The Making of an Instrument: From Concept to Market

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ABSTRACT

This is an account of the steps one goes through in the development of a new device or instrument. It starts with the conditions that generate the need and then the concept of a new instrument and goes through the process of designing it and protecting it with a patent; it then proceeds through the development of a working prototype and a final refined product. It provides an outline of the steps needed to get the device into the national or international market by selling or licensing it to a company willing to develop it.

To be able to demonstrate this process of invention and give real life to the steps involved in the making of an instrument as mentioned above, I describe the circumstances that generated the idea and the development of the Christoudias Tissue Approximator Grasper. The patent is published as issued to demonstrate its different components.

Key Words: Laparoscopy, Instrumentation.

INTRODUCTION

The introduction of modern video equipment in laparoscopic surgery has led to a widespread acceptance of this modality as the dominant method for many procedures in all surgical specialties. This revolution in the art of surgery, however, has in turn created a great need for new instrumentation. Multifunctional instruments that decrease or eliminate the need for repeated instrument exchanges or decrease the number of ports needed for a certain procedure are areas of continuous research and development with hundreds, if not thousands, of engineers who are currently addressing the issue.

As surgeons practicing minimally invasive surgery, we are generally the first to identify the need for a new instrument that could perform a certain function in a better way. The need in turn can generate the idea or concept which may then lead to the design and development of a new instrument. If that instrument provides features that facilitate or advance the art of surgery and, at the same time, provides an opportunity to the instrument companies to realize a financial gain, then it may gain the attention of the practicing surgeons and deserve the interest of the surgical companies.

THE STEP-BY-STEP ACCOUNT OF THE PROCESS

The Need

I started doing TAPP herniorrhaphies approximately six years ago. The frustration generated by the difficulty in approximating the peritoneum at the end of the TAPP herniorrhaphy forced the idea for the development of an instrument that could do the job safer, faster and more efficiently.

Bringing together, with one grasper, the opposing edges of the opened peritoneum at the end of the TAPP herniorrhaphy is at times an impossible task, more so for the inexperienced minimally invasive surgeon. Usually one edge of the peritoneum is grasped first and brought to the opposing edge; the jaws are then opened to accommodate the opposing edge in addition to the first edge. More often than not, the edge engaged first slides off the open jaws and forces repeated attempts until the engagement of
both edges by the same grasper succeeds, allowing stapling or suturing of the peritoneal edges.

One way of facilitating the approximation process is to use two graspers. The first one enters through the stapler’s port, engages the more mobile inferior edge and brings it close to the superior edge, allowing the second grasper to engage both of the approximated edges with one move. The first grasper is then removed and the stapler inserted to fix the approximated edges together.

This, however, is time consuming and demands repeated instrument exchanges before closure of the peritoneal opening is accomplished, especially if leaving of the peritoneum occurred during the dissecting phase. Whenever I reached that point of the TAPP herniorrhaphy, I kept saying to myself over and over again, “There has to be a better way.” The need for an approximating instrument had made its presence known to me in a very clear and convincing way.

The Idea

A new instrument was generated in my mind which I called “The Approximator.” This new instrument’s principal property was the ability to grasp the tissue at a first point, advance it to a tissue at a second point and grasp tissue without dropping the first one; this effectively approximates the tissues at the two desired points. The approximator would do just that if it had two independently operated jaws; the first jaw would grasp the more mobile edge of the peritoneum, advance it to the less mobile edge, which will then be engaged by the second jaw, approximating the edges in a very fast, safe and expeditious manner. The development of the approximator was conceived by designing a central plate on the head of the instrument with a separate jaw functioning independently on each of its sides (Figures 1, 1a, 1b, 1c, 1d).

Conceptually, the approximator appeared fine at the level of the independently operated jaws, although it was evident that a totally innovative design for two independently operated controls had to be developed. It just came to mind that the standard ratcheted grasper had a relatively bulky handle, which, at times, presented in itself some difficulty during the opening or closing of the jaws during the course of laparoscopic operations. I then pictured two ratcheted controls on a more bulky handle, each needing active release and active recapture. That, to me, spelled a very user-hostile instrument, if it could be made functional at all. A user-friendly control had to be devised if the approximator’s concept had any chance for realization.

