Abstract: This study investigated the handling properties and clinical performance of two commercially available resin materials with slight differences in filler composition for the fabrication of fixed interim restorations. In a dental university setting, patients requiring prosthetic treatment were supplied with fixed interim restorations fabricated from two commercially available resin materials. To clarify the handling properties of the resin materials, dentists and undergraduate students completed a questionnaire. Prior to insertion of the definitive restoration, the interim restorations were analyzed by calibrated examiners using a modification of the United States Public Health Service criteria. Eighty-two fixed interim restorations with a mean clinical service period of 44.5 (±28.3) days were included, including 39 single crowns, 30 fixed denture prostheses, 10 blocked crowns, and 3 partial coverage restorations. No significant differences between the two materials in the rating of their handling properties were identified, with the exception of the parameter “surface”. Failures due to fractures were observed in 13% of the interim restorations. No significant differences between the materials in the rating of the clinical performance were identified. These results indicate that slight changes in the filler composition of commercial formulations account for few differences in handling properties and clinical performance.

Keywords: fixed interim restoration; composite; resin; crown; fixed dental prostheses.

Introduction

Despite improvements in oral health in industrialized countries, fixed prosthodontic restorations such as crowns and fixed dental prostheses are still frequently required. The conventional workflow for fabrication of fixed prosthodontic restorations includes the preparation of abutment teeth; subsequently, impressions of the prepared teeth are made, and these are finally forwarded to a dental laboratory for fabrication of the definitive prosthetic restoration. Fixed interim restorations can be fabricated either directly or indirectly employing CAD/CAM technology and are usually luted to the abutment teeth with provisional zinc oxide-based cements. Fixed interim restorations restore function and esthetics, shape marginal gingival areas, and protect the prepared teeth from chemical or thermal irritations (1). Currently, the most common approaches for fabrication of direct interim restorations include the impression technique, where an alginate or silicone impression is made prior to preparation of the abutment teeth; the impression serves as a negative mold for subsequent fabrication of the interim restoration. While this simple technique works particularly well for restorations such as single crowns or small FDPs, it is more convenient to employ the mold technique for fabrication of extended fixed interim restorations. In such cases, a diagnostic cast is fabricated from an impression of the abutment teeth prior to preparation,
and a vacuum-formed mold is manufactured to produce a negative of the original tooth form. Despite the advantages of CAD/CAM-fabricated fixed interim restorations, such as a superior fit and better fracture resistance (2), many dentists still use direct methods to manufacture fixed interim restorations because direct techniques are simpler and cheaper. Generally, fixed interim restorations fabricated via a direct approach are manufactured from auto-polymerizing resin materials. Various materials are available for the fabrication of fixed interim restorations, including polymethyl methacrylate (PMMA) and ethyl methacrylate resins, polyvinyl methacrylate resins, composite-based resins, and urethane-based resins (3,4). Most frequently, contemporary materials are filler-supplemented composite-based resins provided in the form of auto-mix systems, and feature an auto- or double-curing mode. Although a number of material-associated properties of polymeric materials for the fabrication of fixed interim restorations, such as flexural strength, marginal and internal fit, fracture strength and mode, or polymerization temperature, have been investigated in laboratory studies (2,4-7), data on the handling properties of these materials are currently lacking. Although fixed interim restorations are intended to fulfill important functions during prosthetic treatments, few scientific data on their clinical performance are currently available. Therefore, the present randomized, double-blinded clinical study was conducted to investigate the handling properties and clinical performance of two commercially available composite-based resin materials with slight differences in filler composition for the fabrication of fixed interim restorations. It was hypothesized that the investigated materials would show no differences in the rating of their handling properties (I) or clinical performance (II).

