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Experimental studies for maxillofacial prosthesis linings

KEYWORDS: bonding strength, maxillofacial prosthesis lining, silicones, tensile shear test, tensile test

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ABSTRACT Marginal gaps might appear between maxillofacial prostheses and adjacent soft tissues causing insufficient fit, which a lining might improve. Here, the bonding strength of lining silicones on basic maxillofacial prosthesis materials was tested under conditions approximating clinical practice.

Addition-curing cross-linking silicones were used. Surface treatment was with a scalpel, a miller or untreated as control. Furthermore, different storage media (artificial saliva solution or vegetable oil) were evaluated for all surface states simulating contact with body fluids. Tensile and tensile shear tests examined the bonding strength.

Tensile shear tests revealed lower bonding strengths than tensile tests. After surface conditioning, the bonding strengths with the basic material conditioned by a miller were statistically significant higher. Stored in oil, they were statistically significantly lower.

Lining might compensate fitting deficits from impression or manufacturing shortcomings. For maxillofacial prostheses in patients, the contamination effect of dermal fat and saliva/tissue fluid makes lining seem unpromising.

Introduction

After the removal of facial and oro-pharyngeal tumors, the functions of the orofacial system are frequently impaired [1–5]. Whenever a reconstruction with musculo-cutanous flaps is not possible, the provision of a maxillofacial prosthesis might be an alternative therapeutic option for rehabilitation. The use of maxillofacial prostheses can result in gaps between the marginal silicone and the adjacent parts of the face. These gaps might have been caused during the manufacturing of the maxillofacial prosthesis arising from the impressions and/or laboratory production [6]. On the other hand, marginal gaps might appear during the use of the maxillofacial prosthesis caused by changes of the adjacent soft tissues such as scar contractions or later resections [7]. These gaps and therefore a reduced fitting accuracy might result in discomfort for the patients. Air leakage can impair speech. Furthermore, the leakage of saliva might hamper the patients' social life . When occurring in PMMA prosthesis (removable dental prosthesis), the lining of gaps with various materials is considered as an option [8]. For the bonding between PMMA prosthesis in the edentulous mandible and non-hardening silicone linings, positive results have been reported [9–11]. The procedures to evaluate the bonding strength between PMMA and silicones has been described by various studies [12–15]. As maxillofacial prostheses are frequently manufactured from silicone, there are conflicting statements on the compensation of the missing parts by silicone lining [7,16,17]. If linings utilizing a successful bond between the silicone of a maxillofacial prosthesis and a silicone lining material, the manufacturing of a new maxillofacial prosthesis would only be required at a later point in time. This would mean reduced physical and psychological stress for the patients concerned and could also reduce costs.

The objective of the study was the experimental evaluation of the bonding strength of selected silicones as a model for the clinical situation in which maxillofacial prosthesis linings are applied. Up to now, the importance of simulating clinical conditions has been described for an artificial saliva solution and for simulated skin contact in bonding strength tests for other materials [18–21].

Therefore, clinically relevant models were used for this purpose [22].

The following hypotheses were tested:
The new system for the 45° tensile shear test , which is equivalent to the clinical situation of the loosening of an maxillofacial prosthesis on the patient, is a modification of the T-peel test [23] - and the tensile test provide comparable results.

The industrially recommended removal of the surface layer of the base material (prior to the application of the lining silicone) leads to an increase of the bonding strength to the lining material.

The storage of the base material before application of the lining silicone in a saliva substitute solution (simulating the contact with saliva and/or tissue fluids) or in oil (simulating the contact with dermal fat) leads to a reduced bonding strength between the base and lining silicones.

The bond strengths of the various silicone combinations tested were similar.

Materials and methods

Materials and specimens
Metallic samples of cast pure titanium were used to test the bonding strength of selected addition-curing cross-linking silicones. Prior to coating, the cleaned and machined titanium test body surfaces were blasted with aluminum oxide (Alustral, OMNIdent Rodgau,

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Germany, particle size: 110 µm, 2 bar, 30 seconds). Subsequently, the Silicoater technology was used to achieve a firm bonding between the titanium and the silicone [24]. The Sur A Chem VG 02 handheld silicoater device (Sur A Chemicals, Jena, Germany) was used to coat the titanium surfaces ten times for 2 seconds each time. After cooling of the specimens, the Sur A Chem 5201 (Sur A Chemicals, Jena, Germany) bonding agent for addition-curing cross-linking silicones was applied according to the manufacturer's instructions. The materials Mucopren E (Kettenbach Dental, Eschenburg, Germany), Mucopren soft (Kettenbach Dental, Eschenburg, Germany) und Episil E (Dreve – Dentamid, Unna, Germany) were selected for testing [25–27]. The addition-curing cross-linking process of these silicones takes place at room temperature [28]. The processing was done in accordance with the manufacturer's instructions. The following combinations of materials were tested:

Mucopren E / Mucopren E
Mucopren E / Mucopren soft
Mucopren E / Episil E
Episil E / Mucopren soft
Episil E / Episil E.

