Clinical Evaluation of Wear Resistance and Bioactivity of Self cured Bioactive Resin Composite.

A Thesis Protocol

Submitted for partial fulfillment of the requirements of the

Doctor Degree in Dental Science of Conservative Dentistry

Research code:

Submitted By

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"Thesis Research Protocol"

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1. Abstract

Introduction:

Resin-based composites (RBCs) have become the gold standard in restorative dentistry due to their superior aesthetics, adhesion, and minimally invasive application. However, wear remains a critical drawback, compromising their longevity and clinical performance. Various techniques have been suggested to measure the clinical performance of (RBCs). Recent advancements in digital dentistry, such as intraoral scanning, offer a more precise and efficient approach for quantitative wear assessment.

Aim:

This study aims to evaluate wear resistance and bioactivity of self cured bioactive resin composite vs nanhybrid resin composite.

Methodology:

Twelve healthy patients with 24 carious molar teeth will be selected where each patient should have two oclusso- mesial cavities. Standardized

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oclusso- mesial cavities will be prepared for all the selected teeth, for each patient the first tooth will be restored with conventional nanohybrid RBC (M1). Meanwhile, the second tooth will be restored by self-cure bioactive RBC (M2). Then, wear resistance will be evaluated by intraoral scanner immediately after restoration (T0), six months later (T1), after 12 months (T2), 18 months (T3) and 24 months (T4). Software analysis will be done by superimposing the 3D digital impression and evaluate the restoration wear by calculating the 3D volume loss.

Also, bioactivity of the restoration will be measured by measuring the mineral density beneath the restoration. Digital radiographic images will be taken for the restoration by parallel technique and grey scale of the pixels under restoration will be measured by software immediately after restoration (D0), one month later (D1) and after 3 months (D2).

2. Introduction and Background

Resin-based composites (RBCs) are currently the most widely used materials for dental restorations due to their favorable esthetics, mechanical properties, cost-effectiveness, versatility, and overall acceptable clinical performance. However, their long-term clinical durability remains a concern and requires further enhancement **(Ferracane, 2024).**

Among the major causes of failure and replacement of resin composite restorations is secondary caries, with incidence rates reaching approximately 60%. This high rate highlights a significant

limitation in the longevity of conventional resin based restorative materials **(Pinto et al., 2023).**

In last few decades, bioactive resin composite materials have emerged as a trial to overcome such a problem. These materials are designed to release ions, such as calcium and phosphate, in a controlled and localized manner at the tooth-restoration interface. This ion exchange with surrounding saliva and tooth structure contributes to maintaining mineral balance and promoting remineralization, thus supporting tooth integrity and preventing its demineralization **(Garcia et al., 2021).**

Recently, self cured resin based bioactive bulk fill material (**Stela, SDI, Australia**) was launched to the market as a recent bioactive RBC that contains fluoride, calcium and strontium for enhanced biomimetic and bioactive properties. Unfortunately, bioactive RBCs, vary significantly in formulation, particularly in terms of the type, size, and concentration of ion-releasing components. These differences influence their solubility, permeability, and ultimately their ability to sustain ion release over time. While such modifications are beneficial for caries prevention, they may also compromise the physical properties of such materials, especially wear resistance under continuous masticatory forces. This becomes even more critical considering that wear behavior of dental RBCs is highly dependent on their chemical constituents **(Garcia et al., 2021).**

It is worth mentioning that occlusal wear is a critical factor affecting the success of posterior composite restorations. So that, high wear resistance is essential for maintaining the function and longevity

of restorations. In contrast, poor wear resistance can lead to clinical complications such as tooth shifting, temporomandibular joint discomfort, and periodontal issues **(Garcia et al., 2021).**

The manufacturer claimed that **Stela** is an innovative bioactive material with high strength properties. It offers an unlimited depth of cure and low-stress polymerization with a gap-free interface **(SDI Limited, 2023).** Therefore, the primary objectives of this study are to clinically evaluate the wear resistance and the bioactivity of such material.

