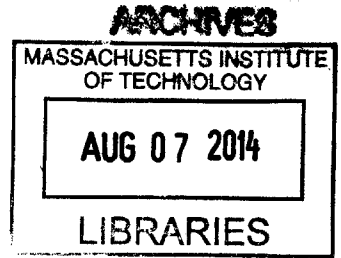Shape Grammar for Medical Injectors

by

David Luciano

Submitted to the
Department of Architecture
in Partial Fulfillment of the Requirements for the Degree of

Bachelor of Science in Architecture

at the

Massachusetts Institute of Technology

June 2014

Signature redacted

Signature of Author_____

Department of Architecture
May 23, 2014

Signature redacted

Certified by ___,

George Stiny, PhD
Professor of Design and Computation
Thesis Supervisor

Signature redacted

Accepted by _____

Meejin Yoon
Director of the Undergraduate Architecture Program

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Abstract

This thesis explores the applicability of algorithmic design for biomedical device design through the use of the shape grammar formalism. This method is expressed as an algorithm that describes the computational mechanism for composing shapes utilizing symbols, geometry, and algebraic operations. The generation of medical injector designs and their successful testing demonstrates the applicability of shape grammars to design synthesis in a high-performance design setting.

Thesis Supervisor: George Stiny, PhD

Title: Professor of Design and Computation

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Introduction

This thesis explores the applicability of the rule-based design method of shape grammars in the function design of medical injectors, using shape grammars as an exploratory design tool for typological design analysis and synthesis.

The shape rules used involve addition, subtraction, and union. Addition in shape rules introduces new elements into the design, subtraction deletes existing elements from the design and sum fuses shapes together in the design. Constraints introduce relations that define the context of a specific design problem, and limit the range of possible rule applications and design solutions. The constraints can both indicate relations between variables, including geometric and material restraints, which describe or define the object being designed and express design knowledge in algorithmic rules, guiding shape rule applications.

The grammar was then used to generate different injector designs and one design was chosen to be further developed into a fully functioning prototype and then tested for efficiency and usability.

