Enhancement of the Intravenous Cannulation Catheter Process

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Abstract

Intravenous (IV) cannulation is a procedure common to admitted patients, with about 90% receiving intravenous therapy in some form.[1] The efficacy, timeliness, and comfortability of this procedure are highly dependent on the first pass, or first attempt to insert the cannula. Due to providers' need for palpable and visual cues for vein location the current first pass rate is 60% for adult and 36% pediatric patients.[2] Therefore, the aim of this project was to create cost-effective devices that could be seamlessly added to the current IV cannulation process and increase first pass rate. It was also determined that the issues of angle of insertion, advancement, and rolling veins needed to be addressed. As a result, a bubble level clip, marked catheter, and skin stretcher were created to address the issue of angle of insertion, advancement, and rolling veins (respectively). The accuracy of the bubble level had the positive predictive value was 0.80 and the negative predictive value being 0.64 and an overall success rate of 0.71. Running a two-tailed, unpaired t-test yielded a $p = 0.537$. Thus, the average change in length of both the current and novel skin stretching methods are statistically equivalent. Lastly, a two-tailed, unpaired t-test was run between the unmarked and marked catheter device, yielding a $p = 0.089$. Statistically, it can be concurred that the both methods yield approximately equivalent results, meaning further testing/improvements should be investigated.

Introduction

A peripheral IV-line insertion (cannulation) is typically one of the first invasive procedures a medical practitioner performs on a patient, *Figure 1*. The IV cannulation process has existed for around 350 years.[3] However there are still unmet needs within the process as IV cannulation

Figure 1 - Intravenous Cannulation Catheter: The above figure demonstrates the general components of the insertion of an IV cannulation catheter. Typically, the protocol is to stabilise the patient's limb with gentle pressure, remove the cap on the catheter and insert the needle with minimum angle (as parallel to the skin as possible). Flashback of blood in the catheter's flashback chamber indicates that the vein has been hit. The catheter is advanced to cover the tip of the needle, the angle is lowered, and the rest of the catheter is advanced into the skin. The needle is then retracted, a covering (tegaderm) is placed on the catheter port, and the tourniquet is removed.

depends on palpable and visual cues for vein location. Therefore, when a patient's veins do not readily produce the visual cues needed for vein location, they are labeled a 'tough (or hard) stick'.

Consequently, of those receiving an IV line, 40% of adult patients require more than one attempt to open a line, and that number increases to 64% in pediatric patients.[2] More often than not medical practitioners are blamed for an unsuccessful first pass. Research conducted following the insertion of an IV found that 89% of patients reported the most influential factor for a successful first pass is the capability of the medical practitioner performing the procedure.[2] Repetition of this invasive procedure to obtain a successful line can be distressing for patients and in some cases, can lead to distrust of medical practitioners.[2] Over 50% of adult patients and 82% of pediatric patients reported the procedure caused them moderate to severe pain, stress, and/or discomfort.[2] This could possibly affect the patients' outcome and dramatically increase the amount of time spent by a medical practitioner on a patient.

To combat the issues that arise during IV cannulation many medical practitioners use simple methods, such as utilizing a warm compress, tourniquets, and mild agitation (slapping) of the vein

to increase the likelihood of a successful first pass. While these methods are fairly simple to initiate, cost effective, and unobtrusive to the patient, the low first pass rates indicate other methods need to be explored. As such, technologically enhanced methods are currently in use for better vein visualization including near infrared (NIR), ultrasound, and transillumination technologies.[5] These technologically advanced methods use either sound, in the case of ultrasound, or light, in the case of NIR and transillumination to visualize the vein. The most popular choice among these three, especially within the University of Virginia Hospital, is ultrasound. These technical methods are expensive, require trained experts, and do not alleviate problems unrelated to vein visualization.

As a result of these constraints, hospitals often invest in only a couple devices rather than a complete implementation. Hard stick patients are often placed on a list waiting for an expert to arrive to gain IV line access with one of the few vein visualization devices, drastically increasing the time a patient must wait in order to begin the process of care. Improvement of first pass rates in IV cannulation is important in the mitigation of patient stress, time management of medical practitioners, and cost effectiveness in hospitals.[1] Achievement of these aims will allow for consistency in first pass rates among medical practitioners and improve patient experience. As a result of training in this area being difficult and inconsistent between hospitals, a simplistic solution to improve first pass rates across the board is important. A device to improve first pass rates could even out any disparity between teaching methods and experience, and aid in patient recovery by lowering patient stress.

