

מדינת ישראל
STATE OF ISRAEL



Ministry of Health
Public Health Laboratories
Central Virology Laboratory

To : Avi Kafzan
General Manager
Fresh Cup

משרד הבריאות
המעבדות לבריאות הציבור
המעבדה המרכזית לנגיפים

Ultra Wash dental instrument cleanser
Report no. 02

Introduction:

In the first series of experiments poliovirus type 2 vaccine strain was used as a model for stable viruses like hepatitis virus B enteric viruses and adenoviruses and that according to international standards. It's clear that unstable viruses like HIV and respiratory viruses that are much more sensitive to various environmental conditions will be inactivated and removed during a similar cleaning process.

Results:

The tests were carried on according to the procedures and conditions written by the manufacture and the F.D.A demands.

Batch No.	Initial contamination pfu/ batch	Test efficiency %	Final concentration pfu/batch
1. 5 instruments	$7.2 \cdot 10^6$	88.8	<0
2. 1 instrument (dressing pliers)	$5.7 \cdot 10^6$	88.8	<0
3. 6 instruments	$1.8 \cdot 10^7$	17.6	<0

The results demonstrate a cleaning capability of more than $3 \cdot 10^6$ infective particles from the instruments tested.

Additional experiments are needed for final conclusion.

Sincerely

Yossi Manor

Environmental virology department/ director



BioScience Technology Laboratories (B.S.T) Ltd.
מעבדות טכנולוגיות מדעי החיים (ב.ס.ט.) בע"מ

TO: FreshCap system
(DEEA Technologies)
Hbrecha No 11 str.
Ramat Hasharon 47231
Israel

RE: UltraWash dental instruments cleanser.

Report 9826 - 1 / 14456

The aim of this test was to examine the efficiency of the UltraWash machine to eliminate microbial contamination and blood residual.

Six dental instruments were used in the test. 1. Spatula 2. Dental mirror
3. Explorer 4. Elevator 5. Forceps 6. Cotton & Dressing Plier.

Contaminating microorganisms were.

E.Coli (ATCC-8739), *Streptococcus faecalis* (ATCC-29212), *Staphylococcus Aureus* (ATCC-6538), *Pseudomonas aeruginosa* (ATCC-9027) [bacteria],
Candida albicans [Yeast] (ATCC-10231).

Each microorganism was cultivated in special selective media two days before the examination. On the day of examination suspension from each organism was prepared after which a mixture from the above organisms was made containing approx. 10^7 - 10^8 organisms per ml. together with Sheep Red Blood Cells (SRBC).

Test procedure :

Each instrument was immersed in Beaker containing the microorganisms mixture together with SRBC to mimic human blood after dental treatment. The contaminated instruments with microorganisms and SRBC were left to air dry for at least 45 min., after which with the aid of sterile swab a smear sample from the contaminated area, was taken. this is the - Before wash sample.

The contaminated instruments were put into UltraWash Regular tray, and washed. Wash procedure was: Normal cycle ** with Long Delay & Regular detergent, with improved nozzle - USA type.

At the end of wash procedure a smear sample was taken from the contaminated area. This is the - After wash sample.

** Normal cycle = water at 90 C°.



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-2-

Results:

** cfu = Colony Forming Unit

Air dried	<u>US type nozzle</u>			
	<u>Normal cycle</u>		<u>Long delay</u>	
	<u>Regular detergent &</u>		<u>Regular tray</u>	
	<u>Before wash</u>		<u>After wash</u>	
<u>Instrument</u>	<u>Bacteria</u>	<u>Yeast</u>	<u>Bacteria</u>	<u>Yeast</u>
	<u>cfu **</u>	<u>cfu</u>	<u>cfu</u>	<u>cfu</u>
Spatula	91 x10 ⁶	5x10 ⁶	0	0
Dental mirror	94x10 ⁶	4.6x10 ⁶	0	0
Explorer	58x10 ⁶	2.7x10 ⁶	0	0
Elevator	77 x10 ⁶	3x10 ⁶	0	0
Forceps	120 x10 ⁶	7x10 ⁶	0	0
Cotton&Dressing Plier	84x10 ⁶	37x10 ⁶	0	0

The instruments were clean from SRBC and free from infected microorganisms.

Rami Tannenbaum

B.S.T Lab.

TEL AVIV UNIVERSITY תל אביב יפו
THE MAURICE AND GABRIELA GOLDSCHLEGER SCHOOL OF DENTAL MEDICINE

Founded by Alpha Omega International Dental Fraternity

Department of Oral Rehabilitation

Ramat Aviv 69973, Israel

Fax: 972-3-6409250

The Effect UltraWash on the Dimensional Changes of Heat-cured Acrylic Resin.
(Interim report)

Israel Lewinstein DMD PhD

Introduction

Disinfecting of dental prostheses before insertion and after removal from the mouth is demanded in the dental office. Ultrawash () is one of the new products which are supposed to have the ability of disinfecting (reducing the number of microorganisms) of dental hand tools and prostheses.

