Clinical Evaluation of a Self-Etching Adhesive for All-Ceramic Indirect Restorations

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DEDICATION

To my wife Monica and my son, Rodrigo.

To my parents, Augusto and Zoila.

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To my Lord and Savior Jesus Christ for blessing me abundantly.

To my parents, Augusto and Zoila, for giving me the opportunity to further my professional training in the United States of America.

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1.1 Background and Significance

Introduction

Adhesive bonding has changed the practice of dentistry. This revolution of adhesion, started by Buonocuore in 1955, has evolved through many generations in which adhesives have become stronger, easier to use, and have gained wide acceptance by the profession.[1]

Despite their great popularity among clinicians as well as researchers, some problems cloud the success of adhesion in dentistry. The most persistent problem with adhesives is post-operative sensitivity. Christensen states that the problem of sensitivity keeps resurfacing, because class I, II and V restorations are among the most common procedures dentists accomplish, and many of the dentin-bonding concepts are over promoted in terms of preventing post-operative tooth sensitivity.[2] Since the method for bonding indirect restorations (i.e. crowns, inlays, onlays, etc) is similar to the method for bonding direct restorations, post-cementation sensitivity is also a problem with indirect restorations. In 1995, Trowbridge stated that luting cements are still a source of frustration to the dentist and that none of the cements currently available satisfies everyone, including the patient.[3] The author concluded that the cause of post-cementation sensitivity continues to be a perplexing problem.

It is still not clear what causes post-operative sensitivity and hence, several theories have been proposed. Brannstrom and Johnson developed the hydrodynamic theory to

explain dentin sensitivity.[4] Their study in 1970 stated that the movement of fluids within the dentinal tubule caused by thermal or concentration changes, activated receptors related to the odontoblasts. This is probably the most widely accepted explanation for sensitivity physiology. Eick et al, in 1986, proposed the polymerization shrinkage of composite restorations as the causative factor for post-operative sensitivity.[5] In 1990, Kanca proposed an alternative explanation for the post-operative sensitivity.[6] He presented the possibility that the inflammatory response in pulpal tissues noted in early studies when dentin was treated with phosphoric acid was not caused by the acid. He suggested that the inflammatory response was caused by the prolonged exposure to zinc oxide-eugenol and documented many reports showing ZOE to be a relatively toxic material. In 2000, Bergenholtz presented another explanation for dentin sensitivity: the presence of bacterial leakage at the restoration-tooth interface.[7] Modern restorative procedures involving resin and resin-bonded restoratives must still rely on the ability of the pulp to cope with the injurious elements to which it may be exposed during and after the procedure. The review examined factors that may govern the pulp's response to restorative procedures that involve adhesive technologies. It was concluded that an intact, although thin, wall of primary dentin often enables the pulp to overcome both toxic material effects and the influences of bacterial leakage. A lack of controlled clinical studies in this area of dentistry calls for confirmation that pulpal health prevails over the long term following the use of total-etch and resin-bonding techniques.

The most likely explanation for post-operative sensitivity is a combination of factors: 1) pulpal inflammation due to the carious extension or the cavity preparation procedures, 2) toxicity of the materials, 3) the presence of bacteria within the tubules after caries

removal, 4) the inability to properly seal the dentin tubules and 5) hyperfunctional occlusal contacts developed by the restoration.

All the theories were accompanied consequently with a philosophy of treatment or at least a technique to overcome the causative factor. The different techniques to “direct” polymerization shrinkage, the development of non-eugenol materials, and the use of antibacterial solutions prior to the bonding procedure, have been studied and tried, but the problem persists.

The development of self-etch adhesives makes the bonding procedure less aggressive to the pulp as it obviates the use of a strong acid to etch the tooth structure. Self-etching adhesives are believed to prevent postoperative sensitivity when used under posterior resin-based composite restorations. Swift stated in a review article published in 2001 that the self-etch approach reduces the incidence of postoperative sensitivity.[8] However, the long-term clinical performance of self-etch materials, particularly those that use a single solution to etch, prime, and bond, is not yet proven.

Assessment of Sensitivity

Only a few publications regarding post-operative sensitivity exist; probably because it is difficult to assess sensitivity (pain). Sensitivity or pain are subjective experiences and therefore cannot be objectively measured. The use of assessment tools such as the Visual Analog Scale (VAS), Pain Questionnaire and Self-report have been tried in an attempt to measure sensitivity (or pain). The simplest and most widely used tool is the VAS because it allows the possibility of assigning numeric values to the responses, which can be statistically analyzed and conclusions can be made. It is also very simple for patients to understand and its reliability has been proven in the literature. Holland published a review

article in 1997 reporting the consensus of a committee that convened to discuss the subject of clinical trials on dentin hypersensitivity and stated that sensitivity may be assessed either in terms of the stimulus intensity required to evoke pain or the subjective evaluation of pain produced by a stimulus using a visual analog or other appropriate scale.[9] Other authors also recommend the use of an analog scale.[10-17]

1.2 Objectives and Hypotheses

Primary Objective

The **primary objective** of the proposed research is to evaluate the sensitivity in teeth receiving indirect restorations cemented with a new self-etch, self-cure adhesive (XENO IV/ SCA). The sensitivity will be determined as a change in the response to thermal stimuli from baseline (pre-operative) to every recall (post-operatively).

Secondary Objective

Evaluate the clinical performance of cemented all-ceramic indirect restorations using seven categories of the modified USPHS clinical evaluation criteria.

Hypotheses:

H_{o1}: There is no significant tooth sensitivity using the new self-etch, self-cure adhesive for all-ceramic indirect restorations.

H_{a1}: There is a significant tooth sensitivity using the new self-etch, self-cure adhesive for all-ceramic indirect restorations.

H_{o2}: There is no loss in restoration retention using the new self-etch, self-cure adhesive for all-ceramic indirect restorations.

H_{a2}: There is a significant loss in restoration retention using the new self-etch, self-cure adhesive for all-ceramic indirect restorations.

1.3 Review of the Literature

1.3.1 Adhesives

Buonocuore introduced the concept of enamel etching in 1955 after observing the way ships were treated prior to painting. The metal surfaces are etched with an acid solution to provide more retention for the acrylic paint.[1] He tried this idea on enamel (mineralized tissue) to provide better retention for the acrylic restorations that were placed at that time. An acid solution was applied to the enamel and the demineralized surface provided microretention where the restorative material would be locked. Prior to his ideas, the approach was merely that of macromechanical retention achieved by creating undercuts, grooves, lugs, boxes, etc. to provide retention for the restorative materials. This approach implied the removal of a considerable amount of sound tooth structure.

In 1962, Bowen introduced the Bis-GMA (Bisphenol-Glycidylmethacrylate) resin.[18, 19] Composite resins are made of a matrix and filler. The Bis-GMA resin was used as the matrix. It is also the original component of the first dental bonding agent.

In 1980, Fusayama developed the Total-etch technique.[20] He proposed that enamel and dentin can be etched, thus obtaining retention in both dental substrates and increasing the bond strength. The Total-etch technique was introduced in the USA by Bertolotti in 1984.[21] It took a long time for this new technique to be accepted by the profession due to the fact that dentin is a permeable layer that communicates to the pulpal tissue, and the application of an acid solution to the dentin was thought to cause damage to the pulp.

In 1992, Nakabayashi described the hybrid layer.[22-24] This “Hybrid Layer” was the zone of interdiffusion of the adhesive and the exposed collagen fibers of the demineralized surface of dentin that provided seal and retention for the restorations bonded to dentin.

Buonocuore started this revolution and adhesives have evolved through 7 generations:

In 1956, Buonocore and colleagues demonstrated that use of a glycerophosphoric acid dimethacrylate-containing resin would bond to acid-etched dentin.[25] This first generation ignored the smear layer and the bond strength was very low, only 2-3 MPa.[26] In the late 1970s, the second-generation systems were introduced. Adhesion to dentin increased with improvements in the adhesive coupling agents for composites. The majority of these incorporated halophosphorous esters of unfilled resins such as bisphenol-A glycidyl methacrylate, or bis-GMA, or hydroxyethyl methacrylate, or HEMA.[27] This second generation left the smear layer almost intact; a slightly higher bond strength range was made possible: 4.5–6 MPa.[26] The third generation removed or at least altered the smear layer, thus reaching amazing bond strength values: 16-26 MPa.[26] This effect is due to the pK of the primer solution. The acid opens dentinal tubules partially and increases their permeability. The acid must be rinsed completely before the primer is applied. The primer contains hydrophilic resin monomers which include hydroxyethyl trimellitate anhydride, or 4-META, and biphenyl dimethacrylate, or BPDM. The primers contain a hydrophilic group that infiltrates the smear layer, modifying it and promoting adhesion to dentin, and the hydrophilic group of the primer creates adhesion to the resin. Following primer application, an unfilled resin is placed on dentin and enamel. These third-generation adhesion systems usually use a hydrophilic dentin-resin primer. Dentin primers may be 6 percent phosphate penta-acrylate, or PENTA; 30 percent HEMA; and 64 percent ethanol. Following etching

and primer application, the unfilled resin adhesive is applied to dentin and enamel.[28, 29] With the fourth-generation bonding systems, the smear layer is completely removed. In 1982, Nakabayashi and colleagues reported the formation of a hybrid layer resulting from the polymerized methacrylate and dentin. The hybrid layer is defined as “the structure formed in dental hard tissues (enamel, dentin, cementum) by demineralization of the surface and subsurface, followed by infiltration of monomers and subsequent polymerization.” [30] The use of the total-etch technique is one of the main characteristics of fourth-generation bonding systems. The total-etch technique permits the etching of enamel and dentin simultaneously using phosphoric acid for 15 to 20 seconds. The surface must be left moist (“wet bonding”), however, in order to avoid collagen collapse; the application of a hydrophilic primer solution can infiltrate the exposed collagen network forming the hybrid layer. [31-33]

The steps involved with these systems were, etch with a weak acid such as citric acid, prime and bond. The fourth generation completely removed the smear layer using a strong acid such as phosphoric acid (35-37%). The bonding agent not only provided retention from the enamel micromechanical interlocking, but also from the dentin where the bonding agent interlocked with the exposed dentinal collagen fibers. This was known as the Total-Etch technique.[26] This technique is considered the “gold-standard” for bonded restorations because it provides the highest bond strength.

Bonding to etched enamel and dentin while relying on the entanglement of resin monomers with dental substrates, or hybridization, is now considered the fundamental mechanism for retention of resin-based composite restorations.[34]

In 1993, Van Meerbeek described the three zones of the hybrid layer.[35, 36] The author examined the treated dentin by both scanning and transmission electron

microscopy (SEM & TEM) confirming the presence of the resin-dentin interdiffusion zone as the junction between the deep unaltered dentin structure and the restorative resin. Within the interdiffusion zone, three sublayers were identified (Figs. 1 and 2)

An upper diffuse black layer contained few structural features. Underneath, partially altered collagen fibrils were closely packed, mostly running parallel with the interface and perpendicular to the dentinal tubules. At the base of the upper layer, several stained projections were found to bulge out into the underlying collagen network and appeared to be confined by obstructive, parallel-running collagen fibrils. Finally, the third dense layer demarcated the superficially demineralized dentin layer from the deeper unaltered dentin. Resin diffusion into the decalcified dentin surface layer was evident, but diminished with depth, presumably reducing deeper resin impregnation into the interfibrillar spaces. The citric acid applied on dentin probably caused denaturation of the superficial collagen fibrils. Its decalcifying effect gradually weakened with depth, leaving behind hydroxyapatite crystals at the base of the interdiffusion zone.

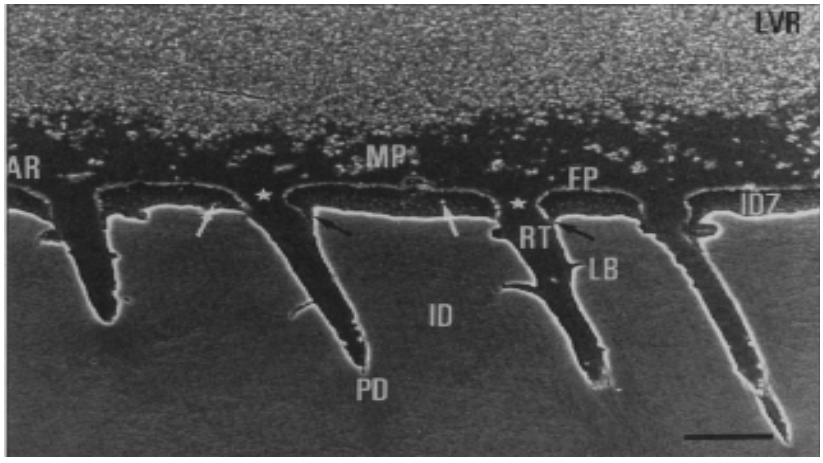

Figure 1: SEM photomicrograph showing the resin-dentin interdiffusion zone disclosed after an argon-ion-beam-etching procedure. AR=Adhesive Resin; FP=Filler particles demarcating the border of the interdiffusion zone; ID=Intertubular Dentin; IDZ=InterDIffusion Zone; LB=Lateral Branches; LVR=Low-Viscosity Resin; MP=islands of Microfiller Particles displaced from the low-viscosity resin; PD=Peritubular Dentin; RT=Resin Tag; white arrows=filler

particles infiltrated into the IDZ; black arrows= triangular laterally resin impregnated intertubular dentin; and white asterisks= constricted outline of resin tag. The bar represents 5 m. (Taken from Van Meerbeek, 1993)

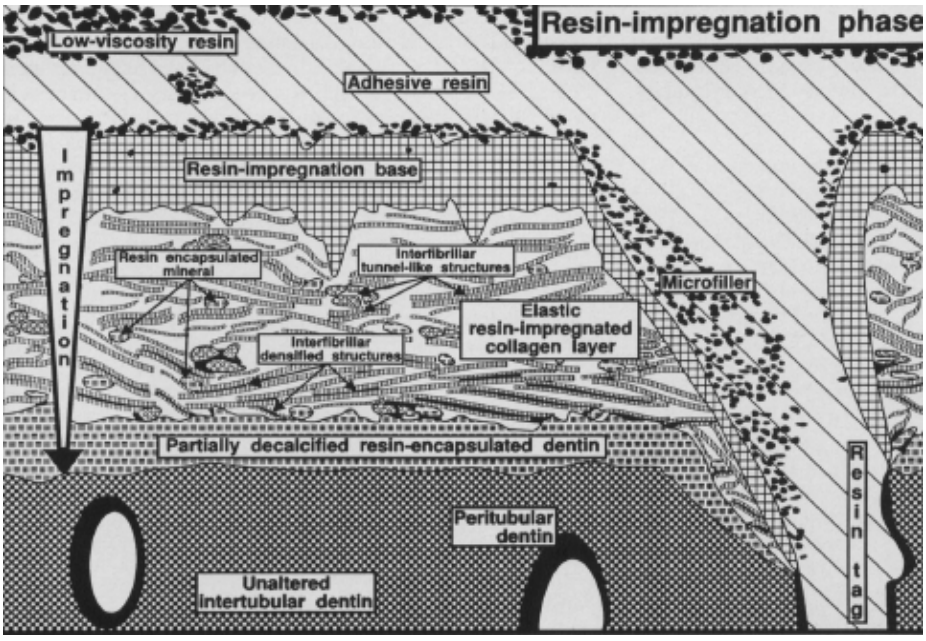

Figure 2: Schematic representation explaining the ultrastructure of the resin-dentin interdiffusion zone at the resin impregnation phase. (Taken from Van Meerbeek, 1993)

This interdiffusion zone, or hybrid layer, not only provides the retention for the restoration, but it also seals the dentin surface. This seal is supposed to keep bacteria out while providing thermal insulation.

