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The effect of collaborative relationship between medical doctors and engineers on the productivity of developing medical devices

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Abstract

Previous research on medical devices R&D paid close attention to the role of medical doctors as users of medical devices, but they did not examine enough the interdisciplinary collaboration between medical doctors and engineers as a team of developing a medical device. In this paper, I looked at the effect of collaborative relationship between medical doctors and engineers on the productivity of the development based on interviews on R&D of artificial retina and bibliometric analysis on R&D of cochlear implant.

In the interviews with medical doctors and engineers involved in R&D of artificial retina in the U.S., Germany and Japan, we found that medical doctors and engineers perceive that the collaboration is one of the key factors to the success in inventing and developing medical devices, but that the good collaborative relationship is difficult to maintain. Next we examined such collaboration quantitatively by conducting bibliometric analysis of research articles and patents related to the development of

cochlear implant, and found the important role played by medical doctors and their collaboration with engineers when designing and improving the medical device, and that more collaboration between medical doctors and engineers is seen in the more productive R&D group.

Considering those findings, development of a medical device needs not only the “user-led” forces of medical doctors but also close interdisciplinary collaboration between medical doctors and engineers as a team. For such collaborative team effort to succeed, absorptive capacity of both sides and proximity between them are important, while there are barriers between a medical doctor and an engineer including cognitive, organizational, social, and institutional factors. To overcome those barriers, experiences of cooperation, education, geographic proximity, good leadership or member’s personality can promote some elements of proximity to compensate for lack or shortage of other elements of proximity.

1. Introduction

Not all developments of major medical devices necessitated the involvement of medical doctors, but significant proportion of development involved the efforts of both medical doctors and engineers.[1] Blume (2009), who studied R&D of cochlear implant, observed that “a technically inclined physician or surgeon, dissatisfied with an existing technique, begins to sketch out what a better one might be.” The role of medical doctors in R&D on medical devices has been studied mainly as one type of “user-led” innovation (von Hippel, 1988), that is, the development needs the involvement of medical doctors as knowledgeable users of the device. Those studies pointed out the importance of users as sources of innovation when users see more economic rents in innovation than manufactures. Some of those studies did case studies on R&D of medical devices and focused on the role of medical doctor as a user of medical devices. One characteristic of medical doctors as users is that they have very advanced knowledge in the fields of medical sciences.

Shaw (1985) argued that any equipment that is to be introduced into clinical use needs clinical assessment and trial, and the “state of the art” clinical and diagnostic knowledge resides in clinicians as

[1] Medical device is an instrument, and so on “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease” (US Food and Drug Administration (FDA), http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm, accessed in November 16, 2014). And see Saltzman (2009, Table 12.2) on examples of biomedical inventions.

a user. Lettl et al. (2006) pointed out that medical doctors who contribute to innovation as users have high motivation for discovering a new solution, have a variety of competencies as a set, and play a role as an entrepreneur. Other studies that analyzed the importance of medical doctors as a user are Shah and Robinson (2006), Chatterji et al. (2008) and Lüthje (2003). Significant factors that motivate physicians as a user to develop medical devices other than seeing more economic rents are peer approval, patient approval, and "instinct of workmanship" (Fuchs, 1998).

But I argue that what is needed for a successful development of a medical device would be not only the involvement of medical doctors as a user but also close interdisciplinary collaboration between a medical doctor as a user of the device and an engineer as a designer of the device. It is necessary to share knowledge, skills and techniques, especially when the development needs a technological breakthrough (Katz and Martin, 1997). As Saltzman (2009) explained in his textbook on biomedical engineering, engineers, scientists and physicians work closely as a team when inventing, designing, and building a medical device.

What previous research on R&D of medical devices did not explore enough was when, in what degree and how medical doctors and engineers collaborate when developing medical devices and its effect on R&D productivity. In this paper, I intend to examine the importance and hurdles of the collaborative relationship between medical doctors and engineers (abbreviated as "CME" hereafter) for development of medical device based on interviews on R&D of artificial retina, and then examine CME's effect on the productivity of developing a medical device based on bibliometric analysis on R&D of cochlear implant.

I do not deny that there are many studies that analyzed R&D collaboration between firms, between firms and universities, or that analyzed collaboration among researchers based on their informal networks. Those studies pointed out the importance of the links between firms and universities or involvement by firms and government labs in research joint ventures. In addition, there are studies conducted on “impact of interfirm networks on performance” or “the effects of interfirm networks on patenting, access to information, and the generation of novel ideas.” Firms can use interorganizational networks effectively as a means to “pool or exchange resources and jointly develop new ideas and skills,” especially when the scientific or technological progress is rapid and it is difficult to have all the necessary knowledge (Powell and Grodal 2006).

In addition to the studies on inter-organizational collaboration, there are studies that looked at the role of informal ties or knowledge sharing between persons belonging to different firms. There are studies that looked at the network of scientists, often termed “invisible colleges.” It is an “informal network of researchers who form around a common problem or paradigm.” There are many studies that tried to understand how such structure of scientific communities affects the expansion of knowledge. (Powell and Grodal 2006, p.73)

What I intend to do in this study relating to collaborative efforts of developing a medical device is different from those studies on inter-organizational collaboration or collaboration among researchers based on informal network relations. Rather it relates to the recently emerging research field of the studies on science of team science or team R&D. Science on team science’s focus is more on to explore under what conditions interdisciplinary type of collaboration succeeds in a research team and to understand how to overcome the inter- or trans-disciplinary barriers among team members in order to achieve their common goal. Those studies try to understand and enhance “the processes and outcomes associated with team-based initiatives that are undertaken to promote cross-disciplinary research, training, and translation of science into improved practices and policies” (Stokols et al, 2012). This study’s intention is shared by those studies on team science, but it differs from those studies in that this study focuses on the R&D of medical devices, which needs inter- or trans-disciplinary collaboration.

In sum, previous research found out the important role of medical doctors in the development of medical devices as users of medical devices. But the focus of the studies is on the role of medical doctors as users and as a result not much attention was paid to CME. In addition, a quantitative analysis on a network for developing a medical device has not been conducted. In order to bridge those gaps, I intend to look at the effects and difficulties of CME, and to do so especially by bibliometric analysis.

2. Methodology

The research methods for this study include interviews with researchers involved in the development of artificial retina, and bibliometric analysis of development of cochlear implant.

2.1. Interviews

The purposes of the interviews are to 1) know the degree with which the importance of CME for the development of medical devices is perceived among interviewees and 2) to know the CME’s difficulties and how to overcome them qualitatively before conducting quantitative bibliometric analysis. Co-authorship and research collaboration is not always the same (Katz and Martin, 1997), and it is important to know what kind of collaboration takes place at the same time as conducting bibliometric analysis. The interviewees are medical doctors and engineers who were or are involved in the development of artificial retina.

Artificial retina (or artificial prosthesis) is a surgical medical device that tries to restore vision by stimulating retina electrically in patients suffering from blindness due to retinitis pigmentosa (RP) or age-related macular degeneration (AMD) (Ameri et al, 2007). Different from cochlear implant, this medical device had not been commercialized and was at the stage of clinical trial at the time of the interviews. I chose this medical device because 1) there are currently competing research teams in the world, 2) this medical device is an advanced medical device that needs intensive R&D, and 3) there are technically common elements between R&D of cochlear implant and artificial retina. I conducted interviews in the U.S., Germany and Japan in order to increase the generalizability of the findings. However, since there are many kinds of medical devices, we need caution when generalizing the result of the interviews. [2]

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[2] There are many kinds of medical devices: medical devices for diagnostic, surgical or rehabilitation purposes. They can also be classified by application areas such as digestive system, ear/nose/throat system, urinary system, orthopedic system and so on, or by types of markets (commodity products or innovative medical devices products) (Mehta, 2008, p.8).