Different methods of teaching methods of this procedure are being explored to determine whether or not a new educational program would improve first pass rates. Some practitioners argue that confidence and experience are incredibly important in performance of this procedure. Additionally, it is difficult to accurately simulate a human arm. Movement, rolling veins, dehydration, and thin skin are among the many factors that a training arm cannot accurately replicate. Studies have found that there is no significant difference in first pass rates, but self-reported confidence levels are higher in students that have successfully started an IV on a human arm.[6]

As stated, existing technologies used in the cases of 'tough sticks' mainly address the issue of locating the vein. Other more simplistic methods (warming and tourniquets) cause vasodilation, allowing the medical practitioner easier access due to an increased cross sectional area, but are only mildly effective.[7,8] Refinements and modifications to the design of the intravenous cannulation catheter are necessary to improve first pass rates without the use of expensive and time-consuming imaging technology. Therefore, the aim of this project was to create cost-effective devices that could be seamlessly added to the current IV cannulation process and increase first pass rate.

Methods and Materials

Training and Insertion Materials

The Laerdal IV training practice arm (*Supplemental Figure 1A)* is currently in use in many nursing schools and similar institutions for practicing IV insertions. This device was intended to be used to test the novel devices. However, testing methods had to be altered due to access issues in the Spring 2020. Many different versions of these arms are available in different skin tones and sizes. Additionally, seen in *Supplemental Figure 1B*, BD Insyte™ Autoguard™ shielded IV catheters were used in this research project. These materials were donated by the Clinical Simulation Learning Center at UVA.

Interview Processes

Our team utilized interviews, observations, and research to identify three main problems to address: rolling veins, over advancement of the needle, and angle of insertion. The initial interviews were collected from the medical practitioners in the Cardiac Transition Unit (CTU) of the UVA Hospital. These surveys were self-reported ICore questionnaires, conducted by members of our team. The survey inquired about experience level, estimated first pass rates and time taken for the procedure, current techniques for hard sticks, and suggestions for areas of focus in our project (*Supplemental 2*). The questionnaire as a whole was designed to be in person and brief in order to obtain the most detail as possible without interrupting a medical practitioner's typical workday flow. We also

obtained the kits currently in use from the UVA hospital and were able to inspect the different components, especially the current design of the Bard Access. Fifteen medical practitioners were surveyed total. Additionally, each team member shadowed two intravenous cannulations (for a total of 6 observations).

Our second-round interviews and observations were conducted with the Intravenous Ultrasound Team (IV Team) at the UVA Hospital. This is a group of ultrasound trained nurses that travel around the hospital and use an ultrasound device to help other units of the hospital. We spoke to them about our then-current designs (the first iterations of the vein stabilizing device and the bubble level) and took into account their feedback.

The third-round interviews originally would have asked questions about whether the practitioners surveyed would use our devices and asked for changes that might need to be made (from the point of view of someone performing the procedure daily) while they were able to hold and physically inspect the devices. However, due to limited time, we decided to conduct a short phone survey with yes or no questions to determine whether the practitioner would use the device. The questions asked can be found as *Supplement 3*.

Original Testing Design

Originally, our team intended to perform the IV insertion procedure on Laerdal Multi-Venous IV Training Arms (Peripheral Intravenous Therapy) after completing a training session in conjunction with the UVA health system, more specifically the nursing school. Following competency of the procedure, we would perform 10 IV insertions with the current kit and procedure, measuring our first pass rates, time taken to perform the procedure, and our reported confidence levels. Then we would each perform an additional 10 insertions using our devices, again measuring first pass rates, time taken, and confidence levels. *We hypothesized that our first pass rates and confidence levels would increase with no statistical change in time taken to perform the procedure.* A one-tailed, unpaired t-test would be performed for each variable. In addition to these quantitative measurements, we intended to perform closing surveys during which medical practitioners could physically manipulate our devices and try using them to receive feedback. These surveys would focus on whether our devices were useful and preferable to current procedure. This original testing method was not completed due to access issues in Spring 2020, leading to the following testing methods being used.

Vein Stabilizing Device Material and Testing Method

Stetrix Tissue Retention System (TRS) material, which is used in bariatric surgery to hold excess skin and fat out of the surgeon's way was modified to prototype the vein stabilizing device.

Currently, there is no standardized quantitative metric to measure rolling veins. In order to test our device, we made the assumption that measuring the stretch of the skin would determine whether this device would serve as an adequate replacement for the current technique. *We hypothesized that our device would stretch the skin as much or more than the current method used by practitioners.* In order to test this hypothesis, two members of our team drew two lines 1cm apart on their skin and used both methods of stretching. We gathered 20 total data points for each method and compared the two using a two-tailed, unpaired t-test to determine whether or not there was a statistically significant difference in the skin stretching abilities of the two methodologies.

