Clinical Performance Between two Types of Composite Resin in Direct Restorations and Its Impacts on QoL

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Abstract

Background: Public health problems associated with oral disease affect large numbers of people in countries around the world. Dental caries continues to be the main cause of premature tooth loss in patients and can negatively affect the Quality of life (QoL) related to oral health for both the individual and their family. Depending on their stage of advancement of caries, a restorative procedure is required, since caries injuries generally involve changing the shape, function or esthetics, restoring is intended to extend the life of the teeth, The purpose of this study was evaluated direct restorations on posterior teeth with conventional and bulk-fill composite resins performed by public health professionals and their effect on Quality of life.

Methods: The sample consisted of 100 teeth in 50 patients. The teeth selected for the restorative procedure were randomized in the two study groups according to restorative material. Group 1 - Bulk fill composite resin, or Group 2 - Conventional composite resin. At the end of 12 and 24 months, the restorations were evaluated according to USPHS criteria, by two evaluators. To evaluate the Quality of Life related to oral health, Oral Health Impact Profile – 14 (OHIP-14) was used before and after restorative treatment (12 months).

Results: After 12 months, 90 restorations were evaluated that showed no statistical difference (p> 0.05), after 24 months, 80 restorations evaluated and also showed similar clinical performance and no statistical difference (p> 0.05). The analysis of quality of life detected a statistical difference only in the psychological discomfort domain (p = 0.024), improving their values at the end of the treatment. There are no differences between the clinical performance with conventional resins or bulk-fill system. Restorative treatment improved the perception of concern and stress suffered by patients by dental problems.

Clinical Trial Registry: RBR-7hbmjp

Introduction

Public health problems associated with oral disease affect large numbers of people in countries around the world. Dental caries continues to be the main cause of premature tooth loss in patients and can negatively affect the quality of life (QoL) related to oral health for both the individual and their family [1, 2]. Depending on their stage of advancement of caries, a restorative procedure is required, since caries injuries generally involve changing the shape, function or esthetics, restoring is intended to extend the life of the teeth, but this does not maintain them free from the possibility of recurrence of a new caries lesion [3, 4].

Among the materials used for a restorative procedure, composite resins have been extensively studied and improved in recent decades [5], they can be used safely as they provide good fracture resistance when used in direct restorations on posterior teeth [6]. These materials and protocols have been frequently evaluated on the best quality performance and longevity of restorations and have become essential in dental practice thanks to the improvement of adhesive technology and the increasing demand of patients in search of esthetics with focus in the preservation of dental structure [7]. By bringing these materials to Public Service work, the possibilities for use are further expanded to reverse loss of structure from carious lesions of posterior teeth. The cost of these materials is relatively low, and we have the possibility of recovering patients’ self-esteem and quality of QoL by restoring the esthetics and function of their teeth [8].

The resin restoration technique is considered sensitive and requires precision to ensure that the restoration does not fail over time. Conventional composite resins require a dry field to work and must be handled in increments of a
maximum of 2 mm to control their polymerization shrinkage [5], in addition to ensuring that light penetrates all material [9]. However, this protocol requires a lot of professional time to complete a successful restoration, especially in extensive restorations.

In last years, great efforts have been made to develop materials and techniques that reduce the time of the procedure, without reducing the durability of the materials and addressing new polymerization control strategies [10]. Among the improvements, modifications in the organic matrix of the resins have allowed the evolution to new materials, such as "bulk fill type resin" (BFR). According to the manufacturers, this material has been developed for use in a single layer, in deep cavities of 4 to 5 mm [11].

The clinical signs associated with contraction of resin polymerization may involve internal and marginal leaks, microcracks in the enamel, marginal space, post-operative sensitivity, and secondary caries [12–14]. These factors are responsible for most substitutions of composite resin restorations [15–17] and, consequently, for psychological impacts on the patient, since the presence of sensitivity can significantly affect the performance of activities, daily like eating and working [2]. In addition, maintaining these restorations flawlessly over time helps reduce the costs of long-term treatment, especially in the public health system.

