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Incorporating Engineering Standards Throughout the Biomedical Engineering Curriculum

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Abstract

Knowledge of how to identify and apply engineering standards is a necessary skill for biomedical engineers seeking to enter into the engineering industry. The use of engineering standards is often reserved for capstone courses; however, little evidence exists to determine whether this limited exposure at the end of the curriculum is enough to prepare students to identify and apply engineering standards after they graduate. The objective of this study is to assess how increasing exposure to engineering standards in the biomedical engineering curriculum improves students' abilities to find and use relevant standards. Due to a curriculum change that was implemented over multiple years, four cohorts of students with varying degrees of exposure to engineering standards emerged. In-class lessons in a formative Junior Design course improved students' abilities to identify and apply standards; however, this skill did not always transfer to Senior Design. Repeated exposure to standards in formative courses improved students' abilities to identify, but not execute, engineering standards in Senior Design. The results of this study support the need for repeated, spaced practice with engineering standards throughout the biomedical engineering curriculum.

Introduction

Engineering standards are "a set of technical definitions, instructions, rules, guidelines, or characteristics set forth to provide consistent and comparable results" [1]. In the medical device industry, standards are important for regulatory approval processes. For example, the United States Food & Drug Administration (FDA) maintains a database of recognized consensus standards [2], and the Center for Devices and Radiological Health (CDRH) of the FDA encourages voluntary use of these consensus standards in premarket submissions to expedite review and promote quality [3]. Engineering standards serve as frameworks to define design inputs, develop verification and validation methods, and interpret results.

Affirming the value of standards, the American National Standards Institute (ANSI) published the United States Standards Strategy in 2015 (a revision of the original National Standards Strategy for the United States, published in 2000) [4]. One of its goals is to "establish standards education as a high priority within the U.S. private, public, and academic sectors" [4]. Along these lines, ABET-accredited academic programs require that students partake in a major design experience that builds upon prior coursework and incorporates "appropriate engineering standards and multiple realistic constraints" [5]. Furthermore, industry expects that engineers apply standards in practice. In a 2010 survey, nearly 75% of the 15 engineering management respondents in the medical industry indicated that "employees are required to research, locate, and apply standards" very or quite often [6]. In this same survey, over 80% of the 12 respondents in the medical engineering field affirmed that there is "a need for engineers who possess the fundamentals of standards development and the knowledge to find and apply standards prior to employment" [6]. Clearly, there is a need for students in engineering academic programs to learn about engineering standards.

Practicing engineers must both identify and apply engineering standards; therefore, to prepare them for industry, students need to be trained in the importance of standards and the application of standards during projects [7]. A variety of instructional techniques have been implemented to introduce engineering students to standards, such as workshops [8] and stand-alone courses [6]; however, many biomedical engineering undergraduate curricula do not have space for an additional stand-alone course on standards. Other strategies include incorporating standards into already existing courses, such as capstone [9, 10], medical devices [11], and experimental design [12, 13], and using the support of engineering librarians [13]. Unfortunately, these courses are often taken in the senior year or in graduate programs [9-11, 13], and limited data exist to assess the efficacy of these instructional strategies. Despite a recommendation made by a panel at the 2012 Capstone Design Conference that faculty should introduce engineering standards earlier and throughout the curriculum [10], no prior literature expands upon and directly assesses the instructional methods used to incorporate engineering standards beyond a single course. In addition, abundant literature highlights the need for students to have repeated exposure and practice when learning new skills [14], suggesting the benefits of incorporating engineering standards throughout the biomedical engineering curriculum.

The **objective** of this study is to assess how increasing exposure to engineering standards in the biomedical engineering curriculum improves students' abilities to find and use relevant standards. We evaluated whether in-class lessons in a formative course improved student use and application of engineering standards. Then, we evaluated whether this increased exposure through formative courses improved students' abilities to transfer these skills to senior design (summative). We previously presented a Work-in-Progress [15] that documented preliminary results on how our biomedical engineering curricular improvements led to gains in students' abilities to identify relevant engineering standards. Here, we present our full dataset, which includes analysis of all 4 cohorts' abilities to both identify relevant engineering standards for use as design criteria justifications and apply engineering standards to execute test methods.

