Abstract: Minimal intervention is generally achieved by using direct composite resin (CR) restorations. However, deep caries lesions may lead to pulpal complications. This study evaluated the risk of endodontic complications after CR restoration in relation to depth of caries lesions. Data on 507 teeth from 316 adults treated with CR were analyzed. Caries depth was expressed as a percentage of the distance between the outer edge of the dental enamel and the pulp base on preoperative radiographs. The interval between CR restoration and follow-up root canal treatment was obtained from electronic treatment records for a period of 24 months. A Cox proportional hazards model was used to investigate the association between risk of endodontic complications and caries depth. Sixteen teeth (3.2%) required root canal treatment within 24 months. No root canal treatment was required after CR treatment for caries affecting <50% of the outer edge of enamel and pulp. As compared with CR treatment of caries lesions with a size of >80%, there was a significantly higher risk of root canal treatment for caries lesions with a size of 80% to 89% (hazard ratio, [95% CI]: 34.68 [4.23-284.11]) and ≥90% (92.01 [10.36-817.41], respectively).

Keywords: clinical study, operative, prognosis, radiography, risk factors

Introduction

In 2002, the World Dental Federation (FDI) issued a policy statement entitled “Minimal Intervention (MI) in the Management of Dental Caries.” These recommendations are now accepted worldwide and are considered the most important concepts in caries treatment [1-3]. Surgical removal of infected dentin leaves the remaining tooth structure fragile, which sometimes results in tooth fracture that leads to root canal treatment or tooth extraction. More-conservative interventions aim to minimize loss of sound tooth structure by extending their lifespan [4]. Surgery should be regarded as a last resort, and the amount of sound tooth structure removed should be minimized [5].

Dental adhesive technology has progressed, and composite resin (CR) restoration is now the most viable minimally invasive option [6]. Several studies have examined outcomes of CR restoration after periods exceeding 10 years. A study of clinical variables 12 years postoperatively concluded that repair using CR restorations was a good clinical option because of their increased longevity and the minimal invasiveness of the procedure [7]. Heck et al. [8] reported that the overall 10-year success rate was 76.9% for posterior bulk fill material and 86.7% for hybrid composite, which indicates clinically acceptable performance. Moreover, Borgia et al. [9] reported that 98% of CR restorations of posterior teeth were still functional and that mean survival time of the restorations was 11 years, 7 months.

Deep caries lesions may lead to symptoms of pulpitis even after treatment. In such cases, follow-up for a root canal is necessary, which is a known early failure in restorative dentistry [10]. Many studies recommend avoiding pulp exposure in deep caries treatment, since accidental pulp exposure may cause a pulpal reaction [11-14]. However, few quantitative studies have evaluated the risk of endodontic complications for patients with deep caries lesions. Innes et al. [15] defined deep caries as a lesion reaching the inner pulpal third of dentin, as indicated by a radiograph, while Duncan et al. [16] defined it as caries reaching the inner quarter of dentin. Because the association between caries lesion size and risk of CR treatment failure (i.e. endodontic complication) is not well understood, this study examined the risk of endodontic complications after CR restoration in relation to caries depth.

Materials and Methods

Study participants

This study used data from clinical records at Tokyo Medical and Dental University (TMDU) Dental Hospital (Tokyo, Japan). Patients at TMDU Dental Hospital are usually referred from dental clinics and, after considering their symptoms, age, and systemic condition, are assigned to the appropriate section for treatment. Patients older than 20 years with vital teeth who do not have spontaneous pain, acute pulpitis, or cavities reaching the pulp are treated in the Operative Dentistry section.

The flow diagram of the study participant selection is shown in Fig. 1. The present participants were patients undergoing an initial consultation at the Operative Dentistry section (TMDU Dental Hospital) in 2016. In total, 1,396 teeth from 1,186 patients were assessed. Patients without preoperative radiographs, those who did not receive CR restorations, those with caries lesions not detected by preoperative radiography, those with non-vital teeth, and those who had undergone pulp extraction for intra-operative pulp exposure were excluded, as were those who did not return after treatment. Ultimately, data from 316 patients were included in the analyses.