### Materials and Methods

Between November 2016 and August 2017, patients of the Department of Prosthetic Dentistry at the Regens-
burg University Medical Center receiving prosthetic treatment with partial coverage restorations, crowns, and fixed denture prostheses were included in the trial; patients requiring removable restorations and patients with bruxism, insufficient oral hygiene, or untreated periodontal diseases as well as underage and pregnant patients were excluded. The patients were treated by either experienced dentists (specializing in prosthodontics) or supervised undergraduate students (who had successfully completed preclinical education and were taking their clinical training courses under permanent supervision by experienced dentists). After preparation of the abutment teeth, the patients were supplied with an interim fixed restoration; the interim restorations were fabricated using a direct approach employing either the impression technique (silicone impression made of the teeth prior to preparation) or the mold technique (vacuum-formed mold that had previously been manufactured on a cast model). Two commercially available resin materials (Structur 2/Structur 3, VOCO GmbH, Cuxhaven, Germany) were used for fabrication of the interim restorations in accordance with the instructions provided by the manufacturer; occlusal adjustments and polishing were performed with conventional burs and polishers in compliance with these guidelines. The restorations were finally luted temporarily with a Eugenol-free temporary zinc oxide-based cement (Provicol QM, VOCO).

Subsequent to fabrication of the fixed interim restorations, dentists and undergraduate students completed a questionnaire designed to assess the handling properties of the resin materials. Data were collected using a Likert-type scale; each item in the questionnaire had a scoring range from A (best) to C (worst) (cf. Table 1). Prior to final insertion of the definitive restoration, one of three calibrated examiners (S.H., M.B., C.K.) analyzed the fixed interim restorations and completed a second questionnaire designed to assess the clinical performance of the materials (cf. Table 2); collection of data was performed using a modification of the United States Public Health Service (USPHS) criteria with an Alpha, Bravo, and Charlie rating. Prior to the initial analyses, the examiners were calibrated using a variety of fixed interim restorations employed in distinct clinical settings. In situations where a patient received multiple restorations, one interim restoration was randomly selected by one of the calibrated examiners prior to the final examination.

Before insertion of the definitive prosthetic restoration, patients were asked to rate the comfort of the fixed interim restorations using a Likert-type scale including the values 1 (“satisfied”), 2 (“indifferent”), and 3 (“poor”).

A double-blinded randomized study design was employed, as the manufacturer supplied two composite-based resin materials in different colors (A1, A2, A3, A3.5, B1, B2, and B3), but with blinding to the auto-mix packaging (Structur 2/Structur 3; VOCO), thus preventing any conclusion regarding the type of material made by the undergraduates, dentists, and examiners. Randomization of patients to one of the two materials was performed adaptively and decentrally by a third party who was neither involved in the fabrication of the fixed restoration nor the evaluation of the materials (M.R.) in order to facilitate allocation concealment.

Table 2 Rating of the handling properties of the materials by dentists and undergraduate students at the baseline (insertion of the fixed interim restoration). Frequencies (n) are indicated.

|                  | Rating                          | Structur 2 | Structur 3 | P-value between the materials |
|------------------|---------------------------------|------------|------------|------------------------------|
| Discoloration    | matches adjacent teeth          | A          | 18         | 19  | 0.436 |
|                  | fair                            | B          | 17         | 21  | 0.617 |
|                  | does not match adjacent teeth   | C          | 5          | 1   | 0.438 |
| Stability        | no fractures and no wear        | A          | 32         | 30  | 0.571 |
|                  | visible wear                    | B          | 4          | 5   | 0.571 |
|                  | fracture during clinical service (failure) | C  | 5          | 6   | 0.571 |
| Marginal adaptation | no defects                    | A          | 21         | 26  | 0.438 |
|                  | few and little defects          | B          | 20         | 12  | 0.438 |
|                  | extensive defects               | C          | –          | 3   | 0.438 |
| Roughness        | no visibly increased surface roughness | A  | 17         | 10  | 0.571 |
|                  | visibly increased surface roughness | B  | 19         | 28  | 0.571 |
|                  | very rough surface              | C          | 5          | 3   | 0.571 |
| Gingival tissues | no clinical signs of inflammation | A          | 30         | 32  | 0.944 |
|                  | slight inflammation             | B          | 10         | 9   | 0.944 |
|                  | clinical signs of inflammation, bleeding on probing | C  | 1          | –   | 0.944 |
The design of the study was reviewed and approved by the ethics committee of the University of Regensburg (16-101-0197).