Interviews were conducted with ten researchers in Japan, at the engineering and medical departments of universities and firms. Six interviews were conducted in the U.S. and five interviews in Germany.[3] The information collected in the interviews were facts and beliefs/attitudes related to CME. The questions I asked in interviews include: what is the current status of the R&D and CME; how CME is important for the R&D for medical devices; what the hurdles for collaboration are; and what you need to maintain CME by overcoming the hurdles. The answers to those questions were given in an open-ended manner. The interviews were recorded, and its contents were transcribed.

2.2. Bibliometric analysis

We analyze CME when developing cochlear implants by bibliometric analysis. The purpose is to look at the characteristics of CME and its effects on R&D productivity. Cochlear implant is a widely-used surgical medical device for assisting a person who has difficulty in hearing by stimulating electrically the cochlear in internal ear. [4] The reason why I chose this medical device is that 1) cochlear implant is a

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[3] Interviews were conducted in Japan in September and October 2008 (3 medical professor, 6 engineering professors, 1 firm manager), in the U.S. in December 2008 (2 medical professors, 2 engineering professors, 1 firm manager), and in Germany in January 2009 (2 engineering professors, 1 firm manager, 2 policy researchers in public research institute).

[4] In the U.S., 1.2 million children and adults were estimated as potential implant candidates. The total number of recipients in the U.S. in 2009 was estimated at 70,000 adults and children, yielding a utilization rate of 5.6% among the candidate population. (Sorkin, 2013)

successful medical device, and there have been R&D efforts of the research teams in the world, 2) their efforts are well-documented by previous studies, and 3) cochlear implant has common technical elements with artificial retina. As stated above, we need caution when interpreting the results.

Coauthorship and coinventorship analysis are conducted in order to analyze the network of collaboration. The tools used for the analysis are VantagePoint for data mining, and Pajek for analyzing and visualizing social network (Morel et al, 2009). Bibliographic information is downloaded using Web of Science and Derwent Innovation Index. We identify if the author or inventor is a medical doctor, engineer, or other. I define medical doctor as a graduate of medical school irrespective of whether he/she currently practices medicine or not. Information on authors or inventors is obtained from websites of the institutions or websites of themselves. The mapping of the network of CME is depicted and observed (de Nooy et al., 2005).

As to Web of Science, we used citation index expanded edition and the period is up to September 25, 2010, and as to Derwent Innovation Index, the search period was from 1963 to September 25, 2010. Search word was "cochlear implant." The number of hits is 2,910 for articles and 714 for patents. After checking the content, we restricted the data to top 100 authors or inventors in terms of the number of papers or patents. We chose data on 1,428 articles and 392 patents.

The purpose of conducting bibliometric analysis here is not just to visualize coauthorship or coinventorship relationships. In other words, visualization is not the purpose but the means to look at the degree of collaboration between medical doctors and engineers for the development of this medical device. As Börner and Boyack (2012) pointed out, the purpose of mapping is "simply to visually display the results of analysis to enhance communication of those results" and visualization itself is not analysis.

3. Results

3.1. Interviews

a. United States

There are two major research teams on artificial retina in the U.S. One team, Boston Retinal Implant Project, is the team composed of researchers at Harvard University and Massachusetts Institute of Technology (MIT). The other is the team composed of researchers at University of Southern California (medical school); University of California, Santa Cruz; and Second Sight.[5] The former research team started in the late 1980s.[6] The latter team started at almost the same period as the Boston project. Second Sight is a private firm established in 1998 by Alfred Mann, who established Advanced Bionics in 1993.

In the interviews, the starts of the research projects were explained by an engineering professor (Eng. Professor A): "the project started from the idea of a medical doctor. He visited our department at the university. At the time, I did not know anything about retinal implant, and he did not know electronics. He was trying to find an engineer with whom he can work together." The medical doctor who visited

[5] The explanation in this section is based on the information at the time of conducting interviews, and may change afterwards.

[6] Boston Retinal Implant Project http://www.bostonretinalimplant.org/ (accessed at November 16, 2014)

the engineer explained (Med. Professor A) that “the project started in the late 1980s. My specialty was retinal transplantation and tried to recover the vision of patients who have diseases in retina by implanting retinal cells. One day I came up with an idea to use microelectronics technology. With this idea in mind, I contacted many engineers and discussed about its feasibility.” They found out that they shared a common interest in human vision. Eng. Professor A explained that “we had common interest, and that was very important when starting the project.” Another engineering professor in another research group (Eng. Professor B) explained that “a medical doctor working at a university hospital contacted me. He came to my office and asked me if it was possible to make light into electric signals. There was a hypothesis that stimulation of retina by implanted electrodes could recover lost vision.” In those stories, the initiative of medical doctors to contact with engineers and start the projects on their initiatives was noteworthy.

Then the importance of CME and its difficulty were pointed out. In the words of Eng. Professor B, “interdisciplinary collaboration is important for developing a medical device. Medical doctors play the role of pull, and engineers play the role of push.” Eng. Professor A said, “engineers have knowledge on devices that medical doctors would like to use. Medical doctors know that they cannot develop without collaborating with engineers. Collaboration may be difficult, but necessary.”

As to the difficulties on CME, first, understanding of technical terms was pointed out. Eng. Professor A told me on his research career: “I have an engineering background, so I needed to study medical science. In interdisciplinary research, it is necessary to study in order to understand what collaborators are saying.” Eng. Professor B explained the same story: “I did not know about medicine and biology. There is a barrier to speak over disciplines, but you can overcome it if you continue working.”

Second point is about allocation of time and efforts. This may be general problems of collaborative research. “Problems can happen, for example, if the participants allocate only a little time for the project. We try to meet at least once a week and understand each other” (Eng. Professor B). Eng. Professor A explained that “I teach and clinicians work in a hospital. Engineers and medical doctors have many goals other than the project.”

In order to overcome those difficulties, first, importance of leadership and personality of members were pointed out. Eng. Professor A explained that “the reason why the project goes well is that the leader of the project, who is a clinician, is not a person difficult to work with. Another important factor is personality type of members. Our team is consisted of researchers who are easy to talk to and straightforward.” Eng. Professor B pointed out that “the role of leadership is important for good team work. Team members need to trust each other.” Secondly, the importance of close distance was pointed out. Med. Professor A explained that “there is a community of scientists in this region. In particular, researchers at Harvard and MIT are cooperative each other.” Another medical doctor (Med. Professor B) pointed out the regional advantage of being in his region. Importance of close distance was pointed out also by engineers and a firm manager. According to a firm manager (Manager A), “many medical doctors and engineers participate in the project. Our lesson is that proximity is very important. Being proximate leads to better results.” Thirdly, the importance of education was pointed out. Med.

