“Redesigning and Incorporating the EpiPen into a Smartphone Case.”

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Abstract

In the event of anaphylaxis, people need an immediate injection of epinephrine. The EpiPen has provided such injections, but its size can make it somewhat unwieldy for people to carry around. This leads to many people simply not having it with them. The aim of this project is to design an epinephrine auto-injector that is more portable by integrating it into a smartphone case. While the EpiPen uses a spring mechanism, other options such as gas were explored. After testing, it was clear that a gas cartridge could supply sufficient power for injection. In the proposed design, using a gas cartridge helped minimize the size of the device and enabled the needle to be retracted after injection. The design is not only smaller than the current EpiPen, but is also able to be carried with an iPhone case.

1. Background

People with allergies face the potentially deadly threat of anaphylaxis, a severe allergic reaction that can occur within seconds of being exposed to an allergen, which commonly includes things like peanuts or the venom of a bee sting. The flood of chemicals from the immune system in response to the allergen can lead to shock as well as a drop in blood pressure and a narrowing of airways which hinders breathing (Mayo Clinic, 2013). Victims require immediate attention at an emergency room as well as an injection of epinephrine. This need for a shot of epinephrine led to the creation of epinephrine auto-injectors, the most prominent of which is the EpiPen. The device delivers two different dosages: 0.15mg of epinephrine for children and 0.30mg for adults. While the EpiPen has enjoyed over 95% market share among epinephrine auto-injectors (Goldenberg, 2013), it still has shortcomings that can be improved upon.
One common complaint about the EpiPen is its size. When encased, the device measures out to about 6 inches in length, which can make it uncomfortable to carry. In turn, some people simply choose to not have an EpiPen on their person even though it is recommended that the EpiPen should be available at all times. According to a survey from Sanofi (PR Newswire, 2013), nearly two-thirds of patients and caregivers do not carry their EpiPens as recommended. In addition to the EpiPen being left behind, due to ergonomic factors, general forgetfulness, or other reasons, there is also an issue of usability. In another survey done by Sanofi, nearly half worry that others will not know how to use their, or their child's, epinephrine auto-injector correctly during an emergency. While most medical professionals and EpiPen carriers know how to use the device, there are plenty of people who are unfamiliar with the device and even use it incorrectly. A study by Nguyen (2012) showed ineptitude of school staff in using EpiPens. Among personnel in elementary schools, the majority of which were teachers and lunch aids, only 23.7% were able to use the EpiPen properly, which is incredibly poor given that 89.2% of participants reported prior training in using an EpiPen. These results are particularly worrying because in the case with elementary school children, many may not be able to use an EpiPen themselves and thus rely on teachers and staff to be able to perform the injection. While this does show the need for a more intuitive epinephrine auto-injector, it also points to other necessary factors for an effective device, such as proper training.

1.1 Understanding Injection Mechanisms

In order to design a new epinephrine auto-injector, it was necessary to understand how the devices currently on the market worked and what areas could be improved upon. The two
chosen devices were the EpiPen and the most recent device, the Auvi-Q. Multiple EpiPens were taken apart in order to understand the mechanics of the device in addition to information provided by the patent. An Auvi-Q could not be acquired, so only the patent was available for understanding the mechanism.

The EpiPen works with a spring loaded mechanism. A compressed spring is coiled around the plunger and held in place by the slightly wider top of the plunger. The top of the plunger has a hollowed opening that houses the blue safety cap. When activating the device, the blue safety cap is removed. The needle end of the EpiPen is then pushed against the person’s outer thigh, which pushes the contents of the device upward. This pushes the plunger upward into a narrower hole, causing the top to squeeze in. By squeezing the top of the plunger, the spring is released and allowed to expand. This pushes the plunger downwards, forcing the needle through its cover and into the person’s leg and pushing the fluid out of the vial. As the vial is pushed down, it releases two locking teeth represented as number 340 in Figure 2. This releases a spring in the needle end of the device, expanding the orange sheath, seen in Figure 1, to cover the needle.

![Figure 1: EpiPen Taken Apart](image-url)
The Auvi-Q is the latest epinephrine auto-injector and competitor to the EpiPen. Unlike the cylindrical design of the current EpiPen, it is shaped more like a smartphone. The Auvi-Q is also smaller than the current EpiPen, coming in at 3.5 inches tall, 2 inches wide and a half inch thick. In addition to shape, another major difference from the EpiPen is that the injection from an Auvi-Q is powered by gas rather than a spring. The device is still activated by the release of a spring, but this spring (part 3560 in Figure 3) pushes an azide gas container (part 3412) into a
puncturing mechanism (part 3612). The gas is released and this force pushes down the plunger and the needle, injecting the epinephrine fluid. After the injection, the gas is released from the device and the springs on either side of the needle expand, retracting the needle.

