Survival and Complication Rates of Polymer-Infiltrated Ceramic-Network Single-Tooth Restorations with an Observation Period of up to Three Years

Keywords

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ABSTRACT

This study evaluated the clinical performance of a polymer-infiltrated ceramic-network (PICN) material for up to 3 years. Patients (N=286) received 581 indirect restorations as crowns (417), overlays (131), and inlays/veneers (33) fabricated using the PICN (VITA Enamic) by CAD/CAM procedures using intraoral scanning (Cerec Omnicam) and milling systems (Cerec MC XL). The restorations were evaluated annually and in case of complications. Data were analyzed using Kaplan-Meier estimate. Complications were classified as biological or technical failures. Until final recall (mean observation period: 18.3 months) with a dropout rate of 4.8%, 3 biological and 10 technical complications were observed. The overall success rate of the placed restorations was 97.7%. Biological complications included pulpitis and pulp necrosis. Technical complications were debonding (n=7) and fracture (n=3). PICN materials can be used as an alternative to lithium-disilicate or zirconium dioxide for single tooth reconstructions, providing that early failures included debonding and fractures.

INTRODUCTION

Minimally invasive treatment methods have become a priority in both restorative and prosthetic dentistry due to advances in adhesive dentistry which enabled practitioners placing restorations with minimal or no teeth preparation saving healthy dental tissues.[1] Traditional treatment methods require significant removal of tooth structure in order to create macro-retention. This can lead to biological complications after preparation, such as hypersensitivity, pulp inflammation or pulp necrosis.[2,3] Minimally invasive techniques allow dentists to perform defect-oriented dentistry but require the use of suitable dental materials. Dental ceramics, composites and the combination of both materials enable minimally invasive restorations.[3] In addition to adhesive dentistry, digital concepts have also advanced rapidly introducing new materials in reconstructive dentistry. CAD/CAM procedures and intraoral scanners have been available to dentists for years which provide predictable results with high accuracy and precision.[4]

Chairside systems can combine intraoral digital scanning with chairside fabrication of dental ceramics. This allows indirect restorations to be fabricated in a single visit without the need for provisional restorations. The workflow is completely digital and contains no analog steps.[5] Both ceramics and resin-based composites are used in CAD/CAM technology. Silicate and glass ceramics, lithium disilicate ceramics, oxide ceramics, resin composites, and polymer-infiltrated ceramic-network (PICN) are examples of such materials,[6] where the latter combines the favourable properties of resin-matrix composites and ceramics.[7]

PICNs exhibit an e-modulus of 30 GPa. This value is ranges between the elasticity modulus of enamel (90 GPa) and dentin (16 GPa) which is dictated by the ceramic network, infiltrated with the polymer.[8,9] It has been postulated that the monolithic material is not prone to chipping and reduces stress on the antagonistic teeth.[10,11] The combination of ceramics and resin composite allows for greater stability at the margins of the restoration.[12] Yet, the material thickness must be taken into consideration for a successful application where the minimum thickness for anterior teeth is suggested as 1.5 mm at the incisal edge and 0.8 mm circularly. Restorations in the posterior region should have a thickness of 1.5 mm at the cusps, 1 mm at the fissures and 0.8 to 1.5 mm circularly. Inlays on the other hand require a minimum thickness of 1.5 mm at the isthmus and the veneers should have a thickness of 0.3 mm at the incisal edge and labial surface.[13]

PICN material offers several advantages for use in clinical practice in that the material does not need to be sintered and can be used directly after milling. This allows the practitioner to shorten the treatment time, which is expected to increase the patient satisfaction as a result.[14] Unfortunately, the clinical performance is not well documented yet, as only few publications investigated the novel material.[13,14] Therefore, the objective of this study was to evaluate the clinical performance PICN material for single-tooth restorations with a focus on survival and complication rates.

MATERIALS AND METHOD

STUDY DESIGN

The brands, manufacturers, and chemical compositions of the materials in this study are listed in Table 1. Material characteristics of the studied material are listed in Table 2.

Patients in need of indirect restorations were recruited in this study. Inclusion criteria were defined as follows: Patients at least 18 years old or older, with vital teeth or sufficient endodontic treatment, healthy periodontal status, no probing depth more than 4 mm, no signs of bruxism. Patients with bad oral hygiene (Plaque index- PI> 50%), craniomandibular disorders, patients in need of endodontic treatment, and patients who were not suitable for adequate adhesive protocol were excluded from the study.

