Evaluation of Dwell Time of Hydrophilic Biomaterial Midline Catheters: A Product Evaluation

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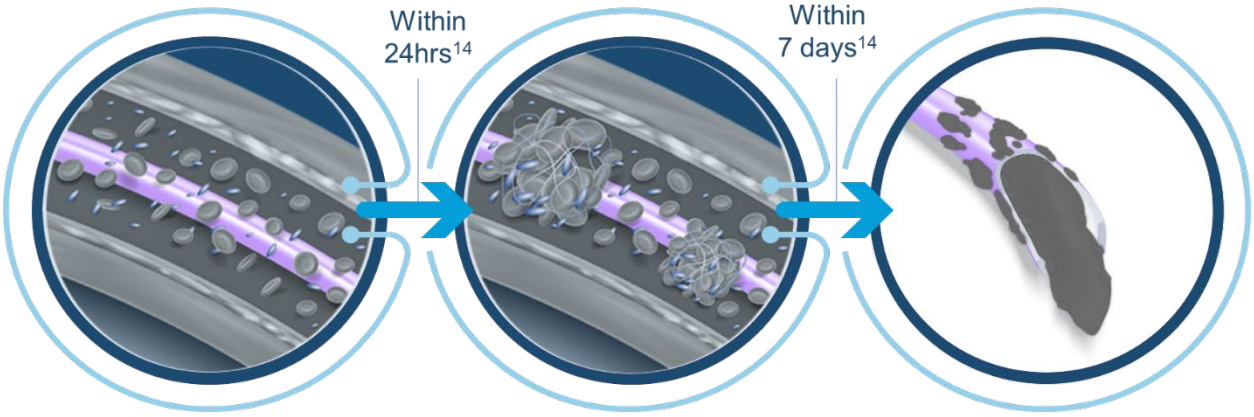
Introduction

A midline catheter (MC) may be the appropriate choice of vascular access device (VAD) when a peripheral venous catheter (PVC) for short-term therapies is inadequate, and a central venous catheter (CVC) is not required. Clinician's selection criteria of a VAD are multi factorial, including length of therapy, patient health status, accessibility of veins, type of infusate, amount of infusate, and required frequency of use.[1] In addition, complications and failures associated with specific types of VADs must also be considered, for instance central line-associated bloodstream infections. The recommended dwell for MCs is typically 5-14 days with less than 30 days the typical indication for use. However, first attempt failure rates of MCs have been reported to be as high as 26% in adults and 54% in children, with an average dwell time 44 hours.[2] These failures may result in many downstream risks and consequences including repeat invasive needle sticks, venous depletion, escalation to more invasive central venous access devices, and prolonged hospital stays. This highlights the importance of preventing common issues with MCs such as catheter occlusion, phlebitis, and other thrombosis-related failures.

Catheter Materials and Thrombosis

VADs are commonly manufactured from polyurethanes or silicones that provide flexibility, durability, and strength. However, these polymeric materials are hydrophobic and are susceptible to non-specific protein adsorption.[3] When blood contacts the catheter materials, the body's foreign body response is activated. A layer of plasma proteins instantly forms a thin conditioning film to their extraluminal and intraluminal surface.[3] As the conditioning film forms, more proteins adhere to the inner surface of the catheter material.[3] The cascade forms a fibrin mesh that trap blood cells and promotes thrombus formation.[3] This process is illustrated in Figure 1. Conversely, when in contact with blood, hydrophilic materials evade the foreign body response, and therefore thrombus formation.

Figure 1 – Illustration of the foreign body response mechanism after insertion of a standard (TPU) catheter.



HydroMID® Technology

Access Vascular, Inc.'s HydroMID® device is a 4F 20 cm trimmable MST midline that is available in a variety of kit configurations depending on the needs of the inserter. It is constructed of a proprietary

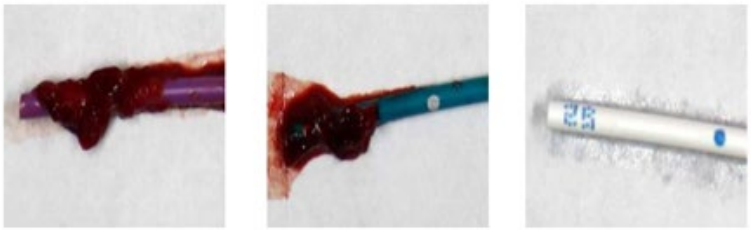
combination of biocompatible polymers to create a high-strength hydrogel material. Hydrogels inherently possess low interfacial tension, which has been shown to resist thrombus adhesion. The surface of the HydroMID® device contains large extended, hydrophilic polymer chains that provide a steric barrier to repel protein adsorption. For decades, the medical device industry has focused on grafting hydrogels or hydrophilic polymers to surfaces of more durable biomaterials to decrease their thrombogenicity. Access Vascular, Inc. has engineered around this problem by developing a unique hydrogel composition that combines the superior mechanical properties of polyurethanes with the intrinsically low thrombogenicity of hydrogels into a single bulk material, called MIMIX™.

