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Exploring the Frontiers of Biomedical Engineering: An Overview of Historical and Current Considerations

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The article that follows is an updated version of the Alza Lecture I presented to the Biomedical Engineering Society in 1985. It was subsequently published in the *Annals of Biomedical Engineering* in 1986.[1] This annual lecture is sponsored by the Alza Corporation, Palo Alto, California, a pioneer in the development of implantable micropumps that deliver minute amounts of drugs to specific physiological sites. Biochemist Alejandro Zaffaroni founded Alza in 1968. Today the corporation has over 1,500 issued or pending patents worldwide, for many medical devices including Ocusert, which controls the administration of pilocarpine to the eye for the treatment of glaucoma, and Progestasert, which slowly releases progesterone into the body to control fertility. The Alza Corporation, incidentally, is no longer the lone producer of implantable pumps.[2]

We have now added to the original paper some background notes on the development of biomedical engineering. Biomedical engineering, sometimes also called bioengineering, encompasses all the disciplines that combine engineering knowledge with biological and medical systems. Historically the term biomedical engineering emerged first, but some people began using bioengineering because it was shorter. Many of the different areas encompassed by biomedical engineering, including agricultural and clinical engineering, are contiguous;[3] for example, clinical engineering emerged in the last 20 years as a specialty that applies the information produced by biomedical engineering. It also encompasses important management functions, information systems, and health-care-delivery systems in hospitals.[4,5] In addition, the borders between biomedical engineering, biophysics, biotechnology, and medical physics are unclear. For example, medical physics developed around the turn of the century with the study of X rays, but it has now merged with biomedical engineering. Biotechnology, the modification of genetic properties according to the insight gained from molecular biology, was initially a different field entirely from biomedical engineering. But it is now fusing with biomedical engineering, since electrical techniques have become some of the most potent for accomplishing genetic changes.[6]

Definition

Biomedical engineers design not only prostheses, pacemakers, and kidney machines, but also imaging systems that use X rays, computed tomography, ultrasound, nuclear magnetic resonance, and digital radiography[7] to scan internal organs. They examine the effect that the corrosion of metals used in implants has on body fluids. They conduct sensory research studies of the transmission and coding of stimuli in the nervous system, information that, when combined with computer systems, may eventually be used to create artificial eyes and ears.[8] Biomedical engineers also determine the biocompatibility of implant materials with human tissue, and they measure the effects of microwave exposure on tissue. In an unusual multidisciplinary approach to a common problem, they are studying osteogenesis, the development and formation of bone, in combination with electrical stimulation of bone, to aid in healing fractures.

And, for about 15 years, biomedical engineers have not only been developing an artificial pancreas, but also portable insulin-infusion pumps.[9] These developments would certainly have interested F.G. Banting, C.H. Best, and other pioneers in the field of diabetes.

One of the latest innovations involving the controlled release of insulin (or other drugs) into the body concerns magnetic modulation. A brief article in the *British Medical Journal* reports on a device developed by Robert Langer and colleagues, Massachusetts Institute of Technology (MIT), Cambridge, in which a drug and magnetic beads are dispersed together inside a polymer matrix. *In vitro* tests suggest that, when exposed to an oscillating external magnetic field, the magnetic beads in the matrix move and squeeze the drug out of the adjacent polymer.[2]

In view of the multidisciplinary nature of biomedical engineering, it is not surprising that students in such programs must be fluent in the chemical, physical, mathematical, and computer sciences, as well as in the life sciences and engineering. In fact, many researchers in biomedical engineering begin their careers studying traditional areas of engineering and applied sciences.

