ASME Journal of Biomechanical Engineering
Online journal at:
https://asmedigitalcollection.asme.org/biomechanical

Expert View

Catalyzing Clinically Driven Undergraduate Design Projects at the Nexus of Engineering, Medicine, and Business

Byron D. Erath
Mem. ASME
Department of Mechanical and Aerospace Engineering,
Clarkson University,
8 Clarkson Ave Box 5725,
Potsdam, NY 13699
e-mail: berath@clarkson.edu

Kevin B. Fite
Mem. ASME
Department of Mechanical and Aerospace Engineering,
Clarkson University,
8 Clarkson Ave Box 5725,
Potsdam, NY 13699
e-mail: kfite@clarkson.edu

Laurel Kuxhaus[1]
Fellow ASME
Department of Mechanical and Aerospace Engineering,
Clarkson University,
8 Clarkson Ave Box 5725,
Potsdam, NY 13699
e-mail: lkuxhaus@clarkson.edu

Design projects, particularly those related to assistive technology, offer unparalleled educational opportunities for undergraduate students to synthesize engineering knowledge with a clinically driven need to produce a product that can improve quality of life. Such projects are most effective when engineering, clinical, and business perspectives are considered throughout. However, the logistics of successfully implementing such interdisciplinary projects can be challenging. This paper presents an auto-ethnography of 12 undergraduate design team projects in assistive technology performed by 87 students from five majors (including engineering, business, and clinical students) over the course of 5 years. The overarching goal of our work was to establish an undergraduate integrated design experience at a university in the absence of a dedicated biomedical engineering major. The focus of this experience was to foster the creation of student-led prototypes to address real-world problems for people with disabilities while keeping commercialization potential at the forefront throughout. Student participation demonstrated a clear enthusiasm for completing biomedical engineering-themed projects. To encourage the implementation of similar approaches at universities where a biomedical engineering major does not exist, we identify common obstacles that can arise and present strategies for mitigating these challenges, as well as effective approaches for catalyzing cross-disciplinary collaborations. High impact practices include close involvement of end-users in the design process; cross-disciplinary team composition (e.g., engineering, business, and health sciences students); and choosing cross-disciplinary leads for project management. Teams experienced a high degree of success with all 12 teams producing functional prototypes. We conclude that at universities that do not offer a biomedical engineering major, health-focused integrated design experiences offer students important interdisciplinary perspectives, including a holistic approach to project implementation. Furthermore, for many students, these projects ultimately served as a gateway to subsequent careers and graduate study in biomedical engineering. [DOI: 10.1115/1.4064717]

Introduction

Design projects offer unparalleled opportunity for students to synthesize their classroom knowledge and wrestle with the unpredictable nature of real-world problems that often involve

[1]Corresponding author.
Manuscript received August 22, 2023; final manuscript received January 31, 2024; published online March 7, 2024. Assoc. Editor: Victor Lai.

competing optimization criteria. Simultaneously, these projects serve as a meaningful introduction to the research process [1]. Product designs conceptualized during these undergraduate design experiences may have market potential, but many languish following the end of the academic term investment.

Prior literature has described tools and techniques for identifying clinically relevant projects that need engineering solutions [2], global student collaborations [3], the importance of design projects as a vehicle to meet ABET goals [4], and best practices in structuring a design course [5]. Although engineers readily identify how products can be improved, within the context of assistive technology, it is the end-users and their caregivers who can best identify barriers to participation in activities of daily life. Thus, involving end-users and caregivers in the design process is critical to new assistive-device design [6]. For assistive technology concepts to become market-ready solutions, the incorporation of engineering, clinical, and business perspectives is essential. Prior literature has described the importance of including an entrepreneurial perspective in biomedical engineering design projects [7], but did not explicitly emphasize the inclusion of clinical perspective in undergraduate-level projects. This paper seeks to fill that gap with a practical description of work done at a relatively small institution.

It has been established that disciplinary cross-training is essential for advancements in translational medicine [8] and to prepare students for industry careers [9]. One way to approach this cross-training is through interdisciplinary design teams such as those discussed here. However, there are substantial challenges endemic to such multidisciplinary collaborations [10,11], particularly at the undergraduate level. For example, at Clarkson University although the graduate health sciences programs encourage (and in some cases require) participation in research, those programs run on a quarter system that is not well-aligned with the undergraduate semester. A further complication is that capstone courses for students in nonengineering programs (such as business and/or health sciences) have substantially different learning outcomes and deliverables from those in engineering design courses. This same problem can also arise when organizing design teams from different engineering disciplines.

There are some well-established curricula for teaching interdisciplinary biomedical design (e.g., Stanford Biodesign [12,13]) in larger institutions [14]. Conversely, many universities provide curricula in traditional engineering topics but lack a biomedical engineering major and, hence, are not equipped to implement a large-scale interdisciplinary biomedical design experience. In response, this paper presents outcomes from a de novo multidisciplinary biomedical engineering design experience that was created at Clarkson University, a midsized, R2 institution that offers an undergraduate minor (but not major) in biomedical engineering. The overarching goal was to establish a biomedical-engineering-focused interdisciplinary undergraduate design experience that fostered the creation of student-led prototypes with commercialization potential to address real-world problems for people with disabilities. The emphasis was placed on mobility and communication, the research strengths of the advising professors.

This effort involved the completion of 12 undergraduate design team projects in biomedical engineering over 5 years. We present strategies for overcoming common obstacles as well as effective approaches for catalyzing cross-disciplinary collaborations in newly established biomedical engineering undergraduate design experiences. We note that this paper is intended to be an auto-ethnographical sharing of our observations and best practices that have emerged, and we discuss them within the context of existing scholarship. We anticipated (but did not formally hypothesize prior to embarking on this work) that the population of students who self-selected and opted in to these projects might not be a uniform subset of all eligible students.

