Original Article

Development of Chairside Dry Heat Sterilizer Using Halogen Lamps as a Thermal Radiation Source

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Abstract

Purpose: A chairside dry heat sterilizer using halogen lamps as a heat radiation source was developed, and its potential for clinical application was investigated.

Methods: The temperature in the sterilization chamber was measured in two groups: one group in which the central temperature was set and maintained at 330°C, and another group in which the central temperature continuously increased. Then, changes in the physical properties of a stainless-steel K-file irradiated with the lamp were examined by observing the surface by scanning electron microscope and by bending and torsion tests. Finally, sterilization tests were conducted using spore-forming bacteria and indigenous oral bacteria.

Results: The temperature in the light condensing area stabilized after about 20 s, with little effect on the physical properties of the K-file. Sterilization of spore-forming bacteria took several tens of seconds, while that of indigenous oral bacteria took 3–5 s on a paper point and 7–10 s on a cotton ball.

Conclusion: It is suggested that the chairside dry heat sterilization using a thermal radiation source is useful for dental materials.

Key words: simple dry heat sterilizer, halogen lamp, stainless-steel K-file, strength test, spore-forming bacteria

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Introduction

Aseptic treatment in dentistry is one of the most important principles to improve treatment outcomes and prevent the spread of infection via treatment instruments. In particular, endodontic treatment requires thorough removal of bacterially infected tooth structures and antiseptic treatment of healthy dentin. In addition, root canal treatment possesses the risk of contamination by blood and saliva during the procedure, and also by necrotic tissue that has been infected by bacteria, making it necessary to re-disinfect the treatment instruments during the procedure.

In recent years, from the perspective of nosocomial infection, dental care workers have needed to be especially careful about their own infection potential to prevent bacterial infections caused by methicillin-resistant *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Treponema pallidum*[1,2]. Viral infections include infections caused by viruses of the herpesvirus family, hepatitis B and C viruses, and human immunodeficiency virus, and these microorganisms have also been detected in dental pulp and periodontal tissues[3–5]. Recently, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has caused a worldwide pandemic and the infection is still spreading, so patients must be treated with caution during dental care[6,7].

Small sharp instruments such as reamers and files, which are frequently used in endodontics, are classified as critical instruments and are sterilized by gas or high-pressure steam sterilization before use[8]. However, once they come into contact with fingers, saliva, or infected dentin, bacterial contamination of the instruments is inevitable, and because these instruments are used repeatedly during the procedure, frequent sterilization during treatment is necessary.

Many endodontic dry heat sterilizers that can be used chairside have been described in the literature, including 1) devices using molten tin-based alloys, 2) devices using salt as a medium, 3) bead sterilizers using small glass beads or metal balls, 4) electric furnace-type dry heat sterilizers with heaters wrapped around quartz tubes, and 5) sterilizers that heat brass blocks with slits[9–18]. However, sterilizers that use molten metal or small balls, such as glass beads, introduce the possibility that the metal or balls will become attached to the sterilized instrument and be transported directly into the root canal, resulting in blockage of the canal[11,12], harm to the human body due to heavy metal poisoning, and burns due to scattering of hot material.

Meanwhile, other sterilizers also have problems, such as unbalancing the table of the dental unit due to the excessive weight of the entire sterilizer, media spillage when the sterilizer is tipped over, and salt coagulation due to humidity in hot salt sterilizers. Furthermore, all sterilizers take time to heat the media, so advance preparation is necessary. Finally, in recent years, opportunities for home-visit dental care, in addition to dental care in the clinic, have been increasing, and thus there is a demand for easy, safe, and portable sterilizers that can be brought into a typical residence.

In this study, we developed a simple dry heat sterilizer that uses halogen lamps as a thermal radiation source to convert electrical energy into thermal energy and directly apply it to materials to be sterilized in the form of electromagnetic waves. Then, we investigated the characteristics of the sterilizer to determine its potential for clinical application.

Materials and methods

1. Experimental equipment

An overview of the prototype sterilizer and peripheral apparatus is shown in Fig. 1. The prototype sterilizer was composed of two metal plates, each 154 mm in width by 70 mm in height, and two heat sinks, each 100 mm in width by 70 mm in height. These were combined on a metal chassis measuring 180 mm wide by 120 mm deep by 55 mm tall. A hole 1 cm in diameter was made in the center of the upper metal cover, and halogen lamps were installed in the heat sinks.

A halogen lamp spot heater (HSH-30, Fintech, Hyogo, Japan) with a focal length of 40 mm, a light condensing area diameter of 10 mm, and power of 75 watts was used for the experiment. Irradiation was carried out in both directions on opposite sides of the device's coaxial axis, and the material to be sterilized was placed in the irradiation field in the middle of the heater. The voltage was supplied by a 100 V household power supply, which was converted to 24 V for use, and the current was set at 3.125 A.

