Scientific Compendium









CAD/CAM Block

The DIRECTA SYSTEMS with it's natural concept of the layering technique is the quintessence of bioesthetics, bio-mimetics and bio-compatible restorations in direct, semi-direct and indirect digital workflows.

It offers the clinical user as well as the technician a precise understanding of the inner structure of the natural tooth, it's optical as well as functional properties enables the development of unsurpassed bio-esthetics and bio-function with simple, controllable technical and clinical procedures.

It's unique patented production process consists of a modern laser sintering and vitrification process that produces a material with outstanding physical and esthetic properties.

The end result of this manufacturing process is a single glass-phase embedded in a hybrid matrix to obtain a material that:

- 1. resembles esthetics of pure glass ceramics
- 2. strength of particle filled ceramics
- 3. simulates the modulus of elasticity of dentin

The bio-mechanical properties have been reconstructed optimally, merged together with natural bio-esthetics.

Content

Ι.	INTRODUCTION	4
	1. Composition	5
	2. Manufacturing Process	6
п.	MECHANICAL PROPERTIES	8
	1. Fatigue Behaviour and Microleakage Studies	8
	2. Surface Roughness Evaluation of Ceramir Restorative Material	10
	3. Surface Roughness of CAD/CAM blocks	12
	4. Surface Analysis of Ceramir CAD/CAM Blocks	17
	5. Internal Structure of Ceramir CAD/CAM Blocks	18
	6. Marginal Fit and Fracture Resistance	19
ш.	OPTICAL PROPERTIES	21
	1. Depth of Cure	21
	2. Fluorescence and Opalescence of Ceramir CAD/CAM Blocks	22
IV.	BIOCOMPATIBILITY	23
	1. Determination of Presence of BPA	23
	2. Cytotoxicity of Ceramir CAD/CAM Blocks	25
	3. Confocal Laser Microscopy Images	26
	4. Toxicity Profile of CAD/CAM blocks	27
	5. Intracutaneous Reactivity Test of Ceramir Products	28
V.	CERAMIR CAD/CAM BLOCK VS.	
	COLTENE BRILLIANT CRIOS DISC	29
VI.	CLINICAL COMPARISON:	
	TWO CAD/CAM SYSTEMS IN ONE PATIENT	32
VII.	CLINICAL CASE STUDIES	34

I. Introduction

Ceramir CAD/CAM Blocks is designed by combining three dental technologies into a single block, taking the advantages of each system, and merging it to produce a highly esthetic block and yet at the same time a material that rivals ceramics in strength.

The Ceramir material consists of combining pure glass ceramics, particle filled ceramics and resin technologies into one block. The hybrid glass block offers superior esthetics because of its glass like nature. Thus, the esthetics of glass ceramics is taken advantage of without its brittleness by incorporating the particle filled ceramic technology into the block. A small portion of resin is added to the material to allow for resilience and "shock absorbing effect" as well as the advantage of easy chairside repairability. Zinc oxide nanoparticles and fluoride provides antibacterial properties.

This block belongs to a different class of materials, namely a hybrid glass block. This is produced through a controlled laser sintering technology joining the glass crystals. The finished glass product is characterized by a single-phase glass crystal that is embedded in a resin matrix. Being of a homogenous crystalline glass phase, Ceramir CAD/CAM Blocks does not require any further post-sintering process, hence the advantage of a superior fit where no shrinkage is involved in the processing.







1. Composition

THE CERAMIR MATERIAL CONSISTS MAINLY OF:

- Dental barium silica glass
- Bis-GMA, Bis-EMA, UDMA dental resins
- Additives, pigments, catalysts
- Inorganic filler particle size
- Volume of inorganic fillers

17 [%] 1 [%] 0.02 – 0.7 μm 65 %-vol

82 [%]

THE ELEMENTAL ANALYSIS SHOWS THE FOLLOWING COMPOSITION:

- Glass: barium/ silica glass
- Aluminium oxide
- Zinc oxide nanoparticles
- Resin
- Fluoride



Elemental analysis of Ceramir CAD/CAM.

2. Manufacturing Process

All systems manufactured by DIRECTA Ceramir undergo a unique and patented manufacturing process combines the best of ceramic and composite technologies into a single block. The initial starting point of the manufacturing process is the material being heated and injected into special moulds at very high temperatures, the mass is then polymerized thermally under high pressure as well as through high intensity light and then tempered. This results in a solid homogenous glass like solid mass.



The material is heated and injected into special moulds.



The material is polymerized under high pressure and high intensity light.

This is followed by the core of the treatment. A laser now penetrates the entire thickness of the material. This sinters the glass particles leaving a solid homogenous glass phase. The resin portion is extracted from the material leaving a solid homogenous glass phase. Finishing is then done; the extracted resin portion is replaced by dispersed vitrified layer of fine glass particles throughout the entire thickness of the material. The result is an inorganic, high gloss, glass surface fused with the sintered, dynamic composite core.



