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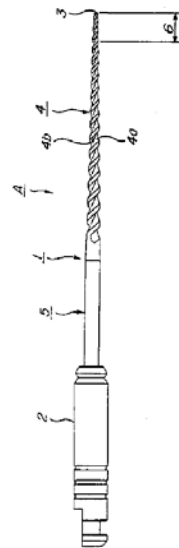
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(54) (TITLE OF THE INVENTION) Root canal treatment apparatus**(57) (ABSTRACT)**

(PROBLEM) Provide a highly durable root canal treatment apparatus that is unlikely to become damaged in the event that flex acts upon it while rotating during root canal formation.

(MEANS FOR SOLVING) Work portion 4 of a designated length from tip 3 is formed on file A serving as the root canal treatment apparatus, which has a shaft-shaped needle portion 1 made of nickel-titanium alloy on which a shank 5 is formed continuously with work portion 4, and at least a portion or the entirety of work portion 4 is subjected to heat treatment focused on resistance to rotating fatigue.

(SELECTED DRAWING) Fig. 1



(2)

(SCOPE OF PATENT CLAIMS)

(CLAIM 1) Shaft-shaped root canal treatment apparatus made of nickel-titanium alloy, on which a work portion of a designated length from the tip is formed and on which a shank is formed continuously with said work portion, which root canal treatment apparatus is characterized in that at least a portion or the entirety of the work portion is subjected to heat treatment focused on resistance to rotating fatigue.

(DETAILED DESCRIPTION OF THE INVENTION)

(TECHNICAL FIELD)

(0001)

This invention relates to a root canal treatment apparatus for dental care, particularly to a root canal treatment apparatus that has improved resistance to wear arising from rotation of a root canal treatment apparatus that performs the intended treatment by rotating, entering and exiting in the length direction, or repeatedly switching between forward and reverse by roughly 1/4 of a rotation.

(BACKGROUND ART)

(0002)

Examples of apparatuses for the treatment of the root canal of a tooth by rotation that shape the root canal by cutting include a file and a reamer. These root canal treatment apparatuses are comprised of a member shaped by forming a work portion provided with a cutting edge or projection on a finely tapered axial rod in accordance with the treatment objective, or forming a work portion by shaping a tapered axial rod into a spiral shape. Furthermore, depending on the model, a handle or grip allowing the doctor to grasp and operate the apparatus may be integrally attached to the end of the aforesaid member to allow the doctor to directly operate the apparatus or grip the apparatus by means of the chuck of a handpiece or the like.

(0003)

Root canals are very fine and there is considerable disparity in their shape and thickness from person to person. For this reason, even the same model of root canal treatment apparatus comes in a variety of models of differing thickness. For example, if using a file to form the root canal by cutting, it is necessary to deform the file according to the shape of the root canal in order to keep from damaging the tissue surrounding the root canal, i.e. it is necessary for the file to have appropriate elasticity.

(0004)

The technology in Patent Literature 1 has been proposed as a root canal treatment apparatus with high elasticity and shape restorability of the kind described above. This technology relates to a root canal treatment apparatus manufactured by forming a work portion on shape memory-treated axial rod material having superelastic property by performing removal processing while retaining at below the shape memory treatment temperature.

(0005)

In the aforesaid root canal treatment apparatus, the axial rod on which a work portion has been formed deforms supply according to applied external force and rapidly regains its original shape when the external force is removed. For this reason, it is able to follow the shape of the root canal very closely, making it possible to form a root canal to a high level of precision.

(0006)

(PATENT LITERATURE 1) Japanese Patent Publication No. 3375765

(DISCLOSURE OF THE INVENTION)

(PROBLEM TO BE SOLVED BY THE INVENTION)

(0007)

In the root canal treatment apparatus in the aforesaid Patent Literature 1, the entire length of the work portion has uniform superelastic property, for which reason when the work portion is bent, the work portion on the free end attempts to return to its original shape, producing stress as the tip is inserted into the root canal and bent during root canal treatment. In particular, when shaping the root canal, because rotation occurs with primarily the tip of the work portion bent, flex stress acts on the work portion, producing an issue whereby there is a higher likelihood of damaging the narrow tip portion.

(0008)

The objective of this invention is to provide a root canal treatment apparatus that is unlikely to become damaged in the event that flex acts upon it while rotating during root canal formation, i.e. that is highly durable.

(MEANS OF SOLVING THE PROBLEM)

(0009)

(3)

To solve the aforesaid problem, the root canal treatment apparatus in this invention is a shaft-shaped root canal treatment apparatus made of nickel-titanium alloy, on which a work portion of a designated length from the tip is formed and on which a shank is formed continuously with said work portion, in which root canal treatment apparatus at least a portion or the entirety of the work portion is subjected to heat treatment focused on resistance to rotating fatigue.

(EFFECT OF THE INVENTION)

(0010)

In the root canal treatment apparatus in this invention, subjecting at least a portion or the entirety of the work portion to heat treatment focused on resistance to rotating fatigue makes it possible to achieve high resistance to flex occurring as a result of rotation during root canal treatment.

