RCT on posterior partial crowns made by two different lithium disilicate materials: 8-year results

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Abstract

Background
This trial wants to evaluate the clinical behavior of two lithium disilicate systems after 8 years of clinical service.

Methods
60 patients in need of receiving a partial adhesive crown on natural abutment posterior teeth were made. 60 restorations were realized. Sample crowns were divided into two groups: Group 1 IPS e.max press (Ivoclar-Vivadent, Schaan, Liechtenstein), and Group 2 Initial LiSi press (GC Co., Tokyo, Japan). The restorations were followed up for 8 years, and the FIT evaluation was used FOR each recall to evaluate their clinical performances. Accordingly, with the FIT system, 7 clinical parameters (Interproximal, Occlusion, Design, Mucosa, Bone, Biology and Margins) WERE evaluated, using a 0–1-2 scoring scheme, by an oral radiograph and occlusal and buccal pictures. Statistical analysis was made using Mann-Whitney 'U' test and the level of significance was set at $p < 0.05$. Also, the "success" of the crowns (restoration in place without any biological or technical complication) and "survival" (restoration still in place with biological or technical complication) were evaluated.

Results
Regarding FIT scores, when compared to the 3-years results all partial crowns showed a slight decrease in scores, mainly due to bone loss of alveolar crest in the radiographic evaluation and consequent recession of gingival tissue. Similarly happened to several partial crowns of both groups about interproximal contact parameters, were also related to a modification of the contour of the crowns. Any way all evaluated parameters showed high scores, and no statistically significant differences were noted between the two groups in any of the assessed variables ($p > 0.05$). All FIT scores were compatible with the outcome of clinical success no one restoration was replaced or repaired and the survival and success rate were 100%.

Conclusions
The two groups of lithium disilicate systems showed similar results after 8 years of clinical service and no statistically significant differences were found. Both systems were shown to be clinically predictable and reliable,

Trial registration
The study protocol was approved by the Ethical Committee of the University of Siena (clinicaltrial. gov - NCT 01835821), 'retrospectively registered'.

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Keywords

Partial crowns, lithium disilicate, randomized controlled trial

INTRODUCTION

In the last years, lithium disilicate become very popular thanks to its mechanical properties such as flexural strength and is mainly indicated for single full and/or partial crowns (1, 2,3). Right now, lithium disilicate competes with porcelain materials and reinforced resin composites for high aesthetics but its higher flexural strength makes it preferable whenever the tooth defect exceeds a certain dimension (4,5).
The oldest and first proposed into the market lithium disilicate formulation was made by press technology and in this study was the one clinically evaluated. Pressed lithium disilicate results were very promising (6,7) and recently the evaluation of a new lithium disilicate material (Initial LiSi press, GC) has been reported [8-10]. Only a few clinical trials are available on lithium disilicate partial crowns, the majority of them being retrospective studies (11-13) and only a few being randomized controlled trials (RCTs)(8-10,14).
The clinical evaluation of partial crowns on posterior teeth is usually performed following standardized clinical systems such as Ryge and Snyder clinical parameters (15) or the modified FDI criteria (16). The evaluation is usually performed after luting at baseline, and then at recalls after 1,6,12, 24, and 36 months. Also, RCTs are done by blinded, calibrated and experienced dentists who can perform the follow-up evaluation (17,18).
However, Ryge and Snyder clinical parameters and modified FDI criteria were defined to evaluate direct restorations, therefore there was the need to deliver a new clinical system to properly evaluate indirect restorations. Clinical criteria should reflect the patients' perception of the restorations, fulfilling teaching purposes and being easily applicable in daily practice [19,20]. Recently, the FIT system was proposed (9-10) FIT is a clinical index for the assessment of the prosthetic results of lithium disilicate crowns, based on seven restorative-periodontal parameters, that evaluate crowns placed on natural abutments, and wants to be a reliable and objective instrument in assessing single partial crown success and periodontal outcome as perceived by patients and dentists.
The aim of this study was to clinically evaluate two lithium disilicate systems after 8 years of clinical service. The tested null hypothesis was that there was no statistically significant difference in the clinical performance of the two lithium disilicate systems after 8 years of clinical service.