History

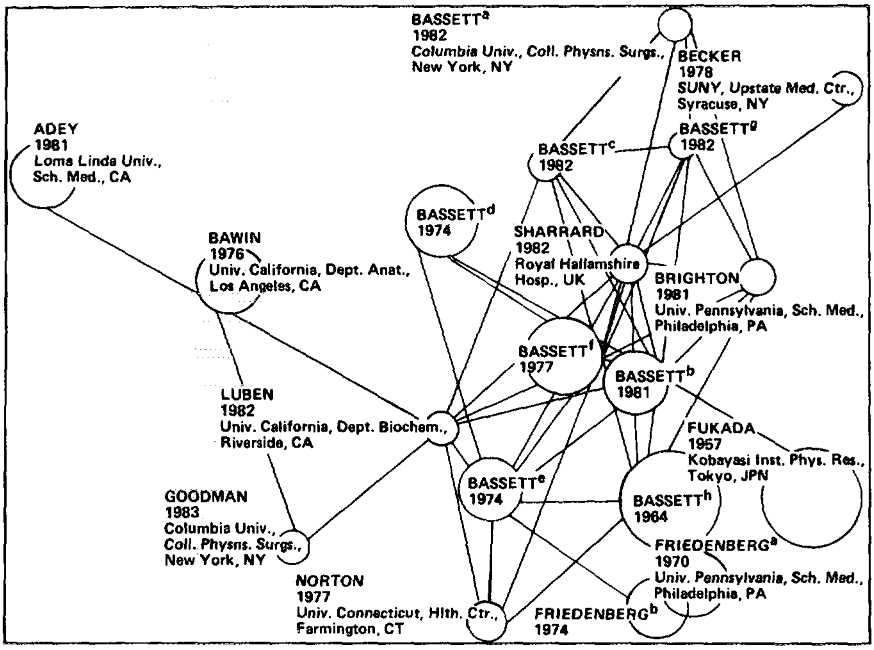
As a formal discipline, biomedical engineering is relatively young—most of its major contributions have been made since the 1950s (cardiac monitors) and 1960s (pacemakers, dialysis machines, ultrasound[7])—even though the utility of applying engineering principles to biological functions was recognized in Galileo's time and earlier.[10] For example, heat was used to treat cancer as early as 3000 BC,[11] while electricity was employed therapeutically in the sixteenth century.[12] Other notable scientists who contributed to the field were William Harvey (1578-1658), Robert Boyle (1627-1691), Thomas Young (1773-1829), and Hermann von Helmholtz (1821-1894).[10]

But it was not until after World War II that any attempt was made to formally organize biomedical engineering as a field. In 1947 the Institute for Radio Engineers and the American Institute for Electrical Engineers (who merged in 1963 to form the Institute of Electrical and Electronics Engineers [IEEE]) established administrative committees to study biological and medical areas related to engineering. In 1948 these committees began sponsoring an annual conference that is still held today; now it is administered by the Alliance for Engineering in Medicine and Biology, an organization established in 1969 expressly for that purpose.[13]

The first independent professional society devoted solely to biomedical engineering—the Biomedical Engineering Society—was established in 1968;[13,14] in 1972 it began publishing the *Annals of Biomedical Engineering*. Today there are additional societies, including the International Federation of Medical and Biological Engineering (1959), and smaller, more specialized groups such as the Society for Biomaterials (1974) and the Bioelectromagnetics Society (1978).[14] The Engineering in Medicine and Biology Society (1977) is a subgroup of the IEEE. A national umbrella organization does not presently exist to unite the 10,000 members of the different US societies.[14]

Academically, biomedical engineering has been included in university curricula as a major area of study only in the last 20 years. An early exception was the Oswalt Institute for Physics in Medicine, Frankfurt, Germany, established in 1921 and today known as the Max Planck Institute for Biophysics.[14] Most biomedical engineers had to educate themselves through personal associations and individually arranged interdisciplinary studies[3] until the late 1950s and early 1960s. Around that time the National Institutes of Health (NIH) established a training program in the field and made funds available to qualified academic institutions interested in starting programs. Johns Hopkins University, Baltimore, Maryland, was one of the first institutions to receive NIH funding, along with the University of Rochester, New York, the University of Pennsylvania, and Drexel University, both in Philadelphia.[13,14] Today there are still

Figure 1: Multidimensional-scaling map showing links between the 19 core papers for the 1985 *SCI®/SSCI®* research front #85-0241, **"Effects of low-frequency electromagnetic-field treatment on bone healing."** The size of the literature that cited each paper in 1985 is indicated by the size of the circle around each point on the map. A total of 125 articles from 1985 cited this research front. Authors with more than one paper are marked on the map with letters. The accompanying key provides bibliographic data for the papers. The majority of the papers concern pulsing electromagnetic fields and their effect on tissues. C.A.L. Bassett appears as an author on nine of these. Three papers deal with related issues; their titles are provided below. The total number of 1955-1986 *SCI®* citations for each paper is listed in parentheses after each reference.



