Innovation and Entrepreneurship: Perspectives From Orthopedic Surgery

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abstract

Orthopedic surgeons are tasked with treating complex patients while employing critical surgical skills, clinical knowledge, and new technologies. The constant inundation of information, coupled with hours in the hospital setting, provides unique perspectives on various aspects of how health care is delivered, thereby creating a milieu ripe for innovation. The rigors of an orthopedic career make it challenging for physicians to translate an idea into a great product. Through the authors' experiences at a tertiary orthopedic practice, they review the process of taking an idea from concept to fruition. [*Orthopedics*. 201x; xx(x):xx-xx.]

Orthopedic surgeons are responsible for treating complex patients while employing critical surgical skills, clinical knowledge, and new technologies. As a result of their being inundated with information and spending many hours in the hospital setting, they have unique perspectives on various aspects of how health care is delivered. This provides a milieu ripe for innovation. The authors recognize that introducing innovation into a field that predominantly practices within an accepted standard of care may be difficult. Although unmet clinical needs abound, early attempts to introduce new technology or products may be met with unforeseen obstacles and controversy. However, the authors think that the standard of care is not static. The introduction of innovative products, processes, and ideas will further advance the delivery of health care and how physicians can best care for patients, thus advancing the dynamic target of the standard of care.

Reading through the following paragraphs, you may recall some of your own innovations throughout your career. However, a large chasm exists between a "great idea" and a tangible solution brought to market. The rigors of an orthopedic career make it challenging for physicians to translate an idea into a great product. Furthermore, many orthopedic surgeons do not have formal training in business, innovation, technology transfer, or intellectual property (IP). The authors attempt to review the process of taking an idea from concept to fruition. They acknowledge that there are multiple successful approaches to innovation and offer this path as one means to get there. Overall, everyone should pursue the strategy that is most readily available and with which they feel most comfortable.

STEP 1: THE IDEA

You have an idea or concept, but now what? You've identified a problem or question and your idea offers a reasonable solution, but how do you take that idea from concept to practice? The natural tendency is to get tunnel vision and focus solely on the idea. It's essential to step back and

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complete your own due diligence in understanding the big picture. Has someone else already thought of this but you just don't know about it? If so, is the existing solution identical to yours? Even if you aren't first to the market with your idea, is your innovation more cost-effective, accessible, or simple to use? Begin to identify the novelty of your own idea relative to competitive solutions. If your idea concerns a new surgical implant or procedure, consider the technical hurdles. A new implant that requires 5 hours for implementation by only the most skilled surgeon will not yield high surgeon or market adoption. Focus on innovations that improve efficiency, outcomes, and reproducibility while reducing waste, inventory, cost, and procedural challenges.

The next step is to perform a patent search for concept and novelty. This type of search can take time, but those who have gone through the process will tell you that it is an invaluable step that must be taken. Typically, inventors start with their own preliminary patent search as well as a comprehensive evaluation of the relevant literature. This helps to reveal not only whether a patent already exists, but also the prior art and the search terms associated with your invention. Free searchable patent databases include the US Patent and Trademark Office (http://patft.uspto.gov), Free Patents Online (http://www.freepatentsonline.com), and Google Patents (https://patents.google.com). The US Patent and Trademark Office is the most up-to-date database, but it can be difficult to navigate. Be sure to use the advanced search options to improve the scope of your search. You will invariably find new keywords that describe your invention's feature set that will steer you in several different directions. Exploring these tangential paths is what constitutes a broad patent search. Despite your best efforts, it is critical to follow your initial search with a professional patent search. These services typically cost between $500 and $1500, and they will give you a recommendation as to whether your idea is novel and patentable. These professional searches reliably identify prior works that you may not have come across during your search, so it is always a good idea to hire someone with this skill set.

Completing your own provisional patent search also helps to define your value proposition. A value proposition is a statement that describes the value your future customers will receive by using your invention. While developing your value proposition, consider the potential value your invention brings to multiple customers and market segments, thus capturing that value in your proposition. The more you think about other solutions and competitive products and play your own devil's advocate, the better prepared you will be moving forward. Don't be afraid to make changes to your value proposition if the market calls for a pivot or vertical expansion.