The material Mucopren soft has only been admitted/indexed as a "lining material".

The materials were available using cartridge systems to prevent dosage and mixing errors.

Test design
The shape of the test specimens are shown in figures 1 and 2.

Figure 1– Sample preparation for the tensile shear test (Ti – Titanium, BS – Basis –Silicone, LS – Lining -Silicone). The layer thicknesses were 1 mm each.

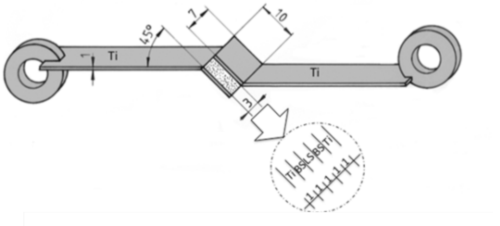
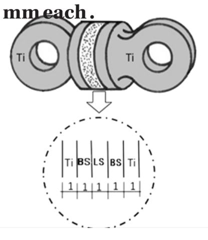


Figure 2 – Sample preparation for the tensile test (Ti – Titanium, BS – Basis - Silicone, LS – Lining - Silicone). The layer thicknesses were 1 mm each.



For both, the 45° tensile shear test and the tensile test, the silicone bonding surface was 70 mm^2. The silicone coating was applied using moulding and coating tools (coating aids). All the dimensions were controlled by a digital sliding calliper (type: Absolute Digimatic; Mitutoyo, Coventry, UK). Each test specimen was used only once for the study. Eight specimens were evaluated in each series. Conditioning of the base material was performed by removing the superficial layer (0.5 mm maximum) either using Form No. 15 disposable scalpels (Paragon, Sheffield, UK) or an ISO 310 104 155 172 060 type milling instrument (Busch, Engelskirchen, Germany) shown in figure 3 and 4.

Figure 3 – Partial portrayal of the cutting edge of a scalpel blade

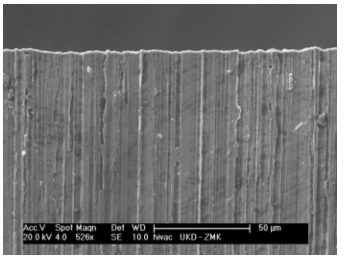
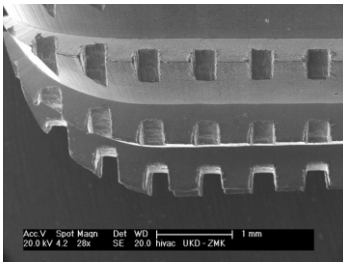
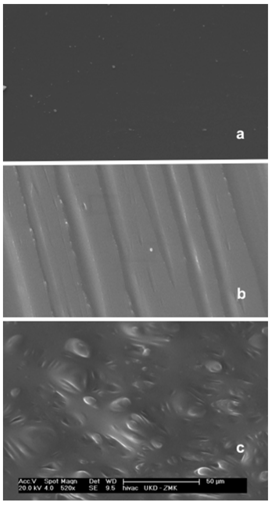


Figure 4 – Cut of the milling cutter used for conditioning



Examples of the resulting surfaces are shown in comparison in figure 5.

Figure 5 – Examples of conditioned silicone surfaces; top (a) - without conditioning; middle (b) - following processing with a scalpel; bottom (c) - after processing with a milling cutter. The enlargement is identical in all three samples.



Next, the influence of various storage conditions on the bonding strength of the base material was evaluated. On the one hand, the test specimens were stored in a saliva substitute solution to resemble the contact with saliva and tissue fluids. The saliva substitute solution was produced in accordance with the standard formulation of the pharmacy of Dresden University Hospital (pH = 7.1). Furthermore, vegetable oil was used as a storage medium to simulate the contact of the maxillofacial prosthesis with dermal fat when it is worn [18]. Remainders of the oil or the saliva solution, as the case may be, were removed from the scalpel blades and the milling cutters after each use.

