SEIV-Cath: Self-Expanding IV Catheter for Improved Drug and Fluid Delivery

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Executive Summary

Placing an intravenous (IV) catheter in elderly, very young, or critically ill patients presents great difficulty due to the constricted and generally uncooperative nature of their vasculature. Doctors must therefore use catheters with smaller diameters to better access the veins, and are often unable to deliver drugs at a rate fast enough to meet the patients' urgent care needs. Current workarounds are painful and invasive - options include cutting the skin to expose veins or drilling to inject drugs directly into bone marrow. To address this issue, we are developing a small catheter that expands after injection, enlarging the vein and thus increasing the rate of fluid flow. Our solution will in turn minimize the tissue damage and catheter waste that come from using incorrectly sized catheters, problems that plague all current IV fluid delivery methods.

Problem & Clinical Need

- 4 million IV catheters placed per day in emergency situations alone
- Target group: critically ill patients with peripheral difficult venous access (PDVA) conditions
  - diabetes, hyperthermia, obesity, etc.
- When these patients need urgent care (i.e. high rate of drug delivery) they cannot get it
  - Smaller needles dictated by the constricted veins limit the delivery rate
- Current workarounds are very invasive: drilling into bone marrow or cutting arm open
- Need: catheter that goes in small and expands

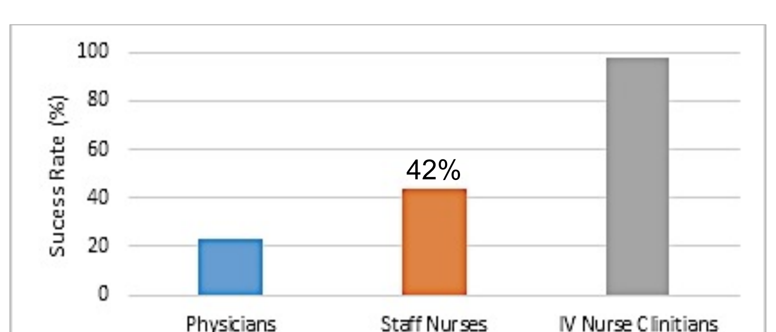


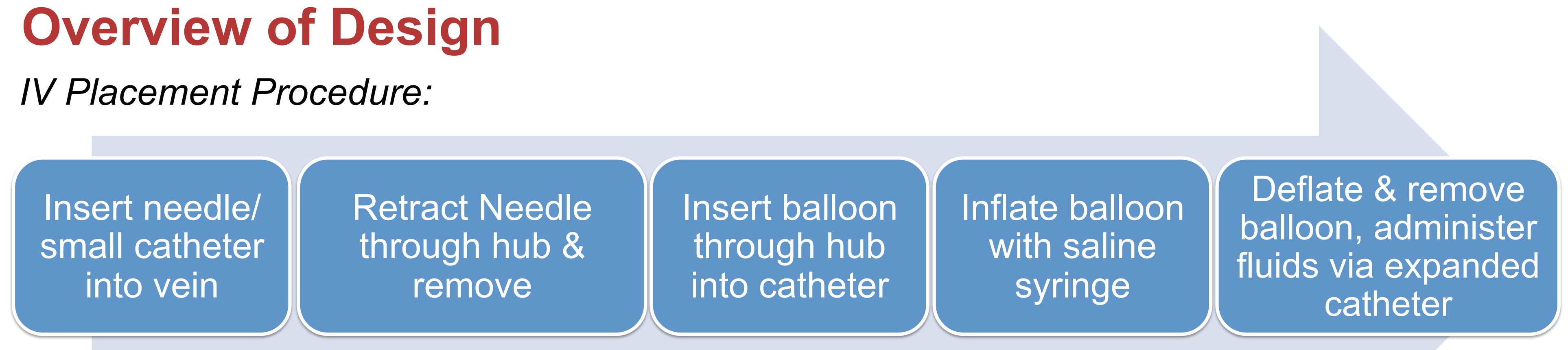
Fig. 1 Success rate of IV catheter insertion from various hospital staff

Market Analysis

- 300 million catheters sold yearly, projected to grow
- Catheter industry is stable and worth $445 million
- IV catheter manufacturers rely on bulk producing to make a significant profit
- Harsh competition and price erosion discourage startups in this industry
- Projected SEIV-Cath cost: ~$45-70 to offset costs
- Premium IV catheters range from $10-20, so the material cost will need to be significantly lower for our product to be impactful in this industry

Overview of Design

IV Placement Procedure:



Three-part design:

(1) Composite IV catheter tube: elastomer embedded with stent
- Elastomer maintains tube integrity & minimizes turbulence
- Stent stabilizes expanded state

(2) Traditional catheter hub that houses a needle and connects to catheter tube
- Modification: compressible, leak-proof ring of material placed between the catheter and hub at their connection to maintain system integrity during catheter expansion. The specific material is yet to be determined, but similar parts are used in gaskets

(3) Small angioplasty balloon that inflates to permanently expand the catheter (see Fig. 3)

