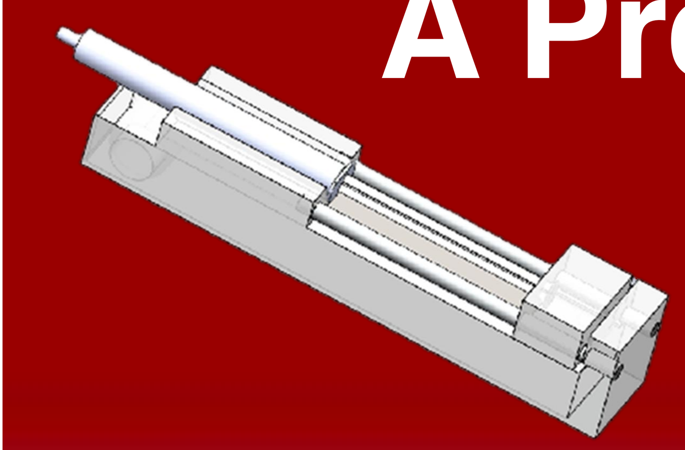

A Precise Handheld Injection Device for Cardiac Interventions

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Abstract

Our client is studying the restoration of function to cardiac muscle cells after myocardial infarction via the injection of stem cells directly into the heart. The current protocol calls for the manual injection of stem cells through a syringe and catheter system. Manual injection leads to inaccuracy due to human error through changes in pressure which compromises the viability of the cells. We are to design a constant force device to safely deliver the cells to their end location.

Motivation and Background

Our client, Dr. Amish Raval, researches how stem cells can restore cardiac function. He is concerned about the consistency of data due to the current manual injection process involving a stopwatch to inject 200μL over a 15-30s time period. Human variability causes changes in injection pressure, which causes shear stress on the cells, presumably compromising the viability of the cells. Another problem with human variability arises when comparing results from test to test as well as with other labs. Dr. Raval has asked our team to design an injection device that will produce more reliable results by being able to consider the injection pressure as an experimental control.

Existing Devices

Figure 1 – The SpringFusor, a spring-driven infusion pump. The flow rate is controlled by microbore tubing of fixed diameters. As seen in Figure 2, the mean flow rate decreases by as much as 20% through the injection process, increasing the shear stress on the cells.
Figure 3 – NE-300 "Just infusion" Syringe Pump. This is the most inexpensive electronic option that was found ($275). It is not able to be sterilized and is too bulky (1.63kg) for our client to use in the tight operating space. Finally, electronic options such as this are rate-controlled and thus have no way to limit or monitor the force on the syringe head.

Figure 1

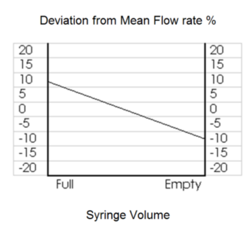

Figure 2

Figure 3

Client Requirements

- Small handheld device
- Disposable
- Simple operation
- Injects at constant, preset rate and pressure

- Low cost to manufacture
- Portable/cordless
- Maintains cell functioning

Final Design

The final design is a mechanical system. The injection is controlled by the release of a constant force spring and the body of the device is constructed out of high density polyethylene. The top block contains a groove in which the syringe can fit into. Once the syringe is loaded, the back block can be adjusted as it slides along the two dowels and can be stopped at the appropriate loading position by tightening the screw. The spring is loaded in a hole in the base block and is wrapped around a dowel. The spring is then fed along a groove in the base block under the syringe and is screwed to the bottom of the moving block. Once the setup is ready for injection, releasing the screw allows the spring to pull the block forward, pressing on the syringe at a constant force.

