

In Vitro and Clinical Outcome of Sandwich Restorations with a Bulk-Fill Flowable Composite Liner for Pulpotomized Primary Teeth

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Objective: The present study determined whether primary molar pulpotomies showed equal in vitro and clinical success when restored with sandwich restoration with a bulk-fill flowable composite (BFRBC) liner versus a stainless steel crown (SSC) restoration. **Study design:** Sixty extracted human primary second molars with proximo-occlusal cavities were selected for in vitro test. The specimens were randomly divided into three groups ($n = 20$) and restored with sandwich restoration with a BFRBC liner, composite (RBC) restoration and SSC. In addition, sixty teeth were selected from 20 children and each child had at least three primary molars (first and/or second primary molar) requiring pulpotomy. The patients were recalled for clinical and radiographic evaluation at approximately 6- and 12-month intervals. **Results:** The SSC restoration had significantly higher microleakage than the others. Although there was a significant difference between the RBC and the SSC ($P = 0.02$), the differences between the BFRBC and the RBC, as well as between the BFRBC and the SSC, were not statistically significant at the 12-month radiographic evaluation ($P = 0.33$ and $P = 0.11$, respectively). **Conclusion:** In laboratory conditions, sandwich restoration with BFRBC liner showed a superior seal margins of pulpotomized primary molars. Based clinical and radiographical evaluation, teeth treated with formocresol pulpotomy and restored with sandwich restoration with BFRBC liner were as successful as those restored with a SSC.

INTRODUCTION

Pulpotomy is considered the treatment of choice following vital, iatrogenic, carious, and traumatic pulp exposed primary molars due to its easy application and its rate of success.^{1,2} Numerous published studies have reported that the final restoration of the pulpotomized tooth is significantly associated with the success of the pulpotomy.³⁻⁹ One of the most important aspects of the final restoration and the subsequent success of pulpotomy is that it provides a biological seal to prevent bacterial infiltration of the remaining vital pulp tissue.⁹⁻¹¹

The stainless steel crown (SSC) is the “gold standard,” or restoration of choice, because it protects the tooth from fracture (full coronal coverage), minimizes the possibility of leakage, and ensures a biological seal.¹⁻⁹ However, increasing demands by

parents to provide esthetic restorations for children have made resin-based composites popular for the restoration of primary posterior teeth.^{9,12}

Despite innovative improvements during the years and excellent acceptance of methacrylate-based restorative dental materials, polymerization shrinkage stress remains a major problem with such materials. Several in vitro studies found a significant correlation between marginal adaptation of dental composite or microleakage and reduced shrinkage stress.¹³⁻¹⁵

Positive effects have been reported with the use of flowable composites as stress-absorbing intermediate layers.¹⁵ Flowable liners are considered to decrease sensitivity and to wet the cavity better than restorative composites due to their flowability. Thus, they exhibit better adaptation to the dentinal surface, with fewer voids at the interface of the restoration and the tooth structure when compared with bonding agent and resin composites alone.^{15,16}

Recent advances by manufacturers have resulted in the availability of bulk-fill flowable resin-based composite (BFRBC) bases for use beneath conventional resin-based composite (RBC) materials, with a reported depth of cure in excess of 4 mm.^{17,18} This would allow a 4 mm bulk placement in one layer due to reduced polymerization stress¹⁹ and a covering of a 2 mm layer of conventional RBC.²⁰ Recent trials to modify the dynamics of the polymerization reaction by incorporating a photoactive group in a BFRBC showed a 60–70% reduction in shrinkage stress when compared to conventional methacrylate-based resin composites.²¹

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To the best of our knowledge, there is no documentation regarding sandwich restoration with a BFRBC liner for pulpotomized primary molars. Even if the composite restoration leaks, the BFRBC liner would create a barrier to seal off the remaining vital pulp tissue from any bacterial invasion. For this reason, parents who insist on more esthetic restorations for their children's teeth that undergo pulpotomies could be told that the expectation for success with the treated teeth would be equal that of an esthetic restoration.

Therefore, the present study compared the microleakage of pulpotomized primary teeth restored with sandwich restoration with a BFRBC liner versus RBC restoration and SSC and determined whether primary molar pulpotomies showed equal clinical success when restored with the more esthetic sandwich restoration with a BFRBC liner versus a SSC restoration.

