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## EFFECTS OF FLASH-FREE TECHNIQUE ON PLAQUE RETENTION, WHITE SPOT LESIONS, AND BRACKET FAILURE: A RANDOMIZED CLINICAL TRIAL

By

Payam Ishani Afousi, D.D.S

### A THESIS

Presented to the Faculty of The Graduate College in the University of Nebraska In Partial Fulfillment of Requirements For the Degree of Master of Science

> Medical Sciences Interdepartmental Area Oral Biology

Under the Supervision of Professor Sundaralingam Premaraj

University of Nebraska Medical Center Omaha, Nebraska

December, 2016

Advisory Committee: Thyagaseely Premaraj, BDS, PhD Peter J. Giannini, DDS, MS Stanton D. Harn, PhD



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#### ABSTRACT

### EFFECTS OF FLASH-FREE TECHNIQUE ON PLAQUE RETENTION, WHITE SPOT LESIONS, AND BRACKET FAILURE: A RANDOMIZED CLINICAL TRIAL

Payam Ishani Afousi, DDS

University of Nebraska, 2016

Advisor: Sundaralingam Premaraj, BDS, MS, PhD, FRCD(C)

A side effect of orthodontic treatment is the development of white spot lesions (WSLs). This thesis attempted to evaluate the effects of the use of APC™ Flash-Free (FF) and conventional adhesives in bonding of orthodontic brackets on plaque formation and retention, WSL development, and bracket failure *in-vivo*. This was accomplished by collecting plague samples from around orthodontic appliances and analyzing them using ATP-driven bioluminescence; scanning enamel surfaces using the Canary System™ to evaluate WSL development, and counting the number of spontaneous debonding of brackets of the 4 maxillary incisors in the first 6 months of treatment. It was found that there were no significant differences in plaque formation and retention between brackets bonded with FF adhesive and those bonded with conventional adhesives. Furthermore, there were no significant differences in WSL development between FF adhesives and conventional adhesives during the same study period; however, demineralization of enamel surfaces took place in our sample with mesiofacial and distofacial surfaces being most affected. Failure rates of 5.26% and 0% were observed for FF and conventional brackets during the first 6 months of orthodontic treatment, respectively. The present study revealed that the presence or absence of excessive adhesive (flash) around fixed orthodontic appliances may not play a significant role in plague retention and white spot lesion development in patients undergoing orthodontic treatment during the first 6 months of orthodontic treatment with fixed appliances. Furthermore, FF brackets may fail more often than conventional brackets during the first 6 months of orthodontic treatment with fixed appliances.



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### LIST OF ABBREVIATIONS

ATP: adenosine triphosphate Canary T1: Canary scan at 2 weeks ± 2 days Canary T2: Canary scan at 6 months ± 2 days CV: coefficient of variation FF: APC<sup>™</sup> Flash-Free PBS: phosphate buffered saline Plaque T1: plaque collection at 2 weeks± 2 days Plaque T2: plaque collection at 6 weeks ± 2 days QLF: quantitative light-induced fluorescence RLU: relative light units SD: standard deviation WSL: white spot lesion



#### **CHAPTER 1: INTRODUCTION**

One of the side effects of orthodontic treatment with fixed appliances is development of enamel decalcification or white-spot lesions (WSLs) around fixed orthodontic appliances (Figure 1.1). The WSLs can be defined as "subsurface enamel porosity from carious demineralization" which presents as "a milky white opacity located on smooth surfaces" (Summitt, Robbins et al. 2006). The prevalence of WSLs in orthodontic patients is variable and is reported to be 50% in one study (Gorelick, Geiger et al. 1982) and 73-95% in others (Lovrov, Hertrich et al. 2007; Richter, Arruda et al. 2009), with maxillary incisors and first molars having the highest prevalence of white spot lesions (Gorelick, Geiger et al. 1982; Mizrahi 1982).

Development of WSLs may create significant esthetic problems after completion of orthodontic treatment (Gorelick, Geiger et al. 1982; Mizrahi 1982; Artun and Brobakken 1986; O'Reilly and Featherstone 1987) and areas of decalcification may persist for many years, posttreatment (Ogaard 1989). A number of post-orthodontic treatment options to address WSLs have been proposed in recent years, but these treatment options may place a financial burden on patients with lengthy treatment time and/or less than ideal outcomes (Heymann and Grauer 2013); therefore, prevention of WSLs is of great interest to clinicians.

WSLs can develop as a result of prolonged retention of acid-producing bacteria in dental plaque around fixed orthodontic appliances (Gorelick, Geiger et al. 1982; Mizrahi 1982; Artun and Brobakken 1986; O'Reilly and Featherstone 1987). Fixed orthodontic appliances make oral hygiene practices more challenging for patients. Poor oral hygiene is an important risk factor in development of WSLs during orthodontic treatment (Heymann and Grauer 2013); however, other risk factors such as bracket type and ligation may contribute to greater retention of plaque and development of WSLs (Pellegrini, Sauerwein et al. 2009; Srivastava, Tikku et al. 2013).

Conventionally, after etching and placing bonding agent on the tooth enamel surface that is about to receive the orthodontic bracket, adhesive is placed onto the orthodontic bracket base and the bracket is then placed onto the tooth surface. The excess adhesive (commonly referred to as flash) is then removed from around the orthodontic brackets and the adhesive is light cured



to begin the polymerization reaction within the adhesive and fully bond the orthodontic bracket onto the tooth surface.

A relatively new orthodontic bracket adhesive called APC<sup>™</sup> Flash-Free (FF) has been introduced by the 3M Unitek Company in recent years (APC<sup>™</sup> Flash-Free Adhesive Coated Appliance System, 3M Unitek, Monrovia, CA). The FF Adhesive is contained within a non-woven form-fitting fiber mesh on the base of the orthodontic bracket and conforms to the tooth surface to create a uniform contact between the bracket base and the tooth enamel (http://www.3m.com/3M/en\_US/orthodontics-us/).

The bonding of FF brackets onto the tooth surface is similar to that of conventional brackets except that no adhesive is placed onto the bracket base of a FF bracket (since the brackets are already pre-coated with the FF adhesive), therefore, no excess adhesive (flash) needs to be removed from around the orthodontic brackets once the FF brackets are placed onto the tooth surface. The FF brackets are comparable in size, shape and biomechanics to those of conventional brackets.

We hypothesized that the conventional bonding of orthodontic brackets onto the tooth surface may create areas of void and/or excess adhesive at the bracket-enamel interface, which may contribute to plaque retention and development of WSLs. We hypothesized that the FF brackets may lead to a more uniform bond between the bracket base and the enamel and may not lead to areas of void and/or excess adhesive and therefore reduce plaque retention and development of WSLs (Figure 1.2). Furthermore, we tested the null hypothesis that there are no differences in the bond failure rate of brackets bonded with conventional adhesives and FF adhesives and technique.

The purpose of this study was to compare the effects of FF brackets (that use FF adhesive) on plaque formation and retention, white spot lesion development and bracket failure with those of conventional brackets (that use conventional adhesive) in orthodontic patients treated with fixed appliances.



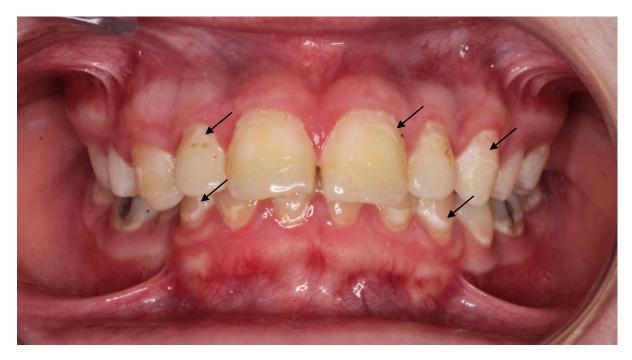
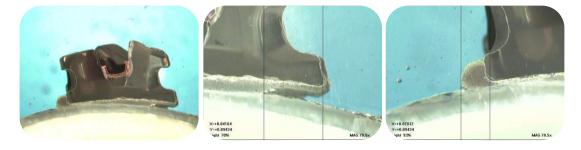


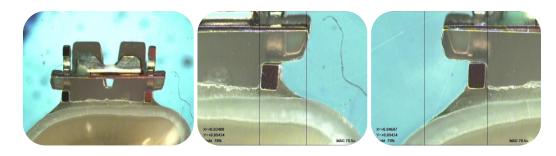
Figure 1.1. White Spot Lesions, Post Orthodontic Treatment Arrows indicate areas of decalcification.







b.



### Figure 1.2. Bracket-Enamel Interface.

**a.** Bracket bonded onto the tooth surface using conventional adhesives. Note the areas of void and excess at the bracket-enamel interface.

**b.** APC<sup>™</sup> Flash-Free bracket bonded onto the tooth surface. Note the uniform layer of adhesive at the bracket-enamel interface.

(Image Courtesy of Mr. Tom Irvin, 3M Unitek)



#### **CHAPTER 2: STUDY AIMS**

#### 2.1 Statement of the Problem

One of the unfavorable side-effects of orthodontic treatment using fixed appliances is increased accumulation of plaque and development of white spot lesions (WSLs) on the enamel around the orthodontic brackets. The development of WSLs is mainly associated with increased plaque accumulation due to orthodontics appliances, and de-mineralization of enamel by acidproducing bacteria in the plaque.

Conventionally, the enamel surface is prepared for bonding of orthodontic brackets by pumice, etchant (37% phosphoric acid), and primer. The base of each bracket is then coated with adhesive (composite resin) and the bracket is pressed onto the enamel surface, which results in excessive adhesive material (flash) surrounding the bracket. The clinician attempts to remove the flash; however, areas of excess and void can be created that may lead to increased plaque accumulation and development of white spot lesions.

#### 2.2 Null Hypothesis

There are no differences between FF brackets and conventional brackets in plaque formation and retention, development of WSLs, and spontaneous bond failure rate in orthodontic patients treated with fixed appliances.

#### 2.3 Specific Aims of Current Study

This study will compare the plaque accumulation levels, incidence of WSLs, and spontaneous bond failure rate of FF brackets and conventional brackets in orthodontic patients treated with fixed appliances.



#### **CHAPTER 3: LITERATURE REVIEW**

#### 3.1 WSL Epidemiology

The prevalence of WSLs is variable and is reported to be between 2% to 96% depending on the definition of WSL, method of diagnosis, and study design (Gorelick, Geiger et al. 1982; Mizrahi 1982; Ogaard, Rolla et al. 1988; Mitchell 1992). Studies show that the prevalence of WSLs in patients before orthodontic treatment ranges from 15.5% to 40% (Gorelick, Geiger et al. 1982; Artun and Brobakken 1986; Lovrov, Hertrich et al. 2007) whereas, the incidence of new WSL development during orthodontic treatment ranges from 30% to 70% (Mizrahi 1982; Artun and Brobakken 1986; Ogaard, Rolla et al. 1988; Richter, Arruda et al. 2009; Enaia, Bock et al. 2011; Tufekci, Dixon et al. 2011). Maxillary anterior teeth are most commonly affected, with maxillary lateral incisors having the greatest rate of incidence for developing WSLs (Gorelick, Geiger et al. 1982; Artun and Brobakken 1986; Chapman, Roberts et al. 2010).

#### 3.2 WSL Etiology

There are three main factors implicated in the etiology of WSLs: host, environment, and cariogenic bacteria. The host factors include quality and quantity of saliva, enamel composition, and diet. The environmental factors include orthodontic appliances that encourage plaque retention and create challenges for removal of plaque. Cariogenic bacteria include *Streptococcus mutans* and *Lactobacilli*, both of which play an important role in decalcification and caries formation (Heymann and Grauer 2013). Upon bonding of fixed orthodontic appliances, there is a rapid shift in the bacterial flora of plaque with higher levels of acidogenic bacteria, including *Streptococcus mutans* and *Lactobacilli* (Lundstrom and Krasse 1987).

Poor oral hygiene due to lack of patient compliance is the most important factor for accumulation and retention of plaque and subsequent development of WSLs (Ogaard, Rolla et al. 1988); however, it has been shown that the type of orthodontic appliance can play a role in plaque accumulation and retention. One study shows that self-ligating brackets may reduce the amount of bacteria around orthodontic brackets (Pellegrini, Sauerwein et al. 2009). Another study



found no differences in self-ligating versus conventional brackets in terms of WSL formation (Polat, Gokcelik et al. 2008). Other studies showed that using elastomeric rings led to greater numbers of cariogenic bacteria compared to teeth ligated with stainless steel ligature wires (Forsberg, Brattstrom et al. 1991; Turkkahraman, Sayin et al. 2005). The clinical effects of FF brackets on plaque accumulation and white spot lesion development have not been investigated.

#### 3.3 WSL Diagnosis

One of the most common means of diagnosing WSLs *in vivo* is visual probing using the WSL index. The scoring system ranges from 0 to 3, with a score of "0" corresponding to no visible white spot or surface disruption, a score of "1" corresponding to visible WSL that covers less than one-third of the surface without surface disruption, a score of "2" corresponding to visible WSL that covers more than one-third of the surface, with roughened surface, but not requiring restoration, and a score of "3" corresponding to visible cavitation, requiring restoration (Gorelick, Geiger et al. 1982).

Another method to diagnose WSLs in live patients is quantitative light-induced fluorescence (QLF). QLF takes advantage of the auto-fluorescence of teeth. When exposed to high-density blue light, teeth emit light in the green part of the visible light spectrum. Upon demineralization, less light is absorbed by the enamel and therefore there is a lower intensity of fluorescence. The degree of demineralization can then be quantified by the differences in fluorescence between healthy and demineralized tooth enamel (Heinrich-Weltzien, Kuhnisch et al. 2003; Zandona and Zero 2006). Studies show that QLF can be used in vivo to detect and monitor changes in mineral content of incipient enamel lesions (Al-Khateeb, Forsberg et al. 1998; van der Veen and de Josselin de Jong 2000).

A relatively new technology, called the Canary System<sup>™</sup> (Canary System<sup>™</sup>, Quantum Dental Technologies, Toronto, Canada) was introduced in 2011 (figure 3.1). This device is a lowpowered laser which is equipped with an intra-oral camera and takes advantage of photothermal radiometry and luminescence technology to detect de-mineralization/re-mineralization and dental caries. The Canary System<sup>™</sup> can quantify the degree of demineralization for early carious



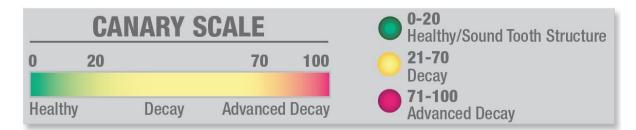
lesions as small as 50 microns on all tooth surfaces, including beneath dental sealants and bonded fixed orthodontic appliances. Research indicates that the Canary System<sup>™</sup> has a sensitivity of up to 97% (Jeon, Mandelis et al. 2003; Jeon, Han et al. 2004; Matvienko, Jeon et al. 2008; K, Abrams et al. 2010; Abrams, Sivagurunathan et al. 2011; Hellen, Mandelis et al. 2011; Kim, Mandelis et al. 2012; Carey and Coleman 2014; Wong, Abrams et al. 2014; Wong, Silvertown et al. 2014; Wong, Sivagurunathan et al. 2015). Upon scanning the tooth surface, the Canary system provides a number ranging from 0 to 100. The manufacturer indicates that numbers from 0-20 indicate healthy tooth structure, 21-70 indicate demineralization and caries, and 71-100 indicates advanced caries (figure 3.2). The manufacturer reports that lower numbers suggest healthy enamel whereas higher numbers suggest presence of demineralization and caries (http://www.thecanarysystem.com/about.php).





Figure 3.1The Canary System<sup>™</sup> The Canary System<sup>™</sup> allows for tooth surface scans on live patients to detect decalcification and dental caries. (Image obtained from the Canary System<sup>™</sup> website. http://www.thecanarysystem.com. Retrieved on 8-14-2016)





### Figure 3.2 The Canary Scale

Upon scanning a tooth surface, The Canary system<sup>™</sup> provides a number ranging from 0-100. Higher numbers indicate areas of decalcification and decay. (Image obtained from the Canary System<sup>™</sup> website. http://www.thecanarysystem.com. Retrieved on 8-14-2016)



#### **CHAPTER 4: MATERIALS AND METHODS**

#### **4.1 Patient Selection**

After obtaining approval from IRB (UNMC- IRB# 447-15) for this prospective study, twenty two subjects were randomly recruited from the pool of patients needing orthodontic treatment at UNMC, College of Dentistry, Orthodontic Department. The criteria for inclusion in this study were as follows: willingness to participate in this research project; minimum age of 10 years old; fully erupted maxillary central and lateral incisors, and requiring at least 6 months of orthodontic treatment with fixed appliances. The criteria for exclusion in this study were as follows: patients with peg maxillary lateral incisors; patients who are pregnant, currently using or have used antibiotics, corticosteroids or mouth rinses in the past 3 months; current smokers or those who have smoked in the past 3 months, and discolored, restored, presence of caries or WSLs on maxillary central and lateral incisors.

Each patient and legal guardian (if patient was under the age of 19) signed an informed consent, stating their desire to participate in this research project (Appendices A and B). In addition a "youth information sheet" was provided to patients under the age of 19 (Appendix C).

#### 4.2 Randomization of Treatments

Patients were randomly assigned to receive FF brackets (APC<sup>™</sup> Flash-Free Adhesive Coated Appliance System, 3M Unitek, Monrovia, CA) on either the maxillary right lateral and central incisors (teeth numbers 7 and 8, respectively) or maxillary left central and lateral incisors (teeth numbers 9 and 10, respectively) by the UNMC, Graduate Orthodontics Clinic staff member. The opposing maxillary left or maxillary right central and lateral incisors along with all the remaining teeth received conventional orthodontic brackets (Clarity<sup>™</sup> Advanced not pre-coated, 3M Unitek, Monrovia, CA) with conventional adhesives (Pad Lock<sup>™</sup> no-fluoride, Reliance Orthodontic Products, Inc, Itasca, IL). All patients were under the care of first year orthodontic residents at UNMC, College of Dentistry, Orthodontic graduate program.



#### 4.3 Patient Education and Information

All patients were provided with the same oral hygiene kit, which included an electric tooth brush (Oral B Pro 5000 Smartseries, Oral B, Cincinnati, OH) along with a large tube of fluoridated tooth paste (Crest Prohealth Advanced, Crest Company, Cincinnati, OH) and dental floss (SuperFloss, Oral B, Cincinnati, OH). Patients were given standard oral hygiene instructions which included brushing at least twice a day for 4 minutes and flossing at least once a day. All patients were instructed not to use mouth rinse for the first 6 weeks of treatment. The patient and guardian were also instructed that the patient must refrain from brushing on the day of and also refrain from eating or drinking one hour before the patient's research appointments. Patients and guardians were also instructed to inform the researchers of any changes in the patient's health or dental history. Each patient was compensated with a \$10 gift card for every research appointment attended.

#### 4.4 Bonding and Treatment Protocols

After randomly assigning Flash-Free brackets to either teeth numbers 7 and 8 or teeth numbers 9 and 10, and conventional brackets to the opposite maxillary central and lateral incisors, the brackets were bonded to the experimental teeth by first isolating all the teeth, then pumicing the facial aspects of the teeth, followed by application of 37% phosphoric acid (Etch Royale <sup>™</sup>, Pulpdent Corporation, Watertown, MA) for 20 seconds. The teeth were then rinsed and fully dried. A primer (Ortho Solo<sup>™</sup>, Ormco corporation, Orange, CA), was then applied onto the facial surfaces of teeth. The bonding agent was thinned out using air from the air/water syringe and light cured for 3 seconds. The FF brackets were then placed onto the tooth surfaces of assigned teeth and light cured for 12 seconds each. Conventional brackets on the opposite central and lateral incisors were then bonded by first applying adhesive (Pad Lock <sup>™</sup> no-fluoride, Reliance Orthodontic Products, Inc) at the base of the brackets by an orthodontic assistant, followed by placement onto the facial surfaces of assigned teeth and then removal of "flash" to the best of the clinician's ability using a short probe instrument and then light curing for 12 seconds each. The FF brackets were identical in terms of size, shape,



and prescription. After bonding, all patients initially received either a 014 or 016 Nickel-Titanium wire and the main arch wire was tied using steel ties on maxillary anterior teeth (teeth numbers 7, 8, 9, 10). None of the patients received orthodontic functional appliances during this research study. Advancement in wire size and type during the treatment were specific to the needs of the patient and were variable; however, most patients had the following wire sequence: round Nickel-Titanium, Rectangular Nickel-Titanium, Rectangular Stainless Steel wire. The orthodontic treatment (including bracket bonding and placing steel ties) were performed by first year orthodontic residents at UNMC, College of Dentistry, graduate orthodontic program.

#### 4.5 Research Timeline

Figure 4.1 demonstrates the timeline of this research project. All data and sample collection during appointments was performed by the main author. The patients were recalled for a total of 3 appointments to complete this research project as follows:

#### First Appointment

Patients presented 2 weeks  $\pm$  2 days after bonding for the first plaque collection (plaque T1) and the first Canary scan (Canary T1).

#### Second Appointment

Patients presented 6 weeks ± 2 days after bonding for the second plaque collection (plaque T2) Third Appointment

Patients presented 6 months ± 2 days after bonding for the second Canary scan (Canary T2).

#### **4.6 Dental Plaque Collection**

Patients presented to the UNMC, College of Dentistry, graduate orthodontic clinic at plaque T1 (2 weeks ± 2 days post-bonding) and plaque T2 (6 weeks ± 2 days post-bonding) for plaque collection. The maxillary main arch wire was removed. Plaque was collected from the four maxillary incisor teeth (maxillary left or right central and lateral incisors with FF brackets and maxillary left or right central and lateral incisors with conventional brackets and adhesives) using a separate, sterilized Hollenbeck dental instrument. Plaque was collected from around the orthodontic brackets of teeth numbers 7, 8, 9, 10, only. Plaque collection for each tooth was



standardized by a 4-pass technique sweep around the bracket base (Figure 4.2). The 4 pass technique was used 3 times for each tooth, and the plaque from each tooth was placed in separate sterilized centrifuge tubes (1.5ml micro-centrifuge conical tube natural color, VWR International, Radnor, PA) containing 0.5ml of PBS (Phosphate Buffered Saline). The centrifuge tubes containing the plaque were then stored at -80°C until the day of plaque analysis.

#### 4.7 Plaque Analysis

Bacterial numbers in plaque can be quantified using rapid adenosine triphosphate (ATP)– driven bioluminescence assays. BacTiter-Glo<sup>TM</sup> Microbial Cell Viability Assay (G8231 Promega, Madison, WI) is capable of measuring the amount of ATP in plaque samples (Robrish, Kemp et al. 1978; Robrish, Kemp et al. 1979; Ronner, Friel et al. 1999). Studies show that there is a strong correlation between ATP measurements and bacterial numbers in plaque, including numbers for oral streptococci (Pellegrini, Sauerwein et al. 2009; Fazilat, Sauerwein et al. 2010). ATP-driven bioluminescence uses luciferin enzyme and luciferin substrate that interact with bacterial ATP, as well as O<sub>2</sub> and Mg<sup>2+</sup> to produce AMP, oxyluciferin, pyrophosphate (PPi), CO<sub>2</sub>, and light of 560 nm wavelength (Robrish, Kemp et al. 1979; Karl 1980).

All plaque analyses were performed using BacTiter-Glo<sup>™</sup> Microbial Cell Viability Assay Kit (G8231 Promega, Madison, WI), and ATP-driven bioluminescence was measured by TD-20/20 lumionometer (Tuner Biosystems, Sunnyvale, CA). Relative light units (RLU) were calibrated using a standard curve of ATP. All T1 plaque collections were analyzed on the same day, and all T2 plaque collections were analyzed on the same day along with the ATP standard curve.

