CDIO Experiences in Biomedical Engineering: Preparing Spanish Students for the Future of Medicine and Medical Device Technology

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ABSTRACT

Biomedical engineering is one of the more recent fields of engineering, aimed at the application of engineering principles, methods and design concepts to medicine and biology for healthcare purposes, mainly as a support for preventive, diagnostic or therapeutic tasks. Biomedical engineering professionals are expected to achieve, during their studies and professional practice, considerable knowledge of both health sciences and engineering. Studying biomedical engineering programmes, or combining pre-graduate studies in life sciences with graduate studies in engineering, or vice versa, are typical options for becoming qualified biomedical engineering professionals, although there are additional interesting alternatives, to be discussed.

According to our experience, the graduates and post-graduates from multidisciplinary engineering programmes, not just from biomedical engineering, but also from more traditional fields including industrial, mechanical and telecommunications engineering, can play varied and very relevant roles in the biomedical industry and in extremely complex biomedical device development projects. In spite of the different ways of becoming a professional of the biomedical engineering field, it is true that their impact as successful professionals can be importantly increased, by means of an adequate integration into their curricula of fundamental biomedical engineering design concepts, methodologies and good practices, applied to the development of biomedical devices.

In this study we present the complete development and comparative study of three courses, belonging to different plans of study taught at the Technical University of Madrid and benefiting from using a CDIO approach focused on the development of biomedical devices. The three courses are “Development of Medical Devices”, “Bioengineering Design” and “Biomedical Engineering”, respectively belonging to the “Bachelor’s Degree in Biomedical Engineering”, to the “Master’s Degree in Industrial Engineering” and to the “Master’s Degree in Mechanical Engineering”. During the courses, groups of students live through the development process of different biomedical devices aimed at providing answers to relevant social needs. Depending on their background and European credits assigned to the different courses, students carry out more conceptual projects or are able to live through more complete CDIO experiences. Main benefits, lessons learned and future challenges, linked to these courses, are analyzed, taking account of the results from 2014-2015 academic year.

KEYWORDS:

CDIO as Context, Integrated Learning Experiences, Active Learning, Biomedical Engineering, Biomedical Engineering Design. (Standards: 1, 3, 5, 7, 8).

INTRODUCTION

Biomedical engineering a quite recent engineering field, as the first Biomedical Engineering programmes appeared at US universities in the late 1950s, with Drexel University, the Johns Hopkins University, the University of Pennsylvania and the University of Rochester as pioneers. In the late 1960s and 1970s other relevant universities followed them, including: Boston University, Carnegie Mellon, Harvard and MIT, Ohio State University, the University of Illinois, among other interesting examples (Fagette, 1999). Biomedical Engineering is aimed at the application of engineering principles, methods and design concepts to medicine and biology for healthcare purposes, mainly as a support for preventive, diagnostic or therapeutic tasks. Biomedical Engineering professionals are expected to achieve, during their studies and professional practice, considerable knowledge of both health sciences and engineering. Studying Biomedical Engineering programmes or combining pre-graduate studies in life sciences with graduate studies in engineering, or vice versa, are typical options for becoming qualified biomedical engineering professionals, although there are additional interesting alternatives, to be discussed. According to our experience, graduates and post-graduates from more traditional and multidisciplinary engineering programmes, especially industrial engineering, can play varied and very relevant roles in the biomedical industry and in extremely complex biomedical device development projects, even outperforming the graduates from programmes mainly focused in bioengineering. However, such impact of industrial engineers in the biomedical field can be importantly increased, by means of an adequate integration of biomedical engineering design concepts, methodologies and good practices into the traditional engineering curricula.

