BUKTI KORESPONDENSI
Jurnal Internasional Bereputasi
Sebagai Syarat Khusus

Judul Artikel	:	Apical debris extrusion during instrumentation of oval root canals in primary teeth using manual versus motorized files: an ex vivo study.
Penulis	:	BhaggyashriA. Pawar, Ajinkya M. Pawar, JatinAtram, Alexander Maniangat Luke, Anuj Bhardwaj, Anda Kfr, Zvi Metzger & **Dian Agustin Wahjuningrum**
Jurnal	:	Scientifc Reports | (2021) 11:3859 https://doi.org/10.1038/s41598-021-83522-4
Penerbit	:	Springer Nature

1	Manuscript was submitted to Journal **"Scientifc Reports"**	**Received: 15 September 2020**
	Thank you for submitting your manuscript to scientific reports	
2	**Manuscript revision** announcement	**Received: 28 September 2020**
	We are pleased to let you know that your manuscript has now passed through the revision stage and is ready for the revision	
3	**Amendment received**	**Received: 27 oktober 2020**
4	**Revision** was resubmitted to Journal	**29 Oktober 2020**
	Thank you for submitting your revision to scientific reports	
5	Decision: **Accepted for Publication**	**4 Februari 2021**
6	**Published online**	**16 Februari 2021**
7	**Published on Scientifc Reports | (2021) 11:3859.**	**16 Februari 2021**

Submission history

Publishing and rights	
Submission is in publishing and rights	04 Feb 2021
Peer review	
Submission accepted	04 Feb 2021
Submission under peer review	03 Feb 2021
Submission passed technical check	03 Feb 2021
Revision received	02 Feb 2021
Submission under peer review	04 Jan 2021
Submission passed technical check	04 Jan 2021

Amendment received	04 Jan 2021
Amendment received	02 Jan 2021
Revision received	28 Dec 2020
Submission under peer review	19 Nov 2020
Submission passed technical check	19 Nov 2020
Amendment received	19 Nov 2020
Amendment received	18 Nov 2020
Revision received	16 Nov 2020
Submission under peer review	29 Oct 2020
Submission passed technical check	29 Oct 2020
Amendment received	29 Oct 2020
Amendment received	27 Oct 2020
Revision received	23 Oct 2020
Submission under peer review	15 Sep 2020
Technical check	
Submission passed technical check	15 Sep 2020
Submission is under technical check	15 Sep 2020
Submission received	
Submission received	15 Sep 2020

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id>

Scientific Reports - Receipt of Manuscript 'Apical debris extrusion...'

1 pesan

Scientific Reports <srep@nature.com> 15 September 2020 pukul 12.22
Kepada: dian-agustin-w@fkg.unair.ac.id

Ref: Submission ID bb8820d7-2369-4cc8-a634-2517b22c3a52

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Your manuscript is now at our initial Quality Check stage, where we look for adherence to the journal's submission guidelines, including any relevant editorial and publishing policies. If there are any points that need to be addressed prior to progressing we will send you a detailed email. Otherwise, your manuscript will proceed into peer review.

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Peer Review Advisors
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agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.i

Scientific Reports: Decision on your manuscript

8 pesan

Scientific Reports <srep@nature.com> 28 September 2020 pukul 14
Kepada: dian-agustin-w@fkg.unair.ac.id

Ref: Submission ID bb8820d7-2369-4cc8-a634-2517b22c3a52

Dear Dr Wahjuningrum,

Re: "Apical debris extrusion amid instrumentation of oval root canals in primary teeth using manual vs. mechanized files. Running Title: Apical extrusion of debris in primary teeth."

We are pleased to let you know that your manuscript has now passed through the review stage and is ready for revision. Many manuscripts require a round of revisions, so this is a normal but important stage of the editorial process.

Editorial Board Member comments
Having intensively reviewed your draft, your submitted draft has been rated controversially by our external reviewers, at least to some extent. Thus, I have double checked your submitted draft (R #1). To finalize your paper convincingly, and to meet both SCIENTIFIC REPORTS' quality standards and our readership's expectations, please stick to ALL reviewers' comments. No doubt, the number of minor and major shortcomings would seem astonishing when reflecting on the number of (co-)authors (being assumed to have contributed, read, and revised your draft).

Please note that it is not considered our reviewers' task to co-author your manuscript (this clearly is a constructive comment, so please try your best to improve your draft, and to revise the other parts not mentioned here if necessary). Remember that a non-convincing revision (not considered acceptable with regard to language, reviewers' constructive criticism, content, generalizable outcome, and/or Authors' Guidelines) will lead to outright reject.

Moreover, please double check the available literature, and discuss the aspects given there more thoroughly. With the current version of your paper, some recently published papers have been ignored, please see
- https://pubmed.ncbi.nlm.nih.gov/30951620/
- https://pubmed.ncbi.nlm.nih.gov/30264472/
- https://pubmed.ncbi.nlm.nih.gov/29267525/

In-house Editor comments
In-house editorial comment:/n/n To aid our readers, and to maximize the accessibility of your manuscript, the title should have a clear, precise scientific meaning. Where possible, the title should be read as one concise sentence which is under 20 words long. /n/nPlease could you re-write the title ensuring that it is informative and appropriate./n/n

To ensure the Editor and Reviewers will be able to recommend that your revised manuscript is accepted, please pay careful attention to each of the comments that have been pasted underneath this email. This way we can avoid future rounds of clarifications and revisions, moving swiftly to a decision.

Once you have addressed each comment and completed each step listed below, please upload your revised submission along with the final file here:

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1. Please upload a point-by-point response to the comments, including a description of any additional experiments that were carried out and a detailed rebuttal of any criticisms or requested revisions that you disagreed with. This must be uploaded as a 'Point-by-point response to reviewers' file.

You'll find a handy one-page PDF on how to respond to reviewers' comments here:

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Please note that use of an editing service is neither a requirement nor a guarantee of publication. Free assistance is available from our resources page: https://www.springernature.com/gp/researchers/campaigns/english-language-forauthors

To support the continuity of the peer review process, we recommend returning your manuscript to us within 21 days. If you think you will need additional time, please let us know and we will aim to respond within 48 hours.

Kind regards,

Andrej Kielbassa
Editorial Board Member
Scientific Reports

Reviewer Comments:

Reviewer 1
This revised and re-submitted paper would seem satisfying now, and is considered ready to proceed.

Reviewer 3
Dear Editor/ authors,

I would like to thank you for the opportunity of the present revision. The authors properly addressed the main suggestions. This study will certainly contribute to the body of knowledge regarding the root canal treatment of primary teeth.

Summary:

The recommendation: Accept.

Reviewer 2
I appreciate the authors for considering my opinions in improving the manuscript presentation.
However, I request the authors to provide the "ethical clearance certificate" issued by the 'institutional ethical committee' to provide my final recommendations to the present research.

Our flexible approach during the COVID-19 pandemic

If you need more time at any stage of the peer-review process, please do let us know. While our systems will continue to remind you of the original timelines, we aim to be as flexible as possible during the current pandemic.

---

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 27 Januari 2021 pukul 11.58
Kepada: Anuj Bhardwaj <dranuj_84@yahoo.co.in>

[Kutipan teks disembunyikan]

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id>

Revision Quality Check: Apical debris extrusion amid instrumentation of oval root canals in primary teeth using manual vs. mechanized files. Running Title: Apical extrusion of debris in primary teeth.

3 pesan

Rishikesh Khilari <srep@nature.com> 27 Oktober 2020 pukul 13.25
Balas Ke: Rishikesh Khilari <srep@nature.com>
Kepada: dian-agustin-w@fkg.unair.ac.id

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3. In-house editorial comment: To aid our readers, and to maximize the accessibility of your manuscript, the title should have a clear, precise scientific meaning. Where possible, the title should be read as one concise sentence which is under 20 words long. Please could you re-write the title ensuring that it is informative and appropriate.
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Pada tanggal Sel, 27 Okt 2020 pukul 13.26 Rishikesh Khilari <srep@nature.com> menulis:

COVID 19 and impact on peer review
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2. Please ensure that the abstract section exactly matches on the submission system and in the manuscript.
3. In-house editorial comment: To aid our readers, and to maximize the accessibility of your manuscript, the title should have a clear, precise scientific meaning. Where possible, the title should be read as one concise sentence which is under 20 words long. Please could you re-write the title ensuring that it is informative and appropriate.
4. Please provide a statement to confirm that all methods were carried out in accordance with relevant guidelines and regulations in the manuscript.
5. Please could you clarify
   where the drawing in figure 1 has
   been obtained from? If this image was drawn by you or one of your co-authors, please send an email to **rishikesh.khilari@springernature.com** confirming
   who drew the image.

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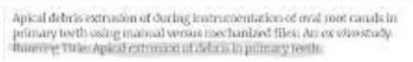
Sincerely,

Rishikesh Khilari
Editorial Assistant
Scientific Reports


Apical debris extrusion of during instrumentation of oval root canals in primary teeth using manual versus mechanized files: An ex vivo study.
Running Title: Apical extrusion of debris in primary teeth.

Capture.PNG
27K

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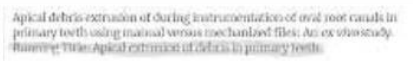
agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 29 Oktober 2020 pukul 13.23
Kepada: Anuj Bhardwaj <dranuj_84@yahoo.co.in>

[Kutipan teks disembunyikan]


Apical debris extrusion of during instrumentation of oval root canals in primary teeth using manual versus mechanized files: An ex vivo study.
Running Title: Apical extrusion of debris in primary teeth.

Capture.PNG
27K

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id>

Re: Revision Quality Check 2.1: Apical debris extrusion amid instrumentation of oval root canals in primary teeth using manual vs. mechanized files. Running Title: Apical extrusion of debris in primary teeth.

2 pesan

Rishikesh Khilari <srep@nature.com> 29 Oktober 2020 pukul 13.16
Balas Ke: Rishikesh Khilari <srep@nature.com>
Kepada: dian-agustin-w@fkg.unair.ac.id
Cc: dranuj_84@yahoo.co.in

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Dear Prof. WAHJUNINGRUM,

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Sincerely,

Rishikesh Khilari
Editorial Support at Scientific Reports

On Wed, 28 Oct at 5:02 AM , agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> wrote:

[External - Use Caution]

Dear Rishikesh Khilari
Yes, we confirm that all methods were carried out in accordance with relevant guidelines and regulations in the manuscript.
warm regards
Dian

(Press/Click on the above link to be automatically sent to the web page.)

Please make the requested amendments only, before selecting the “Submit manuscript” button on the “Review” page.

If you have any questions please feel free to contact us.

Sincerely,

Rishikesh Khilari
Editorial Assistant
Scientific Reports

---

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 27 Oktober 2020 pukul 13.47
Kepada: Anuj Bhardwaj <dranuj_84@yahoo.co.in>

[Kutipan teks disembunyikan]

---

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 28 Oktober 2020 pukul 12.01
Kepada: Rishikesh Khilari <srep@nature.com>
Cc: Anuj Bhardwaj <dranuj_84@yahoo.co.in>

Dear Rishikesh Khilari
Yes, we confirm that all methods were carried out in accordance with relevant guidelines and regulations in the manuscript.
warm regards
Dian
[Kutipan teks disembunyikan]

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id>

Revision Quality Check: Apical debris extrusion of during instrumentation of oval root canals in primary teeth using manual versus mechanized files: An ex vivo study.

2 pesan

Rishikesh Khilari <srep@nature.com> 18 November 2020 pukul 14.51
Balas Ke: Rishikesh Khilari <srep@nature.com>
Kepada: dian-agustin-w@fkg.unair.ac.id

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2. Please ensure that the title and the abstract section exactly matches on the submission system and in the manuscript.
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5. Please provide valid email address for the author-**Bhaggyashri Pawar** on the submission system.

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Please make the requested amendments only, before selecting the "Submit manuscript" button on the "Review" page.

If you have any questions please feel free to contact us.

Sincerely,

Rishikesh Khilari
Editorial Assistant
Scientific Reports

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agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 18 November 2020 pukul 16.35
Kepada: Anuj Bhardwaj <dranuj_84@yahoo.co.in>

[Kutipan teks disembunyikan]

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id>

Re: Revision Quality Check 3.1: Apical debris extrusion of during instrumentation of oval root canals in primary teeth using manual versus mechanized files: An ex vivo study.

3 pesan

Rishikesh Khilari <srep@nature.com> 19 November 2020 pukul 15.56
Balas Ke: Rishikesh Khilari <srep@nature.com>
Kepada: dian-agustin-w@fkg.unair.ac.id

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Dear Prof. WAHJUNINGRUM,

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Sincerely,

Rishikesh Khilari
Editorial Support at Scientific Reports

> On Wed, 18 Nov at 7:51 AM , SREP <srep@nature.com> wrote:
> **COVID 19 and impact on peer review**
> As a result of the significant disruption that is being caused by the COVID-19 pandemic, we are very aware that many researchers will have difficulty in meeting the timelines associated with our peer review process during normal times. Please do let us know if you need additional time. Our systems will continue to remind you of the original timelines but we intend to be highly flexible at this time.
>
> Dear Prof. WAHJUNINGRUM,
>
> Thank you for submitting your revision to Scientific Reports. However, in order to further process your paper, we will require the following to be included:

1. Kindly provide the manuscript with '**marked changes'/'track changes**' in the '**related files'** section and the '**clean version**' of the manuscript in the '**manuscript file'** section.
2. Please ensure that the title and the abstract section exactly matches on the submission system and in the manuscript.
3. Please provide a statement to confirm that all methods were carried out in accordance with relevant guidelines and regulations in the manuscript.
4. Please provide 'OLD-FIRST ROUND MANUSCRIPT WITH MARKED CHANGES' file in the related file section.
5. Please provide valid email address for the author-**Bhaggyashri Pawar** on the submission system.