Background

Medical injectors

Injectors are used primarily to deliver specific drugs to the target area directly or systemically. They provide immediate and effective treatment that cannot be achieved through other, current delivery mechanisms. These clinical applications involve treatment of chronic diseases and disorders as well as acute conditions. A variety of novel injectors have been developed in recent years to meet a large number of clinical demands, and to bring improvements in patient compliance and convenience. These newer devices aim to address the limitations of current designs as several have been proven effective in clinical settings. Safety, patient compliance and drug compatibility of the injectors provide the design criteria for these devices. Companies continue to augment injectors to meet both the clinical and technological demands. As a result many functional differences between injectors there are many permutations and dimensional changes from injector as can be seen in Figure 1. Some injectors have multiple chambers for drugs and solution, some use pressure differentials to encourage mixing, and some use flow with high shear rates to achieve drug dissolution. Despite potentially having different functionality from one another all medical injectors are consisting of the same three parts: a barrel, a plunger, and a load space, although any of these parts may be broken down into more specialized parts.
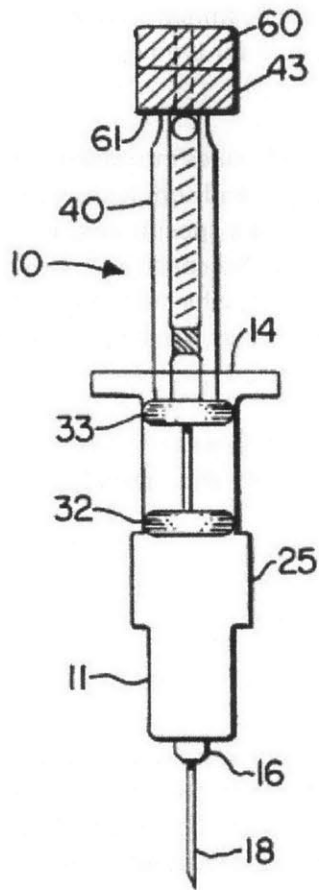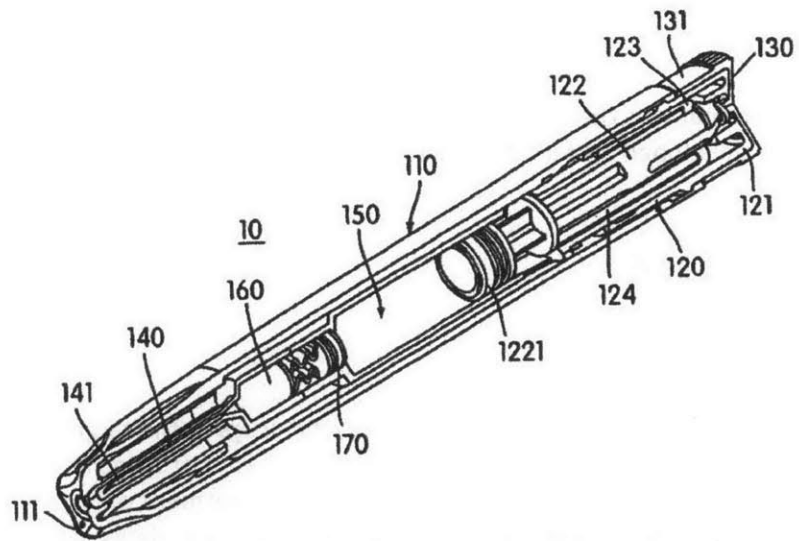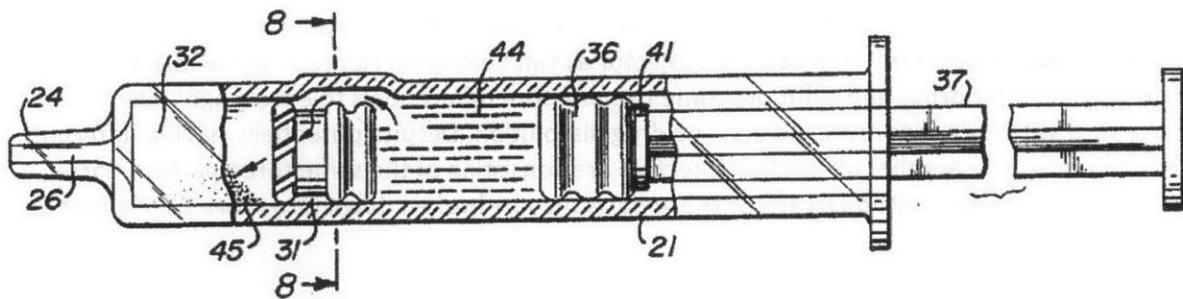
Figure 1. Medical Injectors: (a) Dual Chamber Syringe Apparatus, (b) Wet/Dry Automatic Injector Assembly, (c) Two-Component Syringe Assembly[1][2][3]

[1] Bachynsky: US 5971953 (1998).

[2] Hill: US 6702278 (2000).

[3] Grimard: EP 0172990 (1984).

Shape Grammars

A shape grammar is a design technique that uses application of design principles to explore design variation. Rules are a way of describing designs, and they can be used to understand designs. A rule specifies some condition, context, or an action that can be performed if certain prior conditions are met. Shape grammars provide a means to formulate rules that deal with geometric objects and properties in a design. In the context of shape grammar, design is interpreted as a set of objects in a relation; here the objects are geometric shape- and the relations are spatial compositions that are depicted by the rule, and they determine the way that shapes are combined. The rules of a shape grammar do not have predefined structure. They can be modified at every stage of design process.

Shape grammars provide a mechanism for form generation. The meaning associated with these forms is not developed as part of the formalism. However, with insertion of qualitative judgments and the integration of the other rule systems such as structural, social, and environmental rules into the formalism, meaningful designs can be generated.

Previous Applications

Shape grammars have been used traditionally in two ways: for the analysis of historic buildings, and for the generation of form from scratch. Both applications are constructive in the form generation stage of the design process. In using shape grammars to create new designs two and three dimensional shapes are used to generate designs within the given rule set. This method was first explored by Stiny (1976, 1980)[4] and then developed and elaborated by Knight (basic shape grammars and color grammars)[5] for use in design teaching and practice. For example, shape grammars are used as a form generation method for the projects: "Fallen Tower," museum in San Gimignano, Italy by Rand Brown, an Art museum complex in Taipei, Taiwan by We Cheng Chang, and a housing complex in Manhattan by Murat Sanyal.[6]

A Shape Grammar for Medical Injectors

The grammar for functional design of a medical injector is a two-dimensional shape grammar of the devices' cross sectional view. After a rotation about its central axis and potentially a few holes a functional model of an injector is produced. The functional model contains one or more chambers to mix that have their volume adjusted for based on the type of load that the injector is being design for.

