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Effect of component dismantling on quality of sterilization of mechanical torque limiting devices (pilot study)

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Objectives Dental instruments may serve as a route of infection transmission. The necessity of dismantling of Friction-Style (FS) and Spring-Style (SS) mechanical torque limiting devices (MTLDs) prior to disinfection and sterilization is a matter of debate, aside fromthe fact that it is difficult and time-consuming. This study sought to assess the effect of dismantling of components on quality of sterilizationof MTLDs.
Materials and Methods This *in vitro* experimental study was performed on 96 torque devices. Forty eight FS-MTLDs of two manufacturers (n = 24) namely Astra Tech (Hader SA, La Chaux-de-Fonds, Switzerland) and Dr. Idhe (Dr. Idhe Dental, Eching, Munich, Germany) and 48 SS-MTLDs of two manufacturers (n = 24) namely Nobel Biocare (Nobel Biocare, Goteborg, Sweden) and Straumann (Institut Straumann, Basel, Switzerland). After coding, specimens were inoculated with *Bacillus stearothermophilus* (PTCC1713) and 24 devices of four manufacturers each were divided into two groups (n = 12) for disinfection in assembled or disassembled form. Each group was then divided into two subgroups (n = 6) for sterilization in assembled or dismantled form. After disinfection and sterilization, bacterial proliferation was assessed for all MTLDs. In case of observing turbidity, Gram-staining and differential tests were performed. The results were expressed as presence or absence of contamination.
Results Growth of *B. stearothermophilus* did not occur in any plate (no turbidity). Only one plate showed growth of *Staphylococcus saprophyticus.*
Conclusion Dismantling of components had no significant effect on quality of sterilization of MTLDs.
Keywords dental implants, dismantling, friction-style, mechanical torque limiting devices, spring-style sterilization

Introduction

Reuse of dental instruments for diagnostic and therapeutic purposes is allowed on two conditions: they must be sterilizable and should maintain their accuracy and efficacy after sterilization.[1] Mechanical torque limiting devices (MTLDs) are available in two forms of spring-style (SS-MTLDs) and friction-style (FS-MTLDs) and are among complex dental instruments that need to be sterilized after each time of use. Although the internal structure and method of application and control of target torque are different in these two mechanical torque devices, they are both used in implant treatment during surgical and prosthetic phases for implant and prostheses placement. It has been reported that SS-MTLDs have higher accuracy in clinical use than FS-MTLDs;[2,3] however, some other studies have reported that none of the two devices have adequately high accuracy.[4,5]

Some FS-MTLDs are one-piece while some others are composed of several components, which can be dismantled prior to sterilization. Although the manufacturers of FS-MTLDs generally recommend dismantling of components for cleaning and washing and their subsequent lubrication, this step has been reported as one reason for insufficient precision and low accuracy of these devices.[3] Studies on the independent effect of sterilization on the accuracy of FS-MTLDs have shown that the process of dismantling and sterilization has a negative effect on the accuracy of some FS-MTLDs. However, these changes in most cases have been close to the clinically acceptable range (10% difference with target torque).[6] Fayaz et al.[7] evaluated the effect of sterilization and number of use on the accuracy of these instruments and reported maximum error in one-piece devices, which did not allow dismantling prior to washing, disinfection, lubrication, and sterilization. Guttierez et al.[4] evaluated FS-MTLDs used in dental clinics and reported high level of inaccuracy up to 450% difference with the target torque. The reported value exceeded maximum error value, which can cause screw loosening or fracture in the clinical setting.[8]

Effect of sterilization on the accuracy of SS-MTLDs has been previously evaluated. Mahshid et al.[9] showed that the process of sterilization negatively affected the accuracy of some SS-MTLDs. However, Mahshid et al.[10] in another study in 2013 showed that the process of sterilization and number of use, did not significantly affect the clinical accuracy of Straumann (ITI) and Nobel Biocare instruments irrespective of their dismantling. In their study, SS-MTLDs were subjected to steam sterilization with 100 cycles in assembled and dismantled forms and their accuracy was then measured using a torque gage and compared with their baseline accuracy. Santos et al,[5] evaluated the SS-MTDs in private clinics in Brazil and reported that they did not have high accuracy.