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If you have any questions please feel free to contact us.

Sincerely,

Rishikesh Khilari
Editorial Assistant
Scientific Reports

Capture.PNG
6K

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agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 19 November 2020 pukul 17.26
Kepada: Anuj Bhardwaj <dranuj_84@yahoo.co.in>

[Kutipan teks disembunyikan]

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6K

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agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 3 Agustus 2021 pukul 19.49
Kepada: ferysetiawanjprime@gmail.com

---------- Forwarded message ---------
Dari: **Rishikesh Khilari** <srep@nature.com>
Date: Kam, 19 Nov 2020 pukul 15.56
Subject: Re: Revision Quality Check 3.1: Apical debris extrusion of during instrumentation of oval root canals in primary

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id>

Scientific Reports: Decision on your manuscript

2 pesan

Scientific Reports <srep@nature.com> 8 Desember 2020 pukul 00.01
Kepada: dian-agustin-w@fkg.unair.ac.id

Ref: Submission ID bb8820d7-2369-4cc8-a634-2517b22c3a52

Dear Dr Wahjuningrum,

Re: "Apical debris extrusion during instrumentation of oval root canals in primary teeth using manual versus motorized files: An ex vivo study."

We are pleased to let you know that your manuscript has now passed through the review stage and is ready for revision. Many manuscripts require a round of revisions, so this is a normal but important stage of the editorial process.

Editorial Board Member comments
Having intensively reviewed your draft, our external reviewers have indicated that your submitted draft still would not seem satisfying, and have forwarded recommendations differing to some extent. Thus, I have double checked your submitted draft, to come to a more balanced decision. Please remember that this is a re-re-review process not considered usual, and I have decided to give respect to our reviewers work and commitment, to improve your paper. There will be a PDF forwarded by one of the reviewers, with additional suggestions to further improve your draft.

Notwithstanding, please accept our position that it is not considered our reviewers' task to co- or to ghost-author your manuscript. No doubt, please note that you should indeed follow the reviewer's comments, to finalize your paper convincingly, and to meet both PLOS ONE's quality standards and our readership's expectations. It should be clear that a further non-convincing revision (not considered acceptable with regard to language, reviewers' constructive criticism, content, generalizable outcome, and/or Authors' Guidelines) will lead to outright reject.

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In-house Editorial comment:

To aid our readers, and to maximize the accessibility of your manuscript, the title should have a clear, precise scientific meaning and should not contain a punctuation (full stops, hyphen, semi-colons). Where possible, the title should be read as one concise sentence which is under 20 words long.
Please could you re-write the title ensuring that it is informative, appropriate.

To ensure the Editor and Reviewers will be able to recommend that your revised manuscript is accepted, please pay careful attention to each of the comments that have been pasted underneath this email. This way we can avoid future rounds of clarifications and revisions, moving swiftly to a decision.

Once you have addressed each comment and completed each step listed below, please log in here with the same email you used to submit your manuscript to upload the revised submission and final file:

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https://www.nature.com/documents/Effective_Response_To_Reviewers-1.pdf

2. Please highlight all the amends on your manuscript or indicate them by using tracked changes.

3. Check the format for revised manuscripts in our submission guidelines, making sure you pay particular attention to the

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id>

Your revision will due shortly on 'Apical debris extrusion during instrumentation of oval root canals in primary teeth using manual versus motorized files: An ex vivo study.'

2 pesan

Vaishnavi Anil Khadamkar <srep@nature.com> 24 Desember 2020 pukul 11.49
Balas Ke: Vaishnavi Anil Khadamkar <srep@nature.com>
Kepada: dian-agustin-w@fkg.unair.ac.id

Dear Dr Dian,

On checking our records, I notice that you are due to submit your revision within seven days.

When you are ready, please use the link below to submit your revised manuscript:

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Kepada: Anuj Bhardwaj <dranuj_84@yahoo.co.in>

[Kutipan teks disembunyikan]

Dear Editor/ authors,

I would like to thank you for the opportunity of the present revision. The authors properly addressed the main suggestions. This study will certainly contribute to the body of knowledge regarding the endodontic treatment of primary teeth.

Summary:

The recommendation: Accept.

Comments to the authors/editor:

- Abstract:
• Conclusion: Indeed, the occurrence of reduced postoperative symptoms following the use of the distinct instruments was not investigated. In this sense, I would like to suggest that the authors maintain the previously conclusion, that attended directly to the primary and secondary objectives of the study; adding a possible beneficial aspect to the sentence. As a suggestion, the conclusion could be amended as:

"Within the limitations of the present study, it may be concluded that motorized files extruded less debris and required less instrumentation time compared to traditional K-files, which could benefit paediatric patients with root canal treatment needs. "

- Introduction:
• Please, revise in the last paragraph, the word motorizeded.

- Materials and methods:
• Regarding the working length, established 1 mm short of the apex, I would like to suggest the insertion of reference(s), such as: Trairatvorakul & Chunlasikavan, Pediatric Dentistry 2008;30(4):303-308; or Barcelos et al., Int J Paed Dent 2011 DOI: 10.1111/j.1365-263X.2011.01210.x; or Subramaniam & Gilhotra, J Clin Ped Dent 2011;35(4):365-370; or Cassol et al., Braz Oral Res 2019; doi.org/10.1590/1807-3107bor-2019.vol33.0002; or Barasuol et al. Eur Arch Paed Dent 2020, doi.org/10.1007/s40368-020-00530-0. The first three references are randomized clinical trials, while the last is an in vitro study.

- Conclusion:

• Please, consider reporting the conclusion as suggested for the abstract section

Reviewer 2
Reviewer appreciates the hard work done by the authors in completing the systematic review entitling "Apical debris extrusion during instrumentation of oval root canals in primary teeth using manual versus mechanized files: An ex vivo study."

Though the authors made the suggested corrections partially, the authors failed to address a few queries requested in the first revision. In addition, there are a few major clarifications that need to be addressed by the authors before processing the manuscript further.

The major concerns were as follows:
1. Authors quoted a reference published in 2019 for sample size calculation, to the present study with ethical approval in 2018 (Understood from the ethical clearance number).
Please clarify.
2. In the manuscript first submitted, it was mentioned that a total of 12 ml of irrigating solution was used in each group, whereas in the revised manuscript it was mentioned that 4 ml was used.
Please clarify.
3. Please modify tables as suggested in the revision (highlighted in yellow in the manuscript with correction word file).

Authors are requested to highlight the corrections in yellow for making the review process easy.

Our flexible approach during the COVID-19 pandemic

figure resolution requirements:

https://www.nature.com/srep/publish/guidelines

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Please note that use of an editing service is neither a requirement nor a guarantee of publication. Free assistance is available from our resources page: https://www.springernature.com/gp/researchers/campaigns/english-language-forauthors

To support the continuity of the peer review process, we recommend returning your manuscript to us within 21 days. If you think you will need additional time, please let us know and we will aim to respond within 48 hours.

Kind regards,

Andrej Kielbassa
Editorial Board Member
Scientific Reports

Reviewer Comments:

Reviewer 1
No doubt, this revised manuscript has been considerably improved. Notwithstanding, however, the authors have re-submitted a paper still lacking from some minor and major shortcomings considered perfectible before proceeding with this paper will be possible.

Abstract
- Maximum word count is 200 words, see Guidelines for Authors. Please shorten carefully.

Intro
- "A growing body of literature has recognized the importance of reducing apically extruded debris9." This undoubtedly seem right. With this in mind, some kind of "crown-down" technique might be helpful along with a correctly assessed working length using an apex locator. Again, please go to https://pubmed.ncbi.nlm.nih.gov/12539034/ , and note that this paper has revealed that "estimating the root canal length just short of the apex would seem helpful, and that using such a device will not be influenced by tooth type, root canal type, status of the periapex, or clinical condition".
- Tha latter aspect has not been included by the authors. Again, please go to https://pubmed.ncbi.nlm.nih.gov/12539034/ , and discuss. Please note that your response to the recent comment ("We do refer to this paper and to the issue of apical resorption in primary teeth (...)") obviously has led to an erroneously included aspect.
- Still, some minor typos would seem perfectible. See, for example, "motorizeded". Revise carefully.

Meths
- Again, please provide complete information on the materials used, and double check manufacturer information. For example, "(Filtek Supreme; 3 M/ESPE, St Paul, USA) must read "(Filtek Supreme; 3M ESPE, St Paul, MN, USA)". Remember that the typesetter is neither a dentist nor a scientist, so provide a flawless manucript.
- This section aims to ensure that other scientists will be able to replicate your study. Again, please provide complete information. See, for example, that the latter still is missing with "Eppendorf tube", "rubber dam", and so on.
- Again, revise for "°C". See, for example, "warm (37 oC) distilled water", and use the correct symbol (°).

Disc
- Again, please revise for uniform formatting of your references. See "(...) when the files are engaged in the apical third of the canal [20]." revise thoroughly.
- "The effect of apical resorption, which is common in primary teeth 25 on apical extrusion of debris should be addressed in future studies." Please see comments given above. Again, please go to https://pubmed.ncbi.nlm.nih.gov/12539034/ , and discuss that electrometric working length control will help reducing apical debris extrusion.

Refs
- Again, please revise for uniform formatting. See, for example, "techniques in primary", "(2012).doi:", or "J.Clin.Diagn.Res.11,".
- Same with "doi:10(...)", "doi: 10(...)", "doi.org/10(...)", or "doi:org/10(...)". Revise thoroughly.
- Please note that all authors must read your paper prior to submission. This surely will help to minimize such minor shortcomings.

Reviewer 3

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id>

Scientific Reports: Decision on your manuscript

2 pesan

Scientific Reports <srep@nature.com> 27 Januari 2021 pukul 11.54
Kepada: dian-agustin-w@fkg.unair.ac.id

Ref: Submission ID bb8820d7-2369-4cc8-a634-2517b22c3a52

Dear Dr Wahjuningrum,

Re: "Apical debris extrusion during instrumentation of oval root canals in primary teeth using manual versus motorized files: An ex vivo study. "

We are pleased to let you know that your manuscript has now passed through the review stage and is ready for revision. Many manuscripts require a round of revisions, so this is a normal but important stage of the editorial process.

Editorial Board Member comments
While two recommendations related to your revised and re-submitted paper would seem satisfying (including my own pre-review check, see R #1), please note that our third reviewer has requested some further clarifications.

1) You quoted a reference published in 2019 for sample size calculation; however, date of approval of your ethical vote would seem unclear. At least the ethical clearance number refers to 2018. Please clarify.

2) As you have indicated, date of approval of your ethical committee was 31/12/2019, thus approval would seem given to a study already started in 2018. This would seem puzzling, and most unlikely. Please clarify. Additionally, please forward the copy of your ethical approval issued by the institution.

3) Quantity of irrigating solutions must be clarified, since there are some variations in the revised manuscript not corresponding to your previous draft. This again would not seem convincing. Please clarify.

To ensure the Editor and Reviewers will be able to recommend that your revised manuscript is accepted, please pay careful attention to each of the comments that have been pasted underneath this email. This way we can avoid future rounds of clarifications and revisions, moving swiftly to a decision.

Once you have addressed each comment and completed each step listed below, please log in here with the same email you used to submit your manuscript to upload the revised submission and final file:

https://submission.nature.com/submit-revision/bb8820d7-2369-4cc8-a634-2517b22c3a52

CHECKLIST FOR SUBMITTING YOUR REVISION

1. Please upload a point-by-point response to the comments, including a description of any additional experiments that were carried out and a detailed rebuttal of any criticisms or requested revisions that you disagreed with. This must be uploaded as a 'Point-by-point response to reviewers' file.

You'll find a handy one-page PDF on how to respond to reviewers' comments here:

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2. Please highlight all the amends on your manuscript or indicate them by using tracked changes.

3. Check the format for revised manuscripts in our submission guidelines, making sure you pay particular attention to the figure resolution requirements:

https://www.nature.com/srep/publish/guidelines

Finally, if you have been asked to improve the language or presentation of your manuscript and would like the assistance of paid editing services, we can recommend our affiliates, Nature Research Editing Service: https://authorservices.springernature.com/language-editing and American Journal Experts: https://www.aje.com/go/springernature

If you need more time at any stage of the peer-review process, please do let us know. While our systems will continue to remind you of the original timelines, we aim to be as flexible as possible during the current pandemic.

---

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 8 Desember 2020 pukul 00.38
Kepada: Anuj Bhardwaj <dranuj_84@yahoo.co.in>

[Kutipan teks disembunyikan]

3. Check the format for revised manuscripts in our submission guidelines, making sure you pay particular attention to the figure resolution requirements:

https://www.nature.com/srep/publish/guidelines

Finally, if you have been asked to improve the language or presentation of your manuscript and would like the assistance of paid editing services, we can recommend our affiliates, Nature Research Editing Service: https://authorservices.springernature.com/language-editing and American Journal Experts: https://www.aje.com/go/springernature

Please note that use of an editing service is neither a requirement nor a guarantee of publication. Free assistance is available from our resources page: https://www.springernature.com/gp/researchers/campaigns/english-language-forauthors

To support the continuity of the peer review process, we recommend returning your manuscript to us within 28 days. If you think you will need additional time, please let us know and we will aim to respond within 48 hours.

Kind regards,

Andrej Kielbassa
Editorial Board Member
Scientific Reports

Reviewer Comments:

Reviewer 1
General remark
- English remains a concern. Please re-edit carefully.

