

Prototyping the Need: Using Prototyping Early in the Design Process to Strengthen Understanding of the Need and Increase Student Engagement

Meghana Nerurkar, Stanford University, Mussallem Center for Biodesign, 318 Campus Drive, E100, Stanford, CA, 94305, USA

Lyn Denend, Stanford University, Mussallem Center for Biodesign, 318 Campus Drive, E100, Stanford, CA, 94305, USA

Ross Venook, Stanford University, Department of Bioengineering, 443 Via Ortega, Stanford, CA, 94305, USA

Ravinder D. Pamnani, Stanford University, Mussallem Center for Biodesign, 318 Campus Drive, E100, Stanford, CA, 94305, USA

Joseph Towles, Swarthmore College, Department of Engineering, 500 College Avenue, Swarthmore, PA, 19081, USA

Dan Azagury, Stanford University, School of Medicine, 291 Campus Drive, Stanford, CA, 94305, USA

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Abstract

Challenge: In traditional design courses, prototyping is most often initiated after a problem has been identified, constraints have been defined, and multiple solutions have been conceived. Accordingly, students tend to narrowly perceive prototyping as a step towards a designated endpoint (e.g. building and testing a final product) rather than as a flexible method for expanding their understanding throughout a design project.

Novel Initiative: We designed a “prototyping the need” exercise and piloted it in an undergraduate course focused on the early stages of the health technology innovation process. Students defined important questions about their unmet needs and then built models to help them explore the answers and deepen their understanding of the problem, the population it affects, and/or the desired outcome if the need is solved.

Reflection: The exercise provided students with the opportunity to build hands-on prototyping/modeling skills earlier than usual in the design process, expanded their understanding of prototyping as an exploratory tool, and strengthened their engagement and empathy. In this article, we describe the “prototyping the need” method, spotlight two student projects, and share lessons from the pilot.

Keywords

Needs finding, biodesign innovation process, prototyping, prototyping the need, undergraduate engineering education

Challenge Statement

In many traditional design courses, prototyping is initiated after a problem has been identified, constraints have been defined, and multiple solutions have been conceived. [1] Accordingly, students tend to narrowly perceive prototyping as a step towards a designated endpoint (e.g. building and testing a final product) rather than a flexible method for expanding their understanding throughout a design project. [2] Some in the design community have been stretching the limits of traditional prototyping to generate insights throughout the innovation process [3] but, to our knowledge, these principles have not been widely adopted in undergraduate biomedical engineering design courses.

In our own biomedical engineering design courses, we teach a need-driven approach to health technology innovation that requires students to spend substantial time identifying and researching unmet needs before they advance to concept generation and prototyping. This delays students from embarking on traditional prototyping activities for many weeks into a class. In our experience, aspiring engineers, eager to build and test, can find this frustrating. Moreover, their desire to begin hands-on building activities can cause them to prematurely jump to solutions before appropriately understanding the core requirements surrounding their unmet need.

As many instructors do [4], we previously taught prototyping as a process for asking questions about a *concept* and attempting to answer them by designing models and tests that produce data from which a team can learn. However, we hypothesized that this question-driven approach to prototyping could be equally valuable in enriching student understanding of their *need*. Accordingly, we set out to create a learning exercise that would 1) reposition prototyping as a technique for problem exploration and learning, and 2) enable students to undertake solution-agnostic prototyping activities earlier than usual.

Novel Initiative

We first piloted the “prototyping the need” exercise in a three-week, full-time intersession course for rising undergraduate sophomores called Needs Finding in Healthcare. In this class, 12 students focus entirely on the earliest stages of the health technology innovation process to highlight the importance of getting the need right before inventing anything. Specifically, they receive instruction on performing health-related observations and then conduct physician shadowing in pairs over three days. Next, in parallel with lectures on the listed topics, individual students 1) draft preliminary need statements from their observations, 2) perform primary and secondary research to strengthen their understanding of each need area, and 3) use what they have learned to scope and refine their need statements before filtering to a lead project. They do not ideate solutions to their unmet needs, so the original curriculum did not include prototyping.

