

Effect of adhesive retention on maxillofacial prostheses. Part I: Skin dressings and solvent removers

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Statement of problem. The success of most maxillofacial prostheses depends on retention by medical adhesives. Products such as Smith-Nephew's Skin-Prep (SP) are available that can be used on the skin that could improve prosthesis adhesion protective dressing. The removal of adhesive from the skin is also problematic, so solvents, such as Uni-Solve adhesive remover (US), are often used.

Purpose. This study measured the removal force of silicone elastomer strips with 2 adhesives from the skin of human subjects during the day, as affected by the use of SP and US, and determined the site of adhesive failure.

Material and methods. Silicone rubber strips were applied in a predetermined random order to the ventral arm surfaces of 20 human subjects. US was applied to half the sites 1 day before testing. SP was also applied to half the sites just before Epithane-3 (E3) or Secure² Medical Adhesive (SMA) were used to adhere the strips. They were peeled from the skin 6 hours later in an Instron at a rate of 10 cm/min.

Results. A 3-way within-group MANOVA revealed significant differences without interactions between adhesives (SMA=96.3 N·m, E3=24.1 N·m; $P<.0005$) and between use or nonuse of SP (SP=65.8 N·m, no SP=54.6 N·m; $P<.0005$). The use of US was not significant (no US=61.8 N·m, with US=58.6 N·m; $P=.197$). SMA adhered to the prostheses, whereas E3 adhered to the skin, leaving a residue (Fisher exact test; $P<.0003$).

Conclusion. The combination of SMA and SP showed the highest adhesive bond strength. Overall, SMA was 3 to 5 times more retentive than E3. SP improved adhesion of both SMA (15%) and E3 (27%). SMA was still far more retentive. US had no effect on retention. SMA remained on the prostheses, whereas E3 left a difficult-to-remove residue on the skin. (J Prosthet Dent 2000;84:335-40.)

CLINICAL IMPLICATIONS

Skin-Prep protective dressing applied to the skin before adhering maxillofacial prostheses created a barrier that enhanced the strength of the 2 adhesives tested up to 6 hours. Secure² Medical Adhesive was 3 to 5 times more retentive than Epithane-3 adhesive. Uni-Solve adhesive remover did not affect the strength of either adhesive.

The success of adhesive-retained extraoral facial prostheses depends on retention of the artificial part to the skin that is often scarred secondary to surgery and/or radiation treatment. Facial prostheses are retained by adhesives, mechanical means, and/or craniofacial implants.¹⁻⁴ Attaching prostheses to the skin with an adhesive is an effective and commonly used method. The interaction of adhesive materials

with skin presents problems, such as the longevity of the bond, dermatologic (sensitivity) problems, and the ability to completely remove adhesive residue. Maintenance of the skin and prosthesis requires considerable daily effort and dexterity by the patient.

Skin-Prep protective dressing (Smith & Nephew, Inc, Largo, Fla.) (isopropyl alcohol, butyl ester of polyvinyl methacrylate/methyl methacrylate copolymer, acetyl tributyl citrate) is used where "skin needs protection from adhesive, trauma, abrasion, chafing, irritation, and exposure to fecal and urinary effluent" (according to Smith & Nephew product literature). It "creates a physical, waterproof barrier that is nonirritating...and allows the skin to breathe." Wilborn⁵ studied skin punch biopsies by SEM to determine the effect of adhesive tape removal on skin protected by Skin-Prep protective dressing. Trauma was reduced when this product was used. Salius et al⁶ found that

Presented at the International Association for Dental Research meeting, Vancouver, British Columbia, Canada, March 1999.

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Table I. Materials used in this study

Product	Manufacturer	Batch no.
Silastic MDX4-4210 medical grade elastomer	Dow Corning Corp, Midland, Mich.	HH079690
Silastic medical adhesive silicone type A	Dow Corning Corp	OL00618
Secure ² Medical Adhesive	Factor II, Inc, Lakeside, Ariz.	HH037003-1
Epithane-3 Adhesive ES	Daro Products Inc, Muskego, Wis.	06238
Skin-Prep protective dressing	Smith & Nephew Inc, Largo, Fla.	420400
Uni-Solve adhesive remover	Smith & Nephew Inc	402300
Dial soap (gold)	The Dial Corp, Scottsdale, Ariz.	81140

Skin-Prep protective dressing, applied to the forearm, improved the retention of simulated prostheses bonded with 3 skin adhesives at 1 hour. They thought that this product would be useful for facial prostheses. Uni-Solve adhesive remover (C-10, C-11 isoparaffin, isopropyl alcohol, dipropylene glycol methyl ether, aloe extract, fragrance) is used to remove adhesives from the skin and prosthesis. It is not known if this product interacts with adhesives or improves or degrades bond strength.