After some intense thinking, the push-button active jaw opening and passive jaw closure control emerged (Figure 1a). Activation of the spring-loaded control will open the jaw, and release of the control will close the jaw and engage the tissues. This design will allow plenty of room on the handle to accommodate a second control. Furthermore, since each control can be activated easily, both controls can be activated together if desired in a simple, efficient and expeditious manner.

So, “The Approximator” was now ready in the mind but it
needed to be transferred onto paper to a functional level. For me, being mechanically inclined, designing the instrument was easy. It only took about one hour to complete the conceptual design of my approximator (Figure 1a). Help from a mechanical engineer may of course be necessary in the event that you are unable to translate your instrument idea into a drawing.

Applying for a Patent

Certain criteria have to be met for patent eligibility. An idea, instrument or device has to be sufficiently different from prior technology. At this point, having conceptually produced a new instrument, we are ready to proceed to the next step of protecting it with a patent application, preferably with the help of a patent attorney. The patent application includes the abstract of the invention (Figure 1), which describes in short the content and intent of the invention; the text (Figure 2a, 2b) and drawings (Figure 1a, 1b, 1c, 1d) follow and then, finally, the claims of the invention (Figure 2a, 2b). The text includes the “background of the invention,” indicating the circumstances leading to its development; a “summary of the invention” follows, which describes in short the apparatus and its function and associated advantages and objects which are further described in the “description of the drawings.” A “detailed description of the invention” is a detailed account of the different instrument portions and the way the instrument is used. The most important part of the patent relates to the claims (Figure 2b). This is the section where you spell out what you consider to be the new elements which make up your invention and claim them as yours. They could include the actual components of the instrument in part, the instrument as a whole and the method in which this instrument is used. In the case of the approximator, the claims are focused on the presence
of two independently operated jaws by two independently operated controls and the method of grasping and approximating tissues with one instrument. These are features that are not present in any other instrument. The issuing of a patent, however, may prove a long, expensive and time consuming process which can take two or more years. Once the patent application is received by the patent office, the idea, instrument or device, goes on file and is protected, provided that no one else has laid claim on it before. This should be determined by a patent search, which the patent attorney can do for you, or you may be able to check it out on the Internet if you are a computer-sophisticated individual.

The First Prototype

With the patent application on file, we can now proceed to the manufacturing of the first prototype that will give flesh and blood to our idea. There are two ways to go about it. The first would be to find an instrument maker to manufacture the prototype for you. The other way would be to offer your idea, as developed to this point, to the different surgical companies and see if anyone has any interest in developing it. The first option is more expensive but it gives you more control on proceeding with the prototype development and “reduction to practice,” which legally means actual application of your idea into practice.
The whole process of patenting and developing a prototype can be an expensive proposition, but if one believes that the new instrument is really needed then it may be worth the expense. Of course we cannot lose sight of the fact that if the patented instrument does not eventually make it to the market, we wind up with an expensive plaque we can use to decorate the wall. The alternative is to get a surgical company interested in your idea, which can prove a frustrating process. You need to find the right person in the company who has the ability to comprehend what your idea really is and how it works. Furthermore, that person has to be interested in pursuing your idea. The "right" person of the surgical company can be the director of research and development or the director of marketing of the company. Both are generally extremely busy people involved with quite a lot of different projects and responsibilities with too little time to devote to your idea or invention. I have found this route to be very unproductive and, at times, frustrating, so I generally prefer to have my own instrument maker develop my first prototype. This gives me the freedom of decision-making and the ability to proceed with the production of the prototype in an expeditious manner. Once the prototype is manufactured and tested in vitro, necessary modifications are done, and the instrument can be used in the operating room. By actually taking my idea to the final step of applying it in an actual procedure, it can prove whether it is functional or not. Provided the instrument does fulfill my expectations, I then have the advantage of being able to do a video presentation of my invention to such advantage as to make a very good impression on the prospective companies.
invention in action and can demonstrate its function in a clear and convincing way. The video of a prototype, I believe, is much superior to any verbal or written description of what the proposed new instrument could do or, to paraphrase an old saying, if “a picture is worth a thousand words,” then the video is worth a thousand pictures.

