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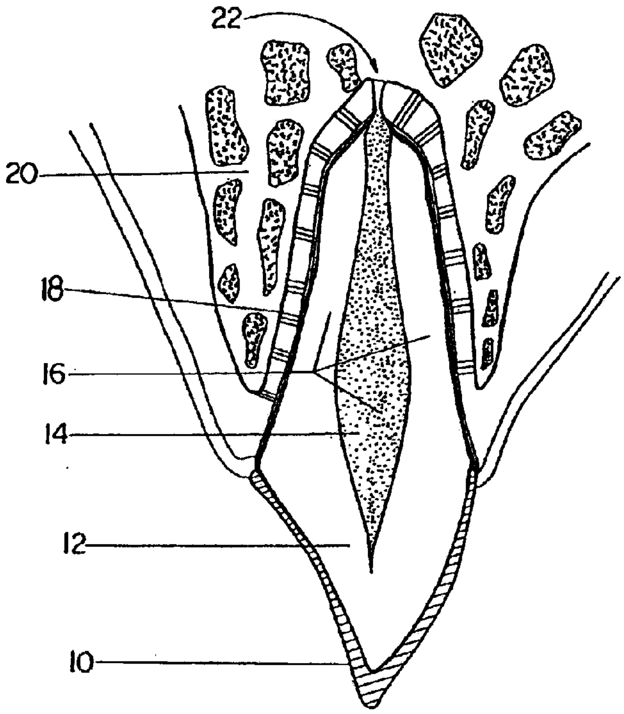

FIG 1

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

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Dental and Medical Instruments Comprising Stainless Steel

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority from United States Provisional Patent Application No. 61/138,867 filed December 18, 2008.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[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 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 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 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 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. An endodontic instrument described in ISO (International Organization for Standardization) 3630-1:2008 "Dentistry - Root-canal instruments - Part 1: General requirements and test methods" is used for gross removal of pulp material 26 from the root canal through the coronal access opening 30. ISO 3630-1:2008 is incorporated herein by reference. The void 32 formed is enlarged as in Figure 2d with an endodontic instrument described in ISO 3630-1:2008, 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., as described in ISO 3630-1:2008 or other patents, 34) are utilized to clean and enlarge the long narrow tapered root canals. While most endodontic instruments perform entirely satisfactorily when cleaning and enlarging a straight root canal, problems have been encountered when using certain endodontic instruments 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 endodontic instrument 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 an endodontic instrument 34 of Figure 2d in a bent position. The endodontic instrument 34 has a shaft 42 mounted at its proximate end 47 to a handle 43. The shaft 42 may include calibrated depth markings 45 and further includes a distal end 48. The shaft 42 may include 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 the endodontic instrument 34 can easily bend to fit the curved shape of a canal due to the flexibility of the small diameter shaft 42, with increasingly larger sizes of instruments, it 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 instrument 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 instruments, 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. 5,915,964 proposes the use of a cutter inside a file guide to solve this problem. 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] It can be appreciated from these above patents that superelastic alloys such as nickel-titanium have become the preferred material in the manufacture of endodontic files. Although stainless steel has been used in the manufacture of endodontic files, stainless steel has generally fallen out of favor as a material in the manufacture of endodontic files. Reasons for this include the lack of flexibility of stainless steel that can make it more difficult to insert through the curved portion of the canal.

[0012] Although stainless steel endodontic files have sufficient hardness, they have been deemed to be not flexible enough for some endodontic work. However, while nickel-titanium endodontic files are more flexible than stainless steel files, the flexibility of nickel-titanium endodontic files can be excessive for certain applications. Also, nickel-titanium endodontic files have low tensile strength which can lead to file separation when the file's torque is exceeded and the flutes do not maintain a sharp edge for multiple uses. Consequently, nickel-titanium endodontic files can be unsuitable for use as standardized instruments (ISO 3630-1:2008). The result is that nickel-titanium endodontic files are manufactured with greater tapers to compensate for their lack of torque strength (ISO 3630-1:2008).

[0013] Therefore, there remains a need for alternative medical and dental instruments, and particularly endodontic instruments, such as drills, burs and endodontic instruments described in ISO 3630-1:2008, 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

[0014] 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 shaft having a cutting edge extending from a distal end of the shaft along an axial length of the shaft. The shaft comprises a stainless steel alloy, and the shaft is prepared by heat-treating the entire shaft at a temperature above 25°C in an atmosphere consisting essentially of a gas unreactive with the shaft. The shaft has high ductility, 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.

[0015] In another aspect, the invention provides an endodontic instrument for use in performing root canal therapy on a tooth. The instrument has an elongate shaft having a cutting edge extending from a distal end of the shaft along an axial length of the shaft. This version of the invention also solves the problems encountered when cleaning and enlarging a curved root canal. The shaft consists essentially of a stainless steel alloy. A shaft that consists essentially of a stainless steel alloy avoids the use of complex two material systems that are expensive to produce and are prone to delamination of the materials.