In Fig. 2, K-type thermocouples (Φ 0.3 mm) were placed alternately facing each other at 5-mm intervals

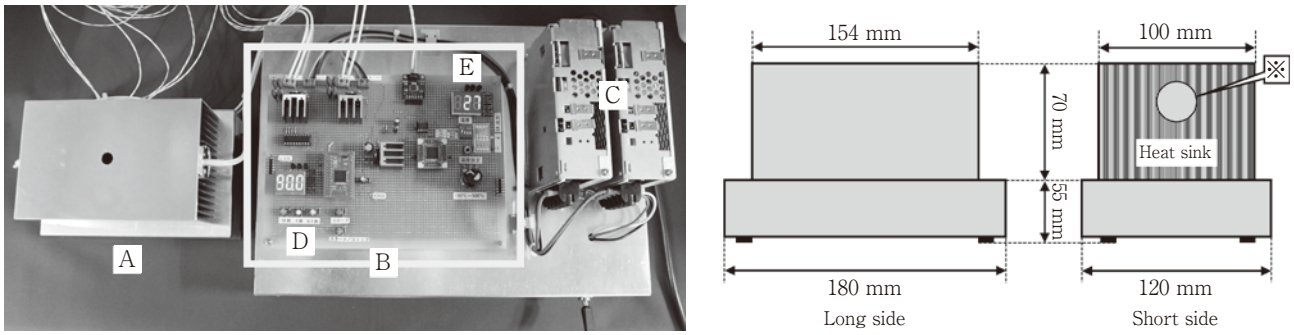

Fig. 1

(a) Overview of prototype sterilizer and peripheral apparatus : (A) Prototype sterilizer, (B) Control apparatus, (C) Power supply unit, (D) Irradiation switch, (E) Temperature control apparatus

(b) Schematic diagram of prototype sterilizer (※ : Base of the halogen lamp)

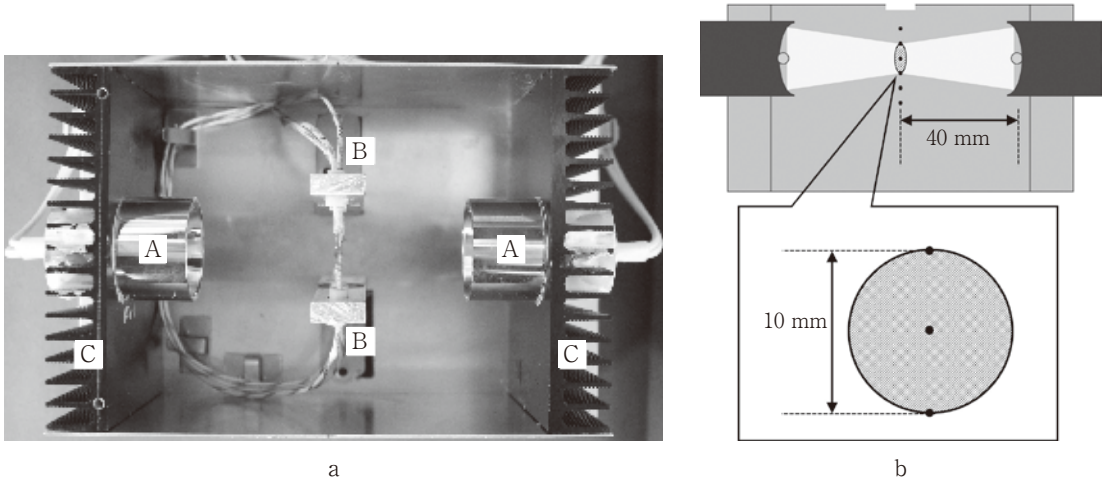

Fig. 2

(a) Prototype sterilizer (Fig. 1, A), top view : (A) Halogen lamps, (B) K-type thermocouples, (C) Heat sinks

(b) Cross-sectional schematic diagram of the prototype sterilizer : the entire circle is the light condensing area, and the circumference is the outer edge. The black points represent the tips of the K-type thermocouples (depths of 10, 15, 20, 25, 30, and 35 mm from the top).

up to 35 mm from the side of the apparatus to measure the temperature of the sterilization area. The light condensing area (10 mm) at the focus of the halogen lamp was set at a depth of 15–25 mm from the hole, with 15 and 25 mm at the outer edge of the light condensing area and 20 mm at the center of the light condensing area.

The irradiation time could be set from 0.1 to 99.9 s at 0.1-s intervals, and a countdown system was adopted. There was also a temperature control switch that could be set from 100℃ to 500℃ in 1℃ increments. Two settings for halogen lamp irradiation were established:

Ⅰ: When the control switch is turned on, the lamp cycles on and off to reach and maintain the set temperature automatically.

Ⅱ: When the control switch is turned off, continuous irradiation is performed and the temperature increases until the switch is turned off.

2. Experimental details

The following items were investigated to determine the effects of this device on endodontic instruments and materials.

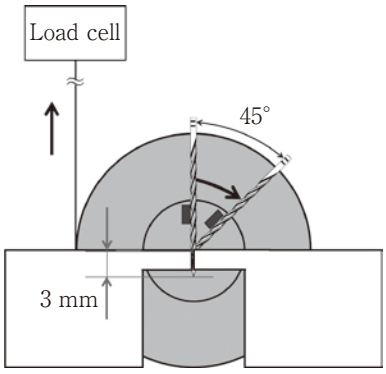

Fig. 3　Bending test machine
The first 3 mm of the file tip is fixed with a chuck, and the bending torque is measured when the file is bent to 45°.

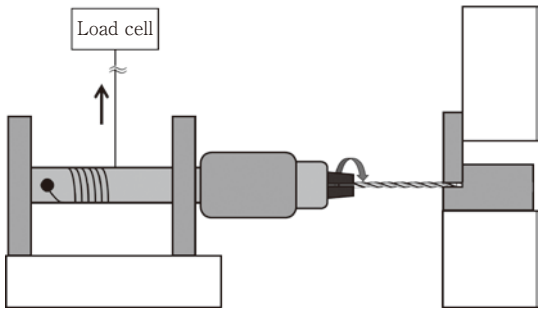

Fig. 4　Torsion test machine
The first 3 mm of the file tip is fixed with a chuck, the file is twisted until it breaks, and the torsion torque and rotation angle at the time of failure are measured.

