The seven stages of an idea

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See related articles on pages 559 and 710.

Norman Shumway, recalling the pioneering days of heart transplantation, described the seven stages the idea went through before it eventually entered the field of routine clinical practice:

1. Initial stage: "*Won't work; been tried before.*"
2. After successful experiments in animals: *"Won't translate to man."*
3. After 1 successful clinical patient: "*Very lucky; doubt if patient really needed transplant.*"
4. After 4 or 5 clinical successes: "*Highly experimental, too risky, immoral, unethical; I understand they have had a number of deaths they are not reporting.*"
5. After 10 to 15 patients: "*May succeed occasionally in carefully selected cases but very few patients really need an operation anyway.*"
6. After a large series of successes: "*So and so has been unable to duplicate their results. I hear that a number of their patients are now dying late death.*"
7. Final stage: "*This is a very fine contribution. A straightforward solution to a difficult problem. I predicted this. In fact, in 1939 I had the same idea. Of course, we didn't publish anything. We had no cyclosporin.*"

The time frame of this evolution took more than 20 years, between 1960 and 1982.

The heroic days of ground-breaking cardiac surgery have long passed, and progress now relies on evidence-based medicine. To enter the field of routine clinical practice, new ideas (including techniques or technologies) need comparison with the established gold standards and demonstration of statistically superior measurable end points. Until prospective, randomized, controlled trials possibly close discussions between the supporters and doubters, who will turn into "early adopters" and "laggards" if the technique becomes the next gold standard, it is desirable and rational to debate ideas and comment on data. Nonetheless, before reading the editorials about robotics, one should recall that the report of data from a "large cohort" represents a level B of evidence, whereas expert opinion corresponds to a level C.[1]

Besides evidence-based medicine, progress in 2007 is as dependent on a "vision" as it was 40 years ago. The vision that supports the development of robotics in cardiac surgery is simple: it is that the next challenge our profession needs to face is to decrease its complications and costs.[2] This correlates entirely with a decrease in physiologic insult, that is, invasiveness of the surgical procedures. The technology-based reduction of invasiveness is a natural step in the evolution of a mature surgical discipline. It has happened in gynecologic, digestive, vascular, and neurosurgical fields, as well as in urology, otorhinolaryngology, and so on. In every single case, the time frame between the initial "idea" stage and the maturity of the procedure has been lengthy. Many of us will recall the early days of these techniques when they were described as "purely cosmetic" by their opponents.

In the arena of cardiac surgery, the challenge of minimal invasiveness is complicated. Foremost, the consequence of failure is dramatic—rapidly irreversible or lethal—as opposed to other disciplines. This fact hinders the willingness to radically change successful procedures. Second, dealing with fragile microstructures such as coronary arteries or mitral chordae from a distance could not be achieved with the existing endoscopic cameras and instruments. The advent of robotic telemanipulation, coupled, as discussed in this issue of the *Journal*,[3] with the possibility of a safe bail-out mode, paved the way for closed-chest heart surgery. Although the point was not to reinvent the wheel and perform new types of operations, this resulted in a

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huge paradigm shift in the operating room. The successful adoption of this paradigm shift has been reported as the ultimate example of a team effort.[4]

This point is clearly explained in the editorial by Damiano,[5] which reports that the expectations were high. However, this editorial does endorse the great responsibility of declaring that a project of significant magnitude has a place in the obituary column. The magnitude of the project to bring robots to the cardiac operating room, I must admit, involves not only medical, but also scientific, technologic, and even financial implications. The project is made possible by the converging work of more than 200 engineers and numerous surgeons.

The surgeons who authored the article about robotics are all from an academic background, and robotics is indeed only a small fraction of their practice. They strongly believe that they are the gatekeepers of their patient's interests, and they will not hesitate to present negative results to their peers.

