TECHNOLOGY EVOLUTION

The Technology Spectrum and Its Application to Orthopedic Technologies

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Abstract

The evolution of clinical technologies presents potential adopters with considerations in planning for clinical program development that include the stage and the rate of a technology's evolution. This paper presents a conceptual framework for these considerations and applies the framework to orthopedic technologies. Eight orthopedic surgeons were asked to assess 14 orthopedic technologies and position each of them along a spectrum of research, clinical, and adopted technologies. The distribution of responses for each technology–year combination is presented, and estimates of central tendency, dispersion, and variances provide measures of the change in the distribution of responses over time for each technology and the change in the degree of rater consensus over time for each technology. While orthopedic trauma was chosen to illustrate the technology spectrum model, the model and assessment methodology is applicable to other medical specialties as well. Adoption of this framework in a hospital setting should enable more systematic and effective clinical program development.

Keywords: Technology, Adoption, Assessment, Planning, Orthopedics

In today's cost- and quality-conscious health care environment, it is essential to plan adequately for the adoption of new technologies so that the conversion from older to newer technologies is smooth and appropriately timed. The cost of premature (or substantially delayed) adoption of technologies will be more carefully scrutinized and less tolerated in the current resource-constrained setting.

Adequate planning for technology adoption requires knowledge of: a) the stage in the evolution of a technology at which it will be adopted; b) the current stage

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of development; and c) the rate of development (historic and projected). We present a framework for describing the evolution of a technology and apply it to 14 orthopedic technologies by having eight orthopedic surgeons assess and position them along a spectrum of research, clinical, and adopted technologies for the years 1986, 1991, and 1996.

THE EVOLUTION OF MEDICAL TECHNOLOGIES

Technologies may originate from many sources, such as inspiration, accident, the output of basic research, or a combination of all three. Once conceived, it becomes the focus of a series of research efforts. The first phase involves in vitro research; the laboratory work focused on understanding what the technology is, what it does, and how it works. Next comes applied research. Here the focus is on learning how the technology affects living organisms. The initial testing may be done on body fluids, tissues, or cell culture, progressing to a series of animal studies. In these first two phases, the ultimate structure and function of the technology may be unclear. Development occurs rapidly, and the technology may undergo substantial transformation in its early phases of development. If successful, the technology moves on to application in humans, progressing from controlled experimental settings out into the clinical environment. The primary concern of initial studies is the safety of the technology and the nature and severity of its adverse effects. Larger studies are then conducted to determine clinical benefits, efficacy rates, and frequency of adverse effects. Although the technology is continually refined during this phase, it is fairly well developed and approaching its final form.

Two other characteristics must be established before a medical technology can pass from research into clinical practice: its cost-effectiveness and its appropriate role. The cost-effectiveness of a technology differs from efficacy in that it considers broader, longer-term measures of clinical outcome such as mortality, morbidity, longevity, and patient function, as well as the impact of the direct and indirect cost of care. For example, to measure the efficacy of a cardiovascular drug, one may measure the reduction in cholesterol levels, whereas cost-effectiveness would measure reductions in angina, acute myocardial infarction, etc., and their economic implications in relation to the cost of the drug itself and the cost of its side effects. Moreover, to be meaningful, the measure of cost-effectiveness should be compared to the cost-effectiveness of alternative technologies. The appropriate role for the technology must also be established: whether it should be preventive or therapeutic, at what stage of disease it is to be used, and how it relates to other medical/surgical tools. Although the cost-effectiveness and a role of a technology may begin to emerge from the studies conducted for safety and efficacy, more often controversy over these issues continues, with the debate on the appropriate definitions of "cost" and "effect" as well as differences in practice patterns and philosophy.

Next, the technology passes from medical research to routine clinical practice. Adoption spreads to more doctors and more hospitals. Insurers begin to recognize the technology as cost-effective and approve reimbursement, accelerating adoption. The emphasis is on patient selection and reaching all patients who could benefit. Even after broad-based adoption, the technology itself may continue to undergo minor evolutionary changes that improve ease-of-use, safety, or efficacy.

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Finally, the technology may be replaced as the standard of care when a newer technology emerges, limiting the use of the older technology to settings that lag behind standard of care clinical practice (3;4;9).