Definitely, the presence of cavitation in the teeth influences the shame, well-being and specifically the social well-being of the patients. There are very few studies that correlate restorative treatments with quality of life domains, which generally correspond to esthetic rather than functional interventions. It should be borne in mind that aspects of the QoL of patients could be affected by restorative treatment with composite resin.

Aim of this study

Therefore, the objective of this work was to evaluate, through a randomized clinical trial, the clinical performance of direct restorations in posterior teeth between convectional v/s Bulk fill composite resins, and the impact of restorative treatment on the QoL of patients a 24-month follow-up.

Methods

This randomized clinical randomized double blind, and split mouth design trial, approved by the Committee for Ethics in Research of the local university, in accordance with the number of protocol (pending number). It was registered at Rebec identification number (pending number) and held in full corresponding with the Declaration of Association Medical world of Helsinki [18]. All the volunteers signed the term of consent free and clear and the study was conducted in the Center Specialty Dental location Jan to March in 2018, and ratings made on local University the period from January 2019 to February of 2020.

Sample

The participants of this study were patients between 18 and 60 years, who attended the service dental in Center Specialties Dental of (pending name of city) and were met by a professional specialist this service.

For the calculation sampling, the first resulting was calculated on the basis of previous study [19], considering a 15% rate of success in the most posterior restorations resin, a power of 0.8, and a level of significance of 0, 05. Over more, a 20% of loss in follow-up was n = 50 restorations (2 for each patient).

Criteria of eligibility
To be included in the study, patients had to have the presence of at least two molars with caries interproximal to be restored with Class II; occlusal contact with the healthy antagonist tooth or with direct restorative material; and in good state of health overall. Patients with chronic disease with oral manifestations were excluded from the study; habits of bruxism, pulp exposure during the removal of caries or cavities with imminent risk of pulp exposure; patients with teeth that would be used as pillars for dentures removable or partial fixed.

Allocation, groups, and blinding

The teeth that met the criteria for inclusion were distributed randomized by means of envelopes sealed to establish in which group each tooth would be allocated, the following way:

Group I (experimental) - G1: Opus Bulk Fill FGM composite resin. Group II (control) - G2: conventional composite resin Opalis FGM.

The study was double-blind (patient and evaluator blind), split mouth, equal allocation between the groups.

Clinical procedure

Before restoration, all patients responded to the quality of life questionnaire (OHIP-14) [21], were instructed by researchers on proper hygiene to maintain oral health, and an X-ray was taken of all selected teeth with the generic Hyena Dentistry positioner. After removing of the affected tissue with low-rotation burns and dentin, isolation and selection of enamel conditioning with 37% acid phosphoric acid (Condac, FGM - Joinville - Brazil) was performed for 30 seconds, then washed with jet of water and dried with absorbent paper. The universal system adhesive (Ambar, FGM, Joinville, Brazil) was actively applied and light-cured for 20 seconds with the Radii Cal lamp (SDI, Bayswater, VIC, Australia) with intensity measured at 1,000 mW / cm2.

Group I (experimental): The Unimatrix steel matrix (TDV) was inserted to then start the fabrication of the restoration with Opus Bulk Fill (FGM, Joinville, Brazil) composite resin in increments of up to 4 mm. First, the proximal walls were made at the level of the marginal ridge of the neighboring tooth. Each increment was photoactive for 20 seconds and then ended with the occlusal box.

Group II (control): The Unimatrix steel matrix (TDV) was inserted to then start the fabrication of the restoration with composite conventional Opalis (FGM, Joinville, Brazil) by the technique incremental with increments of up to 2 mm. First, the proximal walls were made up to the height of the marginal ridge of the neighboring tooth. Each increment of up to 2 mm, was light cured for 20 seconds with Radii Cal lamp and then made the box occlusal also in of 2 mm increments.

At the end of the restorations, it was achieved the proper adjustments with paper carbon contact (Angelus, Londrina, Brazil) and finishing and polishing to high speed.

