Medical device innovation has maintained momentum, irrespective of changing socioeconomic trends, as medical device companies recognize the need to innovate. However, the translation of device innovation into clinical practice continues to be a daunting, and often a complex and protracted process.

The clinical community is diverse. On one end of the spectrum are the “innovators and early adopters” (interventional cardiologists, endovascular key opinion leaders, and neuroradiologists), who are enthusiastic about adopting new ideas (Figure 1).1-3 The most prominent example is the late professor Edward B. Diethrich, who was one of the early vascular surgeons to introduce and adapt endovascular grafts in the history of vascular surgery. Then the “early majority” (vascular and endovascular specialists), mostly from the United States, continental Europe, Ireland, and New Zealand, who are keen to use something new but only after they feel it is safe to do so. Then, the “late majority,” mostly from the United Kingdom, Japan, Australia, Brazil, and Argentina, who follow everyone else’s lead. Finally, the other end of the spectrum constitutes the rest—the laggards, who will never accept any solution, no matter how many others use it or how promising it has been. Although there is a natural tendency to lag and avoid the burden of rapid development, there is no excuse for not being open to the adoption of newer technologies as we move forward.

The three individual innate traits that mandate our future goals and act as our natural differentiators are expertise, creative thinking, and intrinsic motivation (Figure 2).4 Innovators tend to have outstanding educational credentials and often a state-of-the-art facility, but without motivation, there is no hope for accomplishment. Therefore, we believe that “excellence is not competitive.”

Our autonomy and freedom fosters creativity and heightens our intrinsic motivation and sense of ownership. Freedom allows us to approach problems through our expertise and creative thinking. Intrinsic motivation and interest in solving a problem are key driving factors, which are independent of material gain. The intrinsic motivation of relishing a challenge, and our drive to crack a challenging situation that no

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**Keywords**

device design, creative thinking, technological innovations, challenges, Parodi paradox

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*Why Are Medical Device Multinationals Choking Disruptive Technology and Killing Innovation? Challenges to Innovation in Medical Device Technology*

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one else has been able to solve is self-propelling. The currency of innovation is not in denominated dollars or euros. Instead, innovation is driven by the individual, internal motivation to create something that heretofore did not exist. It is this sort of innate stimulus that Mark Twain referred to when he said, “Find a job you enjoy doing, and you will never have to work a day in your life.”

When we exchange ideas and data, we grow our collective knowledge, which ultimately translates into a better outcome for the patient. However, competition and human psychology can override these utopic scenarios.

Challenges

There are many challenges to innovation, both at the personal and professional levels.

Vascular interventionalists face daily challenges while managing complex vascular procedures. Overcoming these challenges requires business acumen and imaginative thinking, which only occur with expertise and motivation. However, legal regulations and systemic processes are often hindering the path forward, and this includes narrowminded views from multinational corporations. Creative thinking is a natural talent, where we try out solutions that depart from the status quo and turn problems into challenges, often combining knowledge from different fields.

An aptitude for technical problem solving requires knowledge in the fields of medicine, engineering, chemistry, biology, and biochemistry that was attained through formal education, practical experience, and continuous interaction with other professionals. The more extensive the network of scientific exploration that we are involved in, the better our expertise and knowledge.

The medical device industry—known for producing life-saving innovations and creating millions of jobs across the world—stands at the forefront of the innovation. It seeks to hire eager, creative people to bring freshness on board; however, more often than not, these bright, imaginative individuals do not realize their potential and are left disappointed. This is because of the fact that 9 out of 10 medical device innovations fail. As a result, the medical technology industry is progressively adopting regressive strategies to collaborate with design agencies or acquiring start-up companies to offload risk and the costs of research and development.

