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Evaluation of Brasseler USA XP-3D Shaper and its effect on apical foramen size.

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Introduction:

Adequate working length (WL) and minimal enlargement of the apical foramen are important for successful endodontic outcomes [1,2]. Even though procedural errors, such as unintentional enlargement of the apical foramen, are not the direct cause of treatment failure, they can potentially cause a treatment failure or diminished long-term prognosis. It has been suggested that enlargement of the canal to 3 sizes larger than the first apically binding file is sufficient and additional enlargement of the canal will not cause any further benefits [3]. Additionally, some even suggest that no apical enlargement is necessary in order to achieve proper disinfection of the root canal system [4]. Introduction of rotary nickel-titanium (NiTi) files and their constant improvement had allowed to minimize procedural iatrogenic errors and better control over cleaning and shaping procedures. Advancements in metallurgy allowed for introduction of multiple new instrumentation systems and single files that claim to perform fast, accurate and adequate cleaning and shaping of the root canal systems without excessive enlargement of the apical foramen[5,6].
Brasseler XP-3D Shaper is a new rotary file with adaptive core design that allows it to conform to canal morphology ranging from size #30 to #90 at a .02 to .08 taper. The instrument is designed so when it rotates, its orbit expands and contracts to equally abrade the broad and narrow aspects of the canal as it continually adapts to the canal's anatomy [7]. Research indicates that when using the XP-3D Shaper, the final taper of the canal will indeed vary according to the original size and shape of the root canal system [8,9]. In addition, XP-3D shaper was evaluated when used at the foramen and was found to enlarge but not deform the apical foramen [10]. However, it is not known how the apical size may change when the file is taken inadvertently longer than the established WL. Correct WL can be established with the electronic apex locator (EAL) 96% of the time [11]. EAL use can help to reduce the risk of instrumenting and obturating beyond the apical foramen but it cannot eliminate it [12]. Different conditions, such as large periapical lesions, perforations, defective restorations or files contacting metal restorations, could potentially cause an incorrect WL determination and would inadvertently cause a clinician to instrument short of or beyond the proper WL [13]. Instrumentation beyond the proper WL could potentially cause excessive changes to the size of the apical foramen. The aim of this study was to determine whether Brasseler XP-3D Shaper will significantly enlarge the apical foramen after instrumentation when the file is taken 1mm and 2mm longer than the established WL.

Materials and Methods:

Forty-two simulated root canal blocks were used (Fig. A). Prior to instrumentation, the apical diameter of each block was measured under magnification with hand files and recorded. WL was established by inserting a #10 k file until the file was flush with the edge of the block as visualized under the dental microscope. Three groups (n=14 in each group) were established to be instrumented to the determined WL, 1 mm beyond the determined WL and 2 mm beyond the determined WL. The blocks were masked using black tape with only stimulated canal orifice being visible and randomized for instrumentation using an online research randomizer (randomizer.org). Prior to using the XP-3D Shaper (Fig. B), a glide path was established with a #15.02 hand file. All instrumentation and irrigation procedures followed the manufacturer's recommendations and were all performed by a single blinded operator. The assistant was responsible for setting WL and re-checking WL each time the operator stopped the instrumentation. The XP Shaper file was operated at 900 rpm and 1 Ncm torque. The tip of the instrument was inserted into the canal containing an irrigant and 3 long, gentle in-and-out motion strokes were applied. If WL was not reached in three strokes, the operator stopped, and the canal was irrigated and recapitulated with a #10.02 hand file before proceeding. The instrument was never forced and was always spinning while in the canal. Once the pre-determined apical extent of instrumentation was reached, the canal was re-irrigated with Saline using a plastic syringe with a 30-gauge needle and the instrument was placed in the canal for another 5 seconds with operator working the instrument in long, gentle strokes. Once the pre-determined apical extent of instrumentation was reached, the final apical diameter was measured with hand files and the number was recorded by the assistant. Brand new file was used for each block and discarded after use.

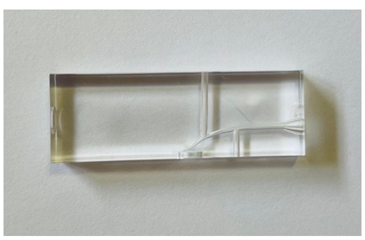

Fig. A Simulated root canal block

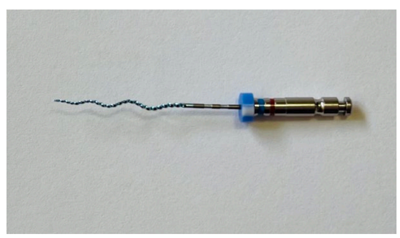

Fig. B Brasseler B XP-3D Shaper

Statistical Analysis:

Exploratory analysis was conducted on continuous data to verify the assumption of normality and homogeneity of variances based on the Shapiro-Wilk test and Levene's F test respectively. Consequently, measures of central tendency and dispersion are reported as means and standard deviations. A between-groups analysis of variance (ANOVA) was performed to test the hypothesis that final apical size varies based on the working length assigned to each group. Significance was declared at $P < 0.05$. All analyses were conducted using SPSS v25 (IBM, Armonk, NY, USA).

