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SCIENTIFIC SECTION

In vivo evaluation of two new moisture-resistant orthodontic adhesive systems: a comparative clinical trial

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Abstract

Objective: To evaluate and compare the clinical performance of two new moisture-resistant orthodontic adhesive systems: a chemically-cured composite resin (Unite, 3M Unitek, Monrovia, California, USA) in conjunction with a special moisture-resistant primer (Transbond MIP, 3M Unitek, Monrovia, California, USA); and a fluoride-releasing light-cured compomer (Assure, Reliance Orthodontic Products, Inc., Itasca, Illinois, USA).

Design: Randomized controlled clinical trial using the 'split-mouth' technique.

Setting: Department of Orthodontics, Aristotle University of Thessaloniki.

Subjects (Materials) and Methods: Twenty-five consecutively started patients (13 females and 12 males) requiring fixed appliance orthodontic treatment.

Interventions: Four-hundred-and-thirty-six stainless steel brackets bonded to all teeth except molars using two different moisture-resistant orthodontic adhesive systems.

Main outcome measures: Bond failure rates during a period of 9 months were estimated for each adhesive system and the corresponding bracket survival curves were plotted using the Kaplan–Meier product-limit estimate. Bracket survival distributions with respect to adhesive material, tooth location, patient's gender and operator, were then compared by means of a log-rank test. Bond failure interface was determined using the Adhesive Remnant Index.

Results: Assure recorded a higher bond failure rate (13.8 per cent) than Unite & MIP (7.3 per cent). The corresponding bracket survival curves were found to be significantly different ($P < 0.05$). Premolars exhibited higher bond failures than incisors and canines ($P < 0.001$), while half (49.8 per cent) of the total bond failures occurred during the first 2 months of treatment. The predominant mode of failure was within the bonding material.

Conclusion: The new moisture-resistant adhesive systems under study were found to be clinically efficient, though Assure exhibited a significantly higher bond failure rate than Unite and Transbond MIP. The higher frequency of adhesive failures observed with Assure might indicate a possible weak point at the adhesive-bracket interface.

Index words:
Clinical trial, moisture-resistant adhesive, orthodontic bonding.

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Introduction

Most of the current orthodontic bonding materials are composite resins based on the bis-GMA formula. Although the use of these materials is well accepted, one major problem is the need for obtaining and maintaining a completely dry operating field throughout the bonding procedure.[1] This is important because moisture contamination of the enamel surface is regarded as the commonest reason of bond failure.[2]

Moisture control, however, can be a problem during bonding in hard-to-reach areas, such as second molars, lower premolars, and partially erupted teeth, or in extreme situation, such as recently exposed impacted

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canines. This is reinforced by the fact that a number of clinical studies have reported higher probability of bond failure for the lower and the posterior teeth.[3–5]

This has resulted in an increasing interest by manufacturers to introduce orthodontic bonding systems that can perform in the presence of moisture. One recent development has been an orthodontic primer (Transbond MIP, 3M Unitek, Monrovia, California, USA), which is claimed to be capable of achieving sufficient bond strength even if the etched enamel surface has been contaminated with moisture. This material is chemically identical to a hydrophilic dentin-bonding agent (Single Bond, 3M Unitek, Monrovia, California, USA) and contains 2-hydroxyethyl methacrylate, polyalkenoate co-polymers with carboxylate groups, and ethanol.[6] The manufacturer recommends its use in conjunction with chemically- or visible light-cured resin adhesives.

Another recently introduced orthodontic adhesive (Assure, Reliance Orthodontic Products, Inc., Itasca, Illinois, USA) is marketed as both moisture-resistant and fluoride-releasing. Assure is a light-cured polyacid-modified composite resin or compomer. Compomers are single-component systems consisting of aluminosilicate glass in the presence of carboxyl-modified resin monomers and light-activated conventional resin monomers.[7] They were developed to bring the advantages of glass ionomer cements (fluoride release, chemical adhesion, or chelation) to resin based adhesives.

There are already a few *in vitro* studies that aim to estimate the shear bond strength of these two novel orthodontic systems.[6,8–12] Although these *in vitro* measurements of shear bond strength provide useful information about the bonding efficiency of different types of materials, they should be interpreted with caution because of inherent limitations and because they cannot take into account a number of factors that play an important role in the mouth.[13] Therefore, they may not be fully representative of the clinical reality.

