Project based Learning and Biomedical Devices: The UBORA Approach towards an International Community of Developers Focused on Open Source Medical Devices

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Keywords: Project-based Learning, Biomedical Engineering (BME), Open Source Medical Devices (OSMD), Service Learning, Collaborative Design, Co-creation, Collective Intelligence.

Abstract: The engineering design of successful medical devices relies on several key factors and constitutes an extremely challenging process, which requires from multidisciplinary collaboration. In consequence, preparing engineers in general and biomedical engineers in particular to work in the medical industry, in connection with biodevice development, is complex. The teaching learning processes, through which the trainees should acquire a broad overview of the medical field and biomedical industry, a well-balanced combination of general and specific knowledge according to the chosen specialization, several technical abilities linked to modern engineering tools and a wide set of professional skills, have to be strategically planned and implemented. Among the existing teaching-learning methodologies that can be employed for providing such holistic training, project-based learning is presented here and illustrated by means of successful experiences. Trends in the field of collaboratively developed open source medical devices (OSMDs) are presented and main current R&D challenges analyzed. To illustrate the OSMD field, the "UBORA" project (meaning "excellence in Swahili) is highlighted as a paradigmatic example, in which research and training aspects are importantly interwoven. In fact, this Euro-African initiative is focused on the promotion of OSMDs by means of innovation through education, by the creation of a sort of "Wikipedia" of medical devices, the "UBORA e-infrastructure", which also guides designers in the engineering design process and supports online collaboration through the process, and by the constitution of an international community of developers devoted to OSMDs. Results from project-based learning activities within the UBORA project, which include competitions, design schools and final degree theses, are presented. The "UBORA e-infrastructure", with more than 100 open source biodevices concepts and prototypes already developed in collaboration by a global community of around 350 users, and shared through such online platform, are also analyzed.

1 INTRODUCTION

The engineering design of successful medical devices relies on several key factors, including: orientation to patients' needs, collaboration with healthcare professionals throughout the whole development process and the compromise of multi-disciplinary research and development (R&D) teams formed by well-trained professionals, especially biomedical engineers, capable of understanding the connections between science, technology and health and guiding such developments. Preparing engineers in general and biomedical engineers in particular to work in the medical industry, in connection with biodevice development, is a challenging process, through which the trainee should acquire a broad overview of the medical field and biomedical industry, a well-balanced combination of general and specific knowledge, according to the chosen specialization, several technical abilities linked to modern engineering tools and professional skills.

Among the varied existing teaching-learning methodologies that can be employed for providing such a holistic training, project-based learning (PBL), especially in connection with the CDIO "conceive-design-implement-operate" approach applied to the biomedical field (Crawley, et al., 2007, CDIO standards), is discussed here and illustrated by means of successful experiences.

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Besides, new approaches to the development of innovative medical devices, including open source and collaborative engineering design strategies, which are bound to impact the medical industry in a relevant way in the very near future and to support the democratization of medical technology, need to be considered for training the “biomedical engineers of the future”. Trends in the field of collaboratively developed open source medical devices (OSMDs) are also presented along this document (De Maria, et al., 2014 & 2015, Ahluwalia, et al., 2018).

To illustrate the OSMD field, the “UBORA” project is put forward as a recent paradigmatic example. This Euro-African initiative is focused on the promotion of OSMDs by means of innovation through education, by the creation of a “Wikipedia” of medical devices, the “UBORA e-infrastructure”, which also guides designers in the engineering design process and supports online collaboration through the process, and by the constitution of an international community of developers devoted to OSMDs. The varied project-based learning activities performed within the first couple of years of UBORA project’s endeavors are presented and some results illustrated. Besides, the “UBORA e-infrastructure” and the more than 100 open source biodevices concepts and prototypes developed in collaboration by a global community of around 350 users, and shared through such online infrastructure, are also analyzed, focusing on advances since its official presentation (Ahluwalia, et al., 2018a, 2018b, 2018c). Finally, some potentials and challenges in the OSMD field are discussed.