All test series were performed without using an adhesive agent due to the fact that the Mucopren adhesive is exclusively applied for bonding of silicone to polymethylmethacrylate (PMMA). The following test series were performed to evaluate the various factors influencing the bonding strength:

- without any conditioning
- pre-treatment of the base material only with a scalpel

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- processing of the base material only with a milling instrument
- after storage in artificial saliva solution (24 hours) with no other processing
- after storage in artificial saliva solution (24 hours) with subsequent scalpel processing of the base material
- after storage in substitute saliva solution (24 hour) and subsequent milling of the base material
- after storage in vegetable oil (24 hours) with no other processing
- after storage in vegetable oil (24 hours) with subsequent scalpel processing of the base material
- after storage in vegetable oil (24 hour) and subsequent milling of the base material.

The average room temperature was 23°C.
The bonding strength was tested using a type TIRA test 2720 universal test device (TIRA, Schalkau, Germany). The measuring inaccuracy of the device system ranged between 0.12 and 0.15%. The feed motion was set at 1 mm per minute. The criterion for ending the test was a drop in bonding strength of 80 %. The design of the test specimen enabled a self-centering of the specimen in the testing device when the force was applied ensuring an axial force transmission. The arrangement of the new tensile shear test allowed force transmission in an angle of 45° simulating a situation when a maxillofacial prosthesis separates from the edge of the defect. Immediately after each test, a visual assessment was performed without magnifying aids to see whether the reason for the deplacement was an adhesion failure, a cohesion failure or a combination of both. The manufacturing and the testing of the specimens were performed using standardized conditions.

Data analysis and statistics
The following formulas were used to determine the values of the bonding strength:

For the tensile shear test $T_{max} = F_{max} * \cos 45^{o} / S_{o}$ [N/mm² equivalent to Mpa]

For the tensile test $R_{max} = F_{max} / S_{o}$ [N/mm² equivalent to Mpa]

Explanation of the abbreviations:
T_{max} – maximum shear stress
F_{max} – maximum force [N]
S_{o} – working face exposed to the forces [mm²]
R_{max} – maximum tensile stress

The comparison of mean values of the test series was performed using a U-test (Mann and Whitney, α =.05, both sides) and Bonferroni adjustment. The statistical testing of the combinations of properties of the test series was performed using an univariate analysis of variance (primary and interaction effects) and the subordinate Bonferroni test (post hoc test) [29].

Results
The means and standard deviation values calculated for the shear and tensile stress tests are shown in tables 1 and 2.

Table 1 – Tensile shear test; shearing stress values and assessment levels for the various types of conditioning and storage and combinations of materials; a – calculated shear stress values – means ± standard deviations [MPa] / b – assessment levels: level 1 – up to 0.10 MPa / level 2 – 0.11 up to 0.20 MPa / level 3 – 0.21 up to 0.30 MPa / level 4 – 0.31 up to 0.40 MPa / level 5 – 0.41 up to 0.50 MPa / level 6 – 0.51 up to 0.60 MPa / level 7 – 0.61 up to 0.70 MPa.

Conditioning/ storage types	Combination of material					Means assessment level per type of conditioning/ storage
	Mucopren E / Mucopren E a / b	Mucopren E / Mucopren soft a / b	Mucopren E / Episil E a / b	Episil E / Mucopren soft a / b	Episil E / Episil E a / b	
Without	0.18±0.04 / 2	0.21±0.01 / 3	0.15±0.05 / 2	0.16±0.02 / 2	0.20±0.02 / 2	2.2
Scalpel	0.52±0.08 / 6	0.63±0.09 / 7	0.24±0.04 / 3	0.24±0.07 / 3	0.19±0.03 / 2	4.2
Milling cutter	0.64±0.03 / 7	0.60±0.04 / 6	0.47±0.05 / 5	0.31±0.08 / 4	0.28±0.05 / 3	5.0
Saliva storage	0.10±0.03 / 1	0.08±0.02 / 1	0.10±0.03 / 1	0.09±0.02 / 1	0.12±0.04 / 2	1.2
Saliva storage and scalpel	0.14±0.03 / 2	0.16±0.02 / 2	0.18±0.02 / 2	0.17±0.04 / 2	0.17±0.03 / 2	2.0
Saliva storage and milling cutter	0.32±0.04 / 4	0.30±0.02 / 3	0.21±0.04 / 3	0.20±0.01 / 2	0.39±0.09 / 4	3.2
Oil storage	0.05±0.01 / 1	0.07±0.02 / 1	0.07±0.03 / 1	0.05±0.01 / 1	0.06±0.02 / 1	1.0
Oil storage and scalpel	0.07±0.03 / 1	0.07±0.03 / 1	0.10±0.02 / 1	0.08±0.02 / 1	0.14±0.03 / 2	1.2
Oil storage and milling cutter	0.14±0.03 / 2	0.14±0.05 / 2	0.12±0.03 / 2	0.13±0.05 / 2	0.18±0.04 / 2	2.0
Means assessment level per material combination	2.9	2.9	2.2	2.0	2.2	

