Analysis of Blood Extraction from a Lancet Puncture

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ABSTRACT

A computational model was created utilizing the CFD-ACE+ software to model blood flow from a lancet puncture of the skin. A two-dimensional axisymmetric model was developed and the skin tissue was modeled as a porous media. The permeability of the porous media was adjusted to match the blood volume of an experimental end-cap for use with a lancet device. A parametric analysis of the end-cap radius shows that volume of blood collected increases as the opening increases, until a saturation point is reached for end-cap radii greater than 7 mm. A similar trend was found when compared with experimental data taken with the same constraints.

Keywords: lancet, blood extraction, CFD

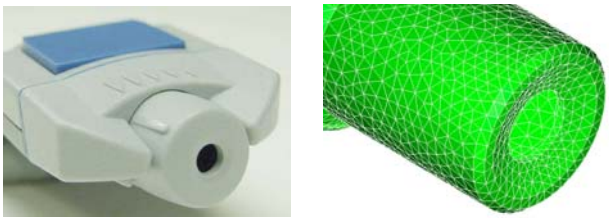
1 INTRODUCTION

An important tool in maintaining tight control over blood glucose levels for people with diabetes is self-monitoring blood glucose (SMBG). The American Diabetes Association recommends that SMBG be performed several times daily for patients with diabetes [1]. Traditional SMBG requires lancing a fingertip with a device to acquire capillary blood. Most commercially available lancet devices utilize a stainless steel lancet that is spring loaded. When released, the lancet is launched forward and its tip momentarily protrudes through an aperture (end-cap) that is pressed flush against the user's skin surface. The lancet pierces the tissue, allowing a blood sample to form on the skin's surface. The patient typically squeezes or milks the finger near the puncture site until a sizable blood drop is obtained, which is then transferred to the testing device. This is generally considered a painful process, and repeated frequent sampling from the fingertip can generate tenderness. Pain is recognized as a major complaint of patients performing finger sticks [2] and is not conducive to testing in compliance with physician testing frequency recommendations.

The ability to perform SMBG on samples collected from sites other than the fingertip (forearms, thighs, palms, abdomen, etc.) may reduce pain and result in better testing compliance [3]. Such areas have a lower density of nerve endings [4]; therefore, blood collection is generally described as less painful. The ability to vary the site of testing can decrease the cumulative trauma to the fingertips. Some patients may also prefer to obtain samples in a less conspicuous area such as the forearm, thigh, or abdomen. One challenge to obtaining blood from these less painful sites is the lower capillary density of some alternative sites. The capillary density of the palm is 2.5 to 3.5 times higher than that of the forearm, abdomen, or thigh [5]. The fingertip appears to have an even higher capillary density than the palm [6].

2 PRIOR WORK

Several innovative techniques have been introduced to acquire blood samples from alternate sites for diagnostic purposes. The Microlet™ Vaculance™ Lancing Device developed by Bayer Corporation (Elkhart, IN) utilizes a plunger mechanism to actuate the lancet and create a vacuum around the puncture site. The device is pressed against the skin and the lancet is fired by completely depressing the plunger mechanism. An airtight seal is then formed by slowly releasing the plunger, which creates a vacuum. This causes the skin to bulge into a round transparent end-cap, dilating the puncture and increasing the flow of blood [7].



a) b)

Figure 1: a) Photograph of Microlet™ Lancing Device (Bayer Corporation, Elkhart, IN) end cap. b) Computational mesh of an end cap design candidate.

The AtLast™ Blood Glucose Monitoring System by Amira Medical (Scotts Valley, CA) was introduced to target alternate site testers. The device promotes blood flow with a stimulator ring that is pressed against the skin surrounding the puncture site. The initial depression of the device both lances the skin and kneads the surrounding skin tissue. It is sometimes necessary to pump the device multiple times in order to acquire an adequate sample size. The stimulator tip that interfaces with the skin's surface

enhances blood flow by locating the skin for a consistent lancing depth. It also applies tension to the skin, which keeps the puncture site open for increased blood flow. And it kneads (or milks) the penetration site forcing blood to the skin's surface [8].