This cohort study conforms to Strengthening the Reporting of Observational Studies in Epidemiology guidelines. Informed consent was obtained in the form of opt-out from all patients. Information on the study was posted in the outpatient treatment room and on the department’s website. Ethical approval for this study was obtained from the Ethics Review Board of TMDU (D2019-015).

Measurements

Participant data were collected from the clinical records of a university hospital. CR treatment was performed by 48 clinicians in the Operative Dentistry section. The clinicians’ experience ranged from 2 to 33 years (mean: 7.43 years). This study assumed that they all followed the standard treatment procedure in the Operative Dentistry department, as described below.

Firstly, the caries cavity was approached by using a fine diamond bur with a dental air turbine, which was used to remove outer carious dentin (infected dentin). To preserve the inner carious dentin (affected dentin), caries removal was performed by using a micromotor hand piece (CAG01, Osada, Tokyo Japan) and a stainless round bur (MI stainless bur CA, Mani, Utsunomiya, Japan) with cavities-detector dyes (Caries check, Nishika, Shimonoseki, Japan). A low speed was used to avoid heat damage to dental pulp [17,18]. When dental pulp was accidentally exposed, despite the careful excavation process, the tooth was automatically excluded from this study because such treatment was categorized as direct pulp capping by CR. Subsequently, the cavity was restored by using a two-step self-etching adhesive (Clearfil SE Bond 2, Kuraray Noritake Dental, Tokyo, Japan) and composite resin and cured with an LED light-curing unit. Various resin composite and light-curing units (and light-curing conditions) were used.

The quantitative caries extension index (CE index) uses radiographs...
to determine caries depth for each diagnostic score [19]. Kühnisch et al. evaluated the validity and reproducibility of the CE index, when performed by two dentists and four students without any calibration training, and reported that the index yielded exact caries depths [19]. In this study, caries lesion size was measured on a digital radiograph by a clinician (with 8 years of work experience) using data from three focal points, regardless of caries location (Fig. 2). Point “A” is the outer edge of the radiolucent carious lesion along the enamel, Point “B” is placed at the dentin border of the radiolucent area, and Point “C” is the pulp border. The ratio AB/AC defines caries lesion size (expressed as a percentage).

CR treatment failure was defined as root canal treatment after deep caries treatment. The date of endodontic complications for these cases was ascertained by using the same electronic dental treatment records. Information from the 24-month postoperative follow-up examination was used to update prior data, including sex, age, type of insurance, type of tooth, cavity position, and type of caries. The Japanese health insurance system covers nearly all residents of Japan. In this study, information from the 24-month postoperative follow-up examination was used to update prior data, including sex, age, type of insurance, type of tooth, cavity position, and type of caries. The Japanese health insurance system covers nearly all residents of Japan. In this study, information from the 24-month postoperative follow-up examination was used to update prior data, including sex, age, type of insurance, type of tooth, cavity position, and type of caries.

Analysis

This study summarized the number and proportion of teeth in relation to above classifications and calculated mean patient age. The proportion of patients requiring root canal treatment after CR treatment and mean tooth-months of follow-up were calculated and analyzed in relation to caries lesion size, which was classified as <80%, 80% to 89%, and ≥90%.

A survival curve for CR treatment was created by using the Kaplan-Meier method. A Cox proportional hazards model was estimated in order to evaluate the risk of endodontic complications after CR treatment in relation to caries size. All analyses were performed with Stata/SE 15.0 (Stata Corp, College Station, TX, USA).

Results

The characteristics of the study participants are shown in Table 1. The 316 eligible patients (203 women [64.2%] and 113 men [35.8%]) had a mean age of 52.63 ± 16.28 years. With regard to insurance coverage, 162 patients (51.3%) were general employees, 123 (38.9%) were covered by national health insurance, 26 (8.2%) were enrolled in the long-life medical care system, and 5 (1.6%) were receiving public assistance. Among the 507 examined teeth, 16 required root canal treatment (3.2%). There were 149 front teeth (29.4%), 160 premolars (31.6%), and 198 molars (39.0%), and cavity position was classified as occlusal in 29 cases (5.7%) and proximal in 478 cases (94.3%). Caries type was classified as primary in 303 cases (59.8%), secondary in 142 cases (28.0%), and desorption in 62 cases (12.2%).

