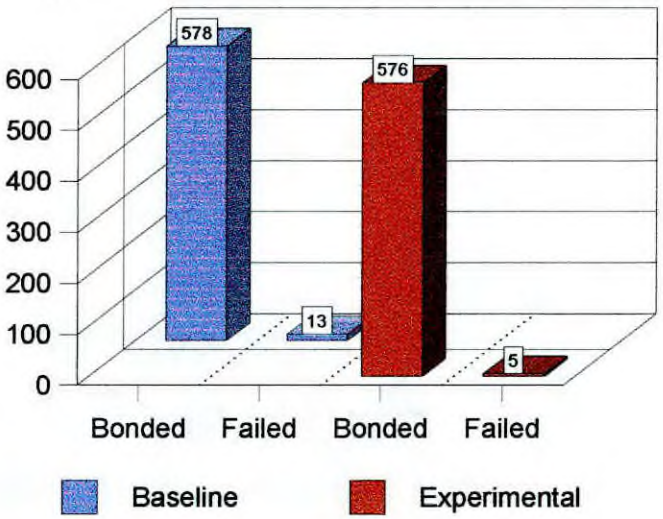


Fig. 5. -- Baseline vs. Experimental: Gender Related Bonds/Failures

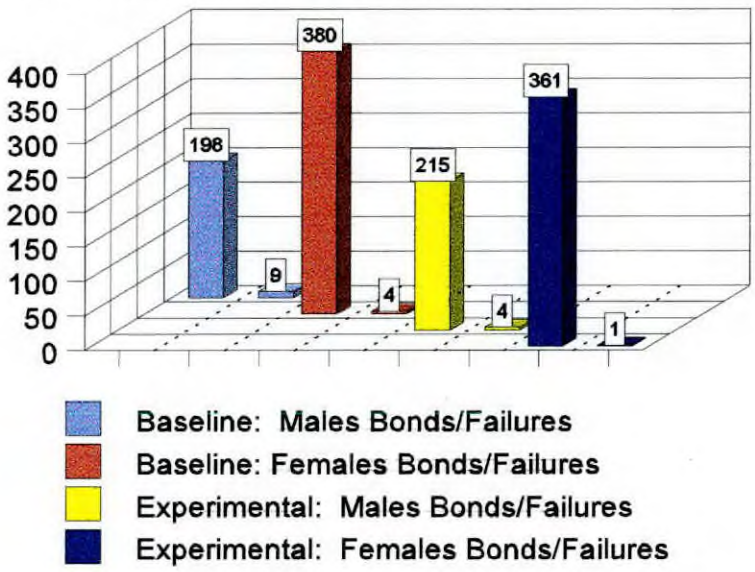
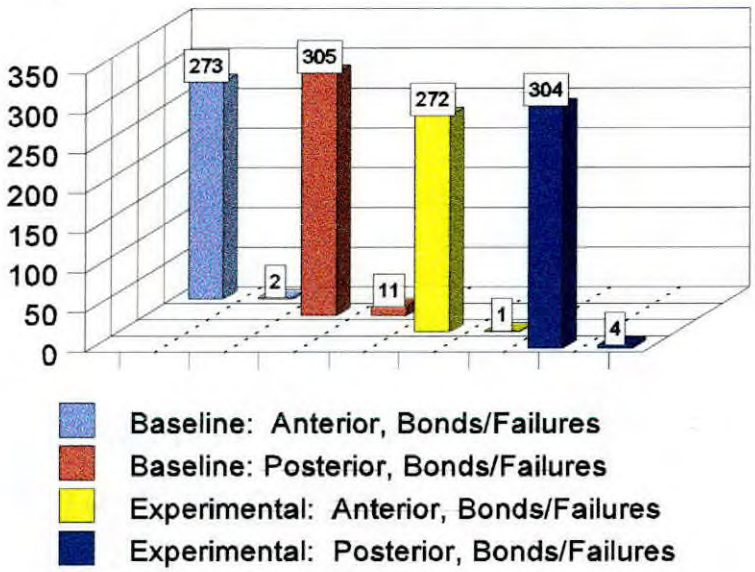


