

# Resorbable Collagen Barrier Impeding the Extrusion of Obturating Material in Primary Molars Undergoing Resorption – A Randomized Clinical Trial

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**Objective:** To evaluate the effectiveness of placing a resorbable collagen barrier in impeding the extrusion of obturation material in primary molars undergoing resorption. **Study design:** All the 94 canals in 47 mandibular molars were allocated to 2 groups- Group 'A'- 47 canals with collagen barrier (Test group) and Group 'B'- 47 canals without collagen barrier (Control group) based on randomization protocol. Pulpectomy was performed and obturation of both test and control canals were radiographically assessed. Pearson's chi – square test was applied to analyze the results. The significance level was predetermined at  $p < 0.05$ . **Results:** Among the test group, 93.6% of the canals showed no extrusion while, 6.4% showed visible extrusion of the material outside the apex. In the control group, 83% showed no extrusion whereas 17% of the canals showed visible extrusion outside the apex. But no significant difference was noted ( $p > 0.05$ ). **Conclusion:** The placement of resorbable collagen barrier in the apical third of the canal prevented the extrusion of obturating material beyond the apex in resorbing primary molars.

**Keywords:** Apical barrier, Collagen plug, Primary molars, Pulpectomy, Resorption,

## INTRODUCTION

The major goal of a pediatric dentist is to maintain the integrity of primary dentition until normal exfoliation.<sup>1</sup> The assessment of accurate morphology of root canal system determines affluent root canal management in deciduous molars. The physiologic resorption of primary teeth, which initiates shortly after the root development, modifies the anatomy of root canal.<sup>2,3</sup> Also, pathological process due to pulp and/or periodontal inflammation hastens the root resorption.<sup>4,5</sup> The most viable treatment option to avoid premature loss of deciduous teeth is pulpectomy. Retention of primary dentition aids to maintain the arch length, preserve occlusal function and provide eruption guidance for the permanent teeth.<sup>6</sup>

In primary teeth undergoing resorption, complete debridement of canal space and achieving an apical seal is an arduous task. Despite of myriads of obturation materials and techniques used, overfilling/ over extrusion of obturating material is a common outcome in the deciduous teeth which may pave way to deleterious effects on the underlying permanent dental follicle. Application of resorbable apical biological barrier in the form of collagen is a well-practiced strategy for apexification procedure.<sup>7</sup> Also it has been widely used as a pulp dressing material following pulpotomy in primary teeth.<sup>8</sup> These materials act as an interface between restorative materials and biological tissues. During the evolving year's, much progress has been made in expanding the scope of collagen in soft tissue engineering and repair.<sup>9-12</sup>

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Johnson *et al*<sup>13</sup> did an *in vitro* study to prevent extrusion of obturating material beyond apex by placing resorbable collagen barrier at apical one third of the root canal and found that not completely but it significantly plummeted the possibility for over obturation in resorbing primary molars. To the best of our knowledge, the literature lacks sufficient evidence regarding the efficacy of placing an apical barrier in resorbing primary teeth. This randomized clinical trial was undertaken to find out whether positioning of a resorbable barrier of collagen have any significant effect in impeding the extrusion of obturating material in primary molars undergoing resorption.

## MATERIALS AND METHOD

The institutional ethics committee received the study protocol and gave its approval vide Ref. No: TMDCRC/IEC/18-19/PPD1 dated 22/1/2019. A total of 60 child patients were screened at Department of Pedodontics and Preventive Dentistry, and 47 children who gratified the inclusion criteria demanding pulpectomy procedure in 47 primary mandibular molar teeth were included in this study. It was a randomized clinical trial in which 94 canals in 47 primary molars were equally allocated to Group A and Group B, based on randomization protocol and all the procedures were performed and evaluated by a single operator (N.M.S). Calculation of sample size was done following power analysis which was 80% for this study. After parent's consent, pulpally involved mandibular primary molars with at least two third of root length in children aged 7-9 yrs<sup>14</sup> with behavior rating of Frankel's Class 3 or 4 without any systemic disease were included in the study.<sup>15,16</sup> However, perforation of pulpal floor due to resorption, extreme tooth mobility, dentition with congenitally missing permanent tooth bud, radiographic sign of any internal or external resorption and radiolucencies in radicular area were excluded from the study.

