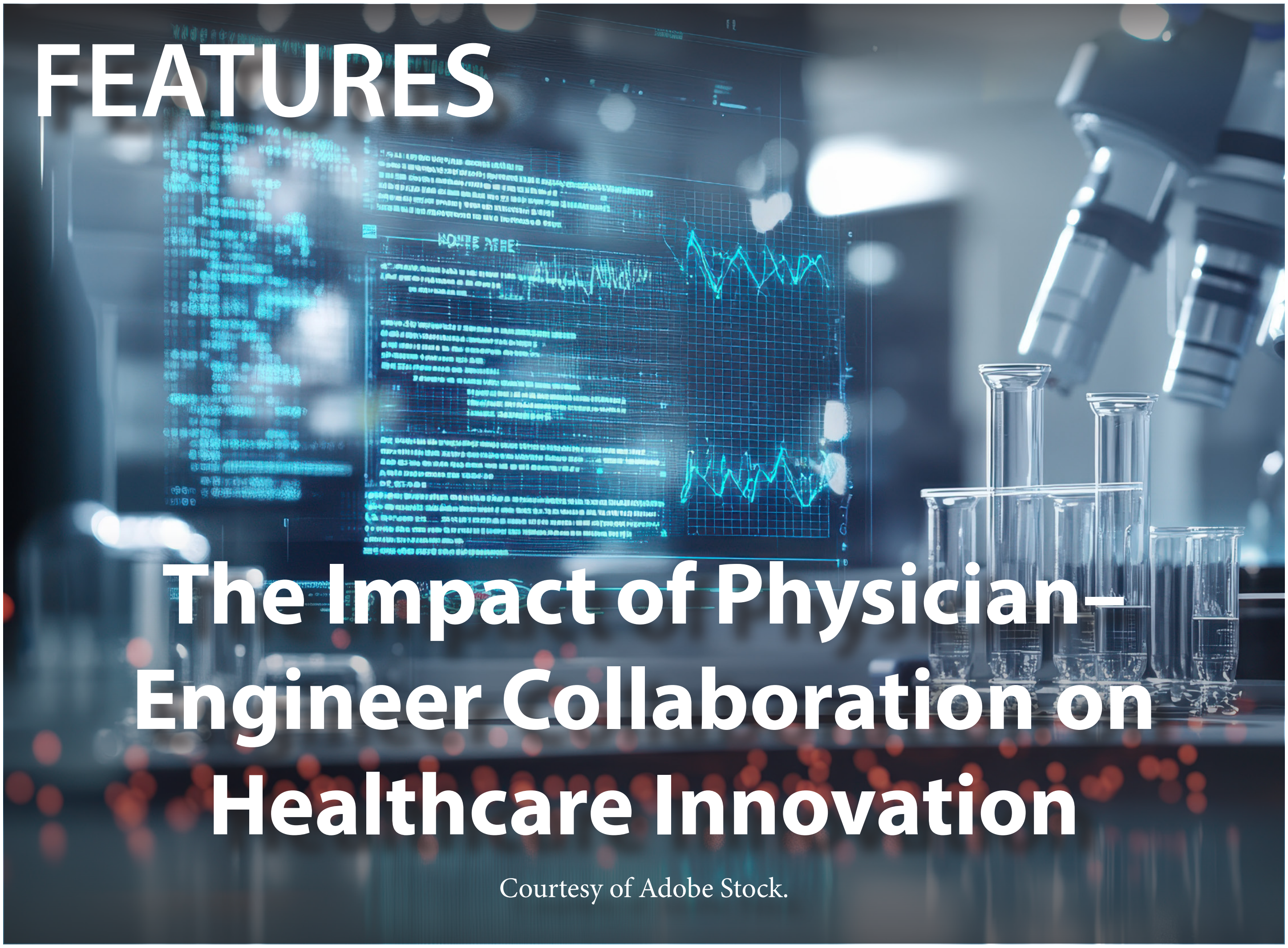

FEATURES

The Impact of Physician–Engineer Collaboration on Healthcare Innovation

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Introduction

Bioengineering—also known as biomedical engineering—is the interdisciplinary study that applies engineering principles in biological contexts to uncover new knowledge, improve existing systems, and solve issues in healthcare and other biologically relevant areas. Bioengineering is a rapidly growing field. The percentage of Harvard College undergraduates concentrating in engineering, many of whom are interested in healthcare applications, has grown from six to 19 percent from 2007 to 2017 (Lee & Xie, 2017). Beyond Harvard, 13,222 bachelor's degrees were awarded in biomedical engineering in 2022 (Data USA, n.d.).