Fig. 6. -- Baseline vs. Experimental: Bonds/Failures related to Location



DISCUSSION

There was no significant difference between the bond failure rate of the brackets bonded with the use of the antisialogogue in conjunction with conventional methods and the brackets bonded using only conventional methods. This is contrary to what one might expect. Common sense would seem to indicate that use of a pharmaceutical agent that reduces salivary flow in combination with standard methods of isolation would lead to less salivary contamination and hence fewer bond failures. The results of this study cannot be compared with results from any other study since there is no report in the literature of a similar study. It is well published in the literature however, that poor isolation technique during the bonding procedure increases bond failure (Sheykholeslam and Brandt (1977); Gorelick (l977); Beech et al., l981). One explanation for our findings is that only one quadrant at a time was etched and brackets bonded which makes it easier to isolate from salivary contamination. In a twelve month assessment of bonding metal brackets to enamel by Gorelick, (l977) preparation and bonding of brackets was limited to four teeth at a time in order to reduce risk of contamination. Although preparing teeth and bonding brackets in this manner might lead to higher bond success of the brackets, is not practical in busy orthodontic practices. In modern day orthodontic offices, all teeth are usually prepared at the same time. Preparing teeth in this manner may allow for more chance of contamination than when teeth are prepared and bonded one quadrant at a time as in the

experimental group. The fact that the overall failure rate for brackets in the baseline group was higher number than in the experimental group may be an indication of this point.

When comparing the baseline group to the experimental group, there are differences that can be found that would lead to higher bracket failure in the baseline group. The baseline group had all the teeth prepared for bonding at the same time. Preparation of the teeth for bonding in this manner allows more chance of contamination since the teeth that are bonded last are exposed to the oral environment for a longer period of time prior to having brackets placed. Another explanation for the differences in bond failures between the experimental and the baseline groups is that in the experimental group, all of the teeth were prepared by the orthodontist, whereas in the baseline group, they were prepared by the staff. As mentioned in the literature review, increased operator experience in bonding leads to fewer bond failures.

Another possible explanation for the overall lower bond failure rate for the experimental group when compared to the baseline group may have been due to a phenomena in psychology called the "Hawthorne Effect". The Hawthorne effect comes into play when participants of a study are aware that they are taking part in an experiment. This phenomena may have influenced the practitioners performance when bonding the brackets to the teeth. Extra care and attention to detail may have been taken when placing the brackets in the experimental group. This phenomena may have also influenced the patients in the experimental group who may have been more aware of the importance of not breaking brackets.

The results of this study showed higher bond failure in the posterior segments

(premolar and molar) than in the anterior (cuspid to cuspid) for the experimental and baseline groups. This difference may be due to several factors. Increased forces of occlusion during mastication are found in posterior segments which may be responsible for high posterior bracket failures than anterior. Also, as mentioned in the literature review, thicker areas of adhesive are found in the buccal groove area of the molar teeth. It has been shown that increased polymerization shrinkage occurs in thicker areas of adhesive hence leading to weaker bond strength. Lastly, the posterior segments are the most difficult to isolate and protect from salivary contamination. Pooling of saliva in the posterior segments of the lower arch can be especially difficult to control in some patients, leading to increased contamination and increased bracket failure.

The results also indicated higher bond failures in males than females. This seems to be consistent with anecdotal clinical beliefs held by many practitioners. A possible explanation for higher bracket failures in males than females might be that boys are often more active in contact sports than girls. The increased risk of trauma to the face in these types of sports may lead to increased bracket failure. Both increased posterior bracket failure and higher bracket failure in males than females are in accordance with a five year clinical review of bond failure by Millett and Gordon, 1994.

Many factors that influence bonded bracket success or failure have been discussed in this study. There are many pros and cons to a study of this nature. Because of the many variations that occur between and within individuals, such as type and quality of enamel, type of malocclusion and amount of salivary secretion, a within patient design was used as recommended by O'Brien et al., (1988). This design is probably most ideal for this type of

study since the above mentioned factors which are very important to bonded bracket success or failure would be impossible to match in a between subject design. The negative aspect of this type of design is that the exact bond strength of each bracket is unknown. An ideal study would be to prepare all of the teeth for bonding, place all of the brackets and then extract the teeth and analyze bond strength in a laboratory setting to determine exact bond strength, which is not practical, of course.

