




# Effect of Time-Lapse between Intermediate Restoration and Final Restoration on Survival Rate and Changing of Radiographic Periapical Lesion

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## Abstract

**Objective** This study aimed to assess the impact of intermediate restoration time-lapse on the survival rate and changes in radiographic periapical lesions of endodontically treated teeth.

**Materials and Methods** The included treatment records and periapical films of 62 patients were divided into two groups based on the time-lapse of intermediate restoration: within 4 months group ( $\leq 4$  m group) and more than 4 months group ( $> 4$  m group).

**Statistical Analysis** Survival analysis was conducted using Kaplan–Meier and log-rank test. The predictive clinical factors were assessed using a Cox regression model and hazard ratio, considering both clinical and radiographic outcomes from the latest recall appointment. Changes in periapical index (PAI) scores on radiographs were evaluated using the Chi-square test. Statistical significance was set at  $p < 0.05$ .

**Results** The mean survival rate of endodontically treated teeth was 77.4%. The survival rates of the  $\leq 4$  m group and  $> 4$  m group were 83.3 and 69.2%, respectively, without statistical significance. None of the clinical factors significantly affected the clinical outcome. However, the  $> 4$  m group exhibited significantly worse changes in PAI scores between the final restoration appointment and the latest recall.

**Conclusion** Different time-lapses for intermediate restoration did not significantly affect the survival rate. However, an intermediate restoration time-lapse of more than 4 months tended to result in worse changes in PAI scores.

## Keywords

- ▶ endodontics
- ▶ intermediate restoration
- ▶ periapical pathology
- ▶ radiographic image interpretation
- ▶ treatment outcome

## Introduction

Most endodontically treated teeth often experience significant loss of tooth structure, necessitating immediate placement of permanent cuspal coverage restoration to prevent tooth fracture and bacterial recontamination into the obturated root

canal system and give better tooth survival rate.<sup>1,2</sup> However, there are instances where immediate placement of the permanent restoration is not feasible, such as when monitoring the improvement of a large periapical lesion, awaiting evaluation of the outcome of periodontal treatments, and awaiting a

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restoration treatment plan in a dental school system. In such cases, an intermediate or interim restoration must be placed over the access cavity.<sup>3</sup>

Intermediate restoration refers to a material that provides a bacterial-tight seal before the final restoration is replaced. Additionally, the intermediate restoration should protect the remaining tooth structure from fracture.<sup>3</sup> Therefore, the most appropriate materials for intermediate restoration are bonded restoration, composite resin, and glass ionomer cement.<sup>4</sup> On some occasions, other materials are used with those bonded restorations, such as temporary crowns or orthodontic metal bands.<sup>3</sup> Although the sealing ability and ability to protect the remaining tooth structure have been proven in both laboratory<sup>5-7</sup> and clinical study,<sup>8,9</sup> previous studies have shown that delaying crown placement for >4 months after endodontic treatment increases the risk of extraction by threefold compared with crowns placed ≤4 months.<sup>10</sup> This is because prolonged duration before crown placement can lead to leakage of the intermediate restoration. In addition, retrospective studies have also demonstrated that direct restorative materials have a lower survival rate than permanent cuspal coverage restorations.<sup>2,9</sup> Thus, it can be concluded that endodontically treated teeth should receive permanent cuspal coverage restoration as soon as possible after receiving intermediate restoration to achieve successful outcomes.

The outcome of root canal treatment is evaluated through both clinical examination and radiographic interpretation.<sup>11</sup> Clinical examinations are based on patient responses, including percussion and palpation tests, whereas radiographic interpretation is based on objective findings.<sup>12</sup> Radiographic interpretation allows for the assessment of periapical lesion healing by comparing it to the preoperative status.<sup>12,13</sup> In some cases, periapical lesions may progress or remain unchanged, but clinical examination may demonstrate normal function and pain absent.<sup>14</sup> Therefore, radiographic interpretation after root canal treatment provides a measurable and comparable assessment of the outcome more than only clinical examinations. Previous studies on the effect of the time-lapse before intermediate restoration on periapical lesion using national insurance databases have only considered tooth survival as a measure of success,<sup>15</sup> and the reliability of radiographic healing for evaluating endodontic outcomes remains unknown.<sup>10</sup>

Therefore, the objective of this study is to investigate the effect of the time-lapse before intermediate restoration on the outcome of root canal treatment and the radiographic changes in periapical lesions.

