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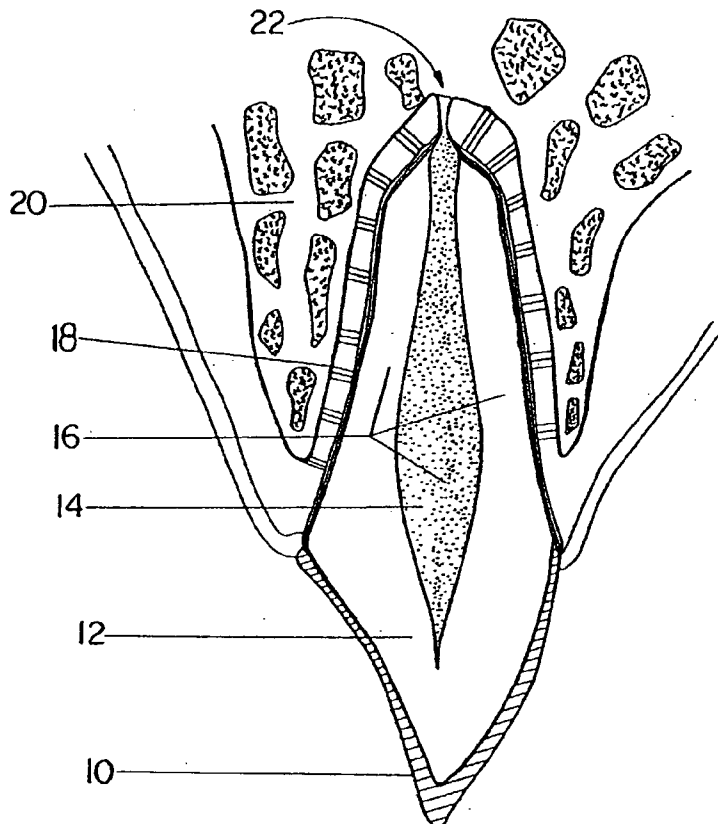
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(54) Title: DENTAL AND MEDICAL INSTRUMENTS COMPRISING TITANIUM



(57) Abstract: Endodontic instruments for use in performing root canal therapy on a tooth are disclosed. In one form, the instruments include an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. The shank comprises a titanium alloy, and the shank is prepared by heat-treating the shank at a temperature above 25 °C in an atmosphere consisting essentially of a gas unreactive with the shank. In another form, the endodontic instruments have an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. The shank consists essentially of a titanium alloy selected from alpha-titanium alloys, beta-titanium alloys, and alpha-beta-titanium alloys. The instruments solve the problems encountered when cleaning and enlarging a curved root canal.

WO 2005/122942 A1



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Dental and Medical Instruments Comprising Titanium

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority from United States Provisional Patent Application No. 60/578,091 filed June 8, 2004.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

5 **[0002]** Not Applicable.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0003] The invention relates to instruments used in medicine and dentistry. More particularly, the invention relates to medical and dental instruments such as
10 drills, burs and files, and to endodontic instruments such as drills, burs and files used by dentists.

2. Description of the Related Art

[0004] Endodontics or root canal therapy is the branch of dentistry that deals with diseases of the dental pulp and associated tissues. One aspect of
15 endodontics comprises the treatment of infected root canals by removal of diseased pulp tissues and subsequent filling.

[0005] Figure 1 shows a representation of a tooth to provide background. Root canal therapy is generally indicated for teeth having sound external structures but having diseased, dead or dying pulp tissues. Such teeth will generally possess
20 intact enamel 10 and dentin 12, and will be satisfactorily engaged with the bony tissue 20, by among other things, healthy periodontal ligaments 18. In such teeth, the pulp tissue 14, and excised portions of the root 16, should be replaced by a biocompatible substitute. Figure 1 also shows the apical foramen 22 through which blood and nerves pass to support the pulp tissues.

[0006] One method for the preparation of a root canal for filling is represented
25 by Figures 2a-2e. A tooth having a basically sound outer structure 24 but diseased pulp 26, is cut with conventional or coated dental drill 28 creating a coronal access opening 30. A broach is used for gross removal of pulp material 26 from the root canal through the coronal access opening 30. The void 32
30 formed is enlarged as in Figure 2d with file 34, to result in a fully excavated cavity

36. Debris is removed from this cavity by flushing and the cavity cleansed to remove all diseased tissue. The excavated canal is then ready for filling.

