4.6 Final Concept Selection

INTRODUCTION

The team started with duct tape, tubing from the hardware store, and the mesh from a flour sifter. Now it has three working prototypes that prove the solution is feasible. But there is only enough time, money, and manpower to take one forward into detailed development. In a move that can feel a lot like betting everything on a single hand of poker, innovators must decide which solution is most likely to come to fruition, challenge the "gold standard" in the current treatment landscape, align with the needs of key stakeholders in a way that compels them to adopt it, and support the development of a sustainable business.

OBJECTIVES

- Understand how to combine the data about intellectual property (IP), regulatory, reimbursement, business models, and technical feasibility gathered up to this point through the biodesign innovation process to efficiently identify leading solution concepts.
- Recognize how to apply a structured approach, such as the Pugh method, in developing a concept selection matrix to identify a final concept.

The purpose of final concept selection is to use everything that has been learned to date about the concepts under consideration to choose the one that will be brought forward into development. This final concept will continue to be refined, tested, iterated, and improved during development and implementation, but by choosing a single concept, innovators are able to focus on optimizing one idea rather than continuing to divide their attention across multiple needs and concepts.

In the chapters leading up to final concept selection – 4.1 Intellectual Property Basics, 4.2 Regulatory Basics, 4.3 Reimbursement Basics, 4.4 Business Models, and 4.5 Concept Exploration and Testing – innovators began screening their solution ideas and eliminating those few with fatal flaws (also called killer risks) that render them truly infeasible. The set of leading concepts that survived these screens can now be researched in more depth, and the data from this additional research combined to select a single, final concept to take forward.

While some experienced innovators are able to make this final decision based on gut instinct, most benefit from a more systematic process, including the incorporation of techniques such as the Pugh method (described within the chapter). While incorporating a structured approach as part of final concept selection may not initially appeal to everyone, it helps ensure that key user and design requirements are kept at the forefront of this important decision. Additionally, it provides a mechanism for reflecting any

important data gathered through this rigorous research and screening process in the team's increasingly detailed user and design requirements.

See ebiodesign.org for featured videos on final concept selection

FINAL CONCEPT SELECTION FUNDAMENTALS

Selecting a final **concept** is considered by some innovators to be one of the most crucial steps in the product development process.[1] Teams should take their time and use care in deciding on a final concept to avoid the mistake of anchoring on a single solution too early, without fully exploring a range of potentially viable alternatives to identify the one with the greatest likelihood of addressing the **need**.

Choosing a final concept is essentially an exercise in risk mitigation. Figure 4.6.1 informally depicts how concept selection works. After ideation, innovators identify a group of interesting concepts to evaluate, out of potentially tens to hundreds of solution ideas, by selecting those that best satisfy the need statement and must-have need criteria (see 3.2 Initial Concept Selection). They then begin researching these *multiple* concepts to understand the critical risks associated with each one. In particular, they consider the IP, regulatory, **reimbursement**, and business model implications associated with the potential solutions (as described in chapters 4.1, 4.2, 4.3, and 4.4,), building on what has already been learned about issues such as relevant markets and **stakeholders**. In any one of these areas, the team may find a glaring risk – that is, a problem so profound that it makes clear that the solution under consideration cannot go forward. Those without killer risks, that make it through these screens, are considered *viable* concepts and can then be evaluated for their technical feasibility through concept exploration and testing (as described in chapter 4.5). Again, the team will set aside solutions that prove to be technically impossible, while those that show technical promise advance to become the team's *leading* concepts.

Of course, as is common with so many other activities in the biodesign innovation process, these steps are not nearly as linear as they appear in the diagram – it is typical, for instance, for innovators to initiate their

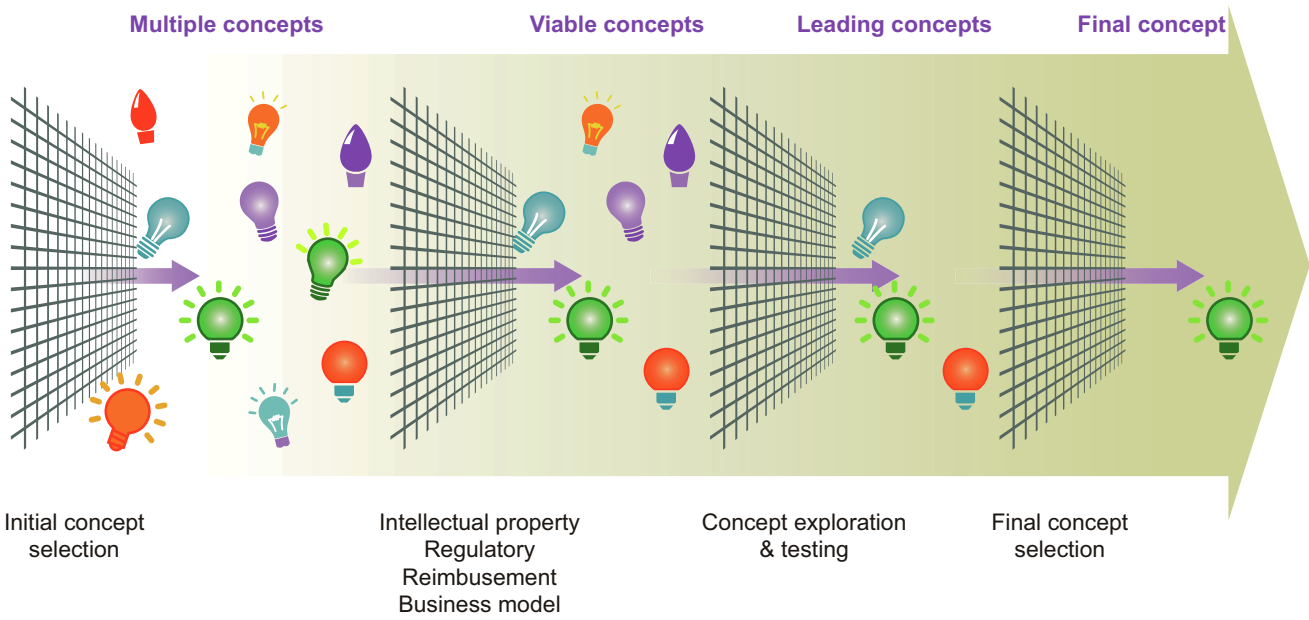


FIGURE 4.6.1
A visual representation of concept screening and final concept selection (courtesy of John Woock).

assessments of IP, regulatory, reimbursement, and business models in parallel with **prototyping**. The point is that concepts are evaluated – and some are eliminated – on a rolling basis until only a few remain. At that point, innovators have a sufficient understanding of the risks inherent in each solution, and how they can potentially be mitigated, to formally decide which one *final* concept to take forward.

Efficiently getting to a set of leading concepts

During the first part of the concept screening stage, innovators have been on the look-out for killer risks. As counter-intuitive as it may seem, innovators should celebrate the discovery of these fatal issues because it means that they have been successful in avoiding one of the most common traps that teams can fall into – namely, pursuing an expensive and time-consuming development path only to find out much later that the project is doomed. Mark Deem, co-founder of medical device **incubator** The Foundry, acknowledged that he and his team routinely set aside solutions based on little more than the IP, regulatory, reimbursement, or business model risks they entail. As an example, he noted, "There's no sense in going out and spending a lot of time coming up with a great idea if it's something that will require a 1,000 patient study with five years of follow up that's never going to get done with a venture capital financing structure."[2] Similarly, if innovators learn that a great deal of IP has already been filed related to one concept under consideration, whereas the other concepts are relatively clear, they may decide to drop the concept with the IP risk. By necessity, this first round of concept research and analysis, is more broad than deep. As Deem described, "We're not going into great detail when we do this initial assessment, but a top-level analysis gives you a pretty good sense of the risks you're facing," and, in turn, the concepts that should be swiftly eliminated.

While innovators certainly will have identified a number of killer risks through their work to date (and, in turn, eliminated some concepts), they also will have uncovered issues that are troublesome but not necessarily fatal (as initially described in chapter 4.1). As these issues are identified, teams are advised to pay attention to them, but not necessarily to eliminate a concept from consideration without further research. It takes judgment and a great deal of further work to calibrate how serious these issues actually are. As mentioned, IP issues, for example, seem to wind up in this "intermediate zone" fairly often. In fact, it is almost uniformly the case that once innovators have done a reasonably detailed IP search, they will have serious concerns about freedom to operate and/or patentability.

At this point in the process, innovators can use the information they have gathered about the risks associated with their concepts to create a risk scoring matrix. This can be done by expanding the simple scoring system used initially to assess IP risks: red (troublesome issues), green (looks OK), and yellow (some problems raised). It is important to emphasize that a red rating is different than a killer risk. A killer risk indicates a barrier of sufficient magnitude to grind a project to an immediate halt. In contrast, a red rating flags an issue that is problematic in terms of substantially increasing the uncertainty, complexity, time, and/or expense associated with an effort, but it is not necessarily a "deal breaker." By combining IP, regulatory, reimbursement, and business model risks into a common assessment, the team gains a cohesive (although simplified) picture of the risk profile for each concept.

The team should give itself a realistic yet finite amount of time to complete a risk matrix for all of the concepts across the four primary screening categories (as shown in Figure 4.6.2). If the scoring has been done with reasonable diligence, it is unusual to find a concept that is "green" across all categories. But a combination of mainly greens and yellows means that a concept is viable and probably worth taking further. Based on experience, a team of several fellows in the Stanford Biodesign program is likely to spend a few days to one week generating the information required to complete the matrix for approximately 10 concepts. Since this work can, at times, be frustrating because the team is not "getting to the bottom" of all the key issues, imposing a deadline with the goal of doing the best possible job in the time allotted can help keep the innovators focused and minimize their frustration.

