Technical information

Application technical and scientific product documentation 2009

implantlink® *semi*

Removable Implant Cement, semipermanent

Long-term provisional implant cement for cementing superstructures stable when chewing, dual curing

Finally: secure retention, removal of restorations

without damage

1. Introduction

The permanent fastening of implant structures on widely differing abutments and inserts has been transformed considerably in the past years. 10 – 15 years ago, the definitive fastening of implant crowns and bridges by means of vertical and horizontal screw fastening stood absolutely in the foreground. In the meantime experienced implantologists dispense in most cases with such screw fastenings and "cement" the implant prosthetic structures onto the abutments. However, if long-lasting cements with very high adhesion are used for this purpose, the advantage of screw fastening, that one can remove the attached superstructures again without destruction, is not applicable.

To facilitate removal of the superstructures without destruction despite this, temporary cements known from tooth conservation are applied by many users. The disadvantages of conventional, temporary cements are known, e.g. too low adhesive force and compression strength, the cement gap being washed out, bacteriological colonization, uncertain removal of surpluses (residues) etc. implantlink® semi now for the first time offers safe fixing of the superstructure by balanced adhesion with low displacement resistance, low film thickness and high marginal seal, enabling removal without destruction. Here it is possible, even necessary, to dispense with the use of additional separating agents to reduce the adhesion.

2. Characterisation

implantlink® semi is a two-component dual curing cement on urethane methacrylate basis. In areas which are not accessible to light, the cement cures reliably within 5 – 6 minutes thanks to the chemically initiated polymerization mechanism. The cement can be irradiated with light from commercially available polymerization lamps to accelerate curing. This is of especial advantage for removing surpluses extruded out in the marginal gap region. After a few seconds, the so-called gel phase is reached, in which the surpluses can be removed especially easily and in large pieces. Flowability is very high and the pronounced thixotropy prevents dripping. implantlink® semi is suitable for all material combinations and it is free of eugenol and antibacterial. implantlink® semi is largely neutral in odor and taste because of its special composition.

3. Determining the film thickness according to EN ISO 9917*

*Extract from "Materials scientific analysis of temporary cements" (Department of Dental Medical Propedeutics/Community Dentistry, Dental Clinical Centre, Ernst-Moritz-Arndt University, Greifswald) 1/2009

"The glass plates were cleaned with isopropanol, then rinsed with deionized water and lightly blown dry. Two glass plates were placed above one another and their thickness measured accurately to 1 µm with the aid of the digital micrometer screw. The determined value is designated as measurement A. The upper glass plate was removed and the mixed implant cement applied by means of cannula to the lower plate. The upper glass plate was placed back on the lower plate with the cement in the same alignment as in the determination of measurement A. The specimen was then placed centrally between the ram of the universal test machine (Zwick

Z050/THA3). Ten seconds before the end of the working time stated by the manufacturer, a force of 150 ± 2 N was applied with 20 N/s, vertically and centrally above the upper glass plate and the cement located below. Here it had to be ensured that the cement fills the intermediate space between the glass plates completely and the upper plate does not move. After 10 minutes application of a controlled force of 150 ± 2 N, the plates were removed from the universal test machine and the combined thickness of the two glass plates and the cement film located between them was measured with the aid of the digital micrometer screw. This determined value was designated as measurement B. The film thickness resulted from the difference between the two measurements (measurement B – measurement A).

The measurements A and B from which the film thickness is calculated are listed in the Tables 1 to 3 for the different temporary implant cements, in each case for 5 specimens.