Results:

Descriptive statistics associated with the assessed WL groups are reported in Table 1. Five files separated during instrumentation and were therefore excluded from final calculations. The numerically smallest mean apical size was associated with the 0 mm group ($M = 35$, $SD = 3.9$). Conversely the numerically largest apical size was associated with the 2mm group ($M = 47$, $SD = 5$). Post-hoc analysis revealed no difference in final apical size between the 0mm and 1mm file groups, $P = 0.11$. However, both had significantly lower final apical size measurements compared to the 2mm group, both $P<0.01$.

Table 1. Descriptive Statistics for Final Apical Size Across WL Groups

File Group	N	M	SD
0 mm	14	35	4
1 mm	11	39	5
2mm	12	47	5

Discussion:

Stimulated root canal blocks were used to ensure minimal variation between the samples and establish high comparability for the three groups. However, this also was a limitation of the study considering in vitro samples and conditions often vary greatly from in vivo samples and conditions. We recognize that the complex anatomic conditions in clinical situations were not fully reproduced but this research may help clinicians to understand the limitations of XP-3D Shaper and to choose the most appropriate situations and cases for the file to be used.

The most significant enlargement of the apical foramen was associated with the 2mm beyond WL group. Such a result could potentially be associated with the XP-3D file design and its pulsatile expansion capacity considering the file was taken out of the constraints of the root canal. The file's unique spiral-like shape allows the file to spin, continually adapting to the canal's natural anatomy [7]. Apical foramen enlargement was previously observed when XP-3D Shaper was taken to the established apical constriction as when the file was spinning within the constraints of the root canal [10]. Based on the results of this study, this effect could be potentiated when no constraints are present, as when the file is taken beyond the apex. Careful establishment of the WL and maintenance of this length as the file is repeatedly used in the canal will ensure minimal apical enlargement and predictable final apical size.

Frequent irrigation and gradual advancement of the file in an in-and-out motion were performed during the instrumentation. This technique was used to prevent any abrasive action on the walls and to prevent any transportation of the apical foramen [15,16]. Comparable technique was also used in a similar study and no transportation of the apical foramen was recorded [10]. Frequent irrigation also prevented debris accumulation and subsequently may have helped avoid transportation of the canals.

It was also noted that five files separated in the apical third with all of the separations occurring when files were taken 1 mm or 2 mm beyond the WL. Root canal preparations also caused deformations of multiple SP-3D Shaper files that were visible under the microscope and, in some cases, was even visible to the naked eye. This could be caused by XP-3D previously mentioned unique design and pulsatile expansion capacity. As the file is taken out of the constraints of the root canals system, excessive deflection of the file as it spins in pulsatile motion could potentially cause excessive strain on the file and fracture. The file's metallurgic design allows it to transform from martensitic and more malleable shape at 68 degrees Fahrenheit to austenitic and stronger but also stiffer shape at 95 degrees Fahrenheit [7]. Therefore, our in vitro setting could not reproduce the true chairside clinical performance of the XP-3D Shaper and therefore no firm conclusions can be formed in regards to the causes of file separations. Further in vivo and in vitro research is needed to allow to test for the file's true capacity when used in the proper temperature and clinical setting.

Conclusion:

The results of this study indicate that establishing and maintaining an accurate WL when using the Brasseler XP-3D Shaper is crucial during use in order to avoid excessive enlargement of the apical foramen.

The views expressed herein are those of the author(s) and do not reflect the official policy of the Department of the Army, Department of Defense or the U.S. Government.

References:

1. Ricucci D. Apical limit of root canal instrumentation and obturation, part 1. Literature review. Int Endod J. 1998 Nov;31(6):384-93. doi: 10.1046/j.1365-2591.1998.00184.x. PMID: 15551606.

2. Ng YL, Mann V, Gulabivala K. A prospective study of the factors affecting outcomes of nonsurgical root canal treatment: part 1: periapical health. Int Endod J. 2011 Jul;44(7):583-609. doi: 10.1111/j.1365-2591.2011.01872.x. Epub 2011 Mar 2. PMID: 21366626.