Clinical evaluation of restorations

The evaluation of the restoration was done by two evaluators calibrated and blinded to the type of material, at Baseline, 12 and 24 months after realization, based on criteria clinical the evaluation (Alpha, Bravo Charlie), proposed by the United States Public Health Service (USPHS) [20] ( Table 2 ).
Interproximal and periapical radiographs were used for the evaluation during the returns. The sensitivity was evaluated in the application of an air jet with the triple syringe for 5 seconds on the restored teeth.

The clinical time spent in minutes for each group after preparation of the cavity was also assessed and tabulated, that is, precisely the time spent in the insertion and photopolymerization of the restorative material.

Assessment of patients Quality of Life (QoL)

For the evaluation of the quality of life (QoL) related to oral health, were used the questionnaire Oral Health Impact Profile in a resumed version (OHIP-14) validated for the local idiom, (ref pending) with a total of 14 questions answered by the patient in the period reference before treatment and 12 months after treatment.

**Statistical Analysis**

The statistical analyzes followed the protocol of intention to treat according to the suggestion of CONSORT (Consolidated Standards of Reporting Trials) [21]. A descriptive statistical analysis of the groups was carried out, highlighting the relative frequencies of each score. The independent variables were: type of resin (Bulk Fill and conventional), the evaluation time (12 and 24 months) for all items (dependent variables): retention, restoration staining, discoloration marginal, marginal adaptation, secondary caries, surface texture, anatomical shape and thermal sensitivity. After verifying that the data did not have a normal distribution (Shapiro-Wilk, p > 0.05), the Kruskal Wallis test was used to test the hypothesis if there was a statistically significant difference between the groups in relation to the dependent variables.

For the analysis of the clinical time spent on the restorative procedure, the data were tabulated and, because they had a normal distribution, the T-student test was applied.

For the analysis of the questionnaires the total OHIP-14 score, a quantitative analysis methodology was used, in order to explore the behavior of a group through the QoL before and after 12 months after the restorative procedure, so the questions were divided into domains (Table 3) and since the data did not show a normal pattern, the Wilcoxon test was applied.

Statistical analyzes were performed using SPSS 24.0 software (IBM company, SPSS Statistic, USA), with a 5% significance was considered.

**Results**

Fifty patients participated in the study, in which 100 restorations were performed, of these 70 in the first molars and 30 second molars (Table 4). The restorations were evaluated at 12 months and 24 months, with a return rate of 90% and 84%, respectively.

Table 5 shows the relative frequency of each score according to the dependent variable. It is noticed that the relative frequencies were similar between the groups regardless of the variable evaluated. The test Kruskal Wallis test showed no difference significant (p > 0.05) in any of the analyzes are carried out are, ie, the type of resin, the evaluation time were not factors that influenced the variable marginal fit, anatomical shape, discoloration marginal thermal sensitivity, color of the restoration, secondary caries, retention and surface texture of the restorations.
At 12 months, 90 restorations evaluated, which characterized a loss of 10% of the sample, and at 24 months after making the restorations, 42 patients returned for evaluation, totaling 84 evaluated restorations, which characterized a loss of 16% of the sample.

In the individual analyzes, it was possible to observe that the materials showed good retention rate, at 12 months only one restoration of the experimental group and none of the control group were lost and at 24 months only one restoration of the experimental group and two of the control group were lost. For marginal adaptation, analyzed after interproximal radiographic taking of all restorations, regardless of the group, the vast majority were classified as Alpha (excellent), some restorations from both groups already showed some mismatch, however still acceptable and which will be monitored in the long term. Post-operative air-jet sensitivity was observed in three patients in the experimental group and two in the control group at 12 months. One of the patients was probably due to the presence of secondary caries in one of the teeth. And at 24 months in none of the groups there was sensitivity. In the other criteria, the restorations showed good clinical behavior.

At the time of the evaluations, the missing restorations and those with secondary caries were redone by the instruction of ethical committee.

