



US005628674A

# United States Patent [19]

[11] Patent Number: **5,628,674**

Heath et al.

[45] Date of Patent: **May 13, 1997**

[54] **ENDODONTIC INSTRUMENT**

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[75] Inventors: **Derek E. Heath; Jerry A. Mooneyhan**, both of Johnson City, Tenn.

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[73] Assignee: **Tulsa Dental Products, L.L.C.**, Tulsa, Okla.

An Initial Investigation of the Bending and Torsional Properties of Nitinol Root Canal Files, *Journal of Endodontics*, Jul. 1988, vol. 14, No. 7, pp. 346-351.

[21] Appl. No.: **646,030**

Superelastic Ni-Ti Wire, *Wire Journal International*, Mar. 1991, pp. 45-50.

[22] Filed: **May 7, 1996**

*The Grinding Wheel*, Lewis and Schleicher, Third Edition, The Grinding Wheel Institute, pp. 382-383.

### Related U.S. Application Data

[63] Continuation of Ser. No. 76,367, Jun. 14, 1993, Pat. No. 5,527,205, which is a continuation of Ser. No. 787,945, Nov. 5, 1991, abandoned.

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[51] Int. Cl.<sup>6</sup> ..... **A61C 3/00**

### [57] ABSTRACT

[52] U.S. Cl. .... **451/48; 433/102; 433/224**

A method of fabricating an endodontic instrument by a machining operation is disclosed, and wherein a wire-like rod composed of a titanium alloy is advanced past a rotating grinding wheel at a relatively slow feed rate, with a sufficient depth of cut to remove all of the material on a given surface without over grinding a previously ground surface, and with the grinding wheel rotating at a relatively slow surface speed. The disclosed method is able to efficiently produce endodontic instruments having a high degree of flexibility, high resistance to torsional breakage, and with sharp cutting edges along the working length.

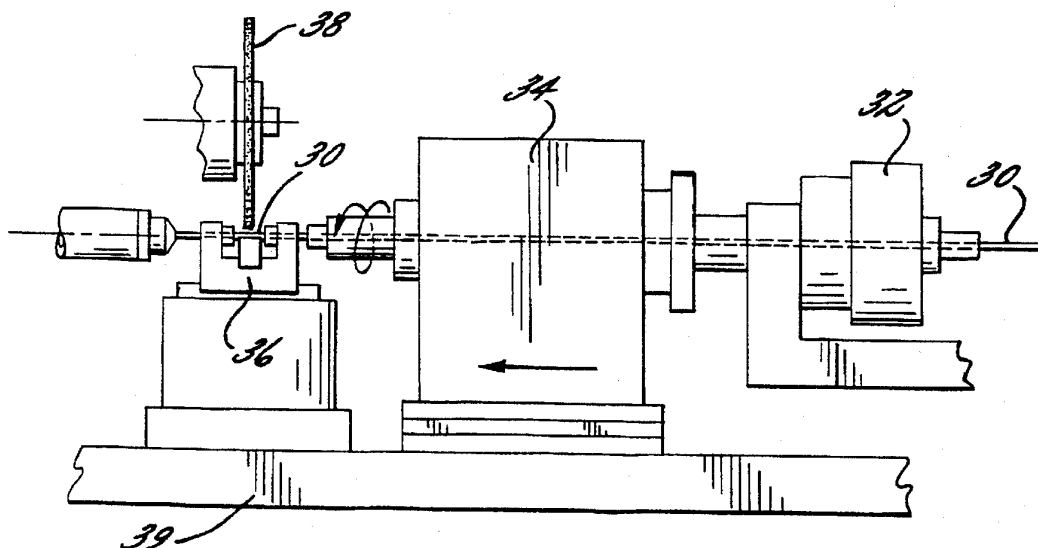
[58] Field of Search ..... 451/28, 48; 433/165, 433/102, 224, 225

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**7 Claims, 3 Drawing Sheets**