[0007] During this procedure, small endodontic instruments (e.g., file 34) are utilized to clean and enlarge the long narrow tapered root canals. While most files perform entirely satisfactorily when cleaning and enlarging a straight root canal, problems have been encountered when using certain files to clean and enlarge a curved root canal. As will be understood by those skilled in the art, a very large portion of the root canals encountered by a practicing dentist and/or endodontist are of the curved variety, and thus this problem is a significant one for the profession.

[0008] When performing an operation on a curved root canal with a smaller diameter file, the file can easily be inserted into the curved canal and will easily bend to fit the curved shape of the canal due to the flexibility of the small diameter file. In Figure 1a, there is shown the file 34 of Figure 2d in a bent position. The file 34 has a shank 42 mounted at its proximate end 47 to a handle 43. The shank 42 may include calibrated depth markings 45 and further includes a distal end 48. The shank 42 includes two continuous helical flutes 51 as shown in Figure 1b that extend along its lower portion. The flutes 51 define a cutting edge. A helical land 53 is positioned between axially adjacent flutes as shown in Figure 1b.

[0009] While file 34 can easily bend to fit the curved shape of a canal due to the flexibility of the small diameter shank 42, with increasingly larger sizes of files, the file becomes significantly less flexible and becomes more and more difficult to insert through the curved portion of the canal. In some cases, the relatively inflexible file will cut only on the inside of the curve and will not cut on the outside of the curvature of the root canal. Thus, the problems, which occur during the therapy of a root canal, are often the result of the basic stiffness of the files, particularly with the respect to the instruments of larger diameter.

[0010] Various solutions have been proposed to limit the problems encountered when cleaning and enlarging a curved root canal with a file. For example, U.S. Patent No. 4,443,193 describes a shaped endodontic instrument that is said to solve this problem. U.S. Patent No. 5,380,200 describes an endodontic instrument having an inner core and an outer shell wherein one of the

cores or shell is a nickel-titanium alloy and the other core or shell is selected from stainless steel, titanium alpha alloy, titanium beta alloy, and titanium alpha beta alloy. (For background on beta-titanium, see U.S. Patent Nos. 4,197,643; 4,892,479; 4,952,236; 5,156,807; 5,232,361; 5,264,055; 5,358,586; 5,947,723; 6,132,209; and 6,258,182.) U.S. Patent No. 5,464,362 describes an endodontic instrument of a titanium alloy that is machined under certain specific operating parameters to produce an instrument having high flexibility, high resistance to torsion breakage, and sharp cutting edges. U.S. Patent No. 6,315,558 proposes the use of superelastic alloys such as nickel-titanium that can withstand several times more strain than conventional materials without becoming plastically deformed. This property is termed shape memory, which allows the superelastic alloy to revert back to a straight configuration even after clinical use, testing or fracture (separation).

[0011] In spite of the aforementioned advances, there remains a need for medical and dental instruments, and particularly endodontic instruments, such as drills, burs and files, that have high flexibility, have high resistance to torsion breakage, maintain shape upon fracture, can withstand increased strain, and can hold sharp cutting edges.

SUMMARY OF THE INVENTION

[0012] The present invention overcomes the problems encountered when cleaning and enlarging a curved root canal. In one aspect, the invention provides an endodontic instrument for use in performing root canal therapy on a tooth. The instrument includes an elongate shank having a cutting edge extending from a distal end of the shank along an axial length of the shank. The shank comprises a titanium alloy, and the shank is prepared by heat-treating the shank at a temperature above 25°C in an atmosphere consisting essentially of a gas unreactive with the shank. The shank has high flexibility, high resistance to torsion breakage, maintains shape upon fracture, can withstand increased strain, and can hold sharp cutting edges. Thus, it solves the problems encountered when cleaning and enlarging a curved root canal.

[0013] In another aspect, the invention provides an endodontic instrument for use in performing root canal therapy on a tooth. The instrument has an elongate

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