Bubble Level Material and Testing Method

The bubble level was designed using aquatic airline tubing 4.76 mm in diameter. The final iteration included 80 proof vodka as the containment liquid. The tubing was capped with standard hot glue.

In order to measure the device's accuracy, we clipped the bubble level to the BD Insyte™ Autoguard™ shielded IV catheter. The angiocath with the bubble level was held at 7 different angles (0, 25, 40, 45, 50, 55, and 60 degrees) as measured by a protractor for 3 trials each. These results were then categorized based on where the bubble theoretically should have been (true/false) and where it was observed to be (negative/positive). Based on this information, we calculated a positive and

negative predictive value and the overall success rate of the device.

Marked Catheter Material and Original Testing Method

As mentioned, one of the major areas of focus for this project is the advancement of the needle and/or catheter during this procedure. Ideally, the cannula will remain still until the catheter advances to the tip of the needle (and not further) and is then retracted. In order to address this, we marked the catheter with a permanent marker to create a guideline for the distance that the catheter needs to be advanced to cover the needle.

In order to test this marked catheter and determine whether it was helpful in mitigating over advancement, we again intended to use the IV training arm. Frequently, there would be flashback that would quickly recede, indicating that the needle had pierced the vein, but continued entirely through until there was no longer 'blood'. However, this method of testing has its drawbacks, the most obvious being that this is no way to visually observe the 'vein', nor is it completely accurate. Regardless, we were unable to use this method of testing, as the Simulation Center at UVA's Nursing School closed before we started our testing. As an alternative we developed the following advancement testing method.

Alternative Catheter Advancement Testing Design and Methodology

As we were unable to use the Laerdal arm to test for over advancement, we found artificial tattoo skin in 3mm thickness (used by tattoo artists to practice) and intended to design a device on which we could test our first pass rates and visualize the advancement of the needle. The tattoo skin was placed over a handmade silicone mold. The silicone mold was prepared from GE Clear 100% Silicone Sealant caulk, designed for windows, doors, etc. This material was chosen due to its penetrability and flexibility most similar to human tissue given accessibility constraints of the time. The caulk was dispensed into a plexiglass frame and allowed to dry, then placing plastic tubing within the silicone to model a vein. This would allow for visualization of over advancement after performing the insertion, but not during, making this testing method close to ideal for measuring over advancement. Unfortunately, we were unable to find plastic tubing that the needle was capable of puncturing without the catheter being caught on the tubing. After attempting to model our vein with straws and tubing, we decided to design a different method of testing.

Since we were unable to find an at-home model of the vein, we opted to test the advancement of the needle and the catheter purely by distance, rather than over advancement. While this may not have been ideal, it allowed us to also determine whether the catheter had been fully advanced to the tip of the needle rather than just the over advancement of the needle. In order to do this, the cannula was inserted through the tattoo skin in a similar manner as the actual procedure, but to a standardized measurable depth. The catheter was then advanced as it would be in the procedure, using the tick marks as a guideline for the marked catheter. Ten trials were performed with both the marked and unmarked catheter, and the position of the catheter and the needle relative to the standardized depth were recorded. An unpaired, two tailed t-test was run to determine whether or not the marked catheter significantly altered advancement of the needle and catheter.

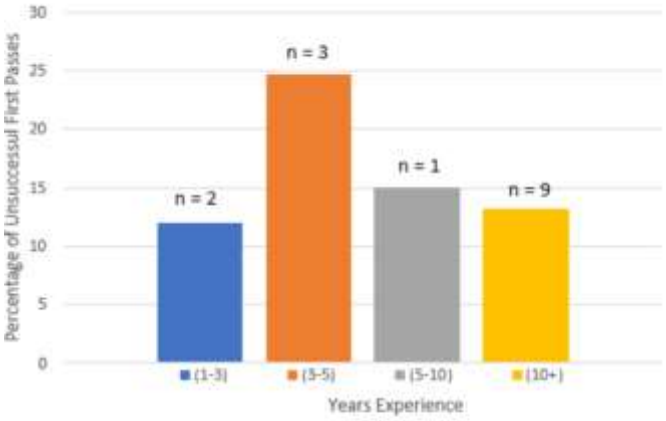

Figure 2 - Unsuccessful First Passes vs. Experience: The above figure details the relationship between medical practitioner's years of experience and their self-reported percentage of unsuccessful first passes. n is the number of medical practitioners who reported within the years of experience category.

