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Original Article

Indian Journal of Dental Sciences E ISSN NO. 2231-2293 P ISSN NO 0976-4003

A Comparative Evaluation Of Shear Bond Strengths Of Composite To Dentin, Using Total Etch And Self Etch Dentin Bonding Agents - An In Vitro Study

Abstract

Objectives: The purpose of this in-vitro study was to comparatively evaluate the shear bond strength of newer dentin bonding agents i.e. two-step etch & rinse adhesives i.e. Prime & Bond NT and one-step self etching agents i.e. G Bond, Xeno V & two step self-etching adhesive i.e. Adper SE Plus

Materials and Methods: Eighty freshly extracted non-carious intact human molars were ground flat, exposing the dentin surface. They were randomly divided into four groups according to adhesive system used (n=10/group), namely group I-prime & bond NT, group II-Xeno V, group III-Adper SE Plus and group IV-G Bond. Each group was treated with its respective bonding agents, as per the manufacturers' instructions. Cylinders of composite resin were built up using Teflon mould and cured. Specimens were stored in distilled water (3710;C, 24 hours) and then thermocycling was carried out. Shear bond strengths were tested using Instron machine (crosshead speed of 1 mm/min) and recorded in MPa. The results were statistically analyzed using One-way Anova and Tukeys HSD Test.

Results: The Mean Shear bond strength values (MPa) for the groups I, II, III and IV were 23.48; 22.08; 19.97 and 17.35 respectively. Group I (Total etch adhesive) exhibited a significantly higher value than all other groups (Self etch adhesives) (p<0.005), whereas Group IV had the lowest value

Conclusions: Within the limitations of this in vitro study, it can be concluded that all the adhesives agents evaluated showed optimal shear bond strength of 17-20 MPa. However, the results demonstrated the capacity of traditional etch & rinse adhesive to outperform the self-etch adhesives.

Key Words

Dental students, attitude, tobacco cessation, counseling

Introduction

Restorative Dentistry has irrevocably entered a revolutionary era of aesthetic restorative materials. Patients' demand for aesthetic restorations & the search for filling materials that can provide longterm stability are leading to development of new products in adhesive dentistry at an unprecedented rate[1].

The foundation of modern adhesive dentistry was laid in 1955 when Buonocore reported that acids could be used to alter the surface of enamel to render it more receptive to adhesion[2]. Acid etching of the enamel with phosphoric acid produced micro porosities in the enamel allowing resin bonding via micro-mechanical retention[3].

total etch techniques, in which both the technique & Self-etching systems[4]. enamel and dentin surfaces are acid Dentin Adhesives are currently available conditioned to allow for resin adherence as two step, and single step systems to both enamel and dentin surfaces[3]. Bonding to enamel is more reliable steps of etching, priming and bonding to

whereas bonding to dentin represents a greater challenge and has proved to be more difficult and less predictable. Difficulties in bonding to dentin are a result of inherent characteristics of this substrate (Perdiago, 2002; Lopes et al, 2002; Perdiago, Lopes, 1999)[4]. While enamel is 92% inorganic hydroxyapatite by volume, dentin is about 45% inorganic & the rest being organic & water.

To counteract these problems constant active research in the field of adhesive dentistry has resulted in the rapid evolution of dental adhesive systems through several generations with changes in chemistry, mechanisms, number of bottles, application techniques & clinical effectiveness.

Adhesive dentistry involves two Acid etching of the enamel gave way to methods: the total-etch bonding depending on how the three cardinal

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tooth substrate are accomplished or simplified. Two step systems are subdivided into the self priming adhesives that require a separate etching step, and the self etching primers that require an additional bonding step. The recently introduced all in one adhesives further combined these three bonding procedures into a single step application[5].

The current concept has proved itself both scientifically and clinically .The concept reduces the clinical steps, can be placed inexpensively, provides adequate bonding to enamel and dentin and most importantly, ensures the patients post operative comfort[6].

The purpose of this in-vitro study was to comparatively evaluate the shear bond strength of these newer dentin bonding agents i.e. two-step etch & rinse adhesives i.e. Prime & Bond NT and onestep self etching agents i.e. G Bond, Xeno V & two step self-etching adhesive i.e. Adper SE Plus.

