Simulation and Verification of Steam Sterilization of Medical Device Trays

A Dissertation

Submitted in the fulfilment of

Requirement for the degree of

Master of Engineering

In

Thermal Engineering

by

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CERTIFICATE

This is to certify that the dissertation report entitled "***Simulation and Verification of Steam Sterilization of Medical Device Trays***" submitted by Amanpreet Singh, Registration No. 802383002, in the evaluation of the requirements for the award of the degree of Master of Engineering in Thermal Engineering contains the Bonafide work of his done under our supervision and that the same work has not been submitted elsewhere for the award of any degree to the best of our knowledge.

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The project "**FEA Simulation for Cases and Trays**" was successfully completed under the guidance of Mr. Ashutosh Suri Sr. Engineer R&D, Joint replacement Department.

Amanpreet Singh was seen as a responsible and committed individual. We wish him all the best for all his future endeavors.

For **Stryker Global Technology Pvt. Ltd**

Gurgaon

Amit Singh Bisht
Manager-Human Resources

DECLARATION

I hereby declare that the dissertation entitled "***Simulation and Verification of Steam Sterilization of Medical Device Trays"*** is an authentic record of my study carried out as requirements for the award of the degree of Master of Engineering in Thermal Engineering at Thapar Institute of Engineering and Technology, Patiala under the supervision of Dr. Rohit Kumar Singla, Associate Professor, Thapar Institute of Engineering and Technology, Patiala, Mr. Amandeep Oberoi, Associate Professor, Thapar Institute of Engineering and Technology, Patiala, Ms. Ashutosh Suri, Senior Design Engineer, Stryker Global Technology Centre, Gurgaon, from 22nd July 2024 to 11th June 2025. No part of the matter embodied in this dissertation has been submitted to any other Institute for the award of any degree.

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ABSTRACT

The sterilization of surgical instruments is essential in the medical field to prevent the transmission of germs, bacteria, and viruses. This can be achieved using an autoclave, a device that sterilizes instruments through the application of steam. In this thesis, the processes of steam generation in the steam generator and its distribution within the sterilization chamber have been analysed numerically. This study included an in-depth review of relevant literature and standards to identify the worst-case scenario that could be simulated among multiple trays. It also examined the dynamics of evaporation-condensation, steam distribution within the autoclave, and the effective elimination of microorganisms from the instruments. This research leverages existing numerical studies in steam sterilization to evaluate their relevance and efficacy in real-time tray sterilization applications. These studies offer valuable insights into the crucial parameters and conditions necessary for achieving optimal sterilization results, including temperature, pressure, and cycle duration. Thermocouple readings taken at six locations within the tray closely aligned with the thermal simulation results, showing only a minimal deviation of 0.0084%. The average surface temperature of the Acetabular shell trials was recorded at 132.72°C which is requires for the deactivation of the microorganisms and the average pressure maintained during the sterilization phase is also stabilized to 3.2 bar using a user defined function. This study provides valuable insights that support the new product development phase by guiding the design of trays to enhance steam penetration and to minimize the necessity for comprehensive tray testing. This simulation technique demonstrates an actual use of simulation methods in the design process. By incorporating simulation from the beginning, companies can identify potential design defects before they happen, employ correction procedures more effectively, and progress towards actual manufacturing with more confidence. This entire developmental process also benefited by saving time and expenses and enhancing efficiency in the product's reliability.

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ABBREVIATIONS

CAD	Computer-Aided Design
CFD	Computational Fluid Dynamics
DR	Design Review
EMA	European Medicines Agency
FDA	Food and Drug Administration
NCGs	Non-Condensable Gases
RANS	Reynolds-Averaged Navier–Stokes
RCT	Rigid Container Trays
SAL	Sterility Assurance Level
SBS	Sterilization Barrier System
SIMPLE	Semi-Implicit Method for Pressure Linked Equations
QUICK	Quadratic Upstream Interpolation for Convective Kinematics
UDF	User-Defined Function
VOC	Voice of customer

SYMBOLS

P	Pressure
y	Distance from the wall to the first cell center
u_τ	friction velocity
ν	kinematic viscosity of the fluid (in m^2/s)
T_l	Liquid Temperature
T_{sat}	Saturation temperature
ρ_l	Density of liquid phase
α_{al}	Volume fraction of liquid phase
m_{lv}	Mass transfer due to phase change
k	turbulent kinetic energy
ε	turbulent dissipation rate

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Chapter 1 Introduction

1.1 Steam Sterilization

Steam sterilization refers to the use of saturated steam at controlled pressure and temperature to eradicate all types of microbial life, such as bacteria, viruses, fungi, and spores. Usually conducted in an autoclave, the procedure is based on wet heat to denature proteins and successfully sterilize heat- and moisture-resistant equipment and materials.

1.2 Why Steam sterilization is important?

In healthcare settings, it plays a pivotal role in maintaining aseptic conditions, especially for reusable surgical instruments. Steam sterilization is important because it provides a highly effective, reliable, and efficient method for eliminating all forms of microbial life from medical instruments, surgical tools, and other equipment. Its importance lies in several key factors:

- ✓ **Ensured Patient Safety**: By eliminating pathogens, it prevents infections and cross-contamination during medical and surgical procedures.
- ✓ **Highly Effective**: Capable of destroying even the most resistant microorganisms, including bacterial spores.
- ✓ **Fast and Economical:** Compared to other sterilization methods, steam sterilization is relatively quick, energy-efficient, and cost-effective.
- ✓ **Non-Toxic**: It leaves no harmful chemical residues, making it safe for both patients and staff.
- ✓ **Widely Applicable**: Suitable for a broad range of instruments and materials that can withstand heat and moisture.

Overall, steam sterilization is a cornerstone of infection control practices in healthcare and laboratory environments. The sterilization of reusable medical instruments such as dental equipment, surgical tools, and tubing is commonly achieved using steam-based processes. This method, implemented through autoclave systems, relies on the phase change of steam into liquid upon contact with cooler surfaces, which enables efficient thermal energy transfer. Since microbial destruction is highly sensitive to temperature conditions and other environmental parameters, steam sterilization is particularly effective for fast and reliable decontamination.

1.3 Basic Overview of sterilization phases

The sterilization procedure typically unfolds in three distinct stages (see Figure 1). The initial step, often referred to as the air removal or preconditioning phase, is dedicated to eliminating trapped gases, primarily air, from the chamber. These non-condensable gases (NCGs) hinder heat transfer by acting as insulating barriers, especially in devices with confined geometries like dental handpieces. To ensure complete purging of such gases, multiple vacuum cycles are often used [2].

Next comes the sterilization phase, during which the system is pressurized and heated to predetermined values—approximately 3.2 bar absolute and 136 °C. These conditions are maintained for a fixed duration to allow sufficient microbial inactivation. Following this plateau, the system transitions into the drying and cooling phase. Another vacuum is drawn to lower the boiling point of residual water, prompting evaporation from the chamber walls and instrument surfaces. This assists in both drying and lowering the chamber temperature. Once completed, the chamber is re-pressurized with filtered air to equalize internal and external pressure, making it safe to open.

International and regional standards, including those from US, European and German regulatory bodies, provide detailed guidelines for this sterilization methodology.

To avoid condensation of steam on the chamber walls during the critical sterilization period, an issue that can compromise uniform heating, the chamber is often preheated. Traditional designs use electrical heating elements for this, but uneven heat distribution and added costs are typical drawbacks. A more advanced alternative employs a dual-chamber design, in which the primary sterilization compartment is surrounded by an external chamber. This outer jacket is fed with steam from a generator, which condenses on the inner walls and raises the temperature evenly throughout the chamber [3].

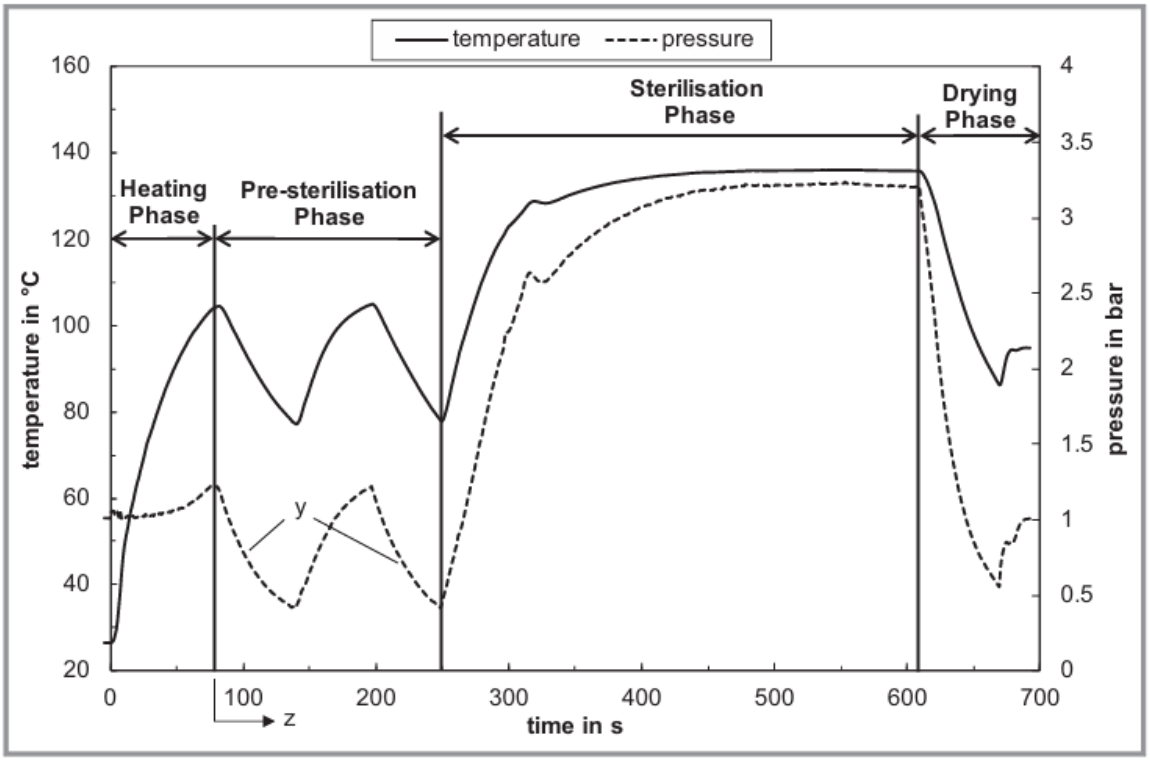


Figure 1-1 Different phases of the sterilization cycle [8]

1.4 Background

The fundamental goal of sterilization is the complete removal of all forms of microbial life, including bacteria, viruses, spores, and fungi. Traditional sterilization methods, such as steam sterilization, have long been regarded as the gold standard due to their proven efficacy and reliability. The principle underlying steam sterilization is the use of pressurized saturated steam to denature proteins and disrupt cellular structures, resulting in microbial death. The effectiveness of this process is governed by the interplay between temperature, pressure, and exposure time. As Dion and Parker (2013) elucidate, the time required for sterilization is inversely proportional to temperature; higher temperatures enable shorter exposure times to achieve sterility [4].

A critical aspect of steam sterilization is the need for direct steam contact with the surfaces to be sterilized. Air pockets or inadequate steam penetration can compromise the process, necessitating the use of vacuum pumps to evacuate air from the chamber prior to steam introduction. Following sterilization, thorough drying is essential to prevent recontamination, typically achieved by applying vacuum pressure to remove condensate[1].

Despite its widespread adoption, steam sterilization is not universally applicable. Certain materials and products, such as heat-sensitive pharmaceuticals, medical devices, and electronics, cannot withstand the high temperatures and moisture inherent to this method. This limitation has spurred the development of alternative sterilization technologies, including ethylene oxide (EtO), radiation, dry heat, filtration, and vaporized hydrogen peroxide (VHP)[2].

There are six critical factors to the steam sterilization principles shown in Figure 2, adapted from Dion and Parker (2013) [4].

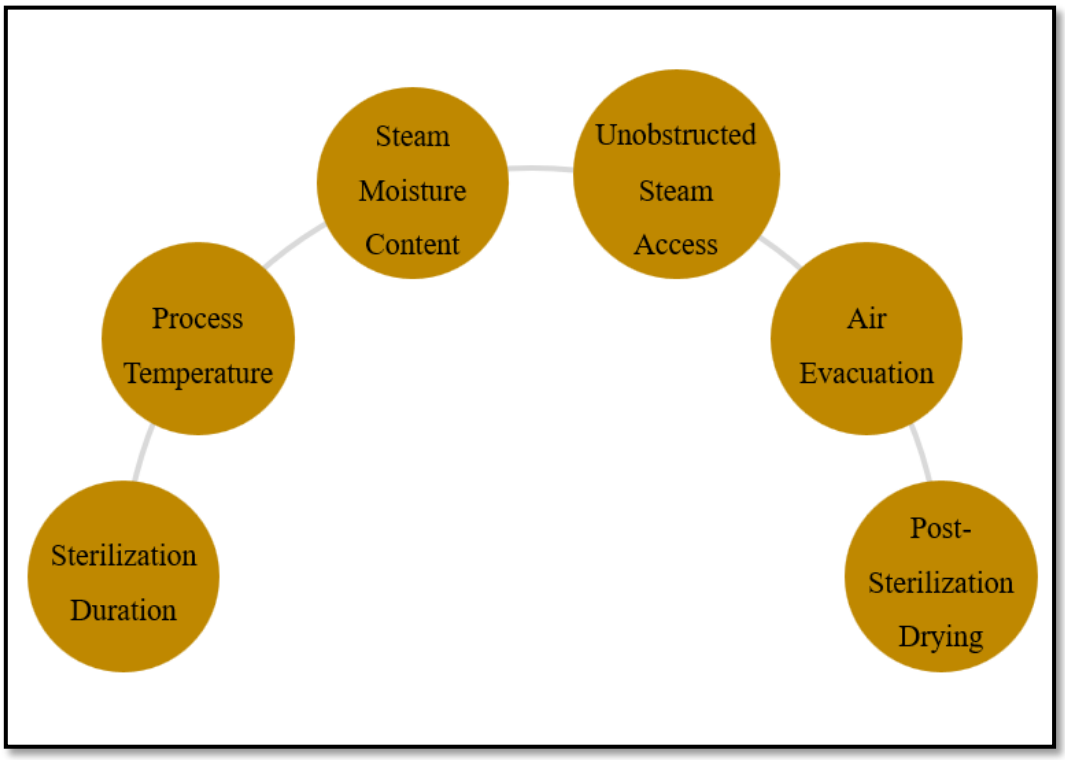


Figure 1-2 Critical factors to the steam sterilization principles [4]

The exposure time during sterilization plays a crucial role, as not all microorganisms present on medical equipment are destroyed simultaneously. Certain organisms exhibit greater resistance to elevated temperatures and moisture, necessitating longer sterilization periods. Generally, the time needed to achieve effective sterilization is inversely related to the temperature: as the temperature rises, the required sterilization time decreases, as illustrated in Figure 1.2. [4].