The resultant is a solid homogenous material.



The finished material consists of a fused hybrid glass material with the sintered, dynamic composite core.



The resultant material is similar to natural enamel.

The biomechanical properties of natural tooth enamel have been reconstructed optimally, merged together with natural bio-esthetics.

Scanning electron microscopy (SEM) shows a distinct homogenous layer of fused glass particles. The high-density glass particles are completely joined to form a single hybrid glass phase resulting in an extremely glossy surface.



Scanning electron microscopy shows a smooth inorganic surface without visible composite structure.

The solid hybrid glass phase gives the final material its high gloss and long-lasting shine. Aluminium oxide is added to the material to provide sufficient strength required for restorations. It contains zinc oxide for antibacterial properties and resin to provide flexibility and resilience to the material. Through this unique manufacturing process, the physical properties of the material are enhanced. The compressive strength is 550MPa which is similar to that of ceramics. The surface hardness is 100HV giving it a wear resistance that is not damaging to the opposing teeth, unlike that of ceramics which wear down opposing teeth.

	COMPOSITE	FLOWABLE	VENEER
Flexural Strength	150 MPa	120 MPa	200 MPa
Compressive Strength	480 MPa	350 MPa	550 MPa
Flexural Modulus	12.5 - 16 GPa	6 GPa	20 GPa
Surface Hardness	80 HV	68 HV	100 HV
Polymerization Shrinkage	2.50 %	N.A.	_

II. Mechanical Properties1. Fatigue Behaviour and Microleakage Studies

Dr. Didier Dietschi, University of Geneva

AIM

The aim of this in-vitro study was to test the hypothesis that the Ceramir material, cemented onto enamel and dentin, would sufficiently resist simulated occlusal fatigue loads. Attention was also given to the quality of all interfaces in order to identify the restoration's most vulnerable areas.

SPECIMEN PREPARATION

Five freshly extracted human third molars were used for this study. Minimally invasive veneer tooth preparations were prepared. The preparation was made about halfway into the enamel and the dentin. The cavities were prepared using coarse diamond burs under profuse water spray (Cerinlay No 3080.018 FG; Intensiv, Viganello, Switzerland), and finished using fine grit burs of the same shape (Cerinlay No 3025.018 FG; Intensiv, Viganello, Switzerland). The restoration was initially cemented into place using manual pressure. After removal of excess composite using a probe and dry microbrush, each restoration surface was lightcured for 40 s using the same LED curing light.

MECHANICAL LOADING

After cementation, the samples were stored in saline for 24 hours before the stress test was performed. All specimens were submitted to 1,000,000 cycles using 100 N of occlusal loading force applied to the occlusal margin of the restoration. These conditions simulate approximately 4 years of clinical service.

RESULTS

SEM evaluation of marginal and internal adaptation demonstrated excellent performance of the restorations under simulated functional loading. Almost no defects were observed either before or after loading, at both the enamel and dentin margins. The most relevant demonstration of satisfactory behaviour was obtained from the evaluation of the internal adaptation of the restoration. No defects were discovered at the interface of the enamel or in-between the composite cement and the veneer. These results confirm the excellent bond strength at both the composite-enamel or composite-veneer interfaces. At the dentin level, no significant defects were noticed in proportion of the overall dentin-composite cement interface.



Internal adaptation observations. Full section of a molar restored with Veneer (right side), in which half of the surface was bonded to enamel and the other half to dentin.



View of the interface area between the enamel and dentin. The interface is stable and resistant to occlusal loading.

The interface of enamel demonstrated to be free of any defects after the loading test.

The adaptation to dentin showed no major defects after the loading test.

2. Surface Roughness Evaluation of Ceramir Restorative Material

INTRODUCTION

The clinical success of esthetic dental restorations relies on some essential features like long lasting shine and a smooth surface. These features are heavily reliant on the surface roughness. Surface roughness refers to the irregularities on the surface. Surface roughness leads to loss of shine as well as discoloration over time. Surface roughness facilitates microbial plaque formation, especially in areas where the restorative material is in contact with the gingiva. A restoration with a rough surface can also abrade the opposing dentition or restoration.

ΑΙΜ

The aim of this study was to determine the surface roughness of Ceramir restorative material using a profilometer.

MATERIALS AND METHODS

Specimens were prepared and evaluated for surface roughness using surface profilometry. In the current study, surface roughness (Ra) values were obtained using a surface roughness tester and measured in micrometers (μ m).

RESULTS

The mean Ra value obtained for Ceramir material was 0.057 μ m. When compared to other ceramic CAD/CAM blocks. ProCAD (0.43 μ m), Emax (0.24 μ m)1–4 Ceramir showed the smoothest surface indicating a more glossy surface compared to other ceramic CAD/CAM blocks (see table below). Ceramir when compared to dental composites also performs better with composites generally having a surface roughness of about (Z350, 0.48)5.

