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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 develop and 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.

INDEX TERMS Biomedical engineering education, medical devices, mechanical design, mechatronics.

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 course with the hypothesis that education and translational research can (and should) be merged. In just one semester, teams comprising clinician-investigators, seniors and graduate students follow an industry-modeled design process, culminating in a working proof-of-concept prototype and quality documentation. Growing out of Mechanical Engineering's *Precision Machine Design* (2.75), in fall 2013 the course will be cross-listed with Electrical Engineering and officially called *Medical Device Design*. Similar successful programs exist at Stanford, University of Minnesota and Johns Hopkins.

The results of this translational 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.

The course is supported by CIMIT, via a US Army Medical Research Agreement, which covers the fabrication of prototypes, MIT, which provides teaching staff and facilities, and corporate sponsors, who make unrestricted donations towards engineering education.

Course website: web.mit.edu/2.75/

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

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

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 open-ended, without hardened, pre-conceived solutions, so 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 an average $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 often unexpected solutions, which represent translation from outside engineering experience. Furthermore, permitting students to self-select projects and teams promotes passion and a sense of ownership, a powerful catalyst. This self-section has been found to be far more effective than assigning teams in order to balance out skill sets or personalities.

Clinicians are expected to be active collaborators, rather than clients, with responsibilities including team meetings every second week, giving students a direct phone number, participating in brainstorming and providing access to clinical facilities to view procedures, source equipment and conduct testing. By clearly stating clinicians' responsibilities as team members, those who are most likely to enjoy working with student teams also self-select.

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 14-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 course.

Course instructors, all of whom have hands-on building experience, 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. The importance of peer design reviews, outside of mentor meetings, is emphasized. Throughout, a dedicated communications instructor helps the course fulfill undergraduates' general requirements and hones all students' professional presentation, writing and team collaboration skills.

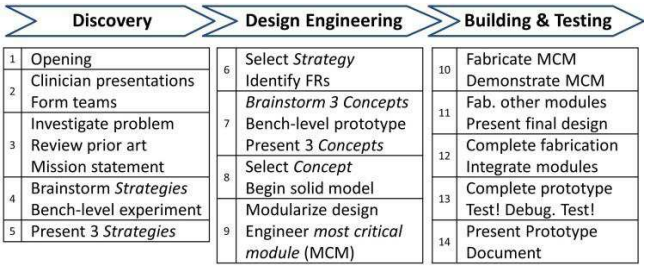

FIGURE 1. Three stage prototype design process and 14 weeks of sub steps.

Beginning with *Discovery*, the first step is to develop a deep understanding of current clinical practice not just as presented by the clinician, but also 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 and modify (break) existing tools, which clinicians are sometimes able to source for their team. Eventually, the most rational strategy is selected.

The *Design Engineering* phase begins with identification of the most critical functional requirements. Various concept mechanisms and circuits are generated, prototyped in-house and bench-level tested. The concept that exhibits the most reasonable functionality/complexity ratio is selected, i.e. that which addressed the critical functional requirements with a well-defined mechanism or circuit of known technology. The goal is not to develop new science, but rather to apply technology, often from fields outside medicine, effectively, with Occam's razor emphasized as an important tool in avoiding feature creep. Specifications, including torques, ranges of motion, power requirements, sensor resolution, etc. are then explicitly stated. The design is separated into modules, ordered by criticality, as a means to address risk and conserve resources. The first to be focused on is the most critical module (MCM) that encompasses the device's core functionality.

In the final *Building & Testing* phase, CAD models are completed, drawings made and parts fabricated. Teams are

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encouraged to use their $4000 budget[2] to outsource fabrication as needed; learning when and how to work with vendors is valuable. Instructors share their ''friendly'' contacts and encourage students to begin cultivating their own networks 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.

C. 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 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 with formal, confidential team 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.

Team reviews are administered using the CATME (Comprehensive Assessment of Team Member Effectiveness) online tool, www.catme.org, which has been found effective in comparing students' perceptions of their own performance and that of their peers and identifying common team failure conditions. This tool is deployed twice each semester, first as a way for students to identify and (hopefully) correct team dynamics issues, and then after completion of the projects as a grade component.

