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Evaluating a Sophomore-Level Medical Devices Course in Biomedical Engineering: Insights from a Multi-Year Study

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Abstract

To better prepare biomedical engineering undergraduates for the workforce, we developed a new, required, sophomore-level course, BMEG260: Introduction to Medical Device Design. This paper describes the course structure and provides a sample schedule and assignment templates. We report on the findings of pre- and post-course surveys administered across 3 years (2023-2025), a focus group with students who took the course in 2024, and a survey of seniors who took the course as sophomores. The pre- and post-course survey asked questions about biomedical engineering professional identity, career path and future aspirations, self-efficacy for teamwork, and self-efficacy for engineering design process skills. From the pooled 2023/2024 data, students' confidence in their engineering design skills significantly increased. We also measured unexpected declines in some dimensions related to identity and career path and future aspirations, which conflicted with the focus group findings. We speculated that the 2023/2024 survey data reflected a response-shift, so we presented a subset of the items using a retrospective format on the 2025 survey. The retrospective items all resulted in either statistically significant increases or no change, contrasting with the 2023/2024 survey results. Overall, the seniors agreed that the course was useful and provided a foundational experience that influenced their educational journeys and career aspirations in the biomedical engineering field. This study demonstrates not only the effectiveness of the BMEG260 course in increasing students' confidence in their engineering design skills but also highlights how the design of measurement instruments significantly affects the interpretation of the findings. Using multiple assessment measures and a retrospective survey design can lead to more robust interpretations.

1 Introduction

Biomedical engineering (BME) education must prepare trainees to meet the nation's workforce demands. Here, we describe three gaps we believe are limiting our BME students' preparation for careers in industry and offer a critical reflection of our own program's undergraduate curriculum. To attempt to address these gaps, we introduced a new, required course into our curriculum.

1.1 Workforce-relevant skills gap

To prepare biomedical engineering undergraduates for the workforce, we must understand the skills employers are seeking. When evaluating job postings relevant to biomedical engineering students, Jamison et al. identified technical documentation or communication, quality, and design and development as commonly listed job responsibilities [1]. "Collaborative team player" and computer-aided design (CAD) software, including SolidWorks, were listed as common qualifications [1]. Similarly, through mining job advertisements for skills listed in the O*NET database [2], another study identified CAD/SolidWorks (17%) and FMEA (14%, failure mode and effects analysis, an element of engineering design and regulatory affairs) as frequently listed technical skills and problem solving (61%), systems analysis (60%), and coordination (27%, an element of teamwork) as frequently listed professional skills for biomedical engineering bachelor's-level job postings [3]. O*NET defines systems analysis as "Determining how a system should work and how changes in conditions, operations, and the environment will affect outcomes" [2]. Consistent with these prior findings, medical devices industry members surveyed at the 2024 Council of Chairs Biomedical Engineering Educational Summit indicated preferences for hiring employees with skills in CAD, manufacturing, and regulatory affairs [4]. Taken together, to be successful in industry, biomedical engineering undergraduates must develop skills in CAD, regulatory processes, the engineering design process, and teamwork.

These skills may be developed through specifically developed courses or activities, guest speakers integrated into existing courses, certificates, micro-credentialing, projects (particularly industry-sponsored), or co-curricular programs [4], [5], [6]. These skills are often embedded into senior design capstone courses, but a single exposure at the end of the curriculum is likely insufficient [7]. Others have described course sequences that cover these topics. For example, Adamo et al. describe a two-semester course sequence that covers medical device FDA regulatory affairs, intended for Master's students [8], LaMack et al. describe a course covering professional topics (including regulations, standards, quality, and documentation) that precedes capstone [9], and Ebenstein et al. describe four courses spanning junior and senior years that cover topics such as regulatory, teamwork, CAD, and design [10]. Our prior curriculum lacked sufficient instruction on these topics, and the instruction we did have was late in the students' studies (junior and senior years).

1.2 Professional identity and self-efficacy gap

A focus group study in our College of Engineering revealed that our BME undergraduates struggled to identify as engineers [11]. Engineering professional identity is generally defined as the extent to which individuals view themselves as engineers [12]. It includes elements of interest, recognition by others, and performance/competence [13]. A unique intersection of disciplines, prior work has shown that biomedical engineers strongly identify as both engineers and scientists, with recognition from others being the strongest predictor of professional identity [14]. Group situations influence salient identity [15], which indicates that team projects have the potential to shift how students view themselves as engineers. Identity is important because it influences behavior [15].

Self-efficacy also influences behavior [16]. Self-efficacy relates to professional identity formation but is a distinct construct [12], [13]. Defined by Bandura as "beliefs in one's capabilities to organize and execute the courses of action required to produce given attainments" [17], perceived self-efficacy is often considered a measure of an individual's confidence in their task-specific abilities. What an individual thinks they can do (not just what they actually can do) is associated with their academic performance, sense of belonging, perceived help-seeking, effort, and critical thinking behavior [18], [19], [20]. Mastery experiences are particularly important for self-efficacy development [20].

Prior work has demonstrated that engineering identity and its subdimension of performance/ competence beliefs hit lows in the second year of engineering undergraduates [21]. Consistent with this finding, other studies describe the phenomenon of the "sophomore slump," in which student performance, persistence, and enjoyment of classes decline in the second year [21], [22]. Because of the high number of prerequisite courses, biomedical engineering-specific coursework may be delayed until junior year [23]. These findings suggest that the sophomore year warrants additional attention to ameliorate these declines. We were particularly interested in measuring biomedical engineering identity, engineering design process self-efficacy, and teamwork self-efficacy (two industry-valued skills, noted above) in sophomore biomedical engineering students.

1.3 Knowledge of career opportunities gap

Compared to other engineering disciplines, biomedical engineering is an especially broad field, and many students enter with narrow or preconceived notions, which makes it even more important to deliberately educate students about the profession [24]. Consistent with this notion, prior feedback from both our biomedical engineering alumni and current students indicated a desire for more career guidance, which aligns with alumni and student feedback reported from other biomedical engineering programs [23]. Although biomedical engineering undergraduate students increase their knowledge of career opportunities over the course of their academic training, further work is needed in helping students identify and explore these opportunities [25]. Pierrakos et al. noted four themes that distinguished first-year engineering students who persisted in engineering from those who switched out: knowledge of the profession and exposure to engineering, interest in engineering and influences to enter the major, sense of preparedness, and sense of belonging and fit [15]. Although this prior study focused on first-year students, it highlights the value of providing opportunities for students to gain practical knowledge about the engineering profession. We sought to increase our biomedical engineering students' awareness of career opportunities in the medical devices industry.

1.4 Existing curriculum

Our existing biomedical engineering undergraduate curriculum and electives already contained several biomedical engineering design-focused courses:

- *Biomedical Engineering Senior Design* (BMEG450, 6 credits), our required, interdisciplinary engineering capstone course [26]. Students work in teams to develop real-world solutions to unmet needs sponsored by local clinicians, industry, or academics.
- *Biomedical Engineering Junior Design* (BMEG360, 3 credits), a required course that models senior design but is comprised of only biomedical engineers and introduces students to prototyping skills, in addition to working through the engineering design process.
- *Clinical Immersion for Engineers* (BMEG350, 3 credits), an elective course offered during our abbreviated Winter session term (January) [27]. Students spend 100 hours shadowing at a local clinical site and documenting unmet clinical needs. Students do not develop prototypes or solutions, but sometimes these needs become future senior design projects.
- *Medical Device Development* (BMEG464, 3 credits), an elective course for juniors and seniors. It focuses on the design process from research and development to regulations and commercialization. It is intended for students who plan to enter the medical device industry. Students do not identify unmet needs or generate prototypes.

Our required design sequence was dense and back-loaded (spring junior year and fall senior year), lacking any design exposure in the sophomore year. Although the existing junior and senior design courses were team-based, students did not learn about the roles an engineer may have working on a medical device team in industry. Alumni feedback frequently noted the absence of CAD in the curriculum as a weakness that needed to be addressed — indeed, our CAD instruction was limited to a single lesson and introductory assignment in Biomedical

Engineering Junior Design. Valuable, industry-relevant skills, such as needs-finding and regulatory affairs, were limited to elective courses.

1.5 Goals

To address these gaps, we developed a new course, BMEG260: Introduction to Medical Device Design, which leveraged industry and clinical connections. Overall, the objectives of incorporating this new course into the core undergraduate biomedical engineering curriculum were to

- Increase students' industry-relevant skills and confidence in those skills (engineering design process, CAD, FDA/regulatory, teamwork)
- Increase students' biomedical engineering professional identity, and
- Introduce students to the variety of career opportunities within the medical devices industry.

These overarching objectives are separate from, but in alignment with, the six course learning goals stated in [28], which first described the course. In the current paper, we build upon this prior work by expanding on details of the course design and providing multi-year evaluation results of students' self-efficacy and professional identity.

2 Methods

Here we describe the course design, its rationale, and evaluation.

2.1 Course Details

BMEG260: Introduction to Medical Device Design was piloted with 10 students in spring 2022, as described in [28]. Since then, the course has been taught annually in spring semester and is required of all biomedical engineering undergraduate students. This paper focuses on the 2023, 2024, and 2025 iterations of the course (enrollments: 44, 50, 53 students). The course is structured to meet three times a week, divided into two 55-minute lectures with the full class and one 125-minute studio. There are three studio sections for the course. The highest studio enrollment during this time period was 19 students. The course learning goals were described previously [28]. The course introduces students to the engineering design process with a focus on defining the need and design inputs, benchmarking, and failure analysis; SolidWorks; FDA regulatory processes to market medical devices in the United States; high-impact teamwork practices; ethical and professional responsibilities; and roles and tasks in the medical devices industry.

As described above, our existing curriculum already contained both a junior and senior design course, in which students work through the full engineering design process to design, prototype, and test a new product to solve an unmet need. Therefore, BMEG260 focuses on how existing medical devices work, the decisions required to bring these products to market, and current challenges associated with these devices (unmet needs). Each year, we work through three different medical device units (**Table 1**). Each unit lasts approximately 4 weeks. A sample course schedule is provided in **Appendix A**.

