A COMPARATIVE EVALUATION OF TENSILE BOND STRENGTH AND MICRO-LEAKAGE OF A NOVEL SELF-ADHESIVE FLOWABLE COMPOSITE AND SELF-ETCH ADHESIVE COMPOSITE SYSTEM – AN IN -VITRO STUDY

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This is to certify that the dissertation titled "**A COMPARATIVE EVALUATION OF TENSILE BOND STRENGTH AND MICRO-LEAKAGE OF A NOVEL SELF-ADHESIVE FLOWABLE COMPOSITE AND SELF-ETCH ADHESIVE COMPOSITE SYSTEM – AN IN-VITRO STUDY**" is a bonafide work done by **Dr. M.KAMATCHI,** Postgraduate student, during the course of the study for the degree of **MASTER OF DENTAL SURGERY** in the specialty of **PEDODONTICS AND PREVENTIVE DENTISTRY** , Vivekanandha Dental College for Women, Tiruchengode, during the period of 2015-2018.

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DECLARATION

TITLE OF DISSERTATION	A comparative evaluation of tensile bond strength and micro-leakage of a novel self-adhesive flowable composite and self-etch adhesive composite system-an in-vitro study
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Post Graduate Student

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S.No.	ABBREVIATIONS	EXPANSIONS
1.	BIS-GMA	Bisphenol A-Glycidyl methacrylate
2.	HEMA	Hydroxy ethyl methacrylate
3.	TEGDMA	Triethylene glycol dimethacrylate
4.	BIS-EMA	Bisphenol A ethoxylate dimethacrylate
5.	UDMA	Urethane dimethacrylate
6.	GPDM	Glycerol-phosphate dimethacrylate
7.	SAF	Self-adhering flowable composite resin
8.	SEA	Self-etch adhesive flowable composite resin
9.	TBS	Tensile bond strength
10.	NL	Without cyclic loading
11.	L	With cyclic loading
12.	µ	Micro-leakage
13.	SEM	Scanning electron microscope
14.	N	Newton
15.	MO	Mesio-occlusal
16.	CTE	Co-efficient of thermal expansion

Adhesion is a complex set of physical, chemical, and mechanical process that allow the attachment and binding of one substance to another dissimilar substrate. According to the American Society for Testing and Materials (ASTM; specification D 907), adhesion is defined as “the state in which two surfaces are held together by interfacial forces which may consist of valence forces or interlocking forces or both”.

An adhesive is a viscous fluid material which joins two substrates together and solidifies, and henceforth is able to transfer a load from one surface to another. Four different mechanisms of adhesion have been described in the literature. Firstly, mechanical adhesion, that is, interlocking of the adhesive with surface irregularities of the substrate. Second is the adsorption adhesion which is chemical bonding between the adhesive and the substrate. The forces involved may be primary or secondary valence forces. Third is the diffusion adhesion which means interlocking between unstable molecules, such as the adhesion of two polymers through diffusion of polymer chain. Fourth mechanism is the electrostatic adhesion in which an electrical double layer at the interface of a metal with a polymer that is part of the total bonding mechanism. [1]

The trend of adhesion in dentistry commenced at the mid 1960s with the advent of the first commercial resin monomer BIS-GMA [Bisphenol A-Glycidyl methacrylate] invented by Bowen

Bonding of resins to tooth structure may be a result of four probable mechanisms:

1. Mechanical: Penetration of resin and formation of resin tags within the tooth surface.

2. Diffusion: Precipitation of substances on the tooth surfaces to which resin monomers can bond mechanically or chemically.

3. Adsorption: Chemical bonding to the inorganic component or organic collagen components of tooth structure.

4. A combination of the all the above mechanisms.

To obtain good adhesion, an intimate surface contact should exist between the adhesive and the adherend (tooth surface). Furthermore, the surface tension of the adhesive must be lower than the surface energy of tooth structure. [2]

The goal and functions of a dental bonding adhesive system are to provide strong durable bond resisting separation of an adherend substrate from a restorative or cementing material so that there exists optimum retention, distribution of stress along bonded interfaces, better color stability, and sealing the interface between dentin and/or enamel and the bonded material ensuring no or minimal microleakage. Hence, an adhesive system should assure decreased risk of post-operative sensitivity, marginal leakage, and secondary caries. [1]

Modern adhesive dentistry offers certain significant advantages as it allows hard tissue conservation, which in turn paves way for effective and efficient restoration. The foundation for modern adhesive dentistry was laid in 1955, when Buonocore reported that acid etching created the ability to produce clean, high energy, roughened tooth surfaces capable of establishing a micro-mechanical retentive interface with resin-based luting and restorative materials. Presently, acid etching is one of the most effective ways to achieve restoration retention and it ensured a sealed interfacial joint at restoration margins. Acid etching has markedly expanded the use of resin-based restorative materials as it provided a intricate, strong, durable bond between resin and tooth structure. [2] Since that time, the dental adhesive systems evolved through a number of generations with changes in their chemistries, mechanisms of bonding, number of bottles, methods of application, and clinical effectiveness. [3]

Etching and bonding mechanisms differ for enamel and dentin due to its physical and chemical differences. Enamel has little potential for bonding by micromechanical retention because the surface appears smooth. Phosphoric acid is the most commonly used acid to etch the tooth surface as described by Buonocore. On acid-treatment, the ultra-structure of the enamel surface is modified considerably. Phosphoric acid solution is difficult to control when applied to the smooth surface of enamel. Some acid inevitably contacts other areas of tooth, which are not intended to be etched. Development of acidified gels alleviated this problem and provided a confined etched tooth surface. The acidified gel contains 37% phosphoric acid in viscous aqueous gel, which shall be applied onto the enamel surface in well-controlled manner in the desired area. [4]

The pattern of etching enamel can be variable. Silverstone in 1975 identified 3 basic types of etching patterns. Most commonly [type 1] the enamel prism cores are removed preferentially and the prism peripheries remain intact. The type 2 etching pattern is the exact converse of type 1, where the cores are being left intact and the prism peripheries are removed preferentially. The type 3 etching pattern appears with resemblance of both type 1 and type 2 along with less distinct areas where the pattern of etching does not correlate to the morphology of enamel prism.

Bonding mechanism to enamel involves the resin to penetrate into the relatively porous surface of the enamel, which has been etched to form an interlocking mechanically. It was thought many years ago that a similar pattern of bonding mechanism could be used on dentine surface too. This procedure involve acid-etching of the exposed dentinal surface to expose the patent dentinal tubules into which the resin penetrated to form resin tags. Potential damaging effect on exposed dentine by phosphoric acid etching was the hurdle in achieving bond. This was considered as an established fact that phosphoric acid-etching in contact with vital dentine caused irritation and/or irreversible pathological damage to the pulp. Etching dentine opens dentinal tubules and encourages dentinal fluid flow. Adhesive resin monomers are relatively hydrophobic. The moisture content of the dentinal surface due to the dentinal fluid flow is likely to make bonding more difficult.

A major problem recognized was the inability of the hydrophobic adhesive resin monomers to wet the moist dentinal surfaces and hindrance to close enough adaptation of adhesive resin to dentinal surfaces to meet bonding criteria. Drying of dentine as an important step in the bonding procedure was the earliest attempts to achieve bonding. Currently, drying procedures lead to desiccation of dentine and tries to overcome the moisture problem by the use of primers and solvents. Moisture content of dentin before applying adhesives may have effect on their bond efficacy. However, the effect of moist or dried dentin on the efficacy of bond strength of adhesives in dental clinical procedures has not been fully documented. [5] Nevertheless, it is also recognized that in anaesthetized teeth, dentinal tubular fluid flow is negligible due to the vasoconstrictor effect of the local anaesthetic solution. The dentinal tubule openings occupy only about 5% of the cut dentine surface at the dentino-enamel junction. This increases to nearly 20% in deep dentine. Therefore, it was suggested that when the adhesive monomer penetrates into dentinal tubules for the formation of resin tags, the relatively small proportion of the area being utilized would limit the bonding effectiveness to dentine. In the 1970s and 1980s, dentine bonding was considered desirable. Numerous researches sprouted in an attempt to achieve bonding to dentine through the formation of chemical links between adhesives and chemical moieties in the dentine surface. These events soon led to a burgeoning growth in the manufacture of different adhesive monomers and bonding techniques, into the beginning of the twenty-first century. Concepts in adhesive dentistry have been changing continuously during the past decades, and steadily gained pivotal importance.

Current strategies in adhesive dentistry involve two distinct methods. Firstly, the total-etch bonding technique, which is characterized by the complexity of its components and of the bonding procedure. Simultaneous etching of enamel and dentin is the basis for the total-etch technique, which leads to hybridization at resin-dentine interface by a molecular level mixture of adhesive polymers and dentinal hard tissues. [6]

In etch-and-rinse adhesives, an initial etching step is compulsorily followed by a rinsing phase. This etching step de-mineralizes dentin and removes the smear layer and smear plugs to achieve a micro-porous surface for enhanced bonding capacity. Originally, etch-and-rinse systems typically consisted of three separate application steps: (a) conditioning / etching; (b) priming; and (c) adhesive resin application. An adhesive system following this sequence of clinical procedure is called a three-step etch-and-rinse adhesive. A two-step etch-and-rinse adhesive has been designed as an attempt of simplification, which combines the priming and bonding steps into one. In three-step etch-and-rinse adhesives, the priming step should ensure sufficient wetting of the exposed collagen fibrils and remove remaining water aiding in adhesive resin infiltration. HEMA [Hydroxy ethyl methacrylate] or TEGDMA [triethylene glycol dimethacrylate] are some important hydrophilic monomers that are very frequently added in primer solutions. Both three- and two-step etch-and-rinse adhesives possess similar mechanism of adhesion. [7]

Nowadays, efforts are being made to simplify and shorten bonding procedures while retaining the effectiveness of dentin adhesives. [8] The second strategy in adhesive dentistry is the self-etching systems. Self-etch adhesives do not require a separate “etch-and-rinse” phase because of its acidic monomer content, which simultaneously condition and prime the tooth surface when applied. Hence, the smear layer, which has dissolved and de-mineralized products are not rinsed away. However, they are incorporated in the adhesive resin. Self-etching adhesive systems were developed to eliminate dentist variables and minimize chair-side time. [9]

A two-step and a one-step self-etch adhesive systems exist just like the etch-and rinse adhesives. Two-step self-etch systems consisted of an acidic primer application, followed by an adhesive resin. Recently, “all-in-one” adhesives or one-step self-etch adhesives have been evolved that combine etching, priming and conditioning in one solution. Since, single-bottle systems are highly hydrophilic adhesive monomers, which means they are permeable to water movement, it was concluded that they were the best promising adhesive approach. [10] Solvent-free self-etch adhesive in which the solvent contained in all other adhesive systems having been removed was introduced later. [11] This type of adhesive has created a possibility of an interactive ionic bond between the tooth minerals and the resins of the bonding agent without the use of water, acetone, or alcohol. [11,12]

When compared with etch-and-rinse adhesives, self-etch adhesives have many advantages. Omitting the rinsing phase in etch-and-rinse adhesives and thus reducing the chair-side time. Conditioning, rinsing and drying steps are eliminated, which is critical and difficult to standardize in clinical scenario. Technique sensitivity in mechanism of bonding to dehydrated demineralized dentin has been eliminated, as it avoids rinsing and drying. Collagen network collapse is prevented, as monomers infiltrate concomitantly as they get demineralize. Rewetting of dentin by dentinal fluid from the tubules is prevented, as the smear layer and smear plugs are not removed. Hence, potential post-operative sensitivity has been reduced. [13]

Prolonged mouth opening and maintaining the operatory field moisture free during composite restoration procedures in young children is a challenge to every pediatric dentist. Conventional, total-etch or self-etch adhesive systems are time consuming and hectic procedures in pediatric care. However, the introduction of a novel self-adhesive flowable composite dramatically decreased the chairside time. Limited studies have been conducted in comparing the bond strength efficacy of conventional systems and self-adhesive flowable composite resins.

Currently, Constic DMG, a novel self-adhesive flowable composite, has been evolved that eliminates both etching and bonding steps in composite restoration and associated time expenditure when treating young children in pediatric dental care. [14,15] They possess a superior esthetic properties and low viscosity, which makes them easier to place and more self-adaptable than conventional composite resins. [16] Self-adhesive flowable composite resin hybrids the merits of adhesive and restorative technologies in single product. Hence, it is a direct composite resin restorative material that has an adhesive resin together with a flowable composite resin with BIS-GMA as a principal resin matrix. [17] The bonding technology of Constic DMG self adhesive flowable resin is unclear and necessitates future investigations on these perspectives. Another self-adhesive flowable composite, Vertise-Flow [Kerr] that uses glycerol-phosphate dimethacrylate (GPDM) to etch enamel/dentin, and a hydrophilic monomer HEMA to enhance penetration by resin into exposed dentin. [18] This resin not only bonds micromechanically between the polymerized monomers of the self-adhering flowable composite resin and the collagen fibers and smear layer of dentin but also chemically between the phosphate groups of a GPDM monomer and the hydroxyapatite of tooth structure. [17,19]

Effective replacement of tooth structure is the major goal of restorative treatment. The interface must resist dimensional changes in order to prevent deterioration of the seal between adhesive resin and dentin. The restoration may deteriorate eventually due to chemical, thermal, and mechanical load stresses even when the polymerization shrinkage is controlled. It is mandatory to formulate a methodology using different stresses, since rapid evolution of adhesive resins does not allow for long-term clinical trial evaluations. Therefore, it has been advocated to apply in-vitro methodologies using different types of stresses to simulate the aging of restorations. These stressing strategies could hasten deterioration of the dentin/adhesive interface, and enable better evaluation of adhesive materials exposed to stresses in a similar pattern existing in the oral environment. [20]

Differences existing in the coefficient of thermal expansion between enamel/dentin and adhesives or restorative resins might induce degradation of the tooth-restoration interface. Thermal cycling test in composite resin restorations is frequently employed in laboratory studies evaluating micro-leakage in order to simulate changing intraoral temperature conditions. [21]

Teeth are subjected to occlusal stresses when they come in contact in both centric and eccentric positions. [22] Compressive stresses arise on the tooth aspect being bent, while tensile stresses are generated simultaneously on the opposite tooth aspect. Exactly a same scenario occurs in cervically restored teeth when subjected to occlusal loading, which may lead to restoration dislodgement at their cavo-surface margin. [23] Thus, in terms of leakage, the marginal integrity of resin composite restorations is highly affected by cyclic loading.

