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Global Dental Science Phase III Report

In Vitro Wear of AvaDent FM

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Purpose: Compare the wear of the experimental AvaDent FM denture tooth material to the wear of Dentsply IPN denture tooth material in a simulated oral environment.

Executive Summary: There is no statistically significant difference in the wear of the two materials ($p > 0.10$) for any of the wear parameters. The total combined wear of the AvaDent FM material (upper + lower) measured by volume was $0.018 \pm 0.004 \text{ mm}^3$ at 300K cycles and $0.026 \pm 0.005 \text{ mm}^3$ at 600K. The corresponding numbers for Dentsply IPN were $0.019 \pm 0.005 \text{ mm}^3$ at 300K cycles and $0.028 \pm 0.008 \text{ mm}^3$ at 600K. The Dentsply IPN wear is equivalent to the wear found previously for IPN denture teeth using similar wear parameters (Coffey *et al. J Prosthet Dent* 1985 54(2):273-79). The wear rates between 300K and 600K cycles are also similar for the two materials: AvaDent FM: $0.007 \pm 0.004 \text{ mm}^3/\text{year}$; Dentsply IPN: $0.009 \pm 0.007 \text{ mm}^3/\text{year}$, assuming 300K cycles equals one year of clinical wear.

Method and Materials

Materials:

- Two different plastic materials were used: AvaDent FM and Dentsply IPN.
- The AvaDent FM material was milled to tooth shapes using CAD/CAM.
- The Dentsply IPN teeth were standard plastic denture teeth currently available.

Test Samples:

- Each test sample consisted of a second premolar and first molar in clinical alignment.
- Upper and lower samples were made using maxillary and mandibular teeth, respectively.
- The upper and lower teeth were aligned to produce the correct occlusion.
- Test samples were opposed by samples of the same material.

Wear Simulation:

Material wear was done using the University of Minnesota ART 1 wear simulator (DeLong R, Douglas WH. An artificial oral environment for testing dental materials. *IEEE Trans Biomed Eng.* 1991 Apr; 38(4):339-45), Figure 1. The simulator reproduces the motion and forces of human chewing using servo-hydraulic actuators. The closing velocity, tooth contact time, and occlusal force profile are designed to match those of human chewing. A vertical force is applied to the sample by the vertical actuator following a force profile that resembles half a sine wave, Figure 2. The applied force, which is measured by a load cell, is compared to the programmed force, and any deviations from the program are corrected through closed-loop control.

Lateral forces are normally, not monitored in the simulation. It is quite possible that the horizontal force is significantly larger than the vertical force; how large depends on cusp angles and friction. To minimize effects related to lateral forces, samples with similar anatomy and similar contact locations are recommended.

A previous study measuring friction between opposing natural teeth using several different lubricants, which included deionized water, spun saliva, and artificial saliva, found no significant differences between lubricants (Douglas WH, Sakaguchi RL, DeLong R. Frictional effects between natural teeth in an artificial mouth. *Dent Mater.* 1985 Jun;1(3):115-9). As a

result of this study, 37 °C deionized water is used as the lubricant because it is readily available in our laboratory.

Calibration of the chewing system by correlating clinical and simulated wear of a dental composite found that 300,000 simulated cycles was approximately equal to one year of clinical wear (DeLong R, Pintado MR, Douglas WH, Fok AS, Wilder AD Jr, Swift EJ Jr, Bayne SC. Wear of a dental composite in an artificial oral environment: A clinical correlation. *J Biomed Mater Res B Appl Biomater* 2012 Nov; 100(8):2297-306. Epub 2012 Sep 21). At one cycle per second, it would take nearly three and a half days to complete one year's equivalent wear. To reduce machine time, the chewing path was truncated by removing that portion of the path where the teeth were not in contact, Figure 2. This enabled a chewing rate of four cycles per second, or one day to complete one year's equivalent wear. Tooth contact parameters (force, velocity, and contact time) were not altered.