Table 1. Medical Device Units

Year	Medical Device Units
2023	1. Wearable EMG Biofeedback Device 2. Breast Pumps 3. Stents
2024	1. Surgical Staplers 2. Breast Pumps 3. Cochlear Implants
2025	1. Surgical Staplers 2. Continuous Glucose Monitors 3. Stents

The six medical device units that were developed were chosen based on several factors:

- Availability of clinical contacts and medical device users for voice of the customer videos (described below)
- Industry contacts who work at companies that develop these devices
- Availability of products for the students to interact with
- A physical component that could be measured and modeled in CAD
- Demonstration of different engineering fundamentals (e.g., mechanics, instrumentation, signals, chemical processes, materials, etc.)
- Different FDA classifications

2.1.1 Course Delivery Format

The lectures focus on content that will be important to the unit deliverables (e.g., design inputs, failure analysis, etc.) and guest speakers. The guest speakers, who vary by year and topic, often come from the medical devices industry. Many of the course topics are mapped to sections of the textbook *Biomedical Engineering Design* by Tranquillo, Goldberg, and Allen [29]. Several lectures are set aside as work time for SolidWorks lessons.

The SolidWorks lessons are delivered primarily through asynchronous video recordings that students watch individually. Each asynchronous lesson has a “check” activity that students submit to ensure they were able to follow along with the video. The CAD skills students develop through these lessons are then applied to their individual CAD assignments throughout the semester and to their team deliverables for each medical device unit.

Studios are used to kick off each medical device unit with an interactive lesson, either in stations or “labs.” For example, the surgical stapler unit contains a lab led by industry representatives where students use actual surgical staplers on tissue. In the breast pumps unit, each student team receives a breast pump and attachments and is asked to non-destructively explore (assemble the pump and attachments, use it on a balloon, wash with soap and water, etc.). In a separate lesson, each studio section performs a destructive dissection of a breast pump as a whole class to visualize the internal components. The stent, cochlear implant, and continuous glucose monitor units each include an overview lesson with 5-6 stations set up throughout the classroom. Students rotate through the stations, engaging in activities such as role playing, creating physical models using craft supplies, drawing pictures or comics, examining and comparing products, interpretating data, reading or watching videos, etc. to learn background on the relevant anatomy/physiology and current devices. Once the station is completed, the instructor or teaching assistant signs the student's "passport." When not used for a new unit overview lesson, the extended duration weekly studios typically include a short instructional component, often focused on project management or high-impact teamwork skills, with the remaining time for students to work in their teams and make progress toward their unit deliverables.

2.1.2 Student Teams

Students are divided into teams of 3-4 (using CATME Team-Maker tool [30]) and retain these teams for the entire semester. At the start of the semester, students define medical devices industry-based job titles and roles for each team member (e.g., quality engineer, new product development engineer, regulatory affairs specialist, etc.). They rotate these roles for each unit. Separate assessments are being conducted to evaluate the efficacy of these job titles/team roles and are not the focus of this paper.

2.1.3 Voice of the Customer Videos

Corresponding with each medical device unit are "voice of the customer (VoC) videos," recorded interviews with users of these medical devices, such as clinicians, patients, or researchers. Each unit has 4-9 corresponding VoC videos that the students are asked to watch and subsequently reference in their team deliverables. These VoC videos have been described in detail previously [31] and are available online at https://sites.udel.edu/meddevicesvoc/. As described in our prior work, students use the VoC videos to inform their development of need statements and design inputs [31]. The VoC videos help students develop empathy for users of medical devices and engage in the course content [31].

2.1.4 Student Team Deliverables

At the end of each medical device unit, student teams submit a series of deliverables. Templates for some of these deliverables were adapted from actual forms used at a medical device company.

- *F01- Product Initiation Request Form:* Combining the VoC videos with additional background research, students propose a need statement, regulatory strategy, clinical context, and testing requirements to address a challenge related to the existing medical devices on the market.
- *F02- Design Inputs:* Students propose functional and design requirements to address their need statement and justify these with VoC videos, background research, and engineering standards.
- *F03- Design Details:* Students choose a specific existing product and describe its form and function (how it works), engineering justifications, and relevant patents. Because this is a sophomore-level course, the students have not yet taken the core biomedical engineering courses (e.g., mechanics, instrumentation, etc.) necessary for deep engineering analysis. Therefore, one section of this form asks students to list a necessary design justification or calculation and align it with their future coursework (which future course(s) do they think will teach them how to do this engineering analysis), serving as a motivator for their future coursework.

- *F04- Failure Mode and Effects Analysis (FMEA):* Students choose a specific existing product, identify potential failure modes, effects, and causes, and rate severity and occurrence to calculate a risk priority number (RPN). They propose ways to mitigate these risks. They apply the FDA MAUDE database to help them brainstorm potential failures.
- *F05- CAD Model:* Students use calipers and radius gauges to measure components of an existing product and create a model and/or assembly (depending on the unit) in SolidWorks.

These deliverables repeat but build with each unit as students continue to learn. For example, in the first unit, the students have not yet learned about engineering standards, so the F01 and F02 templates for unit 1 do not ask students to identify relevant standards. Similarly, F04 is not included in unit 1. Unit 3 templates for forms F01-F04 are provided in **Appendix B**.

2.2 Evaluation

The evaluation protocol was submitted to and granted exempt status by the University IRB. Three different assessments were implemented: pre- and post-course surveys, a survey of seniors who had taken BMEG260 as sophomores, and focus groups with students at the end of the semester. The purpose of these assessments was to evaluate students' biomedical engineering identity, self-efficacy, and opinions of the course.

2.2.1 Pre- and Post-Course Surveys

Students enrolled in BMEG260 were asked to complete a survey at the start (pre-survey) and end (post-survey) of the semester. The purpose of the survey was to evaluate students' biomedical engineering identity, teamwork self-efficacy, engineering design skills self-efficacy, and career goals. The survey was administered through a Qualtrics link sent by a professional external evaluator directly to the enrolled students' email addresses. Participation was voluntary, and no identifiable information was collected. The instructor set aside time on the first (pre) and last (post) classes to complete the survey. Multiple follow-up emails were sent to increase the response rate. Unique identifiers were created to match pre- and post-survey responses.

The survey was implemented in 2023 and 2024 (**Appendix D**). The survey was also implemented in a modified form in 2025 (described further in the Results section, **Appendix E**). Using or adapting previously published instruments, the pre- and post-course survey asked questions about 1) biomedical engineering professional identity, 2) career path and future aspirations, 3) future career plans, 4) self-efficacy for teamwork, and 5) self-efficacy for engineering design process skills.

Biomedical engineering identity was assessed using a modified version of the Measure of Engineering Identity (MEI) instrument by Godwin [13] that replaced "engineer/engineering" with "biomedical engineer/engineering." Eleven items were answered on a seven-point Likert scale ranging from 0 ("*Strongly disagree*") to 6 (*"Strongly agree"*). The MEI contains two three-item and one five-item subscales, each measuring a different dimension of engineering identity:

- Recognition – students' feeling of recognition by others;
- Interest – students' interest in the subject; and
- Competence – students' beliefs about their performance/competence in the subject area.

Respondents were asked to rate, "*To what extent do you agree or disagree with the following statements*?" Responses to the three subscales were summed and averaged separately, and respondents received a score for each subscale.

Students' career path and future aspirations were assessed using a modified version of the Rohde et. al 2018 survey instrument [32]. Again, “engineer/engineering” was replaced by “biomedical engineer/biomedical engineering.” Eleven items were answered on a seven-point Likert scale ranging from 0 ("*Strongly disagree"*) to 6 (*"Strongly agree"*). The Rohde instrument contains one four-item, two three-item, and one single-item subscales, each measuring a different dimension of career aspirations:

- Perceptions of Future – the extent to which students have a positive attitude towards their future in biomedical engineering;
- Perceived Instrumentality – perceived utility of the specific academic task in the present;
- Belongingness – perceptions of belonging within biomedical engineering to include a sense of community and general perceptions of fit within the field; and
- Identity – seeing oneself as a biomedical engineer.

Respondents were asked to indicate the extent to which each item describes them. Responses to the four subscales were summed and averaged separately; respondents received a score for each subscale.

Post-undergraduate plans were assessed through an open-ended question: “*What is your desired post-graduate job?”*

Self-efficacy for teamwork was assessed using a revised version of the Personal Efficacy Beliefs Scale (PEBS) [33] that replaced “job” with “team or teamwork.” PEBS assesses an individual's comfort with and motivation to exhibit behaviors that facilitate their job performance, or in our case, teamwork. Ten items were answered on a five-point Likert scale ranging from 1 (*"Strongly Disagree"*) to 5 (*"Strongly Agree"*). Items were summarized; respondents received an overall teamwork self-efficacy score.

Self-efficacy for engineering design process skills was measured using a modified version of Carberry's Design Self-Efficacy Instrument [34]. Questions were asked under four primary categories: (1) self-efficacy (measured as confidence), (2) motivation, (3) ability to succeed (measured as success), and (4) anxiety to conduct engineering design. For each of these categories, respondents were asked to provide a rating, using a 11-point scale anchored from 0 to 100, in nine subcategories: (1) conduct biomedical engineering design (modified from original instrument), (2) identify a design need, (3) research a design need, (4) develop design solutions, (5) select the best possible design, (6) construct a prototype, (7) evaluate and test a design, (8) communicate a design, and (9) redesign. Each of the four categories was summed and averaged separately. Respondents received a composite score across subcategories for the four primary categories.

Data from 2023 and 2024 survey responses were pooled. A Shapiro-Wilk test was conducted to test for normality, and paired t-tests were used to examine score changes from pre- to post-survey.

2.2.2 Seniors Survey

At the end of the fall semester in 2024 and 2025, upon completion of senior design, a survey was administered to the senior biomedical engineering students who had taken BMEG260 as sophomores (i.e., in spring 2023 or spring 2024). Three Likert-based questions on a 0 (*"Strongly Disagree")* to 6 scale ("S*trongly Agree"*) were adapted from the perceived instrumentality subscale of the Rohde et al. instrument [32] to gather a retrospective snapshot of how helpful the students perceived BMEG260 to be now that they had completed their entire biomedical engineering design sequence. A link to the survey was emailed to 42 students in 2024 and 46 students in 2025. Descriptive statistics are presented. Additionally, one open-ended question asked students to describe the impact (if any) the BMEG260 Introduction to Medical Design Course had on their future plans and preparation for these plans.