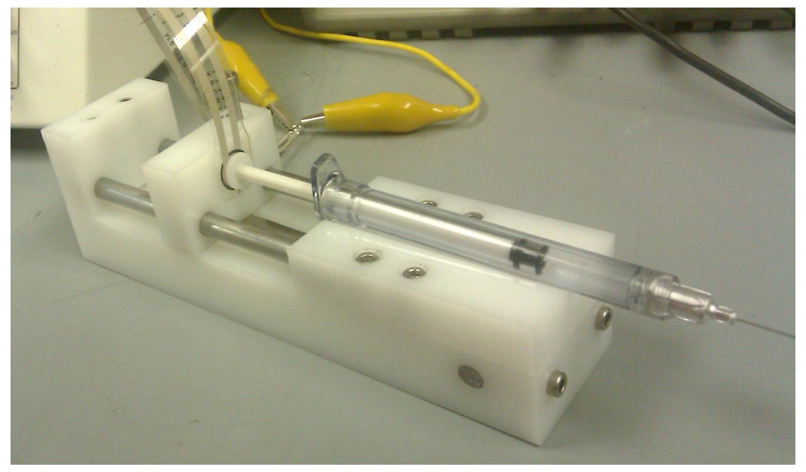

Figure 4: Final design

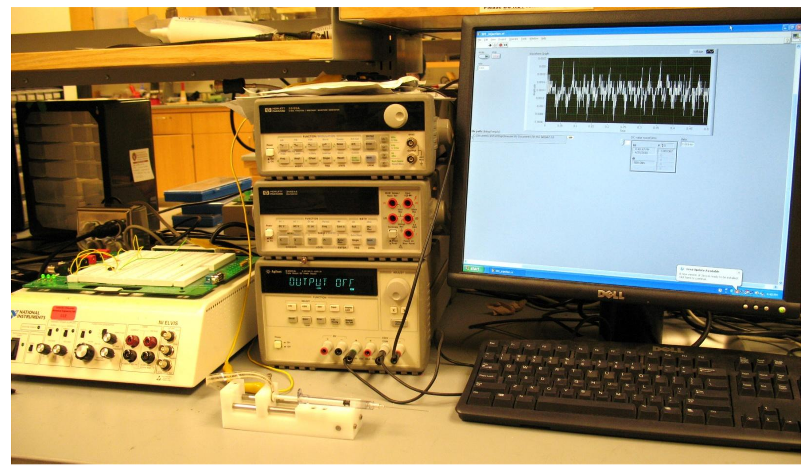

Figure 5: Testing setup

Testing

•Flexiforce™ force sensors were used to measure the force that was applied at the top of the syringe (figure 7).
•Testing was performed with the smallest and largest constant force springs under the conditions in table 1.
•Proved that the final block design was able to exert a constant force on the syringe head.
•Variability in the Flexiforce™ sensor made it impossible to calculate the magnitude of the actual force.

Test	Volume (μL)	Injected Into	Spring Force (lb)	Time (sec)
1a	100	Air	0.44	100
1b	100	Stopper	0.44	30
2a	100	Air	0.66	31
2b	100	Stopper	0.66	30

Table 1: Preliminary testing conditions and injection times

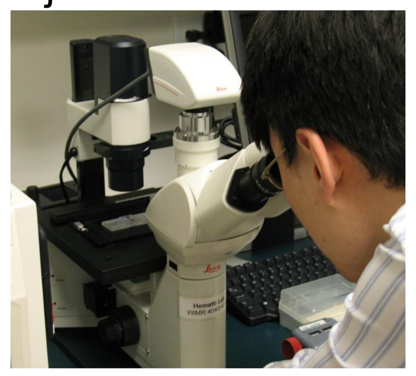

Figure 6: Cell viability counting

Voltage vs. time for H_2O through catheter

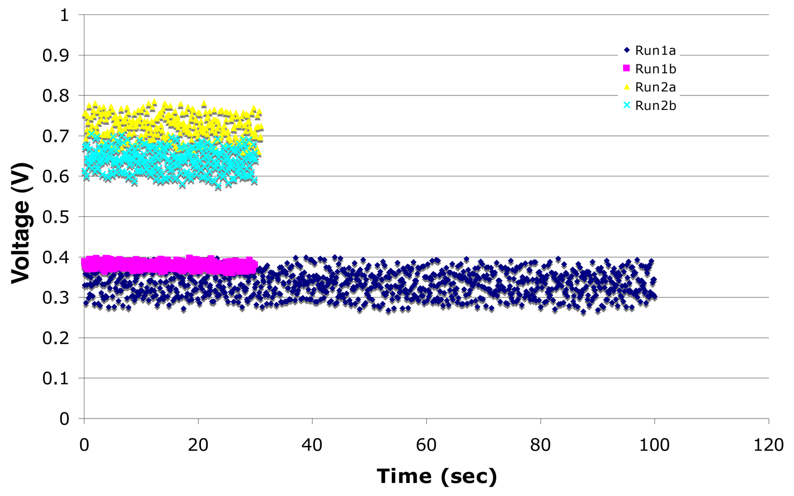

Figure 7: Preliminary Flexiforce™ data

Cell Viability Testing

-Cells were subjected to two kinds of forces:
  -Pressure (when injected into rubber stopper)
  -Shear stress (through catheter)
-Proved that the design maintained cell viability over a range of injection rates. Starting with a cell sample with 90% viability, all of our test runs ended with 85% or greater viability.
-Further testing is needed to determine the relationship between injection rate, pressure and overall cell function.

Test	Volume (μL)	Injected Into	Spring Force (lb)	Time (sec)	Starting Viability	Ending Viability
1	750	Air	0.44	300	90%	90%
2	750	Stopper	0.44	300	90%	88%
3	750	Air	0.66	105	90%	85%
4	750	Stopper	0.66	300	90%	86%
5	550	Air	by hand	70	90%	89%

Table 2: Cell viability data

Budget

-Products from McMaster Carr for production & testing: springs, force sensors, polyethylene, and Springfusor = $286.05
-Production of 1 device: HDPE = $5, hardware = $2, spring = $6
→ Total = $13 *
*Note: mass production could lower unit cost

Future Work

-Testing to match specific spring force for desired flow rate
-Make device smaller and more compact
-Apply for patent
-Create stem cell injection kit

Acknowledgements

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