1）Measurement of temperature in the light condensing area

The K-type thermocouples placed inside the sterilizer were used to record the temperature change over time at 100-ms intervals when the temperature was controlled at 330℃ with setting Ⅰ and when the temperature was continuously increased with setting Ⅱ. The irradiation time was set to 90 s for both settings.

The measurement data were recorded on a PC (Inspiron 15 7000 Gaming, DELL, Round Rock, TX, USA) using a data logger (NR-1000, KEYENCE, Osaka, Japan). Temperature measurements were performed at room temperature (25℃) and humidity (55%).

2）Surface observation of K-files after heat irradiation

The surface of #40 stainless-steel hand K-files (MANI, Tochigi, Japan) was observed under a scanning electron microscope (SEM, S-4000, Hitachi, Tokyo, Japan) after halogen lamp irradiation to detect any change in the surface properties.

Five experimental groups were established. The first group was subjected to natural air cooling to room temperature after 5 s of irradiation, and this cycle was repeated 10 times at setting Ⅱ. The second and third groups were subjected to the same treatment, but at irradiation times of 10 s and 15 s. In addition, two control groups were set. An untreated group was used as a negative control and a flame-treated group was used as a positive control. In the flame-treated group, the blade was set at the position of the oxidizing flame of the gas burner (about 1,500℃) and heated for 10 s by grasping the top, then the K-file was allowed to cool by natural air cooling to room temperature, and this process was repeated 10 times. We observed the surface changes by SEM for each group (n=1).

3）Strength testing of files after heat irradiation

The changes in physical properties of the files after irradiation with halogen lamps were tested according to the international standard ISO 3630-1[19] for small dental instruments and judged according to the standard values of ISO 3630-5.[20] Two types of #15–40 stainless-steel hand K-file were used for the test: K-file and Senseus K-FlexoFile (Dentsply Sirona, Charlotte, NC, USA). Since there was a risk of bias with a single type of sample, we made a comprehensive judgment by comparing two K-files with their respective untreated groups.

Non-irradiated files were used as a control group, and the experimental group consisted of files that were irradiated 10 times with halogen lamps for 10 s at setting Ⅱ (n=10 for each group). All instruments were allowed to stand at room temperature (25℃) for 30 min after each irradiation before the next irradiation. Before each test, the handle of the file was removed with wire cutters at the point where it was attached to the instrument shaft.

(1) Bending test (ISO 3630-1)

The bending test machine and test method are shown in Fig. 3. A section of the K-file up to 3 mm from the tip was fixed vertically in the chuck section of the bending test machine and rotated at a speed of 100 mm/min to induce bending. The maximum bending torque was measured and the average value of 10 files was used as the maximum bending torque (mN・m).

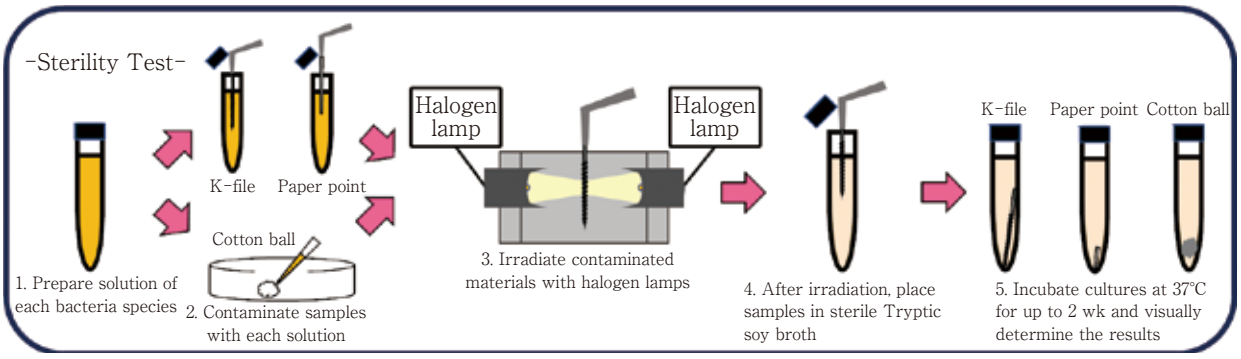

Fig. 5 Sterilization test procedure

(2) Torsion test (ISO 3630-1)

The torsion test machine and test method used are shown in Fig. 4. Each sample was set in the chuck of the motor, and a section of the file up to 3 mm from the tip was fixed in the chuck on the opposite side. The torque measuring device on the top of the machine was connected to the torsion testing machine by a wire, and the motor was operated at 100 mm/min. The average value of 10 files was used as the maximum torsional torque (mN・m) and fracture angle (°).

4) Heat sterilization tests for K-files, paper points, and cotton balls

Various microorganisms were applied to different dental materials to evaluate the sterilization effectiveness. *Bacillus atrophaeus* ATCC9372 was used because it is regarded as an indicator organism for dry heat sterilization in ISO 11138-4[21]. *Fusobacterium nucleatum* ATCC23726, *Streptococcus intermedius* NCTC11324, *Actinomyces oris* (formerly known as *A. viscosus*) T14V[22], and *Streptococcus mutans* MT8148[23] were used as representative of indigenous oral bacteria. In addition, *Escherichia coli* W3110 was also included, for a total of six bacteria species used in the experiment.

B. atrophaeus and *F. nucleatum* were purchased from the American Type Culture Collection (ATCC), and *S. intermedius* was purchased from the National Collection of Type Cultures (NCTC). *E. coli* W3110 was obtained from the Institute of Medical Science, University of Tokyo.

