Viscous Heating Assists Jet Formation During Needle-free Jet Injection of Viscous Drugs

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Abstract
Objective: Jet injectors use a high-pressure liquid jet to pierce the skin and deliver drug into underlying tissues. This jet is formed through a short, narrow orifice; the geometry of the orifice and the properties of the fluid affect the nature of the flow. We aimed to discover information about the turbulent and viscous processes that contribute to pressure loss and flow patterns during jet injection. Methods: We used computational fluid dynamics methods and experimental observation to investigate the effects of nozzle geometry, fluid viscosity and viscous heating, on jet production. We experimentally verified the temperature change of the jet during ejection, using an infrared camera. Results: Our models accurately predict the average jet speed produced for two example nozzle geometries over two orders of magnitude of viscosity. The models reveal the previously unreported importance of viscous heating in the formation of the jet. Temperatures > 65 °C were predicted at the edge of the flow as a result of viscous heating. These caused a significant local reduction in viscosity and effectively allowed the fluid to lubricate itself. Our experiments confirmed changes in mean jet temperature of up to 2.5 °C, which are similar to those predicted by our model (~2.8 °C). Conclusion: These results reveal the importance of the viscous heating properties of a fluid in the formation of high-speed jets for drug delivery. Significance: This property is crucial to consider when formulating new drugs for needle free jet injection.

Index Terms— computational fluid dynamics, drug ampoule design, infrared, needle-free jet injection, thermal imaging, viscous drugs, viscosity.

I. INTRODUCTION

Jet injectors are drug delivery devices that form a high-speed fluid jet (~150 m·s⁻¹) from a liquid drug in order to pierce through the skin surface without using a needle. The jet can then deliver the drug to the dermal, subcutaneous, or muscle tissue layers under the skin surface [1], [2]. The container of the drug, often referred to as an ampoule, uses a reduction in diameter (a “nozzle”) to form a jet through an orifice. Typically, the reduction is from approximately 4 mm diameter in the body of the ampoule to 200 µm diameter at its orifice. While the flow of fluid through the nozzle during an injection has often been assumed to be inviscid [3], it has been shown [4], [5] that there are energy and pressure losses within the nozzle, which reduce the speed of the jet. These losses are correlated with viscosity, and comprise two components: turbulent loss (arising from eddies forming in the flow field) and frictional loss (a result of the interaction of the fluid with the wall, and the smooth flow of the fluid particles past each other).

The fluid mechanics of high-velocity flow through small orifices has been an area of previous research interest [6], [7] but has been little explored in the context of drug delivery. Nakayama et al. [8] developed a computational model of an air-pressure driven jet injector, which included the flow of the jet after emission from an orifice. They revealed that orifice diameter had little effect on the speed of the jet, as long as the diameter was similar to the commonly used 200 µm. Nakayama et al. modeled only water as the fluid, considered turbulence a minor contribution to loss, and explored only one geometry. Subsequently, Portaro et al. [9] used this model to explore the effect of drug viscosity on jet stagnation pressure and jet geometry. They concluded that jet stagnation pressure (and thus, average jet speed) decreases with increasing fluid viscosity, while the jet shape becomes more confined as the jet propagates in air.

In addition, in-depth research into high speed jets has been pursued in the design of diesel fuel injectors. These have geometries broadly similar to those of drug injectors, involving an orifice diameter of approximately 150 µm through which a jet is formed. They differ in the ratio of the nozzle reduction (9:1 diameter ratio for diesel fuel injectors vs. 18:1 for jet injectors), and the passage of the flow through an annular valve gap prior to the final orifice [10]–[17]. Multi-hole fuel injectors also require their flows to travel through a bend of up to 90°. Often, the contraction to orifice diameter in fuel injectors is sharp, causing flow separation and pressure reduction below atmospheric levels that can result in cavitation. During diesel fuel injection, cavitation may be desirable [11], as it tends to increase the dispersion of the jet when it exits the nozzle.

