Effect of adhesive retention of maxillofacial prostheses. Part 2: Time and reapplication effects

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Statement of problem. The success of most non–implant-retained extraoral prostheses depends on retention derived from skin adhesives. Part 1 of this study found that Skin-Prep Protective Dressing improved the retentive properties of adhesives and that Secure[2] Medical Adhesive was stronger than Epithane-3. Part 2 investigates the application of a second layer of adhesive to the prosthesis, which was earlier noted to improve retention at later time periods.

Purpose. This study measured the force needed to remove silicone elastomer strips with Secure[2] Medical Adhesive from the skin of human subjects. Testing was performed before and after the removal of the strips and reapplication of the adhesive.

Material and methods. Secure[2] Medical Adhesive was painted on silicone rubber strips and placed in a nonsequential random order of the 3 variables to 3 sites on the ventral forearms of 21 human subjects and tested over an 8-hour period. The bond strength was measured at 0, 4, and 8 hours. After a reapplication of adhesive over the existing adhesive, additional bond strength measurements were made at 4 and 8 hours. Testing was at 10 cm/min in an Instron. All subjects had Skin-Prep coating applied before adhesive application.

Results. Bond strengths for both single applications and reapplications of the adhesive were greater at 0 hours and became significantly weaker after the 4- and 8-hour periods. The second application of the adhesive produced the strongest bonds when measured at 4 hours (110 N/m). Bonding was significantly higher at 8 hours if a second application of adhesive was applied at 0 or 4 hours.

Conclusion. The results of this study indicate that the bond strength of silicone elastomer to skin decreased over an 8-hour interval. After removal of the silicone rubber strip and reapplication of Secure[2] Medical Adhesive over the existing adhesive, bond strengths increased. (J Prosthet Dent 2001;85:438-41.)

CLINICAL IMPLICATIONS

The results of this study indicate that bond strengths decrease during the course of the day, perhaps because of perspiration and normal body motion. The application of a second coat of adhesive after an interval of 4 to 8 hours enhanced the retention of the silicone elastomer strips.

The field of maxillofacial prosthetics, a subspecialty of prosthetic dentistry, restores lost or compromised facial anatomy caused by cancer, trauma, or birth defects with the use of artificial substitutes such as silicone elastomer. In the United States, patients with head and neck cancer number 35,000 per year. As the population becomes older, moves to the Sunbelt, and spends more time in the sun, this number may increase. Trauma patients are also treated with extraoral prostheses made to rehabilitate compromised facial anatomy that results from automobile accidents, gunshot wounds, and so forth. Despite advances in plastic surgery, there is still the need to rehabilitate small and large portions of the face with alloplastic

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Table I. Materials used in this study

Product	Manufacturer	Batch number
Silastic MDX4-4210 (medical grade elastomer)	Dow Corning Corp, Midland, Mich.	HH 079690
Silastic Medical Adhesive (silicone type A)	Dow Corning Corp, Midland, Mich.	0000148142
Secure[2] Medical Adhesive	Factor II, Inc, Lakeside, Ariz.	HH 037003-1
Skin-Prep Protective Dressing	Smith & Nephew, Inc, Largo, Fla.	492987 1,2
Dial soap (gold)	The Dial Corp, Scottsdale, Ariz.	81140

materials. Maxillofacial prosthetics provides the skills, methods, and materials to satisfy the extraoral prosthetic needs of afflicted patients.

Gettleman et al[1] and Salius et al[2] developed methods for the current study. In Part 1 of this study, Kiat-amnuay et al[3,4] reported the effect of a single application of 2 adhesives and 2 skin preparation products on the retention of a silicone elastomer in 20 human subjects for 6 hours. It was found that Secure[2] Medical Adhesive (Factor II, Lakeside, Ariz.) was much more retentive than Epithane-3 adhesive (Daro Products Inc, Muskego, Wis.). When applied to the skin before the adhesive, Skin-Prep Protective Dressing (Smith & Nephew, Largo, Fla.) improved the adhesion of both materials. Secure[2] left no residue on the skin and adhered more to the prostheses, whereas Epithane-3 separated from the silicone prosthesis and left the skin sticky to the touch.