Identifying viable concepts using IP, regulatory, reimbursement, and business model data as described

FIGURE 4.6.2
An example of a simple risk scoring matrix for multiple concepts under consideration.

above next blends naturally into the step of concept exploration and testing (as described in chapter 4.5). By **prototyping** different solutions, innovators generate additional data that can help them gauge the technical feasibility of the ideas and the likelihood that they can reasonably be brought to fruition to address the defined need. In this way, technical feasibility serves as an additional screen that enables a team to get to a small set of leading concepts. It is called out separately in Figure 4.6.1 primarily to emphasize the critically important role that prototyping plays in concept screening.

Using a structured approach to select a final concept

For the leading concepts that are left following the screening steps described above, innovators can move toward a final concept by evaluating the extent to which the ideas satisfy important **user** and design requirements. In doing so, it usually makes sense to directly compare the leading solutions (and how they perform against the user and design requirements) because these requirements tend to apply more universally across all (or many) solutions. Innovators typically compare solutions to one another and/or to the current **standard of care** (as described in the section on the Pugh method). Given the comparative nature of this assessment, teams (especially those just starting out) are often well-served to take a structured approach to help ensure the objectivity, accuracy, and thoroughness of the exercise.

Because user and design requirements play a core role in enabling teams to select a final concept, innovators should spend some time assessing these criteria before comparing solutions against them. The original and most basic user and design requirements come from the **need specification** in the form of must-have and nice-to-have **need criteria**. However, innovators will naturally modify and refine some of these requirements based on the information gathered about IP, regulatory, reimbursement, business models, and technical feasibility. For example, through their research, the innovators may have uncovered new stakeholder requirements – that is, criteria based on the needs of the influential stakeholders who have some important role in the selection, deployment, and use of the technology. Or, as they studied the concept area, they may have identified some features of the technology or design itself that have clearly become important. Often, requirements for new features are related to broader need criteria that were there from the start but, by virtue of the deeper knowledge the team has gathered, it is now possible to put more precise and measurable parameters around them. If time is not taken to incorporate these learnings into user and design requirements, innovators may find themselves with a fundamentally flawed concept under development, a product that does not effectively address critical stakeholder needs, or other problems that can threaten to send them back to the drawing board.

Although this chapter advocates a structured approach to comparing leading solutions and selecting a final concept, innovators should recognize that a wide variety of approaches to final concept selection exist. In simple terms, they can be thought about on a continuum. At one end, innovators depend on extensive research supported by a structured method to help them objectively

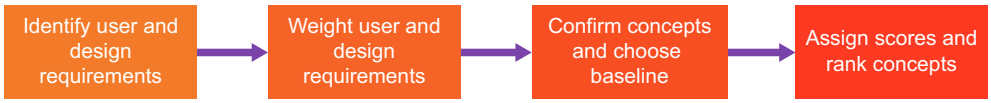


FIGURE 4.6.3
General steps of the Pugh concept selection method.

analyze and act on that information. At the other, they rely primarily on intuition, developed through years of experience, to make this important decision. Most innovators usually employ a combination of both types of approaches – structured and intuitive – to get to a final concept.

Seasoned innovators sometimes argue that they do not need to utilize a systematic process in their overall approach to concept selection. However, when probed about their reasons for making certain choices, it often becomes apparent that (consciously or not) they use a semi-structured approach for picking a winning concept. While possibly more informal than some of the well-defined methods used in the medtech field, their favored process has likely been honed through years of experience but is nonetheless rigorous enough for evaluating important factors – such as market size, regulatory pathway, likelihood of reimbursement, match between product and user type, etc. – before deciding on a final concept to pursue.

The Pugh method

The Pugh method is one of the most widely referenced and easily understandable structured approaches for final concept selection, as it focuses on user and design requirements and employs a fairly straightforward ranking system. It was developed in 1981 by Stuart Pugh, a professor at the University of Strathclyde in Glasgow, Scotland. Details of the method can be found in Pugh's book *Total Design*.[3] Since it is relatively simple and generally effective, the Pugh method can be quickly and easily utilized by experienced medtech practitioners and novices. Other benefits of the Pugh method include the following:[4]

- It compels the design team to review the user and design requirements in detail and to understand how the requirements apply to the concept.
- It provides a framework that enables the team to look beyond the obvious first concept and fully explore a wider range of concepts.
- It provides an objective way to evaluate concepts.
- It results in a concise, auditable document for the product's design history file that is easily understood and defensible (see 5.5 Quality Management).

In its most basic form, the Pugh method has four steps, as shown in Figure 4.6.3. Through this process, the innovator creates a two-dimensional decision matrix to facilitate the quantitative evaluation of the leading solution concepts against a baseline concept. The idea is that by comparing each potential solution to a baseline (rather than assessing each one against every other alternative), the analysis is significantly simplified.

Another factor to keep in mind is that, even though this method is useful in helping select a final concept, the process of refining and adjusting a solution is by no means complete once that solution is chosen. In fact, as the concept undergoes development, design modifications will undoubtedly be generated. The Pugh method can repeatedly be used to select from among different variations of the concept, using increasingly specific requirements. Certain early concept-specific technical specifications that have been learned through prototyping can also be incorporated into these later rounds of selection. This point underscores once again how iteration and progressive refinement are hallmarks of the biodesign innovation process.

To illustrate how the Pugh method works, the example introduced in 4.5 Concept Exploration and Testing will continue to be followed. This example involves an innovator working on the need for *a way to prevent strokes in patients with atrial fibrillation caused by left atrial appendage (LAA) thrombus*. As noted, the LAA is a small, pouch-like structure attached to the left atrium of the heart in which blood can coagulate to form clots, or thrombi, in patients with an abnormal heart rhythm

(such as atrial fibrillation). These clots can then dislodge and travel to the brain, where they have the potential to create a blockage in an artery that supplies blood to the brain, leading to a stroke.

Step 1 – Identify user and design requirements Innovators should begin final concept selection by referring back to the need criteria outlined in the need specification. These criteria, particularly the must-have criteria, continue to represent the most important, overarching requirements that the final concept must meet in order to satisfy its target audience. Recall that need criteria are defined *before* the innovator begins considering specific solutions to address a need. This is why they play such a central role in **brainstorming** and then screening and refining the list of ideas that is generated (see 3.2 Initial Concept Selection). All of the potential solutions taken forward into concept selection should satisfy the need criteria.

Once innovators have revisited the need criteria to refresh their memories, they should compile the most important user and design requirements. In contrast to need criteria, user and design requirements emerge as individual solutions are investigated through iterative brainstorming, as research is performed related to IP, regulatory, reimbursement, and business models, and through concept exploration. For this reason, they are typically much more detailed than need criteria and may become specific to a particular concept. For instance, in the LAA example, the idea to fill the LAA with glue would eventually have design requirements that are quite distinct from those related to the concept of placing a mesh in the aorta, even though both concepts support an approach to obstructing LAA thrombi. At a fundamental level, user and design requirements begin to resemble **product specifications**.

When choosing which requirements to use for final concept selection, a careful balance is required. Using too many requirements that resemble precise, product-like specifications at this stage can skew the comparison of the concepts toward one particular idea (this is a particular temptation if the team already favors one of the concepts). In the LAA case, for example, specifying that the procedure can be done using a catheter of 7-French caliber or smaller might specifically favor the glue solution. On the other hand, though uncommon, including *only* general requirements that closely resemble the need criteria (e.g., device must be delivered percutaneously) will not allow the innovator to adequately differentiate between concepts. While there is no hard and fast guide to setting the right level of specificity, the goal is to define a well-rounded set of requirements that can be met by more than one of the solutions being considered, yet still illuminate important distinctions between the concepts being evaluated. No more than three to seven user or design requirements should be chosen to keep the assessment manageable and sufficiently encompassing.

Although many user and design requirements are discovered through prototyping, as alluded to earlier, innovators should also take into consideration key facts uncovered through the activities described in chapters 4.1, 4.2, 4.3, and 4.4, both to understand the limitations of certain concepts as well as to help shape how some of the requirements are worded and weighted (see below). For example, if an innovator learns that pursuing a premarket regulatory approval trial is something that certain stakeholders would not support (e.g., investors might not tolerate the typically long premarket approval pathway or patients might not want to participate in a trial if existing treatments are readily available), the concepts that could utilize a **510(k)** pathway might be favored. Thus, intelligence such as this can be used to help shape the way user and design requirements are selected and worded.

Step 2 – Weight user and design requirements Once a meaningful set of requirements has been defined, the team must then assign weightings to reflect their relative importance. At a high level, this process is similar to that performed in 2.5 Needs Selection, although in this case weightings are applied to user and design requirements instead of the important factors used to assess needs. For example, using a scale of 1 to 5, an inventor might assign a "5" to requirements that are "essential" or "must-have" and a "1" to those considered "nice-to-have." Each user or design requirement (along with its weighting) should be captured in the selection matrix. For the LAA example,

the requirements might be chosen as shown in Table 4.6.1.

Assigning weightings is a relatively subjective process. However, through developing prototypes and understanding information gathered about IP, reimbursement, regulatory issues, and business models, innovators gain a reasonably good idea of the issues that are important for users that should be translated into design requirements. For instance, in the LAA example, the team may have learned that a comparable procedure can be performed in 30 minutes, which allows physicians to complete a certain number of cases and generate a particular level of reimbursement every week. Accordingly, these issues, related to the physician's business as well as reimbursement, result in a specific user requirement that will play out in the design of the concept ultimately selected. Other issues relating to IP, regulatory issues, reimbursement, or business models may have a different yet distinct impact in helping rule in or rule out certain concepts.