Professor A observed that “in general, the collaboration between medical doctors and engineers go well in the U.S. There are well-established systems and programs at major universities.”

b. Germany

In Germany, Federal Ministry of Education and Science started a research project called Neuro-Technology in 1994. It provided funding in 1995 for two research projects for developing artificial prosthesis: epiretinal-type system and subretinal-type system. The government funding for those projects continued until 2003. There are private companies that are trying to commercialize each type of artificial retinas: Intelligent Medical Implants for epiretinal method and Retina Implant for subretinal method.

One of the research team, according to one engineering professor (Eng. Professor C), was composed of interdisciplinary members. He explained that “when we started a project, the backgrounds of 12 team members include mathematics, computer science, physics, engineering, material science, opto-electronics, opt-biology, neurobiology, and ophthalmology.” He commented on the importance of collaboration that “medical doctors, engineers, and biologists sit on the same table and started discussing on the project. At first, they said that it is impossible to develop such an advanced medical device. Then interesting thing happened. After three months, we started to trust each other and to think that we may be able to solve the problem by working together.”

In the interviews, a couple of difficulties for CME were pointed out. Firstly, the difficulty of maintaining collaborative relationship among members was pointed out. One analyst of medical devices development at a public research institute (Analyst A) explained that it is difficult for medical doctors and engineers to maintain an equal partnership, since clinicians tend to think that only they know what is good for patients. Secondly, as to a problem of time pressure, especially for clinicians, another researcher at a public research institute (Analyst B) observed that clinicians are busy and that makes it difficult for medical doctors and engineers to collaborate on a research project, since it is difficult for clinicians to have a balance between patients and research.

In order to overcome those difficulties, the importance of good leadership and communication was emphasized. As to the importance of good leadership, Eng. Professor C said, "clinicians in general play the role of a leader and tend to dominate a multidisciplinary research team. It is necessary for such person to understand he should contribute as a team member according to his expertise." He added that "our members have a cooperative personality. Members say what they would like to say, and we think there are no stupid questions."

c. Japan

In Japan, NEDO funded a project on artificial prosthesis for 5 years between 2001 and 2006. NEDO is a public funding agency in applied R&D area. The leader of the project was at the medical school of Osaka University. The development of the system was conducted by a private firm, Nidek. Nidek was in charge of the development of technologies and the device system. Nara Institute of Science and Technology and the engineering department of Osaka University collaborated with regards to the development of the electronic device.

The difference with the U.S. and German groups was that a company was given a major role from the start of the project and "user-led" force by medical doctors was stronger, both of which reflected the fact that Japanese team was a late comer and needed to catch up quickly. In the interview, one medical doctor (Med. Professor C) explained on the role of medical doctors that "we are in a position of evaluating the product the firm produced. I have a periodic meeting with the firm. We examine the product by embedding it in a rabbit's eye." A company participant (Manager B) said, "medical professors made many requests based on the result of the experiments, for example, on the shape of the device." Another medical professor (Med. Professor D) commented that "it is difficult for researchers at engineering department to do research on medical devices by themselves. Such research should be led by medical doctors. It is necessary to examine the reaction of human body to the device."

Although the importance of CME was pointed out in the interviews, its difficulties were emphasized. Firstly, as to understanding of technical terms, one engineering professor (Eng. Professor D) explained that "when we started research, we did not understand the language of other disciplines. It takes time to understand the field." Another engineering professor (Eng. Professor E) explained that he did not understand at the start of the joint research the words like "optic disk," "vitreous humour," "retinitis pigmentosa" or "macular degeneration." Secondly, different expectations and goals of medical doctors and engineers were pointed out. Yet another engineering professor (Eng. Professor F) explained that "medical doctors expect a medical device that can be used immediately for patients, even if the device lacks novelty. However, if the medical device lacks novelty, engineers cannot write a research article." Thirdly, there were many comments on the difficulty in communication, Eng. Professor D pointed out that "there is a problem of communication between medical and engineering researchers. In general, clinical researchers are all busy and do not have enough time to respond to engineer's request immediately." Another engineering professor (Eng. Professor G) explained that "medical professor's thinking is that they have absolute authority in their specialty, and as a result it is difficult to do research in a bottom-up approach," which makes frank bottom-up communication difficult.

In order to overcome those difficulties, the importance of frequent communication and education on medical engineering were pointed out. As to frequent communication, Eng. Professor E observed that "in the project, we had periodic meetings. We took enough time in the meetings for discussion and engineers started to understand what medical doctors are trying to say." As to the importance of education on medical engineering, another medical professor (Med. Professor D) emphasized that "lack of human resources in this field is a large problem. In Japan, it is when you start a joint research project that you start learning other fields and look for common language."

In sum, medical doctors and engineers perceive that CME is one of the important factors to the success in developing medical devices. From those observations, we could reasonably assume that there is CME if there is coauthorship or coinventorship relationship between them. At the same time, the good collaborative relationship is pointed out to be difficult to be built and be maintained. There are hurdles to overcome.

Various hurdles for building a collaborative relationship and a couple of factors that promote collaboration were pointed out, although those are not meant to be exhaustive. Firstly, most interviewees pointed out the importance of good leadership, personality of members and good communication for successful collaboration. Such good collaboration would make it enjoyable for researchers to learn the unfamiliar field and learn from each other. Relating to that, close distance of researchers was pointed out to be effective for maintaining more frequent interactions. Secondly, programs on medical engineering at universities not only provide education to students who want to do research in the field of medical technology, but also function as a place to conduct R&D on medical devices cooperatively.

3.2. Bibliometric analysis

Before explaining the result of the bibliometric analysis, I explain the R&D process of cochlear implant briefly.[7] In 1957, Professor Eyries, who was of the medical faculty in Paris, tried to give a deaf patient some hearing by an electrode implanted into his ear. Eyries collaborated with his colleague Djourno, who was studying electrical stimulation of the auditory nerve in animals. Dr. House, an ear surgeon in Los Angeles, tried to implant a more complex electrode into a deaf man in 1961, and collaborated with an engineer to construct it. Professor Simmons, who was at Stanford University Medical School, tried in 1962 what House did. He implanted a six-electrode device in 1964, collaborating with an expert in auditory psychophysics.

By the mid-1970s, other research groups were involved. At the University of California at San Francisco (UCSF), Dr. Michelson, who was a physicist-turned-otologist, implanted electrodes for four patients. In Australia, in 1970, Professor Clark, a chair in otolaryngology at the University of

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[7] This section draws on Blume (2009), Chapter 2 "The Making of the Cochlear Implant."

Melbourne, started developing multiple electrodes inserted at different positions in the inner ear and a prototype was implanted into the first volunteer in 1978.

Cochlear implantation gained credibility in the profession, and industry became interested in the late 1970s. 3M was the first company to market a cochlear implant in the U.S. 3M made contractual agreements with House and the Hochmairs, Austrian electrical engineers, in 1981, and the House/3M device became the first cochlear implant to be approved by FDA in 1984. Clark's industrial partner was Nucleus. The Nucleus implant became the second system to be granted FDA approval in 1985. The ownership of the 3M/House device was sold to the Nucleus-daughter Cochlear Ltd. (Cochlear Corporation) later. Three manufacturers now dominate the world market. The Cochlear Ltd. is the market leader. The other manufacturers are MedEl (an Austrian firm established by the Hochmairs in 1989) and Advanced Bionics, which developed a commercial implant based on work at UCSF.

a. Analysis on coauthorship and coinventorship

Figure 1 shows coauthorship relations.[8] Each node shows a researcher and each line shows a coauthorship relation. The number in the node (1-10) refers to the ranking of researchers in terms of

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[8] Since appropriate number of nodes for looking at network relationship is 500 at the most, only researchers with more than or equal to three articles were included and the number of researchers in the figure was reduced from 2,267 to 506. By including only coauthorship relation with more than or equal to 4 coauthored articles, the number was further reduced to 314. Although the number is reduced, the number of researchers is larger since there are coauthors to those researchers.

the number of published papers. The wider the width of a line is, the larger the number of coauthored articles. The color of nodes shows type of occupations: yellow for a medical doctor, green for an engineer, red for others (including biomedical scientists), and blue for unknown. There are medical doctors, engineers, and biomedical scientists, and collaborative relationship of those researchers can be observed.