One mesial and one distal canal of each selected tooth were randomly assigned to test or control group by using flip coin method by the parent. After that local anesthesia was administered, rubber dam isolation was done followed by entry into the pulp chamber by means of a high speed sterile round bur sequenced by pulp extirpation and copious irrigation with 3% sodium hypochlorite and normal saline. The location and number of root canals were recorded using a double ended endodontic explorer. After pulp extirpation, each canal's working length was radiographically determined by using No. 15 k file of 21 mm length. In order to accommodate 2mm of apical barrier, the final instrumented length of test canal was kept 2mm minus radiographic apex. To maintain standardization, the final working length of control canal was also kept 2mm short of radiographic apex.<sup>13</sup> After thorough debridement and canal preparation with hand protaper files (SX till F2) the canals were dried to receive obturation.

A silicone stop cone was placed on an endodontic plugger and set to final working length. A 2mm square piece of resorbable collagen (Coloplug, Cologenesis Healthcare Pvt Ltd, Tamilnadu, India) (Figure-1) was placed into the test canal and condensed till the final instrumented length (2mm short of the radiographic apex) using the same endodontic plugger. The selected canals (test and control) were then obturated by a pre-packed syringe delivery system containing a mixture of calcium hydroxide and iodoform paste (Metapex, Meta Biomed Co Ltd, Chuncheonbuk-Do, South Korea). The tip was positioned into the canal and the paste was

pushed gradually withdrawing the syringe till the obturation material streamed back into the pulp chamber. With the help of a moist cotton pellet, material was lightly pushed into the canal. All the remaining canals were obturated in the similar way.

After obturation of all the canals, a postoperative radiograph was obtained using radiovisiography (RVG)(Kodak Carestream RVG 5200, Health, Inc, NY, USA) (Figure- 2). Additional radiograph was done only in cases of superimposition. This was followed by glass ionomer cement restoration and placement of a stainless steel crown. The pre and post-operative digital radiographs for the presence of overfilling of the obturation material were assessed by the same operator. The canal showing optimal filling or the canal with 1 to 2 mm short of apex was considered as "acceptable" i.e. No Extrusion (NE). In case of extravasation of material into the periapex, it was considered as over filled i.e. Extruded (E) beyond apex.

The data for the existing study was moved in to Microsoft Excel 2007 and evaluated by means of Statistical Package for Social Sciences Software (SPSS, IBM Corporation, USA) version '23.0' to evaluate the difference of overfilling in canals with barrier and without barrier. The inter group comparison was done using paired Chi Square test to discover the dissimilarity among the individual groups. The level of the significance for the present study was pre-determined at  $p \leq 0.05$ .

## RESULTS

The mean age of the child participants in this study was  $7.7 \pm 0.832$  years among boys and  $7.47 \pm 0.624$  years among the girls. A total of 30 boys and 17 girls received the treatment. Among the test group, 93.6 % canals showed no extrusion of material beyond the apex, while 6.4 % showed visible extrusion of the material beyond the apex. In the control group, 83.0% showed no extrusion of material beyond the apex whereas 17 % of the canals showed visible extrusion beyond the apex (Figure- 3). The difference among the test and control groups was statistically not significant when analyzed using the Chi Square test at  $p > 0.05$  (Table 1 and Graph 1).