In assigning weightings, innovators should try to ensure that they use a range of different values that actually reflect the true importance or impact of the requirement. If all weightings are high (e.g., all "5s") or low (e.g., all "1s" or "2s"), then it will be difficult to distinguish concepts from one another. In the sample weightings shown in Table 4.6.1, the first requirement that a "device must be delivered percutaneously and not through a surgical incision" may have been weighted so high because it is directly linked to a key need criterion and is also tied to research showing that a percutaneous solution would be more likely to utilize a 510(k) regulatory pathway, which is preferred by key stakeholders. In contrast, the requirement that a "device must be less than 12 French in diameter" may have been weighted on the low side if the innovator's research showed that smaller alternatives are preferred but larger French sizes are routinely used in the need area.

When in doubt, innovators can ask business advisors, physicians, nurses, patients, or other subject matter experts to weigh in on the relative importance of the requirements they have defined. This kind of external input can help keep the process grounded in the real world and safeguard against any **biases** that may have inadvertently surfaced within the team. Some teams wonder how many experts to approach. Conventional business wisdom is to seek out a broad range of opinions in order to get a diverse and objective set of perspectives. On the other hand, there are advocates for a more focused approach. Todd Alamin, an entrepreneur and practicing spine surgeon, recommends the following: "Find one clinician who you think is smart and creative and knows a lot about his field, and stick with him. If you talk to too many people, you end up creating a cacophony of noise that doesn't make any sense, with some physicians recommending exactly the opposite course from what other physicians recommend. The risk in asking too many people for their advice is that you'll end up getting stuck doing nothing."[6] Ian Bennett, Louie Fielding, and Colin Cahill, who worked with Alamin to found Simpirica Spine, agreed, but acknowledged that there are times when more than one opinion will be helpful. In these cases, Bennett advised learning about the physicians in advance of seeking their input. "You have to know a little bit about their backgrounds, what they like to do, and their natural tendencies so that you can frame their answers with these factors in mind," he said. "This provides a context for their answers and helps you understand them a little bit better," rather than

Table 4.6.1 Sample user and design requirements and assigned weighting.

Requirement	Weight
Device must be delivered percutaneously and not through a surgical incision	5
Device must be able to be used in a cardiac catheterization environment	3
Device must not lead to iatrogenic thrombi development	5
Device must be less than 12 French[5] in diameter	1
Device must allow procedure to be performed in less than 30 minutes	3
Device or solution must be reversible at the time of the procedure	4

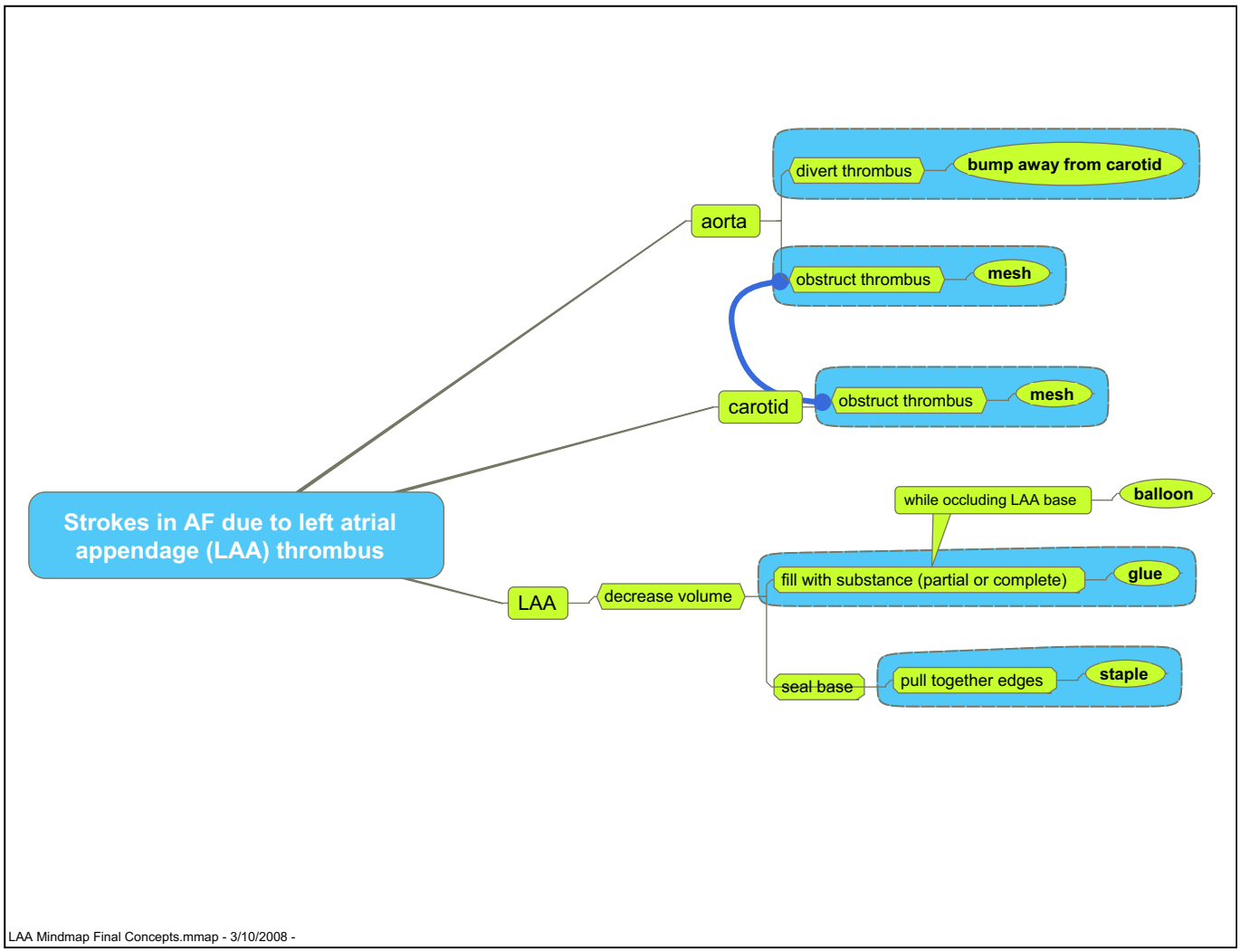


FIGURE 4.6.4
Key concepts from a sample mind map for preventing strokes in patients with atrial fibrillation caused by LAA thrombus (provided by Uday N. Kumar).

necessarily taking their input at face value. Once the right experts are identified, "Be prepared to meet them anytime, anywhere. Their schedules are crazy," noted Bennett. Additionally, Cahill emphasized, "Self-educate as much as possible before the first interaction. If you're new to the field, you will not get everything totally right, but at least you'll show that you've done your homework."

Step 3 – Confirm the concepts and choose a baseline
The next step is to confirm which concepts will be evaluated. This should include the most promising solutions that have made it through the concept screening process and were not eliminated due to undue risks related to IP, regulatory, reimbursement, business model, or technical feasibility. Typically, no more than three to five concepts should be under consideration at this point. For the LAA example, Figure 4.6.4 shows a list of the potential solutions that were chosen via concept screening for further investigation.

It is also essential to choose a baseline concept against which all solutions can be compared. This could be one of the team's solutions that it believes is most likely to achieve success, the "gold standard" among existing treatment options, or a competitor's solution.[7] The important thing is to gain enough information about the

FIGURE 4.6.5
The WATCHMAN LAA device incorporates a permeable fabric over a nitinol frame. It is implanted using a catheter to deliver it into the LAA (courtesy of Atritech).

baseline to be able to effectively evaluate each new solution concept against it. For the LAA example, a baseline could be provided by the WATCHMAN®, depicted in Figure 4.6.5. This device (introduced in chapter 2.2) has been used in US human **clinical** trials, but is not yet **FDA** approved as of the time of this writing.

Step 4 – Assign scores and rank concepts using the selection matrix Each concept should next be rated against the user requirements based on how likely it is to exceed the performance of the baseline concept (+1), lag behind it (–1), or perform at a comparable level (0). Because it serves as the point of comparison, the ratings for the baseline solution should be set at (0) for each requirement. Even if the baseline does not perform particularly well against a certain requirement, it should still be given a (0) rating since this level of performance represents the current standard.

The total score for each concept can be obtained by multiplying the score for each user criterion with its weight, and then totaling the results. The concept with the highest total score is the leader. Graphically, a matrix can be constructed with each concept listed in its own column, with the baseline solution furthest to the left. For the LAA example, a completed selection matrix could appear as shown in Table 4.6.2. In this example, the LAA glue concept emerges as the clear leader.

In some cases, numerous concepts may score poorly against the baseline. Assuming that the requirements are generally sound, this may suggest that the baseline concept meets both the need and the currently defined user and design requirements relatively well (indicating that the innovator may face a difficult market). Alternatively, it may mean that the new concepts have not been developed to a sufficient degree of detail such that they can possibly satisfy more requirements. Sometimes more than one concept scores well or no clearly superior concept emerges from the exercise. In these cases, the innovators should reexamine the user and design requirements to see if there is adequate specificity and check that the weightings of the requirements are appropriate.

In the case where the requirements and weightings seem adequate, but there is no front-runner emerging from the concepts, it is most likely time to perform additional ideation to be certain that the most promising concepts have, indeed, been identified. In this round of ideation, the team should consider if successful elements of one concept could be applied to other concepts to make them stronger and boost their likelihood of success. Additional prototyping, in an iterative loop, may provide valuable insights about these questions. After taking these steps, and revalidating the requirements and weightings in the selection matrix, the team should assign scores to each concept again, repeating this process until a lead concept becomes clear.

