Original paper

Comparison of bond failure with resin-modified glass ionomer cement and visible light-cured composite bonding systems in orthodontic patients: A split-mouth randomized controlled trial

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Abstract

Background. Resin-modified glass ionomer cement (RMGIC) is considered a fluoride-releasing bonding agent.

Objectives. The aim of the study was to evaluate the rate of bracket bond failure with light-cured composite (LCC) and RMGIC, and to evaluate factors that contribute to the rate of bracket failure with both bonding agents.

Material and methods. A randomized controlled trial was conducted on a sample size of 33 patients. The patients were randomly allocated for bonding with visible LCC (control group) or RMGIC (intervention group) using the lottery method. The study was double-blinded. The rate of bracket bond failure was assessed after a follow-up of minimum 3 months and evaluated using the survival regression analysis, taking into account the effects of bonding agents and other factors influencing bracket bond failure.

Results. A total of 33 participants were recruited for the study, and 66 quadrants for the intervention and control groups were randomly selected and analyzed. The data was normally distributed and the mean age of the subjects was comparable between both bonding systems. The results of the regression analysis indicated that there was no statistically significant difference between the rate of bracket bond failure with RMGIC and LCC ($p = 0.081$). However, after analyzing the mean days of survival, it was found that bracket survival was negligibly low with RMGIC, with a mean of 216.00 ±133.72 days as compared to LCC, with a mean survival of 224.11 ±124.59 days. No adverse effects were observed during the course of the trial.

Conclusions. There was no difference in the rate of bracket bond failure between the intervention and control groups. The survival rate of brackets treated with RMGIC was found to be comparable to that of LCC, with a minimal difference.

Keywords: bonding agent, bond strength, bracket failure

Introduction

The bonding of brackets to the tooth surface is a technique-sensitive procedure that requires proficient operator control.[1] The ideal orthodontic bracket bonding materials should have adequate shear bond strength to reduce the incidence of bracket breakage.[2,3] Factors that contribute to the loss of bond strength between the bracket and the tooth include mastication occlusal forces, orthodontic stresses exerted by the archwire, the oral environment, and, most importantly, the bonding technique.[4–6] The occurrence of repeated breakages not only increases the duration of treatment but also compromises the treatment outcomes. For every bracket breakage, there are approx. 15 days of expected treatment time.[7,8] Frequent bracket bond failure may be indicative of poor patient cooperation toward orthodontic treatment.[9,10]

To increase the shear bond strength and reduce the rate of bond failure, a range of bonding agents have been introduced, including composite, resin-modified cement and polyacid-modified composites (compomers).[11,12] Each bonding material is polymerized by a different curing mechanism.[13] Composite, which is either polymerized by a self-activated chemical reaction or visible blue light activation, is a widely used material for orthodontic bracket bonding.[14]

In recent years, light-cured composites (LCCs) have been rapidly replaced by chemical cure bonding systems.[15] The LCC system contains camphorquinone, which serves as an initiator and is triggered by visible blue light at 420–450 nm.[16] The advantages of LCCs include increased working time, easier manipulation and increased accuracy of bracket placement while bonding.[17] The disadvantages of light-cured bonding systems include harmful effects of visible blue light and increased armamentarium.[18]

Patients undergoing orthodontic treatment are usually at high risk of caries. Previous reports have proven that the fluoride-releasing properties of glass ionomer cements (GICs) decrease the risk and progression of dental caries.[10,13,16] Fluoride is discharged as a result of the reaction between polyacid and aluminosilicate glass. As the glass network breaks down, it releases Ca^{2+}, Al^{3+} and F ions.[6] Glass ionomer cements also absorb fluoride from toothpaste or mouthwash rinses and re-mineralize themselves, releasing fluoride continuously. This eventually results in a reduction in the incidence of caries and white spot lesions (WSLs) around the brackets in orthodontic patients.[19] After the introduction of GICs, researchers observed that their bond strength was significantly lower than that of conventional composite (CC) materials, as reported in both in vivo and in vitro studies.[11,12] This led to the development of resin-modified GIC (RMGIC) in 1997.[19,20] Resin-modified GIC has combined the strength of the resin bond to enamel and the fluoride-releasing ability of GICs. This makes it a favorable material with a reduced bracket failure rate and a reduced occurrence of demineralized WSLs (DWSLs).[20] Despite all the efforts, RMGIC has not gained popularity due to a lack of publications on the subject. A study by Gaworski et al. evaluated the bracket failure rate of RMGIC and self-cured composite and concluded that the bracket failure rate of RMGIC was 25%, as opposed to the 7.4% bracket failure rate of CC.[21] A study by Choo et al. found no difference in the bracket failure rate between the 2 agents.[12] Similarly, a single-arm randomized controlled trial by Hitmi et al. demonstrated a clinically acceptable bracket failure rate with RMGIC.[20]

