Classroom to Clinic: Merging Education and Research to Efficiently Prototype Medical Devices

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***Abstract*— Innovation in patient care requires both clinical and technical skills, and this paper presents the methods and outcomes of a nine-year, clinical-academic collaboration to efficiently evaluate new medical device technologies, while teaching mechanical engineering. Together, over the course of a single semester, seniors, graduate students and clinicians conceive, design, build and test proof-of-concept prototypes. Projects initiated in the course have generated intellectual property and peer-reviewed publications, stimulated further research, furthered student and clinician careers, and resulted in technology licenses and start-up ventures.**

I. Introduction

IN their practices, clinicians frequently identify challenges that require new technological solutions; however most lack the time, funding and engineering skills to turn a notion into a prototype. When open-space, creative design is needed, an academic – clinical partnership can provide the means to rapidly and economically evaluate a wide range of challenges and design possibilities.

Since 2004, MIT and the Center for Integration of Medicine and Innovative Technology (CIMIT)[1] have collaborated to develop a Medical Device Design Class with the hypothesis that education and translational research can (and should) be merged. In just one semester, teams comprised of clinician-investigators and senior/graduate students follow an industry-modeled design process, culminating in a working proof-of-concept prototype and quality documentation. Similar successful programs exist at Stanford, University of Minnesota and Johns Hopkins.

The results of this experiment are promising: Projects initiated in the course have generated intellectual property (IP) and peer-reviewed publications, stimulated additional research, furthered student and clinician careers and, recently, resulted in technology licenses and start-up ventures. This paper presents our best-practice design methods, exemplary case studies and outcomes. Course website: http://web.mit.edu/2.75/

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[1] CIMIT was founded in 1998 as a Boston-based, non-profit consortium of teaching hospitals, laboratories and engineering schools: www.cimit.org.

II. The Project Process

A. Project Selection & Team Formation

The first key to successful outcomes is the recruitment of enthusiastic clinicians and appropriate project selection. Each spring a call for proposals is distributed to the Boston-area medical community. Only two pages are requested, covering the clinical challenge, its significance, current practices, background references, desired solution functional requirements and disclosure of any previous work. Selection is competitive and good proposals define the challenge, but are sufficiently open, without hardened, pre-conceived solutions, such that students start with a clean slate. Projects must require the development of new mechanical and mechatronic hardware and fit reasonably within the constraints of one semester, a workbench and $4,000 budget. Students are offered a diversity of projects, commensurate with their broad interests and skills.

Finalist clinicians pitch their proposals to the 50 student class and the ultimate selection is made by the students, who self-form into teams of 3-5 people. This size facilitates efficient interaction and work distribution. Students' lack of clinical background, rather than being a hindrance, leaves them open to ingenious solutions which often represent translation from outside engineering experience. Clinicians are expected to be active collaborators, rather than clients, with responsibilities including biweekly team meetings, participating in brainstorming and providing access to hospitals to view procedures and laboratories for testing.

B. Design Process

The second key is a structured, managed process that is driven by clinicians' needs, rather than technology. The course follows a deterministic design philosophy [1] that evolved from the scientific method and industry practices and has been optimized to maximize ideation, minimize complexity and cost, and place prototype devices into clinicians' hands rapidly. The fourteen week process moves from coarse to fine in three phases, shown in Fig. 1. The goal is demonstration of base function, not a beautiful,

ergonomic device; form and finish can be improved in a follow-on product development class.

Course instructors serve as project managers and mentors, meeting with each team weekly to review progress, brainstorm solutions to current challenges, suggest resources and, if needed, assign action to individual team members. Good documentation is emphasized and all important drawings, calculations and findings are recorded in bound lab notebooks, which preserve IP. A secure wiki serves as a design history file and facilitates team communication as well as archiving. Teams upload scanned sketches, working papers, testing notes, presentations, videos and CAD models.

Discovery		Design Engineering		Building & Testing	
1	Opening	6	Select *Strategy* Identify FRs	10	Fabricate MCM Demonstrate MCM
2	Clinician presentations Form teams	7	*Brainstorm 3 Concepts* Bench-level prototype Present 3 *Concepts*	11	Fab. other modules Present final design
3	Investigate problem Review prior art Mission statement	8	Select *Concept* Begin solid model	12	Complete fabrication Integrate modules
4	Brainstorm *Strategies* Bench-level experiment	9	Modularize design Engineer *most critical module* (MCM)	13	Complete prototype Test! Debug. Test!
5	Present 3 *Strategies*			14	Present Prototype Document

Fig. 1. Three stage prototype design process and 14 weeks of sub steps.