Materials and Method Materials used in the study: (Figure 1) **Dentin Bonding Agents used:**

Bonding Agent	Manufacturer	Туре	Composition
			Di- and Trimethacrylate resins
			PENTA (dipentaerythritol penta acrylate monophosphate)
			Nanofillers-Amorphous Silicon Dioxide
Prime & Bond NT	Dentsply Caulk	Total-etch	Photoinitiators
			Stabilizers
			Cetylamine hydrofluoride
			Acetone
			Bifunctional acrylate
			Acidic acrylate
			Functionalized phosphoric acid ester
Xeno V	Dentsply Caulk	One-step self-etch	Acrylic acid
			Water
			Tertiary butanol
			Initiator
			Stabilizer
			Liquid A:
			Water
			HEMA
			Surfactant
			Pink colorant
Adper SE Plus	3M ESPE	Two-step self-etch	Liquid B:
			UDMA
			TEGDMA
			тмртма
			(hydrophobic trimethacrylate)
			HEMA phosphates
			MHP (methacrylated phosphates)
			Bonded zirconia nanofiller
			Initiator system based on camphorquinone.
			Acetone,
			4-META
			(4-Methacryloxyethyltrimellitate anhydride),
			UDMA (Urethane dimethacrylate),
G Bond	GC	One-step self-etch	Phosphate monomer,
			TEGDMA (Triethyleneglycol dimethacrylate),
			Water,
			Fumed silica fillers,
			Photoinitiator.

Operative Procedure

Sample collection, cleaning and storage: Eighty freshly extracted non-carious intact human molars were selected for this study. Teeth with restorations, cracks, attrition and other structural defects were excluded. After extraction all the teeth collected were cleaned of blood and saliva in running water. Calculus was removed with the help of a scaler followed by thorough cleaning with pumice slurry and rubber prophylaxis cup. The teeth were then stored in normal saline solution. These specimen teeth were utilized for this study within six months of extraction as per ISO standards (G. Oilo, 1993).

Preparation and grouping of the specimens for shear bond strength:

To standardize depth of cavity, depth holes were drilled in the deepest part of central fossa of each tooth. The occlusal surfaces of all the teeth were ground on water-cooled orthodontic trimmer to obtain a flat dentinal surface.

Steel moulds of dimension 2.1 x 2.1 cm were placed in position over the teeth. A thin mix of auto-polymerizing acrylic

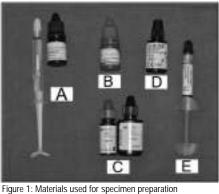


Figure 1: Materials used for specimen preparation Bonding Agents A : 37% phosphoric acid and Prime & Bond NT B : Xeno V C : Adper SE Plus D : G-Bond Composite Material E : Filtek Z350 XT

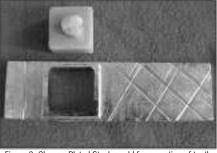


Figure 2: Chrome Plated Steel mould for mounting of tooth specimen

resin was poured in the moulds to embed the prepared tooth, exposing the crown portion of the tooth (**Figure 2**). The prepared specimens were then randomly divided into four groups, based on dentin bonding agent used, with twenty specimens in each group, namely: Group I – for Prime & Bond NT Group II – for Xeno V Group II – for Adper SE Plus Group IV – for G Bond The mounted teeth were then stored in normal saline at room temperature.

Application of bonding agent and composite build up:-

Bonding agent (Prime&Bond NT, G Bond, Xeno V, and Adper SE Plus) was applied on the flat dentinal surface of each mounted tooth of all the four groups according to the manufacturers' instructions.

The split-teflon mould was placed over the bonded surface at the pre-designed location in the mould holder. Filtek Z350 XT (3M ESPE) was placed in increments into the circular punch hole measuring 3 mm \times 3 mm in a Teflon sheet and cured layer by layer for 20 seconds with SmartLite PS (Dentsply) (intensity >500 mW/cm2) (Figure 3 a and b).

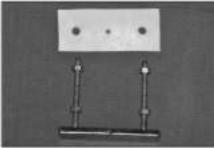


Figure 3 a: Chrome plated steel mold holder and Split Teflon mould used in shear bond strength study

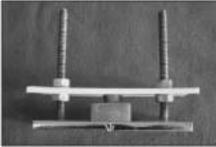


Figure 3 b: Chrome plated steel mold holder and Split Teflon mould with tooth specimen in place for composite build-up

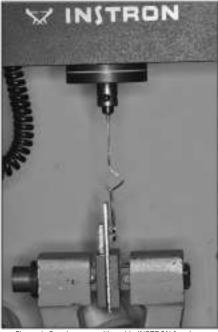


Figure 4: Specimens positioned in INSTRON for shear testing.