OPERATIVE PROCEDURES

From March 2015 to December 2018, one operator with experience in adhesive dentistry and digital procedures made the preparations, intraoral scanning and bonding of 581 PICN (VITA Enamic, VITA Zahnfabrik, Bad Säckingen, Germany) restorations (417 crowns, 131 overlays, 33 inlays/veneers) in a total of 286 patients (115 female, 171 males; mean age 54.2 years) *(Table 3)*.

Preparation of vital teeth was performed under local anesthesia (Ultracain D-S, Sanofi, Paris, France), using only rounded cylinder burs to avoid sharp edges. Each preparation was smoothened after initial preparation with a red strip bur. Preparation guidelines for CAD/CAM manufactured restorations were followed *(Figure 1)*.[1] After preparation for inlays, onlays, overlay and crowns, a digital impression was taken with the intraoral scanner Cerec Omnicam (Sirona, Bensheim, Germany). The impression was made while retracting the cheeks and lips of the patient using Optragate (Ivoclar Vivadent, Schaan, Lichtenstein). During preparation and computer aided design, the minimum thickness of material was respected. Computer aided manufacturing was done by the milling unit Cerec MC XL (Sirona, Bensheim, Germany). Burs used for milling was Step Bur 12 and Cylinder pointed Bur 12 (Sirona). After milling procedure, the ceramic restorations were polished. During insertion of the finished restoration, insulation was achived using Optragate (Ivoclar Vivadent). The tooth surface was cleaned with a polishing brush and a fluoride and oil-free cleaning paste. Enamel was etched for 30 seconds, dentine for 15 seconds with 36% phosphoric acid (Ivoclar Vivadent). Multilink primer (Ivoclar Vivadent) was applied for 30 seconds on enamel and dentine and air-blowed to form a thin layer. Simultaneously, PICN restorations were etched using hydrofluoric acid 5% (Vita Enamic etch, VITA, Bad Säckingen, Germany) for 60 seconds. After cleaning with water and drying with air, silane was applied on ceramic restorations for 60 seconds (Monobond Plus, Ivoclar Vivadent). Adhesive bonding of restorations was completed using a resin cement (Multilink Automix, Ivoclar Vivadent). Excess material was removed immediately with a foam pellet and restoration was photo-polymerized 40 s from each direction. Interdental spaces were cleaned with floss. Occlusal fitting was examined and an X- ray was made to examine the correct fit and control of the excess cement. After baseline recordings, restorarions were evaluated annually and patients were instructed to call upon experience of a failure.

EVALUATION

Restorations were evaluated by the same operator who inserted the restorations up to 3 years during annual controls. The evaluation protocol involved technical (chipping, debonding or fracture of tooth/restoration) and biological failures (caries or endodontic complications).[15] A complication dependent intervention was performed if the patients showed up earlier due to biological or technical complications. Rebonding was performed on teeth upon debonding, and a new restoration was manufactured in case of fracture. The observer focused solely on the technical and biological copmlications and did not evaluate the esthetic outcome.

Table 1. Brands, types, manufacturers and chemical compositions of main materials used in this study.

Brand	Type	Manufacturer	Chemical Composition
VITA Enamic	Polymer-infiltrated ceramic-network (PICN)	VITA Zahnfabrik, Bad Säckingen, Germany	SiO_2 58-63%, Al_2O_3 20-23%, Na_2O 9-11%, K_2O 4-6%, B_2O_3 0.5 - 2%, ZrO_2 <1%, CaO <1%, TEGDMA and UDMA 14 wt% / 25 vo%
Total Etch	Phosphoric Acid	Ivoclar Vivadent, Schaan, Liechtenstein	37% Phosphoric acid
Multilink Primer A	Adhesive base	Ivoclar Vivadent	Water 85.7%, Initiators 14.3%
Multilink Primer B	Adhesive catalyst	Ivoclar Vivadent	Phosporic acid acrylate 48.1%, Hydroxyethylmethacrylate 51.9%
Multilink Automix	Dual polymerized luting cement	Ivoclar Vivadent	Base: Dimethacrylate, HEMA 33.1%, Ba, Al, Fluorosilicate-glassfiller 37.4%, Ytterbiumtrifluorid 23%, SiO_2 Filler 5.4%, catalyst stabilizer 1%, pigments <0,03% Catalyst: Dimethacrylate, HEMA 32.4%, Ba, Al, Fluorosilicate-glassfiller 37.4%, Ytterbiumtrifluoride 23%

Table 2. Material characteristics of polymer-infiltrated ceramic-network (VITA Enamic).