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[4] Stiny, G., 1976, "The Two Exercises in Formal Composition," *Environment and Planning B*, Vol. 3, pp. 187 - 210.
Stiny, G., 1980, "Kindergarten Grammars: Designing with Froebel's Building Gifts," *Environment and Planning B*, Vol. 7, pp. 409 - 462.
[5] Knight, T., 1989, "Color Grammars: Designing with Lines and Colors," *Environment and Planning B*, Vol.16, 1989, pp. 41-449.
[6] Knight, T., 2000, "Shape Grammars in Education and Practice: History and Prospects," web paper,

Rule 1 takes an initial load space label I and surrounds it with a barrel and plunger above it and the load space label I goes to L. The center line in rule 1 is the axis of radial symmetry that the 3-D cylindrical model, and as a result the line of symmetry in the 2-D model for the grammar. Rules 2 and 3 add an exit port to the devices so that when the plunger is pushed down the load with go through the exit port. In rule 2 the exit port is through the plunger and in rule 3 the exit port is through the barrel. Rules 4 through 8 deal with how the load space is divided. Rule 7 adds a divider near the exit port and rule 8 adds to the other end. The transformation of labels L, 3, and 4 to L',3', and 4' insure the rules can only be applied a limited number of times such that there is either a divider or there is not.

Rule 1   Rule 2   Rule 3

Rule 4   Rule 5   Rule 6

3 4

L $\longrightarrow$ L'   3 $\longrightarrow$ 3'   4 $\longrightarrow$ 4'

Rule 7   Rule 8

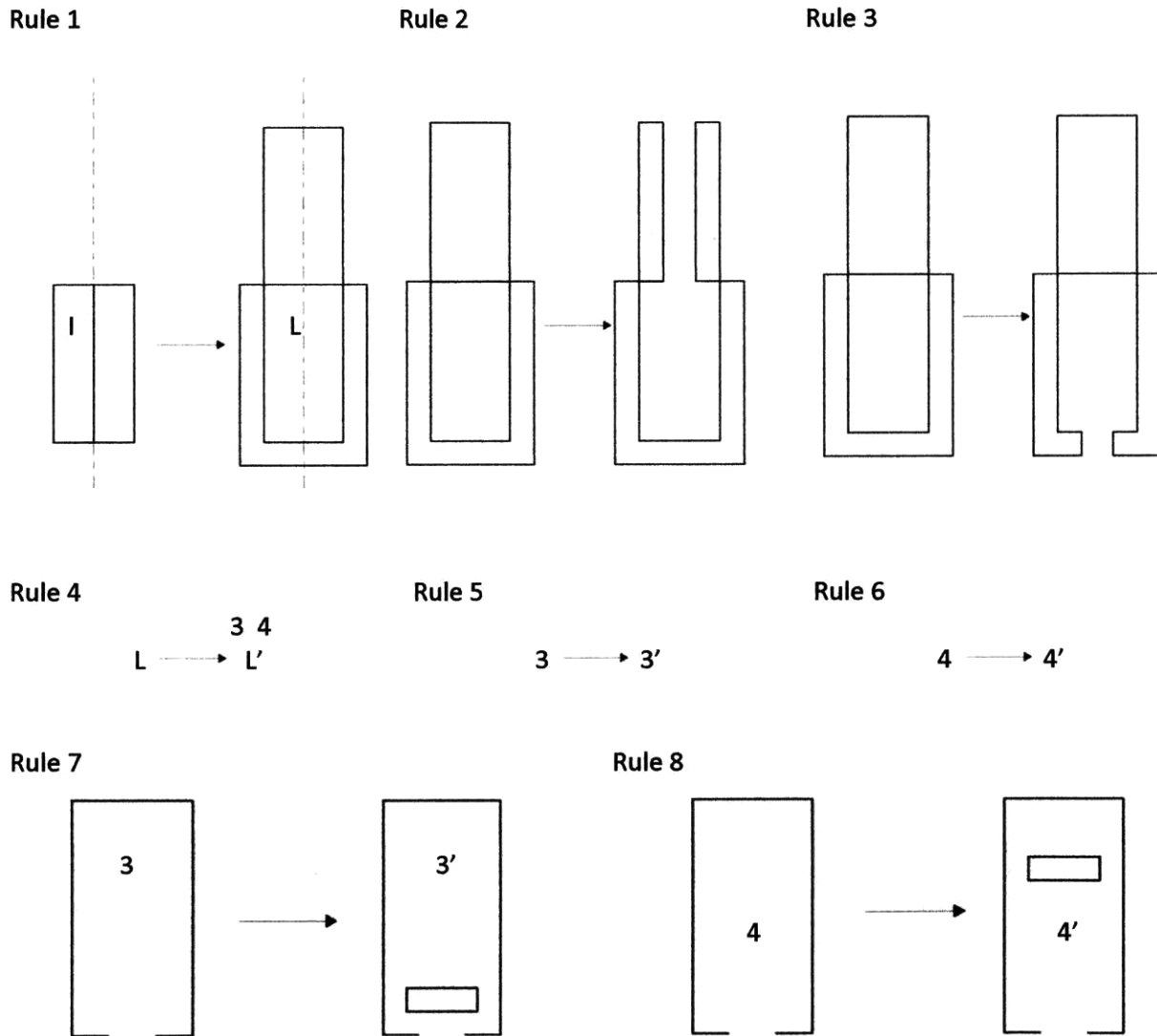3   3'   4   4'