Results

Identification of Sub-Aims and Constraints

To gain insight into what is causing a low first pass rate, a comprehensive analysis was generated pulling from three sources: our advisor's input, observations made while shadowing the procedure, and a questionnaire conducted on 15 medical practitioners. The entire questionnaire results can be found within the *Supplement 4*.

Questionnaire Results

To highlight the most key findings relevant to our overarching aim, 40 % of responses indicated that an individual medical professional will fail to achieve a first pass on at least 1.5 out of the 10 patients they see a day. When asked what methods are used to increase the likelihood of a first pass, greater than 85% of the responses detailed simplistic methods (warming, tourniquet, palpation, etc.) where the most advanced answer was the usage of topical anesthetic. UVA hospital's protocol is that a medical practitioner is allowed two unsuccessful IV attempts before either a more experienced medical practitioner or the IV team (utilizes ultrasound technology) is called in to intervene. Results indicated that only 20% of the time the ultrasound technology is called upon, thus heavily relying on more experienced medical practitioners. A post data correlation analysis between years of experience of the interviewed medical practitioners and their self-reported unsuccessful first pass rates was generated to see if there was consistency with the protocol for escalation. You can see in *Figure 2* there are higher rates of unsuccessful first sticks in the less experienced medical practitioners (1-5 years of experience), but the correlation is not linear throughout. As a result of this varying data, it led our team to conclude that other factors besides experience were at play. When asked what are some factors that increase the difficulty of getting a successful first pass, hydration level, patients of older age, and rolling veins were the top three results. Lastly when asked what our team could create to mitigate unsuccessful first passes, the largest percentage of responses revolved around the creation of a device, ideally easy and quick to use and perhaps in a kit design.

Observational and Discussion Input

In conjunction with this data, some key observations were incorporated into the questionnaire results to formulate the sub aims and constraints. After observing both the CTU and the IV Team, it became apparent that the calling system used by a medical practitioner to utilize the IV Team's services, dramatically increased the wait time for a patient. Additionally, our team noticed a large variation of angles of insertion, some reaching degrees too high for a peripheral intravenous procedure. Discussion with our advisor indicated the angle of insertion of a peripheral intravenous catheter should not exceed 45 degrees. Further discussion of our team's observations led to the arrival of how over advancement of the needle-catheter device past the veins lower wall can be a significant contributor in an unsuccessful first pass. Often times a medical practitioner will advance the needle into the vein, obtain a flashback of blood indicating they are in the vein, but when they advance the catheter over the tip of the needle, the needle perforates past the lower vein wall causing the catheter to be not within the vein, resulting in no blood flow. More often than not, this occurrence leaves medical practitioners confused and left to troubleshoot with a blown vein. The last major observation our team made while doing CTU and IV team observations, is that to mitigate rolling veins, medical practitioners will use a thumb and a finger to stretch the skin parallel to the insertion site, anchoring the rolling vein with tension. This process leaves the medical practitioner with only one hand to insert the IV catheter and dress the area.

Comprehensive Analysis

Combining all of this information our team aimed to make a kit of accessory devices that improve first pass rates by targeting three different areas: angle of insertion, rolling veins, and catheter advancement. The kit components must not be highly technological advanced in order to increase availability and usability, Additionally, it was important to not entirely modify the protocol followed in order to combat resistance to change. More specifically, any desired modifications to the angiocath would have to be added on as needed.

Bubble Level Device

The bubble level device is a clip-on accessory device that is designed to ensure the angle of insertion of the needle is between 0 and 45 degrees relative to the horizontal plane of the insertion site. The clip-on portion is designed to attach to the beveled holding area of a BD Insyte™ Autoguard™ shielded IV catheter

Evaluation of Prior Art

To date, there is no prior art utilized by medical practitioners that accomplishes standardization of angle insertion. At most, training methods are utilized to establish that an angle less than 45 degrees should be used during a intravenous catheter. This angle of insertion has been researched to be most important during advancement of the catheter, as advancement of the catheter following flashback yields a catheter abrasively hitting the lower vein wall.

It is worth noting however, the bubble level device originated as a twist on a typical construction level. The idea was to incorporate the target window concept but place it on a clip that can be used as an accessory to current protocol. The construction level is designed to standardize an angle of 0 degrees, with little to no variation. Much of the trial and tribulation of the bubble level design revolved around configuring the window for a much larger degree range.

Design Iterations

In an attempt to widen the level's window, it became apparent a lengthy device would be needed using ethanol (the typical solution within a construction level). Keeping in mind the device is to be an accessory that is to work adjunctly with an angiocath, the size of the device must be relatively small. As such, different fluids were investigated to test bubble responsiveness and accuracy. Water was evaluated first, however the bubble did not free flow throughout the tube but rather adhered to the tube walls. To find a solution moderately in the middle, 80 proof vodka (60% water, 40% alcohol) was used. Surprisingly, this liquid provided the responsiveness, accuracy needed, and length of window desired.