An in-vitro simulation of masticatory loads is necessary to measure the effect of cyclic loading on micro-leakage at the resin–dentin interface. [20] The most frequently used laboratory tests to study the mechanisms that may minimize, or eliminate, the leakage around composite restorations are microleakage tests using dye-penetration technique. A microleakage test is a useful method in the investigation of resin composite restorations though the clinical relevance of the tests does not always correlate appropriately with the clinical situation. [24] Moreover, the consequences of both thermal cycling and cyclic loading on the micro-leakage of self-adhesive flowable composite resin used in cervical composite restorations have yet to be completely analyzed.

Since there is a paucity of information regarding self adhesive flowable composite, the present study was conducted to test tensile bond strength and microleakage of self adhesive flowable composite and self etch adhesive composite.

Aim:

Aim of this in-vitro study was to compare the bond strength of self-adhesive flowable [SAF] composite with that of self-etch adhesive [SEA] systems. Also, to evaluate the longevity of the composite restoration seal in response to mechanical stresses, in terms of micro-leakage.

Objectives:

1. To measure and compare the tensile bond strength of self-etch adhesive-composite system and self-adhesive flowable composite regarding to dentin.
2. To determine whether or not cyclic loading influences the bond strength of the materials compared.
3. To assess and compare the degree of micro-leakage between self-etch adhesive-composite system and self-adhesive flowable composite by using dye penetration technique.
4. To determine whether or not artificial ageing like occlusal cyclic loading influence micro-leakage.
5. To determine the efficacy of self adhesive flowable composite in terms of bond strength in children.

Nelson et al [25] [1952] experimented the fluid exchange at the margins of dental restorations. Temperature changes of teeth and restorations in the mouth cause a fluid exchange between the teeth and restorations made of gutta-percha, zinc oxide and eugenol cement, silicate cement, zinc phosphate cement, amalgam, cast gold, gold foil and acrylic resin. This marginal percolation is caused in part by a difference in the coefficients of thermal expansion of the tooth and the restoration and by thermal expansion of the fluid occupying the crevice between the tooth and the restoration. In light of the present concepts of the mechanisms of dental caries, marginal percolation may be an explanation for the recurrence o f caries at the margins of some restorations. Further observation of the influence of marginal percolation as a factor in the efficiency of the direct filling resin as a permanent filling material is required.

Kidd et al [26] [1978] studied the cavity sealing ability of composite restorations subjected to thermal stress and concluded that thermal percolation may not be of clinical significance in relation to composite restorations.

Luscher et al [27] [1978] investigated the microleakage and marginal adaptation of composite resin restorations in class II cavities. It has been shown that the use of a sealant offered no advantage with respect to the retentive strength of a composite resin restoration. However, for the improvement of marginal seal and adaptation, the results indicate that enamel etching and the application of a sealant, in conjunction with use of a cavity geometry which reduces shrinkage strain, are absolute necessities.

Fusayama et al [28] [1979] investigated the non-pressure adhesion of clearfil bonding system employing tensile test. The material was found to be adhesive to both enamel and dentin as well as to carious dentin and showed strong adhesion to all substrated which were tested. Additionally they found that acid etching further increased the adhesion to dentin

Harper et al [29] [1980] studied the in-vivo measurements of thermal diffusion through restorations of various materials. Temperature diffusion was highest through amalgam restorations and slowest through unfilled resin restorations. The rate of diffusion through composite resins and silicate cement fell between the extremes. Bases of both zinc phosphate cement and zinc oxide-eugenol cement reduced the rate of temperature change on the floor of the cavity beneath amalgam restorations. The temperature change was generally less under the 1 mm base than the 0.5 mm base. Bases used beneath the nonmetallic restorations did not reduce the magnitude of temperature change on the cavity floor.

Crim and Mattingly [30] [1981] evaluated two methods such as thermocycling and constant temperature immersion in basic fuschin dye to assess the marginal microleakage. The results of this study showed significant differences between these two methods and concluded that thermocycling was effective in testing microleakage because it simulates oral conditions.

Quist [31] [1983] evaluated the effect of mastication on marginal adaptation of composite restorations in vivo. The results showed that functional mastication has a major influence on the marginal adaptation of composite restorations in the oral environment and must therefore be considered in the planning of future leakage experiments.

Lee and Eakle [32] [1984] studied the possible role of tensile stress in the etiology of cervical erosive lesions of teeth. It was proposed that when occlusion is not ideal, lateral forces cause the teeth to bend. The tensile stresses created during bending disrupt the chemical bonds of the crystalline structures of enamel and dentin. Small molecules may enter between the crystals and prevent the reestablishment of the chemical bonds. As a result, the disrupted tooth structure is more susceptible to loss through dissolution and abrasion and results in the development of the typically wedge-shaped lesions.

Crim et al [33] [1985] compared the effectiveness of four thermocycling techniques, with basic fuchsin dye and ^{45}Ca radio-isotope used as the tracers. This investigation revealed no significant difference among the four thermocycling techniques. The use of a dye or an isotope was equally effective and penetrated the tooth/restoration interface to a similar degree. The extent of tracer penetration appeared to be independent of the dwell time in the thermal baths. They also suggested that all procedures involving thermal changes were more potent in demonstrating leakage than the non-cycled method.

Darbyshire et al [34] [1988] evaluated the microleakage in Class II composite restorations bonded to dentin using thermal and load cycling. All restorations exhibited microleakage which was unaffected by load cycling. Both the dentin bonding agent and the glass ionomer cement liner significantly reduced microleakage independently. When glass ionomer cement liner was present, the additional presence of the dentin bonding agent did not provide a statistically significant additional reduction of microleakage.

Munksgaard and Irie [35] [1988] studied the effect of load-cycling on bond strength between composite fillings and dentin established by Gluma and various resins like Silux, P-30, or Concise in cylindrical dentin cavities. They concluded that fillings made of Silux, P-30, or Concise exhibited margins without stain upon axial loading in most cases and added that load cycling does not affect the marginal seal.

Meerbeek et al [23] [1993] compared the clinical effectiveness of two dentin adhesives, Clearfil New Bond and Scotchbond-2, was evaluated in two different cavity designs. It was concluded that the adhesion of current dental materials to dentin is more promising. Although the clinical effectiveness of present dentin bonding agents has not achieved the efficacy of enamel bonding agents, a trend of improvement is apparent with specific products. Nevertheless, more longitudinal in vivo studies are necessary to support their effectiveness. Clinical marginal adaptation is directly influenced by the type of composite resin used.

Van Meerbeek et al [36] [1993] comparatively examined the ultra-structure of the resin-dentin inter-diffusion zone through scanning and transmission electron microscopes. It was concluded that diffusion of resin monomers into the decalcified dentin surface layer diminishes with depth, probably resulting in resin encapsulation of remaining hydroxyapatite crystals at the base layer of the interdiffusion zone. The acidic dentin pretreatment probably caused de-naturation of superficial collagen fibrils.

Nakabayashi and Saimi [37] [1996] described the bonding mechanism of the adhesives to the intact dentin. It has been reported that the presence of a smear layer on dentinal substrates can compromise bonding. Typically, smear layers are removed by acidic agents that selectively extract calcium salts from dentin surfaces to leave a collagen-rich substrate. Hybrid layers identified under microscopic examination demonstrated resistance to both hydrochloric acid and sodium hypochlorite treatments, suggesting that the hybrid layer was not defective, and that bonding was stable.

Christensen [38] [2001] reviewed the four categories of dentin-bonding agents available, viz, three and two component materials of the total-etch concept and two and single component materials of the self-etching primer concept. He concluded that The "self-etching" primer concept has proved itself both scientifically and clinically. The concept reduces clinical steps, can be placed inexpensively, provides adequate bonding to dentin and enamel and, most importantly, ensures the patient's postoperative comfort.

Eliades et al [10] [2001] studied the diverse supply of one-bottle adhesive monomers in the resin-dentin inter-dispersion zone. It is beyond any doubt that the clinical use of single-bottle adhesives, especially when applied in a single-layer, simplifies and shortens restorative treatment. However, monomer separation as found in the present study along with the previously documented moisture sensitivity of these adhesives preclude any extrapolation of original adhesives preclude any extrapolation of original adhesive film properties to the clinical analog. A re-assessment of the design of single-bottle adhesives aiming to the development of products with structural homogeneity of the polymer network formed in the resin infiltrated dentin may substantially improve clinical performance.

Meerbeek et al [39] [2001] provided an overview of commercial adhesives recently used and classified according to their adhesive approach towards enamel and dentin. Some critical steps in the rather technique-sensitive bonding procedure are discussed in detail. Finally, bonding effectiveness of a selected group of adhesives is presented in terms of micro-tensile bond strength to enamel and dentin and by clinical retention rates in Class V non-carious cervical lesions. An adhesive restoration, in conclusion, has many advantages over conventional non-adhesive restorative techniques except that it cannot yet be realized in a simple way.

Perdigao and Swift [40] [2002] published the fundamental concepts of enamel and dentin adhesion. They described the four basic four mechanisms of adhesion to substrates. They are mechanical, adsorption, diffusion, and electrostatic adhesive mechanisms. However, the first three mechanisms holds true for adhesion to happen with the tooth structure. Various generations of dental adhesives were described according to the bonding strategies used.

Swift [3] [2002] reviewed the dentin and enamel adhesives. He described the current strategies for bonding composite resin materials to tooth structure. The two main methods described were the total-etch and self-etch adhesives. Either of the strategies had their own advantages and disadvantages. It was concluded that there was a market shift towards the self-etch adhesives due to its less post-operative sensitivity. However, there were no proven clinical performance studies regarding these materials.

Pazinatto et al [24] [2003] studied the effect of the number of thermocycles on microleakage of resin composite restorations and concluded that there is no direct relation between the use of the thermocycling test and an increase of microleakage of resin composite restorations. The number of thermocycles did not increase microleakage.

Bedron-de-Casro et al [20] [2004] studied the result of thermal and mechanical load cycling on nanoleakage of class II composite resin restorations and concluded that thermal and mechanical load cycling combined adversely affected nanoleakage. In addition they also stated that simulation of the oral condition might be crucial to better evaluate and understand the performance of adhesive materials.

Yoshida et al [12] [2004] comparatively evaluated the adhesive performance of functional monomers. Mild self-etch adhesives demineralize dentin only partially, leaving hydroxyapatite around collagen within a submicron hybrid layer. They hypothesized that this residual hydroxyapatite may serve as a receptor for chemical interaction with the functional monomer and, subsequently, contribute to adhesive performance in addition to micro-mechanical hybridization. Therefore, chemically characterized the adhesive interaction of three functional monomers with synthetic hydroxyapatite, using x-ray photoelectron spectroscopy and atomic absorption spectrophotometry. They further characterized their interaction with dentin ultra-morphologically, using transmission electron microscopy. The monomer 10-methacryloxydecyl di-hydrogen phosphate (10-MDP) readily adhered to hydroxyapatite. This bond appeared very stable, as confirmed by the low dissolution rate of its calcium salt in water. The bonding potential of 4-methacryloxyethyl trimellitic acid (4-META) was substantially lower. The monomer 2-methacryloxyethyl phenyl hydrogen phosphate (phenyl-P) and its bond to hydroxyapatite did not appear to be hydrolytically stable. Besides self-etching dentin, specific functional monomers have additional chemical bonding efficacy that is expected to contribute to their adhesive potential to tooth tissue.

Stalin et al [13] [2005] evaluated tensile bond strength, fracture mode and microleakage of fifth and sixth generation adhesive systems in primary dentition and concluded that concerning the single step application with similar efficacy, the self-etching adhesive is better for bonding in primary dentition.

Dhanyakumar et al [8] [2006] compared the micro-shear bond strength of adhesive resins to dentin at crown versus dentin at pulpal floor and concluded that micro-shear bond strength was higher to coronal dentin when compared to dentin at floor of pulp chamber.

Mitsui et al [21] [2006] evaluated the influence of different thermal and mechanical cycling protocols on microtensile bond strength to cervical dentin margins of Class II restorations using two total-etch adhesives and one self etching primer. The effectiveness of the cycling protocols showed different behaviors according to the adhesive system evaluated. They concluded that the higher the amount of thermal/mechanical cycles, the greater the number of mixed failures and the lower the percentage of adhesive failures.

