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Fatigue of Dental High-speed, Air-driven

Handpiece by Steam Sterilization

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ABSTRACT

Autoclaving dental high-speed, air-driven handpieces (HPs) is a recommended standard for infection prevention and control. Subjection to repeated sterilization may cause fatigue, and possible corrosion, for most HP mechanics. **Objective:** The purpose of this study was to evaluate the effect of steam sterilization on the mechanical properties of HPs and to determine whether sterility inside the HP lumen can be maintained after thermal cyclic fatigue induced by repeated sterilization. Methods: Six commercially available brands of HPs (n = 6/brand) were selected: TiMax-Z (NSK), Mastertorque-mini-Lux (Kavo), Experttorque-Lux (Kavo), Midwest Tradition Pro-TBF (Dentsply), Midwest Phoenix ZRK (Dentsply), and Midwest Stylus Plus-SPK (Dentsply). The HPs were subjected to 180 cycles of gravity displaced sterilization without lubrication to accelerate the effect of fatigue aging. The HPs were exposed to nonsterile conditions prior to each sterilization cycle and then sterilized (Tuttnauer 2540EKP). Bacterial loads were quantified at the initial, 60th, 90th, 120th, and 180th sterilization cycles only. Using a custom-made universal testing machine (ACUMEN, MTS), HP fatigue parameters such as stall torque, power, and revolution per minute (RPM) were measured. Data were analyzed with repeated measures ANOVA/Tukey (α =0.05). **Results:** Experttorque-Lux, Mastertorque-mini-Lux, Midwest Phoenix ZRK, Midwest Stylus Plus-SPK, and TiMax-Z maintained similar power as baseline over 180 cycles of steam sterilization. Midwest Tradition Pro-TBF demonstrated the greatest loss in power (20%) and RPM (18%) over 180 cycles than all other five brands, but still maintained the greatest power. After 120

cycles of repeated sterilization without lubrication, one Midwest Tradition Pro-TBF HP experienced mechanical failure and was excluded from further testing. No signs of corrosion or fractures were noted. No bacterial colony formation was observed inside the lumen for any HP after 180 cycles of steam sterilization. **Conclusion:** All HPs, except one HP from the Midwest Tradition Pro-TBF group, maintained functionality after the sterilization processes. Routine care with appropriate maintenance is strongly advised to maximize longevity and optimal performance of dental HPs.

INTRODUCTION

Air-driven, high-speed handpiece has assumed a key role in dentistry. Nonetheless, the untimely malfunction of a handpiece remains a nuisance during dental procedures. Events such as stalling, ball bearing corrosion, thermal stress cracking, and reductions in torque, bur speed, and power, are common problems frequently observed for both non-metallic and metallic parts of a dental rotary handpiece. Although handpiece "wear and tear" is inevitable, with proper maintenance, handpiece life expectancy can be extended. [1-3]

The performance and efficiency of a handpiece are greatly dependent on the resistance of its bearing-spindle-turbine unit to the impact of repeated chemical disinfections and autoclaving regimes. Although autoclave is the preferred method for sterilizing critical dental and surgical devices and instruments, prolonged routine autoclave can generate corrosive wear to the mechanical components of any equipment, gradually incurring irreversible damages and ultimately leading to instrument's failure. Even though dental handpieces have long been manufactured to be autoclavable, past studies [4, 5] have shown that stress and strain from repeated sterilization and daily clinical operations – possibly mishandlings or abuses – can dramatically reduce a handpiece's life expectancy. On the contrary, dental handpieces and their attachments, unless adequately disinfected, can harbor pathogenic organisms, resulting in healthcare-associated infections. Furthermore, dental handpieces are categorized by Spaulding classification as critical devices. Thereby, sterilization but also sterility. This practice must be performed with a repeatable and verifiable, standardized process along with

proper oversight and documentation [5]. Therefore, the impact of autoclave on dental handpiece performance is a legitimate concern that requires further investigation and research.

To assess the performance of a dental handpiece and the efficiency of its bearingspindle-turbine cartridge, various laboratory- and practice-based failure stimulations have been investigated. [6-9] For example, Worthington and Martin (1996) measured the freerunning speed as a predictor for handpieces that underwent one year of clinical operatory uses and autoclaves. [10] They found a 24-64 % decline in free-running speed for the majority of their tested handpieces. Besides the free-running speed, Leonard and Charlton (1999) measured power, fiber-optic illumination, eccentricity, noise, chuck performance, and water coolant spray pattern. [9] They realized if handpieces were not appropriately maintained, these equipment can have an increased risk of failure after subjection to approximately 500 clinical uses/sterilizations. Their results were checked by Nagai and Takakuda (2006). They found with appropriate lubrication, there was a minimal (1-4%) decline in handpiece free-running speed after 300 cycles of sterilization. [11]