More and more students are choosing to study this discipline for various reasons, including career potential. According to the Bureau of Labor Statistics, bioengineering jobs in the U.S. are estimated to grow seven percent in the next ten years, faster than the four percent projection for all occupations (U.S. Bureau of Labor Statistics, 2024a; U.S. Bureau of Labor Statistics, 2024b). The industry's growth is not limited to the United States—the global bioengineering technology market is currently valued at $320 billion, an almost $40 billion increase from the $282 billion valuation in 2023 (The Business Research Company, 2024). Market valuation is estimated to continue growing at a compound annual rate of 13.5% (The Business Research Company, 2024). Furthermore, healthcare and biotechnology continue to be highly innovative fields, producing 3D-bioprinted devices and new cancer therapy drugs and spurred by the ever-present need for medical remedies.

Despite the rapid growth of bioengineering, healthcare professionals have been slower to embrace emerging technologies designed for their area of work. A 2018 study by German researchers found that doctors were less enthusiastic about adopting novel digital health technology than patients and other medical staff, and they cited several reasons (Safi et al., 2018). For one, they felt that these technologies directly challenged their relationships with patients and their independence in diagnosing and treating patients. Also, doctors expressed that their proficiency in technology development was low and could be supplemented by IT support and training (Safi et al., 2018). This suggests that doctors may feel uncomfortable using new technology simply because they do not have enough knowledge or input in its design.

Even when doctors accept newly-engineered technologies, it is often a transaction of a final product between the designers and consumers, as opposed to a collaborative design process. This can lead to a dissonance between the engineers' design and the appropriate solution for a patient's medical needs, resulting in inefficient innovations and sometimes disastrous consequences.

Björk-Shiley Convexo-Concave Heart Valve

One example is the Björk-Shiley Convexo-Concave (C/C) Heart Valve. A heart valve is a flap that opens and closes pathways for blood flow through the heart, strictly controlling blood pressure and flow timing. Diseased heart valves lead to insufficient flow of oxygenated blood to cells and often need to be replaced with prosthetic heart valves (Fielder, 1995). In 1979, Shiley Inc. introduced the 60° C/C valve, which involves inlet and outlet struts to hold a disc in place as it swings open and closed to mimic normal valve function **(Fig. 1)**. Clinical trials showed that the valve significantly decreased blood clotting, causing doctors to transplant it into approximately 85,000 patients in the late 1970s and 1980s (Birkmeyer, 1992). However, the outlet strut fractured in many implanted valves, dislodging the disc from the rest of the device and leading to uncontrolled blood flow (Fielder, 1995). This complication led to patient death within minutes to hours. Shiley, and later Pfizer, voluntarily recalled C/C valves starting in 1980, and several patients elected to have their Björk-Shiley valve explanted or replaced, but the damage had been done. By 1993, 386 patients had died due to fractured heart valves (Fielder, 1995). Even today, patients with the Björk-Shiley valve weigh the risks between its tendency to fracture and the expenses, time, and risks involved with another invasive valve replacement (Birkmeyer, 1992).

