



Editorial

Innovation in Surgery[☆]



Innovación en Cirugía

According to the dictionary of the Spanish *Real Academia Española*, “innovation” is the creation or modification of a product and its introduction to the market. Personally, I prefer a more practical definition: research is the use of money to generate knowledge, and innovation is the use of knowledge to generate value. In healthcare, “value” refers to the correlation between healthcare results (clinical effectiveness + perceived quality – adverse effects) and costs (economic and human resources + time + CO₂), as proposed by Michael Porter in his article in the *NEJM* in 2010¹ and later expanded upon by Muir Gray.²

There are different classifications to define innovation types. “Incremental” are those that cause small improvements in a product or service, which increase or maintain costs. In contrast, “disruptive” innovations completely transform a procedure, service or sector with new, more effective solutions that entail a reduction in overall costs (greater value). “Frugal” innovations are developed with rudimentary solutions (low cost) in developing countries. Furthermore, according to the results, they are classified as innovative processes or products.

In the last decade, innovation has become a social priority. This is even more evident in healthcare, in which Spain has achieved notable research results but not much of an impact on innovation³ compared with other countries in our setting. Our continuously growing knowledge and technological advances have facilitated the proliferation of innovative projects amongst biomedical researchers, bioengineers and medical professionals, favoured by strategies like Horizon 2020 in Europe and the NIH in the US. When combined with the economic crisis and the challenging sustainability of our healthcare systems, three key factors have come into play to boost the search for new products or services that create greater value.

Surgical Innovation

Surgery is a discipline that traditionally incorporates new concepts because their application is needed to resolve

practical problems.⁴ Currently, and due to the aforementioned factors (economic crisis, system sustainability, technological advances), we surgeons use innovation as a strategic priority.⁵ Within our sector, as in other specialties, only a small group of professionals (around 3%) are true innovators.⁶ The remainder behave according to the social model for adopting technologies: *early adopters* (visionaries), *early majority* (pragmatics), *late majority* (conservatives) and *laggards* (sceptics). The majority are either pragmatic or conservative.

Surgical innovation is comprised of 3 large areas: (a) technical, (b) practical organisation, and (c) innovative devices and instruments.⁷ Among these, the greatest potential is found along six lines:

1. Omics and information technologies (virtual and augmented reality, simulation, Big Data and support systems for decision making, process reengineering)
2. Imaging (multimodal imaging, surgical planning and navigation, molecular imaging for monitoring results)
3. Automation/robotics (mini-robots)
4. Regenerative medicine (new tissues and compatible organs)
5. 3D printing (printing of organs and viscera, individualisation of prostheses, individualisation of surgical instruments)
6. Biomaterial and nanotechnology (materials that are more integrable, compatible and resistant to infection)

A common error is assuming that only major research groups are innovators. In reality, successful innovation lies in being able to integrate social innovation with new business models and technological advances. Indeed, new technologies are standardised without simultaneous reengineering of processes and changes in the training of specialists (causing a movement of “pragmatic” professionals to the “visionary” group).

Therefore, another priority is to develop an efficient model for the inclusion of these innovations into surgical practice, such as the IDEAL collaborative initiative.⁸⁻¹¹ This framework

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involves 4 phases. In phase 1 (idea phase), very few surgeons or work groups participate, with few patients and a methodology based on structured clinical cases. The objective is to demonstrate the viability of the proposal. One example is NOTES. In the second phase (development), more groups participate, once again with few patients. The methodology utilised is that of a prospective study that investigates the safety of the innovation. One example is the use of optical systems to assess the risk of leaks in bowel anastomoses. In phase 2b (exploration), there are many patients and surgeons involved. The methodology usually involves the analysis of a database or a controlled clinical trial. An example of this is single-port surgery. Phase 3 (assessment) involves many patients, extended indications, and more specialists. The methodology used is a randomised clinical trial, and the objectives are short- and long-term results and cost-effectiveness. An example is colorectal robotic surgery. Phase 4, the last phase, includes all patients and surgeons. The tools used are usually registries and large databases, while the objectives are the evaluation of the long-term results and quality. An example is bariatric surgery.

In Spain, the IDEAL model can be promoted and supported by innovation units (IU).

Innovation Units: What Can They Do for Surgeons?

IU became widespread in Spanish hospitals after the first call for research proposals of the ISCIII of the ITEMAS network, which is currently a platform that groups the IU, collaborators and associated entities.¹² Furthermore, it also organises the management of technological innovations at a national level.

As surgical innovation requires the collaboration of professionals from several fields and the integration of different areas of knowledge, IU can and should function as an ecosystem that facilitates the cycle and framework of innovation, while supporting, promoting and spreading the work of the innovators at each institution both nationally and internationally.

In the IU that I direct at the *Instituto de Investigación Sanitaria San Carlos*,¹³ a multidisciplinary team of physicians, engineers and experts in communication has consolidated a collaborative network throughout academic institutions, hospitals and companies in Spain, the United States, the United Kingdom, Germany, Japan, Italy, México, Hungary, Romania and Bosnia-Herzegovina, with a project volume of more than 20 million euros in the last 4 years. Moreover, and thanks to the Alliance with the Massachusetts Institute of Technology within the Madrid-MIT MVision Consortium,¹⁴ we have established a new model for innovation that has had an impact not only on biomedical technology projects but on the training of medical students and attracting talent to our centre. The benefits have also reached our residents of surgery who, for example, have been the first in Europe to experiment with a new mobile simulation application for their training: TouchSurgery.¹⁵

In short, surgical innovation is a strategic priority that should be incorporated into the culture of our organisations. But, additionally, the results we have obtained indicate that we as surgeons can and should play an active role in healthcare-related innovations, and not only those that are specifically surgical in nature. Our training in teamwork, decision-making under pressure and performance in uncertain situations can be a benefit to the leadership of major, complex, innovative healthcare projects.

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