To further probe the cause-effect relationship between maintenance and longevity of handpieces, Monaghan et al. (2005) measured other risk parameters, such as bearing resistance, noise, and stall torque, and investigated how these parameters could provide insights to the failure criteria of dental handpieces. Using a custom-made machine, they confirmed that a reduction in free-running speed was a result of an increase in bearing resistance. Additionally, they concluded that a substantial increase in handpiece noise was an indicator of imminent bearing failure [12]. These results were later verified by Wei et al. (2013). They showed failure of the bearing-spindle-turbine cartridge was not only associated with corrosive wear of the rolling contact between balls and raceway, but bearing failure was also linked with the amount of pressures, during "cutting" operation, that were applied to the spindle [12,13]. This combination of corrosive wear and excessive axial-radial pressure – along with poor or no lubrication – was often the culprits behind the acceleration of dental handpiece deterioration.

In general, dental handpieces are well-constructed and robust instruments. However, with repeated exposure to autoclaving, resulting in fatigue-related microdeteriorations, question, such as whether these micro-cracks can act as sites for contaminants to enter, adhere, and be entrapped, remains. Furthermore, the internal gearings, turbine mechanisms, and narrow lumens of a dental handpiece can add another layer of complexity and challenge for conducting sterilization. As such, the handpiece internal lumens can merge or bifurcate, whereby restricting steam ingress from reaching all of the inner surfaces for sterilization.

Accordingly, the purpose of this study was to investigate the effect of repeated autoclaving processes on the fatigue deterioration of 6 popular dental-handpiece brands during 180 autoclave cycles. Based on the aforementioned studies, three key parameters (free-running speed, stall torque, and power) were determined to be linked with handpiece fatigue deterioration. To measure these three parameters, this study utilized a custom-built machine. Additionally, this study evaluated the effectiveness of gravity displaced steam sterilization of dental handpieces inoculated with bacteria and tested whether sterility inside the handpiece lumen can be maintained after thermal cyclic fatigue induced by repeated sterilization. The null hypothesis was that there would be no deterioration amongst the 6 popular handpiece brands in free-running speed, stall torque, power, and bacterial contamination of the handpieces after 180 cycles of sterilization without lubrication.

MATERIALS AND METHODS

Six popular and commercially-available brands of dental high-speed handpieces (6 handpieces per brand) were selected. See Table 1 for handpiece brands, salient features, and manufacturer technical specifications.

Handpiece Speed, Power, Stall Torque, and Efficiency

All handpieces were received from the manufacturers in new conditions. Prior to any sterilization, a baseline measurements of the free-running speed (revolution per minute, RPM), power (J/s), and stall torque (N mm) were recorded. Afterwards, handpieces were individually packaged into sterilization pouch along with a chemical indicator (Comply SteriGage, 3M, St Paul, MN, USA). This chemical indicator is a Class 5 steam integrator, which was used for monitoring the efficacy of sterilization. Per manufacturer sterilization instructions, NSK, Kavo, and Dentsply handpiece brands were sterilized at 132 °C for 15 minutes, 135 °C for 10 minutes, and 135 °C for 10 minutes, respectively, all with a 30-minute drying time. All handpieces were subjected to 180 cycles of gravity displaced steam autoclave (Tuttnauer 2540 EKP), simulating approximately 6 months of sterilization with the assumption of one autoclaving cycle per day. Additionally, to accelerate the effect of autoclaving fatigue and aging, each handpiece was exposed to nonsterile condition and was not lubricated prior to the next sterilization cycle. Studies [1,4,11] that closely mimicked the daily clinical use have indicated that lubrication mitigated the effect of autoclave-induced corrosion, extending the service lifetime of a handpiece. However, to the best of authors' knowledge, no study has assessed the performance of dental handpieces without the confounder variable, "lubrication". This type of accelerated testing is not only efficient – saving time, cost, and resources for the evaluative process; but, it is also necessary to compare the outcomes between routine (expected) and extreme (unexpected) conditions. From there, meaningful prediction for handpiece reliability can be extrapolated.

Bacterial inoculations were performed after the completions of the 59th, 89th, 119th, and 179th sterilization cycles, and then the next sterilization cycle followed. After the completions of the 60th, 90th, 120th, and 180th sterilization cycles, bacterial loads were quantified. See next section for details in bacterial analyses and quantifications. Furthermore, stall torque, power, and free-running speed were measured for each handpiece after the completions of the 30th, 60th, 90th, 120th, and 180th sterilization cycles. Additionally, each handpiece was visually inspected for signs of corrosive fatigue and fractures. To visualize whether deteriorations have occurred internally to the turbine and gears, the handpieces were dissected for observation under a Stereo-Microscope (Olympus SZX16, Tokyo, Japan).