The plaque samples along with the BacTiter-Glo<sup>™</sup> buffer and BacTiter-Glo<sup>™</sup> substrate were thawed at room temperature overnight (approximately 10 hours) prior to the day of plaque analysis. All pipette tips and centrifuge tubes used during plaque analysis were sterilized by autoclaving.

On the day of plaque analysis, the BacTiter-Glo<sup>™</sup> buffer and BacTiter-Glo<sup>™</sup> substrate were mixed to form the BacTiter-Glo<sup>™</sup> reagent. The reagent was equilibrated at room



temperature for 1 hour. Each plaque sample from a single tooth was then mixed using a digital vortex mixer (Fisher Scientific, Hampton, NH) at 3000rpm for 30 seconds. The tip of a manual pipette was placed in the middle of the original plaque sample and 100µl of the original sample was transferred into a new centrifuge tube (1.5ml micro-centrifuge conical tube natural color, VWR International, Radnor, PA). This process was repeated for all plaque samples. 100µl of BacTiter-Glo<sup>™</sup> reagent was then added to each 100µl of the plaque samples in new centrifuge tubes and mixed with a digital vortex mixer (Fisher Scientific, Hampton, NH) at 500rpm for 10 seconds and incubated at room temperature for 15 minutes before analyzing the samples with the TD-20/20 lumionometer. This process was repeated 3 times for every tooth plaque sample and the mean was calculated.

An ATP standard curve was created by serial dilutions of known ATP concentration. The serial dilution ranged from 5 millimolar to 0.1 micromolar. Each ATP concentration was measured 3 times using the BacTiter-Glo<sup>™</sup> Microbial Cell Viability Assay Kit (G8231 Promega, Madison, WI) and mean RLU values were derived. Coefficient of determination was calculated for the ATP standard curve.

#### 4.8 Decalcification Analysis

The Canary System<sup>™</sup> (Quantum Dental Technologies Inc, Toronto, Canada) was used to measure the extent of decalcification and development of WSLs. Patients were recalled at Canary T1(2 weeks ± 2 days post-bonding) for an initial scan and at Canary T2 (6 months ± 2 days post-bonding) for a final Canary scan. The scan values were then compared. The Canary System<sup>™</sup> allows for detailed scan of the facial surfaces of anterior teeth by separating the facial aspect of the tooth into 9 segments (figure 4.3). Upon taking an intra-oral image of the desired tooth, each of the 9 segments of the tooth can be scanned individually. The scans are performed directly on the tooth surface with the intra-oral image serving as a guide, and the extent of decalcification is numerically displayed on each segment of the tooth (figure 4.4).

In this study, at plaque T1/Canary T1, after collecting plaque samples from the four maxillary incisors (as explained previously in section 4.6), all four maxillary incisors were brushed



using a disposable manual tooth brush by the researcher for one minute. The Canary System™ was calibrated using the calibrator provided by the manufacturer prior to every patient scan. The maxillary teeth were then isolated by a single cotton roll placed in the maxillary labial vestibule and all teeth were fully dried, the researcher proceeded to take intra-oral images and then performed scans using the Canary System™. Each tooth site was scanned 3 times and Canary numbers were recorded manually on a sheet and the mean of the 3 readings was calculated. For each tooth, the center segment was not scanned due to the presence of the orthodontic bracket. and the other 8 segments were named a-h (figure 4.5). To more accurately scan the same area of each segment of each tooth, the orthodontic bracket was used as a guide. The scans were performed along the cross-lines of the bracket slot for segments b, d, e, g, and 45 degrees to the cross-lines for segments a, c, f, h (figure 4.6). Patients were then recalled at Canary T2, during which the Canary System<sup>™</sup> was calibrated, then the orthodontic main arch wire was removed, the four maxillary incisors were brushed and isolated as previously described, and the researcher proceeded to obtain intra-oral images and scans using The Canary System<sup>™</sup>. Each tooth site was scanned 3 times and Canary numbers were recorded manually on a sheet and the mean of the 3 scans was calculated (Figure 4.5).

#### 4.9 Treatment Type Nomenclature

For the plaque and Canary scan analysis, the maxillary anterior teeth were named by the type of treatment as follows: C1 (conventional bracket on maxillary central incisor), C2 (conventional bracket on maxillary lateral incisor), FF1 (APC<sup>™</sup> Flash-Free bracket on maxillary central incisor), and FF2 (APC<sup>™</sup> Flash-Free bracket on maxillary lateral incisor). Depending on the treatment assignment, C1 can represent either the maxillary left or maxillary right maxillary central incisor with FF1 representing the contra lateral maxillary central incisor. In addition, C2 can represent either the maxillary lateral incisor with FF2 representing the contra-lateral maxillary lateral incisor.



#### 4.10 Reliability of the Canary Scan Measurements

To test the reliability of the Canary scan measurements, one of the certified dental assistants at the UNMC, College of dentistry, orthodontics department was trained by the researcher to perform repeat Canary scans of patients immediately after the researcher. Five randomly selected patients (patients number 8,11,12,18,19) at Canary T1, and five randomly selected patients (patient numbers 2,3,5,7,8) at Canary T2, were subjected to scans by both the researcher and the dental assistant immediately after one another. Scan measurements were used to calculate the inter-examiner reliability.

#### 4.11 Bond Failure

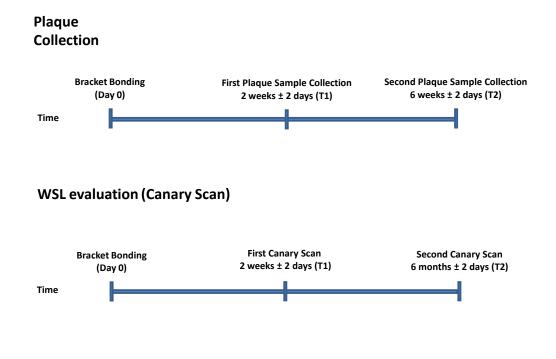
FF and conventional brackets on the maxillary central and lateral incisors were monitored for the first 6 months after bracket placement to evaluate the bond failure. No other brackets other than the maxillary incisors were included in this evaluation.

#### 4.12 Statistical Analysis

Paired t-test of the RLU differences of central incisors at plaque T1 and plaque T2 were performed, as well as paired t-test of the RLU differences of lateral incisors at plaque T1 and plaque T2. The significance level was set at p < 0.05.

Paired t-test was performed to analyze the differences in Canary scan measurements between Canary T1 and Canary T2. The Pearson correlation coefficient was derived to analyze the reliability of the Canary scan measurements. The significance level was set at p < 0.05. Spontaneous bond failure of FF brackets and conventional brackets were reported as a percentage.

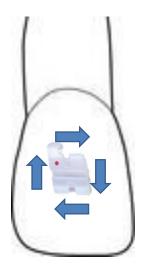




#### Figure 4.1. Experimental Timeline.

Patients were recalled a total of 3 times. Plaque samples were collected 2 weeks  $\pm 2$  days (Time 1) and 6 weeks  $\pm 2$  days (Time 2) after bonding. Canary scans to determine the degree of decalcification of enamel surfaces were performed at 2 weeks  $\pm 2$  days (Time 1) and then 6 months  $\pm 2$  days (Time 2).

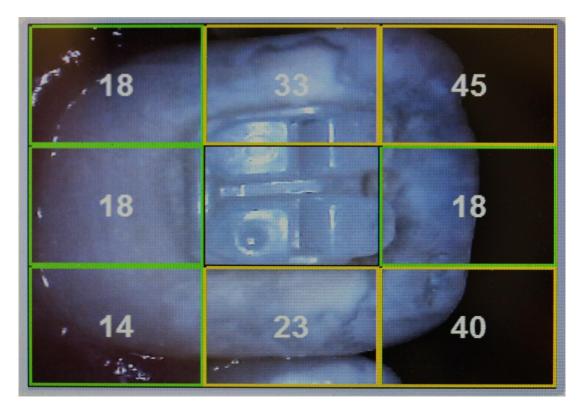




### Figure 4.2. Plaque Collection Technique: 4-Point Pass Technique

The initial pass starts at the incisal interface of the bracket and the tooth, followed by mesial, gingival, and finally distal surfaces. This technique was repeated 3 times for each tooth.





### Figure 4.3. The Canary Scan

Intra-oral photo of a test tooth at T2 (6 months  $\pm$  2 days after bonding). The Canary System<sup>TM</sup> divides the facial surface of photograph of an incisor tooth into 9 equal segments. Note higher numbers on multiple segments of this tooth, which are identified with the yellow color which correspond to the presence of WSLs visually.

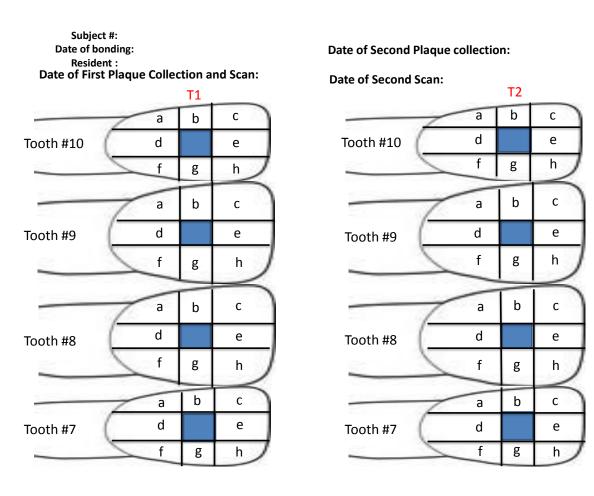




### Figure 4.4 Canary Scan Demonstration on an Extracted Tooth

The Canary scan is performed by holding the tip of the scanner on the desired tooth surface to be scanned. An extracted maxillary anterior tooth bonded with APC<sup>™</sup> Flash-Free bracket is being used to demonstrate the Canary scan.

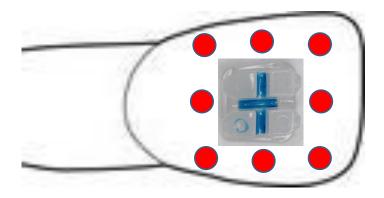




#### Figure 4.5 Canary Scan Recording Sheet

Scan numbers were manually recorded on the above sheet for every patient. Note each tooth is broken down into 8 segments (**a** through **h**), omitting the central segment (marked blue) where the orthodontic bracket is bonded. Each segment of each tooth was scanned 3 times at T1 (2 weeks  $\pm 2$  days post-bonding) and T2 (6 months  $\pm 2$  days post-bonding).





### Figure 4.6 Orthodontic Bracket Used as a Guide for the Scans

The cross-lines of the bracket slot (blue lines in the middle of the bracket in this image) were used to more accurately scan the same segment of each tooth when performing Canary scans. Segments b, d, e, g (as outlined in figure 3.4) were scanned using the cross-lines, and segments a, c, f, h (as outlined in figure 3.4) were scanned by placing the scanner tip 45 degrees relative to the cross-lines of the bracket slot. The red circles represent the placement of the tip of the scanner of the Canary System<sup>TM</sup> on the tooth surface.



#### **CHAPTER 5: RESULTS**

#### **5.1 Patient Recruitment**

Twenty two subjects were initially recruited for this study. All subjects were patients who presented to UNMC, College of Dentistry, graduate orthodontic clinic to receive orthodontic care. Two of the 22 patients were excluded from the study since they needed to undergo treatment with an orthodontic functional appliance prior to bonding orthodontic brackets and would not fit the timeline of this research project. A total of 20 patients participated in this research project (8 males and 12 females). There were a total of 5 patients age 19 and over (1 male and 4 females) and a total of 15 patients between the ages of 10 to18 (7 males and 8 females). 17 patients were Caucasian, 1 patient was African American, and 2 patients were Hispanic (table 5.1).

Twenty patients presented for and completed the plaque collection at plaque T1, and plaque T2. Twenty patients also presented for and completed the Canary scan at Canary T1. However, 1 patient (patient #12) relocated out of state and two patients had bracket failures (patient #9: tooth number 10 with FF treatment, and patient #19: tooth number 7 with FF treatment) prior to the Canary scan at Canary T2. Therefore, patient #12 along with tooth number 10 in patient #9 and tooth number 7 in patient #19 were excluded from the Canary scan analysis.

FF brackets were randomly assigned to patients by a clinical staff at UNMC, College of Dentistry, graduate orthodontic clinic. Treatment assignment is outlined in table 5.2.

#### 5.2 Plaque Analysis Results

Plaque samples were analyzed and the mean of the 3 RLU measurements were recorded for each tooth at plaque T1 (tables 5.3-5.6) and plaque T2 (tables 5.7-5.10). The differences of the means between the maxillary central incisors (teeth numbers 8 and 9) and maxillary lateral incisors (teeth numbers 7 and 10) were derived for plaque T1 (table 5.11) and plaque T2 (table 5.12). A visual example of the differences in plaque for patient #1 at T1 and T2 are shown in figures 5.1 and 5.2, respectively.



It was found that there were no significant differences in plaque retention when comparing conventional versus FF brackets bonded to maxillary central incisors (C1 to FF1) at plaque T1 (figure 5.3) and at plaque T2 (figures 5.5). In addition, it was found that there were no significant differences in plaque retention when comparing conventional versus FF brackets bonded to maxillary lateral incisors (C2 to FF2) at plaque T1 (figure 5.4) and at plaque T2 (figure 5.6). ATP standard curve was created as previously noted and is shown in figure 5.7.

#### 5.3 Decalcification Analysis Results

The Canary scan measurements were recorded at Canary T1 and Canary T2 and the mean of the 3 scans for each segment (a-h) of each tooth treatment (C1, C2, FF1, and FF2) was taken along with standard deviation, coefficient of variation, and the differences in mean from Canary T2 to Canary T1 (T2-T1) (appendix D).

Using the Canary scan, the same segment (a-h) of the same tooth treatment (C1, C2, FF1, FF2) were compared between Canary T1 and Canary T2 for potential development of decalcification within each treatment category. T-tests were performed for every segment of each treatment category. A significant increase in Canary scan measurements was found in segments "c", "g", and "h", of C1 treatment (conventional bracket on either maxillary left or maxillary right central incisor) (figure 5.8 parts 1 and 2); segments "b", and "g" for treatment C2 (conventional bracket on either maxillary left or maxillary left or maxillary right lateral incisor) (figure 5.9 parts 1 and 2); segments "g" and "h" for treatment FF1 (APC™ Flash-Free bracket on either maxillary left or maxillary left or maxillary right central incisor) (figure 5.10 parts 1 and 2); segments "b", and "g" for treatment FF2 (APC<sup>™</sup> Flash-Free bracket on either maxillary left or maxillary left or maxillary left or maxillary right lateral incisor) (figure 5.11 parts 1 and 2); segments "b", and "g" for treatment FF2 (APC<sup>™</sup> Flash-Free bracket on either maxillary left or maxillary left or maxillary right lateral incisor) (figure 5.11 parts 1 and 2). Statistical analyses of Canary measurements of other tooth segments that were found to be statistically insignificant are presented in appendix E.

Using the Canary scan, each segment of each treatment group was compared to its contra-lateral side. Segments (a-h) of each maxillary central incisor with conventional brackets were compared to the same segment (a-h) of the contra-lateral maxillary central incisor with FF bracket (C1a-FF1a, C1b-FF1b, C1c-FF1c, etc). Segments (a-h) of each maxillary lateral incisor



with conventional brackets were compared to the same segment (a-h) of the contra-lateral maxillary lateral incisor with FF bracket (C2a-FF2a, C2b-FF2b, C2c-FF2c, etc). Differences were analyzed using paired t-tests. It was found that there were no significant differences in Canary scan measurements when comparing conventional brackets to FF brackets on either the maxillary central or the maxillary lateral incisors. Statistical analyses are displayed in appendix F.

#### 5.4 Inter-Examiner Reliability for the Canary Scan

Five randomly selected patients (patients number 8,11,12,18,19) at Canary T1 and five randomly selected patients (patient numbers 2,3,5,7,8) at Canary T2 were scanned by the researcher followed immediately by a certified dental assistant at UNMC, College of Dentistry, Orthodontics Department. The Canary scans were compared using the Pearson correlation coefficient. For Canary T1 a correlation coefficient of 0.7828 was found (figure 5.12), for Canary T2 a correlation coefficient of 0.9377 was found (figure 5.13). A combined correlation coefficient of 0.8924 was calculated for both Canary T1 and Canary T2 scans (figure 5.14).

#### 5.5 Bond Failure Results

A total of 19 patients were included in the bond failure portion of the study with 38 brackets being conventional and 38 brackets being FF. Two FF brackets bonded to lateral incisors (FF2 treatment) of two different patients failed within the first 6 months of treatment. Both patients were bonded by the same operator. The two failed FF brackets represent a 5.26% failure rate for the FF brackets in our sample within a 6 month period. None of the conventional brackets failed within the first 6 months of treatment, which represents a 0% failure rate for the conventional brackets within the first 6 months of treatment.



Subject Characteristics	Number of Patients
Caucasian	17
Hispanic	2
African American	1
Female	12
Male	8
Between 10 to 18 years old	15
Over 19 years old	5

### **Table 5.1 Characteristics of Subjects**

A total of 20 patients participated in this research project. The majority of patients were Caucasian and between the ages of 10 to 18, with 12 being female and 8 being male.



Subject Number	Maxillary Anterior Side Receiving Flash-Free Brackets	Teeth Receiving Flash-Free Brackets	Teeth Receiving Conventional Brackets	Note
1	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	N/A
2	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	N/A
3	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	N/A
4	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	N/A
5	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	N/A
6	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	N/A
7	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	N/A
8	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	N/A
9	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	Tooth#10 Excluded
10	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	N/A
11	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	N/A
12	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	Patient Excluded
13	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	N/A
14	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	N/A
15	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	N/A
16	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	N/A
17	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	N/A
18	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	N/A
19	maxillary right	tooth#7 & tooth#8	tooth#9 & tooth#10	Tooth#7 Excluded
20	maxillary left	tooth#9 & tooth#10	tooth#7 & tooth#8	N/A

## Table 5.2 Treatment Assignment

APC<sup>™</sup> Flash-Free brackets were assigned to either maxillary left or maxillary right incisor teeth.



Time	Patient Number	Mean	SD	CV
T1	1	624.8	48.83	7.815301
T1	2	755.1	65.58	8.684942
T1	3	103.9	40.7	39.17228
T1	4	96.82	4.509	4.657096
T1	5	34.99	9.632	27.52787
T1	6	106.6	14.72	13.80863
T1	7	44.65	12.45	27.88354
T1	8	427.7	67.72	15.83353
T1	9	470.1	68.97	14.67135
T1	10	904.8	59.33	6.55725
T1	11	384	35.57	9.263021
T1	12	198.2	35.82	18.07265
T1	13	403.1	34.17	8.476805
T1	14	112.6	17.11	15.19538
T1	15	36.63	4.194	11.44963
T1	16	65.35	13.69	20.94874
T1	17	688.9	43.88	6.369575
T1	18	4.757	0.2206	4.637376
T1	19	238.3	16.86	7.075115
T1	20	225.7	28.38	12.57421

# Table 5.3 Maxillary Central Incisor Bonded with Conventional Bracket: Means, SD, and CV at T1

Mean values of the 3 plaque measurements for tooth "C1" (maxillary central incisor bonded with conventional bracket) along with SD (standard deviation), and CV (coefficient of variation) are derived for patients 1-20 at plaque collection T1 (2 weeks  $\pm$  2 days post-bonding). Note all measurements are in RLUs (relative light units).



Time	Patient Number	Mean	SD	CV
T1	1	1465	171.8	11.72696246
T1	2	727.5	179	24.604811
T1	3	180.2	24.05	13.34628191
T1	4	148.6	23.76	15.98923284
T1	5	63.96	18.87	29.50281426
T1	6	28.25	3.406	12.05663717
T1	7	98.96	12.03	12.15642684
T1	8	618.2	64.82	10.48527984
T1	9	922.8	115.8	12.54876463
T1	10	1218	145.1	11.91297209
T1	11	246.3	16.35	6.638246041
T1	12	488.9	97.3	19.90182041
T1	13	512.8	15.06	2.936817473
T1	14	334.8	59.06	17.64038232
T1	15	95.23	1.643	1.72529665
T1	16	152.7	28.18	18.45448592
T1	17	554.2	109.1	19.68603392
T1	18	35.83	2.109	5.886128942
T1	19	523	121.7	23.26959847
T1	20	360.8	61.41	17.02050998

# Table 5.4 Maxillary Lateral Incisor Bonded with Conventional Bracket: Means, SD, and CV at T1

Mean values of the 3 plaque measurements for tooth "C2" (maxillary lateral incisor bonded with conventional bracket) along with SD (standard deviation), and CV (coefficient of variation) are derived for patients 1-20 at plaque collection T1 (2 weeks  $\pm$  2 days post-bonding). Note all measurements are in RLUs.



Time	Patient Number	Mean	SD	CV
T1	1	744.1	89.55	12.03467
T1	2	624.1	104.6	16.76013
T1	3	134.2	11.19	8.338301
T1	4	210.7	9.346	4.435691
T1	5	119.5	11.13	9.313808
T1	6	40.65	1.594	3.921279
T1	7	59.99	9.518	15.86598
T1	8	205.2	31.12	15.16569
T1	9	624.4	27.41	4.389814
T1	10	117.1	5.787	4.94193
T1	11	492.6	42.69	8.666261
T1	12	383.3	68.1	17.76676
T1	13	314.8	36.82	11.69632
T1	14	408.3	69.44	17.0071
T1	15	45.58	2.102	4.611672
T1	16	58.32	3.951	6.774691
T1	17	381.8	24.71	6.471975
T1	18	5.801	0.2766	4.768143
T1	19	62.52	10.55	16.8746
T1	20	110.8	19.7	17.77978

# Table 5.5 Maxillary Central Incisor Bonded with APC<sup>™</sup> Flash-Free Bracket: Means, SD, and CV at T1

Mean values of the 3 plaque measurements for tooth "FF1" (maxillary central incisor bonded with APC<sup>™</sup> Flash-Free bracket) along with SD (standard deviation), and CV (coefficient of variation) are derived for patients 1-20 at plaque collection T1 (2 weeks ± 2 days post-bonding). Note all measurements are in RLUs.



Time	Patient Number	Mean	SD	CV
T1	1	776.9	147.3	18.95997
T1	2	1307	215.7	16.50344
T1	3	95.19	13.03	13.68841
T1	4	235.8	19.89	8.435115
T1	5	150.7	44.96	29.83411
T1	6	46.65	7.242	15.52412
T1	7	49.28	16.17	32.8125
T1	8	258.2	35.26	13.65608
T1	9	237.6	41.69	17.5463
T1	10	1564	211.9	13.54859
T1	11	472.7	63.45	13.42289
T1	12	578	75.6	13.07958
T1	13	501.1	24.8	4.949112
T1	14	203.6	19.97	9.808448
T1	15	39.81	9.528	23.93369
T1	16	45.19	4.384	9.701261
T1	17	645.3	131.1	20.31613
T1	18	35.66	0.4141	1.161245
T1	19	800.7	124.9	15.59885
T1	20	162.3	31.66	19.50709

# Table 5.6 Maxillary Lateral Incisor Bonded with APC<sup>™</sup> Flash-Free Bracket: Means, SD, and CV at T1

Mean values of the 3 plaque measurements for tooth "FF2" (maxillary lateral incisor bonded with APC<sup>™</sup> Flash-Free bracket) along with SD (standard deviation), and CV (coefficient of variation) are derived for patients 1-20 at plaque collection T1 (2 weeks ± 2 days post-bonding). Note all measurements are in RLUs.