[0016] In yet another aspect, the invention provides a method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy. The method comprises creating or enlarging the opening in the tooth using an instrument according to the invention.

[0017] These and other features, aspects, and advantages of the present invention will become better understood upon consideration of the following detailed description, drawings, and appended claims.

Brief Description of the Drawings

[0018] Figure 1 is a cross-sectional view of a tooth.

[0019] Figure 1a is a side elevational view of an endodontic instrument.

[0020] Figure 1b is a partial detailed view of the shaft of the endodontic instrument shown in Figure 1a.

[0021] Figures 2a-2e represent a prior art procedure for preparing a tooth for endodontic restoration.

[0022] Figure 3 shows an apparatus for measuring maximum torque and angular deflection in accordance with in ISO 3630-1:2008.

[0023] Figure 4 shows an apparatus for measuring stiffness in accordance with in ISO 3630-1:2008.

Detailed Description Of The Invention

[0024] One embodiment of the invention provides an improved endodontic instrument for use in performing root canal therapy on a tooth. This embodiment of the invention is an endodontic instrument as shown in Figure 1a that includes an elongate shaft 42 mounted at its proximate end 47 to a handle 43. The shaft 42 may be about 15 to about 35 millimeters long. The proximate end 47 may have a diameter of about 0.5 to about 1.6 millimeters. The shaft 42 may include calibrated depth markings 45 and further includes a distal end 48. The shaft 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. The cutting edge may extend from 2 to 30 millimeters from the distal end 48. A helical land 53 is positioned between axially adjacent flutes as shown in Figure 1b.

[0025] Table 1 shows the ISO 3630-1:2008 - standard-sized endodontic instrument nominal size designations and dimensions where d1 is the diameter of the projection of the working part at the tip end, d2 is the diameter at three millimeters from the tip, and d3 is the diameter at sixteen millimeters from the tip. An endodontic instrument according to the invention can be dimensioned to comply with ISO 3630-1:2008.

TABLE 1

Nominal size	d1 (mm.)	d2 (mm.)	d3 (mm.)
006	0.06	0.12	0.38
008	0.08	0.14	0.40
010	0.10	0.16	0.42
015	0.15	0.21	0.47
020	0.20	0.26	0.52
025	0.25	0.31	0.57
030	0.30	0.36	0.62
035	0.35	0.41	0.67
040	0.40	0.46	0.72
045	0.45	0.51	0.77
050	0.50	0.56	0.82
055	0.55	0.61	0.87
060	0.60	0.66	0.92
070	0.70	0.76	1.02
080	0.80	0.86	1.12
090	0.90	0.96	1.22
100	1.00	1.06	1.32
110	1.10	1.16	1.42
120	1.20	1.26	1.52
130	1.30	1.36	1.62
140	1.40	1.46	1.72

[0026] According to ISO 3630-1:2008, the tip portion of the instrument is the part of the root-canal instrument which is intended as the point; the working part is the portion of the root-canal instrument with an active cutting surface; the shank is the part of the root-canal instrument to be connected into a handpiece; the handle is the part of the root-canal instrument to be manipulated by the user by hand; and the operative part is the portion of the root-canal from the tip to the handle or shank. In the present application, the term "shaft" can be used to designate the "operative part" under ISO 3630-1:2008. Under ISO 3630-1:2008, the length of the working part should be a minimum of 16 millimeters. Under ISO 3630-1:2008, the taper of the tip size is 2% for standard-sized instruments.

[0027] In one example embodiment, the endodontic instrument can be manufactured from a stainless steel wire as follows. The stainless steel wire may be formed of any suitable stainless steel material. Non-limiting examples for the stainless steel include: (i) American Iron and Steel Institute (AISI) 300 Series austenitic chromium-nickel alloys such as Type 301, Type 302, Type 304, and Type 316; (ii) AISI 400 Series ferritic and martensitic chromium alloys such as Type 409 ferritic, Type 410 martensitic, and Type 420 martensitic. One preferred stainless steel wire is formed from austenitic stainless steel Type 304 V, which includes: 0.08 wt.% maximum C, 18-20 wt.% Cr, 66.345 - 74 wt.% Fe, 2 wt.% maximum Mn, 8-10.5 wt.% Ni, 0.045 wt.% maximum P, 0.03 wt.% maximum S, and 1 wt.% maximum Si, and is vacuum melted. Type 304 V has a melting point of 1400-1455°C.

