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Automatic Intramyocardial Stem Cell Injection Device

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Treating heart failure by injecting mesenchymal stem cells (MSC) into the myocardium via an injection device and a needle-tipped catheter is a novel approach that can improve quality of life. The procedure is currently performed manually (10 - 14 sequential injections), so MSCs are delivered into the myocardium at an uncontrolled flow rate with susceptibility to rapid injections that reduce cell retention in the myocardium and induce cell reflux and damage. While slower injection rates improve cell retention, they incite operator hand fatigue, resulting in inconsistent cell delivery that causes therapeutically ineffective MSC clumping. As a result, a novel automatic injection device is required to improve stem cell delivery and enhance the clinical success of intramyocardial MSC injections. The design must integrate with the procedural syringe-catheter system, limit operator intervention to promote procedural use, provide two slow, controlled injection rates to maximize cell retention, and maintain standard cell viability. It also needs a feedback system that displays the injection force throughout each procedure, increasing injection efficacy by assisting with catheter insertion and establishing catheter obstruction susceptibility. Although existing infusion pump systems and automatic injection devices are a promising solution, they are not approved for stem cell delivery, are not compatible with the intramyocardial syringe-catheter system, and can not display intramyocardial MSC injection forces. These are critical limitations that prevent their use, especially since MSC viability is pertinent to the success of each procedure.

To achieve accurate injections, the injector consists of a stepper motor that autonomously rotates a fully threaded metal bolt to drive a force application block toward the procedural syringe, injecting 0.5 mL of MSCs into the myocardium at a 30 or 60 second injection rate. A syringe clamp mold within the injector base fastens the required 1 mL syringe in place, preventing any displacement during each injection. Following each successful injection, the force application block moves back to the starting position, allowing syringe removal and insertion to take place within the required 15 second dwell time between injections. The injector feedback system is controlled by an Arduino Uno microcontroller and detects force via an FSR force sensor attached to the force application block, receiving and displaying the force applied by the injector to the syringe throughout each injection. An LED built into the feedback circuit signals when the 2.40 N threshold is reached to indicate potential catheter obstruction.

Injection testing verified that each injection rate delivered the complete 0.5 mL of solution within the required time. A calibration curve was developed for the FSR sensor based on initial reliability testing and subsequent force detection testing confirmed that all output force values over the typical injector force range were accurate within the required 20% error margin. Threshold value testing validated that the LED turned on when the FSR received at least 2.40 N of force. Following assembly of the entire injector, MSC viability testing verified that each injection rate kept MSC viability within 5% of initial cell survival, in congruence with typical intramyocardial injections. Overall design functionality was confirmed with a clinical MSC injection procedure simulation that demonstrated 0.5 mL of MSCs were properly delivered with both injection rates and that the FSR feedback system correctly displayed force values and alerted the user when threshold was exceeded.

The design specification testing results validate the efficacy of the injection device, confirming its reliability and accuracy. The injector provides the required slow, consistent injection rates, maintaining cell viability and maximizing cell retention. Its automatic MSC delivery at the required flow rates and dwell time limits operator intervention, meeting design specifications and promoting its clinical applicability. The feedback system accurately receives and displays the force throughout each injection, correctly alerting the operator when catheter obstruction is imminent. As a result, it meets all feedback system requirements, providing a simplistic interface that assists the operator with each injection, increasing MSC injection procedural success. With the injection device, the user is no longer subject to hand fatigue and the susceptibility to rapid injections is removed, promoting procedural efficacy. This device is thus a critical component of improving the treatment of myocardial infarction and mitigating cardiac arrest risk.