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ORIGINAL RESEARCH

An *in vivo* Evaluation of different Root Canal Filling Materials used in Primary Teeth

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ABSTRACT

Aim: The main purpose of this clinical study was to evaluate and compare the clinical and radiographic efficacy of four obturating materials—Endoflas , 3Mix with zinc oxide (ZO), RC Fill, and zinc oxide-eugenol (ZOE) in primary molars, for a period of 3, 6, and 9 months.

Materials and methods: Endodontic treatment was performed on 40 pulpally involved primary molars in 3 to 8 years children, the root canals were obturated with Endoflas in group I, 3Mix with ZO in group II, RC Fill in group III, and ZOE. Follow-up examinations were done at 3, 6, and 9 months and again clinical signs and symptoms were noted, and a radiograph was recorded at each interval for evaluating radiographic changes. The data were then collected and subjected for statistical analysis.

Statistical analysis: Chi-square test.

Results: At 9 months, Endoflas FS gave the best results with the highest success rate of 95.7% followed by 3Mix with ZO (90.5%), RC Fill (88.9%), and ZOE (85%) respectively, but was not statistically significant.

Conclusion: Endoflas appeared to reduce the clinical signs/symptoms and periapical/furcation radiolucencies at a faster rate than the other materials used, as demonstrated by the highest success rate of 95.7%. Thus, it can be considered to be an effective root canal filling material in primary teeth due to its healing ability, bone regeneration characteristics, without depleting from the root canals during the course of root resorption.

Keywords: 3mix-MP, Calcium hydroxide, Endodontic treatment, Endoflas, Pulpectomy, RC fill, Zinc oxide-eugenol.

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INTRODUCTION

Endodontic procedure helps in preservation of a pulpally involved primary tooth by eliminating bacteria and their products and ensures hermetic seal of the root canals with different root canal filling materials so that the primary tooth can complete its function until normal exfoliation can occur without harming the successor or affecting the health of the patient.[1]

An ideal root canal filling material must possess the necessary properties of being antibacterial, resorbable at the same rate of the root, and harmless to periapical tissues and the developing tooth bud. In addition, it must easily fill the canals, adhere to the walls, should not shrink, must readily resorb if passed beyond the apex, be easily removed if necessary, must be radiopaque, and causes no discoloration of the tooth.[1]

Since 1930s, zinc oxide-eugenol (ZOE) has been the material of choice, but has certain disadvantages, such as slow resorption, irritation to periapical tissues, necrosis of bone and cementum, and alters the path of eruption of succedaneous tooth.[2] It is also reported that ZOE paste, if extruded through the apex during filling procedure, could remain in the apical tissues during the process of physiological root resorption and could take months or even years to resorb.[3]

The first clinical use of calcium hydroxide as a root canal filling material was probably by Rhoner in 1940. The two most important reasons for using calcium hydroxide as a root canal filling material are stimulation of the periapical tissues to maintain health or promote healing and secondly for its antimicrobial effects.[4] Calcium hydroxide being resorbable and biocompatible can be used in primary teeth. However, the rate of resorption of this material from within the canals is faster than the rate of physiologic root resorption.[5]

Morphology of the root canals in primary teeth makes endodontic treatment difficult.[6] To compensate for the incomplete debridement due to complexity of the root canal system in primary teeth, it becomes necessary to destroy the microorganisms in tissue remnants and to render them unsuitable for supporting microbial life. The iodoform content could achieve this.[7] The newer materials like a mixture of three antibacterial drugs (3Mix-metronidazole, ciprofloxacin, and minocycline)

can sterilize carious lesions, necrotic pulps, and infected root dentin of primary teeth. This prevents too much enlargement of root canals and unnecessary irritation of periapical tissues.[8]

The main purpose of this clinical study was to evaluate and compare the clinical and radiographic efficacy of four obturating materials—Endoflas, 3Mix with zinc oxide (ZO), RC Fill, and ZOE in primary molars, for a period of 3, 6, and 9 months.