A number of studies have compared the shear bond strength of GIC with various polymerization techniques of composite.[18–20] Glass ionomer cements are being used as restorative materials, luting agents, cavity liners, and sealants.[20] However, the shear bond strength of GIC is questionable when compared with composite for the bonding of brackets. A novel modification has recently been introduced, comprising a combination of glass ionomer particles and resin composite filler particles, with the objective of increasing its strength. Previous reports have indicated that RMGIC is not only less technique-sensitive than composite resins but also exhibits caries resistance and has an efficient bond strength.[21,22]

Previous studies have compared the shear bond strength of various bracket bonding techniques.[14,23] For example, Hegarty and Macfarlane found a 16% bracket breakage rate with RMGIC bonding systems and a 3% bond failure rate with LCC.[23] They also reported no significant difference in the rate of bond failure between RMGIC and visible LCC.[23]

Objectives

The aim of the study was to compare the rate of bond failures in RMGIC and visible LCC over a three-month period. The null hypothesis was that there was no significant difference in the rate of bond failure between RMGIC and visible LCC.

Material and methods

Trial design

A double-blind, split-mouth, randomized controlled trial was conducted after obtaining ethical approval from the Aga Khan University Hospital (AKUH) Ethical Review Committee (approval No. 2022-5282-23281). The protocol for this clinical trial was registered in the ClinicalTrials.gov database (registration No. NCT06602154). There was no deviation in the protocol after registration. After the acceptance of the protocol and the commencement of the trial, no alterations were made to the assessment of the outcome. The principles of Good Clinical Practice (GCP) and the Declaration of Helsinki were strictly followed throughout the course of the study. The PICOS model used for this clinical trial is as follows: the Participants were orthodontic patients; the Intervention was RMGIC; the Control was LCC; the Outcome was bracket bond failure; and the Study design was a split-mouth randomized controlled trial.

Study sample

The enrollment of participants started in October 2020, and the last participant was enrolled in January 2022. The patients were recruited from an orthodontic clinic of the Aga Khan University Hospital in Karachi, Pakistan. In the study, we included all patients who expressed willingness to initiate orthodontic treatment with fixed appliance therapy and who were aged between 14 and 40 years and perceived to be compliant. All patients who were willing to participate in the study signed the consent form. The age range of patients who preferred fixed orthodontic mechanotherapy was considerable. Consequently, age was included as a stratification variable in the regression analysis, with the objective of eliminating age as a confounding factor. Patients with enamel surface defects, fluorosis, or syndromic conditions (e.g., hypodontia or microdontia) were excluded from the study. Similarly, patients at high risk of dental caries and those who chose ceramic brackets due to aesthetic concerns were also excluded.

Interventions

All patients included in the study were bonded with fixed 0.022” slot metal brackets (3M™ Unitek™; 3M, Diegem, Belgium) in accordance with the Roth prescription. The bonding of the brackets was performed after full-mouth scaling and polishing, using a direct bonding approach in a split-mouth design. The control and intervention groups were bonded on the opposite arches in the contralateral quadrants and vice versa. Etching was conducted with 37% phosphoric acid for 15 s in both bonding systems. The nickel titanium (NiTi) wires were used for leveling and alignment, beginning with 0.012” NiTi wires and progressing sequentially to 0.018” Stainless Steel (SS) wires. The procedure was concluded with the use of a 0.07 × 25” SS wire. All molars were sealed with GIC.