MATERIALS AND METHOD

The study protocol was approved by the Ethics Board of the Medical Faculty of Erciyes University, and all patients gave written informed consent to participate before study entry.

Evaluation of restorative margins in vitro

Sixty extracted human primary second molars with proximo-occlusal cavities indicated for extraction due to caries or orthodontic reasons were selected and stored in an aqueous solution of 0.5% chloramine T at 4°C for up to 30 days. Two surfaces of the proximo-occlusal cavities were prepared with a high-speed bur under water coolant, and the cervical margins were placed in the enamel. All the pulpotomy procedures were carried out using a conventional technique in which caries were completely removed. After the roof of the pulp chamber was removed, the pulp tissue was removed, 6 carbide round bur in a slow-speed handpiece completed the final convenience form of the pulp chamber exposing the canal orifices, and irrigation was performed with a normal saline solution. Reinforced zinc oxide eugenol (ZOE) paste (IRM, Densply, DeTrey, Konstanz, Germany) was mixed according to the manufacturer's recommendation in a 5:1 powder: liquid ratio until it had a "thick putty" consistency. It was applied to pulp chamber (approximately 2 mm thick) and allowed to set for approximately 2 minutes. The ZOE paste was not extended to the outer margin of the cavity. A glass ionomer cement (GIC) base (Aqua Meron, Voco, Cuxhaven, Germany) (approximately 1 mm thick) was placed over the ZOE base. The teeth were then randomly assigned to one of three final restorative treatment protocol groups.

The specimens were randomly divided into three groups ($n = 20$) and restored with sandwich restoration with a BFRBC liner and RBC restoration: Groups I and II were restored with Aelite LS Posterior (Bisco, Schamburg, IL, USA) with and without a BFRBC liner (SDR, Densply, DeTrey, Konstanz, Germany), respectively, and group III was restored with prefabricated SSC, cemented with GIC (Aqua Meron, Voco, Cuxhaven, Germany).

For group I and II, the cavities were rinsed with water, etched with 37.5% phosphoric acid etching gel (Kerr Gel Etchant, Kerr Co., Washington, USA) for 15 seconds, and rinsed with a water jet for 20 seconds. Excess water was removed with a cotton pellet. There was no pooling of water on the cavity, and slightly moist surfaces appeared shiny or glossy. An ethanol-based adhesive system (Clearfil SE Bond, Kuraray, Osaka, Japan) was applied to the cavity and solvent evaporation, with gentle air spraying for 3

seconds. The bonding agent was cured with a light-emitting diode unit (Valo, Ultradent, South Jordan, USA) for 20 seconds according to the manufacturer's instruction.

Group I (Sandwich restoration with the BFRBC liner): The first layer was filled with 4 mm of SDR flowable composite, followed by finishing with Aelite LS Posterior. The BFRBC and composite were light cured for 20 seconds.

Group II (composite resin restoration): Aelite LS Posterior was placed in incremental layers. Each layer was light cured for 20 seconds.

Water-cooled microfine diamond finishing burs (D+Z, Diamant GmbH, Lemgo, Germany) were used to contour and remove excess restorative material, and the restorations were polished with an aluminum oxide polisher (Finishing Discs, Bisco co., Schaumburg IL, USA) immediately after filling.

The teeth were stored in distilled water at 37°C and thermocycled for 1,500 cycles from 5° to 55°C, with a 30-second dwell time and a transfer time of 3 seconds. The root apices of the specimens were sealed with sticky wax. All the external surfaces were covered with two layers of nail varnish, except for 1.0 mm around the restorations, and then immersed in a 0.5% basic fuchsin dye solution for 24 hours. The specimens were rinsed in running water and then dried. The teeth were sectioned mesiodistally through the restoration with a low-speed diamond saw (D+Z, Diamant GmbH) under a water spray.

The depth of the dye penetration along the cavity wall was measured with a stereomicroscope (Nikon Eclips E600, Tokyo, Japan) at 20 × magnification. Two independent precalibrated investigators blindly scored the penetration (microleakage) of the dye along the tooth-restoration interface, and consensus was reached when disagreements occurred. The extent of the cervical microleakage was recorded²² where "0" was no evidence of dye penetration, "1" was superficial dye penetration, "2" was dye penetration along the gingival floor and up to the axial wall, "3" was dye penetration along the axial wall and across the pulpal floor, and "4" was dye penetration into the pulp chamber from the pulpal floor.