Table 1: Film thickness of implantlink® semi

implantlink semi 02277/#2187C			
Specimen number	Measurement A [mm]	Measurement B [mm]	Film thickness [mm]
Specimen 1	9.772	9.779	0.007
Specimen 2	9.796	9.804	0.008
Specimen 3	9.803	9.811	0.008
Specimen 4	9.784	9.792	0.008
Specimen 5	9.806	9.815	0.009
		Mean value	**0.008**
		Standard deviation	**±0.0007**

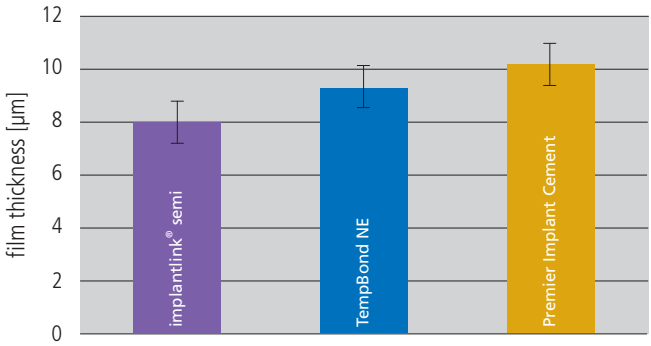
Table 2: Film thickness of Temp Bond NE

Temp Bond NE 3088668			
Specimen number	Measurement A [mm]	Measurement B [mm]	Film thickness [mm]
Specimen 1	9.758	9.767	0.009
Specimen 2	9.759	9.769	0.010
Specimen 3	9.775	9.783	0.008
Specimen 4	9.767	9.776	0.009
Specimen 5	9.761	9.771	0.010
		Mean value	**0.009**
		Standard deviation	**±0.0008**

Table 3: Film thickness of Premier Implant Cement

Premier Implant Cement #3001450			
Specimen number	Measurement A [mm]	Measurement B [mm]	Film thickness [mm]
Specimen 1	9.771	9.781	0.010
Specimen 2	9.772	9.781	0.009
Specimen 3	9.792	9.803	0.011
Specimen 4	9.789	9.800	0.011
Specimen 5	9.765	9.775	0.010
		Mean value	**0.010**
		Standard deviation σ_x	**±0.0008**

Fig. 1: Average film thickness of the different temporary implant cements



It is shown that implantlink® semi, with an average film thickness of 8 µm, has the lowest film thickness. This is followed by Temp Bond NE with 9.2 µm and Premier Implant Cement with 10.2 µmd average film thickness (Fig. 1).

The extraordinarily low film thickness of implantlink® semi ensures secure positioning of the superstructure on insertion and leads to very small gap dimensions between abutment and structure.

4. Determination of the adhesive force*

* Extract from "Materials scientific analysis of temporary cements" (Department of Dental Medical Propedeutics /Community Dentistry, Dental Clinical Centre, Ernst-Moritz-Arndt University, Greifswald) 1/2009.

"The implant analogs with screw-fastened abutments and superstructures were cleaned with isopropanol, rinsed with deionized water and lightly blown dry. Within 60 seconds after the end of mixing, the superstructures were filled completely with the temporary implant cement and brought onto the abutments. The superstructures were pressed with a continuous pressure of 20 N onto the abutments with the aid of a loading device, excess cement surpluses swelling out were removed. After 60 minutes the specimens were stored for a period of 23 h ± 0.5 h in 37°C ± 1°C warm deionized water.

The implant analogs with the screw-fastened abutments and the cemented superstructures were clamped individually in the specially fabricated specimen holder and transferred to the universal test machine. The superstructure is locked with an eye on the upper force transducer (1 kN force sensor). After clamping of the individual specimens, the superstructures were pulled off from the abutment slowly with a speed of 1 mm/min. After the adhesive force examinations the superstructures were cleaned and newly

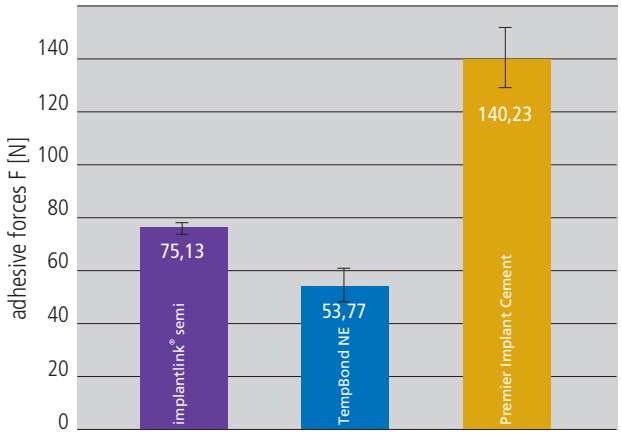
cemented. All tests were performed without the use of additional separating agents.