TECHNOLOGY SPECTRUM

The technology spectrum is a useful construct to position a particular technology in terms of its "evolution" or "life cycle" and to characterize its rate of development. In positioning a technology on the spectrum, the focus is not only on where the technology happens to be at a given point in time, but also on how quickly the technology is moving along the spectrum. For planning purposes, the principal concern is clearly with the technology's future rate of development; however, understanding the past rate of development and impediments may provide valuable insight into its likely future course.

For institutions seeking to formulate policies on the timing of technology adoption based on the maturation of the technology, the technology spectrum provides a framework for such considerations. From a planning standpoint, if a particular technology is of interest but has not yet sufficiently matured (developed), then anticipating its rate of development is important in order to plan for its adoption and implementation. This is particularly true in the case of technologies that require any of the following: a) substantial capital allocations; b) major facility adaptation; or c) significant training/retraining of technical staff and users (physicians). The lead times that may be necessary to allocate the capital, prepare the facility, or train the staff will prevent an institution from adopting/implementing a particular technology even though it may have "arrived" at a strategically appropriate point on the spectrum. An analysis of the technology in the context of the spectrum can substantially enhance the planning process for new technologies by more tightly linking the optimal timing for the adoption of a new technology with the adequate preparation necessary for successful and timely introduction.

The technology spectrum (Figure 1) itself integrates a variety of "continua" and terminology often used to describe developmental states of a technology. Each continuum or set of terms is actually describing the same underlying spectrum. The major categorical split in positioning a technology is between "medical research" and "clinical practice." Connecting this dichotomy is the notion of moving along the continuum that begins with the creativity and uncertainty of state-of-the-art technologies and evolves to the "state of the science," where technologies are applied in a more deliberate fashion based on the solid evidence of accumulated experience and data. This latter extreme is reached when a technology becomes so well accepted (and proliferated) that all aspects of it are known with "scientific" precision.

Central to the technology spectrum is the concept of "edges"—a specific continuum that describes a medical technology at any point in its evolution. In a previous paper, Mikhail et al. (5) developed an early version of the technology spectrum with three regions. The spectrum has been expanded to five distinct regions: virtual, cutting, leading, standard, and trailing. The *virtual edge* refers to technologies that are still in the conceptual phase. The *cutting edge* refers to technologies that are experimental or those that are just emerging from the realm of basic research into the very beginning of applied research. For these technologies, feasibility has not yet been established. The research itself is still in the in vitro or animal stages, although some very limited human testing may be conducted. At

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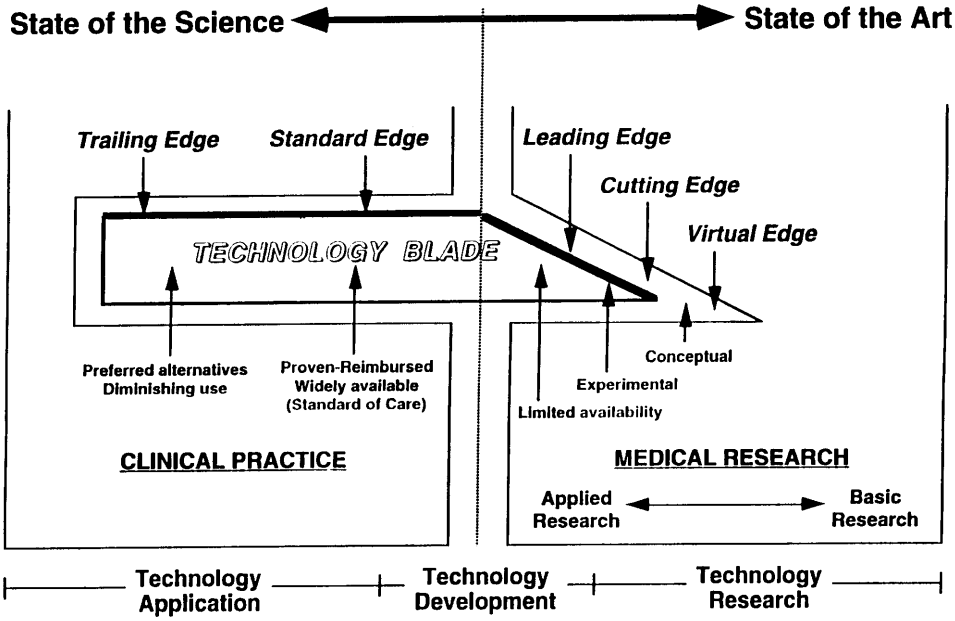


