

The Effects of Primers and Surface Bonding Characteristics on the Adhesion of Polyurethane to Two Commonly Used Silicone Elastomers

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Abstract

Purpose: When restoring facial defects, maxillofacial prosthodontists and anaplastologists are often limited by material deficiencies. Silicone elastomers bonded to a polyurethane liner best satisfy the functional and esthetic requirements necessary for facial prostheses; however, patients using silicone prostheses with polyurethane liners often experience varying degrees of debonding at the polyurethane–silicone interfaces. This may result in failure of such prostheses. The purpose of this investigation was to evaluate the effects of five primers on bonding between polyurethane and two commonly used silicone elastomers.

Material and Methods: Six bonding regimens were used to join polyurethane and silicone materials. Each treatment group consisted of 12 specimens. Bonding regimens included (1) a 40:60 mixture of MDX4-4210 and Silastic Medical Adhesive Type A, in conjunction with Dow Corning 1205 primer (Udagama's technique); (2) silicone A-2000 with Dow Corning 1205 primer; (3) silicone A-2000 with A-330-G primer; (4) silicone A-2000 with Mucopren primer; (5) silicone A-2000 with Sofreliner T primer; and (6) silicone A-2000 with Sofreliner MS primer. Following fabrication, specimens were attached to a universal testing machine and separated in tension at a crosshead speed of 25.4 mm/min. One examiner performed the assessment of T-peel strength (N/mm), peak load (N), and peel distance (mm) for all specimens. Mean data were analyzed using one-way ANOVA followed by Fisher's protected significant difference multiple comparison of the means ($\alpha = 0.05$).

Results: A statistically significant difference (p < 0.05) in T-peel strength was found among specimen groups. Post hoc analysis indicated that Sofreliner MS primer (1.32 ± 0.13 N/mm) and Sofreliner T primer (1.25 ± 0.11 N/mm) increased the bond strengths significantly compared to A-330-G primer (0.91 ± 0.10 N/mm) and Udagama's technique (0.13 ± 0.02 N/mm). Cohesive failure between silicone A-2000 and polyurethane liner was observed when Sofreliner MS primer and Sofreliner T were used.

Conclusion: Within the limitations of this study, the use of Sofreliner MS primer and Sofreliner T primer produced significant increases in the bond strength of silicone elastomer to polyurethane liner material. Based on T-peel strength, peel distance, and peak load data, the combination of silicone A-2000 and Sofreliner MS primer resulted in the greatest mean bond strength for silicone-to-polyurethane applications.

According to the American Cancer Society, head and neck cancers account for 3 to 5% of all cancers in the United States. These cancers are more commonly found in males and in persons over age 50. Moreover, an estimated 40,500 U.S. citizens develop head and neck cancers each year.¹ Because many head and neck cancers are treated surgically, the resulting defects can be esthetically compromising and emotionally devastating.

Advances in prosthetic therapy and reconstructive surgery have yielded significant improvements in function and appearance. Facial prostheses can be constructed using elastomers



Figure 1 Gypsum mold formed in a brass denture flask.

tinted to match the skin and subsequently attached to the face. The accompanying improvements in appearance and selfesteem permit many of these patients to lead near-normal lives.

Silicone elastomers are most commonly used in maxillofacial applications due to their physical properties, ability to accept internal and external colorants, and similarities to skin texture and elasticity.^{2,3} Unfortunately, silicone elastomers have many shortcomings as well.^{3,4} These materials exhibit poor tear resistance, especially in thin films commonly found at the edges of prostheses. Fungal and bacterial colonization often occur due to surface porosity and the use of adhesives. Furthermore, silicone elastomers tend to absorb facial oils, which can adversely impact prosthesis longevity.

In 1987, Udagama reported the use of a polyurethane liner to overcome certain deficiencies exhibited by silicone elastomers.⁵ Udagama's technique involves adding Silastic Medical Adhesive Type A to MDX4-4210 silicone and treating the associated polyurethane liner with Dow Corning 1205 primer. When bonded to the surface of a facial prosthesis, polyurethane seals the more porous silicone material, yields increased tear strength, and provides improved marginal integrity. A polyurethane liner also makes the tissue surface more receptive to water-based adhesives.^{5,6} In turn, the use of water-based adhesives results in improved cleansability, as well as decreased bacterial and fungal growth. Polyurethane films are much more resistant to the penetration of facial oils, which can cause accelerated degradation of silicones. Udagama's technique



Figure 2 Masking tape used to create a 1.0-cm-wide nonbonded section for Instron attachment.

has since become the gold standard for joining polyurethane liners and silicone elastomers to be used in maxillofacial applications.