(PREFERRED EMBODIMENT OF THE INVENTION)

(0011)

The root canal treatment apparatus in this invention is an apparatus for the treatment of a root canal by rotation, and applies to all apparatuses made using axial-shaped material made of nickel-titanium (Ni-Ti) alloy. In root canal treatment apparatuses of this kind, a work portion having a shape most suited to the intended treatment is formed on one end, and an operation portion operated by the doctor is formed on the other end. This operating portion is formed into a handle if directly operated by hand by the doctor, or is furnished with a handle in a shape most suited to the structure of the grip of said apparatus in the event that an apparatus such as a handpiece is used.

(0012)

In particular, subjecting at least a portion or the entirety of the work portion to heat treatment focused on resistance improves the durability of the site on which flex acts during root canal treatment, making it possible to eliminate the risk of breakage.

(EMBODIMENT 1)

(0013)

Preferred embodiments of the root canal treatment apparatus in this invention will be described below using the drawings. Fig. 1 is a drawing showing a file that is a representative example of a root canal treatment apparatus. Fig. 2 is a schematic drawing illustrating the composition when performing a fatigue rupture test for the tip of the file.

(0014)

The shape of file A will be described by means of Fig. 1 to represent the aforesaid root canal treatment apparatus. File A is an apparatus that cuts the wall of the root canal, and is comprised of a needle 1 and handle 2.

(0015)

A tapered work portion 4 is formed on needle 1 over a span of a designated length from tip 3, and a straight shank 5 is formed continuously with work portion 4. Work portion 4 can have a rectangular, triangular or square shape depending on the type, each of which is constituted in such a way as to be able to exert its own unique functions.

(0016)

In File A in this embodiment, forming the rectangular cross-section into a spiral shape along work portion 4 produces a groove 4a and cutting edge 4b along said groove 4a.

(0017)

Shank 5 has the function of being attached to handle 2. As indicated in Fig. 2, a handle can be constituted in such a way as to be gripped by the chuck of a handpiece or allow a doctor to grip it while operating the apparatus, with each formed into a shape and from a material corresponding to its function.

(0018)

For example, the handle 2 shown in the drawing is made of a metal such as stainless steel, and shank 5 is inserted into a hole formed in the axis and fastened by bonding. If forming a handle operated by having a doctor grip it by hand, shank 5 is sometimes fastened by integrally insert-molding by injection-molding with a synthetic resin.

(0019)

Needle 1 is made of nickel-titanium (Ni-Ti) alloy and is formed using a wire having a diameter corresponding to the diameter

(4)

of needle 1 comprising file A, with portion 6, which is a portion of work portion 4, being subjected to heat treatment focused on resistance to rotating fatigue (hereinafter referred to as "durability heat treatment").

(0020)

Moreover, in this embodiment, durability heat treatment of file A is performed only on portion 6 from tip 3 of work portion 4, but naturally, it is also acceptable to perform durability heat treatment over the entirety of work portion 4 in this invention.

(0021)

There is no particular restriction on the length of portion 6 of work portion 4. In tests of this invention and the like, there were many instances of breakage at the region 2 mm to 3 mm from the tip when the entirety of the work portion was made to have superelastic property. For this reason, the length of portion 6 of work portion 4 must be at least 2 mm from tip 3, and at most the full length of work portion 4. The range for the preferable length of portion 6 is on the order of 3 mm to 10 mm from tip 3 when the length of work portion 4 is 16 mm, 3 mm or 4 mm being particularly preferable.

(0022)

Furthermore, the length of portion 6 may be altered to correspond to the taper of file A. For example, if the taper is 2/100, the portion furthest from tip 3 of work portion 4 (base) will not have a large diameter, so by using a designated length range from tip 3 for portion 6 and giving the other portions superelastic property, it is possible to retain the strength of the base. If the taper is 4/100 or 6/100, the diameter of the base is large, so the strength of the base will be retained even if the entirety of work portion 4 is subjected to durability heat treatment, and operability will be good.

(0023)

Durability heat treatment of portion 6 of work portion 4 is performed by heating the portion intended for durability heat treatment (portion 6 or the entirety of work portion 4) to a temperature obtained by testing to be described below, and retaining the raised temperature for a length of time obtained by testing. This durability heat treatment sets the Af temperature of the Ni-Ti alloy serving as the material of the file to a temperature greater than normal temperature, thereby making the site of portion 6 able to exert shape memory function.

(0024)

In a file A comprised in the manner set forth above, prior to treatment, a doctor is able to pre-curve portion 6 in accordance with the shape of the root canal or the shape of the apical foramen. By thus performing pre-curving, it becomes possible for tip 3 and portion 6 to closely follow the root canal when tip 3 is inserted into the root canal while performing treatment. Subsequent to completion of treatment and removal from the root canal, the doctor can apply force to cause it to regain its original shape, or heating can be performed to a temperature greater than the Af temperature set by durability heat treatment to cause it to regain its original shape.