The average adhesive forces FH [N] of the different temporary implant cements with Au superstructures and the relevant standard deviations from the mean value can be seen in Table 5. It was shown that Temp Bond NE has the lowest adhesive force (53.77 N). For implantlink® semi the average adhesive force is 75.13 N and for Premier Implant Cement 140.23 N (Fig. 3).

Table 5: Average adhesive forces and standard deviations of different temporary implant cements; superstructure Au

	implantlink semi	Temp Bond NE	Premier Implant Cement
Mean value	75.13 N	53.77 N	140.23 N
Standard deviation	2.55 N	7.16 N	12.50 N

Fig. 3: Average adhesive forces FH of the different temporary implant cements for Au superstructures



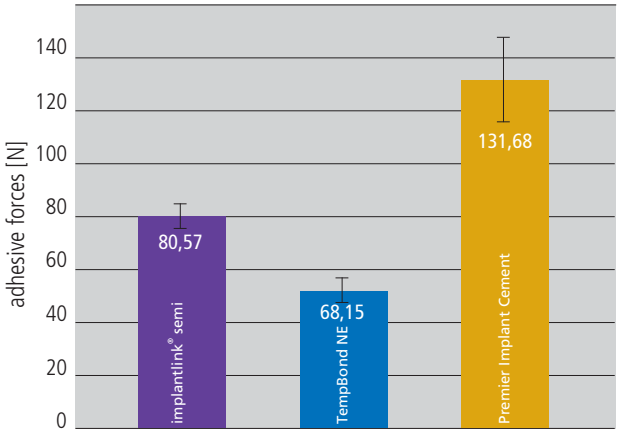
Der The average adhesive forces FH [N] of the different temporary implant cements with ZrO_2 superstructures and the relevant standard deviations from the mean value can be seen in Table 6. It is shown that Temp Bond NE has the lowest adhesive force (68.15 N).

For implantlink® semi the average adhesive force is 80.57 N and for Premier Implant Cement 131.68 N (Fig. 4)."

Table 6: Average adhesive forces FH and standard deviations of different temporary implant cements; ZrO_2 superstructure

	implantlink semi	Temp Bond NE	Premier Implant Cement
Mean value	80.57	68.15	131.68
Standard deviation	5.49	5.57	15.71

Fig. 4: Average adhesive forces of the different temporary implant cements for ZrO_2 superstructures



The determined adhesive forces show for both material combinations that Premier Implant Cement adheres very strongly and makes remo-

val of the superstructure without damage very difficult. To facilitate removal, the manufacturer recommends the use of separating agents (e.g. Vaseline, lubricant gel) to reduce the adhesive force. However, when a separating agent is used, the marginal seal is questionable. TempBond NE has too low adhesive forces and there is a risk of loss. The adhesive forces for implantlink® semi are balanced so that the adhesion is high enough to hold permanently, but not too high for removing the structures with normal exercise of force. By comparison: permanent cements achieve adhesive forces of more than 300 N.

5. Determination of the compression strength according to EN ISO 9917*

* Extract from "Materials scientific analysis of temporary cements" (Department of Dental Medical Propedeutics/Community Dentistry, Dental Clinical Centre, Ernst-Moritz-Arndt University, Greifswald) 1/2009

"The mold, the object carriers as well as the screw clamps were conditioned to 23°C ± 1°C and cleaned with isopropanol. Within 60 seconds after the end of mixing, the mixed cement was filled with a slight surplus into the mold. A cellulose acetate foil as well as an object carrier were placed on the top and bottom of the filled mold and all was clamped in a screw clamp. The specimens were then stored for 60 minutes in a warming box at 37°C ± 1°C at a relative humidity of at least 30%. The screw clamp, the object carriers as well as the foils were then removed and the ends of the specimens were sanded with wet sandpaper (grain size 400). The specimens were removed from the mold directly after surface preparation, examined for air bubbles or chipped edges by a visual test and stored for 23 h ± 0.5 h in 37°C ± 1°C warm, deionized water. Defective specimens were rejected.