For years several authors have been proposing explanations for the postoperative sensitivity and suggesting methods to avoid or at least diminish it.[2, 5, 37-44] Practitioners around the world have been trying them, but the issue of sensitivity is still there. One way to approach this problem is by using new materials and new adhesives. Self-etch adhesives have been proposed as a better way to form a hybrid layer without the undesired effect of sensitivity. Few clinical studies have dealt with sensitivity and the adhesives that have been tested have not proven effective.[34]

1.3.2 Total-etch vs. Self-etch

The fifth generation of dental adhesives can be summarized as the etch and bond technique.[26] The fifth generation consists of two different types of adhesive materials: the so-called “one-bottle systems” and the self-etching primer bonding systems.[45]

To facilitate clinical use, “one-bottle” systems combined the primer and adhesives into one solution to be applied after etching enamel and dentin simultaneously (the total-etch wet-bonding technique) with 35 to 37 percent phosphoric acid for 15 to 20 seconds. These bonding systems create a mechanical interlocking with etched dentin by means of resin tags, adhesive lateral branches and hybrid layer formation and show high bond-strength values both to the etched enamel and dentin.[46]

Watanabe and Nakabayashi developed a self-etching primer that was an aqueous solution of 20 percent phenyl-P in 30 percent HEMA for bonding to enamel and dentin simultaneously. The combination of etching and priming steps reduce the working time, eliminate the washing out of the acidic gel and also eliminate the risk of collagen collapse. However, the self-etching primer solution also has some disadvantages. For example, the solution must be refreshed continuously because its liquid formulation cannot be controlled where it is placed, and often a residual smear layer remained in between adhesive material and dentin. Also the effectiveness of self-etching primer systems on properly etching the enamel was less predictable than the result obtained with phosphoric acid gel.[47] Toida advised that removal of the smear layer by a separate etching step before bonding would produce a more reliable and durable bond to dentin. Bond strength tests made under laboratory conditions often did not demonstrate statistically significant differences between one-bottle systems and self-etching primer bonding systems.

Leakage tests conducted under laboratory and clinical conditions showed that the seal achieved at the enamel margins with one-bottle systems is superior to that resulting from self-etching primer.[48]

In recent times, several bonding systems were developed and proposed as the sixth generation of adhesive materials. The sixth generation eliminated the need for the etching step. These bonding systems achieve a proper bond to enamel and dentin using only one solution. The first evaluations of these new systems showed a sufficient bond to conditioned dentin, but not so to enamel. The sixth-generation systems are composed of an acidic solution that cannot be kept in place and have a pK that is not enough to properly etch enamel.[45]

Several studies show that self-etch adhesives achieve similar bond strengths to the total-etch adhesives. Toledano et al. determined the bond strength of five adhesive systems to either superficial or deep dentin.[49] They used extracted human third molars and had their crowns transversally sectioned either just below the occlusal DEJ or next to the pulp, to expose flat, superficial or deep dentin surfaces. The surfaces were bonded with: 1) three 2-step, total-etch, self-priming adhesives (Single Bond, Prime&Bond NT, and Excite), 2) a 2-step, self-etching primer (Clearfil SE Bond), and 3) a single-step, self-etching all-in-one adhesive (Etch & Prime 3.0) according to manufacturers' directions. Composite build-ups were constructed incrementally with Z250. Bonded interfaces were examined by TEM. Nanoleakage was examined using a silver-staining technique. Single Bond, Prime&Bond NT and Clearfil SE Bond performed equally when bonded to superficial dentin; the lowest value was obtained with Etch & Prime 3.0. On deep dentin, the highest bond strengths were attained with Clearfil SE Bond and Prime & Bond NT. Nanoleakage was manifested to a variable extent within all hybrid layers examined.

Molla et al. compared five 2-step and two 3-step total-etch (TE) bonding systems, two systems with self-conditioning (SC) primers, and one SC all-in-one adhesive by use of the microtensile bond test.[50] Hybrid resin composites were bonded to the occlusal dentin of 50 extracted human molars. Microtensile bond strength was determined and debonded surfaces were examined under the SEM for mode of failure. Mean bond strengths of the simplified (2-step) TE systems (OptiBond Solo, Gluma One Bond, Solobond M, Prime&Bond NT, One Coat Bond; 19.9 MPa to 39.9 MPa) were not significantly lower than that of the traditional 3-step TE systems (EBS Multi: 26.0 MPa; OptiBond FL: 32.7 MPa), and not related to phosphoric acid concentration. Dentin treatment with SC primers (Clearfil Liner Bond 2: 22.0 MPa; Clearfil Liner Bond 2V: 22.4 MPa) was as effective as etching with phosphoric acid. The SC all-in-one adhesive (Etch&Prime 3.0: 10.1 MPa) produced significantly lower bond strength than all other systems evaluated. The authors concluded that the use of adhesive/composite combinations including simplified bonding systems does not necessarily result in reduced bond strength to dentin. SC primers (2 bottle self-etch adhesives) offer a promising alternative to phosphoric acid etching as far as bonding to dentin is concerned. In contrast, the SC all-in-one adhesive evaluated needs to be improved.

These studies corroborate that the 6th generation adhesives perform in a similar way to 5th generation adhesives. All-in-one adhesive Etch&Prime 3.0 (6th generation) though, has proven to achieve significantly lower bond strengths.

Atash et al. compared the shear and tensile bond strengths of eight adhesive systems to the enamel and dentin of primary bovine teeth.[51] They used two hundred and fifty-six noncarious bovine mandibular primary incisors. The tested adhesives were: Clearfil SE bond (SE); Adper Prompt L Pop (LP); Optibond Solo Plus Self-etch (OB); AdheSE

(AS); Xeno III (XE); Scotch Bond 1 (SB); Etch & Prime 3.0 (EP); and I Bond (IB). For the shear bonding test and the tensile bonding test, the labial surfaces of primary incisors were used. Shear bond strength values ranged from 18.1 to 8.9 MPa on enamel (in decreasing order, SE, LP, OB, AS, XE, SB, EP and IB) (Table 1), and from 17.8 to 8.2 MPa on dentin (in decreasing order, SE, SB, OB, AS, XE, LP, IB and EP) (Table 2). Tensile bond strength values ranged from 13.1 to 6.7 MPa on enamel (in decreasing order, SE, OB, AS, LP, XE, IB, SB and EP) (Table 3), and from 12.1 to 5.7 MPa on dentin (in deceasing order, SE, SB, OB, AS, XE, LP, IB and EP) (Table 4). The differences in bond strengths between the eight systems on enamel and dentin were all statistically significant for both the shear and tensile bond strengths. The authors found that the highest shear bond strength was achieved by SE on enamel and dentin, and the lowest by IB on enamel and EP on dentin. The highest tensile bond strength was obtained by SE on enamel and dentin, and the lowest by EP. Shear bond strengths were significantly higher on enamel when compared to dentin for five of the eight adhesives systems, and tensile bond strengths were significantly higher on enamel when compared to dentin for all but two systems.

Vuu et al. investigated the tensile bond strengths of 37% phosphoric acid/One-Step Plus (PA, 5th generation) and Tyrian SPE/One-Step Plus (SPE, 6th generation) bonding systems to human enamel and superficial dentin with 5 composites.[52] Buccal and lingual enamel and superficial dentin surfaces of molars were prepared. Five composites were used for bonding to the teeth with 2 bonding systems in the form of a truncated cone. Bonding systems were used following manufacturer's instructions. Specimens were subjected to 1000 thermocycles in 5^{o} and 55^{o}C water with a dwell time of 20 seconds in each temperature bath. Specimens were debonded with a testing machine at 0.5 mm/min. After thermocycling, the PA bonding system had higher bond strengths than the SPE

bonding system in both enamel and dentin with all 5 composites. The SPE bonding system performed better on enamel than dentin with all 5 composites. Some authors suggest therefore, the use of acid-etch only on enamel to improve the bond strength of self-etch adhesives.

Van Landuyt et al. tested the hypothesis that the two-step self-etch adhesive Clearfil SE Bond (C-SE; Kuraray, Osaka, Japan) bonds equally effectively to enamel/dentin either with or without prior etching with phosphoric acid. Bur-cut enamel/dentin surfaces prepared from human molars were partially split in two halves by cutting a shallow groove.[53] One half was first etched with 40% phosphoric acid (K-etchant), while protecting the other half by holding a razor blade in the groove. Next, C-SE was applied strictly following the manufacturer's instructions, after which the surface was built up using Z100 (3M Espe). After 24-h water storage, micro-specimens were prepared with the interface circularly constricted using a Micro-Specimen Former prior to micro-tensile bond strength (TBS) (MPa) measurement. In addition, interfaces of C-SE with enamel/dentin prepared with and without acid etching were examined by Field Emission Gun-Scanning Electron Microscopy (Feg-SEM) and Transmission Electron Microscopy (TEM). Etching significantly increased the bonding effectiveness of C-SE to enamel. A clearly more micro-retentive surface was revealed by TEM and Feg-SEM when enamel was etched. Phosphoric-acid etching prior to C-SE application on dentin significantly decreased the TBS to dentin. TEM provided indications of a low-quality hybrid layer with phosphoric-acid etching. Using C-SE, additional etching with phosphoric acid to improve bonding effectiveness should be limited to enamel.

Self-etch adhesives do not remove the smear layer completely. The weak acidity of the primer or adhesive cannot remove the smear layer completely, but they penetrate it to

reach the underlying dentinal structures. Wang and Spencer provided information regarding morphology, quality and chemistry of the interfaces between three self-etching primers/adhesives and dentin.[54] The occlusal one-third of the crown was removed from 18 human third molars. The prepared dentin surfaces were randomly selected for treatment with one of three commercial self-etching bonding agents according to manufacturers' instructions. One 2-step self-etching adhesive (Clearfil SE Bond) and two 1-step self-etching adhesives (One-Up Bond F and Prompt L-Pop) were selected. Five-micron-thick sections of adhesive/dentin interface specimens were cut and stained with Goldner's trichrome for light microscopy. Companion slabs were analyzed with micro-Raman spectroscopy and scanning electron microscopy (SEM). It was shown that the difference in aggressiveness of the three self-etching systems produced a different thickness of hybrid layer. Staining technique showed a distinct colored line/zone at the adhesive/dentin interfaces for all three bonding systems. The width of this line varied, and was approximately 1, 1-2, 2-3 micron for Clearfil SE Bond, One-Up Bond F and Prompt L-Pop, respectively. The color differences in the stained interface sections, which are reflected by the extent to which the adhesive encapsulates the demineralized dentin matrix, indicated that collagen fibrils at the interfaces were not totally encased in all three self-etching adhesives. Raman results showed that Prompt L-Pop is the most aggressive system in this study. It almost totally demineralized the 2-micron deep subsurface dentine, while Clearfil SE is mild, and only partially demineralized the first micron deep dentine. In comparison with two-step self-etching system, the aggressive one-step system produces more complex interfaces. It is believed that a part of the smear layer is removed and the remainder is penetrated through diffusion channels which permits the adhesive to infiltrate dentin substrates, hence creating a hybrid layer through the smear layer.[55, 56]

Suppa, in a correlative Field Emission InLens-Scanning Electron microscopy / Transmission Electron Microscopy (FEISEM/TEM) study found in a TEM of Clearfil SE Bond, a 1- m-thick, partially demineralized hybrid layer that included loose smear layer remnants along the surface of the hybrid layer.[55]

Arrais evaluated the morphology and thickness of the resin-infiltrated dentinal layer after the application of adhesive systems.[57] The dentin-bonding agents were evaluated on flat dentinal preparations confected on the occlusal surfaces of human teeth. The test specimens were prepared and inspected under scanning electron microscopy at a magnification of 2,000x. The adhesive systems were responsible for different hybrid layer thicknesses ($p < 0.05$), and the mean values were: for Scotchbond MP Plus (SM), 7.41 +/- 1.24 micrometer; for Single Bond (SB), 5.55 +/- 0.82 micrometer; for Etch & Prime 3.0 (EP), 3.86 +/- 1.17 micrometer and for Clearfil SE Bond (CB), 1.22 +/- 0.45 micrometer. The results suggest that the conventional three-step adhesive system (SM) was responsible for the thickest hybrid layer, followed by the one-bottle adhesive (SB). The self-etching adhesives, EP and CB, formed the thinnest hybrid layers. The author concluded that self-etching adhesives form a much thinner hybrid layer than any of the total-etch systems.

The studies reviewed showed that the self-etch adhesives, by having less acidity, penetrate less into the dentin, forming a thinner hybrid layer. This means that the adhesive has less depth of exposed collagen to penetrate and it is therefore easier to seal than the acid-etch removed dentinal surface.