Ultimately, innovators choose their final concept by taking into account all of the information gathered and analyzed, formally and informally, through the entirety of concept screening activities as roughly depicted in Figure 4.6.1. Again, the process in practice is much more iterative than linear, with ideation, research, and prototyping, as well as adjusting requirements and weightings, guiding innovators to a "lead horse." If a team does this cycle only once, there is a chance that the chosen concept is a good candidate, but it may not be as risk-free as it could be with additional research and

Table 4.6.2 Sample selection matrix showing requirements, weightings, ratings, and total rank scores for the LAA example.

Requirement	Weight	WATCHMAN® (baseline)	Aortic Bumper	Aortic Mesh	Carotid Mesh	LAA Glue	LAA Stapler
Device must be delivered percutaneously and not through a surgical incision	5	0	0	0	1	1	−1
Device must be able to be used in cardiac catheterization environment	3	0	0	0	0	0	0
Device must not lead to iatrogenic thrombi development	5	0	0	−1	−1	0	1
Device must be less than 12 French in diameter	1	0	−1	−1	1	1	0
Device must allow procedure to be performed in less than half an hour	3	0	1	0	0	1	0
Device or solution must be reversible at time of procedure	4	0	−1	0	0	−1	−1
Rank Score			**−2**	**−6**	**1**	**5**	**−4**

analysis. That is not to say that any final concept is ever risk-free, but an iterative approach to final concept selection can help optimize a solution concept as much as is reasonably possible.

Alternate approaches to concept final selection

As noted, there are many different ways to tackle final concept selection that span a continuum from highly structured and systematic to more informal and intuitive. Some innovators are able to take what looks like (at least from the outside) a more instinctual approach to concept selection. Often these are experts who have had experience in assessing many technologies and have developed "pattern recognition" skills that allow them to short-circuit a more systematic evaluation process. Again referencing the Simpirica Spine team, Fielding recalled that Alamin was one of these intuitive experts who was able to quickly sift through a number of the team's concepts and "use his imagination to see through to something that could be realistic." From the list that the team presented to him, Alamin focused on one concept for a minimally invasive implant that clinically made sense to him. Even though Alamin's decision-making approach seemed more intuitive on the surface, as with many experienced innovators, there was some structure to his internal process that boiled down to a few key steps. According to Alamin, he routinely assesses if: (1) the device has a clear function; (2) it addresses a clear clinical need; and (3) it offers the simplest possible solution for solving the given problem. "Particularly with the spine," he noted, "anything that's too mechanically complicated isn't going to work because you have to worry about wear debris being created over time and individual pieces malfunctioning. Anything that is designed to repetitively take on axial load over the life of the patient is also a concern because the likelihood of ultimate failure is high." This is pattern recognition in action. Finding an expert like this is, of course, one of the most effective strategies for helping the team decide on the most promising concept to pursue. In this case, Alamin ultimately

agreed to join Simpirica as a co-founder, working with the team to bring the concept forward to the market (for more information about Simpirica Spine, see 6.2 Strategy Integration and Communication).

Additional examples, in the form of the short case studies that follow, demonstrate other techniques that innovators use to assist them with the important decision of final concept selection. The first story about medtech legend Advanced Cardiovascular Systems provides a classic illustration of how one set of experienced innovators approached final concept selection in the founding of ACS. Note that although they did not formally use the Pugh method, there are strong similarities between Pugh's approach and the one they employed – well-defined criteria were used to evaluate the concepts against a baseline solution before making a decision.

A second story about the experience of the team that developed the OneBreath ventilator underscores the benefits of bringing a certain level of structure and rigor to concept selection, especially for innovators who are just starting out in the medtech field.

FROM THE FIELD ADVANCED CARDIOVASCULAR SYSTEMS

Driving concept selection through intuition and an intimate understanding of user requirements

Advanced Cardiovascular Systems (ACS) was the first cardiovascular medical device start-up in California's Silicon Valley. Founded in 1978 by cardiologist John Simpson and entrepreneur Ray Williams, it pioneered the development of percutaneous balloon angioplasty catheters and over-the-wire catheter systems. Carl Simpson, who was working as the lead technician at Stanford's catheterization laboratory when he met John Simpson (no relation), later became the company's first full-time employee. Together, with the help of cardiologist Ned Robert and a team of engineers, they revolutionalized the treatment of coronary heart disease and helped create the field of interventional cardiology.

John Simpson, who was training in cardiology at Stanford at the time, became intrigued with angioplasty when he heard a presentation by Andreas Gruentzig, the creator of this innovative new technique. Gruentzig's approach used a fixed-stylet catheter system and balloon to widen a coronary artery that had narrowed or become obstructed through the build-up of atherosclerotic plaque. Although initially skeptical, Simpson went to Switzerland to learn about the procedure and became convinced of its benefits. Back in the US, he ran into several problems. First, given that the procedure was considered quite radical in its approach, he did not receive much support from colleagues to perform it. Second, as a young cardiologist assumed to be lacking in experience and training, he had difficulty obtaining the parts and tools he needed to perform the angioplasty procedure when he ordered a catheter system from Gruentzig. Nevertheless, with a strong commitment to the therapeutic benefits of coronary angioplasty and faced with no other alternative, John Simpson and his colleague, Ned Robert, began experimenting with materials to build a balloon angioplasty system of their own. In the process, they came to believe that Gruentzig's device was somewhat difficult to use, especially due to the fixed-stylet system. They also recognized that his technique required such a high skill level that it would be challenging for an average cardiologist to replicate.

As John Simpson began developing prototypes and testing concepts, Carl Simpson was managing Stanford's cardiac catheterization laboratory. He helped the young innovator by connecting him with various engineers within the hospital, such as people in

the machine shop, before leaving Stanford to join Hewlett-Packard. John Simpson continued to "tinker" and eventually met Ray Williams, a prominent investor, to whom he showed some of his prototypes. Williams saw the market potential of Simpson's ideas and put together a network of angel investors to fund the creation of ACS. At its core, ACS was focused on developing the tools and techniques that would provide a better way to perform coronary angioplasty. After ACS was created, John Simpson contacted Carl Simpson, who then joined the company to accelerate the process of designing, prototyping, and testing device concepts. The team would ultimately have to develop three primary components for its system – a balloon catheter, a guidewire for catheter navigation, and a guiding catheter.

One of the crucial things the ACS team did early in the biodesign innovation process was to define clear user requirements that its balloon catheter would have to meet in order to provide a significant improvement over the available technology. According to Carl Simpson, these requirements included creating a balloon that had a relatively low profile (thin enough to penetrate severe lesions), was relatively non-compliant (did not keep expanding beyond the maximum desired diameter), and could sustain a certain pressure without rupturing. "That was our focus. We knew what we had to do," he said. "You might have 10 ideas for how to make it better, but you can't try to do everything. You have to make a choice on what's most important and stick with it. Because if you don't, that's the kiss of death."

Likewise, in understanding how a guidewire should perform, they realized that it first had to be very fine in order to navigate the small branches of the heart's coronary arteries. Given the complex and tortuous anatomy of the coronary arteries, the guidewire would also have to be flexible, but in a way that could be controlled. Through many unsuccessful attempts to navigate the coronary anatomy with shaped guidewires, they ultimately determined that one of the guidewire's most important design requirements was to be "torqueable," with the tip responsive to guided control from the other end. This key design requirement (which was integral to the clinical problem) eventually helped make ACS guidewires the standard in the industry.

While ACS initially had an entire "tree" of potential user requirements, Carl Simpson advised innovators to be wary of becoming distracted by "nice-to-haves," especially in the early stages of product development. "You're never big enough to do more than three or four things right at any given time," he noted. ACS identified its top priority user and design requirements, including the need for a torqueable guidewire, by using its prototypes to facilitate detailed and extensive interactions with cardiologists. ACS routinely sent its engineers to the cath lab to observe catheter-based procedures and study what competitive products, like the Gruentzig system, could and could not do well. "You need to understand better than the physicians what the real needs are," he said. "The company has to have a really high IQ when it comes to understanding what drives user requirements."

Once these requirements were identified, the ACS team was able to weight them to assist the company in making trade-offs during design and prototyping. "We weighted them based on what we learned from being so involved on a daily basis with what the customer needs next," said Carl Simpson. For example, in the development of the balloon catheter, the requirement for a thin balloon profile was given highest priority. "Profile was always number one," he explained, "because if you can't get across the lesion, you can't dilate it." If necessary, he recalled, the team was willing to make sacrifices around other requirements such as inflation pressure, to maximize the desirability of the balloon's profile. Carl Simpson reiterated, "Trade-offs must be driven by the clinical need. That's why the engineers must understand the medical need so well that they can make those decisions intelligently."

Fundamentally, because there was only one competing product in the market, Gruentzig's device was the baseline against which all of ACS's test results were compared. The company worked through multiple concepts before finally deciding on one to take into development. When asked how the team made that decision, Carl Simpson replied, "We just knew it." When the prototype of the balloon catheter concept could perform better than the baseline device on all three of the fundamental user requirements the company had chosen, ACS knew it was ready to move forward (see Figure 4.6.6). At that stage of the process, Carl Simpson said, "If it's not intuitively obvious, you need to get some help. Talk with other successful entrepreneurs that have a track record in this business." He also advised inventors to go back to physicians and get more input until they feel certain that the concept will satisfy their most important requirements.