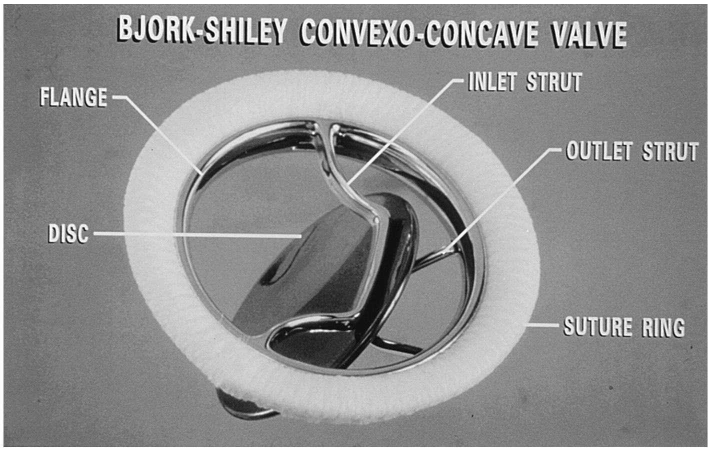

Figure 1. Björk-Shiley 60° convexo-concave heart valve, with labeled parts (Walker, 1995).

According to Dr. J.H. Fielder of Villanova University, Shiley may have altered the valves and sent them out to be implanted in patients without adequately informing surgeons and patients of their risk (1995). Had surgeons been aware of the true quantification of complications, they could have opted to implant other prosthetic heart valves in their patients. "By working on changes while still marketing the valve, Shiley was treating surgeons and patients simply as a means to its marketing program and not acknowledging their right to make informed choices about participating in it" (Fielder, 1995). This highlights the consequences of a lack of rigorous collaborative safety checks and clear communication between engineers and cardiac surgeons, further emphasizing the importance of collaboration between physicians and engineers at every level of the design process, from conceptualization to implementation.

The Living Heart Project

Some professionals within the healthcare innovation field are pioneering the way for such collaboration. Steve Levine is an engineer spurred by his daughter's heart condition to found The Living Heart Project, which offers analytic modeling of an individual patient's heart (Levine, 2024). The process starts with a CT or MRI scan of the heart for diagnosis. These scans can be utilized by virtual twin technology—an innovation used in the aerospace and automotive industries—to create 3D simulations of a heart complete with a heartbeat profile and blood and oxygen flow **(Fig. 2)** (Levine, 2024).

Over the past decade, the Living Heart Project has grown steadily, attracting numerous collaborators like Dr. David Hoganson, a pediatric cardiac surgeon at Boston Children's Hospital (Russell, 2023). He works with engineer Peter Hammer and his team to envision his young patients' hearts and to determine the best course of action during his surgeries. The engineering team

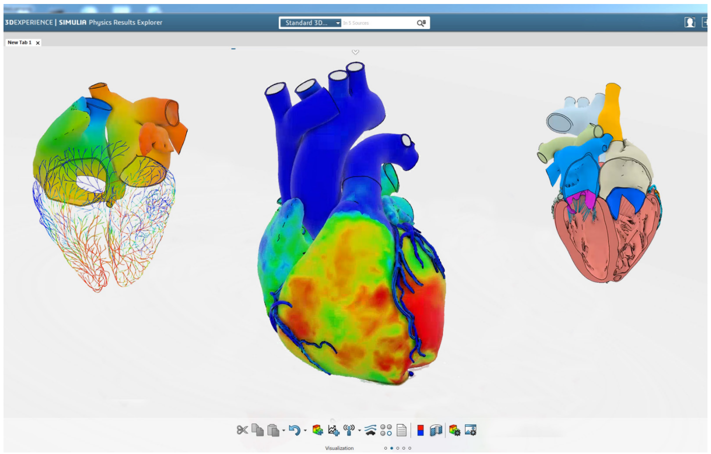

Figure 2. Example digital human heart model on 3DEXPERIENCE platform (Dassault Systèmes, n.d.).

uses the 3DEXPERIENCE platform to create a real-time connection between the real and virtual world, which can be easily displayed on a screen or in virtual reality. This allows them to simulate the problem and potential solutions using real-life scientific principles and under different contexts (Russell, 2023).

During one case, Dr. Hoganson was presented with a child whose heart had holes that needed to be filled with patches to restore proper oxygenated and deoxygenated blood flow throughout the heart and body (Russell, 2023). Although he had patch material, he had to determine the proper size and shape of the patch to withstand the high blood flow pressures within the heart. Hammer and his team worked to simulate the young patient's heart, ultimately creating a workflow using the mechanical properties of the patch material to test whether different patch configurations would be able to close the holes safely and effectively. Thus far, the team of engineers has created more than 900 models to help Dr. Hoganson and to make patients' families feel more involved (Russell, 2023). This consistent collaboration between physicians and engineers has ensured the success of many difficult surgeries and better lives for many patients.

