Proceedings of the 28th IEEE
EMBS Annual International Conference
New York City, USA, Aug 30-Sept 3, 2006

A Portable Needle-free Jet Injector Based on a Custom High Power-density Voice-coil Actuator

Andrew J. Taberner, Nathan B. Ball, N. Catherine Hogan, Ian W. Hunter

Abstract—**We have constructed a portable needle-free drug injection (NFI) device based upon a custom voice-coil linear actuator. Our actuator is optimized to provide high instantaneous force (> 200 N) and power (4 kW) while still allowing a total stroke of 25 mm. The actuator is relatively inexpensive, compact, and lightweight, allowing it to serve as the force generator in a portable, reusable, handheld NFI system. The actuator is capable of accelerating liquid drug in quantities of up to 250 µL to a speed of more than 200 ms^{-1}. The repeatability of a 50 µL volume ejection is better than ± 1 µL.**

I. Introduction

Needle-free delivery of a liquid drug can be achieved by pressurizing the drug and rapidly ejecting it through a narrow orifice, thereby creating a high speed jet which can readily penetrate skin and underlying tissue. Typically, this technique requires a pressure of 10 to 60 MPa to be developed on the drug over a few milliseconds, and then maintained for up to 100 ms.

Needle-free drug delivery has several advantages over needle-based delivery, particularly when many successive injections are required or injection discomfort is a major concern. However, in order for NFI devices to become ubiquitous, they need to be controllable, repeatable, portable, and inexpensive.

Until very recently, most of the portable devices developed for jet injection have relied on springs [1] or compressed gases [2]-[4] to store and then rapidly release energy in order to create the high pressures required. A major drawback of these energy storage and delivery methods is that they allow very little control of the pressure applied to the drug during the time course of injection. However, recent studies have proposed that the pressure time-course (pressure profile) has an important effect on the quantity and depth of drug delivery [5], [6].

Manuscript received April 3, 2006. This work was supported in part by Norwood Abbey, Inc. of Victoria, Australia.

A. J. Taberner is a Research Scientist with the Bioinstrumentation Lab, Mechanical Engineering Department, Massachusetts Institute of Technology, Cambridge, MA02139.
(phone 617 324 6052, e-mail: taberner@mit.edu)

N. C. Hogan is a Research Associate with the Bioinstrumentation Lab, Mechanical Engineering Department, Massachusetts Institute of Technology, Cambridge, MA02139. (e-mail: hog@mit.edu)

N. B. Ball is a Masters candidate with the Bioinstrumentation Lab, Mechanical Engineering Department, Massachusetts Institute of Technology, Cambridge, MA02139. (email: nball@mit.edu)

I. W. Hunter is Hatsopoulos Professor of Mechanical Engineering and Director of the Bioinstrumentation Laboratory, Massachusetts Institute of Technology, Cambridge, MA02139. (email: ihunter@mit.edu)

An alternative, superior approach to jet drug delivery is to store energy in electrical form, and impose a time-varying pressure-profile on the drug volume through the use of a monitored and servo-controlled electromechanical actuator [7]. Monitoring force, pressure, or delivered drug volume allows the time course and volume of drug delivery to be tightly defined, and controlled in real-time.

Linear Lorentz-force (voice-coil) actuators are a form of electromechanical motor that can generate the high force, pressure, and stroke length required for jet drug delivery. Their inherent bi-directionality allows the applied pressure to be controlled and even reversed when necessary. However, commercially available voice-coil actuators that meet the power demands of this application are typically too large, heavy and expensive to be appropriate for a portable hand-held NFI device.

With the recent advent of comparatively inexpensive high energy density rare-earth magnets (Nd-Fe-B) it is now possible to construct quite compact, yet sufficiently powerful voice coil actuators for jet drug delivery. Additionally, high energy and power density capacitors allow sufficient energy to be locally stored and delivered rapidly to effect a needle-free injection in a portable, handheld device.

Fig. 1. Hand-held needle-free injector; recharging dock.

In this paper we discuss the design and performance of a portable NFI system based on a custom voice-coil actuator.

Our portable system, with a mass of about 0.5 kg, is recharged from either a battery powered dock (~90 s recharge time) or a high voltage supply (~1 s recharge time) and provides a single injection per recharge. A second, computer-controlled bench-top device is used as a test-bed for evaluating drug and device performance.

II. Design

The portable NFI delivery device consists of a disposable commercially-available 300 µl NFI ampule (Injex™ Ampule, part# 100100) attached directly to a custom-designed moving-coil Lorentz force actuator.

