A prospective, multi-center, randomized, and controlled clinical trial for the evaluation of the safety and efficacy of Filtek™ Bulk Fill Posterior Restorative in the direct restoration of Class I and II cavities of posterior teeth

Statistical Analysis Plan

V1.1

Statistical Analysis Unit:	Medical Statistics Department of National Cardiovascular Center
Sponsor:	3M ESPE Dental Products
Release Date:	March 3, 2020

- round enough after cavity preparation

SIGNATURE PAGE

Study Title:	A prospective, multi-center, randomized, and controlled clinical trial for the evaluation of the safety and efficacy of Filtek™ Bulk Fill Posterior Restorative in the direct restoration of Class I and II cavities of posterior teeth	
Sponsor:	3M ESPE Dental Products	
Study No.:	MDI 0102	
Release Date:	March 3, 2020	
Version Number:	V1.1	
Sponsor/Agent CRO	Title: _____ Signature: _____	Year Month Day
Principal Investigator	Title: _____ Signature: _____	Year Month Day
Author of the Plan (NCCD)	Title: _____ Signature: _____	Year Month Day
Approver of the Plan (NCCD)	Title: _____ Signature: _____	Year Month Day

Table of Contents

ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviations	Definitions of Terms
AE	Adverse Event
SAE	Serious Adverse Event
FAS	Full Analysis Set
PPS	Per Protocol Set
SS	Safety Set
CRF	Case Report Form

1. Introduction

This document describes the specific contents of the Statistical Analysis Plan of a prospective, multi-center, randomized, controlled, and noninferiority clinical trial for the evaluation of the safety and efficacy of Filtek™ Bulk Fill Posterior Restorative in the direct restoration of Class I and II cavities of posterior teeth. When all the subjects are enrolled and complete the 1 year (±1 month) follow-up visits after the filling procedure or the trial is terminated early and the database is locked, a statistical analysis report for preoperative and 1 year (±1 month) follow-up visits after the filling procedure will be submitted for registration application. Please refer to the relevant tables, checklists, and graphs in the Statistical Analysis Plan for specific analysis items.

2. Background of the clinical trial

2.1 Background data of the disease

Composite resins for posterior restoration have been applied rapidly since the 1990s. At present, the composite resin is widely used in many countries to restore the tooth defect, contour, and function of posterior tooth in a nearly complete replacement of silver amalgam. This is mainly due to the fact that the resin has the following characteristics that the silver amalgam does not have: ① esthetic ② environmentally friendly ③ its adhesion to dental tissues is through chemical and micro-mechanical adhesion rather than simple mechanical adhesion ④ maximized preservation of healthy dental tissues. In comparison, the composite resins for posterior restoration have been greatly improved in terms of distribution, particle size, and content of filler and also mechanical and physical properties, resulting reduced polymerization shrinkage, enhanced wear resistance performance, and greatly improved clinical operational performance.

The bulk-fill material for posterior restoration (a translucent composite resin material with higher curing depth) was first applied in clinical restoration and treatment of posterior tooth defects at the start of 2000. In vitro experiments showed that the success rate of less but thicker material is the same as that

of incremental filling at a smaller thickness, while the risk of voids or failure due to thinner increment could be avoided. It is also reported in the literature that the bulk-fill materials have acceptable creep deformation, which is within the range of other composite resin materials.

3M™ Filtek™ Bulk Fill Posterior Restorative is a bulk-fill material. It is a filling and restoration composite material that can be activated by visible light and is optimized to restore posterior tooth more simply and quickly. When Filtek™ Bulk Fill Posterior Restorative is applied in a tooth with the methacrylate-based dental adhesive (such as the dental adhesive manufactured by 3M ESPE), the restoration can be permanently adhered to the tooth tissue. This bulk-fill resin material is more convenient and quicker to apply in comparison to the traditional composite resin materials and can save the operation time for the filling procedure.

3M™ Filtek™ Bulk Fill Posterior Restorative was marketed and sold in the United States, Canada, and Western Europe in September 2014 and has been widely used clinically without any AE report or complaint up to now. This trial is a pre-marketing clinical validation trial in China, and will comply the Helsinki Declaration and CFDA's Good Clinical Practice of Medical Device Clinical Trial (March 23, 2016), and will be designed and implemented in references to the requirements of CFDA's Technical Review Guidelines for the Registration of Dental Resin Filling Materials [9] and the Clinical Trial Guideline for Polymer-based Dental Restorative Materials [10] in order to evaluate the clinical safety and efficacy of Filtek™ Bulk Fill Posterior Restorative 1 week and 1 year after the restoration of Class I and II cavities of posterior teeth using a randomized controlled trial design method.

3. Overall design of clinical research

3.1 Trial objective

Evaluation of the safety and efficacy of Filtek™ Bulk Fill Posterior Restorative 1 week and 1 year after its application in the filling of Class I and II cavities of posterior teeth.

3.2 Selection and justification of methodology

The investigational product is a bulk-fill resin. As required in CFDA's Technical Review Guidelines for the Registration of Dental Resin Filling Materials, its clinical trial should be conducted in reference to the Clinical Trial Guideline for Polymer-based Dental Restorative Materials, which is applicable to the polymer-based dental restorative materials used in the direct restoration of posterior tooth defects, to restore Class I and II cavities of posterior teeth, in order to evaluate the safety and efficacy of 3M's Filtek™ Bulk Fill Posterior Restorative in clinical application (not including the evaluation of other new functions).

3.3 Evaluation methodology of efficacy

1) The primary efficacy measure is the clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure

According to the Clinical Trial Guideline for Polymer-based Dental Restorative Materials (YY/T 0990-2015), the definition of clinically acceptable filling at the 1 year follow-up visit is: grade A for retention and fracture of the filling 1 year after the filling procedure; grade A or B for marginal fracture, contour, and marginal adaptation of the filling.

3.4. Secondary efficacy measures

1) Clinical acceptance rate of the filling at the 1 week follow-up visit after the filling procedure:

According to the Clinical Trial Guideline for Polymer-based Dental Restorative Materials (YY/T 0990-2015), the definition of clinically acceptable filling at the 1 week follow-up is: grade A or B 1 week after the filling procedure for all the evaluation measures, including retention and fracture of the filling, marginal fracture, contour and marginal adaptation, proximal contact, color match, surface roughness, surface staining, marginal discoloration, secondary caries and pulp status;

2) Proximal contact, color match, surface roughness, surface staining, marginal discoloration, secondary caries and pulp status 1 year after the filling procedure

Scoring criteria for each item are listed in Appendix 1 of the protocol. The score of each item shall be recorded in the original medical record and case report form of the trial as required.

3.5 Evaluation methodology of safety

All AEs and SAEs will be collected and recorded from the time when the subject signs the Informed Consent to the time when the subject completes the trial or withdraws from the trial early. Primary measures include the examination of oral soft tissues and secondary caries and pulp stimulation. Because the investigational device is filling resin for posterior tooth, which will be used by local application, its safety evaluation is mainly concentrated in the oral cavity. The evaluation will be conducted before filling, immediately after filling, 1 week after filling, and 1 year after filling, in which the oral soft tissues to be examined include but not limited to buccal mucosa, lip, upper jaw, floor of mouth and tongue, and record all abnormalities and conduct statistical analysis.

The subjects can also report any local and systemic abnormalities to the investigator at any time. If necessary, they can make an appointment with the investigator for examination as soon as possible.

Evaluation methodology of secondary caries and pulp status are as stipulated in Appendix 1 of the protocol, and should be conducted before filling, immediately after filling, 1 week after filling, and

1 year after filling. If there is any abnormality and the investigator determines that it is clinically significant, it should be determined as an AE.

4. Investigational device/control product

4.1. Investigational device

Product name: 3M™ Filtek™ Bulk Fill Posterior Restorative

Specifications and Model:

Kits: 4863TK, 4864TK

In syringes: 4863A1, 4863A2, 4863A3, 4863B1, 4863C2

In capsules: 4864A1, 4864A2, 4864A3, 4864B1, 4864C2

4.2. Control device

Product name: 3M™ Filtek™ Z350XT Restorative

Specifications and Model:

In syringes: 7018A1B, 7018A2B, 7018A3B, 7018A3.5B, 7018B1B, 7018C2B

4.3 Indications of the products

4.3.1 Indications of the investigational device

- Direct restoration of anterior and posterior teeth (including occlusal surface)
- Base/liner under direct restorations
- Core build-ups
- Splinting
- Indirect restorations, including inlays, onlays, and veneers
- Restorations of deciduous teeth
- Extended fissure sealing in molars and premolars
- Repair of defects in porcelain restorations, enamel, and temporaries

4.3.2 Indications of the control device

- Direct restoration of anterior and posterior teeth (including occlusal surface);
- Post-core technique;
- Splinting;
- Indirect restorations, including inlays, onlays, and veneers.

5. Subject selection

5.1 Inclusion criteria

1） Male or female, 18-70 years old (including 18 and 70 years)

2） Healthy, with no major systemic disease

3） Normal mouth openness

4） Molar (preferred) or premolar

5） Cavities satisfying any of the following 4 conditions:

a) Class I cavities, including those that need to be restored again after a previously failed filling;

b) Class II cavities, with a lesion on tooth locations other than second molars (including a failed previous filling, which needs to be filled again now), and the gingival margin after cavity preparation on the proximal surface located at the gingival crown margin;

c) Class II cavities, with a lesion on second molars, no missing third molars (including a failed previous filling, which needs to be filled again now), and the gingival margin after cavity preparation on the proximal surface located at the gingival crown margin;

d) Class II cavities, with a lesion on second molars, missing third molars, lesion on the Mesial Occlusal (MO) or Mesial Occlusal Distal (MOD) surface of second molars (including a failed previous filling, which needs to be filled again now), and the gingival margin after cavity preparation on the proximal surface located at the gingival crown margin;

6） Cavity size: minimum buccolingual distance on the occlusal surface (approx.) not less than 1/3 of buccolingual distance between the cusps;

7） The opposing tooth is natural;

8） Depth of the lesion reaching at least the middle layer of dentin with normal pulp vitality;

9） The subjects agree to participate in the trial and sign the Informed Consent;

10） The subject is compliant and committed to follow-up visits.

5.2 Exclusion criteria

1） Allergic constitution or allergic to multiple drugs; allergy history of polymer based materials, such as dental resin;

2） Aggressive caries; severe periodontitis; abnormal salivary gland function; temporomandibular joint disorder;

3） Poor oral health, DMFT: > 4 for 18~34 years old; >5 for 35~70 years old;

4） Teeth with special staining;

5） Non-carious tooth diseases, such as pathological wear (nocturnal molars, clenching habits), acid erosion, or subfissure;

6） Abnormal occlusion;

7） Severe systemic diseases; mental illness;

8） Breastfeeding, pregnant (positive pregnancy test result) and at childbearing age with intention to conceive;

9） The subject is determined to be poor compliance and could not complete the trial as required as determined by the investigator;

10） The cavity is determined to be unsuitable for resin filling by the investigator;

11） Pulp already exposed or close to be exposed at the bottom;

12） The subject plans to go overseas within 1 year or cannot complete the 1 year follow-up visit after the procedure due to other reasons;

13） The subject also participates in a clinical trial of the other drug or medical device, which has not reached its clinical endpoint;

14） The subject is not tolerant of or willing to use the rubber dam.

If multiple caries of a subject meet the inclusion/exclusion criteria, the investigator will select the enrolled tooth by giving priority to molars; If all the teeth that meet the inclusion/exclusion criteria are molars, the investigator can enroll any tooth and indicate the enrolled tooth number in the original medical record and case report form. If other teeth that are not included need to be treated at the same

time, the name of filling resin (when other marketed products than Filtek^{TM} Z350XT are required) and the tooth location number for such filling should be recorded.