Carl Simpson acknowledged that developing this kind of intuition was not easy. "You learn by doing it," he said. However, even for new innovators, "After a certain accumulation of knowledge, the right solution should start to present itself." He also issued a reminder that success is often built on a series of failures. "There is no right formula, other than knowing what the patient and the customer really needs." Simpson has personally dedicated himself to helping other inventors develop this sense of intuition. During his tenure at ACS, the company became informally known as the University of Medical Devices for Silicon Valley, training individuals who would go on to found over 100 medical device companies.[8] ACS was sold to Eli Lilly in 1984 and spun off to Guidant in 1994.

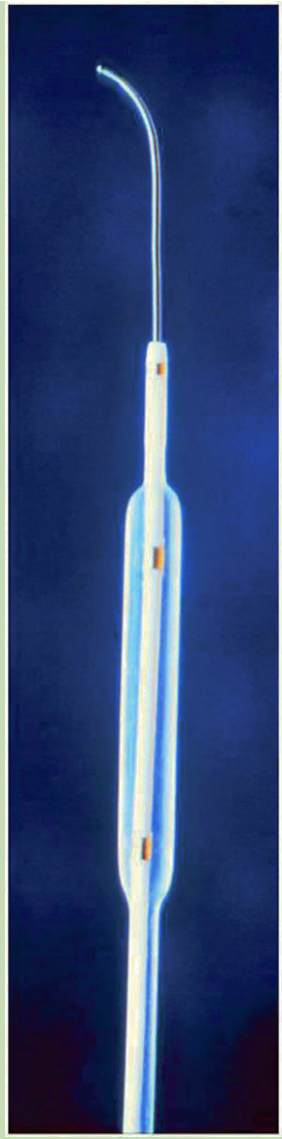


FIGURE 4.6.6
An early Simpson–Robert version of ACS's first catheter (courtesy of Carl Simpson).

FROM THE FIELD ONEBREATH

Reflections on an alternate approach to concept screening

Matthew Callaghan was a surgery intern at University of California at San Francisco when the avian flu was becoming a global concern. This illness can severely compromise an individual's respiratory system and its treatment often calls for ventilators to help patients breathe. Analyses of hospital preparedness conducted by the US government revealed that, in a pandemic scenario, a shortage of trained healthcare providers would be the greatest challenge in the government's ability to respond. The second biggest constraint would be providing enough mechanical ventilators to treat all those in need. Traditional ventilators are expensive, require specialized training to deploy, and have to be regularly maintained, making them impractical to stockpile for emergencies. As Callaghan described, "Mechanical ventilators were the rate limiting step: the most expensive, the most cumbersome, the most complicated, and the least adaptable equipment."

An engineer by training, Callaghan was intrigued by the idea of designing a better, lower-cost ventilator that could be used for disaster relief in pandemics and mass casualty events. Around this time, he met Bilal Shafi, another engineer-surgeon, who joined Callaghan in seeking to address this challenge. Shafi and Callaghan were both working fulltime in other capacities, but began meeting on the weekends to further investigate the problem. Their initial research pointed to two main target markets for a new ventilator: (1) the disaster relief market, with the US government as the main purchaser of equipment for emergency preparedness; and (2) the general hospital market, particularly resource-constrained facilities that needed access to effective but more affordable ventilator equipment.

Three main types of mechanical ventilation products are currently available in the market. Full-featured ventilators,

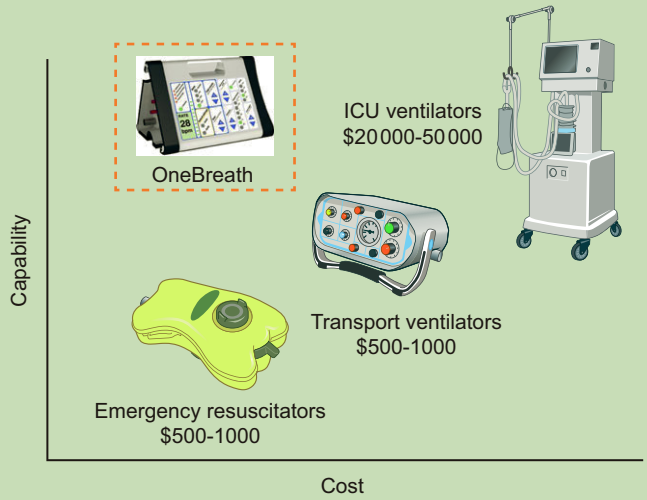


FIGURE 4.6.7
The treatment landscape for mechanical ventilation as depicted by the OneBreath team (courtesy of OneBreath).

used in state-of-the-art intensive care and emergency rooms settings, cost $20,000–$50,000 and require a skilled operator as well as a reliable external power supply. Portable or transport ventilators are less expensive ($8,000–$15,000), but have a short battery life and are not approved for critical care patients. Finally, the most basic devices are low-cost resuscitators that cost approximately $500–$1,000 and are manually operated by a skilled doctor or nurse. Callaghan and his team hoped to position to the new device on the lower end of the cost spectrum, but at the higher end of functionality and effectiveness (see Figure 4.6.7).

Callaghan and Shafi augmented their knowledge of the ventilator space by diving into available clinical literature and guidelines published by the US Health and Human Services Department for required features for pandemic ventilators.[9] Based on their accumulated understanding of the problem, they decided to focus on the need for *a way to affordably ventilate and support patients in acute respiratory distress*. They further defined low-resource environments as settings with limited

infrastructure (power, medical gas, climate control, and repair capabilities), as well as novice users (newly minted RN). The team next created a need specification that included the following need criteria to help guide concept generation:

1. Affordability: Inexpensive enough that hospitals can allocate the device on a one-per-patient basis (the team's preliminary cost target was $3,000 per ventilator).
2. Portability: Ability to operate as a self-contained unit, without electricity or compressed gas, with a long battery life and low maintenance requirements.
3. Operability: Simple enough for a floor nurse to operate without specialized training.
4. Adaptability: Flexible enough to be used on both adult and pediatric patients (unlike most available devices).
5. Compatibility: Universally compatible with currently available breathing tubes and other disposable equipment.

Armed with these need criteria, the team members initially thought they could jump straight into engineering. "Coming from a background in product design, one of the first things we wanted to do was take apart the ventilators that were already out there," Callaghan said. "Our first idea was to take everything that was metal and make it out of plastic to cut the cost in half." But after borrowing existing equipment to dissect, they realized that would not be feasible due to the complex and precise nature of the component parts. "You can't just make them out of cheap plastic," he noted. "We realized that existing devices were built on legacy technology and it would be impossible to make them cheaper in their current form. No one ever went back and started over. It was like layers upon layers of paint, as far as the design went, and no one had peeled off the old paint for decades," Callaghan continued. After weeks of tinkering, they determined that a more creative approach to concept generation would be required. "We probably shouldn't have started with a reverse engineering, tinkering approach," Callaghan admitted. On the other hand, he pointed out, one of the benefits of this exercise was that it motivated the team to conduct additional research to fully understand the mechanics of respiratory distress – how people breath, how the airways function, and how that potentially can be replicated – which served as critical input to their subsequent ideation efforts.

According to Callaghan, the team conducted multiple rounds of ideation but, because the members were working fulltime, they did not follow a traditional ideation process. "We would meet every night and bat around ideas," he said, recalling that they would sketch ideas on a whiteboard and discuss them as a group. Afterwards, they would divide up the ideas among the team members, based on who had the most experience in the relevant area. Team members would then dig more deeply into promising ideas, independently sketching in their notebooks and working on the ideas that had been discussed so they could bring more information back to the next ideation session.

Through this informal process, Callaghan stated, "We came up with probably 20–30 ideas, including some rather unrealistic ones like modern extra-thoracic ventilation (an updated iron lung). Then we refined these on paper until we couldn't exclude something without seeing if it worked." This approach allowed them to whittle down the list of potential concepts to roughly six promising ideas. At that point, they started prototyping. However, instead of taking their concepts forward into a parallel concept screening process, they decided to pursue one idea at a time and jump right into engineering. "The first prototype made sense on paper in terms of physics, but it didn't work at all when we built it," Callaghan remembered.

The next most promising concepts included a pneumatic electrical solution and an idea for a combined pneumatic and software approach. The team started prototyping the pneumatic electrical idea. "It was closest to our backgrounds [in mechanical engineering], easiest to build, and we didn't have to write any code with this idea," Callaghan said. As they worked on various prototypes, he and Shafi refined their need criteria and added several additional requirements that they derived

from analyzing possible use cases of the new ventilator. Unfortunately, after several months, they were forced to admit that the pneumatic electrical approach would never meet the need criteria and user and design requirements that they had defined.

Moving on to the next idea, they started working on models that would use software to control ventilator function via breath delivery algorithms. Roughly six generations of prototypes later, they felt confident that the concept would satisfy the need specifications and had the design that would become the OneBreath v1 ventilator.

Reflecting on this experience, Callaghan acknowledged the limitations of the team's linear approach to concept screening and final concept selection. "We were too quick to jump to fleshing out engineering concepts rather than trying to mate [the concept] to our design target. We would get away from our need specification and hang too tightly to what we were most familiar with. If we'd followed the biodesign innovation process more closely, we would have saved ourselves close to a year in getting to a final concept. This approach cost us time, and we were lucky it didn't kill the project."

According to Callaghan, "We did a good job of understanding the problem, but we didn't give the need spec enough authority." Had the team members more thoroughly and realistically evaluated their solution concepts against the need criteria, they potentially could have anticipated earlier that some of the ideas would not have been able to meet those requirements. "Concepts that didn't meet the need spec should have been rejected earlier," he acknowledged. As engineers, he added, they had a tendency to believe that with a little more ingenuity or hard work they could overcome fundamental limitations inherent in the idea.