Figure 2: Shape Grammar Rules 1-8

Rule 9 puts a central shaft in the load space if the exit port is via the plunger. Then rule 10 either merges the divider with the shaft or rule 11 splits the divider about the shaft. Rule 12, 13, and 14 relate how the shaft interfaces with the plunger. Rule 12 split the shaft from the barrel if a divider was merged with the shaft. Rule 13 adds a channel to the shaft if both of the dividers were merged with the shaft. Rule 14 keeps the shaft attached to the barrel, but adds a channel in the middle of the shaft and pores to allow flow. Rules 15 and 16 relates how the plunger and barrel interact, these changes allow for flow after the plunger is pushed down.
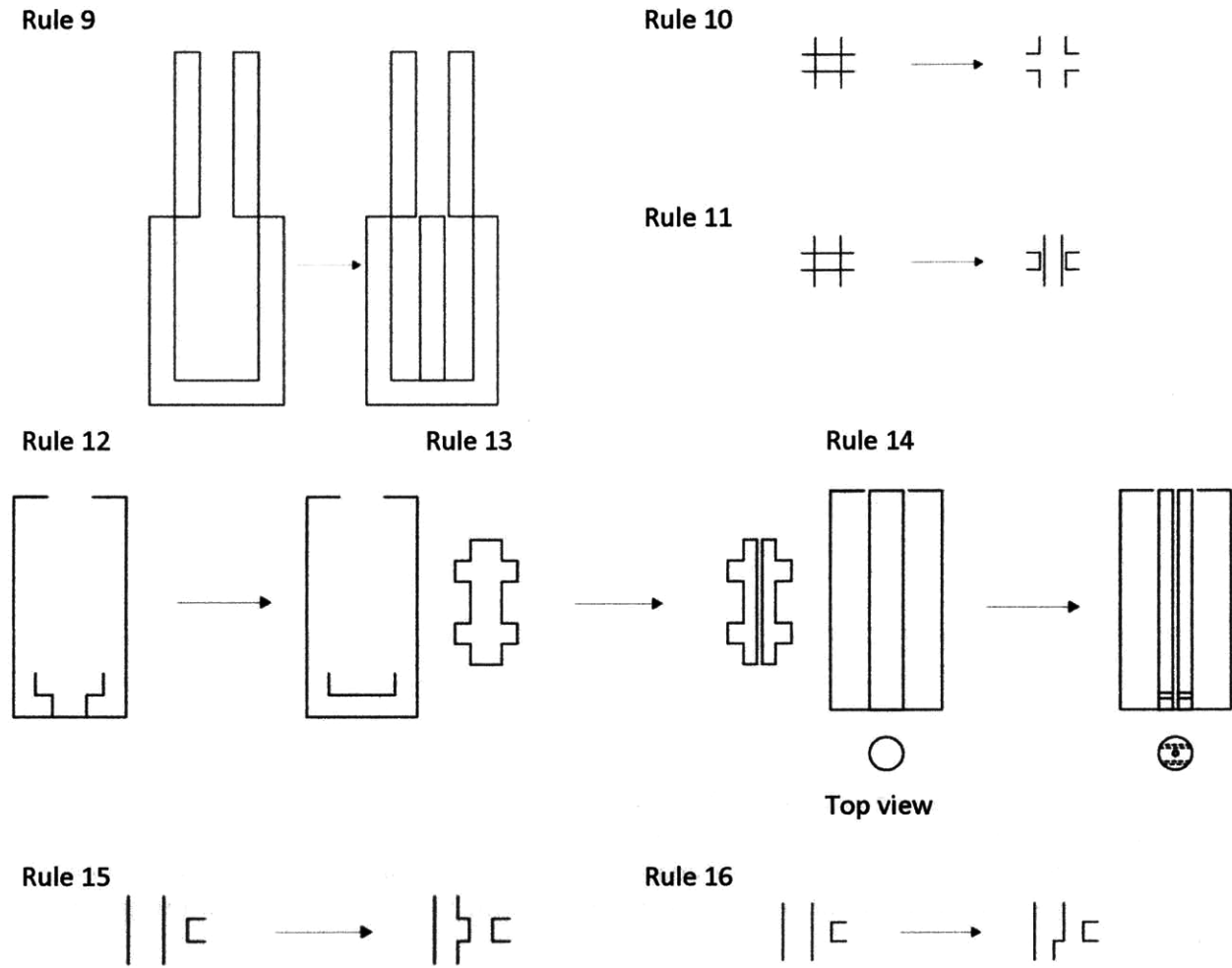
Rule 9