The flow produced by different fuel injector geometries has been explored using commercially-available computational fluid dynamics (CFD) solvers such as KIVA3 [10] and FLUENT[14], [15], in addition to the development of specialized code [13], [17]. The results indicate that smooth profiles and small angles reduce turbulence and the likelihood of cavitation, thus increasing the jet speed. However, the work in this field has been limited to fluids with the viscosities of diesel and light petroleum-based fuels (typically 1 mPa·s to 10 mPa·s).

There is some concern that drugs are exposed to high shear as they pass through a jet injection ampoule [1], [18]. Such shear rates could denature proteins, such as monoclonal antibodies, reducing their effectiveness as a drug therapy. Studies by Bee et al. [19] and Thomas and Geer [20] showed that shear rates up to 250,000 s⁻¹ could be experienced by...
protein solutions without denaturation. Bee et al. predicted that shear rates above $10^7 \text{s}^{-1}$ would be the minimum required for denaturation without cavitation or an air-liquid interface. Mitragotri notes that the duration of drug exposure to shear forces in jet injection is considerably shorter than is seen in needle injection [18]. CFD simulation can estimate the intensity of the shear within the flow, and these values can be used to help determine the expected level of denaturation of a protein solution during a jet injection.

The primary goal of this work is to use CFD to determine the turbulent and viscous physical processes that contribute to pressure loss and flow patterns within jet injection ampoules. We compare the flow- and pressure-loss characteristics within two ampoules of smooth and stepped geometric profiles, exploring and quantifying these characteristics across a range of viscosities. Additionally, we compute the shear experienced by drugs within these ampoules, and estimate the degree of denaturation that would be expected during a jet injection of these drugs. The model is also used to predict the effects of viscous heating on the formation of the jet. Using infrared imaging, we then seek to experimentally verify the predicted temperature changes arising due to viscous heating.

II. METHODS

A. CFD Simulations

We examined the flow through two nozzle geometries using a commercially-available CFD solver, ANSYS FLUENT. The first geometry was that of a commercially available polycarbonate jet injection ampoule (Injex 30™, Ampoule 1), and the other was of a custom-built stainless-steel ampoule using a commercially available orifice insert (ZMNS-8-M3.5-SS-BN, O’Keefe Controls) (Ampoule 2). For each nozzle, the flow was studied for fluids with Newtonian viscosities ranging from $10^{-3} \text{ Pa} \cdot \text{s}$ to 0.08 Pa·s to determine the flow rate as a function of applied pressure, along with the spatial distribution of shear and turbulence. The properties of glycerol-water solutions were used in preference to those of protein solutions, as glycerol solutions are easier to work with experimentally [21], and provide a conservative estimate of the behavior of protein solutions, which commonly exhibit shear-thinning [22].

1) Nozzle Geometry and Mesh

The nozzle geometries were measured using high-resolution micro-CT scanning (Bruker SkyScan 1172, Bruker microCT, Kontich, Belgium), with the resultant point-clouds smoothed in MeshLab [23] and imported into SolidWorks, as shown in Fig. 1. The model geometry of Ampoule 2 does not include the initial reduction in diameter from the cylinder bore to the interior of the orifice insert, which is a relatively small reduction (2:1) compared to the reduction to the final orifice (16:1). The hexagonal geometry at the entrance to the orifice insert was also ignored, as this is a region with only low-velocity flow.

For each ampoule, we assumed that the physics could be accurately captured using an axisymmetric model, and we fit a 2-D axisymmetric profile to each measured geometry. The profile of Ampoule 1 exhibited 23 µm RMS error between the 2-D profile curve and three 2-D equally spaced wall profiles extracted from the 3-D scan. Although Ampoule 2’s orifice was slightly off-center (~ 10 µm), we assumed that this would have an insignificant effect on the fluid flow. The 2-D profile of Ampoule 2 exhibited 13 µm RMS error. Each axisymmetric model was initially meshed using quadrilateral elements with a minimum size of 0.1 µm, as shown in Fig. 2. Along the ampoule wall, we then applied an inflation layer to the mesh to better capture the wall shear, as shown in the inset. The inflation layer comprised 20 elements between the wall and a parallel boundary 15 µm from the wall, with the elements increasing in size at a ratio of 1.05 between neighboring elements, from the wall to the interior. We refined the mesh in regions that initially suffered from high residuals during the solution. These regions were where the diameter approaches that of the orifice for both ampoules, and where the diameter starts to reduce for Ampoule 2 only (Fig. 2). Within these regions, the elements...
were refined to a size of 2.5 μm and 1.3 μm in the meshes of Ampoule 1 and 2, respectively.