In hindsight, a more objective, comparative process that explicitly enabled the evaluation of potential solutions against key user requirements could have helped OneBreath more efficiently select a final concept. Callaghan likened the optimal process to the rigorous approach used to screen and select needs: "Once you come up with needs, you beat them up to make sure you've got them right. And you validate them across different stakeholders, not just one MD who told you this was a problem for him/her. In other words, you try and 'kill' them. We get attached to things that interest us – which is important; you need passion to keep working on something for long hours with no pay – but this needs to be balanced with whether or not the dog really wants that dog food. The same goes for choosing a design concept."

OneBreath is now focused on developing its low-cost ventilator for the disaster relief market, as well as resource-constrained facilities in developing countries. The company has set up a wholly owned subsidiary in India, which is its first target market, and closed a Series A financing from international investors in 2013. OneBreath plants to launch its first product in early 2015.

Online Resources

Visit www.ebiodesign.org/4.6 for more content, including:

Activities and links for "Getting Started"

- Complete research, prototyping, and preliminary concept screening
- Identify user and design requirements
- Weight user and design requirements
- Confirm the concepts and choose a baseline
- Assign scores and rank concepts using the selection matrix

Videos on final concept selection

CREDITS

The editors would like to acknowledge Carl Simpson of Coronis Medical Ventures for sharing the ACS story and Matt Callaghan for providing the OneBreath case. Many thanks go to Todd Alamin, Ian Bennett, Colin Cahill, and Louie Fielding of Simpirica Spine and Mark Deem of The Foundry for offering examples, as well as Ritu Kamal and John Woock for their assistance updating the chapter. Steve Fair contributed to the original material.

NOTES

1 David Warburton, "Getting Better Results in Design Concept Selection," *Medical Device Link*, http://www.devicelink.com/mddi/archive/04/01/006.html (November 20, 2013).

2 From remarks made by Mark Deem as part of a lecture for the Biodesign Innovation course offered by Stanford's Program in Biodesign, 2010. Reprinted with permission.

3 Stuart Pugh, *Total Design: Integrated Methods for Successful Product Engineering* (Addison-Wesley, 1991).

4 Ibid.

5 The French catheter scale is used to measure the outside diameter of a cylindrical medical instrument. 1 French (Fr) is equivalent to approximately 0.33 mm.

6 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.

7 Pugh, op. cit.

8 Carl Simpson biography, Stanford Biodesign: People, http://biodesign.stanford.edu/bdn/people/csimpson.jsp (November 20, 2013).

9 "Advanced Development of Next Generation Portable Ventilators," Solicitation HHS-BARDA-08-20, April 18, 2008.

Acclarent Case Study

STAGE 4: CONCEPT SCREENING

To determine whether the idea of using balloons to address chronic sinusitis was feasible, Makower and Chang had to take the concept through steps described in the concept screening stage of the biodesign innovation process. Even though they were not directly comparing the balloon solution against another idea, they had to be sure it would clear all appropriate hurdles before making a decision as to whether or not this would be their final concept. "We realized that there were a million questions that needed to be answered once we had cleared the simple hurdle of widening a sinus passageway. But none of these questions were worth asking if we did not know if we could find a technology that worked," Makower said.[1]

4.1 Intellectual Property Basics

To assess the intellectual property (IP) landscape, Makower and Chang spent considerable time researching patents in the ENT field. They were particularly focused on understanding existing patents related to the nose. "We looked at this area in detail," Chang summarized, "and it seemed pretty open." He elaborated:

> *There was some IP around epistaxis [nosebleeds]. There was a fair amount of IP around turbinate reduction, cutting things, reducing things, and a lot of energy delivery. But the field was generally pretty wide open in terms of interventional devices, as well as methods and different procedures. We found some patents related to drug delivery, but not really specific to ENT. This was important because we recognized from early on that drug delivery could eventually become part of our solution. As we started to hone in on balloons and catheters, we knew that these devices had been around for a long time in cardiology and other spaces, so we focused on aspects of these technologies that were unique and novel to this application and started to create a massive set of disclosures.*

As they performed more research and consulted with an IP attorney, Makower and Chang relatively quickly became convinced that their solution would be patentable. They decided that the first step in this process was to focus on building a picket fence around their unique method of using balloons and other tools designed specifically for the nose. According to Chang, "We recognized from the get-go that the method was where we would really shine." Then, as they learned more about the devices and how they would be used, they began to build increasingly stronger IP protections around what made them uniquely different from existing balloons and other tools for cardiovascular interventions.

"So we filed a series of patent applications," said Chang. "Our first ones were not provisionals. We worked extremely hard and fast with our IP attorney and decided to put in a tremendous effort up-front into our patents." He described using a comprehensive approach to these early applications. "While we clearly described our preferred technology and preferred way of using it, we also put in many other technologies and methods to lay the groundwork for future products. There are multiple approaches to achieve a desired outcome and if you don't cover them, someone else will after they see what you are doing" (see Figure C4.1).

One unexpected outcome from these IP efforts was the decision to operate in what the team called "stealth mode." As they learned more and more about the opportunity, Makower became increasingly concerned about another company learning of the idea and trying to beat them to market with a similar solution. They intentionally decided to disclose their ideas to as few people as possible, and agreed to use carefully constructed nondisclosure agreements (NDAs) when a disclosure was

US007462175B2

(12) **United States Patent**
Chang et al.

(10) **Patent No.: US 7,462,175 B2**
(45) **Date of Patent: Dec. 9, 2008**

(54) **DEVICES, SYSTEMS AND METHODS FOR TREATING DISORDERS OF THE EAR, NOSE AND THROAT**

(75) Inventors: **John Y. Chang**, Mountain View, CA (US); **Joshua Makower**, Los Altos, CA (US); **Julia D. Vrany**, Sunnyvale, CA (US); **Theodore C. Lamson**, Pleasanton, CA (US); **Amrish Jayprakash Walke**, Milpitas, CA (US)

(73) Assignee: **Acclarent, Inc.**, Menlo Park, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 524 days.

(21) Appl. No.: **11/037,548**

(22) Filed: **Jan. 18, 2005**

(65) **Prior Publication Data**

US 2006/0095066 A1 May 4, 2006

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/829,917, filed on Apr. 21, 2004, and a continuation-in-part of application No. 10/912,578, filed on Aug. 4, 2004, now Pat. No. 7,361,168, and a continuation-in-part of application No. 10/944,270, filed on Sep. 17, 2004.

(51) **Int. Cl.**
A61M 31/00 (2006.01)

(52) **U.S. Cl.** **604/510**

(58) **Field of Classification Search** 604/509–510, 604/94.01, 103.1, 103.04, 103.05, 96.01, 604/164.01, 164.09, 164.1, 164.11, 164.13, 604/164.08, 171, 173, 101.02
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

705,346 A 7/1902 Hamilton

2,525,183 A 10/1950 Robison

(Continued)

OTHER PUBLICATIONS

Strohm et al. Die Behandlung von Stenosen der oberen Luftwege mittels rontgenologisch gesteuerter Balloondilation Sep. 25, 1999.*

(Continued)

Primary Examiner—Kevin C Sirmons
Assistant Examiner—Deanna K Hall
(74) *Attorney, Agent, or Firm*—Robert D. Buyan; Stout, Uxa, Buyan & Mullins, LLP

(57) **ABSTRACT**

Sinusitis, mucocysts, tumors, infections, hearing disorders, choanal atresia, fractures and other disorders of the paranasal sinuses, Eustachian tubes, Lachrymal ducts and other ear, nose, throat and mouth structures are diagnosed and/or treated using minimally invasive approaches and, in many cases, flexible catheters as opposed to instruments having rigid shafts. Various diagnostic procedures and devices are used to perform imaging studies, mucus flow studies, air/gas flow studies, anatomic dimension studies and endoscopic studies. Access and occluding devices may be used to facilitate insertion of working devices such asendoscopes, wires, probes, needles, catheters, balloon catheters, dilation catheters, dilators, balloons, tissue cutting or remodeling devices, suction or irrigation devices, imaging devices, sizing devices, biopsy devices, image-guided devices containing sensors or transmitters, electrosurgical devices, energy emitting devices, devices for injecting diagnostic or therapeutic agents, devices for implanting devices such as stents, substance eluting or delivering devices and implants, etc.

21 Claims, 44 Drawing Sheets

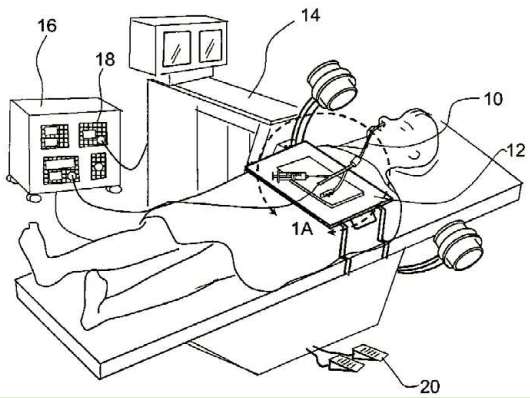


FIGURE C4.1
The first core Balloon Sinuplasty patent was finally issued to Acclarent in December 2008 (provided by Acclarent).

absolutely necessary. As Chang explained, "With the balloon idea, we were basically working with well-understood technology. There are a lot of companies that have experience with balloons, guides, and wires. There are smart people out there who could potentially do this and they might get a hint about what we're doing and invent in front of us. The longer we could keep the potential competition in the dark, the better."