## Materials and Methods

### Study Design and Population

This retrospective study involved undergraduate dental students at Thammasat University, Thailand. Data were collected from treatment records spanning from January 2017 to December 2021. The study received ethical approval from the Human Research Ethics Committee of Thammasat University (COE No. 011/2566).

### Inclusion Criteria

1. Complete records including patient medical and dental history, radiographic data during treatment and follow-up appointments, and dates of appointments for each step, including final restoration procedures and all follow-up appointments.
2. Acceptable root canal filling quality with no voids and the limit of root canal filling short of the radiographic root apex by 0.5 to 2 mm.
3. All endodontically treated teeth having final restorations with acceptable clinical and radiographic margins.
4. Intact interim restorations in both radiographs and treatment records if the teeth had not received the final restoration during the follow-up appointments.

### Exclusion Criteria

1. Unacceptable radiographic quality which could not interpret the radiographic outcome such as visible scratches on the suspected teeth and periapical area, poor contrast, or incomplete coverage of periapical lesions.
2. Follow-up after receiving the intermediate restoration less than 1 year.
3. Poor quality of final restoration compromising coronal leakage.
4. Present periodontitis or bone loss exceeding  $\frac{2}{3}$  of the crestal bone level.

### Root Canal Treatment Procedures

All root canal treatments were performed by undergraduate dental students under the direct supervision of endodontic specialists. Aseptic protocols were strictly followed, with rubber dam isolation applied in all cases. The area was disinfected using 1.5% tincture of iodine followed by 70% ethyl alcohol swabbing. After accessing the pulp chamber, the working length was determined using an apex locator (Root ZX, J Morita Corp, Osaka, Japan) set at 0.5 mm, and confirmed radiographically. The initial file size used was no. 15 or larger. If a smaller file was required, the canals were negotiated and enlarged until the no. 15 file reached the 0.5 mm mark, after which the working length was confirmed radiographically. Mechanical preparation of the root canals was performed using hand endodontic k-files (Dentsply Sirona, Charlotte, NC, USA), enlarging the canals by at least three file sizes beyond the initial size. The root canals were copiously irrigated with 2.5% sodium hypochlorite (NaOCl) throughout instrumentation. In cases of nonsurgical root canal retreatment, the previous root canal filling material was removed using hand files with eucalyptol as a solvent, followed by radiographic confirmation of complete removal. The master apical cones were selected and confirmed radiographically, after which calcium hydroxide paste was applied as the root canal medicament. Prior to obturation, the canals were irrigated with 17% EDTA for 1 minute to eliminate the smear layer. The canals were then obturated using gutta-percha and a zinc oxide-eugenol-based sealer (CU root canal sealer, Bangkok, Thailand) with the lateral condensation technique. Radiographs were taken to confirm the quality of obturation. After obturation

the canals, teeth were placed intermediate restoration with materials such as Cavit (3M ESPE, Seefeld, Germany), IRM (Dentsply Sirona, Charlotte, NC, USA), composite resin (3M ESPE, Seefeld, Germany), resin-modified glass ionomer cement (Fuji II LC, GC Corp, Tokyo, Japan), or other provisional restorations such as temporary crowns or orthodontic bands. Typically, there was a 2-week interval between root canal treatment steps. Upon completion of root canal therapy, patients were placed on a waiting list for final restoration, which was performed by other undergraduate students. The waiting period for final restorations ranged from immediate placement to a maximum of 6 months.

