Improving IV Drip Controlling in Ghanaian Hospitals and Clinics

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Final Report

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Background and Problem

In the summer of 2016, students in the University of Michigan's Global Health Design Initiatives (GHDI) program participated in a clinical needs assessment trip to Korle Bu Teaching Hospital in Accra, Ghana. During this trip, students observed that nurses often needed to adjust patients' intravenous fluid line (IV) drip rates two or three times over the course of a single 30-45 minute administration period because they had changed from their initial setting [1]. As the hospital was often filled beyond capacity, with patient beds lined up along the hallways, the re-adjustment of IV drip rates was observed to be a time-consuming and overwhelming process [1].

Medical fluid administration via intravenous fluid line (IV) is a common method of delivering drugs, electrolytes, and blood to patients. IV fluid administration is advantageous because it delivers fluids directly to the bloodstream, allowing for rapid uptake of injected pharmaceuticals by the body [2]. Currently, hospitals and clinics in Ghana use basic IV equipment with plastic roller clamps to set IV drip rates [1], [3]. The roller clamp consists of a plastic housing that encases the IV tubing and an attached wheel that is rolled along the tubing; the further down the tubing the wheel is rolled, the more pressure the wheel applies to the tubing, pinching it to reduce the drip rate.

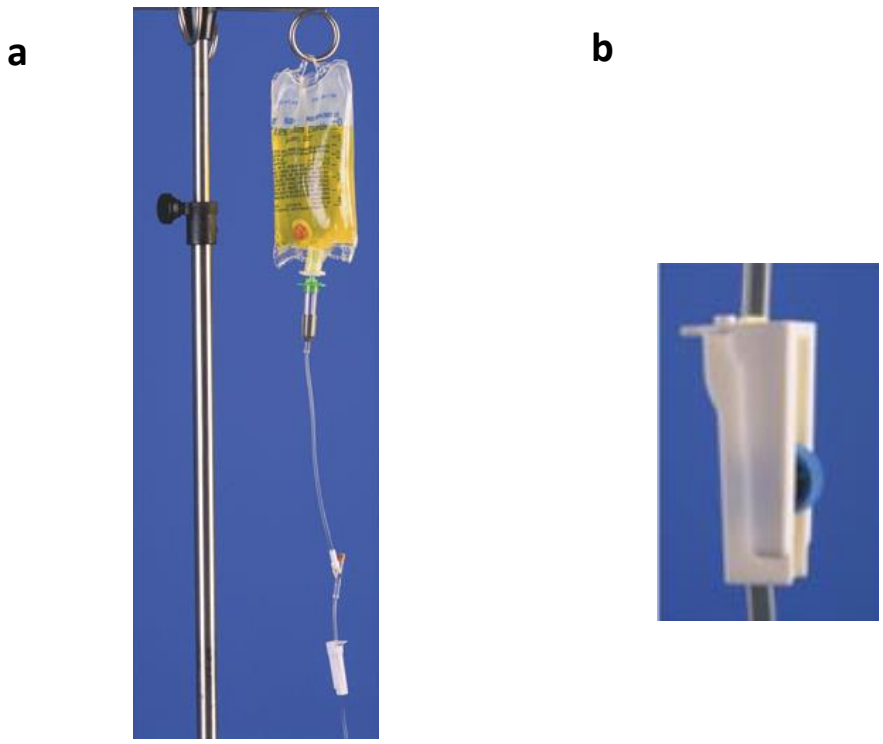

Figure 1. a: Hanging IV bag and tubing setup, with rate-setting roller clamp near bottom of tube [4]. **b:** Close-up of rate-setting roller clamp [4].

To set the drip rate for an IV administration, nurses adjust the position of the roller clamp wheel and count the rate at which fluid droplets fall through the IV drip chamber. Intended drip rates can vary based on the fluids being administered, patient need, patient age, and patient weight. For reasons including lack of robustness of the IV system, patient movement, and manipulation of IV tubing by patients, drip rates set by roller clamps often change from their initial setting over the course of an IV administration [1], [3]. In particular, the pressure applied on the roller clamp's wheel by the IV tubing causes the wheel to "drift" upward if the clamp is not robustly-constructed. Consequently, nurses must attend to each patient who is connected to an IV and manually re-count and re-adjust IV drip rates [1].

Well-funded medical facilities often use more advanced methods to administer IV fluids. Infusion pumps, for example, are a broad class of IV administration devices that allow the treatment provider to digitally enter an administration rate, following which the device will apply controlled pressure to a pharmaceutical-filled syringe, delivering fluids to the patient at a constant rate [5]. However, infusion pumps are expensive; Komfo Anokye Teaching Hospital (KATH), the second-largest teaching hospital in Ghana, only possesses a few for the entire facility [1].

This Honors Capstone project is an outgrowth of continued University of Michigan design team work that has been ongoing for several years. The project was first taken up in a two-semester design workshop through the M-HEAL Incubator program in September 2017. The workshop group became an M-HEAL exploratory team in September 2018 and a full M-HEAL project team as Team Flow in April 2019. Team Flow communicates regularly with its community partner in Ghana, Mr. Emmanuel Acheampong, who is an emergency nurse at KATH. Many design and use considerations were taken from communications with Mr. Acheampong as well as needs assessment conducted by a Team Flow member who participated in the 2019 University of Michigan GHDI trip to Ghana (separate from the 2016 trip described earlier).

Problem Statement

Nurses in hospitals and clinics in Ghana must often readjust IV drip rates several times during a single administration period partly due to imperfections in current rate-setting roller clamps.

Need Statement

There is a need for a time-efficient and cost-effective method to control the release of IV fluids into patients in Ghanaian hospitals and clinics to address current roller clamps' ineffectiveness in maintaining constant drip rates.

Existing Products

Wolf Medical Supply Dial-A-Flow

The Dial-A-Flow is a cylindrical manual flow regulator that has markings to indicate approximate drip rates [6]. It comes pre-attached to tubing that can be spiked directly into the IV bag or attached to a port in the IV line. Wolf Medical Supply states that the Dial-A-Flow offers protection against solution free flows and tube crimping. Notably, they also state that it offers protection against roller clamp drifting.