Step 2: Know Your Situation

Physicians are all in different situations; they work for different health care organizations and have access to different resources, both personal and professional. Start by understanding what you can and cannot do with your idea. Each employment contract is slightly different, so know what's in yours. Get a copy of your hospital's or practice's IP clause and employee handbook. Before disclosing any innovation, send these documents to an IP attorney who can review them and report back to you. If your idea was created during working hours, using hospital resources or technology, it is likely you will be advised to begin discussions with the hospital's technology transfer office (ie, New Business Development, Innovation Center, etc). Do not do this on your own. You may need to consider hiring an IP attorney if no one on your team has formal training in these areas. Let your attorney guide you through the process to maximize your position. Depending on your contract and state laws, you may be able to claim 100% ownership if you created your idea on your own time, outside of the hospital, using your own resources. Alternatively, partnering with your institution may provide you with access to otherwise inaccessible resources that may help you on your path to commercialization. Either way, it is essential to determine your situation before going too far down the development road.

Step 3: Identifying Mentors and Advisors

Mentorship is an invaluable resource. No matter how good the idea, many orthopedic surgeons do not have a strong background or extensive experience in innovation and new business development. Intellectual or competency voids in the formation team can be filled with an appropriate mentor. For example, a formation team weak in finance could reach out to an accountant. A team weak in law could reach out to a lawyer. The perspectives provided by individuals with different career backgrounds are valuable and essential for growth. That said, be thoughtful, be precise, and be mindful of what you need. Every time you bring someone on board, you risk diluting your own stake in the game. In developing your mentorship or advisory board, challenge yourself to create new connections that may push you and your idea beyond your comfort zone. Be realistic in the type of mentorship you are seeking. In an ideal scenario, you have an open line of communication with your advisors (ie, text, e-mail, and phone) and communicate monthly. An exceptionally high-profile mentor who is unavailable for support and guidance is unlikely to be of much help. One critical area to seek mentors or advisors is in the financial realm. The main goal of the innovation may be to improve patient care and outcomes. However, innovation and new products must also generate revenue. Investors will not invest in companies in which revenue generation is not a top priority. As physicians often lack training and experience in

this field, mentors and advisors are key in providing guidance on the financial intent of the innovation.

Effective mentorship can be beneficial to start, but you will soon reach a point where more formal, structured advice is required. Advisory boards can help with multiple aspects of your company and/or the development of your idea. You may choose people in a similar field, or you may be looking for people to take you through a capital raise. Generally, their roles are fluid and can change based on the stage of your project's development. Initially, choose people you know. As you gain more traction, start targeting people who can help you in other ways. At some point, you may have to put together a compensation package for your formal advisors. There are different industry standards for compensation of advisory board members, but there are also important nuances to consider. Reflect on the advisor's interests, past or present involvement, and capital (social, financial, etc).

Turning an idea into a successful venture requires a multidisciplinary effort. Key players in the formation of a team may include those with expertise in business, law, finance, and technology. It is imperative to precisely define your needs. Don't be afraid to carefully reach out to fill voids. Before spending countless hours developing a detailed business plan (or buying dozens of books telling you how to), take the time to identify what you need to move forward efficiently. If you have a product that requires IP protection or Food and Drug Administration clearance or approval, you will need an attorney. Get one early. Reach out to colleagues, family, and friends to find someone you trust to help you move forward. Be careful here! Before disclosing your concept, make sure you're protected. Don't be intimidated by nondisclosure agreements; use them. Anyone who is honest and trustworthy has nothing to lose by signing a nondisclosure agreement. If someone you want to discuss your idea with refuses to sign a nondisclosure agreement, be wary of that individual's true intentions and move on to the next candidate.

Step 4: Establishing the Formal Company

After forming a team, establishing a business entity is likely the next step to create a legal and financial distinction between your personal and business actions. In addition to mitigating your legal liability, companies and corporations offer potential financial advantages and equity or growth opportunities. Typically, corporations and limited liability companies are the most popular entities for start-ups because of the liability protection they afford owners (**Table 1**).[1,2] The authors think that a C corporation may be the more desirable and beneficial company structure for orthopedic surgeon entrepreneurs. Although the limited liability company provides a flexible structure, it may be subject to additional taxes, and investors have traditionally been wary of this corporate structure. However, a C corporation allows for multiple classes of stock, well-established legal precedent, no restriction on who can hold shares, and widespread acceptance by venture capitalists and large investors.

Regarding company formation, it is also important to consider the state of formation. Delaware has the most developed body of law for business entities and is the state most commonly chosen for company formation, regardless of the physical address of the business' founders. However, there is certainly value to incorporating elsewhere. For example, state-specific resources are only available to companies registered in that state. Likewise, there may be value to having your company rooted in the culture in which you plan to sell your product.

