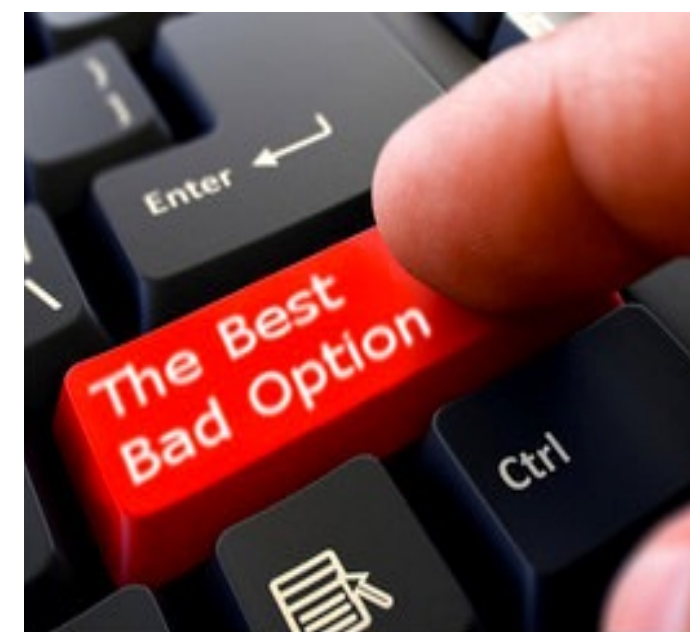




Introduction

- The ability to collect urine in ICU patients is standard of care
- Urine alerts the physician about end-organ perfusion.
 - Appropriate fluid provision requires knowledge of urine output.
 - Urine analysis is important to diagnose urinary tract infection, electrolyte abnormalities, and nephrolithiasis.
 - Novel urine tests to diagnose AKI are being incorporated into clinical care algorithms.
- Urine output is important to define AKI
- In the AWARE Study¹,
 - Failure to account for oliguria will miss 18% of acute kidney injury (AKI)
 - AKI events that are only identified by urine output are associated with comparably poor outcomes compared to those diagnosed by changes in SCr alone
 - Those who meet both criteria had worse outcomes than those meeting only one.
 - Oliguria is a worse risk factor for bad outcomes compared to serum creatinine
 - In a recent study in premature neonates by De Mul et al.²
 - Failure to account for oliguria missed 27% of AKI episodes
 - Neonates with Urine Output < 1.5 ml/kg/hr have 5.0 times higher Odds of Death (95% CI = 2.4-11) vs. those without AKI, even after controlling for important confounders. (AUC = 0.73 (95% CI = 0.66 – 0.80)
 - Urine collection devices for neonates and small children are fraught with problems such that clinicians and nurses are left to choose the best bad option.
 - Urine catheters are difficult to use and traumatic.
 - Urine collection bags are ineffective and the tape can damage the fragile skin of premature neonates
 - Diaper weights are misleading (if they quantify stool).
 - Cotton balls absorb proteins³ and can't be used to test for a UTI