Gettleman et al⁷ developed methods to measure the bond strength of various adhesives to experimental maxillofacial prosthetic materials against pig and human skin. Mechanical testing has been performed by using tensile,^{1,8-10} shear, or peel tests,^{6,11} with hard^{1,7,8-11} or soft¹² testing apparatus.

The purpose of this study was to measure the force necessary to remove strips of medical grade silicone elastomer from the skin of human subjects treated with Skin-Prep protective dressing and use of Uni-Solve adhesive remover (Smith & Nephew, Inc). Two medical-grade adhesives (Secure² Medical Adhesive, Factor II, Lakeside, Ariz.; and Epithane-3, Daro Products, Muskego, Wis.) were measured in a hard peel-testing procedure. The site of adhesive failure was noted and compared with the various combinations tested.

MATERIAL AND METHODS

On the basis of the pilot data on 1 subject with several repeats by Salius et al,⁶ an estimate of the variance to be expected when using Skin-Prep protective dressing and 3 adhesives was obtained. Sample size and power analysis were accomplished using the IML Power program.¹³ With the use of a standard deviation estimate of 10 N·m and a correlation estimate of 0.3, it was determined that 10 subjects would provide statistical power to detect a difference of 20 N·m between presence or absence of Skin-Prep protective dressing. Because the sample data were for repeats of 1 subject only, it was decided that a test group of 20 subjects would be preferable. This sample size would afford good power even if the standard deviation was larger than 10 N·m and would enable a more accurate estimation of parameters.

University Human Studies Committee approval No. 258-98 to use 20 subjects was received before starting the trial. Strips of maxillofacial prosthetic elastomer were processed into 60 × 20 × 3 mm 6-sided gypsum molds using a mixture of 60% room temperature-vulcanizing silicone elastomer (dimethylsiloxane triacetoxo-terminated silane, Silastic Adhesive A) and 40% vinyl-terminated dimethylsiloxane (MDX4-4210, both Dow Corning Corp, Midland, Mich.).^{14,15} Elastomers were allowed to cure for 24 hours; all materials used in this study are listed in Table I.

Twenty human subjects (7 men, 13 women, ages 22-58 years; median age 40) were recruited. The sample included 12 white, 4 Asian, and 4 African-American subjects. At the first visit, approximately the same time of day for all subjects, clear acetate stencils were used to define the sites on the volar surfaces of each subject's right and left arms where the 4 test strips were placed. Each stencil had four 60 × 20-mm openings running diagonally in a inferiolateral to superiomedial direction. Landmarks for each subject were drawn with a marker on each stencil so that it could be repositioned subsequently. The day before the tests in this study, Uni-Solve was applied to half of the 8 sites predetermined in a random pattern to simulate the removal of prostheses and the cleaning of the adhesive residue from the skin. The subjects were then given a bar of Dial soap (The Dial Corp, Scottsdale, Ariz.) to use the next morning during bathing and were asked to thoroughly wash and rinse their arms.

The next day, when all the subjects returned in the morning, stencils were used again to determine which of the 4 randomized sites on the arms of each subject was to receive Skin-Prep protective dressing (Fig. 1). The 2 adhesives (Secure² Medical Adhesive or Epithane-3 adhesive) were also applied randomly to half of the silicone rubber strips. The 8 strips were immediately applied to the skin through the mask, and the subjects were then dismissed.