A smooth surface implies a longer lasting shine with less chance of discolouration.



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Surface roughness values for Ceramir material:

Data	aView o	of Su	rface Ro	ughne	ss Tester	V1.3	1									-
age C	Operate Tool	config	gure Analysis	Curve H	elp										_	
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	b	²⁰ 4	± 🐕	- 	>											
	2018-	04-24	4 10:28:0	9										 		
	0.057	¦Ìm	0.16	6 ¦Ìm	0.217	Ìm	0.476	¦Ìm	0.383	¦Ìm	3.550		0.336			
	Ra		R	,	Rp		Rt		Rz		Rku		Rsk			
	0.074	¦Ìm	0.19	8 ¦Ìm	0.268	¦Ìm	0.217	¦Ìm	0.020	mm	0.026	mm	1			
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3. Surface Roughness of CAD/CAM blocks

Aleksandra Špadijer Gostović, Stefan Vulović, Aleksandra Milić Lemić, Aleksandar Racić, Tijana Vukić, Katarina Puzović , University of Belgrade, Serbia

BACKGROUND

Monolithic CAD/CAM dental ceramic materials, such as lithium disilicate, zirconia and hybrid ceramic have been nowadays indicated for implant-supported restorations. Despite numerous mechanical and esthetic advantages, neither of these materials is durable to surface degradation over time after long-term application in the oral cavity. Widely accepted method for simulating process of hydrothermal aging of dental materials in the oral environment is thermal cycling (TC).

ΑΙΜ

The aim of the study was to evaluate and compare surface roughness of CAD/CAM ceramic materials for implant-supported restorations before and after TC. The research hypotheses were that TC would notably affect the surface roughness with significant differences among materials before and after TC.

MATERIALS AND METHODS

Flow chart of the study protocol is presented in Fig. 1. Eighty disc-shaped specimens (5 mm diameter and 2 mm thickness) were prepared, finished and polished according to manufacturer and divided into five groups:

- Lithium disilicate polished (LDP) and glazed (LDG), (IPS e.max CAD, Ivoclar Vivadent, Schaan, Liechtenstein)
- Zirconia polished (ZRP) and glazed (ZRG), (IPS e.max ZirCAD Prime, Ivoclar Vivadent, Schaan, Liechtenstein)
- Hybrid ceramic (HC), (Hybrid Block, DIRECTA AB, Upplands Väsby, Sweden).



Flow chart of the study protocol:

Surface roughness was analysed using profilometer, where Ra (average roughness) and Rz (maximum roughness) were measured, supported with line graphs, and using scanning electron microscopy (SEM). After 10 000 thermal cycles, that simulates one year in the oral cavity, analyses were repeated on the same specimens. Data were examined in SPSS 22.0 program, Kolmogorov-Smirnov test revealed non-normal data distribution, so the data were compared among groups using Kruskal-Wallis and Dunn's post hoc tests and presented with median (minimum - maximum).

RESULTS

Profilometer analysis results showed significant differences among groups for both Ra and Rz before and after artificial aging. Glazed groups (Lithium disilicate glazed and Zirconium glazed) presented higher Ra and Rz values, compared with the polished groups hybrid ceramics (Ceramir CAD/CAM). Surfaces of hybrid glass Ceramir CAD/CAM Block specimens were smoother than LDG and ZRG.

Group	<i>Ra</i> (μm) Median (min-max)	<i>Ra</i> (μm) Median (min-max)	<i>Ra</i> (µm) change	Rz (μm) Median (min-max)	<i>Rz</i> (μm) Median (min-max)	<i>Rz</i> (µm) change
	before TC	after TC		before TC	after TC	
LDP	0.09 (0.07–0.16)°	0.51 (0.45–0.58) ^b	0.42 (p < 0.001)	0.44 (0.39-0.66) ^d	3.26 (2.43–3.98)°	2.82 (p < 0.001)
LDG	0.43 (0.34-0.53) ^{a, b}	0.64 (0.58-0.71) ^a	0.21 (p < 0.001)	2.18 (1.56–2.78) ^{a, b}	4.30 (3.38-5.00) ^a	2.12 (p < 0.001)
ZRP	0.10 (0.08–0.14)°	0.52 (0.47-0.61) ^b	0.42 (p < 0.001)	0.52 (0.36-0.66) ^{c, d}	3.33 (2.78–4.00) ^{b, c}	2.81 (p < 0.001)
ZRG	0.44 (0.38-0.54) ^a	0.84 (0.70-0.96) ^a	0.40 (p < 0.001)	2.29 (1.78–2.97)ª	4.53 (3.87-5.12) ^a	2.24 (p < 0.001)
НС	0.31 (0.25-0.40) ^b	0.47 (0.40-0.57) ^b	0.16 (p < 0.001)	1.38 (1.05–2.00) ^{b, c}	3.99 (3.14-4.65) ^{a, b}	2.61 (p < 0.001)

Profilometer analysis results (Ra and Rz).



