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Evaluation of Sterility of Various Commercially Available Endodontic Instruments - A Pilot Study

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Abstract: ***Aim: The aim of this research is to compare and determine whether new endodontic files, as supplied in packages from the manufacturer, are sterile. Objective: The main objective is to test and compare the sterility levels of new endodontic files with and without sterilisation before using. Background: Most of the dentists directly use the packaged new endodontic files into the patients mouth assuming that they are sterile. Even though the new files are completely packaged, one should not draw a conclusion that all of the packaged instruments are sterile. Thus this study is to compare the sterility of various commercially available, unused endodontic files. Reason: Sometimes unused or packaged files may be contaminated with various microorganisms .The goal of instrument sterilisation in dentistry is to protect patients from cross contamination via instruments. Thus, utmost care should be taken to clean and sterilise each and every instrument before it is used in patients.***

Keywords: Sterilization, contamination, files, broth

1. Introduction

The prevention of the transmission of infectious diseases among dentists, staff and patients is of great importance in dentistry. For this reason, disinfection and sterilization are especially important in endodontics because microorganisms are the main causes of many endodontic diseases.

While the whole world is looking at the eradication of existing infectious diseases and preventing any new infections, sterilisation of instruments is significant to ensure optimal patient care. In contemporary endodontic practice, the instruments directly come in contact with tissues, blood and tissue fluids, saliva and gingival crevicular fluid which may seep through the rubber dam if not properly placed. Today the universal norm is if you can sterilise an instrument, sterilise it, otherwise dispose it off.

Infection control procedures are essential to modern dentistry and have an impact on all clinical practices [(1)].They are the most important components for providing a safe environment for patients and staff within a dental practice[(2)]. The instruments that can be used are classified as critical, non critical and semi-critical items.

Instruments that contact vital areas of the body, enter the vascular system or penetrate the oral mucosa are classified as 'critical items' and must be sterilised before use. The classification of critical instruments includes all hand and rotary instruments, reamers, endodontic files, surgical instruments, elevators, forceps, burs, periodontal knife. Thus, these instruments should be sterile before use and reuse.[(1)]

The non-critical items include items that do not contact body fluids or any break in soft tissue. In endodontics, the ones that do not contact the root canal space such as glass slab, cement spatula need to be disinfected.

Re-usable or semi critical items include all plastic impression trays, amalgam carriers. These can be disinfected alone. Absorbent paper points and root canal filling materials like silver points, gutta-percha points and Resilon points should be disinfected before use.

In the absence of adequate infection control procedures, there is a realistic potential to transmit pathogenic microbes via endodontic instruments. The complex, miniature architecture of endodontic files makes the pre cleaning and sterilisation difficult. Devising a sterilisation protocol for endodontic files requires care [(3)]. Sterilisation plays a very important role in the prevention of cross infection [(4)] .Sometimes unused or packaged files may be contaminated with various microorganisms.

The reason for this study is that the boxes of new endodontic hand instruments such as files, reamers, pluggers does not mention as 'sterile' or sometimes mentions as ' non sterile'. But the routine practise is to use these instruments straight from the new box once opened. Hence there is a need to create awareness among the practitioners that the new files ought to be sterilised before use and also there are only limited amount of previous studies demonstrating this lacunae between knowledge and the practise. Thus, the main objective of this study was to evaluate and analyse the sterility of new, unused endodontic files.