MATERIALS AND METHODS

As in the previous reports at 3-year recall (9), the Functional Index for Teeth (FIT) was used (Table 5a-5b). The following clinical parameters were evaluated: Interproximal Contacts and Papillae, Static and Dynamic Occlusion, Design Contour and Color, Quality and Quantity of Mucosa, Bone level in x-ray, Biology related to Bleeding on Probing (BoP) and Plaque Index (PI) and Stain and Gap at Margins.
The clinical evaluation was done at THE last recall (8-year follow-up) by an experienced operator.
60 patients in need of a single partial crown on posterior teeth (upper and lower premolars and molars), accessing the Department of Prosthodontics and Dental Materials of the University of Siena, Italy, in the time period between September 2015 and January 2016 were treated and collected in this trial. Selected patients, periodontally healthy or successfully treated in need of one posterior restoration, had a mean age of 37 (±7.5) years (between 18 and 70) (29F, 31M). Exclusion criteria were: age <18 years, pregnancy, disabilities, prosthodontic restoration of the tooth, spontaneous sensitivity, pulpitis, non-vital or endodontically treated teeth, (chronic) periodontitis, deep defects (close to pulp, <1mm distance) or pulp capping, heavy occlusal contacts or history of bruxism, systemic disease or severe medical complications, allergic history concerning methacrylates, rampant caries, xerostomia, lack of compliance, language barriers, plaque index higher than 2 (Table 1).
Patients' written consent to the trial was obtained after having provided a complete explanation of the aim of the

Inclusion criteria
Age: 43 (±9.5) years (between 18 and 72)
Sex: 83F, 67M
Periodontally healthy or successfully treated patients
In need of one restoration onto posterior teeth
Exclusion criteria
Not proper age (< 18 years);
Pregnancy
Disabilities
Previous prosthodontic restorations of abutment teeth
Spontaneous sensitivity, pulpitis, non-vital or endodontically treated teeth
Sever and/or chronic periodontitis
Deep defects (close to pulp, < 1mm distance on customized xRay) or pulp capping
Heavy wear signs on occlusal surfaces due to bruxism
Systemic disease or severe medical complications
Allergic history concerning methacrylates
Rampant caries
Xerostomia
Lack of compliance
Language barriers
Plaque index higher than 20

Tab. 1 Demographic data, inclusion and exclusion criteria.

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1a
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1b
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-8
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4-8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	/
Sample size	7a	How sample size was determined	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	/
Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	7
	11b	If relevant, description of the similarity of interventions	/
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	/
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9-10
	13b	For each group, losses and exclusions after randomisation, together with reasons	/
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	/
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	5
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	5
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	7-8
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	/
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9-10
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	/
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10-12
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-12
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	/

Tab. 2 CONSORT 2010 checklist.

study. The study protocol was approved by the Ethical Committee of the University of Siena (clinicaltrial.gov # NCT 01835821). All procedures performed in this study involving human participants were in accordance with the ethical standards of the Institutional and National Research Committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study adheres to CONSORT guidelines (Table 2).

Randomization selection of the patients and masking of examiners

After recruitment, all patients received oral hygiene instructions and prophylaxis to achieve optimal plaque control and gingival health before starting the treatment. Probing pocket depths (PPD)(21), bleeding on probing (BoP)(22), and full-mouth plaque index (PI)(21) clinical assessment was performed.

The treatments were performed under local anesthesia (Articaine with 1:100.000 epinephrine) by the same experienced operator. Also, intraoral radiographs were made before starting the treatment and to standardize the radiographic examination, an X-ray individual tray was realized for each sample tooth of each patient, to be sure to have the radiogram in the same position at each recall.

All patients were randomly assigned to one of the two experimental groups (n=30), which were defined based on the material to be used for the restorative treatment:

Group 1: IPS e.max press (Ivoclar-Vivadent, Schaan, Lichtenstein)

Group 2: Initial LiSi press (GC Co., Tokyo, Japan)

The main characteristics of the two prosthodontic materials are reported (Table 3).

Treatment assignment was noted in the registration and treatment assignment form that was kept by the study. Allocation concealment was performed by using opaque sealed, sequentially numbered envelopes. The statistician made the allocation sequence by means of a computer-generated random list and instructed a different subject to assign a sealed envelope containing the type of lithium disilicate material to be used. The opaque envelope has been opened before material selection and communicated to the operator. At the 3-year recall blinding of the examiner has been applied.