Background and Aim

Monolithic CAD/CAM ceramic materials, such as lithium disilicate, zirconia and hybrid ceramic have been indicated for implant-supported restorations. Despite numerous advantages, neither of them is durable to surface degradation over time in the oral cavity. Accepted method for simulating process of hydrothermal aging of dental materials in the oral environment is thermal cycling (TC). The aim was to evaluate and compare surface roughness of CAD/CAM ceramic materials before and after TC. The research hypothesis was that TC would notably effect the surface roughness, with significant differences among materials before and after TC.

Methods and Materials

Eighty specimens were prepared according to manufacturer and divided into five groups: lithium disilicate polished (LDP) and glazed (LDG) (IPS e.max CAD, Ivoclar Vivadent, Schaan, Liechtenstein), zirconia polished (ZRP) and glazed (ZRG) (IPS e.max ZirCAD Prime, Ivoclar Vivadent, Schaan, Liechtenstein) and hybrid ceramic (HC) (Hybrid Block, Edelweiss, Wolfurt, Austria). Surface roughness was analysed using profilometer, where *Ra* (average roughness) and *Rz* (maximum roughness) were measured, supported with the line graphs, and using scanning electron microscopy (SEM). After 10000 thermal cycles, that simulates one year in the oral cavity, analyses were repeated on the same specimens.

Presented at



on surface roughness of CAD/CAM ceramic materials for implant-

ulović, Aleksandra Milić Lemić, Aleksandar Racić, Tijana Vukić, Katarina Puzović



polished lithium disilicate, zirconia and hybrid ceramic. Hybrid ceramic surfaces showed the highest resistance to thermal cycling. Surface roughness is related to gloss, staining and microbial adhesion with risk of peri-implant diseases, therefore the reported results might be of importance for the proper selection of material for implantsupported restorations.

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Profilometer analysis results (line graphs) – Glazed groups (Lithium disilicate glazed and Zirconium glazed, LDG & ZRG) presented higher Ra and Rz values, compared with the polished groups hybrid ceramics (Ceramir CAD/ CAM- HC, LDP & ZRP). Surfaces of hybrid glass Ceramir CAD/CAM BLOCK specimens were smoother than Lithium disilicate and zirconium blocks.

4. Surface Analysis of Ceramir CAD/CAM Blocks

AIM

To compare the surface structure of Ceramir CAD/CAM Blocks and compare to other blocks using SEM.

RESULTS



 Imm
 Mag = 7.66 KX
 EHT = 3.00 kV
 Signal A = InLens
 Brightness = 42.8 %
 ZELX

 Imm
 Mag = 7.66 KX
 EHT = 3.00 kV
 Signal B = 5E2
 Contrast = 31.3 %
 ZELX

The Ceramir CAD/CAM Block shows a homogenous layer of glass almost fused to form a single unit. There is a complete absence of voids or defects on the surface structure. The surface shows almost complete joining of the glass particles to form a solid single phase.



Another company CAD/CAM block: Irregularly shaped structures on the surface presenting an uneven,



inhomogeneous surface structure. Several voids and cracks appear on the surface.

5. Internal Structure of Ceramir CAD/CAM Blocks

The internal structure was analyzed using Nano CT scans.





Nano CT Scans show a homogenous internal structure devoid of any voids or imperfections within the internal structure of the Ceramir CAD/CAM Block.

6. Marginal Fit and Fracture Resistance

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AIM

To evaluate and compare the influence of two preparation designs on the marginal fit and fracture resistance of endocrown restorations fabricated using CAD-CAM Lithium disilicate and Ceramir processed CAD/CAM Block.

MATERIAL AND METHODS

Forty-two mandibular first molars were restored with endocrowns fabricated using CAD/CAM technology, divided into six groups based on materials (lithium disilicate-LD, HIPC composite resin-CB, and Ceramir CAD/ CAM Block-CE and two preparation designs as LD1, LD2, CB1, CB2, CE1, CE2. The marginal gap was examined pre- and post-cementation by scanning electron microscope (SEM), and fracture resistance was tested using the universal testing machine.

RESULTS

Group CE2 recorded the least mean marginal gap ($30.89\pm3.524\mu m$) pre-cementation and (33.83 ± 3.217) post-cementation. There was a statistically significant difference between group LD and group CE as well as group LD and group CB pre- and postcementation. Group CE1 showed the highest fracture resistance value (2856.48 ± 644.008 Mpa) and Group LD1 showed the lowest fracture resistance value (1948.96 \pm 610.67 Mpa). Independent t-test did not show a statistically significant (p<0.05) difference in fracture resistance between two designs in the same group (Group LD1 and LD2), (Group CE1 and CE2) or (Group CB1 and CB2). There was a significant difference in fracture resistance between LD and CE (p value -0.037 and LD and CB group (0.033), there was no significant difference in fracture load between CE and CB group (p value - 0.999).

