CHAPTER 3

MATERIALS AND METHODS

3.1 Research design

This study was a prospective randomized clinical trial. All primary molars with deep caries or reversible pulpitis that met the clinical and radiographic inclusion criteria were recruited from healthy pediatric patients. This study was approved by the Research Ethics Committee of the Faculty of Dentistry, Chiang Mai University (Appendix A). The flow chart below shows the overall experimental procedure in this study (Figure 3.1).

3.2 Research populations and samples

3.2.1 Study populations

All subjects participating in this study were recruited from healthy 3-12 years old pediatric patients attending the Pediatric Dentistry Clinic, Faculty of Dentistry, Chiang Mai University. All subjects had at least one primary molar with deep carious lesions diagnosed as normal pulp or reversible pulpitis according to AAPD guideline in 2010-2011[5].

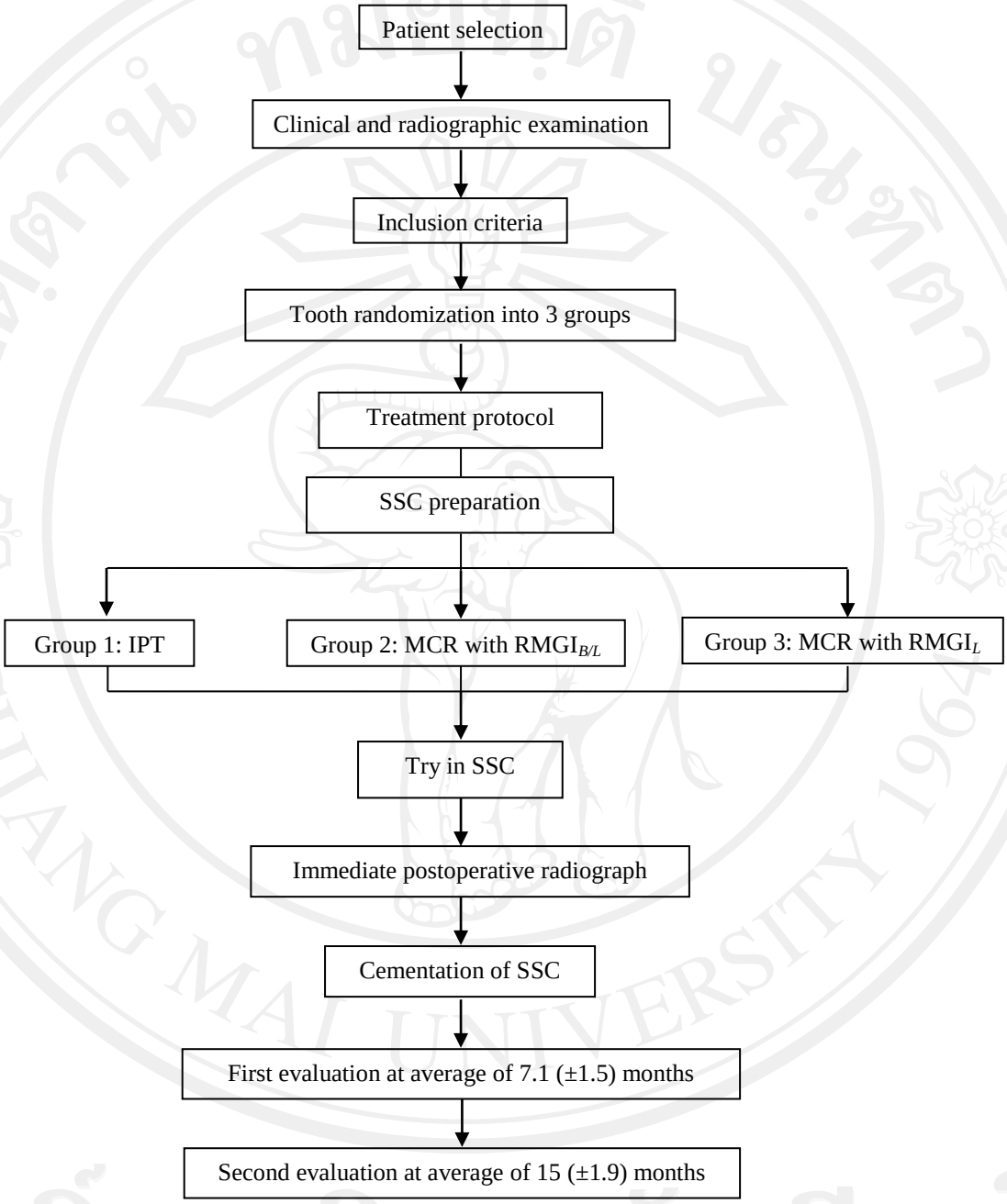

Figure 3.1 Flow chart of the experimental procedure

Note:

IPT: indirect pulp treatment

MCR with RMGI$_{B/L}$: minimal caries removal with both resin-modified glass ionomer base material and luting cement

MCR with RMGI$_{L}$: minimal caries removal with only resin-modified glass ionomer luting cement

SSC: stainless steel crown

All primary molars were clinically screened according to the inclusion and exclusion criteria as follows (Appendix B).

3.2.1.1 Clinical criteria

3.2.1.1.1 Clinical inclusion criteria

1. Healthy pediatric patients aged between 3-12 years old.
2. The legal guardians let the child participate in the study and signed the informed consent.
3. Deep dentin carious lesion involving occlusal and/or proximal surfaces of primary molars and a risk of pulp exposure if completely excavated.
4. Absence of clinical symptoms or presence of provoked pain only with existing stimulation such as complaints of impaction from food when eating and no sign of irreversible pulpitis such as spontaneous pain.