Based upon the foregoing considerations, the use of polyurethane liners in conjunction with silicone elastomers offers undeniable advantages. Unfortunately, adhesive failures between polyurethane and silicone components are commonly encountered in clinical practice.^{2,3,5,6} In addition, Udagama's technique requires a considerable percentage of Silastic Medical Adhesive Type A, which gives off pungent and potentially corrosive acetic acid vapors throughout polymerization (i.e., curing). As a result, the search for improved techniques, treatments, and materials continues.

New elastomers and primers have been developed to enhance polyurethane–silicone bonding, but controlled testing of these materials has been minimal. Two commonly used maxillofacial prosthetic silicone elastomers are MDX4-4210 (Dow Corning Corp., Midland, MI) and silicone A-2000 (Factor II, Inc., Lakeside, AZ).³⁻⁶ Each is a pourable, two-component silicone rubber polymerized using a platinum catalyst.

A review of the literature reveals few studies comparing the effects of primers upon polyurethane–silicone bond strengths. In 1992, Wang et al evaluated bond strengths of a 40:60 mixture of MDX4-4210 and silastic medical adhesive silicone Type A to a polyurethane liner using a technique described by Udagama.⁷ The polyurethane was treated using Dow Corning 1205 primer or Dow Corning S-2260 primer. The silicone mixture was then introduced, and specimens were exposed to various polymerization processes. The authors concluded that a 1-hour 1205 primer reaction time combined with 3 hours of exposure to dry heat at 70°C produced the highest mean bond strength between the silicone mixture and the polyurethane liner.

In 2004, Deng et al⁸ evaluated the bond strength of a platinum-based silicone (A-222 PSE-70, Factor II, Inc.) to a polyurethane liner. The investigators used a manufacturerrecommended primer (A-330-G, Factor II, Inc.) on the polyurethane surface prior to introducing the platinum-based silicone. Following completion of the polymerization process, the investigators immersed specimens in a Joy soap cleaning solution maintained at 22 or 56°C. Results indicated a significant decrease in bond strength following immersion in the cleaning solution. This difference was attributed to water damage at the polyurethane–silicone interface.

The purpose of the current investigation was to evaluate the bond strengths between polyurethane liner and silicone

Silicone type	Primer	No of specimens	Mean ±SD		
			Peel strength (N/mm)	Peak load (N)	Peel distance (mm)
MDX4-4210 w/Type A	1205	12	0.13 ± 0.02	3.40 ± 2.48	12.57 ± 2.08
A-2000	1205	12	0.36 ± 0.07	2.82 ± 0.62	9.44 ± 2.11
	A-330-G	12	0.91 ± 0.10	5.02 ± 0.84	5.79 ± 1.35
	Mucopren	12	1.02 ± 0.23	6.06 ± 1.06	4.80 ± 2.95
	Tokuyama Sofreliner T	12	1.25 ± 0.11	7.13 ± 1.00	2.82 ± 0.66
	Tokuyama Sofreliner MS	12	1.32 ± 0.13	7.72 ± 0.80	1.32 ± 0.46

Table 1 Mean peel strength, peak load, and peel length

elastomers in conjunction with the following polyurethane surface treatments:

- a 40:60 mixture of MDX4-4210 and silastic medical adhesive silicone Type A in conjunction with 1205 primer (this treatment regimen served as a control, because it is a clinically acceptable technique for polyurethane–silicone bonding introduced to maxillofacial prosthetics by Udagama);
- (2) silicone A-2000 in conjunction with 1205 primer;
- (3) silicone A-2000 in conjunction with A-330-G primer;
- (4) silicone A-2000 in conjunction with Mucopren primer (Kettenbach Dental, Eibelshausen, Germany);
- (5) silicone A-2000 in conjunction with Sofreliner T primer (Tokuyama Corp., Tokyo, Japan);
- (6) silicone A-2000 in conjunction with Sofreliner MS primer (Tokuyama Corp.).

