

Perception of Paediatric Dentists on Use of i-Grip vs Flossed Endodontic Files during Pulpectomy Procedures in Children: A Quasi-experimental Study

ISHANI RATNAPARKHI¹, J JASMIN WINNIER², SHILPA NAIK³, SONAL TANDEL⁴, DEEPSHIKHA MEHROTRA⁵, DIVYA SHETTY⁶



ABSTRACT

Introduction: Mishaps such as the accidental ingestion of endodontic instruments and crowns may occur during dental treatment in children. Although such accidents are rare, they can be potentially harmful to patients. The use of a rubber dam is not always possible in paediatric dentistry; thus, the attachment of floss to endodontic files is commonly done during the pulpectomy procedure. However, there are some challenges associated with using Flossed Endodontic Files (FEFs). To overcome these difficulties, a system called i-Grip was introduced.

Aim: To evaluate the perception and compare the ease, convenience and safety of i-Grip versus FEFs as perceived by Paediatric Dentists during pulpectomy procedures in children.

Materials and Methods: A post-test quasi-experimental study was conducted in the Department of Paediatric and Preventive Dentistry, D.Y. Patil University, School of Dentistry, Navi Mumbai, Maharashtra, India, among 40 Paediatric Dentists over a period of three months. The Paediatric Dentists were asked to use

the i-Grip for four weeks, after which they completed validated questionnaires. Statistical Package for the Social Sciences (SPSS) software version 23.0 was used for data analysis. The answers to the questions were statistically analysed using the Z-test of proportion.

Results: The mean age of males were 35±0.743 years and females were 25.37±0.543 years. A total of 27 (67.5%) participants found placing the file in the i-Grip to be very easy. 22 (55%) found the i-Grip to be very convenient to use. 31 (77.5%) Paediatric Dentists found the i-Grip to be extremely safe, 6 (15%) considered it to be moderately safe and none found it to be extremely unsafe. There was a statistically significant difference between the ease, comfort and safety of i-Grip compared to FEF ($p < 0.05$).

Conclusion: Paediatric dentists reported that the i-Grip was easy to use, convenient and safe when compared to FEF. The i-Grip is an innovative safety tool that can be utilised in paediatric patients during pulpectomy procedures instead of FEF.

Keywords: Aspiration, Dental floss, Paediatric dentistry, Safety measures

INTRODUCTION

One of the main goals of paediatric dentistry is to maintain the integrity of primary dentition until exfoliation. A pulp-treated primary tooth allows for proper mastication, phonation, swallowing and preserves the space for the permanent successor [1]. However, mishaps such as the accidental ingestion of endodontic instruments and crowns may occur if the treatment is carried out without the application of a rubber dam, especially in child patients. Although these mishaps are rare, they are potentially harmful to patients and can cause parental anxiety [2].

Susini G et al., reported that the prevalence of aspiration was 0.001 per 100,000 root canal treatments (2.2%) and the prevalence of ingestion was 0.12 per 100,000 root canal treatments (18% of all ingested items) [3]. Hospitalisation was required in 100% of aspiration cases and 36% of ingestion cases [4]. Other retrospective and longitudinal studies have reported incidence rates ranging from 0.00012% to 0.004% [4,5].

There is a low level of reporting in such cases, as not all clinicians facing such an accident would report it. A rubber dam is considered to be the safest method to prevent these catastrophes [6]. It was reported that less than 20% of dentists used a rubber dam routinely, while the vast majority (60%) reported never using a rubber dam during endodontic procedures [7]. In cases where rubber dam application is not possible, attaching a floss ligature to files is a common practice [8]. However, there are some disadvantages to

using the floss ligature, such as the need to change the floss before every patient, the floss getting entangled while working and the time consumed for flossing [9].

To overcome these difficulties, a system called i-Grip was introduced by Integrated Endodontic Pvt. Ltd. (India) in 2014. It is an autoclavable silicone instrument that is 30 cm in length. It has a cuff with a diameter of 6 cm that fits in the operator's hand and an elastic arm into which the file can be inserted. Moreover, it can be used as a stopper and the tip can be cut after repeated use if necessary [10]. However, its ease of use and comfort have not been evaluated in endodontics. Thus, the aim of the study was to evaluate the perception and compare the ease, convenience and safety of i-Grip versus FEFs as perceived by Paediatric Dentists during pulpectomy procedures in children. The null hypothesis was that there is no difference in the ease, comfort and safety of i-Grip when compared to FEFs.