6. General statistical considerations

6.1 Determination of the sample size and its justifications

6.1.1 Statistical design (Test of Hypothesis)

This trial will adopt a prospective, multicenter, randomized, and controlled design, using the Filtek^{TM} Z350XT as the control, which is also a resin filling material and has similar and comparable characteristics, uses, and indications to the investigational device. The noninferiority design will be adopted to prove that the safety and efficacy of the investigational device are not inferior to the control device, which was already approved for marketing with clinically validated safety and efficacy. Corresponding statistical design and test of hypothesis are:

$$H_0 : p_T - p_C \leq -\Delta$$
$$H_1 : p_T - p_C > -\Delta$$

Where p_T is the expected success rate of the filling in corresponding treatment group, p_C is the expected success rate of the control group and Δ is the noninferiority margin (absolute value).

6.1.2 Total sample size

It is estimated that 240 patients will be enrolled in this trial, and randomly assigned to the treatment or control group at 1:1 ratio. The number of cases in each group is 120. The calculation of the sample size is based on the primary endpoint measure, i.e. clinical acceptance rate of the filling at the 1 year follow-up visit.

Since the scope of application of the investigational device is direct or indirect restoration of both anterior and posterior teeth, and based on existing clinical evidence and estimation by the clinical experience of experts, and assuming the clinical acceptance rate in the control group 1 year after treatment is 97% and it is estimated that the treatment group can reach the same effective level after using the investigational product, with a clinically recognized noninferiority margin of 7% after discussion, a significance level of 5% at two tails, a statistical power of 80%, and a maximum possible dropout rate of 20%, about 120 patients should be included in each group with a total of 240 patients to be included in both groups.

Corresponding sample size calculation is:

$$n = \frac{\left[\mu_{1-\alpha}\sqrt{2\overline{p}(1-\overline{p})} + \mu_{1-\beta}\sqrt{p_T(1-p_T)+p_C(1-p_C)}\right]^2}{(\Delta-(p_T-p_C))^2}$$

Where p_T is the expected fusion effectiveness of the treatment group, p_C is the expected effectiveness of the control group, $\overline{p}$ is the mean effectiveness of both groups, Δ is the noninferiority margin, μ is the quantile of standard normal distribution, α is the level of Type I Error, which is set at 0.025, and β is the level of Type II Error, which is set at 0.2.

6.2 Analysis population

1) Safety Set (SS): include all the subjects who are enrolled, receive the filling, and complete at least 1 follow-up visit.

2) Full analysis set (FAS): the set of subjects determined according to the Intention-To-Treat principle, which refers to the data set composed of all the subjects who are included in randomization and receive the investigational product.

3) Per Protocol Set (PPS): refers to the subgroup of treatment population who are included in randomization and receive the investigational product, while excluding those who seriously violate the protocol (referring to the violation of the inclusion criteria or exclusion criteria by the subjects, etc.).

The analysis of primary efficacy measures will be based on the FAS and PPS at the same time. In addition, all baseline demographic data and analysis of secondary efficacy measures will be based on the FAS, so as to the safety evaluation (SS is the same as FAS in terms of definitions, and thus is not defined separately).

6.3 Determination rules and flow diagram of analysis population data set

(1) No investigational device is used: the subject is assigned a random number, but does not receive any trial related treatment (treatment group, control group, or a third-party product);

(2) Violation of the inclusion and exclusion criteria: the subject does not meet the inclusion criteria or meets the exclusion criteria defined by the protocol, and their violation of the protocol will seriously affect the evaluation results of primary efficacy measures; such violations will be determined jointly by the sponsor, investigators, and biometrician on whether they seriously affect the evaluation results of the primary efficacy measures via discussion in the peer review meetings;

(3) Lost to follow-up in the trial: the primary endpoint measure of a subject - clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure - cannot be acquired.

(4) Cross assignment: The subjects randomly assigned to the treatment group use the product for the control group, and vice versa;

(5) Use of an investigational product out of spec: the specifications of the device used by the subject is not within the range specified in the protocol;

(6) Use of a third-party product: the subject who is randomly assigned to the treatment or control group receives a third-party product;

(7) FAS = number of randomly assigned subjects - number of subjects who do not receive any investigational device;

PPS = FAS - number of subjects who are in serious deviation to the protocol;

Number of subjects who are in serious deviation to the protocol = number of subjects who fail inclusion and exclusion criteria + number of subjects who are lost to follow-up in the trial + number of subjects who are crossly assigned + number of subjects who receive an out of spec investigational product + number of subjects who receive a third party product;

Priorities of deviations to the protocol are: lost to follow-up in the trial; cross assignment; use of a third party product; use of an out of spec product; failing inclusion and exclusion criteria. If a subject satisfies two or more above violations, they will be categorized by the aforesaid priority;

All deviations to the protocol in tabulated statistical analysis will be listed depending on actual situations. If the number of subjects who receive out of spec products is 0, it cannot be displayed in the table. At the same time, the subjects who do not receive any investigational device or are in serious deviation to the protocol will be listed, including the center code, randomization number, group, gender, age, type, reason, FAS, and PPS.

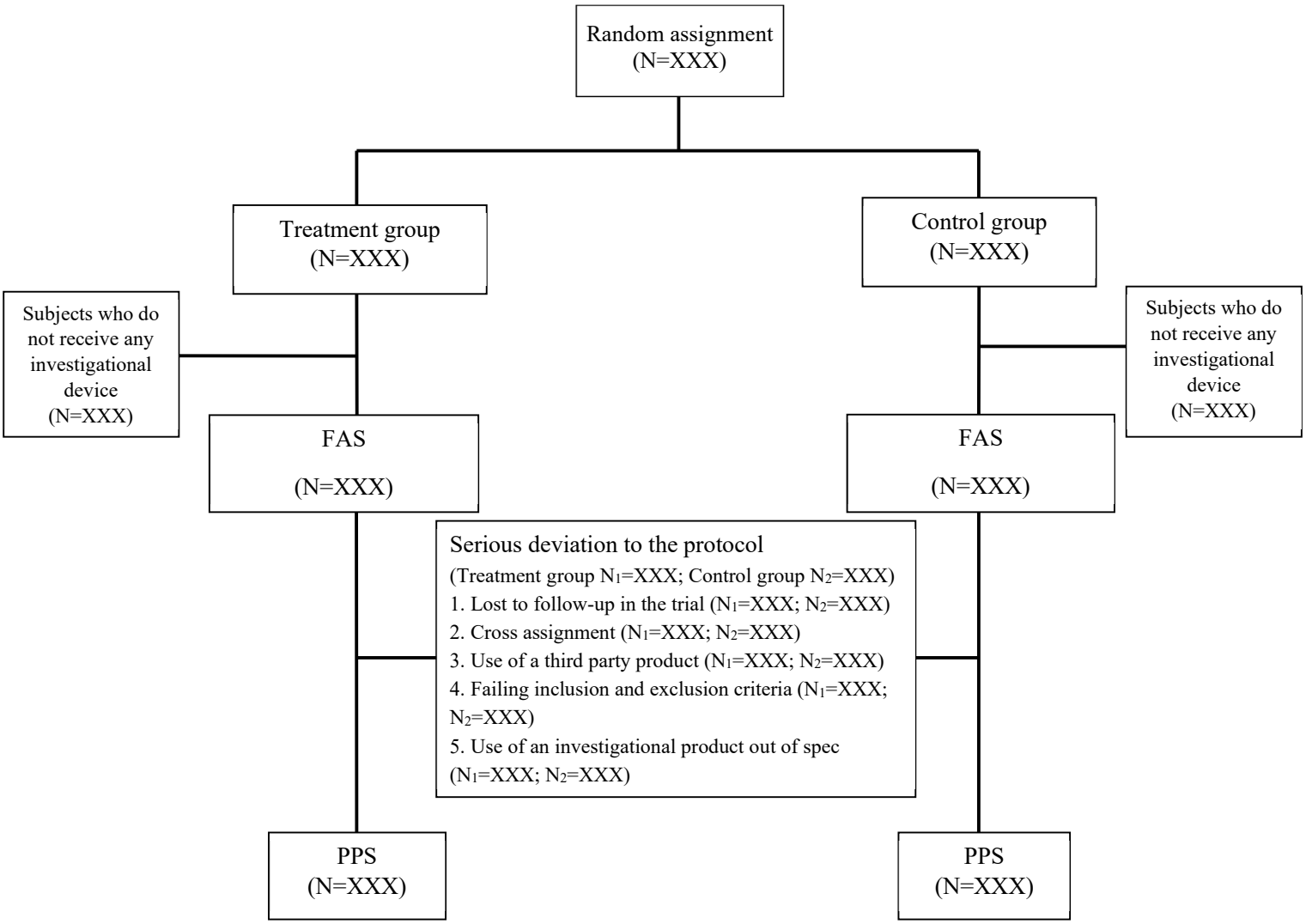

Fig. 1 Determination flow diagram of analysis population data set

6.4 Missing values, abnormal values, and outliers

For the analysis of possible missing data in the process, Carry Forward methods will be used for missing data of primary efficacy measures in principle. For the primary endpoint measures, CMH Chi square test adjusted for center effect will be used for estimating the difference between two groups on clinical acceptance rate and its 95% Confidence Interval. In above analyses, the Worst Case Carry Forward (WCCF) and Last Observation Carried Forward (LOCF) approaches will be used to carry forward the missing data of primary endpoint measures. For the missing data of other measures, Carry Forward strategy will not be applied, while actual observation data will be analyzed directly.

Wrong and unreasonable data will be handled in the data cleaning process before statistical analysis. The information of patients, who withdraw or are removed from the trial, will be included in the final statistical analysis. In the Statistical Report, specific reasons for all withdrawals or removals will be described in detail, while those missing primary measures due to early withdrawal will be analyzed according to the aforesaid missing value handling strategy.

6.5 Significance level and statistical analysis software

For primary endpoint measures, a significance level of 0.025 at one tail (corresponding to one side 95% CI) will be set for all statistical analyses. For other measures, all statistical analyses will be performed a significance level of 0.05 at two tails (except for those are specially noted). All statistical analyses will be performed using the statistical software SAS® 9.4.

6.6 Consolidation of centers

This trial will be carried out in several clinical trial institutions at the same time, and the actual numbers of successful enrolled subjects in each center will be different. In order to avoid the impact of small sample size in each center on stability and reliability of the analysis results of primary endpoints, the centers where less than 10 subjects are successful enrolled will be consolidated. Based on past experience and reference, the following two methods will be generally adopted for the consolidation of centers:

(1) The centers with the number of actually enrolled subjects < 10 will be sorted by the center code and then directly consolidated until the number of consolidated subjects is ≥ 10;

(2) The centers will be consolidated based on adjacency, and the number of consolidated subjects should be ≥ 10;

Analysis methods for the consolidation of centers in statistical analysis will be determined jointly by the sponsor, investigators, and biometrician via discussion in the peer review meetings.

7. Statistical analysis measures and methodology

7.1 Demographic data and other baseline data

Demographic data include age, sex, and clinical diagnosis. Other baseline data include previous medical history, vital signs, general condition as determined by preoperative examination and other physical conditions, openness, dental examination, pregnancy test, oral soft tissue examination, preoperative preliminary screening results, cavity preparation of diseased teeth, whether to perform X-ray periapical radiograph before cavity preparation, digital photos taken before cavity preparation, records of cavity preparation process, digital photo taken after cavity preparation, oral soft tissue examination after cavity preparation, screening results in cavity preparation phase and other relevant measures.

Where,

Age = (Date of Informed Consent - Date of Birth) /365.25;

These measures are mainly descriptive information. Count data will be described by frequency and constituent ratio. Measurement data will be described by mean value, standard deviation, median, interquartile range, maximum, and minimum. Likelihood $\chi 2$ test will be used for group comparison of the count data, while Fisher's exact test will be used when the theoretical frequency is lower than 5 in more than 25% cells. For group comparison of measurement data, group t-test will be used for those that are normally distributed, while Wilcoxon Rank Sum test will be used for those that are not normally distributed.

7.2 Operation information

The intraoperative information includes the information of all diseased teeth recorded during the operation, intraoperative records, digital photos taken immediately after the filling procedure, oral soft tissue examination during the filling procedure, immediate evaluation after the filling procedure, and other relevant measures.

