PROMEPLA

FLUID MODELING IN THE DEVELOPMENT OF A MEDICAL DEVICE SOLUTIONS

HAB
HERRMANN
APPARATEBAU GmbH

INTRODUCTION

Promepla OEM solutions is one of the world's leading contract-based companies specializing in the production of single-use medical devices. We are involved in the manufacture of a diverse range of medical devices from start to finish, including the design, development and manufacture of medical devices. We have currently partnered with Herrmann Apparatebau to develop and manufacture a dental dispenser intended for the treatment of dental cavities. The key to our approach in the manufacture of this device is the use of computational fluid dynamics. Computational fluid dynamics is the prediction of flow patterns of fluids using computer simulations or modeling. Computational fluid dynamics (CFD) analysis, when combined with experimental data, can serve as a time and cost-effective approach to the design and development of medical devices by providing a better understanding of fluid flow dynamics affecting medical device performance.

PART 1 THE MOUTH DISPENSER

FIG 1A: *The two halves of the mouth dispenser before solvent bonding along with the input tubing.*

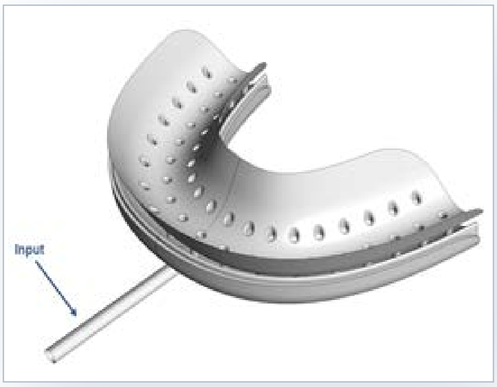


FIG 1B: *An illustration of the completed mouth dispenser.*

Hermann Apparatebau is a world leader in the production of ozone and colonic hydrotherapy devices. Promepla is currently developing an ozone mouth dispenser in partnership with Hermann Apparatebau. The mouth dispenser under development is a single-use device to be used for exposing the entire jaw area to ozone gas. Such exposure of the entire jaw area can serve as a preventative measure in the treatment of dental cavities. This oral dispenser, designed by Promepla, is made of thin and flexible material to facilitate the formation of a seal around the patient's jaw. The mouth dispenser, being a single-use device, was developed by solvent-bonding two separate and non-identical halves into a single piece. One of the halves has three rows of holes through which the gas can diffuse. The solvent bonding of the two halves, produced by injection molding, is an innovative solution applied for the first time by Promepla in the design of medical devices. The mouth dispenser is attached to a short tube that can be connected to the source of the gaseous fluid. The short tube has a female Luer lock to be connected to a male Luer lock emanating from the source device. We used computational fluid dynamics to assess the ability of our prototype to homogeneously expose the jawbone to the gaseous fluid and used the predictions to optimize the dispersion of the gas from the mouth dispenser.

PART 2 WHAT IS COMPUTATIONAL FLUID DYNAMICS?

Computational fluid dynamics involves the simulation or modeling of the flow dynamics of gaseous and liquid fluids on the basis of differential equations governing thermodynamics and fluid mechanics. CFD, in other words, involves producing quantitative predictions of flow dynamics using computer-based solutions of the aforementioned differential equations. Understanding the flow pattern of the fluid, using CFD, involves taking into account the various physical properties of the fluid including its velocity, pressure, viscosity, temperature, and density. CFD, thus, requires the use of high-performing computers to simulate the flow patterns of liquids and gases along with their interaction with solid surfaces. A traditional approach to understanding the flow dynamics of fluids involves the experimental measurement of variables influencing flow patterns. Such an approach is costly, time-consuming, and is constrained by the ability to measure the flow patterns. Although computational fluid dynamics does not eliminate the need for experimental measurements, it restricts the amount of data required from experimental data. Computational fluid dynamics can thus provide time and cost-effective patterns of fluid-flow in a medical device and thus play a vital role in the design and development of medical devices.

PART 3 EXAMPLE OF APPLICATION OF CFD

At Promepla, we used CFD to determine the flow patterns of a gaseous fluid in our mouth dispenser prototypes. The intended use of the mouth dispenser is to bathe the entire jawbone with the gaseous fluid. The first prototype of the mouth dispenser designed by us consisted of equal sized holes to achieve homogeneous diffusion of the gas. We deployed computational fluid dynamics to determine the efficiency of this prototype in homogeneously exposing the entire jawbone to the gaseous fluid. The aim of the numerical simulations was to characterize the flow of the fluid inside the device and the dispersion of the gas through the holes on the bottom surface of the mouth dispenser. The computer-aided design (CAD) was developed by Promepla, and the CFD simulations were carried out by a partner organization specializing in CFD simulations. The CAD model is a representation of the physical geometry of the device being simulated. CAD model generation is followed by generating a mesh that divides the flow space into subdomains. The accuracy of the simulation provided by CFD depends on the generation of high-fidelity CAD models and the choice of the mesh pattern and requires expertise.