Clinical Procedure

For standardization purposes, all clinical procedures were performed by the same trained operator. Following anesthesia, A rubber dam was placed, all carious lesions were excavated, and any restorative material was removed. Preparation was performed using conventional diamond burs in a high-speed handpiece, with no bevel on margins. The preparation design was dictated by the extent of decay, pre-existing restorations and the preparation guidelines defined by the manufacturer of the restorative materials. The Residual Dentin Thickness (RDT) was evaluated on a periapical radiograph, and teeth with RDT thinner than 0.5 mm were excluded. Cavities' preparation provided at least 0.5-1 mm space at the margin and 1.0-1.5 mm of clearance occlusaly. Margins were mainly into enamel and only interproximal boxes had cervical margins below the cementum-enamel junction for no more than 1 mm. At least one cusp was

Properties (as provided by manufacturers)	Units	IPS e.max Press	Initial LiSi Press
Manufacturer	-	**Ivoclar Vivadent**	**GC**
Components	-	Lithium disilicate crystals (approx. 70%), Li2Si2O5, embedded in a glassy matrix	Lithium disilicate micro-crystals equally dispersed in a glass matrix
Crystal system	-	Lithium disilicate - crystals measure 3 to 6 µm in length.	Lithium disilicate - crystals measure 1.5µm x 0.5µm
Flexural Strength	MPa	433*	454*
Biaxial Flexural Strength	MPa	>500	>500
Vickers hardness		(HV10) 5900 ± 100 Mpa	600 HV
Chemical solubility	mg/cm^2	40 ± 10	5.4 µg/cm2
Liner thermal expansion CTE	x 10-6/K	Coefficient of thermal expansion (100 – 400 °C) 10.15 ± 0.4 $10^{-6}K^{-1}$ Coefficient of thermal expansion (100 – 500 °C) 10.55 ± 0.35 $10^{-6}K^{-1}$	Liner thermal expansion CTE (25-500°C) 9.8 x 10-6K-1
Glass transition temperature	°C	560	520
Density	g/cm3	2.5 ± 0.1	2.4

Tab. 3 Mechanical properties of IPS e.max press and GC InitialTM LiSi press materials

Scoring Scheme	0	1	2
Interproximal Contacts & Papillae	major discrepancy (2x incomplete)	minor discrepancy (1x complete)	no discrepancy (2x complete)
Occlusion Static & Dynamic	major discrepancy (supra-contact)	minor discrepancy (infra-occlusion)	no discrepancy
Design Contour & Color	major discrepancy (contour)	minor discrepancy (color)	no discrepancy
Mucosa Quality & Quantity	non-keratinized non-attached	non-keratinized attached	Keratinized attached
Bone X-Ray	radiographic bone loss >1.5 mm	radiographic bone loss <1.5 mm	radiographic bone loss not detectable
Biology BoP & PI	BoP and PI present	BoP present	no clinical impairment
Margins Gap & Stain	detectable gap and visible stain	detectable gap or visible stain	no clinical impairment
Max Score			14

Tab. 4 Functional Index for Teeth (FIT): definitions and scores.

covered. All teeth were kept vital.
Hybridization of dentin with adhesive material was done using Adhese Bond Ivoclar-Vivadent, Schaan, Liechtenstein, in Group 1 and G-Premio Bond, GC Co., Tokyo, Japan in Group 2, and then a thin layer of flowable WAS applied on top (Tetric Flow, Ivoclar-Vivadent in Group 1 and Genial Flow, GC Co, in Group 2). After the final preparation, an impression of the prepared tooth was taken with an elastomeric material (Exa'lence, GC Co.), and poured in stone (FujiRock, GC Co.). The restoration was then waxed and pressed in lithium disilicate, strictly following the manufacturer's instructions. A temporary restoration of the prepared tooth was provided and after one week the lithium disilicate restoration was luted following THE manufacturer's instructions. The intaglio surface of the restoration was etched with 10% hydrofluoric acid for 1 minute, silanized with Monobond Plus (Ivoclar-Vivadent, Schaan, LIECHTENSTEIN) in Group 1 and G-Multi Primer (GC Co.) in Group 2, and then luted using MultiLink Sprint (Ivoclar-Vivadent) in Group 1 and LinkForce (GC Co.) in Group 2. During luting procedures, all sample teeth were isolated by a rubber dam.

Follow-up

All patients were enrolled in a dental hygiene program in which recalls were planned every 6 months. A clinical exam and standardized intraoral radiographs were performed immediately after the seating of the crowns (baseline), as well as after 1, 2, 3 and 8 years of clinical service (follow-up).