These measures are mainly descriptive information. Their statistical analysis methodology is the same as those in 7.1.

7.3 Primary efficacy measures

Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure

Calculation:

According to the Clinical Trial Guideline for Polymer-based Dental Restorative Materials (YY/T 0990-2015), the definition of clinically acceptable filling at the 1 year follow-up visit is: grade

A for retention and fracture of the filling 1 year after the filling procedure; grade A or B for marginal fracture, contour, and marginal adaptation of the filling.

① For the "retention and fracture", "marginal fracture", and "contour and marginal adaptation", if any of the above measures is void or NA, the clinical acceptance is "Void";

② If the "retention and fracture" is scored as A and "marginal fracture" and "contour and marginal adaptation" are scored as A or B, the clinical acceptance is "Yes";

③ If the "retention and fracture" is scored as B or C, or "marginal fracture" is scored as C, or "contour and marginal adaptation" is scored as C, the clinical acceptance is "No";

For the primary efficacy measure, CMH Chi square test adjusted for center effect will be used for group comparison, and the difference between groups on efficacy and its 95% CI will also be estimated. If the 95% CI of the difference between groups on efficacy is greater than -7%, the investigational product is deemed as not inferior to the control product. Meanwhile, the clinical acceptance rate and its 95% CI estimated by Tipping Point (Cut-off value approach) will be used as the results of the sensitivity analysis.

If the trial results show that there are significant differences between the treatment and control groups on other baseline variables (such as age, sex, etc.), these situations will be fully communicated with the investigators in the data analysis phase. Based on one way analysis results of baseline variables and primary endpoint measures, previous literature references and the experiences of clinical experts, unbalanced measures between groups that affected the primary end points, namely, confounding factors, will be further clarified. These factors will be considered to be put into the generalized linear model for correction, as the sensitivity analysis of the primary endpoint measure.

7.4. Secondary efficacy measures

(1) Clinical acceptance rate of the filling at the 1 week follow-up visit after the filling procedure

Calculation:

According to the Clinical Trial Guideline for Polymer-based Dental Restorative Materials (YY/T 0990-2015), the definition of clinically acceptable filling at the 1 week follow-up is: grade A or B 1 week after the filling procedure for all the evaluation measures, including retention and fracture of the filling, marginal fracture, contour and marginal adaptation, proximal contact, color match, surface roughness, surface staining, marginal discoloration, secondary caries and pulp status;

① In all of the measures 1 week after the filling procedure, including retention and fracture, marginal fracture, contour and marginal adaptation, proximal contact, color match, surface roughness,

surface staining, marginal discoloration, secondary caries and pulp status, if any of above measures is void or NA, the clinical acceptance is “Void”;

② If all the measures 1 week after the filling procedure, including retention and fracture, marginal fracture, contour and marginal adaptation, proximal contact, color match, surface roughness, surface staining, marginal discoloration, secondary caries and pulp status, are scored as A or B, the clinical acceptance is “Yes”;

③ If all the measures 1 week after the filling procedure, including retention and fracture, marginal fracture, contour and marginal adaptation, proximal contact, color match, surface roughness, surface staining, marginal discoloration, secondary caries and pulp status, are scored not as those in ① or ②, the clinical acceptance is “No”;

(2) Proximal contact, color match, surface roughness, surface staining, marginal discoloration, secondary caries and pulp status 1 year after the filling procedure

These measures will be analyzed based on actual data and are mainly descriptive information. Their statistical analysis methodology is the same as those in 7.1.

7.5 Safety measures

(1) Incidence of SAEs (Serious Adverse Events)

(2) Incidence of AEs (Adverse Events)

This section will provide the incidences of AEs and SAEs and the results of group comparison analysis. Their statistical analysis methodology is the same as those in 7.1.

7.6 Follow-up data

Follow-up data include data from oral soft tissue examination, filling treatment, digital photos, evaluation of follow-up measures, and other measures. The follow-up time points include 1 week (± 3 days) after the filling procedure and 12 months (± 1 month) after the filling procedure.

Descriptive analysis will be mainly used for the relevant measures of follow-up data.

7.7 X-ray examination

For X-ray examination measure, the results of descriptive analysis will be provided, i.e., whether X-ray (periapical radiograph) examination is performed immediately, at the 1 week (± 3 days) and 12 months (± 1 month) follow-up visit after the filling procedure, and whether X-ray examination results are abnormal. In addition, the outcomes immediately after the filling procedure, at the 1 week (± 3 days)

and 12 months (± 1 month) follow-up visit after the filling procedure in comparison to the screening period will also be provided , including four situations: “Normal → Abnormal”, “Normal → Normal”, “Abnormal → Normal”, and “Abnormal → Abnormal”, mainly using the descriptive analysis methods.

7.8 Device defects

Device defects will be presented in a list. List specific descriptions of device defects for subjects will include the center code, randomization number, group assignment, age, gender, applicable items to a device defect, attribution of the device defect, number, name of the device defect, starting time, ending time, details of the device defect, results of the device defect, measures taken, any resulting medical events, diseases, or injuries, whether to return to the sponsor and other measures.

7.9 AEs and SAEs

AEs and those related to the investigational device will be provided by a list and summary of subjects. The list of subjects for AEs and those related to the investigational device will include the center code, randomization number, group assignment, gender, age, name of AE, occurrence time (days) after the procedure, remission time (days), characteristics of AE, number of paroxysmal attacks, severity, record and report of AEs, relationship to the investigational device, outcomes, sequela, corrective treatment, withdrawal, SAEs, and other measures.

Where the AEs related to the investigational device refer to AEs that are “possibly related” or “quite possibly related” or “definitely related” to the investigational device.

Occurrence time after the procedure (days) = starting date of AE - date of cavity filling,

Remission time (days) = ending date of AE - starting date of AE.

The summary table will list the total number of AEs/those related to the investigational device, and the total cases of all AEs/those related to the investigational device.

Where the total cases of AEs refer to the number of subjects with AEs. A subject with one occurrence of AE will be deemed as “Yes”;

SAEs and those related to the investigational device will be provided by a list and summary of subjects. The list of subjects for SAEs and those related to the investigational device will include the center code, randomization number, group assignment, gender, age, name of SAE, occurrence time (days) after the procedure, remission time (days), characteristics of SAE, number of paroxysmal attacks, severity, relationship to the investigational device, outcomes, sequela, corrective treatment, withdrawal, report type, SAE situations, and reports.

Where the calculation of occurrence time after the procedure (days) and remission time (days), summary table format, and statistical principles are the same as those for AEs.

7.10 Concomitant medication

Concomitant drugs will be presented in a list. List of subjects for concomitant drugs include the center code, randomization number, group assignment, age, gender, drug name, whether still in use, administration route, dosage, unit, indications, and treatment reasons.

8. GENERATION OF STATISTICAL TABLES, LISTS, AND GRAPHS

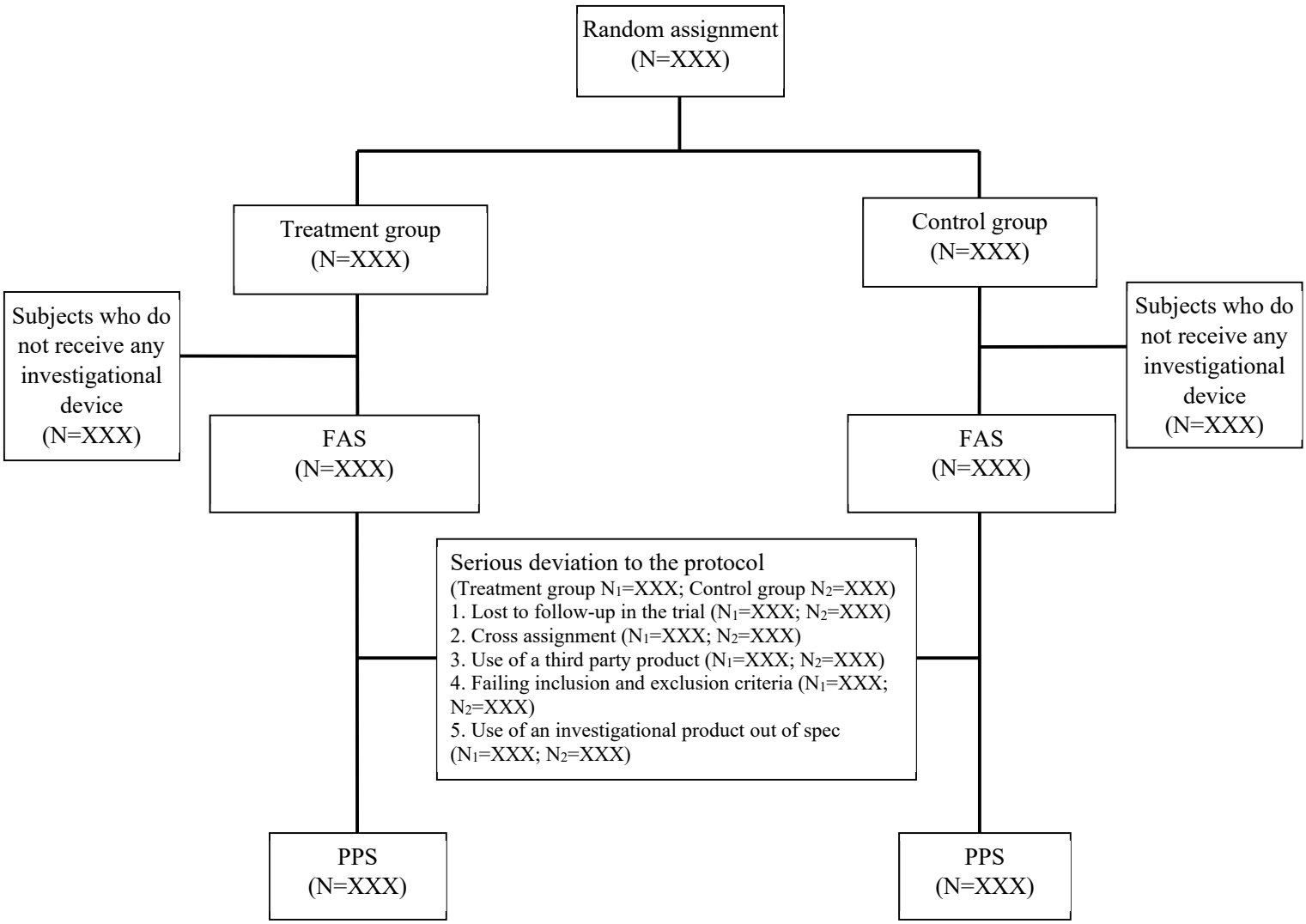

Fig. 1 Determination flow diagram of the analysis population data set

Table 1 Determination of the analysis population

Measures	Treatment group	Control group
Random assignment	XXX (XX.X%)	XXX (XX.X%)
Subjects who do not receive any investigational device	XXX (XX.X%)	XXX (XX.X%)
Serious deviation to the protocol		
Failing inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Lost to follow-up	XXX (XX.X%)	XXX (XX.X%)
Cross assignment	XXX (XX.X%)	XXX (XX.X%)
Use of a third party product	XXX (XX.X%)	XXX (XX.X%)
Use of an investigational product out of spec	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1: FAS = number of randomly assigned subjects - number of subjects who do not receive any investigational device;
PPS = FAS - number of subjects who are in serious deviation to the protocol;

2: No investigational device is used: the subject is assigned a random number, but does not receive any trial related treatment;
Lost to follow-up in the trial: the primary endpoint measure of a subject - clinical acceptance rate at the 1 year follow-up visit after the filling procedure - cannot be acquired.
Failing inclusion and exclusion criteria: the subject does not meet the inclusion criteria or meets the exclusion criteria defined by the protocol;
Use of an investigational product out of spec: the specifications of the device used by the subject is not within the range specified in the protocol;
Cross assignment: The subjects randomly assigned to the treatment group use the product for the control group, and vice versa;
Use of a third-party product: the subject who is randomly assigned to the treatment or control group receives a third-party product;

3: Number of subjects who are in serious deviation to the protocol = number of subjects who fail inclusion and exclusion criteria + number of subjects who are lost to follow-up in the trial + number of subjects who are crossly assigned + number of subjects who receive a third party product + number of subjects who receive an out of spec investigational product;

4: Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 2 List of subjects who do not receive any investigational device or are in serious deviation to the protocol

Center code	Randomization No.	Group	Sex	Age	Type	Reason	FAS	PPS
XXX	XXX	XXX	XXX	XXX	……	……	……	……
XXX	XXX	XXX	XXX	XXX	……	……	……	……

Notes: fill out a "√" for subjects included in SS and FAS (PPS) analysis and an "×" if not.

