Authors have nothing to disclose with regard to commercial support.

PLAN, SCAN, MODEL, PRINT, MANUFACTURE, AND IMPLANT PERSONALIZED EXTERNAL AORTIC ROOT SUPPORT (PEARS)

To the Editor:

New technologies of their nature present previously unimagined opportunities. In the case of 3-dimensional (3D) printing, the opportunity is to do more precisely planned, individualized procedures.¹ In 2000 when the engineer Tal Golesworthy stood up in an audience of people with Marfan syndrome and their families, to question the lecturer (T.T.), he spoke in a language that we surgeons did not understand. “Computer-aided design” and “rapid prototyping” were arcane phrases² but, now known as 3D printing, the concept and its implementation are easier to grasp.

The central picture makes the point. The 2 men are father and son. Each is holding a 3D printed copy of his ascending aorta. Both have the morphology that we associate with Marfan syndrome. In the 37-year difference in their ages, the father’s had become dangerously large; the son’s would inevitably have followed a similar trajectory. The father’s and the son’s aortic models were used to manufacture the mesh sleeve that was implanted around their aortas in December 2016, 12 days before this picture was taken. The rigid 3D models, on which the sleeve was made, have now done their job, and the 2 men have them to take home.

As elegantly demonstrated by Hermesen and colleagues,¹ it is now possible to have a 3D replica of the anatomy so that thinking, planning, and (in their instance) rehearsing the operation, can be done in advance. This diminishes the need for “workmanship of risk” and brings the surgical operation closer to the “workmanship of certainty.”³ We no longer accept “trial and error” as the surgeon’s lot in life: we have to reduce error to a minimum. The less time that that is spent thinking it out and making tentative

surgical steps against clock, the smaller is the degree of collateral damage of lengthy operations and the nearer we get to an ideal anatomical result.

A 3D modeled Personalized External Aortic Root Support (ie, PEARS) has now been implanted in more than 99 people followed for approaching 356 patient years. The closeness of the fit allows complete incorporation of the mesh support,⁴ stabilization of the aortic dimensions,⁵ and maintenance of aortic valve competence. The precision manufacturing made possible by 3D printing has made this a personalized approach with a predictable result.

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PLOWING WITH UNICORNS

Reply to the Editor:

“Innovation is not just novelty; it is novelty that works.”

— Joshua Sharfstein¹

“It is easy to be mesmerised by the purported benefits of the digital age.”

— Douglas Ruschkoff

We read with interest the letter by Treasure, Austin, and Pepper² and congratulate them on their early results with

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Authors have nothing to disclose with regard to commercial support.

personalized external aortic root support (PEARS).³ They state that whereas “computer aided design” and “rapid prototyping” were previously arcane phrases, 3-dimensional (3D) printing is now a “concept and implementation...easier to grasp.” With regard to specific cardiac operations, the primary questions are: Despite this ease, is it the right thing to do? and, Is it the right thing to do for this operation?

Treasure and colleagues² point to 3D printing as a means by which to move the trial-and-error phase out of the operating room. Conceptually this seems in order. However, it should be recognized that 3D printing has limitations. As we previously commented,⁴ it can replicate structure and anatomy, but not function or physiology. The available materials are nowhere near replicating human cardiac tissue. We should consider the specifics of each cardiac lesion and question whether 3D printing, as a surgical aid for that lesion, should also go through its own trial-and-error phase. As the authors have published, for PEARS there was prior experience with polyethylene terephthalate mesh as well as aortoplasties to support the concept, and the PEARS technique, although novel, is a revisitation of older ideas.

Further, the collateral damage that Treasure and colleagues² ascribe to surgical trial and error and lengthy surgical operations may also be a risk with 3D printing in myectomy. Specific to myectomies, how would an inexperienced surgeon cognitively adjust to a different exposure or different handling of the actual tissue relative to the 3D model? Is there a risk of overreliance on commitment to attaining the practiced resection volume, potentially resulting in an inadvertent ventricular septal defect? What of the issue of conduction block, which cannot be mapped out with 3D printing? Although Treasure and colleagues³ state that with PEARS “no bridges are burnt,” this is not true of a false step with myectomy. As an illustration of collateral damage with 3D printing, we have personal experience of a case wherein a 3D-printed model of an atrial septal defect closure device seemed to ensure an adequate percutaneous solution. The device embolized into the pulmonary artery, was percutaneously retrieved, and the patient ultimately underwent operative repair not only of the atrial septal defect, but also of the resulting complex iatrogenic tricuspid valve injury (Video 1).