Figure 3: Auvi-Q Patent Drawing (Edwards, 2011)

1.2 Parts of the EpiPen

The EpiPen has two springs: the spring around the plunger and the spring that pushes out the needle sheath. The springs measure 4.625 and 3 inches in length, respectively. Both springs were hung from a ladder and then had different weights attached to them. The spring extensions were recorded to calculate each spring’s spring constant using Hooke’s law. The larger spring (part number 530 in Figure 2) was measured with standard 2.5, 5, 7.5, and 10 pound weights, respectively. The smaller spring (part number 153 in Figure 2), on the other
hand, was too weak to handle the larger weights and thus required other objects around the lab that were first weighed in grams and then converted to pounds. These weights came out to .19287, .33069, .64375, and 1.12877 pounds, respectively. A linear regression was used for both sets of data in order to find the spring constants. The larger spring that provided the power for the injection had a calculated spring constant of 8.6466 lbs/in, which falls into the ballpark of a similar Duke study (Addison, 2006) that concluded that the spring constant for the bigger spring was between 8 and 10 lbs/in. The spring constant for the smaller sheath spring came out to 0.6266 lbs/in, although no other study was found to confirm it.

![Graph showing spring constants and linear regressions of EpiPen springs](image)

**Figure 4: Spring Constants and Linear Regressions of EpiPen Springs**

Some of the other major parts of the EpiPen that will likely need to be included in a new device include the vial, the needle, and the plunger. The vial, made of borosilicate glass, is approximately 4.5cm in length with an inside diameter of 9mm and a wall thickness of about 1mm. It has a cross sectional area of about .636cm² and a volume of around 3mL. The needle
used for injection in the EpiPen is a 7/8in, stainless steel 22 gauge needle, and it is covered by a sheath to protect it from damage and to keep it sterile.

1.3 Cell Phone Case

One of the main goals of this project was to design an epinephrine auto-injector that could be incorporated into a cell phone case. This would make it easier for someone to have it on their person at all times. As an example, the iPhone 5 measures 2.31in x 4.87in x 0.3in as a standalone device. Some original design ideas incorporated the injection mechanism on the back of the phone, using a flatter elliptical-shaped vial and plunger; however, there were concerns of the mechanism making the case too thick. In one proposed design, the device rests on the side of the iPhone, adding width to the phone rather than depth.

1.4 Gas Cartridges

In the interest of minimizing size and being able to retract the needle, it was decided that a gas cartridge should be used as the main power source for injection. The cartridges tested for the device were two mini gas cartridges (models 40106 and 40106IN21750, Leland Limited Inc., South Plainfield, NJ). Both cartridges had nearly identical dimensions and measured only one inch in length, as seen in Figure 5, which is ideal for a device that is trying to minimize size. The two cartridges came filled with different gases at different pressures: one was filled with carbon dioxide at 850 psi and the other was filled with nitrogen gas at 1750 psi. Figure 5 shows a model of one of the gas cartridges.
2. Methods

Various makeshift puncture devices were made to puncture the gas cartridges as the manufacturer did not offer any puncture devices for their mini cartridges. In order to see how the cartridges reacted when punctured, they were first held by a clamp and then punctured with a hammer and nail as seen in Figure 6. Both cartridges showed a nearly instantaneous release of gas, with the nitrogen-filled cartridge feeling a little more forceful, likely due to the higher pressure.
The next puncture device used was a modified syringe, as seen in Figure 7, with one end soldered close in order to create an airtight environment. A nail was soldered into the plunger and seal to act as the puncturing mechanism. Within the syringe there was a containment unit for the gas cartridge. Using a 3-D printer (Replicator 2X, Makerbot Industries, LLC, Brooklyn, NY), two cylinders were printed to form the containment unit. One held the cartridge in place and prevented it from wobbling, while the other covered the top with 5 holes as seen in Figure 8.
The gas cartridge was placed in the containment unit with the puncture region facing the holes. The center hole lined up the nail with the puncture region, while the surrounding holes were used for expelling gas. In testing, the syringe was held in place by a clamp with the soldered end pointing downwards. The plunger was tapped downward in order to puncture the gas cartridge. Both the carbon dioxide and nitrogen-filled cartridge were able to expel the plunger, although it appeared the nitrogen-filled cartridge did so with much more force.
It was also necessary to get the force needed to puncture a gas cartridge. A strain gauge load cell (MLP-200, Transducer Techniques, Rio Nedo Temecula, CA) was used to measure force, while a data acquisition and analysis system (MP100 and AcqKnowledge v3.5.1, Biopac Systems Inc., Goleta, CA) collected the data. A custom screw was printed with the 3-D printer to fit into the load cell and to hold the gas cartridge in place. A piece of tape was wrapped around the gas cartridge to get a tighter fit so there would be no wobbling. In order to puncture the cartridges, a press head was also printed and used to hold the nail in place. The experiment setup can be seen in Figure 9.
Prior to data collection, it was necessary to find a relationship (i.e. calibration) between volts and pounds of force for the load cell since data would be recorded in volts. To do so, varying known weights were placed on the sensor in a randomized order. This would give a reading of volts which was recorded and served as the calibration for the sensor. This data was put into a scatter plot and then put through a linear regression to find the relationship between
volts and pounds, as seen in Figure 10, which was then applied to the recorded data to convert volts into pounds of force.