Table 3 Statistical analysis results of subjects in serious deviation to the protocol (CRF collection)

Measures	Treatment group	Control group
Group assignment	XXX[#1] (XXX[#2])	XXX (XXX)
Informed Consent process not followed	XXX (XX[#2], XX.X%[#3])	XXX (XX, XX.X%)
Failing inclusion/exclusion criteria	XXX (XX, XX.X%)	XXX (XX, XX.X%)
Procedures/steps not in compliance with the protocol	XXX (XX, XX.X%)	XXX (XX, XX.X%)
Procedures/steps omitted	XXX (XX, XX.X%)	XXX (XX, XX.X%)
A certain visit is omitted	XXX (XX, XX.X%)	XXX (XX, XX.X%)
Record/report of AEs not as required	XXX (XX, XX.X%)	XXX (XX, XX.X%)
Use of investigational or control device not by Instruction for Use	XXX (XX, XX.X%)	XXX (XX, XX.X%)
Clinical visits required by the protocol are not in specified time window	XXX (XX, XX.X%)	XXX (XX, XX.X%)
Storage of investigational/control device not as required	XXX (XX, XX.X%)	XXX (XX, XX.X%)
Other	XXX (XX, XX.X%)	XXX (XX, XX.X%)

Notes: 1. #1: Total number of deviations to the protocol
#2: Total cases of deviations to the protocol
#3: Percentage = total number of a deviation/total cases of deviations to the protocol*100%.

Table 4 List of subjects in serious deviation to the protocol (CRF collection)

Center code	Randomization No.	Group	Sex	Age	Follow-up visit time window	Type	Details of deviations to the protocol	Measures taken	SS	FAS	PPS
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……											
……											
……											

Table 5 Determination of the analysis population at Peking University Hospital of Stomatology

Measures	Treatment group	Control group
Random assignment	XXX (XX.X%)	XXX (XX.X%)
Subjects who do not receive any investigational device	XXX (XX.X%)	XXX (XX.X%)
Serious deviation to the protocol		
Failing inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Lost to follow-up	XXX (XX.X%)	XXX (XX.X%)
Cross assignment	XXX (XX.X%)	XXX (XX.X%)
Use of a third party product	XXX (XX.X%)	XXX (XX.X%)
Use of an investigational product out of spec	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1: FAS = number of randomly assigned subjects - number of subjects who do not receive any investigational device;
PPS = FAS - number of subjects who are in serious deviation to the protocol;

2: No investigational device is used: the subject is assigned a random number, but does not receive any trial related treatment;
Lost to follow-up in the trial: the primary endpoint measure of a subject - clinical acceptance rate at the 1 year follow-up visit after the filling procedure - cannot be acquired.
Failing inclusion and exclusion criteria: the subject does not meet the inclusion criteria or meets the exclusion criteria defined by the protocol;
Use of an investigational product out of spec: the specifications of the device used by the subject is not within the range specified in the protocol;
Cross assignment: The subjects randomly assigned to the treatment group use the product for the control group, and vice versa;
Use of a third-party product: the subject who is randomly assigned to the treatment or control group receives a third-party product;

3: Number of subjects who are in serious deviation to the protocol = number of subjects who fail inclusion and exclusion criteria + number of subjects who are lost to follow-up in the trial + number of subjects who are crossly assigned + number of subjects who receive a third party product + number of subjects who receive an out of spec investigational product;

4: Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 6 Determination of the analysis population at Hospital of Stomatology Wuhan University

Measures	Treatment group	Control group
Random assignment	XXX (XX.X%)	XXX (XX.X%)
Subjects who do not receive any investigational device	XXX (XX.X%)	XXX (XX.X%)
Serious deviation to the protocol		
Failing inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Lost to follow-up	XXX (XX.X%)	XXX (XX.X%)
Cross assignment	XXX (XX.X%)	XXX (XX.X%)
Use of a third party product	XXX (XX.X%)	XXX (XX.X%)
Use of an investigational product out of spec	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1: FAS = number of randomly assigned subjects - number of subjects who do not receive any investigational device;
PPS = FAS - number of subjects who are in serious deviation to the protocol;

2: No investigational device is used: the subject is assigned a random number, but does not receive any trial related treatment;
Lost to follow-up in the trial: the primary endpoint measure of a subject - clinical acceptance rate at the 1 year follow-up visit after the filling procedure - cannot be acquired.
Failing inclusion and exclusion criteria: the subject does not meet the inclusion criteria or meets the exclusion criteria defined by the protocol;
Use of an investigational product out of spec: the specifications of the device used by the subject is not within the range specified in the protocol;
Cross assignment: The subjects randomly assigned to the treatment group use the product for the control group, and vice versa;
Use of a third-party product: the subject who is randomly assigned to the treatment or control group receives a third-party product;

3: Number of subjects who are in serious deviation to the protocol = number of subjects who fail inclusion and exclusion criteria + number of subjects who are lost to follow-up in the trial + number of subjects who are crossly assigned + number of subjects who receive a third party product + number of subjects who receive an out of spec investigational product;

4: Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 7 Determination of the analysis population at Beijing Stomatological Hospital Capital Medical University

Measures	Treatment group	Control group
Random assignment	XXX (XX.X%)	XXX (XX.X%)
Subjects who do not receive any investigational device	XXX (XX.X%)	XXX (XX.X%)
Serious deviation to the protocol		
Failing inclusion and exclusion criteria	XXX (XX.X%)	XXX (XX.X%)
Lost to follow-up	XXX (XX.X%)	XXX (XX.X%)
Cross assignment	XXX (XX.X%)	XXX (XX.X%)
Use of a third party product	XXX (XX.X%)	XXX (XX.X%)
Use of an investigational product out of spec	XXX (XX.X%)	XXX (XX.X%)
FAS	XXX (XX.X%)	XXX (XX.X%)
PPS	XXX (XX.X%)	XXX (XX.X%)

Notes: 1: FAS = number of randomly assigned subjects - number of subjects who do not receive any investigational device;
PPS = FAS - number of subjects who are in serious deviation to the protocol;

2: No investigational device is used: the subject is assigned a random number, but does not receive any trial related treatment;
Lost to follow-up in the trial: the primary endpoint measure of a subject - clinical acceptance rate at the 1 year follow-up visit after the filling procedure - cannot be acquired.
Failing inclusion and exclusion criteria: the subject does not meet the inclusion criteria or meets the exclusion criteria defined by the protocol;
Use of an investigational product out of spec: the specifications of the device used by the subject is not within the range specified in the protocol;
Cross assignment: The subjects randomly assigned to the treatment group use the product for the control group, and vice versa;
Use of a third-party product: the subject who is randomly assigned to the treatment or control group receives a third-party product;

3: Number of subjects who are in serious deviation to the protocol = number of subjects who fail inclusion and exclusion criteria + number of subjects who are lost to follow-up in the trial + number of subjects who are crossly assigned + number of subjects who receive a third party product + number of subjects who receive an out of spec investigational product;

4: Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 8 (FAS) Analysis results of demographic data in the screening period

Measures	Treatment group	Control group	Statistics	P value
Age (yr)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX. XX ± XX. XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Sex				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Male	XXX (XX.X%)	XXX (XX.X%)		
Female	XXX (XX.X%)	XXX (XX.X%)		
Clinically diagnosed caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
Clinically diagnosed other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Age = (Date of Informed Consent - Date of Birth)/365.25;
5. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 9 (FAS) Analysis results of past medical history in the screening period

Measures	Treatment group	Control group	Statistics	P value
Smoking history				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Never	XXX (XX.X%)	XXX (XX.X%)		
Still	XXX (XX.X%)	XXX (XX.X%)		
Quit	XXX (XX.X%)	XXX (XX.X%)		
Smoking history Still Years of smoking				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Smoking history Still Number of cigarettes / d				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Smoking history Quit Years of smoking				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Smoking history Quit Years of quiting				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Allergy history				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
Subject had a dental history prior to enrollment				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
Had dental history Currently taking medication				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
Had dental history Cured or not				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 9 (FAS) Analysis results of past medical history in the screening period (cont.)

Measures	Treatment group	Control group	Statistics	P value
History of other diseases				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
History of other diseases Currently taking medication				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		
History of other diseases Cured or not				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 10 (FAS) Analysis results of vital signs in the preoperative examination

Measures	Treatment group	Control group	Statistics	P value
Systolic (mmHg)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Diastolic (mmHg)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Heart rate (beats/minute)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX. XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Respiration rate (times/minute)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		

Notes: 1. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
2. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
3. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 11 (FAS) Analysis results of general condition as determined by the preoperative examination and other physical conditions

Measures	Treatment group	Control group	Statistics	P value
General condition				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Very good	XXX (XX.X%)	XXX (XX.X%)		
Good	XXX (XX.X%)	XXX (XX.X%)		
General	XXX (XX.X%)	XXX (XX.X%)		
Poor	XXX (XX.X%)	XXX (XX.X%)		
Very poor	XXX (XX.X%)	XXX (XX.X%)		
Heart disease				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
Heart disease Coronary disease				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Heart disease Hypertension				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Heart disease Arrhythmia				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Heart disease Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Respiratory diseases				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
Respiratory diseases Cough				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Respiratory diseases Asthma				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Respiratory diseases Pneumonia				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 11 (FAS) Analysis results of general condition as determined by the preoperative examination and other physical conditions (cont. 1)

Measures	Treatment group	Control group	Statistics	P value
Respiratory diseases Bronchitis				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Respiratory diseases Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Infectious diseases				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
Infectious diseases Hepatitis				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Infectious diseases HBsAg positive				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Infectious diseases Tuberculosis				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Infectious diseases AIDS				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Infectious diseases Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Other conditions Diabetes				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Other conditions Nephrosis				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Other conditions Rheumatism				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 11 (FAS) Analysis results of general condition as determined by the preoperative examination and other physical conditions (cont. 2)

Measures	Treatment group	Control group	Statistics	P value
Other conditions Mental illness				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Other conditions Epilepsy/convulsion				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Other conditions Fever				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Other conditions Hemorrhagic tendency				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Other conditions Malignant tumor				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Other conditions Regurgitation and belching				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Other conditions Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 12 (FAS) Analysis results of openness in the preoperative examination

Measures	Treatment group	Control group	Statistics	P value
Openness				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal	XXX (XX.X%)	XXX (XX.X%)		
Limited	XXX (XX.X%)	XXX (XX.X%)		
If limited, the width of openness (cm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 13 (FAS) Analysis results of dental examination in the preoperative examination (tooth level)

Measures	Treatment group	Control group	Statistics	P value
Dental examination (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Done	XXX (XX.X%)	XXX (XX.X%)		
Not done	XXX (XX.X%)	XXX (XX.X%)		
Caries (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
Number of caries (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Location of caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Code of UR caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Code of UL caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 13 (FAS) Analysis results of dental examination in the preoperative examination (tooth level) (cont. 1)

Measures	Treatment group	Control group	Statistics	P value
Code of LL caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		
Code of LR caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		
Missing (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
Number of missing (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Location of missing				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Code of UR missing				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 13 (FAS) Analysis results of dental examination in the preoperative examination (tooth level) (cont. 2)

Measures	Treatment group	Control group	Statistics	P value
Code of UL missing				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		
Code of LL missing				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		
Code of LR missing				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		
Fillings (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		
Number of fillings (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Location of filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 13 (FAS) Analysis results of dental examination in the preoperative examination (tooth level) (cont. 3)