Outcome variables

"Success" was set when the restoration was in place at the last recall without any biological or technical complication, whilst "Survival" was when the restoration was still in place at the last recall but with biological or technical complications that needed to be treated and/or the crown to be remade. "Failure" was set when the restoration was not in place anymore at the last recall or, because of mechanical or biological complications, needed to be replaced.

Statistical analysis

The Mann-Whitney 'U' test was applied to verify the statistical significance of the difference between the two groups in the scores recorded for each assessed variable. The level of significance was set at p<0, .05. The statistical analysis was handled by the PASW Statistics 18 software (IBM, Armonk, NY, USA).

RESULTS

The recall rate of patients was 100% and for that, no loss to follow- up was recorded. Survival rate was 100%. No failure was recorded. No technical or biological complications were observed during follow-up.
Clinical examinations of periodontal parameters showed mean scores for PI of 17.0 (SD 2.4; range: 15–21) and 17.4 (SD 2.2; range 16-20) at 8-year follow-up, and PPD of 3.7 (SD 0.5 mm; range: 1–4) and 3.4 (SD 0.5 mm; range: 1–4), and a mean score for BoP of 17.5 (SD 2.4; range: 16–25) and 16.9 (SD 1.8; range: 15–22), in Group 1 and Group 2 respectively. However, it must be considered that all patients were in a professional recall program and the home maintenance of patients can justify the good scores of periodontal parameters after 8 years OF clinical service.
At the 8-year follow-up, the mean total FIT score was 11.96 and 12.36 for Groups 1 and 2 (range: 10–14)

	Group 1	Group 2	
Variables	IPS e.max (n=30) (total) (median)	GC Initial™ LiSi (n=30) (total) (median)	Total Score Each Outcome
Interproximal Contacts & Papillae	26 (1.73)	30 (2)	56
Occlusion Static & Dynamic	30 (2)	29 (1.93)	59
Design Contour & Color	28 (1.86)	30 (2)	58
Mucosa Quality & Quantity	30 (2)	29 (1.93)	59
Bone X-Ray	30 (2)	30 (2)	60
Biology BoP & PI	29 (1.93)	29 (1.93)	58
Margins Gap & Stain	26 (1.73)	28 (1.86)	54
Total Score Each Group	199 (13.26)	205 (13.66)	

Tab. 5a Radiographic and clinical scores based on FIT for each group after 3 years of clinical service

respectively with a slight decrease when compared to FIT scores at 3-year recall (Tables 5a). A couple of partial crowns showed bone loss alveolar crest with recession of soft tissues at the radiographic evaluation. Similarly, in both groups, several other restorations had lower scores of Interproximal contacts and of Contour, due to slight chipping of the crowns. Also, the "stain and gap at margins" parameter was the most affected by THE decrease IN scores and were 1.54 (SD 0.8; range 0-2) in Group 1 and 1.67 (SD 0.7; range 1-2) in Group 2 respectively and resulted to be the most challenging to satisfy (Table 5b). All other parameters had a light decrease of scores.
However, as it was at 3-year recall and also at 8-year recall no statistically significant differences were recorded between the two groups in any of the assessed variables ($p>0.05$).

DISCUSSION

The most well-known systems to clinically evaluate clinical trials of single restorations are Ryge and Snyder criteria (15) and the modified FDI criteria (16-18,23). The first and oldest clinical system evaluates parameters such as post-operative sensitivity, retention, marginal gap, marginal discoloration, fracture, interproximal contacts and secondary caries, scoring each parameter in alpha, beta, charlie and delta and is still the most used clinical criteria to evaluate direct restorations. The modified FDI system evaluates similar parameters such as aesthetic, functional and biological properties with four sub-categories each. Each sub-category is then divided into 5 quality scores from clinically excellent/very good to clinically poor, for a total of 16 criteria that might not be all used in the same case (16). A calibration by e-calib system of the FDI criteria is available and its main goals were to efficiently train and calibrate clinical dental research workers using e-learning tools, to reduce the variability of the outcome of dental restorations in clinical studies using standardized assessment criteria, to better compare the results of clinical trials on dental restorations among different clinics in the world, to render clinical calibration programs more efficient, to improve daily clinical practice and to be used as a teaching tool in dental schools (18).
The FIT evaluation (Table 4), that was recently proposed, is scoring 7 clinical parameters: interproximal, occlusion, design, mucosa, bone, biology, and margins. Although its targets resemble the ones of the modified FDI criteria, which is limited to the tooth and the restoration without evaluating the periodontal tissues, FIT can also include the periodontal tissues behavior by 'Interproximal', 'Mucosa', 'Bone' and 'Biology' parameters.
The RCTs are usually carried out by blinded, calibrated, and experienced dentists working in specialized centers (23) and that is considered for some experts a limit to predict the real behavior of that protocol when performed by general practitioners. FIT as any other available clinical system should make practitioners more familiar with the most common clinical parameters scoring them at each recall of patients. Anyway, it should be considered that the operator's experience can be a key factor when a Randomized Controlled Trial (RCT) is done and a scoring system is applied. However, to explain the high success rate found in this RCT, the oral hygiene maintenance (professional and at home) of the selected