Specifically, we tested **four hypotheses** related to identifying and applying relevant engineering standards in formative and summative courses:

1) **In-class activities** in a formative course improve students' abilities to **identify** relevant engineering standards as **design input justifications**.
2) **In-class activities** in a formative course improve students' abilities to **apply** relevant engineering standards as **executable test methods**.
3) Increased student exposure to engineering standards through formative courses improves students' abilities to **identify** relevant engineering standards as **design input justifications** in senior design (summative).
4) Increased exposure to engineering standards through formative courses improves students' abilities to **apply** relevant engineering standards as **executable test methods** in senior design (summative).

Cohorts

We performed this study at a large Research I land-, sea-, and space-grant university in the mid-Atlantic United States. The Department of Biomedical Engineering, started in 2010, offers both a doctoral program and an undergraduate program. The historical biomedical engineering undergraduate cohort size has been ~55 students. The undergraduate program is ABET accredited.

Due to a biomedical engineering undergraduate curriculum change that was implemented over multiple years, four cohorts of students with varying degrees of exposure to engineering standards emerged (**Table 1**). Engineering standards are implemented in three courses: Senior Design (required capstone, senior year), Junior Design (required course, junior year), and Cell & Tissue Laboratory (required course, sophomore year).

Table 1. Cohorts. Due to a curriculum change, 4 cohorts of students had different exposures to engineering standards. X- students used standards in that course, n- number of team reports included in analysis

		Required to use engineering standards as		
	Graduation	**Sophomores (BMEG211)**	**Juniors (BMEG360)**	**Seniors (BMEG450)**
Cohort 1	2016			**X** (n=18)
Cohort 2	2017		**X** (n=13)	**X** (n=14)
Cohort 3	2018	**X**	**X** (n=13) + engineering librarian	**X** (n=16)
Cohort 4	2019	**X**	**X** (n=14) + engineering librarian + activity to identify test method	**X** (n=13)

All cohorts were expected to use engineering standards in Senior Design; however, each cohort had different levels of exposure to standards prior to Senior Design. The new curriculum launched in fall 2015, so Cohort 1's only exposure to engineering standards occurred during their Senior Design capstone course, when they were asked to include a relevant standard as a design metric and for testing. For Cohort 1, Senior Design acted as both their first exposure and summative assessment of use of engineering standards. Cohort 2 took the Junior Design course (formative), but they did not take the Cell & Tissue Lab. Cohort 3 was the first cohort to take the Cell & Tissue Lab (formative). In addition, when Cohort 3 took Junior Design, we invited the engineering librarian to present a lesson on resources to identify engineering standards. Finally, Cohort 4 had the most exposure to engineering standards through Cell & Tissue Lab (formative), Junior Design (formative), and Senior Design (summative), and an added class activity in Junior Design to identify relevant engineering test methods using standards.

Senior Design

Senior Design is a 1-semester, interdisciplinary course co-offered with mechanical engineering. All mechanical (ME) and biomedical (BME) engineering students take this course, and some civil/environmental (CIEG) and electrical/computer engineering students (ECE) take it as well. Students are divided into teams and paired with a project sponsor from local industry, clinical sites, or academic labs. Each team also has a faculty advisor. All projects have a design-focus (rather than research-focus), and the students are expected to act as consulting engineers to understand the client's unmet need, develop design criteria, produce a prototype, and perform verification (and validation when possible) testing. Teams are typically 3-5 students, though in some circumstances with an extremely large project scope, the team size may be larger. The team composition (number of BME, ME, CIEG, and ECE students) is dependent upon the expected needs of the project. This study includes only those teams in which BME students comprised at least half of the team (e.g., ≥2 out of 4 students on a team).

Our design courses follow four key milestones with associated deliverables that denote four distinct, stage-gate phases of the design process (**Table 2**). At the conclusion of each of these phases, the student teams submit a report. Each subsequent phase is an addition to the previous phase(s) so that by the end of the semester, the students have written a complete design report. Students receive faculty feedback after each phase report submission, and students are expected to incorporate this feedback in subsequent submissions. For example, in a phase 2 submission, students are expected to revise and resubmit their phase 1 content (background, design criteria) and add their phase 2 content (concept generation and selection). Students are specifically expected (i.e., they receive a grade) to identify and apply engineering standards in their phase 1 and phase 4 submissions.

Table 2. Design Phases. Senior and Junior Design courses follow a 4-phase design process with distinct deliverables.

