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# A SOCIO-COGNITIVE MODEL OF TECHNOLOGY EVOLUTION: THE CASE OF COCHLEAR IMPLANTS

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This paper examines the social and cognitive processes that unfold over time as a technology develops. Our model focuses on the relationship between the beliefs researchers hold about what is and is not technically feasible, the technological artifacts they create, and the routines they use for evaluating how well their artifacts meet with their prior expectations.

The historical development of cochlear implants serves as an illustration of the model. The evidence suggests that there is a reciprocal interaction between beliefs, artifacts, and routines that gives rise to two cyclical processes. One is a process of inversion at the micro-level of individual cognition wherein evaluation routines designed to judge specific artifacts begin reinforcing researchers' beliefs. Once evaluation routines become the basis for constructing individual reality, technological claims are perceived as relevant only to those who employ the same routines while appearing as noise to those who employ different routines. The other is a process of institutionalization at the macro-level of shared cognition. By institutionalization we mean the development of a common set of evaluation routines that can be applied to all technological paths. Commonly accepted evaluation routines represent a shared reality that strongly shapes the direction of future technological change.

The micro- and macro-level processes that shape individual and shared realities create a paradox. In order to succeed in the competitive struggle among researchers pursuing different technological paths, individuals create their own realities which then become self-reinforcing. To the degree in which they are successful in fostering their individual reality, however, researchers can become less adroit in their ability to embrace the emerging shared reality when it does not match their own. How well this paradox is managed can profoundly influence who emerges as the victor or the vanquished during the genesis of a technology.

KEYWORDS: Technology evolution; cognition; social construction; institutionalization; path creation.

## Introduction

Among organization scholars there is a growing interest in the technological wellspring—and with good reason. Technological change can permeate all spheres of human activity, but no where are the effects of such change more discernible than with industry. New technologies can dramatically alter the competitive landscape, and by doing so, shake the foundation of the largest and most formidable firm, while bolstering the entrepreneurial dream of an individual who possess little more than the power of an idea. It is precisely this creative and destructive duality first noted by Schumpeter (1975) that gives technology its allure.

Previous attempts to understand technological change show how even the simplest of questions can become elusive: for example, *how do new technologies emerge?* While cursory observations into this question may suggest a linear progression from the conception of an idea to its commercial application, a more probing examination exposes a complex web of interactions between those who develop the technology, the physical artifacts they create, and the institutional environments they foster.

By scrutinizing one or more of these interactions, several different perspectives on technological change have been proposed.

One perspective examines the macro-level processes that can only be appreciated through the careful examination of the long-term struggle for survival among organizations. It is suggested that a new technology's emergence can be explained in terms of its capacity to diminish or enhance the value of a firm's existing human and capital investment (Abernathy and Clark, 1985; Tushman and Anderson, 1986). Technologies that diminish existing competencies are more likely to be introduced by newly created firms, while technologies that enhance existing competencies are more likely to be introduced by established firms. Thus, understanding the characteristics of a technology can help to explain whether a firm will embrace it or avoid it, and consequently, the likelihood that its emergence will cause a major disruption within an industry.

Another approach is to examine the micro-level dynamics of technological emergence. Historians have examined how a combination of individuals and events lead to the creation of alternative technological paths (Rosenberg, 1982; David, 1985; Arthur, 1988). In a similar vein, other scholars have examined how individuals create the institutional environment that shapes a technology's emergence (Barley, 1986; Weick, 1990). The "institutional" perspective has given rise to the notion that technological development is a co-evolutionary phenomenon, wherein there is a continual and reciprocal interaction between a technology and its environment (Rosenkopf and Tushman, 1993; Van de Ven and Garud, 1993). The co-evolutionary perspective provides an appreciation of the view that, when studied over time, the environment is both medium and outcome of the reproduction of technological practices (Giddens, 1979). The environment constrains as well as enables the development of a new technology a co-evolutionary fashion.

The co-evolutionary perspective underscores that technological development must be studied contemporaneously. We cannot fully understand the emergence of technology by means of assessments after the fact (Bijker, Hughes and Pinch, 1987; Latour, 1987). Indeed, when we observe technology-in-the-making, there is very little about the process of technological change that is obvious: it involves the "constant negotiation and renegotiation among and between groups shaping the technology" (Bijker, et al., 1987: 13). Therefore, it is important to closely follow researchers in order to understand how their negotiations influence what form technology will or will not take (Latour, 1987).

The view that technology is socially constructed stops short of asking how it is that individuals create a new technology with nothing else but the sheer strength of their ideas and beliefs. However, as Usher (1954) suggests, it may be important to scrutinize the cognitive roots of a technology to understand its subsequent development. Thus, while previous investigations have pointed to how the socially negotiated order of institutional environments directs technological change, we suggest that, it may also be useful to examine the negotiated order of beliefs themselves. Beliefs are the generative forces that set in motion *path-creation* processes—that is, the initial conception and enactment of technological artifacts and evaluation routines when nothing else exists but beliefs about what is or is not feasible.

Much can be learned from the literature on social and organizational cognition (e.g., Bateson, 1972; Berger and Luckmann, 1967; Neisser, 1976; Weick, 1979).

From the point-of-view of cognitive theory, reality is selectively perceived, cognitively rearranged, and interpersonally negotiated. At the extreme, social order has no existence independent of its members. Technology in the abstract resides in the minds of individuals, and therefore, can be understood more clearly through cognitive variables and decision premises than through behavior (Weick, 1990).

In this paper we seek to bridge the gap between the social and the cognitive processes that eventually become manifest in the form of technological artifacts. We propose a socio-cognitive model of technology evolution, which we illustrate with data on the development of cochlear implants—a surgically implanted electronic device that provides the profoundly deaf with a sensation of sound. While previous studies of cochlear implants (Garud and Van de Ven, 1987; Van de Ven and Garud, 1993) have examined the social creation of the institutional environment, in the present study, we show how the interaction between beliefs, artifacts and evaluation routines leads to the creation of alternative technological paths. In contrast to conventional methods used to study intra-organizational cognitive structures, we use interpretive methods to present evidence on the inter-organizational belief system—that is, the social-cognitive structure of a technological field.

## Socio-Cognitive Model of Technology

The foundation of the socio-cognitive model we propose rests on three basic definitions of technology: technology as beliefs, artifacts, and evaluation routines. The first definition of technology is based on its representation as knowledge (Rosenberg, 1982; Laudan, 1984; Layton, 1984). Technology as knowledge provides the critical connection with the cognitive theory literature, where cognition is defined as "the activity of knowing: the acquisition, organization, and use of knowledge" (Neisser, 1976:1). Defining technology as knowledge has important implications for how we comprehend technology-in-the-making because it conceivably includes not only what exists, but what individuals believe is possible. These beliefs may include the "rules of thumb" (Sahal, 1981) or "search heuristics" (Nelson and Winter, 1982) that researchers employ to address technological problems. At a deeper level, beliefs may include a mosaic of cause-and-effect relationships between different facets that might influence the technological outcomes (Huff, 1990). To understand the evolution of technology from this perspective requires an appreciation of how beliefs form over time.

The second definition, physical artifacts, highlights the form and functional characteristics of a technology (Sahal 1981; Constant, 1987). Constituents of a technology's form may vary, but it usually implies attributes such as its dimensional shape and material of construction. Functional characteristics refer to how the technology is used. To understand the evolution of technology from this perspective requires an appreciation of not only how the form evolves but also what functions the technology serves over time.