III. CASE STUDIES

A. ACL REPAIR GUN

One of the earliest successful projects was a gun to help repair torn anterior cruciate ligaments (ACL), a condition that affects over 450,000 Americans per year. The ACL is located in the center of the knee joint and bathed in synovial fluid, which 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 CO_2 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.''

FIGURE 2. Student prototype ACL Repair Gun with inset showing second generation prototype.

Post course, while none of the students were able to 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 second prototype. The gel, along with a 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

Development of 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

[2] Some teams need more, some less. All major purchases need to be justified, and no team is allowed to ''burn'' a potential surplus.

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.

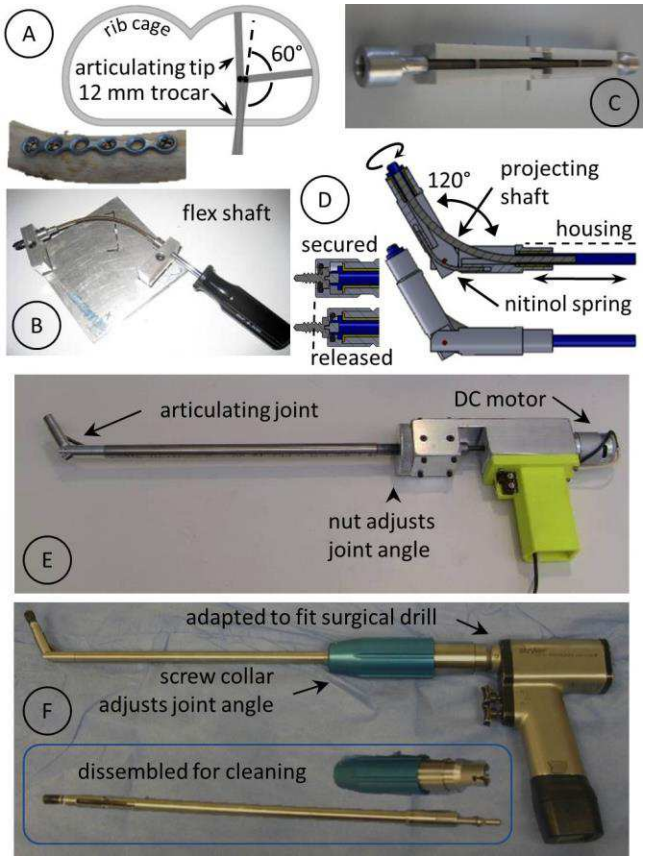

FIGURE 3. Thoracoscopic screwdriver design from need to final prototype.

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!

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 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 (DMD) Conference [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 public.

C. SLEEP SENSING SHIRT

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 Americans 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?

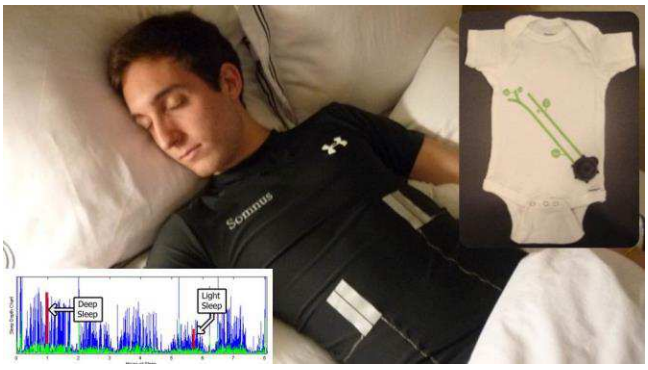

FIGURE 4. Rest Devices Inc. co-founder Pablo Bello demonstrating the sleep sensing shirt. Insets show raw data and the latest infant monitoring model.

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-planar, capacitive plates that would measure the fabric's stretch as the patient breathed, shown in Fig. 4. 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. Company site: www.restdevices.com.

IV. OUTCOMES & FUTURE WORK

This course demonstrates a method that facilitates rapid, fail-fast, lean development and evaluation of potential new medical technologies. This is especially significant as US healthcare expenditures for 2011 totaled $2.7 trillion, comprised 17.9% of the GDP and continue to rise [8]. Companies too are becoming interested in economical designs as a way to access secondary, developing markets.

As seen in Fig. 5, since 2004 student enrollment has more than doubled, from 20 to 48 students, and submitted projects more than quadrupled from 6 to 27. Team size has been maintained at 3 – 5 students and, therefore, project selection has steadily become more competitive; in 2012 of the 27 eligible projects received, only 10 were presented to the students who selected 9.