The aim of the present randomized clinical trial was to evaluate and compare the clinical performance of Unite and Transbond MIP, and Assure, when used for direct bonding of orthodontic brackets. The null hypothesis was that there was no difference in bracket survival distribution for brackets bonded with either bonding agent, during a specified period of active orthodontic treatment.

Materials and Methods

Sample

The subjects of this study were patients seeking treatment at the Department of Orthodontics, School of Dentistry, Aristotle University of Thessaloniki. Following ethical approval, 25 consecutive patients (13 females and 12 males, age range: 10–17 years) who required orthodontic therapy by means of fixed appliances, were selected and treated by the first two authors. The adhesives were randomly allocated using the split-mouth design. Enrolment had as a prerequisite the informed consent of the patients. The mouth of each patient was divided into quadrants and the contralateral bonding pattern was randomly alternated from patient to patient in order to assure an equal distribution of adhesives between the right and the left side of the dental arches. All teeth, except the molars, were directly bonded. The selection criterion was the absence of occlusal interferences on any of the bonded brackets, chosen in an effort to eliminate the influence of trauma on failure rate. Enamel surfaces presenting caries, fillings, or gingival hyperplasia were likewise excluded from the study. Bracket failures caused by known operator error were immediately excluded from the calculation.

Half of the brackets were bonded using a no-mix chemically cured composite resin (Unite, 3M Unitek, Monrovia, California, USA) in conjunction with a special moisture-resistant primer (Transbond MIP, 3M Unitek, Monrovia, California, USA). The remaining half were bonded with a fluoride-releasing light-cured moisture-resistant compomer (Assure, Reliance Orthodontic Products Inc, Itasca, Illinois, USA). The same brackets were used with both adhesives and were twin stainless steel edgewise brackets (Mini, Forestadent, Pforzheim, Germany).

Method

A standardized protocol of tooth preparation and bracket bonding was adopted for all the patients. After fitting and cementing molar bands onto the first and second permanent molars, all teeth were isolated and cleansed with a mixture of water and pumice using a rubber-polishing cup on a low speed hand piece. The teeth were rinsed and dried with an oil-free air syringe, and were etched with the conventional acid etching technique (37 per cent orthophosphoric acid applied for 30 seconds). They were subsequently rinsed thoroughly

with water to ensure total removal of etchant and dried according to the manufacturer's instructions.

A liberal coat of the Moisture-Insensitive Primer was applied to the etched area of the teeth destined for Unite and Transbond MIP using a nylon brush. The brush was dipped in the primer for each tooth to be primed. Air was gently blown on each tooth for 2–5 seconds, aiming the air stream perpendicular to the enamel surface. After this, a thin coat of the conventional primer supplied in conjunction with Unite was applied to the bracket base, followed by the adhesive paste. The bracket was then applied to the enamel surface and adjusted to final position by exerting a pressure to firmly seat it. Excess adhesive surrounding the bracket was gently removed.

To the remaining teeth to be bonded with Assure, the special liquid activator was applied in two coats, left for 10 seconds, lightly dried, and then light-cured for 10 seconds. Subsequently, the adhesive paste was applied to the bracket base using a wooden stick supplied by the manufacturer. The bracket was then positioned on the etched surface and pressed firmly. Excess resin was gently removed, and the adhesive was light-cured for 20 seconds from the incisal edge and then 10 seconds from each additional side, giving a total curing time of 50 seconds per bracket.

Initial wires were fitted 10–15 minutes after bonding completion. For each case, a similar treatment approach (e.g. archwire sequence) was adopted in the context of the straight wire technique. The patients were followed for a period of 9 months. Bond failures were recorded in each patient's special record, with the time of bond failure identified as the date when bond failure was noticed. A code was assigned to each bonded bracket indicating that it survived the observation period or had failed. The following information was also recorded in a similar way for each bracket:

(1) the adhesive used;
(2) the date of bonding;
(3) the date and the alleged reason of bond failure;
(4) the Adhesive Remnant Index (ARI) score.[14]

All patients received the same instructions and were seen at 3–4-week intervals. They were, however, requested to attend as soon as possible once a bond failure was apparent. They were instructed to brush with a manual toothbrush using a fluoride-containing toothpaste.