Once the composite was cured, the split teflon mould was gently lifted out and specimens were obtained.

Thermocycling of the specimens:-

Specimens were then stored in distilled water at 37I0;C for 24 hours. The thermocycling of specimens of each group was carried out in accordance with the ISO standards that are 500 cycles at 5°C and 55°C, dwell time of 30 seconds and transfer time of 15 seconds (G.Oilo, 1993).

Table 1. Shear Bond Strength in Megapascals (Mpa)

No Of Samples	Group I	Group II	Group III	Group IV
1	23.451	20.988	19.56	16.543
2	24.82	21.84	20.564	16.78
3	22.495	21.302	20.86	17.432
4	21.224	22.754	19.53	17.34
5	20.95	22.75	15.534	17.783
6	24.56	24.657	20.34	18.534
7	22.875	23.785	20.763	16.32
8	23.65	22.95	20.546	19.76
9	23.657	22.454	21.56	17.65
10	24.886	20.77	20.432	16.432
11	26.785	24.758	17.765	17.543
12	27.544	21.65	20.645	18.543
13	23.896	20.836	21.556	17.324
14	22.876	21.67	23.56	18.34
15	21.757	22.67	16.9	17.324
16	23.864	21.849	20.34	16.742
17	24.1	20.64	19.564	19.43
18	21.85	21.784	20.61	17.542
19	22.675	22.39	18.56	15.5
20	24.3	20.76	19.654	14.762
AVG (MPa)	23.47943	22.0799	19.9709	17.35071
SD	1.692879	1.217825	1.666203	1.155526

Table 2: Mean and standard deviation values for shear bond strength

Value	Ν	Mean	Std. deviation	Minimum	Maximum
Group I	20	23.479	1.692	20.853	24.886
Group II	20	22.079	1.217	20.421	24.758
Group III	20	19.970	1.666	17.765	23.56
Group IV	20	17.350	1.155	14.762	19.76

= 8.1968, P < 0.005 vhs

Table 3: Intergroup comparison of shear bond strength values

Value					
Mean difference	t	р			
1.399	3.609	.005 vhs			
3.508	8.673	.005 vhs			
6.128	12.452	.005 vhs			
2.109	4.927	.005 vhs			
4.729	10.451	.005 vhs			
2.620	5.748	.005 vhs			
	1.399 3.508 6.128 2.109 4.729	1.399 3.609 3.508 8.673 6.128 12.452 2.109 4.927 4.729 10.451			

Shear bond strength testing:-

Specimens were then mounted on a Universal Testing Machine in the Department of Textile Engineering, Indian Institute of Technology (IIT), Delhi and loaded until resin-dentin interface fractured. The machine was adjusted to operate on a load of 100 Kgs. A cross-head speed of 1 mm/minute was used and the breaking load was measured by recording the reading on the display panel of the machine. The breaking load in kilograms was then converted into bond strength in megapascals.

For shear bond strength testing, the steel moulds with the prepared specimens

adapted in them, were adjusted vertically in the inferior (static) jaw of the Universal Testing Machine. The placement of the specimen in the steel mould was such that the composite build up stood parallel to the floor. A key with dimensions same as that of the composite cylinder (3 mm x 3 mm), gripped in the superior jaw of the Instron machine, was adapted on to the composite build up. The shear force was then applied at the resindentin interface until the dislodgement of the composite cylinder from the dentinal surface occurred (**Figure 4**).

The results of all four groups were then statistically analysed using SPSS 10 software for one-way ANOVA tests followed by Tukeys HSD test to determine if significant differences existed between the groups.

Results

Shear bond strengths (MPa) of each specimen of all four groups were obtained (**Table 1**), and then put to statistical analysis.

The results revealed that samples of Group I (Prime & Bond NT) had the maximum shear bond strength (23.479 MPa).

When a comparison of the shear bond strength of total etch and newer self etch adhesives was made using one-way ANOVA, it showed high statistically significant results. (Table 2)

p < 0.005. So our experimental results will give 0.05% error or 95% confident level at significance level. Hence, multigroup comparison was done using Tukeys HSD Test.