### Follow-up Procedures

Follow-up appointments were scheduled for 6 months, 1 year, 2 years, and up to 4 years after the interim restoration was placed. Patients were allowed to request follow-up by telephone by undergraduate student, after which recall appointments were arranged for clinical and radiographic evaluations. At each follow-up visit, the root canal-treated teeth were assessed for restoration quality. Intermediate restorations were evaluated for functional integrity and marginal adaptation. While final restorations were assessed for marginal fit and adaptation as well. Additionally, pocket depth, mobility, percussion, and palpation tests were performed. Radiographic imaging was conducted at every follow-up to detect any signs of leakage or recurrent caries beneath both intermediate and final restorations. If the final restoration indicated leakage, it would be excluded according to the exclusion criteria that previously mentioned. The outcomes of root canal treatment were compared with baseline radiographs, with any detected abnormalities, such as restoration failure due to fracture, leakage, secondary caries, or failure of the root canal treatment itself, leading to referral for retreatment or alternative treatment planning.

### Final Restoration Procedures

Final restorations were performed under the supervision of prosthodontic specialists, with radiographs taken during the try-in and permanent cementation stages after tooth preparation and the final impression was taken. If a post was placed, an additional radiograph was obtained during both the post try-in and cementation stages. Final restorations consisted of porcelain-fused-to-metal crowns, full metal crowns, coping, or all-ceramic crowns.

Over the course of the entire treatment, including final restoration and follow-up visits, ~9 to 15 radiographs were taken. Radiographic aids (Super-Bite, Kerr Dental, Kolten, Switzerland) were used for anterior and posterior teeth to ensure consistent imaging angles. All radiographs were captured using digital phosphor plates (VitaScan, Durr Dental, Bietigheim, Germany).

### Data Collection

Patient records, including the number of root canals, age, gender, occupation, medical systemic diseases, clinical findings, pulp and periapical status, interim restoration

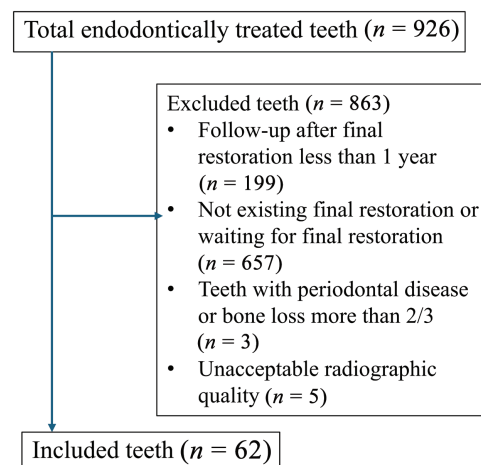
time-lapse, and treatment duration, were collected from endodontic charts from 2017 to 2021. Radiographs from preoperation, intermediate restoration, and final restoration were obtained from DBSWIN 5.1.7.0. (Durr Dental SE, Bietigheim-Bissingen, Germany). After assessing a total of 926 cases, 62 cases were selected for further investigation (► Fig. 1). These selected cases' radiographs were scored using the PAI score system. The data were then divided into two groups: within 4 months and more than 4 months<sup>10</sup> ( $\leq 4$  m group and  $>4$  m group, respectively).

### Assessment of Endodontic Treatment Outcomes, Survive, and Failure

The outcomes of endodontic treatments were collected from treatment records. To assess the survival rate of endodontically treated teeth, we utilized and modified the nonstrict criteria of Friedman. Teeth defined as "healed" and "healing" at the end of the last recall appointments, with a decrease in size or remaining the same size of the periapical lesion, along with normal clinical signs and symptoms, were considered as "survive." Conversely, teeth defined as "diseased" were considered as "failure," which included cases where periapical lesions were larger or remained the same size, with clinical signs and symptoms such as pain, swelling, or the presence of a sinus opening.<sup>16</sup> The evaluation of root canal treatment outcomes "survive or disease/failure" was conducted at the most recent follow-up visit, to calculate the survival analysis.