SUMMARY AND CONCLUSIONS

As stated previously, the goal of the present study was to evaluate the efficacy of an antisialogogue in conjunction with conventional methods for creating a dry environment within the oral cavity during orthodontic bonding procedures. This was compared to the use of conventional methods alone as measured by the rate of bracket failure. It is well documented in the literature in both *in vivo* and *in vitro* studies that salivary contamination is a major factor causing orthodontic bond failures. Efforts to create a dry field within the oral cavity using conventional methods, such as high vacuum suction and cotton rolls has proven to be challenging and not always effective. In an attempt to decrease the chances of salivary contamination, the use of a supplemental pharmaceutical agent in conjunction with these conventional methods has been recommended in the literature. However, there has never been a study conducted that shows that a dry field created by use of an antisialogogue in conjunction with conventional methods is more effective in preventing salivary contamination than a dry field created by conventional methods alone. This information would be very valuable to practitioners as it is important to know the risk/benefit factors of administering a systemic drug for enhanced bond success.

The challenge of this study was to create a scientifically sound study design that could fairly and accurately compare both methods of creating a dry field during bonding

and examine how it relates to bond failure.

In the field of orthodontics, bonding of brackets to teeth is a very technique-sensitive procedure. It is a documented fact that salivary contamination of the bracket adhesive and/or tooth enamel will lead to bond failure of the bracket. Bond failures can delay treatment time and that may increase the risk of enamel decalcification, gingival disease and root resorption as well as create excess overhead expenditures by consuming unnecessary practitioner and staff time.

This study was critical as it is important for practitioners to know whether or not use of a pharmaceutical agent is warranted when bonding brackets. Either a positive or a negative result of this study was valuable information for a practitioner. If the outcome was positive, and it was shown that antisialogogues can reduce bracket failure, then orthodontists could administer the drug with confidence knowing that treatment time and overhead expenses may be reduced. On the other hand, if the outcome was negative and it was shown that antisialogogues do not help reduce bracket failure, then orthodontists could discontinue administration of the drug and eliminate any potential drug reaction or complication to the patient.

This study demonstrated no statistically significant differences in the number of bond failures when an antisialogogue is used compared to bonding without the use of an antisialogogue. There were more posterior bond failures than anterior bond failures and there were more bond failures in males than in females. This study concludes that careful technique (i.e., avoiding contamination and paying attention to detail) during the bonding process is probably more important in determining bonding success than antisialogogue use. Therefore, use of antisialogogues for routine bonding procedures is not advocated.

LIST OF APPENDICES

Appendix One:	Tables 1 through 14
Appendix Two:	Informed Consent to Participate in Research Form
Appendix Three:	Health History Form

APPENDIX ONE

Table1.- Experimental Group: Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Total Brackets Bonded	Total Bracket Failures
1	23	0
2	14	0
3	23	0
4	28	0
5	24	0
6	24	0
7	22	0
8	12	0
9	23	0
10	20	0
11	23	0
12	22	0
13	28	0
14	24	0
15	26	1
16	23	1
17	27	0
18	24	0
19	27	0
20	17	0
21	22	0
22	16	0
23	28	1
24	28	1
25	28	1
Total	576	5

Table 2.- Experimental Group (Using Antisialogogue): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Total Brackets Bonded	Total Bracket Failures
1	12	0
2	7	0
3	11	0
4	14	0
5	12	0
6	12	0
7	11	0
8	6	0
9	12	0
10	10	0
11	11	0
12	12	0
13	14	0
14	12	0
15	13	1
16	11	1
17	14	0
18	12	0
19	13	0
20	9	0
21	11	0
22	8	0
23	14	0
24	14	0
25	14	0
Total	289	2

Table 3.- Experimental Group (No Antisialogogue): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Total Brackets Bonded	Total Bracket Failures
1	11	0
2	7	0
3	12	0
4	14	0
5	12	0
6	12	0
7	11	0
8	6	0
9	11	0
10	10	0
11	12	0
12	10	0
13	14	0
14	12	0
15	13	0
16	12	0
17	13	0
18	12	0
19	14	0
20	8	0
21	11	0
22	8	0
23	14	1
24	14	1
25	14	1
Total	287	3

Table 4 - Experimental Group (Females): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Total Brackets Bonded	Total Bracket Failures
1	23	0
2	14	0
4	28	0
5	24	0
6	24	0
7	22	0
8	12	0
11	23	0
12	22	0
13	28	0
14	24	0
18	24	0
19	27	0
21	22	0
22	16	0
25	28	1
Total: 16	361	1

Table 5.- Experimental Group (Males): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Total Brackets Bonded	Total Bracket Failures
3	23	0
9	23	0
10	20	0
15	26	1
16	23	1
17	27	0
20	17	0
23	28	1
24	28	1
Total: 9	215	4

