

The World's First and Only ...



Pure Silver Argentum

ZERO FREE MERCURY AMALGAM



SILVERFIL PRODUCT RANGE







ZERO FREE MERCURY AMALGAM





Jars of 250 Capsules 1, 2 or 3 Spill













Stop By for a Demo Booth #4048

www.silverfilusa.com







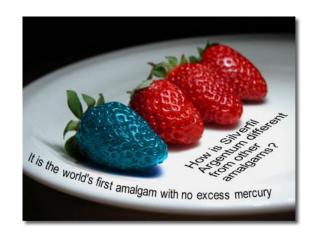
ADA 2015

Washington DC Silverfil USA booth

Prof. Masudi Emerging Techniques

> Microleakage open Sandwich Restoration







Silverfil does not contain ANY unreacted or excess mercury!

- ☐ Non-Toxic
- ☐ \$\$ Savings- No Special Storage Required.
- No Environmental Contamination
- **☐** Eliminates moisture issues
- □ Contains Free Silver Anti microbial properties
- ☐ \$\$ Savings- No Amalgam Waste Disposal Cost
- ☐ Superior Marginal Seal
- Mixes completely in only 5 seconds!

History of Dental Amalgams

SILVERFIL

- Has been used for more than 150 years.
- Presence of Excess Mercury in the fillings. Why?
- Awareness and Concern over the last 20-30 years.



Mercury Concerns :

Problem of Excess Mercury in Fillings

The American Dental Association and the US FDA have long acknowledged that excess mercury in the fillings can be released as vapour and can be absorbed into the body system.

Release of mercury vapour can occur during removal of old amalgams.

The Solution!

- ✓ Silverfil Argentum does not have any unreacted or excess mercury in the fillings.
- √ Thus, no mercury is available to be released when Silverfil Argentum fillings are removed.

No Excess Mercury

✓ Tests have confirmed that there is no unreacted or Excess Mercury in Silverfil Argentum fillings.



- Metallographic Study and
- X-ray Mapping.



- Absorption Spectroscopy.
- X ray diffraction study.

(At the Institute of Advanced Sciences, University Malaya, Dental Faculty, University Malaya)

FDA Admission on Risk from Mercury in Dental Amalgams

June 5, 2008 -- Mercury from amalgam dental fillings may be toxic to children and developing fetuses, the FDA now admits.

On its web site, the FDA has dropped much of its reassuring language about dental amalgam. And it has added what amounts to a warning: "Dental amalgams contain mercury, which may have neurotoxic effects on the nervous systems of developing children and fetuses."

The changes comes in response to a lawsuit filed by consumer groups and individuals concerned about mercury exposure. To settle the suit, the FDA agreed to update its web site.

The Solution!

- ☐ Genotoxicity studies on `Silverfil amalgams' was conducted by Universiti Sains Malaysia in 2006.
- ☐ The studies have proven that there was no evidence of genotoxicity in Silverfil Argentum.
- ☐ This study was published in the Indonesian Dental Journal in 2010 & in the Int. Medical Journal in Aug. 2013.

Current Position taken by FDA

- For the first time in 150 years, FDA has now reserved it's unanimous support on the safety of amalgams with regards to excess mercury.
- In 2009, FDA introduced new rules & guidelines pertaining to amalgams.

Health Concerns :

In the United Kingdom

The dept. of health in U.K. way back in 1998, advised dentists to avoid using amalgams in pregnant patients and that a temporary filling be placed instead.

They could later replace them with amalgams after the pregnancy is over.

Solution:

Silverfil amalgams do not have any evidence of genotoxicity.

FDI Policy Statement on Amalgams:



FDI POLICY STATEMENT

Safety of Dental Amalgam

Adopted by the FDI General Assembly: 26th October 2007, Dubai

"alternatives to amalgam may have adverse effects"

The Continued Use of Dental Amalgams



The FDI & ADA continue to endorse the use of amalgams `quite simply because we haven't yet invented anything which does the job better'. (FDI News May/June 1991, No. 177)





Composites are technique sensitive, have low wear resistance, and are not cost effective.

Newsweek (Feb. 11, 2008) - `The Chemicals Within' (Pg. 35)

BPA – Bisphenol A - a plastic strengthener, used in Dental Composites.

In animal studies and human cell cultures, they mimic hormones with effects even at parts per billion.

