Prototyping strategies for stakeholder engagement during front-end design: Design practitioners' approaches in the medical device industry

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Prototypes are fundamental tools used throughout design processes. During early design stages, including problem definition and concept development, prototypes can support stakeholder engagement, which is considered critical for success. However, the ways in which engineering designers leverage prototypes within front-end stakeholder engagements are not well described in the literature. This research explored front-end prototyping strategies for stakeholder engagement through semi-structured interviews with medical device design practitioners. Our research findings describe seventeen strategies design practitioners used to engage stakeholders during front-end design activities. The findings add rich detail to the existing strategies broadly described in the literature, and have implications for designers across expertise levels, as they can be used to develop intentional approaches to engage stakeholders during front-end design.

Keywords: prototypes, product design, design practice, engineering design, stakeholder engagement

Design is sometimes described as domain-specific; design methods, tools, stakeholders, and artifacts vary across disciplines (Visser, 2009). Design is also described as domain-general because there are broadly applicable practices that span multiple design disciplines (Daly, Adams, & Bodner, 2012; Goel & Pirolli, 1992; Visser, 2009; Zimring & Craig, 2001). Examples of domain-general practices include the gathering of information prior to the development of a solution and the use of intermediate representations of problems and solutions (Goel & Pirolli, 1992), including prototypes. The ways in which prototypes are used can be domain-specific or domain-general as well.

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Within engineering design, prototypes are often recommended for use in understanding and evaluating promising design concepts in mid to late design process phases, evidenced by design practice textbooks (e.g., Dieter & Schmidt, 2013; Ullman, 2010; Ulrich & Eppinger, 2008). Engineering design "back-end" prototyping strategies have focused on the number and order (e.g., in parallel, in series) of prototypes to use, and how to embody intermediate representations (e.g., physical, virtual) (Camburn et al., 2015; Christie et al., 2012), including strategies for selecting prototype manufacturing and testing techniques (Hansen & Özkil, 2020).

Prototypes can also contribute to design success if used in the "front end" of design. The front end can broadly be defined as including background research, needs finding, problem scoping and definition, requirements or attribute elicitation, specifications development, concept generation, and concept development (Atman et al., 2007; Cooper, 1988; Ulrich & Eppinger, 2008). The front end presents unique challenges; for example, designers' understanding of problems and solutions co-evolve (Dorst & Cross, 2001) in a process that lacks the structure of later design execution stages (Khurana & Rosenthal, 1998). A key factor in design success is proficient front-end work. Gupta and Wilemon (1990) noted that product development delays were attributed to inadequately executed front-end design activities, specifically, poorly defined requirements. Thomke and Fujimoto (2000) described the association between product failure and the failure to "front-load," emphasizing the importance of "shifting problem solving trajectories upstream" to accelerate product development through the identification of problems and solutions earlier in a design process. A properly executed front end entails conducting fast, iterative cycles of representing early ideas in tangible forms; testing early ideas with customers or users; collecting customers' and users' feedback; and revising design requirements (Cooper, 2018).

Some prototyping research in the engineering design literature encourages the use of prototypes to engage stakeholders during front-end work, with stakeholders defined as anyone who impacts or is impacted by the design (Freeman, 2010). For instance, studies have focused on engaging stakeholders with prototypes to uncover design requirements (Jensen, Elverum, & Steinert, 2017), seek stakeholder feedback on proposed solution concepts (Deininger et al., 2017; Deininger, Daly, Lee, Seifert, & Sienko, 2019; Elverum & Welo, 2014), and consider stakeholders' wants, needs, and priorities (Menold, Jablokow, & Simpson, 2017, 2019). Although the field of human-computer interaction (Houde & Hill, 1997) and co-design processes (Sanders & Stappers, 2014) have described prototyping uses broadly, including throughout front-end design phases, traditional engineering design literature has described prototyping uses more narrowly, typically focusing on usage

during the later phases of design. Further, while design practitioners may leverage front-end prototyping strategies with stakeholders, these uses have not been documented extensively in the literature, as the existing front-end prototyping literature has primarily focused on novice designers' approaches (e.g., Viswanathan & Linsey, 2009; Yang & Epstein, 2005). Additionally, known strategies would benefit from nuanced details necessary for successful implementation by others. For example, human-centered design methods call for designers to perform rapid prototyping and obtain feedback (IDEO.org, 2015), but the provided methods embed additional choices within their stepwise processes without necessarily providing the specific actions that may lead to successful execution.

Thus, our study sought to identify specific strategies used by design practitioners during front-end design engagements with stakeholders. We chose to focus this initial investigation on design practitioners from a specific design domain—medical devices. Similar to other industries, medical device design practitioners typically engage with stakeholders throughout multiple phases of design processes. However, medical device design practitioners also engage with stakeholders, particularly users, when performing user need analyses, human factors engineering, and field trials to comply with regulatory requirements and standards (Vaquero Martín, Reinhardt, & Gurtner, 2016). Further, medical device design processes generally explore specific clinical needs (Privitera, Evans, & Southee, 2017) through the use of methods including contextual inquiry and direct observations (Mohedas, Sabet Sarvestani, Daly, & Sienko, 2015; Vincent, Li, & Blandford, 2014), which necessarily engage stakeholders in some capacity. The findings from our study can inform novice and practitioner design methodologies within medical device design contexts as well as support engineering education and training.

1 Background

1.1 Prototyping in engineering design

Prototypes can be conceptualized as "approximations" of a product (Ulrich & Eppinger, 2008). They have historically been defined within engineering design as "physical models of the product that are tested in some way to validate the design decisions that have been made up to that point in the design process" (Dieter & Schmidt, 2013, p. 370). However, prototypes can be created in various forms and formats, including physical models and virtual simulations, and represent whole ideas or components of an idea (Ulrich & Eppinger, 2008). Recent engineering design research suggests that prototypes are being used throughout a design process (Lauff, Kotys-Schwartz, & Rentschler, 2018). A broad definition of prototyping, which is adopted in this paper, encompasses creating "any representation of a design idea regardless of

medium" (Houde & Hill, 1997, p. 379) through which concepts can be discussed, changed, and negotiated (Henderson, 1995).

Since prototyping has long been recognized by professionals as an effective and necessary design activity (Kelley, 2001; Schrage, 2000), numerous strategies exist to guide engineering designers in using prototypes for product testing, evaluation, and refinement (Hilton, Linsey, & Goodman, 2015) once design objectives have been defined. Camburn et al. (2017) described a prototyping strategy as the "planned combination of techniques to achieve an objective." Examples of more specific prototyping strategies include "begin each iteration of a design at a component level" (Hilton et al., 2015); "support building with analytical calculations" (Camburn, Dunlap, Viswanathan, Linsey, & Jensen, 2013; Viswanathan, 2012); and develop prototypes that adhere to a "reduced" version of design targets when appropriate (Camburn et al., 2017; Moe, Jensen, & Wood, 2004). Engineering design processes typically position prototyping-related content after concept selection (Dieter & Schmidt, 2013; Pietzsch, Shluzas, Paté-Cornell, Yock, & Linehan, 2009; Zenios et al., 2010); as such, many prototyping strategies emphasize later design phase idea testing and refinement. However, prototypes serve as essential tools that can be used throughout a design process, including in early stages (Coughlan, Suri, & Canales, 2007).

