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Start with Problems or Solutions? Medical Device Design in Industry and Academia

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ABSTRACT Design processes can be influenced by their practice environments. Although design processes of industry engineers have been examined in multiple research studies, few studies have investigated design processes of academic engineers. As academia and industry have different sociocultural norms and constraints, their design processes likely also differ. To examine this question, we conducted semi-structured interviews with both academic and industry engineers who had successfully designed medical devices. Our qualitative findings revealed that engineers in industry described their design process as a sequence with problem definition, solution exploration, detail design, evaluation, and communication. Academic engineers, in contrast, described their design process as beginning with a discovered solution, then searching for application problems, evaluating compatibility between problems and solution, and finally, communicating their findings through publications. Understanding differences in design processes of academic and industry engineers can facilitate knowledge sharing and promote collaboration between academia and industry. The findings also highlight the impact of sociocultural norms on practices, even in disciplines with highly trained and clearly defined processes.

INDEX TERMS Design processes, design practice, design problems, innovation

I. INTRODUCTION

Collaboration between industry and academia has been key to continuous technological innovations, with knowledge and technology transfer flowing in both directions between industry and academia [1]. Academic connections with industry have the potential to maximize the development of innovative ideas and methods for commercial products [2] as academia often serves as a hub of knowledge creation that is shared with industry [3], [4]. For instance, an empirical analysis of technology transfer mechanisms in over 2,000 firms demonstrated successful academic technology transfer was an important ingredient in economic growth and technological progress [5].

However, various cultural gaps between industry and academia, such as limited understandings of each other's work environments and differing communication approaches, have been identified as posing impediments to successful collaboration [6]. Different work environments in industry and academia set different priorities and values and likely affect how and when information is transferred. These cultural gaps need to be bridged to improve collaboration, in part through better understandings of the norms and needs of each work environment.

Both academia and industry, particularly in medical device development, have similar goals to develop technologies for commercial or publication purposes. Further, both industry and academic professionals in medical device design identify open-ended problems, generate solutions, test their solutions, and communicate their outcomes [7]. However, industry and academic practitioners have different cultural norms and constraints that may affect their design processes; design processes have been shown to be influenced by various cultural norms that put constraints on design, which have to be dealt with and balanced [8]. Due to different sociocultural norms, we suspected that design processes may differ between these engineering contexts.

Thus, the objective of our research was to examine design processes of practicing engineers in academia and industry using semi-structured interviews, and to identify strategies and goals within those processes. We focused on front-end design processes, defined to include problem definition and concept generation [9], as we were particularly interested in divergent and convergent design activities at the time when the problem and solution are most open and evolving. To limit variations in the findings that could arise in different

fields, we recruited engineers experienced in the field of medical device design.

II. BACKGROUND

Practitioners in a variety of disciplines (e.g., the arts, architecture, software, and engineering) engage in design processes not exclusive to a single discipline [10]. The search for solutions to ambiguous and ill-defined problems with many uncertainties is key in definitions of design [11]–[13]. Simon [14] described characteristics of design as solving problems without correct answers (only better or worse solutions), and continuing to iterate and receive feedback. In engineering, design processes overlap with other complex processes; for example, research—a systematic investigation into a subject to increase knowledge [15]—and technology transfer—further development and commercialization of scientific findings [16]—share commonalities with design processes, such as ill-defined problems, better or worse solutions instead of right or wrong, iterative feedback loops, and high costs associated with every action. When engineering practitioners engage in both research and technology transfer, their activities can be viewed through the lens of a design process where they develop novel device designs to address open-ended, ill-defined problems.

Design process models in engineering describe sequences of design, typically including problem definition, solution generation, evaluation, and communication [7, 8]. The problem definition phase includes understanding the initial problem, which can be given by a client or found through observations and interviews with stakeholders. Problem definition is an important phase in a design process that shapes outcomes because the initial problem sets the trajectory for the rest of a design process. Solution generation involves considering multiple, diverse concepts to address the problem with minimal evaluation early in a process. Concepts are then further developed, and tested (in the evaluation phase) to ensure that designs fulfill performance requirements for operation, manufacturing, and sales [11]. Once a final concept selection is made, the design is communicated through production documents and presented in physical forms. Design process models frequently include iterative returns to earlier phases.

Design processes often include both convergent and divergent activities. Divergent thinking, defined as considering many appropriate alternatives [17], is used throughout design to consider possible perspectives, pathways, and solutions. Divergent thinking is particularly important in the front-end of design to promote a broad exploration of the design problem and possible solutions. In contrast to divergent thinking, convergent thinking emphasizes focusing and narrowing options. Cross [11] characterized overall design processes as being convergent, but also emphasized deliberate divergence throughout to search for new ideas. Liu and colleagues [18] discussed a possible ideal approach in developing concepts as repeated divergence and convergence to “increase the effectiveness

of explorability of concepts with minimum compromise to the richness of the solution space explored.” Combining both divergent and convergent activities allows designers to explore a wide variety of alternatives and pursue appropriate choices to help them achieve design success.

However, these specified engineering design processes take place within a situated and social context. Esbjörn-Hargens stated that intentional, behavioral, cultural, and social aspects should be considered to understand reality [19], [20]. Research has documented that design is often a collaborative social activity that is affected by norms [21]. Designers consider other stakeholders’ decisions, priorities, culture, and traditions [22] to effectively navigate a design process. Research in many disciplines, including architecture, arts, engineering, and human-computer interaction, has documented that design is affected by its context [10]. For example, Bucciarelli’s work stated that design is a social construct because each designer approaches design in quite different ways [23]. Goel and Pirolli [24] articulated 12 features describing the characteristics of design tasks; in particular, one feature is *being influenced by negotiable* (such as social and political) and *non-negotiable* (including physical and chemical) *constraints*. These social and political constraints impact both the context external to the design team as well as the context internal to the design team. For example, the larger cultural context in which designers operate can guide their approaches. Clemmensen and colleagues [25] found that cultural knowledge, either as shared by some team members of cross-cultural teams, shaped reasoning patterns, and design decision making. Designers in low- or middle-income contexts have shown to rely on design practices that leveraged virtual prototypes and underutilized physical prototypes to engage with stakeholders [26]. Culture and perception of norms have been shown to significantly impact problem space investigations when designers and lead-users from Western and East Asian cultures worked together [27].

The discipline of the designers could also impact their processes. For example, in the U.S., design processes in medical device design must abide by the Food and Drug Administration regulations [28] and international standards on design and testing techniques to develop requirement specifications that define product functionality [29].

Beyond disciplinary contexts, work environments likely also impact design processes. In industry settings, financial and resource limitations constrain design practices. For example, one study demonstrated that cash flow and capital investment affected their success to design as they needed to invest in manufacturing the new product design [30]. Cooper and Press argued that conflicts within companies, such as a culture of competition among design, engineering, and marketing departments, can constrain design [31]. An interview study demonstrated that resistance from senior management based on tradition-bound behaviors affected design processes [30]. Organizational culture – the shared beliefs and values of its members – affect their norms and guiding behavior. Culture provides an environment to which

the individuals accommodate to fit in. [32]. In academic settings, the culture appears to differ from industry because government funding often supports academia's efforts [33], which may lead to different priorities and stakeholder needs.

Further differences between the culture of industry and academia were evident in a case study of a successful university-industry collaboration that demonstrated differing interests as the industry can emphasize the business elements while the academia focuses on publications and research dollars [34]. In academia, the complex incentive structures of scholarly publications introduce norms and values that prioritize knowledge transfer [35]. Due to differences, research has documented the challenges of developing collaboration opportunities between academia and industry in designing solutions [36]. In software engineering, industry practitioners may not see the direct value in collaborating with academic engineers who focus on scientific knowledge because industry practitioners face tough competition and short time-to-market, requiring them to focus on product development instead of scientific research [37]. Much of the literature documenting collaboration opportunities between academia and industry has emphasized outcomes and less on processes.