[0028] The stainless steel wire from which the endodontic instrument is to be manufactured may be supplied already drawn in a selected polygonal cross sectional shape. Alternatively, the wire may be supplied in a circular cross section and then shaped to the desired cross section. With regard to wire diameter, endodontic instruments are sized in accordance with established standards such as shown in Table 1 above, which range from a thickness at the distal end 48 of 1.4 millimeters (size 140) to a thickness at the distal end 48 of 0.06 millimeters (size 06). The wire diameter can be selected to meet these standard size dimensions. The continuous wire is first cut to a desired length, and the cut length is then torsioned to produce an intermediate instrument comprising an elongate shaft having a cutting edge extending from a distal end of the shaft along an axial length of the shaft. The cutting edge derives from the longitudinal edges of the polygonal shape. The intermediate instrument has a first microstructure. By "intermediate", it is meant that the instrument is subjected to at least one further manufacturing step.

[0029] The entire shaft of the intermediate instrument is then heat-treated at a temperature above 25°C in an atmosphere consisting essentially of a gas unreactive with the shaft to produce the endodontic instrument. Preferably, the temperature is from 400°C up to but not equal to the melting point of the stainless steel alloy (which in the case of Type 304 V stainless steel is about 1400°C). Preferably, the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, nitrogen, and radon. In one example embodiment, the shaft is heat-treated for a minimum of 1 hour. However, other temperatures are suitable as they are dependent on the time period and the time period is dependent of the selected temperature for heat exposure. For example, the heat-treating temperature can be in the ranges of 400°C-1100°C, 400°C-1000°C, 500°C-900°C, 600°C-800°C, 600°C-700°C, 700°C-800°C, 650°C-750°C, or 800°C-1000°C. Other time periods such as 15 minutes, 30 minutes, 45 minutes, 90 minutes, 2 hours and 3 hours are also suitable. The heat treatment produces a second microstructure different from the first microstructure.

[0030] In one alternative method for manufacturing the endodontic instrument, the cutting edges of the intermediate instrument can be formed by grinding a continuous wire and cutting the ground wire into individual lengths. In another alternative method for manufacturing the endodontic instrument, the cutting edges of the intermediate instrument can be formed by grinding individual cut lengths of the wire. The intermediate instruments may be formed by other means such as cutting, grit blasting, machining, and the like. The intermediate instruments may be formed by any of these means can be heat treated as detailed above to form the endodontic instrument.

[0031] When an austenitic stainless steel is used to form the endodontic instrument, a surface layer of an S-phase of the austenitic stainless steel can be formed on the endodontic instrument by nitriding the endodontic instrument at a temperature below 480°C. The S-phase of the austenitic stainless steel is also termed "expanded austenite" and represents a solid solution of nitrogen in the austenitic steel. Formation of the S-phase of the austenitic stainless steel increases the surface hardness and wear resistance.

[0032] Present medical and dental practice entails cutting of hard tissues such as bone or teeth with instruments manufactured of carbide steel, stainless steel and nickel-titanium. Present endodontic practice entails the preparation, cleaning, and shaping of root canals in teeth utilizing carbide steel, stainless steel and nickel-titanium instruments for hand, mechanical and rotary applications. It may be coated (as described below) or uncoated. Today a growing number of physicians and dentists (endodontists) are utilizing engine driven drills and files with various names and applications. This includes instrumentation that will facilitate the cleaning and sealing of the root canal system. In addition, a coating or heat-treatment may relieve stress in the instrument to allow it to withstand more torque, rotate through a larger angle of deflection, change the handling properties, or visually exhibit a near failure of the instrument. This aspect of the invention relates to all drills, burs, files, and instruments used in medicine and dentistry.

[0033] In another aspect, the present invention provides for coating and optionally thereafter heat-treating dental and medical instruments including the coatings to maintain and/or improve their sharpness, cutting ability, reactivity/corrosion properties and/or instrument longevity. Such an instrument may be manufactured from stainless steel, carbide steel, as well as other materials. These instruments may be electropolished before or after coating or heat-treating. These instruments will include medical, dental and endodontic instruments (both hand and engine driven), cutting burs (drills), and enlarging instruments including hand, mechanical and rotary.

[0034] The coating processes may include but not limited to the following processes: composite electroless plating (see, e.g., U.S. Patent Nos. 4,820,547; 4,997,686; 5,145,517; 5,300,330; 5,863,616; and 6,306,466); chemical vapor deposition (see, e.g., U.S. Patent No. 4,814,294); microwave deposition (see, e.g., U.S. Patent No. 4,859,493); laser ablation process (see, e.g., U.S. Patent No. 5,299,937); ion beam assisted deposition (see, e.g., U.S. Patent No. 5,725,573);

physical vapor deposition (see, e.g., U.S. Patent Nos. 4,670,024, 4,776,863, 4,984,940, and 5,545,490); Molybdenum Disulfide Coating (MoS_2) (see, e.g., U.S. Patent No. 5,037,516 or SAE Standard AMS2526); electropolishing; coatings including titanium nitride and titanium aluminum nitride commercially available under the trademark Firex™; coatings such as titanium nitride (TiN), titanium carbonitride (TiCN), titanium aluminum nitride (TiAlN), aluminum titanium nitride (AlTiN); S-phase nitriding or multiple coatings or combinations of coatings.