Personal Protective Equipment (PPE) for the COVID-19 Pandemic

The importance of teamwork between doctors and engineers is heightened in times of crisis. During the first surge of the COVID-19 pandemic in 2020, decreased manufacturing due to lockdown policies and the increased risk of exposure to the virus for healthcare workers led to an unmet demand for PPE (Brownell, 2020). Engineers and facilities with 3D printers sought to address this need, printing and distributing as many face masks as possible to healthcare workers. Unfortunately, the combined efforts of industrial labs, college makerspaces, and 3D printing enthusiasts were insufficient to provide enough masks for the healthcare force.

Dr. James Weaver, a Research Associate at Harvard, aimed to design an effective mask that could be mass-produced at the regional scale (Brownell, 2020). He interviewed clinicians and other healthcare professionals on their face mask material preferences and their opinions on convenience, gathering information and inspiration to guide PPE design. Then, he collaborated with Wyss Core Faculty member Dr. Jennifer Lewis, other Wyss members, researchers from Columbia University, and a local plastic food packaging company called Lacerta Group, Inc. to bring the face mask designs to fruition. His efforts resulted in the Dome Shield, a full-coverage, anti-fogging face mask made of a single food-grade material and priced at only $0.75 **(Fig. 3)**. More importantly, the team was able to produce 400,000 masks a day using Lacerta Group's manufacturing facilities and distributed over seven million masks over four months to frontline healthcare workers and the rest of the community (Brownell, 2020).

Dr. Weaver attributes the team's openness to collaboration for the success of the Dome Shield initiative. According to a Wyss Institute article, he reported that

Figure 3. Dome Shield, designed and produced by Wyss Institute and Lacerta (Brownell, 2020).

the designers, researchers, physicians, hospitals, and industrial partners "committed time, effort, and resources into helping develop these face shields [...], saying 'yes' when they could have easily said 'no.'" (2020). The joint effort allowed engineers and researchers to quickly create enough masks while meeting the crucial needs of frontline workers, emphasizing the positive impact that healthcare professionals' clear communication can have on creating effective medical solutions.

Future Directions

To date, the potential of collaboration between physicians and engineers is only beginning to be uncovered. Some examples of healthcare issues that are still prevalent are antibiotic resistance, chronic disease management, and mental health treatment access. Clinicians have an insider perspective of how antibiotic resistance plays out in an infected patient, what challenges exist for patients living with chronic diseases like diabetes, and why mental health care may still be inaccessible to many patients. Their insights can offer engineers invaluable guidance on what medical problems require solutions and how to solve them, creating a streamlined and effective workflow.

One way to promote this collaboration is to introduce engineering principles, as well as the resulting notion of innovation, early on in medical education. According to physicians from the University of California, Los Angeles and Tufts University, design thinking is "directly transferable to the practice of clinical medicine when troubleshooting a broad range of issues, such as improving health outcomes, standardizing clinical processes, and reducing costs" (Rambukwella et al., 2021). The physicians further corroborate that a deeper understanding of technological principles would increase their comfort in adapting to new technological innovations throughout their clinical practice. In response, Texas A&M's EnMed Program at the School of Engineering Medicine, the Harvard-MIT Program in Health Sciences and Technology (HST), and other programs are integrating the practices of innovation, design, and collaboration, all characteristics distinctive to engineering.

Effective communication and collaboration between physicians and engineers play a key role in improving patient care and driving medical innovation. Engineers working on health applications can gain valuable perspectives from physicians in order to design and iterate solutions that address real-world clinical needs. Similarly, informed by their first-hand experience with patients during daily rounds or consultations, physicians can collaborate with engineers to bridge gaps in the healthcare system. By working together, doctors and engineers can drive meaningful progress in healthcare, shaping safer, lower-cost, and more effective treatments to improve patient lives.

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