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Clinical Research

Pure Ormocer vs Methacrylate Composites on Posterior Teeth: A Double-blinded Randomized Clinical Trial

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Clinical Relevance

The clinical behavior of pure ormocer composite is reliable when used in class II restorations after 24 months of evaluation.

SUMMARY

Objective: The aim of this study was to evaluate the clinical performance of class II restorations made using pure ormocer and methacrylate composites in a period of 24 months, using a split-mouth double-blinded randomized design.

Methods and Materials: Thirty patients received two class II restorations (n=60) performed with different composites: GrandioSO (methacrylate, nanohybrid) and Admira Fusion (pure ormocer, nanohybrid). The universal adhesive system (Futurabond M+) was applied in all restorations using the self-etching mode. The composites were placed by the incremental technique. The restorations were evaluated using the FDI World Dental Federation criteria after 7 days and 6, 12, and 24 months postoperatively.

Results: After 24 months, 23 patients attended the recall and 46 restorations were evaluated. Fisher's statistical analysis (5%) showed no difference between the materials. One pure ormocer restoration and one methacrylate restoration presented small fractures. Only one tooth suffered a fracture of the remaining tooth structure. Admira Fusion presented, respectively, 100%, 95.66%, and 100% of accept-

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able performance in general scores for esthetic, functional, and biological properties. GrandioSO presented, respectively, 100%, 91.31%, and 95.66% of acceptable performance in the same scores.

Conclusion: After 24-month follow-up, nonsignificant differences between the tested composites was detected. Both materials provided acceptable clinical performance in class II restorations.

INTRODUCTION

The demand for dental materials with high esthetics and longevity led to the research and development of new composites. Composition, size, shape, distribution, and content of filler particles are paramount for the composite's properties.[1,2] Great efforts in recent years have been made to improve the filler technology, increasing the mechanical and esthetic properties of these materials, resulting in the current nanohybrid and nanoparticle containing composites.[3] However, few changes were performed in relation to the organic matrix, and many traditional dimethacrylate monomers are still in use.

Bis-GMA (bisphenol A-glycidyl methacrylate) has been the main monomer used in composite formulations since its development in 1956 by Bowen.[4] Due to its high viscosity, it is necessary to add low molecular weight monomers in the blend to achieve the appropriate viscosity on the final formulation for clinical use.[5] However, these diluent monomers increase the polymerization shrinkage and water sorption of the composites.[6] In addition, unreacted monomers are eluted from the cured material, increasing its cytotoxicity to the pulp cells.[7] Thus, aiming to improve the properties of the composite restorative materials, new monomers have been investigated.

Ormocer is the acronym for organically modified ceramic. They are produced by hydrolysis and polycondensation reactions (sol–gel processing) to form a molecule with a long inorganic silica chain backbone and organic lateral chains.[8] Compared with Bis-GMA, the ormocer molecule has more methacrylate groups available to set bonds.[9] The composites with ormocer are expected to demonstrate higher degree of conversion and increased wear resistance and toughness due to the formation of a polymer network more highly crosslinked.[10] Another advantage of ormocer would be higher biocompatibility, because the increased number of chemical bonds between the methacrylate groups would reduce the amount of unreacted free monomers in the polymer network.[11]

However, the first generation of ormocer composites contained, besides the ormocer molecules, regular low molecular weight dimethacrylate monomers acting as diluents. The presence of such diluents may have hampered the expected results, and no clear advantages were observed when using the first-generation ormocer-based fillings in comparison with conventional composites.[12,13] Recently, a pure ormocer composite was developed. According to the manufacturer, there is no diluent methacrylate monomer in the composition, because special ormocer molecules of various viscosities were created.

In comparison with methacrylate composites, the new ormocer material may offer advantages of lower polymerization shrinkage and water sorption.[14,15] In addition, this new material was reported to present higher microhardness and degree of conversion.[16] However, there is still a lack of information regarding its clinical performance. Thus, the aim of this study was to investigate the clinical performance of a pure ormocer and a methacrylate-based resin composite in class II restorations. The null hypothesis tested was that the monomer composition (ormocer × methacrylate) does not influence the restoration clinical behavior in relation to esthetic, functional, and biological properties.

