SHARE: ”Medical Device Design Innovation Challenge”, A Final Project for Biomaterials Course

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Abstract

Project-based assignments are valuable in undergraduate engineering education with demonstrated benefits for student learning, teamwork, and professional preparedness. Prior studies show that project-based learning improves self-directed learning, mirrors industry practice, and can positively impact program-level outcomes such as student retention. This work presents the development and implementation of a comprehensive and adaptable final project for biomedical engineering courses that integrates technical content with real-world medical device design challenges. The project emphasizes teamwork, communication, and engagement with primary literature while encouraging students to identify unmet clinical needs and propose solutions informed by technical, ethical, economic, and sustainability considerations. Implemented through scaffolded milestones with continuous feedback, the project culminates in an industry-style innovation pitch and informational deliverable evaluated by both faculty and medical device professionals. The project is flexible across course types and academic calendars and provides a scalable model for incorporating industry-relevant, collaborative learning experiences into biomedical engineering curricula.

Motivation and Challenge

Literature suggests that project-based assignments offer several advantages for undergraduate engineering students. The teaming requirement central to project-based assignments better reflects the reality of the engineering workplace and these assignments require students to adopt a self-directed approach, which better equips them for future challenges and lifelong learning [1], [2], [3]. Project-based assignments can also be leveraged to provide comprehensive and systems-level exposure to real industry problems that better reflect the type of projects that students will work on during their careers [4].

To that end, we strive to create a project that asks students to interpret content with respect to real-world scenarios and examine a biomaterial based on the synthesis of multiple topics. Our goal is to challenge students to think about all of the design decisions that are intertwined when developing a medical device. Built on the foundational content covered in the classroom, students must pitch a well-motivated, next-generation improvement on a current device on the market. This project-based assignment functions to expose students to real industry problems, which better reflects the type of projects that students will work on during their careers. This project provides students with an opportunity to engage creatively with course topics, synthesize multiple topics, and apply design skills at this stage of their curriculum.

Presented here is an effort to develop a comprehensive final project that blends design and technical content in an engaging, real-world, and applicable format. A central goal was to create an adaptable project that promotes student communication and teamwork skills in novel dimensions and that can be implemented in a variety of biomedical engineering courses. Additionally, we sought to frame the project in such a way that it required students to think about their roles within the larger context of the field. This work does not use data from humans and therefore, does not meet the definition of human subjects research; IRB review is not required.

Learning objectives for this project included that students should:

1. Synthesize concepts from fundamental course topics (materials science, immunology, tissue-biomaterial interactions, regulatory affairs, bioethics, materials testing, and sustainability etc.) and existing and unsolved medical device design challenges [Rubric 1-5]

2. Extract important concepts from primary literature (peer-reviewed original research and review articles) and implement them in their own work [Rubric 1]

3. Communicate scientific ideas in multiple formats (verbal and visual) to a technical but non-specialized audience [Rubric 6-9]

4. Identify an unmet need and suggest improvements to solve this need with an awareness of economic, environmental, and social factors [Rubric 1,4]

5. Contribute effectively to a team by demonstrating leadership, fostering inclusive collaboration, organizing tasks, and achieving project outcomes. [Rubric 10-11]

Implementation

The project was implemented in biomaterials courses (35-55 students/semester) at Rose-Hulman Institute of Technology and Duke University. These courses are compulsory for biomedical engineering majors and are typically completed by students during their second or third years of study. These courses covered traditional topics in materials science, such as the structure and properties of metals, ceramics, and polymer materials, and the applications of these materials in biomedical engineering with a focus on tissue-material interactions. Course content was communicated through traditional lectures, readings, guest speakers, and case studies. Case studies and guest speakers provided context for how medical devices are designed in response to current challenges (ex: titanium dental implants can cause X-Ray artifact and stress shielding on the jaw, perhaps carbon fiber-reinforced polymers can solve this challenge). A series of scaffolded assignments was designed to keep students on track and provide continuous instructor feedback.

Semester-Long (15 weeks) schedule:

- Week 2: After a case study, introduce the project, all deliverables (Appendices 1-2), and the rubric/grading scheme (Appendix 3). Students can pick any device that they feel has a significant associated challenge in overall device functionality or with respect to quality of life or co-morbidity of a specific demographic.

- Week 3: Form student groups (3-5 students/group).

- Week 5: Process Assignment 1: Each group submits their project topics. The instructional team provides feedback on the topic regarding appropriateness for course content.
- Week 7: Sociotechnical Assignment 1 [5]: A modified "Business Model Canvas" [6] named the "BioMaterials Canvas" is due (Appendix 1). This deliverable asks students to link sociotechnical content and recognize the "push" and "pull" of each of their design decisions. Here, students should fill out the right side of the canvas. The instructional team provides feedback, focusing on "Device Functions" and "Design Constraints."
- Week 9: Process Assignment 2: One-page literature review and associated graphical abstract (Appendix 2) are due. The instructional team provides feedback, focusing on the design of the graphical abstract and the "concepts/aspects where the team is uncertain".
- Week 12: Sociotechnical Assignment 2: Completed BioMaterials Canvas is due. This includes any adjustments to the previously submitted canvas. The instructional team provides feedback, focusing on the "Material Platform", "API", and "Innovation".
- Week 14: Final projects are due. Each group develops an "innovation pitch" via either a poster or podium presentation and an additional one-page informational pamphlet. The instructional team prints posters and one-page supplements for the final presentations.
- Week 15: Students showcase their proposed solution to an existing biomedical problem to a panel of faculty and medical device industry experts. Panelists provided informal feedback both in real time and in a delayed, written format.
- Post-semester: Students are graded based on a standards-based rubric (Appendix 3) with an emphasis on technically sound proposals that leverage course content. Students are also graded on the creativity and innovation of their solutions.