Newseek Article:

Chemicals Used in Dental Sealants



Feb 11, 2008 Edition

PROJECT GREEN

The Chemicals Within

Many common household products contain compounds that could be affecting our health.

grandfathered in without scrutiny. These include the three classes of compounds targeted in "Is It in Us?"—a plastic strengthener called bisphenol A (BPA), brominated flame retardants known as PBDEs and plastic softeners called phthalates. The chemical industry says these compounds have been used safely for decades, and certainly they do not have the overtly toxic properties of mercury or lead. But in ani-

Take bisphenol A. It's a basic constituent of the polycarbonate plastics found in many baby bottles, sippy cups and juice bottles. A highly versatile compound, it is also found in dental sealants, CDs, DVDs and the resin linings of food and beverage containers, including many cans and takeout cartons. But

A recent study published in the **Journal of the American Academy of Pediatrics**, July 2012 has raised the awareness and concern about the release and exposure of Bisphenol A (BPA) from composite filling materials and dental sealants that are routinely being used and applied to children's teeth.



The problem with BPA is that as a chemical it mimics the action of estrogen within the human body.

Science News reported: "[the] study finds that children who have their cavities filled with a white composite resin known as bis-GMA appear to develop small but quantifiable drops in psychosocial function. To put it simply:

Treated kids can become more moody, aggressive and generally less well adjusted."1

Bisphenol A (BPA) is a chemical that is used in the manufacture of thousands of plastics and plastic products and is found in both the bis-GMA and bis-DMA that these composite dental materials are made from. Thus is capable of disrupting the proper balance and function of the hormonal system as well as interfering with the neurological and immune systems.

Safety Concerns :

Removal of old amalgams

- The ADA and FDI caution dentists against removal of several fillings at one sitting due to possibility of mercury vapor release.
- Use of high suction is recommended.

Solution!

Removal of Silverfil Argentum fillings will not be a cause for concern as there is no excess mercury to be released.

Mercury can only be released if it is available in a free form.

Safety Measures Recommended by the FDI and ADA

Patient Safety:

SILVERFIL

Use of high suction when drilling out old fillings. Preferably not more than one filling at each sitting.



Safety Measures Recommended by the FDI and ADA For Waste Amalgam.



Storage in sulphite solution is recommended.



Fitting of separators/filters to dental spittoons.



Disposal: Regarded as `Scheduled Waste'.

Must be managed by a waste management company. Recycling or recovery involves the use of strong chemicals.



Easy Storage of Silverfil Waste Amalgam:

Silverfil Argentum waste amalgam can be stored in any dry container, no need for any special storage measures.



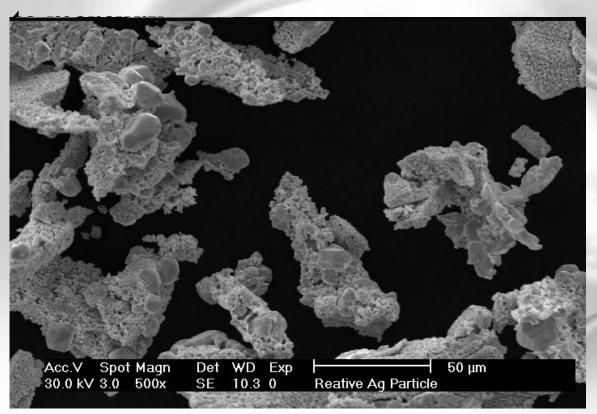
Comparison Between Silverfil Argentum and Conventional Amalgams

Silverfil Argentum

Conventional Amalgams

Silverfil Argentum is produced through a chemical process, making the silver particles very highly reactive to mercury.	Traditional amalgams are produced through a molten process. Silver is alloyed with other metals and it is not highly reactive to mercury.
The chemical reaction of Silverfil powder and mercury is completed within 30 minutes after mixing.	The reaction is said to continue for weeks if not months.
The rapid reaction with mercury produces a short crystallization time, which tremendously reduces expansion.	Tin is used as an agent to control the expansion caused by silver.
There is a percentage (6-9%) of free silver still present within the amalgam. This further infers that there is in fact insufficient mercury to react with all of the silver used.	Free silver is not available as the metals (in the unreacted particles) are in an alloy form.
Very resistant to corrosion because it has only the noble or gamma 1 phase which has been proven in dentistry to be the most resistant phase in amalgams.	Reduced corrosion as there is still tin & copper.

Component 1: Chemically processed silver particles (Ag) that are highly reactive

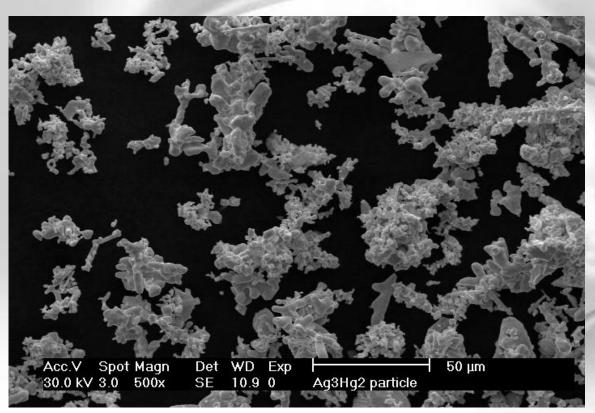


Microscopic appearance of reactive silver particles.