Time	Patient Number	Mean	SD	CV
T2	1	1565	168.5	10.76677
T2	2	1060	137.1	12.93396
T2	3	207.4	22.71	10.94986
T2	4	598	27.04	4.521739
T2	5	189.8	27.7	14.59431
Т2	6	1706	71.04	4.164127
Т2	7	160.3	18.79	11.72177
T2	8	2200	196	8.909091
Т2	9	1663	60.58	3.642814
Т2	10	2366	119.3	5.042265
Т2	11	1011	119.5	11.81998
Т2	12	623.3	36.11	5.793358
T2	13	2788	268	9.612626
Т2	14	763.5	132.8	17.39358
Т2	15	165.5	21.73	13.12991
Т2	16	943.7	80.87	8.569461
T2	17	400.8	31.51	7.861776
Т2	18	389.9	25.67	6.583739
T2	19	38.28	4.262	11.13375
T2	20	160.6	6.889	4.289539

# Table 5.7 Maxillary Central Incisor Bonded with Conventional Bracket: Means, SD, and CV at T2

Mean values of the 3 plaque measurements for tooth "C1" (maxillary central incisor bonded with conventional bracket) along with SD (standard deviation), and CV (coefficient of variation) are derived for patients 1-20 at plaque collection T2 (6 weeks  $\pm$  2 days post-bonding). Note all measurements are in RLUs.



Time	Patient Number	Mean	SD	CV
T2	1	2897	497.4	17.16948567
T2	2	1185	137.5	11.60337553
T2	3	1370	57.87	4.224087591
T2	4	573.7	129.7	22.60763465
T2	5	397.6	49.95	12.56287726
T2	6	2200	185.8	8.445454545
T2	7	1590	125.5	7.893081761
Т2	8	2588	174.2	6.731066461
T2	9	2422	137	5.656482246
T2	10	5398	110.7	2.050759541
T2	11	2667	484.2	18.1552306
T2	12	1072	107.5	10.02798507
T2	13	3870	388.9	10.04909561
T2	14	1260	193.9	15.38888889
T2	15	500.9	104.3	20.82251946
T2	16	2022	477.9	23.63501484
T2	17	580.9	112.9	19.43535893
T2	18	1873	150	8.008542445
T2	19	377.9	26.82	7.097115639
Т2	20	353.6	29.62	8.376696833

# Table 5.8 Maxillary Lateral Incisor Bonded with Conventional Bracket: Means, SD, and CV at T2

Mean values of the 3 plaque measurements for tooth "C2" (maxillary lateral incisor bonded with conventional bracket) along with SD (standard deviation), and CV (coefficient of variation) are derived for patients 1-20 at plaque collection T2 (6 weeks  $\pm$  2 days post-bonding). Note all measurements are in RLUs.



Time	Patient Number	Mean	SD	CV
T2	1	2298	234.8	10.21758
T2	2	1038	161.7	15.57803
T2	3	134.4	17.84	13.27381
T2	4	319	34.39	10.78056
T2	5	278.2	39.98	14.37096
T2	6	1941	126.8	6.532715
T2	7	408.3	30.15	7.384276
Т2	8	1725	186.5	10.81159
T2	9	2421	210.5	8.694754
T2	10	1285	63	4.902724
T2	11	789.2	112.3	14.2296
Т2	12	557.2	55.41	9.944365
T2	13	4086	174.4	4.268233
T2	14	442.1	30.5	6.898892
T2	15	180	21.93	12.18333
T2	16	2013	254.3	12.63289
T2	17	647.1	107.3	16.58167
T2	18	195.6	13	6.646217
T2	19	32.52	5.335	16.40529
T2	20	121.5	1.818	1.496296

# Table 5.9 Maxillary Central Incisor Bonded with APC<sup>™</sup> Flash-Free Bracket: Means, SD, and CV at T2

Mean values of the 3 plaque measurements for tooth "FF1" (maxillary central incisor bonded with APC<sup>™</sup> Flash-Free bracket) along with SD (standard deviation), and CV (coefficient of variation) are derived for patients 1-20 at plaque collection T2 (6 weeks ± 2 days post-bonding). Note all measurements are in RLUs.



Time	Patient Number	Mean	SD	CV
T2	1	4031	120.8	2.996775
T2	2	2200	452.1	20.55
T2	3	1029	157.6	15.31584
T2	4	812.9	86.79	10.67659
T2	5	358.6	19.12	5.331846
T2	6	4425	283.1	6.39774
T2	7	2049	218.4	10.65886
T2	8	1912	175.8	9.194561
T2	9	750.9	45.03	5.996804
T2	10	4556	167.5	3.676471
T2	11	1440	97.37	6.761806
Т2	12	1015	66.92	6.593103
T2	13	3414	243.4	7.129467
T2	14	821.8	4.912	0.597712
T2	15	149.3	9.019	6.040857
T2	16	2707	240.4	8.88068
T2	17	991.3	160.1	16.15051
T2	18	1271	142.8	11.23525
T2	19	231.4	12.23	5.28522
T2	20	178.4	24.55	13.76121

# Table 5.10 Maxillary Lateral Incisor Bonded with APC<sup>™</sup> Flash-Free Bracket: Means, SD, and CV at T2

Mean values of the 3 plaque measurements for tooth "FF2" (maxillary lateral incisor bonded with APC<sup>™</sup> Flash-Free bracket) along with SD (standard deviation), and CV (coefficient of variation) are derived for patients 1-20 at plaque collection T2 (6 weeks ± 2 days post-bonding). Note all measurements are in RLUs.



Time	Patient Number	C1	C2	FF1	FF2	C1-FF1	C2-FF2
T1	1	624.8	1465	744.1	776.9	-119.3	688.1
T1	2	755.1	727.5	624.1	1307	131	-579.5
T1	3	103.9	180.2	134.2	95.19	-30.3	85.01
T1	4	96.82	148.6	210.7	235.8	-113.88	-87.2
T1	5	34.99	63.96	119.5	150.7	-84.51	-86.74
T1	6	106.6	28.25	40.65	46.65	65.95	-18.4
T1	7	44.65	98.96	59.99	49.28	-15.34	49.68
T1	8	427.7	618.2	205.2	258.2	222.5	360
T1	9	470.1	922.8	624.4	237.6	-154.3	685.2
T1	10	904.8	1218	117.1	1564	787.7	-346
T1	11	384	246.3	492.6	472.7	-108.6	-226.4
T1	12	198.2	488.9	383.3	578	-185.1	-89.1
T1	13	403.1	512.8	314.8	501.1	88.3	11.7
T1	14	112.6	334.8	408.3	203.6	-295.7	131.2
T1	15	36.63	95.23	45.58	39.81	-8.95	55.42
T1	16	65.35	152.7	58.32	45.19	7.03	107.51
T1	17	688.9	554.2	381.8	645.3	307.1	-91.1
T1	18	4.757	35.83	5.801	35.66	-1.044	0.17
T1	19	238.3	523	62.52	800.7	175.78	-277.7
T1	20	225.7	360.8	110.8	162.3	114.9	198.5

## Table 5.11 Differences in Mean for Plaque Analysis at T1

Mean values of the 3 plaque measurements for teeth "C1" (maxillary central incisor with conventional adhesive), "C2" (maxillary lateral incisor with conventional adhesive), "FF1" (maxillary central incisor with APC<sup>™</sup> Flash-Free adhesive), and "FF2" (maxillary lateral incisor with APC<sup>™</sup> Flash-Free adhesive) are derived for patients 1-20 at plaque collection T1 (2 weeks ± 2 days post-bonding). The difference is taken by subtracting the RLU (relative light unit) value of the Flash-Free plaque from conventional plaque. Note all measurements are in RLUs.

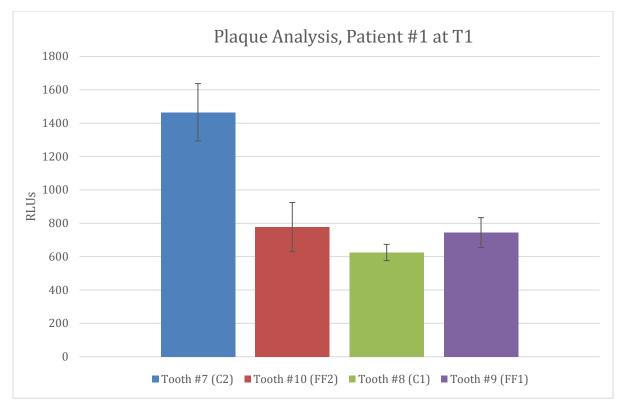


Time	Patient Number	C1	C2	FF1	FF2	C1-FF1	C2-FF2
T2	1	1565	2897	2298	4031	-733	-1134
T2	2	1060	1185	1038	2200	22	-1015
T2	3	207.4	1370	134.4	1029	73	341
T2	4	598	573.7	319	812.9	279	-239.2
T2	5	189.8	397.6	278.2	358.6	-88.4	39
T2	6	1706	2200	1941	4425	-235	-2225
T2	7	160.3	1590	408.3	2049	-248	-459
T2	8	2200	2588	1725	1912	475	676
T2	9	1663	2422	2421	750.9	-758	1671.1
T2	10	2366	5398	1285	4556	1081	842
T2	11	1011	2667	789.2	1440	221.8	1227
T2	12	623.3	1072	557.2	1015	66.1	57
T2	13	2788	3870	4086	3414	-1298	456
T2	14	763.5	1260	442.1	821.8	321.4	438.2
T2	15	165.5	500.9	180	149.3	-14.5	351.6
T2	16	943.7	2022	2013	2707	-1069.3	-685
T2	17	400.8	580.9	647.1	991.3	-246.3	-410.4
T2	18	389.9	1873	195.6	1271	194.3	602
T2	19	38.28	377.9	32.52	231.4	5.76	146.5
Т2	20	160.6	353.6	121.5	178.4	39.1	175.2

## Table 5.12 Differences in Mean for Plaque Analysis at T2

Mean values of the 3 plaque measurements for teeth ""C1" (maxillary central incisor with conventional adhesive), "C2" (maxillary lateral incisor with conventional adhesive), "FF1" (maxillary central incisor with APC<sup>™</sup> Flash-Free adhesive), and "FF2" (maxillary lateral incisor with APC<sup>™</sup> Flash-Free adhesive) are derived for patients 1-20 at plaque collection T2 (6 weeks ± 2 days post-bonding). The difference is taken by subtracting the RLU (relative light unit) value of the APC<sup>™</sup> Flash-Free plaque from conventional plaque. Note all measurements are in RLUs.

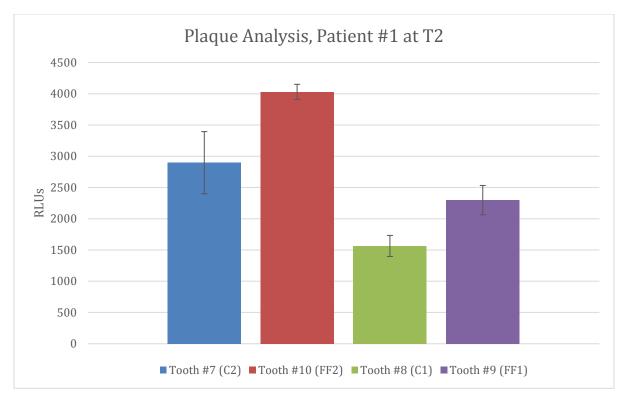




## Figure 5.1 Plaque Analysis, Patient #1 at T1

In this example, RLU values of plaque for tooth number 7 (C2) signified by the blue bar is compared to tooth number 10 (FF2) signified by the red bar. RLU values of plaque for tooth number 8 (C1) signified by the green bar is compared to tooth number 9 (FF1) signified by the purple bar. Standard deviation is shown as error bars. The differences in RLU values between C1 and FF1, and between C2 and FF2 at T1 (2 weeks ± 2 days post-bonding) are used to calculate any significant differences using a paired t-test.





## Figure 5.2 Plaque Analysis, Patient #1 at T2

In this example, RLU values of plaque for tooth number 7 (C2) signified by the blue bar is compared to tooth number 10 (FF2) signified by the red bar. RLU values of plaque for tooth number 8 (C1) signified by the green bar is compared to tooth number 9 (FF1) signified by the purple bar. Standard deviation is shown as error bars. The differences in RLU values between C1 and FF1, and between C2 and FF2 at T2 (6 weeks ± 2 days post-bonding) are used to calculate any significant differences using a paired t-test.



	Time= T1							
Ν	Mean		Std Dev	Std Err		Min	imum	Maximum
20	39.16	18	229.4	51.	2977		-295.7	787.7
Mean 95% CL Mean Std Dev 95% CL Std Dev								

146.5

39.1618

-68.2055

Difference: C1 - FF1

I	DF	t Value	Pr >  t
	19	0.76	0.4546

229.4

174.5

335.1

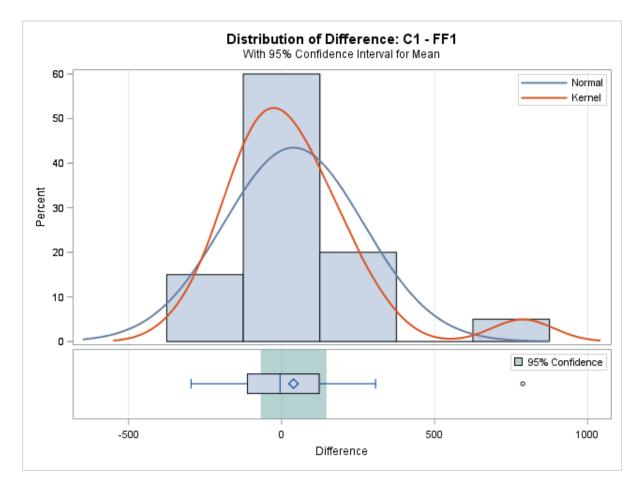


Figure 5.3 Paired T-test for Plaque Retention Differences between Maxillary Central Incisors with Conventional versus APC<sup>™</sup> Flash-Free Brackets (C1 and FF1) at T1 Paired t-test shows no significant differences in plaque retention when comparing conventional brackets to APC<sup>™</sup> Flash-Free brackets bonded to maxillary central incisors at 2 weeks ± 2 days post-bonding.



lime: 11							
Ν	Mean	Std Dev	Std Err	Minimum	Maximum		
20	28.5175	303.7	67.9204	-579.5	688.1		

Difference: C2 - FF2

Mean	95% CL Mean		Std Dev	95% CL Std Dev	
28.5175	-113.6	170.7	303.7	231.0	443.6

DF	t Value	Pr >  t
19	0.42	0.6793

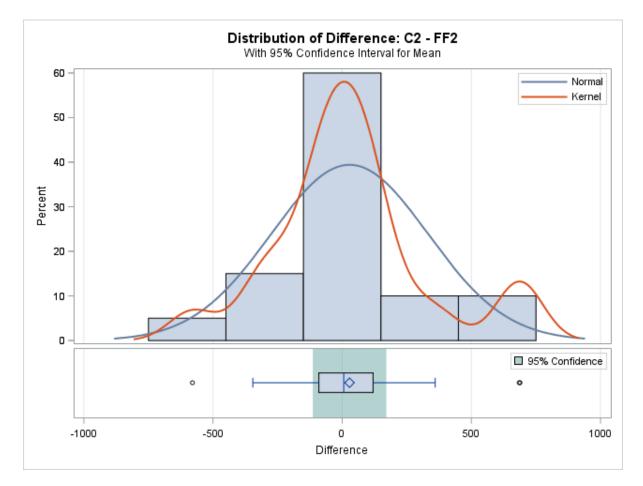


Figure 5.4 Paired T-test for Plaque Retention Differences between Maxillary Lateral Incisors with Conventional versus APC<sup>™</sup> Flash-Free Brackets (C2 and FF2) at T1 Paired t-test shows no significant differences in plaque retention when comparing conventional brackets to APC<sup>™</sup> Flash-Free brackets bonded to maxillary lateral incisors at 2 weeks ± 2 days post-bonding.



Difference: C1 - FF1 Time= T2							
Ν	Mean	Std Dev	Std Err	Minimum	Maximum		
20	-95.6020	543.7	121.6	-1298.0	1081.0		

Mean	95% CL	. Mean	Std Dev	95% CL	Std Dev
-95.6020	-350.1	158.9	543.7	413.5	794.1

DF t Value		Pr >  t	
19	-0.79	0.4414	

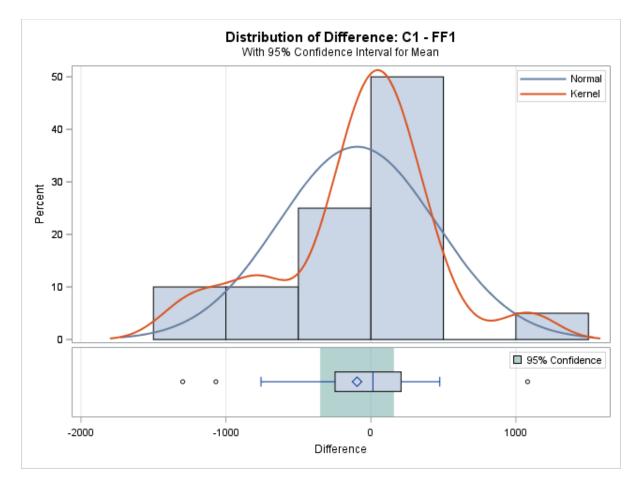


Figure 5.5 Paired T-test for Plaque Retention Differences between Maxillary Central Incisors with Conventional versus APC<sup>™</sup> Flash-Free Brackets (C1 and FF1) at T2 Paired t-test shows no significant differences in plaque retention when comparing conventional brackets to APC<sup>™</sup> Flash-Free brackets bonded to maxillary central incisors at 6 weeks ± 2 days post-bonding.



lime: 12						
Ν	Mean	Std Dev	Std Err	Minimum	Maximum	
20	42.7500	878.4	196.4	-2225.0	1671.1	

Difference:C2-FF2

Mean	95% CL	. Mean	Std Dev	95% CL	. Std Dev
42.7500	-368.3	453.8	878.4	668.0	1282.9

DF	t Value	Pr >  t
19	0.22	0.8300

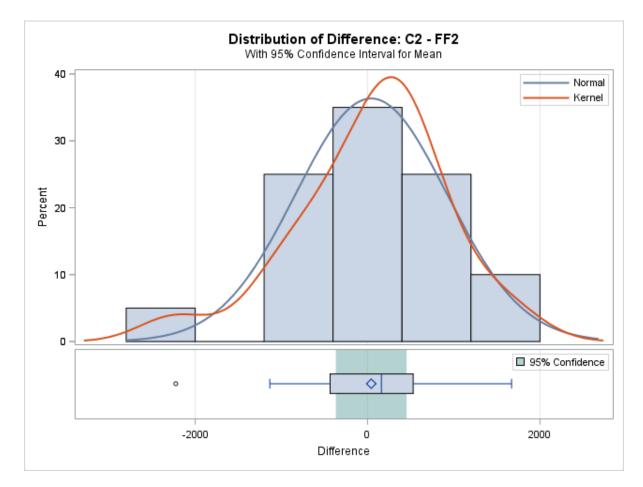
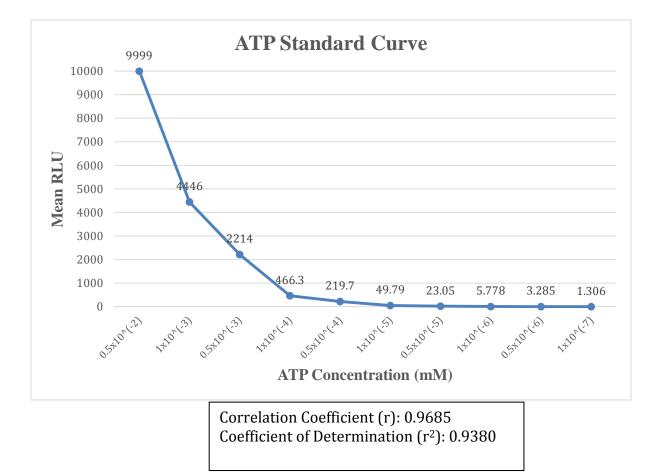


Figure 5.6 Paired T-test for Plaque Retention Differences between Maxillary Lateral Incisors with Conventional versus APC<sup>™</sup> Flash-Free Brackets (C2 and FF2) at T2 Paired t-test shows no significant differences in plaque retention when comparing conventional brackets to APC<sup>™</sup> Flash-Free brackets bonded to maxillary lateral incisors at 6 weeks ± 2 days post-bonding.



ATP Concentration	Mean RLU	SD	C۷
0.5x10^ (-2)	9999	0	0
1x10^ (-3)	4446	38.21	0.8594
0.5x10^ (-3)	2214	26.27	1.187
1x10^ (-4)	466.3	11.41	2.447
0.5x10^ (-4)	219.7	5.254	2.391
1x10^ (-5)	49.79	0.8571	1.721
0.5x10^ (-5)	23.05	1.052	4.564
1x10^ (-6)	5.778	0.1887	3.266
0.5x10^ (-6)	3.285	0.2493	7.589
1x10^ (-7)	1.306	0.0837	6.409



## Figure 5.7 ATP Standard Curve

Each known ATP concentration was measured 3 times and mean RLU (relative light unit) values were taken. Correlation coefficient and coefficient of determination were calculated.



#### Difference: Time2 - Time1 Trt\_Site=C1c

Ν	Mean	Std Dev	Std Err	Minimum	Maximum	
19	3.7895	6.8360	1.5683	-4.0000	21.0000	

Mean	95% CL Mean		Std Dev	95% CL Std Dev	
3.7895	0.4946	7.0843	6.8360	5.1654	10.1093

DF	t Value	Pr >  t
18	2.42	0.0265

#### Difference: Time2 - Time1 Trt Site=C1g

Ν	Mean	Std Dev	Std Err	Minimum	Maximum	
19	3.5789	7.4186	1.7019	-13.0000	17.0000	

Mean	95% CL Mean		Std Dev	95% CL	Std Dev
3.5789	0.00331	7.1546	7.4186	5.6056	10.9708

DF	t Value	Pr >  t
18	2.10	0.0498

#### Difference: Time2 - Time1 Trt Site=C1h

Ν	Mean	Std Dev	Std Err	Minimum	Maximum	
19	4.7368	7.1246	1.6345	-4.0000	24.0000	

Mean	95% CI	_ Mean	Std Dev	95% CL Std Dev		
4.7368	1.3029	8.1708	7.1246	5.3835	10.5361	

DF	t Value	Pr >  t
18	2.90	0.0096

Figure 5.8 (part 1 of 2) Statistically Significant Increase in Canary Scan Measurement for Maxillary Central incisor with Conventional Bracket (C1) between T1 and T2



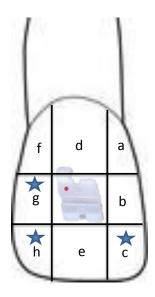


Figure 5.8 (part 2 of 2) Statistically Significant Increase in Canary Scan Measurement for Maxillary Central incisor with Conventional Bracket (C1) between T1 and T2

Segments c, g, and h (signified by a blue star) had a significant increase in Canary scan measurement from T1 to T2 for treatment C1. T1: 2 weeks  $\pm$  2 days post-bonding

T2: 6 months ± 2 days post-bonding



Trt_Site=C2b									
Ν	Ме	an	Std	Dev	St	d Err	Mir	nimum	Maximum
19	4.21	05	7.4	1728	1.	7144	-14	4.0000	18.0000
Μ	Mean 95% CL M		_ Mea	an	Std [	Dev	95% C	L Std Dev	
4.2	105	0.6	880	7.81	23	7.4	728	5.6465	11.0509

Difference: Time2 - Time1

DF	t Value	Pr >  t	
18	2.46	0.0244	

Figure 5.9 (part 1 of 2) Statistically Significant Increase in Canary Scan Measurement for Maxillary Lateral Incisor with Conventional Bracket (C2) between T1 and T2



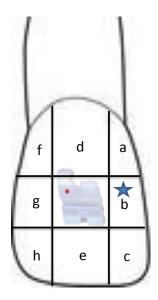


Figure 5.9 (part 2 of 2) Statistically Significant Increase in Canary Scan Measurement for Maxillary Lateral Incisor with Conventional Bracket (C2) between T1 and T2 Segment b (signified by a blue star) had a significant increase in Canary scan measurement from T1 to T2 for treatment C2.

