# Clinical Performance of Minimally **Invasive Monolithic Ultratranslucent** Zirconia Veneers: A Case Series up to Five Years of Follow-up

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## **Clinical Relevance**

The ultratranslucent zirconia treated with silicatization and silane seems to be an excellent option for aesthetic treatment with minimally invasive laminate veneers.

## SUMMARY

There is a lack of reports in the literature on the long-term clinical performance of ultratranslucent zirconia, especially considering its use in manufacturing monolithic veneers. The purpose of this case series is to describe the aesthetic treatment steps of three patients with minimally invasive ultratranslucent zirconia veneers and to report the clinical findings up to five years. Three patients (woman: 2, man: 1; mean age: 30 years) unsatisfied with their dental aesthetics sought dental treatment. The treatment plan involved cementing ultratranslucent zirconia veneers. Airabrasion was performed on the internal surface of zirconia with alumina particles coated by silica (silicatization), followed by silane and adhesive applications for the adhesive cementation. All veneers were adhesively cemented to enamel with resin cement (Variolink Esthetic, Ivoclar).

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The patients were clinically evaluated annually masidering the Ryge modified/ California Dental Association criteria. After a mean followof 4.33 years (4-5 years), a survival rate of was detected for the 28 minimally invasive ultratranslucent zirconia veneers cemented in = 3 patients. There were no absolute failures such as debonding, veneer fracture, or secondary aries. Superficial marginal discoloration was abserved in one element (maxillary left lateral mcisor) of one patient. Ultratranslucent zirconia 2 viable option for manufacturing veneers due its excellent clinical performance and longevity. However, further long-term clinical studies are essential to consolidate this material as an option for esthetic restorations.

## INTRODUCTION

Deramic veneers are a conservative treatment that two been widely used to enhance dental aesthetics by being the shape, size, color, and/or positioning of teeth. The technological advances in ceramic and athesive materials, fabrication methods, and workflow two contributed to the excellent predictability and thical performance of this treatment. Silica-based to their excellent optical properties and aesthetics. The estimated cumulative survival rate of laminate to their excellent optical properties and aesthetics. The estimated cumulative survival rate of laminate the estimated of silica-based material is satisfactory: 195% CI: 84% to 94% in a median follow-up period of 9 years. However, fracture/chipping of the teramic was one of the most common failures.

The type of ceramic material may influence the fracture occurrence of laminate veneers.5 In this context, the use of zirconia, a polycrystalline ceramic, manufacturing veneers may be an advantage due to its excellent mechanical properties. Zirconia has become the most versatile ceramic material in the oral rehabilitation field due to its wide range of clinical indications. The changes in microstructures and composition of this material enable the association of well-known zirconia characteristics, excellent mechanical properties, and biocompatibility, with improved optical properties and aesthetics.6 Three generations of zirconia are currently available: the first generation, conventional zirconia (~900 to 1200 MPa);7 the second generation, translucent zirconia (≈900 to 1200 MPa);7 and the third generation, ultratranslucent zirconia (≈400 to 800 MPa).7

Ultratranslucent zirconia presents improved optical characteristics and aesthetics, but lower mechanical

strength than the first and second generations.8 These characteristics are due to the increased amount of yttria in the ceramic composition (4-5mol% yttria) and the greater proportion of isotropic cubic phase, which presents reduced light scattering and increased translucency.7 However, these factors also suppress the transformation toughening mechanism of zirconia responsible for the tetragonal to monoclinic phase transformation, which contributes to the higher mechanical strength of the previous generations. Moreover, it has been reported that the third generation seems to be more resistant to hydrothermal degradatation.6 In vitro studies have reported that the translucency of the third-generation zirconia is higher than the first and second generation, but inferior to lithium disilicate. 8,9 In addition, studies have shown that the mechanical strength of ultratranslucent zirconia is similar to or higher than lithium disilicate, and lower than the earlier generations of zirconia.8-10