Saturated steam is widely favoured in sterilization processes because its high moisture content promotes the coagulation and denaturation of proteins, ensuring effective microbial

destruction. For optimal energy transfer, the steam must come into direct contact with the surfaces being sterilized. To achieve this, any air present inside the chamber must be evacuated, typically using vacuum pumps, since air acts as a barrier that impedes steam distribution. When steam interacts with cooler surfaces, it condenses, forming moisture that must be thoroughly removed to prevent possible recontamination of the sterilized items. The application of vacuum pressure assists in eliminating this residual moisture by inducing evaporation before the chamber is opened. Companies like Getinge strive to refine sterilization validation procedures by lowering the consumption of water, steam, and fuel sources such as natural gas. Substantial research efforts continue to focus on making these procedures more environmentally sustainable, quicker, and more cost-efficient. [4].

1.5 Overview of Modern Sterilization Techniques

A comprehensive survey of sterilization methods reveals a spectrum of options, each tailored to specific product characteristics and regulatory requirements. The selection of an appropriate method is influenced by factors such as material compatibility, microbial load, process scalability, and cost-effectiveness. Table 1 summarizes the most common sterilization methods and their typical applications:

Table 1-1 Sterilization techniques, their uses and compatibility with different materials [26]

Sterilization Technique	When to Use	Compatible Materials
Steam (Autoclaving)	For heat-resistant materials like production equipment, culture media, etc.	Stainless steel instruments, glassware, some plastics (e.g., polypropylene), fabrics
Ethylene Oxide (EtO)	For heat- and moisture-sensitive products like medical devices and electronics	Complex polymers, electronics, multi-material assemblies, catheters, syringes
Radiation (Gamma, E-beam)	Large-scale sterilization of single-use devices and packaging materials	Thermoplastics (e.g., PVC, polyethylene), sealed packaging, prefilled syringes
Dry Heat	For materials that tolerate high heat but are moisture-sensitive	Glassware, metal instruments, powders, oils
Filtration	For sterilizing heat-sensitive liquids and gases	Aqueous solutions, pharmaceutical-grade air/gas, injectable drugs, enzyme solutions
Vaporized Hydrogen Peroxide	For sterilizing surfaces and medical devices in healthcare settings	Electronic equipment, endoscopes, plastic surfaces, optical instruments

Regulatory agencies such as the FDA and EMA generally favour terminal sterilization methods (e.g., steam, radiation) due to their reliability and ability to provide a high sterility assurance level (SAL). Aseptic processing is reserved for cases where terminal sterilization is not feasible.

Sterilization validation is a multi-step process encompassing method selection, installation qualification (IQ), operational qualification (OQ), performance qualification (PQ), and thorough documentation. Each phase is designed to ensure that the sterilization process is effective, reproducible, and compliant with regulatory standards. Biological and chemical indicators are routinely employed to challenge the process and verify its efficacy, particularly in performance qualification.

Previous research on steam sterilization has been based on empirical measurement and one-dimensional (1D) description of the heat and mass transfer within the autoclave chamber. Lau et al. (2012) formulated a quasi-steady-state model for an empty steam sterilizer, which was well comparable with experimental pressure and temperature profiles. Follow-up developments enabled prediction of the heat transfer to charged chambers but were inherently limited by being unable to resolve local information, e.g., spatial temperature gradients or wrapping and orientation effects of the device [5]. These are serious constraints since experimental investigation especially by van Doornmalen and Dankert as shown that fewer than 40% of tested sterilizers repeatedly pass through to required sterility assurance levels (SAL), and this necessitates more sophisticated modelling methods [6].

The effect of load configuration, device position, and wrapping on the sterilization process is well established. Van Doornmalen et al. (2012) showed that handpiece orientation and quality of pouch or fabric wrap have a significant effect on penetration by steam and in turn microorganism inactivation [6]. The existence of non-condensable gases (NCGs), including residual air, also makes the process more complicated by lowering local heat transfer rates and inducing cold spots throughout the facility load. Burian et al. (2021) and subsequent work highlighted that trace amounts of NCGs produce disproportionate adverse effects on sterility and therefore are stringent regulatory boundaries on acceptable NCG content in sterilizer specifications [7]

1.5.1 Simulation-Based Approaches

In an awareness of the limitations of 1D and empirical models, increasing use has been made recently in the literature of the application of computational fluid dynamics (CFD) as a method of simulation of the steam sterilization process in great detail. CFD enables solution of three-dimensional, transient velocity fields and the interaction of fluid flow, heat transfer, phase change, and microbiological kinetics. Feurhuber et al. (2017) created a three-dimensional CFD model to simulate heat transfer, fluid dynamics, and microbial inactivation in a contemporary steam sterilizer [8]. Their method employed a multiphase Eulerian model for simulation of liquid and vapor phases and the realizable k-ε model was employed to model turbulence. Particularly, the model utilized user-defined functions (UDFs) to approximate the time- and temperature-dependent inactivation of microorganisms through first-order reaction kinetics according to the Arrhenius equation.

One of the original contributions of Feurhuber et al.'s (2017) work was modelling of inactivation of the microorganism using steam sterilization [8]. Experimental measurements of

paper permeability and pressure drop were used to inform the CFD model, enabling realistic simulation of the resistance to steam flow imposed by pouches. The model also accounted for wall condensation effects, which are central to the high heat transfer rates achieved during sterilization. Validation against experimental data collected via a network of thermocouples and pressure sensors within the autoclave chamber and at the load centre demonstrated excellent agreement, both globally and locally, across the entire sterilization cycle.

The literature further underscores the importance of accurate process monitoring and validation. The healthcare-associated infections directly linked to inadequate sterilization, reinforcing the critical need for robust, predictive models that can inform both device design and process control [1]. Vadrot and Darbor (2006) compared the efficacy of steam sterilization with chemical methods for prion inactivation, highlighting the unique advantages and limitations of thermal processes [9].

Chapter 2 Literature review

2.1 Introduction

Sterilization of reusable surgical instruments is a critical component of infection control in modern healthcare. While the importance and evolution of sterilization techniques, particularly steam sterilization, are well documented, research focusing on the simulation and computational modeling of these processes remains limited. This literature review begins by outlining the necessity and historical development of sterilization methods, before highlighting recent advances in simulation techniques that offer new opportunities to optimize sterilization efficiency and reliability.

2.2 Literature review

Effective sterilization of reusable surgical instruments is a fundamental requirement in modern healthcare to prevent healthcare-associated infections (HAIs), which contribute to significant patient morbidity, prolonged hospital stays, and increased costs worldwide. Among various sterilization methods, moist heat sterilization using saturated steam remains the most prevalent technique due to its proven efficacy, relative cost-effectiveness, and environmental compatibility compared to chemical or low-temperature alternatives [1]. The physics and engineering behind steam generation, transport, condensation, and drying form the basis for designing sterilizers and instrument trays that ensure consistent sterilization while minimizing energy and resource use.

Moist heat sterilization relies on the unique thermodynamic properties of saturated steam, primarily its high latent heat of vaporization. When steam condenses on a cooler surface, it releases a substantial amount of thermal energy, rapidly increasing the temperature of the surface to a level sufficient to destroy pathogenic microorganisms, including resistant bacterial spores (ISO 17665-1).

Panta et al. (2019) had performed a country-level cross-sectional systematic study to assess the efficiency of steam sterilization of reusable medical devices in primary and secondary care government hospitals in Nepal. The study had tested 189 cycles of sterilization in 13 hospitals with the help of biological indicators, Class-5 chemical indicators, sterilization tape, and physical monitoring techniques. The review highlights the critical necessity of systemic interventions, such as improved autoclave maintenance, standard operating procedures, mandatory monitoring indicator usage, and regular staff training. Notable also is the necessity

of having strong process validation and documentation in securing sterilization efficacy, especially in resource-constrained healthcare facilities [2].

The importance of steam quality was established early on and has been reinforced by more recent studies. Dion and Parker (2013) describe that steam with excessive entrained water droplets reduces the proportion of thermal energy available as latent heat, which can lead to wet loads and inadequate sterilization [4]. Conversely, steam that is superheated (dry) contains little or no moisture, which limits heat transfer because sensible heat must first be shed before condensation can occur. As a result, sterilizer manufacturers aim to maintain a dryness fraction of about 97–100% at the chamber inlet, striking an optimal balance for heat transfer efficiency [11].

The physical generation of this steam involves intricate phase change processes. Modern steam generators typically employ shell-and-tube or electric coil configurations to produce steam at controlled pressures and flow rates. Carey (2020) provides a detailed thermodynamic analysis of boiling heat transfer, highlighting the significance of nucleate boiling in promoting stable vapor production at moderate heat fluxes. If the heat input exceeds a critical threshold, boiling transitions to a film boiling regime, creating an insulating vapor layer that reduces heat transfer rates and degrades steam quality. Maintaining appropriate heating rates and surface temperatures within the steam generator is therefore crucial to prevent unstable boiling and liquid carryover [3].Selecting appropriate polymers such as PEEK or PEI ensures structural integrity across different sterilization methods, Table 2-1 show the compatibility of polymers with different sterilization techniques [1].

Once generated, steam must be effectively distributed within the sterilizer chamber to achieve uniform exposure of all instrument surfaces. Lau et al (2015) were among the first to conduct systematic experiments mapping temperature and pressure distributions in loaded sterilizers, revealing that inadequate air removal leads to persistent cold spots and incomplete sterilization. They demonstrated that even small residual air pockets can act as thermal insulators, preventing direct steam contact with certain surfaces [12]. These investigations form the basis of existing standards such as ISO 17665-1 which require specific vacuum pulsing cycles to remove non-condensable gases prior to sterilization.

Van Doornmalen, Tessarolo, and Kopinga (2014) implemented a case study in order to assess the adequacy of traditional steam sterilization monitoring practices, that is, the shortcomings of resorting to single readings of pressure and temperature alone. The research established that even though the autoclave levels may reflect autoclave levels of sterilization standards attained, single readings alone are insufficient to ensure complete sterilization in complicated or heavily

loaded loads. Findings highlight the fundamental lack of validation procedures for sterilization, which requires complete control using chemical and biological indicators and extensive physical parameters. The authors are promoting the multidirectional approach, especially with regard to adherence to international standards of sterilization like ISO 17665 and EN 285 [13]. Fil, Kini, and Garimella (2020) present a detailed summary of dropwise condensation (DWC), from its theoretical foundations, modeling methods, experimental research, to real-world applications. The authors highlight DWC's better heat transfer compared to film wise condensation due to effective drainage of condensate droplets and small thermal resistance. The review provides key theoretical features of droplet nucleation, growth, and coalescence inherent to condensation heat transfer performance. It also emphasizes the development of single-droplet and population models that simulate heat transfer behaviors on different surfaces. As much as modeling efforts have been made, the authors emphasize the experimental validation of the models with improved accuracy to narrow down the gap between reality and theory. The thermodynamics of condensation of steam on load surfaces has also been the subject of significant research because of its direct influence on sterilization effectiveness [14]. Lau et al. (2015) created and experimentally validated a computational model to model the steam-air sterilization process in an industrial autoclave process. The paper was intended to circumvent shortcomings that have been discovered with current models by considering actual load configurations as well as multiphase flow properties. Thus, a more realistic and practical model setting was achieved. With a computational fluid dynamics (CFD) approach, the authors simulated heat and mass transfer coupled processes involving steam and air mixtures for sterilization processes. Load geometry and packaging effects on steam distribution, temperature uniformity, and condensation behavior were included in the model. The simulation results were matched with experimental data collected from actual sterilization runs, and the outcome claimed in-point agreement that is, the accuracy of the model in prediction of thermal response within the autoclave chamber. One of the main contributions of this research is that it can detect thermal non-uniformities as well as possible "cold spots" within intricate load configurations, which would undermine sterility performance. Additionally, the model was constructed from widely used software packages, making it feasible and adaptable for industrial use, especially in the food and drug industry [15].