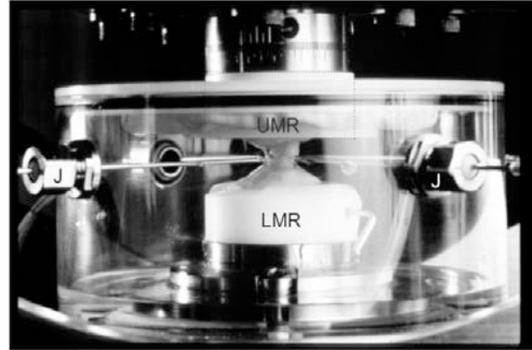


Figure 1: ART 1 Environmental Chamber. LMR – lower mounting ring. UMR – upper mounting ring (ring is outlined by the dashed line). The UMR is fixed to the load cell, which is just visible at the top of the image, and does not move. The LMR moves laterally and vertically to produce the chewing motion. J – Lubricating jets. Four adjustable jets spaced uniformly around the sample direct the lubricating media onto the samples.

- No preconditioning of the samples was done; samples were used as delivered.
- Each molar, premolar sample was placed in a mounting block for positioning in the oral simulator, Figure 3a.
- A test couple, which consisted of upper and lower sets of teeth, was mounted in ART 1, Figure 3b.
 - When mounted in the test system there was only one point of contact.
 - No occlusal adjustment was done to increase the number of contact points.

ART 1 Chewing Parameters:

- Force profile: half a sine wave
- Maximum force: 30N
- Cycle rate: 4 Hz
- Lateral slide: 1 mm
- Lubricant: Deionized water
- Temperature: 37 °C

Scanning of Test Samples:

Digital models of all samples were created at baseline, 300K cycles, and 600K cycles. With the exception of Sample 1, all samples were digitized

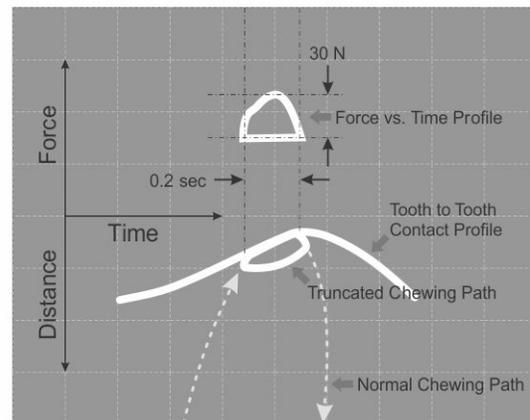


Figure 2: Cathode Ray Display of ART 1. Two profiles are displayed: force vs. time (upper profile) and distance vs. time (lower profile). The contact curve is generated by moving the lower tooth laterally against the upper tooth under a constant force.

using a custom contact profiling system, Figure 4. Sample 1 was scanned using the Lavascan non-contact digitizer. Because of the transparency of the models, it was necessary to coat the samples with a powder. The powder had a tendency to mask the small wear facets, which made it difficult to identify and quantify the wear. Therefore, the contact profiler was used for the remaining samples.

Profiler Parameters:

- Accuracy: <0.010 mm for surface angles < 55 degrees to the horizontal plane.
- Precision: <0.002 mm for surface angles < 55 degrees to the horizontal plane.
- Step Size: X: 0.100 mm; Y: 0.050 mm
 - X is the distance between profiles
 - Y is the horizontal distance between points in a surface profile

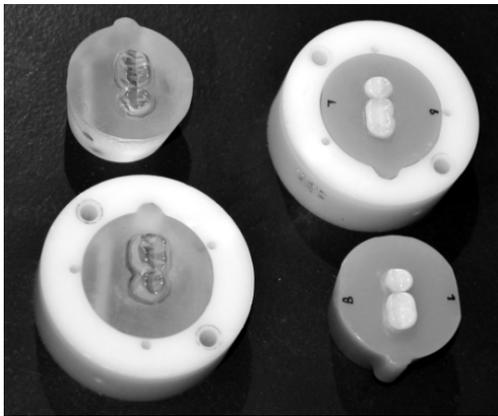


Figure 3a: Test samples with mounting rings. AvaDent FM samples are clear; Dentsply IPN samples are white.