Figure 2 shows coinventor relationship.[9] The largest group is at Cochlear Ltd. and other group's sizes are almost the same. What is different from the coauthorship relations is that there are not many medical doctors in the research groups, and most of the researchers belong to private companies. Only the research group at Cochlear Ltd. includes medical doctors.

(Insert Figure 1 and Figure 2)

Figure 3 revised the size of the nodes in Figure 1 based on the size of "betweeness centrality" of each node, that is, the proportion of all geodesics between pairs of other nodes that include this node (de Nooy, et al, 2005).[10] Geodesics means the shortest path between two nodes. The size of this indicator means the degree with which a node occupies the central position in the network. This graph shows

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[9] The inventors with more than or equal to 2 applications and with more than or equal to 2 coinventor relationships are included. The number was reduced from 506 to 177.

[10] There are other indices for comparing the centrality of nodes, such as "degree centrality" and "closeness centrality." Degree and closeness centrality are based on the reachability of a person within a network, and the concept of betweeness depends on the idea that the more a person is a go-between, the more central his or her position in the network. Both indices can be used for the current purpose.

how medical doctors occupy the central position in each research group. Likewise, Figure 4 is made based on Figure 2. In the patent data, engineers occupy central positions in each research group. It is interesting to note that there are no centrally-positioned dominant researchers different from the data on research articles.

(Insert Figure 3 and Figure 4)

Next, “network betweeness centralization” of each research group was calculated. “Network betweeness centralization” means the variation in the betweeness centrality of nodes divided by the maximum variation in betweeness scores possible in a network of the same size. The higher the indicator is, the more centralized the network is. Network betweeness centralization based on research articles is larger than that based on patents, which means that there are more dominant research leaders in research groups at article-writing phase[11] as Figure 3 and 4 show.

Cohesion of each research groups is examined next. For this purpose, average degree of nodes was examined. Degree is defined as the number of lines incident with it, and average degree of nodes is

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[11] As to the data on research articles, network betweeness centralization of research groups at Medical University Hannover, Johns Hopkins University, University of Sydney, University of Southern California, and Medical University of Vienna was 0.817, 0.526, 0.809, 0.643, and 0.463 respectively. As to the patent data, network betweeness centralization of research group at Cochlear Ltd., Advanced Bionics, Medtronic, MED-EL, and Greatbatch, Ltd. was 0.522, 0.373, 0.461, 0.598, and 0.314 respectively.

calculated by averaging the degrees of all the nodes in a research group.[12] The difference between the sizes of "average degree" of the research groups in data on articles and patents was not statistically significant.[13]

b. Relationship between CME and research group's productivity

The relationship between the total number of articles[14] and the proportion of the number of the coauthorship relations between a medical doctor and an engineer to the total number of the coauthorship relations (%) for each research group is examined. A research group is defined as a group of researchers who shows coauthorship relationship in Figure 1, and one or more of whose members

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[12] "Density" is another indicator for measuring cohesion. Average degree of all nodes is a better index, because density depends on network size and is not appropriate to use for comparing networks of difference sizes.

[13] As to research articles data, average degree for the research groups at University of Sydney, Medical University Hannover, Johns Hopkins University, University of Southern California, and Medical University of Vienna are 7.10, 6.20, 7.44, 4.0, and 7.45 respectively. As to the data on patents, average degrees for the research groups at Cochlear Ltd, Advanced Bionics, Medtronic, MED-EL and Greatbatch, Ltd. are 7.30, 6.75, 12.6, 6.32, and 13.5 respectively

[14] The number is calculated as the sum of the number of articles written by an author or authors which at least include a "medical doctor", an "engineer", or "other" in Figure 1 or Figure 2. Duplication is deleted in this analysis. In other words, when A, B, and C in the same research group write a paper jointly, the number of papers of the group is calculated as 1, not 3.

are among the top 20 authors in terms of the number of articles written. The correlation coefficients for coauthorship and coinventorship are positive and statistically significant at 10% and 1% respectively.[15] In addition, the correlation between centralization and the number of articles or patents for research groups, and the correlation between cohesion (average degree of nodes) and the number of articles or patents were examined. Any statistically significant relationships were not found. In other words, a group where one dominant research leader occupies the central position or a group with higher cohesion of members does not produce more research articles or patents. The reason would be that collaborative relationship among research members are not based on one-way command and control from a leader but on more equal and looser interdisciplinary collaborative research relationship among members. As to cohesion, the reason would be that each member collaborates not with all, but with a part of members.

c. Dynamics of CME

Figure 5 shows the change in proportion of types of coauthorship, that is, whether between a medical doctor and an engineer (we call it type 1 collaboration), between medical doctors (type 2 collaboration), or between engineers (type 3 collaboration), in articles. Proportion of the type 2 collaboration is high since the late 1980s up to the present. This is expected from Figure 1, since there are many medical

[15] Correlation coefficient between the number of articles and the proportion is 0.620 (p-value=0.056, n=10) and correlation efficient between the number of articles and the proportion is 0.996 (p-value=0.0043, n=4).

doctors who write an article, collaborating with each other. Proportion of the type 1 collaboration is high in the early 1980s. Although it declined, the proportion of the type 1 collaboration is maintained at 20-30% and such type of collaboration is sustained in the R&D process.

Likewise, Figure 6 shows the change in proportion of each type of coinventorship, in patents. Different from the coauthorship, the type 3 collaboration, conducted at private firms, dominates.

(Insert Figure 5 and Figure 6)

In sum, the following is observed in the bibliometric analysis.

1) In data on coauthorship, medical doctors themselves are authors to research articles and the important role played by medical doctors and CME, as was observed in the interviews, is observed (Figure 1). Figure based on network betweeness centralization shows the important role played by medical doctors in networks of researchers (Figure 3) (3.2 a.).

2) There are few medical doctors in the map of coinventor relationship compared with coauthorship relationship (Figure 2). The reason would be that the role of medical doctors and CME is important, particularly during the stage of concept generation and reflection of needs, and the role of engineers in firms becomes indispensible in commercialization stage. In addition, the network is more centralized in research group on articles than that on patents, suggesting that creative activities in a group at research stage is led more by a few dominant researchers than at applied stage (3.2 a.).

3) We found the positive correlation between the number of articles for each of the research groups, and the proportion of the number of the coauthorship between a medical doctor and an engineer of the

group to the total number of the coauthorship relations. Likewise, we found the positive correlation between the number of patents and the proportion of coinventorship relations (3.2 b.).

4) Either for data on coauthorship or on coinventorship, CME is important during the initial stage of R&D. The more R&D proceeds toward commercialization and later stage, the larger the role of engineers becomes (3.2 c.).

