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Assessing the Effect of Two Endodontic Spacers on the Microflora Within the Root Canal of Primary Molars - An Interventional Study

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ABSTRACT

Background

Early childhood caries often progresses to pulpal involvement in primary teeth, requiring pulpectomy. In multi-visit procedures, prevention of inter-appointment microbial contamination is crucial to reduce postoperative symptoms such as pain, tenderness, and swelling. Endodontic spacers help maintain canal sterility; however, conventional cotton pellets may compromise the coronal seal. Polytetrafluoroethylene (PTFE) tape has been suggested as an alternative with improved sealing ability.

Aim

To evaluate and compare the effect of cotton pellet and PTFE tape as endodontic spacers on clinical signs, symptoms, and microbial contamination in primary molars undergoing pulpectomy.

Materials and Methods

This interventional study included 40 children aged 3–7 years requiring pulpectomy in primary mandibular molars. Participants were randomly divided into two groups: cotton pellet (n=20) and PTFE tape (n=20). Microbiological samples were collected at baseline and after 7 days using sterile paper points, and colony-

forming units per millilitre (CFU/mL) were measured. Clinical evaluation at the second visit included pain, tenderness on percussion, swelling, and sinus tract formation. Statistical significance was set at $p < 0.05$.

Results

Pain was reported in 50% of the cotton group and 20% of the PTFE group, without statistical significance ($p = 0.097$). Tenderness on percussion was significantly higher in the cotton group (65%) compared to the PTFE group (10%) ($p < 0.001$). Swelling was observed in 10% of the cotton group and none in the PTFE group ($p = 0.487$). No sinus tract was noted in either group. The PTFE group showed significantly lower CFU counts at 7 days ($p < 0.001$).

Conclusion

PTFE tape showed superior performance, particularly in reducing tenderness and microbial contamination, supporting its use as an effective alternative endodontic spacer

Keywords

Endodontic spacer, polytetrafluoroethylene (PTFE) tape, cotton pellet, primary teeth, tenderness, pulpectomy

INTRODUCTION

Early childhood caries (ECC) is a major global public health problem and one of the most prevalent chronic diseases affecting young children. It often leads to premature loss of primary teeth, resulting in loss of arch space, malocclusion, difficulties in mastication and speech, and adverse psychosocial effects that can impact a child's growth and quality of life. ECC is frequently associated with pain, infection, and potential damage to developing permanent teeth. Children with premature loss of primary teeth are more likely to experience space loss and require early orthodontic intervention. Additionally, ECC increases the risk of future caries in both primary and permanent dentitions, making it a lifelong concern.[1,2,3]

The prevalence of dental caries in preschool children remains high worldwide, ranging from 41.6% to over 70% in countries such as China, Turkey, and India.[4] In India and other low- and middle-income countries, ECC is often untreated, leading to significant morbidity and reduced quality of life.[5] Despite occasional systemic influences, dental caries remains the primary cause of early tooth loss.

Dental caries is a biofilm-mediated, multifactorial disease characterized by cycles of demineralization and remineralization. It results from the interaction of cariogenic microorganisms, dietary carbohydrates, host factors such as saliva and tooth structure, and environmental influences.[6] Frequent sugar intake, poor oral hygiene, low socioeconomic status, and inadequate fluoride exposure are major risk factors.[7] Increased levels of mutans streptococci and lactobacilli contribute to acid production, leading to enamel demineralization and cavitation.[8]

Primary teeth are highly susceptible to rapid caries progression due to thinner enamel and dentin, larger pulp chambers, and lower mineral content. These features facilitate early pulpal involvement and infection.[6] As the disease progresses, the microbial environment becomes more complex, with diverse biofilm-associated microorganisms present in dentin, pulp, and root canals.[9] Common pathogens include Streptococcus species, Enterococcus faecalis, Pepto streptococcus species, and anaerobes such as Fusobacterium nucleatum.[10] These organisms, along with biofilm formation, contribute to persistent infections and resistance to antimicrobial measures.[11]

Viral components such as Herpesviridae have also been detected, though their role remains unclear.[12]

Pulpectomy is indicated for primary teeth with irreversible pulpitis or necrosis when tooth preservation is essential. It involves removal of infected pulp, disinfection of canals, and obturation with a resorbable material.[13] While single-visit procedures are preferred, multi-visit pulpectomy is required in cases of severe infection or when intracanal medicaments are used.[14]

The complex anatomy of primary teeth and limitations in achieving complete sterilization make prevention of inter-appointment contamination critical. Temporary restorations and endodontic spacers play an essential role in maintaining a coronal seal during multi-visit procedures.[15] An ideal spacer should provide an effective seal, prevent microleakage, and allow easy placement and removal.