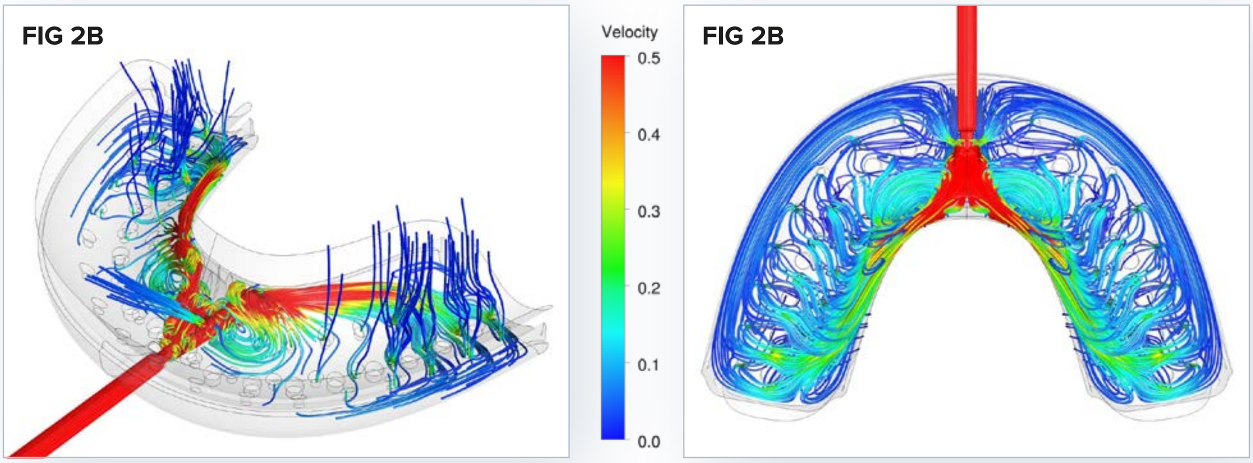


FIG 2A *and* **2B** *show the flow rates (color coded according to speed) and the patterns of fluid flow within the 1st prototype of the mouth dispenser.*

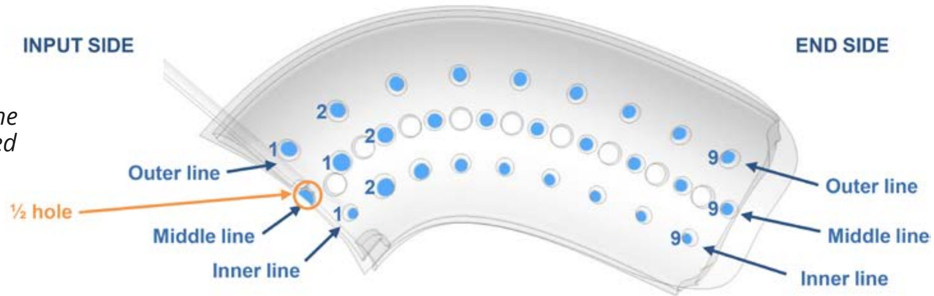
The CFD analysis of our first prototype showed that the velocity was maximal as the gas entered the device (**FIG 2A and 2B**). Some of the gas escaped immediately after entering the device whereas the rest split into two streams. The diffusion of the gas in the device measured in terms of mass flow rates was not homogeneous. The velocity (**FIG 4**) and the mass flow rates (**TABLE 3**) were highest through the inner line of holes (facing the oral cavity) and through the holes near the input tube. Furthermore, the ratio between the maximal flow rate and the minimal flow rate observed in this prototype was 3.34, indicating a non-uniform pattern of gas dispersion.

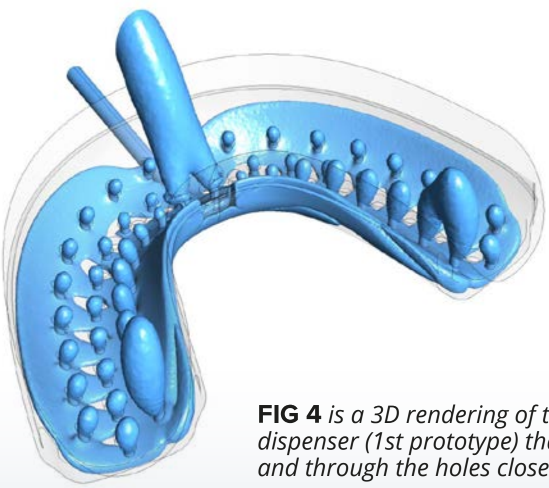
Mass flows (kg/s)										
Hole n°	1/2 hole	1	2	3	4	5	6	7	8	9
Outer line	-	1,85E-07	1,90E-07	2,01E-07	2,16E-07	2,30E-07	2,43E-07	2,55E-07	2,65E-07	2,74E-07
Middle line	1,27E-07	1,26E-07	1,56E-07	1,86E-07	2,02E-07	2,14E-07	2,28E-07	2,43E-07	2,59E-07	2,65E-07
Inner line	-	3,86E-07	1,31E-07	1,76E-07	2,51E-07	2,99E-07	3,23E-07	3,44E-07	3,86E-07	4,21E-07