Beginning with *Discovery*, the first step is to develop a deep understanding of current clinical practice not just as presented by the clinician, but from direct observation. By analyzing a procedure step by step, project scope is narrowed to only those tasks identified as hindering procedural efficiency. Reviewing prior art encompasses identifying existing devices, finding pertinent patents and reading clinical literature. This culminates in crafting a pithy, precisely focused mission statement.

Next teams, including the clinician, brainstorm possible solution strategies. These are intended to be broad approaches, rather than specific mechanisms, e.g. rough sketches are preferred over detailed CAD models, so as to avoid premature design "lock down." Literature reviews, analysis and bench-level experiments are conducted to evaluate the basic physics behind each strategy. Students may build small mockups, manipulate animal tissue samples, modify (break) existing tools (pilfered by clinicians). Eventually, the preferred strategy is selected.

The *Design Engineering* phase begins with identification of the most critical functional requirements. Various concept mechanisms and circuits are generated, in-house prototyped and bench-level tested. That concept which exhibits the most reasonable functionality/complexity ratio is selected. Specifications, including torques, ranges of motion, power requirements, sensor resolution, etc. are then explicitly stated. Recognizing that resources are limited, the design is modularized and effort first focused on the most critical module (MCM) that encompasses the core functionality.

In the final *Building & Testing* phase, CAD models are completed, drawings made and parts fabricated. Teams are encouraged to use their $4000 budget to outsource fabrication as needed; learning when and how to work with vendors is valuable. Instructors maintain a wealth of friendly contacts for supplies, fabrication and technical assistance.

Once the MCM is demonstrated, supporting modules are engineered and fabricated and the entire device is assembled. Testing occurs in a myriad of locations: in a wet lab with animal tissue, in a clinical setting and even at home in bed, in the case of the sleep sensing project.

The final deliverables include a working prototype, which is demonstrated to an invitation-only academic, clinical and industry audience, a crisp journal quality paper, a one-page prospectus and, often, demonstration videos. The availability of professional documentation, as opposed to a rambling "final report," has proven essential to project continuation, review by MIT's and hospitals' technology licensing offices and contacting potential corporate licensees and sponsors.

A. *Curriculum*

The third key is a supportive curriculum, with clear educational goals. Formal lectures, which are held for only the first two thirds of the semester, teach fundamental mechanical and electrical engineering design principles and supporting guest presentations cover literature and IP searching, teamwork, real product case studies and clinical topics. Supplementary tours to medical device industry facilities, such as Ximedica in Providence, RI, are also organized. The educational goals include learning a design process, multidisciplinary teamwork, hands-on prototyping, project management and effective communication of technical material. The grading metric encompasses mastery of the lecture material, following the process to a functional prototype and individuals' performance, as observed during weekly meetings and validated by formal, confidential team peer reviews. This is a realistic research experience, and while final designs often demonstrate the impracticality of a chosen solution path, the learning goals are still met.

III. Case Studies

A. *ACL Repair Gun*

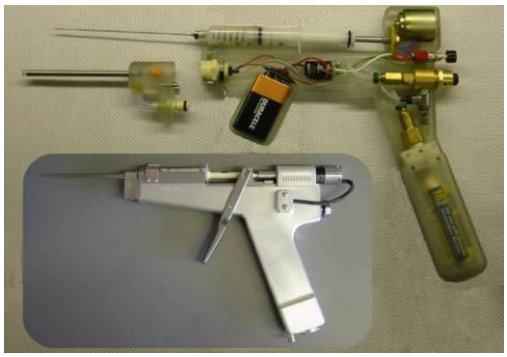

Fig. 2. Student prototype with inset showing second generation prototype.

One of the earliest successful projects was a gun to help repair torn anterior cruciate ligaments (ACL), a condition that affects over 450K Americans per year. The ACL's location in the center of the knee joint and bathed in synovial fluid prevents normal clotting and healing, thus grafts have not proven long term stability. In 2004, Dr. Martha Murray of Children's Hospital Boston explained how she had

developed a gel containing platelets and collagen, which could serve as a scaffold to enable healing, but needed a tool to warm, mix and deliver the gel during arthroscopic ACL repair surgery. By the end of the fall semester she and her graduate student team had developed a "gel gun," employing a heater and a collapsible augur, which served double duty as mixer and plunger, and a nozzle to deliver both a drying CO2 blast and then a precisely metered amount of gel, all through a 1 cm incision. Quoting Dr. Murray: "The engineers helped us a great deal. They are working on a crucial component of the project, and they are enthusiastic, dedicated and smart. We've really benefited from CIMIT helping us access some terrific engineering talent."

Post course, while none of the students were able continue with the project, Dr. Murray obtained a $100K CIMIT Proof of Principle Grant and engaged a professional design firm to harden the prototype. Both are shown in Fig. 2, where all the original design elements are retained in the "professional" prototype. The gel, along with as third generation device is currently undergoing testing with support from a NIH RO1. Preliminary results indicate significantly stronger ACL repairs [2, 3]. Dr. Murray is now scientific co-founder of Connective Orthopaedics, a venture backed startup.