Statistical analysis

Bond failure rates during a period of 9 months were estimated for each adhesive system and the corresponding bracket survival curves were plotted using the Kaplan–Meier product-limit estimate. Bracket survival distributions with respect to adhesive material, tooth location (upper/lower, anterior/posterior, right/left side), patient's gender, and operator, were then compared by means of a log-rank test. Bond failure interface was determined for each bonding agent using the ARI score distribution.

Results

Adhesive

A total of 46 bond failures were registered during the 9 months of the observation period: 16 (7.3 per cent) occurred with Unite and Transbond MIP, while 30 (13.8 per cent) with Assure (Table 1). The corresponding bracket survival curves were plotted using the Kaplan–Meier product-limit estimate (Figure 1). The log-rank test, revealed that Assure had a higher bond failure rate than Unite and Transbond MIP ($P < 0.05$).

Tooth location

We also found there was no difference between the upper and the lower dental arches (Table 2), or between

Table 1 Bond failure rates for the orthodontic adhesives

Adhesive	Brackets	Failures	Failure rate
Unite & Transbond MIP	218	16	7.3%
Assure	218	30	13.8%

Table 2 Bond failure rates: upper vs. lower arch

Adhesive	Upper			Lower			Log-rank test
	Brackets	Failures	Failure rate	Brackets	Failures	Failure rate	
Unite & Transbond MIP	115	6	5.2%	103	10	9.7%	NS
Assure	112	12	10.7%	106	18	17.0%	NS
Total	227	18	7.9%	209	28	13.4%	NS

NS, not significant.

the right and the left side (Table 3). Premolars, however, exhibited higher bond failure rate than incisors and canines ($P < 0.001$). This was also true when each bonding agent was examined separately (Table 4).

Patient's gender

No difference was found in the frequency of bond failures with respect to the patient's gender (Table 5).

Investigator

The difference in the failure rates observed between the two operators was found to be non-significant ($P > 0.05$), thus enhancing the reliability of the reported results (Table 6).

Bond failures as a function of time

Half of the total bond failures (49.8 per cent) occurred during the first 2 months of treatment (Figure 2).

Bond failure interface

The predominant mode of failure was within the bonding material (cohesive failure) for both adhesives. However, Assure exhibited a higher frequency of ARI score of 3 (all adhesive remaining on the enamel), which