In Silicon Valley, the term “unicorn” is used to describe venture-backed companies attaining valuations of more than \$1 billion. The term was chosen for its ability to convey the concept of rarity.⁵ One of the most notorious of these, Theranos, attained a valuation of \$9 billion on the premise that more than 200 diagnostic tests could be run on a finger

Repair After Atrial Septal Defect Device Embolization and Complex Iatrogenic Tricuspid Valve Injury

Dawn S. Hui MD, Richard Lee MD MBA

VIDEO 1. Repair after atrial septal device embolization and complex iatrogenic tricuspid valve injury. Video available at: [http://www.jtcvsonline.org/article/S0022-5223\(17\)30603-7/addons](http://www.jtcvsonline.org/article/S0022-5223(17)30603-7/addons).

prick of blood. The downfall of the company was in the numerous technical and procedural failures. Sadly, venture capitalists were not the only victims, because 2 years' worth of patient tests had to be voided. Reflections by laboratory scientists have pointed to the company's attempts to jump over the hurdles of scientific evidence straight to Food and Drug Administration clearance.⁶ Many others saw these warning signs early on⁷; the company rebuttal was that fearless innovation is often met with resistance.

Unicorn was also chosen for its mythical connotations.³ Reflecting on past promises, the Internet was supposed to diminish inequalities in knowledge and wealth; the recent election demonstrated the fallacies of sophisticated polling in the digital age. In an era where technology predominates everyday life, we should not continue to fall prey to fairytale promises that only good can come from innovation. The heavy lifting done by traditional workhorses to sow and reap the benefits of new ideas cannot be abandoned for unicorns jumping over hurdles of due diligence and rigorous evaluation. When technology beckons, it is our duty to not only be pioneers but also gatekeepers for patient safety.

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NO FREE LUNCH: EVEN WITH A DIET HEAVY ON PEARS

Reply to the Editor:

We appreciate the comments on our work¹ and also the work of Treasure and colleagues² in using patient-specific 3-dimensional printing to aid the manufacture of the Personalized External Aortic Root Support (PEARS). Their work is an excellent example of the application, integration, and manipulation of advanced imaging technologies to develop new paradigms of surgical care.

As investigators who are also exploring ways to apply 3-dimensional printing technologies to clinical medicine,¹ we believe that the work of Treasure and colleagues² is a definitive first step toward the holy grail of additive manufacturing in cardiovascular medicine: the printing of patient-specific replacement parts, especially heart valves. Dr DeBakey's wife long ago proved to us that endothelial biochemical functionality does not need to be replicated when she successfully created prosthetic grafts with Dacron polyester fabric; with the 3-dimensional printer now standing in for the sewing machine, it seems that the next big challenge is to identify an inert, durable, and nonthrombogenic printing material. That this material will then be used to create patient-specific replacement parts seems inevitable when viewed within the context of our world's logarithmic technologic progress.

To a clinical heart surgeon (J.L.H.), PEARS is an interesting new twist on the old surgical trick of vascular wrapping. Albert Einstein, who underwent cellophane wrapping of an aortic aneurysm, would certainly be proud.

J.L.H.'s wife has performed paid work as consultant for Medtronic. B.R. has nothing to disclose with regard to commercial support.

Or would he? Fifty years ago, PEARS might have seemed like a cure for Marfan aortopathy, but in today's world of routine valve-sparing root replacement, the bar for PEARS is much higher. PEARS may easily find a niche for older patients as a lower-risk surgical intervention for prophylaxis of acute aortic syndromes. For young patients, however, the jury will be deliberating for some time before delivering this verdict. Not only does PEARS have to prove long-term protection against adverse aortic outcomes, but the hazard of reoperation after PEARS will need to be tracked. As a congenital surgeon, my mind immediately wanders to the "next operation" and a cohort of young patients with aortopathy who will, in time, have cardiac surgical indications for conditions such as mitral valve prolapse, coronary artery disease, infectious endocarditis, and pericardial disease. The difficulty and danger encountered in reoperating in a PEARS chest (think fashioning and sewing coronary buttons) could be considerable. Free lunch remains elusive.

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