

A Clinical Evaluation of a Self-Etch, Self-Adhesive Resin Cement for Bonding Indirect All-Ceramic Restorations

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DEDICATION

To my wife Hanie Yukching, my sons Eric and Nathan,
for without their love and support, this would not have been possible

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Chapter 1

1.1 Introduction and Background

An increasing number of all-ceramic materials and systems are currently available for clinical use. They offer preferred optical properties for highly esthetic restorations.¹ The various all-ceramic materials have different mechanical and optical properties that affect their indications and limitations, as well as their laboratory and clinical manipulation:²

Leucite-reinforced glass-ceramics (IPS Empress, Ivoclar Vivadent) can be fabricated by using either a heat-pressing procedure or via CAD/CAM technology. These restorations are highly translucent and may be the material of choice when high translucency is required. However, they typically are not recommended for cases where the underlying abutment is discolored and /or opaque. They are highly successful when used for fabricating crowns in the anterior segment.

The lithium disilicate glass-ceramic core material (IPS Empress 2, Ivoclar Vivadent) is fabricated with a heat-pressing procedure. It was developed for anterior and posterior crowns and for three-unit FPDs. However, as an FPD, it is confined to replacing a missing tooth anterior to the second premolar.

The glass-infiltrated alumina (In-Ceram Alumina, Vident) infrastructure was developed for anterior and posterior crown copings, as well as for three-unit anterior FPDs. Infrastructures are fabricated using either the slip-casting technique or CAD/CAM technology. The material is strong but relatively opaque.

Glass-infiltrated magnesium alumina (In-Ceram Spinell, Vident) is twice as translucent as the glass-infiltrated alumina and therefore may be used in clinical scenarios where maximum translucency is required. However, these cores are weaker than the conventional glass-infiltrated alumina cores and are thus recommended for use only as anterior crowns.

Glass-infiltrated alumina with partially stabilized zirconia (In-Ceram Zirconia, Vident) combines the use of glass-infiltrated alumina with 35% partially stabilized zirconia as a core for posterior crowns and FPDs. Slip-casting technique or CAD/CAM technology can be used for the infrastructure fabrication. However, the core has high opacity.

Densely sintered high-purity aluminum oxide (Procera AllCeram system, Nobel Biocare) is a glass-free, high-strength ceramic core material. It is recommended for anterior and posterior crowns. CAD/CAM technology is used for the fabrication of the ceramic copings.

Yttrium tetragonal zirconia polycrystals (Cercon, Dentsply Ceramco; Lava, 3M ESPE; Procera AllZirkon, Nobel Biocare) is a glass-free, high-strength ceramic material indicated for the fabrication of anterior and posterior crown copings and FPD frameworks. These are designed using either conventional waxing techniques or CAD technology, while CAM is used for the material's processing.

The inherent brittleness of some ceramic materials, specific treatment modalities, and certain clinical situations require resin bonding of the completed ceramic restoration to the supporting tooth structures for long-term clinical success. Multiple clinical studies document excellent long-term success of resin-bonded restorations, such as porcelain

lamine veneers, ceramic inlays and onlays, resin-bonded fixed partial dentures, and all-ceramic crowns. A strong, durable resin bond provides high retention,³ improves marginal adaptation and prevents microleakage,⁴ and increases fracture resistance of the restored tooth and the restoration.⁵ Based on the current evidence, adhesive cementation procedures are necessary to support all-ceramic materials.⁶

Resin-based composites are the material of choice for the adhesive luting of ceramic restorations. They consist of inorganic fillers embedded in an organic matrix. They can be classified according to their initiation mode as autopolymerizing (chemically activated), photoactivated, or dual-activated materials. Resin cements with reduced filler contents offer improved flow, increased surface wettability, and optimal positioning of the restoration. Highly filled resin cements may improve abrasion resistance at the marginal area, reduce polymerization shrinkage, and facilitate removal of excess cement.

Most resin cement systems involve first etching the tooth with an acid solution followed by rinsing, application of a bonding agent, and finally application of the cement. This is both time-consuming and may contribute to post-operative sensitivity. A new generation cement system known as self-adhesive cement uses low pH resin primers to simultaneously demineralize and penetrate tooth surfaces. No etching or bonding is needed. This simplifies the procedure to a great extent and reduces chair time. It may result in less post-operative sensitivity.

1.2 Aims and Purposes

The purpose of the study is to evaluate the clinical performance of a self-adhesive resin cement system, **MAUI** (Dentsply Caulk, Milford, DE) to bond indirect all-ceramic restorations; and to compare it to a control cement, **RELY-X UNICEM** (3M ESPE, St Paul, Mn). The specific aims are as follows:

1. To clinically evaluate a new self-adhesive resin cement for bonding indirect all-ceramic restorations, based on United States Public Health Service (USPHS) criteria, at 1 week and 6 months after cementation.
2. To compare the clinical performance of the new resin cement to a control self-adhesive resin cement.
3. To evaluate the issue of post-cementation sensitivity, comparing it at 1 week and 6 months to baseline (pre-op).
4. To determine the failure rate and the mode of failure of all-ceramic restorations cemented with the self-adhesive resin cement at 6 months.

1.3 Hypotheses

Ho1: There is no significant difference in the clinical performance between the new test cement and the control cement.

Ha1: There is a significant difference in the clinical performance between the new test cement and the control cement.

Ho2: The test cement has no effect on post-cementation sensitivity at 1 week or 6 months after cementation.

Ha2: The test cement has a significant effect on post-cementation sensitivity at 1 week or 6 months after cementation.

1.4 Literature Review

1.4.1 Cements

Rely-X Unicem (3M ESPE) is a self-adhesive universal resin cement which is popular and has been on the market for a few years. Rosentritt et al reported that the difference in marginal integrity between Unicem without any tooth pre-treatment and conventional resin cements after total-etching, priming and bonding was not significant,⁷ and that Unicem can provide a marginal adaptation at dentin which is comparable to established luting agents.⁸ Luthy et al evaluated the shear bond strength of different cements to densely sintered zirconia ceramic after aging by thermocycling, and found that the bond strength of Unicem was not affected by thermocycling, and gave superior results comparable to Panavia 21, Panavia F and Superbond C&B.⁹

The new self-adhesive cement system (Dentsply/Caulk) consists of base and catalyst pastes contained in a double-barrel syringe and a self-mix tip. It is a dual-cure, high-strength cement which releases fluoride. It has shown shear bond strength, compressive strength, diametral tensile strength and flexural strength in the laboratory that equal or exceed those of successfully marketed products. The cured cement is essentially hydrophobic, minimizing post-cure water sorption, solubility and hygroscopic expansion. It is available in five tooth-colored shades: light, medium, dark, translucent and opaque. The biocompatibility profile of the system reveals no concerns for potential toxicity. The material combines the chemistry of bonding agents with that of resin cements.

Composition

- Urethane Dimethacrylate (UDMA) and Urethane Modified Ethoxylated Bisphenol "A" Dimethacrylate (EBPADMA-Urethane) as the primary structural monomers.
- PENTA, an acidic, adhesive polyfunctional methacrylate that promotes bonding to dentin, enamel, composites, ceramics and metals.
- Triethylene Glycol Dimethacrylate (TEGDMA) & Trimethylolpropane Trimethacrylate (TMPTMA): reactive diluents / crosslinking agents that improve mechanical properties and reduce paste viscosity.
- Filler: silanated barium fluoro alumino borosilicate glass with different average particle sizes to further increase mechanical strength and maintain the desired paste consistency.
- Chemical initiator Cumene Hydroperoxide (CHPO) in the catalyst paste; accelerator Benzoylthiourea (BTU) in the base paste. Self-cure occurs when the two pastes are mixed.
- Photoinitiator Camphorquinone (CQ).
- Stabilizers: BHT to provide shelf life stability to the formulation.
- Other fillers such as fumed silica to help control the paste rheology and adjust the flow characteristics.
- Pigments such as titanium and iron oxides to adjust the shade and opacity.

Indications for use

1. Adhesive cementation of ceramic, porcelain and composite inlays/onlays, veneers and crowns.
2. Adhesive cementation of all-metal crowns, bridges, inlays/onlays including precious, semi-precious and non-precious metals.
3. Adhesive cementation of PFM crowns and bridges.
4. Adhesive cementation of prefabricated and cast posts.
5. Adhesive cementation of resin-bonded retainer bridges (Maryland bridges).

1.4.2 Postcementation Sensitivity

Increased sensitivity to hot or cold stimulation is an occasional, but perplexing, unwanted consequence of a newly cemented restoration. Brannstrom discussed the causes of pulpal damage.¹⁰ The main cause is infection, the bacteria originating in the smear layer or deep in the dentinal tubules, inaccessible to caries-excavating procedures. A poorly fitting provisional crown may expose cut dentin to the oral fluids, and mechanical trauma caused by frictional heat during preparation may also damage the pulp. He recommended the following precautions during precementation procedures to reduce the risk of an inflammatory response in the pulp: (1) The provisional crown should be well fitting, covering cervical dentin but not impinging on the periodontal tissues. The permanent crown should be cemented as soon as possible. (2) The superficial smear layer should be removed and the dentinal surface should be treated with an antibacterial solution before the provisional crown is placed. (3) To decrease dentinal permeability under the provisional crown, the dentinal surface should be covered with a liner that can

be easily removed before final cementation. (4) To ensure optimal micromechanical bonding, the dentinal surface should be thoroughly cleaned, and the dentin should be kept moist until cementation. (5) The occlusion should be carefully checked before cementation of the crown.

This is a well-written article, addressing the problem of temperature sensitivity dentists occasionally face after crown cementation. It is interesting to note that the author thinks most permanent restorative materials in common use today do not tend to irritate the pulp, and therefore sensitivity is not attributed to the luting agent itself. He gives useful tips on procedures that may reduce sensitivity, such as avoiding desiccation, checking occlusion, well-fitting provisional that should not be left for too long; which still apply today. The effectiveness of treating the dentinal surface with an anti-bacterial solution before crown cementation, however, may be questionable.

Rosenstiel et al obtained dentists' opinions via an Internet survey as to the prevalence, causes, and prevention of postcementation sensitivity and compared their responses with published data on the problem.¹¹ The respondents were asked about their experience as to postcementation hypersensitivity and whether they had implemented measures to reduce or eliminate it. They were also asked to rank the importance of each of 15 factors in reducing or eliminating postcementation hypersensitivity; and what in their opinion is the single most important factor. A total of 466 valid responses were received. The incidence of postcementation sensitivity was estimated to be less than 2% by 68% of respondents; 13% reported sensitivity of 6% or greater. The "most important" factors were desiccation (19%), luting agent (18%), and occlusion (16%). These, together with provisional restoration and water spray, were considered "very important" by more

than 50% of the respondents. Least often mentioned as “most important” were hemostatic agent, core material, rotary instrument type, time between preparation and cementation, and varnish use. Desensitizing agents were considered the most important by 10% of respondents, more than bonding agents (7%) or antimicrobials (5%). The conclusions that can be drawn from the survey results and the available scientific evidence: (1) A comparison of the survey with clinical studies indicates that practitioners underestimate the incidence of postcementation sensitivity. (2) Respondents consider dessication the most significant factor in causing postcementation sensitivity. (3) There is little evidence to support the use of antimicrobial, desensitizing, or bonding agents; general dentists are more likely than prosthodontists to be convinced of the efficacy of these agents. (4) Luting agent choice is considered an important variable by many respondents; and again general dentists place more importance on the choice of luting agent. (5) Prosthodontists place comparatively more importance on tooth reduction, the provisional restoration, and water spray.

This is a very comprehensive survey, as many as 15 factors were included. The inclusion of such factors as bur type and core materials used is rather surprising, as they are quite unlikely to cause post-cementation sensitivity. I have reservation about the conclusion that most dentists ‘underestimate’ the incidence of post-cementation sensitivity. Dentists who took part in the survey based their estimates on their actual experiences and their patients’ responses, and it so happened that only a small percentage of their patients reported or actually experienced post-cementation sensitivity. Though published data may indicate a higher percentage, there is no definite percentage of patients who should be experiencing post-cementation sensitivity.

Christensen discussed the need for resin cements, and described ways to prevent postoperative sensitivity and what to do if it occurred.¹² A recent Clinical Research Associates report showed that when using resin cements, practitioners saw postoperative sensitivity within the first year after cementation in about 37% of their patients with crowns; with some brands of cement and bonding agents, up to 11% of the teeth required endodontic treatment within the first year. Currently, most North American dentists are using resin-reinforced glass ionomer (RRGI) cements such as Rely X-Vitremer (3M); Fuji Plus (GC) for routine cementation of PFM and all-metal crowns. Only on a few occasions are dentists using a resin adhesive as their routine cement. The major types of crowns for which resin cement is used are some types of all-ceramic crowns, polymer crowns and metal crowns needing optimum retention. Empress crowns, Inceram crowns and fixed prostheses, fired porcelain restorations such as porcelain veneers require the use of resin cement to achieve adequate strength. Empress 2 crowns and fixed prostheses can be used with RRGI cement (Protec Cem); resin cement can be used if additional strength is desired. Procera crowns can be successfully cemented with conventional cements and RRGI is the most popular. Some techniques suggested for preventing postoperative sensitivity:

- Placing a bonding agent on the surface of the acid-etched tooth preparation and curing it just before cementation. However, thick layers of cured bonding resin produce resistance to proper crown seating. This is one of the least predictable techniques.
- Placing a bonding agent on the preparation after the provisional is made, but before the impression. However, the bonding agents can contaminate the impression materials during the impression procedure. Additionally, the bonding resins are relatively

chemically inactive at the time of cementation due to the time lapse between the tooth preparation and the crown seating.

- Placing a desensitizer (Gluma) after acid etching, then the typical priming-bonding solution, seating the restoration with resin cement, and curing the cement and the bonding agent through the restoration. This is successful for seating thin indirect restorations such as porcelain veneers or shallow inlays or onlays.

- Using a self-etching primer and bond, regarded as the most successful and predictable to date. The most popular material and technique in this category is Panavia 21 or Panavia F used with the self-etching primer, ED Primer. The tooth preparation is not acid-etched in the conventional manner. The smear layer of the tooth preparation is left on the tooth, and the self-etching, self-curing ED Primer is incorporated into the existing smear layer. The self-etching, dual-cure product Clearfil Liner Bond 2V is one of the most predictable desensitizing products for use in the cementation of tooth-colored inlays or onlays with resin cement.

- Using a 4-META cement, C&B-Metabond, which has an unprecedented history as a crown-cementing product that does not induce sensitivity. The new Parkell 4-META product, TotalBond, has a longer working time and is easier to clean up than C&B – Metabond.

When sensitivity occurs after crown cementation with resin, Christensen¹² prefers to wait for up to six weeks to determine whether the sensitivity resolves by itself. If the pain worsens, the crowns must be removed. Subsequently, when a provisional is placed with an obtundent cement such as zinc oxide-eugenol (ZOE) cement, the pain often resolves in a few days or weeks. Contrary to popular belief, he thinks there is no problem

in using a ZOE temporary cement on a tooth preparation that will receive resin cement. He suggests that the ZOE cement be left in place for at least two weeks before resin cement is used. If the tooth continues to be sensitive, endodontic therapy is needed.

This article gives us the impression that resin cements have a higher chance of causing tooth sensitivity compared to, say, resin-modified glass ionomers. The figures quoted: 37% experiencing post-operative sensitivity and 11% of teeth requiring endodontic treatment within the first year after cementation, are alarmingly high. The author did not discuss how the data were collected, and what the sample size was. He also mentioned that there is no problem in using a ZOE temporary cement on a tooth preparation that will receive resin cement, contrary to the belief that eugenol may affect the bonding of resin cement to tooth structure. He did not further explain or elaborate. Another interesting point is the course of action when the patient complains of post-operative sensitivity: tell the patient that the sensitivity will eventually go away and do nothing; or if we want to do something, how long are we going to wait? The author suggests 6 weeks, which may be a reasonable time span.

Denner et al, in a 2-year follow-up study, compared the postoperative sensitivity of teeth restored with full coverage restorations retained with either conventional glass-ionomer cement (Ketac-Cem) or a new adhesive resin cement containing 4-methacryloxyethyl trimellitate anhydride (4-META) (Chemiace II).¹³ Sixty patients received 120 full-coverage restorations on vital abutment teeth, cemented with either of the two cements.

A randomized split-mouth design and a patient double-blind data acquisition protocol were used. The teeth were examined before cementation, after 1 week, and after

6, 12, and 24 months. With regard to postcementation sensitivity, a low incidence was observed for both groups. With the resin cement, little postoperative hypersensitivity was observed after 1 week (13.3%), 6 months (5.9%), 12 months (2.1%), and 24 months (none); results were similar with the conventional glass-ionomer cement Ketac-Cem after 1 week (5.9%), 6 months (5.9%), 12 months (6.4%), and 24 months (none). After 24 months, no cases of postoperative hypersensitivity were recorded for either group. In this study, the incidence of postoperative hypersensitivity after cementation of full-crown restorations with a conventional GIC and a new adhesive resin cement was similar.

This is a good study, with a good design (randomized split-mouth) and adequate sample size (60 patients with 120 restorations). Ketac-cem, which has been associated with post-cementation sensitivity in the past, was shown to have a low incidence of sensitivity, comparable to the new adhesive resin cement containing 4-META, which is known as a crown-cementing product that does not induce sensitivity. Again past sensitivity issues with Ketac-cem could have been due to improper cementation procedures such as excessive dessication rather than the luting agent itself.

Sensat et al believe that areas of sensitive dentin contain open dentinal tubules that become accessible to external stimuli.¹⁴ In one scanning electron microscope study, hypersensitive dentin had 8 times as many open dentinal tubules as nonsensitive dentin. The diameter of open dentinal tubules in sensitive teeth was twice that of dentinal tubules in nonsensitive teeth. These results are significant because most treatment modalities attempt to occlude the dentinal tubules. The hypersensitive root surfaces of selected teeth were randomized to receive 1 of 3 treatments: (1) coating with a newly developed composite cement (Linkmax, GC) that contains a self-etching, dual-polymerized resin

adhesive system; (2) application of a commercially available composite cement (RelyX ARC, 3M) that involves the use of phosphoric acid-etching followed by a single-bottle, light-activated primer/resin-based adhesive (Single Bond); (3) no treatment (negative control). The sample size was 22. Dentin sensitivity was ascertained with an accurate cold testing device that slowly decreased in temperature. Tooth sensitivity was measured both immediately and at 7 days after placement. With Linkmax treatment, the temperature at which teeth responded was reduced by 8.4 C immediately after placement; while RelyX ARC reduced the temperature at which teeth responded by 9.4 C. After 1 week, these temperature reductions were 7 and 4.3 C respectively. Untreated controls at the 2 intervals showed a mean decrease in cold sensitivity of 3.6 and 4.1 C. Linkmax treatment resulted in a significant reduction in tooth root sensitivity over 1 week ($P=.02$) compared with untreated controls, whereas RelyX ARC did not ($P=.066$).

In this study, the sample size was adequate, and appropriate statistical analyses were carried out to show the significant reduction in tooth root sensitivity by Linkmax. The authors suggest that Linkmax may have the potential to reduce the incidence of postcementation sensitivity, as the same mechanism produces cold sensitivity in both newly cemented restored teeth and in teeth with exposed root surfaces. This is, however, unproven. The authors also suggest that postcementation sensitivity is unlikely to appear after the 1-week interval investigated in this study. Again this is from clinical experience and anecdotal reports, not substantiated by any clinical study.