Rule 10

Rule 11

Rule 12   Rule 13   Rule 14

Top view

Rule 15   Rule 16

Figure 3: Shape Grammar Rules 9-16

From Design to Prototype and Testing

Using the medical injector grammar a functional design was generated to tested and prototyped.
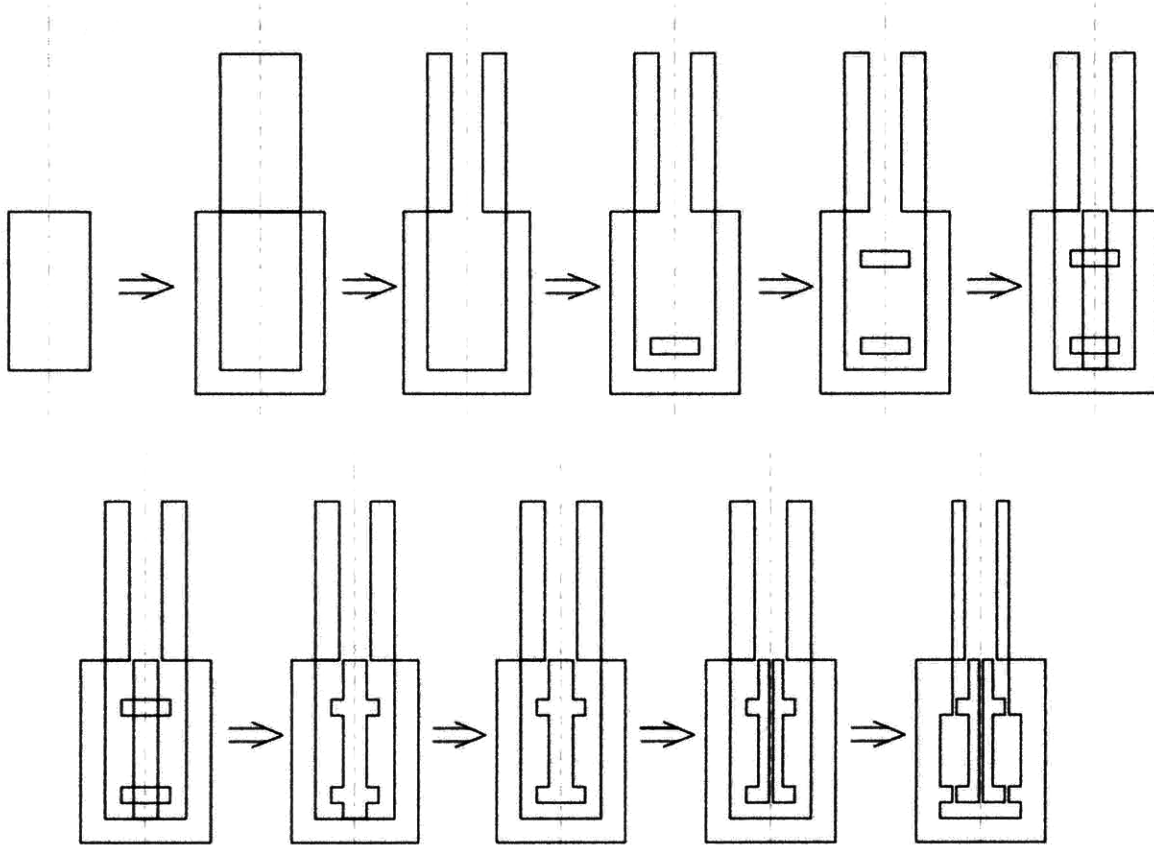

