Orchid SRV™ (Safety Release Valve) Reduces IV Dislodgement by 92 Percent in Clinical Simulation Tests

Introduction

Some 70 to 90 percent of acute care patients in the U.S. require intravenous access every year, with dislodgement rates estimated at 1.8 to 24 percent, or 5 percent of all intravenous catheters. Estimated events per year are more than five million. [1,2,3,4,5,6,7,8]

A survey of 1,567 nurses providing direct patient care and replacement of intravenous catheters found that more than 95 percent of clinicians agreed that IV dislodgements pose significant safety risks for patients and hospitals, with more than 66 percent "often" encountering dislodgement; the survey found that half of all catheters dislodge even with extra securement.[9]

The Orchid SRV™ (Safety Release Valve) is a sterile, single-patient-use connector for needle-free access, placed between the existing IV extension set and general IV tubing connection intended to be used for delivery of fluid to and from an IV catheter. The Orchid SRV™ can be used during direct injection, intermittent infusion, and continuous infusion. When tension across the device exceeds a predetermined threshold, the device separates into two halves, activating valves that create sterile seals for the fluid pathway, with the goal of retaining IV site integrity.

Linear Health Sciences conducted a clinical simulation study to characterize the effectiveness of the Orchid SRV™ at preventing IV dislodgment via simulated clinical conditions.

Method

Testing was performed in a manner that simulated clinical conditions, which included connection to a fluid line, commercially available securement devices, and porcine skin. Testing exerted forces in three opposing directions against the IV securement and at different speeds, using 371 Orchid SRV™ devices. Samples of the Orchid SRV™ consisted of ETO sterilized T=0 and real-time samples aged 1.8 years. The study also examined securing the IV line with both Tegaderm™ IV Film Dressing alone, and Tegaderm™ IV Film Dressing with securement tape over the needle hub.[10]

Dislodgment was defined as complete removal of the catheter from the skin. Delamination was defined as dressing partially peeled off of the skin. New dressing is defined as replacement of the IV catheter, securement device, and tape if applicable to the test case.

Results

The Orchid SRV™ prevented IV dislodgment by 91.9 percent across all test groups in which the device separated, and no dislodgment occurred, with an average separation force of 2.84 lbf, at a standard deviation of 0.36 lbf. Forces ranged from 2.09 lbf to 4.12 lbf.

The speed that the IV line was pulled had a marginal difference in preventing dislodgement. IV dislodgement was prevented by 88.3 percent pulling slowly at 20 in/min. Moving more than four times faster, at 94 in/min, resulted in an IV dislodgement prevention of 95.6 percent. Pulling more slowly resulted in higher separation forces.

Summary Results Table

	Dislodgment Prevention %	Formula
Overall	91.9	Total occurrences where device activated with no dislodgment divided by the total number of samples (qty. 360)
Low Pull Speed	88.3	Total occurrences running at the low speed where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 180)
High Pull Speed	95.6	Total occurrences running at the high speed where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 180)
X-Direction	92.5	Total occurrences pulling in the x-direction where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 120)
Y-Direction	94.2	Total occurrences pulling in the y-direction where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 120)
Z-Direction	89.2	Total occurrences pulling in the z-direction where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 120)
Tegaderm™	91.1	Total occurrences using Tegaderm™ only where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 180)
Tegaderm™ & Tape	92.8	Total occurrences using Tegaderm™ & Tape where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 180)
T=0	89.4	Total occurrences using T=0 samples where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 180)
T=1.8yr RT aged	94.4	Total occurrences using T=1.8yr RT samples where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 180)
Worst-Case (Low pull speed, Z-Direction, Tegaderm™ only, T=0)	36.7%	Total occurrences under worst-case conditions where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 15)

Best-Case (High pull speed, Y-Direction, Tegaderm™ and Tape, T=1.8yr RT)	100.0	Total occurrences under best-case conditions where activation occurred with no dislodgment divided by the total number of samples applicable (qty. 15)

Histogram of Peak Activation Force (lbf)