Lam and Wilson, in their review, discussed the dynamics of the liquid continuum of the pulpo-dentine complex and pulpal pressures in relation to forces and pressures of

cementation.¹⁵ They also discussed the concept of dentin sealing to preserve pulpal health.

The pulpo-dentin complex represents a continuum between intratubular dentinal fluid and pulpal fluid. A direct result of this continuum is the effect of restorative dentistry on the health of the dental pulp, as evidenced by the pulpal necrosis rate of 1% year for vital crowned teeth. Dentin is composed of approximately 50% mineral, 30% organic matter, and the remainder is fluid. There are four elements that make up the hydrated composite of mineral and organic matter: (i) dentinal tubules, surrounded by (ii) a peritubular zone, embedded in (iii) an intertubular matrix, and perfused by (iv) dentinal fluid. Dentinal fluid dynamics can be analysed in three parts, namely the pulpal, intratubular and peripheral ends. It has been shown that the typical force used for crown cementation was initially 60 N for the first few seconds, followed by a constant force of 20-30 N. During cementation, the cut dentinal tubules provide a pulpward route for the less viscous cement constituents that are potentially toxic. A protocol using a combination of a low force together with internal crown relief for cement space and perforation venting to achieve clinically acceptable seating is advocated. There are two aims to dentin surface treatment postoperatively: to modify or remove smear layer in order to improve the quality and quantity of dentin substrate for optimizing adhesive bond strength; and to occlude the dentinal tubules exposed following operative procedures. The strategies devised in dealing with the smear layer are (i) modification to produce a resin-impregnated smear layer, (ii) partial removal to preserve the smear plugs and create only a limited resin-impregnated dentin layer, and (iii) complete removal and decalcification of the dentin top layer to produce a resin-impregnated hybrid layer.

Different topical agents have been devised in an attempt to occlude the dentinal tubules, and they can be broadly classified into three groups: (i) fluoride-containing products, e.g. sodium fluoride which precipitates calcium fluoride to reduce dentin permeability; (ii) oxalates such as potassium oxalate. However, the oxalate crystals may interfere with subsequent attempts to bond cements or adhesive resins to the treated surfaces; (iii) resin and adhesives, dentin bonding agents recommended in prophylactically sealing the dentinal tubules of crown-prepared teeth, thereby reducing fluid flow through the tubules. It is proposed that sealing of dentin before crown cementation would be a useful clinical procedure that may be beneficial and which is unlikely to be harmful.

This article provides a detailed discussion of the pulpo-dentin complex, pulpal haemodynamics and fluid flow through the dentinal tubules. A number of mathematical equations on fluid filtration and diffusive transport are discussed, which are quite difficult to understand. The cementation force may be big enough to force unwanted toxic products from the cement through the dentinal tubules towards the pulp. The authors suggested that sealing of dentin before crown cementation with dentin bonding agents would be a useful, beneficial procedure. However, they mentioned that the evidence of efficacy of such a procedure remains largely anecdotal, but early laboratory and animal studies are promising and supportive of such a concept.

Hilton et al compared the post-operative results of cementing full crowns (all metal or PFM) with either a conventional (Fuji I, GC; n=102) or a resin modified GI luting cement (Rely X, 3M/ESPE; n=107) in a practice-based setting.¹⁶ Ten private practitioners fabricated 209 crowns using standardized preparation/luting criteria and randomly assigned cements. Patients self-reported temperature and biting sensitivity, on a 0-10

scale with 0 = no pain and 10 = worst imaginable pain, at 24 hours, one week, one month and three months post-cementation. Of all patients, 50.7% reported any sensitivity at any time period. Mean sensitivity for all patients on the 10-point scale was 0.52 for temperature and 0.23 for biting, quite low for both cements. There were many significant (though low) correlations between the sensitivity measures and age (inverse relationship) and dentin area of preparation (direct). The resin-modified glass ionomer (RMGI) cement retains the benefits of the conventional formulation of glass ionomer, namely, the consistent fluoride release and chemical adhesion to tooth structure, while having a higher pH upon mixing and less solubility in fluids. There were no differences in cold, heat or biting sensitivity at any time period between the two cements. Age is inversely correlated to all sensitivity measures. Younger patients have larger pulps, and older teeth tend to have more sclerotic and/or tertiary dentin formation. These dentin types often reduce or preclude dentin fluid flow and, therefore, any stimulus is less likely to alter pain transmission. Preparation dentin surface area is directly related to all sensitivity measures. This can be explained by the hydrodynamic theory. Increasing the dentin preparation area would increase the number of dentin tubules exposed and, therefore, the total volume of dentin fluid available to be affected by the transmission of cold temperature through the crown. The practice-based research protocol used in this study provided a precise, efficient alternative to institutionally based studies in oral health.

This is quite a large study, with a sample size of 209 restorations. The authors claimed that the practice-based format provided a viable alternative to performing controlled clinical trials which are expensive and typically include too few patients to provide adequate statistical power. However, ten operators were involved and inter-

operator variability could not be controlled. Though standardized preparation/luting criteria were provided and followed (hopefully), individual preferences as to the choice of materials, methods of preparing teeth, isolation and cementation, use of adequate water spray etc, could create too many variables, considering the fact that so many factors could be involved in postcementation sensitivity. It was only mentioned that the cements were randomly assigned, and apparently no split-mouth design was used. So inter-patient variability could have come into play.

Johnson et al evaluated the contribution of zinc phosphate and glass ionomer cements in causing pulpal sensitivity or necrosis by controlling technique variables.¹⁷ Zinc phosphate has been in clinical use for more than a century and has demonstrated a long-term clinical track record of success. As a result, zinc phosphate cement is often considered the “gold standard” against which other cements are evaluated. Suggested causes of sensitivity associated with the use of GICs include: pre-existing pulpitis, traumatic tooth preparation, bacterial contamination, cement in the dentinal tubules, removal of the smear layer, acidity of the cement, high occlusion, dessicated dentin, and biological incompatibility of the cement. Ten dental officers served as clinicians. Patients were selected who had an asymptomatic, vital tooth, free from periodontal disease or dental caries and whose treatment plan called for a full-coverage cast restoration. Standard clinical and laboratory procedures were carried out. To document any immediate sensitivity, local anesthetic was generally not used during cementation. Participants were randomly assigned to zinc phosphate (Fleck’s, Mizzy) or glass ionomer (Ketac-Cem, ESPE-Premier) cement groups. Data were recorded at a pretreatment consultation, during a preparation appointment, at cementation, one to two weeks after

cementation and three months after cementation. Sensitivity to biting (biting firmly on the end of a cotton-tipped applicator), air (stream of air directed onto the tooth's facial surface for 10 seconds using an air-water syringe), and cold water (5 cc of ice water irrigated onto the tooth using a plastic syringe) were tested. The subjects then recorded the level of sensitivity using a visual analog scale ranging from zero to 10, zero being "no sensitivity". The pretreatment response served as the control. For biting and air stimuli, the levels of sensitivity were low and clinically insignificant before and after treatment. Ice water generally yields a response of 3.5 for an unrestored tooth on the visual analog scale. This level of normal sensitivity is between mild and moderate pain. The study found no association between GIC and increased pulpal sensitivity. There were significantly more reports of sensitivity at cementation and two weeks after cementation for the zinc phosphate group as compared to the GIC group. At three months, there were no sensitivity differences between the two groups, and the sensitivity did not differ from pretreatment levels.

This is another well-controlled study, though zinc phosphate is rarely used as a luting agent nowadays because of its low pH at initial set and cementation, and absence of fluoride release and adhesion to tooth structure. The sample size was adequate (101 crowns cemented with zinc phosphate, 113 with glass ionomer). Sensitivity tests to biting, air and cold water were clearly explained. Again ten clinicians were involved, and split-mouth design was not used on patients, and so inter-operator and inter-patient variability were not controlled.

Kern et al evaluated clinical tooth vitality and sensitivity, crown retention, and secondary caries after cementation of restorations with Ketac-Cem Maxicap GIC. A zinc

phosphate cement also provided in a trituration capsule system was used as the control.¹⁸ In 60 patients, 120 partial and full-coverage restorations were cemented on vital abutment teeth with either cement. During an average observation period of 17.3 months there were no differences between the two types of luting cements in regard to subjective and clinical parameters. A high incidence of postoperative hypersensitivity, often said to accompany the use of GICs, was not observed. Capsule systems make the clinical handling of GICs safe and easy, and reduce problems related to the mixing procedures. This study also found that the hypersensitivity rate for partial-coverage crowns was smaller than for full-coverage restorations. This can be explained by the more conservative approach of tooth preparation in the former restorations, which resulted in less dentin removal.

This is a similar study, however, a split-mouth design and a patient blind data acquisition protocol were used, hence a more valid comparison of the 2 cements tested. It was found that the hypersensitivity rate for partial-coverage crowns was smaller than for full-coverage restorations, probably because less dentin was cut, exposing less dentinal tubules. This leads to an interesting question: should we be more conservative in tooth preparation, leaving intact tooth structure, and go for a partial-coverage restoration; or include the remaining tooth structure in the preparation and go for a full-coverage crown which protects and seals the tooth and hopefully takes care of the sensitivity problem the patient might originally have?

1.4.3 Visual Analog Scale

The Visual Analog Scale (VAS) is utilized in the study to record the patients' subjective responses to cold stimuli applied to their teeth. It is a horizontal line, 10 cm in length, with the left end indicating no sensitivity at all, and the right end indicating severe or maximum possible sensitivity. The patient is asked to draw a vertical up-and-down line across the horizontal line, indicating level of sensitivity. The patient is also asked to indicate sensitivity verbally with a number, on a numerical scale of 0 to 10, where 0 is no sensitivity (corresponding to the left end of the VAS) and 10 is maximum possible sensitivity (corresponding to the right end of the VAS).

Mottola describes the visual analog scale (VAS) as a valid and reliable method to measure subjective phenomena such as pain and sensitivity which are often difficult to describe in concrete terms.¹⁹ The VAS is a horizontal line, 10 cm in length, with right angle 'stops' and anchor phrases at each end of the line which represent the extreme boundaries of the phenomena being measured. In the case of sensitivity, the anchor phrases can be 'no sensitivity' and 'extreme sensitivity'. The respondent is instructed to place a mark through the visual analog line at the point that corresponds to the extent to which he experiences sensitivity. The distance between the subject's mark and the left stop is measured in millimeters in scales oriented left to right. Obtained scores can range from 0 to 100 which can be subjected to various parametric techniques for statistical analysis. The validity of the VAS has been demonstrated by examining the degree of correlation between VAS scores and other tools measuring the same phenomenon, such as the McGill Pain Questionnaire in the case of pain. The reliability of the VAS has been demonstrated by a correlation of .99 between pain scores obtained on a vertical and those

obtained on a similar horizontal scale; and by a correlation of .78 between pain ratings on days 1, 3, 5 and ratings obtained on days 2, 4, 6 (test-retest reliability). Its ease of construction, use, and scoring makes the VAS a viable tool for use in clinical situations, and its validity and reliability are well supported.

This article gives us a detailed introduction to the VAS, its format, use, scoring, validity and reliability are well explained. The author obviously finds this tool very useful for measuring abstract constructs such as pain and sensitivity. It is free of the constraints imposed by words and verbal responses, which are often subject to distortion and misinterpretation. However, the VAS, simple and easy to use as it may be, may not be the best tool to measure such multidimensional phenomena as pain and sensitivity. Perhaps it can be coupled with additional measurement tools to give us a more complete picture of the phenomenon we are investigating.

Langley et al, on the other hand, are doubtful on the validity of the VAS as a pain rating scale.²⁰ A common assumption is that the VAS provides a linear measure of pain, when in fact, the interaction between the behavioural tendencies of patients and the physical characteristics of the scale makes it non-linear and prone to response bias. The McGill Pain Questionnaire measuring several dimensions of pain appears to be a better alternative. The visual analog pain severity scale (VAPSS) is discussed. The lower endpoint of this scale, 'no pain', though finite, is influenced by the patients' pain threshold and requires the difficult distinction between unpleasant sensation and pain to be made. The upper endpoint, 'worst pain ever', is infinite because patients might always feel more pain than they previously considered to be their worst. This creates a dilemma for those who mark their pain as worst ever, then feel more pain. They are forced to mark

‘worst pain ever’ again, which will be recorded as ‘no change’ when a real change has occurred. This upper endpoint produces a cramming or ‘ceiling’ effect as pain severity approaches it. Another scale, the verbal rating scale (VRS), is discussed. It consists of a set of word descriptors such as none, slight, mild, moderate, severe, extreme, and worst pain ever. Patients are required to select the word which best describes their pain severity. A comparison between the VRS and VAPSS concluded that a sigmoidal relationship existed between the two scales, suggesting that pain scores in the middle of the scales are linearly related, but not those at the upper and lower extremities.

This article discusses the various scales, VAS, VAPSS and VRS in sufficient detail, and their limitations are clearly explained and well understood. The major pitfall is their inability to measure aspects of pain other than intensity. Pain is a diverse experience influenced by many factors including personality, past memories of painful events, emotion and culture. The McGill Pain Questionnaire, which is sensitive, reliable and discriminative, is regarded as a good multidimensional pain descriptor scale.

Tammaro et al studied how 5 pain descriptors commonly used in verbal rating scales (VRS) were represented on a visual analog scale (VAS) by different subjects.²¹ The subjects were 80 dental students, 48 patients undergoing periodontal therapy, and 31 dental phobic patients, making a total of 159. Each group represented a different degree of apprehension, ranging from a relaxed (students), tense (periodontal patients) to very tense state (dental phobic patients). Five adjectives: mild, weak, moderate, strong and intense were printed below a 100 mm VAS line in a random fashion. The subjects were asked to draw a line from each adjective, to the point on the VAS that they considered best corresponded to the pain level suggested by the adjective. Results showed that ‘mild’

and 'moderate' were scored similarly among groups, while the other descriptors revealed differences. 'Weak' differed significantly between phobic and periodontal patients (12 and 19 mm respectively). 'Strong' varied between 67 mm (periodontal patients) and 75 mm (students); 'intense' was 80 mm for periodontal patients and 89 mm for students; these were both significant. When significant differences were detected, higher pain descriptor values were always assigned by the group that was assumed to be in the least apprehended state, supporting the view that stress and fear result in overestimation of the noxious stimulus. Further analyses indicated no gender difference, but the descriptors 'strong' and 'intense' correlated significantly with age.

One limitation of this study was the significant difference in age distribution between the groups. The mean ages of the periodontal patients, phobic patients and students were 59, 36 and 28 respectively. The age difference between periodontal patients and students may account for some of the variation found, and direct comparison of the two groups may be risky due to this confounding age factor. Another limitation with the use of VRS is that different individuals may ascribe different meanings to the pain descriptors which may result in false interpretations. Furthermore, VRS may not be sensitive enough to detect small pain intensity variations due to the absence of intermediate values between 2 pain descriptors. The handling of VRS data by parametric statistical tests, which assume that distances between pain descriptors are equal, may be questionable.

Gillam et al did a pilot study to establish the usefulness and comparability of selected verbal and non-verbal methods in the quantification of sensory and affective aspects of dental pain associated with dentin hypersensitivity (DH). Twenty-five subjects

(mean age 42.6 years) took part in the study. They were asked to rate their perception of dental pain following tactile (Yeaple Probe – an electronic pressure-sensitive probe) and evaporative (cold air from a dental air syringe) stimulation; together with an overall assessment of perception to daily stimuli such as cold air/water, toothbrushing, sweet and sour foods. The assessment methods used were a continuous visual analog scale (VAS), a 0-10 numerical rating VAS scale (NRS), and a separate intensity verbal descriptor (IVD) and unpleasantness verbal descriptor (UVD) word scales. Gradings were recorded over a range of 0-10. Results indicated that cold air appeared to cause greater discomfort to the patient than tactile sensitivity. For air sensitivity, IVD and NRS peaked at severity scores of 3-5 and 3-6 respectively, while VAS peaked at 2-4. UVD showed a very erratic response with an initial peak at 2-4 followed by a sharp dip at 5 and a marked peak again at 6. This would seem to suggest that the score 5 descriptor for the UVD scale (slightly distressing) was inadequate and needed to be replaced, while the score 6 descriptor (distressing) was probably a better descriptor of score 3 or 4 on the UVD scale. All methods peaked at score 2 for tactile sensitivity. NRS and IVD scales therefore appeared to provide acceptable alternatives to VAS, but the UVD scale, probably because of the imprecise nature of the words used in the scale which provided misleading information in terms of both accuracy and sensitivity, did not, except at very low levels of discomfort.

Intensity and unpleasantness word descriptors as defined by Duncan et al:²³

IVD	UVD	Numerical value
no sensation	nothing	0
barely perceptible	not bad at all	1
very mild	annoying	2
mild	unpleasant	3
moderate	disagreeable	4
barely strong	slightly distressing	5
strong	distressing	6
intense	intolerable	7
very intense	the most unpleasant imaginable	8
extremely intense		9
the most intense imaginable		10

Duncan et al compared 2 currently available methods, verbal descriptor and visual analog scales.²³ Pain evoked by a noxious stimulus is a multidimensional process that involves both a subjective evaluation of the sensory aspects of the stimulus (intensity, duration, location) as well as an affective or emotional response. There are intensity and unpleasantness dimensions of the pain experience. Subjects were 8 healthy drug-free volunteers between the ages of 21 and 26. Five second pulses of heat stimuli were presented to each of 6 spots of skin on the forearms, with 6 stimulus intensities between 42 and 51°C. Each subject rated either the intensity or the unpleasantness using either verbal descriptor scales (VDS) or visual analog scales (VAS). The VDS has 2 lists with

words describing relative levels of intensity and unpleasantness, and numerical values were assigned to the descriptors. Results showed that the subjective magnitude of both the perceived intensity and unpleasantness of the stimuli increased with the actual physical intensity of the stimuli. So both VAS and VDS can be used to differentiate levels of thermal stimuli within this range. However, using the VAS, these estimates of intensity and unpleasantness were not significantly different. In contrast, the same comparisons, using the verbal descriptors as the measurement tool, demonstrated a highly significant effect, with an even larger difference between the intensity and unpleasantness at the higher temperatures. So the verbal descriptors may provide the more sensitive tool for quantitatively separating the intensity from the unpleasantness of noxious stimuli, the descriptive words probably providing an aid to subjects for differentiating sensory-intensity and affective dimensions of pain.

This study provides a good comparison between VDS and VAS. The sample size, however, is rather small, leading to inadequate statistical power. For the unpleasantness dimension, the apparent difference in the 2 scales was not significant with the limited number of subjects. With a larger sample size, the difference would have been significant.

Lund et al did a cross-sectional study where patients with their pain classified according to its etiology (chronic/idiopathic, nociceptive and neuropathic pain) self-assessed their actual pain intensity using a continuous VAS, 0-100, and a discrete five-category VRS.²⁴ Eighty patients (mean age 42.8) participated. The chronic/idiopathic pain was described as generally persistent, distributed without neuro-anatomical distribution and present without noxious stimulus. Nociceptive pain was a response to

activation of damaged tissue where the local pain intensity increased during movement or loading of the affected tissue. Neuropathic pain was located at and /or below the level of the damaged neural structure, in this case the spinal cord injury, in an area with altered sensibility and persistent or spontaneous pain unrelated to loading. The VAS was a continuous, horizontal scale (0-100) with the anchor points, 'no pain' and 'worst possible pain' respectively. Alternatives for the VRS were – no pain (0), mild (1), moderate (2), severe (3), worst possible pain (4). An overlapping of the VAS records relative to the VRS categories was seen in all pain groups. In the test-retest a low percentage of patients agreed to the same pain level on the VAS (low intra-scale agreement) while the opposite held for the VRS. So the assessments on these 2 scales were not interchangeable. The cut-off positions for the VAS records related to the VRS categories were lower in patients with nociceptive pain compared to the other 2 groups, meaning that the rated pain intensity had different meaning depending on pain etiology. The findings were in favor of using the VRS in pain intensity assessments, and indicated a risk to over or under estimate the patient's perceived pain when interpreting condensed VAS data.