Abstract
- "The XP-endo Shaper expelled significantly less dirt with a value of (...)." Do not use the word "dirt" with your scientific paper. Please revise.
- A clear conclusion not simply repeating your results is missing.
- With your revision, please stick to the 200-word limit.

Intro
- With your revision, please stick consequently to Sci Rep's Guidelines for Authors. Revise thoroughly, and re-edit headings and format of in-text references. Consult some recently published Sci Rep papers.
- This section is considered too long, with too many common places. Shorten considerably.
- BOTH aims AND objectives must be clearly elaborated. Please clarify why this study was necessary. There have been many studies revealing similar outcomes, and your paper is considered mainly confirmative only.

Meths
- Why do you repeatedly mention your ethical vote? See: "This current study was approved by the local review board and ethics committee (CDSH/IEC/2018- 19/004)." and "The study was also approved by the College of Den- tal Science & Hospital Ethics Committee (Certificate CDSH/IEC/2018-19/004)." Please revise thoroughly.
- "This sample size was calculated by projecting the power, effect size, and significant level as 0.91, 0.697, and 0.05, respectively." Rationale would seem unclear, please add information.
- With ALL materials and methodologies, please use general names with your text, followed by (brand name; manufacturer, city, country). Enable future readers to reproduce your research.
- Do not use legal terms with your text. Delete Inc., and so on.

Results
- Please indicate units with your tables.

Disc
- Do not simply repeat your results here. Remember that your heading is called "Discussion", but not "Repetition".
- Same with aspects of literature review.
- Discuss, explain, and speculate on methodology and results, respectively. This must be a critical discourse.
- "Therefore, the aim of this study was to quantify (...)." Please see comments given above. This section is NOT intended to elaborate the aims. Revise thoroughly.
- What about the limitations of your study?

Concl
- "This study is the first quantitative assessment of the debris extrusion during instrumentation with primary teeth using

the XP-endo Shaper file." This is not considered a conclusion. Please delete, or copy & paste elsewhere to your Disc section.
- Remember to provide a clear and generalizable extension of your outcome. This must stick to you re-elaborated aims.

Refs
- This section must be uniformly formatted. Again, please stick exclusively to Sci Rep's Guidelines for Authors.

In total, this submitted draft is not considered ready to proceed. Please remember that you have stated that "all authors critically re-vised drafts and approved the final work". This would seem doubtful when reflecting on the many minor and major shortcomings.

Reviewer 2
Reviewer's suggestion to the authors:
The reviewer appreciates the hard work done by the authors in completing the systematic review entitling "Apical debris extrusion amid instrumentation of oval root canals in primary teeth using manual vs. mechanized files."

Though, the manuscript was well presented there are few major concerns that need to be addressed by the authors. The major concerns were as follows:
General concerns:
1. The manuscript would have better visibility and relevance in any 'Pediatric Dentistry' journals.
2. Please address all grammatical mistakes and sentence formation issues.
3. Please expand all abbreviations in the text when they are used for the first time.

Abstract:
1. Please address the corrections suggested in the pdf.

Introduction:
2. Sentence formations need to be modified for better understanding.
3. In the third paragraph it was mentioned that "This induces post-operative pain, inflammation, and inhibit healing".
Did the authors mean 'peri-apical healing'?
If yes, please mention that.
4. It was mentioned that "Furthermore, very few studies have been conducted on Kedo-S pediatric rotary files [19,20]."
Doid authors mean 'very few studies conducted on Kedo-S files on debris extrusion'??
If yes, please mention that clearly for better understanding.

Methods:
5. Please mention the type of study, where and when the study was conducted.
6. It was mentioned that "Furthermore, forty-five primary canines were selected from a pool of recently extracted primary teeth".
Please mention,
How these samples were cleaned?
How do samples were stored?
Please mention and explain with references.
7. It was mention that "This sample size was calculated by projecting the power, effect size, and significant level as 0.91, 0.697, and 0.05, respectively".
Authors, please address
The values mentioned were taken from any previously published article?
If yes please mention the article as reference.
Or, these variables observed from any pilot study?
Please mention.
8. It was reported that "These included no evidence of resorption, a closed apex, and along through short canal diameter ratio of ≥ 2 at 5 mm from the apex".
How this diameter of more than 2 mm at 5 mm from apex was measured?
Please explain.
"mm" Please expand the term when it was used first time in the manuscript.
9. In root canal instrumentation section of Group 1: Hand K-files, it was mentioned that, "The root canals were instrumented before the estimated WL, using quarter turn and pull motion."
Authors, please explain the following:
It was mentioned earlier that each sample was standardized to have 15 mm length.
In that case, instrumentation was done till 14 mm (1 mm short of apex) in all samples?
If that is the case, authors can directly mention that "instrumentation was done till 14 mm from the coronal reference point.
Please expand the term "WL".
10. In root canal instrumentation section of Group 2: it was mentioned that "The 16 mm long Kedo-S E1 files were used in rotary motion of 300 rpm and 2 Ncm torque, powered by an electronic endomotor (X-Smart Plus; Dentsply Maillefer,

Ballaigues, Switzerland), according to the manufacturer's instructions.
What is the percentage of taper in these files?
Do these files directly inserted after access cavity preparation? or ant widening of the canal orifice is required?
In how many motions the file system was used?
Any standardization of procedure?
If yes please mention.

11. It was mentioned that "The canal was further irrigated, patency confirmed using a #15/0.02 K-file, and then re-introduced and retracted once WL was reached and the canal irrigated".
Please explain the irrigation protocol followed here.

12. In root canal instrumentation section of Group 3: it was mentioned that "The root canals were cleaned and shaped with the use of a 21 mm XP-endo Shaper file at 800 rpm and 1 Ncm, powered by an endomotor (X-Smart Plus), until WL was realized.
Authors, please explain
How many files are there in this system?
Does XP Endo shaper file have D1 of 0.30?
What is the filing system indicated by the manufacturer.
Please add all this information for a better understanding.

13. It was mentioned that "The file was used 4–5 times by the application of long gentle strokes towards WL, according to the manufacturer's instructions, and on attainment of this phase, was withdrawn and cleansed, the apical patency verified, the canal flooded with warm distilled water, and then reused for an additional 15 strokes to WL".
Please mention 'what was withdrawn'?
Was the number of strokes (15) standardized?
or recommended by manufacturer?

14. It was mentioned that "Furthermore, the irrigation during the root canal instrumentation were performed similarly for the samples in Groups 1 and 2, where a total volume of 12 ml distilled water, used in the course of the procedure and the final flush, was delivered with a syringe and needle".
Authors, please address
What is the flow rate of the irrigating solution?
How many ml of irrigation solution was used in how many minutes, because if this is not standardized, there are chances of bias in the experimental procedure?

15. In assessment of apically extruded debris section, it was mentioned that "Then, the tubes were placed in an incubator at 70 °C for 5 days to permit the evaporation of moisture before the determination of the mean weight of the contents obtained from three consecutive weights in milligrams, and the calculation of the dry mass of the apically extruded debris".
Please add a reference to this methodology.

Results:

16. It was reported that "All the instrumentation protocols examined exhibited debris extrusion, with the resultant weights of the extrusions represented in Table 1.
Please mention clearly regarding the P values in the Post-Hoc analysis.
The presentation in Table 1 is a bit confusing.

17. It was mentioned that "Consequently, the XP-endo shaper procedure was associated with the least debris extrusion, followed by the Kedo-S, with the hand K-file method producing the highest amount of debris, as revealed by The Tukey's post-hoc test".
Though Group 3 samples showed the least apical extrusion of debris, it has to be significantly different from the other 2 groups to recommend its use than the other two.
Thus, authors are requested to present the significant values more clearly for accurate interpretation and understanding.

18. In Table 2
Please present the P values of Tukey's post hoc test more clearly for better understanding.

Discussion:

19. Please mention if any limitations observed in the present study and suggest future directions for research.
The limitation of in-vitro study design needs to be mentioned and for future directions, randomized controlled are recommended to strengthen the findings that need to be added.

Conclusion:

20. It was mentioned that "In addition, the time required to complete root canal instrumentation was observably shorter compared to the Kedo-S and hand K-files".
Does this statement is related to XP-Endo shaper files?
If yes, please re-frame the sentence.

21. It was mentioned that "Hence, the adaptive XP-endo Shaper file is considered an instrument of choice in the root canal treatment of primary teeth".
Authors need to be cautious while writing the generalized statements.
The reasons are:

a) Authors have evaluated XP-endo shaper files only in canines, so they cannot generalize the statements to whole

primary teeth.
They need to be testes on other types of teeth as well.
b) Is in an in-vitro study, with successful in-vitro studies, authors cannot recommend the new file systems directly. They need to be tested for efficiency (ideally randomized controlled trials) in clinical conditions, and then only these generalized statements can be written.

Reviewer 3
Dear Editor/ authors,

I would like to thank you for the opportunity of the present revision, which I hope would contribute to the final paper.

Summary:

The recommendation: Revise, with the possibility of resubmission after minor revision.

Comments to the authors/editor:

The theme is relevant and the authors addressed it properly regarding the methodology. Perhaps, the authors could consider including some information at the materials and methods section to contribute to the reproducibility of the study. This review was based on a guideline for reporting pre-clinical in vitro studies on dental materials (J Evid Base Dent Pract 2012;12:182-189).

- Materials and methods:

- Please, report how the freshly extracted teeth were processed and stored until the experimental procedures.
- Please, consider reporting the method used to generate the random allocation sequence.
- Perhaps, the authors could report if the single operator was experienced in endodontics or was previously trained or calibrated.
- Perhaps, the authors could consider reporting if a blinded evaluator performed the extruded debris assessment.

- Discussion:

- Please, consider reporting the study limitations.
- Please, consider suggesting future studies.

Please, English needs attention.

Our flexible approach during the COVID-19 pandemic

If you need more time at any stage of the peer-review process, please do let us know. While our systems will continue to remind you of the original timelines, we aim to be as flexible as possible during the current pandemic.

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agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 28 September 2020 pukul 14.58
Kepada: Anuj Bhardwaj <dranuj_84@yahoo.co.in>

[Kutipan teks disembunyikan]

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agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id> 29 September 2020 pukul 18.26
Kepada: Scientific Reports <srep@nature.com>

Dear Editor and Reviewer
Thank you so much for your support. Reviewer 2 mentioned (relating to abstract) that he has made corrections on a PDF. Unfortunately I did not get a PDF in my email. Would you like to help me please.
Warm regards
Dian
[Kutipan teks disembunyikan]

---

agustin wahjuningrum Dian <dian-agustin-w@fkg.unair.ac.id>

Scientific Reports: Decision on your manuscript

1 pesan

Scientific Reports <srep@nature.com> 4 Februari 2021 pukul 12.47
Kepada: dian-agustin-w@fkg.unair.ac.id

Ref: Submission ID bb8820d7-2369-4cc8-a634-2517b22c3a52

Dear Dr Wahjuningrum,

Re: “Apical debris extrusion during instrumentation of oval root canals in primary teeth using manual versus motorized files: An ex vivo study. ”

We’re delighted to let you know your manuscript has now been accepted for publication in Scientific Reports.

Editorial Board Member comments
As has been indicated by our external referees, this revised and re-submitted paper would seem satisfying now. Compliments, congratulations, and stay healthy, please.

Andrej M. Kielbassa, Prof. Dr. med. dent. Dr. h. c.
Academic Editor

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Once again, thank you for choosing Scientific Reports, and we look forward to publishing your article.

Kind regards,

Andrej Kielbassa
Editorial Board Member
Scientific Reports

Reviewer Comments:

Reviewer 2
I thank authors for considering my inputs in improving the quality of manuscript.

Reviewer 1
This revised and re-submitted paper is ready to proceed.

P.S. If appropriate, you may also consider uploading any protocols used in this manuscript to the protocol exchange, part of our online web resource, https://protocolexchange.researchsquare.com. By participating, you are enabling researchers to reproduce or adapt your methodology. The protocol exchange is fully searchable, providing your protocols and paper with increased utility and visibility. Protocols can also be easily updated via versioning. Please submit your protocol to https://protocolexchange.researchsquare.com/submission. You may need to create a new Research Square account. Please provide details of this article in the associated publications section. You'll find more information at: https://protocolexchange.researchsquare.com

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Our flexible approach during the COVID-19 pandemic

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3. Please expand all abbreviations in the text when they are used for the first time.

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Introduction:

2. Sentence formations need to be modified for better understanding.
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   Did authors mean 'peri-apical healing'?

   If yes, please mention that.
4. **It was mentioned that "Furthermore, very few studies have been conducted on Kedo-S pediatric rotary files [19,20]."**

   Doid authors mean 'very few studies conducted on Kedo-S files on debris extrusion'??

   If yes, please mention that clearly for better understanding.

Methods:

5. Please mention the type of study, where and when the study was conducted.
6. **It was mentioned that "Furthermore, forty-five primary canines were selected from a pool of recently extracted primary teeth".**

   Please mention,

   How these samples were cleaned?

   How does samples were stored?

   Please mention and explain with references.

7. **It was mention that "This sample size was calculated by projecting the power, effect size, and significant level as 0.91, 0.697, and 0.05, respectively".**

   Authors, please address

   The values mentioned were taken from any previously published article?

   If yes please mention the article as reference.

   Or, these variables observed from any pilot study?

   Please mention.

8. **It was reported that "These included no evidence of resorption, a closed apex, and a long through short canal diameter ratio of ≥ 2 at 5 mm from the apex".**

   How this diameter of more than 2 mm at 5 mm from apex was measured?