In the washing cycle the prostheses are washed with tub and hot (about 80° C) water. The aim of this study was to investigate the dimensional changes of samples made of heat cured acrylic resin, after washing cycles in the Ultrawash machine.

Material and Methods

"V" shaped specimens (Fig 1) of Vertex Heat-cured resin (Dentimex, Zeist, Holland) were prepared in a specially designed split mold built in a brass flask. The resin was mixed with a powder-to-liquid volume ratio of 3:1. After the material was packed the flask was placed in boiling water according to the manufacturer's recommendations. After deflasking was performed the samples were stored in water at 23° C for one week.

The sample was then wiped and placed in a traveling microscope for measurements.

The distance "L" and the angel "θ" between the arms of the V shape specimen (Fig.1)

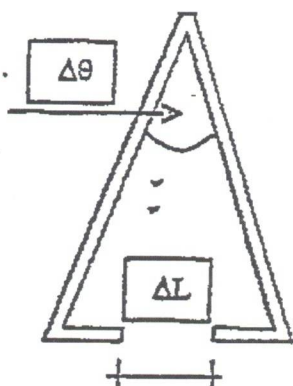


Fig.1 A schematic illustration of the "V" shape spacemen

Were measured 3 times for each parameter. The sample was placed in the Ultrawash for 2 long cycles (total time 8 minutes). The sample was aloud to cool to room temperature for 10 minutes and new measurements of "a" and "θ" were conducted.

The differences between the measurements before and after the cycles were calculated. The data were subjected to "t" test at 95% level of confidence.

Results

The results are summarized in table 1. The mean difference of the $\Delta\theta$ and ΔL are before and after the Ultrawash treatment, respectively.

Table 1: Angular and dimensional changes of acrylic resin

Units	Degree		mm	
Sample	angel B	angel A	Length B	Length A
1	27.000	27.667	13.253	13.369
2	26.766	27.070	13.820	13.766
3	29.367	29.567	14.635	14.882
Average			0.390	0.139
Degree			23'	

Discussion and conclusion

The geometry of the "v" shape specimen makes it very sensitive for detection of any dimensional or angular changes. These types of specimens have to be much more sensitive to changes and distortions than removal dentures.

The small dimensional and angular changes found in our study are in the order of the measuring accuracy. The results indicate that the Ultrawash treatment has no effect on the dimension and angulation of the tested samples. Therefore, it might be concluded that the Ultrawash treatment has no effect on removal dentures made of acrylic resin.

TEL-AVIV UNIVERSITY
The Maurice and Gabriela Goldschleger
School of Dental Medicine
Department of Prosthodontics
Ramat Aviv 69978, Israel
Fax: 972-3-6409250

Study Report

28 May 2000

**Effect of Ultrawash treatment on dimensional accuracy of
impression materials**

This study was conducted by:

I. Lewinstein DMD PhD, O. Baddash DMD and Y. Ganor DMD

The entire dental staff is routinely exposed to pathogens that have the potential to cause serious illness. Contamination of dental impressions with varying amounts of blood and saliva is a routine occurrence in the dental operator¹. Because of the increasing number of infected patients, the dental profession has become acutely aware and concerned that impressions have a potential source of infectious diseases². Ultrawash is a disinfectant washing machine, based on washing cycles of cold, hot acidic and basic solutions.

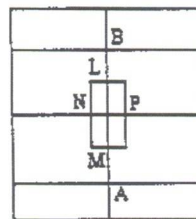
The purpose of our investigation was to study the effect of Ultrawash treatment on the linear dimensions of two impression materials.

MATERIALS AND METHODS

A stainless steel master model and a base were fabricated to simulate a single tooth with a sulcus, prepared for a crown. The model and the base were grooved with lines creating reference distances between points: AB, NP, LM (Fig.1).

Fig 1: Overview on the master model

Overview on the Master Model



Custom-made trays made of acrylic resin were prepared. Special care was taken to obtain an acrylic resin thickness of 3mm. The tested materials were: "President" (addition silicone Polyvinyl siloxane-type, Coltene) and "Blueprint alginate" (irreversible hydro-colloid, Dentsply). Trays for elastomeric impression materials had 2mm of relief whereas 6 mm of relief was provided for tray to be used with irreversible hydrocolloid material.

a) Impressions with elastomeric polyvinylsiloxane (President):

Six impressions were taken with a patty/wash (two-stage) technique. The model was covered with a Polyethylene spacer sheet. The tray was filled with a putty material and then was seated on the model. After setting the tray was removed and a light body was injected to fill the initial putty impression. The tray was then resealed directly on the model for the final impression. After 5 minutes, completing the setting time, the

tray was removed. The impression was then placed in the Ultrawash machine and a (long) cycle of 4 minutes was applied. The linear dimensions of the final impression were measured using a travelling microscope under x10 magnification, 30 minutes after mixing. Each impression was measured three times for each reference distance and an average reading was obtained.