First, only *B. atrophaeus* was inoculated in 50 m*l* of Shaeffer's medium[24] as a spore-forming medium, and cultured at 37℃ with shaking for 24 h. The spores were then removed from the shaking incubator and stored at room temperature for 1 wk. After confirming sufficient spore formation by Wirtz's spore staining method, the spores were collected by centrifugation at 3,000×*g* for 15 min, washed three times with sterile distilled water, and then heat-treated at 75℃ for 30 min to kill the vegetative form bacteria. Other bacteria were inoculated in brain heart infusion (BHI: Becton, Dickinson and Company, Sparks, MD, USA) broth and incubated at 37℃ for 24 h.

For experimental samples, we used a #40 stainless-steel hand K-file, #40 sterile paper points (Absorbent Paper Points, Zipperer, Germany), and cotton balls with a diameter of 3 mm (Micro Cotton Ball #3, Iwatsuki, Tokyo, Japan). The K-file was cut with wire nippers just below the handle, and the cotton balls were removed from their container, placed in sterilization bags, and sterilized by high-pressure steam in an autoclave for the experiments.

The procedure of the sterilization test is shown in Fig. 5. The K-file was immersed up to 16 mm from the tip of the blade in a bacterial solution adjusted to 1.0×10^8 colony forming units (CFU)/m*l* for each species. Contaminating bacteria on the paper points and cotton balls were prepared at approximately 2.0×10^3 CFU/m*l*. The paper points were immersed in 2.0×10^6 CFU/m*l* of bacterial solution up to 10 mm from the tip (about 1 μl), and the cotton balls were contaminated by dropping 10 μl of 2.0×10^5 CFU/m*l* bacterial solution. The cotton balls were then placed in a sterile Petri dish for 30 min at 37℃ to dry them before use in the experiments.

For the K-files, the irradiation time was set to 0[Control (+)], 3, 5, 7, and 10 s with setting II for all bacteria. For the paper and cotton samples, setting I was used, and the irradiation time was set to 0 [Control (+)], 3, 5, 7, 10, 15, 20, 30, and 40 s for *B. atrophaeus* and 0, 3, 5, 7, and 10 s for other bacteria (n=20 for each

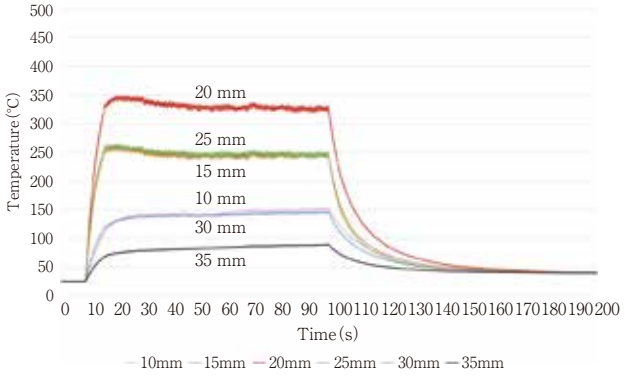

Fig. 6 Temperature measurement during irradiation at setting Ⅰ

Irradiation was started 10 s after the start of temperature measurement.

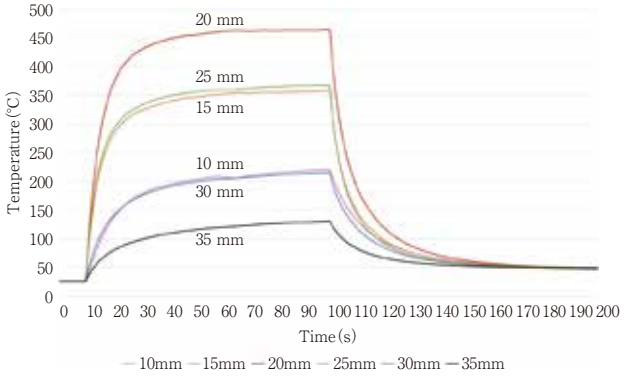

Fig. 7 Temperature measurement during irradiation at setting Ⅱ

Irradiation was started 10 s after the start of temperature measurement.

group). The test samples were irradiated with halogen lamps and incubated in sterile Tryptic soy broth (Becton, Dickinson and Company) at 37℃ for 24 h, 48 h, 72 h, 1 wk, and 2 wk, the results were visually checked, and those with increased turbidity or precipitation were judged as positive for culture. For each group, the number of samples that were culture negative was counted, divided by 20 (the total number of samples), and multiplied by 100 to calculate the culture negative achievement rate.

The paper points were cut 10 mm from the contaminated tip before being fed into the sterilizer.

3. Statistical analysis of strength

Student's *t*-test was performed on the data obtained from the strength tests. The statistical significance level was set at less than 5%, and IBM SPSS ver. 25 was used as the statistical software.

Results

1. Temperature measurement of sterilization area

The temperature of the sterilization area was measured for 90 s when the temperature was controlled to around 330℃ with setting Ⅰ (Fig. 6). When this temperature was reached, the control apparatus could not react quickly enough, and the center temperature rose to 349℃. However, 20 s after the start of control, the temperature stabilized at around 330℃. The amplitude during each on/off switching cycle was about 10℃, which maintained the temperature at around 325–335℃ until the end of irradiation.

At 15 mm and 25 mm, which were the outer edges of the condensing area, the temperature rose to approximately 260℃ and remained at around 240–250℃ until the end of irradiation. The temperature dropped sharply outside the condensing area, reaching only 120–150℃ at 10 mm and 30 mm and 70–90℃ at 35 mm.