2 PROJECT-BASED LEARNING AND BIOMEDICAL DEVICES

Biomedical engineering (BME) has been since its origins a truly transformative field of engineering, which may even lead to equitable access to healthcare technologies and universal health coverage in the near future, according to World Health Organization’s objectives (United Nations General Assembly, 2012). However, this field and related transformations rely on the collaboration of engineers from all fields, whose training should make them successful developers of effective, efficient, safe, replicable, cost competitive, ethically responsible, sustainable and regulation compliant medical devices. Project-based learning, connected to the development of real medical devices, is arguably the best strategy for training engineers, from a wide set of environments, towards successful professional practice in the medical industry.

Some guidelines, proposals and ideas for the straightforward successful design, implementation and operation of PBL experiences in the biomedical engineering field and focused on the design, manufacturing and testing of biodevices, based on author’s experience and recommendations from key references (King, 1999, King, et al., 2003, 2006, Krishnan, et al., 2011, Morss Clyne, et al., 2016), are provided in the following subsections.

2.1 Planning the Learning Objectives

When planning project-based teaching-learning experiences, it is interesting to start by analyzing the purpose and by listing down the learning objectives envisioned for the concrete course or programme of studies. Asking ourselves how our students may be involved in the medical industry in their future career paths and what we would like them to master, as regards the development life cycle of innovative medical devices seems a good start option. A set of high-level learning objectives for any bioengineering design course focused on training students through the complete development process of medical technologies may include the following:

O.1. Ability to conceive, design, produce and operate innovative medical devices by applying systematic engineering-design methodologies for improved results when addressing global health concerns.

O.2. Ability to promote research and innovation strategies in biomedical engineering and in the medical device industry, so as to better take into consideration the voice of patients, associations and healthcare professionals.

O.3. Understanding the fundamental relevance of standardization and the need for considering existing regulatory paths, so as to achieve safe and compliant prototypes of medical devices ready for production.

O.4. Capability to create value proposals linked to innovative medical devices or technologies and to generate viable entrepreneurial activities within the biomedical industry.

O.5. Capability to learn for researching and developing innovative technologies and to mentor their application to innovative medical devices with improved performance, usability and societal impact, as compared with current gold standards.

Once the learning objectives are defined, the context and boundaries need to be established, in accordance with the temporal framework and available resources for our course and considering the overall objectives and desired outcomes of the complete engineering programme.

2.2 Establishing the Context: PBL and Service Learning

Student and professor motivation are the keys of success in engineering education and establishing a motivating context of shared dreams is essential, towards truly successful and career inspiring PBL experiences, especially in such a transformative field as BME: Our students should always understand that engineering must aim at improving the world and our global society. Medical technologies are part of this process of change, in connection with the UN Global Goal number 3 on "Good health and well-being", but also linked to numbers 8 on "Decent work and economic growth" and 9 on "Industry, innovation and infrastructure" among others.

In consequence, PBL experiences in the BME field, if possible, should be contextualized in connection with relevant health concerns and try to respond to the needs of patients and healthcare professionals. Ideally, when external advisors from hospitals, associations, companies or NGOs working in low-resource settings are involved, the context and ideas for the projects, to be developed by student groups within the PBL experience, can be linked to real specific needs or concrete challenges, hence transforming the PBL experience into a service learning challenge, in which ethical issues can be additionally developed in class.

Evidently the context is marked also by the background of our students and by the global objectives and outcomes of the whole programme: A medical device engineering design course within a robotics engineering programme may concentrate on medical robotics projects (i.e. design of surgical manipulators or artificial hands); while student projects in a mechanical engineering programme may focus on the design and manufacturing of implants (i.e. prostheses for articular repair or artificial valves). At the same time, biomedical PBL experiences in materials science programmes may even connect with the field of biofabrication, through the design of scaffolding materials and other artificial constructs (at least conceptually); while PBL tasks in industrial organization engineering may tackle supply chain problems or focus on quality and risk management, in connection with real production processes, to cite some examples.