2) CFD Model and Boundary Conditions

Model boundary conditions were defined as indicated on the meshes in Fig. 2. The wall was specified to be adiabatic, so heat would not be transferred across the boundary during an injection. At the left-hand-side of the model, the inlet boundary condition was set to a constant gauge pressure of 10 MPa, and flow constrained to be perpendicular to the inlet. The outlet pressure at the orifice was set to atmospheric pressure. The purple line in the figure indicates the rotational axis of symmetry for the model.

To include the effect of surface roughness, we cut Ampoule 1 in half and used a surface roughness tester (Surfertest SV-2100, Mitotuyo) to measure the roughness height [24]. We found this to be ~1 μm, and used the same roughness for the Ampoule 2 simulation.

Our simulations were performed within ANSYS Workbench, using the FLUENT package. The finite volume method was employed [25], using Menter’s shear stress transport (SST) model [26] to handle turbulence. The structure of this model avoids the sensitivity to inlet turbulence properties and severe pressure gradients characteristic of other models. The solution was considered converged when the RMS average of all residuals had reached a value less than 10⁻⁷.

We simulated the flow of three fluids: water and aqueous solutions of glycerol at 60 %, and 85 % volume fractions, all at a constant gauge pressure of 10 MPa, assuming a smooth profile with no oil-based friction. An estimate of the piston’s dynamic friction coefficient was required to match the applied force of the injector coil to the pressure in the ampoule. We assumed that the friction coefficient of the piston in Ampoule 1 was 0.17, a value consistent with the range given in literature for rubber sliding on polycarbonate [28]–[30]. The friction coefficient of Ampoule 2 was set to 0.11, corresponding to results in the literature for rubber on stainless steel at an injection pressure of 10 MPa, assuming a smooth profile with no oil-based lubrication [31].

### III. Results

#### A. Mesh Independence

A mesh convergence study confirmed that the simulations demonstrated mesh independence (Tables 1 & 2). Water was the fluid used in this convergence study, as the largest variations were observed in the least viscous solutions. For both ampoules, simulation 5 represents the conditions chosen for the remaining analyses. The y⁺ values for these meshes were 0.36 (Ampoule 1) and 0.73 (Ampoule 2). Under these conditions (using an Intel i7-4770 3.4 GHz processor) simulations with Ampoule 1 required less than four hours to converge while Ampoule 2 required less than three hours. Additionally, we confirmed that the jet velocity results were independent of the turbulence intensity at the inlet.

#### B. Jet Velocity Profiles

The axial jet velocity profiles across the width of the orifice outlet are shown for both ampoules in Fig. 3. The simulated jet profile changes shape and decreases in mean jet speed as viscosity is increased. The jet velocity profile for water is similar to plug flow, with high flow gradients near the walls. The Reynolds number (Re) of this flow at the orifice is 24,500 for Ampoule 1 and 22,400 for Ampoule 2. The predicted jet velocity profile of Ampoule 2 is similar, with the addition of a moderately sloped section moving away from the wall. The slope of this section increases as the room temperature (25 °C)

#### TABLE 1 – AMPOULE 1 MESH CONVERGENCE

<table>
<thead>
<tr>
<th>Simulation</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5*</th>
<th>6</th>
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<tr>
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<td>15</td>
<td>12</td>
<td>9</td>
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<td>6</td>
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<tr>
<td>Ref. Element Size (μm)</td>
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<td>6</td>
<td>4</td>
<td>3</td>
<td>2.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Nodes (000’s)</td>
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<td>47.2</td>
<td>65.9</td>
<td>99.4</td>
<td>133</td>
<td>290</td>
</tr>
<tr>
<td>Elements (000’s)</td>
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<td>46.6</td>
<td>65.0</td>
<td>98.3</td>
<td>131</td>
<td>287</td>
</tr>
<tr>
<td>Mean Jet Speed (m·s⁻¹)</td>
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<td>135.3</td>
<td>135.3</td>
<td>135.4</td>
<td>135.4</td>
<td>135.4</td>
</tr>
<tr>
<td>Δvₓ (m·s⁻¹, relative to 6)</td>
<td>0.20</td>
<td>0.17</td>
<td>0.16</td>
<td>0.13</td>
<td>0.12</td>
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#### TABLE 2 – AMPOULE 2 MESH CONVERGENCE