The control in our study was the gold standard LCC (Transbond XT Light Cure Adhesive; 3M). The intervention was light-cured with Riva, resin-reinforced glass ionomer restorative cement (HV capsules refill). All patients included in the study underwent bonding with both LCC and RMGIC in the contralateral quadrants of the opposing arches. All participants were given the same instructions regarding the care of their brackets and the necessity of avoiding the consumption of hard food items, especially using the front teeth, as well as the need to refrain from fiddling with brackets using the tongue or fingers. Patients were asked to attend orthodontic visits at three-week intervals. During these visits, any bracket breakages were recorded. The procedure was conducted over a three-month period.

Outcomes

The primary objective of this study was to compare the incidence of bracket bond failure in the contralateral quadrants, from the central incisor to the second premolars, in both arches, between the use of RMGIC and LCC. In our clinical practice, bracket bond failure for all orthodontic patients is recorded in well-maintained orthodontic record files. These files also contain other variables, including pre-treatment extraoral and intraoral photographs, findings from model casting, and cephalometric variables. After 3 months, the incidence of bracket bond failure was assessed based on the files of all included patients, without knowing the type of bonding agent used for bracket attachment. Additionally, the duration of bracket survival and the total number of breakages were documented.

The secondary objective of this study was to identify the factors that can contribute to bracket bond failure in both bonding systems. The dataset included data from the incisors to the premolars in all quadrants, but excluded data from the molars. In the assessment of outcomes, only first-time bracket breakage and the duration of bracket survival were recorded. In accordance with standard clinical practice, all orthodontic patients with bracket breakages underwent rebonding with LCC.

Sample size

The sample size was calculated using OpenEpi v. 3.01 sample size calculator (https://www.openepi.com/Menu/OE_Menu.htm), based on the findings of Hegarty and Macfarlane, who reported a bond failure percentage of 30% with light-cured adhesive and a risk ratio of 2.6 (1.7–3.9) for RMGIC as compared to resin-based LCC.[23] In order to maintain the above risk ratio at a 5% level of significance (α) and 80% power of study (1-β), a minimum of 33 subjects were required for this study (Fig. 1).

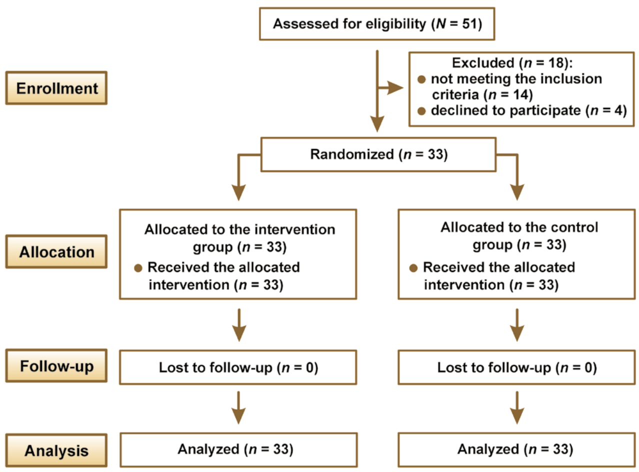

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram

Interim analyses and stopping guidelines

During the course of the study, no interim analysis was performed, and no adverse events were reported by any of the participants.

Randomization (sequence generation, allocation concealment, implementation)

Brackets were bonded in the contralateral quadrants by randomization. The upper right quadrant was bonded with RMGIC and LCC using a simple random lottery method, while the remaining quadrants were bonded in accordance with the split-mouth design. Patients were recruited, and the investigator (HQ) provided an overview of the study design and objectives.

Blinding

This trial was double-blinded. The patients were unaware of the bonding system used in each quadrant, as visible blue light was used to bond both RMGIC and LCC. The investigator responsible for recording the rate of bracket breakage from the patient files was also blinded.

Statistical analysis

The normality of the data was evaluated using the Shapiro–Wilk test on the IBM SPSS Statistics for Windows software, v. 23.0 (IBM Corp., Armonk, USA). Subsequently, the data was analyzed using the Software for Statistics and Data Science (STATA, v. 12.0; StataCorp LCC, College Station, USA). Normally-distributed data was reported as means and standard deviations for continuous variables. All categorical variables were presented as frequency and percentages. The comparative analysis of the rate of bracket bond failure and the assessment of the factors influencing the bracket survival rate were conducted using the survival regression analysis.

Results

Participants flow

The participants were recruited from October 2020 to January 2022. A total of 33 participants were included in the study, and 66 quadrants were randomly bonded with each bonding system.