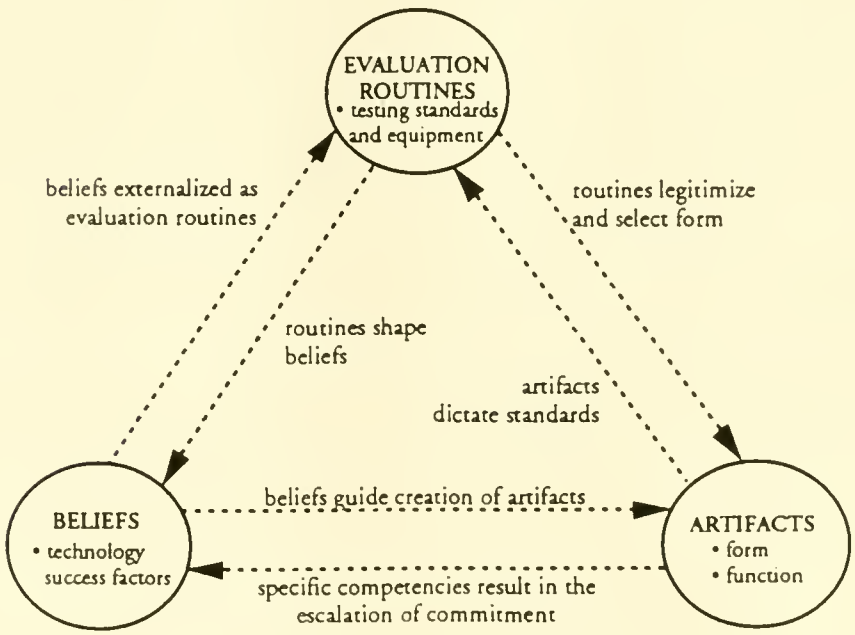
Technology can also be defined in terms of a set of evaluation routines. For example, Jagtenberg (1983) suggests that technology manifests itself in certain practices that become institutionalized within a community of researchers. Such practices consist of testing routines and normative values that sustain and define the technology—what Constant (1987) calls "traditions of testability." The traditions of

testability are inextricably linked to the instruments employed to generate the facts that are required to evaluate the technology (Latour and Woolgar, 1979). To understand the evolution of technology from this perspective requires an appreciation of how these evaluation routines emerge over time.

Each definition in our model highlights a unique, and therefore necessary, aspect of the process of technological development. In our approach, we draw on Neisser's (1976) cognitive theory of perceptual cycles, which consists of interactions between schema, perceptions and objects. Neisser defines a schema as an organization of experience that serves as an initial frame of reference for action and perception (Neisser, 1976:54). A schema directs an individual's perceptual explorations, which in turn leads to a selective sampling of the object, which in turn results in a modification of the schema. In this manner, the perceptual cycle revolves between schema, perceptual exploration and objects. Parallel with Neisser's model, we propose a "technology cycle" linking researchers' beliefs, the artifacts they create, and the evaluation routines they foster (see Figure 1). However, in contrast to Neisser's one-way interaction, we posit a reciprocal interaction between the three constituent constructs, whereby the genesis of a technology begins with the co-evolution of beliefs, artifacts and evaluation routines over time.

FIGURE 1

Socio-Cognitive Model of Technology Evolution



*Reciprocal Interactions Between Beliefs and Artifacts*

Weick (1979, 1990) suggests that technologies reside in two intersecting arenas—the mental and the physical (see also Kelly, 1963). At the intersection of these two arenas, is the idea of enactment where people "actively put things out there" (Weick, 1979: 165) in the form of physical artifacts. Physical artifacts put sense-making in motion. Individuals interpret artifacts in an abstract way in order to cope with the complexity involved (Weick, 1990). Artifacts are cognitively worked upon by categorizing them with reference to existing beliefs. At the same time, individuals interact with and constitute these artifacts thereby shaping their evolution in particular directions.

Thus, there is a reciprocal linkage between beliefs and artifacts. This reciprocal linkage is discussed by Dosi (1982) in terms of technological trajectories. Trajectories represent specific paths of technological change based on researchers' beliefs. Early on, during the development of a technology, researchers may hold divergent beliefs about "what is feasible or at least worth attempting" which leads them to pursue different paths (Nelson and Winter, 1982: 258-259). Because of the high degree of uncertainty involved (Anderson and Tushman, 1990), it is not possible to *ex ante* determine the success or failure of any particular technological path. Different researchers therefore "place their bets" on different paths.

Researchers develop specific technological competencies over time. These competencies accumulate in a path-dependent manner as earlier technological choices direct future options and solutions (Cohen and Levinthal, 1990; Arthur, 1988; David, 1985). As competencies become specialized, researchers find it increasingly difficult to redirect themselves to other paths. As a consequence, there are powerful incentives for a researcher to persist along a chosen path.

*Reciprocal Interactions Between Beliefs and Evaluation Routines*

Geertz (1973: 5) describes man "as an animal suspended in webs of significance he himself has spun" through the process of enactment and interpersonal negotiation (Weick, 1979). Similarly, Kelly (1963) suggests that individuals create visual templates which they attempt to fit over the realities of which the world is composed. These templates consist of constructs that enable individuals to validate knowledge and evaluate phenomena. Employing insights from gestalt psychology, Bateson (1972) argues that "individual validation" is required because we operate more easily in a universe in which our own psychological characteristics are externalized.

From this perspective, evaluation routines are an external manifestation of our beliefs and serve as second-order frames (Bateson, 1972: 187). Data inconsistent with an individual's evaluation routines are either ignored or appear as noise. Data consistent with evaluation routines are perceived as information and cognitively rearranged in a manner that reinforces an individual's beliefs. Given bounded rationality, this bracketing of perception occurs because individuals may be more interested in confirming their beliefs than in actively trying to disprove them (Weick, 1979). In this manner, an individual's beliefs are externalized, then objectified, and finally internalized (Berger and Luckmann, 1967). When this process occurs in groups, it may lead to multiple environments, with each subgroup enacting its' own

environment and finding itself constrained by it. However, through a process of negotiation and shared interpersonal experiences, a "consensual validation" (Munroe, 1955) occurs about facets of reality that groups can agree upon.

Weick (1990) suggests that insights from cognitive psychology are particularly useful in exploring the development of new technologies for several reasons. First, new technologies are complex and therefore reside as abstract notions in the minds of their users and developers. Second, there is often little agreement about a technology's ultimate form or function. Third, the amount of raw data concerning new technologies places tremendous demands on the information processing capabilities of individuals. Given these challenges, individual and consensual validation become important processes whereby institutional environments are created.

Researchers externalize their technological beliefs by creating routines (Constant, 1987) that are then employed to evaluate the technology. The evaluation routines, in turn, filter data in a way that influences whether or not researchers perceive information as useful. Researchers with different beliefs attempt to sway each other with respect to the routines utilized to judge the technology. It is in this sense that technological systems are negotiated. Therefore, competition between different paths occurs not only in the market, but also in the institutional environment (Meyer and Rowan, 1977; Constant, 1987). Eventually, certain evaluation routines are institutionalized, reinforcing some technological paths in place of others, and thereby enabling their dominance.

*Reciprocal Interactions Between Evaluation Routines and Artifacts*

The reciprocal linkage between evaluation routines and artifacts demonstrates why routines are required to legitimize a new technology, why they may result in the escalation of commitment and conflict, and how they develop the power to select out specific paths. Kuhn's (1970) theory of scientific revolutions is suggestive in this regard. By introducing the idea of scientific paradigms, which embody accepted examples of scientific practice as they relate to laws, theory, application, and instrumentation, Kuhn points out that researchers whose activities are based on shared paradigms are committed to the same rules and routines for scientific evaluation. While routines are particularly well-suited to study phenomena from within the perspective of a paradigm, they are ill-suited to study the phenomena from a contrasting paradigm. Therefore, evaluation routines have a tendency to reinforce an established paradigm and preclude the emergence of others.

More recently, Dosi (1982) has utilized the notion of paradigms in the study of technological development. Dosi points out that technological paradigms have a powerful "exclusionary effect" rendering researchers blind to alternative technological possibilities. This is because researchers are unable to evaluate (or perceive as noise) data about new technological paradigms when they employ their traditional evaluation routines. Consequently, the application of existing evaluation routines to the assessment of the artifacts created within a new technological paradigm may prematurely terminate its growth.