Table 6.- Experimental Group (Anterior): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Total Brackets Bonded	Total Bracket Failures
1	11	0
2	6	0
3	10	0
4	12	0
5	12	0
6	12	0
7	12	0
8	6	0
9	12	0
10	10	0
11	12	0
12	12	0
13	12	0
14	12	0
15	12	0
16	11	1
17	12	0
18	12	0
19	12	0
20	8	0
21	10	0
22	8	0
23	12	0
24	12	0
25	12	0
Total	272	1

Table 7.- Experimental Group (Posterior): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Total Brackets Bonded	Total Bracket Failures
1	12	0
2	8	0
3	13	0
4	16	0
5	12	0
6	12	0
7	10	0
8	6	0
9	11	0
10	10	0
11	11	0
12	10	0
13	16	0
14	12	0
15	14	1
16	12	0
17	15	0
18	12	0
19	15	0
20	9	0
21	12	0
22	8	0
23	16	1
24	16	1
25	16	1
Total	304	4

Table 8- Experimental Group: Listed by Gender, Age and Days until First Debond

Patient Number	Gender	Age in Years.Months	Days until 1st Debond
1	Female	15.5	0
2	Female	13.3	0
3	Male	13.3	0
4	Female	14.6	0
5	Female	11.3	0
6	Female	16.11	0
7	Female	10.8	0
8	Female	12.4	0
9	Male	39.4	0
10	Male	12.2	0
11	Female	16.4	0
12	Female	12.8	0
13	Female	14.2	0
14	Female	11.0	0
15	Male	11.9	1
16	Male	13.4	17
17	Male	14.7	0
18	Female	28.0	0
19	Female	15.8	0
20	Male	12.7	0
21	Female	16.6	0
22	Female	11.7	0
23	Male	15.3	31
24	Male	13.6	33
25	Female	14.2	45
Total	9 Males / 16 Females	Avg. Age = 15.2	Avg. No. Days = 7.76

Table 9.- Baseline Group: Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Gender	Total Brackets Bonded	Total Bracket Failures
1	Male	23	2
2	Female	22	0
3	Female	28	1
4	Male	28	0
5	Male	28	1
6	Female	26	0
7	Male	22	2
8	Female	24	1
9	Female	23	0
10	Male	27	1
11	Male	23	2
12	Male	28	1
13	Female	27	0
14	Female	26	0
15	Female	24	1
16	Female	26	0
17	Female	24	0
18	Female	28	1
19	Female	26	0
20	Female	23	0
21	Female	27	0
22	Male	19	0
23	Female	26	0
Total		578	13

Table 10.- Baseline Group (Males): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Gender	Total Brackets Bonded	Total Bracket Failures
1	Male	23	2
2			
3			
4	Male	28	0
5	Male	28	1
6			
7	Male	22	2
8			
9			
10	Male	27	1
11	Male	23	2
12	Male	28	1
13			
14			
15			
16			
17			
18			
19			
20			
21			
22	Male	19	0
23			
Total	8	198	9

Table 11- Baseline Group (Females): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Gender	Total Brackets Bonded	Total Bracket Failures
1			
2	Female	22	0
3	Female	28	1
4			
5			
6	Female	26	0
7			
8	Female	24	1
9	Female	23	0
10			
11			
12			
13	Female	27	0
14	Female	26	0
15	Female	24	1
16	Female	26	0
17	Female	24	0
18	Female	28	1
19	Female	26	0
20	Female	23	0
21	Female	27	0
22			
23	Female	26	0
Total	15	380	4

Table 12.- Baseline Group (Anterior): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Gender	Total Brackets Bonded	Total Bracket Failures
1	Male	12	0
2	Female	11	0
3	Female	12	0
4	Male	12	0
5	Male	12	0
6	Female	12	0
7	Male	11	0
8	Female	12	1
9	Female	12	0
10	Male	12	0
11	Male	12	0
12	Male	12	0
13	Female	12	0
14	Female	12	0
15	Female	12	0
16	Female	12	0
17	Female	12	0
18	Female	12	1
19	Female	12	0
20	Female	12	0
21	Female	12	0
22	Male	11	0
23	Female	12	0
Total		273	2

Table 13.- Baseline Group (Posterior): Total Brackets Bonded vs. Total Bracket Failures

Patient Number	Gender	Total Brackets Bonded	Total Bracket Failures
1	Male	11	2
2	Female	11	0
3	Female	16	1
4	Male	16	0
5	Male	16	1
6	Female	14	0
7	Male	11	2
8	Female	12	0
9	Female	11	0
10	Male	15	1
11	Male	11	2
12	Male	16	1
13	Female	15	0
14	Female	14	0
15	Female	12	1
16	Female	14	0
17	Female	12	0
18	Female	16	0
19	Female	14	0
20	Female	11	0
21	Female	15	0
22	Male	8	0
23	Female	14	0
Total		305	11

Table 14.- A Comparison of Bond Failure Rates Using Four Groups: Baseline Group vs. Experimental Group and Antisialogogue Group vs. No Antisialogogue Group.