   Please explain.

   "mm" Please expand the term when it was used first time in the manuscript.

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   Authors please explain the following:

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   In that case, instrumentation was done till 14 mm (1 mm short of apex) in all samples?

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   Please expand the term "WL".

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    What is the percentage of taper in these files?

    Does these files directly inserted after access cavity preparation? or ant widening of the canal orifice is required?

    In how many motions the file system was used?

    Any standardization of procedure?

    If yes please mention.

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    Please explain the irrigation protocol followed here.

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    Authors please explain

    How many files are there in this system?

    Does XP Endo shaper file have D1 of 0.30?

    What is the filing system indicated by the manufacturer.

    Please add all this information for better understanding.

13. **It was mentioned that "The file was used 4–5 times by the application of long gentle strokes towards WL, according to the manufacturer's instructions, and on attainment of this phase, was withdrawn and cleansed, the apical patency verified, the canal flooded with warm distilled water, and then reused for an additional 15 strokes to WL".**

    Please mention 'what was withdrawn'?

    Was number of strokes (15) standardized?

    or recommended from manufacturer?

14. **It was mentioned that "Furthermore, the irrigation during the root canal instrumentation were performed similarly for the samples in Groups 1 and 2, where a total volume of 12 ml distilled water, used in the course of the procedure and the final flush, was delivered with a syringe and needle".**

    Authors please address

    What is the flow rate of the irrigating solution?

    How many ml of irrigation solution was used in how many minutes, because if this is not standardized, there are chances of bias in experimental procedure?

15. **In assessment of apically extruded debris section, it was mentioned that "Then, the tubes were placed in an incubator at 70 °C for 5 days to permit the evaporation of moisture before the determination of the mean weight of the contents obtained from three consecutive weights in milligrams, and the calculation of the dry mass of the apically extruded debris".**

    Please add reference to this methodology.

Results:

16. **It was reported that "All the instrumentation protocols examined exhibited debris extrusion, with the resultant weights of the extrusions represented in Table 1.**

    Please mention clearly regarding the P values in Post-Hoc analysis.

The presentation in Table 1 is a bit confusing.

17. **It was mentioned that "Consequently, the XP-endo shaper procedure was associated with the least debris extrusion, followed by the Kedo-S, with the hand K-file method producing the highest amount of debris, as revealed by The Tukey's post-hoc test".**

    Though, Group 3 samples showed least apical extrusion of debris, it has to be significantly different with other 2 groups to recommend its use than other two.

    Thus, authors are requested to present the significant values more clearly for accurate interpretation and understanding.

18. In Table 2

    Please present the P values of Tukey's post hoc test more clearly for better understanding.

Discussion:

19. Please mention if any limitations observed in the present study and suggest future directions for research.

    The limitation of in-vitro study design needs to be mentioned and for future directions, randomized controlled are recommended to strengthen the findings need to be added.

Conclusion:

20. **It was mentioned that "In addition, the time required to complete root canal instrumentation was observably shorter compared to the Kedo-S and hand K-files".**

    Does this statement is related to XP-Endo shaper files?

    If yes, please re-frame the sentence.

21. **It was mentioned that "Hence, the adaptive XP-endo Shaper file is considered an instrument of choice in the root canal treatment of primary teeth".**

    Authors need to be cautious while writing the generalized statements.

    The reasons are:

    a) Authors have evaluated XP-endo shaper files only in canines, so they cannot generalize the statements to whole primary teeth.

       They need to be testes on other types of teeth as well.

    b) Is in an in-vitro study, with successful in-vitro studies, authors cannot recommend the new file systems directly.

       They need to be tested for efficiency (ideally randomized controlled trials) in clinical conditions, and then only these generalized statements can be written.

Apical debris extrusion during instrumentation of oval root canals in primary teeth using manual versus mechanized files: An *ex vivo* study.

Running Title: Apical extrusion of debris in primary teeth.

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Keywords: Apical extrusion, debris, hand files, K-files, Kedo-S files, XP-endo Shaper files

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Abstract

This study aimed to assess the apical extrusion of debris during instrumentation of oval canals in primary canines using three endodontic file types. Forty-five extracted primary canines with oval canals were randomly assigned to three groups (n=15): Group 1, hand K-files; Group 2, Kedo-S files; and Group 3, XP-endo Shaper files. The apically extruded debris produced during the procedure was collected and dried in pre-weighed Eppendorf tubes, and the mass of debris was calculated. The time required for the endodontic procedure was also recorded. Analysis of variance (ANOVA) and Tukey's post hoc test were used with a significance level set at 5%. XP-endo Shaper and Kedo-S files extruded significantly less debris compared with hand K-files with means of 0.84 ± 0.31 and 1.20 ± 0.67 mg, respectively, compared to 2.13 ± 0.31 mg ($p < 0.0001$). No significant difference was identified between the two mechanized files. Less time was required to complete the procedure with the XP-endo Shaper compared to the hand K-files ($p < 0.0001$) and Kedo-S files ($p < 0.0001$). Within the limitations of the present study, it may be concluded that the motorized files extruded less debris and required less time compared to traditional K-files.

Autor
Kommentar [1]: Please expand the abbreviation.

Autor
Kommentar [2]: Please modify this statement.

Autor
Kommentar [3]: Please clarify motorized file here.

Introduction

Pulpectomy and root canal procedures remain the first treatment option in primary teeth with pulpal involvement[1]. This therapy aims to heal and/or maintain the involved periapical tissue and salvage the teeth until the eruption of permanent successors[2].

Traditionally, root canal shaping was achieved with hand instrumentation, such as K-files. However, the use of such files may result in canal aberrations, perforations, inadequate cleaning and transportation of the root canal. Hand instrumentation also requires a rather long chair time for patients[3].

Kedo-S paediatric nickel titanium (NiTi) rotary files (Reeganz Dental Care, Chennai, India) were introduced to overcome some of the above problems[4]. The files are shorter than the common NiTi rotary files (total length 16 mm), and their flexibility allows better adaptation to curvatures that are often found in primary teeth[4]. The file has a triangular cross-section and a non-cutting tip with a 12-mm long active part and a taper that gradually changes from 0.04 to 0.08. These files are used as a single file system.

Autor
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Root canals with an oval cross-section are common in primary dentition[5]. Oval canals present a challenge to all rotating files that have a central metal core. Rotating endodontic files have a tendency to create a space with their own shape with a round cross-section. Such root canal preparation may leave uninstrumented recesses in which tissue remnants and debris may be left untouched[6]. The recently introduced XP-endo Shaper (FKG Dentaire, La Chaux-de-Fonds, Switzerland) was specifically designed to meet the challenge of oval root canals[7]. The file has a size 30 “booster tip” design that includes a combination of a smooth bullet-shaped tip followed by six cutting edges and a smooth transition from the tip base to the helical shaft made of a size 30 wire with a 0.01 taper. This file is made from a special thermomechanically treated shape-memory Ni-Ti alloy and has a snake-like shape at room temperature (martensite phase). When exposed to 37°C, a transfer to the austenite phase occurs, and the snake-like

Autor
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shape is enhanced and assumes a greater rotational envelope of motion that is equivalent to size 30 tip with a 0.04 taper. This dimension is achieved with no solid central part[8]. When used at 800 rounds per minute and with long in-and-out pecking motions, the tip of the file enters repeatedly into and cleans the recesses of the oval canal. The XP-endo Shaper is a single file system.

All endodontic instrumentation methods have a tendency to push debris through the apical foramen and into the periapical tissues[9,10,11]. Such debris may consist of necrotic pulp tissue, dentin chips and bacteria. Extrusion of such debris may induce postoperative pain and inflammation and may inhibit periapical healing[9,10,11]. A growing body of literature has recognized the importance of reducing apically extruded debris[9,10,11].

The extent of debris extrusion and the time required for instrumentation of the canals of primary teeth using adaptive XP-endo Shaper files have not been reported to date. Very few studies have been conducted on debris extrusion by Kedo-S paediatric rotary files[12,13].

The present study aimed to measure and compare the amount of apically extruded debris using Kedo-S paediatric rotary files and the new XP-endo Shaper files and to compare both to traditional hand-operated K-files. Measuring the time required to complete the procedure by these three files was a second goal of the present study.

This study examined the following two-fold null hypothesis: (a) there is no difference in apically extruded debris between hand-operated K-files and the two mechanized systems and (b) the time required for completing the procedures is not different among the three tested files.

Autor
Kommentar [6]: delete

Autor
Kommentar [7]: did authors mean 'bio-mechanical preparation'?
If yes please mention

Autor
Kommentar [8]: Authors are requested to mention what are mechanized files earlier or here.
Quoting the mechanized files directly may confuse the readers.

Autor
Kommentar [9]: File systems

Materials and methods

Sample allocation and ethical approval. This *ex vivo* study was approved by the College of Dental Science & Hospital Ethics Committee (Certificate CDSH/IEC/2018-19/004). Forty-

five primary canines were selected from a pool of recently extracted primary teeth. The roots of the teeth were cleaned using periodontal curettes, and the teeth were stored in water with 5% thymol at 4°C until use in the experiments[14]. This sample size was calculated by projecting the power, effect size, and significance level as 0.91, 0.697, and 0.05, respectively, based on the results of a previous study[12].

Autor

Kommentar [10]: The quoted reference was published in 2019, whereas the present study got ethical clearance in 2018 (as understood from ethical committee number provided earlier). How come authors estimated the sample size in 2018, using a reference article published in 2019???
Please clarify and provide correct information.

Inclusion criteria. The inclusion criteria were a single canal and foramen as confirmed by bucco-lingual and mesio-distal radiographs. These criteria also included no evidence of resorption, a closed apex, and a long through short canal diameter ratio of ≥ 2 at 5 millimetres from the apex, as measured from bucco-lingual and mesio-distal radiographs[15]. Access cavities were made, and canal patency was assessed for all samples by inserting a #10 K-file (Mani, Tokyo, Japan) until visible at the apical foramen. The working length (WL) was established as 1 mm short of the apex. The clinical crowns of the teeth were further ground using a high-speed diamond straight fissure bur under air-water spray to obtain a total length of 15 mm and WL 14 mm in the standardization of all samples. The 45 samples were then sequentially numbered and randomly divided (www.random.org) into 3 groups (*n=15)* for cleaning and shaping by one of three methods, including hand K-files, Kedo-S paediatric rotary files, and XP-endo Shaper files.

Experimental model. The model was proposed by Myers and Montgomery[16], and modifications to the apparatus which were suggested by Kfir et al.[11] were used to measure the apical extrusion of debris (Figure 1). Forty-five 1.5-millilitre Eppendorf tubes were obtained, and the caps of the tubes were separated. The tubes without caps were weighed to 10^{-5} g precision using a microbalance (Sartorius Intec; Hamburg, Germany). Additionally, three consecutive weight measurements were acquired per tube, and the mean value was recorded. Subsequently, fifteen tubes were assigned to each of the three groups.

Forty-five glass scintillation vials were acquired, and holes were created in the caps where a primary canine was inserted with the apex facing down to the level of the cementoenamel junction. The teeth were secured in place with a flowable composite (Filtek Supreme; 3 M/ESPE, St Paul, USA). Additionally, a 25-gauge needle was also placed and secured in the cap to equalize air pressure in and out of the vial. A small holding template was created on the bottom of the vial using silicon impression material (Coltene/Whaledent, Langenau, Germany) to hold and stabilize each Eppendorf tube so that when the caps were fitted onto the vials, the root tip was located within the Eppendorf tube without touching its walls. The glass vials were then covered with a rubber dam such that the operator was blocked from viewing the debris extrusion amid tooth canal preparation. (Figure 1) The entire apparatus was exclusively handled by the scintillation vial.

Root canal instrumentation Group 1: Hand K-files. The root canals were instrumented to 14 mm from the coronal reference point using quarter turn and pull motion. Stainless steel hand operated K-files were utilized in a sequence of #15/0.02, #20/0.02, #25/0.02, and #30/0.02 (Mani, Tokyo, Japan). Irrigation was performed before and after each file using a syringe and needle (NaviTip 31G; Ultradent, South Jordan, UT, USA). The needle was inserted at each stage and withdrawn 2 mm short of where it engage at this stage or 2 mm short of WL. One mL of distilled water was used for irrigation at each stage with a total irrigation volume of 4 mL per tooth.

Root canal instrumentation Group 2: Kedo-S paediatric rotary files. Kedo-S is a single file system, and the E1 file used in the present study has a #30 tip and gradually changing taper from 0.04 to 0.08 (Reeganz Dental Care, Chennai, India). The 16-mm long files were used in rotary motion of 250 rounds per min and 2 Newton-centimetre torque powered by an electronic endomotor (X-Smart Plus; Dentsply Maillefer, Ballaigues, Switzerland) according to the manufacturer's instructions. No preflaring was required. Gentle in-and-out motions

were used to reach WL. Once the file met resistance, the file was retracted, cleaned with a gauze and applied again. Once the file reached WL, apical patency was verified, and the file used with five in-and-out motions to WL, as per manufacturer's instructions. Irrigation was performed using a syringe and needle (NaviTip). The needle was inserted at each stage and withdrawn 2 mm short of where the needle engaged at this stage or 2 mm short of WL. One mL of distilled water was used for irrigation before insertion of the file into the canal, after the first withdrawal of the file (for cleaning), after reaching WL (before the final 5 in-and-out movements) and after completing the instrumentation with a total irrigation volume of 4 mL per tooth.