Although there were no statistical differences in the clinical quality of the procedure, it was also possible to analyze the clinical time in minutes (Table 6) spent for each procedure after cavity preparation, that is specifically, the time spent in the insertion and photopolymerization of the restorative material, and it was possible to account that the single increment procedures - G1, used a clinical time of almost 30% less than resins with incremental technique.

Quality of Life (OHIP-14)

The responses given to the OHIP-14 quality of life questionnaire were tabulated and analyzed before and 12 months after the restoration was performed. The statistical analysis of quality of life (Table 7) did not detect any significant difference between groups in all domains except domain 3 (psychological discomfort), where greater discomfort to patients was observed when they answered the questionnaire before the restorative procedure, as well as an improvement in scores at 12 months after treatment. (p < 0.05)

Discussion

The use of bulk fill composite in posterior restorations to class I and class II cavities has been increasingly common and with clinical effectiveness similar to the conventional composite resin used the incremental technique [22]. Likewise, several in vitro studies [23, 24] conducted comparing bulk fill resins with resins inserted by the incremental technique have shown good results for bulk fill resins [25]. However, in vitro evaluations do not reflect the real behavior of these materials and have a variety of limitations that allow considering this evidence to support clinical decision-making. For this reason, randomized clinical trials are the best study model for this purpose.

This study was characterized as a prospective, randomized, double-blind split-mouth design, which allowed the same patient to establish the two stud groups in the same clinical conditions and evaluation. Thus, this study evaluated the clinical performance and the impact on the quality of life of patients who received different class II restorations performed by public service professionals. Regarding the clinical performance of the different
composite resins, and based on the results of the modified USPHS clinical evaluation criteria (anatomical shape, marginal discoloration, surface texture, post-operative sensitivity, retention, secondary caries, color and marginal adaptation), no significant differences were found between the two materials tested for all assessment periods (12 months and 24 months).

These results are in accordance with previous and recent clinical studies that also found no differences when different restorative strategies were used in class II cavities [26, 27]. It is crucial to understand how the use of a bulk-fill composite can improve the marginal adaptation of restorations. The findings of this study showed an average rate of 90% of restorations with alpha criteria values (excellent). Although the evaluation time is relatively short, the good performance in this parameter of the bulk-fill composite resin can be associated with the consistency of the material used. The bulk-fill composite resin of the study has regular consistency, which allowed the entire restoration to be carried out with the same material, in addition to facilitating the construction of the proximal wall. Some in vitro studies [23, 24] have shown that composite bulk-fill have similar behavior that incrementally resin composite technique. In a recent study [24] was investigated the relationship between gap volume, pore volume and polymerization shrinkage volume of bulk composite resins and conventional resin and found the similar performance of these materials. Those explain the good radiographically proven results of marginal adaptation of the performed restorations. The bulk-fill composite resin, due to its modification in the resin matrix, higher translucency, and low modulus of elasticity, facilitate the accommodation in a single increment and reduce the stress of polymerization contraction, contributing to the maintenance of marginal integrity [23, 24]. Another essential aspect that deserves to be highlighted is post-operative sensitivity. For the two groups studied, the average sensitivity rate was 97.4% with alpha criteria after 24 months of study. The optimal response of this criterion can be related to the type of adhesive system used. The present study used Ambar Universal, using phosphoric acid only in enamel and applying the self-etching adhesive to dentin. This strategy is reported in the literature for showing good results over time, mainly for the post-operative sensitivity factor [28, 29]. The findings of the present study for this parameter are inconsistent with the recent study [26] who reported persistent sensitivity for one of the groups that used bulk-fill composite resin. The maintenance of sensitivity could be related to the adhesive technique of conditioning dentin with phosphoric acid. The use of adhesives in the self-etching modality combined with the fact of working with a composite resin that allows insertion and restoration of the cavity in a single increment makes the procedure more dynamic and less dependent on the operator. In this regard, it is essential to mention that the average time to perform a restoration with bulk-fill composite resin was significantly less than the time spent with conventional composite resin. This great difference is directly related to the incremental technique that needs to be applied to conventional resin, since the use of higher volumes for conventional composite resins leads to more significant contraction stress. It brings the deleterious effects of this phenomenon for restoration [23, 24]. These findings also corroborate the results of the recent study [30], who observed a significant reduction in the average time to make a restoration when using bulk-fill composites in different presentation modes, regardless of the adhesive strategy used.