Although ultratranslucent zirconia is not commonly considered for producing laminate veneers, it is one of the manufacturer's indications and has been reported in a clinical case.11 Souza and others11 showed that there were no fracture or debonding failures of the six ultrathin laminate veneers manufactured by ultratranslucent zirconia after one-year follow-up. The veneers were air-abraded with alumina particles coated with silica followed by a 10-methacryloxydecyl dihydrogen phosphate monomer (10-MDP) silane agent before adhesive cementation. The association of mechanical (air-abrasion) and chemical (ceramic primer with 10-MDP) methods seem to be the most suitable surface treatment for zirconia restorations with no mechanical retention to preparations, such as laminate veneers. 12-14

Hence, the use of third-generation zirconia in manufacturing laminate veneers may be an advantage due to higher mechanical strength, which may decrease the fracture of the veneers during the try-in stage and clinical use. 11 Considering the scarcity of long-term clinical reports on the performance of ultratranslucent zirconia laminate veneers, the present study aimed to report a case series with up to five years of follow-up.

# **CLINICAL CASE REPORT**

This study presents a case series of three patients, named LVA (patient #1); LOADA (patient #2); and PPB (patient #3) (2 women and 1 man), aged between 28 and 32 years (mean age: 30 years) who sought dental aesthetic treatment in the local Dental Schools. These patients are part of a clinical study approved by the Ethics Committee (no 2.484.387) and registered as a Clinical Trial (https://ensaiosclinicos.gov.br/

Table 1: Material, Trademark, Manufacturers, and Chemical Composition of the Materials Used for Veneer Fabrication
and Cementation Steps

and Cementation Steps	Trademark	Manufacturer	Composition	
Material  Ultratranslucent zirconia	Prettau Zirkonzahn		$ZrO_2>85$ wt%, $Y_2$ $O_3<12$ wt%, $Al_2O_3<1$ wt%, $SiC$ max.0.02 wt%, and $Fe_2O_3$ max 0.02 wt%	
Aluminum oxide particle	Anterior Cojet	3M ESPE Aluminum oxide and synthetic amorphous s fumed, crystalline free		
coated with silica Silane	Monobond N	Ivoclar Vivadent	Alcohol solution of silane methacrylate, phosphoric acid methacrylate and sulphide methacrylate	
Phosphoric acid 35%	Ultra-Etch	Ultradent	Phosphoric acid, cobalt aluminate blue spine and siloxane	
Adhesive System	Tetric N-Bond Universal	Ivoclar Vivadent	Methacrylates, ethanol, water, highly dispersed silicon dioxide, initiators, and stabilizers	
Resin cement	Variolink Esthetic LC	Ivoclar Vivadent	ytterbium trifluoride, urethane dimethacrylate, glycerin-1.3-dimethacrylate, 1,10-decandiol dimethacrylate	

rg/RBR-33v2cd). All patients signed an informed consent authorizing the treatments and use of images. The aesthetic treatment of the patients involved the cementation of 28 minimally invasive monolithic ultratranslucent zirconia veneers from July 2017 to May 2018. The materials used in the treatments are described in Table 1.

## Patient #1

A 30-year-old male patient, LVA, sought dental aesthetic treatment with the complaint of dissatisfaction with the size and color of his maxillary teeth. The presence of pigmented resin composite veneers and a fracture at the incisal edge of element 12 was found in the clinical examination (Figure 1A). A width/length

ratio of 95% and 97% for right and left maxillary central incisor, respectively, and the need to correct the gingival contouring of maxillary right lateral incisor and canine was observed during the digital smile design (DSD). The treatment plan involved zirconia minimally invasive laminate veneers for the maxillary right second premolar to the left second premolar (10 veneers) and gingivoplasty in the maxillary right lateral incisor and canine to promote smile evenness.

## Patient #2

A 32-year-old female patient, LOADA, sought dental aesthetic treatment because she was unsatisfied with her smile aesthetics. Agenesis of the lateral incisors was detected in the clinical examination, with the canines

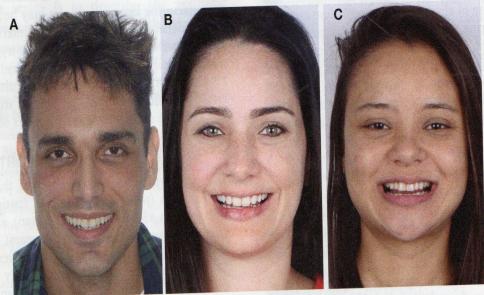


Figure 1. Frontal view of the initial facial appearance of the patients. (A) Patient #1. (B) Patient #2. (C) Patient #3.