McCabe and Walls [4] [2008] reviewed about various adhesive strategies available in the literature. It was concluded that contamination of an etched dentinal / enamel surface with saliva or gingival crevicular fluid would prevent bonding and facilitate microleakage as a sequel. Furthermore, they are di-methacrylate-based adhesives and would undergo apparent shrinkage during polymerization. Whilst the luting space ought to be relatively small, in most instances, the C factor is very large as the only free surface is the restoration margins. This might not be a problem for extra-coronal restorations. It is however a problem with inlays where considerable tensile load strain continues to be applied on the remaining tooth structure.

Mandava et al [6] [2009] compared the TBS of total-etch adhesives and Self-etch adhesives with single and multiple consecutive applications and concluded that the application of multiple coats of total-etch adhesive improves bond strength to dentin.

Miyasaka and Okamura [16] [2009] studied the dimensions of conventional and flowable composite resins by means of a laser dislodgment sensor and concluded that the polymerization shrinkage was less and compressive strength was higher for the conventional composite resins than flowable composite. In lights of the results obtained in this study, the newly developed displacement meter with a laser displacement sensor proved to be effective for in-depth investigation of the polymerization shrinkage of dental composites.

Vichi et al [35] [2009] evaluated a six-month follow-up period of the clinical outcome of restorations performed with a new self-adhering flowable composite resin. It was concluded that all the evaluated restorations remained in place and in acceptable conditions over the 6-month follow-up period. No post-operative sensitivity was recorded at any evaluation.

Ameri et al [22] [2010] illustrated the consequence of load cycling on nanoleakage of butt joint, occlusal enamel margins with bevelling in Class V composite resin restorations, and concluded that load cycling influences nanoleakage of margins of Class V composite restorations, but enamel margin configuration does not affect nanoleakage. Since enamel margin configuration does not affect nanoleakage, there is no need for enamel beveling of shallow Class V cavity preparations for composite restorations at present

Poss et al [18] [2010] described a technique of utilization of a New Self-Adhering Flowable Composite Resin and concluded that using a flowable composite system that has multiple uses, and because it is a self-adhering composite, chair time is saved for both the clinician and the patient.

Hedge et al [9] [2012] carried out a estimation of new total etching and self etching adhesive system interfaces with dentin morphologically. The adaptation of self-etch adhesives to the resin- dentin interface was good without voids or separation of phases; showing a thin, continuous hybrid layer. It was concluded that such an adaptation of resin with dentin tissue, as in the case of self-etch adhesives, was required for better treatment outcome to reduce postoperative sensitivity.

Rengo C et al [41] [2012] evaluated the influence of preliminary phosphoric acid etching on the microleakage of a self-adhering flowable composite and a self-etch adhesive used in combination with the proprietary flowable composite. They concluded that the early sealing ability of the self-adhering flowable composite and the self-etch adhesive in Class V restorations did not significantly advantage from selective enamel etching and added that preliminary phosphoric acid etching of dentine negatively exaggerated the quality of the seal when using the adhesive-free flowable composite.

Sadeghi [14] [2012] studied an in-vitro microleakage of class V cavities restored with a new self-adhesive flowable composite resin and different flowable materials and concluded that the application of self-adhesive flowable composite provided better occlusal marginal sealing.

Bektas et al [17] [2013] evaluated the micro-shear bond strength and microleakage of a self-adhering flowable composite and arrived at a conclusion that self-adhering flowable composite resin combined with adhesive resin provided stronger dentin bond strength and a better marginal seal than when it was used individually.

Fu et al [42] [2013] studied the bonding act of a recently developed step-less all-in-one system on dentin and concluded that there are significant differences in the bond durability between the newly developed step-less 1-step system, self-adhering light-cured flowable composite resin and the 2-step systems.

Swathi et al [43] [2014] evaluated the effect of single and multiple consecutive applications of all-in-one adhesive on tensile bond strength to dentin and concluded that the bond strength with two consecutive applications of all-in-one self etch adhesive was significantly higher than with a single application, but application of further coatings caused a decrease in bond strength..

Malik et al [5] [2014] determined the tensile bond strength of total etch and self etch adhesives on air dried and moist dentin substrates and post operative sensitivity after one week, under clinical conditions and concluded that the post-operative sensitivity after one week was found to be maximum in total-etch bonding agent, moist dentin group.

Koliniotou-Koumpia et al [11] [2014] compared the shear bond strength of a solvent free adhesive and current adhesive systems. It was concluded that elimination of the solvent from a self-etch adhesive system may lead to decrease of infiltration of the adhesive components into the dental tissue’s microstructures, debility of hybrid zone formation and eventually to a decrease of the bond strength to the dentin.

Abo El Naga et al [44] [2015] evaluated the act of a self-adhesive flowable composite and two self-etching adhesive systems, when subjected to cyclic loading inorder to prevent the nanoleakage of class V restorations and concluded that the self-adhesive flowable composite provided superior sealing ability. Although two tested adhesive systems showed increased nanoleakage as a result of cyclic loading.

Materials used in the study:

The following materials and equipments were used in the study

- **Filtek Z350 XT flowable restorative resin – A2 shade (3M ESPE)**

Product Description

3M ESPE Filtek Z350 XT universal restorative is a visible light-activated composite designed for use in anterior and posterior restorations. All shades are radiopaque. A dental adhesive, such as those manufactured by 3M ESPE, is used to permanently bond the restoration to the tooth structure. The restorative is available in a wide variety of Dentin, Body, Enamel and Translucent shades. It is packaged in syringes and single-dose capsules.

Indications for Use

Filtek Z350 XT restorative is indicated for use in:

• Direct anterior and posterior restorations (including occlusal surfaces)

• Core build-ups

• Splinting

• Indirect restorations (including inlays, onlays and veneers)

Composition

The resin contains bis-GMA, UDMA, TEGDMA, and bis-EMA resins. The fillers are a combination of non-agglomerated/non-aggregated 20 nm silica filler, non-agglomerated/non-aggregated 4 to 11 nm zirconia filler, and aggregated zirconia/silica cluster filler (comprised of 20 nm silica and 4 to 11 nm zirconia particles). The Dentin, Enamel and Body (DEB) 3 shades have an average cluster particle size of 0.6 to 10 microns. The Translucent (T)4 shades have an average cluster particle size of

0.6 to 20 microns. The inorganic filler loading is about 72.5% by weight (55.6% by volume) for the translucent shades and 78.5% by weight (63.3% by volume) for all other shades.

- **Constic – self adhesive flowable resin- A2 shade (DMG)**

Product description

Constic is a self-etching, self-adhesive, radiopaque, flowable composite which is light-cured. The composite is immediately ready for use because the preparatory steps of etching, priming and bonding are contained in Constic.

Indications

- Small restorations of class I.
- Cavity liner for class I and II.
- Fissure sealing.
- Repairs of composite restorations.
- Modifications to temporaries and long-term temporaries.
- Blocking out and filling of undercuts in cavities.
- Small occlusal primary tooth cavities.

Contra-indications

- Do not use Constic in the case of allergies to any of the components or in the event of contact allergies.
- Application of the material is contraindicated if dry isolation or the recommended application technique is not possible.
- Do not apply to the exposed pulp.
- Do not use on etched dentine.

Composition

Barium glass in a Bis-GMA-based matrix from dental resins. Pigments, additives and catalyst. Filler content: 65 wt.-% = 38 vol.-%. The range of variation of the inorganic filler particles is between 0.02 and 2.3 μm.

The other materials and equipments are as follows:

- Single bond – Universal – adhesive (3M ESPE)
- Self cure acrylic resin
- Micromotor with diamond disc
- Light curing unit.
- Metal split mold -5mm height and 4 mm diameter.
- Applicator tip
- Luer lock tip syringe
- 26 gauge ligature wire
- Basic fuschin dye
- Dental stone
- Universal testing machine [Lloyd LRX Plus II universal testing machine - Ametek, Inc.,USA; Model UNITEK-94100; FIE Pvt. Ltd]
- Stereomicroscope - X40 magnification [Olympus]
- Thermocycling unit [RTD dental products, France]

Materials to be compared:

I. Self-etch adhesive [SEA] system - Filtek Z350 XT, 3M ESPE [Figure 1a]

II. Self-adhesive flowable [SAF] composite resin - Constic, DMG [Figure 1b]

Sample size calculation:

Single Mean - Hypothesis testing - one population mean

Standard Deviation = 1.5, Sample mean = **3.95**, Population mean = 4.5

Alpha Error(%) = 5, Power (%) = 80, sided = 2, Effect Size = .4533

$$E = z_{\alpha/2} \cdot \frac{\sigma}{\sqrt{n}} \qquad n = \left[\frac{z_{\alpha/2}\sigma}{E} \right]^2$$

Number needed (n)= 30

Using the above formula , sample size of 30 was obtained. Henceforth 30 sample was selected for each group**.**

Sample collection:

A total of 120 intact non-carious human maxillary premolars [n=120] extracted for orthodontic treatment were collected and cleaned, explored, and decontaminated. Exclusion criteria included carious teeth, teeth with extrinsic and intrinsic stains, enamel hypoplasia and fractures.

Criteria to be evaluated: [Groups]

Group A1: Tensile bond strength with cyclic loading [TBS-L].

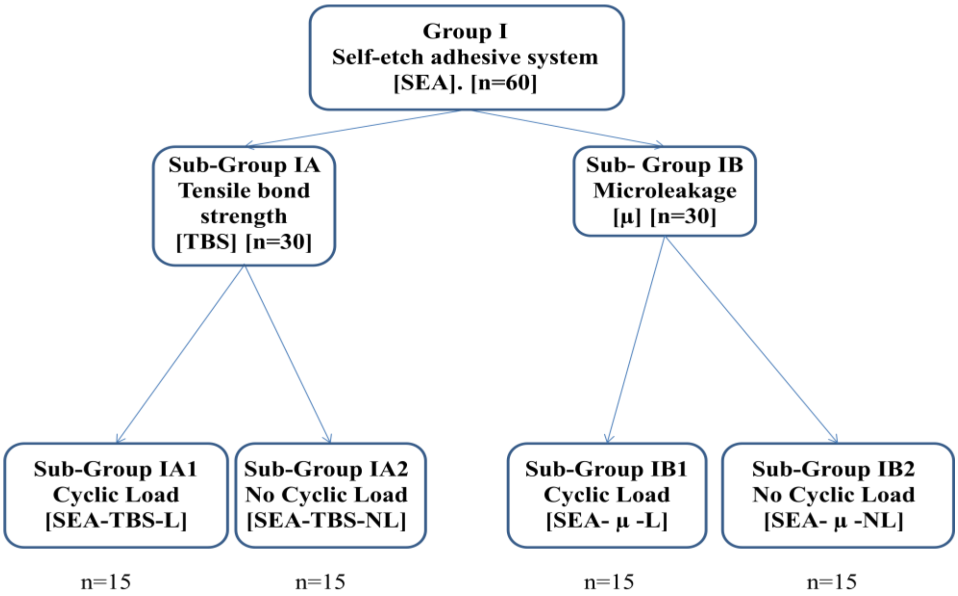
Group A2: Tensile bond strength with no cyclic loading [TBS-NL].

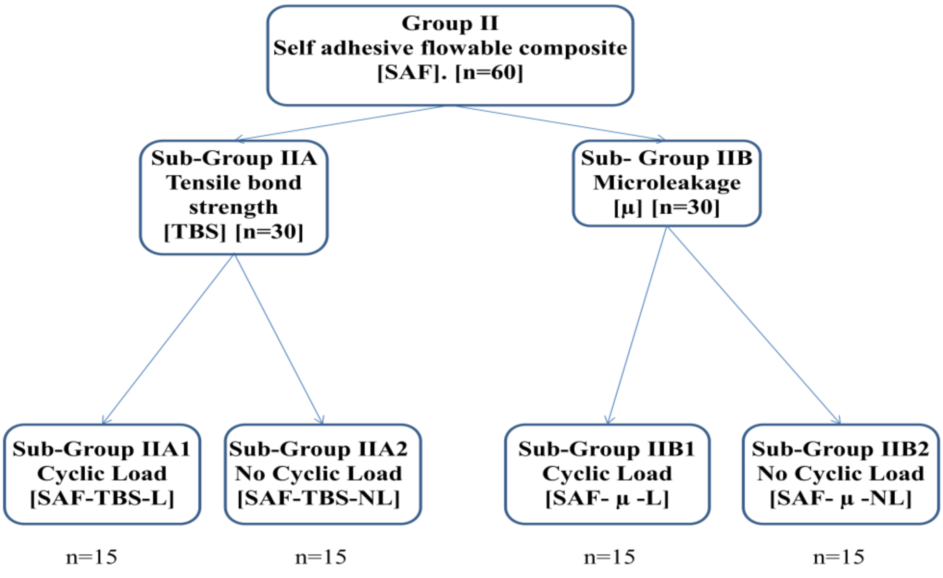
Group B1: Micro-leakage with cyclic loading [μ-L].

Group B2: Micro-leakage with no cyclic loading [μ-NL]

Grouping of the samples:

Teeth were subjected to random division into two main groups i.e., tensile bond strength group [TBS, n=60] and micro-leakage group [µ, n=60]. Under each main group, two different materials were evaluated.