Max. : 4,21e^{-07} kg/s
Min. : 1,26e^{-07} kg/s
Average : 2,41e^{-07} kg/s
Ratio Max. / Min. = 3,34

TABLE 3 *show the numerical values for flow rates through individual holes located on one half of the dispenser (1st prototype).*

FIG 3 *shows the location of the holes in the dispenser indicated in* **TABLE 3.**





To address the shortcomings of the first prototype in terms of the non-uniform dispersion of the gas, we developed a second prototype. We utilized the information regarding the flow and diffusion patterns of the gas from the CFD analysis and devised a solution that involved selective modification of the diameter of holes in certain areas of the dispenser (**FIG 5**).

FIG 4 *is a 3D rendering of the speed of diffusion of the gas through the different holes of the dispenser (1st prototype) that shows a higher speed of diffusion through the inner lie of holes and through the holes close to the input tubing.*

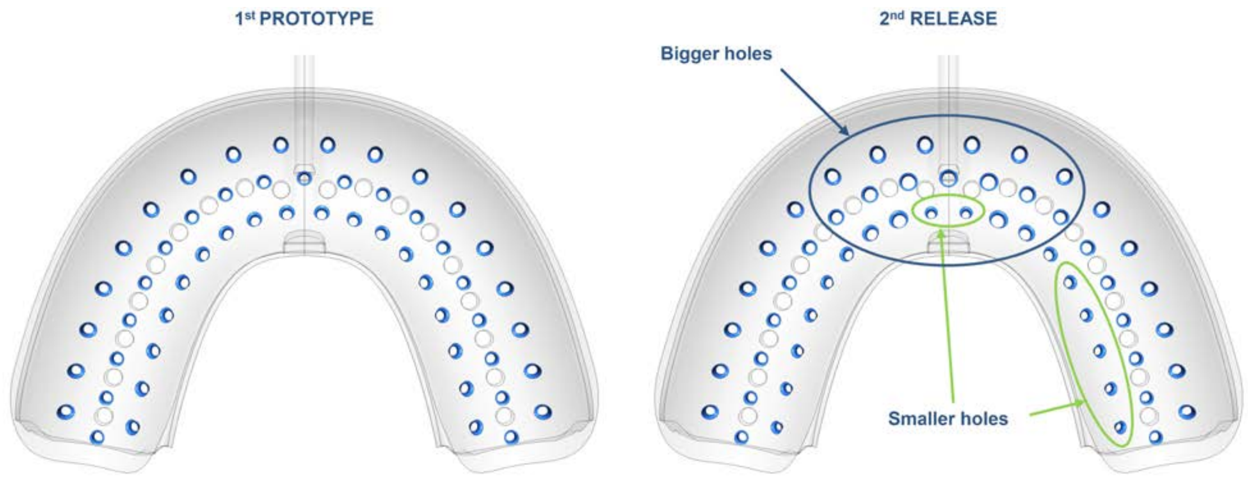


FIG 5 *Based on our CFD simulations, we improved our 1st prototype by selectively modifying the diameter of the holes in specific sections of the dispenser.*

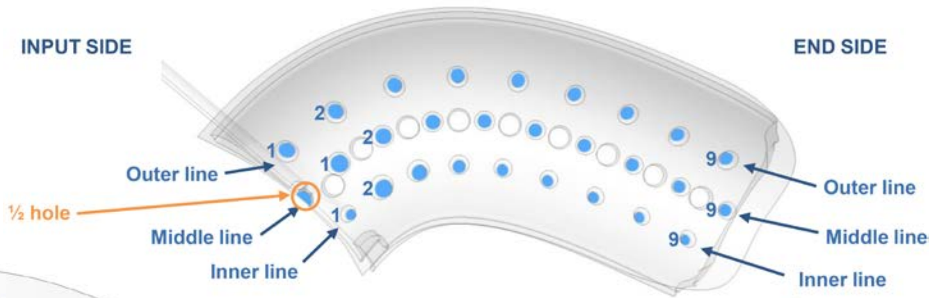
We also conducted CFD analysis on the second prototype to characterize the flow and diffusion patterns of the gas. The flow patterns in the second prototype were similar to the first one. However, the diffusion of the gas, as computed by CFD, was much more uniform in the second prototype relative to the previous one. Higher mass flow rates were observed from the holes near the input tube, but the difference between the maximum and minimum flow rates was narrowed (**TABLE 6**). The ratio between the maximum and minimum flow rates was 1.92 relative to 3.34 with the first prototype, demonstrating the effectiveness of the CFD analysis and our capability to harness it successfully. The 3D rendering of the velocity of the gas dissipating across the surface of the mouth dispenser also showed a uniform pattern (**FIG 7**).