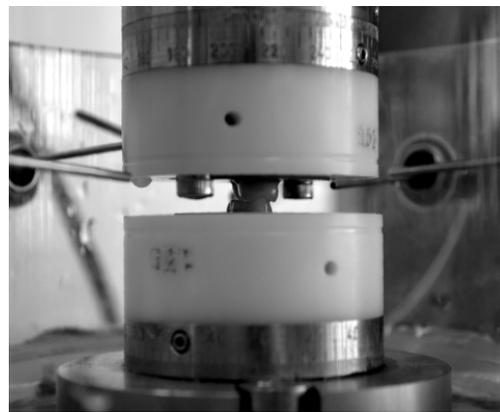


Figure 3b: Dentsply IPN teeth mounted in ART 1

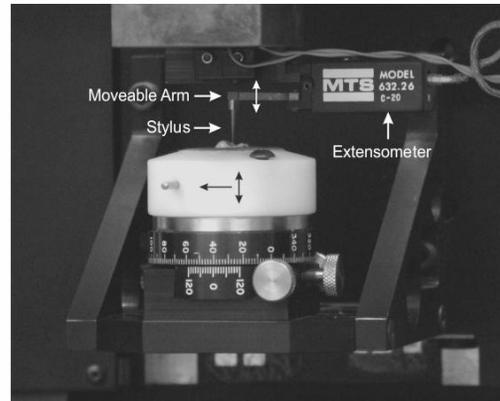
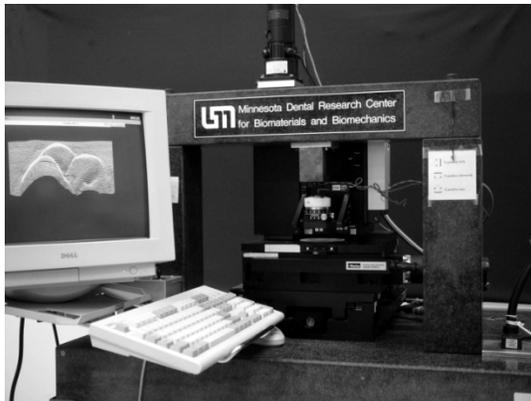


Figure 4: MDRCBB Contact Profiling System. This system uses a unique method to profile surfaces. The stylus is mounted on an extensometer, which is very sensitive to vertical movement. The stylus is brought into contact with the surface and deflected upwards a fixed amount. As the surface moves under the stylus horizontally, the stylus wants to move up or down depending on the anatomy of the surface. Closed loop circuitry moves the surface in the direction opposite to the deflection of the stylus; thus, keeping the stylus tip at the fixed offset. The vertical movement of the stylus and the surface are combined to determine the height of the surface. The final shape of the surface is corrected for the shape of the stylus tip.

Analysis:

Wear was measured using Cumulus Alpha Build V 0.8 20121023. Cumulus is a custom software program developed in the Minnesota Dental Research Center for Biomaterials and Biomechanics. The program aligns two or more digital models using an optimization algorithm to minimize the absolute distances between the points in the digital models. Regions where the models differ significantly are excluded from the alignment process. Surface changes are characterized using volume loss, maximum depth, and mean depth.

- **Volume Loss:** Calculated as the volumetric difference between the two aligned surfaces over a defined region. The region is normally defined as the area where the differences between the two surfaces are greater than the mean of the absolute differences for the aligned surfaces; see Quality of Digital Model Alignment.

Volume is the preferred parameter for comparisons because it is independent of the shape of the wear facet (DeLong R. Intra-oral Restorative Materials Wear: Rethinking the Current Approaches: How to Measure Wear. Dent Mater. 2006 22(8): 702-11). Dentistry has historically used depth to measure wear because it was the only parameter that they could measure, and it relates to vertical dimension. The problem with depth is that for the same volume of material removed you can have an infinite number of depths. Depth also depends on the direction it is measured: vertically or normal to the surface. Finally, theoretically, volume loss is linear with time whereas depth is not. Depth shows an initial rapid increase, which decreases with time.

- **Maximum Depth:** This is the maximum difference between the two surfaces within the defined wear region. It is measured normal to the unworn surface.
- **Mean Depth:** Calculated as the average of all depths within the defined region.

Statistics:

The two materials were compared using t-tests (Microsoft Excel 2010).

Results

Accuracy of Measurements (calculated from test measurements):

- **Volume:** $0.002 \pm 0.001 \text{ mm}^3$ – calculated as the average of the projected wear area times the absolute mean distance for all samples.
- **Maximum Depth and Mean Depth:** $0.005 \pm 0.001 \text{ mm}$ – calculated as the average absolute mean distance for all samples.