Methods

Our approach, supported by NSF (#1510367, Walking and Talking: Improved Quality of Life Through Enhanced Mobility and Communication; original PI Kuxhaus and final PI Erath, with Co-PI Fite throughout), was to create interdisciplinary design teams to tackle clinically motivated meaningful design projects to improve quality of life for persons with disabilities. Our goal was for each design team to be comprised of a mixture of self-selected undergraduate students in the Mechanical Engineering (ME) program, at least one business student (including those in the Engineering and Management (E&M) program), and at least one student from the Health Sciences program. Note that Clarkson University offers an undergraduate minor in biomedical engineering but no major. At the time these projects were conducted, students enrolled in the biomedical engineering minor could use these projects to fulfill a biomedical design requirement for the minor. Teams typically involved 4–6 ME students, 1–2 E&M students, and a graduate student from one of Clarkson's graduate Occupational Therapy (OT), Physical Therapy (PT), or Physician's Assistant Studies (PA) programs. The ME and E&M students participated via capstone design courses, which constitute the culminating design requirements for each program. The clinical graduate students used the design activities to meet clinical project requirements of their respective programs.

In addition to the undergraduate and graduate students, each team also included a primary faculty advisor, a clinical consultant often but not always affiliated with one of the graduate clinical programs, a patient end-user of the assistive technology to be designed, and a technology-transfer/commercialization specialist. The faculty advisor was responsible for overall project oversight and team management and met with the team at least weekly, provided feedback on project progress, and provided the midterm and final assessments (both group and individual) for purposes of course grading. The clinical advisor served as a consultant to the team with respect to the clinical aspects of the design project. Together with the end-users, the clinical advisor worked with the team from conceptual design all the way through final prototype development and testing to help ensure that the assistive technology being developed addresses a clinically relevant problem and was a solution beneficial to and desired by the patient end-user. Because this was a de novo integrated design experience for which established clinical collaborations were limited by the faculty advisor's existing collaborations/network, flexibility was intentionally allowed for the identification of a design problem and the associated end-user/population. Three types of end-users were ultimately utilized: (1) a general population group, (2) a specific individual, or (3) a clinical provider that would benefit in the treatment of patients. Rounding out the advisory team was a commercialization and technology-transfer specialist from Clarkson's Shipley Center for Innovation. This individual provided education as appropriate for protection of intellectual property and development of a commercialization plan to bring the resulting technology to market. Depending upon the nature and scope of the resulting prototype, the plan for bringing the product to market involved small business creation and/or licensing of the technology to existing commercial enterprises.

While the main design effort occurred over the course of the spring semester of each academic year, the composition of each team was determined midway through the previous fall semester. Teams were organized following standard practices in Clarkson's ME senior design course. Students expressed preferences for projects based on faculty classroom presentations about the clinical problem (but not a specific proposed solution, which was ultimately determined by the design groups after performing a needs assessment). Final composition was determined by instructors to balance student preferences across all teams. Note that students enrolled in Clarkson's biomedical engineering minor were required to complete a health-focused design project and could opt in to one of these projects to fulfill that requirement. To catalyze inter- and intrateam dynamics, teams engaged in a short (1–2 week) design competition with an assistive technology (AT) focus. Each team was given a modest budget and tasked with the design and initial prototyping of an AT product. Demonstrations of each team's solution were held in conjunction with a reception hosted by one of the faculty mentors,

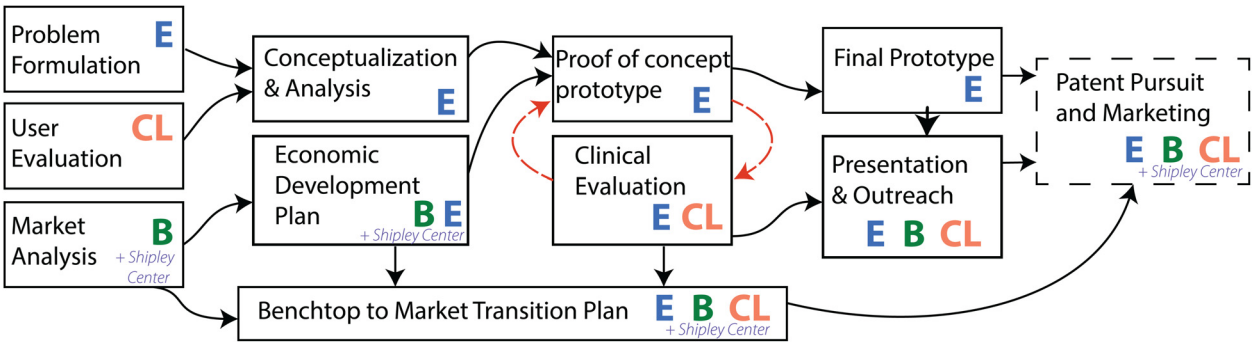

Fig. 1 Idealized workflow (E = engineering; B = business; CL = clinical)

providing an informal setting in which to showcase design solutions while concomitantly seeding the development of the interpersonal relationships important to overall team performance.

Figure 1 depicts a diagram of the idealized workflow for each design project. At the start of the spring semester, each design team met with their faculty advisor, clinical consultant, and patient end-user. Over the course of these initial meetings, a clinical need was identified along with a list of design requirements. Based on the type of end-user (general population, specific individual, or clinical provider) the needs assessment was tailored accordingly and performed via a (1) survey of the population group, (2) individual interview, (3) survey of clinical providers, or some combination of the three (see Supplemental Materials on the ASME Digital Collection). Following the needs assessment, teams developed conceptual designs to address the design requirements of the AT product. The multidisciplinary composition of the team helped to ensure that the design solutions consider the engineering, clinical, and economic components critical to development of a functional product with commercialization potential. Based on the conceptual design work, each team fabricated one or more proof-of-concept prototypes for preliminary experimental testing. These prototypes were often comprised of subassemblies to enable engineering evaluations of specific product functions and, as appropriate, subjective evaluations by the clinical consultant and patient end-user. Each team employed an iterative design process resulting in multiple design revisions that incorporate the knowledge gained from benchtop testing and end-user feedback. Preliminary design activities spanned the first half of the semester leaving the remainder of the term to focus on detailed engineering design of the final solution, fabrication of the final design prototype, and experimental evaluations of its functional performance.