Table 2-1 Compatibility of polymer with different sterilization techniques [1]

Polymer	Steam	EtO	Radiation	VHP
PEEK (Polyetheretherketone)	Good	Good	Good	Good
PEI (Polyetherimide)	Fair	Fair	Good	Good
PC (Polycarbonate)	Fair–Poor	Good	Good	Good
PS (Polystyrene)	Poor	Good	Good	Good

Design of packaging and tray is essential to all these operations. Multidisciplinary experimental and numerical research by Tessarolo et al. (2020) revealed that densely packed trays with few perforations retard steam flow, create shadow areas where steam penetration is delayed or incomplete, and hold condensate that increases drying times [16]. They employed arrays of thermocouples and biological markers to delineate sterility assurance for different tray shapes and found that small design variations, such as adding perforations or repositioning tray supports, significantly enhance steam flow channels.

Marchand et al. (2020) compared a new sealed sterile container and instrument tray system to see if it enhanced the efficiency of surgical trays. What they found in their research was that redesigned trays decreased instrument number, sterilization cycle time, and assembly time for trays without affecting sterility or clinical outcomes. Tray layout also improved contamination prevention and handling effectiveness. These findings highlight the relevance of tray configuration and packaging in enhancing sterilization process, resource consumption, and operating room workflow. This study deserves consideration of design innovations towards maximizing both sterilization effectiveness and operational efficiency [17].

Due to the richness and interdependence of such physical behavior, experimental investigation alone is usually inadequate to supply detailed point-by-point information of local flow and temperature conditions within sterilizers. Computational Fluid Dynamics (CFD) has been found to be a valuable supplement to experimental techniques as it can supply virtual prototyping and parametric study without involving the cost and time for actual testing. Feurhuber et al. (2019) were the first to apply CFD to steam sterilization, simulating steam-air

mixture removal and flow conditions within an industrial sterilizer. They found that their simulations were in reasonable agreement with the measured temperature and pressure profiles, proving CFD to be a tool for cycle optimization and design [18].

Consequently, Lau et al. (2015) established a more sophisticated CFD model with transient flow, heat transfer, and phase change to examine steam penetration in complex load configurations [15]. Their findings confirmed the occurrence of stagnation areas in the chamber, where trapped air or inefficient steam flow may reduce sterilization confidence. They further demonstrated the influence of instrument positioning on local heat transfer, which can guide tray designers in planning arrangements for ensuring unobstructed steam penetration to all surfaces.

To tackle more sophisticated physics on the scale of the instrument and tray, Ansari (2021) on sterilized surfaces [19]. They were able to simulate coalescence, run-off, and formation of droplets for differing chamber pressures and tilts of the surface and obtained useful insights in terms of drying efficiency. The study confirmed that horizontal surfaces support thinner films of water for greater durations than inclined or vertical surfaces, suggesting tray geometry must be designed to minimize horizontal planes or incorporate drainage channels [19].

Wang et al. (2023) advanced the state of the art by coupling CFD with experimental validation for optimizing steam sterilization of packaged food, a process with physical similarities to medical sterilization. Their model integrated boiling, condensation, and non-condensable gas transport, highlighting the need for high mesh resolution near phase interfaces to capture transient heat and mass transfer accurately. The computational expense of such detailed models remains a challenge for large-scale parametric studies but demonstrates the potential for high-fidelity CFD to drive design decisions [20].

From a sustainability perspective, sterilization accounts for a significant portion of a hospital's resource consumption, particularly in terms of water, electricity, and natural gas (Emmanuel, 2021 [21]. Manufacturers have recognized this challenge and are actively investing in technological improvements to reduce cycle times, reclaim waste heat, and design trays and packaging that require less energy for drying. CFD is central to these efforts, as virtual testing reduces the number of costly and resource-intensive physical prototypes, aligning with environmental and economic objectives [16].

Overall, this body of research establishes that achieving effective and sustainable steam sterilization requires a synergistic understanding of thermodynamics, fluid mechanics, material science, and computational modelling. Steam must be of high quality and uniformly distributed, air must be completely evacuated, and condensation must occur efficiently on all

load surfaces while ensuring rapid condensate removal. Tray and load design are not passive considerations but active factors that determine steam penetration pathways, thermal gradients, and drying efficiency.

Despite these advancements, opportunities remain to deepen the granularity of CFD simulations, particularly at the tray scale and under diverse practical loading scenarios. Many studies to date assume simplified geometries or idealized steam inlet conditions, which may not accurately capture the effects of partial loads, varied tray designs, or accidental blockages [20]. Further work integrating high-resolution multiphase models, experimental validation, and parametric optimization will close this gap.

This thesis fills these gaps head-on by using case-tested CFD methods to model steam generation, and penetration in real world scenario, inside the medical tray sterilization specifically. By careful analysis of the effect of design variables like perforation patterns, tray spacing, and instrument setup on steam penetration and drying, this research gives practical insight to inform tray design to ensure consistent sterilization performance with less reliance on expensive empirical testing.

Chapter 3 Objective and Problem Formulation

3.1 Problem Formulation

In the field of medical device manufacturing, sterilization validation is a critical and mandatory step to ensure patient safety. Conventionally, sterilization performance is verification through extensive physical testing, which is both time-consuming and cost intensive. With the increasing demand for rapid product development cycles and cost-effective solutions, there is a growing need to adopt advanced simulation tools to predict sterilization performance accurately and reliably.

During this project, we addressed this challenge by simulating the steam sterilization process of medical device trays using Computational Fluid Dynamics (CFD) in ANSYS. The objective was to evaluate the temperature and steam distribution inside the sterilization chamber and trays, and to compare the simulation results with actual physical test data. This comparative analysis aimed to establish confidence in the simulation model and assess its capability to predict real-world sterilization performance.

The project highlighted the potential of CFD as a reliable tool for sterilization validation, offering opportunities to reduce the dependency on physical testing in future product cycles. However, it also revealed challenges related to accurately modeling complex heat transfer and fluid dynamics phenomena, especially in geometrically intricate assemblies.

This experience sparked my interest in thermal sciences and motivated me to pursue a Master of Engineering in Thermal Engineering. I aim to deepen my knowledge in heat transfer, fluid dynamics, and advanced simulation techniques, and contribute to developing efficient, simulation-driven validation methodologies for the medical device industry and beyond.

3.2 Objective

The primary objective of this research is to explore the feasibility of using Computational Fluid Dynamics (CFD) to simulate the steam sterilization process of medical device the focused product is trays. By evaluating temperature and steam distribution within the sterilization chamber and comparing simulation outcomes with experimental data, the study aims to validate the reliability of CFD as a cost-effective and time-saving alternative to conventional physical testing in sterilization verification.

Chapter 4 Methodology

4.1 Introduction

This research employs an integrated method of experimental verification and Computational Fluid Dynamics (CFD) simulation in investigating the feasibility and precision of modelling steam sterilization cycles for medical device trays. Figure 4.1 is a detailed flowchart illustrating the strategy employed in this research.

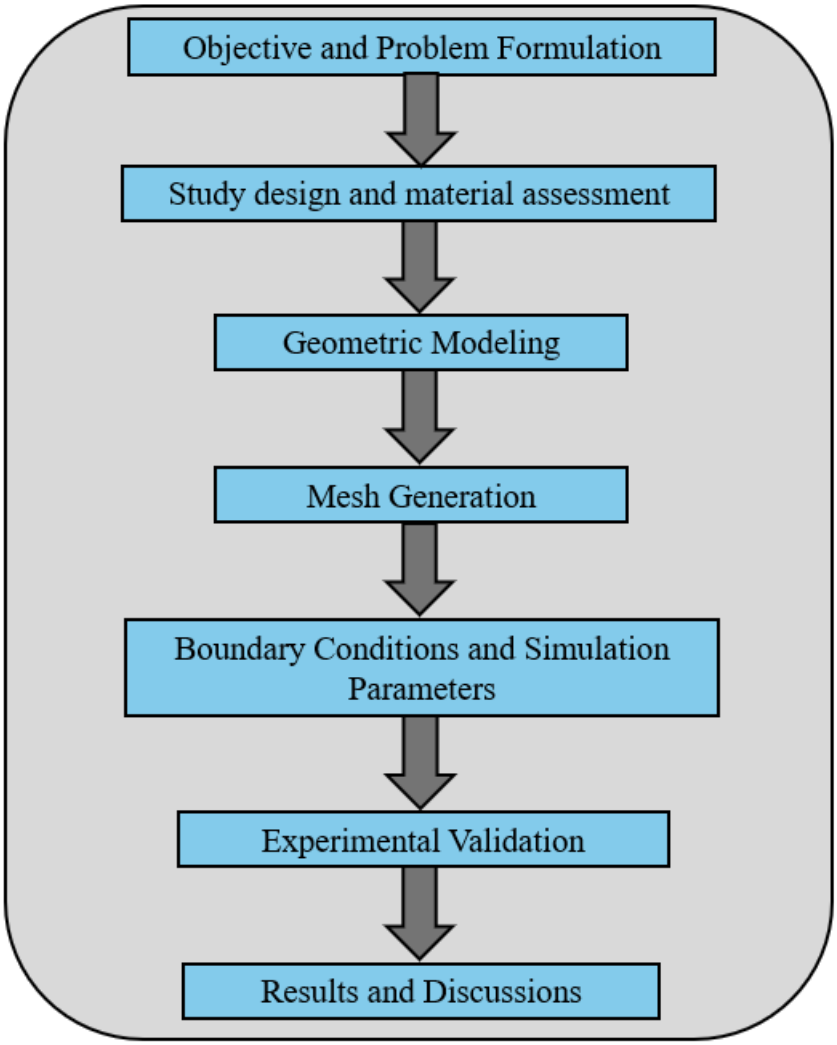


Figure 4-1 High-Level Process Flow Diagram

4.2 New Product Development Cycle

Figure 4.2 depicts sequential activity in the new product development (NPD) process. NPD is organized around eight major design reviews (DRs), collectively encompassing all stages from voice of the customer (VOC) to launch.

- **DR1** is dedicated to converting VOC into clear, actionable design inputs.
- Risk analysis is carried out once the design inputs have been established as part of **DR2** to ensure that any identified risk against functional outputs has been noted and mitigated.
- **DR3** is employed to ensure that user requirements have been fully translated into design requirements in the process also ensuring that any accompanying risks have been dealt with.
- **DR4** ensures completion of the risk assessment against the medical instrument or implant based on defined design inputs.
- **DR5** confirms that product and process designs are stable to enable successful and repeatable production of instruments or implants.
- Product and process designs are finalized (frozen) in **DR6,** and overall safety and performance requirements—e.g., those within the I3 Tolerance Document—are confirmed.
- **DR7** is test-focused, encompassing design verification and process validation. Any design alterations needed are confirmed at this point.
- Lastly, **DR8** confirms that the risks of the medical devices have been quantified and within reasonable limits.

Since all eight design reviews were done perfectly, the product continues to be released, with particular emphasis on timely launch and according to customer specifications. The results of this research are portable at the New Product Development (NPD) stage to minimize the necessity for extensive physical prototype testing before conclusive proof (DR7). Simulation-based testing can be performed to establish the acceptability of the design such that issues are identified early, and more logical design decisions are made prior to formal verification.

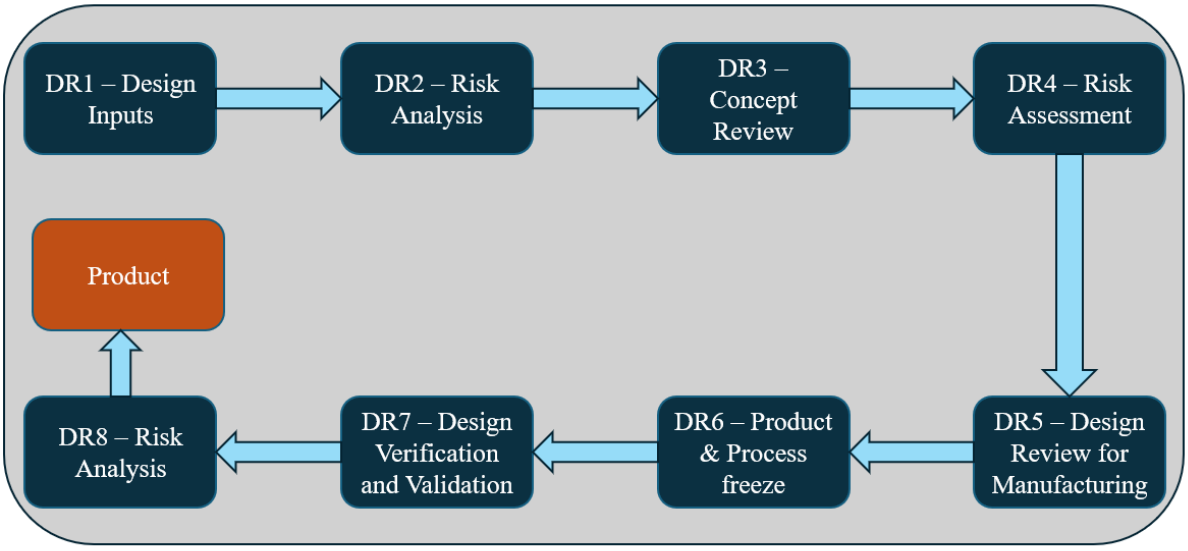


Figure 4-2 New Product Development Cycle

4.3 Selection of worst case.

According to ISO 17665-3, the worst case should be determined in a systematic manner in order to guarantee that the sterilization process provides the required sterility assurance level (SAL) in the most unfavorable realistic conditions [22]. ISO 17665-3 (Sterilization of health care products — Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization) gives guidance on worst case selection and process challenge devices for use in the validation and routine control of moist heat sterilization processes. Sterility Assurance Level (SAL) is the chance of a single viable microorganism remaining on a product following a sterilization procedure. It is stated as a negative exponent (i.e., 10^{-6}), which describes that there is not more than a one in a million chance that there is a single organism on an item that is sterilized. A level of SAL 10^{-6} is usually required in pharmaceutical and medical use, particularly for high-risk devices that penetrate sterile locations within the body. The 10^{-6} level indicates extremely high levels of microbial kill and adherence to international norms like ISO 17665.