1.3.3 Sensitivity

One disadvantage of bonding procedures is the post-operative sensitivity[3, 34, 43, 44, 58]

The Total-Etch technique exposes the dentinal tubules after removing the smear layer. According to the hydrodynamic theory, it is believed that the removal of the smear plug allows for movement of dentinal fluid within the dentinal tubules, causing sensitivity.[59, 60] Alternative explanations were the presence of remaining bacteria[7] or the prolonged use of Zinc Oxide Eugenol cements (ZOE-cements)[6] as the cause of the post-operative sensitivity. Some authors also believed that the postoperative sensitivity could be related to cuspal deformation caused by the polymerization shrinkage and composite deformation under occlusal stress. In 2002, in an opinion article, Christensen stated that the subject of sensitivity is brought-up in many courses by practitioners. The author calls postoperative sensitivity an “unpredictable problem” in dentistry that practitioners face despite of meticulous use of adhesives.

Akpata et al. in 2001 compared objective and subjective assessments of post-operative sensitivity when class 1 cavities, lined with glass-ionomer or adhesive bonding system, were restored with resin-based composite (RBC).[38] Occlusal cavities on homologous contra-lateral posterior teeth in 44 male patients attending primary health centers in Riyadh, Saudi Arabia were restored with RBC after a cavity lining of either a light-cured glass-ionomer cement (Vitrebond) or an adhesive bonding system (One-Step). Cold response measurements 24 hrs, 7 days and 1 month post-operatively showed that the threshold of pulpal response was significantly lower ($P< 0.05$) in the restored teeth when the adhesive bonding system served as cavity liner. In addition, based on the patients' subjective assessments, the prevalence of mild or severe post-operative sensitivity was significantly higher ($P< 0.05$), 24 hrs and 7 days post-operatively, in the teeth with the adhesive bonding system as a cavity liner. After a post-operative period of 1 month, however, there was no significant difference ($P> 0.05$) between the prevalence of

post-operative sensitivity when the restored teeth received a lining of either glass-ionomer or adhesive bonding system.

Perdigao et al. in 2003 placed 30 restorations with the Clearfil SE (Clearfil SE Bond, Kuraray America, New York) and 36 restorations with Prime & Bond NT (Dentsply Caulk, Milford, Del.), which uses 34 percent phosphoric acid to etch enamel and dentin simultaneously.[34] Teeth were restored with the proprietary hybrid resin-based composite indicated for posterior restorations: Clearfil AP-X for Clearfil SE Bond or Esthet-X Micro Matrix Restorative for Prime & Bond NT. The restored teeth were evaluated preoperatively and at two weeks, eight weeks and six months postoperatively for sensitivity to cold (ice stick), compressed air and masticatory forces as the patient's spoken response to a visual analog scale from 0 to 10, as well as for marginal discoloration. This study revealed no statistically significant differences in postoperative sensitivity between the SE and TE materials at any recall time. Only one tooth displayed sensitivity to occlusal forces at six months. The authors concluded that the SE adhesive did not differ from the TE adhesive in regard to sensitivity and marginal discoloration. Perdigao didn't find a significant difference between adhesives and concluded that the technique is probably more important than the adhesive type itself.[34]

Hayashi et al. in 2003 stated that post-operative sensitivity (POS) may be observed in recently placed posterior composites. This study examined a retrospective analysis of the findings of a unique multi-center clinical trial to investigate the five-year risk of failure of posterior composites with POS and to determine the factors likely to have an important impact on the prognosis of the restorations. Longitudinal five-year data from the multi-center trial of Occlusin were analyzed.[61] Data pertaining to a total of 1,101 restorations were included in the study. The analysis revealed that the restorations of Occlusin with

POS were more likely to have failed at five years than the restorations of Occlusin without POS, with odds ratios ranging from 1.73 (95% CI: 1.04, 2.87) to 1.97 (95% CI: 1.36, 2.85). Distributions of patient age and cavity size were significantly different for successful and failed restorations (chi-square test, $p < 0.05$). Logistic regression indicated that cavity size was the only factor likely to have influenced the prognosis of the restorations with POS ($p = 0.041$, odds ratio 3.21, 95% CI 1.05: 9.70). Restorations with POS in large cavities were more likely to have failed by five years than restorations in small cavities. It was concluded that the restorations with Occlusin included in the Occlusin trial program were more likely to have failed at five years if POS occurred within one month of placement. Cavity size has been shown to have been an important factor in the prognosis of Occlusin trial restorations with POS.

Sarret in 2005, in a review article, stated that the clinical problems related to early composite materials are no longer serious clinical challenges.[62] The author concluded that post-operative sensitivity appears to be more related to the dentin adhesives' ability to seal open dentinal tubules rather than the effects of polymerization shrinkage on cuspal deflections and marginal adaptation.

De Souza et al. in 2005, evaluated the clinical performance of two packable and one microhybrid resin composites in occlusal cavities of posterior permanent teeth after 1 year.[63] Sixty occlusal restorations were placed in 18 patients. The restorations were divided into three groups according to the restorative material: G1 (Surefil + Prime&Bond NT); G2 (Filtek P60 + Singlebond), and G3 (Suprafill + Suprafill). They were placed by two previously calibrated operators. The restorations were directly evaluated for color matching, marginal discoloration, secondary caries, wear, marginal adaptation, and postoperative sensitivity. Of the total restorations, 66.7% were scored A (ideal) for color

matching; 98.2% for marginal discoloration; 100% for secondary caries; 92.6% for wear; and 92.6% for marginal adaptation. Postoperative sensitivity was reported in 5% of the restorations.

Sobral et al. in 2005, evaluated the effects of pre-treatments with a 35% hydroxyethyl metacrylate/5% glutaraldehyde dentin desensitizer (Gluma Desensitizer) and a 2% chlorexidine-based cavity disinfectant (Cav-Clean) on postoperative sensitivity.[64] Three premolar teeth with no pain symptoms were selected from each one of 17 patients, totaling 51 teeth, for which Class II restoration using a composite was indicated. Each one of the three premolar teeth of the same patient was submitted to a different treatment. After acid etching, only a dental adhesive was applied to the first tooth, which served as the control. Gluma Desensitizer dentinal desensitizer was applied to the second premolar tooth prior to applying the dental adhesive. Cav-Clean cavity disinfectant was used on the third premolar tooth before applying the dental adhesive. All premolar teeth were restored with a condensable composite. Sensitivity to different stimuli (cold, heat, sweet and dental floss) was assessed on Day 1, Day 4 and Day 7 by questionnaire following restorative procedures. The results showed that there was no statistically significant difference in the three different treatments ($P>0.05$). Postoperative sensitivity resulting from Class II restorations using composite resin cannot be completely eliminated with the prior use of a dentinal desensitizer or a cavity disinfectant. In day-to-day clinical treatment, postoperative sensitivity may possibly be related to the technique employed.

Sensitivity, being a form of pain, is a subjective experience. The same stimuli that can elicit a response in one subject can be imperceptible by another. To be able to study sensitivity, it must be somehow quantified [65]. Several attempts were made in the past to try to measure it.[12, 65-68] The instruments to measure pain can be qualitative or quantitative

and vary from a visual analogue scale (VAS), a numerical rating scale from 0 to 10 (NRS), a verbal rating scale (VRS), the McGill Pain Questionnaire, to the Integrated Pain Score (IPS) which is an instrument designed at the Pain Therapy and Palliative Care Division of the National Cancer Institute of Milan to integrate pain intensity and duration in a single measure.[15]

1.3.4 Visual Analog Scales

The Visual Analog Scale, originally developed over 70 years ago, is popular for measuring subjective phenomena. Huskisson used a VAS to measure intensity of pain and researchers have been using it ever since, to measure pain.[69]

A Visual Analog Scale is a useful instrument to measure the response to stimuli. It consists of a 100mm line with a start and end point that are the limits. The start point means “no pain” and the end point means “severe pain”. The patient being tested is asked to place a vertical mark on the line indicating the level of the response to the stimulus. Visual Analog Scales measure the intensity or magnitude of sensations and subjective feelings, and the relative strength of attitudes and opinions about specific stimuli. The reliability of the Visual Analog Scale (VAS) has been determined by many authors in several studies and has been tested many times.[16, 70, 71]

Holland in a review article published in 1997 reporting the consensus of a committee of interested persons from academia and industry that convened to discuss the subject of clinical trials on dentin hypersensitivity stated that sensitivity may be assessed either in terms of the stimulus intensity required to evoke pain or the subjective evaluation of pain produced by a stimulus using a visual analog or other appropriate scale.[9]

Price et al. used the Visual Analog Scale to measure sensory and affective responses to 6 noxious thermal stimuli (43, 45, 47, 48, 49 and 51 degrees C) applied for 5 sec to the forearm by a contact thermode. Sensory VAS and affective VAS responses to these temperatures yielded power functions with exponents 2.1 and 3.8, respectively; these functions were similar for pain patients and for volunteers. The power functions were predictive of estimated ratios of sensation or affect produced by pairs of standard temperatures (e.g. 47 and 49 degrees C), thereby providing direct evidence for ratio scaling properties of VAS. VAS sensory intensity responses to experimental pain, VAS sensory intensity responses to different levels of chronic pain, and direct temperature (experimental pain) matches to 3 levels of chronic pain were all internally consistent, thereby demonstrating the valid use of VAS for the measurement of and comparison between chronic pain and experimental heat pain.[71] Internal consistency can be defined as the extent to which tests or procedures assess the same characteristic, skill or quality. It is a measure of the precision between the observers or of the measuring instruments used in a study. This type of reliability often helps researchers interpret data and predict the value of scores and the limits of the relationship among variables.[72]

In a review of the literature in an article published in 2004 by Coll et al. that included papers published since 1983, the author found that the definition of pain has been evolving and so have the methods to measure it.[14] This shows the vast array of measurement tools are not consistent and lead to ineffective pain management. VAS was found to be methodologically sound, conceptually simple, easy to administer and unobtrusive to the respondent. Hence, it seems to be the most suitable for measuring intensity of pain.

Averbuch in a randomized double-blind naproxen sodium and placebo-controlled trial using the hip osteoarthritis (OA) flare-up pain mode, in which pain was measured on

both visual analog and categorical scales simultaneously, found that both appeared as effective.[10] The authors concluded, though, that a combined metric scale for pain measurement that provides the subject with multiple cues may improve communication and concordance between scales for individual pain determination

The VAS is the most widely used assessment tool in the measurement of pain and has been widely recommended for the study of pain and sensitivity. It allows the researcher to quantify a subjective experience and make statistical calculations with the measurements obtained.

Torabinejad et al. in 2005 used the VAS in a study that compared levels of postoperative discomfort after cleaning and shaping of root canals using two protocols for removal of smear layer. Seventy-three consecutive patients requiring root canal treatment were included.[73] At random, canals were cleaned and shaped with one of the following protocols. In group 1, 5.25% sodium hypochlorite was used as the root canal irrigant. The smear layer was removed by placing 17% EDTA in the canal(s) for 1 min followed by a 5-ml rinse with 5.25% NaOCl. In group 2, canals were irrigated with 1.3% NaOCl; the smear layer was removed by placing MTAD in the canal(s) for 5 min. Access cavities were closed with a sterile cotton pellet and Cavit. The patients recorded degree of discomfort at various time intervals after cleaning and shaping on a visual analogue scale (VAS) for 1 wk. No significant statistical difference was found in the degree of discomfort between the two groups ($p = 0.58$).

Polat et. al. in 2005, in a study to determine the pain sequelae in fixed orthodontic treatment and to evaluate comparatively the analgesic effects of nonsteroidal anti-inflammatory drugs for the control of this pain used the VAS.[74] One hundred and fifty orthodontic patients who were to have teeth bonded in at least one arch were randomly

assigned to one of six groups: (1) placebo/placebo, (2) ibuprofen/ibuprofen, (3) flurbiprofen/flurbiprofen, (4) acetaminophen/acetaminophen, (5) naproxen sodium/naproxen sodium, and (6) aspirin/aspirin. The pain evaluations were made during chewing, biting, fitting the front teeth, and fitting the back teeth using a 100-mm visual analogue scale (VAS) for seven days. All the analgesics succeeded in decreasing the pain levels compared with the placebo group. However, naproxen sodium and aspirin groups showed the lowest pain values, and the acetaminophen group showed VAS results similar to those of the two analgesics.

Burke et al. in 2000, in a study to examine the effectiveness of a dentin bonding system in the treatment of dentinal hypersensitivity in dental practice conditions used the VAS.[75] Dentists in two dental practices agreed to carry out the project. One practice was in the UK, the other in India. A total of 34 patients who were diagnosed to have dentinal hypersensitivity were treated using the dentin bonding system. Patients were requested to record their perception of their pain on a 100mm linear scale, pre-treatment, one day and one week post-treatment. All patients experienced relief of pain, both 1 day and 1 week after treatment. Profile plots of the patients' perceived pain scores for the two practices separately indicated that there was a general trend for these to fall quite sharply one day after treatment and then generally level out one week post-treatment. There was evidence indicating a possible difference in pain perception in the two communities from which the patients were drawn. The author concluded that the dentin bonding system evaluated was successful in reducing the pain of dentinal hypersensitivity, at least in the short term.

Caselli et al. in 2006, evaluated the postoperative sensitivity of posterior Class I composite resin restorations, restored with a self-etching or a total-etch one-bottle adhesive system. [76] One hundred four restorations were replaced by one clinician in 52

patients. Each patient received two restorations. After cavity preparations were completed under rubber-dam isolation, they were restored using Clearfil SE Bond or Single Bond and a resin-based restorative material (Filtek Z250). Sensitivity was evaluated at 0 and 7 days and 6 months using cold stimuli, and recorded using a visual analogue scale. If sensitivity was experienced on day 7, patients were also contacted on days 14 and 30 to assess the degree of sensitivity. No statistically significant differences in sensitivity were found between the two adhesive systems at days 0 and 7 or at 6 months. No spontaneous postoperative sensitivity was reported. The author reported that the adhesive systems used in this study showed no differences in postoperative sensitivity, and did not show spontaneous sensitivity after 6 months.