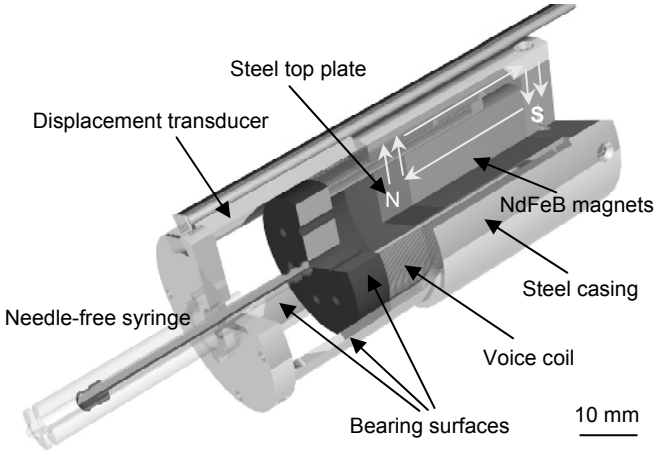

Fig. 2. Cut-away view of NFI linear actuator.

The syringe is screwed into the front plate of the NFI device, and the syringe piston is captured by a snap-fitting on the front of the moving coil. Drug can then be gently drawn into the syringe by the motor, from a vial, with the aid of a vial adapter (Injex™ vial adaptor, part# 200203.) Alternatively, the syringe can be pre-filled or manually filled prior to loading into the device. The orifice at the tip of the syringe has a diameter of 165 µm; the piston diameter is 3.16 mm.

The moving voice coil consists of 582 turns of 360 µm diameter enameled copper wire wound (using a custom-made coil winding machine) six layers deep on a thin-walled former. The voice-coil former is machined from Acetal copolymer (rather than a metal such as aluminum) in order to minimize the moving mass (~50 g), and to avoid the drag caused by induced eddy currents in a conducting former. The total DC resistance of the coil is 11.3 Ω.

As the voice coil moves in the motor, it slides freely and smoothly on the inside of the same steel extrusion from which the magnetic circuit is constructed. This approach obviates the need for the extra size and length of a separate linear bearing. Holes in the rear of the casing allow air to escape freely.

Flexible electrical connections are made to the moving coil by means of plastic-laminated copper ribbons. The position of the voice coil actuator is monitored by a 10 kΩ linear potentiometer with > 1 kHz bandwidth.

The magnetic circuit (Fig. 3) consists of two 0.4 MN/m^2 (50 MGOe) NdFeB magnets inserted into a 1026 carbon-steel casing. Care was taken in this design to avoid stray magnetic field leaking from the device due to magnetic flux saturation in the steel. The magnetic flux density B in the field gap was approximately 0.6 T.

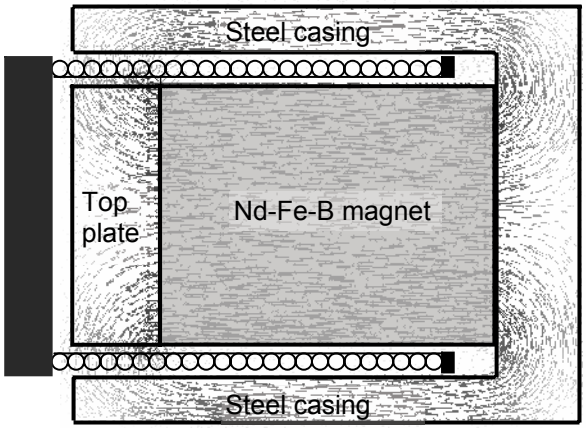

Fig. 3. Magnetic finite element model of NFI linear actuator.

In our portable NFI device, the voice coil motor is energized from a low inductance electrolytic capacitor. The bench-top test system is driven by a 4 kW linear power amplifier, controlled by a PC-based data acquisition and control system running in National Instruments Labview™ 7.1. This approach readily allows for a variety of voltage waveforms to be tested on the device, while its current and displacement performance is monitored and recorded.

III. Results

The performance of our jet injector voice-coil motor has been quantified by measuring its frequency response, step response and its open-loop repeatability. Additionally we confirmed its efficacy by injecting red dye into post-mortem guinea-pig tissue.

A. Frequency response

The frequency dependent properties of the voice-coil motor can be quantified in terms of the magnitude of its electrical and electro-mechanical admittance (Fig. 4). The electrical admittance (formed by the series resistance and inductance of the voice coil) is approximately that of a first order R-L filter (R = 11.3 Ω, L = 4.6 mH) with a cut-off frequency of approximately 400 Hz. The no-load

electromechanical admittance (velocity per unit of sinusoidal current) provides a measure of the voice coil motor's responsiveness to driving current.