It is for this reason that van den Belt and Rip (1987) suggest that new artifacts be protected from the myopic selection pressures of existing evaluation routines. This can be accomplished by creating routines appropriate to evaluate the form and function of new artifacts (Constant, 1987). Akin to the formation of a new vocabu-

lary and a grammar, evaluation routines help researchers communicate with one another and legitimize artifacts that represent the new technology. Initially, several evaluation routines may exist, each tautological with the specific paths different researchers pursue. Each evaluation routine can therefore create different individual realities. As a result, researchers' claims make sense to those who employ similar evaluation routines and erroneous to those who employ different routines. Faced with ambiguity, researchers continue to commit themselves to their paths in order to demonstrate the validity of their claims.

Evaluation routines develop the power to select out particular paths only when they become widely accepted and commonly applied through a highly negotiated, political process. The application of commonly accepted evaluation routines results in the emergence of a dominant design (Utterback and Abernathy, 1975; Anderson and Tushman, 1990). Subsequent technological activity takes the shape of elaboration of the selected artifacts.

In summary, we propose a socio-cognitive model of technology evolution based on an understanding of the interaction between researchers' beliefs, the artifacts they create, and the evaluation routines they foster. We will now examine the development of cochlear implant technology in order to illustrate this model.

## Research Site and Methods

The evidence presented in this paper comes from a longitudinal study of the development of cochlear implant technology. Cochlear implants are electronic biomedical devices that provide the profoundly deaf a sensation of sound. These devices have been described as unique socio-psychological products because several different interpretations of their safety and effectiveness have been possible. Consequently, the emergence of cochlear implants provides an ideal setting for the socio-cognitive model developed in this paper.

A longitudinal approach is required to examine technology evolution for several reasons. Foremost, it is important to identify and track the beliefs, artifacts and evaluation routines before they become impervious to scrutiny. The uncertainty and ambiguity that pervades the development of a new technology renders post-hoc efficiency and functional explanations inadequate. To avoid this retrospective rationality trap, it is important to provide a symmetric account of different paths irrespective of whether or not they were eventually successful (Bijker, et al., 1987).

Uncovering the different facets of technology requires a comprehensive data collection effort using multiple sources and multiple methods. The study began with interviews and archival data collection to establish a baseline for the history of cochlear implants prior to 1983 (see Garud and Van de Ven, 1987). Real-time collection of data was initiated in 1983 using instruments developed by the Minnesota Innovation Research Program (Van de Ven and Poole, 1990). The instruments consisted of schedules for on-site observations, interviews, questionnaires, and archival records. Periodic meetings were held with several cochlear implant participants so that information could be collected consistently over time.

Starting in 1985 observations were made during one firm's cochlear implant steering committee meetings, initially held twice a month and then once a month. Meeting notes were transcribed and shared with other members of the research

team. This led to an intimacy with the technology, the key researchers involved, and the complex decisions they faced. It also alerted us to other activities that were taking place in the cochlear implant industry.

Several actions were initiated to gain a wider appreciation of events unfolding in the industry. First we attended cochlear implant conferences, which enabled us to conduct interviews with researchers and to collect product and technical information. Second, we initiated a systematic effort in 1985 to access publicly available information from organizations involved in the development of cochlear implants. This effort yielded many sources of data, including: Food and Drug Administration (FDA) status reports, National Institutes of Health (NIH) contract and grant information, insurance agency policies covering cochlear implants, activities of cochlear implant institutional bodies, various trade brochures distributed by cochlear implant manufacturers, and scientific activities conducted by researchers.

A search was conducted using bibliographies and electronic databases to collect scientific and technical papers on cochlear implants. A bibliographic database was created, consisting of 1329 articles written over a period of two decades (see Rappa and Garud, 1992). A chronological analysis was conducted to understand the technical debates and key developments in the field. Crucial articles, as identified by researchers in the cochlear implant field, were content analyzed in order to develop the important points and themes underlying the main technological issues.

In addition to the aforementioned sources, we collected data from the files and notes that several researchers from one organization had accumulated over a nine-year period. The data provided a richness that was not possible by direct observation alone; but more importantly, allowed us to uncover the retrospective bias introduced by respondents due to rationalizations or memory lapses when clarification was sought from them postscriptively.

Following procedures discussed by Van de Ven and Poole (1990), a chronological list of events in the development of cochlear implants was created. Events were defined as critical incidents occurring in major functions related to the development of the technology. A qualitative database was used to record the date, the actor, the action, the outcome (if evident), and the data source of each event (see appendix for an illustration of events). A total of 1009 events were recorded in the database over a period of seven years, including the historical baseline data. The consensus of two researchers was required to identify events to be entered into the data file. The events were also reviewed for content and accuracy by informants engaged in cochlear implant development. It is from this database that events pertaining to beliefs, artifacts and evaluation routines were selected as the basis of the data used in this study.

## The Development of Cochlear Implants

At a cochlear implant consensus development conference organized jointly by the NIH and the FDA in May 1988, NIH director Ralf Naunton quoted Winston Churchill to signify the remarkable legitimacy that the cochlear implant had achieved:

> This is not the end. This is not even the beginning of the end. This is only the end of a beginning.

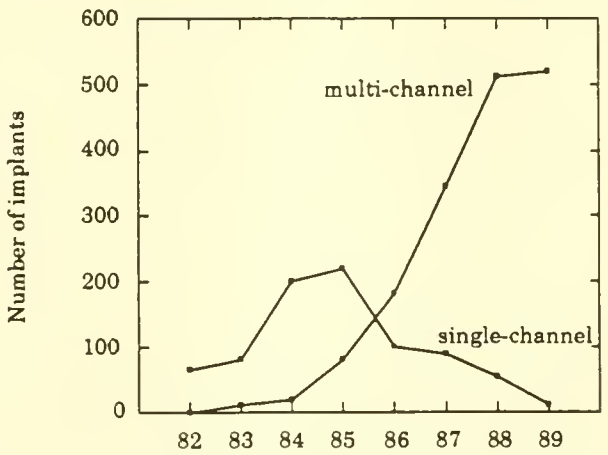
Addressing a crowd of over 400 researchers, Naunton remarked that several years ago, any researcher who became involved with cochlear implant research did so at his or her own professional risk. Indeed, NIH had earlier condemned human implantation as being morally and scientifically unacceptable. It was remarkable, Naunton stated, that cochlear implants had become an acceptable clinical practice in such a short time.

One objective of the NIH/FDA consensus development conference was to help resolve a debate between single- and multi-channel cochlear implants. In a statement released at the conclusion of the three-day conference, researchers came out strongly supporting the superiority of multi-channel devices over single-channel devices (National Institutes of Health, 1988). This conclusion was based on several years of accumulated evidence that multi-channel devices were superior to single-channel devices. Reading the consensus statement, it is difficult to understand why any resources at all were employed to develop the single-channel cochlear implant. However, there was a period during the early 1980s in which the use of single-channel cochlear implants far outstripped that of multi-channel devices (Figure 2). Indeed, some researchers were dedicated to the development of single-channel technology and remained strongly in favor of it even after it became apparent that multi-channel technology might predominate in the future.

Both single- and multi-channel cochlear implants consist of several parts: a microphone, signal processor, transmission device, and an electrode device that is surgically implanted into the cochlea (see Figure 3). Sound impulses detected by the microphone are converted into electrical impulses by the signal processor which are then transmitted through a receiver to the electrodes in the cochlea. The electrical impulses are interpreted as sound by the patient.

FIGURE 2

Annual Number of Single- and Multi-Channel Cochlear Implants, 1982-89




*Source*: Cochlear Corporation, 1990

As with any bio-medical device, cochlear implants would be judged suitable for human use if found to be safe and effective. In the U.S., the government plays a major role in sanctioning the safety and efficacy of medical devices through a regulatory approval process. Applications to the FDA must contain specific and thorough information relating to safety and efficacy (Yin and Segerson, 1986). Consequently, the need to establish safety and efficacy are the two most salient technology constructs that constitute researchers' beliefs.