MATERIALS AND METHODS

A total of 40 carious primary molars, showing signs of pulpal/periapical/interradicular radiolucency with no pathologic mobility and which could be restored after completion of the procedure, were selected from children in the age group of 3 to 8 years with good general health having no history of systemic illness. Parents or guardians were informed about the condition of the child's dentition and the procedure to be conducted. Participation in the study was voluntary and written consent was obtained from the parent or guardian. Clinical and radiographic examination was carried out following which, the teeth were assessed and primary molars requiring pulpectomy were selected showing no internal or pathologic root resorption and inadequate bone support. After obtaining consent from their parents or guardians and clearance from the Ethical Committee of Career Post Graduate Institute of Dental Sciences and Hospital, Lucknow, Uttar Pradesh the children were randomly divided into different groups as shown in Table 1.

The procedure was performed under local anesthesia and rubber dam isolation. Caries was completely removed and access opening was done with a slow speed no. 4 or no. 6 carbide bur with copious water supply and all overhanging tooth structure was removed from the roof of the pulp chamber. The coronal pulp was amputated with a sharp spoon excavator and barbed broaches were used to remove the pulpal debris. Fine reamers were gently inserted into the canals and a radiograph was taken to establish the working length of the root canals. The working length was maintained at 1 mm short of apex and the cleaning and shaping of the root canals were carried out using Hedstrom files, 21 mm (30–35 size) in a pull-back motion. The canals were periodically irrigated with 0.9% saline to remove the debris. Care was taken to file selectively along the outer walls of the canals, as the walls toward the interradicular areas tend to be thin, with an associated risk of perforation. The canals were dried and filled with Endoflas in group I, 3Mix with ZO in group II, RC Fill in group III, and ZOE in group IV. These mixtures were carried to the root canals by hand lentulospirals and pressed in incremental fashion with cotton pellet for proper compaction of the material.

An immediate postoperative Intra oral periapical X-ray was recorded for each obturated tooth and the teeth were then permanently restored. Follow-up examinations were done at 3, 6, and 9 months and again clinical signs and symptoms were noted and a radiograph was recorded at each interval for evaluating radiographic changes. Clinically, the teeth were evaluated for presence or absence of gingival swelling, sinus tract, pain on percussion, and spontaneous pain. Radiographic examination included evaluation of increase or decrease of periapical and furcation radiolucencies. Data were then collected and subjected for statistical analysis.

Table 1: Teeth and groups allocation

Materials used	*Groups*	*Number of teeth*
Endoflas (experimental)	I	10
3Mix with zinc oxide [ZO] (experimental)	II	10
RC Fill (experimental)	III	10
Zinc oxide-eugenol [ZOE] (control)	IV	10

RESULTS

The follow-up examination revealed a marked improvement in terms of clinical outcomes. The radiographic assessment showed progressive healing of the radiolucencies with the passage of time. The radiographic success was taken as the combination of decrease in periapical and furcation radiolucencies as depicted in Figs 1 to 5. The results are summed up in Tables 2 to 4 and Graphs 1 to 3. No statistical difference ($p > 0.5$) between the groups was noticed (chi-square test).

The clinical and radiographic success rates are as follows (Tables 2 to 4):

- Clinical and radiographic success rates in group I were 100 and 87.5% respectively.
- Clinical and radiographic success rates in group II were 71.4 and 71.4% respectively.