Materials and methods

The standard test for peel resistance¹⁰ and Wang et al's study⁷ were used as guidelines for developing this study. Two gypsum molds were formed in brass denture flasks. The lower portion of each flask displayed a flat gypsum surface. A wax template measuring $6.5 \times 6.0 \times 0.6$ cm³ was used to form a standardized mold cavity in the upper portion of each flask (Fig 1).

In each instance, a polyurethane sheet measuring $0.020 \times 16 \times 16 \text{ cm}^3$ (Factor II, Inc.) was cleaned twice by wiping with acetone on a clean gauze applicator. The sheet was heated for 2 minutes and adapted to the flat surface of a mold by vacuum-forming (Sta-Vac, Buffalo Dental Mfg. Co., Inc., Syosset, NY). Masking tape was used to cover a 1.0-cm-wide strip along one edge of each specimen (Fig 2).

At this stage, a brush was used to apply Dow Corning 1205 primer to the exposed polyurethane surfaces. The primer was allowed to react with polyurethane for 30 minutes. At the end of the 30-minute period, silicone materials were prepared. In the first instance, a mixture of 40% MDX4-4210 silicone and 60% silastic medical adhesive silicone Type A was made. Fifteen drops of intrinsic colorant and four drops of intrinsic thixotropic agent (Thixo A-300-I, Factor II, Inc.) were added to the silicone mixture for visual identification and enhanced handling properties, respectively. Before introducing this mixture into the mold, a thin layer of 100% silastic medical adhesive silicone Type A was applied directly to the primed polyurethane liner. The 40:60 silicone mixture was then used to slightly overfill the mold. The mold was closed and compressed, causing

lateral displacement of the excess silicone material. Subsequently, the assembly was transferred to a standard flask press, and the press was tightened until a metal-to-metal contact of the flask components was observed. The silicone material was allowed to polymerize at room temperature for 24 hours.

A similar protocol was followed for all remaining treatments. Individual primers were applied to exposed polyurethane surfaces and allowed to react for 30 minutes. At the end of this period, A-2000 silicone was prepared by mixing equal volumes of the two components. Fifteen drops of intrinsic colorant and four drops of thixotropic agent were added. The silicone A-2000 mixture was then placed, and the assembly was compressed. The mold was then transferred to a flask press, and



Figure 3 Specimen attached to the Instron machine.





Figure 4 Representative plot of mean T-peel strength versus crosshead extension for different primers (from bottom): (1) MDX4-4210 with Type A and primer 1205; (2) A-2000 with primer 1205; (3) A-2000 with primer A-330-G; (4) A-2000 with Mucopren; (5) A-2000 with primer Tokuyama Sofreliner T; (6) A-2000 with Tokuyama Sofreliner MS.

closure was accomplished as previously described. Specimens were allowed to polymerize in a dry heat oven (Stabletherm Gravity Oven, Blue M Electric, Watertown, WI) maintained at 70° C for 3 hours, followed by 24-hour bench cure.

Specimens were then deflasked and cut into strips measuring $0.5 \times 6.0 \times 0.6$ cm³. The masking tape added during specimen fabrication yielded physical separation of the polyurethane and silicone components at one end of each specimen. This "unbonded" portion was used to attach each specimen to a universal testing machine (Model 8510 with Series IX software, Instron Corp., Norwood, MA) (Fig 3).

Table 2 One-way ANOVA test for mean peel strength (N/mm), peak load (N), and peel length (mm) ($\alpha = 0.05$)

	DF	SS	MS	F-value	<i>p</i> -value	Power
Peel strength	5	13.763	2.753	173.465	< 0.0001	1.000
Residual	64	1.016	0.016			
Peak load	5	228.659	45.732	27.176	< 0.0001	1.000
Residual	64	107.701	1.683			
Peel distance	5	1035.211	207.042	63.056	< 0.0001	1.000
Residual	64	210.141	3.283			

The large *F*-value indicates there are more differences between groups than within groups. With a *p*-value < 0.0001, the null hypothesis (there are no differences between different primer groups) is rejected. Post hoc analysis using Fisher's protected significant difference multiple compare test (PLSD) was performed.