[0035] As detailed above, present medical and dental practice entails cutting of hard tissues such as bone or teeth with instruments manufactured of carbide steel, stainless steel and nickel-titanium. Present endodontic practice entails the preparation, cleaning, and shaping of root canals in teeth utilizing carbide steel, stainless steel and nickel-titanium. These can be manufactured as hand, mechanical and rotary instruments. Today a growing number of physicians and dentists (endodontists) are utilizing engine driven drills and files with various names and applications. This aspect of the present invention pertains to the application of coatings and optionally heat-treatment to cutting instruments such as drills and files to produce a sharper cutting edge and a higher resistance to heat degradation that should provide for better cutting, a smooth surface and/or different metallurgical properties than the material from which it was manufactured. This includes instrumentation that will facilitate the cleaning and sealing of the root canal system. In addition, a heat-treatment separately applied or as utilized in the coating process may relieve stress in the instrument which should allow for more instrument longevity by the ability to withstand more torque, rotate through a larger angle of deflection, change the handling properties, remove shape memory or visually exhibit a near failure of the instrument. This aspect of the invention relates to all drills, burs, files, and instruments used in medicine and dentistry.

[0036] One example process of this aspect of the present invention for such instruments is a titanium nitride coating. This coating process is done with physical vapor deposition with an inherent heat-treatment. Another process is a multilayer process utilizing a titanium nitride coating and then a titanium aluminum nitride coating. This last coating process is commercially available under the trademark FIREX™. There are other processes including but not limited to S-phase nitriding.

[0037] Another example process of this aspect of the present invention for such instruments is a metal or metal alloy coating incorporating particulate matter. One process to produce such a coating to an instrument includes contacting the surface of the instrument with a stable electroless metallizing bath comprising a metal salt, an electroless reducing agent, a complexing agent, an electroless plating stabilizer, a quantity of particulate matter which is essentially insoluble or sparingly soluble in the metallizing bath, and a particulate matter stabilizer, and maintaining the particulate matter in suspension in the metallizing bath during the metallizing of the instrument for a time sufficient to produce a metallic coating with the particulate matter dispersed.

Examples

[0038] The following Examples have been presented in order to further illustrate the invention and are not intended to limit the invention in any way.

Example 1

[0039] Work was carried out on austenitic stainless steel files of a stainless steel composition. The files were heated to 800°C for an hour and then S-phase nitrided to harden the surface. This was carried out to see if the ductility of larger sized stainless steel files could be improved. This proved successful and so further study was indicated.

Example 2

[0040] ISO size stainless steel files of austenitic stainless steel Type 304 V were placed in a specially fitted jig for a furnace and heated to 800°C, 900°C and 1000°C to determine if the ductility of a larger size stainless steel instrument or wire could be made more ductile. These same endodontic instruments were then S-phase nitrided to harden the surface. The results from this study indicated that indeed the process does make the instruments more ductile.

Example 3

[0041] ISO size stainless steel files sizes #15 formed from austenitic stainless steel Type 304 V were placed in ovens that had been heated to 650°C, 700°C and 750°C for one hour each. These heat treated files and non-heat-treated files were then tested for bending moment, torque and angular deflection utilizing ISO 3630-1:2008 and ANSI/ADA Specification No. 28 – 2002.

[0042] One mechanical requirement of ISO 3630-1:2008 is resistance to fracture by twisting. The ISO 3630-1:2008 test of resistance to fracture of root-canal instruments is performed by measuring the maximum torque and angular deflection for each root-canal instrument. The apparatus for a ISO 3630-1:2008 torque test, such as shown in Figure 3 or other suitable device, includes the following parts: a low-speed reversible geared motor 1c capable of revolving the test piece at 2 rpm; a torque-measuring device 4c fixed on two linear ball-bearings 5c mounted on the shaft of the device; a chuck 3c with jaws made from soft brass used to clamp the test piece three millimeters from the tip and coaxial with the torque axis; a separate amplifier and digital display for controlling the operation of the motor and recording the torque and angular deflection; and a chuck 2c with jaws made from hardened steel for clamping the test piece at the shank. In the procedure for the torque test, one removes the handle or shank with a suitable wire cutter at the point at which it is attached to the shaft of the root-canal instrument. The torque-measuring device is calibrated for the torque range of the sample to be tested. The test piece is set into the chuck 2c of the geared motor 1c leaving a maximum of one millimeter of the unground portion out of the chuck. The chuck 2c is tightened. The torque-measuring device is slowly slid along the linear bearing 5c until the tip the test piece enters three millimeters into the brass jaws of chuck 3c. One checks to ensure that the test piece is straight and centered into the jaws. The chuck 3c is tightened. Since clamping will probably induce a pre-stress in the test piece, the geared motor 1c is activated in steps until the torque digital display or the strip chart recorder shows a zero reading. After ensuring that the geared motor is set for clockwise rotation as viewed from the test piece shank end, the device is activated. The device shown is designed to stop the operation when the test piece fails. One then records the maximum torque and angular deflection for each piece tested. The maximum torque is expressed in Newton-meters and the angular deflection in degrees. The specified minimum values for the torque and angular deflection are in Table 2 below from ISO 3630-5:2005.