**Table 1. Shows intergroup comparison between the test and control group.**

	No Extrusion of Obturating Material beyond apex N(%)	Extrusion of Obturating Material beyond apex N(%)	Total	Value	df	p value
<b>Test Group</b>	44 (93.6%)	3 (6.4%)	47 (100%)	2.574	1	0.109 (N.S)
<b>Control Group</b>	39 (83.0%)	8 (17.0%)	47 (100%)	2.860	1	0.103 (N.S)

\*df- degree of freedom, N- Number, N.S- Not Significant

Figure 1: Colo Plug (Resorbable Collagen Sponge)

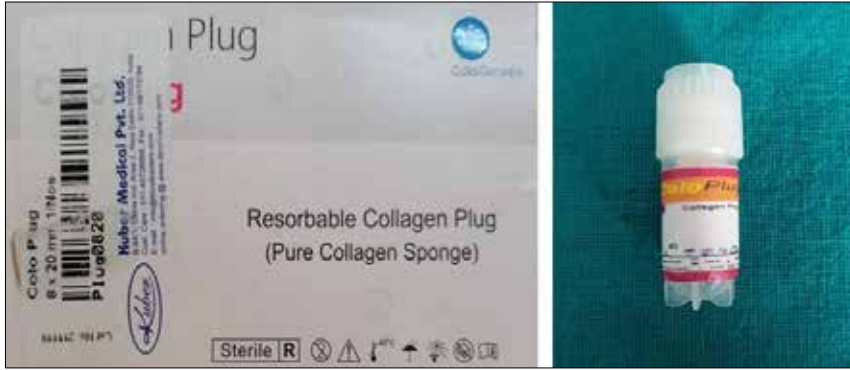


Figure 2A: Pre-operative radiograph of 75



Figure 2B: Post obturation radiograph of 75 delineating the outcome in test canal (T) and control canal (C) respectively

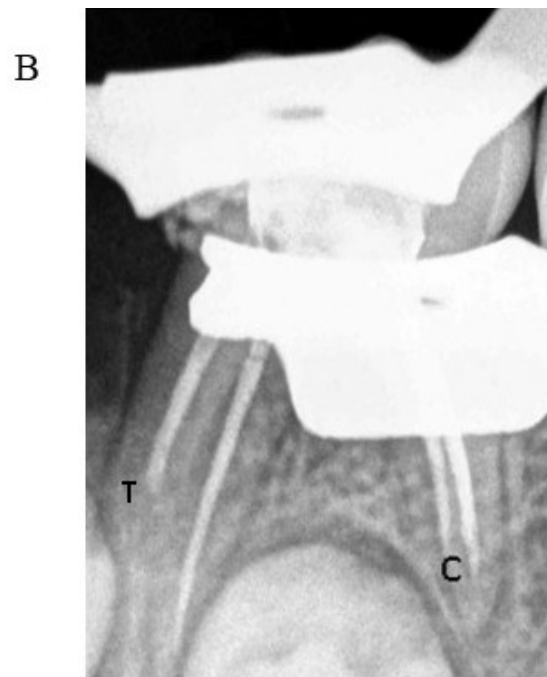
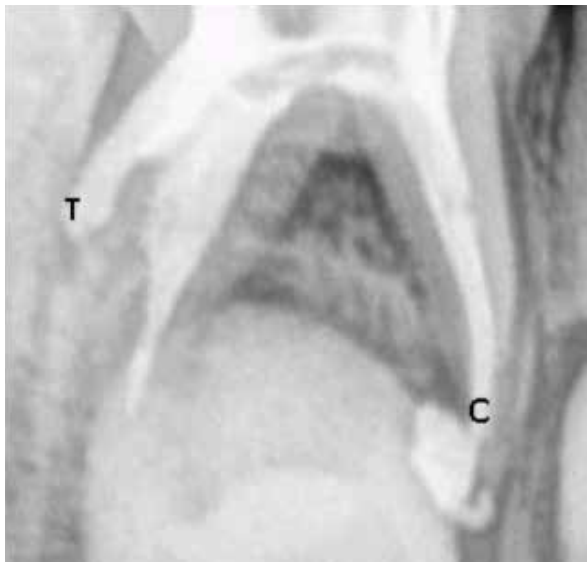
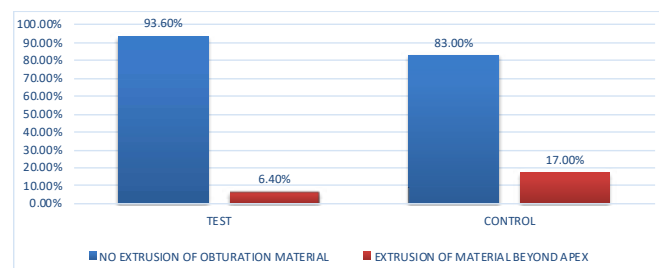