Wear behavior of a micro hybrid composite vs. a nanocomposite in the treatment of severe tooth wear patients was evaluated. A convenience sample of 16 patients with severe tooth wear was chosen. Eight of them were treated with a micro hybrid composite (Clearfil APX, Kuraray) and the other eight with a nanocomposite (Filtek Supreme XTE, 3M). The Direct Shaping by Occlusion (DSO) technique was used for all patients. Clinical records were collected after 1 month (baseline) as well as 1-, 3- and 5-years post-treatment. The maximum height loss at specific areas per tooth was measured with Geomagic Qualify software. The results showed that for premolar and molar teeth, Filtek Supreme showed less wear in bearing cusps, whereas Clearfil APX showed less wear in non-bearing cusps. They concluded that nanocomposite restorations showed significantly less wear at bearing cusps, whereas microhybrid composite restorations showed less wear at non-bearing cusps and anterior maxillary teeth ***(Ning et al, 2021).***

Remineralization effect of natural versus synthetic materials on

deep carious dentin was studied. Extracted human molars with class I carious lesions were collected and randomly assigned into four groups: a control group, a propolis-treated group, a hesperidin-treated group, and a group treated with silver diamine fluoride (SDF). Carious tissues were managed using the stepwise caries removal approach, followed by application of the respective test materials. All cavities were then restored using glass ionomer cement (GIC). Radiographic evaluations were conducted at 6 and 12 weeks to assess changes in mineral density. Among the tested groups, the propolis group exhibited the greatest increase in mineral density, while the hesperidin group recorded the lowest with no significant difference. The findings suggested that both propolis and hesperidin demonstrated notable potential in enhancing dentin remineralization and limiting caries progression, presenting viable alternatives to SDF ***(Anani et al. 2023)***.

Clinical performance and wear resistance of milled resin composite material versus direct nanohybrid bulk-fill resin composite in the restoration of endodontically treated posterior teeth over 1 year was studied. Twenty-six patients with endodontically treated teeth were divided into two groups, where R1 restored with Milled composite, R2 restored with direct bulk-fill composite. Each restoration was assessed for wear resistance immediately and after one year intraorally and extra orally using intraoral scanners and three-dimensional surface-based superimposition software. They found that direct nanohybrid bulk-fill resin composite showed a greater amount of wear without a statistically significant difference. There was no significant reliability/agreement between both methods. They concluded that both milled composite and

direct bulk-fill resin composite restorations in endodontically treated teeth demonstrated minimal wear over a 1-year follow-up period ***(Elhaddad et al, 2024).***

An evaluation of dental paste-like bulk-fill composite wear using intra-oral scanner was done. Six different dental composite materials, including five bulk-fill composites and one conventional composite, were tested alongside natural human enamel as a control group. A computer-controlled chewing simulator was used for wear testing. A one-way ANOVA test was used to identify any significant differences between the means of the tested dental composite materials. The results showed variability among bulk-fill composites, with some demonstrating wear resistance like conventional composites. Significant variability was observed among bulk-fill composites, but the results were comparable to those of conventional composites. The enamel control group demonstrated the lowest wear values, with some bulk-fill composites showing similar wear resistance. The conclusion showed that significant variability was observed among bulk fill composites, but the results were comparable to those of conventional composites. The enamel control group demonstrated the lowest wear values, with some bulk-fill composites showing similar wear resistance ***(Baltacioglu et al., 2024).***

The wear of dental restorations using an intraoral scanner and its correlation with visual assessment was evaluated prospectively. Thirty six patients were followed-up by intraoral optical impression and visual assessment over three appointments over 12 months, where T0 is the base line, T6 after 6 months, and T12 after 12 months. The results

showed that: According to the visual indices, all restorations in this study were clinically healthy. However, in the digital measurement of wear, 94.74% and 94.44% of the restorations during the T0-T6 and T6-T12 observation periods, respectively, showed deterioration greater than 41 microns. Discordant results were obtained in the correlation analysis. In T0-T6, the results were not considered statistically significant; however, the results obtained during T6-T12 showed a correlation. They concluded that wear of dental materials as observed by the human eye did not agree with that observed by intraoral scanning. The scanner effectively measures wear, detecting details that are beyond the capability of the human eye and conventional photographs ***(Urcelay et al, 2025).***