More specifically, Perdigao in 2003 in a study where teeth were restored with the proprietary hybrid resin-based composite indicated for posterior restorations and then tested preoperatively and at two weeks, eight weeks and six months postoperatively for sensitivity to cold (ice stick), compressed air and masticatory forces, used the Visual Analog Scale to record the patients response. This study revealed no statistically significant differences in postoperative sensitivity between the SE and TE materials at any recall time. Perdigao didn't find a significant difference between adhesives and concluded that the technique is probably more important than the adhesive type itself. [34]

1.3.5 Ceramic Restorations

The clinical performance of ceramic restorations has been studied by several authors. The generalized results are that the ceramic inlays and onlays have an excellent clinical performance.

Coelho Santos in a controlled clinical trial evaluated the clinical performance of ceramic inlays and onlays made with two systems: sintered (Duceram, Dentsply-Degussa)

D and pressable (IPS Empress, Ivoclar-Vivadent) after two years. Eighty-six restorations, 44 IPS and 42 D, were cemented into the mouths of 35 patients. Twenty-seven premolars and 59 molars received Class II preparations totaling 33 onlays and 53 inlays. All restorations were cemented with dual-cured resin cement (Variolink II, Ivoclar-Vivadent) and Syntac Classic adhesive under rubber dam. The evaluations were conducted by two independent investigators at the baseline and after one and two years using the modified USPHS criteria. After two years, 100% of the restorations were assessed and all the restorations were considered clinically excellent or acceptable. Among the analyzed criteria, the following received Bravo ratings: marginal discoloration--IPS (31.82%), D (23.81%); marginal integrity--IPS (18.18%), D (11.9%), color match-IPS (4.55%), D (9.52%) and surface texture-IPS (2.27%); D (14.29%). No "Charlie" or "Delta" scores were attributed to the restorations. The author's conclusion is that these two types of ceramic materials demonstrated excellent clinical performance after two years. [77]

In 2005, Hayashi, M et al., evaluated the quality of fired feldspathic ceramic inlay (G-Cera Cosmotech II, GC Co, Tokyo, Japan) after eight years in vivo. [78] Forty-five fired ceramic inlays (for 26 premolars and 19 molars; Class I in 12 teeth, Class II in 31 teeth and onlay in two teeth) were placed in 25 patients. All restorations were evaluated at the time of placement and at 6 months, 1, 2, 4, 6 and 8 years after placement using modified USPHS criteria. Replicas of the restorations were observed with a scanning electron microscope (SEM) to evaluate the degradation of the marginal area and wear loss of the restoration. Longevity was observed in 80% of the fired ceramic inlay restorations at eight years (Kaplan-Meier method), although it was 92% at the six-year observation. Marginal fracture was detected in 11 restorations (22%), including bulk fracture in five (11%), which had first occurred during the last two years. Recurrent caries was observed in three (7%)

cases and marginal discoloration in 14 (31%). SEM evaluation disclosed marginal microfractures in 77% of the restorations, wear in 36% and wear of the resin cement along the margin in 74% at eight years. No significant difference was observed between molars and premolars. This longitudinal eight-year clinical observation suggested that fired ceramic inlay restorations made by the G-Cera Cosmotech II system are clinically acceptable. However, critical failure as bulk fracture may become a future problem since marginal disintegration was detected in 77% of the restorations from microscopic and macroscopic perspectives.

El-Mowafy in a review of the literature that only included studies that lasted over 2 years regarding survival of inlays, onlays and crowns made of IPS-Empress cemented with resin cement, found that the survival for inlays and onlays ranged from 96% at 4.5 years to 91% at 7 years, with most failures being caused by bulk fracture. The survival of crowns ranged from 92% to 99% at 3-3.5 years, with failure caused by fracture. The author concluded that dentists should inform their patients about these survival rates when offering such treatment and that the use of IPS-Empress crowns in the posterior region of the mouth is not recommended until the results of more long-term clinical trials are available. [79]

Ceramic inlays are a very esthetic alternative to the traditional gold restorations. Gandjour et al. in a Cochrane review including publications between 1966 and June 2003 that reported annual survival probabilities and annual observations found that laboratory-fabricated ceramic, chairside CAD/CAM ceramic, and gold inlays had similar failure-free survival rate, but laboratory-fabricated ceramic inlays had the highest costs and, thus, were less cost-effective than chairside CAD/CAM ceramic and gold inlays. [80] This article validates the use of ceramic inlays as alternative to the proven, successful gold since

laboratory-fabricated ceramic, chairside CAD/CAM ceramic, and gold inlays have “a strikingly similar” failure-free survival rate.

All-ceramic crowns were always a desirable, yet unreliable, treatment option. Lehner et al., in a review of articles published between November 1990 and December 1991, stated that despite the good appearance and biocompatibility of dental porcelains, failures are still of considerable concern because of some limited properties (fracture toughness) common to all-ceramic crown systems. The author concluded that only long-term clinical trials will validate achievements compared with other all-ceramic systems and with well-established metal ceramics. [81]

Several materials have been used in search of an esthetic and strong alternative to metal ceramic restorations. There has been a struggle to satisfy the demand for more esthetic options for the posterior region and to have long term success. Leucite-reinforced ceramics, pressable ceramics, etc. have limited success and are recommended for the esthetic zone only. It was the Alumina (AlO_3) and Zirconia (Y-TZP) materials that allowed the use of all-ceramic crowns with confidence in the posterior region.

Luthard et al. in 2002, in a study to determine if the strength and reliability of yttria stabilized tetragonal zirconia (Y-TZP) ceramics were affected by the inner surface grinding of crowns; found that inner surface grinding significantly reduces the strength and reliability of Y-TZP zirconia compared with the lapped control sample. Co-analysis of flexural strength, Weibull parameter, and fracture toughness showed counteracting effects of surface compressive stress and grinding-introduced surface flaws. The authors concluded that grinding of Y-TZP needs to be optimized to achieve the CAD/CAM manufacture of all-ceramic restorations with improved strength and reliability. [82]

Kosmac et al. in 2000, in a study to evaluate the effects of dental grinding and sandblasting on the biaxial flexural strength and Weibull modulus of various yttria stabilized tetragonal zirconia (Y-TZP) ceramics containing 3 mol% yttria, found that surface grinding and sandblasting showed a counteracting effect on the strength of Y-TZP ceramics. Dental grinding lowered the mean strength and Weibull modulus, whereas sandblasting provided a powerful method for strengthening. The finest-grained material exhibited the highest strength after sintering, but it was less damage tolerant than tougher, coarse-grained materials. Upon extraction with the acetic acid solution and the ammonia solution, a significant amount of tetragonal zirconia had transformed to monoclinic, but extensive microcracking and attendant strength degradation had not yet occurred. Standard grade Y-TZP ceramics are more resistant in an alkaline than in an acidic environment, and there was a strong grain-size dependence of the diffusion-controlled transformation. Since a special Y-TZP grade containing a small amount of alumina exhibited the highest damage tolerance and superior stability in an acidic environment, the authors concluded that this material shows considerable promise for dental applications. [82, 83]

Potiket et al.in 2004, in an in-vitro study using extracted intact human maxillary incisors, found that there was no significant difference in the fracture strength of the teeth restored with all-ceramic crowns with 0.4- and 0.6-mm aluminum oxide copings, 0.6-mm zirconia ceramic copings, and metal ceramic crowns. Forty intact, noncarious human maxillary central incisors were divided into 4 groups (n=10): Group MCC (control), metal-ceramic crown (JRVT High Noble Alloy); Group AC4, crown with 0.4-mm aluminum oxide coping (Procera AllCeram); Group AC6, crown with 0.6-mm aluminum oxide coping (Procera AllCeram); and Group ZC6, crown with 0.6-mm zirconia ceramic coping (Procera

AllZirkon). Teeth were prepared for complete-coverage all-ceramic crowns so that a final dimension of 5.5 +/- 0.5 mm was achieved incisocervically, mesiodistally, and faciolingually. A 1.0-mm deep shoulder finish line was used with a rounded internal line angle. All restorations were treated with bonding agent (Clearfil SE Bond) and luted with phosphate-monomer-modified adhesive cement (Panavia 21). Fracture strength was tested with a universal testing machine at a crosshead speed of 2 mm per minute with an angle of 30 degrees to the long axis of the tooth after restorations were stored in 100% relative humidity of a normal saline solution for 7 days. The mode of fracture was examined visually. Means were calculated and analyzed with 1-way ANOVA and Tukey's HSD (alpha=.05). The means of fracture strength were: Group MCC, 405 +/- 130 N; Group AC4, 447 +/- 123 N; Group AC6, 476 +/- 174 N; and Group ZC6, 381 +/- 166 N. There was no significant difference between groups (P =.501). The mode of failure for all specimens was fracture of the natural tooth. [84] This study shows that all-ceramic crowns are as strong as porcelain-fused-to-metal crowns.

White et al. investigated the strength of a wide variety of layered zirconia and porcelain beams to determine whether the inclusion of zirconia cores results in improved strength. Eight types of layered or simple zirconia and porcelain beams (n = 10), approximately fixed partial denture-size, were made of a tetragonal polycrystalline zirconium dioxide partially stabilized with yttria core (Lava System Frame) and a feldspathic dental porcelain (Lava Ceram veneer ceramic). Elastic moduli of the materials were measured using an acoustic method. Maximum force and modulus of rupture were determined using 3-point flexural testing and a universal testing machine. Descriptive statistical methods were used. Beams with porcelain tensile surfaces recorded mean tensile strengths or moduli of rupture from 77 to 85 MPa, whereas beams with zirconia

tensile surfaces recorded moduli of rupture almost an order of magnitude higher, 636 to 786 MPa. The elastic moduli of the porcelain and zirconia materials were 71 and 224 GPa, respectively. Crack propagation following initial tensile cracking often involved the porcelain-zirconia interface, as well as bulk porcelain and zirconia. The layered zirconia-porcelain system tested recorded substantially higher moduli of rupture than have been previously reported for other layered all-ceramic systems. [81]

In 2005, Vult von Steyern performed two simultaneous clinical studies investigating one alumina-based and one zirconia-based material system. The objective was to compare the strength of a zirconia system with that of an alumina equivalent with known long-term clinical performance. [85] The author found that the success rate of the clinical alumina study was 90% after 5 years. After a total of 11 years (+/-1 year), the success/survival rate was 65%. In the second clinical study, the success rates of the 2- and 3-year follow-ups were 100%. In the three in-vitro studies, the following results were found: (1a) the mean flexural strength of the specimens in the group that was exposed to saliva first after glazing was significantly higher ($P < 0.001$) than that of the specimens in the group that was exposed to saliva before glazing, (1b) the FPDs luted on shoulder preparations resisted higher loads than the FPDs luted on chamfer preparations ($P = 0.051$), 2) total fractures were more frequent in the alumina than in the zirconia group ($P < 0.001$), 3) FPDs loaded on implants resisted higher loads (mean = 604 N, SD=184 N) than FPDs loaded on abutment teeth (mean= 378 N, SD=152 N, $P = 0.003$). These studies justified the use of shorter alumina- (< or = three-unit) and zirconia-based (< or = five-unit) FPDs as the clinical results are acceptable. The clinical performance of alumina is, however, not as good as that of comparable high-gold alloy based porcelain-fused-to-metal FPDs concerning fracture resistance. The fracture mode of alumina crowns (total

fractures) differs from that of zirconia crowns (veneer fractures), suggesting that the zirconia core is stronger than the alumina core. The consensus is that crowns made with an aluminous core can be used with confidence to restore teeth in the posterior region. Zirconia core crowns are even stronger and provide better long term results.

In the proposed study, therefore, crowns with a Zirconia core and pressable ceramic inlays and onlays were used to test the self-etch, self-cure adhesive.

1.3.6 Clinical evaluation

To evaluate objectively the quality of dental work several methods have been proposed in the literature. [86-89] To evaluate the clinical performance of the ceramic restorations the most common instrument is the USPHS criteria. The majority of the studies on clinical performance use it. It was originally developed by Ryge and Snyder in 1973 in an attempt to provide a method for rating the quality of restorations (amalgams and composites) clinically. Four operational categories are included, 2 satisfactory (Alpha, Bravo) and 2 not acceptable (Charlie, Delta). [90] The original Ryge criteria have been modified to be used in the evaluation of a variety of restorations. The original categories Alpha, Bravo, Charlie and Delta, have been further subdivided (i.e. Alpha-1, Alpha-2, etc) to suit the evaluation needs in many studies.

Perdigao in 2003, in a study where 30 restorations were placed with the Clearfil SE (Clearfil SE Bond, Kuraray America, New York) and 36 restorations with Prime & Bond NT (Dentsply Caulk, Milford, Del.), which uses 34 percent phosphoric acid to etch enamel and dentin simultaneously used a modification of the original USPHS criteria. The restored teeth were evaluated preoperatively and at two weeks, eight weeks and six months postoperatively for sensitivity as well as for marginal discoloration. Intraoral color

photographs were taken at baseline and at each recall appointment. The operators evaluated marginal discoloration at 6 months using this scale: Alpha= no marginal discoloration; Bravo= slight staining that disappears on polishing; Charlie= discoloration that penetrates the interface and cannot be polished; Delta= evidence of caries. This study revealed no clinical signs of marginal degradation at six months. The authors concluded that the SE adhesive did not differ from the TE adhesive in regards to sensitivity and marginal discoloration. [34]

Kramer et al., in 2005 published a study to clinically evaluate the effect of two different adhesive/resin composite combinations for luting of IPS Empress inlays. [91] Ninety-four IPS Empress restorations were placed in 31 patients in a controlled prospective clinical split-mouth study. The restorations were luted with EBS Multi/Compolute (3M Espe) or with Syntac/Variolink II low (Ivoclar Vivadent) without lining. The ceramic restorations were examined according to modified USPHS codes and criteria at baseline and after 0.5, 1, 2, and 4 years. Two patients including four restorations missed the 4 years recall. After 4 years of clinical service, four restorations in two patients (three luted with Compolute, one with Variolink II) had to be replaced due to hypersensitivity, 90 inlays and onlays were acceptable. Between the five recalls, a statistically significant deterioration was found for the criteria marginal adaptation and inlay fracture (Friedman 2-way ANOVA; $p<0.05$). No statistical difference was found between the adhesives. At baseline, 95% of the restorations revealed luting composite overhangs. After 4 years, 55% of cases had overhangs and 38% showed marginal ditching. No differences were found for surface roughness, color matching, tooth integrity, proximal contact, hypersensitivity, and satisfaction ($p>0.05$). The authors concluded that for luting of ceramic inlays, no difference

between the two luting systems was detectable. The overall failure rate after 4 years was 4%.