5. Absence of clinical swelling, pus exudates/ fistula of soft and periodontal tissues.
6. Absence of abnormal tooth mobility.
7. Absence of pain on percussion.
8. Immediately restorable with SSC.

3.2.1.1.2 Clinical exclusion criteria

1. Pediatric patients who had systemic disease.
2. The legal guardians did not allow the child to participate in the study.
3. Presence of clinical symptoms such as spontaneous pain, pain disturbing night sleep or prolonged pain after the disappearance of stimulation which showed sign of irreversible pulpitis or pulp necrosis.

4. Presence of clinical swelling, pus exudates/ fistula of soft and periodontal tissues.
5. Presence of abnormal tooth mobility.
6. Presence of pain on percussion.
7. Excessive tooth destruction that could not be restored with SSC.

Then, radiographic examinations were performed. Posterior bitewing radiographs were used to evaluate the depth of demineralized carious lesion. Parallel periapical radiographs were used to diagnose and exclude teeth with pathosis according to inclusion and exclusion criteria as follows (Appendix A, Figure 3.2.).

3.2.1.2 Radiographic criteria

3.2.1.2.1 Radiographic inclusion criteria

From a posterior bitewing radiograph,

1. The extension of the dental caries, radiolucency penetrated into three fourths or more of the entire dentin thickness with thin radiopaque dentin layer between radiolucent lesion and dental pulp[17, 47].
2. No superimposition of dental caries radiolucency on dental pulp.

From a periapical radiograph,

1. Absence of widening periodontal ligament (PDL) space.
2. Absence of radiolucencies at furcation area.
3. Absence of radiolucencies at periapical regions.
4. Absence of pathological internal and/or external root resorption.
5. Absence of calcification and/or pulp canal obliteration.