MATERIALS AND METHODS

A post-test quasi-experimental study was conducted in the Department of Paediatric and Preventive Dentistry, D.Y. Patil University, School of Dentistry, Navi Mumbai, Maharashtra, India, among the Paediatric Dentists to evaluate their perception of the use of i-Grip versus FEFs over a period of three months, from August 2022 to November 2022. Ethical clearance was obtained from the Institutional Ethical Review Board of the University (IREB/2022/PEDO/18).

Inclusion and Exclusion criteria: The Paediatric Dentists included in the study had at least five years of experience and performed a minimum of 20 pulpectomies in one month. They also consented to use the i-Grip while hand filing during pulpectomy. Incompletely filled forms were excluded from the study.

Sample size calculation: A pilot study was conducted with 10 Paediatric Dentists who were excluded from the main study. After considering the safety values for floss and i-Grip as 23% and 55%, respectively, at 80% power of the study and a 95% confidence interval, the sample size for the present study was determined to be 33, which was rounded up to 40.

Study Procedure

Questionnaire: Two questionnaires were formulated [ANNEXURE 1]. The first recorded demographic details along with the use of FEFs and the second evaluated the ease, convenience and safety of FEFs and i-Grip. Both questionnaires were validated by 10 experts who rated the questions on a Likert scale of 1-10. Reliability was later assessed by handing the questionnaire to 10 other experts and the results were statistically analysed. The Cronbach’s alpha value was found to be 0.86. The Paediatric Dentists who participated in the validation process were not included in the study. The Strengthening the Reporting of Observational studies in Epidemiology (STROBE) cohort reporting guidelines were followed.

The first questionnaire was sent via Google Forms to 289 Paediatric Dentists. Demographic details such as age, years of experience and willingness to participate in the study were recorded. The Paediatric Dentists were asked if they routinely used FEFs; if not, they were asked to provide reasons for their non use (cumbersome, messy, not feasible, time-consuming, not required, or any other reason). Out of the 289 Paediatric Dentists, 180 responded, yielding a response rate of 62%. Among the 180 responses, 65 dentists routinely used FEFs, while 115 did not or routinely used rubber dams in their practice. These 115 respondents were excluded from the present study. Among the 65 respondents who used FEFs, those with less than five years of experience and who performed fewer than 20 pulpectomies a month were also excluded from the present study.

Once consent to participate in the study was obtained, the Paediatric Dentists were provided with i-Grip and were asked to use it for a period of four weeks during pulpectomy procedures [Table/ Fig-1,2]. Upon completion of the experimental period, the second questionnaire was sent to the participants via Google Forms. Their responses were recorded and statistically analysed.



[Table/ Fig-1]: i-Grip (Integrated Endodontic Pvt. Ltd., India, 2014).

STATISTICAL ANALYSIS

All the data from the present study were analysed using SPSS software version 23.0 (SPSS Inc, Chicago, IL). The data were analysed using the Z-test of proportion at a 95% level of significance, based on the data collected from the Google Form.



[Table/ Fig-2]: i-Grip being used by a paediatric dentist in a patient during pulpectomy procedure.

RESULTS

Out of the 289 Paediatric Dentists assessed for eligibility, 40 were found to meet the inclusion criteria. Among them, there were 15 male and 25 female dentists included in the study. [Table/ Fig-3] shows the mean age and gender distribution of the Paediatric Dentists involved in the study.

Gender	n	Mean age (years)
Males	15	35±0.743
Females	25	37±0.543

[Table/ Fig-3]: Demographic details.

According to the data entered in the Google form, the results were derived. The reasons for not flossing files varied among the participants. A total of 46 (40%) Paediatric Dentists found it to be messy, 34 (30%) considered it time-consuming, 23 (20%) reported that it was cumbersome and 12 (10%) found it not feasible [Table/ Fig-4].