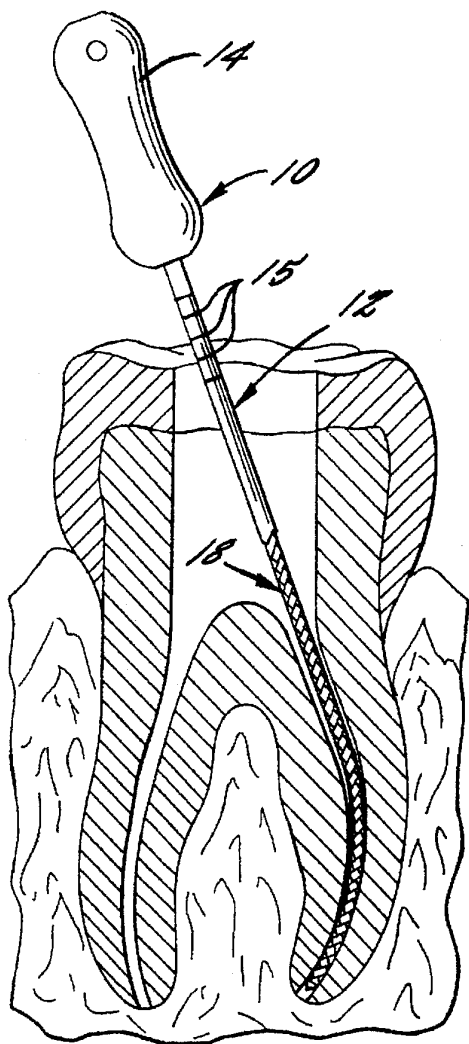


FIG. 1.

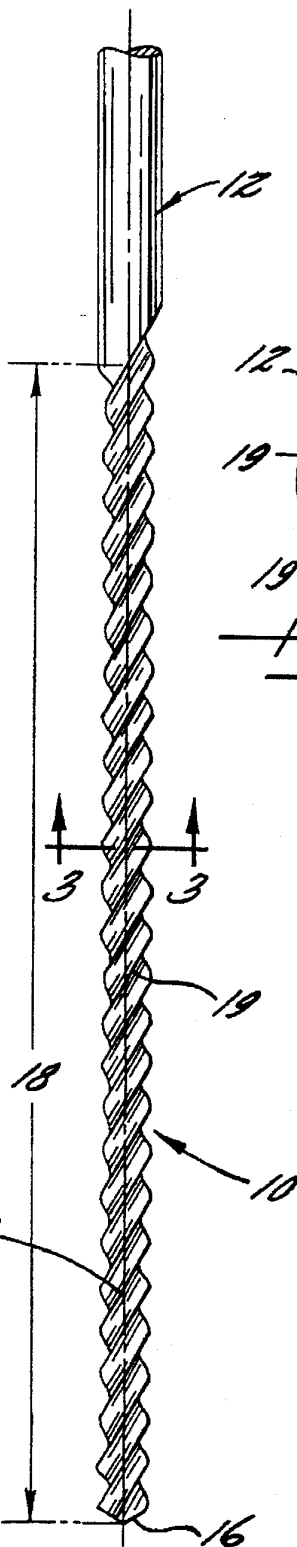


FIG. 2.

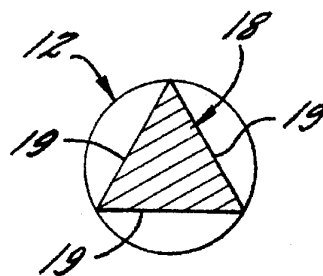


FIG. 3.