Cotton pellets are commonly used due to their availability and ease of use; however, their fibrous and hydrophilic nature can promote moisture absorption, bacterial colonization, and void formation, compromising the coronal seal.[17]

Polytetrafluoroethylene (PTFE) tape has been proposed as an alternative spacer material due to its non-fibrous, hydrophobic, and inert properties. It provides better adaptation, reduces voids, and minimizes microleakage and microbial contamination compared to cotton pellets.[15,16,18]

The success of pulpectomy depends on effective microbial control and prevention of reinfection between visits. Since complete sterilization is rarely achievable, maintaining an adequate coronal seal is essential.

Therefore, the present study was undertaken to evaluate and compare the effectiveness of cotton pellets and polytetrafluoroethylene (PTFE) tape as endodontic spacers in primary molars of children aged 3–7 years, with respect to root canal microflora and microbial colony counts during multi-visit pulpectomy.

AIM AND OBJECTIVES

Aim of the Study

The aim of the study is to evaluate and compare the effect of two different endodontic spacers, cotton pellet and polytetrafluoroethylene (PTFE) tape on microflora within the root canal in primary molar undergoing pulpectomy in children aged between 3-7 years.

Objectives of the Study

1. To assess the total colony count of microorganisms from the root canal after mechanical preparation during the first visit and second visit among study participants undergoing pulpectomy with cotton pellet as the endodontic spacer.
2. To assess the total colony count of microorganisms from the root canal after mechanical preparation during the first visit and second visit among study participants undergoing pulpectomy with polytetrafluoroethylene (PTFE) tape as the endodontic spacer.
3. To evaluate the presence of clinical signs of infection (spontaneous pain, tenderness on percussion, swelling, and sinus tract) between appointments in primary molars treated using cotton pellet as the endodontic spacer.
4. To evaluate the presence of clinical signs of infection (spontaneous pain, tenderness on

percussion, swelling, and sinus tract) between appointments in primary molars treated using polytetrafluoroethylene (PTFE) tape as the endodontic spacer.

5. Intergroup comparison

MATERIALS AND METHODS

Source of Data

The present interventional study was conducted in the Department of Pediatric and Preventive Dentistry, A.J. Institute of Dental Sciences, Mangalore, following approval by the Institutional Ethical Committee. A total of 40children aged 3-7 years were selected from the outpatient department. They were randomly divided into two equal groups (n = 40):

- Group 1 (n=20): Cotton pellet as endodontic spacer
- Group 2 (n=20): PTFE tape as endodontic space

INCLUSION CRITERIA

- Children of age between 3-7 years of age.
- Primary mandibular molars undergoing pulpectomy procedure.
- Children whose parents give informed consent
- Patients willing to return for follow-up examinations.
- Age-group: 3–7years

EXCLUSION CRITERIA

- Patients with systemic illness and under antibiotic.
- Teeth with 1/3rd or more of root resorption.
- Any teeth having fracture line.

Clinical Procedure

The pulpectomy procedure was conducted in two sittings under aseptic conditions. Local anesthesia was administered followed by rubber dam isolation of the teeth. Removal of superficial caries and access cavity preparation were done. The canal orifices were located. Coronal pulp and radicular pulp were removed. Patency of the canals was determined. Irrigation using 5.25% Sodium Hypochlorite (NaOCl) followed by saline was performed to remove the debris and pulpal remnants. The working length was determined by preoperative radiograph, keeping it 1–2 mm short of the apex. The canals were then completely prepared with K-files #20, 25 and then rinsed with normal saline. After mechanical preparation, a sterile size #20 paper point was introduced into the length of the canals as determined previously by the working length radiograph. The paper point was kept in place for 60 seconds and then it was immediately transferred to a test tube containing transport medium. Spacer materials were sterilized. The length of polytetrafluoroethylene (PTFE) tape (approximately 2.5 inches) and the cotton pellet used were also standardized for each sample before insertion. The collected samples were transferred to a test tube containing transport medium and then sent for microbiological examination to check for total colony count within two hours. The spacer materials i.e. cotton pellet and polytetrafluoroethylene (PTFE) tapes were divided into two groups and each group had 20 participants. The participants were randomly assigned to any one of these groups. After placement of cotton pellet and polytetrafluoroethylene (PTFE) tape as endodontic spacers in participants of respective groups, the depth of the cavity was measured with the periodontal probe to ensure that it accommodated the required 3 mm thickness of the temporary restorative material. Participants were recalled for the 2nd visit after 7 days.