KEY

Adey W R. *Physiol. Rev.* 61:435-514, 1981. (86 cites)
Bassett C A L.[a] *Calcified Tissue Int.* 34:1-8, 1982. (18 cites)
Bassett C A L,[b] **Mitchell S N & Gaston S R.** *J. Bone Joint Surg.—Amer. Vol.* 63:511-23, 1981. (64 cites)
Bassett C A L,[c] **Valdes M G & Hernandez E.** *J. Bone Joint Surg.—Amer. Vol.* 64:888-95, 1982. (21 cites)
Bassett C A L,[d] **Pawluk R J & Pilla A A.** *Ann. NY Acad. Sci.* 238:242-61, 1974. (95 cites)
Bassett C A L,[e] **Pawluk R J & Pilla A A.** *Science* 184:575-7, 1974. (110 cites)
Bassett C A L,[f] **Pilla A A & Pawluk R J.** *Clin. Orthop. Related Res.* 124:128-43, 1977. (137 cites)
Bassett C A L,[g] **Mitchell S N & Schink M M.** *J. Bone Joint Surg.—Amer. Vol.* 64:1214-20, 1982. (9 cites)
Bassett C A L,[h] **Pawluk R J & Becker R O.** *Nature* 204:652-4, 1964. (230 cites)
Bawin S M & Adey W R. Sensitivity of calcium binding in cerebral tissue to weak environmental electric fields oscillating at low frequency. *Proc. Nat. Acad. Sci. USA* 73:1999-2003, 1976. (82 cites)
Becker R O & Spadaro J A. Treatment of orthopaedic infections with electrically generated silver ions. A preliminary report. *J. Bone Joint Surg.—Amer. Vol.* 60:871-81, 1978. (26 cites)
Brighton C T, Black J, Friedenberg Z B, Esterhai J L, Day L J & Connolly J F. *J. Bone Joint Surg.—Amer. Vol.* 63:2-13, 1981. (29 cites)
Friedenberg Z B,[a] **Andrews E T, Smolenski B I, Pearl B W & Brighton C T.** *Surg. Gynecol. Obstet.* 131:894-9, 1970. (105 cites)
Friedenberg Z B,[b] **Zemsky L M, Pollis R P & Brighton C T.** *J. Bone Joint Surg.—Amer. Vol.* 56:1023-30, 1974. (66 cites)
Fukada E & Yasuda I. *J. Phys. Soc. Jpn.* 12:1158-62, 1957. (233 cites)
Goodman R, Bassett C A L & Henderson A S. *Science* 220:1283-5, 1983. (17 cites)
Luben R A, Cain C D, Chen M C-Y, Rosen D M & Adey W R. *Proc. Nat. Acad. Sci. USA* 79:4180-4, 1982. (35 cites)
Norton L A, Rodan G A & Bourret L A. Epiphyseal cartilage cAMP changes produced by electrical and mechanical perturbations. *Clin. Orthop. Related Res.* 124:59-68, 1977. (38 cites)
Sharrard W J W, Sutcliffe M L, Robson M J & MacEache A G. *J. Bone Joint Surg.—Brit. Vol.* 64:189-93, 1982. (16 cites)

fewer than 20 US universities that offer accredited undergraduate programs in biomedical engineering; many other biomedical engineering programs exist within traditional engineering departments such as electrical engineering.

If we had more time and space we would discuss biomedical engineering research in other countries. Japan, for example, is responsible for some exciting developments in biosensor technology.[15]