Subjects returned 6 hours later, and the peeling force of the test strips was measured by gently lifting one edge of each strip from the subjects' skin and attached to the pneumatic grip on the Instron TM-M machine (Instron Corp, Canton, Mass.), equipped

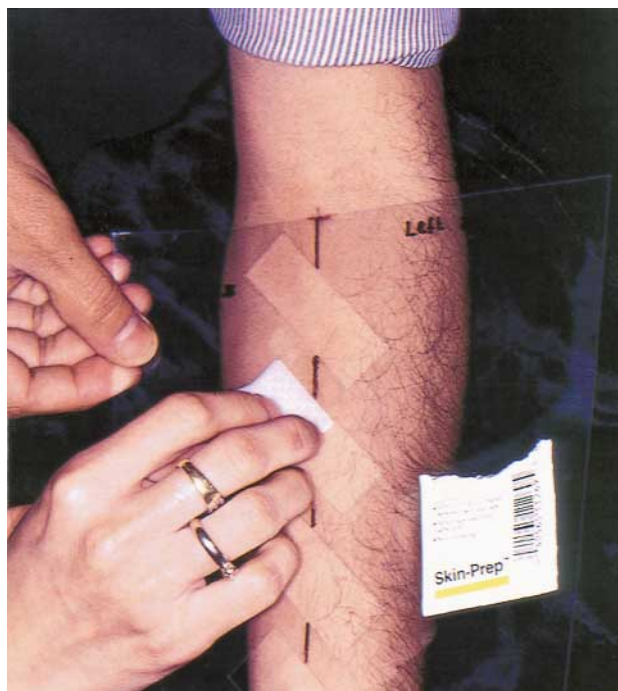


Fig. 1. Maximum adhesive bond strength to skin. Clear acetate masks with four 60 × 20 mm openings and landmarks drawn. Skin-Prep was applied at randomly predetermined sites.

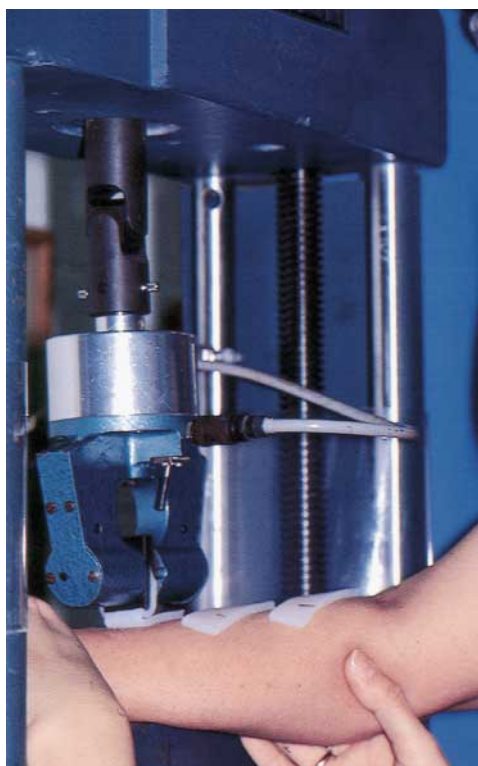


Fig. 2. One edge of each strip was gently lifted from subjects' skin and attached to pneumatic grip of Instron TM-M machine. Subjects rested their arms on crosshead of machine, which was then lowered at 10 cm/min.

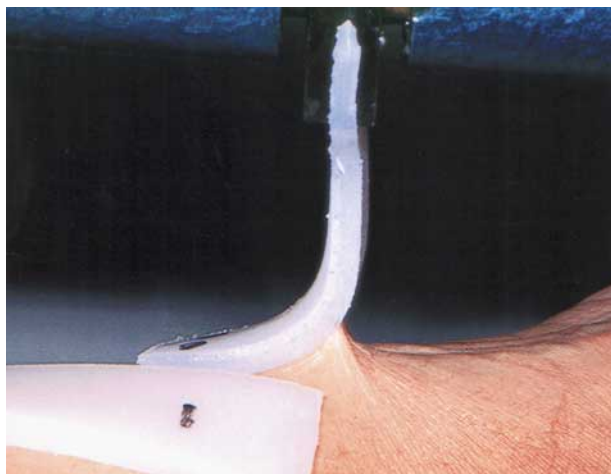


Fig. 3. Peeling at 90 degrees was in inferiolateral-to-superiomedial direction (toward subject's head).