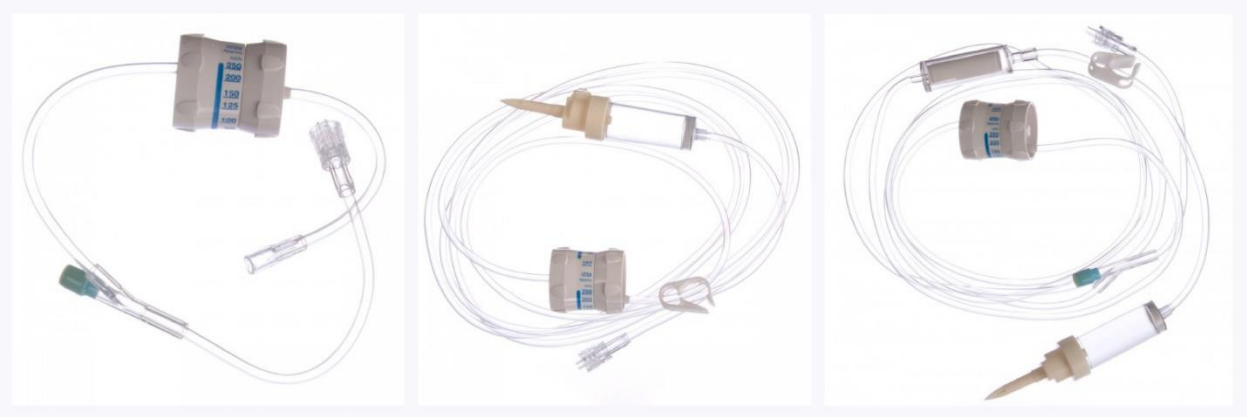

Figure 2. Wolf Medical Supply's Dial-A-Flow rate-setting dial with attached proprietary IV tubing [6]. Figure shows IV tubing that may be attached to IV ports as well as to IV bags.

B. Braun Exadrop

The Exadrop is another dial-based drip rate setting and adjustment solution that has markings to indicate approximate drip rates [7]. It comes pre-attached to tubing that can be spiked directly to a port in the IV line. The Exadrop possesses a rigid flow channel with a capillary tube whose lumen becomes more or less open depending on how far the dial is turned.

Figure 3. B. Braun's Exadrop rate-setting dial with attached proprietary IV tubing [7].

Limitations of Existing Products

The most notable limitation of both the Dial-A-Flow and the Exadrop is that they require that providers purchase an entirely new tubing set to use them, as neither is able to attach directly to existing IV tubing [6], [7]. This places a burden on hospitals and clinics that already have a supply chain established for their current IV tubing. Additionally, since each flow control mechanism is permanently attached to the tubing, neither can be reused. Furthermore, both products possess approximate flow rate dials, but both still require manual drip rate counting to ensure that the set rate is accurate. This can be misleading for anyone who is new to using the products, as, without proper warning, there is a chance that they set drip rates and walk away without verifying their accuracy.

Project Scope and Design Requirements

Project Scope

This Honors Capstone project aims to address a specific facet of a broader problem that M-HEAL Team Flow is working on. Team Flow is working towards developing an IV drip monitoring and controlling solution that will reduce or eliminate the need for nurses to return to patients for the readjustment of drip rates during a single fluid administration period. Drip rate *monitoring* and drip rate *controlling* are two distinct areas of focus to this regard. This Honors Capstone project focuses on drip rate controlling. It had a timeline of three months (late August to early December 2020). Due to prototyping and testing facility limitations caused by the COVID-19 pandemic, the scope of this project was further narrowed to specifically address issues with the current roller clamp, with the goal of developing a prototype for drip rate testing.

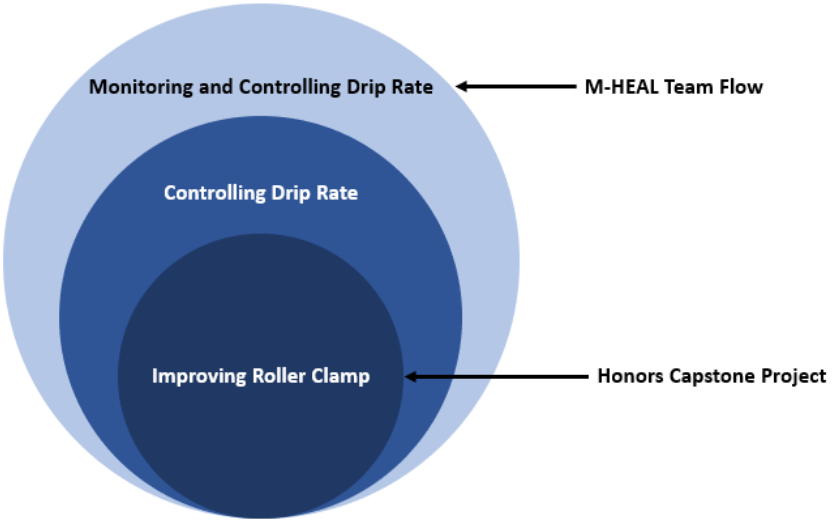

Figure 4. Illustration of narrowed scope for Honors Capstone project from broader scope for M-HEAL Team Flow.

After communicating with our community partner, Mr. Emmanuel Acheampong; reviewing benchmarking and interview materials from the 2019 GHDI needs assessment at KATH; and conducting literature review, three requirements were identified: (1) The device must reduce the number of times nurses must manually re-adjust IV drip rates within an administration cycle from 2-3 times to 0 times, (2) the device must be quick to use, and (3) the device must be implementable in a low-resource setting.

The short-term goals of this project are:

1. To develop low-fidelity prototypes for solutions to our community partner's need.
2. To test and collect data for all developed prototypes.
3. To conduct data analysis to determine whether the prototypes meet our community partner's requirements.

The long-term goals of this project are:

1. To create a high-fidelity prototype for a feasible solution to our community partner's need.
2. To test the solution in Ghanaian hospitals and clinics, having the end users (nurses) use the solution and provide feedback on its efficacy and usability.

Design Requirements

Table 1. Design requirements and specifications.

Design Requirement	Design Specification
Device must reduce the number of times nurses must manually re-adjust IV drip rates within an administration cycle from 2-3 times to 0 times	Device does not allow a deviation of greater than ±10% from initial rates between 0 mL/hr and 250 mL/hr over the full course of an IV administration
Device must be quick to use	Device takes under 10 seconds to attach or adjust
Device must be implementable in a low-resource setting	Device costs under USD 0.10 per use
	Device must be compatible with currently-used IV administration systems, does not require device-specific or proprietary tubing
	Device must be able to work with different dimensions of IV tubing

Device must reduce the number of times nurses must manually re-adjust IV drip rates within an administration cycle from 2-3 times to 0 times

IV drip rates set by roller clamps often change from their initial setting over the course of an IV administration. Consequently, nurses must attend to each patient who is connected to an IV and manually re-count and re-adjust IV drip rates, which is time-consuming and overwhelming. Interviews with Mr. Acheampong and review of interview notes of other nurses from GHDI 2019 have revealed a desire from stakeholders for the need to re-adjust drip rates to be reduced [1], [3]. Literature and interviews show that volume delivery rates of over 250 mL/hr are not commonly used [1], [3], [8].