Six additional impressions were taken and measured with the same technique and time intervals but with no Ultrawash treatment.

b) Impressions with Alginate (Blueprint)

The material was mixed according to the manufacturer's instruction and placed with a custom tray on the master model. The alginate was allowed to set for 4 minutes after placement. The impression was then placed in the Ultrawash machine and a long cycle was applied. The linear dimensions of the final impression were measured using a travelling microscope under x10 magnification 60 minutes after mixing. Six additional impressions were taken and measured with the same technique and time intervals but with no Ultrawash treatment.

RESULTS

The results are summarized in Tables 1,2 and illustrated in figures 2,3.

Time	Ultrawash	Time	Ultrawash	Time	Ultrawash
ΔAB	ΔAB	ΔNP	ΔNP	ΔLM	ΔLM
0.013	-0.121	0.006	0.037	-0.005	-0.026
-0.017	-0.015	-0.017	0.038	-0.019	0.01
0.01	-0.029	-0.008	0.008	0.007	-0.001
0.016	-0.006	-0.035	0.01	-0.015	-0.02
-0.001	0.012	0.005	0.002	0.012	-0.004
-0.005	-0.01	0.023	0.001	0.012	-0.031
Mean Δ	0.003	-0.004	0.016	-0.001	-0.012

Table 1: Differences between reference dimensions as function of time

elapse and Ultrawash treatment for "President".

	Time	Ultrawash	Time	Ultrawash	Time	Ultrawash
	D AB	D AB	D NP	D NP	D LM	D LM
	-0.047	0.124	0.023	-0.113	-0.128	-0.041
	0.051	0.048	0.026	-0.03	-0.029	-0.026
	0.046	0.073	-0.123	-0.124	-0.043	-0.09
	-0.051	0.23	0.003	-0.046	-0.042	0.015
	0.078	0.051	0.148	-0.11	-0.1	-0.057
	0.021	0.02	-0.04	-0.046	-0.096	-0.031
Mean Δ	0.016	0.091	0.006	-0.078	-0.073	-0.038

Table 2 : Differences between reference dimensions as function of time elapse and Ultrawash treatment for "Blueprint".

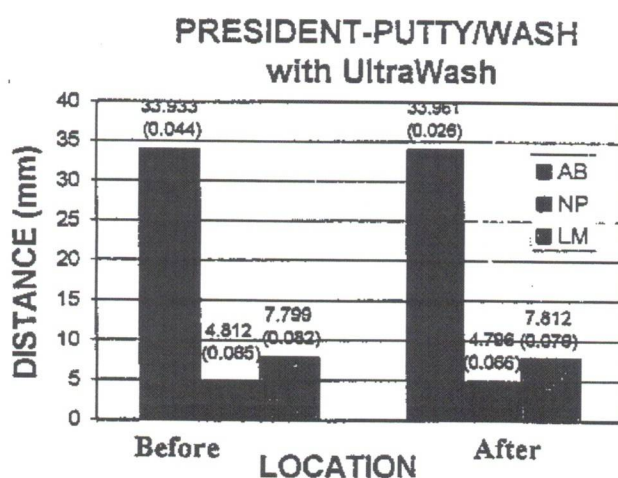


Figure 2. Means and standard deviations of reference distances in "president" impression material.

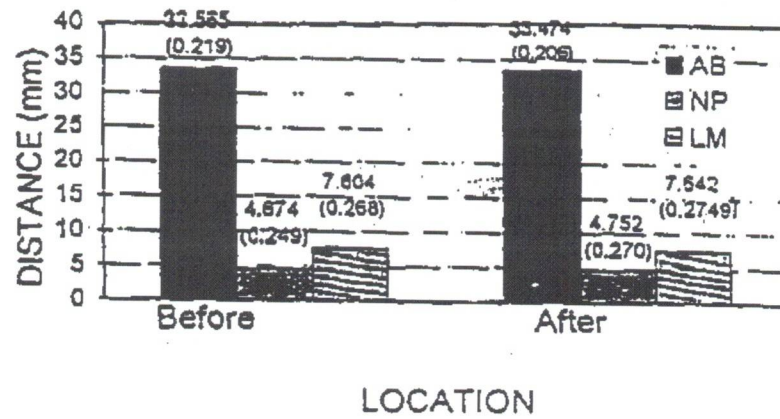


Figure 3. Means and standard deviations of reference distances in "Blueprint" impression material

CONCLUSIONS

- Ultrawash treatment has a minor effect on the dimensional changes of "President" impressions.
- Ultrawash treatment has a mixed effect on the dimensional changes of "Alginate" impressions, however it seems that this changes are clinical accepted.
- Sixty minutes of storage has the same order of dimensional changes as for Ultrawash treatment.
- In regard to dimensional changes, Ultrawash is an effective tool for washing impressions.

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- Matyas ASD, Caputo AA, Lucatorto FM. Effect of disinfectants on dimensional accuracy of impression materials. *J Prosthet Dent* 1990;64:25-31.