The present study also provides an assessment of the QoL of patients who received restorative treatment. QoL is a multidimensional aspect that covers several domains such as well-being, happiness, pleasure and personal fulfillment, with oral health being one of the aspects that can influence it. The assessment aims to understand how the different domains are influenced by the characteristics of the changes that affect the individual [31]. It is proven that dental caries disease has a high negative impact on Quality of Life, especially in families with disadvantaged social conditions [32]. Thus, the use of clinical resources in the assessment of oral conditions has demonstrated the importance that diseases have in the physical and psychological well-being of individuals [31].
When evaluating experiences subjective of individuals to determine the impact of the conditions of health oral well-being and self-esteem is possible to improve the intervention clinics and thus the quality of life. In this study, OHIP-14 was used as an instrument to assess these impacts on patients who sought to improve their esthetic and functional aspect through restorative procedures. To this end, a set of parameters such as functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and social disadvantage were evaluated. OHIP 14 was answered by patients before and 12 months after undergoing the clinical restorative procedure. For each question, patients were given a value on a scale of 0 and 5. This means that the higher the value assigned; the greater will be the impact negative provoked regarding the domain investigated. When comparing the results obtained, it is possible to observe changes before and after completion of the procedure. Although no statistically significant differences were found in the total OHIP-14 total score (p = 0.335), it can be inferred that the applied procedure promoted improvements in the participants’ quality of life, observing a drop in the total score value after the procedure.

Differences like these, also were encountered by McGrath [33], which showed differences positive in areas OHIP after restorative procedures. However, among the domains that make up the OHIP-14, psychological discomfort was the one that obtained the greatest difference between the scores before and after the procedure. This means that the treatment has improved the concern and problems caused by dental changes. With this, the relevance that the esthetic / functional factor of the teeth has, as well as its fundamental role in the individual's QoL, is also considered, interfering even in the social and psychological condition of the same [8]. This finding deserves greater emphasis, since the services offered by the single health system, in Dentistry, may have increased resolvability, complexity and dynamics, with the maintenance of quality. In addition, patients with characteristics similar to those presented in the study will have access to solving a problem that affects their general health, which can have a positive impact on their lives. Based on the findings, and considering the low cost of mate would is involved in research and the environment and context in which were performed the procedures we can recommend and suggest as a way of contributing to streamline care, with quality and reduction of costs long term, that professionals have access to bulk fill type resins (single increment) to be used in specific cases of extensive class I or II restorations to reduce the procedure time and operator / patient fatigue. It can be suggested also to use together with adhesive dental universal type, for the avoidance conditioning acid dentin, which decreases considerably sensitivity post-operative felt by the patient.

The psychological discomfort domain considered an item related to the feeling of self-consciousness, definitely a person with cavitated caries could feel shy, once restored this would improve their confidence. Like another item, consider feeling ashamed, and even now having cavities is a synonym for poverty and lower social status. And finally, this domain considers an item related to feeling tense, which could be related to pain and chewing altered by having cavitated cavities, would be solved with the final restoration [34].

It is essential to highlight that the study, despite being a clinical trial, has the limitation of having a relatively short follow-up, which can prevent the extrapolation of the results to scenarios of greater longevity. Thus, more clinical studies with more clinical follow-up and greater diversity of materials are recommended, as well as their impact on QoL.