The limitation of this study could be the small number of patients and the possible presence of various pain etiologies in some individuals, so the results cannot be generalized to other situations. Though the VRS is the preferred tool, the shortcomings are that the patient is forced to translate a feeling into a predefined word that possibly does not fit exactly to the patient's experience and that the same word does not necessarily mean the same thing to each patient. On the other hand, the lack of operational definition of the VAS can possibly induce insecurity on how to relate to the continuous VAS line, contributing to the low percentage intra-scale agreement.

1.4.4 Marginal Integrity

The clinical success of cemented restorations has been evaluated by measuring marginal fit and microleakage for many years.²⁸ In the case of all-ceramic restorations, microleakage has been correlated with the loss of the integrity of the bond to tooth structure, which has been associated with other problems such as secondary caries, post-operative sensitivity, pulpal inflammation, staining and plaque accumulation due to the clinically undetectable passage of bacteria, fluids, molecules or ions between tooth structure and the cemented restoration.

Rosentritt et al⁷ studied the in-vitro marginal adaptation of all-ceramic class II inlays which were luted with two conventional multi-stage pre-treatment resin cements (Variolink II, Panavia F), one compomer (Dyract Cem Plus), one resin modified glass ionomer (Fuji Plus) and one new resin cement (RelyX Unicem) which requires no conditioning. All tests were performed after thermal cycling and mechanical loading (TCML), which simulated a 5-year wearing period. The superficial marginal adaptation was evaluated with scanning electron microscopy (SEM) and microleakage was examined by a dye penetration test. Fifty-six human molar teeth were prepared for class II (MOD) inlays with mesial dentin and distal enamel finish lines. All-ceramic inlays (Empress 1) were fabricated, randomly divided into the different cement groups and cemented. All samples were stored in distilled water for 24h/37°C, finished and polished. Impressions were taken and replicas (Epoxy die) were made to evaluate the superficial marginal integrity in the initial state, and also after TCML. Marginal quality in SEM was analyzed according to the following criteria: 'perfect margin' for a smooth transition with no interruption of continuity, and 'marginal gap' for slight imperfections with

interruptions in continuity, the forming of gaps or cracks due to loss of cohesion or adhesion. For the dye penetration tests, the teeth were stored in 0.5% fuchsin solution for 16 h (37°C), then cleaned and sectioned. The depth of dye penetration was measured. Both microleakage and SEM analysis were performed at all interfaces between cement-tooth and cement-inlay and whether the preparation lay in dentin or enamel. For the resin cements and Unicem the marginal integrity was higher than 90% before and after TCML. The marginal adaptation was between 55 – 80% for the resin modified glass-ionomer and lower than 20% for the compomer. It was generally lower when the preparation was located in dentin. The microleakage was lower than 20% for all cements, only the compomer showed values up to 100% penetration. Generally the results were higher when the preparation was located in dentin. The difference in marginal integrity between Unicem without any tooth pre-treatment and conventional resin cements after total-etching, priming and bonding was not significant. Resin GIC may be used with restrictions and compomer cement should not be used with all-ceramic class II inlay restorations. The organic matrix of RelyX Unicem comprises newly developed multifunctional phosphoric acid methacrylates. The phosphoric acid groups of these molecules condition the tooth surface and contribute to adhesion. They react with basic fillers in the cement and/or apatite of the tooth structure. This neutralization reaction generates water, which contributes to the initial hydrophilicity of the material and results in a good adaptation of the cement to the tooth structure. It can be concluded that the resin cements and Unicem show good marginal integrity and low microleakage, and Unicem may be a promising, easy applicable alternative to conventional resin cements.

Pre-treatment steps of the tooth's surface include etching with phosphoric acid, priming and/or bonding or the use of a conditioner. The resulting hybrid layer and tag formation provide the optimal adhesive cementation. However, the clinical application of the materials is time consuming and technically sensitive, giving rise to the need of cements which show comparable adaptation but avoid the complex bonding procedures. For Rely-X Unicem which requires no tooth pre-treatment, the smear layer remains on the tooth surface and hinders the creation of resin tags in the dentin tubuli. Systems with modified smear layers often show low bond strength values, but for Rely-X Unicem a bond strength similar to the conventional resin cements is reported. In this article, the reason is not given, mentioning that the mechanism is not fully understood. It is only postulated that there may be a complexation reaction between the calcium ions of the tooth surface and the phosphoric acid methacrylates in the cement. The phosphoric acid may cause a slight etching of the dentin. Water generated during neutralization may help the cement moisten the tooth surface. An additional inter-diffusion of the smear layer with resin monomer may reinforce the bond. The lack of enamel etching is not discussed.

Behr et al⁸ compared the marginal adaptation of a new self-adhesive universal resin cement (RelyX Unicem) to that of established cements and their corresponding adhesive systems. Thirty-two molars were used and prepared, with finish lines in dentin. Empress 2 all-ceramic crowns were fabricated and cemented with (1) Unicem without pre-treatment; (2) Unicem, pre-treatment with Prompt L Pop; (3) Variolink II, a resin cement with a smear-layer removing adhesive system; (4) Dyract Cem Plus, a compomer cement with a smear-layer dissolving adhesive system. After simulation of five years oral stress (TCML), the marginal adaptation was evaluated by dye penetration and SEM

analysis using the replica technique. SEM: All investigated luting agents showed comparable amounts of 'perfect margin' ranging between 88-98% (median). Dye penetration: the self-adhesive system (Unicem) had significantly lower dye penetration (18-25%, median). Without any conditioning or pre-treatment the new self-adhesive universal resin cement (RelyX Unicem) showed a marginal adaptation to dentin which was comparable to well-trying dual-curing composite cement with smear-layer removed dentin adhesive. The interface between cement and dentin had a lower percentage of 'perfect margin' than the interface between cement and restoration. An additional pre-treatment using a (HEMA)-phosphate based adhesive (Prompt L-Pop) did not improve the marginal adaptation after stress application. In Unicem, the content of inorganic fillers is about 72 wt%. The basic fillers undergo a cement reaction with the phosphoric acidic methacrylates in the organic matrix and the pH-value increases from 1 to 6 during the setting reaction. The dominant setting reaction starts with free radical polymerization, which can be initiated both by light or by a redox system. Water will be released which accelerates the neutralization reaction. However, there is no hybrid layer comparable to total etch based dentin adhesive systems.

This article is similar to the previous one, investigating Rely-X Unicem. All-ceramic crowns were used instead of inlays. Again it is only mentioned that there is no hybrid-layer comparable to total etch based dentin adhesive systems, but no explanation is given as to the mechanism of adhesion of Rely-X Unicem. Another drawback of the study is that it was only focused on a finish line in dentin, the behavior in enamel was not investigated.

Osorio et al²⁵ investigated the influence of internal surface treatment and margin location on the microleakage of 2 alumina-reinforced ceramic crown systems: In-Ceram (VITA Zahnfabrik) and Procera AllCeram (Nobel Biocare). Full crowns were produced for each of the 2 systems (n=24) in extracted human premolars, with margins located in enamel (buccal) and dentin (lingual), and luted with Single Bond and RelyX ARC (3M ESPE). Four internal ceramic treatments were tested: (1) aluminum oxide (50 μm) blasting with a microetcher for 20 seconds (AO), (2) AO plus silane (Ceramic Primer, 3M ESPE), (3) hydrofluoric acid etching with a 10% HF gel (Dentsply) applied for 4 minutes and rinsed (HF), and (4) HF plus silane. After thermal cycling, the specimens were immersed in 1% aqueous solution of methylene blue and sectioned across the center of the restoration. Digitized images were used to measure the length (mm) of dye penetration along the gingival wall. Statistical analysis ($P < .05$) showed higher leakage in dentin margins compared to enamel. In enamel, Procera showed greater leakage compared to In-Ceram. Generally, lower microleakage was observed for the AO plus silane treatment. Higher leakage was observed in margins located in dentin because the organic matrix of dentin impairs bonding.²⁶ In enamel, Procera exhibited higher leakage. In-Ceram is composed of 85% by weight alumina core infiltrated with glass.²⁷ Procera is densely sintered alumina ceramic, with 99% by weight alumina,²⁸ and the conditioning of its internal surface may be less effective, thus explaining the increased leakage. The AO treatment improved marginal sealing compared to HF. Acid etchants such as HF used for silica-based ceramics do not sufficiently roughen the surface of aluminum-oxide ceramics.²⁹ Airborne particle abrasion with a micro etcher (50 μm Al_2O_3 at 2.5 bar) revealed significantly higher bond strengths than acid etching with either 9.6% HF or

37% phosphoric acid, grinding with a diamond, or no treatment (control).²⁹ Others reported that surface treatments with silica coating and silanation produced a significant increase in bond strength between resin cement and In-Ceram or Procera. Silane application reduced dye penetration. Silane enhances adhesion of the ceramic material to silica even though the content of silica is minimal in alumina ceramic.

This study tries to take too many factors into consideration, namely, internal surface treatment with AO or HF; silane or no silane; In-Ceram or Procera system; enamel or dentin margins. This combination of factors may be complicated, and how the other variables are controlled when one variable is being investigated is not discussed.

Ibarra et al³⁰ evaluated the performance of Rely-X Unicem for the cementation of ceramic veneer restorations without previous conditioning of the tooth surface, and in combination with a one-bottle adhesive and a self-etching adhesive. Thirty-six premolars received a veneer preparation that extended into dentin. Leucite-reinforced pressed glass ceramic (Empress 1) veneers were cemented according to the following treatment groups (n=9): (1) Variolink-Excite (V+E control), (2) Unicem+Single Bond (U+SB), (3) Unicem+Adper Prompt L-Pop (U+AP), (4) Unicem without conditioning (U). After 24h storage at 37°C, teeth were thermocycled (2000 cycles) at 5 and 55°C, immersed in ammoniacal silver nitrate for 24h, and sectioned. The sections were evaluated for leakage with a microscope. Imaging software was used to measure stain penetration along the dentin and enamel surfaces. One tooth from each group was also prepared for SEM analysis. On dentin, U had significantly less leakage than U+SB and U+AP, but no different than V+E; on enamel U had leakage values that were significantly greater than the groups with adhesives. This may suggest an insufficient etching ability of U to smear

layer covered enamel, and therefore, the lack of development of adequate micromechanical retention. This may be due to the high viscosity that the cement has after mixing and the short interaction time that it has with the tooth surface before light-curing takes place. The initial low pH (<2) may not be sufficient to etch the enamel if etching time is not adequate, and if neutralization reactions take place rapidly. Another explanation could be lack of adequate pressure during the cementation procedure. The role of chemical bonding of U with enamel may be insufficient to obtain an adequate seal between the cement and enamel. In dentin, pre-etching may remove all of the buffer capacity of dentin, interfering with its ability to raise the pH of the acidic resin as it sets, thereby lowering its conversion. This explains the increased leakage observed when dentin was pre-treated with either H₃PO₄ or an acidic monomer from the self-etching system before Unicem was used. A lack of a hybrid layer is evident at the dentin interface when Unicem is used.⁸ This agrees with De Munck et al³¹ who reported no evidence of dentin demineralization even considering the initial low pH of the cement, resulting in the absence of a hybrid layer. Due to the excessive enamel microleakage observed when Unicem was used alone, the authors would not recommend its use for cementing ceramic veneers.

This is a very interesting and informative study. Veneers are so popular today and offer a good esthetic option. Rely-X Unicem enjoys widespread use in the cementation of all-ceramic restorations due to its proven properties, ease and simplicity of use. Since etching actually decreases its bond to dentin, no etching of tooth surface is recommended or required. Hence its bonding to enamel is inadequate due to the presence of the smear layer. The use of Rely-X Unicem should be restricted to all-ceramic crowns and

inlays/onlays where most enamel is gone and the main tooth substrate is dentin. For veneers which are relatively conservative restorations and rely mostly on bonding to enamel, conventional total-etch resin systems such as Nexus-2 should be used.

1.4.5 Bonding to Tooth Structure

Adhesive resin cements have the ability to bond to both tooth structure and restoration. The integration produces reinforcement of both structures, and reduces microleakage at the restoration-tooth interface, postoperative sensitivity, marginal staining and recurrent caries.³²

Hikita et al assessed the bonding effectiveness of five adhesive luting agents to enamel and dentin with different application procedures using a standard micro-tensile bond strength (uTBS) test set-up.³² Enamel/dentin surfaces of human third molars were flattened, and composite resin blocks (Paradigm, 3M ESPE) were luted using (1) Linkmax (LM; GC), (2) Nexus 2 (NX; Kerr), (3) Panavia F (PN; Kuraray), (4) RelyX Unicem (UN; 3M ESPE), or (5) Variolink II (VL; Ivoclar-Vivadent). For some luting agents, modified application procedures with etchants and self-etch adhesive systems were also tested, resulting in other experimental groups which were classified according to the adhesive approach as self-adhesive, etch-and-rinse and self-etch adhesive luting agents. The specimens were stored for 24h in distilled water at 37°C prior to uTBS testing. When bonded to enamel, Unicem (UN) (19.6MPa) scored significantly lower than the rest: VL(49.3MPa), LM(49.2MPa), NX(37.9MPa), PN(35.4MPa) which were not significantly different. All luting agents bonded equally effectively to dentin: NX(22.3MPa), PN(17.5MPa), UN(15.9MPa), LM(15.4MPa), except VL(1.1MPa). VL

revealed an exceptionally high number of pre-testing failures, most likely due to a combined effect of not having cured the adhesive separately and an insufficiently light-cured luting agent. It was concluded that following a correct application procedure, the etch-and-rinse, self-etch and self-adhesive luting agents are equally effective in bonding to enamel and dentin. Some factors negatively influenced the bonding effectiveness; these are: (1) not separately light-curing the adhesive before luting; (2) use of a light-cure adhesive converted into a dual-cure version; (3) use of a dual-cure luting agent with low auto-polymerizable potential; (4) acid-etching dentin with phosphoric acid prior to the use of RelyX Unicem; (5) bonding of RelyX Unicem to enamel without prior phosphoric acid etching.

Forty two third molars were used in the study, divided into 17 experimental groups, making the sample size for each group very small. Rely-X Unicem only superficially interacts with enamel, resulting in limited micro-mechanical retention, hence the relatively low bond strength to enamel. However, acid etching of enamel with phosphoric acid prior to application of the luting cement significantly increases the enamel bond strength. On the other hand, acid etching is detrimental for effective dentin bonding, due to inadequate infiltration of the thick and compact collagen mesh (exposed by phosphoric acid) by the viscous cement. Application of Unicem without pretreatment gives a significantly higher bond strength to dentin, but not to enamel. Selective enamel etching, if feasible, may be the way to go for self-adhesive resin cements.

De Munck et al assessed the bonding performance of RelyX Unicem to enamel and dentin, using a standard micro-tensile bond strength (µTBS) test set-up; and evaluated the interaction of this material with dentin by means of high-resolution electron

microscopy.³¹ The uTBS of RelyX Unicem with and without prior acid etching was determined to enamel and dentin after 24h of water storage and compared to the bonding effectiveness of the control cement (Panavia-F). In addition, diamond-knife cut interfaces of RelyX Unicem and Panavia-F bonded to dentin were examined using field-emission scanning (Fe-SEM) and transmission electron microscopy (TEM). The uTBS of RelyX Unicem to enamel (19.6MPa) was significantly lower than that of the control cement (35.4MPa), whereas no significant difference was found when both cements were bonded to dentin (15.9 vs 17.5MPa respectively). Acid etching prior to the application of RelyX Unicem raised the enamel uTBS (35.6MPa) to the same level as that of the control, but was detrimental for the dentin bonding effectiveness (5.9MPa). The latter must be attributed to inadequate infiltration of the collagen mesh as revealed by Fe-SEM and TEM. Morphological evaluation additionally revealed that RelyX Unicem only superficially interacted with enamel and dentin, and that application using some pressure is required to ensure close adaptation of the relatively high viscous cement to the cavity wall. The best bonding effectiveness with this cement was obtained by selectively acid-etching enamel prior to luting. In dentin, no hybrid layer nor resin tags were observed for RelyX Unicem; however, an irregular interaction zone up to 2 μm was disclosed. Below this zone, cement components appeared to have infiltrated deeper. This zone probably corresponds to the rough and irregular smear layer, which was partially demineralized and subsequently infiltrated by the resin cement. Thus the low demineralization and hybridization effect of Unicem, despite its low initial pH, was confirmed. Phosphoric acid etching of dentin removed the 'weak' smear layer, and the thick and compact collagen mesh prevented the viscous cement from reaching the deeper unaffected dentin,

thus decreasing dentin bonding effectiveness. Consequently, a weak layer of hydroxyl-apatite-depleted collagen remained in between Unicem and unaffected dentin, and this poorly infiltrated collagen mesh is the weak link prone to degradation processes and will also enhance other degradation processes as resin elution and nanoleakage.

In this study, only 18 non-carious human third molars were used, randomly divided into 6 experimental groups, making the sample size very small. Again dentin bonding of Unicem is comparable to conventional resin cement (in this case, Panavia F), but enamel bonding is inferior. Application of Unicem with some pressure due to its viscosity and selective enamel etching are recommended to improve enamel bonding, which is always the weak link with self-adhesive resin cements.

Abo-Hamar et al assessed the bonding performance of RelyX Unicem (RXU) to dentin and enamel compared to four currently used luting systems, using a shear bond strength test with and without thermocycling.³³ Median bond strengths were determined after 24h storage in distilled water at 37°C, or after thermocycling (6,000 cycles, 5-55°C). The luting systems used were: (1) Syntac/Variolink II (SynC/V) as a standard for luting conventional ceramics, (2) ED-Primer II/Panavia F2.0 (EDII/PF2), (3) the compomer system Prime&Bond NT/Dyract Cem Plus (PBNT/DyCP), and (4) glass ionomer cement, Ketac Cem (KetC), as a standard for luting high-strength ceramic and metal-based restorations. The bond strength (MPa) of RXU to dentin (10.8) was not statistically different from those of SynC/V (15.1), EDII/PF2 (10.5) or PBNT/DyCP(10.1), and statistically higher than KetC (4.1). The bond strength of SynC/V was statistically higher than that of EDII/PF2. After thermocycling, RXU (14.9) showed significantly higher bond strength data than EDII/PF2 (7.4) and KetC (4.6), but significantly lower than

SynC/V (19.8). The bond strength of RXU to enamel (14.5) was significantly lower than those of SynC/V (32.8), EDII/PF2 (23.6), and PBNT/DyCP (17.8), but higher than KetC (6.1). After thermocycling, the bond strength of RXU to enamel (6.6) significantly decreased and was statistically lower than SynC/V (27), EDII/PF2 (21.2) and PBNT/DyCP (17), but was still significantly higher than KetC (1.9). For each luting system (without thermocycling), the bond strength to enamel was statistically higher than that to dentin except for RXU, where there was no significant difference. After thermocycling, the bond strengths to enamel were statistically higher than those to dentin except for RXU and KetC, where bond strengths to enamel were significantly lower than those to dentin. In general, the type of tooth substrate significantly affected the bond strength to tooth structure. Regarding thermocycling, it had no significant effect on the bond strength of any of the luting systems to dentin except SynC/V, whose bond strength to dentin was significantly increased after thermocycling. It significantly decreased the bond strength of only RXU and KetC to enamel. In general, thermocycling did not significantly affect the bond strength to dentin, whereas it significantly affected the bond strength to enamel. The use of RelyX Unicem may be considered an alternative to the currently used systems for luting conventional ceramics, high-strength ceramics and metal-based restorations, when no or little enamel is left. It may not be the ideal material for luting inlays and partial crowns, where a considerable enamel surface area is present. However, it seems to be the only material which provides similar bond strength values to dentin and enamel and, to both types of ceramics (IPS Empress 2: 16.8 MPa; Procera AllCeram: 5.9 MPa).³⁴ This may cause a more uniform stress distribution in the clinical

situation than that caused by large differences in bond strengths between the different substrates.