METHODS AND MATERIALS

The description of the experimental design followed the Consolidated Standards of Reporting Trials (CONSORT) statement.[17]

Trial Design, Settings, and Location of Data Collection

This was an equivalence, split-mouth, double-blind (patients and examiner), randomized clinical trial. The study was carried out in the clinics of the School of Dentistry at the local University from August 2014 to January 2017.

The PICO question was stated, and the parameters were defined: P, adult patients presenting two class II cavities; I, restoration performed with pure ormocer composite; C, restoration with methacrylate composite; and O, clinical performance according to FDI World Dental Federation criteria. The research question analyzed was as follows: Do composite class II restorations made with pure ormocer composite present better clinical performance than restorations

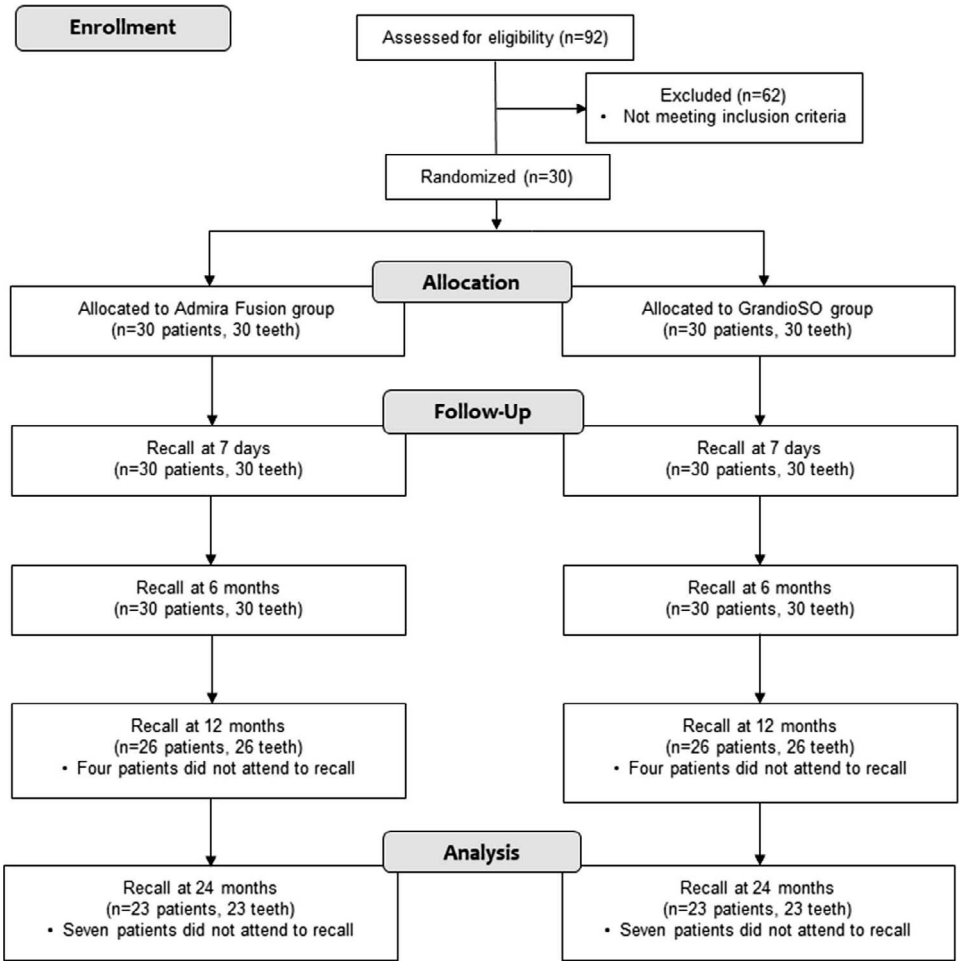

Figure 1. *CONSORT 2010 flow diagram.*

made with methacrylate composite according to FDI criteria?

Recruitment

The patients were selected as they searched for treatment in the local university. No advertisement was made for participant recruitment, forming a sample of convenience.[18]

Eligibility Criteria

A total of 92 participants were examined to form a group with 30 patients that attended to the inclusion and exclusion criteria (Figure 1). Patients were required to have good general health, be older than 18 years old, and present at least 20 teeth in occlusion. Patients with extremely poor oral hygiene, severe or chronic periodontitis, or heavy bruxism habits were excluded from the study. Patients had to present at least two teeth with class II cavities to be restored (two molars or two premolars). The cavities had to present size of the isthmus being no more than two-thirds of the intercuspal distance; the antagonist and the adjacent tooth had to make contact; there needed to be vital pulp; and there needed to be an absence of painful symptoms.