Table 2 shows outcomes after composite resin restoration. The mean duration of follow-up was 17.07 tooth-months, and root canal treatment after CR restoration was performed on 16 teeth (3.2%). No case of debonded or fractured CR material was noted in this study. For lesion sizes of <80%, 80% to 89%, and ≥90%, the incidences of endodontic complications were 0.5% (n = 2), 10.4% (n = 8), and 27.3% (n = 6), respectively. In addition, no endodontic complications were noted after CR restoration when lesion size was <50%. Kaplan-Meier analysis showed that CR restorations for caries with a lesion size of ≥80% were more likely to fail within 24 months of follow-up (Fig. 3).
All caries lesions with a size of <80% were combined, after which estimated hazard ratios (HRs) for endodontic complications after CR treatment were calculated (Table 3). Multivariate analysis adjusted for age and sex showed that caries lesions with sizes of 80% to 89% and ≥90% were associated with significantly higher risks of endodontic complications (HR [95% CI]: 34.68 [4.23-284.11] and 92.01 [10.36-817.41], respectively). When the model was run again after changing the reference category to ≥90% to 89%, the difference between the 80% to 89% and ≥90% groups was not statistically significant (HR [95% CI], 2.84 [0.90-8.95]). Patient age, sex, type of insurance, and type of tooth were not associated with risk of endodontic complications.

Discussion

In this study, 16 teeth (3.2%) required root canal treatment within 24 months of CR restoration. Notably, 8 teeth (10.4%) had a lesion size of 80% to 89%, and 6 (27.3%) had a lesion size of ≥90%. The Cox proportional hazards model yielded an HR (95% CI) of 34.68 (4.23-284.11) for a lesion size of 80% to 89% and an HR of 92.01 (10.36-817.41) for a lesion size of ≥90%. No association was noted for other factors. These results show that cavity lesion size is associated with incidence of endodontic complications.

![Fig. 2 Survival curve of composite resin restorations classified by caries lesion size. The numbers censored are indicated by the values above the line.](image)

Table 3 Statistical analysis of associations of caries lesion size and patient-related variables with composite resin outcome

| Caries lesion size | Model 1 (crude) | Model 2 (adjusted) |
|-------------------|----------------|-------------------|
| 80-89%            | 36.78 [4.53, 299.00] | 34.68 [4.23, 284.11] |
| ≥90%              | 104.39 [12.19, 894.04] | 92.01 [10.36, 817.41] |
| Age               | 0.99 [0.95, 1.04] | 0.99 [0.95, 1.04] |
| Sex               |                     |                   |
| Female            | 1.00                | 1.00              |
| Male              | 1.61 [0.90, 2.11] | 0.50 [0.90, 2.11] |
| Type of insurance |                     |                   |
| General employees | 1.00                | 1.00              |
| National health insurance | 1.17 [0.32, 4.23] | 0.17 [0.32, 4.23] |
| Long-life medical care system | 2.21 [0.21, 23.70] | 2.21 [0.21, 23.70] |
| Public assistance' | -                   | -                 |
| Type of tooth     |                     |                   |
| Front             | 1.00                | 1.00              |
| Premolar          | 3.46 [0.40, 33.70] | 3.46 [0.40, 33.70] |
| Molar             | 2.44 [0.28, 20.95] | 2.44 [0.28, 20.95] |

CI, confidence interval; HR, hazard ratio. *Hazard ratio was not estimated because no event was observed among participants receiving public assistance.

A randomized clinical trial concluded that the restoration survival rate after CR restoration of a class II cavity was 98.7% at 12 months [20]. A clinical study reported that 90% of direct CR restorations assessed with modified United States Public Health Service criteria (tooth color stability, surface texture, marginal integrity, marginal discoloration, secondary caries, gingival inflammation, and restoration color stability) were clinically excellent or acceptable at 24 months [21]. The present study showed that 96.8% of CR restorations did not require root canal treatment within 24 months. Furthermore, a clinical study [22] of endodontic complications after CR restoration reported that dentin and pulp protection by adhesive resins was as effective as a conventional calcium hydroxide lining and that residual dentin thickness appears to be a key determinant of pulpal response after restorative dental treatment. Opdam [23] reported that 9 of 703 posterior resin composite restorations (1.3%) required endodontic treatment within 5 years and that the risk of endodontic complications increased when residual tooth thickness was less than 20%. Schwendicke et al. [24] retrospectively evaluated treatment of advanced lesions (vital permanent posterior teeth with lesions radiographically extending into inner dentin) for which endodontic complications were observed in 53 of 308 teeth (17.2%). The present results are consistent with these previous findings.