For this study, the worst-case scenario was determined with a specific focus on four critical attributes [22] (see Figure 4.3): -

- Instruments design features,
- Weight,
- Material composition, and the

- Sterilization Barrier System (SBS).

These attributes directly influence steam penetration, heat transfer, and drying effectiveness, and these parameters are discussed in detail below.

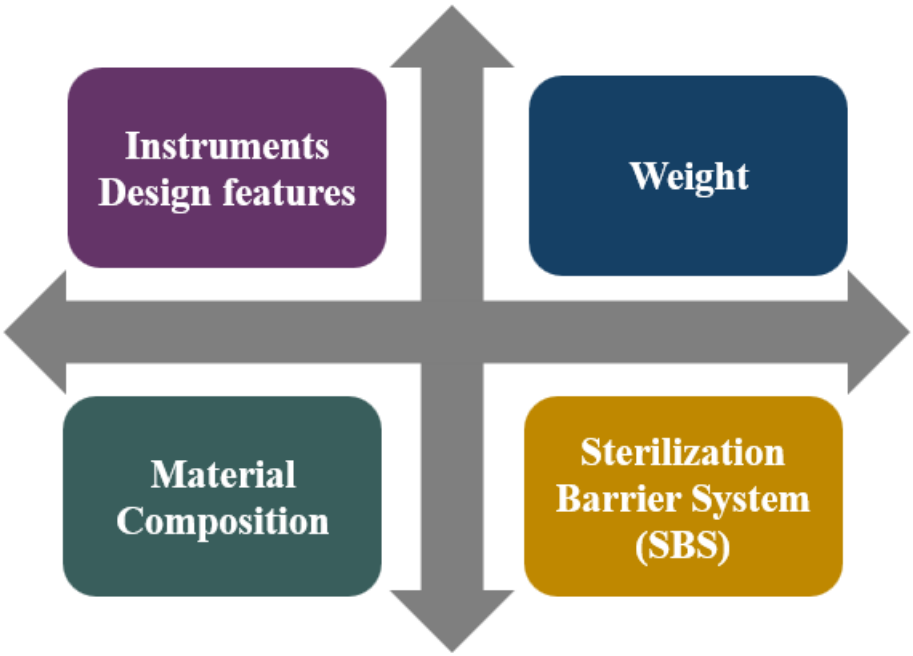


Figure 4-3 Critical Attributes for The Selection of Worst Case

4.3.1 Instruments Design features

ISO 17665-3 establishes minimum design specifications for medical devices intended to be used in moist heat sterilization. Devices must be designed to provide adequate steam penetration and enable effective drainage of the condensate. Fine design features can be a limiting factor to sterilization performance and are generally assessed as worst-case conditions during validation. Table 4.1 establishes in detail many design features, which form the basis for identifying and selecting worst-case configurations [22].

Table 4-4-1 Design Feature for The Selection of Worst-Case Scenario [22]

Structure	Example
Solid, hollow	Bowl, jug, dish, bottle, chisel, single-piece skin retractor, single-component empty instrument tray
Pin and box joints	Scissor, forceps, needle holder
Lumen	Laparoscopic sheath, sucker, cannulated reamer, rigid endoscope, cannulated screws
Porous	Linen, filters, gauze
Tubing, moving parts, tortuous paths	Power tool hose, silicone tubing, dental handpiece, ear, nose, throat drill
Lumen surrounded by a large mass	Drill, cannulated screwdriver, obturator, ratchet handle, bored handle
Other	Pre-filled syringe

For every instrument in the trays, design features are evaluated according to the parameters outlined in Table 4.1. Head press, as exemplified in Figure 4.4, is evaluated for worst-case scenario and all its design features were accordingly evaluated. The tool has a set of intricate features including moving parts, minute holes, and internal gaps, which would impede steam penetration and heat transfer. In addition, it consists of more than one material with varying thermal properties, whose characteristics further affect the performance of the sterilization. For all these purposes, the head press proves to be an ideal platform for evaluating the effectiveness of the sterilization process under challenging conditions.

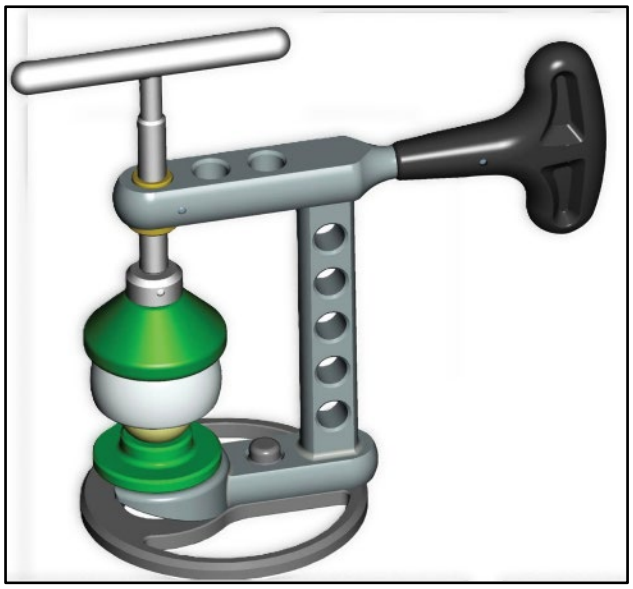


Figure 4-4 Head Press Assembly

4.3.2 Weight

Weight decides the thermal inertia of the tray and load. It takes more energy to get heavier loads to the sterilizing temperature, and they promote slow lag times during heat-up. There are four weight ranges provided in Table 4.2 in ISO 17665-3. According to the ISO 17665-3 definition, the heaviest configuration that is most practicable should be employed for validation since it is the highest energy absorption condition and category will be allocated to that component based on weight category [22]. Hence, for this research, the trays were filled to their maximum safe working weight to capacity with metallic and non-metallic devices of high thermal capacity showcased in Table 4.2 such that heat transfer dynamics capture the highest sterilization complexity.

Table 4-4-2 Weight Categories for The Selection of Worst-Case Scenario [22]

Weight (g)	Category
Less than 50	-
50 to 499	-
500 1999	-
2000 and greater	

4.3.3 Material Composition

Material of instrument and tray influences heat transfer rates and condensation behaviour. Conductive materials (stainless steel) will heat-transfer quickly but will promote local condensate formation that needs to be drained off efficiently so that recontamination is avoided. ISO 17665-3 suggests materials that will present the most difficult heat penetration problem and condensate drainage to be dealt with worst-case selection. Therefore, this test simulates trays and loads made principally of stainless steel, the most frequently used material for reusable surgical equipment, with great mass and great heat capacity and being the usual challenge for steam sterilization [22]. Table 4.3 classifies materials under metals and non-metals, which forms a foundation for assessing their heat behaviour and choosing worst-case conditions.

Table 4-4-3 Material Categories for The Selection of Worst-Case Scenario [22]

Material	Example material	Category
Metal	Stainless steel, carbon steel, copper and copper-based alloys. Other metals or combinations of metal.	-
Non-metal	Glass, cellulose, polycarbonate, PVC, PTFE, silicon. Other non-metals.	

4.3.4 Sterilization Barrier System (SBS)

A Sterile Barrier System or SBS is the barest packaging configuration used to avoid microbial contamination and provide sterility of a product until it reaches its point of use.

The SBS is typically wrapping, pouches, or rigid containers and a barrier layer that has to be open enough to steam penetration but remain sterile after the process. According to ISO 17665-3, the worst-case SBS should be least permeable, longest drying time, and most steam penetration-resistant allowed in clinical application [22]. A metal rigid container tray (RCT) was used for simulation in this research because it is said to extend drying time and can trap air pocket residual if not properly vented. This selection allows steam to diffuse through several barriers of diffusion in an attempt to test the sterilizer in its capacity to establish effective contact with all surfaces. Table 4.4 presents the classification of the sterile barrier system used to choose the worst-case configuration utilized in the present work.

Table 4-4-4 Sterile Barrier System Categories for the selection of Worst-Case Scenario [22]

Sterile barrier system	Category
None	-
Single wrapped/pouch	-
Double wrapped in wrapping material or pouches, double wrapped container or tray, reusable sterilization container according to manufacturer's instructions	-
Combination of two or more systems, for example, a reusable sterilization container with an inner sterile barrier system	

4.3.5 Worst Case Selection

After drafting the problem statement and the project objectives, the next most important step was careful identification and choice of the worst-case condition. It is a requirement to ensure that the sterilization process is being tested under the most onerous and extreme conditions, according to validation principles. The conclusion was made based on the systematic evaluation of the data in Tables 4.1, 4.2, 4.3, and 4.4, each contributing to the determination of factors affecting sterilization efficiency differentially.

Table 4.1 illustrates key design features of surgical instruments that might impair effective steam penetration and drainage of condensate, for example, long lumens, narrow crevices, and trapped geometries. Table 4.2 categorizes the material into metals and non-metals, an important consideration in view of variation in thermal conductivity and condensate holding capacity—both of which are very important considerations in the heat transfer efficiency during sterilization. Additionally, Table 4.3 provides a model for the evaluation of blends of material types, which allows for prioritization of the harder (i.e., non-metallic) materials when mixed material is involved.

Table 4.4 presents the Sterile Barrier System (SBS) class according to critical performance characteristics including steam permeability, drying behavior, and resistance to steam entry.

These are of great importance in order to describe the packaging's behavior during the sterilization process.

In Tables 4.2 through 4.4, the most serious attributes chosen in each category are represented by the yellow-shaded items. This visual feature enables easy recognition of the most severe challenge points chosen to investigate. By extensive integration of information from all four tables, a representative family of products was defined. From this family, the worst-case configuration consisting of the most severe or restrictive attributes was chosen for process challenge tests and verification studies.

Figure 4-5 Instrument Tray

Figure 4-5 depicts an image of the Rigid Container Tray (RCT) used in the study. A similar tray replica was utilized during the simulation to reflect real-world conditions. In accordance with Table 4.4, RCTs were selected as the basis for defining the scope of the simulation, due to their high resistance to steam ingress and drying challenges. The approximated number of trays is 42 which were considered within the scope of the study, requiring a detailed review of 230 engineering drawings (approximated) to evaluate relevant design and material attributes. This evaluation relied heavily on data presented in Tables 4.1 through 4.3. As the scope of the project is defined, an assessment of attributes is conducted, and the worst-case scenario is selected and illustrated through Figure 4-6.

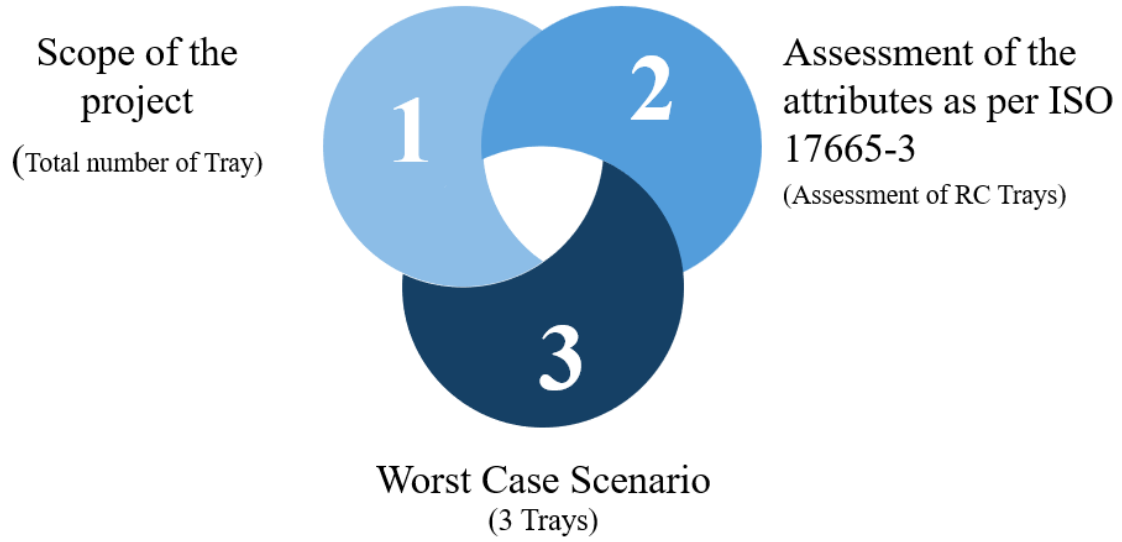


Figure 4-6 Venn Diagram Illustrating the Intersection of the Project Scope, ISO 17665-3 Attribute assessment, and Worst-Case Scenario Evaluation, Forming the Basis of the Sterilization Study Framework

For example, if an instrument comprised both metallic and non-metallic materials, Table 4.3 dictated that the non-metallic component represents the worst-case scenario due to its inferior thermal performance. Accordingly, the material classification and associated worst-case score were assigned based on the non-metallic component.

Using this detailed assessment, product families were constructed and summarized as on Figure 4.7. Each "X" (cross) marked within the table represents the presence of a specific worst-case attribute in a given instrument for each attribute and based on this steam penetration number is assigned by taking reference from ISO 17665-3. After completing the full evaluation, the product family with the highest cumulative steam penetration challenge score was identified and selected as the final worst-case scenario for simulation and further validation.