Measures	Treatment group	Control group	Statistics	P value
Code of UR filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Code of UL filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		
Code of LL filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		
Code of LR filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		
Prosthetic teeth or artificial crowns (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
With	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 13 (FAS) Analysis results of dental examination in the preoperative examination (tooth level) (cont. 4)

Measures	Treatment group	Control group	Statistics	P value
Number of prosthetic teeth or artificial crowns (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Location of prosthetic tooth or artificial crown				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Code of UR prosthetic tooth or artificial crown				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Code of UL prosthetic tooth or artificial crown				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		
Code of LL prosthetic tooth or artificial crown				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 13 (FAS) Analysis results of dental examination in the preoperative examination (tooth level) (cont. 5)

Measures	Treatment group	Control group	Statistics	P value
Code of LR prosthetic tooth or artificial crown				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 14 (FAS) Analysis results of pregnancy test in the preoperative examination

Measures	Treatment group	Control group	Statistics	P value
Results of pregnancy test				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Positive	XXX (XX.X%)	XXX (XX.X%)		
Negative	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 15 (FAS) Analysis results of oral soft tissue examination in the preoperative examination

Measures	Treatment group	Control group	Statistics	P value
Conduct oral soft tissue examination				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Normality of oral soft tissue				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Oral soft tissue area				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Examination results area (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
3	XXX (XX.X%)	XXX (XX.X%)		
4	XXX (XX.X%)	XXX (XX.X%)		
5	XXX (XX.X%)	XXX (XX.X%)		
6	XXX (XX.X%)	XXX (XX.X%)		
7	XXX (XX.X%)	XXX (XX.X%)		
8	XXX (XX.X%)	XXX (XX.X%)		
9	XXX (XX.X%)	XXX (XX.X%)		
10	XXX (XX.X%)	XXX (XX.X%)		
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
19	XXX (XX.X%)	XXX (XX.X%)		
20	XXX (XX.X%)	XXX (XX.X%)		
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23 Dorsum linguae	XXX (XX.X%)	XXX (XX.X%)		
24 Ventral linguae	XXX (XX.X%)	XXX (XX.X%)		
25 Apex linguae	XXX (XX.X%)	XXX (XX.X%)		
26 Lingual margin	XXX (XX.X%)	XXX (XX.X%)		
27 Tongue base	XXX (XX.X%)	XXX (XX.X%)		
28 Epiglottis	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 15 (FAS) Analysis results of oral soft tissue examination in the preoperative examination (cont.)

Measures	Treatment group	Control group	Statistics	P value
Size a (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX. XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size b (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX. XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size a*b (mm) of oral examination result (area level)				
XX*XX	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Clinical significance of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 16 (FAS) Analysis results of the initial screening in the preoperative examination (tooth level)

Measures	Treatment group	Control group	Statistics	P value
Number of teeth passing the initial screening criteria (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
3	XXX (XX.X%)	XXX (XX.X%)		
4	XXX (XX.X%)	XXX (XX.X%)		
5	XXX (XX.X%)	XXX (XX.X%)		
Location of diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Code of UR diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Code of UL diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 16 (FAS) Analysis results of the initial screening in the preoperative examination (tooth level) (cont.)

Measures	Treatment group	Control group	Statistics	P value
Code of LL diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		
Code of LR diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 17 (FAS) Analysis results of cavity preparation of diseased teeth in the screening period

Measures	Treatment group	Control group	Statistics	P value
Location of tooth included in cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Code of UR tooth included in cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Code of UL tooth included in cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 17 (FAS) Analysis results of cavity preparation of diseased teeth in the screening period (cont.)

Measures	Treatment group	Control group	Statistics	P value
Code of LL tooth included in cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		
Code of LR tooth included in cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 18 (FAS) Analysis results of X-ray (periapical radiograph) examination before cavity preparation in the screening period

Measures	Treatment group	Control group	Statistics	P value
X-ray (periapical radiograph) examination before cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Depth of lesion in X-ray findings				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Shallow dentin	XXX (XX.X%)	XXX (XX.X%)		
Middle dentin	XXX (XX.X%)	XXX (XX.X%)		
Deep dentin	XXX (XX.X%)	XXX (XX.X%)		
Abnormal or normal X-ray findings				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 19 (FAS) Analysis results of digital photos before cavity preparation in the screening period

Measures	Treatment group	Control group	Statistics	P value
Take digital photos before cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos before cavity preparation				
Photos of occlusal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos before cavity preparation				
Photos of occlusal surface (with occlusal contacts marked)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos before cavity preparation				
Photos of median occlusion				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos before cavity preparation				
Photos of antagonist tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos before cavity preparation				
Photos of buccal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos before cavity preparation				
Photos of lingual surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos before cavity preparation				
Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 20 (FAS) Analysis results of cavity preparation process records in the screening period

Measures	Treatment group	Control group	Statistics	P value
Removed material during the cavity preparation process				
Detritus				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Removed material during the cavity preparation process				
Original filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Removed material during the cavity preparation process				
Thin-wall and low cusps				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Removed material during the cavity preparation process				
Soft scales				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Removed material during the cavity preparation process				
Calculus				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Removed material during the cavity preparation process				
Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Local anesthesia applied				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Missing third molar				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Cavity classification				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Class I cavities	XXX (XX.X%)	XXX (XX.X%)		
Class II cavities	XXX (XX.X%)	XXX (XX.X%)		
Cavity classification				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
O	XXX (XX.X%)	XXX (XX.X%)		
BO	XXX (XX.X%)	XXX (XX.X%)		
BOL	XXX (XX.X%)	XXX (XX.X%)		
LO	XXX (XX.X%)	XXX (XX.X%)		
MO	XXX (XX.X%)	XXX (XX.X%)		
MOD	XXX (XX.X%)	XXX (XX.X%)		
DO	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 20 (FAS) Analysis results of cavity preparation process records in the screening period (cont. 1)

Measures	Treatment group	Control group	Statistics	P value
Bevel on prepared cavity margin				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Bevel angle (degrees)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Bevel width (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum buccolingual distance on the occlusal plane after cavity preparation (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Buccolingual distance between the cusps (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Cavity size and maximum buccolingual distance after cavity preparation (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Cavity size and maximum proximal-distal mid distances after cavity preparation (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 20 (FAS) Analysis results of cavity preparation process records in the screening period (cont. 2)

Measures	Treatment group	Control group	Statistics	P value
Maximum depth after cavity preparation (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Gingival margin after cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Supragingival	XXX (XX.X%)	XXX (XX.X%)		
Subgingival	XXX (XX.X%)	XXX (XX.X%)		
Not applicable (Class I cavities)	XXX (XX.X%)	XXX (XX.X%)		
Internal line angles of cavity are not rounded enough after cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Overhang enamel at cavity margin after preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Cavity bottom				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Middle and deep dentin (without being close to and not exposing pulp)	XXX (XX.X%)	XXX (XX.X%)		
Pulp red or exposed (already or close to be expose pulp)	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 21 (FAS) Analysis results of digital photos after cavity preparation in the screening period

Measures	Treatment group	Control group	Statistics	P value
Take digital photos after cavity preparation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos after cavity preparation				
Photos of occlusal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos after cavity preparation				
Photos of occlusal surface (with occlusal contacts marked)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos after cavity preparation				
Photos of median occlusion				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos after cavity preparation				
Photos of antagonist tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos after cavity preparation				
Photos of buccal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos after cavity preparation				
Photos of lingual surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos after cavity preparation				
Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 22 (FAS) Analysis results of oral soft tissue examination after cavity preparation in the screening period

Measures	Treatment group	Control group	Statistics	P value
Conduct oral soft tissue examination				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Normality of oral soft tissue				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Oral soft tissue area				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Examination results area (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
3	XXX (XX.X%)	XXX (XX.X%)		
4	XXX (XX.X%)	XXX (XX.X%)		
5	XXX (XX.X%)	XXX (XX.X%)		
6	XXX (XX.X%)	XXX (XX.X%)		
7	XXX (XX.X%)	XXX (XX.X%)		
8	XXX (XX.X%)	XXX (XX.X%)		
9	XXX (XX.X%)	XXX (XX.X%)		
10	XXX (XX.X%)	XXX (XX.X%)		
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
19	XXX (XX.X%)	XXX (XX.X%)		
20	XXX (XX.X%)	XXX (XX.X%)		
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23 Dorsum linguae	XXX (XX.X%)	XXX (XX.X%)		
24 Ventral linguae	XXX (XX.X%)	XXX (XX.X%)		
25 Apex linguae	XXX (XX.X%)	XXX (XX.X%)		
26 Lingual margin	XXX (XX.X%)	XXX (XX.X%)		
27 Tongue base	XXX (XX.X%)	XXX (XX.X%)		
28 Epiglottis	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 22 (FAS) Analysis results of oral soft tissue examination after cavity preparation in the screening period (cont.)

Measures	Treatment group	Control group	Statistics	P value
Size a (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size b (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size a*b (mm) of oral examination result (area level)				
XX*XX	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Clinical significance of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 23 (FAS) Analysis results of screening results in cavity preparation phase in the screening period (tooth level)

Measures	Treatment group	Control group	Statistics	P value
Passed screening and formally included in the filling phase (subject level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Location code of formally included tooth: location of diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Location code of formally included tooth: Code of UR diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Location code of formally included tooth: Code of UL diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		
Location code of formally included tooth: Code of LL diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 23 (FAS) Analysis results of screening results in cavity preparation phase in the screening period (tooth level) (cont.)

Measures	Treatment group	Control group	Statistics	P value
Location code of formally included tooth:				
Code of LR diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 24 (FAS) Analysis results of intraoperative information of all diseased teeth (tooth level)

Measures	Treatment group	Control group	Statistics	P value
Information of caries/disease teeth formally included in the study				
Tooth location code				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Information of caries/disease teeth formally included in the study				
Tooth location code UR				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Information of caries/disease teeth formally included in the study				
Tooth location code UL				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		
Information of caries/disease teeth formally included in the study				
Tooth location code LL				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		
Information of caries/disease teeth formally included in the study				
Tooth location code LR				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 24 (FAS) Analysis results of intraoperative information of all diseased teeth (tooth level) (cont.)

Measures	Treatment group	Control group	Statistics	P value
Other disease teeth that not included are treated at the same time				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Location of caries/disease teeth passing inclusion/exclusion criteria but not included in the study name of product to be used				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
3M™ Filtek™ Z350XT	XXX (XX.X%)	XXX (XX.X%)		
Other	XXX (XX.X%)	XXX (XX.X%)		
Not restored	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 25 (FAS) Analysis results of intraoperative records

Measures	Treatment group	Control group	Statistics	P value
The name of product to be used is Filtek™ Bulk Fill Posterior Restorative				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Name of product to be used: FiltekTM Z350XT				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Code of investigational device to be used				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
XXX	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Shade selections for the treatment group in the study				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A1	XXX (XX.X%)	XXX (XX.X%)		
A2	XXX (XX.X%)	XXX (XX.X%)		
A3	XXX (XX.X%)	XXX (XX.X%)		
B1	XXX (XX.X%)	XXX (XX.X%)		
C2	XXX (XX.X%)	XXX (XX.X%)		
Shade selections for the control group in the study				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A1B	XXX (XX.X%)	XXX (XX.X%)		
A2B	XXX (XX.X%)	XXX (XX.X%)		
A3B	XXX (XX.X%)	XXX (XX.X%)		
A3.5B	XXX (XX.X%)	XXX (XX.X%)		
B1B	XXX (XX.X%)	XXX (XX.X%)		
C2B	XXX (XX.X%)	XXX (XX.X%)		
Filling time (min)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Cover pulp or base				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Rubber dam used				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.
5. Filling time = ending time of filling - starting time of filling.