3. Saini HR, Tewari S, Sangwan P, Duhan J, Gupta A. Effect of different apical preparation sizes on outcome of primary endodontic treatment: a randomized controlled trial. J Endod. 2012 Oct;38(10):1309-15. doi: 10.1016/j.joen.2012.06.024. Epub 2012 Aug 3. PMID: 22980168.

4. Coldero LG, McHugh S, MacKenzie D, Saunders WP. Reduction in intracanal bacteria during root canal preparation with and without apical enlargement. Int Endod J. 2002 May;35(5):437-46. doi: 10.1046/j.1365-2591.2002.00496.x. PMID: 12059915.

5. Perez Morales MLN, González Sánchez JA, Olivieri Fernández JG, Laperre K, Abella Sans F, Jaramillo DE, Terol FD. TRUShape Versus XP-endo Shaper: A Micro-computed Tomographic Assessment and Comparative Study of the Shaping Ability-An In Vitro Study. J Endod. 2020 Feb;46(2):271-276. doi: 10.1016/j.joen.2019.10.027. Epub 2019 Dec 13. PMID: 31839412.

6. Amaral RR, Guimarães Oliveira AG, Braga T, Reher P, de Macêdo Farias L, Magalhães PP, Ferreira PG, Ilma de Souza Côrtes M. Quantitative Assessment of the Efficacy of Two Different Single-file Systems in Reducing the Bacterial load in Oval-Shaped Canals: A Clinical Study. J Endod. 2020 Sep;46(9):1228-1234. doi: 10.1016/j.joen.2020.06.007. Epub 2020 Jul 9. PMID: 32653532.

7. Brasseler XP-3D Shaper By Your Side Brochure. 2021 May; http://xp-3d.com/wp-content/uploads/2017/03/B_4744_XP3D-Brochure_Web.pdf

8. Azim AA, Piasecki L, da Silva Neto UX, Cruz ATG, Azim KA. XP Shaper, A Novel Adaptive Core Rotary Instrument: Micro-computed Tomographic Analysis of Its Shaping Abilities. J Endod. 2017 Sep;43(9):1532-1538. doi: 10.1016/j.joen.2017.04.022. Epub 2017 Jul 20. PMID: 28735789.

9. Versiani MA, Carvalho KKT, Mazzi-Chaves JF, Sousa-Neto MD. Micro-computed Tomographic Evaluation of the Shaping Ability of XP-endo Shaper, iRaCe, and EdgeFile Systems in Long Oval-shaped Canals. J Endod. 2018 Mar;44(3):489-495. doi: 10.1016/j.joen.2017.09.008. Epub 2017 Dec 19. PMID: 29273492.

10. Daou C, El Hachem R, Naaman A, Zogheib C, El Osta N, Khalil I. Effect of 2 Heat-treated Nickel-Titanium Files on Enlargement and Deformation of the Apical Foramen in Curved Canals: A Scanning Electronic Microscopic Study. J Endod. 2020 Oct;46(10):1478-1484. doi: 10.1016/j.joen.2020.07.019. Epub 2020 Jul 22. PMID: 32710894.

11. Shabahang S, Goon WW, Gluskin AH. An in vivo evaluation of Root ZX electronic apex locator. J Endod. 1996 Nov;22(11):616-8. doi: 10.1016/S0099-2399(96)80033-1. PMID: 9198419.

12. Vieyra JP, Acosta J. Comparison of working length determination with radiographs and four electronic apex locators. Int Endod J. 2011 Jun;44(6):510-8. doi: 10.1111/j.1365-2591.2011.01855.x. Epub 2011 Feb 10. PMID: 21306402.

13. McDonald NJ. The electronic determination of working length. Dent Clin North Am. 1992 Apr;36(2):293-307. PMID: 1572500.

14. Silva EJNL, Vieira VTL, Belladonna FG, Zuolo AS, Antunes HDS, Cavalcante DM, Elias CN, De-Deus G. Cyclic and Torsional Fatigue Resistance of XP-endo Shaper and TRUShape Instruments. J Endod. 2018 Jan;44(1):168-172. doi: 10.1016/j.joen.2017.08.033. Epub 2017 Oct 24. PMID: 29079058.

15. Goldberg F, Massone EJ. Patency file and apical transportation: an in vitro study. J Endod. 2002 Jul;28(7):510-1. doi: 10.1097/00004770-200207000-00005. PMID: 12126377.

16. Sanchez JA, Duran-Sindreu F, Matos MA, Carabaño TG, Bellido MM, Castro SM, Cayón MR. Apical transportation created using three different patency instruments. Int Endod J. 2010 Jul;43(7):560-4. doi: 10.1111/j.1365-2591.2010.01710.x. Epub 2010 Apr 23. PMID: 20456517.