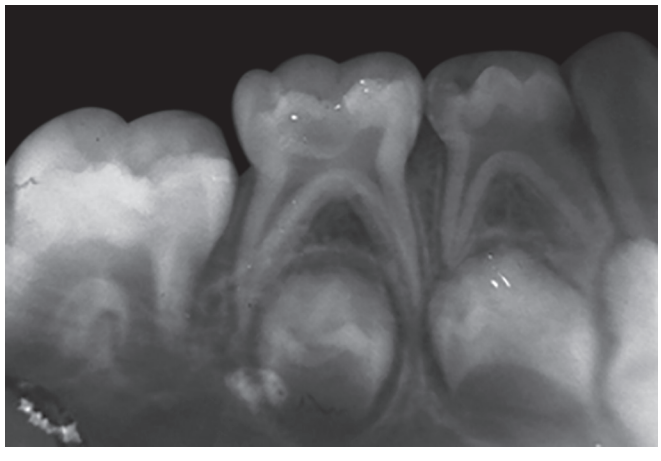


Fig. 1: Radiographic interpretation of Endoflas—preoperative

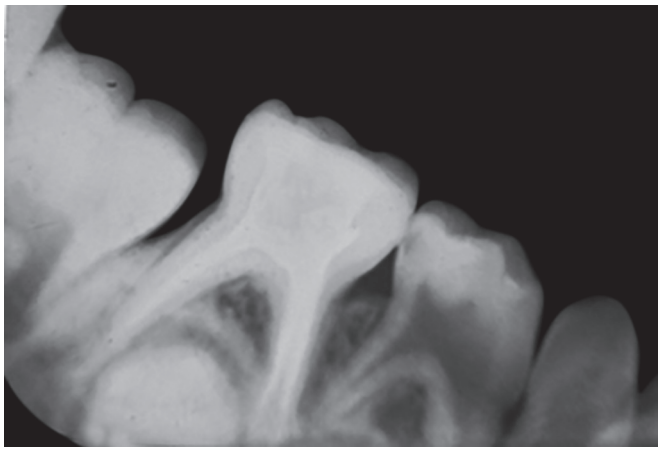


Fig. 2: Radiographic interpretation of Endoflas—immediate postoperative

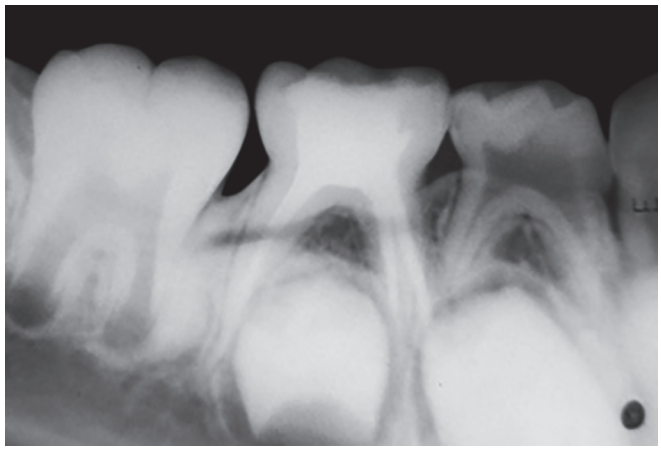


Fig. 3: Radiographic interpretation of Endoflas—3 months—furcation radiolucency seen

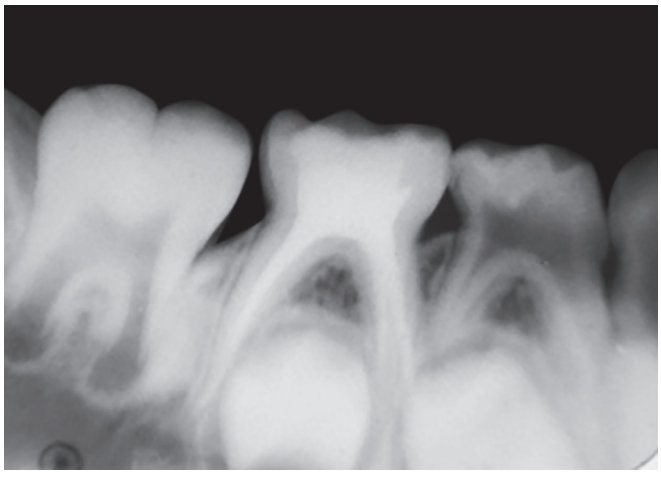


Fig. 4: Radiographic interpretation of Endoflas—6 months—note the reduction in furcation radiolucency

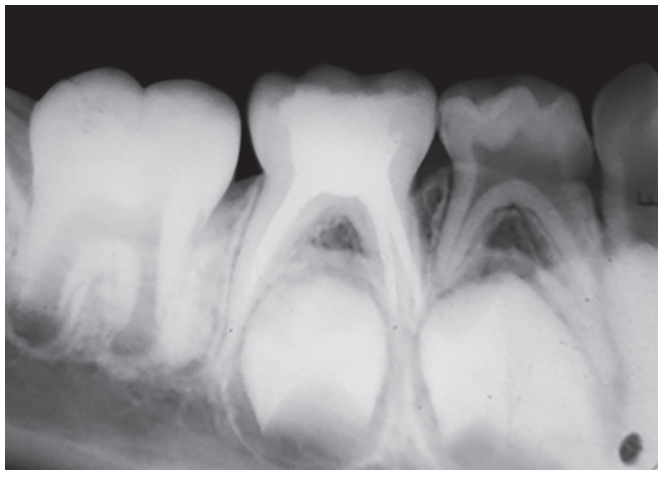


Fig. 5: Radiographic interpretation of Endoflas—9 months—further reduction in furcation radiolucency from bone regeneration