Sample Size Calculation

The sample size calculation was based on the clinical success rate (97.5% at 24 months) of posterior class II composite restorations observed in a previous study.[19] Using a significance level of 0.05, power of 80%, and equivalence limit of 15%, the sample size required per group was 23 teeth. Considering the possible dropouts, a total of 30 patients were selected, totaling 60 restorations, 30 for each group.

Random Sequence Generation and Allocation Concealment

The randomization was performed using online software (www.sealedenvelope.com). A blocked list was generated, and a randomization code was performed according to two treatment possibilities

Table 1: *Materials Used in the Restorative Procedures*

Material	Manufacturer	Composition		
Futurabond M$^+$	VOCO	UDMA, HEMA, 10-MDP, camphorquinone, BHT, ethanol, and water		
GrandioSO	VOCO	Organic matrix: Bis-GMA, Bis-EMA, TEGDMA	Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02-1 μm)	Filler content: 87% w/w
Admira Fusion	VOCO	Organic matrix: organically modified ceramic (Ormocer)	Inorganic fillers: barium aluminum borosilicate glass ceramic filler, silicon dioxide nanoparticles (0.02-1 μm)	Filler content: 84% w/w

Abbreviations: UDMA - urethane dimethyl methacrylate, HEMA – Hydroxyethylmethacrylate, 10-MDP – 10-methacryloyloxydecyl dihydrogen phosphate, Bis-GMA – bisphenol A-glycidyl methacrylate, TEGDMA – triethylene glycol methyl ether methacrylate.

(GrandioSO or Admira Fusion). Thus, the operator started at the first quadrant to be restored and then chose between two opaque sealed envelopes containing the randomization code; the envelopes were prepared by a staff member not involved in any of the phases of the clinical trial.

Interventions: Restorative Procedure

Three operators, each with at least three years of clinical experience, performed all interventions. Shade selection was performed using a VITA Classical shade guide (VITA Zahnfrabrik, Bad Säckingen, Germany). All patients received local anesthesia before the tooth preparation, which was performed using a high-speed handpiece fitted with a round diamond bur under water cooling. When present, carious dentin was removed with a round carbide bur at low speed. The outline shape of the preparations was limited to the removal of caries/defective restoration, without beveling. Isolation with rubber dam and clamps was performed. Each patient received at least two restorations, one using a pure ormocer composite and another using a methacrylate composite, subjecting the different materials to the same clinical conditions and enabling the comparison between them. Table 1 presents the specifications of the materials used.

In deep preparations, a glass-ionomer cement liner (Meron R, Voco, Cuxhaven, Germany) was applied on the pulpal wall. In very deep preparations, calcium hydroxide cement (Dycal, Dentsply, Rio de Janeiro, Brazil) was applied, followed by a thin layer of glass ionomer cement.

Futurabond M+ (Voco) was used in self-etching mode according to manufacturer's instructions for all preparations. A thin layer of adhesive was actively applied for 20 seconds, followed by a gentle blow of air for five seconds and light curing for 10 seconds. The light curing was performed with an LED device having an emittance of 700 mW/cm^2 (Emitter A, Schuster, Santa Maria, RS, Brazil).

Restorative procedures were performed using a precurved metallic sectional matrix (Unimatrix System, TDV, Pomerode, SC, Brazil), associated with a separating ring and a wooden wedge. The composite was applied using an incremental oblique technique. Each increment of 2 mm was light cured for 20 seconds. Finishing was performed with fine-grain diamond burs (KG Sorensen, São Paulo, SP, Brazil). At the proximal surface, any excess was removed with abrasive strips (3M ESPE, St Paul, MN, USA). After seven days, the polishing procedures were performed with abrasive silicone tips (Dimanto, VOCO, Cuxhaven, Germany) and at the proximal surfaces with fine-grained strips.