Baseline data

The descriptive variables, including age, sex, the divergence pattern, overjet, and overbite of the included patients are presented in Table 1.

Table 1. Descriptive statistics of the study participants

Parameter		Value
Sex *n* (%)	females	17 (51.5%)
	males	16 (48.5%)
Age [years] *M* ±*SD*		16.80 ±9.74
Divergence pattern *n* (%)	hypodivergent	10 (18.2%)
	normodivergent	17 (51.5%)
	hyperdivergent	6 (30.3%)
FMA [°] *M* ±*SD*		24.84 ±5.38
Overjet [mm] *M* ±*SD*		5.34 ±3.28
Overbite [mm] *M* ±*SD*		3.81 ±2.25

M – mean; *SD* – standard deviation; FMA – Frankfort-mandibular plane angle.

Numbers analyzed for each outcome, estimation and precision

The rate of bracket bond failure was assessed in 33 patients, with no follow-up loss reported during the course of this study. The stratification for bracket bond failure was conducted for both techniques based on the incisor relationship, vertical mandibular pattern, and the side and site of the jaw.

Comparison of bracket bond failure between the intervention and control groups

A demographics analysis revealed that the mean bracket survival rate for RMGIC was 216.00 ±133.72 days, while the gold standard LCC-bonded brackets survived for a mean duration of 224.11 ±124.59 days (Table 2). In this split-mouth randomized controlled trial, the incidence of bracket bond failure with RMGIC was found to be statistically non-significant (p = 0.291), with a hazard ratio of 1.44 when LCC was used as a reference.

Dentoalveolar factors influencing bracket bond failure

Using incisor class I as a reference, we found a non-significant difference in the incisor relationship of bracket bond failure in class II/1 (p = 0.515), class II/2 (p = 0.060) and class III (p = 0.384). Additionally, no significant difference was observed in bracket bond failure in the mandibular jaw when the maxillary jaw was used as a reference (p = 0.462). Similarly, no significant difference was noted in the posterior segment (p = 0.163) or the left site (p = 0.110) when the anterior segment or the right site, respectively, were used as references (Fig. 2). Moreover, overjet and overbite exhibited no statistically significant influence on bracket bond failure, with hazard ratios of 1.08 and 0.99, respectively (Table 3).

Table 2. Mean bracket survival for resin-modified glass ionomer cement (RMGIC) and light-cured composite (LCC)

Parameter		RMGIC (n = 33) [days]	LCC (n = 33) [days]
Incisor relationship	class I	187.38 ±113.57	197.71 ±117.76
	class II/1	218.40 ±145.14	226.98 ±129.90
	class II/2	256.16 ±89.71	226.98 ±129.90
	class III	246.80 ±129.87	267.11 ±124.90
Divergence pattern	hypodivergent	192.03 ±93.51	192.03 ±93.51
	normodivergent	210.10 ±141.40	210.10 ±141.40
	hyperdivergent	272.16 ±153.86	272.16 ±153.86
Segment	anterior	216.39 ±137.00	227.95 ±123.89
	posterior	215.40 ±129.17	218.37 ±125.88
Arch	maxillary	217.76 ±132.87	218.73 ±126.41
	mandibular	214.18 ±135.00	229.34 ±122.59
Site	right	217.76 ±132.87	270.23 ±132.02
	left	165.78 ±77.82	170.56 ±89.64
RU central incisor		167.26 ±89.05	276.66 ±136.06
RU lateral incisor		167.26 ±89.05	281.16 ±130.83
RU canine		161.73 ±94.60	273.83 ±134.41
RU first premolar		164.60 ±92.88	245.88 ±150.43
RU second premolar		167.26 ±89.05	236.88 ±141.75
LU central incisor		260.00 ±191.94	167.26 ±89.05
LU lateral incisor		261.62 ±134.48	167.26 ±89.05
LU canine		281.16 ±130.83	167.26 ±89.05
LU first premolar		247.83 ±151.35	167.26 ±89.05
LU second premolar		255.88 ±136.19	159.733 ±93.72
RL central incisor		279.11 ±134.56	177.06 ±93.40
RL lateral incisor		259.00 ±189.79	176.56 ±93.72
RL canine		251.41 ±137.15	168.56 ±96.82
RL first premolar		279.11 ±134.56	176.56 ±93.72
RL second premolar		279.11 ±134.56	176.56 ±93.72
LL central incisor		167.26 ±89.05	269.11 ±125.82
LL lateral incisor		153.86 ±85.27	281.16 ±130.83
LL canine		137.60 ±92.22	281.16 ±130.83
LL first premolar		152.66 ±93.58	281.16 ±130.83
LL second premolar		145.73 ±93.14	275.33 ±124.59

RU – right upper; LU – left upper; RL – right lower; LL – left lower. Data expressed as M ±SD.