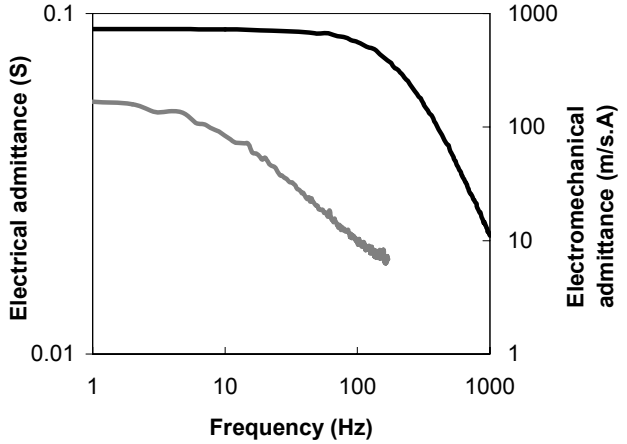

Fig. 4. Magnitude of the electrical admittance (black) and electromechanical admittance (gray) frequency response.

B. Step response

The force sensitivity of a voice coil motor quantifies the relationship between voice coil current and developed force. For a pure Lorentz-force motor, force sensitivity is the product of the magnetic flux density and the total length of coil in the magnetic field. Our voice coil motor has a force sensitivity of 10.8 ± 0.5 N/A averaged along the length of its stroke, reaching a peak of 11.5 N/A at mid-stroke.

By applying a brief 200 V potential to the voice coil, more than 200 N of force can be imposed upon the syringe piston. This generates fluid pressure of ~20 MPa (comparable to that generated by conventional, commercially-available jet injectors) which is sufficient to effect jet injection of a 250 μL volume of drug (Fig 5). The instantaneous power consumed by the voice coil under these conditions is 4 kW, but because the injection is completed in a mere 50 ms, there is negligible heating of the coil (<10 °C).

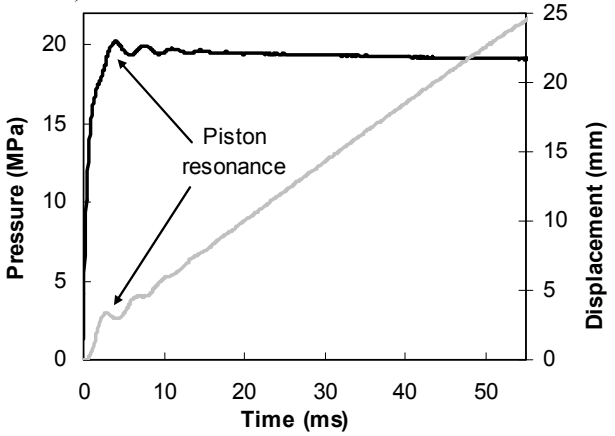

Fig. 5. Pressure (black) and displacement (gray) step response during a 250 μL injection.

The electrical time constant of the voice coil current is 0.4 ms. As the current increases, force rapidly develops on the piston, compressing the rubber tip against the fluid, and accelerating the fluid through the orifice. The resonance of the rubber piston tip decays after a few milliseconds, and the piston reaches a steady state velocity which appears to be mostly determined by the mechanics of the fluid flow through the orifice. Bernoulli's equation for inviscid, steady, incompressible flow gives the relationship between velocity and pressure as:

$$v = \sqrt{\frac{2P}{\rho}} \tag{1}$$

By taking repeated voltage step response measurements (increasing the voltage step in 10 V increments up to 200 V) and fitting to the steady state piston velocity (t > 20 ms), the steady-state jet velocity was computed and then plotted against pressure (Fig. 6). Figure 6 confirms the modeled predictions of Equation (1) and demonstrates that our device is capable of generating the jet velocities that are required for effective jet delivery.

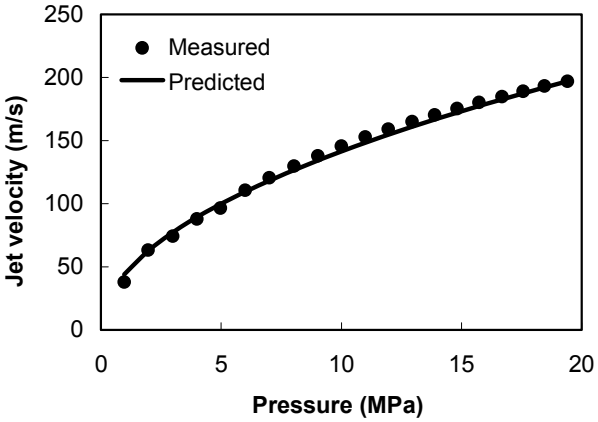

Fig. 6. Measured and predicted (Equation 1) jet velocity.

C. Repeatability

The open-loop repeatability of the NFI system was tested by using a shaped voltage waveform to eject a nominal volume of 50 μl. The voltage waveform consisted of an initial pulse (180 V, 3 ms) to penetrate the skin surface, followed by a follow-through pulse (20V, 30 ms) to obtain the total required volume of delivery. The device was fired four times per syringe refill, 100 times in total. The current and displacement waveforms (averaged over 100 repetitions) are shown in Fig. 7.