Research Fronts

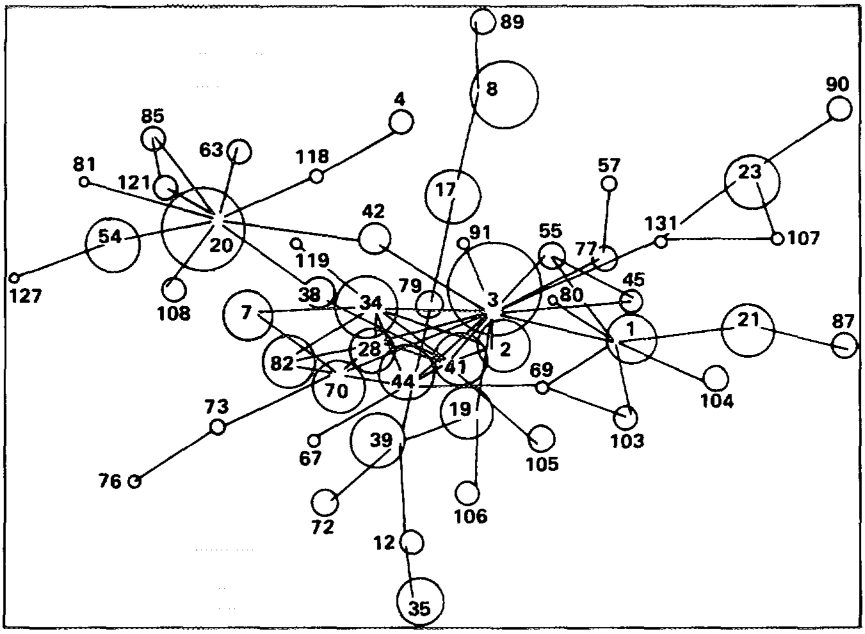
At ISI® we can trace the development of a field such as biomedical engineering by examining the *Science Citation Index®* (*SCI®*)/*Social Sciences Citation Index®* (*SSCI®*) research-front database. Research-front identification is based on citation analysis of the papers most cited in a given year. These "core," or well-cited, papers are then categorized into clusters of papers that have been co-cited at significant thresholds in the current literature. If papers are co-cited frequently, they usually identify emerging fields sharing a commonality of "topics," but the individual core papers do not necessarily treat the same subjects. By using multidimensional-scaling techniques and displaying minimum information, such as publication dates and institutional addresses, we can generate a map of the "invisible college" for a given subject. These maps of co-cited papers are the first (C1) level in a hierarchical clustering process. Figure 1 illustrates a C1-level map that concerns the effects of low-frequency electromagnetic-field treatment on bone healing. Each author's name and affiliation is provided, along with the paper's year of publication. In the accompanying key we have provided condensed references to save space. Full titles are listed for three papers whose subjects concern areas related to, but not strictly about, electromagnetic treatment of bones. For example, the article by R.O. Becker and J.A. Spadaro, State University of New York, Upstate Medical Center, Syracuse, discusses treatment of orthopedic infections with electrically generated silver ions. The inclusion of this paper in #85-0241 illustrates how a research front can be composed of related papers from different areas.

C.A.L. Bassett, now at Bioelectric Research Center, Riverdale, New York, has nine papers in Figure 1; however, he notes that the seminal paper in this field[16] does not appear on the map. But this 1962 paper would undoubtedly have been core to an earlier research front; it has been widely cited by the other authors in Figure 1. (From 1962 to 1986 it received over 200 citations in the *SCI*.) This paper contained the first information on how bone signals looked in the living state; most subsequent research in this field was based on the data it provided. The 1957 Fukada article in Figure 1 concerns that same area of research, but unfortunately it lacks the data required for modelling. That is, it demonstrates the principles but not the specifics.[17]

C1-level research fronts are then clustered to create C2-level fronts, or clusters of clusters; the process is repeated three more times to create successively higher and more generalized intermediate maps of various scientific disciplines, until the highest level, the C5 "global" map of science, is achieved. (The number of levels is, of course, arbitrary. One could create dozens of levels if computer time were unlimited.) In Figure 2 we illustrate the second-highest level map, the C4; it shows the major research areas in the social and natural sciences. Biomedical engineering topics would appear in this map's areas on organ transplantation, cancer treatment, and electrophysiology, to name a few. (For those readers interested, 1984 C2- and C3-level maps of biomedical engineering specialties can be found in the original article from which this essay was adapted.[1] The 1984 global map is also included there.)

Historiographs of research fronts can also be created to trace their history and development. C1-level research fronts from successive years can be linked when the core papers or books cited in two adjacent years remain essentially the same or at specified citation thresholds. Figure 3 shows a string of research fronts spanning 10 years (1976-

Figure 2: Map of C4 cluster #85-0001 showing the major research areas in the social and natural sciences. Lines between nodes represent co-citation strengths. The size of the circle at each point indicates the relative size of the 1985 citing literature for each research area. Numbers correspond to 1985 C3-level *SCI®*/*SSCI®* fronts.