Root canal instrumentation Group 3: XP-endo Shaper. The root canals were cleaned and shaped using a 21 mm XP-endo Shaper file, as a single file, following manufacturer's instructions. The file was operated at 800 rpm and 1 Newton-centimetre, powered by an endomotor (X-Smart Plus), until WL was reached. Initially, the file was placed passively into the canal until resistance was encountered, then the tip retracted 2 mm, and the endomotor activated. The file was then used 4–5 times by the application of long gentle strokes towards WL. Once the file reached WL the file was withdrawn and cleansed, the apical patency verified, the canal flooded with warm (37°C) distilled water, and then the file reused for an additional 15 in-and-out strokes to WL, as recommended by the manufacturer.
Irrigation was performed using a syringe and needle (NaviTip). The needle was inserted at each stage and withdrawn 2 mm short of where it engaged at this stage or 2 mm short of WL. The irrigant was warmed to 37°C to allow transition from the martensite to the austenite phase. One mL of distilled water was used for irrigation before insertion of the file into the canal, after the first 5 strokes, after reaching WL (before the final 15 in-and-out movements) and after completing the instrumentation, with a total irrigant volume of 4 mL per tooth.

Autor
Kommentar [11]: Please re-frame the sentence for better understanding.

Autor
Kommentar [12]: All requested details regarding XP Endo shaper was not included.
Please explain in details here rather than simply writing as per manufacturer's instructions.

Autor
Kommentar [13]: Please add complete details as requested earlier.

Autor
Kommentar [14]: What is the gauge of the needle and length of the needle.

Autor
Kommentar [15]: Provide complete details

Autor
Kommentar [16]: How did the irrigating solution was warmed?
What procedure was followed?
Please explain here for better understanding.

Autor
Kommentar [17]: Of files???
If yes please mention clearly.

Autor
Kommentar [18]: Irrigation protocol need to be clarified.
Please add what is the flow rate of the irrigation solution used in tooth ?
(Requested to add in first revision, but not addressed).

In addition in the first manuscript, it was mention that a total of 12 ml solution was used for irrigation. But, in the revised manuscript, it was mentioned that only 4 ml was used for irrigation.

Please clarify.
The methodology should not be changed in the revisions. Authors are requested to stick to the original method used and please report the methods followed during the study.

A new file was used to prepare each canal, and a single operator performed all the experiments to avoid inter-operator variability. The operator was an experienced paediatric dentist who had intensive experience with the use of each of the three endodontic file systems.

Assessment of apically extruded debris. Following root canal preparation, the caps of the vials were unscrewed and the Eppendorf tubes removed. The surface of the root was washed with 1 mL of distilled water to collect adhered debris into the Eppendorf tubes. Then, the tubes were placed in an incubator at 70°C for 5 days to permit the evaporation of all moisture. The weight of each tube was determined as the mean weight from three consecutive weights in milligrams. The weight of the tube before the procedure was subtracted from the above, thus resulting in the weight of extruded debris [9,11].

Assessment of time required for instrumentation. The duration of the procedure was recorded by the operator performing the study using a digital stopwatch. The starting point was the first insertion of the file into the canal, and the end point was the end of the final irrigation with distilled water.

Statistical analysis. The amount of extruded debris, alongside the time required for the instrumentation, was analysed statistically by the implementation of a one-way analysis of variance (ANOVA) followed by Tukey's *post hoc* test for the execution of multiple comparisons. The level of significance was set at 5%, and all analyses were performed with Statistical Package for the Social Sciences version 20 for Mac (SPSS Inc., Chicago, IL, USA).

Results

Debris extrusion. The amount of apically extruded debris by each of the three file systems is presented in Table 1. The mean weights were 2.13 (± 0.46) mg in Group 1 (Hand K-files), 1.2 (± 0.67) mg in Group 2 (Kedo-S) and 0.84 (± 0.31) mg in Group 3 (XP-endo Shaper). Significant differences among the groups were identified (ANOVA, $p < 0.0001$). Tukey's *post hoc* test revealed that the amount of extruded debris in both the XP-endo Shaper and Kedo-S groups was significantly less than the amount of debris extruded in the Hand K-file group ($p < 0.0001$). However, the amount of debris in the two mechanized file groups did not differ significantly from each other (Table 1).

Time required for instrumentation. The mean time required to complete the procedures was 7.33 ± 1.2 minutes in Group 1, 4.61 ± 0.73 minutes in Group 2, and 2.38 ± 0.58 minutes in Group 3 (Table 2). A significant difference was found among the groups (ANOVA, $p < 0.001$), and Tukey's *post hoc test* indicated that significantly less instrumentation time was required in the XP-endo Shaper group compared to the other two groups ($p < 0.001$). Groups 2 and 3 were also significantly different from each other ($p < 0.0001$, Table 2).

Autor
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Discussion

Data on debris extrusion during the shaping of root canals of primary teeth with the new adaptive XP-endo Shaper were previously non-existent to the best of our knowledge. The present results indicate that both XP-endo Shaper and Kedo-S procedures were associated with less apically extruded debris than the use of hand K-files ($p < 0.0001$). Therefore, the first null hypothesis was rejected.

The findings broadly support previously reported studies[1,2,3,9,12,13,17,18]. Apical extrusion of debris is caused by accumulation of debris in the apical part of the canal where it may be pushed beyond the apex[19]. The high amount of debris extruded by the K-files could result from the filing motion, which may act as a piston when the files are engaged in the apical third of the canal [20]. Furthermore, the K-files have a constant (0.02) taper, which may provide less space in the apical part for dentin chips and debris that have to be transported coronally; consequently, the debris may be pumped apically[21].

It could be expected that the XP-endo Shaper will cause less debris extrusion than the rotary Kedo-S files due to the differences in their shape and mode of action. The Kedo-S rotary file with its bulky core (size 30 and 0.04 to 0.08 taper, Figure 2) fills the apical part of the canal and leaves little space for the suspension of debris compared to the loose space around the XP-endo Shaper (Size 30 and 0.01 taper, Figure 2). Furthermore, when rotating at 800 rpm and at 37°C, the file has an envelope of motion with a 0.04 taper, the centre of which is hollow in contrast to the solid metal core in the Kedo-S file.

The method of debris removal by the two file systems is also completely different. The XP-endo Shaper suspends the debris and carries it coronally with a tornado-like movement of the irrigant created by the speed of rotation (800 rpm) and the snake-like shape of the file[7,19]. Such suspension and transportation of debris was expected to be more efficient than forcing debris coronally by the rotation of the flutes of the Kedo-S file[7,19]. Despite these differences in shape and mode of action and even though the mean amount of apically extruded debris was apparently reduced with the XP-endo Shaper, the difference in apical extrusion of debris between the groups was not statistically significant (Table 1). The reason could be that the piston effect at the apical 2-3 mm of the pecking in-and-out motion used with both instruments had more influence than the potential benefit of the way the XP-endo Shaper file is transporting debris coronally.

Autor
Kommentar [20]: Please mention the names

The XP-endo Shaper was selected for the present study as it is a new device specially designed to overcome a major specific problem in root canal instrumentation. Many root canals in the primary dentition have root canals with an oval cross-section [5]. Most current motorized files, including the Kedo-S file, have a solid metal core and tend to create a space with a circular shape in every root canal, which may limit the cleaning ability of the endodontic procedure. Esentürk et al.[22] recently demonstrated that when rotary files are used in primary teeth, 60% of the canal wall area remains uninstrumented. Canal preparations with a round cross-section are likely to leave tissue, bacteria and debris in the uninstrumented recesses of oval canals, thus jeopardizing treatment prognosis[23].

A dominant benefit of using motorized files in primary teeth is reduction of the time required to complete the endodontic procedure[18,24]. Reducing the time may be especially beneficial when children are treated, as it may enhance patient cooperation. The present results indicate that the use of XP-endo Shaper required 68% less time than hand instrumentation with K files ($p < 0.0001$). The Kedo-S file also reduced instrumentation time by 37%, but the procedure required more time than that with the XP-endo Shaper ($p < 0.0001$). Thus, the second hypothesis had also been rejected.

The difference in time required between the two motorized procedures may have resulted from the mode by which each of the files was used to reach WL. The Kedo-S file has to remove a large amount of dentin with its rather bulky active part before its non-cutting tip may reach the working length. Consequently, one has to stop at least once or twice to remove the accumulated debris from the file's flutes if one does not want to apply excessive force during this procedure. The tip of the XP-endo Shaper has a unique design that makes reaching WL very fast with almost no pressure. The tip is divided into two parts. The apical part of the tip has a non-cutting bullet shape, which then changes into 6 cutting blades that then merge into the thin shaft with a 0.01 taper. It seems that these features allow the XP-

endo Shaper file to reach WL easily and quickly with minimal resistance. The XP-endo Shaper file is not expected to shape the canal but rather clean it with its tip entering the canal irregularities with each of the following 15 long pecking strokes that are recommended by the manufacturer. Further studies with micro CT may be required to examine the effectiveness of cleaning the canals of primary teeth by these two devices.

It must be kept in mind that the present study was conducted using only single rooted primary canines with straight roots. Naturally, the time required to complete treatment of three rooted primary molars may be longer. Primary molars often have curved root canals with oval cross-sections[5]; thus, further studies on the use of XP-endo-Shaper in primary molars may be required using both micro CT and debris extrusion measurements while also measuring the time required to complete the procedure.

Conclusions

Within the limitations of the present study, it may be concluded that the motorized files extruded less debris and required less time compared to traditional K-files.

Autor

Kommentar [21]: Authors are requested to present the conclusion in explanatory manner with at least three important observations from the study.

1. Regarding extrusion of apical debris.
2. Time required for instrumentation
3. Any future recommendations or any other significant finding.

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Author Contributions

A.M.P. and B.A.P. planned and designed the study. B.A.P. performed the experiment. A.M.P. and J.A. drafted the manuscript. A.K., A.B., and A.M.L. prepared the statistical section. Additionally, Z.M. and A.K. conducted the editing and final proofreading of the entire document, and D.A.W. reviewed the article and contributed to the interpretation. However, all authors critically revised drafts and approved the final work.

Competing interests

Furthermore, all authors have no conflicts of interest related to the present study.

Additional information

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Legends to figures

Figure 1. Schematic presentation of the apparatus used to obtain apically extruded debris, originally proposed by Myers and Montgomery with modifications suggested by Kfir et al.

Autor
Kommentar [22]: Not required here.

Figure 2. Radiographic image of the three files in a primary canine (mesio-distal projections) (a) #30 hand K-file, (b) KedoS E1 rotary file, and (c) XP-Endo Shaper.

Legend to Tables

Table 1. Weights of apically extruded debris (mg).

Table 2. Instrumentation time required to complete the procedure in minutes.

Autor
Kommentar [23]: Make sure that the table legends are same everywhere.

Table 1. Apical extrusion of debris

Group	Files	Sample Size	Mean (±SD)	Tukey HSD p values		
				Group 1	Group 2	Group 3
1	Hand K-files	15	2.13 (±0.46)*	--	.000	.000
2	Kedo-S	15	1.20 (±0.67)	.000	--	0.127
3	XP-endo shaper	15	0.84 (±0.31)	.000	0.127	--

- Milligrams of debris

Table 1. Analysis of variations in the mean weight of apical debris using three different file systems.

Group	Files	Sample Size	Mean weight of apical debris in milligrams (±SD)	Tukey HSD p values
1	Hand K-files	15	2.13 (±0.46)	0.000*; 0.000**
2	Kedo-S	15	1.20 (±0.67)	0.127***
3	XP-endo shaper	15	0.84 (±0.31)	

*Comparison between Hand K-files and Kedo-S; ** Comparison between Hand K-files and XP-endo shaper; *** Comparison between Kedo-S and XP-endo shaper;
P value of less than 0.05 was considered as statistically significant.

Table 2. Time required to complete the procedure

Group	Files	Sample Size	Mean (±SD)	Tukey HSD p values		
				Group 1	Group 2	Group 3
1	Hand K-files	15	7.33 (±1.20)*	--	.000	.000
2	Kedo-S	15	4.61 (±0.73)	.000	--	.000
3	XP-endo shaper	15	2.38 (±0.58)	.000	.000	--

- Minutes

Autor
Kommentar [24]: Please modify as suggested in Table 1.

Apical debris extrusion amid instrumentation of oval root canals in primary teeth using manual vs. mechanized files.

Running Title: Apical extrusion of debris in primary teeth.

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Keywords: Apical extrusion, debris, hand files, K-files, Kedo-S files, XP-endo Shaper files

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Abstract

This study aimed to assess the apical extrusion of debris due to oval canal instrumentation in primary canines using three endodontic file types. Furthermore, forty-five extracted primary canine teeth with fully formed apices and single large oval canals were acquired and randomly assigned to three groups for this process. These included Group 1: hand K-, Group 2: Kedo-S, and Group 3: XP-endo Shaper files, where (n = 15). The apically extruded debris produced amid the procedure was obtained and dried in pre-weighed Eppendorf tubes. Subsequently, the mass was calculated by subtracting the pre- and post-instrumentation weights of the tubes. The time required for this process was recorded. Also, analysis of variance (ANOVA) and Tukey's post-hoc test was used with a significance level set at 5%. The XP-endo Shaper expelled significantly less dirt with a value of 0.84 ± 0.31 mg and required a lower time to complete the operation at 2.38 ± 0.58 minutes than the Kedo-S and hand K-files, where $P < 0.001$. Therefore, group 3 reduces the amount of deposit and shortens the procedure time while shaping the oval root canals of primary canines.

Introduction

The anatomy of root canals in primary teeth is complex, therefore endodontic treatment is difficult. However, pulpectomy procedures with pulpal involvement remain the first treatment option [1]. This therapy aims to heal and maintain the involved periapical tissue and salvage the teeth before the eruption of permanent successors [2].

