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SANTA BARBARA • SANTA CRUZ

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DEPARTMENT OF RESTORATIVE DENTISTRY
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TEL: (415) 476-0860
FAX: (415) 476-0858C. Wallace Hayes
President and CEO
Mitech Medical Corporation
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Dear Wally,

The following is a preliminary report on my evaluation of the Mitech LES (low energy sterilizer) prototype sterilizer. The experimental design employed was to verify the time and temperature required to achieve a six log reduction of *B. subtilis*. Ten microliters of inoculum was placed on stainless steel scalpels at a concentration of 10^8 colony forming units (CFU) of *B. Subtilis*. The scalpels were then placed in the LES for a range of times and temperatures. The scalpels were then swabbed with nutrient broth and plated on agar petri dishes. The petri dishes were incubated in 37 C for 3 days and any CFU were counted.

The multifactor ANOVA on 1/3 the observations ($n=235$) indicate that complete sterilization was achieved at temperatures of 110, 120 and 130 C for 30 minutes. There was an obvious reduction of bacteria as a function of time. At 130 C complete sterilization occurred at times as short as 3 minutes. The steam autoclave that was tested for comparison purposes did not achieve complete sterilization at 30 minutes (log 0.250 CFU), but did achieve sterilization at 60 minutes.


To evaluate possible detrimental effects from sterilization, surgical scalpels were run repeatedly and examined using scanning electron microscopy (SEM) with energy dispersive spectroscopy (EDS). Five surgical scalpels were cycled 5 times in the LES at 130 C for 30 minutes per cycle. Similarly, 5 scalpels were autoclaved repeatedly 5 times at 132 C and 25 psi for 30 minutes per cycle. The scalpels sterilized in the LES and those from the autoclave were examined using scanning electron microscopy and compared to new surgical scalpels that had no sterilization procedure using magnifications from 30x to 300x. There were no observed surface changes after sterilization using the LES (similar to new scalpels) by scanning electron microscopy, whereas the steam autoclave sterilized scalpel showed evidence of surface corrosion. Elemental analysis by EDS indicated no changes in the scalpel by either sterilization.

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On the basis of these initial investigations, I am excited about the potential application of the LES for sterilization of surgical instruments. It appears that the LES may make a contribution in the sterilization of instruments. The Department of Restorative Dentistry is willing to assist Mitech Medical Corporation in the research and development of this technology. Through a research agreement, the departments research facilities including microbial sterilization validation, bacterial burden challenge testing, instrument surface science evaluation using SEM and EDS, and performance testing can be made available to Mitech Medical Corporation. Our team has conducted research using microwave devices for sterilization, bacterial reduction from incorporation of disinfectants in dental stone, bacterial contamination of dental X-ray films and bacterial reduction using pulsed infrared lasers. I am happy that the research conducted in the application of lasers in dentistry has proceeded from the laboratory to the operator. Our basic and clinical research has been reviewed by the U.S. Food and Drug Administration and we have assisted manufacturers of medical devices in receiving permission to market there devices by way of the 510K mechanism.

Please feel free to contact me directly if UCSF can be of further assistance in the research and development of this technology.

Sincerely,



Joel M. White, D.D.S., M.S.
Assistant Professor
Division of Biomaterials
Division of General Restorative Dentistry

enclosed:

research publications
C.V.

cc: Mats Ingemanson

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