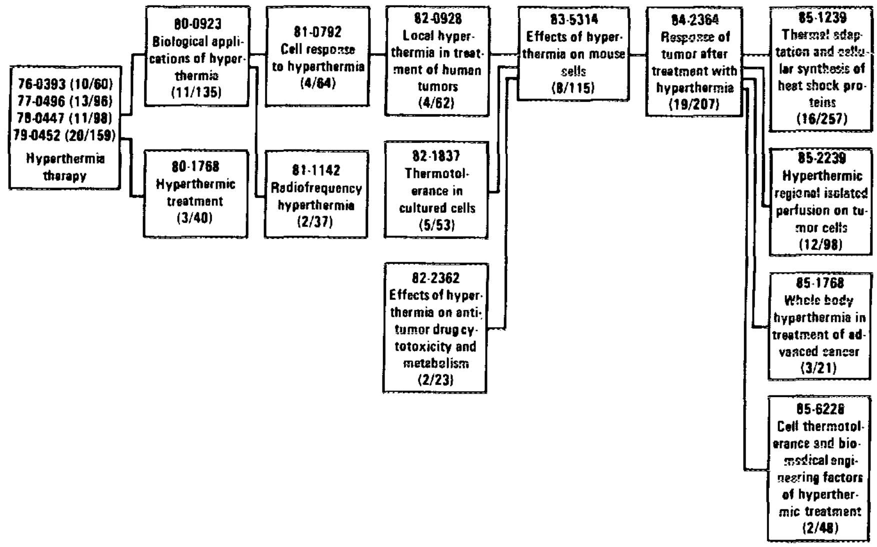
KEY

1 cancer
2 neuroscience
3 genetics & immunology
4 health care
7 respiratory system
8 geoscience
12 environmental science
17 ecoscience
19 plant science
20 behavioral science
21 endocrinology
23 microbiology
28 hematology
34 cardiovascular system
35 biomass
38 electrophysiology
39 agronomy
41 cell membrane
42 neurology
44 lipid metabolism
45 lectins
54 social science
55 cancer treatment
57 arthritis
63 drug abuse
67 calcium metabolism
69 epidemiology
70 prostaglandins
72 marine science
73 gastrointestinal disease
76 gastroesophageal disease
77 immune complexes
79 atmospheric science
80 cancer diagnosis
81 criminology
82 cardiovascular disease
85 statistical analysis
87 sleep research
89 geochemistry
90 pharmacology
91 organ transplantation
103 cancer screening
104 soft tissue tumors
105 beta blockers
106 germination
107 pneumonia
108 behavior therapy
118 medical sociology
119 body composition
121 multivariate analysis
127 social systems
131 bacterial membranes

1985). This historiograph follows the development and progress of hyperthermia, the elevation of tumor tissue temperature to 42-50° C for 30 to 60 minutes to produce therapeutic results in cancer patients. Interestingly, the heat seems to make tumor cells more sensitive to damage by ionizing radiation.[5,11] This research specialty is included in studies of the electrical properties of biomatter.

The study of biomatter is one of the many disciplines that apply engineering concepts to problems in biology and medicine. Others include bioacoustics, bioelectric potentials, bioelectromagnetics, bioinstrumentation, biomechanics, bioprocesses, biorheology, biosensors, electrocardiology, and systems engineering. M. Scott Blois, Departments of Dermatology and Medical Information Science, University of California, San Fran-

Figure 3: Historiograph tracing developments in clinical and laboratory hyperthermia research over the last 10 years. The numbers of core/citing papers are in parentheses.



cisco, is publishing key work in the latter field. His most-cited paper[18] in the 1955-1985 *SCI* concerns electron spin resonance studies on melanin; it has already been cited over 100 times.

Each box of the historiograph includes the research-front name, the number of core articles, and the number of citing papers. However, because the four fronts from 1976 to 1979 had such similar content, we combined them in one box. In 10 years hyperthermic treatment of cancer grew from a field with only one, rather general *SCI* research front composed of 10 cited papers and 60 citing papers to an area having four, more specialized research fronts with a combined total of 33 core documents and 424 citing articles.