	VITA Enamic
Flexural strength	150-160 MPa
E- Modul	30.000 MPa
Compressive strength	383 MPa
Monomer	UDMA, TEGDMA
Composition	Siliciumoxide: 58-63%, Aluminiumoxide: 20-23%, Sodiumoxide: 9-11%, Potassiumoxide: 4-6%,
Filler content	14 wt%, 25 vol%

Table 3. Distribution of the PICN restorations in mandible and maxilla in males and females.

	maxilla	mandible	total
Male	153	151	304
Female	140	137	277
Total	293	288	581

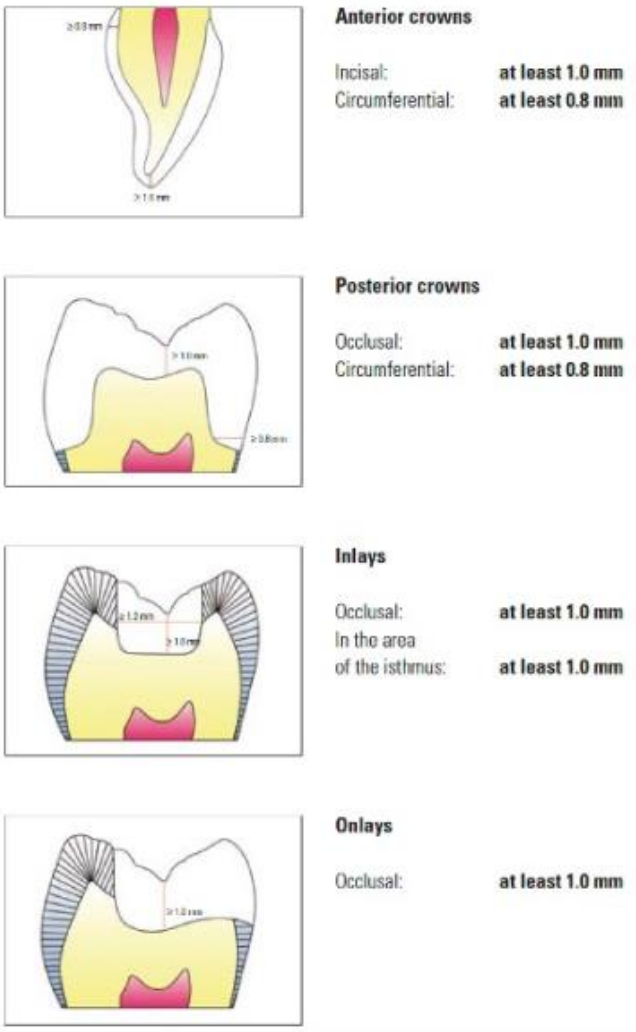

Figure 1: Preparation guidelines of PICN according to the manufacturer.

STATISTICAL ANALYSIS

Data were analyzed using Kaplan-Meier and Log Rank (Mantel-Cox) tests (SPSS 21.0; SPSS Inc., Chicago, IL, USA) (alpha=0.05).

RESULTS

The distribution of the 581 restored teeth and restoration types in the maxilla and mandible are presented in Table 3.

Of the total number of patients, 10 dropped out after the first year and 18 after the second year. This led to a dropout rate of 4.8%. The mean observation period was 18.3 months. Of 581 restorations, 417 were crowns, 131 were overlays and 33 were inlays/veneers. Thirty-eight restorations were placed in the anterior region, 543 in the posterior of which 293 were made in the maxilla and 288 in the mandible.

Of the restored teeth 166 were nonvital and 417 were vital.

During the observation period, three restored teeth showed biological complications where two of them were irreversible pulpitis (tooth numbers: 14, 26) and one showed a pulpal necrosis (tooth number: 36). Technical complications (n=10) were mainly debonding (n=7) (tooth numbers: 3 x 36, 17, 27, 37, 47) and fractures (n=3) (tooth numbers: 16, 2 x 46) *(Figure 2)*.