Digital and conventional methods of wear analysis using two hybrid ceramic materials were compared. Disc-shaped samples (2 mm thick and 10 mm in diameter) were prepared from Vita Enamic and Cerasmart materials and subjected to chewing simulation. Wear evaluation was conducted using two approaches: conventional weight loss assessment before and after simulation, and digital analysis via Geomagic software by superimposing 3D scan images taken with intraoral scanner. The results revealed a positive correlation between the conventional and digital measurement methods. Statistically significant differences were observed between the two materials in terms of wear behavior. Vita Enamic demonstrated considerably more wear than Cerasmart 270 across both evaluation techniques. They concluded that both weight-based and digitally calculated volume loss methods are reliable for wear assessment, with Cerasmart 270 showing

superior resistance to wear compared to Vita Enamic ***(*ElSharouny et al, *2025).***

3. Research Q (RQ):

What is the difference between self cured bioactive and light cured nanohybrid (RBCs) regarding wear resistance and bioactivity after two years of clinical performance?

4. Research Hypothesis, Aim, Objectives & Expected Outcomes

a. Hypothesis

Null hypothesis: There is no significant difference between wear resistance and bioactivity between self cured bioactive RBC and light cured nano-hybrid one.

b. Aim

This study aims to evaluate wear resistance and bioactivity of self cured bioactive RBC in comparison to light cured nanohybrid one.

c. Objectives

1- Assessment of wear resistance of self cured bioactive RBC in comparison to light cured nanohybrid one.
2- Evaluation of bioactivity of self cured bioactive RBC in comparison to light cured nanohybrid one.

d. Expected Outcomes

Self cured bioactive RBC could show slight lower wear resistance than light cured nano-hybrid RBC with remarkable bioactive potential.

5. Research Design and Methods:

I): Materials: All materials that will be used as well as their description, composition, and manufacturers are listed in (Table1).

Table 1: The materials brand names, description, compositions and manufacturers:

Material brand name	Description	Compositions	Manufacturers
STELA Primer	primer	10-MDP, dimethacrylates, methyl ethyl ketone (MEK), water, initiators, stabilizers.	SDI Limited, Australia
STELA	Self cured bioactive bulk fill resin based composite	**Catalyst**: barium-glass, glass, ytterbium trifluoride (YbF3), silica, urethane dimethacrylate, initiators, stabilizers **Base**: strontium fluoroaluminosilicate glass, ytterbium trifluoride agglomerates (YbF3), silica, calcium aluminate (Al2CaO), urethane dimethacrylate, initiators, stabilizers	
Meta Etchant	Acid Etching gel	37% phosphoric acid, distilled water, and a colloidal Silica sol	Meta Biomed, Korea

All-bond uni-versal dental adhesive	One step self-etch adhesive	10-methacryloyloxydecyl dihydrogenphosphate, Bisphenol A glycidyl dimeth-acrylate, 2-hydroxyethyl methacrylate, Etha-nol, Water, Initiators	Bisco, INC Schaumburg, IL, USA
Filtek™ Z250 XT	Nano-hybrid resin composite	**Matrix**: Bis-GMA, UDMA, Bis- EMA. **Filler**: Inorganic fillers : zirconia, silica 78.5 wt % 63.3 vol%	3M ESPE St.Paul,M, USA

II: Methods:

II- 1 Study Setting:

A randomized controlled double-blinded clinical trial will be conducted where both patient and examiners will be blinded to the group assignment. Patients of age group 21–45 years **(Hirani et al, 2018)** will be selected where each patient should have two oclusso- mesial cavities. Patients will be recruited from the outpatient clinic of Conservative Dentistry department in the Faculty of Dentistry, Suez Canal University. During the initial examination, the purpose and the method of the research will be explained to the patients and a written informed consent will be assigned by each individual.

II-2 Sample Selection:

Patients participating in this study will be selected according to the following eligibility criteria:

II-2-a Inclusion Criteria: **(Hirani et al, 2018).**

1. Patients with vital two molar teeth with compound class II deep carious lesions.
2. Both males and females will be included.
3. Patients with good general health.
4. Patients with good oral hygiene.
5. Co-operative patients.
6. Absence of spontaneous pain, mobility or tenderness on percussion.
7. Radiographically: no internal or external resorption, no periapical or furcation radiolucency and no widening of the periodontal ligament space.