Figure 4: Design Synthesis

The prototype was made created with a SLA 3-D printer with an accuracy of 10 microns and feature size of 50 microns. While it was initially intended to be a standalone injector the resolution of the printer was not high enough when features like spiral adapters for needles to made without easily breaking. As a result the design was adapted to fit inside of a syringe to test the functional design that the grammar produced.

Coming from the design from the grammar the first thing that had to be added were ridges for o-rings to be added after the parts were printed so that there would be no water leakage from one chamber to another before the plunger was moved. A port with a cap was added to the barrel so that the drug load could be placed in the middle chamber. The shape of the middle chamber and the bottom chamber were round to enhance fluid flow and prevent stagnation in regions. Finally, ridges were added to the piece that evolved from the central shaft to ensure flow if a blockage were to occur.

While the first generation was successful in mixing liquids, it was still sub-optimal for rapidly mixing a solid into a liquid, and as a result more ports were added to the chamber were the drug was being loaded so that the drug could be distributed more evenly and the volume of the bottom two chambers was further reduced. This improved mixing however the new cap formed a poor seal under pressure and

in turn was changed from being press fit to a rotationally locked. In the final version an o-ring was to the end of the plunger to ensure a water tight seal with the syringe it was place in. The seal was again changed this time to a screw which was able to hold under pressure, and after modeling the prototype in Flow 3-D using computational fluid dynamics the shape and size of the drug and bottom chambers were further optimized for mixing.
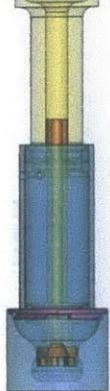
Generation 1	Generation 2	Generation 3	Final
Initial design	The single port was changed to four ports and the shape of the drug chamber was improved.	The seal of the port was changed to reduce leaking and the shape of the drug chamber was improved.	Added o-rings to insure sealing at key points. The outer barrel was divided into two with a tapered screw instead of having a barrel with a cap to ease drug loading. The shape of the drug chamber was improved.

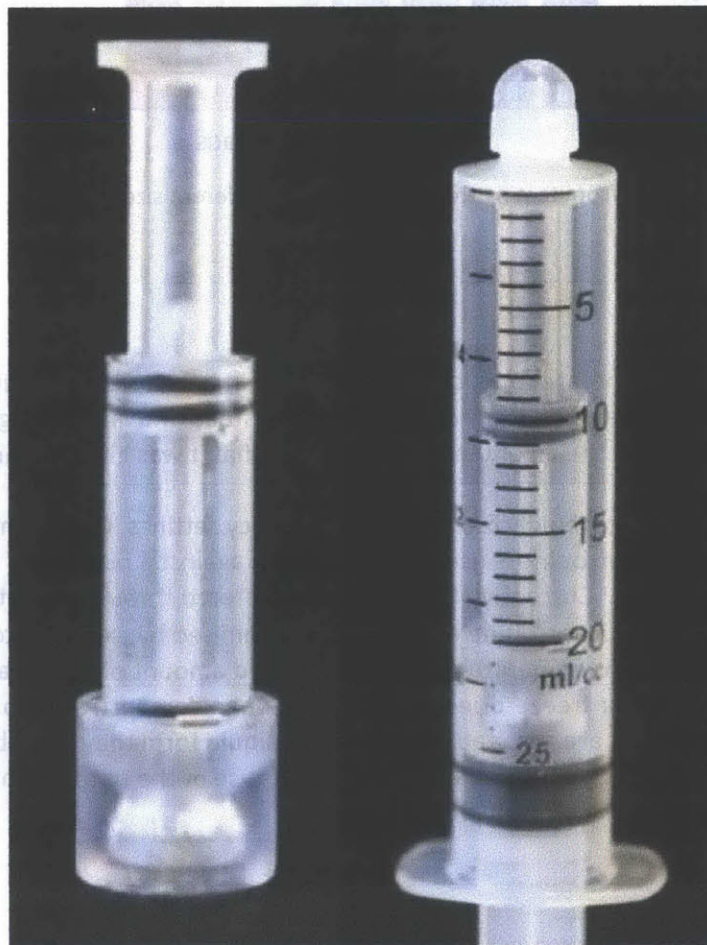Figure 5: Renderings of the generations of the prototype

Figure 6: The 3-D printed prototype assembled with o-rings
(left), the prototype in side of a syringe ready to be tested (left).