The shear bond strength values of the control group Prime & Bond NT (Group I) showed the highest mean bond strength values compared to the experimental groups of self etch adhesives (Group II, Group III and Group IV). Intergroup comparison was done between the adhesives using Tukey HSD test. The shear bond strength values of Group I (Prime & Bond NT) versus Group II (Xeno V), Group III (Adper SE Plus), Group IV (G-Bond), and showed high significance level. This indicated that the total etch adhesives have better bonding ability as compared to the newer self etching adhesives. (Table 3)

Intercomparison was done between the self etch adhesives using Tukeys HSD test. Comparison between Group II (Xeno V) and Group III (Adper SE Plus)

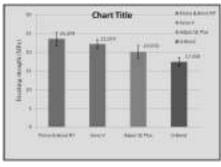


Figure 5. Bar Diagram Showing Comparison of Mean Shear Bond Strengths in MPa of various Study Groups

also showed statistical significant difference (p<0.05) indicating that onestep self etch adhesive Xeno V is a better dentin bonding agent than two-step self etch adhesive Adper SE Plus.

Comparison of Group II (Xeno V) with Group IV (G-Bond), which are both onestep self-etch adhesives, showed high statistically significant difference inferring that Xeno V had comparatively higher bond strength to dentin.

When intergroup comparison was done between Group III and Group IV using Tukeys HSD test, the results proved to be significant statistically, showing that Adper SE Plus had better bond strength than G bond.

Conclusion: Among these four groups, Group I had highest shear bond strength (Avg 23.48 MPa), and Group IV had minimum shear bond strength (Avg 17.35 MPa) (Figure 5).

Discussion

Ever since the introduction of dental composite resins by Bowen (1962) and the concept of retention using acid etching by Buonocore (1955), there has been extensive addition to their plethora of applications. Dental composites with dentine adhesive systems are currently the most popular materials for restorations.

Over the last three decades, numerous dentin adhesive systems have been released in the market, all claiming their own specific adhesion strategy. Clinicians are faced with many challenges when selecting a dental adhesive system to bond resin-based materials to mineralized tooth structure. The current trend in adhesive dentistry is focused on using systems that are simple to use and have minimal chair-side time[7].

Modern dentin adhesive systems generally use one of two adhesion strategies based on method of dealing with the smear layer [8]. One strategy is

to modify and infiltrate the smear layer III) and one-step self-etch adhesive with resin, while the other is based on a so-called hybridization process in which complete removal of the smear layer and concurrent demineralization of the dentin surface layer, followed by resin interdiffusion into the microporosities of the exposed dentinal collagen matrix [9]. Shear type of test is the most commonly used methods as described by the ISO Standards [10]. Barkmeier and Cooley (1992) said that the shear bond strength test is a simple evaluation procedure used to test the adhesion of dental adhesives. In vitro bond strength tests are useful and essential for predicting the performance of adhesive systems and have a correlation with clinical issues [4],[11].

The present in-vitro study compared in vitro shear bond strength of the 5th generation total-etch dentin adhesive Prime and Bond NT with newer self-etch bonding systems Adper SE Plus, Xeno V, and G bond.

Thermal cycling allows bonded specimens to be subjected to extreme temperatures, which mimic intraoral temperature variations (M Miya Zaki et al, 2000)[12]. So in the present study, thermocycling of specimens of each group was carried out in accordance with the ISO standards i.e. 500 cycles at 5°C and 55°C, dwell time of 30 seconds and transfer time of 15 seconds[13].

Shear bond strength testing was done with a Universal Testing Machine, Instron, (Instron - UTM, Model 4202). Instron machine is conventionally popular for evaluating the adhesive ability of adhesive /restorative materials. With the simple technique and relevant results it is considered a benefit for ranking and marketing purposes[14], [15]. So in the present study, the machine was adjusted to operate on a load range of 0-100 kilograms. ISO recommended values of cross-head speed i.e. 0.45-1.05 mm/minute were taken in to consideration and 1 mm/minute cross head speed was used.

Kiremitci A. et al (2004) postulated that minimum bond strength of 17-20 MPA to enamel and dentin is needed to resist contraction forces of resin composite materials [16]. Clinical experiences confirm this bond strength is sufficient for successful retention of resin restoration.[17]

All adhesive systems used in this present study - total etch adhesive Prime & Bond NT (Group I); two-step self-etch adhesive system Adper SE Plus (Group entrapment of this residue within the

systems Xeno V (Group II) and G-Bond (Group IV), achieved the optimal bond strength values for dentin. However, the total etch system Prime & Bond NT showed better bond strength compared to the self etching adhesives - Xeno V, Adper SE Plus and G-Bond.