Few studies have looked at specific design processes in academia. For example, one study on prototyping during an aeronautical project emphasized that academic engineers can focus on creating a design prototype that deviated from an existing solution [38]. In the field of software development, one study demonstrated that academic designers viewed design as an open-ended problem that needed continuous iterations with less emphasis on having a clear timeline to develop a product out to market [39]. In the field of robotics, academic engineers have developed an optimal design of a manipulator and industry can build on this design for commercial applications [40]. Academic engineers provided the knowledge and expertise to develop the initial prototype before industry engineers further developed the design. Additionally, designing in academia often emphasizes developing advanced technologies to address problems [41], [42] as engineers seek to publish their work that would be beneficial for others in both academia and industry. For example, academic designers in one study emphasized creating new materials to mimic the mechanical and physical properties of tissues [41]. Much of the literature documenting design in academia describes a specific process or practice within design rather than overall design processes.

III. RESEARCH DESIGN

A. RESEARCH QUESTIONS

The focus of this study was to investigate design processes in academia and industry with an emphasis on medical device development. The terms academia and industry were used broadly in this study to indicate descriptions of pathways within medical device design—the “industry track” or the “academic track” [43] Our study addressed the following research questions:

- What similarities and differences exist in medical device design processes between industry and academia?
- How do work environments influence design processes in academia and industry?

B. RESEARCH APPROACH AND GUIDING FRAMEWORKS

We leveraged qualitative research methods to allow for the open-ended discovery of design process norms, strategies, and goals. Qualitative research allows for an emergent approach to data collection and analysis instead of requiring hypotheses a priori [44]. Qualitative research was well-suited for this study because the lack of prior research in this area. Qualitative studies focus on in-depth descriptions of phenomena in a context that can lead to a better understanding of complex phenomena involving humans and social interactions. They do not aim to generalize, but rather to allow for transferability of the findings into other contexts based on the rich descriptions provided.

Because a design process can extend over a period of years and involves proprietary information, it was not possible to directly observe designers' process as they occurred. The interview protocol developed as part of the study was guided by two frameworks: design processes and convergent and divergent design activities. The design process framework includes descriptive and prescriptive process models collected by Cross and Dubberly [11], [45], and the common phases of design found across the models. The interview posed questions about common phases represented in design process models, including problem exploration, idea generation, evaluation, iteration, and communication. Our analysis also looked at each of these phases individually and in sequence, comparing the processes to phase norms in the literature.

Convergent and divergent activities within design processes provided another lens that guided both interview protocol development and data analysis. Convergent and divergent activities represent considering alternatives and narrowing down on a decision. For example, in the interview protocol, questions included those on solutions considered (divergent) and discarded (convergent) as well as constraints and goals that affected their decisions to converge on their options.

Data collection and analysis are described in the following sections and depicted in Figure 1.

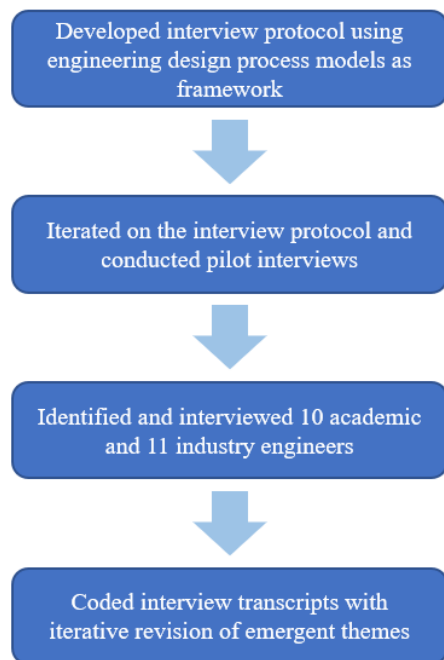


Figure 1. Research steps

C. PARTICIPANTS

Ten academic (labeled A1-A10) and eleven industry participants (labeled I1-I11) in the field of medical device development participated in this study (Table 1). The number of participants is consistent with other qualitative design interview studies [10], [46], [47]. Researchers often attain what qualitative research guidelines call “saturation of data,” meaning no additional themes emerge as additional participant data are added and further data collection may not be necessary. Creswell [28] suggested that 20-30 participants are often sufficient to reach saturation.

We identified engineers who had experience designing at least one physical medical device from beginning to end. It was imperative to recruit participants who had experience throughout an entire design cycle to ensure that they could answer questions about a complete medical device design process. The participants were recruited via email that included information about the researcher and the purpose of the research project. After the initial recruitment, additional participants were recruited through a snowball sampling approach, which leveraged existing networks to recruit additional participants [29].

Academic participants were employed in two large Midwestern U.S. universities in positions including graduate student researchers, postdoctoral researchers, research scientists, and professors. All academic participants had developed multiple devices working on projects funded by government grants and/or outside clients, including companies and medical clinicians. Academic participants had 4 to 20 years (average = 10.75 years) of experience in designing medical devices.

Industry participants were recruited from companies in the Midwest, East Coast, and West Coast of the U.S. Industry. Participants worked in companies of small (less than 50 employees), medium (between 50-249 employees) and large (greater than or equal to 250 employees) sizes. All industry participants were involved in product development. Most of the industry participants first started working in academia before transitioning into industry and had an average of 5.5 years of experience in academia and 3.7 years in industry. All participants in this study reported content expertise in mechanical engineering or biomedical engineering, and they received their highest educational degree or worked in a department of mechanical or biomedical engineering. Participation was voluntary and confidential, and no payment was provided.

Table 1. Participant information

(* indicates engineers with start-up experience)

Pseudonym	Gender	Highest Education	Size of the institution/company	Years in academia	Years in industry
A1	M	Ph.D.	Large	20*	0
A2	M	Ph.D.	Large	16*	0
A3	M	Ph.D.	Large	13	0
A4	M	Ph.D.	Large	7	0
A5	M	Ph.D.	Large	12	0
A6	M	Ph.D.	Large	10	0
A7	M	Ph.D.	Large	16	0
A8	F	Ph.D.	Large	4.5	0
A9	M	M.S.	Large	4	0
A10	M	M.S.	Large	5	0
I1	M	PhD	Medium	14	2
I2	M	B.S.	Small	2	3
I3	F	Ph.D.	Large	4.5	3
I4	M	B.S.	Small	0	3
I5	F	M.S.	Medium	4	6.5
I6	M	Ph.D.	Large	9*	1
I7	M	Ph.D.	Large	8	6
I8	M	Ph.D.	Large	5	10
I9	M	Ph.D.	Small	9	1
I10	M	Ph.D.	Large	2	3
I11	M	Ph.D.	Small	4	2.5

D. DATA COLLECTION

Using semi-structured interviews allowed exploring the perceptions and opinions of participants and enabled probing for more information [48]. Probing can be a valuable tool in ensuring the reliability of the data because it can allow for clarification of responses [49] and eliciting complete information [50]. Probing also helps in recalling information for questions involving memory [51]. Many design studies make use of in-depth questioning to explore participants’ experiences [10], [46], [47], [52].