During the second visit, temporary restorations were removed under rubber dam isolation. The spacers were removed using a sterile tweezer. In order to evaluate the efficacy of endodontic spacers in maintaining the sterility of canals in between appointments, second microbiological sampling was carried out with sterile paper points from the root canal, which were then transferred to a test tube containing transport medium as described above. The collected samples were then sent for microbiological examination to check for microbial growth. The results obtained were tabulated and subjected to appropriate statistical analysis

Microbiological Evaluation

Microbiological assessment was conducted at the Department of Microbiology, A.J. Institute of Medical Sciences, Mangalore, under professional guidance.

- Collected samples were transferred to Brain Heart infusion broth (BHI) (transport medium)
- The broth was serially diluted and incubated for 24hours at 37°C
- Using an inoculation loop, the inoculum was streaked onto solid media: Blood agar
- Incubation was performed using the Anoxomat system
- Colonies were counted and results expressed as colony-forming units per millilitre (CFU/ml)

Clinical Assessment

In addition to microbiological parameters, the following clinical signs and symptoms were recorded at the second visit:

- Pain (present/absent)
- Tenderness on percussion (present/absent)
- Swelling (present/absent)
- Sinus tract

Follow-up Schedule

Participants were evaluated at 2nd appointment after 7 days.

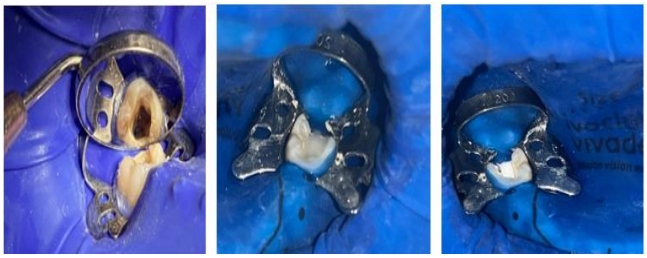


Figure: Access Cavity Prepared, Prepared Tooth with Cotton as Spacer, Prepared Tooth with Ptfe as Spacer.

Figure: Paper Point in Transport Medium, Specimens Collected

Data Analysis

Data were collected, coded, and analyzed using SPSS (Statistical Package for Social Sciences). Descriptive statistics included mean, standard deviation, frequency, and percentages. Inferential statistics used were:

- Paired t-test / Wilcoxon Signed Rank Test – for intragroup comparison (baseline vs. Day 7 CFU)
- Independent t-test / Mann Whitney U Test – for intergroup comparison (cotton vs. PTFE)

- Chi-square test – for association of clinical parameters with study groups

The level of significance was set at $p < 0.05$ at a 95% confidence interval.

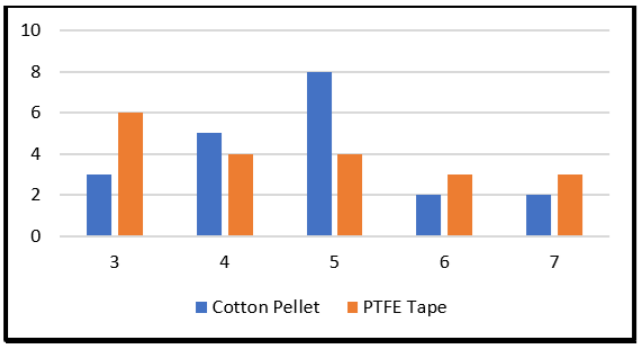
RESULTS

Demographic Characteristics of Study Population

Table 1: Age Distribution of Participants in Both Study Groups

Age (years)	Cotton Pellet n (%)	PTFE Tape n (%)	Total
3	3 (15.0%)	6 (30.0%)	9
4	5 (25.0%)	4 (20.0%)	9
5	8 (40.0%)	4 (20.0%)	12
6	2 (10.0%)	3 (15.0%)	5
7	2 (10.0%)	3 (15.0%)	5

- The majority of participants in the cotton pellet group were 5 years old (40%), whereas the PTFE tape group showed a more even distribution, with the highest proportion at 3 years (30%).
- Overall, children aged 5 years constituted the largest proportion of the total sample (30%).

