Applying TRIZ to Breakthrough Innovations in Healthcare

Valeriy Prushinskiy

Abstract

Learn how TRIZ-tools apply to healthcare. Understand how TRIZ-methodology enables the creation of short-term and long-term next generation ideas in the area of endoscopic surgery from concept, through prototyping, to TRIZ-forecasting via applying the Directed Evolution process, and building an extensive IP portfolio for Natural Orifice Transluminal Endoscopic Surgery (NOTES). NOTES is an experimental surgical technique whereby "scarless" abdominal operations can be performed with an endoscope passed through a natural opening, thus avoiding any external incisions or scars. Leading endoscopic surgeons seriously consider NOTES to be the next major paradigm shift in surgery, just as laparoscopy was the major paradigm shift during the 1980s and 1990s.

One of the main TRIZ concepts is “systems evolve not randomly, but according to objective patterns.” This way, if we believe in this statement, patterns of technological evolution can be identified based on analysis of historical development of technology, markets and various social trends. As a result, identified patterns can be purposefully applied for product or system evolution, avoiding simply searching in the dark. This body of thoughts created the basis for development of various forecasting tools in the framework of modern TRIZ. The subject of this presentation is applying the Directed Evolution (DE) process to healthcare in order to develop new concepts for endoscopic instruments and procedures. Usually, Directed Evolution Process includes the following stages (fig. 1):

- Collection of historical data
- DE diagnostics
- Synthesis of ideas
- Decision making
- Supporting the process of evolution

Fig. 1

This project was implemented by Ideation International Inc. in cooperation with Creighton University; due to this partnership, it was possible not only to conduct the initial stages of diagnostics on the system and to generate ideas, but also to prototype selected ideas, test them, work out selected concepts, develop IP portfolio, and commercialize it.

Since the time of the presentation is limited, only the selected stages of the Directed Evolution process will be illustrated. During the data collection and diagnostics stage, one of the patents of our partners attracted our attention. The main goal of this patent was the development of methods which would help to stabilize the endoscope when it entered into the wide body cavities like the stomach. Stability is important because the endoscope is flexible: while it is held in the narrow passages of the gastrointestinal tract, it flexes in the stomach. Along with the description of proposed methodology, we found the following picture in this patent (fig. 2).
This picture describes an operational endoscope. It looks like a regular scope, but there are two arms on the left and right sides of the device. What is their purpose? Surgeons successfully cut and re-connecting tissues as during various operations; for endoscopic operations they also want to have two tiny and strong arms that are as able as the their own arms during open surgery. Basically, these arms imitate human suturing: one “hand” will be able to cut tissues, and the second one will hold the needle and suture tissues. After studying the problem during the Directed Evolution diagnostic stage, it became obvious, that it would be very hard to implement the given approach because in the process of miniaturization, surgical instruments start to behave differently. For example, when we try to make the hand smaller by making a tiny arm for the endoscope we also have to reduce the size of the needle. However, a smaller needle is not be able to penetrate deeply into the tissues, through their full thickness, and, during suturing, to hold the tissues effectively. The implementation of this making an instrument like a “human” principle to tissue connection makes the system too complex. Very often, on some stages of the system evolution, it is necessary to go through the transition from the “human” principle toward the “machine” principle of action.

How exactly we can do this step was clarified in the later stages of the process. During the Directed Evolution diagnostic stage, we found one device, which could provide interesting resources for tissue connection. This device is called a “power shot,” and it is a long flexible needle, which is able to drive through the tissues of a tiny metal bar with short suture, connected to it. This metal bar, called T-tag (fig. 3), can be driven deep into the tissues, then rotated to serve as a reliable anchor for various surgical devices. Currently, these devices are not utilized for tissue connection.

After the initial diagnostics, during the stage of synthesis of ideas of the Directed Evolution process, we decided to check out how a given device will evolve along the well-known “mono-bi-poly” pattern. Based on this pattern, the concept of the device made use of multiple T-tags connected by continuous suture was generated. Oversimplifying a little, we can imagine that when the tissues are cut, we can shoot many little T-tags along the sides of the cut and then tighten the tissues with a long suture, similar to the way we tighten our shoelaces. Of course, the reality is much more complex, so the next step was to develop the concept of an endoscopic attachment, which would “shoot” the T-tags and be small enough to penetrate into the stomach with the endoscope (fig. 4).

T-Gun concept is a novel suturing device for use in multiple endoscopic operations. The T-Gun apparatus is an endoscopic attachment containing a chamber loaded with T-tags connected by a continuous suture (if required), which is fastened on the distal end of an endoscope. The T-tags are driven through tissues of the gastrointestinal tract or colon mechanically or pneumatically by CO2 powered firing. The chamber is then rotated to introduce the next T-tag for firing. Existing laparoscopic suturing requires complicated choreography performed by a highly trained surgeon. The proposed procedure is manually less difficult for surgeons performing operations requiring full-thickness, continuous suturing. The T-Gun is advantageous for no-needle suturing in procedures such as intraluminal anti-obesity gastroplasty, full thickness colon or stomach suturing, suturing for upper GI bleeding in the stomach, and treatment of Gastroesophageal Reflux Disease (GERD).
The concept of this device went through design and prototyping; in the video, you can this device in action during animal experiments. Usually, after the generation of a concept of a new device, one has to check how the device will behave in the process of various surgical operations, and then adapt the device for each procedure, creating a family of devices which can be used to conduct various operations. For this, it is necessary to study how these operations were carried out in the past, and how they will be done in future.