II-2-b Exclusion Criteria: (Hirani et al, 2018).

1. Patients with systemic decease.
2. Patients with severe or chronic periodontitis.
3. Patients have allergy to the materials used in this trial.
4. Nonfunctioning teeth.
5. Teeth with any pathologic pulpal changes .
6. Teeth with previous restorations.
7. Teeth with surface loss due to non carious lesions .

All patients who will attend the clinic will receive the proposed treatment protocols. However, only those who will meet the inclusion criteria will be enrolled in the study and included in the trial. Patients who

will not fulfill the inclusion criteria will also be treated but will be excluded from the study analysis.

II-3 Cavity preparation:

The same treatment protocol will be followed for all patients where each patient will receive two compound class II cavities in posterior molar teeth distributed in both sides. Local anesthesia will be administered in the beginning of the session and quadrant isolation will be administrated by rubber dam. Access through enamel and outline form will be obtained with a sterile high speed #245 bur. Following the international guidelines, all soft infected dentine will be removed, and a hard sound dentin floor should be reached. For the peripheries of the cavity, carious tissue removal to hard dentine will be performed using a sharp sterile spoon double-ended excavator and a low-speed round bur. The dentinoenamel junction, cavosurface margins and gingival box will be inspected carefully and to be clean, with at least 1.5 to 2 mm rim of peripheral sound tooth structure to provide a firm marginal adhesion for the restoration.

II-4 Randomization:

To minimize selection bias and ensure equal distribution of treatment protocol across both treated molars, simple randomization will be used to randomly determine which molar receives which material. Therefore, randomization will be performed using an online randomization tool (https://www.randomizer.org/) prior to treatment allocation where, each patient will be given a unique study number, ensuring that each patient receives both treatments in a randomly assigned manner.

II-5 Restorative procedures:

Each included patient with the already prepared cavities will receive two different types of restorations. where one of them will be restored with light cured nano hybrid RBC (Filtek™ Z250, 3M ESPE St.Paul,M,USA) (M1) meanwhile, the second cavity will be restored with self-cure bioactive RBC (Stela, SDI, Australia) (M2).

A sectional matrix system will be used to achieve proper proximal contour and anatomically correct contact with the adjacent tooth. Then, the restorative procedure of each cavity will be carried out according to the manufacturer's recommendations of each tested restoration. Before restoration each cavity will be carefully cleaned with copious air water spray before being dried. Restoration of (M1) group will be performed through selective etching of the prepared cavity enamel surface using 37% phosphoric acid gel (Meta Biomed, Korea) for 15 seconds. This will be followed by rinsing with water for 15 seconds and gentle air drying for 5 seconds, leaving the cavity slightly moist. After that, single layer of a universal adhesive bonding agent (Bisco, INC Schaumburg, IL, USA) will be applied to the prepared cavity walls and floor using disposable adhesive micro brush. The adhesive will be subsequently cured for 20 seconds using LED light curing unit (Elipar S10, 3M ESPE, St Paul, Minnesota, USA) with an intensity of 1200 mW/cm2. The nano hybrid RBC (Filtek™ Z250) will be incrementally applied, and light cured according to manufacturer instructions. Finally, finishing and polishing of the restoration using one-step polishing system (Dimanto, Voco, Germany). Then, checking of occlusion and proximal contacts will be done.

Restoration of (M2) group will be performed through conditioning of cavities with a specialized primer (STELA primer, SDI, Australia) according to manufacturer instructions. Then, a self cured bioactive RBC (STELA, SDI, Australia) will be placed in a single increment and allowed to self-cure according to manufacturer instructions. Then, finishing and polishing of the restoration, checking the occlusion and proximal contacts will be done as mentioned before.