In Part 1, if a strip had become detached, subjects were instructed to simply replace it immediately. This raised questions about durability of the adhesive and its reapplication during the day. The purpose of this study was to measure the force needed to remove silicone elastomer strips adhered only with Secure[2] Medical Adhesive from the skin of human subjects over an 8-hour period and to test the same removal forces after removing the strips and reapplying the adhesive.

MATERIAL AND METHODS

As in Part 1, silicone rubber strips were polymerized in 60 × 20 × 3-mm gypsum molds. The strips consisted of 60% Silastic Adhesive A and 40% MDX4-4210 (Dow Corning, Midland, Mich.). Each strip was polymerized for 24 hours (Table I).

Sample size was determined by power analysis from variation in the subject population generated in Part 1 of this study,[4] using the IML Power Program.[5] This analysis showed that a minimum of 13 human subjects using 1 arm only would be needed for the new study. University Human Studies Committee approval was received, and 21 human subjects varying in race, gender, and age were recruited at the University of Louisville Health Sciences Center. The inclusion criteria were the patients' willingness to serve as subjects for this study and their nonparticipation in Part 1. All subjects were tested over a 4-day period in late May 2000.

In accordance with the methods described in Part 1, the new subjects were given a bar of Dial soap (Dial Corporation, Scottsdale, Ariz.) for use during bathing or showering the night before or the morning of the trial to help standardize their skin condition. Clear acetate stencils were used to define 3 sites on the volar surface of each subject's right or left arm (alternately chosen). The 3 variables were assigned in a nonsequential random pattern among the 3 sites placed between the wrist and elbow, 2 cm apart, angled in an inferiolateral to superiomedial direction (toward the subjects' head). Landmark dots for each subject were drawn on the stencil and on the skin for subsequent repositioning. Skin-Prep was applied to all 3 sites and allowed to air dry for a few minutes. Secure[2] Medical Adhesive was applied to the 3 silicone rubber strips according to the manufacturer's instructions, and the strips were applied to the skin.

After 5 minutes, the first strip (A_0) in the inferior, middle, or superior position was chosen from a random number table and peeled from the subject's skin in an Instron TM-M machine (Instron Corp, Canton, Mass.) by gently lifting 1 edge of the strip and attaching it to the pneumatic grip. Subjects then rested their arms on the crosshead of the machine, which was lowered at a rate of 10 cm/min away from the CM load cell. Peeling was from the inferiolateral to the superiomedial direction (toward the subjects' head), resulting in a 90-degree peel from the skin. The maximal peel force was measured in grams force (converted to newtons/meter [N/m], a measure of adhesive force) determined by reading the strip chart recording. A fresh coat of Secure[2] was immediately reapplied to the strip and the strip repositioned at the same site on the skin, to be retested after 8 hours (A_{0+8}).

The subjects returned 4 hours later, when the force necessary to remove strip B_4 for the first time was measured. More Secure[2] adhesive then was applied to the strip, and it was immediately repositioned at the same site on the skin. The subjects returned again 4 hours later (8 hours total) to have all 3 strips (A_{0+8}, B_{4+4}, and C_8) removed and measured as before. The materials used are detailed in Table I, and the experimental design is summarized in Table II.

Within-groups repeated-measures multivariate analysis of variance (MANOVA) from SPSS v. 7.5

Table II. Experimental design

Treatment	Remove strips. Test at 0 h	Remove strips. Test at 4 h	Remove strips. Test at 8 h
Apply strip 1 at 0 h	**21 subjects** A_0		
Reapply at 0 h	**21 subjects**		**21 subjects** A_{0+8}
Apply strip 2 at 0 h		*21 subjects* B_4	
Reapply at 4 h		*21 subjects*	*21 subjects* B_{4+4}
Apply strip 3 at 0 h			21 subjects C_8

Cells in bold used the same test strips. Cells in italics used the same test strips.