with a CM load cell (Fig. 2). The subjects rested their arms on the crosshead of the machine, which was then lowered at 10 cm/min. Peeling was in the inferiolateral-to-superiomedial direction (toward the subject's head) to establish a 90-degree peel test (Fig. 3). The load cell recorded the maximum force necessary to remove the strip as a function of distance peeled. Calibration and measurements were made in grams-force to 3-digit accuracy. This was converted to newton and results are reported in newton divided by the width of the silicone rubber strip in meters:

$$N = 1 \text{ kg} \times \text{m}/\text{sec}^2 = \text{kg} \times 9.8 \text{ m}/\text{sec}^2 = \text{gf} \times 0.0098 \text{ m}/\text{sec}^2;$$

$$20 \text{ mm width}/1000 \text{ mm} = 0.02 \text{ m, so } N\text{-m} = \text{gf} \times 0.0098/0.02$$

Sample size and power analysis were calculated with the IML Power program¹³ using pilot data. Statistical analysis used a 3-way within-groups multivariate analysis of variance (MANOVA) and Pillais/Trace statistic¹⁶ using SPSS v. 7.5 software (SPSS, Chicago, Ill.). Factor 1 consisted of 2 levels: Skin-Prep protective dressing or none (control). Factor 2 had 2 levels: Uni-Solve adhesive remover or no remover (control). Factor 3 had 2 levels: Secure² Medical Adhesive and Epithane-3 adhesive. The dependent variable was the maximal adhesiveness to skin measured in newton-meter.

RESULTS

The means and standard deviations of bond strengths measured from all 8 strips on both arms of all 20 subjects reported in newton-meter are shown in Table II and Figure 4. Values ranged from 20.3 to 110.5 N-m with coefficients of variation from 32% to 69%. The 3-way within-group MANOVA revealed significant differences (without interactions) between adhesives: Secure² medical adhesive (96.3

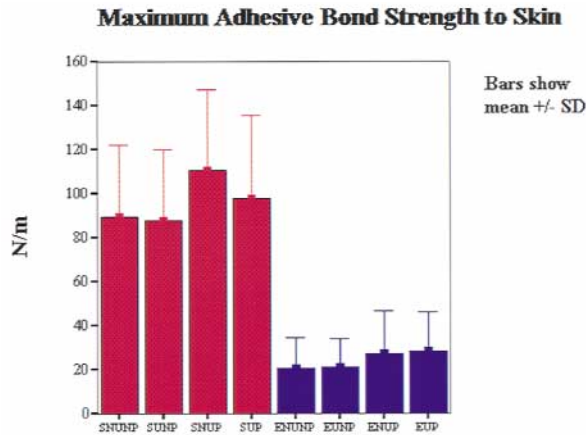


Fig. 4. Mean adhesive bond strength to skin and standard deviation for all variables. SNUNP = Secure² Medical Adhesive/no Uni-Solve/no Skin-Prep; SUNP = Secure² Medical Adhesive/Uni-Solve/no Skin-Prep; SNUP = Secure² Medical Adhesive/no Uni-Solve/Skin-Prep; SUP = Secure² Medical Adhesive/Uni-Solve/Skin-Prep; ENUNP = Epithane-3/no Uni-Solve/no Skin-Prep; EUNP = Epithane-3/Uni-Solve/no Skin-Prep; ENUP = Epithane-3/no Uni-Solve/Skin-Prep; EUP = Epithane-3/Uni-Solve/Skin-Prep.