The mean diameter of the specimens was determined and noted from two measurements accurate to 0.01 mm at a right angles to one another by means of digital micrometer screw. Moistened filter

paper was placed between the two rams of the universal test machine. A new filter paper was used for each measurement. A continuous force was applied on the longitudinal axis of each individual specimen with a speed of 0.75 mm/min., until this burst under the load at a maximum force (F_{max}). The tests and the relevant test reports were saved. The compression strength can be calculated from the individual mean specimen diameters and the relevant maximum force with the following formula:

$$C = \frac{4 F_{max}}{\pi d^2}$$

C	compression strength
F_{max}	the greatest applied force in Newton (maximum force [N]
D	diameter of the specimen, in millimeters

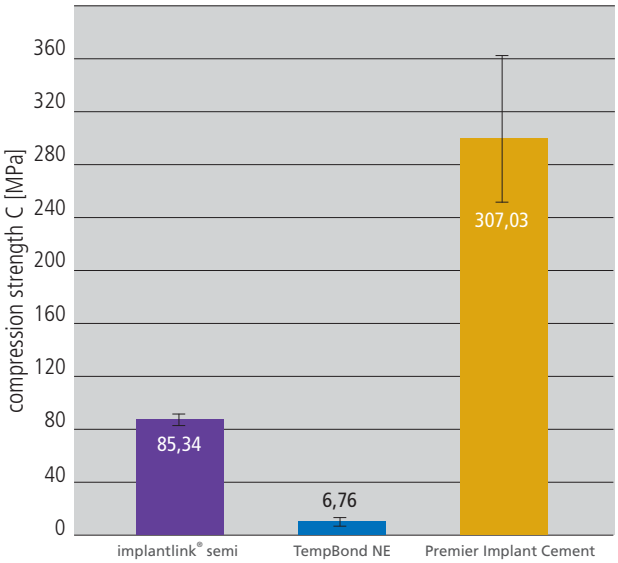
The average compression strengths C [MPa] of the different temporary implant cements and the relevant standard deviations from the mean value can be seen in Table 4. It is shown that Temp Bond NE has the lowest compression strength (6.76 MPa).

This is followed by implantlink® semi with 85.34 MPa and Premier Implant Cement with 307.03 MPa average compression strength (Fig. 2)."

Table 4: Average compression strengths and standard deviations of different temporary implant cements

	implantlink semi	Temp Bond NE	Premier implant Cement
Mean value	85.34 MPa	6.76 MPa	307.03 MPa
Standard deviation	± 5.88 MPa	± 2.07 MPa	± 56.48 MPa

Fig. 2: Average compression strength C [MPa] of the different temporary implant cements, ZrO_2 superstructure



A behavior similar to the adhesive forces is shown for the compression strengths. Premier Implant Cement has high compression strength, whereas Temp Bond NE has an extremely low strength. The properties of implantlink® semi are so balanced here that high stability is provided while removal is still possible.

6. Thermocycling*

* Extract from "Materials scientific analysis of temporary cements" (Department of Dental Medical Propedeutics /Community Dentistry, Dental Clinical Centre, Ernst-Moritz-Arndt University, Greifswald) 1/2009

"The implant analogs with screw fastened abutments and superstructures were cleaned with isopropanol, rinsed with deionized water and lightly blown dry. Within 60 seconds after the end of mixing, the superstruc-

tures were filled completely with the temporary implant cement and brought onto the abutments. The superstructure was pressed onto the abutments with a continuous pressure of 20 N with the aid of a loading device and large, excess cement surpluses swelling out were removed. After 60 minutes the specimens were stored for a period of 23 h ± 0.5 h in 37°C ± 1°C warm deionized water.