The trend of transition from open operations to laparoscopic operations carried out by special thin and long instruments through small openings was identified during the Directed Evolution diagnostic stage. Now we are at the beginning of next step – the transition from laparoscopic operations to operations through natural openings – NOTES. NOTES is an abbreviation for Natural Orifice Transluminal Endoscopic Surgery (NOTES). What is hidden behind this five-letters acronym? NOTES is an experimental surgical technique, through which “scarless” abdominal operations can be performed with an endoscope passed through the natural openings, thus avoiding any external excisions or scars.

The transition toward this new stage requires absolutely different surgical instruments. After study of the existing population of endoscopic instruments, a Map of Potential Evolution of the endoscopic tools was built for NOTES-applications. The development of evolutionary maps enables the integration of separate evolutionary patterns and the visualization of leading trends in the studied field. The main difference in between Evolutionary Maps and the application of separate patterns existing in various types of the TRIZ forecast is opportunity to hybridize several patterns and integrate of solutions obtained by applying individual patterns to the evolution of the selected system. The Map of Potential Evolution is developed through the following steps:

- Research existing trends in the super-system of the given product/system and reveal how they influence further development of the product/system
- Check how known evolutionary patterns apply to the given system
- Define the current position of the given system on the evolutionary pattern
- If possible, determine missed steps in the product/system evolution
- Generate possible follow-up steps along the selected evolutionary pattern, coordinating them with higher level trends of the super-system development
- Repeat the process for other known patterns
- Translate the description of the block of patterns into simple terms that can be understood by subject matter experts involved in the development of the product/system
- Create the initial map, placing existing blocks on the left side and possible future steps of the product evolution on the right side
- Consider hybridization between new blocks by obtaining new sub-lines of technological evolution
- Develop a step-by-step textual description of the Map of Potential Evolution for developing an action plan and storing the bank of new concepts

A fragment of the Map of Potential Evolution for the endoscopic instruments for NOTES procedures is given in figure 5.
Steps describing existing evolution, i.e. past and present time of the product or system, are depicted on the left part of the map. Accumulation of information for this side of the map is started during historical data collection and directed evolution diagnostic stages, and continued in iterations during synthesis of ideas, decision making, and supporting the process of evolution. On the right side of the map are steps for the future development of the product. The key point is reflected on the map in both individual patterns and processes of their interaction. This way, the results of crossing ideas that are obtained after working with several patterns of evolution can give birth to new patterns that will then interact with the original patterns. Crossing (or hybridization process) provides opportunities to obtain new steps and lines/patterns of evolution, and this makes the process of forecasting and problem solving much easier. The blue dotted line on the diagram is an imaginary line separating the past and future. Please note that in this picture, we describe a small segment of the Evolutionary Map that is limited by one power-point slide. Real Evolutionary Maps can consist of many interconnected segments, describing several aspects of the development of product family or system. It is of utmost importance to reveal as many aspects as which lead to mid-term and short-term trends in development of the studied system as possible. This helps to define the direction of development and the application of TRIZ-patterns of evolution for a given system. In the given example, the main trend is transitioning from open operations toward laparoscopic operations, and then to operations through one opening, and further toward operations through the natural openings. This trend defines the shape and behavior of future endoscopic tools.

After finalizing the draft of evolutionary maps, the translating back to “normal” language is required. This step will make communication with decision makers, sales and market development specialists, and IP protection officers, easier. Though we all like TRIZ-terminology, and it is easier for us to use it during the development of new concepts and evolutionary maps, we should translate to the language of regular people, if we want to explain our ideas successfully. After translation, Evolutionary Maps are transferred into textual description: various scenarios for future development of the system are created, and decisions about IP protection, which influence future development and focus of the company are made.

Conclusion

Set of scenarios describing the concepts of product families required to implement various endoscopic operations was developed after applying the Directed Evolution approach. The concepts were separated into short term, mid term, and long term groups. An Intellectual Property portfolio and prototypes were worked out and successfully transferred into the established company for further implementation. The concepts, briefly described above represent breakthrough advancements in healthcare technology in the areas of endoscopic instrumentation and procedures. Inspired technological innovation can bring harmony to the often chaotic collision of politics, business, and public welfare. It is clear, through the example of bariatric surgeries, that patient accessibility in these areas is growing. As patient accessibility increases, so does the profitability of surgical products. Serving patients as well as markets, these innovations progress toward less invasive, patient-friendly procedures that hold the promise of increased effectiveness and higher success rates. Simply put – better quality healthcare yields higher profits and greater return on investment.