Although sterilization of dental instruments, such as SS- and FS-MTLDs is a routine and necessary step in dental implant treatment, the necessity of dismantling of components prior to washing, disinfection, lubrication, and sterilization of these torque devices has not been previously evaluated. Dismantling of components recommended by the manufacturers is time-consuming and relatively difficult and its necessity has yet to be confirmed. Marshburn et al.[11] reported that despite the existing recommendations regarding dismantling of laparoscopic components prior to disinfection and sterilization, they found no significant difference in quality of sterilization of assembled and dismantled groups.

Considering the absence of a protocol regarding the necessity of dismantling of components prior to sterilization of MTLDs, this study sought to assess the effect of dismantling on the quality of sterilization of FS- and SS-MTLDs. The null hypothesis was that dismantling would have no significant effect on the quality of sterilization of MTLDs compared to their sterilization in assembled form.

Materials and Methods

In this *in vitro* experimental study, 96 MTLDs in two types of Spring-Style (SS) and Friction-Style (FS) (each 48) were evaluated. In FS type 48 MTLDs of two manufacturers namely Astra Tech (Hader SA, La Chaux-de-Fonds, Switzerland) and Dr. Idhe (Dr. Idhe Dental, Eching/Munich, Germany) were evaluated (n = 24 each). In SS type also, 48 SS-MTDs of two manufacturers namely Nobel Biocare (Nobel Biocare, Goteborg, Sweden) and Straumann (Institut Straumann, Basel, Switzerland) were evaluated (n = 24, each). These 48 SS-MTLDs and 48 FS-MTLDs had been used in our previous study on the effect of duration of service and sterilization on the accuracy of these devices.[6,7,9,10] Specimens in each group (n = 24 of each manufacturer) were divided into two groups (n = 12) of disinfection in assembled or dismantled form (Figs. 1and 2), each with two subgroups of assembled and disassembled sterilization (n = 12) (Figs. 1 and 2) and coded. *Bacillus stearothermophilus* (PTCC1713) was obtained from the Iranian Research Organization for Science and Technology, passaged in brain heart infusion broth (Merck, Darmstadt, Germany) and incubated at 37°C to proliferate. Next, one loopful of bacteria was cultured on blood agar base (Quelab, Montreal, Canada) and Mueller Hinton agar (Merck, Darmstadt, Germany). Two to three colonies of the Mueller Hinton agar were suspended in 25 cc of saline to obtain 0.5 McFarland standard concentration, which contains 1.5×10^8 bacteria and is used as a reference for comparison of turbidity of bacterial suspensions. It is prepared by mixing 0.5 mL of 0.48 M barium chloride in 99.5 mL of 0.36 M sulfuric acid and can be maintained in screw-top containers for 6 months in the dark.

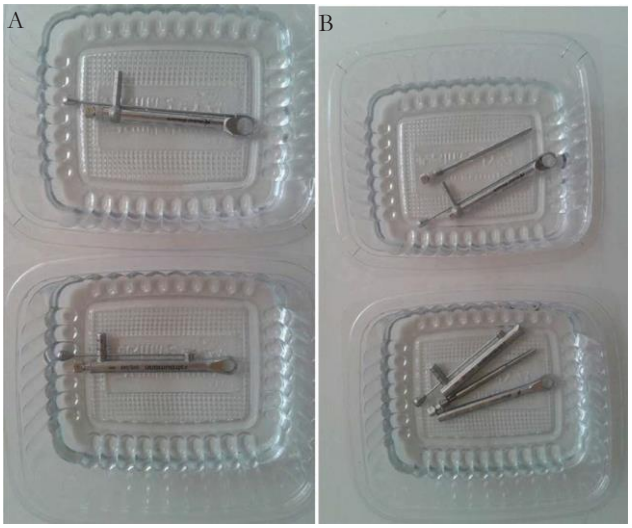

Fig 1. **Assembled (A) and dismantled (B) form of SS-MTLDs. Top: Nobel Biocare. Bottom: Dr. Straumann devices.**

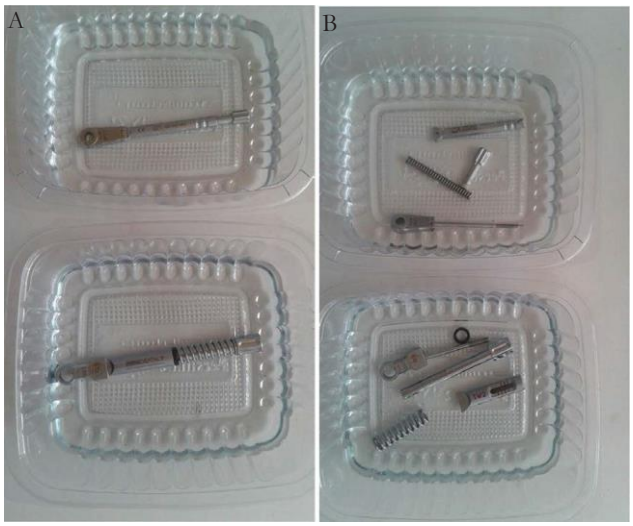

Fig 2. **Assembled (A) and dismantled (B) form of FS-MTLDs. Top: Astra Tech. Bottom: Dr. Idhe.**