To encourage storytelling, our interview protocol asked participants to give us an example of a specific project on which he/she had worked, and all the questions probed on details of that specific experience. Example questions are shown in Table 2, and the complete interview protocol can be found in Appendix A1. The interview questions were developed through ten iterations to ensure clarity of

questions. Four researchers with experience in qualitative methods examined the interview protocol multiple times, and we conducted two pilot interviews with academic engineers to support the protocol development process. For example, one of the initial questions asked “How did you come up with your concepts and ideas?” One pilot participant asked for clarification on what we meant by “concepts and ideas.” Additionally, this participant reported having only one idea instead of multiple ideas. To clarify, we revised this question to, “How did you come up with the solution to address the question?” We also added a follow-up question asking, “Did you have any alternative solutions to the problem?” Data from pilot studies were not included in the analysis.

One interviewer conducted all of the interviews for consistency. Interviews lasted between 30 and 90 minutes and were audio-recorded. The length of each interview differed based on how much the participants elaborated on the details of their work.

As recommended for qualitative research, the researchers identified and recorded their biases regarding expectations of the results [53]. We believed that due to the academic culture that values novelty and new knowledge, academic participants would diverge to consider more novel, varying solutions during concept generation. We developed our interview protocol to limit biases by asking open-ended questions that were not leading.

Table 2. Interview structure and example questions.

Focus Area	Example question(s)
Background	How long have you been working in your field?
Overview	Can you tell me about one device you developed and give me an overview of the process?
Problem exploration	From the experience that you just shared, what was the main goal that you started with? What did you envision the final outcome of this project to be?
Idea generation	How did you come up with the solution to address the question? Did you have any alternative solutions to the problem that you were trying to solve?
Evaluation and iteration	Did you refine your device to make improvements throughout the process? How did you know to make those changes?
Final outcome	At the end, how did you know that you were finished?
Critical constraints	Thinking about the project as a whole, what criteria or constraints were important to your device?
Environment and setting	How did the academic university or industry setting affect the choices and approaches?

E. DATA ANALYSIS

We transcribed all recorded interviews and used an inductive coding approach as described by Creswell [44] to analyze the findings. The codes emerged through interpretations made during detailed readings of raw data multiple times to determine themes and allow theories to emerge from the data. The initial codes were developed based on emergent patterns without any predetermined codes. The initial codes were developed by two authors through regular discussions of the raw transcripts. These initial codes were iterated on with all authors through discussions of the interview data to identify consistent emerging themes. Several codes based on different design phases and constraints were grouped together to create categories. For example, one category was *problem definition*. An example code was *freedom to pursue an idea*, indicated by a participant statement such as:

“I guess the university had the freedom to just go off on a tangent” (Participant A1).

Another category was *idea generation*, and an example code under this category was *limited alternatives*. This code captured statements indicating that a participant did not consider alternative solutions, such as:

“Let me think about, did we have alternative solutions? I don’t think I came up with something else” (Participant A5).

During the analysis, identified codes were continuously compared to newly emergent codes and revised throughout the process. The codebook can be found in Appendix A2, which includes all categories and codes identified. After data analysis, we shared the manuscript with our participants and asked for their feedback, which is a common practice to validate the results [54].IV. FINDINGS

There were some similarities in design processes and decisions made between academic and industry engineers; for example, both academic and industry engineers sought to maximize expertise and look for ideas in the literature during concept generation. Both work environments also emphasized the importance of publishing papers as a way to communicate their results.

However, key differences emerged between academic and industry engineers’ approaches to problem definition and solution generation. Industry engineers’ processes paralleled a “typical” design process sequence, as evidenced in collections of process models [45], beginning with problem definition, then concept generation, detailed design, evaluation, and communication. Industry engineers iterated between problem definition and solution generation to refine their problems and requirements. In the detailed design phase, industry engineers expressed the need to

minimize risks of an extended timeline by selecting promising and practical solutions that were also user friendly and manufacturable. Industry engineers stated that they focused on developing marketable products that would satisfy their users and stakeholders and often published their results in academic papers to help them advertise their products. In contrast, academic engineers began their design processes with concept generation, then turned to problem definition, and then to detailed design, evaluation, and communication (see Figure 2). Academic engineers did not *consider multiple solutions* during concept generation; instead, they described their focus as using existing, set solutions, and searched for problems that the set solutions could solve. If a defined problem could not be addressed with their set solutions, they moved on to different problems. Academic engineers stated that they looked for novel problems to solve, and their aim was to demonstrate

proof of concept that would lead to scholarly publications. An overview of these processes is shown in Figure 2.

The constraints and goals described by engineers for design projects in academia and industry were also different, which led to a different emphasis in their final devices. Industry engineers described their goals as developing products that would be profitable, and satisfy the requirements of their stakeholders, which led to an emphasis on usability and manufacturability. Academic engineers described leveraging their specific, technical expertise to provide solutions to open questions, leading to new knowledge suitable for scientific publication. Academic engineers' emphasis on scientific publication led to focusing on demonstrating proof of concept for the feasibility of an idea without emphasis on usability and manufacturability. Our findings are summarized in Table 3 and elaborated on with interview excerpts in the following subsections.

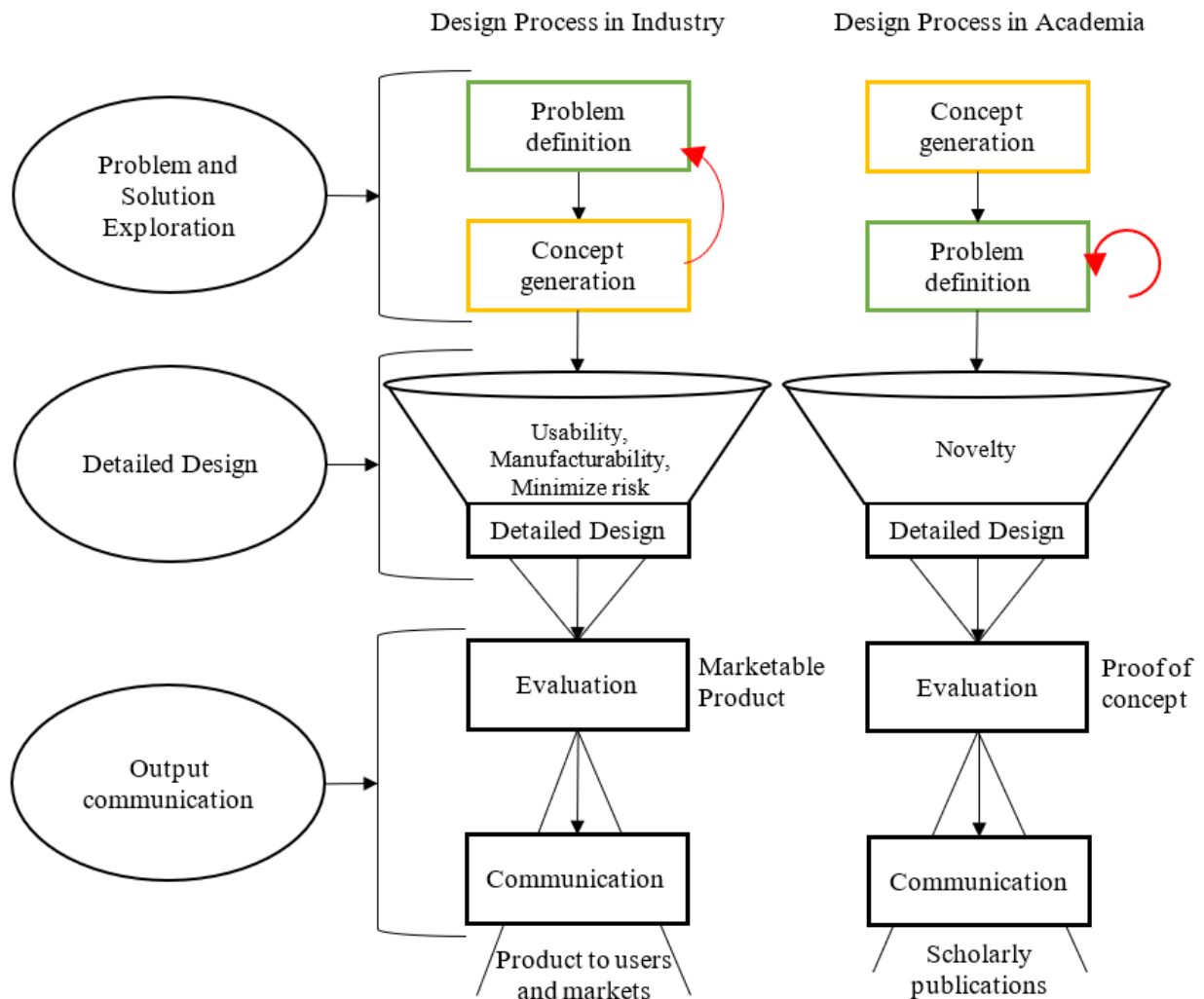


Figure 2. Overview of common elements of design processes in industry and academia