Cochlear implant researchers understood the importance of safety and efficacy, but they differed in how they operationalized these two criteria in the course of their research. This is where the negotiated order of cochlear implant technology came into play. For some researchers, safety implied reducing the immediate potential for neuro-physiological damage to patients from the implanted electrodes. William House, the founder of the House Ear Institute (HEI) and a pioneer in the development of cochlear implants, is perhaps most notable for embracing this philosophy (House, Berliner and Eisenberg, 1979:183). Given the limited state of knowledge regarding hearing, House reasoned that researchers should begin with a simple device, as it would present the least potential for neuro-physiological harm to patients while providing researchers valuable knowledge required for future improvements. This led House to develop single-channel technology, which uses a single electrode implanted at a relatively shallow depth into the cochlea (see Figure 4). By restricting the length of the electrode's insertion, House believed that the likelihood of neuro-physiological damage would be minimized.

House's preference for the shallow insertion of electrodes conformed with his expectation of how the implant should perform. The single-channel device had been designed to provide profoundly deaf individuals a perception of environmental cues rather than an ability to discriminate between spoken words. To accomplish this objective the device transmitted all the sound impulses picked-up from the environment into the cochlea. It was believed that this would allow patients to perceive environmental sounds based on the rate at which electrical impulses were transmitted into the cochlea.

House and others who chose to pursue the single-channel route believed that profoundly deaf individuals would prefer and benefit from a device that could provide them with environmental cues rather than an ability to discriminate between the spoken word. This belief was based on their understanding of the needs of profoundly deaf individuals. House and his colleagues thought that the ability to discriminate spoken words would require considerable time and effort, whereas the ability to perceive environmental sounds would yield immediate benefits. Consequently, those who pursued the single-channel approach believed that the ability to perceive environmental cues should be the appropriate measure of cochlear implant efficacy.

Other researchers held contrasting assumptions about cochlear implant safety and efficacy. They believed that normal hearing could only be replicated with multiple electrodes, each inserted deep into the cochlea so that different frequency signals could be delivered at different spots in the cochlea (see Figure 4). The deeper insertion of multiple electrodes might eventually provide profoundly deaf patients the ability to understand speech.

FIGURE 3

Cochlear Implant Device

(Adapted from Loeb, 1985)

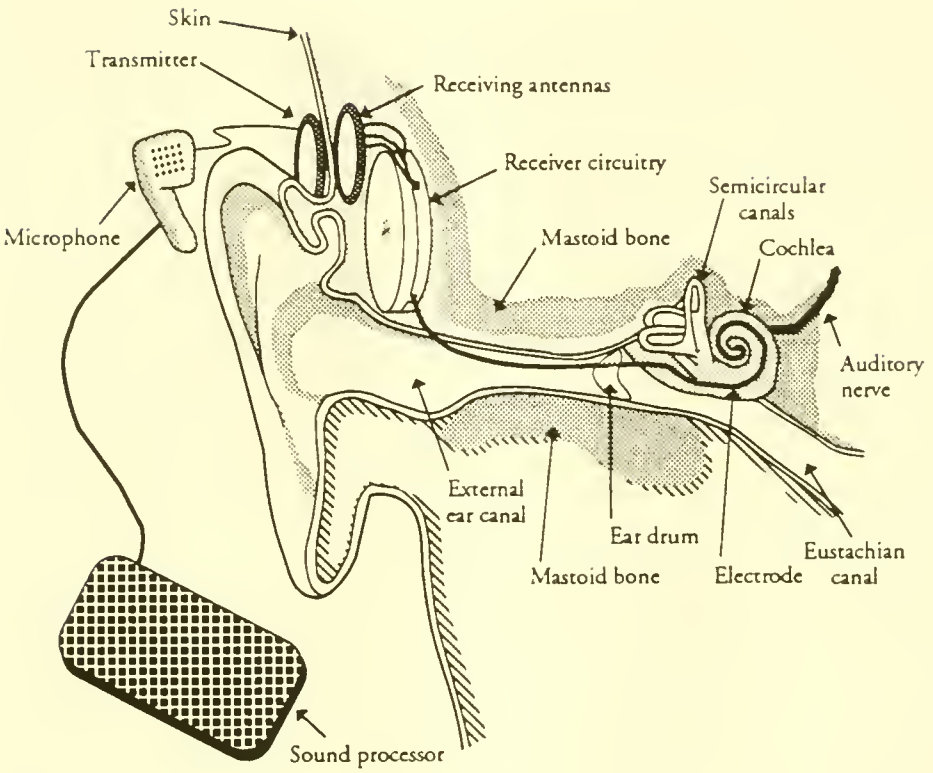
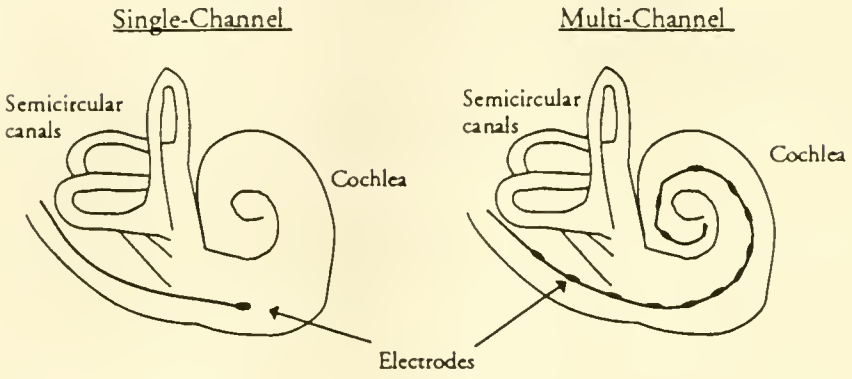


FIGURE 4

Comparison of Single- and Multi-channel Cochlear Implants



Graem Clark, a researcher at the University of Melbourne, embraced the multi-channel philosophy (Clark et al., 1977). For him and his colleagues, the ability to recognize speech, as opposed to environmental cues, was the primary function of cochlear implants and therefore the appropriate measure of efficacy. Indeed, in order to enhance speech recognition, multi-channel researchers designed implants that reduced the perception of environmental sounds by extracting certain frequencies from the sound signals and delivering them to specific spots in the cochlea.

In contrast to the proponents of single-channel technology, advocates of the multi-channel approach perceived the risk to patients differently. Multi-channel researchers rejected the likelihood of cochlear damage, largely because of the lack of scientific evidence that deep electrode insertion would cause neuro-physiological trauma in humans. Instead, multi-channel researchers saw more harm in what they considered to be an inferior single-channel technology. What was of greater concern to them was the potential future damage when single-channel patients sought to replace their implants with multi-channel devices (*Health Technology Assessment Reports*, 1986).

Besides House and Clark, other pioneering researchers include Blair Simmons and Robert White of Stanford University, Robin Michelson of University of California–San Francisco (UCSF), Ingeborg and Ervin Hochmairs of the University of Innsbruck, and Donald Eddington of the University of Utah. Although these researchers played an important role in the development of cochlear implants, we will limit our discussion to the beliefs, artifacts and routines of House's group (in cooperation with 3M Corporation), and Clark's group (in cooperation with Nucleus Corporation) as the House and Clark cochlear implant designs account for over 90% of the patients who received implants in the decade since commercialization began in 1978. By focusing on researchers associated with Nucleus/Melbourne and 3M/House, we seek to highlight the key dynamics during the development of cochlear implants, without necessarily capturing all of the variation within the research community. These dynamics are summarized in Table 1 and described in greater detail employing our socio-cognitive model of technology evolution.

In our description, we also discuss the perspectives of investigators associated with independent evaluation centers who mediated the debate between single- and multi-channel advocates. We single-out the University of Iowa for examination, because it became one of the most influential centers in the United States. Beyond mediating the debate between principle investigators, independent research centers also served as a conduit of information to institutional bodies such as the NIH and the FDA.

*Beliefs and Artifacts in Cochlear Implants*

In 1978, House entered into a licensing agreement with 3M. House's single-channel device embodied safety and efficacy features that allowed 3M's cochlear implant team to pursue their business plan for the commercial introduction of cochlear implants. The plan was to seek early regulatory approval for a safe and simple device in order to create a "window of business opportunity." The early introduction of the House technology would enable 3M to establish itself as a leader in cochlear implants. Meanwhile 3M researchers would have the time to develop a more complex multi-channel device for introduction in the near future.