The root canal shaping achieved with hand instrumentation involves canal aberrations, perforations, inadequate cleaning, transportation, instrument fracture, and long chair time for patients [3]. According to Barr *et al*. 2000 [4], nickel-titanium (Ni-Ti) rotary files were used for root canal preparation. Furthermore, interest in the use of motorized root canal instrumentation while treating primary teeth has consequently increased [5,6].

The use of rotary equipment enhances root canal instrumentation in primary teeth concerning uniform shaping and is therefore beneficial in obtaining adequate three-dimensional obturation [7,8]. However, debris formed during root canal instrumentation is extruded through the apical foramen into the periapical region. This induces post-operative pain, inflammation, and inhibit healing. [3,8]

Furthermore, Jeevanandan[9] introduced and demonstrated a proprietary Kedo-S pediatric rotary file (Reeganz Dental Care Private, Chennai, India) for primary teeth root canal instrumentation in 2017. These files are suggested by previous studies to be more effective than the frequently used manual types in this procedure [10-14].

Furthermore, a new concept involving an adaptive rotary file was recently developed and termed the XP-endo Shaper (FKG Dentaire, La Chaux-de-Fonds, Switzerland). This type was manufactured from a thermo-mechanically treated Ni-Ti alloy and has a #30 tip size with an initial taper of 0.01. The snake-like form expanded and eventually reached a final preparation size of 30 with a 0.04 taper once the temperature was similar to the patients' amid instrumentation. This file also features a booster tip with six cutting edges, a smooth transition from the tip base to the helical shaft [15], and is specifically designed to address the three-dimensional morphology of root canal systems, including

those with oval cross-sections. However, solid metal-cored rotary used in non-round root canals has been reported to be less effective [16].

The primary maxillary canines have a single, oval-shaped large root canal [17]. However, this type poses a challenge in the instrumentation. Also, there have been conclusive reports on rotary files leaving around 40–60% of the area untouched in non-round root canals [18].

Also, a growing body of literature has recognized the importance of reducing the apically extruded debris. The debris extrusion results and shaping time required in primary teeth after root canal instrumentation using adaptive XP-endo files have not been reported to date. Furthermore, very few studies have been conducted on Kedo-S pediatric rotary files [19,20].

This study investigated the usefulness of adaptive XP-endo Shaper in the reduction of debris extrusion and root canal shaping times while instrumenting large oval-shaped root canals in primary canines. The effectiveness of Kedo-S pediatric rotary type was examined as well, while hand K-file instrumentation served as the control. This study examined a two-fold null hypothesis where there is no significant difference in apically extruded debris and time required for shaping among the three tested files.

Materials and methods

Sample allocation

This current study was approved by the local review board and ethics committee (CDSH/IEC/2018-19/004). Furthermore, forty-five primary canines were selected from a pool of recently extracted primary teeth. This sample size was calculated by projecting the power, effect size, and significant level as 0.91, 0.697, and 0.05, respectively. The inclusion criteria were a single canal and foramen as confirmed by Bucco-lingual and mesio-distal radiographs. These included no evidence of resorption, a closed apex, and a long through short canal diameter ratio of ≥ 2 at 5 mm from the apex [21]. Moreover, access cavities were made, and canal patency checked for all samples by inserting a #10 K-file (Mani, Tokyo, Japan) before visibility at the apical foramen. The working length (WL) was established as 1

mm short. These clinical crowns were further ground using a high-speed diamond straight fissure bur, under cold water to obtain a total working length of 15 mm in the standardization of all samples. The samples were then randomly divided into 3 groups, where *n=15* for cleaning and shaping by one of three methods, including hand K-, Kedo-S pediatric rotary, and XP-endo Shaper files.

Experimental model

The model proposed by Myers and Montgomery [22], and modifications to the apparatus suggested by Kfir *et al.* [23] was used to measure the apical extrusion of debris (Picture 1). Furthermore, forty-five 1.5 mL Eppendorf tubes were obtained, and the caps separated. The tubes without caps were weighed to 10^{-5} g precision using a microbalance (Sartorius Intec; Hamburg, Germany). Also, three consecutive weight measurements were acquired per tube and the mean value recorded. Subsequently, fifteen tubes were assigned to each of the three groups.

Furthermore, forty-five glass scintillation vials were acquired, and holes created in the caps where a primary canine was inserted, apex down to the cementoenamel junction. This was further secured in place with a flowable composite (Filtek Supreme; 3 M/ESPE, St Paul, USA). However, a 25-gauge needle was also placed in the cap to equalize air pressure in and out of the ampoule. Also, a small-holding template was created beneath. This was conducted using silicon impression material (Coltene/Whaledent, Langenau, Germany) to stabilize each Eppendorf tube with the root tip, as the caps were fitted onto the vials. The glass vials were covered by a rubber dam; therefore the operator was blocked from viewing the debris extrusion amid tooth preparation. Figure 1 shows the entire apparatus was solely handled by the scintillation.

Root canal instrumentation

Group 1: Hand K-files

The root canals were instrumented before the estimated WL, using quarter turn and pull motion. Furthermore, stainless steel K-files were utilized in a sequence of #15/0.02, #20/0.02, #25/0.02, and #30/0.02 (Mani, Tokyo, Japan).

Group 2: Kedo-S paediatric rotary files

The 16 mm long Kedo-S E1 files were used in rotary motion of 300 rpm and 2 Ncm torque, powered by an electronic endomotor (X-Smart Plus; Dentsply Maillefer, Ballaigues, Switzerland), according to the manufacturer's instructions. Furthermore, gentle in-and-out motions were used to reach WL, although the file was retracted and cleaned on the assumption resistance was met earlier on. The canal was further irrigated, patency confirmed using a #15/0.02 K-file, and then re-introduced and retracted once WL was reached and the canal irrigated.

Group 3: XP-endo Shaper

The root canals were cleaned and shaped with the use of a 21 mm XP-endo Shaper file at 800 rpm and 1 Ncm, powered by an endomotor (X-Smart Plus), until WL was realized. Initially, the file was placed passively until resistance was encountered, then the tip retracted, and the endomotor subsequently activated. The file was used 4–5 times by the application of long gentle strokes towards WL, according to the manufacturer's instructions, and on attainment of this phase, was withdrawn and cleansed, the apical patency verified, the canal flooded with warm distilled water, and then reused for an additional 15 strokes to WL.

Furthermore, the irrigation during the root canal instrumentation were performed similarly for the samples in Groups 1 and 2, where a total volume of 12 ml distilled water, used in the course of the procedure and the final flush, was delivered with a syringe and needle (NaviTip 31 G; Ultradent, South Jordan, UT, USA), subsequently placed 2 mm away from the WL. Conversely, for the samples

in Group 3 where the XP-endo Shaper was used, the distilled water was warmed to 37 °C before employment, and allowed to function in an austenite phase. Meanwhile, a new file was used to prepare each canal, and a single operator performed all the experiments to avoid inter-operator variability.

Assessment of apically extruded debris

Following root canal preparation, the caps of the vials, as well as the Eppendorf tubes were detached, and the surface of the root washed with 1 ml of distilled water to collect adhered debris into the Eppendorf tubes. Then, the tubes were placed in an incubator at 70 °C for 5 days to permit the evaporation of moisture before the determination of the mean weight of the contents obtained from three consecutive weights in milligrams, and the calculation of the dry mass of the apically extruded debris.

Assessment of time required for instrumentation

The duration of the shaping of the root canals for all the files tested was recorded by the operator performing the study, using a digital stopwatch**,** timing from the insertion of the first file into the canal up until the final flush of with 2 ml distilled water.

Statistical Analysis

The amount of extruded debris, alongside the time required for the instrumentation were analyzed statistically by the implementation of a one-way analysis of variance (ANOVA), succeeded by Tukey's *post hoc* test for the execution of multiple comparisons. Meanwhile, the level of significance was set at 5%, and all analysis were performed with Statistical Package for the Social Sciences version 20 for Mac (SPSS Inc., Chicago, IL, USA).

Ethical approval

All executed procedures were in accordance with the ethical standards of the institutional and/or national research committee, in addition to the 1964 Helsinki declaration, as well as the subsequent amendments, or comparable ethical standards. The study was also approved by the College of Dental Science & Hospital Ethics Committee (Certificate CDSH/IEC/2018-19/004).

Informed Consent

A wavier was received from the College of Dental Science & Hospital Ethics Committee as the study was performed on specimen acquired from a pool of freshly extracted teeth.

Results

Debris extrusion.

All the instrumentation protocols examined exhibited debris extrusion, with the resultant weights of the extrusions represented in Table 1. The mean weights were 2.13 ± 0.46 mg, in Group 1 (Hand K-files) 1.2 ± 0.67 mg in Group 2 (Kedo-S) and 0.84 ± 0.31 mg, in Group 3 (XP-endo Shaper). Meanwhile, significant differences were found between the weights of the debris extruded by the tested groups ($p < 0.001$). Consequently, the XP-endo shaper procedure was associated with the least debris extrusion, followed by the Kedo-S, with the hand K-file method producing the highest amount of debris, as revealed by The Tukey's *post-hoc* test.

Time required for instrumentation.

The durations of the procedures were 7.33 ± 1.2 minutes in Group 1, 4.61 ± 0.73 minutes in Group 2, and 2.38 ± 0.58 minutes in Group 3 respectively. Furthermore, a considerable difference was found among the groups ($p < 0.001$; ANOVA), and the reapplication of the Tukey's *post-hoc* indicated the association of significantly less instrumentation time ($p < 0.001$) expended by the XP-endo shaper compared to the other groups (Table 2).

Discussion

Data on the debris extrusion and the time required to shape the root canals of primary teeth using adaptive XP-endo Shaper were previously non-existent according to findings, therefore, the outcomes of this research confirm all instrumentation techniques are useful for this purpose. In this study, the XP-endo Shaper process was associated with the least amount of apically extruded debris (0.00084 ± 0.00031 mg; $p < 0.001$), as well as the least procedural duration (2.38 ± 0.58 minutes; $p < 0.001$). Therefore, both null hypotheses were rejected.

A review of the literature demonstrates scant reports concerning debris extrusion following root canal procedure in primary teeth, and as observations indicated during the treatment, the probability of apical debris extrusion appears to increase in the presence of a wide apical diameter.[19] Furthermore, prior researches revealed the amount of detritus eradicated to vary with the type of motorized files used.[1,2,3,8,19,20] Also, the dentine particles separated from the radicular walls tend to be actively packed toward the apical third, and are subsequently pushed beyond the apex as a result of attempts to reach the WL during root canal arrangement.[23]

Esentürk *et al*.[24] recently investigated the impact of different motors and manual shapers on the surface areas of root canals in primary molars and concluded on the permission of the un-instrumentation of up to 60% of these surfaces produced by rotary files. Also, most of the current motorized files assume a solid metal core and proffer a circular shape upon the root canals. The resulting preparations neglect tissue, bacteria, and debris in the complex structures of these areas, or in the buccal, as well as lingual recesses, in the case of oval canals, therefore preventing the three-dimensional obturation of the canals and jeopardizing treatment prognoses. [25]

Furthermore, several researchers have advocated for increased apical preparation proportions to overcome this shaping constraints [26, 27]. However, this approach may give rise to unwarranted removal of healthy dentine, exposing the root to the risk of strip perforation while using tapered motorized files. Consequently, the XP-endo Shaper was designed with the prior knowledge of the irregular shape of root canals, and compared to conventional instruments, is capable of the preparation of additional

surface area. Therefore, the aim of this study was to quantify the amount of debris extrusion produced by instrumentation while employing this device to clean and shape the oval root canals of primary canines. This method was compared against Hand instrumentation exemplified by K-files, alongside another form of motorized technique represented by the Kedo-S. Also, the oval canal configuration was selected because of the challenge faced by clinicians regarding the effective arrangement of these canals (Figure 2).

In this study, hand K-files was associated with the highest extrusion of debris compared to the motorized groups ($p < 0.001$). The findings broadly supports previously reported studies.[1,2,3,8,19,20,28,29] However, higher amount of debris results from the filing motion, which acts as a piston when engaged in the apical third of canal. Furthermore, constant (0.02) taper provides less space for dentin chips to augur the debris coronal, subsequently results in the latter pumped apically.[30] The pediatric rotary Kedo-S file instrumentation demonstrates higher debris extrusion compared to the XP-endo Shaper ($p < 0.001$). Therefore, excessive amount removed using the Kedo-S file was characterized by variable taper along shafts (from 0.04 to 0.08). This taper possibly produced a slightly larger apical preparation, yields a non-similar final preparation diameter, and consequently explains the differences in debris extrusion.

The XP-endo shaper when used for shaping permanent teeth, is reported to result in fewer debris extrusion compared to the rotary (One Shape) and reciprocating (Reciproc) files.[15,16] These were initially 30/.01 (martensitic phase), although exposure to body temperature causes the snakelike shape to assume a 0.04 taper (austenite phase) with a swaggering movement, and leads to a higher detachment of cut dentin debris as well as biofilm adhering to the canal walls.[15] Despite the tornado-like displacement of debris toward the coronal area resulting from high rotary speed (800 rpm), the debris is suspended in the irrigant. This feature is responsible for the reduced extrusion associated with the XP-endo Shaper.