T1: 2 weeks  $\pm$  2 days post-bonding

T2: 6 months ± 2 days post-bonding



### Difference: Time2 - Time1 Trt\_Site=FF1g

Ν	Mean	Std Dev	Std Err	Minimum	Maximum	
19	3.6316	6.4482	1.4793	-9.0000	13.0000	

Mean	95% CL Mean		Std Dev	95% CL Std Dev		
3.6316	0.5237	6.7395	6.4482	4.8723	9.5357	

DF	t Value	Pr >  t
18	2.45	0.0245

### Difference: Time2 - Time1 Trt\_Site=FF1h

Ν	Mean Std Dev	Std Err	Minimum	Maximum	
19	5.6842	7.1496	1.6402	-3.0000	23.0000

Mean	95% CL Mean		Std Dev	95% CL Std Dev		
5.6842	2.2382	9.1302	7.1496	5.4023	10.5730	

DF t Value Pr >		Pr >  t
18	3.47	0.0028

Figure 5.10 (part 1 of 2) Statistically Significant Increase in Canary Scan Measurement for Maxillary Central Incisor with APC<sup>™</sup> Flash-Free Bracket (FF1) between T1 and T2



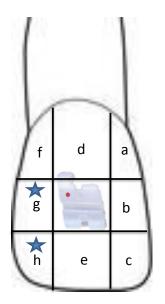


Figure 5.10 (part 2 of 2) Statistically Significant Increase in Canary Scan Measurement for Maxillary Central Incisor with APC<sup>™</sup> Flash-Free Bracket (FF1) between T1 and T2 Segments g and h (signified by a blue star) had a significant increase in Canary scan measurement from T1 to T2 for treatment FF1. T1: 2 weeks ± 2 days post-bonding T2: 6 months ± 2 days post-bonding



## Difference: Time2 - Time1 Trt\_Site=FF2b

Ν	Mean Std Dev		Std Err	Minimum	Maximum	
17	3.0588	5.1292	1.2440	-5.0000	13.0000	

Mean	95% CL Mean		Std Dev	95% CL	6 CL Std Dev	
3.0588	0.4216	5.6960	5.1292	3.8201	7.8063	

DF	t Value	Pr >  t
16	2.46	0.0257

## Difference: Time2 - Time1 Trt\_Site=FF2g

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	4.8824	7.8173	1.8960	-12.0000	20.0000

Mean	95% CL Mean		Std Dev	95% CL Std Dev		
4.8824	0.8631	8.9016	7.8173	5.8221	11.8974	

DF	t Value	Pr >  t
16	2.58	0.0203

Figure 5.11 (part 1 of 2) Statistically Significant Increase in Canary Scan Measurement for Maxillary Lateral Incisor with APC<sup>™</sup> Flash-Free Bracket (FF2) between T1 and T2



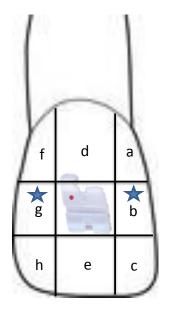


Figure 5.11 (part 2 of 2) Statistically Significant Increase in Canary Scan Measurement for Maxillary Lateral Incisor with APC™ Flash-Free Bracket (FF2) between T1 and T2
Segments b and g (signified by a blue star) had a significant increase in Canary scan measurement from T1 to T2 for treatment FF2.
T1: 2 weeks ± 2 days post-bonding
T2: 6 months ± 2 days post-bonding



Simple Statistics								
Variable	Ν	Mean	Std Dev	Sum	Minimum	Maximum	Label	
Scan A	160	19.10625	5.54524	3057	9.00000	40.00000	Scan A	
Scan P	160	18.38938	6.13641	2942	7.30000	40.00000	Scan P	

Pearson Correlation Coefficients, N = 160 Prob >  r  under H0: Rho=0				
	Scan A Scan P			
Scan A	1.00000	0.78280		
Scan A		<.0001		
Scan P	0.78280	1.00000		
Scan P	<.0001			

## Figure 5.12 Correlation Coefficient for Canary T1

Scan A (performed by the dental assistant) was compared to scan P (researcher) at 2 weeks  $\pm$  2 days post-bonding (T1).



Simple Statistics							
Variable	Ν	Mean	Std Dev	Sum	Minimum	Maximum	Label
Scan A	160	18.07688	9.26539	2892	8.00000	52.00000	Scan A
Scan P	160	18.42938	9.64892	2949	7.70000	57.00000	Scan P

Pearson Correlation Coefficients, N = 160 Prob >  r  under H0: Rho=0					
	Scan A Scan P				
Scan A	1.00000	0.93765			
Scan A		<.0001			
Scan P	0.93765	1.00000			
Scan P	<.0001				

## Figure 5.13 Correlation Coefficient for Canary T2

Scan A (performed by the dental assistant) was compared to scan P (researcher) at 6 months  $\pm 2$  days post-bonding (T2).



Simple Statistics							
Variable	Ν	Mean	Std Dev	Sum	Minimum	Maximum	Label
Scan A	320	18.59156	7.64078	5949	8.00000	52.00000	Scan A
Scan P	320	18.40938	8.07305	5891	7.30000	57.00000	Scan P

Pearson Correlation Coefficients, N = 320 Prob >  r  under H0: Rho=0					
	Scan A Scan P				
Scan A	1.00000	0.89242			
Scan A		<.0001			
Scan P	0.89242	1.00000			
Scan P	<.0001				

### Figure 5.14 Correlation Coefficient for combined Canary T1 and T2

Scan A (performed by the dental assistant) was compared to scan P (researcher), and combined for both T1 (2 weeks  $\pm$  2 days post-bonding) and T2 (6 months  $\pm$  2 days post-bonding).



#### **CHAPTER 6: DISCUSSION**

The ability to reduce plaque retention and prevent WSL development around fixed orthodontic appliances is of great interest in orthodontics. In this randomized prospective clinical study, we compared the degree of plaque accumulation, WSL development and bracket failure of conventional brackets bonded with conventional adhesives to brackets bonded with FF adhesives during the first 6 months of orthodontic treatment with fixed orthodontic appliances. There were no prior clinical studies comparing the effects of conventional versus FF adhesive.

The amount of plaque accumulation around the brackets bonded with conventional versus FF adhesives was measured indirectly by determining the amount of bacterial ATP activity. Plaque samples were collected at two different time points. The results show that there are no significant differences in plaque accumulation when comparing brackets bonded with conventional adhesives versus those of FF adhesives at both time points.

A study by Tufekci, Dixon et al in 2011 demonstrated a sharp increase in the incidence of WSLs during the first 6 months of orthodontic treatment that continued to increase at a slower pace approaching 12 months of treatment (Tufekci, Dixon et al. 2011). In our study, the development of WSLs was monitored using Canary scans, which were taken 6 months ± 2 days apart. Our results show that there are no significant differences in WSL development within the first 6 months of treatment when comparing brackets bonded with conventional adhesives to those with FF adhesives. The lack of significant differences in WSL development is consistent with the lack of significant differences in plaque accumulation and may suggests that the degree of plaque accumulation is correlated with the development of WSLs.

It is well established in the literature that prolonged accumulation of plaque around orthodontic brackets can lead to the development of WSLs (Gorelick, Geiger et al. 1982; Mizrahi 1982; Artun and Brobakken 1986; O'Reilly and Featherstone 1987). An in-vitro study of microleakage under FF adhesives and conventional adhesives found no significant differences between the two (Kim, Kanavakis et al. 2016). The results of this study suggest that the uniform layer formed between the bracket and the enamel by the FF adhesive does not significantly



reduce plaque accumulation and WSL development. Other factors such as oral hygiene, diet and, possibly to a lesser extent, bracket shape or type of ligation, may play a more significant role in plaque accumulation and development of WSLs.

The UNMC College of Dentistry orthodontic residents who placed and bonded the conventional and FF brackets were given as much time as they needed, with the knowledge that the patients are research participants. These combined with the ease of access to the maxillary anterior teeth may have led to better cleaning of "flash" from around the brackets with conventional adhesives, and hence lack of any significant finding between conventional versus FF adhesives in this research project.

The clinicians who bonded conventional and FF brackets in this study reported that the FF brackets would move slightly after placement onto the enamel surface prior to light curing of the brackets. This may be due to the fact that the FF adhesive is less viscous compared to the conventional adhesive that is applied to the base of the conventional bracket. The movement of the FF brackets on the enamel surface may lead to "pooling" of adhesive around the edges of the FF bracket and therefore act as excessive adhesive (flash), leading to no significant finding in terms of plaque retention and WSL development.

Inter-examiner reliability measurements were taken for the Canary scan. The correlation between the measurements performed by the dental assistant and the researcher at time point 1 is lower compared to the correlation between the measurements performed at time point 2. Both the researcher and the dental assistant may have improved their scanning skills and accuracy at time point 2, which may explain the differences in the measurement correlation. The combined correlation coefficient of 0.8924 is highly acceptable.

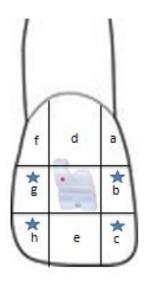
Despite the lack of significant differences in WSL development between brackets with conventional versus FF adhesives, the process of demineralization took place in our study sample. It was found that tooth segments "b, c, g, h" (figure 6.1) had a significant increase in Canary scan value and therefore a significant increase in demineralization. Segment "g" was most commonly affected followed by segments "b" and "h". The least frequently affected segment



was "c". Therefore, our study shows that the mesial and distal segments of the tooth are more commonly affected compared to other segments. The mesial and distal segments of the tooth are more challenging for plaque removal due to the presence of a continuous arch wire and common use of elastic chains. Our study suggests that the mesial and distal segments of the tooth are most susceptible to the development of WSLs.

An in-vitro study showed that shear bond strength is significantly greater for FF adhesive compared to conventional adhesives (Lee and Kanavakis 2016), though another in-vitro study found no significant differences in shear bond strength between the two (Soyland, Ye, et al. 2016). No in-vivo studies on bond strength or bond failure rate were reported in the literature. Failure rates of brackets with conventional versus FF adhesives were recorded in this study. It was found that 5.26% of FF brackets failed within the first 6 months of treatment, whereas 0% of conventional brackets failed during the same period of time. The two failed FF brackets were both on maxillary lateral incisors, and were placed by the same operator. The two failed brackets were in two different patients. This may suggest that FF brackets fail at a higher rate compared to conventional brackets in clinical conditions.





### Figure 6.1 WSL Development in all Treatment Types

WSLs were detected with the Canary system on segments c, g, h for treatment C1 (maxillary central incisor with conventional adhesive), segment b for treatment C2 (maxillary lateral incisor with conventional adhesive), segments g, h for treatment FF1 (maxillary central incisor with APC<sup>™</sup> Flash-Free adhesive), and segments g, h for treatment FF2 (maxillary lateral incisor with APC<sup>™</sup> Flash-Free adhesive).



### **CHAPTER 7: CONCLUSION**

Brackets with conventional and FF adhesives were compared for plaque accumulation, WSL development and failure rate in the first 6 months of orthodontic treatment. Our results show that there were no significant differences in plaque accumulation or WSL development between brackets with conventional adhesives and brackets with FF adhesives. Our study suggests that the process of demineralization does take place within the first 6 months of orthodontic treatment with the mesial and distal segments of the maxillary incisors being more commonly affected. In addition, our study found that the FF brackets demonstrated a 5.26% failure rate, whereas conventional brackets had a 0% failure rate. Overall, our study suggests that the FF adhesive used to bond brackets onto the tooth surface does not reduce plaque accumulation and WSL development and FF brackets may fail more often compared to conventional adhesives.



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## APPENDIX A Adult Consent Form

## IRB PROTOCOL # 447-15-EP

## ADULT CONSENT - CLINICAL BIOMEDICAL

#### **Title of this Research Study**

Effects of Flash-free Brackets on Plaque Retention, Development of White Spot Lesions, and Bracket Failures: a Comparative Clinical Study

#### Invitation

You are invited to take part in this research study. You have a copy of the following, which is meant to help you decide whether or not to take part:

- Informed consent form
- "What Do I need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

## Why are you being asked to be in this research study?

You are asked to participate in this research because you are at increased risk of tooth surface damage and dental cavities due to orthodontic treatment and you meet the following criteria: you are 10 years or older and in need of orthodontic treatment with braces; you have no medical condition that would contradict orthodontic treatment; you have fully erupted maxillary central and lateral incisors; you have no dental abnormalities.

You may not be a part of this study if you fall into any of the following categories: You are pregnant, or plan to become pregnant during this study. You are using or have used antibiotics, corticosteroids, or mouth rinses in the past 3 months. You are using or have used tobacco products in the past 3 months. You have very small upper lateral incisors (second tooth from the midline on the upper jaw). You have staining, active dental cavities, or dental fillings (restorations) on any of the front surfaces of your upper central and lateral incisors (4 upper front teeth).



This study will have about 25 participants, including children and adults, all of which are patients at UNMC, College of Dentistry, Department of Orthodontics.

#### What is the reason for doing this research study?

Tooth surface (enamel) damage and dental cavities are caused by acid-producing bacteria in the mouth. Individuals undergoing orthodontic treatment have a higher chance of developing enamel damage and dental cavities due to more food and bacterial retention around the braces (orthodontic brackets). The conventional glue (adhesive) used to attach (bond) the braces onto the tooth surface may also create roughness around the brackets and contribute to tooth surface damage and dental cavities. Recently, a type of glue is introduced that will not create rough edges around the brackets and therefore may lessen the amount of damage to the tooth surface. This research is trying to see whether the new type of glue will lead to less tooth damage compare to the conventional glue.

We hope that the findings in this research will lead to better prevention of enamel damage and dental cavities in patients undergoing orthodontic treatment.

#### What will be done during this research study?

If you agree to participate in this study, at the time you receive your braces, you will receive two types of brackets: both the brackets with the new type of glue and the bracket with conventional glue.

After you receive your braces (orthodontic brackets), you will be asked to attend a total of 3 research-related appointments. These appointments are in addition to your regular orthodontic adjustment appointments. All research-related appointments will be on a Wednesday and will be at the UNMC, College of Dentistry, Orthodontic Department. The 3 appointments are as follows:

#### **First Appointment:**

two weeks after you receive your braces, you will be asked to come to our clinic for bacterial sample collection from around some of the braces. Also, some of the teeth will be evaluated by an scanner that detects subtle changes in the enamel surface. The scanner uses laser



technology. You will be provided and required to wear safety glasses during the scans, which will take place in the first and third research appointments. This appointment will take about 45 minutes.

#### Second Appointment:

Six weeks after you receive your braces, you will be asked to come to our clinic for a second bacterial sample collection. This appointment will take about 30 minutes.

## **Third Appointment:**

Six months after you receive your braces, you will be asked to come to our clinic for a second scanning of the enamel surfaces of some of the teeth. This appointment will take about 30 minutes.

The brackets and the new type of glue used in this experiment will not be removed from your front teeth after completion of this research. Both the bracket and the new type of glue will remain on your teeth until your orthodontic treatment is complete. However if you choose to remove these brackets and the glue at the end of the research (6 months after you first get your braces), the UNMC Orthodontic

Department will remove these brackets and the glue, and replace them with conventional brackets and conventional glue, for no additional costs to you.

## What are the possible risks of being in this research study?

Other than the risks associated with orthodontics treatment in general, there are no additional risks associated with participating in this study. The orthodontic treatment plan, treatment time, and treatment outcome will be unaffected if you choose to participate in this research.

It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

#### What are the possible benefits to you?



You may receive benefit from participating in this study because the teeth receiving the experimental glue may be at lower risk for developing enamel damage and dental cavities. However, the potential benefit is limited to the two front teeth that receive the experimental glue.

Please keep in mind that you may not get any benefit from being in this research study.

## What are the possible benefits to other people?

The information obtained in this study can potentially be used to lower the chances of developing enamel damage and dental cavities in future orthodontic patients.

## What are the alternatives to being in this research study?

Instead of being in this research study, you can choose not to participate. There will be no changes to your orthodontic treatment.

## What will being in this research study cost you?

Other than the regular fee for your orthodontic treatment, there is no additional cost to you to be in this research study.

## Will you be paid for being in this research study?

You will receive a \$10 gift card at the end of each research appointment. In addition, you will receive an electrical tooth brush that you can keep once the study is completed.

## Who is paying for this research?

UNMC receives money and donated brackets from 3M Unitek to conduct the study.

# What should you do if you are injured or have a medical problem during this research study?

Your welfare is the main concern of every member of the research team. If you are

injured or have a medical problem or some other kind of problem as a direct result of

being in this study, you should immediately contact one of the people listed at the

## end of this consent form.



## How will information about you be protected?

You have rights regarding the protection and privacy of your medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include your medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your research and medical records will be maintained in a secure manner.

#### Who will have access to information about you?

By signing this consent form, you are allowing the research team to have access to your PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your PHI will be used only for the purpose(s) described in the section What is the reason for doing this research study?

You are also allowing the research team to share your PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that your information may be shared with these groups:
  - The HHS Office of Human Research Protections (OHRP)
  - The Food and Drug Administration (FDA)
- The HIPAA Privacy Rule requires the following groups to protect your PHI:
  - o Researchers at UNMC and UNL
  - Your health insurance company

Your PHI may also be shared with the following groups. However, this organization does not have the same obligation to protect your PHI:

• 3M Unitek, which provides funds and donated brackets to conduct this research.



You are authorizing us to use and disclose your PHI for as long as the research study is being conducted.

You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

## How will results of the research be made available to you during and after the study is finished?

Information obtained in the course of the research that will not be shared with you is which teeth are receiving the braces with the new type of glue (adhesive) as opposed to the conventional glue. By signing this authorization, you are temporarily living up your right to see this research-related information while the research is going on. You will be able to see this information if you wish after the research is completed.

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:

UNMC, College of Dentistry.

4000 E Campus Loop, Lincoln, NE, 68583

attn: Dr Payam Ishani Afousi

## What will happen if you decide not to be in this research study?

You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the Institution. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.



## What will happen if you decide to stop participating once you start?

You can stop participating in this research (withdraw) at any time by contacting the

Principal Investigator or any of the research staff.

Deciding to withdraw will otherwise not affect your care or your relationship with the investigator or this institution. You will not lose any benefits to which you are entitled.

If you withdraw you may be asked to undergo some additional tests. You do NOT have to agree to do these tests.

You may be taken off the study if you do not follow instructions of the investigator or the research team.

You may also be taken off the study if you use mouth rinse, tobacco products, antibiotics, corticosteroids, or become pregnant in the first 6 weeks of this study. Any research data obtained to date may still be used in the research.

## Will you be given any important information during the study?

You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want to continue being in the study.

#### What should you do if you have any questions about the study?

You have been given a copy of "*What Do I Need to Know Before Being in a Research Study?*" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

#### What are your rights as a research participant?

You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights or complaints about the research, you can contact any of the following:



- The investigator or other study personnel
- Institutional Review Board (IRB)
  - Telephone: (402) 559-6463.
  - Email: IRBORA@unmc.edu
  - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
  - o Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

## **Documentation of informed consent**

- You are freely making a decision whether to be in this research study. Signing this
- form means that:
- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.
- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject \_\_\_\_\_

Date \_\_\_\_\_

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject. In my judgment, the subject possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.



Signature of Person obtaining consent \_\_\_\_\_

Date \_\_\_\_\_

## **Authorized Study Personnel**

## Principal

\* Ishani Afousi, Payam

alt email: payamishani@gmail.com

phone: 402-472-4919

degree: DDS

## **Participating Personnel**

\* Ellingson, Leslie

phone: 402-472-4919

degree: DDS

\* Stadiem, Jacob

phone: 402-472-4919

degree: DDS

\* White, Kelsey

phone: 402-472-4919

degree: DDS



## Institutional Review Board (IRB)

#### What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the risks of the research? What bad things could happen?

What are the possible benefits of the research? How might this help me?

**How is this research different** than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does everyone in this research study get the same treatment?

Will being in the research cost me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say no?

Can I stop being in the research once I've started? How?

Who will look at my records?

How do I reach the investigator if I have more questions?

Who do I call if I have questions about being a research subject?

Make sure all your questions are answered before you decide whether or not to be in this research.



Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830

402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb



## Institutional Review Board (IRB)

## THE RIGHTS OF RESEARCH SUBJECTS AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

#### To be told everything you need to know about the research before you are

asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

To freely decide whether or not to take part in the research.

To decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

To ask questions about the research at any time. The investigator will answer your questions honestly and completely.

To know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

**To privacy and confidentiality.** The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

To be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.



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## APPENDIX B

#### **Parental Consent Form**

#### IRB PROTOCOL # 447-15-EP Page 1 of 8

## **PARENTAL CONSENT - CLINICAL BIOMEDICAL**

#### **Title of this Research Study**

Effects of Flash-free Brackets on Plaque Retention, Development of White Spot Lesions, and Bracket Failures: a Comparative Clinical Study.

#### Invitation

You are invited to allow your child to take part in this research study. You have a copy of the following, which is meant to help you decide whether or not to allow your child to take part:

- Informed consent form
- "What Do I need to Know Before Being in a Research Study?"
- The Rights of Research Subjects

#### Why is your child being asked to be in this research study?

You are asked to allow your child to participate in this research because your child is at increased risk of developing tooth surface (enamel) damage and dental cavities due to orthodontic treatment and your child meets the following criteria: he/she is 10 years or older and in need of orthodontic treatment with braces; he/she has no medical condition that would contradict orthodontic treatment; he/she has fully erupted upper central and lateral incisors; he/she has no dental abnormalities.

Your child may not be a part of this study if he/she fall into any of the following categories: Your child is pregnant, or plans to become pregnant during this study. Your child is using or has used antibiotics, corticosteroids, or mouth rinses in the past 3 months. Your child is using or has used tobacco products in the past 3 months. Your child has very small upper lateral incisors (second tooth from the midline on the upper jaw). Your child has staining, active dental cavities, or dental



fillings (restorations) on any of the front surfaces of his/her upper central and lateral incisors (4 upper front teeth).

This study will have about 25 participants, including children and adults, all of which are patients at UNMC, College of Dentistry, Department of Orthodontics.

#### What is the reason for doing this research study?

Tooth surface (enamel) damage and dental cavities are caused by acid-producing bacteria in the mouth. Individuals undergoing orthodontic treatment have a higher chance of developing enamel damage and dental cavities due to more food and bacterial retention around the braces (orthodontic brackets). The conventional glue (adhesive) used to attach (bond) the braces onto the tooth surface may also create roughness around the brackets and contribute to tooth surface damage and dental cavities by bacteria. Recently, a type of glue is introduced that will not create rough edges around the brackets and therefore may lessen the amount of damage to the tooth surface. This research is trying to see whether the new type of glue will lead to less enamel damage, due to acid-producing bacteria, compare to the conventional glue.