B. Thoracoscopic Screwdriver

Developing this now licensed technology began in 2009, when Dr. Suresh Agarwal of Boston University Medical Center presented the challenge of stabilizing compound rib fractures. Causing flail chest and compromising breathing, the typical treatment is positive ventilation until healing occurs naturally, however this leads to long recovery times and complications. The alternative is an open thoracotomy, which cuts musculature, to place titanium osteosynthetic plates on the outsides of ribs. The team's mission was "To design a tool or method for minimally invasive video assisted thoracoscopic rib fracture stabilization," so that ribs could be fixed minimally invasively from the inside.

Three main repair strategies were considered: custom, absorbable implants adhered to the rib, modular implants fitting around the rib and a minimally invasive method of installing the same plates currently used in open surgery, seen in Fig. 3 (A). The first two strategies required significant technology development, while the third effectively narrowed the project scope to the design of a single surgical tool – a laparoscopic screwdriver. Key functional requirements included fitting through a 12 mm trocar and articulating by 60° to access fracture sites, as shown in (A). Additionally, the tool needed to positively engage the 2 mm, self-drilling bone screws until placed, deliver sufficient torque and be operable with one hand.

The process accelerated as the team bench-level prototyped and tested mechanical concepts for the critical rotation and angulation functions. A universal joint failed to provide smooth rotation, adequate compactness or a sufficient angular range of motion and the flexible shaft (B) proved more promising, but required a relatively large bend radius. The team also worked to identify a compact angulation method, considering cable drives, push rods and linkages. Then, realizing that a flexible shaft could support both torque and tension, a novel solution emerged!

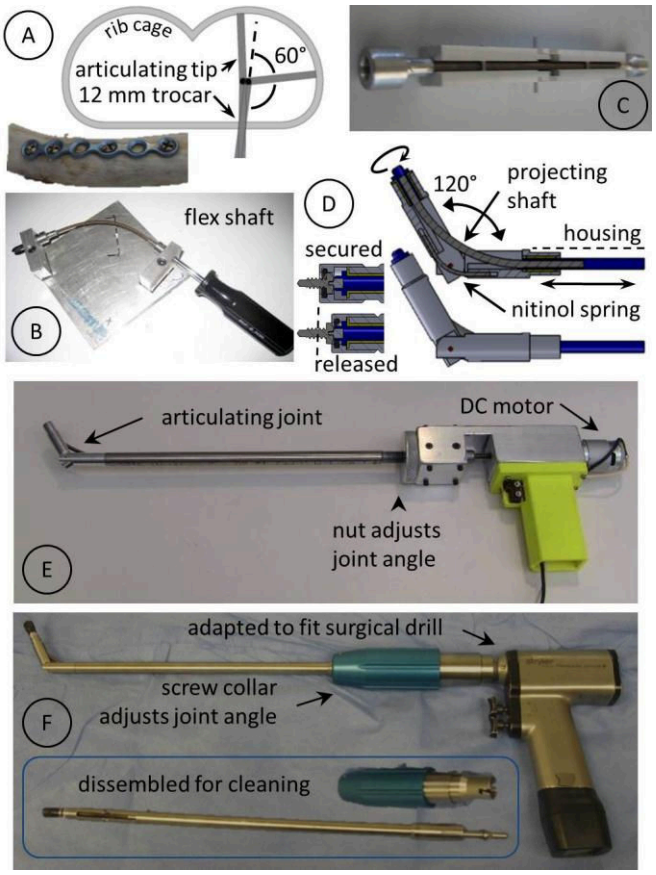

Fig. 3. Thoracoscopic screwdriver design from need to final prototype.

As seen in (C) and (D), the flexible shaft passes through the joint, which is hinged off-center. Pulling on the shaft causes the joint to bend, while a nitinol beam spring provides the return force. By slotting the joint, the flexible shaft is free able to project outwards and maintain its necessary minimum bend radius. This mechanism was first bench level prototyped (C), validated and then the diameter was reduced, bushings and a pocket for the nitinol spring added and tolerances specified. By week ten this shaft and joint MCM was complete. The next module comprised a screwdriver tip and a retaining collar that pops back only once the screw is seated in bone against the plate. Finally, the handle/drive module was constructed, containing a gear motor, a forward and reverse trigger and a nut, which pulls on the housing to actuate the joint.

The entire prototype was completed by week twelve and tested in a surgical simulator. The final paper won a presentation award at the 2010 Design of Medical Devices Conf. (DMD) [4]. Development continued into the spring semester course, culminating in the polished prototype, shown in (E). This was published in the ASME J. Medical Device Design [5], underwent porcine testing and was presented at the 2010 New England Surgical Society Annual

Meeting [6]. Subsequently, the team formed a startup company, acquired the technology and in late 2012 signed a licensing agreement, details of which are not yet public.

