Medical mechanics: Teaching medical device design in cultural context

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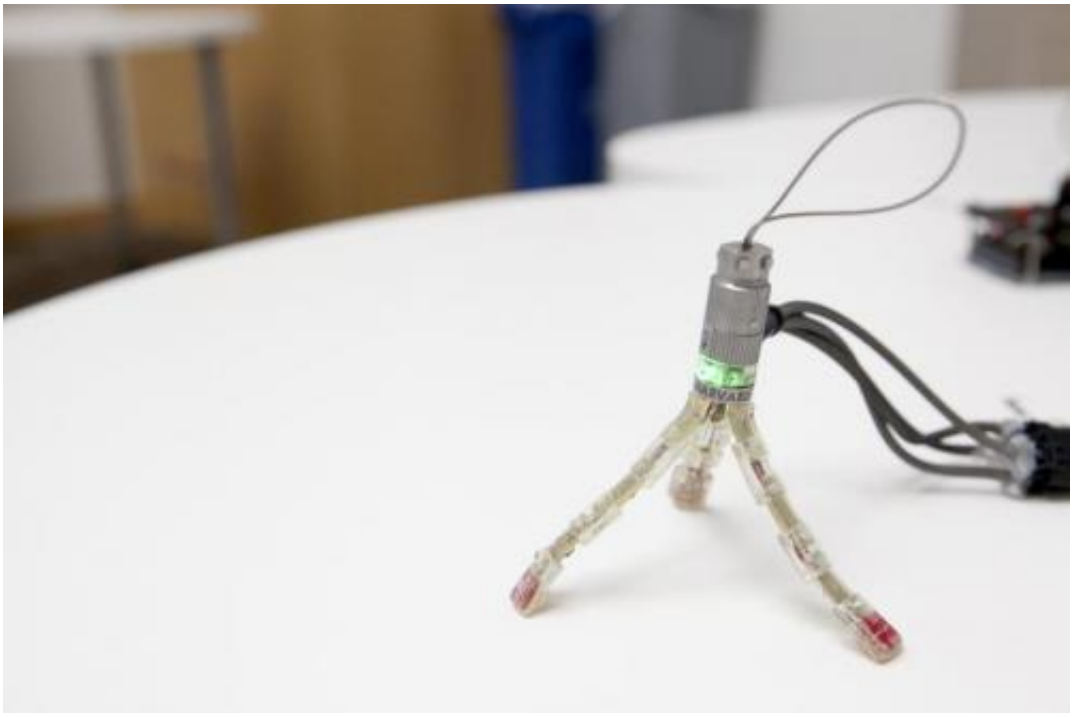

Crafted in a 3D printer and outfitted with rubberized pressure sensors, this inexpensive device designed at Harvard offers surgeons a confident grip on delicate tissue. Credit: Eliza Grinnell, Harvard SEAS.

Removing a malignant tumor from the head of the pancreas is a risky and demanding operation. The surgeon must carefully navigate around the stomach, the gallbladder, the bile duct, lymph nodes, and several high-pressure blood vessels.

But an inexpensive device designed by Harvard engineering students and a surgeon at Beth Israel Deaconess Medical Center offers surgeons a confident grip throughout the delicate procedure. The gentle grasper, equipped with rubberized pressure sensors, has three slender fingers that can slip through a very small incision and tease cancerous tissue away from the pancreas without squeezing too hard.

The device has the potential to reduce hemorrhaging and save lives. For now, it's offering critical lessons in engineering design to a group of undergraduate and graduate students at the Harvard School of Engineering and Applied Sciences (SEAS).

Here, a growing initiative in medical device innovation is taking shape. Engineering faculty, entrepreneurship experts, and clinicians from Harvard's affiliated hospitals are collaborating to solve complex medical problems—and creating an invaluable environment for hands-on education at SEAS.

"One of the most important things we try to teach the students is the importance of taking a rigorous, detailed approach to what can seem like a messy and ill-defined process," says Donal Holland, a visiting Ph.D. student from Trinity College, Dublin, and teaching fellow for ES 227, Medical Device Design, at SEAS. "Anyone can use trial and error to come up with something that works, but good engineers draw on their technical and analytical skills to solve problems in a deterministic way."

That approach, the cornerstone of education at SEAS, is working. The surgical grasper and three other student-designed tools earned prestigious awards from the Design of Medical Devices (DMD) Conference at the University of Minnesota this spring in recognition of the devices' technical quality, medical practicality, and potential for commercial impact.

In ES 227, where several of the winning projects originated, students are asked to help clinicians overcome a problem they face in practice. And they are challenged to design under pressure.

"A lot of clinicians, especially those who are actively involved in research, have brilliant ideas for tools and devices that can improve over current standards of care in their respective fields, but they may not necessarily have the time, personnel, facilities, or technical background to make these ideas a reality," says Joshua Gafford, a Ph.D. student at SEAS who took ES 227 last spring. "The great thing about ES 227 is that it establishes a symbiotic relationship between clinicians, who can see their ideas come to fruition, and engineering students, who have a hands-on opportunity to develop a product with observable medical implications."

"The students act as a catalyst to help make that ideation and design process more in depth, broader, better," says Conor J. Walsh, assistant professor of mechanical and biomedical engineering, who launched ES 227 at SEAS after being a teaching fellow in a similar course with Alex Slocum at MIT. "They bring a lot of passion to the class, because they're really excited to work on solving a real problem. You can't discount that in terms of how it motivates someone—to actually spend time with clinicians, putting in long hours and late nights to work on these projects—and that comes across in the final presentations."

Over the course of a semester, students in ES 227 must clarify the medical problem and practical constraints, brainstorm solutions and rigorously evaluate them, design and fabricate prototypes, iteratively test and improve them, and then present a final, working device in a publication-quality paper.