In parallel with the engineering design activities, design teams also develop a commercialization plan to transition the product to market. Teams conducted preliminary United States (US) patent searches to identify existing patents relevant to the AT product to be developed. Replete with knowledge on the intellectual property landscape, the teams then worked with the commercialization and technology transfer specialist to develop a benchtop-to-market transition plan. The commercialization plan used costs associated with prototype development and estimates of overall market demand as the foundation upon which to devise an economic and business plan for bringing the product to market. If applicable, provisional patent applications were submitted to protect relevant intellectual property rights and enable sharing of the work with the academic and clinical communities; students and faculty worked with the commercialization specialist from the Shipley Center of Innovation to discuss invention disclosures and inventors on any provisional patents filed. The final deliverables for the effort were a fully functional final prototype, detailed engineering drawings of each component, results of numerical and experimental analysis, and a detailed commercialization plan. At least one trainee continued the research and development (including refinement) of promising projects; this often included an intensive summer period, with some continuing into the next academic year.

We assessed success of these projects by whether each team had an end-user identified project, at least one student from each category (ME, E&M, and clinical), and quality of the final deliverables including prototypes and other scholarly output. We also assessed both immediate and ultimate graduate school entry for the undergraduate participants. Finally, we identified frequent challenges among teams and share our best practices in mitigation strategies below.

Results

Student Participant Demographics. From 2015 to 2020 (five academic years), a total of 12 integrated design projects were advised. Table 1 provides data on the students that participated in these projects. A table (see Supplemental Materials) includes complete participation data by project. In total, there were 87 students across 5 majors, with 60 ME majors. During this same time frame, a total of 677 ME students completed 141 integrated design projects (including the current biomedical engineering students/projects). The percentage of ME students participating in the biomedical engineering-themed projects (8.9%) is non-negligible and demonstrates student interest likely exists for programs of this nature at comparable universities where a biomedical engineering major is not offered.

Of the 12 projects, 7 were fully successful, with each of the failures occurring due to lack of involvement by a health sciences student. As will be discussed, this arose due to difficulty in recruiting and providing sufficient incentive/buy-in for the health professions students.

Participation among female students was especially high (48%, or 55.2%), reaching at least 50% for each major. This was particularly noteworthy for ME students (31%, or 51.7%) as only approximately 20% (per University Registrar) of the entire ME undergraduate program is comprised of females. In addition, 8 students (9.2%) with disclosed disabilities participated. This is consistent with the percentage of students that disclose a disability to the Office of Accommodate Services at Clarkson University (10%). It should be noted, however, that the number of students that voluntarily

Table 1 Statistics of student participants in the integrated design projects from 2015 to 2020. Majors are Mechanical Engineering (ME), Engineering and Management (EM), Occupational Therapy (OT), Physical Therapy (PT), and Physician Assistant (PA).

Major	ME	E&M	OT	PA	PT	Totals
No. of students	60	18	2	1	6	87
Female	31	11	2	1	3	48
Disclosed disability	4	3	1	0	0	8
Attended grad school	20	4	NA	NA	NA	24
upon graduation	14	4	NA	NA	NA	18
Ph.D.	4	1	NA	NA	NA	5
Health-related career	16	2	2	1	5	26

disclosed a disability to the integrated design team is likely much lower than those that would disclose a disability to the academic office to receive educational accommodations. Therefore, we expect that participation in assistive device design experiences by students with disabilities will be at least the same as university averages and has the potential to be a significant attractor.

Total graduate school pursuit was also much higher than department averages, which was calculated based on a student response rate of 83.7%. Note, graduate school attendance was not considered for the health professions, as they were already enrolled in a graduate health program during participation in the integrated design projects. The total percent of responding students that ultimately attended graduate school by major was 33.3% and 22.2% for ME and E&M majors, respectively.

Because we posit that participation in integrated design experiences such as these leads to increased awareness of, and desire to attend, graduate school, we then differentiated between students that immediately attended graduate school and those that attended after working in industry. This may elucidate how participation in a design project motivates students to attend graduate school, as those that first worked in industry may have had other contributing factors (e.g., to receive a promotion). Upon completion of an undergraduate degree, 23.3% of ME students and 22.2% of E&M students immediately enrolled in graduate studies. This is a twofold increase when compared with historical, ME department-wide averages of approximately 10% and E&M averages of approximately 9%.

Integrated Design Project Outcomes. While each project produced a final design report and prototype, there were also additional forms of scholarly output. This included two journal articles [15,16], 12 conference publications [17–28], and 8 provisional patent applications. In addition, each of the teams submitted an abstract to the Undergraduate Design Competition in Rehabilitative and Assistive Devices at the Summer Biomechanics, Bioengineering, and Biotransport (SB3C) conference. Per competition rules, only one team per university is allowed to compete. Therefore, despite each team submitting to the competition, only five teams (one each year) were selected as a finalist (top 6). Of those, one team won first place, and two teams were awarded third place.

Challenges. This section outlines the primary challenges that were observed when organizing and coordinating the work of the interdisciplinary teams. Just as the primary mass of an iceberg is concealed below the surface, the "success" of the interdisciplinary design process relied on a number of underlying challenges that are not always easily visible/identifiable. These potential obstacles are illustrated in Fig. 2, where the positive outcomes that are "seen" rely on addressing the often unseen challenges. The torpedoes identify critical components which, if not addressed, have the potential to scuttle the program. Topics with a clock denote important steps that can be carried out asynchronously, thereby providing flexibility in managing the progression of design groups. Each of the identified challenges is discussed below.

Student Logistics and Perception of Workload. Numerous logistical challenges can plague student design teams and can be a real threat to their success (see torpedo icons in Fig. 2). A consistent challenge arose from determining how the integrated design experience would/could contribute to the graduation requirements for each of the participating majors. As previously discussed, the integrated design experience was organized as a two-semester course. ME students are required to complete a two-semester design course sequence for graduation, which made participation straightforward. E&M students are required to complete only a one semester design experience. To remain engaged for the duration of our projects, these students were given the option to enroll in "research for credit," which can be taken as a credit-bearing elective to satisfy graduation requirements. Some health science students (OT, PA) are required to complete a research project as part of their curriculum. However, the expected time commitment and project depth were far lower than what the engineering students committed (8–10 h/week). In addition, the program stipulated only one quarter of participation. Unfortunately, given the structure of the degree requirements and the cohort course model that runs on a different academic calendar, there was no mechanism to provide Health Sciences students with elective credit that would count toward their degree requirements. Consequently, participation from Health Sciences students was dependent upon finding individuals who were excited about the project and willing to devote personal time.