Student background should be also considered, perhaps leaving more conceptual projects to the first engineering courses and those requiring more technical design, manufacturing and experimental skills to the final year of the Bachelor's degrees or to the Master's and even PhD levels.

2.3 Defining Contents and Boundaries

With the previously listed high-level learning objectives in mind (Sect. 2.1 O.1-O.5), for any bioengineering design course focused on training students through the complete development process of medical technologies or biodevices, the following basic contents are proposed. They can serve as topics for lessons or modules depending on the available time and temporal framework of the concrete course. They can act as structuring elements for PBL experiences, which can range from just one week to even a whole academic year, as previous examples have shown (Ahluwalia, et al. 2018b). The proposed basic contents include:

-Engineering design methodologies for biodevices.
-Conceptual design and creativity promotion tools.
-Design for usability and risk mitigation.
-Design considering standards and regulations.
-Prototyping and testing of biodevices.
-Mass-personalization and mass-production options.
-Commercialization paths and supply chain issues.
-Sustainable development of biodevices.
-Ethical issues in the biomedical industry.

These basic contents can be completed with specific modules for adapting a generic or sort of "universal" bioengineering design course to the specific needs of completely varied engineering programmes. For instance, a module on "biosignals" may adapt and reinforce these contents for a electronic engineering programme, while a module on "biomechanics and biomaterials" may be adequate for completing a course for a materials science or mechanical engineering programme. In some cases, specific training for transversal skills may be provided, including seminars on teamwork abilities, project and time management skills, and communication techniques, among others.

Regarding the scope and boundaries of the PBL experience, depending also on the available time and resources, the projects may focus just on the specification and conceptual stages, or reach up to the design, prototyping and testing phases.

2.4 Implementing and Assessing

A good definition of objectives, context and contents typically leads to straightforwardly implementable PBL experiences, although some unforeseen events may always take place. Counting with well-maintained manufacturing resources, with rapid responding suppliers and with software licenses, renewed with enough time before the start of the courses, are among the good practices we can cite.

Promotion of communication between professors and students, with monthly face-to-face meetings and tutorials and with intermediate presentation of results and through a consistent plan of distributed deliverables, is also advisable.

Regarding evaluation, involving students in their own assessment, especially through peer-review activities within the working groups, may be considered as an additional control tool for successful PBL. However the promotion of positive interdependence, by making students work in complex enough projects, and some degree of individual assessment, i.e. through specific questions in oral presentations or by means of additional deliverables or evaluation tasks, are the more basic options for achieving a good ambience of collaboration within the teams, without losing individual control upon students that may fade away in teamwork activities (Díaz Lantada, et al, 2013).

3 THE UBORA OPEN SOURCE COLLABORATIVE MODEL

The UBORA research, development and training model for transforming the biomedical industry towards equitable healthcare technologies derives from experiences conceived, designed, performed and validated within the H2020 "UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education" project (GA-731053) during years 2017 and 2018, which have counted with the fundamental support of the UBORA e-infrastructure, an open-access design environment envisioned for the co-creation of open-source medical technologies according to real needs, as detailed below.

3.1 Open Source Medical Devices

UBORA focuses on the promotion of research and training activities in BME pursuing the collaborative development of open-source medical devices (OSMDs). These devices are developed by sharing concepts, design files, documentation, source-code, blueprints and prototypes, testing results and all collected data, with other professional medical device designers. These interactions should benefit the whole life cycle of the devices or products under development and ideally lead to safer performance, thanks to increased peer-review through the co-creation process (De Maria et al., 2015, Ravizza, et al., 2017, Ahluwalia, et al., 2018a).

3.2 UBORA: Much More than a "Wikipedia" of Biodevices

The UBORA e-infrastructure, implemented for supporting the nascent OSMD community in research, co-creation/-design and teaching-learning tasks (see: https://ubora-kahawa.azurewebsites.net/) includes features such as: a) a section for specifying medical needs, through which patients and healthcare professionals can ask for technological solutions; b) a section for sharing technological solutions, through which engineers can showcase their proposals for the future of medical care; c) a meta-structure for supporting biomedical engineers, engineering students and professors in the field to guide the development of innovative medical technologies, in a step-by-step process following systematic engineering-design processes, answering and filling in the questions and sections provided by the e-infrastructure; d) a community with already more than 350 co-creators; and e) a section for sharing open teaching materials.