2.2.3 Focus Groups

Brief focus group discussions conducted by a professional external evaluator were held with the 2024 BMEG260 students to learn about their experiences in the course. The course instructor was not present to minimize bias. The discussion questions are in **Appendix C**. Due to the number of students enrolled in the course (n = 50), three discussions were held with the students. Each discussion took place during the studio section of the course. All discussions occurred in person at the end of the semester. Discussions were audio-recorded with the students' permission and transcribed by a professional transcription service. The transcripts were examined using thematic analysis. Excerpts are provided to support thematic areas. The "clinician/patient videos" questions and findings have been reported previously [31] and therefore are not reported here.

3 Results

Here, we present the results of the pooled 2023 and 2024 pre-post surveys, the 2025 pre-post survey (modified from previous years), the seniors survey, and the focus groups.

3.1 Pre- and Post-Course Survey Results

Results from the pooled pre- and post-course survey responses from 2023 and 2024 are presented. Because some of these results were surprising, we suspected that we may be capturing a response-shift. Therefore, we modified the survey design for the 2025 implementation. We describe the 2025 survey modifications, rationale, and results.

3.1.1 2023 and 2024 Pooled Survey Results

From the pooled data, we measured unexpected, statistically significant decreases in students' interest and self-reported competence in biomedical engineering (**Figure 1**), their perception of the future related to their career interest in biomedical engineering (**Figure 2**), and perceived instrumentality of what they were learning (**Figure 2, Appendix D**).

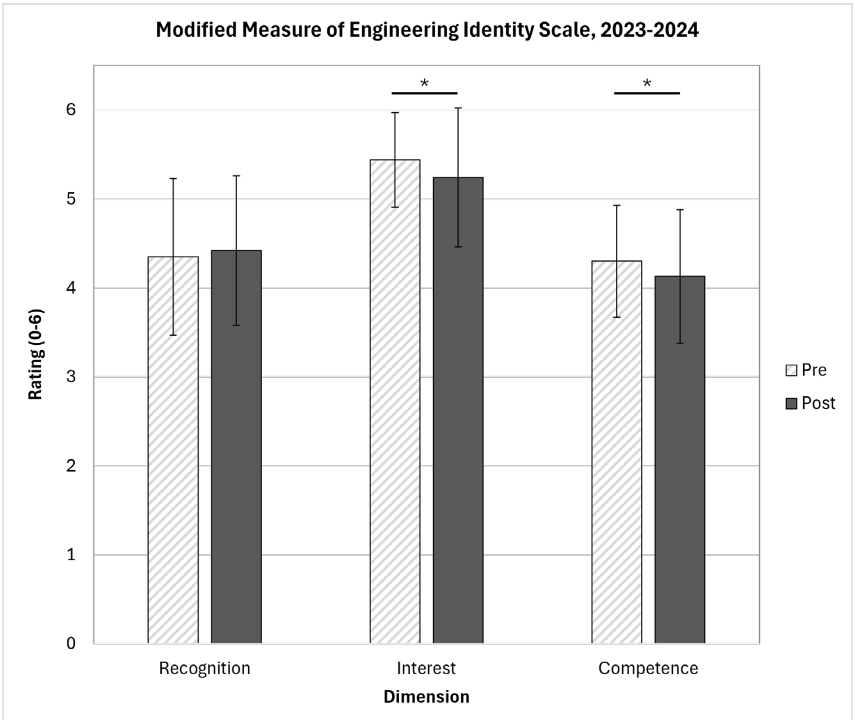

Figure 1. Pre- and post-survey responses from 2023 and 2024 pooled. **Biomedical engineering identity** demonstrated statistically significant declines in the subscales of interest and competence ($n = 58\text{-}59$). Mean ± standard deviation. * $p < 0.05$

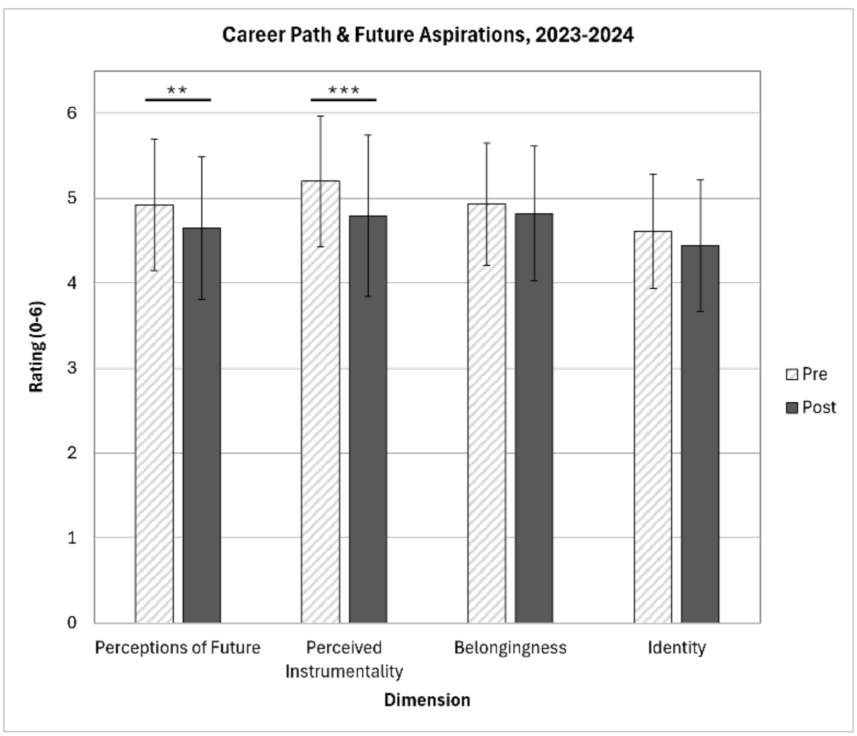

Figure 2. Pre- and post-survey responses from 2023 and 2024 pooled. **Career path and future aspirations** demonstrated statistically significant declines in the subscales of perceptions of the future and perceived instrumentality ($n = 59$). Mean ± standard deviation. ** $p < 0.01$, *** $p < 0.001$

The items that drove these decreases (i.e., the individual items that demonstrated statistically significant declines) were as follows:

- Interest
    - I am interested in learning more about Biomedical engineering.
    - I enjoy learning Biomedical engineering.
- Competence
    - I can do well on exams in Biomedical engineering.
    - I understand concepts I have studied in Biomedical engineering.
- Perceptions of the future
    - My interest in a biomedical engineering major outweighs any disadvantages I can think of.
    - I want to be a biomedical engineer.
- Perceived Instrumentality
    - I will use the information I learn in my biomedical engineering course in other classes I will take in the future.
    - I will use the information I learn in this biomedical engineering course in the future.
    - What I learned in my biomedical engineering course will be important for my future occupational success.

Teamwork self-efficacy was unchanged (mean: pre = 3.93/5, post = 3.90/5, n = 57, **Appendix D**). On the other hand, we measured statistically significant increases in students' confidence in their engineering design skills (overall and across all skills) and a decrease in their anxiety towards these skills (overall and in conducting biomedical engineering design, identifying a design need, and researching a design need, **Figure 3, Appendix D**).

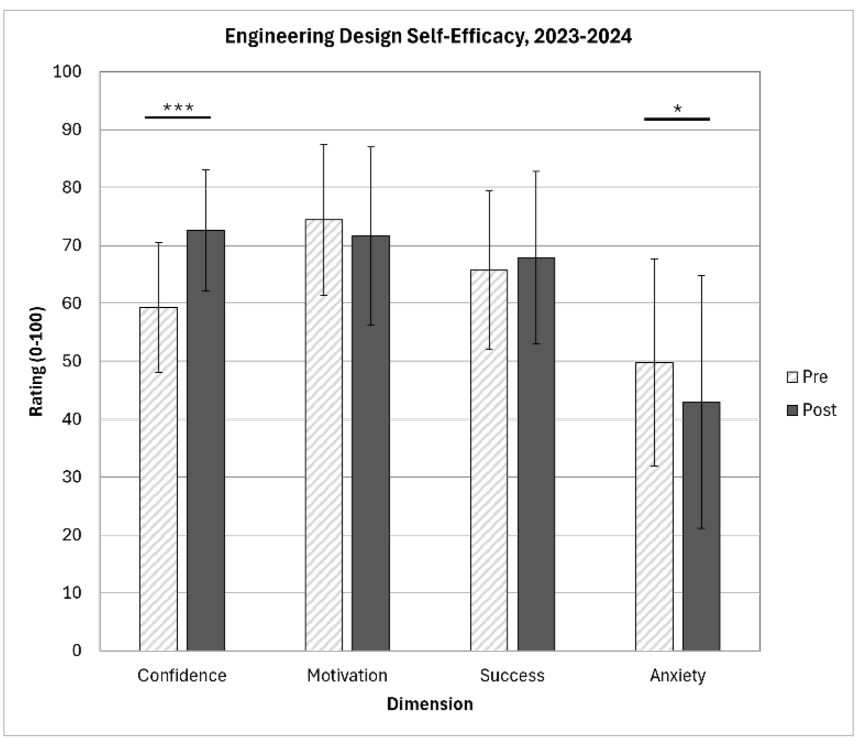

Figure 3. Pre- and post-survey responses from 2023 and 2024 pooled. **Engineering design self-efficacy** demonstrated a statistically significant increase in confidence and decrease in anxiety (n = 54-56).
Mean ± standard deviation.
* $p < 0.05$, *** $p < 0.001$

3.1.2 2025 Survey Re-Design to Address Response-Shift

Because of the surprising declines measured in the 2023/2024 surveys and the incongruence with the focus group findings (described below), we speculated that the survey data were reflecting a response-shift, which occurs when a participant's internal frame of reference changes between measurement time points [35]. Changes in attitudes, beliefs, and expectations are common in educational settings, which can lead to inaccurate pre-test ratings and make it difficult to estimate intervention effects. A response-shift is particularly relevant in STEM education, where students often overestimate their initial skills before engaging with technical material [36].

For example, a student may rate an interest in a topic as high before they engage in a new course; this initial rating is based on a limited understanding of the subject. After completing the course, the student's concept of the topic may become deeper and more complex; therefore, the student may now believe their previous "high" interest was really only "moderate" compared to their new, more sophisticated understanding. The lower interest level that they report on the post-survey represents their expanded understanding and does not mean that the course reduced their interest.