The first design of the clip for the bubble level, seen in *Figure 3*, was designed to fit around the dimensions of the grip portion of the angiocath. Other locations were evaluated, as the device could potentially be obstructive to a grip, however other locations on the angiocath proved more problematic. As such, the clip's sides were originally designed thin to mitigate obstruction, however when secured onto the angiocath, the edges of the device obviously were under strain and snapped due to the thin walls.

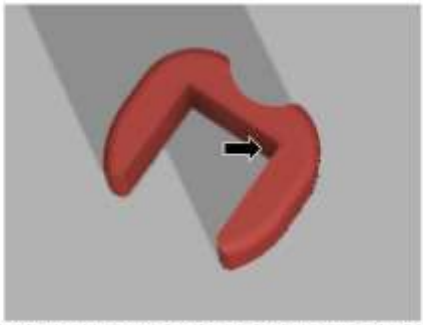

Figure 3 - 1st Iteration Bubble Clip: This design was centered around being the least obstructive as possible on the grip portion of the angiocath. However, when placed on the angiocath it was obvious the device was under strain. The arrow indicates where the device structurally failed due to the large outward pressure faced by the cliping action of the lower wings.

Our second iteration improved on this iteration, with a slight increase in the spacing *(Figure 4*) between the two wings, adding nubs on the end of the wings to promote locking onto the angiocath, increasing the thickness to reinforce the upper corners, as well as using Acrylonitrile butadiene styrene (ABS) instead of Polylactic Acid (PLA) due to ABS being more durable and flexible. While the second iteration was capable of clipping to the angiocath without breaking, it was slightly larger in thickness than necessary. To combat this we designed our third iteration, as seen in *Supplemental Figure 5*, to be slimmer along the wings but thicker in the upper corners to keep the reinforcement aspect. However, we were unable to print this version, and used the second version for testing since we expected no change in functionality between the two.

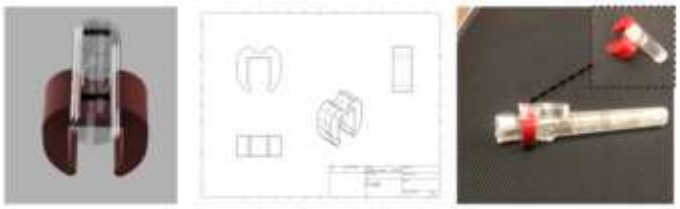

Figure 4 - 2nd Iteration Bubble Clip: This design was modified from the 1st iteration, to be more resilient to the clipping action. In comparison, this device is moderately more bulky in thickness, and was 3D printed using Acrylonitrile butadiene styrene (ABS) instead of Polylactic Acid (PLA) due to ABS being more durable and flexible.

Accuracy Testing

True Positives	8	**False Positives**	2
True Negatives	7	**False Negatives**	4

Table 1 - Bubble Level Accuracy Testing: The following figure demonstrates the accuracy of the bubble level during 21 total trials at 7 various angles. Let that true/false denotes the expected/unexpected location of the bubble, respectively. The positive/negative notates whether or not the bubble was in the window or not, respectively. The positive predictive value was 0.80 and the negative predictive value being 0.64. An overall success rate of 0.71.

Table 1 gives an overview of the accuracy testing results of the bubble level. It should be noted that while the device demonstrated a relatively decent positive predictive value of 0.80, meaning the bubble was within the window 80% of the time that it should have been, there is obvious room for improvement. A false positive is ethically the worst-case scenario as a medical provider would think their insertion angle is acceptable when in reality it is not. During the trials, it was noted that the reason for both false positive cases, the bubble seemed to be adhered to the initial end of the tube. This means in future construction perhaps non air adhering materials should be chosen to mitigate this issue.

<u>Skin Stretcher Device</u>

Evaluation of Prior Art

Observations made in the CTU led to the discovery of how many practitioners currently use a method to stretch the skin in the forearm by bridging the insertion site with their index finger and thumb and pulling parallel to the vein (shown in *Figure 5*). This technique, while useful, takes a hand away from the practitioner and can be inconsistent and difficult for different patients. Knowing this prevents rolling veins, our intent was to recreate its effect on the skin and vein. We spoke to a medical practitioner at UVA

Figure 5 - Current Skin Stretching Method: The following image captures how medical practitioners currently stretch the skin parallel to the line of insertion to reduce the occurence of rolling veins. As an account of effectiveness, a one centimeter mark is measured prior to stretch then remeasured during a stretch, giving a change in lengths.

as well as consulted with our advisor about the most effective ways to do this and how the technique is employed. Following discussion, Stetrix Tissue Retention System (TRS) material, which is used in bariatric surgery to hold excess skin and fat out of the surgeon's way was offered up as a potential material that could be modified to achieve a similar goal. This material is a strong adhesive with a Velcro-like material on the opposite side. The adhesive sticks to the skin and the other side is used to attach to other pieces of the material (*Figure 6*).