In 2004, Santos et al., presented a study to evaluate the clinical performance of ceramic inlays and onlays made with two systems: sintered (Duceram [D], DeguDent) and pressable (IPS Empress [IPS], Ivoclar-Vivadent) after 1 year. [92] Seventy-four restorations - 37 IPS and 37 D - were cemented in 34 patients. Twenty-four premolars and 50 molars received Class II cavity preparations, totaling 28 onlays and 46 inlays. The restorations were evaluated by two independent investigators at baseline, 6 months and 1 year, according to modified USPHS criteria. After one year, 100% of the restorations were assessed and all the restorations were considered clinically excellent or acceptable. Among the analyzed criteria, only the following received "Bravo" ratings: marginal discoloration: IPS (24.32%), D (13.51%); marginal integrity: IPS (10.81%), D (8.11%); color match: IPS (5.41%), D (5.41%); surface texture: IPS (2.70%), D (10.81%). No "Charlie" or "Delta" scores were given to the restorations. The authors reached to the following conclusion: only marginal discoloration differed statistically significantly from the results of the baseline examination for IPS Empress ceramic restorations ($p = 0.008$). No significant differences were found between the two ceramics. The two ceramic systems demonstrated excellent clinical performance after a period of 1 year.

Many other clinical studies have used the modified USPHS criteria for clinical performance evaluation. [77, 93]

In the proposed study, therefore, a modification of the USPHS criteria was used to evaluate the clinical performance of the all-ceramic restorations.

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Chapter 2

Clinical Evaluation of a Self-Etching Adhesive for All-Ceramic Indirect Restorations

2.1 Abstract

Problem: The most persistent problem with dentin adhesives is post-operative sensitivity. An activator to convert a self-etch adhesive (XENO IV/SCA) into a dual cure adhesive was developed for cementation of indirect all-ceramic restorations. Clinical studies of this type of adhesive are however limited.
Purpose: The primary objective of the proposed research was to evaluate the sensitivity in teeth receiving indirect restorations cemented with a new self-etch, self-cure adhesive (XENO IV/SCA). Secondarily an attempt was made to evaluate the clinical performance of cemented all-ceramic indirect restorations using seven categories of the modified USPHS clinical evaluation criteria.
Materials and Methods: Thirty-four ceramic restorations (15 crowns and 19 Inlays/Onlays) were included in the study. Each patient could have only 2 restorations. Preparation and placement of the restorations was performed by 1 operator. A dual cure cement with a self-etching adhesive was used for final cementation following the manufacturer's instructions. Sensitivity was measured using cold water at 40^{o}F as a stimulus and recorded on a visual analog scale (0 to 100 mm) at baseline and each recall (1 week and 3, 6 and 12 months). The following categories were evaluated using the modified USPHS criteria: 1) gingival index, 2) color match, 3) margin discoloration, 4) margin integrity, 5) restoration integrity, 6) recurrent caries and 7) proximal contact. Clinical evaluations were performed by 2 trained evaluators and consensus determined for categories of disagreement. Intraoral photographs were taken of each tooth/restoration. PVS impressions were used to create replicas of the restorations at each recall and these were used to analyze the marginal integrity at each recall under the microscope.
Results: There was no significant difference between the mean sensitivity ratings at each recall ($p>0.05$). No statistical difference was observed between measured values of sensitivity and differences from baseline. The restorations were clinically acceptable after 1 year. Margin integrity was the aspect that presented the most change over time. The majority of the deteriorative changes occurred between 1 week and 3 months.
Conclusions: There is no significant tooth sensitivity or loss in restoration retention using the new self-etch, self-cure adhesive for all-ceramic indirect restorations. The mean sensitivity ratings at each recall do not differ significantly from baseline. The restoration type does not affect the sensitivity ratings. All-ceramic restorations were clinically acceptable after 1 year in seven categories of the modified USPHS clinical evaluation criteria.

2.2 Introduction

Introduction

Adhesive bonding has changed the practice of dentistry. This revolution of adhesion, started by Buonocuore in 1955, has evolved through many generations in which

adhesives have become stronger, easier to use, and have gained wide acceptance by the profession.[1]

Despite their great popularity among clinicians as well as researchers, some problems cloud the success of adhesion in dentistry. The most persistent problem with adhesives is post-operative sensitivity.[2] Christensen states that the problem of sensitivity keeps resurfacing, because class I, II and V restorations are among the most common procedures dentists accomplish, and many of the dentin-bonding concepts are over promoted in terms of preventing post-operative tooth sensitivity.[2] Since the method for bonding indirect restorations (i.e. crowns, inlays, onlays, etc) is similar to the method for bonding direct restorations, post-cementation sensitivity is also a problem with indirect restorations. In 1995, Trowbridge stated that luting cements are still a source of frustration to the dentist and that none of the cements currently available satisfies everyone, including the patient.[3] The author concluded that the cause of post-cementation sensitivity continues to be a perplexing problem.

It is still not clear what causes post-operative sensitivity and hence, several theories have been proposed. Brannstrom and Johnson developed the hydrodynamic theory to explain dentin sensitivity.[4] Their study in 1970 stated that the movement of fluids within the dentinal tubule caused by thermal or concentration changes, activated receptors related to the odontoblasts. This is probably the most widely accepted explanation for sensitivity physiology. Eick et al, in 1986, proposed the polymerization shrinkage of composite restorations as the causative factor for post-operative sensitivity.[5] In 1990, Kanca proposed an alternative explanation for the post-operative sensitivity.[6] He presented the possibility that the inflammatory response in pulpal tissues noted in early studies when dentin was treated with phosphoric acid was not caused by the acid. He suggested that the

inflammatory response was caused by the prolonged exposure to zinc oxide-eugenol and documented many reports showing ZOE to be a relatively toxic material. In 2000, Bergenholtz presented another explanation for dentin sensitivity: the presence of bacterial leakage at the restoration-tooth interface.[7] Modern restorative procedures involving resin and resin-bonded restoratives must still rely on the ability of the pulp to cope with the injurious elements to which it may be exposed during and after the procedure. The author examined factors that may govern the pulp's response to restorative procedures that involve adhesive technologies. It was concluded that an intact, although thin, wall of primary dentin often enables the pulp to overcome both toxic material effects and the influences of bacterial leakage. A lack of controlled clinical studies in this area of dentistry calls for confirmation that pulpal health prevails over the long term following the use of total-etch and resin-bonding techniques.

The most likely explanation for post-operative sensitivity is a combination of factors: 1) pulpal inflammation due to the carious extension or the cavity preparation procedures, 2) toxicity of the materials, 3) the presence of bacteria within the tubules after caries removal, 4) the inability to properly seal the dentin tubules and 5) hyperfunctional occlusal contacts developed by the restoration.

All the theories were accompanied consequently with a philosophy of treatment or at least a technique to overcome the causative factor. The different techniques to “direct” polymerization shrinkage, the development of non-eugenol materials, and the use of antibacterial solutions prior to the bonding procedure, have been studied and tried, but the problem persists.[2, 6, 8-13]

The development of self-etch adhesives makes the bonding procedure less aggressive to the pulp as it obviates the use of a strong acid to etch the tooth structure.

Self-etching adhesives are believed to prevent postoperative sensitivity when used under posterior resin-based composite restorations. Swift stated in a review article in 2001 that the self-etch approach reduces the incidence of postoperative sensitivity.[14] However, the long-term clinical performance of self-etch materials, particularly those that use a single solution to etch, prime, and bond, is not yet proven.

Assessment of Sensitivity

Only a few publications regarding post-operative sensitivity exist; probably because it is difficult to assess sensitivity (pain). Sensitivity or pain are subjective experiences and therefore cannot be objectively measured. The use of assessment tools such as the Visual Analog Scale (VAS), Pain Questionnaire and Self-report have been tried in an attempt to measure sensitivity (or pain).[15-20] The simplest and most widely used tool is the VAS because it allows the possibility of assigning numeric values to the responses, which can be statistically analyzed and conclusions can be made. It is also very simple for patients to understand and its reliability has been proven in the literature. Holland published a review article in 1997 reporting the consensus of a committee that convened to discuss the subject of clinical trials on dentin hypersensitivity and stated that sensitivity may be assessed either in terms of the intensity of the stimulus required to evoke pain or the subjective evaluation of pain produced by a stimulus using a VAS or other appropriate scale.[21] Other authors also recommend the use of the VAS.[15-17, 20, 22-25]

2.3 Research Design and Methods

2.3.1 Patient Recruitment

This study was designed with a sample size of 30 ceramic (15 crowns and 15 Inlays/Onlays) restorations. Patients were recruited from the patient pool at the University of Michigan School of Dentistry teaching clinics. Each patient required a screening examination to ensure that the selection criteria were met. Recent periapical and bitewing radiographs were requested or new x-rays were taken at that time.

2.3.2 Selection Criteria

2.3.2.a Inclusion Criteria

Patients presenting with a need for an all-ceramic crown or an inlay/onlay on second premolars or molars and who were available for a two-year follow-up period were selected for participation. Each patient could have only two restorations included in this study.

The acceptable diagnoses for the abutment teeth included previously unrestored carious lesions, defective restorations and existing restorations with recurrent caries. The abutment teeth had to be periodontally stable, in occlusion and have at least 1 proximal contact.

2.3.2.b Exclusion Criteria

Patients were excluded if any of the inclusion criteria was not met and if the tooth had gross caries approaching the pulp (near exposure). There were no medical exclusion criteria other than those that would preclude a patient from routine, elective (non-emergency) dental treatment.

The time commitment once enrolled in the study was an initial two and one half (2/12) hour appointment for tooth preparation, impression and temporization. A second

one and one half hour (11/2) appointment was scheduled to seat the restoration. Follow-up appointments of forty-five (45) minutes each were scheduled after 1 week, 3 and 6 and 12 months.

2.3.3 Materials & Methods

Each patient signed a consent form (Appendix A) after consultation with the attending dentist. The University of Michigan Health Sciences Institutional Review Board approved the study protocol based upon physical, mechanical, and biological data submitted by Dentsply/Caulk.

Each patient answered a questionnaire regarding previous treatment and existing symptomatology for the selected teeth. A glass of water (at $4^{o}C$ / $40^{o}F$) was given to the patient to measure the pre-operative sensitivity. After swishing for 5 seconds, the patient registered the level of sensitivity on a VAS (Appendix B) by placing a vertical mark on a 100mm line where 0mm was “no sensitivity” and 100mm was “severe sensitivity.” Placement of the 15 all-ceramic crowns and 15 inlays/onlays was performed by one (1) operator. For the teeth selected for treatment, local anesthesia was administered. A standard, conservative preparation for all-ceramic crown or inlay/onlay cavity preparation was completed. A new bur was used after every three preparations. A glass-ionomer liner (Photac Fil Quick Aplicap, 3M ESPE, St. Paul, MN) was placed in any area where caries removal involved a significant portion of the dentin. After cavity preparation a retraction cord was placed in the sulcus where indicated for tissue management and a polyvinylsiloxane (PVS) impression (Aquasil Ultra, Dentsply, Milford, DE) was taken of the prepared tooth. The prepared teeth were temporized using a Bis-Acryl provisional material (Integrity, Dentsply, Milford, DE). A shade for the restoration was taken prior to dismissing

the patient using a VITA shade guide (Vitapan Classical, VIDENT, Bad Sackingen, Germany).

The patient was appointed three weeks after the preparations were completed to seat the crown or inlay/onlay. Local anesthesia was administered and the provisional restoration removed. The teeth were pumiced and the final restoration was placed and evaluated for marginal fit, color match and occlusion. All necessary adjustments were made prior to cementation and the crown or inlay/onlay was repolished with an intraoral porcelain polishing kit (CeramiPro Dialite, Brasseler, Savannah, GA). The teeth were isolated and a dual-cure cement (Calibra, Dentsply, Milford, DE) with a self-etching adhesive (XENO IV/SCA, Dentsply, Milford, DE) was used for final cementation following the manufacturer's instructions.

One laboratory was selected to fabricate the all-ceramic crowns and inlays/onlays.

2.3.4 Evaluation

2.3.4a Direct Evaluation

Sensitivity was recorded at each recall (1 week, 3, 6, 12 months) with a VAS as previously described. The location of the mark was measured in mm. from the line of origin ("no sensitivity") and the results were coded and recorded for statistical analysis.

The following categories were also evaluated using modified USPHS criteria (originally developed by Cvar and Ryge)[26]: color match, margin discoloration, anatomic form, margin adaptation (integrity), surface texture and proximal contact. Written criteria that were used to make the evaluations are listed in detail in an attached table (Appendix C). All evaluations were completed using a standard mouth mirror and a #3 cowhorn explorer. The direct clinical evaluations were performed independently by two trained

evaluators and a consensus was determined for categories of disagreement. Three intra-oral photographs were taken of each restoration (preoperatively, after preparation and postoperatively).

The follow-up examinations were completed in an identical manner at 1 week, 3, 6 and 12 months. One additional category, recurrent caries, was evaluated at these appointments. Additional intraoral photographs and impressions were taken of each restoration at each recall.

The photographs were used as baseline reference and to record the preparations, restoration try-ins and follow-up appointments.

2.3.4b Indirect Evaluation

The follow-up photographs included an occlusal view with articulating paper markings. These photographs were used to determine if there was a relation between sensitivity and occlusal contacts. The occlusal markings were related to the sensitivity test outcome. They were also used to determine whether there was a correlation with the restoration fracture and margin integrity considering the proximity of an occlusal stop to the restoration margin as well as the size of the contact area.

The PVS impressions were poured in a special combination of stones: 50:50 percent by weight of Flowstone Blue and Resin Rock Die Material (Whip Mix Corp., KY, USA) and the casts were used to determine the extent of margin crevices and restoration fractures, under the microscope at 20x magnification (SMZ 1500 with a light source NI-150 High Intensity Illuminator, Nikon Inc., Japan). The extent of margin crevices and restoration fractures was used to determine their stability or progression in time, by comparing casts

from recall impressions. These were also related to the sensitivity test outcome to determine if there was correlation.