Existing medical technology companies are directed by senior managers, who focus mostly on growth and profit. Therefore, they are unwilling to invest in the long game and aim to acquire technologies at a more mature stage of development to gain quick results. They focus on catering for the needs of the “early and late majority,” and this is where the most money is made. The problem is that both “the early and the late majority” are conservative, and they tend to avoid disruptive change. The majority of physicians are willing to accept an improvement on current technology; however, their skepticism overrides their adoption of innovative techniques. Furthermore, physicians are becoming increasingly aware of cost-effectiveness. This strategy discourages innovation, as innovation might not be viable economically at its early phase. This new norm chokes disruption and kills innovation and breeds a culture in which physicians are increasingly reserved about new ideas, which are met with criticism, pessimistic attitudes, and cynical skepticism. At an organizational level, physician adaptation of innovation is discouraged, and although it may be given lip service, attempts to introduce technologies are stifled by red tape and the hurdles that physicians must jump through.

New market leaders have been transforming their tactics from focusing on the return of investment to return on failure. This 360-degree vision allows reverse engineering of challenges and optimizing of failures in an attempt to save millions. New ideas are not always met with open minds. They can be subjected to continuous harsh criticism and an excruciating critique from teams of highly paid lawyers and regulators. It is an interesting dynamic when this occurs within medical device multinationals that hold large intellectual property portfolios. Unfortunately, this sort of negative bias affects creativity and undermines intrinsic motivation.

Infighting, politics, and gossip are damaging to creativity. Political problems abound between multinationals and innovators and leave us feeling that medical device moguls’ agenda threaten progress. Politics are always in the way of open communication, obstructing the flow of information from point A to point B. This culminates in knowledge inertia, and proficiency suffers. Therefore, organizational cultures must promote creative thinking, embrace uncertainty and encourage exploration with a safe environment for passionate innovators to fail. Regrettably, multinational
medical device conglomerates stifle the very innovation that they seek through deep-rooted habits impeding creativity and avoiding risk taking.\textsuperscript{5,7,22}

**Parodi Paradox**

The only way to achieve creative success is to persevere until a creative breakthrough is achieved. The difference between success and failure is persistence.

The “Parodi paradox” is a prime example. Juan Parodi is the father of innovation in endovascular surgery. His most important and impactful invention was abdominal endovascular aortic aneurysm repair (EVAR), but he has also made several other life-saving innovations. These include covered stent-grafts, coronary computed tomography angiography under cardiac arrest, reversal of flow for trans-cervical carotid stenting, and endosutures for endograft anchoring.\textsuperscript{5} However, although his experience in dealing with medical device manufacturers is extensive, Parodi did not benefit financially from his intellectual property.\textsuperscript{5} He learned his lesson the hard way and offers sage advice to future innovators: (1) be careful whom you trust, (2) engage with great patent attorneys and good counselors from an early stage, and (3) if the opportunity exists to develop ideas within a university setting, take advantage of this. It may mean sharing royalties, but it is worth it. After all, it gives much-needed support, including ready access to patent attorneys and experimental laboratories. His final advice, (4) always take royalties and never equities because the former cannot be diluted.

Many other examples of stifling physician innovation exist. For example, recently, a vascular innovator who posted a simple cost-free video of a procedure to manage complex carotid artery on social media received a threatening letter from a med-tech company, which has been published (Figure 3). The relatively small multinational in their wisdom wanted to obstruct an alternative, simple, affordable technology, which they perceived as threatening to their offering. The simpler, cheaper technology could be available to nonprivileged societies who are unable to afford the techniques that the multinational is offering at exorbitant prices (Figure 4).\textsuperscript{28-31} If this is how some multinational conglomerates manage innovators, we have reached a critical threshold of suffocating innovation. Unwittingly standing in the way of the creative process and discouraging creativity with threatening letters creates distrust. Such an unacceptable approach makes us, the innovators, feel overcontrolled and unfulfilled—which damages our intrinsic motivation.\textsuperscript{32} This behavior will slow progress to explore new concepts and put together unique solutions.