Table 3. Comparisons of steps and priorities of industry and academic engineers in their design processes

	Industry	Academia
<u>Problem Definition</u>		
Identifying problems	Given	Chosen
Iterating during problem definition	Problems and solutions	Finding problems
<u>Concept Generation</u>		
Generating concepts	Considered multiple, diverse solutions	Considered few or no alternative solutions
Consulting help	Important	Important
Searching the literature for ideas	Important	Important
Maximizing expertise	Within company	Within individual
<u>Detailed Design</u>		
Taking risks	Minimized by selecting promising solutions	Not addressed
Having strict timelines	Important	Not an emphasis
Focusing on usability	Important	Not an emphasis
Focusing on manufacturability	Important	Not an emphasis
Having competitions	Served as important benchmarks	Not an emphasis
<u>Evaluation</u>		
Delivering a device	Marketable product	Proof of concept that would lead to publications
<u>Communication</u>		
Publishing a journal paper	Used to advertise their product	Used to demonstrate new findings
Communicating with stakeholders and end users of the device	Important emphasis	Not very important

A. PROBLEM DEFINITION

Identifying problems

Engineers in the two work environments displayed differences in how they started their design processes. Industry engineers described their design processes as starting with a defined problem while academic engineers started with solution and looked for applications of their solution. In industry, problems were provided for them by higher management or marketing, and their next step was to generate solutions to solve those problems (a common design process sequence). These problems were based on known customer needs. Industry engineers iterated on problem definition and concept generation phases to refine design requirements. For example, one industry engineer working at a large company after receiving his Ph.D. to develop a medical device related to diagnostics stated:

The business side will [...] go out and then determine there's a customer need... when [you have a condition], right? I'll make a go from that example. The marketing team comes and says, "Hey, we need to know [someone has a condition]. Here's my customer need" (Participant I10).

Similar to Participant I10, who was given problem based on a customer need from the marketing team, Participant I5 emphasized the importance of customer needs as her primary focus in defining her initial problem:

"[A] big driver is our customers. If the customer says, "[...] here's my situation [...] I have this special need," then we can work with the customer to try to address their needs" (Participant I5).

Different from industry, academic engineers began their design processes by actively seeking problems that they could address with their technical expertise or existing solutions. Academic engineers also reported that they had the flexibility to choose and change problems if a proposed problem could not be addressed with their solutions. As technology experts, academic engineers commonly looked for problems that they could solve through new collaboration opportunities. Participant A2 stated that he was openly looking for problems to address with a specific device as the solution method:

“I just wanted to get some experience in the biology lab and talk to biologists, so I didn't care if it was [a topic] or something else. I just wanted to find basically a good application of [my device] ... so it had a practical use” (Participant A2).

In defining problems to solve, academic engineers often looked for collaboration opportunities through discussions with biologists and clinicians. Academic engineers frequently mentioned that biologists and clinicians knew of “good problems” that could not be addressed with any existing solutions. For example, Participant A4 described the benefit of collaborating with biologists and clinicians in identifying problems:

“[Clinicians or biologists] have this question, and it's very important and [clinicians or biologists] cannot answer it. Based on my experience there are a lot of these kind of questions. But as an engineer, we don't know. [Engineers] don't know [clinicians or biologists] need this kind of tool. So, talking or the discussion between the clinicians is very helpful, or biologists” (Participant A4).

Iterating during problem definition

Industry engineers indicated the importance of iterating between the problem statement and potential solutions while academic engineers iterated in identifying new problems that they can solve using their solutions. Industry engineers often did not take the problem as a given; they worked with marketing and engineering teams to iterate on problem definitions and potential solutions based on the capabilities and limitations at their companies. Their design processes did not typically progress linearly in a single cycle from problem definition to concept generation in industry. Participant I10 emphasized this process of understanding the feasibility of a project for their company by iterating on possible solutions and redefining problems with multiple departments within the company:

“Everybody gives input into what they think they can do to achieve this [...] Once marketing understands there is a possibility that this can be

done, then what marketing will do is they'll go out again [...] Marketing comes back and says the average customer is going to be your average consumer. A person at home. They don't want a finger prick. They want it done in 5 minutes. They prefer urine or saliva. They want it easy to read. That gets more defined into a customer-needs document” (Participant I10).

While Participant I10 iterated the problem statement with the marketing department, Participant I4 directly engaged with their users to better understand the design problem; Participant I4 emphasized that iterating on possible solutions and redefining problems in the early phase of design as an important aspect of his process:

“Let's get something that works that we can go and test with our users and find out what's important and then refine, instead of trying to do everything in one shot” (Participant I4).

In their descriptions of iterating on possible solutions and redefining problems, industry engineers emphasized the importance of refining their problems early. This process of defining problems was largely driven by the goal of identifying profitable problems. The problem defined by the company needed to fit into known market needs and be likely to provide financial rewards when the problem is addressed.

Academic engineers iterated on identifying the initial problems and moving on to different problems if their solutions could not address the initial problem. Academic engineers were not bounded by specific problems they needed to solve. For example, one academic participant stated:

“If it didn't work, we weren't going to fiddle around with it [...] We were excited because it was a good fit, but if it didn't fit, we probably wouldn't have worked too much on alternatives. It's a great application, but we weren't that interested in the application” (Participant A1).

Participant A1 was not restricted to solving this one problem. If his technical expertise was not right for the problem, he would not have continued to work on the project. Instead, he planned to move on to a different problem that his solution could address. This freedom to switch problems was considered a primary factor driving the process of problem definition for academic participants and was repeatedly reported. For example, Participant A7 indicated:

“When you are working in university, you can work on anything. Whenever you see a possibility you can go ahead and try it out” (Participant A7).

The academic culture promoted the flexibility in defining problems that allowed the academic engineers to switch directions based on their own interests. Unlike the industry culture that emphasized solving problems that will generate profit, financial reward for solving a problem was not emphasized in academia. By not being bounded to profit generation, the academic culture may have allowed academic engineers to switch and iterate on problems more easily.

B. CONCEPT GENERATION

Generating concepts

Industry engineers searched for multiple solutions that would meet customer requirements, while academic engineers considered limited or no alternative solutions because academic engineers' solutions were often predefined before starting their projects. One industry participant who was working on sorting different types of cells from blood for diagnostics indicated that he considered a range of different solutions during concept generation:

“We had several brainstorming sessions where we thought of several different approaches. This one seemed to work the best, and we pursued it more, but yeah. We had a lot of different ideas, some of them were just not too good.” (Participant I2).

Industry engineers initially generated a number of solutions, often tested several possible concepts, and selected a promising solution at the end. Industry engineers emphasized the importance of diverging during concept generation to find the optimal solutions for their problems.