Two of the Densply IPN samples (3 and 5) had multiple wear facets. For these samples, the volumes of the wear facets were summed to get the total volume removed for a given sample. The maximum depth is the largest maximum depth of the wear facets in the sample. The mean depth is the weighted average of the mean depths for the multiple wear facets on the selected sample. Volume was used as the weighting factor. For all tables, volume is in cubic millimeters, depths are in millimeters, and areas are in square millimeters. Area is the projected area onto the

horizontal plane. Values for the individual samples are provided in Table 1. Average values are shown in Figure 5.

Upper and lower wear values were combined for the different parameters. This is a better representation of the wear. Volume loss was combined by adding the upper and lower volumes. The maximum depths for the upper and lower wear areas were added as were those for the mean depths. Values are provided in Table 2 and displayed in Figure 6.

Summary Results

There were no significant differences between wear parameters for the Dentsply IPN and AvaDent FM denture teeth. The lack of any significant differences is due to the large standard deviations and the small number of samples. Wear is a statistical phenomenon; therefore, one expects variation. Wear also depends on the anatomy of the samples. Small variations in anatomy can cause large variations in wear. This amount of variation is seen in all of our tests, and is not unusual. Even using flat discs with opposing spherical abraders we see a lot of variation, although the variation with flat samples is significantly less than when anatomical forms are used.

Using the combined wear data, which is the better representation of wear, the Dentsply IPN and AvaDent FM wear rates were similar, Table 3. Standard deviations were very large; therefore, there were no significant differences; however, there was a trend for lower wear rates with AvaDent FM; variation was also less.

Volume loss is the preferred parameter for measuring the wear because it does not have a strong dependence on the surface anatomy. Maximum and mean depths depend on the orientation of the measurement. Maximum depth can be influenced by outlier points in the digital models. A second issue with maximum and mean depths is that there are an infinite number of values of both for a given volume value.

A previous study done in ART 1 (Coffey et al. J Prosthet Dent 1985 54(2):273-79) using similar chewing parameters found the total wear on opposing IPN denture teeth to be 0.018 mm^3 , which is similar to the wear found in this study for the Dentsply IPN and AvaDent FM denture teeth.

Conclusions:

Under the conditions of this work:

1. There were no significant differences in the wear of the Dentsply IPN and AvaDent FM denture teeth for any of the wear parameters.
2. There were no significant differences in the wear rates of the Dentsply IPN and AvaDent FM denture teeth from 300K to 600K (first to second year wear rate).
3. There were no significant differences in the wear between the upper and lower teeth of the same material.
4. The volume loss was similar to that found in an earlier test of IPN denture teeth.

Table 1: Wear Parameters for Individual Samples								
Upper								
Sample	300K				600K			
	Volume	Depth (mm)		Area	Volume	Depth (mm)		Area
	(mm ³)	Max	Mean	(mm ²)	(mm ³)	Max	Mean	(mm ²)
Dentsply IPN								
1	0.006	0.028	0.017	0.305	0.010	0.037	0.022	0.376
2	0.010	0.064	0.027	0.318	0.016	0.073	0.032	0.442
3	0.009	0.039	0.018	0.405	0.011	0.047	0.018	0.603
4	0.003	0.035	0.012	0.385	0.005	0.036	0.014	0.370
5	-	-	-	-	-	-	-	-
AvaDent FM								
1	0.011	0.044	0.021	0.465	0.012	0.048	0.025	0.446
2	0.007	0.055	0.024	0.283	0.011	0.078	0.026	0.366
3	0.004	0.050	0.017	0.267	0.008	0.067	0.022	0.354
4	0.014	0.085	0.029	0.409	0.019	0.092	0.036	0.453
5	0.016	0.077	0.030	0.465	0.022	0.085	0.033	0.600
Statistics								
T-test comparing Dentsply IPN wear to AvaDent FM Wear								
T-test	0.25	0.11	0.20	0.64	0.30	0.06	0.19	0.96

