Tests Summary:

AvaDent Bonding Procedure Results:

- The AvaDent bond exceeds ADA requirements.

AvaDent Color Stability Results:

- AvaDent is more color stable than conventional dentures.

AvaDent Acrylic Porosity Results:

- AvaDent shows no micro-porosity resulting in negligible C. Albicans adherence.

AvaDent Residual Monomer Results:

- AvaDent has 20% less residual monomer than conventionally fabricated dentures.

Evaluation of the Properties of AvaDent Processed Denture Material

1. Purpose

The main goal of this study was to evaluate the physical properties of an AvaDent processed denture material and to compare them to traditional processed denture materials.

2. Methods and Materials

When applicable, the following tests have been designed according to ISO and ANSI/ADA standards. Some of these methods have been modified to accommodate the new CAD-CAM denture tests.

- ISO 20795-1 *Dentistry – Base polymers – Part 1: Denture base polymers*
- ISO 22112 *Dentistry – Artificial teeth for dental prostheses*
- ANSI/ADA Specification No. 12 – *Denture Base Polymers*
- ANSI/ADA Specification No. 15 – *Synthetic Resin Teeth*

For this test the denture material processed by AvaDent is Diamond D from Keystone. The conventional materials used in this test are Diamond D by Keystone and Lucitone 199 by Dentsply.

4 different brands of synthetic resin teeth are used:

- BlueLine (Ivoclar-Vivadent)
- Portrait (Dentsply)
- Ivostar (Ivoclar-Vivadent)
- Classic (Dentsply)

2.1 Screening and selection of adhesive and bonding procedure.

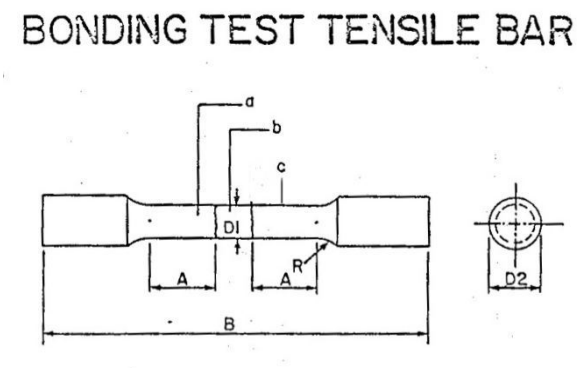
2.1.1 Selection of adhesive

In order to select a suitable adhesive to bond the artificial teeth to the AvaDent processed denture base, a screening test has been performed. 6 different adhesives are tested using a dog-bone sample in a tensile test. The dogbone sample (see picture) is made of two pieces AvaDent processed denture material ‘a’ and ‘c’ bonded together with an adhesive ‘b’

2.1.2 Bonding procedure

The selected adhesive of the tensile test is used in this bonding procedure test.
12 samples per bonding procedure per brand of synthetic resin teeth:
4 bonding procedures are tested:

A= No surface preperation
B= Channel Cut preparation (physical retention)
C= Chemical etch preparation
D= Physical surface etch preparation



For each brand of denture teeth, two groups of 6 teeth are bonded with each of the different bonding procedures to standard acrylic blocks designed and milled in order to reproduce the same testing conditions described below (**2.2**). The samples are stored at 37°C and 100% r.h. Twenty four hours after bonding, the specimens has been tested. Each tooth is loaded on a universal testing machine at 5 mm/min using a loading apparatus as illustrated in Figure 1.
A sample matrix for this test is provided in Table 1.

Figure 1 Tensile testing apparatus

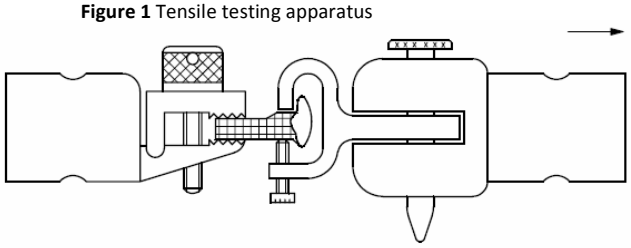


Table 1 Number of specimens for each bonding procedure/Artificial teeth combination to be tested.

	Bonding procedure A	Bonding procedure B	Bonding procedure C	Bonding procedure D
BlueLine	12	12	12	12
Portrait	12	12	12	12
Ivostar	12	12	12	12
Classic	12	12	12	12

The bond passes the test if the fracture path is cohesive within the tooth or the base polymer. Thus, tooth remnants shall remain bonded to the denture base polymer and/or denture base polymer shall remain on the tooth surface. If the fracture is along the bonded area or at the interface, it fails to meet the requirement.

The test is deemed passed if at least 10 out of 12 teeth pass the test. If only eight or nine comply, the test has been repeated with a new set of 6 teeth. If less than eight specimens comply, the denture base polymer/teeth/bonding system combination fails.

