

# Rethinking Innovation

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For the past half century, innovation has been the tonic chord of cardiac surgery. We cannot tell our history without recounting the development of ideas, techniques, and devices that progressively revolutionized our capacity to serve those with heart disease. Over that same half century, nearly everything related to our profession has changed dramatically. In particular, we note the quick diffusion of technology to private practice and the development of non-surgical therapies. This essay discusses how the rapid changes in our professional landscape have altered the way we must think about innovation:

- We are now the final arbiters rather than the central players in the treatment of heart disease.
- Cardiac surgeons have developed reasonably effective treatments for most of the conditions deemed surgical.
- Practical innovations now come from industry rather than academia and therefore arrive with an entirely different set of financial, ethical, and emotional expectations.

Such major changes in the cardiac surgeons' environment should provoke us to rethink exactly what constitutes an innovation and how all innovation should be judged. In order to do this successfully, we require a philosophical starting place to help us reorganize our thinking. We need such a robust framework because our understanding of innovation will deeply color our ethics, our business environment, and ultimately our view of ourselves.

If we consider innovation a form of scientific discovery, we can turn to the work of Karl Popper to guide us through a re-evaluation. He is the preeminent philosopher of science in the 20<sup>th</sup> century and some of his many ideas may help us to rethink innovation. In The Logic of Scientific Discovery, he recognized that all scientific ideas are hypotheses that help us to understand the world. These hypotheses therefore contain information; in fact, we judge the significance of any scientific idea by the amount of information it contains. "Theories," Popper said, "are nets cast to catch what we call 'the world': to rationalize, to explain, and to master it. We endeavor to make the mesh ever finer." This is scientific progress. Popper also recognized an inverse relationship between the information content of a scientific hypothesis and the likelihood of it being correct. For instance, the statement that there will be another earthquake in California doesn't contain much information and is highly likely to be true. The statement there will be an earthquake of magnitude 8.1 along the San Andreas Fault next Thursday at 4PM contains a large amount of information and is much more likely to be untrue. Given that scientific ideas are hypotheses and that the more information they contain, the less likely they are to be true, how do we judge the validity of any scientific idea?

Popper's greatest contribution was to demonstrate conclusively that with the exception of mathematical proofs, no idea, scientific or otherwise, can be proven true. Metaphysical ideas (the existence of God, for instance) are simply assertions that remain beyond logic. Scientific ideas cannot be proven true, but they can be tested and shown to be useful (Newton's Laws). Most important of all, scientific ideas can be falsified. Thus in the classic example, the assertion that all swans are white cannot be proven true, but the discovery of a single black swan can falsify it. We judge the value of scientific ideas, then in two ways: we test them for falsehoods and if found to predict correctly, we ask what further thinking they stimulate. This leads to further hypotheses that will require yet further testing. Zealots and believers may know "the truth," but scientists never do; they struggle with ideas that run the gamut from falsehoods to variably useful approximations of the truth. They reconstruct the world asymptotically.

Before leaving the empyrean realms of philosophy, we must take two further steps before returning to the blood and toil of the operating room. First, serious thinkers recognize that change in any system always admits the possibility of unintended consequences. When we buy gas, for instance, we intend to avoid having to walk home, but unintentionally, we decrease the supply of gasoline and theoretically drive the price higher. This in turn may encourage potential car buyers to seek hybrid vehicles causing a rise in unemployment in Michigan. Whether trivial or profound, we may rest assured that actions produce unintended consequences, and that in medicine it may take time to recognize them, witness the Vioxx scandal. Second, and obvious to all, is the crucial difference between physicians and scientists. Both seek improved hypotheses, but only physicians must protect the sick from harm.

With these few ideas from philosophy, we are almost ready to rethink cardiac surgical innovation. First, however, we may profitably ask what constitutes an innovation. Every innovation begins with a perceived problem and the intention to ameliorate it. This requires an idea, a technique, or a technology to affect the problem, in short, an execution. This execution causes outcomes. By examining the intention, the execution, and the outcome of any innovation we should be able to assess its value to patients. For instance, Bailey recognized that rheumatic mitral stenosis caused the problem of progressive congestive heart failure. He had the idea that closed commissurotomy would reduce heart failure and prolong life. After a famously difficult start, he produced outcomes that confirmed his insight. Similar analyses confirm the value of prosthetic valve replacement, anatomical mitral valve repair, coronary bypass, and internal defibrillators, to name just a few of the many spectacular innovations that have improved the lot of patients with serious heart disease.