CONCLUSIONS

Material selection can affect endocrown restoration fit. Ceramir CAD/CAM material was found to be a good option for restoring endodontically treated teeth with endocrowns. Ceramir showed the best marginal fit in both pre- and post-cementation compared to the lithium disilicate and HIPC. Ceramir CAD/CAM Blocks showed highest fracture resistance compared to the other materials.

CLINICAL IMPLICATION

The study demonstrated that the use of Ceramir CAD/CAM material with a specific preparation design resulted in the lowest marginal gap and highest fracture resistance.



Study design: Chamfer and shoulder margin designs.



X-axis denoting the different groups and Y- axis denoting the mean values in microns (standard deviation) for each group in μ m.



FRACTURE STRENGTH

Fracture strength in MPa with standard deviation. Lithium disilicate-LD, HIPC composite resin-CB, and Ceramir CAD/CAM Block-CE.

III. Optical Properties1. Depth of Cure

AIM

To study the surface hardness of the resin cement light-cured through Ceramir CAD/CAM restorations of different thicknesses and shades.

METHOD

Ceramir Block 2 mm thickness



CONCLUSION

There is complete light polymerization of the cement below 2 mm thickness of CAD/CAM block.

Ceramir CAD/CAM Blocks can be safely used at 2 mm thickness that will ensure complete polymerization of the underlying luting cement.

Surface hardness test



The hardness of the material shows complete polymerization of both top and bottom surfaces indicating light passing through the 2 mm thick Ceramir CAD/ CAM Block. There is no decrease in the light intensity at 2mm thickness of Ceramir CAD/CAM Blocks.



2. Fluorescence and Opalescence of Ceramir CAD/CAM Blocks

Fluorescence and Opalescence are optical proper- cence in teeth occurs with the absorption of light in exhibits higher fluorescence than enamel. Fluores- region (~400 nm) teeth fluoresce blue-white.

ties that make teeth look lifelike in appearance. Dentin the UV region (350-365 nm) and emitted in the visible



Ceramir CAD/CAM Blocks show better fluorescence than a ceramic CAD/CAM block



Ceramir restoration compared to natural tooth showing perfect match in both fluorescence and opalescent lighting conditions.

IV. Biocompatibility1. Determination of Presence of BPA

INTRODUCTION

Bisphenol A is an organic compound used predominantly in the manufacture of products made of polycarbonate plastic and epoxy resins that line food, beverage cans as well as in dental resin cements. Studies have shown that BPA has weak estrogen-like activity and that it is toxic. It has been suggested that BPA may be an endocrine disruptor, BPA also affects the metabolic, thyroid hormone, and androgen systems.

AIM

Considering the overall world-wide current trend towards BPA-free materials, the aim of this study was to determine if Ceramir CAD/CAM Blocks are BPA free.

Prior to its unique manufacturing process, Ceramir composite undergoes dramatic changes to its composition and structure. Its initial organic components are BIS.GMA, BIS EMA, and UDMA.



Bis-GMA Bisphenol A-diglycidyl dimethacrylate



Bis-EMA Ethoxylated bisphenol A dimethacrylate



UDMA Urethane dimethacrylate

METHOD

Qualitative and quantitative characterization of monomers in a novel CAD/CAM block using liquid chromatography/mass spectrometry.

RESULTS

Results of the thermogravimetric analysis revealed a weight loss of 25.12 % when precured samples were calcined up to 500 °C in an air atmosphere. Using this data along with data from by ICPMS (for cations) and ion chromatography (for anions), the relative elemental composition of the pre and postcured samples were deduced (Table 1). The percentage differences indicate notable changes in elemental composition between pre-curing and post-curing samples and the consistent reductions across various elements suggest a systematic shift in the material's inorganic composition during the curing process.

CONCLUSION: The Ceramir CAD/CAM Block is BPA free. There is complete polymerization of both Bis-GMA and Bis-EMA leaving no free radicals is the block. The Ceramir CAD/CAM Block is a safe product and in line with world trends of being the first CAD/CAM block to be 100 % BPA free and bio sustainable.