### Radiographic Interpretations by PAI Score Index

Radiographic interpretations were calibrated by two observers (TH and TT) following the PAI-scoring system.<sup>12,17</sup> The calibration films consisted of 100 radiographic images of teeth that were not included in this study. One of the five PAI-scored points was assigned to each tooth in the radiographs. These two observers underwent PAI-score training twice, with 1 month apart. The radiographic assessments were confirmed by an endodontist (PA). Cohen's Kappa statistic was used to calculate intraobserver and interobserver correlation values. The acceptable range of agreement was 0.81 to 1.00. Then each of the two observers individually interpreted



**Fig. 1** Diagram showing the number of endodontically treated teeth that fulfilled the inclusion criteria.

the 62 included cases. If there was a disagreement in interpretation, the two observers and the PA would discuss and reach a final agreement.

### Statistical Analysis

The survival rate of endodontic treated teeth between  $\leq 4$  m group and  $>4$  m group was analyzed by Kaplan–Meier statistics and the significance of the results was determined by using the log rank test. The assessment of radiographic periapical lesion changes between the two groups based on time-lapse ( $\leq 4$  m group and  $>4$  m group) was conducted by comparing the PAI score of preoperative radiographs, intermediate restoration placement radiographs, final restoration completion radiographs, and the last recall appointment radiographs. The data were analyzed using the Friedman test, with pairwise comparisons of each two time points analyzed using the Dunn test. Additionally, the Chi-Square test was employed to assess the correlation between the time-lapse of interim restoration and the changes in PAI score (no change, improvement, or worse) from the period of final restoration to the latest recall appointment. All statistical analyses were performed using SPSS software (SPSS Statistics 25.0, IBM Corp, Armonk, New York, United States), with a significance level set at  $p < 0.05$ .

### Results

The samples included in the study were collected according to the flow chart shown in ►Fig. 1. Unfortunately, none of the teeth that met the inclusion and exclusion criteria had follow-up periods that reached 4 years. The median follow-up period after receiving the final restoration was 2 years, with the minimum follow-up duration was 1 year and the maximum was 3 years, respectively. ►Table 1 presents the descriptive demographic and clinical parameters of all included teeth. The overall clinical success rate was 77.4%. The success rate of the intermediate restoration for the  $\leq 4$  m group was 83.3%, while the  $>4$  m group had a success rate of 69.2%. The survival rate curve, analyzed by Kaplan–Meier analysis, is depicted in ►Fig. 2. Bivariate or multivariate analyses of each clinical parameter are presented in ►Supplementary Table S1 (available in the online version). The Multivariable Cox regression hazard ratio of clinical factors, type of intermediate restoration, pulpal status, and initial PAI score from both groups ( $\geq 4$  m and  $>4$  m) also failed to identify potentially significant clinical factors (►Supplementary Table S2, available in the online version).

The Cohen's Kappa statistics values calculated for intra-observer and interobserver reliability fell within the almost perfect range of agreement (0.81–1.00). Changes in radiographic periapical lesions, assessed by the PAI score, in the two groups ( $\leq 4$  m and  $>4$  m) were analyzed by comparing radiographs at different time points, including the preoperative radiograph, intermediate restoration placement radiograph, final restoration radiograph, and the latest recall radiograph (►Fig. 3). Both groups showed differences in

changing PAI scores at different observation periods, as indicated by the Friedman test (data not shown).

The  $\leq 4$  m group showed improvement in the PAI score over time. However, the  $>4$  m group showed a trend of relapse in radiographic outcome, with an increase in the percentage of scores 3 and 4 of the PAI score and a decrease in scores 1 and 2 from the final replacement appointment to the latest recall appointment. To explore the correlation between changes in radiographic periapical lesions based on the PAI score (no change, improvement, or worsening) and the two groups' time-lapse of intermediate restoration from the final restoration placement appointment to the latest recall appointment, a correlation analysis was performed. There was a correlation between different interim restoration time-lapses and changes in radiographic periapical lesions ( $p = 0.007$ ; ►Table 2).