Design Phase	Description	Expected Engineering Standard Use
1	Project scope, background research, benchmarking and prior art, design criteria (wants, constraints with associated metrics)	Use at least one relevant engineering standard as a design metric (identify)
2	Concept generation and selection	---
3	Detailed design and prototype	---
4	Verification and validation testing	At least one of these tests must follow a relevant engineering test standard (apply)

Junior Design

The Junior Design course is modeled after Senior Design in that the students work through all 4 phases of the design process and have the same 4 key milestones and deliverables. Unlike Senior Design, Junior Design contains only biomedical engineering students. The students still work in teams; however, the entire class works on the same project. Because this course is the BME students' first fully immersive design experience, its project scope is typically more focused, and the course instruction contains much more scaffolding than Senior Design. Having the entire class work on the same project allows the instructors to more systematically guide the students through identifying and employing relevant engineering standards. The projects associated with each cohort are listed below:

- Cohort 2: A way to provide continual monitoring of hypervolemia, indicated by rapid weight gain, in congestive heart failure patients that will alert the user and doctor of potential health hazards in order to provide the appropriate healthcare in a suitable time frame and reduce hospital readmission rates.

- Cohort 3: A way to address patient instability when unlocking a single axis, manual locking knee prosthesis by incorporating a hands-free unlocking mechanism for K1-level transfemoral amputees in order to reduce fall risk and increase patient confidence in their ability to use the prosthetic.
- Cohort 4: A way to address controlled transitioning between reclined and upright positions in infants with moderate to severe osteogenesis imperfecta that promotes environmental interaction and minimizes risk of skeletal injury.

In addition to their design project, students complete a series of hands-on projects to introduce computer-aided design, hand tools and machine shop skills, and Arduino. When the new curriculum was launched, this course was developed with the intention of better preparing students for senior design.

Cell & Tissue Laboratory

With the implementation of the new curriculum, we developed a new Cell & Tissue Laboratory course. In this required lab/lecture course, sophomore BME students are introduced to biomaterials and medical devices. They begin by learning basic lab skills like pipetting and progress to learning aseptic cell culture techniques. In this course, the students make a tissue engineered construct and perform a common regulatory verification test method (ISO 10993-5: Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity) to determine if any elements of the construct (polymer, solvent, poragen) are cytotoxic [16].

Assessment

Junior and Senior Design phase 1 and phase 4 reports were anonymized and randomized (using MATLAB random permutation). A single evaluator reviewed and scored all the phase 1 (design criteria) and phase 4 (verification and validation testing) reports using a rubric (**Tables 3 and 4**). The evaluator could not be blinded since they taught these courses and knew which projects belonged to which cohort. Although phase 4 reports do include the prior phase 1 content (design criteria), in order to isolate the students' understanding of engineering standards, phase 4 reports were not evaluated on design inputs since the team would have received earlier feedback from their faculty advisor.

Table 3. Phase 1 Scoring Rubric (Junior and Senior Design)

Score	Description
1	**No use** of formal engineering standard used to justify a design input (did not identify)
2	**Improper use or referencing** of formal engineering standard to justify a design input (identified but applied incorrectly)
3	**Appropriate use and referencing of 1** relevant, formal engineering standard to justify a design input (identified and applied)
4	**Appropriate use of multiple** relevant, formal engineering standards to justify design inputs (identified and applied)

Table 4. Phase 4 Scoring Rubric (Junior and Senior Design)

Score	Description
1	**No use** of formal engineering standard to construct a test method (did not identify) or identified irrelevant standard
2	**Improper use or referencing** of formal engineering standard to construct a test method (identified a test method and it is relevant, but applied or justified incorrectly)
3	**Appropriate use and referencing of at least 1** relevant, formal engineering standard to **construct** a test method (identified and applied)
4	**Appropriate use of at least 1** relevant, formal engineering standard to **execute** a test method (identified and applied)

Statistical Analysis

All statistical analyses were performed using non-parametric tests since the ordinal data do not follow a normal distribution. The alpha-level was originally set to 0.05 and subsequently corrected (lowered) to account for multiple pairwise comparisons within each independent dataset. The pairwise comparisons of interest were determined in advance: 1) each consecutive cohort compared to its immediately preceding cohort to determine the effect of each newly added instructional method and 2) the last cohort compared to the first cohort to determine the combined effects of all the added instructional methods. Specific statistical comparisons to test the four hypotheses are described below.

To assess **hypothesis 1** (in-class activities improve ability to identify standards), we compared phase 1 (design criteria) Junior Design report scores of the 3 cohorts using a Kruskal-Wallis test (non-parametric 1-way ANOVA). Because the test was significant ($p \leq 0.05$), pairwise comparisons using a Mann-Whitney test (non-parametric t-test) were made between Cohorts 2-3, Cohorts 3-4, and Cohorts 2-4 to assess increasing exposure. To account for these 3 pairwise comparisons, a Bonferroni correction was used, and significance was set to $p \leq 0.02$.

