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Experimental Analysis of the Performance of an Air-Powered Needle-free Liquid Jet Injector*

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Abstract— **An experimental study was performed using a custom-built air-powered needle-free injector to investigate the various injector parameters governing the dynamics of jet injection. A parametric study using five different nozzle sizes at driver pressure ranging from 4 to 8 bar was carried out. The fluid stagnation pressure of the liquid jet was determined using a Honeywell force sensor. Performance plots as a function of various parameters were constructed. It was determined that as the driver pressure increased both the peak and average stagnation pressure increased almost linearly within the operating range considered. Varying the injection nozzle diameter, whilst keeping the driver pressure constant did not have any significant impact on the peak or average stagnation pressure. The chamber length was also varied and no significant influence was found on peak or average stagnation pressure.**

I. Introduction

Needle-free injections have long been a topic of interest in the scientific community. This concept represents alternate techniques to effectively deliver medication to the different layers of skin other than traditional drug delivery using hypodermic needles [1, 2]. Among different methods of needle-free drug delivery is the liquid jet injector in which a force generated from a power source is imparted on a cylinder which forces a column of fluid containing a drug through a nozzle, where it exits as a high-speed small diameter liquid jet of sufficient pressure penetrating the skin and delivering the appropriate amount of medication. Studies have shown that commercially available injectors produce exit jet velocities greater than 100 m/s with diameters ranging from 100 to 360 μm, and initial pressure changes of 275 bar within 0.5 ms [1-4]. Typical delivery rates for commercial injectors range from 0.1 to 1 ml, with a penetration depth of up to 10 mm. At these depths it is possible to breach subcutaneous layers of the dermis and administer drugs to muscular tissues [1-3]. Needle-free liquid jet injectors are classified by their power source, many use a spring to activate the fluid, and others employ a disposal gas cartridge [4]. More recently, Lorenz-force [5-7] and piezoelectric actuators [8] have been studied as state-of-art needle-free injection devices.

To resolve problems encountered with the early use of liquid jet injectors such as pain, bruising, hematomas, incomplete delivery of medication, excessive penetration and cross contamination [9-12], much research has been conducted on improving their performance by analyzing the mechanics of jet injection and assessing different parameters of the jet injection device for optimal performance [13-14]. Experimentally, Schramm-Baxter and Mitragotri performed a series of investigations using a spring-based jet injector and analyzed the effect of jet parameters on jet injection. For example, by varying the nozzle diameter, a correlation between jet power of the fluid jet and injection penetration as well as dispersion were developed in their work [15-18]. An equivalent parametric study was also performed recently using a controllable jet injection device powered by Lorenz-force effect [19].

The majority of engineering studies analyzed spring powered injectors or focused on the development of Lorenz force injectors, the results therefore cannot readily be extrapolated for air-powered injectors, which is the main focus of this work. This type of needle-free injector utilizes a compressed air source or similarly a disposable gas cartridge usually filled with CO_2. The high-pressure gas chamber is actuated by means of a valve mechanism which is usually triggered by a button on the injector body. Such injectors can maintain a relatively constant injection pressure and hence provide the ability for the resulting jet to penetrate deeper into the skin and deliver larger quantities of medication. In fact, air or gas-powered injectors are commercially available and constantly improved by manufacturers [4]. In this light, an experimental investigation was carried out in this study to further understand the injection dynamics for these devices. A parametric study was performed to assess the effect of injector design parameters, including the driver pressure, the nozzle diameter and the liquid column length on the stagnation pressure and velocity, which are the main jet characteristics governing the injection.

II. Materials and Methods

In order to assess different design parameters governing the performance of air-powered needle-free injectors, a prototype injector was designed and built to perform a parametric study. The present prototype injector was designed such that it is representative of the vast majority of commercially available injectors utilizing a similar power source, propelling the medication in a similar fashion as well as maintaining consistent jet speeds and diameters. Typical commercially available needle-free injection systems that utilize an air or other gas power source are capable of accelerating a volume of 0.5 ml or less to speeds of up to 200 m/s. Generally, jet stagnation pressures of 15 MPa are required in order to penetrate the skin [14]. The design of a prototype injector was made based on these standard values

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and the injector constructed for this experiment makes it possible to vary a number of parameters which are fixed on commercially available units. This allows it to verify the relationships between these parameters and the injector's effectiveness in delivering an injection. Figure 1 illustrates the design of the injector used throughout this study.