II-6- Evaluation of the wear resistance:

A digital impression will be taken immediately after restoration (T0) using an intraoral scanner (Helios 600 intraoral scanner, Eighteeth, Changzhou, China). To ensure optimal performance and accuracy, the scanner underwent regular calibration before scanning each patient, following the manufacturer's recommendations. During the scanning procedure, the device will be positioned at a 90° angle for the occlusal surface and at 45° angles for both buccal and lingual surfaces. Later on, each restoration will be examined at standardized follow-up periods (Table 2 and 3); six months (T1), twelve months (T2), eighteen months (T3) and twenty-four months (T4). The 3D impressions will be analyzed using a software (Geomagic software, 3D Systems Inc., USA) program and the impressions of each two consultative visits will be superimposed to determine the wear volume loss (mm^3). **(Bronkhorst et al, 2022)**

II-7- Assessment of the bioactivity:

Bioactivity of each examined restoration will be determined by the evaluation of mineral density beneath the tested materials. Immediately after restoration (D0), an image plate digital sensor (Xios XG Supreme, Dentsply Sirona, UK) will be used for transmitting the radiographic

image of the selected tooth to the computer. A posterior parallel kit will be used for image standardization. Later, each restoration will be examined at standardized follow-up periods; one month (D1) and three months (D2) (Table 4 and 5). The image plate will be inserted at one end of the parallel kit, while the other end was connected to the x-ray cone. All the radiographs will be evaluated for the outcome by a software (ImageJ software, NIH, USA). The assessment of mineral density will be done by the software through performing the following measurements: in each image a line will be drawn along the CEJ to act as a reference, while another parallel line will be drawn at the bottom of the cavity. The distance between both lines will be standardized for each tooth by measuring the length of a vertical line connecting them. The length of the line centralized at the bottom of the cavity will be determined in pixels directly via the previously mentioned software. Such length will be fixed for each sample throughout assessment intervals. Three points on this line (at its start, middle and end) will be determined. The mineral density value at each of these points will be identified by taking the corresponding three readings from the software and recording them to calculate the average value. The mineral density mean value will be calculated from the software **(Ibrahim et al, 2016).**

Table 2: Variables of the wear resistance test and levels of investigations:

Variable	Level	Referred to
Type of material (M).	**M1**	Light cured nanohybrid RBC.

	M2	Self-cured bioactive RBC.
Time of follow-up (T).	**T0**	Immediately after restoration.
	T1	After six months.
	T2	After twelve months.
	T3	After eighteen months.
	T4	After twenty-four months.

Table 3: Interaction between variables for wear resistance test:

M		**Type of material (M)**		**Total**
		M1	**M2**	
Times (T)	**T0**	M1T0	M2T0	
	T1	M1T1	M2T1	
	T2	M1T2	M2T2	
	T3	M1T3	M2T3	
	T4	M1T4	M1T4	
Total		10	10	20

Sample size: n= 10

Table 4: Variables of the bioactivity test and levels of investigations:

Variable	Level	Referred to
Type of material (M).	**M1**	Light cured nanohybrid RBC.
	M2	Self-cured bioactive RBC.
Time of follow-up for mineral density (D).	**D0**	Immediately after restoration.
	D1	After one month.
	D2	After three months.

Table 5: Interaction between variables for bioactivity test:

M		**Type of material (M)**		**Total**
		M1	**M2**	
Times (D)	**D0**	M1D0	M2D0	
	D1	M1D1	M2D1	
	D2	M1D2	M2D2	
Total		10	10	20

Sample size: n= 10

6- Sample size calculation:

Sample size calculation was performed using G*Power version 3.1.9.2, **(Faul *et al,* 2007)** University Kiel, Germany. Copyright (c) 1992-2014.

$$f = \frac{\sigma_\mu}{\sigma}$$

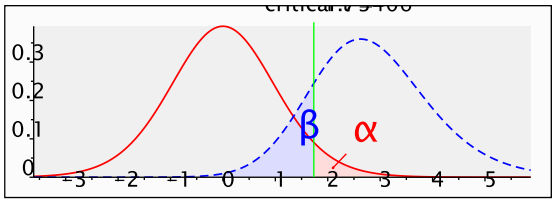
$$\sigma_\mu^2 = \frac{\sum_{i=1}^{k} n_j (\mu_i - \mu)^2}{N}$$

Where:

f: is the effect size; α= 0.05; β= 0.05; Power= 1- β = 0.80

The effect size *d* was **1.22 (large)** according to the previous studies (**Elderiny et al., 2024)** with alpha (α) level of 0.05 and Beta (β) level of 0.05, i.e., power = 80%; the estimated sample size (n) should be **20** samples and will be divided into **two groups**.