TABLE 2
Torque and Angular Deflection (Minimum Values) for Clockwise Rotation

Nominal Size	K-files Torque (mN·m)	K Reamers Torque (mN·m)	Angular Deflection (Degrees)
006	0.34	0.34	360
008	0.5	0.5	360
010	0.6	0.6	360
015	0.8	0.8	360
020	1.76	1.18	360
025	2.94	1.96	360
030	4.42	3.43	360
035	6.38	4.91	360
040	9.81	6.87	360
045	11.78	9.32	360
050	16.68	11.78	360

[0043] Another mechanical requirement of ISO 3630-1:2008 is resistance to bending. The determination of stiffness under ISO 3630-1:2008 is performed by twisting the root-canal instrument 45 degrees. The apparatus of Figure 3 is used with the modification of the clamping jaws and the bending device or catch pin as shown in Figure 4. In Figure 4, there is a reversible gear motor 1e, a stop 2e, a torque measuring device 3e and a catch pin 4e. The amplifier is capable of being set to a pre-selected angular deflection of 45° at which point the test stops. In the procedure, one removes the handle or shank with a suitable wire cutter at the point at which the handle or shank is attached to the shaft of the root-canal instrument.. The apparatus is set to stop the angular deflection at 45°. The chuck is set onto the shaft of the torque-measuring device. The tip of the test piece is set into the jaws of the chuck perpendicular to the axis of the motor to a depth of three millimeters. The chuck is tightened. The catch pin 4e is mounted onto the motor shaft. One slides the torque-measuring device along the linear ball-bearing until the test piece is located above the rotating pin. The motor is rotated in the correct direction in stages until the catch pin 4e is lightly touching the test piece. One ensures that the display shows zero. The torque-measuring device is activated. The applied force is recorded for each piece tested. The stiffness is expressed in Newton-meters. The specified minimum values for the stiffness (bending moment) are in Table 3 below from ISO 3630-5:2005.

TABLE 3
Stiffness (Bending Moment)
Maximum Values Bending at 45°

Size	K Files (mN·m)	K Reamers (mN·m)
006	1.47	1.47
008	1.96	1.96
010	2.45	2.45
015	4.91	4.91
020	7.85	7.85
025	11.78	11.78
030	14.72	14.72
035	18.65	21.59
040	24.53	31.4
045	35.33	36.8
050	44.16	40.24

[0044] The instruments in Tables 2 and 3 include K-type reamers and K-files. In one known method for fabricating a K-type instrument, a round wire of varying diameters is usually grounded into three or four-sided pyramidal blanks and then twisted into the appropriate shapes. These shapes are specified and controlled by ISO. The manufacturing processes for reamers and files are similar; however, files usually have a greater number of flutes per unit length than reamers. Reamers are generally used in a rotational direction only, whereas files can be used in a rotational or push-pull fashion.

[0045] Both sets of files tested in Example 3 passed the requirements of the ISO 3630-5:2005 tests and specifications noted in Table 2 and 3, but the heat treated files in the bending moment test were extremely significant with the P value less than

.0001 utilizing an unpaired “t” test. This can be interpreted to mean that the files are extremely flexible and still maintain the integrity of the instrument. The treated sizes #20 and #25 were likewise tested and the results for the bending moment showed similar results with the P value less than .0001 utilizing an unpaired “t” test.

[0046] Thus, the Examples show that stainless steel heat-treated files exhibit better ductility. Thus, the invention provides medical and dental instruments, and particularly endodontic instruments, such as drills, burs and files, with better ductility and the instruments can hold sharp cutting edges such that the instruments overcome the problems encountered when cleaning and enlarging a curved root canal.

[0047] Although the present invention has not been described in considerable detail with reference to certain embodiments, one skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which have been presented for purposes of illustration and not of limitation. For example, while the present invention finds particular utility in the field of endodontic instruments, the invention is also useful in other medical and dental instruments used in creating or enlarging an opening. Therefore, the scope of the appended claims should not be limited to the description of the embodiments contained herein.

CLAIMS

What is claimed is:

1. A method for manufacturing an endodontic instrument for use in performing root canal therapy, the method comprising:

(a) forming an intermediate instrument including an elongate shaft having a cutting edge extending from a distal end of the shaft along an axial length of the shaft wherein the shaft comprises a stainless steel alloy; and

(b) thereafter heat-treating the shaft at a temperature above 25°C in an atmosphere consisting essentially of a gas unreactive with the shaft to form the endodontic instrument.