Baseline vs Experimental Group	Antisialogogue vs. No Antisialogogue Group
Chi Squared Test (0.05 confidence level)	Paired T-Test
$\chi 2 = 1.33$	$\rho = 0.64$
No significant difference	No statistical difference

APPENDIX TWO

CASE WESTERN RESERVE UNIVERSITY SCHOOL OF DENTISTRY
DEPARTMENT OF ORTHODONTICS
INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Principal Investigator: Jamie M. Signorino, D.D.S
Co-Investigators: Donald Gustovich, D.D.S, M.S.
Roxanna Moussa, D.D.S., M.S.
Geza Terazhalmy, D.D.S., M.S.
Mark G. Hans, D.D.S., M.S.
Suchitia Nelson, PhD.

Title of Project: The Use of Antisialogogues in Orthodontic Bonding Procedures

You are being asked to participate in a research study examining the efficacy of antisialogogues (anti-saliva drugs) in controlling saliva during the bonding of orthodontic brackets to tooth enamel in orthodontic patients.
Purpose: The purpose of the present study is to determine if a drug that dries saliva (antisialogogue) in conjunction with conventional drying methods is more effective in drying the mouth during placement of braces on teeth than conventional methods alone.

Procedure: The patient will schedule a 1 1/2 hour appointment for placement of braces on all the teeth. Tthe lst half of the braces will be placed on the teeth (½ on the upper arch and ½ on the lower arch) without the use of the antisialogogue. Once the lst portion of the braces are placed, the participant will then be administered the antisialogogue and then wait ½ hour in order for the drug to be absorbed into the participants system. Once the drug has been absorbed, the second portion of the braces will be placed on the remaining teeth. The participant will return to the orthodontic office for regular office appointments every 4 weeks. During the first two visits after placement of the braces, the number of loose or missing brackets will be recorded in the patient chart (standard office procedure). The patient will continue regular office visits after the first two appointments without further monitoring of their bracket debonds for research purposes.

Benefits: The benefit of the present study is to prevent unnecessary bond failures due to saliva contamination. Fewer bond failures can decrease the overall treatment time for the patient. By avoiding extended treatment time with orthodontic brackets, the patient will

be at less risk for enamel decalcification, root resorption and gingivitis.

Alternative Procedures: The alternative method for placing orthodontic brackets without the use of an antisialogue is to create a dry field within the mouth using conventional methods of retraction, suction, and cotton rolls.

Risks:

No foreseeable risks are expected if the patient presents **without** the following:

1) Narrow Angle Glaucoma
2) GI obstructions
3) Prostatic Disease
4) Obstructive Uropathy
5) Pregnancy/Nursing
6) Ulcerative Colitis
7) Known Allergy to Probanthine®
8) Heart Disease
9) Myasthenia Gravis

Antisialogogues should not be taken in conjunction with the following drugs:

1) Tricyclic Antidepressants
2) Antipsychotics
3) Anti-histamines
4) Anti-Parkinsonism drugs

Overdose:

Potential signs of overdose include Central Nervous System disturbances, such as restlessness weakness and possible temporary paralyisis or psychotic behavior and flushing. If any of the above symptoms should occur, the following measures can be taken: 1) immediate induction of emesis or stomach lavage 2) injection of 0.5mg physostigmine intravenously up to 5 mg 3) Monitoring/Managing of vital signs. Participation in this study is completely voluntary and refusal to participate will involve no penalty or loss of benefits to which you may otherwise be entitled. It is required by Federal Regulation that you be informed that Case Western Reserve University does not provide medical treatment nor compensation for injury consequent to your participation in this study. No need for such treatment in foreseen.