The dominant benefit of using motorized files include reduced treatment time for primary teeth [1, 2, 3, 8, 20, 21, 28, and 29]. According to the research and previous literature reviews, the phase required for completion of root canal shaping of primary teeth was almost 20% less when using motorized files (the Kedo-S and XP-endo Shaper) compared to the use of manual instrumentation (hand K-files) ($p < 0.001$). In addition, the 35% less instrumentation time ($p < 0.001$) associated with the XP-endo Shaper compared to the Kedo-S was unanticipated. This data is attributed to manufacturer recommendations of XP-endo usage at high-speed (800 rpm), the booster tip has six cutting edges for optimal guidance aimed at shaping more radicular dentine with each pass.

Therefore, clinicians ought to be cognizant with rotary file failures in order to effectively clean and shape root canals with irregular cross-sections. However, the XP-endo Shaper was designed specifically for non-round root canals.

Conclusion

This study is the first quantitative assessment of the debris extrusion during instrumentation with primary teeth using the XP-endo Shaper file. This consequently resulted in less debris extrusion in primary canines during oval root canals arrangement. In addition, the time required to complete root canal instrumentation was observably shorter compared to the Kedo-S and hand K-files. Hence, the adaptive XP-endo Shaper file is considered an instrument of choice in the root canal treatment of primary teeth.

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Legend to figure

Figure 1. shows a schematic presentation of the apparatus used to obtain apically extruded debris proposed by Myers and Montgomery with modifications suggested by Kfir *et al*.

Figure 2. demonstrates the placement of different files tested in oval canals (mesiodistal projections) (a) #30 hand K-file, (b) KedoS E1 rotary, and (c) XP-Endo Shaper. The area of space remaining in these canals is left un-instrumented, especially in #30 hand K-file (a), KedoS E1 rotary (b), and the elliptical loops of XP-Endo Shaper (c). These are advantageous in instrumenting such types of canals by touching the root canal area while in rotary motion.

Legend to Tables

Table 1. Weights of apically extruded debris (mg).

Table 2. Instrumentation time required in minutes.

Author Contributions

A.M.P. and B.A.P. planned and designed the study while B.A.P. performed the experiment. Meanwhile, A.M.P. and J.A. drafted the manuscript while A.K., A.B., and A.M.L. prepared the statistic section. Also, Z.M. and A.K. conducted the editing and final proofreading of the entire document and D.A.W. reviewed the article and contributed to the interpretation. However, all authors critically revised drafts and approved the final work.

Competing interests

Furthermore, all authors have no conflict of interest related to the present study.

Additional information

Also, correspondence and requests for materials are to be addressed to D.A.W.

Table 1.

Group	Files	Sample size	Mean (± Standard Deviation)	P value (ANOVA)	Tukey HSD Test*
1	**Hand K-files**	15	2.13 ± 0.46	<0.001	> 2,3
2	**Kedo-S**	15	1.2 ± 0.67		<1, >3
3	**XP-endo shaper**	15	0.84 ± 0.31		<1,2

***Relation of groups 1-3 to Tukey HSD Test for multiple comparison (p< 0.001).**

Table 2.

Group	Files	Sample size	Mean (± Standard Deviation)	P value (ANOVA)	Tukey HSD Test*
1	**Hand K-files**	15	7.33 (± 1.2)	<0.001	> 2,3
2	**Kedo-S**	15	4.61 (± 0.73)		<1, >3
3	**XP-endo shaper**	15	2.38 (± 0.58)		<1,2

***Relation of groups 1-3 to Tukey HSD Test for multiple comparison (p< 0.001).**

Figure 1

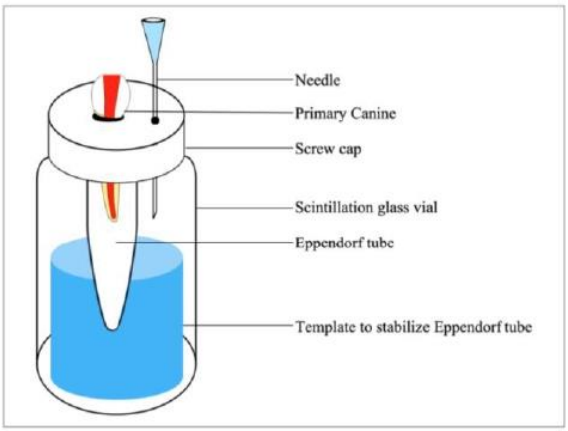
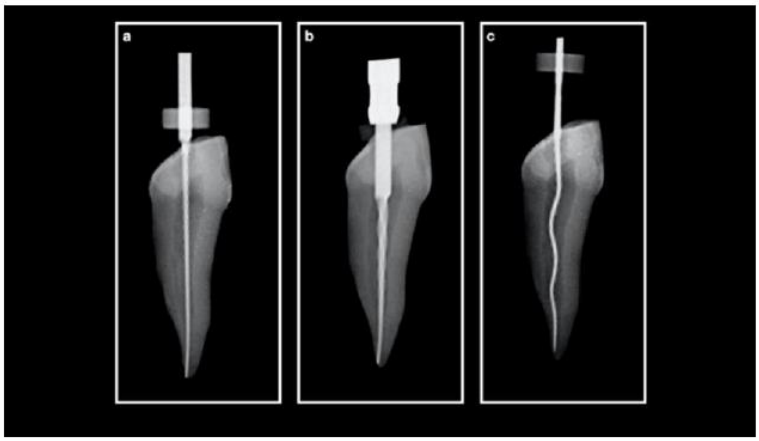

Needle
Primary Canine
Screw cap
Scintillation glass vial
Eppendorf tube
Template to stabilize Eppendorf tube

Figure 2



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Apical debris extrusion during instrumentation of oval root canals in primary teeth using manual versus motorized files: an ex vivo study

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This study aimed to assess the apical extrusion of debris during instrumentation of primary canines using three endodontic file types. Forty-five extracted primary canines were randomly assigned to three instrumentation groups ($n = 15$): Hand K-files; and the motorized Kedo-S files and XP-endo Shaper files. The apically extruded debris produced during the procedure was collected and dried in pre-weighed Eppendorf tubes, and the mass of debris was calculated. The time required for the endodontic procedure was also recorded. Analysis of variance (ANOVA) and Tukey's post hoc test were used with a significance level set at 5%. XP-endo Shaper and Kedo-S files extruded significantly less debris compared with hand K-files with means of 0.84 ± 0.31 and 1.20 ± 0.67 mg respectively, compared to 2.13 ± 0.31 mg ($p < 0.0001$). No significant difference was found between the two motorized files. Less time was required to complete the procedure with the XP-endo Shaper compared to the hand K-files ($p < 0.0001$) and Kedo-S files ($p < 0.0001$). Within the limitations of the present study, it may be concluded that motorized files extruded less debris and required less instrumentation time compared to traditional K-files, which could benefit paediatric patients with root canal treatment needs.

Pulpectomy and root canal procedures remain the first treatment option in primary teeth with pulpal involvement[1]. This therapy aims to heal and/or maintain the involved periapical tissue and salvage the teeth until the eruption of permanent successors[2].

Traditionally, root canal shaping was achieved with hand instruments, such as K-files. However, the use of such files may result in canal aberrations, perforations, inadequate cleaning and transportation of the root canal. Hand instrumentation also requires a rather long chair time for patients[3].

Kedo-S paediatric nickel titanium (NiTi) rotary files (Reeganz Dental Care, Chennai, India) were introduced to overcome some of the above problems[4]. The files are shorter than the common NiTi rotary files (total length 16 mm), and their flexibility allows better adaptation to curvatures that are often found in primary teeth[4]. The file has a triangular cross-section and a non-cutting tip with a 12-mm long active part and a taper that gradually changes from 0.04 to 0.08. The Kedo-S file is used as a single file system.

Root canals with an oval cross-section are common in primary dentition[5]. Oval canals present a challenge to all rotating files that have a central metal core. Rotating endodontic files have a tendency to create a space with their own shape with a round cross-section. Such root canal preparation may leave uninstrumented recesses in which tissue remnants and debris may be left untouched[6]. Recently introduced XP-endo Shaper (FKG Dentaire, La Chaux-de-Fonds, Switzerland) was specifically designed to meet the challenge of oval root canals[7]. The file has a size 30 "booster tip" design that includes a combination of a smooth bullet-shaped tip followed by six cutting

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edges and a smooth transition from the tip base to the helical shaft made of a size 30 wire with a 0.01 taper. This file is made from a special thermo-mechanically treated shape-memory Ni–Ti alloy and has a snake-like shape at room temperature (martensite phase). When exposed to 37 °C, a transfer to the austenite phase occurs, and the snake-like shape is enhanced and assumes a greater rotational envelope of motion that is equivalent to size 30 tip with a 0.04 taper. This dimension is achieved with no solid central part[8]. When used at 800 rounds per minute and with long in-and-out pecking motions, the tip of the file enters repeatedly into and cleans the recesses of the oval canal. The XP-endo Shaper is a single file system.

All endodontic instrumentation methods have a tendency to push debris through the apical foramen and into the periapical tissues[9–11]. Such debris may consist of necrotic pulp tissue, dentin chips and bacteria. Extrusion of such debris may induce postoperative pain and inflammation and may inhibit periapical healing[9–11]. A growing body of literature has recognized the importance of reducing apically extruded debris[9–11]. Estimating the root canal length just short of the apex, using an electronic apex locator, would also seem helpful in reducing the chance of extruding debris beyond the apex. Using such a device will not be influenced by tooth type, root canal type, status of the periapex, or clinical condition[12].

The extent of debris extrusion and the time required for instrumentation of the canals of primary teeth using adaptive XP-endo Shaper files have not been reported to date. Very few studies have been conducted on debris extrusion by Kedo-S paediatric rotary files[13,14].

The present study aimed to measure and compare the amount of apically extruded debris using Kedo-S paediatric rotary and the new XP-endo Shaper files, both of which are operated by an endo-motor (motorized) and to compare both to traditional hand-operated K-files. Measuring the time required to complete the biomechanical preparation by these three files was a second goal of the present study.

This study examined the following two-fold null hypothesis: (a) there is no difference in apically extruded debris between hand-operated K-files and the two motorized systems and (b) the time required for completing the procedures is not different among the three tested file systems.

Materials and methods

Sample allocation and ethical approval. This ex vivo study was approved by the College of Dental Science & Hospital Ethics Committee (Certificate CDSH/IEC/2018-2019/004). Forty-five primary canines were selected from a pool of recently extracted primary teeth. The roots of the teeth were cleaned using periodontal curettes, and the teeth were stored in water with 5% thymol at 4 °C until use in the experiments[15]. This sample size was calculated by projecting the power, effect size, and significance level as 0.91, 0.697, and 0.05, respectively, based on the results of a previous study[13].

Inclusion criteria. The inclusion criteria were a single root canal and foramen as confirmed by bucco-lingual and mesio-distal radiographs. These criteria also included no evidence of resorption, a closed apex, and a long through short canal diameter ratio of ≥ 2 at 5 mm from the apex, as measured from bucco-lingual and mesio-distal radiographs[16]. Access cavities were made, and canal patency was assessed for all samples by inserting a #10 K-file (Mani, Tokyo, Japan) until visible at the apical foramen. Since none of the teeth presented with apical resorption the working length (WL) was established as 1 mm short of the apex[17–19]. The clinical crowns of the teeth were further ground using a high-speed diamond straight fissure bur under air–water spray to obtain a total length of 15 mm and WL 14 mm in the standardization of all samples. The 45 samples were then sequentially numbered and randomly divided (www.random.org) into 3 groups ($n = 15$) for cleaning and shaping by one of three methods, including hand K-files, Kedo-S paediatric rotary files, and XP-endo Shaper files.

Experimental model. The model was proposed by Myers and Montgomery[16], with modifications to the apparatus which were suggested by Kfir et al.[11] were used to measure the apical extrusion of debris (Fig. 1). Forty-five 1.5-ml Eppendorf tubes (IndoSurgical, New Delhi, India) were obtained, and the caps of the tubes were separated. The tubes without caps were weighed to 10^{-5} g precision using a microbalance (Sartorius, Hamburg, Germany). Additionally, three consecutive weight measurements were acquired per tube, and the mean value was recorded. Subsequently, fifteen tubes were assigned to each of the three groups.

Forty-five glass scintillation vials (Cole-Parmar, Mumbai, India) were acquired, and holes were created in the caps where a primary canine was inserted, with the apex facing down, to the level of the cementoenamel junction. The teeth were secured in place with a flowable composite (Filtek Supreme; 3 M ESPE, St Paul, MN, USA). Additionally, a 25-gauge needle (BD India, Gurgaon, India) was also placed and secured in the cap to equalize air pressure in and out of the vial. A small holding template was created on the bottom of the vial using silicon impression material (Coltène/Whaledent, Langenau, Germany) to hold and stabilize each Eppendorf tube so that when the caps were fitted onto the vials, the root tip was located within the Eppendorf tube without touching its walls. The glass vials were then covered with a rubber dam (CricDental, Mumbai, India) such that the operator was blocked from viewing the debris extrusion and tooth during root canal preparation. (Fig. 1) The entire apparatus was exclusively handled by the scintillation vial.

Root canal instrumentation Group 1: hand K-files. The root canals were instrumented to 14 mm from the coronal reference point using quarter turn and pull motion. Stainless steel hand operated K-files were utilized in a sequence of #15/0.02, #20/0.02, #25/0.02, and #30/0.02 (Mani, Tokyo, Japan). Irrigation was performed before and after each file using a syringe and needle (NaviTip 31G; Ultradent, South Jordan, UT, USA). The needle was inserted at each stage and withdrawn 2 mm short of where it engaged at this stage or 2 mm short of WL. One ml of distilled water was used for irrigation at each stage with a total irrigation volume of 4 ml per tooth.