To assess **hypothesis 2** (in-class activities improve ability to execute standards), we compared phase 4 (verification and validation testing) Junior Design report scores of the 3 cohorts using a Kruskal-Wallis test. Because the test was significant ($p \leq 0.05$), pairwise comparisons using a Mann-Whitney test were made between Cohorts 2-3, Cohorts 3-4, and Cohorts 2-4 to assess increasing exposure. To account for these 3 pairwise comparisons, a Bonferroni correction was used, and significance was set to $p \leq 0.02$.

To assess **hypothesis 3** (identify engineering standards as design input justifications in senior design), we compared phase 1 Senior Design report scores of all 4 cohorts using a Kruskal-Wallis test. Because the test was significant ($p \leq 0.05$), pairwise comparisons were made using a Mann-Whitney test between Cohorts 1-2, Cohorts 2-3, Cohorts 3-4, and Cohorts 1-4 to assess increasing exposure in formative courses. To account for these 4 pairwise comparisons, a Bonferroni correction was used, and significance was set to $p \leq 0.01$.

Finally, to assess **hypothesis 4** (apply engineering standards as test methods in senior design), we compared phase 4 Senior Design report scores of all 4 cohorts using a Kruskal-Wallis test.

Statistical analysis was performed using R (version 3.4.3), and graphs were made using MATLAB. All data are presented as box-and-whisker plots with median (red line), 25% and 75% percentiles (box boundaries), and range (whiskers extending to most extreme data points not considered outliers). Outliers (defined as 1.5 x interquartile range) are indicated by x's. Given the small sample size and in order to remain conservative, outliers were not removed from our statistical analysis. Effect sizes were computed using the online tool produced by Lenhard and Lenhard [17].

Results

Statistical significance was attained for all comparisons (Cohorts 2-3, Cohorts 3-4, and Cohorts 2-4) of Junior Design phase 1 reports, indicating that increased exposure and scaffolding produced gains in students' abilities to identify relevant engineering standards as design input justifications (**Figure 1**). Cohen's d effect sizes were 0.8 (Cohorts 2-3), 1.7 (Cohorts 3-4), and 2.7 (Cohorts 2-4). The complete data table is provided in Appendix A (**Table A1**).