Clinical evaluation

Healthy and co-operative children for the study were selected from the patients attending the Outpatient Department of Pediatric Dentistry, Erciyes University, Kayseri, Turkey. All pulpotomy treatment took place by the same investigator.

Sixty teeth were selected from 20 children (12 boys and 8 girls) aged 5 to 7 years who had no medical condition that would contraindicate pulp therapy. Each child had at least three primary molars (first and/or second primary molar) with cariously exposed vital pulp and requiring pulpotomy. The clinical and radiographic criteria^{9,23} selected for the study are given in Table 1.

The primary molars were randomized into three groups for final restorations with the sandwich restoration with the BFRBC ($n = 20$), the RBC ($n = 20$), and the SSC ($n = 20$). Each molar was treated with formocresol pulpotomy. In each child, one molar was finished with sandwich restoration and the other molars with RBC restoration and SSC. The distribution of the treated teeth is shown in Table 2.

A conventional pulpotomy procedure was performed on the selected teeth. The tooth was anesthetized using local anesthesia. Dental caries and overhanging enamel were removed with a #330 high-speed bur with a water spray. The same bur was used to gain

Table 1. Inclusion criteria for the pulpotomy in primary teeth

Clinical	
1	Vital primary molars with previously been treatment planned for a pulpotomy
2	have involved at least 2 carious surfaces and can be restorable
3	No spontaneous or lingering provoked pain
4	Hemorrhage from the amputation site is bright red and easy to control
Radiographic	
1	No evidence internal or external root resorption
2	No evidence intraradicular or periapical bone loss
3	Absence widening of the periodontal ligament space
4	No more than one third physiological root resorption

Table 2. Distribution of primary teeth in to treatment and control period.

Treated primary molars (n=60)			
Maxillary		Mandibular	
First molar	Second molar	First molar	Second molar
18 (30.0%)	13 (21.6%)	12 (20.0%)	17 (28.3%)
6 and 12-month follow-up (n=54)			
First molar	Second molar	First molar	Second molar
16 (29.6%)	12 (22.2%)	12 (22.2%)	14 (25.9%)

access to the coronal pulp, and the entire roof of the pulp chamber was removed. A sharp discoid spoon excavator, large enough to extend across the entrance of the individual root canals, was used to amputate the coronal pulp. The pulp stumps were cleanly excised until the root canal orifices could be seen, with no tags remaining on the pulpal floor. Hemostasis was achieved at the amputation sites with water dampened cotton pellets. A cotton pellet moistened with a 1:5 concentration of formocresol was applied to the pulp chambers for 1 minute. The pellet was then removed and mixed with the reinforced ZOE paste and placed into the pulp chambers.

All the teeth in both groups were treated under rubber dam isolation. One calibrated curing light was used for all the restorations, and one standardized operator performed all the treatments in all the patients.

In the restoration groups (Group I and II), a GIC base (Aqua Meron) (approximately 1 mm thick) was placed over the ZOE base. The cavities were rinsed with water, etched with 37.5% phosphoric acid etching gel (Kerr Gel Etchant) for 15 seconds, and rinsed with a water jet for 20 seconds. Excess water was removed with a cotton pellet. An ethanol-based adhesive system (Clearfil SE Bond) was applied to the cavity and solvent evaporation, with gentle air spraying for 3 seconds. The bonding agent was cured with a light-emitting diode unit (Valo) for 20 seconds according to the manufacturer's instruction.

Group I (Sandwich restoration with the BFRBC liner): The first layer was filled with 4 mm of SDR flowable composite, followed by finishing with Aelite LS Posterior. The BFRBC and composite were light cured for 20 seconds.

Group II (Composite resin restoration): Aelite LS Posterior was placed in incremental layers. Each layer was light cured for 20 seconds

Water-cooled microfine diamond finishing burs (D+Z, Diamant GmbH, Lemgo, Germany) were used to contour and remove the

excess restorative material, and the restorations were polished with an aluminum oxide polisher (Finishing Discs) immediately after filling.

In the SSC group (Group III), at the time of the pulpotomy visit, all the teeth were restored with GIC (Aqua Meron, Voco, Germany). The final restoration with the SSC (Unitek, 3M-ESPE, MN, USA) was made within one week following the pulpotomy procedure.