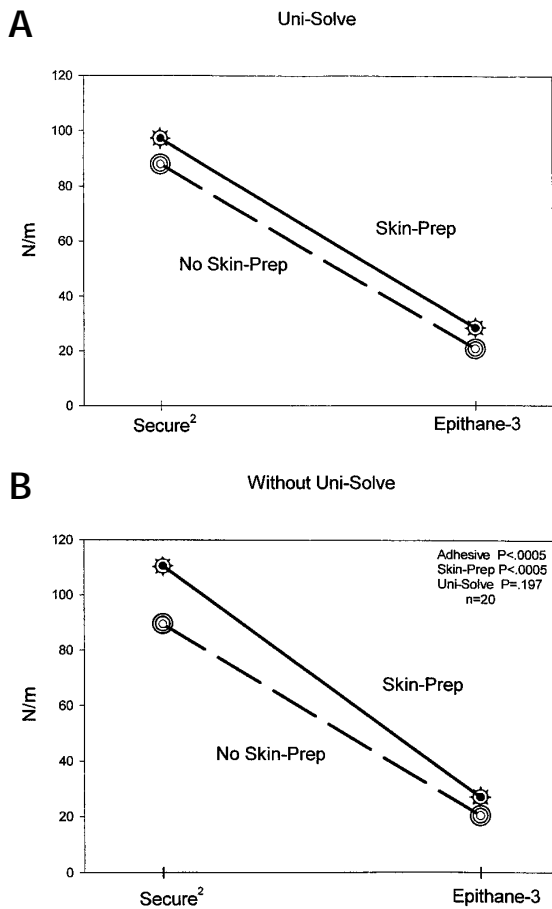


Fig. 5. Three-way within-group MANOVA (A) with Uni-Solve and (B) without Uni-Solve shows lack of interaction.



Fig. 6. Both arms of 1 subject after testing reveal residue of Epithane-3 (E3) adhesive at 2 positions near wrist of right arm, and 2 positions near elbow of left arm. Secure² Medical Adhesive (SMA) is in other 4 positions.

N·m) was significantly stronger than Epithane-3 adhesive (24.1 N·m) ($P < .0005$). Figure 5, A and B, illustrates the changes in bond strength associated with the 3 factors. This classical graphic depiction is used to display possible interactions among the factors.¹⁷⁻¹⁹ The parallel (or near-parallel) lines illustrate the lack of statistical interaction of the factors in this experiment. The use of Skin-Prep adhesive significantly improved the bond strengths of both adhesives (with Skin-Prep 65.8 N·m, without Skin-Prep 54.6 N·m) ($P < .0005$) (Fig. 5, A and B).

Uni-Solve adhesive remover, applied in the evening before application of the adhesive, had no effect on retention (no Uni-Solve 61.8 N·m, with Uni-Solve 58.6 N·m) ($P = .197$) (Fig. 5, A and B).

Secure² Medical Adhesive remained adhered to the prosthesis 75% of the time, whereas Epithane-3 adhered to the skin 84% of the time (Fisher exact test; $P < .0003$) (Table II).

Table II. Means and standard deviations for the 8 cells in the experimental table. Results of Fisher exact test are also shown.

Adhesives	Without Skin-Prep				With Skin-Prep			
	No Uni-Solve		Uni-Solve		No Uni-Solve		Uni-Solve	
	Mean ± SD	p/s	Mean ± SD	p/s	Mean ± SD	p/s	Mean ± SD	p/s
Secure ²	89.5 ± 32.8	3/17	87.8 ± 32.3	3/17	110.5 ± 36.3	5/14*	97.4 ± 38.2	5/15
Epithane-3	20.3 ± 14.1	15/5	20.8 ± 13.0	16/4	27.0 ± 19.5	19/1	28.4 ± 17.7	19/1
		<i>P</i> =.0003		<i>P</i> =.0001		<i>P</i> <.00005		<i>P</i> <.00005

p/s = Denotes whether failure occurs at the prosthesis or skin interfaces, using Fisher exact test.

*Adhesive was left on both prosthesis and skin for 1 subject.

Both arms of 1 subject after testing showed residue of Epithane-3 adhesive at positions R1, R2, L3, and L4 (Fig. 6).

DISCUSSION

The results of this study as shown in Table II indicate that Secure² Medical Adhesive (SMA) (mean adhesion = 96.3 N·m) was 3.99 times more retentive than Epithane-3 (E3) (mean adhesion = 24.1 N·m). Greater retention is usually beneficial, except in cases where a patient's skin is fragile because of age or radiation treatment. Irritation may result if a very strong adhesive is used.

When Skin-Prep protective dressing was applied to the skin before adhesive placement, E3 increased 27%, when compared with SMA, which increased only 15%, but E3 was still far less retentive. A residue of E3 was seen on the skin of 84% of subjects, some more than 1 week after the single application in this clinical trial, regardless of the use of Skin-Prep protective dressing. The lack of effect of Uni-Solve adhesive remover on subsequent adhesive properties of SMA or E3 is advantageous to the patient, as it apparently leaves no residue and may aid the patient in removing adhesive that was applied earlier.