Due to the complex nature of academic, cocurricular, and extracurricular obligations, finding a regular recurring time for all groups to meet on a regular basis posed a substantial challenge. This was a particular challenge for Health Science students because the cohort-scheduling model blocks out almost all regular instruction hours (e.g., 8 a.m.–5 p.m.) each day of the week. It was found that the best way to ensure regular meeting times for the ME and E&M students was to schedule a course through the registrar prior to the start of the projects, for all students to enroll in in lieu of their "home" program's capstone course. The challenge in doing this was that approval from both majors had to be secured to ensure that the new "course" satisfied curriculum requirements and could be counted to satisfy graduation requirements. Additional complications arose due to the need to track course objectives, outcomes, and student performance for ABET accreditation across multiple majors. Despite these challenges, this new course then served to both track and provide credit of design requirements for the different majors, as well as to ensure at least 3 h of shared meeting time throughout the week. To facilitate and integrate participation from Health Science students, however, expectations that group meetings might often have to occur outside of "regular" hours were modeled by project advisors by scheduling and leading group meetings in the early evening at least once per week. CATME [29,30] is a useful tool for mitigating some scheduling concerns; however, given the constraints of forming groups (small number of students per year, and preference for project interest), it was not practical to rely on CATME for group formation. That said, CATME was used on an ad hoc basis (at the project advisor's preference) to assess team functionality and contributions.

Due to the interdisciplinary nature of the design groups, student preconceptions of the design process frequently led to "staying in their (disciplinary) lane" near the start of the project. For example, clinical students would volunteer to design and administer surveys for assessing device needs, ME students would first volunteer to work on the prototype, and E&M students would volunteer to perform the economic analysis. To combat this linear thinking, group members were strongly encouraged to choose a lead for each component of the project whose major did not correspond with the field. This disruptive approach received overwhelmingly positive feedback from the student participants, expanded student education, and fomented cross-disciplinary leadership skills.

Programmatic Support. Successful projects require support at the department level, both in terms of financial support and institutional "buy-in." For these projects, the need for financial support was mitigated by grant funding that supported prototype development and student travel (up to $2k for prototyping, $5k for student travel, and $5k of salary support for up to one student to continue the project over the summer). Students hired over the summer consisted of both undergraduates with one semester to 1 year of course work remaining, as well as graduated students; the specific scenario depended on the situation of the student that was recruited and was not a hiring decision criterion. Financial support in terms of student travel and summer salary support was found to be highly impactful. Not surprisingly, conference attendance resulted in an almost universal increase in student interest in academic research and awareness of career opportunities in the biomedical field afforded by graduate school pursuit. Due to the projects' focus on developing a working prototype, time during the academic year spent preparing for dissemination was usually minimal. Each year, one student from