4.2 Regulatory Basics

When thinking about the regulatory pathway associated with the leading solution, Makower referred back to the mantra "no science experiments." This meant that the solution would need to be a candidate for the 510(k) pathway. "We wanted something with a relatively simple regulatory path," said Chang, along with limited requirements for clinical data. "So, we set up a meeting with a regulatory consultant and started talking about how we could get clearance with this kind of a product." They found a regulatory consultant who had some experience in the ENT field. "His impression was that most ENT devices fall within Class I or Class II," Chang recalled. "From there, we pulled out the regulations to make sure we really understood them. After carefully examining this information with the consultant, they felt confident that the decision to pursue a 510(k) pathway was directly in keeping with the guidelines of the Food and Drug Administration (FDA). The key would be to identify a highly effective set of predicate devices upon which to base their submissions.

4.3 Reimbursement Basics

When it came to reimbursement, the team took great care in understanding the codes, coverage, and payment decisions associated with FESS. As described by William Facteau, who joined the team in November 2004, as the CEO of the soon-to-be company, the ENT specialists performing FESS procedures were heavily invested in how their procedure was reimbursed:

> *Functional endoscopic sinus surgery is the gold standard for the surgical treatment of chronic sinusitis and it is reimbursed by Medicare, as well as all private insurance plans. In its early days, though, there were challenges in getting the procedure reimbursed – this conflict is often referred to as the "FESS mess." The leading physicians in the field used a significant amount of political capital in order to get these codes established. And they are some of the most sacred codes throughout all of otolaryngology – they pay very well, they pay individually by sinus, and physicians also receive additional reimbursement for the follow-up treatments, called debridements [the surgical removal of scar tissue from a wound], which is pretty unique. Due to this favorable reimbursement, sinus surgery is one of the most profitable outpatient procedures for both the physician and the hospital. For this reason, leaders in the field, as well as the [professional] societies, are very protective.*

Because the physicians had fought long and hard to establish codes, coverage, and payment levels, the team knew not to proceed if it seemed to be a questionable fit. On the other hand, if this technology were considered just another device to be used in sinus surgery, it could fit comfortably within the existing reimbursement guidelines and the team would be well positioned from a reimbursement perspective. The codes being considered at the time included those shown in Figure C4.2.

Lam Wang performed a detailed analysis of the reimbursement landscape. While the target population of chronic sinusitis patients was largely covered by private insurance, she used Medicare data as a baseline for payment levels and rates since it was readily available, and also because most private payers followed CMS's lead at that time. For physicians, CMS paid 100 percent for the highest weighted code, and then 50 percent for all additional codes. Use of an image-guidance system was addressed separately as an add-on payment at 100 percent. Facilities were also reimbursed for the first sinus at 100 percent, and at 50 percent for all others. However, while image-guidance received an add-on payment at 100 percent in a hospital outpatient setting, no additional payment was granted in an ambulatory surgical center (ASC) setting. CMS data at the time indicated that approximately 70–90 percent of all sinus surgeries were

CPT Code	Description	Hospital Outpatient		Ambulatory Surgical Ctr		Physician Payment	
		APC	APC Paymt	ASC Grp	ASC Paymt	Total RVUs	Ave Paymt
31254	Nasal/sinus endoscopy, surgical, with ethmoidectomy, partial	0075	$1,112	3	$510	7.92	$296
31256	Nasal/sinus endoscopy, surgical, with maxillary antrostomy	0075	$1,112	3	$510	5.71	$213
31276	Nasal/sinus endoscopy, surgical, with frontal sinus exploration	0075	$1,112	3	$510	14.76	$551
31287	Nasal/sinus endoscopy, surgical, with sphenoidotomy	0075	$1,112	3	$510	6.73	$251
61795	Stereotactic computer assisted volumetric (navigational) procedure	0302	$345.20	N/A	$0	7.05	$263.23

FIGURE C4.2

Sinus surgery was reimbursed by Medicare and private payers under a series of existing codes (provided by Acclarent).

performed in a hospital outpatient facility. Importantly, existing FESS codes could not be used in an office setting. If the team wanted to position its solution as an office-based procedure, it would need to apply for new codes (as well as prove that the treatment was safe to administer in an office setting).

To validate what she had learned and secure a formal opinion, Lam Wang contracted with a professional reimbursement consulting firm – Clarity Coding. In its report, Clarity indicated that the team should qualify to use existing FESS codes, since the objective of the procedure when using balloons would be essentially equivalent to that of FESS using other instruments and fell directly within the language of the code. "In other words," said Facteau, "the codes for functional endoscopic sinus surgery are broad enough that they do not specify how you create an opening in the sinus or what tools you use. It leaves it up to the physicians to decide whatever tool, device, or instrument is appropriate to make the opening." The company's technology would be just one more option available to surgeons when performing this procedure.

Encouraged by this outcome, but still concerned about the sacred nature of the FESS codes, Facteau sought the opinion of another reimbursement consultant when he joined the team. He explained:

> *Reimbursement was a big concern of mine. I worked closely with a legal/reimbursement expert at Reed Smith at a previous job, so one of the first things I did was call her and ask her for her opinion. She did some research and came back with the same opinion as Clarity Coding. In fact, she said, "Bill, I really enjoyed working with you at Perclose. Unfortunately, we're not going to have to do much work on this one. It's pretty straightforward. The existing codes apply and you guys are all set. So, good luck."*

4.4 Business Models

Another issue on Facteau's mind when he joined forces with Makower, Chang, and Lam Wang had to do with the business model. "One of the biggest business risks that I saw was just the fact that it was in ENT. I struggled with whether you could build a sustainable company solely dedicated to ENT. When I researched the space, it was not very impressive. The field just hadn't seen a lot of innovation over the years. It was primarily a reusable and capital equipment environment," he said. Following the path established in interventional cardiology, the devices being designed by Makower and Chang were intended to be disposable. Given the nature of the procedure and the devices themselves, this model made practical sense. More importantly, the team saw this approach as one way to help inject the field with greater innovation. According to Lam Wang, "When you shift from reusable instruments to a disposables platform, you open a field up to much more innovation. That's because the doctors are not stuck with the same tools they used the last year." Facteau elaborated: "Disposables drive innovation. We have seen it in general surgery, with laparoscopy and surgical staplers, orthopedics, spine, and cardiology – they were all driven by implants and

innovative disposable technology. With a disposables model, we can innovate very, very quickly. The question was if ENT physicians would be willing to adopt new disposable technology. To some extent, the business model was predicated on our ability to get doctors addicted to innovation and be able to provide them with new, value-added technology every six to nine months."

One obstacle to introducing this kind of a paradigm shift would be in getting the target population of physicians to give up the reusable instrument sets to which they were so attached. The team also anticipated some resistance related to price – many ENT specialists were known for being somewhat cost conscious. "As a general rule of thumb," Lam Wang noted, "disposables command higher margins." However, convinced that the benefits would outweigh the costs, and encouraged by the relatively straightforward pathways identified in the areas of IP, regulatory, and reimbursement, the team felt comfortable taking on the challenge of building a business in ENT based on a disposable model. Basically, said Chang, "This didn't stop us. We just said, 'Okay, remember that. That's going to be a challenge.'"

4.5 Concept Exploration and Testing

In parallel with these other efforts, Makower and Chang had begun developing basic prototypes in earnest (see Figure C4.3).

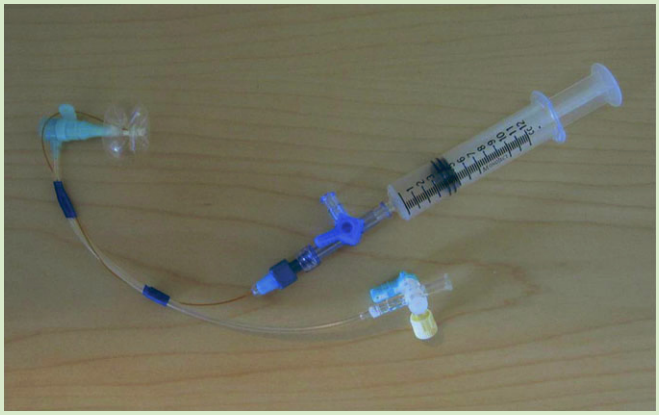


FIGURE C4.3
An early prototype of the stabilized guide access concept (courtesy of Acclarent).

Their goal was to prove the feasibility of the concept. Chang recalled how they got started:

> *We asked ourselves, "Why can't they treat these sinuses better?" One thing was that they operated via endoscopy – in other words, required direct visualization. So that led us to consider alternative visualization methods since our devices would at some point be placed around and behind structures, out of view of most common endoscopes. We looked at fluoroscopy as the most reasonable way to navigate the anatomy, similar to the way interventional cardiologists guide catheters in the heart. So don't remove the anatomy; look around or through it with fluoroscopy. And then there was the fact that there were no flexible instruments for FESS. When you examined what they were doing, they were just chopping, cutting or ripping the anatomy to gain access and make the opening bigger. We asked ourselves if there were less traumatic ways to accomplish this, ways that wouldn't lead to so much bleeding and the scarring cascade that often brought patients back for a revision surgery. We looked at using wires and flexible instruments. And we also thought, "Well, maybe you could dilate the ostium. Would fracturing the bone via balloon dilation be less traumatic? Was it going to cause the mucosa to necrose and cause more problems?" We didn't know. We wanted answers to these questions. And so that led us to prototyping.*

"We'd never read or heard of anyone doing any dilating of bone," Chang continued, "so there were a lot of things that we just didn't know." Using readily available materials, they built a preliminary working model and then went back to the cadaver lab to try it (importantly, they decided that there were no animal models that would serve as an effective proxy for human sinuses). According to Chang, "Not knowing what would work, we were like MacGyver with duct tape and boxes of materials and supplies for cutting, melting, bonding, and shaping existing things. We were ready to make changes right there in the cadaver lab."