Figure 2. Digital smile design (DSD) for determining tooth proportion, analyzing the gingival contouring, and planning the periodontal surgery.

in the position of the lateral incisors after orthodontic treatment, and the presence of unsatisfactory resin composite veneers at maxillary central incisors and canines, unfavorable dental proportion and inadequate gingival contouring (Figure 1B). After the DSD, a dental proportion (width/length ratio) of 100% and the need to correct the gingival zenith was diagnosed. Aesthetics planning was established to improve the dental proportion involving gingivoplasty and zirconia minimally invasive laminate veneers for the maxillary right second premolar to the left second premolar (except the lateral incisors, which were absent) (8 veneers) to improve the width/length ratio, shape, and color.

## Patient #3

A 28-year-old female patient, PPB, sought dental aesthetic treatment with a complaint of dissatisfaction with the shape and size of her teeth and an uneven smile. The presence of unsatisfactory resin veneers on the central incisors and unfavorable dental proportion were observed in the clinical examination (Figure 1C). A width/length ratio of 90% and 100% for the right and left maxillary central incisor, respectively, and a discreet dental midline deviation was detected during the DSD. The treatment plan involved zirconia minimally invasive laminate veneers for the maxillary right second premolar to left second premolar (10 veneers) elements to improve the smile aesthetics.

All patients involved were submitted to the anamnesis, intra- and extraoral examination, photographs, signing the consent form, and initial impression to obtain the diagnostic casts that were mounted in the semi-adjustable articulator with the aid of a facebow in the first stage of the aesthetic treatment. The DSD of each patient was performed to analyze the discrepancy between the facial and dental middle line and inclination of the dental middle line, the necessity of gingivoplasty to correct the gingival contouring and zenith, correction of the dental proportion (approximately

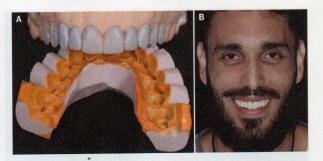


Figure 3. (A) Waxed cast based on the DSD and index for the mock-up. (B) Front view of the mock-up simulating incisal and gingivoplasty.

80%), and shape (Figure 2). The DSD was presented to the patient, and after the approval, the diagnostic wax-up was made on the maxillary cast mounted in the articulator after the DSD measurements. Next, the mock-up was performed with bis-acryl resin A1 (Protemp-4, 3M ESPE, St Paul, MN, USA) to evaluate the aesthetic and functional parameters (Figure 3A-B). The occlusal contacts and eccentric mandibular movements were assessed with metallic articulating film (Arti-fol 12 μm, Bausch Articulating Papers Inc, Nashua, NH, USA). After patient approval, patients #1 and #2 were received gingivoplasty, and 60 days were allowed for healing.

In the next phase, the direct resin composite veneers of the maxillary teeth involved in the aesthetics treatment were removed with multilaminate burs (#H375R.314.018, Komet, Lemgo, Germany) at low speed to expose the enamel substrate (Figure 4A). Condensation silicone (Z) (Zetaplus, Zhermack, Badia Polesine, Italy) index was made from the diagnostic wax to guide the tooth preparation for minimally invasive veneers. 11 All the tooth preparations were performed on dental enamel. A diamond bur (#8862.314.012, Komet) was used to define tilted chamfered margins, to remove a uniform thickness of 0.3 mm of the three dimensions (cervical, middle, and incisal thirds) of the vestibular surface, and to round the angles. The preparations were finished and polished with fine diamond burs, multilaminate burs (#H48L.314.012, Komet), and an Arkansas polisher (#649.314.420, Komet) with the aid of a multiplier contra-angle (Denstply Sirona, Hanau, Wolfgang, Germany) (Figure 4B). Next, the twostep impression of the maxillary arch was made with addition silicone (Express XT [commercially available in the United States as Express VPS], 3M ESPE) and a retraction cord (#000, Ultrapack, Ultradent, South Jordan, UT, USA). The color of the enamel substrate and the veneers were recorded (VITA Classical shade guide, VITA, Bad Säckingen, Germany). Temporary veneers with bisacryl resin were performed in all the