Before thermocycling, exposures were taken on the microscope of the marginal gap between the cemented crown and the implant abutment. The specimen was then subjected to artificial aging with the thermocycling process. Here the specimen was immersed alternately in a cold bath (5°C) and in a hot bath (55°C) with an immersion time of 30 seconds in each case for 1250 cycles. The drip-off time was 4 seconds. After thermocycling, exposures of the marginal gaps were again taken on the microscope. A comparison of the situation before and after took place for the evaluation. Here the width of the marginal gap and the maximum dimension of the wash-out were measured before and after thermocycling and the difference between the measurements (after-before) noted.

Table 7: Results of the measurements before and after thermocycling

implantlink semi						
Specimen	Marginal gap [µm]			Maximum dimension of the wash-out [µm]		
	Before thermocycling	After thermocycling	Difference (after-before)	Before thermocycling	After thermocycling	Difference (after-before)
1	220	235	15	28	76	48
2	290	310	30	60	120	60
3	180	190	10	155	185	30

Temp Bond NE						
Specimen	Marginal gap [µm]			Maximum dimension of the wash-out [µm]		
	Before thermocycling	After thermocycling	Difference (after-before)	Before thermocycling	After thermocycling	Difference (after-before)
1	470	640	170	130	190	60
2	250	1100	850	160	360	200
3	210	670	460	8	not measurable since complete	/

It can be seen in Table 7 that after thermocycling there is a wash-out of the temporary cement in the marginal region. In one specimen (Temp Bond NE, specimen 3) the erosions in the marginal region were so large that the temporary implant cement was fractured completely up to the abutment. The marginal gap had increased in all specimens after thermocycling; with Temp Bond NE more than with implantlink® semi."

The thermocycling tests demonstrate that with implantlink® semi the erosion of the cement in the marginal gap region is minimal and there is a good seal. With TempBond NE on the other hand, there are considerable wash-outs and the seal is no longer provided. In one case there was even total failure.

7. Gingival management

The high polymerization density of the resin cement material prevents penetration of bacteria and swelling or loosening of the cement, so that bacterial irritations and odor formation can be avoided, even in longer wearing time. How bacterially tight the cement is can be seen in Fig. 5 on the internal mucosa, which has started to adhere directly to the margin of the removed zirconium dioxide crown within the first four months' wearing time. The small vessels opened on removal show this clearly. The small adhering vessels of the internal mucosa indicate a bacterially tight cement film after 4 months.

Fig. 5: Internal mucosa after the first four month' wearing time

8. Removal

The customary aids available in a practice (e.g. crown remover), instruments (e.g. Crown Butler) and devices (Corona Flex - KaVo) can be used to remove the superstructures again. One or two applications of the Crown Butler are sufficient as a rule to remove crowns. In special cases the crown can be "embedded" in an acrylate matrix. In this protected cast the superstructure can then be loosened from the abutment by means of forceps etc. In the case of bridges, use of slings inserted between the abutments is recommended.

A very thin and hard adhesive layer remains on the different abutments and in the lumina of the crowns. The residues of the cementing material can be removed easily, quickly, without residue and over a large area.

9. Toxicology

implantlink® semi contains components which are classified as uncritical with regard to their toxicology. This was also confirmed by the toxicological tests performed according to ISO standards. The cytotoxicity test (L929 MEM Elution Test, ISO 10993-5) was passed without biological reactivity, as well as the systemic toxicity test (ISO 10993-11). The tests for sensitization (according to Kligman, ISO 10993-12) and irritation (ISO 10993-10) also showed no evidence of a sensitizing or irritating effect.