After establishing your company, create a mission statement. Define the company's goals, ethics, culture, and patterns for decision-making. Reflect on the purpose of your invention (the problem you're trying to solve), the target market(s), your value proposition, and your company's values. The mission statement should be composed with the entire formation team present and serve as the lighthouse for future decision-making. This step in the formation process can take time and may require several drafts and revisions to get it right.

Step 5: Obtaining Funding

Generally, funding can be broken down into dilutive and nondilutive. Dilutive funds include any that convey with them a portion of equity within the company. Nondilutive funds preserve the prefunding capitalization table. The most basic nondilutive funding method is bootstrapping, in which team members contribute personal funds to help drive the company forward. Investing your own resources makes your team inherently more accountable and makes for a more personal experience (**Table 2**).[3-5] Although straightforward, it can be challenging to generate the funds needed to be successful. Being resourceful with local resources and your partners is critical.

As you fund your company, develop a clear distribution of equity based on those initial investments. You'll need to determine the number of company shares available and the percentage of the company that is free to outside funding. The founders or inventors should try to maximize their equity and resist dilution at all costs early on. Their future potential to raise capital will be largely based on the equity structure at the time of investment. Complex equity structures with multiple small-contribution investors can affect potential capital partners and may make the investment less attractive. One way to prevent this is to create a separate entity that pools cumulative resources from family and friends into one investment aside from the founder's equity, thus allowing more influx of smaller amounts of capital without complicating the investment or equity structure. This should be strategized with your attorney and accountant.

Table 1

Advantages and Disadvantages of Types of Businesses or Corporations

Business Type	Advantages	Disadvantages
Sole proprietorship/partnership	Of the categories presented, the least expensive and easiest to form Tax rates are the lowest among all business structures	Unlimited liability for business debt (personal assets are at risk) Business' funding is limited to the owner's ability to personally raise money, because sole proprietors can't sell stocks to raise money
LLC	Does not affect federal income tax (single-owner LLCs are taxed just like sole proprietorships, and multiple-owner LLCs are taxed just like partnerships) Flexible management structure, does not need to comply with a formal management structure Can offer membership interests in the LLC to employees	May subject the business to additional state taxes (ie, franchise taxes) Investors often wary of LLC structure Renewal fees often higher than a C or an S corporation
S corporation	Pay only 1 level of taxation Not subject to self-employment tax Pays employees a "reasonable" salary (industry norms), while also deducting payroll expenses such as federal taxes and Federal Insurance Contributions Act (FICA) tax. Then, any remaining profits from the company can be distributed to the owners as dividends, which are taxed at a lower rate than income.	More complicated from a tax and legal standpoint than LLC Cannot have multiple classes of stock Must report employee taxable compensation
C corporation	Multiple classes of stock (ie, preferred stock—provides preferred returns and further protective provisions) More favorable setup for employee compensation Allows the owners to take advantage of certain provisions in the tax code regarding exclusion of a certain amount of capital gains and the deduction of certain losses	More complicated from a tax and legal standpoint than LLC A taxable entity (the corporation itself is taxed on its income) Distributions of profits (dividends) are subject to double taxation

Abbreviation: LLC, limited liability company.

Step 6: Identifying Topics for Independent Learning Versus Extended Due Diligence

Despite your finest efforts to compose a well-rounded formation and advisory team, independent learning on your behalf will be required. There is great current and future value in learning some of these adjunctive business skills yourself. You will likely encounter terms and concepts that will be present in future contracts and your own business pursuits. Early mastery of these concepts may afford you the opportunity to avoid bad personal business decisions in the future. In cases of mobile health applications, research into Health Insurance Portability and Accountability Act of 1996 regulations and privacy is important. For novel biologics or medical devices, knowledge of Food and Drug Administration approval and clearance pathways and clinical trials is imperative. In addition to numerous online resources, you can often find local or regional start-up incubators that host multidisciplinary educational sessions. Many large law firms and start-up incubators (eg, Y Combinator) offer free online start-up document templates that are helpful to reference as you finalize your legal strategies. Just remember, the motivation of these companies to facilitate the process is not necessarily altruistic. It's important to have members outside of your team sign a nondisclosure agreement before disclosing your idea. Alternatively, you can have a generic conversation that discusses your concept without compromising its novelty. And finally, push yourself beyond your comfort zone. As a physician entrepreneur, maintain a leadership role. If forming a company will help bring your invention to market, stay on as the chief executive officer, president, or chairman of the board. This will likely maximize your ownership and, possibly, your ability to bring your invention to the customers who need it the most.