Biomedical Engineering Journals

For this study we also looked at the journals categorized as biomedical engineering in the *SCI*. These journals are covered in *Current Contents*® (*CC*®)/*Life Sciences*, *CC/Clinical Medicine*, and *CC/Engineering, Technology & Applied Sciences*. Table 1 lists the 22 journals and shows the number of articles that each journal published in 1985, the total number of citations that all their articles received in 1985, and each journal's 1985 impact factor and immediacy index. These 22 journals published 1,175 articles, or 0.2 percent, of the over 620,000 1985 articles the *SCI* indexed.

However, we know that many more papers in this field are published outside of these 22 journals. Often, according to Herman P. Schwan, Department of Bioengineering, University of Pennsylvania, a paper reporting on some area of biomedical engineering can be published in an engineering journal as easily as a biophysics journal; the results of the paper are of course the same, but the paper is written to suit each particular journal's audience. For example, in a biophysics journal the paper addresses researchers with a biological background, while in the engineering journal it focuses on the technical aspects of the topic. This dual approach in publishing biomedical engineering papers makes a full evaluation of this multi-interdisciplinary field very difficult indeed.[6] For example, the *Annual Review of Biophysics and Biophysical Chemistry* is indexed by ISI as biophysics, so we didn't include it in Table 1, although it undoubtedly publishes articles of concern to

Table 1: Biomedical engineering journals indexed in the 1985 *SCI*®.

Journal	Number of 1985 Articles Published	Number of 1985 Citations Received	1985 Impact Factor	1985 Immediacy Index
Annals of Biomedical Engineering	40	230	.6	.1
Artificial Organs	44	440	.9	.1
Biomaterials	72	269	.7	.1
Biomaterials Medical Devices and Artificial Organs	5	110	.2	0
Biomedizinische Technik	42	176	.5	.1
Clinical Physics and Physiological Measurement	32	120	.5	.2
Computers in Biology and Medicine	35	200	.6	.1
Computers and Biomedical Research	49	682	.6	0
Computer Methods and Programs in Biomedicine	58	496	1.2	.1
CRC Critical Reviews in Biomedical Engineering	10	56	.4	0
IEEE Transactions on Biomedical Engineering	156	1,530	1.1	.2
IEEE Transactions on Medical Imaging	27	NA	NA	NA
International Journal of Artificial Organs	57	299	.7	.1
Journal of Biomechanical Engineering—Transactions of the ASME	56	328	.6	.1
Journal of Biomechanics	85	1,536	.9	.2
Journal of Biomedical Engineering	53	180	.5	.2
Journal of Biomedical Materials Research	83	1,181	.9	.2
Journal of Medical Engineering and Technology	34	80	.2	.1
Medical and Biological Engineering and Computing	108	912	.6	.2
Medical Progress Through Technology	7	107	.6	0
PACE—Pacing and Clinical Electrophysiology	111	965	1.2	.1
Ultrasonic Imaging	11	263	2.5	.4
TOTAL	1,175	10,160		

Table 2: *The 1985 biomedical engineering research fronts (C1 clusters) with the highest number of published (citing) articles from the biomedical engineering journals indexed in the SCI*®.

Rank	Number of Published Items in Research Front	Number of Published Papers in Core Journals	Percent of Items in Core Journals	Cluster Name
1	331	44	13	Iterative reconstruction algorithms for ultrasonic and tomographic imaging methods of tissues and other biological samples (#85-1661)
2	95	22	23	Atrial and ventricular pacing with pacemakers in carotid sinus syndrome and other cardiac conditions (#85-0529)
3	632	20	3	Actin myosin complex and other proteins in human skeletal muscle filament movement (#85-2557)
4	48	18	38	Mechanical and other properties of bone (#85-3548)
5	102	17	17	Adsorption phenomena and other functional properties of protein interactions with surfaces (#85-0913)
	1,208	121	10	TOTAL

biomedical engineers—until 1985 this journal was called the *Annual Review of Biophysics and Bioengineering*.

We can get an idea of just how many papers are published outside the journals in Table 1 by examining the five research fronts with the greatest number of 1985 published (citing) articles from the 22 journals (see Table 2). These five fronts alone account for over 1,200 1985 papers, but only 121 were published in the journal group in Table 1. Although we did not perform a journal-by-journal analysis of the more than 1,000 papers published in journals not listed

Table 3: The 1985 biomedical engineering research fronts (C1 clusters) with the highest percentage of published (citing) articles from the biomedical engineering journals indexed in the *SCI®*.