We hope that the findings in this research will lead to better prevention of enamel damage and dental cavities in patients undergoing orthodontic treatment.

#### What will be done during this research study?

If you agree to give permission for your child to participate in this study, at the time your child's receives the braces, your child will receive two types of brackets: both the brackets with the new type of glue and the bracket with conventional glue.

After your child receives his/her braces (orthodontic brackets), he/she will be asked to attend a total of 3 research-related appointments. These appointments are in addition to your child's regular orthodontic adjustment appointments. All research-related appointments will be on a Wednesday and will be at the UNMC, College of Dentistry, Orthodontic Department. The 3 appointments are as follows:

#### First Appointment:



Two weeks after your child receives his/ her braces, your child will be asked to come to our clinic for bacterial sample collection from around some of the braces. Also, some of the teeth will be evaluated by a scanner that detects subtle changes in the enamel surface. This scanner uses laser technology. Your child will be provided and required to wear safety glasses during the scans, which will take place in the first and third research appointments. This appointment will take about 45 minutes.

#### Second Appointment:

Six weeks after your child receives his/ her braces, your child will be asked to come to our clinic for a second bacterial sample collection. This appointment will take about 30 minutes.

## **Third Appointment:**

Six months after your child receives his/her braces, your child will be asked to come to our clinic for a second scanning of the enamel surfaces of some of the teeth. This appointment will take about 30 minutes.

The brackets and the new type of glue used in this experiment will not be removed from your child's front teeth after completion of this research. Both the bracket and the new type of glue will remain on your child's teeth until his/her orthodontic treatment is complete. However if you or your child choose to remove these brackets and the glue at the end of the research (6 months after your child first get his/her braces), the UNMC Orthodontic Department will remove these brackets and the glue, and replace them with conventional brackets and conventional glue, for no additional costs to you.

#### What are the possible risks of being in this research study?

Other than the risks associated with orthodontics treatment in general, there are no additional risks associated with participating in this study. The orthodontic treatment plan, treatment time, and treatment outcome will be unaffected if you choose to allow your child to participate in this research.



It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that your child could have a side effect that has not occurred before.

## What are the possible benefits to your child?

Your child may benefit from participating in the study because the teeth receiving the experimental glue may be at lower risk for developing enamel damage and dental cavities. However, the potential benefit is limited to the two front teeth that receive the experimental glue.

Please keep in mind that your child may not get any benefit from being in this research study.

## What are the possible benefits to other people?

The information obtained in this study can potentially be used to lower the chances of developing enamel damage and dental cavities in future orthodontic patients.

## What are the alternatives to being in this research study?

Instead of being in this research study, you can choose not to allow your child to participate. There will be no changes to your child's orthodontic treatment.

## What will allowing your child to be in this research study cost you?

Other than the regular fee for your child's orthodontic treatment, there is no cost to you for your child to be in this research study.

## Will you or your child be paid for being in this research study?

Your child will receive a \$10 gift card at the end of each research appointment. In addition, he/she will receive an electrical tooth brush that he/she can keep once the study is completed.

## Who is paying for this research?

UNMC receives money and donated brackets from 3M Unitek to conduct the study.

What should you do if your child is injured or has a medical problem during this research study?



Your child's welfare is the main concern of every member of the research team. If he/she is injured or has a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form.

#### How will information about your child be protected?

Your child has rights regarding the protection and privacy of his/her medical information collected before and during this research. This medical information is called "protected health information" (PHI). PHI used in this study may include his/her medical record number, address, birth date, medical history, the results of physical exams, blood tests, x-rays as well as the results of other diagnostic medical or research procedures. Only the minimum amount of PHI will be collected for this research. Your child's research and medical records will be maintained in a secure manner.

## Who will have access to information about your child?

By signing this consent form, you are allowing the research team to have access to your child's PHI. The research team includes the investigators listed on this consent form and other personnel involved in this specific study at the Institution.

Your child's PHI will be used only for the purpose(s) described in the section "What is the reason for doing this research study?"

You are also allowing the research team to share his/her PHI, as necessary, with other people or groups listed below:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- Federal law requires that the subject's information may be shared with these

groups:

- The HHS Office of Human Research Protections (OHRP)
- The HIPAA Privacy Rule requires the following groups to protect the subject's



PHI:

• The subject's health insurance company

Your child's may also be shared with the following groups. However, this organization does not have the same obligation to protect his/her PHI:

• 3M Unitek, which provides funds and donated brackets to conduct this Research.

You are authorizing us to use and disclose your child's PHI for as long as the research study is being conducted.

You may cancel your authorization for further collection of your child's PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, your child will no longer be able to participate in this research.

# How will results of the research be made available to you during and after the study is finished?

Information obtained in the course of the research that will not be shared with you or your child is which teeth are receiving the braces with the new type of glue (adhesive) as opposed to the conventional glue. By signing this authorization, you are temporarily giving up the right to see this research-related information while the research is going on. You will be able to see this information if you wish after the research is completed.

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your child's identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address: UNMC, College of Dentistry.



#### 4000 E Campus Loop, Lincoln, NE, 68583

#### attn: Dr Payam Ishani Afousi

## What will happen if you decide not to give permission for your child to be in this research study?

You can decide not to give permission for your child to be in this research study. Deciding not to be in this research will not affect your child's medical care or his/her relationship with the investigator or the Institution. Your child's doctor will still take care of him/her. Your child will not lose any benefits to which he/she is entitled.

#### What will happen if you decide to stop your child's participation once it starts?

You can stop your child's participation in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff.

Deciding to withdraw will otherwise not affect your child's care or relationship with the investigator or this institution. Your child will not lose any benefits to which he/she is entitled.

If you withdraw your child, you may be asked to allow your child to undergo some additional tests. You do NOT have to agree to have your child undergo these tests.

Your child may be taken off the study if he/she doesn't follow instructions of the investigator or the research team.

Your child may also be taken off the study if your child uses mouth rinse, tobacco products,

antibiotics, corticosteroids, or become pregnant in the first 6 weeks of this study.

Any research data obtained to date may still be used in the research.

#### Will you be given any important information during the study?

You will be informed promptly if the research team gets any new information during this research study that may affect whether you would want your child to continue being in the study.

#### What should you do if you have any questions about the study?



You have been given a copy of "What Do I Need to Know Before Being in a Research Study?" If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

## What are your child's rights as a research subject?

Your child has rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning his/her rights or complaints about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
  - Telephone: (402) 559-6463.
  - Email: IRBORA@unmc.edu
  - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
  - o Telephone: (402) 559-6941
  - Email: unmcrsa@unmc.edu

## **Documentation of informed consent**

You are freely making a decision whether to give permission for your child to be in this research study. Signing this form means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to permit your child to be in the research study.



- If you have any questions during the study, you have been directed to talk to one of the investigators listed below on this consent form
- You will be given a signed and dated copy of this consent form to keep.

Signature of Parent/Guardian \_\_\_\_\_

Date \_\_\_\_\_

You are agreeing to be in this research study. You have had someone explain the study to you, and answer your questions.

Signature of Subject \_\_\_\_\_

Date \_\_\_\_\_

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the parent(s)/guardian(s) of the subject. In my judgment, the parent(s)/guardian(s) possesses the legal capacity to give informed consent for the subject to participate in this research and is voluntarily and knowingly giving informed consent.

Signature of Person obtaining consent \_\_\_\_\_

Date \_\_\_\_\_

#### **Authorized Study Personnel**

Principal

\* Ishani Afousi, Payam

alt email: payamishani@gmail.com

phone: 402-472-4919

degree: DDS

### **Participating Personnel**

\* Ellingson, Leslie

phone: 402-472-4919



degree: DDS

\* Stadiem, Jacob

phone: 402-472-4919

degree: DDS

\* White, Kelsey

phone: 402-472-4919

degree: DDS



## Institutional Review Board (IRB)

#### What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the risks of the research? What bad things could happen?

What are the possible benefits of the research? How might this help me?

**How is this research different** than the care or treatment I would get if I wasn't in the research? Are there other treatments I could get?

Does everyone in this research study get the same treatment?

Will being in the research cost me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say no?

Can I stop being in the research once I've started? How?

Who will look at my records?

How do I reach the investigator if I have more questions?

Who do I call if I have questions about being a research subject?

Make sure all your questions are answered before you decide whether or not to be in this research.



Academic Research & Services Building 3000 / 987830 Nebraska Medical Center / Omaha NE 68198-7830

402-559-6463 / FAX 402-559-3300 / Email: irbora@unmc.edu / http://www.unmc.edu/irb



## Institutional Review Board (IRB)

## THE RIGHTS OF RESEARCH SUBJECTS AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

To be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

To freely decide whether or not to take part in the research.

To decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

To ask questions about the research at any time. The investigator will answer your questions honestly and completely.

To know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

**To privacy and confidentiality.** The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

To be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.

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## **APPENDIX C**

#### Youth Information Sheet

#### IRB PROTOCOL # 447-15-EP

## YOUTH INFORMATION SHEET

## Title

Effects of Flash-free Brackets on Plaque Retention, Development of White Spot Lesions, and Bracket Failures: a Comparative Clinical Study

#### Description

You are invited to be in this research study. Being a participant in this study is voluntary. You don't have to be in this research study to get treated. If you decide not to be in this study, your doctor will still take care of you with the same quality of care that you deserve.

The goal of this study is to see whether a new type of glue (adhesive) used to attach the braces (orthodontic brackets) onto the tooth surface (enamel) will help decrease the amount of enamel damage and dental cavities that are usually caused by bacteria.

You will come to our clinic a total of 3 times (2 weeks, 6 weeks and 6 months after you get your braces) in addition to your regular orthodontic adjustment appointments for bacterial sample collection from around your braces and scanning and evaluation of your teeth surfaces with a scanner. The scanner uses laser technology, You will be required to wear safety glasses when your teeth are being scanned.

There are no additional risks (other than the ones associated with orthodontic treatment in general) to you if you decide to participate in this study. You may benefit from participation in the study because your teeth that receive the new brackets and glue may be at lower risk for developing enamel damage and cavities. However you may not receive any benefit.



Patie nt #	Treatm ent	Toot h #	Segm ent	Mean (T1)	S D	C V	Mean (T2)	S D2	C V3	Mean Differences (T2-T1)
1	C1	8	a	21	3. 2	15	12	2. 5	21	-9
1	C1	8	b	12	1	8. 3	18	4. 4	24	6
1	C1	8	С	12	2. 9	24	16	0. 58	3. 6	4
1	C1	8	d	51	3. 6	7. 1	39	2. 1	5. 4	-12
1	C1	8	е	15	3. 1	21	11	3	27	-4
1	C1	8	f	19	2. 5 2.	13	15	2. 5	17	-4
1	C1	8	g	14	2. 1 1.	15	15	3. 1	21	1
1	C1	8	h	15	י. 7	11	15	2	13	0
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1	C2 C2	7	a b	19 24	3 3. 5	12 15	14 42	1 3. 1	1 7. 4	-5 18
1	C2	7	c	17	1. 5	8. 8	16	2. 1	13	-1
1	C2	7	d	23	2	8. 7	20	4	20	-3
1	C2	7	e	18	1. 2	6. 7	16	2. 5	16	-2
1	C2	7	f	24	2. 5	10	26	4. 2	16	2
1	C2	7	g	19	0. 58	3. 1	31	3. 2	10	12
1	C2	7	h	18	2. 1	12	18	1. 2	6. 7	0
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1	FF1	9	f	15	4. 7	31	14	2 1. 5	11	-1
1	FF1	9	g	15	1	6. 7	14	2	14	-1

## **DIFFERENCES IN MEANS BETWEEN T2 AND T1**



1	FF1	9	h	14	2	14	15	2. 1	14	1
1	FF2	10	а	16	2. 1	13	10	2	20	-6
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1	FF2	10	b	12	7 4.	39	21	5 2.	17	9
1	FF2	10	С	15	2	28	16	5	16	1
1	FF2	10	d	21	2. 7	13	22	4	18	1
1	FF2	10	е	15	1. 2	8. 0	16	2. 7	17	1
1	FF2	10	f	17	2. 7	16	18	0. 58	3. 2	1
1	FF2	10	g	19	1. 2	6. 3	18	2	11	-1
1	FF2	10	h	15	4	27	14	3. 5	25	-1
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2	C1	9	а	15	5 4.	30	16	1 2.	13	1
2	C1	9	b	32	4	14	16	5	16	-16
2	C1	9	с	41	0. 58	1. 4	49	3. 2	6. 5	8
2	C1	9	d	18	2. 7	15	16	3. 1	19	-2
2	C1	9	е	47	2. 1	4. 5	48	1	2. 1	1
2	C1	9	f	26	4	15	16	2. 7	17	-10
2	C1	9	g	25	2. 9	12	21	4. 2	20	-4
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2	C2	10	d	17	3	18	18	1. 2	6. 7	1
2	C2	10	е	49	3. 8	7. 8	17	1. 5	8. 8	-32
2	C2	10	f	18	0. 58	3. 2	10	1. 2	12	-8
2	C2	10	g	20	3. 6	18	11	3. 6	33	-9
2	C2	10	9 h	37	2. 1	5. 7	43	1	2. 3	6
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2	FF1	8	b	18	3. 6	20	15	2. 9	19	-3
2	FF1	8	с	41	4	10	32	3. 1	10	-9
2	FF1	8	d	17	1. 5	8. 8	34	1	2. 9	17
2	FF1	8	е	32	3. 5	11	47	4. 4	9. 4	15
2	FF1	8	f	21	4. 4	21	14	2. 5	18	-7
2	FF1	8	g	24	2. 3	10	15	4. 2	28	-9
		8	yh		1. 7	4. 4	44	1	20 2. 3	-9
2	FF1	0	11	39	1	4	44	1	3	5
2	FF2	7	а	10	1. 5	15	14	3. 2	23	4
2	FF2	7	b	17	3. 8	22	22	2. 5	11	5
2	FF2	7	С	40	3. 5	8. 8	45	3. 8	8. 4	5
2	FF2	7	d	24	3. 2	13	19	0. 58	3. 1	-5
2	FF2	7		36	3. 6	10	38	2. 3	6. 1	2
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2	FF2	7	g	28	4	14 7.	29	7 2.	9	1
2	FF2	7	h	14	1	1	18	1	12	4
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3	C1	8	a	14	7	19	11	5 3.	14	-3
3	C1	8	b	17	2 3.	12	20	5 1.	18 8.	3
3	C1	8	С	17	1 3.	18	14	2	6 7.	-3
3	C1	8	d	16	5	22	16	2 4.	5	0
3	C1	8	е	14	4 3.	29	10	6 3.	46	-4
3	C1	8	f	16	3. 3.	19	17	5	21 5.	1
3	C1	8	g	13	3. 6	28	19	1	5. 3	6
3	C1	8	h	17	2	12	13	3. 8	29	-4
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3	C2	7	с	13	4	31	31	0. 58	1. 9	18
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3	C2	7	е	14	2. 5	18	14	3. 2	23	0
3	C2	7	f	18	3. 2	18	19	1. 5	7. 9	1
3	C2	7	g	20	2. 3	12	21	1	4. 8	1
3	C2	7	h	14	2. 1	15	14	3. 6	26	0
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3	FF1	9	b	16	4 3.	25	12	5 3.	13	-4
3	FF1	9	С	14	1	22	10	5 2.	35	-4
3	FF1	9	d	18	4 3.	22	13	1 4.	16	-5
3	FF1	9	е	14	1 2.	22	13	2 4.	32	-1
3	FF1	9	f	15	1 2.	14	15	5	30 5.	0
3	FF1	9	g	16	5 3.	16	21	2 3.	7	5
3	FF1	9	h	14	2	23	11	8	35	-3
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3	FF2	10	a b	17 19	2 1. 2	1 6. 3	18 25	2 4. 2	7 17	<u> </u>
3	FF2 FF2	10 10	C	19	2 1. 5	8. 3	13	2 1. 2	9. 2	-5
3	FF2	10	d	13	3. 6	28	13	2 0. 58	2 4. 5	-5
3	FF2	10	e	12	2. 5	20	8.7	0. 58	6. 7	-3.3
3	FF2	10	f	13	1	7. 7	17	3. 2	19	-3.3
3	FF2	10	g	12	1	7 8. 3	17	2 1. 2	6. 3	7
3	FF2	10	y h	17	1. 5	8. 8	12	2. 7	23	-5
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4	C1	9	а	13	4. 2	32	12	3. 5	29	-1
4	C1	9	b	18	3.	17	16	3.	22	-2

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4	C1	9	с	15	1. 5	10	36	2. 1	5. 8	21
4	C1	9	d	15	4. 5	30	25	2. 3	9. 2	10
4	C1	9	е	19	2. 3	12	40	4. 6	12	21
4	C1	9	f	13	3. 1	24	16	1. 5	9. 4	3
4	C1	9	g	16	2. 7	17	28	2. 9	10	12
4	C1	9	h	20	2. 1	11	44	1. 2	2. 7	24
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4	C2	10	а	11	7 3.	15 9.	15	4 2.	27	4
4	C2	10	b	34	2	4	20	1 4.	11	-14
4	C2	10	С	15	5 3.	17	31	2	14	16
4	C2	10	d	15	8 1.	25	10	5 1.	15 6.	-5
4	C2	10	е	17	7 2.	10	20	2 3.	0	3
4	C2	10	f	14	5 4.	18	16	5 2.	22	2
4	C2	10	g	20	2 1.	21 8.	19	1	11	-1
4	C2	10	h	17	5	8	21	4	19	4
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4	FF1	8	a	13	5	12	18	2 3.	11 8.	5
4	FF1	8	b	26	4	15	36	1	6 4.	10
4	FF1	8	C	20	1 2.	11	47	2 0.	3 3.	27
4	FF1	8	d	17	5 3.	15 18	17	58 2.	4	-4
4	FF1 FF1		e f	20	6 2. 1	12	16	1 3.	13	-4
4	FF1	8		17	1 2. 1	12	18 27	2 3. 2	18 12	10
4	FF1	8	g h	17 21	3. 1	12	27 34	2 5. 2	12	13
4	ГГІ	O	11	21		10	34			10
4	FF2	7	а	17	3. 2	19	13	1. 2	9. 2	-4
4	FF2	7	b	25	2	8. 0	33	3. 1	9. 4	8
4	FF2	7	С	17	2	12	15	2.	14	-2



								1		
4	FF2	7	d	14	4	29	17	3. 5	21	3
4	FF2	7	е	15	3. 5	23	18	4. 2	23	3
4	FF2	7	f	14	4	29	14	2. 3	16	0
4	FF2	7	g	20	4. 5	23	32	1. 7	5. 3	12
4	FF2	7	h	18	3. 5	19	17	2	12	-1
5	C1	8	а	10	3. 5	35	13	2. 9	22	3
5	C1	8	b	12	5. 3	44	13	2. 3	18	1
5	C1	8	с	14	1	7. 1	15	1. 2	8. 0	1
5	C1	8	d	13	1	7. 7	10	1. 7	17	-3
5	C1	8	е	12	0. 58	4. 8	12	2. 9	24	0
5	C1	8	f	13	3. 2	25	12	2. 7	23	-1
5	C1	8	g	13	2. 5	19	14	4. 6	33	1
5	C1	8	h	15	2. 7	18	14	1. 5	11	-1
					3.					
5	C2	7	а	8.7	1 3.	36	11	4	36	2.3
5	C2	7	b	16	6	23	12	2. 5	21	-4
5	C2	7	с	13	2. 7	21	26	3. 2	12	13
5	C2	7	d	12	1. 5	13	14	2. 5	18	2
5	C2	7	е	14	4.	34	17	2. 3	14	3
5	C2	7	f	18	0. 58	3. 2	14	2. 7	19	-4
5	C2	7	g	18	4.	24	10	2. 3	23	-8
5	C2	7	h	15	1. 5	10	17	3. 8	22	2
					3.			4.		
5	FF1	9	а	12	6 1.	30 9.	12	4 3.	37	0
5	FF1	9	b	16	5	4	12	5	29	-4
5	FF1	9	C	16	4	25	8	7	21	-8
5	FF1	9	d	11	3.	35	14	3.	25	3



					8			5		
5	FF1	9	е	13	1. 5	12	16	6	38	3
5	FF1	9	f	14	3. 6	26	12	2. 5	21	-2
5	FF1	9	g	12	3. 1	26	13	3. 1	24	1
5	FF1	9	h	10	3. 2	32	14	4. 2	30	4
5	FF2	10	а	10	3. 5	35	10	1. 5	15	0
5	FF2	10	b	12	2. 5	21	9	1. 2	13	-3
5	FF2	10	С	12	3. 2	27	11	4	36	-1
5	FF2	10	d	11	1	9. 1	11	1	9. 1	0
5	FF2	10	е	14	3. 5	25	13	2. 5	19	-1
5	FF2	10	f	14	0. 58	4. 1	15	2. 1	14	1
5	FF2	10	g	9	2. 7	30	14	4. 6	33	5
5	FF2	10	h	8	2. 9	36	13	0. 58	4. 5	5
6	C1	9	а	12	2. 3	19	22	3	14	10
6	C1	9	b	16	3. 1	19	27	2. 1	7. 8	11
6	C1	9	С	17	2. 5	15	26	4. 9	19	9
6	C1	9	d	17	2. 1	12	21	3. 2	15	4
6	C1	9	е	20	2. 1	11	12	2. 5	21	-8
6	C1	9	f	17	2. 5	15	14	0. 58	4. 1	-3
6	C1	9	g	15	1. 5	10	15	3. 6	24	0
6	C1	9	h	16	2. 7	17	17	1. 5	8. 8	1
-		<u></u>	-			-	-	-	-	
6	C2	10	а	9.3	3. 2	34	9.7	3. 5	36	0.4
6	C2	10	b	12	2. 7	23	18	3. 1	17	6
6	C2	10	С	17	2. 1	12	14	3. 5	25	-3
6	C2	10	d	12	2. 5	21	13	4. 2	32	1
6	C2	10	е	17	2.	14	19	4	21	2



					3					
6	C2	10	f	12	3. 2	27	12	3	25	0
6	C2	10	g	16	2. 7	17	14	3. 5	25	-2
6	C2	10	h	19	1. 7	8. 9	16	2. 5	16	-3
6	FF1	8	а	13	3. 2	25	10	1. 5	15	-3
6	FF1	8	b	26	1. 5	5. 8	18	2	11	-8
6	FF1	8	С	16	3. 2	20	35	4	11	19
6	FF1	8	d	14	2. 7	19	29	3. 1	11	15
6	FF1	8	е	34	3. 8	11	28	4. 5	16	-6
6	FF1	8	f	17	1. 5	8. 8	21	2. 5	12	4
6	FF1	8	g	28	3. 2	11	23	2. 1	9. 1	-5
6	FF1	8	h	18	3. 1	17	39	1. 5	3. 8	21
									U	
6	FF2	7	а	12	1. 7	14	15	4. 5	30	3
6	FF2	7	b	15	4	27	28	1. 5	5. 4	13
6	FF2	7	С	12	1. 5	13	22	3. 1	14	10
6	FF2	7	d	13	2. 1	16	16	2. 3	14	3
6	FF2	7	е	17	3. 1	18	18	3. 2	18	1
6	FF2	7	f	18	2. 5	14	19	2. 7	14	1
6	FF2	7	g	23	2. 5	11	20	4	20	-3
6	FF2	7	h	20	3. 1	16	18	3. 8	21	-2
7	C1	8	а	10	2. 1	21	14	4. 2	30	4
7	C1	8	b	16	2. 9	18	36	4. 9	14	20
7	C1	8	С	13	2	15	13	3. 5	27	0
7	C1	8	d	9	2. 7	30	13	2. 7	21	4
7	C1	8	е	14	1	7. 1	12	1. 5	13	-2
7	C1	8	f	12	1.	14	11	1.	14	-1



