Moist Heat Sterilization Simulation for Orthopedic Medical Devices and Trays

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INTRODUCTION: Steam sterilization is extensively used to sterilize orthopedic surgical tools and trays by inactivating microbiological contamination with high-temperature and high-pressure steam [1]. Identifying the optimal sterilization cycle and parameters such as temperature distribution and condensation zones is crucial for effective sterilization, and the simulation could be a useful tool to understand the temperature distribution and to identify the challenging areas for steam sterilization.
Computational Fluid Dynamics (CFD) provides a robust approach in simulating the sterilization process, allowing for the prediction of temperature distribution and the identification of probable condensation zones during surgical tray sterilization [2]. The goal of this study is to validate a CFD-based sterilization model by comparing the temperature distributions calculated from CFD to experimental data gathered during surgical tray sterilization, thereby establishing the reliability of the simulation model for measuring sterilization parameters and performance.

METHODS: The 3D CFD analysis was done on an orthopedic surgical tray placed inside an autoclave chamber, the schematic representation of the simulation workflow is shown in Fig. 1. The fluid region was separated into small control volumes (cells) that contain roughly 9 million tetrahedral cells. The transient simulation was performed using StarCCM+ for 205 seconds (85 s ramping up phase and next 120 s sterilization phase) to capture the sterilization phase dynamics. Steam was treated as an ideal gas, and the energy and momentum equations were solved using a pressure-based solver with a turbulence model. The Autoclave walls were treated with suitable thermal boundary condition. The wall film thickness modeling technique turned on from tool to visualize and measure condensate formation on tray surfaces. The experiment was carried out on trays with similar boundary conditions; temperature was monitored at six distinct sites within the tray, pressure and residual moisture was assessed inside the tray during the sterilizing process.

RESULTS: The temperature distribution at six different locations, the average temperature and pressure inside the tray and the residual moisture during the sterilization process are recorded and presented (Fig. 2). Results show that the autoclave chamber has maintained the sterilizing pressure of 2.05 bar and temperature of 121 °C during the cycle. The average pressure and temperature, as well as the residual moisture content, derived from CFD align well with the experimental results (Fig. 2). The temperature distribution obtained at six locations from CFD is comparable to the experimental data, with less than 5% deviation (Fig. 2 (d)).

DISCUSSION: The simulated results demonstrate the credibility of the developed model, validating the model's accuracy in forecasting thermal behavior during the sterilization cycle and thus the model could be an effective tool for moist heat sterilization of orthopedic medical devices and trays. The workflow has been extended to predict the sterilization parameters on trays loaded with orthopedic surgical tools (to be used for hip and knee arthroplasty) with complex features and manufactured from materials with different grades of metals and polymers, and the results are consistent with the experimental prediction.

SIGNIFICANCE/CLINICAL RELEVANCE: The validated CFD model is a dependable method for assessing the sterilization performance of surgical trays, avoiding the need for repetitive physical testing. It allows for the early detection of design flaws and optimization prior to prototype by properly forecasting temperature distribution, condensation zones, and steam penetration. This considerably decreases the number of required experimental trials, shortens development cycles, and speeds up time-to-market for new instrument and tray designs, all while maintaining high patient safety and compliance to sterilization assurance standards.

REFERENCE:
[1] M. Feurhuber, R. Neuschwander, T. Taupitz, V. Schwarz, C. Frank, C. Hochenauer. A Computational Fluid Dynamics (CFD) model to simulate the inactivation of Geobacillus stearothermophilus spores in different moist heat sterilization environments Phys. Med. (2021), p. 100039, 10.1016/j.phmed.2021.100039.
[2] M. Feurhuber, P. Burian, M. Magno, M. Miranda, C. Hochenauer. Development of a spatially and timely resolved CFD model of a steam sterilizer to predict the load temperature and the theoretical inactivation of bacteria based on sterilization parameters. Phys. Med., 8 (2019), p. 100020, 10.1016/j.phmed.2019.100020

SIMULATION WORKFLOW:

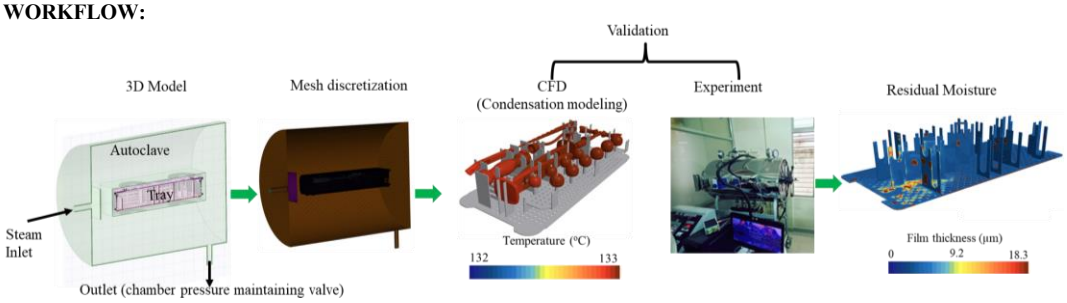

Figure 1: Simulation workflow to predict the performance of the tray sterilization cycle

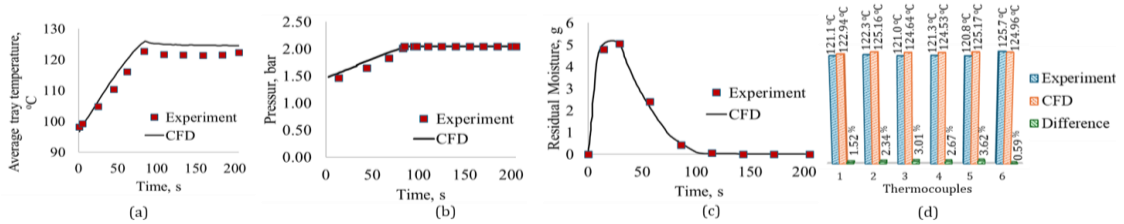

Figure 2: Average tray temperature (a), Pressure (b) Residual moisture (c) obtained during sterilization cycle inside the tray and temperature measured at six different locations inside the tray at 205 s (d)