Prototypes support communication between designers and stakeholders and encourage stakeholders to provide feedback that can inform design decision making during early design phases (Bucciarelli, 1994; de Beer, Campbell, Truscott, Barnard, & Booysen, 2009; Neale & Corkindale, 1998). Lauff et al. (2018) further described the value of using prototypes for conveying concepts, assisting designers with gathering stakeholder feedback, facilitating negotiations, and persuading others. Prototypes have also been shown to be used during engagements with external stakeholders during downstream phases of a design process when it is too late to include the stakeholders' feedback (Lauff et al., 2020). In addition, Jensen et al. (2017) discussed the relationship between prototype functionality and stakeholder involvement with respect to a company's ability to discover design requirements at different design stages. They argued that both functional and non-functional prototypes produced during the early stages of design helped designers elicit a wide variety of requirements in an industry product development context. Broader literature, including outside the scope of engineering design, is described in more detail in section *1.3 Prototyping for stakeholder engagement*.

1.2 Stakeholder engagement during front-end design

Engaging diverse stakeholders is a crucial activity of front-end work that affects early evaluations and iterations of ideas (Khurana & Rosenthal, 1998). Designers leverage a variety of methods to gather information from

stakeholders, including interviews, questionnaires, focus groups, group brainstorming (Nuseibeh & Easterbrook, 2000), and observations (Skaggs, 2010). In other words, stakeholder engagement encompasses information gathering, communication, collaboration, and other activities that involve stakeholders in a design process. Studies have stressed that engagement with stakeholders during the earliest phases of design leads to the definition of product requirements that better fit the needs of end users and stakeholders (Cooper, 2018), as well as better fitting the context in which products will be deployed (Anderson & Crocca, 1993).

Engaging stakeholders during the front end of design can be a challenging task. In a study documenting medical device design professionals' challenges in complying with regulatory requirements pertaining to stakeholder engagement, Privitera et al. (2017) identified multiple barriers, including several that are relevant to designers' interactions with stakeholders. For instance, making sense of unarticulated user requirements, managing users' expectations of what kinds of products can be feasibly designed, reconciling conflicting stakeholders' opinions, obtaining permission and balancing the associated increased development times to conduct formal engagements such as contextual inquiry and formal usability testing, and encouraging users to envision alternative uses or clinical approaches from their training. Martin and Barnett (2012) argued the lack of formal streams to gather and integrate stakeholder information in design decisions may result in delivering a product that while technically sound, may poorly fit the stakeholders' needs, workflow, and context.

In addition to design practitioners, novice designers have been reported to face diverse obstacles when engaging stakeholders. Some examples include covering relevant topics to inform subsequent design decisions during stakeholder interviews (Burnay, Jureta, & Faulkner, 2014), navigating the subjectivity characterizing stakeholder input, discerning between relevant and irrelevant information for design (Mohedas, Daly, & Sienko, 2014), and learning about the appropriate contextual factors that may impact the design (Atman et al., 2008).

Despite the challenges designers might face, an intentional approach for incorporating multiple stakeholders' voices in design decisions can have positive impacts on stakeholders, the designed product, the team, and the organization involved in the design, as was shown in a multiple stakeholder, medical device design context (De Ana, Umstead, Phillips, & Conner, 2013). As such, designers must prepare effective protocols for eliciting relevant information (Agarwal, Mohan & Tanniru, 1990), and bridge communication and disciplinary boundaries (Vincent et al., 2014). Designers must also develop rapport with stakeholders (Strickland, 2001), encourage stakeholders to analyze and integrate ideas and concepts (Leifer, Lee, & Durgee, 1994; Rosenthal &

Capper, 2006), verify stakeholder conclusions and interpretations (Firesmith, 2003; Nuseibeh & Easterbrook, 2000), and use the gathered information to make design decisions. Prototypes may be especially useful for overcoming some of the presented challenges designers face when engaging stakeholders. However, specific strategies to support stakeholder engagement, especially during the front end, have been a limited focus of engineering design research.

1.3 Prototyping for stakeholder engagement

Prototypes act as shared representations between designers and stakeholders that can be perceived, experienced, and analyzed (Kirsh, 2010; Norman, 1993). Prototypes can support stakeholders and designers in discussing abstract ideas (e.g., design requirements in terms of what a design should "do"), as they provide a real, tangible representation of a design concept (Brereton, 2007). Prototypes can be created to reveal both technical and contextual design considerations, which ultimately determine whether a developed product will be relevant to the stakeholders' needs and expectations (Cooper, 2018; Sanders, 2006). For instance, prototypes can demonstrate technical shortcomings (Viswanathan, Atilola, Goodman, & Linsey, 2015), prompt new behaviors (Coughlan et al., 2007), and make unanticipated requirements explicit (Jensen et al., 2017).

Several scholars have examined the effects of prototype characteristics, like fidelity and format, with respect to the outcomes of stakeholder engagements. Rudd, Stern, and Isensee (1996) summarized the pros and cons of using low- and high-fidelity prototypes with stakeholders. Low-fidelity prototypes were deemed useful as early communication tools to establish common ground between the users and the designer and to gather requirements, but low-fidelity prototypes lacked the refinement needed for accurate testing and the uncovering of design shortcomings. In addition to fidelity, prototype aesthetics have been shown to affect users' appraisals and task performance (Sauer and Sonderegger, 2009). Tiong et al. (2019) showed that low fidelity prototypes were best used to evaluate core concepts and basic assumptions with users, but that prototypes of increased dimensionality (i.e., functionality, interaction, and resolution) were most useful for more refined and targeted design questions. Another factor identified as an important consideration when prototyping was the format, referring to how a prototype takes shape (e.g., sketch or 3D physical format). Tangible prototypes, which have a physical format, have resulted in stakeholders regarding concepts more positively (Bao, Faas, & Yang, 2018), and elaborating more on their answers to the designer's questions (Deininger et al., 2019). Deininger et al. (2019) emphasized that in their study, there was not a single prototype format that consistently elicited more thorough responses across stakeholder types, and importantly, that the questions being asked mattered.

A variety of prototype types used for stakeholder engagement have been described in the human-computer interaction and human-centered design literature. For example, "experience prototypes" represent a sensory experience, which can be passive (i.e., like looking at a storyboard of an experience), or active (i.e., like living through an experience which mimics the product, space, or system being designed) (Buchenau & Suri, 2000). Additionally, "provotypes," which are designed objects meant to provoke a reaction in stakeholders and subsequently enable them to express their feelings and reflect on the experiences of interacting with the object, have been used to explore abstract concepts with users and experts (Boer & Donovan, 2012). Horst and Matthews (2016) used "live prototypes" to describe prototypes that can be modified during stakeholder engagements and can serve as a vehicle to collaborative problem formulation and solving, rapid iteration, and consensus building among stakeholders. Live prototypes uncovered misalignments between stakeholders so that they could be resolved in situ (Horst & Matthews, 2016).

In co-design, probes including diaries and cameras, toolkits including 2D and 3D parts, pictures, and buttons, and prototypes have been discussed as having roles in problem exploration and inviting stakeholder participation (Sanders, Brandt, & Binder, 2010). These objects have facilitated different levels of interest and creativity among stakeholders (Sanders & Stappers, 2014), thus enabling different forms of stakeholder engagement, that include providing feedback about design concepts, and co-creating design solutions.