The concept of response-shift may apply to competence, perceived utility, and interest ratings. A prior study evaluating a master's nursing program concluded that a traditional pre-post survey study design would have underestimated the impact to student outcomes ("competence"), and a retrospective study design was a more accurate indicator of change [37]. Eccles et al.'s expectancy–value framework emphasizes that interest and utility value are shaped by learners' experiences, interpretations of task demands, and evolving goals [38]. Because utility value depends on how a learner connects an activity to goals that they are still forming, early ratings may be based on incomplete or inaccurate conceptions of the task. Similarly, interest judgments made before meaningful engagement can reflect stereotypes, expectations, or surface features—not the experienced task itself. As a result, students' initial ratings of these constructs prior to substantive engagement may reflect incomplete or naïve conceptions rather than informed judgments [38]. Consequently, changes in students' reported interest or perceived utility following instruction may reflect changes in the meaning of these constructs for students, consistent with a response-shift [35].

To remedy the potential effect of a response shift in our own survey results, in the 2025 post-course survey, we presented a subset of the items using a retrospective format, a commonly recommended way to attenuate this effect [35]. At the end of the course, the respondents rated the extent to which they agreed with each statement before taking BMEG260 ("then") and after taking BMEG260 at the time of the survey ("now"). The 11 statements that were presented in a retrospective format are as follows:

- All 3 items on the interest subscale of the Measure of Engineering Identity [13]
    - I am interested in learning more about Biomedical engineering.
    - I enjoy learning Biomedical engineering.
    - I find fulfillment in doing Biomedical engineering.
- 3/5 items on the competence subscale of the Measure of Engineering Identity [13]
    - I am confident that I can understand Biomedical Engineering in class.
    - I am confident that I can understand Biomedical engineering outside of class.
    - I understand concepts I have studied in Biomedical engineering.

- 2/4 items on the perceptions of the future subscale of the Rohde et al. survey [32]
    - My interest in a biomedical engineering major outweighs any disadvantages I can think of.
    - I want to be a biomedical engineer.
- All 3 items on the perceived instrumentality subscale of the Rohde et al. survey [32]
    - I will use the information I learn in my biomedical engineering course in other classes I will take in the future.
    - I will use the information I learn in this biomedical engineering course in the future.
    - What I learned in my biomedical engineering course will be important for my future occupational success.

Additionally, because teamwork self-efficacy findings were stable (unchanged), we removed the teamwork self-efficacy questions from the 2025 survey and instead added new questions about empathy in design, as previously described and reported in [31].

3.1.3 2025 Survey Results

The 2025 post-survey contained both retrospective questions and not. **Figures 4-6** depict the 2025 findings, where the "pre" bars are a combination of the true pre-survey responses for questions that did not have a retrospective format on the post-survey and the "then" questions for those questions that were posed in a retrospective format on the post-survey. The retrospective items all resulted in either statistically significant increases or no change, contrasting with the 2023/2024 survey results (**Appendix D, Appendix E, Appendix F**).

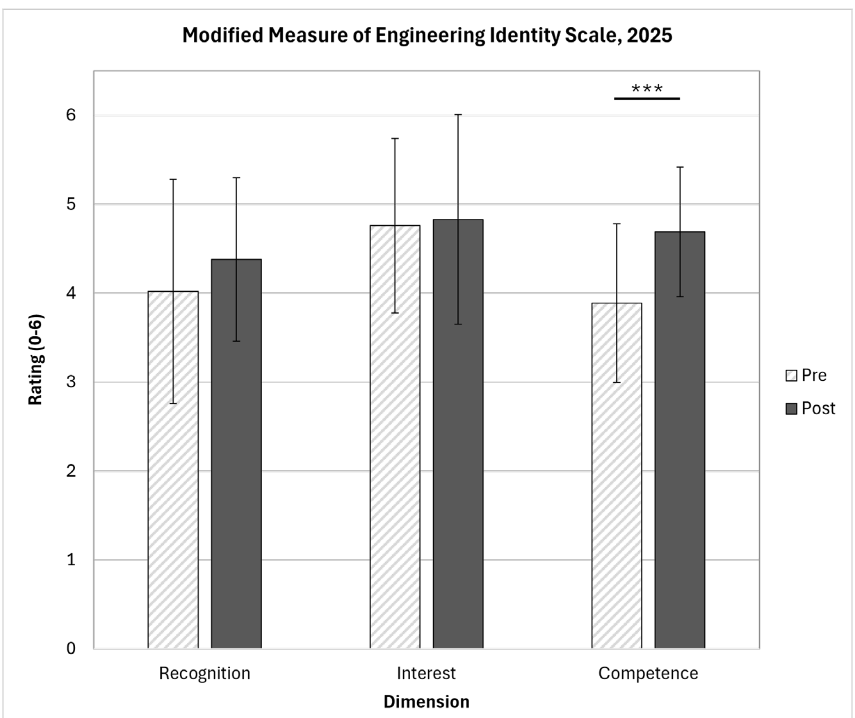

Figure 4. Pre- and post-survey responses from 2025. **Biomedical engineering identity** demonstrated a statistically significant increase in the subscale of competence (n = 34). This result contrasts the declines measured in 2023/2024. Recognition: all 3 questions not retrospective; Interest: all 3 questions are retrospective; Competence: 3/5 questions are retrospective.
Mean ± standard deviation.
*** $p < 0.001$

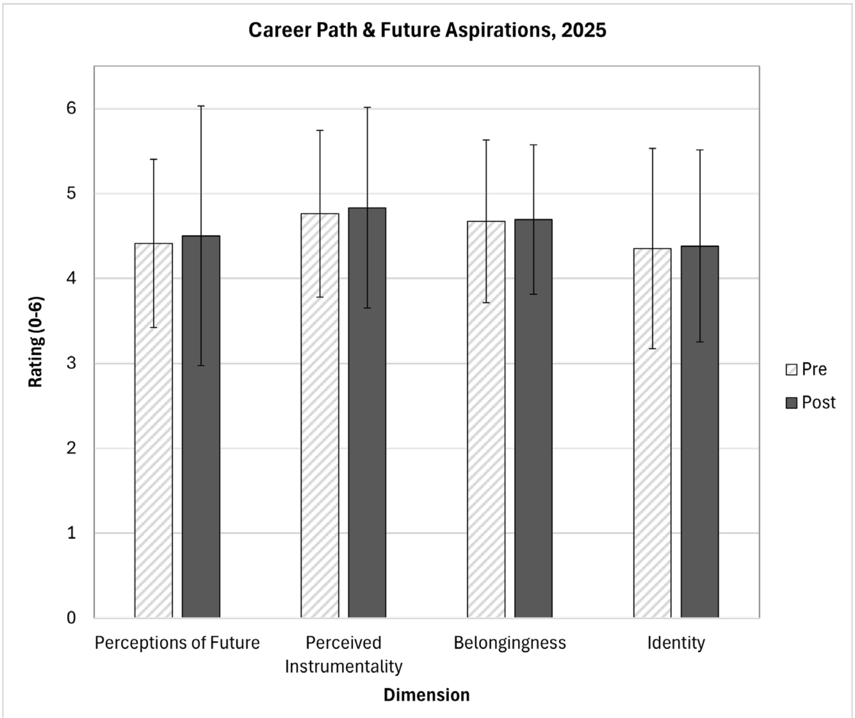

Figure 5. Pre- and post-survey responses from 2025. **Career path and future aspirations** demonstrated no statistically significant changes (n = 34). This result contrasts the declines measured in 2023/2024. Perceptions of Future: 2/4 questions are retrospective; Perceived instrumentality: all 3 questions are retrospective; Belongingness: all 3 questions are not retrospective; Identity: not retrospective
Mean ± standard deviation.

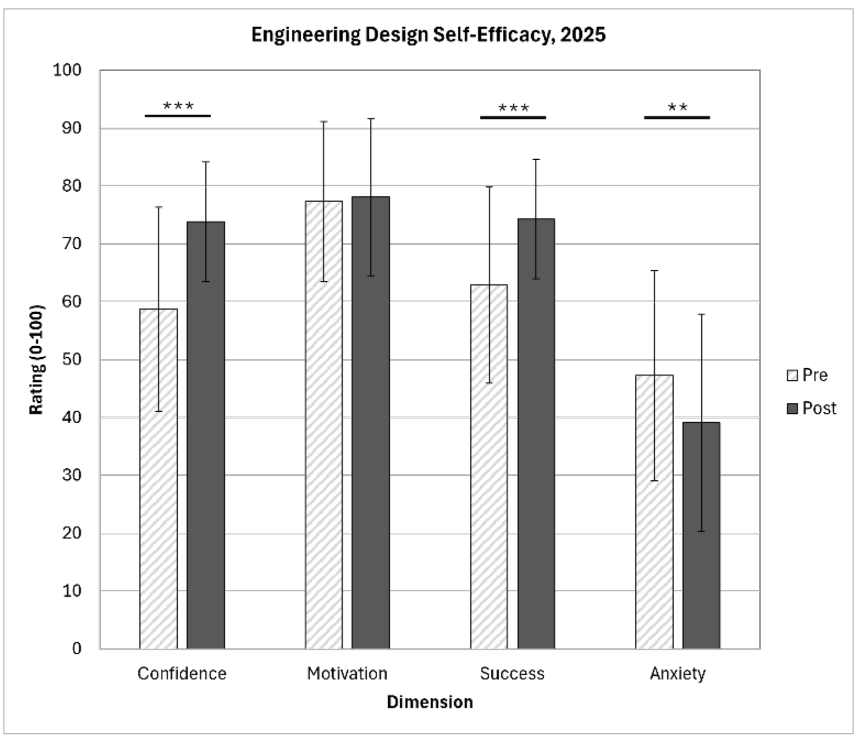

Figure 6. Pre- and post-survey responses from 2025. **Engineering design self-efficacy** demonstrated statistically significant increases in confidence and anticipated success and decreased anxiety (n = 34). No retrospective questions.
Mean ± standard deviation.
** $p < 0.01$, *** $p < 0.001$

To explore how students' career aspirations may have evolved throughout the semester, an open-ended item, "*What is your desired post-graduate job?*" was included on both the pre- and post-surveys. Student's career aspirations spanned a diverse range of paths. While most students did not shift their career fields of interest, many refined or clarified their goals, suggesting that the course experience supported deeper reflection and career exploration. It was not uncommon to see the job titles discussed and simulated in class (e.g., field engineer, R&D or product development engineer, project manager, quality engineer, technical sales representative) reflected in the post-survey responses. The course may have helped students refine vague interests into specific, actionable goals.

3.2 Seniors Survey Results

Additionally, we surveyed seniors who had taken BMEG260 as sophomores to assess the perceived instrumentality of the BMEG260 course. Overall, the seniors agreed that the course was useful (**Table 2**).