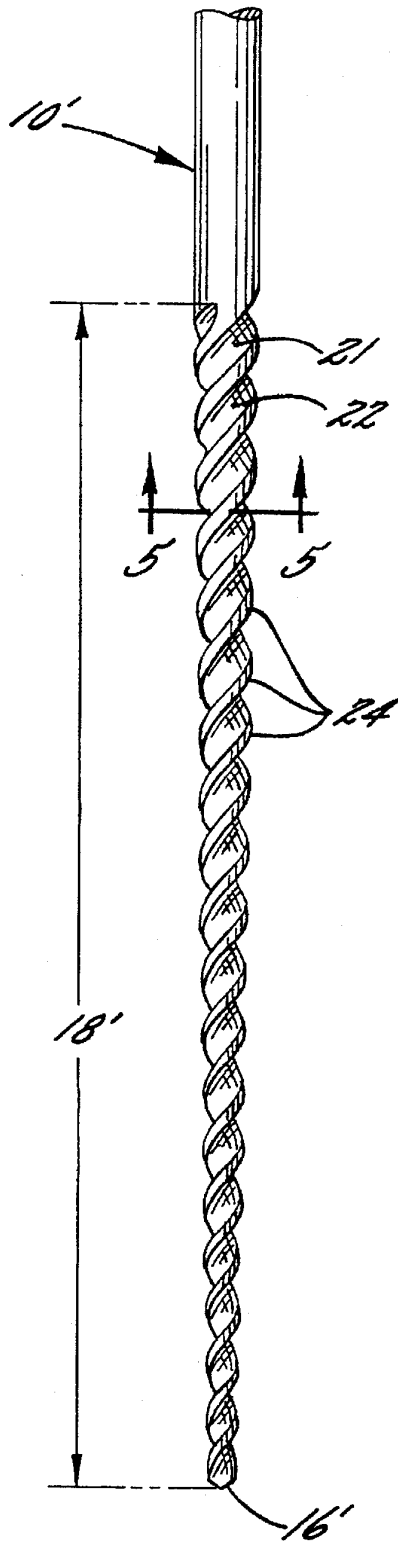


FIG. 4.

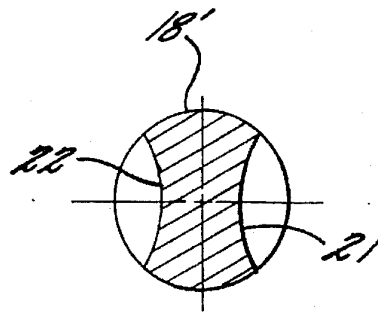


FIG. 5.

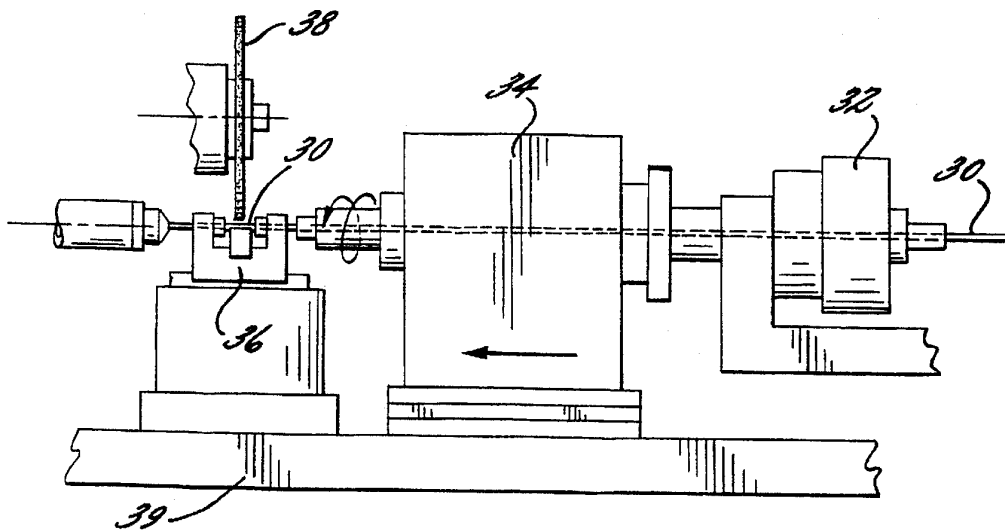


FIG. 6.