4. Discussion

By conducting interviews, we found that medical doctors and engineers perceive that CME is one of the key factors to the success in developing medical devices. By conducting bibliometric analysis, we found the importance of the role played by medical doctors and CME. However, in the interviews, it was pointed out that the good collaborative relationship is difficult to maintain (3.1.). In this section, we would like to discuss why it is difficult.

First explanation is general difficulty in conducting interdisciplinary research.[16] The difficulty, in general, includes differences in methods of inquiry, scientific standards of evidence, communication structures, socialization processes, external recognition, and so forth (Corley et al., 2006). Clinical study is a system of knowledge that intends to cure patients, while engineering is a system of

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[16] In general, the approach of cross-disciplinary research are called as either multidisciplinary, interdisciplinary, or transdisciplinary in the increasing level of disciplinary integration (Stokols, D. et al. 2012). In this study, the term interdisciplinary research refers to R&D on medical devices by drawing on and integrating knowledge of medical sciences and engineering, and relates to both interdisciplinary and transdisciplinary research approaches.

knowledge for designing a thing that is useful for people. Although there are overlaps of those disciplines, there still remain the difficulties.

Second explanation is high degree of tacitness of medical knowledge. Knowledge is a concept different from information (Davenport and Prusak, 1998):"knowledge is a fluid mix of framed experience, values, contextual information, and expert insight that provides a framework for evaluating and incorporating new experiences and information." Michael Polanyi (1958), who proposed the concept of tacit knowledge, was originally trained as a medical doctor. He frequently refers to the education of medical doctors when explaining the concept in his book *Personal Knowledge*[17]. The personal knowledgeness of medical knowledge would be the reason why medical doctors take an initiative in the development (or reason of "user-led" type innovation).

Third explanation relates to special status of medical profession. As Freidson (1970) explains, medical doctors possess "something of a monopoly over the exercise of its work" and "special privilege of freedom from the control of outsiders" because of their high skill and knowledge, and society's trust in them. As a result, other occupations tend to be subordinate to medical doctors in authority and responsibility. Freidson, a sociologist, also points out the characteristic of the mind of clinicians, or

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[17] Polanyi explains as follows: "Connoisseurship, like skill, can be communicated only by example, not by precept. …[T]o be trained as a medical diagnostician, you must go through a long course of experience under the guidance of a master. Unless a doctor can recognize certain symptoms, e.g. the accentuation of the second sound of the pulmonary artery, there is no use in his reading the description of syndromes of which this symptom forms part." (Polanyi, 1958, pp.54-55)

“clinical mind,” as compared to theoretician or investigator. A practitioner of medicine “comes essentially to rely on the authority of his own senses, independently of the general authority of tradition or science.” (Freidson, p.168-170). These characteristics of medical doctors would lead to the difficulty in CME, in the situation where engineers do not have to be subordinate and need to have autonomy in the creative R&D activity.

If CME is essentially difficult as is explained above, the initiative of a medical doctor as a user alone, although it is important, does not make it possible to overcome those hurdles for CME. There would need to be other factors. First, absorptive capacity of both medical doctors and engineers would be important. Cohen and Levinthal (1990) argued that the ability to identify, interpret, and exploit new knowledge is critical to innovative capabilities, and label it absorptive capacity. Their argument focuses on firms, but absorptive capacity of individuals is necessary as a precondition for absorption of technologies to occur (Lane, Koka, and Pathak, 2006). In addition to that, absorptive capacity is important not only for absorption of technologies by a firm, but for conducting collaborative R&D in an interdisciplinary field.

Second, proximity between medical doctors and engineers is important. Boschma (2005) pointed out there are five forms of proximity (geographical, cognitive, organizational, social and institutional) when conducting a collaborative project. He defines cognitive proximity as a function of the similarity between actor’s knowledge bases. Boschma argued that these forms of proximity may substitute each other. When there is no cognitive proximity, other elements of proximity helps. Therefore regional advantage, long historical relationship or past experiences of collaboration compensate for lack of cognitive proximity, as was pointed out in the interviews. Or cognitive proximity itself can be nurtured by education. In case of development of medical devices, since most of the knowledge bases of medical doctors and engineers are not shared, efforts to shorten the distance in the other dimensions of proximity would be important for increasing the productivity of the collaboration.

5. Conclusion

In this paper, by interviewing medical doctors and engineers involved in R&D of artificial retina, we found that medical doctors and engineers perceive that CME is one of the keys to the success in developing a medical device, but that the good CME is difficult to maintain. By looking at such collaboration in bibliometric analysis of research articles and patents, we found the important role of medical doctors and CME. Central positions are occupied by medical doctors in the researcher's network. For each of the research groups, there is positive correlation between the number of articles or patents and the degree of CME represented by coauthorship or coinventorship. In other words, more CME is seen in the more productive R&D group. In addition, data shows that the CME is important during the initial stage of R&D.

Considering those findings, research teams that are able to overcome the difficulties in CME, as are pointed out in the interviews, achieve close collaboration and lead in the development as can be observed in bibliometric analysis. In other words, development of a medical device needs not only the "user-led" forces derived from medical doctors but also close interdisciplinary collaboration between a medical doctor as a user of the device and an engineer as a designer of the device.

For such collaborative efforts to succeed, absorptive capacity of both sides and proximity between them are important, since there are barriers between a medical doctor and an engineer including cognitive (disciplinary), organizational, social, and institutional barriers. To overcome those barriers, education, geographic proximity, and good leadership or member's personality is effective. Those could promote some elements of proximity to compensate for lack or shortage of other elements of proximity such as cognitive proximity among others.

In order to get stronger results on (1) causation between CME and performance of R&D on medical devices, and (2) temporal pattern of CME, it is necessary to do studies on more cases of R&D of medical devices using the same methodology, and do interviews or a survey in other medical specialty. Also it would be interesting to do a longitudinal bibliometric analysis on R&D of medical devices of a firm or industry, and see how the pattern of collaboration is changing with the advent of open innovation.

The important implication of this study for R&D management is that bibliometric analysis on articles and patents, when incorporating data on whether a researcher is either a medical doctor or an engineer, is effective to monitor or evaluate a R&D program or project on medical technology by a interdisciplinary research team, either conducted by a government research institute, a university, or a firm. Especially it would provide valuable data when evaluating the degree of interdisciplinary collaboration of a large government R&D program on a medical device.

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Reference

Ameri, H., Wieland, J.D., Humayun M.S. (2007). Biological Considerations for an Intraocular Retinal Prosthesis, in: Humayun, M.S., Weiland, J.D., Chader, G., Greenbaum E.(Eds), *Artificial Sight: Basic Research, Biomedical Engineering, and Clinical Advances*. Springer, New York, pp.1-29.

Blume, S.S. (1995) Cochlear implantation: establishing clinical feasibility, 1957-1982, in Gelijns C., and N. Rosenberg, eds. 1995b, pp.97-124.

Blume, S.S. (2009) *The Artificial ear: cochlear implants and the culture of deafness*. Rutgers University Press, Piscataway.

Börner, K. and Boyack, K.W. "Mapping interdisciplinary research" pp.457-460. in *The Oxford Handbook of Interdisciplinarity*. Edited by Frodeman, R., Klein, J.T., and Mitcham, C. Oxford University Press.

Boschma, R.A. (2005) Proximity and innovation: a critical assessment. *Regional Studies*. 39, 61-74.

