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Biomaterials Research Report

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RH-Pro11 Sterilization Validation of Handpiece Performance with Expanded Testing

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Introduction:

This study evaluated a dry heat sterilizer having a 21-minute, waterless processing cycle which can reduce or eliminate instrument corrosion by employing high-velocity hot air (HVHA™), a significant advance in sterilizing dental instruments. Elevated sterilization temperatures of 375° F (191° C) used in this process could potentially affect handpiece components or decompose some hydrocarbon-based oil lubricants specific to handpiece reprocessing. In the first phase of our validation of the ***RH-Pro11*** sterilization system (see RR#131, January 2020), we measured the performance of new and used handpieces before and after 250 sterilization cycles using a synthetic lubricant to validate its compatibility with the sterilization process and handpiece function. In this study, we further validated handpiece compatibility with the ***RH-Pro11*** by expanding testing to 500 sterilization cycles, while also applying load to the handpieces via Stall-Torque measurements every 50 cycles to give an increased challenge to the handpieces.

RH-Pro 11

Conclusion:

Handpieces evaluated from 4 different manufacturers showed no decrease in performance through 500 cycles of sterilizer use.

EXPERIMENTAL DESIGN:

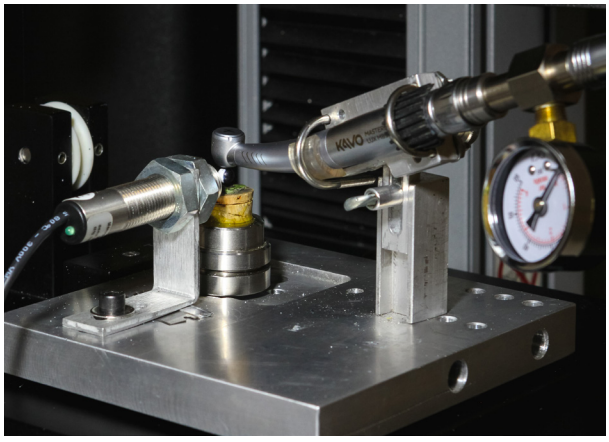
Equipment: DENTAL ADVISOR Handpiece Torque Test Platform and Instron 5866 universal test machine

Handpieces: ***EXPERTtorque LUK E675 L*** (KaVo) @41psi, ***Midwest Phoenix PK*** (Denstply Sirona) @43.5 psi, ***430 SWL Torque Flex*** (Star Dental)@43 psi used with lubricant, ***Synea TA-97 LM*** (W&H) @43.5psi

Tests: Noise (dB), Speed (RPM), Stall Torque(N-mm), Power (W)

Methods:

Performance Testing: The handpiece was attached to the test platform in a handpiece holding assembly including an air pressure gauge connected just prior to the handpiece and coupler. A spindle with a brake sphere was inserted into the chuck of the handpiece and the holding assembly adjusted so that the spindle was aligned with the torque sensor. The speed of the spindle was measured with a Monarch Infrared speed sensor and ACT 3 Electronic Tachometer. The torque sensor was connected to the load cell of the Instron 5866 system on which the test platform was mounted. During the testing, the handpiece was pressed downward along the axis of the spindle shaft with varying loads so that the brake sphere was pushed against the brake, which was attached to the torque sensor. The friction of the brake sphere against the brake produced a torque, which was registered by the load cell as a force while the speed was measured. Several torque versus speed points were taken to define the torque versus speed curve for each handpiece and used to calculate power in Watts. The stall torque was determined as the torque produced at the point during loading when the rotation of the spindle running at maximum speed was braked to zero RPM. Noise level was measured according to ISO 14457 methods by measuring the A-weighted sound pressure 0.45 meters from the handpiece with a type 1 precision sound level meter (DSM403SD, General Tools & Instruments).



Sterilization: Unwrapped handpieces were subjected to 500 sterilization cycles using the ***RH-Pro11*** sterilizer at 375°F under the "handpiece" cycle setting. At every ten cycles, the handpieces were removed, lubricated with ***Lubrifluid*** (Bien Air) using a ***Lubrina*** (Morita) dental handpiece maintenance unit, and operated for at least 120 seconds with bur insertion before proceeding to the next ten sterilization cycles. At every 50 cycles, handpieces were operated and braked until stalling for over 2 minutes to simulate aggressive clinical use and to measure interim performance. Full performance testing was conducted in the initial condition, after 250 sterilization cycles and after 500 sterilization cycles.

Results:

Results Summary												
Manufacturer	KaVo			Dentsply Sirona			Star Dental			W&H		
Handpiece	*EXPERTtorque LUK E675 L*			*Midwest Phoenix PK*			*430SWL Torque Flex*			*Synea TA-97 LM*		
Test	Initial	After 250 Cycles	After 500 Cycles	Initial	After 250 Cycles	After 500 Cycles	Initial	After 250 Cycles	After 500 Cycles	Initial	After 250 Cycles	After 500 Cycles
Average Max Power, W	15	15.5	15.6	24.5	24.4	24.6	23.8	24.1	24.8	11.2	11.8	12.8
Free Running Speed, RPM	428300	436400	429900	413500	414300	411900	392200	422900	432100	330400	346800	351400
Average Noise, Decibel	67.6 (0.5)	68.2 (0.6)	67.9 (0.5)	64.4 (0.4)	64.9 (0.6)	65.4 (0.3)	67.4 (0.7)	68.4 (0.6)	68.3 (0.5)	55.6 (0.4)	56.6 (0.5)	56.8 (0.4)

There was no detectable decrease in performance when measuring noise generation, speed, stall torque or power output after 500 reprocessing cycles with the ***RH-Pro11*** sterilizer for the 4 tested handpieces. As can be seen on the plot of the handpiece power measurements, the average performance measurements either lie along the same curve with nearly identical peak power or were higher after subsequent cycles than the initial condition. The noise level difference before and after reprocessing was less than a decibel difference for all handpieces and was considered equivalent to small ambient noise changes and differences in actual speed of operation.