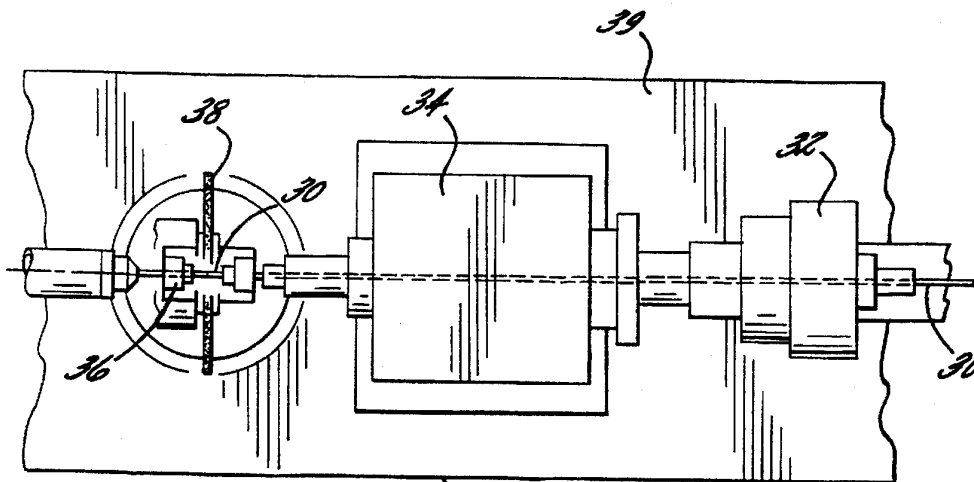
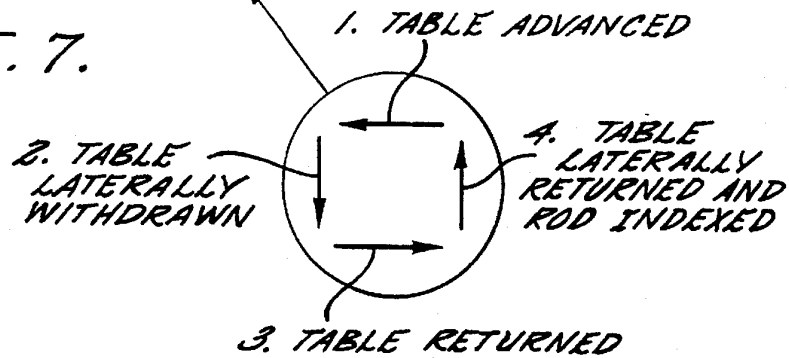


FIG. 7.



## ENDODONTIC INSTRUMENT

This application is a continuation of application Ser. No. 08/076,367, filed Jun. 14, 1993, now U.S. Pat. No. 5,527, 205, which in turn is a continuation of application Ser. No. 07/787,945 filed Nov. 5, 1991 and now abandoned.

## BACKGROUND OF THE INVENTION

The present invention relates to a method of fabricating an endodontic instrument adapted for use in performing root canal therapy on teeth, and which is characterized by high flexibility and high resistance to torsional breakage.

Root canal therapy is a well-known procedure wherein the crown of a diseased tooth is opened so as to permit the canal to be cleaned and then filled. More particularly, a series of very delicate, flexible, finger-held instruments or files are used to clean out and shape the root canal, and each file is manually rotated and reciprocated in the canal by the dentist. Files of increasingly larger diameter are used in sequence, to achieve the desired cleaning and shaping. When the canal is thus prepared, it is solidly filled with a filling material, which typically comprises a waxy, rubbery compound known as gutta percha. In one procedure, the gutta percha is positioned on an instrument called a compactor, and the coated compactor is inserted into the prepared canal and rotated and reciprocated to compact the gutta percha therein. The dentist thereafter fills the tooth above the gutta percha with a protective cement, and lastly, a crown is fitted to the tooth.