Compensation: You should report any injury or illness you believe to be related to this research project to Dr. Jamie Signorino (Principle Investigator) at (216)368-3249 or the chairperson of the this study, Dr. Roxanna Moussa at (216)444-4388. Medical treatment for injury or illness resulting from the research procedures is available at University Hospitals and Clinics. Payment for the medical treatment is your responsibility. Case Western Reserve University; and their agents and employees are not responsible for the payment of medical care or for compensation of any expenses associated with research related illness or injury.

Confidentiality: All data obtained on you during the course of the study will be kept confidential and accessible only to the principal investigator and her assistants on the project. Should the results of the present study be published, you will be referred to only by number.

I have read the above and understand what is involve should I participate in the present study. I have been given the opportunity to ask questions of the investigators regarding the procedure and these were answered to my satisfaction. I consent to undergo

treatment untilizing the drug as described.

Signature of Participant (parent/guardian) Date

Signature of Witness Date

Signature of P.I. (Person who obtains consent) Date

APPENDIX THREE

ORTHODONTIC ACQUAINTANCE CARD

DATE _____ 19 ___

DATE OF BIRTH _____

PATIENTS NAME _____ Initial ___ AGE ___ SEX ___
Last First

RES. ADDRESS _____ ZIP _____ PHONE _____

REFERRED BY _____

PATIENTS DENTIST _____ PHYSICIAN _____

PATIENTS ORAL SURGEON _____

OCCUPATION _____

EMPLOYED BY _____ BUS. PHONE _____

BUS. ADDRESS _____ SOC. SEC. NO. _____

DO YOU HAVE DENTAL INSURANCE? _____

SPOUSE'S NAME _____ OCCUPATION _____

EMPLOYED BY _____ BUS. PHONE _____

BUS. ADDRESS _____ SOC. SEC. NO. _____

DO YOU HAVE DENTAL INSURANCE? _____

MEDICAL HISTORY

IS PATIENT IN GOOD HEALTH? _____ Yes ☐ No ☐

DOES PATIENT HAVE ANY HISTORY OF MAJOR ILLNESS? _____ Yes ☐ No ☐

HAS THE PATIENT EVER BEEN UNDER THE CARE OF A PHYSICIAN FOR ILLNESS? _____ Yes ☐ No ☐

PLEASE LIST: _____

Check any of the following for which the patient has been treated:

Diabetes . . . . . ☐	*Anemia* . . . . . ☐	*Prolonged Bleeding* . . . ☐
Pneumonia . . . . . ☐	*Epilepsy* . . . . . ☐	*Fainting or Dizziness* . . ☐
Heart Trouble. . . . . ☐	*Asthma* . . . . . ☐	*Nervous Disorders*. . . . ☐
Rheumatic Fever . . . . ☐	*Kidney Involvement* . ☐	*Liver Involvement*. . . . ☐
Bone Disorders . . . . . ☐	*Tuberculosis*. . . . . ☐	*Endocrine Problems*. . . ☐

DOES PATIENT HAVE TENDENCY TO COLDS ☐ SORE THROATS ☐ EAR INFECTIONS ☐

HAVE TONSILS AND ADENOIDS BEEN REMOVED? WHAT AGE? _____ Yes ☐ No ☐

LIST ANY DRUGS OR MEDICATIONS NOW BEING TAKEN. GIVE REASONS: _____

LIST ANY ALLERGIES OR DRUG SENSITIVITY: _____

HEIGHT _____ WEIGHT _____

DENTAL HISTORY

HAS THERE BEEN ANY INJURIES TO THE FACE, MOUTH OR TEETH Yes ☐ No ☐

HAS THE PATIENT EVER SUCKED A THUMB OR FINGERS? UNTIL WHAT AGE? _____ Yes ☐ No ☐

DOES THE PATIENT HAVE ANY SPEECH PROBLEMS? _____ Yes ☐ No ☐

IS THE PATIENT A MOUTH BREATHER? WHILE AWAKE? _____ Yes ☐ No ☐

WHILE ASLEEP? _____ Yes ☐ No ☐

HAVE YOU BEEN INFORMED OF ANY MISSING OR EXTRA PERMANENT TEETH _____ Yes ☐ No ☐

HAS AN ORTHODONTIST BEEN CONSULTED PREVIOUSLY? _____ Yes ☐ No ☐

HAS EITHER PARENT HAD ORTHODONTIC TREATMENT? _____ Yes ☐ No ☐

LIST ANY MUSICAL INSTRUMENTS PLAYED: _____

REASON FOR CONSULTATION _____

_____
Signature

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