### Discussions

Although this study could not confirm that more than 4 months of intermediate restoration to final restoration had a risk of failure based on both clinical and radiographic interpretations, the analysis of periapical tissue status change from the final restoration appointment to the most recent recall appointment revealed a higher risk of worsened periapical score index in the group with more than 4 months of intermediate restoration time. This finding contrasts with a previous study that reported a tendency for failure in root canal treatment outcomes with more than 4 months of intermediate restoration,<sup>10</sup> suggesting a possible explanation in the low number of included samples. However, when considering only radiographic outcomes, the  $>4$  m group demonstrated worse outcomes than the  $<4$  m group when comparing between the final restoration appointment and the latest recall appointment. Additionally, the change in periapical lesion status to the latest recall appointment was reduced but increased when comparing between the final restoration appointment and the latest appointment in the  $>4$  m group, despite normal clinical examination findings in these cases. This suggests that radiographic changes may not always correlate with the clinical presentation or functionality or even asymptomatic of unsuccessful root canal treatment.<sup>18,19</sup> Thus, it can be concluded that a time-lapse of more than 4 months for intermediate restoration affects the worse outcome of root canal treatment.

A follow-up period of 4 years is considered an appropriate time for evaluating the outcome of root canal treatment. However, numerous studies have shown significant improvement in periapical lesions within the first year.<sup>20–23</sup> Both groups in this study also showed similar results to previous studies. Nevertheless, longer observation may be needed to clarify the different evaluations of the outcome by clinical and radiographic success between those two groups.

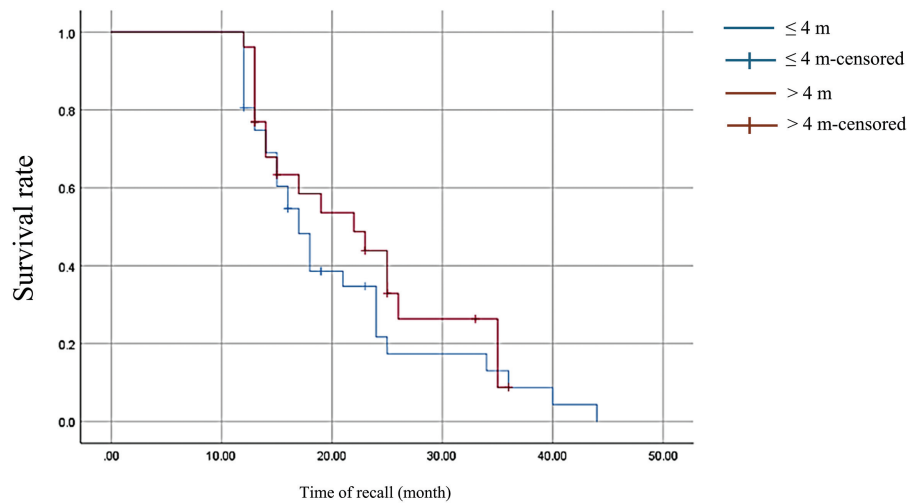
Several clinical factors have been evaluated for their effects on the clinical outcomes of root canal treatment, such as the presence of a preoperative periapical lesion, tooth vitality, type of intermediate restoration, tooth type, number of roots, number of appointments, periodontal