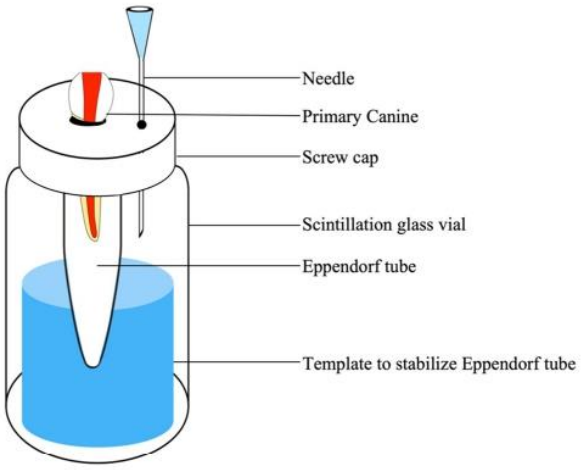

Figure 1. Schematic presentation of the apparatus used to obtain apically extruded debris.

Root canal instrumentation Group 2: Kedo-S paediatric rotary files. Kedo-S is a single file system, and the E1 file used in the present study has a #30 tip and gradually changing taper from 0.04 to 0.08 (Reeganz Dental Care, Chennai, India). The 16-mm long files were used in rotary motion of 250 rpm and 2 Ncm torque, powered by an electronic endomotor (X-Smart Plus; Dentsply Maillefer, Ballaigues, Switzerland) according to the manufacturer's instructions. No pre-flaring was required. Gentle in-and-out motions were used to reach WL. Once the file met resistance, the file was retracted, cleaned with a gauze and applied again. Once the file reached WL, apical patency was verified, and the file used with five in-and-out motions to WL, as per manufacturer's instructions. Irrigation was performed using a syringe and needle (NaviTip). The needle was inserted at each stage and withdrawn 2 mm short of where the needle engaged at this stage or 2 mm short of WL. Irrigation was done with distilled water which was applied at four stages of the procedure: 1 ml of distilled water was used for irrigation before insertion of the file into the canal, 1 ml after the first withdrawal of the file (for cleaning), 1 ml after reaching WL (before the final 5 in-and-out movements) and 1 ml after completing the instrumentation with a total irrigation volume of 4 ml per tooth.

Root canal instrumentation Group 3: XP-endo Shaper. The root canals were cleaned and shaped using a 21 mm XP-endo Shaper file (FKG Dentaire, La Chaux-de-Fonds, Switzerland), as a single file, following manufacturer's instructions: The file was operated at 800 rpm and 1 Ncm torque, powered by an endomotor (X-Smart Plus), until WL was reached. Initially, the file was placed passively into the canal until resistance was encountered, then the tip retracted 2 mm, and the endomotor activated. The file was then used 4–5 times by the application of long gentle strokes towards WL. Once the file reached WL the file was withdrawn and cleansed, the apical patency verified, the canal flooded with warm (37 °C) distilled water, and then the file reused for an additional 15 in-and-out strokes to WL, as recommended by the manufacturer. Irrigation was performed using a syringe and needle (NaviTip). The needle was inserted at each stage and withdrawn 2 mm short of where it engaged at this stage or 2 mm short of WL. The irrigant was warmed to and kept at 37 °C (using a temperature controlled water bath), to allow transition of the files from the martensite to the austenite phase. Irrigation was done at four stages during the procedure: 1 ml of distilled water was used for irrigation before insertion of the file into the canal, 1 ml after the first 5 strokes, 1 ml after reaching WL (before the final 15 in-and-out movements) and 1 ml after completing the instrumentation, with a total irrigant volume of 4 ml per tooth.

Irrigation in all three groups was done at a flow rate of about 0.3 ml per minute.

A new file was used to prepare each canal, and a single operator performed all the experiments to avoid inter-operator variability. The operator was an experienced paediatric dentist who had intensive experience with the use of each of the three endodontic file systems.

Assessment of apically extruded debris. Following root canal preparation, the caps of the vials were unscrewed and the Eppendorf tubes removed. The surface of the root was washed with 1 ml of distilled water to collect adhered debris into the Eppendorf tubes. Then, the tubes were placed in an incubator at 70 °C for 5 days to permit the evaporation of all moisture. The weight of each tube was determined as the mean weight from three consecutive weights in milligrams. The weight of the tube before the procedure was subtracted from the above, thus resulting in the weight of extruded debris [9,11].

Assessment of time required for instrumentation. The duration of the procedure was recorded by the operator performing the study using a digital stopwatch. The starting point was the first insertion of the file into the canal, and the end point was the end of the final irrigation with distilled water.

Group	Files	Sample size	Mean weight of extruded debris in milligrams (± SD)	Tukey HSD *p* values
1	Hand K-files	15	2.13 (±0.46)	0.000*; 0.000**
2	Kedo-S	15	1.20 (±0.67)	0.127***
3	XP-endo shaper	15	0.84 (±0.31)	

Table 1. Analysis of variations in the mean weight of apically extruded debris using three different file systems. *Comparison between Hand K-files and Kedo-S, **Comparison between Hand K-files and XP-endo Shaper, ***Comparison between Kedo-S and XP-endo Shaper. *P* value of less than 0.05 was considered as statistically significant.

Group	Files	Sample size	Mean time in minutes (± SD)	Tukey HSD *p* values
1	Hand K-files	15	7.33 (±1.20)	0.000*; 0.000**
2	Kedo-S	15	4.61 (±0.73)	0.000***
3	XP-endo shaper	15	2.38 (±0.58)	

Table 2. Analysis of variations in the time required to complete the procedure using three different file systems. *Comparison between Hand K-files and Kedo-S, **Comparison between Hand K-files and XP-endo Shaper, ***Comparison between Kedo-S and XP-endo Shaper. *P* value of less than 0.05 was considered as statistically significant.

Statistical analysis. The amount of extruded debris, alongside the time required for the instrumentation, were analysed statistically by the implementation of a one-way analysis of variance (ANOVA) followed by Tukey's post hoc test for the execution of multiple comparisons. The level of significance was set at 5%, and all analyses were performed with Statistical Package for the Social Sciences version 20 for Mac (SPSS, IBM, Chicago, IL, USA).

Results

Debris extrusion. The amount of apically extruded debris by each of the three file systems is presented in Table 1. The mean weights (±SD) were 2.13 (±0.46) mg in Group 1 (Hand K-files), 1.2 (±0.67) mg in Group 2 (Kedo-S) and 0.84 (±0.31) mg in Group 3 (XP-endo Shaper). Significant differences among the groups were identified (ANOVA, $p < 0.0001$). Tukey's post hoc test revealed that the amount of extruded debris in both the XP-endo Shaper and Kedo-S groups was significantly less than the amount of debris extruded in the Hand K-file group ($p < 0.0001$). However, the amount of debris in the two motorized file groups did not differ significantly from each other (Table 1).

Time required for instrumentation. The mean time required to complete the procedures was 7.33 ± 1.2 min in Group 1, 4.61 ± 0.73 min in Group 2, and 2.38 ± 0.58 min in Group 3 (Table 2). A significant difference was found among the groups (ANOVA, $p < 0.001$), and Tukey's post hoc *test* indicated that significantly less instrumentation time was required in the XP-endo Shaper group compared to the other two groups ($p < 0.001$).

Discussion

Data on debris extrusion during the shaping of root canals of primary teeth with the new adaptive XP-endo Shaper were previously non-existent to the best of our knowledge. The present results indicate that both XP-endo Shaper and Kedo-S procedures were associated with less apically extruded debris than the use of hand K-files ($p < 0.0001$). Therefore, the first null hypothesis was rejected.

The findings broadly support previously reported studies[1–3,9,13,14,20,21]. Apical extrusion of debris is caused by accumulation of debris in the apical part of the canal where it may be pushed beyond the apex[22]. The high amount of debris extruded by the K-files could result from the filing motion, which may act as a piston when the files are engaged in the apical third of the canal[23]. Furthermore, the K-files have a constant (0.02) taper, which may provide less space in the apical part for dentin chips and debris that have to be transported coronally; consequently, the debris may be pumped apically[24].

It could be expected that the XP-endo Shaper will cause less debris extrusion than the rotary Kedo-S files due to the differences in their shape and mode of action. The Kedo-S rotary file with its bulky core (size 30 and 0.04 to 0.08 taper, Fig. 2) fills the apical part of the canal and leaves little space for the suspension of debris compared to the loose space around the XP-endo Shaper (Size 30 and 0.01 taper, Fig. 2). Furthermore, when rotating at 800 rpm and at 37 °C, the file has an envelope of motion with a 0.04 taper, the centre of which is hollow in contrast to the solid metal core in the Kedo-S file.

The method of debris removal by the XP-endo Shaper and the Kedo-S files is also completely different. The XP-endo Shaper suspends the debris and carries it coronally with a tornado-like movement of the irrigant created by the speed of rotation (800 rpm) and the snake-like shape of the file[7,22]. Such suspension and transportation of debris was expected to be more efficient than forcing debris coronally by the rotation of the flutes of the Kedo-S file[7,22]. Despite these differences in shape and mode of action and even though the mean amount of

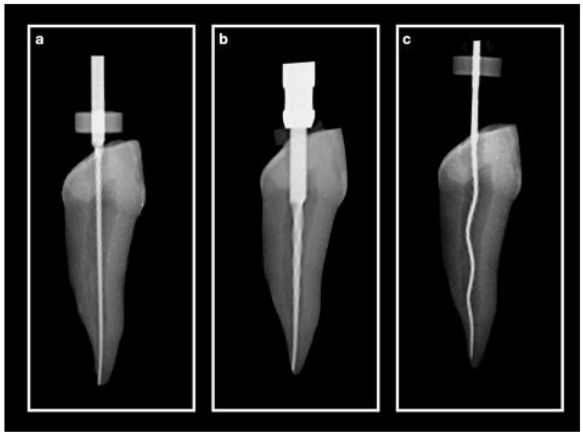

Figure 2. Radiographic image of the three files in a primary canine (mesio-distal projections) (**a**) #30 hand K-file, (**b**) Kedo-S E1 rotary file, and (**c**) XP-endo Shaper.

apically extruded debris was apparently reduced with the XP-endo Shaper, the difference in apical extrusion of debris between the groups was not statistically significant (Table 1). The reason could be that the piston effect at the apical 2–3 mm of the pecking in-and-out motion used with both instruments had more influence than the potential benefit of the way the XP-endo Shaper file is transporting debris coronally.

The XP-endo Shaper was selected for the present study as it is a new device specially designed to overcome a major specific problem in root canal instrumentation. Many roots in the primary dentition have root canals with an oval cross-section[5]. Most current motorized files, including the Kedo-S file, have a solid metal core and tend to create a space with a circular shape in every root canal, which may limit the cleaning ability of the endodontic procedure. Esentürk et al.[25] recently demonstrated that when rotary files are used in primary teeth, 60% of the canal wall area remains un-instrumented. Canal preparations with a round cross-section are likely to leave tissue, bacteria and debris in the un-instrumented recesses of oval canals, thus jeopardizing treatment prognosis[26].

A dominant benefit of using motorized files in primary teeth is reduction of the time required to complete the endodontic procedure[21,27]. Reducing the time may be especially beneficial when children are treated, as it may enhance patient cooperation. The present results indicate that the use of XP-endo Shaper required 68% less time than hand instrumentation with K files ($p < 0.0001$). The Kedo-S file also reduced instrumentation time by 37%, but the procedure required more time than that with the XP-endo Shaper ($p < 0.0001$). Thus, the second null hypothesis had also been rejected.

The difference in time required between the two motorized procedures may have resulted from the mode by which each of the files was used to reach WL. The Kedo-S file had to remove a large amount of dentin with its rather bulky active part before its non-cutting tip may reach the working length. Consequently, one has to stop at least once or twice to remove the accumulated debris from the file's flutes if one does not want to apply excessive force during this procedure. The tip of the XP-endo Shaper has a unique design that makes reaching WL very fast with almost no pressure. The tip is divided into two parts. The apical part of the tip has a non-cutting bullet shape, which then changes into 6 cutting blades that then merge into the thin shaft with a 0.01 taper. It seems that these features allow the XP-endo Shaper file to reach WL easily and quickly with minimal resistance. The XP-endo Shaper file is not expected to shape the canal but rather clean it with its tip entering the canal irregularities with each of the following 15 long pecking strokes that are recommended by the manufacturer. Further studies with micro CT may be required to examine the effectiveness of cleaning the canals of primary teeth by these two devices.

It must be kept in mind that the present study was conducted using only single rooted primary canines with straight roots and no apical resorption. The effect of apical resorption, which is common in primary teeth[28], on apical extrusion of debris should be addressed in future studies. Naturally, the time required to complete treatment of three rooted primary molars may be longer than that of a single rooted canine. Primary molars often have curved root canals with oval cross-sections[5]; thus, further studies on the use of XP-endo-Shaper in primary molars may be required using both micro CT and debris extrusion measurements while also measuring the time required to complete the procedure.

Conclusions

Within the limitations of the present study, it may be concluded that motorized files extruded less debris and required less instrumentation time compared to traditional K-files, which could benefit paediatric patients with root canal treatment needs.

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Author contributions

A.M.P. and B.A.P. planned and designed the study. B.A.P. performed the experiment. A.M.P. and J.A. drafted the manuscript. A.K., A.B., and A.M.L. prepared the statistical section. Additionally, Z.M. and A.K. conducted the editing and final proofreading of the entire document, and D.A.W. reviewed the article and contributed to the interpretation. However, all authors critically revised drafts and approved the final work.

Competing interests
The authors declare no competing interests.

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