A custom-made handpiece testing machine (MTS ACUMEN, MTS, Eden Prairie, MN, USA) based on the design of a previous study [9] was used to analyze and quantify the performance of each handpiece. An air compressor (Sil-Air 50-9-D, Silentaire Technology, Houston, TX, USA) was used to deliver a drive-air pressure of 45 pounds per square inch (PSI) to each handpiece, generating a drive-air pressure of 36 \pm 2 PSI measured right at the connection between the air tubing and the handpiece coupler. The

 36 ± 2 PSI reflected an average PSI that were delivered to a dental handpiece in a typical Air Force clinic. The air flow rate per handpiece (ml/min) was measured with a mass flow meter (FMA 1842A, Omega Engineering Inc., Norwalk, CT, USA).

For each handpiece, the stall torque and RPM were measured by the load cells of the custom-made handpiece machine and a photo-optic tachometer (Monarch Instrument, Amherst, NH, USA), respectively. RPM is defined as the rotational speed of the mandrel whose action is free from any "cutting" load. Stall torque is defined as the maximum torque that can be applied to the mandrel, causing it to stop its rotational movement. Because Power (P, J/s) is a function of stall torque and turbine RPM, power was calculated by using the following equation:

$$P = T * \omega$$
 ,

where T is the stall torque (N mm), and ω is the turbine speed (RPM). The efficiency (revolution per milliliter) is defined as using the least amount of drive air to achieve the highest amount of turbine revolutions and is calculated from the following equation:

$$Efficieny = \frac{RPM}{AFR} ,$$

where RPM is the revolution per minute, and AFR is the air flow rate, as described earlier.

Handpiece Biofilm

Bacterial strains from freezer stocks were diluted 1:100 in suitable sterile growth media in 50 ml propylene conical tubes, and grown overnight at 37 °C with shaking at 200 rpm. The following day, the cultures were diluted 1:10 in the appropriate media and aliquoted into the wells of a polystyrene, 12-well flat bottom plate. The OD600 (Optical Density 600 nm) was read using a spectrometer (Spectramax i3x, Molecular Devices, San Jose, CA). The bacterial cultures were standardized to 1 OD/ml after the OD600 was determined. Serial dilutions of the bacterial cultures were performed to quantify inoculum populations by generating 10-fold serial dilutions from 10^{-1} to 10^{-8} . For specific quantitation, 100 µl per dilution was spread onto nutrient agar plates and placed in a 37°C incubator overnight.

After the bacterial samples were prepared, dental handpieces were placed in the bacterial sample for 30 minutes and allowed to air dry. This occurred after 59, 89, 119

and 179 sterilization cycles. The dental instruments were then exposed to one sterilization cycle, and after the cycle, placed in a 50 ml propylene conical tube containing 10 ml of sterile strain growth media for at least 15 minutes with occasional agitation. Spread plate assays were performed by plating 100 μ l of the media on a 35 mm sterile nutrient agar plate. The agar plates were incubated overnight at 37°C, and Colony Forming Units (CFU's) were counted the following day. The remaining media from the test instruments were kept in the conical tubes for turbidity testing, and incubated overnight at 37°C with shaking at 200 rpm. The following day, 1ml from each tube was aliquoted into one well in a 12-well flat bottom plate. The OD600 was read using the spectrometer. Sterilization efficacy was determined by using spore strips to determine the sterility assurance level (SAL 10⁻⁶) determined by the FDA as being the ability of the sterilization procedure to reduce the bacterial load from 10⁻⁶ to 0 (CDC and FDA 2008). Positive and negative control instruments were used. For sterilization efficacy, CFUs and sterility assurance level were measured. A spore test was completed weekly to ensure the sterilizer was meeting standards.

Sample size estimation/power analysis: Based on the data of Leonard and Charlton (1999), a sample size of 9 per handpiece brand yielded 80% statistical power of identifying a significant effect. [9] We assumed a tighter standard deviation, and evaluated 6 per handpiece brand. Data were analyzed with a two-way repeated measures ANOVA to evaluate the effect of handpiece type and numbers of sterilization cycles on the change of the performance parameters and sterilization efficacy from baseline (alpha = 0.05).