The cumulative survival rate of PICN restorations were 97.7% (Kaplan-Meier, Cl:95%) *(Figure 3)*. No significant difference was found between maxilla and mandible (p>0.05) and anterior and posterior restorations (p>0.05) (Cox regression analysis). Representative photos are displayed in Figure 4a-d.

Regarding the complications of the present study, in case of biological complications, a root canal treatment was performed through the existing crown, while in case of fractures the complete crown was replaced using lithium disilicate ceramic. In case of debonding, restorations were rebonded applying the same adhesion protocol and the same resin cement.

DISCUSSION

This clinical study was undertaken in order to evaluate the clinical performance of PICN restorations. Currently VITA Enamic is the only PICN material on the dental market and it unites the characteristics of resin matrix composites and ceramics which can be produced though CAD/CAM technologies. Although *in-vitro* studies show promising results,[9] only a few clinical studies are available regarding the clinical performance of VITA Enamic.[13,16,17] Therefore, results of this clinical study can be compared to only few other studies.

In a previous study, Chirumamilla *et al.* observed 45 Enamic crowns over a period of 2 years.[18] The crowns were fabricated using the Cerec system and bonded either with a resin-modified glass-ionomer cement or a self-adhesive composite. The crowns bonded with a resin-modified glass-ionomer cement showed a survival rate of 92.8% whereas thos bonded with a self-adhesive composite showed a survival rate of 96.8%. The observation duration was longer and number of restorations were more than ten-fold where only resin cement. Yet, the results can be considered comparable. On the other hand, Spitznagel *et al.* examined 103 PICN inlays and overlays which were luted using a dual-polymerized composite.[13] Survival rate was 84.4% for inlays and 82.4% for overlays. In the study of Beier *et al.* survival of PICN restorations were compared

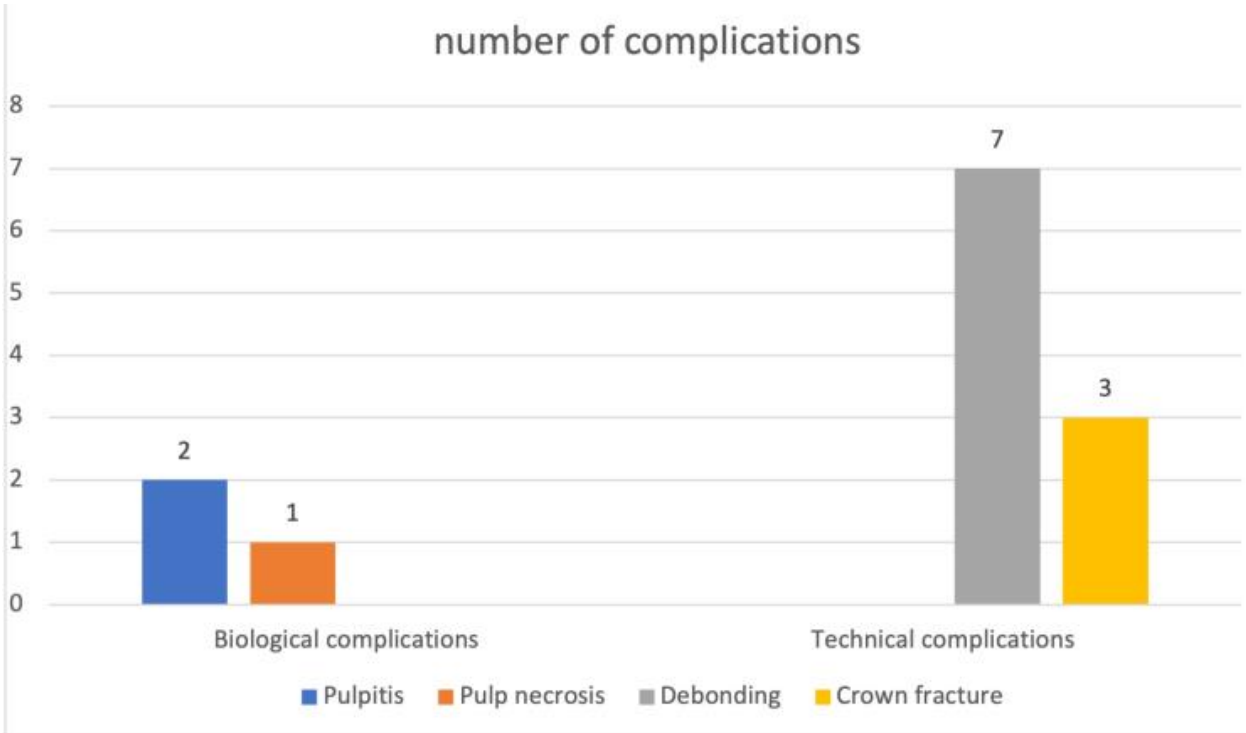

Figure 2: Distribution of complications experienced with 581 PICN restorations at a mean observation period of 18.3 months.