Using this testing arrangement, tensile force was applied at a crosshead speed of 25.4 mm/min and for a distance of 30 mm. Peak load was recorded for each specimen. The T-peel strength for each specimen was determined using average load divided by specimen width, as described in ASTM Standard D 1876-72.¹⁰ The interfacial peel distance between polyurethane and silicone elastomer was measured using a digital caliper accurate to within 0.01 mm (MaxTool, La Verne, CA). In turn, group averages and standard deviations were determined.

One-way analysis of variance (ANOVA) was used to compare the experimental data. When ANOVA indicated a significant difference, Fisher's probability of least significant difference test (PLSD) was used to perform post hoc analysis (p < 0.05). All statistical analyses were accomplished using statistical software (SPSS software, Version 11, SPSS, Chicago, IL).

The mode of failure was evaluated using photographs of specimens obtained during separation. Failure was characterized as adhesive, cohesive, or mixed. For the purposes of this investigation, adhesive failure was defined as separation at the polyurethane–silicone interface. Cohesive failure was characterized by failure (i.e., tearing) occurring entirely within the silicone material. Mixed failure displayed both adhesive and cohesive characteristics.

Results

Plots of T-peel strength versus crosshead extension were generated for all specimens (Fig 4). In addition, numerical values



Figure 5 Peel strength in ascending order: (1) MDX4-4210 with Type A and primer 1205; (2) A2000 with primer 1205; (3) A2000 with primer A-330-G; (4) A2000 with Mucopren; (5) A2000 with primer Tokuyama Sofreliner T; (6) A2000 with Tokuyama Sofreliner MS. Treatments joined by a common bracket indicate that there is no statistical difference based on Fisher's protected significant difference multiple compare test (PLSD).

For example, there was no statistical difference in peel strength between A + Sofreliner MS and A + Sofreliner T. * indicates that there is a statistical difference at p < 0.05. For example the MDX/Type A + P1205 group had a statistically lower peel strength compared to the A+ P1205 group.

for T-peel strength and peak load were determined. Mean peel distances for each group were also measured and recorded. The means and standard deviations for T-peel strength, peak load, and peel distance are presented in Table 1. A 40:60 mixture of MDX4-4210 silicone and silastic medical adhesive silicone Type A in conjunction with 1205 primer produced the lowest mean peel strength and greatest mean peel distance. Silicone elastomer A-2000 with 1205 primer produced the lowest average peak load. In contrast, silicone elastomer A-2000 with Sofreliner MS primer produced the highest average peel strength, highest average peak load, and lowest average peel distance.

ANOVA results (Table 2) indicate statistically significant differences for T-peel strength, peak load, and peel distance.

The mean T-peel strengths for silicone A-2000 with Sofreliner MS primer, and for silicone A-2000 with Sofreliner T displayed statistically significant differences from all remaining treatments (Fig 5). The peak load for silicone A-2000 with Sofreliner MS primer displayed no statistically significant difference from silicone A-2000 with Sofreliner T primer, but was statistically superior to other treatments (Fig 6). Similarly, silicone A-2000 with Sofreliner T primer displayed statistical similarity to silicone A-2000 with Mucopren primer, but was statistically superior to silicone A-2000 with A-330-G primer and both 1205 primer groups.

The mean peel distances for silicone A-2000 with Sofreliner MS primer and for silicone A-2000 with Sofreliner T primer were significantly different from all remaining groups (Figs 7 and 8).

Photographic assessments provided additional information regarding the physical and mechanical behaviors of polyurethane–silicone systems. Initial bond failure for MDX4-4210 silicone with 1205 primer was cohesive in nature, occurring at the junction between silastic medical adhesive silicone Type A and the 40:60 silicone mixture. With continued force application, adhesive failure occurred at the surface of the polyurethane liner. During this phase, silastic medical adhesive silicone Type A separated cleanly from the adjacent polyurethane (Fig 9A).

Pure adhesive failure was observed between silicone A-2000 and 1205 primer (Fig 9B). Adhesive failure within this system resulted in greatest interfacial peel distance.



Figure 6 Peak load in ascending order: (1) MDX4-4210 with Type A and primer 1205; (2) A2000 with primer 1205; (3) A2000 with primer A-330-G; (4) A2000 with Mucopren; (5) A2000 with primer Tokuyama Sofreliner T; (6) A2000 with Tokuyama Sofreliner MS. Treatments joined

by a bracket indicate that there is no statistical difference based on Fisher's protected significant difference multiple compare test (PLSD). * indicates that there is a statistical difference at p < 0.05.