In setting Ⅱ, continuously increasing irradiation was performed for 90 s, and the results were measured over time (Fig. 7). In the light condensing area at a depth of 15–25 mm, the temperature rose rapidly as soon as irradiation started, reaching 275℃ at the center and 215–226℃ at the outer edge 5 s after the start of irradiation. After another 10 s, the temperature reached 368℃ at the center and 280–289℃ at the outer edge, and after 15 s, 408℃ at the center and 307–317℃ at the outer edge. The highest temperatures after 90 s of irradiation were 464℃ at the center and 367℃ at the outer edge.

2. Surface observation of K-files after heat irradiation

The surface of each file was observed by SEM (Fig. 8). The flame-treated group showed a loss of continuity due to the collapse of the file edge, with the metal on the file surface peeling off. In the group irradiated by the halogen lamp, there was no major change in the surface properties of the files irradiated for 5, 10, and 15 s compared with the untreated group, either by visual inspection without magnification or in the SEM images.

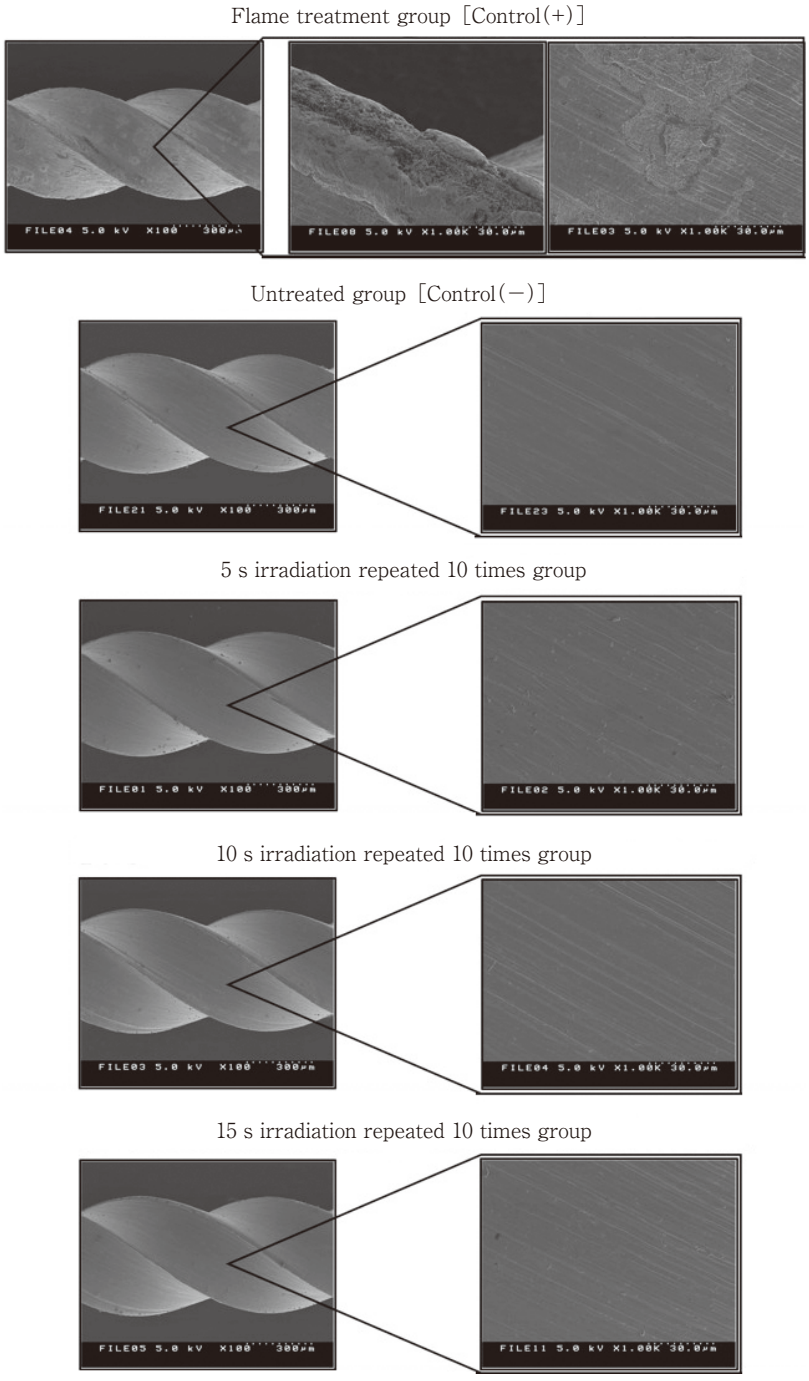

Fig. 8 Surface observation by SEM of K-file irradiated by halogen lamp

3. Strength testing of K-files after heat irradiation

The results of the strength tests are shown in Fig. 9.

1) Bending test

The torques required to bend the files up to 45°are shown in Fig. 9A and B. There was a significant difference between the control and irradiated groups for the #15 MANI K-files ($p<0.05$), and there was no significant difference between the groups for the Senseus K-FlexoFile. The bending torque values in both groups were within the ISO standard values.