Step 7: Tackling the Issue of IP

If you're a practicing physician, you've likely signed an institution-specific IP policy. These policies are often purposefully broad in nature, but typically have 2 common features. To be covered under their IP policy, institutional resources must have been used in the conception of a novel device or method. Alternatively, if the novel idea falls within the scope of your employment description, it is likely covered. Nonetheless, it's important to seek legal guidance before speaking with your institution's or practice's—as many practices will take a member's IP—technology transfer office. The technology transfer office will ask you to submit an invention disclosure, which they will use

Table 2

Funding Sources

Source	Description	Advantages	Disadvantages
Bootstrapping	Using your personal funds	Maintain all equity The surge of crowdfunding	Limited resources May take a long time to save money
Small business grants	Federal or state funds allocated for small businesses	The government does not charge interest or take equity	Long, exhausting process Strict eligibility
Loans/lines of credit	Small Business Administration loan Bank line of credit	The Small Business Administration loan amounts are offered at a lower interest rate because it is guaranteed by the government	Commercial banks may be dismissive of start-ups unless you have personal collateral at risk Requires strong credit history and existing assets
Incubators	Organizations (university company, community organization) that provide resources (office space, marketing, laboratories, consulting, funds) in exchange for equity	Ability to use sophisticated resources from the get-go Formal support structure with inspiring environment and expert advice	May have to give up significant equity Rigorous and competitive application process Incubators are also run like a business and may force adherence to structure and time commitment
Angel investors	$25,000-$250,000 High-net-worth individuals interested in supporting start-ups	Often willing to take risks Typically bring years of expertise to the table and understand what it takes to succeed Flexible business arrangements	May have to give up significant equity No national registry for angel investors (remain hidden and mysterious) May unwillingly be forced to give up some degree of control
Venture capital	Often >$1,000,000 Corporations that make calculated investments in start-up companies that show the best potential of turning a profit	The money is often yours to keep (not a loan) Can become connected to other business leaders who can help	May have to give up significant equity Large time commitment for search (often more than 6 months) Company may not be ready to grow quickly Will often only invest where they anticipate a >10 times return
Form a partnership	Partner with an established company with strategic interest in working to help develop your product (with willingness to advance funding)	Differing strengths, opinions, and experiences Provides immediate access to high-level expertise and large resource networks	Differing strengths, opinions, and experiences

to perform patent, copyright, or trademark searches. Invention disclosures typically assign your IP to the institution. As the owner of your IP, they will act in the best interest of the IP and may not necessarily allow you or your start-up to continue to use your invention. For your start-up or others to use the IP, an exclusive or nonexclusive agreement may be reached. Often the institution will assess the cost of protecting the IP of your proposed invention and reach an agreement such that they recover at least those costs in return from licensing. If your start-up venture is unable to create that much capital, the institution will likely seek an equity stake in your start-up. The percent ownership will be based on your company's valuation. In the case of a start-up valued at $1,000,000 (a common valuation) with $100,000 in IP protection costs, they may seek a 10% equity share for an exclusive licensing agreement in perpetuity.

In some cases, orthopedic surgeons (residents, fellows, or attendings) have an opportunity to formally review and request amendments to the employment contract (institution based or in private practice), specifically regarding the IP ownership, prior to their employment. The fine details of the contract must be critically reviewed. This is especially important if you can prove that the original idea and initial work were generated prior to your employment.

Step 8: Maintaining a Balance Between Work, the Start-up, and Life

A successful start-up is dependent on many factors, and a strict guide for how many hours to work per week doesn't exist. As a side project, most work is typically done in the evenings. When the inspiration is flowing, this can carry over into the

weekends. Of course, this type of commitment isn't always available to physicians; so, efficiency is critical to success. Set aside some of your most productive time for your start-up. Let the ideas flow and write them down. Remember to log your ideas as they come to you, even if it is at 2:00 am. Work with your team to develop managerial skills by assigning appropriate tasks. Engage your team in their tasks so it doesn't feel like work for them. In the end, have fun with it. If you're productive, keep going. If you're burnt out, give it a break. In the end, practice grit. Make your idea a reality!

Conclusion

A start-up project is a rewarding experience that will teach you basic entrepreneurial skills while providing you with the right knowledge to critically analyze future opportunities. Taking the right steps can save you time and headaches while maximizing your chance for success. Like anything, practice makes perfect. So, if you're faced with a failed first project, take what you learned during that experience and apply it to your next project!

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