Figure 3: Post obturation radiograph of 85 showing extrusion of obturating material in control canal (C)



Graph 1. Graphical representation showing intergroup comparison between the groups.



## DISCUSSION

Pulpectomy is the most quotidian treatment to retain the primary teeth. However, it faces the limitation of apical extrusion of the obturating material, which may have harmful influence on the succedaneous tooth germ.<sup>17</sup> The idyllic technique of obturation should deliver a good apical seal without any under filling or over filling.<sup>18</sup> Bawazir *et al*<sup>19</sup> reported no significant difference statistically on evaluating 2 techniques of obturation (lentulosiral mounted in slow speed hand piece and hand held lentulo spiral) in primary dentition. Walia *et al*<sup>20</sup> proclaimed that some limitations (voids and filling quality) are present in all delivery methods for the obturation. Syringe method showed frequent over filling, while superior fillings were observed with lentulo spiral. With these studies it was confirmed that regardless of the obturation technique employed in the canals, overfilling could not be prevented.<sup>19,20</sup>

Zinc oxide eugenol has been the material of choice for obturation of primary teeth. It possesses the quality of ease of handling, operator friendly and cost effectiveness. Nevertheless, it has been disapproved by many authors due to its harmful effects on permanent tooth bud.<sup>21</sup> Garcia *et al*<sup>22</sup> reported that various concentration of eugenol (0.06 to 810  $\mu$ M) created great toxicity in human dental pulp fibroblast of primary teeth. Owing to above mentioned limitations of ZOE, iodoform based materials are slowly replacing ZOE as obturating material.<sup>23</sup> However, inadequate handling properties and viscosity of iodoform based materials result in extrusion beyond the apex. The commercially available pastes with thick and inflexible plastic tips may cause improper or overflow in the narrow apical third of pulp canals. To attain optimum obturation, clinician ends up putting additional pressure on the syringe, which results in excess of filling.<sup>24</sup> Moskovitz *et al*<sup>25</sup> reported 76.3% overfill cases of which 21.1% on follow up showed failure. Coll *et al*<sup>21</sup> reported that under filled or optimum obturation proven to be more successful than overfill obturation, which leads to failure of treatment.

Ozalp *et al*<sup>26</sup> reported that there is no ideal obturation material, iodoform based root canal materials like Vitapex, Endoflas and KRI paste could be used successfully in pulpectomies. In contrast, Petel *et al*<sup>27</sup> affirmed that exposure of iodoform containing filling material done directly or indirectly to high concentrations showed cytotoxic effect on epithelial cells and also on macrophages, whereas low concentrations induced cell proliferation. The results of these research work prove the prevention of extrusion of obturating materials beyond apex in resorbing molars. The theory of using collagen as apical barrier to encourage healing in term of pulp exposure is not unique. Vanka *et al*<sup>28</sup> reported that using an internal matrix of absorbable collagen before placement of MTA gave good results in apexification. Also, the placement of MTA became more predictable with controlled condensation and reduced frequency of appointments.

