

From Bedside to Bench and Back Again: Technology Innovation in Plastic Surgery

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Innovation is the primary driver for success in industry and medicine. Plastic surgery's roots lie in devising innovative solutions to difficult clinical problems. It is likely that clinical innovation will be the key to our ongoing success and survival as a specialty. Unlike neurosurgery or cardiology, plastic surgery does not "own" any part of the human body, and our continued growth depends on the development of new solutions to unmet medical needs. Fortunately, we have an illustrious history of innovation, with advancements such as microsurgery, muscle flaps, tissue expansion, craniofacial surgery, transplantation, liposuction, and laser technology all being driven by practicing plastic surgeons.

Unfortunately, medical innovation in 2009 is far different from how it was in the 1950s and 1960s. Today, there is increased scrutiny by the U.S. Food and Drug Administration on new products, increasing regulatory complexity in human trials, and an exponential growth in the number of patents filed. What this means for plastic surgeons is that we need to develop a systematic way to innovate and change our specialty in the same way our predecessors did. This will require a fresh platform that will be provided by a new meeting supported by our Plastic Surgery Educational Foundation, Plastic Surgery Research Council, and American Society of Plastic Surgeons taking place in the spring 2010, in Monterey, California, called Technology Innovation in Plastic Surgery. This meeting will be held immediately before the Plastic Surgery Research Council meeting in the same location.

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All new technologies begin with an unmet need. To develop a new technology, it is also important to understand the scientific knowledge base in a given area (e.g., what causes cellulite). To innovate also requires a detailed exploration of the technical limitations of existing devices and the economic and reimbursement environment that may stimulate or impede innovation in this area. What is required is an ongoing dialogue between plastic surgeons (who understand the clinical problem) and technology developers (who understand what is technically possible). This will undoubtedly lead to the development of more effective technologies that more fully address the needs of patients and physicians to improve the delivery of medical care.

The innovation and commercialization processes are well understood, and plastic surgeons must be familiar with each step of the journey. The critical beginning for developing new technology is an idea based on a human problem. The moment of invention can occur anywhere: in the operating room, in the office, or while reading the literature. Plastic surgeons, on a daily or weekly basis, think of ways to improve the outcomes for their patients. Unfortunately, these ideas are not routinely translated into products that can change clinical practice and benefit thousands of patients. Once a plastic surgeon thinks of a novel technology, the first step is to look through the literature and the U.S. Patent and Trademark Office database to see whether it already exists. This can be done online in a few hours and will help the practitioner know what alternative technologies may already exist. If the idea is novel, intellectual property should be developed through filing of provisional patents, which can be done for less than \$100 by the surgeon-inventor himself or herself.

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Another key to the process is to scrupulously maintain an inventor's notebook that has numbered and dated pages that will provide a record of the actual date of invention if this is ever needed.

Once patents have been filed, plastic surgeons should develop a plan to "capitalize" the conversion of the idea into a medical device prototype. This fund-raising process can be daunting but can also be very simple. For straightforward medical devices, development can occur with very modest amounts of capital that can often be provided by the inventor directly. For more complex products, the plastic surgeon might need to start a new company to build and distribute the product. This means raising money from friends/family or angel investors, acquiring venture capital, or partnering with an existing company in the area. An understanding of what a corporate sponsor looks for when evaluating your idea includes the strength of the intellectual property, market size, technical risk (will it work), and adoption risk (will physicians use it). If this seems like a foreign language (to you), you are not alone. The overarching goal for the new meeting is to familiarize plastic surgeons, both in academics and in private practice, with what is involved in the innovation and development process for new medical devices.

One might ask, Why is it important for plastic surgeons to lead the way in introducing new technologies for surgical and nonsurgical approaches in the aesthetic and reconstructive arena? Unfortunately, history provides a number of examples where surgeons have chosen to ignore technologies that were not thought to be directly in the surgical domain. The most poignant is the case of cardiac surgeons who deferred to their medical colleagues the entire fields of coronary angiography, angioplasty, stent therapies, and minimally invasive valve replacement. Subsequently, both patient care and clinical flow became dominated by these nonsurgical specialists, leading to an overall diminution of the scope of cardiac surgery. In contrast, vascular surgery has aggressively avoided making this same mistake and has asserted itself as the leader in the field of endovascular surgery. We need to do the same in the fields of aesthetic medicine and reconstructive surgery. Plastic surgeons are the best trained specialists in these areas and should play the leadership role in introducing new technologies, whether surgical or nonsurgical.

One obvious question to ask is, Why introduce yet another meeting into the busy calendar? We strongly feel that for us (plastic surgeons) to continue our role in aesthetic medicine and reconstructive surgery, we must retain our leadership role in clinical innovation.¹ Plastic surgeons have historically invented many of the new technologies in aesthetic medicine and reconstructive surgery. Innovations as different as negative-pressure wound therapy and cosmetic breast augmentation have sprung from the minds of creative plastic surgeons working in a variety of different settings. This meeting in conjunction with the Plastic Surgery Research Council meeting attempts to "jumpstart" this process by bringing together leaders in clinical plastic surgery with medical device engineers and entrepreneurs to evaluate and create new technologies that may revolutionize a field or potentially impacts thousands or millions of patients.

We are optimistic that the Technology Innovation in Plastic Surgery meeting will appeal to both plastic surgeons and industry representatives. Similar meetings in other disciplines, such as the Transcatheter Cardiovascular Therapeutics meeting in cardiology, have become "must-go" meetings for practitioners in their fields. We believe the meeting will provide plastic surgeons with an early window into new technologies that are about to come onto the market (e.g., lasers, new fillers, advanced wound treatments) and some that are farther out on the horizon (e.g., new implant materials, stem cells). It will also provide industry and investors with a window into the clinical areas where unmet needs still exist. The opportunity for the plastic surgery community to come together in a new annual meeting focusing on identifying key clinical problems and working with our colleagues and industrial partners to develop new technologies will be immensely rewarding.

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