Parameters	Frequency (N)	Percentage (%)
Messy	46	40%
Time consuming	34	29.56%
Cumbersome	23	20%
Not feasible	12	10.44%
Total	115	100%

[Table/ Fig-4]: Distribution of reasons for not using FEFs.

The ease, convenience and safety of flossing the file to that of placing the file in the i-Grip is compared in [Table/ Fig-5]. A total of 27 (67.5%) participants found placing the file in the i-Grip to be very easy, whereas only 1 (2.5%) found flossing to be very easy. When considering convenience, 22 (55%) dentists found the i-Grip to be very convenient, in contrast to 5 (12.5%) who found flossed files to be very inconvenient. Additionally, 31 (77.5%) Paediatric Dentists found the i-Grip to be extremely safe, while none found it to be unsafe.

	Ease		Convenience		Safety	
	FEFs n (%)	i-Grip n (%)	FEFs n (%)	i-Grip n (%)	FEFs n (%)	i-Grip n (%)
1	1 (2.5%)	27 (67.5%)	5 (12.5%)	22 (55%)	9 (22.5%)	31 (77.5%)
2	3 (7.5%)	11 (27.5%)	13 (32.5%)	12 (30%)	18 (45%)	6 (15%)
3	13 (32.5%)	2 (5%)	11 (27.5%)	6 (15%)	6 (15%)	3 (7.5%)
4	14 (35%)	0	9 (22.5%)	0	5 (12.5%)	0
5	9 (22.5%)	0	2 (5%)	0	2 (5%)	0

[Table/ Fig-5]: Distribution of ease, convenience and safety of using FEFs and i-Grip.

The distribution of the study population according to the ease, convenience and safety of using dental floss and the i-Grip, using the Z-test of proportion is presented in [Table/ Fig-6]. There was a statistically significant difference in the ease, convenience and safety of the i-Grip compared to flossed files (p<0.05).

Parameters	Total Number	Floss n (%)	i-Grip n (%)	Z-test	p-value
Ease	40	4 (10)	38 (95)	-7.61	<0.001*
Convenience	40	18 (45)	34 (82.5)	-3.48	<0.001*
Safety	40	27 (67.5)	37 (92.5)	-2.79	0.005**

[Table/Fig-6]: Comparison of study population according to ease, convenience and safety of use of dental floss and i-Grip using Z-test of proportion.

*p<0.001: Highly significant; **p<0.05- Significant

DISCUSSION

According to the results of the present study, 115 pedodontists did not floss their files before every patient, as they found it to be cumbersome, messy and time-consuming. They also preferred to use rotary instruments routinely instead of hand filing and did not use rubber dams. Therefore, there is a pressing need to find a better, easier, faster and safer alternative to flossed files.

A total of 55% of the Paediatric Dentists found i-Grip to be very convenient to use for children, compared to 12.5% in the flossed files group. About 15% reported struggling while using the i-Grip on patients. Additionally, 5% of pedodontists found flossed files to be extremely unsafe, as there was still a chance of the floss slipping due to wet conditions in the mouth, such as saliva or blood. However, none found i-Grip to be extremely unsafe, as the control rests in the operator's wrist.

According to the American Academy of Paediatric Dentistry, performing a pulpectomy on primary molars rather than opting for extraction is a reasonable treatment option [11]. The prevention of dental emergencies, especially in paediatric dental practices, is of utmost importance. Treatment under a rubber dam is considered the gold standard, as it not only provides isolation but also enhances safety against mishaps. One of the major challenges during pulp therapy is the behavioural issues of children, which often make the application of a rubber dam extremely difficult, if not impossible. Furthermore, in children with special healthcare needs or in cases where there is significant loss of tooth structure or the presence of extraoral or intraoral swelling, the application of a rubber dam may not be feasible [12].

Accidents such as aspiration and ingestion typically occur when preventive safety measures are not incorporated in dental practice. These accidents can lead to severe complications, such as bowel perforations or obstructions, as the files used are generally sharp, pointed and can pierce the oesophagus or stomach lining [13]. Several incidents of ingestion have been reported in previous literature, particularly involving the use of hand files in children with uncooperative behaviour and disabilities [4,14]. To mitigate such unfortunate events and enhance safety during procedures, it is common practice to attach a floss ligature to manual endodontic files in these cases [15].