But the authors[3] believe also that comments such as the "promise is unfulfilled," "the technology has lived up to its potential," the patients were "put at risk for a purely cosmetic benefit," or the technology "has failed to demonstrate any clinical value, outside of its questionable use for marketing,"[5] are supported by significantly biased shortcuts and numerous errors.

"The Emperor's New Clothes" insists heavily on the lifespan of the project. Even though the modern world is mostly driven by quarterly results, so that 10 years appears to be an obscene period of time for the adoption of new technology, it nonetheless has *not* been "almost a decade" since the first use of robotics. A couple of cases were performed with prototypes in 1998.[6] The da Vinci systems (Intuitive Surgical, Inc, Mountain View, Calif) were introduced in clinical use in 2001. This article reports the early European experience between 2001 and 2005. Data collection and analysis and the publication process took place thereafter. Therefore, the time frame under scrutiny is actually less than 5 years and not 10.

Opponents to robotics[5] refer largely to experience with the late Zeus system (Computer Motion, Inc, Goleta, Calif), which did not initially have mobile articulations at the tip of the instrument.[7–9] The lack of this feature was clearly incompatible with reproducible performance of an anastomosis in the real world, although some astonishing successes were reported.[7] References to the Zeus system[7–9] are namely quoted in this issue of the *Journal*[5] to support the idea that "robotics also have been uniformly shown to slow the completion of gross motor skills," whereas the article by Diodato and associates[9] concludes: "Compared with performance on a standard laparoscopic trainer, robotic assistance allows for increasing speed and consistency while maintaining precision over multiple repetitions."

The editorial[5] tends to demonstrate [as per two previous studies from coauthors of the cited article[3]] the following: that totally endoscopic coronary artery bypass (TECAB) on the arrested heart is not an option owing to long crossclamping and cardiopulmonary bypass (CPB) times; that although "patency was very good," the only "reasonable option" is beating heart surgery, but then beating heart TECAB is "too difficult"; and, finally, that "no attempt was made to compare TECAB to the gold standard."

This again looks like a questionable shortcut. Although long crossclamping and CPB times are obviously not desirable, it is also quite clear, after a steady state was reached in the caseload of off-pump coronary artery bypass, that CPB is not a crime in low-risk patients. The articles that report very long crossclamp times refer to the very first cases that were performed worldwide. Who would have expected short bypass times at this point? In the current experience, which takes place after the learning period, the clamping time to perform anastomosis when the heart is arrested has decreased steeply to about 10 minutes.

If it was hypothesized 10 years ago, when the definition itself of less invasive surgery was unclear, that most of the inflammatory reaction came from CPB, then this has been contradicted. Some evidence has now been published to show that a smaller incision was the catalyst to less inflammatory reaction. Also, as adressed by Damiano,[5] arrested heart TECAB may be easier to perform than beating heart TECAB, thus leading to superior reproducibility. For all those reasons, the authors[3] believe that arrested heart TECAB can remain an option in the future of (multivessel?) surgical revascularization that cannot be discarded at this time.

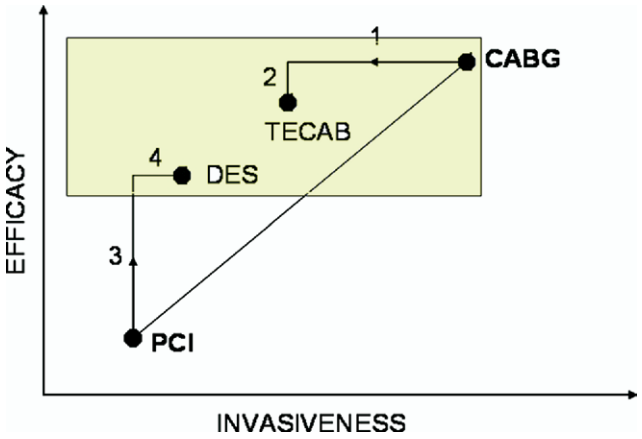

Figure 1. 1 and 3 correspond to added value of TECAB and DES compared to classical CABG and PCI, respectively. 2 and 4 correspond to tradeoffs for those added values, respectively. The measurements of those added values and tradeoffs require PRCTs. Only PRCTs will tell if the decrease in restenosis justifies the increase in late failure/death in DES and if the decrease in complications justifies longer bypass times or lower patency rates in TECAB. At this point, this report[3] can assess that efficacy is in the range of the expected values for CABG from STS on/off pump matched for indications (arbitrary zone of noninferiority is shaded).