	Atrributes																		Steam penetration resistance (estimated)						
	Design								Material		weight				Sterile barrier System										
PF	1	2	3	4	5	6	7	+	1	2	1	2	3	4	1	2	3	4	1	2	3	4	5	6	7
1	X																	X					X		
2	X								X							X								X	
3		X								X	X							X						X	
4			X							X		X			X										X
5					X					X				X			X								X
6						X			X					X		X						X			
7						X			X				X		X								X		
8							X			X				X				X				X			

Figure 4-7 Design Attributes and Steam Penetration Resistance Assessment Table

4.4 Materials Assessment

The following are the main reasons for the material assessment: -

- Thermal and Physical Compatibility: Various materials react differently to heat and humidity. For instance, metals come to a high temperature rapidly but can cause condensation, whereas plastics will insulate and retard the flow of heat.
- Steam Penetration Effectiveness: Porosity and the surface of the material determine how well steam permeates and sterilizes inner surfaces or parts.
- Instrument and Safety Integrity: Materials that are incompatible with one another could degrade, melt, or warp in sterilization processes, particularly in high-temperature steam or pressure.
- Accurate Sterilization Modeling: Operations and performances need to be simulated from reliable material behavior data in order to predict sterilization results accurately.
- Residual Moisture and Drying: Certain materials are saturated with moisture after sterilization, resulting in greater susceptibility to microbial survival or recontamination unless addressed appropriately.

In the present simulation study, a range of multi-material instruments were used to approximate closely the range of material found in representative clinical practice. Materials were used to represent both metal and non-metallic elements, both with distinct thermal and physical properties that have direct bearing on the critical parameters associated with the sterilization process, including steam penetration and thermal transfer capability [25]. For every material type employed, principal thermophysical characteristics—thermal conductivity, specific heat, and surface behaviour were carefully specified in the model simulation. By far-reaching parameterization, exact modelling of real sterilization behaviour in various materials was made possible. Figure 4.4 gives a approximated presentation of test materials, which provides a relative basis of comparison for assessing their respective contribution to overall quality and efficiency of sterilization under simulated conditions.

Sr.No	Material Name	Thermal Conductivity (W/m·K)	Specific Heat (J/kg·K)	Density (kg/m³)
1	[redacted]	16.3	500	8000
2	[redacted]	14.5	460	7750
3	[redacted]	15.5	500	7900
4	[redacted]	0.2	1500	1100
5	[redacted]	15.5	500	7900
6	[redacted]	0.2	1500	1100
7	[redacted]	15.5	500	7900
8	[redacted]	0.83	1200	1320
9	[redacted]	15.5	500	7900
10	[redacted]	15.5	500	7900
11	[redacted] (APX)	15.5	500	7900
12	[redacted]	0.23	1460	1410
13	[redacted]	52.5	380	8750
14	[redacted] (APX)	15.5	500	7900
15	[redacted] (APX)	15.5	500	7900
16	[redacted] (APX)	15.5	500	7900
17	[redacted]	15.5	500	7900
18	[redacted] (APX)	15.5	500	7900
19	[redacted]	15.5	500	7900
20	[redacted] (APX)	15.5	500	7900
21	[redacted]	15.5	500	7900
22	[redacted]-12-2	14.6	460	8000
23	[redacted] (APX)	15.5	500	7900
24	[redacted]	0.23	1460	1410
25	[redacted]	0.35	1200	1280

Figure 4-8 Detailed Material List

4.5 CAD model: Geometry

Here, in the present work, a simplified version of the real sterilization tray geometry has been simulated and used for computational analysis and it is modelled in Creo 10.0.3.0. The major reason for this geometrical simplification is to obtain a reasonable balance between the detail level to account for the major steam flow and heat transfer behaviours and to keep the computational expense at affordable computing resources. The 350 mm × 100 mm × 20 mm tray was simulated with Aluminum as the material. The computational domain, i.e., the autoclave chamber, was approximated with a diameter of 100 mm and a length of 400 mm to simulate from the actual setup employed in tray sterilization simulations.

The reference geometry of the model Figure 4-9 has been obtained from a typical surgical instrument tray, which is commonly characterized by perforated walls, stacking supports, and slots for increased steam penetration and condensate drainage. The tray with a dimension of 350 mm × 100 mm × 20 mm was simulated using the material aluminum. The computational space, i.e., the autoclave chamber, was assumed to be of diameter 100 mm and length 400 mm based on the experimental tray sterilization setup used for simulations. But in the current work, heavily detailed design elements like very tiny perforations, inner ribs, or very heavily detailed instrument holders have been avoided or substituted with their corresponding simple forms. This is understandable because fine-scale features contribute hardly anything to global flow behavior at the macro scale but would greatly contribute to mesh density and computational expense. The simplified geometry retains the major properties important in steam sterilization analysis, including tray size, typical perforation to enable entry and exit of steam, and overall configuration with an impact on internal circulation behavior. Using this simplified model, it will become feasible to perform parametric studies and CFD simulations within a reasonable time without losing the prevailing physical effects important in the steam sterilization performance. The Analysis was performed using Ansys 2024 R2 software [24].

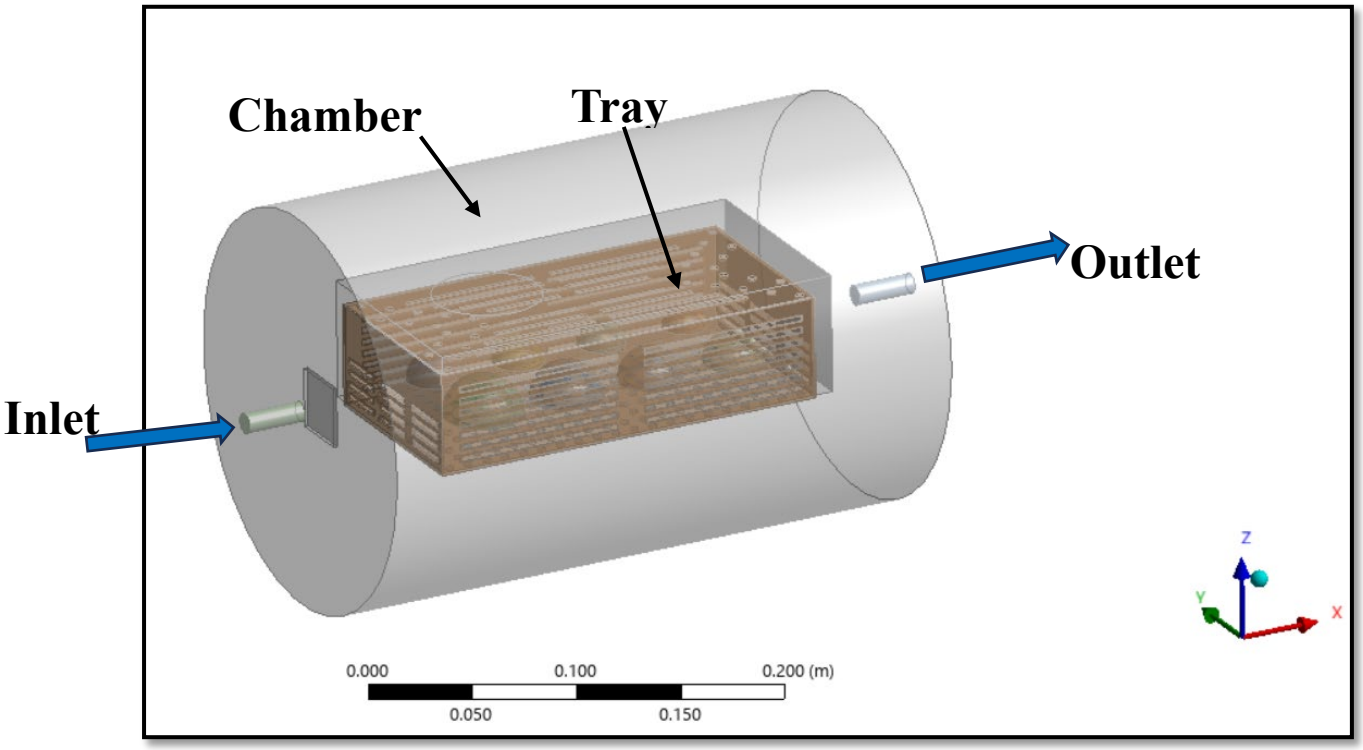


Figure 4-9 3D CAD model of Tray and Chamber

4.6 Mesh Generation

In this present study, the computational domain of the sterilization tray and adjacent steam flow field were modelled with a non-uniform tetrahedral mesh. Tetrahedral elements were chosen because they can be easily flexible in conforming to geometrical complexity and easy to mesh automatically in areas of variable curvature and perforations.

A non-uniform mesh density strategy has been used in order to attain an optimal compromise between computational expense and solution accuracy. Increased resolution mesh elements have been utilized wherever steep gradients of steam condensation, temperature, and velocity are anticipated — i.e., at solid boundaries like the tray walls and perforations. Local refinement is ensured to capture the boundary layer effects with adequate resolution.

4.6.1 Near-Wall Mesh Refinement and y^+ Criteria

The mesh was also rendered thin in the vicinity of instrument walls, as evident from Figure 4.10, to solve temperature gradients there best. This mesh-refinement approach was taken based on calculated y^+ values to provide an efficient representation of the boundary layer. In CFD, in the vicinity of instrument walls, flow and heat transfer need to be solved well to generate meaningful results, particularly in steam sterilization analysis. The non-dimensional wall distance, y+, decides whether the near-wall mesh can resolve the boundary layer appropriately. It is defined as:

$$y^+ = y * \frac{u^\tau}{\nu} \tag{1}$$

y = distance from the wall to the first cell center (in meters),

u^τ = friction velocity,

ν = kinematic viscosity of the fluid (in m^2/s)

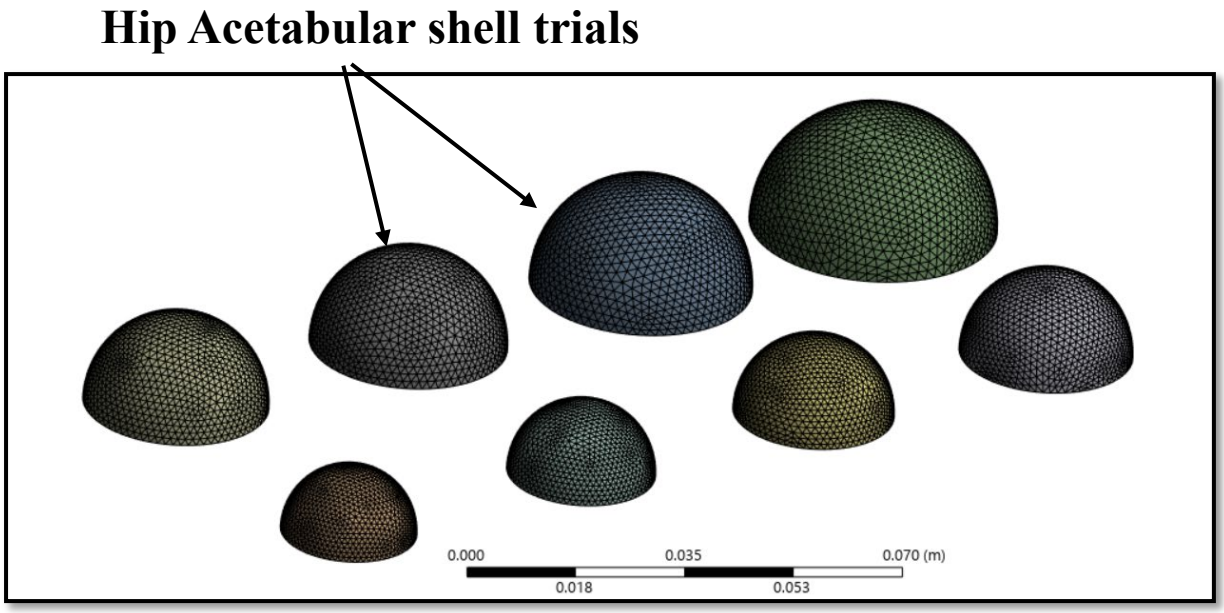


Figure 4-10 Mesh Refinement on Acetabular Hip Shell Trails

The total mesh contains approximately **28,20,000 tetrahedral elements**, with refinement concentrated near solid walls and tray perforations. Figure 4-11 and Figure 4-12 represent the Default mesh size and final mesh size respectively. Mesh refinement involves the intentional reduction of element size or the use of local refinement techniques in critical regions, such as near solid walls, in narrow passages, or in areas with high gradients of temperature or velocity. Refined meshes improve simulation fidelity but increase computational cost.