The scoring range (A-C) for the various items of the questionnaires was converted to numerical values [1-3]. Subsequently, statistical analyses for comparing the handling properties and clinical performance of the two materials were performed using the nonparametric Mann-Whitney $U$-test (SPSS 23.0 for Windows, IBM Corp., Armonk, NY, USA); the level of significance ($\alpha$) was set at 0.05.

**Results**

Data for 82 patients who received prosthetic treatments were recorded, covering an overall total of 82 fixed interim restorations included in the analyses. Thirty-nine single crowns, 30 fixed denture prostheses, 10 blocked crowns, and 3 partial coverage restorations were investigated; details of the data are displayed in Table 3. Fifty-eight interim restorations were manufactured by dentists, while 24 restorations were manufactured by undergraduate students. The fixed dental prostheses featured either an end abutment ($n = 26$) or a cantilever design ($n = 4$) and ranged from a majority of restorations with three ($n = 15$) and four ($n = 6$) units to a maximum of 14 units ($n = 1$).

With regard to the questionnaire addressing the handling properties of the two materials, statistical analyses did not identify any significant differences in the rating of the materials in terms of “processing and handling”, “wetting of the impression or mold”, “stability during removal from the form”, “polishability”, “fit”, “odor”, “marginal fit”, and “color” ($P > 0.05$, respectively; Table 1). Regarding the criterion “surface”, dentists and undergraduates rated Structur 2 significantly more favorably than Structur 3 ($P = 0.038$).

Interrogation of the patients regarding “comfort during clinical service” revealed no significant differences in the rating of the two materials; in both cases, more than 85% of the patients rated the comfort during clinical service as good, while 10% were indifferent.

Regarding the criteria “comfort”, “discoloration”, “stability”, “marginal adaptation”, and “roughness” as well as biological aspects (“gingival tissues”) (Table 2), which were assessed by calibrated examiners prior to insertion of the definitive prosthetic restoration, no statistically significant differences were identified between the two materials ($P < 0.05$).

For both materials, fractures (failures) were infrequent and observed only randomly; in total, 11 of 82 interim restorations failed ($n = 6$ (Structur 2), $n = 5$ (Structur 3)). Fractures were observed for all types of interim

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**Table 3** Details of the types of fixed interim restorations, mean period in clinical service, method of preparation, and antagonistic teeth. Frequencies ($n$) are indicated.

|                | Total | Structur 2 | Structur 3 |
|----------------|-------|------------|------------|
| **Type**       |       |            |            |
| single crown   | 39    | 19         | 20         |
| fixed denture prosthesis (fdp) | 30    | 14         | 16         |
| blocked crown  | 10    | 6          | 4          |
| partial coverage restorations | 3     | 2          | 1          |
| **Pontics in fps** |     |            |            |
| 1              | 17    | 8          | 9          |
| 2              | 7     | 2          | 5          |
| 3              | 3     | 1          | 1          |
| 4              | 1     | 1          | -          |
| 5              | -     | -          | -          |
| 6              | 1     | 1          | -          |
| 7              | -     | -          | -          |
| 8              | 1     | -          | 1          |
| 9              | -     | -          | -          |
| 10             | 1     | 1          | -          |
| 11             | -     | -          | -          |
| 12             | -     | -          | -          |
| **Mean period in clinical service (days; SD)** | 44.5 (28.3) | 41.8 (26.2) | 47.1 (30.5) |
| **Method of preparation** |       |            |            |
| impression     | 47    | 23         | 24         |
| mould          | 35    | 18         | 17         |
| **Antagonistic teeth** |     |            |            |
| fixed          | 63    | 31         | 32         |
| removable      | 18    | 9          | 9          |
| combination    | 1     | 1          | -          |
restorations except for partial coverage restorations; no significant effect of the type of restoration employed (single crown, blocked crown, fixed dental prosthesis, partial coverage restoration) was identified ($P = 0.908$).