3.3 Arranging and Training a Global Community Focused on OSMDs

When planning to arrange and train a global community of designers and developers of OSMDs, in which international collaboration should play a central role for the near future, it became clear for the UBORA consortium that PBL should be used as overall teaching-learning strategy. Consequently, different types and formats of PBL experiences have been conceived and carried out in the last two years, which have involved around 30 mentors and well-beyond 300 students (now engineers), leading to a collaborative community of more than 350 members from some 30 countries distributed through Africa, America, Asia and Europe and interacting through the UBORA e-infrastructure.

UBORA PBL experiences include: thematic medical device design competitions, one-week medical device design schools and final degree theses linked to biodevice development. In 2017 the UBORA Design Competition (online, February-June) and Design School (Nairobi, December) focused on child and maternal health, while in 2018 the UBORA Design Competition (online, January-May) and Design School (Pisa, September) focused on ageing-related issues. More than 100 participants have taken part in each of the competitions, while 40 students have participated in each design school, which follow an "*express PBL approach, from concept to prototype in 5 days*".

These PBL activities are now performed on an annual basis and additional ones (mainly UBORA competitions and UBORA design schools) can be *ad hoc* conceived and implemented for focusing on more specific topics, health issues, contexts or locations, for colleagues and institutions interested in exploring open source approaches to the development of medical technology. Besides, the UBORA e-infrastructure is already supporting the development of different medical technology design courses, within different engineering programmes at the universities involved in the UBORA project consortium. Its use as teaching-learning environment for fostering PBL methodologies in bioengineering programmes is open to all colleagues interested in *learning-by-doing* with their students.

3.4 Some Cases of Success

When exploring the OSMDs developed within the UBORA e-infrastructure it is possible to find technological concepts and prototype solutions for most medical technology missions, including: prevention, diagnosis, surgery, therapy and monitoring. Besides, most medical areas are already being covered, from pediatrics to geriatrics, from internal medicine, through general surgery, to traumatology and orthopedics.

Here, by means of example, we present some selected cases of study mentored by the author and developed together with his students during their final degree projects and during their participation in different courses, in which PBL is used as driving methodology for teaching medical technology development and promoting BME in Spain.

Figure 1 illustrates the personalized design and the 3D printed prototype of a shoulder splint for injured joint immobilization. Computer-aided design is performed, after optical scanning of the healthy volunteer, by using surface based design operation with Siemens NX-11 design software and final meshing with Autodesk Meshmixer. 3D printing for ergonomic validation is accomplished using a BCN-Sigma 3D printer and white poly(lactic acid) (PLA) filament. Figure 2 schematically presents the development of a portable cooler for vaccines based on the use of Peltier cells. The circuit design, based on the use of open source electronics (Arduino control board) and the preliminary 3D printed prototype, with the Peltier cell and refrigerator mounted upon the cooler top and isolating panels placed inside the printed cage, are shown. Additional information on these devices is shared through the UBORA e-infrastructure.