The aforementioned studies indicate that certain prototype types may be better suited to fulfill specific goals, but how these prototypes are leveraged during stakeholder engagements can also impact the type and quality of the interaction and information elicited. Further, much of the work highlighted in this section stems from areas of human-computer interaction, human-centered design, and co-design. Participatory approaches to design and prototyping remain largely within disciplinary boundaries and their integration into engineering design practitioners' design processes is not well understood. More work is needed to understand the intersections of prototyping strategies and stakeholder engagement in engineering front-end design processes.

2 *Research methods*

This study was guided by the following research question: *What prototyping strategies do design practitioners use to engage stakeholders in the front end of design?*

We leveraged qualitative research methods to answer this research question. A qualitative research approach enabled us to collect in-depth descriptions—a foundation of qualitative analysis (Patton, 2015)—of participants' experiences leveraging prototypes with stakeholders during front-end design activities.

Further, a qualitative research approach enabled us to gather concrete experiences and perspectives that were detail-rich, as opposed to generalizations (Weiss, 1994) or self-identified general strategies. We used an emergent approach, a method in which themes were derived inductively from the data (Boyatzis, 1998; Patton, 2015). This methodological decision was informed by our goal to identify strategies used across participants based on the experiences they described.

Qualitative research studies aim for transferability of findings, which involves articulating rich descriptions that support the translation to other contexts (Patton, 2015). Aligned with this goal of transferability, our approach aimed to describe specific ways practitioners used prototypes to engage stakeholders during front-end design and explain patterns and variations among practitioners' approaches, including details about their design contexts that drove their decisions.

2.1 Participants

Practitioners from the medical device design industry were recruited as a preliminary design domain of focus, to provide some consistency among the types of design artifacts discussed. We initially contacted potential participants through personal networks and connections established at a medical device design conference. Prior to enrollment in the study, prospective participants completed an online survey consisting of demographic and prior experience questions. Using a purposeful sampling technique (Biernacki & Waldorf, 1981; Patton, 2015), participants who reported using prototypes to engage stakeholders were invited to participate in the study. Two participants recruited did not complete the online survey, because they were referred to us by colleagues based on their previous experiences using prototypes in past design projects.

Participants included 22 design practitioners from 16 medical device companies who had used prototypes for stakeholder engagement during the design front end of a mechanical or electro-mechanical product. Nine participants worked in companies with 10 000+ employees (large), one in a firm with 50–200 employees (medium), and 12 in firms with 1–49 employees (small), addressing clinical needs in the United States, European Union, and in global health markets. Most participants had job titles aligning with engineering design (n = 14) although some had training in other disciplines, including product design and design research. Their job roles varied; many had senior, lead, or principal design engineering, product design, design research, or technology management roles. As such, the term *design practitioner* is used broadly to represent variation among backgrounds, job roles, and years of design experience (mean = 11.9 ± 9.3 years).

The University of Michigan Institutional Review Board reviewed and granted the study an exemption and consent was obtained from each participant prior to the interviews. Participant information is presented in Table 1.

2.2 Data collection

A semi-structured interview protocol was iteratively developed based on relevant literature. The purpose of the interview was to elicit concrete stories of experiences that practitioners had using prototypes to engage stakeholders during front-end design activities. The structure of the interview was guided by best practices in protocol development (Barriball & While, 1994; Weiss, 1994). We piloted the protocol with 11 participants (different from the 22 participants in our study) to gain familiarity with the protocol and refine questions as per recommended practice (Barriball & While, 1994).

At the start of the interview, we provided participants with definitions for front-end design, products, prototypes, and stakeholders. Defining these terms supported participants in sharing experiences that aligned with our research goals and potentially expanded what they chose to share with us, given that our definitions were intentionally broad. The definitions we used in the interviews were informed by existing literature. The definitions and sources that supported our definitions are included in Table 2.

Table 1 Participants. Fields containing N/A correspond to unreported values

Participant ID	*Gender*	*Age*	*Highest degree*	*Design experience (years)*	*Job tenure (years)*	*Company size*
Participant A	Male	34	Master's	6	4	Small
Participant B	Female	24	Bachelor's	1	1.75	Small
Participant C	Female	35	Master's	9	3	Small
Participant D	Female	38	Bachelor's	17	2	Small
Participant E	Male	31	Master's	6	0.67	Small
Participant F	Female	29	Bachelor's	6	6	Small
Participant G	Male	56	Bachelor's	30	24	Large
Participant H	Female	28	Master's	8	8	Small
Participant I	Male	42	Master's	17	10	Small
Participant K	Female	27	Master's	5	3.5	Small
Participant N	Female	37	Doctorate	6	6	Small
Participant O	Male	N/A	Bachelor's	12	5	Large
Participant P	Male	31	Doctorate	10	0.5	Large
Participant Q	Female	30	Master's	9	8	Large
Participant R	Male	57	Master's	38	8	Large
Participant S	Male	32	Master's	9	7	Large
Participant T	Male	55	Master's	25	7	Large
Participant U	Male	37	Master's	12	6	Large
Participant V	Female	47	Master's	20	5	Medium
Participant W	Male	29	Bachelor's	2	3	Small
Participant Y	Female	47	Master's	12	20	Large
Participant X	Male	25	Bachelor's	3	1	Small

The interview questions prompted participants to focus on a specific past design project that involved the use of prototypes to engage stakeholders during the front end of design. The practice of contextualizing interview questions in the participants' experiences supports the collection of authentic responses and rich descriptions (Weiss, 1994). Follow-up questions were asked to gather additional details specific to each participant's experience (Barriball & While, 1994). Example questions from the interview protocol are listed in Table 3.

2.3 Data analysis

Audio-recordings of the 22 interviews were transcribed, verified against the audio recordings for accuracy, and de-identified. Initial analysis was conducted by two members of our research team; each person read the collection of transcripts and documented emergent themes and associated data representing prototyping strategies for engaging stakeholders during the design front end.

The process of identifying strategies was inductive. Themes were identified by finding an action in the data which involved a stakeholder being engaged with a prototype in the context of a project's front-end design activities. Literature that was used in the development of the interview protocol was consulted when refining theme names and definitions.

Two members of our research team performed the initial analysis and iterated on the collection of strategies comparing the identified strategies to one another and the corresponding original data in the transcripts, which aligned with the method of constant comparison (Boyatzis, 1998; Charmaz, 2006). A final list of prototyping strategies, with their definitions and examples, was created and served as the codebook for the rest of the analysis process.

Table 2 Key definitions used in the interview protocol

Term	*Definition provided during the interview*	*Source*
Front-end Design	"Phases of product development associated with problem identification/needs finding, problem definition (e.g., requirements and specifications development), background research, concept generation, early prototyping, and concept selection."	Adapted from (Atman et al., 2007; Cooper, 1988; Zenios et al., 2010)
Product	"The designed artifact. The prototype could represent a process, a system, or a sub-part of the designed artifact."	Adapted from (Deininger, Daly, Sienko, & Lee, 2017; Ulrich & Eppinger, 2008)
Prototypes	"Include mock ups, CAD models, drawings, scenarios, and other representations of the product or its use."	Adapted from (Deininger, Daly, Sienko, & Lee, 2017; Houde & Hill, 1997; Ulrich & Eppinger, 2008)
Stakeholders	"Anyone who will affect or be affected by the artifact at some point, including end-users, colleagues, manufacturers, clients, policy makers/ministry officials, technicians, procurement officers, etc."	Adapted from (Freeman, 2010, p. 53; Zenios et al., 2010)

Table 3 Interview protocol themes and sample questions

Themes	*Example Questions*
Project specific	• Can you select a project that you would say is the best example of a project you worked on where you used prototypes in the design front-end to engage stakeholders?
Types of prototypes	• Who were the stakeholders you engaged during your project? • How did you choose which type of prototype to make to engage with stakeholders?
Stakeholder interactions	• Can you tell me how you used these prototypes to engage with different stakeholders? Could you describe the interactions in more detail?
Design activities	• Can you tell me about a time when engaging stakeholders with prototypes led to a better understanding of the need? • Could you focus on a requirement that was informed by the use of a prototype with a stakeholder? • How was using prototypes to engage stakeholders more relevant in one design activity than in others?
Generalizing across projects	• When you think across all of your projects during which you have used prototyping during the front end to interact with stakeholders, would you say your strategy changed depending on the design activity for which you are using the prototype? How? Can you give me an example? • What determines whether the approach will be mostly serial or mostly parallel across projects? When does that change?