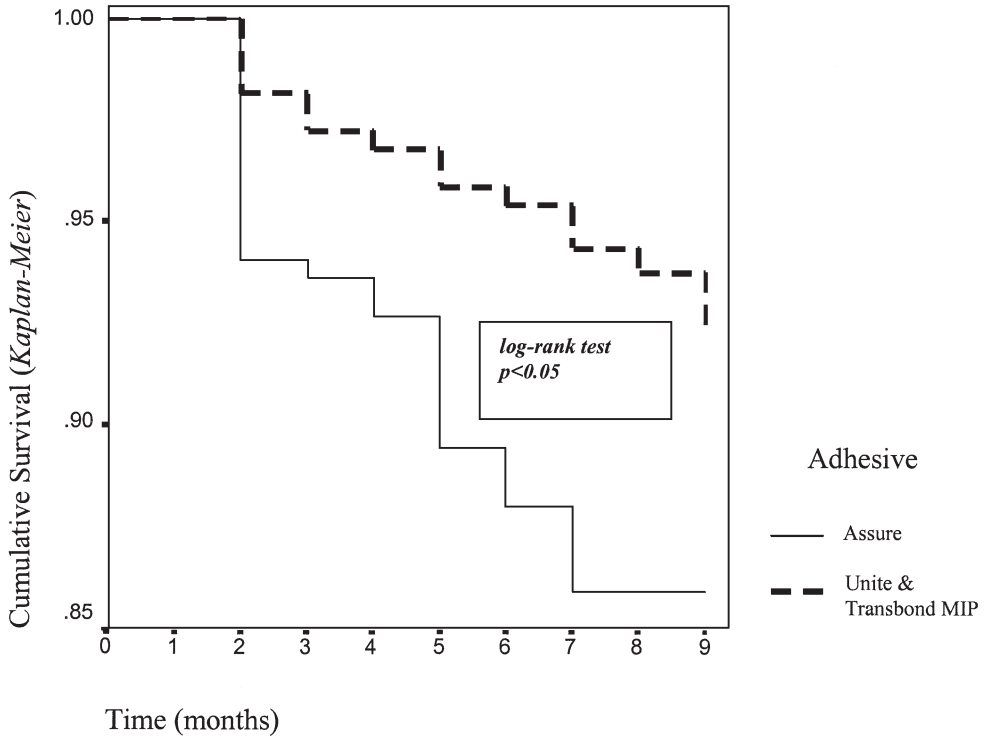

Fig. 1 Bracket survival distribution of both orthodontic adhesives plotted against time.

Table 3 Bond failure rates: right vs. left side of the dental arch

Adhesive	Right			Left			Log-rank test
	Brackets	Failures	Failure rate	Brackets	Failures	Failure rate	
Unite & Transbond MIP	109	8	7.3%	109	8	7.3%	NS
Assure	109	14	12.8%	109	16	14.7%	NS
Total	218	22	10.1%	218	24	11.0%	NS

NS, not significant.

Table 4 Bond failure rates: anterior (incisors, canines) *v.* posterior (premolars) teeth

Adhesive	Anterior			Posterior			Log-rank test
	Brackets	Failures	Failure rate	Brackets	Failures	Failure rate	
Unite & Transbond MIP	137	4	2.9%	81	12	14.8%	$P < 0.001$
Assure	137	12	8.8%	81	18	22.2%	$P < 0.01$
Total	274	16	5.8%	162	30	18.6%	*$P < 0.001$*

Table 5 Bond failure rates: girls *v.* boys

Adhesive	Girls			Boys			Log-rank test
	Brackets	Failures	Failure rate	Brackets	Failures	Failure rate	
Unite & Transbond MIP	114	8	7.0%	104	8	7.7%	NS
Assure	112	14	12.5%	106	16	15.1%	NS
Total	226	22	9.7%	210	24	11.4%	NS

NS, not significant.

Table 6 Bond failure rates between the operators

Adhesive	Operator I			Operator II			Log-rank test
	Brackets	Failures	Failure rate	Brackets	Failures	Failure rate	
Unite & Transbond MIP	111	9	8.1%	107	7	6.6%	NS
Assure	108	13	12.0%	110	17	15.5%	NS
Total	219	22	10.0%	217	24	11.1%	NS

NS, not significant.

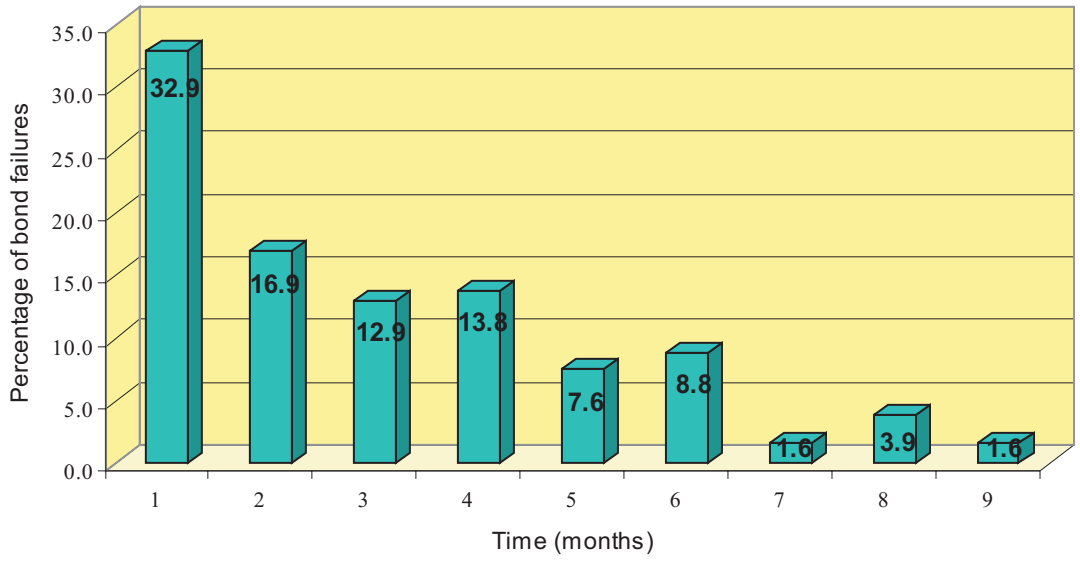

Fig. 2 Bond failure percentage as a function of time.