I. PREPARATION OF SAMPLES FOR TENSILE BOND STRENGTH TESTING:

n=60 samples were mounted in self-cure acrylic resin [Figure 2]. The occlusal surface were ground using a water-cooled diamond disc mounted on a slow speed micro-motor hand piece until all occlusal enamel is removed [Figure 3]. This resulted in the exposure of flat dentin surface, with enamel at periphery. The exposed dentin surface on the occlusal surface were hand polished to 600 grit on a series of silicon carbide papers under running water for 30 s in order to create a standardized smear layer.[43]

Restoration phase for TBS testing:

1. Self-etch adhesive system [Filtek Z350 XT, 3M ESPE]**:**

Among the mounted samples , 30 samples were restored by self etch adhesive system. The flat dentinal surface were treated with 3M single bond universal adhesive and light cured for 20s. A hollow metal split mould with 5 mm height and 4mm diameter [Figure 4a] was held on adhesive treated surface of specimens and then composite resin of thickness 2mm were placed inside the mould and were condensed. A 26-gauge ligature wire [Figure 4b] was twisted at one end, and a loop was formed at other end.

Twisted end was placed inside the 2 mm of uncured composite resin and were light-cured for 20 s [Figure 4c]. Another 2 mm of composite resin was placed and cured. Later 1mm of composite resin was placed and cured incrementally. Following complete curing the metal mould was split and removed [Figure 4d]. [13]

2. Self-adhesive flowable composite [Constic, DMG]:

Remaining 30 samples were restored using self adhesive flowable composite. Using the same hollow metal split mould, SAF of 2mm thickness was directly placed onto the prepared tooth surface with the aid of the Luer-Lock-Tip by pressing the syringe [Figure 5] and massaged for 25 s using the brush. A 26-gauge ligature wire was twisted at one end, and a loop was formed at other end. Twisted end was placed inside the 2 mm of uncured composite resin and were light-cured for 20 s. Another 2 mm of SAF composite resin was placed and cured. Later 1mm of composite resin was placed and cured incrementally. Following complete curing the metal mould was split and removed.

Loading and testing for TBS:

Load cycling protocols and TBS testing were performed at Department of Manufacturing Engineering, Annamalai University, Chidambaram. All the samples were stored in water for 24 hours [Figure 6]. For TBS-L, an occlusal load of 90N for 5000 cycles at a rate of 1 Hz was applied to the flat resin composite buildups [Figure 7] using a 5 mm diameter spherical stainless plunger which was attached to cyclic loading machine [Lloyd LRX Plus II universal testing machine - Ametek, Inc.,USA]. [44] This rate equals to the average cycles of mastication of 0.8-1 seconds. The loop end was then engaged to the hook of servo-controlled universal testing machine [Model UNITEK-94100; FIE Pvt. Ltd] [Figure 8a] and pulled for measurement of tensile bond strength [TBS] at a cross head speed of 0.5 mm/min [Figure 8b].

II. PREPARATION OF SAMPLES FOR MICROLEAKAGE TESTING:

Among 60 samples, 30 samples for group B1, μ-L [Figure 9a] and remaining 30 samples for group B2, μ-NL [Figure 9b]. For all samples, class V cavity were prepared with rounded outlines of 4 mm width, 2 mm height, and 2mm depth with No. 330 bur in airotor hand piece. [Figure 10]

Restoration phase for microleakage testing:

1. Self-etch adhesive system [Filtek Z350 XT, 3M ESPE]**:**

The flat dentinal surfaces were treated with 3M single bond universal adhesive and light cured for 20 s. On adhesive treated surface of specimens, composite resin were placed and cured incrementally for 20 s.

2. Self-adhesive flowable composite [Constic, DMG]:

SAF of were directly placed onto the prepared tooth surface with the aid of the Luer-Lock-Tip by pressing the syringe and massaged for 25 s using the brush followed by light-curing for 20 s.

Thermocycling phase:

Thermocycling was performed at Central Institute of Plastics Engineering and Technology, Ministry of Chemicals and Fertilizers, Govt. of India, Guindy, Chennai. After immersing in water for 24 hours, the samples were thermocycled at 5-55°C for 200 cycles with a dwell time of 30 s and a temperature changing time of 3 min in between each cycle [Figure 11]. After thermocycling, the apices were sealed with dental wax and two coatings of nail varnish were applied on the teeth except for restorations and their margins. [13]

Occlusal loading phase:

For µ-L, occlusal load of 90N for 5000 cycles at a rate of 1Hz was applied. [44] This rate equals to the average cycles of mastication of 0.8-1 seconds.

Testing for Microleakage:

Samples were immersed in 2% aq.solution of basic fuschin dye for 24 hours at room temperature [Figure 12a,12b]. After removal from the dye, the samples were washed, dried [Figure 13a,13b, 13c,13d]. and sectioned labio-lingually through the middle of the restoration using a diamond disk in an air-motor hand piece [Figure 14a,14b]. Each section was examined using a stereo-microscope at X40 magnification to assess dye penetration at the margins of the restorations in the department of Oral Pathology, Vivekanandha Dental College for Women, Tiruchengode. The degree of microleakage [Figure 15a, 15b] was evaluated and scored as follows: [17]

Score	Criteria
0	No dye penetration.
1	Dye penetration within ½ of occlusal or gingival wall.
2	Dye penetration extending to the end of occlusal or gingival walls.
3	Dye penetration through the gingival or occlusal wall to $^{1}/_{3}$ of axial wall.
4	Dye penetration through the gingival or occlusal wall to $^{2}/_{3}$ of axial wall.
5	Dye penetration throughout the axial wall.