SAMPLE ID	Aluminium		Zinc		Barium		Silicon		Fluoride	
	(in mg/L)	(in wt%) (w/w))								
Before curing (SE1)	550.44	53.8	165.64	16.2	9.42	0.92	13.30	1.53	95.41	9.3
After curing (SP1)	446.78	50.7	133.58	15.2	7.72	0.88	10.82	1.47	90.61	8.9

Table 1: Elemental composition of EDP

Retention time (RT in mins)	Before curing (SE1)	After curing (SP1)	RT value matching with standard resins
RT1	3.40	BDL	Standard Bis-EMA (RT 3.4)
RT2	3.84	BDL	Unknown
RT3	4.14	4.41	Standard UDMA (RT 4.41)
RT4	6.67	6.68	Standard UDMA (RT 6.68)
RT5	7.63	7.64	Standard UDMA (RT 7.64)
			Standard Bis-GMA (RT 7.9)
RT6	10.78	BDL	Standard UDMA (RT 10.74)
RT7	12.70	BDL	Standard Bis-GMA (RT 12.6)
RT8	13.10	BDL	Standard Bis-EMA (RT 13.09)

Table 2: Retention time recorded from UPLC

Chromatogram View





ΑΙΜ

To determine the cell viability of human dental pulp stem cells (hDPSCs) when exposed to Ceramir CAD/ CAM Blocks.

CONCLUSION

There was 100 % growth of human pulp cells when exposed to the Ceramir CAD/CAM Block. The block is nontoxic and does not cause any damage to the human dental pulp stem cells.

RESULTS



% MTT assay – cell viability of human dental pulp stem cells (hDPSCs) incubated with Control group and EDL 1, EDL 2 and EDL 3 samples after 24 and 72 hrs.

3. Confocal Laser Microscopy Images

AIM

To observe the cell viability using Confocal Microscopy after exposure to dye, Acridine Orange.

CONCLUSION

Human Dental Pulp Cells exposed to Ceramir CAD/ CAM Blocks remain firmly attached to the substrate with good proliferation indicating that the CAD/CAM blocks are non-toxic. Cells remain viable and retain their original spindle shape.

Ceramir CAD/CAM Blocks do not cause any cytotoxic effects to the human dental pulp stem cells.



Confocal Laser Scanning Microscopy (CLSM) images of cell viability of the human dental pulp stem cells (hDPSCs) incubated with A).Control group and B). EDL 1 C). EDL 2 and D). EDL 3 samples after 72 h stained with acridine orange dye.



Stephan Lampl, Deepa Gurunathan, Jogikalmat Krithikadatta, Deepak Mehta

BACKGROUND

The safety of resin-based dental materials and their CAD/CAM derivatives used in restorative dentistry is an area of ongoing research and is of importance for safety profiling. The zebrafish model is a new but well-established model for studying toxicity and biocompatibility in general and is gaining prominence amongst biomedical and dental researchers.

METHODS

In this randomized, parallel, three-arm, and assessor-blind in vivo study, a zebrafish (Danio rerio) model was used to assess the safety of Ceramir CAD/CAM Blocks. The study comprised three experimental groups, including untreated controls (Group A), vehicle controls using human saliva only (Group B), and treated group with test samples (Group C). Morphological and physiological assessments of embryonic and larval zebrafish were conducted at 48- and 72hours post-fertilization (hpf). Two independent assessors, blinded to treatment groups, utilized a grading system to quantify deformities. Hatching rates (48 hpf), survival rates (72 hpf), and heart rates (72 hpf) were also measured.

RESULTS

Morphological assessments revealed no significant differences among the groups, with all samples receiving a rating of "0," as per the Hermann's grading system. Inter-rater assessments at 48 and 72 hpf were in perfect agreement (Cohen's k: 1). Hatching rates were consistent across groups, ranging from 66.7 % to 77.8 %, with no significant differences. Mean heart rates at 72 hpf were similar among the groups, ranging between 152 and 154 beats per minute. Survival rates were 100 % in Group A, 88.9 % in Group B, and 77.8 % in Group C and the differences between groups were not significant.

CONCLUSION

The findings of this in vivo study indicate the safety of Ceramir CAD/CAM Blocks when tested on embryonic and larval development in zebrafish models, as evidenced by normal morphological assessments, hatching rates, survival rates, and heart rates.



5. Intracutaneous Reactivity Test of Ceramir Products

[AS PER ISO 10993-23: 2021]

METHODOLOGY

Extracts were prepared at extraction ratio of $3 \text{ cm}^2/\text{mL}$ surface area/volume and incubated at 50 ± 2 °C for 70 hours and 53 minutes. 0.2 mL/site of polar extract of the test item was injected intracutaneously at five different sites.

Each site of injection was observed for skin reactions immediately after injection and at 24 ± 2 hrs, 48 ± 2 hrs and 72 ± 2 hrs after injection.

RESULTS

Based on the results of the experiment, it is concluded that the extracts of test item, Ceramir products are "Non-irritant" to the skin as per the ISO 10993 Part 23:2021.

CONCLUSION

The toxicological evaluation of Ceramir CAD/CAM shows that Ceramir CAD/CAM provides a high level of safety and an even higher level than other established composite materials that are applied in a non-polymerized state.

