Reinventing the ties that bind during heart surgery

Hopkins students design system to close sternum

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For most undergraduates, plastic cable ties are things they use to subdue the tangle of computer wires behind their desks.

But for 11 budding engineers at the **Johns Hopkins University**, the simple, sturdy fasteners were the key to solving a problem that has vexed cardiac surgeons for decades - how to do a better repair on a breastbone they saw in half to gain access to the heart.

The undergraduates in associate research professor Robert Allen's two-semester, biomedical engineering design course have conceived and built a hand-held device that can safely join and stabilize the two halves of the sternum, using cable ties that dissolve after the bone has healed.

The plastic straps would replace stainless steel wires that doctors say are difficult to tighten and may damage bone and organs or stab the surgeon's hand.

Doctors consulting for the project's corporate sponsor reportedly declared the students' solution "very elegant" and, with further refinement, "something they would consider using in their practice," said Dr. Malcolm Lloyd, the sponsor and founder of Surgical Transformations LLC.

If approved by the Food and Drug Administration, a finished version of the students' chest-closing device could be ready for market in as little as two years. And if it sells, the four students whose names appear on the provisional patent will share in the royalties. "They could make, in total, hundreds of thousands, if not millions of dollars if this is ultimately used widely," Lloyd said.

"Everyone's really excited about that," said Neha Malhotra, 20, a rising Hopkins senior from Dubai, United Arab Emirates, and one of the patent-holders. "Our parents will be very happy."

It's too soon to say whether the students' invention will win FDA approval or surgeons' acceptance. But Mark Brager, a spokesman for Advamed, the trade association for medical device manufacturers, said more than 3,100 devices were submitted for FDA approval in fiscal year 2004 - the most recent data available.

Most were reviewed and approved in three to four months.

The need for a new chest-closure mechanism emerged from discussions Lloyd had with cardiac surgeons as part of his business - developing new medical devices.

A Dartmouth College-trained physician and a 1994 graduate of Hopkins' biomedical engineering

program, Lloyd, 35, worked in the venture capital industry and later founded a health care information technology company. He also consulted for the pharmaceutical and medical devices industries before founding Surgical Transformations.

"The role we fulfill is to partner up with surgeons who spend time in the [operating room] and realize there are these gaps" in their toolboxes, he said. "They share these problems with my company, and we ... bring them places that can innovate and develop prototypes. It was natural for me to go back to Hopkins."

For decades, surgeons have been using stainless steel wire to stitch sternums back together - more than 500,000 operations a year in the United States alone.

The doctors typically attach a needle to the wire, pass it between the ribs, beneath the breastbone, then up again between the ribs on the opposite side. Then they join the two ends with pliers and tighten them with several twists. Six or more loops of wire may be needed.

"It's a large needle," Lloyd said, and "because you can't see what's going on under the sternum, it can damage arteries or nerves. And the surgeon himself can get a needle stick."

The needle can also puncture a lung or cause other post-operative complications.

The work is especially tricky at the top of the sternum, where the needle must be pushed through the bone, once on each side of the sternum. "It requires an awful lot of pressure to apply to this needle so it will actually penetrate the bone," Lloyd said.

Surgeons also told him it's difficult to gauge how tightly they are joining the bone. Over-tightening can cause the wire to break or cut into the bone - especially in the elderly. Under-tightening can leave the healing sternum unstable and painful.

The wire may also provoke the body's immune system, the doctors said. And once installed, it is there for life. The twisted knot can protrude and become painful, and the wire may heat up or move during magnetic resonance imaging.

To solve these problems, the ideal solution had to be quick. It "can't take an awful lot more time than the existing approach or it won't be adopted," Lloyd said. Surgeons want to get their patients off anesthesia, "or they want to go on to the next operation or they want to go home."

With surgeons more focused on the challenges of the heart surgery itself, he said, the closure issue has persisted for years.

So Lloyd turned to Hopkins' students - not in spite of their inexperience, but because of it.

"Engineers who have worked on things for a long period of time tend to steer away from certain areas" because they have been tried before, he said.

"What's beautiful about these students is that they have a naivete, where there's nothing within them that tells them 'I can't solve this problem.' By their very nature they look outside the box for solutions," Lloyd said.

Their professor, Allen, had 90 students in his design course this past year. It's required for all biomedical engineering majors. Since 1998, Allen said, the course has produced a half-dozen patents, spawned one startup company and one licensing agreement.

The startup is Renal Diagnostics Inc. of Cambridge, Mass. The firm grew out of a student-designed device that can detect signs of kidney failure in intensive-care patients by constantly monitoring changes in urine. The warning comes days earlier than it does with traditional blood tests.

Chief executive Shawn Eric Stovall said the device is still in development, and the company is seeking investors.

The chest closure problem drew the interest of Malhotra and senior Chris Weier, 23, from Sterling Heights, Mich. They led a team of six freshmen and five upperclassmen who chose the project because it seemed important and best-suited to their skills.

Last fall they asked cardiac surgeons at Hopkins what an ideal solution might look like, Malhotra said. Then they tossed around several ideas, including one based on a molten "biomaterial" that would harden around the sternum while it was temporarily clamped together. Unfortunately, nobody seemed to know of any such material.

Cable ties were an early contender, partly because the students knew how strong they were, and partly because they are already used in some medical and veterinary surgeries.

What was missing was an instrument to guide the cable tie safely around the sternum, and then tighten it.

While part of the team set about designing and drawing the device - and finding a builder to fashion a prototype - the others tested the relative strengths of the twisted stainless steel knot, and the cable ties' catch mechanism.

Working partly on cadavers in Hopkins' anatomy lab, Malhotra said, "We found that the lock of the cable ties could withstand a greater amount of force" than the wire twists, and more than enough to secure the sternum.

The group responsible for the instrument designed something similar to a staple gun, but fitted with a slender, curved channel to guide the cable ties safely around the breastbone without damaging surrounding tissue.

By squeezing a handle on the device, the surgeon can draw the notched tie through gradually, sensing its tightness through the grip. A more refined final version may include a gauge to meter the tension precisely, and a snipper to cut off any excess.

Lloyd said his company will further refine the design, develop ties made of an appropriate biodegradable material, and then test it on humans. He's offered Weier a consulting job.

Lloyd said he "never would have imagined that, given the limitations of time and inexperience, the students would have come up with something that hit so many of the engineering requirements that we set out."

So he's already preparing six new problems for presentation to next fall's class.

The professor, too, was satisfied. "It appears simple, yet it's professionally done," Allen said. "They're complaining that I haven't finished the grading, but they'll probably get A's."