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<th>Simulation</th>
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<th>3</th>
<th>4</th>
<th>5*</th>
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</thead>
<tbody>
<tr>
<td>Max. Element Size (μm)</td>
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<td>15</td>
<td>12</td>
<td>9</td>
<td>6</td>
<td>5.5</td>
</tr>
<tr>
<td>Ref. Element Size (μm)</td>
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<td>2.4</td>
<td>1.9</td>
<td>1.65</td>
<td>1.2</td>
<td>1.1</td>
</tr>
<tr>
<td>Nodes (000’s)</td>
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<td>55.3</td>
<td>78.5</td>
<td>111</td>
<td>199</td>
<td>228</td>
</tr>
<tr>
<td>Elements (000’s)</td>
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<td>54.7</td>
<td>77.8</td>
<td>110</td>
<td>198</td>
<td>227</td>
</tr>
<tr>
<td>Mean Jet Speed (m·s⁻¹)</td>
<td>111.1</td>
<td>113.8</td>
<td>114.3</td>
<td>115.4</td>
<td>116.0</td>
<td>115.9</td>
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<td>2.47</td>
<td>1.90</td>
<td>0.93</td>
<td>0.27</td>
<td>n/a</td>
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</table>
viscosity (RTV) of the fluid is increased from 0.001 Pa·s to 0.08 Pa.

The 85% glycerol jet profile (0.08 Pa·s RTV, Re = 140 (Ampoule 1) and 165 (Ampoule 2)) predicted for both ampoules appears more like laminar flow, but a steep gradient in jet speed remains close to the walls. As the flow is not fully developed at the orifice [32], [33], the flow profile forms an atypical shape.

C. Comparison with Experimental Results

The results from the simulation of both ampoules match well with the measured jet speed for the range of glycerol concentrations with RTV up to 0.08 Pa·s (Fig. 4). The error bars in the measured speeds arise from the uncertainty in estimating the friction coefficient and in measuring the orifice diameter.

D. Flow Fields

The pressure profile presented in Fig. 5A shows that the geometry of Ampoule 1 monotonically reduces the gauge pressure to zero along the approach to the orifice. The pressure maps for water (0.001 Pa·s RTV) and 85% glycerol (0.08 Pa·s RTV) simulations were not significantly different for Ampoule 1. While the pressure profiles were also generally similar across the different fluids for Ampoule 2, the sharp edge produced an area of reduced pressure that is more pronounced with water (Fig. 5B & 5C). The simulated gauge pressure decreases below atmospheric pressure by 12 MPa at the sharp edge with water, and by 6 MPa for 85% glycerol, indicating that cavitation would be expected at this location (Fig. 5B and Fig. 5C).

E. Shear Rate

The results for the shear rate in both ampoules are presented in Table 3. The average peak shear rate is the peak shear that the average particle in the flow would experience. The percentage exposed to high shear rates (defined to be above 10⁷ s⁻¹) is indicative of the percentage of the fluid that would be expected to be damaged during an injection, according to [19]. These metrics of shear rate are all lower with increased viscosity, and for Ampoule 1 relative to Ampoule 2. Color maps showing the shear rates for the flow in Ampoule 2 are presented in Fig. 6; shear is most prominent in the turbulent boundary layers downstream of the sharp corner.