**Conclusion**

The restorative treatment has resulted in psychological benefits for patients, improves the consciousness, ashamed and tension included in psychological discomfort domain (QoL).
Abbreviations

QoL
Quality of Life
OHIP-14
Oral Health Impact Profile – 14
BFR
Bulk Fill Resin composite, restoration dental material
USPHS
United States Public Health Service
CONSORT
Consolidated Standards of Reporting Trials

Declarations

Authors’ contributions

SZ, AR, NH, MR and MC designed the study. SL, DM, RM, EF, GJ and CR collected the data. SL, MR, MC and EF analyzed data. SL, DM, RM, EF, GJ, SZ and MC discussed the results. SL wrote the manuscript with input from all authors. All authors read and approved the final manuscript. All authors contributed equally to this work.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval all procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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Tables

| Manufactures | Lot number | Commercial name | Composition |
|--------------|------------|-----------------|-------------|
| FGM          | 290318     | OpaLLis         | Bis-GMA (Bis-Phenol A di-Glycidyl Methacrylate) monomers, BisEMA (Bis-Phenol A di-Glycidyl Methacrylate ethoxylate), TEGDMA (Triethylene glycol dimethacrylate), camphorquinone, cointiator and silane. Micronized barium-aluminum silicate glass, pigments and nanometric silica. |
| FGM          | 270317     | Opus            | BulkUrethane-methacrylic monomers, Methacrylic oligomers with spatial conformation in alpha helix, Fill Urethane oligomers, special initiators (APS System). Charge of silanized silicon dioxide, aluminosilicate barium glass, 10 μm, 2 μm, 1 μm and 0.7 μm. (79% by weight). |
| FGM          | 260717     | Ambar Universal Adhesive | Methacrylic monomers, photoinitiators, cointiators, stabilizer, Inert charge (silica nanoparticles) and vehicle (ethanol) |
Table 2. *United States Public Health Service* (USPHS) Modified Criteria

| Evaluation criteria          | Alpha: no loss of restorative material | Bravo: partial retention | Charlie: missing restoration |
|-----------------------------|---------------------------------------|--------------------------|-----------------------------|
| Retention                   | Alpha: no loss of restorative material | Bravo: partial retention | Charlie: missing restoration |
| Color                       | Alpha: normal color, no staining      | Bravo: acceptable staining | Charlie: unacceptable staining |
| Marginal discoloration      | Alpha: no staining                    | Bravo: light staining, no need for replacement | Charlie: staining in need of replacement |
| Marginal Adaptation         | Alpha: closely adapted, no visible gaps | Bravo: visible gap, with penetrating explorer | Charlie: cavity in which dentin is exposed |
| Secondary caries            | Alpha: absence of caries              | Charlie: caries present  |
| Surface texture             | Alpha: close to enamel texture        | Bravo: rougher surface than enamel, but acceptable | Charlie: unacceptable roughness |
| Anatomical form             | Alpha: continuous restoration with existing anatomical shape | Bravo: slight discontinuity, clinically acceptable | Charlie: discontinuous, unacceptable |
| Postoperative sensitivity   | Alpha: No sensitivity                 | Charlie: sensitivity present at some point in the study |

Table 3 – OHIP-14 domains
Table 4 – Sample Features

| Teeth        | Upper tooth | Lower tooth | Total |
|--------------|-------------|-------------|-------|
| First molar  | 30          | 40          | 70    |
| Second molar | 18          | 12          | 30    |
| Total        | 48          | 52          | 100   |