Chatterji, A.K., Fabrizio, K.R., Mitchell, W. and Schulman, K.A. (2008) Physician-industry cooperation in the medical device industry. *Health Affairs* 27(6), 1532-1543.

Corley, E.A., Boardman, P.C. and Bozeman, B. (2006) Design and the management of multi-institutional research collaborations: theoretical implications from two case studies. *Research Policy* 35, 975-993.

Cohen, W. M. and Levinthal, D.L. (1990) Absorptive capacity: a new perspective on learning and innovation. *Administrative Science Quarterly*. Vol.35, No.1, 128-152.

Davenport, T., and Prusak, L. (1998) *Working knowledge: how organizations manage what they know*. Harvard Business School, Cambridge, MA.

de Jong, J.P.J., and Freel, M. (2010) Absorptive capacity and the reach of collaboration in high technology small firms. *Research Policy* 39 (2010). 47-54.

de Nooy, W., Mrvar, A. and Batagelj, V. (2005) *Exploratory social network analysis with Pajek.* Kindle Edition. Cambridge University Press, Cambridge.

De Vet, J.M. and Scott, A.J. (1992) The Southern California medical device industry: innovation, new firm formation, and location. *Research Policy* 21, 145-161.

Finkelstein, S.N., Neels, K. and Bell, G.K. (1995) Innovation in cardiac imaging, in Gelijns C., and N. Rosenberg, eds. 1995b, pp.125-154.

Freidson, E. (1970) *Profession of medicine: A study of the sociology of applied knowledge*. University of Chicago Press, Chicago.

Fuchs, V.R. (1998) *Who shall live?: health, economics, and social choice*. Expanded Edition. World Scientific Publishing, River Edge, NJ.

Gelijns, C., and Rosenberg, N. (1995a) From the scalpel to the scope: endoscopic innovations in gastroenterology, gynecology, and surgery, in Gelijns C., and N. Rosenberg, eds. 1995b, pp.67-96.

Gelijns C., and Rosenberg, N. eds. (1995b) *Sources of medical technology: universities and industry*. National Academy Press, Washington, D.C.

Ijichi, T., Yoda, T. and Hirasawa, R. (1993) Mapping R & D Network Dynamics: Analysis of the Development of Co-author and Co-inventor Relations. *Journal of Science Policy and Research Management*, Vol. 8, No.3, 263-275.

Katz, J.S. and Martin, B.R. (1997) What is research collaboration? *Research Policy*, 26. 1-18.

Lane, P.J., Koka, B.R. and Pathak, S. (2006) The Reification of Absorptive Capacity: A Critical Review and Rejuvenation of the Construct. *Academy of Management Review*. Vol.31, No.4, 833-863.

Lettl, C., Herstatt, C.H. and Gemuenden, H.G. (2006) Users' contributions to radical innovation: evidence from four cases in the field of medical equipment technology. *R & D Management* 36, 251-272.

Luthje, C. (2003) Customers as co-inventors: an empirical analysis of the antecedents of customer-driven innovations in the field of medical equipment. Proceedings of the 32nd European Marketing Academy Conference, Glasgow, UK.

Mehta, Shreefal S. *Commercializing Successful Biomedical Technologies: Basic Principles for the Development of Drugs, Diagnostics and Devices*. Cambridge University Press. 2008.

Metcalfe, J.S., James, A. and Mina, A. (2005) Emergent innovation systems and the delivery of clinical services: the case of intra-ocular lenses. *Research Policy* 34, 1283-1304.

Morel, C.M., Serruya, S.J., Penna, G.O., and Guimaraes, R. (2009) Co-authorship network analysis: a powerful tool for strategic planning of research, development and capacity building programs on neglected diseases. *PLoS Neglected Tropical Diseases* 3(8), online.

Morlacchi, P., and Nelson, R. (2011) How medical practice evolves: learning to treat failing hearts with an implantable device. *Research Policy* 40, 511-525.

Polanyi, M. (1958) *Personal knowledge: towards a post-critical philosophy*. University of Chicago Press, Chicago.

Powell, W.W., and Grodal, S. (2006). Chapter 3: Networks of Innovators. Pp.56-85. In *The Oxford Handbook of Innovation*. Edited by Fagerberg, J., Mowery, D.C., and Nelson, R.R. Oxford University Press.

Saltzman, W.M. (2009) *Biomedical engineering: bridging medicine and technology* (kindle edition). Cambridge University Press, New York.

Schuman, J.S., Puliafito, C.A. and Fujimoto, J.G. eds. (2006) *Everyday OCT: Handbook for clinicians and technicians*. Slack Incorporated, Thorofare, NJ.

Shah, S.G.S., and Robinson, I. (2006) User involvement in healthcare technology development and assessment: structured literature review. *International Journal of Health Care Quality Assurance* 19(6), 500-515.

Shaw, B. (1985) The role of the interaction between the user and the manufacturer in medical equipment innovation. *R & D Management* 15(4), 283-292.

Sorkin, D.L. (2013) Cochlear implantation in the world's largest medical device market: utilization and awareness of cochlear implants in the United States. *Cochlear Implants Int.* 14(Suppl 1): S4–S12.

Spetz, J. (1995) Physicians and physicists: the interdisciplinary introduction of the laser to medicine, in Gelijns C., and N. Rosenberg, eds. 1995b, pp.41-66.

Stokols, D. et al. (2012) Chapter 32: Cross-disciplinary team science initiatives: research, training, and translation. In *The Oxford Handbook of Interdisciplinarity*. Edited by Frodeman, R., Klein, J.T., and Mitcham, C. Oxford University Press. pp.471-493.

US FDA. Is The Product A Medical Device? http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm (accessed at November 16, 2014)

von Hippel, E. (1988) *Sources of innovation*. Oxford University Press, New York.

Yin, R.K., 1994. *Case Study Research: Design and Methods* (Second Edition). Sage Publications, Thousand Oaks, California.