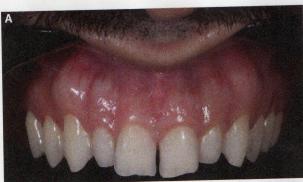




Figure 4. (A) Removal of composite resin veneers before preparation. (B) Aspect after tooth preparation with the aid of the silicon index.

patients. Teflon strips were positioned at the papillae before making the provisional with bisacrylic resin to avoid gingival compression and maintain the space for dental hygiene.<sup>15</sup>

The stone casts were scanned and the digital design of the laminate veneers was performed in a CAD software program (Figure 5A-B). Next, ultratranslucent zirconia (Prettau Anterior, Zirkonzahn, Gais, Italy) disks were milled in a Zirkonzahn CAD/CAM system to manufacture the monolithic minimally invasive veneers. The veneers were characterized before sintering, polishing with rubber tips followed by staining, and new polishing and glaze after sintering. The marginal fit was checked on the casts and clinically through the dry test. The resin cement shade was selected with tryin pastes (Variolink Esthetic Try-In, Ivoclar Vivadent, Schaan, Liechtenstein) (Figure 6). The veneers were then washed and dried with air jets, and the internal surface treatment was performed with silicatization, silane, and adhesive application. Thus, the internal surface of the veneers was air-abraded with aluminum oxide particles coated with silica (CoJet, 3M ESPE) for 20 seconds (2.8 bar, 10-mm standoff distance) and dried. Next, silane was applied (Monobond N, Ivoclar Vivadent) and left to dry for 60 seconds, followed by application of an adhesive layer (Tetric N-Bond Universal, Ivoclar Vivadent) without curing (Figure 7A-B). Prophylaxis was performed on the enamel substrate with pumice and water, then washed and dried with air jets. These surfaces were then etched with 35% phosphoric acid (Ultra etch, Ultradent) for 20 seconds, washed, air-dried, and treated with an adhesive system (Tetric N-Bond Universal, Ivoclar Vivadent) (Figure 8A-B).

Variolink Esthetic LC (Ivoclar Vivadent) light-cured resin cement was deposited on the internal surface of the veneers for the cementation and they were positioned. The excess cement was removed with a brush16 and dental floss and was light cured for 40 seconds (Radii Plus, SDI Limited, Baywater, VIC, Australia, 1200 mW/ cm²) on the buccal and lingual surfaces. Glycerin gel was applied at the margins of the veneers and another light-curing was performed (Figure 9A-B). The excess cement after the photopolymerization was removed with a #12 scalpel blade. The occlusal contacts and eccentric mandibular movements were checked. The occlusal adjustment was not necessary. An occlusal splint was made for all the patients to prevent tooth wear during sleep. The veneers were followed annually by considering the marginal and surface integrity, marginal discoloration, and color match according to the Ryge modified/ California Dental Association (Ryge/CDA) criteria.17

The 28 veneers cemented in the 3 patients were followed annually for 4-5 years (mean: 4.33 years) (Table 2). The clinical examination of the veneers after

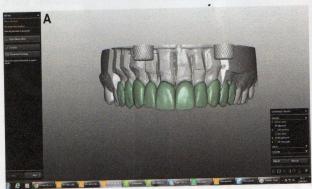




Figure 5. Digital design of ultrathin veneers in CAD software after scanning of the stone casts. (A) Front view. (B) Occlusal view.