The patients were recalled for clinical and radiographic evaluation at approximately 6- and 12-month intervals.

Clinical and Radiographic examination

The criteria used for the clinical evaluation included history of pain, tenderness to percussion, gingival abscess, sinus/fistula, and pathological mobility.

The radiographic examination included an evaluation of internal/external root resorption, periapical/furcal radiolucency, and pulp canal obliteration. The success of the treatment was graded using a modified scale based on that of Zurn and Seale:²⁴ 1 = no change; 2 = questionable change present, not pathological; 3 = pathological change present, observe; and 4 = pathological change present, extract. The teeth were considered to be radiographically successful in the absence of abnormal root resorption, internal root resorption, furcation involvement, and periapical bone destruction. Pulp canal obliteration and pulp calcification were not regarded as failures.²⁵

All pre- and postoperative digital radiographs were taken by two examiners at follow up who were blind to the group being studied.

A nonparametric one-way ANOVA (Kruskal–Wallis) test, followed by paired group comparisons using Mann–Whitney U tests, was conducted to statistically analyze the microleakage scores. The radiographic scores were compared for all the evaluated criteria using Pearson's chi-square analysis (SPSS 17.0, SPSS Inc, Chicago, IL., USA) for the 6- and 12-month follow-up periods.

RESULTS

In vitro evaluation

The microleakage scores obtained from the experimental groups are presented in Table 3. The Kruskal–Wallis analysis of variance revealed significant microleakage differences among the three groups ($P < 0.001$).

When comparing each group individually, the SSC restoration had significantly higher microleakage than the RBC restoration and the sandwich restoration with the BFRBC liner, but there was no significant difference between the restoration groups ($P = 0.26$). The microleakage scores of the experimental groups are presented in Table 3.

Table 3. The microleakage scores of sixty pulpotomy cavities restored with composite resin with and without BFRBC liner and SSC.

Groups	Degree of microleakage				
	0	1	2	3	4
BFRBC	8	9	2	1	0
RBC	6	7	4	3	0
SSC	1	4	6	6	3

BFRBC, Bulk-Fill Flowable Resin Based Composite; **RBC**, Resin Based Composite; **SSC**, Stainless Steel Crown

Radiographic and clinical evaluation

Fifty-four (90%) of the 60 restorations were evaluated at the 6- and 12-month recall. Two patients did not return for the examination. The number of restorations evaluated at each recall is presented in Table 2.

The radiographic scores of the experimental groups are presented in Table 4. At the 6-month radiographic evaluation, 17 teeth (94.4%) in the BFRBC group, 16 teeth (88.8%) in the RBC group, and 17 teeth (94.4%) in the SSC group demonstrated no radiographic changes (Score-1). One tooth (5.5%) in the BFRBC group, two teeth (11.1%) in the RBC group, and one tooth in the SSC group showed a slight change (Score-2), with furcal radiolucency, but all were still deemed successful outcomes. This resulted in 100% success in each group at the 6-month radiographic evaluation.

Table 4. Radiographic scores for three final restorations.

Radiographic scores	<i>BFRBC</i>		<i>RBC</i>		<i>SSC</i>	
	N (%)		N (%)		N (%)	
	6 m N=18	12 m N=18	6 m N=18	12 m N=18	6 m N=18	12 m N=18
1-no changes present	17 (94.4)	13 (72.2)	16 (88.8)	9 (50.0)	17 (94.4)	15 (83.3)
2- questionable/slight furcal and /or periapical radiolucency	1 (5.5)	3 (16.6)	2 (11.1)	4 (22.2)	1 (5.5)	2 (11.1)
3- pathological changes (e.g. periapical radiolucency , minor internal and/or external root rezoption) present, treat by observation only	0	2 (11.1)	0	5(27.7)	0	1 (5.5)
4-pathological changes present, treat by extraction	0	0	0	0	0	0

BFRBC, Bulk-Fill Flowable Resin Based Composite; **RBC**, Resin Based Composite; **SSC**, Stainless Steel Crown