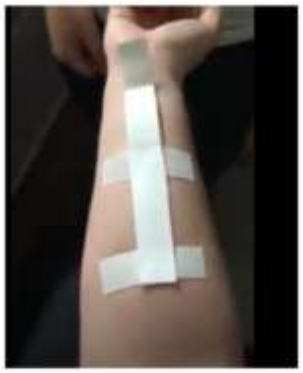

Figure 6 - Skin Stretching Device: The following image captures how the final design of the skin stretching device is to be applied for a cephalic vein insertion.

Design Iterations

The first iteration of the design was similar to a belt; two strips of Stetrix would be adhered to the skin on either side of the cannulation site, with a third strip looping underneath the arm with a 3D printed plastic loop mechanism for adjustability. However, after speaking with our mentor, we found fault with some aspects of this design. The current methodology pulls parallel to the vein, while our belt mechanism would pull perpendicular; this was not ideal as our goal was to mimic the current. Logistical issues, such as the reusability, time to apply the device, and length of adjustable strap were noted and a further iteration was designed.

From our first design, it became apparent that our device for vein stabilization needed to pull parallel to the vein and use only Stetrix for ease of use and reusability. The device (shown in *Figure 6*) is designed to be applied quickly before cannulation. Two strips of Stetrix are adhered distal to the insertion site, perpendicular to the vein. A third strip is attached by the Velcro-like side to the more proximal of the first two and pulled tightly to attach to the second. This stretches the skin similarly to the current method, and frees the hand of the practitioner.

Trial	Original (mm)	Device (mm)
1	2	2
2	1	1
3	2	2
4	2	1
5	2	1
6	3	2
7	1	1
8	1	1
9	2	1
10	2	2
11	2	2
12	1	2
13	1	2
14	2	1
15	1	2
16	1	1
17	2	1
18	2	2
19	2	1
20	1	2
Average	1.8	1.5
Std Dev	0.5026	0.5130

Table 2 - Skin Stretching Analysis: The following figure demonstrates the average change in length during both skin stretching methods, with associated standard deviations. Running a two-tailed, unpaired t-test yielded a p = 0.537. Thus, it can be concurred that the skin stretching device produces approximately equivalent results as the current method used by practitioners.

Performance Comparison Test

Overall, following the comparison test between original and novel device methodology to mitigate rolling veins, little difference was seen between the two methods (*Table 2*). It should be noted however that only change in skin length was measured, not a measure of rolling veins. This can be considered a logical fallacy, however a good place to start in terms of usability. In the future it would be necessary to test on human subjects with a quantitative and qualitative analysis on mitigation of rolling vein's impact on first pass rates.

Catheter Advancement Device

The catheter advancement device is designed to mitigate the change the needle perforates through the bottom of the vein wall by entirely covering the tip of the needle with the catheter. The device can be seen in *Figure 7*.

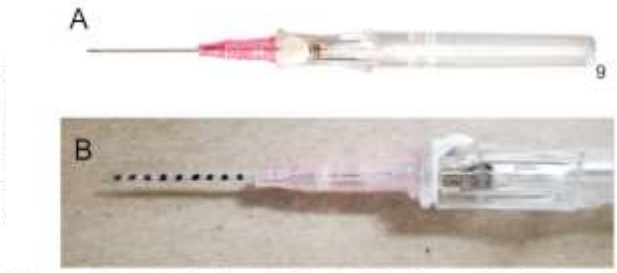

Figure 7 - Standard and *Marked Catheter*: The figure above displays the current catheter design (A) as well as the novel marked catheter (B). The marked catheter is designed to mitigate catheter advancement issues. The space between each depth mark is the disparity between the needle tip and the start of the catheter.

Evaluation of Prior Art

While no device has been discovered by our team that bears similar resemblance and mitigates IV catheter advancement issues, there is however similar depth markings on other catheter types.