In fact, according to the Biomedical Engineering Society, a biomedical engineer uses traditional engineering expertise to analyze and solve problems in Biology and Medicine, providing an overall enhancement of healthcare. Students choose the Biomedical Engineering field to be of service to people, to partake of the excitement of working with living systems and to apply advanced technology to the complex problems of medical care. The biomedical engineer works with other healthcare professionals including physicians, nurses, therapists and technician. Biomedical Engineers may be called upon in a wide range of capacities: to design instruments, devices and software, to bring together knowledge from many technical sources, to develop new procedures, or to conduct research needed to solve clinical problems (BMES). The aforementioned duties are directly connected to the traditional corpus of Industrial Engineering (in its broadest sense) and, being applied tasks in direct relation with real and complex problems (pathologies) and systems (human body), can potentially be taught and promoted by means of project-based learning CDIO-related approaches (Crawley, 2007), both within Biomedical Engineering programmes, and in more traditional ones.

In this study we present the complete development and comparative study of three courses, belonging to different plans of study taught at the Technical University of Madrid and benefiting from using a CDIO approach focused on the development of biomedical devices. The three courses are “Development of Medical Devices”, “Bioengineering Design” and “Biomedical Engineering”, respectively belonging to the “Bachelor’s Degree in Biomedical Engineering”, to the “Master’s Degree in Industrial Engineering” and to the “Master’s Degree in Mechanical Engineering”. During the courses, groups of students live through the development process of different biomedical devices aimed at providing answers to relevant social needs. Depending on their background and European credits assigned to the different courses, students carry out more conceptual projects or are able to live through more complete CDIO experiences. Main benefits, lessons learned and future challenges, linked to these courses, are analyzed, taking account of the results from 2014-2015 academic year.

PROMOTION OF CDIO EXPERIENCES LINKED TO BIOMEDICAL ENGINEERING AT TU MADRID BY MEANS OF THREE COURSES IN DIFFERENT DEGREES

The three courses are implemented for the promotion of CDIO experiences linked to Biomedical Engineering in three different plans of study at TU Madrid. In order to promote students' active learning, project based learning strategies are applied, and seminars for the promotion of professional technical and "soft" skills are included, depending on the level of the degree and on the background of students. To provide a common pedagogical background for training bioengineers, mechanical engineers and industrial engineers, capable of working on projects linked to the development of real medical devices, some essential aspects are provided in form of "fundamentals" common to the three subjects. At the same time, as some courses are more basic and some more specialized, different specialization moduli are included to adjust each course to the expected profile and desired outcomes of our students. The more relevant topics of these courses are listed below:

Common Fundamentals:

- Introduction to Biomedical Engineering and medical devices.
- Introduction to sustainability and ethical aspects in Biomedical Engineering.
- Product planning: The relevance of a medical need.
- Conceptual design and creativity promotion.
- Basic engineering I: From the concept to the design.
- Basic engineering II: From the design to the prototype.
- Basic engineering III: Testing and validation of medical devices.
- Detailed engineering: Standardization and safety issues.

Special topics for "Development of Medical Devices"
(4 credits according to ECTS, BSc in Biomedical Engineering)

- Overview on human biomechanics.
- Overview on biomaterials for biodevices.
- Basic computer-aided design seminar.
- Basic FEM-based modeling seminar.
- Cases of study: Complete development of diagnostic devices.
- Cases of study: Complete development of therapeutic devices.

Special topics for "Bioengineering"
(3 credits according to ECTS, MSc in Mechanical Engineering)

- Advanced computer-aided design seminar.
- Advanced FEM-based modeling seminar.
- Special technologies for the mass production of biodevices.
- Micro- and nano-fabrication of biomedical micro- and nano-systems.

Special topics for "Bioengineering Design"
(12 credits according to ECTS, MSc in Industrial Engineering)

- Key aspects in human biomechanics.
- Key aspects in human fluid mechanics.
- Advanced computer-aided design seminar.
- Advanced FEM-based modeling seminar.
- Special technologies for the mass production of biodevices.
- Micro- and nano-fabrication of biomedical micro- and nano-systems.
- Cases of study: Complete development of diagnostic devices.
- Cases of study: Complete development of therapeutic devices.
- Future trends I: Tissue engineering and biofabrication.
- Future trends II: From labs-on-chips to organs-on-chips.

