STUDY SUMMARY

The in vivo evaluation of the flushing efficiency of different designs of clear needlefree connectors

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PURPOSE

This study was designed to gain additional knowledge about how different needlefree connectors behave in vivo and to determine how much fluid volume is required to flush different types of connectors completely free of blood or blood constituents. For the purposes of the study, three different types of connectors with clear housings were chosen—one negative pressure connector (Baxter ClearLink®), one positive pressure (CareFusion MaxPlus®), and one neutral pressure (ICU Medical MicroClave® Clear).

MATERIALS AND METHODS

One sheep was used in this study to obtain repeated blood samples through a multi-port indwelling catheter. The catheter was placed percutaneously and remained indwelling for three days, allowing each needlefree connector type a separate and distinct port that could be accessed over several days. A baseline blood sample was drawn to determine the CBC: RBC-s (Red Blood cells/uL), Hematocrit (Hct), Hemoglobin (Hgb). The connectors were then pulled free of the bandage and the samples were collected as follows:

- Flush each connector with 5 mL normal saline to ensure patency.
- Disinfect each needlefree connector and attach sterile 3 mL syringe.
- Aspirate 3 mL of blood from lumen and discard.
- Remove blood-saturated connector from catheter lumen port, place a new connector onto the catheter lumen port, and proceed to flush the removed blood-saturated connector as follows:
  - Attach 12 mL syringe filled with 10.0 mL 0.9% sterile saline to needlefree connector.
  - Infuse 0.5 mL increment of saline through connector into uniquely labeled flush capture vessels.
- Analyze each flush capture for hemoglobin concentration.

Two connector types (ClearLink and MicroClave) were flush tested five times; whereas, the third connector (MaxPlus) clotted and was only flush tested four times. An accurate sample flush volume was ensured by weighing the capture vessel while empty and following the addition of 0.5 mL of flush volume.

Samples that contained appreciable amounts of blood (visible to the naked eye) were run at the BioSurg Clinical Pathology Laboratory on an Advia clinical analyzer. The range of reliable and reproducible detection for hemoglobin by the Advia unit is 0.5 g/dL, (500 mg/dL). In addition to the hemoglobin, each sample was analyzed for total erythrocyte count and hematocrit. All samples below the 0.5 g/dL threshold were sent to Equine Laboratories (Houston, TX) for analysis. Equine Laboratories employes a spectrophotometric method (TMB method) to determine total hemoglobin concentration and is reproducible and sensitive to 0.05 mg/dL.

RESULTS

The MicroClave connector was blood free after 2.5 mL of flush volume on average. In three of five runs, the MicroClave was blood free with only a 2 mL flush volume. Initial flushes of the MicroClave were also found to contain lesser blood components when compared to the other connectors tested. By contrast, four out of four of the MaxPlus connectors tested showed residual blood after a 10 mL saline flush, as did two out of five of the ClearLink connectors.

TABLE

Raw data of the samples. Measured hemoglobin mg/dL. Blue indicates values measured on the Advia 120 clinical analyzer. All others measured by Equine Labs by spectrophotometry using a proven TMB colorimetric assay.

Flush Vol (mL)	ICU Medical MicroClave®					CareFusion MaxPlus®				Baxter ClearLink®				
	A1	A2	A3	A4	A5	B1	B2	B3	B4	C1	C2	C3	C4	C5
0.5	600	600	700	300	400	5000	5700	4500	1200	1500	2200	1400	2100	500
1	34.03	15.32	37.82	51.94	26.24	800	800	600	600	77.28	134.89	183.82	124.52	122.06
1.5	1.46	1.3	4.32	7.96	12.53	241.32	118.15	321.42	119.45	18.04	20.8	38.52	60.52	67.65
2	0	0	0	0.26	3.04	171.51	75.32	161.32	85.96	6.24	5.62	12.84	14.03	39.26
2.5	0	0	0	0.78	1.68	86.82	20.24	97.14	48.33	3.2	1.86	4.87	7.29	33.94
3	0	0	0	0.48	1.06	79.81	16.64	69.16	28.81	0.93	1.75	0.99	9.38	26.48
3.5	0	0	0	0.17	0.15	28.12	16.97	47.17	19.87	0.63	1.13	0	1.76	19.02
4	0	0	0	0.14	0	33.9	12.77	37.64	12.63	0.19	0.46	0	1.06	17.15
4.5	0	0	0	0.1	0.26	22.4	9.79	31.94	10.83	0.07	0.36	0	0.4	13.12
5	0	0	0	0.1	0	19.94	8.66	25.74	5.31	3.01	0	0	0.11	9.62
5.5	0	0	0	0.1	0	10.84	5.98	19.09	3.47	1.45	0	0	0	6.4
6	0	0	0	0.24	0	21.69	3.76	18.84	2.07	0.67	0	0	0	7.12
6.5	0	0	0	0.17	0	8.05	2.27	21.36	2.21	0.15	0	0	0	7.88
7	0	0	0	0.14	0	20.98	1.8	15.74	2.01	0.15	0	0	0	4.13
7.5	0	0	0	0	0	1.63	0.72	13.87	1.73	0	0	0	0	7.35
8	0	0	0	0	0	1.71	0.82	13.36	1.33	0	0	0	0	5.08
8.5	0	0	0	0	0	1.14	0.62	13.16	1.22	0	0	0	0	4.52
9	0	0	0	0	0	1.46	0.52	11.55	1.56	0	0	0	0	5.04
9.5	0	0	0	0	0	0.15	0.46	13.48	1.67	0	0	0	0	4.43
10	0	0	0	0	0	1.38	0.41	12.77	0.75	0.97	0	0	0	69.29

CONCLUSION

In summary, the ICU Medical MicroClave connector is superior to either the positive displacement CareFusion MaxPlus or the negative displacement Baxter ClearLink as determined by the total flush volume needed to clear the connector of blood elements. In addition, the flush volume to clear the MicroClave connector had a much narrower range of variability.

Previous studies have demonstrated that the more proteinaceous material (including small blood clots) that resides in the connector hub, the greater the chance of infection.[1-3] Infection is a major concern in the hospital environment and especially so given the issues of antibiotic resistance and hospital-acquired infection. Prevention of such issues is of great concern. The MicroClave shows a definite advantage in this environment compared to the other two tested. While none of the MaxPlus connectors flushed clear of blood or blood residual after a full 10 mL flush, the variability measured with the ClearLink connector may be suggestive of trapping of small pockets of blood and blood elements within the connector proper, thus predisposing this catheter connector to the potential of insufficient flushing, blood retention, and infection issues.

A second potential negative consequence of blood retention within a connector is the loss of catheter patency as occurred with the MaxPlus connector prior to the final test flush. A compromised catheter necessitates placement of a new catheter, resulting in additional expense and discomfort for the patient.

References

1. Jarvis WR, et al. Increased bloodstream infection rates in surgical patients associated with variation from recommended use and care following implementation of a needlefree device. Infect Control Hosp Epidemiol. 1998 Jan;19(1):23-7.
2. Jarvis WR, et al. Healthcare-associated bloodstream infections associated with negative- or positive-pressure or displacement mechanical valve needlefree connectors. Clin Infect Dis. 2009; 49:1821-27.
3. Centers for Disease Control and Prevention. Draft guideline for the prevention of intravascular catheter-related infections. Federal Register 74:211 (Nov. 3, 2009): 56843.