**Table 1** Demographic data of included endodontically treated teeth

Clinical factors	All (n = 62)
Number of root canal	
Single root canal	56 (90.3%)
Multiple root canal	6 (9.7%)
Age (y)	
18–64	49 (79%)
>64	13 (21%)
Gender	
Male	19 (30.6%)
Female	43 (69.4%)
Medical systemic disease	
Hypertension	13 (21.0%)
Diabetes mellitus	4 (6.5%)
Pulp status	
Normal pulp	3 (4.8%)
Asymptomatic or symptomatic irreversible pulpitis	10 (16.1%)
Pulp necrosis	35 (56.5%)
Previously initiated therapy	7 (11.3%)
Previously treated	7 (11.3%)
Periapical status	
Normal periapical tissue	9 (14.5%)
Asymptomatic or asymptomatic apical periodontitis/chronic apical abscess	53 (85.5%)
PAI score at beginning	
PAI score 1	14 (22.6%)
PAI score 2	9 (14.5%)
PAI score 3	10 (16.1%)
PAI score 4	21 (33.9%)
PAI score 5	8 (12.9%)
Type of interim restoration	
Bonded filling (composite resin or resin modified glass ionomer cement)	25 (40.32%)
Temporary filling (IRM with Cavit)	37 (59.68%)
Type of final restoration	
Crown	41 (66.13%)
Resin composite	19 (30.65%)
Metal coping	2 (3.23%)
Intermediate restoration time-lapse to final restoration	
≤ 4 m group	36 (58.1%)
>4 m group	26 (41.9%)

disease, diabetes mellitus, and cardiovascular disease.<sup>24–27</sup> Unfortunately, significant differences were not identified when comparing the two groups of interest. Even factors that have shown an effect on the success rate of endodontic treatment in previous studies, such as the presence of a preoperative endodontic lesion,<sup>27,28</sup> long time-lapse between intermediate restoration to final restoration,<sup>10,15</sup>

and types of intermediate restoration,<sup>9</sup> also failed to demonstrate an effect on the success outcome by regression analysis. This may be due to the insufficient number of samples when grouped into two or three categories, resulting in a lack of statistical power to identify differences.<sup>29</sup> Another reason may be the high success rate of root canal treatment outcomes, leading to a low number of failed cases,



**Fig. 2** Survival rates of both  $\leq 4$  m and  $>4$  m groups of endodontically treated teeth.

**Table 2** The PAI changing outcome of  $\leq 4$  m and  $>4$  m groups

	PAI changing			
	Not change	Better	Worse	Total
$\leq 4$ m group	18	17	1	36
$>4$ m group	11	7	8	26
Total	29	24	9	62

which may have affected the statistical power calculated by the hazard ratio calculation and failed to identify the effect of these clinical factors.<sup>29</sup> The number of teeth excluded is substantial, as most patients declined follow-up appointments since their teeth were functioning well without any symptoms and have no other dental procedures requiring further appointments. Therefore, the actual treatment outcomes may be more successful overall. However, it is still unclear how the number of teeth without these issues affects the factor of duration of time-lapses between intermediate restoration and final restoration in terms of the success rate of root canal treatment or changes in radiographic periapical lesions. Although the treatment was performed by undergraduate students, the root canal treatments were performed under the strict supervision of faculty staff who were endodontic specialists or experienced dentists.<sup>30,31</sup>