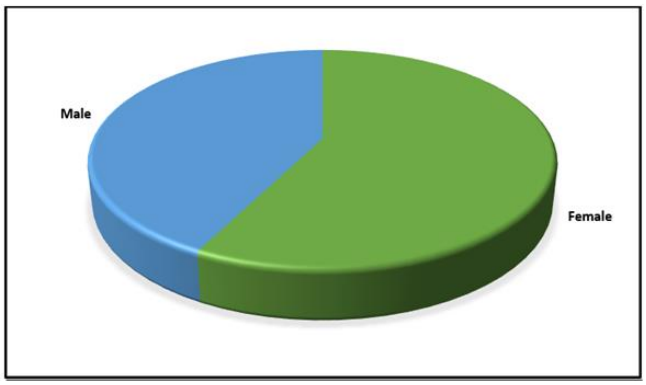


Graph 1: Age Distribution of Participants in Both Study Groups

Table 2: Gender Distribution of Participants in Both Groups

Gender	Cotton Pellet n (%)	PTFE Tape n (%)	Total
Female	14 (70.0%)	9 (45.0%)	23
Male	6 (30.0%)	11 (55.0%)	17

- In the cotton pellet group, females constituted the majority (70%), while males accounted for 30%.
- In the PTFE tape group, males were slightly higher (55%) compared to females (45%).
- Overall, females represented 57.5% of the total study population, whereas males comprised 42.5%.



Graph 2: Pie Chart Showing Overall Gender Distribution

Baseline Microbial Count (After Biomechanical Preparation)

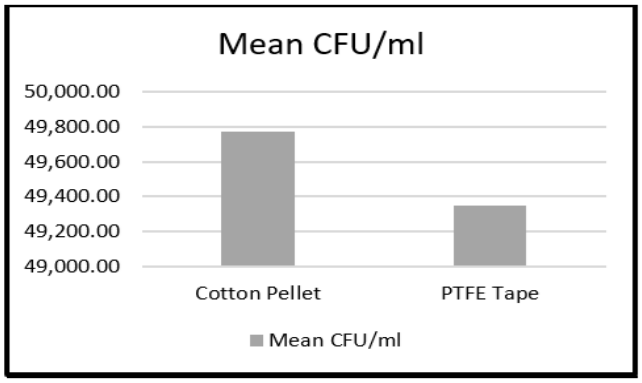
Table 3: Baseline CFU/ml After Biomechanical Preparation

Group	Mean CFU/ml	SD	Median	p-value
Cotton Pellet	49,775.2	2875.58	49,639.0	0.5755
PTFE Tape	49,349.7	1754.60	49,431.5	

Statistical test used: Independent t-test

- The baseline microbial count after biomechanical preparation showed a mean CFU/ml of 49,775.2 ± 2875.58 in the cotton pellet group and 49,349.7 ± 1754.60 in the PTFE tape group.

- The difference between the two groups was not statistically significant (p = 0.5755), indicating that both groups had comparable baseline microbial levels before intracanal medicament placement.



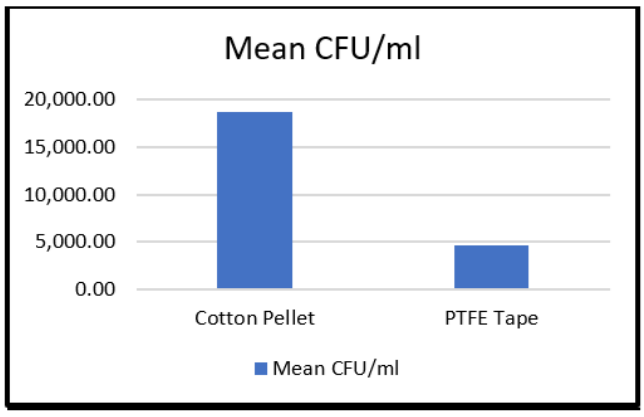
Graph 3: Comparison of Baseline CFU/ml After Biomechanical Preparation

Microbial Count at Second Visit (7 Days)

Table 4: CFU/ml at Second Visit

Group	Mean CFU/ml	SD	Median	p-value
Cotton Pellet	18,682.15	2769.91	19,307.0	2.6×10^{-23}
PTFE Tape	4,641.00	1057.96	4,492.0	

The PTFE group demonstrated significantly lower CFU counts at the second visit compared to the Cotton group ($p < 0.001$), indicating superior antimicrobial effectiveness of PTFE as an intracanal spacer after 7 days.