We believed that adding need prototyping would improve the student experience while deepening their knowledge of their lead need area. During the third week of the course, we challenged students to create a simple prototype that would help them answer an important question about their lead need. Their prototyping work time was prefaced with a lecture on how to build looks-like, works-like, and feels-like prototypes with simple materials to gain insights. In addition, we provided students with a variation of the instructions shown in Table 1.

Table 1 - Instructions for “Prototyping the Need”

	Instructions
1	Make a list of questions about your need. Prototyping is question-driven and question-dependent. Although you may not end up with answers to all of your guiding questions, without them your efforts to build/test a prototype and generate meaningful data likely will be inefficient and potentially unsuccessful.
2	Prioritize questions by risk and relevance of prototyping. Before you invest significant time and energy in any effort, it’s a good idea to tackle the questions whose answers have the greatest potential to change the project’s direction or to derail it entirely. Resist the temptation to emphasize the easiest questions to answer. Instead, prioritize questions based on how much risk they present to the project. Also, keep in mind that not every question about your need is ideally suited to prototyping – some will be better addressed through background research and validation interviews. But think creatively and challenge yourself to find ways to learn about tougher need-related questions with quick/simple prototyping. You’ll be surprised how many questions can be prototyped efficiently, using methods like those described above and in the student examples below.
3	Choose question(s) to address. While you typically want to focus on one top-priority question to prototype, you may find that several questions overlap or address different aspects of the same theme. In those cases, you may be able to address multiple questions through a single prototype or series of prototypes.
4	Make a plan. Before doing anything, be sure you have a relatively thorough plan (at least a written outline of the specific steps, materials, etc.) for what you intend to build/do/test. Your plan should explicitly include what data you intend to generate that provides insight on the question.
5	Build and test your prototype. Now’s the time to dive in and create your prototype! Execute your tests and gather/plot your data.
6	Assess your results.

	Analyze the data you've generated and draw conclusions. Based on what you've learned, you can update your questions list and determine the next steps to take based on your learnings. Consider taking your prototype/results to share in your next stakeholder interview. In some cases, an important next step may be to build another need prototype. If so, return to step 1 and start over again!
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We advised students that need prototypes could range from physical or mathematical models to computer simulations to mock user experiences – anything they could make, build, or do to better understand their need. The classroom was well stocked with craft supplies, hand tools, and whiteboards with markers. We also provided the prompts shown in Table 2, inspired by the three elements of a “need statement” [5] – problem, population, and outcome – to aid the students in their work.

Table 2 - Prompts for helping students get started

What you want to learn could be related to any of the key components of your need statement. For example:
<p>Problem If you're working on a disease-based problem, what about the relevant anatomy or physiology is central to the need? Trying to build a basic physical or mathematical model of the normal physiology and/or the pathophysiology of the condition often can enhance your understanding or identify gaps in your knowledge. If you're working on a problem that's more behavioral or process-oriented, what could you learn by simulating that behavior or process? Sometimes simply creating multiple diagrams of your understanding of the workflow can highlight bottlenecks or enable you to refine your understanding, especially since such artifacts can be an effective tool for gathering concrete feedback from stakeholders/experts.</p>
<p>Population What's it like to be a member of the population targeted in your need statement? Teams have found that trying to act out or create a play-acted scene increases their empathy for individuals in the target group, as well as their relatives or caretakers. What steps could you take to better appreciate your population's perspectives and priorities when they consider potential solutions?</p>
<p>Outcome What could you do to better understand the magnitude of the improvement in outcome(s) necessary to have a meaningful impact on the patient or another key stakeholder? Can you create a before/after physical model of the (patho)physiology? Perhaps you could “run the numbers” by creating a spreadsheet with different projected levels of outcome success and the related potential impact on different stakeholders? Your prototyping of the need should help you increase your expertise in the area you're working and help convince you that the need is real and compelling</p>