Design Iterations

The 20-gauge BD Insyte™ Autoguard™ shielded IV catheter was marked at every 2 mm (this is the distance from the tip of the needle to the end of the catheter) starting from the end of the catheter nearest the tip of the needle. This was marked with a permanent marker, as the testing we planned to undergo was proof of concept and was not being used in a biological model. Further iterations should be marked with ink approved by the FDA for use in the body.

Performance Comparison Test

Table 3 highlights the results of the marked catheter versus unmarked catheter advancement results. A t-test between the marked and unmarked catheter yield results deemed not statistically different ($p = 0.089$), but only moderately different. This lack of difference can be attributed to the inconsistent distances between the depth lines on the catheter, as they were drawn on by hand.

Table 3 - Catheter Advancement Analysis: The above figure demonstrates the change in distance of either the catheter or needle tip following catheter advancement relative to the known initial depth of the needle. A zero-zero pair is ideal. The sum of the absolute value was taken of both the position of the needle and catheter and a two-tailed, unpaired t-test was run between the unmarked and marked catheter, yielding a $p = 0.089$. Statistically, it can be concurred that the both methods yield approximately equivalent results, meaning further testing/improvements should be investigated.

Follow-up Survey Results

Due to limited time, a short phone survey with yes or no questions was conducted to determine whether the practitioner was in support of or not in support of key components of the devices. Looking at *Table 4*, it can be generalized that medical practitioners are in support of the devices created. Obviously, more evaluative methods should be used in the future.

Discussion

Overall, this project has yielded promising results and each of the devices developed has begun to push the field of intravenous cannulation forward. These are novel technologies intended to address problem areas in this procedure that have not been entirely resolved. These devices are intended to be used as general guidelines to improve the IV cannulation process not only for the healthcare provider, but for the patient as well.

Bubble Level

An exhaustive literature search has shown that the bubble level clip is the first of its kind. The varying angle of insertion has not been addressed technologically in this field, and is reliant on practitioner experience. Our short survey has shown that about 50% of the medical professionals we surveyed in our closing interviews are concerned about their angle of insertion. Further studies need to be performed, as this was by no means a comprehensive evaluation. However, it is likely that those new to performing the procedure would be less comfortable with their angle of insertion.

Though further improvements will need to be made to the device, the bubble level has yielded a success rate of 71% and the clip is fully functional. The fluid in the level may need to be re-evaluated to identify the ideal balance between accuracy and sensitivity, and further testing will need to be performed. In addition, more precise methods to mark the tubing will need to be investigated, especially if the device is to be manufactured on a large scale.

Marked Catheter

The marked catheter is a novel approach to the issue of over advancement and blown veins. Currently, the issue is addressed with the flashback chamber; because practitioners are able to see when the needle has pierced the vein (visualized with the flashback) they are able to adjust the angle and advance the catheter. We were unable to report a significant difference in advancement between the current catheter and our marked catheter, however, with improvements in the markings and testing methods we expect that this device will develop into a useful guideline to avoid over advancement.

Further iterations of this device would include more precise markings. As this device moves from proof of concept and efficacious testing to human trials, bio-safe ink (such as the ink used on pharmaceuticals) will need to be used rather than permanent markers. Testing could be improved with a similar model to the tattoo skin with Plexiglass frame if a more penetrable model vein can be found.

This would allow for visualization of any case of over advancement.

Vein Stabilizer

The vein stabilizing device we designed is supported by all of the data we gathered and the surveys we performed. We have found that it is no less effective at stretching the skin than the current methods used by medical practitioners. However, skin stretch has not proven to be an accurate measure of stopping rolling veins. More research needs to be done on whether or not this metric is truly a measure of vein stabilization.

Further research on this device may include more studies on the most effective distance between the two perpendicular strips of Stetrix to optimize the use of the device. Again, further studies need to be conducted on whether or not this stretching the skin adequately and effectively stabilizes veins. Following this research, trials on humans will need to be conducted.

Overall, we have seen promising results with each of these three devices. Further improvements on these devices can be made, but it is important to note that these are novel technologies to address problems in the field of intravenous cannulation for which there are currently no solutions. This project takes a step forward to fill some of the unmet needs in the intravenous cannulation field.