TABLE 1

Elements of the Socio-Cognitive Model for Cochlear implants

| RESEARCH GROUP | SOCIO-COGNITIVE ELEMENTS | | |
|---|---|---|---|
| | BELIEFS | ARTIFACTS | EVALUATION ROUTINES |
| 3M/House | Safety: reduce neuro-physiological trauma during use<br>Efficacy: environmental sounds | Form: simple single-channel device with shallow electrode<br>Function: improve ability to provide environmental sounds | Routines evaluate the ability to perceive environmental sounds and ability to lip read |
| Nucleus/ Melbourne | Safety: reduce trauma of upgrading from single- to multiple-channel<br>Efficacy: speech recognition | Form: complex multi-channel device with deep electrodes<br>Function: improve ability to recognize speech | Routines evaluate the ability to discriminate between open-set speech |
| Food and Drug Administration (FDA) | Before 1984, neuro-physiological safety is more of a concern than efficacy<br>After 1984, focus shifts to upgradability and speech recognition efficacy | In 1984, granted regulatory approvals for 3M/house single-channel device for adults because it is considered simplest and safest<br>In 1987, rejects application for single-channel devices for children | Before 1984, relies on investigators to develop pre-market approval evaluation routines<br>After 1984, begins to employ routines that demand increasing evidence of safety and efficacy |
| National Institutes of Health (NIH) | Before 1973, condemns cochlear implants on moral and scientific grounds<br>After 1973, believes it is important to demonstrate safety and speech recognition efficacy | Before 1973, refuses to support any group working on cochlear implants<br>After 1973, extends grants and contracts to multi-channel development and safety-related research | Sponsors Bilger to compare cochlear implants in 1975 and Iowa to develop comparative evaluation routines in 1983 |
| University of Iowa | Neutral position about safety and efficacy | Before 1987, finds that multi-channel technology is superior with respect to speech recognition ability<br>After 1987, finds that single channel technology can provide speech recognition for children | Develops evaluation routines that subsequently gain widespread acceptance |

3M had recognized the importance of demonstrating device safety during their interactions with the FDA . The FDA's interest in device safety heightened after reports about neuro-physiological damage in animals were published (Berliner and House, 1981). Sensitized to FDA concerns, the issue of device safety dominated the 3M research agenda. Researchers concentrated their efforts on reducing the electrode insertion length of the House design further from 15-mm to 6-mm, while freezing core design changes that might enhance the efficacy of their device.

Researchers at Nucleus were among those who believed that 3M's efforts were misguided. In 1979, Nucleus had entered into a licensing agreement with Clark and his colleagues from Melbourne (after 3M had decided not to pursue a similar arrangement). The Nucleus/Melbourne group felt that providing patients with the ability to understand speech was of central importance. Consequently, while 3M/House researchers reduced the electrode length, Nucleus/Melbourne researchers moved in the opposite direction, toward increasing electrode insertion to 25-mm into the cochlea. Moreover, while 3M sought to establish the safety of their device, Nucleus/Melbourne sought to develop the capability to upgrade their device so that patients could easily benefit from future technological advances.

The Melbourne group was supported by NIH grants totaling $1.7 million between 1985 and 1989 (Hambrecht, 1991). NIH chose not to support the development of single-channel technology monetarily. By doing so, the NIH did more than underwrite multi-channel researchers, it legitimated Nucleus's multi-channel technology at the expense of the 3M/House single-channel technology.

3M moved quickly to prepare the clinical documentation necessary to submit a pre-marketing approval application (PMAA) to the FDA. Fearing early approval of single-channel technology, multi-channel researchers attempted to dissuade the FDA from making a decision, claiming that the 3M/House technology was "archaic." 3M countered by claiming that existing multi-channel technology did not provide a clear enough benefit in speech discrimination to justify the increased possibility of cochlear damage and decreased reliability. Fortunately for 3M, the FDA's ear, nose and throat committee ruled that single-channel devices could not be considered inferior until a superior device was actually available. The FDA committee believed it would be wrong to wait for improved cochlear implant technology when an existing technology could offer immediate benefits to patients.

Based on an application submitted on October 1983, the FDA advisory panel granted approval for the commercial sale of the 3M/House device in June 1984. Noting the historic nature of this approval (actually granted in November 1984), the FDA stated in its press conference:

> This is the first time that one of the five human senses has been replaced by an electronic device.

However, the FDA sent a mixed signal to researchers and potential patients alike by approving the single-channel device while at the same time circulating a report that suggested the possible superiority of multi-channel technology. The FDA report stated:

> The single-channel implant involves the placement of a single electrode within the cochlea. This type of device provides rhythm and intensity information to the patient but it does not provide any perception of pitch and is not effective in speech comprehension. Multi-channel implants have an array of several electrodes placed within the cochlea. Preliminary results indicate that by stimulating the proper electrodes in the array in multi electrode devices, the patient can perceive pitch and may be able to comprehend speech more effectively than with a single-channel implant (*Current Status of Cochlear Implants: 1984 Update*).

Thus, while 3M's efforts to appeal to FDA safety concerns were successful in obtaining early regulatory approval, the FDA effectively undermined single-channel technology by raising reasonable doubts in the minds of potential implant patients. Soon after the FDA's announcement, testimonials appeared in the mass media promoting the superiority of multi-channel devices. Daniel Ling, dean of the School of Applied Health Sciences at the University of Western Ontario and a consultant to Nucleus, stated:

> Single-channel implants are better than nothing. But that is all they are—better than nothing. Why implant a single-channel today when you know a 22-channel is right around the corner? (*Wall Street Journal*, 1984).

The scientific debate between single- and multi-channel proponents quickly became embedded in the mass media. Surgeons pursuing the single-channel route claimed that there was no evidence to suggest that multi-channel devices were superior. In a 1984 newspaper article entitled "Local surgeons involved in ear war over implants," a Yale University researcher stated:

> There is no scientifically controlled evidence to indicate which type of implant is superior to others for most implanted patients. Those who claim the superiority of the multi-channel device over the single- channel device do so to mislead the public either intentionally or out of profound ignorance (newspaper article, source unknown).

Such protests notwithstanding, by March 1985, Nucleus' multi-channel device had, in effect, achieved "FDA-approved" status even though the FDA had yet to make a ruling on the technology. Meanwhile, the usefulness of the FDA-approved 3M/House device continued to be challenged on grounds that the ability to upgrade might be limited, thereby locking early users of single-channel implants into that technology. For instance, one surgeon claimed:

> If it is true that more sophisticated devices will be developed in the future, then it would be wise to postpone the implantation of single-channel units since this will probably cause enough damage of the inner ear so that it cannot later be replaced by me.

3M fully recognized that cochlear implant technology would evolve into more complex devices, but it hoped to exploit the single-channel to establish itself as the leading producer of cochlear implants. This put 3M in the difficult position of hav-

ing to convince practitioners and users (who would be required to undergo delicate surgery) that its cochlear implant would provide immediate benefits while still allowing users to take advantage of potential technological innovations in the future. In a widely read issue of Hearing Instruments, 3M outlined its position in the following manner:

> 3M has designed its cochlear implants to provide the many benefits of today's devices without compromising the patient's ability to benefit from future improvements in technology by preserving the delicate membranes of the cochlea. At this point in the cochlear implant's short history, not enough is known about the long-term effects of implanting an electrode into the cochlea. For this reason, 3M has taken a "prudent" approach to minimizing risk to the cochlea and to preserve remaining functions for the future products and technologies. Several studies have shown that serious, irreversible damage may result from inserting a multi-electrode cluster into the cochlea. This damage may be due to presence of multiple electrodes (up to 22 in one device) as well as the lengths of the electrodes (up to 25 mm long). Based on today's evidence of the neural degeneration from mechanical damage, 3M feels it is irresponsible to take such a risk. Patients who might be able to benefit from deep-penetrating electrodes today may find that in five or ten years the damage to their cochlea may prevent them from using any cochlear implant (*Hearing Instruments*, 1985:14).