The findings of this study should be interpreted carefully, as the clinical data were obtained from the records of a single university hospital. The characteristics of these patients may thus differ from those of the general population, especially since the average age of the present patients was 52.63 years, which could influence the likelihood of root canal treatment. Studies of young patients are therefore warranted. Non-vital teeth with no clinical symptoms might have been missed because no clinical examination of pulp was conducted, which could have led to overestimation of the success rate of CR treatment. Moreover, the number of study participants was small (n = 316), yielding 16 teeth (3.2%) on which root canal treatment was performed within 24 months after CR restoration. The small sample size might explain the high HRs and large CIs. Additionally, there might have been variations in the procedures or materials used for the CR restoration, because 48 clinicians performed the CR treatments. In addition, there was no information on use of local anesthesia, composite resin materials, and hand excavator use. Differences in clinician experience and technique could have led to variability in the amount of excavated dentin and damage to pulp tissue. Therefore, studies that restrict the operative procedures and use a single dentist for all clinical work are expected.

Caries lesions with a size of 80% to 89% and ≥90% had a higher risk of endodontic complications after CR restoration (HR, 34.68 and 92.01, respectively). The European Society of Endodontology position statement defines "extremely deep caries" as those that penetrate the entire inner dentin (the inner pulpal third of dentin [15] or a quarter of the dentin [16]) to define deep caries, the present findings suggest that the risk of endodontic complications was higher for a lesion size of ≥80%.

Figure 1 illustrates the Kaplan-Meier survival analysis of caries lesion size and endodontic complications after CR treatment. The survival curve shows significantly lower survival rates for lesions ≥90% and ≥80% compared to lesions <80% (P < 0.01). The median survival time for lesions <80% was 24 months, while the median survival time for lesions ≥80% was 6 months. The findings of this study should be interpreted carefully, as the clinical data were obtained from the records of a single university hospital. The characteristics of these patients may thus differ from those of the general population, especially since the average age of the present patients was 52.63 years, which could influence the likelihood of root canal treatment. Studies of young patients are therefore warranted. Non-vital teeth with no clinical symptoms might have been missed because no clinical examination of pulp was conducted, which could have led to overestimation of the success rate of CR treatment. Moreover, the number of study participants was small (n = 316), yielding 16 teeth (3.2%) on which root canal treatment was performed within 24 months after CR restoration. The small sample size might explain the high HRs and large CIs. Additionally, there might have been variations in the procedures or materials used for the CR restoration, because 48 clinicians performed the CR treatments. In addition, there was no information on use of local anesthesia, composite resin materials, and hand excavator use. Differences in clinician experience and technique could have led to variability in the amount of excavated dentin and damage to pulp tissue. Therefore, studies that restrict the operative procedures and use a single dentist for all clinical work are expected.
thickness of the dentin and are radiographically detectable when located on an interproximal or occlusal surface. Clinical studies suggest that outcomes for direct pulp capping are disappointing [25-27]; thus, avoiding pulp exposure is important [28]. The Consensus Recommendations on Carious Tissue Removal conclude that preserving pulpal health should be prioritized in deeper lesions, i.e., those extending beyond the inner (pulpal) third of the dentin radiographically, with sensible (vital) pulps [15,29]. A randomized clinical trial found that stepwise removal had a lower risk of pulp exposure, as compared with direct complete excavation, for caries lesions radiographically involving 75% dentin or more [13]. The present study focused on outcomes after CR restorations in which pulp exposure was avoided. Future clinical studies of caries treatment should evaluate the relation between risk of pulp exposure and assessment using preparative radiography.

This study yielded quantitative information on outcomes after CR restoration for dental caries of differing severity. As compared with CR treatment of caries with a lesion size of <80%, the risk of endodontic complications was significantly higher for those with a lesion size of 80% to 89% and ≥90%.

Conflict of interest
The authors received no financial support and declare no potential conflict of interest with respect to the authorship and publication of this article.

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