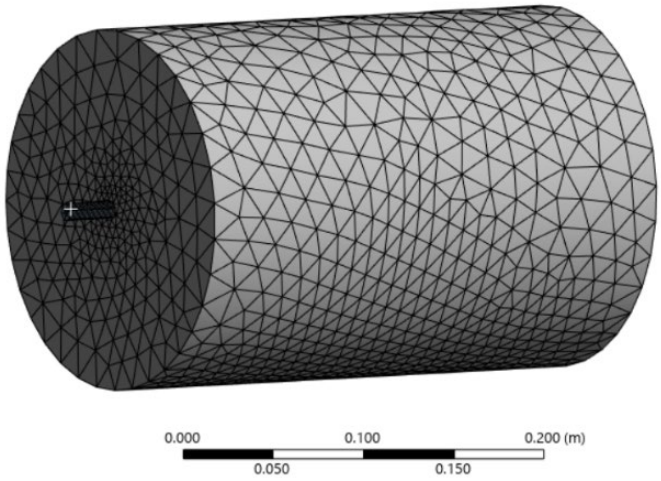


Figure 4-11 Default mesh

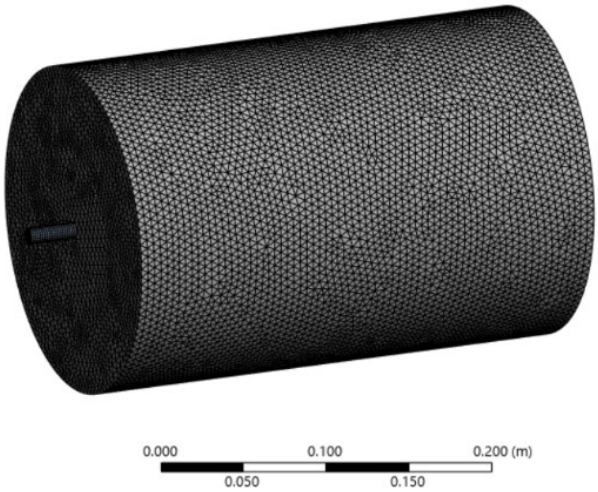


Figure 4-12 Final Mesh After Refinement

Figure 4.13 and Figure 4.14 shows the aspect ratio and skewness of the complete domain. The parameters were also assessed to finalize the mesh size. To ensure stable and accurate numerical solutions, mesh elements must meet certain quality standards.

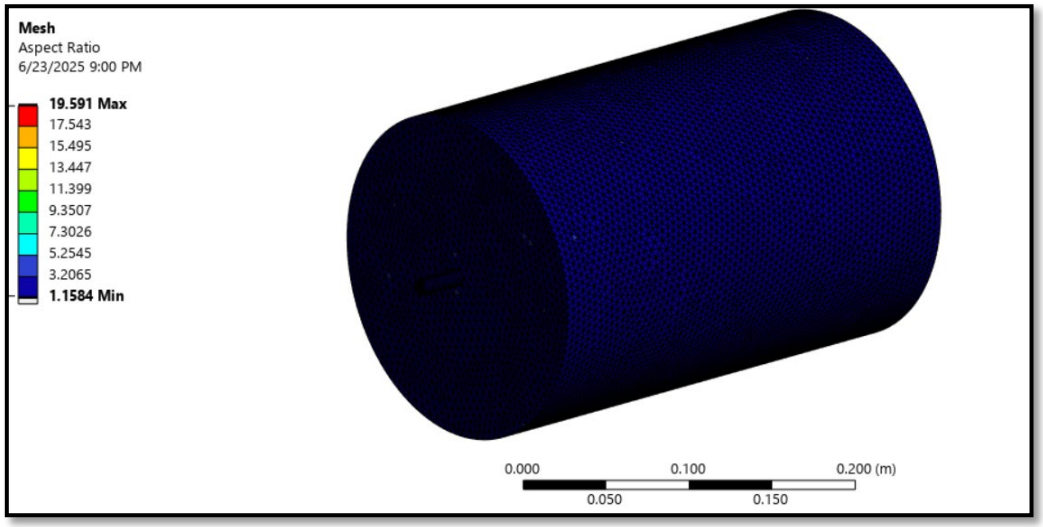


Figure 4-13 Aspect Ratio of Overall Domain

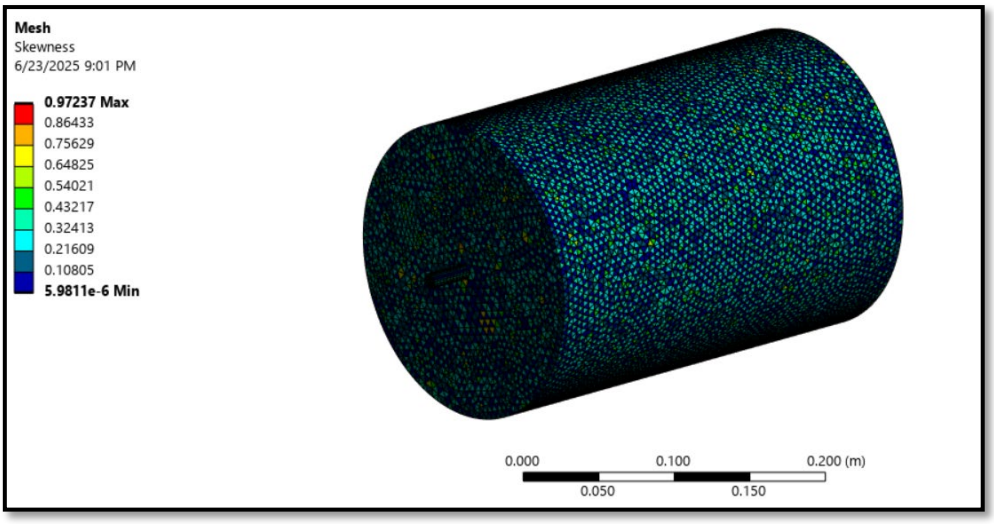


Figure 4-14 Skewness Value of Overall Domain

Furthermore, the mesh size decreased, and 5% convergence was achieved to get the desired results. Mesh Convergence is an important factor which helps in getting the correct results. If the mesh size is not correct there are chances of error in results as this may lead to wrong interpretation of geometry. Every critical feature must be meshed properly as quadratic order is used for this study.

4.7 Turbulence modelling

A double-precision pressure-based solver was used to solve the transient solution of the Reynolds-Averaged Navier–Stokes (RANS) equations describing continuity and momentum. The two-way coupled Eulerian multiphase model was used to simulate the multiphase flow within the steam sterilizer with water vapor and liquid water as the two interacting phases. Turbulence effects were modeled with the realizable k–ε turbulence model, initially proposed by Shih et al. [17], recognized to be optimal in simulating highly curved streamline and rotational flows.

A second-order upwind scheme was used for scalar variables like mass, momentum, turbulent kinetic energy, dissipation rate of turbulent, and energy for obtaining more precise solutions. Quadratic Upstream Interpolation for Convective Kinematics (QUICK) was used for density and volume fraction. Least Squares Cell-Based was used to compute spatial gradients. Pressure–velocity coupling was addressed employing the Phase-Coupled Semi-Implicit Method for Pressure Linked Equations (SIMPLE) where the transient formulation was carried out under a second-order implicit scheme in a bid to promote temporal accuracy.

4.7.1 Turbulence Modelling in Steam Sterilization CFD

Simulation of turbulent steam flow through sterilizers is pivotal in the accurate modelling of high-temperature vapor interaction with medical trays, and perforations. The flow regime within the sterilization chamber is turbulent by nature based on the high Reynolds number of steam injections and the small geometries inducing sudden direction changes and recirculation of the flow. In this research, Shih et al.'s [24] realizable k-ε model was used to model the turbulent flow behaviour inside the steam sterilizer. It requires solving two transport equations: the turbulent kinetic energy (k) equation and the turbulent dissipation rate (ε) equation. The realizable k-ε model is numerically stable and has performed better than the standard k-ε model [23], especially when modelling free shear flows, rotating flows, and internal channel flows. It is thus widely used in industrial CFD calculations because it offers a balance of accuracy and computational cost.

4.8 Heat Transfer and Phase Change Modelling

4.8.1 Importance of Wall Condensation

The efficiency of steam sterilization relies on intimate contact with direct steam and effective heat transfer to the load. Latent heat involved in transferring heat during condensation at the medical instrument and packaging material surface is a characteristic of heat transfer by steam. Simulation of such behaviour in CFD is numerically expensive, particularly if thin liquid condensate film is to be resolved explicitly. Study addressed this by encompassing numerically effective condensation heat transfer within the Lee model of phase change. This method calculates mass transfer rate from liquid to vapor phases in terms of local saturation temperature departures. Condensation happens when the wall temperature drops below steam saturation temperature, giving out latent heat and heating local surface temperatures to sterilization values.

4.8.2 Evaporation and condensation model

In the present investigation, efforts have been made to simulate evaporation and condensation. A simplified numerical algorithm first proposed by Lee in 1980 [23] was used to simulate the process. The scheme offers a numerically simple means of simulating the mass transfer from the vapor to liquid phases for evaporation. The rate of mass transfer m_{lv} is triggered in the model whenever the liquid temperature T_l higher than the local saturation temperature T_{sat}. This is the initiation of phase change from liquid to vapor, a vital process within steam sterilization where precise prediction of evaporation becomes paramount in an effort to

comprehend heat and mass transfer within the chamber. With this inclusion of the constraint on evaporation, the model gains a more effective simulation of thermodynamic response under different thermal loads, helping generally towards the simulation's validity.

$$m_{\iota v} = \eta_{v} * \alpha_{\alpha \iota} * \rho_{\iota} * (T_{\iota} * T_{sat})/T_{sat} \quad (2)$$

4.9 Boundary Conditions Specification

4.9.1 Inlet and Outlet

Inlet boundary was simulated as a pressure inlet, where the steam generator increased the chamber pressure to the sterilization plateau level of around 3.2 bar at 136 °C [23] [8]. Steam quality at inlet was specified as unity, equivalent to saturated vapor. For the sterilization hold, where the chamber needs to be 3.2 bar and 136 °C for 4 minutes, a User Defined Function (UDF) was developed for closure of the inlet by letting its pressure go to zero once the volume-averaged chamber pressure had reached the desired value. Volume-averaged pressure was monitored during the simulation to ensure proper inlet boundary condition.

All the outlets were closed during the sterilization holding cycle to represent the physical working process where the chamber is hermetically sealed for the purpose of pressure and temperature sustenance. This assumption ensures that natural steam condensation takes place within the volume under restraint.

4.9.2 Wall and Ambient Heat Loss

No heat loss to the ambient environment was assumed through the chamber walls, which were modelled as adiabatic. The tray walls and instruments were defined with convective heat transfer boundary conditions, representing heat gain from the surrounding steam, which is at a higher temperature than the instrument surfaces.

4.9.3 Initial Conditions

The sterilization cycle is initiated by a sequence of pre-vacuum phases aimed at evacuating the non-condensable gases (NCGs) from the chamber. These operations play a key role in ensuring the correct steam penetration uniformity as well as maximizing heat transfer efficiency over the load. The initial fluid domain pressure and temperature conditions were, as shown in Figure 1, 0.3 bar and 82 °C, respectively [23][8]. These values have been chosen to describe the state of the chamber at the end of the preconditioning time. Also, the thermal status of the load was

defined using temperature data that were experimentally validated. This procedure is used for reducing non-physical transients at the beginning of the simulation and maintaining numerical stability while enhancing the precision of the model. Simulating the initial conditions to match experimental data enhances the ability of the model to predict, particularly in the case of fluid temperature behaviour and trends in bacterial inactivation during the sterilization process.

Table 4-4-5 Boundary condition and set up parameters [8] [23]

Boundary condition and set up for Fluent	
Pressure at inlet	2 bar
Temperature at inlet	136°C
Initial pressure inside the chamber	0.3 bar
Initial temperature inside the chamber	82°C
Sterilization cycle	4 min.
Chamber walls	Adiabatic (no heat loss)
Tray walls	Convective boundary conditions

4.9.4 UDF-Based Control of Inlet Pressure and Thermal Conductivity in Sterilization Chamber

To achieve the correct simulation of transient steam sterilization in the chamber, two special User-Defined Functions (UDFs) were defined and integrated into ANSYS Fluent: one for dynamic inlet pressure control and the other for stainless steel thermal conductivity depending on temperature.

4.9.4.1 Inlet Closure Based on Chamber Pressure

The UDF was used to automatically close the steam inlet by opening its pressure boundary condition to zero once an internal pressure level had been achieved. This models the actual sterilization process where the supply of steam is closed once the chamber reaches the intended sterilization pressure. The function does this by continuously tracking the volume-averaged pressure of the chamber throughout simulation and in turn closing the inlet accordingly.

```
#include "udf.h"

#define THRESHOLD_PRESSURE 320000.0
#define INLET_PRESSURE     200000.0
#define ZONE_ID            18

DEFINE_PROFILE(inlet_pressure_profile, thread, position)
{
    Domain *domain = Get_Domain(1);
    Thread *t_chamber = [redacted];
    cell_t c;
    real p_sum = 0.0, vol_sum = 0.0;

    begin_c_loop(c, t_chamber)
    {
        real vol = [redacted];
        p_sum += C_P(c, t_chamber) * vol;
        vol_sum += vol;
    }
    end_c_loop(c, t_chamber)

    [redacted];

    face_t f;
    begin_f_loop(f, thread)
    {
        F_PROFILE(f, thread, position) = (avg_p >= THRESHOLD_PRESSURE) ? 0.0 : INLET_PRESSURE;
    }
    end_f_loop(f, thread)
}
```

Figure 4-15 User Defined Function for the Control of Average Pressure Inside the Chamber

This dynamic control is important in transient modeling, particularly under sealed conditions, as it allows smooth pressurization to preserve transition. The justification of the above UDF (Figure 4-15) can be described as:

- At every time step, compute the chamber domain's average pressure.
- If the pressure is at or above a defined value (3.2 bar), automatically set the inlet pressure to zero.
- Otherwise, steam inflow continues.

This approach eliminates manually set or jump-like step-changes and provides a physically motivated, computer-controlled solution for internal chamber conditions.

4.9.4.2 Temperature-Dependent Thermal Conductivity for Stainless Steel

Concurrently, another UDF was used to represent temperature dependence of thermal conductivity of stainless steel. Stainless steel, which is found in the walls of the chamber, has

a temperature-thermal conductivity non-linear relationship, particularly between 80 °C and 200 °C — the standard window for steam sterilization.

```
#include "udf.h"

DEFINE_PROPERTY(thermal_conductivity_stainless, cell, thread)
{
  real T = C_T(cell, thread);
  real k;

  if (T < 373.15)
    k = 16.0;
  else if (T <= 473.15)
    k = 16.0 + (T - 373.15) * (25.0 - 16.0) / (473.15 - 373.15);
  else
    k = 25.0 + 0.02 * (T - 473.15);

  return k;
}
```

Figure 4-16 User Defined Function for Temperature-Dependent Thermal Conductivity

The corresponding conductivity values over the temperature range relevant to steam sterilization (80 °C to 200 °C and beyond) are illustrated in Table 4-6, which serves as the basis for interpolation within the UDF (Figure 4-16).