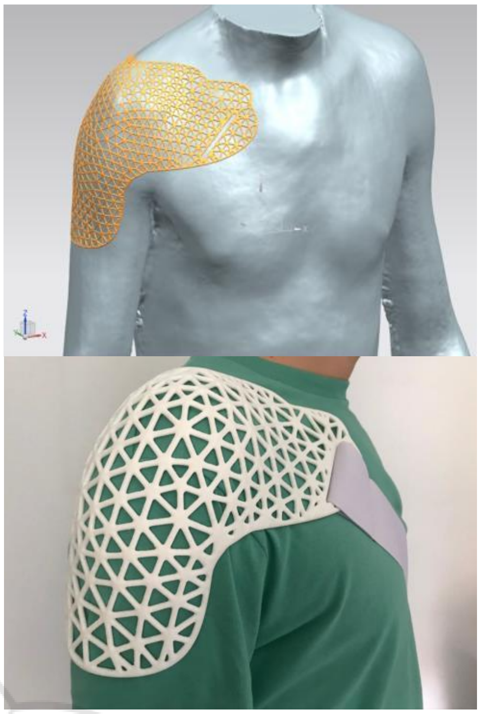

Figure 1: Personalized design and 3D printed prototype of a shoulder splint for injured joint immobilization. Designer: Eduardo Martínez. Collaborator: Marina Maestro. Mentor: Andrés Díaz Lantada.

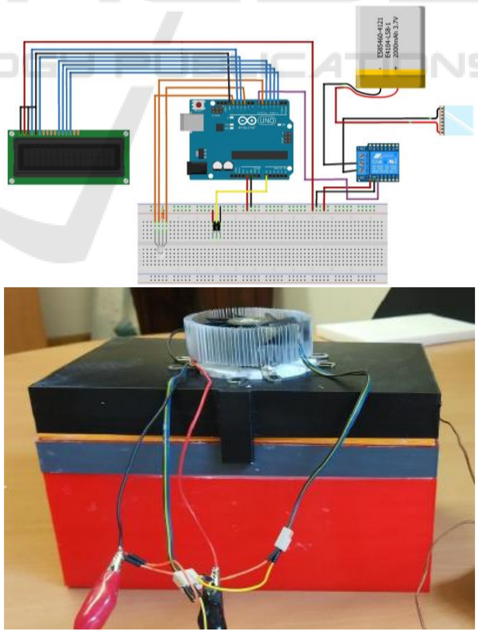

Figure 2: Circuit design and preliminary prototype of a portable cooler for vaccines using Peltier cells. Designers: Isabel Álvarez and Elena Crespo. Mentor: Andrés Díaz Lantada.

4 FUTURE PERSPECTIVES

4.1 Main Potentials

Open source medical devices are here to stay as a changing force, towards a more equitable medical industry and accessible medical technologies. Their benefits for the democratization of these solutions, aiming at global health coverage in the near future, can be understood, if we consider examples from other industries (i.e. electronics and software) already transformed through open source software and hardware.

The co-creation processes, in which these OSMDs rely, also turn out to be very positive for patients and healthcare professionals, due to the promotion of bottom-up innovation. All these beneficial aspects of open source biodevices can be multiplied by means of adequate training strategies, aimed at the creation of a cohort of designers and developers, capable of mentoring this emergent area of open source medical technologies and focused on international, intersectoral and interdisciplinary collaboration throughout the whole innovation chain.

4.2 Key Challenges

Among the more relevant challenges to tackle in this novel open source medical technology co-creation paradigm, it is important to highlight: i) the need for solutions to guarantee the traceability of materials, design files and manufactured components in open design and production lines; ii) the need for resources to systematically and safely track design changes in collaborative design environments and e-infrastructures; iii) the need for changes in existing regulations and for new standards adequately considering and guiding developers, within these collaborative and open design and manufacturing approaches to biodevice innovation.

Capacity building in low-resource settings, by creating a workforce of biomedical engineering and BME professors, in places where access to medical technology is more urgent and where the co-creation with healthcare professionals and patients can be of special relevance, is another fundamental issue.

We expect that all these issues will be solved in the near future through collaboration using co-creation environments, such as the UBORA e-infrastructure, which is open to all medical technology designers and users, as well as educators, for constructive interactions.

5 CONCLUSIONS

Innovation through education (one of the mottos of the UBORA project and community) is an excellent, sustainable and responsible strategy for transforming any industry and for walking towards the fulfilment of the United Nations Global Goals for Sustainable Development. Within BME, training engineers for working in international teams and for collaborating in the development of open source medical technologies can constitute a very relevant driver of change in years to come.

The highlighted UBORA e-infrastructure, a recently created collaborative environment for the co-creation of medical devices, and related UBORA teaching-learning experiences provide pioneering examples of collaborative research and education in BME, as a way for establishing the foundations of the OSMD field.