Despite 3M's cautions, FDA granted regulatory approval for Nucleus' 22-channel cochlear implant device in October, 1985 while not approving the 3M/House single-channel device for implantation in children. Implantation of multi-channel devices subsequently increased, while single-channel devices declined. Reflecting on this outcome, 3M's top management challenged its researchers to demonstrate the commercial viability of the 3M/House device. Unable to show management the commercial viability of the 3M/House implant, 3M researchers discontinued their effort and instead initiated the development of a next-generation device. Despite the overwhelming support that was building for multi-channel technology, 3M researchers decided to pursue another single-channel technology—a variation developed by Austria's Ingeborg and Ervin Hochmairs. The "Vienna" device was considered even safer than the 3M/House technology because of its extra-cochlear orientation, wherein the electrode did not penetrate the cochlea.

3M researchers reasoned that the added measure of safety would enable them to market the device to a much larger pool of potential patients (those with some residual hearing). For these patients, the extra-cochlear orientation reduced the potential of neuro-physiological cochlear damage while providing them with the benefits of enhanced hearing. 3M's earlier decision against a multi-channel device also may have influenced their decision: switching from single- to multi-channel technology now would require a major reorientation achievable only via a long-term R&D project. By embracing the Vienna device, 3M researchers would be able to sustain their cochlear implant effort and emphasize the issue of safety in order to enlarge the potential market. In this manner, the artifacts that 3M researchers developed reinforced their beliefs about safety and efficacy, which in turn influenced their future direction of technological development.

*Beliefs and Evaluation Routines in Cochlear Implants*

It is important to recognize the differences in how cochlear implant researchers operationalized safety and efficacy. Not only are safety and efficacy largely subjective in nature, but any consensus among researchers requires a degree of coordination and agreement about what should be measured and how it should be measured which did not exist during the early years of cochlear implant development. Even as late as 1973, researchers at an international conference at the UCSF decried the absence of systematic routines to evaluate the efficacy and safety of cochlear implants. Several pleas were made to standardize evaluation routines so that research on cochlear implants, as well as other hearing aid devices, could be coordinated and systematic comparisons could be made (Merzenich and Sooy, 1974).

In an attempt to remedy this situation, NIH issued a request for proposal asking researchers to describe how they would evaluate patients fitted with cochlear implants. The contract was won by Robert Bilger, who, with his colleagues at the University of Pittsburgh, set-out to study thirteen patients in 1975. What Bilger found was that any comparative assessment of cochlear implants was severely limited by the lack of systematically collected performance data (Bilger, 1977). Indeed, Bilger characterized the evidence regarding House's implant technology as anecdotal, dealing mainly with reports of patients' experiences and reactions. Nonetheless, Bilger found there were discernible benefits from cochlear implants. While these benefits fell short of what had been claimed in the press, the "Bilger Report" had, in effect, legitimized cochlear implants. Subsequently, a number of researchers were convinced enough to initiate work on the technology.

The need for straightforward measures of safety and efficacy was further reinforced by the regulatory process. To gain FDA approval, cochlear implant manufacturers had to demonstrate the safety and efficacy of their device through controlled clinical trials. The results of the clinical trials were submitted to the FDA in the manufacturer's pre-market approval application—or PMAA (Yin and Segerson, 1986). But no matter how formalized, the FDA process could not mask the fact that what was measured and how it was measured, was subject to interpretation. When 3M first approached the FDA to set the groundwork for PMAA approval, they found that the FDA did not possess the prerequisite knowledge about cochlear implant technology needed to determine an acceptable evaluation scheme. Moreover, the resolution of acceptable measures of efficacy and safety depended on the congruence of beliefs among 3M researchers and FDA administrators. Reflecting on a meeting with the FDA in August 1982, the manager of the 3M Bio-sciences Laboratory explained his frustration with the situation this way:

> [A] considerable amount of teaching was required. There was little discussion about efficacy. They were not familiar with the various audiological tests. Generally, the FDA had to be reminded again and again that our device is the simplest one with the least amount of complexity. But it still provides a clearly demonstrated benefit.

The difference between single- versus multi-channel devices also manifested itself in the kind of tests employed to record implant performance. 3M/House researchers measured a patient's ability to understand environmental sounds—the Monosyllable Tronchee Spondee test—and the resultant improvement in quality of

life. Although these tests evaluated a patient's ability to discriminate between some speech elements, they fell short of measuring a patient's ability to discriminate the kind of speech that occurs in normal conversation. 3M explained that these tests were appropriate because current and near future advances lay "not in solving deafness but in providing useful, conservative devices to improve lip-reading skills to allow for mainstreaming." In contrast, researchers at Nucleus/Melbourne employed tests that measured a patient's ability to perceive speech and tracked improvements in speech recognition over time.

Consequently, each technology led to the development and usage of its own unique evaluation routines, which selectively reinforced the advantages (or ignored the limitations) of the respective devices. A researcher's determination of safety and efficacy ultimately depended upon the evaluation routines believed to be most appropriate. However, the evaluation routines developed by researchers were influenced by individual perceptions of what safety and efficacy meant. The resulting proliferation of evaluation routines made it difficult, if not impossible, to objectively compare test results, leading Gantz to exclaim:

> A major obstacle preventing accumulation of comparative data is that each center has reported results based on different measures, and in some instances investigators have developed tests tailored to their implants (Gantz, Tyler and McCabe, 1985: 444).

Like Bilger, Gantz and his colleagues, with a contract from the NIH, had positioned the University of Iowa as an independent evaluation center. Initially, 3M researchers interacted with the Iowa researchers, as did other cochlear implant research groups. However, 3M began distancing itself from the Iowa group when their test results began to favor the multi-channel technology. While Nucleus supported Iowa in their efforts to develop their evaluation routines, 3M fostered alternative evaluation routines under the auspices of the American Association of Otolaryngology (AAO). Although 3M was successful in helping create several guidelines issued by the AAO, the standards had little tangible effect on the development of cochlear implant technology outside 3M. A member of the AAO committee on the comparison, testing and reporting of cochlear implants suggested this was due, in part, to the group being headed by a researcher associated with HEI.

The negotiated order of cochlear implant development can be further exemplified by researchers' efforts to influence emerging regulatory guidelines. For example, when the FDA sought input for crafting PMAA guidelines, 3M recommended that a minimum of 100 patients be required for establishing efficacy. This number was based on clinical experience with the 3M/House single-channel device. To build support for their position, 3M organized a technical seminar on safety issues for FDA researchers in January 1985. In subsequent meetings, 3M researchers also presented arguments to dispel any "misconceptions about the apparent sophistication and superior performance of multi-electrode devices."

Nucleus also made recommendations to the FDA for PMAA guidelines. The number of patients required to support efficacy claims was important to Nucleus since it had clinical data on only 43 patients when it submitted its PMAA in 1984. If the FDA accepted 3M's proposal and imposed a minimum requirement of 100 patients, the Nucleus PMAA would be significantly delayed. To prevent this eventual-

ity, Nucleus audiologists visited the FDA and argued that the sample size required to demonstrate safety and efficacy should be a function of the actual performance of each device, the claims each manufacturer wanted to make about its device, and the statistical approach adopted to support such claims. The FDA eventually agreed with Nucleus. Draft guidelines circulated in June 1985 stated that the FDA would not specify the number of patients required for a PMAA. Instead, the FDA would leave the minimum sample size flexible so that clinical investigators could tailor their studies to collect sufficient data to achieve statistically valid results (*MDDI Reports*, 1985: 11).