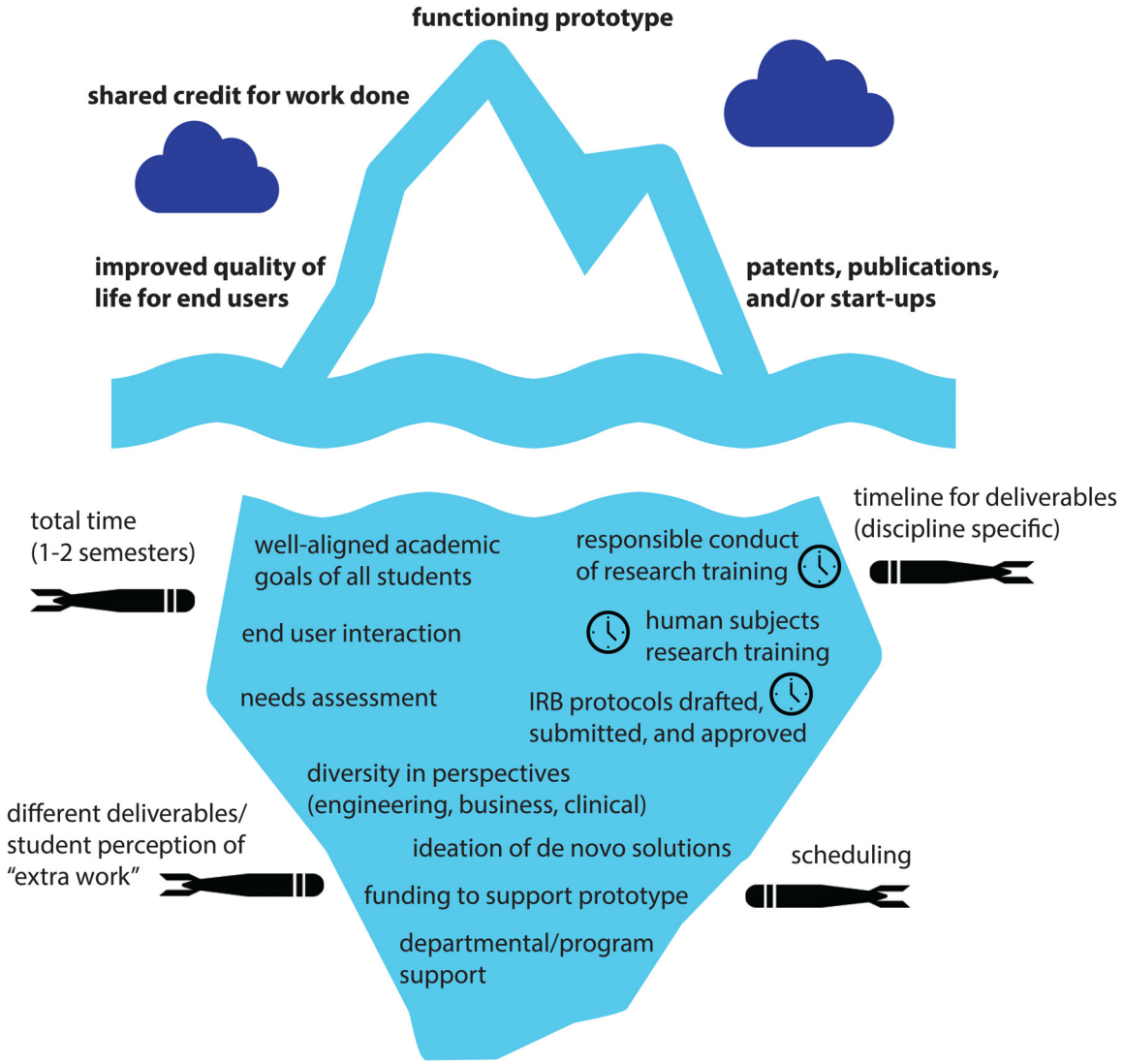

Fig. 2 Schematic of essential components of design projects. Items below the waterline of the iceberg indicate those which are essential, but not always visible. Items with a torpedo indicate critical efforts that have the potential to easily derail a project. Items marked with a clock indicate those that can be performed asynchronously but can also create substantial delays if planning is poor.

a team was hired over the summer to continue the project. This individual was integral in preparing results for dissemination. Both peer-reviewed journal articles that were outcomes of this program were led by undergraduate students hired over these summer terms. For this reason, summer salary support for a student that had participated in the prior academic year's project seemed crucial for increasing the exposure of project outcomes.

Because both ME and E&M majors already required participation in a design project for graduation, departmental support for recruiting and advising students was overwhelmingly favorable. The Department Chairs of each Health Science Program were also enthusiastically supportive of our efforts, despite scheduling challenges. In spite of this, we found the greatest success in recruiting students by first garnering departmental support and then visiting the respective courses that required a research component, introducing the projects, setting clear expectations, and highlighting the benefits of participation. This usually garnered sufficient response. However, as previously mentioned, 5/12 projects were unable to attract consistent clinical student participation.

A significant benefit to the program was the commercialization specialist afforded by the Shipley Center for Innovation, who provided support and guidance on issues related to product commercialization, including filing provisional patents. Each team met with the specialist at least once to learn how they could assist with commercialization efforts. Because the design projects varied by application, end-user, and market audience, the integrated design teams were given flexibility in how they decided to subsequently avail themselves of the resources provided by the Shipley Center for Innovation in support of their project. At minimum, each team completed an analysis to determine market feasibility for their assistive device. Ultimately, six teams pursued, and were awarded, eight provisional patents for their device designs (see Supplemental Materials on the ASME Digital Collection).

Responsible Conduct of Research Education. As identified by the clocks in Fig. 2, there are a number of obstacles that, while necessary, can easily delay progress. However, these obstacles can be managed preemptively. Early student identification (ideally at least 1 month before the start of the project) was found to be crucial for ensuring adequate progression of the project. Because each of these projects involved human subjects, Responsible Conduct of Research and Protection of Human Subjects training were imperative. Additionally, the process of securing Institutional Review Board (IRB) approval of any human subjects research, when necessary, can consume a large portion of the students' limited time. In most cases, the human subjects research were limited to

surveys of end-users, which, as discussed further below, reduced the effort needed for IRB approval.

Training components were assigned to be completed before the start date of the project, as they could be completed individually once group members were identified. This was a critical step as a pressing issue was the timely submission, and approval, of the necessary IRB documents. Jump-starting this training ensured students were prepared to undertake this process at the onset of the project.

Time Management as a Component of Biomedical Engineering Design. Each project included end-user interaction throughout the process, a needs assessment, and an economic plan for market realization. Our interdisciplinary model, including engineering, business, and clinical students throughout, ensured that diversity in disciplinary perspectives was also a top priority.

The ability to perform end-user evaluations of the function of the device designs was found to be prohibitive in almost all of the design projects given the short project duration coupled with the need to have a finalized prototype prior to submitting a protocol to the IRB. These challenges, combined with the IRB meeting schedule (once/month), the common need for multiple revisions of the documents, and the request for investigative device exemptions, became prohibitive. The few projects that did include experimental assessments were part of ongoing efforts that had pre-existing IRB-approved protocols. For the remainder, interaction and feedback from end-users were made possible by collecting survey data from end-users at the onset of each project. This approach was used to perform a needs assessment, identify device design goals, and assess economic interest in the device. This was advantageous as surveys can be designed to avoid collecting personal information and to be confidential. In most cases, this allowed expedited review and provided a quick turnaround in the IRB process. This initial and early contact with the end-user(s) was also beneficial for educating and exposing undergraduate students to common life-altering challenges that people face. This often resulted in a transformative experience for the undergraduates, catalyzing their desire to use their education and abilities to advance the well-being of others.

Surveys were also found to be a useful solution to the challenge of performing final prototype evaluations by the end-users. Near the completion of the project, and after fabricating the final design prototype, many design groups then presented their final prototype to the end-users, and solicited formal feedback through a survey regarding the prototype design and function. This approach was effective at closing the loop on the design process.

Optimizing Project Progression and Outcomes. When selecting specific design projects, we found it advantageous to build upon existing research strengths of the faculty advisor as opposed to *de novo* ideation. By limiting the scope of the potential projects to the general research area of the faculty advisors, in this case speech and mobility, it facilitated the involvement of end-users through existing connections and guided students toward meritorious projects. In addition, this approach provides motivation for the advisor to mentor an integrated design team as they are more likely to support work that promotes progress and yields quantifiable outcomes within their chosen field.

Discussion

It is emphasized that the primary objective of this work was to establish a biomedical integrated design experience for undergraduates in traditional engineering disciplines (e.g., mechanical engineering) at a university without a biomedical engineering major. Consequently, the main contribution of this work should be viewed as informing decisions and strategies for implementing undergraduate biomedical-themed design experiences at similar institutions (e.g., midsize, R2).