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UBORA: Euro-African Open
Biomedical Engineering
e-Platform for Innovation
through Education

REFERENCES

Ahluwalia, A., De Maria, C., Díaz Lantada, A., 2018 The Kahawa Declaration: A manifesto for the democratization of medical technology, *Global Health Innovation*, 1(1), 1-4.

Ahluwalia, A., De Maria, C., Madete, J., Díaz Lantada, A., et al., 2018 Biomedical engineering project based learning: Euro-African design school focused on medical devices. *International Journal of Engineering Education*, 34(5), 1709-1722.

Ahluwalia, A.; De Maria, C., Díaz Lantada, A. et al., 2018 Towards open source medical devices: Challenges and advances. Biodevices 2008, Madeira, Portugal, 19-21 January, 2018.

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

Crawley, E.F., Malmqvist, J., Östlund, S., Brodeur, D.R., 2007 Rethinking engineering education: The CDIO approach, *Springer*, 1-286, 2007.

De Maria, C., Mazzei, D., Ahluwalia, A., 2014. Open source biomedical engineering for sustainability in African healthcare: Combining academic excellence with innovation. *ICDS 2014, The Eight International Conference on Digital Society*, 45-53.

De Maria, C., Mazzei, D., Ahluwalia, A., 2015. Improving African healthcare through open source biomedical engineering. *International Journal on Advances in Life Sciences*, 7(1 & 2), 10-19.

Díaz Lantada, A., et al., 2013 Towards successful project-based teaching-learning experiences in Engineering Education, *International Journal of Engineering Education*, 29(2).

King, P.H. Fries, R., 2003 Designing biomedical engineering design courses, *International Journal of Engineering Education*, 19(2), 346-353.

King, P.H., Collins, J.C., 2006 Ethical and professional training of biomedical engineers, *International Journal of Engineering Education*, 22(6), 1173-1181.

King, P.H., 1999 Design and biomedical engineering, *International Journal of Engineering Education*, 15(4), 282-287.

Krishnan, S., 2011 Project-based learning with international collaboration for training biomedical engineers, *Proceedings of the IEEE Engineering in Medicine and Biology Society*, 6518-6521.

Morss Clyne A., Billiar, K.L., 2016 Problem-based learning in biomechanics: Advantages, challenges and implementation strategies, *Journal of Biomechanical Engineering*, 138(7), 070804.

Ravizza, A., Ahluwalia, A., De Maria, C., et al., 2017. Collaborative open design for safer biomedical devices. *Third WHO Global Forum on Medical Devices*, Geneva, Switzerland.

United Nations General Assembly, 2012 Global health and foreign policy, Resolution A/67/81, on 12th December.

BRIEF BIOGRAPHY

Andrés Díaz Lantada is Associate Professor in the Department of Mechanical Engineering at the Industrial Engineering School of Universidad Politécnica de Madrid (UPM). He finished his 6-year Industrial Engineering Degree in 2005 and his PhD Thesis in Mechanical Engineering and Manufacturing in 2009, which received the Extraordinary PhD Award by UPM and the 2nd PhD Award by the Council of Industrial Engineers of Madrid. His research interests are linked to the development of mechanical systems and biomedical devices with improved capabilities, thanks to the incorporation of smart materials, special geometries and complex functional surfaces and structures, mainly attainable by means of high-precision additive manufacturing processes.

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Andrés has directed 2PhD Theses and more than 100MSc and BSc final degree theses. He has received the "UPM Teaching Innovation Award" in 2014, the "UPM Young Researcher Award" in 2014, and the "Medal to Researchers under 40" by the "Spanish Royal Academy of Engineering" in 2015. Since January 2016 he has the honour of being Member of the Editorial Advisory Board of the International Journal of Engineering Education. His current research dedication is to the field of open source medical devices for the democratization of medical technology, in connection with the UBORA community and with the UBORA e-infrastructure, and to the development of innovative teaching-learning methodologies in the BME field.