Clinical Needs Should Drive Innovation

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The tried-and-true methodology for designing medical devices starts with product ideation and rapid prototyping. But the most vital step starts prior to product ideation—that is, identifying the unmet clinical need. Starting with clear identification of clinical need may take time to fully elucidate and, importantly, may change over time as clinical practices, medical knowledge, and scientific discoveries change the field. Developing tools to address these unmet needs is the goal for medical device developers. When we start with developing tools that address unmet needs, the tools inherently provide added value. Conversely, tools are often developed to implement new technologies without a clear understanding of the need being addressed. Often, these technologies are in search of a clinically relevant use case—these tools become proverbial hammers in search of nails.

In this study from Kumthekar et al[1] in this month's JCE, we learn the results of early feasibility testing of PeriScope in an animal (porcine) study. PeriScope is a novel percutaneous access tool for epicardial access developed to aid in the implantation of epicardial cardiac implantable electronic devices (CIEDs) in both pediatric and congenital patients who require systems at a young age. The clinical conundrum is that young patients who need CIEDs will often require lifelong devices, with transvenous systems often being delayed into adolescence (or later) due to small stature, linear growth, and concerns for causing venous stenosis or occlusion[2, 3]. Additionally, patients with congenital heart disease often have abnormal vasculature and anatomy which may prohibit transvenous CIED systems[4, 5] This clinical problem has been debated rigorously in the pediatric EP community, with reports of transvenous systems placed in some of our youngest and smallest of patients[6]. This has been a longstanding need in the pediatric and congenital community which members of this investigative team have spent years working towards[7-10].

The authors set out to address this issue by creating a tool to ease epicardial device lead placement, and the first step in this multistep plan is epicardial access. The current data presented by Kumthekar et

al[1] demonstrate the use of this tool in an immature porcine model (Yorkshire piglets) to test the implant procedure characteristics and efficiencies. Early results are promising, showing the time from skin nick to sheath access in the pericardium was <10 minutes with a mean total procedure time of 16 minutes. Lead characteristics were acceptable, though not excellent, speaking to the need to develop additional new tools. To address the long-term goal of minimally invasive epicardial device implantation, adjunctive technologies will need to be developed, including leads designed for implantation via a minimally invasive approach and tools to simplify minimally invasive generator implantation. Given the breadth of tools that will be required to meet this need, an academic-industry partnership may emerge as a viable path for co-development.

As with all novel tools and procedures, there is a learning curve and PeriScope is no different. Even within this small study with 6 piglets, there was a learning curve for the operator with piglet #1 having a longer procedure time than the rest of the cohort. Understanding learning curves, or assessments of performance over experience, for new technologies/tools and procedures is itself an entire field of study[11] which over time has created standard learning curve models for guidance with certain types of procedures, including laparoscopic surgical procedures. With PeriScope, there appeared to be a steep learning curve with increased competency after a short experience (n=1). More experience with a varied user group will be invaluable to determining the true learning curve for the device.

Finally, like many innovations developed to a specific clinical need, creative physicians will find novel, often off-label, use cases for technologies that address their own clinical needs. With the growing performance of epicardial ablation, accessing the epicardial space is no longer a need relegated to pediatric and congenital device implants, but is now an emerging need in adult, pediatric and congenital ablation. These changing needs over time are to be expected and reflect advances in medical knowledge and scientific discovery.

By nature, cardiac electrophysiologists are innovators. We are fortunate to practice our field at a time when there is an abundance of devices being developed and engineered to address the unmet clinical needs emerging as we learn more about mechanisms of various substrates and develop best practices. Our mission is to ensure that these novel devices are practical, useful and of benefit to us and our patients.

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