Table 2 – Tensile test; tensile stress values and assessment levels for the various types of conditioning and storage and combinations of materials; a – calculated tensile stress values – means ± standard deviations [MPa] / b – assessment levels: level 1 – up to 0.10 MPa / level 2 – 0.11 up to 0.20 MPa / level 3 – 0.21 up to 0.30 MPa / level 4 – 0.31 up to 0.40 MPa / level 5 – 0.41 up to 0.50 MPa / level 6 – 0.51 up to 0.60 MPa / level 7 – 0.61 up to 0.70 MPa / level 8 – 0.71 up to 0.80 MPa / level 9 – 0,81 up to 0.90 MPa / level 10 – 0.91 up to 1.00 MPa.

Conditioning/ storage types	Combination of material					Means assessment level per type of conditioning/ storage
	Mucopren E / Mucopren E a / b	Mucopren E / Mucopren soft a / b	Mucopren E / Episil E a / b	Episil E / Mucopren soft a / b	Episil E / Episil E a / b	
Without	0.27±0.05 / 3	0.32±0.07 / 4	0.34±0.04 / 4	0.25±0.05 / 3	0.32±0.04 / 4	3.6
Scalpel	0.68±0.11 / 7	0.52±0.09 / 6	0.49±0.08 / 5	0.35±0.05 / 4	0.36±0.06 / 4	5.2
Milling cutter	1.00±0.07 / 10	0.89±0.09 / 9	0.84±0.06 / 9	0.80±0.10 / 8	0.76±0.10 / 8	8.8
Saliva storage	0.18±0.21 / 2	0.19±0.04 / 2	0.26±0.03 / 3	0.08±0.03 / 1	0.18 ±0.04/ 2	2.0
Saliva storage and scalpel	0.38±0.03 / 4	0.12±0.05 / 2	0.22±0.05 / 3	0.18±0.04 / 2	0.20±0.05 / 2	2.6
Saliva storage and milling cutter	0.61±0.15 / 7	0.48±0.09 / 5	0.26±0.04 / 3	0.34±0.06 / 4	0.62±0.07 / 7	5.2
Oil storage	0.07±0.05 / 1	0.09±0.04 / 1	0.08±0.03 / 1	0.14±0.04 / 2	0.09±0.03 / 1	1.2
Oil storage and scalpel	0.26±0.08 / 3	0.27±0.08 / 3	0.29±0.06 / 3	0.25±0.06 / 3	0.30±0.04 / 3	3.0
Oil storage and milling cutter	0.14±0.05 / 2	0.15±0.07 / 2	0.23±0.05 / 3	0.20±0.05 /2	0.33±0.04 / 4	2.6
Means assessment level per material combination	4.3	3.8	3.8	3.2	3.9	

For the comparison of the tensile shear test and the tensile test, the statistical testing revealed a statistically significant difference ($p < .001$). The shear values of the tensile shear test were lower for the tensile values of the tensile tests (Figures 6 and 7).

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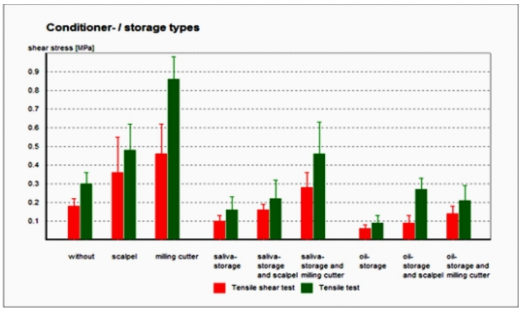
Figure 6 – Comparative graph of the means and standard deviations of all series of tests for the various types of conditioning and storage of the tensile shear tests (red) and tensile tests (green).