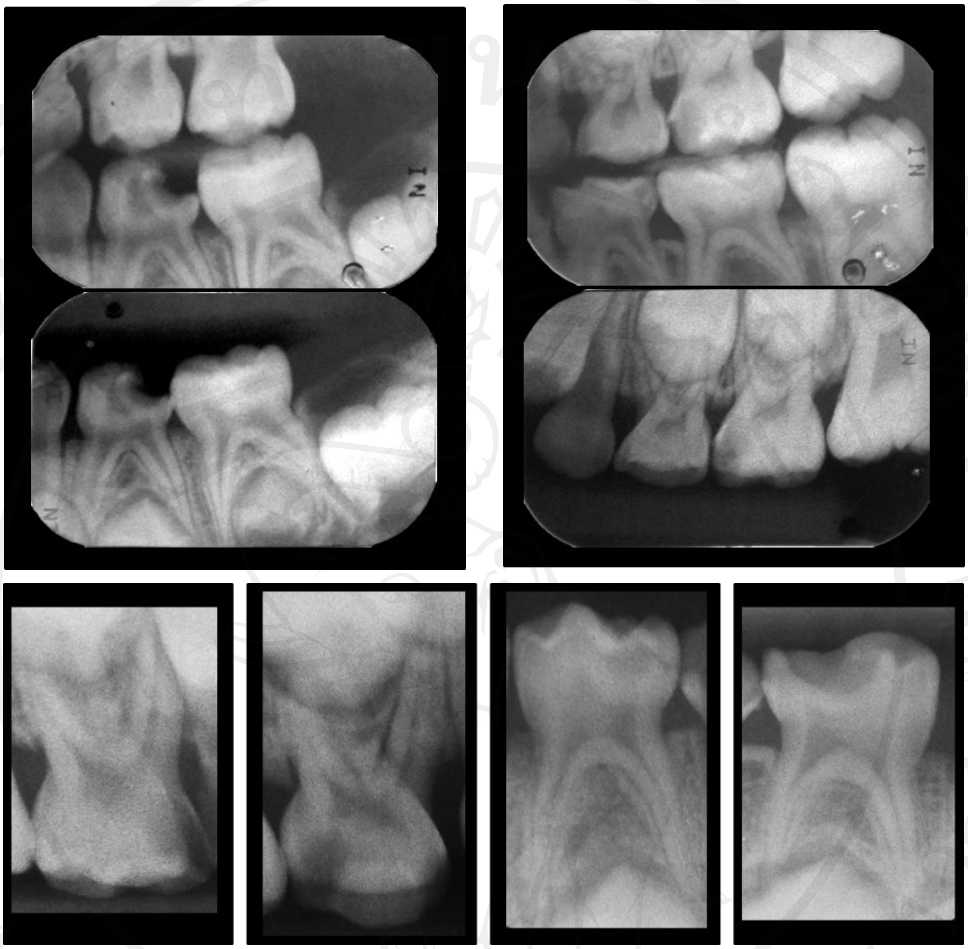

Figure 3.2 The selection of cases from radiograph. Included teeth had carious lesion radiolucency penetrated into three fourths or more of the entire dentin thickness with thin radiopaque dentin layer between radiolucent lesion and dental pulp.

3.2.1.2.2 Radiographic exclusion criteria

From a posterior bitewing radiograph,

1. The extension of the dental caries, radiolucency penetrated less than three-fourths of the entire dentin thickness.
2. No thin radiopaque dentin layer between lesion and dental pulp.
3. The radiolucent dental carious lesions superimposed on radiolucent dental pulp.

From a periapical radiograph,

1. Presence of widening PDL space.
2. Presence of radiolucencies at furcation area.
3. Presence of radiolucencies at periapical regions.
4. Presence of pathological internal and/or external root resorption.
5. Presence of calcification and/or pulp canal obliteration.
6. Poor SSC marginal coverage and adaptation.

3.2.2 Sample size

PS Power and Sample Size Calculation Program, Version (3.0.43)[75] was used for sample size estimation. Sample size was calculated based on previous studies reporting comparing the success rate of IPT (96.7%)[20], Ultraconservative treatment (87%)[70] and Hall technique (91%) [72]. The outcome difference required 960 sample sizes per intervention group, to detect a significant difference (80% power, two-sided 5% significance level). This large amount sample sizes could not be achieved in this limited time. From previous prospective clinical trials, most studies used 19-24 teeth per group[20-22]. The Central Limit Theorem (CLT) stated that the sampling distribution of any statistic will be normal or nearly normal if the sample size is around 30 ($n \geq 30$)[76, 77]. Therefore, 32 teeth in each group of this study has met this standard.

3.2.3 Random sampling

Each tooth was randomly allocated to one of the three techniques by an assistant casting a concealed lot out of a box containing 3×30 lots. The allocations to the

different techniques were not stratified by age. Then, all teeth were randomly assigned into 3 groups.