Table 2. Seniors Survey Results, Mean (Standard Deviation)

	2024 (n = 20)	**2025** (n = 24)
Perceived Instrumentality (0-6)	**4.95 (1.03)**	**4.64 (1.01)**
I used the information I learned in my **BMEG260 Introduction to Medical Device Design** course in other classes I have taken since.	5.40 (0.82)	4.88 (0.99)
I will use the information I learned in my **BMEG260 Introduction to Medical Device Design** course in the future.	5.10 (1.07)	4.71 (0.99)
What I learned from my **BMEG260 Introduction to Medical Device Design** course will be important for my future occupational success.	4.35 (1.69)	4.33 (1.27)

Open-ended responses supported that the course provided a foundational experience that influenced students' educational journeys and career aspirations in the biomedical engineering field, with themes such as skill acquisition, increased confidence, and clarification of career opportunities. For example:

"BMEG260 introduced me to the medical device industry and regulatory affairs, which led me to apply to medical device engineering companies and roles where I would get to interact with them. I will be working with medical devices in my first job."

"Medical Device Design helped provide necessary experience for going into Junior and Senior Design. The design skills and processes I learned in that class have been applicable to every project I have had since then, and will continue to have in school and industry going further. The actual projects in the course helped clarify my goals in what I wanted to pursue through my research."

"I appreciated that we learned about so much FDA regulatory stuff early on, as well as the introductory Solidworks lessons. These tasks were definitely grueling while in the course - <u>if you had asked me how much I appreciated that knowledge as soon as sophomore spring was over I would've said that it was wholly unnecessary</u>. However, now having completed junior and senior design as well as Dr. [redacted]'s Medical Device Development course, that knowledge has

really helped me become a better biomedical engineering student." (underlines added for emphasis)

The underlined section of the last comment highlights how the impact of an intervention may not be realized until later, once students have more experience and are able to see a bigger picture.

3.3 Focus Group Results

The 2024 focus groups identified the **guest speakers, hands-on activities, and CAD lessons** as the most helpful aspects of the course, aligning with 2022 findings [28]. For example:

"I thought that the guest speakers that we had were a good way to see how the stuff that we're doing as a team is reflected in the real world. It was a good way to see how the things that we're doing in a project correlate to what you might actually be doing in a job like that."

"I think a lot of the things like <professor name removed> tried to incorporate a lot of hands-on things too. We had a lab where we stapled [ ] stomachs with the medical staplers so we could actually realize what they were doing and she had fake skin for us to staple. We used a breast pump on a balloon, we took apart the devices. So I feel like actually being able to do it with your hands helped me a lot, learn more about what we're actually making and what we're doing in our career."

"I think for the CAD material specifically, the recordings that <name removed> does to walk us through them were really helpful, especially at the beginning when we were just starting to learn what SOLIDWORKS were."

Students were asked a series of questions about **working in teams**. Students found that simulating industry-relevant job roles on their team helped them understand the interconnectedness of different tasks and the importance of teamwork. Some students emphasized how participating in different roles was beneficial in understanding the variety of job options available, and it exposed them to tasks they found unpleasant, creating a mixed experience. At the same time several students discussed that having the roles was not instrumental as they did not adhere to them, defeating the purpose of the roles in the first place. For example:

"It was interesting to see how my group's like three people and we each have a different role that we assign to our document, but each of us still has to talk to each other while we do each part. So it's interesting to see they're still connected and you still need other people to complete your aspects."

"I feel like our group kind of stuck to the roles pretty strictly and I feel like it was good in the way that you get to see the different types of roles or the jobs that you could do, but it was also kind of negative and that like while you were doing one you could be like, 'Wow, I really don't want to do this in the future. This kind of sucks.' So I feel like it was a double-edged sword."

"Because I think what we did was we picked roles that we seemed that we would be interested in and then we kind of found that we were good at it and then we kind of stuck with that. Because it was very efficient at least for getting the project done and also producing the best quality work that we can rather than experimenting with different roles or learning. Occasionally we would cross talk and check each other's work and sort of help each other out with other aspects of the

project. But I feel like at least with my group, I feel like we mostly stuck to whatever roles that we had from the beginning."

In contrast to the survey outcome of decreased engineering identity, in the focus groups, the students emphasized how the practical activities in the course impacted the **development of their engineering identities** and helped them identify **career paths** that they were or were not interested in. For example:

"I was going to say I definitely feel like this course felt more applicable than previous courses in previous semesters just because we got to physically work with SOLIDWORKS models and stuff like that. I don't know, I feel more like an engineer now that I'm working with the programs and stuff that are relevant. So I feel like that was really important."

"I feel more like an engineer now because I've got into the FDA databases and I can actually understand some of their documents and I understand the processes that medical devices have to go through. I think in the beginning it's a bit daunting because designing something, it seems like a really big task because you don't even know what material to select. You don't know how to do a lot of this stuff. But I think during this class you are doing that, but with existing devices, so you don't have the pressure of creating something innovative, but just looking at what's working and why it works that way and the process behind the design, which is a really long process. So just understanding the documentation and being able to see the work that."

"I think this class was by far and away the biggest jump towards me feeling like a biomedical engineer that we've had from any other class. And granted a lot of our classes freshmen and the beginning of sophomore kind like your prereqs and all of our classes are getting more specialized now. But I think that's what I valued most from this class is the projects felt like, oh, this is in line with what a career path I'm taking can look like. And I think that was what I, out of anything, even beyond the teamwork component and everything like that, that's what I valued the most from this class was just starting to get a real perspective on what we do as a whole."

"I feel like it also helped narrow down what you don't want to do. This class very much taught me, I do not want to go into regulations, I don't like papers, I don't like writing, I don't like any of that. But it also taught me that I do like designing and I like the bio and I like to see how it works with the body. So even though it was super broad, it opened new options but also eliminated ones that you don't want to do. So it was a good balance of broadening and then focusing."

Lastly, the students provided some **practical feedback** to address in the future. For example, based on the 2024 focus groups, the 2025 offering of the course added "milestones" for the unit deliverables to help the students stay on track to make steady progress throughout the unit and connect the lecture content to the deliverables. Additional considerations for the future include increasing the standard group size to 4 students (rather than defaulting to 3 per group and having groups of 4 only when needed) and having more effective use of studio work time for groups.

4 Discussion

We created a new, required course for sophomore biomedical engineering students called BMEG260 Introduction to Medical Device Design. Our existing curriculum included both junior and senior design but was missing design in the sophomore year, which also coincides with the "sophomore slump." By focusing on understanding how existing medical devices work and the decisions required to bring these products to market, students learn valuable skills through these examples that they subsequently apply in junior and senior design courses. Importantly, students develop biomedical engineering skills and identify potential career pathways earlier in their education. Requiring the course in the undergraduate curriculum ensures that all students receive this critical training to enter the workforce. The course incorporates innovative teaching practices, including voice of the customer videos, industry-based roles on teams, and hands-on experiences with medical devices.

Overall, we detected consistent gains in students' confidence in their abilities to conduct the engineering design process at the end of the course compared to the start. In particular, both current students (through focus groups) and the reflections of seniors who had taken the course as sophomores valued the applied learning in the course, which occurred through guest speakers, technical skill development such as CAD, instruction on regulatory, industry-relevant roles on teams, and hands-on interactions with medical devices. Power et al. determined that first-year students especially benefit from activities that simulate engineering practices to develop engineering self-efficacy [20]. Our findings suggest that second-year students also benefit from such practices. These course elements helped the students identify potential career paths and feel more like biomedical engineers. The focus group interpretations conflicted with the initial (2023/2024) survey findings of reduced measures of biomedical engineering identity, particularly interest and competence, perceptions of the future related to their career interest in biomedical engineering, and perceived instrumentality of what they were learning. A redesign of the 2025 survey with a subset of retrospective questions suggests that some of these declines may have represented a response-shift.

Retrospective surveys are sometimes criticized for susceptibility to recall bias, which is when respondents misremember past events, producing an error in their memory retrieval. Prior work has demonstrated that subjects use inference to attempt to extract information about events they cannot recall, which leads to inaccurate responses [39]. This unreliable recall is especially apparent for questions focused on timing or abstract descriptions [39]. Our survey focused on items related to competence, interest, and usefulness, not frequency of particular behaviors or factual events. For constructs such as perceived competence and task value, learning experiences can induce response-shift effects that render traditional pre/post measures non-comparable. In such cases, retrospective surveys may improve construct validity by aligning ratings to a common frame of reference [35], even while potentially introducing some memory-based error [40].

In addition to a response-shift, our survey data suggest two other factors are influencing the findings. First, it is apparent that different cohorts have different "personalities." Comparing the 2025 cohort (pre vs. "now") to the 2023/2024 cohorts, we see some individual survey items show opposite trends; that is, the findings were not consistent between the cohorts. Second, external influences impact the survey responses. The survey item "I can do well on exams in biomedical engineering," which significantly decreased in 2023/2024 but not in 2025, especially highlights this impact. BMEG260 does not have any exams. In other words, as students complete the pre- and post-surveys, they reflect on how the statements apply to them overall, not just within the context of BMEG260. For example, although all the cohorts typically take the same courses concurrent with BMEG260, the instructors of those courses may change in different years, and exams may be harder or easier. For this reason, direct, statistical comparisons between cohorts are not valuable for our project goals. Because BMEG260 is a required course in the curriculum, and because different cohorts may have different experiences, we do not have a reliable control group (i.e., a group that did not take BMEG260), which also limits the interpretations of the findings. However, this study used multiple assessment measures (pre- and post-surveys in three years of the course, surveys of seniors, and focus groups), which allows for a more robust understanding of the impact of the BMEG260 course.

5 Conclusions

In this paper, we describe the development of a core, sophomore-level course for biomedical engineering students, BMEG260 Introduction to Medical Device Design. We have provided an example course schedule and assignment templates as models. We assessed the course using multiple surveys across different years and focus groups. Taken together, this study demonstrates not only the effectiveness of the BMEG260 course in increasing students' confidence in their engineering design skills, but it also highlights how the design of measurement instruments significantly affects the interpretation of the findings. Factors such as differences in cohorts, external influences, and timing of the measurement (e.g., immediately vs. after the students have gained a broader perspective through additional experience) all impact results. Using multiple assessment measures and a retrospective survey design can lead to more robust interpretations.