	Group 1	Group 2	
Variables	IPS e.max (n=30) (total) (median)	GC Initial™ LiSi (n=30) (total) (median)	Total Score Each Outcome
Interproximal Contacts & Papillae	24 (1.61)	26 (1.73)	50
Occlusion Static & Dynamic	28 (1.86)	28 (1.86)	56
Design Contour & Color	24 (1.61)	26 (1.73)	50
Mucosa Quality & Quantity	27 (1.78)	26 (1.73)	55
Bone X-Ray	27 (1.78)	27 (1.78)	56
Biology BoP & PI	27 (1.78)	28 (1.86)	55
Margins Gap & Stain	23 (1.54)	25 (1.67)	48
Total Score Each Group	180 (11.96)	186 (12.36)	

Tab. 5b Radiographic and clinical scores based on FIT for each group after 8 years of clinical service

patients in combination with the experience and skill of the operator must be considered.
The scores recorded in this clinical trial showed high scores for all parameters although with an expected slight decrease when compared to the 3-year recall data, and no statistically significant differences were found between the two tested lithium disilicate materials. Such findings lead to acceptance of the formulated null hypothesis. The lack of differences between the two pressed lithium disilicate materials showed that both can clinically perform properly.
The oldest lithium disilicate material used in this trial (IPS e.max press) was extensively used in the last decades and several clinical studies are available and reporting excellent results at an observation time of up to 10 years (14, 24-27). There is consensus that IPS e.max press (also with the previous name of Empress 2) has good enough longevity when used to restore A single tooth after 5 years (survival of 90%) (24,25) and 71% after 10 years of clinical service (14,26-27). Particularly relevant is the recently published report by Malament (14) in which was found that pressed lithium disilicate restorations (Empress 2) survived successfully over the 10.4 period studied with an overall failure rate below 0.2% per year and primarily confined to molar teeth. However, also in this study's long- term clinical trial (14) the skill and knowledge of the operator and the oral hygiene regime contributed to the impressive success rate.
Regarding the Initial LiSi press, only a few prospective clinical studies are already available and showed 100% survival after 3 years (8-10). This RCT confirmed the quality of this prosthodontic material when used for posterior partial crowns.
Some limitations of this study must be pointed out: the number of recruited patients and the consequent limited number of restorations for each group must be pointed out. Also, accordingly with exclusion criteria, a category of patients without any health issues was really selected. Another possible limitation of the present RCT is the reduced number of tested materials.
It is desirable to perform randomized controlled trials on a larger number of restorations, possibly comparing Ryge and Snyder clinical parameters with the modified FDI and FIT scores and comparing several restorative materials (e.g. reinforced resins in different formulations).

CONCLUSIONS

The findings of this study showed that the two tested lithium disilicate materials had comparable clinical performances, with a very high success rate after 8 years of service.

Abbreviations

FIT: Functional Index for Teeth; RCT: Randomized Controlled Trial; FIPS: Functional Implant Prosthodontic Score; PPD: probing pocket depths; BoP: bleeding on probing; PI: full-mouth plaque index; RTD: Residual Dentin Thickness; FDI: Federation Dental International.

Funding

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Availability of data and materials

All data generated or analyzed during this study are included in this published article.

Authors' contributions

All authors, EFC, DIKP, GV and MF have: 1. made substantial contributions to conception and design, acquisition of data, analysis and interpretation of data; 2. been involved in drafting the manuscript and revising it critically for important intellectual content; 3. given final approval of the version to be published; 4. agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Patients' written consent to the trial was obtained after having provided a complete explanation of the aim of the study. The study protocol was approved by the Ethical Committee of THE University of Siena (clinicaltrial.gov # NCT 01835821). All procedures performed in this study involving human participants were in accordance with the ethical standards of the Institutional and National Research Committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Consent for publication

The authors have given their consent to publish.

Competing interests

The authors declare that they have no competing interests.

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