2) Torsion test

The maximum torque and fracture angle until fracture when torsion was applied to the file are shown in Fig. 9C–F. For the #25 MANI K-file, results for the irradiated group were significantly lower than those for the untreated group, and for the #35 K-file, results for the

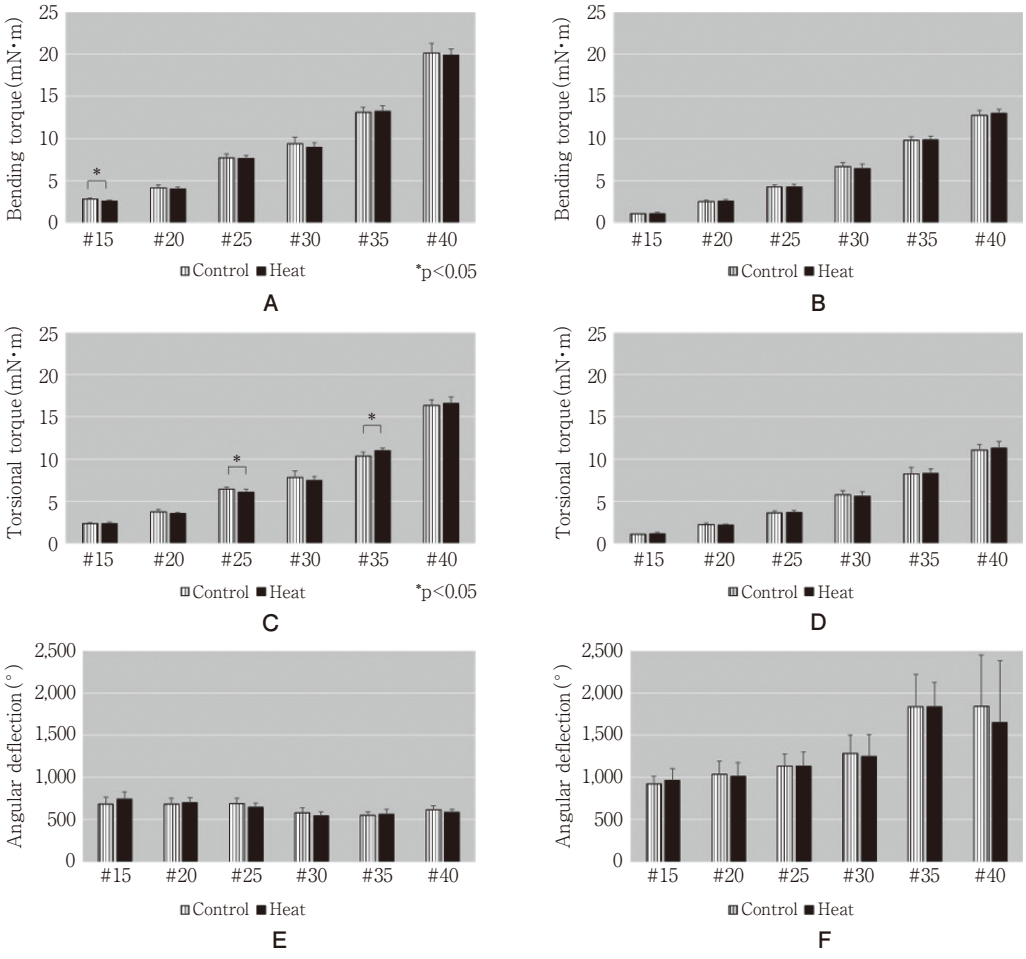

Fig. 9　Bending test and torsion test results (p<0.05, n=20)
(A) MANI K-file bending test results ; (B) Senseus K-FlexoFile bending test results ; (C),(E) MANI K-file torsion test results ; (D),(F) Senseus K-FlexoFile torsion test results

untreated group were significantly lower than those for the irradiated group(p<0.05). The torque failure values for both groups were within the ISO standard values.

There was no significant difference between the groups for Senseus K-FlexoFile, but only one of the 10 #40 K-files had a fracture angle below the ISO standard of 360°. Therefore, 10 additional tests were conducted in accordance with the standard, and all of them were confirmed to meet the standard.

4. Sterilization tests

The results of the sterilization tests are shown in Tables 1–3. The culture results for K-files were all negative after 10 s of irradiation for *B. atrophaeus* and after 7 s for other bacteria. Results for the paper points were negative after 30 s for *B. atrophaeus*, after 5 s for *S. mutans* and *A. oris*, and after 3 s for other bacteria. The culture results for cotton balls were all negative after 40 s for *B. atrophaeus*, after 10 s for *S. mutans*, *A. oris*, and *F. nucleatum*, and after 7 s for other bacteria.

Discussion

Most conventional simple dry heat sterilizers provide sterilization heat through a heating medium, such as glass pellets or molten metal, and it takes several minutes for the heating medium to rise to the sterilization temperature. In contrast, the prototype of the simple dry heat sterilizer used in this study heats the materials to be sterilized by directly radiated heat, which has the advantage of eliminating the need to turn on the power supply and heat the medium beforehand because there is no heating medium. Therefore, it is possible to rapidly heat an object by turning on the power and pressing the irradiation switch.

Table 1 Sterilization test results of K-file (%)

Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk	Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
B. atrophaeus	0 s	0	0	0	0	0	*E. coli*	0 s	0	0	0	0	0
	3 s	0	0	0	0	0		3 s	60	60	60	60	60
	5 s	70	0	0	0	0		5 s	65	65	65	65	65
	7 s	80	35	30	30	30		7 s	100	100	100	100	100
	10 s	100	100	100	100	100		10 s	100	100	100	100	100
Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk	Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
S. mutans	0 s	0	0	0	0	0	*S. intermedius*	0 s	0	0	0	0	0
	3 s	90	80	80	80	80		3 s	80	80	80	80	80
	5 s	95	95	95	95	95		5 s	95	95	95	95	95
	7 s	100	100	100	100	100		7 s	100	100	100	100	100
	10 s	100	100	100	100	100		10 s	100	100	100	100	100
Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk	Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
A. oris	0 s	100	0	0	0	0	*F. nucleatum*	0 s	0	0	0	0	0
	3 s	100	0	0	0	0		3 s	0	0	0	0	0
	5 s	100	90	65	65	65		5 s	85	85	85	85	85
	7 s	100	100	100	100	100		7 s	100	100	100	100	100
	10 s	100	100	100	100	100		10 s	100	100	100	100	100

The percentages of negative achievement rate are indicated (n=20).