MATERIALS USED

Figure 1a: Self etch adhesive composite

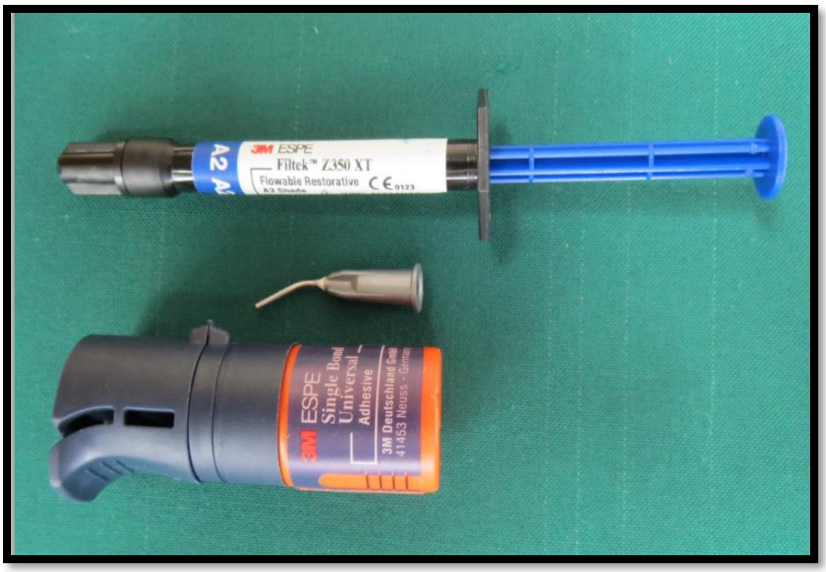


Figure 1b: Self adhesive flowable composite

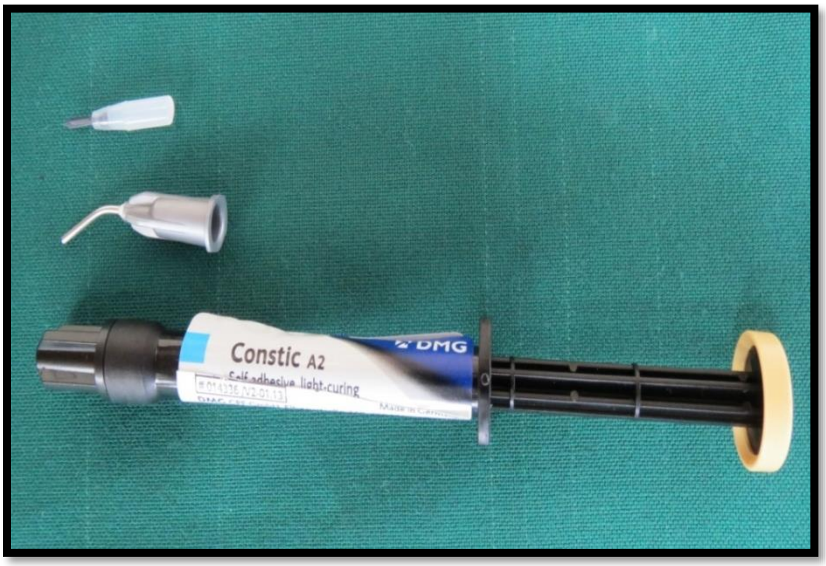


Figure 2: Samples mounted in acrylic resin

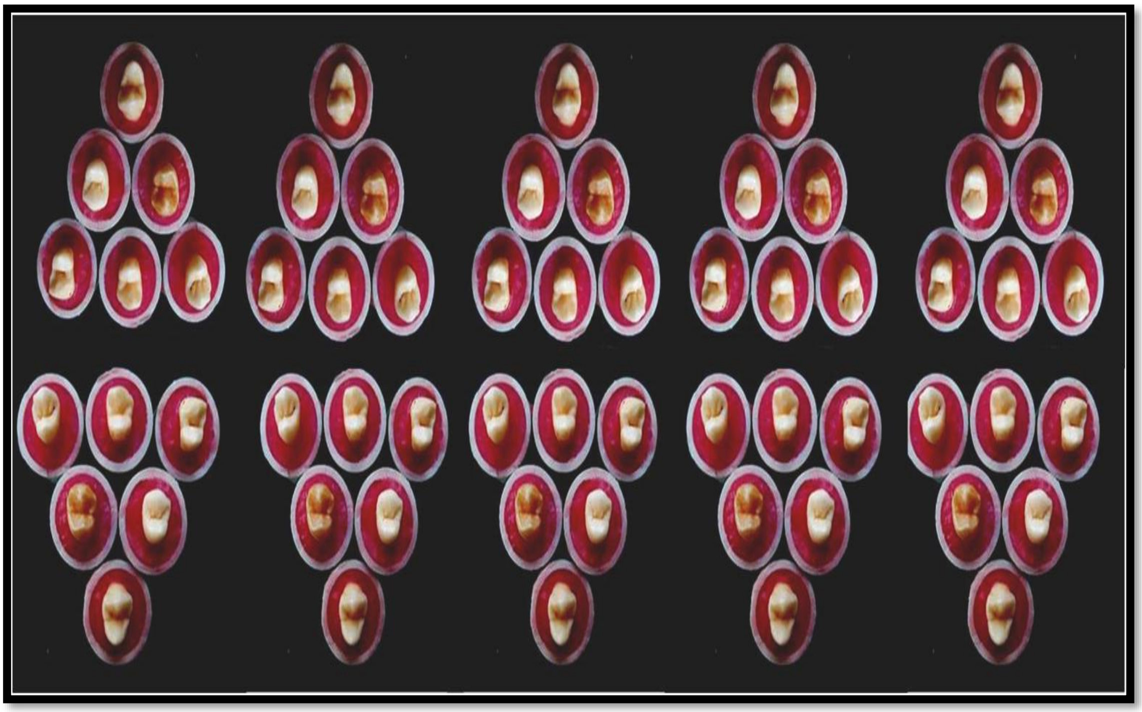


Figure 3: Occlusal grinding of teeth

Figure 4a: Metal split mould

Figure 4b: Twisted ligature wire

Figure 4c: Twisted wire placed in composite resin

Figure 4d: Restoration after the removal of metal split mould

Figure 5: SAF applied onto the prepared tooth surface

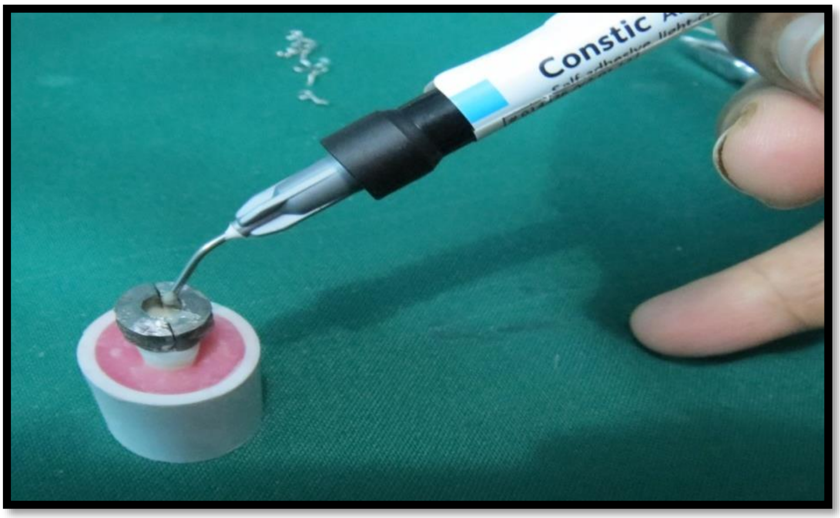


Figure 6: Samples immersed in water

Figure 7: Occlusal load was applied

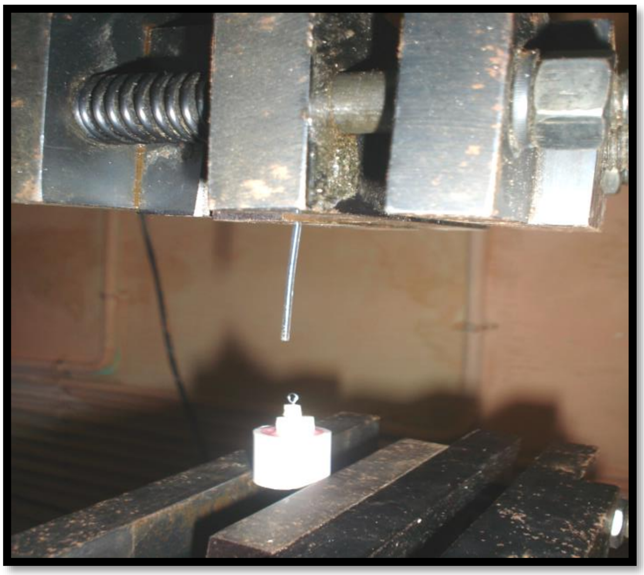


Figure 8: Testing of TBS in universal testing machine

Figure 8a

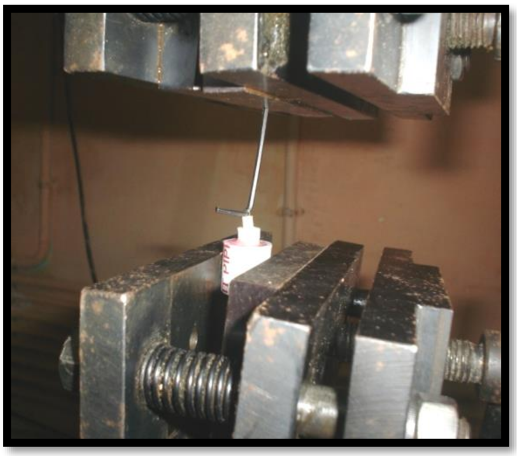


Figure 8b

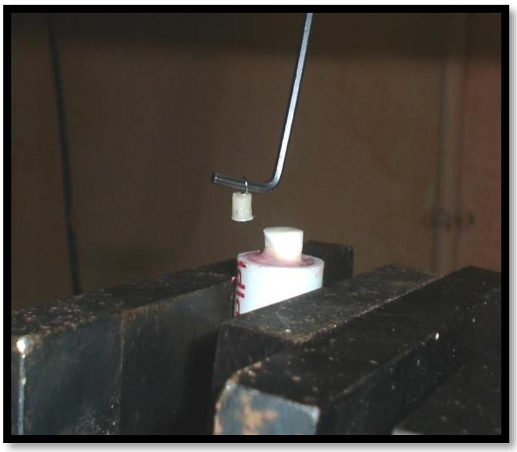


Figure 9a : Samples for group B1, µ-L

Figure 9b: Samples for group B2, µ-NL

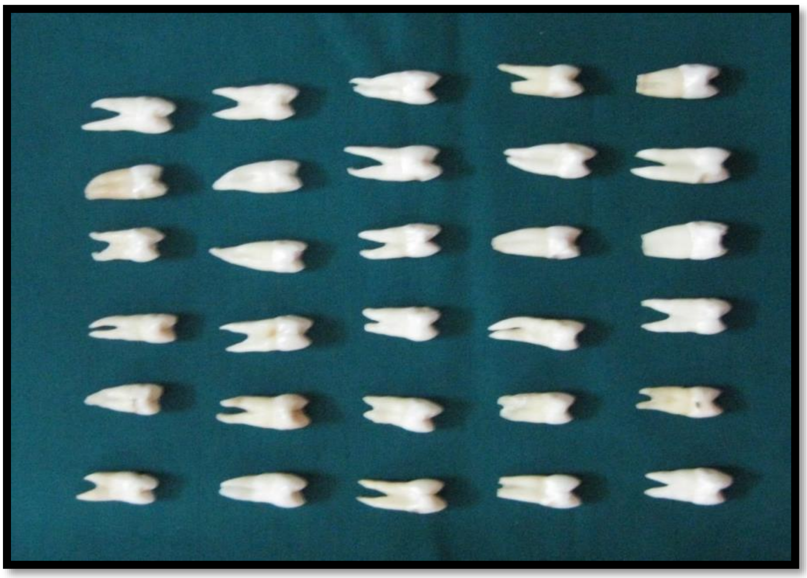


Figure 10: Class V cavity

Figure 11: Thermocycling unit

Figure 12: Samples immersed in basic fuschin dye

Figure 12a

Figure 12b

Figure 13: Samples washed and dried after removal from the dye

Figure 13a

Figure 13b

Figure 13c

Figure 13d

Figure 14: Labio lingually sectioned samples

Figure 14a

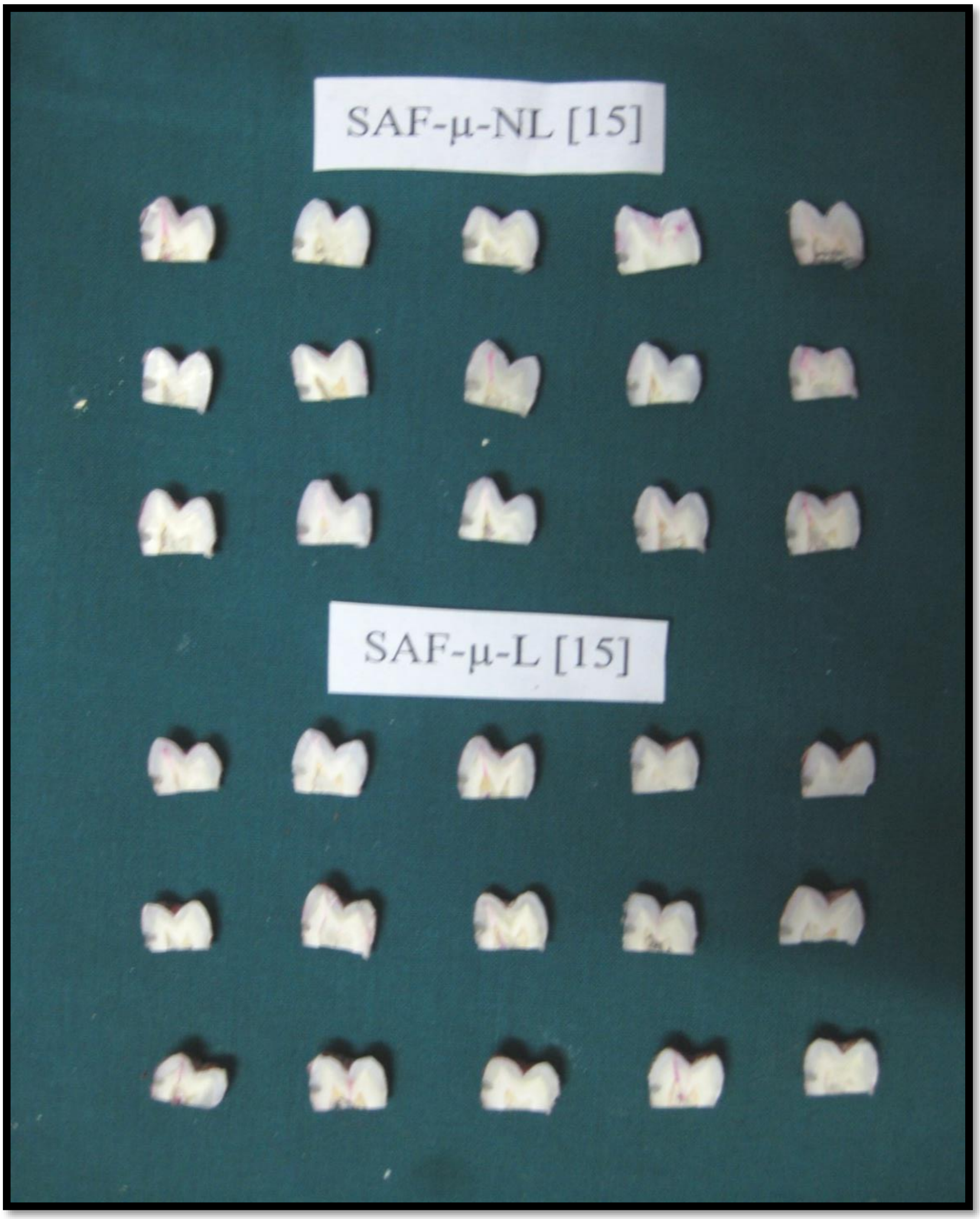


Figure 14b

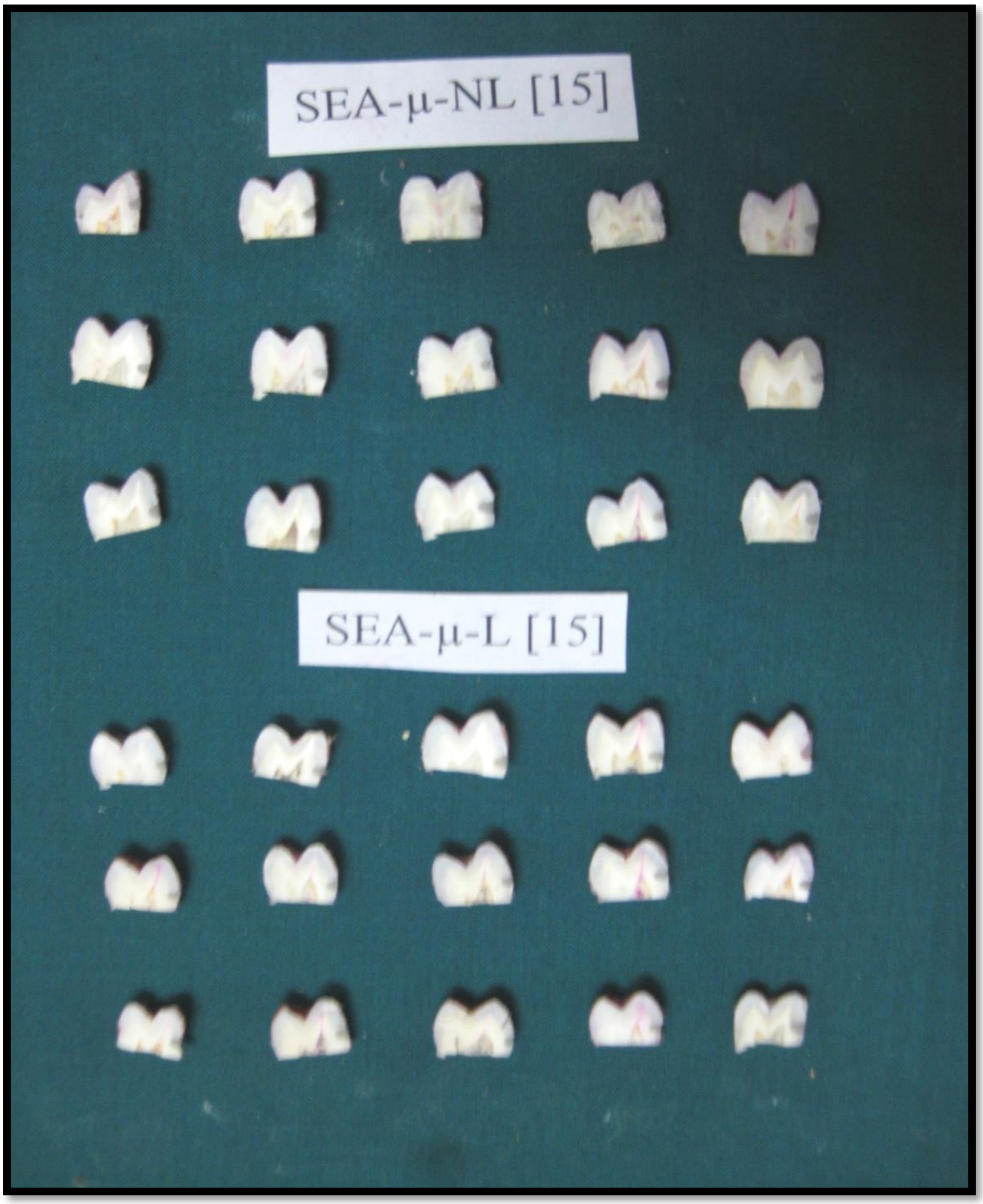


Figure 15a : Sample without microleakage under stereomicroscope

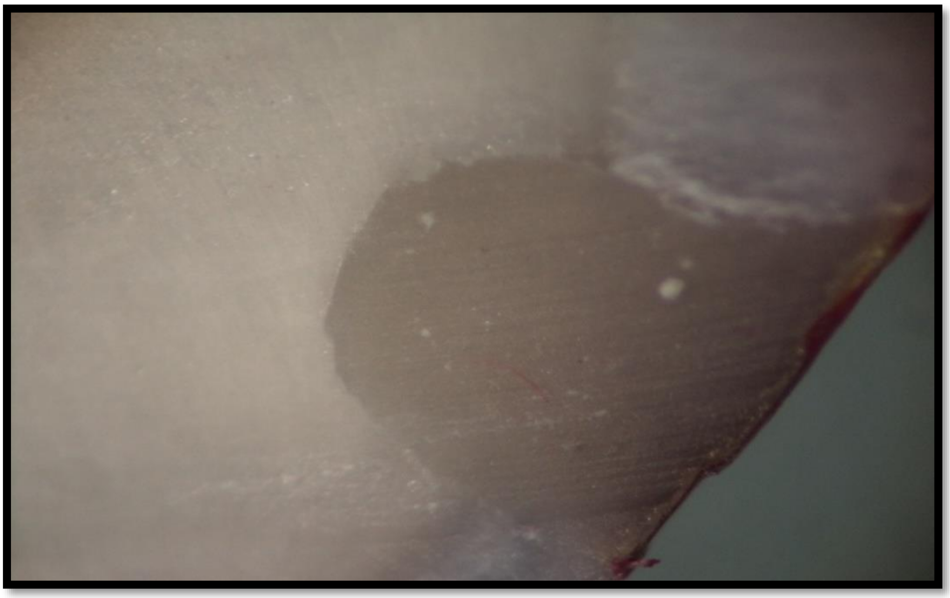
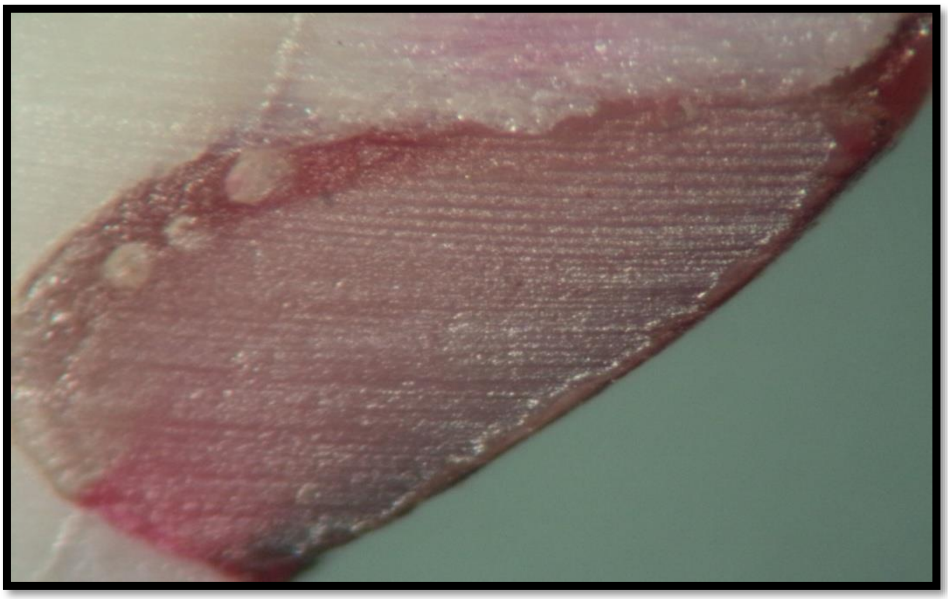


Figure 15b : Sample with microleakage under stereomicroscope



After testing the tensile bond strength of the groups, the data were subjected to ***t*-test for equality of means and 95% confidence interval of the differences [P<0.05]** statistical analysis to identify the significant groups. **Chi-square test** was used to find a statistical difference in microleakage of two groups.

I. TENSILE BOND STRENGTH:

Table 1 and Graph 1:

The mean, standard deviation and t- value for sub-group IA with cyclic loading and without cyclic loading [n=15 each] are presented in Table-1. The mean and standard deviation for the subgroups IA1 [SEA-TBS-L] and IA2 [SEA-TBS-NL] are 4.78±1.02 MPa and 10.31±1.46 MPa respectively. Graph-1 describes the mean of the two sub-groups IA1 and IA2.

Table-1: Tensile bond strength for Self-etch adhesive system [SEA]:

Sub-Groups IA	N	Mean	Std. Deviation	t- value	P- Value
Sub-group IA1: With cyclic loading [SEA-TBS-L]	15	4.783	1.024	10.162	0.000
Sub-group IA2: Without cyclic loading [SEA-TBS-NL]	15	10.3119	1.4675		

Graph 1: Mean value for SEA-TBS-NL & SEA-TBS-L

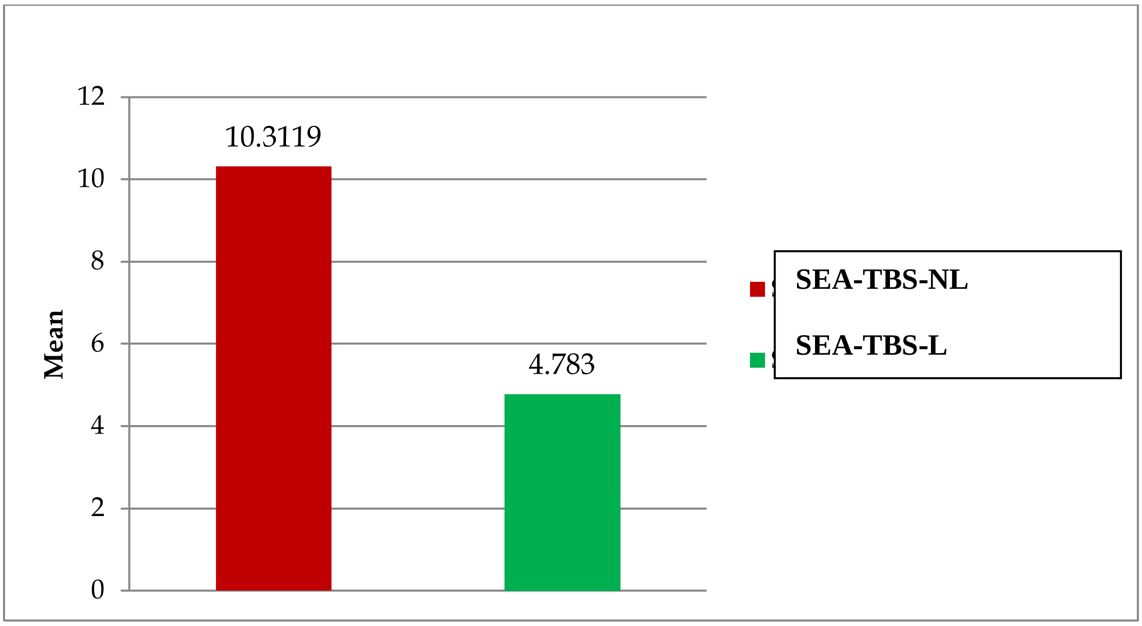


Table 2 and Graph 2:

The mean, standard deviation and t- value for sub-group IIA with cyclic loading and without cyclic loading [n=15 each] are presented in Table-2. The mean and standard deviation for the subgroups IIA1 [SAF-TBS-L] and IIA2 [SAF-TBS-NL] are 11.33±1.09 MPa and 13.82±1.20 MPa respectively. Graph -2 describes the mean of the two sub-groups IIA1 and IIA2.

Table-2: Tensile bond strength for Self Adhering flowable system [SAF]:

Sub-Groups IIA	N	Mean	Std. Deviation	t- value	P- Value
Sub-group IIA1: With cyclic loading [SAF-TBS-L]	15	11.3303	1.0934	6.570	0.000
Sub-group IIA2: Without cyclic loading [SAF-TBS-NL]	15	13.8243	1.2096		

Graph 2 : Mean value for SAF-TBS-NL & SAF-TBS-L

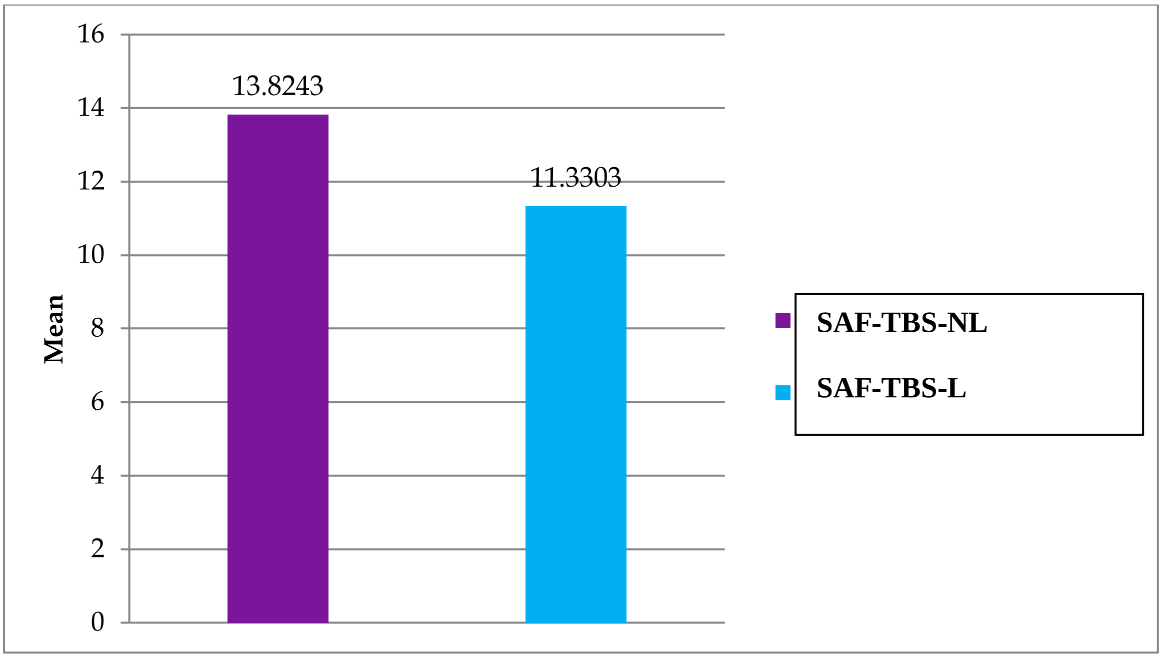


Table 3 and Graph 3 :

The mean, standard deviation and t- value comparing sub-groups IA1 and IIA1 with cyclic loading [n=15 each] are presented in Table-3. The mean and standard deviation for the subgroups IA1 [SEA-TBS-L] and IIA1 [SAF-TBS-L] are 4.78±1.02 MPa and 11.33±1.09 MPa respectively. Graph -3 describes the mean of the two sub-groups IA1 and IIA1.

Table-3: Tensile bond strength for Self-etch adhesive system [SEA] and Self adhering flowable composite [SAF] sub-groups with *cyclic loading*:

Sub-Groups	N	Mean	Std. Deviation	t- value	P- Value
Sub-group IA1: With cyclic loading [SEA-TBS-L]	15	4.783	1.024	14.437	0.000
Sub-group IIA1: With cyclic loading [SAF-TBS-L]	15	11.3303	1.0934		

Graph -3: Mean value for SAF-TBS-L & SEA-TBS-L

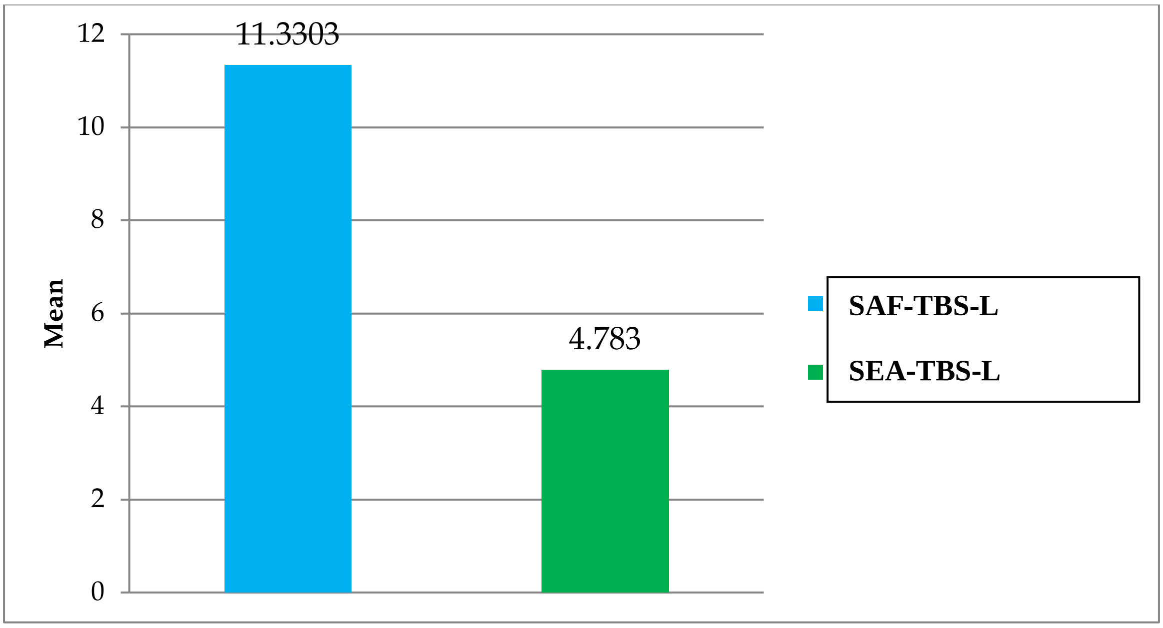


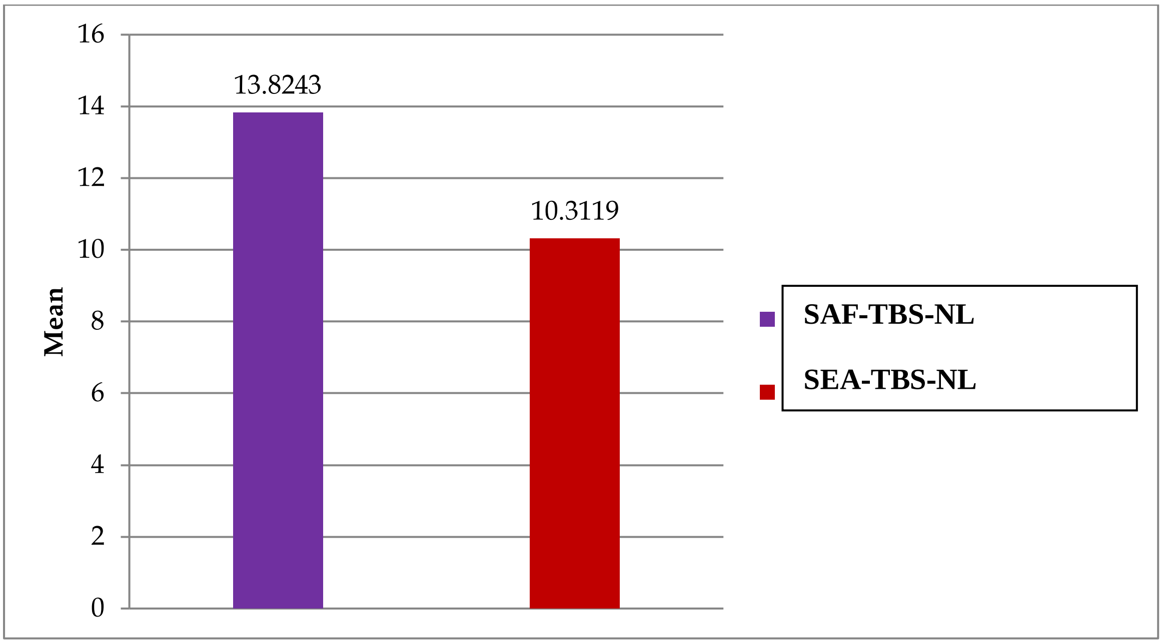
Table 4 and Graph 4:

The mean, standard deviation and t- value comparing sub-groups IA2 and IIA2 without cyclic loading [n=15 each] are presented in Table-4. The mean and standard deviation for the subgroups IA2 [SEA-TBS-NL] and IIA2 [SAF-TBS-NL] are 10.31±1.46 MPa and 13.82±1.20 MPa respectively. Graph -4 describes the mean of the two sub-groups IA2 and IIA2.

Table-4: Tensile bond strength for Self-etch adhesive system [SEA] and Self adhering flowable composite [SAF] sub-groups *without cyclic loading*:

Sub-Groups	N	Mean	Std. Deviation	t- value	P- Value
Sub-group IA2: Without cyclic loading [SEA-TBS-NL]	15	10.3119	1.4675	5.481	0.000
Sub-group IIA2: Without cyclic loading [SAF-TBS-NL]	15	13.8243	1.2096		

Graph 4: Mean value for SAF-TBS-NL & SEA-TBS-NL



When the mean and standard deviation of the tensile bond strength values compared within the groups, either in Group I [SEA] with [L] or without [NL] the application of cyclic loads or in Group II [SAF] with [L] or without [NL] the application of cyclic loads, a statistically significant difference [P<0.05] existed between the sub-groups compared.

II. MICRO-LEAKAGE:

A. Comparison within sub-groups - With loading [L] & Without loading [NL]:

Table 5:

The number and percentage of specimens from each sub-group [IB1 & IB2] with corresponding micro-leakage scores are presented in table-5.

Table-5: Within Sub-Group IB-Self etch adhesive composite resin [SEA]:

Microleakage scores	Sub-group IB		Total [%]
	Sub-group IB1-With cyclic loading [%] [SEA-μ-L]	Sub-group IB2 - Without cyclic loading [%] [SEA-μ-NL]	
0		2 [13.3]	2 [6.7]
1		10 [66.7]	10 [33.3]
2		3 [20]	3 [10]
3	3 [20]		3 [10]
4	9 [60]		9 [30]
5	3 [20]		3 [10]
Total	**15 [100]**	**15 [100]**	**30 [100]**

Table 6:

The Chi-square test to find a statistical difference in micro-leakage within Sub-Group IB is given in table-6. The obtained P value [P=0.000] indicates there is statistically significant difference between the subgroups with and without cyclic loading.

Table-6: Chi-Square Tests:

	Value	d.f.	Asymp. Sig. (2-sided)
Pearson Chi-Square	24.000	4	0.000
Likelihood Ratio	22.006	4	0.000
Linear-by-Linear Association	11.546	1	0.001
N of Valid Cases	30		

Table 7:

The number and percentage of specimens from each sub-group [IIB1 & IIB2] with corresponding micro-leakage scores are presented in table-7

Table-7: Within Sub-Group IIB-Self adhesive flowable composite [SAF]:

Microleakage scores	Sub-group IIB		Total [%]
	Sub-group IIB1-With cyclic loading [%] [SAF-µ-L]	Sub-group IIB2 Without cyclic loading [%] [SAF-µ-NL]	
0		5 [33.3]	5 [16.7]
1		10 [66.7]	10 [33.3]
2			
3	5 [33.3]		5 [16.7]
4	10 [66.7]		10 [33.3]
5			
Total	**15 [100]**	**15 [100]**	**30 [100]**

Table 8:

The Chi-square test to find a statistical difference in micro-leakage within Sub-Group IIB is given in table-8. The obtained P value [P=0.001] indicates there is statistically significant difference between the subgroups with and without cyclic loading.

Table-8: Chi-Square Tests:

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	15.000	1	0.000
Likelihood Ratio	19.095	1	0.000
Linear-by-Linear Association	14.000	1	0.000
N of Valid Cases	30		

B. Comparison between groups: Between Sub-Groups IB [SEA] & IIB [SAF]

Table 9:

The number and percentage of specimens from each sub-group [IB1 & IIB1] with corresponding micro-leakage scores are presented in table-9.

Table-9: Sub-groups IB1 & IIB1 – With Loading [L]:

Microleakage scores	**Sub-group IB1 [%] [SEA-μ-L]**	**Sub-group IIB1[%] [SAF-μ-L]**	**Total [%]**
0			
1			
2			
3	3 [20]	5 [33.3]	8 [26.7]
4	9 [60]	10 [66.7]	19 [63.3]
5	3 [20]		3 [10]
Total	**15 [100]**	**15 [100]**	**30 [100]**

Table 10:

The Chi-square test to find a statistical difference in micro-leakage in Sub-Group IB1 & IIB1 is given in table-10. The obtained P value [P=0.018] indicates there is ***no*** statistically significant difference between the subgroups ***with cyclic loading.***

Table-10: Chi-Square Tests:

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	8.000	2	0.018
Likelihood Ratio	9.561	2	0.008
Linear-by-Linear Association	6.300	1	0.012
N of Valid Cases	30		

Table 11:

The number and percentage of specimens from each sub-group [IB2 & IIB2] with corresponding micro-leakage scores are presented in table-11

Table-11: Sub-groups IB2 & IIB2 – Without Loading [NL]:

Microleakage scores	Sub-group IB2[%] [SEA-μ-NL]	Sub-group IIB2[%] [SAF-μ-NL]	Total [%]
0	2 [13.3]	5 [33.3]	7 [23.3]
1	10 [66.7]	10 [66.7]	20 [66.7]
2	3 [20]		3 [10]
3			
4			
5			
Total	**15 [100]**	**15 [100]**	**30 [100]**

Table 12:

The Chi-square test to find a statistical difference in micro-leakage in Sub-Group IB2 & IIB2 is given in table-12. The obtained P value [P=0.062] indicates there is ***no*** statistically significant difference between the subgroups ***without cyclic loading***

Table-12: Chi-Square Tests:

	Value	**d.f.**	**Asymp. Sig. (2-sided)**
Pearson Chi-Square	5.550	2	0.062
Likelihood Ratio	6.878	2	0.032
Linear-by-Linear Association	4.635	1	0.031
N of Valid Cases	30		

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The main subject of numerous studies since adhesive systems were introduced was adhesion of resins to dentin. The bond strength must be a converse of resistance to the polymerization shrinkage stresses, offer retention and provide marginal seal for the composite restoration. Dentin bonding still faces complications pertained to the appropriate moisture level for better hybridization, pulp protection and adequate seal along the cavity margins. [37]

The total-etch, popularly known as etch and rinse strategy, is characterized by application of 37% ortho-phosphoric acid gel which is, later rinsed away. [28] During etching, the smear layer is removed followed by a water rinse, causing sound dentin de-mineralization. This process opens the dentinal tubules by funneling their orifices and removes all remaining smear plugs. For a few microns, the inter-tubular dentin gets de-mineralized depending upon the concentrations of phosphoric acid, its formations, time and application mode. Mineral phase removal from the superficial dentin allows the dentin organic matrix to get exposed. The so-called hybrid layer is created by the infiltration of resin monomers into the delicate network of de-mineralized collagen fibrils. Resin tags were formed by the penetrations of adhesives into funneled dentinal tubules. The micro-mechanical retention between the de-mineralized dentin matrix and polymerized adhesive system establishes the bond. [36]

Numerous technical inconveniences have been ascertained to this etch and rinse bonding technique, such as, dentin substance must not be over-dried or over wetted. It requires a multiple clinical steps, prolonged application time and post-operative sensitivity. [38] These hurdles are eliminated in bonding procedure without compromising the effectiveness of dentin adhesive by the advent of a self-etching approach, which was quite common in the early 90's. In this strategy, the rinsing step was skipped to lessen clinical operating time. [39]

Appreciably, these self-etching primers result in a minimum discrepancy between the de-mineralization depth and resin infiltration depth as self-etching primer de-mineralize and infiltrate dentin concomitantly. [45] The smear layer from dentin is not completely removed by these self-etching primers, which apparently results in low post-operative sensitivity than total-etch adhesives. [40]

A more recent advance step in the adhesive dentistry is the advent of self-adhering flowable composite [SAF] which remarks the time-consuming procedure used with etch and rinse or self-etch adhesive systems. [14] Advantages of both adhesive and restorative material technologies are combined in one product that brought new horizons in the field of restorative dentistry, since it is a direct composite resin consisting of adhesive resin and a flowable composite resin altogether. [17]

The SAF are found to interact chemically and micromechanically with dentin, when an acidic adhesive monomer incorporated in their composition. [42] They, in fact, alleviate the need for application of bonding agent in a separate clinical step and hence, simplifying the procedure. Therefore, the SAF can be the commencement of the eighth generation of dental bonding systems. [46]

Though *Bektas et al* [17] have concluded that using SAF resin would increase the bond strength, other researchers [41, 47] obtained no significant difference in the bond strength with SAF. Owing to its novelty of SAF, it increased the inquisitiveness to research further about its bond strength.

Bond strength tests are the most frequently used to screen adhesives. Tensile bond strength was selected owing to its advantages which include small bonding surface area, easier sample preparation, use of lesser amount of material and less number of teeth. [48]

In the present in-vitro study conducted, for Group I, the mean TBS with [SEA-TBS-L] and without [SEA-TBS-NL] cyclic loading were 4.78±1.02 MPa and 10.31±1.46 MPa respectively. For Group II, the mean TBS with [SAF-TBS-L] and without [SAF-TBS-NL] cyclic loading were 11.33±1.09 MPa and 13.82±1.20 MPa respectively. Irrespective of the materials compared, cyclic loading drastically decreased the TBS for both Group I and II. When the groups were compared, either with or without cyclic loading, self-adhesive flowable composite had significantly [$P<0.05$] greater TBS than self-etch adhesive flowable composite resin.

For the first time, in vitro self-adhering resin bonding performance under cyclic loading are being described. Current dental literature consist of hardly two studies on SAF composite resin which evaluated dimensional changes hygroscopically and diffusion. Second research evaluated the concurrent solubility of SAF during water sorption or desorption cycles [49, 50]. Furthermore, shear bond tests for Self-adhesive flowable composite resin are available in the literature [51-53]. However, the effects of tensile loading on the bond strength of self-adhesive flowable composites are not yet recorded.

Bui et al. [54] experimented and compared the shear bond strength of SAF composite [Vertise-flow- VF] to dentin with other SEA systems. They found the shear bond strength of SAF [25.1 MPa] was lower than SEA [27 MPa]. However, this difference was not statistically and clinically significant. In a study conducted by Bektas et al. [17], VF demonstrated lower bond strength than SEA. This result agreed with the results obtained by Bui et al.

Despite SAF incorporates the technology of adhesion found in SEA to bond with tooth structure, they exhibited different bond strengths. It was postulated that the addition of in-organic fillers might decrease the bond strength of SAF. Miyazaki et al. [51] concluded that filler in the adhesive resin increased the resin viscosity and might decrease its wettability on the dentinal surfaces. This decreased the monomer penetration and might be a possible sequel for decreased shear bond strength.

Almaz et al. [52] evaluated and compared the shear bond strength of SAF with different SEA composites to dentin and concluded that decrease in bonding procedures, resulted in decreased bond strength and SAF composite had the lowest shear bond strength. Sachdeva et al. [53] evaluated the shear bond strength of conventional SEA and SAF composites to dentin. It was observed that the shear bond strength of conventional flowable composite was significantly greater than SAF composite ($p<0.05$) and opined that the evolution of SAF composites might open new horizons in the field of pedodontics.