The values of force required to debond the specimens has been recorded in order to perform quantitative comparisons among the tested materials.

Results:

Bonding

The bonding test results along with the pass/fail result for each tested group are shown in Table 2. All the groups passed the standard criteria.

Table 2 Results of the bonding test. *N/A: samples not broken due to load cell overload.

Group Name	N	Mean	Std Dev	N/A*	Adhesive fracture	Cohesive fracture (tooth)	Cohesive fracture acrylic)	Pass/Fail
A/Classic	12	364.7	162.0	0	0	11	1	**Passed**
A/Ivostar	12	364.8	145.3	0	0	7	5	**Passed**
A/Blueline	12	462.0	157.4	2	0	7	3	**Passed**
D/Blueline	12	340.2	128.3	0	0	11	1	**Passed**
D/Classic	12	403.2	105.3	0	0	8	4	**Passed**
D/Ivostar	12	467.7	180.4	0	0	8	4	**Passed**
D/Portrait	12	368.5	177.5	0	0	5	7	**Passed**
B/Classic	12	339.3	141.9	0	0	11	1	**Passed**
B/Ivostar	12	503.5	151.6	0	0	12	0	**Passed**
B/Blueline	12	517.9	152.1	0	0	12	0	**Passed**
B/Portrait	12	293.2	124.8	1	0	8	3	**Passed**
C/Portrait	12	356.5	139.1	0	0	10	2	**Passed**
C/Blueline	12	520.1	187.6	2	0	10	0	**Passed**
C/Ivostar	12	457.6	191.6	1	0	11	0	**Passed**

Bonding of artificial teeth to conventional denture base acrylic

The quality of bonding to conventional denture base acrylic are evaluated using the same four brands of artificial teeth that were used for the screening of the bonding procedures. Two denture base materials has been used: Lucitone 199 (Dentsply) and Diamond D (Keystone).

For each denture base material and teeth brand two groups of specimens are prepared. The ridge lap of a set of six maxillary anterior teeth per group are grinded. The teeth has been mounted on a metal former using dental mounting wax, as shown in Figure 2, so that about one-half of the lingual surface projects beyond the metal former.

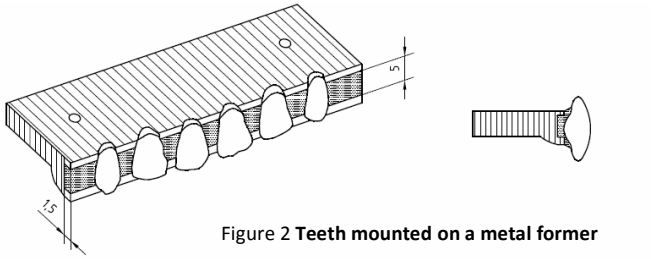


Figure 2 **Teeth mounted on a metal former**

The mounted teeth has been set in dental gypsum using denture flask. The metal former has been removed and the wax has been cleaned with boiling water. After removing all the wax, the denture base polymer has been processed according to manufacturer's instructions.

Table 3 summarizes the samples that has been tested.

Table 3 Samples for bonding of artificial teeth to conventional denture base acrylic testing.

	Lucitone 199	Diamond D
BlueLine	6	6
Portrait	6	6
Ivostar	6	6
Classic	6	6

The same testing conditions and pass/fail criteria used in the screening of the bonding procedures (**2.1.2**) has been applied to the samples.

The bonding test results along with the pass/fail result for each tested group are shown in Table 4. All the groups passed the standard criteria.

Table 4 Results of the bonding test. *N/A: samples not broken due to load cell overload.

Group Name	N	Mean	Std Dev	N/A*	Adhesive fracture	Cohesive fracture (tooth)	Cohesive fracture acrylic)	Pass/Fail
Lucitone/Vivodent	6	697.3	135.7	0	0	6	0	**Passed**
Diamond D/Vivodent	6	227.0	114.4	0	0	5	1	**Passed**
Lucitone/Portrait	6	388.4	153.5	0	0	6	0	**Passed**
Diamond D/Portrait	6	390.2	234.8	1	0	2	4	**Passed**
Lucitone/Classic	6	416.0	214.9	0	0	6	0	**Passed**
Diamond D/Classic	6	467.0	115.8	0	0	5	1	**Passed**
Lucitone/Ivostar	6	650.4	229.5	3	0	3	0	***Passed**
Diamond D/Ivostar	6	499.2	131.7	0	0	3	3	**Passed**

2.2 Color Stability

A group of four disc shaped specimens (50 mm diameter, 5 mm thick) of each material has been made. The specimens has been stored in the oven at 37°C for 24h. Each specimen will then be cut in half. Table 5 specifies the number of samples for this test.