Sponge-Like and Porous appearance of the particles.

Chemical Composition of Silverfil Argentum

Component 2: A partially amalgamated silver-mercury (Ag3Hg2) powder.



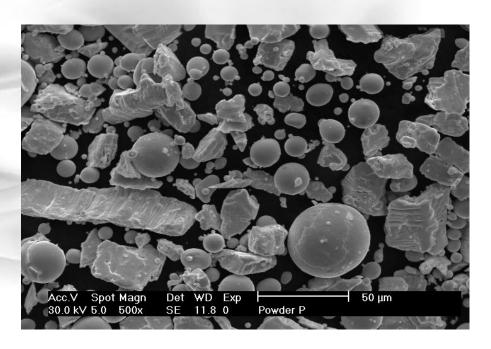
Microscopic appearance of Ag₃Hg₂ particles.

The material appears less porous.

Comparison of Microscopic Structures



Microscopic view of Silverfil Argentum powder.
Again, sponge-like porous characteristics



Microscopic appearance of a traditional Disperse Phase Alloy (Non gamma 2). A mixture of lathe-cut and spherical particles.

Lab Tests: Reaction Time of Silverfil Argentum Powder With Mercury

• Studies have shown that the diffusion rate of mercury to Silverfil Argentum powder is 7.09 x 10-9 m2 s-1.

Such a rapid rate of diffusion of mercury to powder does not exist in traditional amalgams.

 Due to this high coefficient of diffusion, the amalgamation can be achieved within a very short time.

Mixing Times:

1 spill & 2 spill capsules - 5 seconds

3 spill capsules - 7 seconds

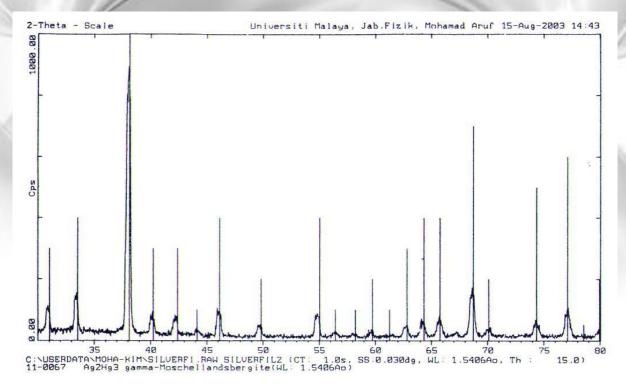
Lab Tests: Chemical Reaction of Silverfil Argentum

$$(Ag + 2Ag3Hg2) + 5Hg = 3Ag2Hg3 + Ag (Free Silver – about 6-9%)$$

X-ray diffraction studies were done on Silverfil Argentum. At the end of 30 minutes, it was found that all the material had been converted into amalgam. This infers that the chemical reaction is completed within 30 minutes.

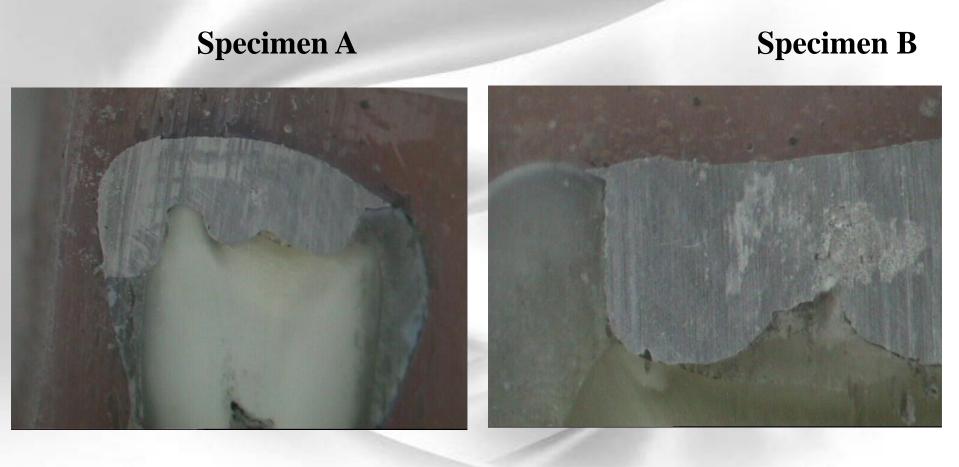
In Silver-tin-copper amalgams, the chemical reaction is said to continue for several weeks

to months.