Academic engineers emphasized using existing solutions and making minor changes for applications they were pursuing. By leveraging pre-existing solutions, academic engineers demonstrated minimal or no divergence in concept generation. An academic participant who had over 20 years of experience building medical devices stated:

“We kind of have a hammer almost ready, and then, if a good application comes up that matches this, then we can tweak and do something towards that” (Participant A1).

For example, a specific expertise such as, using a device to sort small particles based on size and affinity, would be set as the desired solution. Thus, more specific solutions were considered just within this category. In other cases, academic engineers reported setting exact technical solutions before beginning their search for problems. For example, one reported:

“We discovered this effect and we asked ourselves well how can they use this now for a biological [application] out there?” (Participant A3).

Academic engineers typically described their design processes as matching their solutions with new problems; as a result, they reduced effort towards searching for different or better solutions. Eight out of 10 academic engineers indicated that they did not consider any alternative solutions. Even the other two engineers who said they did consider alternatives did not provide details about alternatives identified. When asked whether they considered alternative solutions, most academic engineers responded that they had a single solution they had developed using their expertise, or that they made minor adjustments to existing technologies to address the problem. A common response was that no alternative solutions were considered:

“Let me think about, did we have alternative solutions? I don't think I came up with something else” (Participant A5).

Participant A5 was satisfied with a single solution because his solution addressed the problem he had identified; so, he did not find it necessary to come up with alternatives. In another case, Participant A10 focused on using an existing technology in his lab, and he made small adjustments to it to fit his new problem:

“I basically just tinkered with the original design. We came up with the [channel dimension change], and we came up with maybe different methods too for the [fabrication] part [...] Other than that, we didn't play around with it too much. We got it to work and that was the most important thing. We just went with that” (Participant A10).

Consulting help

Both industry and academic engineers emphasized the importance of consulting with other professionals to help them consider and test their solutions. Industry engineers actively collaborated with experts both within their company and in academia. By consulting with other experts, industry engineers were able to think of ideas outside of their own current technical capabilities. When required expertise was not available within their companies, they engaged with university researchers. As one participant noted:

“[Company] will also help us to establish connections with [a] university, if we need anything, any help, or if we want to look into any technologies, professors have [...] already developed” (Participant I1).

Although academic engineers also valued consulting with others during the early phases of design, academic engineers mainly relied on lab members and collaborators working on similar problems. Consulting with lab members often influenced their design choices:

“Maybe I would have come up with a different design if I didn't have these two important discussions with my lab mates” (Participant A7).

Searching the literature for ideas

Searching the literature for potential solutions was emphasized by both academic and industry engineers. Nine out of 11 industry participants indicated that they generated ideas by reading the academic literature. For example, Participant I4 considered multiple alternatives to best address his needs and he scanned the literature to find various methods:

“I did a literature [search] of all the different ways that channels are closed... We went through and said, “Well, that kind of gets what we want.” We looked at everything that's available (in literature)” (Participant I4).

Similarly, academic engineers used the literature to gain new knowledge and generate a solution. For example, Participant A4 emphasized the importance of reading the literature that helped him think of new idea from other people's experiences:

“The literature reading is very, very important, because the idea, or the solution, doesn't come out of nowhere. It comes out of your experience, your knowledge. So you have to have that base, in order to make innovations. The very first thing is to read. Read intensively, even sometimes the paper doesn't look very relevant. Maybe [it] can spark your ideas” (Participant A4).

Maximizing expertise

Both academic and industry engineers emphasized the importance of leveraging expertise to solve design problems. Industry engineers worked with a number of experts in different areas to help them build and test different solutions while academic engineers relied on their own expertise. Industry participant I7 was developing a device to test the effectiveness of different drugs and emphasized that his company had engineers with different skills who could help him build and test his design:

“The company has people with different talent: optics, electronics. For that part, I don't need to worry about. Again, when I think about or decide, those people can help me to prepare the prototype in order to test” (Participant I7).

Unlike industry, academic engineers often had the tendency to rely on their own expertise to solve problems, which may have limited alternative solutions they considered. For example, Participant A3 indicated that when he thought of solutions for his project, his mind automatically went to solutions that used his own expertise:

“Whenever I'm thinking about making devices my mind is automatically going to go to things that can be made using laser cutting, soft lithography or possibly micromilling because those are the tools that I have in my lab. Someone who has a background in silicon micro-machining might think of devices and techniques that exploit silicon as the channel material. Your perspective obviously comes from what your background is [...] That definitely limits the type of projects that you do. I won't say limit because I could go ahead and do a silicon-based project for example, but when you're envisioning ideas, your mind always goes to things that it knows already” (Participant A3).

Academic engineers focused on maximizing their own expertise to solve problems and explored solutions from their backgrounds.

C. DETAILED DESIGN

Taking risks

Industry engineers emphasized minimizing risk in their design while taking risks was not indicated as a key factor for academic engineers. Industry engineers were concerned about testing “risky” ideas that would be difficult to achieve and require a long development time because they needed to ensure that their products are functional within a given timeline:

“You propose a possible solution, and then you characterize that, mostly in terms of risk, resources and reward. Right? How likely is it that this solution that you propose is actually going to work? [...] That's maybe a nice idea but it's just, there's no way it's going to work [...] I've proposed something to my supervisor where [he] said, yeah, that looks like it would provide a lot of reward, but the technical risk is very high, I don't think it's going to work, or it's not going to work easily” (Participant I8).

Having strict timelines

Time constraints were impacted design processes for industry engineers, but academic engineers did not indicate time as an important factor in their design processes. Industry engineers had the tendency to look for solutions that would be feasible and practical when developing them

into products. For example, Participant I5 emphasized the need to allocate his time and prioritize his effort in developing a product:

“There's always a time limit. It's really important to assess what's the best use of your time. You might run into something where you say, ‘Oh, that might be cool to try,’ but then, later down the road, you might have some time to pursue it. Or you might just have to say, ‘Okay, well, I don't have time for that, and it wouldn't be worth pursuing because something else has priority.’ The biggest issue is usually just time” (Participant I5).

Industry engineers emphasized that they lacked time to explore all possible solutions and test them, as they needed to deliver their product in a timely manner.

Focusing on usability

Industry engineers noted the importance of creating user-friendly devices, while usability was not viewed as an important requirement for academic engineers. Industry engineers focused on usability to make their devices more attractive for their stakeholders. For example, Participant I4 indicated that she focused on the usability of her device to have an advantage over her competitors' devices:

“I think that's an area where some of our competitors and a lot of the academic labs have generated some very high quality results, there's a big gap there in terms of getting to something that's usable... We looked at everything that's available and said, ‘How can we do this, that enables our users...’” (Participant I4).

While industry engineers focused on usability, academic engineers placed less emphasis on making their devices user-friendly. Four out of 10 academic participants acknowledged that usability needed improvement before multiple users could handle devices outside of their labs.

“It just requires a lot of training and patience to build the device and it's not easy to get a person that is interested and motivated to follow the procedures of the device because it's so difficult. To them, it would be frustrating if they need to fail ten times before they get the first success” (Participant A9).

One explanation for limited considerations of usability may be due to the emphasis of using the devices in academia to answer novel research questions rather than delivering devices for other users:

“Now, the goal of most of the good studies is not to have a device in the end. The goal is to answer a question that cannot be answered with other tools.” (Participant A4).