Lower								
Sample	300K				600K			
	Volume	Depth (mm)		Area	Volume	Depth (mm)		Area
	(mm ³)	Max	Mean	(mm ²)	(mm ³)	Max	Mean	(mm ²)
Dentsply IPN								
1	0.014	0.024	0.017	0.488	0.016	0.024	0.015	0.591
2	0.020	0.075	0.034	0.491	0.034	0.106	0.042	0.689
3	0.007	0.043	0.016	0.410	0.011	0.047	0.018	0.544
4	0.006	0.041	0.018	0.286	0.008	0.041	0.018	0.375
5*	0.009	0.058	0.025	0.314	0.014	0.078	0.033	0.358
AvaDent FM								
1	0.006	0.026	0.017	0.320	0.006	0.029	0.015	0.397
2	0.008	0.052	0.020	0.371	0.011	0.056	0.021	0.453
3	0.004	0.038	0.018	0.178	0.009	0.047	0.020	0.399
4	0.012	0.070	0.030	0.348	0.016	0.068	0.031	0.437
5	0.010	0.053	0.023	0.401	0.015	0.056	0.025	0.523
Statistics								
T-test comparing Dentsply IPN wear to AvaDent FM Wear								
T-test	0.32	0.97	0.94	0.23	0.34	0.64	0.66	0.35
T-test comparing upper and lower wear of teeth of the same material								
Dentsply IPN	0.21	0.58	0.49	0.40	0.28	0.54	0.59	0.47
AvaDent FM	0.39	0.22	0.46	0.38	0.38	0.05	0.15	0.97

* The baseline data for Dentsply IPN Sample 5 was lost and could not be recovered.

Table 2: Wear Parameters for Combined Upper and Lower Wear						
	300K			600K		
	Volume	Depth (mm)		Volume	Depth (mm)	
Sample	(mm ³)	Max	Mean	(mm ³)	Max	Mean
Dentsply IPN						
1	0.020	0.052	0.034	0.026	0.061	0.037
2	0.030	0.139	0.061	0.050	0.179	0.074
3	0.016	0.082	0.034	0.022	0.094	0.035
4	0.009	0.076	0.030	0.013	0.077	0.032
5	-	-	-	-	-	-
AvaDent FM						
1	0.017	0.070	0.038	0.018	0.077	0.040
2	0.015	0.107	0.044	0.022	0.134	0.047
3	0.008	0.088	0.035	0.017	0.114	0.042
4	0.026	0.155	0.059	0.035	0.160	0.067
5	0.026	0.130	0.053	0.037	0.141	0.058
Statistics						
T-test comparing Dentsply IPN combined wear to AvaDent FM combined wear						
T-test	0.95	0.37	0.50	0.84	0.49	0.60
Areas were not included because they cannot be combined in a meaningful way.						

Table 3: Wear Rates for the Combined Wear Data			
	Volume Loss	Max Depth	Mean Depth
	mm ³ /year	mm/year	mm/year
Dentsply IPN	0.009 ± 0.007	0.016 ± 0.017	0.005 ± 0.005
AvaDent FM	0.007 ± 0.004	0.015 ± 0.011	0.005 ± 0.003