Table 4-4-6 Thermal Conductivity vs. Temperature for Stainless Steel [27]

Sr. No.	Temperature (K)	Thermal Conductivity (W/m.K)
1	293	16.2
2	373	16.2
3	473	18.4
4	573	18.4
5	673	19.6
6	773	21.5
7	873	19.8
8	1073	22.6
9	1273	25.4
10	1473	28
11	1773	31.7

Rather than being assigned a constant value, the UDF compares the thermal conductivity (k) dynamically at every cell within the computational domain through temperature-dependent interpolation. The model is developed on sound experimental data and uses a piecewise method:

- Below 100 °C, a standard constant conductivity is taken (e.g., 16 W/m·K).
- Between 100 and 200 °C, linear interpolation between measurement values (e.g., from 16 to 25 W/m·K).
- Above 200 °C, a slight slope is introduced to further extend the curve for high temperature operation.

This innovation introduces thermal realism in the simulation by considering the thermal response of metal boundaries on heating, an aspect that is extremely important in true simulation of surface temperatures, heat transfer, and steam condensation performance.

4.9.4.3. Coupled Effect and Implementation in Fluent

The two UDFs were developed in Fluent's conventional compiled UDF paradigm. The pressure UDF was linked with the pressure inlet boundary condition, and the thermal conductivity UDF was linked with the walls of the chamber's material property definition.

This two-pronged approach enables Fluent to:

- Exegetically forecast chamber pressure rises and auto-terminate inflow.
- Simulate the impact of fluctuating material conductivity with local cell temperature.
- Offer a strong transient model that accurately simulates the physical cycle of sterilization.

Collectively, these UDFs offer the bridge between rudimentary boundary assumptions and an enhanced, dynamic simulation environment suitable for sterilization applications.

5.1 Introduction

This chapter presents the design verification by comparing CFD simulations results with experimental data. The evaluation focuses on surface temperature distribution on the instruments, pressure variations, and steam penetration within the chamber.

5.2 Sterilization Assessment

Figure 5-1 Sterilization Assessment Flow Chart

5.3 Temperature and Pressure inside the chamber

The simulation starts at the start of the sterilization phase with initial chamber conditions of 0.30 bar and 82 °C and runs to the end of the phase, to about 3.2 bar and 136 °C. These boundary conditions represent real pressure and temperature changes that take place during the process of sterilization and are the foundation on which heat transfer and fluid flow in the chamber can be tested. As illustrated in Figure 5-2, the mean pressure within the chamber towards the end of the simulation validates the functionality of the user-defined function (UDF) as in Figure 4.15, used to decrease the inlet pressure to 0 bar once the mean chamber pressure had risen to 3.2 bar. The range of the pressure inside the chamber lies between 3.13 bar and 3.25 bars and this verifies that the pressure control approach was successfully implemented in the simulation environment. The average temperature inside the chamber during the sterilization phase of 4 minutes is 131.1°C.

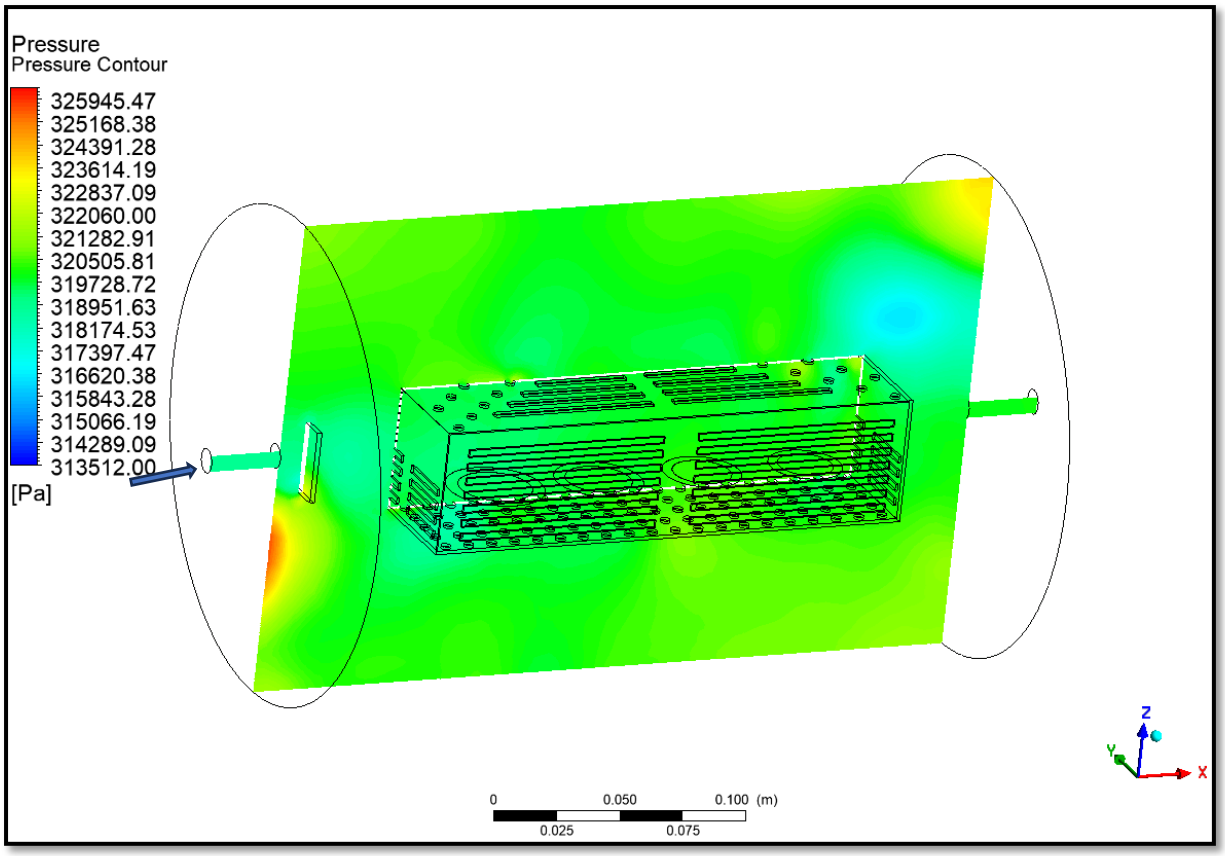


Figure 5-2 Pressure Contour During Sterilization Cycle Along Mid of the Y-Axis in XZ Plane

5.4 Temperature on the surface of the instruments

Complete knowledge of the surface temperature and time required to achieve correct exposure is needed to guarantee sterility. There must be high wall temperatures for this to take place. For the ease of confirming extreme heat transfer as computed from the CFD model, the simulated extreme temperatures were verified against the experimentally measured values. Figure 5.3 illustrates the contour of the surface temperature of the shell trials. The temperature range on the shells spans from 132.18°C to 133.03°C, with an average temperature of 132.72°C. This narrow range and consistent average strongly indicate that the required temperature has been successfully achieved in the simulation.

Considering that surface temperature is so important in deactivating bacteria, special care was given to this parameter. Surface temperature distribution throughout the shells is shown in Figure 5.3 again confirming the CFD predictions of real thermal conditions.

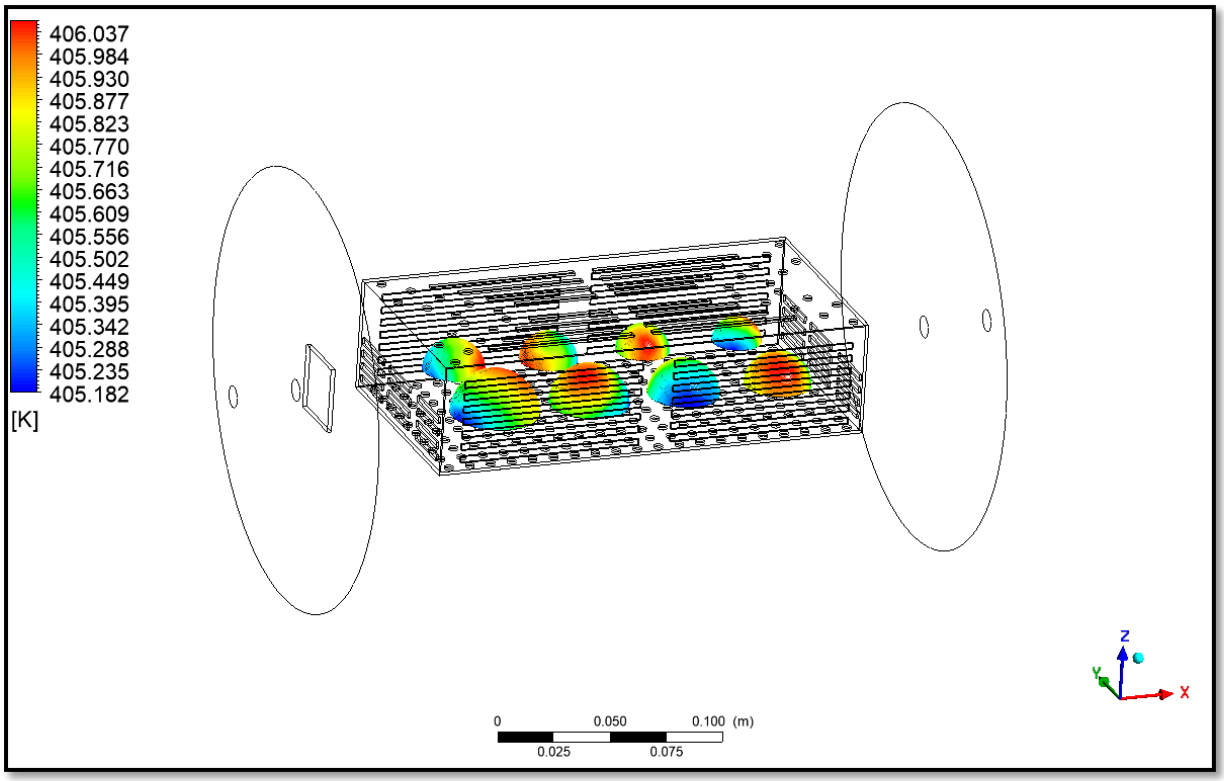


Figure 5-3 Temperature on the Surface of the Hip Acetabular Shell Trails

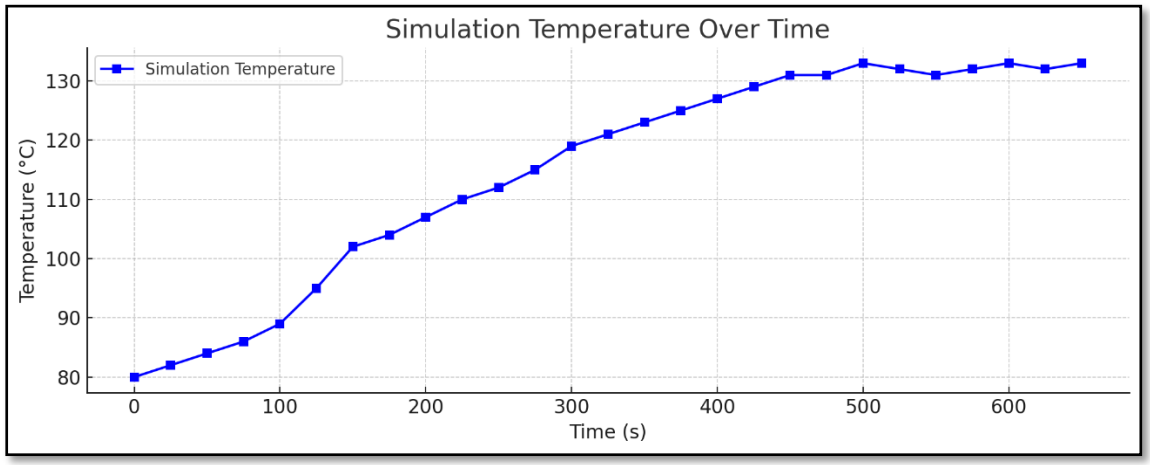


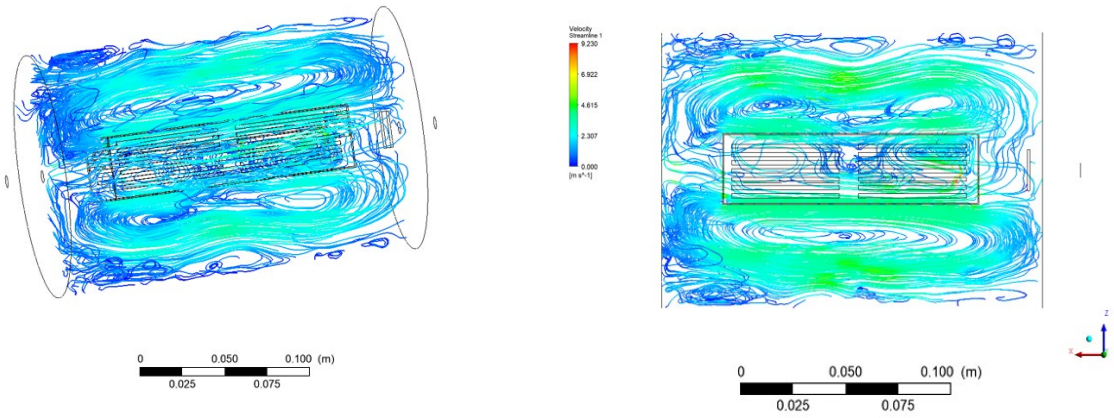
Figure 5-4 Simulated Average Temperature of the Chamber

Figure 5-3 demonstrates the pattern of load surface temperature with respect to a 650-second sterilization process based on CFD simulation outcomes. The temperature rises linearly from initial 82 °C, representing the heat-up period due to steam condensation and conduction. From

300 to 500 seconds, the trend of temperature becomes flat, representing when thermal equilibrium within the chamber begins to set in. The cycle process ends with the load in a steady 132–133 °C. The smooth and consistent ramp-up without crazy oscillations assures the efficiency of pre-vacuum in removing non-condensable gases and ensuring homogeneous steam distribution. The homogenous thermal trend accredits the ability of steam simulation to simulate heat transfer to the load, which is central to sterilization efficiency and microbial inactivation validation.