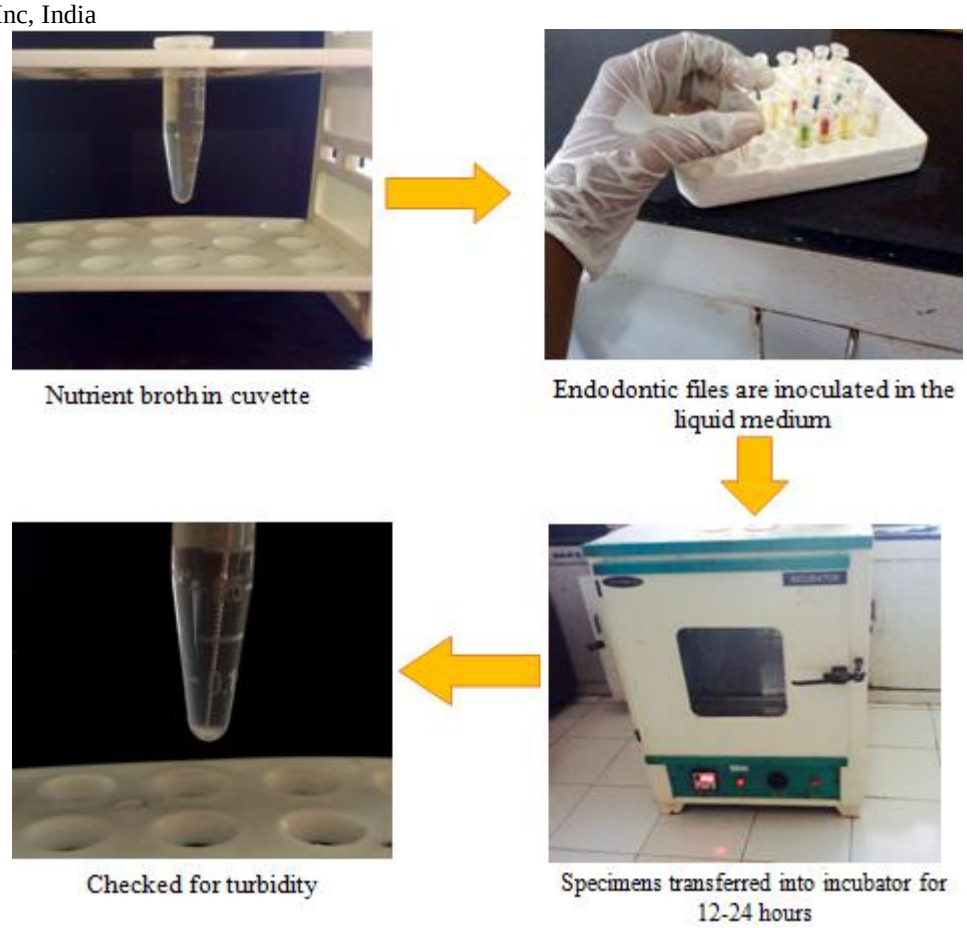
2. Materials and Methods

The sterility of new unused endodontic files were analysed. The test was conducted with three different companies of commercially available new, unused endodontic K files. Each group had 5 unused endodontic files of various sizes, a total of 15 files. All the files were of standard size 15~35.The new set of unused files from sealed packets were tested immediately. Each file was inoculated in Nutrient Broth (liquid media) and incubated at 37ºC for 12-24 hours. Sterile gloves and sterilised forceps were used during the

complete procedure. The nutrient broth were then observed for microbial growth. The cuvettes were examined for a total of 24 hours, and any signs of bacterial growth such as turbidity were documented.

Totally three company files were used for the procedure. Each company were designated with a name.
Group A – Mani Inc, India
Group B –Kerr Sybron, USA
Group C –Densply Sirona, USA
All the curettes were numbered accordingly from 1-15.