To represent the prevalence of a strategy within the data set, full transcripts were selected as the unit of analysis. Each transcript was analyzed to determine which of the identified strategies listed in the codebook were used by each participant. Two members of our research team independently coded two full transcripts. With the coded transcripts, inter-rater agreement was calculated by taking the total number of agreements for all the strategies per transcript (out of 17 possible) and dividing by the total number of agreements and disagreements per transcript. The resulting inter-rater agreement was 88%, which is considered strong (Campbell, Quincy, Osserman, & Pedersen, 2013). The remaining 20 transcripts were divided between the two researchers for coding. Both coders reviewed one another's coded excerpts for each strategy in each transcript, and all disagreements that emerged from this review process were resolved until full consensus was reached. During this process, code definitions were minimally refined to ensure clarity, specificity, and agreement among our research team members.

The reported frequency for a given strategy indicated how many transcripts showed evidence of that particular strategy. While we analyzed for frequency, we did not interpret it as an indicator of greater or lesser importance of any prototyping strategy.

3 *Findings*

Seventeen prototyping strategies for stakeholder engagement during the design front end were identified in the interviews with medical device design practitioners. Participants sometimes leveraged single strategies, and sometimes used multiple strategies concurrently, examples of which can be seen

in some of the interview excerpts. None of the strategies were evident in all of the participants' shared experiences, and most of the strategies were used by less than half of the participants. The strategies, their definitions, and example excerpts from the interview data are included in Table 4. The sub-sections that follow examine the most and least commonly described strategies, and a subset of strategies which are expanded upon because of their richness and relationship with existing literature beyond engineering design practice.

3.1 Most cited strategies across participants

3.1.1 Show the stakeholder multiple prototypes concurrently

Seventeen of the 22 participants described the strategy of showing stakeholders multiple prototypes during an engagement. Participants described a variety of reasons for bringing more than one prototype to a front-end design engagement, including to help stakeholders articulate feedback, make comparisons across diverse concepts and features, and to communicate the incomplete status of the design project, i.e., that stakeholders had an opportunity to contribute to future design iterations.

Some participants showed stakeholders multiple prototypes to assess whether a clear need existed in a particular design space and to clarify the need. For example, Participant D showed stakeholders multiple prototypes that focused on different potential stakeholder needs in a specific geographic region:

> *"We had those three prototypes, and we went to [the country] and visited a number of hospitals with [community partner] … we were showing multiple prototypes and talking about multiple topics, and really trying to gauge … Is there a need here that's not being filled currently that something like this could fill?"*

Participants also had stakeholders interact with multiple prototypes to help determine what features might be part of a given solution. For example, Participant V provided stakeholders multiple parts they could connect together when discussing potential solutions for a feature:

> *"For [a device] … there were a lot of different ways that you could attach [parts] … we actually used a 3D printer and printed the parts and then we had different ways that you could snap pieces together and different ways in which you could attach [them] … We brought [them] in and had nurses put it together … and give us feedback."*

Participants also used multiple prototypes with stakeholders to translate requirements to engineering specifications. For example, Participant N created

Table 4 Strategies for stakeholder engagement using prototypes during the front end of design (counts (n) refer to the number of transcripts with evidence of the strategy)

Strategy	*Definition*	*Example Interview Excerpts*	*n*
Show the stakeholder multiple prototypes concurrently	Prompt the stakeholder to compare options using multiple prototypes of different needs, concepts, features, form factors, requirements, or engineering specifications.	*"They have 30 of [those prototypes] sitting on the table in front of [the stakeholders]. They pick it up, and they spend about half a second on the ones they don't like. "Nope, I hate that," and then throw it down. Then they pick up the one they do like, and they'll sit with it for a minute just oohing and aahing over it. Sometimes that level of feedback is like, just the amount of time that they're holding it tells you as much as anything else …" (Participant O)*	17
Brief the stakeholder about the project and the prototype(s) shown	Introduce the stakeholder to the project, describe the prototype(s), including defining its purpose and current form and fidelity, and describe expectations of the stakeholder's participation.	"*What I tended to do is introduce the problem, state why we were there, and then pull out the prototype, show some specific aspects that we are looking for feedback" (Participant F)*	16
Observe the stakeholder interacting with the prototype(s)	Prompt the stakeholder to interact with prototypes while observing the interaction.	*"Sometimes, when you give [stakeholders] prototypes, they use it completely differently, and then that becomes human factor input. Even though the session was not created as a human factor session, you get some valuable input by observing." (Participant P)*	15
Show a single prototype to the stakeholder	Engage the stakeholder using one prototype.	*"Given our limited resources, most of the major stuff was done linearly and a single prototype iteration" (Participant A)*	12
Show the stakeholder supplemental materials related to the concept to complement the prototype	Engage the stakeholder using storyboards, test data, computational models, materials, physical models, etc. to elaborate on the details of the prototype.	*"… we would send the picture of the [prototype components], the design, front, back, side view, we were sending the raw materials. So we would actually have a swatch booklet, so we would have just like little swatches of the raw materials that were going into the [product] so that people could touch and feel them to provide feedback … " (Participant H)*	11
Introduce the prototype(s) to the stakeholder in the use environment	Place the prototype in its environment of use when engaging the stakeholder.	*"We gave them the working prototype, and they took it to their health clinic, and they [said] 'Okay, we could keep it here. We could go like this. We could do like that.' They did like a dry run of how this product would be used in their context of use. That's in person, in context." (Participant E)*	11

(*continued on next page*)

Table 4 (*continued*)