Table 5 Number of disc shaped (D=50mm, T=5mm) to be used for the color stability test.

AvaDent	Lucitone 199	Diamond D
4	4	4

One of the half's from each specimen has been covered with aluminum foil. The specimen has been transferred to a test chamber containing a light source so that the specimen has been immersed in water at 37°C while irradiated for 24h. For the irradiation light source, a RS275 watt sunlamp or equivalent has been used. The light has been adjusted as to provide approximately 1700 mw/cm2 and the specimens has been irradiated for 24 hours.

The color difference between the specimens and between the two sides of the irradiated specimen has been evaluated by three independent observers and quantified as ΔE using a chromameter. The test is deemed passed is ΔE is below 3.3 (the minimum color difference detectable by the naked eye).

The color stability results along with the Pass/Fail criteria for each specimen are summarized in Table 6.

Table 6 Results of the color stability test.

Material	Specimen#	Observed more than slight change (Y/N)			ΔE	Pass/Fail
		Observer 1	Observer 2	Observer 3		*ΔE<3.3*
AvaDent	1	N	N	N	0.79	Pass
	2	N	N	N	0.91	Pass
	3	N	N	N	0.90	Pass
	4	N	N	N	0.86	Pass
Lucitone 199	1	N	N	N	1.29	Pass
	2	N	N	N	1.47	Pass
	3	N	N	N	1.18	Pass
	4	N	N	N	5.54	Fail
Diamond D	1	N	N	N	1.11	Pass
	2	N	N	N	2.40	Pass
	3	N	N	N	3.35	Fail
	4	N	N	N	0.43	Pass

All the AvaDent Processed denture base specimens passed the test. Only one specimen of Lucitone 199 and one specimen of Diamond D failed to meet the established criteria (ΔE < 3.3). Note that the criterion is more restrictive than the ISO standard and that all the specimens did comply with the standard according to the assessment by 3 independent observers. It is usually considered that the human eye cannot detect a color difference of less than 3.3 using the CIE color measuring system.

2.3 Freedom from porosity

The milled AvaDent denture acrylic, Lucitone 199 and Diamond D has been tested. A group of six specimen strips of each material has been prepared. Each strip has been 64mm long, 10mm wide and 3.3mm in height. In order to pass the test, at least five out of the six strips shall be completely free of porosity visible to the naked eye. Table 7 indicates the number of specimens to be used for this test.

Table 7 Number of strips (L=64mm, W=10mm, H=3.3mm) to be used for the freedom of porosity test.

AvaDent	Lucitone 199	Diamond D
6	6	6

If no differences on porosity are observed among the materials, optical microscope at 10 and 40X has been used to assess the presence of porous on the surface. If no differences are observed three specimens of each material has been evaluated using AFM.

Results for the specimens that were free of porosity are shown on Table 8.

Table 8 Porosity observations results

Material	Observer #1	Observer #2	Pass/Fail	40X microscope
CAD/CAM	No porosity	No porosity	**Pass**	No porosity
Lucitone 199	No porosity	No porosity	**Pass**	No porosity
Diamond D	No porosity	No porosity	**Pass**	No porosity

No porosity was observed by naked eye or under a 40X magnification in any of the specimens.

Contact angle

Table 9 Contact angle values measured for each material. Superscript letters link statistically equivalent groups.

Material	Mean (SD)
Diamond D[b]	81.3 (11.8)°
Lucitone[a,b]	83.8 (9.9)°
CAD/CAM[a]	96.3 (12.3)°

Significant differences among the contact angle values of the different materials were detected (p=0.025). Avadent Processed material showed the highest contact angle.

2.4 Adherence of C. Albicans

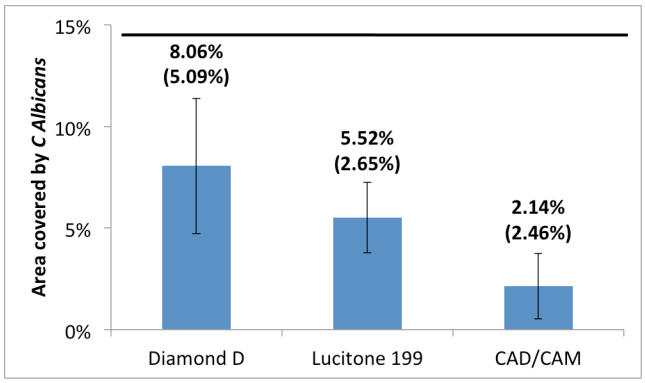
CAD/CAM denture acrylic, Lucitone 199 and Diamond D has been tested. A group of nine specimens of each material has been prepared. Discs measuring 10 mm diameter and 2 mm thick are made. After finishing the surface according to manufacturer's recommendations, the specimens are stored in water at room temperature for 48h, in order to release any residual monomer. Then, the water contact angle has been measured.