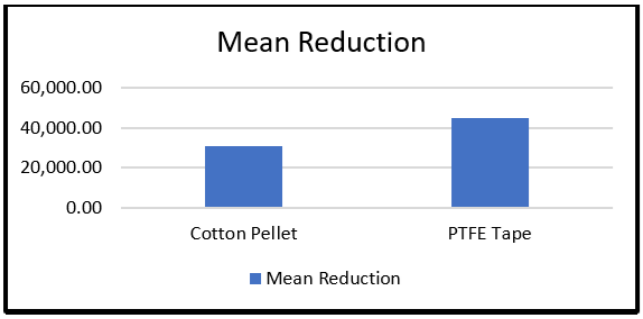
Graph 4: Comparison of CFU/ml at Second Visit

Intragroup Comparison of Microbial Reduction

Table 5: Intragroup Comparison of Baseline and Day-7 CFU Counts

Group	Baseline Mean ± SD	Day-7 Mean ± SD	Mean Reduction	p-value
Cotton Pellet	49,775.20 ± 2875.58	18,682.15 ± 2769.91	31,093.05	3.84×10^{-19}
PTFE Tape	49,349.70 ± 1754.60	4,641.00 ± 1057.96	44,708.70	1.30×10^{-27}

- In the cotton pellet group, the mean CFU/ml decreased from 49,775.20 ± 2875.58 at baseline to 18,682.15 ± 2769.91 at day 7, with a mean reduction of 31,093.05 CFU/ml, which was statistically significant ($p < 0.001$).
- Similarly, in the PTFE tape group, the mean CFU/ml reduced from 49,349.70 ± 1754.60 at baseline to 4,641.00 ± 1057.96 at day 7, showing a mean reduction of 44,708.70 CFU/ml, which was also statistically significant ($p < 0.001$).
- These findings indicate that both groups demonstrated significant microbial reduction over the 7-day period; however, the PTFE tape group showed a greater reduction in bacterial load compared to the cotton pellet group.



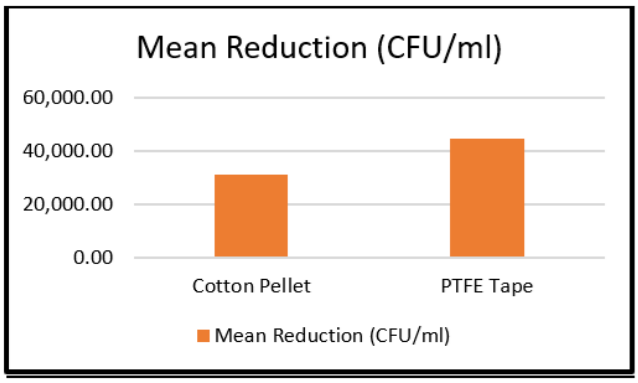
Graph 5: Intragroup Comparison of Mean Microbial Reduction

Intergroup Comparison of Microbial Reduction

Table 6: Comparison of Mean Microbial Reduction Between Groups

Group	Mean Reduction (CFU/ml)	SD	p-value
Cotton Pellet	31,093.05	3,771.67	1.1×10^{-16}
PTFE Tape	44,708.70	1,931.77	

- The mean microbial reduction in the PTFE tape group (44,708.70 ± 1,931.77 CFU/ml) was significantly greater than that observed in the cotton pellet group (31,093.05 ± 3,771.67 CFU/ml).
- The difference between the two groups was statistically significant (independent t-test, $p < 0.001$), indicating that PTFE tape demonstrated superior antimicrobial effectiveness compared to cotton pellet as a spacer material during endodontic treatment.



Graph 6: Bar Graph Showing Mean CFU Reduction Between Groups

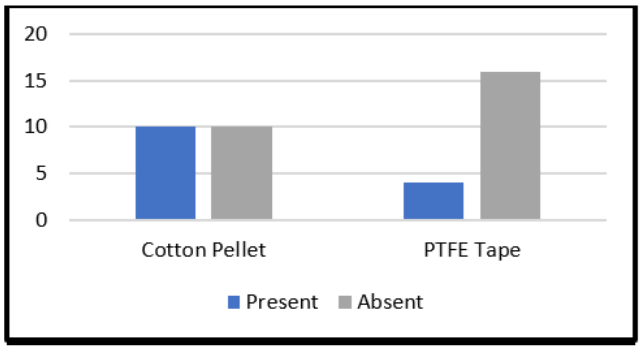
Clinical Signs of Infection Between Appointments

Table 7: Distribution of Pain Between Appointments

Group	Present n (%)	Absent n (%)	p-value
Cotton Pellet	10 (50.0%)	10 (50.0%)	0.097
PTFE Tape	4 (20.0%)	16 (80.0%)	

Statistical test used: Chi-square test

- Pain between appointments was reported in 50% of patients in the cotton pellet group, whereas only 20% of patients in the PTFE tape group experienced pain.
- Although the PTFE tape group demonstrated a lower frequency of postoperative pain, the difference between the two groups was not statistically significant ($p = 0.097$).