2.3.5 Data Analysis

The Wilcoxon Signed-Rank non-parametric test was used for the analysis. It compared the values of paired X and Y columns.

2.4 Results

During the insertion phase of the study, 26 patients were recruited that met the inclusion criteria and 35 restorations were placed in premolar and molar teeth. Prior to the

3 month recall one patient passed away for reasons unrelated to the study and was excluded from the study data. Therefore, 34 restorations were evaluated at each recall as detailed in Table 1. The 34 restorations were 15 full coverage restorations (45.7%), 7 inlays (20%) and 12 onlays (34.3%). Of the 15 crowns placed, 1 was on a premolar and the other 14 on molars. Of the 7 inlays, 2 were placed on premolars and 5 on molars. Of the 12 onlays, 1 was placed on a premolar and 11 on molars.

Table 1. Distribution of Restorations by Tooth Type. Percentages in Parenthesis.

Crowns	15 (45.7)	**Premolar**	1
		Molar	14
Inlays	7 (20)	**Premolar**	2
		Molar	5
Onlays	12 (34.3)	**Premolar**	1
		Molar	11
TOTAL	34 (100)	**Premolar**	4
		Molar	30

A total of 25 patients, 11 male (46%) and 14 female (54%) participated in the study. The distribution of patient population by gender can be seen on Table 2. The sample size was similar for both genders. No more than 2 restorations were placed in any one patient.

Table 2. Distribution of Restorations per Patient by Gender. Percentages in Parenthesis.

Gender	N	One Restoration	Two Restorations

Male	11 (46)	5	6
Female	14 (54)	11	3
TOTAL	25 (100)	16	9

2.4.1 Sensitivity

The mean values of sensitivity measured with a VAS scale at baseline and each recall can be seen in Table 3.

The One-Way ANOVA test showed no significant differences between the mean sensitivity scores from baseline and each recall (p value = 0.65) (Table 4). Since each patient had a different baseline sensitivity level, the change in sensitivity from baseline was also determined (Table 5), with the hope that the variance could be reduced. However, there were no significant differences between the "recall minus baseline" values (p value = 0.7) and variances remained high (Table 6).

Table 3: Mean Sensitivity Ratings Taken from a VAS. Standard Deviations in Parenthesis.

Type	N	Baseline	One Week	Three Months	Six Months	Twelve Months
Inlay	7	20.43 (20.65)	19.5 (22.82)	25.43 (30.94)	23.64 (26.49)	19.14 (24.16)
Onlay	12	3.25 (3.89)	15.25 (24.16)	10.96 (11.93)	10.46 (16.19)	7.46 (5.52)
Crown	15	20.53 (25.27)	28.10 (25.88)	22.13 (22.32)	16.47 (16.19)	22.33 (26.28)
Total	34	14.91 (20.58)	22.11 (24.66)	18.87 (21.67)	15.82 (18.70)	16.43 (21.35)

Table 4: Analysis of Variance of the Measured Values for Sensitivity.

Source	Sum of Squares	DF	Mean Square	F-Ratio	P

Time	1149.33	4	287.33	0.64	0.65
Error	76125.46	165	461.37		

Table 5: Measured Values of Sensitivity and Differences from Baseline. Standard Deviations in Parenthesis.

Category	N	Baseline	1 Week	3 Months	6 Months	12 Months
Actual Measured Values	34	14.41 (20.58)	21.79 (24.66)	18.87 (21.67)	15.82 (18.70)	16.43 (21.35)
Differences From Baseline	34	0	7.09 (24.59)	4.49 (23.84)	1.41 (23.15)	1.97 (21.97)

Table 6: Analysis of Variance of the Differences from Baseline.

Source	Sum of Squares	DF	Mean Square	F-Ratio	P
Time	690.80	3	230.27	0.42	0.74
Error	72321.18	132	547.89		

2.4.2 Gingival Index

The gingival index showed no gingival inflammation for the majority of the patients at baseline, 3, 6 and 12 months. Mild inflammation with slight color change and edema, but no bleeding, was present on an average of 6 subjects at each time interval. Only 1 patient presented with moderate inflammation at 3 months, showing redness, edema and glazing, and bleeding upon probing, but this was not present at later recall appointments (Table 7).

Table 7: Gingival Index. Percentages in Parenthesis.

Gingival Score	One Week	Three Months	Six Months	Twelve Months
0	27 (79.4)	26 (76.5)	30 (88.2)	26 (76.5)
1	7 (20.6)	7 (20.6)	4 (11.8)	8 (23.5)
2	0	1 (2.9)	0	0
3	0	0	0	0
TOTAL	34 (100)	34 (100)	34 (100)	34 (100)

2.4.3 Color Match

The restorations were either an ideal color match or slightly detectable (evaluated wet at 12" for 3-4 sec). Using the Wilcoxon Sign Rank Test for changes over time, the only significant difference was between one week and twelve months (p value=0.034). There was no significant difference of color match between any other recall ($p > 0.05$) (Table 8).

Table 8: Color Match. Percentages in Parenthesis.

Category	One Week	Three Months	Six Months	Twelve Months
Alpha	23 (65.7)	28 (82.3)	27 (79.4)	29 (85.3)
Bravo	11 (34.3)	6 (17.7)	7 (20.6)	5 (14.7)
Charlie	0	0	0	0
TOTAL	34 (100)	34 (100)	34 (100)	34 (100)

2.4.4 Margin Discoloration

No margin discoloration was detected at baseline or after 12 months in any of the restorations (Table 9).

Table 9: Margin Discoloration. Percentages in Parenthesis.

Category	One Week	Three Months	Six Months	Twelve Months
Alpha	34 (100)	34 (100)	34 (100)	34 (100)
Bravo-1	0	0	0	0
Bravo-2	0	0	0	0
Charlie-1	0	0	0	0
Charlie-2	0	0	0	0
TOTAL	34 (100)	34 (100)	34 (100)	34 (100)

2.4.5 Margin Integrity

The majority of the restoration margins were rated as Alpha-1 (undetectable margins). However, an average of 40 percent of the margins exhibited a slight catch from tooth to restoration, and roughly 6 percent of the margins presented a catch from restoration to tooth. Three restorations had margins rated Bravo-1 with visible evidence of crevice formation into which the explorer penetrated along less than 50% of the exposed margin, each one noted at different time intervals (Table 10). Wilcoxon Sign Rank Test showed significant difference between one week and twelve months (p value=0.008). There was no significant difference between any other recall.

Table 10: Margin Integrity. Percentages in Parenthesis.

Category	One Week	Three Months	Six Months	Twelve Months

Alpha-1	21 (61.8)	15 (44.1)	16 (47.1)	13 (38.2)
Alpha-2	11 (32.4)	14 (41.3)	14 (41.3)	16 (47.1)
Alpha-3	2 (5.8)	4 (11.7)	2 (5.8)	2 (5.8)
Bravo-1	0	1 (2.9)	2 (5.8)	3 (8.9)
Bravo-2	0	0	0	0
Charlie	0	0	0	0
Delta	0	0	0	0
TOTAL	34 (100)	34 (100)	34 (100)	34 (100)

2.4.6 Restoration Integrity

Ninety seven percent of the restorations were intact at the end of the 12 month period. One had a minor chip on the occlusal surface which was rated Bravo (a small fracture that can be polished). At 3 months, another restoration presented a small fracture at the marginal ridge without compromising the margins of the restoration and was rated Charlie (fracture of material which needs repair but not replacement). The restoration was polished to smooth the rough areas, but the repair was postponed to be done after the 24 month recall. At 6 months and at 12 months, there were no additional fractures (Table 11).

2.4.7 Caries

No recurrent caries were detected at baseline, 3, 6 or 12 months (Table 12).

Table 11: Restoration Integrity. Percentages in Parenthesis.

Category	One Week	Three Months	Six Months	Twelve Months
Alpha	33 (97.1)	32 (94.2)	32 (94.2)	33 (97.1)
Bravo	1 (2.9)	1 (2.9)	1 (2.9)	0
Charlie	0	1 (2.9)	1 (2.9)	1 (2.9)
Delta	0	0	0	0
TOTAL	34 (100)	34 (100)	34 (100)	34 (100)

Table 12: Recurrent Caries. Percentages in Parenthesis.

Category	One Week	Three Months	Six Months	Twelve Months
Alpha	34 (100)	34 (100)	34 (100)	34 (100)
Charlie	0	0	0	0
TOTAL	34 (100)	34 (100)	34 (100)	34 (100)

2.4.8 Proximal Contact

At 1 week, all the proximal contacts (54) were rated Alpha, i.e. a tight contact to the passage of floss. At 3 and 6 months, 2 contacts were rated Bravo (light, but visually closed). However, at 12 months all contacts were rated Alpha (Table 13).

2.4.9 Failure Mode

The failure mode was determined clinically using digital pictures of the restored tooth and microscopically on replicated models. The three categories observed were: “No evidence of margin failure”, “Cement wear” and “Small fracture”. No evidence of wear was

defined as having the margins with no apparent change over time. Cement wear was defined as a deepened area (crevice) at the interface that was originally filled by the cement but in time the cement exposed characterizing evidence of loss of material. Small fracture was defined as evidence of pieces of the restoration that fractured off, thus leaving the enamel wall and cement exposed.

Only thirteen restorations had occlusal margins, seven inlays and six onlays. At 1 week, 11 restorations presented no evidence of change and 2 restorations presented fractures. At 3 months, 2 restorations presented no evidence of change and at 6 and 12 months, only 1 restoration presented no evidence of change. However, after 12 months, there were no restorations loose or lost due to retention failure (Table 14).

Table 13: Proximal Contact. Percentages in Parenthesis.

Category	One Week		Three Months		Six Months		Twelve Months	
	m	d	m	d	m	d	m	d
Alpha	29 (100)	25 (100)	28 (96.5)	24 (96)	27 (93)	25 (100)	29 (100)	25 (100)
Bravo	0	0	1 (3.5)	1 (4)	2 (7)	0	0	0
Charlie	0	0	0	0	0	0	0	0
TOTAL	29 (100)	25 (100)	29 (100)	25 (100)	29 (100)	25 (100)	29 (100)	25 (100)

Table 14: Failure Mode for Inlays and Onlays. Percentages in Parenthesis.

Category	One Week	Three Months	Six Months	Twelve Months
No Evidence of Margin Failure	11 (84.6)	2 (15.4)	1 (7.8)	1 (7.8)
Cement Wear	0	7 (53.8)	6 (46.1)	5 (38.5)
Small Fracture	2 (15.4)	4 (30.8)	6 (46.1)	7 (53.7)
TOTAL	13 (100)	13 (100)	13 (100)	13 (100)

2.5 Discussion

There was no effort to recruit an equal number of males and females, but by random selection the sample size was very similar for both genders (11 male and 14 female). No more than 2 restorations were placed in any one patient.

2.5.1 Sensitivity

The mean value of sensitivity at baseline (Pre-Operative) was 14.9 mm. (Table 3). An initial increase in sensitivity after cementation was noted and may be attributed to the preparation and cementation procedures. Other causes can be attributed to previous restorations on the selected teeth and heavy occlusal contacts. There were 4 cases of persistent sensitivity: one was related to root exposure where the patient could not determine the exact location of the sensitivity, two were related to depth of preparation and 1 was related to occlusion and the depth of preparation. After 6 months the mean value of sensitivity continued to decrease, and the 4 cases of increased sensitivity showed improvement. There was only 1 case of significant increased sensitivity that could be attributed to other dental treatments (the recall appointment was shortly after the patient had 11 veneers and a 3 unit all-ceramic bridge cemented). At 12 months the mean sensitivity was slightly increased to 16.4. This can be explained by the marked increase in sensitivity in 3 specific patients. From observing the data set, the tooth type and location in the mouth (premolar or molar; maxillary or mandibular) did not seem to affect the sensitivity ratings.

Nine patients presented very mild pre-operative sensitivity. After the restorations were placed, these patients presented a decrease in the sensitivity. Six patients that did not present with any pre-operative sensitivity developed an increase after the restorations

were placed. Finally, three patients never reported any change after cementation and their values remained virtually unchanged throughout the study.

The One way ANOVA for mean sensitivity ratings and for the differences between recall and baseline ratings did not show significance. This result can probably be attributed to the large standard deviation, which can be explained by the variability of the values obtained from the VAS. The VAS records the patient's perception of pain. The subjective nature of perception allows a variety of values for a starting point (baseline) making it impossible to establish a "point zero". The values obtained at each recall may be higher than or lower than the baseline. The mean sensitivity rating reflected the perceived changes in general, but the variability of the values that created a large standard deviation made these changes not significant statistically.

It is possible that the ratings for sensitivity could have been more accurate if a more localized stimulus had been used (a cotton tip applicator and Endo-Ice). Also, many variables affect the patient's response to the cold stimulus, for example the time of the day, the season of the year, the test being performed right before or after a meal, concomitant dental treatments, the periodontal condition of adjacent teeth, etc. These variables can not always be controlled and represent a challenge for the researchers in clinical studies.

2.5.2 Gingival Index

The gingival index showed no gingival inflammation for the majority of the patients at baseline and 3 months. Mild inflammation with slight color change and edema, but no bleeding, was present in roughly 20% of the patients. Only 1 patient presented with moderate inflammation at 3 months, showing redness, edema and glazing, and bleeding

upon probing. This was an isolated case and could be just a localized temporary condition related to hygiene in a specific period of time (Table 7).

A similar study by Thordrup et al. (1994), evaluated the clinical performance of four types of tooth-colored inlays. The authors concluded that no apparent increase in plaque accumulation or gingival inflammation could be related to treatment with inlays.[27] In the present study, the gingival index was not related to cement failure or changes in proximal margin integrity over 12 months.

2.5.3 Margin Integrity

All the restoration margins were rated Alpha at one week. At three months only 2.9% of the restorations had a margin rated Bravo. At six months 5.8% of the restoration margins were rated Bravo and at twelve months, 8.9% of the restoration margins were rated Bravo (Table 10). Hayashi et al., found 13 % of the 45 restorations studied clinically, with margin fractures after eight years in a study published in 2000. [28] It is possible that the restoration margins in this study would further deteriorate over time to a value similar to the one found by Hayashi.