Table 10 Number of disc shaped (D=10mm, T=2mm) to be used for the residual adherence of C. Albicans test.

CAD/CAM acrylic	Lucitone 199	Diamond D
9	9	9

The superficial porosity of the specimens has been evaluated microscopically and the number of pores per area unit ant the pore size distribution has been assessed by image analysis.

The specimens has been immersed in human saliva at 37°C for 30 min in order to condition the surface. Then, the samples has been incubated for 1h in a standardized C Albicans suspension at 37°C. After this time, the specimens has been washed in sterile PBS by gently dipping them 10 times in the solution. The adherent cells that remain on the sample surface after this period has been evaluated using microscopic techniques to determine the number of cells per area unit. If the AvaDent processed denture material did not increase the bacterial adhesion significantly when compared to the other two materials, the test has been deemed passed.



Data entry, tabulation and analysis

The measured parameters has been tabulated and analyzed using ANOVA in order to determine if significant differences exist among the tested processing methods. Correlation tests has been performed in order to determine whether a relationship exists between the different studied parameters. All statistical analysis are performed at 95% confidence level.

Bacterial adhesion

Figure 11 summarizes the results of the bacterial adhesion test.

ANOVA revealed significant differences among the denture materials (p=0.007). The AvaDent processed material was found to adhere less *C Albicans* than Diamond D (p=0.005).

The AvaDent processed material is more hydrophobic than the conventional processed material what will result in a more bio-hygienic denture.

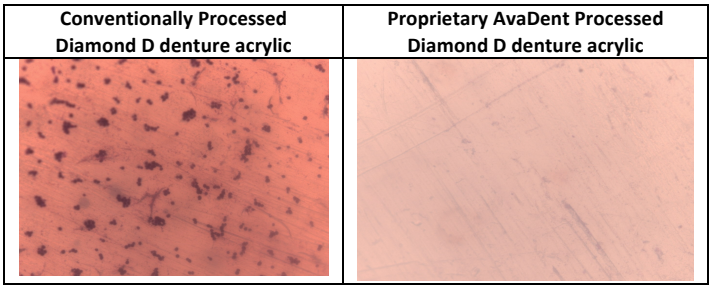


Figure 11 Results from *C Albicans* adhesion. Values above each column show mean (SD) values for each group. Horitzontal lines link groups that did not reveal significant differences.

2.5 Residual methyl methacrylate monomer

AvaDent Processed denture acrylic, Lucitone 199 and Diamond D have been tested. For each material, a group of 3 discs 50mm diameter and 3 mm thick was prepared. The discs will be kept in the dark in a laboratory environment for 24h. Then, the specimens were grinded sequentially on wet P500 and P1200 SiC paper. Both sides of the specimens were grinded until a thickness of 2 mm was obtained. The periphery of the specimen was then be grinded against the P1200 SiC paper until the entire periphery was abraded and smooth.

The ground specimens were stored in the dark in a laboratory environment for 24h. The MMA monomer was extracted with a 2% hydroquinone solution in acetone. The dissolved polymer was precipitated using a 2% hydroquinone solution in methanol and separated by centrifugation. The residual monomer content was be determined by GC using n-pentanol as internal standard. The test is deemed passed if the residual methyl methacrylate is below 2.2% mass fraction.

The residual methyl methacrylate content results along with the Pass/Fail criteria for each specimen are summarized in Table 11.

All the AvaDent processed denture base specimens passed the test. Only one specimen of Diamond D and one specimen of Diamond D failed to meet the established criteria (content of residual methyl methacrylate monomer below 2.2%).

Material	Specimen#	MMA% w/w	Pass/Fail
			MMA%<2.2 %
AvaDent	1	0.31%	Pass
	2	0.34%	Pass
	3	0.31%	Pass
	4	0.71%	Pass
	5	0.38%	Pass
	6	0.38%	Pass
	7	0.65%	Pass
	8	0.62%	Pass
	9	0.51%	Pass
Diamond D	1	0.68%	Pass
	2	0.46%	Pass
	3	0.97%	Pass
	4	0.71%	Pass
	5	0.52%	Pass
	6	7.39%	Fail
	7	0.58%	Pass
	8	0.47%	Pass
	9	0.86%	Pass
Lucitone 199	1	0.91%	Pass
	2	0.35%	Pass
	3	0.55%	Pass
	4	0.78%	Pass
	5	0.81%	Pass
	6	0.42%	Pass
	7	0.46%	Pass
	8	0.52%	Pass
	9	0.51%	Pass

Table 11 Results of the residual methyl methacrylate (MMA) monomer test

Note that the ISO standard only requires that 7 of the specimens comply with the requirement, so all the materials passed the standard test. No significant differences among the materials were detected for the average methyl methacrylate monomer content (p=0.11).