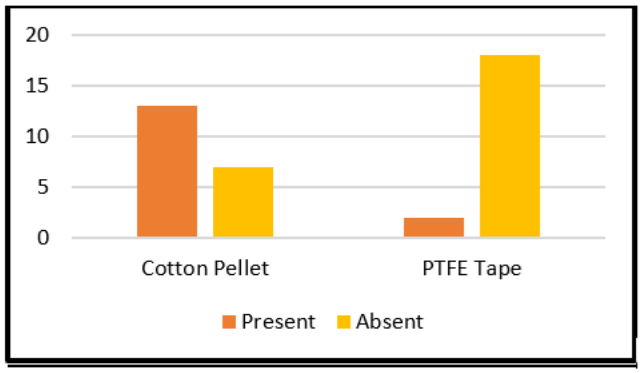


Graph 7: Bar Graph Showing Pain Distribution

Table 8: Distribution of Tenderness on Percussion

Group	Present n (%)	Absent n (%)	p-value
Cotton Pellet	13 (65.0%)	7 (35.0%)	0.00033
PTFE Tape	2 (10.0%)	18 (90.0%)	

- Tenderness on percussion was observed in 65% of patients in the cotton pellet group, whereas only 10% of patients in the PTFE tape group exhibited tenderness.
- The difference between the two groups was statistically significant ($p = 0.00033$), indicating lower postoperative tenderness in the PTFE tape group.

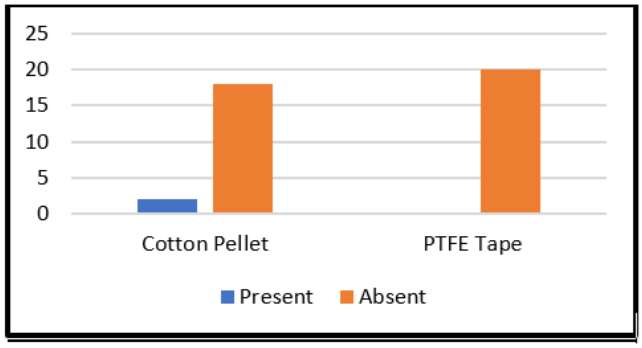


Graph 8: Bar Graph Showing Tenderness Distribution

Table 9: Distribution of Swelling Between Groups

Group	Present n (%)	Absent n (%)	p-value
Cotton Pellet	2 (10.0%)	18 (90.0%)	0.487
PTFE Tape	0 (0.0%)	20 (100.0%)	

- Swelling was observed in 10% of cases in the cotton pellet group, while no cases were reported in the PTFE tape group.
- However, the difference between the two groups was not statistically significant (p = 0.487).



Graph 9: Bar Graph Showing Swelling Distribution

Table 10: Distribution of Sinus Tract

Group	Present n (%)	Absent n (%)	p-value
Cotton Pellet	0 (0%)	20 (100%)	1.000
PTFE Tape	0 (0%)	20 (100%)	

- No cases of sinus tract formation were observed in either the cotton pellet group or the PTFE tape group.
- Therefore, no statistically significant

DISCUSSION

The maintenance of a sterile intracanal environment during the inter-appointment period is a fundamental prerequisite for the long-term success of multi-visit pulpectomy in primary teeth. Microorganisms play a central role in the etiology of pulpal and periapical disease, and re-contamination of the root canal system between visits remains a significant clinical challenge. Endodontic spacers, placed beneath provisional restorations, are critical in preventing microbial ingress and maintaining canal integrity. Conventionally, cotton pellets have been widely used; however, their fibrous, hydrophilic, and organic nature predisposes them to microbial wicking, void formation, and compromised sealing ability.[19,20] In contrast, polytetrafluoroethylene (PTFE) tape, being an inert, hydrophobic, and non-fibrous material, has emerged as a promising alternative with superior sealing potential.[17,21]