2. The method of claim 1 wherein:
the temperature is from 400°C up to but not equal to the melting point of the stainless steel alloy.

3. The method of claim 1 wherein:
the temperature is from 600°C to 1000°C.

4. The method of claim 1 wherein:
the temperature is from 600°C to 800°C.

5. The method of claim 1 wherein:
the temperature is from 600°C to 700°C.

6. The method of claim 1 wherein:
the temperature is from 700°C to 800°C.

7. The method of claim 1 wherein:
the temperature is from 650°C to 750°C.

8. The method of any of claims 1 to 7 wherein:
the shaft is heat-treated for a minimum of 1hour.

9. The method of any of claims 1 to 8 wherein:
the stainless steel alloy is selected from austenitic chromium-nickel alloys, and ferritic and martensitic chromium alloys.

10. The method of any of claims 1 to 8 wherein:
the stainless steel alloy is austenitic.

11. The method of any of claims 1 to 10 wherein:
step (a) comprises torsioning a wire to produce the intermediate instrument.

12. The method of any of claims 1 to 10 wherein:
step (a) comprises grinding a wire to produce the intermediate instrument.

13. The method of any of claims 1 to 12 wherein:
the stainless steel alloy is austenitic, and
the method further comprises forming a surface layer of an S-phase of the austenitic stainless steel alloy on the endodontic instrument.

14. The method of any of claims 1 to 13 wherein:
the endodontic instrument is a file or a reamer, and
the endodontic instrument has a minimum torque in Newton-meters as measured and specified in accordance with ISO 3630-5:2005.

15. The method of any of claims 1 to 13 wherein:

the endodontic instrument is a file or a reamer, and

the endodontic instrument has a minimum angular deflection in degrees as measured and specified in accordance with ISO 3630-5:2005.

16. The method of any of claims 1 to 13 wherein:

the endodontic instrument is a file or a reamer, and

the endodontic instrument has a maximum stiffness at 45 degrees in Newton-meters as measured and specified in accordance with in ISO 3630-5:2005.

17. The method of any of claims 1 to 16 wherein:

the shaft has a total length of 15 to 35 millimeters.

18. An endodontic instrument for use in performing root canal therapy on a tooth, the endodontic instrument comprising:

an elongate shaft having a cutting edge extending from a distal end of the shaft along an axial length of the shaft,

wherein the shaft comprises a stainless steel alloy, and

wherein the shaft is prepared by heat-treating the shaft at a temperature above 25°C in an atmosphere consisting essentially of a gas unreactive with the shaft.

19. The instrument of claim 18 wherein:

the gas is selected from the group consisting of helium, neon, argon, krypton, xenon, nitrogen, and radon.

20. The instrument of claim 18 wherein:

the temperature is from 400°C up to but not equal to the melting point of the stainless steel alloy.

21. The instrument of claim 18 wherein:

the temperature is from 600°C to 1000°C.

22. The instrument of claim 18 wherein:

the temperature is from 600°C to 800°C.

23. The instrument of claim 18 wherein:

the temperature is from 600°C to 700°C.

24. The instrument of claim 18 wherein:

the temperature is from 700°C to 800°C.

25. The instrument of claim 18 wherein:
the temperature is from 650°C to 750°C.

26. The instrument of any of claims 20 to 25 wherein:
the shaft is heat-treated for a minimum of 1hour.

27. The instrument of any of claims 18 to 26 wherein:
the stainless steel alloy is selected from austenitic chromium-nickel alloys, and ferritic and martensitic chromium alloys.

28. The instrument of any claims 18 to 26 wherein:
the stainless steel alloy is austenitic.

29. The instrument of any claims 18 to 28 wherein:
the shaft consists essentially of the stainless steel alloy.

30. The instrument of any claims 18 to 29 wherein:
the endodontic instrument is a file or a reamer, and
the endodontic instrument has a minimum torque in Newton-meters as measured and specified in accordance with ISO 3630-5:2005.

31. The instrument of any claims 18 to 29 wherein:
the endodontic instrument is a file or a reamer, and
the endodontic instrument has a minimum angular deflection in degrees as measured and specified in accordance with ISO 3630-5:2005.

32. The instrument of any claims 18 to 29 wherein:
the endodontic instrument is a file or a reamer, and
the endodontic instrument has a maximum stiffness at 45 degrees in Newton-meters as measured and specified in accordance with in ISO 3630-5:2005.

33. The instrument any claims 18 to 29 wherein:

the shaft has an angle greater than 10 degrees of permanent deformation after torque at 45° of flexion.

34. The instrument of any claims 18 to 29 wherein:

the shaft has a diameter of 0.5 to 1.6 millimeters.

35. The instrument of any claims 18 to 29 wherein:

the cutting edge or lack of cutting edge is formed on the shaft.