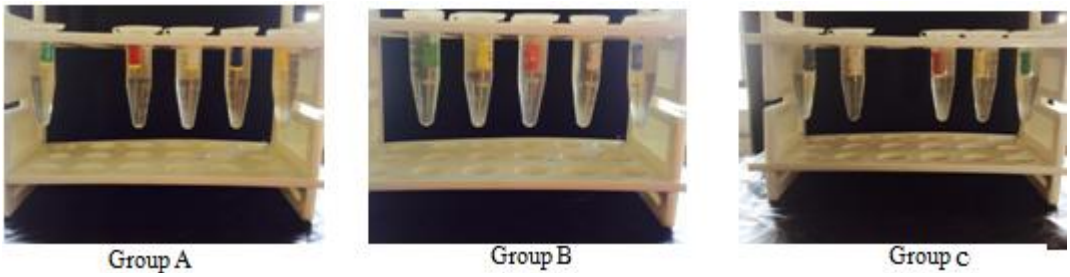
3. Procedure



A colour change, cloudy broth and visible precipitate in the cuvettes were all considered indicative of bacterial growth. If the solution remained clear throughout the incubation period, the sample was considered sterile.

4. Results

Many endodontic files which were new and un-used showed growth of the micro-organisms. New items, as packaged by the manufacturer, were found not to be sterile completely. There was formation of turbidity in the nutrient broth inoculated with files after 24 hours while the broth (control) without file was found to be sterile.



The result showed that out of 15 files which were used in this study, 12 files showed signs of turbidity which in turn showed that 12 files were found to be contaminated.

S.No	Groups	Total No of Files	Turbidity Absent	Turbidity Present
1.	Group A	5	1	4
2.	Group B	5	0	5
3.	Group C	5	2	3

Group A: It includes 5 files out of which 1 was found to be sterile while 4 were found to be contaminated .

Group B: Out of 5, all the files were found to be contaminated.

Group C: Group c includes 5 files out of which 2 files were sterile while other 3 files were found to be contaminated.

5. Discussion

In the recent years there has been much discussion concerning standardized and non-standardized instruments and its importance. Much has been written about the poor compliance of the manufacturers of endodontic instruments concerning standardization. As received from the manufacturers, new endodontic files are expected to be sterile. Endodontic files, as supplied by the manufacturers to the endodontists are not pre-sterile routinely. But recently certain endodontic files have been introduced into practice which are pre-sterile. However in one survey of 150 newly supplied endodontic files, 13% were found to be positive for microbial culture[5]. Such findings raise the issue of sterility assurance and raise the question whether an endodontic file should be sterilised prior to use or not.

Even though the packaged instruments used in other studies were sterile with no growth one should not draw a conclusion that all of the packaged instruments are sterile. Microscopic analysis of the new instruments that were removed from the packaging of the manufacturer showed that all instruments had a certain amount of metallic debris[6].Thus it should not be assumed that all unused files are sterile. When the packaging does not completely seal the contents from the external environment, there is a potential for the files to become contaminated. Also, it was mentioned as non sterile on the packages of the files examined in this study. The bacterial growth on files removed from the manufacturer's packaging may be expected to be low but Standards Australia[7] recommends that files be sterilized in appropriate packaging prior to use to ensure sterility of the instruments. The importance of biological debris removal should not be disregarded.[6] A theoretical risk of CJD transmission via oral tissues and maintenance of the cutting efficiency of the files are factors that support achieving effective removal of biological debris from the files.

According to the previous data, most unused endodontic instruments from different manufacturers are not sterile, and different metal and organic particles, as well as epithelial cells, can be found on their surfaces.[6] Sonntag &Peters found stained and unstained debris on new, unused files after immersion in stain solution. One of the recent study showed that only four of 48 instruments had stained particles, but all 48 instruments had metallic and unstained debris on their surfaces. The fact that residual debris not only act as an infective agent, but also as antigens and irritants, means that new instruments need to be cleaned before they are used. Roth et al. found positive bacterial cultures on new endodontic instruments and stated that the sterilization of unused instruments is necessary[6].