The present study included 40 children aged 3–7 years, randomly allocated into two groups: cotton pellet (Group 1, n=20) and PTFE tape (Group 2, n=20). Microbiological samples were collected at baseline and after 7 days using sterile paper points placed within the root canal system. A comparable study design was employed by Prabhakar AR et al., who included 17 children undergoing pulpectomy of lower second primary molars bilaterally, with cotton and PTFE tape placed randomly on either side and microbiological samples collected at baseline and after 7 days from both the access cavity and the spacer

material.[22] Khatab and Abdelhafez similarly evaluated 20 children each in the cotton and PTFE groups using bilateral primary molars for pulpectomy under a comparable inter-appointment 1-week evaluation protocol.[23] Somani et al. included 30 primary second molars in three groups of 10 each (cotton, PTFE, and foam pellets) and assessed microbial contamination at baseline and after 7 days from the pulp chamber, thereby maintaining methodological similarity in terms of evaluation period but differing in sampling location.[18] The present study's sample size of 20 per group, calculated using a pooled standard deviation with high statistical power, was larger than that of Prabhakar et al., thereby enhancing the robustness and reliability of the findings.

A notable methodological distinction between the present study and several previously published investigations pertains to the site of microbiological sampling. While studies such as those by Prabhakar AR et al. and Somani et al. predominantly obtained samples from the access cavity or pulp chamber, the present study employed intracanal sampling using sterile paper points placed directly within the root canal system.

This difference is clinically and scientifically significant. Sampling from the pulp chamber primarily reflects superficial contamination, including microorganisms associated with the spacer material or coronal leakage, and may not accurately represent the microbial status within the root canal system. In contrast, the root canal constitutes the principal site of infection and is the most critical determinant of endodontic success.

By obtaining samples directly from the canal, the present study enables a more precise and clinically relevant assessment of microbial penetration and spacer efficacy. This approach reduces the potential influence of coronal contamination and provides a more accurate evaluation of the ability of spacer materials to prevent bacterial ingress into the deeper regions of the canal system. Consequently, intracanal sampling may be considered a more valid and reliable method for assessing microbiological outcomes in studies evaluating inter-appointment sealing ability.

Baseline CFU/ml values following biomechanical preparation were comparable between the cotton pellet group (49,775.20 ± 2875.58) and the PTFE tape group (49,349.70 ± 1754.60), with no statistically significant difference ($p = 0.5755$). This indicates that both groups had similar microbial loads at baseline, thereby validating the randomization process and ensuring that subsequent differences observed were attributable to the spacer material rather than pre-existing variation. This finding is in agreement with Prabhakar AR et al., who reported zero microbial colonies at baseline in both the cotton and PTFE groups prior to spacer placement, confirming that the root canal was rendered sterile immediately following mechanical preparation.[22] Somani et al. also recorded a baseline colony count of zero in all three groups—cotton, PTFE tape, and foam pellets—before spacer placement, reinforcing the principle that effective biomechanical preparation creates a clean intracanal environment at the start of the inter-appointment phase.[18] Pisal et al. similarly documented comparable microbial loads at baseline across all groups in their ex vivo study on permanent premolars and molars,

underscoring the universal validity of this observation across both primary and permanent dentitions.[24]

At the second visit (Day 7), the microbial count in the PTFE group (4,641.00 ± 1057.96 CFU/ml) was markedly lower than that in the cotton pellet group (18,682.15 ± 2769.91 CFU/ml), and this difference was highly statistically significant ($p < 0.001$), demonstrating the superior antimicrobial sealing ability of PTFE tape. This observation is in close agreement with Prabhakar AR et al., who reported a significant increase in bacterial colony count after 7 days in the cotton group, with 15 out of 17 cotton samples showing contamination of both the spacer and access cavity, whereas only 2 out of 17 PTFE samples demonstrated microbial contamination and only one showed access cavity involvement.[22] Khatab and Abdelhafez further corroborated these findings by demonstrating a statistically significant increase in colony counts from both the spacer material and access cavity in the cotton group after one week, while the PTFE group exhibited minimal contamination with no significant difference between baseline and follow-up values.[23] Somani et al. similarly reported a statistically significant increase in CFU in the cotton group after 7 days, while the PTFE group demonstrated negligible microbial ingress, highlighting the superior sealing performance of PTFE.[18] Olsson et al., in their study on permanent molars, found that 15 out of 24 cotton spacers were positive for bacterial growth compared to only 2 out of 24 PTFE spacers over a 2–4 week period, further reinforcing the superior sealing capacity of PTFE across different dentitions and evaluation durations.[25]