Calibration Procedures for Clinical Evaluation

Two examiners who did not participate in restoration placement were trained for restoration evaluation with an online calibration tool (www.e-calib.info) in August 2014. Intraexaminer and interexaminer agreement of at least 85% was necessary before beginning the evaluation.[20]

Blinding

The study was classified as double-blind, because participants and the examiners (who were not involved with the restoration procedures) were blinded to the intervention.

Clinical Evaluation

Intraoral photographs were taken at baseline and at the recall appointments. Digital images were obtained using a Canon T3i camera with a Macro lens (Canon, Ota, Tokyo, Japan).

Restorations were evaluated after 7 days and 6, 12, and 24 months according to the FDI criteria.[21,22] Visual assessment of restorations was performed

Table 2: *Number of Lesions According to Sex and Age of Patients*

Characteristics of Patients	Number of Lesions
Sex	
Female	48
Male	12
Age (years)	
20-29	4
30-39	4
40-49	10
50-59	8
≥60	4

under dental unit overhead light without magnification. Cotton roll isolation was used to ensure a dry field. The marginal adaptation was analyzed with special probes. The marginal gap width was classified using two special probes (Deppeler, Rolle, Switzerland) with tip diameters of 150 and 250 μm. The firmness of the contact was first checked with a waxed dental floss. If it was considered weak, metal blades of increasing thicknesses (25, 50, and 100 μm) were inserted into the interdental space, determining the thickest one that could enter the interproximal area. For each of the evaluated parameters, one of the following scores was assigned: clinically very good; clinically good; clinically sufficient/satisfactory; clinically unsatisfactory; and clinically poor. Disagreements between examiners were discussed to reach a consensus.

Statistical Analysis

The statistical analyses followed the intention-to-treat protocol according to the CONSORT recommendation.[17] This protocol includes all subjects in their originally randomized groups, even those that were not able to keep the scheduled recall visits. This approach is considered more conservative and less open to bias.

Descriptive statistics were used to describe the distributions of the evaluated criteria. Statistical analysis for each individual item was performed, as well as for each overall parameter. The differences in the ratings of the two groups after 24 months were tested with the Fisher's exact test, with a significance level of 5%.

RESULTS

The restorative procedures were implemented exactly as planned, and no modification was performed. Sixty-two of 92 subjects were not enrolled in the study because they did not fulfill the inclusion criteria. Thus, 30 subjects were selected. Details regarding the characteristics of the research subjects and the restored cavities are shown in Tables 2 and 3.

Table 3: *Characteristics of Restored Cavities*

Characteristics of Restored Tooth	Number of Lesions
Tooth distribution	
Premolars	36
Molars	24
Dental arch distribution	
Maxillary	38
Mandibular	22
Presence of antagonist	
Yes	60
No	0
Pulp protection	
Yes	53
No	7
Faces involved	
OM	15
OD	27
MOD	18
Width	
Small	17
Medium	18
Large	25
Depth	
Shallow	9
Medium	28
Deep	23
Reason for restoration	
Caries	3
Fracture	14
Caries and fracture	3
Esthetic	26

The percentage of patients that attended recall evaluations was as follows: 100% (7 days), 100% (6 months), 87% (12 months), and 77% (24 months). The qualitative evaluation according the FDI guidelines is presented in Table 4. The overall Cohen's κ statistics showed excellent agreement between the examiners in the 7-day (0.93), 6-month (0.96), 12-month (0.96), and 24-month (0.91) follow-up.

After 24 months, only one restoration made with pure ormocer composite and one made with methacrylate composite presented small fractures, which did not indicate the need for replacement of the restoration. Only one tooth presented fracture of the remaining dental structure (one nonsupporting

Table 4: *Number of Evaluated Restorations and Classification According to the FDI Criteria*