Table 25 (FAS) Analysis results of intraoperative records (cont. 1)

Measures	Treatment group	Control group	Statistics	P value
Matrix band placed				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Not applicable	XXX (XX.X%)	XXX (XX.X%)		
Brand of adhesive system				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
3M ESPE Single Bond Universal Adhesive	XXX (XX.X%)	XXX (XX.X%)		
Other	XXX (XX.X%)	XXX (XX.X%)		
Curing time of adhesive				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
10 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Number of resin layers				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
3	XXX (XX.X%)	XXX (XX.X%)		
4	XXX (XX.X%)	XXX (XX.X%)		
5	XXX (XX.X%)	XXX (XX.X%)		
Thickness of 1st layer (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Thickness of 2nd layer (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Thickness of 3rd layer (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Thickness of 4th layer (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 25 (FAS) Analysis results of intraoperative records (cont. 2)

Measures	Treatment group	Control group	Statistics	P value
Thickness of 5th layer (mm)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing method				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Light Cure	XXX (XX.X%)	XXX (XX.X%)		
Other	XXX (XX.X%)	XXX (XX.X%)		
Brand of curing light				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
3M^{tm} Elipar S10 LED Curing Light	XXX (XX.X%)	XXX (XX.X%)		
Other	XXX (XX.X%)	XXX (XX.X%)		
Output power of curing light measured before each curing (Mw/cm^2)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Cavity type of diseased tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Class I cavities	XXX (XX.X%)	XXX (XX.X%)		
Class II cavities	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 1st resin layer - Class I cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
20 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 1st resin layer Other (seconds) - Class I cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing time of 2nd resin layer - Class I cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
20 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 2nd resin layer Other (seconds) - Class I cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M^{TM} Filtek^{TM} Z350XT.

Table 25 (FAS) Analysis results of intraoperative records (cont. 3)

Measures	Treatment group	Control group	Statistics	P value
Curing time of 1st layer on occlusal surface - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
10 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 1st layer on occlusal surface Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing time of 1st layer on buccal surface - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
10 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 1st layer on buccal surface Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing time of 1st layer on lingual surface - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
10 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 1st layer on lingual surface Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing time of 2nd layer on occlusal surface - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
10 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 2nd layer on occlusal surface Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 25 (FAS) Analysis results of intraoperative records (cont. 4)

Measures	Treatment group	Control group	Statistics	P value
Curing time of 2nd layer on buccal surface - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
10 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 2nd layer on buccal surface				
Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing time of 2nd layer on lingual surface - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
10 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 2nd layer on lingual surface				
Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing time of 1st layer - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
20 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 1st layer				
Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing time of 2nd layer - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
20 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 2nd layer				
Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 25 (FAS) Analysis results of intraoperative records (cont. 5)

Measures	Treatment group	Control group	Statistics	P value
Curing time of 3rd layer - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
20 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 3rd layer				
Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing time of 4th layer - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
20 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 4th layer				
Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Curing time of 5th layer - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
20 s	XXX (XX.X%)	XXX (XX.X%)		
Other (seconds)	XXX (XX.X%)	XXX (XX.X%)		
Curing time of 5th layer				
Other (seconds) - Class II cavities				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX.XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Occlusion adjustment after filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Occlusal contact	XXX (XX.X%)	XXX (XX.X%)		
No occlusal contact	XXX (XX.X%)	XXX (XX.X%)		
Cusps of antagonist tooth pressing on margin ridge of the filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Brand of Polishing System to be used				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
3M™ Sof-lex Finishing and Polishing System	XXX (XX. X%)	XXX (XX.X%)		
Other	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 26 (FAS) Analysis results of digital photos taken immediately after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Take digital photos immediately after filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of occlusal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of occlusal surface (with occlusal contacts marked)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of median occlusion				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of antagonist tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of buccal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of lingual surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 27 (FAS) Analysis results of oral soft tissue examination in the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Conduct oral soft tissue examination				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Normality of oral soft tissue				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Oral soft tissue area				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Examination results area (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
3	XXX (XX.X%)	XXX (XX.X%)		
4	XXX (XX.X%)	XXX (XX.X%)		
5	XXX (XX.X%)	XXX (XX.X%)		
6	XXX (XX.X%)	XXX (XX.X%)		
7	XXX (XX.X%)	XXX (XX.X%)		
8	XXX (XX.X%)	XXX (XX.X%)		
9	XXX (XX.X%)	XXX (XX.X%)		
10	XXX (XX.X%)	XXX (XX.X%)		
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
19	XXX (XX.X%)	XXX (XX.X%)		
20	XXX (XX.X%)	XXX (XX.X%)		
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23 Dorsum linguae	XXX (XX.X%)	XXX (XX.X%)		
24 Ventral linguae	XXX (XX.X%)	XXX (XX.X%)		
25 Apex linguae	XXX (XX.X%)	XXX (XX.X%)		
26 Lingual margin	XXX (XX.X%)	XXX (XX.X%)		
27 Tongue base	XXX (XX.X%)	XXX (XX.X%)		
28 Epiglottis	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 27 (FAS) Analysis results of oral soft tissue examination during the filling procedure (cont.)

Measures	Treatment group	Control group	Statistics	P value
Size a (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX. XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size b (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX ± XX. XX	XX.XX ± XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size a*b (mm) of oral examination result (area level)				
XX*XX	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Clinical significance of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures Q1: 25th quantile Q3: 75th quantile.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 28 (FAS) Analysis results of evaluation immediately after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Location of tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Location code of UR tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Location code of UL tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 28 (FAS) Analysis results of evaluation immediately after the filling procedure (cont.)

Measures	Treatment group	Control group	Statistics	P value
Location code of LL tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		
Location code of LR tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		
Cavity classification				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Class I cavities	XXX (XX.X%)	XXX (XX.X%)		
Class II cavities	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 29 (FAS) Analysis results of consistency evaluation immediately after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Retention and fractures of the filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No marginal fractures of the filling	XXX (XX.X%)	XXX (XX.X%)		
B. Minor marginal fractures of the filling without exposed dentin, clinically acceptable;	XXX (XX.X%)	XXX (XX.X%)		
C. Marginal fractures of the filling with exposed dentin, clinically unacceptable	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Marginal fractures of the filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No marginal fractures of the filling	XXX (XX.X%)	XXX (XX.X%)		
B. Minor marginal fractures of the filling without exposed dentin, clinically acceptable;	XXX (XX.X%)	XXX (XX.X%)		
C. Marginal fractures of the filling with exposed dentin, clinically unacceptable	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Contour and marginal adaptation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Intact contour and continuous probing between the filling and tooth	XXX (XX.X%)	XXX (XX.X%)		
B. Pits on the surface of the filling and discontinuous probing between the filling and tooth without exposed dentin;	XXX (XX.X%)	XXX (XX.X%)		
C. Severe attrition and dents on the surface of the filling with exposed dentin, or probes hooked at the margins of the filling	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Proximal contact				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Firm proximal contact	XXX (XX.X%)	XXX (XX.X%)		
B. Proximal contact is clinically acceptable	XXX (XX.X%)	XXX (XX.X%)		
C. No proximal contact	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Color match				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Matching color and transparency between the filling and adjacent tooth tissues	XXX (XX.X%)	XXX (XX.X%)		
B. Pits on the surface of the filling and discontinuous probing between the filling and tooth without exposed dentin;	XXX (XX.X%)	XXX (XX.X%)		
C. Severe attrition and dents on the surface of the filling with exposed dentin, or probes hooked at the margins of the filling	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 29 (FAS) Analysis results of consistency evaluation immediately after the filling procedure (cont.)

Measures	Treatment group	Control group	Statistics	P value
Surface roughness				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. After air drying, the surface of the filling is smooth with luster and matching with surrounding tooth tissues	XXX (XX.X%)	XXX (XX.X%)		
B. After air drying, the surface of the filling is smooth without luster	XXX (XX.X%)	XXX (XX.X%)		
C. After air drying, the surface of the filling is rough with defects	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Surface staining				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No staining on the surface of the filling	XXX (XX.X%)	XXX (XX.X%)		
B. Abnormal staining on the surface of the filling	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Marginal discoloration and secondary caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No discoloration at the interface between the filling and tooth	XXX (XX.X%)	XXX (XX.X%)		
B. Partial discoloration at the interface between the filling and tooth, but not extending to pulp and removable by polishing;	XXX (XX.X%)	XXX (XX.X%)		
C. Partial discoloration at the interface between the filling and tooth extending to pulp and not removable by polishing, or secondary caries	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Secondary caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No discoloration at the interface between the filling and tooth	XXX (XX.X%)	XXX (XX.X%)		
B. Partial discoloration at the interface between the filling and tooth, but not extending to pulp and removable by polishing;	XXX (XX.X%)	XXX (XX.X%)		
C. Partial discoloration at the interface between the filling and tooth extending to pulp and not removable by polishing, or secondary caries	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Pulp status				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Normal (temperature test)	XXX (XX.X%)	XXX (XX.X%)		
B. Temporarily sensitive (temperature test)	XXX (XX.X%)	XXX (XX.X%)		
C. Sensitive and continuous pain, or delayed pain (temperature test)	XXX (XX.X%)	XXX (XX.X%)		
D. No response (electric pulp testing)	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 30 (FAS) The analysis results of primary efficacy measure - clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure[#1]				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure[#2]				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)		
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		
Difference in acceptance rate (treatment - control) and 95% CI		XX.X% [XX.X%; XX.X%]		
p value of non-inferiority test		X.XXXX		
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure[#3]				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)		
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		
Difference in acceptance rate (treatment - control) and 95% CI		XX.X% [XX.X%; XX.X%]		
p value of non-inferiority test		X.XXXX		

Notes:
1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. #2: Analyze with CMH Chi square test adjusted for center effect;
3. #1: Primary efficacy measures of subjects who are lost to follow-up will not be processed;
   #2: Primary efficacy measures of subjects who are lost to follow-up will not be acceptable for carry forward;
   #3: Primary efficacy measures of subjects who are lost to follow-up will be carried forward by last follow-up visit results;
4. The definition of clinically acceptable filling at the 1 year follow-up visit is: grade A for retention and fracture of the filling 1 year after the filling procedure; grade A or B for marginal fracture, contour and marginal adaptation of the filling.
5. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.
6. Borderline value of noninferiority is set to 7%.

Table 31 (FAS) The analysis results of primary efficacy measure - clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure (Tipping Point analysis results)

Supplement of subjects who are lost to follow-up				Clinical acceptance rate				Difference in acceptance rate # (treatment - control) and 95% CI
Treatment group		Control group		Treatment group		Control group		
Acceptable	Not acceptable	Acceptable	Not acceptable	Acceptable	Not acceptable	Acceptable	Not acceptable	
XXX	XXX	XXX	XXX	XX.X (XX.X%)	XX.X (XX.X%)	XX.X (XX.X%)	XX.X (XX.X%)	XX.X% [XX.X%; XX.X%]
……	……			……	……			……

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. #: Analyze with CMH Chi square test adjusted for center effect;
3. The definition of clinically acceptable filling at the 1 year follow-up visit is: grade A for retention and fracture of the filling 1 year after the filling procedure; grade A or B for marginal fracture, contour and marginal adaptation of the filling.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.
5. Borderline value of noninferiority is set to 7%.

Table 32 (FAS) The analysis results of primary efficacy measure - clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure (subgroup analysis of each center)

Measures	Treatment group	Control group	Statistics	P value
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure at Peking University Hospital of Stomatology				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure at Hospital of Stomatology Wuhan University				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure at Beijing Stomatological Hospital Capital Medical University				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		

Notes:
1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. The definition of clinically acceptable filling at the 1 year follow-up visit is: grade A for retention and fracture of the filling 1 year after the filling procedure; grade A or B for marginal fracture, contour and marginal adaptation of the filling.
3. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
   Control group: 3M™ Filtek™ Z350XT.
4. Borderline value of noninferiority is set to 7%.