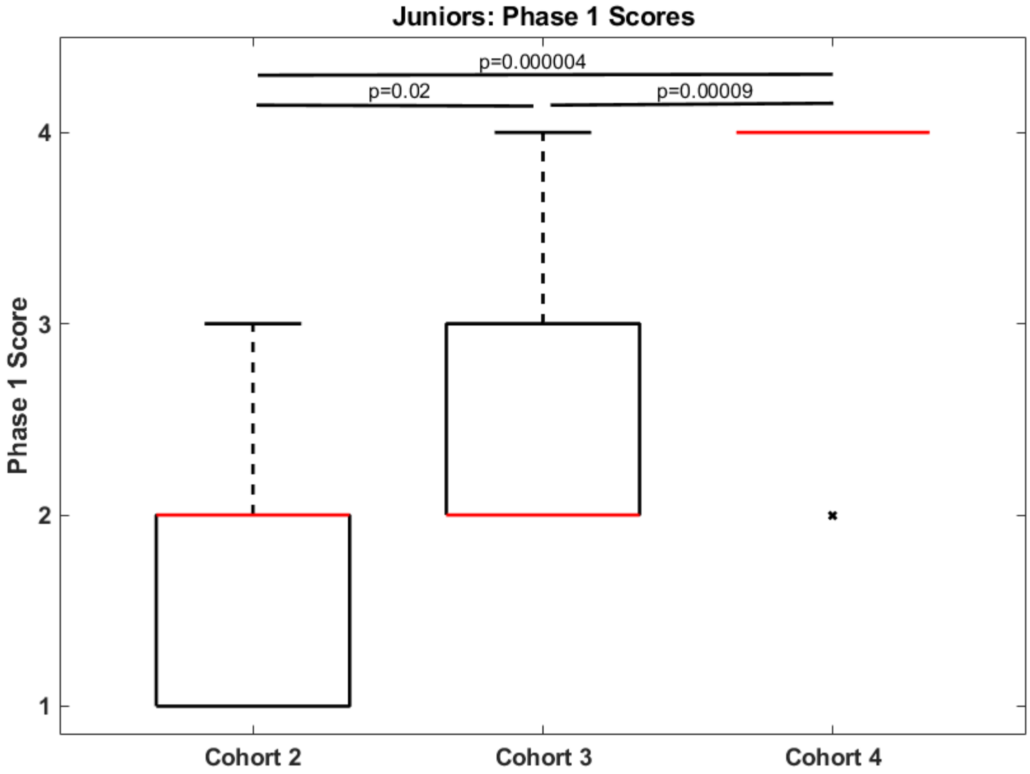

Figure 1. Increased exposure through in-class activities (Cell & Tissue Lab, engineering librarian lesson, dissecting a test method) increased students' abilities to identify relevant, formal engineering standards to justify design inputs.

In comparing Junior Design phase 4 report scores, statistical significance was attained comparing Cohorts 3-4 and Cohorts 2-4 (but not Cohorts 2-3), indicating that increased exposure and scaffolding produced gains in students' abilities to execute relevant engineering standard test methods (**Figure 2**). Cohen's d effect sizes were 1.6 (Cohorts 3-4) and 1.9 (Cohorts 2-4). The complete data table is provided in Appendix A (**Table A2**).

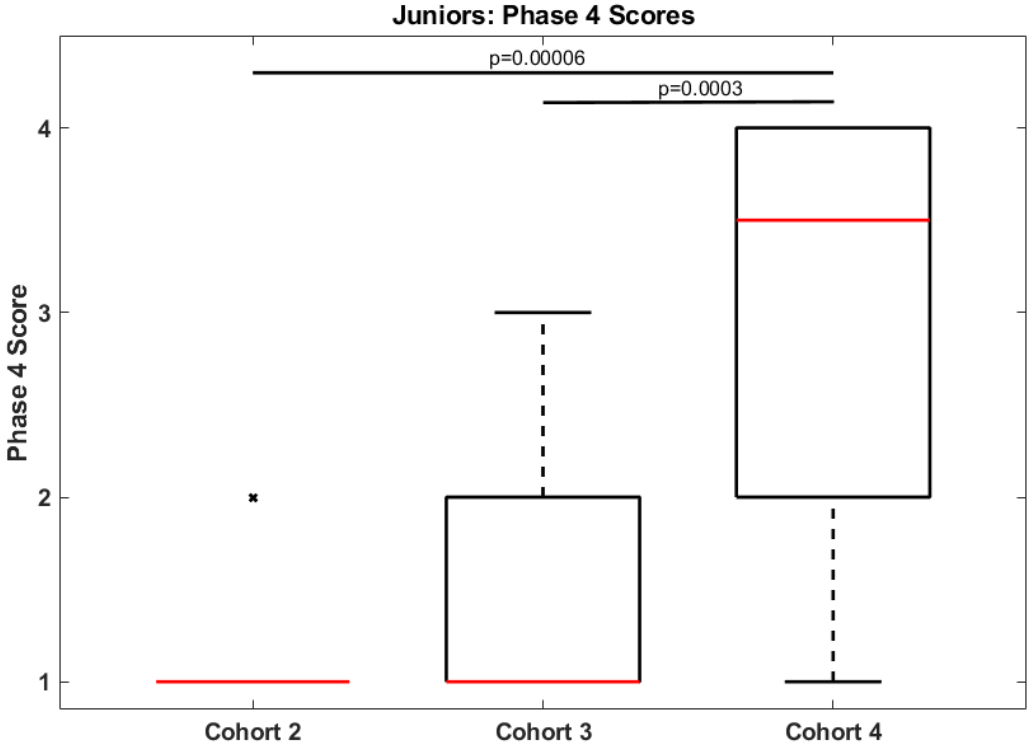

Figure 2. The addition of an in-class lesson and activity on how to apply an engineering standard test method significantly increased students' abilities to execute relevant engineering standard test methods in Junior Design.

The number and percentage of Senior Design teams using ISO 10993 as design criteria justification in phase 1 is shown in **Table 5**. Cohort 4, which had the greatest exposure to engineering standards through formative courses, demonstrated statistically significant increased ability to identify relevant engineering standards as design input justifications in Senior Design compared to Cohort 1 (Cohen's d effect size = 1.0, **Figure 3**). No other comparisons reached statistical significance (Cohorts 1-2, Cohorts 2-3, Cohorts 3-4). The complete data table is provided in Appendix A (**Table A3**).