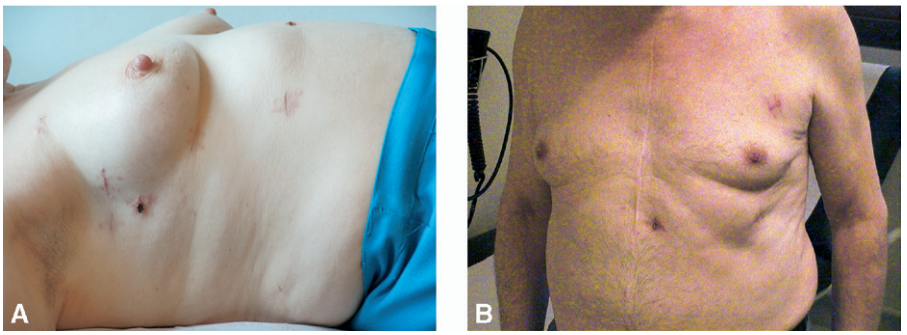

Figure 2. TECAB procedural added value at a glance: 3 weeks postoperative status after 2 vessels arrested heart TECAB (A) and beating heart TECAB (redo in high-risk patient; B).

As far as beating heart TECAB is concerned, high rates of conversion were no surprise either in the early days of the procedure. The fact that conversion does not compromise the outcome is seen as a bail-out, which is part of the overall procedural safety. The rate of conversion is clearly correlated with the learning curve.[3]

It is not correct that "no attempt was made to compare these results to either open coronary bypass grafting, or MIDCAB procedures." The results were compared with a Society of Thoracic Surgeons cohort that was matched for indications and techniques (single left internal thoracic artery to left anterior descending artery, on-pump, or off-pump). This comparison is commented on throughout the text and in Table 4 of the report.[3]

The reality is, at present, no one, including the authors of the study, can predict whether robotic technology is or is not going to play a major role in the future of cardiac surgery and what the time frame will be.

The success or failure of robotics will rely on many variables, some outside the surgical community: factors such as the willingness of a monopolistic industry to further invest in the refinement of the system, the development of adjuvant platforms to make the operations more operator friendly, and the development of training programs, databases, and networks.

It is a fact, though, that patients reported in our pilot study have been operated on and the results reviewed by the Food and Drug Administration. The report of this fact can be valuable to the members of our community. It enables the authors to affirm that closed-chest coronary artery bypass grafting is feasible. When compared with the gold standard, the results demonstrate no statistical difference in mortality or patency. The authors[3] believe that this enables them to address the issue of safety and efficacy of robotics. In the early days of a new technology, the concept of noninferiority (Figure 1) might have been used and would have been an even better case to support the hypothesis.[10]

However, mostly, it is the added value that TECAB generates that will make it a success or not. This added value was not the end point of the article and, for the sake of clarity, needs to be adressed in future reports.

In summary, what the candid observer would tend to call pure cosmesis (Figure 2) actually means no blood–air interface, leading to much less inflammatory reaction, no risk of infection, and no aortic cannulation: in short, eviction of the maneuvers that generate most of the morbidity in coronary artery bypass grafting.

In the end, the patients and their cardiologists might be willing to take advantage of this added value if it is reproduced routinely in numerous institutions throughout the world. It is a semantic error to call it marketing. Added value is one definition of progress.

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