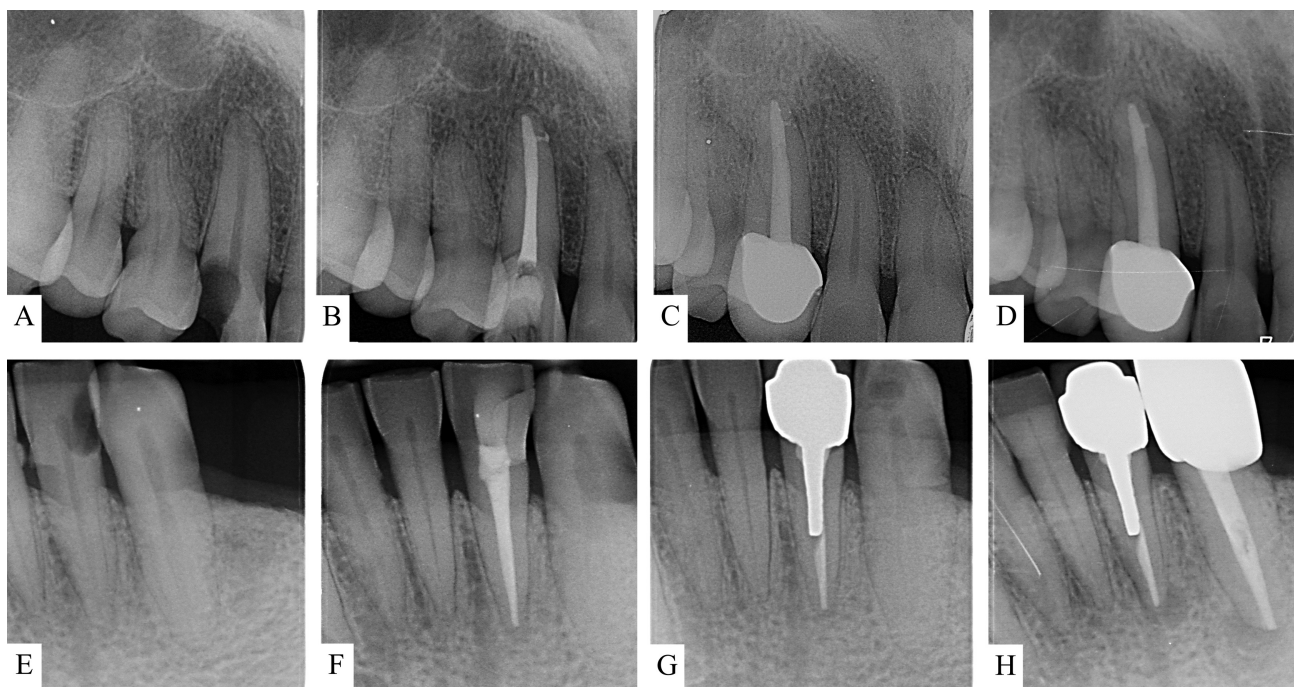
The study excluded teeth with periodontal disease because the disease compromises tooth support and can affect tooth survival in the oral environment. Even if root canal treatment is successful, compromised periodontal supporting tissue can lead to extraction and influence outcome interpretation.<sup>32,33</sup> Furthermore, the study excluded teeth that had undergone root canal treatment with errors, such as perforations, overinstrumentation, overfilling, and inadequate root canal obturation, presence of voids, or short filling, as these factors can affect the prognosis of root canal treatment.<sup>24,34,35</sup> These factors may interfere with or have an impact on the time-lapse between intermediate restoration and final restoration.

Although this study was performed with limitations, including the number of samples and shorter follow-up, it can be concluded that failure can be identified through periodic radiographic recall. If the intermediate restoration exceeds 4 months, the chance of failure increases, which can be observed  $\leq 1$  year after placing the final restoration (**Fig. 3**). Thus, monitoring of this situation is necessary. The worse outcome of periapical lesion improvement may be explained by the cuspal deflection phenomenon, where endodontically treated teeth suffer from gross tooth structure loss, leading to deflection between cusps due to the loss of the marginal ridge.<sup>36</sup> Although most intermediate restorations in this study were bonded restorations, composite resin, and resin-modified glass ionomer cement, failures were observed. Therefore, the results of this study support that the final restoration, including cuspal coverage, should be done as soon as possible. Nevertheless, the intermediate restoration should not exceed 4 months.

In conclusion, under the limitations of this study, it can be concluded that the time-lapse between intermediate restoration and final restoration did not affect the survival rate of root canal treatment outcomes. However, a time-lapse of more than 4 months between the restoration types tends to increase the worse outcome based on radiographic interpretation during periodic follow-up appointments.

#### Conflict of Interest

None declared.



**Fig. 3** Panel (A) to (D) illustrated periapical radiographic changing of 13 from  $\leq 4$  m group with an initial PAI score of one. (A) preoperative film, (B) intermediate restoration placement film, (C) final restoration placement film, (D) 1-year recall film. Panel (E) to (H) illustrated periapical radiographic changing of 32 from  $>4$  m group with an initial PAI score of three. (E) preoperative film, (F) intermediate restoration placement film, (G) final restoration placement film, (H) 4-year recall.

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