Opinion: What are the barriers to innovation in medicine?

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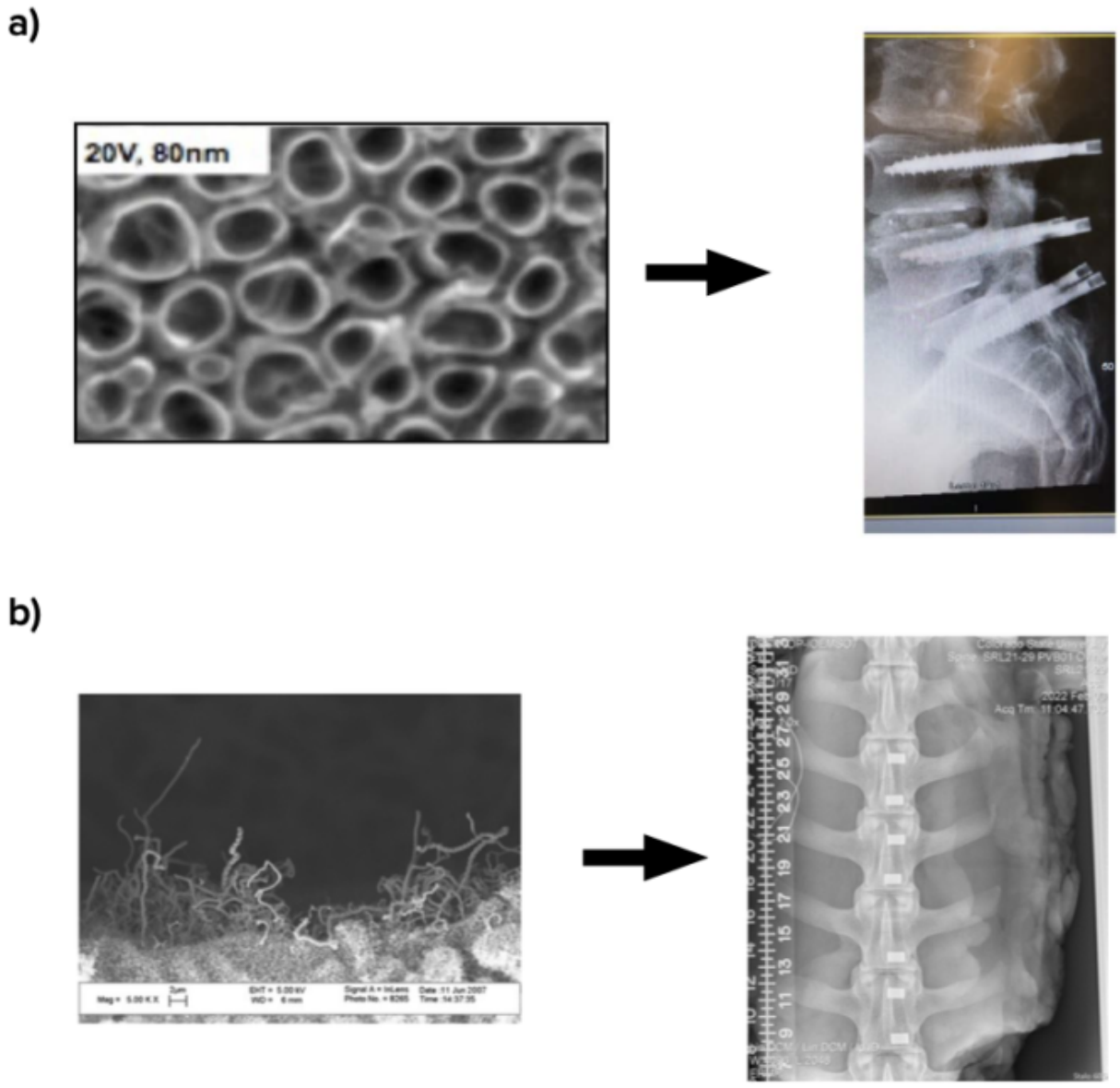

Figure 1: a) Nanotextured spinal implants now in over 30,000 humans with no cases of failure [2]. Such implants are being commercialized by Nanovis. b) Nanosensors now being used to detect the presence of bacteria, inflammatory cells, or bone-forming cells on implants. Such nanosensors can communicate to handheld devices and can respond in real-time to reverse adverse events. Such sensors have been implanted in sheep for up to 12 weeks showing the ability to promote bone growth.