Silverfil Argentum has been tested according to ISO 10993 at the Institute for Medical Research Kuala Lumpur.

- Primary Skin Irritation
- Skin Sensitization
- Cytotoxicity



Cross sectional view of Silverfil filling (after exposure to gentian violet dye over a period of seven days).

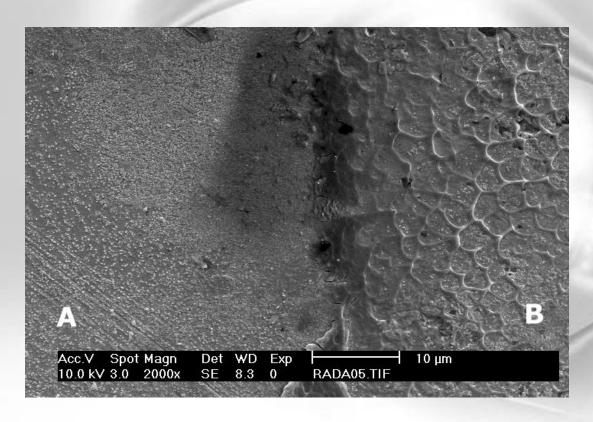
Tests conducted on specimens (8mm x 4mm)

- Compressive Strength = Average of > 50 MPa (after 1 hour).
- Dimensional Change = +0.72 (after 1 hour).
- Creep = < 1 %
- Diametral Tensile Strength = 72.71 MPa +/- 10.23 (GS-80 = 39.32+/- 7.79 & Disperse Phase Alloy= 41.66 +/- 7.78)

(Tests were conducted at Dental Faculty, University Malaya)

Lab Tests: Silverfil Argentum Fillings Can Be Work-Hardened

• Laboratory tests conducted over 24 hours using the Rolling Ball Technique showed that Silverfil Argentum can be work hardened. The Vickers Hardness increases by about 2 times in 24 hours.



- A Surface of the amalgam before work hardening. Average Vickers Hardness is 53.
- B Appearance of surface after work hardening for 24 hrs. Average Vickers Hardness is 106.

 Silverfil was used as a retrograde filling after apicectomy and was found to show good sealing ability

 This Study was presented by USM as a poster presentation at the World Endodontic Conference, Vancouver, Canada 2006 as well as the APDC in Bangkok 2008 X-ray diffraction studies have shown that this Silverfil amalgam is similar to a mineral that exists in nature found in the region of `Moschelle', district of `Landsberg' in Germany.

This mineral is identified as `Moschellandsbergite'.

Thus, Silverfil waste amalgam is considered environmentally friendly.

Presence of 'Free' Silver

- Silverfil contains 6-9% of free silver within the completed filling.
- Anti-bacterial and Anti-Microbial studies conducted at Universiti Sains Malaysia showed that Silverfil amalgam has more antibacterial properties when compared with other amalgams, composites as well as glass ionomers.

Smooth Pluggers recommended.

Use of smooth pluggers recommended for condensing Silverfil amalgam



Appearance of freshly condensed Silverfil amalgam using a serrated plugger.



Appearance of freshly condensed Silverfil amalgam using a smooth plugger.

The technique for using Silverfil Argentum is similar to conventional amalgams.

- Burnishing with Silverfil Argentum is recommended as there is no excess mercury.
- The post-treatment instructions for Silverfil Argentum is the same as for conventional amalgams.



Silverfil amalgam can be polished after 24 hours with just silicone rubber with water.