As can be appreciated, all subjects have a similar structure, with a first block linked to engineering design fundamentals, and a second block of specific knowledge and special topics for an improved personalization of each subjects to the expected inputs and outputs. Students from the master's degrees receive more in depth sessions on modeling and simulation technologies, while those from the bachelor degree receive some introductory seminars, as these resources are new to them. In all cases, they are divided into groups (of 2 students in the cases of "Development of Medical Devices" and "Bioengineering" and of 6 students in the case of "Bioengineering Design") and each group faces the development of a medical device. We aim at complete CDIO experiences, although in some cases it is only possible to cover in depth the conceptual and design phases, due to time restrictions. However, in many cases the complete CDIO cycle can be achieved as further discussed in the results section.

In these subjects, the conceptual stages are supported by creativity-promotion tools such as TRIZ, morphological boxes and systematic procedures for promoting the generation, combination and selection of ideas. The design stages count with industrial state-of-the-art modeling and simulation software of main engineering disciplines. In addition, the subjects count with the support of the "Product Development Lab", the "Material Strength Lab", the "Fluid Mechanics Lab" and the "Biosignals Lab", where several design and simulation software, testing facilities and rapid prototyping technologies, usually by means of additive manufacturing and rapid form copying, are available. Such facilities are very relevant for letting students live trough the complete development process of a new medical device, from the conceptual and design phases, to the implementation and operation stages, which are normally more difficult to achieve (Díaz Lantada, 2013). Arduino kits and libraries of sensors and actuators are also available, as well as biomechanical models for performance evaluation.

Regarding students' assessment, it is important to note that the proposed biodevices are complex enough to promote positive interdependence between members of the teams, so that each of the members is needed for the overall success and that there is enough workload to let all students work hard and enjoy the experience, thanks to learning a lot. In addition, we are encouraging individual assessment, complementing the teamwork activities with individual deliveries and during the public presentations of their final results (which account for a 30% of the global qualification). The evaluation of professional skills counts with the help of ad hoc designed rubrics, as part of an integral framework for the promotion of engineering education beyond technical skills, consequence of recent educational innovation projects (Hernández Bayo, et al., 2014), and we are also considering the introduction of peer-evaluation techniques to some extent.

The different courses contribute to the strategy for the overall promotion of CDIO-based teaching-learning experiences and of the related application of CDIO standards, which we are trying to achieve in different degrees. Following the advice from "CDIO Standard 5: Design – Implement Experiences", we are focusing on improving the curricula with two or more design-implement experiences, including at least one at a basic level (as in the case of "Development of Medical Devices") and at least one at an advanced level (as happens with the other two courses taught at Master's level). Even though the detailed experiences correspond to different curricula, it is also true that the "Bachelor' Degree + Master's Degree" structure (which is quite new in Spain) promotes the personalization of Higher Education. Some students may even finish the BSc in Biomedical Engineering and specialize with a MSc in Mechanical or Industrial Engineering, so it is interesting to have incorporated different special topics and seminars, as a complement to common fundamentals. It is also important to note that the proposed projects help to provide, in the different courses, integrated learning experiences, according to Standard 7. Additional details are provided further on.

COMPARATIVE STUDY OF THE THREE BIOMEDICAL CDIO EXPERIENCES: MAIN RESULTS, LESSONS LEARNED, GOOD PRACTICES AND CHALLENGES

The main basic information and results obtained during academic year 2014-2015 carrying out the three biomedical CDIO experiences in the three different subjects already described are summarized below in Tables 1 and 2. Table 1 presents the more relevant figures of the three subjects and details the different projects developed and the time devoted to the different phases of the CDIO. Table 2 presents data linked to success ratios, attendance and other motivation parameters.

Table 1. Basic information about the different subjects and the CDIO experiences linked to the development of biomedical devices. Academic year 2014-2015.