The mean reduction in microbial colony count in the present study was significantly greater in the PTFE group compared to the cotton group ($p < 0.001$), indicating that PTFE not only limited microbial re-entry but also maintained a cleaner intracanal environment throughout the inter-appointment period. This is consistent with the findings of Pisal et al., who reported statistically significant differences in microbial contamination between cotton and PTFE groups in their ex vivo study, with PTFE demonstrating superior performance.[24] SaiKrishna et al. further supported these findings in an in vivo study, reporting statistically significant intergroup differences favoring PTFE tape even in the absence of intracanal medicaments.[26] Additionally, a PRISMA-guided systematic review by Mathew et al. concluded that PTFE tape consistently demonstrated lower microbial contamination compared to cotton pellets across both laboratory and clinical studies, with no study reporting inferior performance of PTFE.[27]

The superior antimicrobial sealing ability of PTFE over cotton observed in the present study can be attributed to its intrinsic material properties. Cotton's fibrous, organic, and hydrophilic nature predisposes it to bacterial wicking, poor compaction, and gap formation, facilitating microbial ingress.[27] In contrast, PTFE tape is non-fibrous, hydrophobic, and non-compressible, allowing better adaptation and reducing the likelihood of marginal leakage. This property-based advantage has been demonstrated by Shetty A et al., who reported significantly higher bacterial counts in cotton spacers compared to PTFE, and by Alkadi and Alsalleeh, who demonstrated significantly higher Enterococcus faecalis counts in cotton samples using a dual-chamber model.[17,28]

With respect to clinical outcomes, the present study revealed that pain was reported in 50% of patients in

the cotton group and 20% in the PTFE group; however, this difference was not statistically significant ($p = 0.097$). In contrast, tenderness on percussion was significantly higher in the cotton group (65%) compared to the PTFE group (10%) ($p < 0.001$), indicating increased periapical inflammation associated with greater microbial leakage. Swelling was observed in a small proportion of patients in the cotton group (10%) and was absent in the PTFE group, although this difference was not statistically significant ($p = 0.487$). No cases of sinus tract formation were observed in either group. These findings are consistent with those of Prabhakar AR et al. and Somani et al., who reported that improved microbial sealing with PTFE was associated with better clinical outcomes.[18,22]

Collectively, the findings of the present study are consistent with a substantial body of evidence from in vitro, ex vivo, in vivo, and systematic review studies by Prabhakar AR et al., Shetty A et al., Alkadi and Alsalleeh, Khatab and Abdelhafez, Pisal et al., Mathew et al., Somani et al., and SaiKrishna et al., all of which consistently support the superior sealing ability and reduced microbial contamination associated with PTFE tape compared to cotton pellets.[17,18,22–24,26–28]

The strengths of the present study include its in vivo design, adequate sample size with high statistical power, randomized allocation, and comprehensive microbiological evaluation. Importantly, the use of intracanal sampling enhances the methodological rigor and clinical relevance of the findings. The inclusion of clinical parameters such as pain, tenderness, swelling, and sinus tract formation further strengthens the study by providing a holistic assessment of treatment outcomes.

However, certain limitations must be acknowledged. The short follow-up period of 7 days limits the evaluation of long-term sealing efficacy. The absence of additional comparator materials such as foam pellets or cellulose sponge restricts broader material comparison. Furthermore, intracanal medicaments were not included, which may not fully reflect routine clinical practice. Finally, the restriction to mandibular primary molars limits generalizability to other tooth types with different anatomical and microbial characteristics.

Within these limitations, the present study provides strong and clinically relevant evidence supporting the use of PTFE tape as a superior endodontic spacer for maintaining intracanal sterility and improving inter-appointment outcomes in multi-visit pulpectomy in primary teeth.

CONCLUSION

The present in vivo interventional study demonstrated that PTFE tape is significantly more effective than cotton pellet as an endodontic spacer in reducing inter-appointment microbial contamination in primary molars. The mean Day 7 CFU count was substantially lower in the PTFE group compared to the cotton group, with a highly statistically significant difference ($p < 0.001$). The mean microbial reduction was also significantly greater in the PTFE group ($p < 0.001$), confirming its superior sealing ability.

In terms of clinical outcomes, the PTFE group exhibited significantly less tenderness ($p < 0.001$), while pain and swelling, although lower in the PTFE group, did not show statistically significant differences ($p = 0.097$ and $p = 0.487$, respectively).

No sinus tract formation was observed in either group, indicating that both materials are clinically safe within the study period.

These findings are consistent with existing literature, including studies by Prabhakar et al. (2018), Khatab and Abdelhafez (2020), and Somani et al. (2022), as well as the systematic review by Mathew et al. (2021), all of which support the superior performance of PTFE tape.

Within the limitations of the study, PTFE tape can be recommended as a reliable and clinically superior alternative to cotton pellet for maintaining intracanal sterility between appointments in pediatric endodontic practice.

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