F. Temperature

The model predicts that there will be a significant temperature increase due to viscous heating. This occurs primarily at the walls, as shown in Fig. 7, where a temperature in excess of 55 °C is predicted with 85% glycerol in Ampoule 2. The expected viscosity profile resulting from this heating is also shown in Fig. 7. This demonstrates how viscous heating has the effect of lubricating the fluid through the orifice. A similar level of heating was predicted for 85% glycerol with Ampoule 1, where maximum temperatures in excess of 65 °C were predicted at the walls. Simulations with water predicted relatively modest local temperature increases due to viscous heating (less than 5 °C) in both ampoules.
IV. MEASUREMENT OF JET TEMPERATURE

Given that the model predicts such a significant increase in temperature as a result of viscous heating, which has not been previously reported in the jet injection literature, we sought to verify this result experimentally.

A. Experimental Setup

An infrared camera (Gobi-384, Xenix) was used with an existing jet injection system [34] to obtain an infrared video recording of a jet injection (Fig. 8). The camera recorded at a frame rate of 27 fps over a field of 384 pixel by 288 pixel. Calibration of the thermal image was performed using an external temperature sensor (K-type thermocouple, “80TK thermocouple module”, Fluke) to measure the temperature of a vessel of warm water as it cooled. An emissivity of 0.96 was assumed for the water.

The injection system [34] used the same 200 µm diameter stainless steel orifice and ampoule that has been modelled as Ampoule 2 (ZMNS-8-M3.5-SS-BN, O’Keefe Controls). The injection system differed from that used for the model validation experiments as it was capable of much larger injection volumes (>1 mL) allowing many frames to be taken by the camera over the course of the injection. This system was used to capture seven injections of 85 % glycerol at jet speeds from 50 m/s to 160 m/s.

B. Results

An example frame from the 160 m/s infrared video recording is shown in Fig. 9. This image shows a significant temperature increase in both the orifice and the jet. Within similar images from each of the injections, two areas were manually selected to represent the jet and the orifice. The mean temperature change within these areas was then tracked over the course of the injection to quantify the temporal behaviour of the temperature increase. The resulting temperature change versus time plot for the 160 m/s injection is shown in Fig. 10. This demonstrates that the temperature of the ejected jet was 2 °C to 2.5 °C greater than the ambient temperature, while the orifice increased in temperature during the injection by 6.8 °C. The maximum temperature change of the jet was found for each of the injections and plotted against jet speed in Fig. 11. Here, a positive trend can be observed between the temperature change and jet speed.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Amp. 1 water</th>
<th>Amp. 1 85 % glycerol</th>
<th>Amp. 2 water</th>
<th>Amp. 2 85 % glycerol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. Shear Rate (s⁻¹)</td>
<td>1.1 × 10⁸</td>
<td>3.3 × 10⁷</td>
<td>2.7 × 10⁸</td>
<td>1.8 × 10⁷</td>
</tr>
<tr>
<td>Average Peak Shear Rate (s⁻¹)</td>
<td>1.5 × 10⁶</td>
<td>1.3 × 10⁶</td>
<td>3.3 × 10⁶</td>
<td>7.8 × 10⁵</td>
</tr>
<tr>
<td>% exposed to high shear</td>
<td>3.8</td>
<td>0.9</td>
<td>8.6</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Fig. 5. Visualization of the simulated pressure in response to a 10 MPa pressure applied at the inlet. A: The pressure profile within Ampoule 1, which was consistent across all fluids. B: The pressure profile for Ampoule 2 with water. C: The pressure profile for Ampoule 2 with 85 % glycerol.

Fig. 6. 2-D color map of shear rate near the orifice of the stainless-steel ampoule for two fluids. A: Water. B: 85 % glycerol.

TABLE 3 - SHEAR RATES IN WATER AND 85 % GLYCEROL
V. DISCUSSION

The significant temperature increases resulting from viscous heating that were predicted by the model were experimentally verified using the infrared camera. The model predicted temperatures in excess of 55 °C near the walls of Ampoule 2 as 85 % glycerol was ejected from the orifice, under an inlet pressure of 10 MPa. Based on the temperature profile presented in Fig. 7 we would expect the jet to increase in temperature by an average of 2.8 °C. The infrared camera observed temperature increases of up to 2.5 °C at a jet speed of 150 m/s, while a maximum increase of 1.7 °C was observed at pressure and jet speed comparable to that used in the model (Fig. 11).