Makower described their initial experience using a prototype:

> *John and I went in with very crude guides, wires, and balloons. We didn't even have a scope for our first study. We went in and poked around. And, to our amazement, we were able to wire all the major sinuses in a cadaver head, and pass balloon catheters up over those wires, and deploy stents, and deliver balloons. It was unbelievable. The first time we tried, we got it to work. So, in terms of the feasibility, we said, "Okay, this is doable!" Now, what we didn't have was any real way of assessing what we had done. And we didn't know what pressures to inflate the balloons to. We saw that at some point the balloons would crack open, and we saw that we were dilating bone. We just didn't know exactly whether we were doing something bad or good.*

Encouraged by these early results, Makower and Chang eagerly pressed forward. "We brought Dave Kim in, under a confidentiality agreement, to help with those early exploratory studies. And he brought a scope with him. For the first time, we got to see what it looked like, and it looked pretty good. So, that's when we realized it was time to really talk to some rhinologists and figure out whether this thing had any merit."

They put together a brief presentation on their concept that included the need specification, an overview of the prototyped technology, and the approach, results, and X-rays from the preliminary feasibilities studies. Tapping into a member of their network, they arranged a meeting with Dr. Mike Sillers, who was president of the American Rhinological Society (ARS) at the time. According to a friend who had pitched various ideas to Sillers in the past, he had a reputation for being a tough critic, so they were prepared for the worst. Makower recalled the meeting:

> *When we sat down with Mike [who agreed to sign an NDA], he was silent for most of the presentation. When we got to the end, he pushed himself away from the table and looked at us and said, "If this works, it's going to change everything we do." So then I asked the question, "What would you need to see before you'd be willing to try it on a patient?" And he said, "Well, I'd want to do it on a cadaver head." So, we said, "Okay. We'll get you out to the cadaver lab. What next?" He said, "Well, try it on some patients." And then I said, "Well, how many patients would you need to see, and what kind of study would you need to see before you think we could commercialize it?" And his first response was, "You know, this is a just a tool. If I see that with this tool, in a handful of my own patients, I can make a wider opening, I don't need any clinical studies beyond that. I know that in the right patients, if I made a wider opening, it's going to be good for the patient."*

4.6 Final Concept Selection

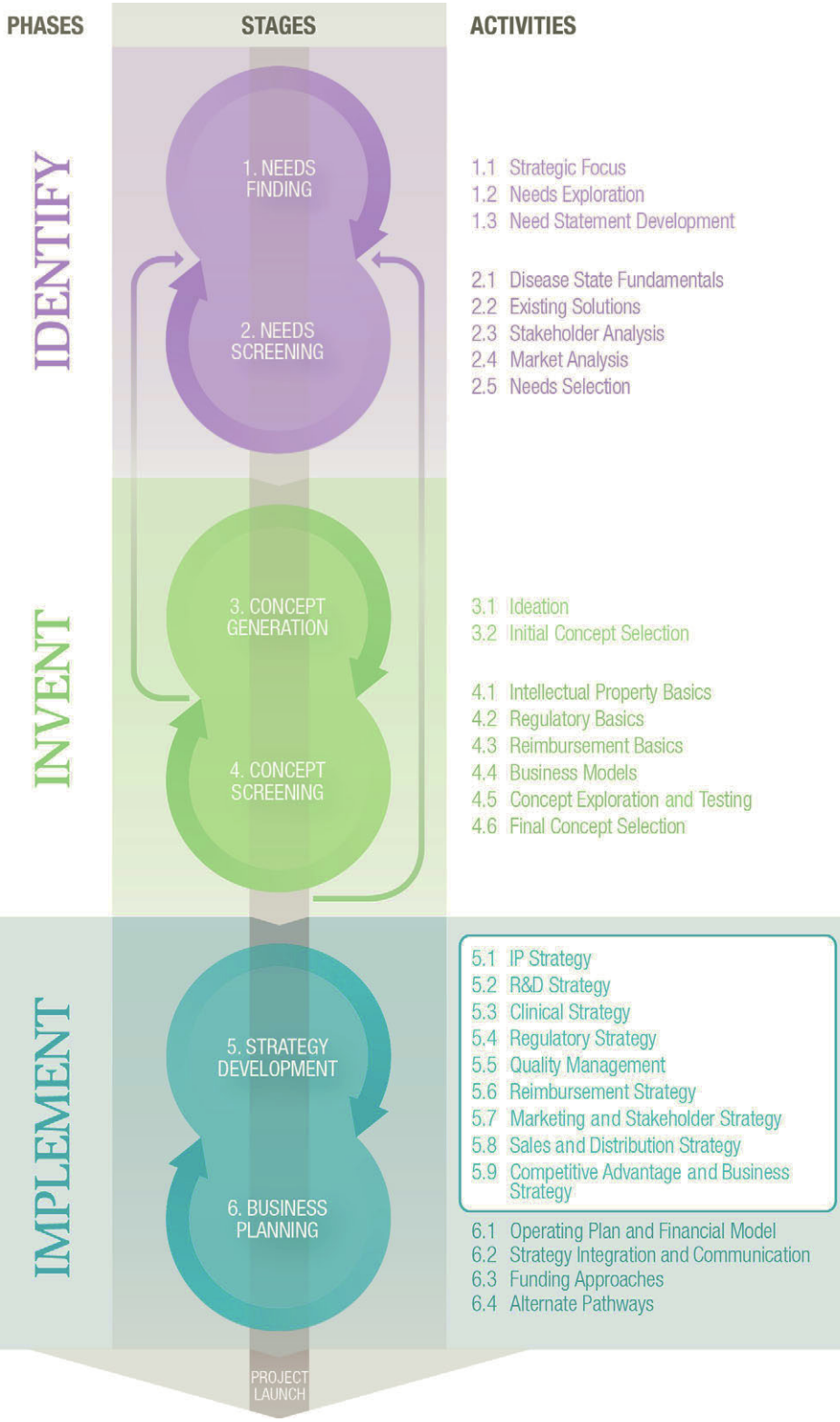
With this feedback from Sillers, Makower and team had reached a decision point. "John and I sat in that lobby after that meeting with Mike," he remembered. "We knew that there were still a lot of other pages to turn, but we realized at that moment that we had hit upon something. If an important potential critic couldn't come up with anything to kill the concept, then we knew we wanted to move forward with balloons. We looked at each other and said, 'I think we found the one. Let's go for it.'"

Because all of the key issues to consider in the concept selection process had panned out relatively favorably (IP, regulatory, reimbursement, business model, and prototyping), they felt comfortable making this decision informally, in lieu of a structured concept selection exercise. However, just to be sure, they took the idea to one more leading specialist in the field – Dr. Bill Bolger, a famous surgeon and anatomical expert in ENT. When Bolger (who also signed an NDA) was equally impressed with their presentation and willing to play an ongoing role in the development of the device, the team committed itself to proceed, initiating the development of the devices that became known as *Balloon Sinuplasty*™ technology.

NOTES

1 All quotations are from interviews conducted by the authors, unless otherwise cited. Reprinted with permission.

IMPLEMENT Strategy Development



Failing to plan is planning to fail.

Alan Lakein[1]

Always in motion is the future.

Yoda[2]

5. STRATEGY DEVELOPMENT

By this point, you've taken steps to Identify and Invent. Now it's time to consider how to Implement. As Tom Fogarty, surgeon inventor extraordinaire says: "A good idea unimplemented is no more worthwhile than a bad idea. If it doesn't improve the life of a patient, it doesn't count."[3]

This is by far the longest and most complex stage of the biodesign innovation process, with good reason. Regardless of the validity of the need, the ingeniousness of the concept, and the size and scope of the market, at the end of the day, sound business underpinnings are essential if a product is to be delivered to the bedside, in a box, with a toll-free number on the side for sales and service.

Getting to this reality requires a balanced consideration of the rules of the road from Stage 4 (intellectual property, reimbursement, regulatory, and business models) with the addition of a series of overlying and overlapping strategies. These strategies focus more deeply on the following key areas: (1) intellectual property integrated with ongoing research and development and clinical plans; (2) regulatory strategy, including quality management; (3) reimbursement strategy; (4) basic business blocking and tackling – marketing, sales, and distribution; and (5) combining all assets to develop a sustainable competitive advantage.

Heretofore, a small team may have the wherewithal to work independently; now is the time to involve "varsity players." Use them as consultants or mentors, retain them on a part-time basis, or hire them. Without deep technical knowledge, failure is likely.

What to do first? Gordon Bethune's book chronicling the turnaround of Continental Airlines, called *From Worst to First*, espoused the importance of tackling problems and opportunities right away and all at once.[4] The lessons are that few things are simply sequential, that nothing can be considered in a vacuum, and that time waits for no one. Given the fast pace of change in the medtech space, a six-month delay may leave you behind your competitors.

NOTES

1 Unsourced quotation widely attributed to Alan Lakein, author of *How to Get Control of Your Time and Your Life* (New American Library, 1973).
2 From the movie *Star Wars: Episode V – The Empire Strikes Back*.
3 From remarks made by Thomas Fogarty as part of the "From the Innovator's Workbench" speaker series hosted by Stanford's Program in Biodesign, January 27, 2003. Reprinted with permission.
4 Gordon Bethune, *From Worst to First: Behind the Scenes of Continental's Remarkable Comeback* (Wiley, 1999).