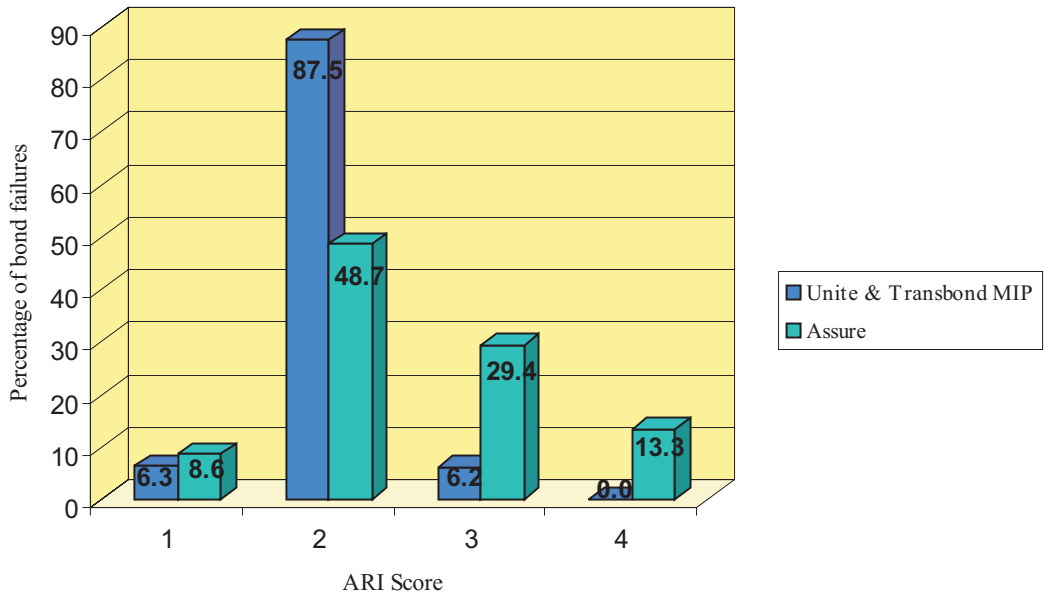

Fig. 3 Distribution of ARI scores for each adhesive.

indicates a greater tendency towards adhesive failure (Figure 3).

Discussion

Study design

In vitro investigation of bond strength plays an important role in evaluating the bonding efficiency of newly introduced orthodontic systems. While it is true that certain aspects of physical and chemical adhesive properties may be clarified by *ex vivo* approaches, the actual performance of the system can only be evaluated in the environment where it was intended to function.[13] Therefore, the most reliable method to illustrate the clinical efficiency of new bonding materials is the evaluation of clinical bond failure rate using randomized controlled clinical trial methodology.

The bonding systems studied were not water-activated, but moisture-resistant, which means that their manufacturers claim that they can perform even on moisture contaminated enamel. In fact, in a number of previous *in vitro* studies,[9–11] the shear bond strength values obtained using the same orthodontic adhesives under moist conditions were inferior to those obtained under dry conditions. The authors believe that the most probable benefit from using these bonding materials could be minimizing the effects of accidental enamel contamination in areas, where efficient moisture control is challenging, such as second molars, partially erupted (particularly lower) premolars or just exposed impacted teeth. As a consequence, for ethical reasons, but also due to the difficulty in standardizing not only the amount of moisture to use, but also the type (water, saliva, blood),[12] the present clinical study was performed under dry conditions, which is current clinical practice.