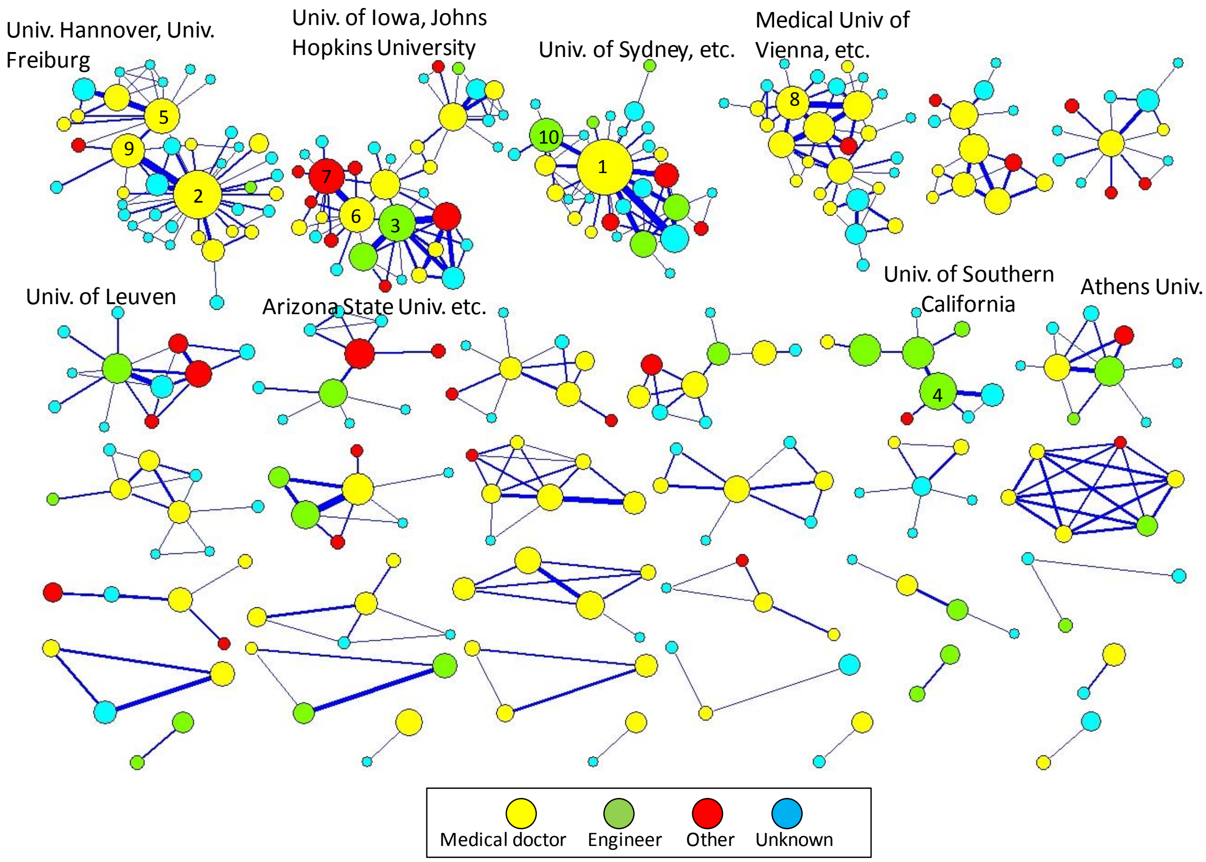


Figure 1: Coauthorship relationship among researchers related to cochlear implant

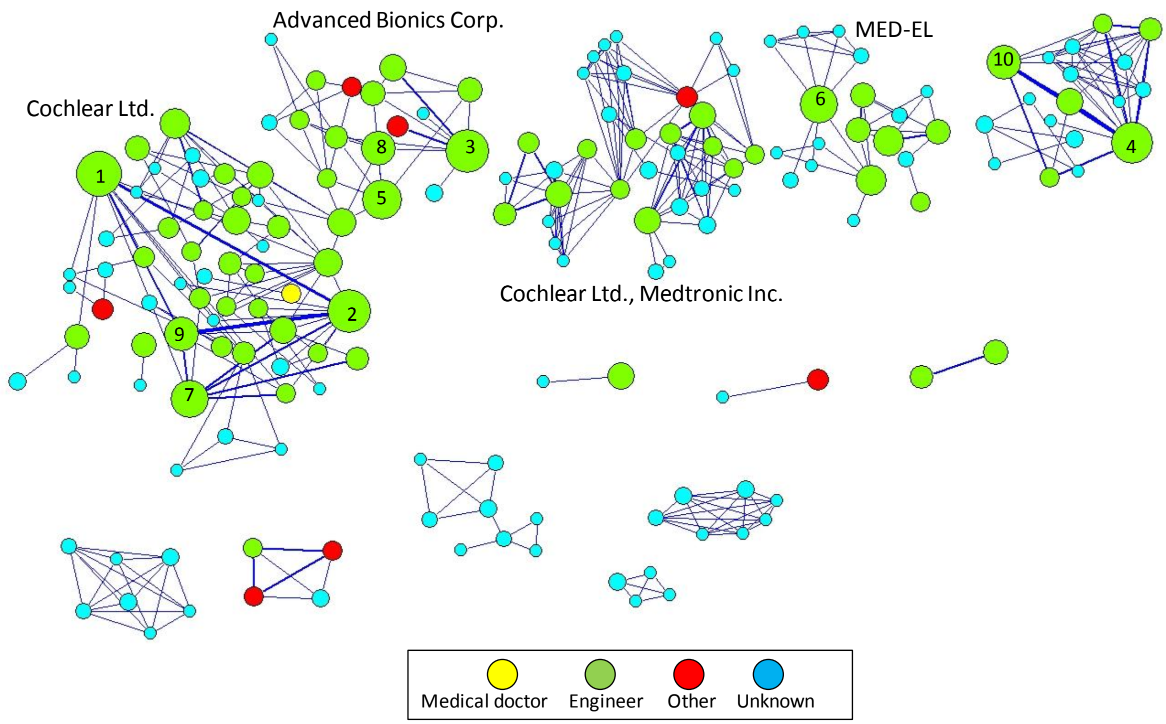


Figure 2: Coinventorship relationship among researchers related to cochlear implant

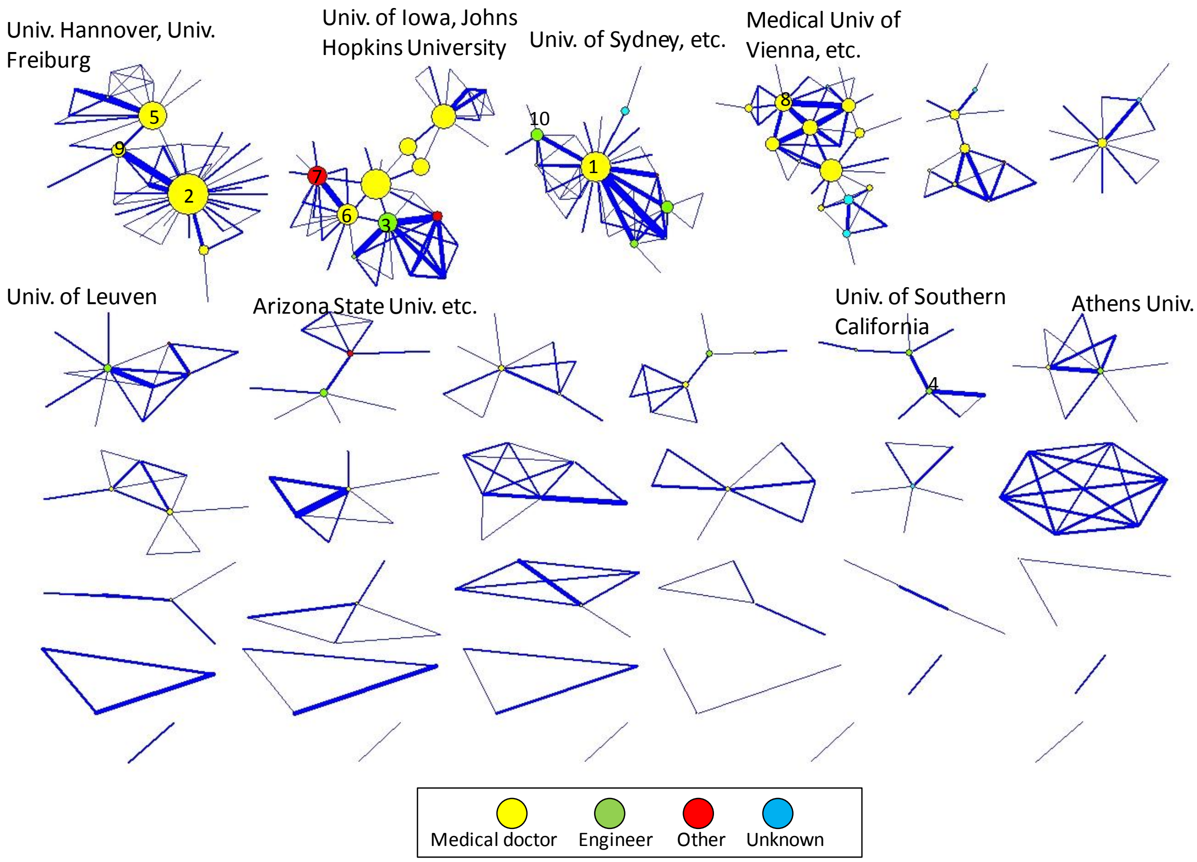


Figure 3: Centralization of nodes (coauthorship relationship among researchers related to cochlear implant)