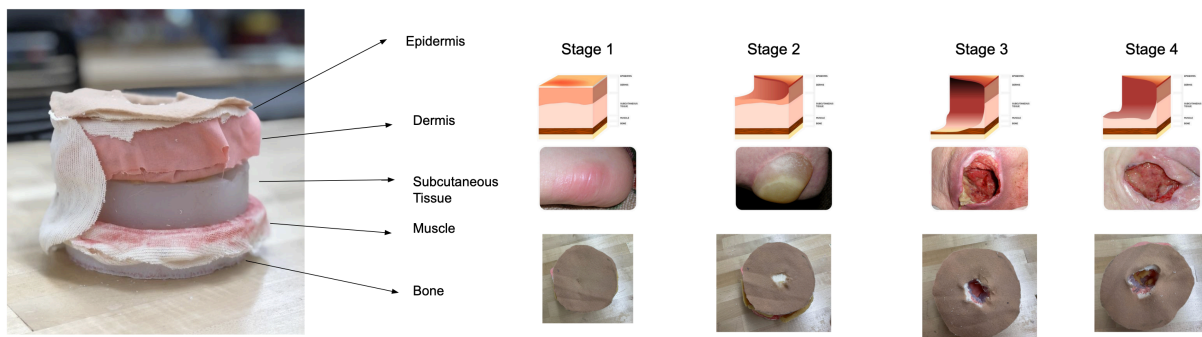
Two brief examples are provided to demonstrate the types of projects students explored and the resulting lessons. Both students consented to have their work anonymized and reviewed for educational research and publication purposes (IRB approval, protocol 56713).

The first example is from a student whose need was improving at-home care for patients over 65 with chronic open wounds to increase the rate of healing. Concerned that the interaction between the pressure ulcer and the patient could be a source of risk that could affect the success of an eventual solution, she prioritized the following questions: 1) what does the structure of different stages of wounds look like in 3-dimensional space? and 2) how

does it feel for patients to perform wound care? To investigate the answers, the student created a simple physical prototype of layered human skin. She then punctured the prototype in stages to demonstrate the formation of wounds (Figure 1). “I wanted to feel the problem and see for myself how a wound might form and what could be the difficulties associated with treating it,” she explained. Through the exercise, she gleaned the following insights:

- Wound architecture and shape – The fundamental structure of the wound is problematic. The wound is large and gaping at its outer layer but, as it gets deeper, the diameter gets smaller and more difficult to access and visualize. This makes more advanced wounds significantly more difficult to inspect, clean, and treat.
- Difference in physical properties of the tissue layers of the wound – The layers of a wound differ in terms of their thickness, hardness, and sensitivity. This could create the opportunity for different treatment mechanisms to heal different layers of a wound.
- Empathy for the patient – As the student explained, “It’s one thing to look at a picture of a chronic wound, and it’s another to stare down into the model and imagine seeing your own bone at the base of the wound. Since most wound care is done at home, I could imagine how hard this must be for patients and their caregivers.”

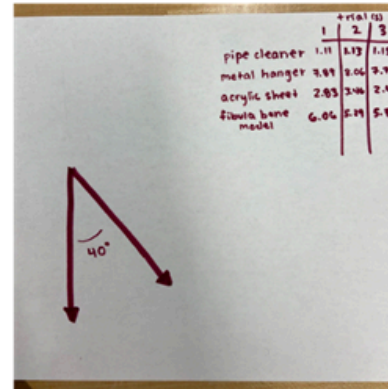
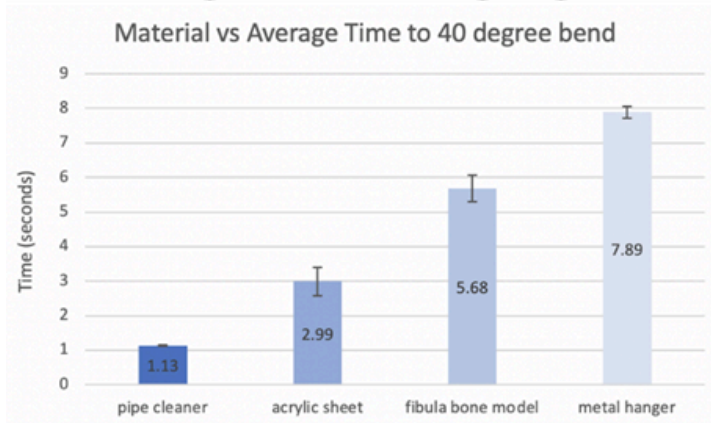
**Fig. 1 Model of a chronic wound (left).
Simulation of how chronic wounds progress (right).**