Focusing on manufacturability

In addition, manufacturability was an important consideration with industry engineers to ensure that their devices are easy to fabricate and build but manufacturability was less emphasized among academic engineers. For example, Participant I10 indicated the importance of ensuring that when a device left the “proof of concept” phase, it needed to be ready for mass production:

“Once you leave this proof of concept phase, that's when you really start digging into the weeds like all right, I can do this once, now can I make 1,000 of them. Can I make 10,000 of them and can they all work the same... That's really how that process works. Once you show that you can do this on a 10,000 scale, then it's like all right... Now let's make a million of them and have them work, all million.” (Participant I10)

Academic engineers described building only a few devices to demonstrate proof of concept. Their devices were often very difficult to manufacture and required extensive training to fabricate. Four out of 10 academic engineers reported that their device was challenging to manufacture:

“It would require probably to change the setup a little bit in terms of how easy it was to put together and to assemble. For me, it was easy because I did it almost every day, but it takes some time if you're a first-time user and things like that” (Participant A10).

Having Competition

Industry engineers described the importance of ensuring that their devices were superior compared to their competitors' products; however, academic engineers did not emphasize competition as an important constraint in building their devices. Industry engineers used competitors' devices for “benchmarking” to understand their capabilities, and aimed to produce even better devices themselves:

“We know what the product needs to do based on what our competitors can do. Is it sensitive enough? What do these other kits do? We need to be that good or better. Is it reproducible? What do these other kits do? We look at what all the competitors do and when we're better than them, as soon as we hit that goal, we stop development in that area and then we'll be there” (Participant I11).

D. EVALUATION

Delivering a device

The evaluation phase includes finalizing and testing a design. All industry engineers focused on developing marketable products that address their customers' needs, while academic engineers aimed to demonstrate proof of concept with promising potential. Industry engineers emphasized the importance of sellability:

"It needs to be a product for sale. That's our driving force, our goal. We're making a product that's going to be on the market soon." (Participant I11).

On the other hand, academic engineers did not emphasize the need to develop marketable products as the final endpoint. Instead, academic engineers noted the importance of demonstrating "proof of concept" and sharing knowledge about potential applications using their devices:

"The milestone is that we treat the product with different drugs so that it can behave differently, and if we can tell the difference using our device, meaning that we can prove this device has a clinical potential, and we've done that. So that was a milestone" (Participant A7).

E. COMMUNICATION

Publishing paper

Both industry and academic engineers noted the importance of publishing research papers, but the two sectors used publications for different purposes. Industry engineers indicated that publishing scientific papers was not a requirement, but scientific papers helped them gain publicity for their work. By publishing different use cases of their products and validation their capabilities through publications, industry engineers leveraged publications as an opportunity to advertise their products:

"Part of it is advertising. People would read your paper and read that oh, you used these kits from this company, or this is how these kits work from this company, that's really neat" (Participant I11).

Academic engineers focused on publishing their results in scientific journals to demonstrate novel findings using their devices. An important deliverable for academics was demonstrating that their devices can generate data for publications. Instead of focusing on building devices, they emphasized gaining new knowledge:

"I guess the sign to finish is because, at the end, we publish a paper. We do what we need to and if we finished all the experiments, then we are done. It is more publication driven" (Participant A5).

Similar to Participant A5 who emphasized the importance of publishing papers, Participant A8 described the goal as submitting a manuscript to publish her work. Once she had sufficient data for her project to wrap up a complete story, it was time to end her project:

"When I almost finished my project, I feel there is not many questions coming in for my specific project. I feel like, 'Oh, it might be almost like wrapping up with that. Maybe my story is complete enough to tell other people and they can get some like understanding for my project.' I think that might be my intuition that my project will be almost finish with that... Finally, I send my manuscript and get accepted" (Participant A8).

Engaging with stakeholders

Industry engineers focused on reaching out to their end users and stakeholders to validate their devices while academic engineers placed less emphasis on communicating with stakeholders. Industry engineers ensured that all design requirements were met, and that their customers were satisfied with their products:

"Now you'll have done hundreds of testing for each functional performance to assure that this design produces repeatability and reproducibility, then you take that final design to the customer again and [do] a human factor study. You assess with the panel of customers whether that design that you created... that you're ready to launch [and] really meets all of the requirements that they wanted. [...] to make sure that when you do release this product, that people will pay for it." (Participant I3).

Academic engineers expressed the importance of solving problems using their devices but placed very little emphasis on how the information and concepts could be transferred to other users. For example:

"This is a research scale and I just try to pinpoint or solve the practical problem in my own known problems. If it happens that... [the] concept is being used in, let's say hospital or other area, it is not my business" (Participant A5).

This perspective demonstrated that unlike the industry engineers, academic engineers placed less emphasis on considering the end-users of their publications and devices.

V. DISCUSSION

A. DESIGN PROCESSES IN ACADEMIA AND INDUSTRY

Our analysis of the experiences of industry and academic engineers in designing medical devices revealed several similarities and differences in their design

processes. Both academic and industry engineers emphasized the importance of maximizing expertise and using scientific literature during concept generation. Both industry and academic engineers started concept generation within their own or their company's expertise and leveraged scientific papers to further explore solutions.

A major difference between industry and academic engineers occurred in the sequence of problem definition and concept generation in the front-end of design. Design processes in industry closely mirrored typical models of design processes, following a sequence of problem definition, solution exploration, evaluation and communication [11], [55]. Industry engineers began projects with pre-defined problems after studying the market and customer needs. Subsequently, marketing and engineering departments iterated on problem definitions and solution generation to define requirements based on the capabilities of their companies, demonstrating problem solution co-evolution, defined as refining the problem and solutions with constant iteration [56]. During the concept generation phase, industry engineers diverged to search for multiple, diverse solution ideas by using academic literature that informed them about solutions from the established pool of technologies and by collaborating with experts within their companies and with academics.

However, academic engineers did not follow this typical design process of problem definition followed by generating solution concepts; instead, they reversed or "flipped" this process by starting with their existing solutions and searching only for problems to fit. Academic engineers emphasized problem finding rather than solution generation by beginning the process with candidate solutions – in the form of technical devices, specific technology or area of expertise – in mind. Then, academic engineers looked for problems that could be addressed using their specific solutions. If their expertise could not solve a given problem, they moved on to consider a different problem. Academic engineers fixated on solutions and openly diverged to search for problems. Design fixation, defined as an inability to generate a range of innovative solutions to a design problem [47], can be viewed as a negative trait in design as fixation can limit the designer's ability to generate creative solutions [57]. On the other hand, experienced designers can intentionally fixate on their ideas and pivot when they recognize the need and find opportunities [58]. Our study revealed that academic engineers intentionally "fixated" on their solution to maximize their expertise and diverged to identify existing or new problems to solve.

Academic engineers followed a "technology push" model that leveraged existing technologies and identified problems that could be solved using those technologies. Technology push serves as an important source of innovation because new technologies bring radical changes that are dissimilar from prior inventions [59]. Ullman [60] argued that the majority of design projects are driven by a realized problem or market space, but design processes for

technology-driven projects may be different, as technology-driven projects seek to leverage novel capabilities of new technologies [61]. Our findings for the academic engineers displayed an example of a technology-driven process and demonstrate that successful design processes do not require starting with problem definition.

Previous studies examining design in academia have focused on examining a particular design phase or practice. One study documented that academic engineers can focus on prototyping innovative, new ideas [38]. Our finding mirrors this result in that academic engineers aimed to develop new technologies and were driven to create technologies for publication purposes. Another study in software design indicated that academic designers continue to iterate during their design processes [39] with limited consideration for the timeline. Our study has found a similar result demonstrating iterations for academic engineers. However, our study adds to this previous research as we have discovered *where* and *how* academic engineers emphasized iteration; academic engineers showed minimal iterations on solution generation and spent most of their effort on problem exploration. By understanding the entire design processes of academic engineers, we have discovered and articulated differing design phases and practices throughout their process.