1. Group 1: IPT
2. Group 2: MCR with $RMGI_{B/L}$
3. Group 3: MCR with $RMGI_{L}$

3.2.4 Patient selection and examination

Following a clinical examination, a radiograph of each deep carious lesion was obtained under standardized conditions. Standardized periapical with parallel technique and posterior bitewings radiographs were taken by using a No. 0 Kodak InSight dental film (Insight®; Eastman Kodak company; New York; USA). To evaluate the depth of carious dentin, posterior bitewing radiographs were obtained by a bitewing tabs. To evaluate the furcation and periapical tissue, parallel periapical technique radiographs were obtained by a film holder (Snap-A-Ray, Dentsply RINN, USA). The patients wore lead aprons and lead thyroid collars in order to minimize patient's exposure to radiation. The Asahi Roentgen dental x-ray machine (Kyoto, Japan) operated at 60 kV, 10 mA, and a 0.26-second exposure time was used with the beam perpendicular to the tooth. All radiographs were examined using a standard viewing box.

If the subject had at least one primary molar that met the inclusion criteria, the study information was explained to the legal guardians. Then, the legal guardians were asked to decide whether to let the child participate in the study. If they agreed to participate, they were asked to sign the informed consent (Appendix C).

3.3 Treatment protocol

All teeth were treated by one postgraduate in pediatric dentistry. After assuring the clinical and radiographic examinations, a topical anesthesia was applied (One touch®; Hager Worldwide; Ontario, Canada). Then, a local anesthesia 2% lidocaine with 1:100,000 epinephrine (Medicaine inj®; Huons Co., Ltd.; Kyunggi-do, Korea) was administered and rubber dam isolation was placed. The first step was SSC preparation[48].

3.3.1 SSC preparation

3.3.1.1 Occlusal reduction

The depth of the cusps of the tooth was reduced and general contour of the occlusal surface was followed approximately 1.0 mm of clearance with the opposing teeth by using a football-shape diamond bur (Jota AG, Switzerland).

3.3.1.2 Proximal reduction

The proximal surfaces were reduced using thin taper diamond bur (Jota AG, Switzerland). Reductions on proximal surfaces were performed until the contact was broken and an explorer could be passed freely between the prepared tooth and the adjacent tooth in single sweeping motion. The gingival margin of the preparation on the proximal surface should be a smooth feather-edge finishing line. All line angles were rounded using thin taper diamond bur (Jota AG, Switzerland).

After SSC preparation in all teeth, soft demineralized dentin around lateral walls of cavity were removed with the depth of 1.0 mm by a low-speed round tungsten carbide burs 1mm in diameter (Jota AG, Switzerland) (Figure 3.3B). The cavity was

cleaned by water spray and dried with air syringe. Then, each tooth was randomly allocated to one of the three groups: IPT, MCR with $RMGI_{B/L}$ and MCR with $RMGI_{L}$