I came across an instrument maker who could produce the approximator, while attending an advanced laparoscopic course in Boston. We reached an agreement for the manufacturing of a prototype, and I proceeded to send him the plans.

At the same time an application for a “510(K)” form for Federal Drug Administration (FDA) approval of the instrument was filed by the instrument maker on my behalf. The FDA approval was received by the time the first prototype was made. Since then, new FDA regulations have waived the need for FDA approval for free hand held instruments such as the approximator. It is prudent that you consult with your patent attorney licensing it.

In two months, I had a prototype (Figure 3, 4) which I tested in the TAPP herniorrhaphies. It was very rewarding to see the new instrument perform just as I had hoped it would (Figure 5). For the first time I breezed through the peritoneal approximation phase without frustrations.

Licensing the Instrument

I made sure that the use of the instrument was recorded on video on every occasion it was used. I then put the video clips together and contacted the appropriate persons for evaluating the instrument in different surgical companies. I explained what the instrument was about.
and asked them whether they had any interest in looking at it. If they agreed to evaluate it, I proceeded to ship the actual instrument to them. The two giant companies I sent the instrument to first liked it but were not interested in developing and marketing it, probably because it could not be made into a disposable item. I then mailed it to another big company after talking to the director of research and development, and I discussed it with the director of marketing of a smaller company of mainly reusable instruments. The director of research and development of the bigger company showed immediate interest and wanted his company to enter into negotiations for licensing the instrument for development and marketing.

He talked to the director of marketing, and he was in the process of exploring the possibilities of manufacturing and marketing the instrument. After several weeks, I sent the second prototype to a smaller company. I received a call from the director of marketing the very day he received the prototype and the video. He informed me that he believed the approximator would be an “impact instrument,” and his company was very interested in licensing it. Soon thereafter, we negotiated an agreement. By the time the machine of the big company was put into motion, I had already finalized an agreement with the smaller company. What I liked about the small company was that the people I was dealing with could make final decisions and give me definitive answers or commitments just as I could do for them.

Within a week, we had a written agreement which spelled out the royalties, exclusivity, timetable for production and marketing guarantees.

Production and Marketing

The instrument was redesigned with my specifications into a more refined, less bulky and easier to manipulate final product (Figure 3, 4). The jaws were redesigned (Figure 4) to hold firmly the engaged tissues without choking and at the same time cause only minimal trauma to the tissues (Figure 5). The final prototype was manufactured and given to me for evaluation. After three months of intensive use, there was one more modification needed. This final modification would allow the operator to associate the controls with the corresponding jaws. The solution was to color code the jaws, which are viewed on the monitor with corresponding tactile coding of the controls. The jaws were made into one “golden” and one “silver” (Figure 5) and the controls into a “high” bubble and a “low” dimple control (Figure 3). The gold is always higher than the silver, and, therefore, the “high” bubble control corresponds to the golden jaw and the “low” dimple control to the silver jaw. After intensive use of the instrument in more than 60 laparoscopic herniorrhaphies and cholecystectomies, the approximator proved to be an extremely useful and helpful tool in laparoscopic surgery. It was, subsequently, produced and introduced to the national and international market.

SUMMARY

The practicing surgeon is generally the first to identify the need for a new device, instrument or technique. Identifying the need can lead to the concept of a new instrument or device. In turn, designing, patenting and developing this instrument may facilitate the performance of surgery and advance the art of surgery to a higher level. The steps that lead from concept to market of a new instrument are outlined in a concise fashion.

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