While evaluation routines were congruent with the beliefs held by researchers, routines in turn reinforced the beliefs of some researchers. This can be understood by considering the charges of exaggeration researchers leveled against each others' claims. From the vantage point of 3M, researchers felt that proponents of multi-channel technology had overstated the benefits and minimized the risks. Responding to a survey made by the American Speech Hearing Association (ASHA) in May 1985, a 3M spokesman stated:

> One of 3M's biggest concerns is the issue of realistic expectations. To be sure, the cochlear implant is an exciting medical advance; it is the first device that can substitute for one of the body's five senses. 3M believes that it is the responsibility of everyone in the cochlear implant field to present a balanced picture of this new technology. We are particularly concerned about the accuracy of some of the stories that have appeared recently in the mass media. We urge hearing health professionals to take an active role in providing accurate, responsible information to their communities (ASHA, 1985).

In their counterattacks, multi-channel proponents alleged that 3M exaggerated the performance of their single-channel device. During the Thirteenth International Conference on Cochlear Implants held in 1985, 3M researchers used clinical results obtained in Europe to promote the efficacy of their Vienna device. However, researchers associated with Nucleus and Symbion questioned the validity of 3M's claims on device performance, arguing that 3M should first replicate the European findings in the U.S.

Although researchers accused each other of making claims that were based on faulty assumptions or lacked scientific rigor, given the divergence of technological paths, it was not clear who, if anyone, was exaggerating most. The claims simply reflected the beliefs and evaluation routines that each researcher had adopted. Indeed, if anything, the escalation of claims in the face of opposition illustrates the tendency for researchers to become even more committed to their artifacts and routines in order to validate their claims. Rather than being persuaded by "objective" evaluations, controversy was more likely to lead researchers to become even more entrenched in their own positions.

It is here that one can observe the tremendous influence researchers' beliefs had on how they perceived what was or was not technologically possible. House and Berliner (1990: 16) note that Bilger's study was inadvertently swayed by the prevailing view that single-channel devices could not aid a patient in speech recognition. Since, as Bilger (1977: 4) stated, "it is well accepted that subjects using auditory prosthesis cannot understand speech with them," they did not even attempt to eval-

uate patients for speech discrimination. House and Berliner (1990) suggest that this omission had a profound impact on researchers' beliefs in the efficacy of single-channel implants. They claim that the Bilger report:

> ...continued to fuel the then existing assumption that no speech understanding was possible with a single-channel device. The belief that single-channel cochlear implants could not provide speech discrimination persisted throughout the 1970's and had lasting effects on device development. It greatly narrowed the perspective of workers in this field and excluded from pursuit many possible approaches to signal processing (House and Berliner, 1990: 17).

The struggle to define safety and efficacy, and then measure it, illustrates how researchers projected their own beliefs onto cochlear implants and attempted to influence each other—including regulators. The evaluation routines adopted by researchers were congruent with their beliefs about cochlear implants. These routines, in turn, further reinforced researchers' beliefs.

*Evaluation Routines and Artifacts in Cochlear Implants*

The lack of agreement on evaluation routines during the early years of cochlear implants created a situation in which media reports inevitably distorted the scientific evidence. Simmons likened one particularly extravagant news story on cochlear implants to the headline: "Mom gives birth to a 2-year-old baby" (Simmons, 1988). Unfortunately, media hyperbole had the affect of discouraging researchers from working in the field, thereby leaving it more or less dormant for a considerable number of years (House and Berliner, 1990: 6; Simmons, 1985: 4).

The leeway in designing evaluation routines led researchers to formulate tests that tended to highlight the benefits of their devices and thus validate the claims they were making. Calvert, the program manager of one of the business firms stated:

> The clinical trials allow the claims of each manufacturer to be proven. It is important that the tests be standardized. That should include both the method used to administer the tests and the type of tests used (*The Hearing Journal*, 1986: 9).

With time, some tests did become standardized among researchers. However, initially, these tests did little to help in the comparison of devices, since different clinics employed variants of the same test. One example was the Minimum Auditory Capability (MAC) test. Developed by Elmer Owens of UCSF in the early 1980s, MAC is a diagnostic tool used to measure the auditory capability of patients prior to implantation by having them listen and respond to taped cues.

According to Owens, the original MAC tapes were poorly recorded, prompting centers to retape the cues with the help of an articulate speaker. In some cases male voices were used, while in others, female voices were used. As Owens explained, even though these modifications undoubtedly improved the reliability of the MAC test, they also reduced its validity: patients were tested against a voice pattern that they would not actually encounter in real life. Moreover, the proliferation of different MAC versions made it difficult to compare test results from center to center.

Nonetheless, comparative tests conducted by Iowa researchers (with their own version of the MAC test) were influential because Iowa was seen as an independent evaluation center. The Iowa results, which appeared in clinical journals in 1985,

showed that multi-channel devices were superior to single-channel devices. To the dismay of single-channel proponents, the results had an enduring impact on perceptions. A manager from 3M stated:

> People think that if an article is published, it will be forgotten after a couple of months. But, actually, other people keep on referencing [it] and [it] never really dies away.

One organization influenced by the Iowa findings was the Office of Health Technology Assessment (OHTA). The OHTA conducted an extensive review of the growing literature to evaluate the suitability of cochlear implants for Medicare coverage. In its report, the OHTA joined with the Iowa researchers to suggest that multi-channel devices might be superior to single-channel devices. Ernest Feigenbaum, a health science analyst with OHTA, explained the difficulties involved in reaching their conclusion. Referring to implants as a unique "psycho-social" therapy, he stated:

> One fascinating issue in this area is the fact that different aspects of the technology require different types of underlying methodologies to evaluate. For instance, there are speech pathologists, social scientists, audiologists and other involved. Consequently, it is very difficult to pinpoint what an "objective scientific" method should be to evaluate the performance of a device such as the cochlear implant.

The influence of the Iowa study was widespread. In addition to the FDA status report, a study published by ASHA also sided with multi-channel devices (ASHA, 1986). The fact that Iowa researchers were instrumental in many of these forums led one 3M researcher to exclaim that "the University of Iowa is controlling our destiny."

In 1987, however, comparative evidence emerged, which was inconsistent with the theory that single-channel devices were too simplistic to provide speech recognition (Berliner, Tonokawa, Dye and House, 1989). Notably, Richard Tyler of the University of Iowa found that ten of the Hochmairs' best single-channel patients could discriminate aspects of speech. Similarly, Jean Moogs from the Central Institute for the Deaf, evaluated patients with 3M/House implants and found encouraging performance among children. Previously a staunch critic of single-channel technology, Moogs conceded that she had to reexamine her assumptions.

In light of the new results, HEI's Berliner and Eisenberg (1987) called on fellow cochlear implant researchers to reevaluate single-channel technology: "We should be more open to possibilities and less tied to theory, at least until we have an objective basis for defining our expectations." They admitted that the initial expectations of HEI's own clinicians' about the performance limits of the single-channel device had led them to commit a "serious error" in not exploring the full potential of the technology:

> Unfortunately, because of our past assumption, we never routinely tested for [a patient's ability to understand speech]. Worse yet, we dismissed some of our own patients' reports of this as their lack of understanding of other cues they might have been using (Berliner and Eisenberg, 1987).

The call for a renewed investigation of single-channel devices came too late. The NIH/FDA consensus development conference in 1988 set forth funding and regulatory guidelines that favored multi-channel technology. Although House raised objections based on the results documented by Moogs and Tyler, few at the conference were persuaded. From the conference a consensus emerged that multi-channel devices were superior to single-channel devices—at least in adults (National Institutes of Health, 1988). 3M's Group Vice President lamented that although theory had initially driven research, incongruities between theory and clinical results did not lead to a reexamination of strongly held theoretical biases but rather a reinterpretation of the clinical results. Berliner viewed the consensus statement as an attempt by otologists' to "converge onto the multi-channel device in order to reduce cognitive dissonance on the choice of the most appropriate device that they should implant." While conceding that multi-channel devices had become the dominant design, 3M's lab manager stated that other design aspects had yet to be resolved. He spoke of a hierarchy of designs and the battle now shifting to processing schemes and other aspects of the cochlear implant.