Table 2: Overall clinical outcome of four groups at pre- and posttreatment periods

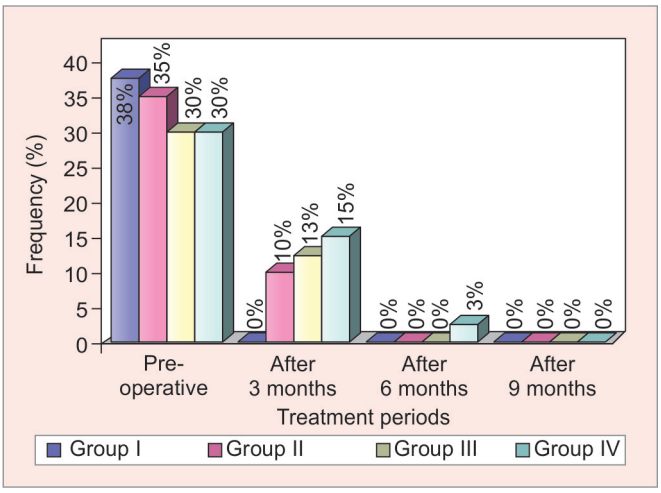
Periods	*Group I (n = 40)*	*Group II (n = 40)*	*Group III (n = 40)*	*Group IV (n = 40)*	*Chi-square value (df = 3)*	*p-value*
Preoperative	15 (38%)	14 (35%)	12 (30%)	12 (30%)	0.76	0.859
After 3 months	0 (0%)	4 (10%)	5 (13%)	6 (15%)	6.11	0.107
After 6 months	0 (0%)	0 (0%)	0 (0%)	1 (3%)	3.02	0.389
After 9 months	0 (0%)	0 (0%)	0 (0%)	0 (0%)	NA	NA
Total	0 (%)	4 (10%)	5 (13%)	7 (18%)	7.22	0.065
Success rate (%)	100.0%	71.4%	58.3%	41.7%	–	–

Table 3: Overall radiological outcome of four groups at pre- and posttreatment periods

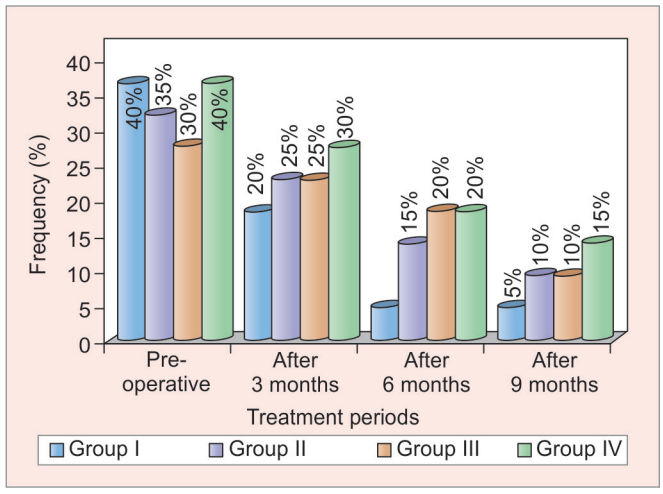
Periods	*Group I (n = 20)*	*Group II (n = 20)*	*Group III (n = 20)*	*Group IV (n = 20)*	*Chi-square value (df = 3)*	*p-value*
Preoperative	8 (40%)	7 (35%)	6 (30%)	8 (40%)	0.60	0.898
After 3 months	4 (20%)	5 (25%)	5 (25%)	6 (30%)	0.53	0.912
After 6 months	1 (5%)	3 (15%)	4 (20%)	4 (20%)	2.35	0.503
After 9 months	1 (5%)	2 (10%)	2 (10%)	3 (15%)	1.11	0.774
Success rate (%)	87.5%	71.4%	66.7%	62.5%	–	–

Table 4: Total outcome (clinical + radiological) of four groups at pre- and posttreatment periods