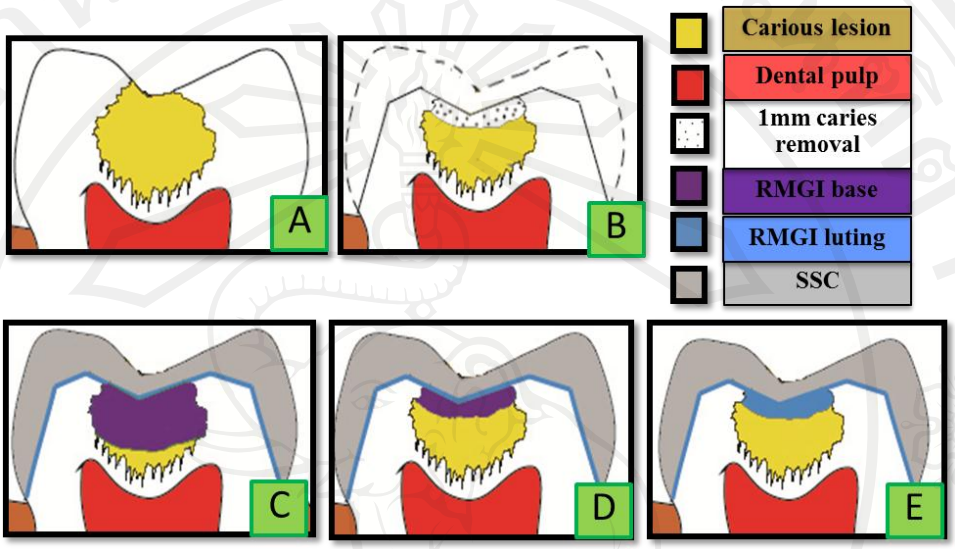

Figure 3.3 Diagrams showing 3 different incomplete caries removal techniques: (A) Deep carious lesion, (B) SSC preparation, (C) IPT, (D) MCR with $RMGI_{B/L}$ and (E) MCR with $RMGI_{L}$.

Group 1: IPT (Figure 3.3C and 3.4)

The additional demineralized dentin around lateral walls and superficial necrotic dentin of cavity were repeatedly removed until the remaining carious dentin was close to the pulp and if caries removal was continued would result in pulp exposure. The cavity was cleaned by water spray and dried with air syringe. The remaining caries and the rest of cavity were covered with RMGI base material (Vitrebond™; 3M ESPE; St. Paul, Minnesota, USA) which derived from mixing one scoop powder and one drop liquid (a powder-to-liquid-ratio of 1.4/1.0 by weight) together within 10-15 seconds. Then, the light cure (Dental curing light 2500, 3M, Minnesota, USA) was applied for 30 seconds.

Teeth were excluded from this study if accidental pulp exposures occurred or if the caries were unintentionally completely removed at the end of cavity preparation. If the excavation procedure led to pulp exposure, the teeth were treated with pulpotomy. If the caries were completely removed at the end of cavity preparation, the protective base was placed at the cavity floor and followed by SSC.

Group 2: MCR with RMGI$_{B/L}$ (Figure 3.3D and 3.5)

No additional caries removal was performed in this group. The remaining caries and the rest of cavity were covered with RMGI base material (Vitrebond™; 3M ESPE; St. Paul, Minnesota, USA) which derived from mixing one scoop powder and one drop liquid (a powder-to-liquid-ratio of 1.4/1.0 by weight) together within 10-15 seconds. Then, the light cure (Dental curing light 2500, 3M, Minnesota, USA) was applied for 30 seconds.

Group 3: MCR with RMGI$_{L}$ (Figure 3.3E and 3.6)

Neither the additional caries removal nor the placement of RMGI base material was performed in this group.

3.3.2 SSC restoration

All teeth were immediately restored with SSC restoration (3M ESPE, St. Paul, Minn). The correct size of SSC for tooth was selected and placed. Before SSC cementation, a parallel technique of periapical radiograph was taken to ensure the SSC's margin coverage and adaptation. The tooth and SSC were rinsed and dried. The SSC was cemented with RMGI luting cement (Rely X Luting Plus cement ®; 3M

ESPE; St. Paul, Minnesota, USA) which derived from fully depress clicker lever to dispense “2 click” of Rely X Luting Plus cement ® on to the mixing pad and hand-mixed for 20 seconds until paste had the same mousse-like consistency. In all teeth, immediately after the luting cement was mixed, the inner two thirds of SSC was filled with luting cement. Then, SSC was placed and seated over the tooth for a snap fit by finger pressure and then the child was instructed to bite down firmly. Excess cement was removed, and the child was asked to keep biting on SSC until the cement set in five minutes. Excess cement was removed from all areas of the margins.