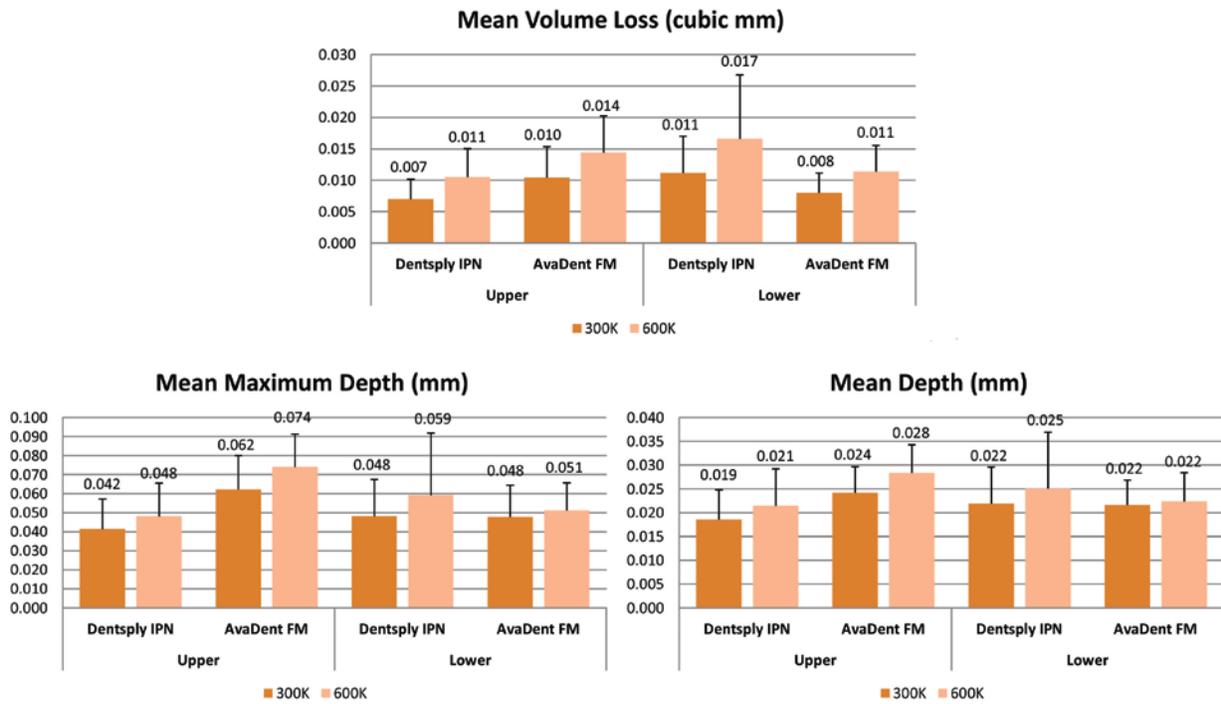


Figure 5: Average Parameter Values. There were no statistical differences between Dentsply IPN and AvaDent FM. The number of samples for Dentsply IPN and AvaDent FM were 4 and 5, respectively. The error bars represent one standard deviation.

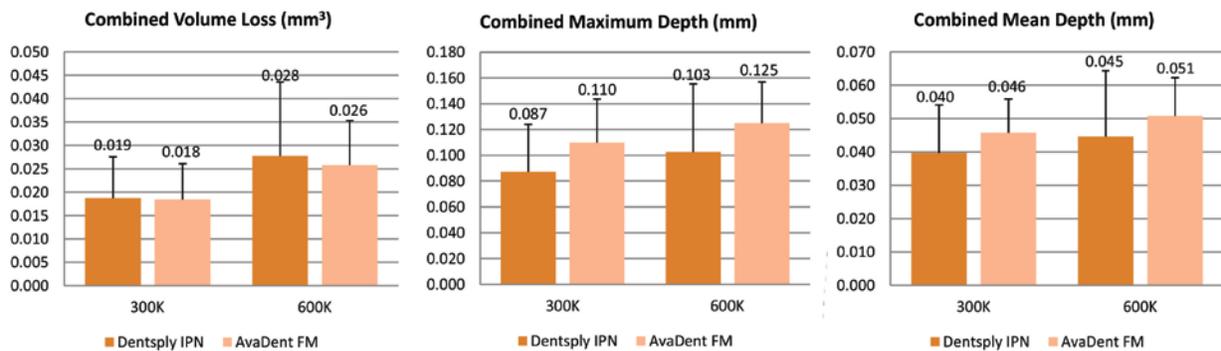


Figure 6: Combined Wear Results. Upper and lower values for a wear parameter were combined to give the total wear for the two materials. There were no statistical differences between Dentsply IPN and AvaDent FM. The number of samples for Dentsply IPN and AvaDent FM were 4 and 5, respectively. The error bars represent one standard deviation.

Appendix: Quality of Digital Model Alignment

The first samples for both the Dentsply IPN and AvaDent FM denture teeth were scanned using the LavaScan digitizer. Because of the need to spray the models with powder and the small amount of wear, which could be masked by the powder, it was decided to use the contact profiler for the remaining samples. The quality of the alignment values, which are measured by the mean absolute distances between the points on the baseline model and the 300K or 600K models, are given in Table 4 along with the statistical comparisons.

Conclusion: There is no difference in the quality of the digital model alignments.