Studies have shown that instruments used in endodontics, such as files and reamers may carry infected organism or their breakdown products. These residues may be present even after washing and can retain their potency to induce infections.[8] The safest method to ensure that there are no residual infected micro-organism is through incineration.[9] The instruments should be mechanically cleaned before they are subjected to sterilization to inactivate any debris that can be visualized. Ultrasonic cleaning reduces the chances of direct handling of the instruments thereby ensuring operator safety. This is much more efficient than manual cleaning.[10,11]Root canal instruments should be subjected to chair-side sterilization. This is advocated to prevent cross contamination between root canals or teeth in the same patient. In case of a premolars or molar tooth, one of the canals could be infected while one canal could be uninfected.[12] Transmission of infected material to the uninfected canal intereferes the chance of success of root canal treatment. Aslin et al, in their study tried to sterilize Kfiles with glass bead steriliser for chairsidesterilization. In this study, K files were heated up from 2 seconds till 14 seconds. Their result showed that glass bead sterilizer was able to destroy the Enterococcous from 2 seconds. As glass bead sterilizer shows good sterilization within few seconds, it is comfortable for sterilizing all small handed instruments in the dentistry.[13]

Fahid et al studied to determine the effect of cleaning endodontic files with either dry gauze or alcohol-saturated gauze prior to placement of the files into a hot bead sterilizer. The study indicated that an alcohol wipe was more effective than a dry wipe. It also suggested that using an alcohol wipe and 3 seconds in a hot bead sterilizer for No. 10 files or 5 seconds for either a No. 30 or a No. 45 file was equivalent in disinfecting ability. [14]

Luper et al did a study to investigate the effect of different sterilization methods on the fatigue life of finger pluggers. One hundred pluggers were used of which 10 were not sterilized and used as control group. Ninety finger pluggers for each of the four sizes (A, B, C, and D) were subdivided into subgroups of 10. Each subgroup was subjected to 1, 8 or 15 cycles of steam autoclave, dry heat or bead sterilization. The study concluded that any of the three sterilization methods could be used without fear of plugger failure.[15]

Hurtt et al did a study comparing different methods of sterilizing hand files. The methods used were salt sterilization, glutaraldehyde and autoclave. Six test groups of each 15 files were studied using Bacillus stearothermophillus as the test organism. This study concluded that only proper steam autoclaving produced completely sterile instruments and that salt sterilization and glutaraldehyde solutions may not be adequate sterilization methods for endodontic hand files and should not be relied on to provide completely sterile instruments.[16]

Powell et al did a study to compare the ability of three lasers (argon, CO2, and NdYAG) to sterilize dental instruments such as Endodontic reamers. The results indicated that argon laser is capable of sterilizing at the lowest energy level (1 watt for 120 seconds) of the three lasers tested. The other

two lasers were also able to sterilize the instruments, but at higher energy levels. [17]

Whittaker et al did a study to see the effective use of a commercial gas plasma etcher in the cleaning of endodontic files. This study suggested that plasma cleaning offered a safe and effective method for decontamination of dental instruments, thus reducing the risk of iatrogenic transmission of disease during dental procedures.[18]

Raj Kumar et al did a study to investigate the efficacy of two accepted methods of sterilizing endodontic instruments one was autoclaving of endodontic files when placed in a endodontic instruments box and the other was by placing in synthetic sponge. Also the efficacy of glass bead sterilizer at different time intervals were evaluated. The study concluded that files should be autoclaved in either an endodontic instrument box or a synthetic sponge at 121°C for 15 pounds pressure to achieve complete sterilization. It also concluded that glass bead sterilization of files for 45 seconds at 240°C after wiping them with 2 X 2 inch fold gauze soaked with spirit could be considered as a chair side alternative.[19]

Boyd et al did a study to evaluate the sterility of files and spore strips following autoclaving in a sponge. The study concluded that the insertion of files into the sponges used in this study does not obstruct the autoclaving process.[20]

6. Conclusion

Within the limitations of the study, ndodontic files as packaged by the manufacturer, were not sterile and should therefore be sterilized before first use. The goal of instrument sterilization in dentistry is to protect patients from cross contamination via instruments. Thus, utmost care should be taken to clean and sterilize each and every instrument before it is used in patients.

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