To account for dropouts, the sample size will be expanded by 20%, which produced 12 restorations for each group instead of 10.



Statistical analysis:

All collected data will be calculated, tabulated, and statistically analyzed using suitable statistical tests as follows: **A normality test:** will be done to check normal distribution for data by Shapiro-Wilk test. **Descriptive statistics:** will be calculated in the form of mean ± standard deviation (SD), range (Max-Min). Qualitative data will be presenting as (%) frequencies (n) and percentages. **T- test or Mann-Whitney test**

(***According to the types of data***). Independent Student's T-test or Mann-Whitney will be performed for pair wise comparison between groups in each time at P value < 0.05. **The Chi-square test** will be used to test significance of association between categorical variables. **Pearson's correlation coefficient:** will be used for estimating the relationship between quantitative variables. **P<0.05** is considered significant. Statistical analysis will be performed using the computer program SPSS software for windows version 26.0 (statistical package for social science, ARMONK, NY: IBM Corp).

7. Ethics consideration:

The present research will be conducted after the approval of the Research Ethics Committee (REC) of the faculty of Dentistry, Suez Canal University. Ethical considerations regarding patient well-being and confidentiality will be undertaken by the researcher and informed written consent will be signed by the patients before commencing the study explaining all clinical examinations, procedures, and follow-up. (Attached appendix I)

8. Time Plan

Starting after approval of the ethical committee and faculty council.

Ending after 24 months.

Activity/Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Patient selection	☒	☒	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Material application	☐	☐	☐	☐	☐	☒	☒	☒	☒	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Statistics	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐
Writing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☒	☒	☒	☐	☐	☐	☐	☐
Revision	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☒	☒	☒	☒

9. Research Estimated Budget in Egyptian Pound

Supplementary						Publications	Total
Material	**Scanning**	**Softwares**	**Tests**	**Statistics**	**Others (Designing)**	**International publication**	
15,000	5000	53000	12000	5000	-	10,000	100000

10. References:

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11. Appendices

Appendix I

Suez Canal University

Faculty of Dentistry

Research Ethics Committee (REC)

Investigator Application Form

1-Name of researcher: Nada Ismail Mohammed Saleh

2-Name of Department: conservative dentistry.

3-Address of researcher: Ismailia, Egypt

a- Email: nada.saleh@su.edu.eg

b- Phone number: 01063488822

4- Names of Co-investigators:

Prof. Dr. Rehab Elsafy and Dr. Basma Hosny

5- Grade of protocol:

*M.D.Sc. ( ) *Ph.D. ( ) *Doctorate degree (D.D.Sc.) (√) *Other ( )

*Domestic (√) *Multi-Centre within Egypt ( )
*International ( )

6- Title of the research: **Clinical Evaluation of Wear Resistance and Bioactivity of Self cured Bioactive Resin Composite.**

7-Type of the research:

*Drug trial ( ) *Surgical technique ( ) *Investigative technique (√)

*Devise study ( ) *Survey study ( ) *Blood sampling ( )

*Review of old records ( )

8-Subjects of research:

*Children (< 18 years): ( ) *Adults (>18 years) (√)

* Vulnerable groups (yes) or (no)

9-Request is being made to *waive* (give-up) informed consent:

Yes: ( ) No: (√)

10- The research is for the good of society:

Yes: (√) No: ( )

11-Study design:

a-Phase type

I: ( ) II: ( ) III: ( )

b-Randomization:

Yes: (√) No: ( )

c-Placebo:

Yes: ( ) No: (√)

d-Genetic sampling:

Yes: ( ) No: (√)

e-Other: Yes: ( ) No: ( )

12-Facilities for the research are available:

Yes: (√) No: ( )

13- List the risks of the study:

No risks have been reported.

14- List the potential benefits, if any, to the subjects:

The patient will receive the treatment with no fees.

15-Are the risks reasonable to the potential benefits to the subjects, if any, or to the knowledge to be gained?

Yes: (√) No: ( )

16-Privacy and confidentiality of subjects are assured

Yes: (√) No: ( )

17-The subject of the research could quit at any time without penalty or loss of any benefits to which they would otherwise be entitled

Yes: (√) No: ( )

Signature of the principal investigator:

Date:

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