The MediSense™ SofTact™ Monitor by Abbott Laboratories (Bedford, MA) combined the lancing device and meter into one automated device intended for people who want alternative site testing with the touch of a button. To initiate a test, the user rests the device over the test site and the system automatically pricks the skin, draws the sample, and transfers it to the test strip. The monitor utilizes a vacuum-lancet nosepiece that interfaces with the skin's surface. A vacuum pump is used to draw the skin into the nosepiece and extract the blood from the puncture site after the lancing process [9].

In recent years, many technological advances have occurred that makes AST more feasible using sites with lower capillary density than the fingertip. In particular, the blood volume required for accurate testing with many meters has dropped to 1 μL or less over the past several years. For example, the Ascensia™ CONTOUR™ Blood Glucose Monitoring System (Bayer Corporation, Elkhart, IN) uses a test strip that requires a blood sample of only 0.6 μL [10]. This is a significant difference when compared to earlier AST devices such as the AtLast™ and the SofTact™ that required sample sizes of 2 μL and 2-3 μL, respectively [11]. In this realm, it may be possible to reliably acquire a sufficient blood sample from alternate sites without pumping or milking the site, or with a device that does not utilize a vacuum – maybe just some pressure for a couple seconds. This is extremely attractive, particularly when developing a cost-effective AST lancet device or an integrated system that automatically performs the SMBG process with a touch of the button.

Therefore it is of great interest to develop an end-cap or nosepiece design that interfaces with the skin tissue in a way to reliably extract a blood sample from a lancet puncture. Due to the complex nature of skin tissue and the numerous design possibilities, much experimental work must be performed to optimize a particular end-cap design, which is an expensive and time-consuming process. In order to minimize the development time and costs associated with such extensive studies, computer modeling of the system may prove beneficial. This is a first documented attempt at using computational fluid dynamics (CFD) to optimize the end-cap geometry of a lancing mechanism for maximizing blood flow from a lancet puncture. The CFD-ACE+ software package from CFD Research Corporation (Huntsville, AL) was employed for this purpose.

3 BACKGROUND

Given the geometric and material complexity of soft tissue structures and that they are subjected to complicated initial and boundary conditions, finite element models (FEMs) have been very useful for quantitative structural analyses. Recent applications of poroelastic and mixture-based theories and the associated FEMs for the study of the biomechanics of soft tissues, as well as future directions for research in this area have been surveyed [12].

Due to the great variability in the human physiology it is extremely difficult to actually quantify capillary blood flow from human tissue. Numerous factors can affect the capillary structure of the dermis layer such as aging, disease, temperature, etc. - all can contribute to person-to-person variability in blood flow from a puncture [13]. Therefore, the primary objective of this investigation is not to obtain quantitative results from the CFD analysis, but to acquire a qualitative sense of the system using a computational model for an engineering design analysis. Useful trends could be deduced from these results providing important design information that can be used for optimizing the device.

4 METHOD AND FLOW MODELING

All computational models of the skin simulated and presented here are time-efficient two-dimensional axisymmetric. The skin contains a slit (created by a lance) of known dimensions (0.38 mm diameter hole). The porous media feature of the CFD-ACE+ software was used to model the seeping of the blood from the puncture. This module allows the modeling of flow in materials consisting of a solid matrix with an interconnected void. In order to validate the feasibility of these simulations in obtaining useful design information, the modeling work will be divided into several parts. The first of which is presented in this paper where the skin is entirely modeled as a porous media and the flow rate of blood through the face of the slit is to be predicted and compared with experimental results.

