CONNECTING THE DOTS WITH CDIO: A MULTIDISCIPLINARY INTRODUCTION TO BIOMEDICAL DESIGN ENGINEERING

Sumitra Rajagopalan
Department of Mechanical Engineering, McGill University, Montreal
Quebec, Canada

Abstract
This paper presents a new integrated approach to teaching biomedical design engineering introduced at McGill University, Canada in 2004. While this course was designed with no prior knowledge of the CDIO initiative, it shares many of its same standards and practices. CDIO standards lend themselves well to the teaching of multidisciplinary curricula such as biomedical engineering, for its emphasis on integrated learning, life-cycle design, systems engineering, communications and teamwork. This new holistic approach to teaching engineering as enshrined in CDIO could also serve as a framework for other emerging engineering disciplines.

Keywords: biomedical engineering, clinical needs, multidisciplinary design, clinical readiness, life-cycle engineering, , communications, teamwork, regulatory issues.

Introduction
Over the years, Biomedical Engineering has emerged as the "melting point" of the engineering disciplines drawing practitioners from a range of fields including physics, mechanical engineering, chemistry, computer science, electrical engineering, physiology, among many others. This unique convergence of otherwise disparate disciplines creates tremendous opportunities for ground-breaking innovation, while also posing formidable challenges in course design and instruction.

An informal survey of existing programs in Canadian and U.S universities suggests that biomedical engineering programs are more prevalent at the graduate level. These programs offer graduate-level courses that generally follow the seminar format whereby different professors are invited to give single lectures on their subject of expertise, with students left to connect the dots on their own. Moreover, there are few, if any, courses that offer a comprehensive introduction to

the field of biomedical engineering design. The multidisciplinary nature of the field, as well as the diversity of incoming students, calls for a comprehensive introduction – one that would weave together all the different sub-disciplines and aspects into a cohesive whole.

In response to this need, the department of mechanical engineering at McGill University offered an introduction to biomedical device design. This course piloted in 2004 (1), is in its third year running and has underpinnings strikingly similar to the CDIO approach and philosophy (2).

The ensuing sections describe the course in detail as well as its relevance to the CDIO framework.

Course Outline and Structure

The course consists of weekly 3-hour sessions, taught over 13 weeks is detailed below:

a) Engineering Physiology: Given the varying backgrounds of the participants, this section offers a brief introduction to the field by describing the human body from an engineering perspective. In this section, the students are exposed to basic notions of structural biological materials, biomechanics and electrophysiology.

b) Defining Clinical Needs: Medical devices and implants should be designed only in response to a clear clinical need. To that end**,** the section offers a clear roadmap to teaming up and communicating with a surgeon so as to identify the clinical problem and formulate a possible technical solution. This collaboration takes the form of a questionnaire and an interview and covers the entire life cycle of product development from design to surgical implantation to monitoring. In doing so, the biomedical engineer and surgeon identify not only the structural and functional attributes of the device but also surgical limitations and performance post-implantation. The objective of this section is also to bridge the "cultural divide" between engineers and clinicians and facilitate effective teamwork.

c) Formulating Design Requirements & Assembling the Team: Once the clinical needs are ascertained, we moved on to documenting the design requirements for the device using a specifications template specially formulated for the course. Thereafter, the right team is put together among students: material scientists, chemists, mechanical engineers, electrical engineers etc. The emphasis of teamwork and communications are once again emphasized and mock exercises are carried out.

d) Medical Device Design: Once the basic principles, clinical needs and design requirements are clearly formulated, we move on to the design phase. A more systematic design process – choice of material, use of actuators, mechanical design, interface engineering, biomedical characterization, are all elaborated. Specific examples include orthopedic, cardiovascular, neural and urological implants. To evaluate the design to the requirements, we formulated a benchmarking tool called the Clinical Readiness Levels akin to the Technology Readiness Level created by NASA to assess the spaceflight readiness of various hardware and software. Accordingly then CRL consists of a scale from 1 to 10, with 1 denoting a successful proof of concept and 10 denoting an implant or device ready for clinical trials.

e) Clinical Trials and Regulatory Issues: This section deals with the Implementation and Operation segment of the course and details the procedures required to design a clinical trial as well as an overview of the regulatory environments in Canada, the U.S.A and Europe.