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The final version of the prototype was able to output between 85% and 95% of the payload of Atropine that was place in the drug chamber.
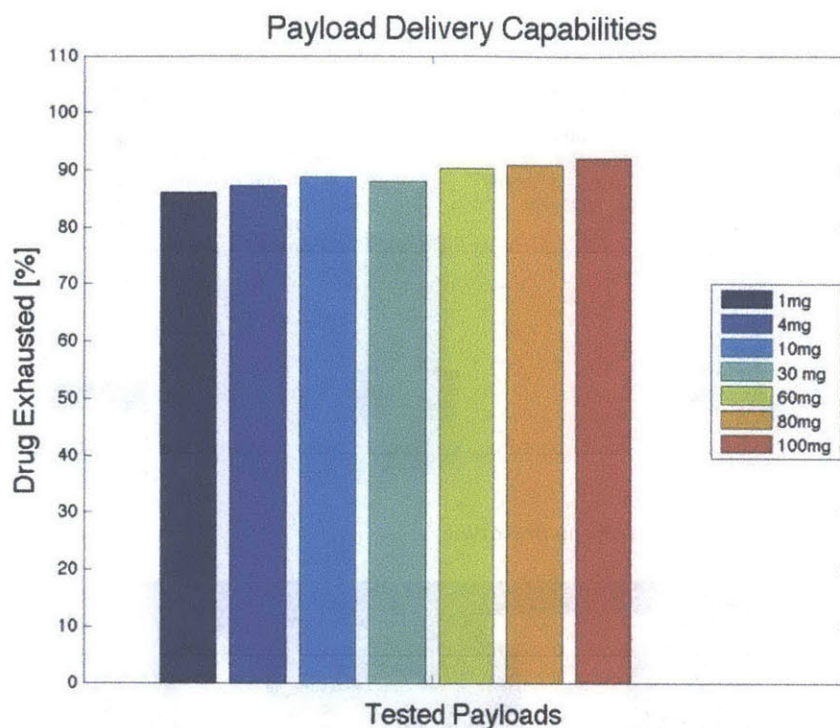

Figure 6: Results from testing the prototype with different sized payloads of Atropine

Discussion

The grammar is used to generate functional design medical injectors. Due to limiting prototyping methods the design was made to fit inside of a syringe instead and after four generations of design it was able to exhaust almost the all of the solid drug load that it was given to mix.

The ability to mix solid drugs rapidly is crucial in emergency settings. One example is the military's use of atropine. A liquid form of atropine is used as an antidote against a number of dangerous chemical agents, including nerve gas. Currently atropine is administered through an auto-injector called Atropen, but studies suggest that liquid atropine efficacy is compromised by exposure to heat.[7] Atropine subjected to extremely high temperatures for an extended amount of time may lead to chemical degradation. Lyophilized, or freeze-dried, atropine has been demonstrated to be very stable. Although a number of pharmaceuticals are not stable long-term in liquid form they must be administered into the body as a liquid. This presents a significant problem because of the potential need for immediate medication in a variety of extreme environments.

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[7] Gill, M. A., A. Z. Kislik, et al. (2004). "Stability of advanced life support drugs in the field." American Journal of Health-System Pharmacy 61(6): 597-602.

Many of the designs produced by this grammar allow for separate compartments of powder drugs and liquid for immediate combination and delivery. By keeping the drug in powder form, the goal of the packaging is to allow for stability in a variety of settings where temperature cannot be controlled as well as to increase the shelf life of the drug.

The prototype is designed to fit and operate within a standard syringe and worked as well as a standalone medical injector. When activated, the compartments open to allow the components to mix and reconstitute before being injected into the body. Overall the benefits that these designs will provide to military and ambulatory settings include long term storage without the need for refrigeration, improved logistics for replenishing stocks, a wider range of operating temperatures, durable packaging for troops to carry and simple operation with little or no training. By creating a preloaded device with the proper ratio of drug to liquid, the product aims to eliminate unnecessary measuring in emergency situations. Each design will need to be sized differently depending on the drug and the dosage.

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