Device must be quick to use

Building from the previous requirement, efficient use of caregivers' time is of importance. Interviews with Mr. Acheampong and review of interview notes of other nurses form GHDI Ghana 2019 have revealed a desire from stakeholders for the time to implement the solution, whether it be the initial setup or any changes that need to be made during an administration, to take under ten seconds [1], [3].

Device must be implementable in a low-resource setting

Lower-resourced hospitals, such as many in Ghana, cannot afford to expend substantial per-patient and per-use costs for treatments, including for IV administration. A per-use rate of approximately USD 0.10 was calculated by the GHDI Ghana 2019 as being the cost of using an

infusion pump three times per day for 15 years, which is approximately the usage rate of peristaltic pumps at KATH [9]. The per-use cost rate is applicable to both single-use solutions and reusable solutions. Purchasing new IV tubing sets would introduce an additional cost and supply chain re-establishment for hospitals. As such, the specification also mandates that the solution must not require device-specific or proprietary tubing, meaning that the solution should be compatible with current tubing that is used and able to handle different dimensions of tubing.

Concept Generation

Concepts were generated with prototyping and testing limitations in mind. Due to the COVID-19 pandemic, it was assumed that access to University of Michigan design spaces, including those with low- and mid-fidelity prototyping resources as well as 3D printing services, would be limited. Consequently, concepts were generated with the understanding that solutions with significant assembly or CAD design that required extensive 3D printing would need to be tested computationally. Conversely, very simple designs that required little to no physical assembly that could be constructed and tested with household items or cheap materials had potential for physical building and testing. Likewise, designs that needed some, but not extensive, 3D printing were originally in consideration. Additionally, the time frame of this project — approximately three months — was accounted for.

The initial decision in the concept generation process was to determine whether the solution should interface with the roller clamp itself or be separate from the roller clamp, for example, by attaching to the IV tubing upstream or downstream from the roller clamp itself. This would provide a more constrained ideation space. The next consideration, which was informed in part by the COVID-19 limitations described previously, was whether the solution should either (1) be completely novel, or (2) incorporate currently-available elements, whether through selective implementation of elements of existing solutions or repurposed application of existing components or materials.

It was decided that the solution should interface with the roller clamp itself. Both approaches would provide insight into the effectiveness of the designed solution in improving drip rate control. However, a solution that interfaces with the roller clamp would provide additional potential for providing insight into the reasons for which roller clamps have problems in the first place, allowing for more conclusions to be drawn from the project and, importantly, greater clarity regarding future steps in this work.

Both novel solutions and solutions incorporating parts of existing solutions or repurposed manufactured materials were considered to allow for flexibility in determining what may work best to address the partner community’s needs as well as fit within the constraints of the project.

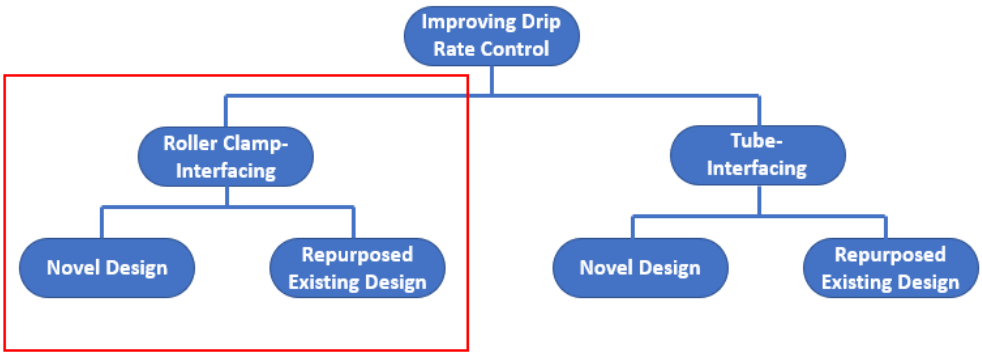

Figure 5. Graphic depicting chosen solution space for concept generation, boxed in red.

Concept generation began with the listing out of different requirements for the solution (specific to the solution space at hand) and brainstorming methods to address each of them independently of the other requirements. These ideas are recorded in Table 1.

Table 2. Functional decomposition table of most feasible methods.

Function	Secures Clamp Wheel	Allows for Rapid Implementation	Allows for Rapid Adjustment	Allows for Rapid Removal
Method 1	Temporary adhesive	"Click" on	Remove housing	Remove housing
Method 2	Friction	"Slide" on	Adjust straps	"Cut" off
Method 3	Pressure	"Loop" on	Remove completely and reattach	Unwrap
Method 4		Fasten		"Slide" off

These independent ideas were reviewed and discussed with the advisor for this project, Dr. Melissa Wrobel (Lecturer III, Biomedical Engineering - University of Michigan). Discussion led to brainstorming of possible solutions, both novel and with repurposed materials. Selected potential solutions are listed below.

Concepts

Compressing roller clamp with tape

To address the issue of roller clamp drift, securing the clamp's wheel to the surrounding housing more effectively with tape was considered (Fig. 6). This method is extremely cheap, with a 700-inch roll of transparent Scotch tape costing USD 1.59 from Target [10]. If a 3-inch segment of tape is used with each IV administration, this works out to under USD 0.01 per use. Manufacturability and distribution would not be an issue with such a widely-used product, and

the size of the tape segment can be varied depending on the size of the roller clamp. However, this solution requires the application and removal of an adhesive material, which can be cumbersome and may take over 10 seconds to do. It is also a single-use solution, requiring caregivers to use a new piece of tape with every IV administration.

Figure 6. Potential solution — tape fixing roller clamp wheel to roller clamp IV housing.