## Discussion and Conclusion

We began with the premise that technology should be viewed as beliefs, as artifacts, and as evaluation routines. While each perspective is useful in and of itself, together they form the basis for unraveling the path-creation process that occurs during the genesis of a technology. Pioneering researchers build artifacts that bare the imprint of what they believe can and should be done. In turn, the form and function of an artifact affects the kind of routines that are created to evaluate how well expectations are met. The discrepancies that arise between reality and expectation subsequently influence the beliefs that researchers hold, thereby giving further impetus to the cyclical dynamic of path-creation.

What is equally important to recognize is that the pattern of influence runs in both directions. It is difficult to create evaluation routines when artifacts do not exist or are not fully developed. Without evaluation routines, a technology cannot gain legitimacy in the eyes of researchers who have no other choice but to apply their existing routines to evaluate an incommensurate technological artifact. Moreover, without legitimacy, it is difficult to attract others to participate in developing the technology to a more advanced state. Thus, a new technology is in a precarious state during its early stages of conception.

The historical development of cochlear implants illustrates how each facet of a technology mutually shapes the other. In order to maintain interest in cochlear implants, for example, pioneering researchers created their technological paths by externalizing beliefs as artifacts. They also had to develop evaluation routines to make sense of their path and establish its legitimacy. But at the same time, the evaluation routines used by researchers prescribed their boundaries of exploration. In the case of 3M/House, researchers reinforced their own beliefs about single-channel technology on the basis of "avoided tests" (Weick, 1979: 149-152) rather than on the basis of tests that could have proven that speech recognition was possible. Thus, once created, the evaluation routines became the basis for the construction of reality.

Such a situation can be viewed as a process of "inversion" (Latour and Woolgar, 1979: 240) wherein routines designed to evaluate specific artifacts begin reinforcing researchers' beliefs, which we represent by the counter-clockwise arrows connecting beliefs, artifacts and evaluation routines in Figure 1. Once evaluation routines become the basis for constructing reality, technological claims are seen as relevant only to those who employ the same routines, and appear as noise to those who employ different routines.

The existence of divergent evaluation routines leads researchers to be suspicious of each other's claims. However, given the lack of commonly accepted testing and reporting standards, it is not clear who, if anyone, is at fault. Indeed, the apparent extravagance of various claims may simply reflect the diversity of researchers' paths. The ambiguities facing researchers lead them to simply enact a solution (Daft and Lengel, 1986; Weick, 1979). Cochlear implant researchers could do little else but embellish their routines while persisting in their efforts to develop specific artifacts in order to demonstrate to their colleagues that their claims were indeed "true." When multiple routines surfaced, each with the power to select data that shape beliefs without the power to select specific artifacts themselves, the result was an escalation of commitment and conflict.

Only when evaluation routines become widely accepted, do they have the power to select-out certain artifacts while reinforcing others. Thus, the critical question is: How do certain evaluation routines become commonly accepted? Economists have traditionally looked to markets for an answer. But only "efficient" markets have the power to select-out paths. When it comes to complex technologies that are difficult to evaluate, such as cochlear implants, markets are often inefficient. Patients are ill-equipped to evaluate the safety and efficacy of different cochlear devices, and therefore cannot be expected to choose between alternatives. Consequently, patients have to rely on audiologists and otologists to act on their behalf. However, audiologists and otologists themselves must rely on information made available by researchers directly engaged in the development of the technology, and as we illustrated, the information that researchers make available represents only one facet of technological reality.

It is unlikely that markets are able to select-out complex technologies. At the macro-level of shared beliefs, institutional closure is required for such technologies (van den Belt and Rip, 1987). It is for this reason that independent testing and regulatory institutions, such as the NIH and the FDA, exist. Nonetheless, the timing of closure is open to question. If undertaken prematurely, institutional closure may preclude promising avenues of inquiry; if undertaken too late, an escalation of commitment and a waste of resources may result.

When institutions sanction comparative tests, evaluation routines develop the power to select-out certain paths and reinforce others. This happened when researchers at the University of Iowa, with the support of NIH, initiated comparative testing. Iowa's efforts represent the beginning of a period of "institutionalization." By this, we mean the development of a common set of evaluation routines that can be applied to all technological paths. During the process of institutionalization, which we represent by the clockwise arrows connectng beliefs, artifacts and evaluation routines in Figure 1, researchers attempt to shape the activities of independent testing centers in their own favor. The widespread acceptance of certain practices

represents normative control (DiMaggio and Powell, 1983). Subsequently, normative control becomes coercive control when institutions such as the FDA begin to regulate the form and function of the artifacts that researchers create. It is interesting to see that despite the normative and coercive controls, 3M/House researchers continued advocating the single-channel path.

There are two processes that unfold simultaneously during the evolution of a technology. One is a process of inversion at the micro-level of individual cognition. The second is a process of institutionalization at the macro-level of shared cognition. It is at the nexus of these two processes that the form and function of an artifact is manifested over time. Researchers attempt to manage this nexus. At one level, they externalize their beliefs as evaluation routines that then create their personal reality. At another level, they attempt to shape the realities of other researchers who evaluate their technology.

The micro- and macro-level processes that shape individual and shared realities create a paradox. In order to succeed in the competitive struggle among researchers pursuing different technological paths, individuals create their own realities which then become self-reinforcing. To the degree in which they are successful in fostering their individual reality, however, researchers can become less adroit in their ability to embrace the emerging shared reality when it does not match their own (Weick, 1979: 218). It has been suggested that technological development is not about nature, but about a "fierce fight to construct reality" (Latour and Woolgar, 1979:243), where reality is the consequence of the settlement of a dispute rather than its cause (Latour, 1987). Those who emerge from the dispute victorious, shape what history will remember. Others, we say, were tangled in webs of their own significance.

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## APPENDIX

## Illustrative Events in the Development of Cochlear Implants

| DATE | EVENT | DESCRIPTION | SOURCE |
|---|---|---|---|
| 01/01/73 | First Intl conference on the electrical stimulation of the acoustic nerve at UCSF | Otologic community recommends development of routines to increase objective evaluation of subjects fitted with cochlear implants | Report on workshop on Cochlear Implants, 1973. |
| 12/21/81 | Eddington of MIT advises 3M on evaluation routines | Eddington states that there are an infinite number of psycho-acoustic tests that could be performed on subjects and that without a very specific goal, it would be difficult to decide which of these tests should be implemented. | Letter from Eddington to 3M researcher dated 12./21/81. |
| 02/17/84 | PMAA approval meeting at the FDA | 3M researchers explain that they have used the MTS and environmental sound tests as these best measure the performance capability of the 3M/House device in helping patients distinguish between environmental sounds. | Notes from PMAA presentation dated 02, 17, 1984. |
| 02/01/85 | Nucleus researchers provide an overview of their cochlear implant program | Nucleus researchers report that they have been using three tests including the MAC battery, live voice presentation and a speech tracking test. | Seminars in Hearing, Vol. 6, No. 1. pp. 41-51. |
| 04/01/85 | University of Iowa article appears in Laryngoscope assessing the development of cochlear implants | Gantz of University of Iowa states that comparative uniform evaluation of cochlear implants is vital to the future development. A major obstacle preventing accumulation of data is that each center has reported results based on different measures and in some instance investigators have developed tests tailored to their implants. | Laryngoscope, 95, 1985 pp. 443-49 |
| 07/22/85 | FDA pre-market-approval guidelines | Guidelines leaves patient sample size requirement flexible so that a clinical trial sponsor can tailor its study to collect sufficient data to achieve statistically valid results while keeping to a minimum the number of patients at risk. | MDDI reports dated 07/22/1985, p. 11. |
| 08/01/86 | Review article on cochlear implant status published in The Hearing Journal | Calvert of Storz states that it is important for tests to be standardized, including both the method used to administer the tests and the type of tests used. | The Hearing Journal, 39: 9 |
| 05/02/88 | NIH/FDA consensus development conference | NIH/FDA cochlear implant consensus development conference. Consensus that emerges is that multi-channel stimulation produces superior speech recognition performance in adults compared with single channel stimulation. However, interpretation of present data is complicated by a lack of common body of standardized tests. It is not possible to determine which type of device is superior for children based on available evidence. | National Institutes of Health, Consensus Develop. Conf. Statement, 1988 |

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