

Field: R&D**Number: 1-04****Version: A****Subject: temperature test****Date:6.10.2013**

1. PURPOSE AND SCOPE

The purpose of this study is to compare the temperature produced in a tooth when comparing the MediNRG Gentlefile system to two commercially available rotor taper file systems.

2. REFERENCES AND APPLICABLE DOCUMENTS

The references listed here should be considered when applying this guide. Referenced documents will be binding only if referred to by this document, and then, only to the extent to which they are referred to. Unless stated otherwise, the latest revision is applied.

The following specifications, standards and documents of the exact issue shown form a part of this specification to the extent specified herein. In the event of conflict between the documents referenced herein and the contents of this specification, the contents of this specification shall be considered a superseding requirement.

- [A.1] BMDP Statistical Software (1993), Chief Editor: W. J. Dixon, University of California Press, Los Angeles.

3. DEFINITIONS & ABBREVIATIONS

None

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4. SUMMARY OF TESTING ACTIVITIES

Summary and background of the study.

5. TEST EQUIPMENT / MATERIALS / TOOLS

- 5.1. MedicNRG Model# Gentlefile Model# red
- 5.2. Protaper Model# red
- 5.3. Gates Glidden Model# 70
- 5.4. DELL Laptop for data collection.
- 5.5. BMDP Statistical Software.
- 5.6. Temperature probe Model# PT-100
- 5.7. Clamping jig.
- 5.8. Teeth (source)- Dr. Sabin clinic

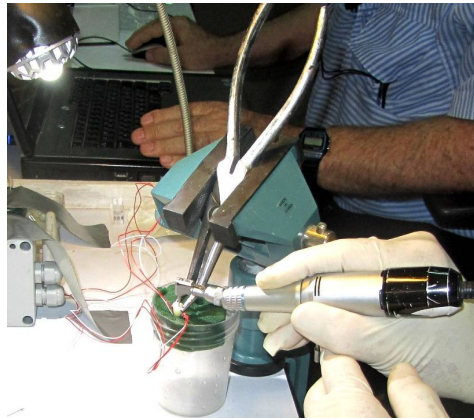
6. SAMPLE SIZE DETERMINATION

For the test, each system was tested on 10 teeth and the temperature was measured using 2 temperature sensors.

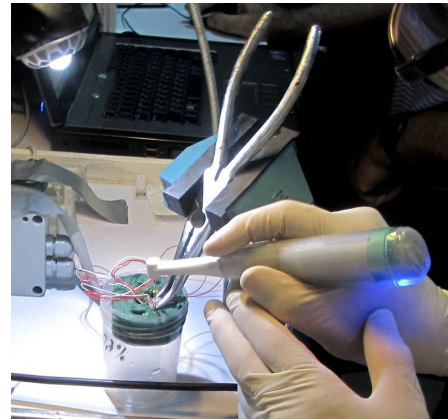
The average temperature was calculated and the means were compared using the statistical package BMDP (ref), the data were analyzed using Analysis of Variance (ANOVA) with repeated measures.

7. TEST METHOD

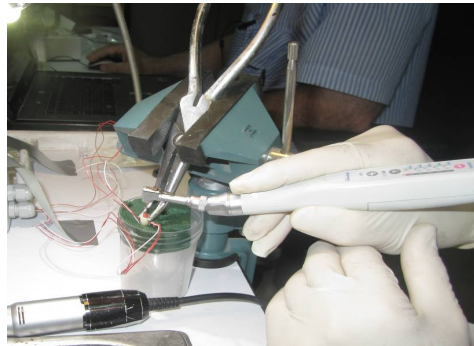
Each tooth was clamped in the jig and the temperature sensors placed in 2 points: one sensor at the thin wall point and the second sensor at the thickness point of the oval cross section. The tooth was drilled continuously for 30 seconds and the temperature profile was measured. A new file was used for each tooth Test system. Setup Gregory. Connection and configuration data logger.

Field: R&D**Number: 1-04****Version: A****Subject: temperature test****Date:6.10.2013**

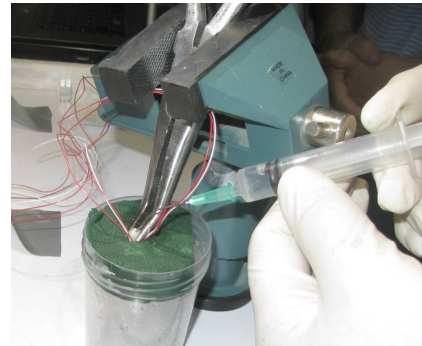
Gate Glidden - 70



MedicNRG Gentlefile- red



Protaper -red



Rinse with disinfectant

8. ACCEPTANCE CRITERIA

The temperature generated in the tooth by the MedicNRG Gentlefile should not be significantly greater than temperature generated in the teeth by the two other devices.

9. TEST DATA

All three tools and both locations showed a highly significant rise in temperature over 30 seconds ($p < 0.001$).

Comparing location 1 with location 2 for each tool separately, we found a significant interaction between location and increase in temperature over 30 seconds [i.e. the rate of increase in temperature was greater in location 1 than in location 2] ($p = 0.002$, $p = 0.001$ and $p < 0.001$ respectively, for tools 1, 2 and 3).

Using location 1 only, we then compared the effect of the three tools on increase in temperature over 30 seconds:

- Comparing MedicNRG with Protaper, no significant interaction was found ($p = 0.678$)
- Comparing MedicNRG with Gates Glidden, we found a highly significant interaction ($p < 0.001$)
- Comparing Protaper with Gates Glidden, we found a highly significant interaction ($p < 0.001$)

Field: R&D**Number: 1-04****Version: A****Subject: temperature test****Date:6.10.2013**

Using location 2 only, we then compared the effect of the three tools on increase in temperature over 30 seconds:

- a) Comparing MedicNRG with Protaper, no significant interaction was found ($p=0.238$)
- b) Comparing MedicNRG with Gates Glidden, we found a highly significant interaction ($p<0.001$)
- c) Comparing Protaper with Gates Glidden, we found a highly significant interaction ($p<0.001$)

10. CONCLUSION

The MedicNRG Gentlefile system no more heat than two systems in the comparison test.