(0025)

The aforesaid portion 6 is extremely flexible, which makes it possible to extend the length of time until breakage when work portion 4 is rotated while bent while tip 3 is inserted into the root canal, or when entering and exiting in the length direction, or when repeatedly switching between forward and reverse by roughly 1/4 of a rotation.

(0026)

In particular, because work portion 4 is formed in a tapered shape, when work portion 4 is bent with tip 3 as the fulcrum, shank 5 will remain essentially straight, making shank 5 of work portion 4 an arc shape with a small curvature, while the curvature increases moving towards portion 6 such that the arc becomes more prominently curved, and portion 6 will be significantly bent. In short, work portion 4 is not bent uniformly, but is rather bent in accordance with the taper. When the bending of work portion 4 is released, sections other than portion 6 return to their original shape (for example straight) and portion 6 retains its bent shape.

(0027)

Next, the testing method for setting the heat treatment temperature and retention time (heat treatment conditions) when performing heat treatment focused on resistance to rotating fatigue over either portion 6, which is a portion of work portion 4, or the entirety of work portion 4, will be described together with results thereof.

(5)

(0028)

The objective of this testing is to investigate the heat treatment conditions most conducive to achieving high durability in file A, assuming the most extreme rotation during root canal treatment involving rotating, entering and exiting in the length direction or repeatedly switching between forward and reverse by roughly 1/4 of a rotation, as well as to investigate the heat treatment conditions common to different Ni-Ti alloys.

(0029)

For this reason, this testing was performed by producing files A with the same specifications using as raw material a plurality of types of Ni-Ti alloy wire, performing fatigue rupture test on a plurality of samples subjected to heat treatment under different temperature and retention times using the device shown in Fig. 2, measuring the time until rupture, and comparing the measured results, thereby discovering the heat treatment conditions focused on durability to rotating fatigue.

(0030)

It is best for the time until occurrence of fatigue rupture in file A to be as long as possible. However, because there must be some benchmark in order to make a judgment, in this test, the benchmark was set to roughly 20 minutes without the occurrence of fatigue rupture when tested with the fatigue rupture tester described below.

(0031)

Using a wire with a diameter of roughly 1.0 mm composed of Ni: 55.76 wt%, remainder Ti (material 1), Ni: 55.91 wt%, remainder Ti (material 2), Ni: 55.97 wt%, remainder Ti (material 3), Ni: 55.90 wt%, remainder Ti (material 4) and Ni: 55.89 wt%, remainder Ti (material 5) as the material comprising file A, a plurality of no. 30 files were produced, each having a tip diameter of roughly 0.3 mm, taper 4/100, rectangular cross-sectional shape, roughly 25 mm length of needle projecting from handle 2 and roughly 15 mm length of work portion.

(0032)

Next, samples were produced from the files A produced from materials 1 to 5, one not subjected to heat treatment (untreated), one heat treated by retaining at 300°C for 30 minutes (heat treatment condition 1), one heat treated by retaining at 400°C for 30 minutes (heat treatment condition 2), one heat treated by retaining at 500°C for 30 minutes (heat treatment condition 3), and one heat treated by retaining at 600°C for 15 minutes (heat treatment condition 4), and a fatigue rupture test (durability) was performed, with a bending test and torsion test performed corroboratively.

(0033)

Moreover, during each test, in one sample, heat treatment was performed by inserting the needle 1 made of Ni-Ti alloy into an electric furnace and subjecting the entirety of work portion 4 to heat treatment, while in another sample, heat treatment was performed only for portion 6 from tip 3. Five samples were tested under the same conditions. Indicated values are a summary of test data.

(0034)

First, the bending test method and results will be described. The bending test was performed using a sample in which the entirety of needle 1 was heat treated, by bending to 45° while grasping a location 3 mm from the tip 3 of work portion 4 and measuring the maximum torque. The results of the bending test for untreated samples 1 to 5 were within the range of 40gf-cm to 50gf-cm, for heat treatment condition 1 samples 1 to 5 within the range of 40gf-cm to 55gf-cm, for heat treatment condition 2 samples 1 to 5 within the range of 35gf-cm to 40gf-cm, for heat treatment condition 3 samples 1 to 5 within the range of 30gf-cm to 40gf-cm, and for heat treatment condition 4 samples 1 to 5 within the range of 35gf-cm to 40gf-cm, showing no significant difference.

(0035)

Next, the torsion test method and results will be described. The torsion test was performed using a sample in which the entirety of needle 1 was heat treated, by grasping a location 3 mm from the tip 3 of work portion 4 and rotating, and measuring the maximum torque and angle at the time of rupture. The results of the torsion test for the untreated condition samples 1 to 5 were within the range of maximum torque 70gf-cm to 80gf-cm and angle 400° to 500°, for heat treatment condition 1 samples 1 to 5

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