This result was in accordance with Bouillaguet et al, Chuang et al, Kerby et al who concluded that self etching adhesives have lower bond strength as compared to total etch bonding systems [18], [19], [20]. Senawongse et al also demonstrated that 2 self etching systems, One - up bond and Clearfil SE bond, had lower bond strength than did the total etch system Single bond.[14] According to Hashimato et al, self etch adhesives produced thinner and shorter resin tags than those produced by phosphoric acid etching and thus resulted in inferior bond strength as compared to total etch adhesive systems.[20], [21]

The highest shear bond strength of Prime & Bond NT (Group I) when compared with the various other dentin bonding agents used (Group II, Group III & Group IV) can be explained by the fact that PENTA in Prime & Bond NT is a molecule of mild acidity that behaves as a conditioning agent (Perdigao et al, 1994)[22]. PENTA is claimed to bond ionically to dentinal calcium [22] and is an adhesion promoter that facilitates the penetration of resin monomer into the dentin for micromechanical bonding. UDMA in Prime & Bond NT is a hvdrophobic monomer for proper polymerization and cross linking and bonds to surface-bound hydroxyl groups through its urethane groups (Andre V. Ritter et al, 2000)[23]. This could have resulted in better penetration through smear layer and improved contact of monomer within the exposed collagen fibres, resulting in a homogenous interface with no voids and hence, better bonding.

According to the present study self etch adhesives showed lower bond strength as compared to total etch bonding systems. Self etching adhesives provide lower bond strength than total etch systems because of their semi permeability, incorporation of smear layer, shorter resin tag formation, residual acidity and hydrolytic instability[24]. The phosphoric acid etching and water rinsing in total-etch to remove dissolved calcium phosphate would prevent otherwise interfere with resin penetration as seen in self etching adhesives [25].

Self etching adhesive systems rely on acidic monomers to simultaneously demineralize and infiltrate enamel and dentin. This acidity must be neutralized by the mineral content of the tooth structure to allow complete polymerization of the adhesive film [26]. With total-etch adhesive, smear layer and dissolved mineral are removed during the rinsing step. But because of some questions regarding residual acidity of the self-etch adhesives, and the fact that the smear layer is not removed, the issue of long term hydrolytic stability of the self etching adhesive systems still remains unresolved [3], [27]. Further the presence of smear layer in self-etch adhesives could have inhibited the penetration of the primer/resin into collagen fibres[28].

However, Kiremitci et al (2004) concluded that self etching adhesive system produced higher bond strength than conventional total etch systems, especially all in one system which produced the highest bond strength.[17] Whereas, Sensi et al (2005) have asserted that self etch and total etch primer showed comparable dentin bond strength.[4]

Among the self etching adhesive systems tested, Xeno V (Group II) showed the highest bond strength compared to all other experimental groups i.e. G-Bond (Group IV) and Adper SE Plus (Group III) and the results came out to be statistically significant (p<0.05).

"Strong" self-etch adhesives usually have a pH of 1 or below. This high acidity results in rather deep demineralization effects. At enamel, the resulting acid etch pattern resembles a phosphoric-acid treatment following an etch & rinse approach. At dentin, collagen is exposed and nearly all hydroxyapatite crystals are dissolved (B. Van Meerbeek et al, 2003).[24], [29]

The good bond strength values obtained with Xeno V, which is an intermediately strong self etch adhesive, has been attributed to its acidic pH of 1.4. This acidic nature results in better micromechanical interlocking to enamel and dentin compared to mild self etch adhesives [30]. Low pH ensures etching through thick smear layers to engage underlying intact dentin to form thin zones of demineralization that are simultaneously infiltrated by resinsto

bonding resin layer which might provide strong adhesion. It is also suggested that the residual hydroxyapatite at the hybrid layer base may still allow for chemical intermolecular interaction.[29]

The self etching systems which were tested in different studies showed significant differences in performance in terms of bond strength. These differences could be attributed to the efficiency of their respective monomers at infiltrating the smear layers and producing resin tags.[18], [31]

Two-step self-etch system, showed a superior in vitro performance in comparison with one-step self-etch systems [2]. Adper SE Plus (Group III) which is two step self etching adhesive resulted in higher shear bond strength than other self etch adhesive i.e. G-Bond (Group IV), even though it showed low bond strength compared to Xeno V (Group II) (p<0.05). Achievement of strong micromechanical bonding depends on the depth of monomer penetration into demineralized dentin (Erikson, 1992). The superior bonding of Adper SE Plus can be attributed to this two-step procedure for dentin bonding wherein first step prepares and conditions the tooth surface leading to more depth of penetration and in a way mimics total etch technique but with a different mechanism. The second step produces identical depths of etching and penetration of the adhesive. Nanoleakage resulting from an insufficient penetration depth of the adhesive can be minimized by this mechanism. In addition, this keeps the collagen fibers from collapsing and eliminates dependence on "moist bonding" characteristic of the 5th generation systems. The adhesive part of Adper SE Plus Self-Etch Adhesive contains phosphoric acid esters, which under aqueous conditions will etch the surfaces of dentin and enamel to allow for the micromechanical bonding to the tooth. AdperTM SE Plus Self-Etch Adhesive contains a bonded zirconia nanofiller which helps to develop a uniform film, which in turn can lead to higher bond strengths [32].