					7			5		
7	C1	8	g	16	0. 58	3. 6	16	4. 4	28	0
7	C1	8	h	15	2. 1	14	16	2. 7	17	1
7	C2	7	а	11	1	9. 1	19	0	0	8
7	C2	7	b	17	0. 58	3. 4	34	3. 1	9. 1	17
7	C2	7	С	15	2	13	18	1. 2	6. 7	3
7	C2	7	d	12	1. 2	10	16	1. 7	11	4
7	C2	7	е	14	1. 2	8. 6	17	3. 2	19	3
7	C2	7	f	13	1. 5	12	15	2. 7	18	2
7	C2	7	g	18	1. 5	8. 3	31	2	6. 5	13
7	C2	7	h	18	1. 5	8. 3	16	1. 5	9. 4	-2
					4				0	
7	FF1	9	а	10	1. 5	15	11	1	9. 1	1
7	FF1	9	b	12	1. 7	14	16	2.	13	4
7	FF1	9	с	35	1. 5	4. 3	44	1. 2	2. 7	9
7	FF1	9	d	14	3. 2	23	13	1. 5	12	-1
7	FF1	9	е	12	2. 7	23	13	3. 2	25	1
7	FF1	9	f	13	3. 6	28	11	2. 1	19	-2
7	FF1	9	g	17	2. 1	12	17	2	12	0
7	FF1	9	h	12	2. 7	23	14	2. 5	18	2
						9.		5.		
7	FF2	10	а	11	1 2.	3. 1	13	5	42	2
7	FF2	10	b	22	9	13	17	1.	7.	-5
7	FF2	10	с	13	2. 1	16	12	0. 58	4. 8	-1
7	FF2	10	d	16	3. 2	20	17	2. 7	16	1
7	FF2	10	е	13	2. 3	18	15	4. 6	31	2
7	FF2	10	f	8.3	2. 3	28	12	3. 5	29	3.7
7	FF2	10	g	34	3.	9.	22	4.	21	-12



					2	4		7		
7	FF2	10	h	11	2. 7	25	14	4. 7	34	3
8	C1	9	а	13	2. 1	16	14	3. 5	25	1
8	C1	9	b	17	1	5. 9	13	2	15	-4
8	C1	9	С	24	4. 7	20	22	4	18	-2
8	C1	9	d	17	2. 5	15	17	1	5. 9	0
8	C1	9	е	18	1. 2	6. 7	18	0. 58	3. 2	0
8	C1	9	f	16	2. 3	14	16	1. 5	9. 4	0
8	C1	9	g	33	2. 9	8. 8	20	0. 58	2. 9	-13
8	C1	9	h	17	1	5. 9	17	0. 58	3. 4	0
								4		
8	C2	10	а	17	2. 5	15	14	1. 7	12	-3
8	C2	10	b	15	2. 5	17	17	3. 2	19	2
8	C2	10	С	27	1	3. 7	21	2. 1	10	-6
8	C2	10	d	17	0. 58	3. 4	17	2. 1	12	0
8	C2	10	е	18	1	5. 6	8.3	2. 3	28	-9.7
8	C2	10	f	15	2. 7	18	33	3. 5	11	18
8	C2	10	g	14	1. 5	11	40	2. 3	5. 8	26
8	C2	10	h	16	2. 7	17	18	2. 3	13	2
8	FF1	8	а	15	2. 1	14	12	1. 2	10	-3
8	FF1	8	b	28	4. 9	18	34	1. 5	4. 4	6
8	FF1	8	С	17	1. 5	8. 8	17	2. 3	14	0
8	FF1	8	d	18	4.	24	21	5. 2	25	3
8	FF1	8	е	15	3. 5	23	17	1. 5	8. 8	2
8	FF1	8	f	17	2. 5	15	16	3. 5	22	-1
8	FF1	8	g	17	4. 9	29	18	4	22	1
8	FF1	8	h	17	3	18	20	0.	2.	3



								58	9	
					1.	7.			4.	
8	FF2	7	а	16	2	5	25	1	0	9
8	FF2	7	b	22	2. 1	10	23	3. 2	14	1
8	FF2	7	С	17	1	5. 9	21	7. 8	37	4
8	FF2	7	d	33	3. 2	10	36	3. 2	8. 9	3
8	FF2	7	е	18	2. 3	13	13	3. 8	29	-5
8	FF2	7	f	34	3. 2	9. 4	56	2. 3	4. 1	22
					3.			4.		
8	FF2	7	g	21	6	17 5.	21	9 2.	23	0
8	FF2	7	h	17	1	9	17	1	12	0
0	C1	0	_	0.2	3. E	20	10	2.	10	2.7
9	C1	8	а	9.3	5 1.	38	13	1	16	3.7
9	C1	8	b	13	5 1.	12	26	3 3.	12	13
9	C1	8	С	15	7 2.	11	26	1 3.	12	11
9	C1	8	d	14	1	15	13	5 2.	27	-1
9	C1	8	е	14	5	11	27	7	10	13
9	C1	8	f	13	2. 3	18	15	3. 5	23	2
9	C1	8	g	20	1. 5	7. 5	16	1. 5	9. 4	-4
9	C1	8	h	15	4. 3	29	26	2. 3	8. 8	11
						-		-	-	
9	C2	7	а	9.7	3. 1	32	22	4	18	12.3
9	C2	7	b	15	2. 1	14	26	3	12	11
9	C2	7	С	14	1. 2	8. 6	22	2. 1	10	8
9	C2	7	d	14	2. 7	19	14	2	14	0
9	C2	7	e	16	0. 58	3. 6	30	2. 5	8. 3	14
					3.			2.		
9	C2	7	f	16	1 2.	19	18	1 1.	12 5.	2
9	C2	7	g	15	5 1.	17 8.	29	5 4.	2	14
9	C2	7	h	17	5	8	27	2	16	10



9	FF1	9	а	8.7	2. 3	26	10	1. 5	15	1.3
9	FF1	9	b	13	2. 5	19	16	2	13	3
9	FF1	9	С	13	3. 1	24	16	2. 7	17	3
9	FF1	9	d	12	4. 5	38	13	1. 7	13	1
9	FF1	9	е	15	3	20	14	1. 2	8. 6	-1
9	FF1	9	f	12	1. 5	13	24	4	17	12
9	FF1	9	g	17	1. 5	8. 8	28	2. 1	7. 5	11
9	FF1	9	h	16	3. 2	20	14	3. 8	27	-2
					N/	N/		N/	N/	
9	FF2	10	а	N/A	A	A	N/A	A	A	N/A
					N/	N/		N/	N/	
9	FF2	10	b	N/A	А	А	N/A	А	А	N/A
					N/	N/		N/	N/	
9	FF2	10	С	N/A	Α	A	N/A	Α	A	N/A
0	FFO	40		N1/A	N/	N/	N1/A	N/	N/	N1/A
9	FF2	10	d	N/A	A	A	N/A	A	A	N/A
9	FF2	10	е	N/A	N/ A	N/ A	N/A	N/ A	N/ A	N/A
5	112	10	U	11/7	N/	N/	11/7	N/	N/	11/71
9	FF2	10	f	N/A	A	A	N/A	A	A	N/A
					N/	N/		N/	N/	
9	FF2	10	g	N/A	А	А	N/A	А	А	N/A
					N/	N/		N/	N/	
9	FF2	10	h	N/A	Α	A	N/A	Α	А	N/A
					2.			3.		
10	C1	9	а	14	7	19	19	6	19	5
10	04	0	k	0.0	4.	40	40	1.	7.	07
10	C1	9	b	9.3	5 2.	48	19	5 2.	9	9.7
10	C1	9	С	18	2. 1	12	14	2. 7	19	-4
10	01	3	U	10	5.	12	14	3.	13	-7
10	C1	9	d	19	1	27	22	6	16	3
		-	-		3.	-	_	3.	-	-
10	C1	9	е	17	2	19	21	2	15	4
	_				3.			0.	3.	
10	C1	9	f	21	6	17	18	58	2	-3
40	04	0		4-		5.	00	2.	8.	40
10	C1	9	g	17	1 2.	9	29	5	6	12
10	C1	9	h	16	2. 7	17	26	3. 6	14	10
		-			-			-		
					3.			3.	9.	
10	C2	10	а	20	5	18	39	5	0	19
<u>.</u>										



10	C2	10	b	12	3. 1	26	19	1	5. 3	7
10	C2	10	С	17	2. 1	12	16	2. 1	13	-1
10	C2	10	d	26	4. 2	16	44	4. 5	10	18
10	C2	10	е	13	1. 5	12	15	1. 7	11	2
10	C2	10	f	11	4. 2	38	12	4	33	1
10	C2	10	g	14	4	29	18	2. 1	12	4
10	C2	10	h	19	2. 7	14	19	4	21	0
10	FF1	8	а	12	2. 3	19	11	3. 5	32	-1
10	FF1	8	b	19	3. 5	18	16	2. 3	14	-3
10	FF1	8	С	21	2. 7	13	22	1. 7	7. 7	1
10	FF1	8	d	13	2. 1	16	16	2. 5	16	3
10	FF1	8	е	23	2. 5	11	27	2. 7	10	4
10	FF1	8	f	14	1. 2	8. 6	16	3. 2	20	2
10	FF1	8	g	20	2. 1	11	16	1	6. 3	-4
10	FF1	8	h	18	2. 1	12	24	3. 1	13	6
10	FF2	7	а	5.7	1. 5	26	21	3. 8	18	15.3
10	FF2	7	b	14	3. 5	25	19	1. 7	8. 9	5
10	FF2	7	С	20	0. 58	2. 9	31	4. 4	14	11
10	FF2	7	d	21	4. 9	23	21	4. 4	21	0
10	FF2	7	е	36	2. 5	6. 9	28	2	7. 1	-8
10	FF2	7	f	13	1. 5	12	15	1. 5	10	2
10	FF2	7	g	18	0. 58	3. 2	29	4. 4	15	11
10	FF2	7	h	18	3. 5	19	20	4. 9	25	2
11	C1	8	а	17	2. 5	15	15	1. 5	10	-2
11	C1	8	b	24	2. 7	11	22	1	4. 5	-2



11	C1	8	с	31	2. 1	6. 8	38	1. 5	3. 9	7
11	C1	8	d	18	0. 58	3. 2	17	4. 4	26	-1
11	C1	8	е	29	2. 1	7. 2	28	4	14	-1
11	C1	8	f	14	1	7. 1	27	2. 5	9. 3	13
11	C1	8	g	16	3	19	30	2. 1	7. 0	14
11	C1	8	h	21	3. 1	15	31	1. 2	3. 9	10
11	C2	7	а	14	3. 5	25	15	3. 8	25	1
11	C2	7	b	14	1	7. 1	24	2	8. 3	10
11	C2	7	с	21	3. 6	17	18	1. 7	9. 4	-3
11	C2	7	d	20	4	20	19	3	16	-3
11	C2	7	e	20	3. 5	18	17	1. 5	8. 8	-3
11	C2	7	f	13	1	7. 7	17	3. 1	18	4
11	C2	7	g	17	1. 2	7. 1	26	1. 5	5. 8	9
11	C2	7	h	14	1. 5	11	16	2	13	2
11	FF1	9	а	16	2. 9	18	15	3. 8	25	-1
11	FF1	9	b	27	2. 1	7. 8	21	2. 7	13	-6
11	FF1	9	С	25	2	8. 0	33	3	9. 1	8
11	FF1	9	d	31	2. 7	8. 7	35	2. 1	6. 0	4
11	FF1	9	е	30	3. 1	10	31	2. 5	8. 1	1
11	FF1	9	f	40	6. 3	16	41	3. 6	8. 8	1
11	FF1	9	g	17	1	5. 9	28	2. 3	8. 2	11
11	FF1	9	h	33	2. 3	7. 0	40	0. 58	1. 5	7
11	FF2	10	а	7.3	1. 2	16	9.7	0. 58	6. 0	2.4
11	FF2	10	b	15	4. 4	29	14	3. 5	25	-1
					2.	8.		3.		
11 11	FF2	10	с	29	2. 5 3.	6	26	6	14	-3 2



					2			5		
					1.	6.		2.		
11	FF2	10	е	19	2	3	18	2. 3	13	-1
					2.			1.	9.	
11	FF2	10	f	11	5	23	16	5	4	5
11	FF2	10	g	12	2. 9	24	24	4. 2	18	12
	112	10	9	12	5	5.	27	4.	10	12
11	FF2	10	h	36	2	6	26	2	16	-10
	•	-			N/	N/		N/	N/	
12	C1	9	а	N/A	A N/	A N/	N/A	A N/	A N/	N/A
12	C1	9	b	N/A	A	A	N/A	A	A	N/A
		-			N/	N/		N/	N/	
12	C1	9	С	N/A	Α	А	N/A	Α	Α	N/A
12	C1	9	d	N/A	N/	N/	NI/A	N/	N/	NI/A
12	C1	9	u	IN/A	A N/	A N/	N/A	A N/	A N/	N/A
12	C1	9	е	N/A	A	A	N/A	A	A	N/A
	_				N/	N/		N/	N/	
12	C1	9	f	N/A	A	A	N/A	A	A	N/A
12	C1	9	g	N/A	N/ A	N/ A	N/A	N/ A	N/ A	N/A
12	01	0	9	1 1/7 1	N/	N/	11/7 (	N/	N/	11/7 \
12	C1	9	h	N/A	А	А	N/A	А	А	N/A
		10			N/	N/		N/	N/	
12	C2	10	а	N/A	A N/	A N/	N/A	A N/	A N/	N/A
12	C2	10	b	N/A	A	A	N/A	A	A	N/A
					N/	N/		N/	N/	
12	C2	10	С	N/A	Α	Α	N/A	Α	Α	N/A
10	C2	10	d	N/A	N/	N/	NI/A	N/	N/	NI/A
12	62	10	u	IN/A	A N/	A N/	N/A	A N/	A N/	N/A
12	C2	10	е	N/A	A	A	N/A	A	A	N/A
			_		N/	N/		N/	N/	
12	C2	10	f	N/A	A N/	A N/	N/A	A N/	A N/	N/A
12	C2	10	g	N/A	A	A	N/A	A	A	N/A
			3		N/	N/		N/	N/	
12	C2	10	h	N/A	А	А	N/A	А	А	N/A
10		0		N1/A	N/	N/	N1/A	N/	N/	N1/A
12	FF1	8	а	N/A	A N/	A N/	N/A	A N/	A N/	N/A
12	FF1	8	b	N/A	A	A	N/A	A	A	N/A
					N/	N/		N/	N/	
12	FF1	8	С	N/A	A	A	N/A	A	A	N/A
12	FF1	8	d	N/A	N/ A	N/ A	N/A	N/ A	N/ A	N/A
12	FF1	8		N/A	N/	N/	N/A	N/	N/	N/A
ΙZ		0	е	N/A	IN/	IN/	N/A	IN/	IN/	IN/A



12       FF1       8       f       N/A       A       A       N/A       A       A         12       FF1       8       g       N/A       A       A       N/A       A       A <t< th=""><th></th><th></th><th></th><th></th><th></th><th>А</th><th>А</th><th></th><th>А</th><th>А</th><th></th></t<>						А	А		А	А	
12       FF1       8       f       N/A       A       A       N/A       A       A       A       N/A       A <td< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></td<>											
N/         N/         N/A         A <td>12</td> <td>FF1</td> <td>8</td> <td>f</td> <td>N/A</td> <td></td> <td></td> <td>N/A</td> <td></td> <td></td> <td>N/A</td>	12	FF1	8	f	N/A			N/A			N/A
NV         NV         NV         NV         NV         NV           12         FF1         8         h         N/A         <											
12       FF1       8       h       N/A       A       A       N/A       A	12	FF1	8	g	N/A			N/A			N/A
12       FF2       7       a       N/A       A       A       N/A       A       N/A       A       N/A       A       A       N/A       <	40		0	h	N1/A			N1/A			N1/A
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	12	FF1	8	n	N/A	A	A	N/A	A	A	N/A
$\begin{array}{cccccccccccccccccccccccccccccccccccc$						NI/	NI/		NI/	NI/	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	12	FF2	7	а	N/A			N/A			N/A
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$			•	<u> </u>							
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	12	FF2	7	b	N/A			N/A			N/A
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	40	550	-		N1/A			N1/A			N1/A
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	12	FF2	1	С	N/A			N/A			N/A
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	12	FF2	7	d	N/A			N/A			N/A
12       FF2       7       e       N/A       A       A       N/A       N/A       A       A       N/A       N/A       A       A       N/A       N/A       A       A       A       N/A       N/A       N/A       A       A       N/A       N/A       A       A       N/A       A       A       N/A       N/A       A       A       N/A       N/A       A       A       N/A       N/A       A       A       N/A       N/A       A											,
12       FF2       7       f       N/A       A       A       N/A       A       A       N/A       A       A       N/A       A       A       N/A	12	FF2	7	е	N/A			N/A		А	N/A
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	10		_		N. 1 / A			N. 1 / A			N1/A
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	12	FF2	1	t	N/A			N/A			N/A
12       FF2       7       h       N/A       A       A       N/A       N/A       A       A       N/A       A       A       A       N/A       A       A       A       N/A       A	12	FF2	7	a	N/A			N/A			N/A
12FF27hN/AAAN/AAAN/AN/A13C18a1551016711113C18b2031516586-413C18c171918582113C18c171918582113C18d13431265131313C18e1451817212313C18f1442913721-113C18f1442913721-113C18h1492126261213C18h1492126261213C18h1492126261213C27b1243717521513C27b1243717521513C27d1423020210613C27d1423020210613C			•	9	1.077			1.077			14/7
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	12	FF2	7	h	N/A			N/A			N/A
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$											
$\begin{array}{cccccccccccccccccccccccccccccccccccc$		_									
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	13	C1	8	а	15	5	10	16			1
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	13	C1	8	h	20	З	15	16			-4
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	10	01	U	6	20	0		10			
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	13	C1	8	С	17	1		18			1
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$			_								
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	13	C1	8	d	13		31	26	5	13	13
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	13	C1	8	۵	14		18	17	2	12	З
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	10	01	0	U	14	0	10	17		12	0
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	13	C1	8	f	14	4	29	13	7	21	-1
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$			_			_	_				_
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	13	C1	8	g	18		0	19			1
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	13	C1	8	h	14		21	26			12
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	10	01	Ű			Ŭ	- 1	20	-	Ű	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$							6.		3.		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	13	C2	7	а	15			17	2	19	2
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$											_
13       C2       7       c       33       4       12       28       7       1       -5         13       C2       7       d       14       2       30       20       2       10       6         13       C2       7       e       16       5       22       18       2       7       2	13	C2	7	b	12	4	37	17			5
4.         13       C2       7       d       14       2       30       20       2       10       6         3.       1.       6.         13       C2       7       e       16       5       22       18       2       7       2	13	C.2	7	c	33	Δ	12	28			-5
13       C2       7       d       14       2       30       20       2       10       6         3.       3.       1.       6.       1.       6.         13       C2       7       e       16       5       22       18       2       7       2	10	02	'	U	55		12	20	1	1	5
13 C2 7 e 16 5 22 18 2 7 2	13	C2	7	d	14	2	30	20	2	10	6
13 C2 7 f 16 2. 13 18 3. 18 2											
	13	C2	7	f	16	2.	13	18	3.	18	2



					1			2		
13	C2	7	g	15	1. 5	10	30	4. 2	14	15
13	C2	7	h	21	2. 1	10	18	2	11	-3
					0			0		
13	FF1	9	а	13	3. 2	25	17	2. 5	15	4
13	FF1	9	b	15	1. 7	11	15	2	13	0
13	FF1	9	С	20	4. 6	23	22	3. 5	16	2
13	FF1	9	d	16	1. 7	11	28	1. 5	5. 4	12
13	FF1	9	е	17	1	5. 9	25	3. 5	14	8
13	FF1	9	f	12	2. 1	18	16	3	19	4
13	FF1	9	g	16	1	6. 3	26	1. 7	6. 5	10
13	FF1	9	h	12	1. 7	14	24	4	17	12
								2.		
13	FF2	10	а	17	3	18	17	7	16	0
13	FF2	10	b	14	0. 58	4.	16	3.	19	2
13	FF2	10	С	18	0. 58	3. 2	16	2. 5	16	-2
13	FF2	10	d	15	3. 1	21	13	2. 5	19	-2
13	FF2	10	е	21	4. 9	23	20	3. 5	18	-1
13	FF2	10	f	13	3. 1	24	20	2. 7	14	7
13	FF2	10	g	15	1. 7	11	24	4. 2	18	9
13	FF2	10	h	18	2. 1	12	27	2. 5	9. 3	9
					2			0	2	
14	C1	9	а	10	2. 1	21	17	0. 58	3. 4	7
14	C1	9	b	17	1	5. 9	27	2.	7. 8	10
14	C1	9	С	14	1. 5	11	17	2. 5	15	3
14	C1	9	d	14	1	7. 1	20	1	5. 0	6
14	C1	9	е	16	3. 8	24	28	4. 2	15	12
14	C1	9	f	14	1. 2	8. 6	20	2. 1	11	6
14	C1	9	g	16	2.	18	21	3.	18	5



					9			8		
14	C1	9	h	14	2. 3	16	22	3	14	8
	01	Ű			Ū	10				Ű
14	C2	10	а	14	4	29	17	3. 8	22	3
14	C2	10	b	15	2	13	18	2. 7	15	3
14	C2	10	С	27	3. 6	13	32	3. 8	12	5
14	C2	10	d	9	3	33	16	1	6. 3	7
					2.			2.		
14	C2	10	е	15	7 1.	18	23	9 0.	13 5.	8
14	C2	10	f	14	5 1.	11	11	58	3	-3
14	C2	10	g	17	7	10 6.	14	4 3.	29	-3
14	C2	10	h	16	1	3	15	1	21	-1
					0.	4.		2.		
14	FF1	8	а	12	58 2.	8	16	9 4.	18	4
14	FF1	8	b	16	5	16	29	2	14	13
14	FF1	8	С	12	3. 8	32	17	1. 5	8. 8	5
14	FF1	8	d	14	1. 5	11	16	3	19	2
14	FF1	8	е	27	4	15	21	4	19	-6
14	FF1	8	f	14	1	7. 1	17	2. 5	15	3
14	FF1	8	g	14	1	7. 1	18	4	22	4
14	FF1	8	h	16	3. 5	22	21	4. 7	22	5
		Ū		10	Ŭ					Ű
14	FF2	7	а	12	1. 2	10	11	2	18	-1
14	FF2	7	b	16	2. 7	17	19	3. 5	18	3
14	FF2	7	c	28	4. 6	16	34	3. 2	9. 4	6
						31		1.		1
14	FF2	7	d	13	4		14	5 4.	11	
14	FF2	7	е	29	2	11	26	2 3.	16	-3
14	FF2	7	f	20	5 2.	25	21	2 0.	15 3.	1
14	FF2	7	g	16	1 4.	13	19	58 2.	1	3
14	FF2	7	h	15	4.	29	17	2. 1	12	2