10. Technical data

Mixing volume:	5 ml (mini-mix)
Mixing ratio:	4:1
Product colors:	
Base:	white-opaque
Catalyst:	semitransparent
Mixing time:	not applicable
Working time:	80 sec.
Gel phase:	after 2-3 min. (time for removal of surpluses)
Setting time in the mouth:	5-6 min.
Setting time with light curing:	approx. 20 sec. per surface, according to light permeability
Film thickness:	< 10 µm

11. Sources

*Materials scientific analysis of temporary cements (Department of Dental Medical Propedeutics/Community Dentistry, Dental Clinical Centre, Ernst-Moritz-Arndt University, Greifswald) 1/2009

Dr. med. Hans-Dieter Beyer, Mannheim, 2/2009
Andreas Blesch, Zahnarzt, Karlsruhe, 3/2009
Dr. med. Dietrich Münchgesang, Karlsruhe, 3/2009

Version: FEA DETAX März 2009

implantlink®*semi*

Removable Implant Cement

Lanzeitprovisorischer Implantatzement zur kaustabilen Zementierung von Suprakonstruktionen, dualhärtend, kompatibel mit allen Materialkombinationen.

Long-term provisional implant cement for positive, occlusally stable cementing of superstructures, dual-curing. Compatible with all material combinations.

DETAX Ettlingen / Germany
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www.detax.de/implantlink

CE 0197

Flowchart

Abutments und Restauration gründlich reinigen & trocknen

Clean & dry abutments and restoration thoroughly

implantlink® semi dünnschichtig applizieren

Apply a thin layer of implantlink® semi

Restauration einsetzen, mit leichtem Druck fixieren. Beginn der Gelphase nach ca. 2-3 Min.

Insert restoration and fix it with slight pressure. Start of the gel phase after approx. 2-3 min.

Überschüsse während der Gelphase (vor dem entgültigen Aushärten) entfernen

Remove any excess material during gel phase, before complete setting

2009/10/2009

Autopolymerisation

Light curing

Beginn der Gelphase bzw. die Aushärtung kann durch Lichtpolymerisation beschleunigt werden.

Begin of the gel phase resp. setting time can be accelerated by light curing.

"In total very good adhesion properties, low film thicknesses as well as high marginal seal resulted with implantlink® semi".*

*Materials scientific analysis of temporary cements (Department of Dental Medical Propedeutics/Community Dentistry, Dental Clinical Centre, Ernst-Moritz-Arndt University, Greifswald) 1/2009

12. What users say

"The low-viscosity cement can be introduced and distributed quickly with the tip of the Duomix mixing cannula. The cement does not drip and sets slowly enough so that one can also insert several crowns in one jaw with appropriate drying, which relieves the operator considerably!

Should the reconstruction be removed for control or other purposes, the cement residues can be removed very easily, almost in one piece. After short disinfection, the reconstruction can be fastened again with very little effort."

Dentist Andreas Blesch, Karlsruhe

Standard packing REF 03092
5 ml cartridge mini-mix, 10 mixing cannulas, brown 4:1

"Handling is easy, cemented superstructures can be removed well with customary force."*

"With implantlink® semi, a new fastening cement that takes account of this circumstance is at last available. The crown is cemented firmly, but can be removed relatively easily. To this extent implantlink® semi is a valuable addition to the range of dental aids and a successful innovative cementing material. It clearly makes implant treatment safer."

Dr. med. Dietrich Münchgesang, Karlsruhe

"The consistency (flowability) of the mixed material guarantees a fine restoration or joint gap even at low insertion pressure. However the possibility of controlled initiation of the gel phase of the surpluses by means of light (in each case 20 seconds vestibular and oral) and the directly resulting possibility of fast and easy cleaning must be emphasized especially. Since the pre-cured surpluses can be peeled off practically completely, there is scarcely any risk of overlooking residues of the cement in the critical subgingival region.

The comparatively easy ability to remove implant crowns cemented with implantlink® semi is also especially convincing. Crowns could be removed with one or two applications of the Crown Butler. A very thin and hard cement layer on the different abutments and in the lumina of the crowns was very impressive.

Altogether, implantlink® semi has convinced us that we don't want to be without it in the future."

Dr. med. Beyer, Mannheim

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