Endodontic instruments of the described type are conventionally fabricated by permanently twisting a stainless steel rod of triangular or square cross section. The apices of the triangular or square cross section thus form cutting edges which spiral along the length of the instrument. More recently, such instruments have been produced by a machining process, and wherein a cylindrical rod of stainless steel is moved past a rotating grinding wheel, and while the rod is slowly rotated about its axis so as to impart a desired helical configuration to the ground surface and form a spiral flute on the surface. The rod is thereafter indexed and again moved past the wheel, and these steps are repeated as many times as are necessary to form the rod into a triangular or square cross section. By appropriate control of the process, helical lands may be formed between the spiral flutes as illustrated in U.S. Pat. No. 4,871,312 to Heath.

It is well-known by clinicians that inadvertent errors can occasionally arise during root canal therapy as described above. These errors can include the formation of a ledge in the wall of the canal, the perforation of the canal, and a separation or fracture of the instrument. Many of these errors which occur during the therapy of a canal have a common genesis, i.e. the basic stiffness of the stainless steel instruments, particularly with the respect to the instruments of larger size. Efforts have been made to improve the flexibility of stainless steel instruments based upon different cross sectional shapes, but without significant success.

Recently, a series of comparative tests of endodontic instruments made of nickel-titanium (Nitinol) alloy and stainless steel were conducted. The results of the tests were published in an article entitled "An Initial Investigation of the Bending and the Torsional Properties of Nitinol Root Canal Files", *Journal of Endodontics*, Volume 14, No. 7, July 1988, at pages 346-351.

The Nitinol instruments involved in the above tests were machined in accordance with the procedure and operating parameters conventionally used in the machining of stainless steel endodontic instruments. More particularly, this standard procedure involves the following parameters:

## 1. Feed Rate

The rod from which the instrument is to be formed is moved axially past a rotating grinding wheel at a feed rate of about ten inches per minute. The rod is slowly rotated about its axis as it is axially advanced so as to impart a helical configuration to the ground surface.

## 2. Depth of Cut

The depth of each cut is sufficient to remove all of the material on a given surface without over grinding a previously ground surface. For example, in the case of an instrument triangular cross-section, the rod is moved past the wheel three times, once for each surface, with about 25 percent of the diameter being removed on each cut.

## 3. Speed of Wheel

An aluminum oxide grinding wheel is provided which is rotated at a surface speed of about 6000 feet per minute, and the wheel has a grit size of about 220.

The above tests demonstrated that the Nitinol instruments produced by the described machining process exhibited superior flexibility and torsional properties as compared to stainless steel instruments, but the cutting edges of the instruments exhibited heavily deformed metal deposits, which rendered the instruments generally unsatisfactory for use.

It is accordingly an object of the present invention to provide a method of fabricating an endodontic instrument which is characterized by high flexibility and high resistance to torsional breakage.

It is another object of the present invention to provide a method of efficiently fabricating an endodontic instrument which is composed of a titanium alloy, such as a nickel-titanium alloy, and which exhibits high flexibility and high resistance to torsional breakage, and which is also characterized by sharp cutting edges.

## SUMMARY OF THE INVENTION

The above and other objects and advantages of the present invention are achieved in the embodiments illustrated herein by the discovery that when an endodontic instrument of titanium alloy is machined under certain specific operating parameters, a totally satisfactory instrument, having high flexibility, high resistance to torsion breakage, and sharp cutting edges, may be produced. The specific operating parameters are not suggested by the known procedure for machining stainless steel instruments as summarized above, and indeed, the parameters which are effective in producing a satisfactory instrument are directly contrary to accepted practices for machining titanium alloys as presented in authoritative literature, note for example the brochure entitled "RMI Titanium", published by RMI Company of Niles, Ohio.

More particularly, the present invention involves the steps of (a) providing a cylindrical rod of metallic material which is composed of at least about 40% titanium and which has a diameter less than about 0.06 inches, and (b) axially moving the rod past a rotating grinding wheel at a feed rate of not more than about 5 inches per minute, while rotating the rod about its axis, and so that the wheel removes at least about 25% of the diameter of the rod at the point of maximum removal and forms a helical surface on the rod. The grinding wheel is rotated at a relatively slow surface speed of not more than about 3000 feet per minute, and preferably not more than about 2200 feet per minute. Also,

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