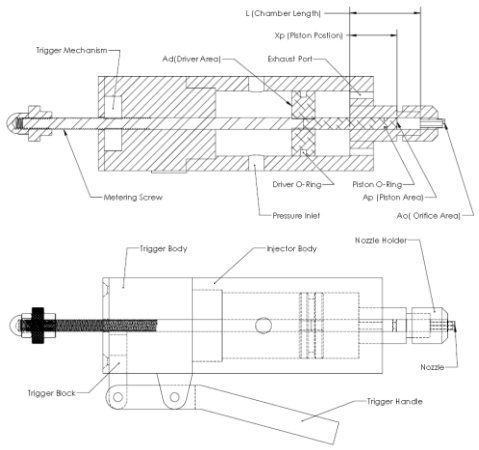

Figure 1. A technical drawing of the air-powered injector prototype.

In order to produce an injection it is first necessary to set the desired injection volume by adjusting the metering screw, this will determine the injection chamber length L. The injection chamber was filled with the desired liquid and the nozzle was threaded on to the tip sealing the chamber. The driver chamber can then be pressurized to a desired pressure. It is important to note that during pressurization the driver and the injection piston will not move. This is due to the design of the trigger mechanism, which consists of a partially threaded rod that links both the driver and the injection piston. The trigger block, locks on to the threads of the metering screw during pressurization, holding the entire injection assembly in place. Once the chamber is fully pressurized and the injection is to be administered the trigger handle is depressed, thereby disengaging the trigger block from the metering screw, allowing both the driver and the injection piston to move forward and create a high speed jet. The injector was able to create a high speed jet by utilizing the area ratio between the driver and the plunger. In order to size the prototypes so that it can simulate the behavior of commercially available injectors, the stagnation pressure necessary to penetrate skin was first prescribed. A stagnation pressures up to 25 MPa on jet diameters of up to 200 µm was chosen for this design. The sizing was accomplished by computing the force required to produce the necessary pressure on the area of the plunger as well as determining the maximum pressure that can be obtained from readily available compressed air. Knowing the driver pressure p_D and the jet stagnation pressure p_o then makes it possible to determine an area ratio between the driver A_D and the plunger A_p in order to produce a high speed jet capable of penetrating human tissue. Although typical gas-powered injectors utilize nitrogen cartridges, they were not used during this study, due to the elevated quantity of injections to be performed. An air compressor enables repeated charging of the injector, without the added cost of nitrogen filled cartridges.

$$\frac{A_D}{A_P} = \frac{p_{o_{jet}}}{p_D} \tag{1}$$

Using (1), it was possible to estimate the area ratio for the injector used in this study. The area of the plunger was pre-determined due to machining limitations. Consequently, the plunger has a diameter of 6.35 mm, which yields an area of 3.166×10^{-5} m^2, and this implies that a maximum pressure of 20 MPa would result in a force of 650 N. The maximum pressure available to drive the injector measures 800 kPa, and it must produce a force greater than 650 N, thereby resulting in a driver area greater than 8.125×10^{-4}m^2. The friction forces generated by the seals as well as the damping force of the fluid also have to be considered, consequently, the area ratio was increased from 25 which results when no losses are considered to 30. Table I illustrates the important design characteristics of the injector.

TABLE I. VALUES OF VARIOUS INJECTOR PARAMETERS

Injector Parameters	
Nozzle Diameter	100 µm - 260 µm
Driver Pressure	3 bar - 10 bar
Injection Volume	0 ml - 1.2 ml
Piston Diameter	6.35 mm
Driver Diameter	38.1 mm
Mass of Piston-Driver Assembly)	80 g

The above dimension makes it possible to construct a prototype capable of penetrating skin as illustrated by Fig. 2. These figures demonstrate qualitatively the penetration capability of the jet at three different driver pressures, into bloom 250 ballistics gel that was formulated at a 10% wt. ratio in order to mimic muscle tissue. The jet was also photographed using a high-speed camera PCO.1200hs and the velocity determined from the images was within the same range exhibited by commercially available units.

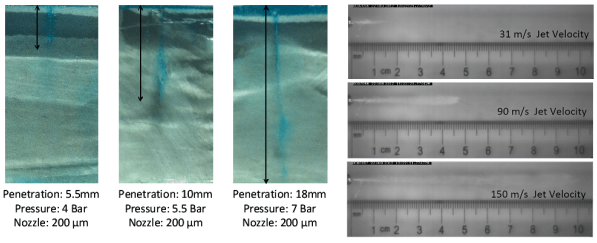

Figure 2. Sample pictures showing a) the jet penetration generated by the air-powered injector into the ballistic gel; and b) jet as it existed the nozzle.