Table 3 Primer composition-all data were obtained from MSDS (material safety data sheet)

Primers	Solvent	Active Ingredients
1205	Propylene glycol methyl ether and butyl glycol acetate	Toluene and epoxy resin
A-330-G	Ethylmethylketone and dichloromethane	Polyacrylates
Mucopren	Ethyl acetate	Methyl 2-methyloprop-2-enoate, methyl 2-methylpropenoate, and methyl methacrylate
Tokuyama Sofreliner T	Ethyl acetate	Polymethyl methacrylate with polyorganosiloxane
Tokuyama Sofreliner MS	Methylene chloride	Polymethyl methacrylate with polyorganosiloxane

Pure cohesive failure was observed when silicone A-2000 was used with Sofreliner MS primer or Sofreliner T primer. During the initial stages of tensile testing, the silicone–polyurethane assembly underwent elastic deformation instead of interfacial separation (i.e., peeling). When peel strength exceeded the tear strength of silicone, tearing was observed. This resulted in failure within the body of the silicone but no delamination at the polyurethane–silicone interface (Figs 9E, F).

Mixed failure was observed for silicone A-2000 with A-330-G primer and for silicone A-2000 with Mucopren primer (Fig 9C, D). Areas of adhesive failure appeared bare or shiny, while areas of cohesive failure were characterized by irregular projections of tinted silicone. A statistically significant difference in the mean peel distance was observed between the Sofreliner MS primer group and the Sofreliner T primer group. The mean interfacial peel distance associated with Sofreliner T primer was approximately twice the mean value recorded for Sofreliner MS primer (Table 1, Fig 8).

Discussion

Data from this experiment indicate statistically significant differences in bond strengths for the included systems. To understand these differences, it is important to examine the chemical properties of the silicones and primers used in the investigation.



Figure 7 Interfacial peel distance in descending order: (1) MDX4-4210 with Type A and primer 1205; (2) A2000 with primer 1205; (3) A2000 with primer A-330-G; (4) A2000 with Mucopren; (5) A2000 with primer Tokuyama Sofreliner T; (6) A2000 with Tokuyama Sofreliner MS Treat-

ments joined by a common bracket indicate that there is no statistical difference based on Fisher's protected significant difference multiple compare test (PLSD). * indicates that there is a statistical difference at p < 0.05.

Both MDX4-4210 and A-2000 are platinum-cured silicone elastomers. MDX4-4210 is a two-component material. The elastomer component consists of a dimethylsiloxane polymer, reinforcing silica, and a platinum catalyst. The curing component consists of a dimethylsiloxane polymer, an inhibitor, and a siloxane crosslinking agent. Polymerization of the mixture may be accomplished at room temperature or at slightly elevated temperatures.

Silicone A-2000 is a two-component material introduced by Factor II as an alternative to the aforementioned MDX4-4210/silastic medical adhesive silicone Type A mixture. Polymerization involves the crosslinking of polysiloxanes via addition reactions. Such reactions generally involve the addition of silyl hydride groups (-SiH) to vinyl groups (-CH = CH₂), which are attached to the primary polymer chain.³ These silicones are not truly room temperature vulcanizing (RTV), since polymerization requires heating the material at 70 to 150°C for about an hour.

Silastic medical adhesive silicone Type A is a onecomponent, low-slump, translucent material used for bonding silicone elastomers to one another, as well as to some synthetics and metals. Chemically, this material is a preparation of methyl triacetoxysilane crosslinked silicone that may be polymerized at room temperature. As previously noted, McElroy et al warned that the use of medical adhesive silicone Type A in the fabrication of facial prostheses may pose health risks for patients and operators.¹⁰ This is related to the release of acetic acid vapor, which can cause skin burns, permanent eye damage, and irritation to the mucous membranes. The associated health concerns have provided an impetus to develop a suitable substitute for silicone Type A.

Primer A-330-G is recommended by Factor II for bonding platinum-cured silicone elastomers to acrylic resin or polyurethane liners. It contains a solution of polyacrylates in ethylmethylketone and dichloromethane for the purpose of creating reactive sites for the silicone.¹¹ The hydrophilic and hydrophobic groups on the reactive sites react with the functional groups of silicone and polyurethane. Hence, primer molecules may collectively serve as chemical intermediate.