In this study, 200 non-cariou human third molars were used. For each substrate, the specimens (n=100) were divided into 10 groups of 10 specimens each (with and without thermocycling for each of the 5 luting systems). The sample size was reasonable. Thermocycling, which simulates oral stress conditions, does not affect bond strength to dentin, but affects bond strength to enamel. So Unicem is indicated for luting all-ceramic crowns, but may not be suitable for inlays/onlays or partial crowns where significant enamel is still present. However, the similarity of bond strengths with enamel and dentin may cause a more uniform stress distribution in clinical situations, which may be advantageous.

Yang et al evaluated the micro-tensile bonding strength (uTBS) of three luting resins to human regional dentin.³⁵ Dentin disks from non-cariou third molars were prepared from different regions (s, superficial dentin; d, deep dentin; c, cervical dentin), and divided into groups based on anatomical locations and luting resins (Super-Bond C&B: SB; Panavia F 2.0: PF; RelyX Unicem: RU): SB-s, SB-d, SB-c; PF-s, PF-d, PF-c; RU-s, RU-d, RU-c. Luting resins were used to bond 1 mm diameter composite rods to the dentin specimens under a load of 7.5 N, in the self-curing mode. After storage for 1 or 3 days, uTBS was tested. The bonding interface and fractography analyses were performed with SEM and TEM. uTBS to superficial dentin was significantly higher than to deep or cervical dentin for all three luting resins. SB-s and PF-s, with the highest uTBS, failed primarily cohesively in luting resin. uTBS of SB-d and SB-c were significantly higher than those of PF and RU. For RU, with the lowest regional uTBS, most failures were

found to be adhesive along the dentin surface or partially adhesive failures with a thin layer of cohesively fractured luting resin. SEM and TEM showed that adhesive failures in SB and PF occurred at the top of the hybrid layer (HL), but no obvious HL was observed in RU. It is now recognized that the smear layer should be removed or modified and the underlying dentin demineralized to expose the three-dimensional collagen network that can be infiltrated by adhesive resin monomers to form a hybrid layer (HL) between luting resins and dentin. In superficial dentin there is more intertubular dentin area rich in collagen fibrils than in deep and cervical dentin. Therefore, the uTBS was significantly higher due to the opportunity for more micromechanical adhesion to collagen fibrils in the HL. RelyX Unicem is a heavily filled (72 wt% reactive glass fillers) and highly viscous luting resin. The smear layer and underlying dentin have been regarded as solid buffers that probably rapidly buffer the acidity of viscous solutions, thereby limiting the etching ability of acidic monomers. The inability of RU to penetrate demineralized dentin is supported by SEM observation of insufficient infiltration of resin into the collagen network. The uTBS to regional dentin sites was relatively low due to the very thin to nonexistent HL. Another reason for the low uTBS in RU groups is that RU was used in self-curing mode, and the polymerization was not complete.

There were 12 specimens in each of the 9 test groups, making a reasonably adequate sample size. For Unicem, the failure mode was mostly adhesive, indicating the relatively low bond strengths to regional dentin sites due to the thin to nonexistent hybrid layer. However, it should be noted that the self-cure version of Unicem was used in the study, and the low bond strength observed could be due to incomplete polymerization. In most clinical situations, the dual-cure product is the more commonly used version.

1.4.6 Bonding to Ceramic

Pisani-Proenca et al evaluated the microtensile bond strength (uTBS) of 3 resin cements to a lithia disilicate-based ceramic (IPS Empress 2) submitted to 2 surface conditioning treatments.³⁶ Eighteen ceramic blocks were fabricated and duplicated in composite resin (Tetric Ceram). They were then divided into 2 groups (n=9): no conditioning (control); 5% hydrofluoric acid etching for 20 seconds and silanization for 1 minute (HF + SIL); cemented to the composite resin blocks with RelyX Unicem, Multilink or Panavia F. They were stored in humidity at 37°C for 7 days, sectioned, thermal cycled and tested in tension. Fractured specimens were examined with a stereomicroscope and classified as adhesive, mixed or cohesive. The surface conditioning factor was significant (HF + SIL > no-conditioning). In the unconditioned groups, the uTBS of RelyX Unicem was significantly higher (9.6 MPa) than that of Multilink (6.2) and Panavia F (7.4). Previous etching and silanization yielded statistically higher uTBS values for RelyX Unicem (18.8) and Multilink (17.4) when compared to Panavia F (15.7). They concluded that etching and silanization treatments appear to be crucial for resin bonding to a lithia disilicate-based ceramic, regardless of the resin cement used. For the self-adhesive cement RelyX Unicem, the manufacturer's claim to eliminate the need for pretreatment of the ceramic surfaces seems doubtful. IPS Empress 2 is a pressable multiphase glass ceramic composed of 70 vol% leucite, which confers improved mechanical properties. The HF attacks the glassy phase of the glass ceramic, dissolving the surface to the depth of a few microns, and the lithium disilicate crystals protrude from the glassy matrix,³⁷ providing micromechanical retention. The silane coupling agents present bifunctional characteristics, promoting a chemical interaction between the silica

in the glass phase of ceramics and the methacrylate groups of the resin through siloxane bonds. Etching and silanization increase the surface energy and the wettability of the ceramic substrate, which decreases the contact angle between the ceramic surface and the resin cement.³⁷

In this study, the treatment group (n=9) was divided into 3 subgroups (n=3), each using a different cement. The sample size was rather small. For Unicem, treating the ceramic surface with HF and silane almost doubled the bond strength. So the instruction of no surface treatment needed for tooth and ceramic for this self-etch, self-adhesive resin cement may be refuted. The restoration (IPS Empress or Empress 2) that comes in from the laboratory is usually etched, but not silanated. After try-in and initial check of proximal contacts and color match, etc, it should be re-etched and then silanated before final cementation.

Kim et al evaluated the tensile bond strength of composite resin to 3 different all-ceramic coping materials with various surface treatments.³⁸ Thirty specimens each of lithium-disilicate ceramic (IPS Empress 2[E]), alumina ceramic (In-Ceram Alumina[I]), and zirconia ceramic (Zi-Ceram[Z]) were fabricated. Feldspathic ceramic (Duceram Plus[F]) was used as the control. Each material was divided into 3 groups (n=10), and 3 different surface treatments were performed: (1) airborne-particle abrasion with 50um alumina particles (Ab); (2) airborne-particle abrasion with 50um alumina particles and acid etching with 4% hydrofluoric acid (Ae); (3) or airborne-particle abrasion with 30um alumina particles modified with silica acid – silica coating (Si). Composite resin cylinders were then light polymerized onto the ceramic specimens. Each was subjected to a tensile load until fracture. It was concluded that alumina and zirconia ceramic

specimens treated with the silica coating technique (Si) and the lithium disilicate ceramic specimens treated with airborne-particle abrasion and acid-etching technique (Ae) yielded the statistically highest tensile bond strength values to the composite resin evaluated. Alumina and zirconia ceramic are not sufficiently roughened by airborne-particle abrasion or etched with hydrofluoric acid, and do not sufficiently react with a silane coupling agent due to their low silica content:³⁹ alumina (below 5 wt%) and zirconia (below 1 wt%), as compared to conventional feldspathic ceramic (50 to 60 wt%). In silica coating, alumina particles modified with silica acid are sprayed and high heat is produced, which, together with pressure, cause the silica acid-modified alumina particles to be embedded within the ceramic surface. The high tensile bond strengths that result can be explained by the increased surface roughness and increased silica content resulting from the silica coating. For lithium disilicate ceramic, airborne-particle abrasion roughens the surface, and acid etching dissolves the weaker glassy phase and exposes lithium disilicate crystals, both of which serve as retentive features.

In this study, 30 specimens of each ceramic material were divided into 3 groups (n=10), each receiving a different treatment. The sample size seems adequate. The study demonstrated that the intraoral repair of all-ceramic restorations with exposed copings due to fractured veneering ceramics could be clinically performed with appropriate surface treatments to achieve adequate bond strengths to composite resin. This could also be related to the cementation of all-ceramic restorations with composite resin cements.

Suliman et al evaluated porcelain repair by use of various surface treatments and bonding resins.⁴⁰ Vita VMK 68 542 body porcelain powder and liquid were mixed, prepared and fired in a computerized oven to make the samples. The surface treatments

were (1) air abrasion (sandblasting with 50 um aluminum oxide particles for 15s), (2) roughening with a diamond, (3) etching with 9.6% hydrofluoric acid (HF) and, (4) combination of (2) and (3). A silane coupling agent was applied to all porcelain surfaces, and a hybrid composite resin (Prisma AP.H) was bonded to porcelain with All-Bond 2, Amalgambond, or Clearfil Porcelain bonding agents. Shear bond strengths were determined. The most effective surface treatment was (4), the combination of diamond roughening and HF etching. The Clearfil Porcelain Bond system showed a greater repair strength than the other two materials. Coarse diamond improves repair strengths by roughening the porcelain surfaces, HF etching facilitates micromechanical retention of composite resin. Silane coupling agents improve the bond of composite resin to porcelain by approximately 25%. Hybrid composite resins generally provide higher bond strengths than microfilled composites.

Sixty specimens assigned to one of four groups (n=15) for surface treatments seemed adequate. Surfaces that were etched with HF, with or without prior mechanical roughening, recorded greater bond strengths with repairing composite, as is true with feldspathic porcelain cemented with resin cement.

Clelland et al evaluated the effect of interfacial bonding quality on the interface failure initiation loads of 2 all-ceramic systems.⁴¹ One leucite-reinforced ceramic, IPS Empress (E1), and 1 lithia disilicate glass-ceramic, IPS Empress 2 (E2), were used to form disks (n=45). The specimens were divided into 3 subgroups (n=15) that were cemented with Nexus 2 (Kerr) using 1 of 3 bonding conditions: (1) Control group followed ideal bonding protocol, (2) group Cer had bond that was compromised between the cement and the ceramic by incorporating a thin film of silicone grease on the ceramic

surface, (3) group Sub had bond compromised between the substrate and the cement by placing a thin film of the silicone grease on the dentin-like substrate surface. All luted specimens were loaded at the center with a 10 mm-diameter ball indenter in a universal testing machine. Intermittent loads were applied in increasing increments of 50N until fracture. The maximum load applied prior to crack observation was recorded as the failure initiation load. Group E2 had the greatest mean observed load to failure (715.6N), which was significantly greater than group E1 (477N). The average masticatory force has been reported as 246N.⁴² Therefore, both materials should survive the normal masticatory loads of an average person under ideal bonding conditions. For both systems, the control groups had significantly greater mean fracture initiation loads than either of the interface-inhibited Cer and Sub groups. For E2, disruption of the ceramic-cement interface had a more detrimental effect on the load-bearing capacity of the simulated restoration than the disruption of the cement-dentin interface. This suggests that a thin layer of resin bonded to the ceramic surface may act to reinforce the ceramic material. However, the amount of overall reinforcement from the cement is small compared to the total strength of the completely bonded system. Catastrophic fracture has been the most frequently reported reason for failure of all-ceramic inlay or onlay restorations.^{43,44} It was reported that wear of the resin cement resulted in a loss of support for the ceramics, introducing microfractures that developed into bulk fractures.⁴⁵ Poor initial bond quality or degradation of the bond quality over time may contribute to the potential for restoration failure in service.

This article points out the fact that bond quality plays an important part in the longevity of all-ceramic restorations, especially inlays and onlays, which may fracture

under occlusal load. Self-adhesive cements such as Rely-X Unicem may have to be used with caution since the bond to enamel is not as good as conventional total-etch cement systems.

Atsu et al compared the effects of different surface treatment methods on the bond strength of zirconium-oxide ceramic to a resin luting agent.⁴⁶ Sixty zirconium-oxide ceramic (Cercon) specimens and composite resin (Z-250) cylinders were prepared. The ceramic surfaces were airborne-particle abraded with 125um aluminum oxide particles and then divided into 6 groups (n=10) treated as follows: (1) Group C, no treatment (control); (2) Group SIL, silanized with a silane coupling agent (Clearfil Porcelain Bond Activator); (3) Group BSIL, application of the adhesive MDP-containing bonding/silane coupling agent mixture (Clearfil Liner Bond 2V/Porcelain Bond Activator); (4) Group SC, silica coating using 30um Al₂O₃ particles modified by silica (CoJet System); (5) Group SCSIL, silica coating and silanization (CoJet System); and (6) Group SCBSIL, silica coating and application of an MDP-containing bonding/silane coupling agent mixture. The composite resin cylinders were bonded to the treated ceramic surfaces with Panavia F. Their shear bond strength was tested. Debonded specimen surfaces were examined with a stereomicroscope to assess the mode of failure. The bond strengths (MPa) were as follows: Group C, 15.7; Group SIL, 16.5; Group BSIL, 18.8; Group SC, 21.6; Group SCSIL, 21.9; Group SCBSIL, 22.9 which was significantly higher than Groups C, SIL and BSIL. Failure modes were primarily adhesive at the zirconium/cement interface in Groups C and SIL, and primarily mixed and cohesive in Groups SC, SCSIL, and SCBSIL. The results recommend the use of tribochemical silica coating (CoJet System) and an MDP-containing bonding/silane coupling agent mixture to increase the

adhesive resin bond strength between an airborne-particle-abraded surface of the zirconium-oxide ceramic and a phosphate monomer-containing resin luting agent (Panavia F).

This article serves as a guideline for the surface treatment and cementation of reinforced ceramic restorations, such as zirconium-oxide ceramics (Cercon). Cercon crowns are ideal, strong, durable esthetic alternatives to all-metal and PFM crowns for posterior teeth. It was suggested that the use of phosphate-modified resin cement Panavia 21 after airborne particle abrasion (110 μm Al_2O_3 at 2.5 bar) provided a long-term durable resin bond to zirconium oxide ceramic.⁴⁷

Valandro et al evaluated the effect of 2 surface conditioning methods on the microtensile bond strength of a resin cement (Panavia F) to 3 high-strength core ceramics: high alumina-based (In-Ceram Alumina [AL], Procera AllCeram [PR]) and zirconia-reinforced alumina-based (In-Ceram Zirconia [ZR]) ceramics.⁴⁸ Ten blocks of each were fabricated and duplicated in composite. The specimens were assigned to the following treatment conditions: (1) Grit blasting (GB): airborne particle abrasion with 110 μm Al_2O_3 particles + silanization; (2) Silica coating (SC) with 30 μm SiO_x particles (CoJet, 3M ESPE) + silanization. The composite blocks were bonded to the surface-conditioned ceramic blocks with Panavia F. They were then stored at 37°C in distilled water for 7 days prior to bond strength tests. The bond strengths (MPa) were as follows: AL-GB(17.3), ZR-GB(15.1), PR-GB(12.7), AL-SC(31.2), ZR-SC(26.8), PR-SC(18.5). Silica coating and silanization provided higher bond strengths of the resin cement than with airborne particle abrasion and silanization for the three ceramics; and Procera (PR) exhibited lower bond strengths after both Al_2O_3 and silica coating compared to AL and

ZR. In silica coating, the blasting pressure results in the embedding of silica particles in the ceramic surface, rendering the silica-modified surface chemically more reactive to the resin through silane coupling agents. Silane molecules, after being hydrolyzed to silanol, can form a polysiloxane network or hydroxyl groups covering the silica surface. Monomeric ends of the silane molecules then react with the methacrylate groups of the adhesive resins by the free-radical polymerization process. Air-particle abrasion removes loose contaminated layers, and the roughened surface provides some degree of mechanical interlocking or “keying” with the adhesive. The increased roughness also forms a larger surface area for the bond. However, this produced lower mean bond strength values than with silica coating and could be associated with the phenomenon of less wettability and contact angle between the silane coupling agent and the deep grooves on the ceramic surfaces caused by grit blasting. Tribochemical coating on glass-infiltrated alumina (AL) (alumina content 80%) is more effective than on dense alumina ceramic (PR) (99.9% alumina content). It is likely that particle deposition and thereby embedding of silica is easier on the glass with lower hardness (AL), while alumina crystals of PR present higher hardness, impairing the silica particle penetration.

This is another good study, with adequate sample size. The ceramic-composite blocks were eventually cut to produce bar specimens (n=30) where bond strength tests were performed. It also reinforces previous studies that silica coating with silanization produces higher bond strength than airborne particle abrasion with 110-micron alumina, and that Procera exhibits lower bond strengths than In-Ceram Alumina and Zirconia because of its densely sintered high-alumina content with no glass infiltration.

Derand et al evaluated the bond strength of dental resin agent to zirconia ceramic after surface pre-treatment with different techniques.⁴⁹ Specimens of hot isostatic pressed (HIP) yttrium-oxide-partially-stabilized zirconia blocks (ZF) were fabricated (Procera Zircon) and compared to glossy dense zirconia blocks (ZG). They were divided into the following treatment groups: (1) ZF (n=5) and ZG (n=5) without any pre-treatment, (2) ZF-s (n=5) and ZG-s (n=5) treated with silane solution, (3) ZF-P (n=10) and ZG-P (n=10) treated with RF plasma spraying using a reactor, (4) ZF-p (n=10) and ZG-p (n=10) treated with micro pearls of low fusing porcelain (720°C) on the surfaces. Composite cylinders were luted with Variolink II to the test specimens, which were then stored in air for 1h before shear loading in a universal testing machine until failure. The specimens with a glazed surface (ZG) generally showed lower bond strength values. Plasma spraying treatment improved bond strength by a factor of three. Treatment with low fusing porcelain micro pearls increased the bond strength by a factor of 10 compared to untreated surfaces. No significant difference was seen between the surfaces treated ZF-p and ZG-p specimens. The thickness of the glass pearls layer did not exceed 5 um. SEM showed dense grain borders of ZF and a flat glossy texture of ZG. Plasma is a partially ionized gas containing ions, electrons, atoms, and neutral species. A high frequency generator is used to ionize the gas into plasma under vacuum conditions. The plasma-spray technique may give a good bond even if the bonding energy is still hard to explain. A possible explanation is that the surface texture of the ZF specimens improves the bond strength due to micro retentions. Fusing glass pearls to the zirconia surface increases microretention, and these pearls can be successfully silanized prior to cementation, obtaining even higher bond strength values.

In this study, the sample sizes were not uniform across the treatment groups, with $n=5$ for the specimens with no treatment and silane treatment, but $n=10$ for specimens that received plasma and micropearl treatments. For zirconia-based ceramics, hydrofluoric acid etching and silane treatment are not effective. Apart from the treatments in the study, plasma spray and fusing glass pearls, air-borne particle abrasion is an alternative.