Bond failure rate

In this *in vivo* study the bond failure rate of Unite in conjunction with Transbond MIP was 7.3 per cent. In a parallel study[15] performed by the same authors, in the same clinic and under the same conditions, the bond failure rate of a standard composite resin (System 1+, Ormco, Orange, California, USA) was found to be 5.1 per cent. Bond failure rates below 10 per cent are generally considered as clinically acceptable, although the direct comparison between studies should be interpreted with caution, since there is not yet a standardized protocol for such clinical studies.[16]

Very recently, comparison of the clinical failure rates of brackets bonded using a prototype hydrophilic primer, designed to be insensitive to moisture, with brackets bonded with a conventional primer was reported. It was concluded that the hydrophilic primer—that was also the basis of the presently used primer—could not be recommended for routine clinical use.[17] The other moisture-resistant adhesive in our study, a compomer

(Assure), recorded a significantly higher bond failure rate (13.8 per cent). Compomers, which are polyacid-modified resins, have been developed in an attempt to bring the positive properties of glass ionomer cements to light-cured composite resins. Although they behave primarily like resins, it is postulated that light curing initiates a delayed acid-base reaction, that may release fluoride from the aluminosilicate glass upon water absorption, but their physical properties are inferior to those of the composite resins.[18] The shear bond strength of Assure was found significantly lower (though still clinically acceptable) in comparison with a light-cured composite resin in two recently published *in vitro* investigations.[9,11]

We also found that there was no difference in bond failure rate between the upper and lower dental arch. This is in agreement with previous clinical studies,[19–24] although in some others more failures were reported in the lower arch.[2–4,25–27] This could be attributed to the difficulty of moisture control in the lower arch, as well as to the occlusal forces having more pronounced effect on the lower teeth. In another study, more failures were found in the upper arch leading to the conclusion that occlusal forces do not play a major role in bond failure rate.[28]

The failure rate of brackets bonded to the posterior teeth (first and second premolars) was found to be three times higher than the brackets bonded to the anterior teeth (incisors and canines), confirming the findings of previous studies.[2–4,20,21,25,27,29–32] The high incidence of bracket failures in the posterior parts of the dental arch could be associated to a number of factors, such as the poor moisture control,[2,27,31] the partial eruption of second premolars,[4,33] the heavier occlusal forces exerted on the posterior teeth during mastication,[21,34] and the larger amounts of aprismatic enamel on premolars affecting the quality of micromechanical bond.[25,35] However, in two recent clinical studies no statistically significant difference was found between the six anterior and the four posterior (first and second premolars) teeth.[18,22]

The bond failure rate with respect to the side of the dental arch has not received much attention in previously published clinical studies. The few reports available are contradictory since they found more bond failures in the left[21] or the right side of the dental arch.[29] There are several possible factors in determining the difference of bond failure rate between the two sides: the clinicians being right-handed could make access, bracket placement, and moisture control easier on the right side, the habitual side during mastication, and the difference in pressure exerted during toothbrushing.[36] In the present study, we found no differences in bond failure rates between the right and the left side, although both clinicians and the majority of patients were right-handed (Table 3).

The gender of patients did not influence the bond failure rates obtained in the present study (Table 5), confirming previous clinical reports.[15,29,31,37] However, the authors of another study concluded that boys exhibit more failures, the girls, presumably, taking better care of the appliance.[22] There are reports of statistically significant differences between the operators in terms of bracket survival time.[25,37,38] This was not the case in the present study, thus enhancing the reliability of the reported results (Table 6). This could be attributed to the operators having the same clinical experience, as well as to the study being performed in the same postgraduate clinic, using the same treatment approach and appliances.

The predominant mode of failure was within the bonding material (cohesive) for both adhesive systems under study, since the 93.7 and 76.1 per cent of bond failures with Unite and Transbond MIP, and Assure, respectively, were characterized by ARI scores of 1 and 2 (Figure 3). However, Assure exhibited a significant percentage (15.3 per cent) of failures at the adhesive-bracket interface (adhesive), confirming the findings of a previous *in vitro* study where the relevant number was 17.5 per cent.[11] This could indicate a possible weakness at the adhesive-bracket base interface.

Conclusion

The results of this study suggest the following:

1. Unite and Transbond MIP could be a useful alternative to conventional orthodontic adhesives.
2. Assure, a polyacid-modified composite resin with fluoride-releasing capacity, was associated with a higher bond failure rate, which could be related to the observed tendency for more adhesive failures at the adhesive-bracket interface, indicating some possible weakness at the interface adhesive-bracket.

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