Securing roller clamp wheel with rubber band

Roller clamp drift may also be addressed by stretching a small rubber band upstream of the roller clamp wheel in order to mitigate the wheel's tendency to be pushed due to the pressure of the IV tubing. This method is also cheap, with a pack of 300 small bands costing USD 2.66 on Amazon.com [11]. Even if the bands were single-use, they would cost under USD 0.01 per use, and there is potential for the bands to be reused. As with tape, manufacturability and distribution would not be an issue with rubber bands, and this solution would also be flexible enough to work with varied roller clamp dimensions. However, in order to be used, the rubber band would need to be slid from one end of the IV tubing — either from the bag spike or the patient end — and worked towards the roller clamp, which would take well over 10 seconds to accomplish.

Securing roller clamp wheel with Velcro strap

As with the rubber band solution, roller clamp drift may be addressed by fastening a Velcro strap upstream of the roller clamp wheel in order to mitigate the wheel's tendency to be pushed due to the pressure of the IV tubing. This method is cost-effective, with a pack of 50 8-inch Velcro zip ties costing USD 6.99 on Amazon.com [12]. If the Velcro straps were used merely twice, their cost per use would be under USD 0.10, and they have the potential to be reused many more times than this. This solution is also straightforward to implement, adjust, and remove. To attach the Velcro strap, one must pull one end of the strap through a notch at the other end and pull, creating an ever-smaller loop that can snugly fit the roller clamp. The excess strap length can be

wrapped around and secured to the loop, as the material is Velcro, so the strap adheres to itself. Adjustment and removal are performed by unfastening the excess strap end from the loop, tightening or loosening the loop, and reattaching the excess end to the loop. Manufacturability and distribution are likely not to be issues with this solution.

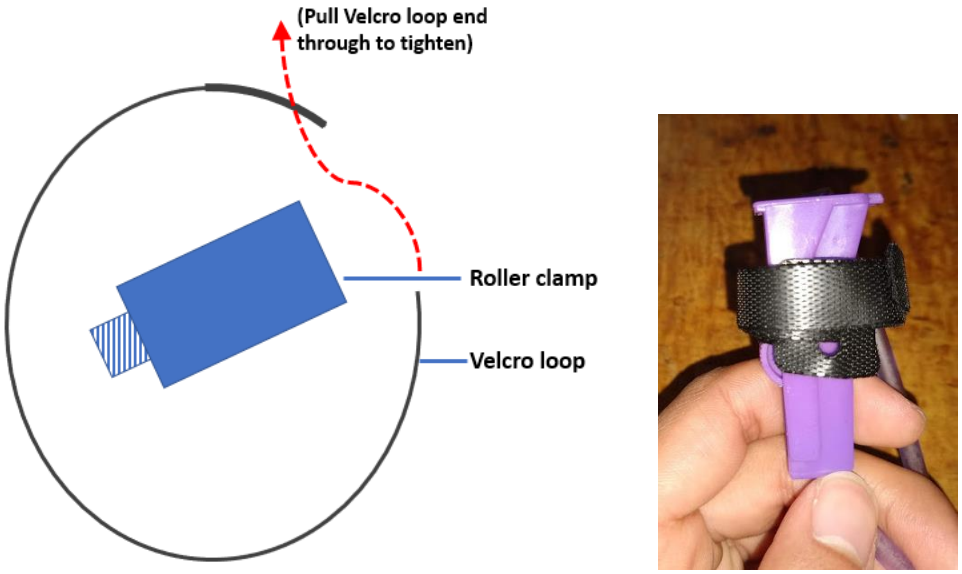

Figure 7. Potential solution — Velcro tie loop to fix roller clamp's wheel in place.

Securing roller clamp wheel with specially-built housing

Roller clamp drift could be addressed by a specially-designed housing that encases the roller clamp and applies pressure to the roller clamp wheel or blocks the roller clamp's path to move upstream. Such housing could be 3D printed and, ideally, reused hundreds of times, bringing its cost per use down. The solution could be secured to the roller clamp using a lock with a latch or click-in feature for rapid implementation and adjustment capabilities. Such a solution would be much more challenging to manufacture and distribute to hospitals and clinics in Ghana than the previously-proposed solutions, given its novelty and higher complexity.

Pugh Matrix

A Pugh matrix was constructed to determine which of the described solutions to proceed with for purchase and/or prototyping as well as testing (Table 2). Five different criteria were assessed: (1) Adaptability to different roller clamp sizes, (2) ease of use, (3) ease of manufacturing, (4) cost, and (5) reusability. The criteria were given a weight between 1 and 5, with 1 being the lowest possible weight (least important) and 5 being the highest possible weight (most important). Each solution was assessed against each criteria on a scale of 0 to 2, with 0 being a relatively low compliance with the criterion and 2 being a relatively high compliance with the criterion.

Table 3. Pugh matrix comparing potential solutions against weighted criteria.

	(Weight)	Tape	Rubber Band	Velcro Band	Custom Housing
Adaptability to different roller clamp sizes	5	2	2	2	1
Ease of use	4	1	0	2	2
Ease of manufacturing	3	2	2	1	0
Cost	3	2	2	2	1
Reusability	2	0	1	2	2
(Total)		***26***	***24***	***31***	***20***

The Velcro band solution yielded the highest value (31) from the Pugh matrix evaluation, followed by tape (26), rubber band (24), and custom housing (20). The margin between the Velcro band and tape was large enough to comfortably proceed with a Velcro band-based solution.

Details of Final Solutions

Two Velcro-based final solutions were used for testing and are described below.

Velcro Zip Ties, No Modification

One Amazon Basics 8-inch black Velcro reusable cable zip tie from Amazon.com is used for this solution, with no modifications [12]. The Velcro tie is wrapped firmly around the roller clamp immediately above where the clamp's wheel is set (Fig. 8).

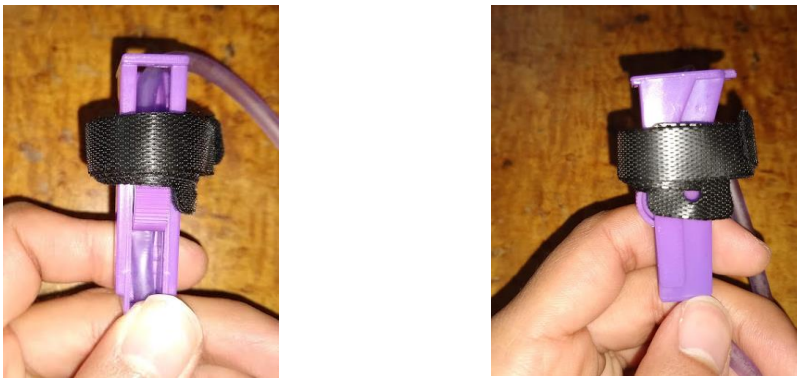

Figure 8. Attachment and securement of Velcro zip tie to roller clamp.