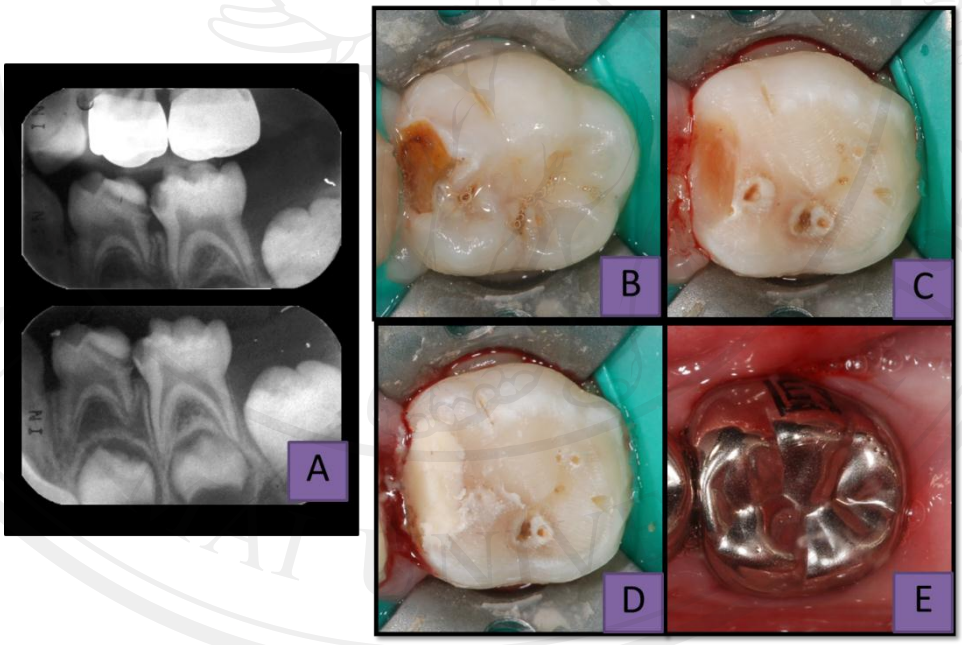

Figure 3.4 Radiographs and clinical photographs depicting the IPT group of mandibular left second primary molar: (A) Pre-operative radiographs, (B) Tooth with deep carious lesion prior to the treatment, (C) Tooth after SSC preparation and caries removal, (D) RMGI base material was placed over the remaining carious dentin, and (E) immediate SSC restoration.

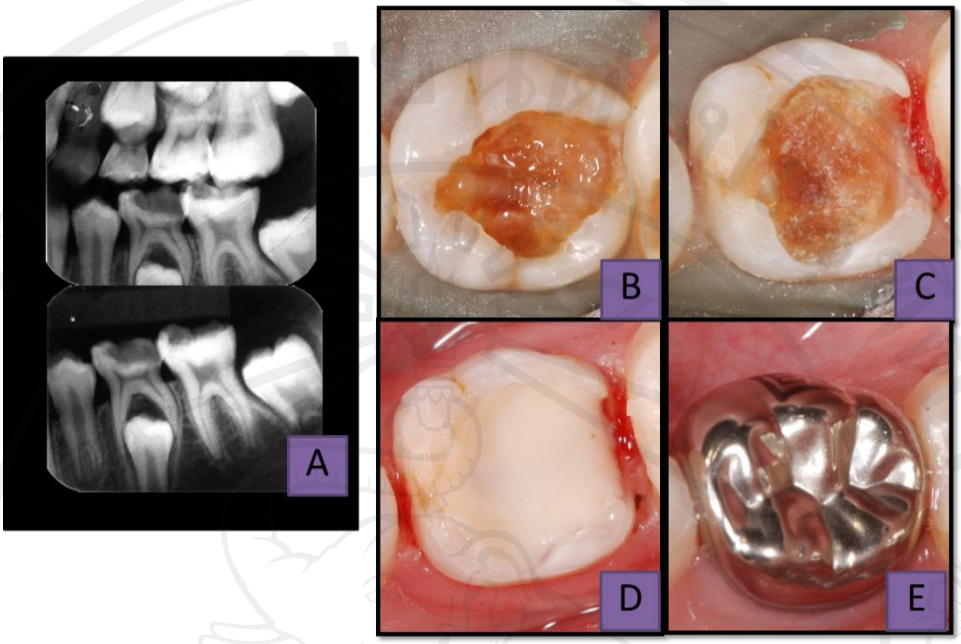

Figure 3.5 Radiographs and clinical photographs depicting the MCR with $RMGI_{B/L}$ group of mandibular left second primary molar: (A) Pre-operative radiographs, (B) Tooth with deep carious lesion prior to the treatment, (C) Tooth after SSC preparation and caries removal, (D) RMGI base material was placed over the remaining carious dentin, and (E) immediate SSC restoration.

