APPLICATION

OF

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FOR

LETTERS PATENT OF THE UNITED STATES

FOR

ENDODONTIC INSTRUMENT WITH MODIFIED MEMORY AND FLEXIBILITY PROPERTIES AND METHOD

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BACKGROUND

[0001] The present invention relates to endodontic instruments and to methods of making such instruments. In particular, the invention relates to nickel-titanium or "NiTi" endodontic instruments that exhibit beneficial properties and characteristics for working in a manner so as to avoid difficulties associated with prior instruments including, but not limited to, undesired lateral transportation in curved canals, difficulties with enlarging curvilinear canals while substantially maintaining the original center axis of the canals, and problems with binding and/or "screwing in" of prior NiTi instruments in such canals.

BRIEF DESCRIPTION OF THE DRAWINGS

[0002] Further features, aspects, and advantages of the present disclosure will become better understood by reference to the following detailed description, appended claims, and accompanying figures, wherein elements are not to scale so as to more clearly show the details, wherein like reference numbers indicate like elements throughout the several views, and wherein:

[0003] FIG. 1A shows a further somewhat schematic representation of a tooth root canal being operated on using a dental instrument;

[0004] FIG. 1B shows a somewhat schematic representation of a tooth being operated on using a dental instrument;

[0005] FIG. 2 shows a two-dimensional plot of torque data (vertical axis) versus angular deflection data (horizontal axis) for untreated ("control") NiTi instruments;

[0006] FIG. 3 shows a two-dimensional plot of the data in FIG. 2 wherein the data sets have been fitted to conform to third degree polynomial equation curves;

[0007] FIG. 4 shows a two-dimensional plot of torque data (vertical axis) versus angular deflection data (horizontal axis) for several NiTi instruments treated according to one embodiment of the invention;

[0008] FIG. 5 shows a two-dimensional plot of torque data (vertical axis) versus angular deflection data (horizontal axis) for several NiTi instruments treated according to another embodiment of the invention;

[0009] FIG. 6 shows a two-dimensional plot of torque data (vertical axis) versus angular deflection data (horizontal axis) for several NiTi instruments treated according to a further embodiment of the invention;

[0010] FIG. 7 shows a two-dimensional plot of torque data (vertical axis) versus angular deflection data (horizontal axis) for several NiTi instruments treated according to an additional embodiment of the invention;

[0011] FIG. 8 shows a two-dimensional plot of the data in FIG. 7 wherein the data sets have been fitted to conform to third degree polynomial equation curves;

[0012] FIG. 9 shows an apparatus used to test cyclical fatigue of a dental instrument;

[0013] FIG. 10 shows a two-dimensional plot of torque data (vertical axis) versus angular deflection data (horizontal axis) for twenty NiTi instruments treated according to an embodiment of the invention;

[0014] FIG. 11 shows a two-dimensional plot of the data in FIG. 10 wherein the data sets have been fitted to conform to third degree polynomial equation curves; and

[0015] FIG. 12 shows the two-dimensional plot of torque data (vertical axis) versus angular deflection data (horizontal axis) shown in FIG. 11 further including a superimposed curve generated from the average values of the coefficients for the third degree polynomial equations used to fit the data from FIG. 10 in the curves shown in FIG. 11.

DETAILED DESCRIPTION

[0016] Various terms used herein are intended to have particular meanings. Some of these terms are defined below for the purpose of clarity. The definitions given below are meant to cover all forms of the words being defined (e.g., singular, plural, present tense, past tense). If the definition of any term below diverges from the commonly understood and/or dictionary definition of such term, the definitions below control.

mN: the force unit symbol for milli-Newton.

m: the length unit symbol for meter.

mm: the length unit symbol for millimeter.

Working portion: That part of an endodontic instrument which includes surface features for removing material from a root canal including, but not limited to, surface features for scraping, shaving, cutting, penetrating, excavating, and/or removing material from canal wall surfaces in an effort to shape and/or enlarge a root canal.

[0017] FIGS. 1A and 1B show somewhat schematic representations of a tooth 10 including a natural root canal 12 in which an endodontic instrument 14 is being used to extirpate the natural root canal 12. When devices such as the endodontic instrument 14 shown in FIG. 1A are made from nickel-titanium (or "NiTi" or "Nitinol"), such devices tend to have improved flexibility properties relative to similar devices made of stainless steel. This property of NiTi and other similar alloys is sometimes referred to in part as superelasticity or psuedoelasticity and is often lauded as a unique and beneficial characteristic of endodontic files made from NiTi.

[0018] As FIG. 1A shows, however, when NiTi endodontic devices such as tapered files are used to navigate, for example, the natural root canal 12 of the tooth 10, the tendency of the device 14 to veer to a path contrary to the natural root canal 12 shape is a continuous concern for a dental practitioner—particularly when the instrument is used along a natural root canal with excessive curvature. A first deviation path 16 and a second deviation path 18 are shown in FIG. 1A to illustrate the manner in which an instrument made of NiTi tends to create disproportionate lateral forces along an inner surface 20 of the natural root canal 12 at certain locations. If this

tendency is not carefully monitored by a dental practitioner, such instrument could easily (and often does) deviate from the natural root canal 12, boring an artificial structure which has the potential to compromise an entire tooth structure.

[0019] In an attempt to address the drawbacks associated with NiTi dental instruments as used in endodontic procedures discussed above, the inventor has performed a number of experiments in an effort to increase the beneficial flexibility properties of NiTi which, in turn, decreases the lateral forces exerted by a NiTi dental instrument on the inner surface of a tooth root canal. The inventor has surprisingly found a method for treating machined NiTi instruments that increases the flexibility of such instruments.

[0020] In a first study, the Applicant performed twenty five tests using ADA guidelines (discussed *infra*) on five groups of endodontic files for properties including torque and angular deflection to see if various heat treatment methods had any effect on the relative performance of the files. Trends of interest became apparent based on the visual "signature" of each set of data sets. Table 1 below indicates relationships between each group of tests with various parameters.

TABLE 1

	Ave. Torque (mN·m)	Ave. Angular Deflection (Revolutions)
Control Group	about 2	1.61
Experimental Group 1	less than 2	2.89
Experimental Group 2	unstable data	3.32
Experimental Group 3	unstable data	3.69
Experimental Group 4	about 2	4.05

[0021] Graphs shown in FIGS. 2-8 plot torque (vertical axis) versus angular deflection (horizontal axis). In each of the graphs shown in FIGS. 2-8, 240 measurement samples for torque versus angular deflection were taken per one full axial (twisting) revolution of the instrument. FIG. 2 shows a graph of four data sets representing four separate test samples included in the control group which included only NiTi instruments that had not been heat treated according to Applicant's treatment method. A fifth data set in the control group was discarded because of a testing fault with the sample. As can be seen in FIG. 2, all of the test runs of the control group displayed a similar graphical signature which is more easily seen in FIG. 3

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