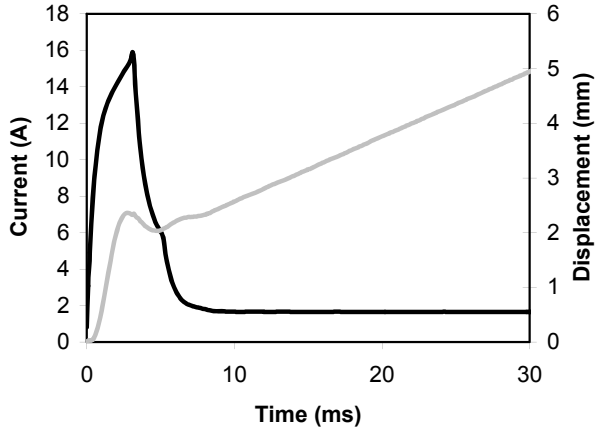

Fig. 7**.** Current (black) and displacement (gray) responses for 50 µL delivery.

Using this waveform, the volume of fluid delivered per shot was 50.9 ± 1 µL (mean ± sd, n=100). This repeatability is similar to that claimed by commercial jet injectors, and could be further enhanced through the used of closed-loop position control.

D. Drug delivery

The efficacy of the device for drug delivery was tested in the following manner. A voltage waveform was designed (140 V, 1.5 ms, followed by 20 V, 10 ms) to eject a nominal 10 µL quantity of fluid. Upon establishing the repeatability of the ejected volume, the bench-top device was used to inject red tissue marking dye (Polysciences Inc, Warrington, PA) into post-mortem guinea-pig skin. The tissue was then counterstained with Mayer's Hematoxylin (DakoCytomation, Glostrup, Denmark). Figure 8 contrasts non-injected and injected tissue showing that during this delivery, the injected dye has reached the targeted lower dermis.

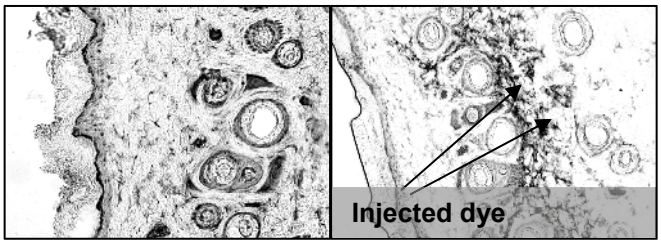

Fig.8**.** Photomicrographs of 10 µm guinea pig cryosections: before (left panel) and after (right panel) injection with marking dye.

IV. FUTURE DIRECTIONS

A significant advantage offered by the voice-coil motor used in this device is the ability to servo-control the motor force, pressure or displacement in real time. This would allow real-time feedback control of pressure and volume of drug delivery, and would permit the device to tailor delivery to the drug type or injection site. To this end, we are developing a closed-loop control system consisting of a compact switching amplifier controlled by a microprocessor. This system will be embedded in future versions of our handheld device. Furthermore, the addition of a force transducer to the moving coil could allow the device to be used as a dynamic material analyzer. Non-linear system identification techniques could be used to interrogate the properties of the tissue prior to injection, allowing the device to customize an injection waveform appropriately for the tissue.

ACKNOWLEDGEMENT

The authors wish to thank Brian Hemond and Dawn Wendell for their valuable advice during the design and development of this device.

REFERENCES

[1] J. S. Parsons, "Needleless hypodermic jet injector" U.S. Patent 5704911, January 6, 1998.

[2] T. P. Castellano, "Modular gas-pressured needle-less injector," U.S. Patent 6,613,010, September 2, 2003.

[3] E. C. Cohen, "Vacuum compression injector," U.S. Patent 4,403,609, February 24, 1981.

[4] S .J. Lilley, H. F. Taylor, D. R. Theobald, C. J. Carlson, D. I. Rosen, "Medical injection system and method, gas spring thereof and launching device using gas spring," U.S. Patent 5599302, February 4, 1997.

[5] D. M. Wendell, B. D. Hemond, N. C. Hogan, A. J. Taberner, I. W. Hunter, "The effect of jet parameters on jet injection" *Proceedings of the 28th Annual Conference of the IEEE EMBS2006*, submitted for publication.

[6] O. A. Shergold, N. A. Fleck, T. S. King, "The penetration of a soft solid by a liquid jet, with application to the administration of a needle-free injection,"*J. Biomech.*, in press.

[7] C. N. McKinnon Jr, J. T. Potter, K. Mattocks, "Electrically powered jet injector," US Patent 5505697, April 9, 1996.