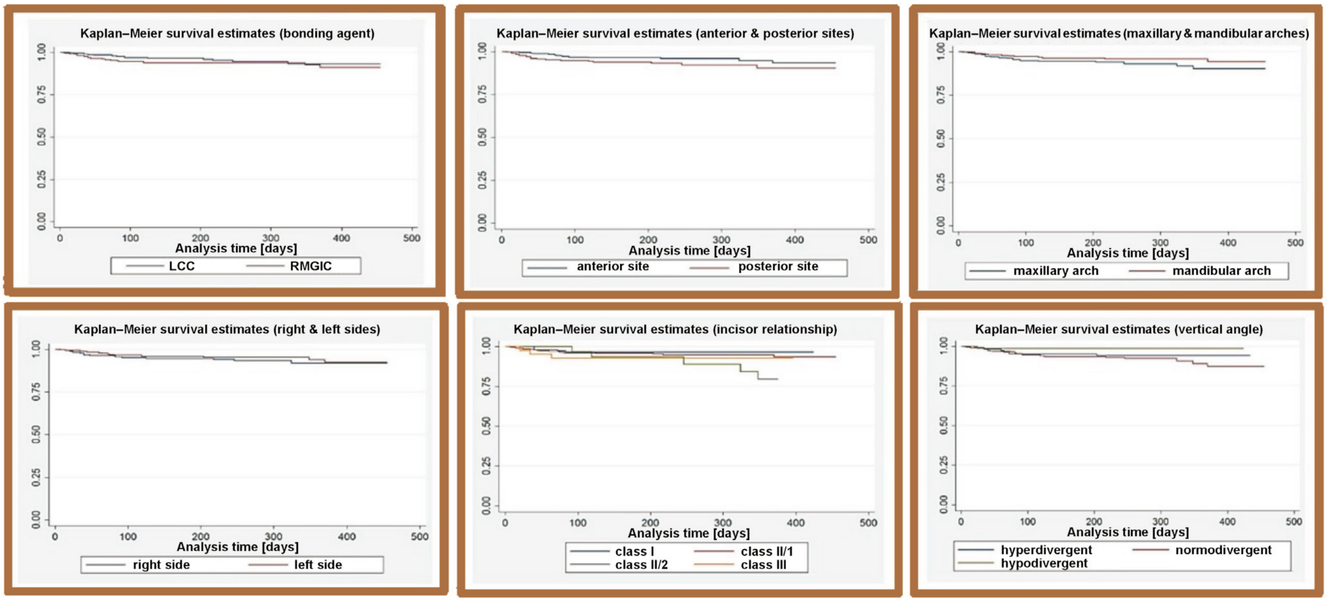

Fig. 2. Kaplan–Meier survival estimate graphs

Table 3. Factors influencing the survival of brackets

Variable		Hazard ratio	95% CI	p-value
Age		0.86	0.77–0.97	0.021*
Overjet		1.08	1.02–1.20	0.010*
Overbite		0.99	0.89–1.10	0.874
FMA		1.01	0.95–1.08	0.551
RMGIC (LCC used as a reference)		1.44	0.72–2.86	0.290
Divergent pattern (normodivergent pattern used as a reference)	hypodivergent	0.20	0.06–0.69	0.012*
	hyperdivergent	0.59	0.24–1.46	0.252
Mandibular jaw (maxillary jaw used as a reference)		0.77	0.39–1.53	0.465
Posterior segment (anterior segment used as a reference)		0.60	0.30–1.21	0.163
Left side (right side used as a reference)		1.73	0.88–3.40	0.103

* statistically significant (p ≤ 0.05, survival regression analysis); CI – confidence interval.