Table 33 (PPS) The analysis results of primary efficacy measure - clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure

Measures	Treatment group	Control group
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure[#]		
Cases (Nmiss)	XXX (XXX)	XXX (XXX)
Acceptable	XXX (XX.X%)	XXX (XX.X%)
Not acceptable	XXX (XX.X%)	XXX (XX.X%)
Difference in acceptance rate (treatment - control) and 95% CI	XX.X% [XX.X%; XX.X%]	
p value of non-inferiority test	X.XXXX	

Notes:
1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. #: Analyze with CMH Chi square test adjusted for center effect;
3. The definition of clinically acceptable filling at the 1 year follow-up visit is: grade A for retention and fracture of the filling 1 year after the filling procedure; grade A or B for marginal fracture, contour and marginal adaptation of the filling.
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
   Control group: 3M™ Filtek™ Z350XT.
5. Borderline value of noninferiority is set to 7%.

Table 34 (PPS) The analysis results of primary efficacy measure - clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure (subgroup analysis of each center)

Measures	Treatment group	Control group	Statistics	P value
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure at Peking University Hospital of Stomatology				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure at Hospital of Stomatology Wuhan University				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		
Clinical acceptance rate of the filling at the 1 year follow-up visit after the filling procedure at Beijing Stomatological Hospital Capital Medical University				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		

Notes:
1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. The definition of clinically acceptable filling at the 1 year follow-up visit is: grade A for retention and fracture of the filling 1 year after the filling procedure; grade A or B for marginal fracture, contour and marginal adaptation of the filling.
3. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
   Control group: 3M™ Filtek™ Z350XT.
4. Borderline value of noninferiority is set to 7%.

Table 35 (FAS) The analysis results of secondary efficacy measure - clinical acceptance rate of the filling at the 1 week follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Clinical acceptance rate of the filling at the 1 week follow-up visit after the filling procedure				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)		
Acceptable	XXX (XX.X%)	XXX (XX.X%)		
Not acceptable	XXX (XX.X%)	XXX (XX.X%)		

Notes:
1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. #: Analyze with CMH Chi square test adjusted for center effect;
3. The definition of clinically acceptable filling at the 1 week follow-up is: grade A or B 1 week after the filling procedure for all the measures, including retention and fracture of the filling, marginal fracture, contour and marginal adaptation, proximal contact, color match, surface roughness, surface staining, marginal discoloration, secondary caries and pulp status;
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
   Control group: 3M™ Filtek™ Z350XT.

Table 36 (FAS) The analysis results of secondary efficacy measures for evaluation - proximal contact, color match, surface roughness, surface staining, marginal discoloration, secondary caries and pulp status 1 year after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Proximal contact				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Firm proximal contact	XXX (XX.X%)	XXX (XX.X%)		
B. Proximal contact is clinically acceptable	XXX (XX.X%)	XXX (XX.X%)		
C. No proximal contact	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Color match				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Matching color and transparency between the filling and adjacent tooth tissues	XXX (XX.X%)	XXX (XX.X%)		
B. Pits on the surface of the filling and discontinuous probing between the filling and tooth without exposed dentin	XXX (XX.X%)	XXX (XX.X%)		
C. Severe attrition and dents on the surface of the filling with exposed dentin, or probes hooked at the margins of the filling	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Surface roughness				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. After air drying, the surface of the filling is smooth with luster and matching with surrounding tooth tissues	XXX (XX.X%)	XXX (XX.X%)		
B. After air drying, the surface of the filling is smooth without luster	XXX (XX.X%)	XXX (XX.X%)		
C. After air drying, the surface of the filling is rough with defects	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Surface staining				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No staining on the surface of the filling	XXX (XX.X%)	XXX (XX.X%)		
B. Abnormal staining on the surface of the filling	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Marginal discoloration and secondary caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No discoloration at the interface between the filling and tooth	XXX (XX.X%)	XXX (XX.X%)		
B. Partial discoloration at the interface between the filling and tooth, but not extending to pulp and removable by polishing	XXX (XX.X%)	XXX (XX.X%)		
C. Partial discoloration at the interface between the filling and tooth extending to pulp and not removable by polishing, or secondary caries	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Secondary caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No discoloration at the interface between the filling and tooth	XXX (XX.X%)	XXX (XX.X%)		
B. Partial discoloration at the interface between the filling and tooth, but not extending to pulp and removable by polishing	XXX (XX.X%)	XXX (XX.X%)		
C. Partial discoloration at the interface between the filling and tooth extending to pulp and not removable by polishing, or secondary caries	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.

2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 36 (FAS) The analysis results of secondary efficacy measures - proximal contact, color match, surface roughness, surface staining, marginal discoloration, secondary caries and pulp status 1 year after the filling procedure (cont.)

Measures	Treatment group	Control group	Statistics	P value
Pulp status				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Normal (temperature test)	XXX (XX.X%)	XXX (XX.X%)		
B. Temporarily sensitive (temperature test)	XXX (XX.X%)	XXX (XX.X%)		
C. Sensitive and continuous pain, or delayed pain (temperature test)	XXX (XX.X%)	XXX (XX.X%)		
D. No response (electric pulp testing)	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 37 (FAS) Analysis results of oral soft tissue examination at the 1 week (± 3 days) follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Conduct oral soft tissue examination				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Normality of oral soft tissue				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Oral soft tissue area				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Size a (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX±XX.XX	XX.XX±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size b (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX±XX.XX	XX.XX±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size a*b (mm) of oral examination result (area level)				
XX*XX	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Clinical significance of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures, Q1: 25th quantile; Q3: 75th quantile
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 37 (FAS) Analysis results of oral soft tissue examination at the 1 week (± 3 days) follow-up visit after the filling procedure (cont.)

Measures	Treatment group	Control group	Statistics	P value
Examination results area (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
3	XXX (XX.X%)	XXX (XX.X%)		
4	XXX (XX.X%)	XXX (XX.X%)		
5	XXX (XX.X%)	XXX (XX.X%)		
6	XXX (XX.X%)	XXX (XX.X%)		
7	XXX (XX.X%)	XXX (XX.X%)		
8	XXX (XX.X%)	XXX (XX.X%)		
9	XXX (XX.X%)	XXX (XX.X%)		
10	XXX (XX.X%)	XXX (XX.X%)		
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
19	XXX (XX.X%)	XXX (XX.X%)		
20	XXX (XX.X%)	XXX (XX.X%)		
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23 Dorsum linguae	XXX (XX.X%)	XXX (XX.X%)		
24 Ventral linguae	XXX (XX.X%)	XXX (XX.X%)		
25 Apex linguae	XXX (XX.X%)	XXX (XX.X%)		
26 Lingual margin	XXX (XX.X%)	XXX (XX.X%)		
27 Tongue base	XXX (XX.X%)	XXX (XX.X%)		
28 Epiglottis	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures, Q1: 25th quantile; Q3: 75th quantile
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 38 (FAS) Analysis results of filling treatment and digital photos at the 1 week (± 3 days) follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Filling needs treatment				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Take digital photos				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of occlusal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of occlusal surface (with occlusal contacts marked)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of median occlusion				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of antagonist tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of buccal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of lingual surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 39 (FAS) Analysis results of evaluation results at the 1 week (± 3 days) follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Location of tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Location code of UR tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Location code of UL tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 39 (FAS) Analysis results of evaluation results at the 1 week (± 3 days) follow-up visit after the filling procedure (cont.)

Measures	Treatment group	Control group	Statistics	P value
Location code of LL tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		
Location code of LR tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		
Cavity classification				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Class I cavities	XXX (XX.X%)	XXX (XX.X%)		
Class II cavities	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 40 (FAS) Analysis results of consistency evaluation results at the 1 week (± 3 days) follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Retention and fractures of the filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No marginal fractures of the filling	XXX (XX.X%)	XXX (XX.X%)		
B. Minor marginal fractures of the filling without exposed dentin, clinically acceptable;	XXX (XX.X%)	XXX (XX.X%)		
C. Marginal fractures of the filling with exposed dentin, clinically unacceptable	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Marginal fractures of the filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No marginal fractures of the filling	XXX (XX.X%)	XXX (XX.X%)		
B. Minor marginal fractures of the filling without exposed dentin, clinically acceptable;	XXX (XX.X%)	XXX (XX.X%)		
C. Marginal fractures of the filling with exposed dentin, clinically unacceptable	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Contour and marginal adaptation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Intact contour and continuous probing between the filling and tooth	XXX (XX.X%)	XXX (XX.X%)		
B. Pits on the surface of the filling and discontinuous probing between the filling and tooth without exposed dentin;	XXX (XX.X%)	XXX (XX.X%)		
C. Severe attrition and dents on the surface of the filling with exposed dentin, or probes hooked at the margins of the filling	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Proximal contact				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Firm proximal contact	XXX (XX.X%)	XXX (XX.X%)		
B. Proximal contact is clinically acceptable	XXX (XX.X%)	XXX (XX.X%)		
C. No proximal contact	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Color match				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Matching color and transparency between the filling and adjacent tooth tissues	XXX (XX.X%)	XXX (XX.X%)		
B. Pits on the surface of the filling and discontinuous probing between the filling and tooth without exposed dentin;	XXX (XX.X%)	XXX (XX.X%)		
C. Severe attrition and dents on the surface of the filling with exposed dentin, or probes hooked at the margins of the filling	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 41 (FAS) Analysis results of consistency evaluation results at the 1 week (± 3 days) follow-up visit after the filling procedure (cont.)

Measures	Treatment group	Control group	Statistics	P value
Surface roughness				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. After air drying, the surface of the filling is smooth with luster and matching with surrounding tooth tissues	XXX (XX.X%)	XXX (XX.X%)		
B. After air drying, the surface of the filling is smooth without luster	XXX (XX.X%)	XXX (XX.X%)		
C. After air drying, the surface of the filling is rough with defects	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Surface staining				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No staining on the surface of the filling	XXX (XX.X%)	XXX (XX.X%)		
B. Abnormal staining on the surface of the filling	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Marginal discoloration and secondary caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No discoloration at the interface between the filling and tooth	XXX (XX.X%)	XXX (XX.X%)		
B. Partial discoloration at the interface between the filling and tooth, but not extending to pulp and removable by polishing;	XXX (XX.X%)	XXX (XX.X%)		
C. Partial discoloration at the interface between the filling and tooth extending to pulp and not removable by polishing, or secondary caries	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Secondary caries				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No discoloration at the interface between the filling and tooth	XXX (XX.X%)	XXX (XX.X%)		
B. Partial discoloration at the interface between the filling and tooth, but not extending to pulp and removable by polishing;	XXX (XX.X%)	XXX (XX.X%)		
C. Partial discoloration at the interface between the filling and tooth extending to pulp and not removable by polishing, or secondary caries	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Pulp status				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Normal (temperature test)	XXX (XX.X%)	XXX (XX.X%)		
B. Temporarily sensitive (temperature test)	XXX (XX.X%)	XXX (XX.X%)		
C. Sensitive and continuous pain, or delayed pain (temperature test)	XXX (XX.X%)	XXX (XX.X%)		
D. No response (electric pulp testing)	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 42 (FAS) Analysis results of oral soft tissue examination at the 12 months (± 1 month) follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Conduct oral soft tissue examination				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Normality of oral soft tissue				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Oral soft tissue area				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Size a (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX±XX.XX	XX.XX±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size b (mm) of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Mean ± SD	XX.XX±XX.XX	XX.XX±XX.XX		
Median	XX.XX	XX.XX		
Q1; Q3	XX.XX; XX.XX	XX.XX; XX.XX		
Minimum; Maximum	XX.XX; XX.XX	XX.XX; XX.XX		
Size a*b (mm) of oral examination result (area level)				
XX*XX	XXX (XX.X%)	XXX (XX.X%)		
…	XXX (XX.X%)	XXX (XX.X%)		
Clinical significance of oral examination result (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures, Q1: 25th quantile; Q3: 75th quantile
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 42 (FAS) Analysis results of oral soft tissue examination at the 12 months (± 1 month) follow-up visit after the filling procedure (cont.)