The second example focuses on Peyronie’s disease, which occurs when a fibrous plaque containing excessive collagen forms in the penis and causes curved, painful erections. The standard of care is a series of injections to break down the excess collagen, surgery, or traction therapy. Each option varies in terms of its effectiveness, pain, complications, and patient time commitment. The student had learned that the hardness of the plaque could vary from fleshy to calcified and wondered if patients could benefit from different approaches to reversing curvature depending on the state of their plaque build-up. Concerned about the risk of affecting the calcification, she made this top priority. She decided to test how long it would take to bend a variety of materials of different hardness 40 degrees, which is the average curve in patients. However, working in the classroom and under a specific timeline, her options were limited. “I didn’t have any actual plaque and there wasn’t time to do more research or create a compound that would accurately mimic plaque in different states. So I pulled things off the shelf, just to get started,” she said. She used a pipe cleaner, an acrylic sheet, a fibula bone model, and a metal hanger. “What I was trying to show was fairly obvious – that the harder the material, the longer it would take to bend. But the results were very inaccurate. I was using one hand to bend the material, while using the other to do the timing on my phone. And my hand positioning varied from material to material, so the results just weren’t very useful,” she explained (Figure 2).

Fig 2 Time to bend to 40 degrees.

How pliable is the plaque?



As expected, harder material => longer curve time

Unsatisfied with these results (and the extent to which they addressed the risk she was most concerned about), she pivoted. She went back to her research and focused her next questions on the trade-offs inherent in currently available treatment options. Rather than starting with risks related to the mechanism of the problem, she revisited the data she had collected on patient experience and chose to investigate what patients would want most from an improved treatment. “It seemed like there were three variables: time, pain, and effectiveness,” she recalled, “with no current treatment able to deliver all of them. I wanted to learn more about the ideal combination from the patient’s point of view so I could use this information when it was time to come up with solution ideas.” Rather than trying to prototype this question with a physical device, she decided to create a patient survey. Based on how individuals responded, she would better understand the tradeoffs they were most willing to accept from a new intervention.

Both students completed the work in less than one hour, yet they found it valuable in improving their understanding of their need. As student #1 described, “I was initially really focused on thinking ahead to how I would come up with a novel innovation in the area of chronic wounds. But I realized that prototyping aspects of the need can be just as impactful because it gives you a new perspective on the problem you’re trying to solve.” Student #2 added, “Initially I was so focused on physical prototyping. But after some additional consideration, I think the data from a survey would be much more important for informing my understanding of the problem and, eventually, what new solutions could be most attractive and impactful in the need area.”

With this initial implementation of the prototyping the need exercise, we did not plan a robust assessment approach to evaluate its effectiveness. However, we did include a single question on this topic in the regular pre- and post-course survey that all students complete to help us assess the impact of the course on their learning. The results from the relevant students are shown below in Table 3a, with answers on a scale of 1 (low) to 5 (high).