Overall, the design experience was rewarding for students, faculty mentors, and end-users, and satisfied our objectives for student design experiences. Examples highlighting select final prototypes are shown in Fig. 3. Our student design teams worked together and the demographic diversity within our teams was greater than that of the University's student population, as expected from Ref. [4]. We attribute this to the emphasis on improving quality of life through product design that may have attracted more diverse students, and that our funded projects offered students more opportunities to interact with end-users, present their work, and the possibility of a national conference presentation. This is synergistic with nationwide emerging work suggesting that design projects with explicit relevance to equity appeal to students [31]. We explicitly observed that the SB3C Undergraduate Design Competition was a strong motivator, particularly in years when multiple teams submitted abstracts because only one team per university could be a finalist. We believe that this "friendly competition" was particularly motivating.

We observed that the most successful outcomes were achieved by teams that worked for 2 semesters, and had a team member continue the work (with funded support); this led to additional publications, including two journal papers. An additional benefit of project continuation (beyond offering professional development to trainees) is that this additional product development can set the stage for patents, small business opportunities, and other commercialization (e.g., I-Corps, SBIR/STTR, or NSF PFI proposals). None of these projects were immediately translated into student-led companies, though many students (Table 1) did pursue careers in healthcare-related fields, including the medical device industry and government (e.g., at the FDA).

In many instances, these projects served as gateways to research and healthcare-related engineering work for students who previously professed disinterest in pursuing a graduate education or healthcare-related occupations, which agrees with existing literature that research and design are often synergistic [1]. Many of the students that ultimately attended graduate school or pursued healthcare-related careers in industry were not even thinking of it when they started the projects. Our gains of building confidence in research capability in students may be comparable to those seen by a summer REU program [32], yet do so within the context of the typical academic year and avoid the selection bias inherent in REU programs, which self-select for students predisposed to research pursuit. Future work could study the effect of these team design projects on developing scientific identity and fostering a sense of belonging. Additionally, we note that this approach of "meeting students where they are" in a required capstone course offers a smooth entry pathway to research-minded projects and complements established larger-scale undergraduate research experiences [33] while having a lower barrier to implementation for faculty.

We note that relatively small monetary investments produced high-impact outcomes that provide direct benefits to both undergraduate students and end-users of assistive technology. In our case, external funding catalyzed our vision of multidisciplinary design projects, and enabled financial support for specific activities (e.g., device design and fabrication, conference travel, summer student funding). We realize that these activities can be prohibitive for many institutions, though many of our activities to enhance team dynamics, such as including multidisciplinary students and needs assessments, can be done at no- or low-cost. We strongly encourage faculty mentors to take advantage of external funding for projects, including industry support as well as opportunities like NSF REU supplements and sites, NSF Design Supplements (available for those who hold active NSF awards from the Engineering Directorate), or other larger opportunities like the NIH R25 opportunity for Team-Based Design in Biomedical Engineering Education. Finally, though it can be challenging to track the long-term impacts of any single design project, we strongly encourage funders (federal or industrial) to continue to support these potentially impactful efforts.

Our students thrived when they established direct personal contact with the end-user (or group) to establish design goals. This helps students gain an appreciation for the challenges faced by the end-users (sometimes accompanied by wide eyes during meetings,

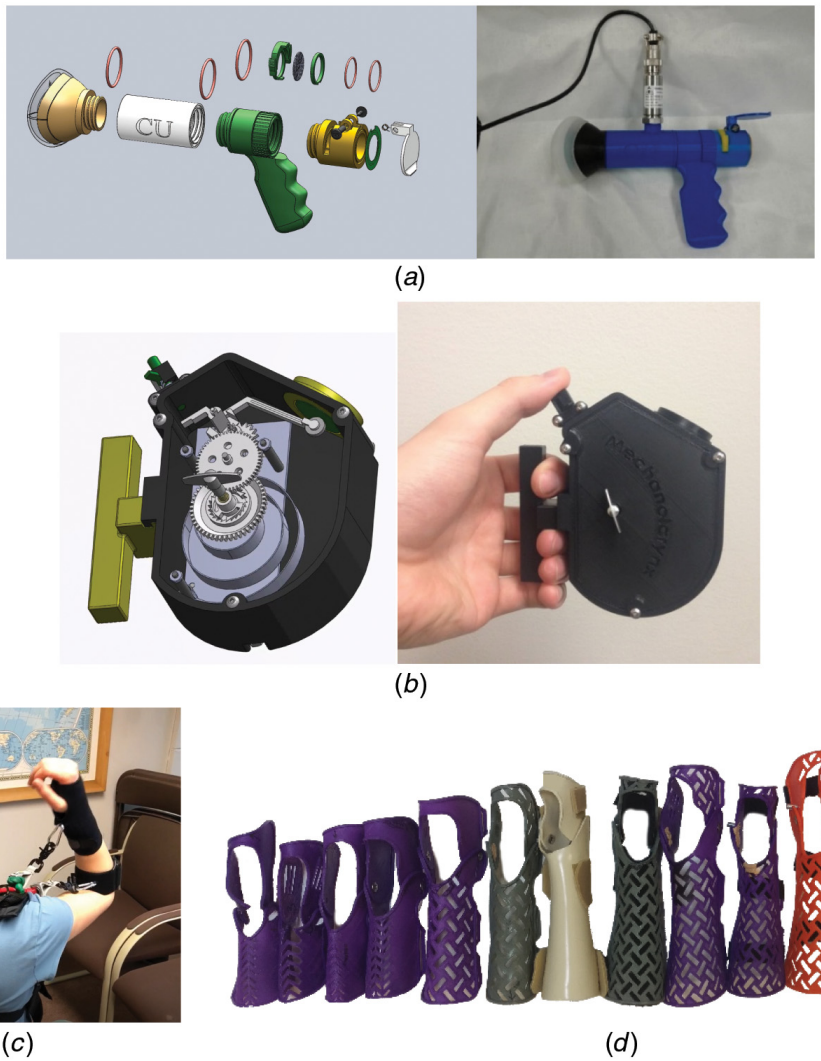

Fig. 3 Example assistive technology prototypes developed: (*a*) solid model and experimental prototype of an artificial cough prosthesis, (*b*) a solid model and experimental prototype of mechanically driven artificial larynx, (*c*) an energy-storage-and-release device to assist Nordic ski poling for individuals with muscular degeneration in the upper arm, and (*d*) multiple prototypes for a limited-motion wrist brace

and intense fervor in group discussions about how to improve quality of life for persons with disabilities). We note that these important interactions often required facilitation and logistical coordination by faculty members, which may limit the scalability of this approach.