Table 2 Sterilization test results of paper point (%)

Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk	Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
B. atrophaeus	0 s	0	0	0	0	0	*E. coli*	0 s	0	0	0	0	0
	3 s	0	0	0	0	0		3 s	100	100	100	100	100
	5 s	15	0	0	0	0		5 s	100	100	100	100	100
	7 s	25	25	25	25	25		7 s	100	100	100	100	100
	10 s	50	50	50	50	50		10 s	100	100	100	100	100
	15 s	60	60	55	55	55	Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
	20 s	75	65	65	65	65	*S. intermedius*	0 s	0	0	0	0	0
	30 s	100	100	100	100	100		3 s	100	100	100	100	100
	40 s	100	100	100	100	100		5 s	100	100	100	100	100
Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk		7 s	100	100	100	100	100
S. mutans	0 s	0	0	0	0	0		10 s	100	100	100	100	100
	3 s	100	95	65	65	65	Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
	5 s	100	100	100	100	100	*F. nucleatum*	0 s	0	0	0	0	0
	7 s	100	100	100	100	100		3 s	100	100	100	100	100
	10 s	100	100	100	100	100		5 s	100	100	100	100	100
Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk		7 s	100	100	100	100	100
A. oris	0 s	100	0	0	0	0		10 s	100	100	100	100	100
	3 s	100	35	35	35	35							
	5 s	100	100	100	100	100							
	7 s	100	100	100	100	100							
	10 s	100	100	100	100	100							

The percentages of negative achievement rate are indicated (n=20).

Table 3 Sterilization test results of cotton ball (%)

Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
B. atrophaeus	0 s	0	0	0	0	0
	3 s	0	0	0	0	0
	5 s	0	0	0	0	0
	7 s	0	0	0	0	0
	10 s	0	0	0	0	0
	15 s	0	0	0	0	0
	20 s	0	0	0	0	0
	30 s	45	45	45	45	45
	40 s	100	100	100	100	100
Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
S. mutans	0 s	0	0	0	0	0
	3 s	15	0	0	0	0
	5 s	100	45	30	25	25
	7 s	100	80	65	55	55
	10 s	100	100	100	100	100
Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
A. oris	0 s	100	0	0	0	0
	3 s	100	0	0	0	0
	5 s	100	60	45	45	45
	7 s	100	95	95	95	95
	10 s	100	100	100	100	100
Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
E. coli	0 s	0	0	0	0	0
	3 s	10	10	10	10	10
	5 s	95	80	80	80	80
	7 s	100	100	100	100	100
	10 s	100	100	100	100	100
Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
S. intermedius	0 s	0	0	0	0	0
	3 s	60	25	25	25	25
	5 s	95	95	95	95	95
	7 s	100	100	100	100	100
	10 s	100	100	100	100	100
Species and Irradiation		24 h	48 h	72 h	1 wk	2 wk
F. nucleatum	0 s	0	0	0	0	0
	3 s	10	0	0	0	0
	5 s	70	50	50	50	50
	7 s	75	70	70	70	70
	10 s	100	100	100	100	100

The percentages of negative achievement rate are indicated (n=20).

In our prototype sterilizer, the time from pressing the "on" switch to stabilizing the temperature in the light condensing area was about 20 s. It was reported that it takes 9 min for the temperature to stabilize at 230℃ for glass beads, 5 min for salt, and 6 min for molten metal, which are conventional heating media[13]. Therefore, the setup time was greatly reduced, and the sterilizer could be used immediately. This feature is useful not only in daily clinical practice, but also in home-visit dental care if the device can be made smaller.

In addition, it is possible to set the temperature at the center of the light condensing area with a control switch and select setting Ⅰ, which controls the temperature by cycling the lamp, or setting Ⅱ, which performs continuously increasing irradiation. The paper points and cotton balls, which have poor thermal conductivity, were irradiated with setting Ⅰ, while K-files, which are stainless steel and have good thermal conductivity, were irradiated with setting Ⅱ.

The reason why the temperature was 330℃ in setting Ⅰ, which is slightly higher than that of conventional sterilizers (200–280℃)[9–18], is that the prototype sterilizer reflects more of the radiant heat projected onto the sterilized materials compared with the conventional type that uses a heating medium, and not all of the heat energy incident on the materials can be used. This is also the reason why the core temperature of N.I. dry heat sterilizers using radiation heat has been increased to around 360℃ in the past[16].

There is no clear ISO standard for simple dry heat sterilizers, and each sterilizer is designed with its own optimal temperature. The temperature difference between the center of the light condensing area and the outer edge of the light condensing area was 80℃. Although the temperature at the outer edge was not lower than the temperature of a conventional sterilizer, the temperature of the sterilized material may be lower than the apparent temperature for paper and cotton products in a sterilizer with low thermal energy efficiency. Currently, almost no sterilizers available on the market can heat K-files up to 330℃, and N.I. sterilizers have only been reported to heat cotton plugs and paper points[16].

In this study, we observed the surface of the heated files and performed bending and torsion tests according to ISO 3630-1 to observe the changes in physical properties (Figs. 7 and 8). Compared with the untreated group, images of the flame-treated group showed metal peeling off the surface of the file and the blade disintegrating and blunting due to heat, while the halogen lamp-irradiated group showed no major changes.