Reviewing students' teaching evaluations', ''overall rating of the subject'' from 2006 – 2011 evidenced an upward trend, which moved the course from an ''average'' rating to within the first quartile of courses in the mechanical engineering department. Write-in comments are carefully reviewed for feedback and are a great source of encouragement, for example: ''Probably the most rich and useful class I've taken. I finally confidently feel that I can design a product as an engineer.'' ''Most valuable: Using the tools of fundamental

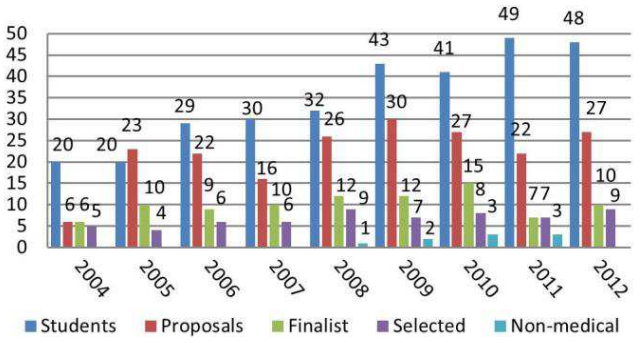

FIGURE 5. Student enrollment and project statistics 2004 – 2012. The model has also been applied to select non-medical projects.

principles to inspire ideas for design, and then experiments and analysis to make sure that things will work before you build them.'' ''Most valuable is going through the coarse to fine process, with my team, and communicating our ideas with the clinicians effectively.''

Negative feedback is also reviewed and, given the course's open-ended projects and focus on final deliverables, providing quantitative feedback throughout the semester to students, as opposed to qualitative during design reviews, is a problem. Two in-class tests were added in 2012, but they overloaded students. Short 1 – 2 hour design case homework assignments and lightning 5 minute quizzes look more promising. Workload, particularly at the end of the semester, is also a concern, and students may need more assistance with project management skills. Reviews from 2012 also indicate challenges with incorporating electrical engineering material into the curriculum so that it is meaningful to mechanical engineering students.

At least half of enrolled students now indicate that they selected the course, not only for the design experience, but to discover whether they wish to work in the medical device design field. Direct feedback from graduated students, and limited alumni database data, indicates success in placing students into medical device industry jobs.

Over two dozen papers have been published and aided students', clinicians' and instructors' careers and currently half a dozen patents are pending. Each project is now evaluated at the end of the fall term for IP, potential for publication and continuation. The number of conference and journal publications has increased and for the last 4 years student teams have presented their work at the DMD Conference in Minneapolis each April, with some teams receiving ''pitch'' awards. Further information on past projects is provided on the course website.

In summary, the key elements of the course are: A careful selection of diverse, clinician-driven projects that can be addressed in a single semester by a motivated team for students to choose from, close clinical collaboration, detailed procedural understating and precise functional requirements definition, a structured coarse to fine design process that minimizes complexity, but still explores a range of solutions, emphasis on analysis and testing, course instructors with

hands-on fabrication experience, a network of friendly vendors, a real-world team experience and an emphasis on peer review and effective communications.

Significant work remains, however, to improve project continuation and commercialization. Currently, students' schedules and requirements do not permit making this a full-year course and, therefore, promising projects and skilled students do not necessarily proceed into the follow-on course. Stalled projects are a source of continual angst, though some can be continued as senior theses and graduate work. Another, well known, disconnect is that between the Academy and industry; rarely are proof-of-concept prototypes and associated IP sufficient for cold-calling companies. Therefore, the team is actively seeking relationships and direct contacts within medical device companies' R&D divisions; these are invited to the final presentations. The goal is to raise additional funding, provide student recruitment opportunities and garner support for specific projects. Ideally, it is hypothesized that companies will be willing to support more early-stage projects if given the opportunity to guide them towards commercially viable design. Companies are also welcome to propose design projects where they see value in a fresh perspective. There are also plans to increase involvement of the Sloan School of Management and Martin Trust Center for MIT Entrepreneurship. Overall, the goal is to build a support ecosystem for translational medical device design research, local clinicians and our students.

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