Thomas J. Webster, PhD provides a firsthand account of the obstacles hindering innovation in medicine, covering publishing, conferences, politics, funding, universities, and industry

Innovation is hard. Such a simple word, but so many obstacles exist to innovate and, more importantly, to turn your innovation into a medical product that actually improves human health for ultimate technology validation. As I look back at my almost 25-year career innovating in medicine, I find myself continuously reflecting on how I was able to develop innovative solutions for improving medicine despite constant obstacles. One particular innovation that I am extremely proud of involves my efforts to integrate nanotechnology into orthopedic implants. How did my team and I develop nanotextured orthopedic devices now in over 30,000 patients in which zero implants have failed to date (no infection, no chronic inflammation, and no implant loosening) when the industry average shows orthopedic implant failure rates over 10%, increasing daily (Figure 1)?[1, 2]

How did we develop and use in such work an innovative equation that predicts implant nanoscale surface feature dimensions that can eliminate medical device infection, reduce inflammation, and promote tissue growth for almost any kind of medical device (which has been independently tested and confirmed over a dozen times)? [3] Further, how are we now growing sensors from implants to communicate in real time what type of tissue (bone, scar tissue, and/or bacteria biofilms) is growing next to an implant? Or how did we develop an inhalable self-assembled nanomaterial that can bind to numerous viruses (such as HIV, SARS-CoV-2, rhinovirus, influenza, and more) and stop them from replicating inside mammalian cells (Figure 2)? Or how did we develop the next generation of metallic nanoporous capsules for treating diabetes (Figure 3)? The list goes on for our's and everyone's efforts in innovating medicine.

Although not a focus of traditional conferences and/or publications, it is critical for all of us to reflect on how we innovative. Were all of these innovations an accident? Simply luck? Hard work? Are there any lessons that my team can pass on to others? Are systems in place that I should be grateful for? Could such innovations happen again today? Is it harder? The bottom line is how did all of these innovations happen?

Universities and innovation

These are complicated questions with no easy answers, and innovation hardly follows one common path – but I can make a few conclusions based on my experiences. As I have spent my entire 25-year career at universities, an immediate question for me is whether universities have helped me innovate in these technologies. Unfortunately, my answer is 'no'. This is a subject I have written a lot about before. [4]

Sadly, I have viewed my university experiences as more of a hindrance than a help in innovation. Yes, it is easy to be innovative in education at universities, but universities have presented more obstacles to me than help when innovating in research. Universities gave my team and I extensive bureaucracy licensing my patents to industry for commercialization (even driving away partners), numerous meetings with conflict of interest committees and countless confusing forms, a requirement to obtain my own funds to develop my own innovations (yet requiring a 66% return on all revenue from my innovations), jealous faculty filing for my innovations and accusations of academic

dishonesty, difficulty developing a diverse lab (both in terms of ethnicity and associated ideas), and one particular university even shut down my lab at the height of COVID when we were innovating to stop SARS-CoV-2 spreading.

Yes, it is crystal clear to me that I could have developed more innovations (and faster) in medicine had it not been for the universities I worked at, and it is getting worse and more difficult to truly innovate at universities.