Figure 6. Color selection of resin cement with try-in paste.

the follow-up periods of patient #1 (Figure 10A-E), patient #2 (Figure 11A-E), and patient #3 (Figure 12 A-E) indicated that there was no absolute biological or technical failure such as debonding, crack or fracture of the zirconia veneers, or secondary caries. The survival rate of the zirconia veneers after 5 years was 100%. All veneered teeth were classified as Alpha for the clinical parameters of the Ryge/CDA criteria (marginal and surface integrity, marginal discoloration, and color match) after the follow-up period, except for one element. A discreet marginal discoloration was detected in the left lateral incisor in patient #2 and rated as B (superficial discoloration; does not penetrate in pulpal direction) (Figure 13). However, this marginal discoloration was clinically acceptable, the zirconia veneer did not need to be replaced, and clinical followup has been performed.

## DISCUSSION

The zirconia veneers showed excellent functional and aesthetic performance after a follow-up of 4-5 years (mean follow-up: 4.33 years). There were no absolute biological or technical failures reported such as ceramic fracture or chipping, severe discolorations, debonding,

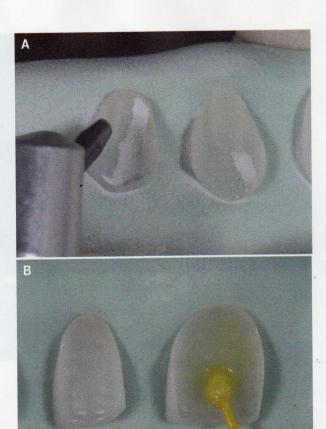


Figure 7. (A) Silicatization (CoJet, 3M ESPE) of ultrathin veneers. (B) Application of silane (Monobond Plus, Ivoclar Vivadent) and adhesive (Tetric N-Bond Universal; Ivoclar Vivadent).

or secondary caries during the clinical examinations. Only a superficial marginal discoloration was detected in the left lateral incisor of patient #1. Ultratranslucent zirconia is the third and most recent zirconia generation indicated for manufacturing monolithic aesthetic restorations as veneers, inlays, onlays, and anterior and posterior crowns. This ceramic presents an advantage due to its excellent optical properties, with translucency parameters close to lithium disilicate. <sup>18</sup>





Figure 8. (A) Enamel appearance after etching with phosphoric acid (35%). (B) Application of the adhesive system.

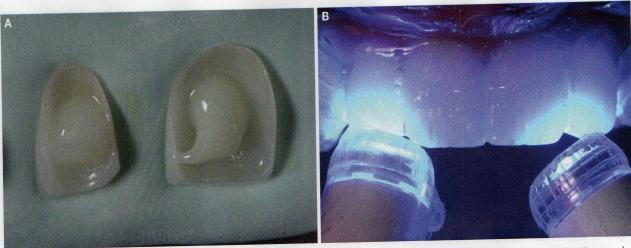


Figure 9. (A) Insertion of resin cement. (B) Light curing after removal of excess resin cement and application of glycerin gel at the margins of the veneers

There are few clinical reports in the literature with third generation zirconia. 11,19,20 Souza and others 11 reported the clinical one-year follow-up of six ultratranslucent zirconia ultrathin veneers (from maxillary right canine to left canine) for the first time in the literature. The authors related that there were no clinical failures and excellent functional and aesthetical performance, corroborating the clinical findings of this study. The ultratranslucent zirconia in this study showed excellent aesthetics aspects and the patients reported satisfaction with the treatment during the follow-up appointments.

Although the mechanical properties of ultratranslucent zirconia are lower than previous zirconia generations due to the reduced amount of tetragonal phase, 8-10 the flexural strength is higher than silica-based ceramics. 8 Even in reduced thickness of 0.5 mm, de Carvalho and others 21 reported flexural strength higher than 400 MPa. The use of a more resistant ceramic for manufacturing veneers may reduce the risk of chipping and fracture of the ceramic during the try-in step and the clinical performance of this restoration, especially in patients with existing parafunction activity.