4.1 Porous Media Model of Skin

Owing to the great difference in length scales between the micron-sized capillaries, and the end-cap diameter, it is computationally intractable to model the complete vasculature of the skin. Diffusion mechanisms of solutes within, across and between the intercellular lamellae of the mammalian stratum corneum may be modeled as a porous medium [14]. The skin is therefore modeled as a porous media, and taking advantage of the cylindrical symmetry involved, our problem is reduced to a two-dimensional axisymmetric model. A blood reservoir is introduced below and maintained at capillary pressure. The diameter of the end-cap defines the external model bounds.

Steady state simulations are performed using a laminar incompressible flow. The mass flow rate is multiplied by the blood collection time giving the blood volume obtained. The permeability of the porous media is adjusted to match experimental results for a nominal end-cap. Finally, parametric simulations are performed varying the end-cap radius to investigate how this parameter affects volume of blood collected.

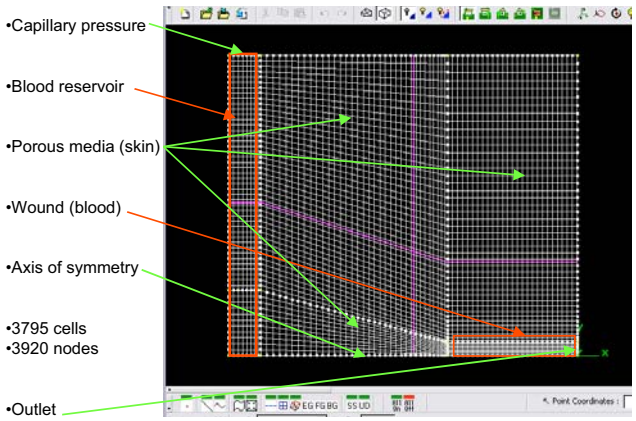


Figure 2. Axisymmetric grid of skin used for simulations. The horizontal X-axis is axis of symmetry.

Fig. 2 shows the computational mesh used. The X-axis is the axis of symmetry. The blood reservoir (capillary pressure boundary condition at top) is at the left, and the skin surface is at the right. The lancet puncture is modeled as a blood-filled cavity, and is at the lower right. A natural pressure boundary condition is used to model the outlet of the puncture. Porous media regions model the epidermis, papillary dermis and reticular dermis of the skin.

4.2 Governing Equations

Transport through porous media is governed by the conservation equations of mass, momentum, energy and species. The pore dimensions may often be in the sub-micron range, and their overall effect is represented through volume-averaged quantities. Here, we present only the volume-averaged conservations for mass and momentum [15], as we are not solving for temperature, phase changes, species dilution, chemical reactions or electro-chemistry.

Mass conservation is given by the equation

$$\frac{\partial}{\partial t}(\varepsilon\rho) + \nabla \bullet (\varepsilon\rho\mathbf{U}) = 0 \qquad (1)$$

The conservation equation for momentum within the porous regions may be written as:

$$\frac{\partial}{\partial t}(\varepsilon\rho\mathbf{U}) + \nabla \bullet (\varepsilon\rho\mathbf{U}\mathbf{U}) = -\varepsilon\nabla p + \nabla \bullet (\varepsilon\hat{\mathbf{o}}) + \varepsilon\mathbf{B} - \frac{\varepsilon^2\mu}{\kappa}\mathbf{U} - \frac{\varepsilon^3 C_F \rho}{\sqrt{\kappa}}|\mathbf{U}|\mathbf{U} \qquad (2)$$

where ρ is the fluid density, p is the pressure, μ is the viscosity of the fluid, C_F is a quadratic drag factor, $\boldsymbol{\tau}$ is the shear stress tensor, $\mathbf{B}$ is the body force vector, and $\mathbf{U}$ is the fluid velocity. ε is the porosity of the medium, and represents the volume occupied by the pores to the total volume of the porous solid, while the permeability κ is a quantity representing the surface area to volume ratio of the porous matrix. The last two terms in Eq. (2) represent an additional drag force imposed by the pore walls on the fluid with the pores, and usually results in a significant pressure drop across the porous solid. In a purely fluid region, e _ 1 and k _ ∞, and the standard Navior-Stokes equation is recovered. In terms of boundary conditions, no special treatment to the momentum and pressure correction equations is required at fluid-porous solid interfaces.