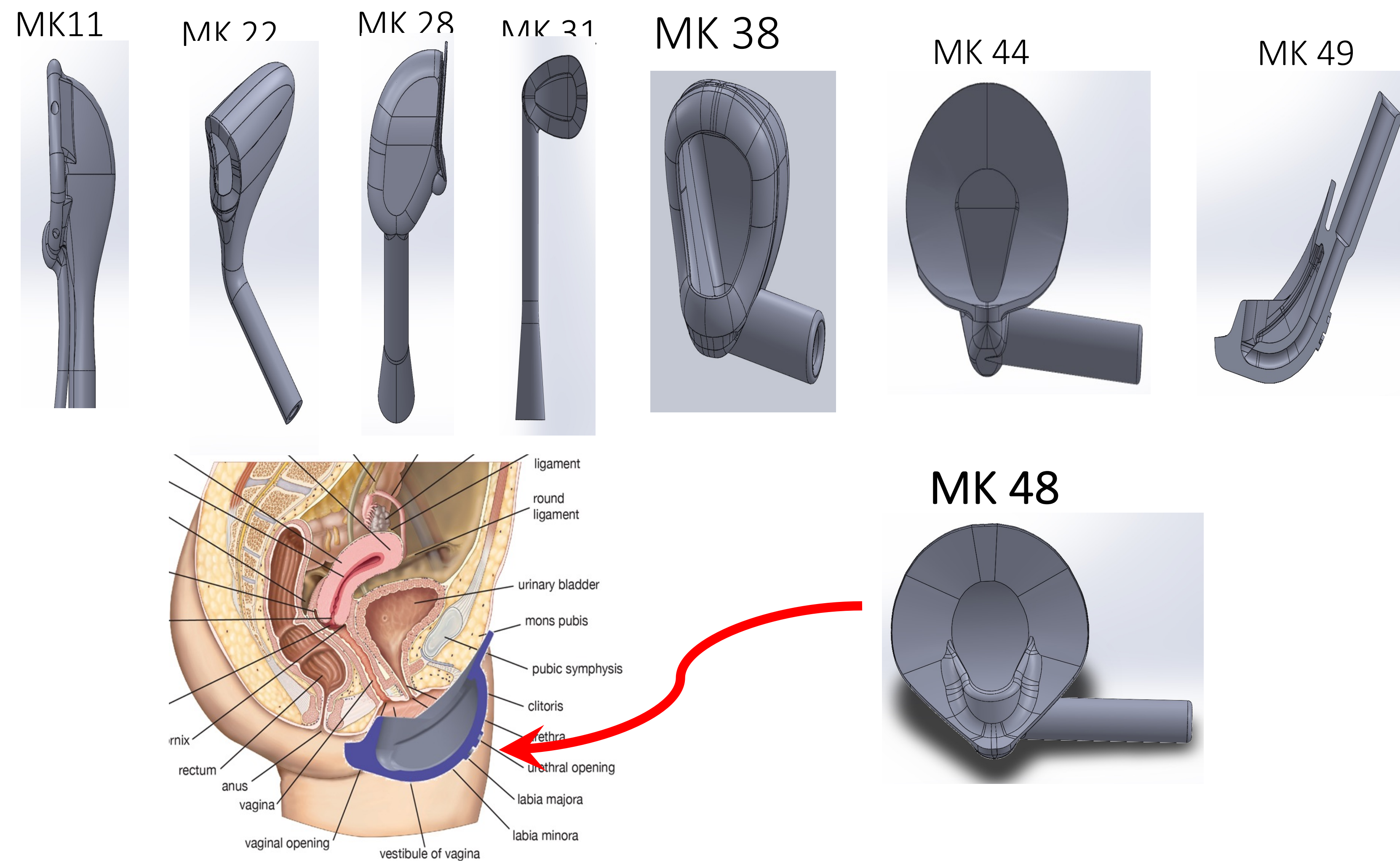
Methods

- Using an iterative process, we developed an external urine collection device designed with the female newborns in mind.
- Each cycle included designing, 3-D printing, testing and evaluation.
- For each cycle, 3-5 female participated after informed consent from the family.
- During one cycle, we used a device designed to incorporate wall suction, which was set at 20 mmHg.
- Silicone adhesive tape/gel was used to adhere the device to the skin.
- Testing of skin color, temperature, turgor, moisture and integrity were performed at 3 timepoints (before, after removal, and 24 hours after removal)

Special Thanks

To the patients, nurses and families who have participated in this study.
To Jim Wilkie, Eva Ovitt, Bruce Ovitt, Shelby Leverett, Lynn Dill, Amanda O'Hara, Meagan Reagan, the team at RexMed, Maynard Cooper Gale Law Firm, and the UABRF for their assistance in this project.

Results



- **Population** - 82 female neonates and infants
 - average weight = 2.42 kg.
 - corrected gestational age range = 24 weeks to 72 weeks.
- **Designs**
 - 49 were designed
 - 8 were 3-D printed and used in participants.
 - MK49 was designed and tested using wall suction at 20 mmHg.
 - The final design is MK 48
 - Found to be ergonomic
 - Has a ramp to limit urine leak
 - Molds have been made for the full size and a ¾ size
 - Tests on this design have shown minimal leak.
- **Safety**
 - In all applications (except the one with wall suction) we did not find any issues with skin integrity based on formal skin tests,
 - In the 5 neonates that were tested with wall suction, 4/5 had mild transient skin changes..



Conclusions

Zorro-Flow® is an external urine collection device designed for neonates and small children.

Current plans are underway to manufacture a device which will include tubing, a urine reservoir bag, and other necessary items in one kit.

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Acknowledgements

DA, ED, and MH are listed as inventors in the international patents in 5 countries
DA is Founder and Chief Scientific Officer of Zorro-Flow Inc.

DA serves as consultant and has received grant funding from Baxter, Nuwellis, Seastar, Bioporto, Leadient and Portero

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- 3 Boohaker, L. et al. Absorbent Materials to Collect Urine Can Affect Proteomics and Metabolomic Biomarker Concentrations. *Clin Chem Lab Med* **57**, e134-e137 (2019).

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