The SAFE alloy alternative to traditional amalgams









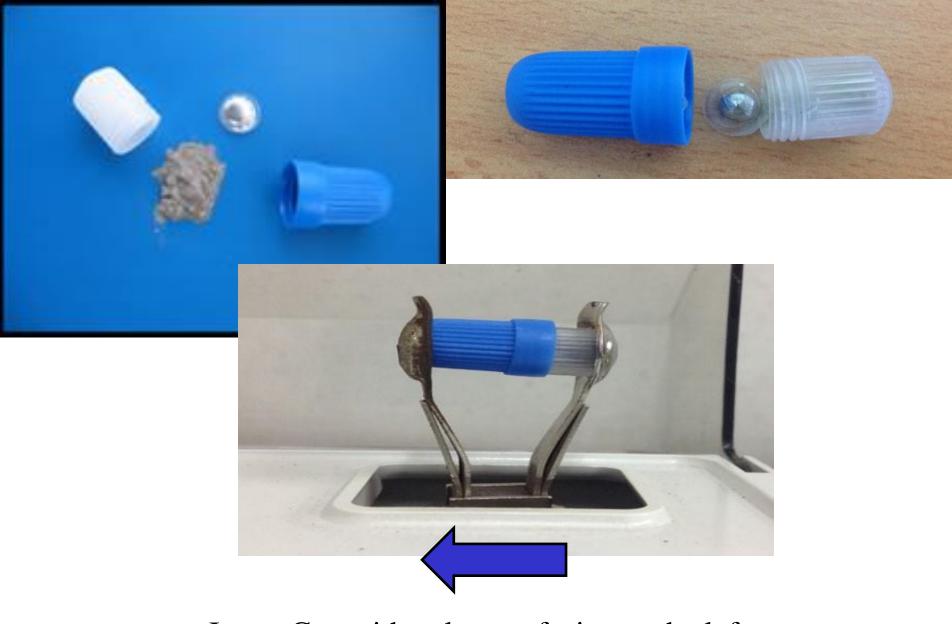


Available in containers of 250 self activating capsules.

MERCURY SEALED WITH-IN PLASTIC POUCHES



NO MERCURY EXPOSURE TO ASSISTANT, DR OR PATIENT



Insert Cap with color top facing to the left As shown above



Medium energy. D-650



Medium energy



Medium energy. SDI



Medium energy. TAC- 400M





Easy to use

Three pre-timed buttons

LOW VIBRATION

The Silverfil **automat** is designed to operate at low speed to ensure quite mixing with minimum vibration and reduce/eliminate heat formation.

EASY TO CLEAN

The one surface cover facilitates infection control cleaning and the non-porous plastic surface can be cleaned with any dental disinfectant.

SAFETY FEATURE

The micro-switch automatically halts trituration when the lid of the **automat** is lifted.

VERSATILE

The multi-use **automat** is suitable for all types of encapsulated dental materials.

For additional information visit <u>silverfilusa.com</u> Or email: <u>info@silverfilusa.com</u>

Silverfil USA, Inc.

automat

Low Speed Amalgamator





Characterization and Development of Biosystems and Biomaterials



Structural and Compositional Characterization of Silverfil Amalgam

Chanthiriga Ramasindarum, Vengadaesvaran Balakrishnan, Noor Hayaty Abu Kasim and Mohd Ambar Yarmo

Springer: Advanced Structured Materials

Characterization and Development of Biosystems and Biomaterials

Editors: Öchsner, Andreas, da Silva, Lucas F. M., Altenbach, Holm (Eds.)

Page(s): 153 - 166

Microleakage in Open-Sandwich Class II Dental Restorations

Sam'an Malik. Masudi, DDS, MS

Assoc. Prof. in Restorative Dentistry, School of Dental Sciences, Universiti Sains Malaysia (USM)

The integrity and durability of the marginal seal has always been of prime concern...... to overcome the inherent composites disadvantages such as the polymerisation shrinkage......

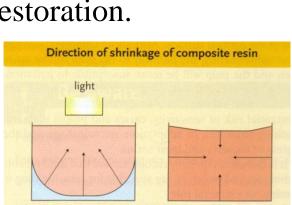
and the weaker adhesion at the composite-dentin interfaces

- -The step-by-step incremental technique,
- -transparent matrices,
- -reflecting wedges and
- -improved adhesive systems

..... solved only partially these problems.

CLSM images of dentin area in longitudinal section

Showing Microleakage with Rhodamine B dye in interface with restoration.

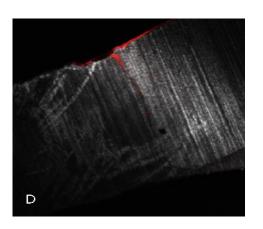


autocured

C-Factor

Factors that influence stress formation include volumetric polymerization shrinkage; elastic modulus and flow of the resin composite:

light activated



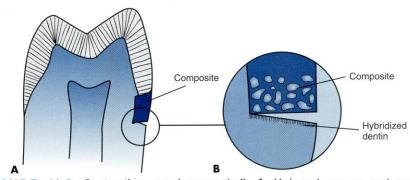
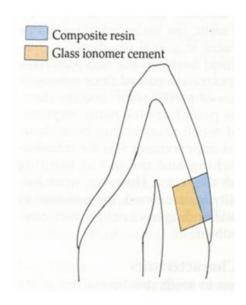
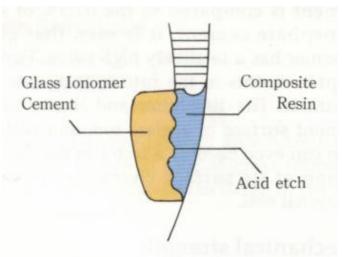
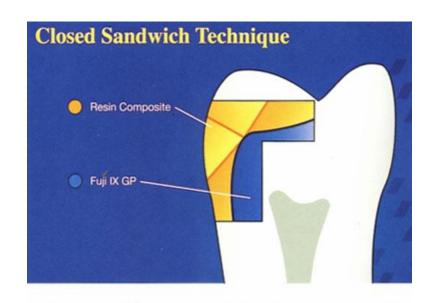
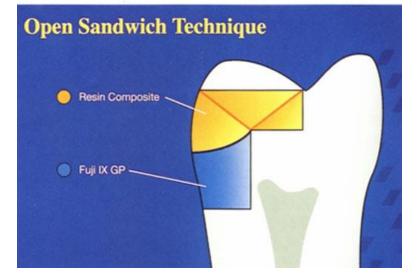