In order to determine the validity of the simulation, results were compared to experimental values obtained from a test end-cap or nosepiece similar to the one used with the Microlet™ Lancing Device (Bayer Corporation, Elkhart, IN) [16]. Table 1 presents the dimensions, material properties and simulation parameters used in the computational model.

Dimension	**Value**
End-cap radius	4.72 mm
Depth of skin	5 mm
Depth of puncture	2.03 mm
Diameter of lance	0.38 mm
Depth of blood well	0.5 mm
Material property	
Blood viscosity	0.004 kg/m-s
Blood density	1060 kg/m^3
Skin porosity (porous medium)	0.3
Skin permeability (porous medium)	3.0e-14 m^2
Simulation parameter	
Blood capillary pressure	3684 Pa
Time of blood collection	10 s

Table 1: Dimensions, material properties and simulation parameters used for simulations.

First we adjust the permeability of the porous medium of the nominal end-cap design. We find that at a permeability of 3.0e-14 m^2 produces a volume of blood equivalent to that collected experimentally (Fig. 3.) [16].

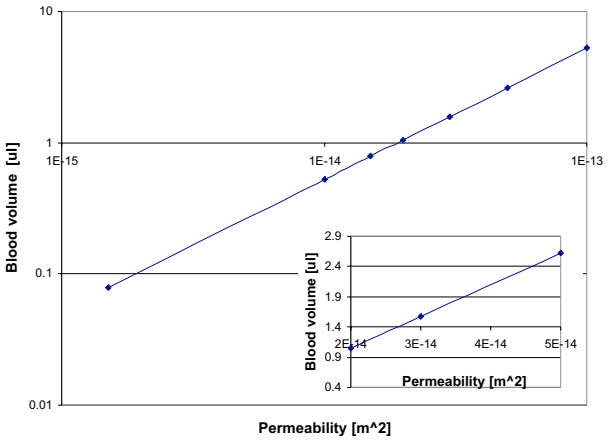


Figure 3. Volume of blood collected as a function of permeability for nominal end-cap radius of 4.72mm.

Simulation results for the nominal end-cap are shown in Fig. 4. Colors represent the pressure drop through the model. Arrows represent the direction and magnitude of the blood flow. Pressure drops off gradually through the porous medium, which offers greatest resistance to flow. Fluid velocities are greatest in the regions of the lancet puncture.

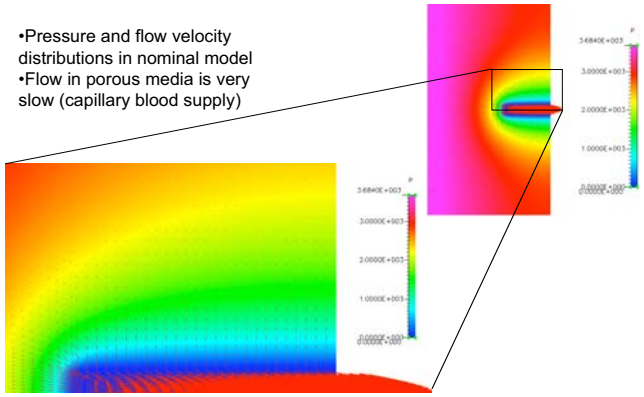


Figure 4. Simulated pressure distributions (colors) and flow velocity vectors (arrows). Inset shows model (top) and symmetry results rendered below.

5 RESULTS

Simulations were performed for end-caps with diameters ranging from 1.18 to 9.45 mm. Pressure distributions for these simulations are presented in Fig. 5. As the diameter of the porous region area is increased, a saturation point is reached beyond which no further benefit to blood collection volume is obtained. The incremental increase to blood flow from distant radial areas is insignificant compared to the flow from below.