FDI Criteria	Score	7 Days		6 Months		12 Months		24 Months	
		OR	MA	OR	MA	OR	MA	OR	MA
Esthetic properties									
1. Surface luster	Clinically excellent	30	30	27	28	21	22	18	16
	Clinically good	—	—	3	2	5	4	5	7
2. Staining									
a) Surface	Clinically excellent	30	30	27	26	22	19	20	17
	Clinically good	—	—	3	4	4	7	3	6
b) Marginal	Clinically excellent	30	30	28	27	19	‘8	14	13
	Clinically good	—	—	2	3	7	8	9	10
3. Color match and translucency	Clinically excellent	26	28	26	28	22	23	19	18
	Clinically good	4	2	4	2	4	3	4	5
4. Esthetic anatomical form	Clinically excellent	30	30	30	30	26	26	23	23
Functional properties									
5. Fracture and retention	Clinically excellent	30	30	30	30	25	26	20	21
	Clinically good	—	—	—	—	1	—	1	1
	Clinically satisfactory	—	—	—	—	—	—	1	—
	Clinically unsatisfactory	—	—	—	—	—	—	1	1
6. Marginal adaptation	Clinically excellent	30	30	27	28	23	24	18	18
	Clinically good	—	—	3	2	3	2	4	3
	Clinically satisfactory	—	—	—	—	—	—	1	2
7. Occlusal contour and wear									
a) Qualitatively	Clinically excellent	30	30	30	30	26	26	23	23
b) Quantitatively	Clinically excellent	30	30	30	30	26	26	23	23
8. Proximal anatomic form									
a) Contact point	Clinically excellent	24	23	24	24	21	20	19	18
	Clinically good	2	2	2	1	1	1	—	1
	Clinically satisfactory	4	5	4	5	4	5	4	4
b) Contour	Clinically excellent	30	30	30	30	26	26	23	23
9. Patient’s view	Clinically excellent	30	30	30	30	26	25	23	22
	Clinically good	—	—	—	—	—	1	—	—
	Clinically satisfactory	—	—	—	—	—	—	—	—
	Clinically unsatisfactory	—	—	—	—	—	—	—	1
Biological properties									
10. Postoperative sensitivity	Clinically excellent	25	22	28	27	25	24	21	21
	Clinically good	5	7	2	3	1	2	1	1
	Clinically satisfactory	—	1	—	—	—	—	1	1
11. Recurrence of caries, erosion and abfraction	Clinically excellent	30	30	30	30	25	25	23	23
	Clinically good	—	—	—	—	1	1	—	—
12. Tooth integrity	Clinically excellent	30	30	30	30	26	26	23	22
	Clinically good	–	–	–	–	–	–	–	–
	Clinically satisfactory	–	–	–	–	–	–	–	–
	Clinically unsatisfactory	–	–	–	–	–	–	–	–
	Clinically poor	–	–	–	–	–	–	–	1
13. Periodontal response	Clinically excellent	25	24	27	28	24	24	22	22
	Clinically good	5	6	3	2	2	2	1	1
14. Adjacent mucosa	Clinically excellent	29	28	30	30	26	26	22	22
	Clinically good	1	2	–	–	–	–	1	1
15. Oral and general health	Clinically excellent	30	30	30	30	24	24	21	21
	Clinically good	–	–	–	–	1	1	1	1
	Clinically satisfactory	–	–	–	–	1	1	1	1

Abbreviations: MA, methacrylate composite; OR, pure ormocer composite.

cusp). The fractured areas were restored with the same technique and materials applied at the baseline. Fisher's exact test detected no significant difference ($p>0.05$) among evaluated FDI criteria for the two materials after 24 months.

In general scores for esthetic, functional, and biological properties, the pure ormocer composite presented, respectively, 100%, 95.66%, and 100% of clinically acceptable scores and the methacrylate composite presented, respectively, 100%, 91.31%, and 95.66%.

DISCUSSION

The results of this study showed that the different composites did not influence the clinical performance of class II restorations after 24 months. Thus, the null hypothesis tested was accepted.

Minimizing polymerization shrinkage is still the main goal of composite science development, because it remains as the principal reason for restorations failure. Shrinkage occurs during polymerization as weak van der Walls forces are converted into covalent bonds, reducing the distance between monomer molecules while forming a polymer.[23] The shrinkage stress at the tooth-restoration interface can produce cuspal deflection, fracture of the remaining tooth structure, and formation of marginal gaps, which have been associated with marginal staining and postoperative sensitivity.[23] A previous study found lower polymerization shrinkage in the latest version of ormocer composites compared with traditional methacrylate-based materials.[14] This may be due to the fact that ormocer molecules are larger than the Bis-GMA,[9] promoting a lower volumetric reduction of the material. However, the results of the current study showed no significant differences between the pure ormocer and the conventional methacrylate composite, regarding the marginal stain and postoperative sensitivity. This may be due to the incremental technique that may have reduced the effects of the polymerization shrinkage[24] and masked the differences between the composites.