B. CONSTRAINTS AND GOALS INFLUENCING DESIGN DECISIONS

The differing work environments for industry and academic engineers appeared to be associated with the differences in engineers' design processes. An important goal described by academic engineers was demonstrating the capability of their devices through scientific publications. Academic engineers mainly used their device to answer scientific questions, and they took a minimalist approach to the design considerations of user-friendliness and manufacturability. Also, the academic culture is open-ended in exploring the problem space, which may have encouraged academic engineers to stay within their solution expertise and search instead for problems. In addition, academic engineers expressed feeling free to stop a project and move on to a different project if needed. These differences in academic practices influenced their explorations of alternative solutions. Past research supports this finding that structure and cultural norms associated with different design settings can shape the problem spaces identified [27].

Industry engineers were focused on designing profitable devices and described their goals as creating physical products that were user-friendly, manufacturable, and reliable, and that filled known customer needs. Industry engineers explored a diverse set of potential solutions for their problems to select the best solution. At the same time, industry engineers could not fully explore and test solutions due to strict timelines and resource limitations; consequently, they looked for promising but practical solutions. Research has demonstrated that time

management is a significant constraint in design processes [44] and our study revealed the effects of time constraints in limiting solution exploration in medical device design within industry. In the end, industry engineers chose solutions that would meet all the user requirements for their problems, and included features for usability, reliability, and manufacturability to give them an advantage over competitors' products. With different goals and constraints, academic and industry engineers prioritized different aspects of design.

Within the literature, both "technology push," and "market pull" have been identified as important sources of innovation [62]. Based on our findings, innovation arises from "technology push" in academic design processes, where new solutions drive the search for potential problem applications. Engineers in academia appeared to generate technology push by developing new solution methods and identifying qualities and potential applications. However, in industry's design processes, new ideas enter through the "market pull" of identified needs and problems leading to potential solutions. The industry setting introduces new problems through constant identifications of problems and the search for promising solution methods. Through this qualitative study of medical device design, differing design processes of each sector were apparent, pointing to the importance of considering sociocultural settings within communities of practice [23, 24]. Thus, it is important to investigate the context in order to detect major differences in design practices.

C. LIMITATIONS

The study sample included engineers in one product field (medical devices), and findings in other fields may differ. This study did not explore differences among engineers beyond their work environments, such as demographics, years of experience in the field, types of product development, differences in types of companies and academic labs, which limits the analysis to comparing only the work environments without describing different nuances. Our convenience sample was sufficient for a qualitative study, but as only 3 females are included, it failed to represent varying perspectives from the diverse demographics of the field.

This study relied on engineers' self-reported experiences; consequently, other features important to design may be omitted in their responses because of lack of awareness. In particular, focused questions on the engineers' views of the contextual factors influencing their design processes may have added to identified differences. A richer question set to engage with the sociocultural setting may uncover other factors or influences on design processes. The interview protocol did not incorporate the interviewer's observations of each interview, which may have been helpful in examining question comprehension and interview structure. In addition to interviews, conducting direct observations of design practices within context would be helpful in extending these findings.

D. IMPLICATIONS

Understanding differences in approaches between engineers with different experiences or within different contexts can elucidate opportunities for shifts in design approaches. A direct implication is that understanding the strengths and focus areas of design in both industry and academia may improve communication and collaboration between them. Knowing design processes that occur in related sectors will help those creating new scientific publications (academic engineers) and those making use of these findings (both academic and industry engineers). Companies that can successfully gather information about technologies are more likely to be innovative and demonstrate higher performance [63]. Collaboration between academia and industry can help increase the performance of both sectors, with industry benefitting from leveraging new technologies from academia and industry providing funds and questions to academic research [3], [64]–[66].

There is also an opportunity to strengthen the connection between the academic engineers' goal (proof of concept) and industry's desire to commercialize products with tight timelines. Much of the literature examining collaboration between academia and industry has studied the end outcomes and described the benefits of these collaboration opportunities [67]. Studies have also examined the challenges of establishing effective collaborations given that industry may be seeking prototypes ready for commercialization due to shorter time-to-market schedules [37]. It may be risky for industry to translate academic research findings into commercial devices due to additional development time requirements. Our study revealed that engineers in academia and industry have different design processes that can affect their ability to collaborate. Academic engineers may be technology experts who have a deep understanding of their solution methods. Identifying collaboration opportunities to maximize their existing solution methods may facilitate success beyond the more typical approach of collaborating to consider multiple, alternative solutions to a problem.

By understanding differing design processes, engineers in both settings can strategically leverage design tools to support their goals. Research has demonstrated the benefits of implementing design tools in helping engineers succeed in each phase of the design process [68]–[71] and engineers in industry and academia may use different tools specific to their needs. For example, academic engineers typically seek out problems that match their solution expertise, so they may benefit from focusing on identifying problems and opportunities using an existing technology [72] and reframing problems to find a match between their technology and problems [73]. Additionally, academic engineers may be further trained on customer engagement and needs finding interview methods to help them identify problems through interdisciplinary collaborations. For industry engineers focusing on generating diverse solutions for their problems, learning about implementing ideation

methods to support creative thinking and problem solving may assist them in leveraging design tools [68], [69], [71], [74].

Finally, the findings showing differences in design processes due to contexts suggest a similar pattern may occur in other design disciplines. Other research has shown that engineers from various fields often leverage similar design principles [10]; however, our findings suggest important differences also occur within a design field. By examining other areas of design such as software design, we may determine whether other academic engineers follow similar practices where solutions are fixed, and problems are explored. Previous research on design in academia has focused on the end outcomes of their technology development, e.g., [40], [41], or specific design practices, e.g., [38], [39], not on design processes in how they achieved their outcomes. Further research is needed to understand how engineers successfully identify important applications for new technologies. For example, engineers have recently developed innovative technologies without intended applications (e.g. graphene, 3D printing, and shape memory alloy) [75]–[77], and more information about how academic engineers explore problems to solve may be helpful across fields of design. These results also suggest the power of sociocultural norms to influence practice; given that all engineers receive accredited training, the differences in their design processes point to the culture of practice as a major influence.

VIII. CONCLUSION

This study explored differences in design processes between academic and industry engineers developing medical devices. Industry engineers described their process as a standard engineering design process, with identifying problems, seeking out varied solutions, choosing the best of multiple solutions, and developing concepts into final products. The main goal in industry was to create a new device that filled a known commercial need. In contrast, academic engineers described their goal as maximizing their specific expertise and technologies. Academic engineers started with their solution methods, and searched instead for new problems, evaluating the fit between problems and their solution methods, and producing “proof of concept” devices leading to publications. The different sociocultural settings for academia and industry practice appear to influence engineers’ design processes. Academic engineers emphasized freedom to pursue any problem and flexibility to shift to new problems, allowing them to explore the problem space. Thus, academic engineers leveraged their expertise or existing solutions to solve a wide variety of problems. In contrast, industry engineers indicated that they were often fixed on solving given problems and had to explore diverse alternatives solutions. We also documented similarities in their design approaches; specifically, both academic and industry professionals heavily relied on academic literature to generate ideas and gain an understanding of the current technologies. By

documenting similarities and differences in design processes, this study may provide opportunities for better collaboration between academia and industry and encourage both sectors to consider the role of the sociocultural context in their design processes.

Future work investigating specific strategies to support solution-first processes is important given that no explicit professional education is aimed toward this alternative design process. Identifying and leveraging design strategies have been shown an effective tool to support both novice and experienced engineers within a design process [68]–[70]. However, the current literature offers little information about *how* to identify problems using their innovative technologies as solutions. Research on identifying and implementing strategies to support problem definition within solution-first design processes can facilitate collaboration between industry and academia. Defining a problem is a critical phase in design for both academic and industry engineers; industry engineers may look for problems that are driven by the market or customer needs [78], while academic engineers need to discover applications of their technological solutions. By supporting all engineers in developing their solution-first processes, perhaps further innovation by both academic and industry engineers will occur.