Skeletal factors influencing bracket bond failure

In this study, we found that the hypodivergent profile had a statistically significant influence on bracket bond breakage ($p = 0.020$), with a hazard ratio of 0.20 when the normodivergent pattern was used as a reference. Conversely, the hyperdivergent profile demonstrated a non-significant influence ($p = 0.251$).

Adverse effects

No adverse effects were observed or reported during the course of the trial.

Discussion

In this split-mouth randomized controlled trial, no significant difference was observed in bracket bond failure between RMGIC and the gold standard LCC. Furthermore, our findings suggest that age and the hypodivergent profile significantly influence bracket bond failure in both bonding systems. In this study, we only assessed the first-time bracket bond failure for all participants who had been bonded with either RMGIC or LCC.

Available research on methods to reduce the prevalence and incidence of WSLs among orthodontic patients is still inconclusive, with significant discrepancies in the reported outcomes.[24–27] These discrepancies could be attributed to the lack of a gold standard method for the detection of demineralized spots on enamel surfaces.[26] Studies that employed clinical photographs for the comparison of WSLs with RMGIC and LCC exhibited no statistically significant difference over a three-month period.[24–26] However, Benson et al. reported that there was a significant difference in the severity of WSLs with RMGIC and LCC in the long-term follow-up.[24] Hence, in accordance with previous literature,[25–27] RMGIC should be used for bracket bonding in high caries-risk orthodontic patients to prevent further demineralization during treatment.

This study was designed to address the limitations of the available literature on the comparison and evaluation of bracket bond failure using RMGIC and LCC. Previous studies were limited by their comparison of similar outcomes between different subgroups of patients, which introduced numerous confounding factors, such as differences in oral hygiene maintenance, dietary patterns and habits, for all subjects.[24–26] Therefore, this study was designed as a split-mouth randomized controlled trial in which each participant was bonded with RMGIC as well as LCC.

Comparative ex vivo studies claimed that RMGIC forms a weak bond with the enamel surface compared to LCC.[27,28] This could be because the enamel tags do not form at an appropriate depth in dried extracted teeth. Consequently, this study was conducted among orthodontic patients to compare the incidence of bracket bond failure between the 2 bonding systems on the wet enamel surface of vital teeth. The GIC of RMGIC forms a chemical bond, whereas resin particles form a mechanical bond with the enamel tags.[20]

The findings of our study indicate that the bracket survival rate with RMGIC is clinically acceptable, thereby preventing the severity of enamel demineralization. Similar bond failure results with RMGIC were obtained in the studies conducted by Powis et al.[25] and Fricker.[26] We found that there was no significant difference in bracket bond failure between RMGIC and LCC. In contrast to these findings, Fricker's study reported a significant difference in bracket bond failure between the mandibular and maxillary jaws.[26] This discrepancy may be attributed to the fact that their study was not a split-mouth trial, with different patients allocated to receive RMGIC and LCC. Additionally, their results could be due to the difference in occlusal forces and deep bite in the studied population.

Moreover, researchers have claimed that light-cured RMGIC not only decreases the severity of WSLs but also has multiple clinical benefits, including fast setting time and a reduction in the inconvenience associated with primer application.[24–26] A study conducted by Kaup et al. claimed that light-cured RMGIC has greater bond strength compared to chemically-cured RMGIC.[27] Similarly, our study suggests that light-cured RMGIC should not only be clinically acceptable but also be the preferred bonding agent for orthodontic patients at high risk of caries.

The major strength of this trial is its split-mouth design. A recent study conducted by Qabool et al. described a new technique for the bonding of orthodontic brackets to reduce aerosol generation during the coronavirus disease 2019 (COVID-19) pandemic.[29] We propose that RMGIC and LCC should also be compared with this new technique. However, to generate strong clinical evidence, further clinical trials with larger sample sizes are required. Furthermore, future studies should be conducted with long-term follow-up to evaluate the first evidence of WSLs.

Conclusions

The results of this randomized controlled trial indicate that there is no statistically significant difference in the incidence of bracket bond failure between light-cured RMGIC and LCC. The rate of bracket survival with RMGIC is clinically acceptable to justify its use in orthodontic patients at high risk of dental caries.

Ethics approval and consent to participate

The study was approved by the Aga Khan University Hospital (AKUH) Ethical Review Committee (approval No. 2022-5282-23281). All patients who were willing to participate in the study signed the consent form.

Data availability

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

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