Table 5. Incorporation of ISO 10993 as Design Criteria in Senior Design Phase 1

Cohort	Took Cell & Tissue Lab?	# (%) of Teams Using ISO 10993 as Design Criteria	Pooled
1	No	2/18 (11%)	5/32 (16%)
2	No	3/14 (21%)	
3	Yes	5/16 (31%)	8/29 (28%)
4	Yes	3/13 (23%)	

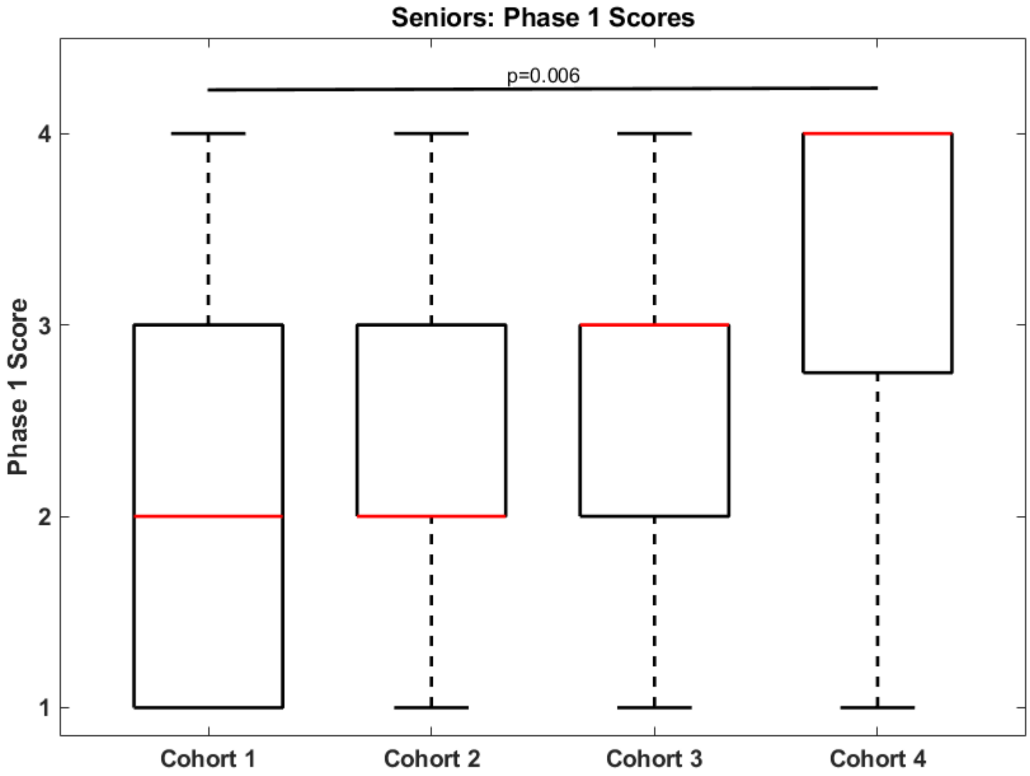

Figure 3. Cohort 4, which had the greatest formative exposure to standards, could better identify relevant engineering standards to use as design input justifications in senior design, compared to Cohort 1.

No significant differences in ability to apply relevant engineering standards as executable test methods were detected between Cohorts in phase 4 of Senior Design (**Figure 4**). The complete data table is provided in Appendix A (**Table A4**).