Single bottle adhesives are complex mixtures of hydrophilic and hydrophobic resin monomers dissolved in water / solvent combinations. Most single step self etch adhesives contain hydroxyethyl methacrylate (HEMA), hydrophilic primer, and the presence of HEMA is advisable for maintaining resins in solution and preventing phase

separation[33] that is, it helps to mix hydrophobic and hydrophilic components into one single solution, as well as it serves as a co-solvent to dissolve the diverse active ingredients into water . Self-etch adhesives need water for providing an ionization medium to enable self-etching [33]. On the other hand. HEMA lowers the vapor pressure of water when added to a water mixture, making it more difficult to remove water from the adhesive and retaining water within the adhesive layer[34]. So, HEMA being hydrophilic holds water within the adhesive layer, thereby hindering the polymerization process and thus be detrimental to the bond on the long term. It promotes water to be bonded in unstable soft hydrogels prone to hydrolytic degradation [33]. It even enhances water uptake from the tooth as well as the outer oral environment, rendering the bond more prone to degradation with time [5], [27] Hence, HEMA free single step self etch adhesives were developed (G-Bond).

In accordance with the results of the present study, the lowest shear bond strength was obtained by the self etching HEMA free adhesive G-bond (Group IV). The consequence of the HEMA-free formulation of G-Bondis that upon evaporation of the acetone solvent (once supplied within the cavity), the adhesive monomers separate from the water content (Van Landuyt et al., 2005). Following this phase separation, water droplets are formed within the adhesive layer. The convergence of small blisters into larger ones tends to produce honeycomb structures that may jeopardize the bonded interface [27], [33]. This could be the probable reason for the lowest shear bond strength of G-Bond in the present study. Moreover, G-Bond contains 4-methacryloxyethyl trimellitic acid (4-META) which has a weaker bonding potential (Yoshida Y. et al, 2004) [35].

Of all the adhesive system tested, the total-etch Prime & Bond NT provided a highest shear bond strength and among the self etching adhesives Xeno V showed the highest bond strength compared to all other experimental groups.

Within the limitations of this in-vitro study it can be concluded that all the adhesive agents evaluated showed optimal shear bond strength. However, total etch adhesives recorded a higher shear bond strength than the newer self

etching bonding agents. But the existing self-etch adhesives are popular because they are easy to handle, convenient, and less confusing for the clinician than the multistep adhesive systems and also as their bond strength lies in the optimal range for clinical success [36].

Even though dental adhesives have been available over several generations with an array of new materials being launched every year, clinical studies are not 6. Christensen Gordon. J (2001) Self abundant in the literature. There has been frequent practice among manufacturers to launch a new version of a specific 7. Kimmes NS, Barkmeier WW, adhesive even before the previous one has been fully tested. As a result of all these limitations, clinicians still rely on data from laboratory studies to predict the behaviour of adhesive materials. Hence, since the materials that were used in the present study were relatively new, further studies need to be done for further clinical evaluation.

Conclusion

Within the limitations of this in vitro study, it can be concluded that all the adhesives agents evaluated showed optimal shear bond strength of 17-20 MPa. However, the one bottle total-etch adhesive Prime & Bond NT recorded higher shear bond strength than the newer self etch bonding agents. In this study, it was seen that among the self etch adhesives, Xeno V showed the highest shear bond strength and G-Bond showed the lowest shear bond strength.

Therefore, this in-vitro study concluded that shear bond strengths of dentin bonding agents with old concept of twostep total-etch technique are superior to that of newer self-etch systems, although their bond strength values also lies within the acceptable range of clinical requirements.

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Source of Support : Nill, Conflict of Interest : None declared

Nakayama Y, Okazaki M, Shintani H, Inoue S, Tagawa Y, Suzuki K, Munck J. De and Meerbeek B.V (2004) Comparative Study on Adhesive Performance of Functional Monomers. J Den Res.83(6): 454-458.

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