C. *Sleep Sensing Shirt*

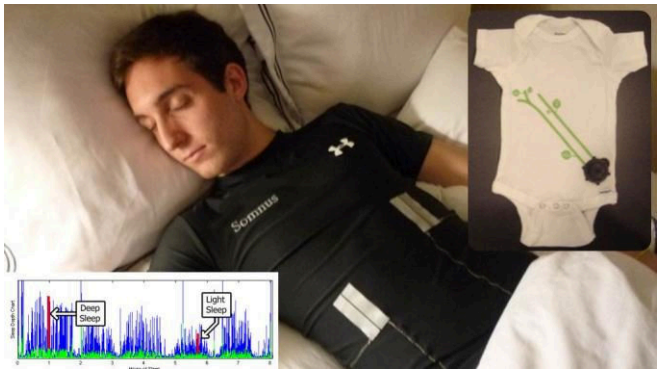

Fig. 4 - Rest Devices Inc. co-founder Pablo demonstrating the sleep sending shirt, insets showing raw data and the latest infant monitoring model.

This case study presents a technology that in just one year launched an angel-funded startup and in two began clinical trials. In September 2010 Dr. Matt Bianchi, a Massachusetts General Hospital (MGH) neurologist, explained that 1 in 3 American reported sleeping problems, yet diagnosing them relies on in-hospital sleep labs that are inconvenient, uncomfortable, with sensors stuck all over a patient and, at $2,000 each, too expensive. Would it be possible to create an at-home sleep monitor that would produce clinically significant data?

Three undergraduate roommates, who had vowed to select the "best" project and launch a company, signed on to the project. Studying current practice they realized that most primary care physicians receiving sleep study data relied on an aggregate "sleep score" to diagnose and refer; maybe a single sensor could provide data that would serve the vast majority of cases. After exploring a myriad of modalities, they hit upon the idea of a shirt with non-contact, co-planer, capacitive plates that would measure the fabric's stretch as the patient breathed. Machine sewing wire and bonding metal foil failed; the end design comprised silk screened metallic pads and traces, protected by iron-on vinyl appliqués. Circuits were first bread boarded and then ordered from a vendor. The final device features a tiny, snap on, micro-USB equipped data logger. As important as the patented hardware design, was a custom algorithm capable of processing a night's worth of data into sleep stages and equivalent diagnostic scores, in under 30 seconds. These results also won a presentation award at the 2011 DMD [7]. By July 2011 funding was secured and the sewing machine, silk-screening frame and heat press transferred from MIT to Rest Devices' Boston office.

From Dr. Bianchi, now promoted to director of the MGH Sleep Lab: "The course was an ideal setting to match clinical need with engineering solutions, and the resulting product has not only fueled my research productivity and career advancement, but also holds great potential for advancing patient care." Currently, the product is being sold to sleep labs for research purposes and a consumer baby monitor is under development. The work was presented in 2012 at the Associated Professional Sleep Societies Conference and the Military Health System Research Symposium.

IV. Outcomes & Conclusion

This course demonstrates a method that facilitates rapid, fail-fast and lean development and evaluation of potential new medical technologies. This is especially significant as US healthcare expenditures, currently totaling over $2.65 trillion and comprising 17.6% of the GDP [9], continue to rise. Companies too are becoming interested in economical design as a way to access secondary, developing markets.

As seen in Fig. 5, student enrollment has increased along with project submissions and selectivity. Student evaluations rate it significantly above average and in the 1st quartile. Over two dozen papers have been published and aided students', clinicians' and instructors' careers and currently half a dozen patents are pending. Alumni data also shows students consistently landing jobs in the medical device design industry. Significant work remains, however, to improve project continuation and commercialization.

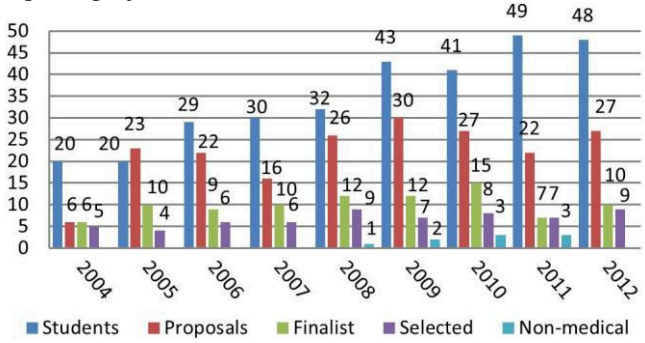

Fig. 5. Student enrollment and project statistics 2004 – 2012. The model has also been applied to select non-medical projects.

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