Now we can return to the question of why our relationship to innovation has changed. First of all, we are no longer the only therapeutic option. The evolution of catheter-based interventions has relegated us to the role of final therapeutic option for those with coronary disease when others have failed or cannot succeed. For most of our history, we strove to perform larger and more complicated procedures while cardiologists used catheters for diagnosis. When cardiologists discovered the potential of catheters to deliver therapy, it was only natural that they should develop the potential of catheter-based therapy, and they have.

Perhaps in the long run this will change as it is changing for our vascular surgery colleagues but for now, we must concentrate on innovations that make us stronger final arbiters. This means we must have the intent to solve the most difficult problems, we must discover techniques that are simple enough to execute well, and we must produce outcomes that are at least as good as they are now. Unlike our cardiology colleagues, we do not have the luxury of remanding our failures to a more definitive solution. We are the court of last resort and our innovations must reflect that responsibility.

This is a very tall order because we have already developed serviceable solutions to most of the clinical problems we face. The history of coronary bypass without the pump is a case in point. When it was first proposed in the late 90's, it created a fascination bordering on hysteria among some of us. After nearly ten years of development, most of us agree that the intent to avoid sternotomy, shorten recovery, and reduce strokes has not been realized. Most of the randomized clinical trials show that it produces outcomes on a par with the standard operation. This modest success may dishearten some, but it merely illustrates how robust an operation coronary bypass has become over its much longer evolution. The same results are likely to prove true for aortic valve replacement and anatomic mitral valve repair. Based on these ideas, it is easy to predict that catheter-based intervention will develop to treat the simpler end of the spectra of other diseases we now treat, and that progress at the difficult end will be slow. Furthermore, through most of our history, we could compare an innovation to supportive or medical therapy. Because we now have so many serviceable, if imperfect therapies, we must compare a new idea to the results of the standards we ourselves created. For instance, a recent article from Europe announced the robotic repair of an atrial septal defect. This required several hours of pump time and groin cannulation. Can we believe that this approach will ever be preferable to a small inframammary thoracotomy with central cannulation and a 30-minute pump run? We sense that such an innovation lacks serious enough intent and proposes too difficult execution to improve upon the nearly perfect outcomes we now achieve.

We can, however, make progress if we focus on innovation as we have defined it here. We run a significant risk of failure if we spend too much time and effort on competition, marketing, spin, and liquidity, the rubrics of business, and not enough on intention, execution, and outcomes. We must propose new ideas with the hope that further testing will either recognize some value or falsify them. Marketing a new idea in advance of this step is not a moral activity. Moreover, this approach fails in the marketplace as the Heartport debacle demonstrated. We have seen another recent example of this in a live broadcast of a percutaneous aortic valve replacement that resulted in the patient's death. Is this technique ready for prime time? How many animals have survived for one year after percutaneous aortic valve replacement? How many survivors showed no paravalve leaks? Similar though less egregious thinking has plagued the introduction of robotic techniques to cardiac surgery. Some of our colleagues have asserted that robotic assisted mitral valve repair has been shown to be the equal of the standard approach on the basis of a handful of cases with no control group and no long-term follow up. In one small series, patients were sent home the day after surgery in the hope that this would help to demonstrate the superiority of the robotic approach. Only a randomized trial could do this. Sending patients home the day after a marginally tested operation ignores the likelihood of unintended consequences and breaches

the standard of care. Meanwhile only a few of us have mastered the simpler small incision approaches that use standard techniques and have been demonstrated to be effective in thousands of cases.

None of these sad examples mean that percutaneous valve replacement or robotic assisted operations cannot have value for patients. They do reveal that some of us are rushing to the test without having done the homework. What should we be doing? Let's divide this question among the three interrelated groups that determine the fate of an innovation. Our professional societies should establish guidelines to declare significant innovations as "experimental," "possibly useful," "standard of care," or "not recommended at this time." This will reduce the pressure on clinicians to embrace untested ideas in the name of progress. Investigators and champions of new technologies should propose modestly, propose with control groups and randomized trials, and minimize breaching the standard of care until their innovation has demonstrated its superiority. Clinicians should assume the null hypothesis, demand large and/or randomized trials before adopting an innovation, and never adopt unproven technology as a marketing gimmick. This will cause damage to our patients and to our reputation as the final arbiters of the sick. Successful innovations in the future will intend to treat serious problems, they will simplify execution, and they will improve outcomes. If we fail to think this way, we risk confusing the glories of the past with the challenges we face today.