It has long been believed that sensitization (a chromium deficiency phenomenon caused by grain precipitation due to chromium carbonization on the surface of the file), which is the cause of intergranular corrosion in 18-8 stainless steel, occurs when steel is heated for a long time at 500–800℃. In this experiment, the temperature was about 410℃ even after the longest irradiation of 15 s, so it is thought that the files were undamaged because the temperature was not high enough to cause grain precipitation[25].

In the bending tests, torque was significantly lower in the MANI #15 K-file, and in the torsion tests, torque was significantly lower in the MANI #25 K-file with respect to the untreated group. However, in both tests, the torque did not decrease significantly compared to the untreated group, and the ISO standard values[20] were met, so the K-files would still be acceptable for clinical use.

There was no significant difference in the fracture angle among all groups, but one Senseus K-FlexoFile #40 fractured at an angle under the ISO standard value. The additional 10 pieces tested in accordance with the standard all exceeded the standard value. The results of these strength tests are in agreement with those of Asakura[26], who reported that the mechanical properties of K-files were not affected until they were heated at 400℃ for 1 h in an electric furnace.

In the sterilization test, we used *B. atrophaeus* (Gram-positive bacteria), which is an indicator bacterium for dry heat sterilization and has the ability to form spores; *S. mutans*, *S. intermedius*, and *A. oris* as Gram-positive bacteria indigenous to the oral cavity; and *F. nucleatum* as Gram-negative bacteria. In addition, *E. coli* was used as a general Gram-negative bacterium. The amount of bacteria applied to the paper points and cotton balls was set at 2.0×10^3 CFU/m*l*, under the assumption that these materials would be used before provisional sealing at the end of treatment, because the number of glove bacteria in the second half of treatment, just before the working length was determined and provisionally sealed, has been reported to be approximately $1.0–3.0\times10^3$ CFU[27].

For the paper points, negative cultures were obtained after 3–5 s of irradiation for non-spore-forming bacteria, but after 30 s for spore-forming *B. atrophaeus*. Because the central temperature of the condensing area rises to 330℃, this area seems to be able to kill bacteria in a short time. However, the temperature decreases away from the center, and the temperatures of the ends of the samples (tip of the paper point and edge of the cut) located in the outer edge reach only 240–250℃. Therefore, the spores that survive there could germinate.

Cotton balls were culture negative after 7–10 s of irradiation for non-spore-forming bacteria, but took 40 s for spore-forming *B. atrophaeus*. The longer time required for a negative culture compared to the paper points for all species was thought to be due to the fact that the depth from the surface to the center of the cotton ball required more time for heat conduction, allowing interior bacteria to survive.

In the K-files, the length of contamination was 16 mm, some of which was not placed within the condensing area, and despite the large number of contaminating bacteria, the culture was negative after 10 s for spore-forming *B. atrophaeus* and after 7 s for other bacteria species. This is probably due to the good thermal conductivity of the metal, unlike paper or cotton. Because it is rare to come into contact with highly thermostable bacteria in general dental practice, the results confirmed that clinical sterilization could be achieved by irradiating the K-files for 7 s with setting Ⅱ, and the paper points for 5 s and small cotton balls for 10 s with setting Ⅰ at the temperature settings used in this study.

The results show that it was able to quickly and safely heat the materials to be sterilized and achieve sterilization in the light condensing area. This prototype sterilizer had the necessary control boards and equipment in order to achieve sufficient performance. However, since some equipment could be omitted in actual clinical applications, it is possible to reduce the size of the sterilizer, and since there is no heating medium compared to the conventional type, it is possible to reduce the weight. Moreover, the lack of a heating medium prevented the material from being bent

when it was inserted into the sterilization area and eliminated contamination of the material by a heating medium. The results also suggest that this sterilizer is effective for infected root canal treatment, where a large amount of necrotic pulp or infected dentin is handled, or where contamination is suspected due to small instruments falling outside the clean area or being exposed to saliva. Moreover, although they do not come into direct contact with the sterilized materials, the internal walls of the equipment can be sterilized by autoclaving if they are assembled, with the exception of the halogen lamps, which require wiring, so maintenance is considered possible.

However, as with conventional sterilizers, it is necessary to insert long instruments, such as tweezers or K-file handles, that are not heat resistant to direct light exposure. In addition, sterilization of materials exposed to a large amount of microorganism contamination will require a conventional autoclave. The bacterial count set for this study corresponds to that observed during clinical procedures, and it is therefore desirable to sterilize any suspected contaminated items after cleaning them with gauze.

In addition, the temperature tended to drop rapidly away from the center of the light condensing area. Thus, this instrument is effective for sterilizing small areas contaminated during use, and conventional methods are required to achieve complete sterilization of the entire instrument. Once used, instruments should only be used for the same patient, and autoclaves or dry heat sterilizers should be used to sterilize instruments between patients.

Conclusion

1. In setting I in which the central temperature of the condensing area was maintained, the temperature was stable at a central of around 330℃ and an outer edge of around 250℃ after irradiation for 20 s.

2. In setting II with continuous irradiation, the center temperature reached 368℃ and the outer edge temperature increased to around 280℃ after irradiation for 10 s.

3. In SEM observation of the irradiated K-file, there was no change compared to unirradiated file.

4. In the bending test and the torsion test of the K-file, there was a tendency that no significant difference was observed between the conditions with and without irradiation.

5. The time required for 100% of the spore-forming bacteria to be sterilized was 10 s for the K file, 30 s for the paper point, and 40 s for the cotton ball. For other bacterial species, it took 7 s for the K file, 3 to 5 s for the paper point, and 7 to 10 s for the cotton ball.

These results suggest that this sterilizer is effective as used in this experiment, which was conducted under the assumption of clinical procedures.

The authors declare no conflicts of interest associated with this manuscript.

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