An additional comparison of the two bonding strength testing methods was possible after the determination of the percentage of the standard deviations based on the mean values of the bond strengths. The percentage of the average standard deviation was 21% for all tensile shear tests and 25% for all tensile tests. Thus, both test methods showed a consistent reproducibility.

Levels of assessment were introduced to obtain a better overview and achieve comparability of the large volume of data. These and the corresponding average values are shown in tables 1 and 2, likewise. The figures of the "without" series are to be regarded as reference data.

Using the 45° tensile shear tests, we observed the highest bonding strength after mechanical processing of the base material with a milling instrument or scalpel (Table 1). This result was confirmed by the statistical tests (Table 3).

Table 3 Statistical evaluation of the tensile shear test for the various types of conditioning and storage; univariate variance analyses (Hotelling Spur); significance (both sides): *(p< .05); ** (p< .01); *** (p< .001); ns. – non significant.

	Without	Scalpel	Milling cutter	Saliva storage	Saliva storage+Scalpel	Saliva storage+milling cutter	Oil storage	Oil storage+scalpel	Oil storage+milling cutter
Without	-	<.001 ***	< .001 ***	.004 **	1.000 ns.	< .001 ***	< .001 ***	.001 **	1.000 ns.
Scalpel		-	< .001 ***	< .001 ***	< .001 ***	.007 **	< .001 ***	< .001 ***	< .001 ***
Milling cutter			-	< .001 ***	< .001 ***	< .001 ***	< .001 ***	< .001 ***	< .001 ***
Saliva storage				-	.084 ns.	< .001 ***	1.000 ns.	1.000 ns.	1.000 ns.
Saliva storage + Scalpel					-	< .001 ***	< .001 ***	.025*	1.000 ns.
Saliva storage + milling cutter						-	< .001 ***	< .001 ***	< .001 ***
Oil storage							-	1.000 ns.	.003 **
Oil storag e+Scalpel								-	.540 ns.
Oil stora ge+milling cutter									-

Statistically significant lower bond strengths were found for the entire test series stored in oil with and without mechanical conditioning) and after storage solely in artificial saliva solution.

The same results were observed for the tensile tests (Table 2) and were confirmed by the statistical tests likewise (Table 4).

Table 4 Statistical evaluation of the tensile tests for the various types of conditioning and storage; univariate variance analyses (Hotelling Spur); significance (both sides): ** (< .01); *** (< .001); ns. – non significant.

	Without	Scalpel	Milling cutter	Saliva storage	Saliva storage+Scalpel	Saliva storage+milling cutter	Oil storage	Oil storage+scalpel	Oil storage+milling cutter
Without	-	<.001 ***	< .001 ***	< .001 ***	< .001 ***	< .001 ***	< .001 ***	1.000 ns.	.004**
Scalpel		-	< .001 ***	< .001 ***	< .001 ***	1.000 ns.	< .001 ***	< .001 ***	< .001 ***
Milling cutter			-	< .001 ***	< .001 ***	< .001 ***	< .001 ***	< .001 ***	< .001 ***
Saliva storage				-	2.55 ns.	< .001 ***	.160 ns.	1.000 ns.	.980 ns.
Saliva storage + Scalpel					-	< .001 ***	< .001 ***	.927 ns.	1.000 ns.
Saliva storage + milling cutter						-	< .001 ***	< .001 ***	< .001 ***
Oil storage							-	< .001 ***	< .001 ***
Oil storag e+Scalpel								-	.239 ns.
Oil stora ge+milling cutter									-

Differentiation of the combination of materials was possible only in individual cases (Tables 1 and 2). Compared to other combinations of materials, this applied only to the values for Mucopren E / Mucopren soft and Mucopren E / Mucopren E. The corresponding results of the statistical tests (Tables 5 and 6) only confirmed this for the tensile shear tests.

Table 5 Statistical evaluation of the tensile shear tests for the various combinations of materials; univariate variance analyses (Hotelling Spur); significance (both sides): *(p < .05); ** (p < .01); ns. – non significant.

	Mucopren E / Mucopren E	Mucopren E / Mucopren soft	Mucopren E / Episil E	Episil E / Mucopren soft	Episil E / Episil E
Mucopren E / Mucopren E	-	1.000 ns.	.210 ns.	.014 *	.489 ns.
Mucopren E / Mucopren soft		-	.074 ns.	.004 **	.193 ns.
Mucopren E / Episil E			-	1.000 ns	1.000 ns.
Episil E / Mucopren soft				-	1.000 ns.
Episil E / Episil E					-

Table 6 Statistical evaluation of the tensile tests for the various combinations of materials; univariate variance analyses (Hotelling Spur); Post-hoc test: Bonferroni; significance (both sides); ns. – non significant.