Velcro Zip Ties with Rubbery Adhesive Lining

One Amazon Basics 8-inch black Velcro reusable cable zip tie from Amazon.com is used for this solution [12]. The intent of this design is to include a rubber-like lining inside of the Velcro tie in order to create a higher-friction interface between the tie and the plastic of the roller clamp. Inspiration for this modification came from oven mitts, which sometimes possess rubber-like silicone ribbing to provide extra grip when carrying items. In order to mimic this rubber-like quality, a hot glue gun was used to apply a strip of melted hot glue to the inside of a flat, unused Velcro tie. When the hot glue dried onto the Velcro tie, it possessed a grippy, rubber-like quality similar to that of the rubber-like silicone material on oven mitts (Fig. 9).

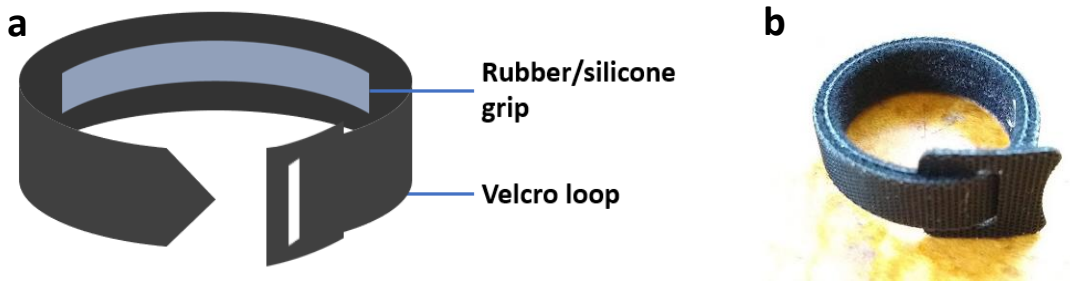

Figure 9. a: Illustration of Velcro zip tie with applied rubbery grip material. **b:** Photograph of Velcro zip tie with applied and dried hot glue, which is a rubbery material. Glue appears black due to its translucent nature.

This solution is applied to the roller clamp in the same fashion as the unmodified Velcro tie is. The Velcro tie is wrapped firmly around the roller clamp immediately above where the clamp's wheel is set (Fig. 8).

Testing Protocols

Ease of Use Testing

The speed with which the Velcro tie could be attached to the roller clamp was testing by requesting that six random individuals attempt to tie the Velcro loop immediately above the roller clamp's wheel (as in Fig. 8) as rapidly, but effectively, as they could. Each individual was shown how to perform the procedure as many times as they requested and was permitted to ask questions about what constitutes a "finished" trial. No further instructions, such as advice on how to fasten the Velcro more quickly or easily, were given. If an individual claimed to be finished without fully fastening the Velcro loop or sticking the loose end of the Velcro tie to the loop, the individual would be prompted to correct their work until it was satisfactory. Data were collected over five trials for each individual.

Drip Rate Testing

IV Bag and Tubing Setup

The first step in drip rate testing was to set up the IV bag and tubing. Testing was conducted using a Denshine 1200 mL enteral delivery gravity bag set, which has 3/16 inch diameter tubing [13]. The bag was filled with approximately 600 mL (half-maximal capacity) of tap water, and the cap on the bag was closed. Water was used because it behaves similarly to many IV fluids, which are almost entirely water with minute amounts of solute (e.g. salt, drugs) dissolved.

As an IV pole was not available, the bag was hung from a wall hook located approximately 66 inches above the ground, as in Fig. 10. Although most tubing hung vertically, excess tubing laid horizontally on the ground; this is similar to what occurs in real life, with the patient lying on the hospital bed and IV tubing running horizontally prior to entering the patient's vein via needle. A cup was placed at the end of the tubing to collect water.

Figure 10. IV bag and tubing setup, with bag attached to wall hook and water draining into a cup on the floor.

Drip rates over time were calculated for three different conditions: (1) control (no treatment to roller clamp), (2) unmodified Velcro tie, and (3) Velcro tie with hot glue. The setup and data collection for each were identical and are outlined below. Five trials of each of the procedures below were conducted, for a total of 15 trials.

Control Setup and Testing

For the control setup, the IV bag and tubing were arranged as described above. The roller clamp was adjusted until a drip rate of 36 drips/minute was reached. Drip rate was calculated by counting the number of drops falling over a 20-second span and multiplying the value by 3. 36 drips/minute is a drip rate commonly used for saline when using a 3/16 inch diameter IV tube [14], [15]. Once the drip rate reached 36 drips/minute, a timer was started. Drip rates were calculated using the same method as the initial drip rate every five minutes (counting for twenty seconds at the start of a five-minute interval) for thirty minutes and tabulated in a table like Table 4, below.

Table 4. Example table for collecting drip rate data for one experimental trial.

CONTROL	**Time (min)**	**0**	**5**	**10**	**15**	**20**	**25**	**30**
	Drip Rate (drops/min)	36						

This process was repeated five times. Note that the IV bag was not refilled to 600 mL between trials if there was enough leftover water in the bag to run another trial.

Velcro With No Modification Setup and Testing

For the testing of the Velcro with no modification, the IV bag and tubing were setup as described previously, and testing was conducted in exactly the same manner as in the control trials. The lone difference in procedure is that a Velcro loop was tightly fastened immediately above the roller clamp's wheel as soon as the initial drip rate was calculated to be 36 drops/minute. The attachment procedure is shown in Fig. 8. Five trials were conducted.

Velcro Loop With Glue Setup and Testing

This procedure was the exact same as that for the Velcro with no modification, except that the Velcro loop that was used had a strip of dried hot glue on the inside, as described in the Details of Final Solutions section. Five trials were conducted.

Statistical Testing

Statistical methods for analyzing the results of the experiments were determined prior to running the experiments. Two different tests were used:

1. One-way ANOVA with Scheffe post-hoc test to compare mean drip rates between the control and treatment groups after 15 minutes and after 30 minutes. The intent of this test was to see whether there was a significant difference in drip rates between the groups at each of the two time points stated.
2. Repeated-measures ANOVA with Bonferroni post-hoc test to compare mean drip rates at each time point for a single treatment group. Repeated for each treatment group. The intent of this test was to see whether there was a significant difference in drip rates between any two time points for a single treatment condition. The repeated-measures ANOVA is able to compare all time points to all other time points.