36. A method for creating or enlarging an opening in a tooth of a patient undergoing root canal therapy, the method comprising:

creating or enlarging the opening using an instrument according to any of claims 18 to 35.

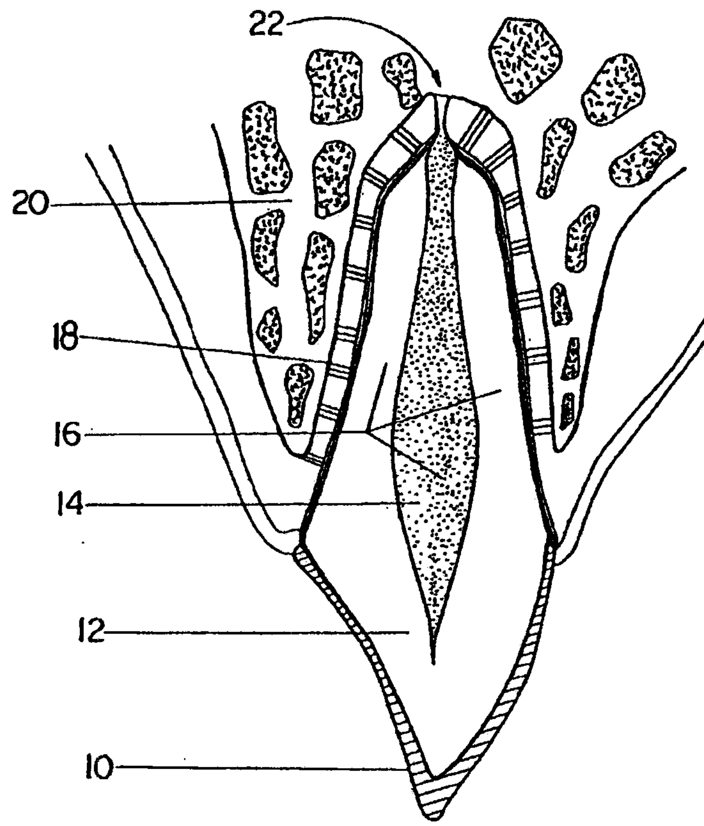
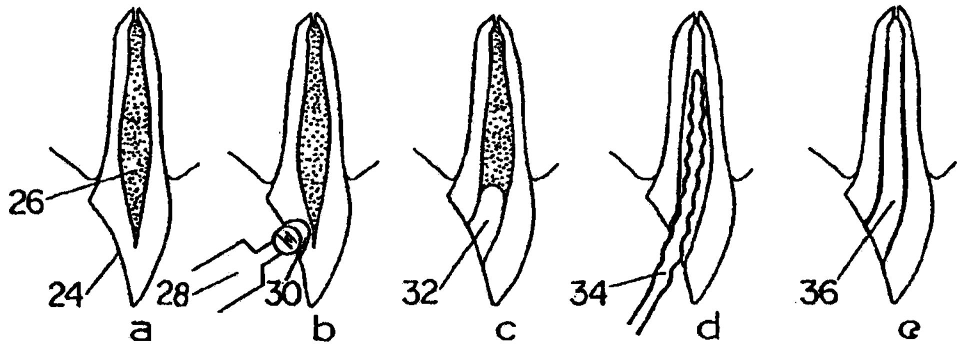