Nonsignificant differences were detected between the composites in the parameters related to the esthetic properties. They presented only "clinically excellent" and "clinically good" scores. Both composites tested contain the same nanohybrid particles and similar filler content (w/w). The filler size and distribution are the main determining factors for surface properties such as roughness and gloss after polishing.[25] In addition, the nanoparticles present size below the wavelength of visible light (0.1-100 nm) that provides translucency and opalescence to these materials, enhancing their esthetic properties.[26]

Nonsignificant differences were detected between the composites in the parameters related to the functional properties. After 24 months, only one restoration made with pure ormocer and one made with methacrylate composite presented small fractures with partial loss (less than half of the restoration). A previous review showed that the incidence of fractures is higher in the first three years after the placement of the restoration.[27] Thus, we may speculate that in the next follow-ups, the fracture rate of the restorations will tend to remain low, indicating an excellent performance of the composites.

Both composites showed similar biological properties results. No caries recurrence was observed in the present study, which may be an indication that the restorations with both composites present an excellent polishability, reducing the biofilm retention. However, it should be highlighted that secondary caries trends occur later, being detected in longer-term follow-up periods.[27] Thus, a longer follow-up time may be necessary to confirm the observed results.

Soft tissue response to dental materials may be detected by effects on the periodontium and adjacent mucosa. These effects may be related to presence of residual unreacted monomers, roughness, and biofilm accumulation.[21] A previous *in vitro* study showed that the methacrylate and the ormocer composite tested present a low surface roughness, even after abrasive episodes.[16] The Bis-GMA molecule has two polymerizable units, whereas the ormocer has numerous organic polymerizable ones that increases the probability of interaction and chemical bonding with neighbor molecules and reduces free monomers after curing.[9] Thus, pure ormocer composites are expected to present better biological properties. However, within the limits of this study, it was not possible to demonstrate better clinical behavior of the improved ormocer restorative material in relation to the conventional nano-hybrid composite over two years. A longer period of evaluation may be necessary to show potential relevant differences.[28]

Previous studies demonstrated the role of the adhesive system on the clinical performance of a dental restoration, mainly related to postoperative sensitivity, marginal staining, retention, and sec-

ondary caries.[28,29] In the current study, all restorations were performed with a self-etching adhesive containing 10-MDP acidic monomer, which is incorporated in different adhesive formulations by various manufacturers. Besides micromechanical retention provided by the hybrid layer and tag formation, 10-MDP showed chemical bonding to the tooth structure, contributing to the bonding durability.[30,31] The adhesive system used was compatible with the pure ormocer restorative material formulation. According to the manufacturer, the adhesive system tested can be used with or without total or selective acid etching. They claim that the formulation is capable of effectively etching enamel and dentin without previous acid treatment, which was demonstrated in previous *in vitro* studies.[32,33] Therefore, it was decided to test the clinical performance of the material in association with ormocer material in its more challenging situation, based only on its self-etching properties. Previous clinical trials demonstrated adequate performance of this adhesive in the self-etching mode only, in association with methacrylate-based composites.[19,34]

According to the guidelines proposed by the American Dental Association, adhesive-based materials can be considered clinically acceptable if, after a six-month follow-up, they present less than 5% failure rate.[35,36] For full acceptance, the restoration losses cannot exceed 10% after a period of 18 months. Thus, the materials tested in this study could obtain complete acceptance, because the fracture rates of the pure ormocer and the methacrylate composites were both 3.33% (one failure in 30 restorations). The advantages of the ormocer technology that has been demonstrated *in vitro*[14-16,37] offers potential clinical advantages that may be proven with continued clinical studies.

CONCLUSION

After a 24-month follow-up, ormocer and methacrylate-based composites showed acceptable clinical performance in class II restorations. Nonsignificant differences were detected between both materials.

Acknowledgement

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Regulatory Statement

This study was approved by the local Institutional Review Board (no. 924.098) and registered in a National Clinical Trial Registry System under protocol RBR-9W5P8Q. The participants were informed about the nature and objectives of the study, and a consent form was signed by each one.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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