	Mucopren E / Mucopren E	Mucopren E / Mucopren soft	Mucopren E / Episil E	Episil E / Mucopren soft	Episil E / Episil E
Mucopren E / Mucopren E	-	1.000 ns.	1.000 ns.	1.000 ns.	1.000 ns.
Mucopren E / Mucopren soft		-	1.000 ns.	1.000 ns.	1.000 ns.

Mucopren E / Episil E			-	1.000 ns	1.000 ns.
Episil E / Mucopren soft				-	1.000 ns.
Episil E / Episil E					-

The testing of the primary effects revealed highly significant differences for the types of conditioning and storage for the tensile shear tests ($p < .001$). The various combinations of materials did not differ in a statistically significant way ($p = .219$). A similar behaviour was revealed performing the tensile tests (for the types of conditioning and storage, $p < .001$; for the material combinations, $p = .219$). The interactions between the conditioning and storage conditions as well as the combinations of materials were also highly significant for both types of test (in each case, $p < .001$). All failures were found to be failures of adhesion between the base and lining material.

Discussion

General aspects

For removable dental prostheses made of PMMA, there are known repair options, including linings with various materials [8].

Bonding strength tests of material bonds between PMMA and silicones simulate the clinical situation of non-hardening lining of complete dentures prostheses made of PMMA in edentulous lower mandibles. Positive results have been published for this situation with regard to the bonding strength of PMMA and lining silicone when various primers are used [9–11]. However, no reliable studies were found in literature for lining silicone maxillofacial prostheses. Silicones are frequently used as materials for maxillofacial prostheses [16]. As wearing times of silicone maxillofacial prostheses are roughly one-third shorter compared to the previously extensively used PMMA maxillofacial prostheses, the option of using silicone linings would be an important step in postponing the fabrication of new maxillofacial prostheses, which causes stress for the patients, while simultaneously reducing costs [7,17]. If we look at the two groups in which "restoration" is necessary, defects in the maxillofacial prosthesis might be due to problems with the impression or due to the laboratory manufacturing. In everyday practice, this corresponds to the group of silicone maxillofacial prostheses not yet worn (only fitted and tried out) by patients. The other group includes the formation of gaps at the edge of the maxillofacial prosthesis developing during the period in which the maxillofacial prosthesis is worn. Examples of this include cicatricial contraction and secondary resections in the area of the defect [7,17]. The types of storage selected for the study - in artificial saliva solution and in oil - simulate stresses on a maxillofacial prosthesis which is clinically used by a patient. The importance of simulating clinical conditions was described for an artificial saliva solution and for simulated skin contact in bonding strength tests for other materials [18–21]. For material bonds, reference was also made to the roughening of the contact surfaces for base resin and silicones used in prostheses [30, 31]. In the present study, this was achieved by mechanical conditioning using scalpels or milling instruments. The performed removal of the surface layer for the test series that were previously stored in artificial saliva solution or oil was the removal of the superficial, "contaminated" material layer.

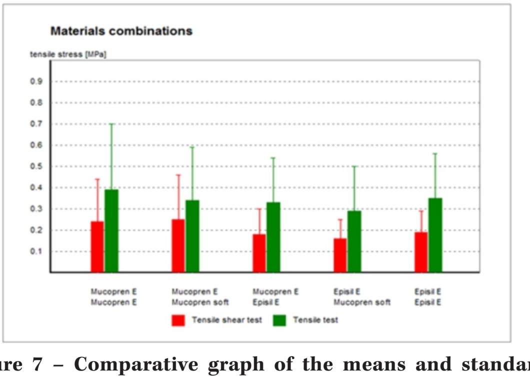


Figure 7 – Comparative graph of the means and standard deviations of all series of tests for the various material combinations of the tensile shear tests (red) and tensile tests (green).

Methodological aspects

In the literature, various tests were used for bonding strength testing of PMMA and silicones. Tensile and peel tests are frequently cited procedures. Considering peel tests, the directions of force vary by 90 or 180° to the material surface [12–15, 23]. The new system for the 45° tensile shear test , which is equivalent to the clinical situation of the loosening of an maxillofacial prosthesis on the patient, is a modification of the T-peel test [23].