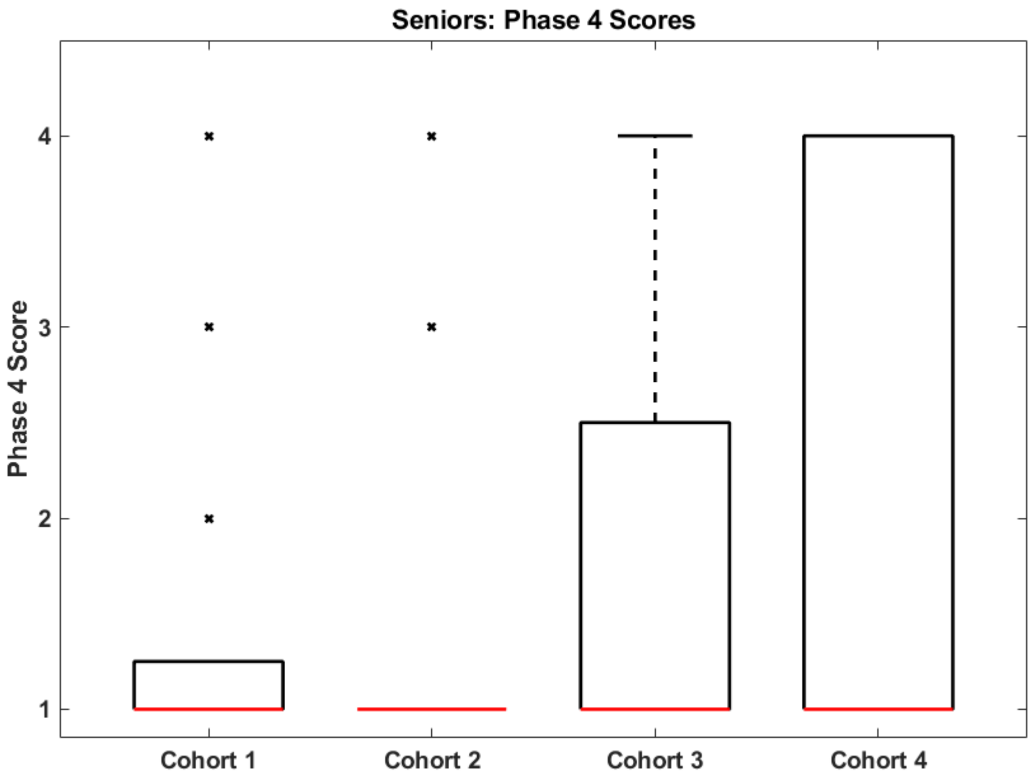

Figure 4. No significant differences were detected between Cohorts' abilities to apply engineering standards as executable test methods in Senior Design.

A summary of all statistical comparisons and results is provided in **Table 6**.

Table 6. Summary of Statistical Comparison Results

		Cohort Comparisons			
		1-2	**2-3**	**3-4**	**1-4 or 2-4**
	Added instructional methods	+ Junior Design	+ Cell & Tissue Lab + Engr Librarian	+ Identify test method	+ All preceding additions
Juniors	**Phase 1**	---	**p=0.02**	**p=0.00009**	**p=0.000004**
	Phase 4	---	NS	**p=0.0003**	**p=0.00006**
Seniors	**Phase 1**	NS	NS	NS	**p=0.006**
	Phase 4	NS	NS	NS	NS

NS = not statistically significant

Discussion

Results support hypothesis 1 that increased exposure and scaffolding through in-class activities improved students' abilities to identify relevant engineering standards as design input justifications in Junior Design. Compared to Cohort 2, Cohort 3 had exposure to engineering standards in Cell & Tissue Lab (ISO 10993-5) and through a Junior Design in-class lesson provided by the engineering librarian. Cohort 4 had an additional lesson and class activity on how to dissect an engineering standard test method and apply it for verification. All of these activities appear to have significantly improved students' abilities to identify standards.

Results support hypothesis 2 that increased exposure and scaffolding through in-class activities improved students' abilities to execute relevant engineering standard test methods in Junior Design. These results suggest that the in-class lesson on dissecting and applying an engineering standard test method significantly improved students' abilities to construct and execute test methods. Exposure to a standard test method (ISO 10993-5) in Cell & Tissue Lab in itself did not improve students' abilities to construct and execute tests, as demonstrated by the lack of statistical significance attained in comparing Cohorts 2-3.

The findings from the Junior Design comparisons indicate that small in-class lessons can have a profound impact on students' abilities. The measured Cohen's d effect sizes are all large (≥ 0.8), supporting practical (in additional to statistical) significance of these lessons.

To evaluate the extent to which students were able to transfer knowledge of engineering standards gained from prior courses, we compared Senior Design reports from cohorts of different formative exposures. Hypothesis 3 (increased ability to identify relevant standards as design inputs in senior design with increased exposure to standards in formative courses) was somewhat supported. Although no statistically significant gains were measured between cohorts of consecutive years (Cohorts 1-2, Cohorts 2-3, and Cohorts 3-4), we did detect a statistically significant difference between Cohorts 1-4. These results imply that the incremental improvements in exposure each year led to pronounced gains when combined (i.e., a single activity had only a small effect size, but when combined, the effect size was additive). Through exposure to standards in Cell & Tissue Lab and Junior Design (engineering librarian lesson and lesson to apply test method), students developed skills that allowed them to transfer this knowledge and apply it to a new project in Senior Design. These findings support the educational practice of "spacing" [18] and repetition. Furthermore, although statistical analysis could not be performed, we did measure a greater percentage of teams that incorporated ISO 10993 as design criteria justification in phase 1 of Senior Design when they had taken Cell & Tissue Lab (which includes ISO 10993-5 as a lab procedure) compared to when they had not (28% vs. 16%).