Strategy	*Definition*	*Example Interview Excerpts*	*n*
Have the stakeholder interact with the prototype(s) in a simulated use case	Replicate relevant conditions of the product's environment of use in a simulated setting where the stakeholder interacts with the prototype(s).	*"We used simulation mannequins and the simulation, the [program name] at the hospital a lot when we'd meet with like users so that they could try it out … Because you can look at something and kind of know, but until you try it out and use it in a mannequin you don't really know. So, we did pick the setting of them being able to be as true to how they would normally do the procedure." (Participant N)*	11
Polish the prototype(s) shown to the stakeholder	Create or modify a prototype to show to the stakeholder that more closely resembles the final form of the concept versus the current status of the project.	*"So when I am trying to put something out in the field, I'm trying to get it as finished as possible even just aesthetically. If I need to spray paint it or something [because] people will look at a 3D print and be like, "why is it this color?" Well it's like, it can be any color, it doesn't matter that's just the color that the 3D printer had in it at the time … if I'm going to stakeholders outside of the office, I don't want them to get distracted on those types of questions. I want to get to the heart of it as quickly as possible …" (Participant A)*	9
Encourage the stakeholder to envision use cases while interacting with the prototype(s)	Prompt the stakeholder to imagine how they would use the prototype in use cases.	*"You're going to have to … start probing 'consider when you're using the distal … grip and you're doing a [type of procedure]. Tell me about it. What about this gets in your way? What about this is problematic for you? Consider that use case and tell me about this … '" (Participant O)*	7
Reveal only relevant information to the stakeholder specific to the prototype or its use	Strategically reveal relevant information to the stakeholder, leaving out details about the prototype(s), such as functionality, or rationale behind design decisions.	*"We would brief them about the product we were hoping to test with them, what we were trying to test or what we were trying to see, but we would also try to do it in a way where we didn't tell them what outcome we wanted … we might say "we want to test to see how this product supports you around your [limb] while you [do this activity]". We wouldn't tell them, "we're looking to see specifically if you have pain on your [specific body part] when you [do this activity] or to see if you're uncomfortable when you [do this other activity]." (Participant W)*	7
Task the stakeholder with creating or changing the prototype(s)	Prompt the stakeholder to create or modify the prototype(s) by physically altering prototypes, writing, or drawing ideas. In this strategy, the stakeholder, rather than the practitioner, makes or changes the prototype(s).	*"We had the big alpha prototype we would give them these supplies and say what would be all the functions that you'd want to see in a device? And we kind of talked through that. So it's like on and off buttons, you want multiple settings of intense and less intense […]. We would bring out these pieces and ask them, okay take your favorite on button and display and so forth, can you tell us where on the device you want these things to go?" (Participant F)*	6

(*continued on next page*)

Table 4 (*continued*)

Strategy	*Definition*	*Example Interview Excerpts*	*n*
Prompt the stakeholder to select prototypes and prototype features	Ask the stakeholder to choose or prioritize ideas based on provided prototypes.	*"They sort of rotated doctors and nurses through a whole bunch of stations, and one of the stations was looking at these different devices and getting feedback and ranking which one they liked the best and what qualities they want in a device." (Participant D)*	6
Standardize the refinement of prototypes shown concurrently to the stakeholder	Present prototypes that are at the same level of refinement (fidelity, functionality, and finish) when shown simultaneously to the stakeholder.	*"I would try to have the prototypes [be] as similar to each other as possible so that you don't have something [with] very bright colors and very attractive and some lower [quality prototypes]." (Participant P)*	6
Present a deliberate subset of prototypes to the stakeholder	Present fewer, carefully selected prototypes to the stakeholder than the full set of prototypes created.	*"You don't want to have 20 different concepts, and sometimes certain concepts are still similar and it's really confusing and you don't get as much information out of it as you want." (Participant P)*	6
Modify the prototype(s) in real time while engaging the stakeholder	Make changes to the prototype(s) while the stakeholder is present. In this strategy, the practitioner rather than the stakeholder, makes the changes to the prototype(s).	*"We were out to a user discussing one of these prototypes, […] and they didn't like it. We got out our modeling clay and said, let's take this and do something different. Do you like this?" … You're changing stuff on-the-fly when it's appropriate." (Participant G)*	5
Make prototype extremes to show the stakeholder	Exaggerate prototype characteristics that represent a feature at a specification's upper or lower limit, or represent opposite characteristics.	*"The main question that we really had to answer was does this need to actually have liquid in it or does it have to be dry? And half of our stakeholders told us one thing and half told the other, so we said okay, let's make two very different prototypes. One is going to be wet. One is going to be dry. And just kind of show them and let them try and see in the end, what did they end up using." (Participant K)*	4
Lessen a prototype's refinement when showing it to the stakeholder	Engage the stakeholder with less sophisticated and/or complete prototype(s) than the current project status.	*"If we were trying to get a function, something that just conveys the motion, or the actuation of something, there are actually times where we will intentionally choose a less refined method of prototyping […] and almost like not whittling, but close. There's actually some times where that's valuable, because it helps set the tone of the session that something is really early phase." (Participant U)*	4

prototypes that represented different variants of potential solutions' subsystems:

> *"We had two different materials, two different rigidities for the main [component] of it and we had two different flexibilities of the [subcomponent] and so we did all the combinations and put them all down on the table and had [the stakeholders] try each one multiple times without saying anything about [them]. They were just A, B, C, and D. And then let them interact them with it without pre-biasing them saying, this one's stiffer, that one's more flexible … we definitely put them in a setting where it was all there at once … so that we can really compare what's a noticeable difference, what's not a noticeable difference, what's desirable, what's not … So just understanding [a product requirement]. You just don't know until you're trying it … it's not something anybody can throw a number at, they have to feel it."*

3.1.2 Brief the stakeholder about the project and the prototype(s) shown

Sixteen participants discussed the importance of the introductory remarks of the engagement session for building rapport, conveying goals, and managing stakeholders' expectations. Participants described using prototypes to assist with conveying the goals of the front-end engagement and the status of the solution concept(s). For example, Participant T described the use of this strategy to elicit feedback about a design's intended functionality during an early stage of his team's design process:

> *"[We tried] to show the functionality but also emphasize that we didn't have a form factor and we were a long way from the right form factor or final design ….The feedback wasn't things like this is too big, or this doesn't seem very reliable, or this handle isn't ergonomic, or any of those kinds of things. We were much earlier and these prototypes didn't address any of those issues, so we tried to set expectations. Where are we at? At a high level we tried to set the expectations of where we were at so that the prototypes were viewed appropriately, and we could get the right type of input on that we were looking for in that stage."*

In another example of this strategy, Participant N prepared stakeholders to engage with a prototype by telling them to pay attention to a specific aspect of the prototype and asking them to disregard other aspects of the design:

> *"We frequently would introduce it to them with, this is what we're trying to figure out, to focus them on one aspect of it. So I guess you could consider that a strategy where we tried to kind of prep them for, this is what you're going to see and ignore these things. This is similar to how it will be, this*

is not similar to how it will be. And, we want to know this … to get them tuned into exactly what we're looking for."

3.1.3 Observe the stakeholder interacting with the prototype(s)

Fifteen participants described the strategy of observing stakeholders interact with a prototype. Encouraging stakeholders to interact with prototypes provided participants with information about requirements, unexpected behaviors, design shortcomings, and usability issues. For example, Participant F described observing a stakeholder place a component of a prototype in an unexpected direction, that led to a subsequent design modification:

"On one of our early prototypes … people would try twisting [the component] the opposite way [we had intended], and they would get stuck, and then you'd see them go the other way, or they'd put the [component] backwards, and so they'd have to put it back in, and [we made] a lot of feature adjustments based on very, very early observations."

Participants also discussed observing stakeholders' silent reactions, including stakeholders' unspoken emotional reactions when interacting with a prototype. Participant T described these unspoken reactions as complementary feedback that may otherwise not be articulated by the stakeholder during the session:

"[We] observe that their hand is slipping, or see that they are having to turn a handle say fifty times and it looks like they are annoyed by that, but they don't necessarily say, oh, I'm turning the handle too much. You need to change this."

3.2 Least-cited strategies across participants

3.2.1 Modify the prototype(s) in real time while engaging the stakeholder

Five of the 22 participants described the strategy of modifying the prototype(s) during the engagement session. Modifications of prototypes were prompted by stakeholder feedback, but implemented by the designers during the engagement session. Participants noted that the use of this strategy generated particularly rich stakeholder feedback because stakeholders perceived that they were actively contributing to the development of a potential solution by physically manipulating the prototype that they were being prompted to assess.