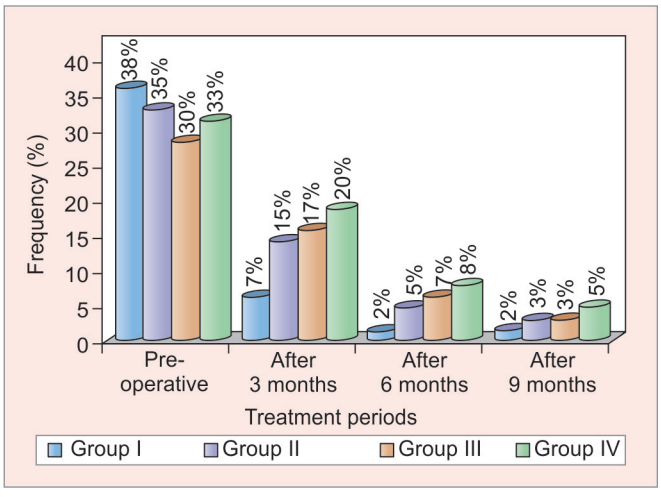
Periods	*Group I (n = 60)*	*Group II (n = 60)*	*Group III (n = 60)*	*Group IV (n = 60)*	*Chi-square value (df = 3)*	*p-value*
Preoperative	23 (38%)	21 (35%)	18 (30%)	20 (33%)	0.96	0.810
After 3 months	4 (7%)	9 (15%)	10 (17%)	12 (20%)	4.65	0.199
After 6 months	1 (2%)	3 (5%)	4 (7%)	5 (8%)	2.85	0.416
After 9 months	1 (2%)	2 (3%)	2 (3%)	3 (5%)	1.03	0.793
Success rate (%)	95.7%	90.5%	88.9%	85.0%	–	–



Graph 1: Overall clinical outcome of four groups at pre- and posttreatment periods



Graph 2: Overall radiological outcome of four groups at pre- and posttreatment period



Graph 3: Total outcome (clinical + radiological) of four groups at pre- and posttreatment periods

- Clinical and radiographic success rates in group III were 58.3 and 66.7% respectively.
- Clinical and radiographic success rates in group IV were 41.7 and 62.5% respectively.

The overall success rate (Table 4 and Graph 3) between the groups is as follows:

- Group I—95.7%
- Group II—90.5%
- Group III—88.9%
- Group IV—85.0%

DISCUSSION

Zinc oxide-eugenol is the most frequently used root canal filling material for primary teeth.[9] The ZOE pastes are not bactericidal, unless mixed with drugs, such as formocresol (Grossman L). Due to various side effects of formaldehyde, the use of it is questionable.[10] Also, eugenol in particular has been reported to be cytotoxic and neurotoxic (Markowitz et al).[11] In this study, ZOE gave an overall success rate of 85.0% which was comparable with the results obtained by Gupta and Das,[12] and Trairatvorakul and Chunlasikaiwan[13] who reported a success rate of 85.71 and 85% respectively. Even better outcomes have been observed by Pinto et al[14] reporting 87.5 and Nadkarni and Damle[15] who noted 88.57% success rate with ZOE. Whereas, Holan and Fuks[16] observed 65%, Reddy and Fernandes[17] 80%, Barr et al[18] 82.3%, and Mortzavi and Mesbahi[19] 78.5% success rates with ZOE which were in contrast with the results of this study. The lowest success rate of ZOE paste in this study can be attributed to the fact that ZO powder has no significant antibacterial properties, due to lack of acidity and lack of release of antibacterial agents, which was reported by Daugela et al.[20] Also, Alexandra et al reported least antibacterial activity of ZOE in an *in vitro* study comparing the antibacterial activity of four root canal filling materials for primary teeth.[21]

Iodoform is another material, which is commonly used in root canals of primary teeth. It is used either in pure form

or is combined with other materials like ZOE and calcium hydroxide. It is a potent bactericidal, nonirritant, radiopaque, and resorbable material.[12] Castagnola reported that iodoform paste is bactericidal to microorganisms in the root canal and loses only 20% of its potency over a 10 year period.[22] Iodoform containing pastes are easily resorbed from the periradicular region, and cause no foreign body reaction like ZOE.[5] In this study, RC Fill (ZOE with iodoform) gave a success rate of 88.9% which was close to the results reported by Ramar and Mungara[1] showing an overall success rate of 90.5%, thus showing better results than the control group, i.e., ZOE group.