Results and Observations

Ease of Use

Results of the Ease of Use testing are presented in Figure 11.

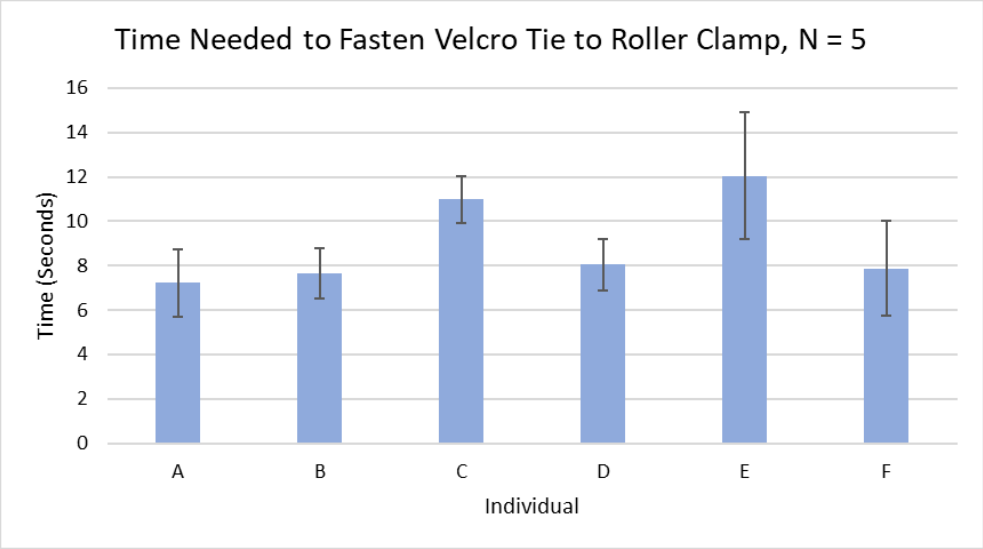

Figure 11: Average time for six individuals to properly fasten Velcro tie to roller clamp. Error bars indicate standard deviation. N = 5 trials per individual.

Individuals C and E believed that they were finished prior to truly fastening the Velcro tie properly during their first trials and required prompting to successfully complete the task. Individuals occasionally struggled to rapidly feed the tip of the tie through the slot on the other end of the tie in order to create a loop.

Drip Rate

Average drip rates across five trials of each treatment are shown in Fig. 12. Significances were determined using the one-way ANOVA test described in Testing Protocols section, with alpha value of 0.05.

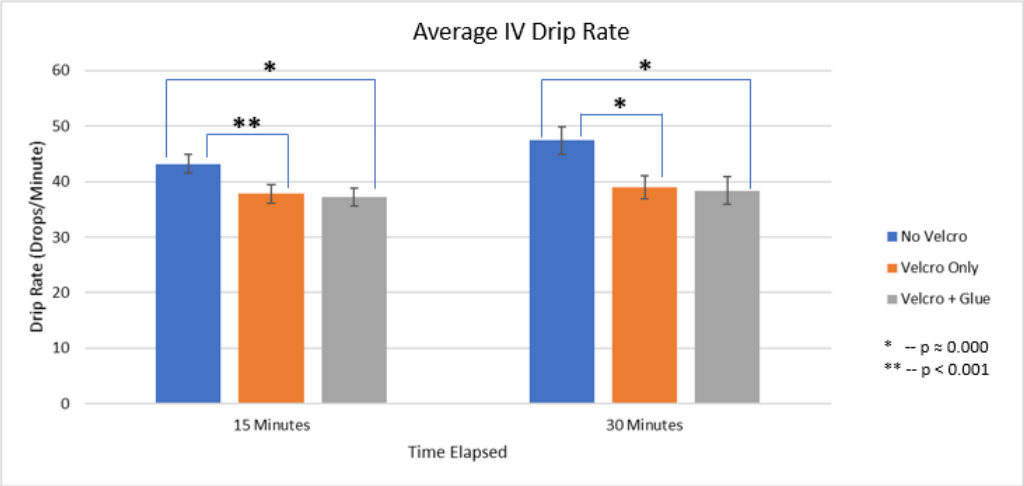

Figure 12: Average IV drip rate at t = 15 minutes and t = 30 minutes for control and two treatment conditions. Error bars indicate standard deviation. N = 5 trials per condition.

Average drip rate at each time point for all treatment groups are shown in Fig. 13. Significances were calculated using the repeated-measures ANOVA test described in the Testing Protocols section, with alpha value of 0.05. Note that significant differences in drip rate at different time points were only present in the control group.