FIGURE 12-2 Contraction gap (exaggerated). A, V-shaped gap on root surface. B, Restoration-side vector is composite; root-side vector is hybridized dentin.

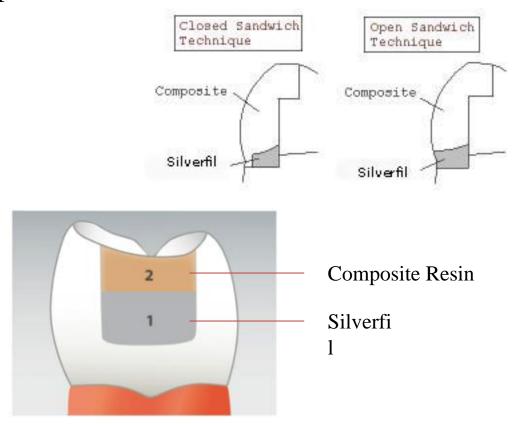




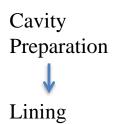


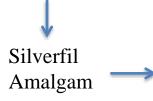


The new SilverFil-CR open-sandwich technique was proposed



Silverfil Amalgam provides a fracture toughness almost double that of a conventional composite. This makes SilverFil Amalgam the strongest possible sub-structure to reinforce any composite restoration in large preparations.









Amalgam Bonding







Why SilverFil Amalgam??

Microleakage Study.....

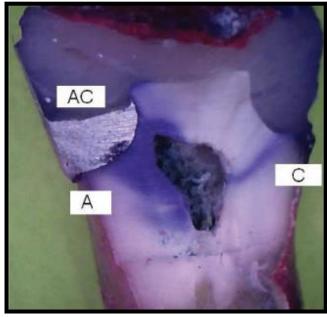


Figure shows the tooth-material interface at longitudinal view

A : Amalgam-tooth

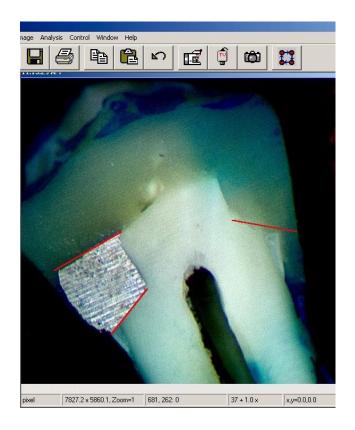
Interface,

AC : Amalgam-composite

Interface,

C : Composite-tooth

Interface



mean gap widths and SD (µm) obtained from each experimental group between dentin and the materials tested

Group	Mean gap width (μm)
1. SilverFil® with Panavia F amalgam bonding + CR	4.6 ± 2.2*
2. Ketac N100 nanoionomer RMGI + CR	5.2 ± 2.7*
3. Conventional Fuji II™ GIC+ CR	20.6 ± 6.9
4. Full CR Filtek Z350 XT	$3.8 \pm 2.1^*$

* Indicate no significant difference (p>0.05).

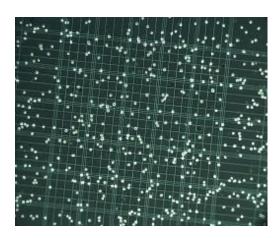
Mann-Whitney and Kruskal-Wallis Tests.

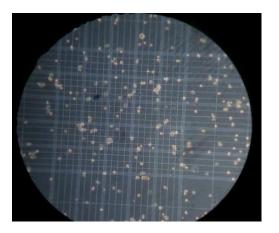
CR= Composite Resin; GIC= Glass Ionomer Cement; RM GIC= Resin Modified Glass Ionomer

Cytotoxicity Study using SHEDs

Cells culture preparation

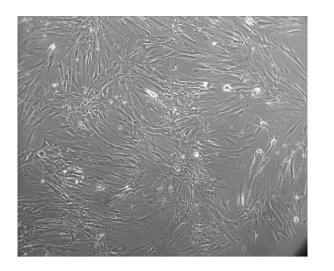
•In this study, stem cells of human exfoliated deciduous teeth [SHEDs] were cultured in Alpha Modification of Eagle's Medium supplemented with 20% Fetal Bovine Serum (FBS), 100 μM L-ascorbic acid 2-phosphate, 2 mM L-glutamine, 100 U/ml penicillin and 100 μg/ml streptomycin. The culture was incubated at 37°C in 5% CO2. The SHEDs between 3rd and 5th passages was used in this study.