Amaral et al evaluated the effect of 3 surface conditioning methods on the microtensile bond strength of resin cement to a glass-infiltrated zirconia-reinforced alumina-based core ceramic.⁵⁰ Thirty blocks of In-Ceram Zirconia ceramics were fabricated and duplicated in resin composite. The specimens were assigned to 1 of the 3 treatment conditions ($n=10$): (1) Airborne particle abrasion with 110 μm Al_2O_3 particles + silanization, (2) Silica coating with 110 μm SiO_x particles (Rocatec Pre and Plus) + silanization, (3) Silica coating with 30 μm SiO_x particles (CoJet) + silanization. The ceramic-composite blocks were cemented with Panavia F and stored at 37°C in distilled water for 7 days prior to bond tests. Silica coating with silanization either using 110 μm or 30 μm SiO_x particles increased the bond strength of the resin cement (24.6 and 26.7 MPa respectively) to the zirconia-based ceramic significantly compared to that of airborne particle abrasion with 110 μm Al_2O_3 (20.5 MPa). The silica layer left by silica coating on the ceramic surface provides a basis for silane to react; and the presence of the glassy phase in ceramics favors better siloxane bonds. The reason for lower results obtained after 110 μm grain sized Al_2O_3 particle deposition could be due to the weak bond between Al-Si-O as reported.⁵¹ However, the bond values obtained for the ceramic tested in this study could be considered sufficient with both conditioning methods.

This is a very practical study, in that the surface treatment methods for zirconia-reinforced ceramic based on airborne particle abrasion could be performed chairside with micro-etcher and different types of sand particles. This significantly increased the bond strength to resin cement. The abrasive process removes loose contaminated layers and the roughened surface provides some degree of mechanical interlocking with the adhesive. There may also be physico-chemical changes that affect surface energy and wettability. In this study, the use of 30 um particles seemed to produce a higher bond strength than 110 um particles, which was not explained. The finer particles may produce more roughening and provide a larger surface area for the bond.

Luthy et al evaluated the shear bond strength of different cements to densely sintered zirconia ceramic after aging by thermocycling.⁹ The following luting cements for bonding ZrO₂.TZP (tetragonal zirconia polycrystals) were used: (1) Ketac-Cem (KC), a glass ionomer cement, (2) Nexus (N), a conventional BisGMA resin composite, (3) Superbond C&B (Super), a 4-META adhesive resin, and three adhesive resin composites containing phosphoric acid monomers, (4) Panavia 21 (P21), (5) Panavia F (Pan F) and (6) RelyX Unicem (Unicem). Shear test specimens were prepared by bonding small cylindrical stainless steel rods tribochemically silica-coated with the Rocatec system to sandblasted ceramic disks made of TZP. Prior to testing, all bonded specimens were stored in distilled water at 37°C for 2 days, and half of them were additionally subjected to thermocycling TC (10,000X) in water (5/55°C). Finally the specimens were subjected to shear bond strength testing. Overall, P21 possessed the significantly highest mean bond strength, while KC and N had the weakest bond, regardless of thermal aging treatment or not. The ranking behind P21 was Pan F, Super, Unicem, with or without TC.

While the influence of TC significantly affected (decreased) the bond strength of KC, N and Super, the strength of P21 was increased in a significant way. Pan F and Unicem did not change significantly. Long-term water storage and thermal cycling are the conditions most often used to test the durability of resin bonds, and are clinically relevant aging parameters. The highest bond to sandblasted zirconia was obtained with Panavia 21. The phosphate ester group of the MDP in this cement is reported to directly bond to metal oxides of zirconia.⁴⁷ The bond strength even increased significantly after TC with a completely cohesive failure mode. Two hundred and ten shear test specimens were used, giving an adequate sample size.

Blatz et al evaluated and compared the bond strengths of different bonding/silane coupling agents and resin luting agents to zirconia ceramic before and after artificial aging.⁵² Composite cylinders were bonded to airborne-particle-abraded intaglio surfaces of Procera AllZirkon specimens (n=80) with either Panavia F (PAN) or Rely X ARC (REL) resin luting agents after pretreatment with Clearfil SE Bond/Porcelain Bond Activator (Group SE). In another group, Rely X ARC was used with Single Bond/Ceramic Primer (Group SB). PAN without any bonding/silane agent (Group NO) was the control. Subgroups of 10 specimens were stored in distilled water for either 3 or 180 days before shear bond strength was tested; 180-day-old specimens being repeatedly thermal cycled for 12,000 cycles between 5 and 60°C. Failure modes were examined. The shear bond strengths (MPa) were as follows: after 3 days, SE-REL (25.15), SE-PAN (20.14), NO-PAN (17.36), SB-REL (16.9); after 180-day storage and thermal cycling, SE-PAN (16.85), SE-REL (15.45), NO-PAN (9.45), SB-REL (1.08). SE-REL and SE-PAN groups had significantly superior mean shear bond strengths compared with NO-

PAN and SB-REL, both at 3 days and after 180-day storage. Artificial aging significantly reduced bond strengths. The modes of failure varied among 3-day groups but were 100% adhesive at the ceramic surfaces after artificial aging. The results of this in vitro study recommend a bonding/silane-coupling agent containing an adhesive phosphate monomer to enhance long-term resin bonds to airborne-particle-abraded surfaces of Procera AllZirkon restorations. The clinical use of zirconium oxide (ZrO_2) as a core material provides favorable optical properties and a high flexural strength of over 1000 MPa. A unique property is the so-called “transformation toughening”, where a partially stabilized zirconium oxide can actively resist crack propagation through a transformation from a tetragonal to a monoclinic phase at the tip of a crack, accompanied by a volume increase. Airborne-particle abrasion with Al_2O_3 is the preferred surface treatment method for high-strength ceramic materials. Surface roughening methods increase surface energy and, therefore, wettability.¹ Resin luting agents have the ability to “heal” minor surface flaws created by airborne-particle abrasion and, therefore, significantly strengthen ceramic materials.⁶

The sample size was adequate in this study. Extensive water storage and thermal cycling are important parameters to simulate intraoral conditions. It was concluded that thermal cycling had a much higher impact on the durability of the resin bond strength to zirconia than did water storage at a constant temperature alone. This in-vitro investigation favors the use of MDP-containing bonding/silane agent, however, care should be taken before clinically relevant conclusions are drawn.

Palacios et al determined the ability of selected luting agents to retain a representative zirconium oxide ceramic crown under clinically simulated conditions.⁵³

Human molars were prepared with a flat occlusal surface, 20-degree taper, and 4-mm axial length. Specimens were distributed into 3 groups (n=12). Zirconium oxide ceramic copings (Procera AllZirkon) were fabricated using CAD/CAM technology and airborne-particle abraded with 50-um Al₂O₃. They were then cemented using (1) a resin cement with adhesive (Panavia F 2.0 and ED Primer A&B [PAN]); (2) a resin-modified glass ionomer cement (Rely X Luting [RXL]) or (3) a self-adhesive modified resin (Rely X Unicem [RXU]). The cemented copings were thermal cycled at 5 and 55°C for 5000 cycles, and then removed along the path of insertion using a universal testing machine. The removal force and nature of failure were recorded. Mean dislodgement stresses (MPa) were RXL (6.1), PAN (5.1), RXU (5.0), revealing no significant differences in mean crown removal stress among the 3 cementation groups. The predominant mode of failure was cement remaining principally on the zirconium oxide copings in 46% of the specimens, followed by cement found on the tooth in 25.7% of the specimens. The use of a composite resin cement with a bonding agent (PAN) did not yield higher coping retention compared to the other 2 cements tested. All 3 commonly used luting agents are capable of retaining zirconium oxide crowns successfully with no additional internal surface treatment other than airborne-particle abrasion with 50 um aluminum oxide followed by appropriate cleaning of the crown prior to cementation.

In this study, the sample size seemed adequate (n=12). Kern and Wegner⁴⁷ concluded that only the phosphate-modified composite resin cement (Panavia F 2.0 and Panavia 21) provided a long-term durable bond and resulted in the highest bond strength values after airborne-particle abrasion for zirconia ceramics. This study finds the self-adhesive resin cement, Rely-X Unicem, comparable to Panavia F 2.0, and therefore

serves as a good alternative for the cementation of zirconia restorations. It is surprising to note that the resin-modified glass ionomer (RMGI) cement, Rely X Luting, has dislodgement stress value comparable to or even exceeds those for Panavia and Unicem.

1.4.7 Clinical Evaluation of All-Ceramic Restorations

Fradeani et al determined the reliability of the IPS Empress ceramic material for fabricating inlays and onlays in the posterior region of the mouth.⁵⁴ A total of 125 IPS Empress pressed glass ceramic inlays and onlays were placed for 29 patients in a private practice. The restorations were observed for a period of 7 to 56 months, with a mean of 40.3 months. About 60% of the restorations were placed in molars, and 40% in premolars. Patients who exhibited bruxism, severe malocclusion, periodontitis, serious gingival inflammation, poor oral hygiene, or high caries rates were ineligible for the study. Standard clinical and laboratory procedures were carried out. At cementation, the inner surfaces of the restorations were etched with 4.5% hydrofluoric acid (Porcelain Etch) for 2 minutes, cleansed, dried, and then treated with a silane solution (Monobond S). Enamel margins of the tooth preparations were etched with 35% phosphoric acid gel for 30 seconds, rinsed with water, sprayed, and air dried. The dentinal surface was treated with dentinal bonding agents (Syntac Primer and Adhesive). The cavity preparations and inner surface of the restorations were covered with a layer of bonding agent (Heliobond) which was air thinned but not light cured. A total of 91 tested restorations were cemented with Dual cement, whereas 34 were cemented with Variolink cement. The restorations were evaluated clinically at insertion and subsequent review appointments with a mirror, a sharp probe, and intraoral photographs according to a modified US Public Health

Service criteria suggested by Ryge and Cvar. The criteria included marginal integrity, contour, marginal discoloration, recurrent dental caries, and color match. Four ceramic inlays failed because of fracture. The estimated Kaplan-Meier survival rate at almost 5 years was 95.6%. Marginal discoloration recorded the lowest percentage of alpha ratings (65.3%), probably related to properties of the luting agent and to residual cement excesses. Contour, marginal integrity, color match, and recurrent dental caries criteria were satisfactory in most observations. Marginal discoloration and integrity appeared to deteriorate with time, but marginal discoloration preceded degeneration of the margins. Alpha marginal discoloration always implied Alpha marginal integrity, but the reverse was not true. Variolink cement performed slightly but not substantially better than Dual resinous cement. It is also apparent that ceramic inlays without an adequate cavity depth and wide isthmus are at higher risk of fracture.

This is a good clinical study with adequate sample size. Some patients were followed up for almost 5 years. The exclusion criteria were clearly stated, as well as the restoration distribution on premolars and molars. Parameters used and their rating criteria were outlined in detail. It is interesting to note that marginal integrity and marginal discoloration were judged sufficient but not excellent. They are related and both will deteriorate with time. If there is good marginal integrity, any marginal discoloration can be due to incomplete cement removal and incomplete refinement of the inlay margins.

Kramer et al studied the performance of IPS Empress inlays and onlays with cuspal replacements and margins below the cemento-enamel junction (located in dentin).⁵⁵ Ninety six IPS Empress fillings were placed in 34 patients by 6 clinicians. They were luted with 4 different composite systems: Dual Cement, Variolink Low, Variolink

Ultra, and Tetric. The dentin bonding system Syntac Classic was used in addition to the acid-etch technique. At baseline and after 6 months, 1, 2 and 4 years after placement the restorations were assessed by two calibrated investigators using modified USPHS codes and criteria. A sample of the restorations was investigated by SEM to evaluate wear. Seven of the 96 restorations had to be replaced (failure rate 7%; Kaplan-Meier). Four inlays had suffered cohesive bulk fractures and 3 teeth required endodontic treatment. After 4 years in clinical service, significant deterioration was found in the marginal adaptation of the remaining restorations, with 79% exhibiting marginal deficiencies, independent of the luting composite. Neither the absence of enamel margins, nor cuspal replacement significantly affected the adhesion or marginal quality of the restorations. Hypersensitivity was observed in 13% of the cases at baseline, but reduced rapidly thereafter. SEM evaluation showed marginal ditching independent of the luting composite used.

This is another 4-year clinical study with a sample size of 96. The restorations were done by 6 operators, and inter-operator variability could have played a part and affected the reliability of the study. Marginal ditching seems to be the predominant problem, and may be due to propagation of microcracks produced by occlusal adjustments with rotary instruments which are not well polished. Adequate preparation depth and therefore material thickness, and cuspal coverage seem to be important factors, but they did not seem to correlate with ceramic fractures in this study.

Kramer and Frankenberger, in the same study, continued to follow up on the same group of patients and assessed the restorations at 6 and 8 years.⁴⁴ The recall rate until the 4 years investigation was 100% and dropped to 60% due to the voluntary character of the

eight-year recall (n=57 restorations). All patients were satisfied with their restorations. Thirty-nine restorations could not be examined after 8 years due to failure (n=8) or missed recall investigation (n=31, drop out). The remaining 57 investigated restorations revealed no statistically significant differences regarding proximal contact, sensitivity, radiographic check and subjective satisfaction. Statistically significant differences over time were observed for the following criteria: Surface roughness (loss of gloss), color match (improving with time), anatomic form (inlays were less worn under stress than adjacent enamel), anatomic shape at margins (step formations became rounded over time), marginal integrity (distinct deterioration with marginal fractures especially at 8 years), tooth integrity (more cracks and abfractions in enamel, but all within Bravo scores), inlay integrity (continuous deterioration over time, mainly chipping of the ceramic), and hypersensitivity (no complaints after 8 years). Eight of the 96 restorations had to be replaced (failure rate 8%; Kaplan-Meier): Six inlays suffered cohesive bulk fractures, two teeth required endodontic treatment. After 8 years of clinical service, significant deterioration was found for marginal adaptation of the remaining restorations. Ninety-eight per cent of the surviving restorations exhibited marginal deficiencies, independent of the luting composite. Neither cusp reconstruction nor preparation margins below the CEJ were limiting factors for good clinical success. Secondary caries did not occur at all. The predominant failure scenario with ceramic inlays is still the integrity of the inlay itself. 'Half-moon' fractures in the restorations were detected as early as 2 years, and were observed exclusively in occlusally loaded marginal ridges. In each case of catastrophic failure, occlusal adjustments were performed which may not have been polished sufficiently. These microcracks may lead to later catastrophic fractures.

Therefore, the clinician should pay attention to a careful polish of inlay areas having been previously subjected to rotary occlusal corrections to prevent this problem.

In this 8-year study, the sample size dropped to 56 due to failures and missed recalls. Those restorations that had to be replaced for whatever reasons and teeth that needed endodontic treatment were counted as failures. Marginal deficiencies and chipping of the restorations seem to be the predominant problems. Whether the restorations have to be replaced or just repaired depends on the clinical situation and the operator's judgment.

Kramer et al, in another study, evaluated the effect of two different adhesive/resin composite combinations for luting of IPS Empress inlays.⁴³ Ninety-four restorations were placed in 31 patients in a controlled prospective clinical split-mouth study. They were luted with EBS Multi/Compolute (3M ESPE) or with Syntac/Variolink II low (Ivoclar Vivadent); and examined at baseline and after 0.5, 1, 2, and 4 years according to modified USPHS codes and criteria. After 4 years of clinical service, 4 restorations in 2 patients (3 luted with Compolute, 1 with Variolink II) had to be replaced due to hypersensitivities, 90 were acceptable (failure rate 4%; Kaplan-Meier survival analysis). Between the 5 recalls, a statistically significant deterioration was found for the criteria marginal adaptation, inlay fracture and tooth integrity. For marginal integrity, the rating 'alfa' dropped from initially 'composite overhang' (95%) and changed over time (4-year recall) to mainly 'marginal ditching' (59%) and 'discoloration' (16%). Between the adhesives no statistical difference was found. The incidence of inlay fracture over time increased from 4% at baseline to 19% after 4 years, which was mainly chipping in occlusal-proximal contact areas. In relation to tooth integrity, significant differences were

detected between baseline and the 4-year recall. After 4 years, 43% of the restored teeth showed small enamel cracks with an increase of 50% from the time of insertion of the restorations. Of the restored teeth, 12% suffered enamel cracks directly after insertion of the restorations. No differences were found for surface roughness, color matching, proximal contact, hypersensitivity, complaints, radiographic check and subjective contentment. Luting ceramic inlays is predominantly characterized by 2 main clinical problems. (1) Due to the brittleness of ceramics, bulk fractures are still the predominant reason for failures. However, optimization of luting and polishing procedures lead to acceptable rates of fractures. (2) Postoperative hypersensitivities are still reported to be between 3 and 5% in recent studies.⁵⁵ In this study, EBS Multi, an etch-and-rinse adhesive, is compared with Syntac, a self-etch adhesive for luting with dual-cured resin composites (Compolute, Variolink II low). The etch-and-rinse system EBS Multi resulted in more postoperative hypersensitivity, but not statistically significant. In each case of ceramic chipping, rotary occlusal adjustments had been performed potentially weakening the ceramic. The thickness of the inlays apparently did not influence these findings.

In this study, marginal integrity, restoration integrity and tooth integrity are the parameters that change significantly over time. However, tooth integrity is not a parameter in the proposed study. The etch-and-rinse adhesive system seems to produce more, though not significant, sensitivity than the self-etch adhesive system. It is interesting to know if the self-etch, self adhesive cement (no etch, no adhesive) will produce even less sensitivity, which is claimed to be one of the major advantages of the system.

Toksavul et al evaluated the clinical performance of all-ceramic crowns made with the IPS Empress 2 system after an observation period of 12 to 60 months.⁵⁶ Seventy-nine crowns were placed in 21 patients, with 2 being placed on endodontically treated teeth. The crowns were etched with 5% hydrofluoric acid for 60s, then rinsed, dried, and silanated with Monobond S for 60s. Prepared tooth surfaces were conditioned with 37% phosphoric acid gel for 30s. Syntac Primer and Syntac Adhesive were applied to the rinsed and air-dried dentin surfaces. Then a bonding agent (Heliobond) was brushed onto the dentin surfaces and internal surfaces of the crowns. Cementation was done with a low-viscosity dual-cure resin composite cement (Variolink 2). The US Public Dental Health criteria were used to evaluate the quality of the crowns. The criteria were: anatomic form, marginal adaptation, color match and surface texture, caries, and postoperative sensitivity. The crowns were evaluated clinically, radiographically, and using clinical photographs. The evaluations took place at baseline (2 days after cementation) and at 6-month intervals for 12 to 60 months. Survival rate of the crowns was determined using Kaplan-Meier statistical analysis. Porcelain fracture and partial debonding that exposed the tooth structure and impaired esthetic quality or function were the main criteria for irreparable failure. The overall survival rate was 95.24%. The estimated survival rates were 95.24% and 100% for anterior and posterior crowns, respectively. One restoration failed in the anterior region: the endodontically treated tooth without a post-and-core fractured at the cervical margin 12 months after cementation. Alfa was awarded to 97.43% of crowns for anatomic form, 70.51% for marginal adaptation, 87.17% for color match and surface texture, 100% for caries, and 100% for postoperative sensitivity. The IPS Empress 2 system derives its strength from a heat-

pressed lithium-disilicate glass-ceramic framework veneered with a fluoroapatite ceramic. It is described as having improved physical characteristics over previous generations of leucite glass-ceramic materials. Because of its high strength, it may be used in the fabrication of single crowns or fixed partial dentures in the anterior and premolar region. It was concluded that the IPS Empress 2 crowns exhibited a satisfactory clinical performance during an observation period from 12 to 60 months, with a 4.76% failure rate.

In this study, crowns were studied instead of inlays/onlays. Less marginal ditching should be seen as the marginal areas are not subjected to occlusal load. Any porcelain fracture may be due to the inherent strength (brittleness) and thickness of the material. Marginal integrity problems may be due to improper or inadequate finishing of the margins, cement dissolution and partial debonding, exposing the margins. Endodontically treated teeth should not have been included in the study. Sensitivity cannot be measured, and there may be other complications such as crown and root fractures.