The restoration rated Bravo at the 3 month did not change over the 12 month period. On the other hand, one restoration rated Bravo at the 6 month recall reversed to Alpha at 12 months. Two restorations were rated Bravo at 12 months, but were rated Alpha at every previous recall appointment. It is possible that this is a reflection of the intra-evaluator variability. The evaluators were blinded to ratings of their previous evaluations. Even though the evaluators were very experienced in clinical trials, their variability played an important role when determining the status of the marginal integrity.

Marginal Integrity is the category that presents the most change in time in many studies. Other categories, such as recurrent caries, proximal contact, color match or gingival index, present minimal changes in time. In this study, the most evident change was between the one week and the three month recall. Although changes continued at a slower rate, the statistical analysis showed that the only statistical difference was between the one week and the twelve month recall.

2.5.4 Restoration Integrity

At 1 week 33 of the restorations were intact and 1 had a minor chip on the occlusal surface which was rated Bravo (a small fracture that could be polished). This could be related to the occlusion (centric stops) being close to the margin of the restoration. At 3 months, another restoration presented a small fracture at the marginal ridge without compromising the margins of the restoration and was rated Charlie. In this case, the reason seemed to be the occlusion (centric stops) as well as the amount of unsupported porcelain used to replace not only the marginal ridge, but also the mesio-lingual cusp. At 6 months and 12 months no fractures were recorded other than the ones already present (Table 11).

These results differ from Hayashi et al. in 2000, who found bulk fracture which occurred during the last two years, in five (11%) of the 45 restorations studied clinically for eight years.[28] During the first 6 years the authors had no bulk fractures, only small marginal fractures.

Kramer et al., in 2005 published a study that evaluated the clinical performance of IPS Empress inlays and onlays with cuspal replacements and proximal margins below the

cemento-enamel junction over eight years. The authors found that six (6.3%) of ninety six inlays suffered cohesive bulk fractures.[29]

It is possible that after 8 years of service, restoration fractures could proliferate. In this study only one restoration presented a bulk fracture of a marginal ridge and that was polished to delay replacement. One restoration was rated Bravo at 1 week, but reversed to Alpha at 3, 6 and 12 months. Similarly, one restoration rated Bravo at 3 and 6 months reversed to Alpha at 12 months. The intra-evaluator variability is again the most likely explanation for these results. The only restoration in the present study rated Charlie at 3 months remained unaltered over the 12 month recall period.

2.5.5 Caries

There were no incidences of recurrent caries for any of the restorations (Table 12). The restorations were properly adapted and sealed with the resin cement. Recurrent caries would not be an expected adverse event, particularly in such a short period of time. However, Thordrup et al., published a study in 1994 to evaluate the clinical performance of four types of tooth-colored inlays (ceramic and composite) in 37 patients.[27] The authors had to replace one composite inlay after 1 year of service due to recurrent caries. None of the ceramic restorations, though, had to be replaced due to caries.

2.5.6 Proximal Contact

The contacts remained virtually unaltered throughout the study (Table 13). This is expected when evaluating porcelain restorations as opposed to composite restorations where the wear rate may alter the contacts in time. At three and six months two contacts were rated Bravo. It is important to note that a mesial contact rated Bravo at 3 and 6

months reversed to Alpha at 12 months. Similarly, one distal contact rated bravo at 3 months and a mesial contact rated Bravo at 6 months reversed to Alpha in the subsequent recalls respectively.

2.5.7 Failure Mode

The majority of the changes occurred between the 1 week recall and the 3 month recall (Table 14). In general, the areas of deterioration were related to the occlusion. The cement wear was evident in functional contact areas and the fractures were related to the occlusal stops and areas where the margins of the porcelain restorations were thinner than anticipated. This is probably due to the way pressed ceramic restorations are fabricated. Pressed ceramic restorations are waxed first, then, using the lost wax technique, a heated ingot is pressed into the form. During waxing, a thicker margin is created (Figure 3), so that when polishing the margins to adapt to the model those wouldn't fracture (Figures 4 & 5). In reality, the margins tend to be either polished too much, leaving the cement line exposed, or not be polished enough leaving a thin lip that may fracture during function (Figure 5-7). This finding is in agreement with a study by Hayashi et al., who used SEM analysis of the restoration replicas and found a margin deterioration rate of 77%.[28] In 2004, the same group of investigators analyzed quantitatively and morphologically the longitudinal marginal changes of ceramic inlays and determined the mechanism for those changes.[30] They identified a sequential three-stage pattern of marginal deterioration; initial rapid progress of wear of resin composite cement in the first stage (0 to 6-21 months), followed by a second stage without any remarkable visible change (6-21 to 72 months), then rapid progression of microfractures of ceramics and/or enamel in the third stage (after 72 months). During the first stage (0 to 6-21 months) there was no evidence of

microfractures of enamel or ceramic. Differences in the marginal deterioration became statistically significant at eight years after placement.

In the present study, small fractures were observed as early as the 1 week recall and rapid cement wear at the margins was observed as soon as at the 3 month recall, after which the restorations did not change significantly. Since the restorations in the present study were only followed for 12 months, it is possible that the restorations that presented cement wear could at later recalls follow the pattern found by Hayashi et al.

2.5.8 Indirect Evaluation

The restorations were evaluated indirectly by examining replicated stone dies with a microscope. With this technique, it was possible to detect areas of cement wear or small fractures that were not evident in the clinical pictures or with intraoral examination (Figures 8-13). Even though the stone dies were helpful, they presented some difficulty. The dies were fabricated using a combination of a blue and a white stone (50:50% by weight of Flowstone Blue and Resin Rock Die Material, Whip Mix Corp., KY, USA) for better contrast. The white stone grains, visible with the microscope, created undesirable light reflection. Also the surface texture made some areas indistinguishable, i.e. blurred the margins. A lower magnification (20x) was used since it provided the best contrast.

Figure 3. Lip of over contoured porcelain.

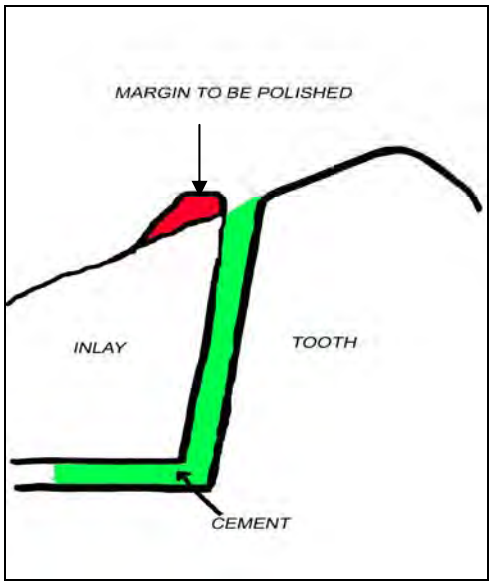


Figure 4. Polishing of over contoured margin.

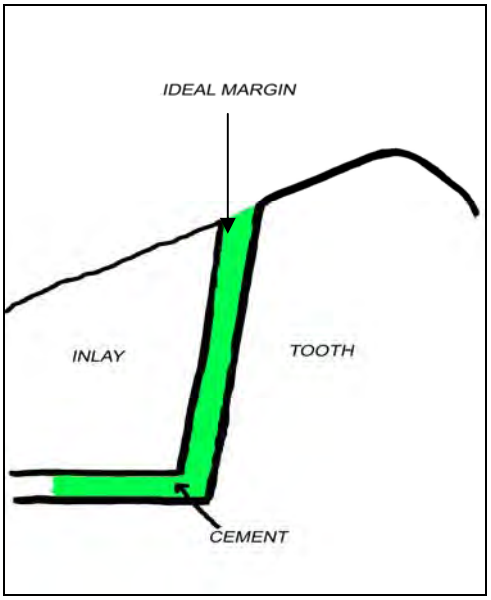


Figure 5. Final ideal margin.

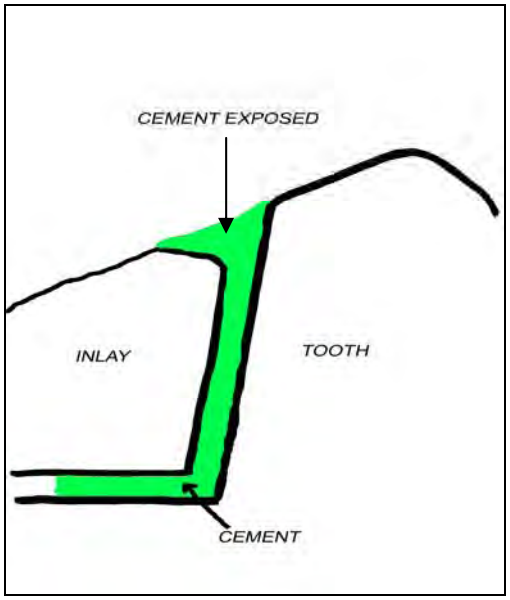


Figure 6. Margin defects observed clinically.

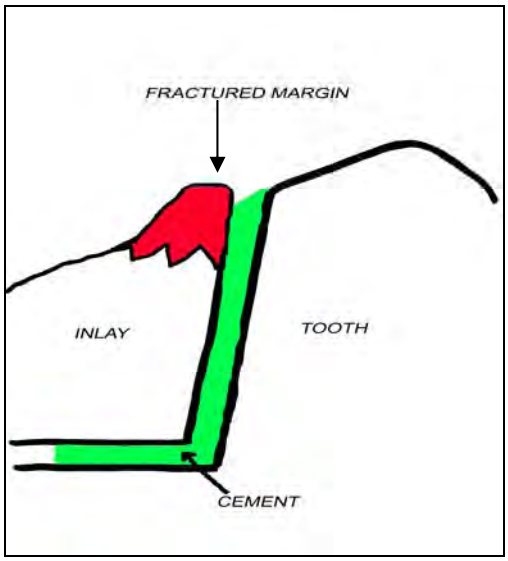


Figure 7. Margin defects observed clinically.

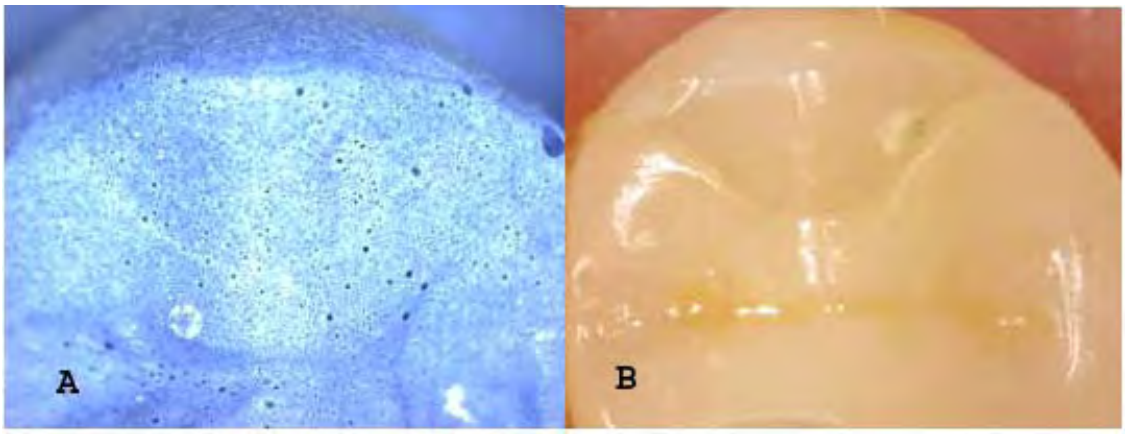
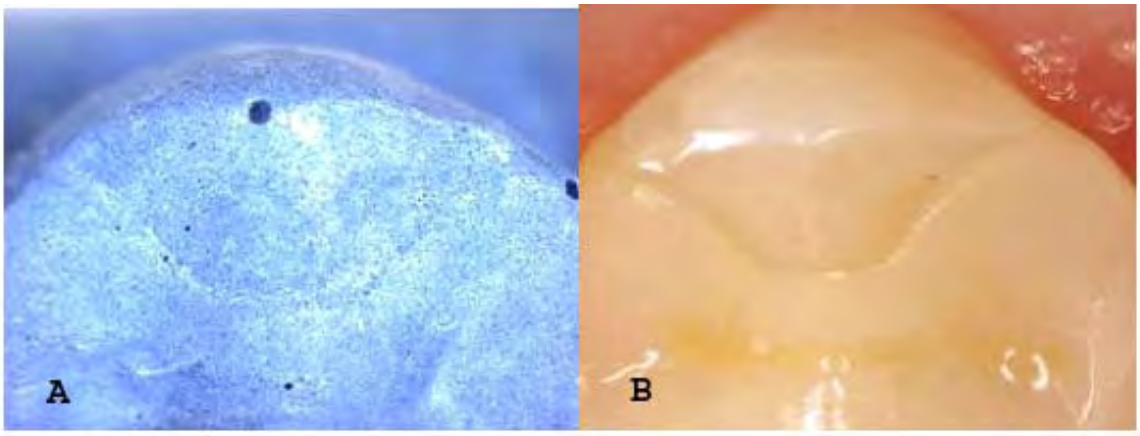


Figure 8: Intact inlay margin at baseline. (A) Stone die at 20x. (B) Digital clinical picture.



Figures 9: The restoration in Figure 8 at the 1 year recall with well preserved margins. (A) Stone die at 20x. (B) Digital clinical picture.