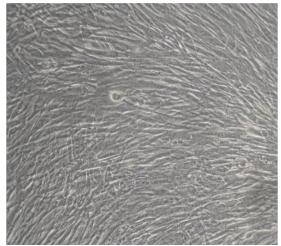




SHEDs under Light Microscope

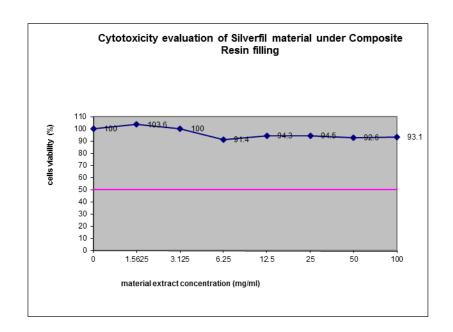
The SHEDs between 3rd and 5th passages was used in this study





In this test, material was extracted in the complete culture medium (100mg/ml) and introduced to the stem cells of human exfoliated deciduous teeth [SHEDs]. Cells viability was measured by using 3-(4,5-demethylthiazol-2-yl)-5- (3-carboxymethoxy phenyl)-2-(4-sulphonyl)-2H tetrazolium (MTT) assay and ELIZA reader was used to measure metabolic activity of the cells.

This result ,similar to the cytotoxicity evaluation of Silverfil Amalgam material under Composite Resin filling showed that Silverfil was not toxic to the cells. The result showed that Silverfil material did not cause a significant decrease in MRC-5 cell viability (Graph). IC_{50} was not observed even at the highest concentration (100 mg/ml).



The graph showed no 50% inhibition colony at the highest concentration of 100mg.

In Vivo Study using Male Swiss Webster Strain Mice



The specimens and control were implanted with pliers in the subcutaneous abdomen area of mice



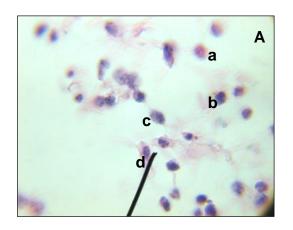
After sacrifice of mice, laparatomy treatment were done at the area of implanted specimen

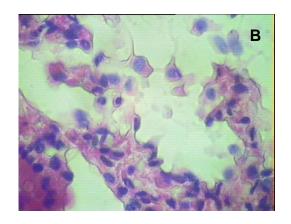


Properly identified tissue blocks were taken for histological specimens

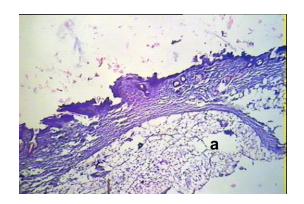
Mean Percentage of Inflammatory Cells

		Mean Persentage of Cells*						
	Total	PMN						
Observation Time	Sample	Neutrophil	Basophil	Eosinophil	Limphocyte	Macrophag	Mast Cell	Plasma Cell
Control	4	17,65	9,15	6,25	53,44	11,21	1,04	1,25
1 st day	4	34,51	4,57	8,1	44,19	15,34	1,25	2,04
1 st week	4	11,52	4,03	6,05	54,68	15,76	6,2	1,76
2 nd week	4	16,68	9,28	7,84	55,48	7,89	2,83	0
3 rd week	4	14,93	8,08	8,24	52,67	8,13	1,36	0,78
4 th week	4	10,47	5,27	5,06	40,73	7,72	0,74	0,61
Mean		20,46 ± 12,87	$7,90 \pm 5,22$	$7,59 \pm 6,55$	50,20 ± 13,59	$9,68 \pm 6,67$	2,80± 4,30	1,37 ± 1,99



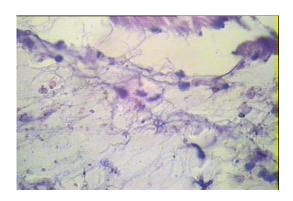


Inflammatory cells at subcutaneous area after Silverfil implantation
A. First day of evaluation at 1,000x magnification. Eosinophil (a);
Basophil (b); Neutrophil (c) and Lymphocyte (d)
B. First week of evaluation at 400x of magnification showed increases of Lymphocytes and decreases of inflammatory cells



Subcutaneous area on second week of evaluation at 400x of magnification.