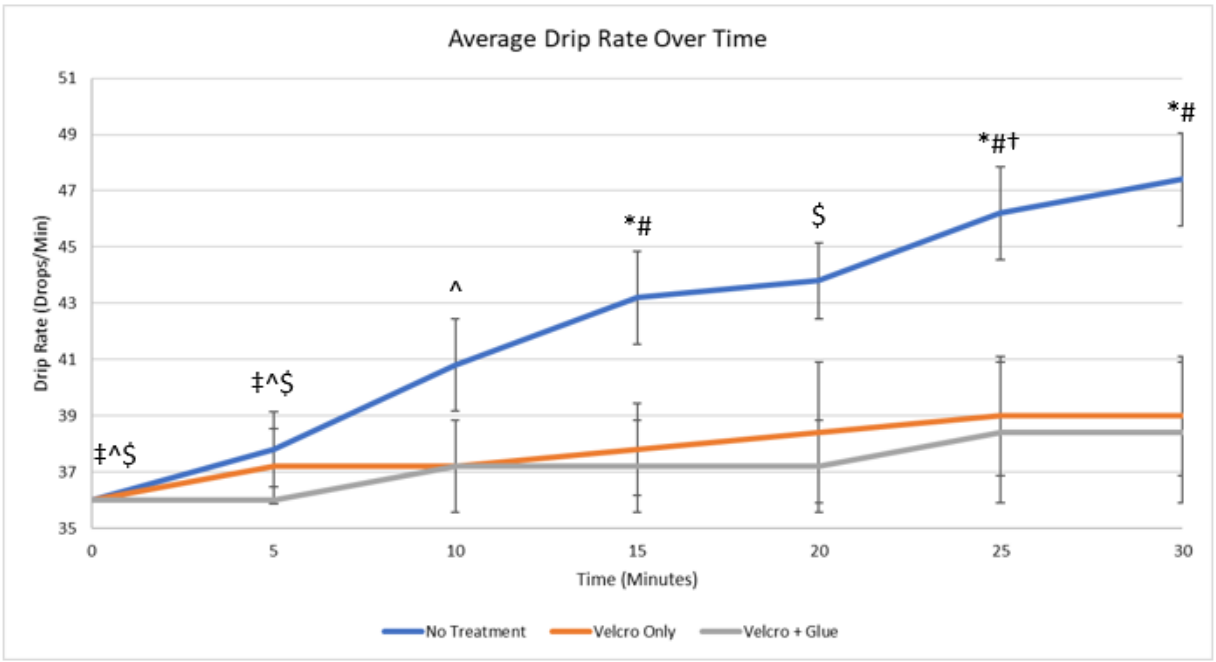

Figure 13: Average IV drip rate at over time for control and two treatment conditions. Symbols represent a statistically-significant difference ($p < 0.05$) in drip rate compared to other specific time points. Symbols and their respective time points (in minutes) are listed: * - 0; # - 5; † - 10; ‡ - 15; ^ - 25; $ - 30. For example, the drip rate at t = 0 minutes is significantly different from that at 15, 25, and 30 minutes. Error bars indicate standard deviation. N = 5 trials per condition.

Percent change in the drip rate from zero minutes to 36 minutes may be calculated using Eq. 1, below, where p = percent change, r_1 = rate at 0 minutes, and r_2 = rate at 30 minutes. Errors may be propagated using Eq. 2, where σ_p = error in p, σ_{r1} = error in r_1, and σ_{r2} = error in r_2. Note that, since our standard deviation for all t = 0 measurements equals zero, we may always set σ_{r1} equal to zero.

$$Percent\ Change = p = \frac{r_1 - r_2}{r_1} \times 100\% \quad (1)$$

$$\sigma_p{}^2 = \left|\frac{\partial p}{\partial r_1}\right|^2 \sigma_{r_1}{}^2 + \left|\frac{\partial p}{\partial r_2}\right|^2 \sigma_{r_2}{}^2 \quad (2)$$

Table 5. Initial and final average drip rates and associated percent differences. Errors in drip rates represent standard deviation. Errors in percent differences are propagated.

	Drip Rate (drops/min), t = 0 min	Drip Rate (drops/min), t = 30 min	Percent Difference (%)
No Velcro	36 ± 0.0	47 ± 2.5	+32 ± 7.0 %
Velcro Only	36 ± 0.0	39 ± 2.1	+8.3 ± 5.9 %
Velcro + Glue	36 ± 0.0	38.4 ± 2.5	+6.7 ± 7.0 %

There were limited notable qualitative observations across all trials. In Trial 4 of the control experiments, the IV bag ran out of fluid prior to the completion of the 30-minute testing period. Consequently, the trial was ended, the bag refilled, and the trial performed again. The second iteration of this trial did not produce any outliers.

Analysis and Discussion

Four of six individuals who participated in the Velcro fastening trials were able to appropriately fasten the Velcro tie to the roller clamp in under 10 seconds, while Individual C took an average of 11.0 ± 1.0 seconds (errors indicate standard deviation), and Individual E took an average of 12.0 ± 2.9 seconds. These results indicate that, while the majority of participants were able to perform the task in under 10 seconds, the solution does not guarantee a consistent sub-10-second rate of application, particularly for individuals who are just beginning to apply it without ever having done it before. There is also evidence that the task becomes easier with repetition. The second attempt for each individual was, on average, 2.1 ± 1.6 seconds faster than the first, a possible indicator of increased familiarity with the materials and methods after the first attempt. Given this degree of improvement following the first attempt, it is likely that the application of

the Velcro tie to the roller clamp does not take very long to learn how to do, making it appropriate for caregivers who may have to perform these actions in a hurry.

Comparison of the average drip rate across the control and two treatments at both t = 15 minutes and t = 30 minutes showed a statistically-significant difference in drip rate between the control group and each of the treatment groups, but not between the treatment groups themselves. This indicates that both treatments were successful in producing drip rate changes that were lower than those when no treatment is introduced, but also that the glue might not have made any difference in the Velcro's effectiveness in reducing drip rate changes.

Comparison of the average drip rate across time within the control group and each treatment group showed that there were statistically-significant increases in drip rate between time points in the control group, but no statistically-significant differences between time points in both of the treatment groups. Additionally, the drip rate for the control trials from t = 0 minutes to t = 30 minutes experienced a +32 ±7.0 % change, whereas that for the Velcro-only trials was +8.3 ± 5.9 %, and that for the Velcro-with-glue trials was +6.7 ± 7.0 %. This indicates that the Velcro was, on average able to bring the drip rate change to below ±10 % of the original drip rate, which partially-satisfies the main design requirement, which is that the device should not allow drip rate deviations of greater than ±10 % from the initial drip rate for initial rates between 0 mL/hr and 250 mL/hr.

The success of the Velcro ties in mitigating drip rate changes also provides evidence that it is indeed roller clamp drift that is partially responsible for changes in drip rate. The Velcro ties are intended to prevent the roller clamp from traveling upstream to relieve pressure. There may be other explanations for why the Velcro ties were as successful as they were; however, the stated explanation is the most likely one.

Possible Sources of Error

The experimental design allowed for potential errors to be introduced into testing. Firstly, the IV bag was not refilled to the exact same level for every single trial. Rather, the bag was allowed to drip until it was nearly empty, upon which it was refilled with water to 600 mL. Fluid mechanics calculations or experiments with differing IV bag fluid volumes would need to be performed to determine if the volume and/or height of the fluid in the bag contributes to fluid flow rate out of the bag in any way.

Additionally, the drip rates per minute were calculated by multiplying the number of drops per 20 seconds by three. Consequently, all recorded drip rate measurements were multiples of three. Had drops been counted for a full 60 seconds, the recorded values may have been different, opening the possibility for conclusions different from those drawn in this section.

Finally, the Velcro ties were not secured to the roller clamp with any kind of quantitatively-determined positioning. Rather, they were placed as subjectively close to the roller clamp wheel as determined by the user. This may have introduced variabilities on a trial-to-trial basis.

Likewise, the tightness with which the Velcro ties were attached also varied on a trial-to-trial basis. However, this is likely how the ties would be attached in clinical practice.