Clinical experience with thousands of Ceramir CAD/ CAM Blocks being used since its introduction and no undesired effects relating to biocompatibility issues have become apparent.

Ceramir CAD/CAM Blocks pose no risk to the patient and the benefits of the product exceed any residual risk if any. Ceramir CAD/CAM Blocks are delivered and used in a polymerized state; thus, any risk of sensitization is very low.

V. Ceramir CAD/CAM Block vs. COLTENE BRILLIANT Crios Disc

The aim of this document is to compare milling of dental restorations out of a BRILLIANT Crios Disc vs. out of an Ceramir CAD/CAM Block regarding costs as well as expenditure of time. Moreover, the advantages of the Ceramir material shall be illustrated.

ASSUMPTION

The size of the BRILLIANT Crios Disc allows to mill up to 40 restorations out of it, hence the costs and time to mill 40 Veneers out of one disc vs. out of 40 Ceramir Blocks will be compared.

TABLE 1:

	Ceramir CAD/CAM Block	COLTENE BRILLIANT Crios Disc			
1. Designing Veneers to be milled	Same amount of ti	ime for both options			
2. Preparation and installa- tion of workpiece	 2.1 Putting block into milling machine (20 sec.) 2.2 Scan of block by machine (10 sec.) 2.3 Loading of milling data (10 sec.) Time for one block: 40 sec. Total time for 40 blocks: 27 min. Note: Lab milling machines allow for 6 blocks to be milled without re-clamping. This would reduce the time exposure even further. 	Note: milling 40 Veneers in one session is possible but would lead to a high risk of breakage since the individual Veneers are interconnected (see picture 1). Picture 1: 40 Veneers on 1 disc Image: Comparison of the individual veneers are interconnected (see picture 1). Picture 1: 40 Veneers on 1 disc Image: Comparison of the individual veneers are interconnected (see picture 1). Picture 1: 40 Veneers on 1 disc Image: Comparison of the individual veneers indidual veneers individual veneers individual veneers individual vene			
3. Milling time	12 min. per Veneer/Block Total time for 40 Veneers: 8 h	Total time for 40 Veneers if milled in one go: 11 h 55 min			
4. Reworking (cutting off connectors and polish- ing)	1 min. per connecting element Total time for 40 Veneers: 40 min.	1 min. per connecting element 2-3 connecting elements; ¼ would have 3 connectors and ¾ would have 2 connectors Total time for 40 Veneers: 1 h 30 min.			
Total time expenditure	9 hours 7 minutes (without designing of veneers)	14 hours 33 minutes (without designing of veneers)			
There of technician time	53 minutes	2 hours 38 minutes			

1. KINDER TO THE MILLING BUR (LESS WEAR)

Cost of burs vary depending on the manufacturer that is why the difference in wear is most interesting. Table 2 shows wear of different burs used for milling 40 veneers.

TABLE 2: WEAR AFTER MILLING 40 VENEERS

Diameter of bur	Ceramir CAD/CAM Block	COLTENE BRILLIANT Crios Disc
	Wear in %	Wear in %
2 mm	40	75
1 mm	15	34
0,6 mm	8	27

Tests show that **burs can be used up to three times longer with Ceramir CAD/CAM Blocks.** Moreover, composites of competitors tend to clog up burs which also leads to shorter usage times respectively to the need of replacing them considerably earlier and more milling errors than when using Ceramir material.

5. EASY FINISHING AND LONG-LASTING SHINE

Since Ceramir material is pre-sintered and vitrified, only polishing with a goat hair brush is necessary. BRILLIANT Crios needs to be polished like a classic composite with multiple polishers (different grain sizes). However, the achieved gloss is usually lost within 10 days.

2. FASTER MILLING

See Table 1 for comparison.

3. BETTER MILLING RESULTS

With Ceramir material smoother chip-free margins of the finished restorations and a much "softer" feel on the CAD/CAM milling bur can be observed.

4. DRY MILLING POSSIBLE

Ceramir CAD/CAM Blocks can be milled in dry mode which is impossible for materials like BRILLIANT Crios. Milling machines that operate in dry milling mode are usually cheaper than those who operate in a wet mode. A SEM Analysis of the surfaces of Ceramir and BRILLIANT Crisos shows significan differences that explain the experienced differences.



Picture 2: SEM-Analysis of Ceramir Block



Picture 3: SEM-Analysis of BRILLIANT Crios

A complete absence of voids or defects on the surface structure make the Ceramir material more stable under occlusal forces preventing any fractures and better wear resistance. The absence of surface voids and defects makes the Ceramir CAD/CAM Block more color stable preventing surface staining.

6. PERMANENT SOLUTION

Key opinion leaders of Ivoclar and Coltene call material like Brilliant Crios, based on the mechanical properties, a "temporary material" whereas Ceramir is recognised as a permanent solution.