Results obtained from different test methods and different materials are not directly comparable. The test method performed influences the bonding strength values [32]. This was also confirmed in the present study. The bonding strength values for the tensile shear tests were found to be lower than those for the tensile tests. This might be caused by the combined shear and tensile forces in the area of the material bonding zone in the 45° tensile shear test. The application of both test methods seems to be possible for the selected hypothesis as analogous results regarding the effects of the types of conditioning and storage using both test methods were obtained.

Currently, no adequate data directly comparing the results of the present study were found in the literature. The similar (modified) test specimen shape, bonding surface size and test procedure were performed to test the bonding between titanium and the silicone for maxillofacial prostheses [24]. However, the bonding strength values obtained cannot be directly compared as they refer to a bonding between metal and the material for maxillofacial prostheses. The Episil E used in that study showed bonding strength values between 0.10 and 0.40 MPa. The results of the tensile test were higher compared to those of the tensile shear tests in the current study. Other authors also observed a large number (90%) of adhesion failures performing shear and tensile tests [32]. This indicated a relative weakness of the silicone-silicone bonding. Elastosil M 3500 was to correct the maxillofacial prostheses completely manufactured of silicone described by Gehl [17]. Using the lining that he described was not possible for the materials applied in the present study. The maxillofacial prosthesis silicone Elastosil M 3500 had already been removed from the market by the time the current study set up. Thus, it could not be used for direct comparison.

Assessment of the hypotheses

The following can be noted with regard to the hypotheses:

Comparing the test methods, the new 45° tensile shear test seems to be suitable for the evaluated subject. This hypothesis can be accepted. For mechanical conditioning using the milling instrument, significant increases in bonding strength were found. Thus, this hypothesis can be accepted. The storage in artificial saliva solution and oil resulted in statistically significant reduced values for the bonding strength. This hypothesis cannot be accepted for this. The bonding strength of various combinations of materials only showed differences in individual cases. The hypothesis is to be accepted.

Conclusion

Both the 45° tensile shear test and the tensile test might be used for the bonding strength testing described in the present study. The mechanical conditioning with a milling instrument resulted in the highest values for bonding strengths. The storage of the base material in vegetable oil seemed to lead to insulation of the materials and reduced the bonding strength. Material deficits due to the impression or manufacturing processes might be compensated with linings. However, after use of a silicone maxillofacial prosthesis by patients, a lining does not seem the appropriate method due to the insulating effect of dermal fat and saliva/tissue fluid regarding the combinations of materials evaluated in the present study. Such an experimental study supports the selection of the types of conditioning for clinical application.

Conflict of interest The authors declare that there is no conflict of interest.