Table 3 - Pre- and post-course survey results from the 2024 class

	Question	Pre-Course Median	Post-Course Median	Percent Change
1	Do you know the difference between tech-push and need-pull innovation?	3	5	67%

2	How familiar are you with the Biodesign innovation process?	3	5	67%
3	Do you know what a need statement is?	3	5	67%
4	Do you know what need criteria are?	2	5	150%
5	How comfortable are you interacting with physicians and other care providers?	4	5	25%
6	Do you know how to behave responsibly when conducting observations in a clinical environment?	2	5	150%
7	Please list 5 one-word “clues” you would watch for when performing observations in an effort to identify compelling unmet health-related needs.			
8	How confident are you in your ability to identify interesting innovation opportunities through observations?	3	4	33%
9	To what extent do you agree with the statement “ Only some of the problems observed in the clinic represent compelling unmet needs”?	2	4	100%
10	How comfortable do you feel constructing a need statement (with all of its requisite parts) based on a clinical observation?	3	5	67%
11	Do you know what the four pillars of need research are?	2	4	100%
12	How comfortable are you preparing for and conducting validation interviews?	3	5	67%
13	Do you know how to use prototyping to advance your understanding of an unmet health-related need?	2	5	150%
14	Do you know how to use an objective approach to screen and prioritize unmet health-related needs to decide on a top project?	2	5	150%
15	How familiar are you with different career pathways in health technology innovation and what’s required to pursue them?	4	4	0%
16	When you have been provided with a grading rubric for an assignment, how helpful was it? / When we provided you with the grading rubric for need statements, how helpful was it?	4	5	25%

As shown in question 13, students were asked, “Do you know how to use prototyping to advance your understanding of an unmet health-related need?” Answer options were: 1) I have never heard of this, 2) I have prototyping experience, but don’t know how to use it to advance my understanding of an unmet health-related need, 3) I understand the basics of using prototyping to advance my understanding of an unmet health-related need, 4) I know how to do this and can explain it to others, and 5) I know how to do this and have used it on a project to advance my understanding of an unmet health-related need. The same question was repeated on the exit survey. For the 2024 offering of the class, the 12 students’ pre-course median response was a 2, while the post-course median response was a 5 ($p < 0.01$, Wilcoxon Signed-Rank Test), indicating a 150% change in their understanding of prototyping the need. Although this does not confirm whether they found the exercise valuable, it indicates that their understanding of the concept of prototyping the need significantly improved after taking the course.

Reflection

Overall, we believe that this pilot resulted in numerous benefits. We also identified some limitations that can be overcome in subsequent implementations of the activity.

First, as described in the literature, giving students the opportunity to learn using experiential, activity-driven methods leads to stronger student motivation and better contextual learning. [6] The hands-on exercise added a new experiential dimension to the curriculum. Anecdotally, we observed high levels of engagement and curiosity during these sessions, which helped us demonstrate to students how prototyping can be used as a technique for learning and exploration. Going forward, we plan to make this a more integrated component of the curriculum and course learning objectives.

Second, the exercise seemed to satisfy students' desire to build and test while keeping them in a solution-agnostic mindset. Some students struggled to conceive of prototyping questions that were not solution oriented and required additional support from the teaching team to think more creatively. Without this guidance, they quickly defaulted to ideating and prototyping solutions. As we repeat this exercise, it will be helpful to be able to show students examples of need-based prototypes and the learnings they catalyzed to help them better understand how they might proceed on their own projects.

Third, the exercise had a positive effect on deepening student empathy for the populations indicated in their need statements. Simulating the user experience is known as an effective technique for increasing designers' empathy for patients. [7] We did not initially anticipate this as a benefit of the need prototyping exercise, but uniformly observed students becoming more empathetic to stakeholders in their need area as they investigated questions through prototyping. Going forward, we anticipate deepening empathy development by encouraging students to take advantage of multimedia resources such as video capture and editing.

Finally, this question-driven exercise spawned new questions that led students to take novel directions in their research. It also motivated them to go deeper and re-energized them around their research, which can sometimes be perceived as a tedious necessity rather than a value-added activity in undergraduate courses.

Looking towards the future, we have several opportunities. Most importantly, we intend to collect additional quantitative and qualitative data from students to understand which aspects of prototyping the need are most beneficial so we can refine the activity. Additionally, we will use the approach with learners at different levels (undergraduate, graduate, and post-graduate) to see how results vary. We anticipate that prototyping the need may need to be presented to different audiences in different ways to maximize its effectiveness. We look forward to sharing the outcomes of future studies as our efforts continue.

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