"It pushes students to really achieve their best and produce quality prototypes in a shockingly short amount of time," says Paxton Maeder-

York '14, who will graduate in May with an S.B. in engineering sciences.

Students at Harvard SEAS are working with clinicians to design new medical devices with real-world applicability. This portable cranial drill, designed in 2011, could save a life by quickly and safely relieving pressure on the brain. Credit: Eliza Grinnell, Harvard SEAS.

With a team of other students, and with mentorship from Holland, Walsh, and Dr. Catherine Wee at Spaulding Hospital for Continuing Medical Care, Maeder-York designed a soft, wearable device to help patients regain normal thumb movement—and therefore the ability to

grasp objects—after a stroke. The project won the Three-In-Five contest at DMD, as did another of Gafford's devices. The students now have the opportunity to submit their findings for accelerated review by the prestigious *ASME Journal of Medical Devices*.

"Design courses like these are crucial to an engineer's skill set," says Maeder-York. "The theory classes provide background and history into the physics behind systems, but the most rewarding skills I have harnessed from my Harvard education have been time management, team dynamics, creative thinking, and iterative design."

After graduation, he intends to work at a start-up company in San Francisco that makes microsurgical robots.

In ES 227, students learn how to write high-quality research papers, register patents, and present at prestigious conferences—all vital skills for graduate school and careers in engineering.

"I learned a lot about the design process, how to develop a product with the end user in mind, and how to communicate design requirements to external vendors and get high-quality parts manufactured," says Gafford, who studies in Walsh's lab and was lead author of three of the winning papers at this year's DMD conference.

Approximately 30 undergraduates have also conducted research in the Harvard Biodesign Laboratory. The results are impressive. This year's crop of capstone design projects by Harvard College seniors pursuing the Bachelor of Science through SEAS includes a prosthetic hand, tools to improve cardiac catheters, new minimally invasive surgical devices, and a wearable machine that could help infants who have trouble walking.

Walsh's course is just one aspect of a growing suite of biomedical design

initiatives at SEAS that also includes international research experiences and summer design fellowships. Enabled by a grant from the National Collegiate Inventors & Innovators Alliance, along with foundational and corporate support, the program is built on the premise that effective medical design requires immersion in a real clinical setting—whether that's in Boston's world-renowned hospitals or in a rural infirmary overseas.

"Building up our presence in biomedical engineering makes tremendous sense for SEAS," says Dean Cherry A. Murray, John A. and Elizabeth S. Armstrong Professor of Engineering and Applied Sciences and professor of physics. "Focusing on applications in the developing world is especially interesting because not only does it fit exactly with our mission of improving life through technology; it has the potential to be disruptive for the developed world too. Our students are excited about that, and I think they recognize it as an opportunity."

In 2012, with support from the Harvard South Asia Institute, Walsh established a program that lets students from across Harvard spend the summer in Bangalore, India, visiting private and government-run hospitals. They have the opportunity to innovate in a different cultural and economic context and then bring those ideas back to Harvard. The program has continued in 2013 and 2014 with support from the President's Innovation Fund for International Experiences, and Walsh has established a partnership with the Indian Institute of Science to jointly create new design opportunities for students during the summer.

"These initiatives are ideally suited to Harvard, where it's not unusual for a student to be interested in engineering, public health, economics, and cultural studies all at once," says Walsh, who is hoping to expand the program in the future. "Students participating in the program gain an appreciation of how they can use their skills for the benefit of others. They often continue the projects for their senior thesis, a class, an

extracurricular project, or even after they graduate."

For some students, engineering design can also result in patents and start-ups.

Pratheev Sreetharan '06, Ph.D. '12, developed a pop-up fabrication technique as part of the National Science Foundation–funded RoboBee project. Building on Sreetharan's advance, Gafford and his collaborators at SEAS and the Wyss Institute for Biologically Inspired Engineering have demonstrated very small active cutting devices, powered by piezoelectric actuators like those onboard the robotic insect prototypes, that could fit inside an artery to clear a blockage. That project won the grand prize in the DMD Emerging Medical Innovation Valuation Competition.

"Despite a substantial amount of intellectual property generated thus far—in terms of the fabrication technique itself and medical applications thereof—we're really just scratching the surface in terms of the medical potential," Gafford adds.

The collaborative environment at SEAS, where multiple lab groups and courses tackle challenging projects together, complements other efforts at Harvard, such as Harvard Medical School's Catalyst educational workshops, courses on biomedical innovation at Harvard Business School, and the work of the Office of Technology Development and the Wyss Institute.

"When it comes to innovation in the classroom, SEAS is sort of the connector of all those different parts—the medical, the business, the economics—as all are important when designing and innovating," says Walsh, who is also a Wyss Institute core faculty member. "We would love to see more students from across Harvard participate in our programs."

Six student projects from SEAS have earned awards at the DMD conference in the past two years, and ES 227 was offered again this spring, producing another set of innovative devices.

"I'm delighted that they have received recognition for all their hard work," says Holland. "I think it proves how worthwhile it is to provide students with hands-on design experiences and access to great facilities."

More information: Joshua Gafford, Samuel Kesner, Robert Wood and Conor Walsh, "Monolithic Fabrication of Millimeter-Scale Surgical Devices with Integrated Sensing," ASME Journal of Medical Devices, DOI: 10.1115/1.4027045

Joshua Gafford, Ye Ding, Andrew Harris, Terrence McKenna, Panagiotis Polygerinos, Dónal Holland, Arthur J. Moser and Conor Walsh, "Shape Deposition Manufacturing of a Soft, Atraumatic, Deployable Surgical Grasper," ASME Journal of Medical Devices, DOI: 10.1115/1.4027048

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