Lempel et al tested the utilization of a generally accepted quality criteria system (United States Public Health Services Modified Quality Criteria) in the authors' practice, in the cases of all ceramic inlays and onlays.⁵⁷ Forty-one ceramic inlays/onlays – 29 pressed and 12 laminated – were made for 28 patients. The restorations were evaluated after 2 years of cementation. According to the USPHS criteria system the following parameters were evaluated: anatomic contour, marginal integrity, marginal discoloration, color match, secondary caries, and surface roughness. In addition, postoperative sensitivity, patient's satisfaction and tooth vitality were examined as well. The USPHS

quality system together with the complementary data proved to be an objective examination method that was easily applicable to clinical practice. On the basis of these studies the utilization of this system together with patient's satisfaction, tooth vitality and sensitivity records appeared a good basis for a regular quality control system for ceramic inlays and onlays.

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Chapter 2

2.1 Abstract

Problem: The conventional resin cement used for cementing all-ceramic restorations requires the use of an acid and a bonding agent. This is time-consuming, technique-sensitive, and may result in post-cementation sensitivity. The self-adhesive resin cement can form a bond to tooth structures without pre-treatment, saves time, and may result in less post-cementation sensitivity.

Purpose: To evaluate the clinical performance of a self-adhesive cement using United States Public Health Service (USPHS) criteria, and to evaluate post-cementation sensitivity.

Materials and Methods: Fifty-three subjects were recruited from patients attending the General Dentistry Clinic of the University of Michigan School of Dentistry, contributing to a total of 76 all-ceramic restorations. Fifteen anterior crowns, 15 posterior crowns and 16 inlays/onlays were cemented with the test cement; while 15 posterior crowns and 15 inlays/onlays were cemented with Unicem (control). Not more than 3 restorations were placed in any one subject. Standard operative procedures were followed for tooth preparations, impressions, temporizations and cementations. All preparations and cementations were done by a single operator. The restorations were evaluated and assessed at 1 week (baseline) and 6 months after cementation by 2 independent evaluators. The clinical parameters evaluated included sensitivity; gingival index; color match; marginal discoloration; marginal integrity; restoration integrity; recurrent caries and proximal contacts. Sensitivity was evaluated by applying a thin stream of cold water (40°F) with a syringe onto the tooth/restoration, and the subject was asked to indicate the response on a Visual Analog Scale (VAS). Other evaluations were performed using a mouth mirror, explorer and dental floss.

Results: The results show a general decrease in VAS sensitivity ratings from baseline (pre-operative), 1 week to 6 months. A two-way ANOVA shows that the cement chosen or the restoration type did not have a significant effect on the VAS sensitivity ratings at 1 week or 6 months ($p>0.05$). A high percentage of Alfa ratings is observed for all other qualitative criteria that predict performance over the 6 month period for both cements. The failure rates for the cements were similar: 6.45% for the test and 6.90% for the control cement. The modes of failure were both cohesive (fracture) and adhesive (dislodgement) in nature.

Conclusions: The test cement is clinically acceptable after 6 months, and its clinical performance is comparable to the control cement. The test cement has no significant effect on post-cementation sensitivity either at 1 week or 6 months after cementation, regardless of the type of restoration placed.

2.2 Introduction

An increasing number of all-ceramic materials and systems are currently available for clinical use. They offer preferred optical properties for highly esthetic restorations.¹ The various all-ceramic materials have different mechanical and optical properties that affect their indications and limitations, as well as their laboratory and clinical manipulation.²

The inherent brittleness of some ceramic materials, specific treatment modalities, and certain clinical situations require resin bonding of the completed ceramic restorations to the supporting tooth structures for long-term clinical success. A strong, durable resin bond provides high retention,³ improves marginal adaptation and prevents microleakage,⁴ and increases fracture resistance of the restored tooth and the restoration.⁵ Based on the current evidence, adhesive cementation procedures are necessary to support all-ceramic materials.⁶

Resin-based cements are the materials of choice for the adhesive luting of ceramic restorations. They consist of inorganic fillers embedded in an organic matrix.⁷ Most resin cement systems involve etching the tooth with an acid solution followed by rinsing, application of a bonding agent, and finally application of the cement. This is both time-consuming and technique sensitive, and may contribute to post-operative sensitivity.⁸ A new generation of self-adhesive cement uses low pH resin primers to simultaneously demineralize and penetrate tooth surfaces. Etching and bonding are not required. This simplifies the procedure to a great extent and reduces chair time. The cementation of the restorations is simpler and easier for the clinician and more comfortable for the patient.

The cement may be a promising, easily applicable alternative to conventional, total-etch resin cements, with less post-operative sensitivity.⁹

Increased sensitivity to hot or cold stimulation is an occasional, but perplexing, unwanted consequence of a newly cemented restoration. Brannstrom described the cause of pulpal inflammation as infection with bacteria originating in the smear layer or deep in the dentinal tubules and inaccessible to caries-excavating procedures.¹⁰ A poorly fitting provisional crown may expose cut dentin to the oral fluids, and mechanical trauma caused by frictional heat during preparation may also damage the pulp. He recommended well fitting provisional, removal of the smear layer and treatment of dentinal surface with an antibacterial solution, avoiding desiccation, and careful adjustment of the occlusion to reduce the risk of an inflammatory response in the pulp.

Rosenstiel et al obtained dentists' opinions via an Internet survey as to the prevalence, causes, and prevention of postcementation sensitivity.¹¹ The factors considered 'very important' in reducing sensitivity by more than 50% of the respondents were desiccation, luting agent, occlusion, provisional and water spray. There is little published evidence to support the importance of antimicrobials, desensitizing or bonding agents.

Christensen suggested the use of self-etching adhesives, which is the most successful and predictable of the desensitizing crown-cementing procedures when standard resin cement is being used.¹² When postcementation sensitivity occurred, Christensen preferred to wait for up to 6 weeks to determine whether the sensitivity resolved by itself.

Lam et al studied the liquid continuum within the pulpo-dentin complex and demonstrated the flow of fluid in dentinal tubules as a mechanism for sensitivity and pulpal damage.¹³ There was evidence that dentin bonding agents can reduce fluid flow through tubules, both prior to direct restorations and during cementation.

Mottola describes the visual analog scale (VAS) as a valid and reliable method to measure subjective phenomena such as pain and sensitivity which are often difficult to describe in concrete terms.¹⁴ Printing instructions at the top of the scale, providing examples, allowing the individual to practice using the tool, and/or repeating instructions verbally, all help to overcome the difficulty in understanding the use of the scale.¹⁴ High reliability was demonstrated by a correlation of .99 between scores obtained on a vertical and those obtained on a similar horizontal scale.¹⁵ Obtained pain ratings on days 1, 3, and 5 were found to correlate significantly ($r = .78$) with ratings obtained on days 2, 4, and 6, demonstrating test-retest reliability.¹⁶ Validity was demonstrated by significant correlations ranging from .30 to .92 between a VAS and several measures of pain including the McGill Pain Questionnaire.¹⁶

Kramer et al evaluated the clinical performance of 96 IPS Empress inlays and onlays placed in 34 patients.^{17,18} The restorations were bonded with an enamel/dentin bonding system (Syntac Classic) and 4 different resin composite systems and assessed at baseline, 1, 2, 4, 6 and 8 years. Eight restorations had to be replaced (failure rate 8%): 6 inlays suffered cohesive bulk fractures, 2 teeth required endodontic treatment. Ninety-eight per cent of the surviving restorations exhibited marginal deficiencies after 8 years, independent of the luting composite. The absence of enamel margins (preparation margins below the cemento-enamel junction); cuspal replacement or reconstruction;

number of restoration surfaces; size of the restoration; or tooth type did not have any significant influence on the clinical performance of the restorations over the 8 year period. No correlation was found between ceramic thickness and fractures. Secondary caries did not occur at all.

Lempel et al tested the utilization of the United States Public Health Service (USPHS) quality criteria system to evaluate all-ceramic inlays and onlays.¹⁹ Parameters evaluated included anatomic contour, marginal integrity, marginal discoloration, color match, secondary caries, and surface roughness. These, together with patients' satisfaction, tooth vitality and sensitivity records, formed a good basis for a regular quality control system for ceramic inlays and onlays.

The purpose of this study was to perform a pre-market evaluation of a self-adhesive cement for cementing all-ceramic restorations using USPHS criteria and to evaluate post-cementation sensitivity utilizing the Visual Analog Scale (VAS). The null hypotheses are that there is no significant difference in the clinical performance between the test and control cements; and that the test cement has no significant effect on VAS sensitivity ratings at 1 week and 6 months after cementation, regardless of the type of restoration placed.

2.3 Materials and Methods

The study design was a randomized clinical trial comparing a new test cement, Maui, with a currently marketed control cement, Unicem. Maui was the code name used in the study for the test cement, which will be renamed Smart-Cem 2 when it is marketed. A total of 53 subjects were recruited, requiring 76 indirect all-ceramic restorations which were cemented with either the test or control cement. The distribution is shown in Table 1.

Table 1. Restoration Distribution and Ceramic Type

	Maui*	Unicem**	Ceramic Type
Anterior Crown	15	0	IPS Empress (Ivoclar Vivadent, Amherst, NY)
Posterior Crown	15	15	Cercon (Dentsply Caulk, Milford, DE)
Inlay/Onlay	16	15	IPS Empress (Ivoclar Vivadent, Amherst, NY)
Total	46	30	

* Dentsply Caulk, Milford, DE

** 3M ESPE, St Paul, MN

Not more than 3 restorations were included for each subject. Study subjects were recruited from patients attending the General Dentistry Clinic of the University of Michigan School of Dentistry. The study protocol was approved by the University of Michigan Health Sciences Institutional Review Board (IRB).

Inclusion and exclusion criteria are listed as follows:

2.3.1 Inclusion Criteria

- Must be 18 years or older. There was no upper age limit.
- Must be in need of the restoration: posterior crown, inlay or onlay on a molar or premolar; anterior crown on a canine or incisor.
- Must be in good general health.
- Must be available for the required post-operative follow-up visits.
- Tooth receiving the restoration must have contact in centric closure with an opposing tooth; and at least one proximal contact with an adjacent tooth.
- Tooth must be vital, with no pulpal involvement or periodontal disease.

2.3.2 Exclusion Criteria

- Rampant uncontrolled caries or advanced untreated periodontal disease.
- Evidence of severe bruxism or clenching; or in need of TMJ-related therapy.
- Tooth with symptoms of pulpal or periapical pathology.
- Tooth that is non-vital or had root canal therapy.
- Tooth that has been pulp capped; or with near or actual exposure.
- Tooth that has little remaining tooth structure and requires extensive core build-up.

2.3.3 Screening

Each subject and the tooth concerned were screened for compliance using the criteria listed above. The study procedures were explained to the subject, who then read and signed the Consent and HIPAA forms. Clinical photos, radiographs, upper and lower alginate impressions were taken.

2.3.4 Study Treatment

A pre-operative cold sensitivity test was performed on the tooth by using cold water taken from the refrigerator (4°C/40°F). A syringe with a fine tip was used to deliver

a thin stream of water on the tooth for a duration of 10 seconds. The patient was then asked to indicate the degree of sensitivity by drawing a vertical line on a Visual Analog Scale (VAS), which is a 100 mm line with the left end indicating 'no sensitivity' and the right end 'severe sensitivity'. This served as the 'baseline' for sensitivity ratings.

Local anesthesia was given. A standard preparation for all-ceramic crowns, inlays or onlays, as the case might be, was made. Fluorocore (Dentsply Caulk, Milford, DE) was used for core build-up when necessary. A retraction cord, Ultrapak (Ultradent Products Inc, South Jordan, UT), was packed for tissue management. An impression of the preparation was then made with the PVS Aquasil Ultra (Dentsply Caulk, Milford, DE). The light body material was injected onto the preparation with a syringe; the heavy body material was loaded on a triple tray, which was inserted and the patient was asked to bite down. The impression also included a bite registration and the opposing arch. The prepared tooth was temporized with a provisional restoration fabricated with Integrity (Dentsply Caulk, Milford, DE), and cemented with the temporary cement Zone (Dux Dental, Oxnard, CA). The appropriate shade for the final restoration was selected. The patient was then dismissed. The impression was sent to the laboratory for fabrication of the all-ceramic restoration. All restorations in the study were fabricated by the same laboratory (Cornerstone Dental Studio, 42430 W 14 Mile Rd, Novi, MI 48377) .

When the restoration was returned from the laboratory, the patient was appointed for cementation. Local anesthesia was given, and the provisional restoration removed. The restoration was placed and evaluated for marginal fit, proximal contacts and color match. Institutional standards were applied for the quality and fit of the restoration. For anterior crowns and inlays/onlays, the occlusion was checked and adjusted after

cementation. For posterior crowns, the patient was slowly guided into occlusion by the operator, and initial occlusal adjustments were made and the restoration repolished. The prepared tooth was pumiced, rinsed thoroughly and dried. The internal surface of the IPS Empress (Ivoclar Vivadent, Amherst, NY) crowns and inlays/onlays was etched with 9% hydrofluoric acid (HF) (Ultradent Products Inc, South Jordan, UT) for 1 minute, rinsed and air-dried. It was then silanated with Calibra silane coupling agent (Dentsply Caulk, Milford, DE), lightly air-dried and set aside. For the Cercon (Dentsply Caulk, Milford, DE) posterior crowns, air-borne particle abrasion with 30um alumina (Al_2O_3) was done in the laboratory before delivery. The cement (test or control) used was decided at random by opening an assigned envelope containing a slip with the name of the cement.

The tooth was then isolated using cotton rolls and a saliva ejector. An appropriate shade of Maui (Dentsply Caulk, Milford, DE) was selected and the manufacturer's instructions were followed. The syringe cap was removed, a small amount of material from the double-barrel syringe was dispensed and discarded. A disposable mixing tip was then attached and locked in place. The syringe plungers were gently depressed to begin the flow of material. A small amount was dispensed through the mix tip onto a mixing pad and discarded. A thin, uniform layer of cement was applied to the entire internal surface of the restoration, which was then seated onto the prepared tooth. The self-cure cleanup technique was utilized. The cement was allowed to gel for approximately 2 minutes, and the excess was removed. Dental floss was used to remove excess interproximally. Complete excess cement removal was achieved using a scaler with light pressure. All areas of the restoration were then light-cured for 10 seconds from facial, lingual and occlusal. Final occlusion was checked and adjusted, restoration margins were

finished and the restoration polished. Clinical photos of the cemented restoration were taken, and the patient dismissed.

An appropriate shade of the control cement, RelyX Unicem (3M ESPE, St Paul, Mn.), was selected. The cement capsule was inserted into the activator, and the handle was depressed and held for 2 – 4 seconds. The activated capsule was then inserted into the mixing device (triturator/amalgamator) and mixed for 10 seconds. The capsule was removed and inserted into the applicator. The nozzle was opened and the cement was dispensed onto the internal surface of the restoration, which was then seated onto the prepared tooth. The excess cement reached its 'gelled' state in 2 to 2 ½ minutes, and was easily removed. Interproximal excess was removed with floss, and a scaler was used with light pressure to complete excess removal. Each surface was then light cured for 20 seconds. Final occlusion was checked and adjusted, margins were finished as necessary, and the restoration polished.

All tooth preparations and restoration cementations were done by the same operator.

2.3.5 Evaluation

Assessments were made at 1 week and 6 months. Sensitivity rating was recorded at each recall using the cold water test described for baseline. The location of the mark on the VAS was measured in mm from the left end (no sensitivity) and the results were recorded for statistical analysis and compared to the baseline (pre-operative) sensitivity rating. In addition, the following categories were evaluated using modified USPHS criteria (originally developed by Cvar and Ryge): sensitivity, gingival index, color match, marginal discoloration, marginal integrity, restoration integrity, caries and proximal

contacts (Appendix A). All evaluations were completed using a standard mouth mirror, a #3 cow-horn explorer and dental floss. They were performed by two trained independent evaluators other than the operator, and a consensus was reached.

The following is a series of clinical photos illustrating a typical case sequence.



Figure 1. Preoperative view of tooth #9, with large composite build-up.



Figure 2. Tooth preparation for an all-ceramic crown.



Figure 3. IPS Empress crown cemented with Maui.



Figure 4. Crown #9 at 1 week.



Figure 5. Crown #9 at 6 months.

2.4 Results

A total of 53 patients were recruited for the study, and 76 restorations were cemented: 46 with Maui and 30 with Unicem (Table 2). The restorations included posterior crowns on premolars and molars fabricated with Cercon (Dentsply Ceramco, Milford, DE); anterior crowns on incisors and canines fabricated with IPS Empress 1 (Ivoclar Vivadent, Amherst, NY); and inlays/onlays on premolars and molars fabricated with IPS Empress 1 (Ivoclar Vivadent, Amherst, NY). Posterior crowns, inlays and onlays were cemented with Maui or Unicem. Anterior crowns were only cemented with Maui.

Table 2. Distribution of Restorations by Cement Type and Tooth Type.

Posterior crown	30	Maui	15	Premolar	8
				Molar	7
		Unicem	15	Premolar	7
				Molar	8
Anterior crown	15	Maui	15	Incisor	8
				Canine	7
Inlay	15	Maui	8	Premolar	4
				Molar	4
		Unicem	7	Premolar	4
				Molar	3
Onlay	16	Maui	8	Premolar	0
				Molar	8
		Unicem	8	Premolar	4
				Molar	4

Table 3. Distribution of Restorations per Patient by Gender.

	N	One restoration	Two restorations	Three restorations
Male	16	8	7	1
Female	37	24	12	1
Total	53	32	19	2

Sixteen male and 37 female patients participated in the study. The distribution by number of restorations is detailed in Table 3. Most (32) had only one restoration; 19 had two. However, there were 2 patients who received 3 restorations each. The first patient had a fractured inlay, which was discovered at the 6 month recall. It was taken out of the study, but is still included in the data as a failure. A new restoration on another tooth was added as a new study number. The second patient who initially had 2 anterior crowns cemented needed an inlay on a premolar and wanted to participate further in the study. Since it was a different restoration (inlay) on a different tooth (posterior), it was also included.

2.4.1 Sensitivity

Table 4. Sensitivity Ratings (in mm) on a 100 mm Visual Analog Scale (VAS).

Restoration	MAUI			UNICEM		
	Pre-op	1 week	6 month	Pre-op	1 week	6 month
Anterior Crown	9.61 (21.41)	5.22 (5.92)	2.12 (3.19)	-	-	-
Posterior Crown	11.56 (15.39)	6.72 (9.23)	6.17 (8.80)	8.39 (18.59)	9.00 (13.10)	1.86 (3.67)
Inlay	8.33 (10.56)	2.71 (2.91)	1.98 (3.27)	7.14 (6.20)	4.52 (5.69)	2.64 (3.20)
Onlay	11.04 (13.60)	17.50 (27.75)	14.44 (33.75)	12.40 (16.29)	4.90 (6.63)	3.02 (4.76)

Standard Deviation in ()

The cold sensitivity test was performed on each tooth (restoration) at baseline (pre-operative), 1 week and 6 month recalls. The patients recorded their responses by making vertical lines on the visual analog scale (VAS). The lines were measured from the left end (no sensitivity) with a mm ruler. The readings were categorized by restoration type and cement. An average value (arithmetic mean) was computed for each category. The means and the standard deviations are presented in Table 4.

Table 5. Two-Way ANOVA Test for Cement /Restoration Effect on VAS Sensitivity Ratings.