Mucopren, Sofreliner MS, and Sofreliner T primers have similar active ingredients, but different solvents. Mucopren primer and Sofreliner T primer contain an ethyl acetate solvent, while Sofreliner MS primer contains a methylene chloride solvent¹²⁻¹⁴ (Table 3). The differences in observed bond values are believed to be related to the actions of these solvents. Unfortunately, the precise mechanisms of their actions are unknown.

While the potential chemical interactions between silicones, primers, and liners are beyond the scope of this investigation, future efforts should be focused in this area.



Figure 8 Interfacial peel distance: (1) MDX4-4210 with medical adhesive Type A and primer 1205; (2) A2000 with primer 1205; (3) A2000 with primer A-330-G; (4) A2000 with Mucopren; (5) A2000 with primer Tokuyama Sofreliner T; (6) A2000 with Tokuyama Sofreliner MS. Blue arrows indicate the interfacial peel distance, which is measured from nonbonded edge to the edge of separation at the end of 30-mm Instron pull.



Figure 9 Modes of failure: (AF) adhesive failure; (MF) mixed failure and (CF) cohesive failure. (A) MDX4-4210 with Type A and primer 1205; (B) A2000 with primer 1205; (C) A2000 with primer A-330-G; (D) A2000 with Mucopren; (E) A2000 with primer Tokuyama Sofreliner T; (F) A2000 with Tokuyama Sofreliner MS.

Physical testing represents another area of interest. In this investigation, traditional T-peel testing was employed to evaluate the behaviors of polyurethane–silicone systems. The interfacial peel distance was also employed and provided additional insights regarding composite physical behaviors.

When the foregoing tests are employed to assess polyurethane–silicone systems, several outcomes may be observed. Potential outcomes include (1) the polyurethane liner may stretch; (2) the silicone may flex and (3) the polyurethane and silicone may separate (Fig 9). T-peel testing provides important information regarding bond strengths within polyurethane–silicone assemblies. The addition of interfacial peel distance allows the investigator to make additional judgments regarding the effects of elasticity, and the mechanism(s) of failure. The importance of this additional information is explained in the following paragraphs.

In this investigation, post hoc analysis of T-peel results indicated no statistically significant differences between specimens treated with Sofreliner MS primer and those treated with Sofreliner T primer (Figs 5 and 6). The interfacial peel distance, however, indicated that Sofreliner MS had a significantly shorter peel distance despite having similar peel strength (Figs 7 and 8). Based upon this information, it is hypothesized that the bond strength produced by Sofreliner MS primer is much higher than the T-peel test indicated.

Further evaluation revealed that the separation was caused by stretching of the polyurethane liner rather than bond failure between the polyurethane and the silicone. This was confirmed by measuring the peel distance of each specimen (Fig 8). Without observations of interfacial peel distance, valuable insights would have been lost.

The initial high T-peel strength observed for Udagama's technique was due to bond separation between the pure medical adhesive silicone Type A layer and the adjacent 40:60 silicone mixture. After the Type A layer was stretched to failure, adhesive failure occurred at the surface of the polyurethane liner (Fig 9A). Similar observations were reported by Wang et al⁷ and Singer et al.¹⁵

Results from this investigation were enlightening to the authors, and hopefully will form the basis for future testing in this area. Refined testing methods and improved materials appear to be needed.

Clinical significance

This study provides prosthodontists and anaplastologists with information that may be helpful in the fabrication of maxillofacial prostheses. Results indicate that polyurethane–silicone bonding may be improved by treating polyurethane liners with Sofreliner MS primer or Sofreliner T primer, followed by placement of silicone A-2000. It is recommended that the chosen primer be placed on the polyurethane surface 30 minutes prior to the addition of the silicone. The foregoing combination appears to create improved bonding at polyurethane–silicone interfaces.

Conclusions

Within the limitations of this study, the use of Tokuyama Sofreliner MS primer in conjunction with silicone A-2000 produced the greatest bond strengths for polyurethane–silicone interfaces. Bond values were significantly greater than those produced using Udagama's technique. While this information is promising, additional mechanical testing and controlled clinical trials are recommended.

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