Bacteria which are present mainly in the root canals and superficial layer of infected root canal wall may be easily removed by conventional root canal treatment, however, the bacteria, remaining in the deep layers of root canal dentin, may leak out to periapical region and cause complications. Application of antibacterial drugs to endodontic lesions is one of the clinical procedures that can be used to sterilize such lesions.[23] To sterilize such lesions, a single antibacterial drug may not be effective, even if it is a broad spectrum antibiotic. Reason being the bacterial composition of the infected root canals is complex.[24] Since the overwhelming majority of bacteria in the deep layers of infected dentin of the root canal wall consist of obligate anaerobes, metronidazole was selected as the first choice among the antibacterial drugs. Metronidazole even at high concentrations cannot kill all the bacteria indicating the necessity of other drugs. Thus, ciprofloxacin and minocycline, in addition to metronidazole, were added to sterilize infected root dentin.[7]

For primary teeth, the presence of accessory canals, porosity, and permeability in the pulpal floor region indicate a probable connection between pulpal and periodontal tissues. The 3Mix can easily dissipate through these regions and induce a sterile zone, which is expected to promote tissue repair.[8] The penetration ability of these drugs was improved by mixing these drugs with propylene glycol and macrogol to form ointment base and the penetration ability of propylene glycol was clearly demonstrated by Cruz et al.[25] In this study, 3Mix (metronidazole, ciprofloxacin, and minocycline) with ZO gave an overall success rate of 90.5%, which was close to the results obtained by Nakornchai et al[8] who reported a success rate of 88%, whereas, Trairatvorakul and Detsomboonrat[26] reported a low success rate of 36.7% which was in contrast with this study. Thus, 3Mix with ZO powder proved to be more effective than RC Fill and ZOE as a root canal filling material. The effectiveness of this material is attributed to the high antimicrobial activity of 3Mix, i.e., metronidazole, ciprofloxacin, and minocycline, whereas with ZO powder having no significant antibacterial properties, due to lack of acidity and lack of release of antibacterial agents as reported by Daugela et al.[20]

Resorption of obturating materials and resorption of primary tooth root at the same rate is the basic criteria of success of endodontic treatment of primary teeth, as in material known as Endoflas. It is a mixture of calcium hydroxide, ZOE and iodoform is said to have the advantage of resorption limited to the excess extruded exrtaradicularly, without washing out intraradicularly. In this study, Endoflas gave the highest success rate of 95.7% which was comparable with the results obtained by Ramar and Mungara[1] who reported a success rate of 95.1%, and Subramaniam and Gilhotra[27] reporting 93.3% success rate whereas Fuks et al observed a lower success rate of 58% when there was overfilling, however, 83% success in cases with flush and underfilled root canals.[5] The high success rate of Endoflas can be attributed to its broad spectrum of antibacterial activity, therefore, it has the ability to disinfect dentinal tubules and difficult to reach accessory canals that cannot be disinfected or cleansed mechanically. Further, the components of Endoflas are biocompatible and can be removed by phagocytosis, hence making the material resorbable.[3]

CONCLUSION

- Reduction in clinical signs/symptoms and periapical/furcation radiolucencies was evidenced with all the root canal filling materials used.
- Endoflas gave the best results with the highest success rate of 95.7% followed by 3Mix with ZO [90.5%], RC Fill [88.9%], and ZOE [85%] respectively.
- Endoflas, a mixture of ZOE, calcium hydroxide, and iodoform, appeared to reduce clinical signs/symptoms and periapical/furcation radiolucencies at a faster rate than the other materials used, as demonstrated by the highest success rate of 95.7%. Thus, it can be considered to be an effective root canal filling material in primary teeth due to its healing ability, bone regeneration characteristics, without depletion from the root canals.
- Due to the antimicrobial activity of ciprofloxacin, metronidazole, and minocycline, a newer material, 3Mix with ZO can also be effectively used as a root canal filling material in primary teeth.
- A further longitudinal study involving a larger sample size is necessary to evaluate and also the teeth treated in this study need to be monitored until their eventual exfoliation.

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