FIG. 1

FIG. 2



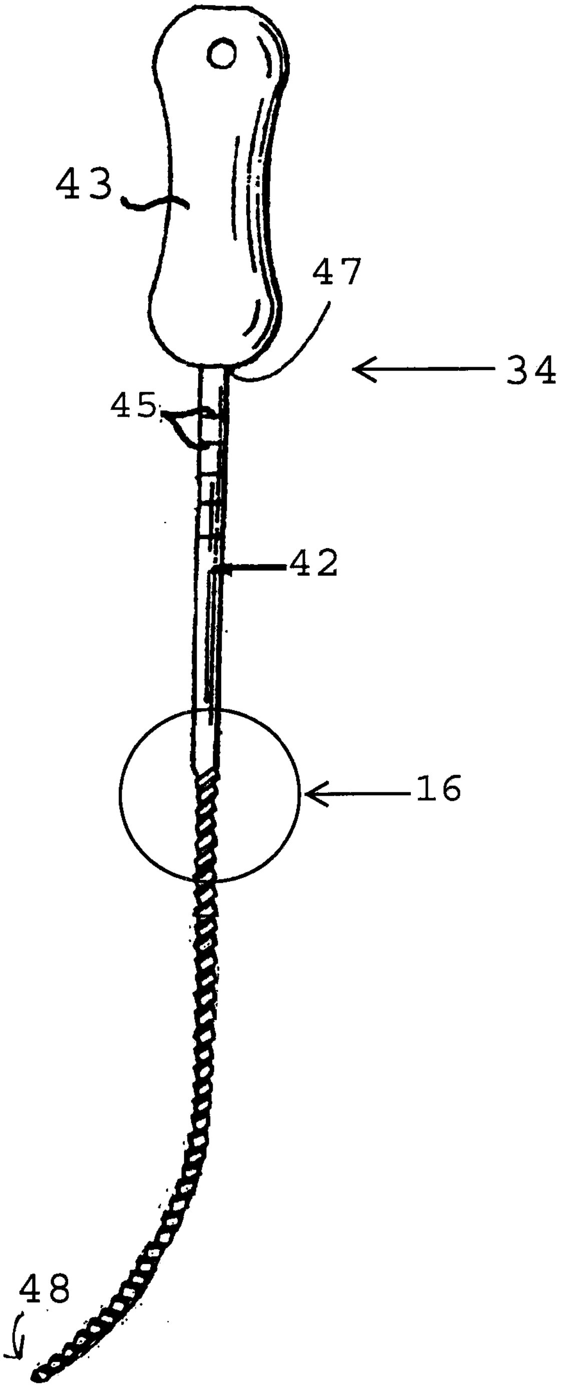


Fig. 1a

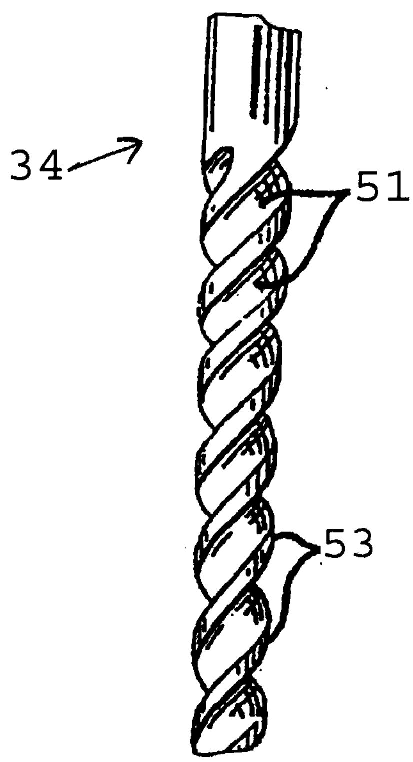


Fig. 1b

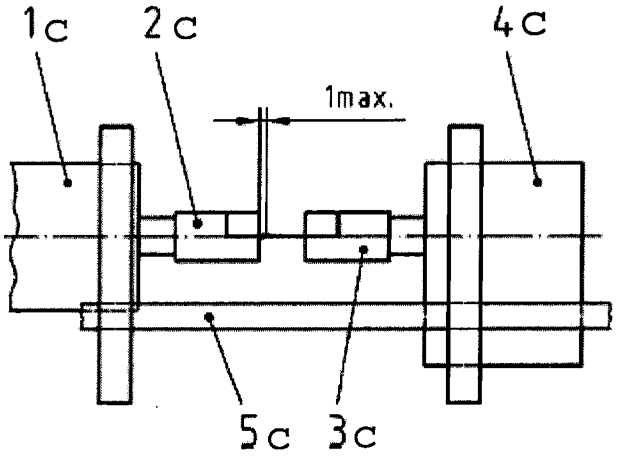


Figure 3

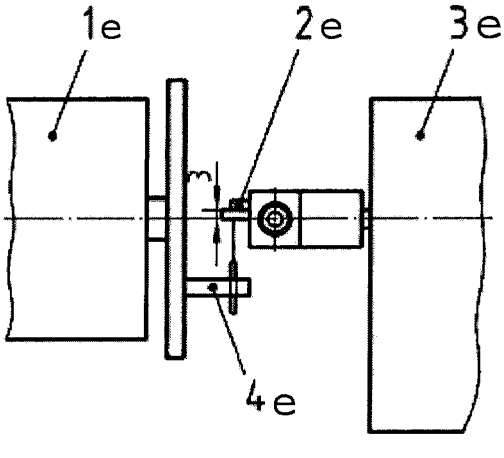


Figure 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/068675

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61C 5/02 (2010.01)
USPC - 433/224
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61C 3/00, 3/02, 5/00, 5/02 (2010.01)
USPC - 76/12, 24.1, 119; 433/102, 224

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/0032260 A1 (LUEBKE) 07 February 2008 (07.02.2008) entire document	1-8, 18-26
Y	US 5,836,765 A (HICKOK) 17 November 1998 (17.11.1998) entire document	1-8, 18-26
Y	US 2007/0154859 A1 (HILLIARD) 05 July 2007 (05.07.2007) entire document	3, 6, 21, 24
Y	US 5,328,361 A (EZCURRA) 12 July 1994 (12.07.1994) entire document	4, 5, 7, 22, 23, 25

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
05 February 2010	19 FEB 2010

Name and mailing address of the ISA/US
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Facsimile No. 571-273-3201

Authorized officer:
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PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/068675

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 9-17, 27-36
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.