RESULTS

Over the course of 180 sterilization cycles, mixed results were observed regarding the various handpiece brands. While the Kavo Experttorque and Kavo Mastertorque Mini handpieces performed relatively similarly from baseline to completion of the 180 cycles; other handpiece brands appeared to lose power. Loss of power was most pronounced in the Midwest Tradition handpieces. See Figure 2. Stall torque remained relatively consistent throughout the 180 cycles except notably the NSK handpieces produced more stall torque as they underwent more sterilization cycles. See Figure 2. Handpiece speed remained relatively consistent over 180 cycles of sterilization in all handpiece brands except for Midwest Tradition which showed a considerable loss of speed. See Figure 2. Efficiency was calculated by dividing rotations per minute by the flow rate to determine how effectively the handpieces convert the air pressure into power. Kavo Mastertorque Mini handpieces were more efficient than the other groups and Midwest Phoenix performed the worst in this category. See Figure 3. In general, Midwest Tradition handpieces had the highest power and RPM despite also having the greatest loss in power over time. Midwest Stylus has less power and stall torque than Midwest Tradition, Midwest Phoenix, NSK TiMax and Kavo Experttorque. While Kavo Mastertorque Mini had the least power and stall torque overall, it had the second highest RPMs. See Figure 4.

Baseline testing did show bacterial colony formation in the positive control test. No bacteria was found on any handpiece after sterilization. See Table 2. Individual handpieces were visually inspected for damage. No obvious fractures are reported.

Notable findings included inability of the handpiece to rotate the mandrel resulting in a "stuck" position. This was remedied by spinning the mandrel around several times in the handpiece or spraying lubricant as needed to get the mandrel to spin again. A stuck mandrel was noted across all handpiece groups and was generally resolved with hand spinning the mandrel, however two individual handpieces from the Kavo Experttorque group required lubrication after thirty cycles of sterilization. One individual handpiece from the Midwest Tradition group experienced failure after 120 sterilization cycles as it was not able to hold the mandrel and the button to release the friction grip became wedged as shown in the photograph and radiographic images. See Figure 5.

DISCUSSION

In our study, resistance to rotation was provided by a rope-brake system, such that when the string tightened around the mandrel the speed decreased until it eventually stopped spinning altogether. In general, and most pronouncedly in the Midwest Tradition group, the more that the handpieces were fatigued by steam sterilization the more that speed decreased. Since speed is a variable in the equation for power, there was a trend towards a reduction in power as the handpieces were sterilized more. The ISO states that each handpiece should be able to withstand 250 cycles of sterilization, however we encountered a mechanical failure of one handpiece by 120 steam sterilization cycles. Therefore, we rejected the null hypothesis that there would be no deterioration of the mechanics of the dental handpiece after sterilization. The method we used, effectively determined the measured parameters of RPM and torque, and using these measurements were able to calculate power. Limitations to this method include inability to measure ball bearing resistance.

Additional parameters not tested in this study such as variation in free-running speed, bearing resistance, illuminance and sound pressure level can be used effectively to monitor changes due to normal use. Noise is a potentially useful indicator of handpiece malfunction. While sound pressure levels were measured routinely throughout our experimentation, the decibel levels recorded while in the Custom Universal Testing Machine were not similar to decibel levels recorded while connected to a dental chair, and so we cannot confirm whether changes in sound pressure level were indicative of potential failure.

The lumen of the handpiece is the most critical area to sterilize as it holds the bur and is placed directly in the patient's mouth. Steam sterilization is capable of penetrating the handpiece lumen [14]. Bacterial biofilm has been detected in the turbine and spray channel after clinical use, however steam sterilization is able to penetrate these areas [15]. We were interested to see if any physical deformations or fractures would occur in the handpieces that could potentially harbor bacteria, however none were found with visual inspection. Electron microscopy looking for microfractures could be the focus of potential future research. We did not routinely lubricate the handpieces as is recommended by the manufacturer. Decontamination of the handpiece lumen can be compromised due to oil impeding access for steam penetration. Some concerns have been raised that the use of lubrication actually interferes with the sterilization process [16]. This aspect of sterilization was not measured in our study. A direct comparison of oil lubricated and non-oil lubricated handpieces may address these concerns, however we recommend following the manufacturer instructions for oil lubricating handpieces for clinical use. Oil lubrication, has no bearing on clinical bond strengths of dentin bonding systems and so the practitioner can be assured that oil spray as a consequence of oil lubrication will not interfere with clinical outcomes of adhesive restorations [17].

Sasaki and Imazato and Winter el al found that gravity displacement autoclaves such as the type used in this study are capable of sterilization but are less reliable than vacuum sterilizers [18,19]. In our study, instruments were individually packaged for each sterilization cycle and we did not find bacterial contamination in the handpiece lumen even after 180 cycles of induced fatigue therefore we failed to reject our second null hypothesis that bacterial contamination would not be found in the dental handpiece lumen despite the potential deformations and microfractures induced from the repeated steam sterilization.