To effectively use undergraduate design projects as a gateway to research experiences, we recommend encouraging entrepreneurial thinking and a curiosity-driven approach along with end-user and clinical professional interaction. We also note that research projects can be critical to building STEM identity [34], which is also critical to retention and career success. Further, we note that our 12 projects led to eight provisional patents across six projects (see Supplemental Materials on the ASME Digital Collection for additional detail). These were made possible by educating students to develop a benchtop-to-market transition plan. In all cases, students and faculty engaged in meaningful dialog about who to list as the inventor. These decisions were all ultimately made by the student teams; in some cases, faculty were included as co-inventors if they had made substantial contribution to the patentable aspects of the device. This approach could help mitigate the valley of death that often exists between ideation in academia and the product's ultimate translation to market.

Our implementation harnessed the strengths of our own institution and we anticipate that our challenges and successes may be useful to others in similar institutions. We also recognize that our implementation of multidisciplinary design projects may not be scalable to larger numbers of students, regardless of institution size, due to the heavy commitment of faculty mentors. Future endeavors could systematically identify effective practices to enable "scale-up."

Conclusions

A pathway for the establishment of an integrated biomedical engineering design experience at an institution without a biomedical engineering major has been outlined. The interdisciplinary student design projects were generally successful, despite the obstacles described. The student experience was enhanced by end-user engagement and the multidisciplinary nature of the approach. Additionally, we note that students who participated in these engineering design projects often treated them as an introductory research project, especially those students who continued work on the project over the summer. Given that research experiences are one of the best ways to attract and retain students in engineering careers [35], we expect well-structured design projects like those we describe will offer a similar pathway to success in science and engineering research. Research experiences are a critically important part toward engaging the so-called Missing Millions [36] in the

nation's science and engineering enterprise, and design projects may provide a pathway toward this goal.

Funding Data

- Clarkson University (MAE Department and Honors Program; Funder ID: 10.13039/100009217).
- Directorate for Engineering (No. CBET-1510367; Funder ID: 10.13039/100000084).

References

[1] Lemley, E., Jassemnejad, B., Mounce, M., Weber, J., Rai, S., Duffle, W., Haubrich, J., and Taheri, B., 2010, "Linking Senior Design Projects to Research Projects," ASEE Annual Conference and Exposition, Louisville, KY, June 20–23, p. 8.

[2] Berry, J. L., Noles, K., Eberhardt, A., and Wingo, N., 2019, "Accelerating Clinical Innovation in Biomedical Engineering Education by Using a Digital Portal for Collaboration," ASME J. Biomech. Eng., **141**(12), p. 121003.

[3] McCullough, M., Msafiri, N., Richardson, W. J., Harman, M. K., DesJardins, J. D., and Dean, D., 2019, "Development of a Global Design Education Experience in Bioengineering Through International Partnerships," ASME J. Biomech. Eng., **141**(12), p. 124503.

[4] Grimm, M. J., 2020, "Design as a Feature of Biomedical Engineering Education-Satisfying ABET and Preparing Students to Address Clinical Needs," ASME J. Biomech. Eng., **142**(11), p. 110802.

[5] Tanaka, M. L., and Fischer, K. J., 2016, "Structure and Management of an Engineering Senior Design Course," ASME J. Biomech. Eng., **138**(7), p. 070802.

[6] Krishnan, S., 2013, "Promoting Interdisciplinary Project-Based Learning to Build the Skill Sets for Research and Development of Medical Devices in Academia," Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Osaka, Japan, July 3–7, pp. 3142–3145.

[7] Eberhardt, A. W., Johnson, O. L., Kirkland, W. B., Dobbs, J. H., and Moradi, L. G., 2016, "Team-Based Development of Medical Devices: An Engineering-Business Collaborative," ASME J. Biomech. Eng., **138**(7), p. 070803.

[8] Chien, S., Bashir, R., Nerem, R. M., and Pettigrew, R., 2015, "Engineering as a New Frontier for Translational Medicine," Sci. Transl. Med., **7**(281), p. 281fs213.

[9] Reyer, S., Williams, S., and Petersen, O., 2005, "Senior Design as a Transition From Academia to Industry," ASEE Annual Conference and Exposition, Portland, OR, June 12–15.

[10] Crabtree, R. A., Fox, M. S., and Baid, N. K., 1997, "Case Studies of Coordination Activities and Problems in Collaborative Design," Res. Eng. Des., **9**(2), pp. 70–84.

[11] Golecki, H. M., Amos, J. R., and Bradley, J., 2023, "Designing Capstone Experiences for Interdisciplinarity in Biomedical Engineering Education," ASEE Annual Conference and Exposition, Baltimore, MD, June 25–28.

[12] Augustin, D. A., Yock, C. A., Wall, J., Lucian, L., Krummel, T., Pietzsch, J. B., and Azagury, D. E., 2020, "Stanford's Biodesign Innovation Program: Teaching Opportunities for Value-Driven Innovation in Surgery," Surgery, **167**(3), pp. 535–539.

[13] Yock, P. G., Zenios, S., Makower, J., Brinton, T. J., Kumar, U. N., Watkins, F. T. J., Denend, L., Krummel, T. M., and Kurihara, C. Q., 2015, *Biodesign: The Process of Innovating Medical Technologies*, Cambridge University Press, Cambridge, UK.

[14] Trellinger, P. N., Buswell, Buswell, N. T., and Walter, D. M. E., 2019, "Designing Senior Design for Student-Led Projects With Large Enrollments," ASEE Annual Conference and Exposition, Tampa, FL, June 16–19.

[15] Tuttle, T. G., and Erath, B. D., 2017, "Design and Evaluation of a Mechanically Driven Artificial Speech Device," ASME J. Med. Devices, **12**(1), p. 011002.

[16] Denning, S. K., Valleau, M. A., Pelowski, W. J., Chaisson, C. M., Grimes, K. E., and Erath, B. D., 2021, "An Automatic Water-Occluding Device to Enable Laryngectomee Participation in Water Activities," PLoS One, **16**(9), p. e0257463.