Three subjects had considerable hair on the volar surfaces of their forearms. An attempt was made to minimize the effect of body hair by peeling toward an area with minimal hair (the medial volar arm surface). Adhesion measurements from the 3 subjects considered to have the most body hair was observed to be no different than subjects with almost no body hair. Future studies will include the premature removal of prostheses, the reapplication of adhesives during the day, and the effect of bond strength over the course of the day. It would also be of interest to investigate the retentive properties of both adhesives combined, because SMA bonds better to the silicone rubber prosthesis and E3 to the skin. A sandwich of the 2 may be more effective than either one alone.

CONCLUSIONS

The use of a protective skin dressing and a removal solvent on adhesive retention of maxillofacial prosthetic

elastomers was evaluated. Within the limits of this study, the following conclusions were drawn:

1. The combination of Secure² Medical Adhesive and Skin-Prep protective dressing showed the highest adhesive bond strength. Overall, Secure² Medical Adhesive was 3.99 times more retentive than Epithane-3.

2. Skin-Prep protective dressing improved adhesion of both Secure² medical adhesive (15%) and Epithane-3 (27%). Secure² Medical Adhesive was still far more retentive.

3. Uni-Solve adhesive remover, when used before adhesion, had no effect on the bonding of either product, which may benefit patients by not leaving a residue that would affect future adhesive application.

4. Debonding apparently occurred at the skin interface for the Secure² Medical Adhesive (residue left on prosthesis) and at the prosthesis interface for Epithane-3 (residue left on the skin).

We acknowledge all volunteer subjects in this study for their generosity.

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0022-3913/2000/\$12.00 + 0. 10/1/109507

doi:10.1067/mpr.2000.109507

Noteworthy Abstracts of the Current Literature

Surface roughness and flexural strength of self-glazed, polished, and reglazed In-Ceram/Vitadur Alpha porcelain laminates

Chu FCS, Frankel N, Smales RJ. *Int J Prosthodont* 2000;13:66-71.

Purpose. Controversy exists regarding the best method to achieve the smoothest and strongest porcelain restorations after adjustment of the surface finish. This study compared 3 methods for reducing surface roughness and improving the flexural strength of porcelain laminate restorations.

Material and methods. Ninety disks, 11 mm in diameter, were fabricated from InCeram (Vita) cores veneered with Vitadur Alpha (Vita) porcelain (core thickness 0.75 mm, veneer thickness 0.5 mm). All disks were autoglazed. Thirty of the disks served as controls (group 1). Six clinicians were chosen to participate in the grinding and polishing phase of the study. Each clinician was assigned 10 disks, and the following instruments were used to finish the specimens: (1) 2 striper fine diamond finishing burs (LSPF 102 VP, Premier); (2) Sof-Lex finishing disks (3M Dental); (3) Jiffy medium silicone rubber point (Ultradent); (4) Ultradent extra fine silicone rubber point; and (5) Ultradent diamond polishing paste. Five of the polished disks from each clinician's group received no further treatment (group 2); 5 polished disks from each group were reglazed (group 3). Using a SurfTest 4 profilometer (Miyutoyo), the average roughness values of all specimens were measured. The measurements were completed in 6 positions on each specimen. Within each of the 3 groups, flexural strength testing was performed on 20 specimens. Ten of these specimens were tested with the veneers in tension, and 10 were tested with the cores in tension on a universal testing machine (Hounsfield H25K). Two specimens from each group were examined with SEM. One of the 2 specimens was analyzed for surface roughness, and the other for evaluation of the fractured surface. Data were analyzed with a 1-way ANOVA and Bonferroni's multiple comparison test ($\alpha=.05$).

Results. Significant differences in surface roughness existed among the 3 groups. Group 3 demonstrated the smoothest surfaces. Analysis of the flexural strength of the veneers showed that groups 1 and 3 were not significantly different; however, the flexural strength of these groups was significantly higher than group 2. The data analysis of the In-Ceram cores showed that no significant differences existed among the groups.

Conclusion. Polished porcelain laminate surfaces that were reglazed exhibited significantly smoother surface texture and higher flexural strength than polished surfaces that were not reglazed. 33 References. —DL Dixon