For very small diameters of the end-cap, simulations indicate blood flows into the puncture from below. For larger end-cap diameters, simulations predict incrementally larger flow of blood will be supplied from the perimeter.

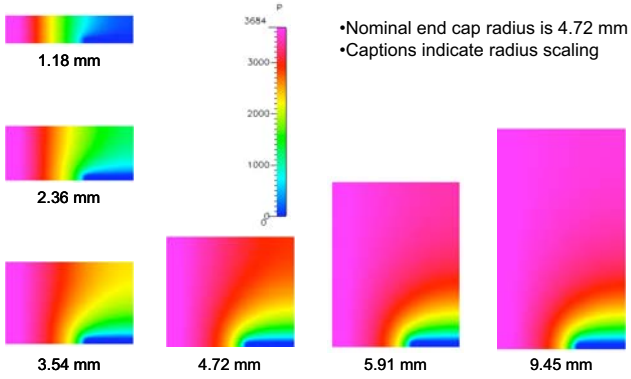


Figure 5. Simulated pressure distributions for various end-cap radii (vertical dimension of model bounds).

Fig. 6 illustrates a comparison of the blood volume collected from the simulation versus experimental values. The experimental results correlate with the computational model, and demonstrate an increase in blood volume with end-cap radius. However, it is difficult to quantify these values with a high degree of confidence due to the large standard deviations encountered during the experimental studies. For example, the average blood volumes obtained increased from 0.59 μL to 1.23 μL as the radius was enlarged from 1.52 mm to 2.8 mm, respectively, but with an average standard deviation 0.36. Other researchers have observed such variations when performing similar blood volume studies [13,17]. This is attributed to the vast variability in the human physiology.

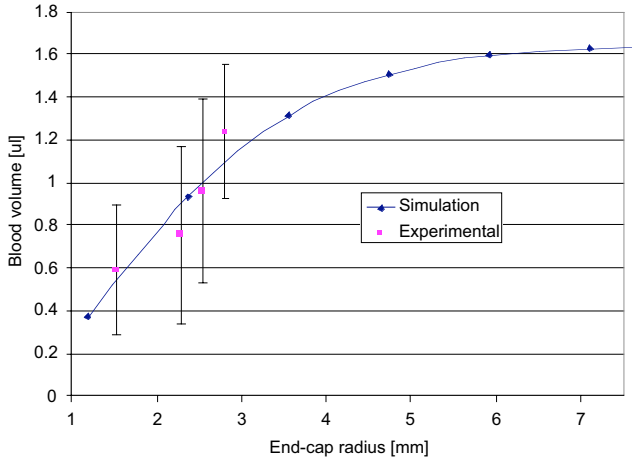


Figure 6. Comparison of blood sample volumes collected from experimental studies versus simulated results generated by the computational model.

5.1 Future work

Future work includes performing simulations where the lancing device is pressed down on the skin around a slit. Such simulations will consist of decoupled sequential elastic and flow simulations where the deformed computational grid from the elastic simulation will be used as a computational grid for the porous media flow simulations. The resulting model will provide a useful template for further investigations. And finally, an experimental coupled-elastic-flow model must be developed. This requires an experimental modification of the CFD-ACE+ solver. A user subroutine must be written to couple the results from elastic simulations with porous media material properties for the flow simulations in a similar sequential analysis procedure. An additional challenge for future work is finding a way of modeling the bulging/stretching of the skin/puncture and how it affects blood volume.

6 SUMMARY

A computational model was created utilizing the CFD-ACE+ software to model blood flow from a lancet puncture of the skin. A two-dimensional axisymmetric model was developed and the skin tissue was modeled as a porous media. The permeability of porous media was adjusted to match blood volume of experimental end-cap. A parametric analysis of the end-cap radius shows that volume of blood collected increases as the opening increases, until a saturation point is reached for end-cap radii greater than 7 mm. A similar trend was found when compared with experimental data taken with the same constraints.

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