With respect to tensile bond strength testing, in the present in-vitro study, SAF exhibited statistically significant higher tensile bond strengths than SEA either with [SAF: 11 MPa; SEA: 5 MPa] or without cyclic loading [SAF: 14 MPa; SEA: 10 MPa]. However, Van Meerbeek [55] systematically reviewed the relationship between the bond-strength tests and their clinical outcomes. He concluded that there were significant differences in the mean bond strength, i.e., micro/macro tensile bond strengths and micro/macro shear bond strengths. In this current study, SAF composite resin had tensile bond strength of 14 MPa without cyclic loading. This result shows that the tensile bond strength of SAF composite resin can be compared favorably to SEA system.

When cyclic load is applied on a flat surface perpendicular to the bonded interface, a compressive stress is expected under the loading sphere in the middle of the tooth. Tensile strength would be expected to develop around the peripheral regions of the occlusal bonded interface. Conversely, cervical cavities on either buccal or lingual surfaces experienced both compressive and tensile stresses during occlusal loading. A 90-N load was used in this study, which is within the range of those encountered under clinical situations. The number of load cycles used in previous studies varies from 1000 to 8000, with 5000 being a median value. [56]

Osorio et al [57] studied the effect of load cycling and in-vitro degeneration on resin-dentin bonds using self-etching primer adhesive and concluded that cyclic loading significantly compromised the bond strength. Aggarwal et al [58] evaluated the effect of thermal and mechanical loading of 5000 cycles at 60 N on micro-tensile bond strength of SEA and arrived at a conclusion that mechanical cyclic loading adversely decreased the TBS. Belli et al. [59] studied the effects of load cycles on micro-tensile bond strengths of dual cure resin cement to dentin when all-in-one adhesive was applied and concluded that load cycles significantly reduced the adhesion. Aggarwal et al. [60] experimented the effect of cyclic loading on marginal adaptation and bond strength in direct versus indirect Class II MO composite restorations and observed significantly decreased bond strength for restorations subjected to cyclic loading.

Determining the bond strength to dentin is a common way to study compatibility between simplified adhesive systems and tooth. Dentin-resin bonds are subjected to numerous immediate stresses in clinical scenario. The effect of mechanical cyclic loading was studied because of its potential effect on the bond strength of adhesives [61],[62] and adhesives lose performance after in-vitro cyclic loading which are apparently evident from the above mentioned studies. The results obtained in the present in-vitro study also ascertain and agree with the previously described studies that cyclic loading decreases the bond strength of the composite resin, either SEA or SAF.

Microleakage studies are one of the methods to identify the etiology for bond failure along the tooth-restoration interface. There are many strategies available in the literature for marginal leakage detection. Some common methods include use of organic dyes, fluorescent dyes, radio-isotopes, silver-nitrate technique, bacteria, neutron-activation analysis, electro-chemical method, etc. Organic dye method was chosen for this in-vitro study owing to its extensive use in the dental literature and ease of use. [63] Certain organic dyes used in the microleakage analysis include basic fuchsin, methylene blue, eosin, aniline blue, crystal violet and erythrosine B. The basic fuchsin dye is one of the most commonly used dyes today. Concentration ranges from 0.5 to 2.0% at present. Therefore, 2% aq.solution of basic fuschin dye was used for evaluating microleakage in this current in-vitro study. The sectioned specimens were viewed through stereo-microscope for confirming dye penetration that commenced from the tooth-restoration interface and not from other paths of dentin. [24] Then, the most infiltrated specimen of each tooth was selected and scored accordingly. This scoring measurement of the microleakage is considered acceptable, since it permits qualitative statistical analyses of data. [24]

Cervical cavities on either buccal or lingual surfaces experiences either compressive or tensile stresses, depending on which cusp incline was being loaded. The stress on a buccal cavity would be tensile when the load imposed was on the inclined surface of the lingual cusp, and vice versa. [32]

Earlier leakage studies combined with load cycling have given inconsistent outcomes. Some researches recorded increased microleakage of the restorations under cyclic loading [64-67] whilst some authors found that load cycling did not affect the marginal seal [68-70]. These variations in reported findings might be due to the materials used, direction of load and value, number of load cycles, and type of cavity and dimensions, and operators [64-67]. Abdalla and Davidson [65] found that some adhesive systems adversely affected by cyclic loading, whilst others withstood such loading forces. Mandras et al [67] reported that restorations placed in molar teeth were drastically affected by occlusal loading than restorations placed in cuspids. This may probably have been due to the increased cavity length in the molar teeth than cuspids. Also, cuspids receive less vertical loads when compared to the molars.

The masticatory forces and mandibular movements during chewing are apparently complex and affected by factors such as age, gender, bruxism and bite habits [71]. Also, the testing machine used could produce only axial load cycles, whilst the masticatory movements in the oral cavity are a three-dimensional pattern [72]. Hence, the test strategies simulate but do not replicate clinical conditions, and this must be considered during the interpretation the results. Additionally, the number of axial load cycles in the testing laboratory might only represent several days or months of masticatory loads encountered in the oral cavity. [56]

Sachdeva et al. [53] evaluated the nano-leakage of conventional and self-adhering flowable composites to dentin. It was concluded that the nano-leakage of both conventional and self adhering flowable composites were comparable. Self adhering flowable composites have combined properties of restorative composites and self etch adhesive monomers, thereby eliminating the need for separate adhesive application and in turn simplifies direct restorative procedure.

A widely acceptable method used in evaluating in-vitro microleakage studies is thermocycling [30, 33, 73] although few researchers consider it to be a questionable strategy [26, 29, 74]. The validity and significance of the thermocycling is debatable. This might be attributed to the fact that the exact temperatures [hot/cold] of food/beverage tolerated by patients might not be the same as used during thermocycling. [75] In thermocycling, the specimens are subjected to thermocycles that can mimic the intra-oral temperature. However, in the existing dental literature, there is a wide range in the extremities of temperature, time taken to transfer and dwell times [63, 76]. Thus, the validity of standardization for thermocycling strategy in microleakage analysis remains questionable, and lead to contradictory discussions in various in-vitro researches. Some researchers had chosen the parameters pertained to the thermocycling method, and are not intended to understand the underlying effects [76]. Hence, in this present in-vitro study the temperature was standardized at 5ºC-55ºC. This temperature range seems to be tolerated by the oral tissues and is equated for clinical scenario. The thermal isolation characteristics of composite resins might be masked by increased dwell times, leaving material fatigue [77]. The number of thermocycles was selected by convenience in many other studies [78].

An important factor suggested to influence microleakage is the Coefficient of thermal expansion [CTE] [25]. This factor is influenced by the presence and the quantity of the inorganic fillers in resin composite. A significant difference in the linear CTE between tooth and restorative material will apparently alter the tooth-adhesive interface dimensions with temperature change [77]. Besides high linear CTE of composite resin, it is a bad thermal conductor. This physical property nullifies the thermocycling effect on microleakage and renders the CTE a time-dependent factor [77].

A dwell time of 15 s is not sufficient to transfer the temperature through composite resin to rupture tooth-adhesive interface because of low thermal conductivity [27]. Crim et al.[33] concluded that microleakage extension seemed to be independent of the dwell time used (4 and 30 s). However, in a research conducted by Schuckar and Geurtsen, [73] thermocycling with a 30 s dwell time promoted microleakage. However, majority of the researches showed that the dwell time has no influence in the micro-leakage perspectives. Hence, in this present in-vitro study, the dwell time of 30 s was adopted.

Pazinatto et al. [24] observed that increasing the thermocycling number did not affect microleakage. A possible explanation for these results could be the polymerization shrinkage which was considered as the responsible factor for the microleakage. There are other factors which also affect the tooth-adhesive interface. Those are hygroscopic expansion, adhesive strength, linear CTE, Young's modulus and thermal diffusibility [78]. These parameters need further extensive researches to improvise the understanding about microleakage.

Numerous microleakage studies have been conducted comparing the effects of thermocycling and non-thermocycling groups [75, 77- 79] and number of thermocycles [80]. In either of the type of studies, no statistically significant difference was observed. These results suggest that thermocycling has no influence on the microleakage of composite resin restorations.

Thus, thermocycling cannot be considered as a suitable test method to simulate the temperature scenario in the oral cavity. However, in some researches [30, 33, 68, 73], there were significant measurable differences in microleakage between thermocycled and non-thermocycled specimens. Nevertheless, many authors suggest that the thermal cycling test per se does not influence microleakage of composite resin restorations.

In this present in-vitro study, 200 cycles were selected for evaluation presuming that increasing or decreasing the thermocycles does not affect the microleakage along the tooth-restoration interface and done to simulate the oral temperature changes only. When the groups are compared, there were no statistically significant differences between SAF and SEA composites, either with [P=0.018] or without [0.062] load cycling. However, in terms of load cycling, there was a statistically significant difference [P=0.000] within the subgroups SAF and SEA composites. Hence, load cycling increased the microleakage of the materials used, which was in accordance with the previous scientific studies conducted.

The present study was conducted on premolars due to its ease of availability [81], on which a class V cavity was prepared to assess microleakage under the influence of occlusal loading. For more appropriate results, the study could have been done on deciduous molars. However, in the pediatric dental literature, various researchers had used either permanent molars [82, 83] or premolars [84-88] in their studies. The probable reason might be the fact that no tooth is resistant to dental caries where premolars cannot be an exception and young adolescents are as equally susceptible to caries as children.

In-vitro simulations of oral environment where enamel and dentin bonding would fail, for example, load cycling, thermocycling, effect of pulpal pressure, water and other solution storage, are difficult. This is because that the factors involved in bond degradation in-vivo are numerous, and not yet known completely. Thus, further clinical trials, though they are time-consuming, expensive, and lack control over important variables, are necessary to obtain more validated, authentic, and proximal results.

Within the limitations of this in-vitro study, the following conclusions are derived:

1. SAF composite resins had higher tensile bond strength than the SEA composite group.
2. Both the composite groups exhibited significant microleakage which was not comparable.
3. Load cycling not only adversely affected the tensile bond strength but also increased microleakage in both the groups compared.

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MATERIAL: SELF-ETCH ADHESIVE FLOWABLE COMPOSITE [SEA]

TEST: TENSILE BOND STRENGTH [TBS]

Sample No.	Bond Strength [MPa]	
	Without Loading [NL]	**With Loading [L]**
1	11.94	4.7
2	13.53	3.1
3	10.35	7.1
4	8.917	3.98
5	8.041	4.7
6	11.146	4.7
7	10.35	4.7
8	10.35	3.98
9	9.554	5.57
10	11.94	4.7
11	10.35	4.7
12	8.757	5.57
13	8.757	6.369
14	9.554	3.98
15	11.146	3.98

MATERIAL: SELF ADHESIVE FLOWABLE COMPOSITE [SAF]

TEST: TENSILE BOND STRENGTH [TBS]

Sample No.	Bond Strength [MPa]	
	Without Loading [NL]	With Loading [L]
1	14.72	13.13
2	11.14	11.14
3	12.73	9.55
4	15.127	12.738
5	15.923	9.554
6	14.33	11.146
7	13.535	12.738
8	13.535	11.146
9	14.33	11.94
10	12.738	11.146
11	13.535	11.94
12	13.535	11.146
13	14.33	10.35
14	15.127	11.94
15	12.738	10.35

MICROLEAKAGE ASSESSMENT SCORING SHEET

Self etch adhesive composite resin without loading [SEA µ- NL] (n=15)

Score / Sample	0	1	2	3	4	5
1		✓				
2		✓				
3		✓				
4	✓					
5		✓				
6			✓			
7		✓				
8		✓				
9			✓			
10	✓					
11		✓				
12		✓				
13		✓				
14			✓			
15		✓				

Self etch adhesive composite resin with loading [SEA μ-L] (n=15)

Sample \ Score	0	1	2	3	4	5
1					✓	
2						✓
3						✓
4					✓	
5					✓	
6						✓
7						✓
8				✓		
9				✓		
10					✓	
11				✓		
12					✓	
13						✓
14					✓	
15				✓		

Self adhesive flowable composite without loading [SAF μ-NL] (n=15)

Score / Sample	0	1	2	3	4	5
1	✓					
2		✓				
3		✓				
4	✓					
5	✓					
6	✓					
7		✓				
8		✓				
9		✓				
10		✓				
11		✓				
12	✓					
13	✓					
14		✓				
15		✓				

Self adhesive flowable composite with loading [SAF] µ-L] (n=15)

Score / Sample	0	1	2	3	4	5
1					✓	
2					✓	
3					✓	
4				✓		
5				✓		
6					✓	
7					✓	
8				✓		
9				✓		
10				✓		
11					✓	
12					✓	
13					✓	
14					✓	
15					✓	

INSTITUTIONAL ETHICS COMMITTEE
VIVEKANANDHA DENTAL COLLEGE FOR WOMEN

SPONSORED BY : ANGAMMAL EDUCATIONAL TRUST

Ethics Committee Registration No. ECR/784/Inv/TN/2015 issued under Rule 122 DD of the Drugs & Cometics Rule 1945.

No: VDCW/IEC/13/2015

Date: 14.12.2015

TO WHOMSOEVER IT MAY CONCERN

Principal Investigator: Dr. M.Kamatchi

Title: A comparative evaluation of tensile bond strength and micro-leakage of a novel self adhesive flowable composite and self-etch adhesive composite system –An in-vitro study.

Institutional ethics committee thank you for your submission for approval of above proposal. It has been taken for discussion in the meeting held on 08 .12.15.The committee approves the project and it has no objection on the study being carried out in Vivekanandha Dental College For Women.

You are requested to submit the final report on completion of project. Any case of adverse reaction should be informed to the institutional ethics committee and action will be taken thereafter.

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