Basic aspect	**"Development of Medical Devices" BSc in Biomedical Engineering**	**"Bioengineering" MSc in Mechanical Engineering**	**"Bioengineering Design" MSc in Industrial Engineering**
Level	Grade (4th Year)	Master's (1st Year)	Master's (1st Year)
Credits assigned (ECTS)	4	3	12
Hours devoted by each student (expected)	100	75	300
Number of students	14	18	28
Number of groups – projects developed	7	9	6
Number of teachers involved	2	2	6
Biomedical devices developed along the different subjects by teams of students, as their central learning experience and the main assessment tool	- App for skin diagnoses - Cell culture device with electrical stimulation - Point-of-care testing device for celiac disease - Autonomous incubator for neonatology - Urine-loss detector - Special wheel-chair - Anti-drowning bottle	- Shoulder prosthesis - Ankle prosthesis - Elbow prosthesis - Knee prosthesis (3 different projects) - Muscle controlled 3D mouse for amputees - Special bicycle for disabled people - Special driver for exoskeleton	- Intra-dermal pump for drug delivery - Extra-corporeal pump for assisted heart surgery - Eardrum protecting device with water detection system - Tissue engineering scaffold for tendon and ligament repair - Device for sleep apnea management - Instrumented artificial heart valve
The projects mainly focus on:	The conceptual stage	The design stage	Whole CDIO cycle
Time devoted to the conceive stage:	60%	30%	25%
Time devoted to the design stage:	40%	70%	25%
Time devoted to the implement stage:	non compulsory, in some cases an additional 20%	non compulsory, in some cases an additional 20%	25%
Time devoted to the operate stage:	non compulsory, in some cases an additional 10%	non compulsory, in some cases an additional 10%	25%

Table 2. Some figures related to student and teacher motivation and implication in the different subjects. Data from academic year 2014-2015.

Control aspect	**"Development of Medical Devices" BSc in Biomedical Engineering**	**"Bioengineering" MSc in Mechanical Engineering**	**"Bioengineering Design" MSc in Industrial Engineering**
Success ratio (student completion rate)	100%	100%	100%
Value of the individual component for the global assessment	10%	20%	30%
Value of the group component for the global assessment	90%	80%	70%
Student attendance to scheduled lessons	>85%	>80%	>90%
Typical number of answers to debate questions	3 – 4	2 – 3	6 – 8
Typical number of student questions / hour	2 – 3	3 – 6	4 – 7
Number of teachers inside the classroom at once	1	1	2 – 4
Frequency of meetings between the teachers of the same subject	1 / month	2 / month	4 / month
Frequency of meetings between the teachers of different departments	1 / month	-	1 / month
Number of interactions with students outside the classroom / week	2 – 3	3 – 4	8 – 10
Resources needed for practical activities	30 – 50 € / student for practical sessions Some students prototyped with their own resources	30 – 50 € / student for practical sessions Some students prototyped with their own resources	75 – 100 € / student for practical sessions 750 – 1.000 € / group for prototyping tasks
Number of professional skills promoted and assessed	4	4	9
Hours devoted by the teachers outside the classroom / class hour	1 – 2	1 – 2	3 – 4
Students living a whole CDIO cycle	33%	15%	100%
Students aiming at enterprise creation based on their results	8%	5%	20% (with one group as finales of UPM Enterprise Creation Competition)