In many engineering undergraduate curricula, capstone may be the only time that a student engages with engineering standards (our Cohort 1); however, our data reveal the importance of repeated exposure throughout the curriculum. Prior to the implementation of the new curriculum, students were asked to use engineering standards in Senior Design but were never formally taught where to find them or how to use them. We found that asking students to use engineering standards in a prior course (Junior Design) did not in itself lead to gains in students' abilities to identify engineering standards in Senior Design (Cohorts 1-2 comparison). This finding highlights the importance of formally teaching students about engineering standards. Extrapolating, this analysis would suggest that exposure to engineering standards through Senior Design alone does not adequately prepare students to identify and apply engineering standards after they graduate; they do not build the required transfer skills through just a single exposure.

Unfortunately, we did not detect any statistically significant improvements in students' abilities to apply engineering standards as executable test methods in Senior Design; hypothesis 4 was not supported. This finding could partly be due to the fact that there are fewer defined, standard test methods than there are defined, standard design criteria. Regardless, our data reveal a persisting gap in our curriculum. We hope to address this gap through small-scale inclusion of engineering standards in other formative courses. For example, the author has since included a homework problem in a core junior-level biomechanics course that required students to read and apply ASTM F543-17: Standard Specification and Test Methods for Metallic Medical Bone Screws to develop a mechanical test method that determines torsion properties of a bone screw. Similar assignments and labs could also be incorporated into bioinstrumentation and experimental design and analysis courses (both required courses in many BME undergraduate curricula).

This study is not without limitations. First, because Cohort 3, compared to Cohort 2, had exposure to standards in both Cell & Tissue Lab and through an in-class lesson by the engineering librarian (Tables 1 and 6), we cannot isolate these effects independent of each other. Junior Design teams were all co-advised by the authors; however, Senior Design teams had a number of different advisors. We did not evaluate the effects of the advisor, team composition (number of BME vs. other majors), or project. Since engineering standards are not defined for every biomedical device, some projects may have more applicable standards than others. Despite these limitations, we believe the findings demonstrate the significant impact that repeated, spaced practice has on student learning.

Conclusion

In conclusion, we have demonstrated that formative exposure through deliberate, in-class lessons improves students' abilities to later identify relevant engineering standards. Our aim is that our curriculum modifications and small-scale instructional techniques may serve as a model for other institutions on how biomedical engineering standards can be integrated throughout an undergraduate curriculum.

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Appendix A: Complete Data

Table A1. Juniors Phase 1 Scores

		Cohort 2		Cohort 3		Cohort 4	
		Count	**%**	**Count**	**%**	**Count**	**%**
Score	**1**	4	31%	0	0%	0	0%
	2	7	54%	8	62%	1	7%
	3	2	15%	3	23%	0	0%
	4	0	0%	2	15%	13	93%

Table A2. Juniors Phase 4 Scores

		Cohort 2		Cohort 3		Cohort 4	
		Count	**%**	**Count**	**%**	**Count**	**%**
Score	**1**	11	85%	9	69%	2	14%
	2	2	15%	3	23%	2	14%
	3	0	0%	1	8%	3	21%
	4	0	0%	0	0%	7	50%

Table A3. Seniors Phase 1 Scores

		Cohort 1		Cohort 2		Cohort 3		Cohort 4	
		Count	**%**	**Count**	**%**	**Count**	**%**	**Count**	**%**
Score	**1**	6	33%	2	14%	2	13%	1	8%
	2	5	28%	6	43%	3	19%	2	15%
	3	4	22%	3	21%	8	50%	2	15%
	4	3	17%	3	21%	3	19%	8	62%

Table A4. Seniors Phase 4 Scores

		Cohort 1		Cohort 2		Cohort 3		Cohort 4	
		Count	**%**	**Count**	**%**	**Count**	**%**	**Count**	**%**
Score	**1**	13	76%	12	86%	11	69%	8	62%
	2	1	6%	0	0%	1	6%	0	0%
	3	1	6%	1	7%	1	6%	1	8%
	4	2	12%	1	7%	3	19%	4	31%