15	C1	8	а	11	0. 58	5. 3	11	1. 7	15	0
15	C1	8	b	17	2. 1	12	15	1. 2	8. 0	-2
15	C1	8	с	19	4. 6	24	20	4. 4	22	1
15	C1	8	d	13	0. 58	4. 5	10	0. 58	5. 8	-3
15	C1	8	е	23	4	17	19	2. 7	14	-4
15	C1	8	f	11	3. 5	32	13	3. 8	29	2
15	C1	8	g	21	3. 2	15	26	4. 7	18	5
15	C1	8	h	14	0. 58	4. 1	17	2. 9	17	3
15	C2	7	а	11	2. 7	25	14	1. 5	11	3
15	C2	7	b	15	1. 2	8. 0	23	3. 8	17	8
15	C2	7	С	18	2. 1	12	28	1. 5	5. 4	10
15	C2	7	d	11	2. 7	25	14	2. 5	18	3
15	C2	7	е	18	3. 8	21	23	3. 2	14	5
15	C2	7	f	18	4. 2	23	38	0	0	20
15	C2	7	g	22	3. 8	17	39	2. 1	5. 4	17
15	C2	7	h	34	2. 5	7. 4	28	2. 7	10	-6
15	FF1	9	а	11	3. 1	28	8	2	25	-3
15	FF1	9	b	14	1	7. 1	15	1. 5	10	1
15	FF1	9	С	11	2. 1	19	15	2. 5	17	4
15	FF1	9	d	15	3	20	13	1. 7	13	-2
15	FF1	9	е	21	3. 1	15	20	4	20	-1
15	FF1	9	f	13	2. 7	21	18	3. 5	19	5
15	FF1	9	g	28	2. 1	7. 5	28	0. 58	2. 1	0
15	FF1	9	h	21	4	19	20	3. 2	16	-1
15	FF2	10	а	9.7	1.	15	10	2	20	0.3



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15	FF2	10	b	15	3. 6	24	14	0. 58	4. 1	-1
15	FF2	10	с	24	3. 5	15	18	2. 1	12	-6
15	FF2	10	d	12	1. 5	13	16	4. 2	26	4
15	FF2	10	е	11	2. 5	23	16	1. 5	9. 4	5
15	FF2	10	f	14	2. 3	16	14	2. 5	18	0
15	FF2	10	g	17	1. 5	8. 8	37	3. 2	8. 6	20
15	FF2	10	h	16	2. 5	16	25	3. 1	12	9
16	C1	9	а	16	2	13	13	2. 1	16	-3
16	C1	9	b	12	1	8. 3	18	2. 3	13	6
16	C1	9	С	13	1	7. 7	14	2. 7	19	1
16	C1	9	d	18	2. 5	14	21	2. 9	14	3
16	C1	9	е	14	0. 58	4. 1	14	3. 1	22	0
16	C1	9	f	12	2. 1	18	14	4. 6	33	2
16	C1	9	g	13	5. 3	41	30	2. 7	9. 0	17
16	C1	9	h	16	2. 7	17	14	1. 5	11	-2
								2.		
16	C2	10	а	7	1	14	8.3	1	25	1.3
16	C2	10	b	16	2. 5	16	23	1. 5	6. 5	7
16	C2	10	С	16	3. 2	20	14	0. 58	4. 1	-2
16	C2	10	d	12	2	17	11	3. 5	32	-1
16	C2	10	е	15	4. 6	31	16	0	0	1
16	C2	10	f	17	1	5. 9	18	2. 7	15	1
16	C2	10	g	18	2. 3	13	21	2. 7	13	3
16	C2	10	h	15	2. 5	17	28	1. 7	6. 1	13
					Λ					
16	FF1	8	а	13	4. 4	34	12	2	17	-1
16	FF1	8	b	13	2.	16	30	2.	8.	17

					1			5	3	
16	FF1	8	С	12	1. 5	13	16	2. 5	16	4
16	FF1	8	d	17	3. 5	21	15	0. 58	3. 9	-2
16	FF1	8	е	18	2. 5	14	15	1. 5	10	-3
16	FF1	8	f	16	3	19	17	2. 7	16	1
16	FF1	8	g	15	2. 7	18	26	3. 2	12	11
16	FF1	8	h	11	1. 2	11	15	3. 1	21	4
16	FF2	7	а	12	4.	37	18	2	11	6
16	FF2	7	b	18	2. 3	13	16	1. 7	11	-2
16	FF2	7	С	15	2. 7	18	25	2. 5	10	10
16	FF2	7	d	15	1	6. 7	27	2. 1	7. 8	12
16	FF2	7	е	15	1. 5	10	16	3. 1	19	1
16	FF2	7	f	17	3. 1	18	18	3. 2	18	1
16	FF2	7	g	14	3. 5	25	29	1	3. 4	15
16	FF2	7	h	14	1. 7	12	16	4	25	2
					1.			2.		
17	C1	8	а	11	2 3.	11	16	1	13 6.	5
17	C1	8	b	14	1 2.	22	15	1 1.	7	1
17	C1	8	С	17	2. 1 1.	12	14	5 2.	11	-3
17	C1	8	d	17	7 2.	10	17	2. 1 2.	12	0
17	C1	8	е	16	1	13	17	1	12	1
17	C1	8	f	16	2. 7	17	16	1. 7	11	0
17	C1	8	g	17	3. 2	19	17	2. 5	15	0
17	C1	8	h	20	3. 8	19	19	3. 8	20	-1
						6.		2.		
17	C2	7	а	15	1 3.	7	17	1 4.	12	2
17 17	C2 C2	7 7	b c	22 18	8 1	17 5.	20 32	2 3.	21 11	-2 14
17	02	1	U	10	I	J.	52	э.	11	14



						6		5		
17	C2	7	d	16	1. 5	9. 4	28	4. 4	16	12
17	C2	7	е	16	1	6. 3	16	2. 5	16	0
17	C2	7	f	15	1. 2	8. 0	17	4	24	2
17	C2	7	g	17	0. 58	3. 4	19	0. 58	3. 1	2
17	C2	7	h	20	1. 7	8. 5	16	2	13	-4
17	FF1	9	а	17	2	12	13	0. 58	4. 5	-4
17	FF1	9	b	13	2. 7	21	15	0. 58	3. 9	2
17	FF1	9	С	17	2	12	18	2. 7	15	1
17	FF1	9	d	13	4	31	17	2. 7	16	4
17	FF1	9	е	15	1. 5	10	16	2. 1	13	1
17	FF1	9	f	10	2. 9	29	18	2. 1	12	8
17	FF1	9	g	16	1	6. 3	26	2. 1	8. 1	10
17	FF1	9	h	14	3. 5	25	20	3. 6	18	6
17	FF2	10	а	12	4. 7	39	17	2. 5	15	5
17	FF2	10	b	18	2. 3	13	17	1	5. 9	-1
17	FF2	10	С	18	1	5. 6	16	1. 2	7. 5	-2
17	FF2	10	d	11	2. 7	25	14	2. 7	19	3
17	FF2	10	е	16	2. 1	13	18	4. 4	24	2
17	FF2	10	f	16	4	25	16	2	13	0
17	FF2	10	g	19	0. 58	3. 1	17	3	18	-2
17	FF2	10	h	17	1	5. 9	18	2. 1	12	1
									6	
18	C1	9	а	12	1. 5	13	11	1	9. 1	-1
18	C1	9	b	31	1. 5	4. 8	34	1. 5	4. 4	3
18	C1	9	С	15	3. 2	21	32	3. 8	12	17
18	C1	9	d	13	2. 9	22	13	2	15	0



18	C1	9	е	16	1. 5	9. 4	15	2. 7	18	-1
18	C1	9	f	12	2. 7	23	12	2. 1	18	0
18	C1	9	g	15	3. 8	25	28	2. 7	10	13
18	C1	9	h	19	1. 7	8. 9	23	2. 6	11	4
18	C2	10	а	13	4. 6	35	12	0. 58	4. 8	-1
18	C2	10	b	14	3. 8	27	12	1. 2	10	-2
18	C2	10	С	34	1	2. 9	37	1. 5	4. 1	3
18	C2	10	d	14	2. 1	15	10	2. 1	21	-4
								3.		_
18	C2	10	е	19	4	21	21	2	15	2
18	C2	10	f	12	1. 5	13	13	0. 58	4. 5	1
18	C2	10	g	17	2. 1	12	14	1. 2	8. 6	-3
18	C2	10	h	16	2. 1	13	18	3. 6	20	2
18	FF1	8	а	12	1. 2	10	14	3. 2	23	2
18	FF1	8	b	14	3. 5	25	18	2. 5	14	4
18	FF1	8	С	12	1. 5	13	17	1. 5	9	5
18	FF1	8	d	11	4. 6	42	15	1. 7	11	4
18	FF1	8	е	13	2. 1	16	25	2. 7	11	12
18	FF1	8	f	12	1. 5	13	13	3	23	1
18	FF1	8	g	16	1	6. 3	16	3. 5	22	0
18	FF1	8	h	13	0. 58	4. 5	36	2. 5	6. 9	23
18	FF2	7	а	15	1. 7	11	13	2	15	-2
18	FF2	7	b	28	3. 6	13	39	3	7. 7	11
18	FF2	7	С	14	2. 7	19	16	2. 3	14	2
18	FF2	7	d	11	2. 5	23	15	2. 1	14	4
18	FF2	7	е	17	4. 4	26	17	2. 7	16	0



18	FF2	7	f	15	2. 5	17	16	0. 58	3. 6	1
18	FF2	7	g	14	3. 2	23	19	1. 2	6. 3	5
18	FF2	7	h	15	2. 1	14	14	2. 7	19	-1
19	C1	9	а	12	2. 1	18	12	1. 7	14	0
19	C1	9	b	15	3. 6	24	22	3. 5	16	7
19	C1	9	С	31	0. 58	1. 9	32	2. 3	7. 2	1
19	C1	9	d	16	3. 1	19	20	4. 9	25	4
19	C1	9	е	13	3. 2	25	15	2. 5	17	2
19	C1	9	f	17	3. 1	18	15	1. 5	10	-2
19	C1	9		17	1. 7	10	18	2. 1	12	1
			g		3.			1.	4.	
19	C1	9	h	26	2	12	33	5	5	7
					2.					
19	C2	10	а	9	7	30	12	4	33	3
19	C2	10	b	18	4. 4	24	25	4. 6	18	7
19	C2	10	с	18	1. 5	8. 3	15	2. 7	18	-3
19	C2	10	d	9	1	11	12	2. 3	19	3
19	C2	10	е	19	2. 1	11	23	3. 6	16	4
19	C2	10	f	15	2. 1	14	15	2. 5	17	0
19	C2	10	g	18	2. 3	13	18	1. 5	8. 3	0
19	C2	10	h	19	0. 58	3. 1	29	2. 5	8. 6	10
19	FF1	8	0	10	1. 5	13	12	2. 5	10	1
			а	12	0.	2.	13		19 6.	
19	FF1	8	b	29	58 0.	0 3.	44	3 2.	8	15
19	FF1	8	С	17	58 5.	4	21	1	10	4
19	FF1	8	d	30	2	17	21	4 2.	19	-9
19	FF1	8	е	17	3	18	22	5	11	5
19	FF1	8	f	15	1. 2	8. 0	17	2. 5	15	2



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19	FF1	8	g	31	2. 1	6. 8	44	2	4. 5	13
19	FF1	8	h	18	4. 2	23	22	3. 8	17	4
					N/	N/		N/	N/	
19	FF2	7	а	N/A	А	А	N/A	А	А	N/A
					N/	N/		N/	N/	
19	FF2	7	b	N/A	A	A	N/A	A	A	N/A
10	ГГО	7	•	NI/A	N/	N/	NI/A	N/	N/	N1/A
19	FF2	7	С	N/A	A N/	A N/	N/A	A N/	A N/	N/A
19	FF2	7	d	N/A	A	A	N/A	A	A	N/A
10	112		u	11/7 (	N/	N/	1 1/7 1	N/	N/	14/73
19	FF2	7	е	N/A	A	A	N/A	A	A	N/A
					N/	N/		N/	N/	
19	FF2	7	f	N/A	А	А	N/A	А	А	N/A
					N/	N/		N/	N/	
19	FF2	7	g	N/A	Α	A	N/A	Α	A	N/A
40		_		N 1 / A	N/	N/		N/	N/	<b>N</b> 1/A
19	FF2	7	h	N/A	A	А	N/A	Α	А	N/A
					4.			2.		_
20	C1	8	а	10	1	41	11	7	25	1
20	01	0	h	25	4	2.	20	2.	4.4	0
20	C1	8	b	35	1 3.	9	26	9 4.	11	-9
20	C1	8	с	26	3. 6	14	25	4. 4	18	-1
20		0	0	20	3.	17	20	1.	8.	
20	C1	8	d	15	1	21	15	2	0	0
					2.	7.		2.	9.	
20	C1	8	е	32	5	8	27	5	3	-5
					1.	8.				
20	C1	8	f	18	5	3	19	3	16	1
	0.1	•			2.	4.0		3.	4 -	
20	C1	8	g	22	7	12	23	8	17	1
20	C1	8	h	20	1	5. 0	16	2. 9	18	-4
20		U	11	20	1	U	10	J	10	-4
						7				
20	C2	7	а	14	1	7. 1	14	2	14	0
20	02	1	a	14	3.	1	14	3.	14	U
20	C2	7	b	12	J. 1	26	13	5. 5	27	1
			~		0.	2.		3.		
20	C2	7	С	21	58	8	22	8	17	1
					1.	7.		1.	7.	
20	C2	7	d	20	5	5	19	5	9	-1
	-	_				4.		4.		_
20	C2	7	е	25	1	0	26	2	16	1
20	00	7	£	10	3.	20	10	3.	20	0
20	C2	7	f	12	6	30	12	1 0.	26 3.	0
20	C2	7	g	19	2. 7	14	15	0. 58	3. 9	-4
20	02	1	9	13	,	1-7	10	00	5	7



20	C2	7	h	22	2. 5	11	26	4	15	4
20	FF1	9	а	9	3	33	10	2	20	1
								1.	6.	
20	FF1	9	b	24	4	17 3.	25	7 3.	8	1
20	FF1	9	С	19	58	1	16	2	20	-3
20	FF1	9	d	15	0. 58	3. 9	17	1. 2	7. 1	2
20	FF1	9	е	17	2. 7	16	18	0. 58	3. 2	1
20	FF1	9	f	16	2. 5	16	17	2. 7	16	1
20	FF1	9	g	26	1. 7	6. 5	27	1. 7	6. 3	1
20	FF1	9	h	18	2. 1	12	16	1. 5	9. 4	-2
									-	
20	FF2	10	а	14	3. 2	23	17	2. 3	14	3
20	FF2	10	b	31	3. 2	10	33	3. 1	9. 4	2
				12	2. 5	21	13	2. 1	16	
20	FF2	10	С		3.			2.		1
20	FF2	10	d	14	2 3.	23	14	1 4.	15	0
20	FF2	10	е	17	6 2.	21	16	9	31	-1
20	FF2	10	f	12	1	18	13	5	12	1
20	FF2	10	g	14	2. 9	21	15	2. 7	18	1
20	FF2	10	h	21	2. 1	10	21	3. 2	15	0

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# STATISTICALLY INSIGNIFICANT FINDINGS

	Difference: Time2 - Time1 Trt_Site=C1a									
Ν	N Mean Std Dev Std Err Minimum Maximum									
19	19 1.1947 4.2135 0.9667 -9.0000 10.0000									

Mean			Std Dev	95% CL Std Dev				
1.1947	-0.8361	3.2256	4.2135	3.1838	6.2311			

DF	t Value	Pr >  t
18	1.24	0.2324

## Difference: Time2 - Time1 Trt\_Site=C1b

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	2.7211	8.3845	1.9235	-16.0000	20.0000

Mean	95% CL Mean		Std Dev	95% CL Std De	
2.7211	-1.3202	6.7623	8.3845	6.3355	12.3993

DF	t Value	Pr >  t
18	1.41	0.1743

## Difference: Time2 - Time1 Trt\_Site=C1d

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	1.3158	5.3025	1.2165	-12.0000	13.0000

Mean	95% CL Mean		Std Dev	95% CL	Std Dev
1.3158	-1.2400	3.8715	5.3025	4.0067	7.8415

DF	t Value	Pr >  t	
18	1.08	0.2937	

Difference: Time2 - Time1 Trt\_Site=C1e



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	1.4737	7.0188	1.6102	-8.0000	21.0000

Mean	95% CL Mean		Std Dev	d Dev 95% CL S	
1.4737	-1.9093	4.8566	7.0188	5.3035	10.3795

DF	t Value	Pr >  t
18	0.92	0.3722

Difference: Time2 - Time1 Trt\_Site=C1f

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	0.2632	4.5196	1.0369	-10.0000	13.0000

Mean	95% CL Mean		Std Dev	95% CL Std De	
0.2632	-1.9152	2.4415	4.5196	3.4151	6.6837

DF	t Value	Pr >  t	
18	0.25	0.8025	

# Difference: Time2 - Time1

# Trt\_Site=C2a

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	2.4211	5.6713	1.3011	-5.0000	19.0000

Mean	95% CL Mean		Std Dev	95% CL Std Dev		
2.4211	-0.3124	5.1545	5.6713	4.2853	8.3869	

DF	t Value	Pr >  t
18	1.86	0.0792

#### Difference: Time2 - Time1 Trt Site=C2c

	TT_0TC=020								
Ν	Mean	Std Dev	Std Err	Minimum	Maximum				
19	3.5789	7.4708	1.7139	-6.0000	18.0000				

Mean	95% CL Mean		an 95% CL Mean Std Dev		95% CL Std Dev		
3.5789	-0.0219	7.1798	7.4708	5.6450	11.0480		



DF	t Value	Pr >  t	
18	2.09	0.0513	

Difference: Time2 - Time1

Trt\_Site=C2d

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	2.2105	5.5436	1.2718	-5.0000	18.0000

Mean	95% CL	. Mean	Std Dev	95% CL Std Dev	
2.2105	-0.4614	4.8824	5.5436	4.1888	8.1979

DF	t Value	Pr >  t
18	1.74	0.0993

# Difference: Time2 - Time1 Trt\_Site=C2e

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	0.1737	9.0570	2.0778	-32.0000	14.0000

Mean 95% CL		. Mean	Mean Std Dev		95% CL Std Dev	
0.1737	-4.1916	4.5390	9.0570	6.8436	13.3937	

D	F	t Value	Pr >  t	
1	8	0.08	0.9343	

Difference: Time2 - Time1 Trt\_Site=C2f

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	2.2632	6.4965	1.4904	-8.0000	20.0000

Mean 95% CL Mean		. Mean	Std Dev	95% CL Std Dev		
2.2632	-0.8681	5.3944	6.4965	4.9088	9.6072	

DF	t Value	Pr >  t	
18	1.52	0.1463	

Difference: Time2 - Time1

Trt\_Site=C2g

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	4.5263	9.4420	2.1662	-9.0000	26.0000



Mean	lean 95% CL Mean		Std Dev	95% CL Std Dev		
4.5263	-0.0246	9.0772	9.4420	7.1345	13.9631	

DF	t Value	Pr >  t	
18	2.09	0.0511	

#### Difference: Time2 - Time1 Trt\_Site=C2h

	Trt_Site=C2h								
Ν	Mean Std Dev		Std Err Minimum		Maximum				
19	1.8947	5.0541	1.1595	-6.0000	13.0000				

Mean	n 95% CL Mean		Std Dev	95% CL Std Dev	
1.8947	-0.5413	4.3307	5.0541	3.8189	7.4741

DF	t Value	Pr >  t	
18	1.63	0.1196	

# Difference: Time2 - Time1 Trt\_Site=FF1a

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	1.0158	4.2037	0.9644	-4.0000	15.0000

Mean	Mean 95% CL Mean		Std Dev	95% CL Std Dev	
1.0158	-1.0103	3.0419	4.2037	3.1764	6.2166

DF	t Value	Pr >  t
18	1.05	0.3061

## Difference: Time2 - Time1 Trt\_Site=FF1b

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	2.3684	7.1431	1.6387	-8.0000	17.0000

Mean	95% CL Mean		Std Dev	95% CL Std Dev	
2.3684	-1.0744	5.8113	7.1431	5.3974	10.5633

DF	t Value	Pr >  t
18	1.45	0.1656



## Difference: Time2 - Time1 Trt\_Site=FF1c

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	3.5789	8.4150	1.9305	-9.0000	27.0000

Mean	95% CL	. Mean	Std Dev	95% CL	Std Dev
3.5789	-0.4770	7.6349	8.4150	6.3585	12.4444

DF	t Value	Pr >  t
18	1.85	0.0802

## Difference: Time2 - Time1 Trt Site=FF1d

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	2.7368	6.3056	1.4466	-9.0000	17.0000

Mean	95% CL Mean		Std Dev	95% CL Std Dev	
2.7368	-0.3023	5.7760	6.3056	4.7646	9.3248

DF	t Value	Pr >  t
18	1.89	0.0747

# Difference: Time2 - Time1 Trt\_Site=FF1e

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	1.6316	5.4794	1.2571	-6.0000	15.0000

Mean	95% CL Mean		95% CL Mean Std Dev		95% CL Std Dev	
1.6316	-1.0094	4.2725	5.4794	4.1403	8.1030	

DF	t Value	Pr >  t	
18	1.30	0.2107	

## Difference: Time2 - Time1 Trt Site=FF1f

Ν	Mean Std Dev		Std Err	Minimum	Maximum		
19	1.6842	4.0284	0.9242	-7.0000	12.0000		

Mean	95% CL Mean		Std Dev	95% CL Std De	
1.6842	-0.2574	3.6258	4.0284	3.0439	5.9573



DF	t Value	Pr >  t	
18	1.82	0.0851	

## Difference: Time2 - Time1 Trt\_Site=FF2a

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	2.2353	4.9560	1.2020	-6.0000	15.3000

Mean	95% CL Mean		Std Dev	95% CL Std Dev	
2.2353	-0.3129	4.7835	4.9560	3.6911	7.5428

DF	t Value	Pr >  t	
16	1.86	0.0814	

## Difference: Time2 - Time1 Trt\_Site=FF2c

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	1.6471	5.2552	1.2746	-6.0000	11.0000

Mean	95% CL Mean		Std Dev	95% CL Std Dev	
1.6471	-1.0549	4.3491	5.2552	3.9140	7.9981

DF	t Value	Pr >  t	
16	1.29	0.2146	

Difference: Time2 - Time1 Trt\_Site=FF2d

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	1.7647	3.4916	0.8468	-5.0000	12.0000

Mean	95% CL Mean		Std Dev	95% CL Std Dev	
1.7647	-0.0305	3.5599	3.4916	2.6004	5.3139

DF	t Value	Pr >  t	
16	2.08	0.0536	

Difference: Time2 - Time1 Trt Site=FF2e

Ν	Mean	Std Dev	Std Err	Minimum	Maximum			



ſ	Ν	Mean	Std Dev	Std Err	Minimum	Maximum
	17	-0.3706	3.1579	0.7659	-8.0000	5.0000

Mean	95% CL	Mean	Std Dev	95% CL Std Dev		
-0.3706	-1.9942	1.2530	3.1579	2.3519	4.8061	

DF	t Value	Pr >  t
16	-0.48	0.6350

Difference: Time2 - Time1 Trt\_Site=FF2f

Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	1.9824	7.1628	1.7372	-17.0000	22.0000

Mean	95% Cl	. Mean	Std Dev	95% CL Std Dev		
1.9824	-1.7004	5.6651	7.1628	5.3346	10.9012	

DF	t Value	Pr >  t
16	1.14	0.2706

#### Difference: Time2 - Time1 Trt Site=FF2h

Ν	Mean	Std Dev	Std Err	Minimum	Maximum						
17	1.0000	4.6098	1.1180	-10.0000	9.0000						

Mean	95% CL Mean		Std Dev	Dev 95% CL Std E	
1.0000	-1.3701	3.3701	4.6098	3.4332	7.0157