Figure 1. The technology spectrum.

this stage, there is no FDA approval. At the *leading edge*, the technology is within the realm of applied (medical) research, while emerging with limited availability in clinical practice. While the technology itself may be reasonably well developed, and may have or be close to FDA approval, its cost-effectiveness and role in clinical practice is not yet fully established. As a technology becomes broadly demonstrated with routine use in leading community hospitals, with sufficient evidence of proven cost-effectiveness for reimbursement, it makes the complete transition from medical research and development to standard of care clinical practice and lies on what may be described as the *standard edge.* Finally, when a new standard of care emerges, the old technology transitions into the *trailing edge*, and its use is limited to settings that tend to lag behind standard of care clinical practice.

Plotting the status of all technologies within any given medical specialty yields the technology spectrum for that specialty.

As a technology moves along the spectrum, the nature of the decision to apply a technology also evolves. This decision is influenced by a number of general considerations that a clinician faces when choosing to apply that technology in any particular situation or set of circumstances. These considerations include:

1. Indications
   The appropriate (clinical) use of the technology;
   The cost-effectiveness of the technology;
2. Outcomes
   The expected clinical results—effect on the patient;
3. Application/Use
   The hands-on procedural/technique considerations in the actual use of the technology.

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As a particular technology matures along the spectrum, the process of development will cause the nature of the decision to change by reducing: a) uncertainty in indications; b) risk/uncertainty in outcomes; and c) difficulty in application. Thus, the maturation process for a technology clarifies indications, improves outcomes, and eases use. Consequently, the perception that a particular technology presents (to both the clinician and the patient) changes as the technology evolves along the spectrum.

RATE OF TECHNOLOGY EVOLUTION

Although all health care technologies must go through the same evolutionary process as described in the technology spectrum, their pace of evolution varies widely along the spectrum. In general, pharmaceuticals have the slowest rate of evolution, while nonimplantable devices have the fastest rate, and implants fall somewhere between. However, within these broad categories, time frames vary widely. Moreover, progress is rarely smooth. Technical, regulatory, economic, and political problems may slow or stop progress at any point along the spectrum, and new data can cause major setbacks.

Several factors influence the speed of technology development and adoption. In order of importance, these are:

1. Regulatory (FDA) requirements;
2. Technological challenges;
3. Degree of clinical benefit/severity of complications;
4. Nature of clinical trials needed to prove benefit and lack of complications;
5. Reimbursement issues;
6. Ease of use.

Each variable will be considered separately, though in reality they are often interrelated.

The need for FDA approval is a phenomenon peculiar to US medical technology. There are no other segments of the US economy in which every product must pass through such a lengthy and complex federal regulatory process prior to commercialization. Although regulatory requirements are strictest in the United States, they are increasing worldwide (4). There are many different routes of approval, depending upon the nature of the technology and its application (9). For example, drugs, biologics, and devices each follow a different regulatory path to approval. The more novel the technology, the longer the typical regulatory time frame. For example, new chemical entity drugs and new implantable biomaterials require a much longer time for approval than do generic drugs or "next generation" devices.

Although the remaining factors are typically less important determinants of the rate of technology evolution, major problems in any one area can bring progress to a near standstill. The technical challenges a technology faces relates to its complexity, how well it is understood, and how demanding the performance requirements are for its application. Novel technologies applied to intractable clinical problems clearly face the greatest challenges and are prone to setbacks. The magnitude of potential patient benefit of a technology relative to complications is also important. Technologies offering major clinical benefits with only minor complications will attract more research effort and money, and therefore may be fast-tracked

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through the regulatory process; these technologies will develop more rapidly than technologies offering only marginal benefits over existing methods, particularly if they have the potential for serious complication. For example, AIDS drugs are fast-tracked through the FDA, while silicone breast implants for cosmetic augmentation have been pulled from the market because of a small (and debated) risk of carcinogenicity. A related factor is the nature of clinical trials needed—the number of patients needed to show statistical significance, length of follow-up, and ease of measuring clinical end points. Difficulty in measuring clinical end points can cause serious delays in technology adoption: clinicians may disagree as to the importance or meaning of available measurements, or may agree on a measure but are unable to use it in the context of a clinical study (e.g., "second-look" invasive procedures). Finally, reimbursement and ease of use are important factors influencing adoption in the clinical practice phase.