A parametric study was performed to verify the effect of various parameters on the injector performance. Among different performance indicators, the stagnation pressure is one of the fundamental measurements in this study as it determines the force at which the liquid jet will penetrate the skin. Consequently, tracking the variation of the stagnation pressure as a function of time over the injection interval, will determine if the jet emanating from the injector is strong

enough to deliver the medication. This will also determine which depths and type of tissue the injector can target. A few specific parameters that can be varied and control the stagnation pressure level are: the driver pressure, nozzle diameter and injection volume. In this study, five different nozzle sizes were used ranging from 120 to 250 μm (O'keefe Controls Co.) manufactured from stainless steel with a precision of 0.00254 mm. The driver pressure considered in this work ranged from 4 to 8 bar provided by an air compressor fitted with a precision regulator. Individual nozzle and pressure combinations were tested a minimum of twenty times in order to ensure consistent and reliable results. Furthermore, it was noted that varying the amount of injection volume did not directly influence the stagnation pressure of the jet, rather it governed the time duration of the injection. As a result, the injection volume was kept constant with a value of 0.1 ml throughout the experiments.

To obtain individual pressure traces of jet stagnation pressures for each experimental condition, the injector chamber volume was first adjusted to the desired volume to be delivered. The liquid to be delivered was then loaded into the chamber by a syringe. This step ensures that air pockets are not trapped in the column. Once the chamber was filled the orifice was then threaded in place. The injector assembly was then positioned within a steel vise, with a stopper for proper repositioning. This ensures precise positioning of the jet relative to the diagnostics (see Fig. 3). The stagnation pressures in this experiment was determined using a Honeywell (FSG15N1A) force sensor, which has a range from 0 to 1500 g and a response time of 0.1 ms. Calibration was conducted by imposing known weights and plotting the voltage response of the transducer. Once the force readings are obtained it is then possible to convert these into stagnation pressure by dividing them by the area of the jet. The force transducer was also coupled to a signal amplifier which imposes a gain of 20 on the output voltage, monitored by a Rigol 100 MHz DS1102E digital oscilloscope. The injection process was tracked over the first 5 ms.

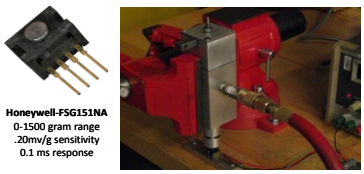

Figure 3. A photo showing the experimental setup and diagnostics.

III. Results and Discussion

Figure 4 depicts one experimental result whereby a 200 micron nozzle injects 0.1 ml of fluid driven at 413 kPa. There is a pressure peak and the pressure oscillates about a mean injection pressure. Previous studies demonstrated that it is this peak which is important in the formation of a fracture in the skin and the subsequent average delivery pressure determines the depth at which the medication is delivered [14, 20, 21]. The magnitude of the peak pressure and average pressure agree with general results obtained from literature [20]. The rise time to peak pressure and subsequent stabilization to the average pressure occurred very rapidly. The rise to peak in most of the studied cases took place within 0.75 ms and the stabilization to the mean pressure was within the same time frame.

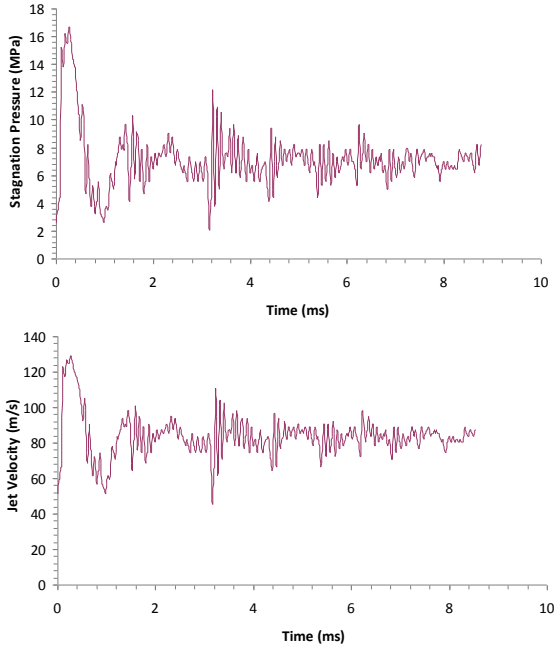

Figure 4. Time evolution of stagnation pressure and jet velocity using a 200μm nozzle and driver pressure p_D = 413 kPa.