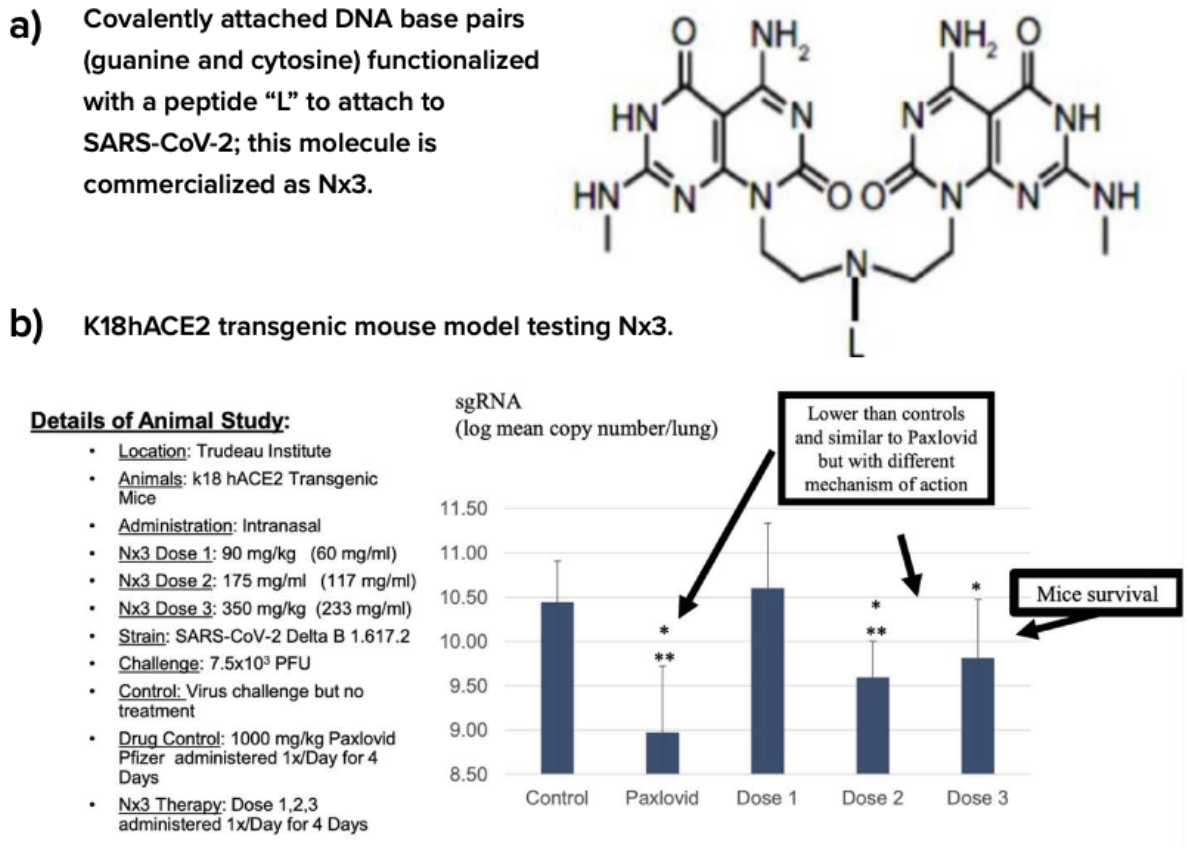

Figure 2: (a) Self-assembled nanomaterials developed to passivate SARS-CoV-2 (b) as tested using well-established in vivo k18 hACE2 transgenic mouse models. The graph shows statistically different (** $p < 0.05$ compared to all others) and statistically similar (* $p < 0.05$ compared to all others) SARS-CoV-2 sgRNA in SARS-CoV-2 infected mouse lungs after 4 days of intranasal self-assemble nanomaterial delivery. Such materials are being commercialized by Audax Medical.

Funding innovation in medicine and other sectors

How about government funding agencies? Did they help my team innovate? This is a tricky one. You cannot innovate without funding, especially in medicine, where animal studies are a requirement for regulatory approval. So, to me, all funding is good funding. But upon further reflection, at this time of my career, my answer is also 'no'. None of what I would consider my greatest innovations now in humans were funded by a government agency; it was all private capital. I remember hearing as an Assistant Professor that in order to get National Institutes of Health (NIH) funding, you have to complete the study first and then apply for funding for that study later. That is not innovation, and it is

symbolic of a broken system. Having served as a reviewer on grants all over the world, it is abundantly clear to me how integrated politics, favoritism, support of fundamental over applied science, and lack of reviewers even reading or understanding grant applications are embedded into the grant review process.

I even attended an NIH review panel once where a recent PhD graduate evaluated their own PhD thesis advisor's grant. Despite my objections, their review was included in the final scoring system. I also remember the advice I received from my own PhD thesis advisor that if you are counting on and waiting for federal funding (sometimes for up to two years after submitting a grant) to support your start-up company, you will never succeed. Federal funding was great for getting tenure (as my university required it), but of little to no meaning for me to innovate.

Publishing and innovation

How about academic journals? It is my experience that the conventional publication peer review process is broken. If you are looking for innovation in publications, or to get inspired for innovation, good luck. Similar to the above, the peer review process for publishing in academic journals is full of politics, favoritism, money requirements, ethnic discrimination, and outright omission of research from certain parts of the Earth. I continue to be astonished at peer-review comments on my own articles, especially when I include authors from China and the Middle East.