One limitation of the current study is not continuing sterilization cycles to 250 as it would have proved interesting if more handpieces were to fail before the specified interval by the ISO. The early failure could be attributed to lack of lubrication. Further research is needed to determine whether steam sterilization induced fatigue affects mechanical properties if all manufacturer recommendations for maintenance are performed to include lubrication. Following the manufacturer instructions for use is critical in preserving the proper functionality of the dental handpiece [20]. Additional areas of research could focus on testing of handpieces that have been mechanically fatigued through the cutting of various materials, such as metals, composites, and ceramics. There is also the question of how water spray affects handpiece performance as it may lead to rust of internal components.

Considerations when purchasing handpieces include the performance over time but also the salient features such as weight and size should be considered. Kavo Mastertorque Mini handpiece, though producing less power and torque than other handpiece brands produced the second highest RPMs of all handpieces tested and remained the most consistent in the power parameter over the testing period. Additionally, it has the smallest head height and diameter, making visibility in tight accesses more feasible than the Kavo Experttorque which has the biggest head of the handpieces tested.

CONCLUSION

All handpieces, except one from the Midwest Tradition Pro-TBF group, maintained functionality after the sterilization processes. Routine care with appropriate maintenance is strongly advised to maximize longevity and optimal performance of dental handpieces.

Disclosures: Handpieces were provided for purposes of completing this research via a Material Transfer Agreement between the handpiece companies and the United States Air Force.

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Handpieco Model	Ti May 79001	Midwest			EXPERTtorque	MASTERtorque	
Handpiece Model	TI Wax 2000L	Phoenix ZR	Stylus Plus	Tradition Pro	LUX E679L	LUX M8900L mini	
Manufacturer	NSK	Dentsply Sirona			KaVo Kerr		
Weight (g)*	41.67	62.09	61.26	46.68	65.76	62.57	
Weight with coupler (g)*	86.71	90.07	89.24	N/A	88.2	85.01	
Head Height (mm)*	12.11	13.13	12.81	12.82	13.61	12.17	
Head Diameter(mm)*	10.82	11.98	10.29	10.2	12.39	10.77	
Noise (Decibel)**	75.6	76.6	72.9	74.7	74.7	75.5	
Spray Ports*	8	8	8	2	4	3	
LED*	Y	Y	Y	Y	Y	Y	
Drive pressure (PSI) [†]	36-44	39-43.5	39-43.5	34-43	30-61	30-51	
Idle speed (RPM) [†]	360-440k	330-410k	370-450k	370-450k	340-420k	380-450k	
Power (W) [†]	23	23+	18-30	20-25	18	23	
Water pressure (PSI) [†]	11-29	29	29	29	12-29	12-36	
Sterilization temperature (°C) [†]	132	135	135	135	135	135	

Table 1. Salient features of dental handpieces

* Values were measured in Air Force laboratory

** Values were measured in Air Force clinical setting

[†] Values were obtained from manufacturer technical specifications



Figure 1. Graphical representation of data captured for Midwest Tradition handpiece after 30 cycles of sterilization, presented here as an example of Power and Stall Torque v RPMM



Figure 3: The efficiency of the six dental high-speed brands were compared. The efficiency of a handpiece is defined as the number of rotations per minute divided by the drive-air flow rate [ml / min]. A standard drive-air flow rate of 43 ± 2.6 ml / min was applied for all testing. Bars with the same case letters are not significantly different than each other (p > 0.05).





Figure 4: The average power, stall torque, and RPM of the six dental high-speed handpiece brands were compared. For each testing parameter, bars with the same case letters are not significantly different than each other (p > 0.05).

Handpiece Model	Ti Max Z800L	Phoenix ZR	Midwest Stylus Plus	Tradition Pro	EXPERTtorque LUX E679L	MASTERtorque	
Manufacturer	NSK		Dentsply Siro	na	KaVo Kerr		
Positive Control (CFUs)	2	1	50+	9	0	0	
Baseline (CFUs)	0	0	0	0	0	0	
60 cycles (CFUs)	0	0	0	0	0	0	
90 cycles (CFUs)	0	0	0	0	0	0	
120 cycles (CFUs)	0	0	0	0	0	0	
180 cycles (CFUs)	0	0	0	0	0	0	

Table 2. Positive controls were determined by culturing handpieces after being handled with bare hands.

Bacterial colonies were not found after any cycle of sterilization.

CFU=colony forming unit