Participant K described an engagement session during which the team was focused on understanding how stakeholders defined "comfort" within the context of the ideas presented:

"[There was] this [prototype] that was developed and a lot of [the session] was … sitting there and sewing and changing one thing and having [the stakeholder] try it and then sewing. Just trying it out and having a variety of options. A lot of that is, that was a project that was going to be worn. It had to be comfortable. It had to have requirements that were much more ergonomic."

Participant G described the importance of being able to quickly modify the prototype based on the stakeholder's response in order to obtain real-time feedback about the modified design:

"We were out [talking] to a user discussing one of these prototypes … and they didn't like it. We got out our modeling clay and said, let's take this and do something different. Do you like this? … You're changing stuff on-the-fly when it's appropriate.

3.2.2 Make prototype extremes to show the stakeholder

Four participants discussed the practice of showing stakeholders prototype extremes to inform the development of requirements and the translation of requirements to quantifiable specifications. Additionally, this strategy helped participants to resolve conflicting feedback.

Participant R discussed the use of a prototype during the design front end to gather information about weight-related extremes:

"It was [a] non-functional [prototype], but the idea was to try to figure out how heavy it could be, so I made different sized weights, and you could put it in there, and you kept getting bigger and heavier until you say, what's too heavy? If it's too small you take it out and say, is this too light? So that was just a design to determine [the] limits on the weight of the device."

Participant K described using prototypes that represented opposing ideas of a requirement to help his team resolve variable and inconsistent stakeholder feedback:

"I was working on a project [where] the main question … was does this need to actually have liquid in it or does it have to be dry? And half of our stakeholders told us one thing and half told the other, so we said okay, let's make two very different prototypes. One is going to be wet. One is going to be dry. And just kind of show them and let them try and see in the end, what did they end up using because I think sometimes you have an idea of what you want but then there is that practicalities of actually doing it in real life."

3.2.3 Lessen a prototype's refinement when showing it to the stakeholder

Four participants described de-emphasizing the design team's investment in an idea by showing less sophisticated versions of prototypes to stakeholders than prototypes that fully captured the current design iteration or stage of the project. This approach was pursued because participants perceived that stakeholders were more comfortable giving honest feedback if the stakeholders perceived that the design was still a work in progress, i.e., stakeholders might be hesitant to critique a design that could not be changed. For instance, Participant N mentioned the use of a hand-drawn sketch of a previously generated CAD model to promote more candid stakeholder feedback:

> *"We did some ... sketching on a paper. I know it doesn't sound like a prototype but the purpose of that is that the more raw it looked, the more input we got. Because if it looked finished, people would just say, oh, yeah, yeah, that's good. And they'd be afraid to offend you … to give their input because they thought it was done. So, sometimes we just tried kind of pencil and paper … like not even printed out from CAD. Like, just redraw what I had in CAD with pencil and paper because then people would give me more, like, oh, she's early on, I can go ahead and give my input, you know."*

Participant T described stripping prototypes of non-defining features or showing crude versions of the features to communicate that these features were not the focus of the engagement session:

> *"Say … a handle was needed [for the prototype] to be functional and ergonomic, but the handle itself wasn't really a defining feature. It might have no handle, or a crude handle, [otherwise …] sometimes, there is a distraction. "Like, why is this handle so big? Or why is this handle not operating smoothly?" Or things like that … I use the handle analogy a lot. Instead of putting a handle on, maybe pliers or grippers on the end that are actuating it, because you don't care about the form factor, you care about the functionality and how it may make it easier to be reliable."*

3.3 Additional strategies representing diversity of prototyping strategies cited across participants

While Table 4 includes a description and example for each of the strategies revealed in this study, in this section, we provide additional data associated with three particular strategies to further highlight the diversity of strategies uncovered in the sample and some of the important nuances among the strategies.

3.3.1 Polish the prototype(s) shown to the stakeholder

Nine of the 22 participants described experiences during which they took additional steps to refine prototypes, rather than show unpolished prototypes to

certain stakeholder groups. Participants claimed that this strategy helped certain stakeholder groups focus on the goals of the session rather than being distracted by the appearance of unfinished prototypes, in contrast to the strategy "Lessen a prototype's refinement when showing it to the stakeholder." Participants mentioned they often "polished" the appearance of the prototypes to leave a good impression with stakeholders from whom they needed buy-in.

Participant R used polished prototypes to avoid comments about a prototype's unfinished look:

> *"The other thing we did to get them past the, that's horrible and disgusting, is we made a lot of … models that were non-functional that looked pretty. Some of them even had LEDs on them. It's crazy I know, but it's true. One of the guys on our team … would make pictures that looked like it was actually real … actual rendering, 3D graphics rendering of prototypes, and we made some for [this stakeholder group] as well. It looked pretty but they didn't do a darn thing, they were just a hunk of metal and plastic, right? That helped too, to be honest, having pretty stuff. For the non-technical [stakeholders], pretty stuff helps."*

Participant C elaborated on making a positive impression with the first presentation of a prototype to a potential user:

> *"… the prototype had one big electronic chip. If [somehow] something like that is being put on [the user], [the caregiver] will be scared. So, we made sure that the prototype, the enclosure of the prototype, is something that doesn't seem as a danger to the [user] … it had to look appealing so the [caregiver] accepted it, because the first impression of anything comes from the first look at an object."*

3.3.2 Task the stakeholder with creating or changing the prototype(s)

Six participants talked about encouraging stakeholders to make modifications to a prototype themselves as a way to better understand stakeholders' thoughts and concerns. In contrast to "Modify the prototype(s) in real time while engaging the stakeholder," where the practitioners were modifying the prototype, stakeholders were prompted to be the main actors and make changes to the prototypes.

Participant U described a session when he instructed stakeholders to directly alter the prototype:

"We also said, okay, here's a pile of 3D printed parts, with bits and pieces of the other ones, how would you arrange them in a way that would be easiest, or most logical, or straight forward, or intuitive to use … We decided that for the build-a-handle exercise, it was more about relative location, and access to the features, than it was picking things based on aesthetic, or tactile feedback … We gave them modeling clay to stick it on there, just stick it where you want it, and then have them actually go through the activity of holding it in their hand, or laying it on the table, and using it … seeing if the way that they put it together was appealing or not. There were a lot of cases where they started out, and they sort of arranged things in a way that was aesthetically pleasing, but then when we went through the mock procedure, they realized that things were in the wrong location. That it looked nice, but there was no way that you could get to something, or things just kind of got in the way, and it was cumbersome. Which is really what we were after."

In this example, Participant U used two strategies: "Task the stakeholder with creating or changing the prototype(s)" and "Encourage the stakeholder to envision use cases while interacting with the prototype(s)," i.e., stakeholders were asked to arrange parts and act out how they would use the prototype.

3.3.3 Introduce the prototype(s) to the stakeholder in the use environment

Eleven participants described introducing the prototype within the intended environment of use. Participants who employed this strategy either asked stakeholders to use the prototype or envision the use of the prototype while being in the use environment, as opposed to in an environment unrelated to its use. In the following example, Participant D described how stakeholders were able to provide feedback that informed sizing and use, by introducing the prototype within its use environment:

" [The stakeholders] instantly wanted to put [the prototype] and actually try it out in the NICU, where it would actually go. Whereas if we hadn't had anything physical ..., I think that topic may not have come up and we might not have realized where they wanted to set it and so forth. So being able to size it correctly […] if we didn't have that cot hanging around, they may not have even thought to mention that. Even if we asked, "Where would you put it in the NICU?" And they might have said, 'Oh, I guess we'll put it on a table or maybe in one of the cots,' the idea of them picking it up and actually seeing if it fits or questioning whether it would fit, that probably wouldn't have even come up."