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Appendix A: Sample Course Schedule

Unit	Structure	Day		Topic	CAD Due Dates*	Unit Due Dates**
	L	Mon	1	Course Intro		
	L	Wed	2	Teamwork		
	S	Th/Fri	3	Project Management: Team Norms & Roles, Taking Measurements		
	L	Mon	4	Need statements		
	A	Wed	5	Solidworks: Intro (Solid Models 1)		
1- Surgical Staplers	S	Th/Fri	6	**Industry Guest Speaker:** Stapler Lab		
	L	Mon	7	Design Inputs, Medical Literature, Review unit deliverables		
	A	Wed	8	Solidworks: Intermediate Operations 1 (Solid Models 2)		
	S	Th/Fri	9	Diversity, Staplers Hands-On		
	L	Mon	10	**Industry Guest Speaker:** Quality Engineering and Surgical Staplers		
	L	Wed	11	Solidworks: Planning Practice	**CAD 1**	
	S	Th/Fri	12	FDA Overview, Project Management: Feedback		
	L	Mon	13	Engineering Ethics		
	A	Wed	14	Solidworks: Intermediate Operations 2	**CAD 2a, 2b**	
	S	Th/Fri	15	Project Management: Goals/Timelines		
	L	Mon	16	**Library Guest Speakers:** Engineering standards & patents		
	A	Wed	17	Solidworks: Assembly 1 and Import		**Unit 1 Deliverables**
2- Continuous Glucose Monitors	S	Th/Fri	18	Continuous Glucose Monitor Overview		CATME 1
	L	Mon	19	**Industry Guest Speaker:** FDA Pathways		
	A	Wed	20	Solidworks: Assembly 2	**CAD 3**	
	S	Th/Fri	21	Project Management: Documenting meetings, Materials & Manufacturing		
				Spring break		
	L	Mon	22	Feedback & Solidworks: Evaluation		
	L	Wed	23	Healthcare & Environment	**CAD 4a, 4b**	
	S	Th/Fri	24	Risk Management		
	L	Mon	25	**Industry Guest Speaker:** Continuous Glucose Monitors		
	L	Wed	26	**Academic Guest Speaker:** U.S. Healthcare System	**CAD 5a-c**	
	S	Th/Fri	27	Project Management: Communication & Conflict Resolution		
	L	Mon	28	Reimbursement Basics		
3- Stents	L	Wed	29	**Industry Guest Speakers:** Stents		**Unit 2 Deliverables**
	S	Th/Fri	30	Stents Overview		CATME 2
	L	Mon	31	Tolerancing		
	A	Wed	32	Solidworks: Engineering Drawings 1		
	S	Th/Fri	33	Guidant Ethics Case Study		
	L	Mon	34	FDA Pathways		
	A	Wed	35	Solidworks: Engineering Drawings 2	**Tolerancing Quiz**	
	S	Th/Fri	36	Research Ethics		
	L	Mon	37	**Industry Guest Speaker:** Medical Devices Business, Sales & Marketing		
	L	Wed	38	Flex Day	**CAD 6**	
	S	Th/Fri	39	**Evaluation Guest Speaker:** Focus Group Discussions		
	L	Mon	40	Career Reflection		
	L	Wed	41	Wrap-Up	**CAD 7**	
		Th/Fri		Last day of classes		**Unit 3 Deliverables** CATME 3

Key
L- Lecture (55 minutes)
A- Asynchronous
S- Studio (125 minutes)
*Does not include due dates for CAD Check assignments
**Does not include due dates for Low-Stakes Activities or Unit Milestones

Appendix B: Unit Deliverable Templates

The following templates are provided to student teams to submit for each medical device unit. The units and deliverables build, so the forms for the third unit (provided below) are the most comprehensive. F01, F02, and F04 were adapted from those used at a medical devices company. The need statement of F01 follows the template in *Biodesign* [41].

- F01- Product Initiation Request Form
- F02- Design Inputs
- F03- Design Details
- F04- Failure Mode and Effects Analysis (FMEA)

F01- PRODUCT INITIATION REQUEST (PIR)

Team #:

<u>Need Statement:</u>

A way to address [PROBLEM] in [POPULATION] in order to [OUTCOME]

Explanation & Justification (include voice of customer <u>and</u> support with additional references):
Problem:

Population:

Outcome:

Each section below must align with the need statement.

<u>Market position:</u>

Include all possible FDA classifications. Add additional sections as needed.
*Sometimes a broad group of medical devices can fall in several different FDA product codes and/or regulations. For example, a device may be implanted, hospital grade, integrated and factory-calibrated, etc., and each of these could be listed with a different code and regulation. Another example is sometimes there are different codes if a device is powered vs. manual. Since you haven't designed/proposed a *specific* product, you should list any codes that could be applicable. It's also possible that there might only be one code for a possible product. Make sure this aligns with your need statement.*

1. FDA Product Code:

   FDA Identification/Definition:

   Device Class: Regulation Number:

   Other Comments/Considerations (including any applicable device-specific guidance document(s) or special controls):

2. FDA Product Code:

   FDA Identification/Definition:

Device Class: Regulation Number:

Other Comments/Considerations (including any applicable device-specific guidance document(s) or special controls):

<u>Clinical Context:</u>

Define the clinical problem with relevant anatomy and physiology. Demonstrate an understanding of normal and pathological structure and function of the body, as it might inform the design of the device.

ICD Codes

List the ICD-11 codes you expect to be associated with the diagnoses and diseases that would lead to the use of your device.

CPT Codes

List the CPT codes you expect to be associated with your product.

Regulatory Strategy:

1. Markets (stats & data)

Report on statistics that help justify the size of the market. For example, how many people are diagnosed with a certain disease, how frequently a certain type of procedure is performed, how many times a particular instrument is used, any applicable failure rates that justify use of a certain device, etc. You can start broad, but make sure you ultimately provide some stats/data that are in direct alignment with your specific need statement.

2. Proposed Indications for Use

3. Expected FDA Regulatory Pathway and Process

Justify which FDA regulatory pathway you expect a new device in this space would be required to undergo (e.g., based on device classification and regulations). Explain the steps and documentation required for this pathway. If multiple pathways are options depending on the final design, explain all.

4. Testing Requirements (include all standards, including FDA Recognized Consensus)

Add more rows as necessary

Standard Number	Standard Title	Description	Explanation/Justification

Potential Predicates & Competitors

Competitors in this market may serve as predicates for the device. Those competitors are as follows (at least 3 are required):

Company				
Device				
510(k)/PMA Number				
FDA Product Code				
Device Description				
Intended Use				
Indications for Use (IFU)				
Cost*				

*as available

Ethics & Impact

1. **Consider the impact of the engineering solution in a societal context**

2. **Consider the impact of the engineering solution in a global context**

3. **Consider the impact of the engineering solution in an economic context**

4. **Consider the impact of the engineering solution in an environmental context**

5. **Describe ethical considerations in the research & development of the solution, including clinical trials. In your explanation, cite at least one example of a previous clinical trial performed on an existing device.**

References

Proposal prepared and submitted by:

Name	Role	Date

F02- Design Inputs

Team #:	DESIGN INPUTS	Form: F02

Need Statement:

Source	Functional Requirement	Design Requirement	Justification	Considered Factors	Engineering Standard(s)

Approvals	
Name	**Role**

Note 1: Design inputs must align with the need statement

Note 2: Inputs must consider public health, safety, and welfare, as well as global, cultural, social, environmental, AND economic factors. If any of these factors relate to a design input, indicate which in the "Considered Factors" column. These factors may not apply to every input.

Note 3: Sources must reflect the Voice of the Customer. Use direct VoC quotes as sources for at least some of the inputs. Not every input row must come from the VoC (e.g., something related to basic function or safety may not be stated by customer because it is assumed, but it should still be included as a requirement).

Note 4: Must apply relevant engineering standard(s), including FDA Recognized Consensus Standards, when applicable. If an engineering standard applies, indicate which in the "Engineering Standard(s)" column. Engineering standards may not apply to every input.

References:

Note: *To cite the VoC videos, you can use a "lecture" citation method listed in the IEEE reference guide.*

F03- DESIGN DETAILS

Team #:

<u>Existing Device</u>

Manufacturer:
Product:
Product link:

<u>Device Description Overview</u>

"Descriptive information also includes a description of the principle of operation for achieving the intended effect and the proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. Information on whether the device is intended to be marketed with accessories." Electronic Submission Template for Medical Device 510(k) Submissions Draft Guidance (issued Sept 29, 2021)

Design Overview

1. **List the components of the device, their function(s), material, and likely manufacturing method**

Component	**Function(s)**	**Material**	**Manufacturing**

2. **Include a figure of the device to communicate form and function. Label components. Cite appropriately.**

Design Details

3. Detailed device description. Explain how the device works.

"an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties." 21 CFR 807.92(a)(4)
"including a description of the technological characteristics of the device including materials, design, energy source, and other device features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A)." Electronic Submission Template for Medical Device 510(k) Submissions Draft Guidance (issued Sept 29, 2021)

4. **Justify 2 design decisions of the device.**

Design Justification 1

a. State the specific design element that needs to be justified.

b. What engineering considerations and analysis are required to justify this design element?

c. How does this design output relate to the design inputs?

Design Justification 2

a. State the specific design element that needs to be justified.

b. What engineering considerations and analysis are required to justify this design element?

c. How does this design output relate to the design inputs?

5. **Align your future coursework with design justifications.** Describe what justifications, calculations, or questions you expect your future coursework would prepare you to answer. Record in the table at least 3. Add rows as necessary.

Justification, Calculation, or Question	**Future Course(s)** (that you think will teach you how to address the question)

<u>**Patents**</u>

6. **Identify 2 relevant patents (for this device or prior art). For each, complete the information and explain how it relates to the current device.**

Patent 1

a. Patent title:
b. Patent number:
c. Patent filing date:
d. Patent issue date:
e. Inventor(s):
f. Assignee (if applicable):
g. CPC Classifications most relevant to this medical device:
h. Summarize the invention and its main claims.

i. Explain how the patent technology relates to the medical device.

Patent 2

a. Patent title:
b. Patent number:
c. Patent filing date:
d. Patent issue date:
e. Inventor(s):
f. Assignee (if applicable):
g. CPC Classifications most relevant to this medical device:
h. Summarize the invention and its main claims.

i. Explain how the patent technology relates to the medical device.