Figure 2 – Images of catheters exposed to 2µL droplets of water on the surface of the MIMIX™ catheters

TPU catheter | MIMIX™ dehydrated catheter | MIMIX™ dehydrated catheter

Quantification of the thromboresistance of the MIMIX material was evaluated in an in vitro blood loop and an in vivo ovine study. Thrombus accumulation and platelet adhesion were assessed in vitro by Thrombodyne, Inc. (Salt Lake City, UT), using an established in vitro blood flow loop model.[4] Samples of catheters constructed of MIMIX were tested and compared against thermoplastic polyurethane (TPU) and fluoro-oligomer modified thermoplastic polyurethane devices.[5,6,7] When compared to TPU, the fluoro-oligomer modified TPU catheter exhibited a 71% reduction in thrombus accumulation, while the MIMIX device exhibited a 97 reduction in thrombus (**Figure 3**).

Figure 3 – Photographs of catheter samples after completing the blood flow loop test and rinsing.



TPU | Modified TPU | MIMIX®

Reduction of thrombus accumulation was evaluated using in vitro and in vivo models. Pre-clinical in vitro/in vivo evaluations do not necessarily predict clinical performance with respect to thrombus formation.

Product Evaluation

This product evaluation was conducted by Access Vascular, Inc. as a preliminary assessment of how bulk hydrophilic biomaterial midline catheters, HydroMID®, maintain function without failure. A mobile vascular access service team of registered nurses performed a product evaluation of 30 HydroMID

midline catheters inserted from January 2022 through Mar 2022 at a 60-bed, long-term, acute care, specialty hospital in Florida, USA. Evaluation focused on performing daily midline checks, from insertion to removal, per the institutional standard of care.[8] Insertion and removal details collected included complications such as phlebitis, occlusion, upper extremity deep vein thrombosis, blood stream infection, and leaking. Patients that were admitted to the hospital who received HydroMID® as part of their care, placed by the vascular access team, during the specified time frame.

Table 1 – HydroMID® Product Evaluation Results

	HydroMID®
Dwell Time (Days)	
N	29
Mean (SD)	15.8 (7.8)
Median	15
Min, Max	3, 39
Catheter to Vein Ratio (%)	
N	30
Mean (SD)	27 (4.0)
Median	28
Min, Max	18, 34
Removal Reason, n (%)	
Discharged	18 (60.0%)
Removed by Patient	4 (13.3%)
Dislodgement	3 (10.0%)
Leaking	1 (3.3%)
Staff Removed	1 (3.3%)
Removed	1 (3.3%)
Deceased	1 (3.3%)
Unknown	1 (3.3%)
Phlebitis	0 (0.0%)
Occlusion	0 (0.0%)
Upper Extremity Deep Vein Thrombosis	0 (0.0%)
Blood Stream Infection	0 (0.0%)

Average dwell time from insertion to removal was 15.8 days. One midline could not be followed until removal but dwelled for 24 days (not included in the analysis). There were no incidences of phlebitis, occlusion, DVT, or BSI reported, and 1 patient had leaking from the insertion site. There were 3 dislodgements, 4 catheters were removed by the patient, 1 death (non-device related), and 1 removed for leaking.

Discussion

Midline catheters are often used for short-term infusions based on the patient's needs, clinical indications, and the specific purpose of the catheter. The individual patient characteristics, clinical indications, and specific healthcare setting play a crucial role in determining the actual dwell time. However, dwell time is a relevant measure of a catheter's endurance without complications.

A previous retrospective study of uses and outcomes of 1,161 midlines across 12 sites showed that midline catheters have a median dwell time of approximately 6 days, and that nearly half (49%) are removed within 5 days of insertion.[9] This product evaluation demonstrated a median dwell time of 15

days, 9 days longer than studied MCs. Longer dwell time allows for extended therapy without the need for replacement or switching to more invasive devices, preventing the negative downstream effects.

Conclusion

Midline catheters are often used for short-term infusions, but their dwell time is often affected by complications. The unique material used to construct HydroMID® catheters may allow for longer dwell times, an indicator of fewer complications.

References:

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