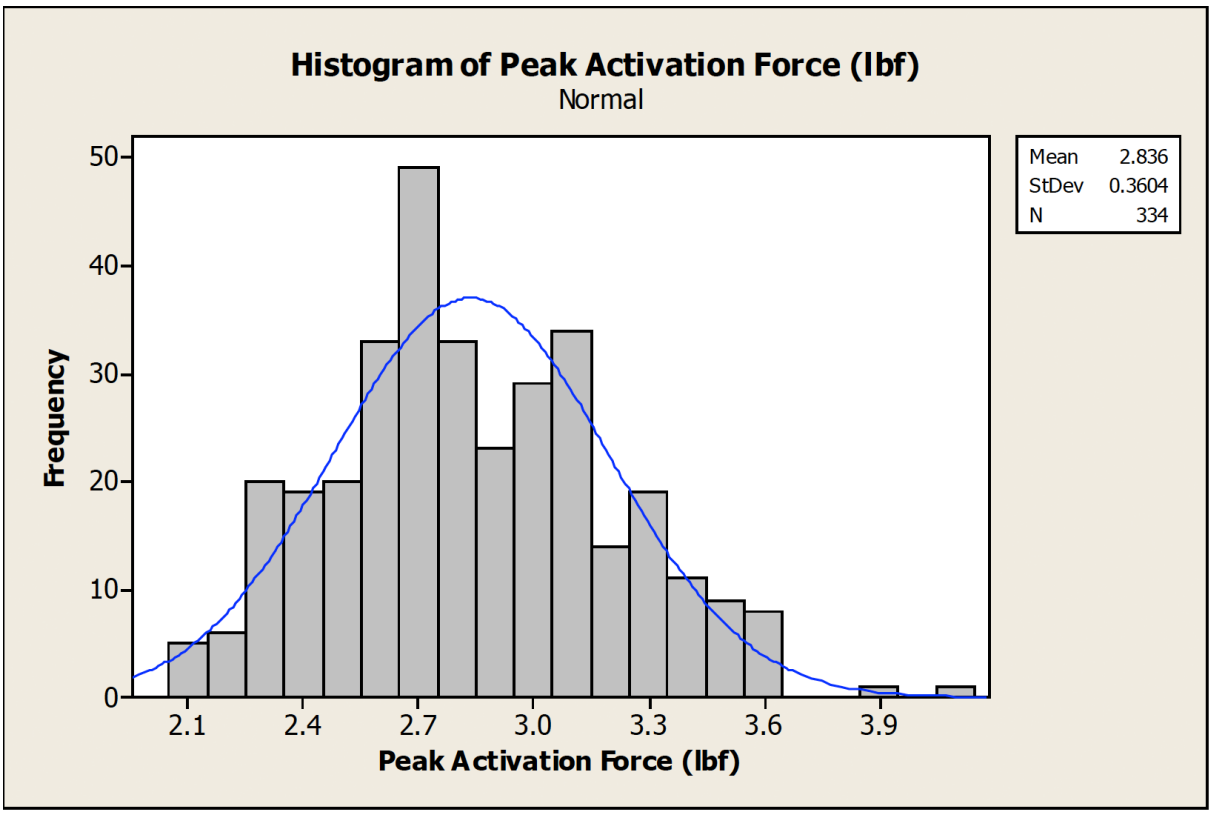

Fig. 4 Histogram of Orchid SRV™ activation forces

Conclusion

The Orchid SRV™ was shown to prevent IV dislodgment in a variety of scenarios and conditions, with an overall 91.9 percent reduction across all test groups in which the device activated, and no dislodgment occurred.

[1] R.E. Helm, J.D. Klausner, J.D. Klemperer, L.M. Flint, Huang E. Accepted but unacceptable: peripheral IV catheter failure J Infus Nurs, 38 (2015), pp. 189-203
[2] B. Dugger, D. Macklin, B. Rand Veni-Gard versus standard dressings on hemodynamic catheter sites Dimens Crit Care Nurs, 13 (1994), pp. 84-89
[3] D. Wood, B. Bowe-Geddes A comparative retrospective analysis of two securement techniques for peripherally inserted central catheters (PICC) and midlines in the homecare setting J Vasc Access, 2 (1997), pp. 3-32
[4] D. Wood A comparative study of two securement techniques for short peripheral intravenous catheters J Intraven Nurs, 20 (1997), pp. 280-285

[5] A.J. Yamamoto, J.A. Solomon, M.C. Soulen, et al. Sutureless securement device reduces complications of peripherally inserted central venous catheters J Vasc Interv Radiol, 13 (2002), pp. 77-81
[6] N. Moureau, A. Iannucci Catheter securement: trends in performance and complications associated with the use of either traditional methods or an adhesive anchor device J Vasc Access, 8 (2003), pp. 29-33
[7] N. Moureau, S. Poole, M.A. Murdock, S.M. Gray, C.P. Semba Central venous catheters in home infusion care: outcomes analysis in 50,470 patients J Vasc Interv Radiol, 13 (2002), pp. 1009-1016
[8] G.J. Schears, A.M. Frey StatLock catheter securement device reduces central venous catheter complications Patient Saf, 1 (2001), pp. 28-37
[9] Moureau N. Impact and safety associated with accidental dislodgement of vascular access devices: a survey of professions, settings, and devices. J Assoc Vasc Access. 2018;23(4):203–15, ISSN 1552-8855. https://doi.org/10.1016/j.java.2018.07.002.
[10] *The safety and effectiveness of this device when used with other types of peripheral IV dressings or securements has not been evaluated. The Orchid SRV™ is designed to be used with standard IV dressings, films, and tape. Nexcare First-Aid Medical Tape and 3M Tegaderm™ 1633 Transparent Film Dressing were used in the evaluation of the Orchid SRV™.*

REC1812-0069-S (DOC-1071) Ver. 0

Approved By:

(CO-230) Admin Update to Clinical Simulation Whitepaper

Description

Admin Update to document number for Orchid SRV Clinical Simulation Whitepaper. Document was originally approved via CO-229 as REC1812-0061-S however this admin change will be to update the document number to REC1812-0069-S. This aligns with the Clinical Simulation Protocol and Report which also have the number sequence of REC1812-0069-P and -R. No changes to the content of the document.

Justification

Admin change to align the whitepaper with the Clinical Simulation Protocol and Report which also have the number sequence of REC1812-0069-P and -R. No changes to the content of the document.

Assigned To:	Initiated By:	Priority:	Impact:
Michelle Mahoney	Michelle Mahoney	Low	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Michelle Mahoney	October 30, 2023 4:24 PM GMT	CO-230	0	Published