Measures	Treatment group	Control group	Statistics	P value
Examination results area (area level)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
None	XXX (XX.X%)	XXX (XX.X%)		
1	XXX (XX.X%)	XXX (XX.X%)		
2	XXX (XX.X%)	XXX (XX.X%)		
3	XXX (XX.X%)	XXX (XX.X%)		
4	XXX (XX.X%)	XXX (XX.X%)		
5	XXX (XX.X%)	XXX (XX.X%)		
6	XXX (XX.X%)	XXX (XX.X%)		
7	XXX (XX.X%)	XXX (XX.X%)		
8	XXX (XX.X%)	XXX (XX.X%)		
9	XXX (XX.X%)	XXX (XX.X%)		
10	XXX (XX.X%)	XXX (XX.X%)		
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
19	XXX (XX.X%)	XXX (XX.X%)		
20	XXX (XX.X%)	XXX (XX.X%)		
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23 Dorsum linguae	XXX (XX.X%)	XXX (XX.X%)		
24 Ventral linguae	XXX (XX.X%)	XXX (XX.X%)		
25 Apex linguae	XXX (XX.X%)	XXX (XX.X%)		
26 Lingual margin	XXX (XX.X%)	XXX (XX.X%)		
27 Tongue base	XXX (XX.X%)	XXX (XX.X%)		
28 Epiglottis	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Group t-test or Wilcoxon Rank Sum test will be used for group comparison of quantitative measures.
3. For quantitative measures, Q1: 25th quantile; Q3: 75th quantile
4. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 43 (FAS) Analysis results of filling treatment and digital photos at the 12 months (± 1 month) follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Filling needs treatment				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Take digital photos				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of occlusal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of occlusal surface (with occlusal contacts marked)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of median occlusion				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of antagonist tooth				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of buccal surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Photos of lingual surface				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Type of photos				
Other				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 44 (FAS) Analysis results of evaluation results at the 12 months (± 1 month) follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Location of tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
UR	XXX (XX.X%)	XXX (XX.X%)		
UL	XXX (XX.X%)	XXX (XX.X%)		
LL	XXX (XX.X%)	XXX (XX.X%)		
LR	XXX (XX.X%)	XXX (XX.X%)		
Location code of UR tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
11	XXX (XX.X%)	XXX (XX.X%)		
12	XXX (XX.X%)	XXX (XX.X%)		
13	XXX (XX.X%)	XXX (XX.X%)		
14	XXX (XX.X%)	XXX (XX.X%)		
15	XXX (XX.X%)	XXX (XX.X%)		
16	XXX (XX.X%)	XXX (XX.X%)		
17	XXX (XX.X%)	XXX (XX.X%)		
18	XXX (XX.X%)	XXX (XX.X%)		
Location code of UL tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
21	XXX (XX.X%)	XXX (XX.X%)		
22	XXX (XX.X%)	XXX (XX.X%)		
23	XXX (XX.X%)	XXX (XX.X%)		
24	XXX (XX.X%)	XXX (XX.X%)		
25	XXX (XX.X%)	XXX (XX.X%)		
26	XXX (XX.X%)	XXX (XX.X%)		
27	XXX (XX.X%)	XXX (XX.X%)		
28	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 44 (FAS) Analysis results of evaluation results at the 12 months (± 1 month) follow-up visit after the filling procedure (cont.)

Measures	Treatment group	Control group	Statistics	P value
Location code of LL tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
31	XXX (XX.X%)	XXX (XX.X%)		
32	XXX (XX.X%)	XXX (XX.X%)		
33	XXX (XX.X%)	XXX (XX.X%)		
34	XXX (XX.X%)	XXX (XX.X%)		
35	XXX (XX.X%)	XXX (XX.X%)		
36	XXX (XX.X%)	XXX (XX.X%)		
37	XXX (XX.X%)	XXX (XX.X%)		
38	XXX (XX.X%)	XXX (XX.X%)		
Location code of LR tooth to be evaluated				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
41	XXX (XX.X%)	XXX (XX.X%)		
42	XXX (XX.X%)	XXX (XX.X%)		
43	XXX (XX.X%)	XXX (XX.X%)		
44	XXX (XX.X%)	XXX (XX.X%)		
45	XXX (XX.X%)	XXX (XX.X%)		
46	XXX (XX.X%)	XXX (XX.X%)		
47	XXX (XX.X%)	XXX (XX.X%)		
48	XXX (XX.X%)	XXX (XX.X%)		
Cavity classification				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Class I cavities	XXX (XX.X%)	XXX (XX.X%)		
Class II cavities	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 45 (FAS) Analysis results of consistency evaluation results at the 12 months (± 1 month) follow-up visit after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
Retention and fractures of the filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No marginal fractures of the filling	XXX (XX.X%)	XXX (XX.X%)		
B. Minor marginal fractures of the filling without exposed dentin, clinically acceptable;	XXX (XX.X%)	XXX (XX.X%)		
C. Marginal fractures of the filling with exposed dentin, clinically unacceptable	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Marginal fractures of the filling				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. No marginal fractures of the filling	XXX (XX.X%)	XXX (XX.X%)		
B. Minor marginal fractures of the filling without exposed dentin, clinically acceptable;	XXX (XX.X%)	XXX (XX.X%)		
C. Marginal fractures of the filling with exposed dentin, clinically unacceptable	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		
Contour and marginal adaptation				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
A. Intact contour and continuous probing between the filling and tooth	XXX (XX.X%)	XXX (XX.X%)		
B. Pits on the surface of the filling and discontinuous probing between the filling and tooth without exposed dentin;	XXX (XX.X%)	XXX (XX.X%)		
C. Severe attrition and dents on the surface of the filling with exposed dentin, or probes hooked at the margins of the filling	XXX (XX.X%)	XXX (XX.X%)		
NA	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 46 (FAS) Analysis results of X-ray examination results before and after the filling procedure

Measures	Treatment group	Control group	Statistics	P value
X-ray (periapical radiograph) examination immediately after the filling procedure				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Abnormal X-ray findings after the filling procedure				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
X-ray (periapical radiograph) examination 1 week (± 3 days) after the filling procedure				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Abnormal or normal X-ray findings 1 week (± 3 days) after the filling procedure				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
X-ray (periapical radiograph) examination 1 year (± 1 month) after the filling procedure				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
Abnormal X-ray findings 1 year (± 1 month) after the filling procedure				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
No	XXX (XX.X%)	XXX (XX.X%)		
Yes	XXX (XX.X%)	XXX (XX.X%)		
X-ray examination (screening→immediately after the filling procedure)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal→Abnormal	XXX (XX.X%)	XXX (XX.X%)		
Normal→Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal→Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal→Abnormal	XXX (XX.X%)	XXX (XX.X%)		
X-ray examination (screening→1 week after the filling procedure)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal→Abnormal	XXX (XX.X%)	XXX (XX.X%)		
Normal→Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal→Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal→Abnormal	XXX (XX.X%)	XXX (XX.X%)		
X-ray examination (screening→1 year after the filling procedure)				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Normal→Abnormal	XXX (XX.X%)	XXX (XX.X%)		
Normal→Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal→Normal	XXX (XX.X%)	XXX (XX.X%)		
Abnormal→Abnormal	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 47 (FAS) Detailed descriptions of device defects

Center code	Randomization No.	Group	Sex	Age	Applicable items to a device defect	Attribution of the device defect	No.	Name of device defect	Starting time	Ending time	Details of device defect	Results of device defect	Measures taken	Any resulting medical events, diseases or injuries	Need to return to the sponsor
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……															
……															
……															

Notes: 1. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 48 (FAS) (AE) Case specific descriptions of adverse event

Center code	Randomization No.	Group	Sex	Age	Name of AE	Occurrence time after the procedure (days)	Remission time (days)	Characteristics of AE	Number of paroxysmal attacks	Severity	Record and report of AEs	Relationship to the investigational device	Outcomes	Sequela	Corrective treatment	Withdrawal from the trial	Serious Adverse Event
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……																	
……																	
……																	

Notes: 1. Occurrence time after the procedure = starting date of AE - date of cavity filling; Remission time = ending date of AE - starting date of AE;
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 49 (FAS) (AE) Summary of adverse events

AEs	Treatment group	Control group	Statistics	P value
Total number of AEs	XXX	XXX		
XXXX	XXX	XXX		
……				
……				
Total cases of AEs				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The total cases of AEs refer to the number of subjects with AEs. A subject with one occurrence of AE will be deemed as "Yes".
2. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
3. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 50 (FAS) Case specific descriptions of adverse events related to the investigational device

Center code	Randomization No.	Group	Sex	Age	Name of AE	Occurrence time after the procedure (days)	Remission time (days)	Characteristics of AE	Number of paroxysmal attacks	Severity	Record and report of AEs	Relationship to the investigational device	Outcomes	Sequela	Corrective treatment	Withdrawal from the trial	Serious Adverse Event
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……																	
……																	
……																	

Notes: 1. AEs related to the investigational device refer to AEs that are “possibly related” or “quite possibly related” or “definitely related” to the investigational device.
2. Occurrence time after the procedure = starting date of AE - date of cavity filling; Remission time = ending date of AE - starting date of AE;
3. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 51 (FAS) Summary of adverse events related to the investigational device

AEs	Treatment group	Control group	Statistics	P value
Total number of AEs	XXX	XXX		
XXXX	XXX	XXX		
……				
……				
Total cases of AEs				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The total cases of AEs refer to the number of subjects with AEs. A subject with one occurrence of AE will be deemed as "Yes".
2. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
3. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 52 (FAS) (SAE) Case specific descriptions of serious adverse events

Center code	Randomization No.	Group	Sex	Age	Name of SAE	Occurrence time after the procedure (days)	Remission time (days)	Characteristics of SAE	Number of paroxysmal attacks	Severity	Relationship to the investigational device	Outcomes	Sequela	Corrective treatment	Withdrawal from the trial	Report Type	SAE situations	Report situations
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……																		
……																		
……																		

Notes: 1. Occurrence time after the procedure = starting date of SAE - date of cavity filling; Remission time = ending date of SAE - starting date of SAE;
2. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 53 (FAS) (SAE) Summary of serious adverse events

Serious Adverse Event	Treatment group	Control group	Statistics	P value
Total number of SAEs	XXX	XXX		
XXXX	XXX	XXX		
……				
……				
Total cases of SAEs				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The total cases of SAEs refer to the number of subjects with SAEs. A subject with one occurrence of SAE will be deemed as "Yes".
2. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
3. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 54 (FAS) Case specific descriptions of serious adverse events related to the investigational device

Center code	Randomization No.	Group	Sex	Age	Name of SAE	Occurrence time after the procedure (days)	Remission time (days)	Characteristics of SAE	Number of paroxysmal attacks	Severity	Relationship to the investigational device	Outcomes	Sequela	Corrective treatment	Withdrawal from the trial	Report Type	SAE situations	Report situations
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……																		
……																		
……																		

Notes: 1. SAEs related to the investigational device refer to SAEs that are “possibly related” or “quite possibly related” or “definitely related” to the investigational device.
2. Occurrence time after the procedure = starting date of SAE - date of cavity filling; Remission time = ending date of SAE - starting date of SAE;
3. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative; Control group: 3M™ Filtek™ Z350XT.

Table 55 (FAS) Summary of serious adverse events related to the investigational device

Serious Adverse Event	Treatment group	Control group	Statistics	P value
Total number of SAEs	XXX	XXX		
XXXX	XXX	XXX		
……				
……				
Total cases of SAEs				
Cases (Nmiss)	XXX (XXX)	XXX (XXX)	X.XXXX	X.XXXX
Yes	XXX (XX.X%)	XXX (XX.X%)		
No	XXX (XX.X%)	XXX (XX.X%)		

Notes: 1. The total cases of SAEs refer to the number of subjects with SAEs. A subject with one occurrence of SAE will be deemed as "Yes".
2. Likelihood $\chi 2$ test or Fisher's exact probability test will be used for group comparison of qualitative measures.
3. Treatment group: 3M™ Filtek™ Bulk Fill Posterior Restorative;
Control group: 3M™ Filtek™ Z350XT.

Table 56 (FAS) List of subjects using concomitant drugs

Center code	Randomization No.	Group	Sex	Age	Drug name	Starting date	Ending time	Still in use	Administration route	Dosage	Unit	Indications	Justifications for treatment
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
XX	XXX	XX	XX	XX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
……													
……													
……													