	Baseline p-value	One Week p-value	Six Month p-value
Cement	0.714	0.647	0.126
Restoration	0.751	0.310	0.118

Significant level at p=0.05

A 2-Way ANOVA test was done to determine if the cement used (Maui or Unicem) or the restoration type (anterior/posterior crown, inlay/onlay) had any effect on the VAS sensitivity ratings at 1 week and 6 months after cementation. Neither the cement used nor the restoration type had any significant effect on the sensitivity at 1 week or 6 months ($p > 0.05$) (Table 5).

Table 6. Sensitivity Ratings as Reported by Patients.

Restoration	Criteria	MAUI		UNICEM	
		1 week	6 month	1 week	6 month
Anterior Crown	Alfa	12	13	-	-
	Bravo	3	0	-	-
	Charlie	0	0	-	-
	Delta	0	0	-	-
Posterior Crown	Alfa	12	13	11	12
	Bravo	2	2	4	1
	Charlie	1	0	0	0
	Delta	0	0	0	0
Inlay/Onlay	Alfa	13	11	14	15
	Bravo	3	3	1	0
	Charlie	0	0	0	0
	Delta	0	0	0	0

The patients were asked whether their teeth had temperature or pressure sensitivity after restoration cementation at 1 week and 6 month recalls. Ratings were then given according to the evaluation criteria for sensitivity. The results are shown in Table 6.

Two anterior crowns cemented with Maui were missing at 6 months. One patient was not available for the 6 month recall. One had root canal treatment shortly after cementation, and was taken out of the study. Two posterior crowns cemented with Unicem were missing at 6 months. One patient left the state and was not available at 6 months. One had root canal treatment, and was taken out of the study before the 6 month recall. Two onlays cemented with Maui were missing at 6 months. One fractured and was subsequently replaced. One dislodged and was re-cemented. Both happened before 6 months and were taken out of the study. In total, 6 restorations were missing at 6 months, 4 cemented with Maui and 2 with Unicem.

2.4.2 Gingival Index

Table 7. Gingival Index

Restoration	Criteria	MAUI		UNICEM	
		1 week	6 month	1 week	6 month
Anterior Crown	0	11	12	-	-
	1	4	1	-	-
	2	0	0	-	-
	3	0	0	-	-
Posterior Crown	0	14	15	13	11
	1	1	0	2	2
	2	0	0	0	0
	3	0	0	0	0
Inlay/Onlay	0	14	14	15	13
	1	1	0	0	1
	2	1	0	0	1
	3	0	0	0	0

The gingival area closest to the restoration margin was evaluated for inflammation and rated as the gingival index (Table 7). The majority of patients at 1 week and 6 months had normal gingiva (rating 0). Mild inflammation with slight change in color and edema, but no bleeding (rating 1) was observed in a few cases. There were 2 onlays with moderate gingival inflammation, showing redness, edema and glazing, with bleeding on probing (rating 2). None of the restorations had severe gingival inflammation (rating 3).

2.4.3 Color Match

Table 8. Color Match.

Restoration	Criteria	MAUI		UNICEM	
		1 week	6 month	1 week	6 month
Anterior Crown	Alfa	14	13	-	-
	Bravo	1	0	0	0
	Charlie	0	0	0	0
Posterior Crown	Alfa	10	10	11	11
	Bravo	5	5	4	2
	Charlie	0	0	0	0
Inlay/Onlay	Alfa	11	12	12	12
	Bravo	5	2	3	3
	Charlie	0	0	0	0

For color match, the crowns were compared to the adjacent teeth, while inlays/onlays were compared to the restored teeth. Most restorations placed had ideal color match (Alfa rating) (Table 8). Some restorations showed readily detectable difference in color, but all of them were clinically acceptable (Bravo rating). The color match was evaluated by looking at the restorations wet at 12 inches for 3 – 4 seconds.

2.4.4 Marginal Discoloration

No visual evidence of marginal discoloration (Alfa) was detected on the restorations except for 1 anterior crown and 1 inlay at 6 months and 1 onlay at 1 week cemented with Maui (Bravo-1, marginal discoloration noted in 1 local area) (Table 9). There were no restorations rated Bravo-2 (marginal discoloration noted in multiple areas); Charlie-1 (marginal discoloration noted penetrating in a pulpal direction in 1 local area) or Charlie-2 (penetrating in a pulpal direction in multiple areas).

Table 9. Marginal Discoloration.

Restoration	Criteria	MAUI		UNICEM	
		1 week	6 month	1 week	6 month
Anterior Crown	Alfa	15	12	-	-
	Bravo-1	0	1	-	-
	Bravo-2	0	0	-	-
	Charlie-1,2	0	0	-	-
Posterior Crown	Alfa	15	15	15	13
	Bravo-1	0	0	0	0
	Bravo-2	0	0	0	0
	Charlie-1,2	0	0	0	0
Inlay/Onlay	Alfa	15	13	15	15
	Bravo-1	1	1	0	0
	Bravo-2	0	0	0	0
	Charlie-1,2	0	0	0	0

2.4.5 Marginal Integrity

Marginal integrity was evaluated by using a #3 cow-horn explorer at the tooth-restoration interface (Table 10). There are 3 categories within the Alfa rating. Alfa-1 denotes a smooth transition from tooth to restoration, or vice versa, with no detectable marginal ditching or crevice. Alfa-2 denotes a catch from tooth to restoration, a detectable restoration over-contour. Alfa-3 denotes a catch from restoration to tooth, with a slightly under-contoured restoration or exposed preparation margin. Forty-one restorations cemented with Maui and 25 cemented with Unicem were rated in the Alfa category at 6 months. There were 2 onlays with Bravo-1 ratings at 6 months (evidence of crevice formation into which explorer can penetrate along less than 50% of the margin). There were no anterior crowns, posterior crowns, or inlays with Bravo-1 rating. There were no restorations rated Bravo-2 (crevice formation into which explorer will penetrate along 50% or more of the margin) or Charlie (crevice formation with exposure of

underlying dentin or base). However, there were 1 inlay and 1 onlay cemented with Unicem with Delta rating at 6 months (restoration is mobile, fractured, or missing in part or in whole). Both restorations were found to be fractured at the 6 month recall. There were no anterior or posterior crowns with Delta rating.

Table 10. Marginal Integrity.

Restoration	Criteria	MAUI		UNICEM	
		1 week	6 month	1 week	6 month
Anterior Crown	Alfa-1	6	1	-	-
	Alfa-2	8	12	-	-
	Alfa-3	1	0	-	-
	Bravo-1,2	0	0	-	-
	Charlie	0	0	-	-
	Delta	0	0	-	-
Posterior Crown	Alfa-1	2	0	6	4
	Alfa-2	12	13	7	6
	Alfa-3	1	2	2	3
	Bravo-1,2	0	0	0	0
	Charlie	0	0	0	0
	Delta	0	0	0	0
Inlay/Onlay	Alfa-1	5	1	4	2
	Alfa-2	10	11	9	10
	Alfa-3	1	1	2	0
	Bravo-1	0	1	0	1
	Bravo-2	0	0	0	0
	Charlie	0	0	0	0
	Delta	0	0	0	2

2.4.6 Restoration Integrity

Table 11. Restoration Integrity.

Restoration	Criteria	MAUI		UNICEM	
		1 week	6 month	1 week	6 month
Anterior Crown	Alfa	15	13	-	-
	Bravo	0	0	-	-
	Charlie	0	0	-	-
	Delta	0	0	-	-
Posterior Crown	Alfa	15	15	15	12
	Bravo	0	0	0	1
	Charlie	0	0	0	0
	Delta	0	0	0	0
Inlay/Onlay	Alfa	16	12	14	13
	Bravo	0	2	1	0
	Charlie	0	0	0	0
	Delta	0	0	0	2

Forty restorations cemented with Maui and 25 cemented with Unicem were rated Alfa at 6 months, with no fractures noted (Table 11). Two restorations cemented with Maui and 1 cemented with Unicem were rated Bravo at 6 months, with small fractures which could be polished. One inlay cemented with Unicem was rated as Bravo as early as 1 week. There were no anterior crowns with Bravo rating. No restoration had Charlie rating (fracture which needs repair but not replacement). As mentioned in the previous section on Marginal Integrity, 1 inlay and 1 onlay cemented with Unicem fractured at 6 months, and were given Delta ratings (fracture which requires replacement of restoration).

2.4.7 Caries

Table 12. Recurrent Caries.

Restoration	Criteria	MAUI		UNICEM	
		1 week	6 month	1week	6 month
Anterior Crown	Alfa	15	13	-	-
	Charlie	0	0	-	-
Posterior Crown	Alfa	15	15	15	13
	Charlie	0	0	0	0
Inlay/Onlay	Alfa	16	14	15	15
	Charlie	0	0	0	0

No recurrent caries were detected at 1 week and 6 month recalls for either cement (Table 12).

2.4.8 Proximal Contacts

Table 13. Proximal Contacts.

Restoration	Criteria	MAUI				UNICEM			
		1 week		6 month		1 week		6 month	
		M	D	M	D	M	D	M	D
Anterior Crown	Alfa	13	14	12	12	-	-	-	-
	Bravo	2	0	0	0	-	-	-	-
	Charlie	0	0	1	0	-	-	-	-
Posterior Crown	Alfa	15	9	15	8	13	12	12	11
	Bravo	0	1	0	2	0	1	0	0
	Charlie	0	0	0	0	1	0	0	0
Inlay/Onlay	Alfa	10	10	9	8	12	8	12	9
	Bravo	0	0	0	0	0	0	0	0
	Charlie	0	0	0	0	0	1	0	0

Most proximal contacts (mesial M and distal D) were rated Alfa (tight, firm contact) (Table 13). A few were rated Bravo (light contact but visually closed, allowing free passage of shimstock or floss). There were no inlays or onlays with Bravo ratings. There were 3 restorations with proximal contacts rated Charlie (contact visually open to light reflection): 2 restorations cemented with Unicem at 1 week and 1 restoration cemented with Maui at 6 months.

Table 14. Longitudinal Evaluation of Clinical Performance by Criteria (% Alfa)

	MAUI 1 WEEK	UNICEM 1 WEEK	MAUI 6 MONTH	UNICEM 6 MONTH
Sensitivity	80.43	83.33	88.10	96.43
Gingival Index	84.78	93.33	97.62	85.71
Color Match	76.09	76.67	83.33	82.14
Marginal Discoloration	97.83	100	95.24	100
Marginal Integrity	100	100	97.62	89.29
Restoration Integrity	100	96.67	95.24	89.29
Caries	100	100	100	100
Proximal Contacts	95.95	93.75	95.52	100

Table 14 is a summary of the previous tables, showing the % Alfa ratings of the different parameters for the 2 cements at 1 week and 6 months. Criteria associated with restoration performance over time (marginal discoloration, marginal integrity, restoration integrity, caries, proximal contacts) were all greater than 89% Alfa after 6 months.

2.4.9 Failures

Table 15. Restoration Failures at Six Months.

CEMENT	N	# of failures		Reasons	Failure rate (%)
MAUI	45 (31)	Anterior Crown	1 (0)	Root canal	6.67 (6.45)
		Onlay	2	Fracture, dislodgement	
		Total	3 (2)		
UNICEM	29	Posterior Crown	1 <0>	Root canal	10.34 <6.90>
		Inlay	1	Fracture	
		Onlay	1	Fracture	
		Total	3 <2>		

Numbers in (): excluding anterior crowns

Numbers in < >: excluding root canal

The failure rates for both cements were similar (Table 15). The failures occurred at or before 6 months. The sample size (N) at 6 months for Maui was 45 instead of 46. One patient with an anterior crown could not be contacted and did not come in after the 1 week recall. The sample size (N) at 6 months for Unicem was 29 instead of 30. One patient with a posterior crown left the state and was not available at 6 months.

Since anterior crowns had no control, they were excluded to make a more valid comparison of the 2 cements. If root canal treatments were excluded also, the failure rates for the 2 cements were very similar (6.45 and 6.90% for Maui and Unicem respectively). One onlay cemented with Maui fractured, another one dislodged. One inlay and one onlay cemented with Unicem fractured. Further discussion of the failed restorations will follow (Appendix B).

The following is a series of clinical views and microscopic views of epoxy-resin dies of restorations at 1 week and 6 months.

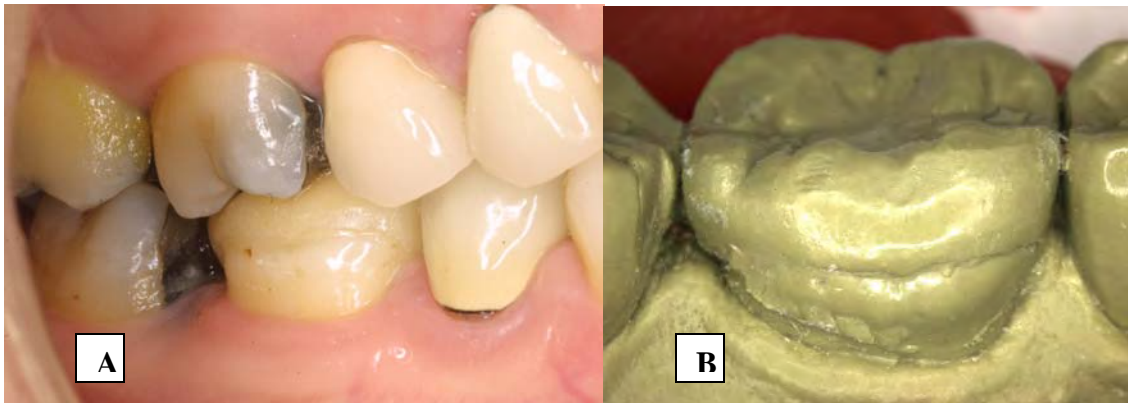


Figure 6. IPS Empress onlay on tooth #30 at 1 week. (A) Clinical view. (B) Microscopic view of epoxy-resin die.

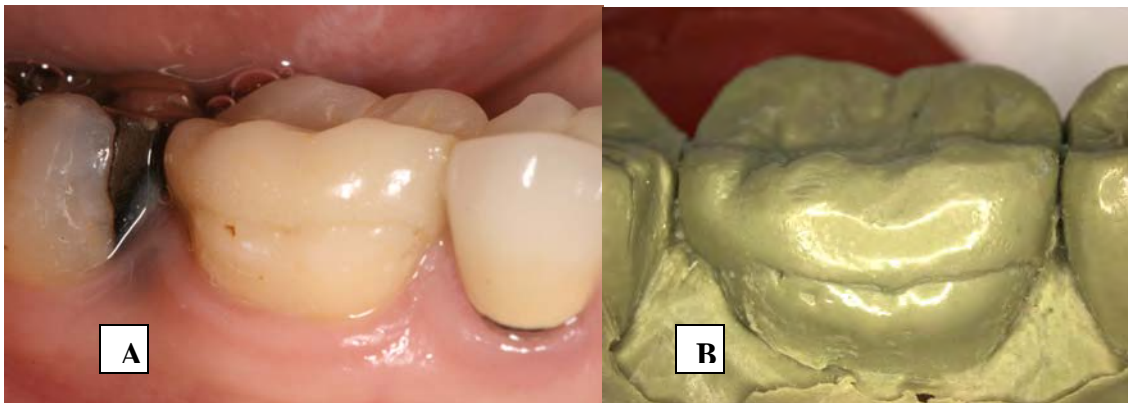


Figure 7. IPS Empress onlay on tooth #30 at 6 months. (A) Clinical view. (B) Microscopic view of epoxy-resin die. Note intact buccal margin.

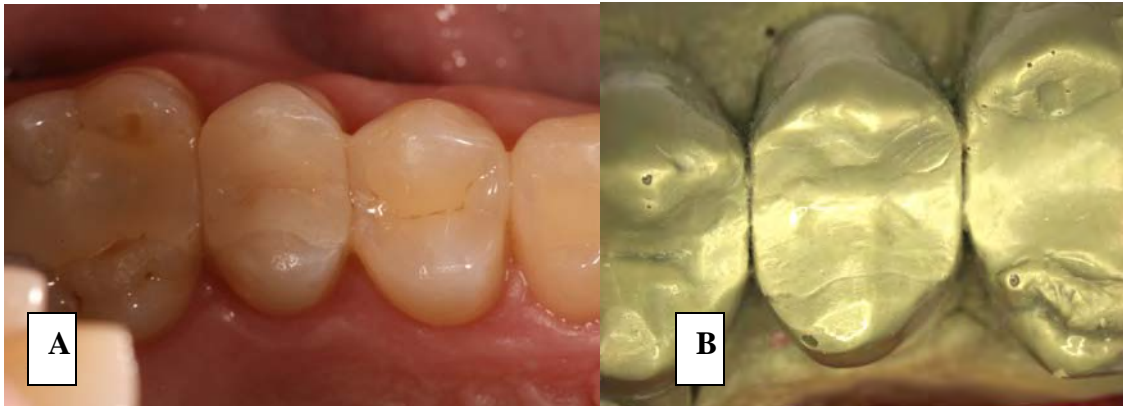


Figure 8. IPS Empress inlay on tooth #13 at 1 week. (A) Clinical view. (B) Microscopic view of epoxy-resin die.

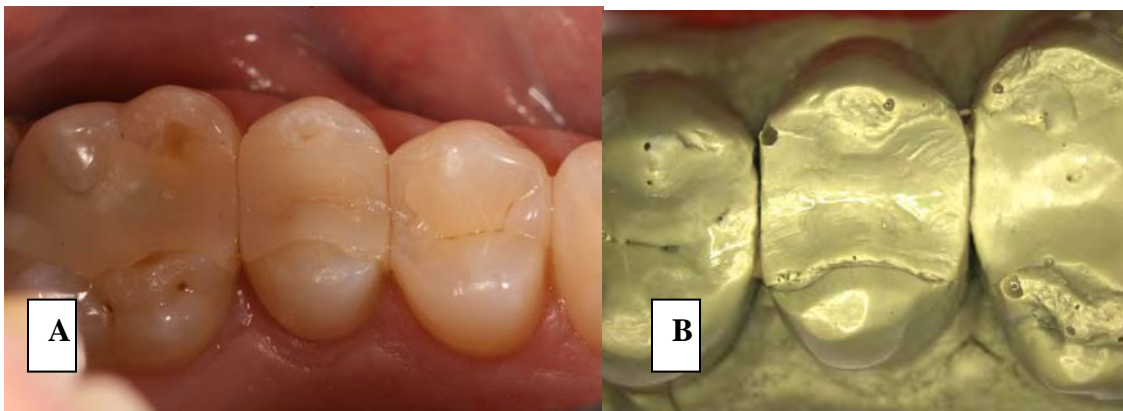


Figure 9. IPS Empress inlay on tooth #13 at 6 months. (A) Clinical view. (B) Microscopic view of epoxy-resin die. Note deteriorating lingual-occlusal margin.

2.5 Discussion

The purpose of this study was to evaluate the clinical performance of a self-adhesive cement over a 6 month period. The distribution of the restorations by cement type and tooth type are listed in Table 2.

The sensitivity ratings on the VAS showed a general decrease from baseline (before tooth preparation) to 1 week and then to 6 months for both cements (Table 4). There was a slight increase in sensitivity for posterior crowns cemented with Unicem at 1 week (9 mm) compared to baseline (8.39 mm). This could be attributed to the preparation and cementation procedures. The rating improved to 1.86 mm at 6 months. The relatively high ratings for Maui onlays at 1 week (17.5 mm) and 6 months (14.44 mm) compared to baseline (11.04 mm) were due to one case of an upper first molar which had buccal cervical abrasion and sensitivity. The patient marked the VAS at about 80 mm at both recalls. If that case was taken out, the ratings for baseline, 1 week and 6 months became 6.55(5.28), 9.05(15.21) and 0.67(0.70) mm respectively (standard deviations in parentheses).