Table 4: Mean Absolute Distance between Aligned Digital Models									
Dentsply IPN (mm)					AvaDent FM (mm)				
	Lower		Upper			Lower		Upper	
Sample	300K	600K	300K	600K	Sample	300K	600K	300K	600K
1	0.005	0.006	0.006	0.007	1	0.008	0.006	0.003	0.003
2	0.007	0.008	0.005	0.005	2	0.006	0.005	0.005	0.005
3	0.006	0.006	0.005	0.005	3	0.005	0.005	0.005	0.005
4	0.005	0.005	0.005	0.005	4	0.005	0.005	0.006	0.006
5	0.005	0.005	0.005	0.005	5	0.005	0.006	0.005	0.005
Average:	0.006				Average:	0.005			
Std Dev:	0.001				Std Dev:	0.001			
Statistics									
T-test comparing the quality of the Dentsply IPN and AvaDent FM digital model alignments at 300K and 600K									
	0.94	053	050	028					
T-test comparing the quality of Dentsply IPN and AvaDent FM digital model alignments: 0.22									

Figure 7 shows a plot of all the absolute distances between the points in the first model to the second model after the alignment. The average number of points used in the alignments was 120,000. Points were ordered from smallest to largest. The percentage of points at or below a defined distance is shown. The error bars are the largest standard deviations for the eight comparisons.

For a perfect alignment, the graph would be a straight line with an absolute mean distance of zero. Normally, however, the graph has a gradual slope with a sharply rising tail approaching 100% of the points. The tail represents outlier points in the digital models.

The accuracy of the contact profiler depends on the surface angle, which is highly variable for dental anatomy. Because the shapes of the ten curves are very consistent, and because more than 80% of the distances are less than the accuracy of the profiler (0.010 mm at 55 degrees of surface angulation), the quality of the alignments is considered excellent.

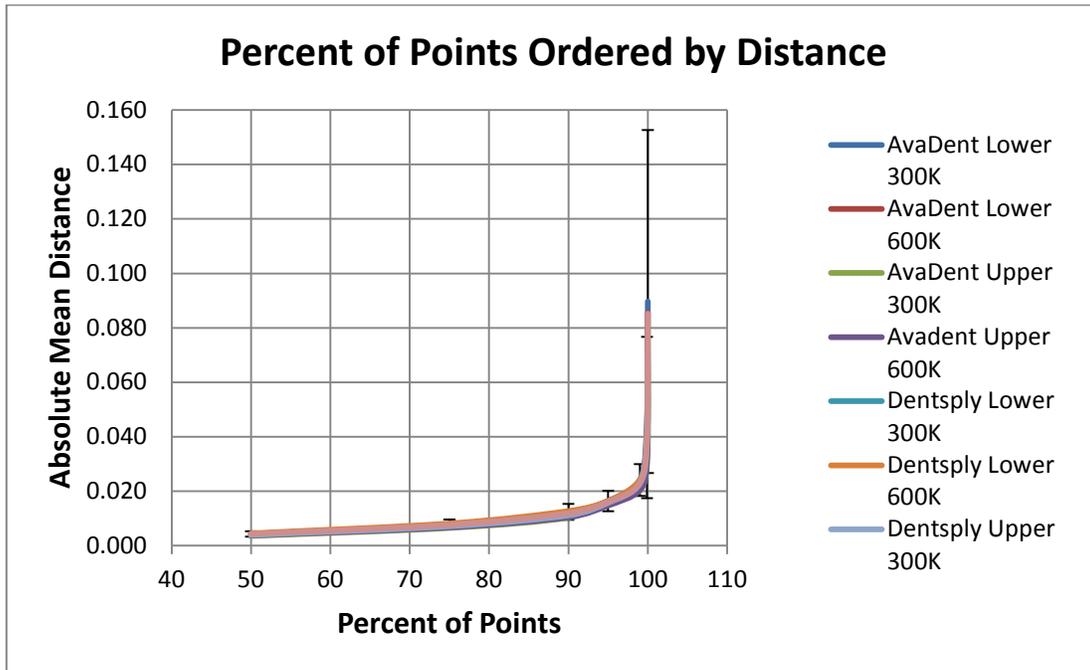


Figure 7: Quality of alignment of digital model. All alignments are to the baseline model. The error bars are the largest standard deviation of the eight comparisons for a given percentage.