Rank	Number of Published Items in Research Front	Number of Published Papers in Core Journals	Percent of Items in Core Journals	Cluster Name
1	19	10	53	Computation techniques for the estimation of body surface potentials and other parameters by moving dipoles and multipoles (#85-5712)
2	17	8	47	Electrical properties of nerves and other tissues (#85-4111)
3	13	5	39	Electrical stimulation of vocal-cord abductors and laser arytenoidectomy in bilateral laryngeal nerve paralysis (#85-7426)
4	48	18	38	Mechanical and other properties of bone (#85-3548)
5	14	5	36	Biomechanics and energy costs of running and other locomotion (#85-3832)
	111	46	41	TOTAL

in Table 1, we can see by examining the articles mapped in Figure 1 that the *Journal of Bone and Joint Surgery—American Volume* publishes a significant number for that biomedical engineering specialty.

The top-ranked front in Table 2 is "Iterative reconstruction algorithms for ultrasonic and tomographic imaging methods of tissues and other biological samples" (#85-1661); it contains more articles—44—from the biomedical engineering journal set (Table 1) than any other 1985 research front. Similarly the other four fronts in Table 2 are relatively broad in scope. In contrast the 1985 research fronts in Table 3, published mainly in the 22 biomedical engineering journals, are more specific and focused. This ranking emphasizes those research fronts not as heavily cited outside the biomedical engineering journals. The highest-ranking fronts in this set are mostly concentrated in biomedical engineering, compared with the broader nature of those in Table 2. Of the 19 papers citing the core literature of the top-ranked research front in Table 3, "Computation techniques for the estimation of body surface potentials and other parameters by moving dipoles and multipoles" (#85-5712), 10—or 53 percent—are from the journals listed in Table 1.

Conclusion

The 1986 *SCI/SSCI* research-front data will be available soon; cluster maps for biomedical engineering will be well worth examining, since, in the next few years, this field will undoubtedly continue to flourish as technology becomes ever more sophisticated. In fact, we can probably expect some of the most exciting medical developments of this century to result from research in this field.

But the rising cost of health care may influence the rate at which these developments occur. One problem with the adoption of magnetic resonance scanners, for example, is their enormous cost.[5] According to J.D. Bronzino, Department of Engineering and Computer Science, Trinity College, Hartford, Connecticut, and colleagues, "some medical innovations are almost certainly justified on a cost-benefit basis. Hip replacement, for example, is relatively inexpensive and provides recipients with freedom from the wheelchair, as well as reduces their dependence on nursing home services. Other medical innovations may be more questionable. Among them are the artificial heart [and] liver transplant...." Dramatic therapies such as these are available only to a few patients and involve prohibitive costs.[19] But of greater concern, perhaps, is that they involve heroic efforts but currently do not much improve the patients' lives.[5]

A broad issue affecting biomedical engineers is the necessary coupling of engineering and clinical research. According to Kenneth R. Foster, Department of Bioengineering, University of Pennsylvania, it can be easier to build biomedical devices than it is to prove that they will actually work.[5] One illustration of this problem involves the electromagnetic treatment of fractures. According to an editorial by John Nixon, Clinical Reader in Orthopedic Surgery, Nuffield Orthopedic Center, Oxford, UK, in the *British Medical Journal*, this process has yet to be proven effective using double-blind controlled trials. However, less controlled trials strongly suggest that electromagnetic treatment results in increased healing.[20] And Bassett cites at least one paper in which double-blind controls involving electromagnetic field therapy of tendinitis showed a clear biological effect in the clinic.[17,21] Hyperthermic treatment of cancer patients is also not yet fully understood as a therapy. Most studies currently treat patients with advanced cancer whose disease was not cured by standard therapies. This makes it difficult to measure the effectiveness of the hyperthermia therapy for persons with earlier stages of the disease.[5]

To address, at least in part, these types of problems, MIT and the Massachusetts General Hospital, Boston, have developed a program in which biomedical engineers work side by side with hospital physicians to gain insight into how doctors actually work. The goal is that, by exposing engineers to the day-to-day needs of patients and by having physicians and engineers work together, all involved may learn to increase the overall economic, social, and ethical value of new technologies as they are developed.[22]

* * * * *

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