First, SS- and FS-MTLDs in both groups were subjected to disinfection and sterilization as recommended by the manufacturers as in previous studies.[6,7,9,10] Next, in a microbiology laboratory, each specimen was placed in a plate containing 99 cc of Mueller Hinton broth (Merck, Darmstadt, Germany) and autoclave-sterilized to ensure no contamination during the experiment. After autoclave-sterilization and cooling, 1 cc of *B. stearothermophilus* (PTCC1713) in 25 cc of stock medium with 0.5 McFarland standard concentration was added to each plate and incubated at 37°C for 24 h. After incubation, bacteria were in logarithmic phase of growth (Fig. 3).

The specimens were then transferred back to the Department of Fixed Prosthodontics of Dental School of Shahid Beheshti University to undergo the following disinfection and sterilization protocols (Table1):

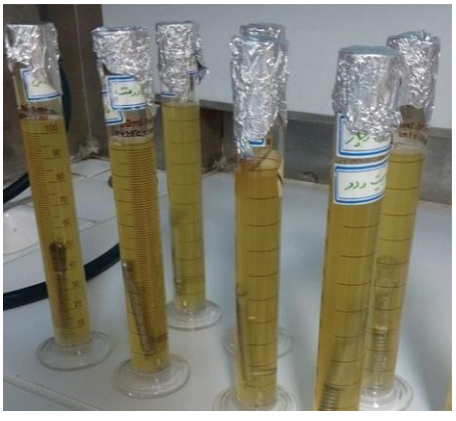

Fig 3. **Specimens in plates demonstrating logarithmic phase of bacterial growth.**

Table 1. **Disinfection and sterilization protocols**

Groups	Disinfection	Sterilization	
		Subgroup 1	Subgroup 2
1	Assembled	Assembled	Dismantled
2	Dismantled	Dismantled	Assembled

Group 1 (n = 12 of each manufacturer; disinfection in assembled from and variable sterilization) was divided into two subgroups. The first subgroup (n = 6 of each manufacturer) was disinfected and lubricated in assembled form (without dismantling) followed by sterilization in assembled form. Lubrication was performed only for FS devices. In this subgroup, the parts were assembled before sterilization.

Subgroup 2 (n = 6 of each manufacturer) was disinfected and lubricated in assembled form followed by sterilization in dismantled form. The sterilization settings were the same in both subgroups.

Group 2 (n = 12 of each manufacturer; disinfection in dismantled form and variable sterilization) was divided into two subgroups.

In subgroup 1, (n = 6 of each manufacturer), disinfection and lubrication were performed in dismantled form, followed by sterilization in dismantled form. Preparation protocol was followed for each group of MTLDs, based on the manufacturer's instruction. As Astra Tech and Dr. Idhe devices should be dismantled for disinfection, cleaning, drying, and lubrication, this was followed at the proposed site. For SS devices (Nobel-Biocare and Straumann) also dismantling was performed for disinfection, cleaning, and drying). In this subgroup, the parts were kept dismantled before sterilization.

Subgroup 2 (n = 6 of each manufacturer) was disinfected in dismantled form and was then subjected to sterilization in assembled form. The sterilization settings were the same in both subgroups.

Disinfection process was performed for all devices in assembled or dismantled form for 15 min using the 2% phenol and aldehyde-free, nonfixing disinfectant (Deconex 53 Plus, Borer Chemie, Zuchwil, Switzerland). Devices were then sterile packed and placed in the steam sterilizing autoclave (Techno - Gaz/, Europa BXP/S.p.A, Parma, Italy) in dismantled or assembled form according to their subgroup. Sterilization characteristics included: Temperature at 134°C, vacuum pressure at 0.9 bar and sterilization time for 18 min.

Next, all devices were returned to the microbiology lab. Each specimen was placed in 100 cc of autoclave-sterilized Mueller Hinton broth to assess the efficacy of disinfection and autoclave-sterilization. All the aforementioned steps were performed in sterile conditions under a hood. Media containing MTLDs were evaluated for turbidity and contamination after 24 h of incubation. One loopful of broth was obtained of each plate and cultured on Mueller Hinton agar to assess bacterial growth.