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References
1 Linden RW. The scientific basis of eating. Taste and smell: salivation, mastication and swallowing, and their dysfunctions. 1st ed., Basel: Karger; 1998.
2 Taylor TD. Clinical Maxillofacial Prosthetics. 1st ed., Chicago/London: Quintessence; 2000.
3 Hatamleh MM, Haylock C, Watson J, Watts DC. Maxillofacial prosthetic rehabilitation in the UK: a survey of maxillofacial prosthetists' and technologists' attitudes and opinions. Int J Oral Maxillofac Surg. 2010;39:1186–1192.
4 Reitemeier B, Unger M, Richter G, Ender B, Range U, Markwardt J. Clinical test of masticatory efficacy in patients with maxillary/mandibular defects due to tumors. Onkologie. 2012;35:170–174.
5 Müller R, Höhlein A, Wolf A, Markwardt J, Schulz M, Range U et al. Evaluation of selected speech parameters after prosthesis supply in patients with maxillary or mandibular defects. Onkologie. 2013;36:547–552.
6 Reitemeier B, Schmidt A, Güntzer J. Preliminary results of the dimensional accuracy of impressions for maxillofacial prostheses in the sitting and reclining patient. J Facial Somato Prosthetics. 1999;5:103–107.
7 Sander U, Lippold A, Schwipper V. Service life of epitheses from various materials and with various retention techniques. In: Schwipper V, Tilkorn H, editors. Progress in craniofacial surgical prosthetics and epithetics. 1 st ed., Reinbek: Einhorn-Presse; 1997: p. 180–187. (in German)
8 Stipho HD, Talic YF. Repair of denture base resins with visible light-polymerized reline material: effect on tensile and shear bond strengths. J Prosthet Dent. 2001;86:143–148.
9 Taft RM, Cameron SM, Knudson RC, Runyan DA. The effect of primers and surface characteristics on the adhesion-in-peel force of silicone elastomers bonded to resin materials. J Prosthet Dent. 1996;76:515–518.
10 Polyzois GL, Frangou MJ. Bonding of silicone prosthetic elastomers to three different denture resins. Int J Prosthodont. 2002;15:535–538.
11 Frangou MJ, Polyzois GL, Tarantili PA, Andreopoulos AG. Bonding of silicone extra-oral elastomers to acrylic resin: the effect of primer composition. Eur J Prosthodont Restor Dent. 2003;11:115–118.
12 Kutay O. Comparison of tensile and peel bond strengths of resilient liners. J Prosthet Dent. 1994;71:525–531.
13 Tanimoto Y, Saeki H, Kimoto S, Nishiwaki T, Nishiyama N. Evaluation of adhesive properties of three resilient denture liners by the modified peel test method. Acta Biomater. 2009;5:764–769.
14 Hatamleh MM, Watts DC. Mechanical properties and bonding of maxillofacial silicone elastomers. Dent Mater. 2010;26:185–191.
15 Hatamleh MM, Watts DC. Bonding of maxillofacial silicone elastomers to an acrylic substrate. Dent Mater. 2010;26:387–395.
16 Peters R VL. Optimizing the margins of a facial prosthesis with a polyurethane sheet. In: Penkner K, editor. Proceedings of the Congress of International Association Surgery Prosthetics and Epithetics. Graz: self-published; 1995, p. 36–38.
17 Gehl G, Sailer HF, Simmen D, Meyer VE. The Challenge of correcting silicone facial prostheses. In: Reitemeier G, editor. Proceedings of the Congress of International Association Surgery Prosthetics and Epithetics. Graz: self-published; 1997: p. 83–91.
18 Polyzois GL, Tarantili PA, Frangou MJ, Andreopoulos AG. Physical properties of a silicone prosthetic elastomer stored in simulated skin secretions. J Prosthet Dent. 2000;83:572–577.
19 Kazanji MN, Watkinson AC. Soft lining materials: their absorption of, and solubility in, artificial saliva. Br Dent J. 1988;165:91–94.
20 Deng H, Zwetchkenbaum S, Noone A. Bond strength of silicone to polyurethane following immersion of silicone in cleaning solutions. J Prosthet Dent. 2004;91:582–585.
21 Kiat-Amnuay S, Gettleman L, Khan Z, Goldsmith LJ. Effect of adhesive retention of maxillofacial prostheses. Part 2: Time and reapplication effects. J Prosthet Dent. 2001;85: 438–441.
22 Della Bona A, Watts DC. Evidence-based dentistry and the need for clinically relevant models to predict material performance. Dent Mater. 2013;29:1–2.
23 ASTM D 1876. Standard test method for Peel Resistance of Adhesives (T-Peel Test); May 2015.
24 Wolf BH, Reitemeier B, Schmidt AE, Richter GH, Duncan G. In vitro testing of the bond between soft materials used for maxillofacial prostheses and cast titanium. J Prosthet Dent. 2001;85:401–408.
25 Reitemeier B, Schmidt A, Richter G, Schowtka L, Techritz K. Results of the experimental study of Elasto-Synsil 30 and Episil E. J Facial Somato Prosthetics. 1998;4:119–122.
26 Eleni PN, Katsavou I, Krokida MK, Polyzois GL, Gettleman L. Mechanical behavior of facial prosthetic elastomers after outdoor weathering. Dent Mater. 2009;25:1493–1502.
27 Abdulhadi LM. Multiple retentive means for prosthetic restoration of a large facial defect - a case report. Chin J Dent Res. 2010;13:61–66.
28 Anusavice KJ. Phillip´s science of dental materials. 12th ed., Philadelphia: Saunders; 2012.
29 Armitage P, Colton T . Encyclopaedia of biostatistics. Chichester: Wiley; 2005.
30 Polyzois GL. Effect of interface roughening on the bond strength of silicone facial elastomers to acrylic resin. Quintessence Dent Technol. 1995;18:207–210.
31 Cavalcanti YW, Bertolini MM, Cury AA, da Silva WJ. The effect of poly(methyl methacrylate) surface treatments on the adhesion of silicone-based resilient denture liners. J Prosthet Dent. 2014;112:1539–1544.
32 Al-Athel MS, Jagger RG. Effect of test method on the bond strength of a silicone resilient denture lining material. J Prosthet Dent. 1996;76:535–540.