A journal even sent me a reviewer's comment, which stated that my article should not be published since it had an author from China. Further, it can easily take over a year for research to be published, which is counter to innovation. I have also been alarmed at the record number of article corrections, corrigenda, and retractions that publishers are conducting today without following standard Committee on Publication Ethics (COPE) guidelines. [(5)] In fact, many of these publications in question were completed decades ago in which publishers asked authors for the original raw data that supported the study in question but was never required during the submission or after acceptance. Unfortunately, these and many other examples highlight that traditional publications are not a source of innovation.

There are new publication efforts, such as post-publication peer-review, which I believe will be the norm in years to follow if embraced by the research community, where an article is published prior to peer review, and the peer review occurs in real-time as people assess and read the article. [(6)] Such new publication processes remove bias, favoritism, ethnic discrimination, and more problems from the publication process, which is now widespread. Now, that's innovation, but keeping up with innovative research in traditional publications never helped me innovate.

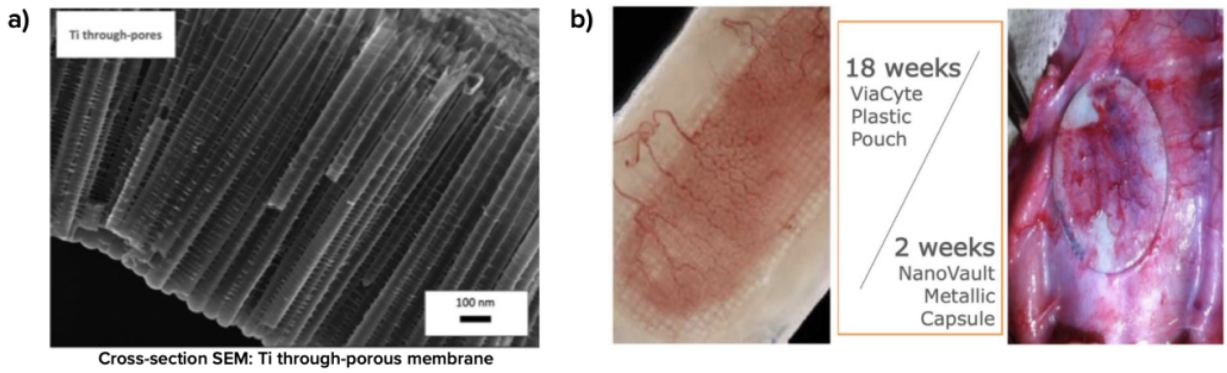

Figure 3: (a) Metallic through-nanoporous capsules for treating diabetes now being commercialized by NanoVault and (b) In vivo (rat) model showing increased new blood vessel formation after subcutaneous insertion surrounding the through- nanoporous metals. ViaCyte is an FDA approved polymer stem cell delivery device which had less new blood vessel formation necessary to maintain stem cell viability than NanoVault's metallic through-nanoporous structures.

Conferences and innovation in medicine

How about conferences? Sadly, I would say that has not helped me with innovation either. Traditional academic societies seem to promote and highlight the same old researchers completing the same old research. Traditional academic societies have not emphasized innovation over attendance or revenue. This is why smaller, new, diverse conferences have emerged over the years to fill the gap that traditional societies have prioritized money over innovation.

People and innovation in medicine

So, that leaves me with people. Here, my answer is a resounding 'yes'. Surrounding yourself with exceptional researchers, colleagues, entrepreneurs, innovators, and yes people who are genuinely interested in advancing medicine through innovation has been my key to success. It is not easy, as there are a lot of 'sharks' out there, but be patient and careful, and believe me, with crises larger than COVID just around the corner (antibiotic resistance bacteria, chemotherapeutic-resistant cancer cells, global warming causing unprecedented disease progression and more), we need those who truly value the person, the research, and innovation.

Without good people pushing true innovation in medicine validated through human trials, we will be stuck in a global healthcare system that has resulted in a decrease (not an increase) in average life expectancy over the past several years. [(7)]

All of my innovations can be attributed to the great people I have surrounded myself with over my 25-year career. I hope they join me in congratulating their innovations as they continue to build their own teams to innovate.

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