Table III. Results from 21 human subjects in trial: Skin bond strength in newtons per meter

	Remove strips. Test at 0 h	Remove strips. Test at 4 h	Remove strips.Test at 8 h
First application of adhesive	**95.5** (32.4) A_0	***91.1*** (36.3) B_4	73.5 (37.4) C_8
Reapplication of adhesive		***110.0*** (41.0) B_{4+4} {8 h total}	**93.3** (30.0) A_{0+8}

Cells in bold used the same test strips. Cells in italics used the same test strips. Numbers in parentheses are standard deviations. Cells are defined in Table II. Connecting line in bottom row indicates no significant difference.

(SPSS Inc, Chicago, Ill.) was used to assess bond strength for all 21 subjects in all 5 groups in 2 ways: with one adhesive application over time measured at 0 (A_0), 4 (B_4), and 8 hours (C_8) and compared with the second application of adhesive measured at 4 (B_{4+4}) and 8 hours (C_8, A_{0+8}).

RESULTS

Results from all 63 strips in 21 subjects are shown in Table III. The factorial repeated-measures analysis showed a statistically significant increase in bond strength that was due to the reapplication of adhesive (P=.002). The other factor, time from 4 to 8 hours, was also statistically significant (P=.004), with a decrease in bond strength over the second 4-hour testing period. The interaction between adhesive reapplication and time was not statistically significant (P=.868).

Bond strengths for the first application were analyzed (groups A_0, B_4, and C_8). The 1-way repeated measures analysis showed overall statistically significant differences (P=.019). The linear downward trend contrast was significant (P=.034).

Bond strengths (in newtons per meter) for both the first and second applications of the adhesive and strips were greater at the initial time and became weaker after 4 and 8 hours. The second application of the adhesive reapplied at 0 hours and tested at 4 hours (B_{4+4}) produced the strongest bonds of all (110 N/m). The reapplication of adhesive after 8 hours (A_{0+8}) was considerably stronger (93.3 N/m) than the first-application measurement (C_8, 73.5 N/m). No adhesive residue was observed on the skin of the subjects.

DISCUSSION

Under the conditions of this study, the bond strengths of Secure[2] to the silicone materials were comparable in Parts 1 and 2 of this study (95.5 N/m at 8 hours vs 110.5 N/m at 6 hours, respectively). Bond strengths decreased during the course of the day, perhaps because of perspiration and normal body motion. This investigation suggests that the application of a second coat of adhesive after an interval of 4 to 8 hours enhances retention.

During the test procedure, bond strengths were greatest for the subjects who commented that their skin was usually dry most of the year. Patients who undergo radiation therapy often have dry skin, and adhesives can become an irritant to the skin's surface. One subject had healed scar tissue from a burn to his arms; adhesion to this subject's skin did not seem to differ from the others.

Future studies would be useful to test the bond strength of reattached strips without fresh adhesive (a common occurrence to extraoral maxillofacial prosthetic patients), after multiple layers of adhesives have been applied, and/or of a combination of different adhesives selectively applied to the skin or the prosthesis.

CONCLUSIONS

Because of the careful choice of variables and a power analysis based on Part 1 of this study, statistically significant differences without interactions produced results that were unusually clear.

The bond strength of silicone rubber to skin decreased during the day (up to 8 hours). Reapplication of Secure[2] Medical Adhesive produced stronger bonds.

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Correction

In the article by Kiat-amnuay et al,"Effect of adhesive retention on maxillofacial prostheses. Part I: Skin dressings and solvent removers," published in the September 2000 issue of the Journal, the unit of measure should have been printed as newton/meter (newton per meter) rather than newton·meter. Newton/meter is a common measure of adhesive force and newton·meter is a unit of torque.