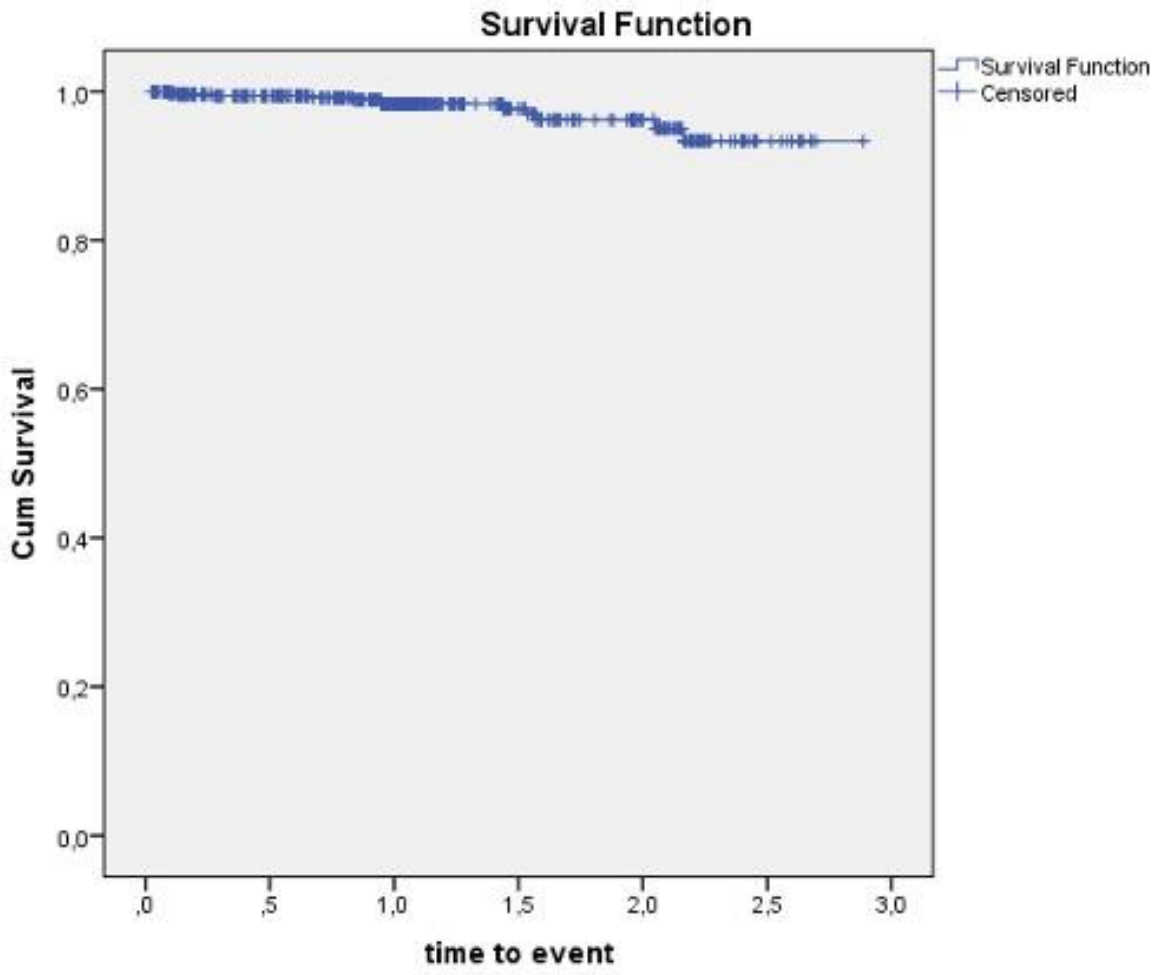

Figure 3: Event-free survival rates of PICN restorations (N=581).