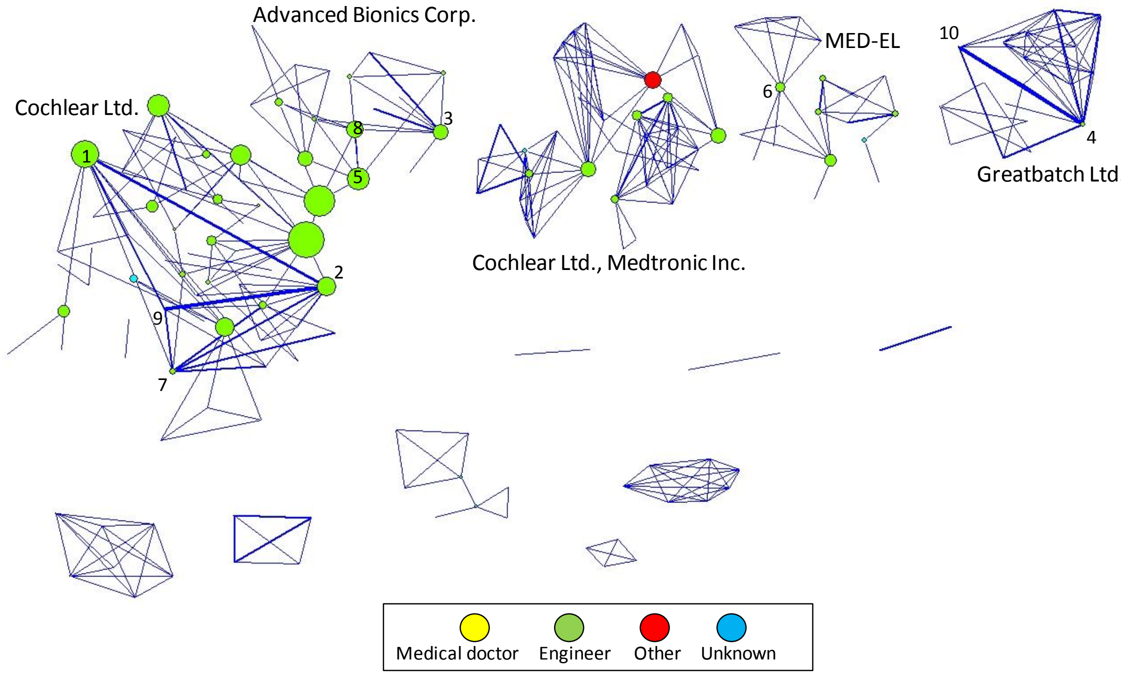
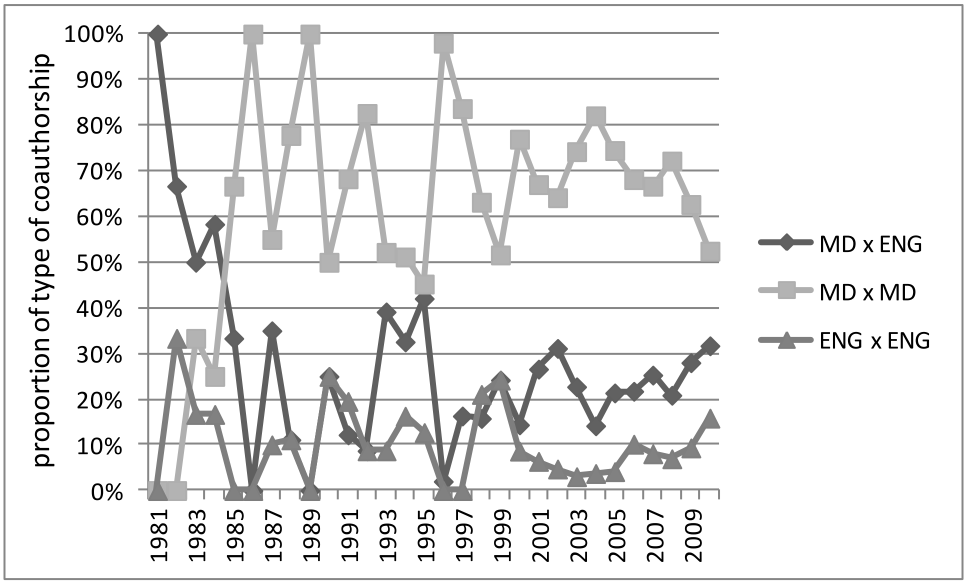
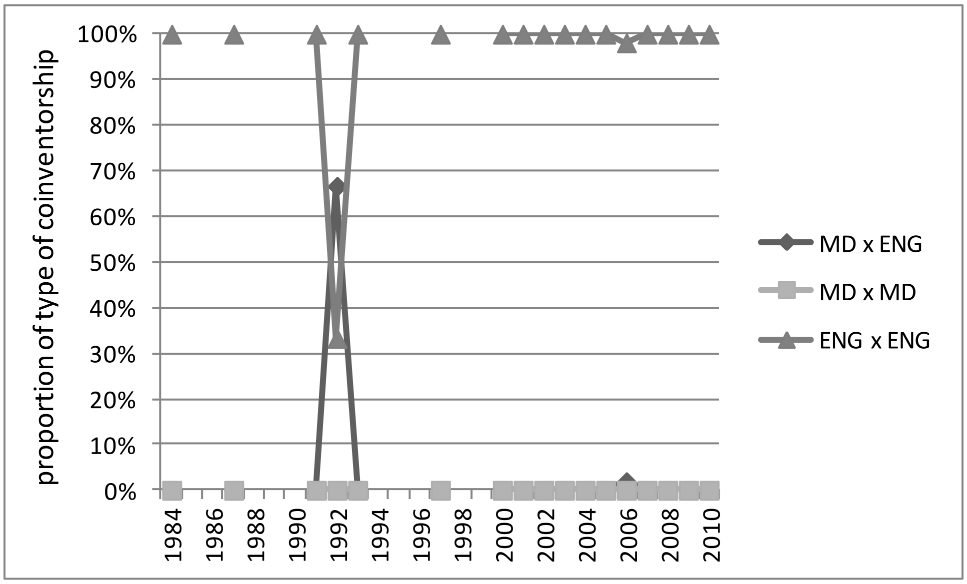


Figure 4: Centralization of nodes (Coinventorship relationship among researchers related to cochlear implant)



Note: MD: medical doctors, ENG: engineers

Figure 5: Change in proportion of types of coauthorship in articles related to cochlear implant



Note: MD: medical doctors, ENG: engineers

Figure 6: Change in proportion of types of coinventorship in patents related to cochlear implant