After the required time period, the plates were read near to the flame. Slides were prepared and observed under a microscope. In case of noticing bacterial growth, Gram-staining and differential tests were performed. The examiner was blinded to the group allocation of specimens in terms of the process of disinfection to prevent bias. The results were reported as presence or absence of contamination. Absence of contamination indicated successful sterilization. Thus, the effect of dismantling on the quality of disinfection and sterilization was separately evaluated.

Results

Two groups of FS-MTLDs and SS-MTLDs of two manufacturers (n = 24) were evaluated in terms of bacterial growth after disinfection and sterilization in dismantled and assembled forms. No bacterial growth (no turbidity) was observed after 24 h in plates of specimens in the three subgroups (assembled disinfection with assembled or dismantled sterilization and dismantled disinfection and dismantled sterilization), which indicated optimal disinfection and autoclave-sterilization (Figure 4).

Only in subgroup 4 (dismantled disinfection followed by assembled sterilization), turbidity was noted in one plate (Astra group). Contents of this plate were cultured (Fig. 5) and slides were prepared of bacterial colonies and Gram-stained, which showed the presence of Gram-positive cocci.

Catalase test yielded positive results, which indicated presence of staphylococci. Positive coagulase test, Novobiocin, mannitol salt agar culture and DNase test indicated the presence of *Staphylococcus saprophyticus*.

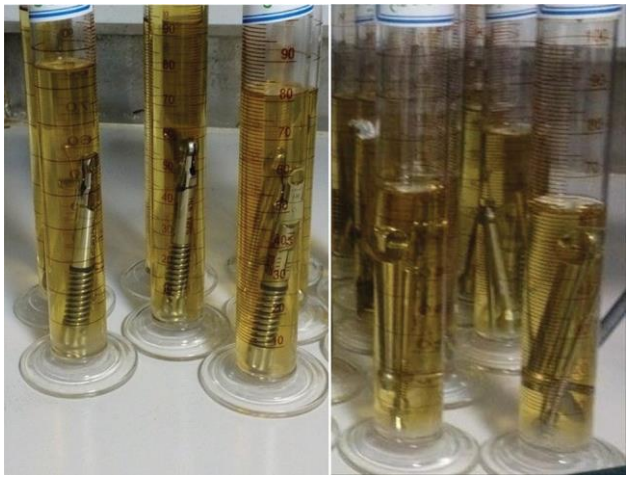

Fig 4. **No bacterial growth (no turbidity) was observed after 24 h in plates of specimens.**

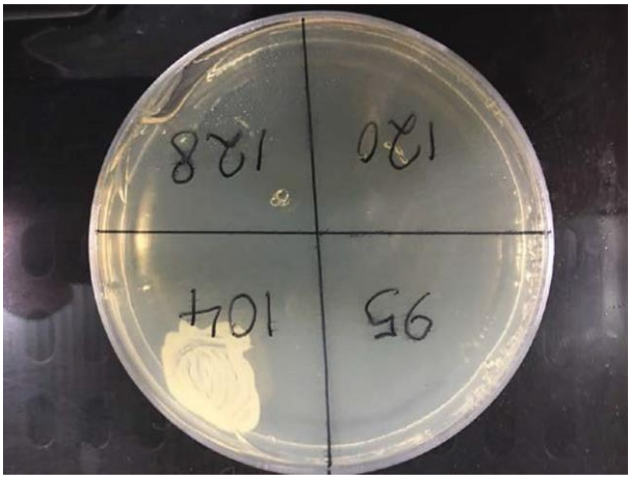

Fig 5. **Culture of plate with turbidity, demonstrating bacterial growth.**

Discussion

The current results confirmed the null hypothesis regarding no significant effect of dismantling on the quality of sterilization of SS and FS-MTLDs. Dismantling or separation of device's components during disinfection is proposed by all manufacturers but sterilization in dismantled form is proposed only by Straumann device's manufacturers. Based on the results of current study, assembling or separation of components during disinfection and sterilization did not show any considerable effect on the quality of sterilization.

Sanchez et al.[12] showed that all cleaning processes (such as disinfection and sterilization) were less effective for complex dental instruments compared to simple instruments. Wichelhaus et al.[13] evaluated orthodontic pliers and showed that hinges, joints, serrations and all structurally complex components were highly susceptible to corrosion due to sterilization. Our current results did not confirm the findings of studies reporting inefficacy of disinfection and sterilization processes for complex dental instruments. This may be due to strict adherence to dismantling and sterilization protocols.