TABLE 3: TECHNICAL DATA OF DIFFERENT CAD/CAM BLOCKS

CAD/CAM BLOCK	Manufacturing Process	Flexural Biaxial 1	Strength Three Point	Compressive Strength	Flexural Modulus	Surface Hardness
Vita Enamic	Dispersed, chemical cured ceramic fillers	n/a	155 MPa	n/a	30 GPa	n/a
Lava Ultimate	Chemical cured ceramic fillers (methacrylate based)	n/a	204 MPa	383 MPa	12.8 GPa	n/a
BRILLIANT Crios	Chemical cured ceramic fillers (methacrylate based)	262 MPa	198 MPa	426 MPa	10.3 GPa	n/a
Shofu HC	Chemical cured ceramic fillers (methacrylate based)	n/a	191 MPa	472 MPa	9.6 GPa	66 HV
Tetric CAD	Chemical cured ceramic fillers (methacrylate based)	273.8 MPa	n/a	n/a	10.2 GPa	n/a
Cerasmart	Dispersed, chemical cured ceramic fillers	246 MPa	n/a	n/a	9.6 GPa	n/a
Ceramir *	Laser cured and sintered glass phase	320 MPa	200 MPa	550 MPa	20 GPa	100 HV

Mimics Dentin & Enamel

Source: edelweiss external technical data from independent University Geneva and gbd Lab GmbH. Competitors technical data from manufacturer's documentation.

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Shofu Dental Corporation, 3M Deutschland GmbH, GC Europe N.V.

TABLE 4: TECHNICAL DATA OF DIFFERENT CAD/CAM SYSTEMS

Data	Ceramir	ЕМАХ	ZIRCONIA
Flexural Strength	200 MPa	250-300 MPa	1000 MPa
Compressive Strength	550 MPa	600 MPa	12000 MPays
Flexural Modulus	20 GPa	100 GPa	200 GPa
Surface Hardness	100 HV	600 HV	1200 HV

VI. Clinical Comparison: Two CAD/CAM Systems in one patient



Ceramir Veneers (11, 12 and 13)

SPLIT-MOUTH CLINICAL STUDY: ONE WEEK AFTER TREATMENT

- Ceramir Veneers maintain its original gloss as a result of its single hybrid glass phase.
- The veneers have a shiny appearance giving it a more natural enamel life-like appearance.

TWO WEEKS AFTER TREATMENT

- Ceramir Veneers still have its glass like shiny appearance maintaining its original gloss.
- There is no sign of wear or abrasion as a result of tooth brushing.
- There is no loss of surface anatomy. Original line angles and surface characterizations still present.

THREE WEEKS AFTER TREATMENT

- Long lasting gloss can still be seen after 3 weeks.
- There are no signs of abrasion or loss of surface anatomy.
- Proper canine guidance can still be observed with no wear facets on the canine veneer.

- Patient says, "The veneers on the right side feel like his original teeth, a very smooth and polished surface".
- Higher magnification shows a very smooth glossy surface devoid of any surface roughness or scratches.











Ceramir



Alternate veneers (21, 22 and 23)

SPLIT-MOUTH CLINICAL STUDY: **ONE WEEK AFTER TREATMENT**

- Alternate veneers seem to loose its original lustre.
- It appears dullish having a more opaque look.
- The dispersed particles within the resin matrix may account for the loss of the original shine over time.

TWO WEEKS AFTER TREATMENT

THREE WEEKS AFTER TREATMENT

- Alternate veneers become duller over time, looking more opaque.
- Some of its original surface anatomy is lost. Original surface contours seem to have been smoothened out.
- Fine micro abrasions start to appear on the surface possibly a result of tooth brush wear on the veneer.

• Patient says, "The veneers on left side feel rough and is not as smooth as the right side of his mouth. It also has a dullish appearance".





- Veneer on tooth 21 chipped on incisal margin, extending to buccal side. It is a cohesive fracture occuring within the material itself.
- Veneer on tooth 23 chipped on mesio-incisal margin. The fracture extends to buccal wall of the veneer.
- Fractures may possibly be a result of the weakness of the material itself. The material cannot withstand occlusal forces because of its lower micro-hardness and elastic modulus values.
- Higher magnification shows a rough surface with scratches.





VII. Clinical Case Studies







Case Study cad/cam block non-prep retroclined teeth





Case Study cad/cam block non-prep bruxism / tooth wear







Case Study cad/cam block non-prep attrition / abrasion



Case Study cad/cam block non-prep attrition / abrasion



Case Study cad/cam block minimal invasive full mouth rehabilitation









Case Study cad/cam block full mouth rehabilitation (implant)





Case Study cad/cam block full mouth rehabilitation (implant)

Case Study cad/cam block non-prep full mouth rehabilitation



Case Study cad/cam block non-prep full mouth rehabilitation





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