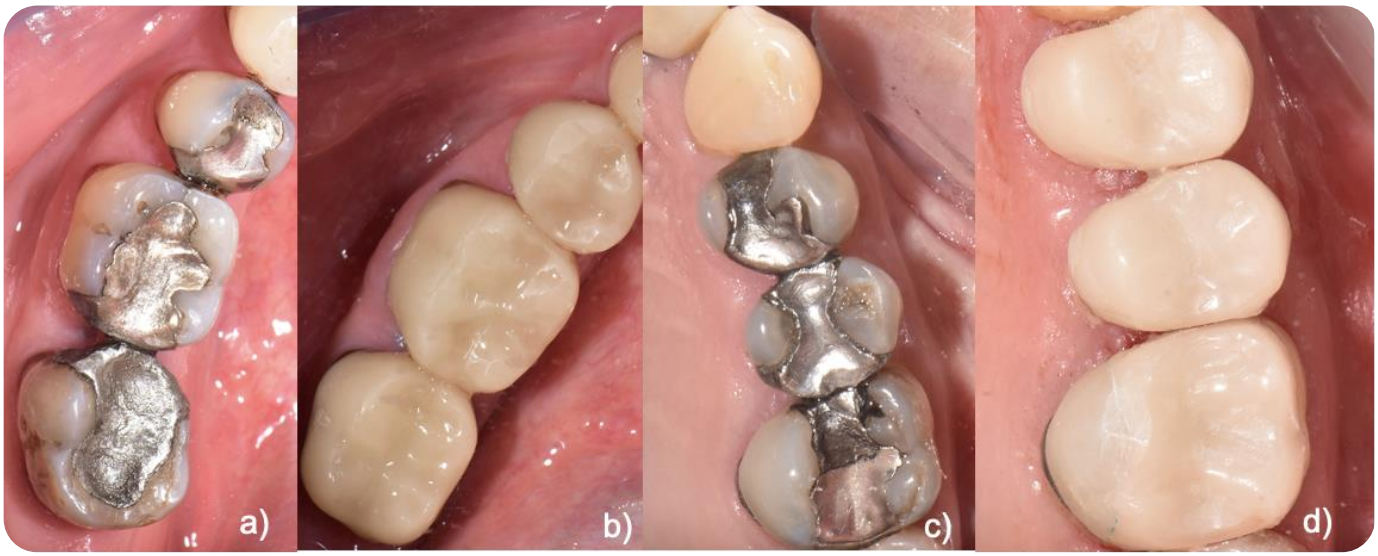

Figure 4a-d: Representative photos of PICN restorations on a-b) 34, 35, 36 as full coverage and c-d) 24, 25, 26 as partial coverage restorations after amalgam removal.

to feldspathic restorations.[19] Both materials were used on endodontically treated teeth as endocrowns on molars. In that study, PICN restorations showed a cumulative survival rate of 97% after 3 years. These results are also comparable to the results in the present study although study design was different.

Regarding the fact that there are only few studies with short observation time for PICNs, comparison to dental ceramics with longer clinical results is required. A study of Beier *et al.* observed 1335 ceramic restorations with a mean observation time of 102 months.[19] The survival rate was 97.3% after

5 years, 93.5% after 10 years and 78.5% after 20 years. Gehrt *et al.* observed 104 E-max crowns on 41 patients where the survival rate after 5 years was 97.4% and 94.8% after 8 years.[20] The studies are comparable among themselves and with PICN restorations. However, shorter observation time for PICN restorations is a concerning limitation for comparability.

PICN restorations in this study were performed by one clinician and also evaluated by the same person annually in a private clinic settings. No comparisons were made with those of other materials as aesthetic outcome of the restorations as the functionality were the primary interest. Yet, technical as fractures and debonding in PICN restorations should be considerdd in choosing restorations in randomized clinical trials.

CONCLUSIONS

From this study, the following could be concluded:

Polymer-infiltrated ceramic-network (Vita Enamic) restorations demonstrated comparable results to other ceramic restorations concerning the survival rate at a mean observation period of 18.3 months in function. The incidence of fractures and debonding should be considered in material selection in future trials and should be communicated with the patients.

DISCLOSURE

The authors did not have any commercial interest in any of the materials used in this study. No funding was received for this study.

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