Some of the variations observed can be explained by the subjective nature of the VAS. There may have been a lack of complete understanding by some patients, and instructions may not have been clearly understood. Some patients made their marks away from the left end when they actually meant no sensitivity at all. As a result the measurements were greater than zero.

Another contributing factor was the location on the tooth or restoration where the stream of cold water was delivered with the fine syringe tip. For the upper molar with high sensitivity, the water was delivered to the buccal cervical abrasion area and the

patient showed a moderate response. The result may have been different if the water was applied on the restoration (onlay) or other parts of the tooth.

The test cement had no effect on post-cementation sensitivity (VAS) either immediately after cementation or after 6 months, regardless of the type of restoration placed (Table 5). The baseline analysis was included to show that there was no difference in the teeth selected for the study as they were included and randomly assigned to each group for cement and restoration type.

When the patients were asked to report on tooth sensitivity at the 6 month recall (Table 6), most reported no sensitivity (Alfa) (88.1% for Maui and 96.43% for Unicem). The results showed a general improvement at 6 months compared to 1 week (80.43% for Maui and 83.33% for Unicem). One patient who had a posterior crown cemented with Maui had significant pressure sensitivity at 1 week (rated Charlie: significant complaint or spontaneous response). The patient had a heavy bite, and occlusal adjustment was done. At 2 and 3 week follow-ups, the ratings improved to Alfa. Eight cases cemented with Maui and 5 cemented with Unicem reported mild sensitivity at 1 week (Bravo rating: mild sensitivity to thermal or pressure stimuli). This could be attributed to the preparation and cementation procedures. They were followed up and most improved at 6 months. This is in agreement with the current literature. In a study of 120 full-coverage restorations using a resin cement containing 4-META (Chemiace II), Denner et al found that the incidence of postoperative sensitivity was 13.3% at 1 week and 5.9% at 6 months.²⁰ It further improved to 2.1% at 12 months and none at 24 months. Kramer et al, in their study of 94 IPS Empress inlays and onlays, noted postoperative sensitivity in 13% of cases at baseline, which also reduced rapidly thereafter.¹⁷

The gingival index showed normal gingiva (rating 0) for the majority of patients (Table 7) (97.62% for Maui and 85.71% for Unicem at 6 months). Mild inflammation with slight change in color and edema, but no bleeding (rating 1) could be due to inadequate oral hygiene or inadequately finished restoration margins at the gingiva where plaque accumulation could occur. Oral hygiene was stressed and restoration margins were further finished at 1 week; and most ratings of '1' improved to '0' at 6 months. None of the restorations had severe gingival inflammation (rating 3).

Most restorations placed had ideal color match (Alfa) (Table 8) (83.33% for Maui and 82.14% for Unicem at 6 months). This is especially important for anterior crowns which are in the esthetic zone. Fourteen anterior crowns cemented with Maui had Alfa rating at 1 week, while only one had Bravo rating (readily perceptible difference in color, clinically acceptable). None of the restorations placed had clinically unacceptable mismatch in color (Charlie rating).

The cements used, which have different shades, may have played a role on the final color match of anterior crowns and inlays/onlays. These were fabricated with IPS Empress which is highly translucent. Maui cement is available in 5 tooth-colored shades: light, medium, dark, translucent and opaque. The translucent and light shades were used most of the time in this study, as the color match of most restorations was deemed satisfactory at initial try-in, and no shade modification was necessary. Therefore most color discrepancies observed can be attributed to operator variability. Posterior Cercon crowns have higher chroma due to the opaque zirconium core which presents a challenge to ideal shade matching. However, this is not an issue directly related to the cements.

Almost all restorations had Alfa rating for marginal discoloration (no visual evidence of marginal discoloration) (Table 9). The 3 Bravo-1 ratings (marginal discoloration noted in 1 local area) were from 3 different patients: an onlay, an inlay and an anterior crown cemented with Maui. There were no restorations rated Bravo-2, Charlie-1 or Charlie-2 (criteria listed in Appendix A).

The percentages of Alfa ratings for Maui and Unicem at 6 months were 95.24 and 100% respectively. In a study of 125 IPS Empress inlays by Fradeani et al for a period of 7 to 56 months, marginal discoloration recorded the lowest percentage of alfa ratings (65.3%) among the parameters evaluated.²¹ This was probably related to properties of the luting agent and to residual cement excesses. The mean follow-up period was 40.3 months and it was hypothesized that marginal discoloration would deteriorate with time. Whether this parameter in the present study will deteriorate with time and score a lower percentage of alfa ratings comparable to Fradeani's study remains to be seen.

When evaluating marginal integrity, most restorations were rated in the Alfa category (Table 10) (97.62% for Maui and 89.29% for Unicem at 6 months). Inadequately finished restoration margins, especially the facial margins of anterior crowns that went sub-gingival, gave rise to Alfa-2 ratings. Under-contoured restoration margins, slightly exposing the preparation margins, led to Alfa-3 ratings. The results show fewer Alfa-1 ratings (perfect margins) at 6 months compared to 1 week, with increases in Alfa-2 and 3 ratings (catches from tooth to restoration and from restoration to tooth respectively). The evaluators were very critical in evaluating this parameter. They probed along the tooth-restoration interface with an explorer, and a distinct catch at any one location would result in Alfa- 2 or 3 ratings. Another factor that could have come

into play was intra-evaluator variability. However, the results may still indicate an actual deterioration of restoration margins over time, especially the occlusal margins of inlays/onlays subjected to occlusal stress.

Two onlays had Bravo-1 ratings at 6 months. One was cemented with Unicem on a molar where a very small part of porcelain chipped off at the distobuccal occlusal margin leading to crevice formation. The other was cemented with Maui on a molar and there was a small porcelain chip at the linguo-occlusal margin where the bite was quite heavy. One inlay and one onlay cemented with Unicem were found to be fractured at 6 months, and were given Delta ratings. The mesial part of the MOD inlay on a molar was fractured and mobile; the patient had a heavy bite. The mesial part of the onlay on a premolar was fractured and missing exposing the mesial cervical wall. The bite was heavy at the mesial marginal ridge area; that area was over-extended to build the mesial marginal ridge into a diastema, creating unsupported porcelain.

Fradeani et al hypothesized that marginal discoloration and marginal integrity were interrelated and appeared to deteriorate with time, but marginal discoloration preceded degeneration of the margins. They observed that Alfa marginal discoloration always implied Alfa marginal integrity, but the reverse was not true.²¹ This was not true in the present study. There were cases of deteriorating margins without any sign of marginal discoloration. For Unicem at 6 months, the percentage of Alfa ratings for marginal integrity was 89.29%; while that for marginal discoloration was 100%, meaning no discoloration. The observation period was short (6 months) compared to Fradeani's (40.3 months).

Behr et al suggested that a self-adhesive resin cement without pre-treatment of the tooth can provide a marginal adaptation at dentin comparable to established 3-step total etch luting agents; but the marginal adaptation in enamel is not as good. They reported that a perfect etch pattern in enamel can only be achieved using 30-40% phosphoric acid.⁹ Other studies have also shown that the bond strength of self-adhesive cement to dentin is comparable to conventional total etch resin cement, but the bond strength to enamel is significantly lower.^{22,23} This may help explain the deterioration in marginal integrity of inlays/onlays where the margins subjected to occlusal stress were in enamel.

With respect to restoration integrity, most restorations were rated Alfa, with no fractures noted (Table 11) (95.24% for Maui and 89.29% for Unicem at 6 months). Four restorations were rated Bravo, with small fractures which could be polished. At 1 week, the inlay on a molar cemented with Unicem had a small porcelain chip at the distal marginal ridge. It subsequently fractured at 6 months. A posterior crown on a molar cemented with Unicem, an inlay on a molar cemented with Maui, and an onlay on a molar cemented with Maui all had small localized defects at 6 months. In all three cases, occlusion appeared to have been the main contributing factor, as shown by photos of articulating paper markings on the restorations after cementation and at 1 week. It is important to ensure light contacts or centric stops especially on inlays and onlays at or near the restoration margins. The two restorations that fractured at 6 months were given Delta ratings, subsequently replaced and excluded from the study.

In the study by Kramer et al, the predominant failure scenario with ceramic inlays was the integrity of the inlay itself.¹⁸ 'Half-moon' fractures in the restorations were detected as early as two years. These fractures were observed exclusively in occlusally

loaded marginal ridges with pronounced overhangs in the direction of the approximating tooth. Bruxism was considered to be associated with the fractures in two cases. The two fractures (with Delta ratings) in the present study had the same scenario: heavy bite and unsupported porcelain as a result of overbuilding the marginal ridge into a diastema.

There were no incidences of recurrent caries for any of the restorations (Table 12). The restorations were carefully cemented with the resin cement, and the margins were finished and polished to achieve an adequate and tight seal. Recurrent caries would be an unexpected adverse event in such a short period of time. In a study of 96 ceramic inlays/onlays by Kramer and Frankenberger, secondary caries did not occur at all after 8 years.¹⁸

Most proximal contacts were rated Alfa (tight, firm contact) (Table 13). A few were rated Bravo (light contact but visually closed). However, 3 restorations had open contacts (Charlie), 2 as early as 1 week. One was a premolar crown with open mesial contact. This probably was not carefully checked before cementation, otherwise the crown could have been sent back to the laboratory for modification. This tooth ended up needing a root canal treatment, so the crown was replaced and the contact problem addressed. The second case was a molar inlay with open distal contact. The adjacent tooth was abscessed and slightly mobile. After root canal treatment, the tooth became firm again and the contact improved. However, the inlay eventually fractured and was replaced.

Even though this parameter was not directly related to the cements, it was evaluated to ensure adequate proximal contacts of the restorations for optimal tissue

health. This, however, would be an important parameter to evaluate if composite restorations (direct or indirect) were studied.

A summary of the different parameters with percentages of Alfa ratings for the 2 cements at 1 week and 6 months is shown in Table 14. There was very little change from baseline, and the high percentages of Alfa ratings for both cements indicated that the 2 cements were comparable in their clinical performance, and that no statistical analysis was necessary or indicated.

Table 15 summarizes the failures of the restorations cemented with the 2 cements. If anterior crowns and root canal treatments were excluded, the failure rates of restorations cemented with Maui and Unicem (6.45 and 6.90% respectively) were similar. Since anterior crowns were only cemented with Maui, they were excluded from the analysis to make a more valid comparison of the 2 cements. Root canal treatments, strictly speaking, were not restoration failures; and may have nothing to do with the cements. They were excluded from the analysis to give a more accurate estimation of the restoration failure rates.

The modes of failure were cohesive (3 fractures) and adhesive (1 dislodgement) in nature. The failures, incidentally, were all inlays/onlays. It is apparent that ceramic inlays without an adequate cavity depth and/or isthmus width are at higher risk of fracture.²¹ A preparation design that provides adequate bulk of porcelain is therefore essential.

In the study by Kramer et al, there is considerable indication that most of the fractures were attributed to fatigue mechanisms.¹⁸ Occlusal corrections may not have been polished sufficiently and the micro-cracks produced may have been prone for later

catastrophic fractures. The clinician should carefully polish inlay areas previously subjected to rotary occlusal corrections.

Though the use of self-adhesive cement is considered less 'technique sensitive', moisture contamination may have been the cause for the dislodgement of the onlay. Adequate moisture control, such as the use of rubber dam, is still essential in the cementation procedure.

2.6 Conclusions

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

1. The failure rates of the test cement, Maui, and the control cement, Unicem, were similar. There was no difference in any of the qualitative criteria that predict performance over the six month period, as shown by the high percentage of Alfa ratings for both cements. Therefore we accept the first null hypothesis, Ho1, that there is no significant difference in the clinical performance between the new test cement and the control cement.
2. Based upon the Two-way ANOVA, we accept the second null hypothesis, Ho2, that the test cement has no significant effect on post-cementation sensitivity at 1 week or 6 months after cementation, regardless of the type of restoration placed.
3. The performance of restorations with the test cement is clinically acceptable after 6 months, and is comparable with a similar, proven control cement.

2.7 References

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Appendix A: Evaluation Criteria

Criteria for Evaluation	Rating
Sensitivity	
No sensitivity	Alfa
Mild sensitivity to thermal or pressure stimuli	Bravo
Significant complaint or spontaneous response	Charlie
Severe sensitivity, intervention required	Delta
Gingival Index (Gingival score for gingival area nearest to restoration margin)	
Normal gingiva	0
Mild inflammation: slight change in color, slight edema, no bleeding on probing	1
Moderate inflammation: redness, edema and glazing, bleeding on probing	2
Severe inflammation: marked redness and edema, ulceration, tendency to spontaneous bleeding	3
Color Match (Evaluated wet at 12 inches for 3 – 4 seconds)	
Adjacent teeth and restoration have ideal color match; can distinguish restoration with some difficulty	Alfa
Readily perceptible difference in color, clinically acceptable	Bravo
Clinically unacceptable mismatch in color	Charlie
Marginal Discoloration (Evaluated with tooth dry)	
No visual evidence of marginal discoloration	Alfa
Marginal discoloration noted in 1 local area or less than 50% of exposed margin	Bravo-1
Marginal discoloration noted in multiple areas or more than 50% of exposed margin	Bravo-2
Marginal discoloration noted penetrating in a pulpal direction in 1 local area or less than 50% of the exposed margin	Charlie-1
Marginal discoloration noted penetrating in a pulpal direction in multiple areas or along 50% or more of the exposed margin	Charlie-2

Marginal Integrity

Marginal ditching (crevice) not detectable	Alfa-1
Probe catches at cavity margin, visible overhang or underfilled margin:	
Catch from tooth to restoration	Alfa-2
Catch from restoration to tooth	Alfa-3
Evidence of crevice formation into which explorer will penetrate along less than 50% of the margin	Bravo-1
Evidence of crevice formation into which explorer will penetrate along 50% or more of the margin	Bravo-2
Crevice formation with exposure of underlying dentin or base	Charlie
Restoration is mobile, fractured, or missing in part or in whole	Delta

Restoration Integrity

No fractures noted	Alfa
Small fracture which can be polished	Bravo
Fracture of material which needs repair but not replacement	Charlie
Fracture which requires replacement of restoration	Delta

Caries

No caries present	Alfa
Caries present associated with the restoration	Charlie

Proximal Contact (mesial and distal)

Tight (firm) contact	Alfa
Light contact but visually closed (allows free passage of shimstock)	Bravo
Contact visually open to light reflection	Charlie

Appendix B: Report on Failed Restorations

1. A crown on tooth #21 cemented with Unicem. The patient had pain and the tooth was found to be abscessed about 3 months after cementation. Root canal treatment was done and a new crown was made. The tooth originally had a gold inlay with recurrent caries. The inlay was removed, followed by caries removal, core build-up and crown preparation. The vitality of the tooth was in question, and trauma from preparation could have contributed to the problem. There was no 6 month recall.
2. An MOD inlay on #3 cemented with Unicem. The mesial part was found to be fractured and mobile at the 6 month recall. The restoration was subsequently removed, the tooth re-prepared and an onlay fabricated to cover the cusps to accommodate a heavy bite. Faulty preparation design: insufficient width of the isthmus, insufficient depth of the pulpal floor and sharp axio-pulpal line angle may have contributed to the failure. Six month recall data was collected.
3. An onlay on #15 cemented with Maui. A small part from the lingual fractured exposing the lingual cervical margin. The lingual cusp was the working cusp, the lingual reduction was probably inadequate and the restoration was rather thin at that area. The restoration was replaced with a new onlay, with further reduction of the lingual cusp. This happened about 5 months after cementation, therefore no 6 month recall data was obtained.

4. An onlay on #4 cemented with Unicem. The mesial part was found to be fractured at 6 month recall exposing the mesial cervical wall. The bite was heavy at the mesial marginal ridge area, as shown by clinical photos with articulating paper markings. The mesial part was over-extended to build the mesial marginal ridge into a diastema, creating unsupported porcelain. The restoration was replaced. Six month recall data was collected.
5. An onlay on #19 cemented with Maui. The whole restoration was dislodged about one-and-a-half months after cementation. It was recemented with another cement. It could be due to faulty preparation design with minimal retention or to inadequate moisture control during the cementation procedure. The restoration was taken out of the study; there was no 6 month recall.
6. An anterior crown on #27 cemented with Maui. The patient has generalized worn and sensitive teeth. This tooth showed a high sensitivity rating (pre-op) of 80 mm on the VAS. The patient did feel better after cementation, and the rating was 0 at 1 week (probably the tooth was becoming necrotic). The patient experienced pain about 1 month after cementation. She was referred to an endodontist and the tooth was diagnosed to be abscessed. Root canal treatment was done. The crown was replaced. There was no 6 month recall.

Appendix C: Consent Form

PATIENT CONSENT FORM

Title of Project: A Clinical Evaluation of a Self-Etch, Self-Adhesive Resin Cement for Bonding Indirect Restorations

Investigators: Peter Yaman, DDS, MS Principal Investigator
Joseph Dennison, DDS, MS Co-Investigator
Anthony Khoo, DMD Co-Investigator
Carol Stamm Clinic Research Coordinator

Sponsor: Dentsply/Caulk – financial and material support (Maui cement).

Purpose: To evaluate the clinical performance of a self-adhesive cement for bonding fillings and crowns first made in the laboratory and then fitted onto the teeth..

Procedure: To participate in the study, your treatment requires an all-ceramic restoration(s)(crown and/or inlay/onlay) that is fabricated by a dental laboratory and cemented onto your tooth with the self adhesive cement. Routine preoperative x-rays, local anesthesia, tooth preparation, impressions and crown fabrication will follow standard dental procedures. As part of the research, clinical photos, evaluations and impression will be taken of the restoration(s). Two different cements (Maui and Unicem) will be used in this study for crowns that are made for back teeth and for inlays/onlays. The first 15 crowns will be cemented with Unicem, and the remaining 15 crowns with Maui. The selection of the cement for the inlays/onlays will be randomized for either Unicem or Maui.

You will also be asked to come in for additional recall visits of 30 minutes each at 6, 12 and 24 months after the cementation, for evaluation of the restoration. You will return for a baseline evaluation between 5-7 days after cementation of the restoration.

Benefits: You will have a comprehensive oral examination, and an all-ceramic restoration that will restore your tooth to proper function and esthetics. The cement used, due to its self-adhesive property, may actually involve less chair time.

Incentive: You will also receive \$70 (if a crown is fabricated for you) at each recall visit, for a total of \$210 for the three visits; or \$50 (if an inlay or onlay is made for you) for each recall, for a total of \$150 for the three visits. Free parking will be provided.

Risks: They are minimal and are the usual risks that accompany routine dental restorative treatment. Possible risks include tooth sensitivity, fracture of the restoration, recurrent decay, the restoration coming off the tooth and possible need for a root canal. If any of the above occurs during the study period the restoration will be recemented with a traditional cement or replaced at the expense of the

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

Date

Signature of Investigator Obtaining Consent

Initial _____

Copy of consent form given

Appendix D:

Analog Scale for Sensitivity – MAUI

Name: _____ Reg #: _____ ID#: M- _____

Address: _____ Phone H/W: _____

City, State, Zip: _____ E-mail: _____ Tooth #: _____

Baseline: _____

No Sensitivity

Severe Sensitivity

1 week Recall: _____

No Sensitivity

Severe Sensitivity

6 month Recall: _____

No Sensitivity

Severe Sensitivity