In the present study, resorbable collagen barrier was used as apical barrier in primary resorbing molars. It is made of type 1 collagen which is derived from Achilles tendon. It absorbs fluids and blood at defect area, its fibers have intrinsic hemostatic properties and resorbs in 10 to 12 days.<sup>29</sup> According to Coll *et al*,<sup>21</sup> prognosis of complete pulpectomy was related to the extent of pre-operative root resorption. The teeth with prior root resorption resulted in pulpectomies with over filled canals, which was considerably lower in teeth without any pre-operative root resorption.

All the primary mandibular molars involved in the study were treated with pulpectomy. Hand protaper technique was used owing to the better control, cost effectiveness and limited cooperative ability of children. The size of collagen selected was measured with help of metallic scale, and was placed into the canal with the help of endodontic plugger. The obturating material used was metapex due to its resorbable properties, ease of handling and antibacterial properties.<sup>24</sup> Ozalp *et al*<sup>26</sup> showed iodoform based material as an ideal material when compared with other obturating materials. In our study, immediately after pulpectomy procedure, obturation was analyzed radiographically by the operator. In this study, canals with 1 to 2 mm short of apex were considered as acceptable.<sup>13</sup>

The mean age among the male subjects was  $7.7 \pm 0.832$  years and mean age among the females was  $7.47 \pm 0.624$  years. The age group (7 to 9 years) was selected based on chronology of eruption, maturation and shedding. This age also known as late primary dentition age where primary teeth resorbs and exfoliates and permanent teeth start erupting.<sup>14</sup> Primary mandibular molars were chosen for the study owing to their early carious involvement and high caries incidence. At 7 years, first primary lower molars start resorbing and the location of premolars in the middle of primary molars favors the root resorption.<sup>30</sup> The results of the present study revealed that 93.6% of test group canals exhibited no extrusion of material beyond the apex, while in the control group 83.0% of canals showed no extrusion of material beyond the apex. Overfilling was observed in 6.4 % of test canals i.e. with barrier and 17.0% of control canals i.e. without collagen barrier. The variance admits the groups were statistically not-significant when evaluated using the Chi Square test at  $p \leq 0.05$ . Findings were within the range of other clinical studies.<sup>13,21,24</sup>

The outcomes of the current study are in harmony with the earlier studies reported by Johnson *et al*<sup>13</sup> and Kakade *et al*<sup>24</sup> where the use of resorbable collagen barrier prevented extrusion of obturating material beyond the root apices. As per the best knowledge of literature available and screened, there is no in vivo study in the literature that had assessed the impact of placing resorbable collagen barrier in the apical one third of primary molar undergoing resorption. This study is first of its kind where the impact of placing resorbable barrier at apical one third was determined. In the current study, canals of same tooth were obturated as test and control canals, so that the direct comparison in both the canals could be done.

Failure in this study could be due to limited tactile sensitivity of endodontic plugger which may end up penetrating the collagen plug, leading to flow of material beyond apex from the space created by plugger or sometimes bypassing the barrier causing voids in the obturation. Further, resorption is three-dimensional-physiological phenomena, while we can only obtain two dimensional image in RVG which sometimes leads to misinterpretation of extent of resorption. Collagen being completely radiolucent and there is no guide regarding the correct termination of collagen plug within the confines of the root canal radiographically. Additionally, inability to match the exact size of collagen plug to that of resorbed apical third of canal can cause imperfect obturation. In spite of the mentioned limitations, results of this study were promising. This randomized control trial introduced a unique concept to improve the result of pulpectomies in primary teeth.

## CONCLUSIONS

In the present study, extrusion of obturation material beyond apex was 6.4% in test canals while 17% in control canals. Although the comparison was statistically not significant, placing a resorbable barrier proved to be more successful in preventing extrusion of obturating material in resorbing primary molars. Future studies can involve advance radiological techniques like computed tomography scan, cone-beam computed tomography etc. for the exact evaluation of the extent and level of resorption. Also, other radiopaque resorbable materials may be used as apical barrier to prevent extrusion of obturating material. The concept of placing a resorbable barrier at apical third of canals should be considered while performing pulpectomies in resorbing primary molars.

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