Takeaways and Future Considerations

At the outset of this Honors Capstone project, it was anticipated that challenges produced by COVID-19 would lead to the pursuit of a project that explored the need for an improved IV control method or device while leaving much room for improvement in the future. This is generally the case for most three-month projects, regardless of global pandemic status. Here, we will address the successes of this project, some of which were initially surprising, while looking forward toward future considerations for both this project in particular as well as the broader project through M-HEAL Team Flow.

This project was successful in developing a method that reduces deviations in IV drip rate over time caused solely by roller clamp drifting. Although this was one of the design requirements, COVID-19 necessitated a highly-resourceful approach to addressing the issue of roller clamp drifting. As a consequence, this project found an extremely cost-effective, easy-to-procure, easy-to-use, and reusable solution to reduce changes in IV drip rate over time. Had resourcefulness been less of a forefront consideration, a deeper foray into the engineering design process involving 3D printing, an array of materials, and parts assembly likely would have produced a far more complicated, though possibly even more effective, solution to this issue. However, for the needs of our community partner and lower-resource healthcare centers in Ghana, a solution as simple, yet effective, as a Velcro zip tie, may actually be preferable to a more complex and challenging-to-procure solution.

Roller clamp drifting is not the only reason for changing drip rates, however. Movement of the IV equipment and manipulation of IV equipment by patients are also reasons cited by Mr. Acheampong for why drip rates change [1]. To test how effective the tested solutions could be against movement, the IV tubing could have been shaken periodically or continuously during additional 30-minute drip rate testing trials, with drip rates calculated every five minutes as described in the testing protocols. Additional initial volume rates of 0 mL/hr and 250 mL/hr should be tested, as well. More effective addressing of IV equipment movement as well as patient manipulation would require a near-complete restart of the design process, with further design requirements clearly defined and concept generation that includes these considerations. Finally, as a long-term goal, a more robust roller clamp or roller clamp replacement could be developed to address the root cause of the issue that was explored in this Capstone project.

This Capstone project dealt with a very specific facet of the work being done by M-HEAL Team Flow. Team Flow is working to ultimately address all of the requirements determined from GHDI 2016 and 2019 takeaways as well as conversations with Mr. Acheampong. Requirements additional to those in this Capstone project include the need for a more time-efficient way to monitor IV drip rate as well as an alarm system for when drip rates exceed minimal or maximal thresholds. Team Flow is currently starting low-fidelity prototyping for the first time. Team Flow's current goal is to develop a prototype that can be used for testing in Ghanaian hospitals or

clinics, such as KATH, and used by stakeholders, such as nurses, for feedback on improvements. Following examination of the takeaways from this Capstone project, it may be worth reflecting on the findings of this Capstone design experience and determining whether it would be appropriate to return to the concept generation phase.

Ultimately, M-HEAL Team Flow could adopt lessons learned from this Capstone design experience, particularly regarding the potential simplicity of solutions. Engineering design does not necessarily need to yield highly-involved solutions that require extensive manufacturing and technical expertise to develop and test for solutions to be effective, as this Capstone design experience has demonstrated. With a plethora of resources at one's disposal, it can, in fact, be a challenge to meet the needs of a community partner as effectively as possible while minimizing design complexity. A balance must be struck between ingenuity and simplicity; often, they stem from the same place.

Conclusion

Despite the centrality of IV infusions in patient treatment, many low- and mid-resource healthcare settings around the world, such as at Komfo Anokye Teaching Hospital (KATH) in Kumasi, Ghana, do not have the sophisticated equipment necessary to provide accurately-measured IV infusions, even over the course of a single IV administration period [1], [3]. The most common apparatus to set the drip rate of IV fluids at KATH is the plastic roller clamp. While simple to manufacture and use, the roller clamp is imperfect because it tends not to keep drip rates constant over time. Current cost-effective alternatives on the market require proprietary tubing and would not be suitable for the needs of hospitals that have established the use of other tubing [6], [7].

This three-month Honors Capstone project was an outgrowth of a long-term design project through M-HEAL Team Flow. Whereas Team Flow's scope is to develop an IV drip rate monitoring and controlling solution for hospitals and clinics in Ghana, this project focused on somehow improving the current roller clamp technology. Design requirements and specifications for this project included lessening the need for nurses to adjust drip rates mid-administration, rapid implementation, and feasibility for use in low-resource settings. Specifications were informed based on conversations with Team Flow's community partner, Mr. Emmanuel Acheampong, who is an emergency nurse at KATH, and records from the 2019 GHDI trip to Ghana. Ideas for roller clamp-interfacing solutions were developed using functional decomposition and general brainstorming, with COVID-19-related prototyping and testing limitations in mind. The ideas were evaluated using a Pugh matrix, upon which it was decided that a Velcro tie-based solution would be pursued.

Two Velcro-based solutions were tested. The first was simply an 8-inch reusable Velcro zip tie that was fastened around the top of the roller clamp's wheel. The second was a modified version of the Velcro zip tie that incorporated a dried hot glue layer on the roller clamp-interfacing surface to provide additional friction, which was intended to further prevent the roller clamp's wheel from drifting. Ease of use testing was conducted by having six individuals attempt to

appropriately fasten the Velcro tie to a roller clamp as quickly as they could. Drip rate testing was conducted by hanging an IV bag and tubing set and implementing each treatment, plus a control, for thirty minute trials. All trials were repeated five times.

The ease of use results showed that the Velcro tie was generally able to be implemented in under 10 seconds by users, with times improving for each individual the more times they performed the action. Most importantly, the drip rate testing results showed that both Velcro solutions were able to significantly decrease drip rate changes when compared to the control, although there was not much difference between the two solutions themselves. Additionally, the drip rate changes over a 30 minute IV administration period were, on average, under 10% for both of the treatment groups. As a consequence, both Velcro solutions met the outlined design requirements.

In the future, the author would like to expand on the testing protocols used in this project to include motion and patient tampering-related elements and a wider range of drip rates. Additionally, it is understood that roller clamps are inherently imperfect, so concept generation could be performed again to develop a more robust, yet affordable, long-term solution to the drip rate change issue. This Honors Capstone project also demonstrated the power that simple solutions to important problems can have. The COVID-19 pandemic required resourceful thinking within the scope of this Capstone experience. This experience could inform the future work of M-HEAL Team Flow as the team continues to work towards the development of an IV drip rate monitoring and controlling solution for healthcare settings like KATH.

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