Relevance to CDIO

As mentioned earlier, the course was conceived in 2004 with no prior knowledge of the CDIO initiative, but in hindsight, shares many of the principles of CDIO. CDIO as a framework lends itself well to the delivery and teaching of such cross-disciplinary disciplines such as biomedical engineering. From the course description above, it can be seen that the course covers CONCEIVE (b-c), DESIGN (d), IMPLEMENT & OPERATE (e), and as such embraces the spirit of the CDIO approach. Some of the other CDIO-equivalent features of the course include:

A "Cradle-to-Grave" Systems Approach to Design: In designing medical devices, particular attention is paid to biocompatibility and device performance post-implantation. Rigorous testing

as well as the use of Clinical Readiness Levels as a benchmark to assess and reasonably predict device performance over its entire lifespan, is another hallmark of this approach.

Communications and Teamwork: According to the CDIO standards, engineering education should include teamwork and communications. Given the fact that medical device design is a multidisciplinary team effort with a surgeon as the end user, effective communications and teamwork with clinicians become paramount and as such is emphasized throughout the course, with questionnaires and formal interviews used as tools to define clinical needs and design requirements.

Integrating Learning: Integrated Learning is at the heart of biomedical design engineering and is emphasized throughout the course. In particular, this course has an introductory section entitled "Engineering Physiology" which studies the human body from an engineering perspective. Unlike the descriptive content found in traditional biology and biochemistry courses, engineering physiology allows the student to perceive the human body as a "living machine" thus making it easier for him/her to provide engineering solutions to biomedical problems.

IV. Coursework and Evaluation

Active Learning and Design-based exercises, both CDIO standards, were integral to the coursework and student evaluation in this course. The evaluation was carried out as follows:

(a) ***Common case study and design (35%):*** As a first exercise, after having covered the basics of orthopedic biomechanics, the students were presented a case study relating to a patient suffering from osteoarthritis and were asked to design a composite bone-cartilage implant. This design exercise required defining requirements and constraints over the entire life-cycle of the implant including often-overlooked aspects such as the method of sterilization, minimizing surgical intervention and implant monitoring. Using the Clinical Readiness Levels as a benchmarking tool, the design was constantly evaluated by the design team in consultation with an orthopaedic surgeon.

(b) Individual case study and design (45%): Following the common case study on the osteochondral implant, students were required to conceive and design a medical implant based on a clinical need either formulated by a surgeon or a review of the medical literature. Thereafter, a surgeon is assigned to the team and the design exercise is carried out as in (a) .

(c) ***Device Evaluation and Re-engineering (20%):*** There have been many high-profile cases of medical device recall over the years and this exercise asks students to evaluate an implant currently in clinical practice, such as a hip implant or a drug-eluting stent. They are required to critique the design and performance vis-à-vis the stated clinical need. Thereafter, the team is asked to consider design improvements and modifications to the device to improve their clinical performance.

In all the above cases, two surgeons, were assigned as resource people for the course and were available for consulations and course evaluations.

Summary and Conclusion

This paper presents a brief overview of a new introductory course in biomedical design engineering piloted a McGill University, Canada. While this course was designed with no prior knowledge of the CDIO initiative, it shares many of its same standards and practices. CDIO standards lend themselves well to the teaching of multidisciplinary curricula such as biomedical engineering, for its emphasis on integrated learning, life-cycle design, systems engineering, communications and teamwork. This new holistic approach to teaching engineering as enshrined in CDIO could also serve as a framework for other emerging disciplines such as environmental engineering, nano-engineering, among others.

Student feedback and course revisions are ongoing and will be discussed in greater detail at the next CDIO meeting.

References

[1] The CDIO Standards", http://www.cdio.org/tools/cdio_standards.html

[2] Rajagopalan, Sumitra MECH 501, "Design of Biomedical Implants and Devices: Lecture Notes", Department of Mechanical Engineering, McGill University, 2004.

Biographical Information

Sumitra Rajagopalan is an Adjunct Professor of biomechanical engineering at McGill University . Her research interests include smart materials, artificial muscles, neural electrodes, biosensors and active cardiovascular and urological devices. Her teaching interests include multidisciplinary engineering education, design engineering, sustainable design and K-12 pre-engineering education. She is the founder of Bioastra Technologies, a start-up in Montreal dedicated to developing medical devices based on smart materials. She also runs ASTRA education – a learning centre on science and pre-engineering education for high-school students.

Sumitra Rajagopalan
Telephone Number: 514-434-1233
Department of Mechanical Engineering,
McGill University,
817 Sherbrooke St. West
Montreal, Quebec H3A 2K6
CANADA
sumitra.rajagopalan@bioastratechnologies.com