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APPENDIX A

Interview Protocol

- How long have you been working in your field?
- What is your training?
- Can you tell me about one device you developed and give me an overview of the process?
- From the experience that you just shared, what was the main goal that you started with?
 - How did you come up with it?
 - What made you pursue this?
 - Why was this important?
- What did you envision the final outcome of this project to be?
- How did you come up with the solution to address the question?
 - What sources helped you to come up with the solution?
- Did you have any alternative solutions to the problem that you were trying to solve?
 - Approximately how many did you come up with?
 - How different were they from each other?
 - How many alternative prototypes did you build and consider?
 - Why did you discard some of the choices?
- In a larger scope, how many possible alternative solutions do you think exist?
- For this project, what would have encouraged you to explore additional ideas to solve the same question?
- During the project, was there an instance that you wanted to pursue an idea further but could not for any reason?
- Did you refine your device to make improvements throughout the process?
- At the end, how did you know that you were finished?
- If you were to do it again, would you do anything different?
- Thinking about the project as a whole, what criteria or constraints were important to your device?
 - What about non-technical constraints?
- How did the academic university/industry setting affect the choices and approaches?
- How did the people you work with affect the choices and approaches?
 - Can you describe your typical interactions with others?
 - Can you give me specific examples?
- What else may have influenced your choices in developing your device?
- Looking at the design process, was this a typical experience in designing/developing a device?
 - If yes, are there particular things that are typical?
 - If no, can you describe some of the differences?
- Is there anything else that you'd like to share to help us get a better picture of developing a device?
- Thank the respondent – ask them if they have any questions about the study.

Appendix B

Codebook

	<u>Code</u>	<u>Definition</u>	<u>Example quote</u>
<u>Category: Problem Definition</u>	Freedom to pursue an idea	Participant had the freedom and flexibility to pursue any idea	“guess the university had the freedom to just go off on a tangent.”
	Freedom to stop a project	If a project didn’t work out, participants changed directions	“We compromise our goal, after a 100 trials, after 1000 trials, if we cannot do it, then we change our goal.”
	Given a problem to solve	Project existed before he/she started working or the problem was given	“It (problem) had already been identified, and in one...”
	Studying needs	Project derived from either studying customer or market needs	“The business side will come up and go out and then determine there's a customer need for a new as say that detects...”
	Iterate on problem definition	Iterate with marketing or other department in defining the problem	“Marketing comes back and says the average customer is going to be your average consumer. A person at home. They don't want a finger prick. They want it done in 5 minutes. They prefer urine or saliva. They want it easy to read. That gets more defined into a customer-needs document.”
	Problem finding in literature	Literature search to find problem to address	“He will ask me to look into these directions and I will go to literature search and combine with my researching experience and expertise.”
	Problem finding through collaborator/others	Problems were defined by conversations with collaborators	"He said “Why don't you come here and just talk to biologists here so maybe you can find some common interests?” And then I started talking to different biologists in his department.”
<u>Category: Concept Generation</u>	Existing solution	Had a pre-existing solution that can address the problem	“... think it happens more often than not. We kind of have a hammer almost ready, and then if a good application comes up that matches this, then we can tweak and do something towards that”
	Limited alternatives	Did not consider or pursue alternative concepts	“Let me think about, did we have alternative solutions? I don’t think I came up with something else”
	Diverse alternatives	Consider multiple concepts in the early phases	“In proof of concept you test out a bunch of different solutions. You'll test out different technology. They'll test out different pumping technologies. Different flow technologies, channel technologies. In proof of concept I guess I like to consider it proof of concept is your very early stage R&D. You go into a lab and you have fun.”
	Collaboration	Collaborators provided help in ideation	“Definitely like brainstorming and discussion with my lab members. I have a lot of my lab mate who work with microfluidics and some similar immune cell studies. They have some idea.”
	Stay within the	Avoided areas that are not	“I personally I don’t want to try anything

	expertise	familiar	out of my expertise.”
	Literature search for ideas	Search for alternatives in literature	“We mainly look at academic papers. I would say for usually the problem posting other, a lot of people has already work on it.”
Category: Detailed Design	Novelty	Device can demonstrate something new and different	“We can make some story which can show the really different, some aspect of device, this is new. Then this result is like some excel compared to the other people. You can show different thing. You can make one story of that.”
	Minimal cost	Device should be affordable to prototype and manufacture.	“Rapid prototyping, it's cheap, you don't have to be in a clean room so you just build the mold once then you're done.”
	Better performance	Device performed better than other technologies	“I always try to benchmark what we're trying to do against other technologies. If it's not better than anything else than there's really no point in doing it.”
	Manufacturable	Device should be easy to manufacture	“the purpose of the development we want it to be easily manufacturable and easily prototyped.”
	Minimize risk	Participant indicated that he/she focused on minimizing technical risk to ensure that the device would work	“... that looks like it would provide a lot of reward, but the technical risk is very high, I don't think it's going to work, or it's not going to work easily”
	User friendly	Participant emphasized user-friendliness/usability of the device as an important feature	“I think that's an area where some of our competitors and a lot of the academic labs have generated some very high quality results, there's a big gap there in terms of getting to something that's usable... We looked at everything that's available and said, ‘How can we do this, that enables our users...’”
	Not user-friendly	Devices were built without other users in mind	“It takes some time if you're a first-time user and things like that.”
	Not manufacturable	Device was originally developed with less emphasis in manufacturability	“(it) is difficult to build the device in some sense. So is the ability of repeating this in a larger quantity is not very easy.”
Category: Output communication	Profit	The end goal was driven by the market and profit	“If it's for diagnostic purpose, the market is not as huge. Money is behind everything.”
	Communicate with stakeholders	Participant engaged with stakeholders and potential users to validate the product	“You assess with the panel of customers whether that design that you created... that you're ready to launch [and] really meets all of the requirements that they wanted. [...] to make sure that when you do release this product, that people will pay for it”
	Publication	Publications served as important milestones to gauge the endpoint	“I guess the sign to finish is because at the end we publish a paper. We do what we need to and if we finished all the experiments then we are done. It is more publication driven.”
	Device as a tool	Participant emphasized the	“Now if you tell someone you can make

		importance of using the device to answer novel questions	a device they'll yawn. It's more about what are the interesting things you can do."
	Data	Participant demonstrated that he/she obtained concrete results at the end	"We came to a point where we had some concrete results, and basically, what it entailed was, we had experimental results, and we compared those with our mathematical models of what we expected to happen."
	Proof of concept	Participant demonstrated that his/her device had a clinical potential	"The milestone is that we treat the product with different drugs so that it can behave differently, and if we can tell the difference using our device, meaning that we can prove this device has a clinical potential, and we've done that."
<u>Category: Factors in decision-making</u>	Equipment	The work was limited with the equipment available	"it also depends on the resource in your lab. It's not like I want to do this and I can do this. You have to be realistic sometimes."
	Expertise	Expertise limited or expanded their ability to make progress	"This lab has this stress, has this expertise. If you want to generate results faster, you better find some area that can utilize your expertise and resources."
	Time	Pressure of time existed to produce results	"It's just that we need to publish it at a certain time. We had to finish the paper at a certain time, so there's time constraint."
	Technical limitations	Technical feasibility of an idea posed limitation	"... technical barrier as well even the solution is good. In general, it helped that if you want to push to the extreme then the technical barrier amplified is so much so I couldn't this process to show the best results."