Clearly understanding these factors and their impact on a technology's rate of evolution is essential to effective preparation for the successful adoption and implementation of a particular technology.

APPLICATION TO ORTHOPEDICS

We applied the technology spectrum to musculoskeletal conditions as a test of its utility as a tool for technology planning. This clinical area is one of the heaviest users of health care technology, including diagnostics/radiology, pharmaceuticals, physical therapy systems, and surgical/interventional products (2;6;7).

METHODS

During the September 1996 meeting of the Orthopaedic Trauma Association, eight board-certified orthopedic trauma surgeons were asked to individually assess 14 relevant technologies and assign each of these technologies to one of the five edges of the technology spectrum. They were asked to assess each technology's status as they perceived it to have been in 1986, 1991, and 1996.

Thus, data were available for each of eight evaluators for each of 3 years for 14 different technologies. For each technology–year combination, each evaluator rated the technology in one of the five technology edges. These ratings were qualitative and nominal. The scaling system used preserved the nominal scale. For each technology–year combination, each rater's evaluation was converted to a five-tuple vector (a vector with five elements). Since the evaluator chose one of five ratings, the entry in the five-tuple vector signified the chosen rating and was scored as one and each of the other four was scored as zero. From this transformation, the mean response for each technology–year combination was evaluated as the centroid (mean) of the eight evaluators' vectors.

The variance estimates for each technology–year combination were based on the variability of the eight evaluators for that technology–year combination. The variability of the eight five-tuple vectors was found in the five-by-five dispersion matrix for the eight evaluators. This disperson matrix was computed from the square of the difference of each evaluator's vector and the centroid vector of all evaluators divided by seven. Thus, the variance for each technology–year combination was the sum of the diagonal elements of the variance–covariance matrix.

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RESULTS

The results are given in Tables 1 and 2. The tables reflect the distribution of responses for each of the 3 years (Table 1), the change in the distribution of responses over time for a given technology, and the change in the degree of consensus over time for a given technology (Table 2).

Table 1 is useful for mapping the migration of individual technologies along the technology spectrum over time. A centroid vector of (0,0,0,0,1) denotes that all evaluators rated the technology the same, while a centroid vector of (0.25,0,0,0.25,0.50) shows that the evaluators were divided between three ratings, with four of the eight evaluators choosing the last rating, and the other four evaluators equally split between the first rating and the fourth rating (1;8). For example, the bioactive bone grouts/glues are shown to migrate from a consensus virtual edge technology in 1986 to a mixed assessment in 1996 that spans from a virtual edge through a standard edge rating.

In Table 2 the variances are collapsed to one number for each technology–year combination and are interpreted as before. A variance of zero reveals no variability among the evaluators, and for our study design a variance of 0.890 was the maximum variability among the evaluators for that technology–year combination.

The total variances shown in Table 2 reflect the degree of consensus among the eight orthopedic surgeons' ratings of the technologies over the 10-year time interval. The greater the variance, the less the consensus among the raters. For example, the greatest consensus (as reflected by the least total variance in the rating [0.250]) was for metallic internal fixation devices. In contrast, lowest degree of consensus was for synthetic bone grafts and ultrasound fracture stimulation (as reflected by the greatest total variance in the ratings [2.069]).

DISCUSSION

Although orthopedic trauma was chosen as the particular medical subspecialty for our study, the model and assessment methodology are readily applicable to any medical specialty. It was not the purpose of this study to draw conclusions regarding orthopedic trauma technology, but rather to use orthopedic trauma to illustrate the model (technology spectrum) and methodology for technology rating. The technology spectrum as an analytic tool characterizes the evolutionary path of a technology and captures the degree of consensus among clinicians with respect to the positioning of that technology along the spectrum.

From a practice perspective, this model may be useful for physicians and hospitals in anticipating the evolution of medical technology and appropriately preparing for that evolution. From an operational perspective, variability in physicians' practices can be highlighted and appropriately managed.

From a strategic perspective, physicians and hospitals can use the model to make explicit decisions regarding their technology options and selected posture. The managerial significance in applying this model rests in aligning the perspectives of the medical staff (regarding various technologies) with the institution's (e.g., the hospital) selected strategic posture regarding technology.