Also, zirconia may allow the milling of thinner restoration margins with less risk of fracture. For lithium disilicate restorations, milling, ultra-thin margin can be challenging.<sup>22</sup> The laboratory may need to mill a large margin for further finishing to reduce the risk of fracture. Another advantage of zirconia is the

possibility of using precolored block/discs (multilayered zirconia) that are intrinsically characterized, which can improve the stability of the characterization over time in comparison to lithium disilicate restorations that are extrinsically characterized and glazed. The extrinsic characterization tends to be removed more easily during the finishing/polishing and wear.<sup>23</sup> Therefore, this material seems to be an excellent option for manufacturing aesthetic restorations.

Another relevant aspect considering zirconia laminate veneers is the adhesion longevity of these restorations to the dental substrate. The tooth preparation for placing laminate veneers does not offer macro mechanical retention between the dental substrate and the restoration; thus, the permanence of the veneers cemented to the dental substrate directly depends on the micromechanical and chemical interlock in the interface tooth/resin cement/ceramic. <sup>15,24</sup> The laminate veneers in this study were cemented to the enamel, which is the dental substrate that presents the best microstructural characteristics for adhesion. The enamel was treated with a conventional protocol: phosphoric acid etching followed by the application of an adhesive system. <sup>25</sup>

The zirconia/resin cement interface has been widely investigated by previous studies. 12-14,26-32 As an acid-resistant ceramic, several surface treatments have been tested to promote microretention and/or chemically

Table 2: Characterization of the Patients									
Case	Patient	Age (years)	Gender	Treated Teeth	Number of Veneers	Follow-up (years)			
1	LVA	30	Man	4-13	10	5			
2	LOADA	32	Woman	4, 5, 6, 8, 9, 11, 12, 13	8	4			
3	PPB	28	Woman	4-13	10	4			

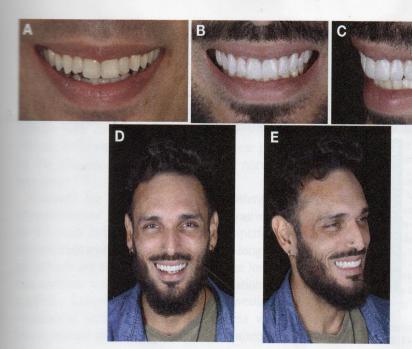


Figure 10. Clinical aspect of the initial smile and the ultrathin veneers after 5-years follow-up of patient #1. (A) Front view of the initial smile. (B) Front view and (C) lateral view of the smile with ultrathin veneers after 4-years. (D) Facial appearance (E) Lateral facial appearance with ultrathin veneers after 4 years.

modify the zirconia surface. The protocols have included air-abrasion with aluminum oxide ( $Al_2O_3$ ) particles or  $Al_2O_3$  coated with silica (silicatization),  $^{27,20,32}$  glaze of the internal surface,  $^{29}$  ceramic primer,  $^{27,28}$  resin cement with functional phosphate functional monomers,  $^{28}$  and silica infiltration,  $^{31}$  among others. Previous studies have indicated that the association of mechanical and chemical treatments of the zirconia improves the bond strength to resin cement and the stability of the adhesion.  $^{12-14}$  The combination of air abrasion with  $Al_2O_3$  particles and primer containing MDP or

silicatization and silane seem to be the treatments which promote the highest bond strength between the zirconia and resin cement.<sup>12,13</sup> Despite the physicochemical differences between the ultratranslucent zirconia and previous generations, the combination of mechanical and chemical methods also presents promising results for the adhesion of the third generation.<sup>33</sup>

The treatment applied to the internal surface of the zirconia laminate veneers in this study was air abrasion with Al<sub>2</sub>O<sub>3</sub> particles coated by silica, followed by application of silane and adhesive. Silicatization has



Figure 11. Clinical aspect of the initial smile and the ultrathin veneers after 4-years follow-up of patient #2. (A) Front view of the initial smile. (B) Front view and (C) lateral view of the smile with ultrathin veneers after 4-years. (D) Facial appearance (E) Lateral facial appearance with ultrathin veneers after 4 years.



Figure 12. Clinical aspect of the initial smile and the ultrathin veneers after 4-years follow-up of patient #3. (A) Front view of the initial smile. (B) Front view and (C) lateral view of the smile with ultrathin veneers after 4-years. (D) Facial appearance (E) Lateral facial appearance with ultrathin veneers after 4 years.