4 Discussion

4.1 Comparing study findings to the literature

In this study, we identified 17 strategies that medical device design practitioners employed to engage stakeholders with prototypes during front-end design activities. While the strategies had similarities, they were each distinct. For example, "Task the stakeholder with creating or changing the prototype(s)" and "Modify the prototype(s) in real time while engaging the stakeholder" are similar in that both require altering a prototype, but distinct with respect to who the main actor is in performing those changes (design practitioner or stakeholder). This specificity across the collection of strategies extends the prior literature that describes prototype uses. Further, the collection of strategies emphasizes the roles that prototypes can have in front-end design beyond those traditionally emphasized in engineering design textbooks, such as for representing products in evolving detail and specificity (Dieter & Schmidt, 2013; Ulrich & Eppinger, 2008). While prior literature highlights uses of prototypes for supporting stakeholder involvement and eliciting requirements (e.g., Jensen et al., 2017), the strategies revealed through this study (and the associated rich transcript excerpts) describe nuanced approaches regarding how to plan and execute front-end stakeholder engagements with prototypes.

The findings also revealed that design practitioners intentionally leveraged these particular strategies with prototypes to engage stakeholders; they believed their choices had specific benefits related to their project goals at the time. The design practitioners in our study articulated their intentional prototyping choices during the planning and execution phases of their stakeholder engagements and routinely used prototypes strategically as intermediate representations of their design work—as probes for promoting meaningful dialogue and gathering information to develop requirements and specifications as well as to evaluate early solution ideas. Related work demonstrated intentional strategy choices among medical device design practitioners when engaging stakeholders with prototypes during the design front end; specifically, practitioners selected prototypes based on who they were engaging with and in which environment the engagement occurred (Coulentianos, Rodriguez-Calero, Daly, & Sienko, 2020a, 2020b).

The strategies discovered bring attention to particular aspects of stakeholder engagements with prototypes. Some strategies focused on how many prototypes to show the stakeholder, other strategies focused on decisions about the quality of the prototypes shown, and still others focused on how to engage the stakeholder with the prototype, including what to tell the stakeholder, what activities to facilitate, and where to perform the engagement. We discuss strategies that demonstrate these different foci in the following paragraphs.

Although we have chosen quantity, quality, engagement, and environment as groupings for exploring these front-end prototyping strategies for engaging stakeholders, we note that there are several other ways in which the strategies might be grouped.

Examples of strategies that brought focus to prototype quantity were "Show the stakeholder multiple prototypes concurrently" and "Show a single prototype to the stakeholder." The prominence of the use of multiple prototypes across practitioners in our study could, in part, be a reflection of the ongoing exploration inherent to front-end design processes. However, participants explained other reasons for their choices. Practitioners who showed stakeholders multiple prototypes concurrently felt that the approach enabled stakeholders to compare design alternatives, convey tangibly that design ideas were still being explored, and encouraged stakeholders' input.

Contrastingly, some participants in our study, at times, also showed stakeholders a single prototype and explained how context, design stage, specific engagement goals, and resource constraints, such as cost and time, sometimes prompted their decision to employ this approach. An analogous trade-off was reported in Moe et al. (2004), which described that cost, schedule, and performance priorities drove the quantity of prototypes and iterations made, but this study was not front end or stakeholder engagement focused.

Decisions about prototype quantity depended on multiple factors for participants in our study, which was also documented in our related work (Rodríguez-Calero, Coulentianos, Daly, & Sienko, 2020). Our study differs from prior work by shifting the focus from determining the number of prototypes based on a product development timeline (Christie et al., 2012) or suggesting that multiple prototypes in parallel are typically beneficial (Camburn et al., 2017; Dow et al., 2012, 2010) to deciding prototype quantity based on stakeholder engagement goals. A universal recommendation on prototyping quantity misses an opportunity to leverage the value that each strategy might bring in different situations.

An example of a strategy that focused on the quality of the prototype was "Lessen a prototype's refinement when showing it to the stakeholder." Participants expressed that they purposely invested time and effort into developing lesser-refined prototypes than the most-up-to-date representations of concept solutions to communicate to stakeholders that there were still opportunities for their input to influence design outcomes. As prototypes tend to evolve along with a design process, it was surprising to find that designers lessened the refinement of their prototypes to fulfill specific goals for stakeholder engagement during the design front end. In the case of practitioners in our study who used this strategy, they invested time to create less polished versions of prototypes, while existing literature recommends low-fidelity prototypes

because they are quick and inexpensive to make (Kelley, 2001). Existing literature also highlights low-fidelity prototyping as supporting iteration and progress (Gerber & Carroll, 2012), informing ideation and concept development (Neeley, Lim, Zhu, & Yang, 2013), exploring basic assumptions, and understanding user mental models (Tiong et al., 2019), reasons that aligned with practitioners' rationales in our study for the strategy to lessen the refinement of prototypes.

In contrast to the previous strategy, there were times participants showed prototypes that were intentionally made to look more refined than the actual state of the design ideas, evidenced by the strategy "Polish the prototype(s) shown to the stakeholder." Participants claimed the strategy was a way to help eliminate distractions and move stakeholder's thinking past the prototype's appearance. The literature provides mixed recommendations with regards to the impact of more or less "polished" versions of prototypes in terms of fidelity, finish, and aesthetics. For example, making prototypes to be aesthetically pleasing has been shown to produce more positive judgments by users in both low and high fidelity versions than with low aesthetic prototypes (Sauer & Sonderegger, 2009), but more finished sketches have been shown to be better regarded by stakeholders than their rougher counterparts (Macomber & Yang, 2011). In contrast, another study found that cross-cultural medical device design stakeholders provided responses with greater variation, less design input, and less rationale when presented with low-fidelity prototypes (sketches and cardboard models) than when presented with more refined prototypes (CAD models and 3D printed prototypes) (Deininger et al., 2019). Considering that both polishing the appearance and lessening the refinement of a prototype were found as strategies, our findings are most consistent with Tiong et al. (2019), who suggested that when using higher fidelity prototypes, these should match the specificity of the design questions being posed. For example, when asking a stakeholder to evaluate overall concepts, too detailed a prototype could distract and bring attention to smaller features instead of the overall functioning of the device.

An example of a prototyping strategy that focused on engagement activities was "Brief the stakeholder about the project and the prototype(s) shown." Participants in our study perceived that the prototypes could have an unintended role in the interaction if left unexplained, such as distracting the stakeholders. Furthermore, to yield quality information, participants indicated they felt the strategy supported rapport building, which aligns with literature describing building trust as an important stakeholder engagement technique (Strickland, 2001). This briefing strategy was one that contributed to a larger goal of preparing stakeholders to successfully engage in the session, an idea discussed further in related work by Coulentianos, Rodriguez-Calero, Daly, Burridge, and Sienko (2019). Reasons participants used this strategy (e.g., to

communicate objectives of the engagement, build rapport, and manage expectations about the prototypes to be shown) are consistent with the usability testing literature that describes the value of telling stakeholders what they are about to see, how they should interact with the prototypes, and what is expected from them during usability testing (Weinger, Gardner-Bonneau, & Wiklund, 2010).