5.5 Steam penetration

The CFD simulation results provide a clear visualization of steam flow and distribution within the sterilizer chamber. Figure 5.5 and Figure 5.6 show the streamlines, in the initial phase of the sterilization. Steam enters the chamber with relatively high velocity near the inlet ports and gradually it moves through the load. The velocity magnitude decreases in regions with dense or complex geometry, such as the gaps between cylinders or trays, where flow resistance is higher.



(a) (b)

Figure 5-5 (a) (b) Velocity Streamlines During the Initial Phase of the Simulation Along Mid of the Y-Axis in XZ Plane

5.6 Verification

The above discussion describes a test case which mimics the approach used in the real sterilization tray simulation. The test case is also able to simulate the fluid flow and heat conditions found in the actual system and achieve similar temperatures. The added user-defined function (UDF) for pressure control has also been validated and works effectively within this setup.

A model of the sterilization tray and eight acetabular shell models were utilized in this test case to visualize the actual arrangement. Figure 5-7 shows the temperature distribution of the surgical instruments with uniform heat exposure. Figure 5-6 is a representation of the velocity distribution within the chamber, showing air flow patterns and ensuring steam penetration efficiency within the tray.

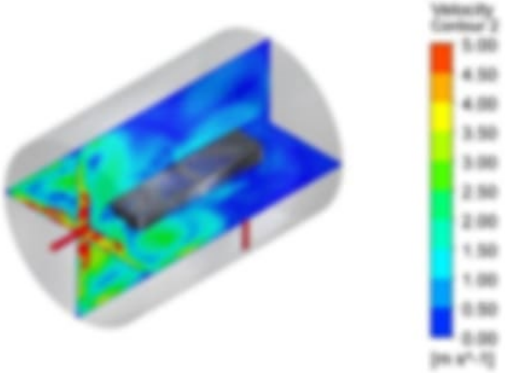


Figure 5-6 Velocity Distribution within the chamber

Figure 5-7 Temperature Distribution of the Surgical Instruments after 240 seconds

Six thermocouples were strategically placed inside the tray to record the temperature during the sterilization process. The six points were selected based on the complexity of the design features of the instruments.

Figure 5-8 Experiment Setup for Testing

The data obtained from these measurements were then compared with the simulation outputs. The approximated results illustrated in Table 5.1 for the comparison between the simulation results and experimental results.

Table 5-1 Comparison Between Approximated Experimental and Simulated Results

Sr. No.	Measuring Points	Experimental Results (°C)	Simulation results (°C)
1	T1	133.5	131.9
2	T2	134.2	133.1
3	T3	134	133.5
4	T4	133.9	132.9
5	T5	133.8	133
6	T6	134.1	132.4

The comparison revealed a strong correlation between the simulated and experimentally measured temperatures, indicating that the simulation model accurately represents the thermal behaviour within the tray and validates its predictive reliability.

Chapter 6 Conclusion and Future scope

6.1 Conclusion

The main aim of this research was to create and calibrate a simulation method that successfully simulates the steam sterilization process of trays by Computational Fluid Dynamics (CFD). The research was conducted successfully to demonstrate sufficiently that CFD can successfully simulate steam performance within an autoclave, with particular emphasis on steam penetration, temperature distribution, and pressure dynamics. The simulation model was constructed in line with ISO 17665-3 guidelines and incorporated exact geometry, material properties, and user-defined functions into the simulation of actual operating conditions.

Simulation output from the CFD was in good agreement with experimental data from physical testing. Thermocouple measurements of six points inside the tray confirmed thermal simulations from the model, within reasonable limits of deviation that is 0.0084%. The average temperature on the surface of the Acetabular shell trials is 132.72°C. Velocity vector and streamline analyses also yielded good steam penetration throughout the chamber.

This strategy demonstrates the possibility of dramatically lowering the volume of physical testing applied in design and development of sterilization cases and trays. Although physical validation is still required, incorporation of more sophisticated simulation methods like CFD can potentially be used in support of optimization of process test conditions, cost savings, and lower time-to-market. The research demonstrates efficient mixing and matching of experimental testing and simulation, and it sets forth a strong and efficient strategy for sterilization process development.

Overall, the work adds to the development of knowledge in steam dynamics in sterilization settings and the verification of CFD as a cost-effective and predictive tool in pharmaceutical and healthcare applications. It is an important step in using simulation-driven methodology in regulatory-compliant sterilization design and validation procedures.

6.2 Practical Application of Simulation-Driven Sterilization Validation in NPD

During the New Product Development (NPD) phase, the design of a medical tray undergoes rigorous testing to ensure compliance with sterilization requirements. This testing process is critical, as any failure in the tray design during this stage can result in significant financial loss due to the high costs involved in creating prototypes and conducting physical tests. Furthermore, each iteration of physical testing consumes substantial time and resources.

To address these challenges, simulation-based testing is being explored as a viable alternative. This approach allows for virtual testing of the tray design under sterilization conditions, reducing the dependency on physical prototypes. Implementing simulation techniques at this stage can serve as a major milestone by significantly cutting down the time and cost associated with traditional testing methods.

Although some prior research has been conducted in the area of simulation for sterilization validation, this effort represents a practical and applied utilization of such techniques. By integrating simulation early in the design process, manufacturers can identify potential design failures sooner, make necessary adjustments, and proceed with more confidence toward final production. This not only streamlines the development cycle but also contributes to overall cost-efficiency and product reliability.

6.3 Future scope

Although this research places a solid CFD-based framework for simulating steam sterilization, there remain a number of avenues for additional improvement and use:

- **Biological Indicator (BI) Incorporation:** Future studies can potentially include the utilization of microbial inactivation models to model the reaction of biological indicators to different thermal and moisture challenges. This would offer a more biologically relevant assessment of sterilization performance to gap the difference between thermal validation and microbial lethality.
- **Use of Artificial Intelligence (AI):** Combining AI and machine learning with CFD modeling holds great promise. AI-driven algorithms can be used to estimate optimal sterilization cycle parameters, categorize process results, and minimize computational effort through the use of previous simulation histories. Combining might also develop adaptive control systems for real-time sterilization monitoring and enable the application of digital twin concepts in industrial processes.

Chapter 7 Reference

1. Rutala WA, Weber DJ, (2013) . "*Disinfection and sterilization: An overview*", American Journal of Infection Control, 41 S2-S5. http://dx.doi.org/10.1016/j.ajic.2012.11.005
2. Panta, Gopal & Richardson, Ann & Shaw, Ian & Chambers, Stephen & Coope, Patricia. (2019) "*Effectiveness of steam sterilization of reusable medical devices in primary and secondary care public hospitals in Nepal and factors associated with ineffective sterilization*": A nation-wide cross-sectional study. PLOS ONE. 14. e0225595. doi:10.1371/journal.pone.0225595
3. Carey, V.P. (2020) "*Liquid-Vapor Phase-Change Phenomena: An Introduction to the Thermophysics of Vaporization and Condensation Processes in Heat Transfer Equipment".* Third Edition (3rd ed.). CRC Press. https://doi.org/10.1201/9780429082221
4. Dion, M., & Parker, W., (2013) "*Steam sterilization principles*". Pharmaceutical engineering, Vol 33, no 6
5. Lau, Wei & Reizes, John & Timchenko, Victoria & Kara, Sami & Kornfeld, Bernard. (2015) "*Heat and Mass Transfer model to predict the operational performance of the steam sterilization autoclave including products*". International Journal of Heat and Mass Transfer 90 800–811, http://dx.doi.org/10.1016/j.ijheatmasstransfer.2015.06.089
6. J.P.C.M. van Doornmalen Gomez Hoyos, R.A.C. van Wezel, H.W.J.M. van Doornmalen, "*Case study on the orientation of phaco hand pieces during steam sterilization processes"*, Journal of Hospital Infection, Volume 90, Issue 1, 2015, Pages 52-58, ISSN 0195- 6701, DOI: https://doi.org/10.1016/j.jhin.2015.01.013.
7. Burian et al., "*Numerical prediction of the chemical indicator response used in steam sterilisers"*, Physics in Medicine, Volume 11, 2021, 100034, ISSN 2352-4510, DOI: https://doi.org/10.1016/j.phmed.2020.100034.
8. Feurhuber et al. (2017). "*Prediction of the fluid flow, heat transfer and inactivation of microorganism at medical devices in modern steam sterilizers using computational fluid dynamics"*. Applied Thermal Engineering, *127*, 1391 1403. DOI: https://doi.org/10.1016/j.applthermaleng.2017.08.085
9. Vadrot C, Darbord JC. (2006) "*Quantitative evaluation of prion inactivation comparing steam sterilization and chemical sterilants: proposed method for test standardization"*. J Hosp Infect. Oct;64(2):143-8, doi: 10.1016/j.jhin.2006.06.007.

10. Rutala WA, Weber DJ. (2016) "*Disinfection and sterilization in health care facilities: An Overview and Current Issues*". Infect Dis Clin N Am 30 609–637. http://dx.doi.org/10.1016/j.idc.2016.04.002.
11. Agalloco, James. (2000) "*Steam sterilization and steam quality"*. PDA journal of pharmaceutical science and technology, PDA. 54. 59-63.
12. W. L. Lau et al. (2015) "*Heat and mass transfer model to predict the operational performance of a steam sterilization autoclave including products"*, International Journal of Heat and Mass Transfer 90 800--811, ISSN 0017-9310, doi:10.1016/j.ijheatmasstransfer.2015.06.08944
13. Van Doornmalen, J. P. C. M., Tessarolo, F., & Kopinga, K. (2014). "*Measurements of only pressure and temperature are insufficient to monitor steam sterilization processes: a case study"*. Zentralsterilisation : Central Service 4, 205-25
14. Bachir El Fil, Girish Kini, Srinivas Garimella (2020) "*A review of dropwise condensation: Theory, modeling, experiments, and applications",* International Journal of Heat and Mass Transfer 160 120172. https://doi.org/10.1016/j.ijheatmasstransfer.2020.120172
15. Lau.et al. (2015), "*Numerical modelling of an industrial steam-air sterilisation process with experimental validation*", Applied Thermal Engineering 75 (2015) 122e134 http://dx.doi.org/10.1016/j.applthermaleng.2014.09.031
16. Tessarolo et al. "*Monitoring Steam Penetration in Channeled Instruments: An Evidence-Based Worst-Case for Practical Situations*". Front Med Technol. 2020 Nov 16;2:566143. doi: 10.3389/fmedt.2020.566143.
17. Marchand K. B. et al. "*Surgical Tray Optimization and Efficiency: The Impact of a Novel Sealed Sterile Container and Instrument Tray Technology*." SURGICAL TECHNOLOGY INTERNATIONAL Volume 37 - Nov, 2020 - PMID: 33245139
18. Feurhuber et al. "*CFD investigations of steam penetration, air-removal and condensation inside hollow loads and cavities*", Applied Thermal Engineering 2019 Jan, 147 1070-1082, doi: 10.1016/j.applthermaleng.2018.10.135
19. Ansari. A "*Numerical Method to Predict the Condensation During Sterilization of Medical Devices*", 2021 October, NWC21-377-b, SGTC Stryker
20. Wang et al. "*Simulation and optimization of the thermal sterilization process of puree cans using the production of chestnut puree as an example*". Frontiers in Microbiology. 20223, Doi: 14. 10.3389/fmicb.2023.1135700.

21. Udomiaye, Emmanuel & Eze, Desy & kalu, Cheche & Haliru, Aminu. "*Environmental Sustainability for Infection Prevention and Control (IPC) in Healthcare Facilities"* Proceedings of the International Conference of Contemporary Affairs in Architecture and Urbanism-ICCAUA. 2021. 4. 677-686. Doi: 10.38027/ICCAUA2021303n7.
22. ISO/TS 17665-3 – Sterilization of health care products Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization
23. Feurhuber et al. "*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*", Physics in Medicine 8 (2019) 100020 doi: https://doi.org/10.1016/j.phmed.2019.100020
24. ANSYS Help guide
25. Rogers, W.J.. "*The effects of sterilization on medical materials and welded devices*." Joining and Assembly of Medical Materials and Devices. 2013. (pp.79-130) Doi: 10.1533/9780857096425.1.79.
26. Ardeshna A, Chavan K, Prakasam A, Ardeshna D, Shah D, Velliyagounder K. "*Effectiveness of Different Sterilization Methods on Clinical Orthodontic Materials*". Journal of Indian Orthodontic Society. 2022;57(2):98-105. doi:10.1177/03015742221109026
27. https://www.matweb.com/search/DataSheet.aspx?MatGUID=7a87941825a3463eaba7979c4333721f&ckck=1

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