References

Prepared and submitted by:

Name	Role	Date

F04- FAILURE MODE EFFECTS ANALYSIS (FMEA)								
TEAM #:								
PRODUCT COVERED:								
PRODUCT WEBSITE:								
					Risk Evaluation			Risk Mitigation
ID#	Item/Function	Potential Failure Mode (Hazardous situation)	Potential Effect(s) of the Failure (Harm)	Potential Cause of Failure	Severity	Occurrence	Initial Risk Priority Number (RPN)	Recommended Action(s) to eliminate/reduce potential failures
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

List Parts (Components) that were included in the FMEA:

Note : Use the FDA MAUDE database to identify potential modes and causes of failure.

FDA MAUDE Database

List which failures from your FMEA table were identified in the FDA MAUDE database. Not every failure in your FMEA must be identified in MAUDE, but you should demonstrate that you have navigated the database and correctly interpreted the Medical Device Reporting (MDRs) to identify potential failures. Include relevant MDR links. Use as many rows as needed.

Summary of MDR Event Description	MDR Link	FMEA ID #

References

Approvals		
Name	Role	Signature/ Date

Appendix C: Focus Group Questions

In-person focus groups led by a professional external evaluator at the end of the 2024 offering of BMEG260 were used to collect student perspectives about the course. Below are the questions used. The "clinician/patient videos" questions and findings have been reported previously [31].

About the course

- What helped you the most to learn the required material?
  Probe: Clinician/patient Videos, working in teams, guest speakers, hands-on device dissections, mixed instructional approach
- Is there anything you learned during the course that you were not expecting?

About working in teams

- How did simulating industry-relevant job roles on your team impact your:
  1. Development of industry-relevant skills?
  2. Ability to identify career pathway options for working as a biomedical engineer (generally) and, more specifically, roles in the medical devices industry?
  3. Confidence to work in the field of biomedical engineering? And specifically, in the medical devices industry?
  4. Interest in a career in biomedical engineering? And specifically, in the medical devices industry?
- What (if anything) would you change about the teamwork aspect of the course?
- What would you make sure wasn't changed?
- What suggestions can you provide for improvements?

Clinician/patient videos

Clinician/patient videos were tools used to support your learning in the course. I would like to hear your feedback on these.

Overall, what did you think about these videos? [Will ask for each Unit]

- What did you find useful/helpful?
- What (if anything) was not useful/helpful?
- What suggestions can you provide for improvements?
- How/did the voice of the customer videos help you understand the clinical context?
- How/did the voice of the customer videos help you identify unmet health needs of existing devices?
- In what way (if any) did the customer videos impact your perspective-taking? Empathy?

Engineering identity/sense of belonging

- Do you see yourself as becoming a Biomedical engineer? If so, why? If not, why?
- How/ did your participation in this course impact how you see yourself as a biomedical engineer?
- Do think others (i.e. your parents, instructors, peers) see you becoming a Biomedical engineer? Why or why not?

Wrap up question

- Is there anything else we didn't discuss about your experience this semester that you would like to mention now?
- Any additional suggestions you can provide for course improvements.

Appendix D. Pre-Post Survey Data Means (Standard Deviations), 2023/2024 (n = 54-59)

Yellow highlights are "negative" and green highlights are "positive" statistically significant findings.

Biomedical Engineering Identity	**Pre**	**Post**	**Change**
Recognition	**4.35(.88)**	**4.42(.84)**	**.07(.75)**
My parents see me as a Biomedical engineer.	4.24(1.19)	4.51(1.18)	.27(1.13)
My instructors see me as a Biomedical engineer.	4.46(1.10)	4.42(1.07)	-.04(1.17)
My peers see me as a Biomedical engineer.	4.36(1.14)	4.32(.96)	-.03(.1.11)
Interest	**5.44(.53)**	**5.24(.78)**	**-.21(.74)***
I am interested in learning more about Biomedical engineering.	5.69(.50)	5.41(.81)	-.29(.74)*
I enjoy learning Biomedical engineering.	5.40(.62)	5.16(.89)	-.24(.89)*
I find fulfillment in doing Biomedical engineering.	5.22(.75)	5.12(.90)	-.10(.97)
Competence	**4.30(.63)**	**4.13(.75)**	**-.18(.61)***
I am confident that I can understand Biomedical Engineering in class.	4.61(.81)	4.41(1.02)	-.20(1.01)
I am confident that I can understand Biomedical Engineering outside of class.	4.20(.92)	4.00(1.01)	-.20(1.01)
I can do well on exams in Biomedical engineering.	4.32(.96)	3.90(1.09)	-.42(1.00)**
I understand concepts I have studied in Biomedical engineering.	4.53(.73)	4.32(.78)	-.20(.76)*
Others ask me for help in Biomedical engineering.	3.85(.93)	4.00(1.05)	.15(1.19)
Career Path & Future Aspirations	**Pre**	**Post**	**Change**
Perceptions of Future	**4.92(.77)**	**4.65(.84)**	**-.27(.73)****
I am confident about my choice of major.	4.86(.96)	4.78(.93)	-.09(.92)
Biomedical engineering is the most rewarding future career I can imagine for myself.	4.58(1.15)	4.42(1.21)	-.15(1.14)
My interest in a biomedical engineering major outweighs any disadvantages I can think of.	4.95(.96)	4.63(.93)	-.32(1.03)*
I want to be a biomedical engineer.	5.29(.70)	4.78(.93)	-.51(.88)***
Perceived Instrumentality	**5.20(.77)**	**4.79(.95)**	**-.41(.90)*****
I will use the information I learn in my biomedical engineering course in other classes I will take in the future.	5.24(.77)	4.88(.87)	-.36(.83)**
I will use the information I learn in this biomedical engineering course in the future.	5.24(.80)	4.78(1.04)	-.46(1.04)**
What I learned in my biomedical engineering course will be important for my future occupational success.	5.12(.87)	4.69(1.16)	-.42(1.13)**
Belongingness	**4.93(.72)**	**4.82(.78)**	**-.11(.62)**
I feel comfortable in biomedical engineering	4.78(.93)	4.76(.92)	-.02(.86)
I feel I belong in biomedical engineering	4.86(.78)	4.75(.96)	-.12(.75)
I enjoy being in biomedical engineering	5.14(.78)	4.95(.82)	-.19(.57)*
Identity – I see myself as a biomedical engineer	**4.61(.67)**	**4.44(.77)**	**-.17(.83)**
Self-efficacy for teamwork	**Pre**	**Post**	**Change**
Teamwork	**3.93(.52)**	**3.90(.43)**	**-.03(.45)**
I have confidence in my ability to work in teams.	4.67(.54)	4.57(.53)	-.10(.61)
There are some tasks required by teamwork that I cannot do well. (R)	3.05(1.07)	2.98(1.29)	-.07(1.46)

When my performance in a team is poor, it is due to my lack of ability. (R)	3.57(1.16)	3.59(1.17)	.02(1.20)
I doubt my ability to work in teams. (R)	4.05(1.07)	4.21(.64)	.16(1.01)
I have all the skills needed to perform very well in teams.	4.38(.67)	4.34(.64)	-.03(.77)
Most people in my line of work can work in teams better than I can. (R)	3.68(.93)	3.72(.84)	.04(.98)
I am an expert at teamwork.	3.44(.96)	3.37(.86)	-.07(1.03)
My future working in teams is limited because of my lack of skills. (R)	4.21(.84)	4.23(.76)	.02(1.01)
I am very proud of my teamwork skills and abilities.	4.21(.70)	4.11(.86)	-.11(.86)
I feel threatened when others watch me work in a team. (R)	3.96(1.20)	3.86(1.01)	-.11(.82)
Self-Efficacy for Engineering Design Process Skills	**Pre**	**Post**	**Change**
Confidence	**59.35(11.24)**	**79.62(10.46)**	**13.27(14.00)****
Conduct biomedical engineering design	51.75(15.71)	72.28 (14.02)	20.53(20.57)**
Identify a design need	64.91(17.94)	79.65(13.62)	14.74(21.47)**
Research a design need	66.14(16.98)	80.00(13.36)	13.86(19.34)**
Develop design solutions	56.96(15.72)	74.46(13.34)	17.50(18.12)**
Select the best possible design	57.54(14.91)	72.28(16.04)	14.74(21.05)**
Construct a prototype	52.28(19.18)	62.46(19.11)	10.18(21.59)**
Evaluate and test a design	58.77(14.40)	67.19(16.60)	8.42(19.89)**
Communicate a design	66.84(17.94)	76.67(14.92)	9.83(19.13)**
Redesign	60.35(17.01)	70.53(17.97)	10.18(21.26)**
Motivated	**74.48(13.01)**	**71.70(15.35)**	**-2.82(15.75)**
Conduct biomedical engineering design	75.09(14.90)	72.11(18.49)	-2.98(20.53)
Identify a design need	77.72(15.59)	72.81(20.24)	-4.91(21.22)
Research a design need	68.57(19.49)	70.89(21.17)	2.32(25.37)
Develop design solutions	76.14(18.30)	75.44(17.94)	-.70(21.70)
Select the best possible design	78.95(13.45)	74.56(16.59)	-4.39(18.03)
Construct a prototype	75.96(21.62)	70.88(19.57)	-5.09(20.71)
Evaluate and test a design	76.14(16.01)	73.33(17.25)	-2.81(17.60)
Communicate a design	70.35(16.79)	68.07(20.48)	-2.28(20.00)
Redesign	71.23(18.43)	67.72(20.36)	-3.51(19.32)
Successful	**65.74(13.72)**	**67.94(14.88)**	**2.20(15.50)**
Conduct biomedical engineering design	64.11(18.37)	68.93(17.34)	4.82(19.73)
Identify a design need	70.36(17.16)	75.36(15.61)	5.00(20.09)
Research a design need	70.36(17.05)	74.29(17.46)	3.93(21.72)
Develop design solutions	65.27(17.09)	67.82(18.53)	2.55(19.27)
Select the best possible design	65.18(15.61)	65.18(17.68)	0.00(20.63)
Construct a prototype	61.25(20.19)	61.79(19.55)	0.54(18.82)
Evaluate and test a design	66.43(17.10)	64.46(18.38)	-1.96(19.95)
Communicate a design	68.57(18.73)	67.68(19.35)	-.89 (20.65)
Redesign	64.11(16.60)	65.18(18.68)	1.07(19.51)
Anxiety	**49.79(17.85)**	**43.00(21.83)**	**-6.79(23.79)***
Conduct biomedical engineering design	53.39(20.47)	43.21(25.73)	-10.18(29.20)*
Identify a design need	43.04(23.81)	34.82(25.44)	-8.21(26.43)*
Research a design need	41.61(23.65)	33.93(25.06)	-7.68(27.96)*

Develop design solutions	50.91(20.21)	42.91(25.58)	-8.00(30.21)
Select the best possible design	49.64(21.99)	49.11(24.66)	-.54(28.25)
Construct a prototype	53.57(23.08)	49.64(24.42)	-3.93(25.63)
Evaluate and test a design	50.91(20.93)	45.09(22.92)	-5.82(25.36)
Communicate a design	49.11(25.32)	45.71(27.16)	-3.39(30.47)
Redesign	50.71(20.17)	44.29(24.85)	-6.43(25.19)

*(R) Reverse coded; Mean difference is significant at the *p<0.05 level; **p<0.01; ***p<0.001*

Appendix E. Pre-Post Survey Data Means (Standard Deviations), 2025 (n = 29-34)

Yellow highlights are "negative" and green highlights are "positive" statistically significant findings.