What multinationals do not appreciate is the excellent assets they have in their intellectual property portfolio. They have a wealth of ideas that were never developed, or which failed to gain commercial success. However, with changes in clinical needs, some ideas may now have viability if they can be adapted for alternative applications.\textsuperscript{33} If multinationals realize the “value of failure,” previously failed experiments, or undeveloped ideas, it could potentially save them millions. However, because only some ideas realize their potential and the majority fail, multinationals need to find ways to offload the risk. One way is to allow start-ups and clinical innovators to take the risk.

Medical device companies make significant financial losses
Figure 4. A sample threatening letter from the medical technology industry to the vascular innovator.
by depending on in-house innovation from their engineers, who may lack clinical immersion or do not have the first-hand experience of challenging cases. This lack of clinical focus or early engagement with end-users leads to many projects failing, but not before incurring substantial costs.

We witnessed such scenarios when approached and asked to review why some of the multinational conglomerates lost a promising developing project. If key opinion leaders and smart medical innovators are involved from the start, it could save the multinational conglomerates millions in lost revenue. However, by failing to engage appropriately with clinicians, they face challenges that could prove catastrophic, not only to the industry itself and to the livelihoods of its employees but also to the health of the patients who benefit every day from its technologies.34

A SWOT (strengths, weaknesses, opportunities, threats) analysis shows the challenges faced by medical technology companies and global medical device innovation35,36:

**Strengths**: Market size, regulatory standards, rising consumerism by empowered patients, an abundance of capital.

**Weaknesses**: Talent, regulatory environment, taxes on medical devices, a lack of permanent research and development tax credits.

**Opportunities**: Growing and aging population, emerging markets, scientific progress.

**Threats**: Globalization challenges, reimbursement difficulties, attracting venture capital.

### Data Sharing and Innovation

Data sharing and collaboration support all three components of creativity. Vilifying failure and killing innovation will become a thing of the past, as big data, artificial intelligence, and machine learning had transform how we manage tasks.5,18,20 Through big data availability, machine learning and artificial intelligence potential exist to accelerate innovation in the medical device industry. Only the leaders of such organizations can support creativity by mandating information sharing and collaboration and by ensuring that political problems do not fester.36

However, medical device connectivity is a significant challenge for innovations.37 Cyber threats are a constant concern for any health organizations using connected systems. Vigilance and preparedness are essential to counter the risk. The benefits of connectivity are immeasurable, permitting patients to achieve more personalized care. Software architects for medical devices are caught between two extremes. On one hand, there are endless benefits from connectivity and big data that unlock exciting opportunities. However, cyber risks raise unprecedented barriers and leave companies vulnerable. The only solution is the cross-industry collaboration.38

### Recommendations

Smart medical innovators should scrutinize the needs of the majority and start with small, incremental improvements to convince others to upgrade. Insidious changes will eventually lead to a robust and safer environment for innovation.39,40

The maintenance of quality for innovation in a health care setting is challenging but necessary.10,23 Process management systems, such as ISO 9000, Six Sigma, and Lean, are shown to increase reliability. However, without flexibility, they have the potential to suppress radical innovation. Systems that are good for standardization are not always suitable for innovation, and we must create a mix of both for further exploration and implementation.

Young innovators should avoid unnecessary or unsolicited propagation of their ideas to avoid the nay-sayers who could crush their ideas rather than nurture them. The corporate world is a competitive playing-field where power struggles and egos value criticism above praise, and executives use negativity toward others to further their ambitions. Introducing a freshly hatched idea into that scenario could be detrimental to confidence and motivation. Remember that corporate managers are not trained to be innovation leaders, and they tend to look for flaws in ideas rather than teasing out any potential.

We advise the greater vascular community and relevant authorities to promote new ideas and use available resources to create a space where an idea can grow and flourish to serve the greater needs of our patients.

To innovate is sublime and to see our patients recover better and suffer less is the greatest joy of our profession. (Juan Carlos Parodi, July 2019)

### Acknowledgments

We would like to thank Professor Kenneth Ouriel for his dedication for innovation and continuous support while drafting this manuscript.

### Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

### Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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