At the 12-month radiographic evaluation, 13 teeth (72.2%), 9 teeth (50%), and 15 teeth (83.3%) in the BFRBC, RBC, and SSC, group, respectively, received the highest score (Score-1). Three teeth (16.6%) in the BFRBC group, four teeth (22.2%) in the RBC group, and one tooth (5.5%) in the SSC group showed a slight change (Score-2), with furcal radiolucency. However, two teeth (11.1%) in the BFRBC group, five teeth (27.7%) in the RBC group, and one tooth (5.5%) in the SSC group showed a pathological change (Score-3), with apparent furcal radiolucency. This resulted in 88.8% success in the BFRBC group, 77.2% success in the RBC group, and 94.5% success in the SSC group at the 12-month radiographic evaluation. Although there was a significant difference between the RBC and the SSC ($P = 0.02$), the differences between the BFRBC and the RBC, as well as between the BFRBC and the SSC, were not statistically significant level ($P = 0.33$ and $P = 0.11$, respectively).

Clinically, 100% success was observed in each group at the 6- and 12-month evaluation. No pain or symptoms of infection was reported by the parents or the children at any follow-up period.

DISCUSSION

Formocresol pulpotomy is still the most commonly used pulp therapy for primary teeth, despite its reported toxic, mutagenic, and carcinogenic properties. It is used by 92.4% of pediatric dentists and endodontists either in pure form or in a diluted solution.²³

SSC is the “gold standard” and most widely recommended type of final restoration for pulpotomized primary teeth; it protects the weakened cavity walls and prevents marginal microleakage.^{2,4,9,10,23} Nowadays, however, patients have a greater awareness of oral health and are much more conscious about esthetics and their social impact.⁹ A previous study revealed that the main concerns of parents in the U.S. regarding restorative materials for their children’s teeth relate to esthetics, with 57% expressing this as their primary consideration.²⁶ Additionally, when SSCs were to be used, 87% of parents demonstrated dissatisfaction. Another study suggested that about 70% of the pediatric dentists questioned felt some parental pressure to use tooth-colored materials and avoid placement of SSCs to restore Class II lesions.² To respond to such concerns, esthetic restorative materials and techniques are constantly being developed.²

Although efforts have been made to create more esthetic SSCs

for posterior teeth, the utilization of veneer SSCs for this purpose has not yet resulted in acceptable long-term outcomes. Issues include chipping of the surface revealing the metal underneath, as well as a visible metal line around the gingival margins.^{2,6,8,9} Several studies have also addressed the development of esthetic restorative options for pulp-tomized primary molars.^{7-9,27,28}

The *in vitro* findings in the present study show that a superior marginal seal can be obtained when a BFRBC liner, used as the base, is covered with a more wear-resistant conventional RBC after primary teeth pulp-tomy. Interestingly, SSCs had the highest marginal leakage score under laboratory conditions in this study. Roggendorf *et al.*¹³ evaluated the *in vitro* marginal integrity of bonded posterior RBC with and without a BFRBC base. They suggested that BFRBC showed good performance with the sandwich technique in cavities deeper than 6 mm in permanent teeth. Ilie *et al.*²¹ analyzed the shrinkage behavior of BFRBCs compared with nano- and microhybrid composite resins for dental restorations and found that BFRBC showed the lowest shrinkage stress. In contrast, Moorthy *et al.*¹⁸ evaluated cervical microleakage of standardized Class II cavities that were incrementally filled with either a composite resin or BFRBC bases and found no associated change in the cervical microleakage in the BFRBC groups.

Several studies have investigated esthetic restorative options for final restoration of pulp-tomized primary teeth.^{27,28} El Kalla and Garcia-Godoy²⁷ restored pulp-tomized molars with amalgam, compomer, and hybrid composites using different bonding agents, showing that bonded restorations of pulp-tomized primary molars could be an alternative restorative option to SSCs in laboratory conditions. Guelmann *et al.*²⁸ assessed *in vitro* microleakage of various restorative materials in two-surface preparations after pulp-tomy and found significantly better results in resin-based restorations when compared to SSCs.