In an earlier paper (5), we identified five distinct technology postures that an institution could adopt as a matter of strategic choice: a) leading edge state of the art; b) close second; c) competitive; d) proven/essential standard of care; and e) technology skeptical—"high touch." The rationale for the choice may be based on

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Table 1. Centroid Report by Technology—1986, 1991, 1996

	Centroid, 1986					Centroid, 1991					Centroid, 1996				
	t	s	l	c	v	t	s	l	c	v	t	s	l	c	v
Bioactive bone grouts/glues	0	0	0	0	1	0	0	0	0.5	0.5	0	0.125	0.125	0.625	0.125
Bone allografts	0	0.5	0.375	0.125	0	0	0.75	0.25	0	0	0	0.125	0.125	0.625	0.125
Pins in plaster for fractures	0.75	0.25	0	0	0	1	0	0	0	0	1	0	0	0	0
Oral narcotics	0.125	0.875	0	0	0	0.25	0.75	0	0	0	0.375	0.625	0	0	0
Synthetic bone grafts	0	0	0.125	0.5	0.375	0	0.5	0.125	0.25	0.125	0.125	0.625	0	0.125	0.125
Ultrasound fracture stimulation	0	0	0	0.25	0.75	0	0.125	0.125	0.5	0.25	0.125	0.25	0.25	0.25	0.125
Nonunion electrical stimulators	0	0.375	0.625	0	0	0	0.75	0	0.125	0.125	0.25	0.5	0.125	0	0.125
Virtual 3D imaging	0	0	0	0.125	0.875	0	0	0.125	0.25	0.625	0	0	0.25	0.5	0.25
Unilateral external fixators	0	0.875	0.125	0	0	0	1	0	0	0	0	0.875	0.125	0	0
Circular thin wire external fractures	0	0	0.375	0.625	0	0	0.375	0.625	0	0	0.125	0.625	0.125	0.125	0
Bone growth factors	0	0	0.125	0.25	0.625	0	0	0.125	0.625	0.25	0	0	0.5	0.25	0.25
Metallic internal fixation devices	0	1	0	0	0	0	1	0	0	0	0	0.875	0	0.125	0
Bioabsorbables internal fixation	0	0	0.25	0.625	0.125	0	0.25	0.625	0.125	0	0.25	0.25	0.375	0.125	0
Antibiotic beads	0	0.5	0.375	0.125	0	0	0.75	0.25	0	0	0	0.875	0.125	0	0

Abbreviations: v = virtual edge; c = cutting edge; l = leading edge; s = standard edge; t = trailing edge.

Table 2. Total Variance for Each of the Technologies

	Variance			
	1986	1991	1996	Total
Bioactive bone grouts/glue	0.000	0.571	0.643	1.214
Bone allografts	0.679	0.429	0.640	1.748
Pins in plaster for fractures	0.429	0.000	0.000	0.429
Oral narcotics	0.250	0.429	0.540	1.219
Synthetic bone grafts	0.679	0.750	0.640	2.069
Ultrasound fracture stimulation	0.429	0.750	0.890	2.069
Nonunion electrical stimulators	0.536	0.464	0.750	1.750
Virtual 3D imaging	0.250	0.607	0.710	1.567
Unilateral external fixators	0.250	0.000	0.250	0.500
Circular thin wire external fractures	0.536	0.536	0.640	1.712
Bone growth factors	0.607	0.607	0.710	1.924
Metallic internal fixation devices	0.000	0.000	0.250	0.250
Bioabsorbables internal fixation	0.607	0.607	0.820	2.034
Antibiotic beads	0.679	0.429	0.250	1.358

a variety of considerations, including institutional mission, market/competition, and internal strengths and weakness. Regardless of how the institution's technology posture is selected, such a choice should be made explicitly with clear criteria, rather than by default. Moreover, technology decisions should generally adhere to this position posture, although occasionally opportunistic and extenuating circumstances may lead to technology decisions that are at variance with the institution's overall posture.

Historically, systematic program development has not existed within hospitals. Technology decisions, which are a major component of clinical program development, have been opportunistically driven by members of the medical staff pursuing their individual areas of interest and expertise. The lack of disciplined, comprehensive program development is currently being addressed in a number of hospitals. Essential to successful resolution of the current program development deficiencies is the effective integration of technology decisions into the program development process. A methodology for forging a medical staff consensus on technology and relating that consensus to the institution's technology posture will contribute significantly to systematic program development.

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