Situational Factors

This project is flexible and can be adapted to any academic calendar and to most biomedical engineering courses. For example, mid-term deliverables can be removed or edited to fit course objectives. The weight of this project can be varied according to course needs or objectives. Indeed, this project can be worth anywhere between 10 – 25 percent of the final grade in the course. Additionally, it allows students the opportunity to apply their technical skills to a problem rooted in industry, while developing their written, verbal, and visual communication skills. This project benefits from having industry collaborators available to attend the final project presentations and provide feedback.

References

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[3] D. Kurpius, "The fifth discipline: The art and practice of the learning organization: Book review," *Consulting Psychology Journal: Practice and Research*, vol. 45, no. 4, pp. 31–32, 1993.

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[6] A. Osterwalder and Y. Pigneur, *Business Model Generation: A Handbook for Visionaries, Game Changers, and Challengers*. Amsterdam: Modderman Druckwerk, 2010.

Appendix 1: BioMaterials Canvas, a Socio Technical Assignment

<table>
<tr><td rowspan="2">Technical Connections to Class</td><td>Material Platform</td><td rowspan="2">Innovation
(Technical Specifications)</td><td>Customer</td><td>Anatomy/Physiology</td></tr>
<tr><td></td><td>Patient needs</td><td>Current Solutions</td></tr>
<tr><td></td><td>Active Pharmaceutical Ingredients
(if applicable)</td><td></td><td>Design Constraints</td><td>Device Functions</td></tr>
<tr><td colspan="2">Manufacturing, Sourcing, and Testing Ethics</td><td colspan="3">Economic, Social, and Geopolitical Factors</td></tr>
</table>

Appendix 2: Midterm Progress Report

Progress Report

In your project, you will be designing a medical device to fulfill a clinical need of your choice. In your midterm progress report, you are being asked to **write a brief (1 page or shorter) literature review/search** of **existing strategies** used to design your proposed device and to analyze advantages/disadvantages. Incorporate within this review **a single graphical abstract describing the function of your device**.

Paper Guidelines:

1. Single page (not including references)
2. Format:
    a. Introduction
    b. Available solutions/materials
    c. Challenges/gaps in the field
    d. Concepts/aspects of the device that your team is uncertain about
    e. References
        i. Ensure references are coming from reputable sources
        ii. Scientific articles, technical papers, patents, etc.
3. Graphical abstract design
    a. Embed this figure in your paper and reference this figure in your paper when relevant.
    b. Provide a caption describing the figure
    c. Resources for figure design
        i. Biorender
        ii. Illustrator
        iii. AI images
            - Note: AI in design is useful, but not always perfect - make sure your graphical AI's are not making gross scientific errors
            - The way that AI makes art is not always the most clear kind of illustration
            - When using AI tools on assignments, students are expected to cite their work appropriately.
            - Students are responsible for verifying their work and ensuring that it is accurate and cited appropriately, and students are encouraged to reflect upon the biases that generative AI tools often employ. Overall, AI tools should be used wisely and reflectively with an aim to deepen understanding of subject matter.

Appendix 3: Standards Based Rubric for the Project

		Not Attempted	C-Level Work	B-Level Work	A-Level Work
1	**Problem and Context**		Problem is unclear or poorly stated	Problem and/or inefficiency is clearly stated but anatomy/pathophysiology is missing	Problem and/or inefficiency is clearly stated, and the anatomy/pathophysiology of the system is well described
2	**Solution - Design Process**		Final solution is unclear and poorly motivated	Final solution is clearly presented but poorly motivated	Final solution is clearly described and motivated by well – established design criteria
3	**Solution - Technical Rigor**		Proposal uses inaccurate or unreasonable science to support technology	Technically accurate but unrealistic proposal that leverages biomaterials in general	Technically realistic and accurate proposal that leverages biomaterials concepts from class
4	**Solution - Plans and Timelines**		Unreasonable, unethical, or inaccurate manufacturing and testing plans	Feasible and sustainable manufacturing <u>or</u> testing plan	Feasible and sustainable manufacturing <u>and</u> testing plans
5	**Innovation**		Proposed design is already on the market	Proposed design is original and creates value for consumers but lacks creativity	Proposed design is original, creates value, and is creative
6	**Presentation - Content**		Presentation distracting and/or does not add to pitch	Presentation supports key points and is accurate but does not enhance understanding	Presentation enhances understanding, is easy to follow, and is concise
7	**Presentation - Q&A**		Responds to questions defensively or without technical merit	Team responds clearly to questions and with baseline technical understanding of innovation	Team responds clearly and confidently to questions with understanding of the innovation, implications, and possible future studies to support proposed solution
8	**Document - Content**		Document has errors and/or is discordant with presentation	Document supports key points and is accurate but does not enhance understanding	Document enhances understanding, is easy to follow, and is concise
9	**Document - Visuals**		Document has a poor use of space, unclear flow, and/or is overly cluttered	Document visuals work well with the presentation but are not completely clear	Document is uncluttered and visually interesting with high-quality graphics that work well with the presentation
10	**Professionalism - Deliverables**		Team submits more than one deliverable late	Team submits at most one deliverable late	Team submits all deliverables on time
11	**Professionalism - Presentation**		Presentation is significantly over time limit	Presentation is somewhat over the time limit	Presentation is within the time limit