Most previous studies on infection transmission through dental procedures have focused on dental instruments as a potential route for transmission of pathogenic microorganisms.[14,15] According to the American Dental Association, surgical instruments and those penetrating into the soft tissue and bone such as tooth extraction forceps, blades, bone chisels and periodontal scalers are categorized as critical tools and must be sterilized or discarded after each time of use. Instruments not penetrating into the soft tissue or bone but contacting the oral mucosa such as amalgam condensers and water and air spray are categorized as semi-critical tools. If they are heat-resistant, they must be sterilized after each time of use. If they are heat-sensitive, they must be sterilized with strong disinfecting agents.[16,17]

Acosta-Gio et al.[18] evaluated sterilization devices in dental offices in Mexico and showed that 74% of offices used autoclaves, 2% used dry heat and 5.6% used chemiclaves. They reported 7.4% bacterial growth in all sterilization methods. Maximum bacterial growth was noted following sterilization with dry heat while minimum bacterial growth was noted following sterilization with chemiclaves and autoclaves. In our study, bacterial growth did not occur in any of the four subgroups. Difference between the results of the two studies may be due to the fact that the previous study[18] evaluated several dental offices using different methods of sterilization and variable techniques for assessment of contamination. Although *B. stearothermophilus* was used in both studies, the type of sterilized instruments was not mentioned in their study. No information was given regarding dismantling of components or assembled sterilization either.

In the study on sterilization of laparoscopic instruments, no difference was noted in the quality of sterilization between assembled and disassembled groups despite the existing recommendations regarding dismantling of components prior to disinfection and sterilization. This result may be due to precise adherence to sterilization guidelines.[11] Their findings were in agreement with ours. Dismantling and lubrication of components prior to disinfection have been recommended by both manufacturers of FS-MTLDs evaluated in our study. Although both manufacturers of SS-MTLDs recommend disassembly of components prior to disinfection, disassembly prior to sterilization is only recommended by Straumann to prevent corrosion. Other than that, sterilization of SS-MTDs is recommended in assembled form. Our results regarding no need for dismantling of FS- and SS-MTLDs is clinically important because dismantling is a difficult and time-consuming process requiring high precision.

Precise adherence to sterilization protocols such as efficient cleaning and washing of components, their transfer to sterilizer, efficacy of sterilizer and method of storage of sterilized instruments can all affect the maintenance of sterility of these instruments.[13,19] In our study, dismantling prior to disinfection or sterilization, or both, had no significant effect on quality of sterilization of any specimen. After inoculation of specimens, disinfection and sterilization, no bacterial growth (turbidity) occurred in any plate after 24 hours. This indicated efficient disinfection and autoclave-sterilization. Turbidity was only seen in one plate of subgroup 4 (dismantled disinfection, assembled sterilization). Differential tests showed contamination of plate with *S. saprophyticus*, which may be due to human error during disinfection, sterilization or transfer. This plate was not contaminated with *B. stearothermophilus*.

Use of *B. stearothermophilus* in our study was due to its high resistance to sterilization compared to vegetative bacteria such as *Mycobacterium tuberculosis* and blood-borne viruses such as HIV and hepatitis B.[18] Considering the use of maximum dose of viable and culturable *B. stearothermophilus* in aqueous environment, which is the reference technique for assessment of bacterial contamination and also use of Mueller Hinton broth as a suitable medium for bacterial growth, no bacterial growth in plates indicates accurate disinfection and sterilization even when performed in assembled form.

Some studies have discussed that complex dental instruments are susceptible to corrosion due to sterilization and have reported this as a weakness of complex devices.[12,13,18] Since SS- and FS-MTLDs are categorized as complex instruments and are extensively used in prosthetic and surgical treatments, similar future studies are required to assess the effect of dismantling on blood-contaminated instruments because components of these torque devices may become contaminated with blood or biological debris. It has been reported that contamination of complex instruments with blood and biological debris further complicates the process of sterilization of dental and medical instruments.[14,15,19]

Considering the qualitative nature of the results of our study and its limitations, further studies on larger sample sizes are required to increase the generalizability of our results to the clinical setting.

Conclusion

Within the limitations of this study, the results showed that dismantling of components had no significant effect on quality of sterilization of SS- and FS-MTLDs.

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