· the advantage of promoting mechanical irregularities at the zirconia surface and depositing silica, creating a silica layer that can chemically react with the silane and resin-based materials.<sup>34</sup> Xie and others<sup>34</sup> compared the bond strength and stability of different physicochemical treatments of the zirconia surface. The silicatization followed by silane application showed a higher and more stable bond strength than most of the protocols tested that involve air abrasion with Al<sub>2</sub>O<sub>3</sub> particles and different combinations of universal adhesives with or without prior application of zirconia primer. The aging performed in this study was thermocycling 20,000 cycles and 40-day water storage. Moreover, albeit both air-abrasion protocols produce considerable surface irregularities, Chen and others35 showed that the roughness produced at the ultratranslucent zirconia surface by the air-abrasion with Al<sub>2</sub>O<sub>3</sub> was higher than the silicatization. The surface irregularities produced by the air-abrasion



Figure 13. Marginal discoloration detected in the left lateral incisor (patient #2).

with Al<sub>2</sub>O<sub>3</sub> may be more aggressive than silicatization, which can be critical to the mechanical properties of an ultrathin restoration.

In addition to these aspects, the clinical finding reported by the authors was a slight marginal discoloration in an element (left lateral incisor) of a patient. Marginal discoloration is caused by the impregnation of pigments in the cementation line, being influenced by the patient's eating habits (high consumption of pigmented food)<sup>36</sup> in addition to other habits such as smoking.<sup>3</sup> Discoloration can also be affected by a thicker cementation line favoring pigments being impregnated in the area.<sup>37</sup>

Previous clinical studies have also reported the marginal discoloration of laminate veneers manufactured from silica-based ceramic. 3,36,38 Follow-up was chosen in the present case because the marginal discoloration was considered discreet and there was no aesthetic compromise or patient dissatisfaction. Another approach for discreet marginal discoloration, but with aesthetic impairment is polishing the region with zirconia rubber tips, which is the most suitable method for polishing ultratranslucent zirconia according to laboratory studies. 10,21 Severe marginal discoloration in ceramic laminate has also been reported in the literature, 3 which may lead to the replacement of the ceramic laminate.

A concern of the clinicians about the zirconia monolithic restorations is the wear of the opposite natural dentition. A previous clinical study with 3Y-TZP zirconia showed that the wear of the opposite dentition was higher than enamel against enamel but lower than feldspathic porcelain after one year.<sup>39</sup>

Moreover, glazed zirconia crowns promote higher wear to the opposite enamel than polished zirconia crowns. 40 For the third generation zirconia (ultraltranslucent), an in vitro study showed that the enamel wear promoted by ultratranslucent zirconia after artificial wear simulation was similar to translucent zirconia and inferior than zirconia-reinforced lithium silicate and lithium disilicate. 41 Moreover, enamel wear promoted by the zirconia is compatible with the normal wear rate range. 41,42

Although the follow-up of the 3 patients of the ultratranslucent zirconia minimally invasive veneers for 4-5 years indicated excellent clinical performance, clinical trials with larger sample sizes and longer follow-up periods are essential to investigate the longevity of this aesthetic treatment and the cementation protocol applied. Laboratory studies that investigate the mechanical surface treatment of zirconia which are less aggressive are also important to find alternatives to air abrasion.

#### CONCLUSIONS

Ultratranslucent zirconia seems to be an excellent alternative for manufacturing minimally invasive veneers indicated for aesthetic dental treatment. There were no absolute failures after the 4-5 year follow-up, showing excellent clinical performance. Moreover, treating the internal surface of the zirconia veneers with silicatization and silane seems to promote satisfactory and reliable adhesion to the resin cement.

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#### **Regulatory Statement**

This study was conducted in accordance with all the provisions of the human subjects oversight committee guidelines and policies of Ethics Committee (no 2.484.387) and registered as a Clinical Trial (https://ensaiosclinicos.gov.br/rg/RBR-33v2cd).

#### **Conflict of Interest**

The authors of this article 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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