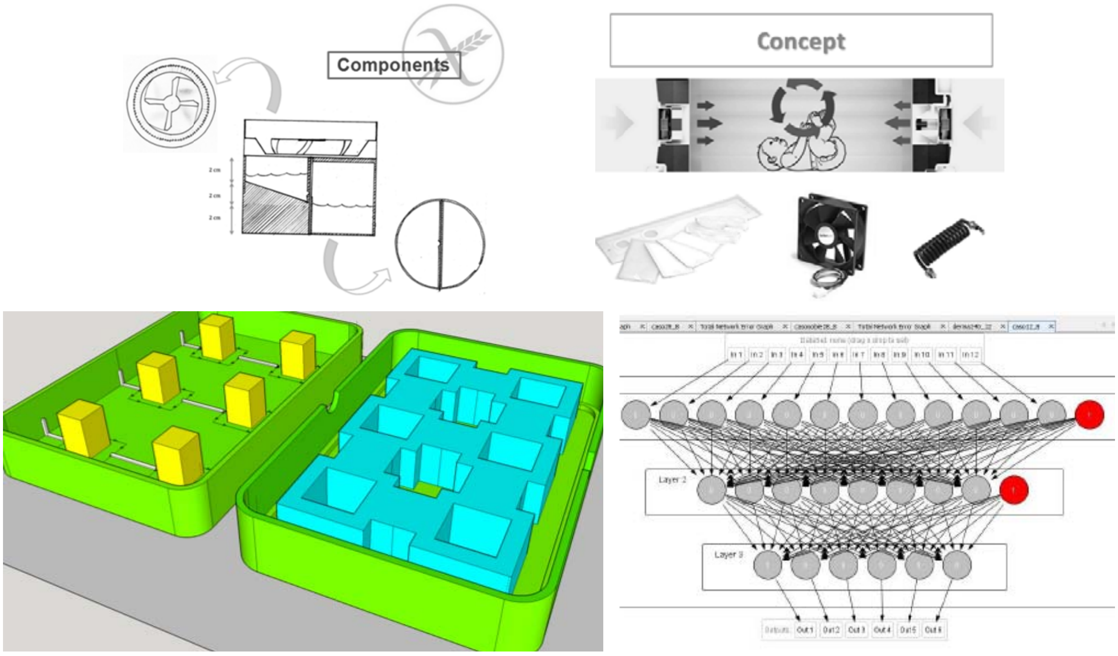

Figure 1. Examples of final results from different projects performed within the "Development of Medical Devices" course at the BSc of Biomedical Engineering. a) Point-of-care testing device for alergies. b) Autonomous incubator for neonatology. c) Cell culture device with electrical stimulation. d) App for skin diagnoses.

Figure 2. Examples of final results from different projects performed within the "Bioengineering" course at the MSc of Mechanical Engineering. a) Elbow prosthesis. b) Mouse for amputees. c-d, f) Knee prostheses. e) Ankle prosthesis.