Figure 4 indicates oscillatory dynamics in the pressure measurement. A number of experiments conducted also exhibited more drastic fluctuations in frequency whilst others did not oscillate and stabilized immediately after the peak to a mean value. It is suspected that this behavior is caused by the pressure transducer not sensing small changes as quickly as the injection progresses. Although it has a response time of 0.1 ms, the sensitivity of the device makes it difficult to acquire both rapid and minute pressure changes. In general, similar pressure evolution was obtained with increasing driver pressures. In practice, only the average and peak pressure is of significance in determining the performance of the device as well as the penetration, consequently, predicting the oscillatory behavior is of lesser importance. Figure 4 also shows the corresponding velocity profile computed from the Bernoulli's equation using the values of stagnation pressure. It is possible to note that the peak velocity also corresponds with the 150 - 200 m/s range described in literature [1-4].

A parametric study of all injector nozzle sizes as well as different operating pressures was performed. Figure 5 depicts both peak and average stagnation pressure obtained from 5 different nozzles and 4 different driver pressures. Error bars for the 95% confidence interval are included; average standard deviations were +/-1.772 and +/-1.019 MPa for peak and stagnation pressure, respectively. Both pressure values appear to increase almost linearly with driver pressure. These results also illustrate another very important notion. The peak pressure for different nozzle at constant driver pressures seems to approach the same value. This can be explained by analyzing the system in terms of energy. Although the area of the nozzle exit is varied, the area of the plunger remains the same which means the total energy

imposed on the fluid for a given driver pressure remains the same irrespective of the exit nozzle area. If fluid damping is not present in the system then one would expect much higher velocities for smaller nozzle areas. However, fluid damping in the system causes there to be more energy dissipation for smaller nozzles due to the force required to push the fluid through a smaller exit area. Consequently, roughly the same stagnation pressure was obtained for the tested nozzles.

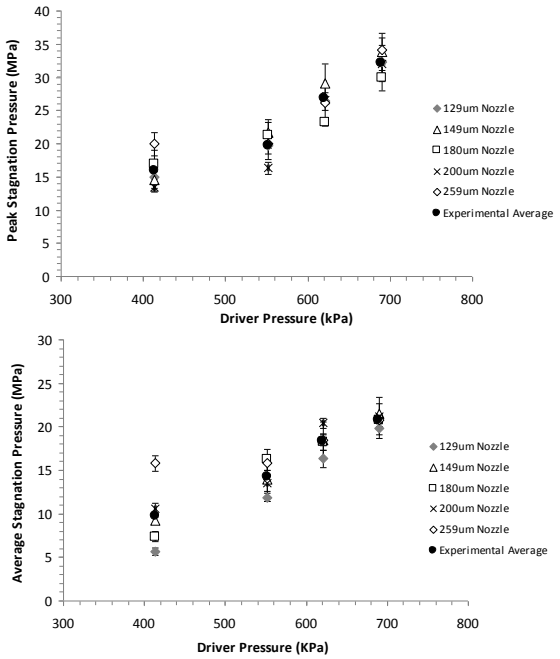

Figure 5. Peak and average stagnation pressures for the five different nozzle sizes operating at four different driver pressures.

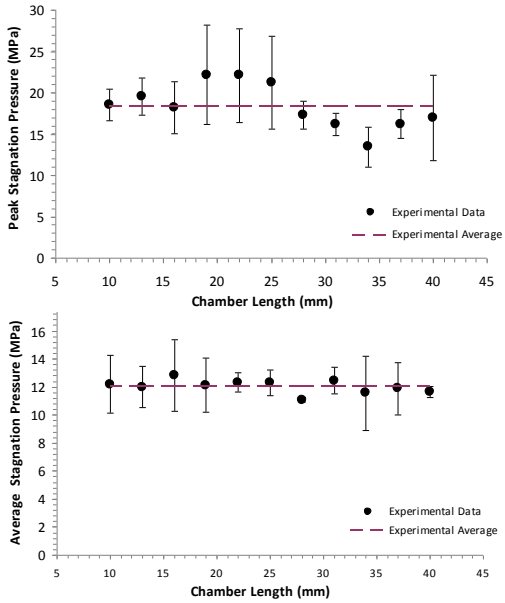

Figure 6. Peak and average stagnation pressures obtained for different chamber lengths of the injector with a 129 µm nozzle and p_D = 575 kPa.

The experimental data also confirmed that the liquid column filled inside the injector does not play a significant role in impacting the peak or average stagnation pressure. Rather it seems that it affects mostly the period over which the damping occurs.

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