Table 5. Clinical evaluation results for each group classified according to the modified USPHS criteria
| USPHS Criteria | (***) | BASELINE | 12 MONTHS | 24 MONTHS |
|----------------|--------|----------|-----------|-----------|
|                |        | G1       | G2        | G1        | G2        | G1        | G2        |
| Retention      | A      | 50/50(100) | 50/50(100) | 45/44(97.7) | 45/45(100) | 42/41(97.6) | 42/40(95.2) |
|                | C      | –        | –         | 45/01(2.3) | –         | 42/1(2.4)  | 42/2(4.8)  |
| Color          | A      | 50(100)  | 50/50(100) | 44/44(100) | 45/45(100) | 41/38(92.7) | 40/38(95.0) |
|                | B      | –        | –         | –         | –         | 41/3(7.3)  | 40/2(5.0)  |
|                | C      | –        | –         | –         | –         | –          | –          |
| Marginal discoloration | A | 50/50 (100) | 50/50 (100) | 44/43(97.7) | 45/45(100) | 41/38(92.7) | 40/36(90.0) |
|                | B      | –        | –         | 44/1(2.3) | –         | 41/3(7.3)  | 40/4(10.0) |
|                | C      | –        | –         | –         | –         | –          | –          |
| Marginal Adaptation | A | 50/50 (100) | 50/50 (100) | 44/42(95.4) | 45/44(97.7) | 41/35(85.3) | 40/33(82.5) |
|                | B      | –        | –         | 44/2(4.6) | 45/1(2.3) | 41/6(14.7) | 40/7(17.5) |
|                | C      | –        | –         | –         | –         | –          | –          |
| Surface texture | A | 50/50 (100) | 50/50 (100) | 44/43(97.7) | 45/45(100) | 41/38(92.7) | 40/36(90.0) |
|                | B      | –        | –         | 44/1(2.3) | –         | 41/3(7.3)  | 40/4(10.0) |
|                | C      | –        | –         | –         | –         | –          | –          |
| Anatomical form | A | 50/50 (100) | 50/50 (100) | 44/44(100) | 45/45(100) | 41/39(95.1) | 40/39(97.5) |
|                | B      | –        | –         | –         | –         | 41/2(4.9)  | 40/1(2.5)  |
|                | C      | –        | –         | –         | –         | –          | –          |
| Postoperative sensitivity | A | 50/50 (100) | 50/50 (100) | 44/41(93.2) | 45/43(95.5) | 41/41(100) | 40/40(100) |
|                | B      | –        | –         | 44/3(6.8) | 45/2(4.5) | –          | –          |
|                | C      | –        | –         | –         | –         | –          | –          |
| Secondary Caries | A | 50/50 (100) | 50/50 (100) | 44/43(97.7) | 45/45(100) | 41/40(97.5) | 40/38(95.0) |
|                | C      | –        | –         | 44/1(2.3) | –         | 41/1(2.5)  | 40/2(5.0)  |

(**) A=Alfa; B= bravo; C = Charlie

Table 6. Time spent in minutes to insert restorative material
| Group                  | Time spent in min average (SD) | P value |
|-----------------------|--------------------------------|---------|
| G1 – Opus Bulk Fill   | 15.0 (±5.0)                    |         |
| G2 - Opallis          | 25.0 (±7.0)                    | 0.033   |

Table 7 - Mean, standard deviation (SD), minimum (min) and maximum (max), of QoL before and after the restorative procedure.

| Domains                          | Before Mean, SD, min and max | 12 months control Mean, SD, min and max | p*   |
|----------------------------------|------------------------------|----------------------------------------|------|
| Functional limitation            | 1.73 (1,804)                 | 0 – 1.78 (1,941)                        | 0.672|
| Physical pain                    | 2.23 (2.001)                 | 0 – 1.94 (1,758)                        | 0.576|
| Psychological discomfort          | 2.93 (2,566)                 | 0 – 1.46 (1,990)                        | 0.024|
| Physical Disability              | 0.54 (1,317)                 | 0 – 0.66 (1,227)                        | 0.675|
| Psychological disability         | 1.57 (1,908)                 | 0 – 1.40 (1,853)                        | 0.971|
| Social disability                | 0.33 (0.674)                 | 0 – 0.55 (0.886)                        | 0.642|
| Handicap                         | 0.66 (1.139)                 | 0 – 0.70 (0.904)                        | 0.512|
| Overal OHIP-14 score             | 9.99 (11.409)                | 0–19 8.49 (10.559)                     | 0.335|

**Supplementary Files**

This is a list of supplementary files associated with this preprint. Click to download.

- Datarepository.pdf