Figure 10: Linear Regression of Relationship Between Pounds and Volts (i.e. Sensor Calibration Curve)

Results and Proposed Design

Two cartridges of each gas were used to test puncture force. In order to account for the nearly simultaneous moment between puncture and gas release, 50,000 samples were collected per second. In each test, the nail was lowered and then left in the cartridge after it was punctured. Figure 11 shows the result of the carbon dioxide cartridges, and while both have similar peaks in force, the differences in gas flow are likely due to inconsistencies in how the cartridges were punctured. The graph for the nitrogen cartridges, shown in Figure 12, shows more consistency in puncturing as both cartridges have a similar pattern of inclines and drops in force. In both graphs, the red line has been adjusted to line up with the other data.
Figure 11: Carbon Dioxide Cartridges; X-Axis is Seconds, Y-Axis is Pounds of Force; Black Line is First Cartridge, Red Line is Second Cartridge
Within the data, the two main points of interest were the point of puncture and peak thrust force from the cartridge. As far as peak thrust force, the two types of cartridges appear to be nearly identical with the carbon dioxide cartridges reaching roughly 20 pounds of force and nitrogen cartridges peaking around 23 pounds. These can be considered the base amount of force, although it would likely increase if the gas were to expand in an enclosed device as opposed to open air.

In order to pinpoint the puncture force, it was necessary to look at the start of each graph. The initial dips to zero, seen clearly in Figure 13, mark the moments where the nail has punctured the cartridge, meaning the cartridge is no longer pushing against the load cell, and the gas has not yet released to create a thrust force. This means that the force reading right before the dip should be the puncture force. For the carbon dioxide cartridges, Figure 11, the
reading was somewhat unclear, although it appeared to be close to 14 pounds. However, this is unlikely given the minimal force that was used in previous puncturing with the modified syringe and the hammer and nail. The data from the nitrogen cartridges, Figure 13, shows the puncture force to be less than 3 pounds, which is much more in line with the force used in previous tests.

![Figure 13: Nitrogen Cartridges; X-Axis is Milliseconds, Y-Axis is Pounds of Force; Black Line is First Cartridge, Red Line is Second Cartridge](image)

### 3.1 Proposed Design

In the proposed design, shown in Figure 14, the epinephrine auto-injector rests in a cylindrical body. The vial and needle components remain unchanged from the current EpiPen, but the plunger has been redesigned, as seen in Figure 16. Although the seal for the vial remains unchanged, the plunger is now designed to hold a gas cartridge rather than a spring.
There is also a spring at the needle end of the device to retract the needle after injection. All of these parts connect together and are put in a cylindrical body that is narrower on the needle end. This body is the put in a larger enclosure, which has a puncture tip lined up with the gas cartridge. The proposed design would be roughly 4.7 inches in length as opposed to the current EpiPen which is around 6 inches. The device could also be able to be attached to an iPhone case as in Figure 15 which is designed for the iPhone 5.

In the event of anaphylaxis, the needle end of the device would be pushed against a person’s outer thigh. This should push the inside cylinder upwards, causing the gas cartridge to be punctured and releasing the gas. The thrust force combined with the expansion of the gas should create a downward force that compresses the spring, injects the needle, and pushes out the epinephrine solution. Once the injection has completed, the gas can be released from the device, which allows the spring to expand and retract the needle.
**Figure 14:** Proposed Design for Epinephrine Auto-Injector

**Figure 15:** Proposed Design to Hold Injection Pen in iPhone 5 Case
4. Discussion

Two necessary additions to the proposed design are a safety mechanism and an easier way for gas to escape once the injection is complete. The current design offers no safety mechanism. One possibility is a cap for the needle end of the device. This would prevent the inner cylinder from being pushed upward, thus preventing the cartridge from being punctured. Either a hole on the side of the device or a removable latch could be used as a means to exhaust the gas more effectively after the injection is complete. Another possible design option is to have the spring in Figure 14 already in a compressed state. The safety could hold this spring in a compressed state, and once released it will expand, push up the contents of the device, and puncture the cartridge. Since the force from the gas cartridge is greater than the necessary puncture force, the spring can still be recompressed and expanded to retract the needle as originally proposed.

There also needs to be further testing on the gas cartridges. Inconsistencies in the data were likely due to human error as there were likely slight differences in the way each cartridge was punctured. This can be remedied in future testing with an automated method of
puncturing and with more samples so as to have more comparable data. Gas cartridges also need to be tested while in an enclosed environment similar to the proposed device as opposed to the initial tests which were in open air.

5. Conclusion

The proposed design is still in its early stages. In addition to adjustments, a prototype needs to be constructed in order to test the puncturing, injecting, and retracting phases of the proposed mechanism to see how its performance compares to devices like the EpiPen and the Auvi-Q. However, regardless of any design changes, it is imperative that the device be incorporated into a smartphone case. While many people forget their EpiPens or choose to not carry it with them, having their phones on them has become second nature. The proposed device is not only smaller and more ergonomic than a current EpiPen, but it is also more likely to be with someone at all times because it is part of their smartphone case.
6. References


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