Non adherence to established safety practices presents a significant challenge in clinical settings, highlighting the need for the implementation of novel solutions like i-Grip. This device has the

potential to optimise protocol adherence, thereby improving patient outcomes and the quality of care.

Limitation(s)

The study is subject to certain limitations. The responses were collected after four weeks; however, it takes between 18 to 254 days to form a habit [16]. Therefore, a longer duration of use should be evaluated. Not all Paediatric Dentists may have used the device for every case. This bias could have been eliminated if the study had been conducted in a hospital-based setting.

CONCLUSION(S)

i-Grip is a safer, easier and more convenient alternative to FEFs. The Paediatric Dentists who used i-Grip found it to be comfortable and acceptable compared to FEFs. Therefore, it can be recommended as a precautionary measure for children during the pulpectomy procedure using hand files. Since this is a new product, further studies are required to evaluate the scope of i-Grip in paediatric dentistry.

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PARTICULARS OF CONTRIBUTORS:

1. Lecturer, Department of Paediatric and Preventive Dentistry, D.Y. Patil University, School of Dentistry, Navi Mumbai, Maharashtra, India.
2. Associate Professor, Department of Paediatric and Preventive Dentistry, D.Y. Patil University, School of Dentistry, Navi Mumbai, Maharashtra, India.
3. Professor and Head, Department of Paediatric and Preventive Dentistry, D.Y. Patil University, School of Dentistry, Navi Mumbai, Maharashtra, India.
4. Postgraduate Student, Department of Paediatric and Preventive Dentistry, D.Y. Patil University, School of Dentistry, Navi Mumbai, Maharashtra, India.
5. Lecturer, Department of Paediatric and Preventive Dentistry, D.Y. Patil University, School of Dentistry, Navi Mumbai, Maharashtra, India.
6. Lecturer, Department of Paediatric and Preventive Dentistry, D.Y. Patil University, School of Dentistry, Navi Mumbai, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Ishani Ratnaparkhi,
Lecturer, Department of Paediatric and Preventive Dentistry, D.Y. Patil University,
School of Dentistry, Sector-7, Navi Mumbai-400706, Maharashtra, India.
E-mail: drishaniratnaparkhi@gmail.com

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[ANNEXURE 1]**Questionnaire No. 1**

Demographic Details:

1. Gender: _____
2. Age: _____
3. Years of experience as a Paediatric Dentist: _____
4. Do you floss your endodontic files
 - a. Yes
 - b. No
5. If no, state your reason:
 1. Cumbersome
 2. Messy
 3. Not feasible
 4. Time consuming
 5. Not required
 6. Other:

Questionnaire No. 2

Ease, Convenience and Safety of Flossed Endodontic Files (FEFs) and i-Grip

- I. On a scale of 1-5, how easy is it to floss the file before every patient?
 1. Very easy
 2. Moderately easy
 3. A little struggle
 4. Moderately Difficult
 5. Very difficult
- II. On a scale of 1-5, how convenient is using flossed files in patients?
 1. Very convenient
 2. Moderately convenient
 3. Struggles a bit
 4. Moderately convenient
 5. Very inconvenient
- III. On a scale of 1-5, how would you rate the safety of flossed files?
 1. Extremely safe
 2. Moderately safe
 3. Same as i-Grip
 4. Moderately unsafe
 5. Extremely unsafe
- IV. On a scale of 1-5, how easy is it to place the file in the i-Grip?
 1. Very easy
 2. Moderately easy
 3. A little struggle
 4. Moderately Difficult
 5. Very difficult
- V. On a scale of 1-5, how convenient is using i-Grip in patients?
 1. Very convenient
 2. Moderately convenient
 3. Struggles a bit
 4. Moderately convenient
 5. Very inconvenient
 6. I-Grip not used
- VI. On a scale of 1-5, how would you rate the safety of i-Grip?
 1. Extremely safe
 2. Moderately safe
 3. Same as flossed files
 4. Moderately unsafe
 5. Extremely unsafe