The surprising inferior *in vitro* performance of SSCs demonstrated in the present study, as well as in previous reports, may be explained by several factors related to luting agents for SSCs and to differences between oral and laboratory conditions. Regarding the former, although none of the luting cements sealed SSC margins completely, they do play an important role in obtaining a suitable marginal seal and reducing microleakage through the crown margins.²⁹ Several studies have reported that conventional GIC significantly increased microleakage when compared with a resin-modified glass ionomer and adhesive resin cement tested with SSCs. Here, the aim was not to assess or compare the effect of different cement materials on the microleakage of SSCs, as this has been examined by numerous previous studies.²⁹⁻³² Therefore, in the present investigation, all the subjects were luted with conventional GIC as an acceptable and most widely used luting agent for cementing SSCs.³³

Regarding the differences in conditions, all of the present results should be evaluated in light of the fact that *in vitro* microleakage assessments present more dye penetration than those carried out in the oral cavity. This is due to the smaller dimensions of dye molecules compared to those of oral bacteria and their by-products, which hinders the diffusion of dye molecules *in vivo*.³³ Equally, the gingival edge around the crown margin creates a barrier for liquid and bacterial penetration, while protein and debris accumulation in the marginal area of the crowns may calcify, improving the restoration

seal in the oral cavity. Thus, intraoral leakage in SSCs will be less than that observed in laboratory conditions.³³⁻³⁶ Therefore, although the results of laboratory analyses have clinical significance, they do not provide complete scientific proof and clinical trials remain the benchmark for performance evaluation of dental materials.¹³ Thus, in the present study, the marginal integrity of the BFRBC layer was evaluated under both *in vivo* and *in vitro* conditions.

This is the first study to systematically evaluate the relationship between laboratory data on marginal leakage and clinical outcomes with the sandwich technique with a BFRBC liner in the final restoration of pulp-tomized primary molar teeth. Here, at the 6- and 12-month evaluation, none of the primary molars in any of the groups showed any clinical signs or symptoms. In addition, at the 12-month radiographic evaluation, the BFRBC, RBC, and SSC groups demonstrated a success rate of 88.8%, 77.2%, and 94.5%, respectively. The present clinical study, which was supported by *in vitro* findings, demonstrated that it is possible to achieve successful restoration with a simplified application procedure using a 4-mm base layer as an open sandwich; this approach is possible in pulp-tomized primary teeth.

A comparison of data from previous clinical trials of post-pulp-tomy coronal restorations shows that different restorative materials have been used after pulp-tomy.^{5,37} Zulfikaroglu *et al.*³⁷ used resin-based materials (compomers and hybrid resin) to restore 75 pulp-tomized primary molars with Class II preparations. At one-year follow-up, they found that the hybrid composite and the compomer demonstrated success rates of 93% and 73%, respectively. Other studies have suggested that these types of restorations cannot be considered as suitable alternative solutions to SSCs until a base material that can block or minimize coronal leakage is developed.^{5,37}

Mineral trioxide aggregate (MTA) is a relatively new material that has been shown, through randomized controlled trials, to have high success rates as a pulp-tomy agent due to its biocompatibility and ability to form a biological seal over amputation sites.⁹ However, despite its good physical and biological properties, MTA does have some disadvantages, including its high cost, and thus it has limited value in routine pediatric dentistry especially in developing countries such as Turkey. In addition, MTA may not be suitable for re-entry into the canal and may not be suitable in teeth with pulp canal obliteration in cases indicated for further pulp therapy. Moreover, treating primary molars with white MTA in pulp-tomy has resulted in gray discoloration in the vast majority of cases, which is problematic for esthetic reasons. Finally, MTA has a long setting time.^{9,23}

SSC is recommended due to its proven efficacy and cost effectiveness. However, the exploration of preventive and alternative restorations of equal or higher quality that are more acceptable to children, their parents, and clinicians is still underway. Based on the clinical and *in vitro* evaluation presented here, the sandwich restoration with a BFRBC liner can be said to minimize coronal microleakage. Therefore, the use of BFRBC in resin-based composite restoration appears to be a successful component in the final restoration of primary molars. Further long-term investigations of BFRBC can add to our understanding of the efficacy and success of liner materials in dental composite restorations of pulp-tomized primary teeth.

CONCLUSIONS

Based on the results presented herein, it can be concluded that, in laboratory conditions and among the materials used to restore pulpotomized primary molars, the sandwich restoration with BFRBC liner provides superior seal margins for pulpotomized primary molars. According to clinical and radiographical evaluation, the treatment of teeth with formocresol pulpotomy and the sandwich restoration with BFRBC liner was as successful as restoration with a SSC.

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