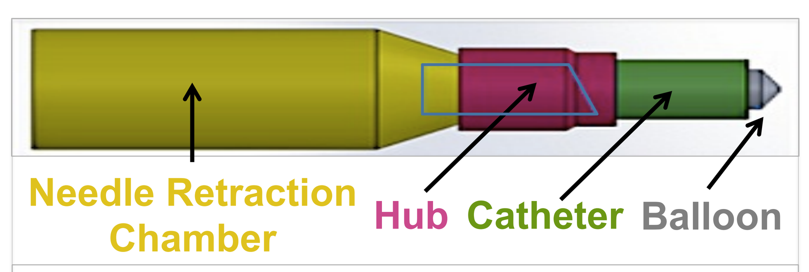


Fig. 2 Assembly of balloon in apparatus, with ghost of removed needle shown in blue

Fig. 3 Conventional angioplasty balloon (A) deflated, (B) inflated, (C) inserted into catheter

Goals for expansion:

Expansion State	Gauge	Outer Diameter (mm)	Length (mm)	Flow Rate (ml/s)
Initial	22 G	0.8	25	0.417
Intermediate	20 G	1.0	33	0.917
Final	18 G	1.2	45	1.25

Final Prototype & Evaluation Testing

- Focused on catheter tube construction: 2 types of metallic stents coated with 2 types of elastomer, respectively
  - PDMS (30:1) chosen based on yield strength extracted from tensile tests
  - Parafilm chosen based on accessibility and ease of use
  - Preferred stent geometry: zig-zag (easier expansion)
- Limitations: unable to make small zig-zag stents, thin enough PDMS
- Evaluation method: pre- and post- expansion flow rate tests

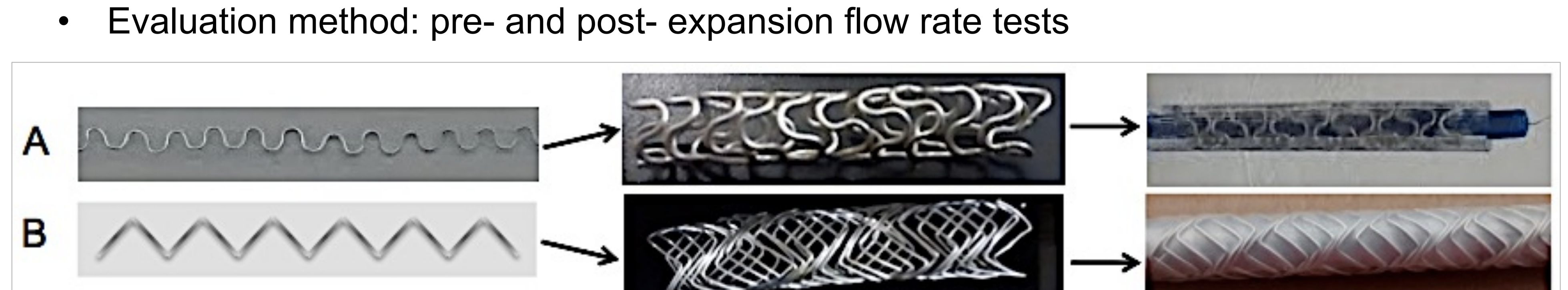


Fig. 4 Prototype manufacturing process for (A) wavy-stent embedded PDMS tube, (B) zig-zag stent embedded parafilm tube

Tube Type	Scale	Initial Outer Diameter (mm)	Final Outer Diameter (mm)	% Expansion	Initial Flow Rate (ml/s)	Final Flow Rate (ml/s)	% Increase in Flow
PDMS & Wavy Stent	6x	5.14	5.22	1.6%	N.A.	N.A.	12.0%
Parafilm & Zig-zag Stent	14x	11.52	15.18	31.2	*35.38	*221.89	627%

Novelty of Concept

- New technology focuses only on aiding insertion of needle and catheter into vein
- Past failed attempts: expanding upon fluid adsorption, unrolling to larger diameter, expanding once freed from constricting encasement
- SEIV-Cath combines ease of insertion and higher drug flow rates by combining a unique and novel mix of current medical and technical trends.

Estimated Product Cost

Material	Price/Unit	Manufacturer	Quantity	Part Cost
PDMS	$0.099/g	Dow Corning Sylgard	~10 g	$0.99
Nylon 12	$0.0075/g	Jiangsu Delta Plastic & Chemical Co.	40 g	$0.30
Hypodermic Needle	$0.25/needle	Taixing Zhiyu Medical Instrument Co.	1 needle	$0.25
Flash Chamber Cotton	$0.50/roll	Baishun Co., Ltd.	0.25 roll	$0.13
Stainless Steel Stent	$30/stent	Peiertech Co.	1 Stent	$30
Labor	$15/hour	N/A	1 min.	$0.25
			Total	$31.92

Regulatory Path & Reimbursement

- Catheter & stent combination → Class II device
- Can submit 510(k) due to product similarity
- ISO Standards to meet: 10555-4 (catheters) & 594 (hub interface lock)
- ASTM Standard to meet: D1599-14 (radial tensile test)
- Medicare/Medicaid-Reimbursed under C1725/C1885 for transluminal angioplasty catheters

Future Work

- Scale down to true size by partnering with medical device company for improved manufacturing capability
- Continue flow/expansion testing: vary tube & stent thicknesses, try new elastomers to optimize catheter elasticity, use medical grade material for stents
  - Eventually test on animal model
- Better define hub design and hub-catheter interface

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