Biomedical Engineering Identity	**Pre**	**Post**	**Change**
Recognition	**4.02(1.26)**	**4.38(.92)**	**.36(1.11)**
My parents see me as a Biomedical engineer.	4.24(1.39)	4.53(1.31)	.29(1.29)
My instructors see me as a Biomedical engineer.	4.00(1.41)	4.44(.93)	.41(1.21)*
My peers see me as a Biomedical engineer.	3.82(1.36)	4.18(1.09)	.36(1.48)
Interest	**4.76(.98)**	**4.83(1.18)**	**.07(1.32)**
I am interested in learning more about Biomedical engineering. (*Ret)*	5.09(.87)	5.00(1.26)	-.09(1.31)
I enjoy learning Biomedical engineering. (*Ret)*	4.59(1.16)	5.74(1.38)	1.14(1.62)***
I find fulfillment in doing Biomedical engineering. (*Ret*)	4.62(1.21)	4.76(1.23)	.147(1.46)
Competence	**3.89(.89)**	**4.69(.73)**	**.80(.71)*** **
I am confident that I can understand Biomedical Engineering in class. (*Ret)*	4.00(1.33)	4.79(.77)	.79(1.15)***
I am confident that I can understand Biomedical Engineering outside of class. (*Ret)*	3.68(.95)	4.47(.90)	.79(.88)***
I can do well on exams in Biomedical engineering.	4.42(.79)	4.45(.87)	.03(.88)
I understand concepts I have studied in Biomedical engineering. (*Ret)*	4.00(1.07)	4.82(.79)	.82(.87)***
Others ask me for help in Biomedical engineering.	3.30(1.36)	3.85(.972)	.545(.272)
Career Path & Future Aspirations	**Pre**	**Post**	**Change**
Perceptions of Future	**4.41(.99)**	**4.50(1.53)**	**.09(1.32)**
I am confident about my choice of major.	4.65(1.43)	4.65(1.13)	.00(.207)
Biomedical engineering is the most rewarding future career I can imagine for myself.	4.68(1.15)	4.15(1.56)	-.53(1.38)*
My interest in a biomedical engineering major outweighs any disadvantages I can think of. (*Ret)*	4.18(1.17)	4.65(1.13)	.47(1.13)*
I want to be a biomedical engineer. (*Ret)*	4.21(1.72)	4.79(1.55)	.59(1.16)**
Perceived Instrumentality	**4.76(.98)**	**4.83(1.18)**	**.07(1.32)**
I will use the information I learn in my biomedical engineering course in other classes I will take in the future. (*Ret)*	4.65(.81)	4.85(1.10)	.21(1.17)
I will use the information I learn in this biomedical engineering course in the future. (*Ret)*	4.56(.82)	4.76(1.16)	.21(1.25)
What I learned in my biomedical engineering course will be important for my future occupational success. (*Ret)*	4.26(1.29)	4.26(1.54)	.00(1.39)
Belongingness	**4.67(.96)**	**4.69(.88)**	**.02(.92)**
I feel comfortable in biomedical engineering	4.62(.99)	4.74(.86)	.12(1.00)
I feel I belong in biomedical engineering	4.44(.99)	4.65(1.07)	.21(1.20)
I enjoy being in biomedical engineering	4.94(1.18)	4.68(1.12)	-.26(1.05)
Identity – I see myself as a biomedical engineer	**4.35(1.18)**	**4.38(1.13)**	**.03(1.17)**
Self-Efficacy for Engineering Design Process Skills	**Pre**	**Post**	**Change**
Confidence	**58.73(17.62)**	**73.86(10.30)**	**15.13(14.11)*** **
Conduct biomedical engineering design	53.53(21.16)	73.53(13.90)	20.00(19.23)***
Identify a design need	65.59(18.94)	82.94(10.31)	17.36(19.00)***

Research a design need	70.00(17.92)	83.25(10.36)	13.24(20.11)***
Develop design solutions	56.47(19.98)	77.35(10.53)	20.88(18.65)***
Select the best possible design	58.24(21.95)	72.94(12.44)	14.71(21.21)***
Construct a prototype	47.35(21.22)	65.59(18.12)	18.24(22.22)***
Evaluate and test a design	53.82(24.62)	62.94(19.47)	9.11(16.94)**
Communicate a design	65.59(23.51)	74.41(15.01)	8.83(20.42)*
Redesign	57.94(23.46)	71.76(16.04)	13.82(21.32)***
Motivated	**77.33(13.85)**	**78.13(13.57)**	**.80(12.76)**
Conduct biomedical engineering design	75.00(17.10)	77.94(18.22)	2.94(22.23)
Identify a design need	76.76(16.46)	78.24(17.66)	1.47(19.41)
Research a design need	73.24(16.65)	75.29(16.19)	2.06(21.29)
Develop design solutions	79.09(16.84)	82.12(14.74)	3.03(17.94)
Select the best possible design	79.41(15.56)	80.88(18.15)	1.47(17.43)
Construct a prototype	77.27(15.26)	80.91(16.27)	3.64(18.17)
Evaluate and test a design	80.29(14.67)	77.65(18.43)	-2.65(18.31)
Communicate a design	74.24(16.96)	73.02(20.23)	-1.21(18.50)
Redesign	75.88(15.98)	75.00(19.73)	-.88(18.65)
Successful	**62.91(16.96)**	**74.29(10.28)**	**11.38(12.69)*** **
Conduct biomedical engineering design	59.71(19.30)	72.06(14.10)	12.35(17.07)***
Identify a design need	67.35(18.31)	79.71(14.03)	12.35(18.43)***
Research a design need	68.24(18.66)	80.88(13.57)	12.65(19.28)***
Develop design solutions	65.00(17.04)	73.13(13.78)	8.13(17.68)*
Select the best possible design	60.00(18.37)	72.42(15.82)	12.42(15.01)***
Construct a prototype	53.24(21.98)	68.53(17.78)	15.29(16.56)***
Evaluate and test a design	56.67(22.31)	67.58(18.03)	10.91(18.09)**
Communicate a design	63.64(21.48)	75.15(14.82)	11.52(19.38)**
Redesign	57.06(21.25)	70.00(16.33)	12.94(20.08)***
Anxiety	**47.29(18.17)**	**39.13(18.76)**	**-8.16(16.67)** **
Conduct biomedical engineering design	50.88(23.53)	42.06(22.53)	-8.82(24.84)*
Identify a design need	41.52(24.76)	32.42(26.10)	-9.09(28.21)
Research a design need	37.94(25.20)	30.88(20.65)	-7.06(18.83)*
Develop design solutions	45.15(24.25)	31.82(22.70)	-13.33(18.31)***
Select the best possible design	49.41(19.53)	45.29(19.73)	-4.12(21.56)
Construct a prototype	53.53(20.73)	44.12(24.51)	-9.41(25.34)*
Evaluate and test a design	49.71(23.16)	44.41(24.76)	-5.29(24.52)
Communicate a design	50.00(24.74)	42.65(26.09)	-7.35(19.43)*
Redesign	51.47(22.58)	41.18(23.84)	-10.29(27.69)*

*(Ret) Retrospective question item, "then"-"now" results are shown; (R) Reverse coded; Mean difference is significant at the *p<0.05 level; **p<0.01; ***p<0.001*

Appendix F. Retrospective Pre-Post Survey Data Means (Standard Deviations)- 2025 (n = 29-34)

Yellow highlights are "negative" and green highlights are "positive" statistically significant findings.
Pre indicates pre-survey responses. "Then" indicates retrospective responses on the post-survey. "Now" indicates current responses on the post-survey. Data in the "Then" and "Now" columns are the same as the Pre and Post data in Appendix E.

Biomedical Engineering Identity	**Pre**	**"Then"**	**"Now"**
Interest			
I am interested in learning more about Biomedical engineering. (*Ret*)	5.41(.70)*	5.09(.87)	5.00(1.26)
I enjoy learning Biomedical engineering. (*Ret)*	5.15(.82)*	4.59(1.16)***	5.74(1.38)
I find fulfillment in doing Biomedical engineering. (*Ret*)	5.12(.98)	4.62(1.21)	4.76(1.23)
Competence			
I am confident that I can understand Biomedical Engineering in class. (*Ret*)	4.44(.79)*	4.00(1.33)***	4.79(.77)
I am confident that I can understand Biomedical Engineering outside of class. (*Ret)*	4.15(1.02)	3.68(.95)***	4.47(.90)
I understand concepts I have studied in Biomedical engineering. (*Ret)*	4.38(.89)*	4.00(1.07)***	4.82(.79)
Career Path & Future Aspirations	**Pre**	**"Then"**	**"Now"**
Perceptions of Future			
My interest in a biomedical engineering major outweighs any disadvantages I can think of. (*Ret)*	4.68(1.22)	4.18(1.17) *	4.65(1.13)
I want to be a biomedical engineer. (*Ret*)	4.88(1.37)	4.21(1.72)**	4.79(1.55)
Perceived Instrumentality			
I will use the information I learn in my biomedical engineering course in other classes I will take in the future. (*Ret)*	5.15(.93)	4.65(.81)	4.85(1.10)
I will use the information I learn in this biomedical engineering course in the future. (*Ret)*	5.18(.87)*	4.56(.82)	4.76(1.16)
What I learned in my biomedical engineering course will be important for my future occupational success. (*Ret*)	5.06(.95)**	4.26(1.29)	4.26(1.54)

*Mean difference compared to "Now" is significant at the *p<0.05 level; **p<0.01; ***p<0.001*