**Discussion**

The results of this clinical investigation suggest partial acceptance of the first research hypothesis as, with the exception of the criterion “surface”, no significant differences in the rating of the handling properties of the two materials were identified. The second research hypothesis can be accepted, as data gathered in this study did not indicate significant differences in the clinical performance of the two materials.

To the knowledge of the authors, the present study is one of the very few to have evaluated the clinical performance of fixed interim restorations fabricated from modern materials using a direct approach. Luthardt and co-workers reported the clinical performance of directly fabricated fixed interim restorations made from self-, dual- or light-curing materials. This group employed a split-mouth design using a self-curing composite material for reference (8). In contrast, the present study investigated the clinical performance of two materials with only slight differences in composition using two parallel groups; this study design was chosen in preference to a split-mouth design as the intention was to include extended constructions for restorations of a full or partial dental arch.

The resin materials investigated in this study were provided in auto-mix systems, which largely exclude mixing errors; this made it possible to exclude any impairment of the materials’ mechanical properties due to incorrect mixing regimes. The strengths of the present study included its double-blinded design, the continuous observation employed, and the final examination of the fixed interim restorations prior to insertion of the definitive restorations. Both dentists and undergraduate students were involved in the fabrication of the interim restorations, reflecting the typical setting at a university dental school. Nevertheless, it is obvious that differences in the level of experience might have influenced the study outcome. However, with regard to failure due to fracture, that data indicated that the frequency of fractures was similar for fixed interim restorations that had been fabricated by dentists and those that had been fabricated by undergraduate students.

Both resin materials investigated were provided by the same manufacturer and featured an identical BisEMA/UDMA resin matrix; however, Structur 2 was supplemented with glass and ceramic filler particles with an average diameter of 2.5-3 μm, while Structur 3 included silica and nanosilica filler particles. It is likely that these differences in filler composition accounted for the different rating of the two materials in terms of the criterion “surface”; however, the lack of significant differences in the clinical performance of the materials indicated that the different filler compositions somewhat influenced the handling properties rather than the clinical performance. Differences in the criterion “surface” corresponded largely to the operators’ subjective perception of stickiness, suggesting that there was no perceived difference in the surface roughness of the restorations prepared from the two materials.

Some researchers have highlighted that indirect approaches produce fixed interim restorations with significantly improved marginal adaptation, which has been attributed to the undisturbed polymerization process of the resin materials in the dental laboratory (9). Composite resin materials such as those employed in the present study have a polymerization shrinkage of around 1-4% (10), which suggests that the marginal fit of the fixed interim restoration might be impaired. In the present study, more than 50% of the fixed interim restorations received a Bravo rating at the baseline, indicating that a marginal gap was palpable with a dental probe. However, although marginal fit is expected to worsen with time in clinical service, more than 50% of the fixed interim restorations received an Alpha rating from the calibrated examiners prior to insertion of the definitive restoration; extensive defects were observed in the marginal areas in only three cases. The differences in the rating at the baseline and prior to insertion of the definitive restoration might have been due to variations in the scoring criteria, as it was initially assumed that marginal fit and integrity would be impaired more markedly during clinical service. Nevertheless, the ratings responded to evaluations of the gingival tissues, where signs of gingival inflammation were observed only randomly and not associated with marginal deficiencies. Previous clinical studies have yielded conflicting results regarding the effects of fixed interim restorations on gingival tissues (11-13). However, the conventional wisdom is that fixed interim restorations featuring adequate marginal adaptation do not induce gingival inflammation, and this was supported by the present results.