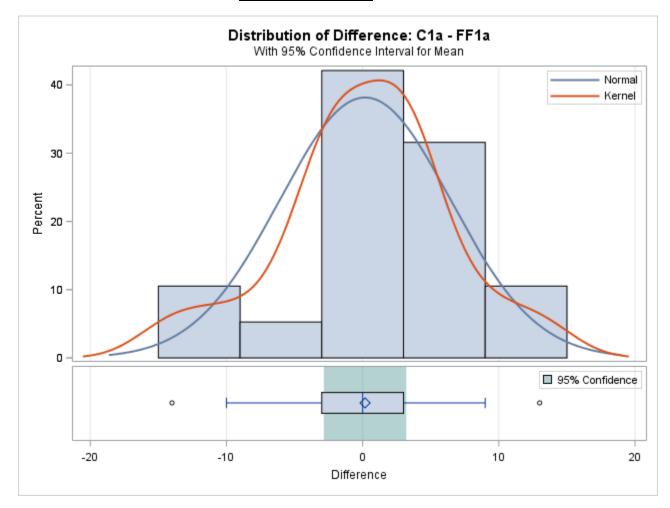
DF	t Value	Pr >  t
16	0.89	0.3844



# Appendix F: Statistical Analysis of the Differences between Conventional Brackets and Flash-Free Brackets between Treatment Groups

	Difference: C1a - FF1a									
N Mean		Std	Dev	Std Err		Minimum		Maximum		
19	0.17	789	6.2	723	1.4	4390	-14	1.0000		13.0000
Mean 9		95	% CL	. Mea	an	Std	Dev	95% C	L	Std Dev
0.1	789	-2.8	3442	3.20	)21	6.2	723	4.739	4	9.2756

DF	t Value	Pr >  t
18	0.12	0.9024

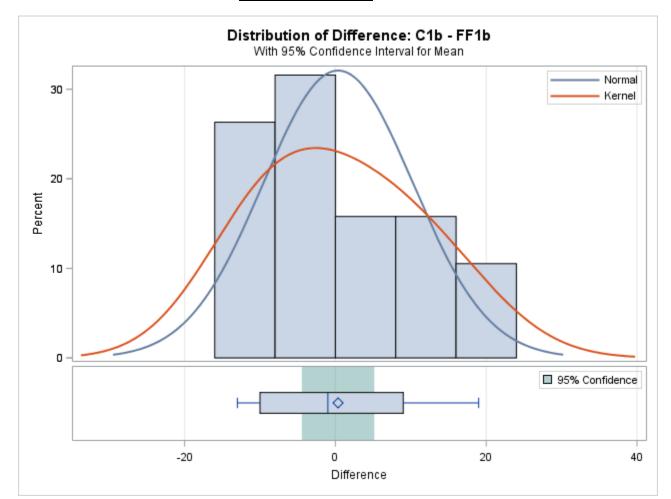




Difference: C1b - FF1b									
Ν	Mean	Std Dev	Std Err	Minimum	Maximum				
19	0.3526	9.9469	2.2820	-13.0000	19.0000				

Mean	95% CL Mean		Std Dev	95% CL Std De	
0.3526	-4.4416	5.1469	9.9469	7.5160	14.7097

DF	t Value	Pr >  t
18	0.15	0.8789

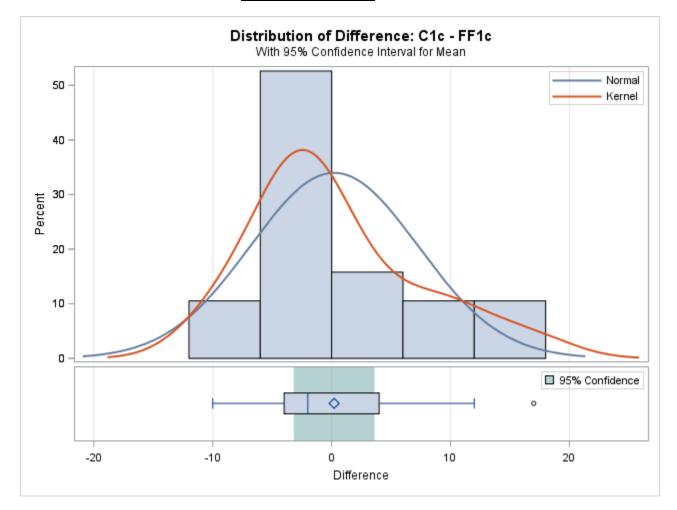




Difference: C1c - FF1c

Mean	95% CL Mean		Std Dev	95% CL Std Dev	
0.2105	-3.1846	3.6057	7.0441	5.3226	10.4170

DF	t Value	Pr >  t
18	0.13	0.8978



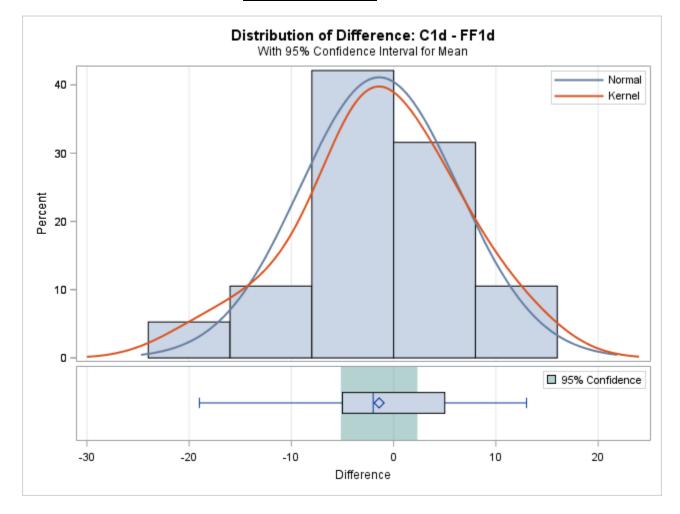
Difference: C1d - FF1d



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	-1.4211	7.7626	1.7809	-19.0000	13.0000

Mean	an 95% CL Mean		Std Dev	d Dev 95% CL Std	
-1.4211	-5.1625	2.3204	7.7626	5.8655	11.4795

DF	t Value	Pr >  t
18	-0.80	0.4353



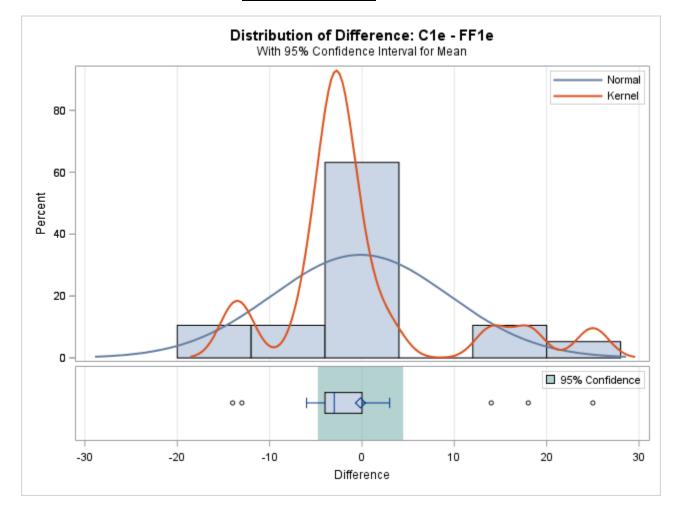
Difference: C1e - FF1e						
Mean	Std Dev	Std Err	Minimum	Maximum		



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	-0.1579	9.5816	2.1982	-14.0000	25.0000

Mean	95% CL Mean		Std Dev	95% CL Std De	
-0.1579	-4.7761	4.4603	9.5816	7.2400	14.1695

DF	t Value	Pr >  t
18	-0.07	0.9435



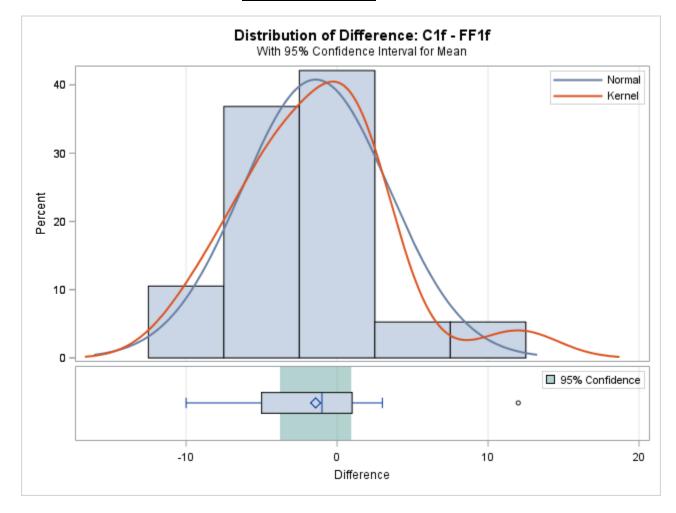
Difference: C1f - FF1f							
Mean	Std Dev	Std Err	Minimum	Maximum			



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	-1.4211	4.8912	1.1221	-10.0000	12.0000

Mean	95% CL	Mean	Std Dev	95% CL	Std Dev
-1.4211	-3.7785	0.9364	4.8912	3.6959	7.2332

DF	t Value	Pr >  t
18	-1.27	0.2215



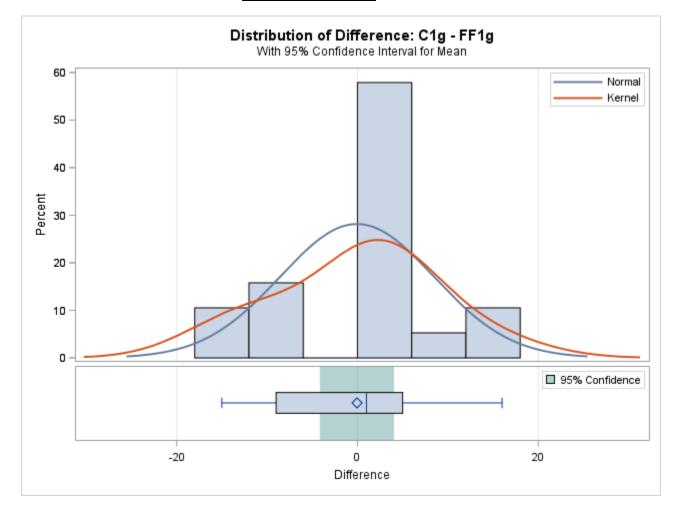
Difference: C1g - FF1g							
Ν	Mean	Std Dev	Std Err	Minimum	Maximum		



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	-0.0526	8.5015	1.9504	-15.0000	16.0000

Mean	95% CL Mean		Std Dev	95% CL Std Dev	
-0.0526	-4.1502	4.0449	8.5015	6.4238	12.5722

DF	t Value	Pr >  t	
18	-0.03	0.9788	



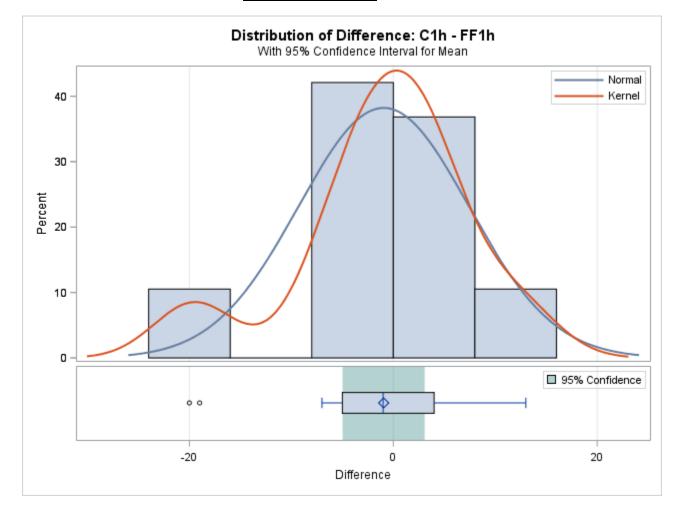
Difference: C1h - FF1h						
Ν	Mean	Std Dev	Std Err	Minimum	Maximum	



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
19	-0.9474	8.3498	1.9156	-20.0000	13.0000

Mean	95% CL Mean		Std Dev 95% CL S		Std Dev
-0.9474	-4.9718	3.0771	8.3498	6.3092	12.3479

DF	t Value	Pr >  t	
18	-0.49	0.6269	



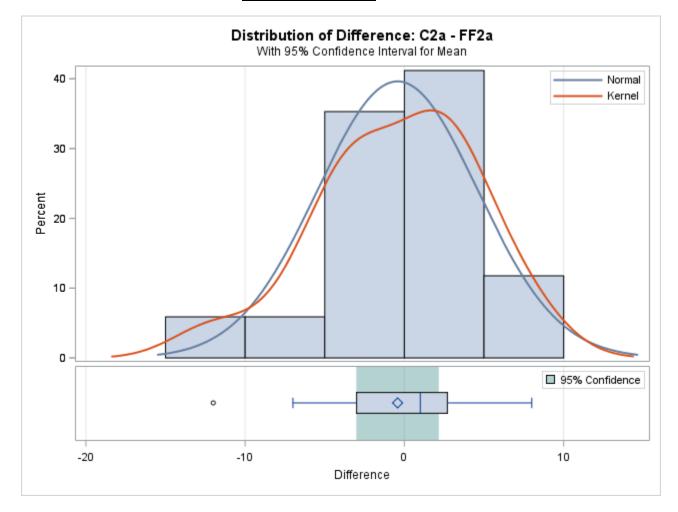
Difference: C2a - FF2a							
Ν	Mean	Std Dev	Std Err	Minimum	Maximum		



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	-0.4294	5.0339	1.2209	-12.0000	8.0000

Mean	95% CL	Mean	Std Dev	95% CL Std Dev	
-0.4294	-3.0176	2.1588	5.0339	3.7491	7.6612

DF	t Value	Pr >  t
16	-0.35	0.7296



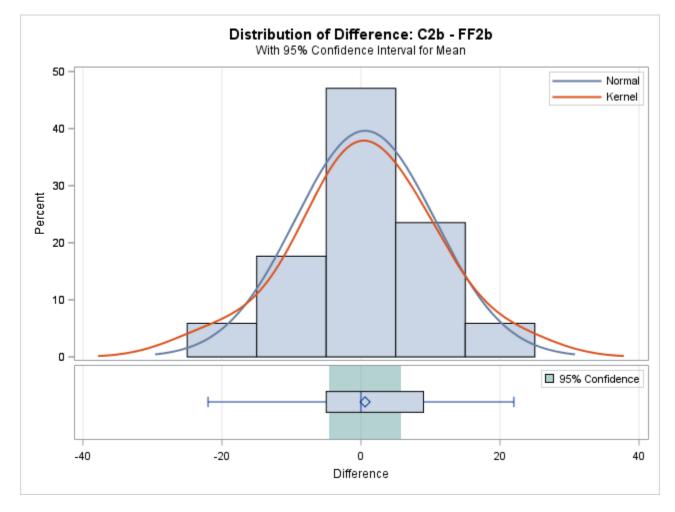
	Difference: C2b - FF2b							
Ν	Mean	Std Dev	Std Err	Minimum	Maximum			



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	0.5882	10.0689	2.4421	-22.0000	22.0000

Mean	95% CL Mean		Std Dev	95% CL	Std Dev
0.5882	-4.5887	5.7652	10.0689	7.4990	15.3241

DF	t Value	Pr >  t
16	0.24	0.8127



	Differe	ence: C2c	; - FF2c	
Mean	Std Dev	Std Err	Minimum	Maximum

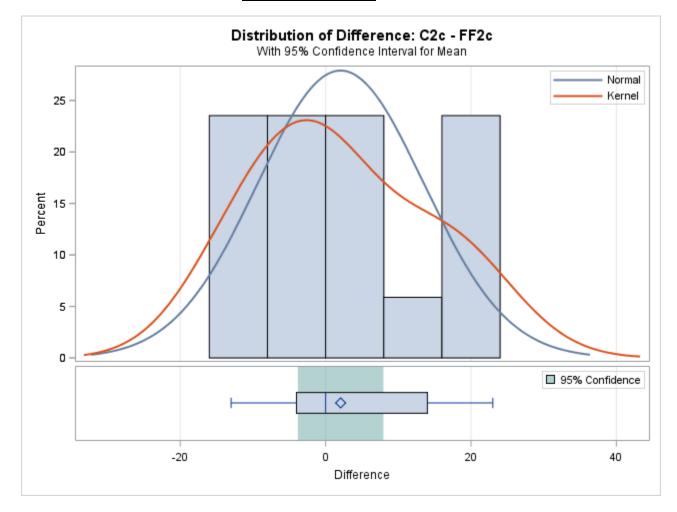


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Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	2.0588	11.4372	2.7739	-13.0000	23.0000

Mean	95% CL	. Mean	Std Dev	95% CL	Std Dev
2.0588	-3.8216	7.9393	11.4372	8.5181	17.4066

DF	t Value	Pr >  t
16	0.74	0.4687



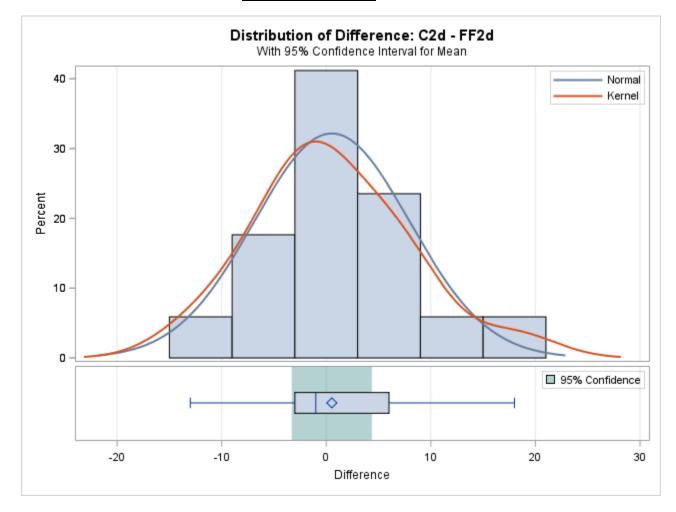
Difference: C2d - FF2d							
Ν	Mean	Std Dev	Std Err	Minimum	Maximum		



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	0.5294	7.4424	1.8051	-13.0000	18.0000

Mean 95% CL Me		. Mean	Std Dev	95% CL Std Dev		
0.5294	-3.2971	4.3560	7.4424	5.5429	11.3268	

DF	t Value	Pr >  t
16	0.29	0.7731



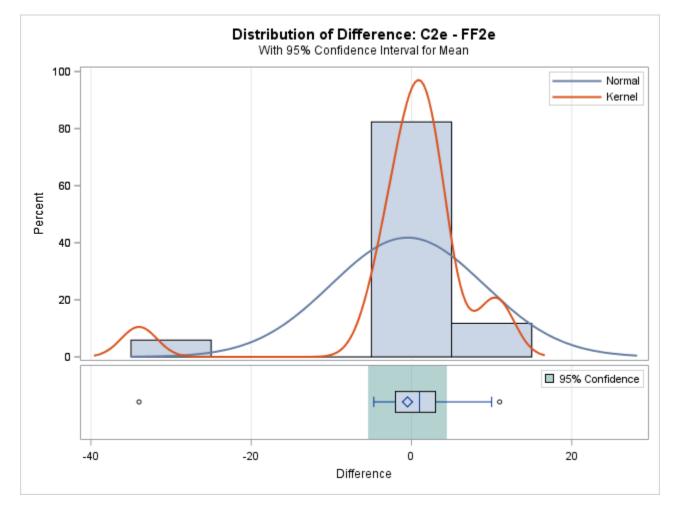
Difference: C2e - FF2e						
Mean	Std Dev	Std Err	Minimum	Maximum		



1	۷	Mean	Std Dev	Std Err	Minimum	Maximum
1	7	-0.4941	9.5454	2.3151	-34.0000	11.0000

Mean	95% CL Mean		Std Dev	95% CL Std Dev		
-0.4941	-5.4019	4.4137	9.5454	7.1091	14.5274	

DF	t Value	Pr >  t
16	-0.21	0.8337



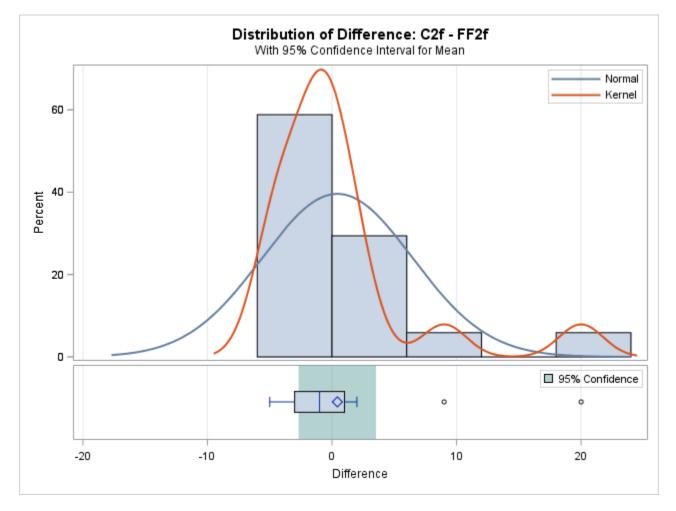
Difference: C2f - FF2f							
Ν	Mean	Std Dev	Std Err	Minimum	Maximum		



Ν	Mean	Std Dev	Std Err	Minimum	Maximum
17	0.4294	6.0454	1.4662	-5.0000	20.0000

Mean	n 95% CL Mean		Std Dev	95% CL Std Dev	
0.4294	-2.6789	3.5377	6.0454	4.5025	9.2007

DF	t Value	Pr >  t
16	0.29	0.7734



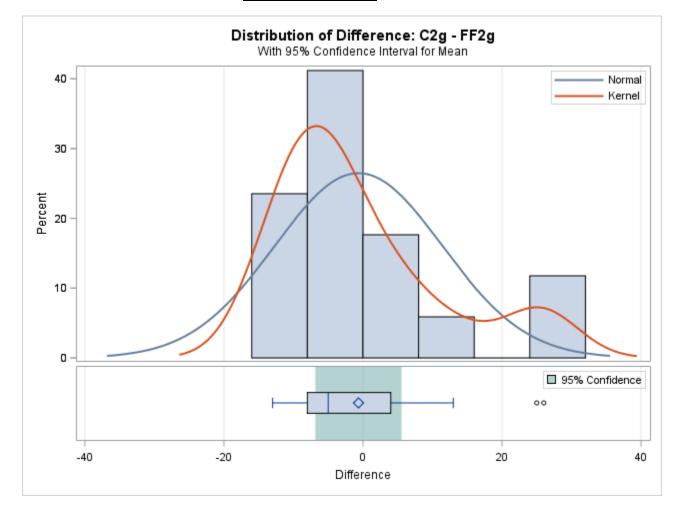
	Difference: C2g - FF2g							
Ν	Mean	Std Dev	Std Err	Minimum	Maximum			



	Ν	Mean	Std Dev	Std Err	Minimum	Maximum
1	17	-0.6471	12.0569	2.9242	-13.0000	26.0000

Mean	95% CL	Mean	Std Dev	95% CL Std Dev	
-0.6471	-6.8461	5.5520	12.0569	8.9796	18.3497

DF	t Value	Pr >  t	
16	-0.22	0.8277	



	Difference: C2h - FF2h				
Ν	Mean	Std Dev	Std Err	Minimum	Maximum



I	N	Mean	Std Dev	Std Err	Minimum	Maximum
1	7	-0.0588	7.0309	1.7052	-15.0000	12.0000

Mean	95% CL Mean		Std Dev 95% CL Std		Std Dev
-0.0588	-3.6738	3.5561	7.0309	5.2364	10.7006

DF	t Value	Pr >  t	
16	-0.03	0.9729	