Other examples of engagement-focused strategies included: "Modify the prototype(s) in real time while engaging the stakeholder" and "Task the stakeholder with creating or changing the prototype(s)." In the former strategy, the designer made the design changes, and in the latter, the stakeholder had the more active role. This contrast aligns with a spectrum of participation where stakeholders can be either subjects of study or co-creative partners (Sanders, 2006; Sanders & Stappers, 2008, 2013). "Modify the prototype(s) in real time while engaging the stakeholder" aligns with literature describing "live prototyping," which is used by designers to build and alter prototypes while engaging stakeholders (Horst & Matthews, 2016). On the other hand, "Task the stakeholder with creating or changing the prototype(s)" aligns with the focus of participatory workshops, though participants in this study seldom described intentional planning of such workshops. While practitioners in our study engaged stakeholders, they did not describe the level of participation that characterizes participatory design approaches (Sanders & Stappers, 2008). This observation could partly be explained by the medical device design context in which participants were working. The objectives of a design team embedded within organizations in a competitive business landscape might not always be aligned with the objectives of participatory methods and co-design.

An example of a strategy focused on the environments for stakeholder engagement with prototypes during the front end was "Introduce the prototype(s) to the stakeholder in the use environment." Participants in our study, when possible, situated stakeholders in settings to yield more authentic information than in settings separated from the environments in which the intended designs would be used. This finding is consistent with principles of contextual design, which promote that prototypes, even low fidelity ones, need to be tested in the stakeholders' actual use contexts and that the prototypes need to support the stakeholders' current tasks to elicit useful knowledge (Holtzblatt & Beyer, 2017). Human factors literature supports that human performance is closely associated with the environment where the tasks and behaviors occur (Flach, 1995). However, being in the actual environment of use was not always an option, and as an alternative, practitioners used other strategies that helped stakeholders connect to the environment, such as "Have the stakeholder interact with the prototype(s) in a simulated use case," and "Encourage the stakeholder to envision use cases while interacting with the prototype(s)." These two strategies reveal the value practitioners placed on the environment

in which the design would be embedded, and when they could not situate the engagement in the actual environment, they sought ways to connect the stakeholders to it.

The prevalence of some of the most commonly used strategies described in the study might be domain-specific to medical devices. For example, the Food and Drug Administration (2016) provides recommendations for designers to ensure safe and effective device use and two of the recommendations focus on user interactions and use environments. Two frequently mentioned strategies from our findings related to user interactions ("Observe the stakeholder interacting with the prototype(s)" (n = 15) and "Encourage the stakeholder to envision use cases while interacting with the prototype(s)" (n = 7)) may have emerged in a large number of transcripts because of their potential roles in supporting the early identification of use-related risks. Similarly, frequently used strategies related to use environments ("Introduce the prototype(s) to the stakeholder in the use environment" (n = 11) and "Have the stakeholder interact with the prototype(s) in a simulated use case (n = 11)) may have facilitated the recognition of potential risks associated with device usage in particular settings. While the prevalence of the strategies may be impacted by the medical device context, the strategies align with existing design approaches described in the design of products beyond medical devices, such as assistive technology, power tools, and consumer electronics, among other physical products (Ulrich & Eppinger, 2008).

4.2 Limitations

One limitation of the study is that participants could have blurred the lines between front-end and back-end prototyping uses for stakeholder engagement. We worked to limit the impact of this limitation by defining front-end design phases at the onset of the interviews, probing for specific examples within early design activities, and excluding back-end strategies as best as possible during analysis. However, the highly iterative nature of design could have resulted in participants sharing strategies that stretched beyond solely front-end activities that we were not able to clearly exclude during analysis. A related limitation is that because we excluded strategies that appeared to be within back-end activities, some of the front-end strategy counts could potentially be lower than participants' actual use within the experiences they shared because of the caution we employed in borderline examples.

Another limitation is that the strategies counted were based on participants' ability to recall their past experiences. We did not observe the strategies in use as they occurred, but rather relied on participants' descriptions of their experiences.

The study is limited in knowledge of the extent to which medical device design practitioners' prototyping strategies during the design front end are representative of front-end processes in other domains. The study's focus was on rich descriptions that can support transferability to other design domains. However, the strategies identified in this work are limited to the practitioners of medical device design included in our study.

The study is also limited in that most participants worked in the United States, therefore primarily reflecting design practices within that region of the world. Additionally, race and ethnicity questions were not included in the study questionnaire, limiting our knowledge on these aspects of diversity across participants.

4.3 Implications

The findings of this study can impact how medical device design practitioners approach their work. Specifically, the findings bring focus to the ways that designers in this domain can engage stakeholders using prototypes within early design work, facilitating awareness of the breadth of strategies that can be considered. Increasing the awareness of strategies used by others can encourage practitioners to build their repertoire and more explicitly support their choices of prototyping strategies to engage stakeholders in front-end design activities.

Beyond medical device design, other domains can benefit from the articulation of strategies that emerged in our findings. While our study did not focus on domains outside of medical devices, many of the strategies we found have commonalities with more general strategies in the broader design literature, suggesting that these strategies are worth considering for use by practitioners in other domains. Within the engineering design literature, there are limited compilations of suggested strategies with the level of specificity in our findings as well as with a focus on prototyping with stakeholders during front-end design. Thus, the collection of strategies in our findings serve as a resource for practitioners to consider as they make design and prototyping choices, allowing them to perhaps consider a greater number of potential strategies than they had considered previously. Further, this collection of strategies can encourage practitioners to articulate why they do or do not consider a strategy useful in their domain, and be more intentional in their prototyping choices for stakeholder engagement in the design front end.

In addition to their potential uses by practitioners, the collection of strategies and associated examples from our findings can also be leveraged as educational and training resources for novice and early career designers. As research has shown that engineering novice designers have limited conceptualizations of prototypes (Lauff, Kotys-Schwartz, & Rentschler, 2017), especially their

application in the front end (Deininger, Daly, Sienko, & Lee, 2017), and struggle in general to know how to engage with stakeholders (Mohedas et al., 2014; Mohedas, Sienko, & Daly, in press), training and pedagogy that leverages the examples revealed in our study could support designers in expanding their use of prototypes during the front end of design to engage stakeholders.

More intentional strategy choices and a broader repertoire of design strategies can ultimately support more successful design outcomes. As the strategies were used by practitioners in our study to better meet the needs of stakeholders, other practitioners may leverage them in their own work, and may be more successful in understanding their stakeholders as they make design decisions. Because stakeholder engagement has been linked to design quality (Atman et al., 2007; Bursic & Atman, 1998), the use of these strategies may improve the prevalence and quality of stakeholder engagement during early design work.

5 Conclusion

Strategies for engaging stakeholders using prototypes during the front end of design have not been documented extensively in the engineering design literature, and existing strategies in engineering design texts lack a focus on front-end work as well as rich detail for how and when particular prototyping strategies may be most useful. Our study identified 17 prototyping strategies that medical device design practitioners intentionally used to engage stakeholders during early design phases. These findings can be used to expand the awareness and repertoire of strategies that practicing engineering and novice designers can leverage. These prototyping strategies can support engineering designers in intentionally facilitating communication and collaboration with stakeholders, eliciting meaningful and detailed information from stakeholders, supporting different levels of stakeholder participation and integration in design processes, and ultimately, having more comprehensive, well-informed, and successful front-end design work.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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