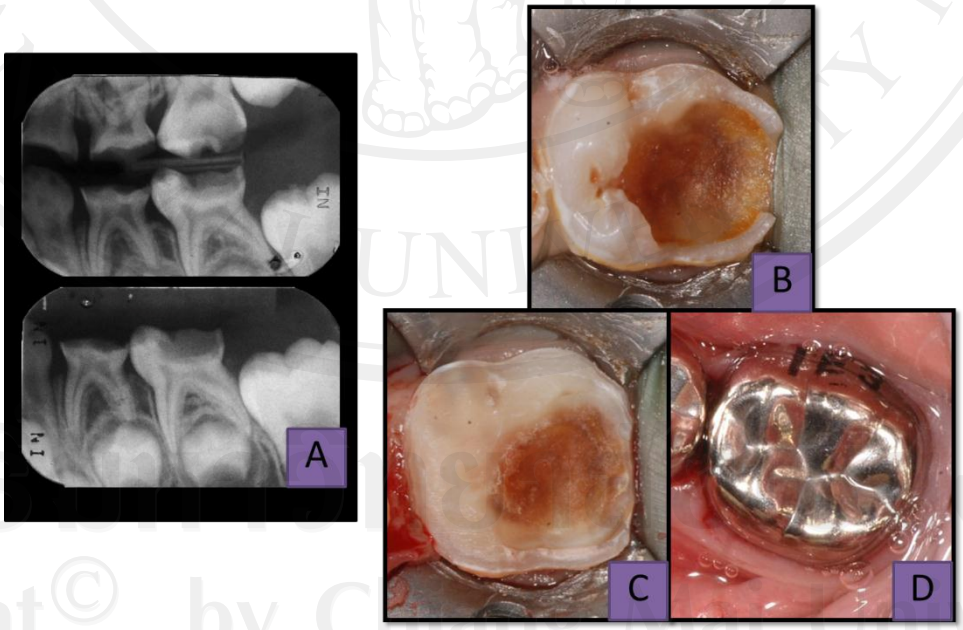

Figure 3.6 Radiographs and clinical photographs depicting the MCR with $RMGI_{L}$ group of mandibular left second primary molar: (A) Pre-operative radiographs, (B) Tooth with deep carious lesion prior to the treatment, (C) Tooth after SSC preparation and caries removal, and (D) immediate SSC restoration.

3.4 The first and second evaluation

All teeth received the clinical oral examination by one operator at the first and second evaluation (Appendix D).

The criteria used for determination of clinical successful outcome were:

1. Absence of postoperative pain.
2. Absence of swelling.
3. Absence of abscess formation.
4. Absence of a pathological mobility.
5. Absence of pain on percussion.
6. No defects of SSC restoration.

The parallel periapical technique radiograph was taken after clinical examination in all patients who came back for follow-up. Two blinded examiners (not the operator) performed the radiographic follow-up examinations. Follow-up radiographs were compared with the immediate postoperative radiographs using a radiographic view box with no magnification. The criteria used for determination of radiographic successful outcome were:

1. Absence of widening PDL.
2. Absence of periapical and/or furcation radiolucency.
3. Absence pathological internal and/or external root resorption that is not compatible with the expected resorption due to the exfoliation process.
4. Good SSC marginal coverage and adaptation.

3.5 Data analysis

The software SPSS (Statistic Package for the Social Science, Chicago, Ill) version 17.0 was used for statistical analysis as following:

- Descriptive statistics were used to describe and summarize the distribution of data obtained in this study by Chi-square test and One-Way ANOVA with 95% confidence level.
- Inference statistic was used to compare the success rates of each group by Chi-square test with 95% confidence level.
- Cohen's kappa statistic was calculated to test the inter- and intra-examiner reliability