This result demonstrates the existence of a phenomenon not previously reported in the jet injection literature. Similar observations have, however, been made in the pipe flow of glycerol [35] and fuel injection literature [36]. We believe that this issue is particularly important for drug formulators. For example, thermoreversible gels [37] are of interest as bases for controlled-release drug formulations. These polymer solutions can exhibit extreme increases in viscosity with temperature; one example, from [38], increases in viscosity by almost 5 orders of magnitude as its temperature is increased from 0 °C - 15 °C. This kind of behavior might pose problems for jet injection, due to the potential for heating to cause an increase in fluid viscosity near the walls of the injection device. However, a detailed understanding of the behavior of complex formulations like these will also require consideration of their non-Newtonian rheology.

The infrared camera setup revealed changes in temperature from 0.5 °C to 2.5 °C, while greater temperatures than this (2.8 °C) were predicted by the model. We believe this discrepancy can likely be explained by the fact the model does not include the effect of heat loss to the ampoule surrounding the fluid. The infrared video shows that the temperature of the stainless-steel ampoule increases by a greater extent than that of the jet itself. This accumulation of heat suggests that including this surrounding material in the model would be required to more accurately predict the temperature changes within the jet. It also indicates that variables such as the shape...
of the ampoule and the thermal properties of this material will influence the heat flux, and thus the temperature changes that occur during a jet injection. These are important areas for further investigation, and raise the interesting question of whether it might be possible to deliberately heat (or cool) the jet as it is formed to achieve some set of desired injection characteristics.

The modeling suggests that the maximum shear rates within both of the ampoules exceed the minimum required level for drug inactivation. The high shear was only evident near the orifice for Ampoule 1, whereas the sharp corner of the profile for Ampoule 2 resulted in the areas of largest shear rate. The results indicate that the smoother profile of Ampoule 1 was beneficial for reducing the shear rate experienced by the fluid. For Ampoule 1, 3.8% of the fluid experienced shear rates greater than 10^7 s^-1, while this value was 8.6% for Ampoule 2. The period of time for which the drug is exposed to high shear is an important determinant of its deactivation, and it has been suggested that the time scale for protein deactivation is minutes [39]. The period that fluid within the jet injector would be exposed to excessive rates of shear as it passes through the orifice is less than 100 ms. Therefore, we do not expect that there would be a significant deactivation of protein during jet injection, an expectation which is in accordance with the results of Hogan et al. [40].

Similarly, the predicted high local temperatures (>65 °C for Ampoule 1, and >55 °C for Ampoule 2) near the wall during viscous injections might cause concern for protein stability, as many proteins are susceptible to irreversible denaturation at temperatures over 40 °C. However, during a jet injection these conditions are only applied for milliseconds at most. The thermodynamics of protein unfolding have been shown [41] to be unchanged from time scales of nanoseconds to hours; on this basis, the Arrhenius equation shows that proteins with appreciable room-temperature stability will be unharmed by this brief temperature spike. For instance, given a protein with a low unfolding activation energy (125 kJ/mol) [42], the inactivation rate will increase from 1 hr^-1 to 0.1 s^-1 as the temperature is increased from 37 °C to 80 °C, corresponding to negligible degradation during an injection.

VI. CONCLUSIONS

The simulation results indicate that viscous heat generation is a significant factor in determining the jet speed achieved by a viscous fluid in a jet injector. The extent of this effect, and the resulting temperature increase, has not previously been reported in the context of jet injection. The models indicate that 85% glycerol, subjected to a 10 MPa inlet pressure, will increase to temperatures in excess of 65 °C at the walls of the orifice (an average increase of 2.8 °C across the entire jet). We were able to experimentally verify the predicted temperature increase of the jet using an infrared camera. Our system recorded that the average temperature of the jet increased by up to 2.5 °C during a jet injection.

These findings indicate that it will be crucial to profile the temperature dependence of a drug’s viscosity in order to predict its ability to pierce the skin. This property should be considered, along with any non-Newtonian behavior, when formulating drug solutions for jet injection. Additional experiments with different fluids, orifices, and jet speeds are required to provide further information about viscous heating in jet injection.

VII. REFERENCES


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