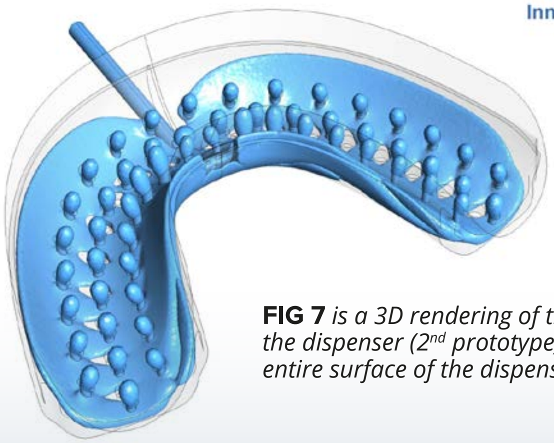
Mass flows (kg/s)										
Hole n°	1/2 hole	1	2	3	4	5	6	7	8	9
Outer line	-	2,66E-07	2,57E-07	2,55E-07	2,52E-07	2,45E-07	2,43E-07	2,37E-07	2,21E-07	2,23E-07
Middle line	2,31E-07	3,39E-07	3,06E-07	2,81E-07	2,69E-07	2,64E-07	2,58E-07	2,57E-07	2,46E-07	2,37E-07
Inner line	-	1,94E-07	3,46E-07	3,01E-07	2,48E-07	2,13E-07	2,13E-07	1,95E-07	1,91E-07	1,80E-07

Max. : 3,46e-07 kg/s Min. : 1,80e-07 kg/s Average : 2,49e-07 kg/s
Ratio Max. / Min. = 1,92

TABLE 6 *show the numerical values for flow rates through individual holes located on one half of the dispenser (2st prototype). Although the mass flow rates were higher through the holes that were closer to the center, the relative difference between maximum and minimum flow rates was smaller.*

FIG 6 *shows the location of the holes on the dispenser*





THE PROTOTYPE HAS BEEN VALIDATED AND WILL BE ENTERING THE PRODUCTION PHASE BY MID-2019.

FIG 7 *is a 3D rendering of the speed of diffusion of the gas through the different holes of the dispenser (2nd prototype). The image shows a uniform pattern of dispersion through the entire surface of the dispenser.*

APPLICATIONS OF CFD IN MEDICAL DEVICE DESIGN

CFD has the potential to play a vital role in the cost and time-effective design and optimization of medical devices.

1. Devices used in heart diseases: Safety is a key issue in the design of medical devices that serve a life-sustaining function in heart conditions. Such devices include arterial stents, replacement valves, blood pumps, and oxygenators. A key concern during the development of these devices is the mechanical and thermal stresses experienced by blood cells and blood vessels due to the introduction of these devices. CFD can play a vital role in the design and development of such devices by producing simulations of the mechanical and thermal stresses produced by the introduction of these devices as well as the changes in blood flow dynamics.

2. Neuraxial anesthesia: Neuraxial anesthesia involves the injection of a local anesthetic around the spinal cord using a syringe or a catheter. This process is very sensitive to the distribution of the anesthesia with mal-distribution resulting in temporary paralysis. The design of the catheter has a huge impact on the distribution of the anesthetic, with small catheters resulting in localized and uneven distribution of the anesthetic and larger catheters allowing a more even distribution. CFD simulations can be used to optimize the design of such catheters.

SUMMARY

We at Promepla OEM solutions, along with our partners at Hermann Apparatebau, have designed and developed a single-use mouthpiece dispenser for the treatment of cavities with the help of computational fluid dynamics (CFD). CFD is a time and cost-effective approach to design optimized medical devices by modeling the flow patterns of the gas and fluids. We effectively utilized CFD during the development of the oral dispenser to ensure homogeneity of the dispersion of gas through the dispenser.

HAB HERRMANN APPARATEBAU GmbH

PROMEPLA

SOLUTIONS FOR SINGLE USE MEDICAL DEVICES

Promepla is a well-established contract-based medical device manufacturer with an expertise in single-use medical devices. We utilize innovative approaches to provide time and cost-effective solutions for the design and development of medical devices. We are a single-source manufacturer with an expertise in angiography, ophthalmology, oral health, and cardiology and can accelerate the production of your product. Please visit us at Promepla to learn more about our services.

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