[17] Davis, B. G., Shea, M., and Kuxhaus, L., 2018, "DART Brace: A Custom Solution for Early Mobilization," ORS Northeast Regional Symposium, Rochester, NY, July 27–28.

[18] Crady, S. D., Drapeau, K. E., Piersall, T. C., Cassady, E. A., Weisner, A. A., Robinson, D. A., Kuxhaus, L., Fite, K., Priganc, V., LaRue, J., and Kelso, M., 2017, "Wearable Rehabilitation: A Customizable Continuous Passive Motion Device for Early Phalangeal Mobilization," Summer Biomechanics, Bioengineering, and Biotransport Conference, Tucson, AZ, June 21–24.

[19] Bertocchi, A., Chrzan, B. P., Doerfler, B. N., Fenoff, T. M., Hambrose, G. J., Kudlacik, C. L., Slocum, K., Hawley, B. L., and Kuxhaus, L., 2018, "Skis and Treads: Products to Promote Independence for Manual Wheelchair Users in Winter Conditions," World Congress of Biomechanics, Dublin, Ireland, July 8–12.

[20] Anderson, A. D., II, Bosquet, B., Curry, M. M., Davis, B. G., Pelton, C. R., Robinson, C., Kuxhaus, L., Shea, M., and Priganc, V., 2017, "DART Brace: Daily Advanced Range of Motion Therapy for Maximizing Function," Summer Biomechanics, Bioengineering, and Biotransport Conference, Tucson, AZ, June 21–24.

[21] Brindisi, T., Costanzo, N., Griffin, M., Jacques, J., Kwiek, T., Macko, D., McGuffey, M., Miele, E., Starr, N., Whelley, M., Sha, T., and Fite, K., 2018, "Development of a Partial-Hand Prosthesis for Pediatric Amputees," World Congress of Biomechanics, Dublin, Ireland, July 8–12.

[22] D'Ambrosio, N., Haltermann, M., Mitchell, A., Tamura, K., Van Herwarde, K., and Erath, B. D., 2017, "Coughing for Better Health: A Prosthesis to Aid in Sputum Expectoration in Laryngectomees," Summer Biomechanics, Bioengineering, and Biotransport Conference, Tucson, AZ, June 21–24.

[23] Chaisson, C. M., Denning, S. K., Grimes, K. E., Pelowski, W. J., Valleau, M. A., and Erath, B. D., 2019, "Creating the Storkel: A Water Occluding Device for Accidental Submersion With a Tracheostoma," The Summer Bioengineering, Biomechanics, and Biotransport Conference (Virtual), June 17–20.

[24] Baldwin, M. R., Kaminiski, K. A., Hrdina, J. A., Cody, E. T., Gillespie, E. A., Tuttle, T. G., and Erath, B. D., 2016, "Substitute Voice Production Via a Mechanically-Driven Artificial Larynx," Summer Biomechanics, Bioengineering, and Biotransport Conference National, Harbor, MD, June 29–July 2.

[25] Shea, M., Davis, B. G., Priganc, V., and Kuxhaus, L., 2018, "Design, Validation, and Functional Testing of a Limited-Motion Wrist Brace," World Congress of Biomechanics, Dublin, Ireland, July 8–12.

[26] Barber, A., Eaton, E., Farmer, J., Gladd, S., Jagelski, N., and Lin, J., 2019, "Assistive Device for Muscular Degeneration in the Upper Arm," The Summer Bioengineering, Biomechanics, and Biotransport Conference, Seven Springs, PA, June 25–28.

[27] DeRidder, M. E., Freeman, D. A., McCann, M. A., Russ, J. A., Stewart, M. E., and Erath, B. D., 2020, "Stoma Submersion Security: A Precautionary Device for Accidental Water Submersion," Summer Bioengineering, Biomechanics, and Biotransport Conference (Virtual), June 17–20.

[28] Korth, H., Martin, R., Murphy, M., Reed, C., Sergeant, K., Williams, C., and Fite, K., 2020, "Adaptations of a Hockey Glove to Enhance Prismatic Prehensile Grasp for a User With Congenital Hand Impairments," Summer Biomechanics, Bioengineering, and Biotransport Conference (Virtual), June 17–20.

[29] Loughry, M. L., Ohland, M. W., and Woehr, D. J., 2014, "Assessing Teamwork Skills for Assurance of Learning Using CATME Team Tools," J. Mark. Educ., **36**(1), pp. 5–19.

[30] Layton, R. A., Loughry, M. L., Ohland, M. W., and Ricco, G. D., 2010, "Design and Validation of a Web-Based System for Assigning Members to Teams Using Instructor-Specified Criteria," Adv. Eng. Educ., **2**(1), pp. 1–28.

[31] Miller, I., Lamer, S., Brougham-Cook, A., Jensen, K. J., and Golecki, H. M., 2022, "Development and Implementation of a Biometrics Device Design Project in an Introductory BME Course to Support Student Wellness," Biomed. Eng. Educ., **2**(1), pp. 75–82.

[32] George, S. M., and Domire, Z. J., 2020, "A Six-Year Review of the Biomedical Engineering in Simulations, Imaging, and Modeling Undergraduate Research Experience," ASME J. Biomech. Eng., **142**(11), p. 111012.

[33] NASEM, 2017, *Research Experiences for STEM Students: Successes, Challenges, and Opportunities*, The National Academies Press, Washington, DC.

[34] Zhu, L., Eggleton, C., Ma, R., Topoleski, L. D. T., and Madan, D., 2020, "Establishing the Need to Broaden Bioengineering Research Exposure and Research Participation in Mechanical Engineering and Its Positive Impacts on Student Recruitment, Diversification, Retention and Graduation: Findings From the UMBC ME S-STEM Scholarship Program," ASME J. Biomech. Eng., **142**(11), p. 111010.

[35] NSF, "NSF 23-601: Research Experiences for Undergraduates (REU)," U.S. National Science Foundation, Alexandria, VA, accessed Aug. 5, 2023, https://new.nsf.gov/funding/opportunities/research-experiences-undergraduates-reu

[36] National Science Board, 2020, Vision 2030, National Science Foundation, Alexandria, VA.