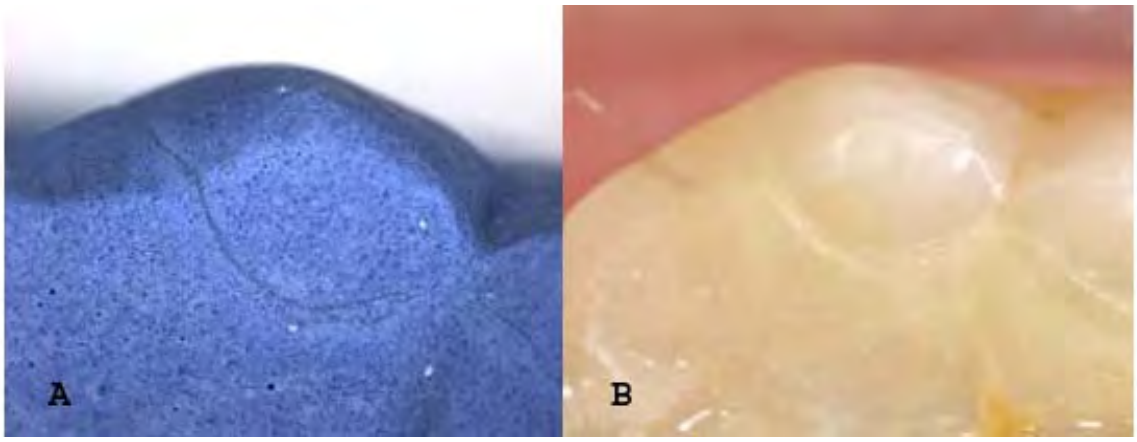


Figure 10: Inlay margin at baseline showing an area of exposed cement. (A) Stone die at 20x. (B) Digital clinical picture.

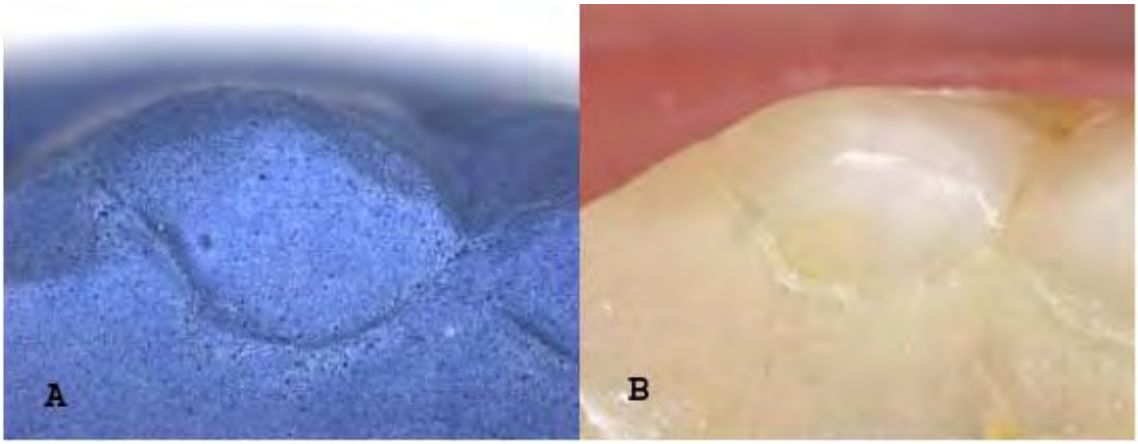


Figure 11: Restoration in Figure 9 at 1 year. There is considerable loss of cement at the margin showing a crevice. (A) Stone die at20x. (B) Digital clinical picture.

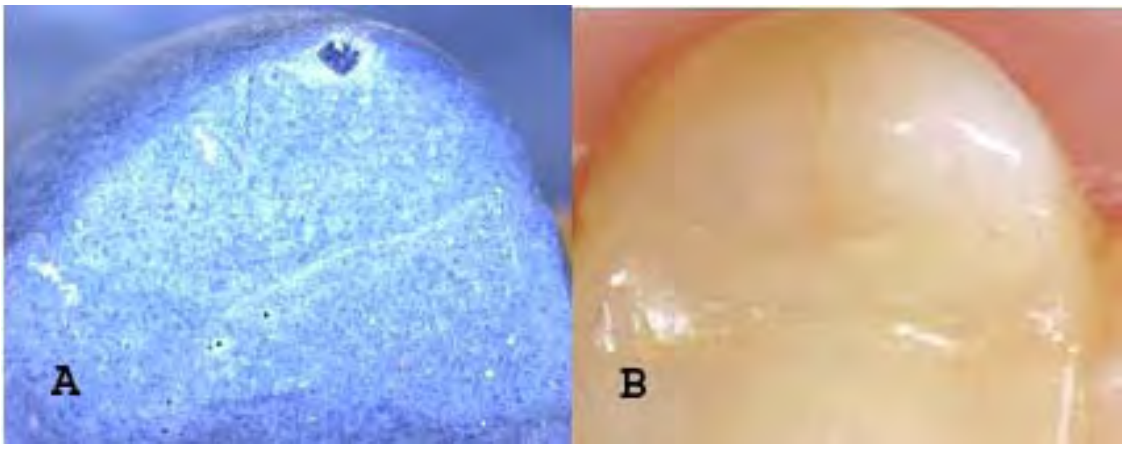


Figure 12: Intact inlay margin at baseline. (A) Stone die at 20x. (B) Digital clinical picture.

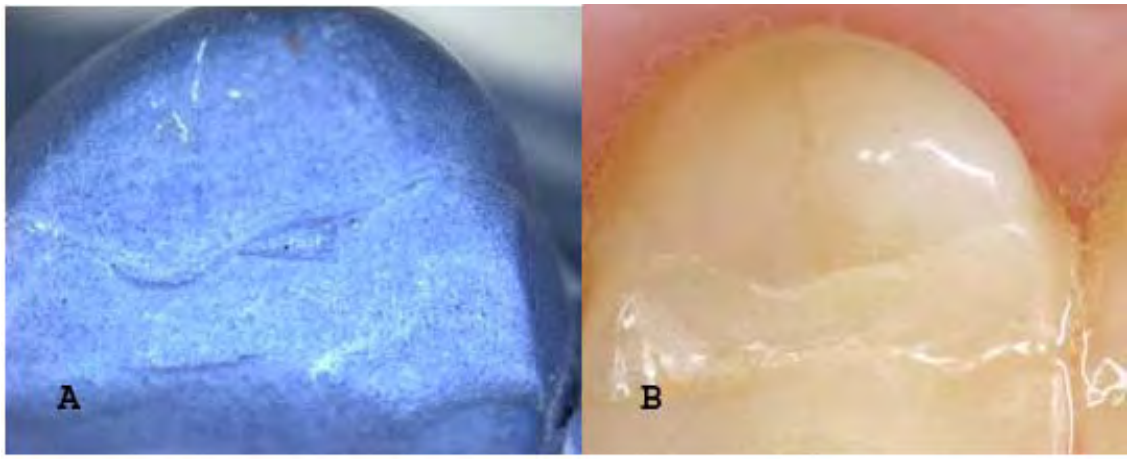


Figure 13: The restoration in Figure 11 at 6 months. A small fracture is evident at the margin. (A) Stone die at 20x. (B) Digital clinical picture.

2.6 Conclusions

Within the limitations of this study using the new self-etch, self-cure adhesive, the following conclusions can be made:

1. The mean sensitivity ratings at each recall did not differ significantly from baseline, although there was an increase at 1 week. Therefore we accept the null hypothesis (H_{o1}).
2. None of the all-ceramic restorations became loose or were lost for the 12 month recall period. Therefore we accept the null hypothesis (H_{o2}).
3. All-ceramic restorations were clinically acceptable after 1 year. There were no significant changes in gingival response, margin discoloration, restoration integrity, recurrent caries or proximal contacts over this period.
4. Margin integrity exhibited significant deterioration between 1 week and 12 months, with a large portion of that change occurring between 1 week and 3 months.

2.7 Recommendations

1. A control group is recommended for future studies in order to make comparisons between the experimental and standard materials for the different categories, especially sensitivity.
2. An ideal stimulus for sensitivity testing should not affect adjacent teeth, only the tooth with the restoration.
3. In order to better follow the status of the margins of these restorations in time, it would be advisable to determine the areas of occlusal load at cementation as a separate margin integrity category and evaluate them separately at each recall. This would allow better follow-up evaluation and analysis of the margin changes.
4. A more homogeneous material with better surface texture and optical properties is recommended for fabricating the dies to be evaluated under the microscope.

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Appendix A : CONSENT FORM

Title of Research Project: **Clinical Evaluation of a Self-Etching Bonding Agent for Bonding Indirect Restorations**

Investigators: Peter Yaman, DDS, MS
Joseph Dennison, DDS, MS
Augusto Robles, DDS

Purpose: To evaluate the clinical performance of a newly developed self-etching (i.e. it doesn't use the acid to prepare the surface) adhesive (Aurora SCA/ Xeno IV) system for bonding indirect restorations.

Procedure: If you agree to participate in this study, you will receive either one or two posterior indirect ceramic dental restorations (Crowns and/or Inlays/Onlays) bonded in place with a new adhesive. The material will be utilized in the same manner as currently marketed alternative adhesives. The finished restoration will then be evaluated by two of the supervising faculty; pictures and an impression will be taken of the tooth only at each visit. This visit should take no more than two hours.

Time Period: The tooth and restoration will be evaluated in a similar manner at recall visits after 3, 6, 12, 24 months. Each recall visit should take no more than 30 minutes. You will also receive a phone call from the study coordinator, Mrs. Chris Melzer, one week after this visit to assess your post-operative comfort with the procedure.

Risks: Any risks associated with the participation in the study are the usual risks that occur during routine dental treatment with adhesives and esthetic materials, such as fracture, sensitivity and recurrent decay.

Benefits: The new adhesive has been improved in properties and should provide less sensitivity as well as simpler handling.

Costs: The cost of the restoration will be that of the General Dentistry Clinic Fee Guide. At every recall, you will receive $50.00. Full parking fees will be paid.

Confidentiality: You will not be identified in any reports in this study. The records and photographs will be kept confidential to the extent provided by federal, state and local law. Only the investigators and the patient coordinator will have access to them.

Compensation for illness or injury: In the unlikely event of physical injury resulting from research procedures, the University will provide first-aid medical treatment. Additional medical treatment will be provided in accordance with the determination by the University of its responsibility to provide such treatment. However, the University does not provide compensation to a person who is injured while participating as a subject in research.

Your participation in this project is voluntary. Subsequent to your consent, you may refuse to participate in or withdraw from the study at any time without jeopardizing your eligibility for treatment within the School of Dentistry.

One copy of this document will be kept together with our research records on this study. A second copy will be placed in your dental record and a third copy will be given to you if requested. Should you have any questions about the research, your rights, or any injury you may feel is related to this study you may contact Mrs. Chris Melzer in restorative research, School of Dentistry, (734) 936-3276.

If you have additional questions during the course of the study about your rights as a research participant you may address them to the University Of Michigan Health Sciences Institutional Review Board: Kate M. Keever, Administrator of the Human Subjects Protection Office, Office of the Vice President for Research, 540 East Liberty, Suite 202 B, Ann Arbor, Michigan 48109-2210; telephone: 734-936-0933.

CONSENT TO PARTICIPATE IN THIS STUDY
Clinical Evaluation of a Self-Etching Bonding Agent for Bonding Indirect Restorations

Date of Birth _____ / _____ / _____
Day Month Year

Last Name: _____ First Name: _____

Address: _____

_____

Telephone Number: ( ) —

I confirm that, after receiving both oral and written explanations, I agree to participate in the study described.
My participation is voluntary and I can withdraw my consent without jeopardizing my present or future treatment.
I will be given a copy of this signed consent form. By signing this form, I have not given up any of my legal rights as a research participant.

Date Signature of Participant _-_ _ _-_ _ _ Clinic Number

Date Signature of Investigator Obtaining Consent

Appendix B: VISUAL ANALOG SCALE

Analog Scale for Sensitivity - Xeno IV / SCA Aurora

Name : _____Reg # : _____ ID # : X-_____

Address : _____Phone H / W : _____ _

City, State, Zip : _____E-mail : _____ __ Tooth # : _____

Baseline : _____

No Sensitivity Severe Sensitivity

1 week Recall : _____

No Sensitivity Severe Sensitivity

3 months Recall : _____

No Sensitivity Severe Sensitivity

Appendix C: CRITERIA XENO IV RESEARCH PROTOCOL

Clinical Evaluation of a New Self-etch Self-cure
DBA for Indirect Restorations

Criteria for Evaluation		Rating
I.	Gingival Index	
	Gingival score for gingival area nearest to the restoration margin; evaluate w/o disclosing.	
	Normal gingival	0
	Mild Inflammation-slight change in color, slight edema, no bleeding	1
	Moderate inflammation-redness, edema & glazing, bleeding upon probing	2
	Severe inflammation-marked redness, edema, ulceration, bleeding	3
II.	Color match (evaluated wet at 12 inches for 3-4 seconds)	
	Adjacent teeth and restoration have an ideal color match; can	
	Distinguish restoration with some difficulty, slightly detectable	Alpha 1
	Readily perceptible difference in color, clinically acceptable	Bravo 2
	Clinically unacceptable mismatch in color	Charlie 3
III.	Marginal discoloration (evaluated with tooth dry)	
	No discoloration anywhere on the margin between the restoration and tooth structure	Alpha 1
	Discoloration along margin noted in one local area or less than 50% of exposed margin	Bravo-1 2
	Discoloration along margin noted in multiple areas or more than 50% of exposed margin	Bravo-2 3
	Discoloration penetrating along margin in one local area or less than 50% of exposed margin	Charlie-1 4
	Discoloration penetrating along margin in multiple areas or more than 50% of exposed margin	Charlie-2 5
IV.	Marginal Integrity	
	Marginal ditching (crevice) not detectable	Alpha-1 1
	Probe catches at cavity margin, visible overhangs or underfilled margins	
	Catch from Tooth to Restoration	Alpha-2 2
	Catch from Restoration to Tooth	Alpha-3 3
	Visible evidence of crevice formation into which explorer will penetrate along less than 50% of exposed margin	Bravo-1 4
	Visible evidence of crevice formation into which explorer will penetrate along more than 50% of exposed margin	Bravo-2 5
	Crevice formation with exposure of underlying dentin or base	Charlie 6
	Restoration is mobile, fractured, or missing in part or in whole	Delta 7
V.	Restoration Integrity	
	No fractures noted	Alpha 1
	Small fracture which can be polished	Bravo 2
	Fracture of material which needs repair but not replacement	Charlie 3
	Fracture which requires replacement of restoration	Delta 4
VI.	Recurrent caries	
	Recurrent caries not evident	Alpha 1
	Recurrent caries diagnosed in association with existing restoration	Charlie 2
VII.	Proximal contact (mesial and distal)	
	Tight contact (firm)	Alpha 1
	Light contact but visually closed (allows free passage of shimstock)	Bravo 2
	Contact visually open to light reflection	Charlie 3