No inflammatory cells detected at area of implantation (a)



50x magnification HE

400x magnification HE

Antibacterial Properties

Comparing zone of inhibition between five dental restorative materials against each type of bacteria; Enterococcus faecalis and Staphylococcus aureus

Variable	Amalgam (n=10) median (IQR)	Silverfil (n=10) median (IQR)	Fuji IX (n=10) median (IQR)	Fuji II (n=10 media (IQR	0) an	CR (n=10) median (IQR)	Control (n=10) median (IQR)	X ² Statistic (df) ²	P value ^a
E. Faecalis	7.24(1.95)	24.40(1.44)	5.85(0.92)	10.46(1.	.50)	0.00(0.00)	0.00(0.00)	41.50(4)	<0.001*
S. Aureus	6.95(0.93)	29.41(2.15)	8.97(0.29)	10.90(1.	.38)	0.00(0.00)	0.00(0.00)	46.05(4)	<0.001*
^a Kruskal-Wallis test.			k	*Signi	ficant				

Comparing zone of inhibition of each material between *Enterococcus faecalis and Staphylococcus aureus*

Variable	E. Faecalis (n=10) median (IQR)	S. Aureus (n=10) median (IQR)	Z statistic ^b	P value ^b
Amalgam	7.24(1.95)	6.95(0.93)	-0.56	0.571
Silverfil	24.40(1.44)	29.41(2.15)	-3.67	<0.001*
Fuji IX	5.85(0.92)	8.97(0.29)	-3.17	0.002 (<0.005)*
Fuji II LC	10.46(1.50)	10.90(1.38)	-0.98	0.326
CR	0.00(0.00)	0.00(0.00)	0.00	1.000
Control	0.00(0.00)	0.00(0.00)	0.00	1.000
^b Mann-Whitney te	est	*Signific	ant	

Silverfil exhibited the most significant antibacterial activity, followed by Fuji II LC, Fuji IX and amalgam towards *S. aureus and E. faecalis*.

Nurul Ain bt Jaafar et al., Antibacterial Properties of Dental Restorative Material:

Intern Medical J.l Vol. 20, No. 4, pp. 490 - 492, August 2013

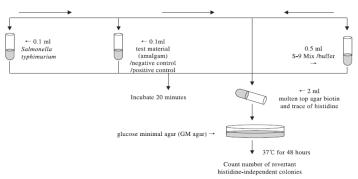


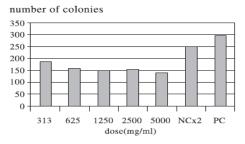
Figure 1. Overview of bacterial reverse mutation test (Ames Test) process

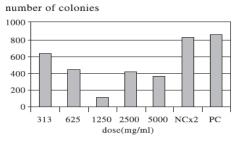
Table 1. Positive Controls

Strain	Positive control	Molar	Positive control	Molar
	chemical (-S9)	concentration	chemical (+S9)	concentration
		(mg/plate) ^a		(mg/plate)
TA98 4-Nit	4-Nitro-o-	2.5	2-Animoantracene	2.5
	phenylenediamine			
TA100	Sodium Azide	5.0	2-Animoantracene	2.5

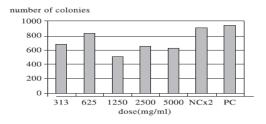
a - Concentration based on 100 x 15 mm petri plate containing 20 to 25 ml of GM agar (Mortelmans and Zeiger, 2000).

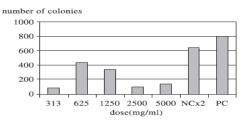
TA98 TA100





Tests in two strains without metabolic activation (-S9 Mix) $_{\mathrm{TA}98}$





Tests in two strains with metabolic activation (+S9 Mix)

Genotoxicity Study:

This study demonstrated that the test material did not exhibit any mutagenic activity under the chosen conditions. Thus, silverfil could be considered to have no genotoxicity effect.

Hassan A. et al. An in vitro Study of Genotoxicity of Silverfil Amalgam:

Intern Medical J.l Vol. 20, No. 4, pp. 409 - 412, August 2013

Conclusions:

SilverFil Amalgam:

- could be used as material of choice for sandwich technique under composite resin fillings
- can protect the tooth and the fillings from fracture in large composite fillings in Class I and Class II restorations
- benefits as a sandwich material in cases of deep gingival floor of cavity where it is difficult to get good moisture controls
- > showed no BPA leaching from Composite resin, thus preventing harm to pulpal tissue
- safe & non toxic to the pulpal cells as well as no inflammatory reaction to the tissues

Thank you for your Attention

Next steps...

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