The findings of the present study indicate that failures of fixed interim restorations are infrequent, with a survival rate of more than 86% until insertion of the definitive restoration. This outcome was surprisingly low, as—most likely due to the university setting and the inclusion of undergraduate students—the fixed interim restorations
were in clinical service for an extended period of more than six weeks. However, the Luthardt group reported an even lower failure rate (8), which might have been due to differences in the experimental design and definition of failure.

Due to the limited number of failed fixed interim restorations, data regarding the impact of the type of restoration on the occurrence of failures need to be interpreted with caution; nevertheless, no significant impact of the type of restoration could be identified, supporting the assumption that even extended fixed interim restorations fabricated from polymeric resin materials have acceptable survival rates. In addition, patients generally expressed high satisfaction with their fixed interim restorations.

The authors are aware that the present study did not sufficiently address all aspects associated with the application of fixed interim restorations for prosthetic treatment. The heterogeneity of the included restorations allowed no simple investigation of plaque and bleeding indices; in addition, endodontically treated teeth were included, which prevented the authors from assessing the impact of the interim restorations on tooth hypersensitivity. As a result, further studies on this topic might focus on specific aspects regarding the evaluation of the performance of fixed interim restorations in a specific clinical setting. Nevertheless, the present study design reflected a random setting corresponding to the clinical routine in dental offices. The present results support the assumption that fixed interim restorations fabricated from polymeric resin materials exhibit adequate handling properties with an acceptable clinical performance, while slight variations in filler composition account for only few differences in handling properties and clinical performance.

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Conflict of interest
The authors have no conflict of interest but declare that previous projects on other topics had been financially supported by VOCO GmbH.

References
1. Burns DR, Beck DA, Nelson SK (2003) A review of selected dental literature on contemporary provisional fixed prosthodontic treatment: report of the committee on research in fixed prosthodontics of the academy of fixed prosthodontics. J Prostheth Dent 90, 474-479.
2. Abdullah AO, Tsitrou EA, Pollington S (2016) Comparative in vitro evaluation of CAD/CAM vs conventional provisional crowns. J Appl Oral Sci 24, 258-263.
3. Patras M, Naka O, Doukoudakis S, Pissiotis A (2012) Management of provisional restorations’ deficiencies: a literature review. J Esthet Restor 24, 26-38.
4. Kerby RE, Knobloch LA, Sharples S, Peregrina A (2013) Mechanical properties of urethane and bis-acryl interim resin materials. J Prostheth Dent 110, 21-28.
5. Karakoutan I, Sayin G, Kara O (2015) In vitro study of fracture strength of provisional crown materials. J Adv Prosthodont 7, 27-31.
6. Abdulmohsen B, Parker S, Braden M, Patel MP (2016) A study to investigate and compare the physicomechanical properties of experimental and commercial temporary crown and bridge materials. Dent Mater 32, 200-210.
7. Pott PC, Schmitz-Wätjen H, Sitesch M, Eisenburger M (2017) Influence of the material for preformed moulds on the polymerization temperature of resin materials for temporary FPDs. J Adv Prosthodont 9, 294-301.
8. Luthardt RG, Stössel M, Hinz M, Vollandt R (2000) Clinical performance and periodontal outcome of temporary crowns and fixed partial dentures: a randomized clinical trial. J Prostheth Dent 83, 32-39.
9. Crispin BJ, Watson JF, Caputo AA (1980) The marginal accuracy of treatment restorations: a comparative analysis. J Prostheth Dent 44, 283-290.
10. Lepe X, Bales DI, Johnson GH (1999) Retention of provisional crowns fabricated from two materials with the use of four temporary cements. J Prostheth Dent 81, 469-475.
11. Waerhaug J, Zander HA (1957) Reaction of gingival tissues to self-curing acrylic restorations. J Am Dent Assoc 54, 760-768.
12. Donaldson D (1973) Gingival recession associated with temporary crowns. J Periodontol 44, 691-696.
13. MacEntee MI, Bartlett SO, Loadholt CB (1978) A histologic evaluation of tissue response to three currently used temporary acrylic resin crowns. J Prostheth Dent 39, 42-46.