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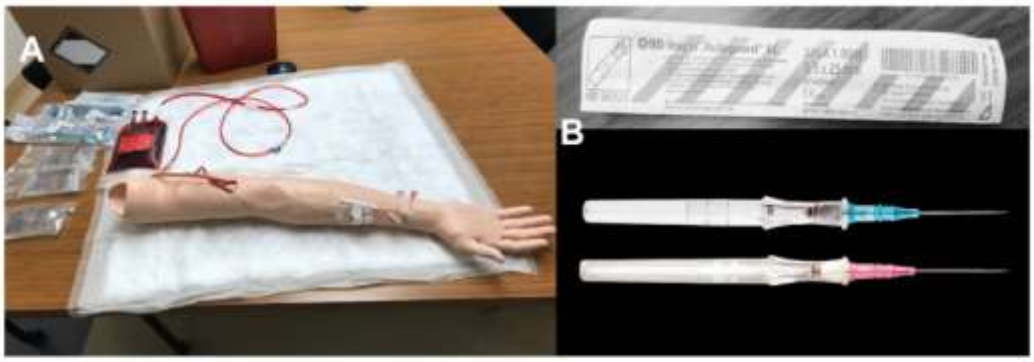
Supplemental Material



Supplemental Figure 1 - Training Materials: Image A details the Laerdal training arm setup. Image B details the 22-gage donated intravenous cannulation catheter used during training. This figure is in an effort to show the current training methods for the device as well as how we tested our own first pass rates and successful sticks.

1. On average, how many IVs do you insert per day?
2. How many years have you been doing this?
3. On average, how many IV insertions require more than one attempt per line?
4. What is your strategy to increase a successful first attempt of an insertion of an IV?
5. What makes one patient harder to stick than another?
6. What is the patient's response if an IV is not obtained on the first try?
7. Do patients often know if they are considered a "hard stick", if so do they offer technique advice?
8. From your experience and on average, how long does it take to insert an IV successfully? (mins)
9. When do you ask for help and what is the protocol for escalation?
10. How would you improve the IV insertion process?

Supplemental Figure 2 - ICor Questionnaire: The following ten questions were used to conduct fifteen in person interviews with medical practitioners within the University of Virginia Hospital. Majority of those interviewed resided within the Cardiac Transition Unit. The questionnaire was designed to unveil current issues faced by medical practitioners when inserting an intravenous cannulation catheter.

1- Do you think you would spend an extra 30 seconds to apply a simple accessory device to combat rolling veins?

2- Are you ever concerned about your angle of insertion?

3- Do you think the current IV cannulation catheter should be adjusted or accessory devices should be used alongside?

4- Do you think the current design of the bubble clip would get in your way?

Supplemental Figure 3 - Final Iteration Questionnaire: A final iteration questionnaire was conducted over the phone using the following questions with five medical practitioners previously contacted for the Icor questionnaire. The questionnaire was accompanied with images and short demonstrative videos of the developed devices.

	Numerical Average	Std Dev	1 Majority Response (%)		2 Majority Response (%)		3 Majority Response (%)		4 Majority Response (%)		Other (%)	
On average number of IV's inserted a day?	2.83	2.19										
How many years experience?			10+	(60.0%)	3-5	(20%)	1-3	(13.3%)	5-10	(6.66%)	0-1	(0%)
Percentage of number of failed first attempts per day?			5-15	(33.3%)	15-30	(33.3%)	0-5	(26.6%)	30+	(6.67%)		
Strategy to increase likelyhood of a successful stick?			Warm Area	(36.6%)	Tourniquet	(16.7%)	Topical Anaesthetic	(10%)	Extensive Search	(10%)	Other x8	(3.3%)
Why are some sticks harder than others?			Hydration	(29.6%)	Older Pts.	(22.2%)	**Rolling Veins**	**(14.8%)**	One Arm Access	(11.1%)	Other x3	(7.4%)
What is the typical patient response to an unccessful first stick?			Anxiety	(29.4%)	Understanding	(23.5%)	No Response	(23.5%)	Unhappy	(17.6%)	Supportive	(5.9%)
Do patient know they are a hard stick?			Yes	(100%)								
Advice given?			Vein Location	(66.7%)	No advice	(13.3%)	Vein's Roll	(13.3%)	Not actually	(6.67%)		
How long to get a successful first pass? (min)			3-5	(60%)	1-3	(20%)	5+ each	(20%)				
Protocol for Escalation?			More Experienced Tech	(80%)	Ultrasound	(20%)						
Suggestions for protocol improvement?			**Better device**	**(26.7%)**	Training	(20%)	Warming	(13.3%)	**Kit**	**(13.3%)**	Other x2	(13.3)

Supplemental Figure 4 - Survey Results: The chart above summaries the Icor questionnaire responses. Let it be noted that the values within the parenthesis indicates the percentage of response received. Within the Other section, x# indicates the number of individual responses each representing (#) percentage. The highlighted results indicate those relevant to device development.

Supplemental Figure 5 - 3rd Iteration Bubble Clip: This design was the mediation between less obstructive but also structurally sound. Some key components are the thicker upper corners, reinforcement nubs at the bottom of the wings, as well as slim wings in general.