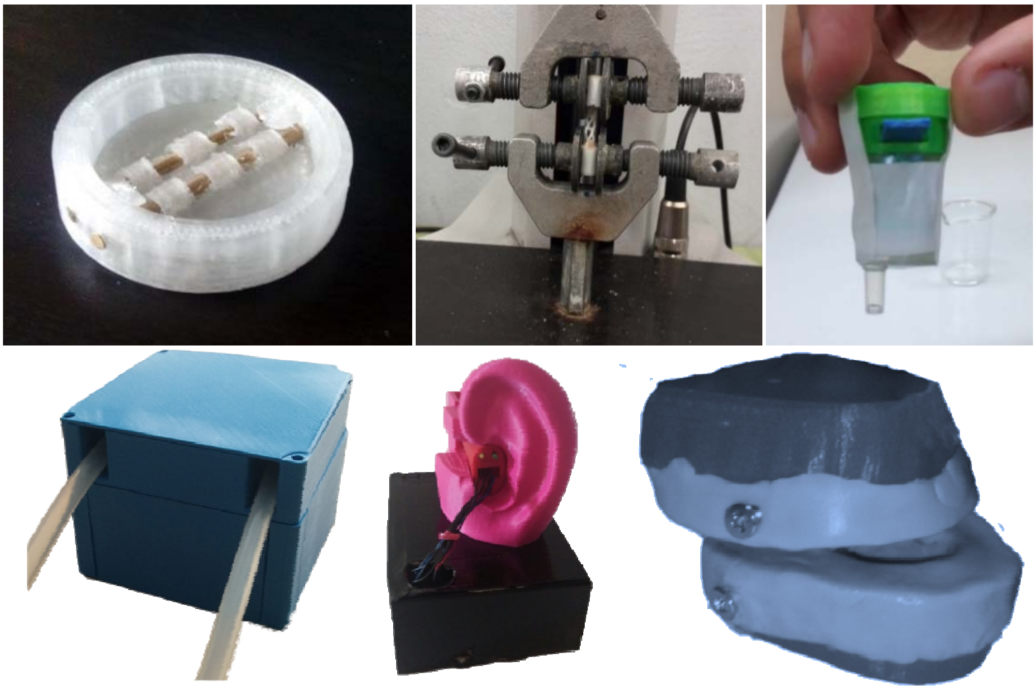

Figure 3. Examples of final results from different projects performed within the "Bioengineering Design" course at the MSc of Industrial Engineering. a) Instrumented heart valve. b) Scaffold for tendon repair. c) Intra-dermal micro-pump. d) Extra-corporeal pump. e) Ear-protecting device. f) Sleep apnea monitoring system.

Thanks to implementing the CDIO approach, students taking part in these subjects lived, for the first time, through the complete development process of an engineering system and are now better prepared for their final theses, as students themselves have highlighted in several occasions during these subjects. Some significant examples are provided in Figures 1, 2 and 3. In addition, they received, again for the first time, training in relevant engineering resources and improved their comprehension and application of several professional skills, all of which adds to the learning outcomes of these subjects. The experiences have been extremely rewarding, both for students and teachers, leading in some cases to spin-off proposals and to final degree theses.

As additional reflection, the proposed two-semester structure for the subject on "Bioengineering Design" is very appropriate, as the "conceive" and "design" phases are adequately carried out during the first semester and the "implement" and "operate" stages are tackled in the second semester. A whole academic year is ideal for maturing the development process of complex products and systems and provides better results, in terms of complete CDIO experiences, than in the one-semester cases of "Bioengineering" and "Development of Medical Devices". In the one-semester courses, only some motivated students are able to reach the implement and operate phases. In any case, the concepts provided by the "Development of Medical Devices" students and the designs provided by the "Bioengineering" students have been carried out with a remarkable degree of proficiency and leading to very interesting results. In any case, it seems interesting to focus mostly on the conceptual phase along the more basic subject on "Development of Medical Devices", while the more advanced subjects at Master's level clearly benefit from concentrating on the design and implementation phases, where students can apply more specific knowledge. Fulfilling the complete CDIO cycle is challenging, but can be achieved if students are well motivated and if teachers help them with a tight control of deadlines and an adequate planning.

Regarding CDIO standards, we have considered several of them for the design of the different teaching learning experiences. All the subjects are connected with standards 1-3, as the three programmes are evolving towards CDIO-based curricula and these subjects provide support to these transitions, as complementary CDIO experiences to the more traditional and common final degree projects. Standards 9-10 are also taken into account: The professors' attendance to CDIO congresses and the promotion of international teaching and research collaborations are part of our compromise with the enhancement of faculty competence. The subjects are implemented as integral learning experiences and promote active learning, in connection with standards 7-8, and the assessment of outcomes are linked to national and international accreditation procedures of the different programmes, which is linked to standard 11.

CONCLUSIONS

In this study we have presented the complete development and comparative study of three courses, belonging to different plans of study taught at the Technical University of Madrid and benefiting from using a CDIO approach focused on the development of biomedical devices. The three courses are "Development of Medical Devices", "Bioengineering Design" and "Biomedical Engineering", respectively belonging to the "Bachelor's Degree in Biomedical Engineering", to the "Master's Degree in Industrial Engineering" and to the "Master's Degree in Mechanical Engineering". During the courses, groups of students have lived through the development process of different biomedical devices aimed at providing answers to relevant social needs. Depending on their background and European credits assigned to the different courses, students have carried out more conceptual projects or have been able to live through more complete CDIO experiences. Main benefits, lessons learned and future challenges, linked to these courses, have been analyzed, taking account of the results from 2014-2015 academic year. Following a CDIO strategy has enabled students to live, for the first time, through the complete development process of engineering systems, linked to the biomedical field, and are now better prepared for their final theses and professional life.

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CDIO Standards 2.0: http://www.cdio.org/implementing-cdio/standards/12-cdio-standards

BIOGRAPHICAL INFORMATION

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